LIAISON® XS (code I0090)

User Manual

LIAISON® XS

Revision G (12/2024)

en-UK

DISCLAIMER

The information contained herein is based on experience and knowledge relating to the subject matter as acquired by DiaSorin Italia S.p.A.

DiaSorin is not liable for any loss or damage, including consequential or special damages resulting from the use and or misuse of the contained information be it negligence or other fault.

This document refers to access at the highest level. Working with lower level access may cause a lack of some functionalities.

LIAISON® XS may only be used by authorized and trained personnel.

This document cannot be considered substitutive of official trainings supported by DiaSorin.

In the event of problems or doubts about using the system, contact the local support.

A document that states the list of LIAISON® XS Software Versions that are covered by the present User Manual revision will be provided separately.

The previous legal manufacturer of LIAISON® XS was DiaSorin S.p.A.

DiaSorin Italia S.p.A.
Strada per Crescentino - 13040 Saluggia (Vercelli) - Italy
www.diasorin.com

CE

AMENDMENT INDEX

Revision	Impacted chapter/section	Description of Change(s)
G	All	New Diasorin Logo
G	1.5.2	New Laser Label
G	1.7.2	Removal of any reference to the Directive 98/79
G	1.8.7	New Laser Label on Figure 1-8
G	1.8.18	New Laser Label on Figure 1-23
G	5.4.4	Figure 5-22 has been updated following the correct instruction provided in the text
G	11.1	Removal of any reference to the Directive 98/79

Table of Contents

1 Introduction

This manual was created to assist the laboratory user with the utilization of the **LIAISON® XS** chemiluminescence analyzer. This manual includes specific definitions as well as handling and maintenance of the instrument.

1.1 Description

The system consists of a robotic instrument, a Panel-PC and software that runs on the Panel-PC. The software provides the user-interface that gives the operator the ability to control the system, and the software performs data reduction on the measurement results (measured by the instrument).

The instrument contains a transport system for plastic cuvettes, a pipetting system with two pipetting arms (one with a steel needle and one that uses disposable tips), an incubator, a washer and a luminescence measurement chamber. In addition to that, the instrument contains modules for loading samples, reagents, tips and cuvettes into the instrument.

Panel-PC and instrument are connected to exchange data.

1.1.1 Intended Use

This manual covers the following products:

- **LIAISON® XS**: Diagnostic System that measures chemiluminescence. It is intended strictly for professional In-vitro-Diagnostic use. It is to be used only with Chemiluminescence Immunoassays, authorized by DiaSorin Italia S.p.A. for the **LIAISON® XS** instrument.

For Professional Use Only.

1.2 Customer Support

If you have any questions about the **LIAISON® XS** Diagnostic System, please contact your local DiaSorin Italia S.p.A. Customer Support Representative to get answers to your inquiries.

For EU only: please be aware that any serious incident that has occurred in relation to this IVD medical device should be reported to DiaSorin and the competent authority of the EU Member State in which the user and/or patient is established.

1.3 Proprietary Statement

Each person assumes full responsibility and all risks arising from use of the Documentation. The Documentation may include technical inaccuracies or typographical errors. DiaSorin Italia S.p.A. reserves the right to make additions, deletions, or modifications to the Documentation at any time without any prior notification.

1.4 Authorization and disclaimers about Documentation

The information contained herein is based on experience and knowledge relating to the subject matter as acquired by DiaSorin Italia S.p.A.

This Document refers to access at the highest level. Working with lower level access may cause a lack of some functionality.

The user manual and the **LIAISON® XS** Chemiluminescence instrument are to be used by authorized personnel only. Operate the Instrument following the indications and procedures described in the operating instructions for the **LIAISON® XS** instrument.

Follow all warnings, cautions, and notes indicated on the **LIAISON® XS** instrument and in the operating instructions. Failure to do this may result in human injuries or damage to instrument.

All samples, if any (printouts, graphics, displays, screens, etc.), are for information and illustration purposes only and shall not be used for clinical or maintenance evaluations. Data shown in sample printouts and screens does not reflect actual patient names or test results.

The Documentation was developed to be used by DiaSorin Italia S.p.A. trained personnel, by other persons knowledgeable or experienced with the operation and service of the product identified, or under the direct supervision and with cooperation from DiaSorin Italia S.p.A. technical sales or service representatives.

All the Standards mentioned in the present User Manual are intended at their latest revision, available at the date of the release of the Manual itself.

This Document cannot be considered substitutive of official trainings supported by DiaSorin Italia S.p.A.

In no event shall DiaSorin Italia S.p.A. or its affiliates be liable for any damages or losses incurred in connection with or arising from the use of the Documentation by persons not fully trained by DiaSorin Italia S.p.A. This limitation shall not apply to those persons knowledgeable or experienced with the operation and service of the product identified, or under the direct supervision and with cooperation from DiaSorin Italia S.p.A. technical sales or service representatives.

In the event that any user of the Information should make any questions, comments, suggestions, ideas or any other kind of oral, written or electronic feedback to DiaSorin Italia S.p.A., any information submitted therewith shall be considered non-confidential, and DiaSorin Italia S.p.A. shall be free to reproduce, edit, publish or otherwise use such information for any purposes whatsoever including, without limitation, the research, development, manufacture, service, use, or sale of products incorporating such information and no liability will be borne by DiaSorin Italia S.p.A. in connection with its content, including its truthfulness and accuracy and its non-infringement of any other person's proprietary rights.

Updates to the Documentation may be provided in either paper or electronic format. Always refer to the latest documents for the most current information.

In the event of problems or doubts about using the system, contact your local support representative.

1.5 Messages, Notes and Symbols

The symbols described hereafter are used in the current manual, on the instrument and on its packaging.

1.5.1 Display of Warnings and Notes

DANGER

The signal word "Danger" and a relating symbol point to imminent dangers.
The non-observance of a danger warning is imminent and might result in death or at least serious irreversible injuries. A damage of the system or an adverse effect on the system function cannot be excluded.

WARNING

The signal word "Warning" and a relating symbol point to potential dangers.
The non-observance of a warning is potential and can result in death or at least serious irreversible injuries. A damage of the system or an adverse effect on the system function cannot be excluded.

CAUTION

The signal word "Caution" and a relating symbol point to potential dangers/ problems.
The non-observance of safety instructions can result in minor injuries. A damage of the system or an adverse effect on the system function cannot be excluded.

CAUTION

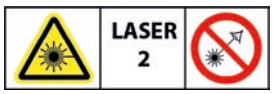
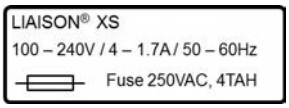
The signal word "Caution" points to potential problems.
The non-observance of a safety instruction can result in damage of the system or an adverse effect on the system function.

NOTE

The signal word "Note" points to potential problems.
The non-observance of notes can result in an adverse effect on the system function (result deterioration).

1.5.2 Used warning symbols

	**Caution, risk of danger to person or damage to equipment! Consult instructions for use!**
	**Biohazard!**
	**Electrical hazard!**
	**Laser hazard!**

  First Type  Second Type	**Laser hazard and laser information label**
	**Caution, hot surface!**
	**Crush hazard!**
	**Magnetic field**
	**Cut injury hazard!**
	**No heavy load**
	**Disconnect main power connector before servicing**
	**Disconnect main power connector before servicing!**
	**Power Supply characteristics**
	**Grounding label**
	**LAN connection**
	**USB label**
	**Waste**

	**Shockwatch label**
	**Tiltwatch label**
	**System Liquid Tank**
	**Wash Buffer Tank**
	**Liquid Waste Tank**
	**Cleaning Tank**
	**DI Water tank**
	**Main Switch**
	**Don't step**

1.5.3 Other Symbols

	Manufacturer
	Date of manufacture
	In vitro diagnostic medical device
	CE mark
	Catalogue number
	Serial number
	Restriction of certain Hazardous Substances (RoHS) in electronic equipment

	Certification label of the Nemko GmbH & Co. KG
	Consult instructions for use
www.diasorin.com	DiaSorin website
EU: ☎ 00 800 60 61 62 63	Toll free number
	**Disposal of Electrical and Electronic Equipment** In the European Union, electrical and electronic equipment must not be disposed of with other household-type waste. It must be collected separately. Please observe the relevant legal regulations effective in the respective country.
	Caution

1.6 Hazard Instructions

1.6.1 General Safety

The following safety instructions must be observed at all times, both before and during operation of the system.

The Instructions for use is provided for user safety and gives important instructions for the handling of the system described.

- Before starting use of the **LIAISON® XS** Diagnostic System, read the following explanations for safety carefully, and understand the contents completely. User must be trained before being allowed to operate the system.
- Keep the Instructions for use near the system.
- When using reagents or chemicals, a properly well-ventilated room should be the responsibility of the user. Failure to comply may result in health issues.
- For maintaining safety, do not modify the **LIAISON® XS** Diagnostic System, do not change the components or accessories, do not use parts either than the specified, and do not remove the safety devices.
- Installation and service of the system or changes in the installation may never be performed by non-authorized persons not approved by DiaSorin Italia S.p.A. Multiple plug sockets different from the one as installed by DiaSorin Italia S.p.A. or its representative personnel are not allowed.
- Do not perform any operations or functions not described in the operating instructions. If trouble occurs on the Diagnostic System, contact DiaSorin Italia S.p.A., or an authorized representative.
- Cautions indicated on the **LIAISON® XS** Diagnostic System and in the operating instructions are prepared after careful examination; however, phenomenon beyond prediction may occur. When performing operation and maintenance, it is imperative to follow the instructions correctly.
- It is mandatory to allow DiaSorin Italia S.p.A. personnel, or an authorized representative, to perform all scheduled and exceptional interventions on the **LIAISON® XS** Diagnostic System that have been indicated as necessary to guarantee the full operational conditions of the system.
- The Instructions for use must be accessible to the user at all times.

NOTE

To guarantee the full operational conditions of the **LIAISON® XS** Diagnostic System, it is mandatory to allow DiaSorin Italia S.p.A. personnel, or any field service authorized representative, to perform all scheduled (one preventive maintenance per year) and unscheduled interventions, whereby required under particular circumstances, including but not limited to inappropriate use, over extraordinary workloads or any inconsistent use in respect of DiaSorin Italia S.p.A. guidelines or recommendations. Ordinary instrument workload is considered up to 180 determinations (assay results) per day.

WARNING

Failure to adhere to the IFU may result in harm for the user or 3rd party persons, damage to the system or adversely affect assay result. See section Operational precautions and limitations.

1.6.2 Liability

The **LIAISON® XS** Diagnostic System is designed and manufactured in accordance with the safety requirements for electronic and medical systems. It is the operators' responsibility to comply with local and national law's regulations and laboratory procedures for installation and operation of the instrument.

The manufacturer has done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The systems are tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

The information contained herein is based on experience and the best knowledge relating to the subject matter as acquired by DiaSorin Italia S.p.A.

DiaSorin Italia S.p.A. is not liable for any loss or damage, including consequential or special damages resulting from the use and or misuse of the contained information be it negligence or other fault of personnel and/or contractors.

- The instrument may only be used in accordance with its intended use.
- Use only the consumables and accessories described herein (e.g. disposable tips, cuvettes).
- The manufacturer assumes no liability for any damages, including those to third parties, caused by improper use or handling of the system.

WARNING

Improper use of the system may result in wrong assay results, damage of the system and personal injury.

1.6.3 Electrical Hazards

The **LIAISON® XS** Diagnostic System does not pose uncommon electrical hazards to operators if it is installed and operated without alteration and is connected to a power source that meets required specifications. See Electrical requirements in chapter 9.1.

National rules and local regulations for the safe electrical operation of the system must be observed.

Basic electrical hazard awareness is essential to the safe operation of any system. Only qualified personnel should perform electrical servicing.

Elements of electrical safety include, but are not limited to the following:

- Where appropriate, the instrument is installed with additional external switch for residual current circuit-breakers with over-current protection.
- Where appropriate it is integrated in UPS device.
- Use only connection and extension cables with a protective conductor and sufficient capacity (performance, power) to connect the system and the peripheral devices to the mains supply.
- Use a properly grounded electrical outlet of correct voltage and current handling capability.
- Never interrupt the grounding contacts.
- Grounding of the system and its peripheral devices to the same protective earth potential must be ensured.
- The multi plug possibly supported can be used only as installed by DiaSorin Italia S.p.A. or its representative personnel. Do not add any other device to the supplied multi plug.
- Determine and correct the cause of a blown fuse or thrown circuit breaker before attempting to resume operation of the system.
- Do not disconnect any electrical connection or service any electrical or internal components while the power is on.
- Keep liquids away from all connectors of electrical or communication components.
- Do not touch any switches or outlets with wet hands.
- Keep the floor dry and clean under and around the instrument.
- Disconnect the instrument power cord before cleaning major liquid spills.
- Clean spilled fluids immediately.
- Damaged connecting cables must be replaced immediately.
- No objects may be placed on the connecting cables.
- Connecting cables must be routed so that they cannot be squeezed or damaged.
- Connecting cables must be routed so that they do not lie in accessible or drivable areas.
- Immediately separate the defective system from the mains supply, if a safe usage is no longer possible.
- Secure the defective system against reconnection.
- Label the defective system clearly as being defective.
- Switch off the system, separate it from the mains supply and protect it against restarting. When system is secured start cleaning, disinfection, decontamination, maintenance or repair operations.
- Ensure that the system is free from personnel and that all covers are attached and closed before reconnecting the system to the mains supply.
- Ensure the positioning of the system during installation is so that the power supply and mains switch are easily accessible.

DANGER

Electrocution/Fire Hazard!

Non-observance of rules and regulations may cause serious personal injury with lethal consequences and material damage.

Improper connection of the system and the peripheral devices to mains supply can cause serious personal injury with lethal consequences and material damage (e.g. fire).

Damaged connecting cables can cause serious personal injury with lethal consequences and material damage (fire).

Defective systems can result in serious injury with lethal consequences and material damage (e.g. fire).

In case of accidental spilling or dropping on electrical or electronical parts or connections, switch off the system and unplug from the mains supply. When the system is secured, call Service support.

DANGER

Danger of Electrocution or Mechanical Injury

If the system is not separated from the main supply before maintenance operations, serious injury with lethal consequences due to electrocution may occur. Additionally, there is the danger that the system starts and may cause injury (e.g. contusion, cuts etc.) to the person working with the system.

WARNING

Danger due to Improper Positioning of Installation

Improper placement of the system can cause accidents with serious injuries with lethal consequences, fire or serious system damages because the system cannot be switched off or be separated from the main supply.

1.6.4 Physical Hazards

1.6.4.1 Laser Light Hazards

- The barcode reader is positioned on the right side of the Sample loading bay. The laser beam exits from an opening positioned on the internal right side of the sample loading bay. The laser beam is orthogonal to the internal right side surface.
- Never look directly into the laser beam.
- Do not introduce optical devices into the system.
- Remove watches and reflective jewelery before operating the laser.
- Caution during operation and testing the laser (bar-code scanner and handheld barcode reader) must be taken due to the laser class (class 2).

WARNING

Eye Injuries due to Laser Radiation

Laser radiation can cause eye irritations when looking into the laser beam for a long period of time.

Incorrect usage of operating elements or of adjustments or the non-observance of processes can cause a dangerous emission of laser radiation.

CAUTION

Do not use the handheld barcode reader for purposes different from reading bi-dimensional control definitions.

1.6.4.2 Heavy Objects

- Use proper lifting techniques when handling full tanks (system liquid, wash, and waste), the full waste basin and the full waste box.
- Use care when handling the tanks to reduce the risk of injury.
- Use care when handling the waste basin and the waste box, in order to avoid falls of contaminated materials.

1.6.4.3 Trip Hazards

The **LIAISON® XS** Diagnostic System is equipped with power cords and various computer connectors. To avoid tripping hazards, ensure cords are properly stowed.

NOTE

In the event of a damage, prejudice or personal injury occurred in connection with the use of the **LIAISON® XS** Diagnostic System, the Field Service Engineer shall immediately contact the local DiaSorin Italia S.p.A. Representative.

WARNING

Overheating

Improper place of installation/operation of the system may cause fire or serious system damage in case of overheating.

- Do not block or cover ventilation slots.
- The air shall be able to circulate.

1.6.5 Mechanical Hazards

The **LIAISON® XS** Diagnostic System is an automated system that operates under computer control. As with most automated equipment, there is potential for injury and bodily harm from moving mechanical components whenever the system is in operation.

The **LIAISON® XS** Diagnostic System minimizes mechanical hazards by providing guards to protect against accidental contact with moving components, and encoding the software with safety features.

During operation of the instrument, user is potentially exposed to the following moving mechanical components:

- Pipettor arms and probes;

Basic elements of mechanical safety include, but are not limited to:

- Avoid contact with the sharp metal edges.
- Never bypass or override a safety device.
- Keep all protective covers and barriers in place.
- Never perform manual tasks on the work surface of the system.
- Never allow any part of your body to enter a range of mechanical movement during system operation.
- Do not wear articles of clothing or accessories that could catch on the system.
- Keep pockets free of items that could fall into the system.
- The right pipettor probe is sharp and potentially contaminated with infectious material. Avoid contact with the probe tip.
- Use caution when performing maintenance or cleaning procedures.
- Be aware that, in the event of a system malfunction or an unexpected sequence of movements, reflex actions could occur, causing injury.

- Select the placement of the system so that the ventilation slots are not blocked or covered.
- Select the placement of the system so that air can circulate.
- Never cover ventilation slots.

1.6.6 Biological Hazards

Performing the following activities user may be exposed to potentially infectious materials:

- Handling samples, reagents, calibrators, and controls;
- Cleaning spills;
- Handling and disposing of waste;
- Performing maintenance procedures;
- Performing cleaning or decontamination procedures.

The following information will help the user in minimizing the impact of this exposure.

User should consider all clinical samples, reagents, calibrators, controls, pipettor needles, and used reaction vessels and consumables (e.g. tips, cuvettes) that contain human-sourced material as potentially infectious. User should consider all system surfaces or components that have come in contact with human-sourced material as potentially infectious. No known test method can offer complete assurance that products derived from human-sourced material will not transmit infection. Therefore, all products derived from human-sourced materials and system components exposed to human-sourced materials should be considered potentially infectious.

Precautions include, but are not limited to the following:

- Observe local and national provisions, legislation and laboratory regulations.
- Use appropriate disposable gloves.
- Use an appropriate lab coat.
- Use an appropriate eye protection.
- Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses when handling human-sourced material or contaminated system components.
- Use proper personal protective equipments when interacting with the probe for maintenance or cleaning procedures.
- Clean, disinfect and decontaminate the system immediately if potentially infectious material has been spilled.
- Any reagent spills should be washed with a chemical use sodium hypochlorite solution with 0.5 % active chlorine (e.g. dilution 1:10 of a solution at 5 % active chlorine) and disposed of as though potentially infectious.
- All samples, biological reagents and materials used in the assays must be considered potentially able to transmit infectious agents. They should therefore be decontaminated and disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each Country.
- Liquid waste must be decontaminated with a chemical use sodium hypochlorite solution with 0.1 % active chlorine (e.g. dilution 1:50 of a solution at 5 % active chlorine) for at least half an hour.

- Do not use broken or chipped tubes or bottles.
- Observe the instructions in the package inserts for a correct use of the reagents.

DANGER

Risk of infection!

All internal parts of the system, that are not defined as user interfaces and for which specific procedures are described, must be treated as being potentially infectious. Improper handling of infectious parts can cause skin irritations, illnesses and possibly death.

DANGER

Disposal of Infectious Waste

Potential infectious material and all parts that may come in contact with potential infectious material must be disposed according to the local and national provisions, legislation and laboratory procedures.

1.6.7 Chemical Hazards

User may be exposed to hazardous chemicals when handling reagents, calibrators and controls.

Exposure to hazardous chemicals is minimized by following instructions provided in the assay-specific documentation (such as a package insert) and on product-specific labels, and product-specific MSDS (Material Safety Data Sheets).

In general, observe the following precautions when handling chemicals:

- Consult MSDS for safe use instructions and precautions.
- Avoid contact with skin and eyes. If contact with material is anticipated, wear impervious gloves, protective eye wear, and clothing.
- Maintain good housekeeping. Do not eat, drink, or store food and beverages in areas where chemicals are used.
- Seek medical attention if irritation or signs of toxicity occur after exposure.

1.6.8 Spill clean-up

Clean spills in accordance with established biosafety practices and follow instructions in the MSDS (Material Safety Data Sheets). In general, safe work practices for cleaning spills include:

- Wear appropriate personal protective equipment, such as gloves, eye wear and lab coat.
- Absorb the spill with absorbent material.
- Wipe the area clean with an appropriate disinfectant such as a chemical use sodium hypochlorite solution with 0.5 % active chlorine (e.g. dilution 1:10 of a solution at 5 % active chlorine).

1.6.9 Waste handling and disposal

Each facility is responsible for labeling all waste tanks and characterizing its waste stream to ensure waste is disposed in accordance with the appropriate local regulations.

See the manufacturer's assay-specific documentation (such as a package insert or reagent application sheet), the product-specific label, or the product-specific MSDS (Material Safety Data Sheet).

WARNING

Misuse of battery

The product may contain an internal lithium manganese dioxide, vanadium pentoxide, or alkaline battery or rechargeable battery. There is risk of fire and explosions which can lead to burns if the battery pack is not handled properly.

- Do not attempt to recharge the battery.
- Do not expose to temperatures higher than 60 °C (140 °F).
- Do not disassemble, crush, puncture, short external contacts, or dispose of in fire or water.
- Spare batteries shall match the values (nominal voltage, nominal current, and type) specified by the manufacturer.
- Dispose used batteries according to the local and national provisions or legislation.

WARNING

Disposal of non-contaminated parts

Material out of use (e.g. packaging material) should be properly disposed. Material that might be used should be kept to avoid future transportation damage.

- Strictly follow the local and national provisions, legislation and laboratory regulations.
- Keep the packaging to allow for safe transportation in case the instrument shall be shipped at some future date.

1.6.10 Caution on electromagnetic wave interference

1.6.10.1 Electromagnetic wave interference given by LIAISON® XS to other equipment

The **LIAISON® XS** instrument has been designed and manufactured in compliance to the applicable EMC standards.

Use the cables attached at the installation for connection between the devices in the system. The proper use of the specified cables minimizes electromagnetic wave interference.

Installation and service of the system or changes in the installation may never be performed by non-authorized persons not approved by DiaSorin Italia S.p.A. Movable multiple plug sockets different from the one installed by DiaSorin Italia S.p.A. personnel are not allowed.

However, there is no guarantee that the **LIAISON® XS** instrument will not cause electromagnetic wave interference.

a. When other equipment may be the cause, turn off the power of the equipment and check the functions of the **LIAISON® XS** instrument.

b. If it is improved, the **LIAISON® XS** instrument probably is the cause.

1.6.10.2 Electromagnetic wave interference that may be given to the LIAISON® XS instrument

If the **LIAISON® XS** instrument is used near equipment that generates strong electric and magnetic field, noises may enter the Instrument to affect the performances and functions.

Use the cables attached at the installation for connection between the devices in the system. The proper use of the specified cables minimizes electromagnetic wave interference.

Installation and service of the system or changes in the installation shall be performed only by authorized persons approved by DiaSorin Italia S.p.A. Movable multiple plug sockets different from the one installed by DiaSorin Italia S.p.A. personnel are not allowed.

However, there is no guarantee that the **LIAISON® XS** instrument will not be affected by electromagnetic wave interference.

a. When other equipment may be the cause, turn off the power of the equipment and check the functions of the **LIAISON® XS** instrument.
b. If they are improved, interference from the equipment is probably the cause.

Try the following to correct the issues.

a. Move the **LIAISON® XS** instrument further away from the equipment that may be the cause.
b. Connect the power cord of the **LIAISON® XS** instrument to an outlet that is on a different circuit from the equipment that may be the cause.
c. Check the electromagnetic wave interference does not affect the other equipment, which is connected with this instrument.

NOTE

Transient Emissions and Interference Resistance

This instrument meets all requirements described in standard IEC 61326 on transient emissions and interference resistance.

- This instrument was developed and tested according to CISPR11 Class A. It can cause radio interference in domestic environments. In this case it may be required to take action to eliminate such interference.
- Before setup and operation of the instrument, the electromagnetic environment shall be evaluated.
- Do not use the instrument in the proximity of sources with excessive electromagnetic radiation (e.g. unshielded, deliberately operated high frequency sources) since they could interfere with the proper operation of the instrument.

CAUTION

Interference by Mobile Phones

Mobile phones can affect the correct function of the instrument.

- Do not use mobile phones next to a running instrument.

1.6.11 Static magnetic field

Magnets are used in the instrument and clearly identified with labels (see chapter 1.8.19).

Concerning precautionary limits of exposure to magnetic fields, international standards establish 0.5 mT (5 gauss) as the magnetic flux density threshold level for static magnetic fields to prevent inadvertent harm to persons with implanted electronic medical devices and implants containing ferromagnetic material.

The 5 gauss line of all magnets in the instruments are either completely within the instrument or are exceeding it to an extent which is not expected to have impact on the user during normal operations.

1.7 Safety residual Risks for User

The aim of this section is to bring to user's attention the status of residual risks despite the inherent safe design measures, safeguarding and complementary protective measures adopted by the Manufacturer to lower the risks to an acceptable level.User must read carefully this section to understand the residual risks and learn the recommended instructions to work safely with the **LIAISON® XS** Diagnostic System.If further clarification should be needed, it is recommended to contact the local DiaSorin Italia S.p.A. representative.

1.7.1 Definitions

a. "hazard" means a potential source of injury or damage to user's health;
b. "danger zone" means any zone within and/or around machinery in which a user is subject to a risk to his/her health or safety;
c. "exposed person" means any user wholly or partially in a danger zone;
d. "user" means the person or persons operating, maintaining and cleaning the machinery;
e. "risk" means a combination of the probability and the severity of an injury or damage to health that can arise in a hazardous situation;
f. "guard" means a part of the machinery used specifically to provide protection by means of a physical barrier;
g. "protective device" means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;
h. "intended use" means the use of machinery in accordance with the information provided in the instructions for use;
i. "reasonably foreseeable misuse" means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behavior.

1.7.2 Inherent safe design and manufacturing process

The instrument has been designed and manufactured following the applicable regulations and harmonized standards.

In regards of risk management, the instrument has been designed and manufactured applying a risk management process, based upon the ISO standard 14971:2007 (Medical devices – Application of risk management to medical devices). By the application of the standard, through an iterative process of risk analysis, the manufacturer has:

- Determined the limits of the instrument, which include the intended use and any reasonably foreseeable misuse;
- Identified the hazards and the associated hazardous situations that can be generated by the use of the machinery;
- Estimated the risks for hazardous situations, taking into account the severity of the potential harm (injury or damage to health) and the probability of its occurrence by the application of an appropriate FMEA (Failure Mode Effect analysis) methodology;
- Evaluated the risks, with a view of determining whether risk reduction has been required;
- Reduced the risk for hazardous situations by the identification, implementation and verification of the effectiveness of appropriate risk control measures.

The above mentioned process will be actively maintained by the Manufacturer until the retirement of the **LIAISON® XS** Diagnostic System from the market. The Manufacturer has also established procedures to review post production information in order to ensure the appropriate safety degree and to maintain the IVD instrument always adequate to the so called “state of the art” as per, and in compliance with, the European Union Regulation 2017/746/EU related to IVD Medical Devices.

The **LIAISON® XS** Diagnostic System has been designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen, but also taking into account any reasonably foreseeable misuse thereof.

The aim of measures taken is to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

In selecting the most appropriate methods, DiaSorin Italia S.p.A. has applied the following principles, in the given order:

- to eliminate or to reduce risks as far as possible (inherently safe machinery design and construction),
- to take the necessary protective measures in relation to risks that cannot be eliminated,
- to inform users of the residual risks due to any shortcomings of the protective measures adopted,
- to indicate whether any particular training is required and specify any need to provide personal protective equipment.

Where possible, the instrument has been designed and constructed to prevent abnormal use if such use would create a risk.

Where appropriate, the instructions draw the user's attention to ways — if the experience has shown might occur — in which the machinery should not be used. The instructions have to be carefully read, paying attention to all warnings, taking into account the way the instrument has to be operated and which are the abnormal uses forbidden.

The **LIAISON® XS** Diagnostic System is supplied with all the special equipment and accessories essential to allow safely usage and maintenance. No other tools from the ones supplied by the Manufacturer must be used; use of unapproved items may endanger user's safety and/or health.

NOTE In no event shall DiaSorin Italia S.p.A. or its affiliates be liable for any damages or losses incurred in connection with or arising from the use of unapproved items used to operate or maintain the instrument.

1.7.3 Materials and Products

The materials and products of which the instrument is made and the agents and reagents used on it do not endanger the user's safety or health, apart from remaining biohazard and chemical risks and the interference they might cause with electrical and mechanical risks. In particular, in the areas where biological fluids are used, the instrument has been designed and constructed to prevent risks due to filling, use, recovery or draining.

1.7.3.1 Waste liquid tank

When user removes the waste liquid tank to empty it, he/she has to disconnect the level sensor together with the tubing. When user reconnect the waste liquid tank than reconnect the tubing together with the level sensor.

NOTE If the waste tank level sensor is not correctly reconnected, the instrument stops using it. The same occurs if the level sensor is out of order.

NOTE The joint connector allows user to manage the insertion/ removal of level sensor and tubing as a single task. See chapter 5.4.6 for details.

WARNING For safe use it is strictly forbidden:

- to alter or modify the level sensor function and/ or use instrument without liquid waste tank correctly connected to the tubing, apart if a direct drain connection is used for waste disposal;
- to use cracked or broken tanks.

During a liquid waste tank disconnection, the user has to prevent dripping of infectious liquid from the tubing waste, when unplugging it. The user has to wear appropriate protective gloves, lab coat and use paper to dry the tubing. In order to minimize the possibilities of contamination of cabinet areas, a specific slot of the waste basin shall be used to position disconnected waste sensors and tubings.

After the tubing and level sensor have been disconnected, the user is asked to carefully handle the tank to prevent spillage and corner, edge or side shocks.

If an accidental tank shock should occur, before reassembling the tubing and sensor, the user is asked to accurately check the plastic surface to detect whether any crack or break occurred. If any crack or break is detected, the tank must not be used and it must be replaced.

The assessment about residual risks has highlighted that a tank crack generated by a shock may also not be detected by the user. In this case a basin can prevent the spillage; because of shape, dimensions and volumes, it does not produce other risks for handling or mechanical interference.

NOTE

Removing the tube connection from the liquid waste tank or open the solid waste drawer stops the instrument. The pipettor move in status hold. No start is possible.

1.7.4 Design of instrument to facilitate handling

Where appropriate, according with remaining risks evaluation results, tanks are equipped with handles in order to facilitate gripping; because of shape, dimensions and volumes, it does not produce other risks for handling or mechanical interference.

1.7.5 Ergonomics

The **LIAISON® XS** Diagnostic System has been designed taking into account the ergonomic principles to reduce at minimum discomfort, fatigue, physical and psychological user' stress under the intended conditions of use.

1.7.6 Safety and reliability of control systems

Control systems are managed in the instrument control software. A foreseeable fault in the hardware or in the software of the control system does not lead to hazardous situations.

Software interface of instrument is validated against foreseeable risks: foreseeable errors in the control system logic do not lead to hazardous situations.

The software is designed to help the user in following the right sequence of operations to be performed to run the instrument. Reasonably foreseeable human errors during operation do not lead to hazardous situations. The instrument cannot start un-expectedly because there are several operations to perform before having it started.

The parameters of the machinery do not change in an uncontrolled way, and may not lead to hazardous situations: the system set up parameters are not accessible to users. They are managed by Field Service Engineers only.

If the stop command has already been given, the instrument cannot be prevented from stopping.

No moving parts of the machinery or pieces held by the instrument can fall or be ejected: there are no parts that fall as consequence of a stop command.

Where applicable, a tip could be ejected into the appropriate waste solid box as a consequence of a stop command. It does not lead to risks because it is part of the intended use of the instrument.

It is strictly forbidden using the instrument with the solid waste bin closed without the EASY waste box on. A SW counter notifies the user when the solid waste box is full and needs to be replaced. User is asked to wear gloves when handling the solid waste bin and the EASY waste box.

1.7.6.1 Main Cover Opening before or during a "moving" status – safe use

The system behaves as follows:

- Whenever the system is in status "initializing" and the main cover will be recognized as open, then the system stops moving; the consequence will be that, within a few seconds, the instrument will stop all movements;
- The same would be true if the main cover opening occurs in combination with the status "maintenance";

- The same would be true if the main cover opening occurs in combination with the status “running”;
- If the software will not be communicating with the analyzer (e.g. if the PC should be switched off), then the analyzer will halt itself anyway.

The interlock protective device (i.e the cover sensor) remains fully effective or gives a stop command also in case is out of order.

WARNING

It is strictly forbidden to alter and / or to modify the intended use conditions and functions of interlocked cover. When open cover condition is ignored, it is strictly forbidden to touch moving parts while running or getting closed to them with hands, arms, shoulders or face/ head.

WARNING

No operation must be performed touching moving parts while they are running!

NOTE

The EMERGENCY STOP can be obtained by cutting energy supply acting on the MAIN SWITCH.

NOTE

An emergency stop device would not lower the risk because it would not reduce the stopping time in comparison with the instrument’s main switch.

1.7.6.2 Emergency stop – safe use

The following conditions may occur and have to be followed after an emergency stop is given:

- the main switch needs to be turned
- wait few seconds, then push the soft power button

After this the instrument and Panel-PC is turned on and the software can be started.

NOTE

The emergency stop function of the main switch is available and operational at any time, regardless of the operating mode.

1.7.7 Failure of the power supply

The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the instrument power supply does not lead to dangerous situations.

Particular attention must be paid on the following aspects:

- the instrument does not start unexpectedly: a SW command given by the user is always necessary to restart movements of the instrument;
- the setting parameters of the instrument do not change in an uncontrolled way in the case power supply fluctuations or failures should occur, not therefore leading to hazardous situations; such parameters are not erasable by the electrical power interruption;

- the instrument is not prevented from stopping if the command has already been given;
- no moving parts of the instrument or pieces held by it can fall or are ejected in case of power supply failure;
- automatic or manual stopping of the moving parts, whatever they may be, are unimpeded;
- the protective devices remain fully effective or give a stop command also in case they are out of order (please: read also chapter 1.7.6.1).

1.7.8 Protection against mechanical hazards

The durability of the materials used is adequate for the nature of the working environment foreseen by DiaSorin Italia S.p.A., in particular as regards the phenomena of fatigue, aging, corrosion and abrasion. To date, there is no evidence of parts showing to be weak.

Insofar as their purpose allows, accessible parts of the instrument have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

The moving parts of the instrument are designed and constructed in such a way as to prevent risks of contact which could lead to accidents or, where risks persist, are fitted with guards or protective devices or warning signals.

A remaining mechanical hazard is related to moving parts.

NOTE

Even if the residual mechanical risk is deemed acceptable, the user might be exposed to biohazard risk in case of minor injury (e.g. cut or scratch).

To prevent mechanical risk, user must not stand close to moving parts of the instrument when the routine is running. To prevent biohazard risk, user must wear the personal protective device as per Good Laboratory Practice and according to local regulations.

WARNING

For safe use it is strictly prohibited:

- to touch moving parts of the instrument while they are running;
- to touch instrument parts, accessories or tools potentially infected without wearing the personal protective devices;
- to assemble / disassemble tanks tubings without wearing glasses or a protective mask or visor;
- to handle samples, reagents or any other biological liquid or agent without wearing coat and gloves;
- to enter the loading bay for sample racks with hand or fingers while the instrument is running;
- to alter and or to modify fixed or interlocked movable guards;
- to use the instrument in end-user intended use without fixed or interlocked movable guards.

1.7.9 Protection against electrical hazards

The **LIAISON® XS** Diagnostic System is designed, constructed, equipped and installed in such a way that all hazards of an electrical nature are or can be prevented. The instrument is designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges.

Where appropriate, the instrument is installed with additional external switch for residual current circuit-breakers with over-current protection. Where appropriate it is integrated in UPS device.

NOTE

National rules and local regulations for the safe electrical operations of the system must be strictly observed.

NOTE

The instrument is not designed and constructed to be operated in a potentially explosive atmosphere. The instrument must not be installed and used in a laboratory with potentially explosive atmosphere.

End user is responsible to assess that such requirement is respected before allowing DiaSorin Italia S.p.A. or its affiliates to install the instrument.

WARNING

For safe use it is strictly prohibited:

- To interrupt the electrical grounding contacts;
- To add any other device to the multi plug supplied with the instrument (if available) with the exception of those installed by DiaSorin Italia S.p.A. authorized representatives;
- To damage connecting cables or not replacing them if damaged;
- To place objects on the connecting cables;
- To leave connecting cables in accessible or drivable areas where they can become additional risk;
- To not immediately disconnect the instrument from the main supply, if a safe usage is no longer possible;
- To cover the switches or have them inaccessible;
- To use the instrument if any switch or controls device is damaged.

1.7.10 Protection against noise hazards

Instrument is designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source. For technical data regarding noise emission, refer to chapter 9.7.

NOTE

The A-weighted emission sound pressure level at workstations does not exceed 70 dB(A).

1.7.11 Protection against electrostatic discharge

CAUTION

Electrostatic discharge

Electronic components can be damaged or destroyed by electrostatic discharge.

Use protective measures against electrostatic discharge.

1.8 Instrument Labeling and Safety Labels

This section provides information on the instrument labeling, with particular focus on the safety labels.

Safety labels are used on the **LIAISON® XS** system and in the documentation to identify potentially dangerous conditions. Before starting to use the instrument, user has to identify these labels and understand the type and degree of potential hazard.

WARNING

Missing Warnings

Missing or unreadable warning labels or type labels can result in non-identified dangers. This can cause serious personal injuries and material damages.

- Check the system on missing or unreadable warning labels and type labels.
- Missing or unreadable warning labels or type labels must be replaced.

1.8.1 Instrument Serial Label

Instrument Serial Label is placed on the right side of the instrument back panel

Figure 1–1: Instrument label positioning

1.8.2 Fuse label

Fuse label is positioned on:
Right side of the instrument, above the main switch

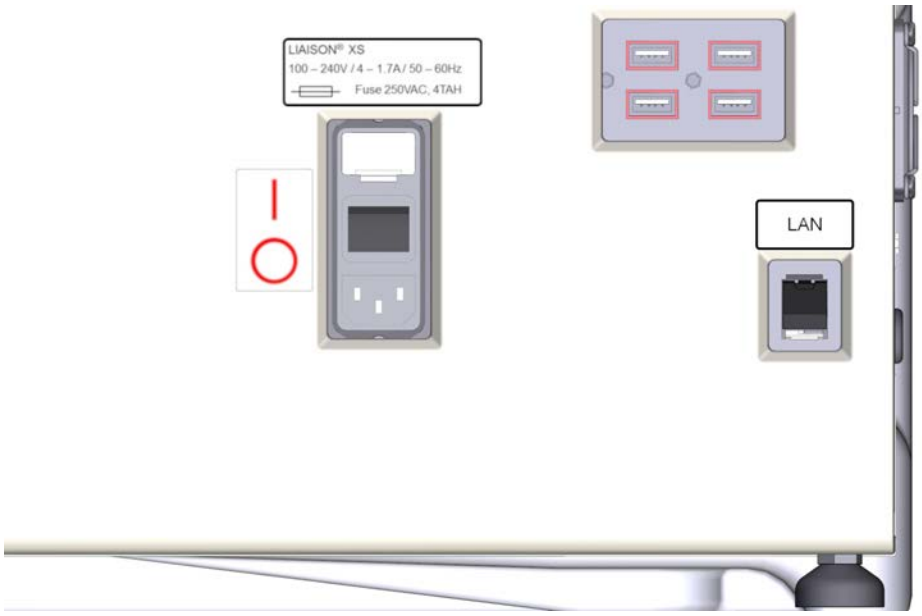


Figure 1–2: Fuse label, right side of instrument

1.8.3 Main Switch label

Main Switch label is positioned on:
Right side of the instrument, to the left of main switch

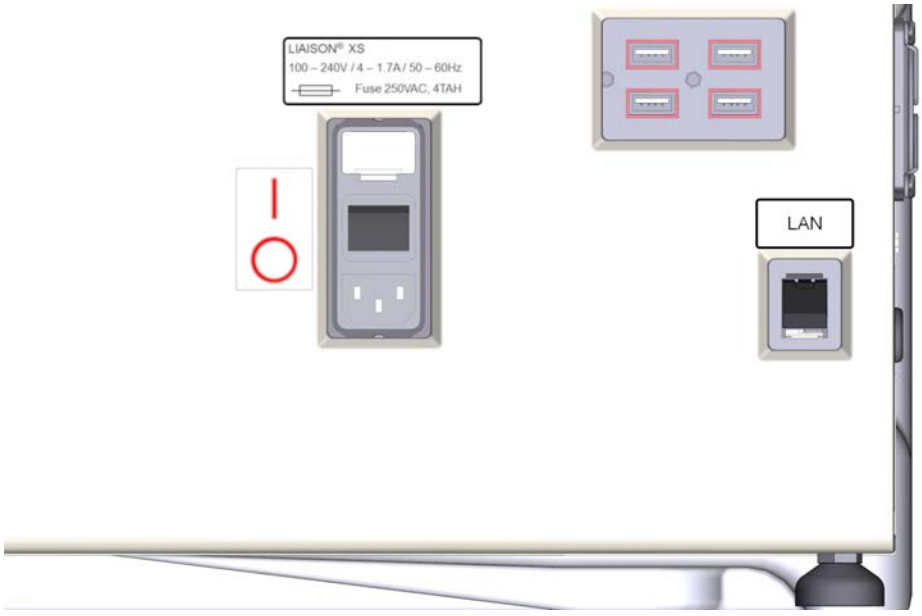


Figure 1–3: Main Switch label, right side of instrument

1.8.4 LAN label

LAN label is positioned on:
Right side of the instrument, above the LAN port

Figure 1–4: LAN label, right side of the instrument

1.8.5 USB label

USB label is positioned on:
Right side of the instrument, above the USB ports

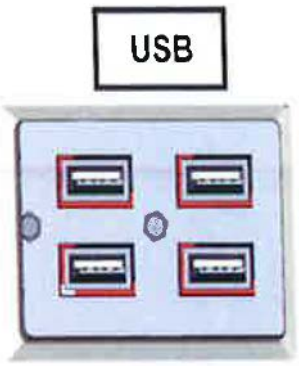


Figure 1–5: USB label, right side of the instrument

1.8.6 Pull Power plug label

Electrical hazard label: Pull power plug is positioned on:

- Right side of the instrument, left of the main switch behind the right cover

Figure 1–6: Pull power plug label, right side of instrument

1.8.7 Laser Label

Laser labels are positioned on:

- Sample module, front view

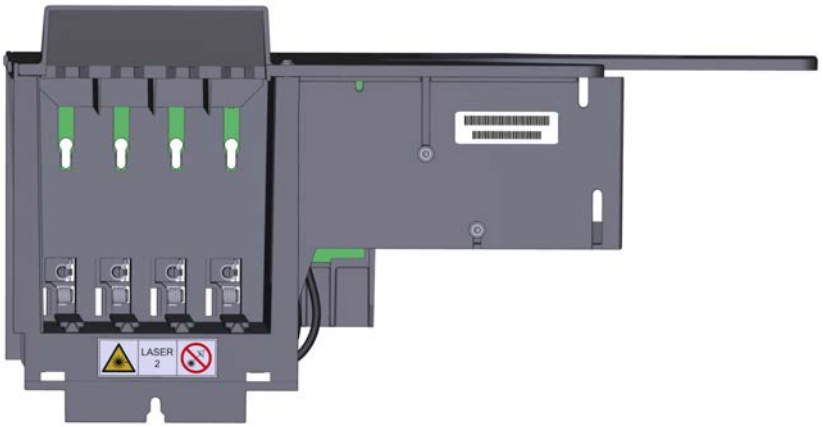


Figure 1–7: Sample Module, laser label

- Sample flap

Figure 1–8: Sample flap, laser label - First Type (A), Second Type (B)

- External barcode reader

Figure 1–9: Barcode reader, laser label

1.8.8 Pipettor label

Moving parts labels, together with hot surface label, are positioned on:

- Left pipettor arm
- Right pipettor arm

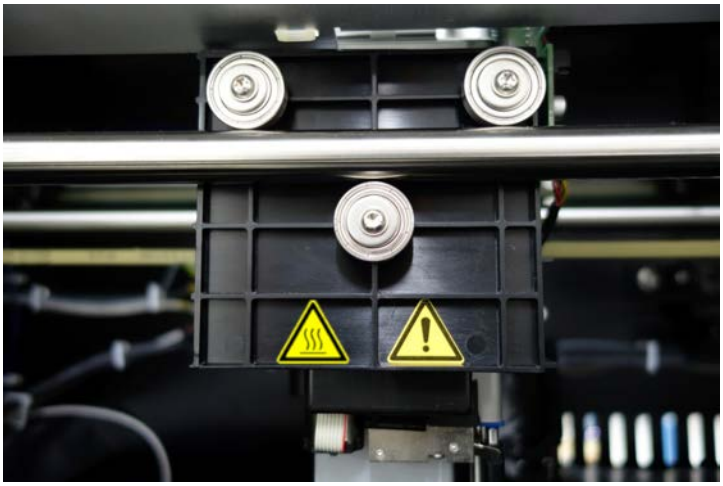


Figure 1–10: Left pipettor arm

Figure 1–11: Right pipettor arm

1.8.9 Solid Waste label

A Biohazard label is placed in the solid waste drawer (Figure 1–12).

Figure 1–12: Solid Waste Drawer label

1.8.10 Liquid Waste label

A biohazard symbol is placed on the front side the liquid waste tank (Figure 1–13), together with a label indicating the content. These symbols indicate the users the presence of contaminated liquids inside.

Figure 1–13: Liquid Waste tank label

1.8.11 Liquid Waste basin labels

A biohazard symbol is placed on both side of the liquid waste basin (Figure 1–14), together with labels to don't step on the basin. These symbols indicate the users the presence of contaminated liquids inside.

Figure 1–14: Liquid Waste basin labels

1.8.12 System liquid label

A symbol, indicating the presence of system liquid inside, is placed on top of the System liquid tank (Figure 1–15).

Figure 1–15: System Liquid tank label

NOTE

For the preparation of the System Liquid solution, refer to the Instruction for Use (IFU) provided with the System Liquid bottles.

1.8.13 Wash Buffer label

A symbol, indicating the presence of wash buffer solution inside, is placed on top of the Wash Buffer tank (Figure 1–16).

Figure 1–16: Wash Buffer tank label

NOTE

For the preparation of the wash solution, refer to the Instruction for Use (IFU) provided with the EASY Wash Buffer bottles.

1.8.14 Cleaning Solution label

A symbol, indicating the presence of cleaning agent inside, is placed on top of the Cleaning Solution tank (Figure).

Figure 1–17: Cleaning Solution tank label

1.8.15 DI Water label

A symbol, indicating the presence of DI Water inside, is placed on top of the DI Water tank (Figure 1–18).

Figure 1–18: DI Water tank label

1.8.16 Bulk fluid label

Caution label is positioned on bulk fluid area.

Figure 1–19: Bulk fluid area label

1.8.17 Top cover labels

A bio-hazard label informs the user about the possible dangers associated to the contact with the inner parts of the instrument, are placed on the internal face of the top covers (Figure 1–20).

DANGER

Risk of infection!

As indicated by the labels applied to the interior face of the left top cover, all internal parts of the system, that are not defined as user interfaces and for which specific procedures are described, must be treated as being potentially infectious. For this reason:

- Open the left top cover only if strictly necessary.
- Wear appropriate protection devices (disposable gloves, lab coat, eye protection) before coming into contact with the internal parts of the system.

Figure 1–20: Biohazard label, inside left and right top cover

In order to prevent possible hand crushings during the opening/closure of the top covers, two specific warning labels are placed on the front cover bar, respectively under the left (Figure 1–21) and the right (Figure 1–22) top covers.

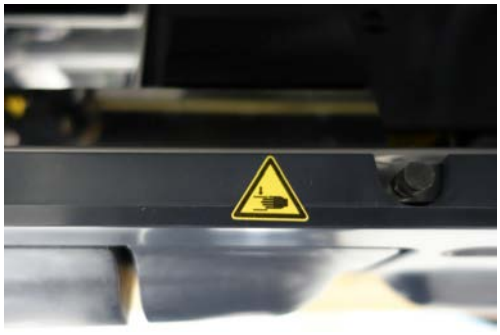


Figure 1–21: “Danger of crushing hands” left label

Figure 1–22: “Danger of crushing hands” right label

1.8.18 Flap labels

No objects shall be put on the flaps of reagent area, sample area and starter area when they are opened. In order to avoid possible misunderstandings of users, a specific label is applied to the flaps (Figure 1–23, Figure 1–24 and Figure 1–25).

Bio-hazard labels are also applied to the sample and reagent flaps, informing the user to pay attention to the possible presence of spills of infectious liquids caused by sample or reagent improper handling.

Figure 1–23: Flap labels - Sample Area - First Type (A), Second Type (B)

Figure 1–24: Flap labels - Reagent Area

DANGER

Clean immediately spills present on flaps, following what indicated in chapter 1.6.6 and 1.6.7.

Figure 1–25: Flap label - Starter Reagent Area

1.8.19 Magnet Label

Magnet labels are positioned on:

- Washer module, on top
- System Liquid tank
- Wash Buffer tank
- Cleaning Solution tank
- DI Water tank
- Instrument rear view
- Front cover, re-suspension tool

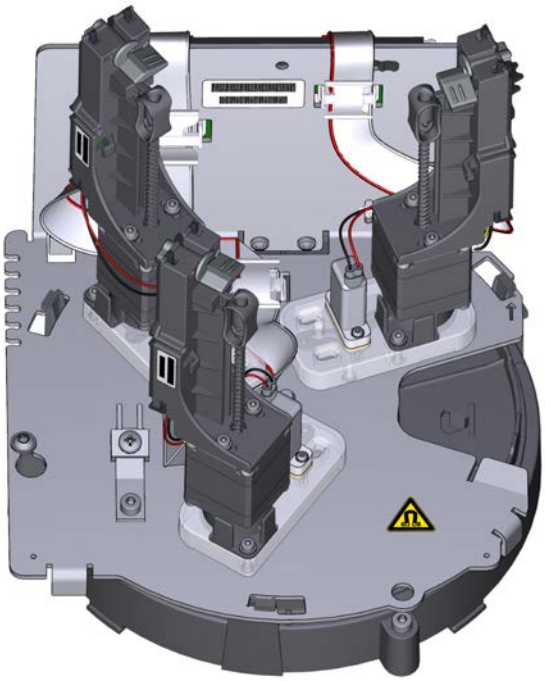


Figure 1–26: Washer Module, magnet label

Figure 1–27: System Liquid tank, magnet label

Figure 1–28: Wash Buffer tank, magnet label

Figure 1–29: Cleaning Solution tank, magnet label

Figure 1–30: DI Water tank, magnet label

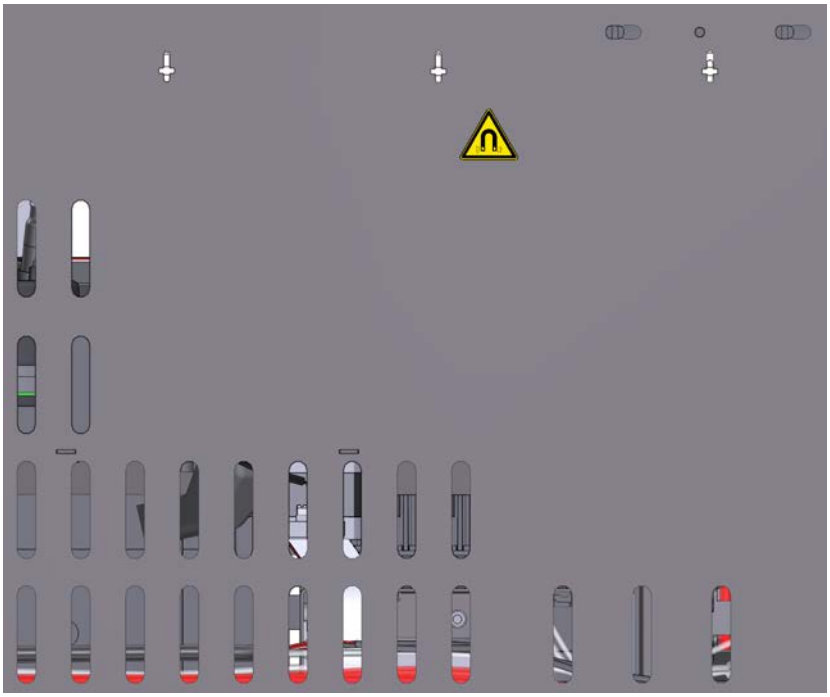


Figure 1–31: Instrument rear side view

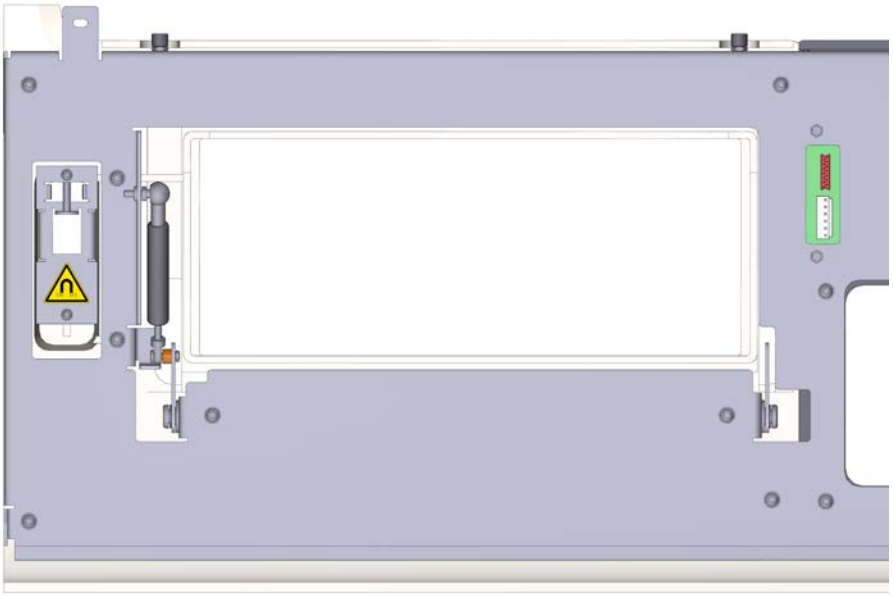


Figure 1–32: Front cover, rear side view

1.8.20 Shockwatch, Tiltwatch and Temperature label

Shockwatch, Tiltwatch and Temperature label: is positioned on:

- Rear side of the instrument

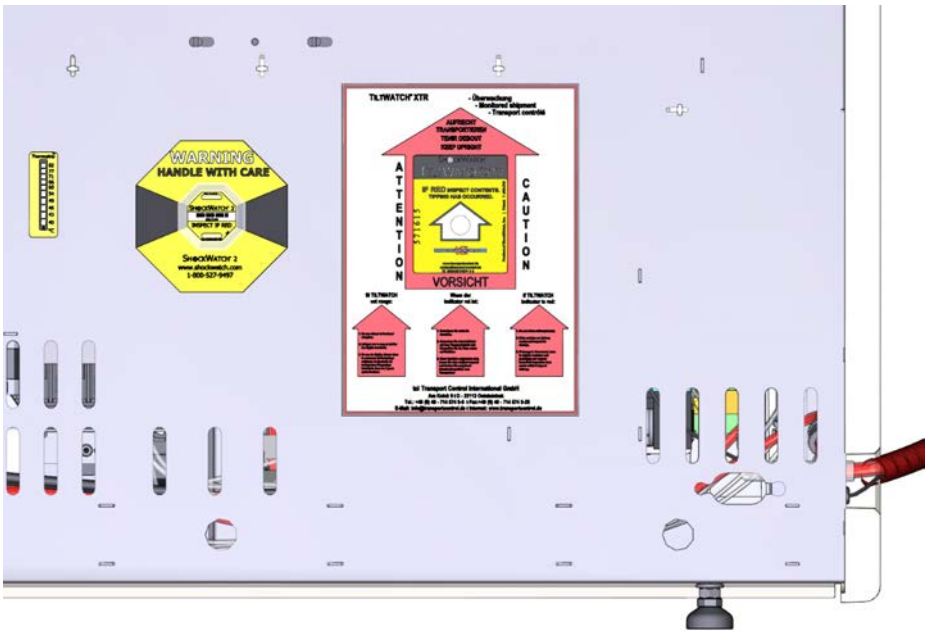


Figure 1–33: Rear side, Shockwatch, Tiltwatch and Temperature label

1.9 Operational Precautions and limitations

This section describes the operational requirements, precautions, and limitations to ensure user safety and accurate assay results.

User must follow these requirements to help ensure proper system performance.

Not following the requirements and precautions provided can impact the system and assay performance and may cause damage to the system or adversely affect assay results.

1.9.1 General requirements

- Ensure the system is out of direct sunlight, heat and drafts, and away from any heat generating device. Exposure to heat and drafts can interfere with the ability of the system to maintain an operating temperature that is within the acceptable range.
- Maintain the required space on all sides of the system. For more information about space requirements, see chapter 9.5. This space buffer is essential for:
  - Accurate temperature control of the system;
  - Adequate cooling of electrical components;
  - Easy access for disconnecting the power cord when required;
  - Easy access for maintenance.

WARNING

Danger due to Overheating

Improper positioning (installation or operation) of the system or improper environment may cause fire or serious system damage in case of overheating.

- Leave the system power on continuously unless instructed otherwise in a maintenance or troubleshooting procedure, or unless an emergency situation occurs.
- Perform maintenance procedures as recommended in chapter 8.
- Do not attempt any maintenance that is not specified in the documentation provided by DiaSorin Italia S.p.A.
- In case of user injury, keep the potential contaminant agent for a subsequent analysis.

1.9.2 Forbidden foreseeable misuse

The following list includes (but is not exhaustive) a set of forbidden foreseeable misuses identified by the Manufacturer. The user must carefully read below notes and follow the indicated safe way to operate to avoid risk of harm.

- Troubleshooting operations to resolve cuvette jamming performed while moving parts are active. Intended use: operation is allowed when moving parts are inactive.
- Introduce body parts in the hazard area while the instrument is active with moving parts. Intended use: any needed operation is allowed when moving parts are inactive.
- Operate the instrument without the EASY waste and the solid waste bin onboard unless during EASY waste box replacement. Intended use: EASY waste box and its bin must be onboard unless during EASY waste box replacement.
- Operate the instrument with no liquid waste tank connected. Intended use: a liquid waste tank must always be connected before operating. This restriction is not applicable if waste tubing is directly connected to a laboratory drain.

1.9.3 System operation

1.9.3.1 Precautions and Requirements before operation

Before beginning to operate the system, the user has to:

- Read this manual thoroughly to understand full functionality of the system and associated hazards.
- Read the sections of the reagent manufacturer's assay-specific documentation that are associated with:
  - Warnings and precautions;
  - Safety precautions.
- Verify that the solid waste bin is equipped with the appropriate EASY Waste box.
- Verify that the liquid waste tank is not full and correctly positioned.

1.9.3.2 Precautions during operation

- Keep all drawers and covers closed if not unless instructed otherwise in a described procedure.
- Do not disconnect any electrical connection while the power is on.
- Respond to system warnings during processing.
- Dispose of all waste material according to local regulations.
- Remove all samples and integrals from the system in case of an emergency stop.

1.9.4 Handling of reagents and consumables

See the manufacturer's assay-specific documentation (such as a package insert), the specific product label, the appendixes of the present manual or the Material Safety Data Sheet (MSDS) for detailed information, including hazard symbols.

1.9.5 Handling of specimens

Carefully read the reagent manufacturer's assay-specific documentation and the present manual for information about specimen collection, preparation, and storage.

Consider all system surfaces or components that have been in contact with human-sourced materials as potentially infectious.

1.9.6 Limitation of result interpretation

Any assay result supplied by the instrument does not aim to be released as medical advice or service without approval by authorized medical personnel.

Assay results must be used with other clinical data such as patient symptoms, other test results, patient history, clinical data, information available from clinical evaluation, and other diagnostic procedures.

The **LIAISON® XS** has been validated for its intended use only. However, errors can occur due to potential operator errors and **LIAISON® XS** System technology limitations. If assay results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

NOTE

Clot Detection System

Not withstanding the instrument is equipped with a clot detection system, the user is not authorized by DiaSorin Italia S.p.A. to load consciously on the instrument sample tubes containing clots. Any default of the system related to a relevant unappropriate use is in the sole responsibility of the user.

1.10 Installation of the System

CAUTION

Installation

Please note that the **LIAISON® XS** system may only be installed by authorized service personnel.

NOTE

The Analyzer is not designed and constructed to be operated in a potentially explosive atmosphere. The Analyzer must not be installed and used in a laboratory with potentially explosive atmosphere.

Customer is responsible to assess that the above requirement is respected before allowing DiaSorin Italia S.p.A. or its affiliates installing the Analyzer.

CAUTION

Note Technical Data

See chapter “Technical Data” (chapter 9) for power requirements, computer and connections, installation dimensions, weight and environmental conditions.

NOTE

After the installation, the user of the **LIAISON® XS** system receives an installation qualification which documents the proper installation of the **LIAISON® XS** system.

1.11 Removal of the System

If the system must be shipped to a new location, user shall contact the local DiaSorin field service representative for assistance.

CAUTION

Removal

The removal of the **LIAISON® XS** system must be performed by authorized service personnel.

CAUTION

Reinstallation

If the **LIAISON® XS** system moves within the plant, the authorized service personnel must perform a complete reinstallation. If this reinstallation is omitted, this can cause damage of the system or irregular pipetting performance.

2 PC security measure

2.1 Introduction

LIAISON® XS software is intended to be used in a controlled environment. Access is allowed only to trained and authorized users.

Nevertheless, usage of the system may be subject to risk of unauthorized access, leading to possible data loss, corruption or unauthorized distribution.

Furthermore, updates to the software modules provided with the system (e.g. Operating System) must be distributed under controlled process, to ensure that the system still behaves according to its intended use after the update.

This chapter describes the policy followed by DiaSorin and partners regarding how software environment is kept secure on systems installed in end-user environment.

2.2 Unauthorized local access

2.2.1 Potential issues

Usage of the system is meant only for trained and authorized users, who are supposed to follow the intended use of the system.

Unauthorized users could access or damage a computer system without the owner's informed consent. Consequences may be software and data loss, corruption or unauthorized distribution.

2.2.2 Protection measures

Access to the **LIAISON® XS** software is based on an access rights structure that allows system operation only to authorized users:

- operating the system, including access to any data, is only possible when typing a user identifier (made of “user name” and “password”), that is unique for each end-user;
- “user name” is unique and cannot be re-assigned;
- both “user name” and “password” must be at least 8 characters long;
- for each “user name”, a “password duration” can be set; within the time frame based on “password duration”, the system will force the user to change the “password”;
- each user can change his/her own password;
- since, during installation of the system, for every user one default “password” will be inserted. it will be in the care of DiaSorin and partners personnel to inform the end-users to modify her/his password at the first usage;
- it’s possible to define a “session expiration time”, i.e. a time interval after which the system logs-off the current user;
- end-users are logged into Operating System with a restricted account;
- end-users have no means to overcome the **LIAISON® XS** software application, i.e. they have no access to the Operating System and other applications.

2.3 Malware

2.3.1 Potential issues

Usage of **LIAISON® XS** computer could lead to voluntary or involuntary introduction of malicious software, like viruses, worms, spyware. This malicious software (also called malware) is designed to infiltrate, damage or steal information from a computer system without the owner's informed consent.

Consequences may be software and data loss, corruption or unauthorized distribution.

The introduction of such malicious software may occur:

- via network;
- via a local USB device.

2.3.2 Protection measures

The state-of-art, widespread approach is to provide network intrusion protection, with specific equipment and/or software, and device software protection, with specific anti-malware products. This approach does not looks adequate for the **LIAISON® XS** computer for several reasons:

- any network firewall should be installed by network administrators and/or skilled technical staff who, in this scenario, are end-users in regards to DiaSorin, therefore DiaSorin has no control on the firewall solution in terms of adequacy;
- any antimalware must be kept up-to-date to be efficient, therefore automatic frequent updates are necessary; the only mode to guarantee this is to connect the computer to an update source over the network or the internet but:
  - it cannot be ensured that all computers will be connected and, also for those connected, connection cannot be guaranteed upfront, while a malware can be introduced anytime, even without network connection;
  - furthermore, continuous automatic updating of the anti-malware product implies that the system configuration is frequently updated while DiaSorin could not guarantee a continuous validation update in a constant changing configuration; for example, an antivirus could unexpectedly recognize as malware and delete files that are necessary part of the validated environment, with the consequence of potential software malfunctioning.

For all these reasons, an alternative integrated approach has been chosen:

- all the Operating System ports, not strictly required by the validated applications, will be blocked and/or disabled on the computer;
- the Operating System integrated firewall will be activated and configured such as any remote access to the system is denied (except specific ports needed for remote access authorized by DiaSorin);
- AutoPlay feature for all USB storage devices will be disabled on the Operating System;
- it is prohibited to install any external removable media USB device (CD/DVD-Rom or Floppy Disk);
- introducing infected files from USB devices is prevented by design, as end-users will have access, on the computer, to the sole features allowed by the **LIAISON® XS**, i.e. access to the Operating System features is inhibited, and **LIAISON® XS** will only allow to import files with specific proprietary extensions, disregarding any file with different extension;

- system boot order starts from the Operating System disk;
- as additional protection, a specific and defined on-demand malware scan tool, relying on heuristic detection methods, is installed on **LIAISON® XS**. No other anti-malware product can be installed on **LIAISON® XS**.

2.4 Unauthorized network access

2.4.1 Potential issues

A **LIAISON® XS** computer connected to a network could be accessed by unauthorized individuals, causing unpredictable effects on installed software and data. Consequences may be software and data loss, corruption or unauthorized distribution.

2.4.2 Protection measures

A software firewall is an application which controls network traffic to and from a computer, allowing or denying communication based on a security policy.

The Operating System integrated firewall is activated and configured to make sure inbound network access is denied.

Theoretically, only computers connected to a network require a personal firewall, but for the sake of uniformity all computers provided with Liaison XS will be protected by the Operating System personal firewall.

2.5 System update

2.5.1 Potential issues

Operating System and other software modules installed on **LIAISON® XS** computer may require to be updated, from time to time, in order to fix specific issues, in particular security vulnerabilities.

2.5.2 Protection measures

Continuous change to software modules leads to a technical risk: the more changes are introduced, and the more frequent they are, the more risks would accumulate in these regards. The described protection measures against external intrusions are considered safe enough to mitigate known risks and risks introduced by new vulnerabilities on the **LIAISON® XS** computer.

For these reasons, the Operating System and other software modules installed on **LIAISON® XS** computer will be updated only if a change is due to known technical reasons.

2.6 Local/network printing

2.6.1 Potential issues

There are two possible printing device types that can be used (only one per system):

- a local printer;
- a network printer.

Usage of a local printer, installed by DiaSorin on **LIAISON® XS** systems as “default printer”, requires installing printer drivers that could affect the system with consequences like software and data loss.

Usage of a network printer, configured by DiaSorin on **LIAISON® XS** systems as “default printer”, requires to install printer drivers, that may be not available for the **LIAISON® XS** computer, or to rely on Operating System printing service, that could affect the system with consequences like software and data loss.

2.6.2 Protection measures

Local printer models, installed by DiaSorin on **LIAISON® XS** systems, are validated against their intended use. No printers that did not pass the validation test will be installed on **LIAISON® XS** systems.

Usage of a network printer will be supported:

- By installing printer drivers, provided that a printer model validation is carried out
  - through the definition of a predefined set of “standard printer models”
  - via dedicated validation for any additional printer model

or relying on the Operating System printing service, without installing printer drivers.

2.7 Desktop Sharing

2.7.1 Potential issues

LIAISON® XS systems may be accessed by DiaSorin support personnel with the purpose of troubleshooting, customer support, and software update. This will be managed through a dedicated application that requires software installation on both Liaison XS computer and support personnel computers.

Remote access may be established through an internet based network connection.

Availability of a network connection may vary depending on countries and specific user technical infrastructure.

Presence of such application could lead to systems being remotely accessed by unauthorized subjects, causing unpredictable effects on installed software and data. These situations could lead to consequences such as software and data loss, corruption or unauthorized distribution.

2.7.2 Protection measures

Remote access connection will be established on a secure communication channel, protected by encryption and authentication to guarantee confidentiality and integrity of data transmission.

DiaSorin certifies that only authorized personnel are allowed to perform remote connection.

No remote connection session can be initiated without the explicit allowance of an operator in front of the system who is able, at any time, to interrupt the same session.

2.8 IoT connection

2.8.1 Potential issues

LIAISON® XS systems may send to a dedicated cloud system telemetry data for the purpose of troubleshooting, customer support.

Furthermore the IoT connection can be used to retrieve updated manuals, assay-relevant files.

This will be managed through a dedicated communication channel that requires activation on the Liaison XS software and the availability of a network connection with internet access.

The availability of a network connection may vary depending on countries and specific user technical infrastructure.

Opening of such communication channel could lead to system being accessed by unauthorized actors, causing unpredictable effects on installed software and data. These situations could lead to consequences such as software and data loss, corruption or unauthorized distribution.

2.8.2 Protection measures

The IoT connection will be established on a secure communication channel, protected by encryption to guarantee confidentiality and integrity of data transmission.

There's no direct access of any personnel to the systems.

DiaSorin adopts a risk based approach to implement adequate technical measures aimed to reduce the risk of the described potential issues.

2.9 Privacy

2.9.1 Potential issues

LIAISON® XS produces analytical results that refer to the health condition of patients.

Therefore, a potential risk of unauthorized disclosure of sensitive patient data may exist in regards to:

a. DiaSorin personnel (directly or indirectly involved in technical activities on the laboratory systems)
b. DiaSorin partners personnel (directly or indirectly involved in technical activities on the laboratory systems)
c. DiaSorin suppliers personnel (indirectly involved in technical activities on the laboratory systems).

Patient health data could be potentially available to the above mentioned subjects in the following situations:

1. during a technical intervention on laboratory systems, personnel of type “a” or “b” may need to access the **LIAISON® XS** software that may contain patient health data, therefore check such data on the screen or print data as hard copy;
2. personnel of type “a”, “b” or “c” could retrieve patient health data as part of data exchanged in electronic or paper format, as part of technical troubleshooting or maintenance activities that involve such personnel.

Furthermore, users different from above listed types could get in contact with patient health data.

Specific country regulations may require different means to address the listed potential issues.

2.9.2 Protection measures

The following measures are adopted in order to make the system compatible with the known regulatory requirements. Measures already listed and described in the present chapter that are in place to protect the patient health data are not repeated here.

1. Both patient health data and demographics are encrypted;
2. No patient demographic data is exchanged through remote access or IoT;
3. It is possible to manually perform a complete back-up of patient health data;
4. It is possible to schedule automated back-up of patient health data;
5. Sample identifier (SID) as well as patient identifier (PID), are conceived as an anonymous sequence of alphanumeric characters, that end-users may use in combination with their laboratory system, in which all patient information are maintained, and particularly patient demographics;
6. The system can perform all analysis without the need to insert patient demographics; as such it is recommended that demographic insertion is avoided both as manual input and LIS transmission;
7. The system allows to fill (either manually or by receiving such information from the LIS system) the fields “name” and “last name” present in the patient information,
8. In case the fields “name” and “last name” (patient demographics) are filled:
   a. access to such data will be restricted, on the system, to specific users, for whom the laboratory responsible people will request activation during system set up;
   b. such measure regards the on screen display and the printed copies of such information, either directly from the Personal Computer connected to the system or from any other Personal Computer on which **LIAISON® XS** software is installed and where data bases are loaded after exporting from the original Personal Computer;
   c. such measure covers both the direct visualization of information (e.g. on screen display of health data in combination with demographics) and indirect search (e.g. the possibility to go back from health data to the SID and from the SID to the personal data);
   d. therefore, not explicitly authorized users will not have the rights to get access to patient demographics, not even in case the user provided the database containing patient demographics.

Regarding end-users responsibilities, where required by local regulations, the end-user is responsible for the following behavior: on **LIAISON® XS** SID and PID must not refer to the patient; such traceability shall be kept on the laboratory tracing systems.

In regards to the responsibilities of DiaSorin, where required by local regulations, DiaSorin responsibility is configured as follows:

a. in case of evidence of a **LIAISON® XS** being operated outside requirements of local applicable privacy regulation, DiaSorin will solicit compliance;

b. DiaSorin is not liable for improper use of data generated through the **LIAISON® XS** once such data is outside of the boundaries of the system itself, i.e. after data has been written, printed, or sent in electronic format to other laboratory systems.

DiaSorin adopts a risk based approach to implement adequate technical measures aimed to reduce the risk of the described potential issues.

2.10 Security Requirements for Operating Environment

The Operating Environment is defined as the complex of physical and logical/IT environment interacting with the **LIAISON® XS** during intended operating conditions.

To integrate the **LIAISON® XS** in the Operating Environment according to security standards and best practices, the Operating Environment shall comply with the following:

1. Applicable data privacy regulations;
2. Adequate security controls including network traffic;
3. Any patch management process shall prevent interoperability/compatibility issues with the **LIAISON® XS**.

3 Measuring principle of the LIAISON® XS immunoassay

3.1 Explanations for Steps of Assays

Assays (also defined as “tests”) that run on the **LIAISON® XS** are divided into major categories:

- 1-step assays
- 2-step assays
- 3-step assays

The numbered steps refer to the required amount of incubation sequences for a test. An incubation sequence is described as the amount of times a sample must enter the incubator during the run.

These categories are described in detail below.

3.1.1 Test Procedure 1-Step Assay

A 1-step assay refers to a test or assay that has:

- 1 incubation sequence (the time of incubation may range depending on the assay).
- 1 wash sequence (the amount of washing for this sequence is assay dependent).

Most assays that are 1-step have an incubation time of 10 minutes. The figure below is only an example. Pipetting sequences are also assay dependent.

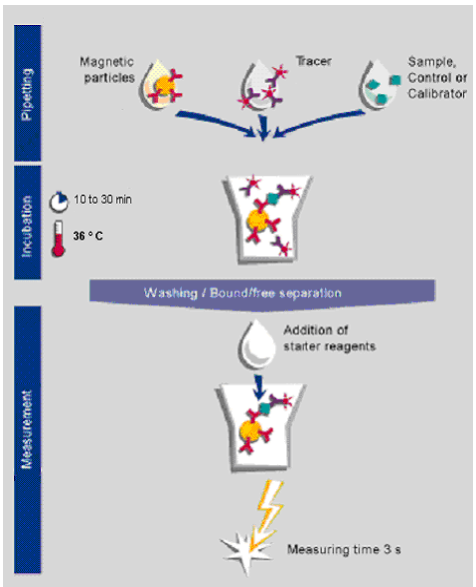


Figure 3–1: Example of test procedure “1-step assay”

3.1.2 Test Procedure 2-Step Assay

A 2-step assay refers to an assay that has:

- 2 incubation sequences (the time of incubation may range depending on the assay).
- 1 or 2 wash sequences (the amount of washing for each sequence is assay dependent).

Most assays that are 2-step have an incubation time of 10 minutes each. The figure below is only an example. Pipetting sequences are also assay dependent.

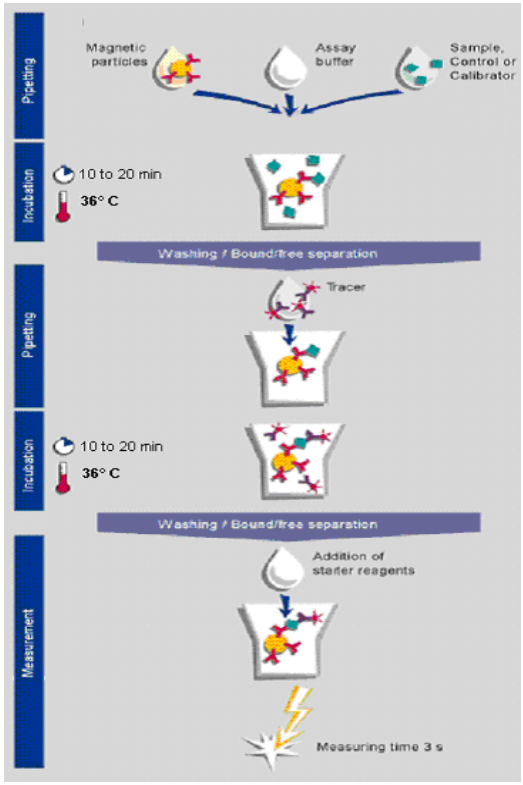


Figure 3–2: Examples of test procedure "2-step assay"

3.1.3 Test Procedure 3-Step Assay

A 3-step assay refers to an assay that has:

- 3 incubation sequences (the time of incubation may range depending on the assay).
- 1 to 3 wash sequences (the amount of washing for each sequence is assay dependent).

3.2 Measuring Principle

- After the last wash cycle has been completed, the cuvette is transported into the Reader.
- When the cuvette reaches the position under the first injection head, starter reagent 1 will be injected.
- The cuvette is transported in the position under the second injection head and the starter reagent 2 will be injected to start the chemiluminescence reaction.
- In this way the pump delay time between the starter 1 and the starter 2 is 2.50 sec minimum.
- The measuring signal is obtained and integrated over the measuring period (3.0 sec for most assays).

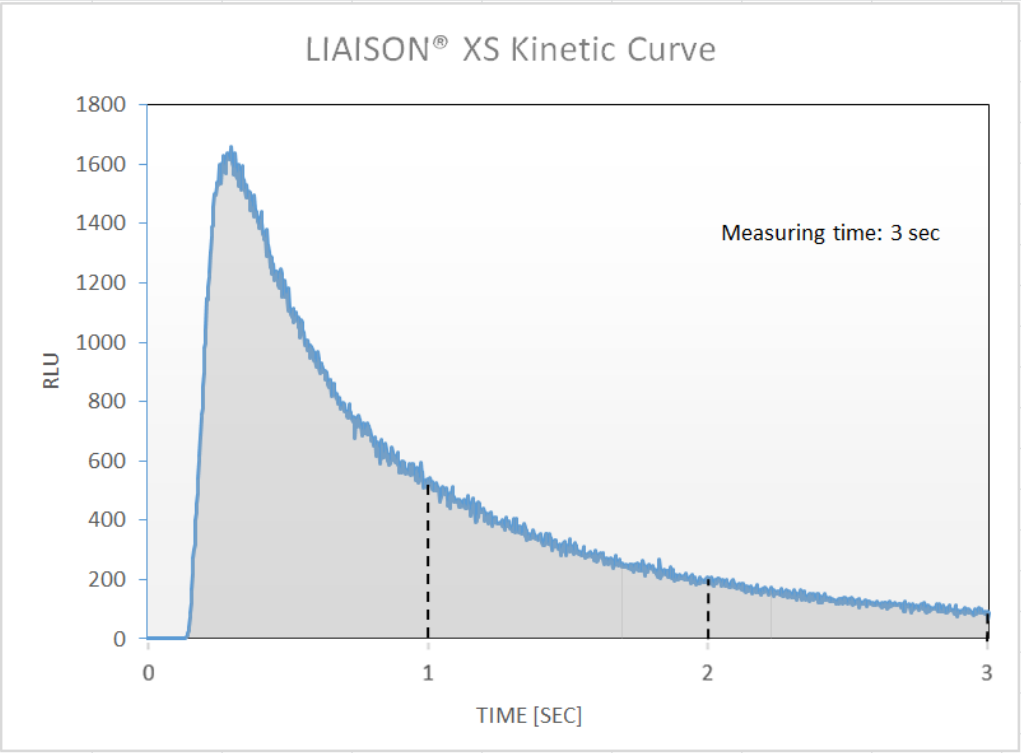


*Figure 3–3: **LIAISON® XS** kinetic curve*

3.3 Measuring Function Description

- The chemically emitted light is measured by a selected highsensitive, low-noise photomultiplier [PMT]. The linear measuring range of the photomultiplier is 300 – 650 nm. The light peak of the chemiluminescence is emitted at a wavelength of 420 nm.
- The PMT is operating as an ultra-fast photon counter. The pulses are amplified by a rapid electronic amplifier. A circuit, which suppresses the PMT signal-noise is also implemented in the PMT box.
- Not the number of counts, but the Relative Light Units [RLU] are used as units of the measurement for the raw data.

3.4 Calibration (quantitative)

Data reduction is performed using a master curve with 2-point recalibration.

The starting point of data reduction is the master curve, stored in the RFTag of each integral of the assays.

To compensate for differences between reagent lots, different analyzers and environmental conditions, assay calibration must be run and validated according to the indications reported in the assay Instructions for Use (indications may vary per assays).

The measuring signals of the calibrators allow the shift of all master curve points to a working curve, corresponding with the actual conditions during measurement. See the following example.

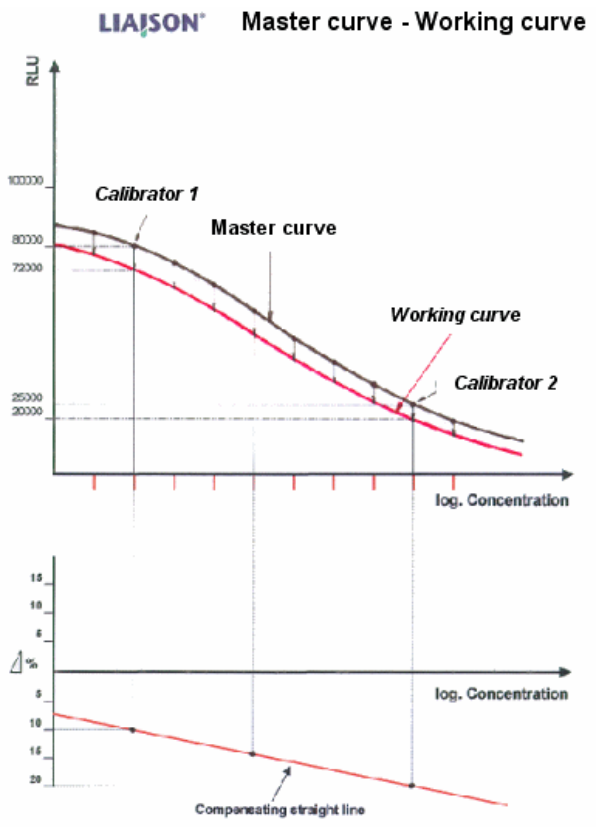


Figure 3–4: Calibration concept: example

Brief description:

- The master curve is generally defined with 10 master curve base points.
- Two calibrators with defined concentration values are measured. These measured signals (RLU) are compared with the master curve signal of the corresponding calibrator concentrations.
- The relative difference between the measured RLU and the master RLU of the calibrators is calculated and a linear extrapolation is performed between the recalculated RLU (Y-axis) and the logarithmic (Log) concentrations (X-axis).
- Based on appropriate compensation factors, a re-adjustment of the master curve points is made in order to achieve, by a “cubic spline function”, the working curve.

WARNING

Wrong Results!

For continuous safety of the diagnostic results, quality control measures are to be maintained, such as routine controls or calibration issues, which are defined in this Operating Instruction.

NOTE

- Safe and intended function of the **LIAISON® XS** Diagnostic System can only be expected with the use of **LIAISON® XS** controls approved by **DiaSorin Italia S.p.A.**
- Observe instructions in IFU of the reagents for Qualiy Control of the assay.

3.5 Calibration (qualitative)

The calculation of a reference level, the cut off (CO), is performed as a linear combination of terms, dependent upon system base signal and calibrators' RLU. Formula applied is the following:

$$CO = a \cdot RLU_{cal1} + b \cdot RLU_{cal2} + c$$

Analytical result is reported as index, the ratio of the unknown sample signal RLU_{sample} vs the *CO*:

$$I = RLU_{sample} / CO$$

Two kinds of QCal are possible, depending upon the number of calibrators:

- in one point qualitative, only calibrator 1 is present: coefficients given are *a* and *c* only;
- in two points qualitative, both calibrator 1 and 2 are present: all three coefficients *a, b* and *c* are given.

Validation of calibration is possible if results scored by the calibrator(s) lie within the related acceptance ranges.

After validation, the cut off is then calculated from the formula above.

4 System description

4.1 Overview

4.1.1 Materials required but not provided

In order to perform immunoassays, the following materials are needed beside specific assay kits:

- **LIAISON®** Cuvettes on Tray (code X0053).
- **LIAISON®** Disposable Tips (code X0055).
- **LIAISON®** EASY Starter Kit (code 319300).
- **LIAISON®** EASY Wash Buffer (code 319301).
- **LIAISON®** EASY System Liquid (code 319302).
- **LIAISON®** EASY Waste (code X0054).

4.1.2 LIAISON® XS System

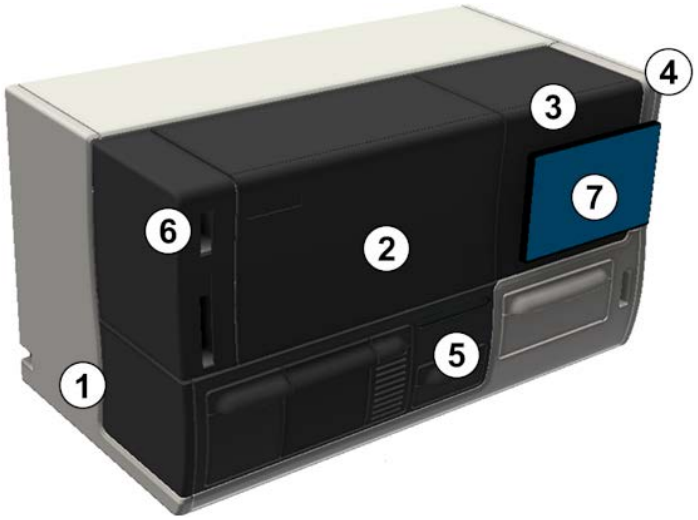


Figure 4–1: ***LIAISON® XS*** *system*

CAUTION Opening the cover during system operations may result in operation interruption and no reported results.

No.	Description
1)	Left side cover
2)	Left top cover
3)	Right top cover
4)	Right side cover
5)	Front Module (starter reagents, drawer for disposable cuvette and tip trays, loading bays for samples, solid waste bin, reagents area and resuspension tool)
6)	Bulk fluid door for Wash Buffer and System Liquid tanks
7)	Panel-PC with touch screen

Table 4–1: ***LIAISON® XS*** *System*

4.1.3 Outer front view

Figure 4–2: **LIAISON® XS** flaps and drawers

No.	Description
1)	3 liter Wash Buffer
2)	5 liter System Liquid
3)	Top Cover Right
4)	Top Cover Left
5)	Panel-PC with touch screen
6)	Starters reagent flap
7)	Disposal tips and cuvettes drawer
8)	Sample bay flap
9)	Solid waste Bin
10)	Status Light
11)	Reagent module flap
12)	Integrated re-suspension tool

Table 4–2: Instrument overview

4.1.4 Left inside view

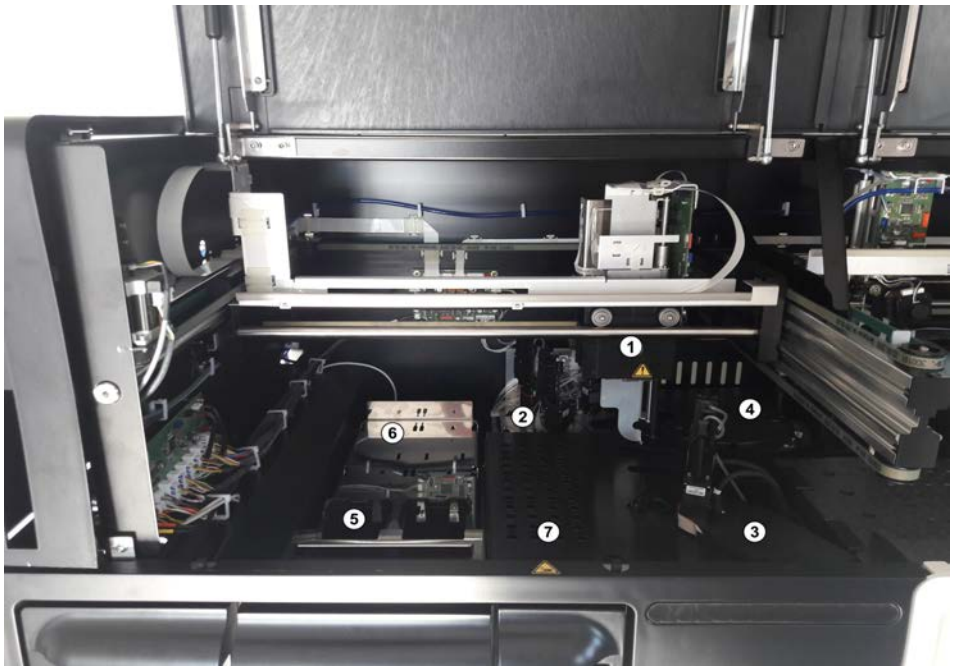


Figure 4–3: Instrument inside left side view

No.	Description
1)	Pipettor left arm (Sample & cuvette gripper)
2)	Washer
3)	Reader
4)	Incubator
5)	Disposable tips area
6)	Cuvettes trays area
7)	Samples area

Table 4–3: Instrument inside left side view

4.1.5 Right inside view

Figure 4–4: Instrument right inside view

No.	Description
1)	Pipettor right arm (SPOLV)
2)	Reagent area module
3)	Wash station
4)	Wash station splash containment

Table 4–4: Instrument right inside view

4.1.6 Left side view

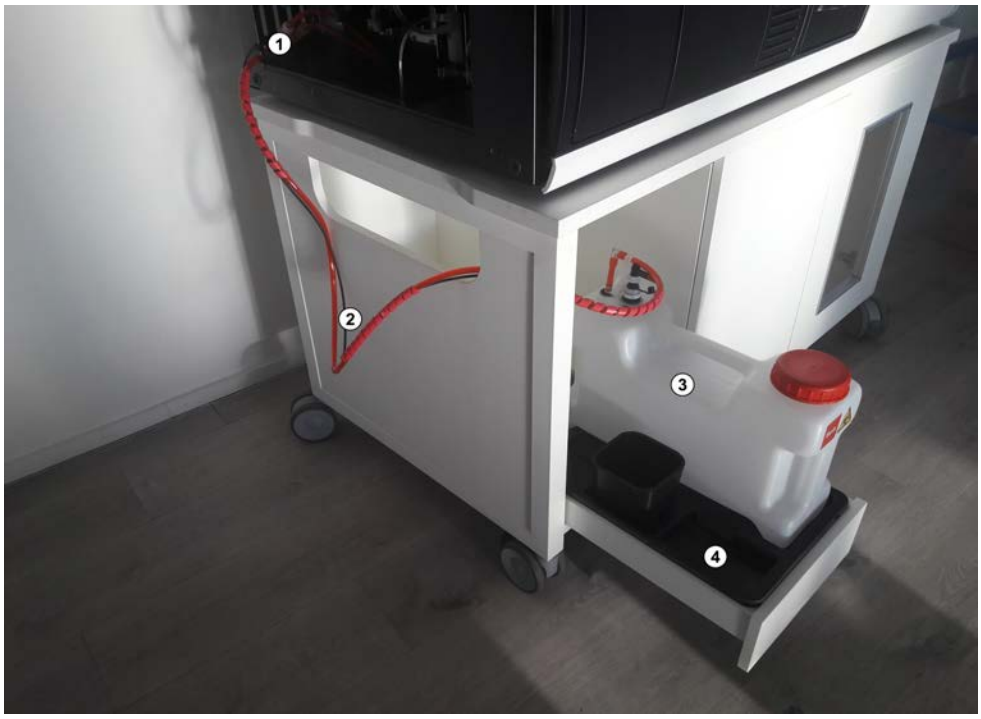


Figure 4–5: Left side view

No.	Description
1)	Liquid waste outlet
2)	Liquid waste tubing and sensor
3)	Liquid Waste Tank
4)	Liquid Waste Basin

Table 4–5: Left side view

DANGER

Wrong placement of the Waste Tank

Too high installation of the Liquid Waste Tank can lead to a liquid drawback!

- It is preferred to place the waste container below the instrument.

The Liquid Waste Tank shall be located below the instrument or on the same stand/table where the instrument is placed.

4.1.7 Right side view

Figure 4–6: Right side view

No.	Description
1)	Main switch
2)	LAN connector
3)	USB connectors
4)	Soft power button

Table 4–6: Right side view

4.1.8 Glossary

Ancillary (reagents)	Anything that can be introduced by operator into Ancillary Area rack, including external reagents for some kits and Light Check.
Barcode Reader	Assembly to read the sample barcode.
BGW	Test to check quality of instrument washing.
Control Rack	8 positions module to host some types of control bottles and external calibrators.
Cuvette	Single cavity plastic module, in which immunometrical reaction can take place.
CV%	Statistical variable that shows dispersion rate of measurements.
EASY Waste	Carton disposable box to increase safety during waste disposal.
Gripper	Mechanism to handle cuvettes loading from trays, exchange cuvettes between incubator and washer and move cuvettes from washer to reader.
Incubator	The incubator offers 32 cuvette positions in the outer ring and 25 cuvette positions in the inner ring in which cuvettes are incubated and pipetted.
Instrument	Part of **LIAISON® XS** system that includes only the **LIAISON® XS** instrument and tanks, but printer and connection cables.
Integral	Reagent cartridge (made up of vials) to be inserted into the Reagent Area.
Integral Holder	Holder used for the handling of integrals outside the instrument. Up to 16 integrals can be transported together.
Kit	Set of reagents used to carry out a specific assay; it may consist of one or more integrals, external calibrators and ancillary reagents.
LC-le	Test to verify precision of the left dispensing pipettor, carried out by Light Check solution.
LC-ri	Test to verify precision of the right dispensing pipettor, carried out by Light Check solution.
Light Check	Test tool provided as lyophilised material.
Light Check adaptor	Plastic adaptor used to insert the Light Check bottles into the Ancillary Area rack.
Liquid Waste Basin	Basin used to collect spillage of contaminated liquid coming from broken liquid waste tank.
Liquid Waste Tank	Tank to collect all the liquid waste of the instrument.
Prime	Start-up cycle for individual parts of instrument involved in fluidics, carried out by using System Liquid, DI Water, Wash Buffer, Starter Reagents and Cleaning Solution.
Rack Holder	12 positions holder used for the handling of sample and control racks outside the instrument.
Reader	Reading area in which chemical reaction and measurements occur.
Reagent Area	Integral and ancillary loading area.

RF-Tag	Micro-chip present on integrals, starters and ancillaries to allow recognition and data storage.
RLU	Relative Light Unit (signal measurement unit).
Sample Area	Loading area for samples.
Sample Rack	12 positions module to host sample tubes.
Samples	Anything that can be introduced by operator into Sample Area racks, including patient samples, controls and external calibrators.
Solid Waste Bin	Container of the system used to host EASY Waste.
SPOLV	Right arm non magnetic stainless steel probe.
Starter (reagents)	Reagents dispensed during the reading to generate chemiluminescent signal.
System	The complete structure installed in the laboratory.
System Liquid	Solution present in the fluidic line of the pipettor, used to wash the pipettor probe.
Tip	Single cavity plastic probe used to aspirate samples with left pipettor arm.
Tray	96 positions modules for hosting Disposable Tips and 35 positions modules for hosting cuvettes equipped in the Disposable Tip and Cuvette drawer.
Vial	Container for just one reagent; more vials form an integral.
Wash Buffer	Solution (to be diluted 1:10 in distilled H_20) used to wash cuvettes.
Wash Station	Washing well for right pipettor needle.
Washer	Washing area in which cuvettes wash occur.

Table 4–7: Glossary

4.2 Use of the Modules

In the following chapters, the individual modules and their use are explained.

4.2.1 Touch Screen and On Screen Keyboard

The integrated touch screen is needed to use the system. All inputs are made with a projected capacitive (PCAP) touch compatible stylus or finger directly on the touch screen. The usage of an external keyboard or mouse is not supported.

Touch Screen Handling

- Operate with a stylus or finger without applying excessive pressure.
- Avoid using sharp edged or hard articles.
- Keep the surface clean by executing periodic maintenance (see chapter 7.6).

NOTE

Improper use could damage the touch screen surface.

Use:

- Mouse emulation:
  - Mouse pointer: Touch the screen with a finger or a stylus and the mouse pointer will follow the moving object.
  - Single mouse click: Touch the screen once.
  - Double mouse click (double click): Touch the screen twice. Do not wait between the first and the second touch.
- On screen keyboard (alphanumeric inputs, e.g. A - Z, 0 - 9, etc):

  The **LIAISON® XS** software provides for input boxes an on screen keyboard to enter letters or numbers. The on screen keyboard is shown automatically after touching an input box. A smaller version is provided for numerical input. The keyboard shows on the top left corner the current edit field content.

Figure 4–7: On screen keyboard

4.2.2 Barcode Reader

A handheld barcode reader is supplied with the system, in order to allow the user to read bi-dimensional barcodes for control definition.

Please, refer to local representative for suitable device.

Figure 4–8: Example of Handheld barcode reader with integrated support

CAUTION

Only the supplied **LIAISON® XS** handheld barcode reader may be used. The use of unauthorized handheld barcode reader is prohibited and may cause damage to the system.

Do not use the handheld barcode reader for purposes different from reading bi-dimensional control definitions.

WARNING

See chapter 1.6.4 for Laser Safety. Refer to handheld barcode reader user manual for safety related instruction.

4.2.3 Disposable Tips and cuvettes

4.2.3.1 Disposable Tips

The drawer of disposable tips and cuvettes trays can be opened while the system is not running to allow refill. When the system is running it is also possible to request the system to suspend accessing the drawer to allow refilling.

The drawer can be filled up to two disposable tip trays with 96 disposable tips each. The loaded disposable tip trays are recorded by the **LIAISON® XS** software (see chapter 6.12.2). An automatic consumption meter allows the exact indication of the disposable tips still present in the instrument.

The loading of the disposable tip trays is described in chapter 5.4.2.

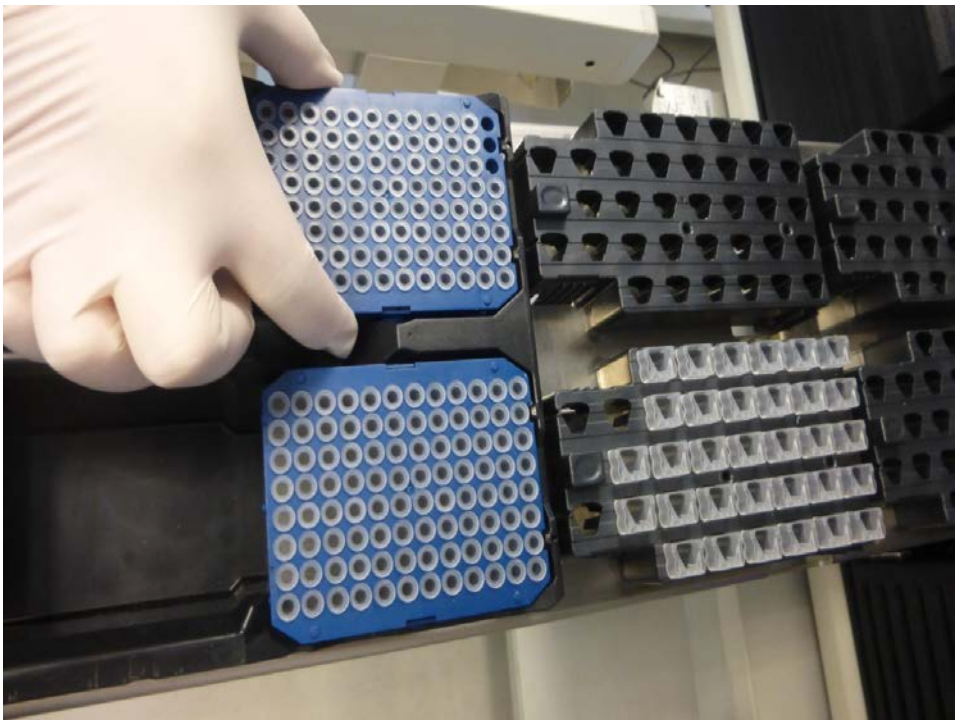


Figure 4–9: Disposable Tips

4.2.3.2 Cuvettes

The drawer of disposable tips and cuvettes trays can be opened while the system is not running to allow refill. When the system is running it is also possible to request the system to suspend accessing the drawer to allow refilling. The cuvettes must be loaded in four trays of 35 cuvettes each.

The loading of the cuvettes is described in chapter 5.4.1.

Figure 4–10: Cuvettes

4.2.4 Loading Bay for Sample Racks

The loading bay for sample racks allows continuous loading of the **LIAISON® XS** system with samples. The samples in the tubes are placed in special racks and loaded in one of the 4 lanes afterwards.

A distinct identification number must be assigned to every sample in the **LIAISON® XS** software. This sample ID can be entered either by scanning the bar-code using the barcode scanner located in the loading bay for sample racks or by typing it manually.

WARNING

See Chapter 1.6.4 for Laser Safety.

To ensure the bar-code scanner can read the bar-code label correctly, the bar-code label must be of a good quality, thus meaning it shall match Category A or B (according to ANSI X3.182 standard) or category 4 and 3 (according to ISO/IEC 15416 standard).

In addition, the following specifics shall be matched:

1. The module width (i.e. the width of the smallest bar or gap in the barcode) shall be in the range 0.167 mm ≤ width ≤ 0.5 mm.
2. For Codabar and 2/5 Interleaved typologies, a minimum of 6 characters is recommended; the bar width ratio (i.e. the comparison in bar widths between the narrow modules and the wide modules) shall be in the range 1:2.5 ≤ ratio ≤ 1:3 (if 0.167 mm ≤ width < 0.2 mm) or in the range 1:2 ≤ ratio ≤ 1:3 (if 0.2 mm ≤ width ≤ 0.5 mm).

NOTE

The Code 128 is the preferred symbology for use to ensure adequately reliable sample traceability and recognition. Other symbologies (e.g. 2/5 Interleaved), particularly when missing a check digit, are less reliable.

Regarding the positioning, the barcode must be applied to the grey section in the middle of the tube as shown in Figure 4–11.

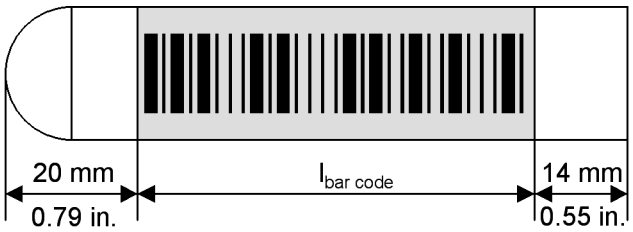


Figure 4–11: Barcode Label

Length of tube:	Max. length of bar-code ($l_{bar\ code}$)
66 mm (2.60 in.)	32 mm (1.26 in.)
75 mm (2.95 in.)	41 mm (1.61 in.)
100 mm (3.94 in.)	66 mm (2.60 in.)

Table 4–8: Length of bar-code label

Ensure that the bar-code labels face towards the right (open side of the rack) when loading otherwise they cannot be properly read.

In addition to the sample racks, racks with calibrators and controls may be loaded in the loading bay for sample racks.

The loading with racks is described in Chapter 5.5.

4.2.4.1 Sample Racks

A sample rack is a holder to store patient samples (placed in sample tubes) for use on the instrument. The sample rack (also known as “patient rack” or “rack”) is designed to hold up to 12 sample tubes (bar-coded or non-bar-coded) and is to be inserted into the instrument in a way such to be registered by the instrument and supports the sample tubes during aspiration by the sample pipettor.

CAUTION

Only the supplied **LIAISON® XS** approved sample racks may be used. The use of unauthorized rack types is prohibited and may cause damage to the system.

All sample racks have the same structure as pictured and described below. The positions are numbered from 1 through up to 12 with number 1 starting farthest away from the handle.

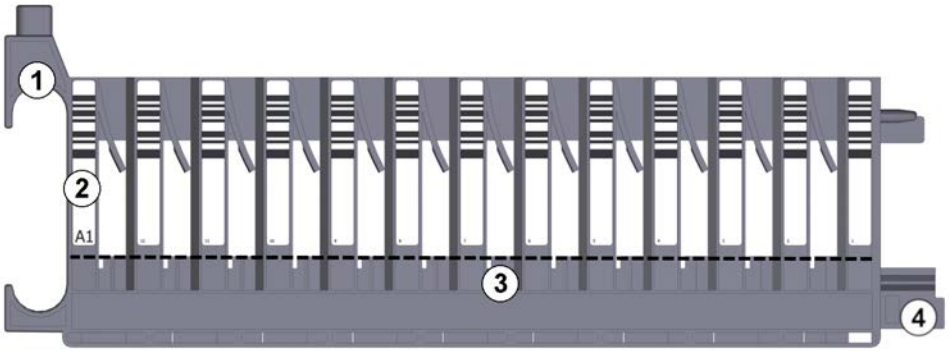


Figure 4–12: Sample rack

No.	Description
1)	Handle
2)	Sample rack identification bar code label
3)	Sample tube positions with position bar code label and a clamp for correct position holding of sample tube
4)	Clamp to lock the sample rack into the loading bay for sample racks

Table 4–9: Sample Rack- Description

NOTE

Rack ID consists of a string, the rack type, and a digit from 1 to 9. Such digit allows to differentiate among different physical racks of the same type. The result detail contains the Rack ID information to support the user in identifying the physical rack where the tube is/was loaded when the aspiration took place.

4.2.4.2 Control Racks

A control rack is a holder to store some types of control bottles and external calibrators for use on the instrument. The control rack (also known as C rack) is designed to hold up to 8 bottles (bar-coded or non-bar-coded) and is to be inserted into the instrument in a way such to be registered by the instrument and supports the bottles during aspiration by the sample probes.

A set of 2 control racks is provided with each instrument.

CAUTION

Only the supplied **LIAISON® XS** control racks may be used. The use of unauthorized rack types is prohibited and may cause damage to the system.

Control racks have the structure as pictured and described below. The positions are labeled from 1 through up to 8 with label 1 starting farthest away from the handle.

Figure 4–13: Control rack

No.	Description
1)	Handle
2)	Control rack identification bar-code label (%C)
3)	Bottle positions with position bar-code label and position holding
4)	Clamp to lock the control rack into the loading bay of the instrument

Table 4–10: Control Racks

4.2.4.3 Rack Types, Tube Diameter and Dead Volume

There are several different types of racks (see the table below). The different types of racks refer to the inner diameter and the total height of the sample tubes and are important for the proper management of samples. As can be noticed, together with standard rack types, 4 typologies (Y, Z, G, O) can be directly customized by field service engineers according to user requirements.

Rack type	Internal diameter of the sample tubes:	Total height of the sample tubes:	Dead volume
Q	6 mm	≤ 55 mm	150 µL
N	7 mm	≤ 55 mm	150 µL
K	8 mm	≤ 55 mm	150 µL
J	9 mm	56 mm - 65 mm	150 µL
X	10 mm	66 mm - 75 mm	150 µL
A	10 mm	86 mm - 100 mm	150 µL
I	11 mm	86 mm - 100 mm	200 µL
F	12 mm	86 mm - 100 mm	250 µL
E	13 mm	86 mm - 100 mm	300 µL
W	14 mm	86 mm - 100 mm	350 µL
B	15 mm	86 mm - 100 mm	400 µL
G	Request Technical Assistance	Request Technical Assistance	Request Technical Assistance
O	Request Technical Assistance	Request Technical Assistance	Request Technical Assistance

Rack type	Internal diameter of the sample tubes:	Total height of the sample tubes:	Dead volume
Y	Request Technical Assistance	Request Technical Assistance	Request Technical Assistance
Z	Request Technical Assistance	Request Technical Assistance	Request Technical Assistance
C	Use only for DiaSorin Italia S.p.A. special large vials (i.e. some types of control bottles or external calibrators)		
H	LIAISON® Stool extraction device (X0034)	Dedicated Adaptor needed (PN: A0214)	300 µL
L	Used only for DiaSorin Italia S.p.A. glass vials (i.e. some types of control bottles or external calibrators)	55 ±0.5 mm	
M	Calprotectin extraction device (X0043)		
P	Used only for pediatric tubes		

Table 4–11: Rack types and sample tubes parameters

According to the above table, the size of the tubes that may be inserted in the sample racks ranges from 6 through 15 mm internal diameter.

Dead Volume

The dead volume is the amount of liquid left in the sample tube that cannot be pipetted by the pipettor due to mechanical limitations and calculations. A specific dead volume level exists for each specific tube type. When an assay is run, the user must have a minimum of the sample amount needed to run the assay plus the dead volume amount in order to run the assay effectively.

Example:

A user wants to run 2 tests with one sample. The sample liquid is in a sample tube with 15 mm diameter. According to the assay Instructions for use, the assay requires 20 µL per test. The user will have to have a total of 440 µL in the tube.

Summary:

Tubes with 15 mm diameter:	400 µL (dead volume)
2 tests with 20 µL:	40 µL (usable sample volume)
Total volume needed:	440 µL

Table 4–12: Dead volume

CAUTION

In the case of plasma gel separator containers, the amount of sample should be at least 500 µL plus the volume required to run the test.

CAUTION

Insufficient or Missing Patient Sample Liquid

Insufficient or missing patient sample liquid might create erroneous sample aspirations. Therefore, a warning message will be given together with an audible signal. The test must be repeated after a sufficient level of sample has been inserted.

4.2.5 Loading Bay for Reagents (Integrals and Ancillary Reagents)

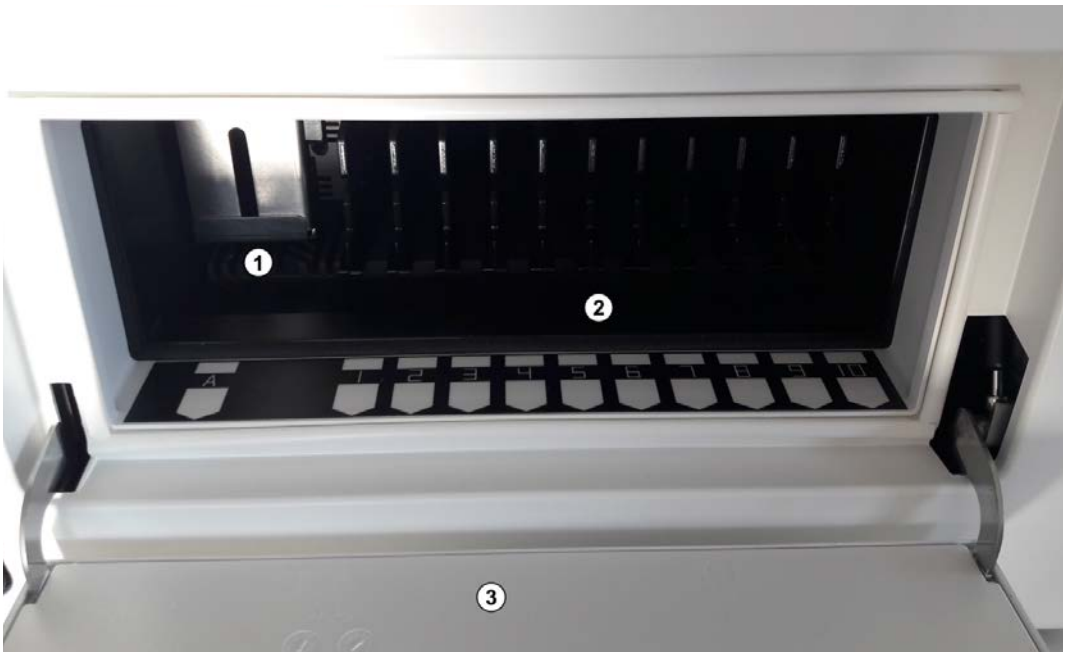


Figure 4–14: Front view of the loading bay for reagents

1)	Lane for ancillary reagents and additional reagents
2)	10 lanes for integrals
3)	Flap

Table 4–13: Loading Bay for Reagents

The loading bay for reagents allows a continuous loading of the **LIAISON® XS** system with reagents in the form of integrals or ancillary reagents.

Integrals:

- Up to 10 integrals can be used at the same time.
- Integrals can be loaded directly into one of the 10 lanes according to the specifications of the **LIAISON® XS**.
- For the front position of the integral, a stirrer drive is provided. With the stirrer drive, magnetic particles can be evenly distributed in the reagent.

Ancillary reagents:

- Up to 4 ancillary reagents or reagents can be used at the same time.
- Ancillary reagents must be placed in an ancillary rack with adapters before usage. Then, the ancillary rack can be loaded in the special lane (on the very left) according to the specifications of the **LIAISON® XS** software.

WARNING

Before using integrals or ancillary reagents, read the IFU (instructions for use) provided in the reagent package (storage, preparation)!

Observe instructions for a correct re-suspension of magnetic particles.

CAUTION

Always use an ancillary rack in combination with the system it has been provided with.

Figure 4–15: Ancillary rack

The information included in the integral or ancillary reagent (RFID label) is read and used in the **LIAISON® XS** software.

The loading bay for reagents is cooled during the complete operation (incl. stand-by mode). The liquid inside the integrals and ancillary reagents are cooled to 13 °C ±2 °C.

NOTE

To avoid temperature errors of the reagent loading bay, the flaps should be opened only briefly for loading and unloading. The system will beep to remind to close it.

4.2.5.1 External Reagents

DiaSorin external reagents are delivered in vials separated from the integral, for example lyophilized kit reagents, or Light Check for troubleshooting.

These vials are of appropriate dimensions made to fit dedicated adaptors for the ancillary rack. This is the only rack type to be used for these vials.

External kit reagents, that shall be used as part of a test routine, are provided mounted on a specific non removable adaptor. Reagents like Light Check, that are not to be used as part of a regular test routine, are to be inserted into adaptors provided with the instrument or are to be inserted into a suitable sample rack.

The information included in the reagent (RFID label) is read from the system and used in the **LIAISON® XS** software.

4.2.6 Integrated re-suspension tool

The integrated resuspension tool is a solid state magnetic device which aids in the dispersal of microparticles prior to placement of a **LIAISON® XS** reagent integral on the **LIAISON® XS** system.

For a **LIAISON® XS** reagent integral to perform as intended, the microparticles must be completely and homogeneously re-suspended. The integrated tool is designed to assist in the preparation of the reagent integral by magnetically drawing the paramagnetic microparticles away from the bottom of the reagent integral microparticle vial. With subsequent agitation of the vial automatically performed by the instrument over a 15 minutes time span, the operator is ensured of a properly prepared reagent integral.

4.2.6.1 Use of the integrated re-suspension tool

1. Slide the reagent integral into the slot until it is fully engaged;
2. Allow the reagent integral to remain in the tool for at least 30 seconds;
3. Remove the integral and inspect for the presence of particles at the bottom of the vial: if microparticles are still present at the bottom, repeat procedure as many times as needed to have a complete removal;
4. After a complete removal of particles from the bottom of the vial has been achieved, insert the integral in an available slot in the reagent area and let it agitate for 15 minutes before starting a run.

4.2.7 Area for Starter Reagents

The area for starter reagents contains the two starter reagents (**LIAISON®** EASY Starter Kit: Starter 1 and Starter 2). The two starter reagent bottles are provided with removable screw caps that have to be removed to allow the insertion of the dedicated tubing. Correct emplacement is ensured by a clamp holding on a reset on the bottle neck. A RFID in the back of the bottle identifies starter reagents and tracks consumption. Since the starter reagents are light sensitive, the flap of the area must always be closed.

To prevent confusion, the information included in the starter reagent (RFID label) is read from the system and used in the **LIAISON® XS** software.

CAUTION

Please read the instructions for use (IFU) concerning the starter reagents (**LIAISON®** EASY Starter Kit).

CAUTION

Always keep the starter reagent area closed to avoid light.

4.2.8 EASY Waste

A special box for solid waste is used in the Solid Waste Bin.

Refer to chapter 5.4.7 for assembling and use.

4.2.9 Liquid Tank

4.2.9.1 System liquid tank

If the level in the system liquid tank falls below a certain mark, the **LIAISON® XS** software indicates to refill the tank soon.

Ongoing tests are still completed. New tests can only start if the contents of the tank are above the switch level.

4.2.9.2 Wash buffer tank

If the level in the wash buffer tank falls below a certain mark, the **LIAISON® XS** software indicates to refill the tank soon.

Ongoing tests are still completed. New tests can only start if the contents of the tank are above the switch level.

4.2.9.3 Cleaning solution tank

The system supports a cleaning procedure with a suitable cleaning solution tank. See chapter 7.

4.2.9.4 DI Water tank

The system supports a cleaning procedure where also DI Water is used, for rinsing purposes. The Cleaning tank shall be used for the maintenance steps where the use of DI Water is required; as alternative, a dedicated DI Water tank can be ordered and used for such steps.

4.2.10 Inside the instrument

4.2.10.1 Incubator

Up to 57 cuvettes are placed in the incubator. The cuvettes are loaded and unloaded from above by a gripper. There are two loading positions: one for the outer ring with 32 positions and one for the inner ring with 25 positions. The two rings are separated by a wall to avoid contamination between rings.

4.2.10.2 Pipettors

The **LIAISON® XS** system is provided with two independent pipettors to distribute samples and reagents throughout the testing processes. The two pipettors can aspirate variable liquid volumes of samples or reagents and dispense them into the cuvettes in the incubator.

Left Pipettor for samples

The left pipettor working with disposable tips aspirates liquid from a specified sample, control or external calibrator and dispenses it into a cuvette. The **LIAISON® XS** software associates the dispensed sample and the test to be processed to the cuvette.

Additionally, the sample pipettor allows the transfer of liquid from one cuvette to another in order to perform sample pre-dilutions.The use of disposable tips prevents cross-contamination between samples, controls or external calibrators.

This pipettor, located on the left side of the system, can only reach the loading bay for samples during a test routine.

Right Pipettor, for reagents

A stainless steel probe pipettor aspirates liquid from one or more reagent vials (integral or ancillary reagent) and dispenses it into a cuvette.

The inside and outside of the steel probe is cleaned in the wash station after the process step, in such a way as to prevent cross-contamination between different reagents.

Checks

To ensure the correct aspiration of liquid, both pipettors are provided with a liquid level detection system and volume aspiration and dispensing monitoring. The combination of the two allows for the aspiration of liquid(s) from the appropriate position and for the control of the accuracy of the dispensation. Additionally, the left pipettor can detect whether there are clots in a sample.

4.2.10.3 Reader

The dispensing of the two starter reagents and the chemiluminescence measurement are carried out in the reader, equipped with a high sensitivity photomultiplier. The reader is sealed from all outside light influences. The two independently controlled injection pumps for injection of the starter reagents are placed outside the reader: each of them operates with a constant volume of 200 µL to inject starter reagents into the cuvette. One injection of each of the two starter reagents (starter 1 and starter 2) is needed in order to develop the chemiluminescent reaction.

The geometrical arrangement of the injectors in the Reader ensures that the injection of starter 1 is directed against the wall of the cuvette. Starter 2 is injected straight into the cuvette. This ensures optimum re-suspension of the magnetic particles. After each individual measurement and before cuvette disposing, the reaction solution is drawn from the cuvette by an aspiration needle. Once completed this operation, the cuvette is then disposed off into the waste box.

4.2.11 Holders

4.2.11.1 Rack Holder

A dedicated holder is available for handling of sample and control racks outside the instrument. Up to 12 racks can be transported at the same time using this holder.

4.2.11.2 Integral Holder

A dedicated holder is available for handling of reagent kits outside the instrument. Up to 16 kits can be transported at the same time using this holder; dedicated positions are available to host kits composed by 2 integrals.

4.2.12 Status Light

In the front of the **LIAISON® XS** system is a status light that informs about the conditions of the instrument:

Figure 4–16: Status light

Color Light	Status	Description
Off	Off	• No Power • Not Initialized • Initializing
Blue	Slow flashing	• Resume • Running • Maintenance
Blue	Steady	• Standby • Ready
Yellow	Fast flashing	• Halted

Color Light	Status	Description
Yellow	Slow flashing	If a beep of the following type is triggered and the status is not “halted”, then the status light change as described until the user mutes the beep or the auto mute is triggered. • System error • Info

Table 4–14: Status Light

4.2.13 Printer

An USB printer can be connected to the instrument by authorized DiaSorin Italia S.p.A. service personnel. Both local and network printers are supported; the printer connected to the instrument shall be set as “default printer”.

5 Use of the System

CAUTION

Conditioning time

The system requires 1 hour for temperature conditioning of the incubator and the reagent loading bay from an off system startup.

In this chapter, the processing of a test from switching on the system to switching off the system for an user is described in regards to starting a worklist.

All functions of the **LIAISON® XS** software are described in Chapter 6.

5.1 Safety and Hints

CAUTION

See chapter 1.6 for all safety hazards.

5.2 Typographical Conventions

Software

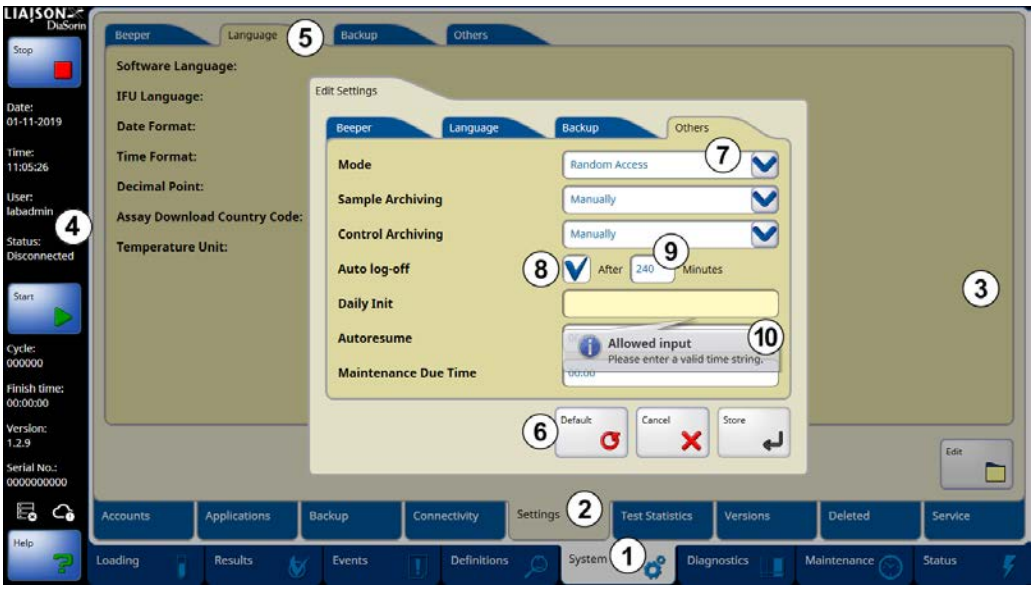


Figure 5–1: Screen

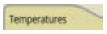
1		**Main categories** Tap on the respective tab to change the main category. Example: Tap on the System main category tab.
2		**Sub categories:** Tap on the respective tab to show details of the sub category in the sub category display. Example: Tap on the Settings sub category tab.
3		**Display:** Shows all details of the selected sub category. Example: The system shows all functions on the Settings sub category display.
4		**Left Header:** Shows information about the system and contains the Stop, Start and Help buttons. Example: The system status is shown on the Left Header.
5		**Tabs:** Subdivides a sub category into different areas. Example: Tap on the Language tab.
6		**Buttons:** Tap on the respective button to start a special function. Example: Tap on the Default button.
7		**Selection boxes:** Tap on the arrow and select one of the shown entries. Example: Select the Random Access entry of the Mode selection box.
8		**Checkboxes:** Tap on the square or circle box to activate a function or option. A checkmark in a square box of a checkbox shows an activated function/option. A point in a radio button shows an activated function/option. These types of radio buttons are organized in groups. Only one radio button for each group can be activated. Example: Activate the Auto log-off checkbox.
9		**Input boxes:** Use the on screen keyboard to write into an input box. If the field has an highlighted background, it contains a wrong value (e.g. it can be a mandatory field). See also section Tooltips below. Example: Enter the new value in the Minutes box.
10		**Tooltips:** Tooltips are used to inform the user about wrong values in input boxes. After entering the correct value, the tooltips disappear.
-		**Groups:** Combines functions to groups. Example: All temperatures are shown in the Temperatures group in Summary sub-toggle.

Table 5–1: Software

Miscellaneous

Status light	Describes signal lamp of the instrument.
SW LEDs	Describe the availability of resources (sample racks, integral and ancillary reagents) on the GUI
Keys	Describes special keys of the on screen keyboard. Example: Press on the Enter key to confirm the entry.
Drives, folders, and files	Describes special drives (hard disks, USB sticks) of the computer or special folders and files on the computer. Example: Choose D:\LiaisonXS\Share as backup path.
Prescribed parameters	Describes special parameters or values to enter into an input box. Example: Enter 10 into the shown input box.

Table 5–2: Miscellaneous

Daily activities plan

Start-up	• Switch-on (only if off) • Log-on • Respect the conditioning time	chapter 5.3
Check	• Check cuvettes, disposable tips, starter reagents and liquid Tanks	chapter 5.4
Load Integrals and Ancillary reagents	• Load integrals • Load ancillary reagents	chapter 5.6
Load Controls and Calibrators	• Load controls • Load calibrators	chapter 5.5 chapter 5.6
Calibrate integrals	• Calibrate integrals • Run controls to validate calibrations	chapter 5.6 chapter 5.5
Load Samples and Assign Assays	• Load patient samples • Assign assays to the patient samples	chapter 5.5
Start Worklist	• Check the upfront estimation • Start the run	chapter 5.7
Results	• Check results	chapter 5.8
Errors and Events	• Check errors and events	chapter 5.8.5
Unloading	• Unload unused sample racks • Unload unused integrals • Unload unused ancillary reagents	chapter 5.10
Shut Down/End of Day Maintenance	• Ensure to have the System Liquid on board and above the availability threshold • Ensure to solid and liquid waste on board and below the availability threshold • If planned for today, perform periodical maintenance	chapter 5.11 and 6.11

Table 5–3: Daily activities

5.3 Start up

Procedure **Switch on and log-on:**

1. Ensure that the cover and the flaps are closed.
2. Ensure that the analyzer main switch is on the “ON” position:

Figure 5–2: Main switch, ON position

3. Check the soft power button and press it when the light stops blinking:

Figure 5–3: Soft power button

The system starts the operating system and the **LIAISON® XS** software on the integrated Panel-PC.

4. After system start, the **LIAISON® XS** software shows the Startup display:

Figure 5–4: Startup display

Function	Description
Shutdown	Shut the PC system software and switch off the computer.
Virus Scan	Starts the virus scan software. In case a virus is reported, please contact local support.
QC	Start the long term quality control (QC) application.
Monitor	Start the procedure to calibrate the touch screen.
Liaison XS	Start the **LIAISON® XS** software.

Table 5–4: Functions available on Startup display

5. Tap on the **LIAISON® XS** button.
   The **LIAISON® XS** software shows the Login display

Figure 5–5: Login

NOTE

There are several security levels of user access rights on the **LIAISON® XS** system. Some system functions are only available for users with an appropriate access level (e.g. changing system options, or setting user accounts).

NOTE

The system spontaneously performs an automated back-up of temporary files upon starting the **LIAISON® XS** software. This action will improve the Panel-PC performance.

6. Enter the user name into the Username box.
   The user name is not case sensitive.
7. Enter the appropriate password into the Password box.
   The password is case sensitive.
8. Tap on the Login button.
9. From the STOP menu, initialize the system.
   The **LIAISON® XS** software initializes the instrument and shows the Loading Samples display.

Conditioning time:

10. Wait for 1 hour. The system requires 1 hour for temperature conditioning of the incubator and the reagent loading bay from an off system startup.

5.4 Check Cuvettes, Disposable Tips, Starter Reagents and Liquid Tanks

At the beginning of each run, the filling level of the liquid tanks and the starter reagents must be checked, as well as sufficient cuvettes and disposable tips available in the instrument.

Procedure

1. Tap on the **Status** main category tab.
2. Tap on the **Summary** sub category tab.

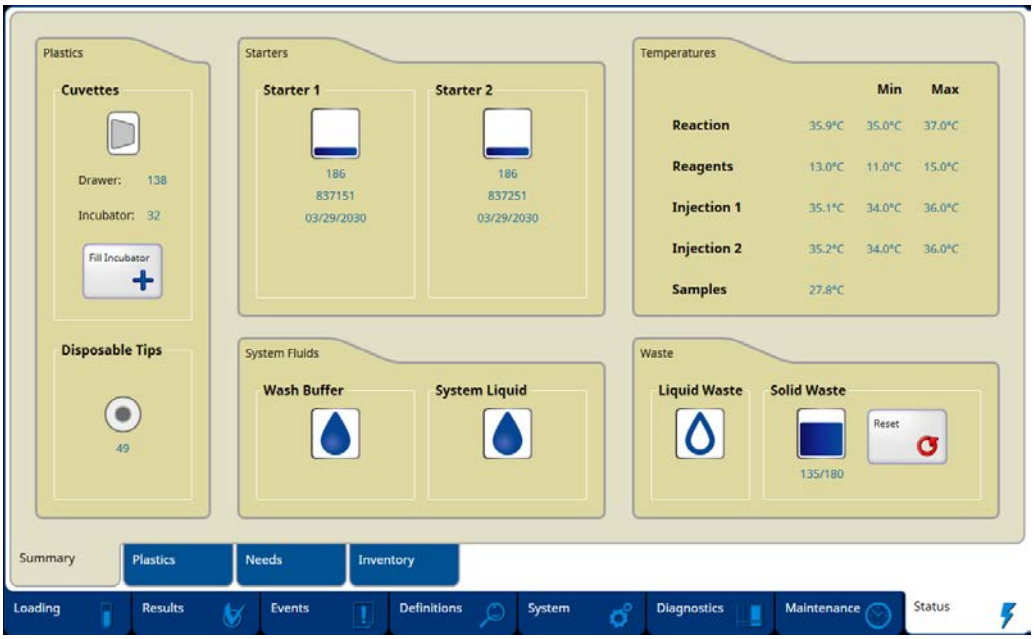


Figure 5–6: Summary

System Liquid

Available	Depleted	Absent
> 1 l	≤ 1 l	
Note: if the “Autoresume” option is enabled (see chapter 6.9.5), ensure that the System Liquid tank is connected and above the availability threshold to successfully prime it. **Note:** System Liquid is also used for periodical SPOLV rinsing in Standby or Ready status.		

Wash buffer

Available	Depleted	Not Primed	Absent
> 1 l	≤ 1 l		
Note: if the “Autoresume” option is enabled (see chapter 6.9.5), ensure that the Wash Buffer tank is loaded and above the availability threshold to successfully prime it.			

Liquid waste

Available	Full	Absent
< 7 l	≥ 7 l	

Starter reagents

Available	Depleted	Not primed/ Expired	Absent	Error
> 4 shots	≤ 4 shots			
Note: Starters can be reported as depleted even in case they have more than 4 shots left if the system hasn't sufficient shots to prime them. If the "Autoresume" option is enabled (see chapter 6.9.5), ensure that the Starter bottles are loaded and above the availability threshold to successfully prime them.				

Cuvettes

Available	Depleted	Absent (drawer pulled out)
> 2	≤ 2	
Note: Cuvettes threshold is referred to the number of cuvettes in trays. If the "Autoresume" option is enabled (see chapter 6.9.5), ensure that at least 2 cuvettes are available in the plastics drawer to successfully prime Wash Buffer and Starters.		

Tips

Available	Full	Absent (drawer pulled out)
> 0	0	

Solid waste

Available	Full	Absent
< 178	≥ 178	

DANGER

See chapter 1.6.6 for Biological Safety.

Consumable group

3. Check the number of cuvettes. If low, refill them (see chapter 5.4.1).
4. Check the number of disposable tips. If low refill them (see chapter 5.4.2).

Starter reagents group

5. Check the levels of the both starter reagent bottles. If low, load the new bottles (see chapter 5.4.3).
The remaining injection counters of all loaded starter reagents are shown. The counter decreases after every injection.

System Fluids group

6. Check the level of Wash Buffer. If low, prepare a new wash buffer (see chapter 5.4.5) according to the Instruction for Use.
7. Check the level of System Liquid. If low, prepare a new system liquid (see chapter 5.4.4) according to the Instruction for Use.

Temperatures

8. Check the temperatures.

Module	Temperatures Min.	Temperatures Max.
Reaction	35.0 °C	37.0 °C
Reagents	11.0 °C	15.0 °C
Injection 1	33.0 °C	37.0 °C
Injection 2	33.0 °C	37.0 °C

Table 5–5: Temperatures

Waste group

9. Check the capacity of the liquid waste tank. If full or nearly full, empty and follow the instructions of chapter 5.4.6.
10. Check the level of the EASY Waste Box. If full or nearly full, close it with its own cap, dispose of it and load a new one into the solid waste bin (see chapter 5.4.7).

After that, tap on the Reset button 

.

5.4.1 Refill Cuvettes

NOTE Before starting the handling procedure, consult Instruction for Use (IFU) for Cuvettes.

NOTE Always keep user box in an upright position, as indicated in the label (Figure 5-5 (a) Ref 1).
Always keep the cuvette tray(s) in an upright position.

1. Tap on the **Status** main category tab and check the **Cuvettes** in the **Plastics** group.

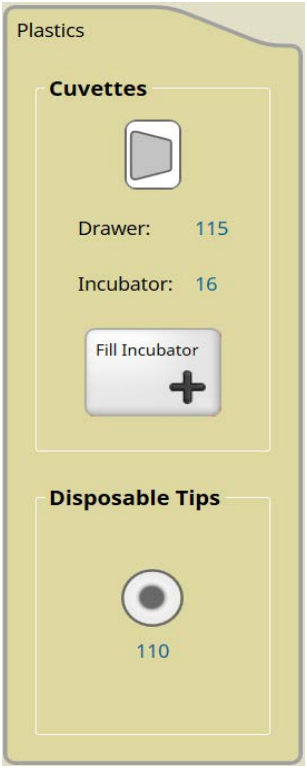


Figure 5–7: Cuvettes status

2. Check that it is possible to open the plastics drawer from the **Status - Plastics** page: the drawer can be immediately opened in case the page reports that this is possible. In case the system has programmed any access to the drawer, it is possible to request the system to suspend the access to the drawer to load tips and cuvettes. For the procedure, see chapter 6.
3. Open the drawer of the Cuvettes and Disposable Tips.
4. If present remove the empty cuvettes tray(s).
5. Hold the user box in upright position and open the box lid by cutting the label along the line (Figure 5-5 (a) Ref 2).
6. Unpack the inner plastic bag and remove the cuvettes on tray(s), keeping it/them by the apposite handle. If the user box is not empty wrap again the plastic bag on the remaining cuvettes on tray(s) and close the box lid (Figure 5-5 (b)).

7. Keeping the tray by the handle,slide it in the drawer following the visual help (laser marking profile) until both front pins are correctly engaged into the proper holes. Push down the button located on the top of the tray handle until it locks into place (Figure 5-6).

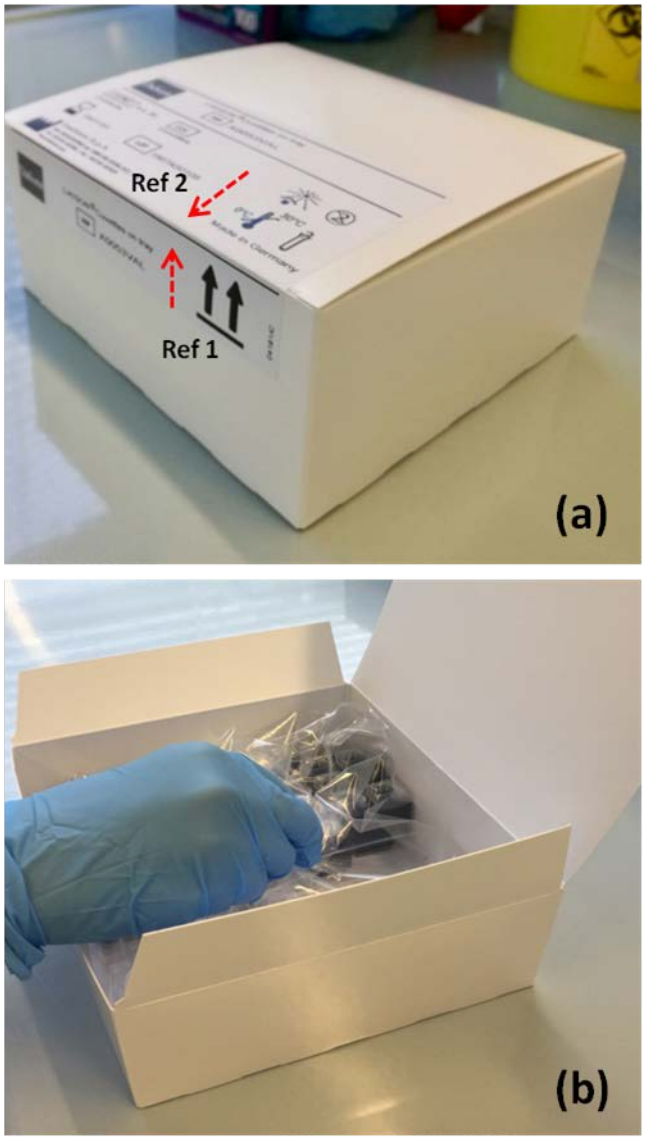


Figure 5–8: Open and close the user box, unpack and wrap the plastic bag

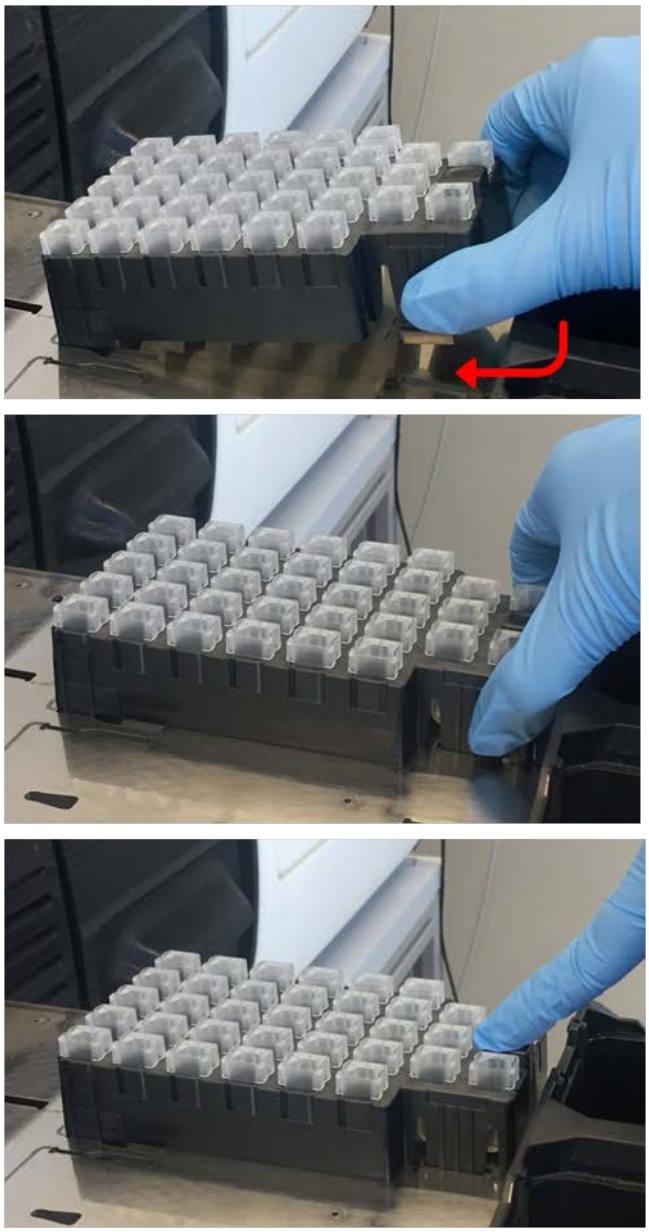


Figure 5–9: Slide, engage and push down the cuvette tray

NOTE Make sure that no cuvettes protrude upwards. Otherwise the drawer cannot be closed.

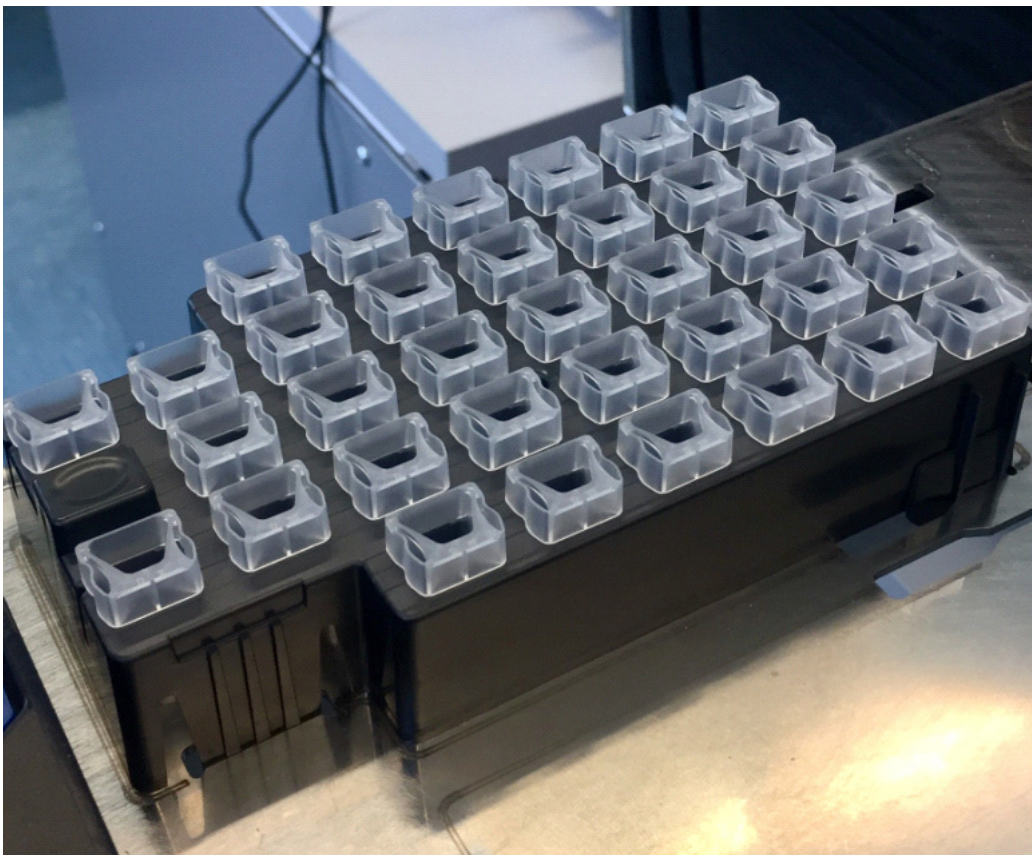


Figure 5–10: Cuvette stands out, drawer blocks

8. In **Status - Plastics** page, use the button “Fill Tray”/“Fill Trays” to assign the loaded cuvette tray(s) (see chapter 6.12.2).
9. Close the drawer.
10. Tap on the **Status** main category tab and check the **Cuvettes** number in the **Plastics** again.

NOTE Cuvettes are for single use only.

5.4.2 Refill Disposable Tips

NOTE Before starting the handling procedure, consult Instruction for Use (IFU) for Disposable Tips.

NOTE Always keep user box in an upright position,
Always keep the tip tray(s) in an upright position.

Procedure

1. Tap on the **Status** main category tab and check the **Disposable Tips** in the **Consumables**.

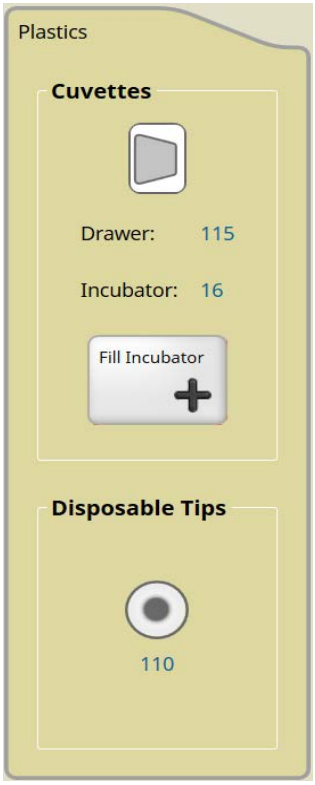


Figure 5–11: Status Disposable Tips

2. Check that it is possible to open the plastics drawer from the **Status - Plastics** page: the drawer can be immediately opened in case the page reports that this is possible. In case the system has programmed any access to the drawer, it is possible to request the system to suspend the access to the drawer to load tips and cuvettes. For the procedure, see chapter 6.
3. Open the drawer of the Cuvettes and Disposable Tips.
4. If present, remove the empty tip plate(s).
5. Take a disposable tip tray from the packaging.

Figure 5–12: Packaging of the Disposable Tips holder

6. Open one side of the folding sleeve by pulling up one of the available flaps (as indicated by the arrow symbols, Figure 5-10).

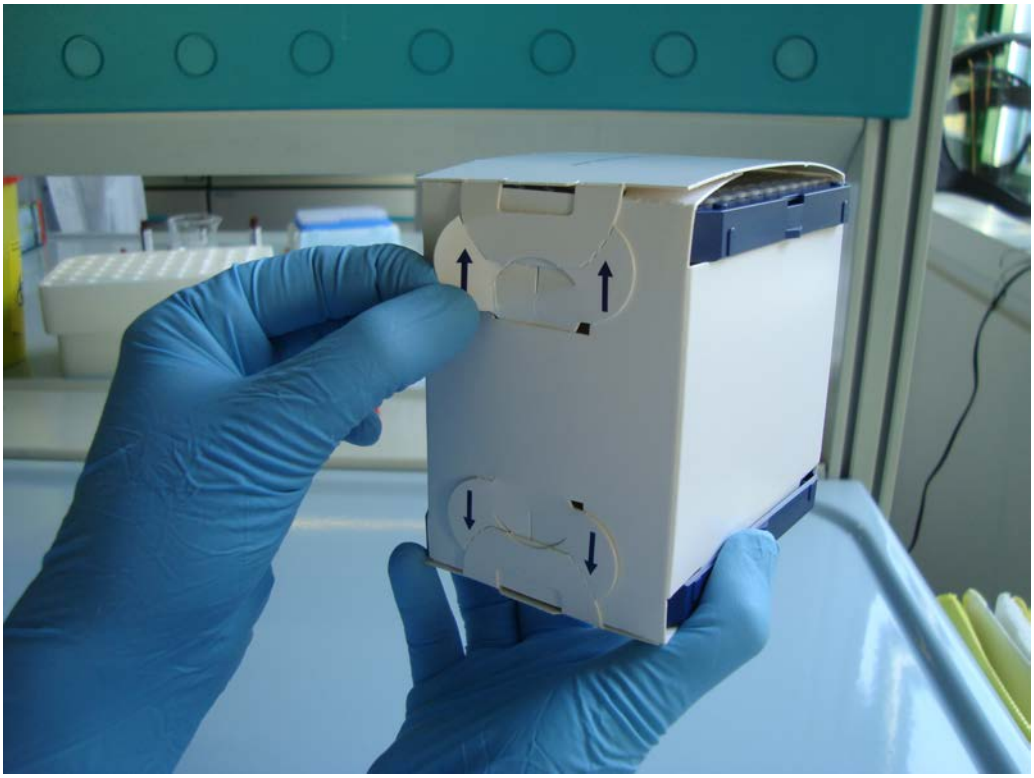


Figure 5–13: Folding sleeve opening

7. Insert the holder in the drawer until it is engaged (Figure 5-11). Push down the holder until it locks into place (Figure 5-12).

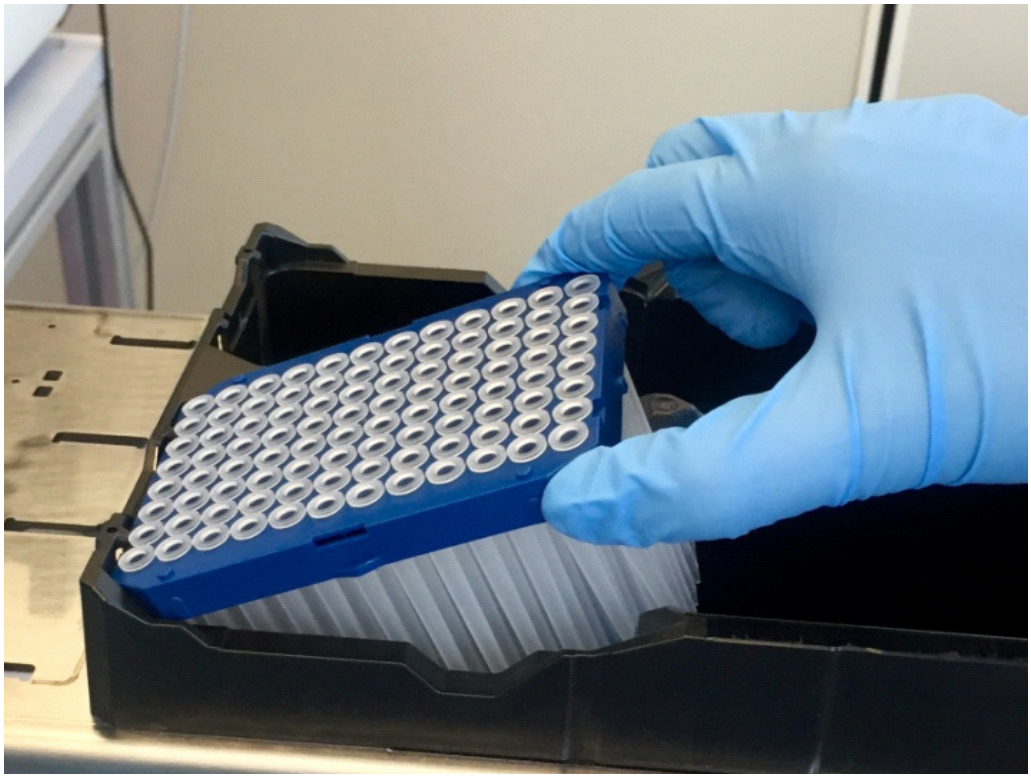


Figure 5–14: Insert the Disposable Tips plate

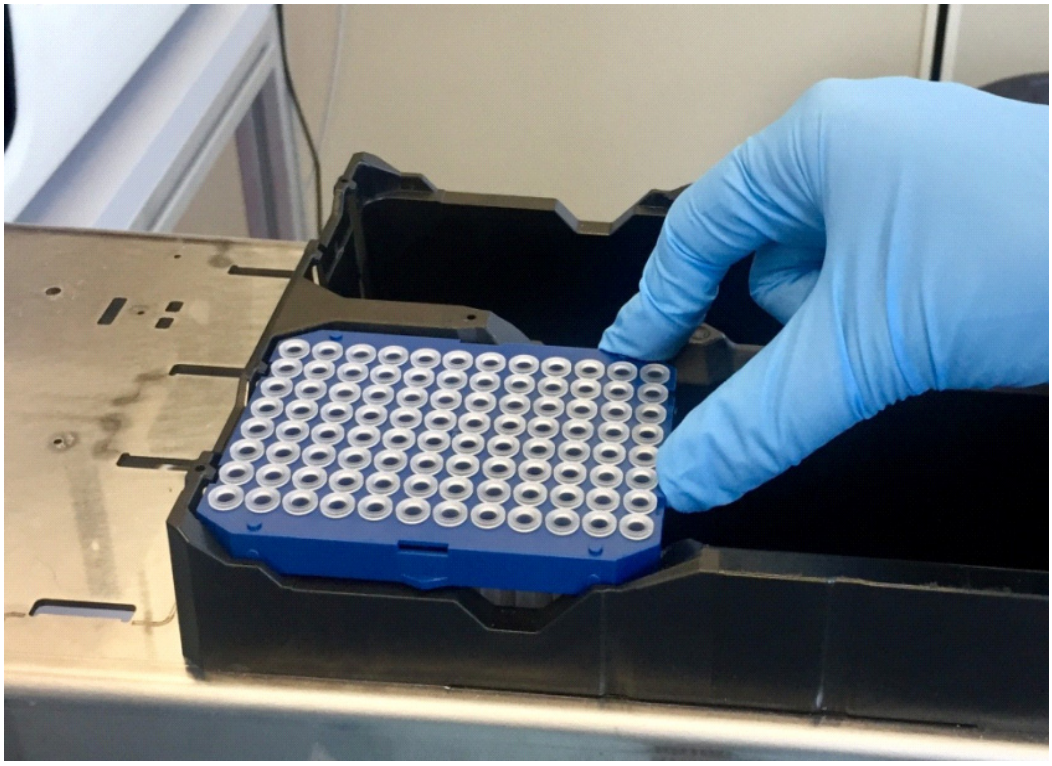


Figure 5–15: Push down the Disposable Tips plate

8. In **Status - Plastics** page, use the button “Fill Plate”/“Fill Plates” to assign the loaded tip plate(s) (see chapter 6.12.2).
9. Close the drawer.
10. Tap on the **Status** main category tab and check the **Tips** number in the **Plastics** again.

NOTE All disposable tips are for single use only.

5.4.3 Load and Unload the Starter

WARNING The starter reagents also include 4 % sodium hydroxide and a 0.12 % peroxide solution. If splashes of the NaOH solution or the alkaline peroxide solution get into eye or in contact with skin, immediate and thorough washing with water or a suitable buffer solution is recommended. If necessary, a physician should be consulted. See also product related material safety data sheet.

WARNING Starter pooling is prohibited!

NOTE Refer to the safety notes (see chapter 1.6).

The **LIAISON®** EASY Starter Kit should be kept away from direct sunlight.

Please comply with the storage and shelf life information for the starter reagents (**LIAISON®** EASY Starter Kit).

1. Tap on the **Status** main category tab in the **Summary** tab and check both starters. If one of the starter is “Depleted”, then unload the respective starter bottle.
2. Ensure that the instrument is not in “running” or “maintenance” status before unload/load the Starter bottles.

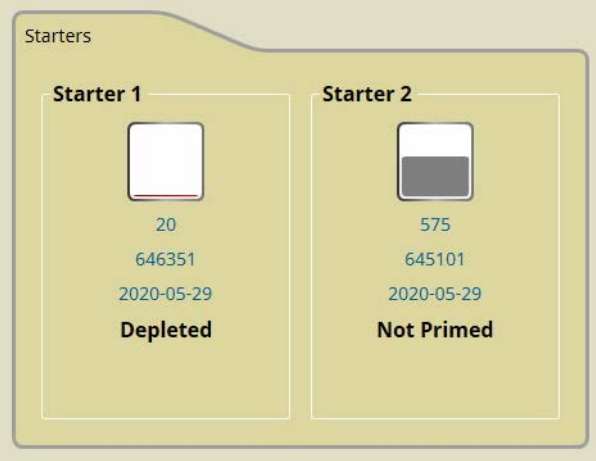


Figure 5–16: Status Starters

Unload Procedure

1. Open the flap for starter reagents.
2. Remove the empty starter reagent bottle by lifting it on the tab.

Figure 5–17: Remove starter reagent bottle

3. Remove the cap of the empty starter reagent bottle by pressing the brackets.

Figure 5–18: Press the brackets

Load Procedure

1. Remove the locking cap of the new starter reagent bottle.
2. Place the **LIAISON® XS** system cap onto the new starter reagent bottle by pressing the brackets.

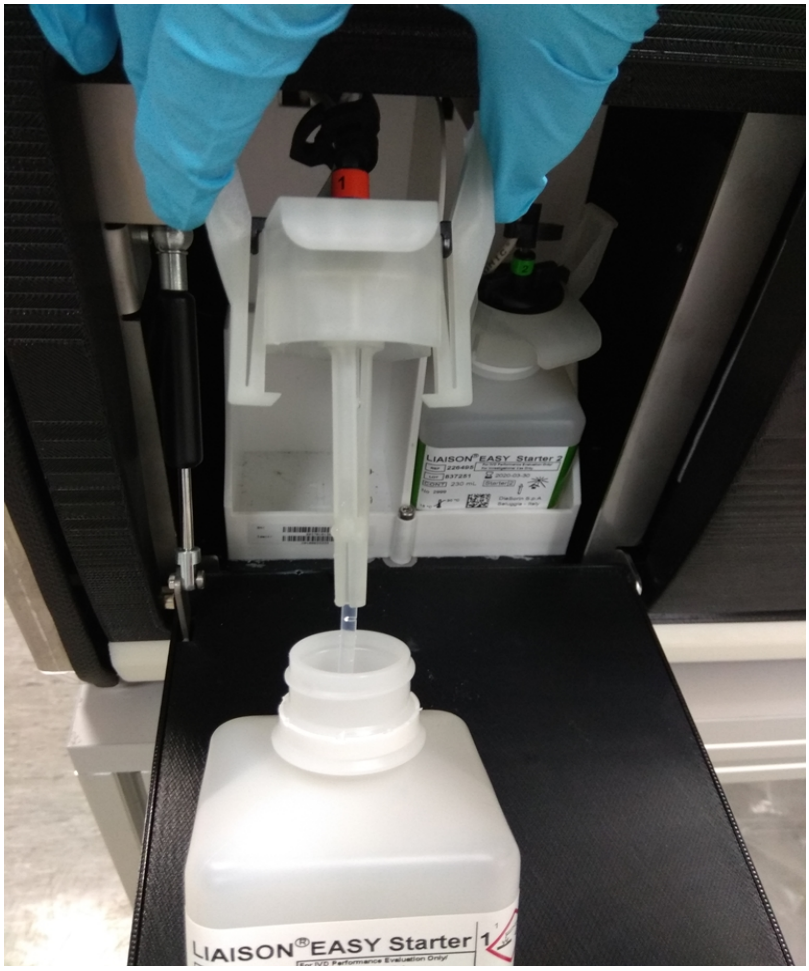


Figure 5–19: Place the cap by pressing the brackets

NOTE It is essential to ensure correct connection to Starter 1 and Starter 2.

3. Insert the new starter reagent bottle into the **LIAISON® XS** system by holding it on the tab.

Figure 5–20: Holding it on the tab

4. Close the flap for starter reagents.

CAUTION

In case lot numbers change, after the starters have been primed it is necessary to recalibrate all integrals. The system will disable all valid calibrations.

5.4.4 Load and Unload the System Liquid Tank

1. Tap on the **Status** main category tab and check **System Fluids**.
2. Ensure that the instrument is not in “running” or “maintenance” status before disconnecting the System Liquid tank.

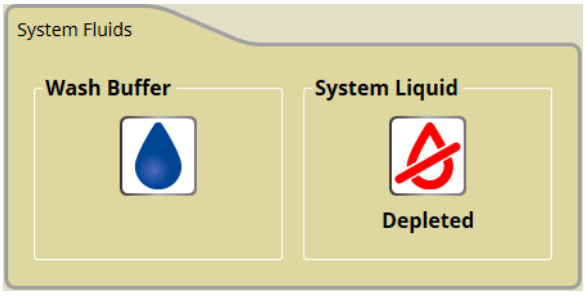


Figure 5–21: Status System Fluids - System Liquid

Preparation

Before the system liquid preparation, the System Liquid tank must be horizontal, as it is on-board the instrument, so that the filling line can be used. The lower edge of the filling line at the opposite side of the tank handle marks the 5 liter level.

Figure 5–22: System liquid tank - 5 liter filling line, lower edge marked in red

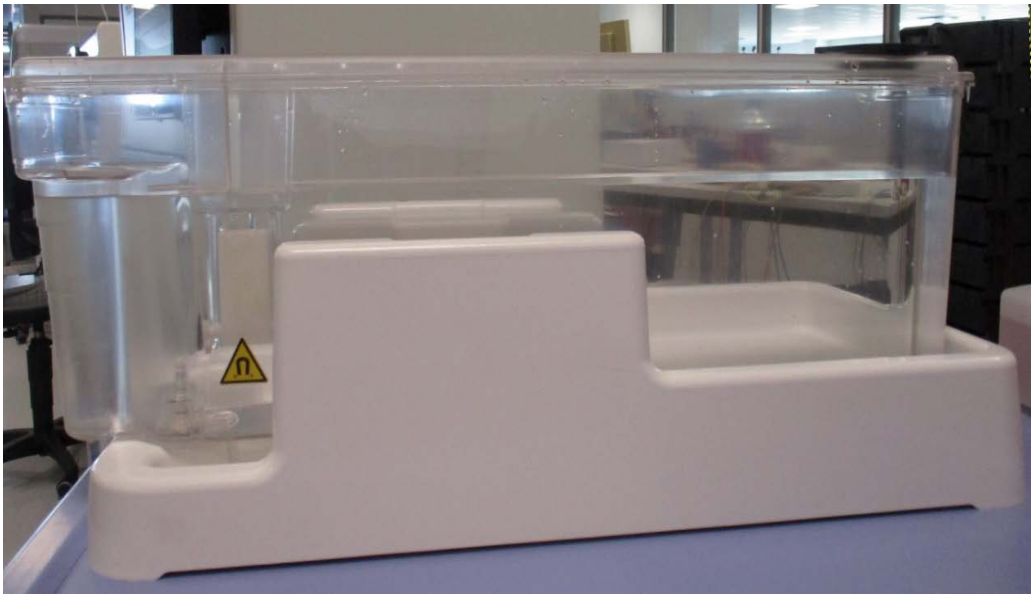


Figure 5–23: Preparation of System Liquid - correct placement of the System liquid tank

NOTE

For the preparation of the system liquid solution, refer to the instructions for use of the **LIAISON®** EASY System Liquid.

NOTE

Before the system liquid is handled or loaded into the **LIAISON® XS** system, the package information is to be read thoroughly and followed by the user. Use the notches available on the tank as an aid during the preparation of the system liquid solution.

CAUTION

The System Liquid tank must fulfill the requested ambient operating conditions during installation and should never be used after defined expiration date for onboard stability.

CAUTION

Incorrect mixed or used solutions in the System Liquid tank

Use of incorrect solutions leads to faulty results and damage to the instrument.

If solutions have been misused, clean the System Liquid tank according to chapter 7.5 before preparing the new system liquid solution. After loading it into the instrument, the system liquid shall be primed before starting any activities.

CAUTION

For the preparation, the System Liquid tank must be horizontal.

Unload Procedure

1. Open the bulk fluid door.
2. Remove the lower tank by lifting it at the handle.

Figure 5–24: Remove the System Liquid tank.

The back-illumination of the tank turns off automatically if the tank is not connected to the instrument.

NOTE

For the preparation of the system liquid solution, the cap of the tank shall be removed.

Figure 5–25: Remove tank cap

Load Procedure

1. Ensure that the cap of the tank is closed.
2. Load the tank on the lower position of the bulk fluid area.

NOTE

If the tank is loaded correctly, the back-illumination will turn on again.

3. Close the bulk fluid door.
4. The System liquid will be displayed as “Not Primed”. Before starting any activities, it shall be primed.

5.4.5 Load and Unload the Wash Buffer Tank

1. Tap on the **Status** main category tab and check **System Fluids**.
2. Ensure that the instrument is not in “running” or “maintenance” status before disconnecting the wash buffer tank.

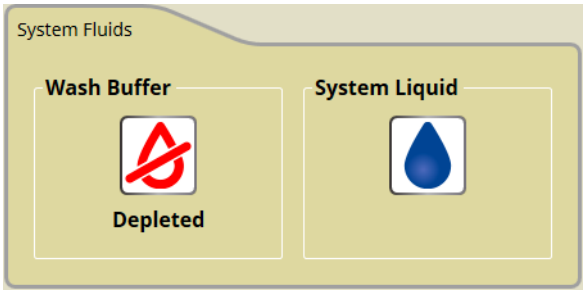


Figure 5–26: Status System Fluids - Wash Buffer

Preparation

1. Before the wash buffer preparation, the Wash Buffer tank must be horizontal, as it is on-board the instrument, so that the filling line can be used. The lower edge of the filling line at the opposite side of the tank handle marks the 2.7 liter level.

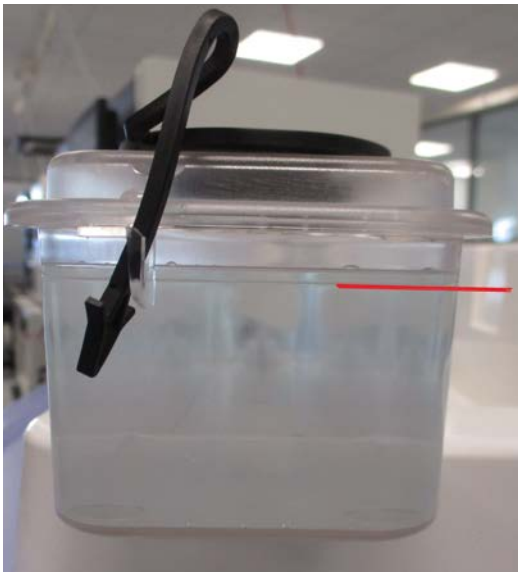


Figure 5–27: Wash buffer tank - 2.7 liter filling mark, lower edge marked in red

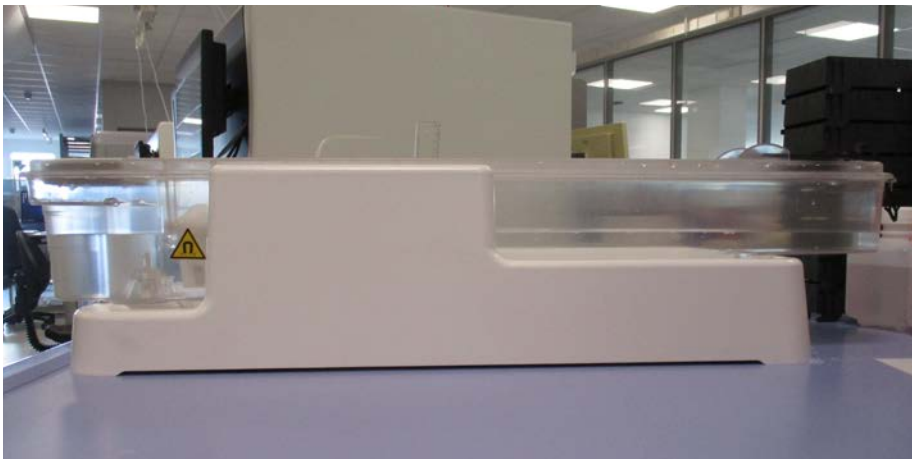


Figure 5–28: Preparation of Wash buffer - correct placement of the Wash Buffer tank

NOTE

For the preparation of the wash buffer solution, refer to the instructions for use of the **LIAISON®** EASY Wash Buffer.

NOTE

Before the wash buffer is handled or loaded into the **LIAISON® XS** system, the package information is to be read thoroughly and followed by the user. Use the notches available on the tank as an aid during the preparation of the wash solution.

CAUTION

The wash buffer tank must fulfill the requested ambient operating conditions during installation and should never be used after defined expiration date for onboard stability.

CAUTION

Freshly prepared or non-degassed wash buffer should not be used in the **LIAISON® XS** system.

CAUTION

For the preparation, the Wash Buffer tank must be horizontal.

CAUTION

The Wash Buffer tank should be kept away from direct sunlight.

CAUTION

Incorrect mixed or used solutions in the Wash Buffer tank

Use of incorrect solutions leads to faulty results and damage to the instrument.

If solutions have been misused, clean the Wash Buffer tank according to chapter 7.5 before preparing the new wash buffer solution. After loading it into the instrument, the wash buffer shall be primed before starting any activities.

Unload Procedure

1. Open the bulk fluid door.
2. Remove the upper tank by lifting it at the handle.

The back-illumination of the tank turns off automatically if the tank is not connected to the instrument.

NOTE For the preparation of the wash buffer solution, the cap of the tank shall be removed.

Figure 5–29: Remove tank cap

Load Procedure

1. Ensure that the cap of the tank is closed.
2. Load the tank on the upper position of the bulk fluid area.

NOTE If the tank is loaded correctly, the back-illumination will turn on again.

3. Close the bulk fluid door.
4. The Wash Buffer will be displayed as “Not Primed”. Before starting any activities, it shall be primed.

5.4.6 Connecting and separating the Liquid Waste

DANGER **See chapter 1.6.6 for Biological Safety.**

1. Tap on the **Status** main category tab and check the **Liquid Waste**.

2. Ensure that the instrument is not in “running” or “maintenance” status before unload/load the waste tank.

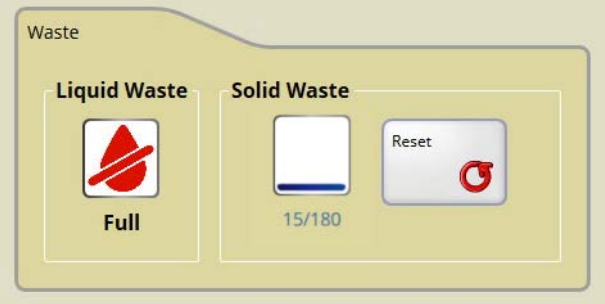


Figure 5–30: Status Waste - Liquid Waste

Description

The joint connector is used to manage the insertion/ removal of both the tubing and the connector for the waste sensor as a single task. A membrane element avoids splashing of liquid when the liquid connector is removed.

Item	Description
1)	Sensor connector
2)	Liquid tubing connector
3)	Plastic joint
4)	Membrane
5)	Rubber strip
6)	Cap
7)	Sensor cable

Table 5–6: Liquid waste tank with sensor/ liquid joint connector

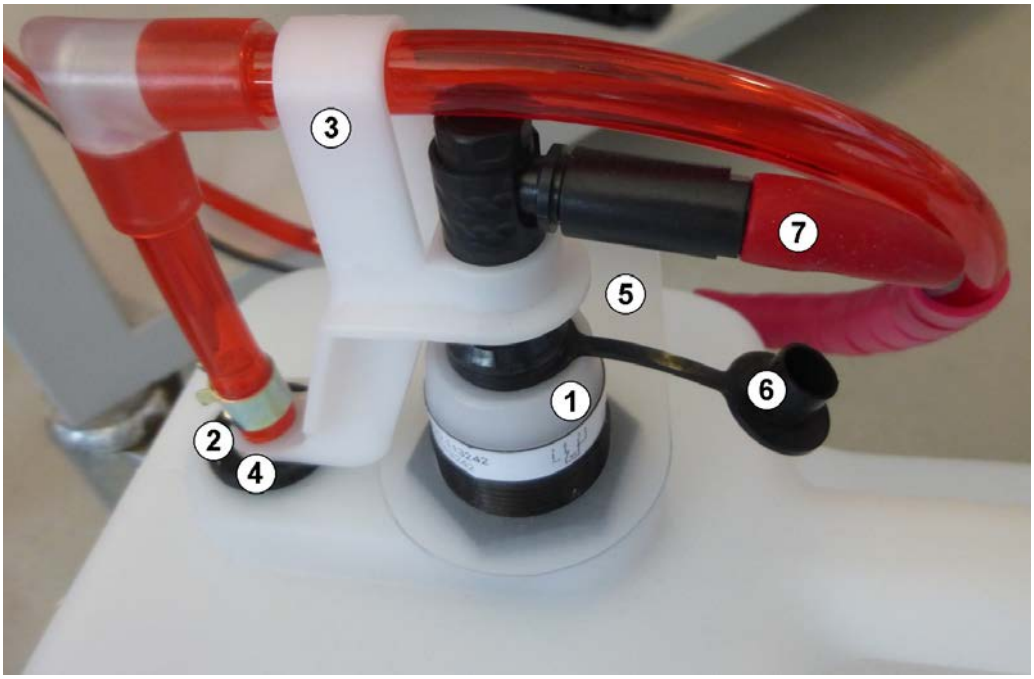


Figure 5–31: Liquid waste tank with sensor/ liquid joint connector

During the unload phase, the removal of the connector from the waste sensor also implies a removal of the liquid tubing from the dedicated membrane; the system is designed as the connector is completely unplugged before the liquid tubing is pulled completely out of the membrane.

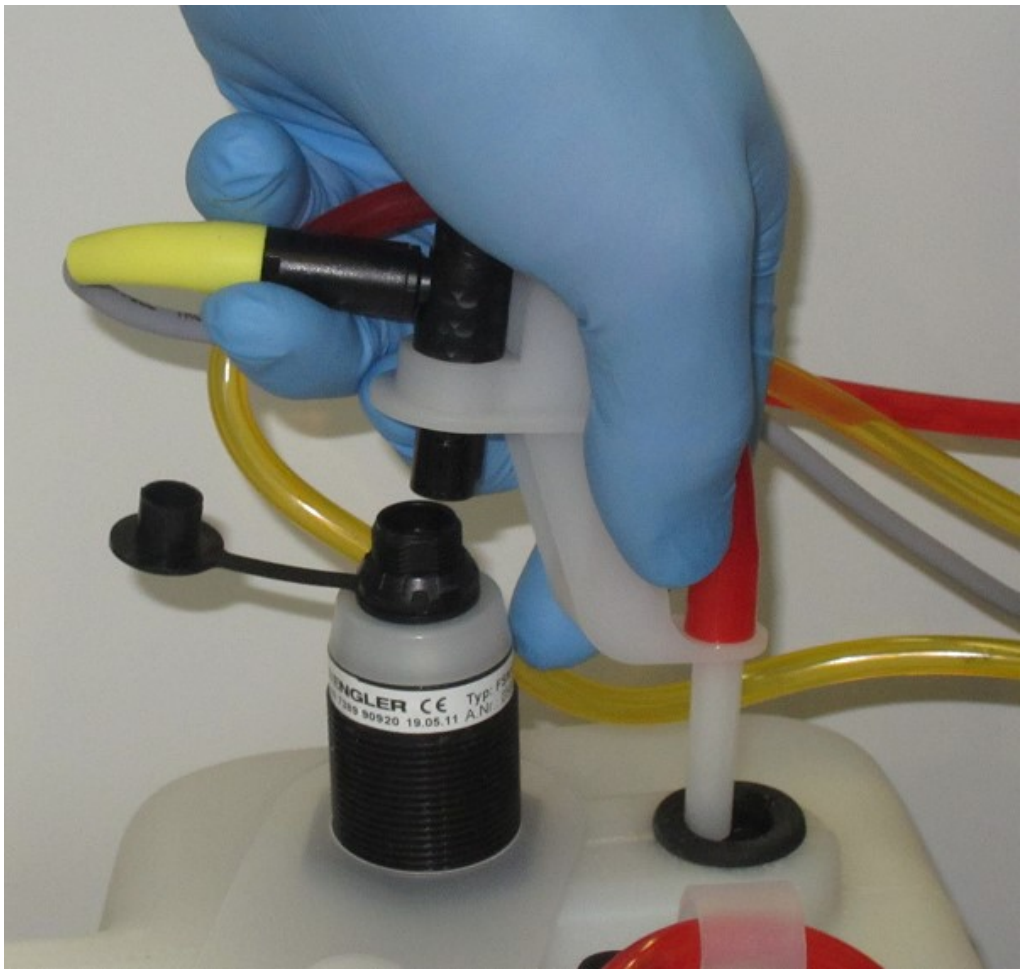


Figure 5–32: When unplugging the connector, the tubing is also pulled out of the membrane

During the load phase the insertion of the liquid tubing into the membrane also implies the connection of the sensor; the tubing is pushed into the membrane before the connector is completely plugged (i.e. an audible click is heard when connection is performed).

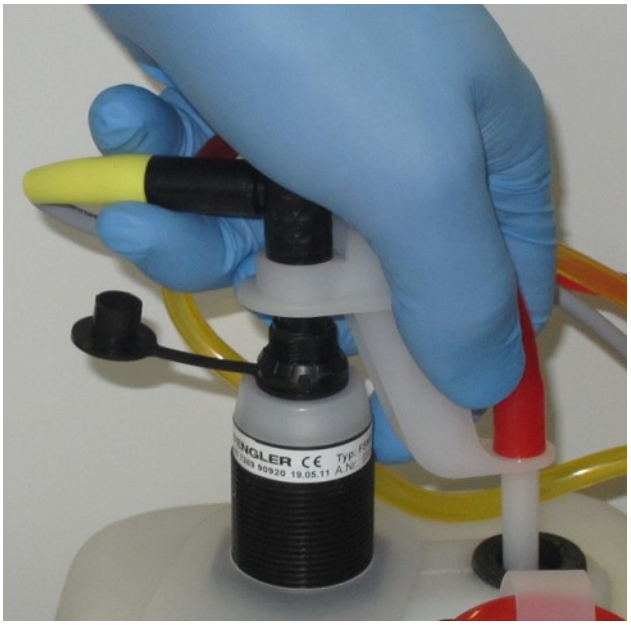


Figure 5–33: When pushing the tubing into the membrane, the connector is also plugged into the sensor

Unload procedure

1. Unplug the sensor connector (1). Due to the presence of the plastic joint (3), the liquid tubing connector (2) will be also removed from the membrane (4). Insert the sensor connector together with the liquid tubing connector inside the dedicated plastic housing (8) of the Liquid Waste Basin (9) (see figure 5–34).

Figure 5–34: Liquid Waste Basin

2. Before moving the tank from the Liquid Waste Basin of the instrument, close the sensor connector with its black cap and turn the rubber strip (5) to cover the membrane (4) by using the available cap (6).

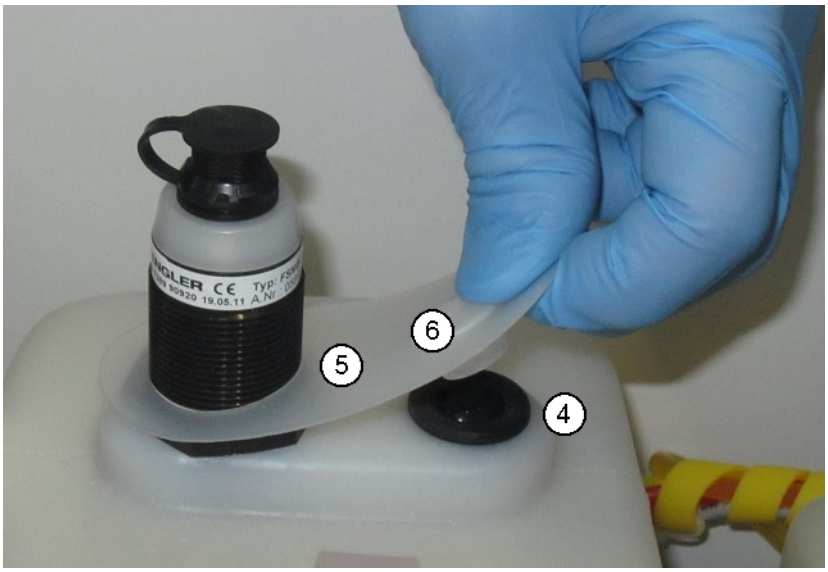


Figure 5–35: Rotation of the rubber strip and closure of the membrane with the cap

DANGER

In order to prevent splashes of liquid waste from the tank, always close the sensor connector and the membrane with their own caps before handling the tank.

3. Once the available waste disposal area is reached in the laboratory, empty the liquid waste tank and preferably add 200 mL of commercial hypochlorite or bleach.

DANGER

During the liquid waste disposal, do not remove the caps from the sensor connector and from the membrane.

Load Procedure

1. Insert the Liquid Waste Tank into the Liquid Waste Basin (see Figure 5–34).
2. Remove the cap (6) from the membrane (4) by turning the rubber strip (5) and the black cap from the sensor connector. Caps shall be removed only just before plugging the sensor connector and the liquid tubing.

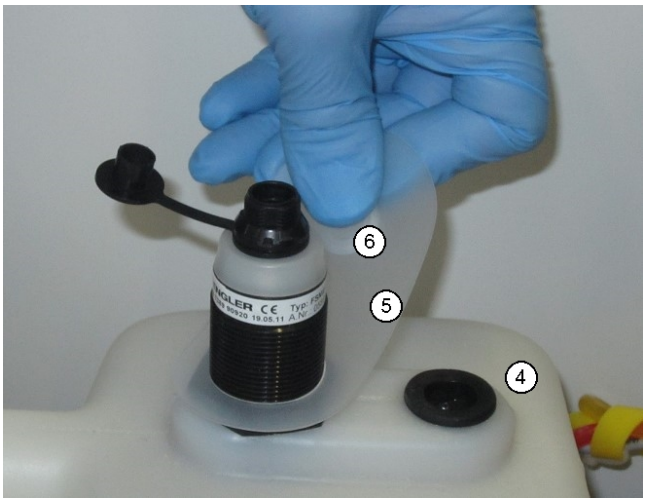


Figure 5–36: Rotation of the rubber strip and opening of the membrane

3. Ensure that the sensor cable is oriented to the front. Also ensure that the male & female grooves are aligned.

Figure 5–37: Sensor connector alignment

4. Push the liquid tubing connector (2) into the membrane (4). Due to the presence of the plastic joint (3), the insertion of the liquid tubing connector (2) into the membrane (4) also implies the insertion of the connector into the waste sensor (1). An audible click is heard when the sensor connection is completed.

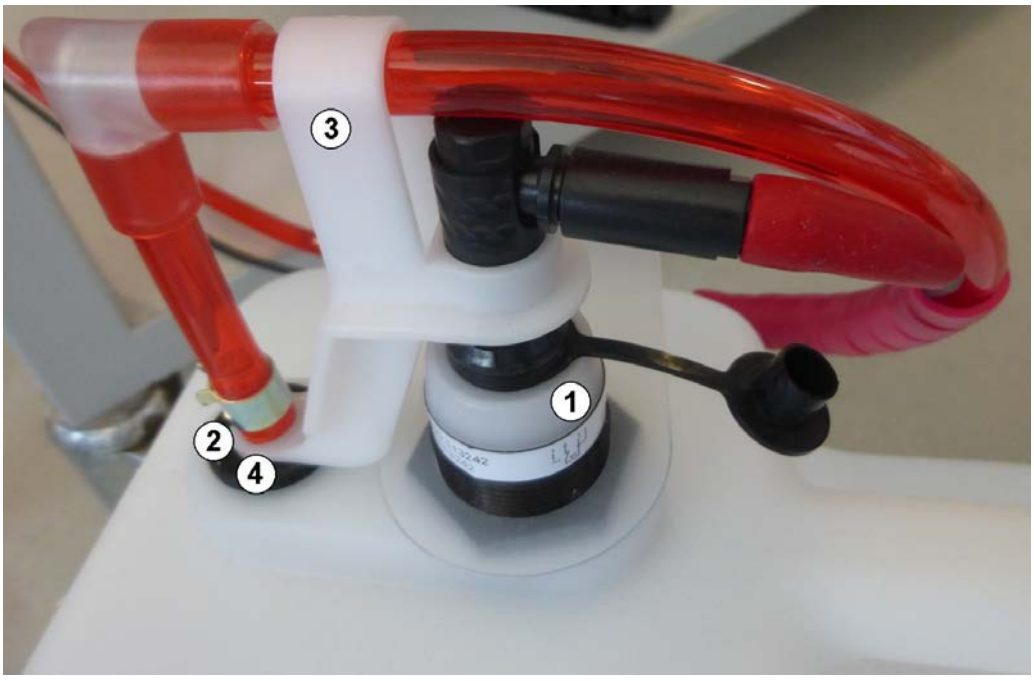


Figure 5–38: Insertion of sensor and liquid tubing connectors

5. Check the **Summary** of the **Status** menu. The **LIAISON® XS** SW must show the symbol for an empty tank correctly connected.

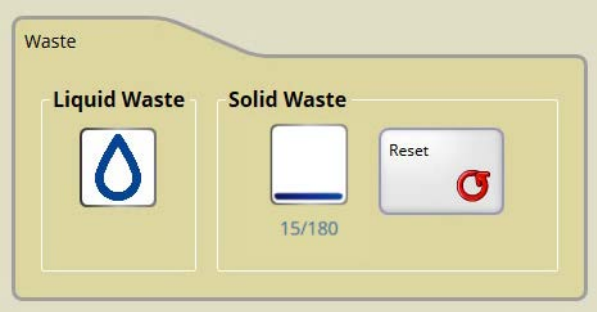


Figure 5–39: Liquid Waste

DANGER

Other symbols may indicate bad/ wrong connection status, therefore leading to malfunctions with consequent risk of spillage of waste liquid.

5.4.7 Load and Unload the LIAISON® EASY Waste

DANGER

See chapter 1.6.6 for Biological Safety.

NOTE

The **LIAISON® XS** system does not monitor the presence of the **LIAISON®** EASY Waste, therefore the user shall ensure that it is loaded before starting a run.

1. Tap on the **Status** main category tab and check the **Solid Waste**.
2. Ensure that the instrument is not in “running” or “maintenance” status before unload/load the solid waste.

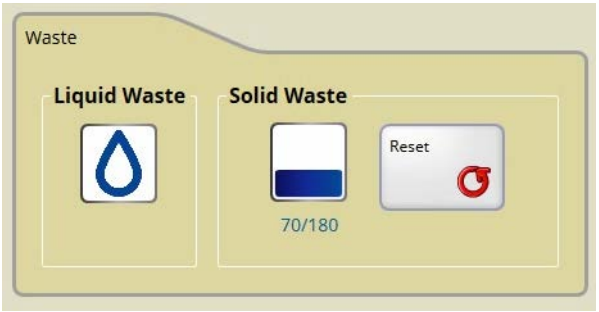


Figure 5–40: Solid Waste

CAUTION

Do not pre-assemble the Easy waste container.

LIAISON® EASY Waste Assembling Instruction

1. Start with the cardboard having the absorbent cloth and with the assembling instruction on the side down.
2. To ensure an easier assembling, fold all the marked crease.
3. Following the marked crease, fold upwards the two side flaps and fold internally the two extremities close to the absorbent cloth; pull upward the side over the absorbent cloth (see Figure 5–41 step A1).

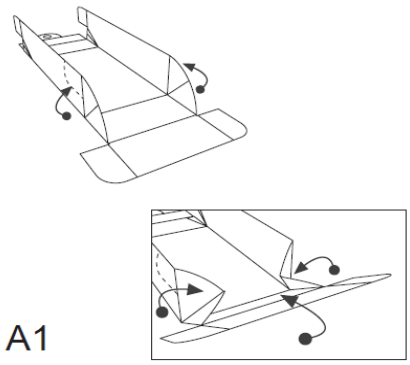


Figure 5–41: ***LIAISON®*** *EASY Waste assembling instruction step A1*

4. Remove the two double-sided adhesive tapes from the cardboard raised in step A1 of the figure 5–41 and glue the two creases folding them on the two side flaps (see Figure 5–42 step A2). Press the two side flaps in order to ensure the complete gluing of the adhesive tapes.

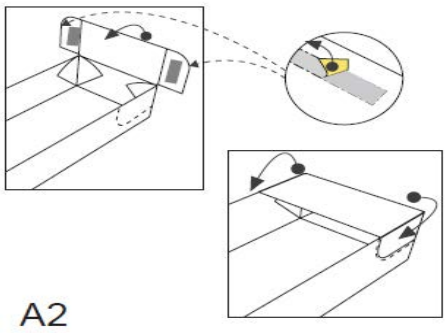


Figure 5–42: ***LIAISON®*** *EASY Waste assembling instruction step A2*

5. Turn the cardboard in front of the side already folded; following the marked crease, fold upwards the two side flaps, fold internally the two extremities and remove the two double-sided adhesive tapes; pull upward the side having the eyelet and glue the two creases folding them on it (see Figure 5–43 step A3). Press the two side flaps in order to ensure the complete gluing of the adhesive tapes.

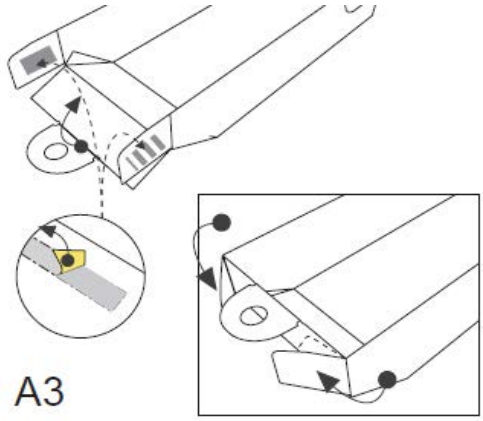


Figure 5–43: ***LIAISON®*** *EASY Waste assembling instruction step A3*

6. Place the assembled cardboard on a cleaned surface and take the other cardboard provided with the EASY waste (cap).
7. Following the marked crease, fold upwards the two side flaps and fold internally the two extremities; fold the flap against the two extremities and fold it again down in order to insert it the corresponding holes (see Figure 5–44 step B1).

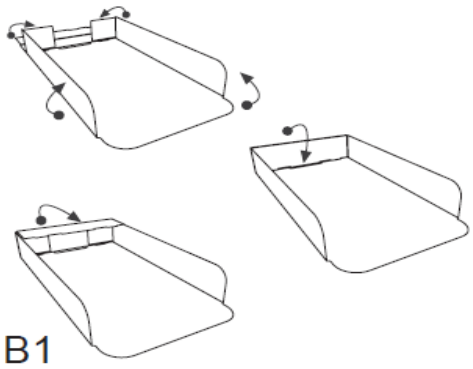


Figure 5–44: ***LIAISON®*** *EASY Waste assembling instruction step B1*

8. When the EASY Waste in the instrument is full, before dispose it in the biological waste, insert the un-folded portion of the cap in the dedicated portion of the box (see Figure 5–45 step C1).

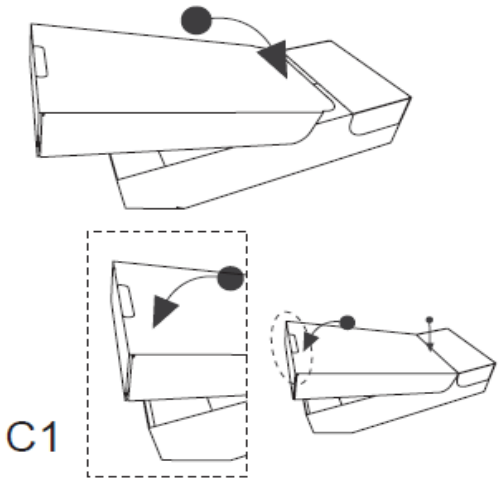


Figure 5–45: ***LIAISON®*** *EASY Waste assembling instruction step C1*

9. Insert the eyelet of the Easy Waste box in the hole of the EASY Waste cap (see Figure 5–46 step C2).

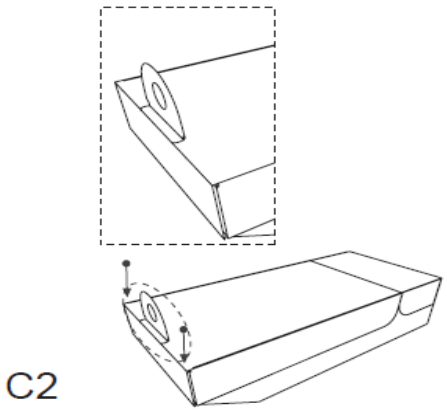


Figure 5–46: ***LIAISON®*** *EASY Waste assembling instruction step C2*

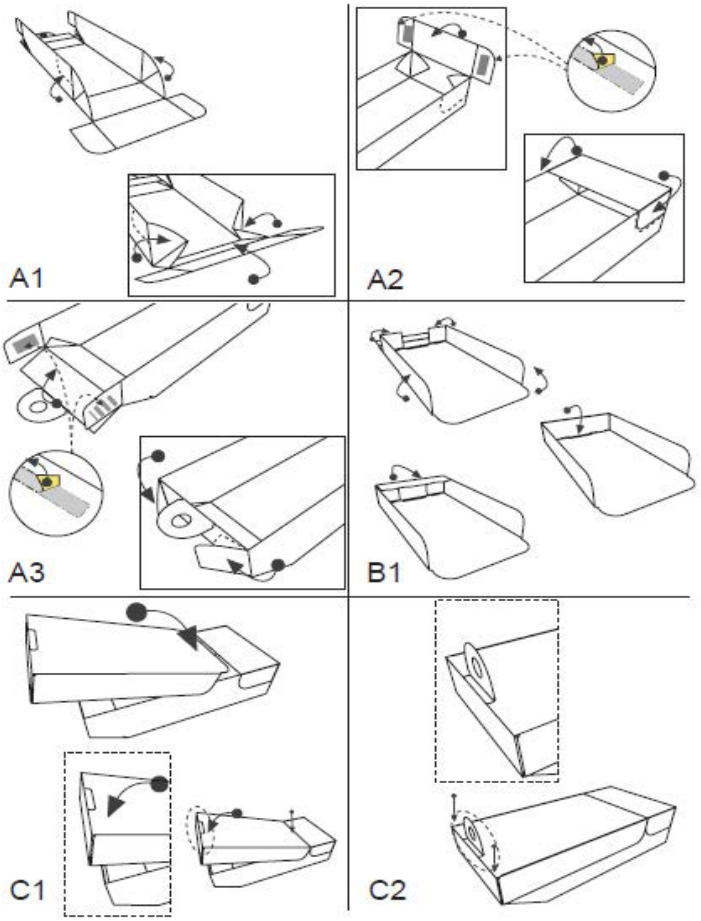


Figure 5–47: **LIAISON®** *EASY Waste instruction*

Figure 5–48: assembled **LIAISON®** EASY Waste

Unload Procedure

1. Pull the solid waste bin out of the **LIAISON® XS** system.

Figure 5–49: Solid waste Bin with EASY waste box in the instrument

2. Remove the eyelet out of the Solid Waste Bin (see Figure 5–50).

Figure 5–50: Box eyelet out of the Solid Waste Bin

3. Push the cap of the **LIAISON®** EASY Waste onto the EASY waste box (see Figure 5–46).

NOTE

Make sure that the un-folded portion of the cap is correctly inserted into the dedicated portion of the box.

4. Insert the eyelet of the box inside the dedicated hole of the cap and lift the EASY waste box before closing the cap (see Figure 5–51).

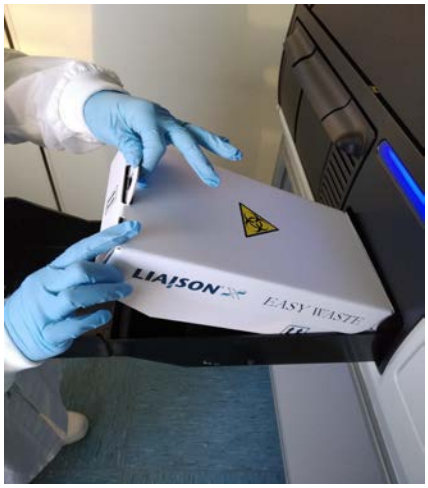


Figure 5–51: EASY Waste closing

5. Remove the **LIAISON®** EASY Waste from the Solid Waste Bin of the instrument.
6. Dispose the closed **LIAISON®** EASY Waste in the biological waste once pulled it out of the drawer.

Load Procedure

1. Store the cap of the EASY waste box. Keep it available to be used for closing the EASY Waste box when full.
2. Place a new EASY waste box into the solid waste Bin. When inserting, observe the direction of the arrow on the box.

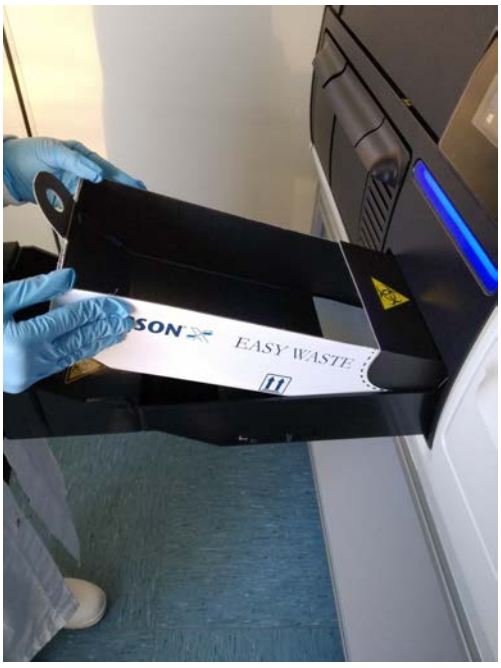


Figure 5–52: Arrow direction on the EASY waste box

NOTE

Make sure that eyelet of the box is correctly folded into the solid waste bin.

3. Insert the solid waste bin with the EASY waste back into the instrument.
4. Check the **Summary** of the **Status** menu and tap on the **Reset** Button.

Figure 5–53: Reset Button in Solid Waste

5.5 Load Patient Samples or Controls and Assign Assays

In this section, it is described how patient samples or controls are loaded into the system and how they can be assigned to one or several assays.

5.5.1 Load Patient Samples

DANGER

See Biological safety in chapter 1.6.6.

Sample Preparation

CAUTION

Traceability of the Diagnostic Results

For maintaining traceability of the diagnostic results, the patient sample should be handled according to the laboratories quality system as described in the local requirements.

CAUTION

Samples Handling

For maintaining safety, the samples must fulfill the requested installation and operating conditions as stated in the assay instruction for use.

CAUTION

Sample Area Flap closure

The sample area flap must be left open only for the time necessary to load sample racks. Leaving the sample area flap open for more than 5', the sample barcode reader will be disabled; in this case, it would be necessary to close the sample area flap and open it to make it work again.

Due to certain mechanical restrictions and safety precautions, the sample to be used on the **LIAISON® XS** system must have the following characteristics:

- Human serum, urine or plasma may be used (sample matrix depends upon assay intended use).
- The anticoagulants citrate, EDTA and heparin may be used (allowed anticoagulants depend upon assay intended use).
- Blood should be collected aseptically by venipuncture, allowed to clot, and the serum separated from the clot as soon as possible.
- Samples having particulate matter, turbidity, lipaemia, or erythrocyte debris may require clarification by filtration or by centrifugation before testing.
- Grossly haemolyzed or lipaemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination should not be tested.
- Check for and remove air bubbles before testing.
- Check that the sample volume is sufficient to run the required amount of tests (as described in the “Instructions For Use” on the kits being used).
- In case of plasma gel separator containers, the amount of sample should be at least 500 µL plus the volume required to run the test.

CAUTION

Air Bubble Formation or Clotting

Air bubble formation or clotting of the samples must be avoided as these may alter the liquid detection functionality and hence cause unreliable results. To avoid clots, the samples should be treated accordingly (e.g. centrifuged) prior to the use in the **LIAISON® XS** system.

After all criteria have been observed concerning the sample quality, the samples must be inserted into tubes and then into sample racks. The following procedure explains in detail the proper steps for doing so.

Procedure

- Only load and unload racks if explicitly requested to do so.
- Only load and unload racks on the specified lanes.
- Check the correct transfer/input of all sample names.
- Remove all caps from the sample tubes.

WARNING

Error at Loading/Unloading of Racks, Reagents and Samples

Improperly loaded or unloaded racks, reagents or samples can cause wrong results due to incorrect pipetting activities.

NOTE

Only tubes of the same type may be used for each rack, to avoid problems during the aspiration of liquids. The tube type must be approved for the relevant rack.

NOTE

Do not rotate bar-coded sample tubes after placement in sample racks. Rotating tubes when placed in sample racks may cause damage to the bar-code and render the label unfit for future usage.

NOTE

Use only exact modelling of tubes and bottles to ensure correct tracking.

1. Place the sample tubes in the sample racks.
   - **Sample tube diameter:**
     Use only sample tubes according to the used rack type (see chapter 4.2.4.3).
   - **Bar coded patient samples:**
     Make sure that the bar-code labels on the individual patient samples face right so that they can be scanned by the bar-code reader when the rack is inserted.
   - **Non bar coded patient samples or unreadable bar-code labels:**
     When using non bar coded sample tubes or tubes with unreadable bar codes, the sample ID's (SID's) must be entered manually (see below). Note that the SID manual entry practice is considered not state-of-art as a potential source of sample mismatch, out of the system control, leading to wrong diagnostic results.
2. Open the sample loading bay flap.
   The software will show automatically the Samples sub category tab of the Loading main category tab. The barcode reader is positioned on the right side of the Sample loading bay. The laser beam exits from an opening positioned on the internal right side of the sample loading bay. The laser beam is orthogonal to the internal right side surface.

WARNING

See Laser safety in chapter 1.6.4.

NOTE

Always use the rack handle when pushing in the racks into the rack system or pulling them out again.

3. Insert the first sample rack (carefully to avoid tipping over and spilling of bottles or tubes) into the sample loading bay on the lane marked by the yellow flashing SW LEDs on the sample display in the software. Place the rack in front of the lane and then push evenly up to the limit stop (with the tippet in the contact opening on the rear panel).
   The rack bar codes and the individual sample tube bar codes are read. If the rack has been inserted properly all the way, the lamp on the screen goes off for this position, and starts flashing at the next position that can be loaded.
4. If the barcode reader was not able to read any barcode ID, an input box appears:
   - Look at the rack label letter (rack identifier) on the front of the rack.
   - Enter the rack identifier manually.
   - Tap on the OK button.

NOTE

Never load more than one rack at a time! For proper bar-code identification the racks must be loaded one after another.

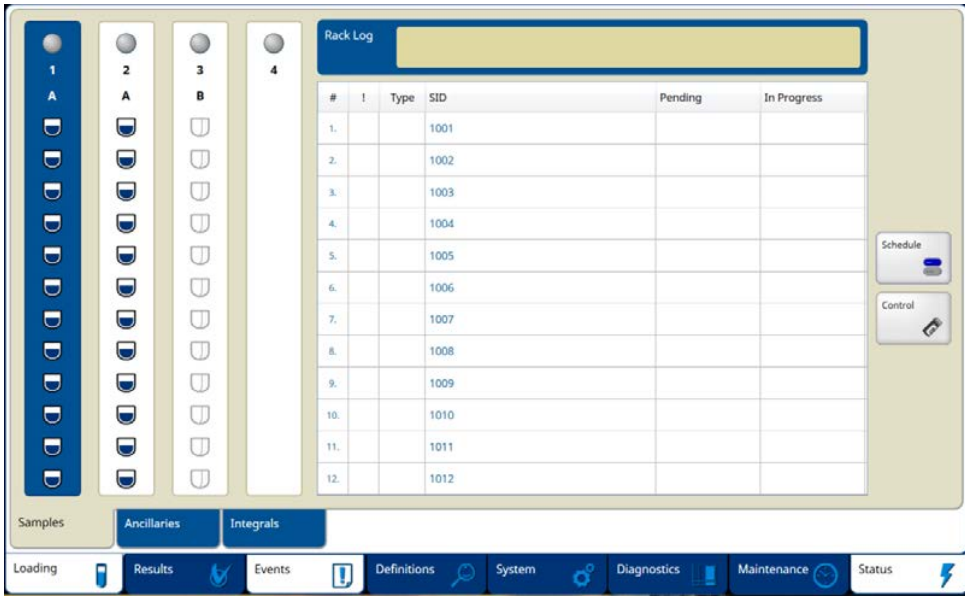


Figure 5–54: Samples Display

Function	Description
1,2,3,4	Lanes of the loading bay for sample racks. • A SW LED reflects the rack status. • Tap on a lane to show all samples in the table on the right side.
Controls	Opens the control picklist and allow the selection of a control name. The bar-code ID related to the selected control name is assigned to the current (empty) ***SID*** field. The ***Control*** button is disabled if the ***SID*** field is not empty.
Rack log	The ***Rack Log*** field shows information about a loaded or selected sample rack. • Loading errors • Positions without bar-code or unreadable bar-code • SID problems (e.g. duplications)
Schedule	Shows the ***Worklist*** tab to create or edit worklists for samples and controls.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 5–7: Functions of the **Samples**sub category*

Column	Description
!	Shows an exclamation mark for high-priority samples (STAT).
Type	Shows an empty cell for samples or a symbol for calibrators and controls: • Calibrators  • Controls  • Light check 
SID	Shows the patient ID, calibrator ID or control ID. The ***SID*** is read via bar-code scanner or entered by operator (if bar-code not present or unreadable). **Notes:** The ***SID*** must be unique. Two or more samples with the same ***SID*** are not allowed to be loaded at the same time. Use only the following characters: • A - Z (a - z are converted to upper case for patient samples) • 0 - 9 • blank space ( ), minus (-), dot (.), dollar sign ($), plus (+), percent sign (%), number sign (#), ampersand (&), equal (=) and slash (/) for patient ID • minus (-) and slash (/) for control ID. A ***SID*** may be 3 to 22 characters long and may not contain heading or trailing spaces. The ***SID*** of external calibrators begins with a predefined prefix character and contains the assay abbreviation or article number. The ***SID*** of controls may not begin with #. **Note** The ***SID*** field is write protected, if any of the following applies: • the rack is in “Error” • the ***SID*** was read via bar-code (and accepted, i.e. not deleted because of duplication or illegal character) • the ***Control*** button was pressed for that ***SID*** at least once since the ***SID*** was recognized (i.e. un-pressing that button does not allow typing, it's necessary to unload and reload the rack) • either a workorder or a patient definition for that ***SID*** is present in the work-database (visible in the sub category ***All*** of the main category ***Results***, see chapter 6.6.1).
Pending	If assays are reassigned to the sample: Shows all assays in status ***Placed*** or ***Failed*** for the sample.
In Process	If assays are assigned to the sample: Shows all started assays in status ***Scheduled***, ***Active*** or ***Measured*** for the sample.

Table 5–8: Columns of the loaded samples table

NOTE

Light-Check must be loaded as ancillary reagent for the right pipettor and as sample for the left pipettor.

Any sample beginning with the special characters (i.e. “#” or “$”) will be displayed as control (if a control definition is available, otherwise the SID is considered invalid) or calibrator, no matter if they will be treated as controls or calibrators or patient samples.

5. Note the Rack Log field for information about the loaded (or selected) sample rack. The Rack Log field shows:
   - Loading errors
   - Empty positions (positions without tubes, without bar-coded tubes or with tubes with unreadable bar-codes)
   - SID problems (e.g. duplications)
6. Tap on the rack shown and check the sample ID's in the SID column of the table.

Symbol	Description
	Loaded sample tube with known ***SID***.
	Loaded sample tube without bar-code or unreadable bar code, or no tube loaded. The **SID** is empty.
	Sample in process.
	Sample off-line, a clot detection or “NoLiquidFound” occurred since last loading (If a sample is off-line, unload it, check its status and reload again when OK.)
	A sample error occurred since last loading and at least one scheduled aspiration has to be completed
	A sample error occurred since last loading and no scheduled aspiration has to be completed

Table 5–9: Symbols

NOTE

Sample IDs should not contain heading and trailing spaces. The system will deny spaces if entered manually via the on screen keyboard or read via bar code.

7. Check all shown SID's of the loaded sample tubes.
   An incorrect SID will be replaced by an empty field (check also the Rack Log): If so:
   - Tap on the affected SID cell.
   - Enter the correct SID.
   - Repeat the steps for all incorrect SID's.
8. Load the other sample racks in the same manner.
9. Close the sample loading bay flap.

5.5.1.1 Loading Error

It is possible to obtain an error while loading a sample rack.

Typical problems may include (but are not limited to):

- Damaged bar codes on the sample rack.
- The sample rack is inserted too fast or too slow. Ask local service support for a tutorial about proper loading speed.
- The bar-code scanner of the sample loading bay is damaged.

Errors with sample racks will appear immediately.

- The Samples display of the **LIAISON® XS** software shows an Error note on the loaded sample rack picture.
- The affected sample loading bay lane will be identified by a flashing LED on the screen.
- The Rack Log on the Samples display shows an error message when that lane is selected.

Troubleshooting:

- Remove the sample rack.
- Check and correct the bar-code labels.
- Insert the sample rack again.
- If the system cannot recognize the rack, check the bar-code scanner of the sample loading bay with another sample rack, and call service if the error occurs again.

5.5.2 Assign Assays to the Patient Samples

Procedure

1. Tap on the Loading main category tab.
2. Tap on the Samples sub category tab.
3. Select a sample rack containing identified patient samples.
4. Tap on the Schedule button to assign assays to the patient samples.

Function	Description
Rack lane	Shows the lane number of the selected sample rack. This button serves as **Select/ Unselect All** button, forces the **Lock button** to be closed. Tap on the arrow bottons next to the ***Rack lane*** button to show another available sample rack, and the sample list will be updated.
Samples list	Shows all samples, calibrators, and controls which are present in the selected rack. Note: empty positions are not shown.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.3.

Table 5–10: Functions

Column	Description
Position	Tube position in the rack.
Type	Shows an empty cell for samples or a symbol for calibrators, controls and light check.
SID	Shows the sample ID, calibrator ID and control ID.
!	Checkbox to assign high-priority to samples (STAT).

Table 5–11: Columns of the rack samples table

Selection Group

The Selection group allows assigning assays (tests) to one or more samples.

Function	Description
Assay Selection in Group	Assays are organized in groups. First it is necessary to choose the assay group. After that it is possible to select one or more assays. The display of an assay shows its relation to the samples: • Colour ○ Blue: The assay is assigned to sample(s). ○ Blue and Grey: The assay is assigned to at least one selected samples ○ Grey: The assay is not assigned to sample(s). • Shape ○ Solid: An integral for the assay is loaded. ○ Broken with two stripes: An integral for the assay is not loaded or is not suitable for starting a test.
Profile Selection	Enables to select a profile (contains several assays, see chapter 6.8.5). Use the arrow buttons to show all available profiles.

Table 5–12: Functions of the Selection group

NOTE See chapter 6 for further details about the Schedule tab.

5. Use the arrows next to the Rack lane button to select the desired sample rack lane.
6. Check the ! checkbox for all high-priority samples (STAT).
7. Tap on the desired row(s) in the table to select one or more samples.
   Use the lock button to change the selection mode:
   - ○ Opened lock: Only one sample entry can be selected (default).
   - ○ Closed lock: It is possible to select more than one sample entry.

NOTE It is not possible to create a worklist selecting samples of different types.

NOTE It is possible to select and work up several patient samples. Additionally tap on the Lock button to use the multiple selection function.

8. Select an assay group in the Assay Selection in Group selection box in the Selection sub tab.
9. Tap on the desired assay button to select one or more assays.
   Use the arrows next to the assays to show all assays of the group.

Style	Description
	The assay is: • currently not loaded on the machine • not assigned to the selected sample(s)
	The assay is: • currently not loaded on the machine • not assigned to all selected samples
	The assay is: • currently not loaded on the machine • assigned to the selected sample(s)
	The assay is: • currently loaded on the machine • not assigned to the selected sample(s)
	The assay is: • currently loaded on the machine • not assigned to all selected samples
	The assay is: • currently loaded on the machine • assigned to the selected sample(s)

Table 5–13: Assay status

NOTE

As soon as a test is started, the status changes to grey (unselected) and may be assigned again, even if the previous test is still running.

10. Select a profile (contains several assays).
    Use the arrows next to the profiles to show all profiles.
11. There is the possibility to assign one or more dilution factors to the assigned assays in the Dilution group (see chapter 6.5.1.1).
12. There is the possibility to change the number of replicates to the assigned assays in the Replicates group (see chapter 6.5.1.1).
13. Assign the other samples with assays in the same manner.
14. There is the possibility to specify patient personal information for the selected patient sample in the Demographics group (see chapter 6.5.1.1).
15. Tap on the Store button to confirm the assignment.
    The **LIAISON® XS** software returns to the Samples display and shows the assigned assays in the Pending column.

5.5.3 Load Controls and Assign to Assays

NOTE Note the safety notes (see chapter 5.6).

Preparation

Before the control is utilized by the user, it must first be prepared. The instruction on the packaging box must be strictly followed.

- Check that the control volume is sufficient to run the required amount of tests (as described in the “Instructions For Use” on the kits being used).
- Check the control specific Instruction For Use for control specific preparation.

Definition

Before controls can be used, the **LIAISON® XS** system must recognize the controls.

1. Tap on the Definitions main category tab.
2. Tap on the Controls sub category tab (see chapter 6.8.2).
3. For DiaSorin Italia S.p.A. controls, tap on the Scan button to open the Control Scan Dialog.
   For controls not provided with the 2 dimensional barcode, it is possible to define the controls manually (see chapter 6.8.2).
4. Scan the bar-code of the control(s) with the provided external bar-code scanner.
5. Tap on the Ok button.
   The **LIAISON® XS** system shows the control(s) in the controls table.

NOTE Do note remove the external barcode scanner while operating.

Loading

1. Load controls in the same way as patient samples. The upper case conversion is not performed.
   The field Type in the samples table shows a special symbol for controls.
2. When using non bar-coded control tubes or tubes with unreadable bar codes, the control ID's (SID's)/control name must be chosen manually:
   - Select the desired position in the table.
   - Tap on the Controls button.
     Only defined controls may be selected.
     Note: in case two controls have been defined with the same name, the system proposes the control that expires later.
   - Tap on the Add button.
     The **LIAISON® XS** system adds the control ID from the chosen control name automatically to the SID field.

NOTE If a control ID with no definition available is manually inserted with the #, it is considered invalid.

Assigning

3. Assign assays to controls in the same way as patient samples (see chapter 5.5.2).

NOTE Do not mix controls and patient samples at assay assignment.

5.6 Integrals, Calibrators, Ancillary reagents

DANGER

See Biological safety in chapter 1.6.6.

WARNING

Do not use reagents that have not been authorized for the LIAISON® XS system!

WARNING

It is prohibited under any circumstances to change the components of one reagent to another even if the reagents contain the same lot number.

CAUTION

- **Failure to follow instructions “on the box” may result in rapid deterioration of reagent life or even immediate expiration of reagent components.**
- **Handling of Reagent Integrals must be followed according to the Assay IFU’s.**
- **In order to avoid system delays and damage to Disposable Tips all caps must be removed from the reagent tubes or bottles before introduction into the instrument.**
- **In order to avoid tipping over and spilling of bottles or tubes racks must be inserted carefully.**

NOTE

- **Only tubes or bottles of the same type may be used for each rack, to avoid problems during the aspiration of liquids. The tube or bottle type must be approved for the relevant rack.**
- **Always insert or remove the racks/integrals into the rack system with the handle.**
- **Never load more than one rack or integral at a time! For proper bar-code identification the racks must be loaded one after the other, as indicated by the LEDs on the screen.**
- **Bar-code labels on integrals, ancillary reagents and starters are not used in the LIAISON® XS system.**
- **Note the Rack Log field for information about a loaded or selected rack (e.g. errors, empty positions).**

5.6.1 Load Integrals

Integral Preparation

Before an integral is utilized, it must first be prepared. The instructed markings on the packaging box of the integrals must be strictly followed.

1. Remove the desired integral from the refrigerator keeping the integral in an upright position at all times.
2. Open the shipping box containing the integral and remove the integral.
3. Visually inspect the integral vials for leaking at the membrane seals or elsewhere. If the vials are found to be leaking, the local customer service should be notified immediately.
4. Visually inspect the integral vials for bubbles. If bubbles are present the integral can not be immediately used. The integral must either set until all bubbles resolve, or the bubbles must be removed before usage (If bubbles are removed, it is important not to cross contaminate vials).
5. Carefully remove the sealing flap of each vial by pulling the tab of the seal across the membrane in a slow fluid motion (pull only the tab in order to prevent cross-contamination of the reagent integral vials).
6. Remove all liquid from the surfaces of the membranes to prevent cross contamination of the reagent integral vials.
7. Prepare the integral according to the related assay Instruction For Use.

Loading

1. Insert the integral into the integrated re-suspension tool and wait 30 seconds (unless otherwise specified in kit IFU).
2. Open the reagent loading bay flap.
   The software will automatically show the Reagents sub category tab of the Loading main category tab.

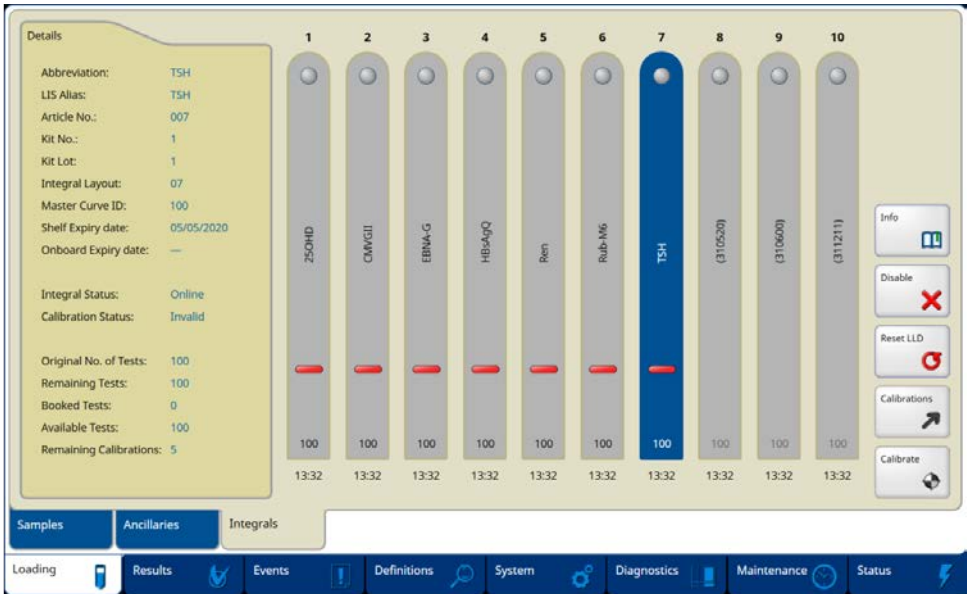


Figure 5–55: Sub category Integrals

Function	Description
Calibrate	Set the calibrator(s) of the selected integral in “Placed” status. In case the external calibrator(s) are not loaded, they are set in “To Do” status. For assays that share calibration within a kit lot, this calibration will be available for all integrals of that kit lot, no matter if loaded on-board or not. If the integral is offline or disabled, the button is greyed out.
Calibrations	Shows the calibration dialog and selects the valid calibration for the selected integral, if any.
Reset LLD	Resets the liquid level of improperly offline vials for the integral selected. It is necessary to unload and reload the integral to allow the system to use it.
Disable/Enable	If disabled the system will avoid using that integral. It has no impact on the resuspension count down.
Info	Opens the Online Help and displays the documents related to the selected integral. If for the selected integral the related package is not available, the download dialog is displayed (see chapter 6.3.1.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

*Table 5–14: Functions of the **Integrals** sub category*

Integrals Group

Function	Description
1...10	Shows the integrals in the reagent loading bay lanes. Tap on a loaded integral to show details.

Table 5–15: Functions of the Integrals group

Details Group

Function	Description
Abbreviation	Abbreviation of the assay.
LIS alias	Assay name on the LIS system.
Article Number	Identification code of the selected integral that allows the **LIAISON® XS** system to associate the integral to an assay.
Kit Number	Kit No number of the reagent integral.
Lot Number	Lot number of the reagent integral.
Integral Layout	Parameter that allows the **LIAISON® XS** system to identify the geometric characteristics of the integral.

Function	Description
Master Curve ID	The ID of the calibration mastercurve used for this reagent integral.
Expiry Date	Date and time when the reagent integral will expire. Note: this is the last day when that reagent integral is allowed to be used.
On-board expiry date	The calculated result obtained with that kit after that day has elapsed will be provided with an indicating flag. Check the on-board stability in the instruction for use of each kit.
Integral Status	Status of the integral availability: • Online: The integral is usable • Offline: The integral cannot be used. The abbreviation is displayed in grey. Possible reasons: ○ No liquid found. ○ The expiration date is exceeded. ○ The compatible assay protocol version is not loaded. ○ The integral has been disabled by user.
Calibration Status	Status of the calibration (e.g. valid, not valid).
Original Number of tests	Max. number of tests with a new integral.
Remaining Tests	Remaining number of determinations for the selected integral. The number is updated (decremented by one) as soon as the first aspiration event for a determination occurs.
Booked Tests	Assigned but not started tests.
Available Tests	Difference between *Remaining Tests* and *Booked Tests*.
Remaining Calibrations	Remaining number of calibrations.

*Table 5–16: Functions of the **Details** group*

3. Insert the first required integral into an empty lane of the reagent loading bay.
   The **LIAISON® XS** software reads the RFID tag of the integral and shows the information about the integral on the display.
4. Load the other required integrals in the same manner following steps 1-3.
5. Close the reagent loading bay flap.
6. Check all loaded integrals (see chapter 5.6.1).

5.6.1.1 Check Integrals

Check the loaded integrals to ensure that:

- No load error (RFID reading error) occurred
- Integral to be used has a valid calibration status
- The number of remaining tests is sufficient

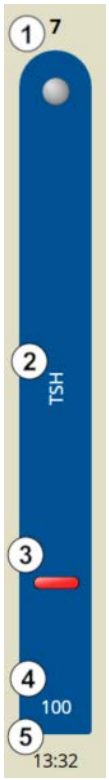


Figure 5–56: Integral

No.	Description
1)	Lane number
2)	Assay name or error symbol !
3)	Calibration status (see table below)
4)	Number of remaining tests
5)	Agitation countdown time The agitation countdown time starts with 15:00 min. and stops at 00:00 min. When it reaches 00:00, the integral can be used (unless otherwise stated in the kit IFU).

Table 5–17: Integral

Symbol	Description
no symbol	No specific symbol is shown if the integral has a valid calibration.
	A calibration is “Created” for the integral.
	A calibration is “Ongoing” for the integral.
	A red bar indicates that no valid calibration is present.

Table 5–18: Calibration status

NOTE

The symbol  shall be considered effective only after the Finish time will be displayed on the header (see chapter 6.4).

5.6.1.2 Particular Aspects of Loading Reagents in Combi-Assays

When inserting the reagent integral of a combi-assay followed by the assignment of this assay to a sample, more measuring results can be obtained: those of the combi-sons and the one of the combi-assay.

5.6.1.3 Lot Binding (Lot Locking)

An assay may require more than one integral for a run. The **LIAISON® XS** system shows the binding between the integrals in the Reagents sub category. When selecting one integral, the other compatible integrals will be marked with a blue frame.

5.6.1.4 Calibrate Integrals

NOTE

Refer to the safety notes (see chapter 5.6).

A calibration cannot be started if any of the following occurs:

- another calibration is in status “Created” or “Ongoing” for the same integral
- another calibration is in status “Created” or “Ongoing” for another integral of the same lot (if that assay shares the Working Curve)
- the calibrators are external and not present on board
- any required resource is detected as missing or empty; see chapter 6.12.3 to check whether the available resources are sufficient.

Preparation

Before an integral is utilized, it must first be prepared. The instructed markings on the packaging box of the integrals must be strictly followed.

1. Remove the desired integral from the refrigerator keeping the integral in an upright position at all times.
2. Open the box containing the integral and remove the integral.
3. Visually inspect the integral vials for leaking at the membrane seals or elsewhere. If the vials are found to be leaking, the local customer service should be notified immediately.
4. Visually inspect the integral vials for bubbles. If bubbles are present the integral can not be immediately used. The integral must either sit until all bubbles resolve, or the bubbles must be removed before usage. (If bubbles are removed, it is important not to cross contaminate vials).
5. Carefully remove the sealing flap of each vial by pulling the tab of the seal across the membrane in a slow fluid motion (pull only the tab in order to prevent cross-contamination of the reagent integral vials).
6. Remove all liquid from the surfaces of the membranes to prevent cross contamination of the reagent integral vials.
7. Prepare the integral according to the related assay Instruction For Use.

Loading

1. Load the integral (see chapter 5.6.1).
2. Load additional calibrators in the same way as patient samples (see chapter 5.5.1).
   The field Type in the samples table shows a special symbol for calibrators.
3. Tap on the Integrals sub category tab of the Loading main category tab.
4. Select the affected integral in the Integrals sub category.
5. Tap on the Calibrate button.
   The calibrators are set to “Placed” status.
6. Tap on the Start button.
   When the calibration is completed, it will be automatically accepted or rejected.
7. When the calibration is completed, check if the calibration status of the affected integral is valid.
   If not, exchange the integral.

Calibration Report

- Select the affected integral in the Integrals sub category and tap on the Calibrations button (available only if a valid calibration exists).

or

- Tap on the Calibrations sub category tab of the Results main category tab.
  - All calibrations (valid, failed, expired…) are stored
- A sample test can be performed without a valid calibration: in this case, only RLU results will be given; the system will automatically assign a dose to all sample results performed within the last 18 hours that have an RLU and not a dose.

5.6.2 Load Ancillary reagents

NOTE

Refer to the safety notes (see chapter 5.6).

Preparation

Before the ancillary reagents are utilized by the user, they must first be prepared. The preparation includes also the pre-storage. The instructed markings on the packaging box must be strictly followed.

1. Remove the desired ancillary reagent from the refrigerator keeping it in an upright position at all times.
2. Open the box containing the ancillary reagent and remove it.
3. Visually inspect the ancillary reagent for leaking. If any leaking is found, the local customer service should be notified immediately.
4. Visually inspect the ancillary reagent for bubbles. If bubbles are present, the ancillary reagent can not be immediately used. The ancillary reagent must either set until all bubbles resolve, or the bubbles must be removed before usage.
5. Prepare the ancillary reagent according to the related assay Instruction For Use.

Loading

1. Open the reagent loading bay flap.
   The software will show automatically the Integrals sub category tab of the Loading main category tab.
2. Tap on the Ancillary sub category tab.

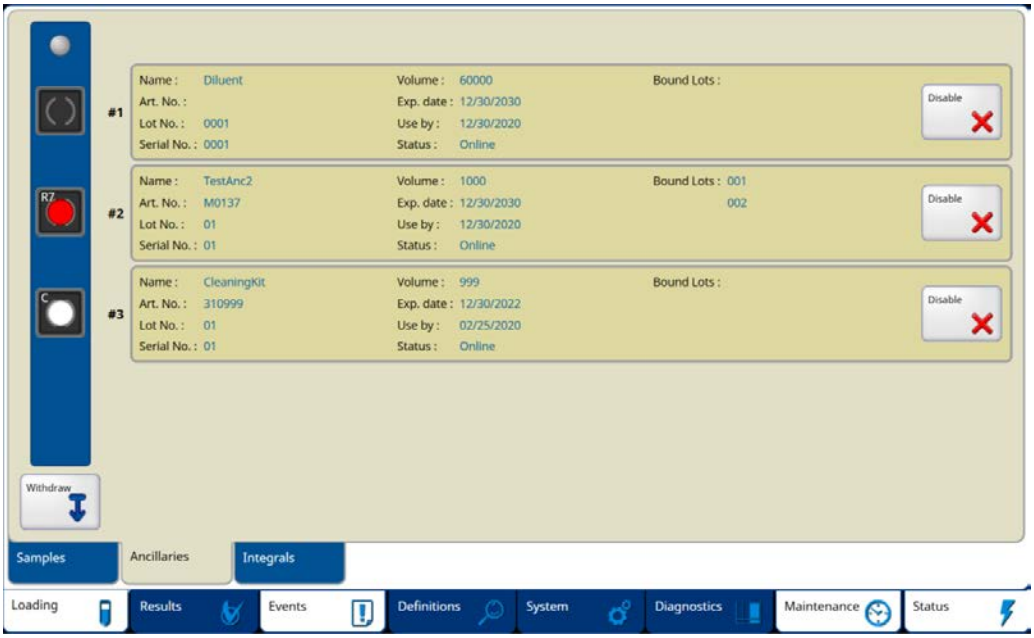


Figure 5–57: Sub category Ancillary

Function	Description
Withdraw	If it is necessary to remove the ancillary rack during a run, press this button to suspend the pipettor access. Re-insert the used ancillaries as soon as possible. Note: this could lead to test failures.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

Table 5–19: Functions of the **Ancillary** *sub category*

Column	Description
No	Position of the ancillary reagent in the ancillary rack.
Name	Name of the ancillary reagent.
Art. No.	Article number of the ancillary reagent.
Lot No.	Lot number of the ancillary reagent.
Serial No.	Serial number of the ancillary reagent.
Volume	Available liquid volume in the bottle.
Exp. date	Date and time when the ancillary reagent will expire.
Use by	Onboard stability expiration date.
Status	Status of the ancillary availability: • Online: The ancillary is usable • Offline: The ancillary cannot be used.
Bound lots	If there is an entry, it is possible to use integrals of the related assay with the reported lot number.

Table 5–20: Columns of the **Ancillary** *sub category table*

NOTE

Some fields may be empty for ancillary reagents not to be used during a routine (i.e. Light Check).

Off-line Status

If an ancillary reagent is off-line, the description text is displayed in grey.

Possible reasons:

- No liquid found
- The expiration date is exceeded.
- The ancillary reagent has a data recognition issue.
- The ancillary has been disabled by user.

3. Remove the ancillary rack (see chapter 4.2.5).
4. Place the ancillary reagent in the ancillary rack.
5. Insert the ancillary rack into the left lane of the reagent loading bay.
   The **LIAISON® XS** software reads the RFID tag of the ancillary reagent and shows the information on the display.
6. Close the reagent loading bay flap.

NOTE

See chapter 5.5.1.1 for details about loading errors.

5.7 Start Worklist

After the checking, loading and assigning of all resources, the **LIAISON® XS** system can start the preparation and evaluation of the samples.

Procedure

1. In Status → Needs, tap on Calculate button and check if the needed resources are available. If not, follow the procedure described in chapter 5.4.
2. Tap on the Start button in the Left Header.
   The **LIAISON® XS** system starts with the worklist.
3. Tap on the Loading main category tab.
4. Tap on the Samples sub category tab.
   Processed samples are marked with a symbol and the assay names are shown in the In Process column of the table.

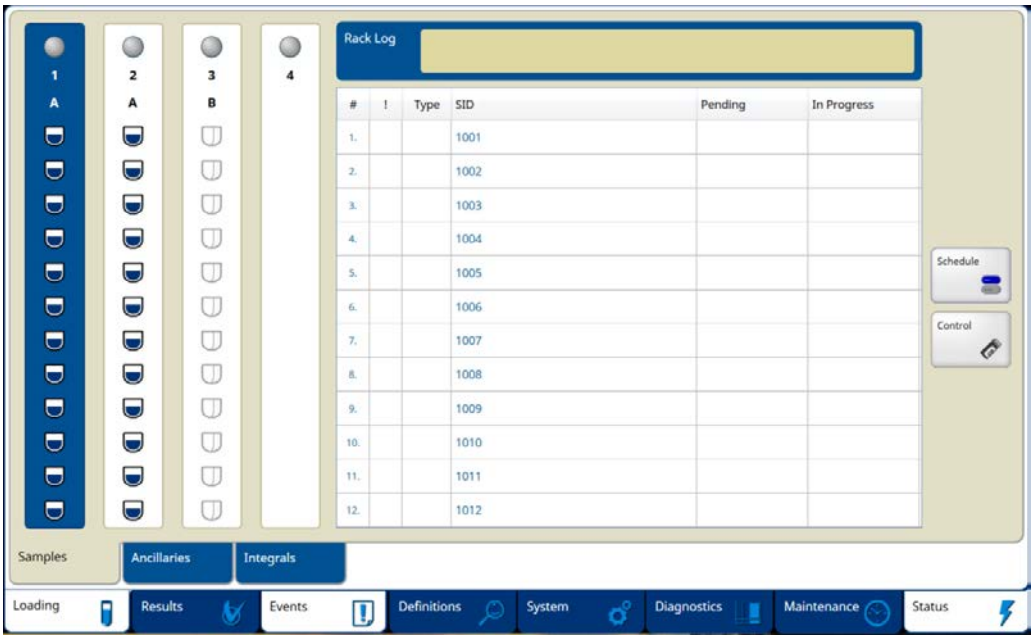


Figure 5–58: Samples display - running worklist

5.8 Results

On the **LIAISON® XS** system, it is not necessary to wait for the entire processing to be finished to view the results. As soon as the processing of one patient sample test, calibration, or control is finished, the system generates the result for it.

The completed results can be accessed via the main category Results as well as its several sub categories.

Sub category	Description	Procedure	Further Details
All	The sub category All shows all entries of applied, started, and finished worklists.	-	chapter 6.6.1
Worklist	The sub category Worklist shows all entries in “To Do” and “Placed” status	-	chapter 6.6.2
Ongoing	The sub category Ongoing shows all entries in “Scheduled”, “Active” and “Measured” status	-	chapter 6.6.3
Done	The sub category Done shows only entries of finished worklists with status “Done”.	chapter 5.8.1	chapter 6.6.4
Failed	The sub category Failed shows only entries of finished worklists with status “Failed”.	chapter 5.8.2	chapter 6.6.6
Calibrations	The sub category Calibrations shows only calibration entries (either valid, expired and failed calibrations).	chapter 5.8.3	chapter 6.6.7
Controls	The sub category Controls shows the results of the controls.	chapter 5.8.4	chapter 6.6.8

Table 5–21: Sub categories of the main category Results featuring completed results.

5.8.1 Results of Sample Tests (Status Done)

Use the sub category Done to show only sample entries of finished tests with status Done.

Procedure

1. Tap on the Results main category tab.
   The **LIAISON® XS** software shows the sub category All.
2. Tap on the Done sub category tab.

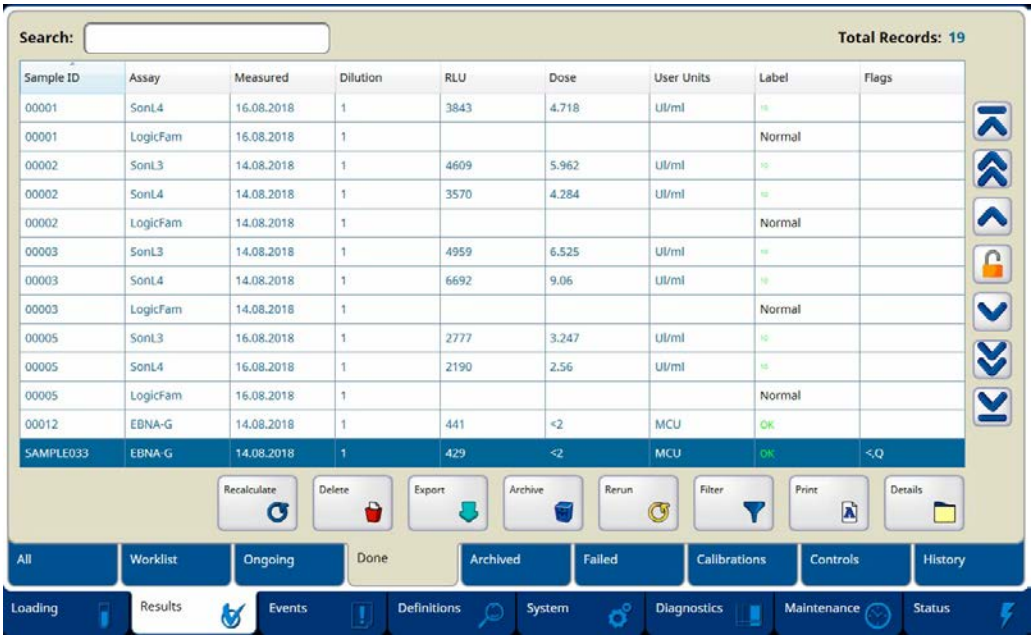


Figure 5–59: Sub category Done

Function	Description
Recalculate	Recalculates the currently selected entries, using the most recent valid calibration for the assigned assay. For Combi Assays, if a Combi Son is selected, all results of the same assay family are recalculated.
Delete	Deletes one or more entries. The deleted entries are moved to a separate database. For Combi Assays, if a Son is selected, a pop-up ask the user to delete the entire family or revoke the request.
Export	Opens the Export display to export one or more entries to a text file.
Archive	Archives the currently selected entries. The archived entries will be shown in the sub category Archived. For Combi Assays, if a Son is selected, a pop-up ask the user to archive the entire family or revoke the request. Note: This button is available only if automatic archiving is not enabled.

Function	Description
Rerun	Allows to repeat the test of one or more entries, opening a selection display (see chapter 6.6.4.2). For Combi Assays, if a Combi Father is selected, all results of the same assay family are recalculated; otherwise, only the selected Combi Son is rerun. Note: the entries will be set either to “placed” (if the sample is present on board) or to “to do” (if the sample is not present on board).
Filter	Opens the ***Select Filter*** display.
Details	Opens the ***Result Details*** display for the selected entry.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 5–22: Functions of the Done sub category

CAUTION

The usage of the Recalculate feature may lead to modifications of already reported results: use it only in accordance with laboratory procedures and local regulations.

Column	Description
Sample ID	Shows the sample ID.
Assay	Shows the assigned assay.
Measured	Result date and time.
Dilution	Dilution factor for the result (only for diluted tests).
RLU	Shows the raw result (in Relative Light Units).
Result	Shows the dose result in user units.
Unit	User units.
Qualitative	Shows the qualitative label for the result (if defined for the assay).
Flags	List of all flags. For details about the flags see chapter 5.8.5.

Table 5–23: Standard columns of the “Done” samples table

3. Pay attention to the Flags column.
   See chapter 5.8.5 for the used flag abbreviations.

NOTE

Dose calculation will be done automatically by the system as soon as a calibration is successful performed, provided that the following conditions are met:

- the samples are successfully analysed but without a dose (i.e. in status Measured),
- the samples were run with the same kit (if the curve is not shared) or with the same lot (if the curve is shared), and
- the samples, that have a RLU result, were run within the last 18 hours.

5.8.2 Results of Patient Sample Tests (Status Failed)

Use the sub category Failed to show only patient sample entries of finished tests with status Failed.

Procedure

1. Tap on the Results main category tab.
   The **LIAISON® XS** software shows the sub category All.
2. Tap on the Failed sub category tab.

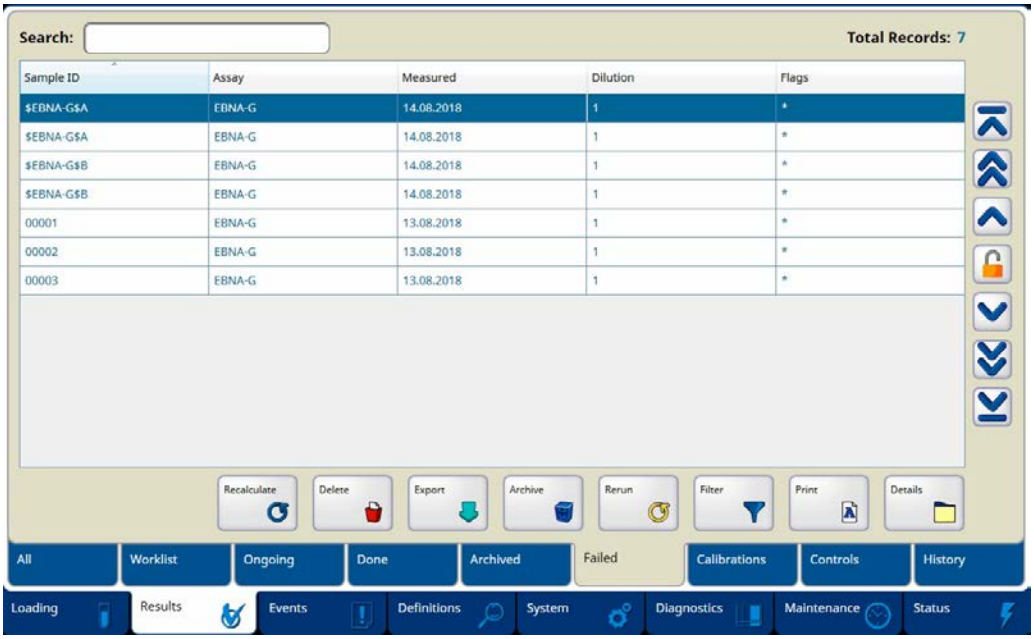


Figure 5–60: Sub category Failed

Function	Description
Recalculate	Recalculates the currently selected entries, using the most recent valid calibration for the assigned assay. For Combi Assays, if a Combi Son is selected, all results of the same assay family are recalculated.
Delete	Deletes one or more entries. The deleted entries are moved to a separate database. For Combi Assays, if a Son is selected, a pop-up ask the user to delete the entire family or revoke the request.
Archive	Archives the currently selected entries. The archived entries will be shown in the sub category ***Archive***. For Combi Assays, if a Son is selected, a pop-up ask the user to archive the entire family or revoke the request. Note: This button is available only if automatic archiving is not enabled.

Function	Description
Rerun	Reschedules one or more entries. For Combi Assays, if a Combi Father is selected, all results of the same assay family are recalculated; otherwise, only the selected Combi Son is rerun. Note: the entries will be set either to “placed” (if the sample is present on board) or to “to do” (if the sample is not present on board).
Filter	Opens the ***Select Filter*** display.
Details	Opens the ***Result Details*** display for the selected entry.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 5–24: Functions of the **Failed** sub category*

CAUTION

The usage of the Recalculate feature may lead to modifications of already reported results: use it only in accordance with laboratory procedures and local regulations.

Column	Description
Sample ID	Shows the sample ID.
Assay	Shows the assigned assay.
Measured Date	Result date and time.
Dilution Factor	Dilution factor for the result (only for diluted tests).
Flags	List of all flags. For details about the flags see chapter 5.8.5.

Table 5–25: Standard columns of the “Failed” samples table

3. Perform the next steps accordingly to the laboratory processes:
   - **Details**: Shows details for a selected sample entry.
   - **Recalculate**: Recalculates the currently selected entries.
   - **Rerun**: Reruns all or only the selected entry/entries.

5.8.3 Results of Calibrations

Use the sub category **Calibrations** to show only entries of all calibrations.

Procedure

1. Tap on the **Results** main category tab.
   The **LIAISON® XS** software shows the sub category All.
2. Tap on the **Calibrations** sub category tab.
3. Pay attention to the ***Status*** column!
   See chapter 6.6.7 for the used status abbreviations (***Created***, ***Ongoing***, ***Failed***, ***Invalid***, ***Valid***, ***Expired***, ***NotUsed***, ***NotUsedLot***, ***Disabled***).

5.8.4 Results of Controls

Use the sub category **Controls** to show only entries of all controls.

Procedure

1. Tap on the **Results** main category tab.
   The **LIAISON® XS** software shows the sub category **All**.
2. Tap on the **Controls** sub category tab.
3. Pay attention to the ***Flags*** column! (see chapter 5.8.5)

5.8.5 List of Flags

NOTE

A flag on results indicates that something happened during the run that may have affected the result on this sample.

The system will not report results in case of detected process anomalies.

Reported results may carry flags in order to inform users about the special conditions under which that result was reported.

Not reported results carry flags in order to describe the process anomalies for which that result was not reported.

Each result flag may belong to one of two tables.

- If a flag from the ”invalidating flags” table is set, then the result is not reported;
- If a flag from the “indicating flags” table is set, then the result is reported.

The column “Applies to” defines to which Result the Flags are applied:

- R: Replicate,
- W: WorkOrder (entire sample test, in case of 2 or more replicates), and
- C: Combi Assay.
  The Column “Inherits” defines which result inherits the flag.

Invalidating Flags

Abbr.	Description	Explanation	Applies to	Inherits
*	Mechanical error	A mechanical error occurred on the system.	**R**	**W,C**
*	Agitation speed out of range	The magnetic particel agitation was out of range while pipetted.	**R**	**W,C**
*	No cuvette available	No cuvette was available to process the job.	**R**	**W,C**
*	Liquid tank removed	Wash Buffer or System Liquid removed	**R**	**W,C**
*	Waste tank full	Processing aborted due to full waste Tank.	**R**	**W,C**
*	Disposable tip not present	The system did not have disposable tips available.	**R**	**W,C**
S	Sample not present	The sample was not found (tube not present or offline).	**R**	**W,C**
R	Ancillary not present	A needed ancillary was not found (vial not present or offline).	**R**	**W,C**

Abbr.	Description	Explanation	Applies to	Inherits
R	Reagent integral not present	A needed integral was not found (integral not present or offline).	**R**	**W,C**
*	Washer aspiration failure	An aspiration failure was detected in the washer.	**R**	**W,C**
*	Incubator temperature out of range	Incubator temperature was out of range when the test was processed.	**R**	**W,C**
*	Starter reagent temperature out of range	Starter reagent temperature was out of range when the test was processed.	**R**	**W,C**
*	Job scheduling failure	A job scheduling failure occurred.	**R**	**W,C**
*	User requested abort	The test was aborted as per user request.	**R**	**W,C**
*	Starter prime not performed	System fails to execute priming cuvette.	**R**	**W,C**
*	Measurement chamber error	The system detected an error in the Reader.	**R**	**W,C**
*	Starter dispense control	Starter Volume Check after Measurement failed	**R**	**W,C**
*	Starter reagent depleted	No Starter to perform Measurement	**R**	**W,C**
*	Pipettor Wash Error	An error during reagent pipettor wash was detected	**R**	**W,C**
*	Disposable tip pickup failed	The system could not pick a disposable tip assumed available.	**R**	**W,C**
S	Sample integrity error	An aspiration or dispense failure was detected by the sample pipettor.	**R**	**W,C**
R	Reagent integrity error	An aspiration or dispense failure was detected by the reagent pipettor.	**R**	**W,C**
S	Pip no sample	No or Not Enough sample liquid found	**R**	**W,C**
R	Pip no reagent	No or Not Enough reagent liquid found	**R**	**W,C**
S	Clot sample probe	Clot in Sample	**R**	**W,C**
*	Internal error	Software Error	**R**	**W,C**
*	High background	Too high noise in the Reader	**R**	**W,C**
*	No mitigation	No successful mitigation was performed	**R**	**W,C**
*	Invalid assay sequence	Assay sequence not valid	**R**	**W,C**
*	Aspiration plausibility error	One aspiration did not occur in the defined time slot.	**R**	**W,C**

Abbr.	Description	Explanation	Applies to	Inherits
D	Overdiluted	The sample was over diluted. (Only for samples with sample specific dilution)	**R**	**W,C**
Z	Divided by zero	For calculation of a combi assay result a division by zero occurred	**C**	
M	Math error	Math error occurred while calculating dose.	**R,W,C**	**W**
*****	Starter lot change	A replicate could not start due to a starter lot change meanwhile occurred.	**R**	**W,C**
X>	Son above assay range	Any combi son is above the assay range.	**C**	
X<	Son below assay range	Any combi son is below the assay range.	**C**	
XM	Combi Son mathematical error	Any combi son has a math error in dose calculation	**C**	

Table 5–26: List of invalidating flags

Indicating Flags

Abbr.	Description	Explanation	ApTo	Inher
E	Reagent on board stability expired	The used integral or ancillary has the onboard expiration date overdue.	**R**	**W, C**
C	No calibration	No usable calibration available to calculate dose	**R, W**	**C**
<	Below assay range	The calculated dose is below the assay range. If the assay range low limit is not defined, than the concentration of the first standard may be used (unless it is equal to zero).	**R,W,C**	
>	Above assay range	The calculated dose is above the assay range. If the assay range high limit is not defined, than the concentration of the last standard may be used.	**R,W,C**	
NL	Below normal range	The calculated dose is below normal range (not for calibrators and controls).	**R,W,C**	
NH	Above normal range	The calculated dose is above normal range (not for calibrators and controls).	**R,W,C**	
QE	Control expired	The control used was expired (for control samples only)	**R**	**W,C**

Abbr.	Description	Explanation	ApTo	Inher
Q	Controls out of manufacturer range	At least one RVC was not satisfied. Controls (not defined as RVC) run before that patient sample have QH/QL flag. Based on last performance of any control defined for that assay. Only for patient samples.	**W,C**	
QL	QC below manufacturer range	Controls below the Manufacturer Range or outside the Assay Range, if a Manufacturer Range is defined (for control samples only).	**W,C**	
QH	QC above manufacturer range	Controls above the Manufacturer Range or outside the Assay Range, if a Manufacturer Range is defined (for control samples only).	**W,C**	
UL	QC below user range	Controls below the User Range or outside the Assay Range, if a Manufacturer Range is defined (for control samples only).	**W,C**	
UH	QC above user range	Controls above the User Range or outside the Assay Range, if a Manufacturer Range is defined (for control samples only).	**W,C**	
RM	Recalculated	The result was recalculated upon user request.	**R**	**W,C**
&	Caused rerun	This result caused a rerun	**W,C**	
X&	Son caused rerun	Any Combi Son of this Result caused a rerun	**C**	
X>	Son above assay range	Any combi son is above the assay range.	**C**	
X<	Son below assay range	Any combi son is below the assay range.	**C**	
XNH	Son above normal range	A combi son was above the Normal Range.	**C**	
XNL	Son below normal range	A combi son was below the Normal Range.	**C**	

Table 5–27: List of indicating flags

Flag Mask

For reporting purpose some flags mask some other flags, i.e.: the presence of a flag avoids another flag of lower importance.

For example, a result with flag “S” is not provided with flag “C”, even if a valid calibration was not available.

Combi Results

For combi assay results some flags reflected the presence of a flag into any combi son results.

The flag for a Combi Son...	...becomes the flag for its Combi Father.
Math error	Son Math error
Below assay range	Son Below assay range
Above assay range	Son Above assay range
Below normal range	Son Below normal range
Above normal range	Son Above normal range
Caused rerun	Son Caused rerun

Table 5–28: Combi results flags

5.9 Routine errors

If an error occurs that could compromise the integrity of the system or could fail a significant amount of results, the run is automatically stopped. A message box with a message describing the error is displayed. Error messages have to be confirmed

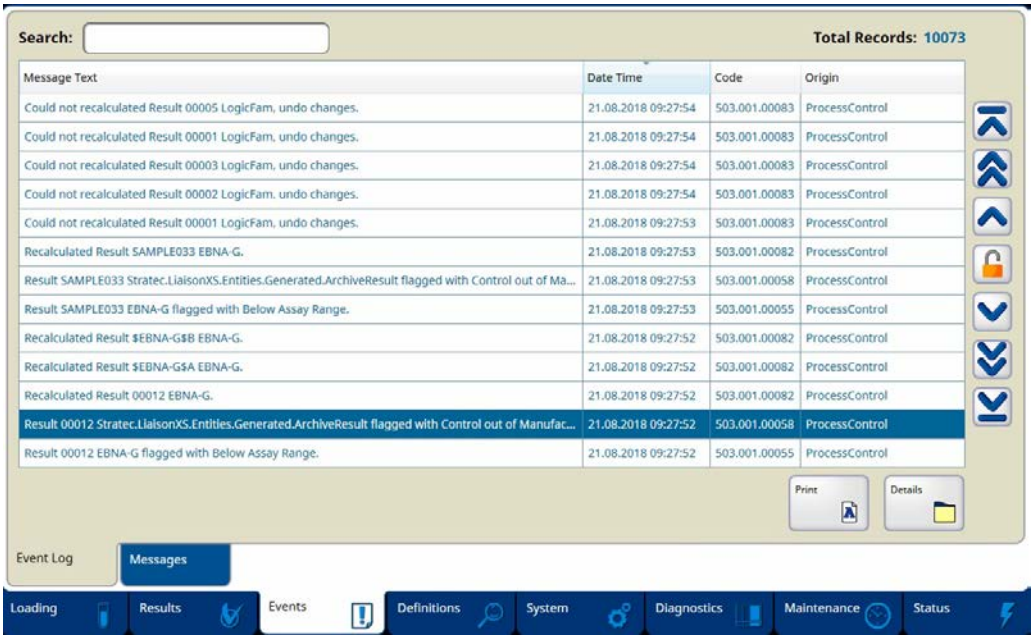


*Figure 5–61: Sub category **Event Log***

All errors and events can be shown in chapter 8.

NOTE Error messages are described in chapter 8.

NOTE If the error reoccurs, please call service.

5.10 Unloading

It is possible to unload unused sample racks or integrals. The **LIAISON® XS** system shows unused resources.

5.10.1 Unload Sample Racks

WARNING

Disposal of Infectious Waste

Potential infectious material and all parts that may come in contact with potential infectious material must be disposed according to the local and national provisions, legislation and laboratory procedures. Handling of waste shall be done using appropriate personal protective equipment (see chapter 1.6.6).

WARNING

Error at Loading/Unloading of Racks and Samples

Improperly loaded or unloaded racks or samples may cause wrong results due to incorrect pipetting activities.

- Only load and unload racks if explicitly allowed by corresponding SW LEDs on the screen.
- Only load and unload racks on the specified lanes.

WARNING

Use of Racks

Remove the racks carefully out to avoid tipping and spilling of bottles or tubes.

NOTE

Always remove the racks by the handle.

NOTE

Never unload more than one rack at the same time.

NOTE

Unload all sample racks before shutting the **LIAISON® XS** system down.

1. Observe the SW LEDS over the sample loading bay lanes on the screen.
2. If there are SW LEDs off, but the lanes are occupied, then open the sample loading bay flap.
3. Hold the handle of an unused sample rack and push the sample rack against backside. Note the audible click.
4. Remove the sample rack carefully.
5. Unload other unused sample racks.
6. Close the sample loading bay flap.

Patient Samples:

NOTE

If the sample tubes are not empty and will be used at a later date:

- Cover and store the patient sample according to laboratory regulations/specifications.

NOTE

If the sample tubes are empty:
Discard tubes or bottles in an appropriate manner.

Controls and Calibrators:

NOTE

If the control or calibrator is not empty:

- Place the appropriate cap on the control or calibrator.
- Place the control or calibrator in a tray in an upright position (if available).
- Place the tray into the refrigerator (see storage information in the control or calibrator instruction).
- If a tray is not available, place the control or calibrator bottle into the refrigerator in a secure upright position.

NOTE

If the control or calibrator is empty:

- Discard the control or calibrator in an appropriate manner.

WARNING

Use of Controls and Calibrators

Do not use controls or calibrators that have not been authorized for the **LIAISON® XS** system environment.

5.10.2 Unload Integrals

WARNING

Disposal of Infectious Waste

Potential infectious material and all parts that may come in contact with potential infectious material must be disposed according to the local and national provisions, legislation and laboratory procedures. Handling of waste shall be done using appropriate personal protective equipment (see chapter 1.6.6).

WARNING

Error at Loading/Unloading of reagent integrals

Improperly loaded or unloaded reagent integrals may cause wrong results due to incorrect pipetting activities.

- Only load and unload reagent integrals if explicitly allowed by corresponding SW LEDs on the screen.

Only load and unload reagent integrals on the specified lanes.

WARNING

Use of Integrals

Remove integrals carefully out to avoid tipping and spilling of integrals.

CAUTION

Do not remove integrals still in use.

NOTE

Always remove the integrals by the handle.

- Look at the SW LEDs on the screen.
- If the SW LED is off, but the lane is occupied, then open the reagent loading bay flap.
- Hold the handle of the unused reagent integrals and remove it carefully keeping it in an upright position.
- Close the reagent loading bay flap.

NOTE

Never unload more than one integral at a time.

NOTE

If the integral is not empty:

- Place the integral in an integral tray in an upright position (if available).
- Place the integral tray into the refrigerator (see storage information in the integral instruction for use manual).
- If an integral tray is not available, place the integral into the refrigerator in a secure upright position.

NOTE

If the integral is empty:

Discard the integral in an appropriate manner.

WARNING

Use of Integrals

Do not use integrals that have not been authorized for the **LIAISON® XS** system environment.

WARNING

Use of Integrals

It is prohibited under any circumstances to modify the integral setup.

5.10.2.1 Proper Storage and Handling of Integrals

Store the integral according to the related Instruction For Use.

5.10.3 Unload Ancillary Reagents

WARNING

Disposal of Infectious Waste

Potential infectious material and all parts that may come in contact with potential infectious material must be disposed according to the local and national provisions, legislation and laboratory procedures. Handling of waste shall be done using appropriate personal protective equipment (see chapter 1.6.6).

WARNING

Error at Loading/Unloading of ancillary reagents

Improperly loaded or unloaded ancillary reagents can cause wrong results due to incorrect pipetting activities.

- Only load and unload ancillary reagents if explicitly requested to do so.

WARNING

Use of Ancillary Rack

Pull the ancillary rack carefully out to avoid tipping and spilling of bottles.

CAUTION

Do not remove ancillaries that are still in use.

NOTE

Always remove the ancillary rack by the handle.

- Look at the SW LED in the ancillary loading page lane (lane “A”).
- If the SW LED is off, but the lane is occupied, then open the reagent loading bay flap.
- Hold the handle of the unused ancillary rack and remove it carefully keeping it in an upright position.

Close the reagent loading bay flap.

NOTE

If the ancillary reagent is not empty:

- Place the ancillary or reagent in a tray in an upright position (if available).
- Place the tray into the refrigerator (see storage information in the ancillary or reagent instruction for use manual).

If a tray is not available, place the ancillary or reagent bottle into the refrigerator in a secure upright position.

NOTE

If the ancillary or reagent is empty:

Discard the ancillary reagent in an appropriate manner.

WARNING

Use of Ancillary Reagents

Do not use ancillary reagents that have not been authorized for the **LIAISON® XS** system environment.

5.11 Shutdown/End of Day Activities

NOTE

The **LIAISON® XS** can be left on after the routine completion, paying attention to leave on board the System Liquid tank above the red phase. The system automatically goes into a “stand-by” condition after some time of inactivity.

NOTE

Shutdown might be possible in case of long period of inactivity (more than 2 weeks). The required procedure for the shutdown and restart of the system from long period is described in the following paragraph 5.11.1.

5.11.1 Procedure for system Shutdown and Wakeup

The following procedure shall be performed in case of long period of instrument inactivity (more than 2 weeks).

NOTE

Before starting the System Shutdown Maintenance task, 1.5 L of Cleaning Solution shall be prepared according to chapter 7.3.

System Shutdown Maintenance Task

1. Ensure that the instrument is not in “running” or “maintenance” status before starting the maintenance;
2. Tap on the **Maintenance** main category and select the **System Shutdown Maintenance** Task;
3. Tap on the “Perform” Button to start the System Shutdown Maintenance Task;
4. Follow the instructions described in the Maintenance Task.

System Wakeup Maintenance Task

1. Switch on the instrument according to chapter 5.3;
2. Ensure that the instrument is not in “running” or “maintenance” status before starting the maintenance;
3. Tap on the **Maintenance** main category and select the **System Wakeup Maintenance** Task;
4. Tap on the “Perform” Button to start the System Wakeup Maintenance Task;
5. Follow the instructions described in the Maintenance Task.

NOTE

In case a system shutdown via main switch is needed, ensure to keep it unpowered for at least 1 minute before switching it on again.

NOTE

In case a forced shutdown is needed, the user shall push the Soft Power button for at least 3 seconds.

6 Software Functions

In this chapter, the complete **LIAISON® XS** software is described in detail. Hereby, the main focus is not on the general context and the process but on a complete description of all functions, buttons, lists etc. This chapter can therefore be considered as a reference book for the **LIAISON® XS** software

NOTE

Software functions not described in this chapter are for field service engineers and developers only. All other users do not have access rights for these special functions.

6.1 Software Startup

On startup **LIAISON® XS** software perform a quick database check for data correctness.

There is no communication to or from the instrument until it is initialized the first time manually with Stop → Initialize.

The start screen shows a progress bar below the manufacturer name.

Figure 6–1: Opening the Login Screen

6.2 Login Screen

The Login Screen is displayed when the **LIAISON® XS** Software is started or the user is logged out.

The ***Login*** Screen is displayed in Display Area only, the Left header and the Toggle Area remain visible but disabled (no interaction possible).

Figure 6–2: Login Screen

Function	Description
Username	Name of the user that wants to login
Password	Each character is displayed as * and not logged as plain text.
Login Button 	Checks whether the user name and the password are valid. • If User does not exist, a hint shall be given. • If the Password is wrong, a hint shall be given. • Otherwise the user shall be logged in.

Table 6–1: Login Screen

6.3 General

In this subchapter, functions that can be used in the complete **LIAISON® XS** software are described.

Function	Symbol	Description
Cancel		Dismisses all changes, closes the dialog and returns to the previous display.
Help		Shows the Online Help (see chapter 6.3.1).
Multiselect		Activate the multiselect function to select more than one consecutive/non consecutive entry in a list. • Opened lock: Multiselect function is deactivated (default) • Closed lock: Multiselect function is activated Selection of consecutive items is supported by swiping a finger across them.
OK		Confirms/saves all changes and returns to the previous display.
Print		Tap on this button to show the printer dialog (see chapter 6.3.3).
Scroll buttons		Jump to the first/last page (active in case of multiple page documents).
Scroll buttons		Jump to the previous/next page (active in case of multiple page documents).
Scroll buttons		Jump to the previous/next values (active in case of multiple page documents).
Scroll buttons		Jump to the previous/next values (active in case of multiple page documents).
Search		Searches for the entered text and shows the results in the table (see chapter 6.3.2).
Store		Confirms/saves all changes and returns to the previous display.
Table sort order		Sorts the rows of a table in ascending or descending order. Tap on a table headline to start the sorting. After the sorting one of the arrows are shown next to the headline.
Total records		Shows the number of rows in the table.

Table 6–2: General functions

NOTE

In some cases it is not possible to select another sub or main category. In this case a function with separate tab (e.g. details) has been selected. Tap on the OK, Store, or Cancel button to return to the sub category.

NOTE

During time consuming operations typically involving a relevant amount of data, the system time (reported on the left header, see chapter 6.4) may be frozen. Once the operation has been concluded, the system will start again updating the system time.

6.3.1 Online Help

The **Help** button provides access to all operating instructions and information necessary to run the system.

When selecting the **Help** button, the system Online help is shown.

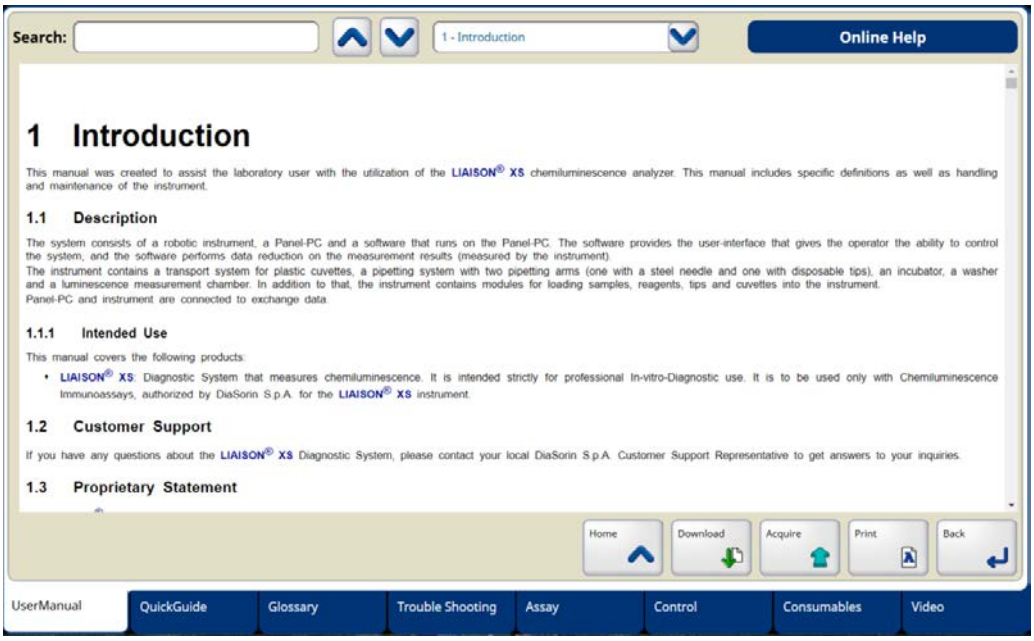


Figure 6–3: Online Help

Function	Description
Search	Searches for the entered text and shows the results. Only alphanumerical characters are accepted (no special characters): a-z, A-Z, 0-9
Download	To send a request to the DiaSorin online repository for downloading contents depending on the selected toggle. • User Manuals for the current software version if the selected toggle is any among: User Manual, Quick Guide, Glossary and Trouble Shooting. • Assay Protocol and accompanying documentation (e.g IFU) if the selected toggle is: Assay • Plastics IFU, if the selected toggle is: Consumable The DiaSorin online repository will reply to the request by matching it with the available contents.
Acquire	Opens a file selection Dialog and allows the user to import from the main path of a connected USB device or from a connected network folder instrument dedicated contents (e.g. packages containing User Manuals, Assay Protocols) to be retrieved from the DiaSorin web site.
Print	Prints the current document on the default printer of Windows or as a PDF file.
Back	Closes the Online Help and returns to the **LIAISON® XS** software main screen.

*Table 6–3: Functions of the **Online Help***

6.3.1.1 Download

In User Manual, Quick Guide, Glossary and Trouble Shooting tabs:

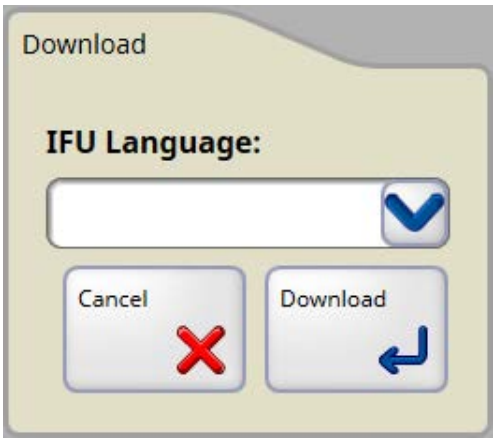


Figure 6–4: Download dialog

Function	Description
IFU Language	Specifies the User preference for the language of the User Manuals. Default: the IFU language as defined in the System-Settings (see chapter 6.9.5). Note: the provided contents may not match with the specified language in case it does not match with any of the DiaSorin approved languages for the involved country.
Download	Start the request for downloading the contents. The system will manage the download of the contents in background. A dedicated message will inform that the download completes or in case of troubles.
Standard Buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3

Table 6–4: Download dialog

In Assay and Consumable tabs:

Figure 6–5: Download dialog

Function	Description
Article No.	Allows to specify the Article Number of the product.
Lot No.	Allows to specify the Lot number of the product.
IFU Language	Specifies the User preference for the language of the documents. Default: the IFU language as defined in the System-Settings (see chapter 6.9.5). Note: the provided contents may not match with the specified language in case it does not match with any of the DiaSorin approved languages for the involved country.
Download	Start the request for downloading the contents. The system will manage the download of the contents in background. A dedicated message will inform that the download completes or in case of troubles.
Standard Buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 6–5: Download dialog

6.3.1.2 Online Help Acquire

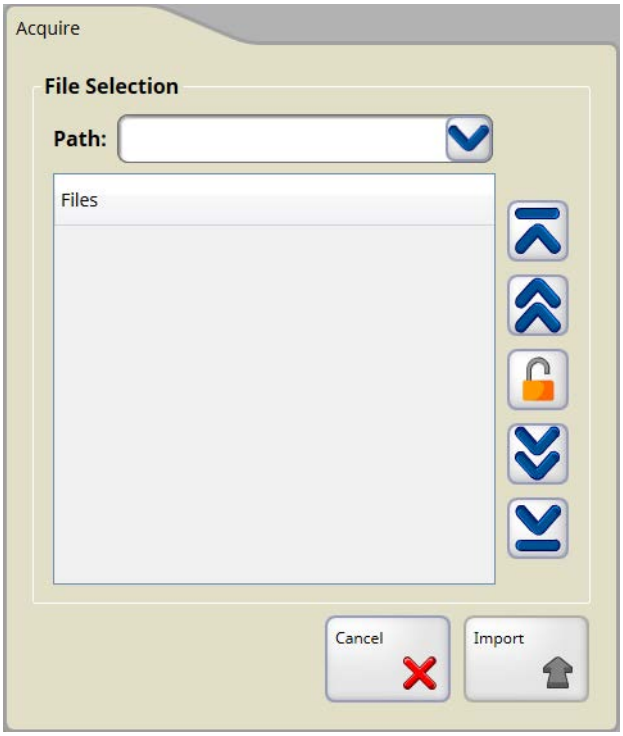


Figure 6–6: Online Help- Acquire

Function	Description
File Selection Path	Select a file for instrument import on an available path.
Import	Import the select file.
Standard Buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 6–6: Online Help- Acquire

6.3.1.3 User Manual

The ***User Manual*** tab shows the online version of this manual.

6.3.1.4 Quick Guide

Short instructions to use the **LIAISON® XS** system are shown on the ***Quick Guide*** tab.

6.3.1.5 Glossary

The ***Glossary*** tab opens the User Manual at a given anchor/bookmark.

6.3.1.6 Trouble Shooting

Help regarding issues with the **LIAISON® XS** system is available through the ***Troubleshooting*** tab. Trouble Shooting tab opens the User Manual at a given anchor/ bookmarks.

6.3.1.7 Assay

The ***Assay*** tab shows information about assays.

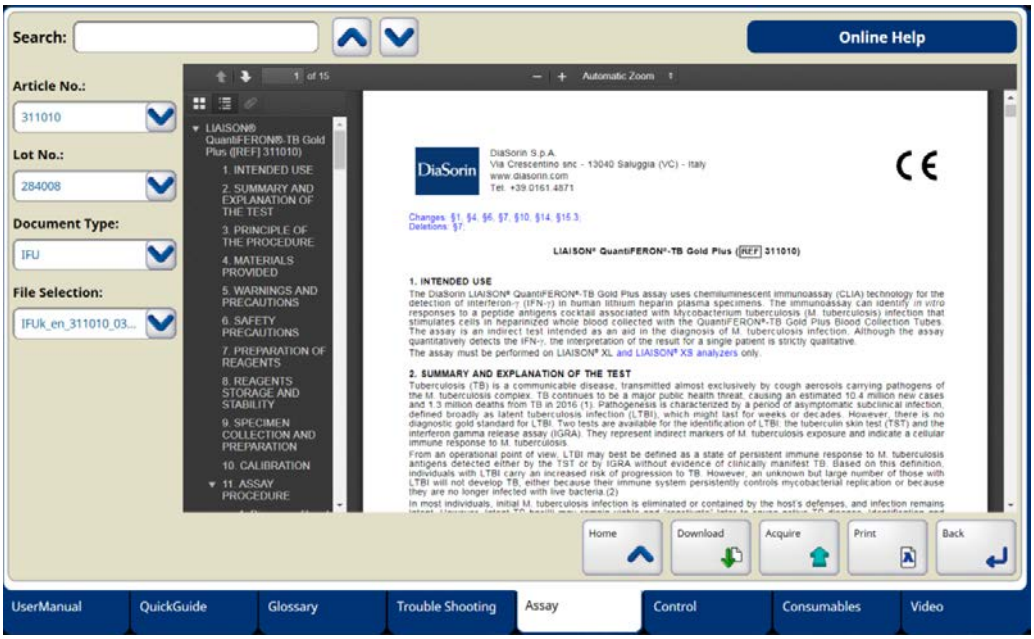


Figure 6–7: Online Help- Assay

Function	Description
Article No.	Article Number
Lot No.	When selection changes, then ***Document*** and ***File Selection*** are cleared.
Document Type	Available values: ***IFU***, ***MSDS***, ***CoA*** and ***Other***.
File Selection	All files with extension ***pdf***. When selection changes, the selected file is displayed.

6.3.1.8 Consumables

The ***Consumables*** tab shows information about consumables.

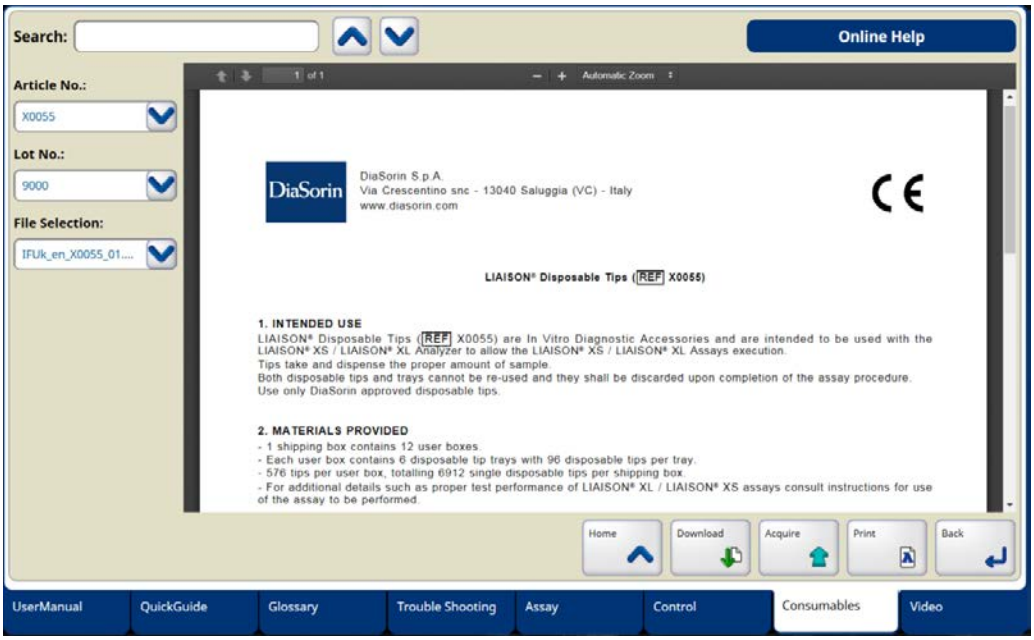


Figure 6–8: Online Help- Consumables

Function	Description
Article No.	Article number of the consumables.
Lot No.	When selection changes, then ***File Selection*** is cleared.
File Selection	All files with extension ***pdf***. When selection changes, the selected file is displayed.

6.3.1.9 Video

The ***Video*** tab allows visualization of video tutorials.

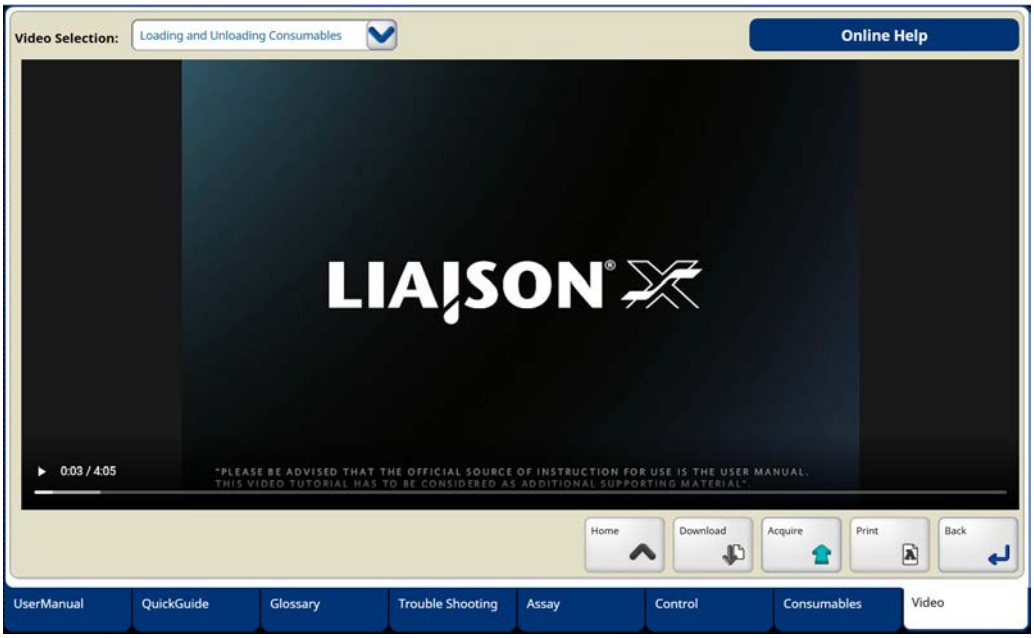


Figure 6–9: Online Help - Video

Function	Description
Video Selection	Allows to select video files to be reproduced.

NOTE For Video tutorials availability, please contact your local support representative.

NOTE ***Control*** tab is currently not provided.

6.3.2 Sorting and Searching

This function allows the user to sort the table entries or to search for entries.

Function	Symbol	Description
Search		Searches for the entered text on the primary sorted column and shows the results in the table. Only alphanumeric characters are accepted (no special characters): a-z, A-Z, 0-9.
Table sort order		Sorts the rows of a table in ascending or descending order. Columns that do not support sorting will not show any arrow.

Table 6–7: General functions

Sorting

To view the table contents, it is possible to sort the shown entries.

Procedure:

1. Tap on one of the table headlines to sort the complete table.
2. The entries will be sorted on the basis of the text in the selected column.
3. A small arrow next to the headline shows the sort order:
   - Ascending sort order All entries are sorted from 0 to 9 and A to Z
   - Descending sort order All entries are sorted from Z to A and 9 to 0

NOTE

For items where the logical content is more relevant than the alphabetical content, the sort order may be not alphabetical but logical (e.g. the “Status” column for test results can be sorted according to a pre-defined non alphabetical order that follows the natural sequence of status for a test).

NOTE

The sort function is case insensitive (e.g. the item “Sample_01” is equivalent to the item “SAMPLE_01”).

Examples

- Unsorted entries:

Column 1	Column 2
Sec_1_ID_2	Failed
Doc_34_ID_5	Done
Sec_1_ID_5	Failed
Sec_1_ID_22	ToDo

Table 6–8: Unsorted entries

- Selected: Column 1/ Sort order: Ascending

Column 1	Column 2
Doc_34_ID_10	Done
Sec_1_ID_2	Failed
Sec_1_ID_22	ToDo
Sec_1_ID_5	Failed

Table 6–9: Sort order: Ascending

- Selected: Column 1/ Sort order: Descending

Column 1	Column 2
Sec_1_ID_5	Failed
Sec_1_ID_22	ToDo
Sec_1_ID_2	Failed
Doc_34_ID_10	Done

Table 6–10: Sort order: Descending

- Selected: Column 2/ Sort order: Ascending

Column 1	Column 2
Sec_1_ID_22	ToDo
Doc_34_ID_10	Done
Sec_1_ID_2	Failed
Sec_1_ID_5	Failed

Table 6–11: Sort order: Ascending

Searching

As the system is used the result and events table's entries will increase. To find particular entries it is possible to search for these entries.

Figure 6–10: Search entry field

Procedure:

1. Tap on one of the table headlines to select the used column for the search process.
2. Select the Search field.
3. Enter a text to search for. Note that all search results must begin with this text.
4. Tap on the Enter key to close the keyboard from screen.The **LIAISON® XS** software shows the first entry of the found entries. If it was already visualized, nothing on the page changes, otherwise the system scrolls the page to the first matching entry.
5. Use the scroll buttons to look for the other found entries.

NOTE

The search function shows always all entries. The function jumps entirely to the first entry of the found entries.

NOTE

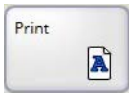
According to the sort order, the first found entry is the topmost entry in ascending order. The last entry is the topmost entry in descending order.

Examples

- Entries:
  Doc_34_ID_10
  Doc_39_ID_2
  Sec_1_ID_5
  Sec_1_ID_5
  Sec_2_ID_7
  Sec_2_ID_9
  Sec_3_ID_4
- Search text: Sec_
- First entry found: Sec_1_ID_5
- Search text: Sec_2
- First entry found: Sec_2_ID_7
- Search text: (empty)
- First entry found: Doc_34_ID_10

6.3.3 Print Reports

It is possible to print the information (e.g. results, events, or assays) reported by the **LIAISON® XS** software.



1. Select desired entries.
2. Tap on the **Print** button.
   LIAISON® XS software shows an adapted dialog.

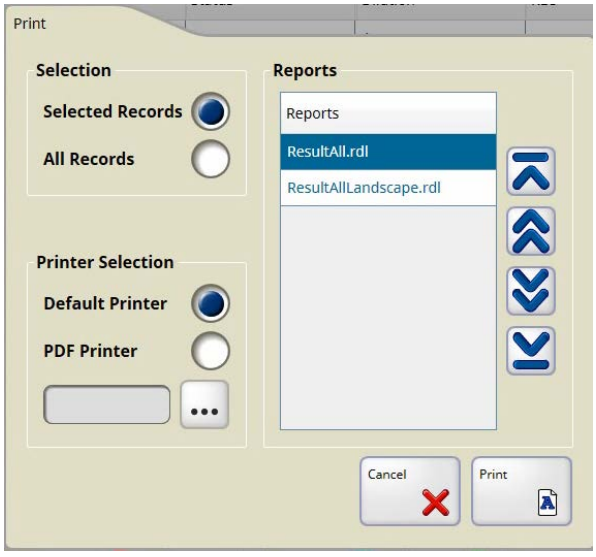


*Figure 6–11: **Print Report** dialog (e.g. result report)*

3. Select the print options:

- ***Selected Records***: Prints only the selected entries
- ***All Records***: Prints all entries currently present on the page list. If a filter is applied before the print then the print will be applied the entries matching the filter criteria.

- Printer Selection:
  Allows to select between the "***Default Printer***" (Windows Default Printer) and "***Portable Document Format Printer***".
  If the "***Portable Document Format Printer***" is selected, the user can select via "File Selection Dialog" ("..." button) where to print the file.

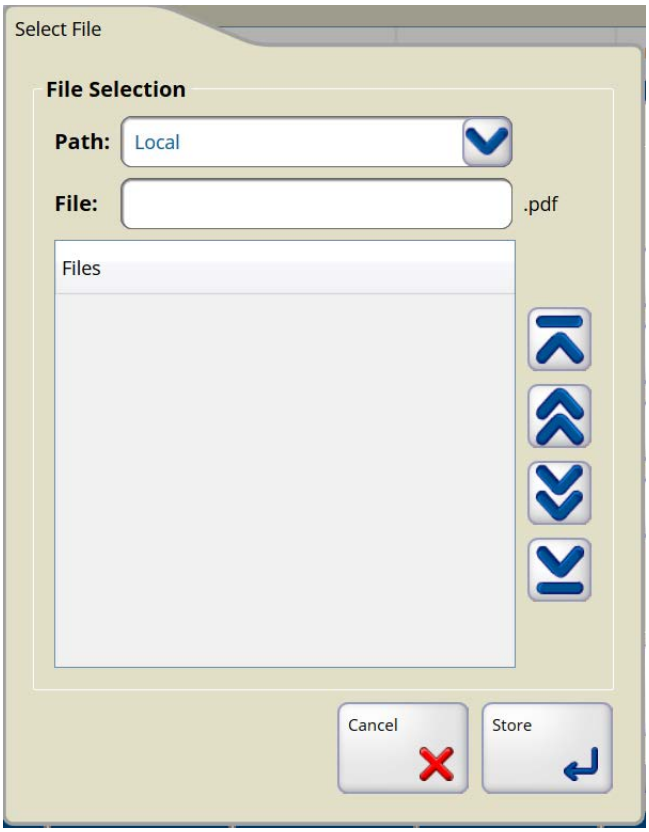


Figure 6–12: File selection dialog

- ***Reports*** allows to select the print layout.

4. Tap on the **Print** button.

NOTE

In case the printer queue should be deleted, it is necessary to interact with the printer itself, as the system does not allow access to the operating system functionalities related to the management the printer.

6.3.4 Available Paths

The system supports the use of local and network paths and USB devices for the following functionalities:

- results export
- print (in PDF)
- backup copy
- auto-backup
- import Assay Protocols
- import and export of other Definition files (e.g. controls, groups)
- acquire from the Online help
- QC files export

NOTE Local folder can be accessed only by DiaSorin authorized personnel

6.4 Left header

Figure 6–13: Left header

Function	Description
	Instrument and Company logo
Stop 	Calls the ***STOP Menu*** Dialog with: • **Abort All** • **Resume** • **Shutdown** • **Initialize**
Date	Shows the current date.
Time	Shows the current time.
User	Shows the currently logged-in user.
Status	Current system status
Start 	Starts a routine or adds to an ongoing routine. Enabled if the system is in (Standby, Ready or Running) and jobs can be started due to system module status. If Starters and/or Wash Buffer are not primed, then Starters and/ or Wash Buffer are automatically primed before schedule.
Cycle	Shows the total number of operativity cycles for the instrument.
Finish time	Estimated finish time of ongoing routine (±20 seconds).
Version	Release version of the **LIAISON® XS** software including Service Pack, if applicable.
Serial Number	Serial number of the instrument.
	Indication for the LIS connectivity/activity. A sign in the right lower corner means: • Disabled  • Enabled  • Data Transfer  • Data Transfer, Error 

Function	Description
	Indication for remote connectivity/activity. A sign in the right lower corner means: • Disabled  • Enabled  • Data Transfer  • Data Transfer, Error 
Help 	Gives access to the On-line help.

Table 6–12: Functions of the Left Header

Status	Description
Disconnected/ Not initialized	The system is not initialized or the user has requested the system to perform a diagnostic task: if the instrument is connected, the system can be initialized upon pressure of the Init button from the **STOP** Menu. Note: this is a non functional status. As long as the system stays in this status, there is no guarantee about the system hardware functionalities, including (but not limited to) reagent cooling, magnetic particles re-suspension, cuvettes movement.
Initializing	The system performs all actions required for mechanical initialization of all modules (e.g. from un-powered start or by user request). The database integrity is also checked.
Standby	All modules are operational, but no tests are running. All subsystem temperatures are maintained at specified temperatures. **LIAISON® XS** software allows starting a new run: the system will take care of performing the necessary activities (including primes). In ***Standby*** mode the system supports loading of reagent integrals, ancillaries, samples and plastic consumables in the drawer.
Maintenance	This status is displayed when: 1. The user requested a routine while the system was in ***Standby*** status: the system performs automatically the priming procedures. 2. The user requested a maintenance task: the system performs the foreseen maintenance activities. 3. The user requested a Resume: the system performs automatically the priming procedures and the system reaches the status ***Ready***. 4. The user pressed the button ***Fill incubator***. 5. The system periodically performs pipettor primes with System Liquid.
Ready	The system is considered ready for assay processing. The **LIAISON® XS** software allows starting a new run. The **LIAISON® XS** system returns into Ready mode when the run is finished and can be started again after test scheduling. After a predefined timeout, the system will return in ***Standby*** mode.
Running	The **LIAISON® XS** system is performing tests. New tests can also be started while the system is in ***Running*** mode.
Halted	A fatal error occurred and all activities are stopped. The previous state is not recoverable. The ***Halted*** mode can be reached from all other states. All ongoing tests will be failed. Note: this is a non functional status. As long as the system stays in this status, there is no guarantee about the system hardware functionalities, including (but not limited to) reagent cooling, magnetic particles re-suspension, cuvette movement.

6.4.1 Stop Menu

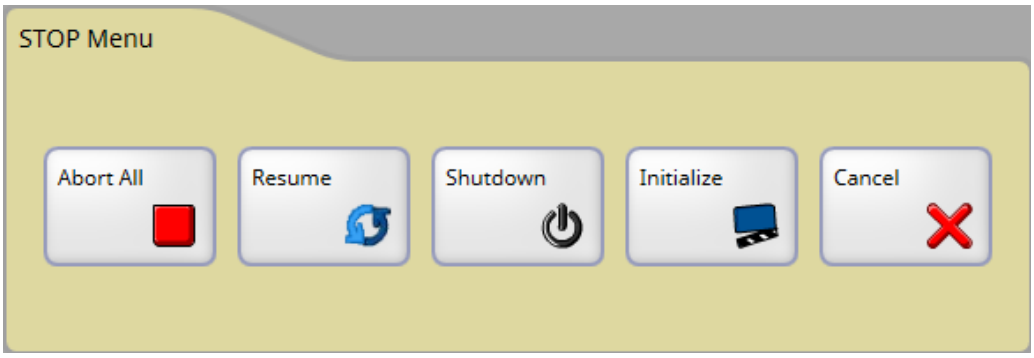


*Figure 6–14: **Stop** Menu*

Function	Description
Abort All	Aborting all jobs shall: • stop (fail) all ongoing jobs within few cycles • put all not started (scheduled) jobs to Placed • allow to start a new routine without Resume
Resume	Changes the System Status from Standby to Ready and performs the priming procedures.
Shutdown	Switches off the Software and the Deskshield is prompted.
Initialize	Initializes the System. Supported smoothly in ***Ready***, ***Standby***, ***Halted***, ***Not initialized***, ***Disconnected***. During Initialization the system needs: • Liquid waste tank • Solid waste drawer loaded on-board.
Cancel	Closes the **STOP** Menu and returns without any changes to the previous display.

*Table 6–13: Functions of the **STOP** Menu*

NOTE While the ***STOP Menu*** is in the foreground the run is not stopped.

6.5 Main Category Loading

With the main category ***Loading***, the **LIAISON® XS** system can be completely loaded and unloaded with samples, integrals and ancillaries. In addition to the loading/unloading, samples can be assigned to assays via the subcategory ***Samples***.

The status of each lane (both for samples and reagents bay) is indicated by a SW LED:

SW LED status	Description
ON	The resource is currently being used and cannot be removed
OFF	• The resource is not used and can be removed • The lane is empty (flap close)
Slow flashing	The lane can be used to load the resource (flap open)
Fast flashing	The resource has not been recognized

Table 6–14: SW LED status

6.5.1 Sub Category Samples

The subcategory **Samples** allows the loading and unloading of sample racks. For every sample tube in the racks, there is the possibility to assign a distinct identification number. This number is either read via bar-code scanner or entered manually. Additionally, one or more assays can be assigned to every sample. After the starting of these assays/tests, it is indicated which samples are being processed.

The samples table shows all positions of the selected rack.

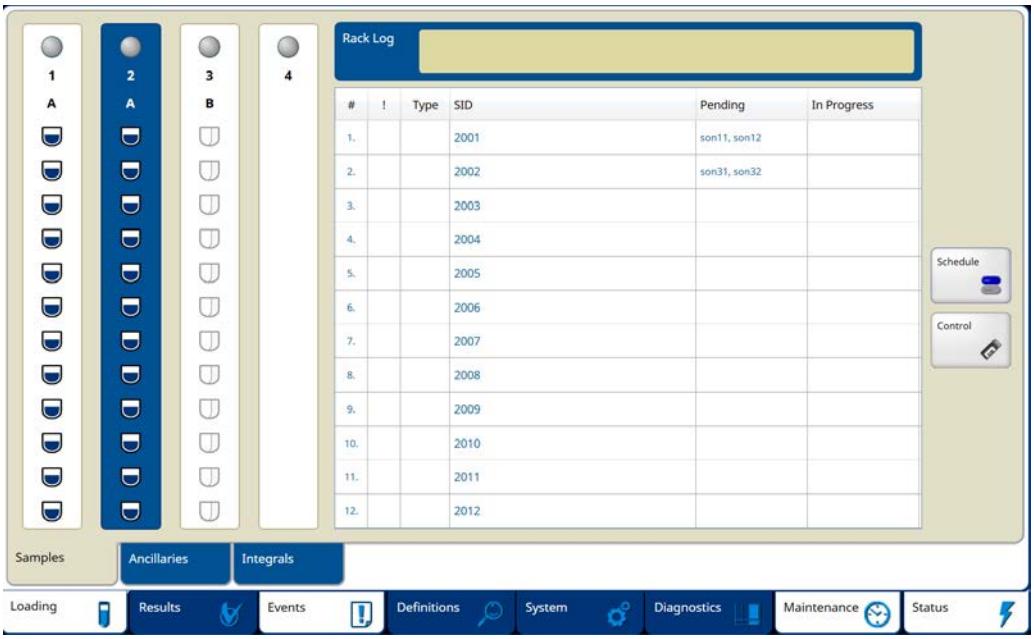


*Figure 6–15: Sub category **Samples***

WARNING

Risk of wrong test assignment

When **Schedule** button is pressed, any SIDs selection in the sub category **Samples** is not maintained. The SID selection must be repeated in the Schedule Display (see Figure 6–18).

Improper test assignment may occur!

Function	Description
1,2,3,4	Lanes of the loading bay for sample racks. • A SW LED reflects the rack status. • Tap on a lane to show all samples in the table on the right side.
Control	Opens the control pick-list and allow the selection of one of the currently defined control names (see figure 6–16). The control ID associated to the control name with the latest expiry date is assigned to the current (empty) ***SID*** field. The ***Control*** button is disabled if the ***SID*** field is not empty.
Rack log	The ***Rack Log*** field shows information about a loaded or selected sample rack. • Loading errors • Positions without bar-code or unreadable bar-code • SID problems (e.g. duplications)
Schedule	Shows the ***Worklist*** tab to create or edit worklists for samples and controls (see chapter 6.5.1.1 and 6.5.1.2).

*Table 6–15: Functions of the **Samples** sub category*

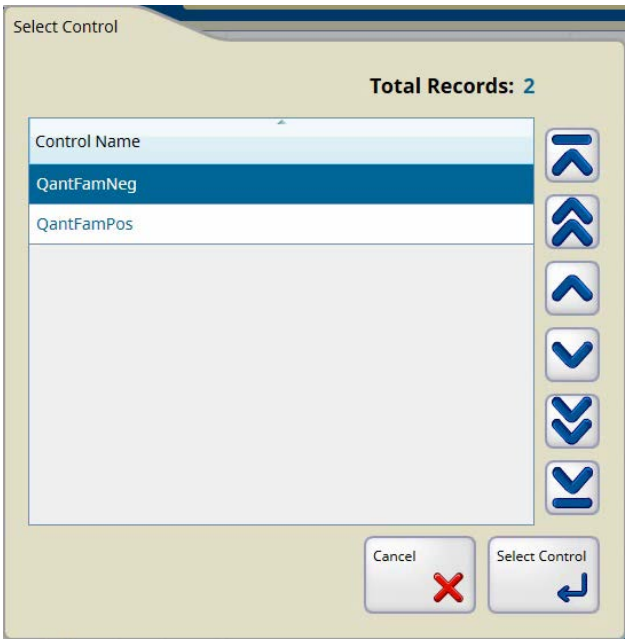


Figure 6–16: Control pick-list

In case of loading errors, the rack lane is displayed with a red exclamation mark:

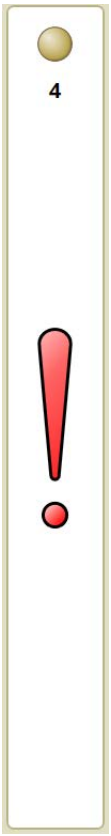


Figure 6–17: Sample rack in error

Column	Description
!	Shows an exclamation mark for high-priority samples (STAT).
Type	Shows an empty cell for samples or a symbol for calibrators, controls and light check: • Calibrators  • Controls  • Light check 
SID	Shows the patient ID, calibrator ID or control ID. The ***SID*** is read via bar-code scanner or entered by operator (if bar-code not present or unreadable). **Notes:** The ***SID*** must be unique. Two or more samples with the same ***SID*** are not allowed to be loaded at the same time. Use only the following characters: • A - Z (a - z are converted to upper case for patient samples) • 0 - 9 • blank space ( ), minus (-), dot (.), dollar sign ($), plus (+), percent sign (%), number sign (#), ampersand (&), equal (=) and slash (/) for patient ID • minus (-) and slash (/) for control ID. A ***SID*** may be 3 to 22 characters long and may not contain heading or trailing spaces. The ***SID*** of external calibrators begins with a predefined prefix character and contains the assay abbreviation or article number. The ***SID*** of controls may not begin with #. **Note** The ***SID*** field is write protected, if any of the following applies: • the rack is in “Error” • the ***SID*** was read via bar-code (and accepted, i.e. not deleted because of duplication or illegal character) • the ***Control*** button was pressed for that ***SID*** at least once since the ***SID*** was recognized (i.e. un-pressing that button does not allow typing, it's necessary to unload and reload the rack) • either a workorder or a patient definition for that ***SID*** is present in the work-database (visible in the sub category ***All*** of the main category ***Results***, see chapter 6.6.1).
Pending	If assays are assigned to the sample: Shows all assays in status ***Placed*** or ***Failed*** for the sample.
In Process	If assays are assigned to the sample: Shows all started assays in status ***Scheduled***, ***Active*** or ***Measured*** for the sample.

Table 6–16: Columns of the samples table

Symbol	Description
	Loaded sample tube with known ***SID***.
	Loaded sample tube without bar-code or unreadable bar code, or no tube loaded. The **SID** is empty.
	Sample in process.
	Sample off-line, a clot detection or “No Liquid Found” occurred since last loading. (If a sample is off-line, unload it, check its status and reload again when OK.)
	A sample error occurred since last loading and at least one scheduled aspiration has to be completed.
	A sample error occurred since last loading and no scheduled aspiration has to be completed.

Table 6–17: Symbols of the samples

NOTE

Light check for the left arm must be loaded as sample.
Light check for the right arm must be loaded as ancillary reagent.

6.5.1.1 Worklist Tab- for patient samples

The ***Worklist*** tab enables the assignment between samples/controls and assays.
This section describes the assignment for patient samples.

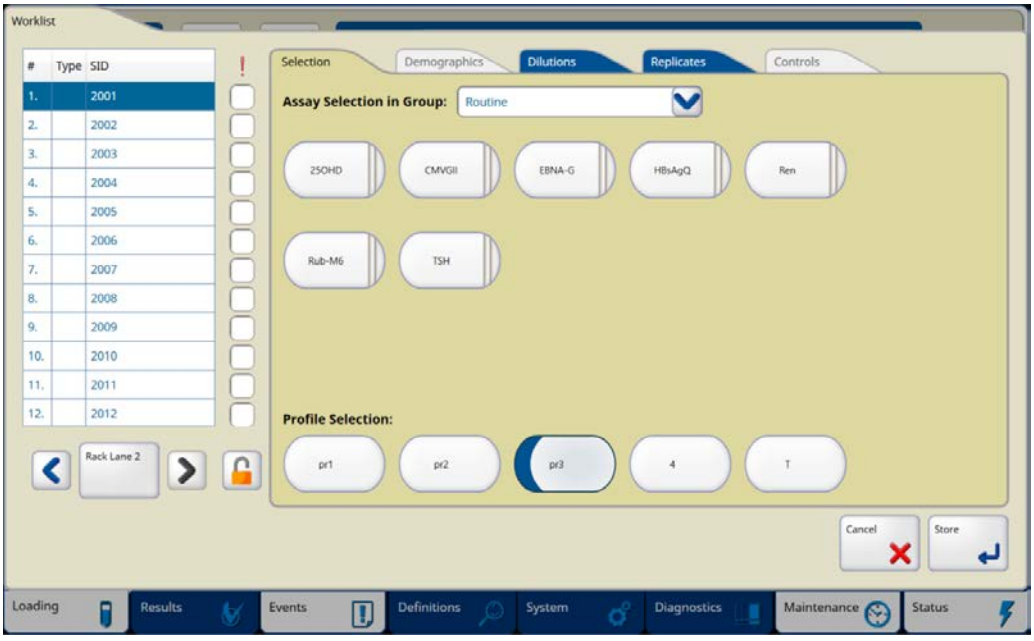


Figure 6–18: Schedule display for patient samples

Function	Description
Rack lane	Shows the lane number of the selected sample rack. This button serves as **Select/ Unselect All** button, forces the **Lock button** to be closed. Tap on the arrow buttons next to the ***Rack lane*** button to show another available sample rack, and the sample list will be updated.
Samples list	Shows all samples, calibrators, and controls which are present in the selected rack. Note: empty positions are not shown.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.3.

Table 6–18: Functions of the rack samples table

Column	Description
Position	Tube position in the rack.
Type	Shows an empty cell for samples or a symbol for calibrators, controls and light check.
SID	Shows the sample ID, calibrator ID and control ID.
!	Checkbox to assign high-priority to samples (STAT).

Table 6–19: Columns of the rack samples table

NOTE It is not possible to create a worklist for patient and control samples at the same time. Select samples separately from controls.

NOTE Use the ***Lock button*** to use the multiple selection function (only for patient samples).

Selection Group

The ***Selection*** group allows the user to assign assays (tests) to one or more samples.

Function	Description
Assay Selection in Group	Assays are organized in groups. First it is necessary to choose the assay group. After that it is possible to select one or more assays. The display of an assay shows its relation to the samples: • Colour ○ Blue: The assay is assigned to sample(s). ○ Blue and Grey: The assay is assigned to at least one selected samples ○ Grey: The assay is not assigned to sample(s). • Shape ○ Solid: An integral for the assay is loaded. ○ Broken with two stripes: An integral for the assay is not loaded or is not suitable for starting a test.
Profile Selection	Enables to select a profile (contains several assays, see chapter 6.8.5). Use the arrow buttons to show all available profiles.

Table 6–20: Functions of the Selection group

Style	Description
	The assay is: • currently not loaded on the machine • not assigned to the selected sample(s)
	The assay is: • currently not loaded on the machine • not assigned to all selected samples
	The assay is: • currently not loaded on the machine • assigned to the selected sample(s)
	The assay is: • currently loaded on the machine • not assigned to the selected sample(s)
	The assay is: • currently loaded on the machine • not assigned to all selected samples
	The assay is: • currently loaded on the machine • assigned to the selected sample(s)

Table 6–21: Assay status

NOTE

As soon as a test is started, the status changes to grey (unselected) and may be assigned again, even if the previous test is still running.

Demographics Group

The ***Demographics*** group allows the user to enter or view detailed information about one selected sample.

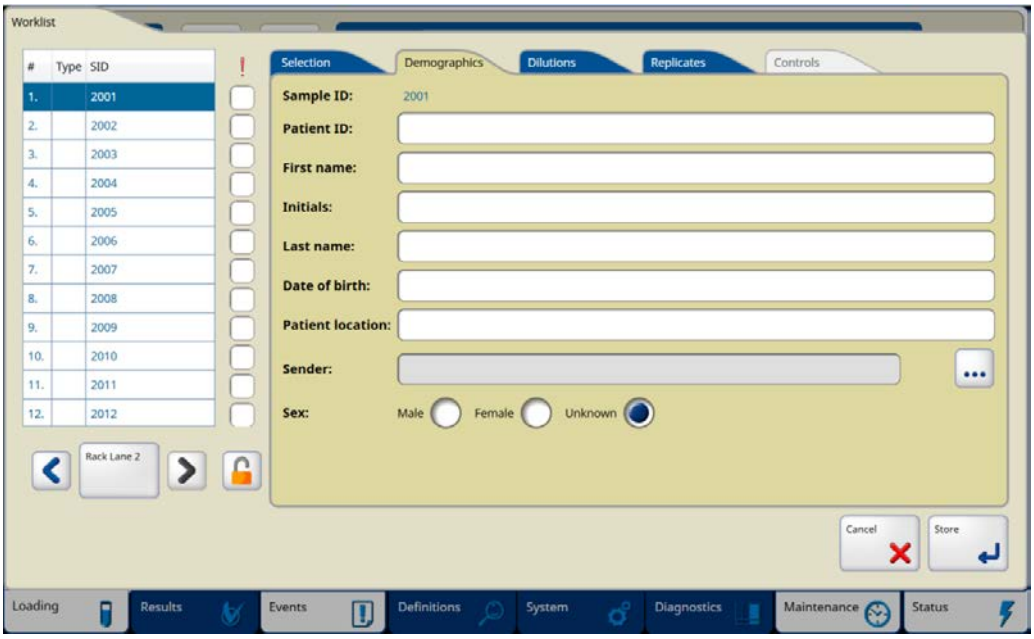


Figure 6–19: Schedule Display Demographics group

Function	Description
Sample ID	Shows the sample ID (it is not possible to edit the sample ID).
Patient ID	ID of the patient.
First name	First name of the patient.
Initials	Patient name initials.
Last name	Family name of the patient.
Date of birth	Date of birth of the patient.
Patient location	Location of the patient.
Sender	Name or code of the doctor. Allows selecting among a pre-defined list of senders.
Sex	Gender of the patient (***Female***, ***Male***, or ***Unknown***).

NOTE

Detailed information of the ***Demographics*** group is only shown if the user has the access right ***Patient Privilege***. The visible data to every user are ***Patient ID***, ***Patient location*** and ***Sender***.

NOTE

Demographic data are not shown and cannot be edited in case for the same sample ID different data are found among the results which are not in Done or Failed status.

NOTE

Demographic data cannot be edited in case they are received from LIS.

Dilutions Group

After having assigned assays to a sample, the ***Dilutions*** group allows the user to view and change dilution work orders for the corresponding sample(s)/assay(s).

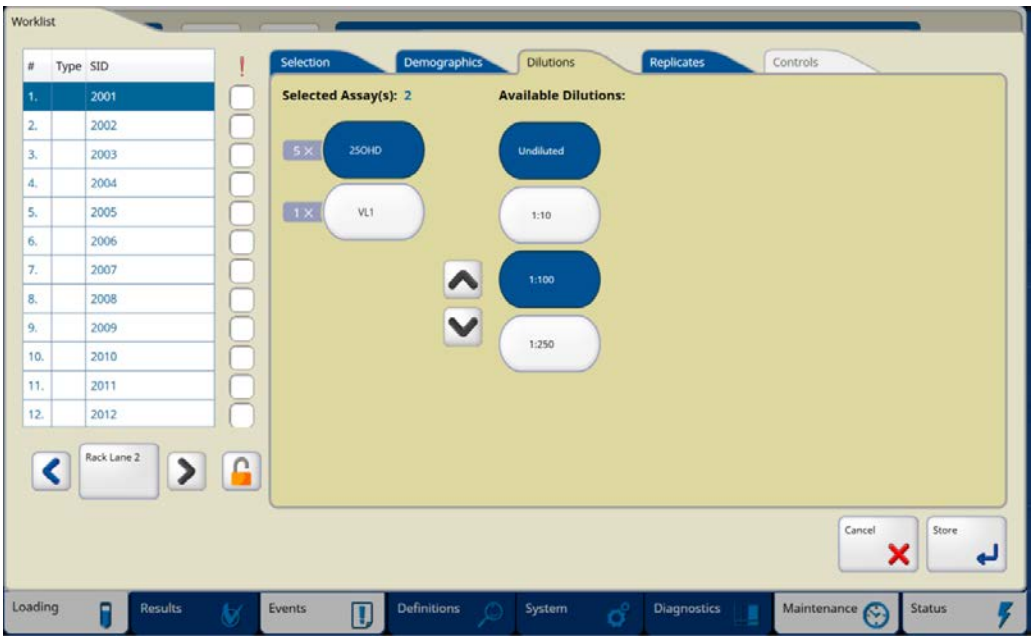


Figure 6–20: Schedule Display Dilutions group

Function	Description
Selected Assay(s)	Shows all selected assay(s). Note: for combi assays, the combi fathers or the combi sons will be shown, depending on specific assays.
Available Dilutions	Shows all available dilution factors. Note: for combi assays, it may be not possible to select more than one dilution or undiluted.

*Table 6–22: Functions of the **Dilutions** group*

Replicate Group

After having assigned assays to a sample, the ***Replicate*** group allows to define a number of replicates different from the default number (indicated in the assay file), up to 20. The replicates can only be increased compared to the default value.

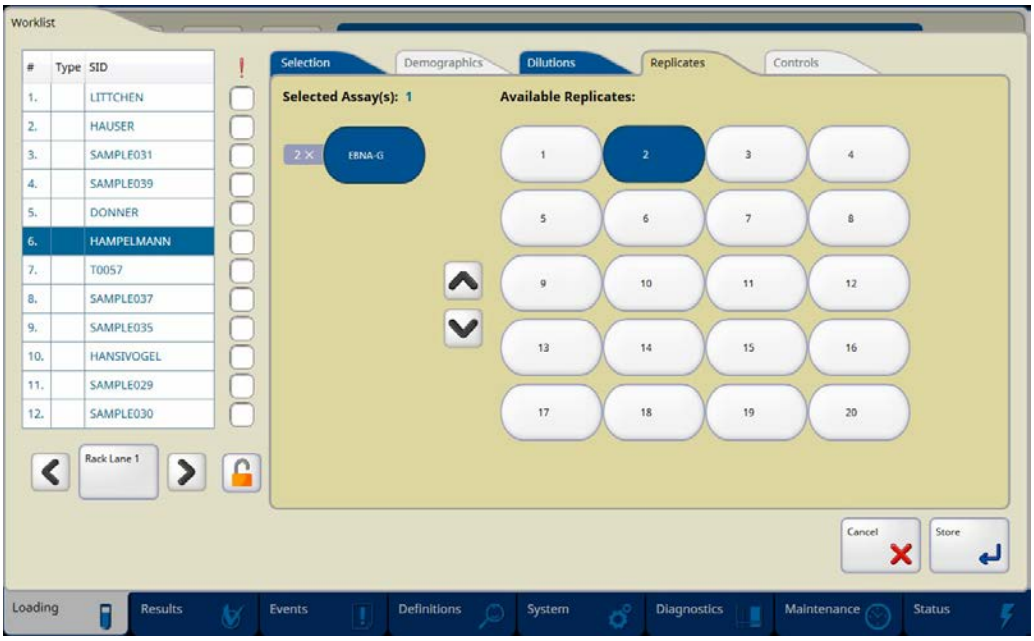


Figure 6–21: Worklist tab- Replicates Group

Column	Description
Assay	Name of the assay.
Available Replicates	Shows all available replicate values.

*Table 6–23: Functions of the **Replicate** tab*

NOTE

For combi assays, the system may show either the replicates for the combi father or the combi sons.

6.5.1.2 Worklist Tab- for control samples

The ***Worklist*** tab enables the assignment between patient samples/controls and assays. This section describes the assignment for controls.

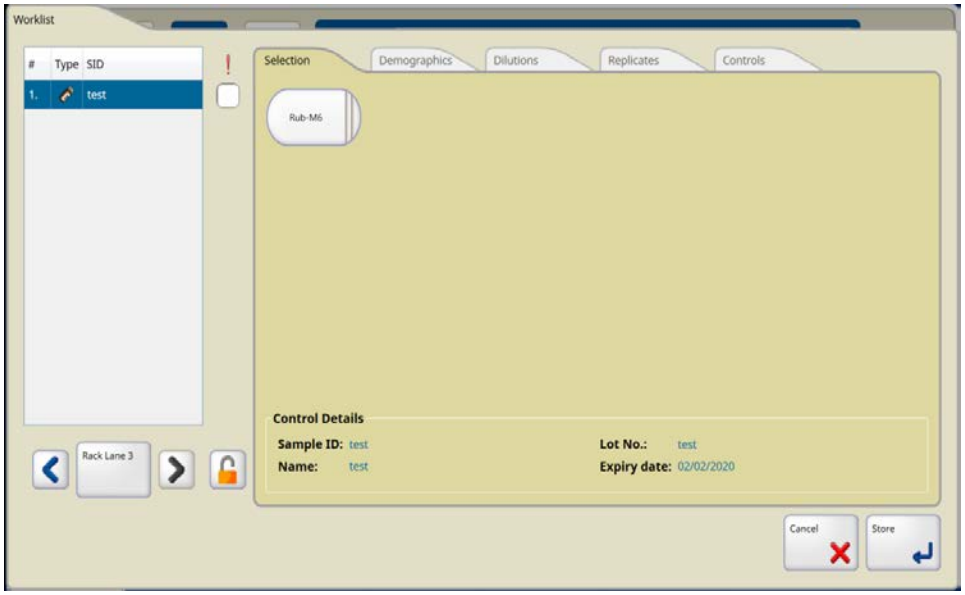


Figure 6–22: Worklist tab

Function	Description
Rack lane	Shows the lane number of the selected sample rack. This button serves as **Select/ Unselect All** button, forces the **Lock button** to be closed. Tap on the arrow buttons next to the ***Rack lane*** button to show another available sample rack, and the sample list will be updated.
Samples list	Shows all samples, calibrators, and controls which are present in the selected rack. Note: empty positions are not shown.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.3.

Table 6–24: Functions

Column	Description
Position	Tube position in the rack.
Type	Shows an empty cell for samples or a symbol for calibrators, controls and light check.
SID	Shows the sample ID, calibrator ID or control ID.
!	Checkbox to assign high-priority to samples (STAT).

Table 6–25: Columns of the rack samples table

NOTE It is not possible to create a worklist for selected samples and controls at the same time. Select samples separately from controls.

NOTE The ***Lock button*** to use the multiple selection function is not supported for controls.

Selection Group

The ***Selection*** group allows the user to assign assays to a control.

Function	Description
Assay Selection	Assays are organized in groups. First it is necessary to choose the assay group. After that it is possible to select one or more assays. The display of an assay shows its relation to the samples: • Colour ○ Blue: The assay is assigned to sample(s). ○ Grey: The assay is not assigned to sample(s). • Shape ○ Solid: An integral for the assay is loaded. ○ Broken with two stripes: An integral for the assay is not loaded or is not suitable for starting a test.
Control Details	The ***Control Details*** section shows the ***Control ID***, ***Control Name***, ***Control Lot*** and ***Expiration Date*** for the selected control.

*Table 6–26: Functions of the **Selection** group*

Style	Description
	The assay is: • currently not loaded on the machine • not assigned to the selected sample
	The assay is: • currently not loaded on the machine • assigned to the selected sample
	The assay is: • currently loaded on the machine • not assigned to the selected sample
	The assay is: • currently loaded on the machine • assigned to the selected sample

Table 6–27: Assay status

NOTE As soon as a test is started, the status changes to grey (unselected) and may be assigned again, even if the previous test is still running.

Controls Group

The ***Control*** group allows the user to select a particular reagent integral and/or ancillary for the ordered control tests.

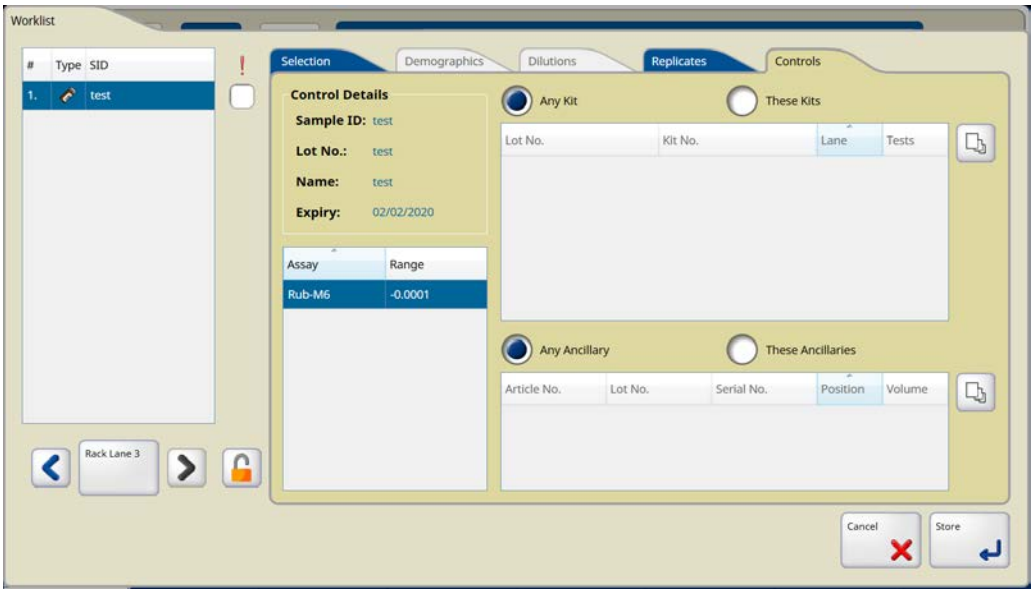


Figure 6–23: Worklist tab - Controls group

Function	Description
Sample ID	The sample ID (i.e. the content of the bar-code).
Name	The name of the control.
Lot No.	The control lot number.
Expiry	The control expiration date.
Assay	The list of all assays that have been assigned to that control in the ***Selection Group***. Note: select an assay to use the “These kits/ancillaries” option for that assay.
Range	The expected concentration range in user units.
Any kit/ These kits ***Any ancillary/ These ancillaries***	When ***Any kit/ancillary*** is selected, then the system will decide which integral to use to run the control. When ***These kits/ancillaries*** is selected, then it is possible to decide and pick one or more integrals/ancillaries from the integral list for the assay selected in the ***Assay*** list. The selected integrals/ancillaries will be used to run that control. If no integral/ancillary is loaded, then ***Any kit*** will be selected and ***These kits*** is disabled.
All/None	If not all inserted kits/ancillaries are selected, then this button selects all. If all are selected, then this button unselects all. In any case, the option ***These kits/ancillaries*** will become selected.
Lot No.	The lot number of each integral/ancillary that is loaded for the selected assay.
Kit No.	The kit number of each integral that is loaded for the selected assay.
Lane	The lane number where each integral is loaded for the selected assay.
Tests	The number of available determinations of each integral that is loaded for the selected assay.
Article No.	The article number of each ancillary that is loaded for the selected assay.
Serial No.	The serial number of each ancillary that is loaded for the selected assay.
Position	The position number where each ancillary is loaded for the selected assay.
Volume	The volume available for each ancillary that is loaded for the selected assay.

*Table 6–28: Functions of the **Control** group*

6.5.2 Sub Category Ancillaries

The sub category **Ancillaries** shows the ancillary reagents that are currently loaded on the instrument.

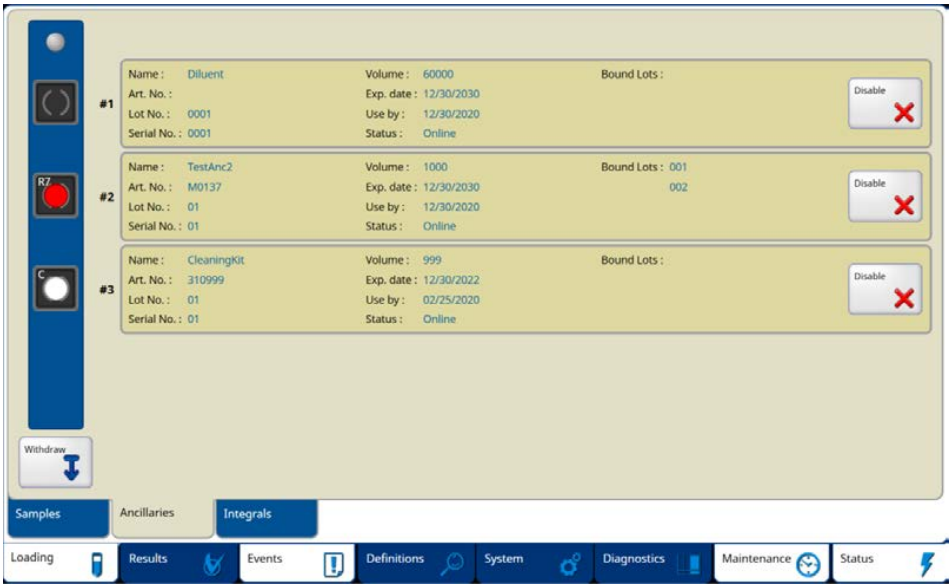


*Figure 6–24: Sub category **Ancillary***

Function	Description
Withdraw	If it is necessary to remove the ancillary rack during a run, press this button to suspend the pipettor access (notified by the SW LED switched off). Re-insert the used ancillaries as soon as possible. Note: this could lead to test failures. If the ancillary removed was still necessary to the system, it will be displayed as greyed out.
Disable	Sets the selected ancillary not suitable for starting a test (displayed as greyed out)
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3
No	Position of the ancillary reagent in the ancillary rack.
Name	Name of the ancillary reagent.
Art. No.	Article number of the ancillary reagent.
Lot No.	Lot number of the ancillary reagent.
Serial No.	Serial number of the ancillary reagent.
Volume	Available liquid volume in the bottle.
Exp. date	Date and time when the ancillary reagent will expire.
Use by	Onboard stability expiry date.
Status	Status of the ancillary availability: • Online: The ancillary is usable • Offline: The ancillary cannot be used.
Bound lots	If there is an entry, it is possible to use integrals of the related assay with the reported lot number.

*Table 6–29: Functions of the **Ancillary** sub category*

Off-line Status

If an ancillary reagent is off-line, the descriptive text is displayed in grey.

Possible reasons:

- No liquid found.
- The expiration date is exceeded.

In case of data recognition issue, the ancillary is displayed with a red exclamation mark:

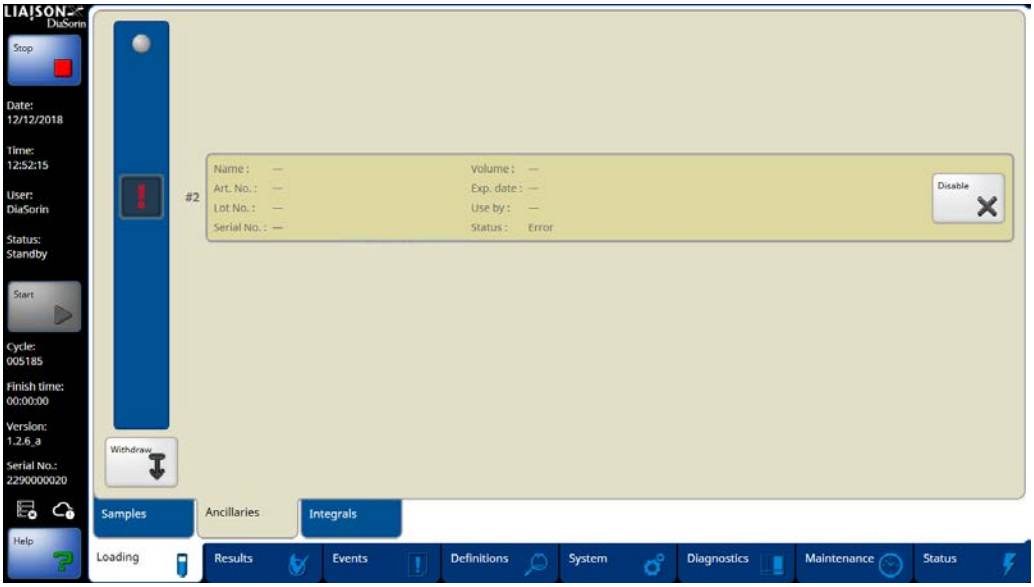


Figure 6–25: Ancillary in error

6.5.3 Sub Category Integrals

The sub category ***Integrals*** can be divided into the ***Integrals*** group (in the right part) showing the reagent integrals that are currently loaded on the instrument, and into the ***Details*** group displaying detail information for any integral that is currently selected.

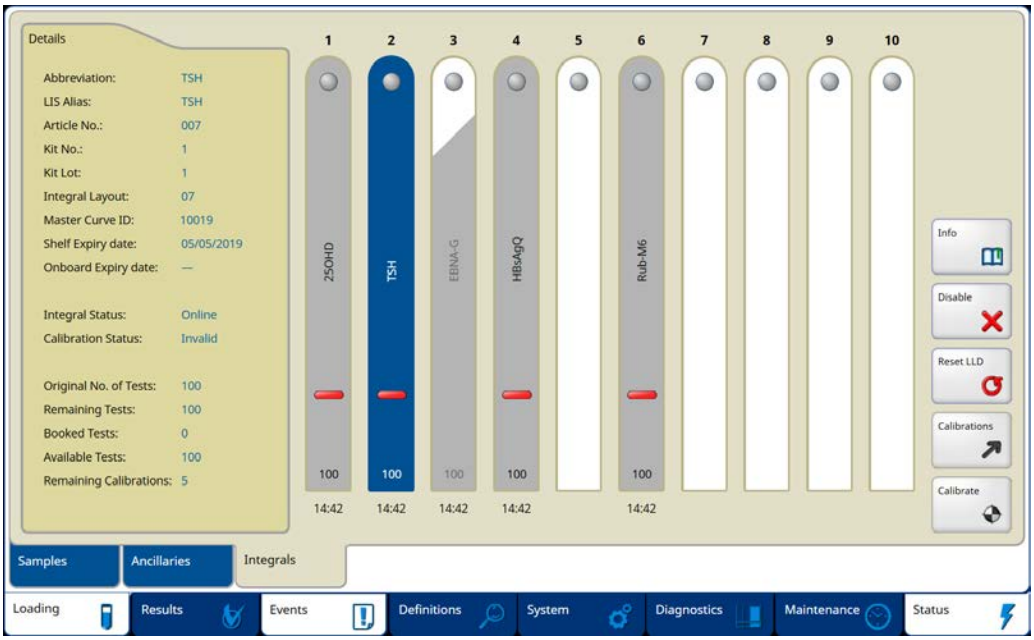


*Figure 6–26: Sub category **Integrals***

Symbol/Status	Description
	Invalid calibration
	Ongoing calibration
	Created calibration
no symbol	No specific symbol is shown if the integral has a valid calibration.

*Table 6–30: Symbols of the **Calibration Status***

Function	Description
Info	Opens the Online Help and displays the documents related to the selected integral. If for the selected integral the related package is not available, the download dialog is displayed (see chapter 6.3.1.1).
Disable/Enable	If disabled the system will avoid using that integral (see Figure 6–27). It has no impact on the resuspension count down.
Reset LLD	Resets the liquid level of improperly offline vials for the integral selected. It is necessary to unload and reload the integral to allow the system to use it.
Calibrations	Shows the calibration dialog and selects the valid calibration for the selected integral, if any.
Calibrate	Set the calibrator(s) of the selected integral in “Placed” status. In case the external calibrator(s) are not loaded, they are set in “To Do” status. For assays that share calibration within a kit lot, this calibration will be available for all integrals of that kit lot, no matter if loaded on-board or not. If the integral is offline or disabled, the button is greyed out.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

*Table 6–31: Functions of the **Integrals** sub category*

Figure 6–27: Integral disabled

CAUTION

A calibration cannot be started if any of the following occurs:

- another calibration is in status “Created” or “Ongoing” for the same integral
- another calibration is in status “Created” or “Ongoing” for another integral of the same lot (if that assay shares the Working Curve)
- the calibrators are external and not present on board
- any required resource is detected as missing or empty; see chapter 6.12.3 to check whether the available resources are sufficient.

Function	Description
1...10	Shows the integrals in the reagent loading bay lanes. Tap on a loaded integral to show details.
Abbreviation	Abbreviation of the assay.
LIS alias	Assay name on the ***LIS*** system.
Article No.	Identification code of the selected integral that allows the **LIAISON® XS** system to associate the integral to an assay.
Kit No.	Kit No number of the reagent integral.
Kit Lot	Lot number of the reagent integral.
Integral Layout	Parameter that allows the **LIAISON® XS** system to identify the geometric characteristics of the integral
Master Curve ID	The ID of the calibration mastercurve used for this reagent integral.
Shelf Expiry date	Date and time when the reagent integral will expire. Note: this is the last day when that reagent integral is allowed to be used.
On-board Expiry date	The calculated result obtained with that kit after that day has elapsed will be provided with an indicating flag. Check the on-board stability in the instruction for use of each kit.
Integral Status	Status of the integral availability: • Online: The integral is usable • Offline: The integral cannot be used. The abbreviation is displayed in grey. Possible reasons: ○ No liquid found. ○ The expiration date is exceeded. ○ The compatible assay protocol version is not loaded. ○ The integral has been disabled by user ○ The integral reagent has a data recognition issue.
Calibration Status	Status of the calibration (e.g. valid, not valid).
Original No. of Tests	Max. number of tests with a new integral.
Remaining Tests	Remaining number of determinations for the selected integral. The number is updated (decremented by one) as soon as the first aspiration event for a determination occurs.
Booked Tests	Assigned but not started tests.

Function	Description
Available Tests	Difference between *Remaining Tests* and *Booked Tests*.
Remaining Calibrations	Remaining number of calibrations.

*Table 6–32: Functions of the **Details** group*

In case of loading errors, the integral lane is displayed with a red exclamation mark:

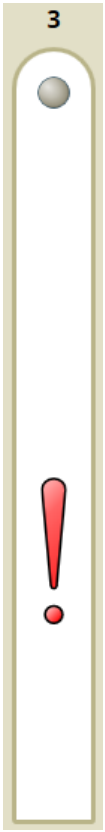


Figure 6–28: Integral lane in error

6.6 Main Category Results

The results of the sample tests or calibrations can be accessed via the main category ***Results*** as well as its several sub categories.

The following table lists all possible columns that can be found in the table of each result page; default columns displayed in each page are reported in the specific chapters.

Possible Column	Description
Sample ID	Shows the sample ID.
Assay	Shows the assigned assay.
Measured	Result date and time (expected for those results that are not yet completed).
Status	Shows the status of the entry (see table 6–35).

Possible Column	Description
Dilution	Dilution factor for the result.
RLU	Shows the raw results (in Relative Light Units).
Flags	List of all flags. For details about the flags, see chapter 5.8.5
Dose	Shows the dose result in user units.
User Unit	Shows the user unit.
Conversion	Shows the conversion factor used to calculate dose.
Label	Shows the qualitative label for the result (if defined for the assay).
Sent to LIS	Date and time when the result was sent to LIS.
Control Name	Name of the control.
Control Lot	The lot number of the control.
Manufacturer Range	The low and high limit of this control definition in user unit.
User Range	The low and high limit of the reference range for this control, in user unit.
Control Expiry	Shelf expiry date of the control.
Sample Lane	Lane in the loading bay where the sample rack was located.
Sample Position	Tube position in sample rack where the sample was aspirated from.
Rack Type	The rack type of the rack where the sample was aspirated from.
Rack ID	The rack ID of the rack where the sample was aspirated from.
Dose CV%	Shows the coefficient of variation (%) for the dose result.
RLU CV%	Shows the coefficient of variation (%) of the RLU result.
Kit No.	Kit number of the used reagent integral.
Kit Lot	Kit lot number of the used reagent integral.
Kit Shelf Expiry	Shelf expiry date of the used reagent integral.
Kit On-Board Expiry	On-board stability expiry date of the used reagent integral.
Starter 1 Lot	Lot number of the used starter 1.
Starter 2 Lot	Lot number of the used starter 2.
Ancillary Lot	Lot number of the used ancillary reagent.
Ancillary No.	Serial number of the used ancillary reagent.
Ancillary Shelf Expiry	Expiry date of the ancillary.
Ancillary On-Board Expiry	On-board stability expiry date for the ancillary reagent.
Calibration ID	Internal unique ID assigned to this calibration record. This ID will be not reused even after the calibration has been deleted.
Calibration Expiry	Date when the calibration will expire.
Assay Range	Shows the low and high limit of the assay range for the assay, in user defined unit.
Normal Range	Shows the low and high limit of the normal range for the assay, in user defined unit.

Table 6–33: Possible Columns in Results pages

Sorting and Searching

See chapter 6.3.2.

6.6.1 Sub Category All

The sub category ***All*** shows all entries of applied, started, and finished worklists. This sub category does not include calibrations and archived results.

Subcategories ***Worklist***, ***Ongoing***, ***Done***, ***Failed***, ***Controls*** are subset of the ***All*** page.

The default available columns are: ***Sample ID***, ***Assay***, ***Measured***, ***Status***, ***Dilution***, ***RLU***, ***Flags***.

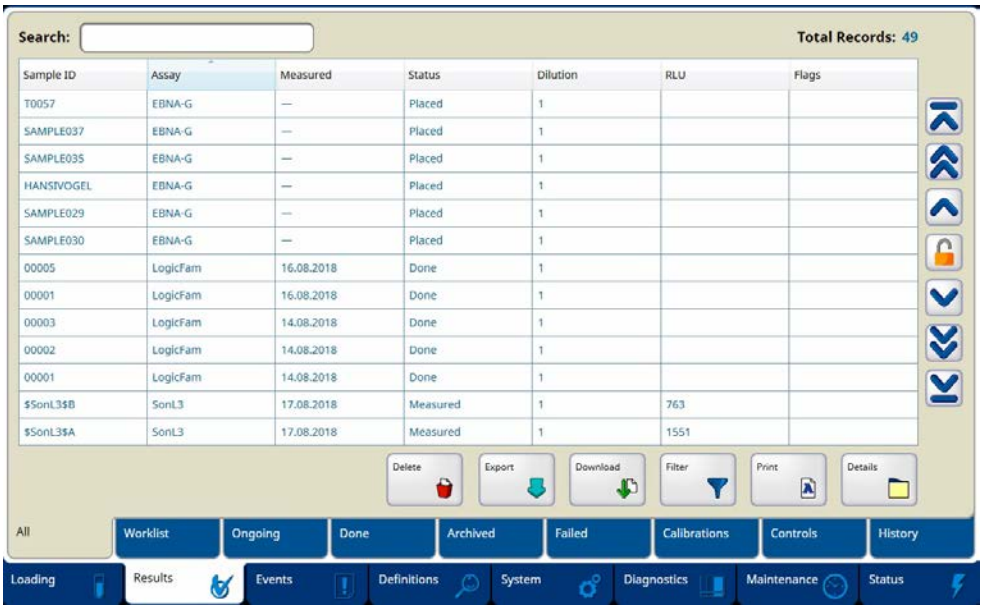


*Figure 6–29: Sub category **All***

Function	Description
Delete	Deletes one or more entries (see chapter 6.6.1.3). Only entries in status ***To Do***, ***Placed***, ***Measured***, ***Done*** and ***Failed*** can be deleted. For Combi Assays, if a Son is selected, a pop-up ask the user to delete the entire family or revoke the request.
Export	Opens the ***Export*** display to export one or more entries to a file (see chapter 6.6.1.1).
Download	Sends a query all message to a ***LIS*** system to initiate transmission of workorders. The **LIAISON® XS** software shows an information dialog.
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Result Details*** display for the selected entry (see chapter 6.6.1.2).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–34: Functions of the **All** sub category*

Results Status	Description
To do	Sample not present on board, not started yet
Placed	Sample present on board, not started yet
Scheduled	Starting soon
Active	Under performance
Measured	Completed but no dose received
Done	Successfully completed
Failed	Unsuccessfully completed

Table 6–35: Result status descriptions

NOTE

In case a sample test is performed with two or more replicates and its status is “failed”, and there are some replicates that still need to be started, they may be restarted when a new routine is started. In this case, the entire sample test would become “active” again.

6.6.1.1 Export

The ***Export*** display allows the exporting of one or more entries to a file.

*Figure 6–30: **Export** display*

Selection Group

Function	Description
Selected Records	Exports only the selected entries from the list.
All Records	Exports all entries currently present on the page list. If a filter is applied before the export then the export will consider also the filter.

*Table 6–36: Functions of the **Selection** group*

Mode Group

Function	Description
Default	Basic set of information (e.g. sample ID, assay, measured date and time, dose result and accompanying flags).
Enhanced	Same as default with additional appended columns (e.g. reagents information).

Table 6–37: Functions of the Mode Group

File Selection Group

Function	Description
Path	Selection among the available path the file can be exported to.
File	Allow to specify file name.
Files list	Visualize the entries stored in the selected path.

*Table 6–38: Functions of the **Export Settings** group*

6.6.1.2 Result Details

The Result Details display is used to display all available information for a test.
Note: the layout may vary depending on the sample and assay characteristics.

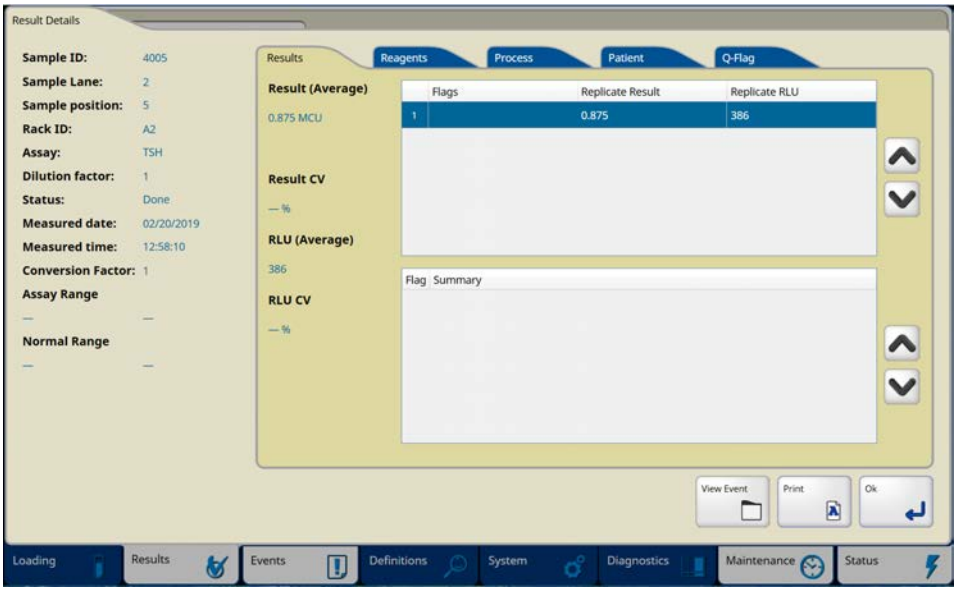


*Figure 6–31: **Result Details** display*

Function	Description
View Event	Shows the event associated with the result
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

Table 6–39: Result Details buttons

Function	Description
Sample ID	Shows the sample ID.
Sample lane	Lane in the loading bay for sample racks where the sample rack was located.
Sample position	Tube position in sample rack where the sample was aspirated from.
Rack ID	The rack ID of the rack where the sample was aspirated from.
Assay	Shows the assigned assay.
Dilution Factor	Dilution factor for the result.
Status	Shows the status of the entry (***To Do***, ***Placed***, ***Scheduled, Active***, ***Measured***, ***Done***, ***Failed***).
Measured Date	The date when the result was measured or the expected result time if the test is Scheduled or Active.
Measured Time	The time when the result was measured or the expected result time if the test is Scheduled or Active.
Conversion Factor	Reports the conversion factor used to calculate dose. Example: • Default unit: g/l • User defined unit: mg/l • Conversion factor: 1000
Assay Range	Shows the low and high limit of the assay range for the assay, in user defined unit. Results are compared against the assay range before being adjusted with the dilution factor. The assay range value used to report an out of assay range result is not multiplied by the dilution factor. When a result falls outside this range, it will be provided with the corresponding flag; it will be shown as “<” followed by the low limit or “>” followed by the high limit. The low limit is included and the high limit is excluded. If a limit field is empty the **LIAISON® XS** software will handle this as “do not care”. This allows to support one-sided ranges.
Normal Range	The low and high limit of the normal range for the assay, in user defined unit. When a result falls outside this range, it will be provided with the corresponding flag. Results are compared against the normal range after being adjusted with the dilution factor. The low limit is included and the high limit is excluded. If a limit field is empty, the **LIAISON® XS** software will handle this as “do not care”. This allows to support one-sided ranges.

*Table 6–40: Functions of the **Result Details** display*

Results Group

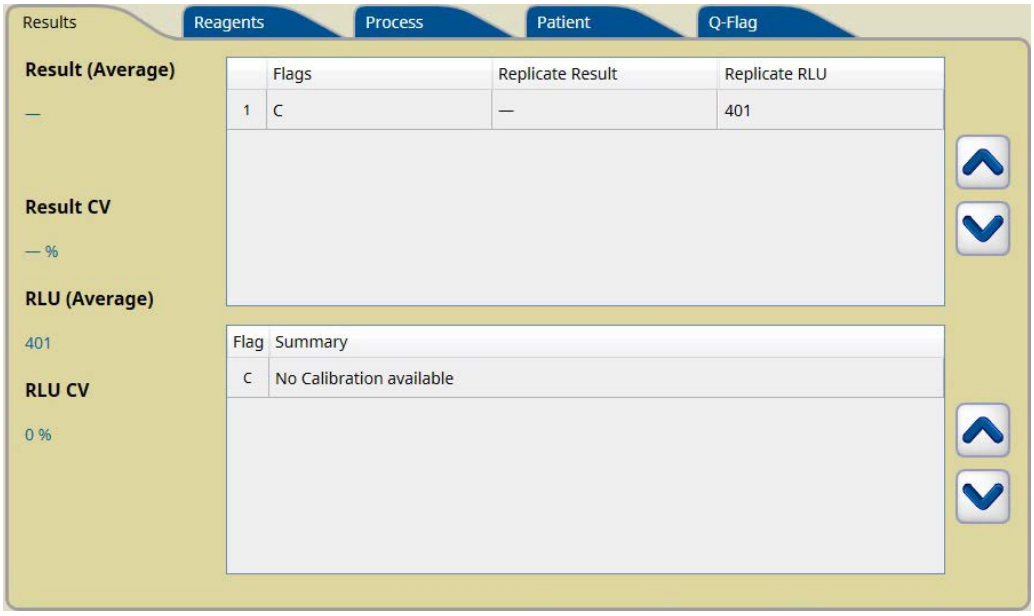


Figure 6–32: Results Group

Function	Description
Result (Average)	Shows the dose result calculated from the mean RLU result. It is reported in user units, adjusted with the dilution factor. Below the mean result, the qualitative label is shown (only for patient samples, if defined).
Result CV	Shows the coefficient of variation (%) for the dose result.
RLU (Average)	Shows the mean RLU result (truncated).
RLU CV	Shows the coefficient of variation (%) of the RLU result.

*Table 6–41: Functions of the **Results** group*

Column	Description
Flags	List of flags per replicate. For details about the flags see chapter 5.8.5.
Replicate Results	List containing all replicate dose results in user units (calculated and converted for each single replicate RLU result).
Replicate RLU	List containing all replicate RLU results.
Flag Summary	List of all flags associated to this specific test, displayed as complete description. For details about the flags see chapter 5.8.5.

*Table 6–42: Columns of the **Results** group tables*

Depending on the used assay(s) the **LIAISON® XS** software will show the following result details/values:

Value	Regular assay	Combi assay
Result (Average)	Dose, Qualitative label	Dose and/or Qualitative label
Result CV	Yes	No
RLU (Average)	Yes	No
RLU CV	Yes	No
Flags	Yes	Yes
Replicate Results	Yes	No
Replicate RLU	Yes	No
Flag Summary	Yes	Yes

Table 6–43: Shown result details/values

Reagents Group

Figure 6–33: Results Details- Reagents Group

Function	Description
Ancillary On-board Expiry date	On-board stability expiry date for the ancillary reagent (if present). Note: ancillaries expire at midnight of the displayed date.
Ancillary Shelf Expiry date	Shelf expiration date of the used ancillary reagent (if present). Note: ancillary expire at midnight of the displayed date.
Ancillary Serial No.	Serial number of the used ancillary reagent (if present).
Ancillary Reagents Lot No.	Lot number of the used ancillary reagent (if present).
Calibration Expiry date	Expiry date of the calibration used for result calculation. Note: calibrations expire at midnight of the displayed date.
Calibration ID	Unique identifier of the calibration used for result calculation.
Kit Shelf Expiry date	Shelf expiry date of the used reagent integral. Note: kits expire at midnight of the displayed date.
Kit Lot	Kit lot number of the used reagent integral.
Kit No.	Kit number of the used reagent integral.
Kit On-board Expiry date	On-board stability expiry date of the used reagent integral. Note: kits expire on-board at midnight of the displayed date.
Starter 1 Lot	Lot number of the used starter 1.
Starter 2 Lot	Lot number of the used starter 2.

Table 6–44: Functions of the Reagents group

NOTE

For Combi Assays, this tab contains all the combi sons information.

Process Group

Figure 6–34: Results Details- Process tab

Function	Description
Rack ID*	The rack ID of the rack where the sample was aspirated from.
Archived by	Name of the user, who was logged in when the result was archived.
Archiving time	Date and time when the result was archived.
Calculated by*	Name of the user, who was logged in when the result calculation was done.
Calculation Time*	Date and time when the result was calculated.
Started by*	Name of the user, who was logged in when the test was started. Note: if a test is started as a consequence of a Rerun Rule, this field is left empty.
Start Time*	Date and time when the first aspiration occurred for the test. Note: In case of two or more replicates this time refers to the first replicate.
Sent by	Name of the user, who was logged in when the result was sent to LIS.
Sent to LIS	Date and time when the result was sent to LIS.
STAT [y/n]*	Shows “Y” for samples with STAT priority, “N” for normal priority samples.
Deleted time	Date and time when the results was deleted (always empty).
Deleted by	Name of the user, who was logged in when the results was deleted (always empty).

*Table 6–45: Functions of the **Process** group*

NOTE

For the fields marked with *, in case of Combi Assays, this tab contains the information for each combi son.

Patient Group

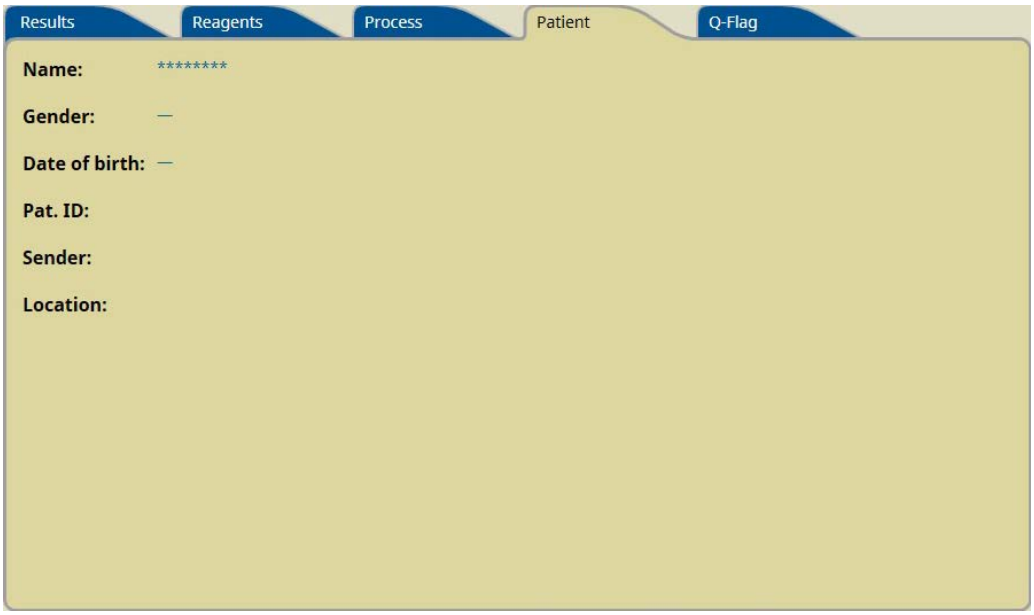


Figure 6–35: Results Details- Patient tab

Function	Description
Name	Patient name.
Gender	Gender of the patient (***Female, Male***, or ***Unknown***).
Date of birth	Date of birth of the patient.
Pat. ID	Unique ID used to identify the patient on a LIS system.
Sender	Name or code of the doctor who will analyze the result.
Location	Location of the patient provenience.

*Table 6–46: Functions of the **Patient** group*

Q-Flag (Patient Sample only)

A table indicating which Control Definition and, if applicable, which rule of the related RVC caused the Q flag (see chapter 6.8.1.2).

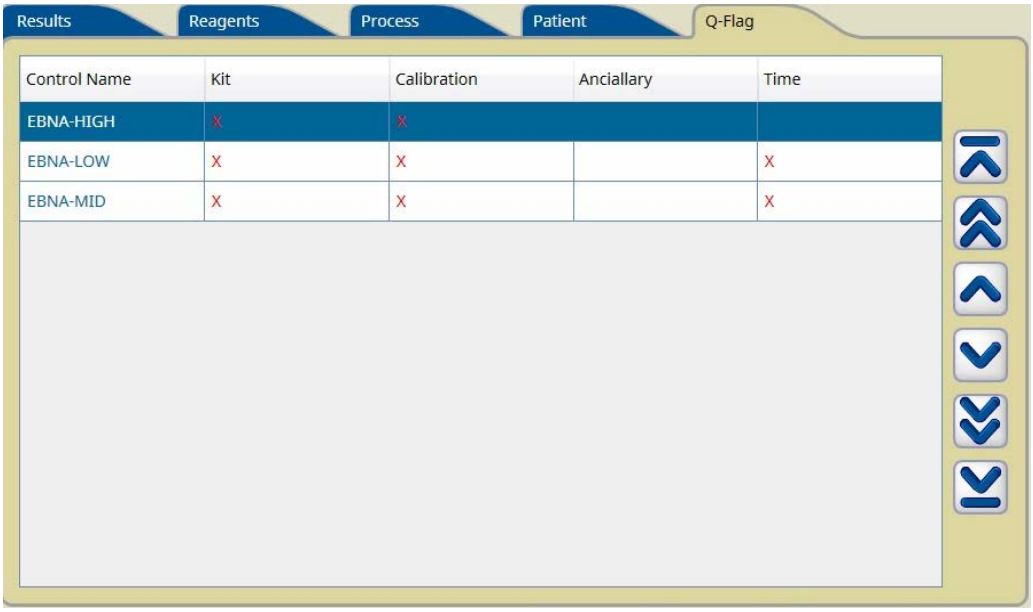


Figure 6–36: Result Details - Q-Flags tab

If the Result has no flag, than the table has no entries, but only headers.

If the Control Definition has no RVC or the RVC has no rule and the last performance of such control was outside ranges, it generates a row without crosses.

Column	Description
Control Name	Name of the control
Kit	Containing a cross if this rule caused a flag, otherwise empty
Calibration	Containing a cross if this rule caused a flag, otherwise empty
Ancillary	Containing a cross if this rule caused a flag, otherwise empty
Time	Containing a cross if this rule caused a flag, otherwise empty

Table 6–47: Functions of the Q-Flags

6.6.1.3 Delete Data

*Figure 6–37: **Delete Data** display*

Function	Description
Selected Records	Deletes all selected entries from the list.
All Records	Deletes all entries currently present on the page list. If a filter is applied before the deletion then the deletion will be applied the entries matching the filter criteria.

*Table 6–48: Functions of the **Delete Data** display*

6.6.1.4 Select Filter

The **Filter** Button opens the Filter Dialog.

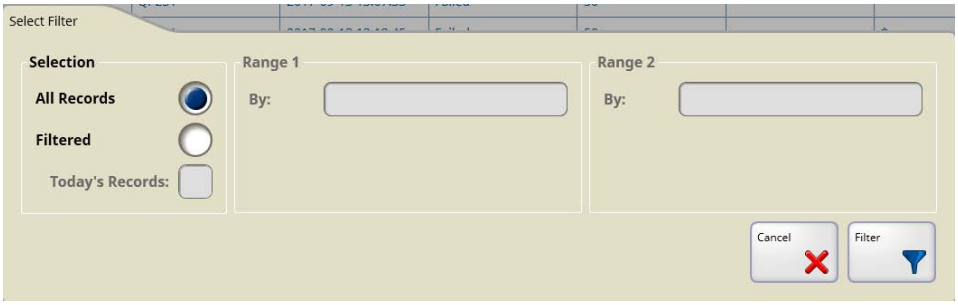


*Figure 6–38: **Select Filter** display*

An indication if any filter is active is located in the top right corner, near the number of total records.

Figure 6–39: Filter applied

Function	Description
All Records	Selects all entries from the list.
Filtered	Selects only the entries according to filters.
Today's Records	Selects all entries from this day from the list. Today refers always to "Measured Date" for Results, "Due" for Maintenance and "Started" for Test Statistics.
Range 1	Selects only entries with the specified conditions By, From, To and Contains from the list.
Range 2	Selects only entries with the specified conditions By, From, To and Contains from the list.
By	Options that can be used for filtering (e.g. Assay, Sample ID)
From/To	Define the range for the filter. Both limits are included.
Contains	Define which value(s) the filtered items shall contain

*Table 6–49: Functions of the **Select Filter** display*

6.6.2 Sub Category Worklist

The sub category ***Worklist*** shows only entries of tests with status ***To do*** and ***Placed***.
The default available columns are: ***Sample ID***, ***Assay***, ***Status***, ***Dilution***.

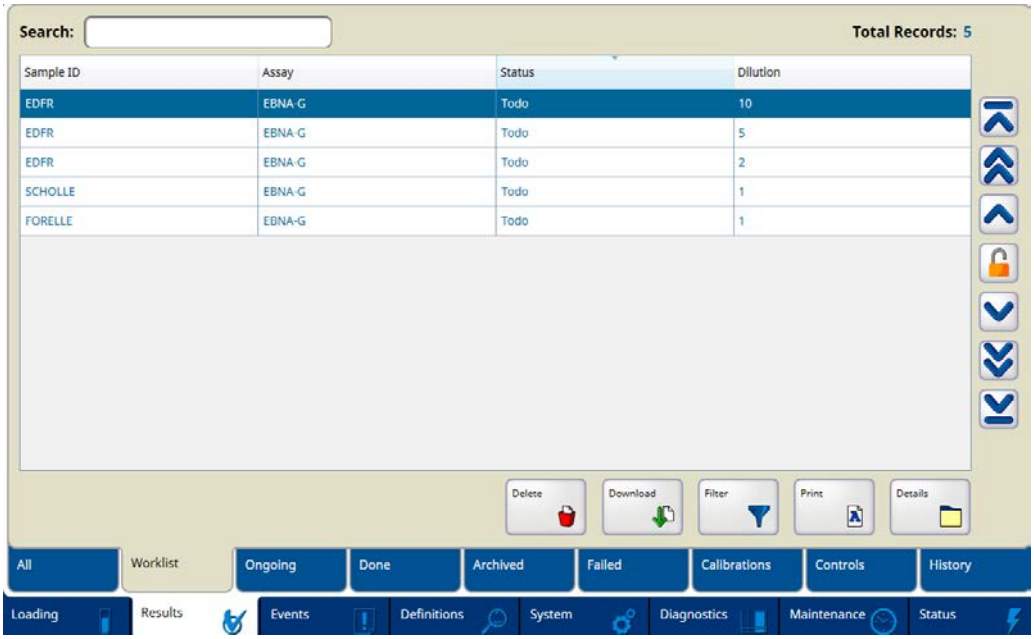


*Figure 6–40: Sub category **Worklist***

Function	Description
Delete	Deletes one or more entries, see chapter 6.6.1.3. For Combi Assays, if a Son is selected, a pop-up ask the user to delete the entire family or revoke the request.
Download	Sends a “query all” message to a ***LIS*** system to initiate transmission of workorders. The **LIAISON® XS** software shows an information dialog.
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Result Details*** display for the selected entry (see chapter 6.6.1.2).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 6–50: Functions of the Worklist sub category

6.6.3 Sub Category Ongoing

The sub category ***Ongoing*** shows only entries of started worklists with status ***Scheduled***, ***Active***, and ***Measured***.

The default available columns are: ***Sample ID***, ***Assay***, ***Measured***, ***Status***, ***Dilution***, ***Flags***.

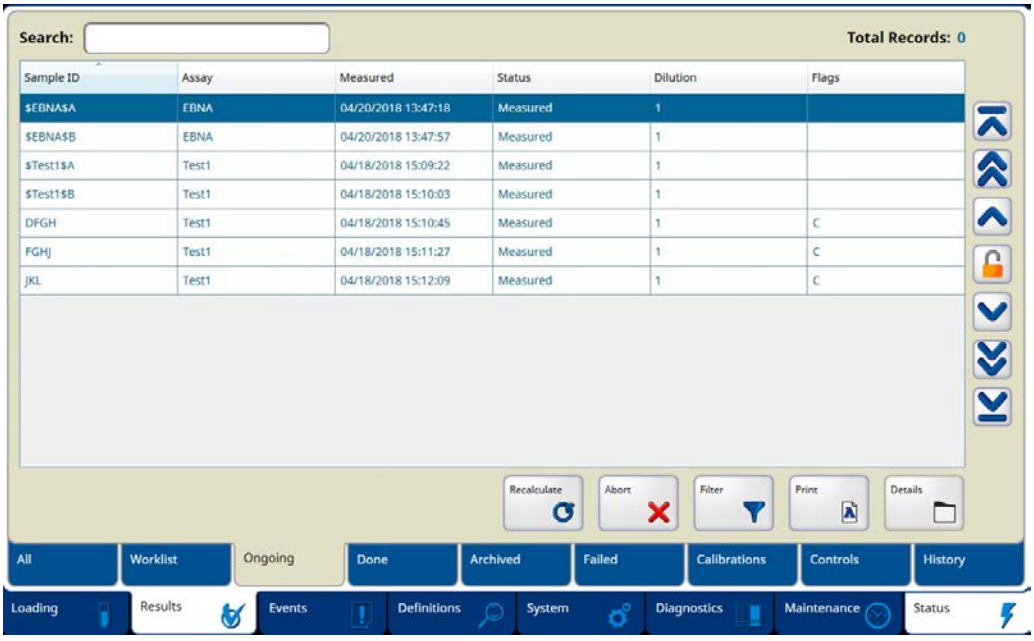


*Figure 6–41: Sub category **Ongoing***

Function	Description
Recalculate	Recalculates the currently selected entries, using the most recent calibration for the assigned assay. For Combi Assays, all results for the same assay family are recalculated.
Abort	Turns the test into ***Failed*** and aborts the related processing.
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Result Details*** display for the selected entry (see chapter 6.6.1.2).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.3

*Table 6–51: Functions of the **Ongoing** sub category*

6.6.3.1 Recalculate

Recalculates the currently selected entries, using the most recent calibration for the assigned assay. For Combi Assays, all results for the same assay family are recalculated.

NOTE

Do not use for ***Active*** tests.

Figure 6–42: Recalculate

Function	Description
Selected Records	Recalculates all selected entries from the list.
All Records	Recalculates all entries currently present on the page list. If a filter is applied before the recalculation then the recalculation will be applied the entries matching the filter criteria.

Table 6–52: Recalculate

6.6.4 Sub Category Done

The sub category ***Done*** shows only entries of finished worklists with status ***Done***.

The default available columns are: ***Sample ID***, ***Assay***, ***Measured***, ***Dilution Dose***, ***User Unit***, ***Label***, ***Flags***.

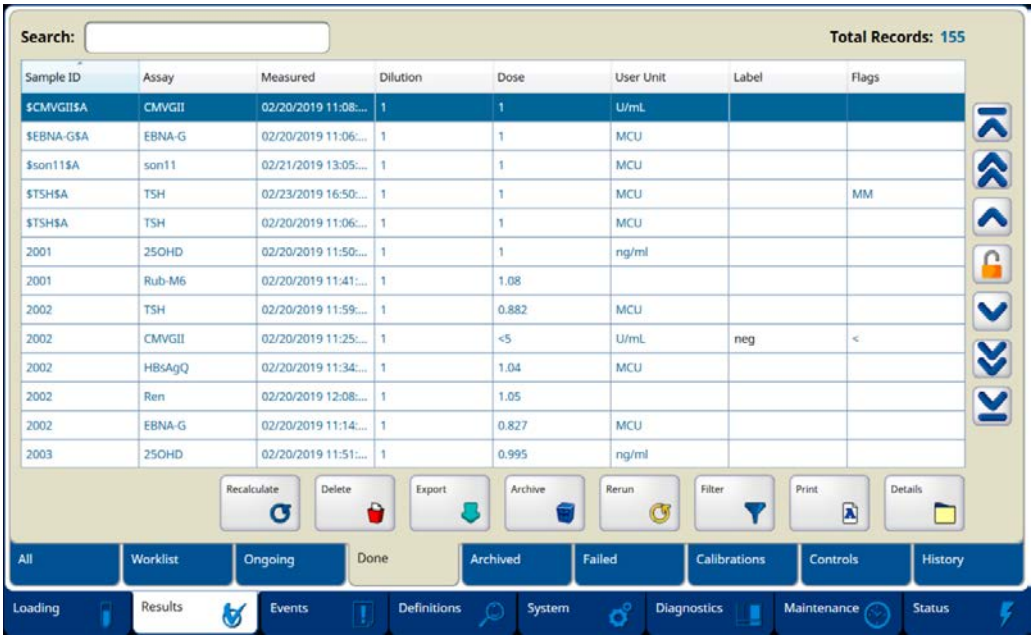


*Figure 6–43: Sub category **Done***

Function	Description
Recalculate	Recalculates the currently selected entries, using the most recent calibration for the assigned assay. For Combi Assays, all results for the same assay family are recalculated.
Delete	Deletes one or more entries, see chapter 6.6.1.3. For Combi Assays, if a Son is selected, a pop-up ask the user to delete the entire family or revoke the request.
Export	Opens the ***Export*** display to export one or more entries to a file (see chapter 6.6.1.1).
Archive	Allows to archive the currently selected entries, opening a selection display (see chapter 6.6.4.1). The archived entries will be shown in the sub category ***Archived***. For Combi Assays, if a Son is selected, a pop-up ask the user to archive the entire family or revoke the request. Note: This button is available only if automatic archiving is not enabled.
Rerun	Allows to repeat the test of one or more entries, opening a selection display (see chapter 6.6.4.2). For Combi Assays, if a Combi Father is selected, all results of the same assay family are recalculated; otherwise, only the selected Combi Son is rerun. Note: the entries will be set either to ***Placed*** (if the sample is present on board) or to ***To Do*** (if the sample is not present on board).
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Result Details*** display for the selected entry (see chapter 6.6.1.2).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3

*Table 6–53: Functions of the **Done** sub category*

NOTE

Dose calculation will be done automatically by the system as soon as a valid calibration is available, provided that all the following conditions are met:

- the samples are successfully analyzed but without a dose (i.e. in status ***Measured***),
- the samples were tested with the same kit (if the curve is not shared) or with a kit from the same lot (if the curve is shared),
- the sample RLU results were obtained no more than 18 hours before the calibration.

6.6.4.1 Archive

Archives the currently selected entries. The archived entries will be shown in the sub category ***Archived***.

NOTE

This button is available only if automatic archiving is not enabled.

Figure 6–44: Archive

Function	Description
Selected Records	Moves all selected entries in the ***Archived*** tab.
All Records	Moves all entries currently present on the ***Archived*** tab page list. If a filter is applied before the archiving then the archiving will be applied the entries matching the filter criteria.

Table 6–54: Functions of Archive

6.6.4.2 Rerun

Reschedules one or more entries.

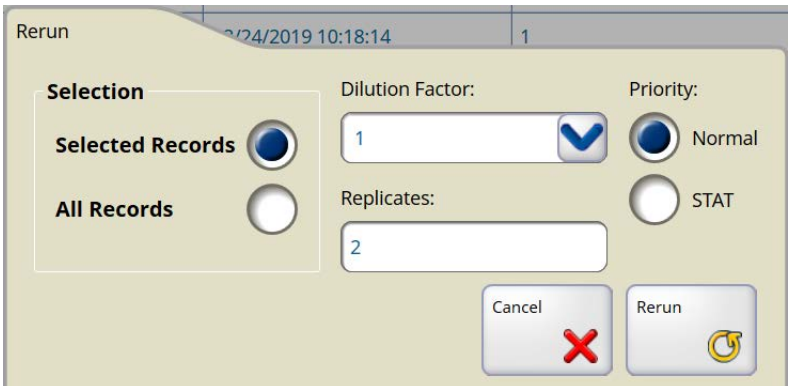


Figure 6–45: Rerun

Function	Description
Selected Records	Reruns all selected entries from the list.
All Records	Reruns all entries currently present on the page list. If a filter is applied before the rerun then the rerun will be applied the entries matching the filter criteria.
Dilution factor	Set the dilution factor to be applied (only if one result is selected).
Replicates	Set the number of replicates to be processed (only if one result is selected).
Priority	Set the sample priority (only if one result is selected).

Table 6–55: Functions of Rerun

NOTE

The entries will be set either to ***Placed*** (if the sample is present on board) or to ***To Do*** (if the sample is not present on board).

6.6.5 Sub Category Archived

The sub category ***Archived*** shows only archived tests. The shown entries are not present in the sub category ***All***.

The default available columns are: ***Sample ID***, ***Assay***, ***Measured***, ***Dilution***, ***Dose***, ***User Unit***, ***Label***, ***Flags***, ***Sent To LIS***.

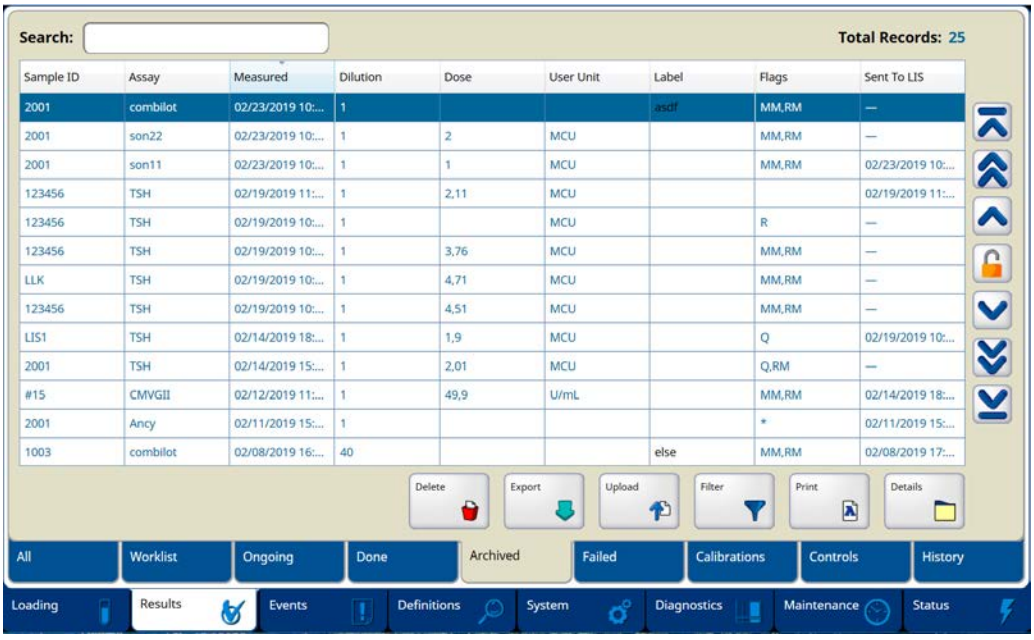


*Figure 6–46: Sub category **Archived***

Function	Description
Delete	Deletes one or more entries,see chapter 6.6.1.3. For Combi Assays, if a Son is selected, a pop-up ask the user to delete the entire family or revoke the request.
Export	Opens the ***Export*** display to export one or more entries to a file (see chapter 6.6.1.1).
Upload	Transmits the selected entries to the LIS system. The **LIAISON® XS** software shows an information dialog.
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Result Details*** display for the selected entry (see chapter 6.6.1.2).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–56: Functions of the **Archived** sub category*

NOTE

The system can be configured to perform a periodical automatic backup and clean up of archived results. Those results can be retrieved using the functionality described in the History page (see chapter 6.6.9).

6.6.6 Sub Category Failed

The sub category ***Failed*** shows only entries of finished tests with status ***Failed***.
The default available columns are: ***Sample ID***, ***Assay***, ***Measured***, ***Dilution***, ***Flags***.

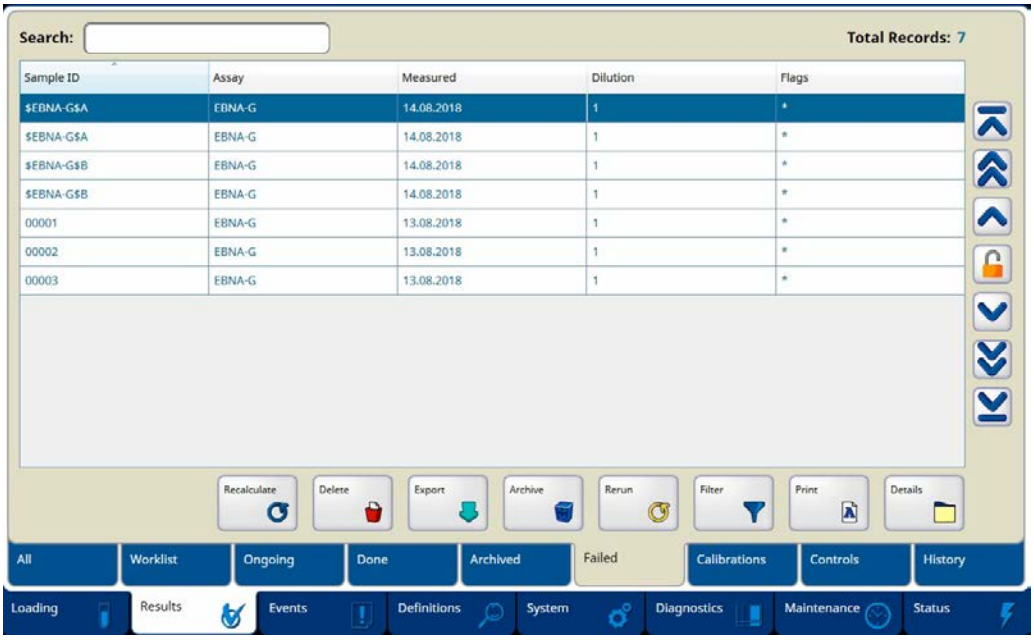


*Figure 6–47: Sub category **Failed***

Function	Description
Recalculate	Recalculates the currently selected entries, using the most recent calibration for the assigned assay (see chapter 6.6.3.1). For Combi Assays, all results for the same assay family are recalculated.
Delete	Deletes one or more entries (see chapter 6.6.1.3). For Combi Assays, if a Son is selected, a pop-up ask the user to delete the entire family or revoke the request.
Archive	Archives the currently selected entries (see chapter 6.6.4.1). The archived entries will be shown in the sub category ***Archived***. For Combi Assays, if a Son is selected, a pop-up ask the user to archive the entire family or revoke the request. Note: This button is available only if automatic archiving is not enabled.
Rerun	Allows to repeat the test of one or more entries, opening a selection display (see chapter 6.6.4.2). For Combi Assays, if a Combi Father is selected, all results of the same assay family are recalculated; otherwise, only the selected Combi Son is rerun. Note: the entries will be set either to ***Placed*** (if the sample is present on board) or to ***To Do*** (if the sample is not present on board).
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Result Details*** display for the selected entry (see chapter 6.6.1.2).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–57: Functions of the **Failed** sub category*

6.6.7 Sub Category Calibrations

The sub category ***Calibrations*** shows only calibration entries (in any possible status).

The default available columns are: ***Calibration ID***, ***Assay***, ***Kit Lot***, ***Kit No.***, ***Measured***, ***Calibration Expiry***, ***Status***, ***Started by***.

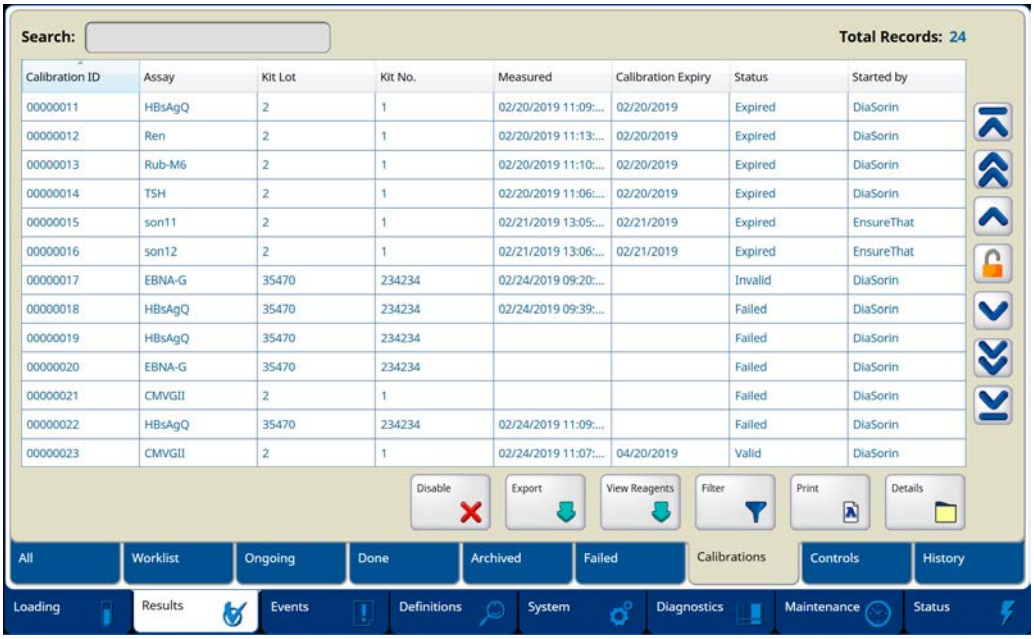


Figure 6–48: Sub category Calibrations

Function	Description
Disable	Disables one or more selected calibration entries, i.e. changes the status of all “Valid” or “Created” calibrations among the selected ones to “Disabled”. Note: all related integrals will need to be recalibrated to produce new dose results.
Export	Opens the ***Export*** display to export one or more entries to a file (see chapter 6.6.1.1).
View Reagents	Opens the sub category ***Integrals*** (see chapter 6.5.3).
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Calibration Details*** display for the selected entry (see chapter 6.6.7.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 6–58: Functions of the Calibrations sub category

Status	Description
Created	The Calibration is just created, not yet measured.
Ongoing	The Calibration is scheduled.
Valid	The Calibration was successfully measured and calculated.
Expired	The Calibration was valid but the expiration period is over.
Invalid	The calibrators were processed, but the calibration result has been rejected by the software.
Not Used	A newer calibration is validated.
Not Used Lot	The calibration is automatically disabled because of a starter lot change.
Failed	One of the calibrators is failed. Note: a failed calibrator replicate out of three could be treated as outlier, and the calibration could result as valid.
Disabled	The calibration is manually disabled.

Table 6–59: Calibration status descriptions

6.6.7.1 Calibration Details

NOTE All calibration values are not editable.

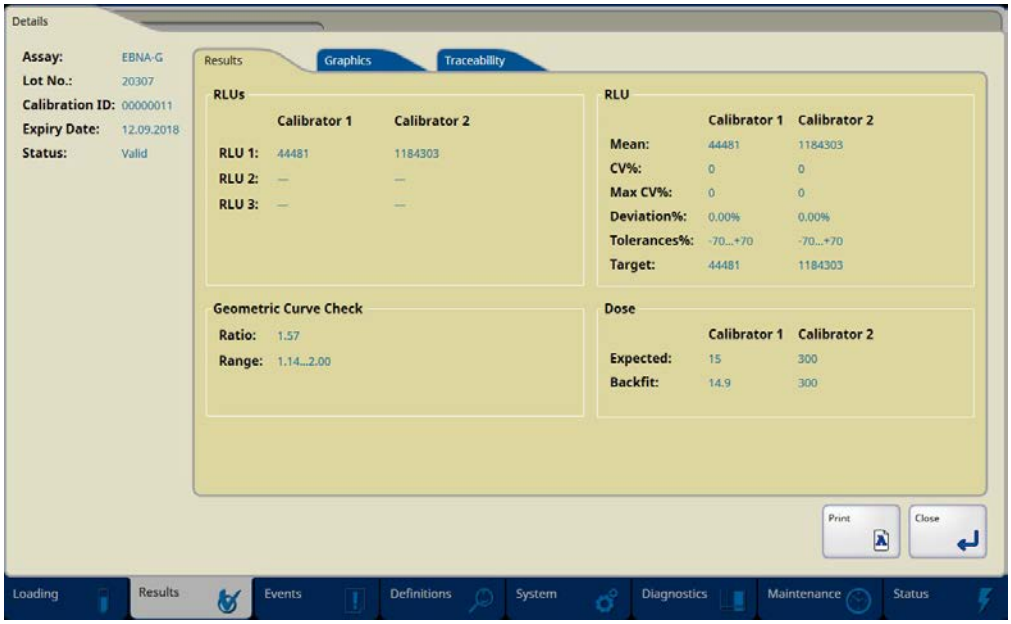


Figure 6–49: Calibration details display

Function	Description
Assay	Assay abbreviation.
Kit Lot	Lot number of the used reagent integral.
Calibration ID	Internal unique ID assigned to this calibration record. This ID will be not reused even after the calibration has been deleted.
Expiry date	Date when the calibration will expire. Note: calibrations expire at midnight of the displayed date.
Status	Shows the status of the entry (***Created***, ***Ongoing***, ***Failed***, ***Invalid***, ***Valid***, ***Expired***, ***Not Used***, ***Not Used Lot***, ***Disabled***).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 6–60: Functions

Function	Description
Calibrator RLU	Displays the RLU values of each calibrator replicates.
Mean (RLU)	Displays the mean RLU value for calibrator 1 and 2.
CV% (RLU)	Displays the percent variation coefficient for RLU results of calibrator 1 and 2. If the CV% exceeds the max RLU CV%, the exceeded value is shown in red. In this case, the calibration will be invalid.
Max CV% (RLU)	Displays the assay max RLU CV% for calibrator 1 and 2.
Deviation% (RLU)	Displays the percent deviation from the nominal RLU value for calibrator 1 and 2. If the mean RLU is out of the tolerance range, the exceeded value is shown in red. In this case, the calibration will be invalid.
Tolerances% (RLU)	The tolerance range for RLU values of calibrator 1 and 2.
Target (RLU)	Shows the nominal values of the RLU results of calibrator 1 and 2 (if applicable).
Ratio (Geometric Curve Check)	The ratio between the RLU values of two given points of the working curve, when a range is defined. The range limits are shown in red if the ratio exceeds the tolerance range. In this case, the calibration will be invalid.
Range (Geometric Curve Check)	The allowed range for the ***Ratio*** field of the Geometric Curve Check, when defined.
Expected (Dose)	Displays the nominal values of the dose of calibrator 1 and 2.
Backfit (Dose)	Displays the obtained dose for calibrator 1 and 2 (if applicable).
Cut-off (Dose)	Displays the factor used for calculate the calibrator dose (if applicable).

*Table 6–61: Functions of the **Results** group*

Graphics Group

The ***Graphics*** group shows the plot of the actual working curve (black) and the acceptance limits derived from the master curve (green). The concentration values are reported in user units. The graphic is available only for quantitative calibrations.

The software automatically adjusts the X and Y axis, in order to fit the obtained working curve.

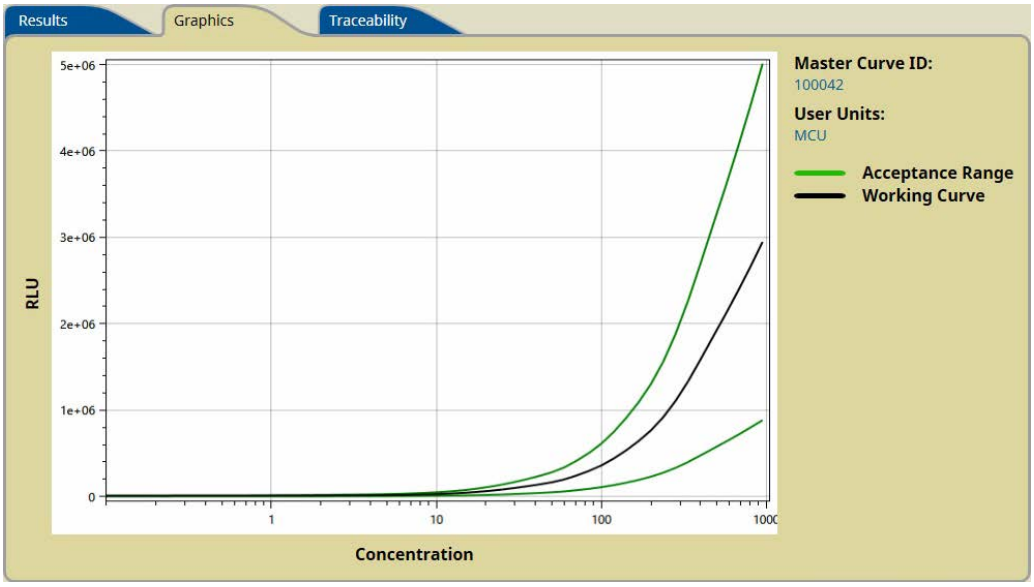


Figure 6–50: Calibration Details- Graphics

Function	Description
Graphic	Displays the obtained working curve and the acceptance range. ***X-Axis*** • Concentration (unit: in user unit depends on assay settings; scale: logarithmic) ***Y-Axis*** • RLU (scale: linear)
Master Curve ID	The ID of the master curve used for this calibration.
User Unit	User unit defined

*Table 6–62: Functions of the **Graphics** group*

Traceability Group

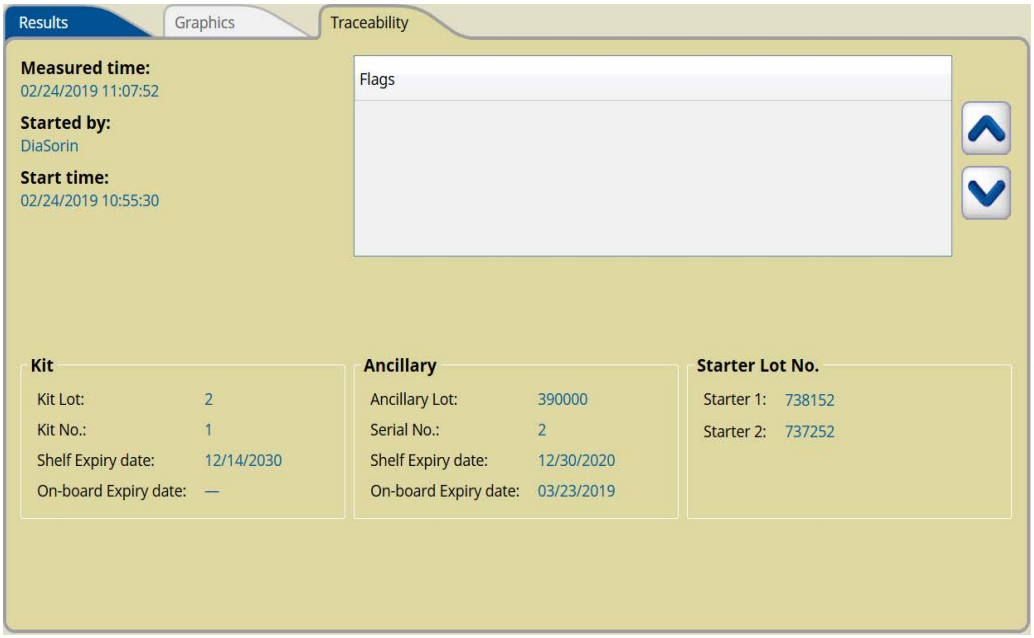


Figure 6–51: Calibration Details- Traceability

Function	Description
Measured time	The date and time when the calibrator RLUs were measured.
Started by	Name of the user, who was logged in when the calibration was started.
Start time	The date and time when the calibration was started.
Flag list	List of relevant result flags obtained for this calibration. For details about the flags see chapter 5.8.5.
Kit Lot	Lot number of the used reagent integral.
Kit No.	Kit number of the used reagent integral.
Shelf Expiry date (Kit)	Shelf expiry date of the used reagent integral.
On-board Expiry date (Kit)	On-board stability expiry date of the used reagent integral.
Ancillary Lot	Lot number of the used ancillary reagent. Only visible if there are ancilliaries in the reagent setup.
Serial No.	Serial number of the used ancillary reagent. Only visible if there are ancilliaries in the reagent setup.
Shelf Expiry date (Ancillary)	Shelf expiry date of the used ancillary.
On-board Expiry date (Ancillary)	On-board stability expiry date of the used ancillary.
Starter lot No.	Lot number of the used starter 1 and 2.

*Table 6–63: Functions of the **Traceability** group*

6.6.8 Sub Category Controls

The sub category ***Controls*** shows the results of the controls.

The default available columns are: ***Sample ID***, ***Assay***, ***Dose***, ***User Unit***, ***Flags***, ***Measured***, ***Control Lot***, ***Control Expiry***, ***Manufacturer Range***, ***User Range***, ***Control Name***.

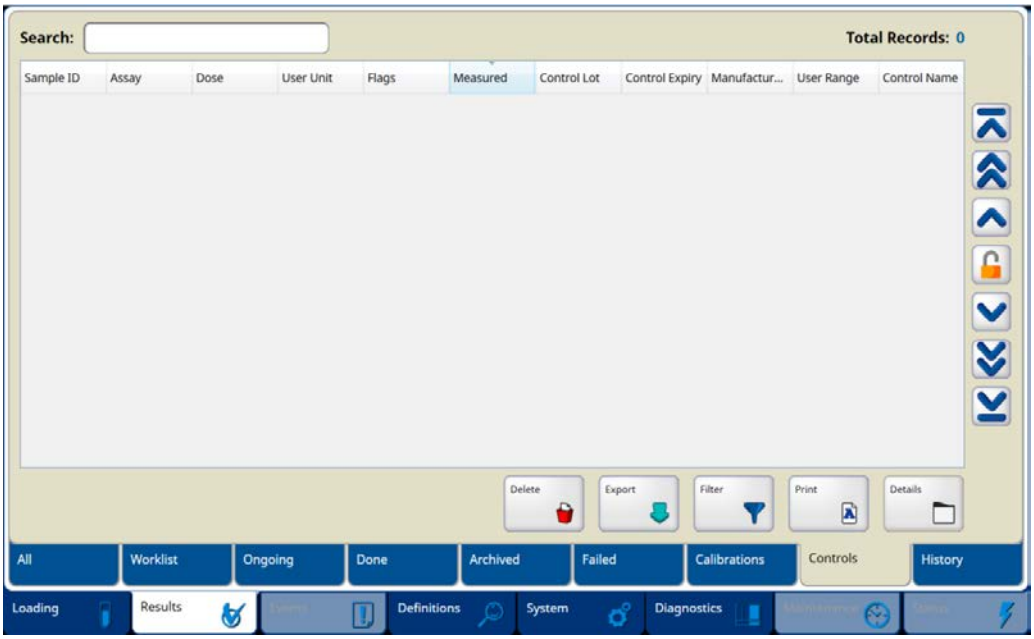


*Figure 6–52: Sub category **Controls***

Function	Description
Delete	Deletes one or more entries (see chapter 6.6.1.3).
Export	Opens the ***Export*** display to export one or more entries to a file (see chapter 6.6.1.1).
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Result Details*** display for the selected entry (see chapter 6.6.8.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–64: Functions of the **Controls** sub category*

6.6.8.1 Control Details

The ***Result Details*** display is used to display all available information for a control.

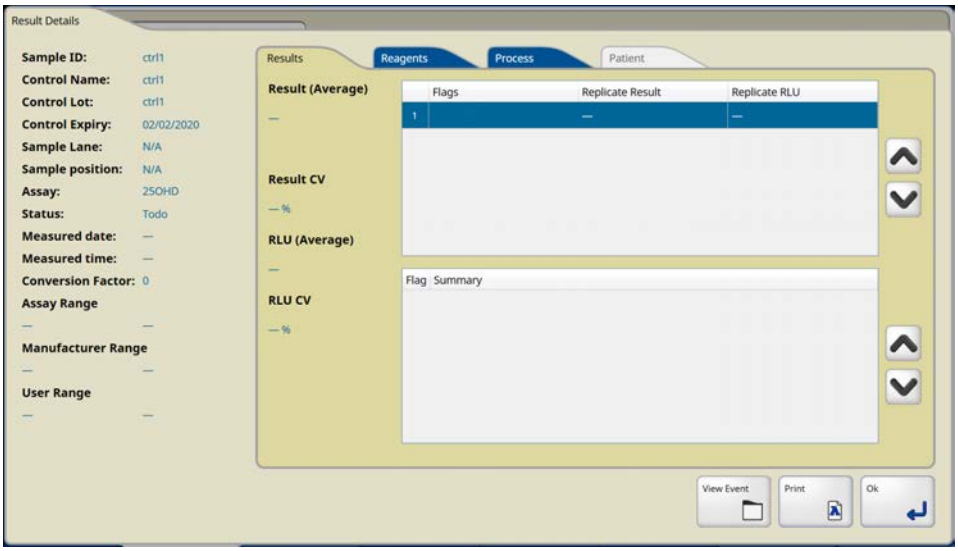


*Figure 6–53: **Results Control Details** display*

Function	Description
Sample ID	Shows the sample ID of the control
Control Name	Name of the control
Control Lot	The lot of the control
Control Expiry	Shelf expiry date of the control
Sample Lane	Lane in the loading bay for where the sample rack was located.
Sample Position	Tube position in sample rack where the control was aspirated from.
Assay	Shows the assigned assay.
Status	Shows the status of the entry (***To do***, ***Placed***, ***Scheduled***, ***Active***, ***Measured***, ***Done***, ***Failed***).
Measured date	The date when the result was measured or the expected result time if the test is Scheduled or Active.
Measured time	The time when the result was measured or the expected result time if the test is Scheduled or Active.
Conversion Factor	Reports the conversion factor used to calculate dose. Example: • Default unit: g/l • User defined unit: mg/l • Conversion factor: 1000
Assay Range	The low and high limit of the assay range for the assay, in user defined unit. When a control falls outside this range, it will be provided with the corresponding flag; it will be shown as “<” followed by the low limit or “>” followed by the high limit.

Function	Description
Manufacturer Range	The low and high limit of the manufacturer range for the control, in user defined unit. When a control falls outside this range, it will be provided with the corresponding flag.
User Range	The low and high limit of the user range for the control, in user defined unit. When a control falls outside this range, it will be provided with the corresponding flag.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

*Table 6–65: Functions of the **Result Details** display*

Results Group

Function	Description
Result (Average)	Shows the dose result calculated from the mean RLU result. It is reported in user units, adjusted with the dilution factor.
Result CV	Shows the coefficient of variation (%) for the dose result.
RLU (Average)	Shows the mean RLU result (truncated).
RLU CV	Shows the coefficient of variation (%) of the RLU result.

*Table 6–66: Functions of the **Result** group*

Column	Description
Flags	List of flags per replicate. For details about the flags see chapter 5.8.5.
Replicate Result	List containing all replicate dose results in user units (calculated and converted for each single replicate RLU result).
Replicate RLU	List containing all replicate RLU results.
Flag Summary	List of all flags associated to this specific control, displayed as complete description. For details about the flags see chapter 5.8.5.

*Table 6–67: Columns of the **Results** group tables*

Depending on the used assay(s) the **LIAISON® XS** software will show the following result details/values:

Value	Regular assay	Combi assay
Result (Average)	Dose	Dose
Result CV	Yes	No
RLU (Average)	Yes	No
RLU CV	Yes	No
Flag Summary	Yes	Yes
Replicate Results	Yes	No
Replicate RLU	Yes	No
Flags	Yes	Yes

Table 6–68: Shown result details/values

Reagents Group

Function	Description
Ancillary On-board Expiry date	On-board stability expiry date for the ancillary reagent (if present). Note: ancillaries expire at midnight of the displayed date.
Ancillary Shelf Expiry date	Shelf expiry date of the used ancillary reagent (if present). Note: ancillary expire at midnight of the displayed date.
Ancillary Serial No.	Serial number of the used ancillary reagent (if present).
Ancillary Reagents Lot No.	Lot number of the used ancillary reagent (if present).
Calibration Expiry date	Expiry date of the calibration used for result calculation. Note: calibrations expire at midnight of the displayed date.
Calibration ID	Unique identifier of the calibration used for result calculation.
Kit Shelf Expiry date	Shelf expiry date of the used reagent integral. Note: kits expire at midnight of the displayed date.
Kit Lot	Kit lot number of the used reagent integral.
Kit No.	Kit number of the used reagent integral.
Kit Onboard Expiry date	On-board stability expiry date of the used reagent integral. Note: kits expire on-board at midnight of the displayed date.
Starter 1 Lot	Lot number of the used starter 1.
Starter 2 Lot	Lot number of the used starter 2.

*Table 6–69: Functions of the **Reagents** group*

NOTE

For Combi Assays, this tab contains all the combi sons information.

Process Group

Function	Description
Rack ID	The rack ID of the rack where the sample was aspirated from.
Archived by	Name of the user, who was logged in when the result was archived.
Archiving time	Date and time when the result was archived.
Calculated by*	Name of the user, who was logged in when the result calculation was done.
Calculation Time*	Date and time when the result was calculated.
Started by*	Name of the user, who was logged in when the test was started.
Start Time*	Date and time when the first aspiration occurred for the test. Note: In case of two or more replicates this time refers to the first replicate.
Sent by	Name of the user, who was logged in when the result was sent to LIS.
Sent to LIS	Date and time when the result was sent to LIS.
STAT [y/n]*	Shows “Y” for samples with STAT priority, “N” for normal priority samples.
Deleted time	Date and time when the results was deleted (always empty).
Deleted by	Name of the user, who was logged in when the results was deleted (always empty).

*Table 6–70: Functions of the **Process** group*

6.6.9 Sub Category History

The subcategory ***History*** shows, by default, all entries that have been moved, by means of the auto backup process, from the ***Archive*** subcategory (historicized results).

For details about the auto backup, see chapter 6.9.5.

The function ***Query*** allows to specify a patient driven query to populate the ***History*** page with all the results matching such query gathered from ***All***, ***Archive*** and ***History***.

The default available columns are: ***Sample ID***, ***Assay***, ***Measured***, ***Status***, ***Dilution***, ***RLU***, ***Dose***, ***User Unit***, ***Label***, ***Flags***.

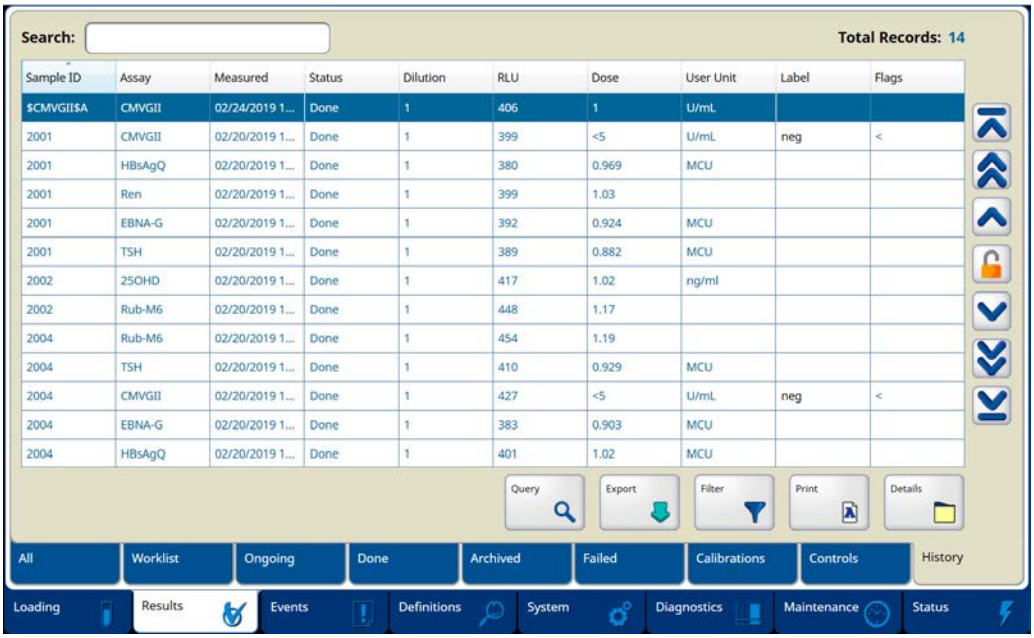


*Figure 6–54: Sub Category **History***

Function	Description
Query	Opens the ***Select Query*** display (see chapter 6.6.9.1).
Export	Opens the ***Export*** display to export one or more entries to a file (see chapter 6.6.1.1).
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Standard Buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 6–71: Functions of the History

6.6.9.1 Query

An indication if any query is applied is located in the top right corner, near the number of total records.

Figure 6–55: Query applied

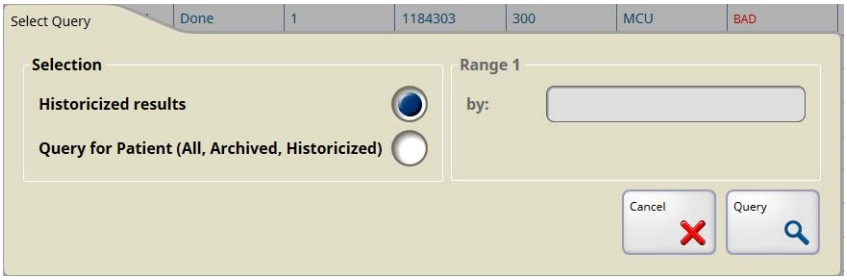


Figure 6–56: Select Query

Function	Description
Historicized results	Shows all results that have been historicized (default).
Query for Patient (All, Archived, Historicized)	Searches the results in databases ***All***, ***Archive*** and ***History*** based on the defined query.
By	Options that can be used to apply the query:Sample ID, Patient ID and Patient Name.
Query	Applies the defined query.

Table 6–72: Select Query

6.7 Main Category Events

In the main category ***Events***, all messages and errors occurred are listed according to their type.

When the main category ***Events*** is opened, then that sub category will be opened too, which has new content in it, i.e.:

1. the sub category ***Messages*** will be opened as long as there are unacknowledged messages,
2. the sub category ***Event Log*** will be opened.

In case of any fatal error or message that requires immediate user attention, a pop up is automatically displayed.

Sorting and Searching

See chapter 6.3.2.

6.7.1 Sub Category Event Log

The sub category ***Event Log*** lists in real time, any event that occurs on the system. This includes errors, log in data, result failures and other information that may help troubleshooting activities.

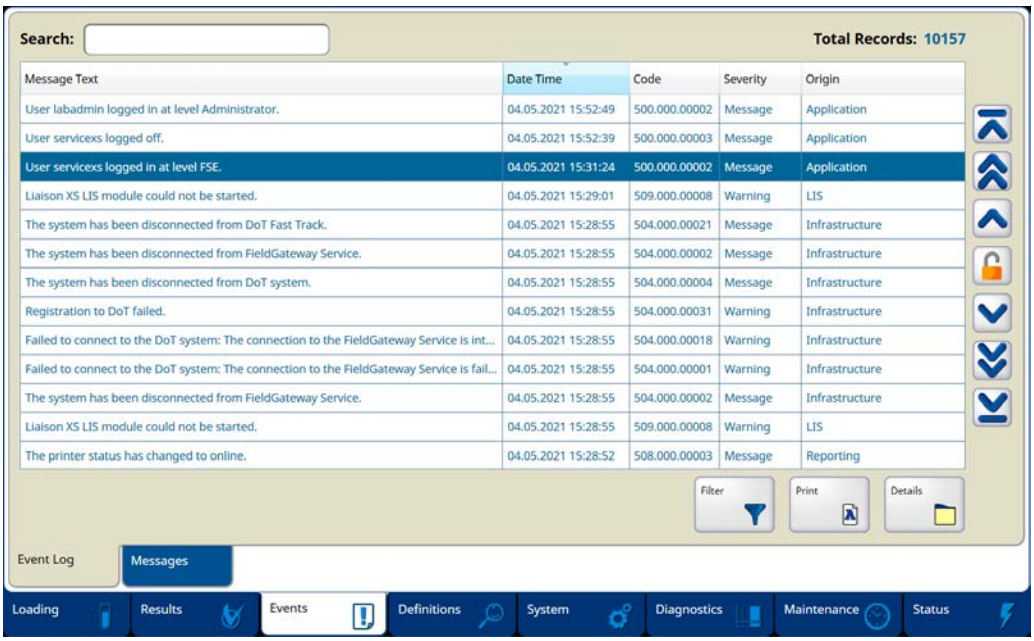


*Figure 6–57: Sub category **Event Log***

Function	Description
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Shows details about the selected entry (see chapter 6.7.1.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

Table 6–73: Functions of the Event Log sub category

Column	Description
Message Text	Shows the event message.
Date Time	Shows the date and time when the event occurred.
Code	Shows the code of the message.
Severity	Shows the severity level of the event (***Message***, ***Warning***, ***Problem***, ***Critical***, ***Fatal***, ***Catastrophic***)
Origin	Shows the name of the module which originated the event.

Table 6–74: Columns of the event log table

When the ***Event Log*** sub category is opened, the event log table is sorted chronologically in descending order.

NOTE

Events are described in chapter 8.

6.7.1.1 Details Event Log

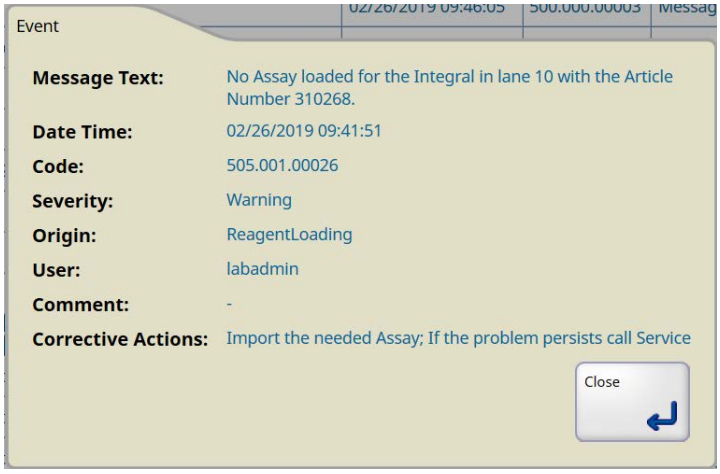


Figure 6–58: Details Event Log

Function	Description
Message Text	Event description
Date Time	Event logging time stamp
Code	Event identifier
Severity	Severity
Origin	A string containing the issuer of the event (module and/ or submodule) as reported in the code.
User	The user account name when the event was logged.
Comment	The verbose event description that better details the event.
Corrective Actions	The suggested action.

Table 6–75: Details Event Log

6.7.2 Sub Category Messages

The sub category ***Messages*** shows all messages that have not yet been acknowledged. Messages are special events containing information that shall be acknowledged by the user.

Every result invalidating flag will be shown as an error message.

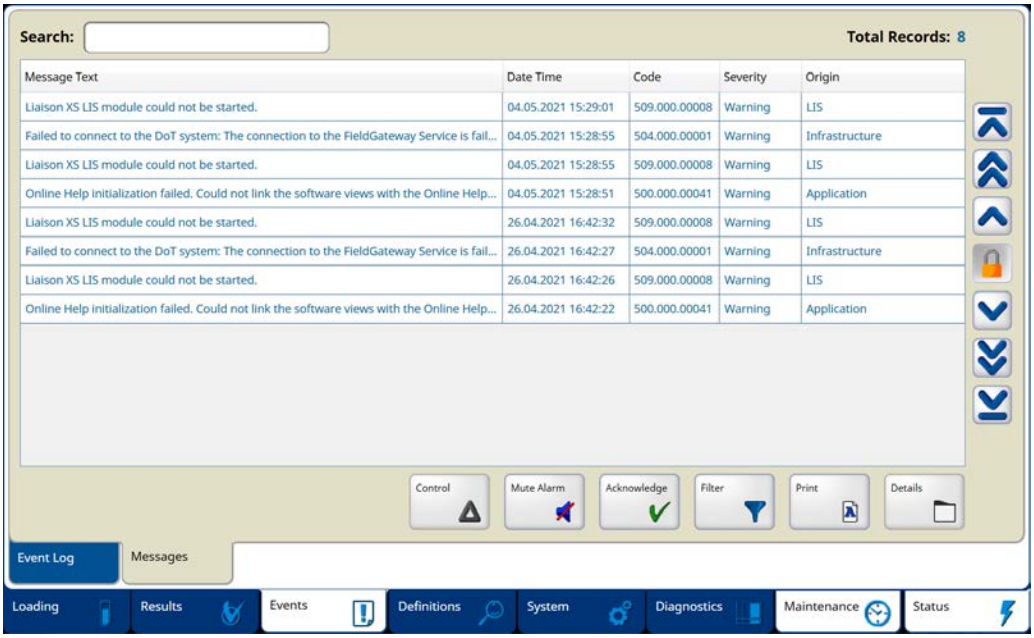


*Figure 6–59: Sub category **Messages***

Function	Description
Control	Displays the sub category ***Controls***. The button is only enabled if there are a “control out of range” events in the message list or upon login if such messages are still present. The button is disabled after it is pressed.
Mute Alarm	Switches off the instrument beeper.
Acknowledge	To accept a selected message tap on the ***Acknowledge*** button. The message will be removed from the list, but it is still available in the sub category ***Event Log***.
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Opens the ***Details Event*** display for the selected message (see chapter 6.7.1.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–76: Functions of the **Messages** sub category*

Column	Description
Message Text	Shows the event message.
Date Time	Shows the date and time when the event occurred.
Code	Shows the code of the message.
Severity	Shows the severity level of the event (***Message***, ***Warning***, ***Problem***, ***Critical***, ***Fatal***, ***Catastrophic***).
Origin	Shows the name of the module which originated the event.

Table 6–77: Columns of the messages table

When the ***Messages*** sub category is opened, the messages table is sorted chronologically in descending order.

NOTE Error messages are described in chapter 8.

NOTE Some events trigger the audible alarm to beep. The emitted noise depends on the severity of the error. Some events trigger also the status light.
For errors that trigger the alarms repeatedly on, use the button ***Mute Alarm*** to turn them off. Acknowledging a message does not turn the alarms off.

6.7.3 Fatal Errors

Fatal errors are a particular category of events that are given when an error occurs for which the system is not able to recover and has to stop any activity.

6.8 Main Category Definitions

In the main category ***Definitions***, the sub categories are information on assays, controls, assay groups, rerun rules, profiles and sender which can be accessed. Additionally, there are several editing possibilities available.

6.8.1 Sub Category Assay

In the subcategory ***Assay***, all assays available in the **LIAISON® XS** system at that moment are indicated. In the table, the assay names and the article numbers and the assignment to an assay group are indicated. There is the possibility to access further information on the individual assays.

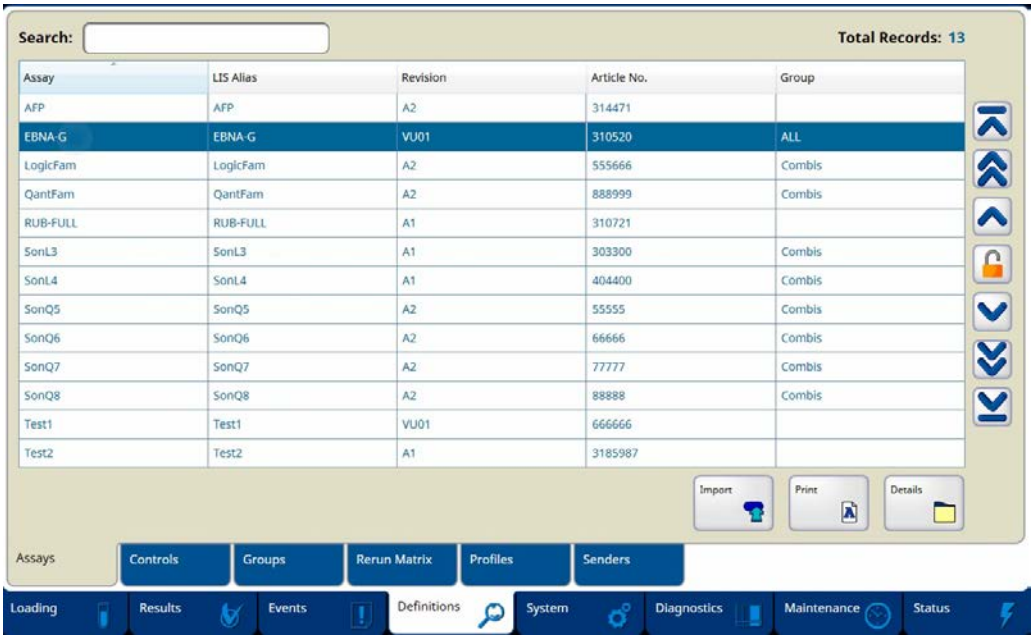


*Figure 6–60: Sub category **Assay***

Function	Description
Import	Imports one or more assays from a file. This function is only available if the instrument is not running (see chapter 6.8.1.1).
Details	Shows details about a selected assay (see chapter 6.8.1.2).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–78: Functions of the **Assay** sub category*

NOTE

If an already existing assay is imported into the **LIAISON® XS** system, only those parameters of that assay which are not user editable will be overwritten. Parameters, which are user editable, will be maintained, unless differently explained by the system.

Column	Description
Assay	Assay name.
LIS Alias	Assay name on the LIS system.
Revision	Revision number of the assay.
Article No.	Article number of the assay.
Group	List of groups the assay belongs to.

Table 6–79: Columns of the assays table

6.8.1.1 Import

Allows multiple file selection. Disabled in Running.

Figure 6–61: Import

Column	Description
Path	Allows to select a directory.
Article No.	Article Number of the assay.
Lot No.	Lot number of the assay.

Table 6–80: Import

6.8.1.2 Assay Details

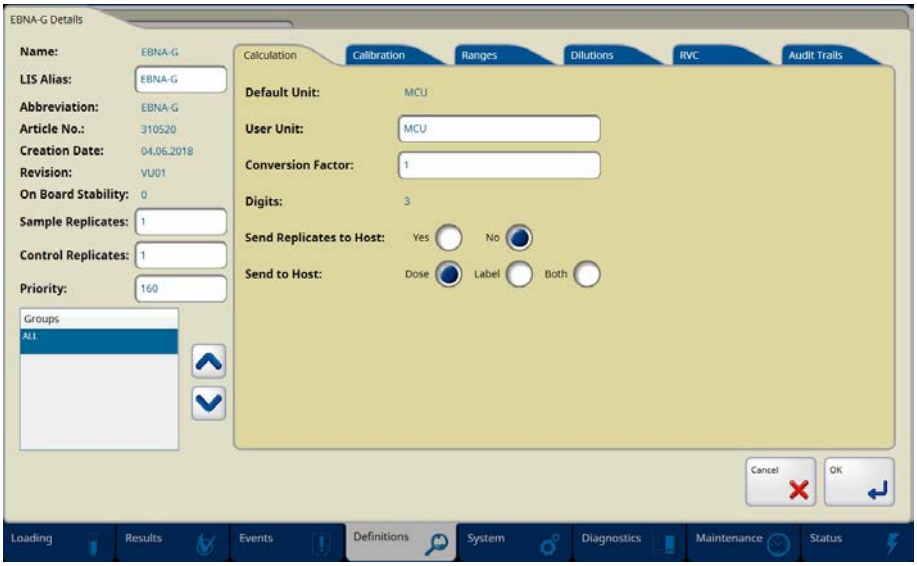


*Figure 6–62: **Details** display*

Function	Description
Name	Assay name.
LIS Alias	Assay name on the ***LIS*** system.
Abbreviation	Abbreviation property of the assay.
Article No.	Article number of the assay.
Creation date	Creation date of the assay.
Revision	Revision number of the assay. Only integrals compatible with this revision can be used.
On-Board Stability	On-board stability of integral.
Sample Replicates	Number of replicates for patient samples, up to 20. It is only allowed to increase the number of replicates, and after to decrease but no lower than the default number (provided in the assay file).
Control Replicates	Number of replicates for control samples, up to 20. It is only allowed to increase the number of replicates, and after to decrease but no lower than the default number (provided in the assay file).
Priority	Scheduling priority (1 to 200) of the assay. Assays with the highest priority number (starting from 200) will be scheduled before assays with lower priority number (up to 1) for samples within a rack (in case of Random Access mode) or within the entire sample area (in case of Batch mode).
Groups	List of all groups which the assay belongs to.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

NOTE

Changing an assay priority would trigger changes in the order of assay execution, with the possible consequence of throughput changes.

Calculation Group

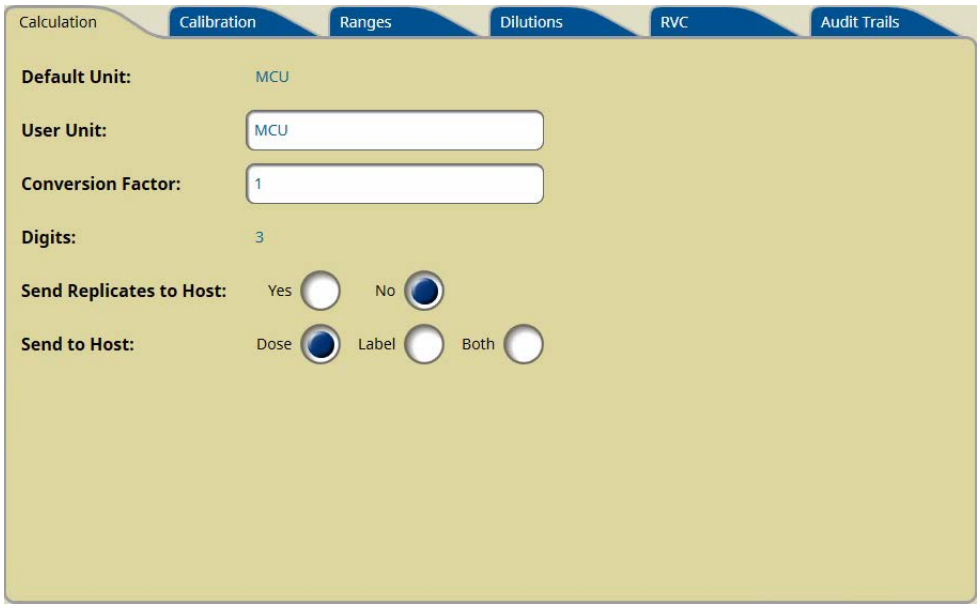


Figure 6–63: Details- Calculation Group

Function	Description
Default Unit	Default unit.
User Unit	User defined unit (e.g. mg/l). See ***Conversion Factor*** below.
Conversion Factor	Conversion factor between default unit and user defined unit. Example: • Default unit: g/l • User defined unit: mg/l • Conversion factor to be specified: 1000
Digits	Shows the number of significant digits to be reported for the result and related ranges/thresholds.
Send replicates to host	Selection for the result transmission of the replicates to the host (***Yes***, ***No***).
Send to Host	Selection for the result transmission to the host (***Dose***, ***Label***, ***Both***). Applicable only if the assay is provided with labels.

*Table 6–81: Functions of the **Calculation** group*

NOTE

Changes of the user unit and the conversion factor affect only new results.

All dose-related ranges are shown according to the user units, as the software automatically converts them.

It is necessary to completely save the changed user unit and the conversion factor and close the Assay detail page, before changing the Normal Range. Changing the Normal Range before closing the Assay detail page may result in a successive update of the Normal Range performed automatically by the system, based on the new user unit and the conversion factor.

Calibration Group

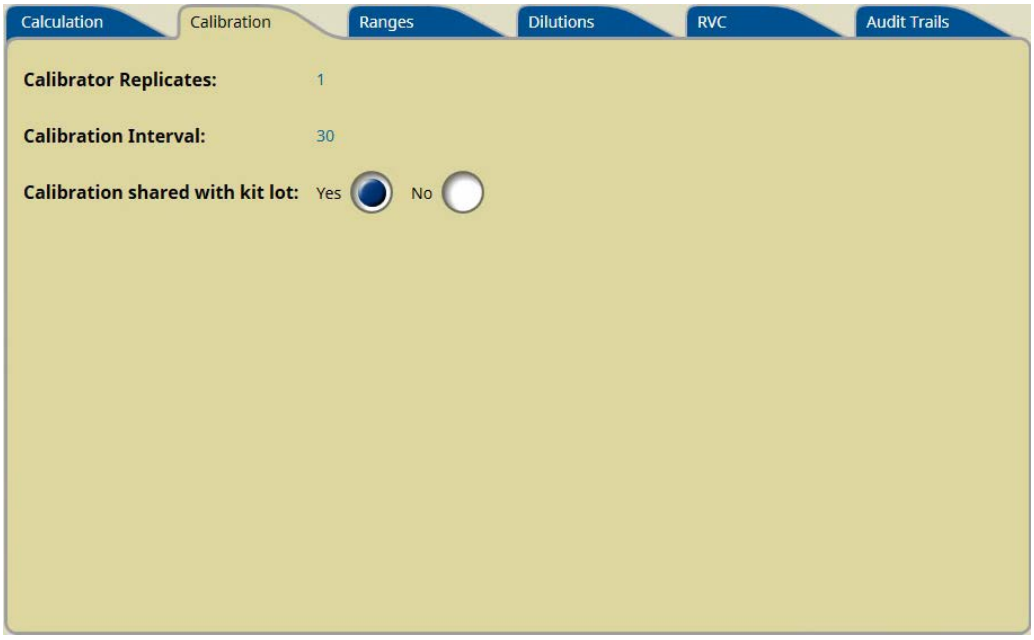


Figure 6–64: Details- Calibration Group

Function	Description
Calibrator Replicates	Shows the number of replicates to be run for calibration.
Calibration Interval	Shows the validity period for calibrations.
Calibration shared within kit lot	***Yes:*** • The calibration is valid for kit lot (“Shared Working Curve” approach). ***No:*** • The calibration is valid for the specific integral (“Not Shared Working Curve” approach). If the default setting is No, it is not allowed to select ***Yes***.

*Table 6–82: Functions of the **Calibration** group*

Ranges Group

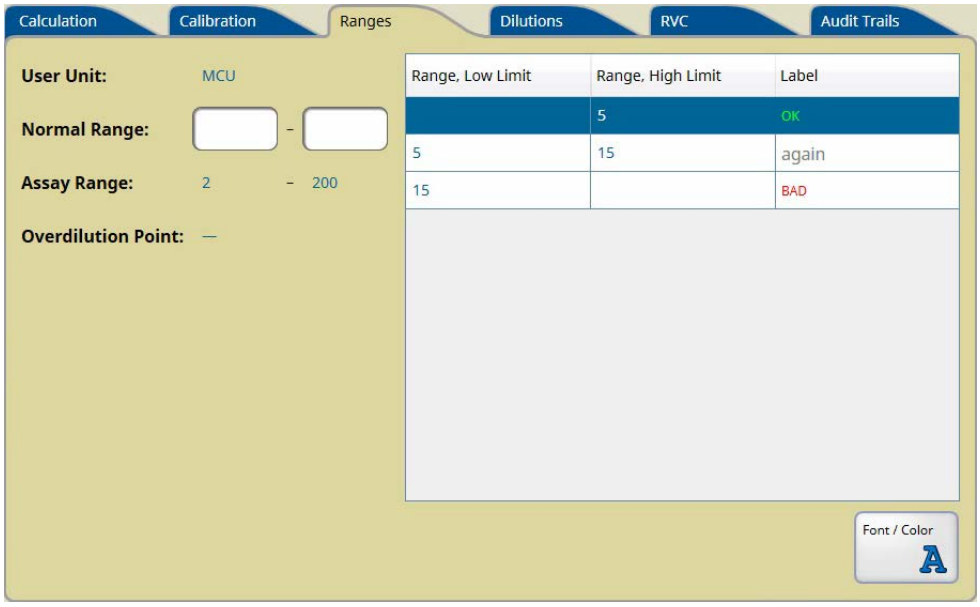


Figure 6–65: Details - Ranges Group

Function	Description
User Unit	User defined unit.
Normal Range	The low and high limit of the normal range for the assay, in user defined unit. When a result falls outside this range, it will be provided with the corresponding flag. Results are compared against the normal range after being adjusted with the dilution factor. The low limit is included and the high limit is excluded. If a limit field is empty, the **LIAISON® XS** software will handle this as “do not care”. This allows to support one-sided ranges.
Assay Range	Shows the low and high limit of the assay range for the assay, in user defined unit. Results are compared against the assay range before being adjusted with the dilution factor. The assay range value used to report an out of assay range result is not multiplied by the dilution factor. When a result falls outside this range, it will be provided with the corresponding flag; it will be shown as “<” followed by the low limit or “>” followed by the high limit. The low limit is included and the high limit is excluded. If a limit field is empty the **LIAISON® XS** software will handle this as “do not care”. This allows to support one-sided ranges.
Overdilution Point	Shows the overdilution point for that assay, in user defined unit. If results get lower than the overdilution point it will be considered not valid and therefore the results will be failed (i.e. dose not given).
Font/Color	Opens the ***Select Font*** /***Select Color*** display to pick up a font to be assigned to the currently selected qualitative label.

*Table 6–83: Functions of the **Ranges** group*

Column	Description
Range, Low Limit and ***Range, High Limit***	The low and high limit for that corresponding qualitative range, in user defined units, for up to 5 qualitative settings. The low limit is included and the high limit is excluded. If a limit field is empty the **LIAISON® XS** software will handle this as “do not care”. This allows to support one-sided ranges. Example: Low: empty; high: 1; Label: neg Low: 1; high: 10; Label: eq Low: 10; high: empty; Label: POS
Label	The qualitative label to be applied to results within this range. The label is displayed using the dedicated font and color defined for that label.

Table 6–84: Columns of the ranges table

Dilutions Group

Shows all (1...max. 10) sample dilution factors, which are defined for the assay.

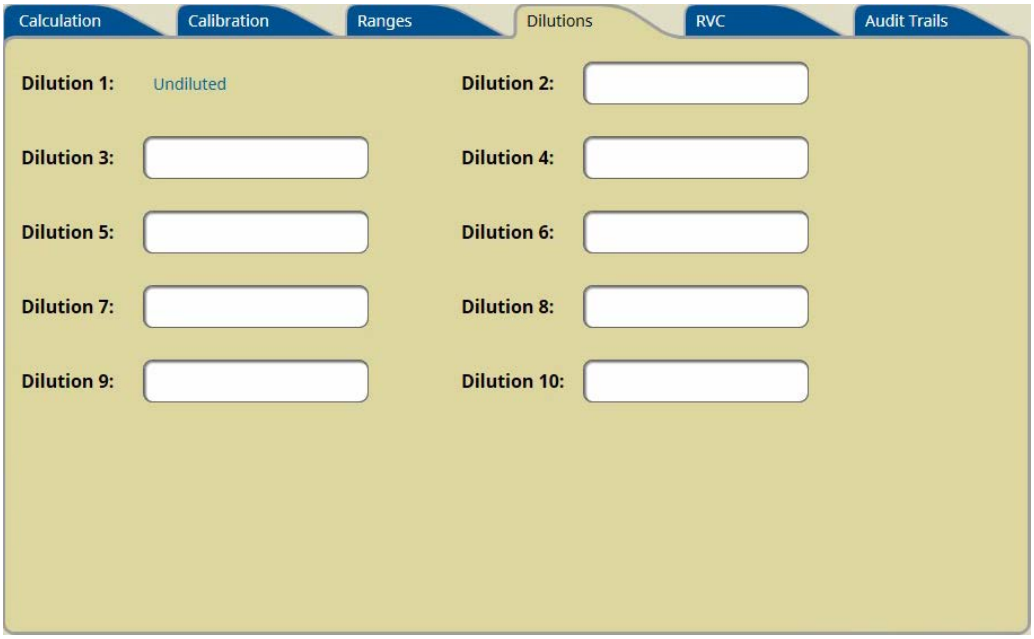


Figure 6–66: Details- Dilutions Group

In each field (Dilution 2...Dilution 10) a dilution factor in the range from 1 to 6250000 can be defined. To delete a dilution factor, it is necessary to press the delete button next to the field.

RVC Group

RVC (Run Validation Criteria) are rules that can be defined either by the manufacturer or by the user; if an RVC is violated, this will result in a Q flag for the patient sample (see chapter 6.6.1.2).

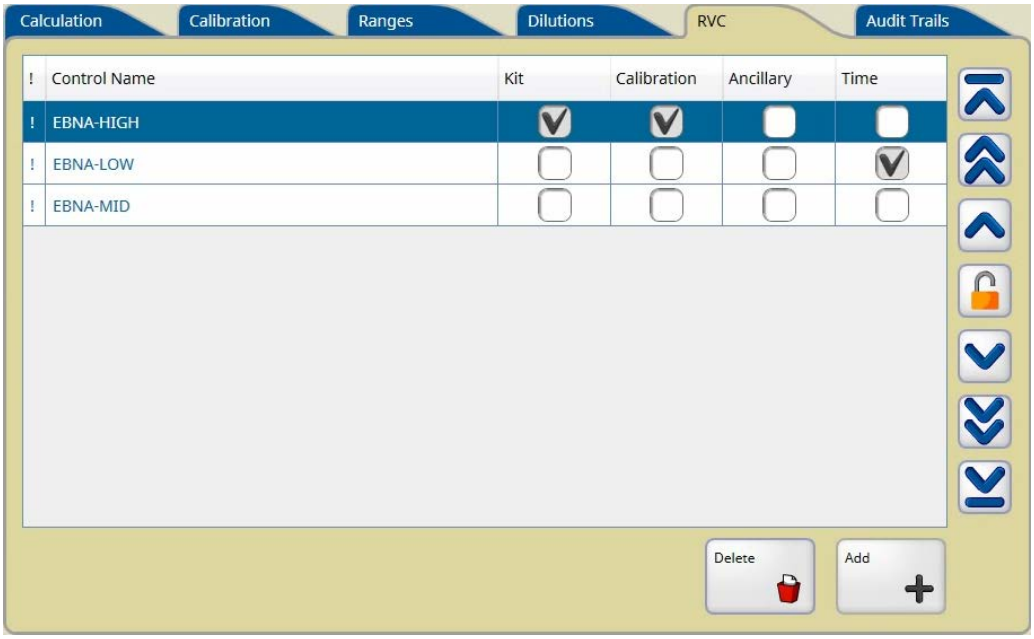


Figure 6–67: Details- RVC Group

Function	Description
Add	Add Run Validation Criteria (RVC).
Delete	Delete the selected Run Validation Criteria (RVC).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 6–85: Functions of the RVC group

NOTE

To add RVC, the control needs to be defined (see chapter 6.8.2).

NOTE

If an RVC is defined by the manufacturer:

- the RVC cannot be deleted
- already enabled criteria cannot be modified
- disabled criteria can be enabled/disabled

Column	Description
Control Name	The name of the Control Definitions for which a control to be executed and in range is required. If no control is present in the list no RVC are applied to the assay
Kit	Requires the control to be in range and executed on the same kit as the patient sample.
Calibration	Requires the control to be in range and calculated with the same calibration as the patient sample.
Ancillary	Requires the control to be in range and executed on the same ancillary as the patient sample.
Time	Use the latest Control that was calculated no more than 18 hours ago.

Table 6–86: Columns of the RVC group table

Audit Trails Group

Shows the history of changes of the:

- LIS Alias
- Sample/Control replicates
- Priority
- User unit/Conversion factor
- Send replicate to host
- Send to host
- Calibration shared within kit lot
- Normal range
- Label font/color
- Dilution factors
- RVC

If the user changes one value out of those, then the Audit Trails group is activated and the user is prompted to type in a reason for the change. The audit trail will track any successful import action.

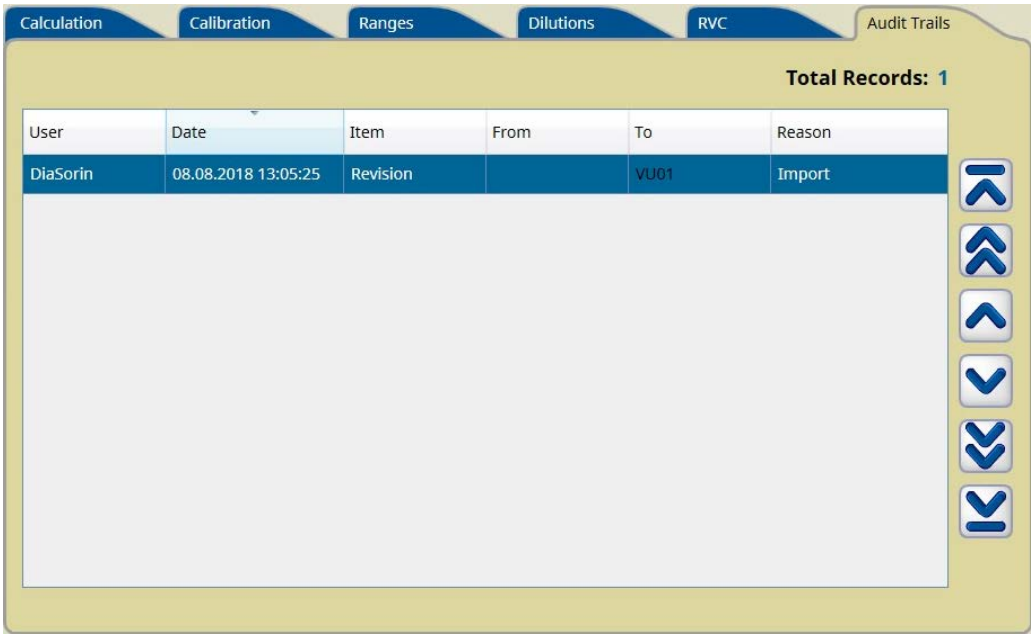


Figure 6–68: Audit Trails Group

Column	Description
User	Name of the user who changed an entry.
Date	Shows the date when the change was made.
Item	Shows the changed field/function.
From	Original value.
To	New value.
Reason	Shows the reason of change.

Table 6–87: Columns of the Audit Trails Group table

6.8.2 Sub Category Controls

In the sub category ***Controls***, detailed information on the control definitions can be accessed.

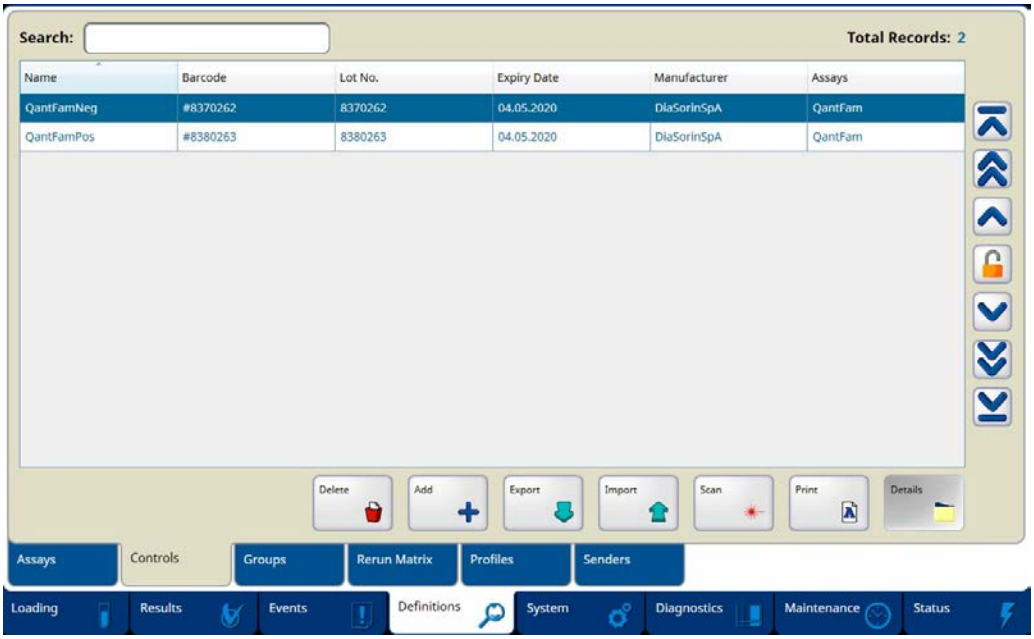


*Figure 6–69: Sub category **Controls***

Function	Description
Delete	Deletes one or more selected control definitions (see chapter 6.6.1.3).
Add	Adds a new control definition (see chapter 6.8.2.2).
Export	Exports a control definition to a file.
Import	Imports a control definition from a file.
Scan	Enables to scan a 2D bar-code of a control definition with a handheld bar-code scanner and displays the read data (see chapter 6.8.2.1). The control will be added to the list.
Details	Shows details about a selected control definition (see chapter 6.8.2.2).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***), see chapter 6.3.

*Table 6–88: Functions of the **Control** sub category*

Column	Description
Name	Shows the name of a control definition.
Control ID	Shows the bar-code of the control reagents.
Lot No.	Shows the lot number of the control reagents.
Expiry date	Shows the expiry day of the control reagents. Note: controls expire at midnight of the displayed date.
Manufacturer	Shows the manufacturer of the control reagents.
Assays	Shows all associated assays.

Table 6–89: Columns of the controls table

6.8.2.1 Scan

The Control Scan Dialog guides the user to scan a 2D Barcode of a Control Definitions and displays the read data.

When scanned, the read characters are displayed after the integrity has been checked.

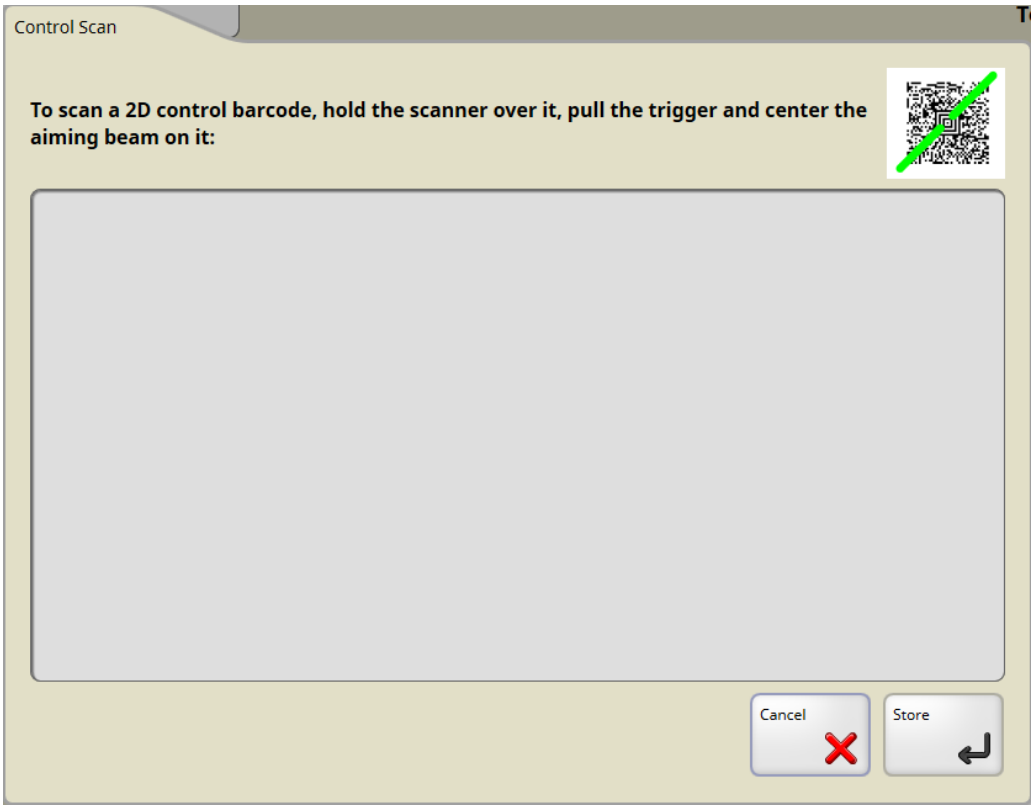


Figure 6–70: Scan Dialog

6.8.2.2 Add Control/ Control Details

Enables user to add a new control to the **LIAISON® XS** system.

The ***Control Details*** display shows detailed information about a control definition. Several fields can be edited.

CAUTION

Controls can not be defined for logical combi assays: they could not result in a numerical result, therefore controls for logical combi assays are not supported by the system.

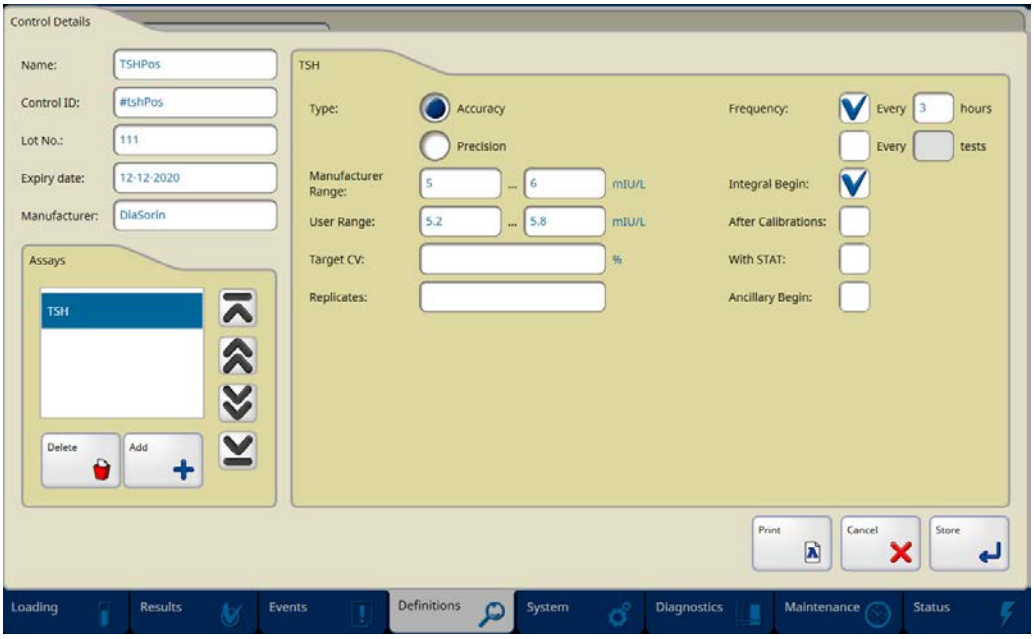


Figure 6–71: Control Details

Function	Description
Add	Opens the ***Select Assay*** dialog to associate a new assay to control. The dialog shows all the assays that can be associated; already associated assays are not reported. (Note: Those assays that do not provide any numerical result are not listed as they cannot be compared against any range). Disabled if control was scanned.
Delete	Deletes the currently selected assay data control definition from the database. Disabled if control was scanned.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***), see chapter 6.3.

Table 6–90: Control Details buttons

Function	Description
Name	Name of the control definition. The control Name in combination with the Lot Number must be unique. Any sequence of alphanumeric characters (spaces, "-" and "/" are allowed) can be entered as a control Name.
Control ID	Bar-code of the control.
Lot No.	Lot number of the control.
Expiry date	Expiration day of the control. Note: controls expire at midnight of the displayed date.
Manufacturer	Manufacturer of the control.
Assay list	Shows all associated assays.

Table 6–91: Fields on left side

NOTE

The fields on the left side of the ***Control Details*** dialog cannot be changed if acquired via 2D barcode.

Control Data Group

Column	Description
Type	To define whether this is an ***Accuracy*** or a ***Precision*** control.
Manufacturer Range	The low and high limit of this control definition in user defined units (result is expected to be in this range).
User Range	The low and high limit of the reference range for this control, in user unit.
Target CV	Contains the target value for the variation coefficient.
Replicates	Defines a number of replicates to be used for control samples. If empty, the ***Control Replicates*** for the related assay is used.
Frequency	Defines the logic the system will use to automatically start controls. • ***After Calibrations*** • ***Every X Hours*** • ***Every Y Tests*** • ***Integral Begin*** • ***Ancillary Begin*** • ***With STAT*** In case the control is not loaded when required by one of these rules, a message will be issued.

Table 6–92: Columns of the controls table

The ***Manufacturer Range*** cannot be changed if the control is acquired via 2D barcode.

NOTE

For assays that have an assay range lower limit defined, a control range lower limit set to 0 would cause the flags QL/UL to be reported whenever the result exceeds the assay range lower limit. Otherwise, a control range lower limit left empty does not cause a flag.

6.8.3 Sub Category Groups

In the subcategory ***Groups***, there is the possibility to include assays in groups. It is necessary to include an assay in a group to be able to assign manually a patient sample to such assay.

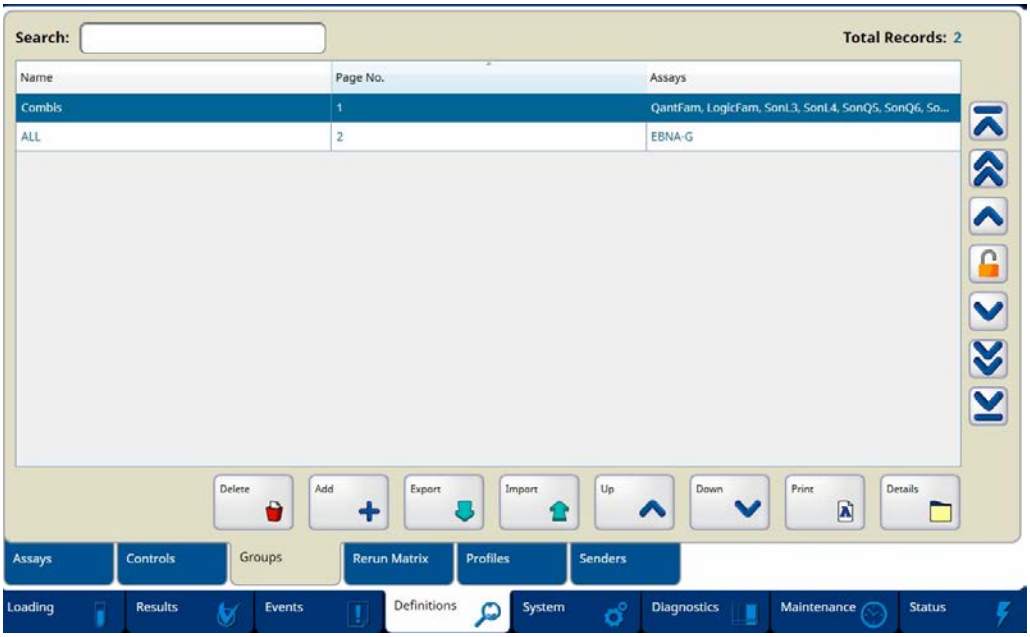


Figure 6–72: Sub category Groups

Functions	Description
Delete	Deletes one or more selected assay groups (see chapter 6.6.1.3).
Add	Shows the ***Group Details*** display to add a new assay group (see chapter 6.8.3.1).
Export	Exports a group definition to a file.
Import	Imports a group definition from a file.
Up/Down	Moves the currently selected group one line up/down and changes the page number accordingly
Details	Shows the ***Group Details*** display to show or edit the selected assay group (see chapter 6.8.3.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print)*** see chapter 6.3.

6.8.3.1 Group Details: Details or Add

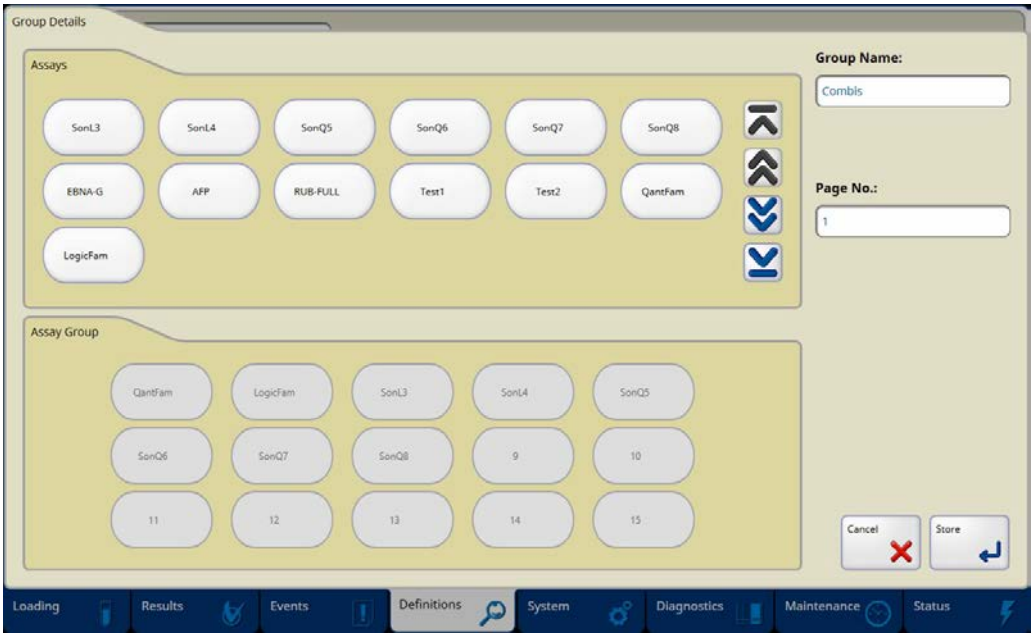


*Figure 6–73: **Group Details** display*

Function	Description
Assay Selection	Shows all available assays (unless they are prevented by usage). Tap on the assay button to assign it to the group.
Assay Group	The ***Assay Group*** shows the name of all assigned assays (up to 15).
Group Name	Name of the assay group. The assay group name must be unique.
Page Number	Used to display the groups in a specific order in the ***Group*** page. This field is mandatory and must be unique.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.3.

Table 6–93: Functions

6.8.4 Sub Category Rerun Matrix

In the subcategory ***Rerun Matrix***, there is the possibility to indicate, modify or generate the rerun rules.

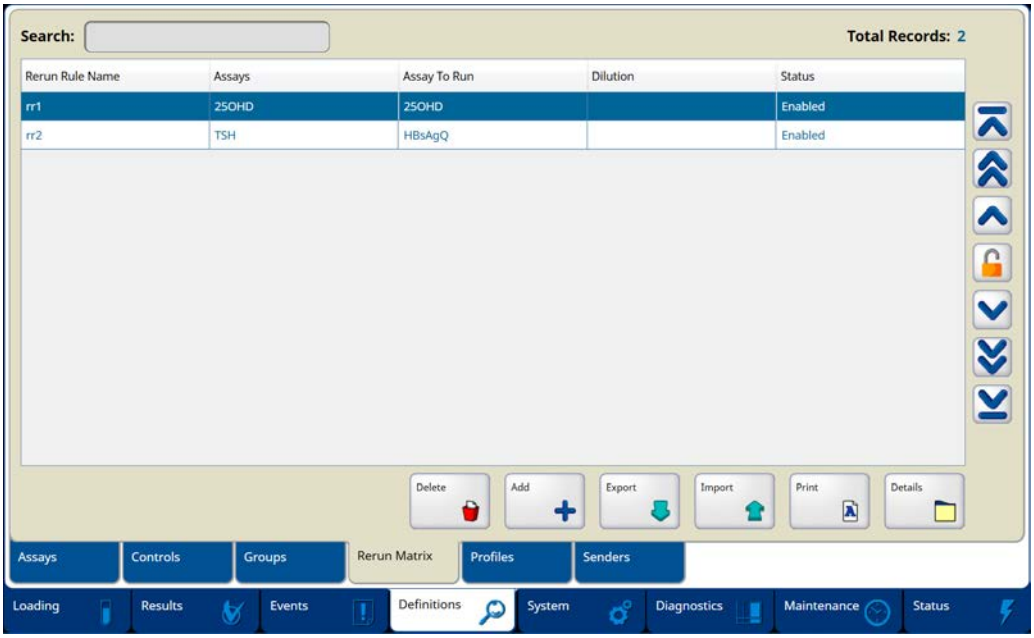


*Figure 6–74: Sub category **Rerun Matrix***

Function	Description
Delete	Deletes one or more selected rerun rules (see chapter 6.6.1.3).
Add	Shows the ***Rerun Rule Details*** display to add a new rerun rule (see chapter 6.8.4.1).
Export	Exports one or more selected rerun rules to a file.
Import	Imports one or more selected rerun rules from a file.
Details	Shows the ***Rerun Rule Details*** display to show or edit the selected rerun rule (see chapter 6.8.4.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–94: Functions of the **Rerun Matrix** sub category*

Column	Description
Rerun Rule Name	Shows the name of the rerun rules. The rerun rule name must be unique.
Assays	Shows the assay(s) that shall trigger the rule.
Assay To Run	Shows the assay that is launched if the conditions are satisfied.
Dilution	Dilution factor assigned to the assay to be run.
Status	Shows the status (***Enabled or Disabled***) of the rerun rule.

Table 6–95: Columns of the rerun matrix table

6.8.4.1 Rerun Rule Details: Details or Add

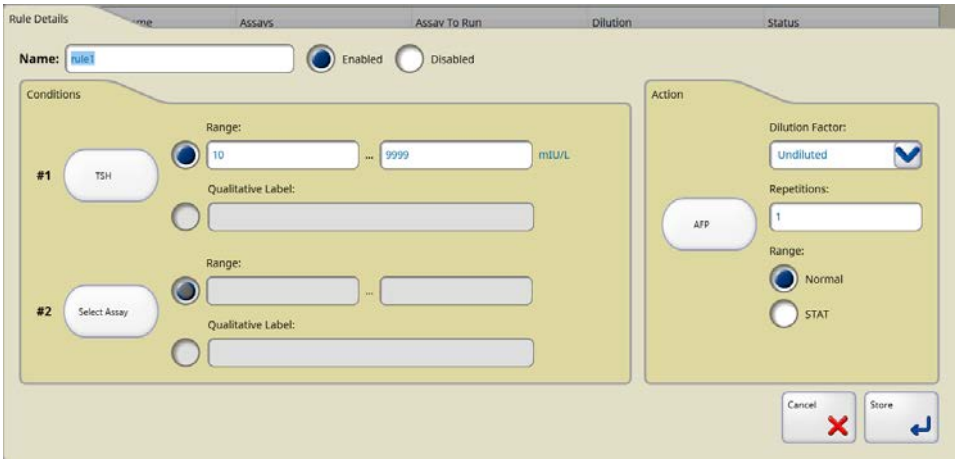


*Figure 6–75: **Rerun Rule Details** display*

Function	Description
Name	Name of the rerun rule. The rerun rule name must be unique.
Enabled / Disabled	Allows disabling a rerun rule without deleting it.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

Table 6–96: Functions

Conditions Group

Function	Description
1st Assay	Mandatory assay for the rerun rule. ***Assay 1*** Tap on the button to open a selection dialog. Pick up an assay in this dialog. ***Range 1*** Specifies the low and/or high limit of the condition range. If empty the **LIAISON® XS** software will treat this as “do not care” and consider this condition as always true. ***Qualitative Label 1*** Specifies the qualitative label of the assay. If empty the **LIAISON® XS** software will treat this as “do not care” and consider this condition as always true.
2nd Assay	Optional assay for the rerun rule. ***Assay 2*** Tap on the button to open a selection dialog. Pick up an assay in this dialog. ***Range 2*** Specifies the low and high limit of the condition range. If empty the **LIAISON® XS** software will treat this as “do not care” and consider this condition as always true. ***Qualitative Label 2*** Specifies the qualitative label of the assay. If empty the **LIAISON® XS** software will treat this as “do not care” and consider this condition as always true.
And	If both assays are defined, both conditions must be fulfilled.

*Table 6–97: Functions of the **Conditions** group*

NOTE If both first and second assay are defined, both conditions must be fulfilled.

NOTE If the result falls outside the assay range, the assay range limit is used to evaluate the rerun rule.

Actions Group

Function	Description
Dilution Factor	***Dilution Factor*** assigned to the assay.
Repetitions	Defines the number of times that assay shall be run for that sample.
Priority	Whether the rerun rule is to be scheduled with ***Normal*** or ***STAT*** priority.
Assay	Tap on the button to open a selection dialog. Pick up an assay (never run assays are excluded) in this dialog.

*Table 6–98: Functions of the **Actions** group*

NOTE

Tests that have been started via a Rerun Rule will not be evaluated against any Rerun Rule.

Samples, that have been erroneously removed while they were displayed as active, may not trigger a Rerun Rule evaluation even after reloading.

NOTE

The rerun rule evaluation will not be performed if the result of one of the two conditions is archived (manually or automatically) before the result of the other condition is done.

NOTE

The rerun rule is effective only if it was stored as enabled before the start of the involved tests.

6.8.5 Sub Category Profiles

In the subcategory ***Profile***, there is the possibility to arrange several assays as a profile. If the user assigns assays to samples, they can select a profile instead of all affected assays. In this way, it is possible to simplify recurrently test arrangements.

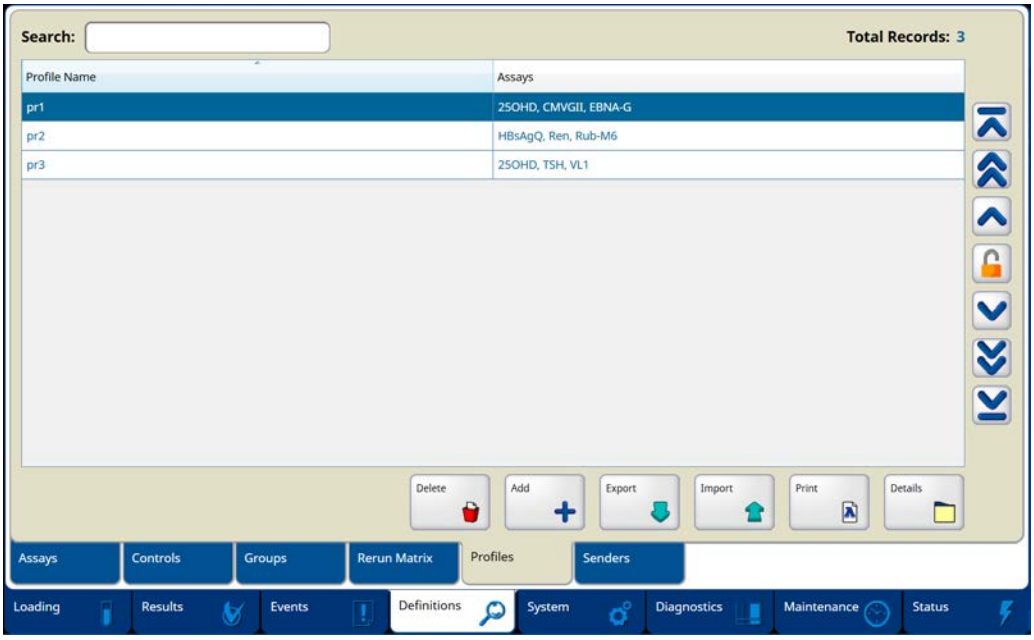


*Figure 6–76: Sub category **Profiles***

Function	Description
Delete	Deletes one or more selected profiles (see chapter 6.6.1.3).
Add	Shows the ***Profile Details*** display to add a new profile (see chapter 6.8.5.1).
Export	Opens the ***Export*** display to export one or more entries to a file (see chapter 6.6.1.1).
Import	Imports a assay profile from a file.
Details	Shows the ***Profile Details*** display to show or edit the selected profile (see chapter 6.8.5.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–99: Functions of the **Profiles** sub category*

Column	Description
Profile Name	Shows the name of the profile.
Assays	Shows all assigned assays.

Table 6–100: Columns of the profiles table

6.8.5.1 Profile Details: Details or Add

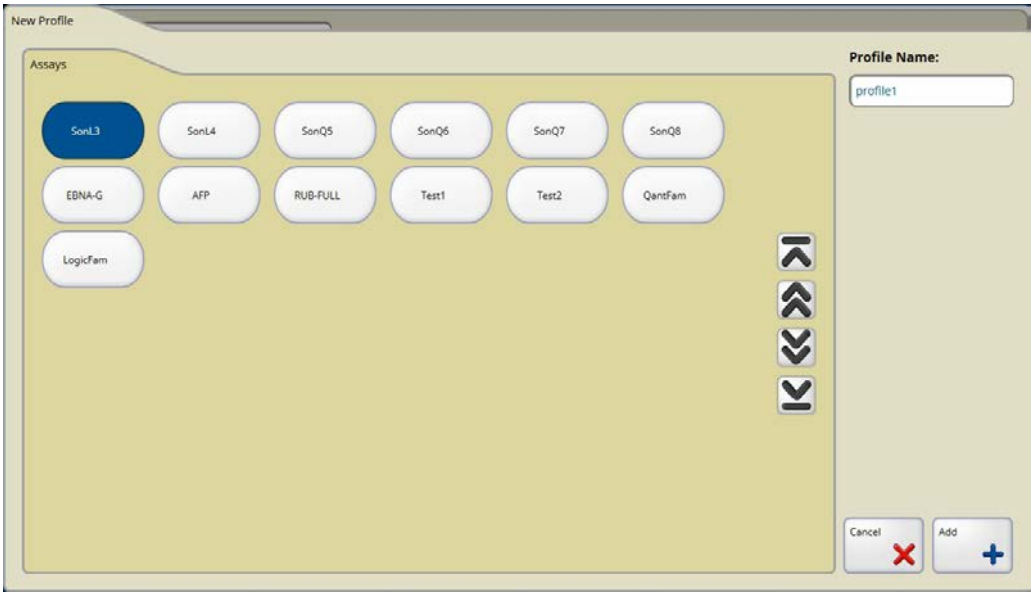


*Figure 6–77: **Profile Details** display*

Function	Description
Assays	Shows all assigned assays
Profile Name	Name of the profile. The assay profile name must be unique.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–101: Fields of **Profile***

6.8.6 Sub Category Senders

In the subcategory Sender, it is possible to store information about the sample source.

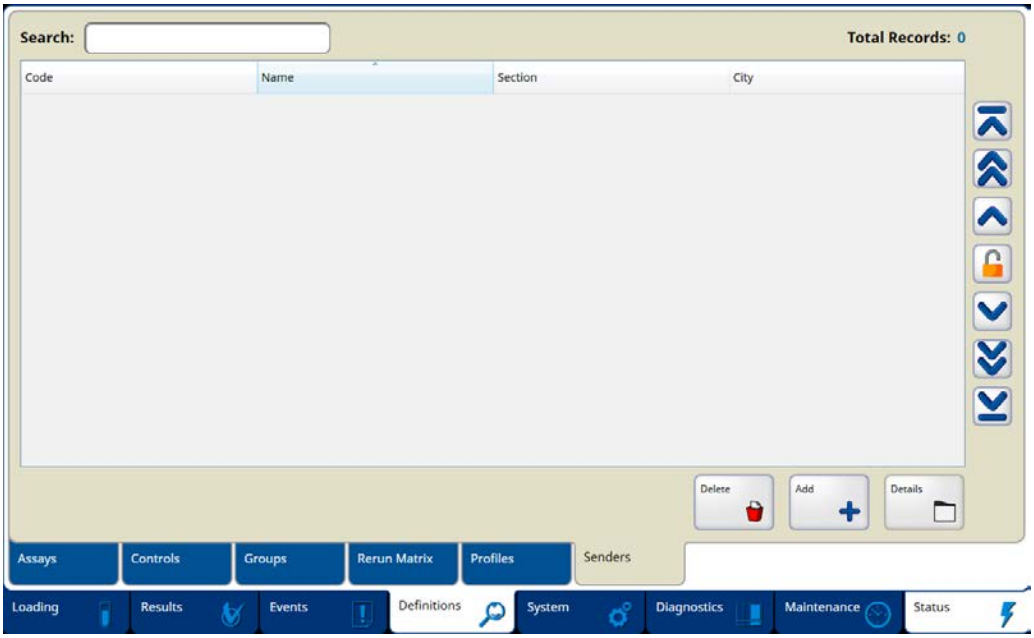


Figure 6–78: Sub category Senders

Function	Description
Delete	Deletes one or more selected sender (see chapter 6.6.1.3).
Add	Shows the ***Sender Details*** display to add a new sender.
Details	Shows the ***Sender Details*** display to show or edit the selected sender.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

*Table 6–102: Functions of the **Sender** sub category*

Column	Description
Code	Code of the doctor.
Name	Name of the doctor.
Section	Department
City	Address of the doctor - city.

Table 6–103: Columns of the sender table

6.8.6.1 Sender Details: Details or Add

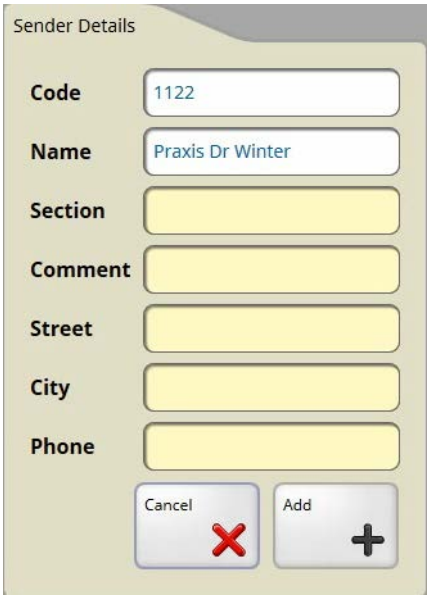


Figure 6–79: Sender Details

Function	Description
City	Address of the doctor - city.
Code	Code of the doctor.
Comment	Comment to the entry.
Name	Name of the doctor.
Phone	Telephone number of the doctor.
Section	Department
Street	Address of the doctor - street.
Cancel	Close the screen.
Add	Shows the ***Sender Details*** display to add a new sender.

Table 6–104: Functions

6.9 Main Category System

The main category ***System*** allows the user to adapt the **LIAISON® XS** system to specific circumstances and needs.

6.9.1 Sub Category Account

The subcategory ***Account*** can be used to manage the system accounts to access the software and its functionalities.

The access (edit/visualize) to specific functionalities and pages depends on the Access Rights associated to each account.

All privileges available for a given Access Right level are also available to Access Right with higher level, with the exception of the Patient Privilege (see chapter 6.9.1.2).

The ***Current User*** tab enables to change the user's own password or to log off the **LIAISON® XS** software.

The ***Users*** tab enables to add a new user or to change the rights of a user.

6.9.1.1 Current User

Shows the current user. The password of the current user can be changed here.

Figure 6–80: Sub category Account

Function	Description
Name	The ***Name*** of the currently logged in user.
Access Rights	The ***Access Rights*** of the currently logged in user (see chapter 6.9.1.2).
Change Password	Opens the Change Password Dialog and allows the user to change his own password.
Logout	Allows current user to log off. If the user logs out while the instrument is running, the run will continue. User intervention on the hardware side (covers, containers...) will be traced, but not associated with a specific user.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

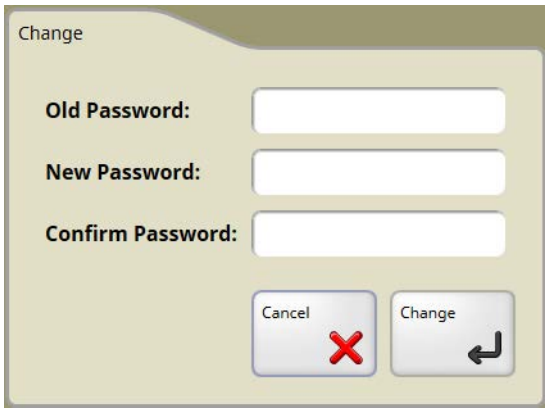


Figure 6–81: Change Password

Change Password

Function	Description
Change	Applies the change of the password. Enabled only if all the fields have a valid value inserted. The new and the old password must not be identical.
Old Password	Each character is displayed as “*” and not logged as plain text.
New Password	Field for the new password. Each character is displayed as “*” and not logged as plain text. Password shall be from 8 to 20 characters long, shall only contain alphanumerical and the following character !”#$%&'()*+,-./:;<=>?@[\]^_`{|}~ The password is case sensitive.
Confirm Password	Field to re-enter the new password. Each character is displayed as * and not logged as plain text.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–105: Functions of the **Change password** dialog*

6.9.1.2 Users

The purpose of the Users tab is to add a new user or change the rights of users with lower Access Rights than the user currently logged in.

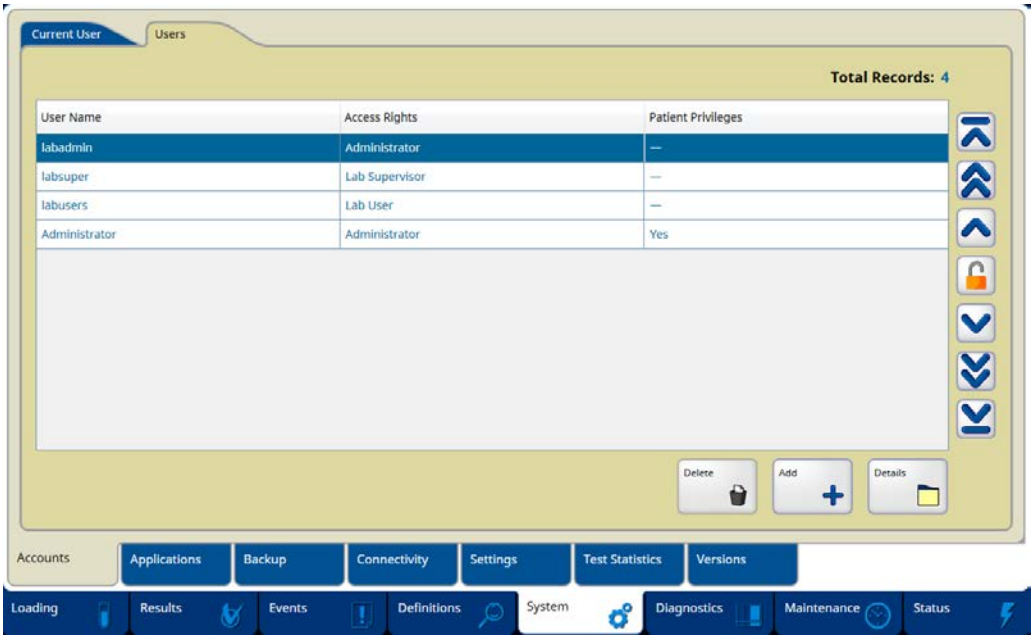


Figure 6–82: Tab Users

Function	Description
Delete	Deletes the selected users after confirmation popup.
Add	Opens the ***Details Dialog*** for a new user.
Details	Opens the Details Dialog of the currently selected user.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

*Table 6–106: Functions of the **Accounts** sub category*

Function	Description
User Name	Name of the user used to login. The user name must be unique. Any sequence of alphanumeric characters (spaces are not allowed) can be entered as a user name. The user name is not case sensitive.
Access Rights	Shows privilege level of the user (3 levels).
Patient Privilege	Defines, if the user has the privilege (***Yes*** or ***No***) to view patient demographical data.
Standard button	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

*Table 6–107: Functions of the User **Setup display***

6.9.1.3 Details Users

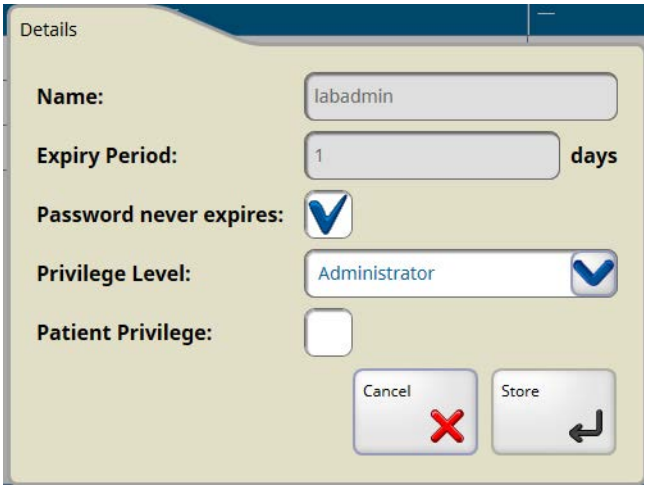


Figure 6–83: Details User

Function	Description
Name	Enabled only for new users, disabled if an existing user is changed.
Expiry Period	Time during which the password remains unchanged. After this interval the password expires and must be changed.
Password never expires	If checked, the user does not have to change the password
Privilege Level	Available values are: • Lab User • Lab Supervisor • Administrator If the edited user is currently logged in user, then all levels below and equal to the current user are displayed. Else, only the levels below the currently logged user are displayed.
Patient Privilege	Gives permissions to the user to see and edit the patient demographic data.
Standard button	For standard buttons (e.g. arrow buttons, lock, Print) see chapter 6.3.

Table 6–108: Details User

6.9.2 Sub Category Applications

The subcategory Applications can be used to start additional applications.

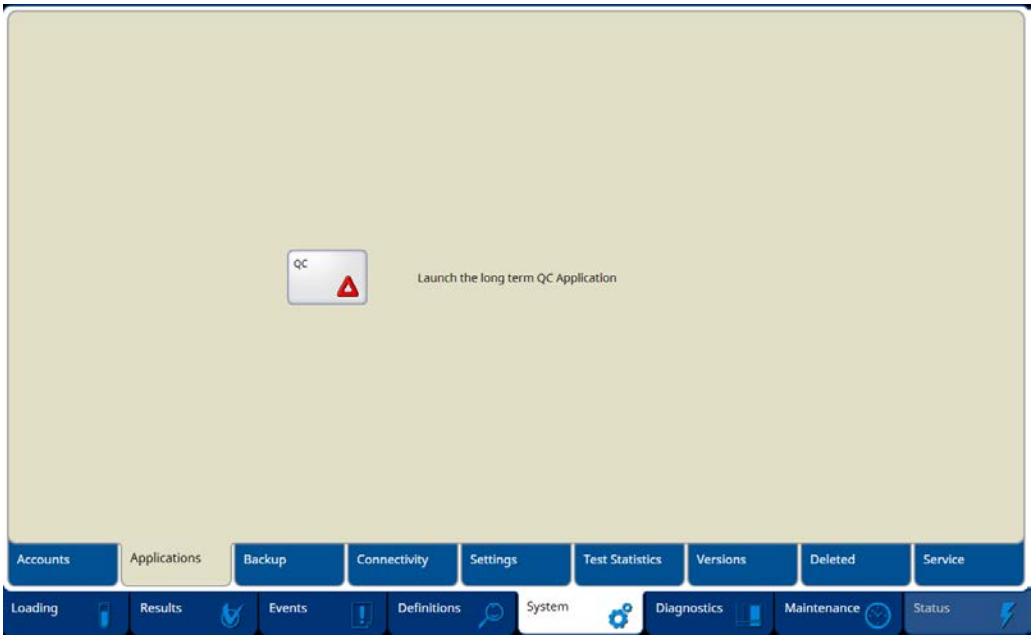


*Figure 6–84: Sub category **Applications***

Function	Description
QC	Starts the long term quality control (**QCStats**) application. Opens the **QCStats** Software in the foreground and keeps the **LIAISON® XS** Software open in the background.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–109: Functions of the **Applications** sub category*

6.9.3 Sub Category Backup

The sub category ***Backup*** provides the option to make a backup of the **LIAISON® XS** system files (e.g. database and settings files).

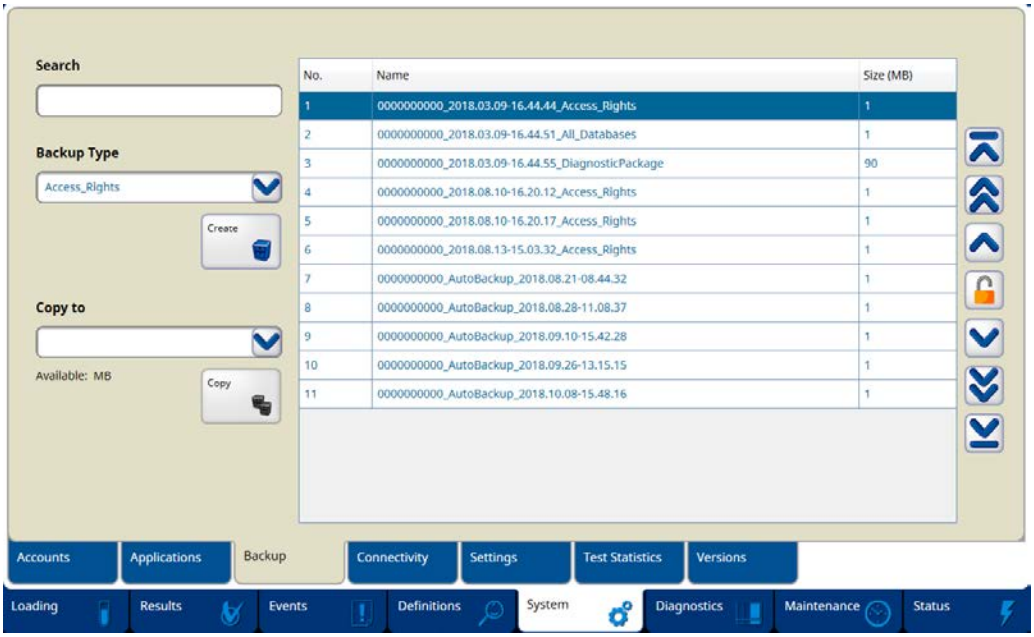


*Figure 6–85: Sub category **Backup***

NOTE

The backup function is only available while the **LIAISON® XS** system is in ***Standby***, ***Ready***, ***Halted***, ***Disconnected*** status, otherwise all controls and buttons are disabled.

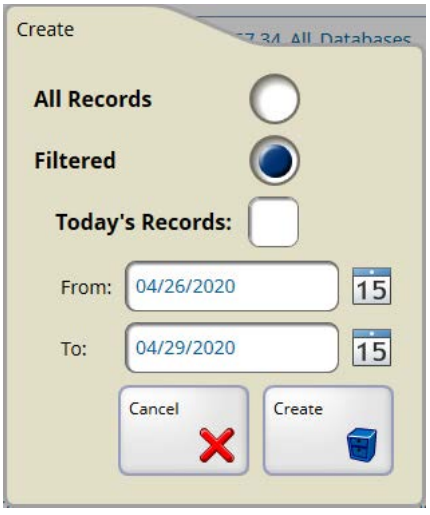


Figure 6–86: Time based filter dialog

Function	Description
Information line	Shows the status of the **LIAISON® XS** system. Additionally the software shows a second line with information about the creation or copying progress (e.g. Backup finished with success).
Backup Type **Create**	Create Allows user to create a new backup. 1. Select the backup type: • ***Access_Rights***: Saves only files to determine the defined accounts. • ***All***: Saves all files relevant for the software (e.g. Databases, Logs). • ***All_Database***: Saves all databases for results, events, and system settings. • ***TroubleshootingShort***: Saves a selection of files useful for a general troubleshooting. • ***TroubleshootingComplete***: Saves all files useful for troubleshooting activities. • ***IoT***: Saves a selection of files useful for IoT troubleshhoting. • ***LIS***: Saves all files generated by host communication and related settings. • ***Results***: Saves a file called FinishedJobs.txt that contains the cumulative history of successfully completed tests. • ***QC***: Saves a selection of files useful for troubleshooting of QC Software. • ***Pre-SW_Installation***: Saves a selection of files useful for installation troubleshooting. 2. Press on the ***Create*** button. Upon selection of an applicable backup type, the dialog in figure 6–86 is opened to allow the user to apply a time based filter. The selected backup type will include files on the basis of the selected period.
Copy to **Copy**	Allows user to copy a backup file on an external storage device, or a network path. 1. Select the external storage device, or network path in the ***Select a Backup to Copy*** list. 2. Select an existing backup file in the backup file table. 3. Press on the ***Copy*** button.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–110: Functions of the **Backup** sub category*

Column	Description
No.	Number of the backup.
Name	Name of the backup file.
Size	Needed storage space on external device.

Table 6–111: Columns of the backup table

NOTE

It is recommended to periodically (e.g. weekly) create and copy a Database backup on an external storage device using the functions from Table 6–110, in order to recover the database if needed.

6.9.4 Sub Category Connectivity

The sub category ***Connectivity*** is used to configure the connection between the **LIAISON® XS** system and ***LIS*** and ***IoT***.

The connection between the **LIAISON® XS** system and a LIS enables the interchange of test requests and test results. Laboratory Information System (LIS) is often called a Host.

Note: For details about the interface protocol ask local service support.

The connection between the **LIAISON® XS** instrument and a ***IoT*** allows the transmission of telemetry data and files to support troubleshooting activities. It also allows to receive, upon request, instrument dedicated files (e.g. Instructions for Use, Assay Protocols, User Manual, see chapter 6.3.1).

NOTE

Before enabling the interface with IoT, ensure that Internet connection is available, otherwise a PC reboot may be necessary.

NOTE

In the associated events (reported in chapter 8), IoT may be reported as DoT, DiaSorin of Things.

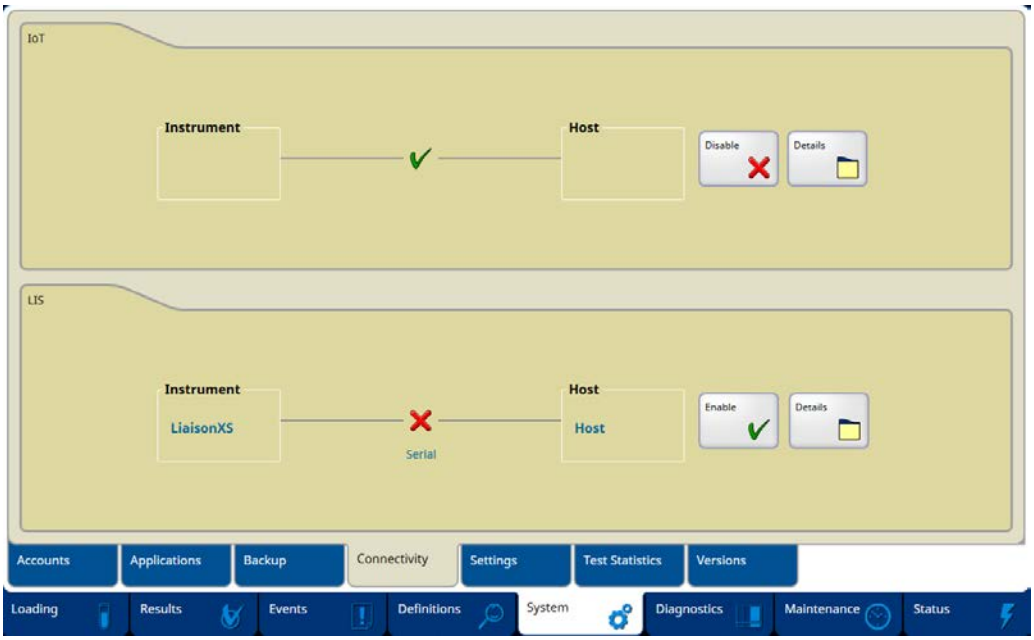


*Figure 6–87: Sub category **Connectivity** tab*

Function	Description
Host	Name assigned to the host.
Instrument	Name assigned to the instrument. It is used to verify that a transmission is intended for this instrument.
Enable/Disable	Enables/disables the connection with a host or the interface with IoT
Details	Shows and allows to customize the details of IoT/LIS connection

*Table 6–112: Functions of the **Connectivity** tab*

6.9.4.1 IoT Details

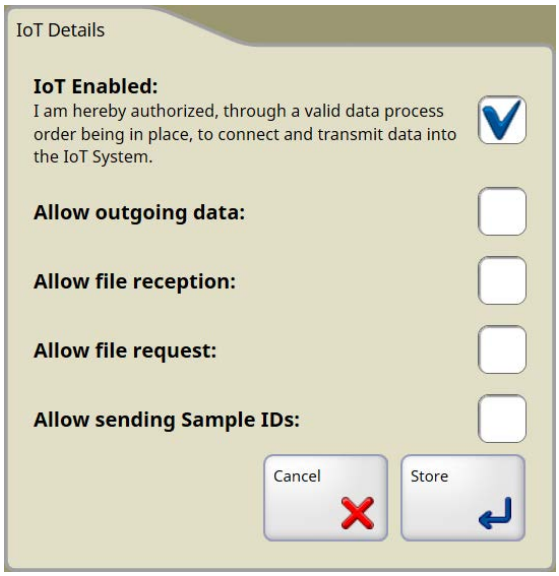


Figure 6–88: IoT Details

Function	Description
Cancel	Closes the dialog and discard all changes.
Store	Closes the dialog and stores all changes.

Table 6–113: Iot details buttons

Function	Description
IoT Enabled: ***I am hereby authorized, through a valid data process order being in place, to connect and transmit data into the IoT System.***	Switches the State to Enabled/Disabled
Allow outgoing data	If enabled, transmission of telemetry data (any kind of data besides File Transmission) is enabled.
Allow file reception	If enabled, the instrument can retrieve files from DiaSorin online repository (e.g. Instructions for Use, Assay Protocols, Manuals).
Allow file request	If enabled, IoT can request files from the instrument, including troubleshooting collections for a given time frame.
Allow sending Sample IDs	If enabled, Sample IDs (included in events and telemetry data) are transmitted. If disabled, the Sample ID is not transmitted.

Table 6–114: Iot details options

6.9.4.2 LIS Details

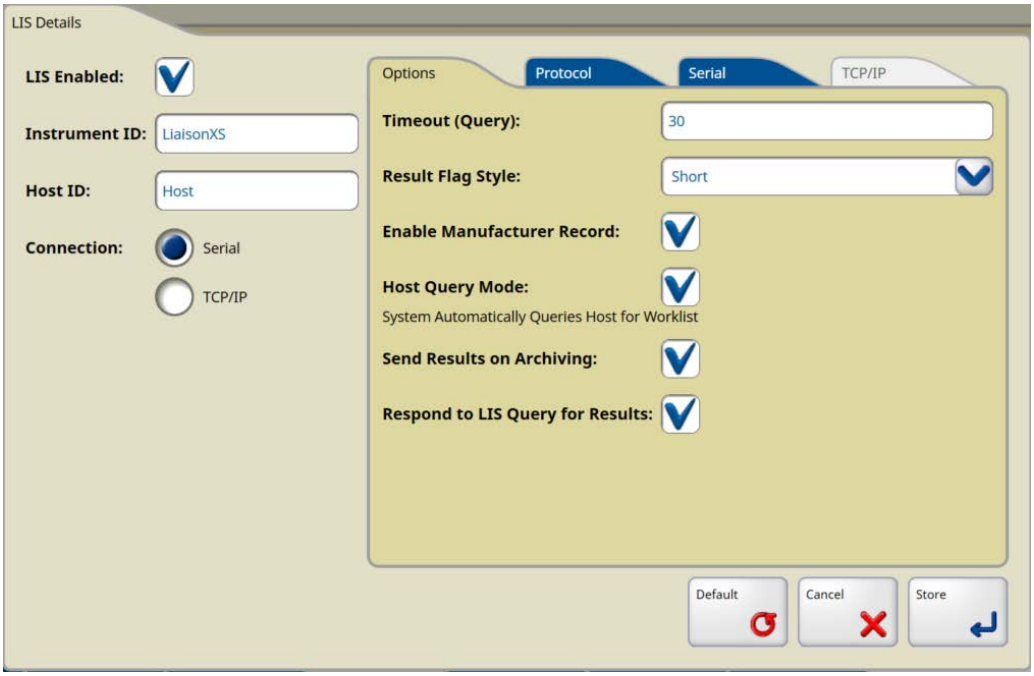


Figure 6–89: LIS Details

Function	Description
LIS Enabled	Switches the state to Enabled/Disabled
Instrument ID	Defines the instrument name
Host ID	Defines the host name
Connection	**Serial** and **TCP/IP**
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

Table 6–115: LIS Details

Options

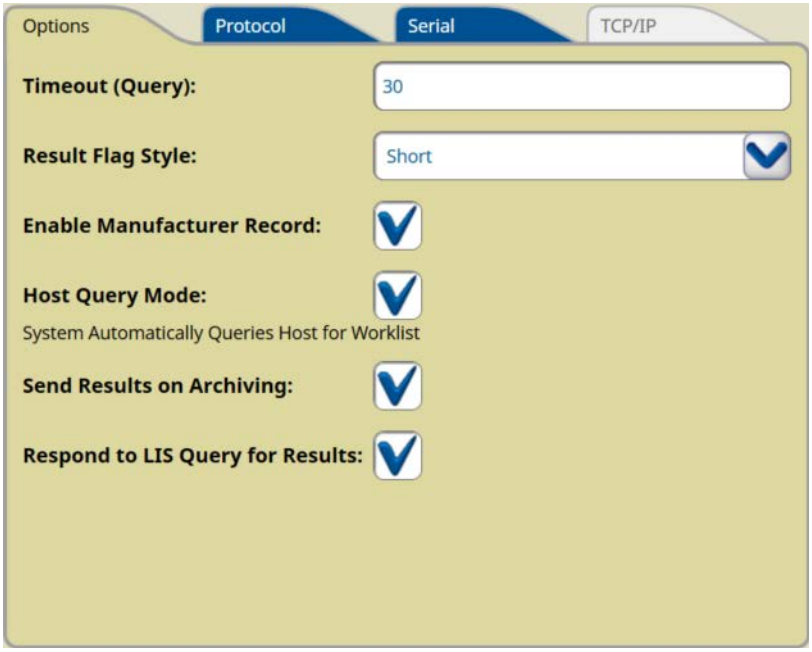


Figure 6–90: Options

Function	Description
Timeout (Query)	Countdown value for the ***Download Orders*** dialog.
Result Flag Style	Defines how the flags are transmitted: • Short: only the symbol is transmitted • Long: the flag verbose description is transmitted.
Enable Manufacturer Record	Sends additional information (reagent kit no., reagent expiration date, reagent lot no., calibration ID, sample rack lane, sample position in the rack) to the host.
Host Query Mode	Scanned and manually entered tube barcodes cause a request for tests to the host.
Send Results on Archiving	When a result is archived, it is automatically send via LIS.
Respond to LIS Query for Results	The instrument responds to queries for results.

Table 6–116: Functions of the Options tab

6.9.5 Sub Category Settings

The sub category ***Settings*** is used for run mode definitions, general and localization settings. The information reported are not editable, to edit them press the button ***Edit***.

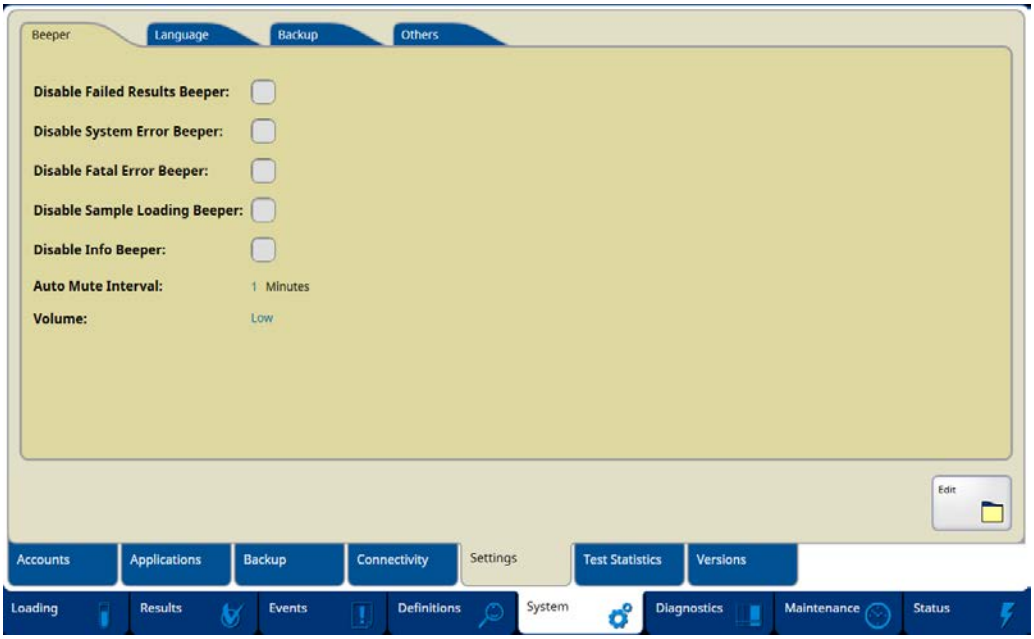


Figure 6–91: Sub category Settings

Function	Description
Edit	Open the Edit Settings to change settings.

Table 6–117: Function of the sub category Settings

Field	Description
Beeper	Shows the beeper settings.
Language	Shows languages and formats (e.g. time and date format).
Backup	Shows the auto-backup options.
Others	Shows general settings (e.g. automatic procedure times, processing mode).

Table 6–118: Groups of the sub category Settings

Beeper

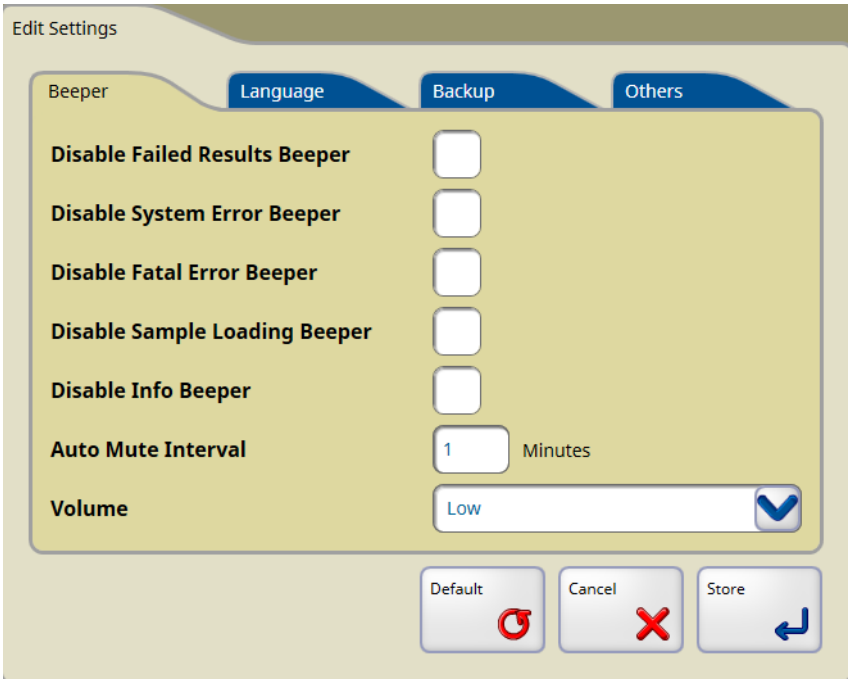


Figure 6–92: Beeper Settings

Function	Description
Disable Failed Results Beeper	Disable the beeper for single occurrence events (e.g. aborted tests).
Disable System Error Beeper	Disable the beeper for system error (e.g. resource availability events).
Disable Fatal Error Beeper	Disable the beeper for fatal error.
Disable Sample Loading Beeper	Disable the beeper when loading a sample rack.
Disable Info Beeper	Disable the beeper for info events (e.g. offline reagents events).
Auto mute Interval...minutes	Defines a time span, after which the audible alarm will be switched off automatically. If set to “0” then the alarms will not be switched off.
Volume	Defines the volume of the audible alarm. Values: High, Medium, Low.

Table 6–119: Beeper

Language

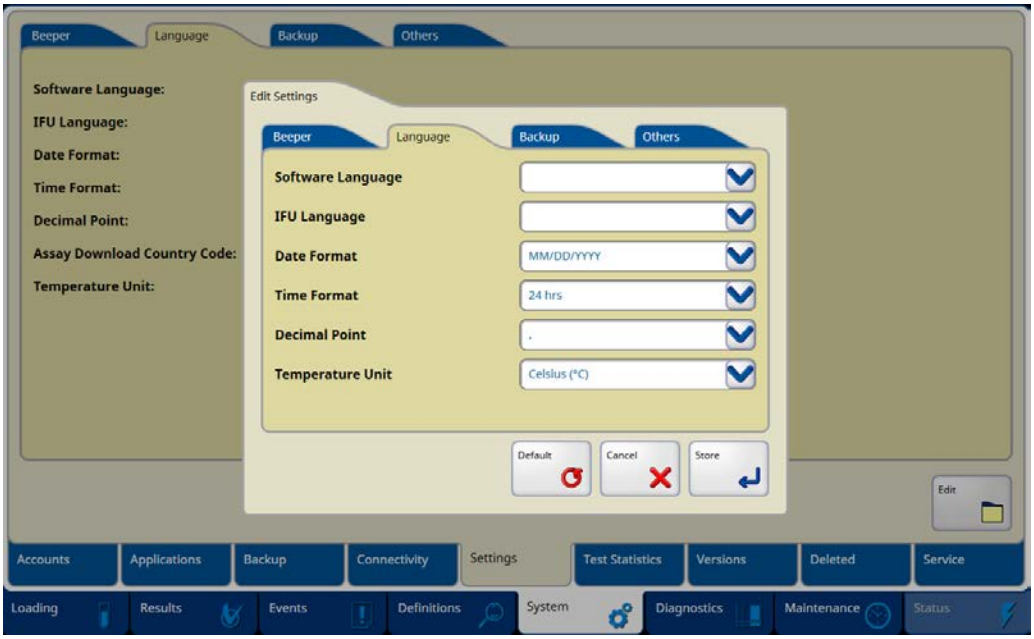


Figure 6–93: Language Settings

Function	Description
Software Language	The language of the software.
IFU Language	The language preference that is used by the system to download the IFU. Note: IFU are provided in the preferred language only if such language is available for the defined country, otherwise they will be provided in one of the available languages for the defined country.
Date Format	Date format used in the software, among the following options: • MM/DD/YYYY • DD.MM.YYYY • YYYY-MM-DD
Time Format	Date format used in the software, among the following options: • 24 hrs • 12 hrs AM-PM
Decimal Point	Set the type of the decimal point, either “.” or “,”.
Temperature Unit	Temperature information can set in either Celsius or Fahrenheit.

Table 6–120: Language

NOTE Any change applied in the Language tab becomes effective after the application restart.

NOTE The System Country Code is visualized in Language tab and cannot be edited.

Backup

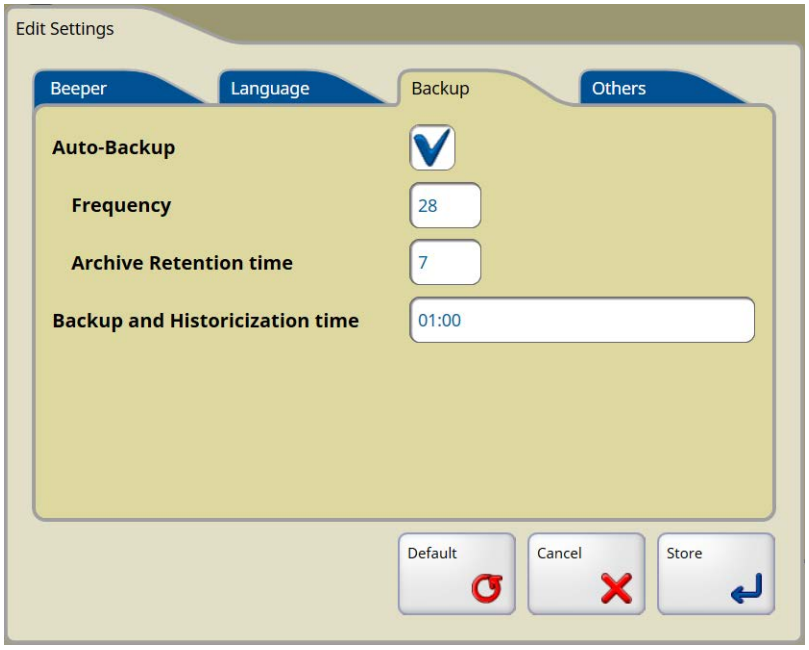


Figure 6–94: Sub category Settings- Backup

Function	Description
Auto-Backup	If unchecked, all items below are disabled.
Frequency	The frequency in days when Auto Backup is performed, i.e. when old Archived results are moved to the History database and they are accessible in the History page (see chapter 6.6.9).
Archive Retention Time	If results have been archived since a number of days equal or greater than the defined days, they are moved from Archived to History.
Backup and Historicization Time	After this time of the day, in the current time settings, the system creates a backup copy of the Archive and History databases and then moves the results from Archived to History as soon as the system is not in Initializing, Running, Maintenance. If a network path is defined (ask to the authorized service technicians to define it), the system will save a copy of the same backup on it.

Table 6–121: Backup

Others

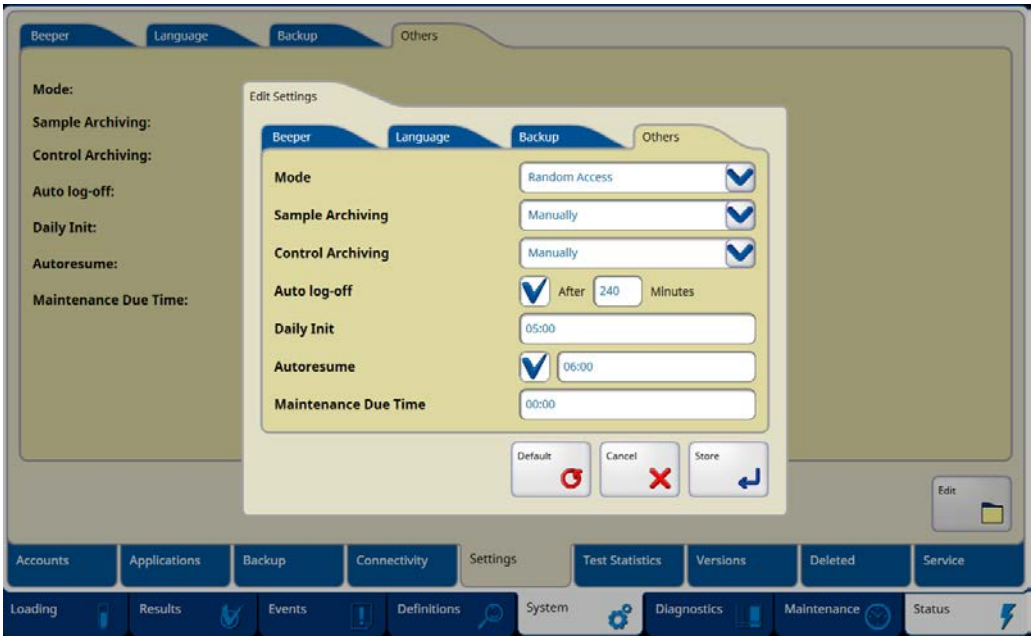


Figure 6–95: Sub category Settings- Others

Function	Description
Mode	Shows ***Random Access*** or ***Batch***, with the following meaning: • in Random Access, the system will schedule first all samples from one rack in order to release it as soon as possible, then move to the next rack • in Batch, the system will schedule all sample loaded in the sample area in order to complete the whole batch as soon as possible.
Sample Archiving	Allows selecting if patient sample/calibrator results are manually or automatically moved to the Archived page.
Control Archiving	Allows selecting if control results are manually or automatically moved to the Archived page.
Auto log-off after...minutes	If checked, the auto log-off time field unlocks, allowing setting a time interval for auto log-off. After this time is passed without user interaction, the log-in page will be prompted.
Daily Init	Time of the daily initialization.
Autoresume	Time at which the system switches from standby to ready and primes resources (i.e system liquid, starters and wash buffer)
Maintenance Due Time	Time when a maintenance task becomes due.

Table 6–122: Others

NOTE It is recommended to set the Autoresume time at least 30 minutes later than the Daily Init time

6.9.6 Sub Category Test Statistics

The sub category ***Test Statistics*** can be used to get information about which among the started tests are failed or successfully completed.

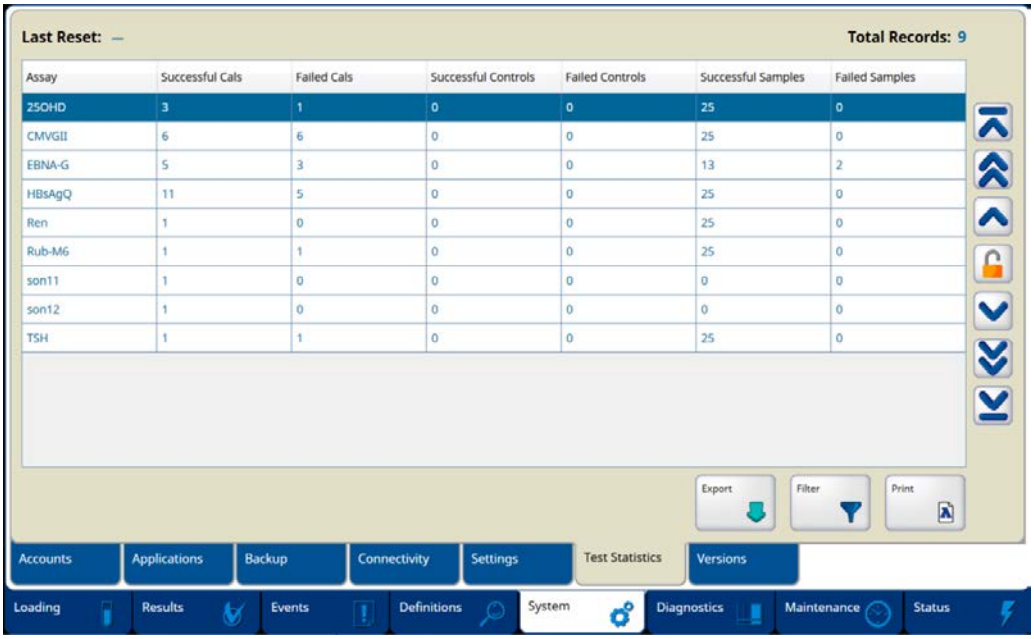


Figure 6–96: Sub category Test Statistics

Function	Description
Export	Exports the test statistics to a file.
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–123: Functions of the **Test Statistics** tab*

Column	Description
Assay	Name of the assay.
Successful Cals + Failed Cals	Number of successfully or unsuccessfully performed calibrator determinations.
Successful Controls + Failed Controls	Number of successfully or unsuccessfully performed control determinations.
Successful Samples + Failed Samples	Number of successfully or unsuccessfully performed patient sample determinations.

Table 6–124: Columns of the test statistics table

6.9.7 Sub Category Versions

The sub category ***Versions*** is used to inform the user about the **LIAISON® XS** software and the **LIAISON® XS** instrument firmware versions.

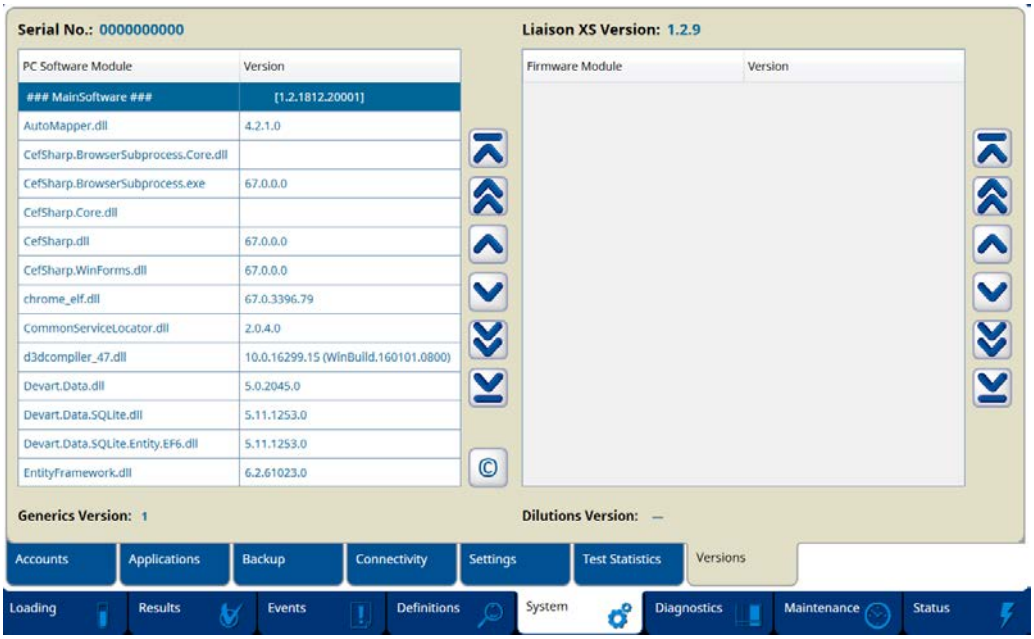


*Figure 6–97: Sub category **Versions***

Function	Description
Serial Number	Shows the serial number of the **LIAISON® XS** instrument.
LIAISON® XS *Version*	Shows the version of the current **LIAISON® XS** software version.
Copyright Button	Shows third party copyright.
Generics Version	Number of version of the generics.
Dilutions Version	Number of version of the dilution.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–125: Functions of the **Versions** sub category*

Column	Description
PC Software Module	Shows the name of several modules of the current **LIAISON® XS** software.
Firmware Module	Shows the name of the modules of the **LIAISON® XS** instrument.
Version	Shows the module version.

Table 6–126: Columns of the version tables

6.10 Main Category Diagnostics

In the main category Diagnostics and its subcategories, information about the **LIAISON® XS** system can be found.

CAUTION

Perform tasks from Diagnostics only guided by local support.

6.10.1 Sub Category Options

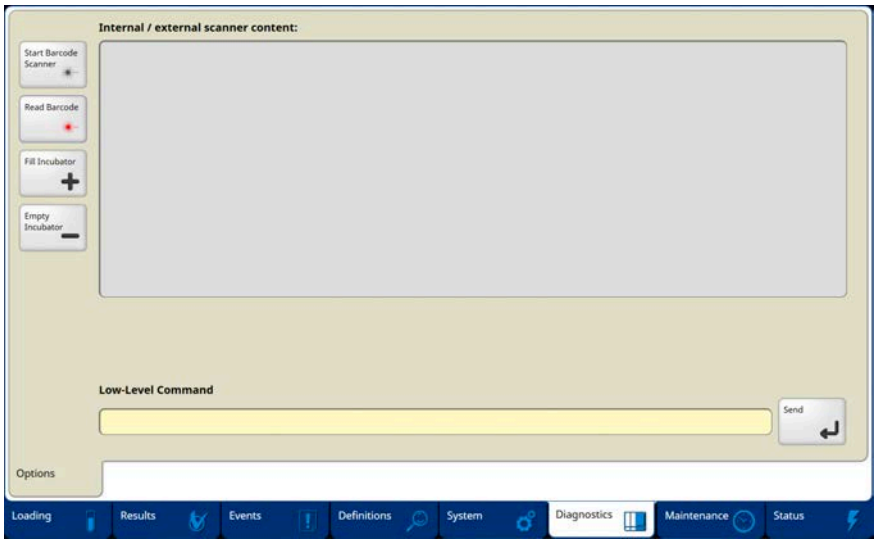


*Figure 6–98: Sub category **Options***

Function	Description
Start Barcode Scanner	Sample bay scanner on standby. May be used to switch on the scanner if the sample flap sensor is broken.
Read Barcode	Scanner ready to read. Clears the field "***Internal/external scanner content***" and enables it to accept the data read by the external barcode scanner.
Internal/external scanner content	Any Sample Rack insertion disables this field, clears and fills it with data read in the rack inserted
Fill Incubator	It fills the incubator with cuvettes. Enabled only in Status Ready.
Empty Incubator	Starts a command to empty the incubator. Enabled only in Status Ready.
Low-Level Command	Input option for commands to the instrument. Use the **Send** button to send the command.
Send	***Send*** low level command to the analyzer. This may bring the system in ***Not Initialized*** mode, to initialize the system press the button ***Leave.***
Printer is online/ offline	Reports the printer status as reported by the operating system.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–127: Functions of the **Options** sub category*

CAUTION

The function "Empty incubator" disposes the cuvettes present in the incubator without washing them in the Washer.

6.11 Main Category Maintenance

The main category ***Maintenance*** and its subcategories allow performing necessary maintenance tasks to obtain the system performance.

6.11.1 Sub Category Tasks

In the subcategory ***Tasks***, maintenance tasks can be managed or started. The individual maintenance tasks can be generated in such a way that they can be started either if required or on schedule. As soon as a scheduled maintenance task is due, this is indicated by a flashing ***Maintenance*** main category tab or ***Tasks*** subcategory tab.

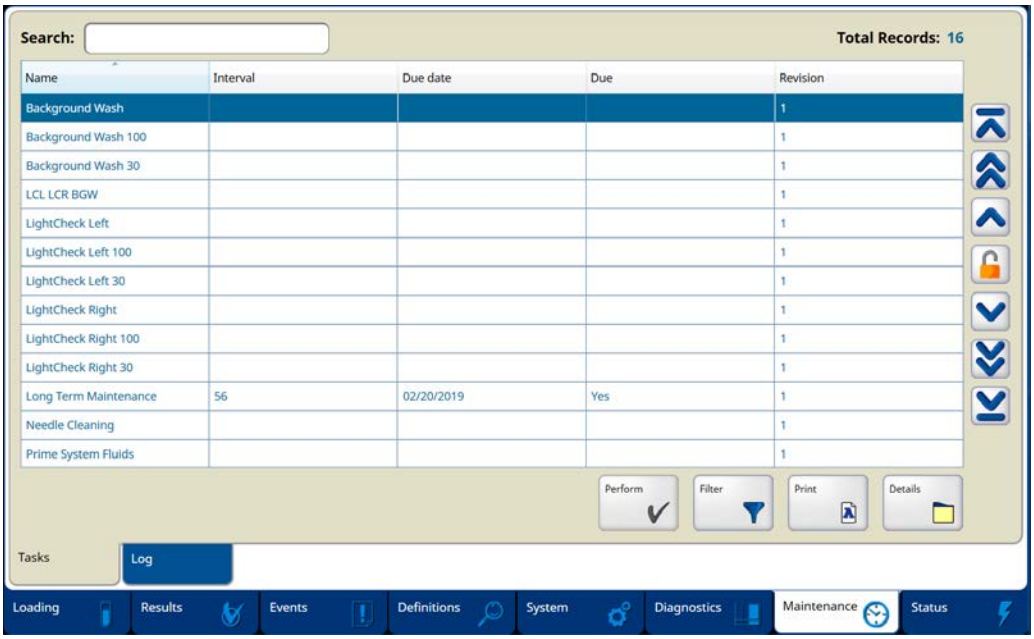


Figure 6–99: Sub Category Tasks

Function	Description
Perform	Opens the ***Perform Task*** dialog (see chapter 6.11.1.2) and starts the selected maintenance task. Follow the instructions on the dialogue. The ***Perform*** button is disabled if the selected maintenance task cannot start (e.g. when the system is in Halted)
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4)
Details	Shows details about a selected maintenance task (see chapter 6.11.1.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–128: Functions of the **Tasks** sub category*

Column	Description
Name	Name of the maintenance task.
Interval	Displays the interval for the maintenance task in days or nothing (‘As needed’) if there is no interval defined.
Due Date	Shows the date when the next run for the maintenance task is due. The cell is empty if interval is 'As Needed’.
Due	Shows if the task is due or not (“Yes” or nothing)

*Table 6–129: Columns of the **Tasks** table*

6.11.1.1 Maintenance Task Details

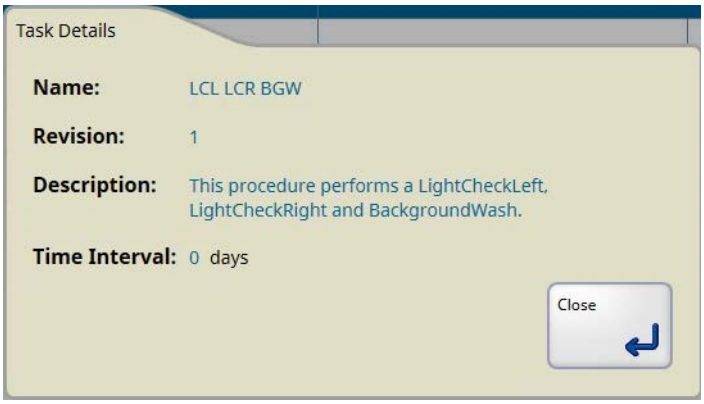


Figure 6–100: Maintenance Task Details

Column	Description
Name	Name of the maintenance task.
Revision	The Revision of the task
Description	Description of the task
Time Interval	Interval for the maintenance task in days

Table 6–130: Maintenance Task Details

6.11.1.2 Perform a Maintenance Tasks

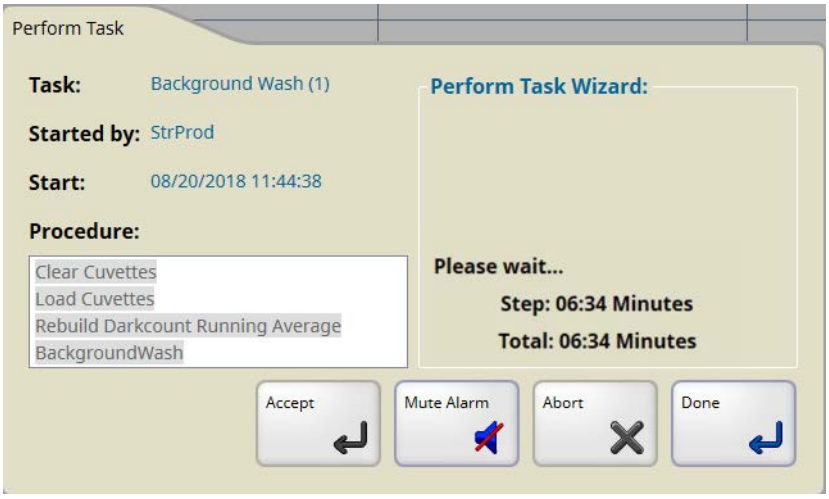


Figure 6–101: Perform Maintenance Tasks

Function	Description
Accept	To accept a selected message by clicking ***Accept*** button.
Mute Alarm	Switches off the instrument beeper.
Abort	Aborts the maintenance task procedure and closes the ***Perform Task*** display.
Done	This button is prompted after the last step is finished or in case maintenance task failed. Allows closing the ***Perform Task*** display.

*Table 6–131: Functions of the **Perform Task** display*

Function	Description
Task	The Name and Revision Index of the Task.
Started by	The Name of the user who started the Task.
Start	The Date and Time when the task was started.
Procedure	The complete procedure list.
Perform Task Wizard	Shows detailed information about the current performed step, including the time required to complete the ongoing step and the complete procedure.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–132: Functions of the **Perform Task** display*

6.11.2 Sub Category Log

The sub category Log shows a list with all maintenance task entries, either successfully or unsuccessfully performed.

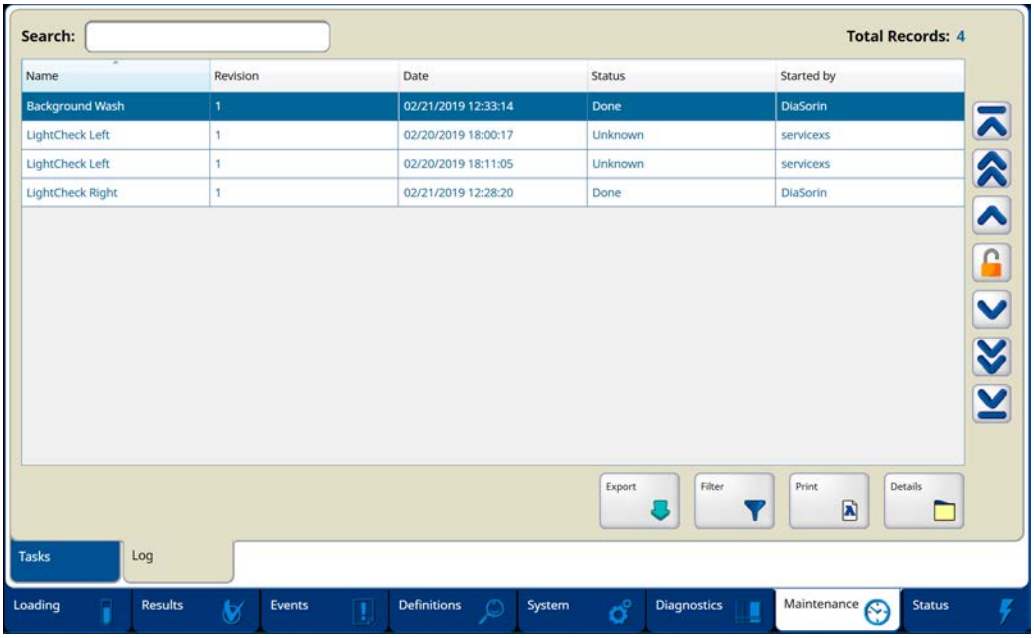


*Figure 6–102: Sub category **Log***

Function	Description
Export	Opens the dialog to export one or more selected maintenance log entries to a text file (see chapter 6.6.1.1).
Filter	Opens the ***Select Filter*** display (see chapter 6.6.1.4).
Details	Open the Details Sub Page of the currently task containing the following items: • The Name of the task • The Revision of the task • The Date & Time the task was started • The Status of the selected task • The User which started the task In addition the Details page contain per step the list of the measured replicates if any (see chapter 6.11.2.1).
Standard buttons	For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.3.

*Table 6–133: Functions of the **Log** sub category*

Column	Description
Name	Name of the maintenance task.
Revision	Revision number.
Date	Shows the date and time when the maintenance task was performed.
Status	Shows the result ***Done*** or ***Failed*** of the maintenance task.
Started by	Shows the name of the user who started the maintenance task.

*Table 6–134: Columns of the **Log** table*

6.11.2.1 Log Details

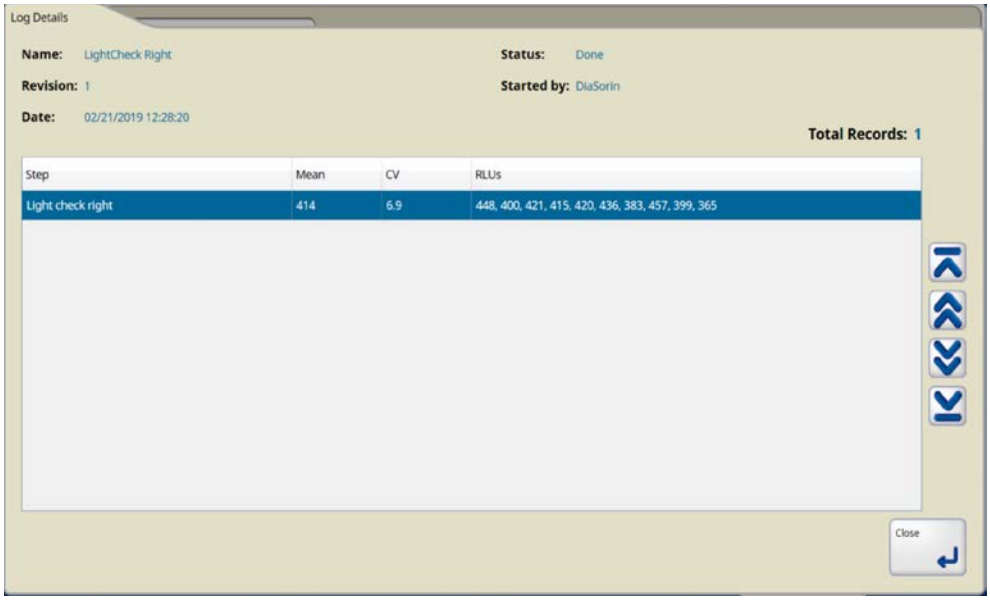


Figure 6–103: Log Details

Column	Description
Name	Name of the maintenance task.
Revision	Revision number.
Date	Shows the date and time when the maintenance task was performed.
Status	Shows the result ***Done*** or ***Failed*** of the maintenance task.
Started by	Shows the name of the user who performed the maintenance task.
Step*	Maintenance step.
Mean*	Mean value
CV*	Standard deviation
RLUs*	Measurement results.
* filled only if a measure step is performed	

Table 6–135: Log Details

6.12 Main Category Status

In the main category Status, the filling level of the different containers, bottles and waste containers can be accessed. Additionally, there is the possibility to check the temperatures of the individual modules. The loading of the system with cuvettes and disposable tips is also performed in this main category.

6.12.1 Sub Category Summary

In the sub category ***Summary***, the indication of the temperatures in the individual modules, the filling level of the different containers, bottles, waste container and the number of cuvettes and tips available are reported.

If a resource is not available (e.g. Absent, Depleted) main toggle ***Status*** and sub toggle ***Summary*** flash.

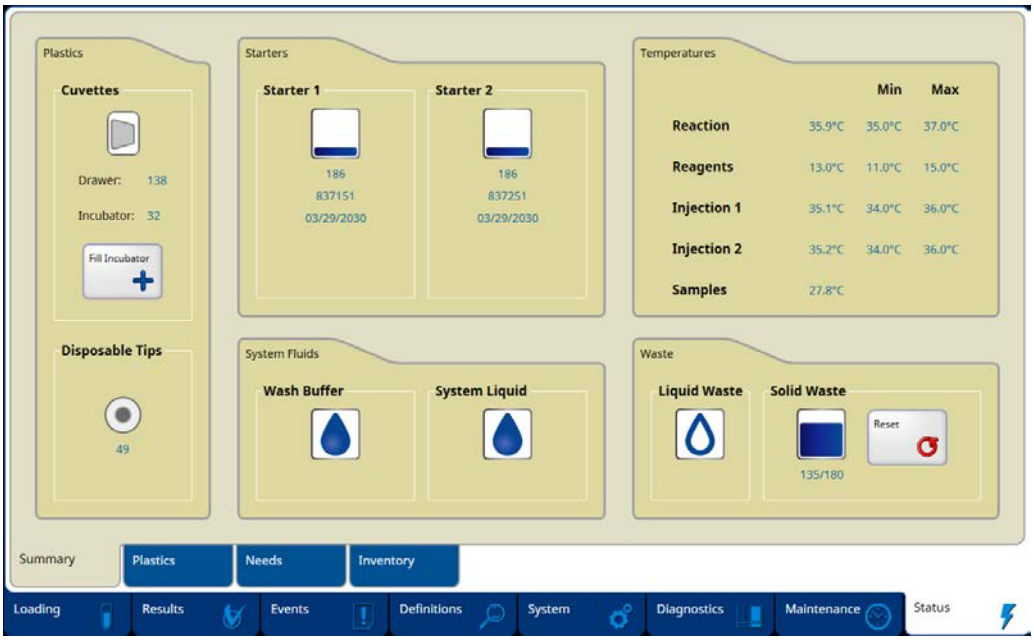


Figure 6–104: Sub category Summary

Plastics Group - Cuvettes

Shows the number of cuvettes in the drawer and in the incubator.

Function	Description
Drawer	Displays the number of cuvettes in the cuvette trays. The number is given in brackets if the drawer is not inserted or not assigned.
Incubator	Displays the number of not used, clean cuvettes in the Incubator.

Table 6–136: Function Plastics - Cuvettes

Symbol	Meaning
	• Cuvettes in the drawer and in the incubator are available and above the availability threshold
	• Absent Not detected by the presence sensor e.g. open drawer
	• Depleted, no cuvette available • Less than the availability threshold of cuvettes available in the drawer ***Availability Threshold Cuvettes*** = 2

Table 6–137: Symbol Consumables Cuvettes

Plastics Group - Tips

Shows the number of disposable tips.

The number is given in brackets if the drawer is not inserted or not assigned.

Symbol	Meaning
	• Tips in the drawer are available and above the availability threshold
	• Absent Not detected by the presence sensor e.g. open drawer
	• Depleted, no tips available ***Availability Threshold Disposable Tips*** = 0

Table 6–138: Symbol Disposable Tips

Starters Group

Shows remaining shots of the loaded starter 1 and 2. The counter decreases after every injection.

The Starters are primed automatically during ***Resume*** (or before starting a routine) if they are ***Not Primed***, one cuvette from the tray is available, Liquid Waste is below red phase and Solid Waste has enough available space.

If the prime fails, then the Starters stay in ***Not Primed***.

Symbol	Meaning
	• Absent • RF-Tag not read
	• Depleted • if not primed: the number of remaining shots is not enough to perform a prime • if primed: the number of remaining shots is not enough to start a routine ***Availability Threshold Starters*** = 4
	• Not primed • Expired If Starters are not primed and the system is in Ready, the main and sub toggles flash
	• Primed • Above availability threshold
	• Error ○ Starter in error ○ Wrong CRC

Table 6–139: Symbol Starter

System Fluids Group - Wash Buffer

The Wash Buffer is primed automatically during ***Resume*** (or before starting a routine) if it is ***Not Primed***, one cuvette from the tray is available, Liquid Waste is below red phase and Solid Waste has enough available space.

If the prime fails, then the Wash Buffer stays in ***Not Primed***.

Symbol	Meaning
	• Absent
	• Not primed
	• Successfully primed • Above red phase
	• Depleted • Usable only for ongoing jobs

Table 6–140: Symbols System Fluids-Wash Buffer

System Fluids Group - System Liquid

The System Liquid is primed automatically during ***Resume*** (or before starting a routine) if it is ***Not Primed*** and Liquid Waste is below red phase.

If the prime fails, then the System Liquid stays in ***Not Primed***.

The System Liquid is also used for periodical SPOLV rinsing in Standby or Ready status, if it is above red phase and the Liquid Waste is not full.

Symbol	Meaning
	• Absent
	• Not primed
	• Successfully primed • Above red phase
	• Depleted • Usable only for ongoing jobs

Table 6–141: System Fluids- System Liquid

Waste Group - Liquid Waste

Symbol	Meaning
	• Absent
	• Below red phase
	• Full • Usable only for ongoing jobs

Table 6–142: Used symbols

Waste Group - Solid Waste

Shows the number of cuvettes disposed in the Solid Waste.

Symbol	Meaning
	• Absent (solid waste drawer removed)
	• Loaded • Below availability threshold
	• Loaded • Above availability threshold

Table 6–143: Used symbols

Function	Description
Reset	Sets the number of Cuvettes in the Waste to 0.

*Table 6–144: Functions of the **Waste** group*

Temperatures

For the following modules the current temperature and the allowed range are given:

- Reaction
- Reagents
- Injection 1
- Injection 2
- Sample (no allowed ranges displayed)

The main and sub-toggle flash and the temperature is displayed in red if it falls outside its range.

The values are displayed using the selected unit (see chapter 6.9.5).

6.12.2 Sub Category Plastics

There are four trays for cuvettes and two plates for tips.

In Running mode the system will place one cuvette in the incubator every cycle if a cuvette from a tray and an empty slot in the outer ring are available.

In the subcategory ***Plastics***, the system can be filled with disposable tips and cuvettes.

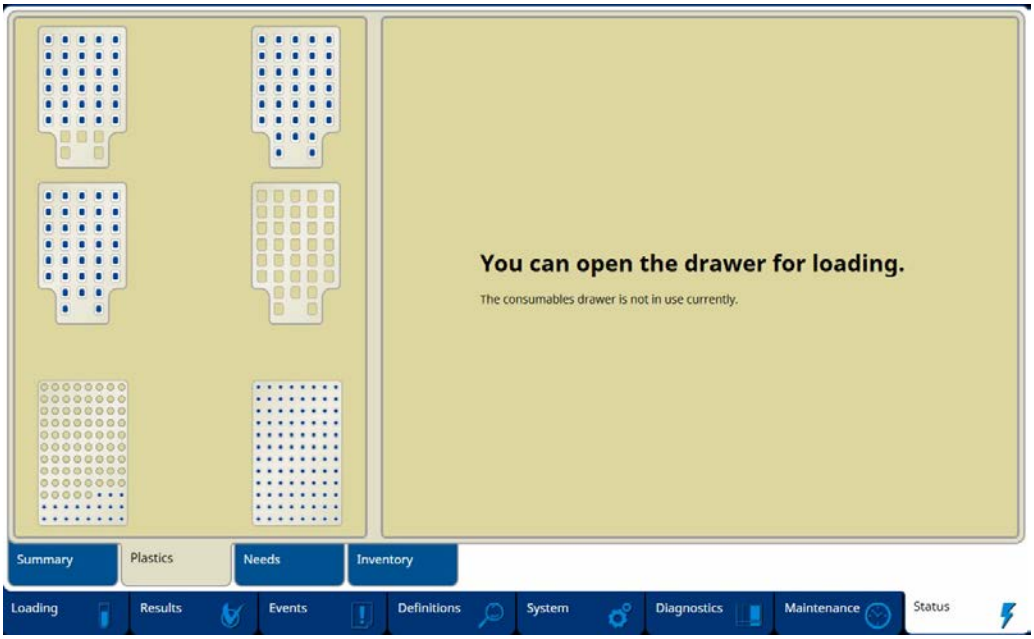


*Figure 6–105: Sub category **Plastics**, closed drawer*

Clear and **Fill** buttons are displayed by opening the drawer for the tips and cuvettes.
The selected Cuvette or Disposable Tip Tray is displayed on the right side.
Clicking on a single slot inverts the occupation (present/not present).
Plastics occupation can be set also by dragging a rectangle over the tray/plate.

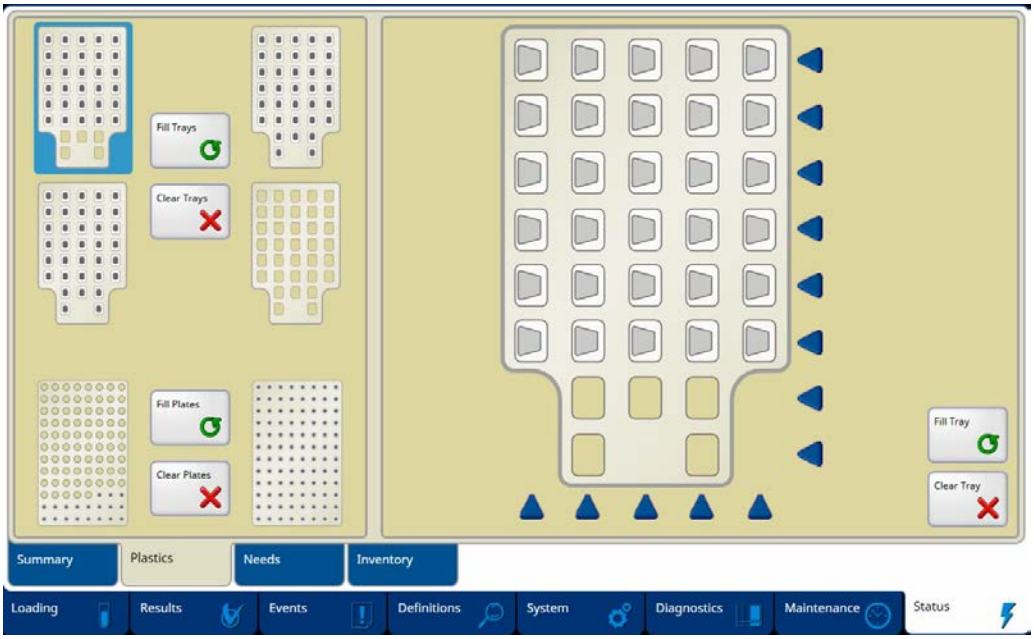


*Figure 6–106: Sub category **Plastics**, open drawer*

Function	Description
Fill Trays	Fills all 4 Cuvette Trays.
Clear Trays	Empties all 4 Cuvette Trays.
Fill Plates	Fills all 2 Disposable Tip Plates.
Clear Plates	Empties all 2 Disposable Tip Plates.
Fill Tray/Plate	Fills the selected tray/plate.
Clear Tray/Plate	Empties the selected tray/plate.
Withdraw	Visible only if the Drawer is inserted and in use. When clicked, an indication will be displayed when it is safe to remove the drawer. This will unschedule all jobs in Placed status.

*Table 6–145: Functions of the **Fill** and **Clear** buttons*

6.12.2.1 Refill Plastics drawer (while not in use)

Either empty trays/plates can be completely exchanged for full ones or individual places can be assigned.

1. Select the page **Status** → **Plastics**: the message “You can open the drawer for loading” is displayed.
2. Open the drawer of the cuvettes and tips. The buttons **Fill Tray/Plate** and **Clear Tray/Plate** are displayed.
3. Replace the tray/plate.
4. Select the tray/plate that has been filled by tapping it. The selected tray/plate is also displayed on the right side. If assignment of individual places needs to be modified, places can be individually selected on the right side.
5. Touch the button **Fill Tray/Plate**.
6. Close the drawer.

6.12.2.2 Refill Plastics drawer (while in use)

If the system is accessing the drawer, it is possible to suspend the access: the jobs in “Scheduled” status will return in “Placed” status.

1. Select the page **Status** → **Plastics**: the message “Do not open the consumable drawer” is displayed
2. Click on the button **Withdraw**
3. Wait until the countdown ends and the message “You can open the drawer for loading” is displayed
4. Open the drawer. The buttons **Fill Tray/Plate** and **Clear Tray/Plate** are displayed.
5. Replace the tray/plate.
6. Select the tray/plate that has been filled by tapping it. The selected tray/plate is also displayed on the right side. If assignment of individual places needs to be modified, places can be individually selected on the right side.
7. Touch the button **Fill Tray/Plate**.
8. Close the drawer.

Note: if jobs were returned to “Placed”, it is necessary to press “Start” to process them

6.12.2.3 Remove cuvettes trays or tips plates

1. Open the drawer of the cuvettes and tips. The buttons **Refill Tray/Plate** and **Clear Tray/Plate** are displayed.
2. Remove the complete tray/plate.
3. Select the tray/plate by tapping it.
4. Touch the **Clear Tray/Plate** button.
5. Close the drawer.

6.12.3 Sub category Needs

The sub category ***Needs*** gives an approximated overview of any needed reagent or consumable, based on system estimations of the currently Placed/ongoing tests.

The page updates when pressing the ***Start*** button or pressing the ***Calculate*** button.

In case Starters/Wash Buffer/System Liquid are not primed, also the resources necessary for priming are taken into account.

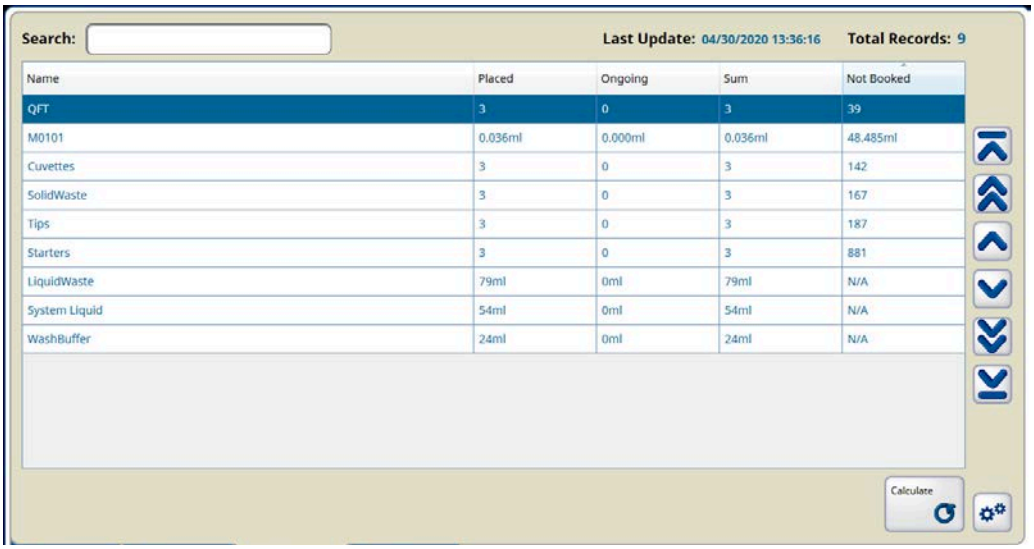


Figure 6–107: Sub category Needs

Function	Description
Calculate	Pressing the **Calculate** button updates the display.
Standard buttons	For standard buttons (e.g. arrow buttons, lock, ***Print***) see chapter 6.3.

*Table 6–146: Sub category **Needs***

Column	Description
Name	Wash Buffer, System Liquid, Liquid Waste, Solid Waste, Starters, Cuvettes, Tips and Reagents (kits and ancillaries).
Placed	Needed for all jobs currently in placed.
Ongoing	Needed for all jobs currently in scheduled or active.
Sum	Sum of the values reported in ***Placed*** and ***Ongoing*** columns.
Not Booked	The total available amount minus Sum. Negative Numbers are highlighted and indicate that the resource is not sufficient for the requested jobs.

*Table 6–147: Columns of the **Needs** table*

NOTE

For combi assays, in brackets is reported the amount calculated from the determination available for the sons, considering combi type and the presence of lot locking.

Resource	Amount
Ancillary	• Each needed Ancillary create a row with Article Number (no Lot or Serial Number). • In case a specific Lot and Serial Number is required, an entry with the needed Article Number, Lot Number and Serial Number is created.
Cuvettes	Number of cuvettes needed. Includes the clean cuvettes from Incubator.
Tips	Number of disposable tips needed.
Integral	• Each needed Integral create a row with Assay Abbreviation (no Lot or Kit Number). • In case that a specific Lot or Kit number is required, an entry with Lot and/or Kit Number is created.
Liquid waste	Liquid waste volume needed for the required tests.
Solid Waste	Available space needed for cuvettes in the solid waste.
Starter reagents	Number of starter shots for the required tests.
Wash buffer	Needed wash buffer volume for the required tests.
System Liquid	Needed System Liquid volume for the required tests.

*Table 6–148: Meaning of **Amount***

6.12.4 Sub Category Inventory

The sub category Inventory shows a list of all loaded and calibrated integrals in the reagent bay including the combi assays. The dialog is updated in regular intervals.

Disabled, offline, empty and expired reagents are not reported.

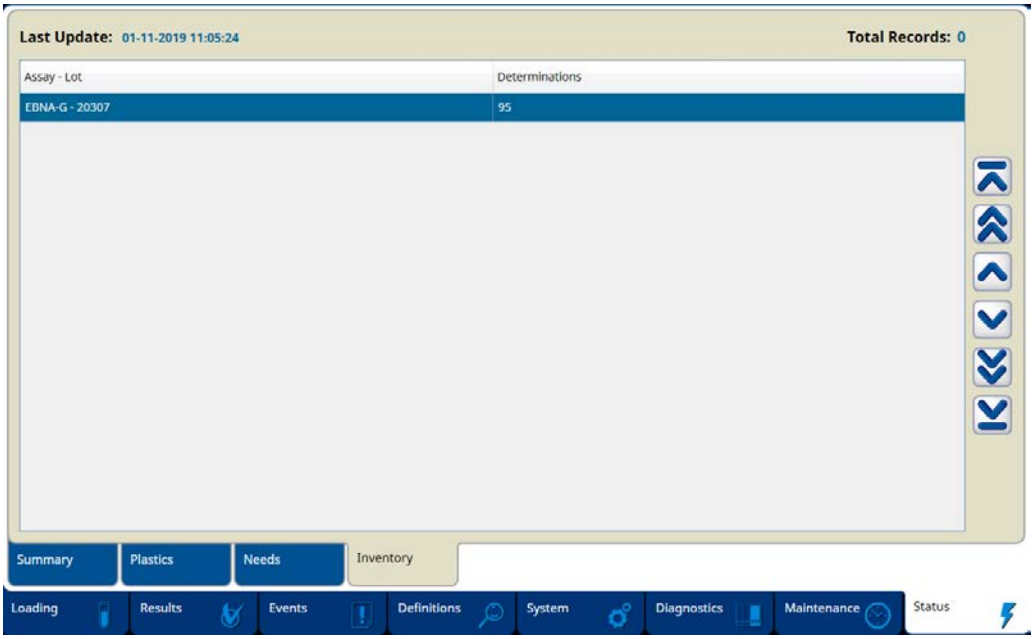


*Figure 6–108: Sub category **Inventory***

Column	Description
Assay-Lot	Assay abbreviation and lot number of the integral.
Determinations	Number of remaining determinations.

*Table 6–149: Columns of the **Inventory** table*

7 Maintenance

In order to operate correctly, it is essential that the **LIAISON® XS** system is maintained in accordance with the maintenance plan and procedures described in the instrument software.

According to given scheduling the system prompts the user when maintenance tasks are due, and it guides the user through the required procedure.

Carefully observe all required steps in order to ensure proper system functionality.

7.1 Safety and hints

DANGER

See Biological Safety in chapter 1.6.6.

DANGER

See Electrical safety in chapter 1.6.3.

WARNING

Improper Maintenance Actions

Improper maintenance Actions can result in serious personal injuries and material damage

- Follow all safety instructions in chapter 1.6 and in this chapter.
- Follow the work instructions stated by the software.
- Take off watches and jewelery before performing any maintenance task.

WARNING

Unapproved or inaccurately performed maintenance actions can result in serious personal injury and material damage.

- Only perform maintenance actions stated by the software.
- Follow closely the steps contained in the individual instructions.
- For the maintenance actions, only use parts or reagents mentioned in this instruction.
- Tests and maintenance actions specified by the manufacturer must be performed to ensure the safe operation of the system and the proper functioning of the system.
- All service and maintenance actions which are not described in this instruction must be performed by qualified and authorized service technicians.
- Any changes made to the instrument that are not authorized by the manufacturer will lead to the loss of guarantee.

WARNING

Handling of Decontamination Products

- Pay attention in managing the decontamination products, because they may be harmful. Read the instructions of the decontamination products before use.
- Do not mix sodium hypochlorite solution (e.g. bleach) or different chlorine cleaning solution (see chapter 7.3) with alcohol or any other flammable.

WARNING

Danger of Electrocution or Mechanical Injury during Required Maintenance Works on the Voltage-Carrying System

If the system cannot be separated from the main supply during required maintenance works, additional precautions must be taken to avoid serious injury with lethal consequences due to electrocution or injury by the system (e.g. contusion, cuts etc.).

- Only switch on the system if this is explicitly required.
- Only explicitly described protective covers may be opened.
- Perform the maintenance works with highest caution.
- Never touch electrical connecting contacts.
- Please note that mechanical components (e.g. pipettor) can move unexpectedly.

WARNING

Disposal

The instrument, the packaging material, and all parts that have been replaced must be disposed according to the applicable local and national provisions, legislation and laboratory procedures.

CAUTION

Cleaning, Disinfection or Decontamination

Observe the following aspects during cleaning, disinfection or decontamination because breakdowns or damages can be the result.

- Liquid cleaning, disinfection or decontamination solutions may only be used with a moistened cleaning tissue. They may not be poured into or sprayed into the system.
- Only cleaning, disinfection or decontamination solutions and procedures stated by the software are approved.
- Cleaning, disinfection or decontamination solutions must not come into contact with bearings and guides, as otherwise the greasy film may dissolve!
- Cleaning, disinfection or decontamination solutions must not be used in the vicinity of circuit boards and light barriers!

CAUTION

Unsuitable Sterilization Method

Containers and components for liquids or waste are seriously damaged by autoclaving.

- Disinfect or decontaminate the containers and components with a suitable disinfection or decontamination method.
- Comply with procedures stated by the software.
- Disposable materials must be incinerated.
- Liquid waste must be decontaminated with a chemical use sodium hypochlorite solution with 0.1 % active chlorine (e.g. dilution 1:50 of a solution at 5 % active chlorine) for at least half an hour.

CAUTION

Handling/Cleaning of Optic Surfaces

Optic surfaces (e.g. scanners, lenses, sensors) must be free of dust and grease.

- Do not touch any optic surfaces.
- Only clean the optic surfaces with a softy and lint-free cloth.
- Do not use any aggressive detergents (e.g. acetone).

CAUTION

Touch Screen Cleaning

Improper cleaning could damage the touch screen surface.

- Use soft clothes with neutral detergent or with ethanol to clean the touch screen.
- Do not use any chemical solvent, acidic or alkaline solution.
- Do not allow liquid to soak into the joint of film and glass as it may result in peeling or malfunctioning.

CAUTION

Organic Solvents

Reagent containers and hoses (water and waste) can be seriously damaged by or become unusable because of organic solvents.

Never use organic solvents.

7.2 Scheduled Maintenance Tasks

LIAISON® XS system informs user about the need to perform a maintenance task (see chapter 6.11). Please perform the scheduled maintenance tasks as requested. Please consult the following sections for procedures.

Local service support may perform or be required to perform maintenance tasks that may be necessary for specific purposes (e.g. troubleshooting).

Local service support is allowed to perform preventive maintenance according to DiaSorin Italia S.p.A. procedures.

7.3 Preparation of the Cleaning Solution in the cleaning tank

NOTE

Before chlorine cleaning agents are handled, the package information and material safety data sheet are to be read thoroughly and followed by the user.

The execution of the Short and Long Term maintenance procedures foresees the use of a cleaning solution that contains a final concentration of 0.1-0.2 % of active chlorine (e.g.using a dilution 1:50 of a solution at 5-9 % of active chlorine). In the following paragraph the preparation of the cleaning solution using one example of cleaning agent is described.

WARNING

In case commercial sodium hypochlorite solutions are used (e.g. bleach), avoid formulations featuring any fragrance, surfactant, other oxidizer or additive.

7.3.1 Cleaning Solution using sodium hypochlorite solution

Follow the instruction to prepare the Cleaning Solution at 0.1-0.2 % of active chlorine using sodium hypochlorite solution at 5-9 % of active chlorine.

1. Fill the Cleaning Tank with 1470 mL of distilled water;
2. Add 30 mL of a sodium hypochlorite solution (e.g. bleach) with a 5-9 % content of active chlorine. In case the available sodium hypochlorite should have a different titer, please adjust the dilution accordingly;
3. Shake the tank gently to remove residuals.

7.4 Short and Long Term Maintenance

NOTE

Before starting each Short or Long Term Maintenance tasks, 1.5 L of Cleaning Solution shall be prepared according to chapter 7.3.

WARNING

In order to guarantee the correct cleaning of the instrument, ensure that the cleaning tank is connected to the proper line as indicated in the maintenance task.
See chapter 5.4.4 and 5.4.5 for the load/unload procedure of the tanks.

Short Term maintenance

7.4.1 Procedure

1. Ensure that the instrument is not in “running” or “maintenance” status before starting the Short Term maintenance;
2. Click on the **Maintenance** main category and select the **Short Term Maintenance** Task;
3. Tap on the “Perform” Button to start the Short Term Maintenance;
4. Follow the instructions described in the maintenance task.

Long Term maintenance

7.4.2 Procedure

1. Ensure that the instrument is not in “running” or “maintenance” status before starting the Long Term maintenance;
2. Click on the **Maintenance** main category and select the **Long Term Maintenance** Task;
3. Tap on the “Perform” Button to start the Long Term Maintenance;
4. Follow the instructions described in the maintenance task.

7.5 Clean the wash buffer and the system liquid tanks

Tanks containing system liquid and wash buffer solution shall be cleaned during the execution of the Long Term Maintenance procedure, as indicate by a dedicate pop-up that appears during the execution of the task.

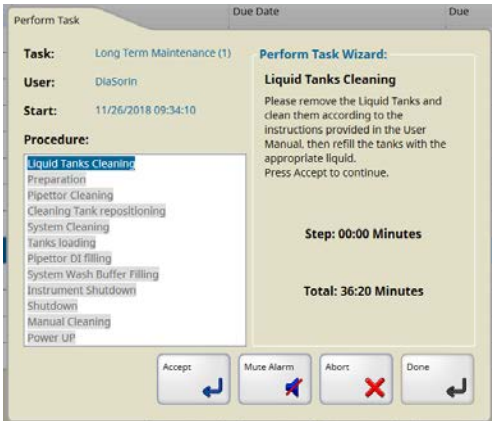


Figure 7–1: pop-up of the instruments tanks cleaning

The cleaning of tanks shall be performed with 1.5 Liter of cleaning solution at 0.1-0.2 % of active chlorine. The following paragraph reports the instructions to clean the system liquid and wash buffer tanks

7.5.1 Procedure

Tanks removal

1. Unload the wash buffer and the system liquid tanks (see chapters 5.4.4 and 5.4.5);
2. Dispose of all residual liquid from the wash buffer and system liquid tanks;

Tanks cleaning

3. Prepare 1.5 Liter of cleaning solution at 0.1-0.2 % of active chlorine in the system liquid tank (e.g. fill the system liquid tank with 1470 mL of distilled water, then add 30 mL of a sodium hypochlorite solution with a 5-9 % content of active chlorine);
4. Prepare 1.5 Liter of cleaning solution at 0.1-0.2 % of active chlorine in the wash buffer tank (e.g. fill the wash buffer tank with 1470 mL of distilled water, then add 30 mL of a sodium hypochlorite solution with a 5-9 % content of active chlorine);
5. Ensure the complete homogenization of the solution;
6. Gently shake each tank, avoiding spilling and limiting the formation of foam.
7. Carefully empty each tank and rinse it thoroughly with distilled water (to ensure adequate rinsing, it is recommended to fill each tank at least at half volume). Water to be used has to be defined according to CLSI guidelines for laboratory water (“Instrument Feed Water” type);
8. Repeat operation at previous point at least two more times for each tank;

Tanks insertion

9. Fill the system liquid tank with the system liquid, plug the cap and load it into the system according to chapter 5.4.4;
10. Fill the wash buffer tank with the dedicated solution, plug the cap and load it into the system according to chapter 5.4.5.

NOTE For the preparation of the wash buffer solution, refer to the instructions for use.

NOTE For the preparation of the system liquid solution, refer to the instructions for use.

11. If all the required cleaning procedures have been completed, press the “Accept” button in the pop-up, otherwise continue with the execution of the other cleaning procedures.

7.6 Manual Cleaning of the instrument

Some parts of the instrument shall be cleaned during the execution of the Short and Long Term Maintenance procedures, as indicated by a dedicated pop-up that appears during the execution of the task.

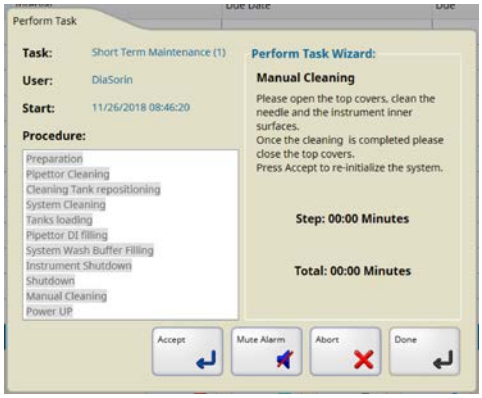


Figure 7–2: Short Term Maintenance - Manual Cleaning pop-up

Figure 7–3: Long Term Maintenance - Manual Cleaning pop-up

The following procedure shall be executed to complete the cleaning:

1. Instrument automatically shuts down all modules;
2. Wipe the external side of the covers (top covers, side covers, front covers) with a tissue saturated with an alcoholic/disinfectant solution (to be executed in the Long Term Maintenance procedure only);
3. Open the sample area flap and extract the available sample racks;
4. Once sample tubes have been removed, wipe each rack with a tissue saturated with an alcoholic/disinfectant solution;
5. Wipe the surfaces of the sample module with a tissue saturated with an alcoholic/disinfectant solution;
6. Push the sample racks back into the sample area and close the flap;
7. Open the reagent area flap and extract the ancillary plate;
8. Wipe the surfaces of the ancillary plate with a tissue soaked with an alcoholic/ disinfectant solution;
9. Wipe the accessible surfaces of the reagent area with a tissue saturated with an alcoholic/disinfectant solution;

10. Push the ancillary plate back into the reagent area and close the flap;
11. Open the starter reagent area flap;
12. Remove the starter bottles;
13. Wipe the surfaces of the starter reagent area with a tissue saturated with an alcoholic/disinfectant solution;
14. Insert starter bottles back into the starter reagent area;
15. Remove the Liquid Waste tank from the Liquid Waste Basin;
16. Wipe the surfaces of the Liquid Waste Basin with a tissue saturated with an alcoholic/disinfectant solution;
17. Insert the Liquid Waste tank on the Liquid Waste Basin;
18. Remove the EASY Waste from the Solid Waste Bin according to chapter 5.4.7;
19. Wipe the surfaces of the Solid Waste Drawer with a tissue saturated with an alcoholic/disinfectant solution;
20. Insert the EASY Waste Box on the Solid Waste Bin according to chapter 5.4.7;
21. Open the top covers and wipe the right arm needle and the pipettor wash station (upper rim) with a tissue soaked with the cleaning solution prepared according to chapter 7.3;
22. Wipe the right arm needle and the pipettor wash station (upper rim) with a tissue soaked with DI water;
23. Wipe the right arm needle and the Pipettor wash station (upper rim) with a dry tissue;

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

24. If all the required cleaning procedures have been completed, close the top covers, press the “accept” button and follow the instruction described in the maintenance task, otherwise continue with the execution of the other cleaning procedures.

7.7 LIAISON® EASY Cleaning Tool

The **LIAISON®** EASY Cleaning Tool (part number 310996) is a DiaSorin Italia S.p.A. product, useful to improve routine maintenance of the **LIAISON® XS** analyzer. A sodium hypochlorite solution cleanses the washer needles and tubes and the measurement chamber. They are rinsed afterwards by the mean of a wash solution.

The **LIAISON®** EASY Cleaning Tool is to be performed once a week after the completion of a daily routine, as the last operation of the day (prior to possible maintenance sessions) or as the first operation of the next day, before the daily routine.

NOTE Refer to the instruction for use of the **LIAISON®** EASY Cleaning Tool before its use.

CAUTION

Maintenance with **LIAISON®** EASY Cleaning Tool does not replace the short and long maintenance of the **LIAISON® XS** analyzer.

7.8 Automated actions performed by the system

After four hours of rest the system switches from Ready to Standby and set the following resources to “Not Primed”:

- System Liquid
- Wash Buffer
- Starters

CAUTION

While the system is in Standby and Ready it performs an automatic pipettor rinsing with System Liquid.

Presence of a connected and above red phase System Liquid tank, as well as connected and below red phase wastes, is necessary to support the periodic pipettor rinsing.

It is recommended to promptly reconnect:

- the System Liquid tank upon refilling
- Liquid and Solid wastes upon emptying.

NOTE

It is not possible to modify the Cuvettes/Tips assignment in case the system status is “Maintenance”, including during the automatic pipettor rinsing execution.

The system automatically performs the following actions at specified times, in order to improve the system performance:

- initialization
- resume
- automated back-up and clean-up of archived results from the Archived menu.

These times are configurable (see chapter 6.9.5).

CAUTION

Systems working overnight

In case the system works overnight without significant interruptions, the automated back-up and the initialization are performed as soon as the system switches to “Ready” or “Standby”.

The resume is not performed if at the due time the system is not in “Standby” status.

8 Troubleshooting and error messages

This Chapter describes error messages or information messages and gives instruction on error recovery.

NOTE If the error reoccurs, please call service.

NOTE The system may automatically reschedule replicates failed for a reason that could be recovered without user intervention.

	Meaning
Parameters {...}	Some error messages show details about the error. With this information, the cause or the affected sample may be found. In the error list these details will be shown as parameters (e.g. {SID}).
Effect	Depending on the fault category, the error will be noted differently. In the error list the notification will be shown in the column effect. • L: adds an entry to the event log • M: shows a message • S: sounds an acoustic signal

8.1 SPOLVRightArm

Device ID: **0xFD**

8.1.1 Sub assemblies

ID (dec)	ID (hex)	Name
17	0x11	General
18	0x12	SctlCU

Table 8–1: Sub assemblies, SPOLVRightArm

8.1.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Right Pipettor	Electronics • If the problem persists call Service	L M S	253.017.00004
A communication error occurred	-	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.017.00005
Syringe motor overload	Affected module: Right Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.017.00010
Syringe motor overload	Affected module: Right Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.018.00010
A communication error occurred	Affected module: Right Pipettor	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.017.00033
Initialization of syringe failed	Affected module: Right Pipettor	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Mechanics	L M S	253.017.00035
Syringe motor overload	Affected module: Right Pipettor	Electronics • If the problem persists call Service Mechanics	L M S	253.017.00037
Target position not reached by syringe	Affected module: Right Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.017.00048

Message	Description	Action	Effect	Event ID
Initialization of syringe failed	Affected module: Right Pipettor	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.017.00052
Syringe overpressure	Affected module: Right Pipettor	Calibration • Initialize the system • If the problem persists call Service Consumable	L M S	253.017.00053

Table 8–2: Message list, SPOLVRightArm

8.2 SingleSledgeZ

Device ID: **0xFD**

8.2.1 Sub assemblies

ID (dec)	ID (hex)	Name
12	0x0C	General
13	0x0D	ZDrive1
255	0xFF	ZDrive2

Table 8–3: Sub assemblies, SingleSledgeZ

8.2.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Right Sledge	Electronics • If the problem persists call Service	L M S	253.012.00004
A communication error occurred	Affected module: Right Sledge	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.012.00005

Message	Description	Action	Effect	Event ID
Z motor overload	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	253.013.00037
Z motor overload	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	253.255.00037
Target position not reached by Z motor	Affected module: Right Sledge	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.013.00048
Target position not reached by Z motor	Affected module: Right Sledge	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.255.00048
Initialization of Z motor failed	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.013.00050
Initialization of Z motor failed	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.255.00050
Initialization of Z motor failed	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.013.00051

Message	Description	Action	Effect	Event ID
Initialization of Z motor failed	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.255.00051

Table 8–4: Message list, SingleSledgeZ

8.3 SingleSledgeY

Device ID: **0xFD**

8.3.1 Sub assemblies

ID (dec)	ID (hex)	Name
7	0x07	General
8	0x08	Y_Drive

Table 8–5: Sub assemblies, SingleSledgeY

8.3.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Right Sledge	Electronics • If the problem persists call Service	L M S	253.007.00004
A communication error occurred	Affected module: Right Sledge	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.007.00005
Target position reached after retry.	Only information	Electronics - Mechanics	L	253.008.00009
Target position not reached by Y motor	Affected module: Right Sledge	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.008.00010

Message	Description	Action	Effect	Event ID
A movement problem has been detected	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	253.007.00023
A movement problem has been detected	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	253.008.00023
Initialization of Y motor failed	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.008.00050
Initialization of Y motor failed	Affected module: Right Sledge	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.008.00051

Table 8–6: Message list, SingleSledgeY

8.4 Pipettor

Device ID: **0xFD**

8.4.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
3	0x03	LeftYMotor
4	0x04	RightYMotor
1	0x01	LeftArm
2	0x02	RightArm
5	0x05	LeftXMain
6	0x06	LeftXMotor
7	0x07	RightXMain
8	0x08	RightXMotor
9	0x09	LeftZMain
10	0x0A	LeftZMotor1
11	0x0B	LeftZMotor2
12	0x0C	RightZMain
13	0x0D	RightZMotor1
14	0x0E	LeftZspipMain
15	0x0F	LeftZspipSctl
16	0x10	LeftZspipHead
17	0x11	RightSpolvMain
18	0x12	RightSpolvSctl
19	0x13	RightSpolvHead
20	0x14	LeftGripper
21	0x15	DrainPump

Table 8–7: Sub assemblies, Pipettor

8.4.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Pipettor	Electronics • If the problem persists call Service	L M S	253.000.00004
A communication error occurred	Affected module: Pipettor	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.000.00005
Target position reached after retry.	Only information	Electronics - Mechanics	L	253.003.00009
Target position reached after retry.	Only information	Electronics - Mechanics	L	253.004.00009
Target position not reached by Y motor	Affected module: Left Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.003.00010
Target position not reached by Y motor	Affected module: Right Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.004.00010
A movement problem has been detected	Affected module: Left Pipettor	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	253.003.00023
A movement problem has been detected	Affected module: Right Pipettor	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	253.004.00023
Initialization of Y motor failed	Affected module: Left Pipettor	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.003.00034

Message	Description	Action	Effect	Event ID
Initialization of Y motor failed	Affected module: Right Pipettor	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.004.00034
Initialization of Y motor failed	Affected module: Left Pipettor	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.003.00035
Initialization of Y motor failed	Affected module: Right Pipettor	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.004.00035
The pipettor is missing target coordinates.	Affected module: Left Pipettor	Configuration • Call Service	L M S	253.001.00048
The pipettor is missing target coordinates.	Affected module: Right Pipettor	Configuration • Call Service	L M S	253.002.00048
Test of the Liquid Level Detection sensor system has failed.	Affected module: Left Pipettor	Electronics • Call Service	L M S	253.001.00052
Test of the Liquid Level Detection sensor system has failed.	Affected module: Right Pipettor	Electronics • Call Service	L M S	253.002.00052
Pipettor has lost a disposable tip.	Affected module: Left Pipettor	Mechanics • Call Service Configuration	L M S	253.001.00055
Gripper has lost a cuvette	Affected module: Left Pipettor	Mechanics • Call Service Configuration	L M S	253.001.00059
The pipettor wash pump is not connected or broken.	Affected module: Right Pipettor	Electronics • Call Service	L M S	253.002.00061

Message	Description	Action	Effect	Event ID
Disposable tip eject failed		Mechanics • Empty the solid waste box • Initialize the system • If the problem persists call Service	L M S	253.001.00062
Undefined OLV dead volume reference value	Affected module: Right Pipettor	Call Service	L	253.002.00096
An internal error occurred	Affected module: Pipettor	Calibration • If the problem persists call Service Electronics	L M S	253.000.00176
An internal error occurred	Affected module: Pipettor	Configuration • If the problem persists call Service Electronics	L M S	253.000.00180

Table 8–8: Message list, Pipettor

8.5 LWP

Device ID: **0xFD**

8.5.1 Sub assemblies

ID (dec)	ID (hex)	Name
21	0x15	General

Table 8–9: Sub assemblies, LWP

8.5.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: LWP	Electronics • If the problem persists call Service	L M S	253.021.00004
A communication error occurred	Affected module: LWP	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.021.00005
Motor overload	Affected module: LWP	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.021.00008
Target position reached after retry.	Only information	Electronics - Mechanics	L	253.021.00009
Target position not reached by pump	Affected module: LWP	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.021.00010

Table 8–10: Message list, LWP

8.6 Gripper

Device ID: **0xFD**

8.6.1 Sub assemblies

ID (dec)	ID (hex)	Name
20	0x14	General

Table 8–11: Sub assemblies, Gripper

8.6.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Gripper	Electronics • If the problem persists call Service	L M S	253.020.00004
A communication error occurred	Affected module: Gripper	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.020.00005
Motor overload	Affected module: Gripper	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.020.00008
Target position reached after retry.	Only information	Electronics - Mechanics	L	253.020.00009
Target position not reached by gripper	Affected module: Gripper	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.020.00010
An internal error occurred	Affected module: Gripper	Calibration • If the problem persists call Service Electronics	L M S	253.020.00176
An internal error occurred	Affected module: Gripper	Configuration • If the problem persists call Service Electronics	L M S	253.020.00180

Table 8–12: Message list, Gripper

8.7 DualSledgeZ

Device ID: **0xFD**

8.7.1 Sub assemblies

ID (dec)	ID (hex)	Name
9	0x09	General
10	0x0A	ZDrive1
11	0x0B	ZDrive2

Table 8–13: Sub assemblies, DualSledgeZ

8.7.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Left Sledge	Electronics • If the problem persists call Service	L M S	253.009.00004
A communication error occurred	Affected module: Left Sledge	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.009.00005
Z motor overload	Affected module: Left Pipettor	Mechanics • Call Service Electronics	L M S	253.010.00037
Z motor overload	Affected module: Gripper	Mechanics • Call Service Electronics	L M S	253.011.00037
Target position not reached by Z motor	Affected module: Left Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.010.00048
Target position not reached by Z motor	Affected module: Gripper	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.011.00048

Message	Description	Action	Effect	Event ID
Initialization of Z motor failed	Affected module: Left Pipettor	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.010.00050
Initialization of Z motor failed	Affected module: Gripper	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.011.00050
Initialization of Z motor failed	Affected module: Left Pipettor	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.010.00051
Initialization of Z motor failed	Affected module: Gripper	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.011.00051

Table 8–14: Message list, DualSledgeZ

8.8 DualSledgeY

Device ID: **0xFD**

8.8.1 Sub assemblies

ID (dec)	ID (hex)	Name
5	0x05	General
6	0x06	Y_Drive

Table 8–15: Sub assemblies, DualSledgeY

8.8.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Left Sledge	Electronics • If the problem persists call Service	L M S	253.005.00004
A communication error occurred	Affected module: Left Sledge	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.005.00005
Target position reached after retry.	Only information	Electronics - Mechanics	L	253.006.00009
Target position not reached by X motor	Affected module: Left Sledge	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.006.00010
A movement problem has been detected	Affected module: Left Sledge	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	253.005.00023
A movement problem has been detected	Affected module: Left Sledge	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	253.006.00023
Initialization of Y motor failed	Affected module: Left Sledge	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.006.00050
Initialization of Y motor failed	Affected module: Left Sledge	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	253.006.00051

Table 8–16: Message list, DualSledgeY

8.9 AirPipettorLeftArm

Device ID: **0xFD**

8.9.1 Sub assemblies

ID (dec)	ID (hex)	Name
14	0x0E	General
15	0x0F	SctlCU

Table 8–17: Sub assemblies, AirPipettorLeftArm

8.9.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Left Pipettor	Electronics • If the problem persists call Service	L M S	253.014.00004
A communication error occurred	-	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.014.00005
Syringe motor overload	Affected module: Left Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.014.00010
Syringe motor overload	Affected module: Left Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.015.00010
A communication error occurred	Affected module: Left Pipettor	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.014.00033

Message	Description	Action	Effect	Event ID
Initialization of syringe failed	Affected module: Left Pipettor	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Mechanics	L M S	253.014.00035
Syringe motor overload	Affected module: Left Pipettor	Electronics • If the problem persists call Service Mechanics	L M S	253.014.00037
Target position not reached by syringe	Affected module: Left Pipettor	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	253.014.00048
Initialization of syringe failed	Affected module: Left Pipettor	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	253.014.00052
Syringe overpressure	Affected module: Left Pipettor	Calibration • Initialize the system • If the problem persists call Service Consumable	L M S	253.014.00053

Table 8–18: Message list, AirPipettorLeftArm

8.10 ComGenDriver

Device ID: **0xEF**

8.10.1 Sub assemblies

ID (dec)	ID (hex)	Name
1	0x01	LeftArm
2	0x02	RightArm

Table 8–19: Sub assemblies, ComGenDriver

8.10.2 Message list

Message	Description	Action	Effect	Event ID
Tip eject failed	Affected module: Left Pipettor	ProcessControl • Initialize the system • If the problem persists call Service	L M S	239.001.00147
New cuvette pickup failed	-	InstrumentHandling • Check consumable states • Perform an initialization • If the problem persists call Service	L M S	239.001.00157
OLV sensor calibration failed	Affected module: Right Pipettor	ProcessControl • Initialize the system and perform the resume • If the problem persists call Service	L M S	239.002.00149
OLV dead volume verification failed	Affected module: Right Pipettor	ProcessControl • Initialize the system and perform the resume • If the problem persists call Service	L M S	239.002.00150
DiTi pickup failed multiple times		ProcessControl	L M S	239.001.00174
Pickup of new cuvette failed multiple times		ProcessControl	L M	239.001.00175

Table 8–20: Message list, ComGenDriver

8.11 FrontCoverDriver

Device ID: **0xE9**

8.11.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–21: Sub assemblies, FrontCoverDriver

8.11.2 Message list

Message	Description	Action	Effect	Event ID
Front Cover is {FlapDrawerState}	-	ProcessControl	L	233.000.00048
Consumable drawer is {FlapDrawerState}.	Only information	ProcessControl	L	233.000.00049
Starter reagent flap is {FlapDrawerState}.	Only information	ProcessControl	L	233.000.00050
Reagent bay flap is {FlapDrawerState}.	Only information	ProcessControl	L	233.000.00051
Sample bay flap is {FlapDrawerState}.	Only information	ProcessControl	L	233.000.00052
Solid waste drawer is {FlapDrawerState}.	Only information	ProcessControl	L	233.000.00053
Reagent bay flap is open for a too long time.	-	ProcessControl • Please, close the reagent bay flap	L M S	233.000.00054

Table 8–22: Message list, FrontCoverDriver

8.12 LiquidSupportDriver

Device ID: **0xE8**

8.12.1 Sub assemblies

ID (dec)	ID (hex)	Name
3	0x03	HeatTube1
4	0x04	HeatTube2

Table 8–23: Sub assemblies, LiquidSupportDriver

8.12.2 Message list

Message	Description	Action	Effect	Event ID
Starter 1 (injection) temperature is out of range	The system is still initializing or resuming; The system was shut down for a long time; Hardware defect	• Wait for the temperature to be back in range • If the problem persists call Service	L S	232.003.00161
Starter 2 (injection) temperature is out of range	The system is still initializing or resuming; The system was shut down for a long time; Hardware defect	• Wait for the temperature to be back in range • If the problem persists call Service	L S	232.004.00161
Starter 1 (injection) temperature is back in range	Only information	-	L	232.003.00162
Starter 2 (injection) temperature is back in range	Only information	-	L	232.004.00162

Table 8–24: Message list, LiquidSupportDriver

8.13 ReagentSampleBayDriver

Device ID: **0xE6**

8.13.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
1	0x01	Reagent

Table 8–25: Sub assemblies, ReagentSampleBayDriver

8.13.2 Message list

Message	Description	Action	Effect	Event ID
Reagent bay temperature is out of range for too long time.	Affected module: Reagent Bay	Environmental • Wait for the temperature to be back in range • If the problem persists call Service Configuration	L M S	230.000.00037
Stirrer rotation frequency too low	-	Electronics • If the problem persists call Service Mechanics	L M S	230.001.00052

Table 8–26: Message list, ReagentSampleBayDriver

8.14 MeasurementDriver

Device ID: **0xE5**

8.14.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
1	0x01	BubbleSensor

Table 8–27: Sub assemblies, MeasurementDriver

8.14.2 Message list

Message	Description	Action	Effect	Event ID
Dark count events occured	Affected module: Reader	ProcessControl • Call Service Electronics Mechanics	L M S	229.000.00085
Aspiration failed for 3 consecutive measurements at reader port	Affected module: Reader	ProcessControl • Perform the Initialization and then the Bubble Sensor calibration • If the problem persists call Service	L M S	229.001.00145

Table 8–28: Message list, MeasurementDriver

8.15 WasherDriver

Device ID: **0xE4**

8.15.1 Sub assemblies

ID (dec)	ID (hex)	Name
1	0x01	Probe1
2	0x02	Probe2
3	0x03	Probe3

Table 8–29: Sub assemblies, WasherDriver

8.15.2 Message list

Message	Description	Action	Effect	Event ID
Aspiration failed for 3 consecutive measurements at washer port 1	Affected module: Washer	• Perform the Initialization and then the Bubble Sensor calibration • If the problem persists call Service	L M S	228.001.00145
Aspiration failed for 3 consecutive measurements at washer port 2	Affected module: Washer	• Perform the Initialization and then the Bubble Sensor calibration • If the problem persists call Service	L M S	228.002.00145
Aspiration failed for 3 consecutive measurements at washer port 3	Affected module: Washer	• Perform the Initialization and then the Bubble Sensor calibration • If the problem persists call Service	L M S	228.003.00145

Table 8–30: Message list, WasherDriver

8.16 IncubatorDriver

Device ID: **0xE3**

8.16.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–31: Sub assemblies, IncubatorDriver

8.16.2 Message list

Message	Description	Action	Effect	Event ID
Incubator (reaction) temperature is out of range.	-	Environmental • Wait for the temperature to be back in range • If the problem persists call Service Electronics	L M S	227.000.00032
Incubator (reaction) temperature is back in range	Only information	Environmental -	L	227.000.00033
Incubator (reaction) temperature is out of range for too long.	Affected module: Incubator	Environmental • Call Service Electronics	L M S	227.000.00037

Table 8–32: Message list, IncubatorDriver

8.17 ServiceDriver

Device ID: **0xE2**

8.17.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–33: Sub assemblies, ServiceDriver

8.17.2 Message list

Message	Description	Action	Effect	Event ID
Prime of {Module} failed.	-	InstrumentHandling • Ensure that all needed resources are correctly loaded • The system will try to perform the failed prime before starting the next routine, maintenance task or resume • If the problem persists call Service ProcessControl	L M S	226.000.00033

Table 8–34: Message list, ServiceDriver

8.18 UserAccessDriver

Device ID: **0xE1**

8.18.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–35: Sub assemblies, UserAccessDriver

8.18.2 Message list

Message	Description	Action	Effect	Event ID
Soft power button was pressed.	Only information	-	L	225.000.00096

Table 8–36: Message list, UserAccessDriver

8.19 DiTiManager

Device ID: **0xD7**

8.19.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–37: Sub assemblies, DiTiManager

8.19.2 Message list

Message	Description	Action	Effect	Event ID
Consumable tray(s) unlocked for user access	-	ProcessControl	L	215.000.00048

Table 8–38: Message list, DiTiManager

8.20 LoadingManager

Device ID: **0xD6**

8.20.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–39: Sub assemblies, LoadingManager

8.20.2 Message list

Message	Description	Action	Effect	Event ID
Instrument cover open while an operation is in progress	-	InstrumentHandling • Close the cover and initialize the system • If the error persists call Service	L M S	214.000.00042
Solid waste has to be present while operation	-	InstrumentHandling • Insert the solid waste bin and initialize the system • If the error persists call Service Electronics	L M S	214.000.00067
Liquid waste has to be present while operation	-	InstrumentHandling • Plug the connector into the liquid waste tank and initialize the system • If the error persists call Service Electronics	L M S	214.000.00068

Table 8–40: Message list, LoadingManager

8.21 Dispatcher

Device ID: **0xD4**

8.21.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
1	0x01	LeftArm

Table 8–41: Sub assemblies, Dispatcher

8.21.2 Message list

Message	Description	Action	Effect	Event ID
System cycle belated by {Delay}	-	Configuration • If the problem persists call Service Electronics Mechanics	L M S	212.000.00034
system delay by {Delay} in worklist queue {QueueId} occurred	Only information, a recoverable delay occurred	ProcessControl	L M	212.000.00035
Pickup of diposable tip failed		ProcessControl	L	212.001.00096
Pressure threshold exceeded by probe (ADPM) for JobId {JobId}	-	ProcessControl	L M	212.001.00104

Table 8–42: Message list, Dispatcher

8.22 AssayManager

Device ID: **0xD3**

8.22.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–43: Sub assemblies, AssayManager

8.22.2 Message list

Message	Description	Action	Effect	Event ID
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00032
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00033
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00034
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00035
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00036
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00037
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00038
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00039
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00040
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00041
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00042
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00043
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00044
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00045

Message	Description	Action	Effect	Event ID
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00046
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00048
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00049
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00050
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00051
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00052
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00053
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00054
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00055
It was not possible to correctly handle the Assay protocol	-	Configuration • Call Service	L M	211.000.00056
Sample pipetting step is used more than once	-	Configuration • If the problem persists call Service	L M S	211.000.00057

Table 8–44: Message list, AssayManager

8.23 JobManager

Device ID: **0xD2**

8.23.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–45: Sub assemblies, JobManager

8.23.2 Message list

Message	Description	Action	Effect	Event ID
Same start cycle as a job already programmed. JobId {JobIdentifier}	A scheduling error has occurred.	Configuration • Start the job again • If the problem persists call Service	L M S	210.000.00035
An internal error occurred while processing JobId {JobIdentifier}	Data garbled	Configuration • If the problem persists call Service	L M S	210.000.00036
An internal error occurred while processing JobId {JobIdentifier}	No assay data	Configuration • Import the Assay Protocol • Start the job again • If the problem persists call Service	L M S	210.000.00038
Required dilution pipetting sequence not stored. JobId {JobIdentifier}	The dilution sequence is missing	Configuration • Call Service	L M S	210.000.00039
The number of resources does not match to the number required by the assay. JobId {JobIdentifier}	Wrong reagent configuration	Configuration • Call Service	L M S	210.000.00040
		•		
Maximum number of reagents exceeded. JobId {JobIdentifier}	Wrong reagent configuration	Configuration • Call Service	L M S	210.000.00042
		•		
Maximum number of pre-treatments exceeded. JobId {JobIdentifier}	Wrong assay sequence	Configuration • Call Service	L M S	210.000.00044

Message	Description	Action	Effect	Event ID
Dilution volume out of range. JobId {JobIdentifier}	Wrong assay sequence	Configuration • Call Service	L M S	210.000.00045
Schedule conflict: Phase is still in use. JobId {JobIdentifier1} and JobId {JobIdentifier2}	A scheduling error has occurred.	Configuration • Initialize the system • Start the jobs again • If the problem persists call Service	L M S	210.000.00049
Job rejected: Assay sequence not plausible. JobId {JobIdentifier}	Wrong assay sequence	Configuration • Call Service	L M S	210.000.00050
An internal error occurred while processing	Invalid assay ID	Configuration • Call Service	L M S	210.000.00052

Table 8–46: Message list, JobManager

8.24 FrontCover

Device ID: **0x40**

8.24.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–47: Sub assemblies, FrontCover

8.24.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Front Cover	Electronics • If the problem persists call Service	L M S	064.000.00004
A communication error occurred	Affected module: Front Cover	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	064.000.00005

Table 8–48: Message list, FrontCover

8.25 WAP

Device ID: **0x35**

8.25.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–49: Sub assemblies, WAP

8.25.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: WAP	Electronics • If the problem persists call Service	L M S	053.000.00004
A communication error occurred	Affected module: WAP	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	053.000.00005
Motor overload	Affected module: WAP	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	053.000.00008
Target position reached after retry.	Only information	Electronics - Mechanics	L	053.000.00009
Target position not reached by washer pump	Affected module: WAP	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	053.000.00010

Table 8–50: Message list, WAP

8.26 WasherDispensePump

Device ID: **0x32**

8.26.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–51: Sub assemblies, WasherDispensePump

8.26.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: WBDP	Electronics • If the problem persists call Service	L M S	050.000.00004
A communication error occurred	Affected module: WBDP	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	050.000.00005
Motor overload	Affected module: WBDP	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	050.000.00008
Target position reached after retry.	Only information	Electronics - Mechanics	L	050.000.00009
Target position not reached by washer pump	Affected module: WBDP	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	050.000.00010
Initialization of pump failed	Affected module: WBDP	Electronics • If the problem persists call Service Mechanics	L M S	050.000.00032
Initialization of pump failed	Affected module: WBDP	Electronics • If the problem persists call Service Mechanics	L M S	050.000.00033

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: WDP	Calibration • If the problem persists call Service Electronics	L M S	050.000.00176
An internal error occurred	Affected module: WDP	Configuration • If the problem persists call Service Electronics	L M S	050.000.00180

Table 8–52: Message list, WasherDispensePump

8.27 LiquidSupport

Device ID: **0x18**

8.27.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
1	0x01	BubbleSensor1
2	0x02	BubbleSensor2
5	0x05	RFIDStarter

Table 8–53: Sub assemblies, LiquidSupport

8.27.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Liquid Support	Electronics • If the problem persists call Service	L M S	024.000.00004
A communication error occurred	Affected module: Liquid Support	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	024.000.00005
An Internal error occurred during self test	Affected module: Liquid Support	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	024.000.00012
Bubble sensor 1 calibration error	Affected module: Liquid Support	Calibration • Initialize the system • If the problem persists call Service InstrumentHandling	L M S	024.001.00080
Bubble sensor 2 calibration error	Affected module: Liquid Support	Calibration • Initialize the system • If the problem persists call Service InstrumentHandling	L M S	024.002.00080
An error occurred while accessing RFTag	Affected module: Starter Reagent Bay	Consumable • If the problem persists call Service	L M S	024.005.00130

Table 8–54: Message list, LiquidSupport

8.28 LoadingBay

Device ID: **0x16**

8.28.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
3	0x03	Stirrer
4	0x04	Cooling
1	0x01	Loading
5	0x05	Scanner
2	0x02	RFID

Table 8–55: Sub assemblies, LoadingBay

8.28.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Loading Bay	Electronics • If the problem persists call Service	L M S	022.000.00004
A communication error occurred	Affected module: Loading Bay	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	022.000.00005
Target position reached after retry.	Only information	Electronics - Mechanics	L	022.003.00009
Target position not reached by stirrer	Affected module: Stirrer	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	022.003.00010
A movement problem has been detected	Affected module: Stirrer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	022.003.00023

Message	Description	Action	Effect	Event ID
Actual temperature is not in allowed range defined by parameters.	-	Environmental • Check module environment (temperature, humidity) • Exchange module Configuration • Check instrument configuration • Run Instrument Setup • Call manufacturer	L	022.000.00033
Reagents temperature is out of range	The system is still initializing or resuming; The system was shut down for a long time; Hardware defect	Environmental • Wait for the temperature to be back in range • If the problem persists call Service Configuration	L S	022.004.00033
Actual temperature is back in allowed range defined by parameters.	-	Enviromental • Check module environment (temperature, humidity) • Exchange module ProcessControl Configuration • Check instrument configuration • Run Instrument Setup • Call manufacturer	L	022.000.00034
Reagents temperature is back in range	Only information	Environmental - ProcessControl Configuration	L	022.004.00034
Temperature sensor fails plausibility check	Affected module: Loading Bay	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Configuration	L M S	022.000.00035
Temperature sensor fails plausibility check	Affected module: Loading Bay	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Configuration	L M S	022.004.00035

Message	Description	Action	Effect	Event ID
Seebeck voltage too low	Affected module: Loading Bay	Electronics • If the problem persists call Service Mechanics	L M	022.004.00037
Seebeck voltage too high	Affected module: Loading Bay	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Mechanics	L M	022.004.00038
Temperature sensor fails plausibility check	Affected module: Loading Bay	Electronics • If the problem persists call Service Configuration	L M S	022.004.00043
Initialization of stirrer failed	Affected module: Stirrer	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Mechanics	L M S	022.003.00048
Initialization of stirrer failed	Affected module: Stirrer	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Mechanics	L M S	022.003.00049
Stirrer motor rotation error fequency too low	-	Electronics Mechanics • If the problem persists call Service	L M S	022.003.00052
Not plausible barcode read. It may be that rack insertion took too long	-	InstrumentHandling • Reload the rack • If the problem persists, initialize the system then reload the rack • If the problem persists call Service	L M	022.001.00083
An Internal error occurred	Affected module: Barcode Scanner	Electronics • Initialize the system • If the problem persists call Service	L M S	022.005.00096

Message	Description	Action	Effect	Event ID
An Internal error occurred	Affected module: Barcode Scanner	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Configuration	L M S	022.005.00097
Barcode length exceeds limits	-	Consumable Configuration	L	022.001.00116
An error occurred while accessing RFTag	Affected module: Loading Bay	Consumable • If the problem persists call Service	L M S	022.002.00130

Table 8–56: Message list, LoadingBay

8.29 PumpStarter2

Device ID: **0x14**

8.29.1 Sub assemblies

ID (dec)	ID (hex)	Name
7	0x07	General

Table 8–57: Sub assemblies, PumpStarter2

8.29.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Starter Pump 2	Electronics • If the problem persists call Service	L M S	020.007.00004
A communication error occurred	Affected module: Starter Pump 2	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	020.007.00005
Motor overload	Affected module: Starter Pump 2	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	020.007.00008

Message	Description	Action	Effect	Event ID
Target position reached after retry.	Only information	Electronics - Mechanics	L	020.007.00009
Target position not reached by pump	Affected module: Starter Pump 2	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	020.007.00010
Initialization of pump failed	Affected module: Starter Pump 2	Electronics • If the problem persists call Service Mechanics	L M S	020.007.00032
Initialization of pump failed	Affected module: Starter Pump 2	Electronics • If the problem persists call Service Mechanics	L M S	020.007.00033
An internal error occurred	Affected module: Starter Pump 2	Calibration • If the problem persists call Service Electronics	L M S	020.007.00176
An internal error occurred	Affected module: Starter Pump 2	Configuration • If the problem persists call Service Electronics	L M S	020.007.00180

Table 8–58: Message list, PumpStarter2

8.30 PumpStarter1

Device ID: **0x14**

8.30.1 Sub assemblies

ID (dec)	ID (hex)	Name
6	0x06	General

Table 8–59: Sub assemblies, PumpStarter1

8.30.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Starter Pump 1	Electronics • If the problem persists call Service	L M S	020.006.00004
A communication error occurred	Affected module: Starter Pump 1	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	020.006.00005
Motor overload	Affected module: Starter Pump 1	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	020.006.00008
Target position reached after retry.	Only information	Electronics - Mechanics	L	020.006.00009
Target position not reached by pump	Affected module: Starter Pump 1	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	020.006.00010
Initialization of pump failed	Affected module: Starter Pump 1	Electronics • If the problem persists call Service Mechanics	L M S	020.006.00032
Initialization of pump failed	Affected module: Starter Pump 1	Electronics • If the problem persists call Service Mechanics	L M S	020.006.00033
An internal error occurred	Affected module: Starter Pump 1	Calibration • If the problem persists call Service Electronics	L M S	020.006.00176
An internal error occurred	Affected module: Starter Pump 1	Configuration • If the problem persists call Service Electronics	L M S	020.006.00180

Table 8–60: Message list, PumpStarter1

8.31 Measurement

Device ID: **0x14**

8.31.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
2	0x02	Rotor
3	0x03	Lift
1	0x01	Measurement
5	0x05	BubbleSensor

Table 8–61: Sub assemblies, Measurement

8.31.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Reader	Electronics • If the problem persists call Service	L M S	020.000.00004
A communication error occurred	Affected module: Reader	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	020.000.00005
Target position reached after retry.	Only information	Electronics - Mechanics	L	020.002.00009
Target position reached after retry.	Only information	Electronics - Mechanics	L	020.003.00009
Target position not reached by rotor	Affected module: Reader	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	020.002.00010
Target position not reached by lift	Affected module: Reader	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	020.003.00010

Message	Description	Action	Effect	Event ID
High Voltage out of range.	Affected module: Reader	Electronics • Call Service	L M S	020.001.00033
An Internal error occurred	Affected module: Reader	Mechanics • Call Service Electronics	L M S	020.000.00034
An Internal error occurred	Affected module: Reader	Electronics • Call Service	L M S	020.000.00035
Measured High voltage reference is out of allowed range	Affected module: Reader	Electronics • Call Service	L M S	020.001.00037
Initialization of lift failed	Affected module: Reader	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	020.003.00048
Initialization of rotor failed	Affected module: Reader	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	020.002.00048
Initialization of lift failed	Affected module: Reader	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	020.003.00049
Initialization of rotor failed	Affected module: Reader	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	020.002.00049
Target position not reached by rotor	Affected module: Reader	Mechanics • Initialize the system • If the problem persists call Service	L M S	020.002.00057

Message	Description	Action	Effect	Event ID
Target position not reached by rotor	Affected module: Reader	Mechanics • Initialize the system • If the problem persists call Service	L M S	020.002.00059
Detected Fan frequency out of allowed range.	-	Electronics • If the problem persists call Service	L M S	020.000.00065
Detected Fan frequency is back in range.	Only information	Electronics -	L	020.000.00066
Detected Fan frequency is invalid.	-	Electronics • Call Service	L M S	020.000.00067
Target position not reached by lift	Affected module: Reader	Mechanics • Initialize the system • If the problem persists call Service Calibration	L M S	020.003.00083
Bubble sensor can not be calibrated or still isn't calibrated.	Affected module: Reader	Calibration • Perform the Initialization and then the Bubble Sensor calibration • If the problem persists call Service InstrumentHandling	L M S	020.005.00144

Table 8–62: Message list, Measurement

8.32 Washer

Device ID: **0x13**

8.32.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
1	0x01	Probe1
2	0x02	Probe2
3	0x03	Probe3
4	0x04	Ring

Table 8–63: Sub assemblies, Washer

8.32.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Washer	Electronics • If the problem persists call Service	L M S	019.000.00004
A communication error occurred	Affected module: Washer	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	019.000.00005
Target position reached after retry.	Only information	Mechanics - Electronics	L	019.001.00009
Target position reached after retry.	Only information	Mechanics - Electronics	L	019.002.00009
Target position reached after retry.	Only information	Mechanics - Electronics	L	019.003.00009
Target position reached after retry.	Only information	Mechanics - Electronics	L	019.004.00009
Target position not reached by probe 1	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.001.00010

Message	Description	Action	Effect	Event ID
Target position not reached by probe 2	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.002.00010
Target position not reached by probe 3	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.003.00010
Target position not reached by rotor	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.004.00010
A movement problem has been detected	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.000.00023
Initialization of probe 1 failed	Affected module: Washer	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	019.001.00034
Initialization of probe 2 failed	Affected module: Washer	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	019.002.00034
Initialization of probe 3 failed	Affected module: Washer	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	019.003.00034

Message	Description	Action	Effect	Event ID
Initialization of rotor failed	Affected module: Washer	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	019.004.00034
Initialization of probe 1 failed	Affected module: Washer	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	019.001.00035
Initialization of probe 2 failed	Affected module: Washer	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	019.002.00035
Initialization of probe 3 failed	Affected module: Washer	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	019.003.00035
Initialization of rotor failed	Affected module: Washer	Mechanics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Electronics	L M S	019.004.00035
Target position not reached by probe 1	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.001.00067

Message	Description	Action	Effect	Event ID
Target position not reached by probe 2	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.002.00067
Target position not reached by probe 3	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.003.00067
Target position not reached by rotor	Affected module: Washer	Mechanics • Initialize the system • If the problem persists call Service Electronics	L M S	019.004.00080
An internal error occurred	Affected module: Washer	Calibration • If the problem persists call Service Electronics	L M S	019.000.00176
An internal error occurred	Affected module: Washer	Configuration • If the problem persists call Service Electronics	L M S	019.000.00180

Table 8–64: Message list, Washer

8.33 Incubator

Device ID: **0x12**

8.33.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–65: Sub assemblies, Incubator

8.33.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: Incubator	Electronics • If the problem persists call Service	L M S	018.000.00004
A communication error occurred	Affected module: Incubator	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	018.000.00005
Motor overload	Affected module: Incubator	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	018.000.00008
Target position reached after retry.	Only information	Electronics - Mechanics	L	018.000.00009
Target position not reached by rotor	Affected module: Incubator	Electronics • Initialize the system • If the problem persists call Service Mechanics	L M S	018.000.00010
An Incubator movement problem has been detected	-	Electronics • If the problem persists call Service Mechanics	L M S	018.000.00043
An internal error occurred	Affected module: Incubator	Calibration • If the problem persists call Service Electronics	L M S	018.000.00176
An internal error occurred	Affected module: Incubator	Configuration • If the problem persists call Service Electronics	L M S	018.000.00180

Table 8–66: Message list, Incubator

8.34 UserAccessPanel

Device ID: **0x11**

8.34.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–67: Sub assemblies, UserAccessPanel

8.34.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	-	Electronics • If the problem persists call Service	L M S	017.000.00004
A communication error occurred	-	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	017.000.00005

Table 8–68: Message list, UserAccessPanel

8.35 PwrCanExtension

Device ID: **0x10**

8.35.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General

Table 8–69: Sub assemblies, PwrCanExtension

8.35.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	-	Electronics • If the problem persists call Service	L M S	016.000.00004
A communication error occurred	-	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	016.000.00005

Table 8–70: Message list, PwrCanExtension

8.36 COP

Device ID: **0x00**

8.36.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	General
2	0x02	CopCom

Table 8–71: Sub assemblies, COP

8.36.2 Message list

Message	Description	Action	Effect	Event ID
An internal error occurred	Affected module: COP	Electronics • If the problem persists call Service	L M S	000.000.00004
A communication error occurred	-	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	000.000.00005
An Internal error occurred during self test	-	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service	L M S	000.000.00012
No communication from PC for too long time.	-	Electronics • Initialize the system • If the problem persists, Switch-off, restart and initialize the system • If the problem persists call Service Configuration	L M S	000.002.00050
Change to FSE operation mode to { Mode }.	Affected module: COP	Configuration • Call Service Subsequent	L M S	000.000.00160

Table 8–72: Message list, COP

8.37 QCStat

Device ID: **0x202**

8.37.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	RulePassed

Table 8–73: Sub assemblies, QCStat

8.37.2 Message list

Message	Description	Action	Effect	Event ID
Quality Control {0} for analyzer '{1}', assay '{2}', control name '{3}' at {4}. The rule type was '{5}' with the comment: '{6}'.	Only information	-	L M S	514.000.00001
Quality Control {0} for analyzer '{1}', assay '{2}', control name '{3}' at {4}. The rule type was '{5}' with the comment: '{6}'.	Only information	-	L M S	514.000.00002
Quality Control gets informed for analyzer '{0}', assay '{1}', control name '{2}'.	Only information	-	L	514.000.00003
Communication error with Quality Control occurred. Please check if all controls are in range.	QC-Stats might be out-of-sync due to communication error.	• Please call Customer Service.	L M	514.000.00004

Table 8–74: Message list, QCStat

8.38 Backup

Device ID: **0x201**

8.38.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	DefinitionFileNotFound

Table 8–75: Sub assemblies, Backup

8.38.2 Message list

Message	Description	Action	Effect	Event ID
The configuration file {0} containing the backup definitions was not found.	-	• Call Service	L M	513.000.00001
The backup operation failed.	-	• Retry to perform the Backup • If problem persists call Service	L S	513.000.00002
The backup type {0} is not found in the backup definitions file.	-	• Call Service	L	513.000.00003
The backup of the database {0} failed.		-	L	513.000.00004
Access denied to the directory {0}	-	• Call Service	L	513.000.00005
Could not create backup of database {0}.	An issue during the access to Database occured	• If the problem persists call Service	L	513.000.00006
Could not copy backup file(s). Error: {0}.	-	• Call Service	L	513.000.00007
Could not copy backup file(s). The system doesn't have permissions to write in the destination directory {0}	-	• Ensure the system has the permission to write in the destination folder. • If the problem persists call Service	L	513.000.00008
There is not enough space on {0} to copy the file(s).	-	• Ensure to have enough space into the destination folder • If the problem persists call Service	L S	513.000.00009
Could not delete the backup file(s). Error: {0}.	-	• Restart the system • If problem re-occurs call Service	L M S	513.000.00010
A Low Level Message was sent.	Only information	-	L M	515.000.00001

Table 8–76: Message list, Backup

8.39 AutoBackup

Device ID: **0x201**

8.39.1 Sub assemblies

ID (dec)	ID (hex)	Name
1	0x01	SecondPathDoesNotExist

Table 8–77: Sub assemblies, AutoBackup

8.39.2 Message list

Message	Description	Action	Effect	Event ID
Could not copy autobackup file {0}. Target directory {1} does not exist.	-	• Ensure that the destination folder is available for the system. • If the problem persists call Service	L M S	513.001.00001
Could not copy autobackup file {0}.	-	• If the problem persists call Service	L M S	513.001.00002
Autobackup operation failed.	-	• Check availability of the destination path (e.g. network path, USB) • If the problem persists call Service	L M S	513.001.00003

Table 8–78: Message list, AutoBackup

8.40 DataReduction

Device ID: **0x200**

8.40.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	CalibrationSetToInvalidDue ToKulovic

Table 8–79: Sub assemblies, DataReduction

8.40.2 Message list

Message	Description	Action	Effect	Event ID
Calibration {0} set invalid due to internal error	-	• Repeat the calibration • If problem persists call Service	L S	512.000.00000
Invalidated Calibration {0} due to max RLU CV.	Only information	• Restart the calibration • If problem persists replace the kit	L S	512.000.00001
Invalidated Calibration {0} due to deleted calibrator result.	Only information	-	L M S	512.000.00004
Set Calibration {0} to NotUsed due to Calibration {1}.	Only information	-	L	512.000.00020
Set Calibration {0} to NotUsedLot due to Starter Lot Switch.	Only information	-	L	512.000.00021
Set Calibration {0} to Expired.	Only information	-	L S	512.000.00022
Set Calibration {0} to Disabled.	Only information	-	L	512.000.00023

Table 8–80: Message list, DataReduction

8.41 TDef

Device ID: **0x1FF**

8.41.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	ProcessInputDescriptionException

Table 8–81: Sub assemblies, TDef

8.41.2 Message list

Message	Description	Action	Effect	Event ID
A communication issue between PC and instrument e occurred	-	• Call Service	L	511.000.00001
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00002
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00003
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00004
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00005
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00006
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00010
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00011
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00025
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00026
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00027
It was not possible to correctly handle the Assay Protocol	-	• Call Service	L	511.000.00033
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00034
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00035

Message	Description	Action	Effect	Event ID
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00037
It was not possible to correctly handle the Assay protocol	-	• Call Service	L	511.000.00041

Table 8–82: Message list, TDef

8.42 ICoL

Device ID: **0x1FE**

8.42.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	UnknownMessage

Table 8–83: Sub assemblies, ICoL

8.42.2 Message list

Message	Description	Action	Effect	Event ID
A communication issue between PC and instrument e occurred	-	• Call Service	L	510.000.00000
A communication issue between PC and instrument e occurred	-	• Call Service	L	510.000.00001
A communication issue between PC and instrument is occurred	-	• Call Service	L	510.000.00002
A communication issue between PC and instrument e occurred	-	• Call Service	L M S	510.000.00003
A communication issue between PC and instrument e occurred	-	• Call Service	L M S	510.000.00004
A communication issue between PC and instrument e occurred	-	• Call Service	L M S	510.000.00005
A communication issue between PC and instrument e occurred	-	• Call Service	L	510.000.00006

Table 8–84: Message list, ICoL

8.43 LIS

Device ID: **0x1FD**

8.43.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	NoResponseToQuery

Table 8–85: Sub assemblies, LIS

8.43.2 Message list

Message	Description	Action	Effect	Event ID
No response to query for workorder for SID {0} within {1} seconds.	No response is provided from the host for that SID until the timeout	• If the worklist for that SID was correctly received, ignore it • If no worklist was provided for that SID, reload the involved Sample • If the problem persists call Service	L	509.000.00001
Structure error in received LIS message.	An error with the LIS protocol is occurred	• Call Service	L M S	509.000.00002
Error while transmitting data to LIS.	An error in the LIS communication occurred	• Retry the transmission	L M	509.000.00004
Liaison XS LIS module running.	Only information	• If the problem persists, call service	L	509.000.00006
Liaison XS LIS module stopped.	Only information	-	L	509.000.00007
Liaison XS LIS module could not be started.	-	• Make sure the cable between the PC and the LIS system is plugged in correctly • Restart the PC • If the problem persists call Service	L M S	509.000.00008
Liaison XS LIS module could not be stopped.	Only information	-	L M S	509.000.00009
Liaison XS LIS module received an invalid message (unsupported message type or structure error).	-	• Retry the transmission • If the problem persists call Service	L M S	509.000.00010

Table 8–86: Message list, LIS

8.44 Reporting

Device ID: **0x1FC**

8.44.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	PrintError

Table 8–87: Sub assemblies, Reporting

8.44.2 Message list

Message	Description	Action	Effect	Event ID
An error occurred while trying to print the report.	Only information	• Call Service	L M S	508.000.00001
The printer settings are not valid.	An error was detected with printer	-	L M S	508.000.00002
The printer status has changed to online.	Only information	-	L	508.000.00003
The printer status has changed to offline.	Only information	-	L	508.000.00004

Table 8–88: Message list, Reporting

8.45 UI

Device ID: **0x1FB**

8.45.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	ImportingAssayFile

Table 8–89: Sub assemblies, UI

8.45.2 Message list

Message	Description	Action	Effect	Event ID
Importing Assay File {0}.	Only information	-	L	507.000.00000
Importing Assay with Abbreviation {0}.	Only information	-	L	507.000.00001
Overwriting Assay with Abbreviation {0} version {1} with version {2}.	Only information	-	L	507.000.00002
Importing assay group file '{0}'.	Only information	-	L	507.000.00003
Importing assay profile file '{0}'.	Only information	-	L	507.000.00004
Exporting selected assay group(s) to file '{0}'.	Only information	-	L	507.000.00005
Exporting selected assay profile(s) to file '{0}'.	Only information	-	L	507.000.00006
Importing dilution sequences file '{0}'.	Only information	-	L	507.000.00007
Importing rerun rules file '{0}'.	Only information	-	L	507.000.00008
Exporting rerun rules file '{0}'.	Only information	-	L	507.000.00009
Importing control definitions file '{0}'.	Only information	-	L	507.000.00010
Exporting control definitions file '{0}'.	Only information	-	L	507.000.00011
Assay '{0}' with article number '{1}', name '{2}' and LIS alias '{3}' deleted.	Only information	-	L	507.000.00012
Importing scanned control definition '{0}', lot number '{1}', barcode '{2}'.	Only information	-	L	507.000.00013
Importing scanned control definition(s) failed.	-	• Scan the control definition again • If the problem persists call Service	L M	507.000.00014
Importing control definitions file '{0}' failed.	Only information	-	L	507.000.00015

Message	Description	Action	Effect	Event ID
Resetting User Unit, Normal Range and Qualitative Labels for Assay {0}.	Only information	-	L	507.000.00020
Overwriting Assay Master Curve Unit from {0} to {1}.	Only information	-	L M	507.000.00021
Overwriting Assay Sample Replicates Manufacturer from {0} to {1}.	Only information	-	L M	507.000.00022
Overwriting Assay Control Replicates Manufacturer from {0} to {1}.	Only information	-	L M	507.000.00023
Overwriting Assay Assay Range from {0} to {1}.	Only information	-	L M	507.000.00024
Overwriting Assay Share Calibrations within Kit Lot Manufacturer from {0} to {1}.	Only information	-	L M	507.000.00025
The Assay {0} is missing for the Control Analyte Value.	Only information	• Import the requested Assay protocol	L M S	507.000.00030
The Control Definition {0} with Lot {1} was not imported as no matching assays was found in the database	-	• Import at least one of the requested Assay protocols and re-import the Control Definition	L M	507.000.00031
Overwrite Control Definition {0} with Lot {1}.	Only information	-	L	507.000.00032
Access rights imported.	Only information	-	L	507.000.00040

Table 8–90: Message list, UI

8.46 Maintenance

Device ID: **0x1FA**

8.46.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	ImportSuccessful

Table 8–91: Sub assemblies, Maintenance

8.46.2 Message list

Message	Description	Action	Effect	Event ID
Maintenance import finished successfully.	Only information	-	L	506.000.00003
An error occurred while importing the maintenance file	Only information	• Call Service	L M	506.000.00004
{0} maintenance task completed successfully.	Only information	-	L M	506.000.00007
Maintenance task {0} started.	Only information	-	L	506.000.00011
Insufficient {0} for starting this maintenance task.	-	• Ensure that the indicated resource is enough for the requested task	L M S	506.000.00012
Maintenance task cannot be started. Starter temperature is out of range.	-	• Ensure that the working conditions are respected • Allow the system to recover • If the problem persists call Service	L M	506.000.00013
Maintenance task cannot be started. Incubator temperature is out of range.	-	• Ensure that the working conditions are respected • Allow the system to recover • If the problem persists call Service	L M	506.000.00014
This maintenance task cannot be started because the instrument is not in the correct state	-	-	L M	506.000.00017
{0} maintenance task aborted manually.	Only information	-	L M	506.000.00019

Message	Description	Action	Effect	Event ID
{0} maintenance task failed.	-	• Ensure all the needed resources are loaded • Restart the maintenance task • If the problem persists call Service	L M S	506.000.00020
A maintenance step is not defined or is not available.	-	• Call Service	L M	506.000.00024
A maintenance step parameter was not found.	-	• Call Service	L M	506.000.00025
All the parameters of a maintenance task are not correctly defined.	-	• Call Service	L M	506.000.00026
Error in maintenance task definition.	-	• Call Service	L M	506.000.00027
Maintenance import files are not valid xml files.	-	-	L M	506.000.00029
Maintenance import file version incompatible with current Software.	-	-	L M	506.000.00030
Maintenance import file has no XML schema version specified.	-	-	L M	506.000.00031
Maintenance procedure not available for maintenance task. Import failed.	-	• Call Service	L M	506.000.00033
Maintenance Task not startable because instrument in {0} state.	Ensure to be in Ready or Standby	-	L M	506.000.00034
Light check left is not loaded.	Only information	• Load the Light Check left and restart the task	L S	506.000.00040
Light check right is not loaded.	Only information	• Load the Light Check right and restart the task	L S	506.000.00041

Table 8–92: Message list, Maintenance

8.47 Waste

Device ID: **0x1F9**

8.47.1 Sub assemblies

ID (dec)	ID (hex)	Name
5	0x05	SolidWasteEmptied

Table 8–93: Sub assemblies, Waste

8.47.2 Message list

Message	Description	Action	Effect	Event ID
Solid waste was emptied.	Only information	-	L	505.005.00000
Solid waste is full.	Only information	• Empty the solid waste	L S	505.005.00001
Solid waste was removed, current level: {0}.	Only information	-	L	505.005.00002
Solid waste was inserted, current level: {0}.	Only information	-	L	505.005.00003
Solid waste is nearly full.	Only information	-	L M S	505.005.00004
Not enough solid waste available for priming.	Only information	• Empty the solid waste	L M S	505.005.00005
Not enough liquid waste available for priming.	Only information	• Empty the liquid waste	L M S	505.005.00006
Not enough liquid waste available for self diagnostics.	Only information	• Empty the liquid waste	L M S	505.005.00007
Prime not possible because solid waste is not loaded.	Only information	-	L M S	505.005.00008

Table 8–94: Message list, Waste

8.48 TopCover

Device ID: **0x1F9**

8.48.1 Sub assemblies

ID (dec)	ID (hex)	Name
7	0x07	TopCoverOpenForPriming

Table 8–95: Sub assemblies, TopCover

8.48.2 Message list

Message	Description	Action	Effect	Event ID
Prime not possible because top cover is open.	Only information	• Close the top cover	L M S	505.007.00000
Top Cover closed.	Only information	-	L	505.007.00098
Top Cover opened.	Only information	-	L	505.007.00099

Table 8–96: Message list, TopCover

8.49 StarterLoading

Device ID: **0x1F9**

8.49.1 Sub assemblies

ID (dec)	ID (hex)	Name
3	0x03	StarterRFIDDataBlockError

Table 8–97: Sub assemblies, StarterLoading

8.49.2 Message list

Message	Description	Action	Effect	Event ID
Starter {0} has wrong RFID data block size.	-	• Remove the Starter in error and re-load it • If the problem persists call Service	L M S	505.003.00000
Starter {0} has wrong identification: '{1}', expected: '{2}'.	-	• Remove the Starter in error and re-load it • If the problem persists call Service	L M	505.003.00001
Starter {0} has wrong CRC checksum.	-	• Remove the Starter in error and re-load it • If the problem persists call Service	L M	505.003.00002
Starter {0} inserted.	Only information	-	L	505.003.00003
Starter from position {0} removed.	Only information	-	L	505.003.00004
Starter in position {0} shelf expired.	-	• Replace the expired Starter bottle	L M S	505.003.00005
Starter in use from position {0} removed.	Only information	-	L M S	505.003.00006
Starter {0} lot has changed and will invalidate all calibrations on prime.	Only information	-	L M	505.003.00007
Starter {0} lot switched from {1} to {2}.	Only information	-	L	505.003.00008
Starter {0} taken offline.	Bubbles were detected in the Starter lines	• If the problem often occurs call Service	L S	505.003.00009
Not enough Starter {0} available for prime.	Only information	• Replace the Starter bottle	L M S	505.003.00010
Starter Flap closed.	Only information	-	L	505.003.00098
Starter Flap opened.	Only information	-	L	505.003.00099

Table 8–98: Message list, StarterLoading

8.50 SampleLoading

Device ID: **0x1F9**

8.50.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	SampleRackInserted

Table 8–99: Sub assemblies, SampleLoading

8.50.2 Message list

Message	Description	Action	Effect	Event ID
Sample rack in lane {0} inserted.	Only information	-	L S	505.000.00000
Sample rack from lane {0} removed.	Only information	-	L	505.000.00001
Sample rack from lane {0} removed while in use.	A needed sample rack was no longer available to the system, either because manually removed or due to instrument failure	• Reload the Sample Rack and restart the failed jobs • If problem persists call Service	L M S	505.000.00002
Sample {0} in lane {1} taken offline.	The sample tube is offline; Possible causes:;- Not enough sample liquid;- Clot detected;- Wrong Rack used for the involved tube	• Check the Sample integrity (no foam, enough liquid) • reload it in the appropriate Rack • Restart the job • If the problem persists call Service	L M S	505.000.00003
Invalid barcode found in lane {0} position {1}: '{2}'.	Only information	• Ensure to use a compatible barcode • Check the label quality • If the problem persists call Service	L M	505.000.00004
Duplicate barcode found in lane {0} position {1}: '{2}'. The same sample is already loaded in lane {3} position {4}.	In the loaded racks, two or more Samples carry the same ID. The system kept the first recognized tube only	• In case also the other tubes shall be tested. • Reload such tubes and ensure that a unique barcode is attached to each of them.	L M	505.000.00005
Invalid rack inserted into lane {0}.	The system cannot recognized the inserted Rack type	• Call Service	L	505.000.00006
RackID '{0}' manually entered.	Only information	-	L	505.000.00007
Rack file '{0}' not found.	Only information	-	L	505.000.00008

Message	Description	Action	Effect	Event ID
Last read position barcode does not match the position defined in the RAC file in lane {0}.	-	-	L	505.000.00009
An aspiration error occurred for sample {0} in lane {1}	-	• Ensure the tube contains the needed amount of Sample • Check Sample integrity • Load the Sample tube in the appropriate Rack • Restart the job • If the problem persists call Service	LMS	505.000.00011
At least one position barcode could not be read in lane {0}.	-	-	L	505.000.00012
The Barcode {0} was denied because Barcode {1} is known in the database. Case conflict	-	-	L	505.000.00010
Sample Flap closed.	Only information	-	L	505.000.00098
Sample Flap opened.	Only information	-	L	505.000.00099

Table 8–100: Message list, SampleLoading

8.51 ReagentLoading

Device ID: **0x1F9**

8.51.1 Sub assemblies

ID (dec)	ID (hex)	Name
1	0x01	IntegralShelfExpired

Table 8–101: Sub assemblies, ReagentLoading

8.51.2 Message list

Message	Description	Action	Effect	Event ID
Integral in lane {0} for assay {1} is shelf expired.	-	• Replace the expired Integral	L M S	505.001.00000
Integral in lane {0} for assay {1} is onboard expired.	-	• Check the product Instruction For Use	L M S	505.001.00001

Message	Description	Action	Effect	Event ID
Integral in lane {0} with Article Number '{1}', Kit Number '{2}' and Lot Number '{3}' is already loaded in the instrument.	-	• Remove the Integral in error and re-load it in a different lane. • If the problem persists call Service	L M	505.001.00002
Integral in lane {0} has wrong identification: '{1}', expected: '{2}'	-	• Remove the Integral in error and re-load it in a different lane. • If the problem persists call Service.	L M S	505.001.00003
Integral in lane {0} has wrong CRC checksum.	-	• Remove the Integral in error and re-load it in a different lane. • If the problem persists call Service.	L M S	505.001.00004
Integral in lane {0} has wrong RFID data block size.	-	• Remove the Integral in error and re-load it in a different lane. • If the problem persists call Service	L M S	505.001.00005
Integral in lane {0} set offline as LLD is 0 while remaining volume is >0.	The system failed to find the liquid in a vial of the involved Integral	• If no used vial is exhausted, check the proper Integral conditions then use the 'Reset LLD' function. • If an used vial is exhausted, replace the Integral. • If the problem often occurs call Service.	L M S	505.001.00006
Integral {0} in lane {1} inserted.	Only information	-	L	505.001.00010
Integral {0} from lane {1} removed.	Only information	-	L	505.001.00011
Onboard stability expired for integral {0} in lane {1}.	-	• Check the product Instruction For Use	L M S	505.001.00012
Integral {0} from lane {1} removed while in use.	A needed Integral was no longer available to the system, either because manually removed or due to instrument failure	• Reload the Integral and restart the failed jobs. • If problem persists call Service.	L M S	505.001.00013
Integral in lane {0} has wrong calibration block CRC checksum.	-	• Remove the Integral in error and re-load it in a different lane. • If the problem persists call Service.	L M S	505.001.00020

Message	Description	Action	Effect	Event ID
Integral in lane {0} has wrong combi block CRC checksum.	-	• Remove the Integral in error and re-load it in a different lane. • If the problem persists call Service	L M S	505.001.00021
Assay {0} has Version {1}, but integrals needs {2}.	The version of the Assay protocol and the one of the loaded Integral do not match	• Ensure that the involved Integral is compatible with the revision of the loaded Assay. • If the versions are not compatible, either use a compatible Integral kit or import a compatible Assay protocol revision. • If no compatible Assay is available download or acquire it, then import it. • If the error has been given using compatible versions, call Service.	L M S	505.001.00022
Integral {0} in lane {1} taken offline (error in position {2}).	-	-	L M S	505.001.00023
Integral {0} in lane {1} disabled.	Only information	-	L	505.001.00024
Integral {0} in lane {1} enabled.	Only information	-	L	505.001.00025
No Assay loaded for the Integral in lane {0} with the Article Number {1}.	-	• Import the needed Assay. • If the problem persists call Service.	L S	505.001.00026
Reset Liquid Levels on Integral {0} in lane {1}. Please unload and reload that Integral	The reset of the liquid levels of the Integral has been successfully completed and it is necessary to unload and re-load the Integral to make it effective	-	L M	505.001.00030
Rack file '{0}' not found.	Only information	-	L	505.001.00032
Reagent Flap closed.	Only information	-	L	505.001.00098
Reagent Flap opened.	Only information	-	L	505.001.00099

Table 8–102: Message list, ReagentLoading

8.52 LiquidContainers

Device ID: **0x1F9**

8.52.1 Sub assemblies

ID (dec)	ID (hex)	Name
6	0x06	WashBufferRemovedWhileInUse

Table 8–103: Sub assemblies, LiquidContainers

8.52.2 Message list

Message	Description	Action	Effect	Event ID
Wash buffer was removed while in use.	Only information	-	L M S	505.006.00000
Not enough wash buffer available for priming.	Only information	• Refill the Wash Buffer	L M S	505.006.00001
Not enough system liquid available for priming.	Only information	• Refill the System Liquid	L M S	505.006.00002
Not enough System Liquid available for self diagnostics.	Only information	• Refill the System Liquid	L M S	505.006.00003
System Liquid was removed while in use.	Only information	-	L M S	505.006.00004

Table 8–104: Message list, LiquidContainers

8.53 Consumables

Device ID: **0x1F9**

8.53.1 Sub assemblies

ID (dec)	ID (hex)	Name
4	0x04	DrawerWithdrawRequest

Table 8–105: Sub assemblies, Consumables

8.53.2 Message list

Message	Description	Action	Effect	Event ID
Consumables Drawer was requested to be removed	Only information	-	L	505.004.00000
Consumables Drawer was removed while In Use.	Only information	-	L M	505.004.00001
Not enough cuvettes available for priming.	Only information	• Load Cuvettes	L M S	505.004.00002
Warn Level for Cuvettes has been reached	Only information	-	L S	505.004.00003
Warn Level for Cuvettes has been left	Only information	-	L	505.004.00004
Warn Level for Disposable Tips has been reached	Only information	-	L S	505.004.00005
Warn Level for Disposable Tips has been left	Only information	-	L	505.004.00006
Consumables Drawer pushed in.	Only information	-	L	505.004.00098
Consumables Drawer pulled out.	Only information	-	L	505.004.00099

Table 8–106: Message list, Consumables

8.54 AncillaryLoading

Device ID: **0x1F9**

8.54.1 Sub assemblies

ID (dec)	ID (hex)	Name
2	0x02	AncillaryShelfExpired

Table 8–107: Sub assemblies, AncillaryLoading

8.54.2 Message list

Message	Description	Action	Effect	Event ID
Ancillary {0} in position {1} is shelf expired.	-	• Replace the expired Ancillary	L M S	505.002.00000
Ancillary {0} in position {1} is onboard expired.	-	• Check the product Instruction For Use	L M S	505.002.00001
Ancillary in position {0} with Article Number '{1}', Vial Number '{2}' and Lot Number '{3}' is already loaded in another position.	-	• Remove the Ancillary in error and re-load it in a different position. • If the problem persists call Service	L M	505.002.00002
Ancillary in position {0} has wrong identification: '{1}', expected: '{2}'	-	• Remove the Ancillary in error and re-load it in a different position. • If the problem persists call Service.	L M S	505.002.00003
Ancillary in position {0} has wrong CRC checksum.	-	• Remove the Ancillary in error and re-load it in a different position. • If the problem persists call Service.	L M S	505.002.00004
Ancillary in position {0} has wrong RFID data block size.	-	• Remove the Ancillary in error and re-load it in a different position. • If the problem persists call Service.	L M S	505.002.00005
Ancillary {0} in position {1} disabled.	Only information	-	L	505.002.00006
Ancillary {0} in position {1} enabled.	Only information	-	L	505.002.00007
Ancillary {0} in position {1} inserted.	Only information	-	L	505.002.00010
Ancillary {0} from position {1} removed.	Only information	-	L	505.002.00011

Message	Description	Action	Effect	Event ID
Needed Ancillary {0} from position {1} removed.	A needed Ancillary was removed before that all its programmed aspirations were completed	• Reload the Ancillary • Re-start again the not started jobs	L M S	505.002.00012
Onboard stability expired for ancillary {0} in position {1}.	-	• Check the product Instruction For Use	L M S	505.002.00013
Shelf expired for ancillary {0} in position {1}.	-	• Replace the expired Ancillary	L M S	505.002.00014
Ancillary {0} in position {1} taken offline.	The system failed to find the liquid in the involved Ancillary vial	• If the Ancillary vial is not exhausted and in proper condition, re-load it for later usage • If the ancillary vial is exhausted replace it • If the problem persists call Service	L M S	505.002.00015
Ancillary rack released.	Only information	-	L	505.002.00016
Ancillary rack removed without release.	Only information	-	L M S	505.002.00017
Needed Ancillary {0} at position {1} inserted.	Only information	-	L M	505.002.00018
Needed Ancillary {0} from position {1} removed and not reinserted.	A needed ancillary was not reloaded or it was reloaded but not in the expected position.	• Relaod the needed ancillary in the expected position	L S	505.002.00019

Table 8–108: Message list, AncillaryLoading

8.55 Infrastructure

Device ID: **0x1F8**

8.55.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	VigilantOnlineFieldGatewayServiceConnected
1	0x01	EventCreationException
2	0x02	DeskShieldLanguageFileNotFoundException
3	0x03	WindowsTimeChanged

Table 8–109: Sub assemblies, Infrastructure

8.55.2 Message list

Message	Description	Action	Effect	Event ID
Connected to FieldGateway Service.	Only information	-	L	504.000.00000
Failed to connect to the DoT system: The connection to the FieldGateway Service is failed.	-	• Disable and Enable the DoT module • Restart the PC • If the problem persists call Service	L M	504.000.00001
The system has been disconnected from FieldGateway Service.	Only information	-	L	504.000.00002
Connected to DoT system.	Only information	-	L	504.000.00003
The system has been disconnected from DoT system.	Only information	-	L	504.000.00004
DoT asked for the files: {0}.	Only information	-	L	504.000.00005
DoT asked for the files: {0} from {1} to {2}.	Only information	-	L	504.000.00006
Uploaded file {0} to DoT.	Only information	-	L	504.000.00007
Connected to DoT FastTrack service	The service for downloading instrument packages from DiaSorin online repository is connected	-	L	504.000.00008

Message	Description	Action	Effect	Event ID
The connection to the DoT system is temporarily interrupted.	The DoT services may be temporarily not available	• If problem persists, call Service	L	504.000.00009
Failed to connect to the DoT system: the authentication failed.	The DoT services may be temporarily not available	• If problem persists, call Service	L	504.000.00010
Failed to connect to the DoT system: an interfacing error occured	The DoT services may be temporarily not available	• If problem persists, call Service	L	504.000.00011
Failed to connect to the DoT system: connection was denied by the DoT provisioning service.	The DoT services may be temporarily not available	• If problem persists, call Service	L	504.000.00012
The internet connection to DoT is currently interrupted.	The DoT services may be temporarily not available	• Disconnect and reconnect the instrument to DoT from the System Setting IoT dedicated page • If the problem persists, check the network cable • If the problem persists, contact the Laboratory IT to check network availability • If the problem persists, call Service	L	504.000.00013
Failed to connect to the DoT system: an error occured at the DoT Hub.	The DoT services may be temporarily not available	• If problem persists, call Service	L	504.000.00014
Failed to connect to DoT FastTrack service.	The service for downloading instrument packages from DiaSorin online repository may be temporarily not available	• If problem persists, call Service	L	504.000.00015
An error occurred during the connection to DoT.	The DoT services may be temporarily not available	• Try to connect to DoT again • If the problem persists, check the network cable • If the problem persists, contact the Laboratory IT to check that the network policy have been correctly set to allow the connection for the DoT services • If the problem persists, call Service	L	504.000.00017

Message	Description	Action	Effect	Event ID
Failed to connect to the DoT system: The connection to the FieldGateway Service is interrupted.	The DoT services may be temporarily not available	• If problem persists, call Service		504.000.00018
The connection to DoT is available.	Only information	-	L	504.000.00019
The system has been disconnected from DoT Fast Track	Only information. The service for downloading instrument packages from DiaSorin online repository has been disconnected	-	L	504.000.00021
The connection to the DoT Fast Track is temporarily interrupted.	The service for downloading instrument packages from DiaSorin online repository may be temporarily not available	• If problem persists, call Service	L	504.000.00022
Registration to DoT succeeded.	Only information	-	L	504.000.00030
Registration to DoT failed	The DoT services may be temporarily not available	• If problem persists, call Service	L	504.000.00031
The requested {0} download is still ongoing.	Only information	-	L	504.000.00032
An error occured creating Event Log Entry for {0}.	-	• Call Service	L M S	504.001.00000
The system could not find the desktop shield language file.	The Desktop Shield is not available in the selected SW language; The English one will be used	• Call Service	L	504.002.00000
The system could not update the desktop shield language file.	-	• Call Service	L	504.002.00001
The Windows Time was changed while LiaisonXS was running.	Only information	-	L	504.003.00000
Trace files up to {0} deleted.	Only information	• If the message re-occurs, call Service	L M	504.004.00001

Table 8–110: Message list, Infrastructure

8.56 ProcessControl

Device ID: **0x1F7**

8.56.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	JobScheduled
1	0x01	AbortOngoingJobOnSWStartOrInitialization

Table 8–111: Sub assemblies, ProcessControl

8.56.2 Message list

Message	Description	Action	Effect	Event ID
Scheduled Job {0} {1} for Cycle {2} with JobId {3} (Replicate: {4}, Dilution: {5}, Finish {6}, Integral Lane {7}).	Only information	-	L	503.000.00000
Unscheduled Job {0} {1} {2} {3} for Cycle {4} JobId {5}.	Only information	-	L	503.000.00001
Started Job {0} {1} {2} {3} for Cycle {4} JobId {5}.	Only information	-	L	503.000.00002
Started Mitigation {0} for cycle {1} phase {2} JobId {3}.	Only information	-	L	503.000.00003
The Start button was pressed	Only information	-	L	503.000.00004
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no system liquid.	Not enough System Liquid for the requested job	• Ensure that the System Liquid tank is primed and its amount is sufficient for the requested routine • Start the job again • If the problem persists call Service	L M S	503.000.00009
Start Jobs that were created by a rerun rule.	Only information	-	L	503.000.00010
A scheduling error occurred	-	• If the problem persists call Service	L M S	503.000.00011

Message	Description	Action	Effect	Event ID
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no wash buffer.	Not enough Wash Buffer for the requested job	• Ensure that the Wash Buffer tank is primed and its amount is sufficient for the requested routine • Start the job again • If the problem persists call Service	L M S	503.000.00012
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no cuvette.	Not enough Cuvettes for the requested job	• Ensure that the number of loaded Cuvettes is sufficient for the requested routine • Start the job again • If the problem persists call Service	L M S	503.000.00013
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no disposable tip.	Not enough Tips for the requested job	• Ensure that the number of loaded Tips is sufficient for the requested routine • Start the job again • If the problem persists call Service	L M S	503.000.00014
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no solid waste.	Not enough space in the solid waste for the requested job	• Empty the solid waste • Start the job again • If the problem persists call Service	L M S	503.000.00015
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no starter.	Not enough Starters for the requested job	• Ensure that the Starter bottles are primed and their amount is sufficient for the requested routine • Start the job again • If the problem persists call Service	L M S	503.000.00016
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no integral.	A needed Integral is not available for the requested job	• Ensure that the needed Integral is onboard, online, with enough remaning determinations and volume • Start the job again • If the problem persists call Service	L M S	503.000.00017
Scheduled Starter Prime Job for cycle {0} JobId {1}.	Only information	-	L	503.000.00018
No jobs could be scheduled for start.	Only information	-	L	503.000.00019
Calibration Data incorrect.	-	• Reload the Integral again • If the problem persists call Service	L M	503.000.00020
A needed Dilution Sequence was not found. Schedule aborted.	-	• Call Service	L M S	503.000.00021

Message	Description	Action	Effect	Event ID
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no ancillary.	A needed Ancillary is not available for the requested job	• Ensure that the needed Ancillary is onboard, online, with enough remaning volume • Start the job again • If the problem persists call Service	L M S	503.000.00026
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), reagent {4} depleted.	A needed reagent is not sufficient for the requested job	• Ensure that the needed reagent is onboard, online, with enough remaning volume • Start the job again • If the problem persists call Service	L M S	503.000.00027
Could not schedule Job {0} {1} (Replicate: {2} Dilution: {3}), no Ancillary for Mitigation available.	-	• Load the needed ancillary as per product IFU • If the problem persists, call Service	L M S	503.000.00028
Needed Control {0} not available.	-	• Load required control Sample and ensure to run it as per product Instruction For Use	L M S	503.000.00030
Prime failed.	Only information	-	L	503.000.00031
Scheduled Job {0} {1} for Cycle {2} with JobId {3} (Replicate: {4}, Dilution: {5}, Finish {6}, Integral Lane {7}, agitiation time insufficient).	The agitation time for the Integral is not sufficient	• Check the product Instruction For Use about resuspension of magnetic particles	L M S	503.000.00041
Three times in a row DarkCount Exceeds Envelop.	An error in the Reader occurred	• Call Service	L M S	503.000.00062
Three times in a row DarkCount out of Range.	An error in the Reader occurred	• Call Service	L M S	503.000.00063
Rerun Rule {0} did not create test {1} for {2} because dilution factor {3} is not defined in the assay.	Only information	-	L	503.000.00067
Rerun Rule {0} did not create test {1} because sample {2} has been unloaded.	Only information	-	L	503.000.00068
Flagged Result {0} {1} with 'caused rerun'.	Only information	-	L	503.000.00069
Result {0} {1} flagged with QC Above Manufacturer Range.	-	-	L M	503.000.00070

Message	Description	Action	Effect	Event ID
Result {0} {1} flagged with QC Below Manufacturer Range.	-	-	L M	503.000.00071
Could not recalculated Result {0} {1}, undo changes.	Only information	-	L M S	503.000.00082
Abort Job {0} {1} {2} {3} for Cycle {4} JobId {5} on SW Start or during Initialization.	The system aborted the involved job because of a previous issue (e.g. because the SW unexpectedly close)	• Start again the aborted job • If the problems persists call Service	L M S	503.001.00001
An internal error occurred	-	• Call Service	L M S	503.001.00002
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to darkcount subtraction.	The system aborted the involved job because of the measured signal was too low	• Start again the aborted job • If the problems persists call Service	L M S	503.001.00003
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to unexpected Result Cycle.	The system aborted the involved job because of a scheduling error	• Start again the aborted job • If the problems persists call Service	L M S	503.001.00004
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to Overdilution.	The system aborted the involved job because the obtained diluted result is below the Overdilution threshold	• Start again the aborted job • If the problems persists call Service	L M S	503.001.00005
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to not plausible Aspiration.	An error was detected during the aspiration of the involved test	• Call Service	L M S	503.001.00006
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to starter prime not performed.	The system aborted the involved job because it was not able to successfully perform the needed automatic prime Cuvette	• Start again the aborted job • If the problems persists call Service	L M S	503.001.00007
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to mitigation not performed.	The system aborted the involved job because it was not able to successfully perform the needed mitigation	• Start again the aborted job • If the problems persists call Service	L M S	503.001.00008

Message	Description	Action	Effect	Event ID
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to divided by zero.	The system aborted the involved job because of a mathematical error occurred during result calculation	• Start again the aborted job • If the problems persists call Service	L M S	503.001.00009
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to math error.	The system aborted the involved job because of a mathematical error occurred during result calculation	• Start again the aborted job • If the problem persists call Service	L M S	503.001.00010
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to sent too late.	The system aborted the involved job because it was sent too late to instrument	• Start again the aborted job • If the problem persists call Service	L M S	503.001.00011
Aborted Job {0} {1} {2} {3} due to starter lot switch.	The system aborted the involved job because it is no longer possible to obtain a result with the same lot of Starter	• Start again the aborted job • If the problem persists call Service	L M S	503.001.00020
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to Reagent Pressure Error during pipetting.	-	• Restart the job • If problem persists call Service	L M S	503.001.00021
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to Sample Integrity Error.	An error occurred during the aspiration of the Sample	• Ensure the tube contains the needed amount of Sample • Load the Sample tube in the appropriate Rack • Restart the job • If the problem persists call Service	L M S	503.001.00022
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to clot detected in the sample probe	The system aborted the involved job because a clot was detected during the Sample aspiration	• Ensure the tube contains the needed amount of Sample • Check Sample integrity • Load the Sample tube in the appropriate Rack • Restart the job • If the problems persist call Service	L M S	503.001.00023
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to missing System Liquid.	The system was not able to detect the System Liquid while processing the involved test	• Ensure that the System Liquid tank is loaded, recognized and primed • Restart the job • If the problem persists call Service	L M S	503.001.00024

Message	Description	Action	Effect	Event ID
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to missing Cuvette.	The system aborted the involved job because not all the expected Cuvettes were available	• Ensure the needed Cuvettes are available and assigned on the system • Start again the aborted job • If the problem persists call Service	L M S	503.001.00025
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to missing Disposable Tip.	The system aborted the involved job because not all the expected Tips were available	• Ensure the needed Tips are available and assigned on the system • Start again the aborted job • If the problem persists call Service	L M S	503.001.00026
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to Tip Pickup Failure.	The Probe was not able to pickup a Tip or to recognize that a Tip was picked up	• Check the assignment of the Tips on the SW • Restart the job • If the problem persists call Service	L M S	503.001.00027
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to missing Starter.	The system aborted the involved job because it was not possible to dispense the needed Starter shots; Possible reasons: - the system detected a problem during Starter aspiration; - the Starter bottle was unexpectedly detected as removed; - the Starter RF-Tag contains wrong data	• Ensure the Starter bottle are loaded and primed • Check liquid integrity • In case the reagent was set offline reset the LLD • Start again the aborted job • If the problem persists call Service	L M S	503.001.00028
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to missing Wash Buffer or System Liquid.	The system was not able to detect the Wash Buffer or System Liquid while processing the involved test	• Ensure that the Wash Buffer and System Liquid tanks are loaded • Recognized and primed • Restart the job • If the problem persists call Service	L M S	503.001.00029
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to Washer Aspiration Error at Port {6}.	The Washer aspiration sensors detected anomalies during the aspiration of the dispensed Wash Buffer	• Restart the job • If the problem often occurs perform the dedicated maintenance tasks • If the problem persists call Service	L M S	503.001.00030

Message	Description	Action	Effect	Event ID
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to not enough or no liquid found in sample tube.	An error occurred during the aspiration of the Sample or the Sample was not available for the programmed aspiration	• Ensure the tube contains the needed amount of Sample • Check Sample integrity • Load the Sample tube in the appropriate Rack • Restart the job • If the problem persists call Service	L M S	503.001.00031
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to missing Sample.	An error occurred during the aspiration of the Sample or the Sample was not available for the programmed aspiration	• Ensure the tube contains the needed amount of Sample • Check Sample integrity • Load the Sample tube in the appropriate Rack • Restart the job • If the problem persists call Service	L M S	503.001.00032
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to not enough or no reagent found in the Integral vial {6}.	An error occurred during the aspiration of the reagent or the Integral was not available for the programmed aspiration	• Ensure the needed amount of reagent is available on the system • Check liquid integrity • In case the reagent was set offline reset the LLD • Start again the aborted job • If the problem persists call Service	L M S	503.001.00033
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to missing Reagent {6}.	An error occurred during the aspiration of the reagent or the Integral was not available for the programmed aspiration	• Ensure the needed amount of reagent is available on the system • Check liquid integrity • In case the reagent was set offline reset the LLD • Start again the aborted job • If the problem persists call Service	L M S	503.001.00034
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to not enough or no reagent found in the Ancillary vial {6}.	An error occurred during the aspiration of the Ancillary reagent or the Ancillary was not available for the programmed aspiration	• Ensure the needed amount of Ancillary reagent is available on the system • Check liquid integrity • In case the reagent was set offline unload and reload • Start again the aborted job • If the problem persists call Service	L M S	503.001.00035

Message	Description	Action	Effect	Event ID
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to missing Ancillary {6}.	An error occurred during the aspiration of the Ancillary reagent or the Ancillary was not available for the programmed aspiration	• Ensure the needed amount of Ancillary reagent is available on the system • Check liquid integrity • In case the reagent was set offline unload and reload • Start again the aborted job • If the problem persists call Service	L M S	503.001.00036
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to starter reagent temperature out of range.	The starter reagent temperature was out of range when the job was measured	• Wait for the temperature to be back in range and restart the job • If the problem persists call Service	L M S	503.001.00037
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to OLV Integrity Error during dispense.	An error occurred during the dispensation of a reagent	• Restart the job • If the problem persists call Service	L M S	503.001.00039
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to Starter Dispense Verification Check.	The Reader aspiration sensor detected anomalies during the aspiration of the dispensed Starters	• Restart the job • If the problem often occurs perform the dedicated maintenance tasks • If the problem persists call Service	L M S	503.001.00040
Aborted Job {0} {1} {2} because calibrator can not be scheduled and its calibration was already started.	Rescheduling error occured	• Restart the job • If the problem persists call Service	L M S	503.001.00041
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to user request.	-	-	L M S	503.001.00042
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to OLV Integrity Error at Integral Lane {6} Position {7}.	An error occurred during the aspiration of a reagent from the Integral	• Check the Integral reagent integrity (e.g. no foam, enough volume) • Restart the job • If the problem persists call Service	L M S	503.001.00043
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to OLV Integrity Error at Ancillary Position {6}.	An error occurred during the aspiration of the Ancillary reagent	• Check Ancillary reagent integrity (e.g. no foam, enough volume) • Restart the job • If the problem persists call Service	L M S	503.001.00044
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to DarkCountOutOfRange.	The system aborted the involved job because the darkcount measurement is not valid	• Start again the aborted job • If the problem persists call Service	L M S	503.001.00045

Message	Description	Action	Effect	Event ID
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to DarkCount Average Invalid.	The system aborted the involved job because the darkcount measurement is not valid	• Start again the aborted job • If the problem persists call Service	L M S	503.001.00046
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to DarkCount Average Exceeds Envelop.	The system aborted the involved job because the darkcount measurement is not valid	• Start again the aborted job • If the problem persists call Service	L M S	503.001.00047
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due to too many Spikes detected.	An error occurred during the measurement	• Restart the job • If the problem persists call Service	L M S	503.001.00048
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5} due Pipettor Wash failure.	-	• Restart the job • If problem persists call Service	L M S	503.001.00049
Instrument halted due to too many Pipettor Wash Errors.	-	• Restart the jobs • If problem persists call Service	L M S	503.001.00050
Aborted Job {0} {1} {2} {3} for Cycle {4} JobId {5}, due to event {6} {7}	-	• Call Service	L M S	503.001.00100

Table 8–112: Message list, ProcessControl

8.57 InstrumentControl

Device ID: **0x1F6**

8.57.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	CoordinateFileNotAvailable

Table 8–113: Sub assemblies, InstrumentControl

8.57.2 Message list

Message	Description	Action	Effect	Event ID
Coordinate file could not be loaded.	-	• Replace the not working coordinate file a working one and teach the system again • If problem persists call Service	L M S	502.000.00000
An internal error occurred	-	• Call Service	L M S	502.000.00001
One or more instrument modules did not initialize properly.	-	• Initialize the system • If the problem persists • Switch off, restart and initialize the system • If the problem persists call Service	L M S	502.000.00003
Instrument halted!	-	• Initialize the system • If the problem persists, switch off, restart and initialize the system • If the problem persists call Service	L S	502.000.00004
Transparent mode required by service software is active.	-	• Call Service	L M S	502.000.00007
Incompatible firmware version: {0}. Expected one of the following: {1}.	A compatibility issue with Firmware versions was detected.	• Call Service	L M S	502.000.00008
A communication error occurred	-	• Switch off, restart and initialize the system • If the problem persists call Service	L M S	502.000.00009
A communication error occurred	-	• Switch off, restart and initialize the system • If the problem persists call Service	L M S	502.000.00010

Message	Description	Action	Effect	Event ID
A communication error occurred	-	• Switch off, restart and initialize the system • If the problem persists call Service	L M S	502.000.00011
Dynamic coordinates could not be downloaded to the system.	-	• Initialize the system • If the problem persists, switch off, restart and initialize the system • If the problem persists call Service	L M S	502.000.00012
Too late to transmit Job with JobID {0}.	A processing error was detected	• Restart the job • If the problem often occurs call Service	L M S	502.000.00013
A scheduling error occurred	-	• Call Service	L M S	502.000.00014
The reported incubator ring status does not match the internal status. Incubator ring will be cleared and reloaded.	-	• If the problem persists call Service	L M S	502.000.00015
An internal error occurred	-	• Restart the test • If problem persists call Service	L M S	502.000.00016
Resource state has changed: {0} changed to {1}.	Only information	-	L	502.000.00017
The ring is completely cleared as status Ready was not entered after Running or Maintenance.	-	• If the problem persists, call Service	L M S	502.000.00018
The import was aborted because the instrument is in Running.	-	• Try the import again when the system is not running	L S	502.000.00020
System Liquid not primed because last Pipettor Wash/Prime failed.	Only information	• Restart the resume • If problem persists call Service	L	502.000.00021
Pipettor wash failed.	Only information	• Restart the job • If problem persists call Service	L	502.000.00023
A fatal error occurred on Instrument. (EventID: {0})	-	• If the problem persists call Service	L M S	502.000.00050
An internal error occurred	-	• If the problem persists call Service	L M S	502.000.00051

Message	Description	Action	Effect	Event ID
FSE Mode disabled.	Only information	-	L M	502.000.00053
FSE Mode enabled.	Only information	-	L M	502.000.00054

Table 8–114: Message list, InstrumentControl

8.58 Database

Device ID: **0x1F5**

8.58.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	RepositoryException

Table 8–115: Sub assemblies, Database

8.58.2 Message list

Message	Description	Action	Effect	Event ID
General database error.	-	• Call Service	L M S	501.000.00000
Failed to connect to the database.	-	• Call Service	L M S	501.000.00001
No database available or connection not possible.	-	• Call Service	L M S	501.000.00003
The database is not compatible with the installed SW version	-	• Call Service	L M S	501.000.00004
A cycle mismatch occured. Backup Cycle: {0} Database Cycle {1} COP Cycle {2} new Cycle {3}	Only information	-	L M	501.000.00010
Database check error occurred: {0}. Please call Customer Service.	-	-	L M	501.000.00012

Table 8–116: Message list, Database

8.59 ComProtocol

Device ID: **0x1F4**

8.59.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	ComProtocolException

Table 8–117: Sub assemblies, ComProtocol

8.59.2 Message list

Message	Description	Action	Effect	Event ID
A communication error occurred	-	• Switch off, restart and initialize the system • If the problem persists call Service	L M S	500.000.00039

Table 8–118: Message list, ComProtocol

8.60 Application

Device ID: **0x1F4**

8.60.1 Sub assemblies

ID (dec)	ID (hex)	Name
0	0x00	Started
999	0x3E7	ResearchAndDevelopment Exception

Table 8–119: Sub assemblies, Application

8.60.2 Message list

Message	Description	Action	Effect	Event ID
Application started. Version (product/file): {0}/{1}	Only information	-	L	500.000.00000
Application ended.	Only information	-	L	500.000.00001
User {0} logged in at level {1}.	Only information	-	L	500.000.00002
User {0} logged off.	Only information	-	L	500.000.00003
File {0} has wrong format	-	• Import the file again • If the problem persists call Service	L	500.000.00004
File {0} has wrong checksum.	The file is corrupted	• Import the file again • If the problem persists retry with a fresh copy of the original file • If the problem persists call Service	L	500.000.00005
Aborted import of file {0}.	Import was not successfully completed	• Import the file again • If the problem persists call Service	L	500.000.00006
File export error.	Export was not successfully completed	• Ensure that the export path is available (e.g. network path, USB) • Export the file again • If the problem persists call Service	L	500.000.00007
File {0} could not be exported.	Export was not successfully completed	• Ensure that the export path is available (e.g. network path, USB) • Export the file again • If the problem persists call Service	L	500.000.00008

Message	Description	Action	Effect	Event ID
Unexpected software error. Application must be closed.	-	• Reboot the system and start the SW again • If the problem persists call Service	L M S	500.000.00009
An internal error occurred	-	• Call Service	L M S	500.000.00010
An internal error occurred	-	• Call Service	L M S	500.000.00011
An internal error occurred	-	• Call Service	L M S	500.000.00012
A timeout has been reached while waiting for a response from the instrument	The instrument did not respond within a reasonable time	• Check power connection • Switch off and restart the system • If the problem persists call Service	L M S	500.000.00013
The system failed to start '{0}'	-	• Switch off and restart the system • If the problem persists call service	L M	500.000.00015
Assay with Abbreviation {0}, Article Number {1}, Name {2} LIS alias {3} could not be imported because of existing Assay with Abbreviation {4}, Article Number {5}, LIS Alias {7}	-	• Ensure that there is not a conflict between the current LIS alias and the LIS alias of the Assay to be imported • If the problem persists call Service	L M	500.000.00016
Assay '{0}' with article number '{1}', name '{2}' and LIS alias '{3}' could not be deleted because it is still referenced by assay group '{4}'.	Only information	• Remove the Assay reference form the specified group and retry to delete it	L	500.000.00017
Assay '{0}' with article number '{1}', name '{2}' and LIS alias '{3}' could not be deleted because it is still referenced by assay profile '{4}'.	Only information	• Remove the Assay reference form the specified profile and retry to delete it	L	500.000.00018
Assay '{0}' with article number '{1}', name '{2}' and LIS alias '{3}' could not be deleted because it is still referenced by control definition '{4}', lot number '{5}'.	Only information	• Remove the Assay reference form the specified control definition and retry to delete it	L	500.000.00019

Message	Description	Action	Effect	Event ID
Assay '{0}' with article number '{1}', name '{2}' and LIS alias '{3}' could not be deleted because it is still referenced by rerun rule '{4}'.	Only information	• Remove the Assay reference form the specified rerun rule and retry to delete it	L	500.000.00020
Assay '{0}' with article number '{1}', name '{2}' and LIS alias '{3}' could not be deleted because it is still referenced by one or more browser results.	Only information	• Archive or delete any browser result related to the involved Assay and retry to delete it	L	500.000.00021
Generic sequences import finished successfully.	Only information	-	L	500.000.00022
Generic sequences import failed.	Only information	• Import the file again • If the problem persists retry with a fresh copy of the original file • If the problem persists call Service	L	500.000.00023
Generic sequences not loaded.	-	• Call Service	L	500.000.00024
Dilution sequences import finished successfully.	Only information	-	L	500.000.00025
Dilution sequences import failed.	Only information	• Import the file again • If the problem persists retry with a fresh copy of the original file • If the problem persists call Service	L	500.000.00026
A problem occurred during the archiving of the old system log files	-	• Ensure that the HDD space is not too low • If the space is too low free some disk space • If the problem persists call Service	L M	500.000.00027
System Settings import finished successfully.	Only information	-	L	500.000.00028
System Settings import failed.	-	• Import the file again • If the problem persists retry with a fresh copy of the original file • If the problem persists call Service	L M S	500.000.00029

Message	Description	Action	Effect	Event ID
System Settings Export finished successfully.	Only information	-	L	500.000.00030
System Settings Export failed.	Only information	• Ensure that the export path is available (e.g. network path, USB) • Export the file again • If the problem persists call Service	L	500.000.00031
Could not delete calibration with Calibration Id {0}. The calibration is still referenced by at least one result.	Only information	• Archive or delete any calibrator browser result related to the involved calibration and retry to delete it	L M	500.000.00032
Assay deletion failed. The following assays are still referenced by other assays: {0}	Only information	• Ensure that all fathers of combi families are deleted before their combi sons	L	500.000.00040
Online Help initialization failed. Could not link the software views with the Online Help chapters.		• Try the import again when the system is not running • If the problem persists call Service	L M S	500.000.00041
Deleted reference to unknown Assay '{0}' in imported group '{1}'.	-	-	L	500.000.00042
Group '{0}' has been overwritten by import.	Only information	-	L	500.000.00043
Patient database could not be opened and has been recreated.	Only information	-	L	500.000.00044
Removed Rerun Rule '{0}' with unknown Assay(s) '{1}' from import.	Only information	-	L	500.000.00045
Rerun Rule '{0}' has been overwritten by import.	Only information	-	L	500.000.00046
At least one combi family was not archived due to a result not in Done or Failed status.	Only information	-	L	500.000.00050
The {0} manuals have been successfully downloaded.	Only information	-	L	500.000.00051

Message	Description	Action	Effect	Event ID
The {0} instrument package for the consumable with article no. {1} and lot no. {2} has been successfully downloaded.	Only information	-	L	500.000.00052
The {0} instrument package for the assay with article no. {1} and lot no. {2} has been successfully downloaded.	Only information	-	L	500.000.00053
The {0} instrument package for the control with control name {1} and control lot {2} has been successfully downloaded.	Only information	-	L	500.000.00054
The {0} manuals could not be downloaded.	Only information	-	L	500.000.00055
The {0} instrument package for the consumable with article no. {1} and lot no. {2} could not be downloaded.	Only information	-	L	500.000.00056
The {0} instrument package for the assay with article no. {1} and lot no. {2} could not be downloaded.	Only information	-	L	500.000.00057
The {0} instrument package for the control with control name {1} and control lot {2} could not be downloaded.	Only information	-	L	500.000.00058
All instrument packages were successfully acquired.	Only information	-	L	500.000.00059
One or more instrument packages could not be acquired.	Only information	• Try to download and acquire the instrument package again • If the problem persists, call Service	L	500.000.00060

Message	Description	Action	Effect	Event ID
Expected Country Code {0} but got {1}.	-	• In case the file was downloaded from DiaSorin online repository, ensure that the country selected for the package matches with the country set in the Main SW • If the problem persists, call Service	L	500.000.00061
The instrument package to be imported has a wrong structure.	-	• Try to download and acquire the instrument package again • if the problem persists, call Service	L	500.000.00062
The connection to the cloud is currently interrupted. The download will start once the connection is established.	-	• Try to download package again • If the problem persists, check the network cable • If the problem persists, contact the Laboratory IT to check that the network policy have been correctly set to allow the connection for the IoT services • If the problem persists, call Service	L	500.000.00063
{0} replicates found in the Results All page. Please, archive or delete Results to maintain proper software performance.	-	-	L M	500.000.00100
Software has to close. {0}	-	• Call Service	L M S	500.999.99999

Table 8–120: Message list, Application

9 Technical data

NOTE

Specification

Values are achieved under optimal conditions and can vary depending on environmental conditions, instrument status and processing conditions.

9.1 Power requirements

Voltage:	100 V - 240 V ± 10 %
Frequency:	50 - 60 Hz
Power consumption:	mean: 200 W (peak: 300 W): 683 BTU/h (peak: 1024 BTU/h)
Input current range:	4 - 1.7 A
Fuse:	primary 250 VAC, T4AH

Table 9–1: Power requirements

9.2 Laser barcode scanner

9.2.1 System laser barcode scanner

Class:	Class 2 laser product
Available bar-codes:	• Code 128/EAN 128 (set as default) • Codabar (set as default) • Code 39 (set as default) • 2/5 Interleaved (to be set) Please check with local service support the enabling status of the barcode types of interest. Barcode types not strictly compliant with this list are not allowed and must not be used on the system. Barcodes quality shall match category A or B (according to ANSI X3.182 standard) or category 4 and 3 (according to ISO/IEC 15416 standard). In addition: • 0.167 mm ≤ width ≤ 0.5 mm • 1:2.5 ≤ ratio ≤ 1:3 (if 0.167 mm ≤ width < 0.2 mm) or • 1:2 ≤ ratio ≤ 1:3 (if 0.2 mm ≤ width ≤ 0.5 mm)
Maximal output radiation:	85 µW
Maximal pulse duration:	112 µs
Emitted wave length:	660 nm
Standards:	IEC 60825-1:2007; IEC 60825-1:2014, except otherwise noted
Reading distance:	45 - 270 mm

Table 9–2: Laser barcode scanner

9.2.2 Handheld barcode reader

Please, refer to handheld barcode reader user manual for technical information.

9.3 Computer and connections

Panel PC	
Processor type:	Intel® (or compatible)
Touch screen type:	Projected Capacitive Touch Panel
User Access Panel *(right hand side of the instrument, see chapter 4.1.7)*	
Ports:	• 1 x RJ-45 • 4 x USB 2.0

Table 9–3: Computer connections

Software	
Operating system:	Microsoft® Windows® 10 IoT Enterprise (64 bit)

Table 9–4: Software

9.4 Dimensions and weight

	Weight	Width	Depth	Height
Instrument:	137 kg (302 lb)	1280 mm (50 in)	750 mm (29.5 in)	720 mm (28 in)

Table 9–5: Dimensions and Weight (including covers)

9.5 System clearance

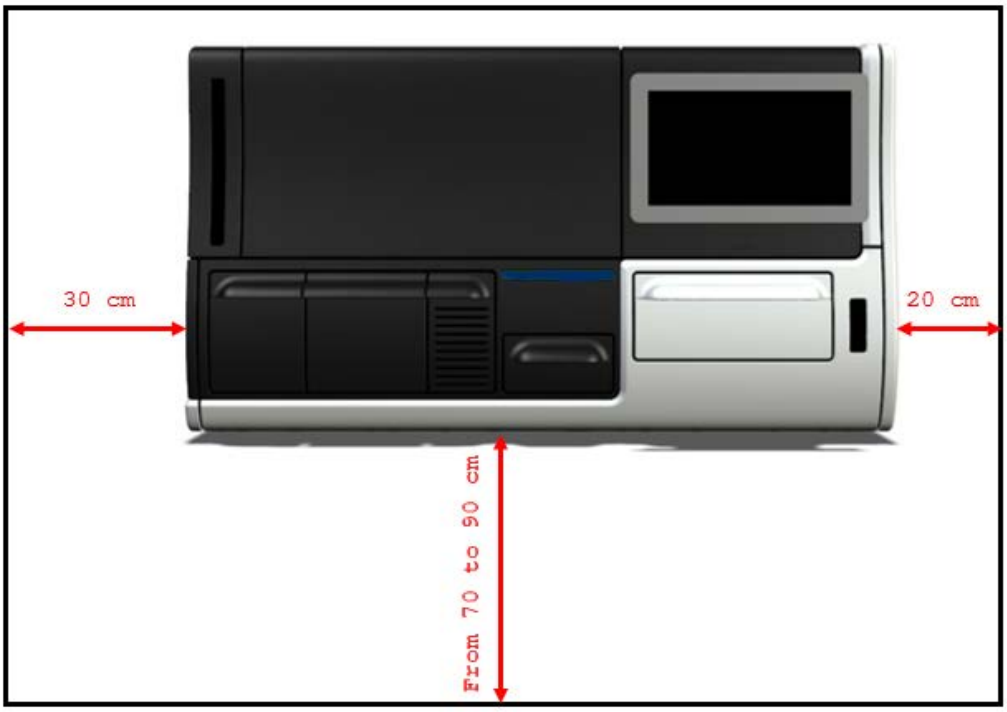


Figure 9–1: System clearance, front view

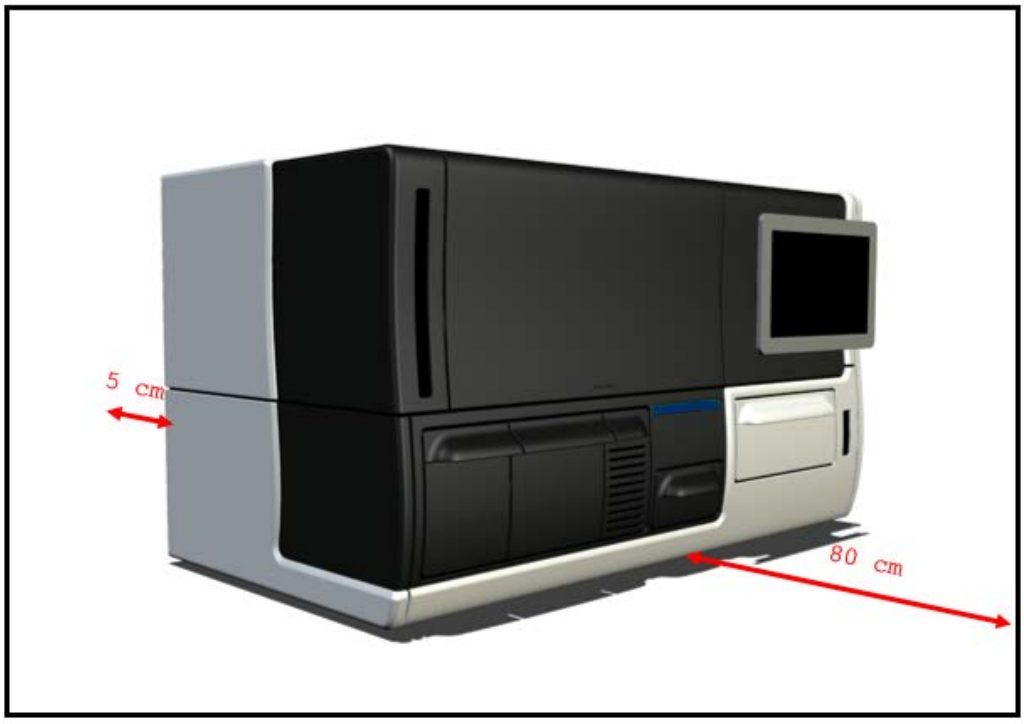


Figure 9–2: System clearance, side view

9.6 Environmental conditions

The following table shows the range of conditions needed to run the system safely.

Environmental Conditions:	The system is made for Indoor use only.	
Temperature:	Operating:	15 °C to 32 °C (59 °F to 89.6 °F)
	Storage:	5 °C to 40 °C (41 °F to 104 °F)
	Transport:	-20 °C to 60 °C (-4 °F to 140 °F) (for no more than 48 hrs)
Humidity:	Operating:	20 - 85 % non-condensing
	Storage:	20 - 85 % non-condensing
	Transport:	10 - 95 % non-condensing
Pollution Degree:	2 (EN 61010-1:2001)	
Installation Class:	2 (EN 61010-1:2001)	
Limit Class:	Class A (For industrial use. Domestic use restricted)	
Sunlight:	No direct sunlight. May mislead optical sensors and affect performance.	
Altitude:	Up to 3000 m (9843 ft) above mean sea level.	
Dust:	No excessive dust.	

Table 9–6: Environmental conditions

9.7 Noise emission

Max value measured at normal user position, with closed cover hood at 1 m distance to enclosure (39.4 in) is 65 dB(A).

Table 9–7: Noise emission

9.8 Temperature Ranges

Ambient Temperature:	15 °C - 32 °C (59 °F - 89.6 °F)
Incubating Temperature:	35 °C - 37 °C (95 °F - 98.6 °F), in liquid
Temperature inside the system:	Ambient temperature ±5 °C (±9 °F)
Reagent Loading Bay Temperature:	11 °C - 15 °C (51.8 °F - 59 °F)
Sample Loading Bay Temperature:	Ambient temperature ±3 °C (±5.4 °F)
Starter tubes Temperature:	34 °C - 36 °C (93.2 °F - 96.8 °F)

Table 9–8: Temperature Ranges

9.9 Water quality

The water to be used for the dilution and reconstitution of the Liaison XS reagents and consumables should comply with the definition of “Instrument Feed Water”, according to CLSI standard “Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline – Fourth Edition”.

In particular, the water shall contain the following characteristics:

- pH: 5.0 – 8.0
- conductivity: < 2 µS/cm
- resistivity: > 0.5 M Ohm-cm
- TOC: < 500 ppb
- SiO2: < 1.0 ppm
- Bacteria: < 10 CFU/ml

10 Disinfection procedure

10.1 Introduction

Purpose of this procedure is to provide instructions to the users to disinfect the analyzer, using disinfectant alcoholic solutions or sodium hypochlorite solution at 0.5 - 0.9 % active chlorine.

The following instructions apply to **LIAISON® XS**.

The scope of the disinfectant procedure is to address decontamination of the instrument with specific reference to:

- Surfaces or components where the disinfection procedure could be applied.
- Disinfection products to be used.
- Particular directions related to the procedure and the contact time for the disinfection products.

Therefore, the procedures are intended as an “extraordinary measure” suggested in case of specific situations (e.g. safety concerns associated to spillage of potentially biohazardous material or any other specific requirements).

This means that the disinfection procedure is not required to ensure the correct functionality of the instrument (which instead is ensured by the regular application of periodical maintenance procedures, prescribed in the chapter 7).

The present procedure describes operations to be executed to make parts of the instrument, which are accessible to the user under standard operative conditions, reasonably safe against possible transmission of infectious diseases, being aware that treatment based on chemical disinfectant does not ensure complete inactivation of all pathogens.

Sodium hypochlorite solution at 0.5 - 0.9 % active chlorine or alcoholic solutions with bactericide and virucide high activity shall be used for the scope. Be sure the virucide/ bactericide agents used are active also against non-enveloped viruses such as (e.g. norovirus, rotavirus, adenovirus, poliovirus).

Disinfection with sodium hypochlorite solution at 0.5 % of active chlorine requires contact time of at least 10 minutes; for alcohol based disinfectants, the user must refer to the contact time recommended by the manufacturer for the specific disinfectant.

Activities herein described must be performed by personnel specifically trained in good laboratory practices, analyzer use and wearing personal protective equipment to prevent transmission of infectious diseases by contact and droplets.

Fully comply with the present procedure in order to avoid instrument damage or malfunction.

10.2 Hazards

Please refer to paragraph 1.6 of present manual, for a detailed and complete description of potential hazards involved in instrument use and maintenance.

10.2.1 Biological Hazards

Performing the following activities may expose the user to potentially infectious materials:

- Handling samples, reagents, calibrators, and controls.
- Cleaning spills.
- Handling and disposing of waste.
- Performing maintenance procedures.
- Performing cleaning or disinfection procedures.

The following information will help the user in minimizing the impact of this exposure.

User should consider all clinical samples, reagents, calibrators, controls, and used reaction vessels and consumables (e.g. tips, cuvettes) that contain human-sourced material as potentially infectious. User should consider all system surfaces or components that have come in contact with human-sourced material as potentially infectious. No known test method can offer complete assurance that products derived from human sourced material will not transmit infection. Therefore, all products derived from human-sourced materials and system components exposed to human-sourced materials should be considered potentially infectious.

Precautions include, but are not limited to the following:

- Observe local and national provisions, legislation and laboratory regulations.
- Use appropriate resistant protective gloves suitable for biological risk.
- Use an appropriate lab coat or other protective clothing.
- Use appropriate eye protection.
- Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses when handling human-sourced material or contaminated system components
- Clean and disinfect the system immediately if potentially infectious material has been spilled.
- Any reagent spills should be washed with a chemical use sodium hypochlorite solution with 0.5 % - 0.9 % active chlorine (e.g. dilution 1:10 of a solution at 5 % active chlorine) and all waste should be disposed of as though potentially infectious.
- All samples, biological reagents and materials used in the assays must be considered potentially able to transmit infectious agents. They should therefore be decontaminated and disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each Country.
- Liquid waste must be decontaminated with a chemical use sodium hypochlorite solution with 0.1 % active chlorine (e.g. dilution 1:50 of a solution at 5 % active chlorine) for at least 30 minutes.
- Do not use broken or chipped tubes or bottles.
- Observe the instructions in the package inserts for correct use of the reagents.

DANGER

Risk of infection!

All internal parts of the system, that are not defined as user interfaces and for which specific procedures are described, must be treated as being potentially infectious. Improper handling of infectious parts can cause skin irritations, illnesses and possibly death.

DANGER

Disposal of Infectious Waste

Potential infectious material and all parts that may come in contact with potential infectious material must be disposed of according to the local and national provisions, legislation and laboratory procedures.

10.2.2 Chemical Hazards

User may be exposed to hazardous chemicals when handling reagents, calibrators and controls.

Exposure to hazardous chemicals is minimized by following instructions provided in the assay-specific documentation (such as a package insert) and on product-specific labels, and product-specific MSDS (Material Safety Data Sheets).

In general, observe the following precautions when handling chemicals:

- Consult MSDS for safe use instructions and precautions.
- Avoid contact with skin and eyes. If contact with material is anticipated, wear impervious gloves, protective eye wear, and clothing.
- Maintain good housekeeping. Do not eat, drink, or store food and beverages in areas where chemicals are used.
- Seek medical attention if irritation or signs of toxicity occur after exposure.

WARNING

Handling of Disinfectant Products

- Disinfectant products may be harmful. Read all instructions provided with the disinfectant products before use.
- Do not mix sodium hypochlorite solution (e.g. bleach) with alcohol based disinfectants.
- Observe the proper dilution of chemicals, as stated by the SW (Software)

WARNING

In case commercial sodium hypochlorite solutions are used (e.g. bleach), avoid formulations featuring any fragrance, surfactant, other oxidizer or additive.

10.2.3 Spill clean-up

Clean spills in accordance with established biosafety practices and follow instructions in the MSDS (Material Safety Data Sheets). In general, safe work practices for cleaning spills include:

- Wear appropriate personal protective equipment, such as gloves, eye wear and lab coat.
- Absorb the spill with absorbent material.
- Wipe and clean the area with an appropriate disinfectant such as a chemical use sodium hypochlorite solution with 0.5 % - 0.9 % active chlorine (e.g. dilution 1:10 of a solution at 5 % active chlorine) or disinfectant alcoholic based solution at recommended alcohol concentration of 60-90 %.

10.2.4 Waste handling and disposal

Each facility is responsible for labeling all waste tanks and characterizing its waste stream to ensure waste is disposed of in accordance with the appropriate local regulations.

See the manufacturer's assay-specific documentation (such as a package insert or reagent application sheet), the product-specific label, or the product-specific MSDS (Material Safety Data Sheet).

10.3 Alcoholic solution specifications

Alcohol based solutions used shall be defined by the manufacturer as high activity bactericide and virucide. Be sure the virucide/bactericide agents are active also against non-enveloped viruses such as e.g. norovirus, rotavirus, adenovirus, and poliovirus. An alcohol concentration of 60-90 % is generally recommended. Refer to manufacturer's instruction for safety handling and other technical information.

10.4 Preparation of sodium hypochlorite solution

Instructions to prepare 1 Liter of sodium hypochlorite solution at 0.5-0.9 % of active chlorine:

1. Fill a graduate cylinder with 0.9 L of water;
2. Add 100 mL of a sodium hypochlorite solution (e.g. bleach) with a 5 - 9 % content of active chlorine. In case the available sodium hypochlorite should have a different titer, please adjust the dilution accordingly;
3. Briskly mix.

10.5 Disinfection procedure Task

NOTE

Before starting the Disinfection Procedure task, 1.5 L of Cleaning Solution shall be prepared according to chapter 7.3.

Disinfection Procedure Task

1. Ensure that the instrument is not in “running” or “maintenance” status before starting the Disinfection Procedure;
2. Click on the **Maintenance** main category and select the **Disinfection Procedure** Task;
3. Tap on the “Perform” Button to start the Disinfection Procedure;
4. Follow the instructions described in the maintenance task.

Some parts of the instrument shall be cleaned during the execution of the Disinfection Procedure, as indicated by a dedicated pop-up that appears during the execution of the task:

1. Quit the Main UI;
2. Switch off the instrument and disconnect it from the main supply.
3. Open the sample area flap and extract the available sample racks; remove the sample tubes.
4. Open the reagent area flaps and extract the reagent integrals, store them according to the corresponding IFUs.
5. Open the top cover and move the right and left arms to a position easy to access.
6. Wipe with a tissue saturated with an alcoholic/disinfectant solution the following parts/surfaces:
   - Sample racks.
   - Left arm adapter (wipe downward)
   - Sample area interior.
   - Reagent area cover.
   - Incubator cover.
   - Monitor.

NOTE

Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

7. Repeat step 6 twice.
8. Wipe with a tissue soaked with a sodium hypochlorite solution at 0.5 - 0.9 % active chlorine the following parts/surfaces:
   - Right arm needle.
   - Tip drop off mechanism, placed on the lower area of the sample arm.
   - Pipettor wash station (upper rim).

NOTE

Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

9. Repeat step 8 twice.
10. Wipe all previous treated surfaces with a a tissue soaked with DI water.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

11. Wipe all previous treated surfaces with a dry tissue.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

12. Empty the liquid waste tank following the User manual instructions.
13. Wipe with a tissue saturated with a sodium hypochlorite solution at 0.5 - 0.9 % active chlorine the following parts/surfaces:
    - Exterior surfaces of the tank.
    - Joint connector probe and the slot for disconnected waste tubing and sensor connector.
    - Waste basin.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

14. Repeat step 13 twice.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

15. Wipe all previous treated surfaces with a a tissue soaked with DI water.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

16. Wipe all previous treated surfaces with a dry tissue.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

17. Open the solid waste bin.
18. Unload the **LIAISON®** EASY Waste holded in the solid waste Bin according to **LIAISON® XS** User Manual, paragraph 5.4.7.
19. Wipe the Solid Waste Bin internal surface with a tissue saturated with a sodium hypochlorite solution at 0.5 - 0.9 % active chlorine.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

20. Repeat step 19 twice.
21. Wipe all previous treated surfaces with a a tissue soaked with DI water.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

22. Wipe all previous treated surfaces with a dry tissue.

NOTE Use a new tissue for each part; dispose of used tissues as biological hazardous materials.

23. If the decontamination procedure has been completed, reconnect the instrument to the main supply and switch it on.

11 Country Specific Notes

11.1 USA

For Customer Service in US and Canada call toll free: 1-800-328-1482

Table in chapter 1.5.3 is integrated by the following:

Symbol	Title	Standard	Reference number	Description
	Manufacturer	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and EU Regulation 2017/746/EU
	Date of manufacture	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.3	Indicates the date when the medical device was manufactured.
	*In vitro* diagnostic medical device	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	5.5.1	Indicates a medical device that is intended to be used as in vitro diagnostic medical device.
	Catalogue number	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Consult instructions for use	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	5.4.3	Indicates the need for the user to consult the instructions for use

	Caution	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reason, be presented on the medical device itself.

11.2 Canada

Manufactured for DiaSorin Inc., 1951 Northwestern Ave, Stillwater, MN, 55082-0285 USA

For Customer Service in US and Canada call toll free: 1-800-328-1482

11.3 Brazil

Distribuído no Brasil por: DiaSorin Ltda - CNPJ 01.896.764/0004-12 - Av. Portugal, 1100 - C-51 - Itaqui – Itapevi SP - S.A.C: 0800 7716216 e-mail: diasorin@diasorin.com.br

11.4 China

11.4.1 Introduction

This paragraph is aimed at acting as an official amendment to the **LIAISON® XS** User Manual (Compliance with ROHS – China).

The reason of this paragraph is to ensure full compliance with Management Methods for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products (ROHS) - Order No. 32 of the China's Ministry of Industry and Information Technology of on January 21, 2016.

Producers and importers of electrical and electronic products shall, in accordance with the national or industry standards for labelling restricted use of hazardous substances in electrical and electronic products, indicate via labelling the hazardous substances contained in the electrical and electronic products that they bring to market, indicate the names and contents of the harmful substances and the components in which they are located.

Names and contents of hazardous substances shall be specified in the product instructions by following the format of the China standard SJ/T 11364-2014.

This requirement is effective from July 1, 2016.

11.4.2 List of components

Names and contents of hazardous substances as required by the Management Methods for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products (ROHS) - Order No. 32 of the China's Ministry of Industry and Information Technology of on January 21, 2016 and according to the format of the China standard SJ/T 11364-2014 are reported here below.

Part Name	Toxic or Hazardous Substances and Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr6)	Polybrominated Biphenyls (PBB)	Polybrominated Diphenyl Ethers (PBDE)
Washer Module (ID 10035323)	X	o	o	o	o	o
Liquid Distribution Valve (10079687)	X	o	o	o	o	o
Starter Pump (10064069)	X	o	o	o	o	o
WBDP Pump (10035808)	X	o	o	o	o	o

O indicates that this toxic or hazardous substance contained in all the homogenous materials of this part / system, is below the limit requirement as specified by China RoHS Regulation

X indicates that this toxic or hazardous substance contained in all the homogenous materials of this part / system, is above the limit requirement as specified by China RoHS Regulation