Liaison® XL Connection Module

Operator's Manual Version 2.1

Document information

Revision history

Manual Version	Revision date	Changes
Draft 1	December 2015	First issue
1.1	January 2016	Diverse changes
1.2	April 2016	Diverse changes
1.3	June 2016	Diverse changes
2.0	September 2016	Update
2.1	August 2017	Final version

Edition notice

Liaison® XL Connection Module Operator's Manual

This document is for users of the **Liaison**® XL Connection Module.

Every effort has been made to ensure that all the information contained in this manual is correct at the time of printing. However, Roche PVT GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument will render the warranty or service agreement null and void. For warranty conditions, refer to the analyzer purchase agreement. Contact your local Roche Diagnostics representative for further information.

Software updates are carried out by Roche Diagnostics service technicians.

Intended use

Liaison® XL Connection Module is intended to be used a connecting device between a Universal Connection Unit (part of the cobas 8100 system) and the Liaison® XL Analyzer. It may only be used for analytical applications together with these devices. Any other usage is considered improper and thus releases the manufacturer from liability.

CAUTION

Operating the Liaison® XL Connection Module in ways other than described in this manual or using it under conditions that fall outside those specified here may impair the safety or performance of the facility.

Off the shelf software

Portions of the system might include one or more Open Source or Commercial Software programs. Copyright and other notices and licensing information regarding such Software programs can be found on the system.

Trademarks

The following trademarks are acknowledged:

COBAS is a trademark of Roche

Liaison is a trademark of Diasorin

UCU is a trademark of Hitachi

All other trademarks are the property of their respective owners.

Instrument approvals

The **Liaison®** XL Connection Module conforms to the currently applicable directives of the European Union. Compliance with all standards and legal obligations is guaranteed.

CE labeling corresponds to the EU directives 98/79/EU (IVD Directive).

The Operator's Manual meets the European Standard EN 591.

A complete list of standards applied and the requirements met can be found in the *Appendix*.

Compliance is demonstrated by the following marks:

Complies with the IVD directive 98/79/EC.

Issued by Intertek (Electrical Testing Lab) for the US and Canada.

Contact address

Manufacturer
Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany

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General Information A

General information

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Preface

NOTICE

Read the Operator's Manual with the utmost care and attention before using the system for the first time. Particular attention should be paid to descriptions of hazards and precautions.

Failure to observe notices pertaining to risks and safety contained in this Operator's Manual can have serious implications for health and safety as well as result in material damage.

Using the Operator's Manual

This Operator's Manual is valid for the Liaison® XL Connection Module. It contains information for the system operators at the application level. The information contained in this manual is not intended for administrators or service technicians.

In order for the Liaison® XL Connection Module to be used properly and as intended, the entire contents of the Operator's Manual must be read and understood by the operator before the initial commissioning.

NOTICE

Keep this manual in a safe place accessible to all operators of the system.

The Operator's Manual is divided into the following sections:

Part	Label	Contents
A	General information	Manual description, safety information
B	System description	System overview, description of the hardware, description of the software, sample flow, reports
C	Operation	Working with the system
D	Maintenance	Maintenance and cleaning instructions
E	Troubleshooting	Describing and remedying faults
F	Appendix	Glossary, technical details, index

Conventions used in this document

Visual cues are used to help locate and interpret information in this manual quickly. This section explains formatting conventions used in this manual.

The following symbols are used:

Symbol	Used for
►	Start of procedure
■	End of procedure
•	List item
👁	Cross-reference
➔	Call-up (software reference)
	Tip
	Safety alert
	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE. The symbol denotes that the equipment must not be disposed of in the municipal waste system.

Safety symbols

Throughout the Operator's Manual, the safety instructions are labeled as follows:

NOTICE

This symbol indicates advice that users should observe to ensure errors do not occur when operating the system.

This symbol indicates a potential hazard. The operator or the system may be at risk if the warning is not heeded.

CAUTION

Caution: Indicates a hazardous situation that, if not avoided, can result in injury to the operator and/or damage to the system.

WARNING

Warning: Indicates a hazardous situation that, if not avoided, could result in death or serious injury.

Abbreviations

The list below contains an explanation of the abbreviations used in this manual:

Abbreviation	Meaning
A	Ampere
AC	Alternating Current
Ah	Ampere hour
ASTM	American Society for Testing and Materials
CE	Communauté Européenne
CPU	Central Processing Unit
dB	Decibel
DC	Direct Current
DIN	Deutsches Institut für Normung (German Institute for Standardization)
EC	European Community
EDP	Event Distribution Protocol
EMC	Electromagnetic Compatibility
EN	European Standard
EPROM	Erasable Programmable Read Only Memory
FCC	Food Chemicals Codex
GB	GigaByte
GUI	Graphical User Interface
Hz	Hertz
IEC	International Electrotechnical Commission
IVD	In-Vitro Diagnostics
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LIS	Laboratory Information System
MB	Megabyte
Mbps	Megabits per second
NN	Normal Null (mean sea level)
NW	Nominal Width
PE	Protective Earth
PIO	Parallel I-O Interface
RAM	Random Access Memory
RS232/422	Recommended Standard 232/422
SiHo	Single Holder
TCP/IP	Transmission Control Protocol/ Internet Protocol
UCU	Universal Connection Unit (device that sends and receives the single holders from the Liaison® XL Connection Module)
V	Volt
VA	Volt-Ampere
WEEE	Directive 2002/96/EG covering Waste of Electrical and Electronic Equipment

Safety precautions

Safety regulations IEC 61010-1 and the applicable national electrical safety guidelines must be observed! Safe operation and reliability of the system can only be ensured when:

- The electrical installation of the system meets appropriate IEC requirements,
- The installation is carried out by a trained service technician in accordance with the Installation Instructions,
- A visual inspection, PE conductor test, insulation test and leakage current test have been carried out by a qualified electrician, in accordance with the national safety guidelines,
- The system is operated in compliance with these operating instructions.

This product, as provided by the manufacturer, has been designed and manufactured according to state-of-the-art design, construction and manufacturing know-how, in accordance with the recognized safety regulations. The applicable EU directives and their national legal implementations have been applied towards the design and creation of these operating instructions.

Nevertheless, hazards to life and limb or damage to equipment and property can arise during usage.

A final statement on operating conditions and safeguards can only be made after the entire facility is considered as part of a risk analysis. This is the responsibility of the manufacturer and/or the operator of the overall facility.

The manufacturer or operator is always responsible for the safety of an automated facility.

Pay attention to the following safety precautions!

If you ignore these precautions, you can suffer minor to moderate injury. Each precaution is important.

Product IT Security

Loss of data integrity or unavailability of the system due to malicious software or unauthorized system access

To avoid infection of malicious software or the unauthorized misuse of the system, the following recommendations are essential:

- Make sure other computers and services on the network (for example: the LIS, archiving share or -service, backup share or -service) are properly secured and protected against malicious software and unauthorized access.
- Laboratory IT is responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment etc.)

Operator qualification

As a user, you are required to have sound knowledge of relevant safety precaution guidelines and standards and of the information and procedures found in the Operator's Manual.

- Do not carry out any operation or maintenance procedures unless you are trained to do so by Roche Diagnostics.
- Carefully follow the procedures specified in the Operator's Manual for operation and maintenance.
- Leave maintenance, installation, or service that is not described in the Operator's Manual to trained Roche Service representatives.
- Follow Good Laboratory Practices, especially when working with biohazardous material.

Protective cover

The protective cover covers the top of the Liaison® XL Connection Module and prevents you from reaching in. It is made of acrylic glass and must be handled carefully. The single knurled screw in the front must first be unscrewed before the hood can be opened. A safety switch will automatically switch off all voltage to the motors as soon as this screw is unscrewed. The touch screen will still be powered on.

NOTICE Acrylic glass is brittle and must be handled with care. It may crack if bent or if fastening screws are overtightened.

Warning labels

Contamination hazard

A contamination warning triangle is located at the top of the Liaison® XL Connection Modules front panel. This label is intended to alert personnel of the hazard posed by spilled sample material.

Make sure that you follow the instructions included in this manual to avoid contamination. You must always wear protective gear (gloves, goggles and a lab coat) when handling hazardous materials.

Figure A-1 Contamination label on front panel of the Liaison® XL Connection Module

Figure A-2 Contamination label

Pinching hazard

A pinching hazard warning label is located at the top of the Liaison® XL Connection Module, just to the left of the lift. This label is intended to alert personnel to the pinching or crushing danger posed by moving parts. On the Liaison® XL Connection Module, this danger is minimized by the safety shut-off mechanism, which ensures that the system stops moving as soon as the protective cover is opened.

Figure A-3 Pinching hazard warning label at top of the Liaison® XL Connection Module

Figure A-4 Pinching hazard warning label

CAUTION

Pinching hazard!

Contact with moving parts may cause serious injury.

Do not reach into the device while it is running.

Electrical safety

There is an electrical hazard warning label on the back of device, as shown below.

Figure A-5 Voltage label at lower rear of the Liaison® XL Connection Module

Figure A-6 Voltage label

The space behind the Liaison® XL Connection Module should always be kept clear so that the rear connection and power supply can be accessed in an emergency. Make sure that there is always at least 80 cm of free space behind the Liaison® XL Connection Module.

WARNING

Electric shock!

Never open or remove the cover when the device is powered on.

Disconnect the electrical mains or voltage of the system before working inside the device (e.g. cleaning the barcode scanner).

WARNING

Danger of electrical shock!

Detachable main power supply cords with inadequate ratings must not be used!

Refer to Chapter 6 *Appendix* for the power supply ratings.

Samples

Blood sample and other biologic/organic materials are to be treated as potentially infectious and hazardous materials. Therefore, the operator must take the utmost care and attention because it is possible that he or she will come into direct contact with patient samples!


WARNING

Risk of infection!

Always wear undamaged gloves when working on the system and comply with applicable laboratory regulations.

If sample material is spilt onto the surface of the system, the affected surface must be cleaned and disinfected in accordance with applicable regulations using standard disinfectants.

Barcodes

All barcodes used with this device should have a checksum. Sample tubes must not have multiple barcode labels. If more than one barcode label is present on a sample tube, the tube could be misidentified by the device.


WARNING

Risk of improper analysis results!

Sample tubes must not have multiple barcode labels. If more than one barcode label is present on a sample tube, the tube could be misidentified by the device. This could lead to improperly reported results.

Check that each sample tube has only one label. Do not use sample tubes with more than one label.

WARNING

Risk of sample mismatch between patients!

Roche Diagnostics and Hitachi High-Technologies Corporation will not be responsible for reading errors caused solely by the absence of a check digit, by a poor quality label, or by failure to perform scheduled maintenance.

The use of a check digit can reduce number of barcode reading errors.

There is a risk of sample mismatch between patients if interleaved 2 of 5 (ITF) barcodes are used without a check digit on the **cobas** 8100 automated workflow series and connected analyzers.

This risk may occur for the following reasons:

- Not using a check digit increases the possibility of incorrect character recognition. With no check digit, characters incorrectly recognized are considered to be correct. If the misread barcode ID is registered in the control unit database, the sample is processed on the **cobas** 8100 automated workflow series and connected analyzers according to the registered test orders for the misread barcode ID. Therefore, all sample results are assigned to the incorrect sample and patient.
- Using a variety of barcode lengths, other than the fixed lengths of 4, 8, 10, or 12 characters, increases the possibility of a partial barcode scan. A partial barcode scan can occur when the scan line of the barcode reader does not cover all of the barcode. When a barcode is partially scanned, only a truncated section of the barcode is read and, therefore, the barcode is improperly recognized. With no check digit, barcodes of a different length than the fixed lengths are considered to be correct. If the truncated barcode is registered in the control unit database, the sample is processed on the **cobas** 8100 automated workflow series and connected analyzers according to the registered test orders for the truncated barcode.
  Therefore, all sample results are assigned to the incorrect sample and patient.

Always use a check digit!

Tubes

Overfilled tubes can cause spillage of contents. The maximum filling level of the tubes must be in accordance with the recommendation of the tube manufacturer.

Processing of open tubes

Only open tubes can be processed in the system. Closed tubes must not be used.

The maximum fill height for open tubes must be respected, otherwise tube contents will be spilled.

Acrylic glass cover

NOTICE

Acrylic glass is brittle and must be handled with care. It may crack when bent or if fastening screws are overtightened.

It must be ensured that the securing screw has been removed before removing the cover!

Disposal of device

Electronic devices contain potentially harmful substances that can have a negative effect on human health and cause damage to the environment. Do not dispose of the module as normal garbage when it reaches the end of its service life. It must be disposed of in compliance with the applicable laws and regulations of the respective country in which it is operated.

Information on Waste of Electrical and Electronic Equipment (WEEE)

The obligation on the part of the producer to take back equipment does not apply to equipment from Roche PVT GmbH. The owner of the equipment must ensure appropriate disposal. It is the responsibility of the owner to ensure disposal in compliance with the respective national and international laws and regulations.

Risk of infection!

Equipment that comes into contact with sample material is to be considered as potentially infectious and harmful to health.

This is the last page of Part A.

System Description B

System description

In this chapter

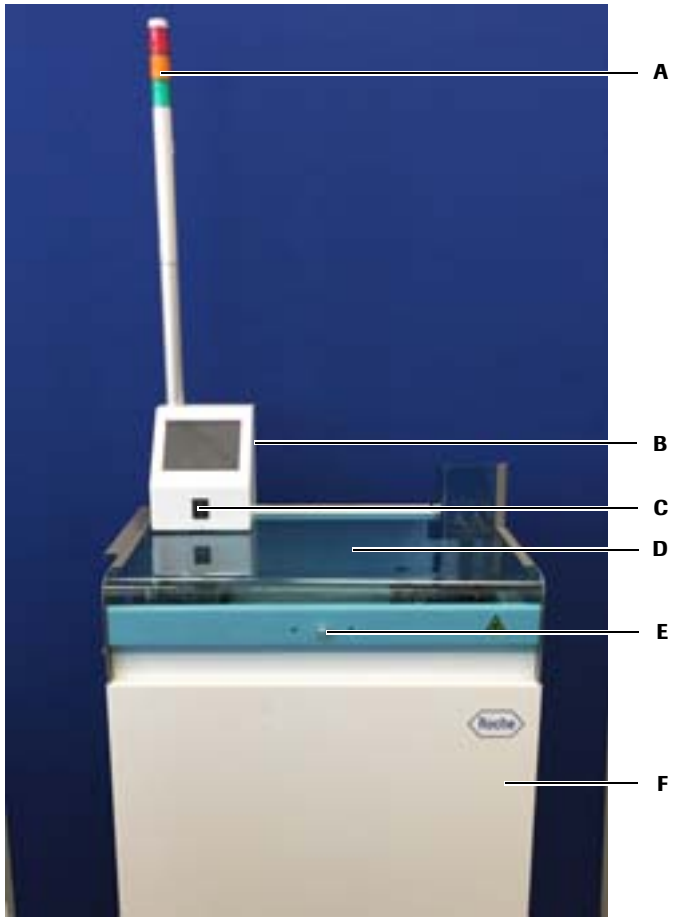
Chapter **2**

Hardware description

The Liaison® XL Connection Module automatically transports and processes open sample tubes.

The Liaison® XL Connection Module is embedded in a laboratory instrument system. It receives sample tubes from a cobas 8100 device via the UCU and presents these sample tubes to a Liaison® XL Analyzer for pipetting of sample liquid. After pipetting the tubes are transferred back to the UCU.

The system is equipped with a control computer and communication connections to a laboratory host (middleware system), the UCU, and the Liaison® XL Analyzer.



A Signal lamp
B Control unit with touch screen
C Main ON/OFF switch
D Protective cover
E Interlock of protective cover
F Enclosure

Figure B-1 Liaison® XL Connection Module instrument (front side)

Ratings plate

The ratings plate is shown below.

Figure B-2 Ratings plate

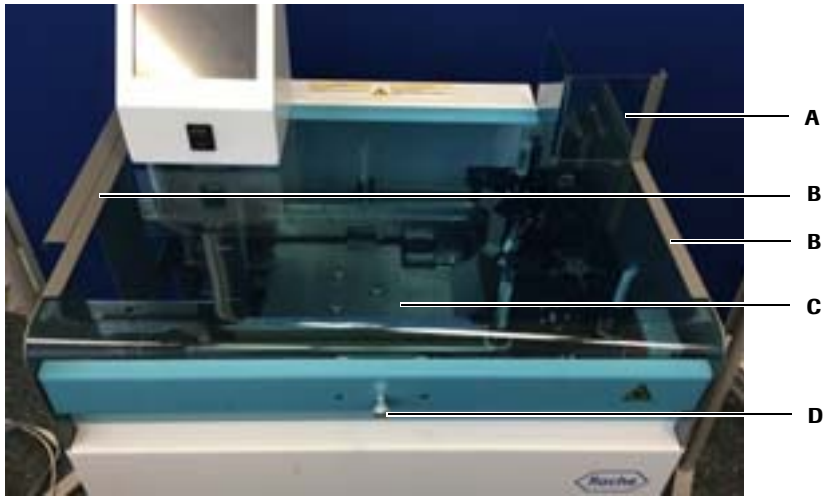
Field	Description
IVD Liaison® XL Connection Module	Product name
REF XXXXXXXXX	Reference number
SN 7701XXXXX	Serial number
~ 100-240 V; 50/60 Hz; 220 W	Power supply and power consumption data
Roche Diagnostics	Address of manufacturer and distributor
⚠ Roche	Warning label, Logo Roche
C/N: 7701WX	Configuration number
20YY-MM-DD	Date of manufacture
CE	Mark of CE / UL compliance
ETL Intertek	Approval from ETL Intertek

Table B-1

Protective cover

The protective cover is a slide-in acrylic glass cover for the work area of the Liaison® XL Connection Module. It is secured using a knurled screw. The screw opens and closes the cover switch. The cover switch cuts off the power for the actuators. When the knurled screw is loosened, operation is automatically stopped.

The protective cover is open in the gripper area to allow movement of the tube lift and pipetting by the Liaison® XL Analyzer.



A Open area for tube lift and gripper
B Protective cover insertion slide-in
C Protective cover
D Knurled screw to secure the protective cover

Figure B-3 Protective cover

Control unit

The control unit consists of a signal lamp and an enclosure housing, a touch screen and mains switch.

A Signal lamp
B Touch screen monitor
C Mains switch

Figure B-4 Control unit

Signal lamp

The signal lamp is located above the touch screen. The green, orange and red lights are used to show the status of the Liaison® XL Connection Module, as shown in the table below.

Light illuminated	Meaning
Green continuous	Liaison® XL Connection Module is ready and operational
Green continuous with flashing orange	Liaison® XL Connection Module is in standby mode
Red continuous	Error
Orange flashing	Ongoing query to analyzer
Alternating flashing green/orange	Liaison® XL Connection Module initializing after startup

Touch screen

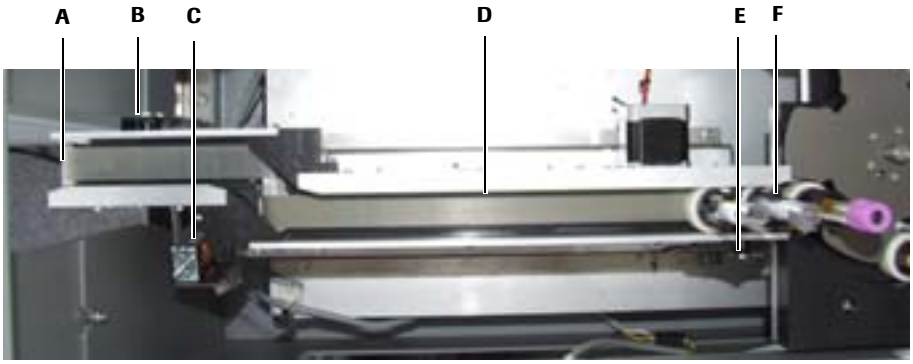
The system is controlled using a touch screen that is mounted on top of the device. Also system and error messages are displayed on the monitor.

Mains switch

The mains switch is located in the housing of the control unit with touch screen.

Tube transport (from UCU)

The sample tubes coming from the UCU are transferred onto the tube transport belt of the Liaison® XL Connection Module.



A Connection from UCU transport belt
B Sensor for detecting the single holder
C Stopper
D Transport belt
E Sensor for detecting the single holder
F Transfer of tubes to carrier star 1

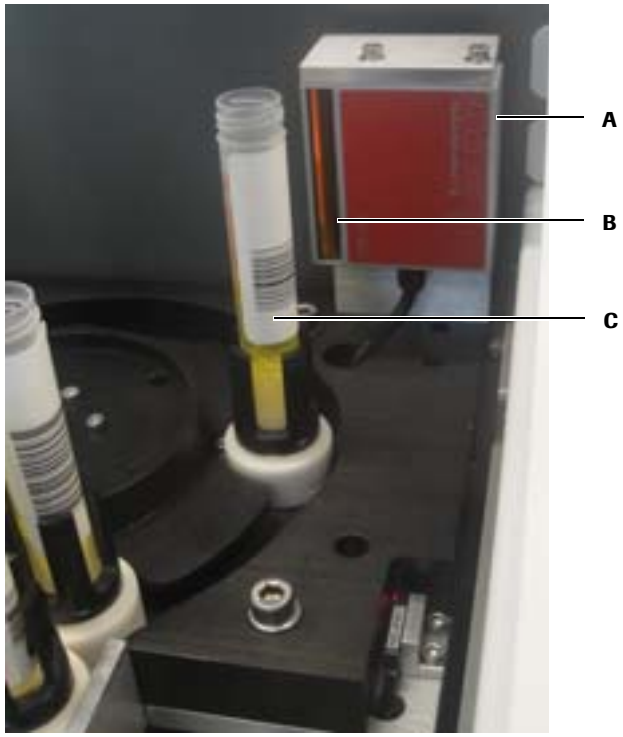
Figure B-5 Tube transport belt from UCU

Barcode scanner

The barcode scanner is located in the enclosure. The barcode scanner reads the barcode on the sample tubes. The Liaison® XL Connection Module then sends the barcode data to the middleware from which it receives the information about the tube type. This information is forwarded to the Liaison® XL Analyzer.

NOTICE

It is recommended to use barcodes with checksums for the sample tubes being scanned. The barcode scanner and Liaison® XL Connection Module by default will only work with checksum-enabled barcodes. It can also read barcodes without checksums after the barcode reader's configuration has been changed.



A Barcode scanner unit **B** Barcode scanner window

C Sample tube in reading position

Figure B-6 Barcode scanner

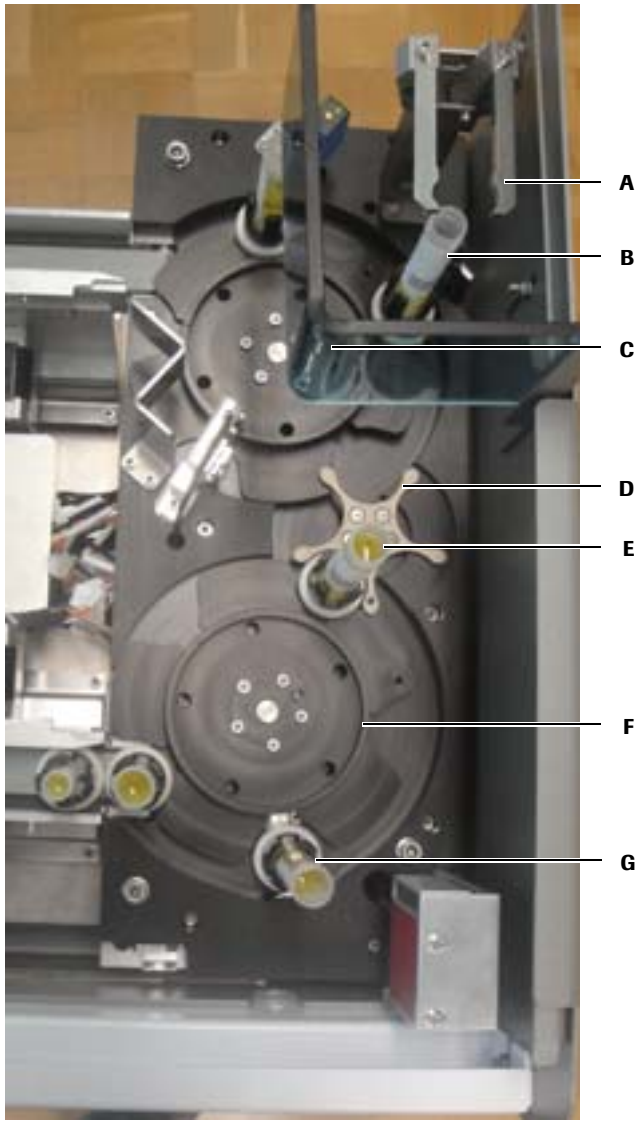
Star connector

Sample tubes loaded in single holders are carried by the inlet conveyor belt from the UCU to the first carrier star. The tube barcodes are read while they are positioned in star 1.

The tubes are forwarded to star 2 which carries them over to star 3. The tube is then lifted up and held by the gripper in the pipetting position.

The pipetting tip of the Liaison® XL Analyzer moves down into the tube and aspirates the sample liquid.

When pipetting is finished, the lift moves down again and the sample tube is transferred onto the output transport belt towards the UCU.



A Tube gripper
B Sample tube in lifting position
C Star 3
D Star 2
E Transfer of single holder to star 2
F Star 1
G Sample tube in barcode reading position

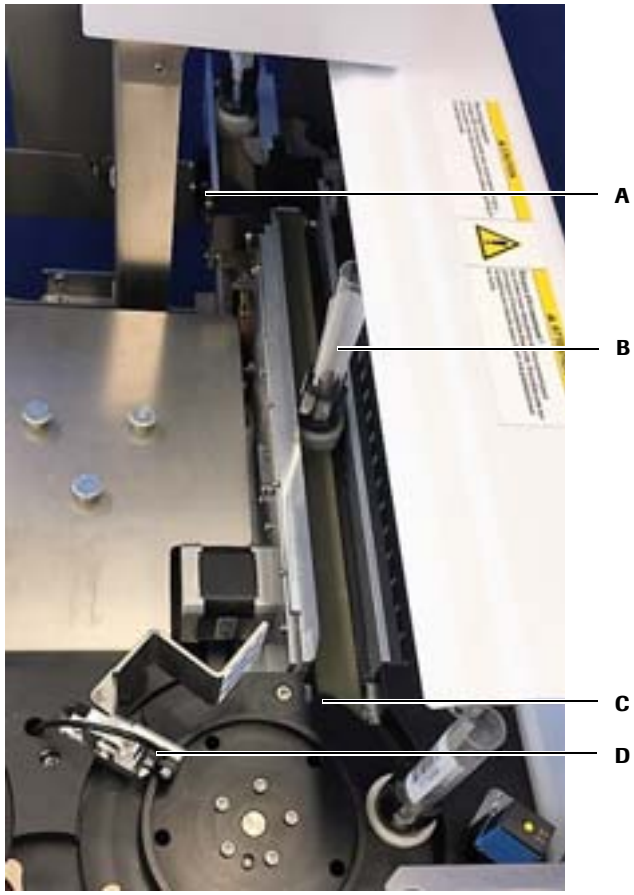
Figure B-7 Star connector and gripper

Tube lift and gripper (pipetting position)

The tube lift lifts up the tube in its single holder into the pipetting position. The gripper centres the tube and holds it during the pipetting.

Tube transport (to UCU)

When a sample has been pipetted, the lift goes down and the single holder with tube is transferred from star 3 onto the transport belt and moved towards the UCU.



A Single holder sensor

B Single holder with tube being transferred to UCU

C Transfer position from star 3 to transport belt

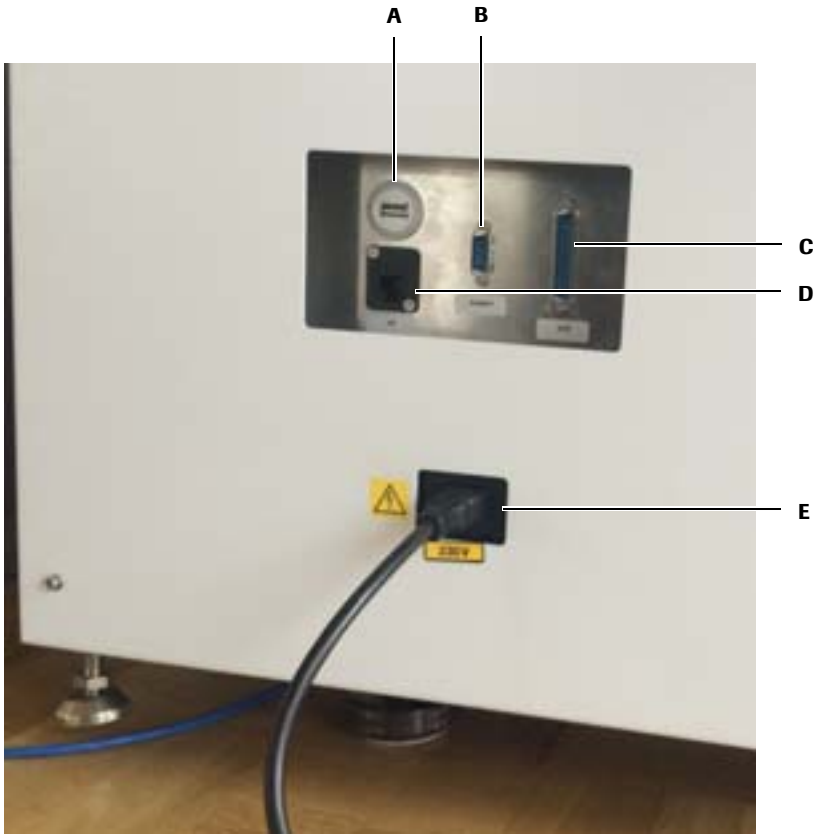
D Initialization sensor for star 3

Figure B-8 Tube transport belt to UCU

Mains connection and system interfaces

Rear connectors

The connections on the rear panel of the Liaison® XL Connection Module are shown below. The Ethernet, UCU and RS232 connection should not be disconnected or changed by the operator.



A USB port: for saving configuration and log files to a USB flash drive

B RS232 connection to Liaison® Analyzer

C Connection to the UCU

D Ethernet connection for connecting the device to the laboratory network

E Power supply connection

Figure B-9 Rear interface panel

Single sample holder

The open sample tubes are transported in single holders. Single holders firmly hold the sample tubes in place.

A Sample tube **B** Single holder

Figure B-10 Single holder (tube carrier)

System initialization

The Liaison® XL Connection Module performs an automated configuration of all motors each time it is switched on. The operating system boots up after the device is powered on. The operating system then starts the control program. The control program performs an automated configuration of all motors each time it is switched on. After a few minutes, the Main menu should be displayed.

After the Liaison® XL Connection Module is switched on and the **Start** button is chosen, it goes through a system initialization. During the initialization, the stopper is lowered and the stars and belts are rotated in reverse. In the event that single holders were not cleared out from the Liaison® XL Connection Module when it was last shut down, this initialization routine ensures that any remaining single holders are sent back to the tube transfer so they can be re-scanned by the barcode scanner. The signal lamp should flash alternatingly between green and orange. A flashing orange light indicates that the Liaison® XL Connection Module is initializing with the Liaison® XL Analyzer. This phase may take up to twenty minutes. After the initialization phase, a continuous green light should be illuminated on the signal lamp.

If faults occur during this procedure, corresponding error messages are displayed on the screen.

Sample flow and sample processing

Overview

The Liaison® XL Connection Module is part of a system for transporting and processing carriers holding sample tubes (referred to as "single holders"). The workflow of the Liaison® XL Connection Module can be generalized by the following steps:

1. The UCU delivers loaded single holders to the Liaison® XL Connection Module's inlet transfer belt.
2. Each carrier is transported sequentially to the Liaison® XL Connection Module's carrier-star unit.
3. The barcode on each sample tube is scanned and the single holders are transported onwards to the lifting station.
4. The tube lift mechanism lifts the single holder along with the sample tube up to the Liaison® XL Analyzer, where it is pipetted.
5. The single holder is lowered back and then transported to the outlet belt.
6. The outlet belt transfers the single holder back to the UCU.

The Liaison® XL Connection Module system consists of the following main components:

- Tube transfer: including the belt and drives for carrying the single holders from the UCU to the carrier-star unit.
- Carrier-star unit: consisting of three stars to transport the single holders from the tube transfer, to the barcode scanner and tube lift, and then to the outlet transfer unit.
- Outlet transfer unit: including the belt and drives for carrying the single holders from the carrier-star unit to the UCU.
- Barcode scanner.
- Electronics: including the power supply and circuit boards located in the lower enclosure, as well as the control computer.
- The touch screen (control panel) used for starting, stopping and configuring the Liaison® XL Connection Module.
- The signal lamp: for signalling the operational status of the device.

Basic information about the software

How to use the menu system

The system is operated by touching the buttons on the touch screen monitor.

Touch screen monitor

The controls of the system can be operated by touching the buttons on the touch screen monitor. For daily work routines, the touch screen monitor is the single most important operating element for controlling the system.

Login and user rights

The system's control software has a default operational level and a special administrator/service level. The operational level is activated automatically during the initialization; there is no need for the operator to log in. The administrator password protects the special service functions. The operator is not permitted to execute these functions.

Software description

Installation

When the Liaison® XL Connection Module is delivered to the customer, the control software, along with a basic initial configuration, is already installed on the device.

Self-test at startup

The operating system boots up when the device is powered on. The operating system then starts the control program. The control program performs an automated configuration of all motors each time it is switched on. After a few minutes, the Main menu should be displayed.

Main menu

The Main menu is displayed after the Liaison® XL Connection Module starts up successfully. Each of the available sub-menus is described further in this chapter.

Figure B-11 Main window

Button	Description
Start	Switches the Liaison® XL Connection Module from standby mode to operating mode (starts processing tubes).
Options	Switch to the Options menu.
Shutdown	Initiate an orderly shutdown of the Liaison® XL Connection Module.

When the **Start** button in the Main menu is chosen, the device carries out an automated self-test procedure (the initialization). The operator is requested to confirm that no pipetting is currently underway. During this self-test, the system checks if a single holder is present in the device. If one or more single holders are detected, it is then processed under normal conditions after the self-test is completed. An initialization handshake with the UCU is also carried out. Thus, the UCU must be switched on for this stage of the self-test to be completed.

Operation menu

The Operation menu is normally displayed on the touch screen when the Liaison® XL Connection Module is processing loaded single carriers in operating mode.

To start Liaison® XL Connection Module operations, choose the **Start** button. While the Liaison® XL Connection Module is processing holders, only the **Stop** button is available.

Figure B-12 Operation menu

Button	Description
Stop	Switches the Liaison® XL Connection Module from operating mode to standby mode

This menu is displayed when the Liaison® XL Connection Module is operating and processing single holders. Choose the **Stop** button to halt operations and switch the device to standby mode.

When the **Start** button is pressed again, then the Liaison® XL Connection Module continues with the work cycle (no initialization will be performed).

Options menu

The Options menu includes additional functions that may be required for the operator to perform daily routines.

Figure B-13 Options menu

Button	Description
System information	Switch to the System information sub-menu.
Backup configuration to USB	Backup your configuration to a USB flash drive (the configuration file is copied to the internal "static" USB flash drive that is inserted inside the Liaison® XL Connection Module which is not accessible by the operator).
Copy logfiles to USB	Copy the system's log files to a USB flash drive (the log files are copied to a USB flash drive inserted into the USB port at the back of the Liaison® XL Connection Module).
User mode	Switch to the User mode sub-menu to change the access level (to Administrator or Service level).
Back	Go back to the Main menu.

System information sub-menu

This sub-menu displays information about the Liaison® XL Connection Module's counters and system version numbers. Counters sub-menu shows the total number of single holders processed since the last counter reset and since the initial installation. This information is used for scheduling maintenance procedures.

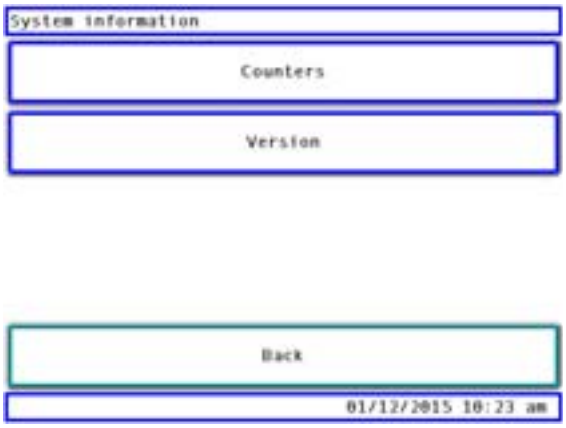


Figure B-14 System information sub-menu

Button	Description
Counters	Display the system counter values (shown below). The number of single holders processed by the Liaison® XL Connection Module is shown.
Version	Display the version information (shown below) including the current version of the control software, the PCB firmware versions and the barcode scanner version.

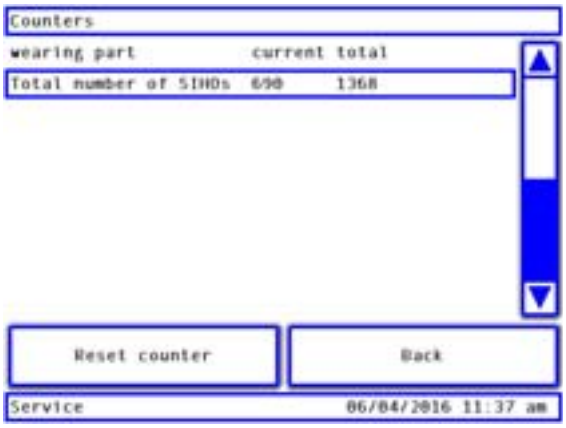


Figure B-15 Counters sub-menu

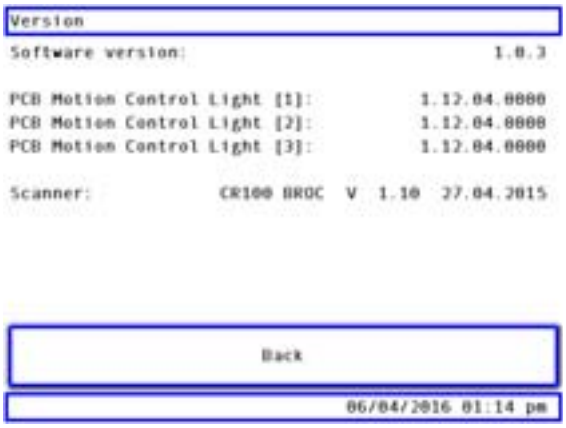


Figure B-16 Version sub-menu

User mode sub-menu

This sub-menu is used to switch to the Administrator or Service access level. Only service technicians may switch to the Service level.

Figure B-17 User mode sub-menu

Button	Description
Operator	Switch to the Operator access level (this mode should always be used during routine operations).
Administrator	Switch to the Administrator access level (this mode may be used by a network administrator for certain limited settings, such as date/time, screen, and network settings).
Service	Switch to the Service access level (the Service level may only be used by service technicians: the Service level functions are not described in the Operator's Manual).

Administration sub-menu

The Administration sub-menu displays the four administrative functions available for the system administrator. The administrator password is required to access these functions. This sub-menu does not include the advanced functionality available at the Service access level.

All menu functions are password-protected and may only be executed by a service technician or laboratory administrator. Use the numeric keypad, as shown below, to enter the password. Then choose the **OK** button to continue to the selected function:

Each of the options in this Administration menu is described below.

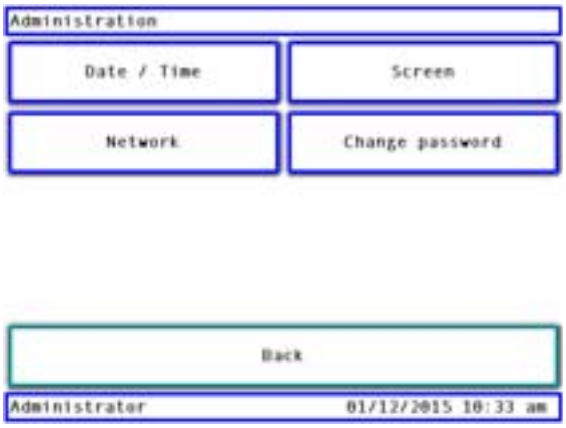


Figure B-18 Administration sub-menu

Buttons	Description
Date/time	Change the system's date or time setting.
Screen	Change the interface language, brightness or sensitivity of the touch screen.
Network	Change the network settings (these settings are described in detail in the Service Manual).
Change password	Change the password.

Date/time sub-menu

The Date/time sub-menu enables you to change the system date and time. Use the numeric keypad to enter the current date (format: YYYYMMDD) or time (format: HHMM). The backspace button can be used to delete the current entry. To confirm your changes and return to the previous window, choose the **OK** button. To discard your changes and return to the previous window, choose the **Back** button.

Figure B-19 Date/time sub-menu

Button	Description
Set date	Set the system date (shown below).
Set time	Set the system time (shown below).

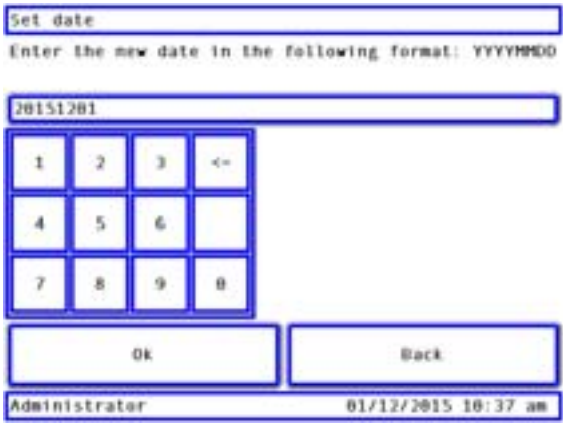


Figure B-20 Set date sub-menu

In this example, the operator is setting the system date to December 1, 2015.

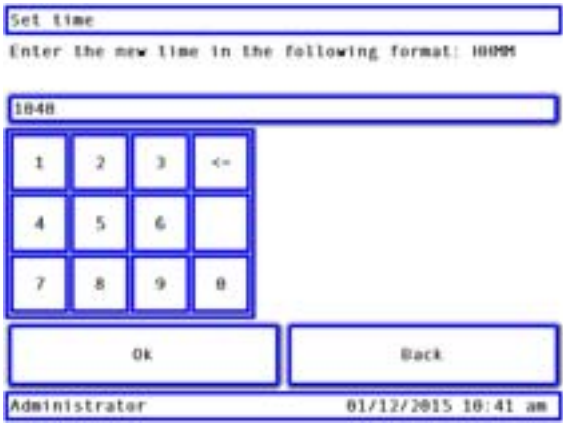


Figure B-21 Set time sub-menu

In this example, the operator is setting the time to 10:40 (24-hour time notation is used).

NOTICE The system does not automatically make provisions for daylight savings. You need to set the system's time accordingly (twice a year).

Screen sub-menu

The brightness and sensitivity of the touch screen can be adjusted from the Screen sub-menu. The language for the interface menus can also be toggled between English and German.

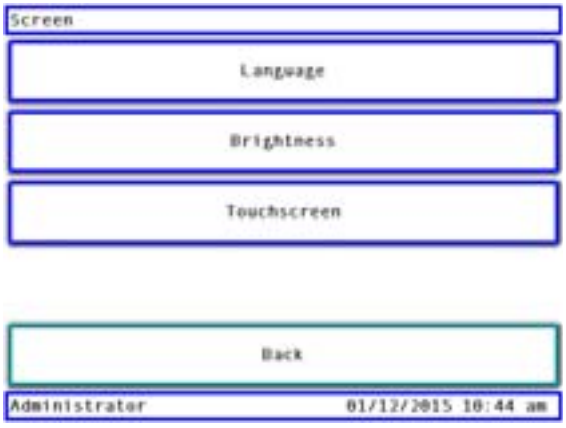


Figure B-22 Screen sub-menu

Button	Description
Language	Set the language to one of the following: German, English, French, Italian, Spanish, Portuguese.
Brightness	Adjust the brightness of the touch screen.
Touch screen	Adjust the sensitivity of the touch screen.

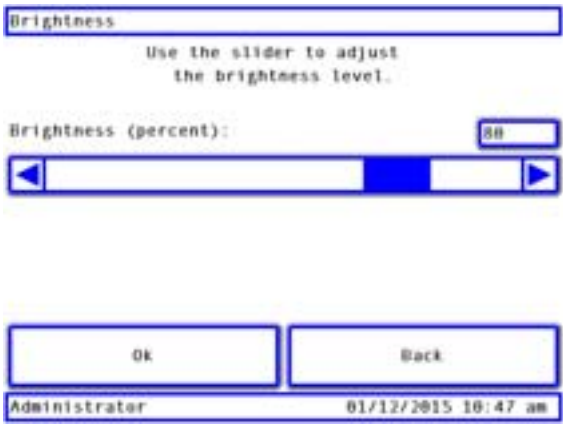


Figure B-23 Adjusting the brightness

Use the slider to adjust the screen's brightness between 0 and 100 percent.

Figure B-24 Calibrating the touch screen

The touch screen may need to be recalibrated if the operator notices that touch reactions are erratic or imprecise. The sensitivity of the screen can be recalibrated here as follows.

► Recalibrating the sensitivity of the screen

1. Choose the **Start** button to initiate the calibration sequence.
2. Touch the screen once to confirm the initial text message.
3. The program will display four crosshairs in succession (one for each corner). Touch the screen at the centre of each crosshair, using your finger or a stylus.
4. Confirm the final message in order to return to the **Screen** sub-menu.
5. Choose the **Close** button.

■

This is the last page of Part B.

Operation C

Operation

In this chapter *Chapter* 3

Table of contents

Commissioning the system

NOTICE You must read the Operator's Manual with the utmost care and attention before using the system for the first time. Particular attention should be paid to descriptions of hazards and precautions!

Daily routine

Trouble-free operating procedures

Using the actions below, you can review the complete work flow of the system step by step.

Actions prior to the daily routine

► **Inspecting connections**

1 Check that the mains plug and communication connections are properly plugged.

■

► **Inspecting the work area**

1 Carefully check the tube transport and star connector for foreign objects such as single holders or sample tubes (including parts of tubes).

■

► **Closing the protective cover**

1 Fasten the protective cover using the knurled screw. Screw the knurled screw in all the way by hand.

■

► **Switching the system on**

1 Switch on the system.

■

Operation – daily routine

► Starting sample processing

1 In the Main menu, choose the **Start** button.

■

► Ending operations

1 Ensure that all samples have been processed and that no tubes remain in the system. In the Main menu, choose the **Stop** button.

■

Actions after the daily routine

► Shutting down the system

1 Choose the **Shutdown** button on the Main menu and confirm the shutdown in the next window displayed.

■

► Switching off the system

1 You may switch off the device using the main switch only after the message "You may now power down the system." is displayed.

■

► Checking the work area

1 Check the work area and tube conveyors for objects such as sample tubes, spilt liquids or samples that may have gathered during operation.

2 Remove any such objects, residue or contaminants if necessary.

👁 For additional information, please refer to chapter *Checking the work area* on page C-9.

■

► Performing care and maintenance procedures

1 Carry out care and maintenance procedures as necessary.

👁 For additional information, please refer to chapter *Dimensions and weight* on page F-9

■

Switching on the system

► Procedure

1. Make sure that the protective cover is completely closed and secured with the knurled screw.
2. Switch on the unit.
3. The main switch must be in the ON position. The system initializes (refer to the *System initialization* section). After a few minutes, the initialization finishes and the Main menu is displayed.

■

A Main switch OFF (O) **B** Main switch ON (I)

Figure C-1 Main switch with control light

Operation

Starting sample processing

The Main menu will appear after the device has finished its self-test at startup. The Liaison® XL Connection Module is now ready to initialize and process single holders. Proceed as follows:

1 Make sure that the UCU, laboratory host (middleware system) and Liaison® XL Analyzer are switched on and operational.

2 Press the Start button to start initializing and processing single holders. The system will then check all motors and sensors. If a single holder is detected in the device, it will be processed normally after the initialization.

3 After all remaining single holders are processed (if any were remaining), the device detects that it is empty and starts processing single holders from the UCU.

■

Interrupt sample processing

There are two methods of interrupting routine operations.

Stop Button

Sample processing can be interrupted if you need to pause the workflow. Note that the steps below will only function properly if the protective hood remains closed.

You can use the **Stop** button at any time.

1 To allow the current work step to be completed and then halt the system, choose the **Stop** button.

2 Wait until the Main menu is displayed.

3 To continue with the work cycle, choose the **Start** button.

Do not reach in the vicinity of the conveyor belts, carrier stars or lift unless the Liaison® XL Connection Module is switched off!

■

Main switch OFF

In an emergency, the Liaison® XL Connection Module may be switched off using the main switch.

Using the main switch to switch off the device may lead to data loss, contamination or hardware damage. Use this method only for an emergency!

Terminating operation after daily routine

Shutting down the system and switching off

► **Procedure**

1 After operations have been stopped, choose the **Shutdown** button in the Main menu.

2 Choose [Yes] to confirm your intention to shutdown in the next dialog.

3 Wait until the system has shutdown.

4 Use the main switch to switch off the system.

■

Checking the work area

Check the carrier stars and conveyor belts for objects such as sample tubes, caps, spilt liquids or samples that may have accumulated during operations. Remove any such objects, residue or contaminants.

WARNING

Risk of infection!

Sample material and all unit parts that may come into contact with the sample material are to be regarded as potentially infectious and harmful to health. Due to the risk of infection, always wear gloves when working on the system!

Care and maintenance procedures

Perform care and maintenance procedures as necessary.

Always switch off the system before performing care and maintenance work. Always disconnect the mains plug of the system from the mains supply!

Ensure that national, international and standard laboratory safety precautions are adhered to when performing the care and maintenance schedule.

👁 For detailed information about cleaning and maintenance, please refer to Chapter 4 *Maintenance*.

This is the last page of Part C.

Maintenance D

Maintenance

In this chapter

Chapter **4**

Table of contents

Device care and maintenance

Care and maintenance procedures include all activities to be performed periodically by the operator. Adhering to the maintenance measures will help to ensure a trouble-free workflow. Therefore, please observe the descriptions contained in the following maintenance schedule.

WARNING

Risk of infection!

Sample material and all unit parts which come into contact with the sample material are to be regarded as potentially infectious.

WARNING

Mains voltage!

Switch off the system and disconnect the mains cable from the power socket before performing any cleaning or maintenance procedures.

CAUTION

Owing to the risk of infection, you must always comply with applicable laboratory regulations and wear protective clothing (lab gown, gloves and face shield) when carrying out cleaning and maintenance work on the system.

Please read and observe the notes about hazards and precautions before you carry out care and maintenance procedures (see chapter *General information*). Therefore, it is imperative that you observe all national, international and conventional laboratory safety regulations when you carry out care and maintenance procedures. Switch off the system before carrying out any cleaning work on it!

Cleaning

Cleaning agents and equipment

WARNING

Risk of Infection!

Sample material and all unit parts which come into contact with the sample material are to be regarded as potentially infectious. Owing to the risk of infection, you must always wear a lab coat, gloves and protective goggles while carrying out work on the system!

Normally, a 70% ethyl alcohol solution and de-ionized water are sufficient for cleaning the Liaison® XL Connection Module. Use dampened cloths to gently clean all surfaces, as described below.

Be sure to observe the safety instructions below:

- Always turn off the power to the device before starting the cleaning procedure.
- You must wear a lab coat, protective gloves, protective shoes and protective glasses during the procedure.

Cleaning schedule

Cleaning is an as-needed action. A visual inspection should be carried out on a daily basis. Look from above. Clean and remove any residues, spillage or misplaced tubes. Follow the instructions described below.

Cleaning preparations

Prepare for the cleaning procedure by following the steps below:

1. Wear a lab coat, protective shoes, protective gloves, and protective goggles.
2. Ensure adequate ventilation. Allow fresh air to come into the room.
3. Prepare a 70% ethyl alcohol solution, de-ionized water and a lint-free cloth.
4. Shut the device down and disconnect it from the power supply.
5. Remove the knurled screw and remove the protective cover.
6. After cleaning, put the protective cover back on and fix the knurled screw.

■

Cleaning a spillage

Proceed as follows:

1. Clean first using a lint-free cloth that is moistened with de-ionized water.
2. Allow the components to dry off.
3. Then clean using a lint-free cloth moistened with 70% ethyl alcohol solution.
4. Allow the solution to remain on the covers and panels until they are dried.

■

Cleaning the outer cover and panels

Take the following steps to clean the outer covering and housing panels:

1. Clean first using a lint-free cloth that are moistened with de-ionized water.
2. Allow the covers and panels to dry off.
3. Then rinse these using a lint-free cloth moistened with the 70% ethyl alcohol solution.

■

Cleaning the touch screen

Clean the touch screen as needed. Use gauze pads moistened with de-ionized water. Wipe dry with a lint-free cloth.

NOTICE

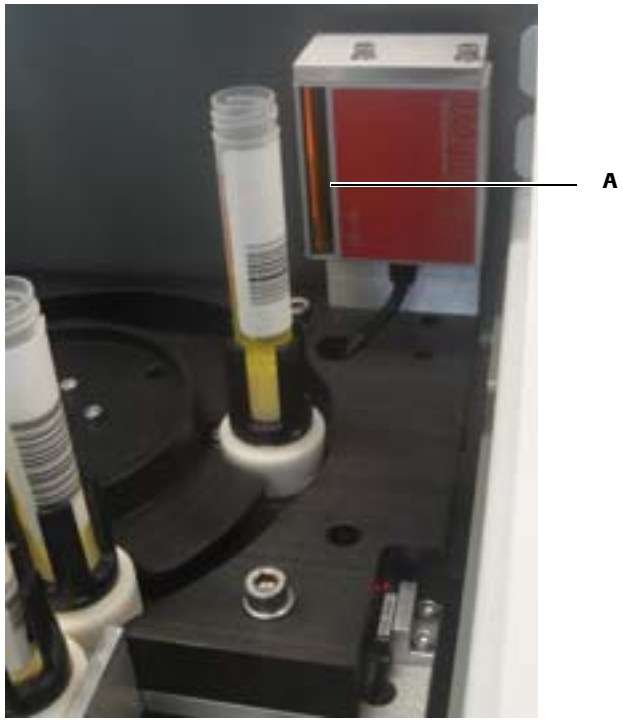
The touch screen can be scratched from abrasive cleaners. Do not use cleaning agents containing abrasive material!

Cleaning the barcode scanner window

Use a lint-free cloth moistened with the 70% ethyl alcohol solution to clean the barcode scanner. Wipe dry with a lint-free cloth.

NOTICE

The barcode scanner window can be scratched from abrasive cleaners. Do not use cleaning agents containing abrasive material!



A Scanner window

Figure D-1 Cleaning the barcode scanner

Cleaning the transport belts

Take the following steps to clean the four transport belts:

1. Use a lint-free cloth moistened with de-ionized water to clean the belt surfaces.
2. Allow the belts to dry off.
3. Rinse the entire surface of the belts using a lint-free cloth moistened with the 70% ethyl alcohol solution.

■

Cleaning the transport rails and other metal components

Take the following steps to clean the transport rails and similar components:

1. Use a lint-free cloth moistened with de-ionized water to clean the transport rails.
2. Allow the rails to dry off.
3. Rinse the entire surface of the transport rails using a lint-free cloth moistened with the 70% ethyl alcohol solution.

■

Maintenance

Maintenance is carried out by a service technician. Maintenance of the system is dependent on the amount of time it has been in operation.

This is the last page of Part D.

Troubleshooting E

Troubleshooting

In this chapter

Chapter **5**

Table of contents

General information

If an error or malfunction occurs, it is important that customer service receives a detailed and precise description of the error. Please make sure that you have enough information to answer the following questions before calling customer service:

- Was the error caused when an entry was being made on the touch screen or was something being done on the Liaison® XL Connection Module?
- Does the error occur sporadically or always in the same situation?
- Does the error occur only with a certain type of tube?
- In which position is the main switch: O or I?
- Is the mains plug connected?
- Is a message displayed on the touch screen?
- Have you followed the troubleshooting instructions displayed with the error message?
- What is the error message?

Preparing a logfile for the support agent

Some cases may require a service technician to review the system's logfile. We recommend keeping an up-to-date copy of the log file ready for customer service. Refer to the *Options menu* section in the Chapter 2 *System description*.

NOTICE

Always inform an administrator or technician if you attempted and failed to correct an error but your actions fail!

Problem scenarios

This section describes several “What do I do if ...” scenarios along with their corresponding remedies for troubleshooting.

- Problem: The Liaison® XL Connection Module has been switched on but does not boot up completely; only a white screen is displayed.

  Operator action: Restart the Liaison® XL Connection Module using the main switch. If problem recurs, contact the service technician.

- Problem: The Liaison® XL Connection Module has been switched on but does not boot up completely; only a black, unlit screen is displayed.

  Operator action: Check the mains power supply. Restart the Liaison® XL Connection Module using the main switch. If problem recurs, contact the service technician.

- Problem: During operations, the lift crashes into star 3.

  Operator action: The carrier stars are no longer properly aligned. Shutdown the Liaison® XL Connection Module and contact the service technician.

- Problem: The barcode cannot be properly read by the scanner.

  Operator action: Make sure that you are using checksum-enabled barcode labels. If the barcode is not recognized, the operator can specify on the touch screen whether to remove the tube manually from the Liaison® XL Connection Module or send it back to the UCU without pipetting. Clean the barcode or barcode scanner if it appears dirty (refer to “Cleaning the barcode scanner” section). If problem recurs, contact the service technician.

- Problem: The Liaison® XL Connection Modules are not moving smoothly or are getting stuck between the UCU and the Liaison® XL Connection Module.

  Operator action: This may indicate that the Liaison® XL Connection Module is not properly aligned with the UCU. Shutdown the Liaison® XL Connection Module and contact the service technician.

- Problem: The pipetting position cannot be reached by the pipetting arm of the Liaison® XL Analyzer.

  Operator action: The Liaison® XL Analyzer may need to be re-configured. Shutdown the Liaison® XL Connection Module and contact the service technician.

- Problem: The sensor LB_STAR3_TUBE1 remains off and does not detect an existing sample tube.

  Operator action: Make sure that a sample tube is in the single holder. The sensor may be defective if this error occurs even when a sample tube is in the single holder. In this case, contact the service technician.

Error messages

The table below lists the error messages along with the corresponding actions for the operator and service technician.

NOTICE In the messages, <item x> refers to variable information, such as the name of the specific hardware component. SiHo refers to a single holder.

Group/error No.	Message	Operator information
0.1	Control module received an unknown command (<item1>).	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
0.2	Unknown case-loop value (<item1>).	Turn off and on the power. If it reoccurs, contact technical support.
0.4	An unknown error occured.	Turn off and on the power. If it reoccurs, contact technical support.
0.5	Process data are inconsistent or invalid. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
1.2	Database access failed.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
1.3	The station <item1> failed to load its configuration data.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
1.5	The protective door has been opened while the system was operating. A restart of the system is necessary for security reasons.	Cover was opened. Turn off and on the power. If it reoccurs, contact technical support.
1.6	Failed to open local port (<item1>). Unable to connect.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
1.7	Connection error to port (<item1>).	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
2.6	An error occurred while opening port <item1>.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
4.1	Checking the state of sensor <item1> has failed.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
4.2	Setting the state of switch <item1> to "<item2>" has failed.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
4.20	Actuator <item1> is not defined within the database.	n.a.
5.40	An unknown mcu interface error occured.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
6.1	The system may now be switched off.	n.a.
6.9	Do you really want to shutdown the system ?	n.a.
6.10	Do you really want to create a backup of the system's configuration data ?	n.a.
6.11	System configuration backup completed.	n.a.
6.13	Select update file on USB stick:	n.a.
6.14	Start installation of [<item1>] ? The action can take up to several minutes and will require the system to be rebooted afterwards.	n.a.

Table E-1

Group/error No.	Message	Operator information
6.15	Start storing log information to USB ? The action can take up to several minutes.	n.a.
6.16	Storing log information to USB completed.	n.a.
6.17	Select configuration data to be restored:	n.a.
6.18	Start creating a full backup ? The action can take up to several minutes.	n.a.
6.19	Full backup completed.	n.a.
6.21	Select a full backup to be restored:	n.a.
6.22	Installing [UPDATE_CFG_NAME] Please wait …	n.a.
6.23	You may now power down the system.	n.a.
6.24	Unable to mount USB memory stick!	Check whether the USB stick is properly inserted into the port at the rear interface panel of the system. Check the USB stick's filesystem.
6.25	Unable to mount USB memory stick!	n.a.
6.26	Insufficient memory left on USB memory stick !	Delete obsolete data from the USB stick
6.27	Insufficient memory left on USB memory stick !	n.a.
6.28	Preparing shutdown. Please wait …	n.a.
6.29	No USB memory stick (system flash) detected. Backup functionality is impaired! Please contact a service technician.	The static USB stick is either defective or not connected. Neither customer data nor system data can be saved. No working USB flash drive)memory stick) found. By choosing the **Ok** button you can continue operation as usual until the next restart (after which the error message will recur).
6.30	[UPDATE_CFG_NAME] successfully installed. Please reboot the system.	Follow instructions on touch screen.
6.31	The recent data installation requires a mandatory reboot. Please select [Shutdown] from the main menu and restart the system.	Follow instructions on touch screen.
6.32	In order to adopt the recent changes to the network configuration, a reboot is mandatory. Please select [Shutdown] from the main menu and reboot the system.	Follow instructions on touch screen.
6.33	The network settings have been changed. The system needs to be rebooted in order to activate these changes. Do you want to reboot the system now?	Restart the Liaison® XL Connection Module.

Table E-1

Group/error No.	Message	Operator information
6.40	Installation of file [UPDATE_CFG_NAME] has failed. Please reboot the system.	Restart the Liaison® XL Connection Module.
6.41	Creating full backup …	n.a.
6.43	In order to activate the new settings the system needs to be rebooted. Do you want to reboot the system now?	Answer Yes or No.
6.44	Save tube type file to USB memory stick? An already existing tube type file on the USB memory stick will be overwritten.	Answer Yes or No.
6.45	Saving tube type file to USB memory stick has failed.	Check whether the USB stick is properly inserted into the port at the rear interface panel of the Liaison® XL Connection Module.
6.46	Saving tube type file to USB memory stick was successful.	n.a.
6.47	No valid tube type file found on the USB memory stick.	n.a.
6.48	Load tube type file from USB memory stick? The existing tube type file of the system will be overwritten.	n.a.
6.49	Loading tube type file from USB memory stick has failed.	Check whether the USB stick is properly inserted into the port at the rear interface panel of the Liaison® XL Connection Module.
6.50	Loading tube type file from USB memory stick was successful.	n.a.
6.51	Save scanner configuration to USB memory stick? An already existing scanner configuration on the USB memory stick will be overwritten.	n.a.
6.52	Saving scanner configuration to USB memory stick has failed.	n.a.
6.54	No valid scanner configuration found on the USB memory stick.	n.a.
6.55	Load scanner configuration from USB memory stick? The existing scanner configuration of the system will be overwritten.	Answer Yes or No.
6.56	Loading scanner configuration from USB memory stick has failed.	Check whether the USB stick is properly inserted into the port at the rear interface panel of the Liaison® XL Connection Module.
6.57	Loading scanner configuration from USB memory stick was successful.	n.a.
7.0	An error occurred at the barcode scanner. (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.

Table E-1

Group/error No.	Message	Operator information
16.1	Configuration of motion control was not successful for motor <item1>. Check CAN-cable. Turn off and on the power. If it reoccurs, contact technical support.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.2	Wrong answer for the request <item1> for motor <item2>. Turn off and on the power. If it reoccurs, contact technical support.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3	Sending command <item1> to motion control for motor <item2> failed. Check CAN-cable. Turn off and on the power. If it reoccurs, contact technical support.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.4	The software tries to access a motion control device with an undefined or invalid device index. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
16.5	The motion control motor <item1> is not defined. Either the motion control configuration has not been loaded properly, or it is defective / incomplete. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
16.6	The motion control sensor <item1> is not defined. Either the motion control configuration has not been loaded properly, or it is defective / incomplete. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
16.7	The motion control switch <item1> is not defined. Either the motion control configuration has not been loaded properly, or it is defective / incomplete. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
16.255	Unknown error to request <item1> for motor <item2>. Turn off and on the power. If it reoccurs, contact technical support.	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.262	Error EMERGENCY STOP OVER PIN RECEIVED (<item1>)	This error occurs when the cover was opened without a software notification. Turn off the power. Close cover. Turn on the power. If it reoccurs, contact technical support.
16.419	Error DEVICE STATE AND MOVING STATE NOT CONSISTENT (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.426	Error CANNOT START MOVES IN EMERGENCY STATE (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.430	Error NO STATE CHANGES ARE ALLOWED WHILE IN EMERGENCY STATE (<item1>	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.2628	Error EXPECTED EVENT DID NOT OCCUR (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3000	Error ProFET0 TIMEOUT EVENT OCCURRED (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3001	Error ProFET1 TIMEOUT EVENT OCCURRED (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3002	Error ProFET2 TIMEOUT EVENT OCCURRED (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.

Table E-1

Group/error No.	Message	Operator information
16.3003	Error ProFET3 TIMEOUT EVENT OCCURRED (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3006	Error ProFET0 OPEN LOAD EVENT OCCURRED (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3007	Error ProFET1 OPEN LOAD EVENT OCCURRED (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3510	Error SPI TRANSMIT OVERRUN ERROR (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3511	Error SPI RECEIVE OVERRUN ERR0R (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3512	Error SPI BUSY (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3513	Error SPI TRANSMITTER NOT READY (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.3514	Error SPI RECEIVER NOT READY (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
16.1001	Error FIX TO FLOAT FIXED POINT WIDTH OUT OF RANGE (<item1>)	Restart the Liaison® XL Connection Module. If it reoccurs, contact technical support.
17.1	LCM has not received a RECEIVE signal from the UCU within 5000 ms. First check if the UCU is powered on and then confirm the message. Turn off and on the power. If it reoccurs, contact technical support.	Check if the UCU is powered on. Turn off and on the power. If it reoccurs, contact technical support.
17.2	The RECEIVE signal <item1> was not reset by UCU, although the SEND-Signal for transfer was reset by LCM. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
17.3	The OPERATION signal <item1> from UCU turns inactive during transfer after <item2> ms. Check if a SiHo is stuck during transfer on LCM or UCU and remove this SiHo in case of damage. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
17.4	Expected SiHo is not detected at sensor <item1> after timeout T3R. Check if a SiHo is stuck or foreign objects cause a blockage. Turn off and on the power. If it reoccurs contact technical support.	Check if the SiHo is stuck or foreign objects cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.
17.5	The SEND signal <item1> from UCU turns inactive during transfer after <item2> ms. Check if a SiHo is stuck during transfer on LCM or UCU and remove this SiHo in case of damage. Turn off and on the power. If it reoccurs, contact technical support.	Check if the UCU is powered on. Turn off and on the power. If it reoccurs, contact technical support.
17.6	UCU did not set the SEND signal <item1> inactive within timeout T4. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
17.7	After reset-mode UCU did not set the OPERATION signal <item1> active after <item2> ms. Check if UCU is still powered on. Turn off and on the power. If it reoccurs, contact technical support.	Check if UCU is in operation. Turn off and on the power. If it reoccurs, contact technical support.

Table E-1

Group/error No.	Message	Operator information
18.1	The communication to analyzer is failed. Check serial cable. Check if analyzer is in operation and communication is active. Turn off and on the power. If it reoccurs, contact technical support.	Check if analyzer is in operation and communication is active. Turn off and on the power. If it reoccurs, contact technical support.
18.2	Please confirm that no pipetting is ongoing.	n.a.
18.3	Analyzer is not in READY and not in RUNNING state. Check if analyzer is in operation and communication is active. How do you want to proceed?	Check status on the analyzer. If the analyzer is in READY or in RUNNING state and this error reoccurs, contact technical support.
18.4	Receive wrong sample ID from analyzer. Turn off and on the power. If it reoccurs, contact technical support.	Compare sample-ID from the analyzer with sample-ID of LCM. Turn off and on the power. If it reoccurs, contact technical support.
18.5	Corrupted sample ID. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
18.6	From analyzer not received SamplingComplete for sample ID = <item1> yet. How do you want to proceed?	Check status on the analyzer. If it reoccurs, contact technical support.
18.7	Please ensure that no pipetting is ongoing and then remove the sample on lift position. Then turn off and on the power. If it reoccurs, contact technical support.	Check if this sample is registered by Cobas 8100. Turn off and on the power. If it reoccurs, contact technical support.
18.8	Is the pipettor arm of the analyzer inside the connector?	n.a.
18.9	You have confirmed that the pipettor arm is inside the connector. Solve the problem and then turn off and on the power. If it reoccurs, contact technical support.	n.a.
18.10	Confirm again: Is the pipettor arm of the analyzer inside the connector?	n.a.
19.1	The communication to middleware is failed. Check network cable. Check if the middleware is in operation and the communication is active. Turn off and on the power. If it reoccurs, contact technical support.	Check if the Middleware is in operation and the communication is active. Turn off and on the power. If it reoccurs, contact technical support.
19.2	Tube type list does not exist or is corrupted. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
19.3	Sample ID <item1> has more than <item2> characters. Remove sample on barcode position. Turn off and on the power. If it reoccurs, contact technical support.	Remove sample on barcode position. Turn off and on the power. If it reoccurs, contact technical support.
19.4	Corrupted sample ID. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
19.5	Unknown sample ID <item1> for middleware. Turn off and on the power. If it reoccurs, contact technical support.	Check if this sample is registered by Cobas 8100. Turn off and on the power. If it reoccurs, contact technical support.
19.6	Receive wrong sample ID from middleware. Turn off and on the power. If it reoccurs, contact technical support.	Compare sample-ID from the middleware or cobas8100 with sample-ID of LCM. Turn off and on the power. If it reoccurs, contact technical support.
19.7	Tube type list is in wrong format. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.

Table E-1

Group/error No.	Message	Operator information
25.1	Unexpected SiHo detected at sensor <item1>. Number of SiHo in system: <item2>. Turn off and on the power. If it reoccurs, contact technical support.	Check number of single holders and contact technical support in case number differs with number shown on display. Turn off and on the power. If it reoccurs, contact technical support.
25.2	Expected SiHo is not detected at sensor <item1>. Check if the SiHo is stuck or foreign objects cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.	Check if the SiHo is stuck or foreign objects cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.
25.3	Sensor signal <item1> remains on. Sensor defective or deadlock. Turn off and on the power. If it reoccurs, contact technical support.	Check if an object cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.
25.4	Initialization of motor <item1> cannot be performed properly. Check if the SiHo is stuck or foreign objects cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.	Check if the SiHo is stuck or foreign objects cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.
25.5	Target position of motor <item1> not reached. Check if a SiHo is stuck or a foreign object cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.	Check if the SiHo is stuck or foreign objects cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.
25.6	Corrupted sample ID. Turn off and on the power. If it reoccurs, contact technical support.	Turn off and on the power. If it reoccurs, contact technical support.
25.7	Unexpected sample detected at sensor <item1>. Turn off and on the power. If it reoccurs, contact technical support.	Clean sensor. Remove foreign object.
25.8	Expected sample is not detected at sensor <item1>. Turn off and on the power. If it reoccurs, contact technical support.	Check if any SiHo is empty and a sample has fallen. Turn off and on the power. If it reoccurs, contact technical support.
25.9	The monitoring of motor position <item1> with sensor <item2> has detected an issue. It is not guaranteed, that the star is located in a defined position. Turn off and on the power. If it reoccurs, contact technical support.	Check if the SiHo is stuck or foreign objects cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.
25.10	Please remove the sample on barcode position. Turn off and on the power. If it reoccurs, contact technical support.	See message.
25.11	Barcode of sample on barcode position could not be read. How do you want to proceed?	If it reoccurs, clean barcode reader. Check barcode label.
25.12	Target position of motor <item1> not reached. Sensor <item2> has actual status=<item3>. Check if a SiHo is stuck or a foreign object cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.	Check if an object cause a blockage. Turn off and on the power. If it reoccurs, contact technical support.

Table E-1

This is the last page of Part E.

Appendix F

Appendix

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Table of contents

Applied Standards

Directives and regulations

Directive / Regulation	Subject
FDA CGMP Part 820 Subpart C: Design Control 820.30	CGMP Requirements of the Quality System Regulation
98/79/EC (IVDD)	In vitro diagnostic medical devices
2011/65/EU (RoHS)	Directive 2002/95/EC on restriction of the use of certain hazardous substances in electrical and electronic equipment
2002/96/EC (WEEE)	Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)

Table F–1 Applicable directives

Quality system standards

EN ISO 13485 +AC / 2012	Medical devices - quality management systems - requirements for regulatory purposes
EN ISO 14971 / 2012	Medical devices - Application of risk management to medical devices
EN 62304 2007-03 AC:2008	Medical device software - Software life cycle processes (IEC 62304: 2006-05)
EN 62366 / 2008-9	Medical devices - Application of usability engineering to medical devices (IEC 62366: 2007-10)
EN ISO 980 / 2008	Symbols for use in the labelling of medical devices
EN ISO 18113-1 / 2013-01	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-3 / 2013-1	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)

Safety-related standards

IEC 61010-1 / 3rd ed.	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 1: General Requirements
DIN EN 61010-2-81 / 2012-09	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes (IEC 66/484/CDV:2012)
IEC 61010-2-101 / 2003-09	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVY) medical equipment (IEC 61010-2-101:2002, modified)
UL 61010-1 / 2004	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
CAN/CSA C22.2 No 61010-1 / 2004	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements (for Canada)

EMC standards

IEC 61326-1 / 2013-07	Electrical Equipment for Measurement, Control and Laboratory Use -EMC Requirements- Part 1: General Requirements
IEC 61326-2-6 / 2013-09	Electrical Equipment for Measurement, Control and Laboratory Use -EMC Requirements- Part 2-6: Particular Requirements - In Vitro Diagnostic (IVY) Medical Equipment

Barcode label requirements

NOTICE

Use barcodes with checksums for the sample tubes being scanned. The barcode scanner and Liaison® XL Connection Module should only be used with checksum-enabled barcodes.

NOTICE

The barcode scanner cannot process multiple barcodes on a single tube! Each tube should be labelled with only one barcode.

- Barcodes should have checksums (CRC), unless the customer specifically wants to work without checksums. However, this is not recommended.
- When using "Codabar" or "Interleaved 2 of 5" labels, we recommend using at least six characters.
- When using "Code 128", "Code 39" or "Code 93" labels, we recommend using at least six characters because the cobas 8100 requires this length.
- We recommend using barcode labels of type "Code 128". According to the Barcode Standard AUTO2-A2, "Code 128" is specified as the preferred and safest type of barcode label. The cobas 8100 requires at least 6 characters.
- We recommend that you adhere to sections 6.2, 6.3, 6.4.2, 6.6, 6.7.1, 6.7.2, 6.7.3 of the AUTO2-A2 standard ("Laboratory Automation: Barcodes for Specimen Container Identification Approved Standard, Second Edition", as compiled by the Clinical and Laboratory Standards Institute).

Sample tube specifications

Usage of plastic tubes is mandatory. Tube diameter and length of the tube are normally rounded up or down on full millimeters in the manufacturer's brochures. Nevertheless, most standard tubes of the manufacturers fit these limitations. For example, the BD 16 x 100 serum tube, has a diameter of 15.3 mm that fits perfectly into the possible tube dimensions of the system.

All established hematology, coagulation, serum, plasma and urine tubes manufactured by BD, Sarstedt, Kabe, Greiner and Terumo can be used.

Tube dimensions

max. length of tube (without cap)	108.0 mm
min. length of tube (without cap)	65.5 mm
max. tube diameter	15.5 mm
min. tube diameter	12.0 mm

An example of a sample tube definition file is shown below. This file defines the types of tubes that can be used by the Liaison® XL Analyzer.

```
#*****************************************************************************
#* This file contains tube type list from Hitachi Cobas 8100.
#* You can edit the last column to assign tube type used by Diasorin Liaison XL
#* to tube type from Cobas 8100.
#*
#* Edit rules:
#* -----------
#* A comment line must begin with #
#* A line might not exceed 128 characters.
#*
#* The mapping table is formatted below:
#* Diameter|Length|Description|HHT|LXL
#*
#*****************************************************************************
16|100|16x100|000|6
16| 92| 16x92|001|10
16| 75| 16x75|003|5
13|100|13x100|010|4
13| 90| 13x90|012|8
13| 75| 13x75|013|3
16|100|16x100plug|100|6
16| 75|16x75plug|103|5
13|100|13x100plug|110|4
13| 75|13x75plug|113|3
16|100|16x100Guard|200|6
16| 75|16x75Guard|203|5
13|100|13x100Guard|210|4
13| 75|13x75Guard|213|3
16|100|16x100GBO|300|6
13|100|13x100GBO|310|4
13| 75|13x75GBO|313|3
16|100|16x100seal|400|6
13|100|13x100seal|410|4
13| 75|13x75seal|413|3
16| 92|16x92Sarst|501|10
16| 75|16x75Sarst|503|5
13| 90|13x90Sarst|512|8
13| 75|13x75Sarst|513|3
16|100|16x100restop|600|6
16| 92|16x92restop|601|10
16| 75|16x75restop|603|5
13|100|13x100restop|610|4
13| 90|13x90restop|612|8
13| 75|13x75restop|613|3
16|100|16x100KabeV|800|6
13|100|13x100KabeV|810|4
13| 75|13x75KabeV|813|3
16|100|16x100KabeG|850|6
16| 75|16x75KabeG|853|5
13|100|13x100KabeG|860|4
13| 75|13x75KabeG|863|3
```

Figure F-1 Example of tube type configuration file

Dimensions and weight

The total weight of the Liaison® XL Connection Module is approximately 80.5 kg. The dimensions are shown in the figures below.

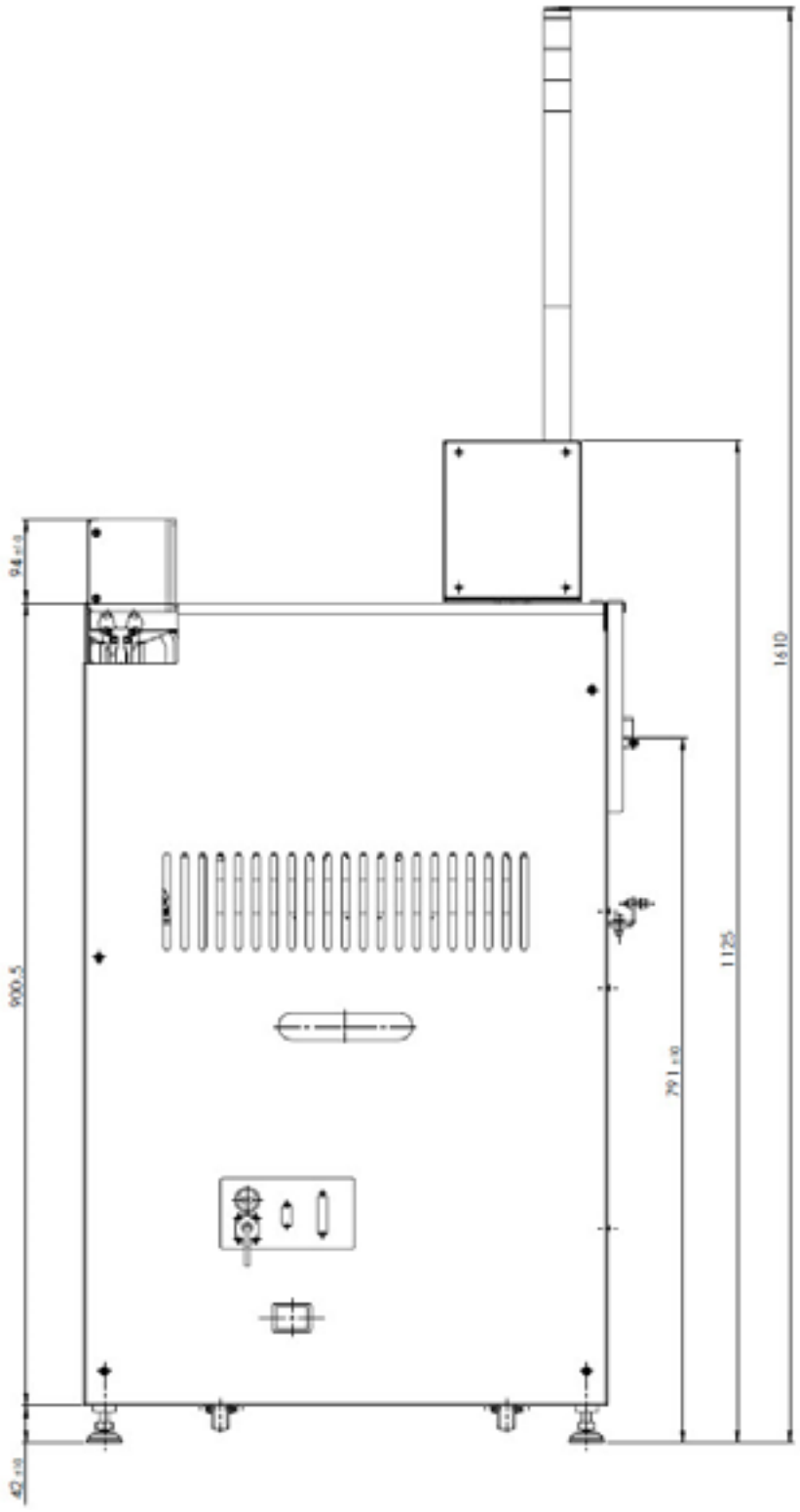

Figure F-2 Dimensions in mm, side view

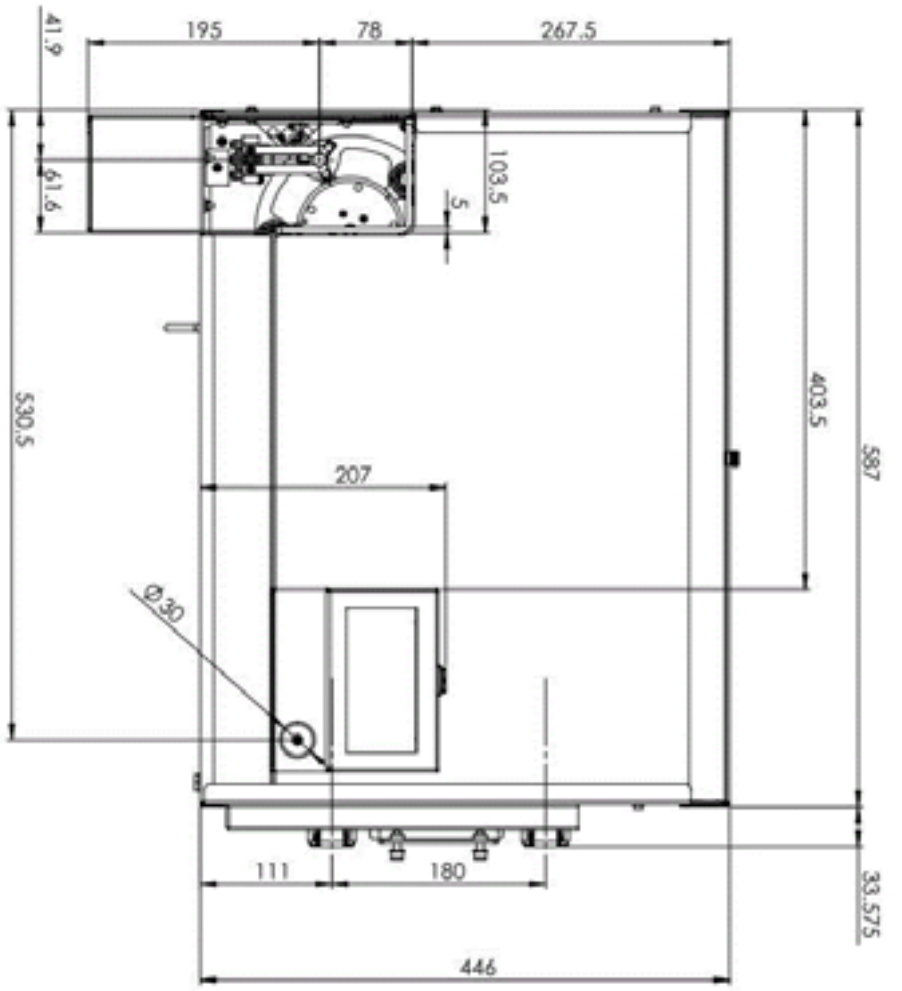

Figure F-3 Dimensions in mm, top view

Ambient conditions

The following ambient conditions and surroundings are required for the Liaison® XL Connection Module:

- A well-ventilated dust-free environment.
- No exposure to direct sunlight.
- Ambient light at barcode scanner: max. 5000 lux.
- A level floor (gradient must be less than 1/200).
- A floor that can support loads of at least 200 kg/m².
- Room temperature of 15 to 32 °C, with temperature gradient of max. ±2 °C/h (59 to 89.6 °F, ±3.6 °F/h).
- Room humidity of 30 to 85%, non-condensing.
- No perceptible vibration.
- No significant power fluctuations. The power supply must be 100 to 240 V (± 10%) at 50/60 Hz.
- No machines that emit ultra-high frequencies (e.g. equipment used in electro-surgery) may be in the vicinity.
- No equipment that generates electromagnetic interference (e.g. mobile phones, cordless telephones, or transceivers) may be in the vicinity.
- A power outlet must be within 5 m of the installed location.
- A three-wire mains cable with a safety ground (where the ground has a resistance of less than 10 Ω) must be used.
- The cables must not be subject to excessive loads. Avoid stepping or bending cables.

Power specifications

The supply voltages and power consumption are listed in the table below:

Parameter	Min. value	Nominal value	Max. value
AC voltage for power box (GS280A24-C4P)	100 V	230 V	240 V
AC voltage frequency	47 Hz	50 Hz	63 Hz
Power consumption with main switch off	N.A.	0.41 W	< 0.6 W
Power consumption during operations	N.A	85 W	180

Table F-2 Power specifications

This is the last page of Part F.