Diasorin

# LIAISON® XL

**cod. I0050**

# USER MANUAL


en-US – Revision L

(02/2026)

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® XL** 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® XL** Software Versions that are covered by the present User Manual revision will be provided separately.

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

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

# AMENDMENT INDEX

| Revision | Impacted chapter/section | Description of Change(s) |
|---|---|---|
| **L** | All | New Diasorin logo |
| **L** | Cover page | New cover page |
| **L** | §1.7.2 | New Grounding and USB label |
| **L** | §1.8.10.3 | Added new paragraph “EMC Compliance” related to IEC 60601-1-2 |
| **L** | §1.8.11 | Added new paragraph “Static magnetic field” |
| **L** | §1.8.12 | Added new paragraph “FCC Radio User Manual Guidance” |
| **L** | §1.10.3 | New USB label |
| **L** | §1.10.5 | New Laser label |
| **L** | §1.10.6 | New Grounding label |

# Table of Contents

1 Introduction ..... 1-1

1.1 Description ..... 1-1
1.2 Customer Support ..... 1-2
1.3 Proprietary statement ..... 1-2
1.4 Authorization and disclaimers about Documentation ..... 1-3
1.5 LIAISON® XL Warranty ..... 1-4
1.6 DiaSorin Warranty ..... 1-4
1.7 Messages, Notes and Symbols ..... 1-5
1.8 Hazard Instructions ..... 1-12
1.9 Safety residual risks for User ..... 1-26
1.10 Instrument Labelling and Safety Labels ..... 1-36
1.11 Operational Precautions and limitations ..... 1-63
1.12 Installation of the System ..... 1-66
1.13 Removal of the System ..... 1-67

2 PC security measures ..... 2-1
2.1 Introduction ..... 2-1
2.2 Unauthorized Local Access ..... 2-1
2.3 Malware ..... 2-3
2.4 Unauthorized access via network ..... 2-4
2.5 System update ..... 2-5
2.6 Local/network printing ..... 2-5
2.7 Remote access ..... 2-6
2.8 Privacy ..... 2-7
2.9 Security Requirements for Operating Environment ..... 2-9
3 Measuring Principle of the LIAISON® XL Immunoassays ..... 3-1
3.1 Explanations for Steps of Assays ..... 3-1
3.2 Measuring Principle ..... 3-5
3.3 Measuring Function Description ..... 3-6
3.4 Calibration (quantitative) ..... 3-7
3.5 Calibration (qualitative) ..... 3-9

4 System Description ..... 4-1
4.1 Overview ..... 4-1
4.2 Use of the Modules ..... 4-15
4.3 Accessories and Consumables ..... 4-48
5 Use of the System ..... 5-1
5.1 Safety and Hints ..... 5-1
5.2 Typographical Conventions ..... 5-2
5.3 Daily activities plan ..... 5-5
5.4 Start-up ..... 5-6
5.5 Check Cuvettes, Disposable Tips, Starter Reagents and Liquid Containers ..... 5-9
5.6 Load Patient Samples or Controls and Assign Assays ..... 5-51
5.7 Integrals, Calibrators, Ancillary reagents ..... 5-68
5.8 Start Worklist ..... 5-81
5.9 Results ..... 5-82
5.10 Routine errors ..... 5-96
5.11 Unloading ..... 5-97
5.12 Shut Down/End of Day Maintenance ..... 5-104

6 Software Functions ..... 6-1
6.1 General ..... 6-1
6.2 Header ..... 6-18
6.3 Main Category Loading ..... 6-22
6.4 Main Category Results ..... 6-43
6.5 Main Category Events ..... 6-86
6.6 Main Category Definitions ..... 6-93
6.7 Main Category System ..... 6-122
6.8 Main Category Diagnostics ..... 6-157
6.9 Main Category Maintenance ..... 6-160
6.10 Main Category Status ..... 6-167
6.11 External Backup Viewer ..... 6-179
7 Quality Control (QC) ..... 7-1
7.1 Overview ..... 7-1
7.2 Starting the Software ..... 7-2
7.3 Loading ..... 7-7
7.4 Results ..... 7-16
7.5 Settings ..... 7-46

7.6 Maintenance ..... 7-62
7.7 Audit ..... 7-76
7.8 Administration ..... 7-78
7.9 Help ..... 7-83
7.10 Error Messages ..... 7-85

8 Maintenance ..... 8-1

8.1 Safety and Hints ..... 8-1
8.2 Scheduled Maintenance Tasks ..... 8-5
8.3 Light Check ..... 8-5
8.4 Preparation of Liqui-Nox® solution ..... 8-6
8.5 Load and Unload the Cleaning Solution Bottle ..... 8-7
8.6 Clean the pipettor probes ..... 8-11
8.7 Clean the analyzer interior ..... 8-12
8.8 Clean the primary and the intermediate tanks ..... 8-13
8.9 Clean the covers ..... 8-26
8.10 Cuvette removal ..... 8-27
8.11 Automated actions performed by the system ..... 8-28

9 Troubleshooting and Error Messages ..... 9-1
9.1 Error Messages and Information Messages ..... 9-1
10 Technical Data ..... 10-1
10.1 Power Requirements ..... 10-1
10.2 Laser of the Bar-code Scanner ..... 10-2
10.3 Computer and Connections ..... 10-5
10.4 Dimensions ..... 10-6
10.5 System Clearance ..... 10-7
10.6 Weight ..... 10-8
10.7 Environmental Conditions ..... 10-9
10.8 Noise ..... 10-9
10.9 Temperature Range ..... 10-10
10.10 Water quality ..... 10-10
10.11 Optional direct plumbing connection specification ..... 10-11

11 Appendix A: Disinfection procedure ..... 11-1
11.1 Introduction ..... 11-1
11.2 Hazards ..... 11-2
11.3 Preparation of Liqui-Nox® solution ..... 11-5
11.4 Alcoholic solution specifications ..... 11-5
11.5 Preparation of sodium hypochlorite solution ..... 11-5
11.6 Disinfection procedure – Front and System Modules ..... 11-6
11.7 Disinfection procedure – Cabinet ..... 11-8
12 Appendix B: Optional direct plumbing connection for DI water ..... 12-1
12.1 Introduction ..... 12-1
12.2 Direct plumbing components ..... 12-2
12.3 Direct plumbing functionalities ..... 12-4
12.4 Clean the primary and the intermediate tanks ..... 12-5
12.5 Error condition and error handling on direct plumbing ..... 12-21

# 1 Introduction

This manual was created to assist the laboratory user with the utilization of the **LIAISON® XL** and **LIAISON® XL with Workcell Upgrade Kit** cchemiluminescence analyser (see chapter 1.1.1). This manual includes specific definitions as well as handling and maintenance of the instrument.

## 1.1 Description

The **LIAISON® XL** is a fully automated chemiluminescence analyzer, performing the complete sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes) as well as the measurement and evaluation. The instrument is controlled via the PC **LIAISON® XL** software. This software, which was specifically designed for this purpose, allows the user to process the pre-defined assays. The clear structure with intuitive user-guidance allows simple and quick operation of daily routine jobs.

**LIAISON® XL Workcell Upgrade Kit**: Components for the **LIAISON® XL** Analyzer that allow the analyzer to be connected to a third party Laboratory Automation System (LAS) having compatible connection capability for the performance of pre- and post-analytical sample handling processes. The **LIAISON® XL Workcell Upgrade Kit** also maintains the **LIAISON® XL** Analyzer's performance as a stand-alone instrument.

### 1.1.1 Intended Use

The **LIAISON® XL** Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for in vitro diagnostic analysis of CLIAs on human specimens cleared for use on the analyzer.

It is only to be used with FDA cleared chemiluminescent immunoassays that are marketed by DiaSorin for the **LIAISON® XL** Analyzer. The analyzer can be connected to a third party Laboratory Automation System (LAS) which has been previously cleared for use with FDA cleared assays.

**NOTE**

All the references to **LIAISON® XL** in this manual are also applicable to the **LIAISON® XL with Workcell Upgrade Kit**. Specific references to **LIAISON® XL with Workcell Upgrade Kit** are explicitly indicated.

**NOTE**

Please check with DiaSorin Italia S.p.A. for the compatibility between a lab automation system and **LIAISON® XL with Workcell Upgrade Kit**.

## 1.2 Customer Support

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

## 1.3 Proprietary statement

The **LIAISON® XL** System software programs and system documentation are protected by copyright laws. All rights are reserved. The software and manual were developed solely for use with the **LIAISON® XL** System and for in vitro diagnostic applications as specified in the operating instructions.

The information, documents and related graphics published herein (the "Documentation" or “Document”) are the sole property of DiaSorin Italia S.p.A. Permission to use the Information is granted, provided that:

- use of the Documentation is for operating DiaSorin products by DiaSorin trained personnel or informational use only;
- the copyright notice appears on all copies;
- the Documentation is not modified in any way; and
- no graphics are used separately from accompanying text.

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® XL** Chemiluminescence analyzer are to be used by authorized personnel only. Operate the Instrument following the indications and procedures described in the operating instructions for the **LIAISON® XL** Analyzer.

Follow all warnings, cautions, and notes indicated on the **LIAISON® XL** Analyzer 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 do 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.

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

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, any information submitted therewith shall be considered non-confidential, and DiaSorin 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 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 LIAISON® XL Warranty

DiaSorin warrants instruments sold by DiaSorin or any of its related company to be free from defects in workmanship and materials during normal use by the original purchaser. Unless otherwise expressly agreed to in writing by DiaSorin, this warranty shall continue for a period of one year, commencing twenty-one (21) days from the date of shipment to the original purchaser, or until title is transferred from the original purchaser, whichever occurs first (the "Warranty Period").

If any defects occur during the Warranty Period, contact your DiaSorin Italia S.p.A. Service Representative immediately, and be prepared to furnish information including the serial number, the model number, and pertinent details concerning the defect.

This Warranty does not cover defects or malfunctions which: (1) are not reported to DiaSorin Italia S.p.A. during the Warranty Period and within one week of occurrence; (2) result from chemical decomposition or corrosion; (3) are caused primarily by failure to comply with any requirements or instruction contained in the applicable DiaSorin Italia S.p.A. User Manual; or (4) result from maintenance, repair, or modification, performed without DiaSorin's authorization, (5) related to normal wear and tear.

DiaSorin Italia S.p.A.'s liability for all matters arising from the supply, installation, use, repair, and maintenance of the instrument, whether arising under this Warranty or otherwise, shall be limited solely to the repair or (at DiaSorin Italia S.p.A's sole discretion) replacement of the instrument or of components thereof. Replaced parts shall become the property of DiaSorin Italia S.p.A. In no event shall DiaSorin be liable for injuries sustained by third parties, consequential damages, and/or lost profits.

The warranty does not cover the software included in the system, which is subject to the warranty stated in the Software License Agreement. The warranty is country dependent, based on local legal requirements.

The foregoing is the sole warranty made by DiaSorin Italia S.p.A. regarding the instrument, and DiaSorin specifically disclaims all other warranties, expressed or implied, including the warranties of merchantability and fitness implied for a particular purpose.

## 1.6 DiaSorin Warranty

DiaSorin Italia S.p.A. makes no representations or warranties of any kind or nature with respect to the documentation. DiaSorin Italia S.p.A. hereby disclaims all representations and warranties, whether express or implied, created by law, contract or otherwise, including, without limitation, any warranties of merchantability, fitness for a particular purpose, title or non-infringement. In no event shall DiaSorin Italia S.p.A. be liable for any damages of any kind or nature, including, without limitation, direct, indirect, special (including loss of profit) consequential or incidental damages arising from or in connection with the existence or use of the information, regardless of whether DiaSorin Italia S.p.A. has been advised as to the possibility of such damages.

## 1.7 Messages, Notes and Symbols

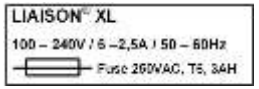
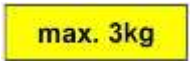
The symbols described hereafter are used in the current manual, on the instrument and on its packaging.

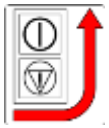
### 1.7.1 Display of Warnings and Notes

| | |
|---|---|
| DANGER  | The signal word **"Danger"** and the relating pictograph describe immediate dangers.<br>The non-observance of a danger warning is immediate and will result in death or at least serious irreversible injury. Damage to the system or an adverse effect on the system function cannot be excluded. |
| WARNING  | The signal word **"Warning"** and the relating symbol describe potential dangers.<br>The non-observance of a warning is potential and can result in death or at least serious irreversible injury. Damage to the system or an adverse effect on the system function cannot be excluded. |
| CAUTION  | The signal word **"Caution"** and the relating symbol describe potential dangers/problems.<br>The non-observance of safety instructions can result in minor injuries. Damage to the system or an adverse effect on the system function cannot be excluded. |
| CAUTION | The signal word **“Caution”** describes potential problems. The non-observance of a caution instruction can result in damage to the system or an adverse effect on the system functionality. |
| NOTE | The signal word **"Note"** describes potential problems. The non-observance of notes can result in an adverse effect on the system function. |

### 1.7.2 Utilized Warning Symbols

| | |
|---|---|
|  | **Caution, risk of danger to person or damage to equipment! Consult instructions for use!** |
|  | **Biohazard!** |
|  | **Electrical hazard!** |
|  | **Laser hazard!** |
|  | **Caution, hot surface!** |
|  | **Mechanical hazard!** |
|  | **Cut injury hazard!** |
|  | **Automatic start-up!** |
|  | **No objects shall be put on the opening flaps.** |

| | |
|---|---|
|  | **Disconnect mains power connector before servicing!** |
|  | **Power Supply characteristics** |
|  | **USB label** |
|  | **Grounding label** |
|  | **Maximum supported load for extensible board.** |
|  | **Maximum load for printer support.** |
|  | **Water Tank** |
|  | **Wash Solution Tank** |
|  | **Cleaning Solution Tank** |

| | |
|---|---|
|   | **Liquid Waste Tank** |
|  | **Indication of the location of Main Switch / Emergency Stop button.** |
|  | **Close the drawer*** <br> * available on instruments with cabinet drawers |
|  | **Don't step*** <br> * available on instruments with cabinet drawers |
|  | **Stumble hazard*** <br> * available on instruments with cabinet drawers |

### 1.7.3 Other Symbols

| 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 98/79/EC. |
|   | 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. |
|   | Batch code | ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied | 5.1.5 | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|   | Use-by date | ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied | 5.1.4 | Indicates the date after which the medical device is not to be used. |
|  | Temperature limit | ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied | 5.3.7 | Indicates the temperature limits to which the medical device can be safely exposed. |
|   | CE mark | - | - | - |
|   | 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. |

| Symbol | Title | Standard | Reference number | Description |
|---|---|---|---|---|
|  | 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 |
|  | Certification mark provided by NEMKO for US and Canadian Markets | - | - | - |
|  | RoHS compliance | - | - | - |
|  | Consult electronic 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 electronic instructions for use |
| www.diasorin.com | DiaSorin website | - | - | - |
| EU: ☎ 00 800 60 61 62 63 | Toll free number | - | - | - |

| Symbol | Title | Standard | Reference number | Description |
|---|---|---|---|---|
|  | **Disposal of Electrical and Electronic Equipment**<br>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. | - | - | - |
|  | 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. |
|  | Caution | ISO 15223-1: Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied | 5.4.4 | Indicates the need for the user to consult the instructions for use for importatnt cautionary information such as warnings and precautions that cannot, for a variety of reason, be presented on the medical device itself. |

**NOTE** For Customer Service in US and Canada call toll free: 1-800-328-1482

## 1.8 Hazard Instructions

### 1.8.1 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® XL** 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® XL** 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 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® XL** 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® XL** 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® XL** Diagnostic System, it is mandatory to allow DiaSorin Italia S.p.A. personnel, or any field service authorized representative, to perform all scheduled (two preventive maintenances 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 guidelines or recommendations. Ordinary analyzer workload is considered up to 500 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, chapter 1.11.**

### 1.8.2 Liability

The **LIAISON® XL** 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 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.**

### 1.8.3 Electrical Hazards

The **LIAISON® XL** 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 10.1.

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 Analyzer 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 possibily supported can be used only as installed by DiaSorin 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 Analyzer.
- Disconnect the Analyzer 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.

## 1.8.4 Physical Hazards

### 1.8.4.1 Laser Light Hazards

- 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 Injury due to Laser Radiation**

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

Wrong 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.

#### 1.8.4.2 Heavy objects

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

#### 1.8.4.3 Trip Hazards

The **LIAISON® XL** 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 occurring in connection with the use of the **LIAISON® XL** Diagnostic System, user shall immediately contact the local DiaSorin Representative.

### 1.8.5 Mechanical Hazards

The **LIAISON® XL** 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® XL** 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 Analyzer, user is potentially exposed to the following moving mechanical components:

- Pipettor arms and probes;
- Cuvette loading mechanism (auger);
- Cuvette orientation mechanism (sorter).

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.
- Do not attempt to resolve a cuvette jamming in the cuvette loader and sorter area when the Analyzer is running.
- 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.

### 1.8.6 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, 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.

### 1.8.7 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.

### 1.8.8 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).

### 1.8.9 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).

## 1.8.10 Caution on electromagnetic wave interference

### 1.8.10.1 Electromagnetic wave interference given by LIAISON® XL to other equipment

The **LIAISON® XL** Analyzer 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 personnel are not allowed.

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

a. When the **LIAISON® XL** Analyzer may be the cause, turn off the power of this Instrument and check radio and television reception.

b. If it is improved, the **LIAISON® XL** Analyzer probably is the cause.

### 1.8.10.2 Electromagnetic wave interference that may be given to the LIAISON® XL Analyzer

If the **LIAISON® XL** Analyzer 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 personnel are not allowed.

However, there is no guarantee that the **LIAISON® XL** Analyzer 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® XL** Analyzer.

b. If they are improved, interference from the equipment is probably the cause.

Try the following to correct the issues.

a. Move the **LIAISON® XL** Analyzer further away from the equipment that may be the cause.

b. Connect the power cord of the **LIAISON® XL** Analyzer 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 Analyzer.

**Transient Emissions and Interference Resistance**

The instrument meets the requirements described in standard IEC 61326 on transient emissions and interference resistance.

NOTE

- This instrument was developed and tested according to CISPR11 Class A. It can cause radio interference in domestic environment. In this case it may be required to take action to eliminate such interference.
- Before setup and operation of the instrument, the electromagnetic environment should be evaluated.
- Do not use the instrument in the vicinity 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.

### 1.8.10.3 EMC Compliance

The **LIAISON® XL** Analyzer has been tested according to the method of IEC 61326-1 and IEC 61326-2-6 using the threshold reported in the Electromagnetic compatibility (EMC) standard IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

The **LIAISON® XL** Analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the **LIAISON® XL** Analyzer should assure that it is used in such an environment.

**Guidance and Manufacturer's Declaration - Electromagnetic Emissions**

| Emission tests | Compliance |
|---|---|
| RF emissions CISPR 11 | Group 1 |
| RF emissions CISPR 11 | Class A |

**Guidance and Manufacturer's Declaration - Electromagnetic Immunity**

| Immunity Test | Compliance Level Against IEC 60601-1-2:2014+A1:2020 |
|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | Contact: ± 8 kV<br>Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV |
| Radiated Immunity Testing<br>IEC 61000-4-3 | 3 V/m 80-2700 MHz 1kHz 80% am<br>9-28 V/m 385-6000 MHz pulse mode |
| Electrical fast transient/burst<br>IEC 61000-4-4 | Power Supply Lines at 100 kHz, ± 2.0 kV |
| Surge<br>IEC 61000-4-5 | Line to Line: ± 1.0 kV<br>Line to ground: ± 2.0 kV |
| Conducted Immunity Testing<br>IEC 61000-4-6 | 3 V: 0.15 – 80 MHz<br>6V: In ISM Bands between 0.15 MHz and 80 MHz<br>80 % AM at 1 kHz |
| Voltage dips<br>IEC 61000-4-11 | 0 % $U_T$; 0,5 cycle, At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % $U_T$; 1 cycle and 70 % $U_T$; 25/30 cycles<br>Single phase: at 0° |
| Voltage interruptions<br>IEC 61000-4-11 | 0 % $U_T$; 250/300 cycle |
| Power frequency (60 Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m at 60 Hz |
| Proximity to Magnetic Fields<br>IEC 61000-4-39 | 134.2 kHz and 13.56 MHz |

- No essential performance has been identified, loss of clinical function will not result in any unacceptable risk.
- Use of this equipment stacked with another equipment is not allowed.
- Avoid using the equipment close to another equipment. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

NOTE

**Electromagnetic Interference (EMI)**

This equipment has been tested and found to comply with the requirements of IEC 60601-1-2 for electromagnetic compatibility. However, to help ensure optimal performance and continued safe operation, avoid placing the device in close proximity to sources of radio frequency (RF) emissions. These include, but are not limited to:

- Mobile phones and wireless communication devices (including 5G millimeter wave)
- RFID readers and EAS (Electronic Article Surveillance) systems
- Wireless Power Transfer devices
- Wireless routers and Bluetooth transmitters
- Industrial equipment generating strong electromagnetic fields

### 1.8.11 Static magnetic field

Magnets are used in the Washer module, Front module, and Left Arm Pipettor of the instrument. 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.

### 1.8.12 FCC Radio User Manual Guidance

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

## 1.9 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® XL** Diagnostic System.

If further clarification should be needed, it is recommended to contact the local DiaSorin representative.

### 1.9.1 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 behaviour.

### 1.9.2 Inherent safe design and manufacturing process

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

In regards of risk management, the Analyzer 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 Analyzer, 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® XL** 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 Analyzer always adequate to the so called “state of the art” as per, and in compliance with, the European Community Regulation 746/2017 related to IVD Medical Devices.

The **LIAISON® XL** 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 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 Analyzer 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 Analyzer has to be operated and which are the abnormal uses forbidden.

The **LIAISON® XL** Diagnostic System is supplied with all the special equipments and accessories essential to allow safely using and maintaining. 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 Analyzer.

### 1.9.3 Materials and products

The materials and products of which the Analyzer 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 Analyzer has been designed and constructed to prevent risks due to filling, use, recovery or draining.

#### 1.9.3.1 Waste liquid tank

When user removes one waste liquid tank to empty it, he/she has to disconnect the level sensor first and then the tubing; reinserting the tank in the Analyzer, user is required to reconnect the tubing first and then the level sensor, to prevent the risk of leakage due to a missing reconnection of the tubing.

**NOTE**

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

**NOTE**

The joint connector allows to manage the insertion/ removal of waste sensor and tubing as a single task. See chapter 5.5.6 for details.

**WARNING**

For safe use it is strictly forbidden:

- to alter or modify the level sensor function and/ or use Analyzer without liquid waste tank correctly connected to the tubing, apart if a direct drain connection (see chapter 4.2.9.6) 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 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 (applicable to instruments with cabinet drawers).

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.

### 1.9.4 Design of Analyzer 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.

### 1.9.5 Ergonomics

The **LIAISON® XL** 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.

### 1.9.6 Safety and reliability of control systems

Control systems are managed in the Analyzer control software. A fault in the hardware or in the software of the control system does not lead to hazardous situations: in case of HW or SW fault the Analyzer cannot work.

Software interface of Analyzer is validated against foreseeable risks: 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 Analyzer. Reasonably foreseeable human errors during operation do not lead to hazardous situations. The Analyzer 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 Analyzer cannot be prevented from stopping.

No moving parts of the machinery or pieces held by the Analyzer 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 bag as a consequence of a stop command. It does not lead to risks because it is part of the intended use of the Analyzer.

It is strictly forbidden using the Analyzer with the solid waste container closed without the solid waste bag on. A SW counter notifies the user when the solid waste bag is full and needs to be replaced. To ensure an appropriate replacement of the waste bag without affecting the ongoing operation of the Analyzer, the system allows 15' from the opening to the closing of the solid waste container, due to the presence of an intermediate case. User is asked to wear gloves when handling the solid waste container and bag.

#### 1.9.6.1 Main Cover Opening before or after a "moving" status – safe use

The interlock protective device (i.e the cover sensor) remains fully effective or gives a stop command also in case is out of order. In particular intended uses, because of specific requirement related to initializing, diagnostic, service or maintenance status and different access profile levels, opening the interlocked cover does not set the Analyzer to a stop command. In details, 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; in case the user access level is an end-user level (strictly lower than Field Service Engineer level) the consequence will be that, within a few seconds, the Analyzer will stop all movements;
- The same would be true if the main cover opening occurs in combination with the status "maintenance", in case the user access level is an end-user level (strictly lower than Field Service Engineer level);
- The same would be true if the main cover opening occurs in combination with the status "running", in case the user access level is an end-user level (strictly lower than Field Service Engineer level);
- In case the main cover opening occurs in combination with the status "service" (i.e. during a diagnostic task), then the open cover condition will be ignored, as there is a pop-up (given at the beginning of a diagnostic action) that reminds to close covers;
- If the SW will not be communicating with the Analyzer (e.g. if the PC should be switched off), then the Analyzer will halt itself anyway (within about 4 seconds);
- If the main cover is opened while the pipettor arms are working during a routine, the System will stop the ongoing routine and get the status "halted"; the routine interruption may be avoided pressing the button "Pause" and waiting for no less than 30'' before opening the cover. In both cases there is no risk of moving pipettor arms while the cover is open.

**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 Analyzer's main switch.

#### 1.9.6.2 Emergency stop – safe use

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

- after the instrument is turned back on, the software believes that the communication with the Analyzer is lost and it will interrupt the communication;
- whenever the PC and the Analyzer are turned on together, there will be no movement at all, and the communication will be kept off; in order to start the communication up, the only way is that the user will press the "Init" button in the software;
- any other action performed before or after turning on the Analyzer will not start the communication up, therefore nothing will move on the machinery;

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

### 1.9.7 Failure of the power supply

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

Particular attention must be paid on the following aspects:

- the Analyzer does not start unexpectedly: a SW command given by the user is always necessary to restart movements of the Analyzer;
- the setting parameters of the Analyzer do not change in an uncontrolled way when in 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 Analyzer is not prevented from stopping if the command has already been given;
- no moving parts of the Analyzer 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 1.9.6.1).

### 1.9.8 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, ageing, corrosion and abrasion. To date, there is no evidence of parts showing to be weak.

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

The moving parts of the Analyzer 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 Analyzer 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 Analyzer while they are running;
- to touch Analyzer 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 Analyzer is running;
- to alter and or to modify fixed or interlocked movable guards;
- to use the Analyzer in end-user intended use without fixed or interlocked movable guards.

### 1.9.9 Protection against electrical hazards

The **LIAISON® XL** 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 Analyzer is designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges.

Where appropriate, the Analyzer 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 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.

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

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 Analyzer (if available) with the exception of those installed by DiaSorin 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 Analyzer from the main supply, if a safe usage is no longer possible;
- To cover the switches or have them inaccessible;
- To use the Analyzer if any switch or controls device is damaged.

### 1.9.10 Protection against noise hazards

Analyzer 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 10.8.

NOTE

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

## 1.10 Instrument Labelling and Safety Labels

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

Safety labels are used on the **LIAISON® XL** system and in the documentation to identify potentially dangerous conditions. Before starting to use the Analyzer, 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 which can cause serious personal injury and/or material damage.

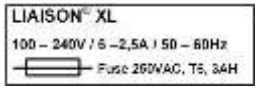
- Check the system for missing or unreadable warning labels and type labels.
- Missing or unreadable warning labels or type labels must be replaced.

### 1.10.1 Instrument Serial Label

Instrument Serial Label is placed in the cabinet, at the top right corner of the wall separating the tank area from the PC area (Figure 1-1).


*Figure 1-1: Instrument Serial label positioning*

### 1.10.2 Power Label




The Power Label, reporting all the characteristics of the power supply to use, is placed on the right side cover, near the switch of the system (Figure 1-2).

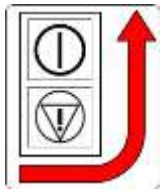
*Figure 1-2: Power label*

### 1.10.3 USB Label

USB label is positioned on the right side of the instrument, above the USB ports (Figure 1-3).
This label was introduced after instrument launch so it is applied from a certain serial number on.


*Figure 1-3: USB label*

### 1.10.4 Emergency Stop Label



In case of emergency, the Analyzer can be automatically stopped using the main switch available at the right side of the instrument. In order to inform properly the user about the positioning of the emergency stop, a specific label is placed on the front side of the right blind cover (Figure 1-4).

*Figure 1-4: Emergency stop label*

### 1.10.5 Laser Hazard Labels

A laser hazard label is positioned on the left side of the sample loading bay (Figure 1-5).

Three different label types are available:

a) First type

b) Second type


c) Third type


d) Fourth type

*Figure 1-5: Sample Area labels*

Labels placed on the front of the barcode reader (Figure 1-6) inform the users about laser radiation characteristics (see chapter 10.2 of this document) and dangers (see chapter 1.8.4.1 of this document).

*Figure 1-6: Barcode reader labels*

### 1.10.6 Grounding Label

Grouding label is positioned on the right side of the reagent module (Figure 1-7).
This label was introduced after instrument launch so it is applied from a certain serial number on.

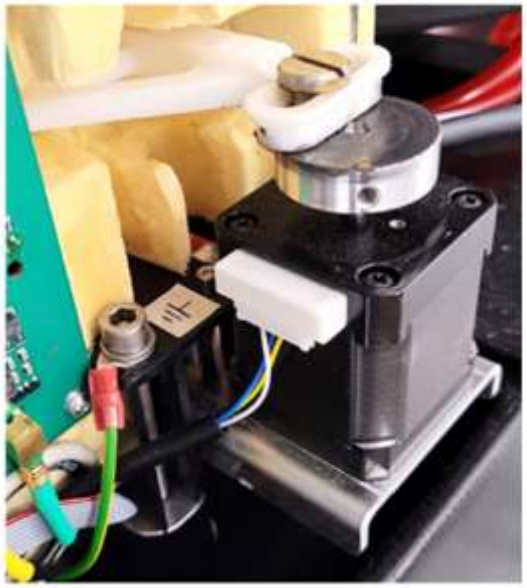


*Figure 1-7: Grounding label*

### 1.10.7 Pipettor Label

Generic warning labels are positioned on left and right arms (Figure 1-8).

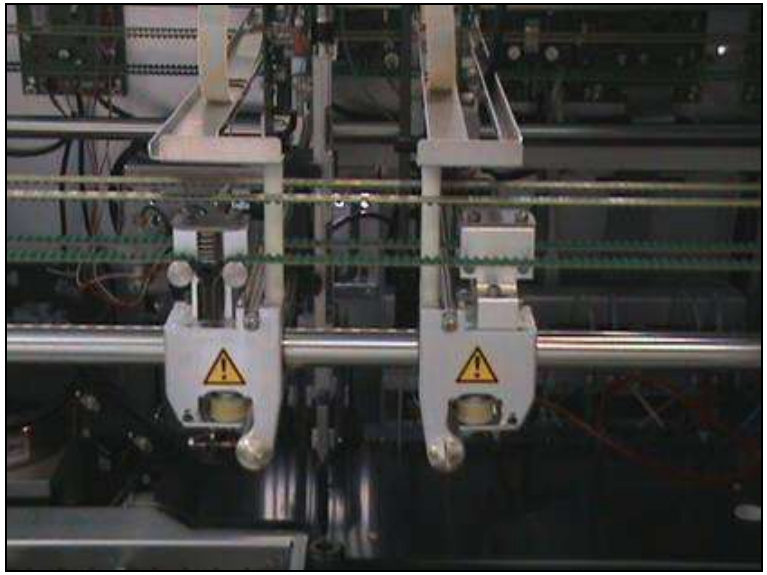


*Figure 1-8: Pipettor labels*

### 1.10.8 Solid Waste Labels

A bio-hazard label is placed on the front cover of the solid waste drawer (Figure 1-9).

*Figure 1-9: Solid Waste Drawer label*

The same bio-hazard symbol is also placed on solid waste bags and on both lateral walls of the solid waste bin (Figure 1-10, see also chapter 4.2.9.8).

All these symbols indicate the users the presence of contaminated materials (tips and cuvettes) inside.

*Figure 1-10: Solid Waste Bin label*

### 1.10.9 Liquid Waste Labels


A bio-hazard symbol is placed on the front side of each liquid waste tank (Figure 1-11), together with a label indicating the content. These symbols indicate the users the presence of contaminated liquids inside.

The same symbols are placed on the floor of the waste basin (see chapter1.10.19).


*Figure 1-11: Liquid Waste tank and basin labels*

### 1.10.10 Water Label


A symbol, indicating the presence of water inside, is placed on the front side of the water tank and intermediate tank (Figure 1-12).

### 1.10.11 Wash Label


A symbol, indicating the presence of wash solution inside, is placed on the front side of the wash solution tank and intermediate tank (Figure 1-12).

A red line indicating the **9 L** level is also available on the front side of the tank: this reference helps the user during the preparation of the wash solution.

**NOTE**

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

### 1.10.12 Cleaning Solution Label


A symbol, indicating the presence of cleaning solution inside, is placed on the front side of the tank (Figure 1-12). In case **LIAISON® diluteX** is connected to the analyzer, Figure 1-12 is not representative; for further details, please refer to **LIAISON® diluteX** User Manual.


a) Tanks

b) Intermediate tanks

c) Cleaning Solution tank

*Figure 1-12: "Water", "Wash" and "Cleaning Solution" labels*

### 1.10.13 "Do not open cover" Label

It is strictly forbidden to open the left top cover of the instrument while the system is running; as a reminder, a label containing this message (Figure 1-13) is applied to the front of the top cover (Figure 1-14).

The label is available in all different languages supported by **LIAISON® XL** system; during the installation of the system, the field service engineer takes care of applying to the cover a label in the proper language.


*Figure 1-13: "Do not open cover" label – English version*

*Figure 1-14: "Do not open cover" label positioning*

### 1.10.14 Top Cover Labels

A caution and a bio-hazard label, informing 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 cover (Figure 1-15).

**Risk of infection!**

DANGER

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.

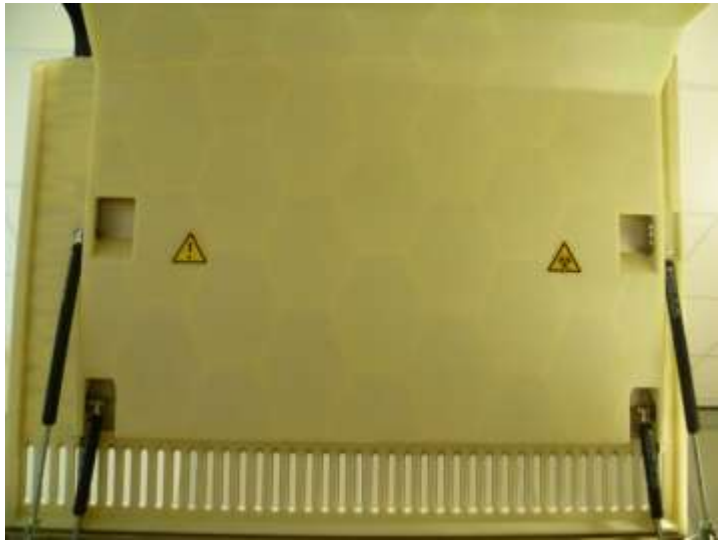


*Figure 1-15: Top Cover labels*

In order to prevent possible hand crushings during the opening/ closure of the top covers, two specific warning labels are placed on the available metal bar, respectively under the left (Figure 1-16.a) and the right (Figure 1-16.b) top covers.

a)

b)

*Figure 1-16: "Danger of crushing hands" labels*

### 1.10.15 Extensible board label

max. 3kg

A label with the indication of the maximum tolerated load is placed into the right front corner of the extensible board (Figure 1-17).


*Figure 1-17: Extensible board label*

### 1.10.16 Printer support label

max. 20kg

A label with the indication of the maximum supported load is placed into the right front corner of the printer support (Figure 1-18).


*Figure 1-18: Printer support label*

### 1.10.17 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 1-19, Figure 1-20 and Figure 1-21).

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 1-19: Flap labels – Sample Area*

*Figure 1-20: Flap labels – Reagent Area*

**DANGER**

**Clean immediately spills present on flaps, following what indicated in chapter 1.8.6 and 1.8.8.**


*Figure 1-21: Flap label – Starter Reagent Area*

### 1.10.18 Cuvette Reservoir Label

A red line indicating the maximum level of cuvettes that can be loaded without causing mechanical crashes of the system is available on the cuvette reservoir (Figure 1-22).

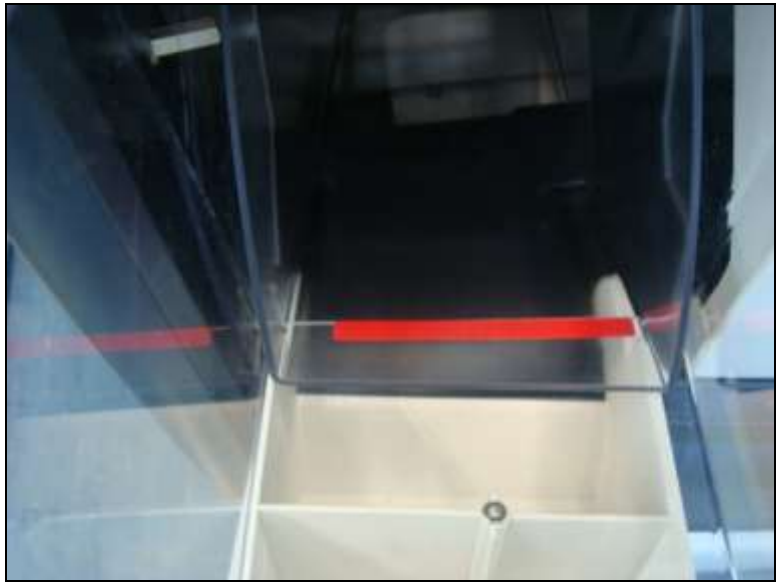


*Figure 1-22: Cuvette reservoir label*

### 1.10.19 Cabinet Drawer Labels

The following labelling applies only to instruments with cabinet drawers.

“Close the drawer” label informs the user to always close the drawers once the loading/ unloading of tanks is completed. A label is placed on the top part of the handle of each drawer (Figure 1-23 and Figure 1-24, ref.a).

“Don’t step” labels inform the user that it is forbidden to step onto the drawers both when the tanks are inserted or extracted. A label is placed on the floor of each tank slot (Figure 1-23 and Figure 1-24, ref.b).

“Stumble hazard” labels inform the user to pay attention not to fall down when the drawers are out of the cabinet. A label is placed on each side of each drawer (Figure 1-24, ref.c).

“Bio-hazard” labels inform the user to pay attention to spillage of contaminated liquid in the area of the waste basin occupied by waste tanks. A label is placed on the slot of each waste tank (Figure 1-23, ref.d).


*Figure 1-23: “Close”, “don’t step” and “bio-hazard” label positioning*


*Figure 1-24: "Close", "don't step" and "stumble hazard" label positioning*

### 1.10.20 Workcell Upgrade Labels

"Danger of crushing hands" labels (Figure 1-25) are placed on the frontside and backside of the workcell upgrade cover, informing the user not to put hands in the area where the sample arm is moving (see also chapter 4.1.6).

These labels apply only to **LIAISON® XL with Workcell Upgrade Kit**.

*Figure 1-25: "Danger of crushing hands" labels for **LIAISON® XL with Workcell Upgrade Kit***

## 1.11 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.

### 1.11.1 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 10.5. 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.

### 1.11.2 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 Analyzer is active with moving parts. Intended use: any needed operation is allowed when moving parts are inactive.
- Operate the Analyzer without the solid waste bag and container onboard unless during waste bag replacement. Intended use: waste bag and its container must be onboard unless during waste bag replacement.
- Operate the Analyzer 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.

### 1.11.3 System operation

#### 1.11.3.1 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 container is equipped with the appropriate bag.
- Verify that the liquid waste containers are not full and correctly positioned.

#### 1.11.3.2 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.

### 1.11.4 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.

### 1.11.5 Handling of specimens

Carefully read the reagent manufacturer's assay-specific documentation and the chapter 5.6.1 of 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.

### 1.11.6 Limitation of result interpretation

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

**Clot Detection System**

NOTE

Notwithstanding the Analyzer is equipped with a clot detection system, the user is not authorized by DiaSorin to load consciously on the Analyzer sample tubes containing clots. Any default of the system related to a relevant unappropriate use is in the sole responsibility of the user.

## 1.12 Installation of the System

CAUTION

**Installation**

Please note that the **LIAISON® XL** 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" (see chapter 10) for power requirements, computer and connections, installation dimensions, weight and environmental conditions.

**NOTE**

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

## 1.13 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® XL** system must be performed by authorized service personnel.

**CAUTION**

**Reinstallation**

If the **LIAISON® XL** 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 measures

## 2.1 Introduction

**LIAISON® XL** 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 undergo the 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 elements are kept updated on systems installed in end-user environment.

## 2.2 Unauthorized Local Access

### 2.2.1 Potential issues

Usage of the system is supposed only to 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® XL** 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; the system allows to enforce use of complexity and history requirements (newly created passwords shall bear at least one upper case, one lower case, one number, one special character and shall differ from the last five used ones);
- 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® XL** software application, i.e. they have no access to the Operating System and other applications.
- an anti brute force mechanism can be enabled to prevent that not authorized people may gain access by guessing username and password by means of multiple consecutive attempts. Contact the local service support to enable it.

## 2.3 Malware

### 2.3.1 Potential issues

Usage of **LIAISON® XL** computer could lead to voluntary or involuntary introduction of malicious software, like virus, worms, spywares. This malicious software (also called malware) is designed to infiltrate or damage 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;
- via a local CD-Rom.

### 2.3.2 Protection measures

The state-of-art, worldwide spread approach is to provide a network firewall, a personal firewall and an integrated protection tool, generically called antimalware. This approach looks not adequate for the **LIAISON® XL** computer for several reasons:

- the network firewall should be installed by network administrators, who in this case are end-users in regards to DiaSorin, therefore DiaSorin has no control on the network firewall in terms of adequateness and update frequency;
- an antimalware must be kept up-to-date to be efficient, therefore almost daily updates are necessary; the sole mode to perform frequent updates is to connect the computer to the internet, but:
    - it cannot be ensured that all computers are connected to the internet, and also for those connected the connection cannot be guaranteed upfront, while a malware can be introduced in any moment, even without internet connection;
    - furthermore, a daily update of the antimalware would necessary mean that the updates are managed directly by antimalware producer; therefore, the system configuration would be frequently updated, while DiaSorin could not guarantee a continuous validation update in such continuously 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 malfunctioning of the software.

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

- all the Operating System service and ports, that are not strictly required for the validated applications, will be blocked on the computer;
- the Operating System integrated firewall is activated, and configured such that all remote access to the system is denied (excluding single specific ports needed for remote access authorized by DiaSorin);
- on the Operating System, the AutoRun for all USB storage devices will be disabled;
- it is prohibited to install any CD-Rom or Floppy Disk USB device;
- importing infected files from USB devices or CD-Rom is prevented by design, as end-users will have access on the computer to the sole features allowed by the **LIAISON® XL**, i.e. will not have access to the Operating System features, and **LIAISON® XL** will allow to import only files with specific proprietary extensions, disregarding any file with different extension;
- as additional protection, a specific and defined antimalware is installed on Liaison XL, mainly counting on its heuristic detection methods. No other antimalware can be installed on Liaison XL.

## 2.4 Unauthorized access via network

### 2.4.1 Potential issues

A **LIAISON® XL** computer connected to a network could be accessed by unauthorized persons, 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 personal firewall is an application which controls network traffic to and from a computer, permitting or denying communications based on a security policy.

The Operating System integrated firewall is activated, to ensure incoming access from a remote station is denied.

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

## 2.5 System update

### 2.5.1 Potential issues

The Operating System and the other software modules installed on **LIAISON® XL** computer may require to be updated from time to time, in order to fix the discovered issues. Typically these are network vulnerabilities.

### 2.5.2 Protection measures

Introducing continuous changes into the software modules introduces also a connected technical risk: the more changes are introduced, and the more frequently they are, the more risks would accumulate in these regards. The described protection measures against external intrusions is considered safe enough to face the known risks on the **LIAISON® XL** computer, that is strictly controlled and shielded even if vulnerabilities would be discovered.

For these reasons, the Operating System and the other software modules installed on **LIAISON® XL** computer will be updated only if such 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.

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

The usage of a network printer, configured by DiaSorin on **LIAISON® XL** systems as “default printer”, requires to install printer drivers, that may be not available for the **LIAISON® XL** 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

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

The 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 Remote access

### 2.7.1 Potential issues

**LIAISON® XL** systems may be connected to servers used by DiaSorin for the purpose of troubleshooting, customer support, device monitoring and software update. This will be managed through a dedicated applications that may require software installation on both **LIAISON® XL** computer and field personnel computers.

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

Presence of such application could be lead to systems remotely accessed by unauthorized persons, 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

The remote connection will be hosted on a communication channel that undergoes cryptography. This prevents unauthorized users from observing the channel.

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

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

## 2.8 Privacy

### 2.8.1 Potential issues

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

Therefore, a potential risk of spreading health 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 personnel in the following situations:

1. during a technical intervention on laboratory systems, personnel of type “A” or “B” may need to access the **LIAISON® XL** 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 overcome the listed potential issues.

### 2.8.2 Protection measures

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

1. Both the patient health data and the demographics are encrypted;
2. If the patient health data have been exchanged on electronic format, this will happen through a encrypted channel;
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 the end-users may use in combination with their laboratory system, in which all the patient information are maintained, and particularly the patient demographics;

6. The system can perform all the analyses without the need to insert the 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 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. the access to such data will be restricted on the system to specific users, for whom the laboratory responsible people will ask for activation (during system installation);
    b. such measure regards the display on screen and the printed hard copies of such information, either directly from the Personal Computer connected to the system, or from any other Personal Computer on which the **LIAISON® XL** software is installed, to which the data bases are loaded after exporting from the system Personal Computer;
    c. such measure covers both the direct visualization of information (e.g. the reading on screen 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 explicitely 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.

As it regards the responsibilities of end-users, where local regulations require so, the end-user is responsible for the following behavior:

on **LIAISON® XL** 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 local regulations require so, DiaSorin responsibility is configured as follows:

a. DiaSorin will solicit the respect of the applicable privacy regulations, if there should be evidence that a **LIAISON® XL** is used without compliance to the rules stated by applicable privacy regulations;
b. DiaSorin is not liable for improper use of data generated through the **LIAISON® XL** once 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.

## 2.9 Security Requirements for Operating Environment

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

To integrate the **LIAISON® XL** 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® XL**.

# 3 Measuring Principle of the LIAISON® XL Immunoassays

## 3.1 Explanations for Steps of Assays

Assays (also defined as “tests”) that run on the **LIAISON® XL** 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.

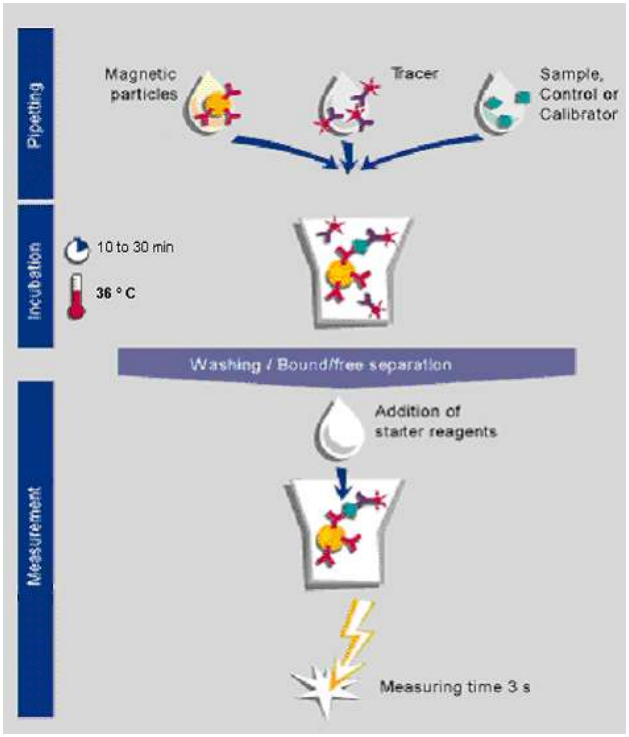



*Figure 3-1: Example of test procedure "1-step assay"*

### 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.

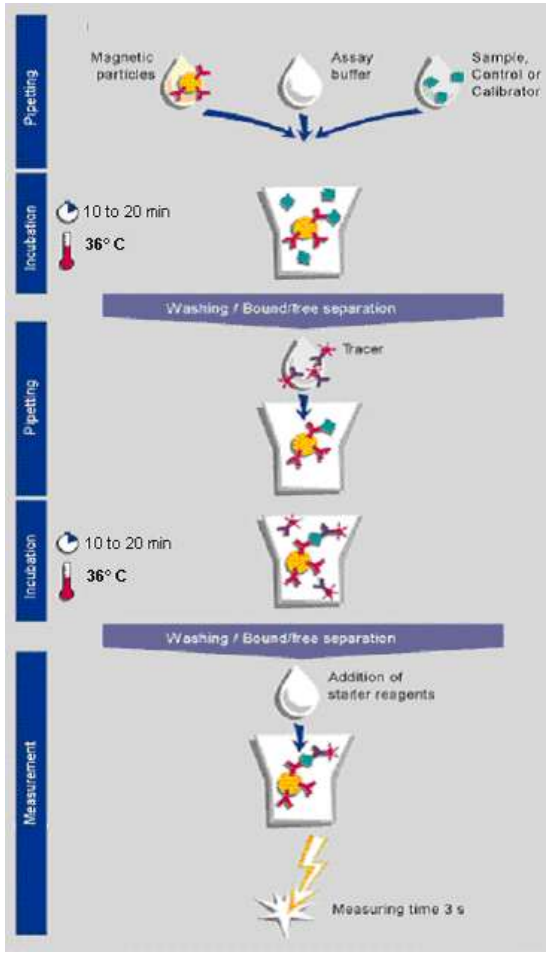



*Figure 3-2: Examples of test procedure "2-step assay"*

### 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 injection head, starter reagent 1 will be injected.
- After an appropriate pump delay time (2.55 sec minimum) the starter reagent 2 will be injected into the cuvette to start the chemiluminescence reaction.
- After the measuring delay time of 0.1 sec, the measuring signal is obtained and integrated over the measuring period (3.0 sec for most assays).

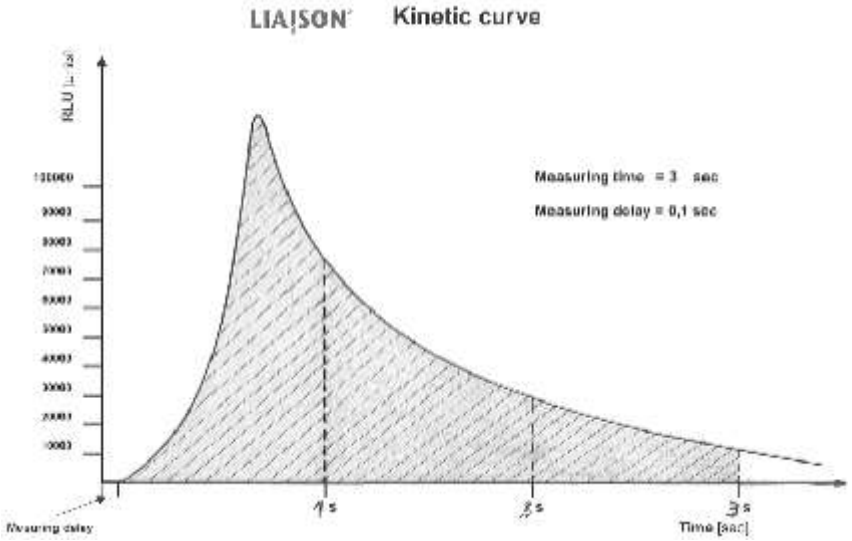



*Figure 3-3: **LIAISON® XL** kinetic curve*

## 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 analyzer.

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.

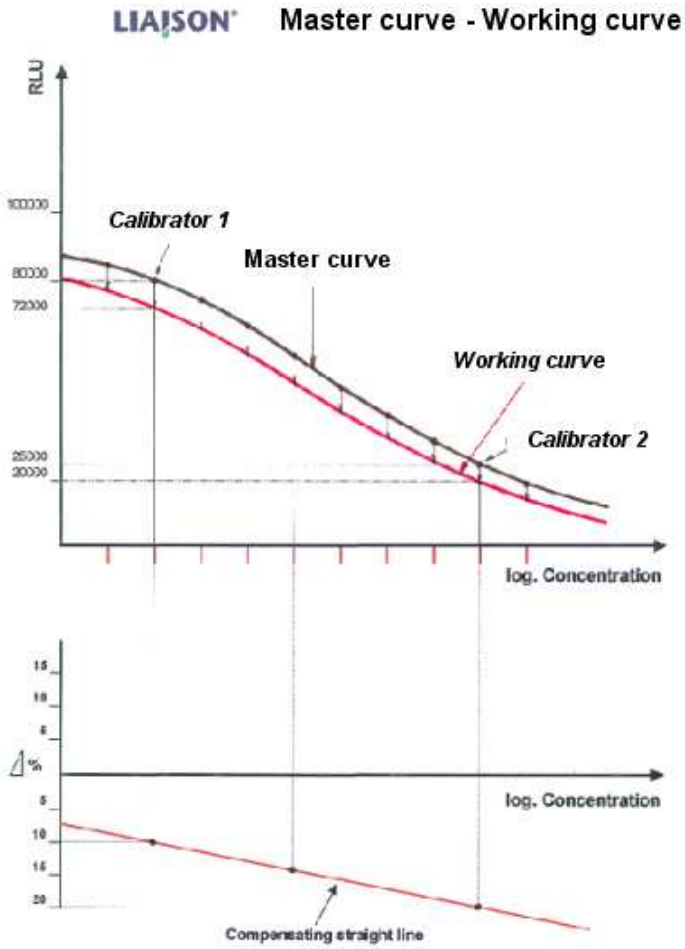



*Figure 3-4: Calibration concept: example*

**Brief description:**

- The stored 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® XL Diagnostic System can only be expected with the use of LIAISON® XL 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, dependant 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:

1. in one point qualitative, only calibrator 1 is present: coefficients given are *a* and *c* only;
2. 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® XL Cuvettes (code X0016).
LIAISON® XL Disposable Tips (code X0015).
LIAISON® Disposable Tips (code X0055).
LIAISON® XL Starter Kit (code 319200).
LIAISON® EASY Starter Kit (code 319300).
LIAISON® Wash/System Liquid (code 319100).
LIAISON® XL Waste Bags (code X0025).

**NOTE** Refer to the Assay IFU of the products for details about the materials that can be used.

### 4.1.2 LIAISON® XL System

| | |
|---|---|
| 1 | Left blind cover |
| 2 | Left top cover |
| 3 | Right top cover |
| 4 | Right blind cover |
| 5 | Front Module (throw in for cuvettes, drawers for disposable tip trays, loading bays for samples, reagents and starter reagents) |
| 6 | Cabinet for liquid tanks, waste liquid tanks, solid waste and PC |
| 7 | Extensible board |
| 8 | Integrated re-suspension tool |
| 9 | Touch screen |

**CAUTION**

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

In case it would be necessary to open the cover, make sure to pause the pipettors (see chapter 6.2.1) and wait for 30'' before opening the cover. This action avoids unnecessarily not reporting results.

Remove the pause condition (see chapter 6.2.1) after cover closure to allow pipettor regular operations.


*Figure 4-1: **LIAISON® XL** system*

### 4.1.3 System Modules

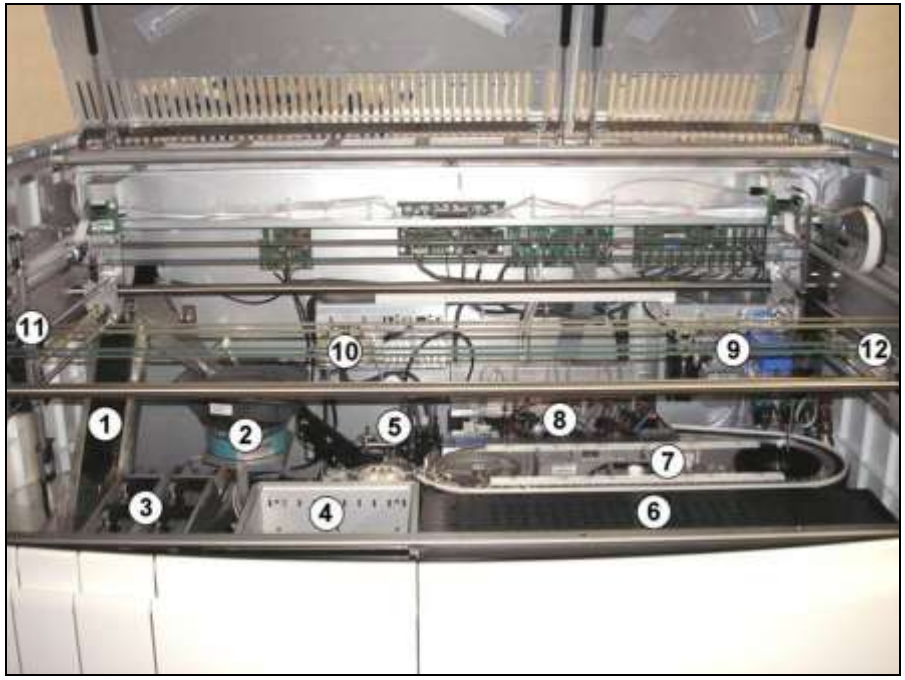



*Figure 4-2: **LIAISON® XL** system modules*

| | |
|---|---|
| 1 | Cuvette transport (Auger) |
| 2 | Cuvette orientation mechanism (Sorter) |
| 3 | Disposable Tip Drawers |
| 4 | Loading bay for sample racks |
| 5 | Reader |
| 6 | Loading bay for reagents and ancillaries |
| 7 | Incubator and Wash / Waste station |
| 8 | Washer |
| 9 | Pump Rack |
| 10 | Starter Reagent Pumps |
| 11 | Air pipettor with disposable tip adapter for sample pipetting (Left Arm) |
| 12 | Pipettor with steel needle for reagent pipetting (Right Arm) |

### 4.1.4 Flaps and Drawers


*Figure 4-3: **LIAISON® XL** flaps and drawers*

| | |
|---|---|
| 1 | Left Top Cover |
| 2 | Right Top Cover |
| 3 | Touch screen |
| 4 | Reservoir for cuvettes |
| 5 | Drawers for disposable tip trays |
| 6 | Loading bay for sample racks |
| 7 | Loading bay for reagents (integrals or ancillary reagents) |
| 8 | Loading area for starter reagents |
| 9 | Extensible board |

### 4.1.5 Cabinet

In case **LIAISON® diluteX** is connected to the analyzer, Figure 4-4 is not representative; for further details, please refer to **LIAISON® diluteX** User Manual.

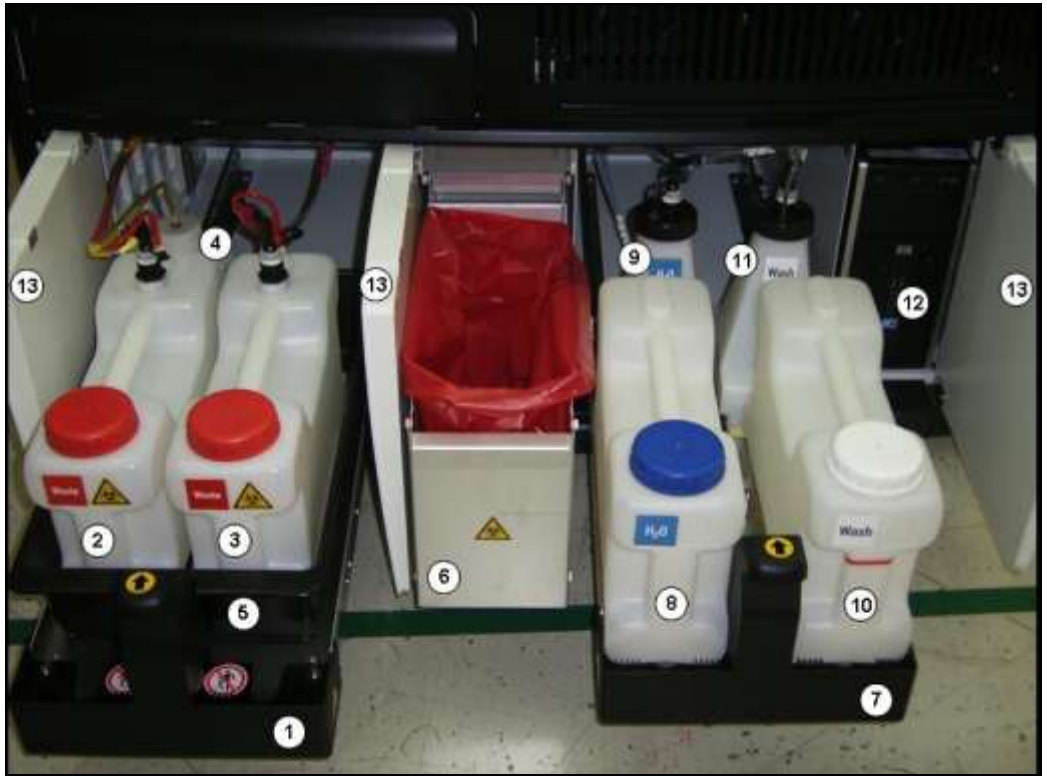



*Figure 4-4: **LIAISON® XL** cabinet with drawers*

| | |
|---|---|
| 1 | Left drawer |
| 2 | Liquid waste tank, Left |
| 3 | Liquid waste tank, Right |
| 4 | Cleaning solution tank |
| 5 | Waste basin |
| 6 | Solid waste drawer |
| 7 | Right drawer |
| 8 | Water tank |
| 9 | Intermediate tank (Water) |
| 10 | Wash buffer tank |
| 11 | Intermediate tank (Wash buffer) |
| 12 | PC |
| 13 | Cabinet doors |

### 4.1.6 LIAISON® XL with Workcell Upgrade Kit

A modified version of the **LIAISON® XL** Diagnostic System, called **LIAISON® XL with Workcell Upgrade Kit**, is designed to allow compatibility with certain types of laboratory automation systems (LAS). As can be noticed in Figure 4-5, the pipettor module is expanded, in order to allow the sample arm to aspirate samples coming from a laboratory automation system.

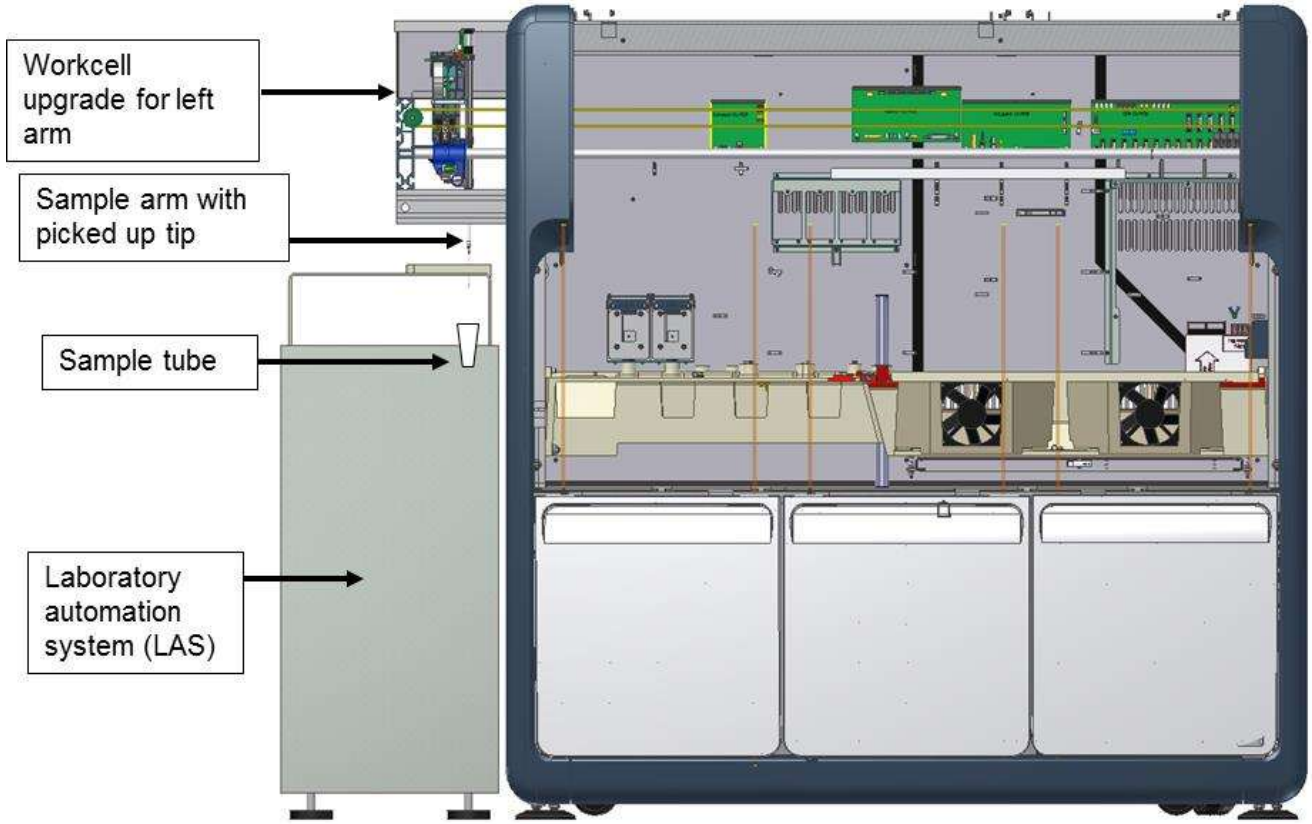



*Figure 4-5: **LIAISON® XL with Workcell Upgrade Kit** system*

A dedicated cover (Figure 4-6 and and Figure 4-7) is mounted as a physical guard to protect the user from contact with the moving pipettor arm.

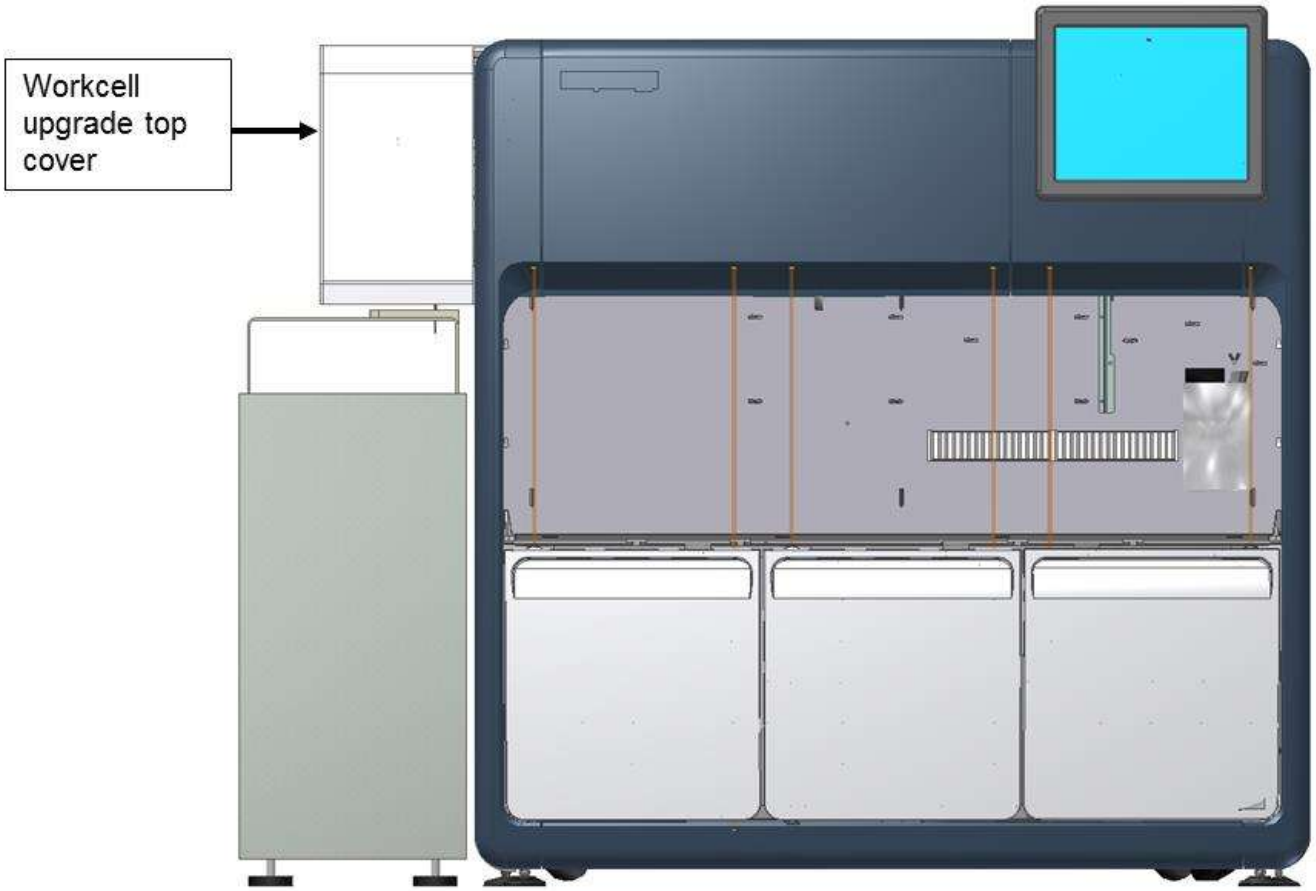



*Figure 4-6: **LIAISON® XL with Workcell Upgrade Kit** – Front view*

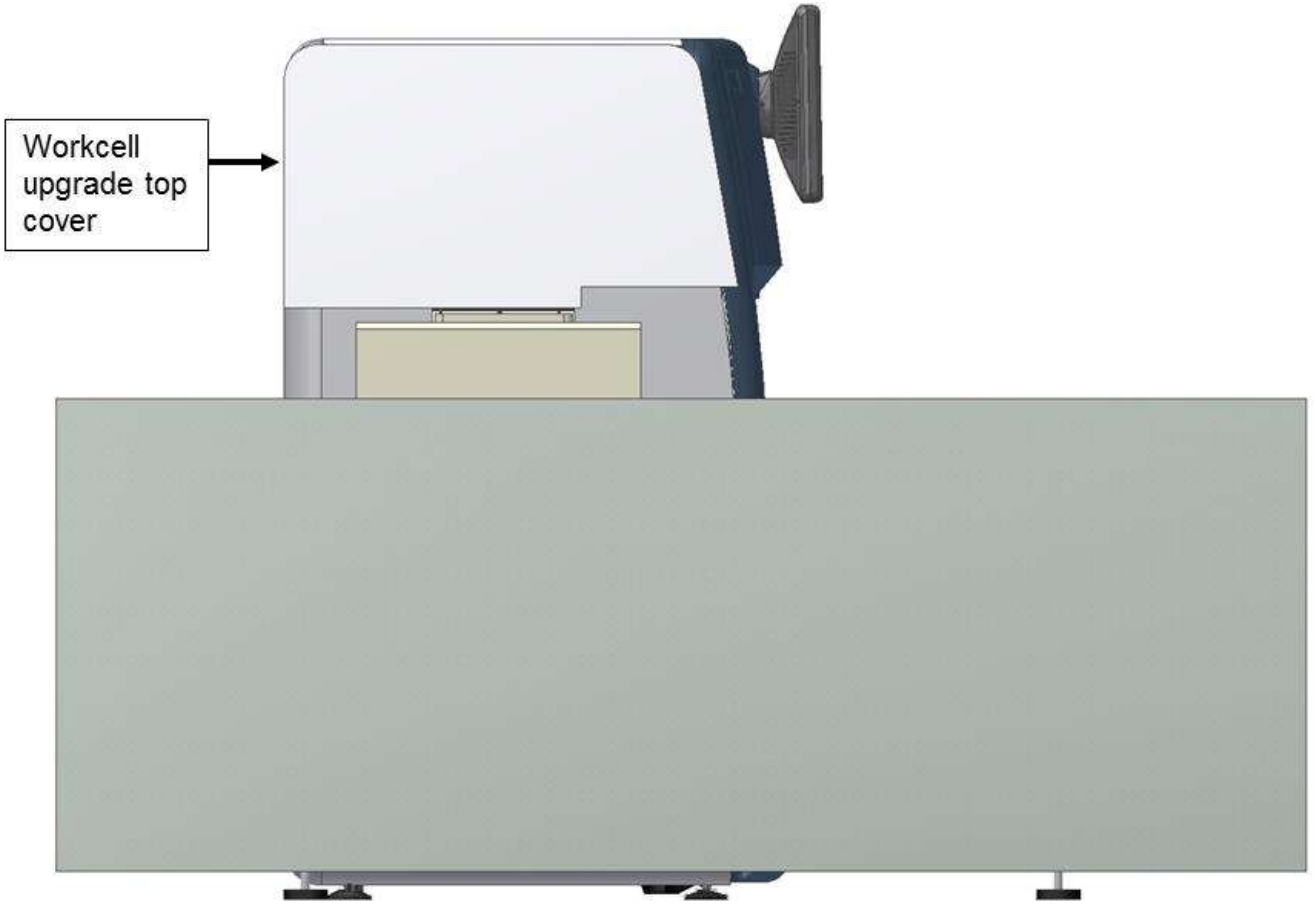



*Figure 4-7: **LIAISON® XL with Workcell Upgrade Kit** – Lateral view*

### 4.1.7 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** | 9 or 6 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 |
| **Incubator** | 80 positions assembly in which cuvettes are incubated and pipetted |
| **Instrument** | Part of **LIAISON® XL** system that contains only the **LIAISON® XL** analyzer and tanks, but not PC, 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 14 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 accuracy of the left dispensing pipettor, carried out by Light Check solution |
| **LC-ri** | Test to verify accuracy 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 |
| **Reader** | Reading area in which chemical reaction and measurements occur |
| **Prime** | Start-up cycle for individual parts of instrument involved in fluidics, carried out by usage of DI Water, Wash Buffer, Starter Reagents and Cleaning Solution |
| **Pusher** | Exchanges cuvettes between incubator and washer or cuvette loading mechanism |
| **Rack Holder** | 12 positions holder used for the handling of sample and control racks outside the instrument. |

| | |
|---|---|
| **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** | Plastic removable container to increase safety during waste bag disposal |
| **Solid Waste Drawer** | Drawer of the system used to host waste bags and the solid waste bin (if equipped) |
| **Starter (reagents)** | Reagents dispensed during the reading to generate chemiluminescent signal |
| **System** | The complete structure installed in the laboratory |
| **Tip** | Single cavity plastic probe used to aspirate samples with left pipettor arm |
| **Tray** | 96 positions modules equipped in the Disposable Tip drawers to host tips |
| **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 |
| **Waste Bag** | Container for used cuvettes and tips |
| **Waste Basin** | Container used to collect spillage of contaminated liquid coming from broken waste tanks |

## 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 stylus (tip R0.8 or over) or finger directly on the touch screen. **The usage of an external keyboard or mouse is not validated therefore it is not supported.**

**Touch Screen Handling**

- Operate with a stylus (tip R0.8 or over), or with a finger without applying excessive pressure.
- Avoid using sharp edged or hard articles.
- Avoid drawing lines along with the edge of the housing which may damage the PET/FILM and cause the failure of the touch panel due to extreme force.
- Keep the surface clean by executing periodic maintenance (see chapter 8.9).

**CAUTION** 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® XL** 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 4-8: On screen keyboard (alphanumerical version)*

### 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.

The following models are available: PN A0096, PN A0179 and PN A0256.

In case of PN A0096 model, a dedicated support (Figure 4-9.b) can be placed in the cabinet, just in front of the PC, and can be used to hold the barcode reader when it is not in use (Figure 4-11); the support can be fixed to the system using the velcro strips (Figure 4-10) attached by the technician during the installation.

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

a) Barcode reader (PN A0096)

b) Barcode reader support (PN A0096)

*Figure 4-9: Barcode reader and barcode reader support (PN A0096)*

*Figure 4-10: Velcro labels for barcode reader support (PN A0096)*

*Figure 4-11: Barcode reader position (PN A0096)*

In case of use of PN A0179 and PN A0256 handheld barcode reader, the velcro strips previously placed into the cabinet for the fixation of the support are no more necessary. In any case it is suggested to place a not-in-use barcode reader into the cabinet, just in front of the PC.

*Figure 4-12: Handheld barcode reader (PN A0179 and PN A0256) with integrated support*

*Figure 4-13: Handheld barcode reader (PN A0179 and PN A0256) placed into the cabinet*

### 4.2.3 Reservoir for Cuvettes

The reservoir for cuvettes allows continuous loading of the **LIAISON® XL** system with cuvettes. The cuvettes must be loaded in units of 200 pieces (1 bag) and remain in the reservoir until they are utilized. The management of the cuvettes in the system is performed by the **LIAISON® XL** software.

The loading of the cuvettes is described in chapter 5.5.1.

### 4.2.4 Drawers for Disposable Tip trays

With two independent drawers for disposable tip trays, a continuous refilling of disposable tips and therefore an uninterrupted operation of the system is possible.

Every drawer can be filled with up to three disposable tip trays with 96 disposable tips each. The loaded disposable tip trays are recorded by the **LIAISON® XL** software (see chapter 6.10.2). 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 5.5.2.

**LEDs**

A LED below the relevant drawer shows the current usage status:

| Description | Status | Action |
|---|---|---|
| The drawer is closed and currently being used. | **LED ON** | Do not open the drawer. |
| The drawer is closed and not in use. | **LED OFF** | It is possible to open the drawer. |
| The drawer is open. | **LED slow flashing** | It is possible to close the drawer. |

*Table 4-1: LEDs on the disposable tip drawers*

### 4.2.5 Loading Bay for Sample Racks

The loading bay for sample racks allows continuous loading of the **LIAISON® XL** system with samples. The samples in the tubes are placed in special racks and loaded in one of the 10 lanes afterwards. As support, a LED below each lane indicates the relevant usage status (see below).

To prevent confusion, a distinct identification number must be assigned to every sample in the **LIAISON® XL** 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 typing it manually.

**WARNING**

See chapter 1-16 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, 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).

Regarding the positioning, the barcode must be applied to the grey section in the middle of the tube as shown in Figure 4-14.


*Figure 4-14: Bar-code label on the tube*

| 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 4-2: Length of bar-code label*

Ensure that the bar-code labels face towards the left (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 5.6.

**LEDs**

A LED below each lane indicates the current usage status when the flap is open, while the status “slow flashing” is not shown with the flap closed:

| Description | Status | Action |
|---|---|---|
| The sample rack is currently being used or could be used soon for a test. | **LED ON** | Do not remove it |
| **Without** sample rack in the lane:<br>• The lane is not activated, and cannot be used to load a sample rack. | **LED OFF** | Do not load a sample rack in this lane |
| **With** sample rack in the lane:<br>• The samples of this rack are not used or scheduled. | **LED OFF** | It is possible to remove it. |
| The lane is activated, and can be used to load a sample rack. | **LED slow flashing (once per second)** | Insert the next sample rack into this lane. |
| The sample rack has not been recognized. | **LED fast flashing (three times per second)** | Remove the sample rack and insert it again. |

*Table 4-3: LEDs on the loading bay for sample racks*

#### 4.2.5.1 Sample Racks

A sample rack is a holder to store patient samples (placed in sample tubes) for use on the analyzer. 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 analyzer in a way such to be registered by the analyzer and supports the sample tubes during aspiration by the sample probes.

**CAUTION**

Only the supplied **LIAISON® XL** 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.

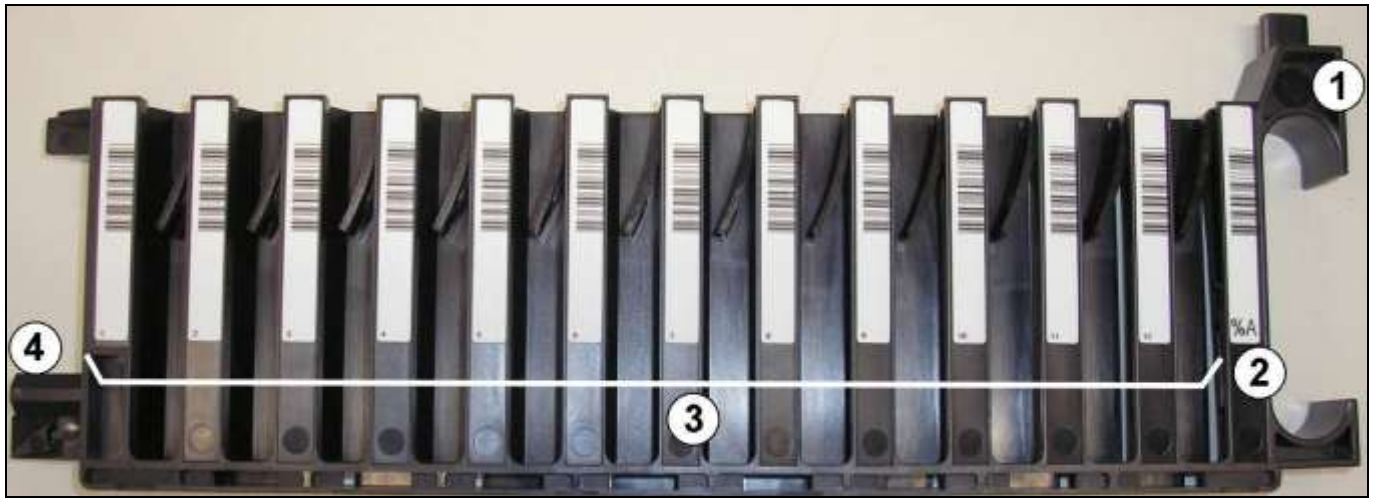



*Figure 4-15: Sample rack A*

| | |
|---|---|
| 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 |

#### 4.2.5.2 Control Racks

**9-position Control Rack**

A 9-position control rack is a holder to store some types of control bottles and external calibrators for use on the analyzer. The 9-position control rack (also known as C rack) is designed to hold up to 9 bottles (bar-coded or non-bar-coded) and is to be inserted into the analyzer in a way such to be registered by the analyzer and supports the bottles during aspiration by the sample probes.

A set of 2 9-position control racks is provided with each instrument.

**CAUTION**

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

**CAUTION**

9-position control rack has to be used only on **LIAISON® XL** systems whose sample bay is not equipped with the top cover (see next picture).

*Figure 4-16: Sample bay not equipped with top cover*

9-position control racks have the structure as pictured and described below. The positions are labeled from A through up to I with label A starting farthest away from the handle.

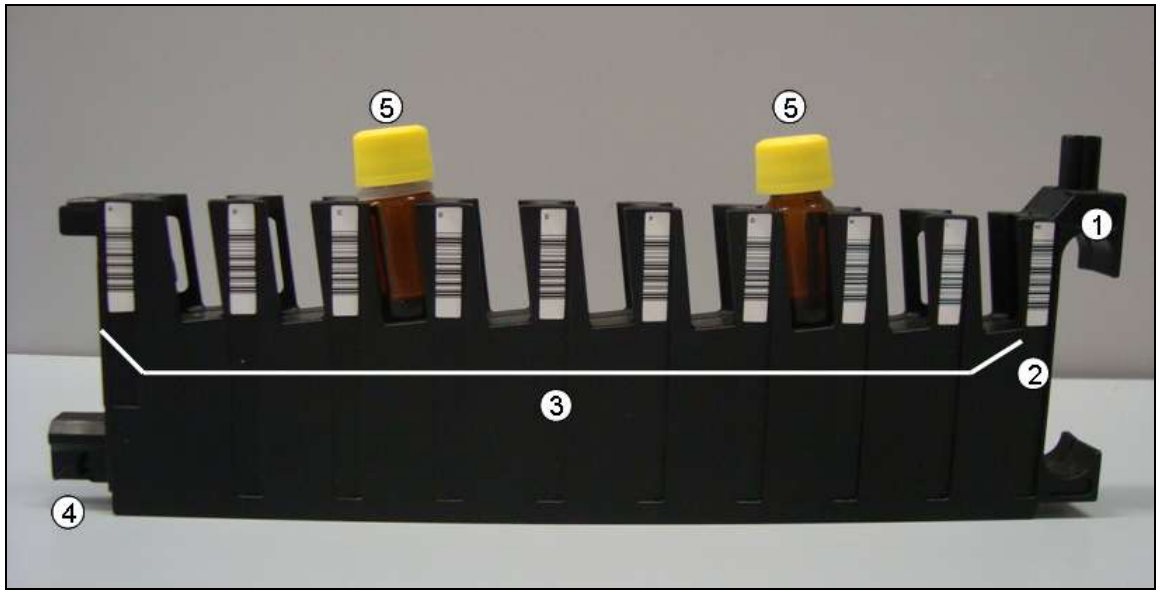



*Figure 4-17: 9-position Control Rack*

| | |
|---|---|
| 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 analyzer |
| 5 | Control bottles or external calibrators placed inside the rack |

## 6-position Control Rack

A 6-position control rack is a holder to store some types of control bottles and external calibrators for use on the analyzer. The 6-position control rack (also known as T rack) is designed to hold up to 6 bottles (bar-coded or non-bar-coded) and is to be inserted into the analyzer in a way such to be registered by the analyzer and supports the bottles during aspiration by the sample probes.

A set of 3 6-position control racks is provided with each instrument.

**CAUTION**

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

**CAUTION**

6-position control rack is designed to fit on **LIAISON® XL** systems whose sample bay is equipped with the top cover (see next pictures), but it can be used on any **LIAISON® XL** systems.

*Figure 4-18: Sample bay equipped with top cover (front view)*

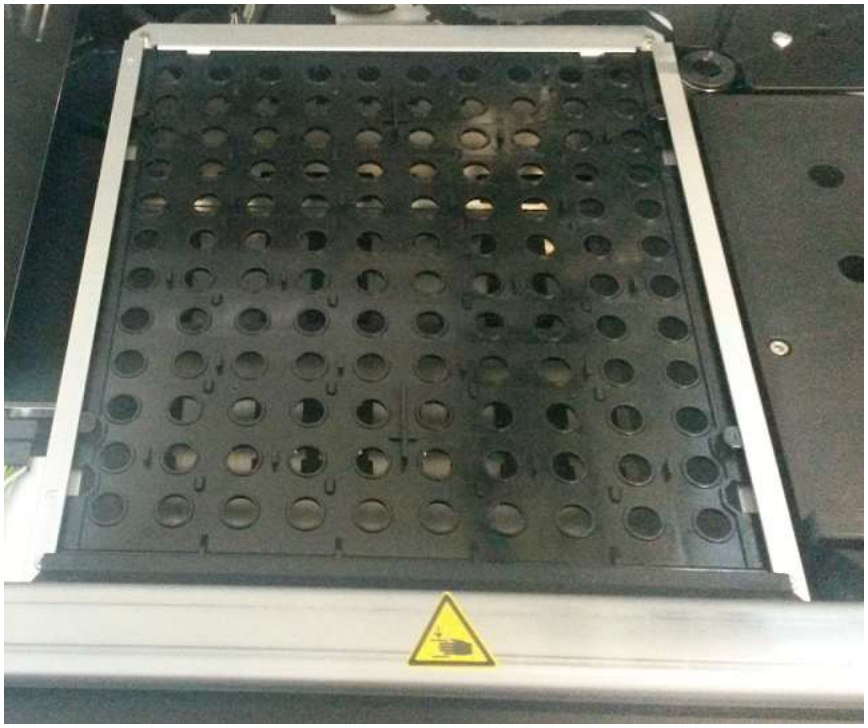


*Figure 4-19: Sample bay equipped with top cover (top view)*

6-position control racks have the structure as pictured and described below. The positions are labeled from A through up to F with label A starting farthest away from the handle.

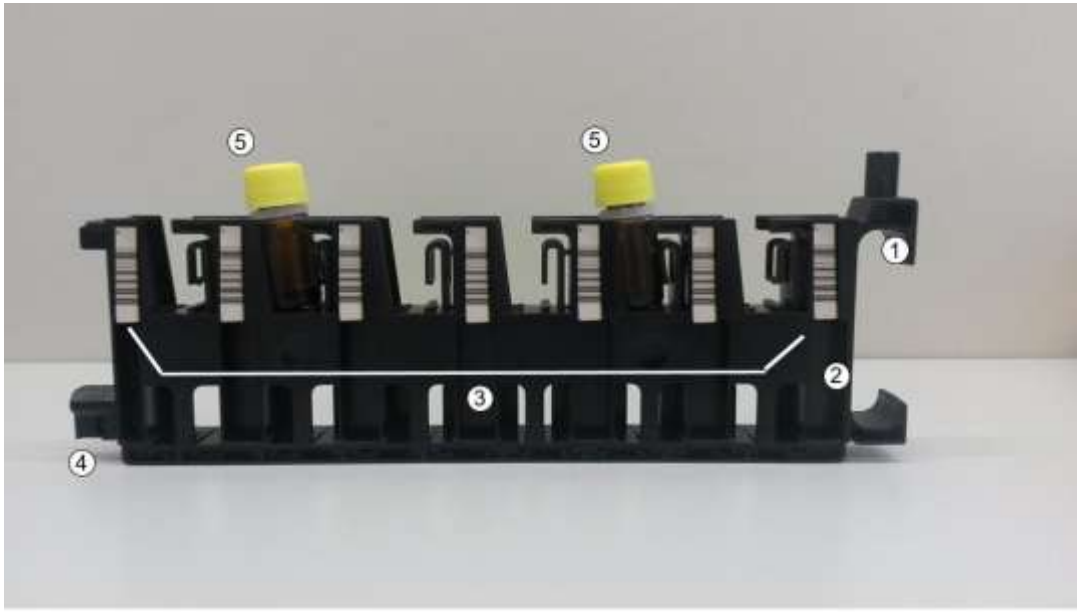



*Figure 4-20: 6-position Control Rack*

| | |
|---|---|
| 1 | Handle |
| 2 | Control rack identification bar-code label (%T) |
| 3 | Bottle positions with position bar-code label and position holding |
| 4 | Clamp to lock the control rack into the loading bay of the analyzer |
| 5 | Control bottles or external calibrators placed inside the rack |

#### 4.2.5.3 Rack Types, Tube Diameter and Dead Volume

There are 19 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, 5 typologies (X, Y, Z, G, H) 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 |
| 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 |
| D | Use only for DiaSorin special large vials (i.e. some types of control bottles or external calibrators and on systems not equipped with sample bay top cover) | | |
| G | Request Technical Assistance | Request Technical Assistance | Request Technical Assistance |
| H | Request Technical Assistance | Request Technical Assistance | Request Technical Assistance |
| X | Request Technical Assistance | Request Technical Assistance | Request Technical Assistance |
| Y | Request Technical Assistance | Request Technical Assistance | Request Technical Assistance |
| Z | 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: |
|---|---|---|---|
| C | Use only for DiaSorin special large vials (i.e. some types of control bottles or external calibrators and on systems not equipped with sample bay top cover) | | |
| T | Use only for DiaSorin special large vials (i.e. some types of control bottles or external calibrators) | | |
| L | Used only for DiaSorin glass vials (i.e. some types of control bottles or external calibrators) | 55 ±0.5 mm | |
| P | Used only for pediatric tubes | | |

*Table 4-4: 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 15mm diameter. According to the assay Instructions for use, the assay requires 20 µL per test. The user will have to have a total of 440µL 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

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

**Insufficient or Missing Patient Sample Liquid**

| | |
|---|---|
| **CAUTION** | 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. |

### 4.2.6 Loading Bay for Reagents (Integrals and Ancillary Reagents)

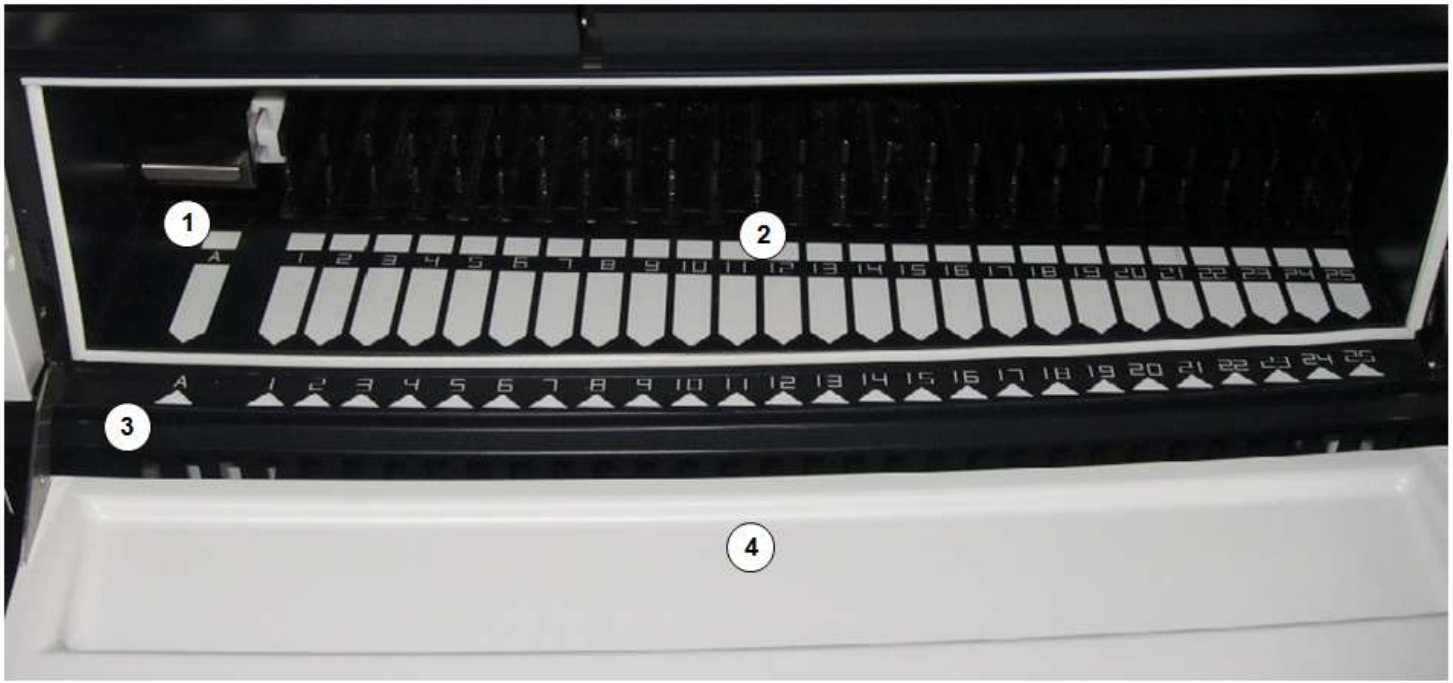



*Figure 4-21: Front view of the loading bay for reagents*

| | |
|---|---|
| 1 | Lane for ancillary reagents and additional reagents |
| 2 | 25 lanes for integrals |
| 3 | LEDs for each lane |
| 4 | Flap |

The loading bay for reagents allows a continuous loading of the **LIAISON® XL** system with reagents in the form of integrals or ancillary reagents. As a guide, a LED below each lane indicates the relevant usage status (see below).

**Integrals:**

- Up to 25 integrals can be used at the same time.
- Integrals can be loaded directly into one of the 25 lanes according to the specifications of the **LIAISON® XL**.
- 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® XL** 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.

Systems can be equipped with one of the following types of ancillary racks:

*Figure 4-22 Ancillary rack with short front wall*

*Figure 4-23 Ancillary rack with increased front wall*

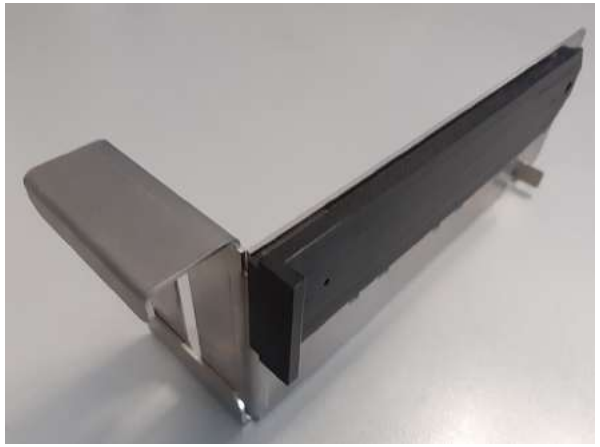


*Figure 4-24 Ancillary rack with increased front wall and plastic block*

**CAUTION**

There is no functional difference between the different types of ancillary racks. Nevertheless, due to geometric considerations, ancillary racks with increased front wall are not compatible with loading bays designed for ancillary racks with short front wall and viceversa.

The information included in the integral or ancillary reagent (RFID label) is read and used in the **LIAISON® XL** 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, it should be opened only briefly for loading and unloading.
The system will beep to remind to close the reagent bay flap.

**LEDs**

A LED below each lane indicates the current usage status when the flap is open, while the status “slow flashing” is not shown with the flap closed:

| Description | Status | Action |
|---|---|---|
| The integral or ancillary reagents are currently being used or scheduled for a test. | **LED ON** | Do not remove it. |
| The integral or Ancillary reagents are not used or scheduled. | **LED OFF** | It is possible to remove it. |
| The lane is activated, and can be used to load an integral or the ancillary rack**.** | **LED slow flashing** (once per second) | It is possible to insert an integral or the ancillary rack into this lane. |
| The integral or ancillary reagents have not been recognized. | **LED fast flashing** (three times per second) | Remove the integral and insert it again. |

*Table 4-5: LEDs on the loading bay for reagents*

#### 4.2.6.1 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.

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

### 4.2.7 Integrated re-suspension tool

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

For a **LIAISON® XL** 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.

#### 4.2.7.1 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.

### 4.2.8 Area for Starter Reagents

The area for starter reagents contains the starter reagents (**LIAISON® XL** Starter Kit or **LIAISON®** EASY Starter Kit). The starter reagent bottles are provided with removable screw caps that are 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® XL** software.

To allow continuous exchange, each position contains one LED which indicates the relevant usage status (see below).

**CAUTION**

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

**CAUTION**

Always keep the starter reagent area closed to avoid light.

An LED indicates for each position the current usage status when the flap is open, while the status “slow flashing” is not shown with the flap closed:

**LEDs**

| Description | Status | Action |
|---|---|---|
| The starter reagent is currently ready to be used for a test. | **LED ON** | Do not remove it. |
| The loaded starter reagent is not used or scheduled. | **LED OFF** | It is possible to remove it. |
| The lane is activated, and can be used to load a starter bottle. | **LED slow flashing** (once per second) | Insert a starter reagent at this position. |
| The starter reagent has not been recognized or it is the wrong type. | **LED fast flashing** (three times per second) | Remove the starter reagent completely and insert it again. |

*Table 4-6: LEDs on the area for starter reagents*

### 4.2.9 Cabinet

All large-volume containers for the liquid supply and disposal are located in the cabinet. In addition, there is a container with a foil bag for the solid waste and a bottle for routine cleaning of the system lines. Some additional devices (waste basin, waste bin) are used to increase safety in the handling of contaminated materials.

#### 4.2.9.1 Water

The water container together with a docking container allows the refilling of water without interruption of the operation of the **LIAISON® XL**. A sensor hereby controls the current liquid level and requests the user to refill water at a certain residual volume. For refilling, the user removes the water container (10 L) and returns it to its original position after refilling. A corresponding docking connector provides the leak proof connection between the two containers.

In case **LIAISON® diluteX** is connected to the analyzer, is is not necessary to refill the water container, since the **LIAISON® diluteX** automatically refills it. For further details, please refer to **LIAISON® diluteX** User Manual.

#### 4.2.9.2 Wash buffer

The wash buffer container together with a docking container allows the refilling of wash buffer without interruption of the operation of the **LIAISON® XL**. A sensor hereby controls the current liquid level and requests the user to refill wash buffer at a certain residual volume. For refilling, the user removes the wash buffer container (10 L) and returns it to its original position after refilling. A corresponding docking connector provides the leak proof connection between the two containers.

In case **LIAISON® diluteX** is connected to the analyzer, is is not necessary to refill the wash buffer container, since the **LIAISON® diluteX** automatically refills it. For further details, please refer to **LIAISON® diluteX** User Manual.

#### 4.2.9.3 Cleaning solution

The cleaning solution container has a volume of 2 liters. Level in bottle is not tracked by the system. The user must ensure that enough liquid is present for required task before starting a maintenance routine.

#### 4.2.9.4 Liquid waste

DANGER

**See Biological safety in chapter 1.8.6.**

To allow a continuous operation of the **LIAISON® XL**, the system is provided with two independent liquid waste containers (2x10 L). As soon as one of the two containers is full, the system automatically switches to the second container and the user is requested to empty the relevant container. At the container itself, there is an LED indicating the usage status (see below).

**LEDs**

| LED Status | Description | Action |
|---|---|---|
| **ON** | The container is currently being used or scheduled for a test. | Do not remove it. |
| **OFF** | The container is not used or scheduled. | It is possible to remove it. |

*Table 4-7: LEDs on the waste containers*

#### 4.2.9.5 Waste basin

A waste basin is placed in the cabinet of the instrument to host waste tanks. This solution is used to avoid a potential contamination of the cabinet caused by spillage of contaminated liquid from a broken waste tank.

Refer to chapter 1.10.7 for labelling and chapter 5.5.6.3 for removal procedures.

#### 4.2.9.6 Direct drain configuration

**LIAISON® XL** system supports also a direct drain configuration, where a waste tube can be directly connected to the system allowing to dispose liquid waste directly into a collector drain. In this case liquid waste containers and basin shall not be installed in the instrument.

Direct drain is an optional solution, all systems are shipped with waste containers. In case of specific request of the users, direct drain configuration can be implemented by field service engineers during the installation of the instrument or at a later point in time.

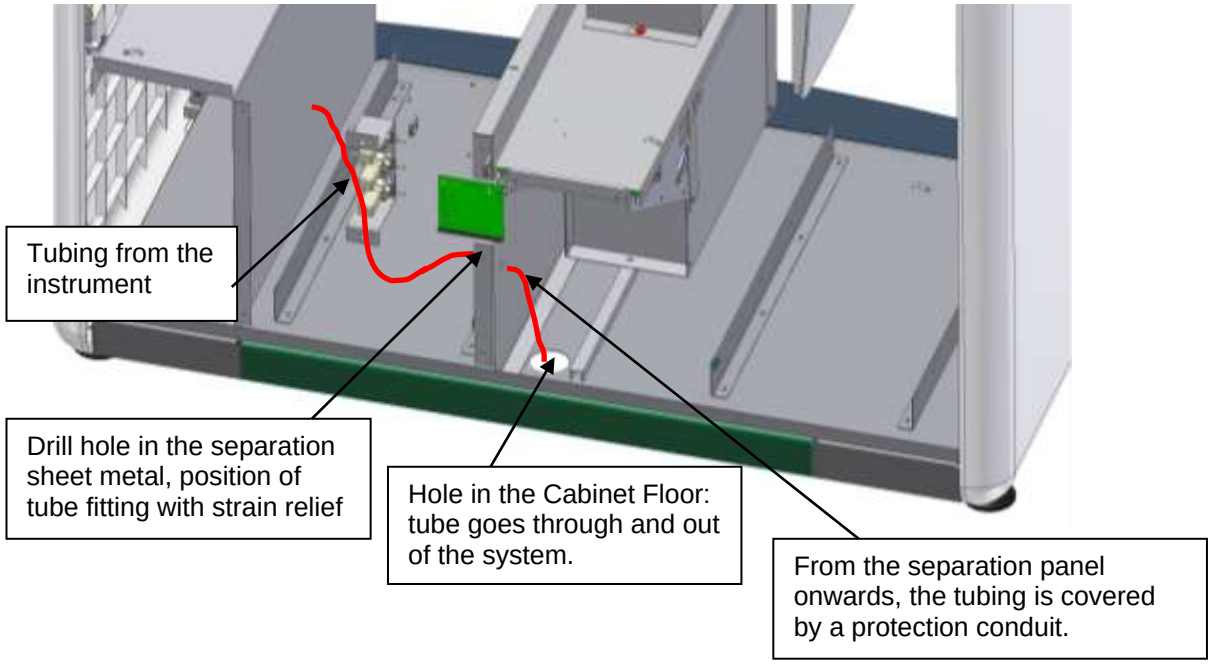



*Figure 4-25: Direct drain connection, back view*

CAUTION

**Direct Drain Installation**

Please note that the direct drain configuration may only be installed by authorized service personnel.

NOTE

The length of the direct drain tubing can reach up to 10 meters, contact the local service support for more information.

CAUTION

Do not modify the direct drain configuration installed by the service technicians

#### 4.2.9.7 Solid waste drawer

Next to the liquid waste containers, there is a drawer for solid waste (cuvettes and disposable tips) accumulated in the **LIAISON® XL** system. To simplify disposal, and contain biological hazards, the container is provided with a foil bag.

To allow continuous operation during the exchange of the foil bag, the system is provided with an additional container. In this additional container, the accumulating solid waste is collected during the replacement of the foil bag and put into the solid waste drawer automatically upon reclosing the solid waste drawer. The filling level of both containers is controlled by the **LIAISON® XL** software.

#### 4.2.9.8 Solid waste bin

In order to increase the safety during waste bag disposal, a solid waste bin can be placed in the dedicated drawer of the cabinet, in order to host the waste bag. The available handles allow the user to remove and reinsert it into the waste drawer, thus avoiding any contact with the bag during the disposal phase.

Refer to chapter 1.10.6 for labelling and chapter 5.5.7 for use.

### 4.2.10 Incubator

In addition to heating, the incubator includes a conveyor belt for the transport of up to 80 cuvettes. The conveyor belt moves every single cuvette to various positions (washer or pipetting positions) when needed.

The working temperature range (36.5 °C – 38.5 °C) is reached at the latest after a heating time of 1 hour. If the temperature falls below or exceeds the expected range value during operation, a warning is issued.

The current temperature of the incubator can be found in the **LIAISON® XL** software in the main category **Status** sub category **Temperatures** (see chapter 6.10.3).

### 4.2.11 Pipettors

The **LIAISON® XL** 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.

**Sample Pipettor**

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

This pipettor, located on the left side of the system, can only reach the loading bay for samples during a test routine, and additionally the ancillary area in the loading bay for reagents during a maintenance routine.

Additionally, the sample pipettor allows the transferal 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.

**Reagent Pipettor**

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 take-up 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.

### 4.2.12 Washer

In the washer, several cuvettes can be processed at the same time. Cuvettes in the washer can be transported either back to the incubator or into the reader after processing, according to the sequence of the requested assay. The washer needles are rinsed after every aspiration cycle.

### 4.2.13 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 bag.

### 4.2.14 Visual Alarm

On top of the **LIAISON® XL** system a visual alarm system may be installed as an option.

The visual alarm system shall provide the user with visual warnings of the system functionality over short distances. It shows a visual signal about fatal and system errors.

The mute and auto-mute functionality for the beeper also turn off the visual alarm.

### 4.2.15 Printer

An USB printer can be connected to the Analyzer by authorized DiaSorin service personnel; a dedicated support can be added to the right side of the instrument, in order to allow a proper placing of the printer. Both local and network printers are supported; the printer connected to the Analyzer shall be set as “default printer”.

**CAUTION** Print only hard copies. Never change the destination printer.

## 4.2.16 Holders

### 4.2.16.1 Rack Holder

A dedicated holder (Figure 4-26) 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.

*Figure 4-26: Rack holder with equipped racks*

### 4.2.16.2 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.

## 4.3 Accessories and Consumables

In order to facilitate tests requested by the user, the instrument requires the following:

Cuvettes – Vessels in which the immuno-chemical reaction between the sample and reagents occurs. The measurement of the immuno-chemical reaction is also achieved in these vessels.

Disposable Tips – The vessels used to transport sample from the laboratory container to the cuvette.

Samples – Liquids obtained from patients in the form of blood, serum, plasma, or urine necessary for determining the results of a certain test for a certain patient.

Reagents – Groups of biological or chemical agents scientifically combined to assess a certain status of a sickness or disease of a given patient.

**LIAISON® diluteX** is an optional accessory of the **LIAISON® XL** and **LIAISON® XL Workcell Upgrade Kit** for the provision of the Wash Buffer and the purified water to the analyzer. Please refer to **LIAISON® diluteX** User Manual for details. The availability of **LIAISON® diluteX** depends upon specific market regulations. Please refer to your local Diasorin Representative for details on availabilty.

These above listed items must be added by the user as pertaining to the respective tests and the amount of tests wanted.

**CAUTION** Use only the consumables and accessories described herein and approved by **DiaSorin Italia S.p.A.**

**NOTE** The Instructions for use for accessories and of consumables are provided for user safety and give important instructions for the handling. The IFU for the consumables can be found in the appendix of this manual.

See chapter 5.5 and chapter 5.7 for the use of accessories and consumables.

# 5 Use of the System

CAUTION

**Conditioning time**

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

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

All functions of the **LIAISON® XL** software are described in chapter 6.

## 5.1 Safety and Hints

CAUTION

**See chapter 1.8 for all safety hazards.**

## 5.2 Typographical Conventions

**Software**


*Figure 5-1: Screen*

| | | |
|---|---|---|
| 1 |  | **Main categories**:<br>Click on the respective tab to change the main category.<br>Example: Click on the **System** main category tab. |
| 2 |  | **Sub categories**:<br>Click on the respective tab to show details of the sub category in the sub category display.<br>Example: Click on the **Settings** sub category tab. |
| 3 | | **Display**:<br>Shows all details of the selected sub category.<br>Example: The system shows all functions on the **Settings** sub category display. |
| 4 | | **Header**:<br>Shows information about the system and contains the **Stop**, **Start** and **Support** buttons.<br>Example: The system status is shown on the ***Header***. |
| 5 |  | **Tabs**:<br>Subdivides a sub category into different areas.<br>Example: Click on the **Others** tab. |
| 6 |  | **Groups**:<br>Combines functions to groups.<br>Example: All functions are shown in the ***Language*** group. |
| 7 |  | **Buttons**:<br>Click on the respective button to start a special function.<br>Example: Click on the **Apply** button. |
| 8 |  | **Selection boxes**:<br>Click on the arrow and select one of the shown entries.<br>Example: Select the ***YYYY-MM-DD*** entry of the ***DateFormat*** selection box. |

| | | |
|---|---|---|
| 9 |   | **Checkboxes**:<br>Click on the square or circle box to activate a function or option.<br>A checkmark in a square box of a checkbox shows an activated function/option.<br>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.<br>Example: Activate the **Auto log-off** checkbox. |
| 10 |  | **Input boxes**:<br>Use the on screen keyboard to write into an input box. See also section Tooltips below.<br>Example: Enter the new value in the ***Minutes*** box. |
| - |  | **Tooltips:**<br>Tooltips are used to inform the user about wrong values in input boxes. After entering the correct value, the tooltips disappear. The tooltips disappear also automatically few seconds after their appearance. |

**Miscellaneous**

| | |
|---|---|
| **LEDs and signal lamps** | Describes LEDs (light emitting diode) and signal lamps of the instrument.<br>Example: The Lane LED of the sample loading bay will illuminate. |
| **Keys** | Describes special keys of the on screen keyboard.<br>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.<br>Example: Choose `D:\LiaisonXL\Share` as backup path. |
| **Prescribed parameters** | Describes special parameters or values to enter into an input box.<br>Example: Enter `10` into the shown input box. |

## 5.3 Daily activities plan

| | | |
|---|---|---|
| **Start-up** | • Switch-on (only if off) | chapter 5.4 |
| | • Log-on | |
| | • Respect the conditioning time | |
| **Check** | • Check cuvettes, disposable tips, starter reagents and liquid containers | chapter 5.5 |
| **Load Integrals and Ancillary reagents** | • Load integrals | chapter 5.7 |
| | • Load ancillary reagents | |
| **Load Controls and Calibrators** | • Load controls | chapter 5.7 |
| | • Load calibrators | |
| **Calibrate integrals** | • Calibrate integrals | chapter 5.7 |
| **Load Samples and Assign Assays** | • Load patient samples | chapter 5.6 |
| | • Assign assays to the patient samples | |
| **Start Worklist** | • Start the run | chapter 5.8 |
| **Results** | • Check results | chapter 5.9 |
| **Errors and Events** | • Check errors and events | chapter 5.9.5 |
| **Unloading** | • Unload unused sample racks | chapter 5.11 |
| | • Unload unused integrals | |
| **Shut Down/End of Day Maintenance** | • No special care | chapters 5.12 and 6.9 |
| | • If planned for today, perform periodical maintenance | |

## 5.4 Start-up

**Procedure**

**Switch on and log-on:**

1. Ensure that the cover and the flaps are closed.
2. Switch on the instrument.
3. Switch on the integrated PC.
   The system starts the operating system and the **LIAISON® XL** software on the integrated PC.
4. After system start, the **LIAISON® XL** software shows the ***Startup*** display:


*Figure 5-2:* **Startup** *screen*

| Function | Description |
|---|---|
| **Backup** | Starts the external backup viewer application (see chapter 6.11). |
| **LiaisonXL** | Starts the **LIAISON® XL** software (see below). |
| **QC** | Starts the long term quality control (QC) application (see chapter 1).<br>*Note: if installed, the QC software V2 is started.* |
| **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. |

*Table 5-1: Functions of the **Applications** sub category*

5. Click on the **LiaisonXL** button.
   The **LIAISON® XL** software shows the ***Login*** display:


*Figure 5-3:* **Login**

**NOTE**

There are several security levels of user access rights on the **LIAISON® XL** 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 may spontaneously require to perform an automated back-up of temporary files upon pressing the **LiaisonXL** button. This action will take few minutes, and will improve the PC performance. Please confirm the related pop-up when prompted.

6. Enter the user name into the ***User*** box.
   The user name is not case sensitive.
7. Enter the appropriate password into the ***Password*** box.
   The password is case sensitive.
8. Click on the **Login** button.
9. From the **STOP** menu, initialize the system (see chapter 6.2.1).
   The **LIAISON® XL** 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.

## 5.5 Check Cuvettes, Disposable Tips, Starter Reagents and Liquid Containers

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

**Procedure**

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

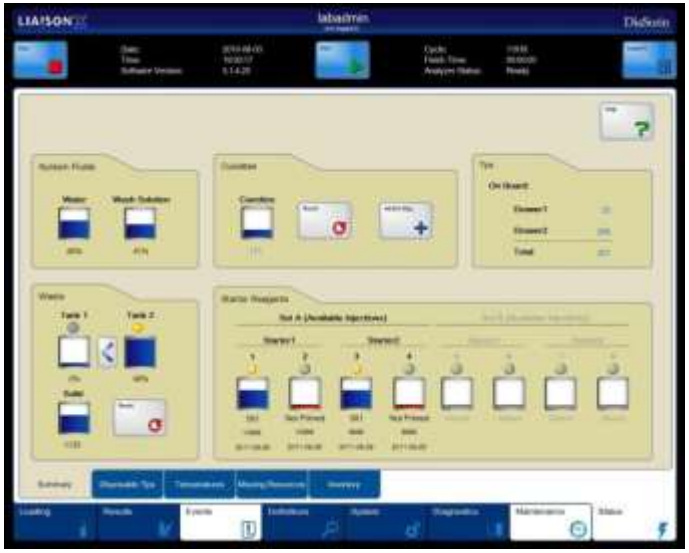


*Figure 5-4: Sub category **Summary***

**NOTE**

It is possible to compare the indicated conditions with the actual filling levels in the relevant containers, bottles and solid waste. If the indicated and actual filling levels are not concordant with each other, a service engineer should be contacted if required.

| |  (blue) |  (yellow) |  (red) | Other possible status | Additional information |
|---|---|---|---|---|---|
| **Water** | at least 30% | in range 13%-30% | running out (less than 13%) | Disconnected | "Active" tests are not counted. |
| **Wash Buffer** | at least 30% | in range 12%-30% | running out (less than 12%) | Disconnected | "Active" tests are not counted. |
| **Starter** | at least 80 injections | less than 80 injections | running out (0,1,2 injections) | Absent (bottle not loaded)<br>Present (bottle not primed)<br>Not Available (bottle empty or offline) | Thresholds are compared with the difference between number of available shots and "active" tests. Red is reached when this difference is 0. |
| **Cuvettes** | cuvettes are detected by sensors | cuvette buffer is empty | running out (less than 3 cuvettes detected) | | Based on sensors detection |
| **Solid Waste (cuvettes/tips)** | no more than 1700 | in range 1700-2000 | nearly full (more than 2000) | Pulled Out | "Active" tests are not counted for yellow status.<br>Red threshold is compared with the sum of number of cuvettes (tips) in waste drawer and "active" tests.<br>When pulled out, there is space for no more than 50. |
| **Liquid Waste** | no more than 70% | in range 70-84% | nearly full (more than 84% liquid) | Absent (tank not loaded) | Thresholds are referred to the total amount of the two tanks.<br>"Active" tests are not counted. |

*Table 5-2: Used colour code*

| Symbol | Meaning |
|---|---|
|  | Container connected and active |
|  | Container connected and inactive |
|  | Container not connected |

*Table 5-3: Used symbols*

**System Fluids Group**

Shows the usable volume of the ***Water*** and the ***Wash Solution*** containers [in percent].

**Notice the *System Fluids* group:**

**3.** Check the levels of both system fluids containers (***Water*** and ***Wash Solution***). If low, refill them.

**Cuvettes Group**

| Function | Description |
|---|---|
| **Added Bag** | Press on this button after refilling of cuvettes. The ***Cuvettes*** counter incremented about 200.<br>(1 cuvettes bag = 200 cuvettes) |
| ***Cuvettes*** | Shows the number of cuvettes in the instrument. |
| **Reset** | Press on this button to set the ***Cuvettes*** counter to 0. |

*Table 5-4: Functions of the* **Cuvettes** *group*

**Notice the *Cuvettes* group:**

4. Check the number of the cuvettes. If low, refill them.
   Refill procedure: see chapter 5.5.1.

**Tips Group**

Shows the number of unused disposable tips in the instrument.

**Notice the *Tips* group:**

5. Check the number of the disposable tips in both drawers. If low, refill them.
   Refill procedure, see chapter 5.5.2.

**Waste Group**

Shows the filling level of the liquid waste containers (***Tank 1*** and ***Tank2***) in per cent, and ***Solid*** waste (cuvettes and disposable tips).

| Function | Description |
|---|---|
| **Reset** | Pressing on this button clears the counter for solid waste. The procedure is due upon empting of the solid waste reservoir |
|  or  | Changes the used waste tank:<br>• ***Tank 1 > Tank2***: Changes tank in use***:*** **from *Tank 1*** to ***Tank 2***<br>• ***Tank 1 < Tank2***: Changes tank in use***:*** **from *Tank 2*** to ***Tank 1*** |

*Table 5-5: Functions of the* **Waste** *group*

**WARNING**

**See chapter 1.8.6 for Biological Safety.**

**Notice the *Waste* group:**

6. Check the levels of both waste liquid containers (***Tank 1*** and ***Tank2***). If full or nearly full, empty and decontaminate it.
7. Check the level of the ***Solid*** waste container. If full or nearly full, empty it. After that, click on the **Reset** button.

**Starter Reagents Group**

Shows remaining injection counters of all loaded starter reagents. The counter decreases after every injection.

**Notice the *Starter Reagents* group:**

8. Check the levels of the starter reagent bottles. If low, load a new bottle.
   The information is reported only when the starters after correctly primed by the system.

### 5.5.1 Refill cuvettes

**NOTE**

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

**Procedure**

1. Holding the cuvette pack so that the perforated end is upright, ensure that all cuvettes in the bag are below the perforated mark.
2. Using one hand to hold the pack under the perforated mark, remove the upper end of the cuvette pack (Figure 5-5) and immediately discard the separated piece.

*Figure 5-5: Opening the cuvette pack*

3. Open the cuvette loading access door on the analyzer.

4. Continuing to hold the cuvette pack in an upright position, place the cuvette pack directly over the cuvette loading access and slowly empty the complete contents of the cuvette pack into the loading access (Figure 5-6)

*Figure 5-6: Loading the cuvette pack*

5. Once the loading has been completed, close the cuvette loading access door and discard the cuvette pack.
6. Select the sub-category Summary of the category Status (refer to chapter 6.10.1). Press Added bag button corresponding to the number of packs loaded.

| | |
|---|---|
| **NOTE** | Always load the complete cuvette bag into the analyzer**.** |
| **NOTE** | Press the button only once for each bag loaded. |
| **NOTE** | Cuvettes are for single use only**.** |
| **CAUTION** | During the loading of cuvettes, verify not to exceed the maximum tolerated level, indicated by the red line available on the cuvette reservoir (see chapter 1.10.16). |

### 5.5.2 Refill Disposable Tips

**NOTE**

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

**Procedure**

1. Click on the **Status** main category tab.
2. Click on the **Disposable Tips** sub category tab.

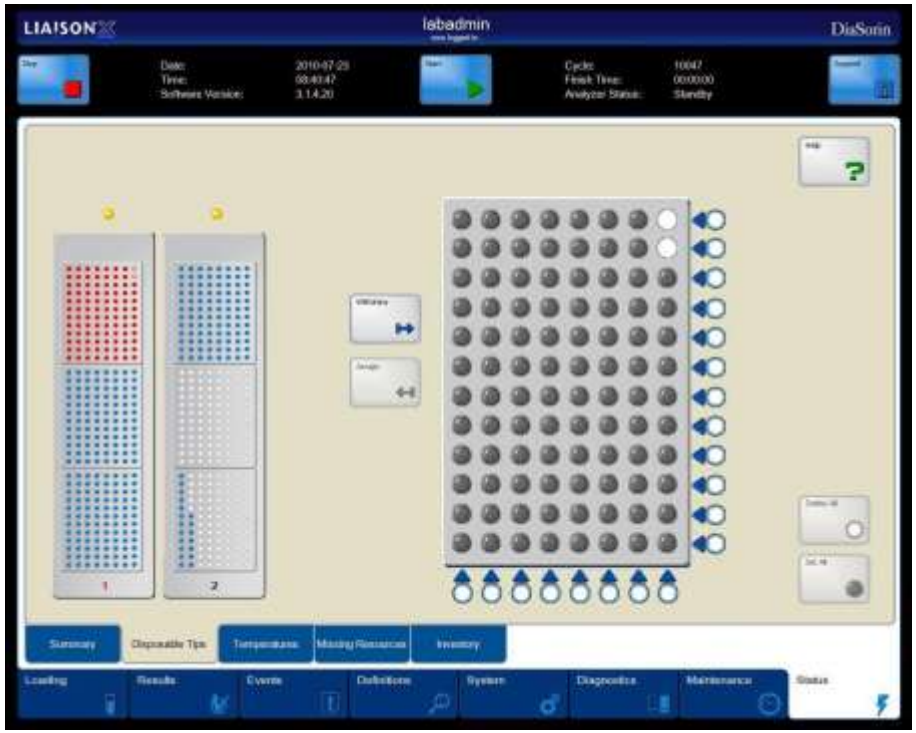



*Figure 5-7: Sub category **Disposable Tips***

| Function | Description |
|---|---|
| **Assign** | Gives the access of the drawer to the pipettor system. The LED below the drawer on the system and the indicator above the drawer in the software display change to yellow.<br>The **Assign** button is only available when the drawer is closed. |
| **Delete All** | Deletes all disposable tips on the single disposable tip tray. |
| **Set All** | Fills the single disposable tip tray with disposable tips. |
| **Withdraw** | Gives the access of the drawer to the user. The LED below the drawer on the system and the indicator above the drawer in the software display change to grey.<br>Note: If the instrument is pipetting, the pipettor will use the other drawer. If the LED does not turn grey, the drawer cannot be released by the system. If the drawer contains no tips, the drawer is automatically withdrawn. |
| Standard buttons | For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.1. |

*Table 5-6: Functions of the **Disposable Tips** sub category*

3. Click on the disposable tip tray position of drawer 1 or 2.
4. Click on the **Withdraw** button.
   The LED below the drawer on the system is flashing off and the indicator above the drawer on the software display changes to grey.

**NOTE**

If the system is pipetting, the pipettor will use the other drawer. If the LED does not turn grey, the drawer cannot be released by the system. If the drawer contains no tips, the drawer is automatically withdrawn.

5. Pull out the selected drawer.
6. If present, remove the empty disposable tip tray(s).
7. Open the user box (1) and pull out a folding sleeve (2).


*Figure 5-8: Disposable Tip user box and folding sleeve*

8. Open one side of the folding sleeve by pulling up one of the available flaps (as indicated by the arrow symbols).

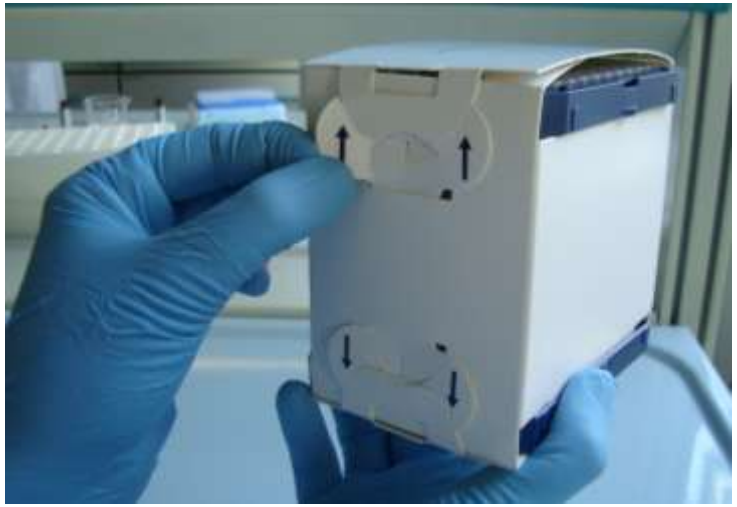


*Figure 5-9: Folding sleeve opening*

**NOTE**

The **LIAISON® XL** Disposable Tip/ **LIAISON®** Disposable Tip user box may be opened only from one side. Each user box contains 3 folding sleeves.

Each folding sleeve contains 2 trays and may be opened from either the top or the bottom sides. Each opening gives the user access to 1 tray. Only one of the openings can be opened at a time.

9. Using one hand, take a disposable tip tray by holding it on the longer side and insert it into the disposable tip drawer on the analyzer.
10. If necessary, repeat points 7-9 until all positions of the drawer have been loaded.

**NOTE**

Insertion of partially filled tip trays is possible; in this case, it is necessary to pay attention to the tip placement and to indicate their placement on the software interface in next steps.

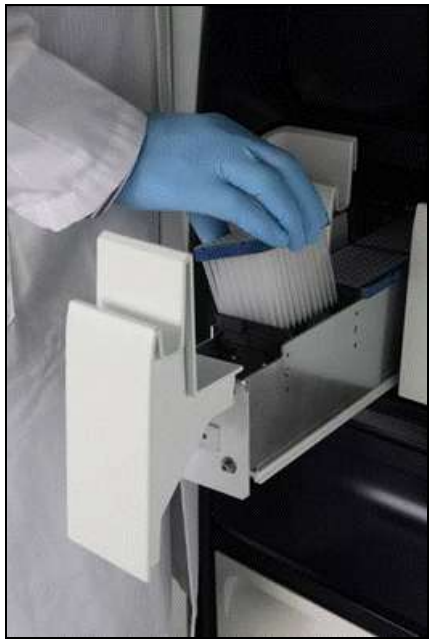


*Figure 5-10: Loading the tip tray*

11. Close the opened drawer.

    **Note**: this step may be performed even afterwards, before pressing the **Assign** button.

12. Click on the **Set All** button.

13. If more than one tray has been loaded in the selected drawer, click on the next refilled disposable tip tray position of the selected drawer and click on the **Set All** button, too.

14. When ready, click on the **Assign** button.
    The LED below the drawer is permanently illuminated and the indicator above the drawer on the display changes to yellow. The pipettor has access to the drawer. From now on, to remove the drawer it is necessary to repeat this procedure from step 1, regardless if the system is running or not.

**NOTE**

All disposable tips are for single use only**.**

### 5.5.3 Load and Unload 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, immediate and thorough washing with water or a suitable buffer solution is recommended. If necessary, a physician should be consulted.

**WARNING**

Starter pooling is prohibited!

**NOTE**

Refer to the safety notes (see chapter 5.7)!

The **LIAISON® XL** Starter Kit or **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® XL** Starter Kit or **LIAISON®** EASY Starter Kit).

**Unload Procedure**

1. Open the flap for starter reagents.
2. The LED below the empty starter reagent bottle must be off.
   If the LED is slow flashing, there is no starter reagent bottle.

   Remove the cap of the empty starter reagent bottle.
3. Remove the empty starter reagent bottle.

**Load Procedure**

1. Remove the locking cap of the new starter reagent bottle.
2. Place the **LIAISON® XL** system cap onto the new starter reagent bottle.

**NOTE**

It is essential to ensure correct connection to starter 1 and starter 2.

3. Insert the new starter reagent bottle into the **LIAISON® XL** system.
4. If the LED below starts flashing fast (three times per second), the starter reagent bottle has not been recognized or it is the wrong starter type.
5. If point 4 has been verified, remove the starter reagent bottle completely and re-insert it.
6. Close the flap for starter reagents.
   The **LIAISON® XL** system will prime the new starter reagents automatically when possible.

**CAUTION**

In case lot numbers change, it is necessary to recalibrate all integrals. The system will disable all existing calibrations.

**NOTE**

Loading starter bottles in all corresponding positions at the same time helps to minimize the amount of starter shots used for prime reasons.

**NOTE**

The system automatically primes the starter bottles, either upon loading or whenever possible. This may lead to delayed results or tests not starting. To ensure that test results will occur according to the expected timelines, check when the related tests are scheduled and expected.

### 5.5.4 Load and Unload the Water Tank

**NOTE**

In case **LIAISON® diluteX** is connected to the analyzer, please do not follow this procedure, but refer directly to **LIAISON® diluteX** User Manual.

**Unload Procedure**

1. Open the cabinet doors.
2. Pull the right drawer out of the cabinet (Figure 5-11).

*Figure 5-11: Right drawer pulled out*

3. Raise the front of the (empty) water tank approximately 2 cm (0.8 inch) (Figure 5-12).

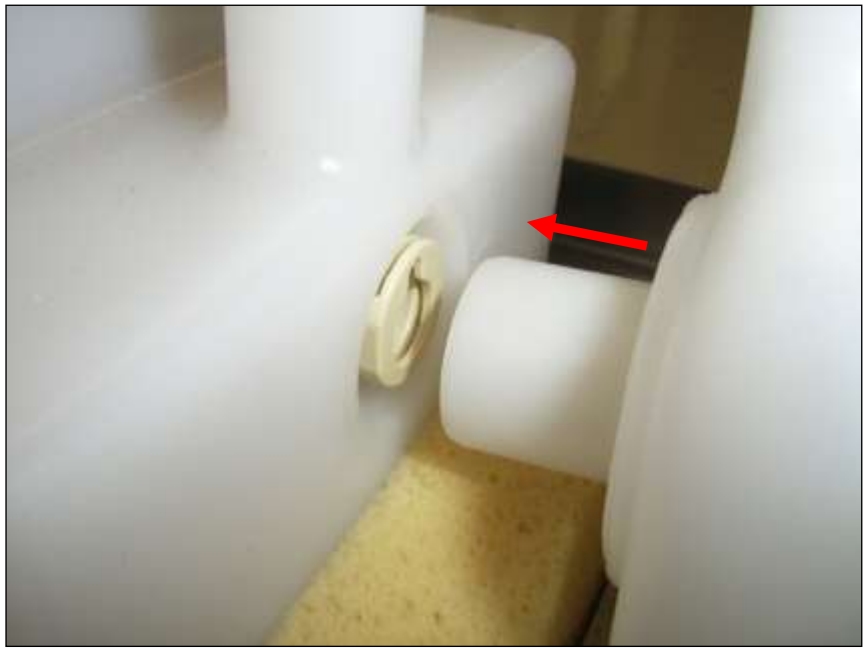

*Figure 5-12: Raise water tank*

4. Pull the water tank out of the **LIAISON® XL** system.

**Load Procedure**

1. Holding the handle of the drawer by hand (Figure 5-13 a), place the full water tank into the the right cabinet drawer of **LIAISON® XL** system.
   Note the audible click.
   The centering pin must fit the intermediate tank (Figure 5-13 b).

a)



b)

*Figure 5-13: Water tank insertion and fitting*

2. Push the right drawer back into the cabinet (Figure 5-14).


*Figure 5-14: Right drawer insertion*

3. Close the cabinet doors.

## 5.5.5 Load and Unload the Wash Buffer Tank

### 5.5.5.1 Preparation

1. See instruction for use.

**NOTE**

Before the wash buffer is handled or loaded into the **LIAISON® XL** system, the package information is to be read thoroughly and followed by the user. Use the red line available on the tank as an aid during the preparation of the wash solution (refer to chapter 1.10.9).

In case **LIAISON® diluteX** is connected to the analyzer, please do not follow this instruction but refer directly to **LIAISON® diluteX** User Manual.

**CAUTION**

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

Please do not take into account this caution if **LIAISON® diluteX** is connected to the analyzer.

**CAUTION**

After completion of the wash buffer preparation, the cap must be placed lightly on the container to allow proper degassing of the wash buffer solution!

Please do not take into account this caution if **LIAISON® diluteX** is connected to the analyzer.

**CAUTION**

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

Please do not take into account this caution if **LIAISON® diluteX** is connected to the analyzer.

**CAUTION**

The **LIAISON® XL** wash buffer container should be kept away from direct sunlight.

### 5.5.5.2 Procedure

**Unload Procedure**

1. Open the cabinet doors.
2. Pull the right drawer out of the cabinet (Figure 5-11).
3. Raise the front of the (empty) wash buffer tank approximately 2cm (0.8inch) (Figure 5-15).


*Figure 5-15: Raise wash buffer tank*

4. Pull the wash buffer tank out of the **LIAISON® XL** system.

**Load Procedure**

1. Holding the handle of the drawer by hand (Figure 5-16), place the full wash buffer tank into the the right cabinet drawer of **LIAISON® XL** system.
   Note the audible click.
   The centering pin must fit into the intermediate tank (Figure 5-13b).
2. Push the right drawer back into the cabinet (Figure 5-14).
3. Close the cabinet doors.

*Figure 5-16: Wash buffer tank insertion*

### 5.5.6 Load and Unload the Liquid Waste Containers

DANGER

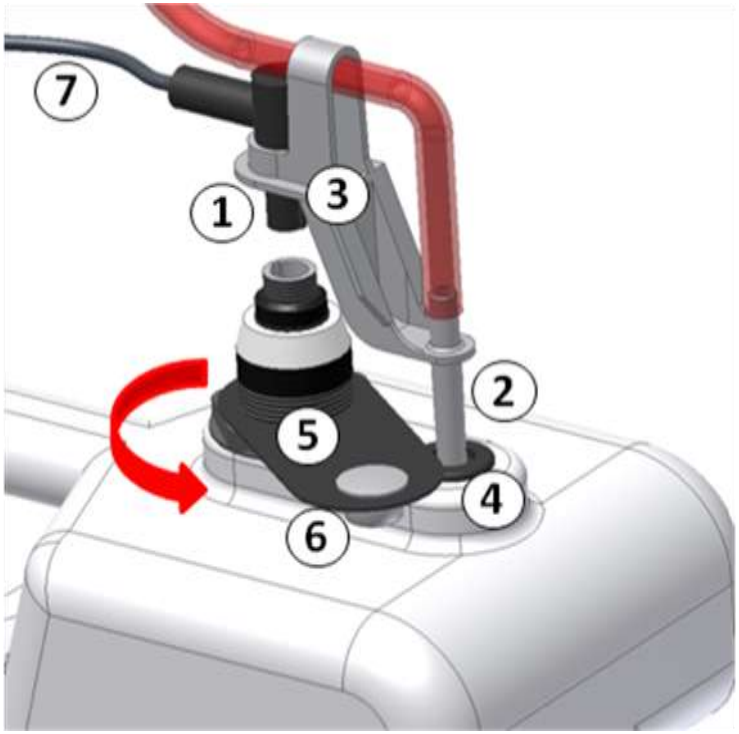
**See Biological safety in chapter 1.8.6.**

CAUTION

Note the control light on the connector and remove only unused liquid waste containers (the control light is off). It is possible to change the liquid waste container currently in use through the dedicated button, see chapter 6.10.1.

#### 5.5.6.1 Joint connector for waste

The joint connector (Figure 5-17) is used to manage the insertion/ removal of the waste sensor and tubing 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 |

*Figure 5-17: Liquid waste container with sensor/ liquid joint connector*

During the unload phase (Figure 5-18) the removal of the sensor connector also implies a removal of the liquid tubing from the dedicated membrane; as a safety requirement, the sensor is completely disconnected before the liquid tubing is pulled completely out of the membrane.

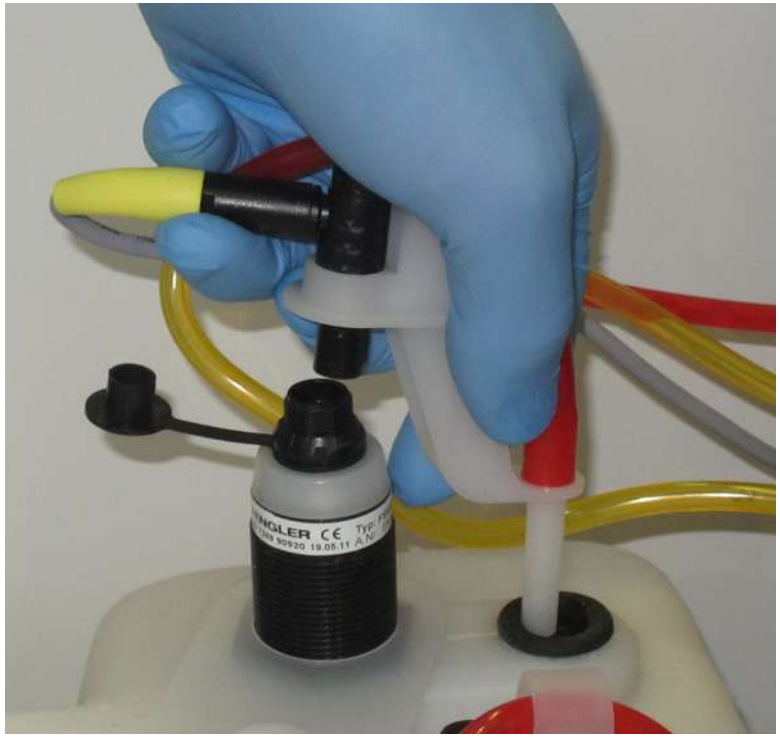


*Figure 5-18: When disconnecting the sensor, the tubing is also pulled out of the membrane*

During the load phase (Figure 5-19) the insertion of the liquid tubing into the membrane also implies the connection of the sensor; as a safety requirement, the tubing is pushed into the membrane before the sensor is completely connected (i.e. an audible click is heard when connection is performed).

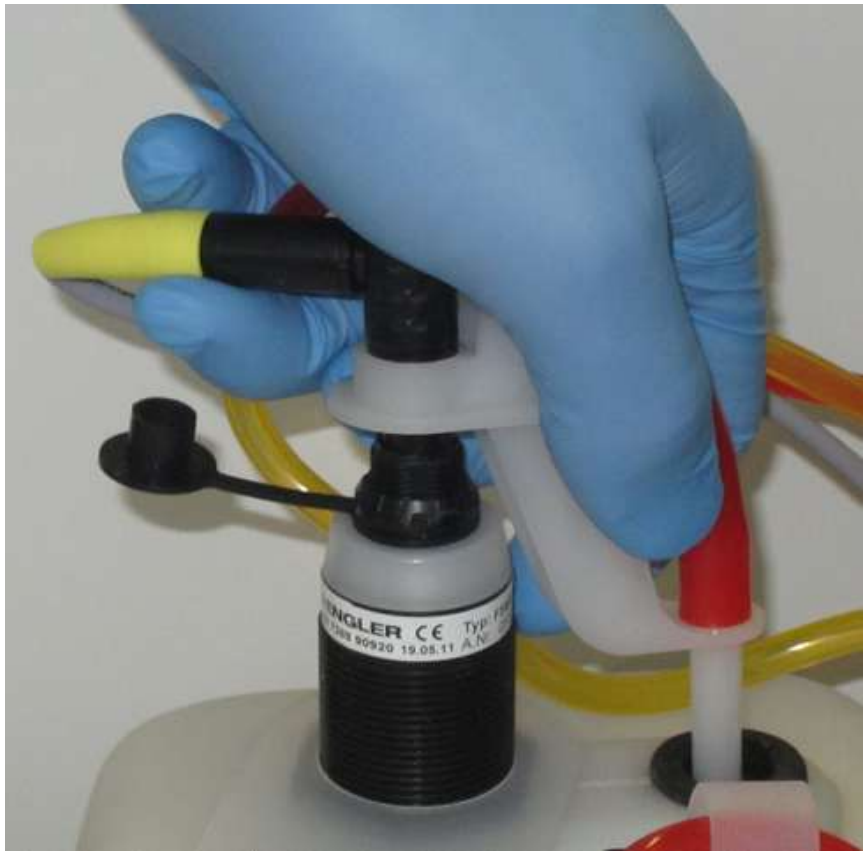


*Figure 5-19: When pushing the tubing into the membrane, the sensor is also connected*

### 5.5.6.2 Procedure

**Unload Procedure**

1. Open the cabinet door.
2. Pull the left cabinet drawer out (Figure 5-20).

*Figure 5-20: Left drawer pulled out*

3. 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).

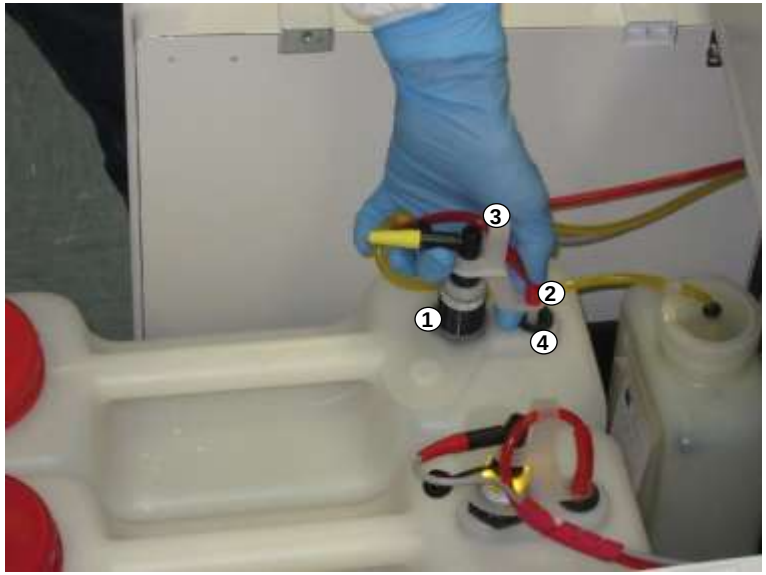



*Figure 5-21: Removal of sensor and liquid tubing connectors*

**DANGER**

As a safety requirement, the sensor is completely disconnected before the liquid tubing connector is pulled completely out of the membrane.

4. Put the liquid and the sensor connectors into the dedicated slot of the basin (Figure 5-22), in order to avoid liquid spills into the cabinet.

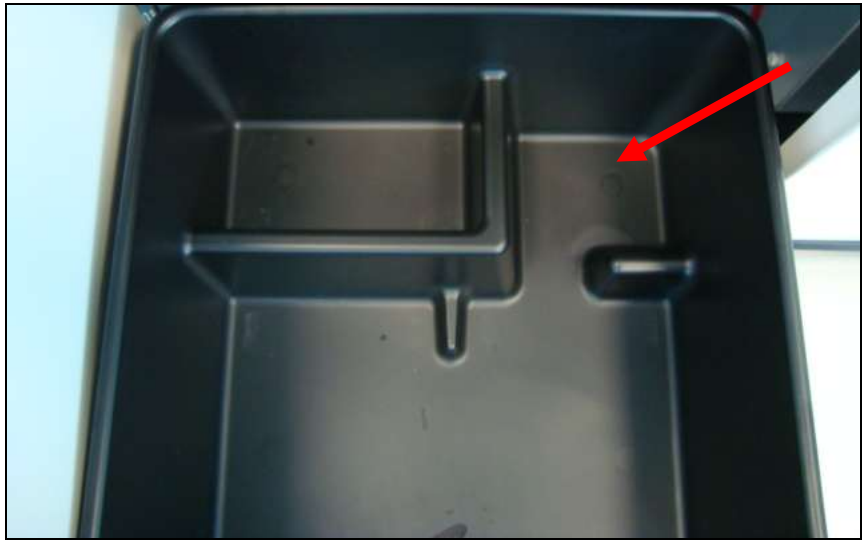


*Figure 5-22: Slot for disconnected waste tubing and sensor*

5. Before pulling the container out of the basin, turn the rubber strip (5) and cover the membrane (4) by using the available cap (6).

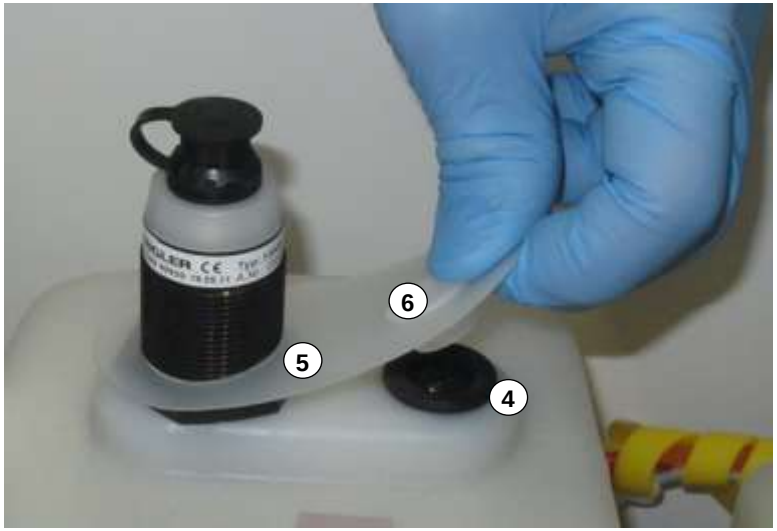



*Figure 5-23: Rotation of the rubber strip and closure of the membrane with the cap*

**DANGER**

In order to prevent splashes of liquid from the membrane, always close the cap before handling the container.

6. Completely remove the waste container (Figure 5-24) from the basin.


*Figure 5-24: Waste container removal*

7. Once the available waste disposal area is reached in the laboratory, empty the waste container and preferably add 200 mL of commercial hypochlorite or bleach. In case commercial sodium hypochlorite solutions are used (e.g. bleach), avoid formulations featuring any fragrance, surfactant, other oxidizer or additive.

**DANGER**

During the liquid waste disposal, do not remove the cap from the membrane.

**Load Procedure**

8. Put the waste container back into the waste basin of the left drawer.
9. Remove the cap (6) from the membrane (4) by turning the rubber strip (5). Cap shall be removed only just before connecting the sensor and the liquid tubing.

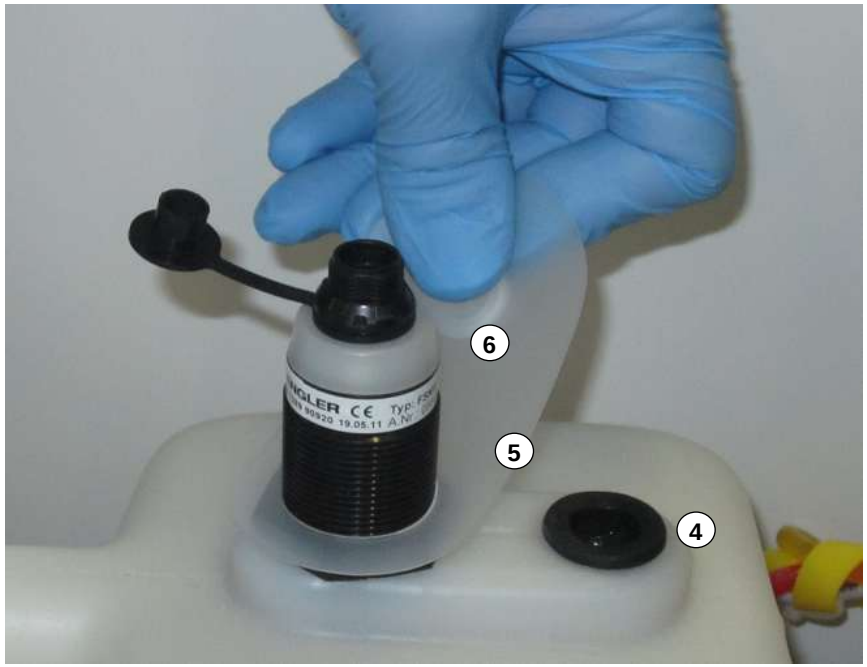



*Figure 5-25: Rotation of the rubber strip and opening of the membrane*

10. Verify the sensor cable (7) is oriented to the front, as represented in Figure 5-26. Also verify that the male & female grooves are aligned, see Figure 5-27.


*Figure 5-26: Sensor cable orientation*

*Figure 5-27: Sensor connector alignment*

11. 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) implies also the connection of the sensor (1). An audible click is heard when the sensor connection is completed.

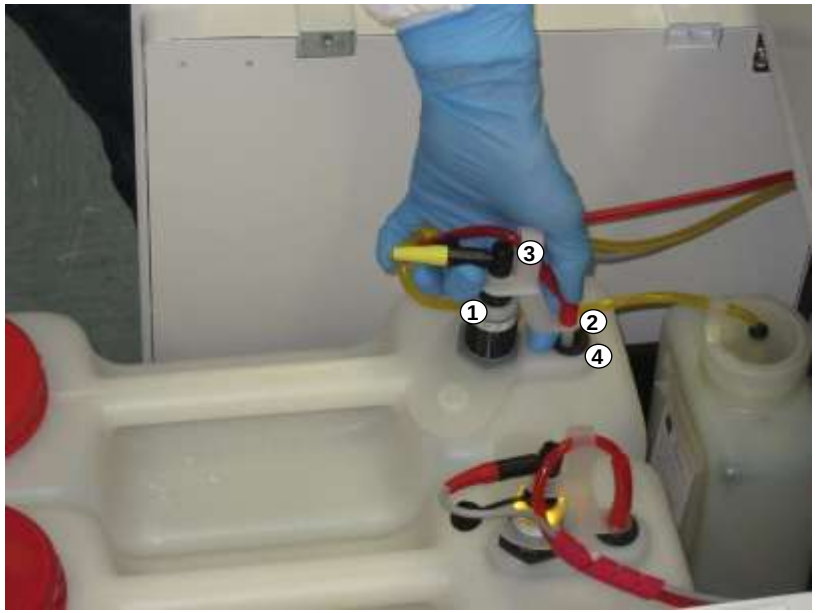



*Figure 5-28: Insertion of sensor and liquid tubing connectors*

12. Push the left cabinet drawer in (Figure 5-29).
13. Close the left cabinet door.

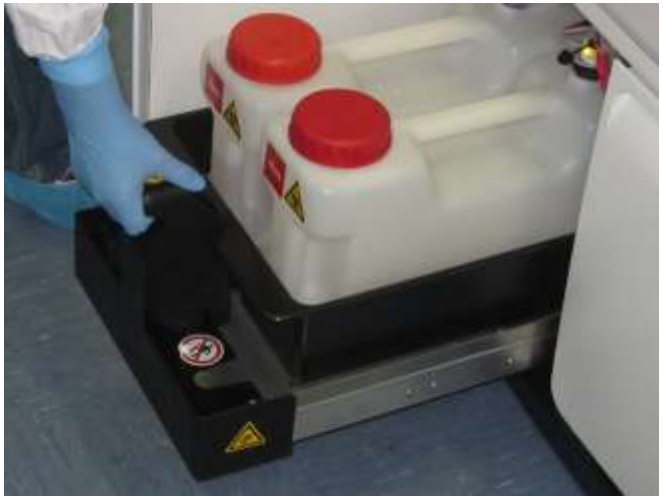


*Figure 5-29: Left drawer pushed in*

14. Check the **Status/ Summary** menu. **LIAISON® XL SW must show 0% for an empty container correctly connected**.

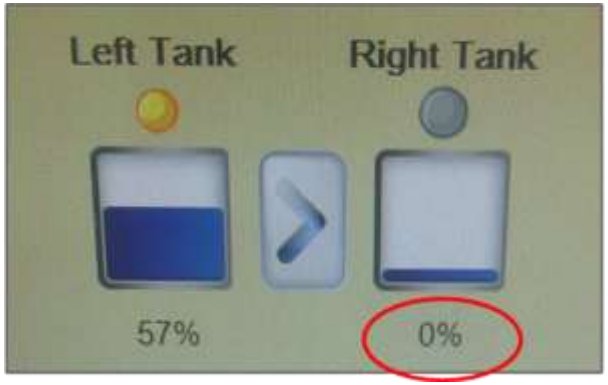



*Figure 5-30: Percentage indicated in case of empty container*

**DANGER**

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

#### 5.5.6.3 Waste basin handling

If spillage from waste tanks occurs, liquid will be collected in the waste basin, thus preventing the cabinet area from contamination.

In case of the presence of liquid inside the waste basin, raise it up from the drawer (Figure 5-31), empty it and perform its decontamination according to what indicated in chapter 1.8.6 and 1.8.8.

The same procedure shall be applied to handle the basin equipped on instruments without cabinet drawers.

*Figure 5-31: Waste basin removal*

### 5.5.7 Load and Unload the Solid Waste Bag

DANGER

**See Biological safety in chapter 1.8.6.**

NOTE

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

**Unload Procedure**

1. Open the cabinet and pull the solid waste drawer out of the **LIAISON® XL** system.
2. Unhook the solid waste bag from the tensioner in the back of the drawer.
3. Unhook the solid waste bag from the front of the drawer.
4. Remove the solid waste bin (with the bag inside) from the drawer of the instrument (Figure 5-32).

*Figure 5-32: Waste bin and bag removal*

5. Close the solid waste bag with the dedicated strap (Figure 5-33).
6. Without removing it from the bin, bring the waste bag to the disposal point (Figure 5-34).
7. Once near the disposal point, dispose the bag once pulled it out of the bin.

*Figure 5-33: Bag closed with the strap*

*Figure 5-34: Bag inside the bin brought to disposal*

**Load Procedure**

1. Insert the solid waste bin into the solid waste drawer (Figure 5-35).

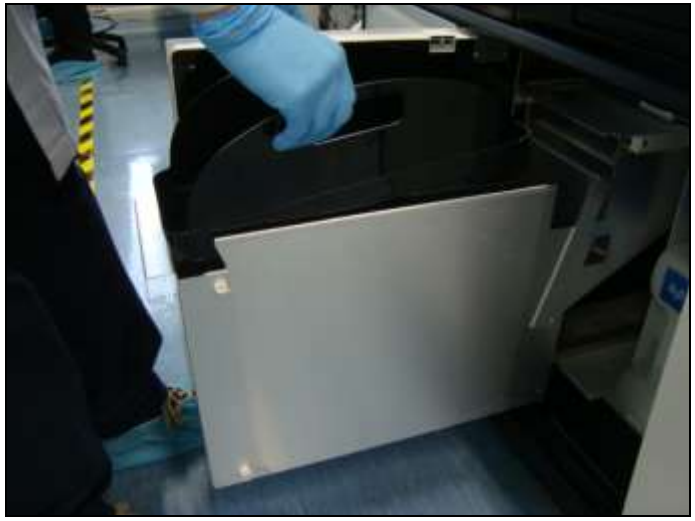


*Figure 5-35: Waste bin insertion*

2. Place a new solid waste bag into the solid waste bin.
3. Hook the solid waste bag to the tensioner available in the back of the solid waste drawer.
4. Hook the solid waste bag to the front of the drawer.
5. Adjust the positioning of the bag inside the drawer, in order to guarantee the availability of the whole volume.
6. Slide the solid waste drawer into the **LIAISON® XL** system.
7. Close the cabinet.
8. Select the sub-category **Summary** of the category **Status** (refer to chapter 6.10.1) and press **Reset** button.

## 5.6 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.

### 5.6.1 Load Patient Samples

DANGER

**See Biological safety in chapter 1.8.6.**

**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

**Maintaining Safety**

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

**Sample Area Flap closure**

**CAUTION**

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® XL** 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 anticouagulants 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.

**Air Bubble Formation or Clotting**

**CAUTION**

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® XL** 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 reagent and 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 4.2.5.3).
- **Bar coded patient samples:**
  Make sure that the bar-code labels on the individual patient samples face left 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.

**WARNING**

**See Laser safety in chapter 1.8.4.1.**

**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 flashing LED. Place the rack in front of the lane and then push evenly up to the limit stop (with the tappet 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 LED goes off for this position, and starts flashing at the next position that can be loaded.
4. If there is a problem with the rack identifier, an input box appears:

- Look at the rack label letter (rack identifier) on the front of the rack.
- Enter the rack identifier manually.
- Click 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, as indicated by the LEDs.

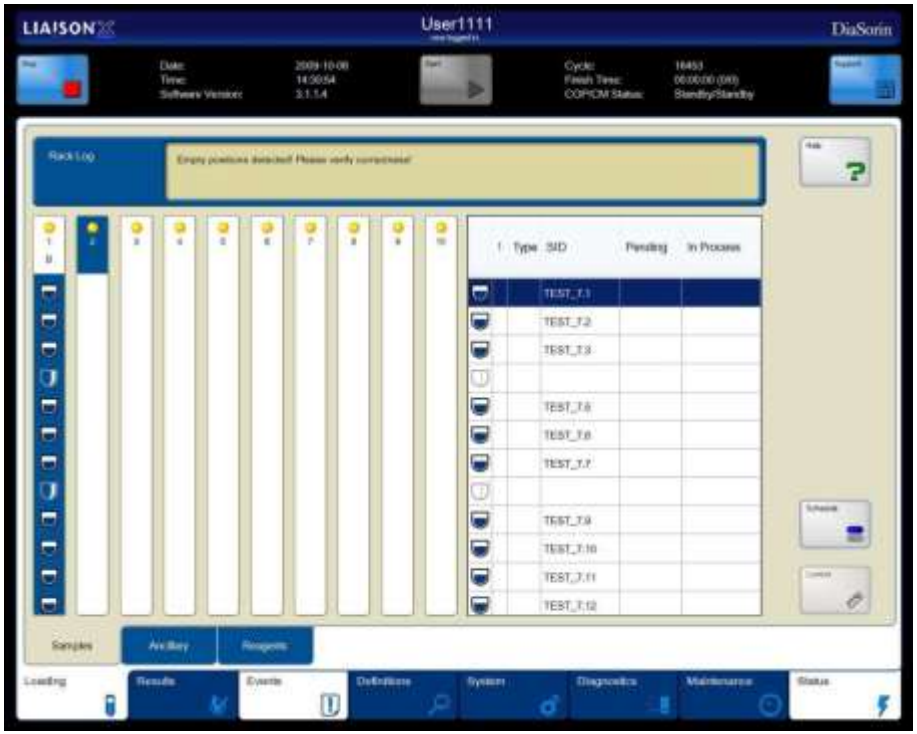



*Figure 5-36: **Samples** display*

| Function | Description |
|---|---|
| ***1*** ... ***10*** | Lanes of the loading bay for sample racks.<br>The display is divided into two parts:<br>• Upper part:<br>Click on the upper part (lane number and indicator) of an empty lane to load a sample rack on this lane.<br>The upper part reflects also the rack status via LEDs below the lane (see chapter 4.2.5).<br>• Lower part:<br>Click on the lower part (sample rack) to select a rack. All samples will be shown in the table on the right side. |
| **Control** | Opens the control picklist and allows the selection of a control or the creation of a new control definition. The bar-code of that control is assigned to the current (empty) ***SID*** field.<br>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.<br>• Loading errors<br>• Positions without bar-code or unreadable bar-code<br>• SID problems (e.g. duplications) |
| **Schedule** | Shows the ***Worklist*** tab to create or edit worklists for samples and controls (see chapter 6.3.1.1). |
| Standard buttons | For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.1. |

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

The samples table shows all positions of the selected rack.

| 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:<br>  Calibrators<br>  Controls<br>  Expired controls |

| | |
|---|---|
| ***SID*** | Shows the sample ID, calibrator ID and control ID. The ***SID*** is read via bar-code scanner or entered by operator (if bar-code not present or unreadable).<br><br>**Notes:**<br>The ***SID*** must be unique.<br>Two or more samples with the same ***SID*** are not allowed to load at the same time.<br>Use only the following characters:<br>• A - Z (a - z are converted to upper case)<br>• 0 - 9<br>• minus (-), dot (.), dollar sign ($), plus (+), percent sign (%), number sign (#), ampersand (&), equal (=), blank space ( ), semicolon (;) and slash (/).<br>• The ***SID*** of controls may not begin with #.<br>A ***SID*** may be 3 to 17 characters long and shall not contain heading or trailing spaces.<br>The ***SID*** of external calibrators begins with a predefined prefix character and contains the assay abbreviation or article number.<br><br>**Note:**<br>The ***SID*** field is write protected, if any of the following applies:<br>• the rack is in "Error"<br>• the ***SID*** was read via bar-code (and accepted, i.e. not deleted because of duplication or illegal character)<br>• 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)<br>• 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 6.4.1). |
| Symbol | See table below. |
| ***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 5-8: Columns of the loaded samples table*

**NOTE**

Light-Check must be loaded as an ancillary reagent.

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

**NOTE**

The support of slash (/) as SID character requires the intervention of field service authorized representative. Please contact your local DiaSorin representatives to enable it.

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. Click 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,<br>**or**<br>no tube loaded. The ***SID*** is empty. |
|  | Sample in process. |
|  | Sample off-line<br>(If a sample is off-line, unload it, check its conditions and reload again when ready for use.) |

*Table 5-9: Symbols*

**NOTE**

Sample IDs shall not contain heading or 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:

- Click 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.

#### 5.6.1.1 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 sample rack is inserted on the wrong lane.
- The bar-code scanner of the sample loading bay is damaged.

**Errors with sample racks will appear immediately.**

- The lane LED of the affected sample loading bay lane will be indentified by a flashing LED.
- The ***Samples*** display of the **LIAISON® XL** software shows an ***Error*** note on the loaded sample rack picture.
- 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.

## 5.6.2 Assign Assays to the Patient Samples

**Procedure**

1. Click on the **Loading** main category tab.
2. Click on the **Samples** sub category tab.
3. Select a sample rack containing identified patient or control samples.
4. Click on the **Schedule** button to assign assays to the patient samples. The **LIAISON® XL** software will show the **Worklist** tab.

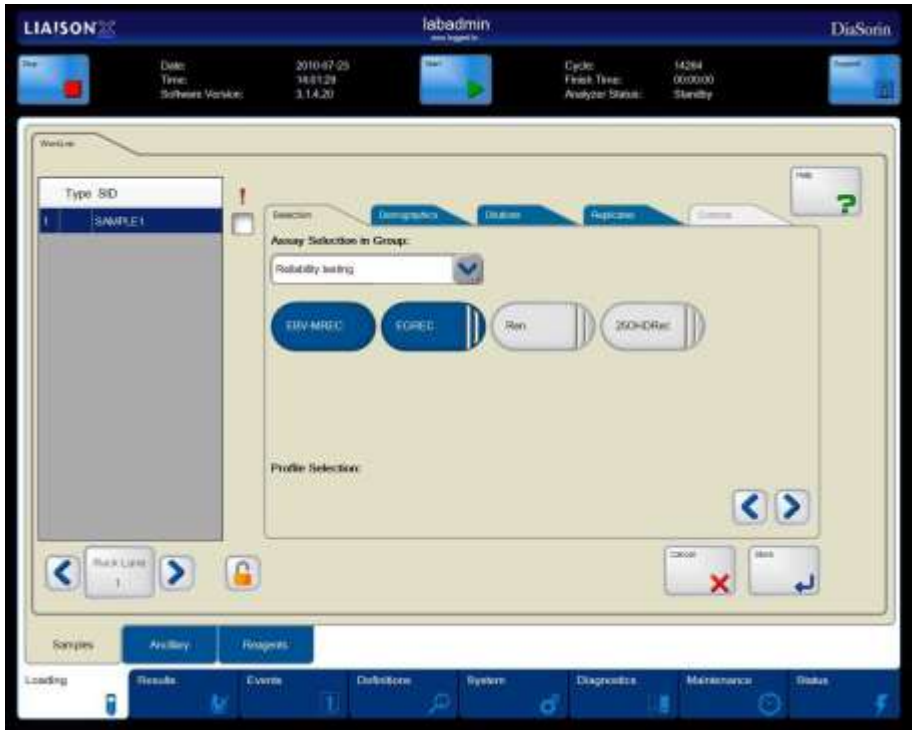



*Figure 5-37: **Worklist** tab*

| Function | Description |
|---|---|
| **Rack lane** | Shows the lane number of the selected sample rack. This button serves also as “Select/Unselect All” button, if the “Lock button” is set to “closed”. Click on the arrow bottons next to the **Rack lane** button to show another available sample rack, and the sample list will be updated. |
| Sample list | Shows all samples, calibrators, and controls which are present in the selected rack.<br>Note: empty positions are not shown. |
| Standard buttons | For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.1. |

*Table 5-10: Functions*

| Column | Description |
|---|---|
| Position | Tube position in the rack. |
| ***Type*** | Shows an empty cell for samples or a symbol for calibrators and controls (see chapter 6.3.1). |
| ***SID*** | Shows the sample ID, calibrator ID and control ID. |
| ***!*** | Check the checkbox for high-priority 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.<br>The display of an assay shows its relation to the samples:<br>• Colour:<br>• Blue: The assay is assigned to sample(s).<br>• Grey: The assay is not assigned to sample(s).<br>• Shape:<br>• Solid: Reagents for the assay are loaded.<br>• Broken with two stripes: Reagents for the assay are not loaded. |
| ***Profile Selection*** | Enables to select a profile (contains several assays, see chapter 6.6.5). Use the arrow buttons to show all available profiles. |

*Table 5-12: Functions of the* **Selection** *group*

**NOTE**

See chapter 6.3.1.1 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. Click on the desired row(s) in the table to select one or more samples.
   Use the lock button to change the selection mode (see chapter 6.1):

- 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 for selected samples and controls at the same time. Select and work up samples separate from calibrators.

**NOTE**

It is possible to select and work up several samples or calibrators. Additionally click 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. Click 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:<br>• currently not loaded on the machine<br>• not assigned to the selected sample |
|  | The assay is:<br>• currently not loaded on the machine<br>• assigned to the selected sample |
|  | The assay is:<br>• currently loaded on the machine<br>• not assigned to the selected sample |
|  | The assay is:<br>• currently loaded on the machine<br>• assigned to the selected sample |

*Table 5-13: Assay status*

**NOTE**

As soon as a test is started, it will no longer be selected 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 6.3.1.1).
12. There is the possibility to change the number of replicates to the assigned assays in the **Replicates** group (see chapter 6.3.1.1).
13. Assign the other samples with assays in the same manner.
14. There is the possibility to specify patient personal information for every sample in the **Demographics** group (see chapter 6.3.1.1).
15. Click on the **Store** button to confirm the assignment.
    The **LIAISON® XL** software returns to the **Samples** display and shows the assigned assays in the ***Pending*** column.

### 5.6.3 Load Controls and Assign to Assays

**NOTE**

Note the safety notes (see chapter 5.7)!

**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® XL** system must recognize the controls.

1. Click on the **Definitions** main category tab.
2. Click on the **Control** sub category tab, see chapter 6.6.2.

3. For DiaSorin controls, click 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 6.6.2

4. Scan the bar-code of the control(s) with the provided external bar-code scanner.
5. Click on the **Ok** button.
   The **LIAISON® XL** 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 (see chapter 5.6.1). 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.
- Click on the **Control** button.
- Select the desired control name entry.
  Only defined controls may be selected (see chapter 6.6.2).

  Note: in case two controls have been defined with the same name, the system proposes the control that expires later.
- Click on the **Store** button.
  The **LIAISON® XL** system adds the control ID from the chosen control name automatically to the ***SID*** field.

**Assigning**

3. Assign controls in the same way as patient samples (see as described in chapter 5.6.2).

**NOTE**

Do not mix controls and patient samples at assay assignment.

## 5.7 Integrals, Calibrators, Ancillary reagents

**DANGER**

**See Biological safety in chapter 1.8.6.**

**WARNING**

**Do not use reagents that have not been authorized for the LIAISON® XL 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 the 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 analyzer.**
- **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.**
- **Bar-code labels on integrals, ancillary reagents and starters are not used in the LIAISON® XL system.**
- **Note the *Rack Log* field for information about a loaded or selected rack (e.g. errors, empty positions).**

## 5.7.1 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 (see chapter 4.1.2) 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.

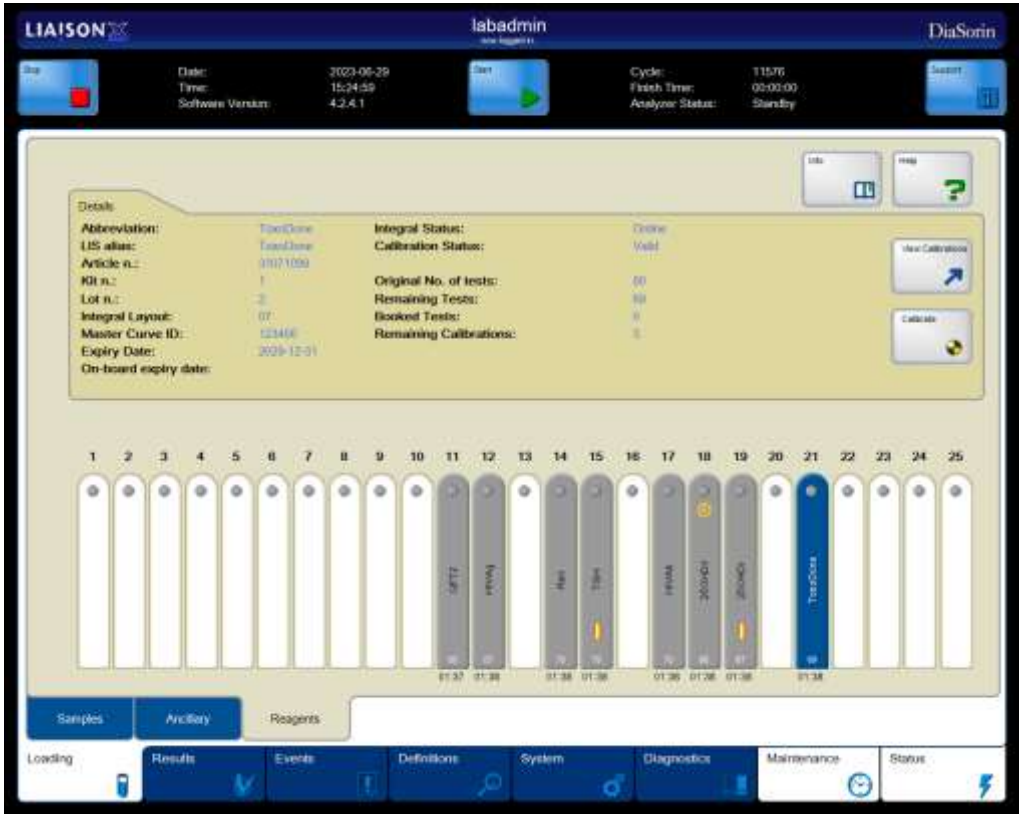



*Figure 5-38: Sub category **Reagents***

| Function | Description |
|---|---|
| **Calibrate** | Starts the calibration of a selected integral.<br>For assays that share calibration within kit lot, this calibration will be available for all integrals of that kit lot, no matter if loaded on-board or not. If the calibration cannot be started (e.g. external calibrators not loaded) a pop-up will inform the user. In this case, no calibration will be created and no jobs will be scheduled. |
| **View Calibrations** | Shows the calibration dialog and selects the valid calibration for the selected integral, if any. |
| **Info** | Opens the Online Help and displays the documents related to the selected integral. |
| Standard buttons | For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.1. |

*Table 5-14: Functions of the **Reagents** sub category*

**Integrals Group**

| Function | Description |
|---|---|
| ***1*** ... ***25*** | Shows the integrals in the reagent loading bay lanes. Click on a loaded integral to show details (see 'Group Details'). |

*Table 5-15: Functions of the **Integrals** group*

**Details Group**

| Function | Description |
|---|---|
| ***Abbreviation*** | Abbreviation of the assay. |
| ***Article No.*** | Identification code of the selected integral that allows the **LIAISON® XL** system to associate the integral to an assay. |
| ***Booked Tests*** | Assigned but not started tests. |
| ***Calibration Status*** | Status of the calibration (e.g. valid, not valid). |
| ***Expiry Date*** | Date and time when the reagent integral will expire. Note: this is the last day when that reagent integral is allowed to beused. |

| | |
|---|---|
| ***Integral Layout*** | Parameter that allows the **LIAISON® XL** system to identify the geometric characteristics of the integral |
| ***Integral Status*** | Status of the integral availability:<br>• **Online**: The integral is useable<br>• **Offline**: The integral cannot be used. The abbreviation is shown in grey.<br>Possible reasons:<br>◦ No liquid found.<br>◦ The expiration date is exceeded.<br>◦ The reagent has a data recognition issue.<br>◦ The compatible assay protocol version is not loaded. |
| ***Kit No.*** | Kit number of the reagent integral. |
| ***LIS alias*** | Assay name on the LIS system. |
| ***Lot No.*** | Lot number of the reagent integral. |
| ***Master Curve ID*** | The ID of the master curve used for this reagent integral. |
| ***On-board expiry date*** | Last date when the reagent integral can be used once it has been inserted on-board. |
| ***Original No. of tests*** | Max. number of tests with a new integral. |
| ***Remaining Calibrations*** | Remaining number of calibrations. |
| ***Remaining Tests*** | Remaining number of determinations for the selected integral.<br>The number is updated (decremented by one) as soon as the first aspiration event for a determination occurs. |

*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® XL** 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 5.7.1.1).

#### 5.7.1.1 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


Lane number

Assay name or ERROR

Calibration status (see table below)

Number of remaining tests

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).

| Symbol | Description |
|---|---|
| no symbol | No specific symbol is shown if the integral has a valid calibration. |
|  | A yellow bar indicates that an expired calibration is present. |
|  | A red bar indicates that no valid calibration is present. |
|  | A calibration is ongoing for the integral. |
|  | The integral has the onboard expiration date overdue. |

*Table 5-17: Calibration status*

**NOTE**

The symbol shall be considered effective only after the ***Finish time*** will be displayed on the header (see chapter 6.2).

#### 5.7.1.2 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.

#### 5.7.1.3 Lot Binding (Lot Locking)

An assay may require more than one integral for a run. The **LIAISON® XL** 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.

### 5.7.2 Calibrate Integrals

**NOTE**

Refer to the safety notes (see chapter 5.7)!

**CAUTION**

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

- another calibration is ongoing for the same integral
- another calibration is ongoing for another integral of the same lot (if that assay shares the Working Curve)
- the calibrators are external and not present onboard
- starters, calibrators, reagents are missing or empty
- starters or reagents are expired

**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 5.7.1)
2. Load additional calibrators in the same way as patient samples (see chapter 5.6.1).
   The field ***Type*** in the samples table shows a special symbol for  calibrators.
3. Click on the **Reagents** sub category tab of the **Loading** main category tab.
4. Select the affected integral in the **Reagents** sub category.
5. Click on the **Calibrate** button.
   The calibration will start automatically.
   When the calibration is completed, it will be automatically accepted or rejected.
6. 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 **Reagents** sub category and click on the **View Calibrations** button.

or

- Click on the **Calibrations** sub category tab of the **Results** main category tab.

**NOTE**

- All calibrations (valid, failed, expired…) are stored on the system database: See **Calibrations** sub category tab of the **Results** main category tab (chapter 6.4.7).
- 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.

### 5.7.3 Load Ancillary reagents

**NOTE**

Refer to the safety notes (see chapter 5.7)!

**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 eagent 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 shown automatically the **Reagents** sub category tab of the **Loading** main category tab.
2. Click on the **Ancillary** sub category tab.

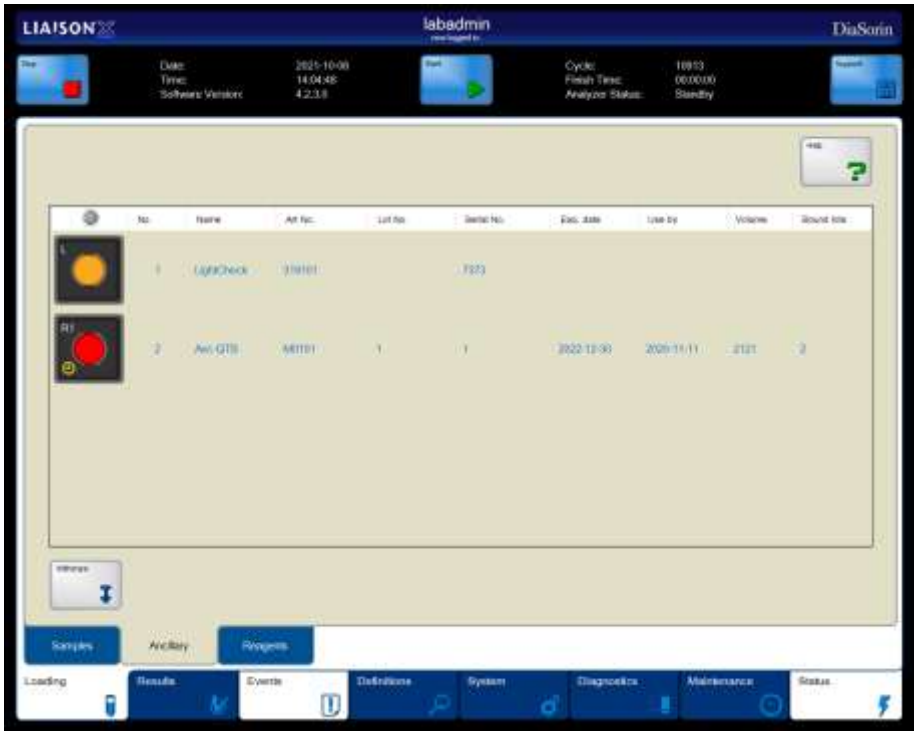



*Figure 5-39: Sub category **Ancillary***

| Function | Description |
|---|---|
| **Withdraw** | If it is necessary to remove the ancillary rack during a run, press this button to suspend the pipettor access. Insert the furthermore used ancillaries as soon as possible<br>Note: this could lead to test failures. |
| Standard buttons | For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.1. |

*Table 5-18: Functions of the **Ancillary** sub category*

| Column | Description |
|---|---|
| ***No.*** | Position of the ancillary reagent in the ancillary rack (1 to 4). |
| ***Name*** | Name of the ancillary reagent. |
| ***Art No.*** | Article number of the ancillary reagent (the color represents the cap color). |
| ***Lot No.*** | Lot number of the ancillary reagent. |
| ***Serial No.*** | Serial number of the ancillary reagent. |
| ***Exp. date*** | Date and time when the ancillary reagent will expire. |
| ***Use by*** | Onboard stability expiration date.<br>Note: if the Ancillary has the onboard expiration date overdue an additional symbol is displayed on Ancillary representation: |
| ***Volume*** | Available liquid volume in the bottle. |
| ***Bound lots*** | If there is an entry: It is only possible to use integrals of the related assay with the reported lot number. |

*Table 5-19: 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.

3. Remove the ancillary rack (see chapter 4.2.6).
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® XL** 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 5.6.1.1 for details about loading errors.

## 5.8 Start Worklist

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

**Procedure**

1. Click on the **Start** button in the header.
   The **LIAISON® XL** system starts with the worklist.
2. Click on the **Loading** main category tab.
3. Click 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. See chapter 6.3.1 for all details.

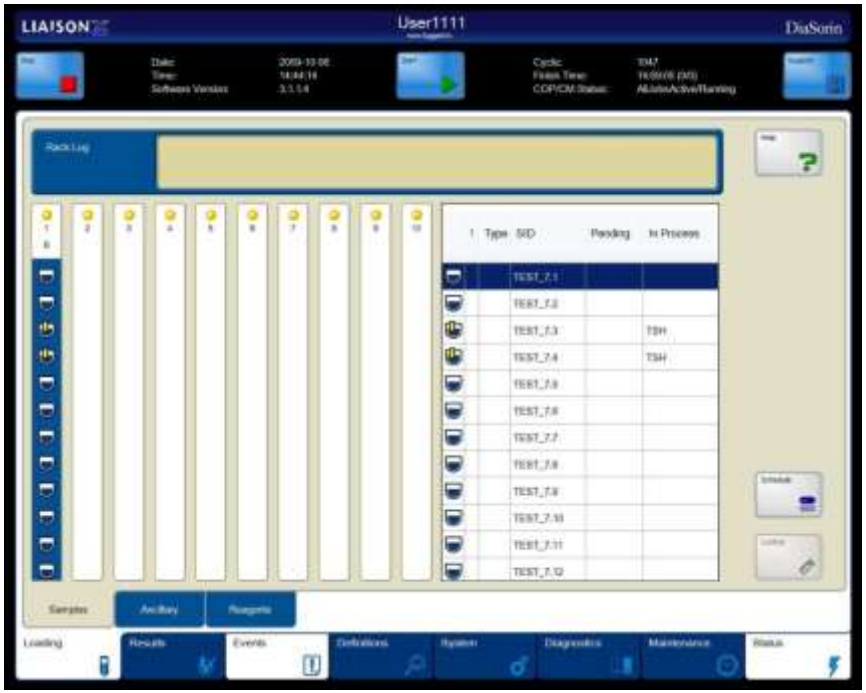



*Figure 5-40:* **Samples** *display - running worklist*

## 5.9 Results

On the **LIAISON® XL** 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 6.4.1 |
| **Done** | The sub category **Done** shows only entries of finished worklists with status ***Done***. | chapter 5.9.1 | chapter 6.4.4 |
| **Failed** | The sub category **Failed** shows only entries of finished worklists with status ***Failed***. | chapter 5.9.2 | chapter 6.4.6 |
| **Calibrations** | The sub category **Calibrations** shows only calibration entries (either valid, expired and failed calibrations). | chapter 5.9.3 | chapter 6.4.7 |
| **Controls** | The sub category **Controls** shows the results of the controls. | chapter 5.9.4 | chapter 6.4.8 |

*Table 5-20: Sub categories of the main category **Results** featuring completed results*

### 5.9.1 Results of Patient Sample Tests (Status *Done*)

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

**Procedure**

1. Click on the **Results** main category tab.
   The **LIAISON® XL** software shows the sub category **All**.
2. Click on the **Done** sub category tab (see also chapter 6.4.4).

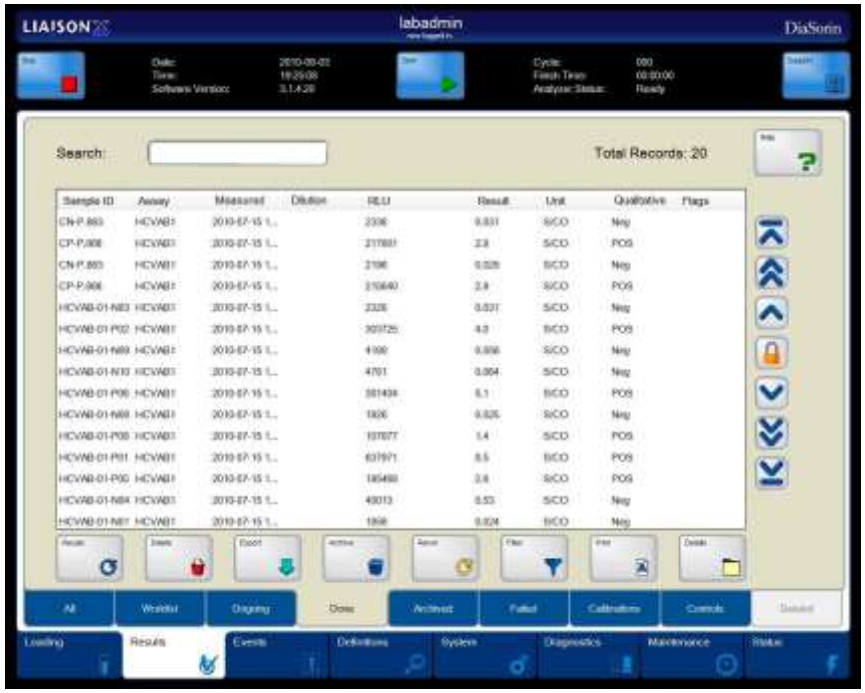



*Figure 5-41: Sub category **Done***

| Function | Description |
|---|---|
| **Archive** | Archives the currently selected entries. The archived entries will be shown in the sub category **Archived**<br><br>Note: This button is available only if automatic archiving is not enabled. |
| **Delete** | Deletes one or more entries (see chapter 6.4.1.4). The deleted entries get the status ***Deleted*** and will be shown in the sub category **Deleted**. |
| **Details** | Opens the ***Result Details*** display for the selected entry (see chapter 6.4.1.3). |
| **Export** | Opens the ***Export*** display to export one or more entries to a text file (see chapter 6.4.1.2). |
| **Filter** | Opens the ***Select Filter*** display (see chapter 6.4.1.5). |
| **Recalc** | Recalculates the currently selected entries, using the most recent calibration for the assigned assay. |
| **Rerun** | Reruns all or only the selected entry/entries. |
| Standard buttons | For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.1. |

*Table 5-21: Functions of the **Done** sub category*

**CAUTION**

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

If using the **Recalc** feature when no valid but expired calibrations are available, the system may use any calibration among the expired calibrations to calculate the dose.

| Column | Description |
|---|---|
| ***Sample ID*** | Shows the sample ID. |
| ***Assay*** | Shows the assigned assay. |
| ***Measured Date*** | Result date and time. |
| ***Dilution Factor*** | Multiplication 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 defined units. |
| ***Qualitative Label*** | Shows the result as qualitative evaluation (e.g. positive, negative etc.) |
| ***Flags*** | List of all flags. For details about the flags see chapter 5.9.5. |

*Table 5-22: Standard columns of the "Done" samples table*

3. Pay attention to the ***Flags*** column!
   See chapter 5.9.5 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 were run not before 18 hours (after sample RLU result is available).

### 5.9.2 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. Click on the **Results** main category tab.
   The **LIAISON® XL** software shows the sub category **All**.
2. Click on the **Failed** sub category tab (see also chapter 6.4.6).

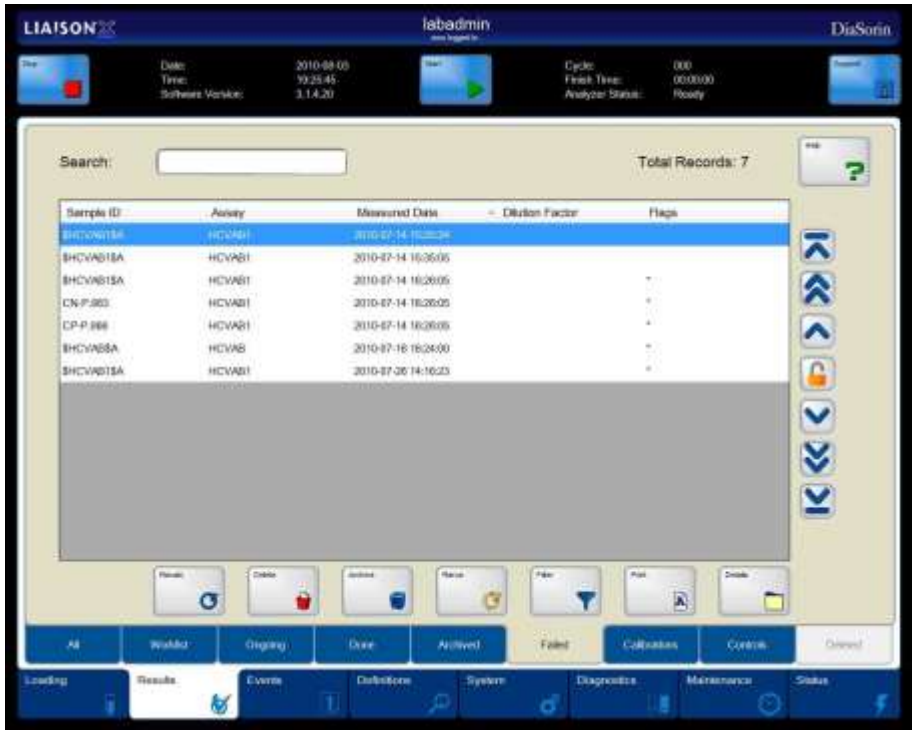



*Figure 5-42: Sub category **Failed***

| Function | Description |
|---|---|
| **Archive** | Archives the currently selected entries. The archived entries will be shown in the sub category **Archived**<br>Note: This button is available only if automatic archiving is not enabled. |
| **Delete** | Deletes one or more entries (see chapter 6.4.1.4). |
| **Details** | Opens the ***Result Details*** display for the selected entry (see chapter 6.4.1.3). |
| **Filter** | Opens the ***Select Filter*** display (see chapter 6.4.1.5). |
| **Recalc** | Recalculates the currently selected entries, using the most recent calibration for the assigned assay. |
| **Rerun** | Reruns the selected routine |
| Standard buttons | For standard buttons (e.g. arrow buttons, lock, **Print**) see chapter 6.1. |

*Table 5-23: Functions of the **Failed** sub category*

**CAUTION**

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

If using the **Recalc** feature when no valid but expired calibrations are available, the system may use any calibration among the expired calibrations to calculate the dose.

| Column | Description |
|---|---|
| ***Sample ID*** | Shows the sample ID. |
| ***Assay*** | Shows the assigned assay. |
| ***Measured Date*** | Result date and time. |
| ***Dilution Factor*** | Multiplication factor for the result (only for diluted tests). |
| ***Flags*** | List of all flags. For details about the flags see chapter 5.9.5. |

*Table 5-24: 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.
- **Recalc**: Recalculates the currently selected entries.
- **Rerun**: Reruns all or only the selected entry/entries.

### 5.9.3 Results of Calibrations

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

**Procedure**

1. Click on the **Results** main category tab.
   The **LIAISON® XL** software shows the sub category **All**.
2. Click on the **Calibrations** sub category tab (see also chapter 6.4.7).
3. Pay attention to the ***Status*** column!
   See chapter 6.4.7 for the used status abbreviations (***Created***, ***Failed***, ***Invalid***, ***Valid***, ***Expired***, ***NotUsed***).

### 5.9.4 Results of Controls

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

**Procedure**

1. Click on the **Results** main category tab.
   The **LIAISON® XL** software shows the sub category **All**.
2. Click on the **Controls** sub category tab (see also chapter 6.4.8).
3. Pay attention to the ***Flags*** column!
   See chapter 5.9.5 for the used flag abbreviations.

### 5.9.5 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.

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

Reported results may carry flags in order to inform users about the special conditions under which that result was 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 “informative flags” table is set, then the result is reported.

The column “Retry” tells whether a replicate may be retried without user invention or not. If it is not retried, it is set to "Failed". If it is retried unsuccessfully a pre-defined number of times, it is also set to Failed. The retry feature is configurable by local service support.

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 | Retry | Applies to | Inherits |
|---|---|---|---|---|---|
| * | Agitation speed out of range. | The magnetic particel agitation was out of range while pipetted. | No | R | W,C |
| * | Aspiration plausibility failure | One aspiration did not occur in the defined time slot. | No | R | W,C |
| * | Cycle occupation failure (normal, dilution) | The system detected a conflict in scheduled activities. | Yes | R | W,C |
| * | Disposable tip not present. | The system did not have disposable tips available. | Yes | R | W,C |
| * | Disposable Tip Pickup failure | The system could not pick a disposable tip assumed available. | Yes | R | W,C |
| * | High background in PMT. | Too high noise in the Reader | No | R | W,C |
| * | Incubator temperature out of range. | Incubator temperature was out of range when the test was processed. | No | R | W,C |
| * | Internal failure detected. | An internal error occurred. | No | R | W,C |
| * | Job scheduling failure | A job scheduling failure occurred. | Yes | R | W,C |
| * | Liquid Container empty. | A liquid container was empty. | No | R | W,C |
| * | Measurement Chamber failure | The system detected an error in the Reader. | Yes | R | W,C |
| * | Mechanical error. | A mechanical error occurred on the system. | No | R | W,C |
| * | No cuvette available | No cuvette was available to process the job. | Yes | R | W,C |
| * | No Mitigation Step performed | No successful mitigation was performed | Yes | R | W,C |
| * | Reagent pipetting step not executed. | A reagent was not pipetted (e.g. pipettor was paused). | No | R | W,C |
| * | Sample pipetting step not executed. | A sample was not pipetted (e.g. pipettor was paused). | No | R | W,C |

| Abbr. | Description | Explanation | Retry | Applies to | Inherits |
|---|---|---|---|---|---|
| * | Pipettor offline. | The test could not be pipetted when needed. | No | R | W,C |
| * | Waste container full. | Processing aborted due to full waste container. | No | R | W,C |
| * | Starter Dispense Verification failure | The liquid volume aspirated from the cuvette after the measurement step was lower than expected. | Yes | R | W,C |
| * | Starter lot change | A replicate could not start due to a starter lot change meanwhile occurred. | No | R | W,C |
| * | Starter reagent temperature out of range. | A scheduled Starter prime could not occur. | No | R | W,C |
| * | Starter prime not performed. | Starter reagent temperature was out of range when the test was processed. | Yes | R | W,C |
| * | Timing violation. | The pipettor was overloaded. | No | R | W,C |
| * | User requested abort | The test was aborted as per user request. | No | R | W,C |
| * | Washer aspiration failure. | An aspiration failure was detected in the washer. | Yes | R | W,C |
| C | No calibration | No usable calibration found. | No | R | W,C |
| D | Overdiluted | The sample was over diluted. (Only for samples with sample specific dilution) | No | R | W,C |
| M | Mathematical error | Math error occurred while calculating dose. | No | R,W,C | W |
| R | Ancillary not present. | A needed ancillary was not found (vial not present or offline). | No | R | W,C |
| R | Reagent depleted. | The reagent pipettor arm found no liquid. | No | R | W,C |
| R | Reagent integral not present. | A needed integral was not found (integral not present or offline). | No | R | W,C |
| R | Reagent integrity failure. | An aspiration or dispense failure was detected by the reagent pipettor. | No | R | W,C |
| S | Clot in sample detected | An aspiration failure was detected by the sample pipettor | No | R | W,C |

| Abbr. | Description | Explanation | Retry | Applies to | Inherits |
|---|---|---|---|---|---|
| S | Sample depleted. | The sample pipettor arm found no liquid. | No | R | W,C |
| S | Sample integrity failure. | An aspiration or dispense failure was detected by the sample pipettor. | No | R | W,C |
| S | Sample not present. | The sample was not found (tube not present or offline). | No | R | W,C |
| X< | Combi Son Below Assay Range | Any combi son is below the assay range. | No | C | |
| X> | Combi Son Above Assay Range | Any combi son is above the assay range. | No | C | |
| XM | Combi Son has mathematical error | Any combi son has a math error in dose calculation. | No | C | |
| Z | Divided by zero | For calculation of a combi assay result a division by zero occurred | No | C | |

*Table 5-25: List of invalidating flags (in alphabetical order)*

**Informative Flags**

| Abbr. | Description | Explanation | ApTo | Inher |
|---|---|---|---|---|
| & | Rerun | This Result matched a Rerun Rule (for patient samples only). | W | |
| < | Below assay range | The calculated dose is below the assay range | 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 (depending on assays). | R,W,C | |
| C | Calibration expired | The calibration used for calculation was expired. | R | W,C |
| E | Reagent On Board Stability Expired | The used integral or ancillary had the onboard expiration date overdue. | R | W,C |
| NH | Above normal range | The calculated dose is above normal range (not for calibrators and controls). | R,W,C | |
| NL | Below normal range | The calculated dose is below normal range (not for calibrators and controls). | R,W,C | |
| Q | Controls out of manufacturer range | Only for samples.<br>Not generated if the range is empty, for “precision” controls - based on last performance of any “control name” defined for that assay. | R,W,C | |
| QE | Control expired | The control used was expired | R | W,C |
| QH | QC above manufacturer range | Only for controls.<br>In case the control is above assay range, this flag is generated as well.<br>Not generated if the control range is empty, for “precision” controls. | R,W,C | |

| Abbr. | Description | Explanation | ApTo | Inher |
|---|---|---|---|---|
| QL | QC below manufacturer range | Only for controls.<br>In case the control is below assay range, this flag is generated as well.<br>Not generated if the control range is empty, for “precision” controls. | R,W,C | |
| RM | Recalculated | The result was recalculated upon user request. | R | W,C |
| UH | QC above user range | Only for controls.<br>In case the control is above assay range, this flag is generated as well.<br>Not generated if the control range is empty, for “precision” controls. | R,W,C | |
| UL | QC below user range | Only for controls.<br>In case the control is below assay range, this flag is generated as well.<br>Not generated if the control range is empty, for “precision” controls. | R,W,C | |
| X& | Son Rerun | A combi son matched a Rerun Rule (for patient samples only). | 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 5-26: List of informative flags (in alphabetical order)*

**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 the calibration was expired.

**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 |
| CausedRerun | Son CausedRerun |

*Table 5-27: Combi results flags*

## 5.10 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

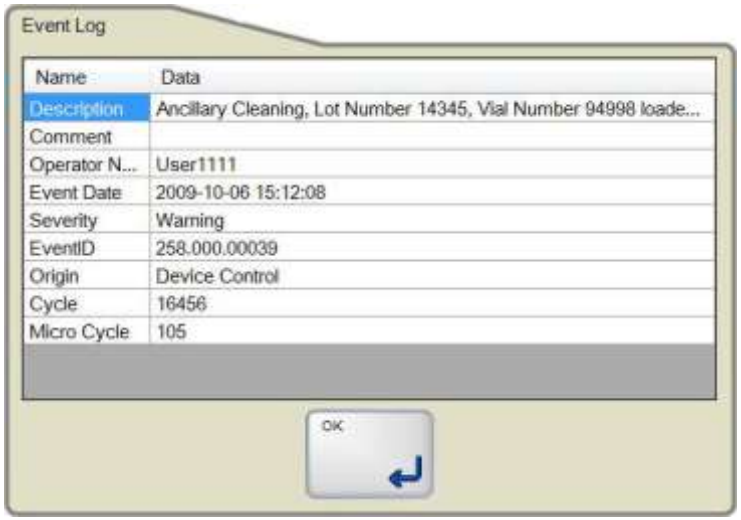



*Figure 5-43:* **Event Log** *Message*

All errors and events can be shown in chapter 6.5.

**CAUTION**

The results obtained in a routine with multiple repeated Instrument Errors should be interpreted carefully. In order to get optimal performance of the instrument the user should highlight any anomalies / error trends and request the advice of the Local DiaSorin Representative.

**NOTE**

Error messages are described in chapter 9.1.

**NOTE**

If the error reoccurs, please call service.

## 5.11 Unloading

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

### 5.11.1 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.

**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 LED (see chapter 4.2.5).
- 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® XL** system down.

1. Observe the LEDs under the sample loading bay lanes.
2. If there are 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® XL** system environment.

### 5.11.2 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.

WARNING

**Error at Loading/Unloading of Racks, Reagents and Samples**

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

- Only load and unload racks if explicitly allowed by corresponding LED (see chapter 4.2.6).
- Only load and unload racks 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.

NOTE

Never unload more than one integral at a time.

1. Observe at the LEDs under the reagent loading bay lanes.
2. If there are LEDs off, but the lanes are occupied, then open the reagent loading bay flap.
3. Hold the handle of an unused integral and remove it carefully in an upright position.
4. Unload other unused integrals.
5. Close the reagent loading bay flap.

**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® XL** system environment.

**WARNING**

**Use of Integrals**

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

#### 5.11.2.1 Proper Storage and Handling of Integrals

Store the integral according to the related Instruction For Use.

### 5.11.3 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.

**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.

- Only load and unload racks if explicitly requested to do so.
- Only load and unload racks on the specified lanes.

**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.

1. Look at the left LED under the reagent loading bay lane (lane “A”).
2. If the LED is off, but the lane is occupied, then open the reagent loading bay flap.
3. Hold the handle of the unused ancillary rack and remove it carefully keeping it in an upright position.
4. 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® XL** system environment.

## 5.12 Shut Down/End of Day Maintenance

**NOTE**

The **LIAISON® XL** can be left on after the routine completion without any special precautions. 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 3 weeks); please contact your local service to arrange a dedicate service visit, therefore a service visit is needed to restart the **LIAISON® XL** analizer. The shutdown and restart of the system from long period requires the assistance of service technical personnel.