illumina®

Operating Manual

Infinium LiHa and Infinium RoMa

0 Preface

For Your Safety

Before performing any work on or with the Infinium LiHa and Infinium RoMa, first read the Operating Manual - Document # 1000000110155 v00 carefully, in particular chapter 2 “Safety”.

0.1 Manufacturer

Address of Manufacturer

Illumina Inc.
5200 Illumina Way
San Diego, CA 92122
United States

0.2 Use of the Product

0.2.1 Intended Use

Intended Use

The Infinium LIHA/ROMA is an automated robotic solution for sample preparation.

Note: *This product is intended for research use only (RUO) and will not be for clinical use.*

0.2.2 Improper Use

Improper Use

The Infinium LiHa and Infinium RoMa must not be used with options or components which are not approved by Illumina.

WARNING

The use of non approved options may impair the safety concept of the Infinium LiHa and Infinium RoMa.
This means that the safety and compliance to national and international standards, as required for UL/CSA certification, by EC directives, etc. cannot be ensured any more.

0.3 CE Conformity

Declaration of Conformity

The Infinium LiHa and Infinium RoMa is designed and built in compliance with the basic safety and health requirements of applicable EC Directives. With the declaration of conformity the manufacturer declares conformity with the provisions of the Directives.

CE Label

The CE label is affixed to the Infinium LiHa and Infinium RoMa.

0.4 CSA Certification

The Infinium LiHa and Infinium RoMa is tested and certified by the Canadian Standards Association (CSA).

CSA Marking

The CSA marking is affixed to the Infinium LiHa and Infinium RoMa.

Canada

IC Compliance

This Class A digital apparatus meets all requirements of the Canadian Interference - Causing Equipment Regulations.

This device complies with Industry Canada license - exempt RSS standards. Operation is subject to the following 2 conditions:

- 1 This device may not cause interference.
- 2 This device must accept any interference, including interference that may cause undesired operation of the device.

0.5 FCC Rules

FCC Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following 2 conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

CAUTION

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

Note: *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 instrumentation 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 users will be required to correct the interference at their own expense.*

Table of Contents

1 About This Manual

Purpose of This Chapter

This chapter points out the purpose of the manual, specifies the product the manual deals with and who the manual is intended for. Furthermore, it explains the symbols, conventions and abbreviations used and offers other general information.

Purpose of This Manual

This manual describes the Infinium LiHa and Infinium RoMa and provides all information required for its safe operation and to maintain it in good working order.

Product Pictures

The delivered instrument may not exactly match the product pictures shown in this operating manual.

Target Group

This manual is intended for everyone who wants to learn about the safe operation of the Infinium LiHa and Infinium RoMa and how to maintain its perfect working condition. In particular, laboratory personnel and operators are addressed.

Laboratory personnel operating Infinium LiHa and Infinium RoMa instruments require also thorough knowledge of applications, instrument functions and software programs as well as all applicable safety rules and regulations.

Scope

This manual is applicable for

- Illumina Infinium LIHA; P/N 20040483
- Illumina Infinium ROMA; P/N 20040482

Symbols and Conventions

- Cross-references appear as follows: e.g. “Refer to section “1.1.1 🗎 1-2“
  - 1.1.1 refers to the corresponding chapter number
  - The symbol 🗎 denotes “page number”
  - 1-2 refers to the page number, whereas the first number stands for the chapter number (chapter 1 page 2)

Note: *The symbols pertaining to safety (WARNINGS and ATTENTIONS) are explained in chapter 2 “Safety”, 🗎 2-1.*

1.1 Reference Documents

Additional reference documents are listed below but are not enclosed or linked.

What Does the Doc. ID Tell You?

The Doc. IDs listed below are root numbers. Therefore, they do not contain information about the language, document version or the medium (data storage medium, hardcopy, downloadable file, etc.) of the document.
Check the scope of the corresponding document to make sure that you are in possession of the correct version.

Note: *The Doc. ID does not represent ordering information. For orders refer to the number on the binder, CD casing, etc.*

Manuals supplied with Infinium LiHa and Infinium RoMa Instruments

The following manuals are included in the shipment and considered part of a Infinium LiHa and Infinium RoMa instrument:

- Infinium LiHa and Infinium RoMa Operating Manual (Document # 1000000110155)
- Infinium Assay Lab Setup and Procedures Guide (Document # 11322460)

Any individual or separate operating manuals for optional equipment according to your order configuration can be applicable.

For information about the liquids to use with the Infinium LiHa and Infinium RoMa, refer to section 3.5 “Chemical Resistance”, 3-17.

1.2 Trademarks

The following product names and any registered and unregistered trademarks mentioned in this manual are used for identification purposes only and remain the exclusive property of their respective owners (for simplicity reasons, the symbols for trademarks, such as ® and ™ are not repeated later in the manual):

- Windows® is a registered trademark of Microsoft Corporation
- Tygon® is a registered trademark of Saint-Gobain Performance Plastics Corporation
- Bacillol Plus® is a registered trademark of the Bode Chemie Hamburg
- Decon90® is a registered trademark of Decon Laboratories Limited
- DNAzap® is a registered trademark of Ambion Inc.

All trademarks are the property of Illumina, Inc. or their respective owners. For specific trademark information, see www.illumina.com/company/legal.html

1.3 Abbreviations

cLLD	Capacitive liquid level detection
CV	Coefficient of variance or variation
DMSO	Dimethyl sulfoxide
EN	European Norm
EPDM	Ethylene Propylene Diene Monomer
ETFE	Ethylene/Tetrafluoroethylene-copolymer
FEP	Tetrafluoroethylene/Perfluoropropylene-copolymer
FFPM	Perfluoroelastomer
FSE	Field service engineer
IAC	Illumina Automation Control
ILID	Integrated liquid detector
LH	Liquid handling
LICOS	Liquid container supervisor
LiHa	Liquid handling arm
MIO	Monitored incubator option
MP	Microplate
MPO	Monitored pump option
PCTFE	Polychlorotrifluoroethylene
PE	Polyethylene
PEEK	Polyetheretherketone
pLLD	Pressure based liquid level detection
PMP	Pressure monitored pipetting
POM	Polyoxymethylene
PP	Polypropylene
PosID	Positive identification option, barcode scanner
PS	Polystyrene
PTFE	Polytetrafluoroethylene
PVC	Polyvinylchloride
PVDF	Polyvinylidenefluoride
RoMa	Robotic manipulator arm
RF	Radio frequency

SPO	Sensored pump option
USB	Universal serial bus
UPS	Uninterruptable power supply
WHO	World Health Organization

2 Safety

This chapter describes the safety concept of Infinium LiHa and Infinium RoMa, provides general rules of correct behavior, and warnings concerning hazards associated with the use of the Infinium LiHa and Infinium RoMa.

2.1 Safety Message Conventions

2.1.1 Signal Words

WARNING indicates the possibility of personal injury or even loss of life if the instructions are not followed.

ATTENTION indicates the possibility of equipment damage, malfunctions or incorrect process results, if instructions are not followed.

2.1.2 Safety Symbols

General warning

Toxic material

Biological hazard

Fire hazard

Electrical danger

Crushing hazard

Laser hazard

Hot surface hazard

Wear protective gloves

Read this

Disturbance of functions by electromagnetic RF waves.
Do not use a cellular phone.

2.2 General Safety Information

WARNING

Infinium LiHa and Infinium RoMa are designed and built in accordance with the present state-of-the-art technology and the recognized technical safety regulations. Nevertheless, risks to users, property and the environment can arise if the Infinium LiHa and Infinium RoMa is used without due care and attention.

The safety of all users and personnel depends on the strict observation of these safety instructions and awareness of the safety-related warnings provided in this manual.

- Please pay great attention to the following general safety information.
- This manual must always be available to all persons performing the tasks described herein.
- Legal regulations, such as local, state and federal laws concerning the use or application, as well as the handling, of dangerous materials in connection with the Infinium LiHa and Infinium RoMa must be strictly followed.
- The operating company is responsible for defining instructions in accordance with company procedures and local legal requirements. The instructions provided by the operating company must be strictly observed.
- Observe the correct environmental conditions for storage and operation.
- Structural changes to the safety devices are forbidden.
- Damaged safety devices must be replaced immediately as described in this manual.
- The Infinium LiHa and Infinium RoMa must not be modified in any way without prior consultation and written approval of Illumina. Authorized modifications to the system may only be performed by an FSE certified for the repair and upgrading of the Infinium LiHa and Infinium RoMa.
  Illumina will reject any claim resulting from unauthorized modifications.
- Fire hazard caused by the improper use of the Infinium LiHa and Infinium RoMa. The Infinium LiHa and Infinium RoMa should not be installed in locations where there is a hazard of explosion.
- Chemical and biological hazards can be associated with the substances used or the samples and reagents processed with the Infinium LiHa and Infinium RoMa (e.g., during loading and unloading). The same applies to waste disposal.
  - Always be aware of possible hazards associated with these substances.
  - Use appropriate protective clothing, safety goggles and gloves.
  - The handling of substances and the disposal of waste may be subject to local, state, or federal law, or to regulations with regard to health, environment, or safety. Strictly observe the corresponding provisions.
- Any contamination must be dealt with immediately as described in this manual.
- The user is responsible for ensuring that the Infinium LiHa and Infinium RoMa is always operated under proper conditions, and that maintenance, service, and repair tasks are performed with care, on schedule, and only by authorized personnel.
- Risk of incorrect measuring results. After system care or maintenance has been performed, operation must only be resumed after the correct system operating conditions have been verified.
- Always use recommended consumables and original spare parts for maintenance and repair to assure good system performance and reliability.

- Lifting or moving the instrument can cause serious injuries
  - Injuries to the back due to overload can occur
  - Lifting or moving the instrument must be correctly prepared and may only occur under the direction of a qualified Illumina person
- Lifting or moving the instrument can cause damage due to unsecured parts
  - Lifting or moving the instrument must be correctly prepared and may only occur under the direction of a qualified Illumina person
- Potentially lethal voltage inside the instrument.
  - Equipment is to be connected to a grounded power source using an approved power cord with grounding (earthing) conductor.
  - Do not remove covers and other parts protecting from electricity.
  - Always keep the areas of electric parts, such as power supply plug, mains switch, etc., dry.
- Though the safety concept assumes that the safety panel is always closed during normal operation, it is necessary to have access to the elements in the working area behind the safety panel for setup, maintenance and troubleshooting purposes.
- Pointed tips and other sharp-edged elements, which might cause injuries when you reach into the working area with the safety panel open.
  - Always be aware of the mechanical hazards.
  - Wear laboratory apparel, rubber gloves, safety goggles, etc. as appropriate.
- Unsafe operating condition and wrong measuring results in the process, if the system is leaking.
  - If liquid is dripping from the tips or other parts of the liquid system, the Infinium LiHa and Infinium RoMa must not be operated any more.
  - Operation may only be resumed if the necessary maintenance or repair work has been performed and the proper condition of the system has been verified.

ATTENTION

Possible malfunction or functional failure.

Proper operation can be interfered by strong electromagnetic fields.

- Evaluate the electromagnetic environment before operating the device.
- Do not operate this system in close proximity to sources of strong electromagnetic fields (for example, unshielded intentional RF sources).

The operating company and the operator is responsible to ensure that a compatible electromagnetic environment for the system can be maintained in order that the device will perform as intended.

- Electromagnetic RF waves from a cellular phone may affect the function of the liquid detection.
  - Faulty detection of the liquid surface may be the consequence, which causes the system to produce incorrect results.
  - Keep a distance of at least 2 m from the instrument when using a cellular phone.
- Chemical and biological hazards can be associated with the substances used or the samples processed with the Infinium LiHa and Infinium RoMa.
  The same applies to waste disposal.
  - Always be aware of possible hazards associated with these substances.

  - Use appropriate protective clothing, safety goggles, mouth/nose protection and gloves.
- The handling of substances and the disposal of waste may be subject to local, state or federal law or regulations with regard to health, environment or safety. Strictly observe the corresponding provisions.
- Caustic substances can cause burns and eye injury.
  - Always be aware of possible hazards associated with these substances.
  - Avoid exposure to caustic substances.
  - Use appropriate protective clothing, safety goggles, mouth/nose protection and gloves.
- The instrument is not explosion protected. Not for use in Ex zones. When using flammable material take the risk of fire into consideration:
  - Avoid the formation and accumulation of flammable vapors.
  - Avoid the spillage of flammable material.
- Regarding all hazards (referring to the listed hazards earlier in this section) pay attention to the following:
  - Prior to using hazardous materials perform a risk assessment.
  - Consider specific workplace conditions, such as temperature, air ventilation, electrostatic discharge.
  - Make sure that the risk is acceptable prior to use of the instrument.
- Wrong sample results due to disturbances, such as electromagnetic fields or supply voltage fluctuations, caused by external devices.
  - Do not place devices emitting electromagnetic fields close to the instrument.
  - Do not connect devices that may interfere with the supply grid to the same power line as the instrument.
- For California residents only: This product can expose you to chemicals such as lead which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/product.

2.3 Operating Company

The operating company must ensure that the Infinium LiHa and Infinium RoMa, in particular the safety features, function properly and that all the personnel in contact with the instrument are adequately trained.

Responsibilities

- Method and process validation.
- Defining the processes in compliance with the Standard Operating Procedures.
- Ensuring that installation and operational qualifications (IQ OQs) have been completed.
- Ensuring that all personnel in contact with the Infinium LiHa and Infinium RoMa are adequately trained.
- Ensuring the availability of appropriate protective clothing and equipment.
- Ensuring the maintenance and safe operation of the Infinium LiHa and Infinium RoMa.
- Requiring adherence to laboratory safety regulations and directives.

2.4 User Qualification

The laboratory personnel must be fully qualified and trained to operate the Infinium LiHa and Infinium RoMa. The work described in this Operating Manual must only be performed by authorized personnel with the qualifications prescribed below.

Laboratory personnel must:

- have suitable technical training,
- be familiar with the laboratory safety regulations and directives,
- be familiar with the instructions for the safety elements of the instrument,
- use protective clothing and equipment,
- be familiar with and adhere to good laboratory practices,
- and have read and understood the instructions in the Operating Manual.

2.4.1 Operator

The operator (lab technician) works for the operating company.

Required Skills

- No specific application or system knowledge
- Command of local languages
- Command of English is preferable

The operator has application software access rights allowing him to run methods and perform system care.

2.4.2 Key Operator

The key operator (application specialist) supports the operating company or works for the same company.

Required Skills

- Extensive application knowledge
- Limited system knowledge
- Command of local languages
- Command of English
- In-depth knowledge of the corresponding software manual

Responsibilities

- Instructing the operator
- Writing, running and validating methods
- Helping the operator to solve problems with the instrument

2.5 Safety Elements

Safety Panels

The space around the worktable is protected with safety panels. Whereas the front safety panel can be opened, the other safety panels are permanently installed on the Infinium LiHa and Infinium RoMa.

WARNING

Injuries caused by moving parts
A not completely opened front safety panel might close automatically.

- Open the front safety panel completely (more than 180°).

Door Locks

During operation the front safety panel is locked by means of two door locks.
The safety concept of the Infinium LiHa and Infinium RoMa assumes that the front safety panel is always closed when the instrument is running.

WARNING

If the options which require modifications on the Infinium LiHa and Infinium RoMa are installed improperly, the safety concept may be impaired.
Always make sure that the options are installed in compliance with the instructions given by the manufacturer.

WARNING

If any safety element fails to operate as expected, e.g. if the door locks fail to lock or open at the expected time, immediately notify the Illumina field service engineer.

Which are Safety Elements?

The following figures show the elements of the Infinium LiHa and Infinium RoMa, which have a protective function or have in any other way to do with safety.

Infinium LiHa and Infinium RoMa with Standard Front Safety Panel

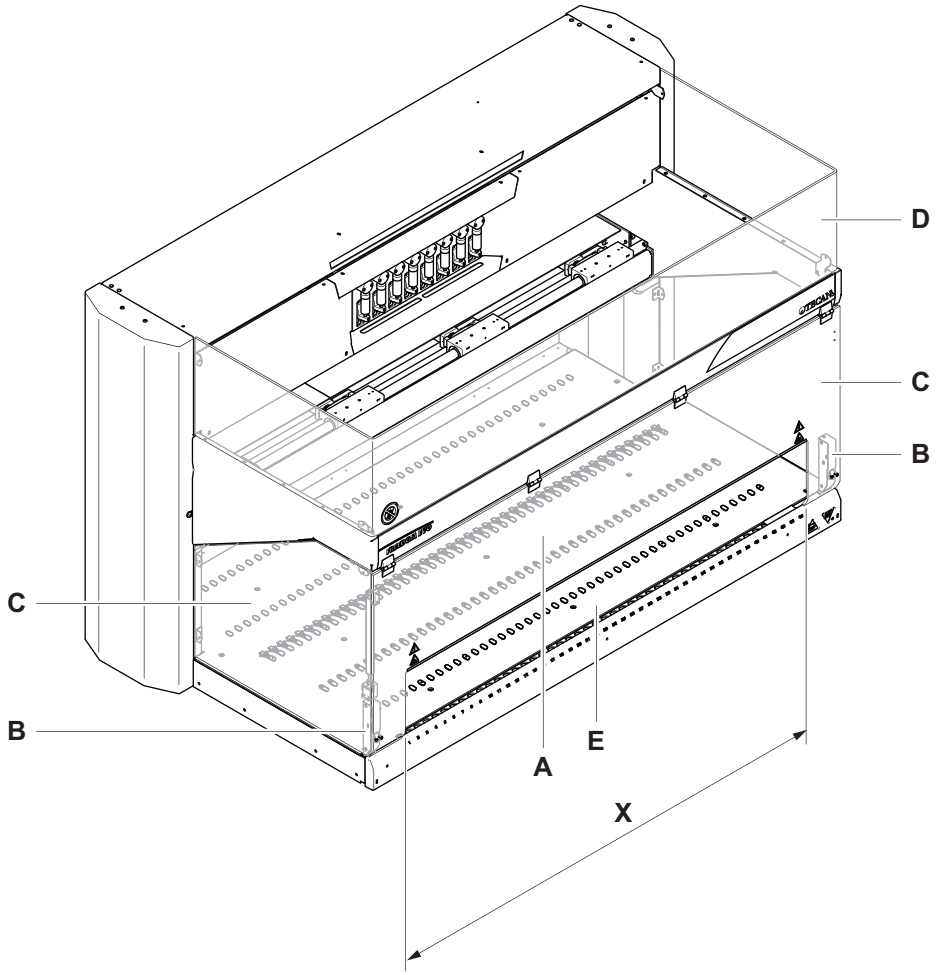


Fig. 2-1 *Safety elements / standard (open) front safety panel*

A	*Standard front safety panel*	***D***	*Top safety panel*
B	*Door lock*	***E***	*Loading interface (optional)*
C	*Side safety panel*	***X***	*Cutout for continuous loading*

General

Removal of Safety Elements

The protective and safety devices installed on the Infinium LiHa and Infinium RoMa must not be removed or disabled during operation.

In the event such elements were removed, e.g. for maintenance work, operation may only be resumed when all protective and safety devices have been completely installed and checked.

2.6 Product Safety Signs

Where are Safety Notices Attached?

Infinium LiHa and Infinium RoMa Instrument

The figure shows the safety notices that are attached to the Infinium LiHa and Infinium RoMa instrument. It also shows their locations:

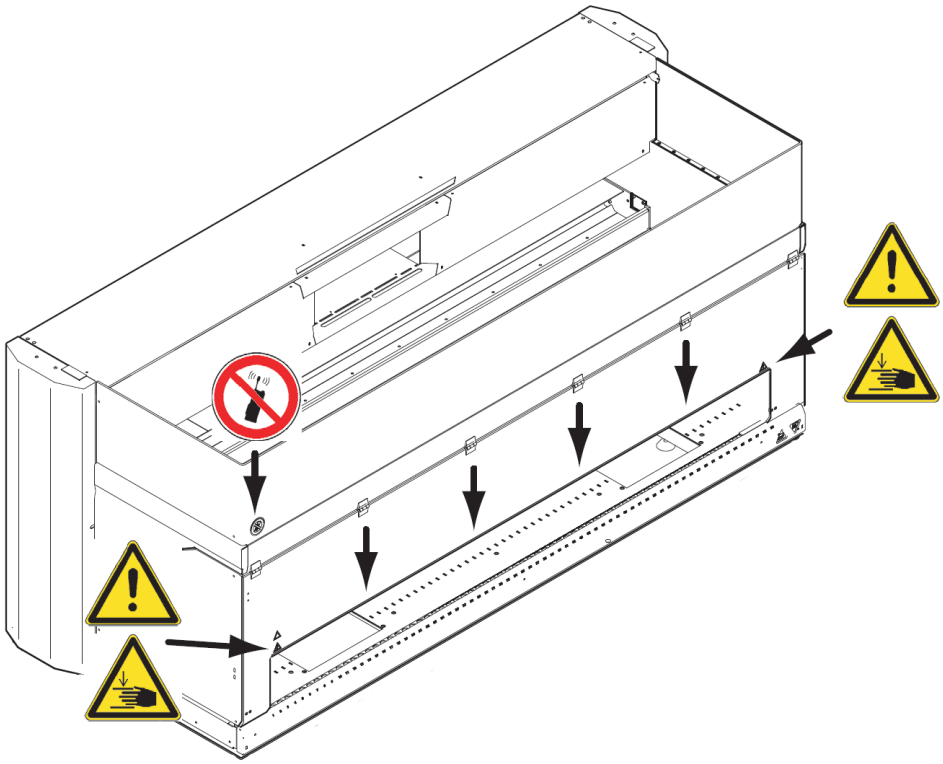


Fig. 2-2 *Safety notices attached to the product*

The following table explains the significance of the notices:

Tab. 2-1 *Significance of the safety notices*

Symbol	Significance
	Warning of hazards if you reach beyond the yellow line (see short arrows)
	Warning of hazards if you reach into the cabinet if, for instance, a reader is installed.
	Do not use a cellular phone

2.7 Laser Radiation

WARNING

Fig. 2-3 *Class 1 Laser Product*

Class 1 Laser Product pursuant to IEC 60825-1:2014
"Complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019."

PosID

Safety Notices on the PosID

The figure shows the safety notices that are attached to the PosID.

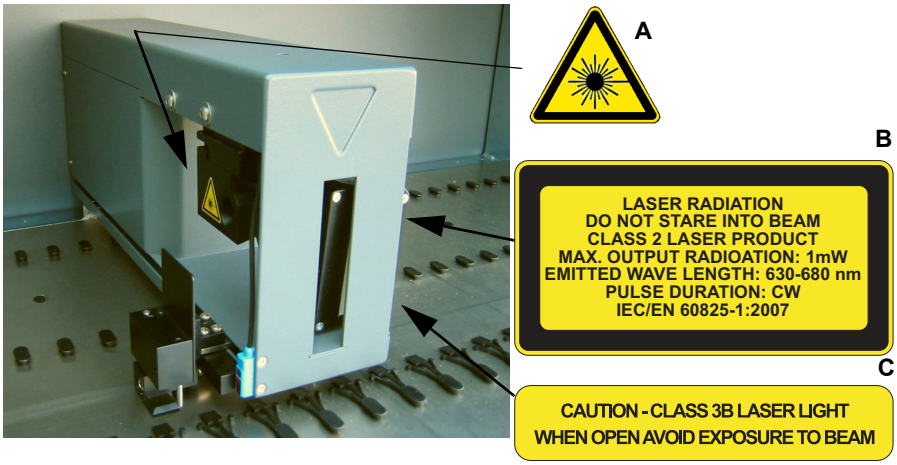


Fig. 2-4 *Laser labelling on PosID*

Class 2 Laser Product pursuant to IEC 60825-1:2007:
"Complies with 21 CFR 1040.10 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007"

Fig. 2-5 *Label on PosID scanner head*

Tab. 2-2 *Significance of the safety notices on the PosID*

Label	Significance	Location
A	**Warning label:** Laser hazard symbol	See Fig. 2-4 , 🗎 2-10
B	**Explanatory label:** Identifies a CLASS 2 LASER PRODUCT[a)] that contains an embedded visible low power laser barcode scanner. Warns against direct viewing into laser beam or its reflections.	On barcode scanner, see Fig. 2-4 , 🗎 2-10
C	**Label for panels:** Warns against removing or displacing of protective housing/panels, which permits human access to the laser light.	On barcode scanner, see Fig. 2-4 , 🗎 2-10
D	**Label for scanner head**: Warns against rotating the scanner head assembly by hand which could damage motor and head assembly.	On barcode scanner head, see Fig. 2-5, 🗎 2-11

a) According to IEC/EN 60825-1

RoMa Barcode Scanner

Safety Notices on the RoMa Barcode Scanner

The figure shows the safety notice attached to the RoMa barcode scanner:

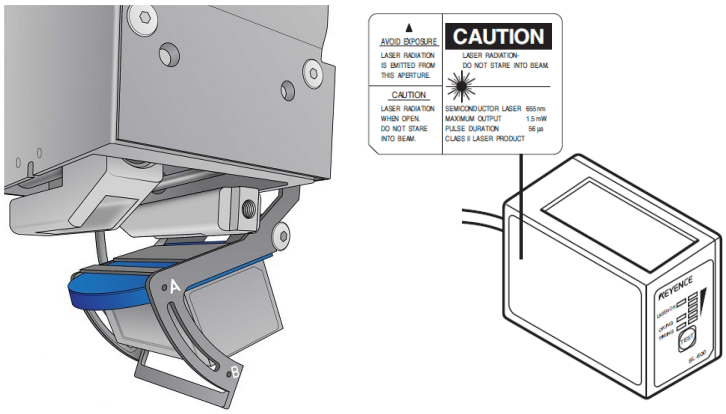


Fig. 2-6 *Laser labelling on the RoMa barcode scanner*

Tab. 2-3 *Significance of the safety notices on the RoMa Barcode Scanner*

Label	Significance	Location
A	Explanatory label: Identifies a CLASS 2 LASER PRODUCT[a)] that contains an embedded visible low power laser barcode scanner. Warns against direct viewing into laser beam or its reflections.	See Fig. 2-6 , 2-12

a) According to IEC/EN 60825-1:2007

WARNING

The barcode scanner on the ROMA arm is a Class 2 laser product. Looking directly at the laser beam may result in serious eye injury.

- Do not stare into the visible-light beam of the barcode scanner.

CAUTION

The laser beam is not harmful to the skin. There is, therefore, no danger in exposing arms or hands to the beam. The only possible health hazard is in exposing the eyes to the laser beam.

- Do not stare into the beam.

2.8 Decontamination Declaration

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Decontamination	See section 7.5 “Decontamination”, 7-22

When to Decontaminate

Apart from regular decontamination, the user must thoroughly decontaminate the instrument according to standard laboratory regulations in the following cases:

- Before any maintenance or service work is performed on the instrument
- In case of accidents (e.g. crash, spilled substances, etc.)
- Before a Illumina field service engineer (FSE) performs any on-site work on the instrument
- Before the instrument or parts of it are returned to Illumina (e.g. for repair)
- Prior to storage of the instrument
- Prior to disposal of the instrument or parts of it
- Generally before the instrument or parts of it leave the user’s site

Decontamination Method

The decontamination method must be adapted to the respective application and the substances associated with it. The user takes the full responsibility for the appropriate decontamination of the entire equipment.

WARNING

Biological or chemical hazard and/or radioactive radiation.

Contamination hazard due to parts of the instrument which are not completely decontaminated.

Not only the parts having direct contact with chemicals or biological material must be treated, but also the tubing system as well as the whole upstream equipment.

Certificate of Decontamination

Before a Illumina FSE carries out any work on the instrument, or before the instrument is returned to Illumina, the owner of the instrument must confirm in writing that the decontamination has been performed properly and in accordance with good laboratory practice guidelines. For this, the owner must enclose a declaration (e.g. Certificate of Decontamination).

Illumina can provide the corresponding forms (Certificate of Decontamination or Repair Order) in case the owner of the instrument has no template for such a declaration at hand. Contact the Illumina helpdesk for further information.

Note: *Illumina reserves the right to refuse any instrument or a part of it, or will charge an extra fee, if the decontamination is not declared sufficiently.*

3 Technical Data

Purpose of This Chapter

This chapter introduces the reader to the Infinium LiHa and Infinium RoMa and its main components. It contains technical data, requirements and performance data.

3.1 Introduction

What is Infinium LiHa and Infinium RoMa?

The Infinium LiHa and Infinium RoMa is a precision instrument designed for automating specific steps in the Illumina Infinium Array Workflow. The Infinium LiHa and Infinium RoMa is an open and flexible platform.

Delivery

The Infinium LiHa and Infinium RoMa is delivered only to Illumina authorized field service engineers, who take responsibility for assessing and investigating each installation at an end-user site to comply with local requirements.

3.1.1 Infinium LiHa and Infinium RoMa Overview

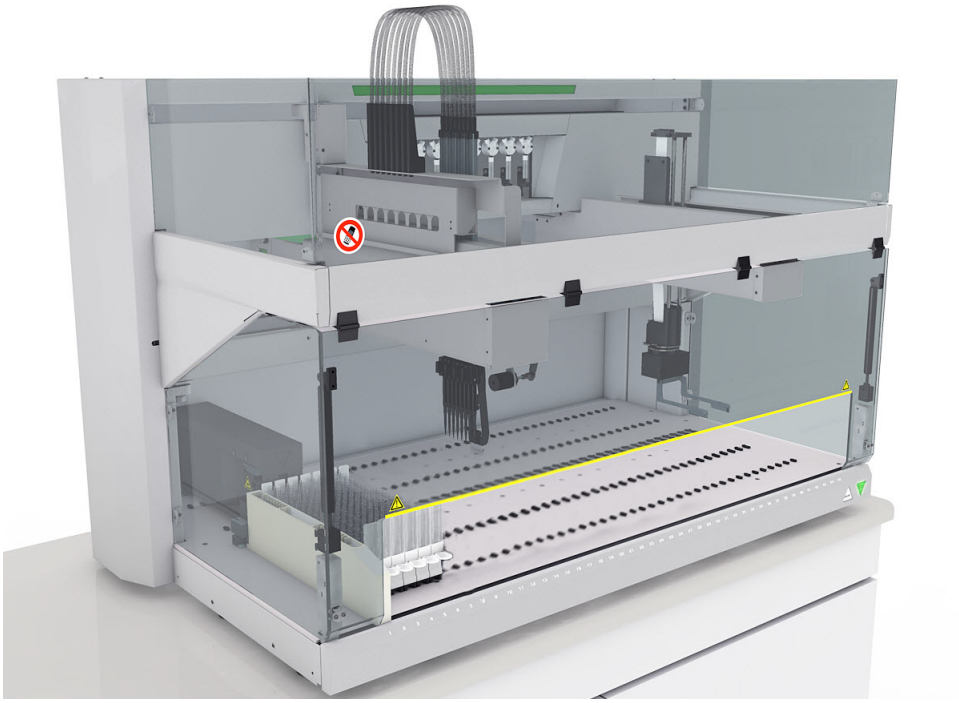


Fig. 3-1 *Instrument overview*

3.1.2 Product Identification and Labeling

Type Plate

Details for product identification can be read from the type plate, which is located on the back side of the instrument near the power inlet.

On the type plate (A) you find the following information:

- Identification data
  - Model
  - REF: Ordering information (material number)/revision level
  - Production date
  - SN: Serial number
- Technical data
  - U, f: Supply voltage (Volts), frequency (Hertz)
  - P: Power consumption (VA)
  - Fuse: Required fuse protection (A)
- Manufacturer’s name and address
- Conformity marking

Serial Number Label

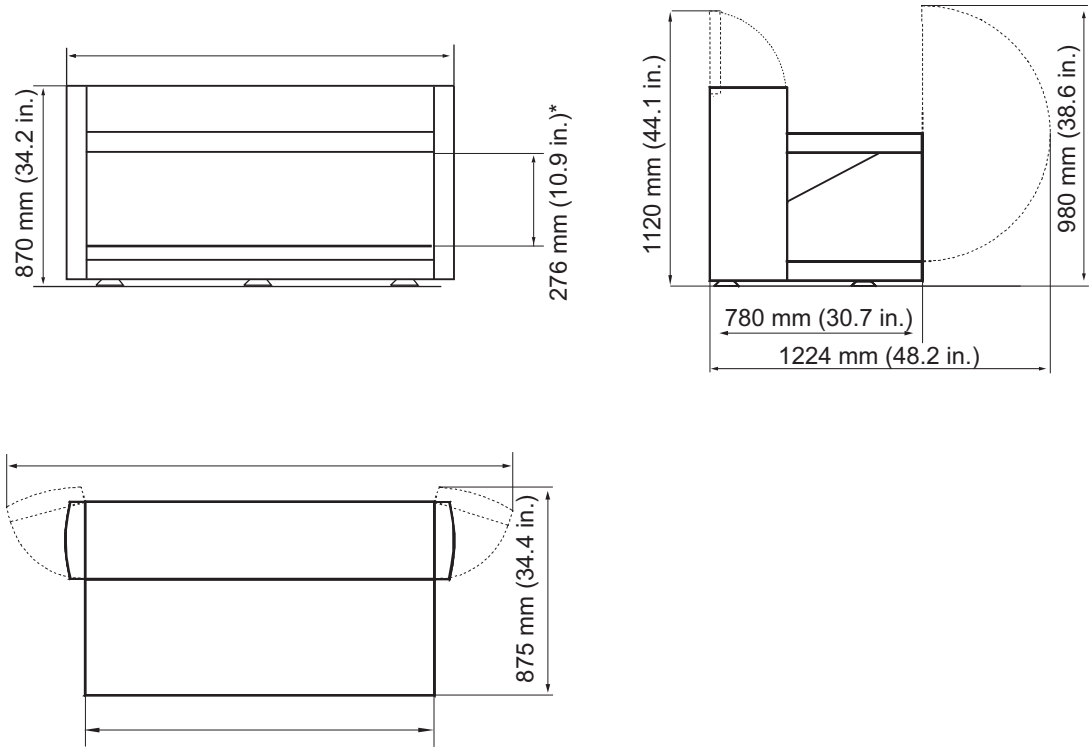
The identification data is also printed on the serial number label (B). This label can be viewed from the front side of the instrument. It is attached below the diluters.

3.2 Technical Data

3.2.1 Dimensions and Weights

Instrument Overall Dimensions

The figure shows the dimensions of the instrument:



*maximum height for objects under the x rail

Fig. 3-2 *Instrument overall dimensions*

Instrument Height

Tab. 3-1 Instrument heights

Instrument equipped with:	Instrument height:	
Liquid handling arm, LiHa	980 mm	38.6 in.
Robotic manipulator arm, RoMa	920 mm	36.2 in.

Weights

Tab. 3-2 Instrument/modules weights

	Infinium LiHa and Infinium RoMa 150
Platform	130 kg / 286.6 lbs
LiHa	9 kg / 19.8 lbs
RoMa standard	6.9 kg / 15.2 lbs
XP SMART[a)]	0.8 kg / 1.8 lbs
PosID	8.9 kg / 19.6 lbs
Packaging	50.5 kg/111.3 lbs

a) Eight diluters, according to instrument configuration

3.2.2 Supplies

Supply Ratings

Tab. 3-3 Supply ratings

	Infinium LiHa and Infinium RoMa 150
Line voltage (single phase)	100 - 120, 220 - 240 V AC (-15% / +10%)
Frequency	50/60 Hz
Power	1200 VA
Fuses	2 x T10A (instrument power) 2 x T2A (main powered options)

Note: *Considering possible undervoltage on the mains supply, the combined power consumption in the lower input voltage band (100 - 120 VAC) must not exceed 1000 VA in order to keep the input current below the fused values.*

Electrical Safety

Classification with regard to electrical safety according to EN/IEC standards:

Tab. 3-4 *Electrical specifications (safety)*

Overvoltage category	II	IEC 60664-1
Pollution degree	2	(EN) IEC 61010-1

Power Switch

The power switch is placed at the level of the front access panel. The power switch does not switch the mains voltage directly, but gives a control signal to the power supply.

Tab. 3-5 *Power switch specifications*

Specification	Description
Circuit break	By unplugging the instrument.
Power on delay	0.2 - 0.5 sec.
Power off delay[a)]	1 - 2 sec.

a) To prevent unintentional switching off, which could result in loss of process data

Note: *At installation or later movement of the instrument, ensure that it is always possible to unplug the mains cable at the instrument.*

3.2.3 Status Lamp

The status lamp is located above the diluters in the center of the instrument front surface. It displays the instrument operational states with red and green light that is either continuous or flashing. When the status lamp light is red, an acoustic alarm sounds (status lamp functions: Refer to 6.2 “Operating Modes”, 6-3).
The illuminated area is 540 x 18 mm (21.26 x 0.7 in.).

3.2.4 Environmental Conditions

All instruments are intended for indoor operation and storage only. The tables below give an overview.

ATTENTION

Barcodes cannot be read due to the influence of sunlight or other light sources on the barcode scanner.

- Do not expose the instrument to direct sunlight.
- Do not install strong light sources that may impair the function of the barcode scanner near the instrument.

Operating Conditions

Operating temperature	15°C to 32°C (59°F to 90°F)
Operating humidity	30% to 80% relative (non condensing) at 30°C (86°F) or below
Operating altitude	max. 2000 m above sea level

Pipetting Conditions

Pipetting temperature	20°C to 27°C (68°F to 80.6°F)
Pipetting humidity	30% to 60% relative (non condensing) at 25°C (77°F) or below

Storage Conditions

Storage temperature	1°C to 60°C (34°F to 140°F)
Storage humidity	5% to 80% relative (non condensing) at 30°C (86°F) or below

Transport Conditions

Transport temperature	-20°C to 60°C (-4°F to 140°F) for maximum 24 hours
Transport humidity	20% to 80% relative (non condensing) for maximum 24 hours

3.2.5 Emissions

Noise Emission

Noise emission (EN61010-1)	< 85 dBA [61.3 dBA (sound pressure), measured at a distance of 1 m from the instrument]

3.2.6 Electromagnetic Compatibility

The system complies with the emission and immunity requirements described in IEC 61326-1 and IEC 61326-2-6.

The system has been designed and tested to CISPR 11 Class A.
In a domestic environment the system may cause radio interference, in which case measures may need to be taken by the operator or the operating company to mitigate the interference.

3.2.7 I/O Interfaces

The instrument is connected via USB to the control PC.

Tab. 3-6 *USB Interface Specification (Instrument)*

Interface	Voltage	Current
USB 2.0	4.4 V to 5.25. V	max. 500 mA

3.3 Requirements

3.3.1 Computer Requirements

- USB port (standard)
- RS232 port (optional)

3.3.2 Software Requirements

This instrument is compatible with IAC 6.0 or higher.

3.3.3 System Liquid Requirements

System Liquid

System liquid refers to a liquid which fills the liquid system and is used as wash fluid.

- Standard liquid
  - Deionized or distilled water with a conductivity between 0.5 µS/cm and 10 µS/cm
- The system liquid must be free of particles.
- Make sure that the system liquid container is clean.
- The system liquid must be free of air bubbles and must be room temperature.
- To reach the pipetting performance we recommend degassing the system liquid. For further information on this issue, please contact your responsible application specialist.
- In order to ensure that during operation no air bubbles form in the pipetting tubing, a sufficient quantity of system liquid must circulate in the system. We recommend at least 60 ml per hour.

Any additives to the system liquid must be validated to evaluate the influence on the pipetting performance and the overall analytical process.

3.3.4 Sample Requirements

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Sample preparation	See section 6.3.4.3 “Preparation of Samples”, 🗎 6-15

The instrument is validated for pipetting deionized water. Other liquids are only allowed after validation according to laboratory practice and state-of -the art by the kit manufacturer or operator of the system.
For sample preparation refer to cross references above.

3.4 System Modules

The system modules are briefly introduced in the following sections. According to your order configuration, some of these options might be installed.

3.4.1 Liquid Handling Arm (LiHa)

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Gravimetric precision test	See 7.4.1 “Liquid Handling Performance Verification Testing”, 7-22

The LiHa arm is used for pipetting actions in different volume ranges, depending on the tip types used and the features of the liquid system.

LiHa Operating Ranges

Tab. 3-7 *LiHa operating ranges (relative movement)*

Axis	LiHa type	Infinium LiHa and Infinium RoMa
X-axis	All	Refer to Tab. 3-3 “Supply ratings”, 3-4
Y-axis	8-tip LiHa[a)]	373 mm (14.7 in.)
Z-axis[b)]	All	210 mm (8.27 in.)

a) at 9 mm spacing
b) each channel individually, no tips installed

LiHa Precision

Tab. 3-8 *LiHa positioning accuracy at 9 mm spacing, with all 8 tips simultaneously*

Axis	Accuracy
X	±0.4 mm (0.016 in.)
Y	±0.4 mm (0.016 in.)
Z	±0.4 mm (0.016 in.)[a)]

a) Worn parts may result in deterioration of accuracy

Tab. 3-9 *LiHa repeatability at 9 mm spacing, with all 8 tips simultaneously*

Axis	Repeatability
X	±0.15 mm (0.006 in.)
Y	±0.15 mm (0.006 in.)
Z	±0.3 mm (0.012 in.)[a)]

a) Worn parts may result in deterioration of repeatability

Equidistant Tip Movement

The equidistant movement of sampling tips in Y direction is:

- from 9 mm ± 0.4 mm
- to 38 mm ± 1 mm

Liquid Level Detection

Each tip can individually detect the surface of a conductive liquid by measurement of changes in capacitance. Each channel has an individual liquid detection. Generally, detection of conductive liquids of following volumes is possible:

- ≥ 50 µl: low-conductive liquid in microplates with round bottoms
- ≥ 100 µl: conductive liquid in sample tubes with a diameter of 10 or 13 mm
- ≥ 150 µl: conductive liquid in sample tubes with a diameter of 16 mm
- ≥ 5 ml: conductive liquid in reagent trough

Wetted Materials

The standard liquid system components that come into contact with either system or sample liquid are of the following materials:

Tab. 3-10 *Liquid system components: materials*

Component	Material
Pipetting tubing	FEP
Tubing (waste, part of aspirating tubing)	Silicone
Distributor 1:4	POM
Aspirating tubing	PVC
Wash stations, Y-connectors	PP
FaWa	FFPM (membrane), PP (body)
Pressure relief valve	PP
Valves (diluters)	PCTFE (Kel-F)
Syringes	Borosilicate glass
Syringes, seals	PTFE
Tips	Stainless steel, PTFE[a)]
Liquid containers	HD-PE

a) Coating

Also refer to section **3.5 “Chemical Resistance”,** 3-17.

3.4.2 Robotic Manipulator Arm Standard (RoMa)

The Infinium RoMa instrument is equipped with a robotic manipulator arm.
The robotic manipulator arm is used to transport objects of the format of microplates, such as reagent blocks, deep well plates, etc. from one to another position on the worktable or for storage onto the shelf.

Tab. 3-11 *RoMa standard technical data*

Force in Z-direction	60 N
Z-range	Total range: 259 mm (10.2 in.) Work range: 257 mm (10.12 in.)
Transportable mass	max. 0.4 kg (0.88 lbs)
Gripper force	10 N
Gripper space range	58 to 140 mm (2.28 to 5.51 in.)
Rotation angle	270° (left or right oriented)

ATTENTION

Improper transport of labware (microplates, etc.)
Use only labware that is rigid enough not to be deformed by the gripper force.

3.4.3 Positive Identification (PosID)

What Is PosID?

The PosID (positive identification module) reads barcodes on carriers and containers e.g. sample tubes, microplates, etc.

Performance Data

The PosID is able to read horizontal and vertical barcodes.

Tab. 3-12 *General PosID performance data*

Number of different container code types per application	Up to 6 different container code types can be used at the same time
Reading positions on carrier	Up to 24 container positions
Max weight of a carrier to be handled by PosID	2.2 kg (4.85 lbs)
Immunity against external light sources	External light below 8000 lux is harmless
Work range for carriers (clear worktable, i.e. no elements, such as incubators that restrict the PosID access range, present)	The PosID can read the carrier ID in any grid position[a)]
Work range for containers on the worktable (clear worktable, i.e. no elements, such as incubators that restrict the PosID access range, present)	Restriction: The PosID cannot read the container IDs of carriers in the two rightmost grid positions[a)]
Throughput: Required time to read 10 strip racks (16 positions)	Max. 90 s (including carrier ID)

a) Restrictions due to additional elements on the worktable, e.g. incubators.

ATTENTION

Barcodes cannot be read due to the influence of strong light sources (direct sunlight, artificial lighting, etc.).

- Make sure that the PosID is not exposed to direct sunlight.
- Do not install strong light sources near the PosID.

Reading Characteristics

The following typical read and detection rates can be expected:

Tab. 3-13 *Reading/detection data*

Item to be detected	Reading speed	Read rate[a)]	Detection rate[b)]
Carrier ID barcode	300 mm/s	99.9%	-
Container ID barcode, tubes of 16 mm diameter in carrier with 16 positions	300 mm/s	99.8%	99.98%
Container ID barcode, tubes of 10 mm diameter in carrier with 16 positions	300 mm/s	99.8%	99.98%
Container ID barcode, tubes of 10 mm diameter in carrier with 24 positions	200 mm/s	99.8%	99.98%
Container ID barcode, 3 microplates on carrier, landscape position	300 mm/s	99.8%	-
Container ID barcode, 100 ml trough on carrier	100 mm/s	99.8%	-

a) Barcode scanner
b) "No Tube" sensor, glass or plastic tube, filled or empty, with or without barcode

Barcode Symbology Types

The PosID recognizes a number of different barcode types. Not all types provide for sufficient reading security.

For that reason, the following considerations must be taken into account when defining the barcode types to be used for container identification:

Tab. 3-14 *Barcode symbology types*

Symbology	Characteristics	Recommendation
Code 128	Variable length, high density, alphanumeric symbology. Three different character sets can encode • upper case and ASCII control characters, • upper and lower case characters, • or numeric digit pairs. Employs a check digit for data security.	Recommended[a]. Widely used and good reading security.
Code 39 Standard[b]	Variable length, alphanumeric symbology. The character set can encode upper case, numeric, and the characters -.*$/+%. The asterisk (*) is reserved as start / stop character. Allows for a (modulo 43) check digit.	Use only with check digit (modulo 43).
Code 39 Full ASCII[b]	Same as code 39 standard, but can encode the complete 128 ASCII character set (including asterisk).	Use only with check digit (modulo 43).
Codabar[b]	Variable length symbology. The character set is restricted to numerics and the characters -$:/.+ABCD, whereas A, B, C and D are used as start and stop characters. Allows for a (modulo 16) check digit.	Not recommended (reading security). May only be used with defined code length and check digit (modulo 16).
Interleaved 2 of 5[b]	Variable length, high density, numeric symbology. Pairs of digits can be encoded in an interleaved manner (bars and spaces). **If partially scanned, there is the possibility of a barcode being decoded as a valid (but shorter) number.** Optionally allows for a (modulo 10) check digit.	Do not use (reading security insufficient). May only be used with defined code length and check digit (modulo 10). At least 6 characters are necessary.

a) Also used for standard carrier ID barcodes

b) The application SW may restrict the use of barcode types. See section "Permissible Barcode Types" below.

Barcode Label Quality

Barcode Label Specifications

The barcode labels must fulfil the following specifications:

- Module width: 5 to 15 mils (0.127 to 0.381 mm)
- Quiet zone (QZ): ≥ 5 mm
- Barcode height: min. 7 mm
- Barcode length: Max. 64 mm (without quiet zone)
- Number of characters: Max. 32
- Black symbols on white background

Standards define the quality of the barcode labels regarding symbol contrast, reflectance and edge determination, etc.

To avoid misreadings, the quality of the barcode labels must be graded **A**, **B** or **C** according to **ANSI X3.182** and **DIN EN 1635**. Illumina recommends using grade **A** for best reading performance.

A quality system in the production of barcode labels must be employed to ensure the conformity to the quality grades mentioned above.

Recommendations

To ensure good reading results, pay attention to the following recommendations:

- Use barcode testing device to verify the barcode quality.
- Print quality: Use barcodes printed by means of a thermal-transfer or photographic printer.
- Barcode label surface must be mat and clean.
- Do not use yellowed, stained, creased, wet or damaged barcode labels.

Barcode Label Positioning

Note: *The legibility of the barcodes can be increased by positioning the barcode labels accurately.*

Barcode Label on Tubes

The figure shows the dimensions for barcode label positioning on tubes.

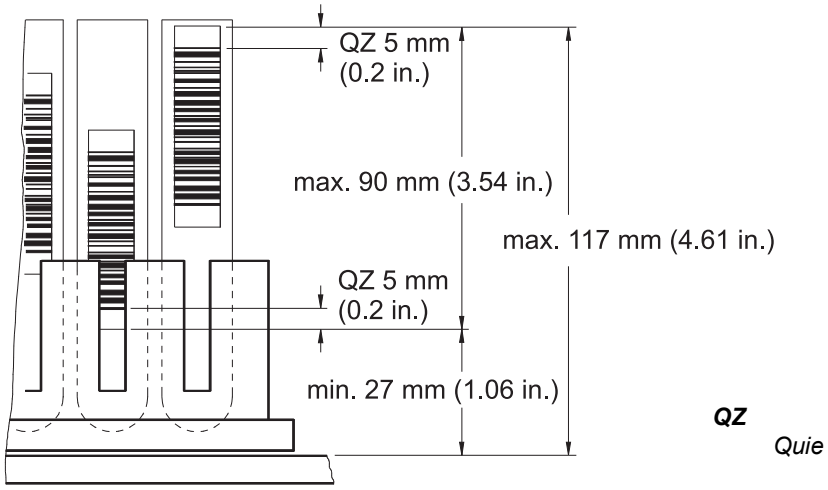


Fig. 3-3 *Barcode label on tubes*

Barcode Label on Microplate

The figure shows the dimensions for barcode label positioning on microplates.

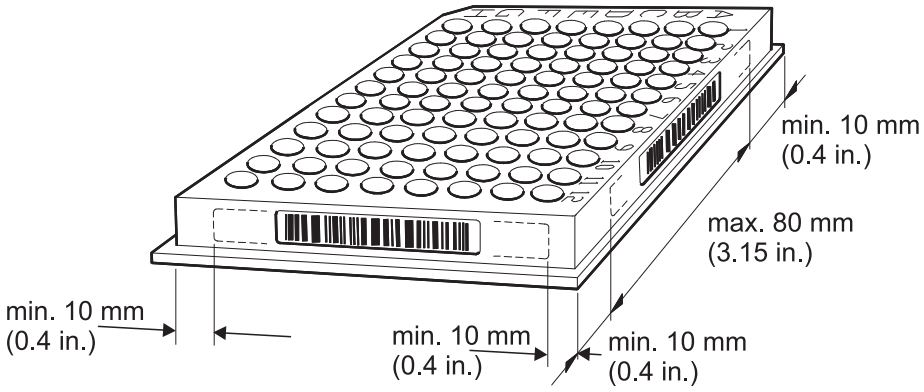
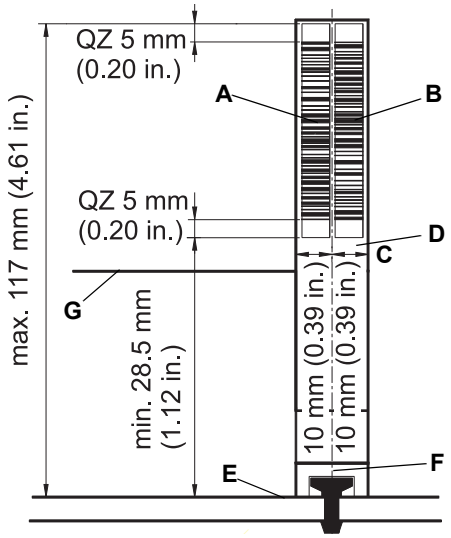


Fig. 3-4 *Barcode label on microplate*

Barcode Label on Carrier

The figure shows the dimensions for barcode label positioning on carriers:



A *Carrier ID code 1*
B *Carrier ID code 2 (used for verification)*
C *Max. distance from pin center*
D *Carrier barcode label support*
E *Worktable surface*
F *Center of positioning pin*
G *Carrier body*
QZ *Quiet zone*

Fig. 3-5 *Barcode label on carrier*

3.4.3.1 Permissible Barcode Types

Note: *Depending on the application software, not all barcode types readable by the PosID may be supported.*

Refer to your Application Software Manual to find out the permissible barcode types.

3.5 Chemical Resistance

3.5.1 Standard Materials Resistance Table

Chemical Resistance

In the following the chemical resistance of the used (standard) materials is specified:

Tab. 3-15 *Chemical resistance table*

Material	FEP	PVC	Silicone	POM	PVDF	PP	PTFE	FFPM	PCTFE[a)]	ETFE
Acetone	o	/	o	x	/	o	o	o	o	o
Acetonitrile (C_2H_3N)	o	/	/	/	x	o	nd	nd	nd	o
Formic acid 100 %	o	x	x	/	x	o	o	x	o	o
Ammonium hydroxide 25 %	o	x	o	/	o	o	o	nd	o	o
Chloroform	o	/	/	x	o	x	o	x	x	/
Dimethyl-formamide	o	/	/	/	/	o	o	o	o	/
DMSO	o	/	x	o	/	o	nd	nd	nd	o
Acetic acid 96 %	o	/	x	/	o	x	o	o	o	x
Acetic acid ethy-lester	o	/	/	x	/	x	nd	nd	nd	x
Ethanol 96 %	o	x	x	o	o	o	o	o	o	o
Formaldehyde 40 %	o	x	x	x	o	o	o	x	o	o
Sulfuric acid 40 %	o	x	/	/	o	o	o	o	o	o
Sulfuric acid 96 %	o	/	/	/	/	x	o	o	o	o
Isopropanol	o	/	x	o	o	o	o	o	o	o
Diluted bleach, NaOCl	o	x	x	/	o	x	o	o	o	o
Methanol	o	x	o	x	o	o	o	o	o	o
Methylene chlo-ride	o	/	/	x	/	/	o	o	o	/
Sodium hydroxide 10M	o	x	o	/	x	o	nd	nd	nd	o

Tab. 3-15 *Chemical resistance table (cont.)*

Material	FEP	PVC	Silicone	POM	PVDF	PP	PTFE	FFPM	PCTFE[a)]	ETFE
Perchloric acid 60 %	o	/	/	x	o	x	o	x	x	/
Petroleum ether 30/50	o	x	/	x	o	/	nd	nd	nd	x
Hydrochloric acid 32 %	o	x	/	/	o	o	o	o	o	o
Trichloroacetic acid 40 %	o	/	/	o	o	/	o	o	o	x

a) Kel-F

Legend:

o	resistant
x	partly resistant, use is possible with frequent replacements
/	not resistant, unsuitable for use
nd	not determined

4 Description of Function

Purpose of This Chapter

This chapter explains the basic principle of the Infinium LiHa and Infinium RoMa, shows how it is structured and gives a functional description of the assemblies.

4.1 Introduction

Main Parts

The instrument consists of a platform that includes worktable, frame, housing, main electronic boards and power supply.

Robotic Arms

It can be equipped with

- liquid handling arm (LiHa). The LiHa includes a liquid system with diluters.
  - The LiHa is used for liquid handling (pipetting, diluting, etc.)
- robotic manipulator arm (RoMa).
  - The RoMa is used to transport racks, such as microplates.

Sample/Carrier Identification

A positive identification module (PosID) is available to automatically identify carriers and containers on the worktable by means of a barcode scanner.

Control

The operator controls the system via a personal computer, on which the instrument software as well as the relevant application software are installed.

4.2 Structure

4.2.1 Mechanical Structure

The figure shows the main parts of the Infinium LiHa and Infinium RoMa:

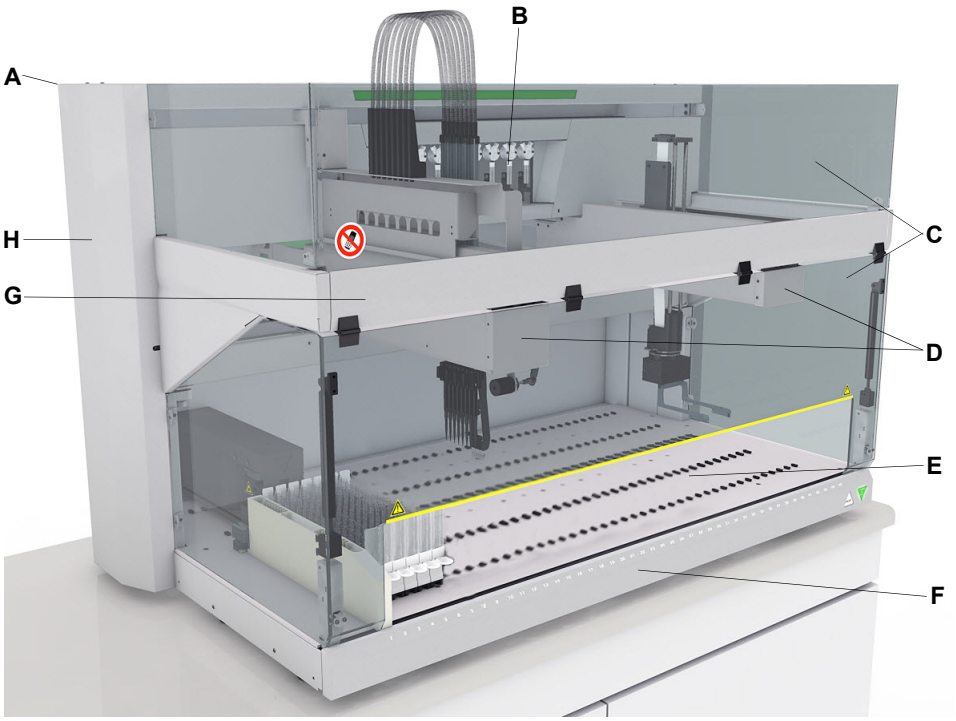


Fig. 4-1 *Infinium LiHa and Infinium RoMa instrument overview*

A	*Housing*	***E***	*Worktable with positioning pins*
B	*Diluters with syringes*	***F***	*Front access panel*
C	*Safety panels*	***G***	*Frame*
D	*Robotic arms*	***H***	*Electronic boards behind lateral covers*

4.2.2 The Infinium LiHa and Infinium RoMa Worktable

Positioning Pins

On the Infinium LiHa and Infinium RoMa worktable, evenly spaced positioning pins ensure proper positioning of all carriers according to the grid represented within the software. One grid position defines the minimal width of carriers, e.g. wash stations and strip racks for tubes. The positioning pins also enable the sliding of carriers/racks in Y-direction.

Sliding Carriers and Racks

Sliding carriers and racks are needed for:

- Replacement (loading/unloading) of carriers or racks during operation,
- The identification of tubes, microplates, troughs etc. on carriers by the PosID.

4.2.3 Liquid System Structure

Liquid System refers to all instrument modules and parts which contain or directly influence liquid. The figure shows an example for an eight-tip configuration with one liquid handling arm.

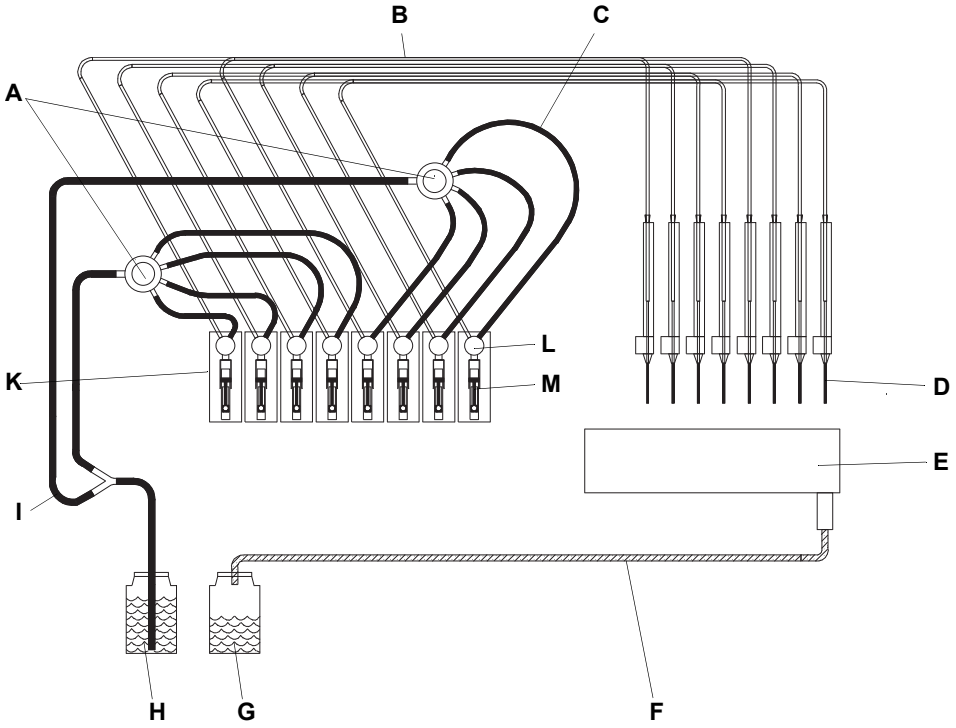


Fig. 4-2 *Liquid system: principal components*

A	*Distributors 1 to 4*	***G***	*Waste container*
B	*Pipetting tubing*	***H***	*System liquid container*
C	*Interconnecting tubing*	***I***	*Aspirating tubing*
D	*Tips*	***K***	*Diluters*
E	*Wash station*	***L***	*3-way valve*
F	*Waste tubing*	***M***	*Syringe*

In case of a second liquid handling arm, each LiHa is equipped with its own parts, i.e. the two liquid systems are independent.

4.3 Function

4.3.1 Liquid Handling Arm (LiHa)

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Fixed tips details	See section 11.5 “Tips and Accessories”, 2 11-5

Overview

The liquid handling arm is part of the liquid system and is used for pipetting tasks.

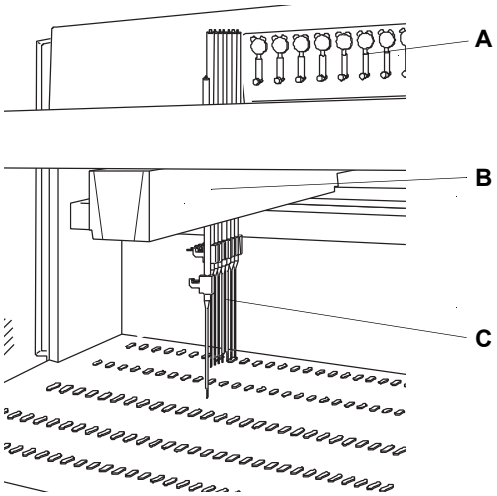


Fig. 4-3 *The liquid handling arm, LiHa*

A *Syringes*
B *Liquid handling arm*
C *Tips*

Function

LiHa Movements

The liquid handling arm moves left and right driven by a servo motor.

Tip Movements

Each sampling tip is raised or lowered by a servo motor within the LiHa.

Two additional servo motors inside the liquid handling arm drive the tips forward and backwards and control the Y-spacing of the tips.

Two, four or eight sampling tips are arranged on one liquid handling arm. The tips can be moved independently in Z-direction. In Y-direction equidistant tip spreading of 9 - 38 mm (0.31 - 1.5 in.) is possible.

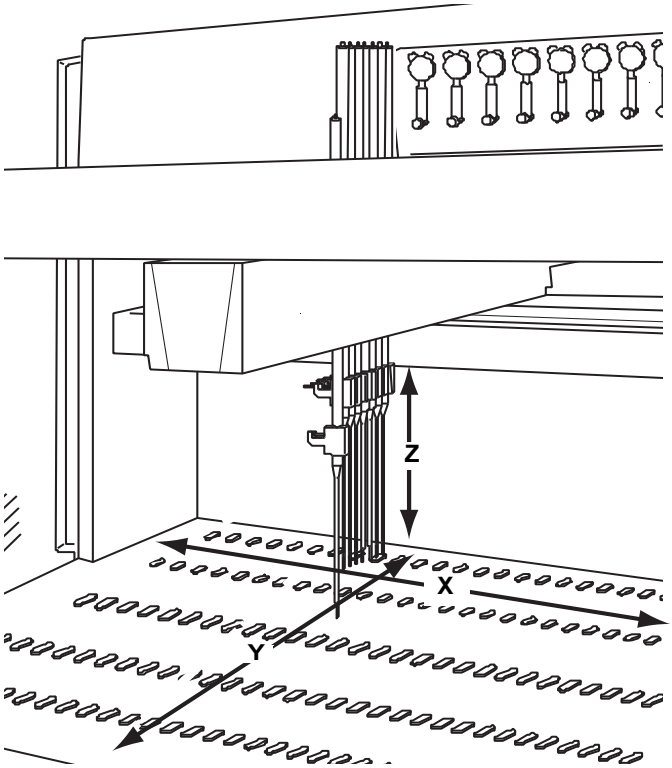


Fig. 4-4 *Liquid handling arm movement*

X *X-range liquid handling arm movement left and right*

Y *Y-range for tip movement and tip spacing front and rear*

Z *Z-range for tip movement up and down*

Tip Types

Tips serve to pipette liquids in different volume ranges.

- Fixed tips

Liquid Level Detection

The LiHa arm holds electronics to detect the level of liquids in plate wells, tubes and liquid containers. For details refer to section “”, 4-14.

4.3.2 Robotic Manipulator Arm Standard (RoMa Standard)

The robotic manipulator arm is used to transport microplates, reagent blocks, deep well plates, etc. to different positions on the worktable or for storage in the microplate shelf.

The RoMa standard coordinate system consists of five axes; the X-axis, the Y-axis and the Z-axis defining linear movements and the R-Axis defining rotational movements. The grippers can move in horizontal direction (G-axis).

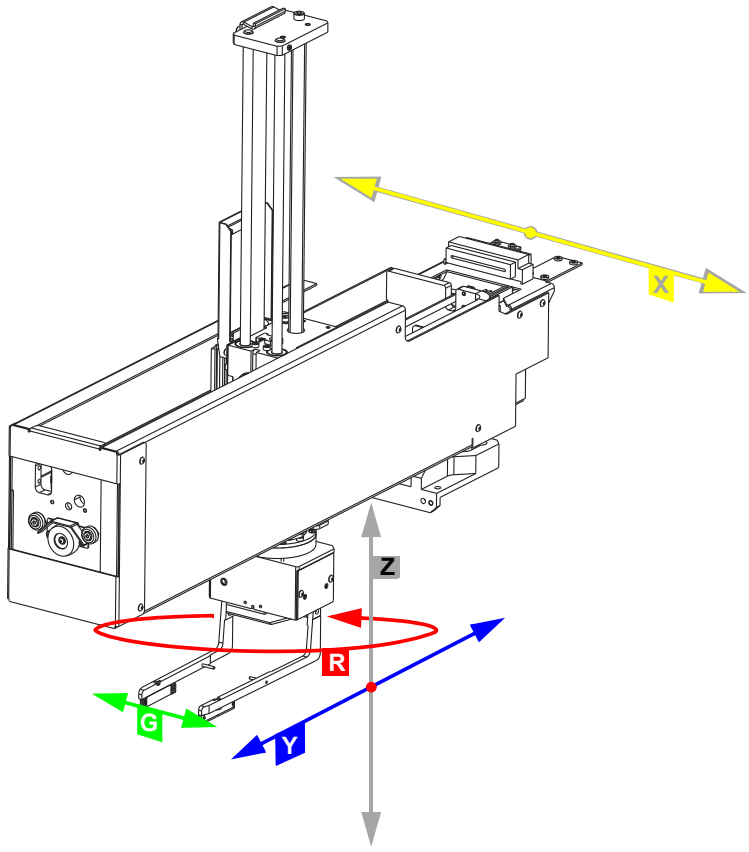


Fig. 4-5 *Robotic manipulator arm RoMa*

G	*Axis for gripper movements*	***Y***	*Axis from front to back of worktable*
R	*Rotational axis*	***Z***	*Vertical axis above worktable*
X	*Axis from left to right of worktable*		

4.3.3 Barcode Scanner on RoMa

Although the Robotic Manipulator (RoMa) arm is traditionally used to transfer labware (eg, microtiter plates, tip boxes) around the instrument worktable, this function is not utilized for the Illumina Infinium assay or platform. Because of this, the RoMa grippers are usually removed by the Illumina FSE prior to installing the RoMa-mounted barcode scanner, which is used by customers who require barcode tracking, as integrated into either Illumina or Clarity LIMS, or their own custom LIMS system.

The Illumina 1D barcode scanner kit is installed on the RoMa arm for all such customers. It is mounted as per ILMN FSB 506 on the bottom of the RoMa arm using special mounting hardware and an adjustable dual bracket, then connected electrically via its cable to the existing RoMa arm cable. The latter powers the scanner and transmits all data back and forth between IAC and the scanner. After performing the scanner alignment using various IAC tools (as outlined in FSB 506), the RoMa-mounted barcode scanner is then automatically positioned and used by the automated IAC method to scan all plate and beadchip barcode labels on the worktable, or in the TeFlow, that are used within an Infinium run. By adjusting the dual bracket to either Position A (30 degrees for all MSA workflows except MSA7 and MSA9), or Position B (60 degrees for MSA7 and MSA9), the RoMa barcode scanner can read all legacy and newer labware barcode labels by virtue of the selected scanning angle, which is manually adjusted prior to starting an automated Infinium run. As a result, DNA plates and their respective downstream MSA plates and beadchips can be tracked via LIMS throughout the entire three day assay. Please note that all reagent tube barcodes are scanned during automated IAC runs using the POSID3 barcode scanner, which comes standard on all new Infinium RoMa instruments.

4.3.4 Safety Elements

Front Safety Panel

The front safety panel is secured in closed position with the door locks. According to the size of the Infinium LiHa and Infinium RoMa and the kind of front safety panel, one or two gas springs facilitate the opening of the panel.

Standard Front Safety Panel

Functions of Safety Panel

The standard front safety panel has the following function:

- Restrict access to moving parts (moving parts, mechanical hazards)
- Protection from spilling sample or reagent

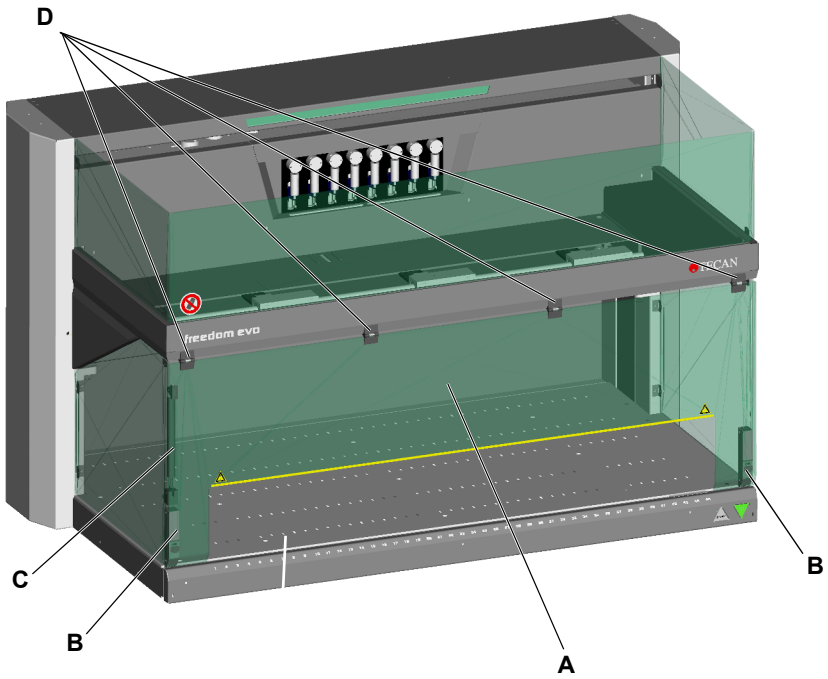


Fig. 4-6 *Infinium LiHa and Infinium RoMa with standard safety panel*

A	*Standard (open) front safety panel*	***C***	*Gas spring*
B	*Door lock*	***D***	*Hinge*

Note: *With this safety panel, loading and unloading of carriers is possible without opening.*

Door Locks

How do the Door Locks Work?

The door locks actively lock the front safety panel during operation of the Infinium LiHa and Infinium RoMa. This is achieved with a software command from the application software.

Application Software

The application software is programmed in such a way that

- if the safety panel is open the process cannot be started.
- the door locks can only be unlocked when the process is stopped or in pause mode.

The figure shows the door locks in connection with the standard and closed safety panel:

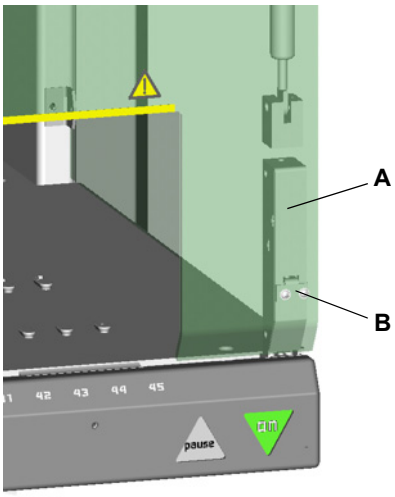


Fig. 4-7 *Door locks*

The door locks consist of a locking device (A) with an electromagnetic actuator on each side of the worktable and a catch (B), which is mounted to the safety panel. A switch in the locking device monitors if the safety panel is open or closed.

4.4 Positive Identification (PosID)

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Barcode types and labels	See section 3.4.3 “Positive Identification (PosID)”, 2 3-13

What Does PosID Mean?

PosID stands for positive identification, i.e. whenever necessary an identification step for carriers or containers (tubes and microplates,) can be programmed in the application software in order to ensure that the correct labware is processed.

The PosID can automatically scan barcodes on carriers and containers by means of a built-in barcode laser scanner. Barcodes can be read on both the primary side (e.g. sample tube), and the secondary side (e.g. microplates). To enable identification with the PosID, all carriers and containers must be labeled with barcodes.

How Does it Work?

The PosID body runs past the carriers to scan the carrier ID barcode (through the front aperture). With its gripper, the PosID pulls the carriers towards the rear of the instrument (passing the barcode scanner) for barcode identification on containers and then shifts the carriers back into operating position.

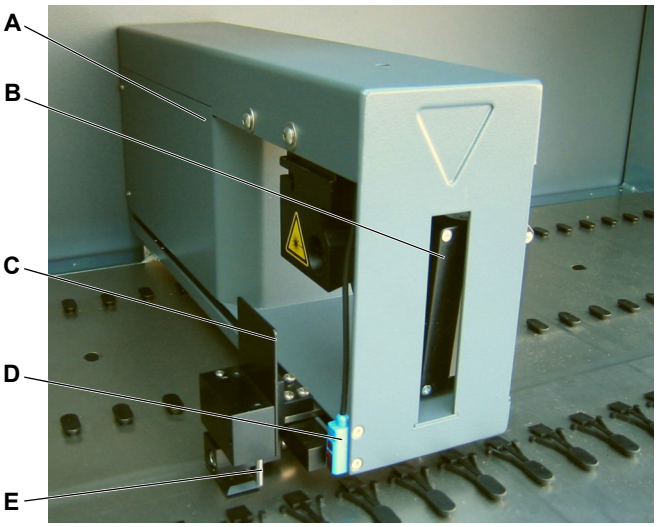


Fig. 4-8 *PosID*

A *PosID body*
B *Barcode scanner*
C *Barcode flag (alignment barcode for verification)*
D *“No Tube” sensor*
E *Gripper*

The barcode scanner is suspended in such a way that it can identify vertical and horizontal aligned barcodes.

Before each container scan the PosID scans the alignment barcode on the barcode flag, which is attached to the gripper, to verify that the barcode scanner and the gripper are in the correct position. This improves identification security for the containers.

Reading Positions

The figure shows how the barcodes for the carrier identification are scanned.

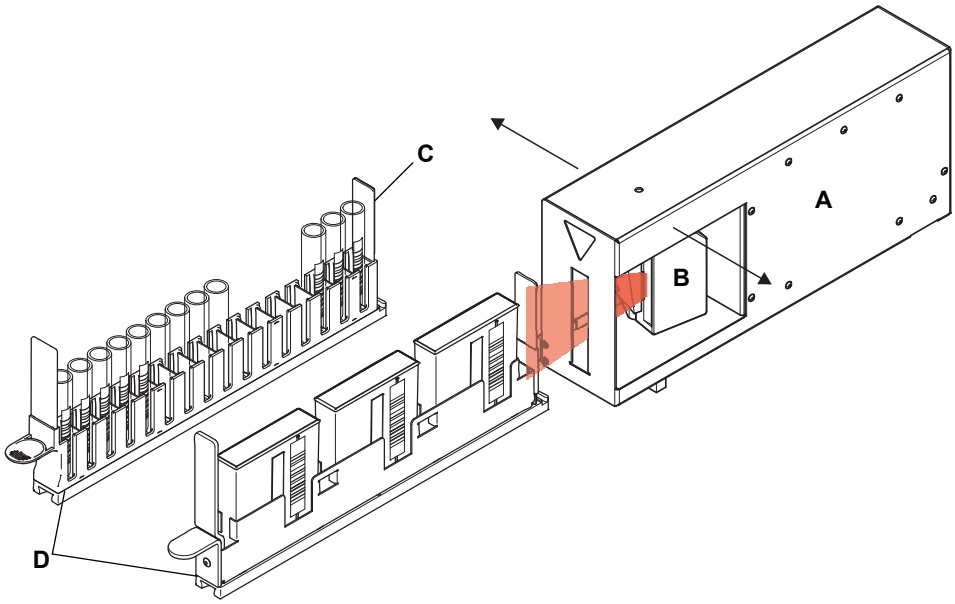


Fig. 4-9 *Barcode scanner position for scanning carrier ID*

A	*PosID body*	***C***	*Carrier ID barcode label*
B	*Barcode scanner*	***D***	*Carrier*

The figure shows how vertical barcodes (e.g. on tubes or reagent troughs) are scanned.

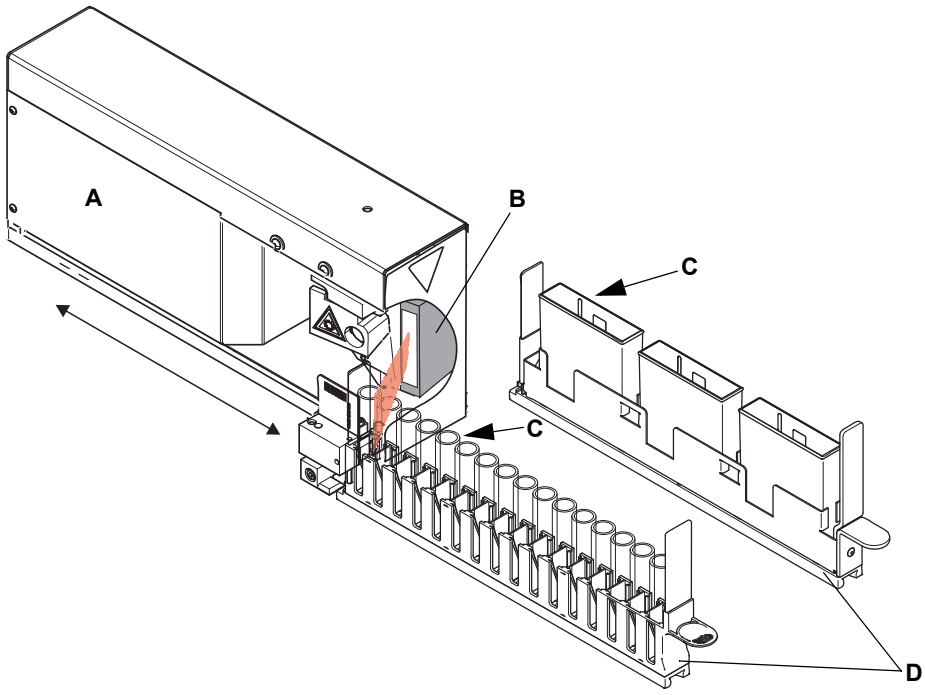


Fig. 4-10 *Barcode scanner position for scanning vertical barcodes*

A	*PosID body*	***C***	*Container barcode label*
B	*Barcode scanner*	***D***	*Carrier*

The figure shows how horizontal barcodes (e.g. on microplates) are scanned.

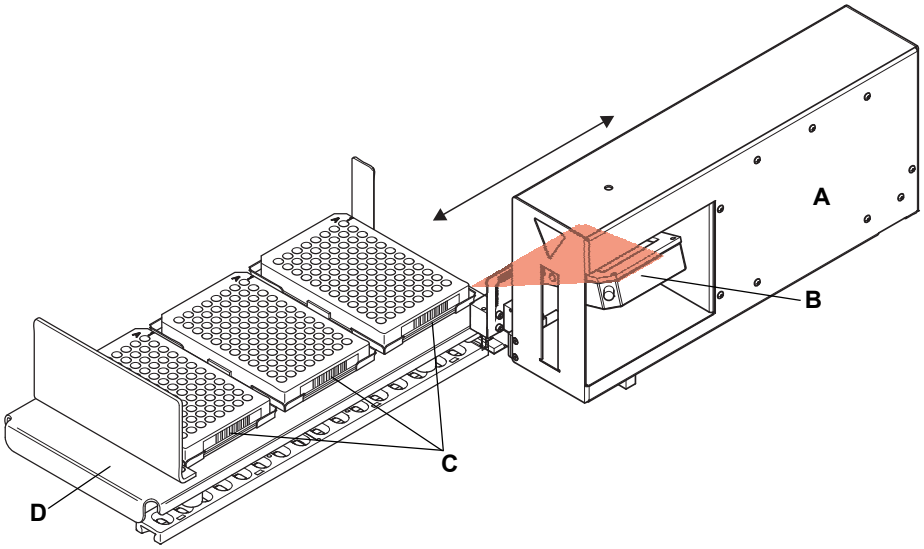


Fig. 4-11 *Barcode scanner position for scanning horizontal barcodes*

A	*PosID body*	***C***	*Container barcode label*
B	*Barcode scanner*	***D***	*Carrier*

“No Tube” Sensor

The “No Tube” sensor checks if a carrier is actually transported when the gripper moves. Furthermore, it monitors the presence of the tubes in the rack. This is necessary, because the barcode scanner cannot distinguish between a tube with missing or incorrectly positioned barcode and a missing tube.

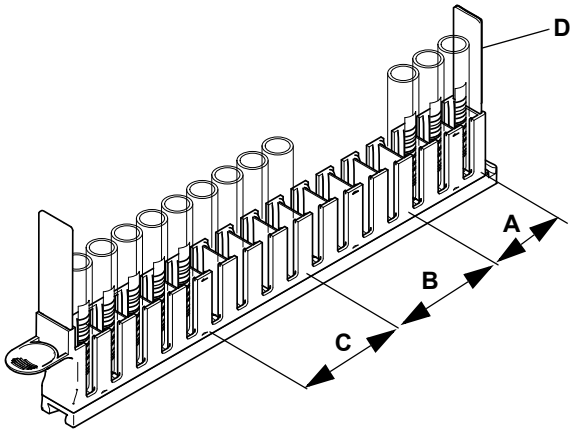
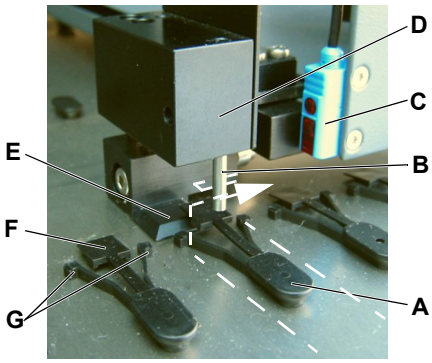


Fig. 4-12 *Detectable situations in a tube rack*

A	*Tubes with readable barcode*	***C***	*Tubes without barcode (or incorrect positioned barcode)*
B	*No tubes present*	***D***	*Carrier ID barcode*

How the Gripper Works

The figure shows how the gripper engages in the carrier to pull the containers past the barcode scanner.



A *Lock pin*
B *Pin (carrier transport)*
C *"No Tube" sensor*
D *Gripper*
E *Wedge*
F *Latch*
G *Retainer*

Fig. 4-13 *PosID gripper and lock pin*

During normal operation the carriers (see dashed line) are positioned at the lock pin (A). The retainers (G) act as a stop for the carrier, because they are locked by the latch (F).

For barcode identification of the containers, the gripper (D) moves next to the carrier, then moves in X-direction (see arrow) to engage the pin (B) in the slot at the rear end of the carrier. At the same time the wedge (E) lifts the latch. The retainers give way and the carrier can be pulled to the rear.

Barcode Value Verification

The PosID verifies the barcode value before transmitting it to the application software. As a standard setting the barcode scanner requires two consecutive identical decoded values to transmit it as a valid result.

Barcode Types

Barcodes on Containers

There is a variety of different barcode types. Not all types are suitable for container identification for data security reasons. Only barcode types that employ a check digit are considered to yield sufficient reading security.

Up to six different container code types per application can be used at the same time.

Barcodes on Carriers

Illumina standard carriers are identified by means of two carrier barcodes (code 128). The second barcode is used to verify the carrier ID (the information on the two barcodes is identical except for one character). This improves identification security for the carriers.

The dimensions of the carrier are stored in the software. After matching the carrier ID with the database, the software is able to identify the carrier's properties.

Barcode Labels

For detailed information on barcode types and proper positioning of barcode labels on carriers and containers refer to cross references above.

4.5 Liquid System

Introduction

The liquid system is a central component of the pipetting function. It transmits the precise movement of the diluter pistons to the tips through the system liquid.

Liquid System Function

The system liquid is delivered to the system in a container and is aspirated and distributed in the whole system via tubes, valves and connectors. The distribution of the system liquid is effected by the movement of the diluter pistons in one or several strokes.

The figure shows the schematic diagram of the standard liquid system:

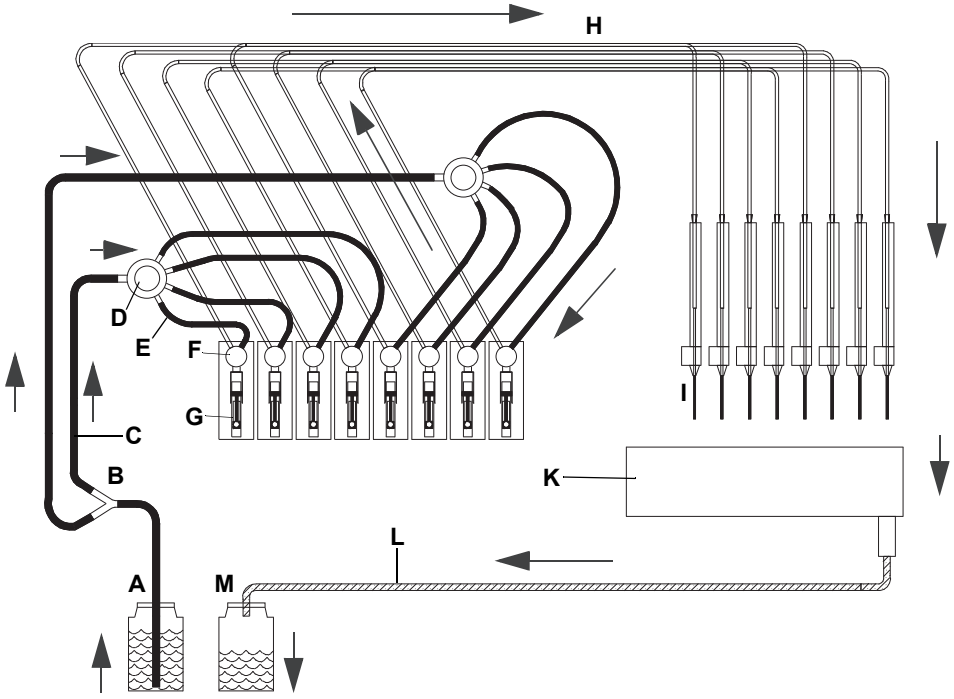


Fig. 4-14 *Liquid system diagram*

Parts in contact with system liquid only

- ***A*** *System liquid container*
- ***B*** *Distributor 1:2 (8-tip instrument only)*
- ***C*** *Aspirating tubing*
- ***D*** *Distributor 1:4 (1:2 for 2-tip instrument)*
- ***E*** *Interconnecting tubing*
- ***F*** *3-way valve*
- ***G*** *Syringe*

Parts in contact with system liquid and/ or sample

- ***H*** *Pipetting tubing*
- ***I*** *Tips*
- ***K*** *Wash station*
- ***L*** *Waste tubing*
- ***M*** *Waste container*

Note: *The arrows indicate the direction of flow.*

4.5.1 Tubing Systems

Flexible tubing connects the liquid system container(s), pumps, valves and tips.

Precision Diluters

Precision diluters assure accurate aspiration and dispensing of liquids and air gaps, the latter to separate the various liquids.

Depending on your application and liquids used, tubing systems are available for 2-tip, 4-tip and 8-tip instruments with optional features, in different materials and with suitable accessories.

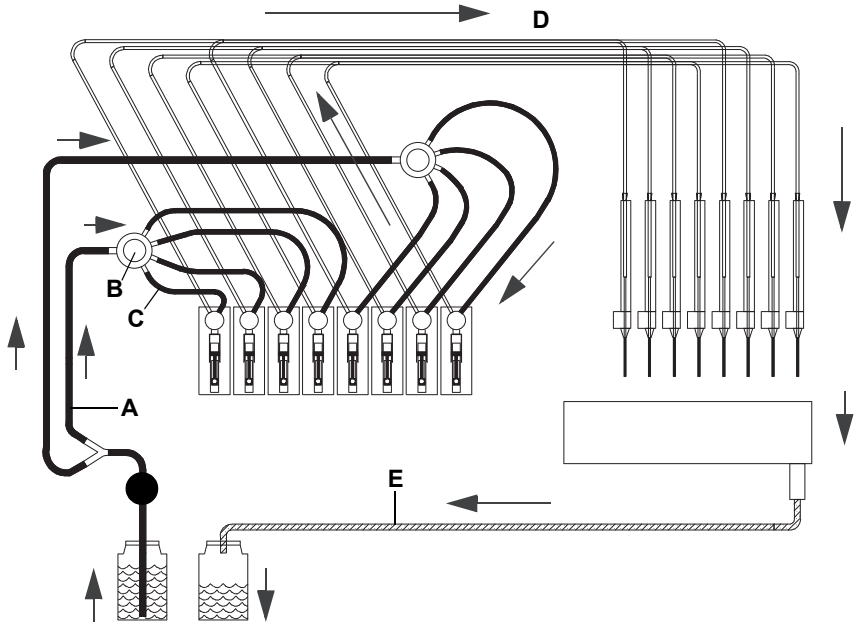


Fig. 4-15 *Liquid system flow direction and tubing*

Aspirating tubing

A *Aspirating tubing*

B *Distributor 1:4 (1:2 for 2-tip configuration)*

C *Interconnecting tubing*

Pipetting tubing

D *Pipetting tubing*

Waste

E *Waste tubing*

Aspirating Tubing

Tab. 4-1 *Aspirating tubing features*

Tubing System	Features
Standard	Standard tubing system composed of PVC/silicone/PP/POM

Pipetting Tubing

With all tubing systems, the pipetting tubing is made of FEP, which is resistant against a wide range of liquids.

5 Putting into Operation

Purpose of This Chapter

This chapter describes how the Infinium LiHa and Infinium RoMa is installed and gives instructions on initial operation.

5.1 Installation

5.1.1 Initial Installation of the Instrument

The initial installation of the instrument may be done by a qualified Illumina service person only.

5.2 Startup

The following section describes all operational steps, from switching the Infinium LiHa and Infinium RoMa on to switching it off.

Cross References

List of cross references to information provided in other sections can be found here:
https://support.illumina.com/content/dam/illumina-support/documents/documentation/chemistry_documentation/infinium_assays/infinium/infinium-assay-lab-setup-and-procedures-11322460-03.pdf

WARNING

Automatically moving parts.
Injuries (crushing, piercing) possible if the safety panels are not in place.

- Before starting the Infinium LiHa and Infinium RoMa, make sure that the safety panel is closed.
- Never operate the instrument with the safety panels open.

WARNING

Automatically moving parts.
Injuries (crushing, piercing) possible when using the instrument with the standard front safety panel.

- Do not reach into the Infinium LiHa and Infinium RoMa through the aperture beneath the yellow line on the instrument front side.

Startup Procedure

For startup instructions refer to Infinium Assay Lab Setup and Procedures Guide (Document # 11322460).

6 Operation

Purpose of This Chapter

This chapter explains the operating elements and possible operating modes. It gives instructions on how to operate the Infinium LiHa and Infinium RoMa properly and safely.

For the options used by your configuration, refer to the separate operating manuals.

6.1 Operating and Display Elements

6.1.1 Operating Elements

Apart from the power ON/OFF switch and the pause button there are no specific operating elements on the Infinium LiHa and Infinium RoMa instrument.

Power ON/OFF Switch

The power ON/OFF switch is located at the instrument's lower right corner. A status light in the switch indicates if the instrument is switched on.

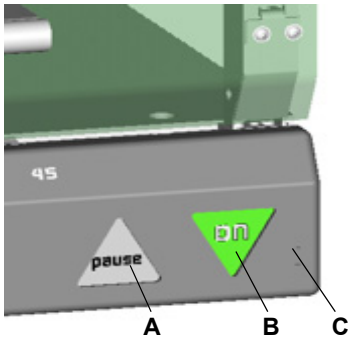


Fig. 6-1 *Power ON/OFF switch and pause button*

A *Pause/resume button*
B *Power ON/OFF switch*
C *Front access panel, closed*

Note: *The control for switching on or off is delayed to accept only definite commands.*

- *For switching on: Keep the power ON/OFF switch pressed for at least 0.5 seconds.*
- *For switching off: Keep the power ON/OFF switch pressed for at least 2 seconds.*

Pause/Resume Button

The pause/resume button allows the user to pause and later resume a test run for access on request.

Note: *During operation, keep the front access panel closed to have access to the switches.*

ATTENTION

Unintended pausing or switching off of the instrument.
To avoid unintended actuation, pay attention to the following:

- When opening or closing the front access panel, make sure that the **pause** button and the power **ON/OFF** switch are not pressed unintentionally.
- Before pressing the **pause** button or the power **ON/OFF** switch, make sure that you will press the intended button.
- Before pressing the **pause** button in order to pause a process, make sure that the instrument is running.
- Before pressing the **pause** button in order to resume a process, make sure that the instrument is pausing and that the safety panel is closed.

WARNING

Injuries caused by moving parts
A not completely opened front safety panel might close automatically.

- Open the front safety panel completely (more than 180°).

Internal Communication

Communication within the Infinium LiHa and Infinium RoMa, and also the communication between the instrument and its modules is achieved by means of cable connections between the respective control electronics.

User Interface

Display functions and controls are available in the software packages and user interfaces on the PC. Depending on your application, refer to the relevant separate documentation.

6.2 Operating Modes

Possible Operating Modes

The Infinium LiHa and Infinium RoMa can be run in two different operating modes:

- Routine operation mode (operator)
  - This is the normal operating mode, in which the application is run.
  - In this mode, the Infinium LiHa and Infinium RoMa is controlled by the runtime controller of the corresponding application software.
    - Refer to cross references above.
- Setup and service mode (field service engineer)
  - Serves to set up the instrument, to make adjustments and to run tests.
  - In this mode, the Infinium LiHa and Infinium RoMa is controlled by the setup and service software.
    - Refer to the “Instrument Software Manual”.

6.3 Operating in Routine Operation Mode

6.3.1 Safety Instructions

WARNING

Automatically moving parts.
Injuries (crushing, piercing) possible if the safety panels are not in place or if the standard front safety panel is installed. The standard front safety panel is partially open, allowing access to the worktable and continuous load

- Before starting the Infinium LiHa and Infinium RoMa, make sure that the safety panel is closed.
- Never operate the instrument with the safety panels open.
- Do not reach into the instrument through the aperture beneath the yellow line on the instrument front side.

WARNING

Contamination risks through contamination of the worktable or frame. Hazardous liquids or samples can be spilled onto the worktable, due to the failure of the liquid system or a handling module, such as the RoMa.

- Visually inspect all hardware components, e.g. the worktable, the RoMa, etc., for possible spillage of hazardous liquids.
- Make sure that the containers are accurately positioned on the worktable.
- Wear appropriate personal protective equipment, such as gloves, lab coats and protective eye wear

Safe Worktable Layout

ATTENTION

Unsafe layout of the worktable can cause e.g.:

- Loss or dropping of microplates
- Spillage of hazardous liquids because of collisions or too high filling level (more than 80%) of cavities
- Spillage due to imprecise pipetting in 96-well microplates placed on the Te-Link
- Cross-contamination because critical elements are placed near the wash station waste (splashes).

Before and during instrument use, check the worktable for the safety of its layout.

Liquid System / Liquids

ATTENTION

Leakage of the liquid system.

By the continuous up and down movements of the syringes during operation, the syringe and plunger lock screws may get loose, if not tightened properly. This causes leakage of the liquid system.

- Check the plunger lock screws and syringe screws and tighten manually before switching the Infinium LiHa and Infinium RoMa on.

ATTENTION

To ensure a proper liquid flow, make sure that the tubings are not twisted or inhibited from free flow.

ATTENTION

Instruments are intended for indoor operation with controlled temperatures.It is important to maintain constant temperature plus air gaps.

Tips

ATTENTION

Two, four or eight tips are arranged on one Liquid Handling arm.

- Each tip must be exactly in line with the center of the tube to maximize the distance between wall and tip.

ATTENTION

Possible malfunction due to tip clogging.
Using liquids with undissolved particles could lead to clogged tips and thus result in liquid not being dispensed.

- Clogging can also result if the tips have not been thoroughly washed.

Applications

For all applications of the Illumina instrument, the user must ensure that the requirements of each protocol are carefully observed. Attention must be given to:

- Sample/reagent volumes and concentrations
- Test plate layout
- Sequence of steps
- Temperature restrictions
- Time limits

Controls, standards, or reference materials should be processed by the Infinium LiHa and Infinium RoMa in the same manner as test samples. Prior to any first time application, test runs should be made with the assay to allow optimization of all liquid handling parameters.

The Infinium LiHa and Infinium RoMa requires accurate positioning of all reagents, samples, racks, and plates on the instrument's worktable. The operator should verify these positions accordingly before executing any program.

In the event of power failure or an otherwise aborted run, all partially processed samples should be discarded. Do not attempt to restart an interrupted program unless the computer screen displays explicit instructions for resuming operation.

Chemical, Biological and Radioactive Hazards

WARNING

All samples and test kit components must be considered potentially hazardous agents.

- A potential risk can arise from the liquids being handled by the instrument, such as infectious biological samples, toxic or corrosive chemicals, or radioactive substances.
- Strictly apply appropriate safety precautions according to local, state and federal regulations.
- Handling and disposing of waste must be in accordance with all local, state and federal environmental, health, and safety laws and regulations.
- Use appropriate protective clothing, safety goggles and gloves.

6.3.2 Enclosed Work Area

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Detailed maintenance procedures	See chapter 7 “Preventive Maintenance and Repairs”, 2 7-1

WARNING

Unexpected, fast movements of arms and tips.
Interfering with the arm and tip movements can lead to serious injuries or equipment damaging.
Never operate the instrument while safety panels, covers or access doors are open or removed.
The operator will be prompted by the software when the worktable setup requires new racks or carriers. Any further interference in the work area is strictly prohibited.

The operator might need to open or remove the work area safety panels for instrument setup, cleaning and maintenance purposes. For detailed procedures refer to cross references above.

6.3.3 Switching the Instrument On

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Checks before starting a run	See section 6.3.4 “Instrument Preparation and Checks”, 6-9

Before switching the instrument on, check the following:

WARNING

Automatically moving parts.
If the safety panels are not in place, injuries (crushing, piercing) are possible.
Before starting the Infinium LiHa and Infinium RoMa, make sure that the safety panel is closed.
Never operate the instrument with the panel open.

To switch the Infinium LiHa and Infinium RoMa on, proceed as follows:

1 Press the power ON/OFF switch for 0.5 seconds to switch the instrument on.
2 Wait until the status light in the power ON/OFF switch is lit.

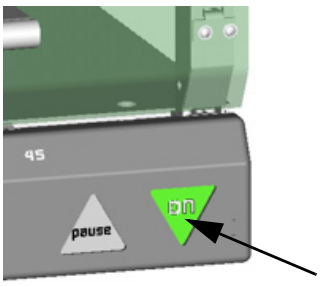


Fig. 6-2 *Lit power ON/OFF switch*

ATTENTION

Before starting an application, thoroughly flush the whole liquid system. Make sure that daily maintenance procedures have been performed. Make sure that there are no air bubbles in the tubing and that there are no liquid droplets on tips.

3 Start up the runtime controller of the application software.

The instrument is now ready to receive commands from one of the available application software packages.

4 Perform the necessary checks before starting a run.
Refer to cross references above.

6.3.3.1 After a Power Failure

Objects Held by PosID, RoMa

If you want to resume operation after a power failure, it is important that objects still held by the grippers of the PosID and the RoMa are removed manually before switching the instrument on. Otherwise, the objects will be dropped during instrument initialization, which may lead to a crash or spillage.

ATTENTION

In the event of power failure or an otherwise aborted run, all partially processed samples should be discarded. Do not attempt to restart an interrupted program unless the computer screen displays explicit instructions for resuming operation.

6.3.4 Instrument Preparation and Checks

Cross References

List of cross references to information provided in other sections:

Subject	Reference
User qualification	See section 2.4 “User Qualification”, 2 2-6
No air bubbles in the tubing	See section 7.3.1.2 “Flushing the Liquid System”, 2 7-12
No liquid droplets on tips	See section 7.3.1.1 “Checking for Leaks”, 2 7-10

General Information

This section contains instructions for routine use. It is intended as a guide to build your SOP (Standard Operating Procedure).
Any modifications of the implemented tests in your Application Software must be carried out by application specialists or expert operators.
Refer to cross references above.

Before starting a run, pay attention to the following:

Containers

1. Empty the waste liquid container if necessary.
   The waste container must remain on floor level to provide for proper waste liquid flow.
2. Empty the disposable tip waste bag if necessary.
3. Check the system liquid container and refill if necessary.
   If possible, place the system liquid container on worktable level to avoid pressure difference in the supply tubing.

Consumables

4. Check the disposable tip rack and add tips if necessary.
5. Make sure that the reagent troughs are filled appropriately.
6. Ensure that the daily maintenance has been carried out according to the maintenance chapter.

Furthermore, take the following notices into consideration:

Worktable

Regarding the worktable, pay attention to the following:

ATTENTION

Improper positioning of objects on the worktable may lead to disturbances or errors in the process, e.g. misinterpretation of barcodes. Do not use free space on the worktable to deposit any objects

ATTENTION

Improper initialization of robotic arms.
The robotic arms cannot initialize properly if there is an object, such as a lost sample tube or a tool, etc., between the arm and the initial stop position.

- Make sure that there are no unwanted objects present in the instrument.
- Check the arm position after the initialization command.

ATTENTION

Before starting an application, thoroughly flush the whole liquid system. Make sure that daily maintenance procedures have been performed. Make sure that there are no air bubbles in the tubing and that there are no liquid droplets on tips. Refer to cross references above.

RoMa Gripper

If the instrument is to be started up anew after a power failure, it is important that any objects still held by the grippers of the RoMa are removed before the start. Otherwise they will be dropped during the startup.

WARNING

Contamination risks through contamination of the worktable or frame. Hazardous system liquids or samples can be spilled onto the worktable, if tubes or microplates held by the grippers of RoMa are dropped after a restart.

- Visually inspect the arm devices whether they still hold any objects between their grippers.
- Remove such objects before starting up the instrument.

6.3.4.1 Carriers

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Carrier cleaning	See section 7.3.8 “Carriers and Racks”, 2 7-18

Carrier Positioning

Slide carriers over the positioning pins until they abut on the lock pins.
Make sure that the barcode on the carrier corresponds to the settings in the Application Software.

Carrier Fixation and Replacement

The positioning pins hold the carriers in defined positions, but still allow carriers to be exchanged during an application. A rail in the carrier base fixes the carrier in X-direction, the stop pins in the third row on the worktable fix the carrier in Y-direction. When prompted to do so by the software, the operator can replace a carrier during an application.

ATTENTION

Make sure that the stop pins limit the carrier movement correctly, otherwise crashes or incorrect pipetting may occur.

Positioning Pins

If a positioning pin is damaged, replace it immediately.
Refer to cross references above.

Place the carriers only on the provided positions as the instrument is adjusted to these positions. Carriers placed e.g. on the left of positioning pin 1 can cause mechanical problems (collision) or errors in the identification of barcoded samples.

Placing Carriers

All carriers must be in close contact with the worktable, so that the capacitive liquid level detection is guaranteed. For this purpose, clean the carriers and the worktable in regular intervals.
Refer to cross references above.
Make sure that the correct rack is used for the carrier.
If a carrier is damaged, replace it immediately.

Carrier ID

Each carrier ID must be unique.

Carriers Identification by PosID

Always place the carriers correctly on the worktable as shown in the figure (B):

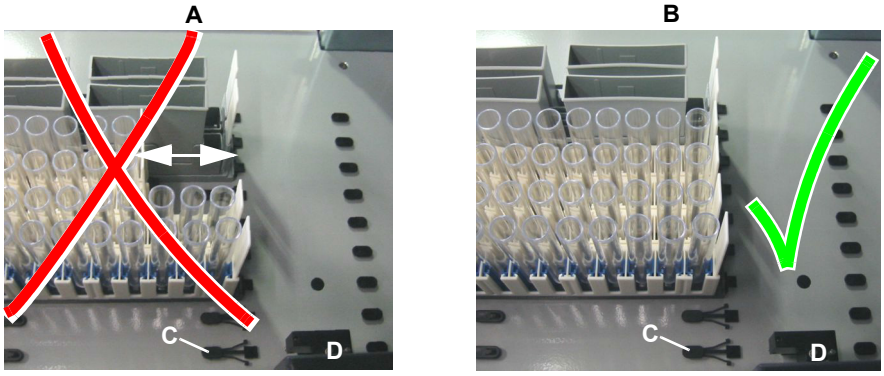


Fig. 6-3 *Carriers on worktable*

A *Incorrect position of carriers (offset of carriers indicated with arrows)*

B *Correct position of carriers*

C *Lock pin*

D *PosID barcode reader*

WARNING

Wrong identification of a carrier.
If carriers are not placed correctly on the worktable and if there are unfavorable circumstances (barcode labels not within specified limit, distance of the incorrectly placed carriers to the barcode reader still enables reading), the barcode reader might read the wrong carrier.

- When loading carriers, always slide them all the way to the stop at the lock pin.
- When carriers need to be removed, always remove them completely from the worktable.
- Never remove or place a carrier on the worktable while the PosID is reading.

6.3.4.2 Racks and Containers

If a rack is damaged, replace it immediately.
Make sure that the correct barcode is used for the rack.

Microplates

Microplates must be positioned correctly on the carrier, seating well in their holder. Make sure that the microplate does not rest on the holder rim in a slanting position.

ATTENTION

Crash or erroneous pipetting results when the wrong tips are loaded on the worktable.

- If tips are longer than expected:
  Crash of the tips with the labware.
  Wrong pipetting results because the tips are pressed against the bottom of the container, which constricts the liquid flow through the tip orifice.
- If tips are shorter than expected:
  Aspiration of air instead of liquid, which may result in erroneous results.
- Make sure that the tip lengths present on the worktable, correspond with the ones defined in the application software.

Containers (Troughs, Bottles, etc.)

ATTENTION

Risk of mixing up containers during loading.

If you load containers without barcode identification, e.g. in a carrier that does not allow the containers to be identified by the PosID, pay attention to the following:

- Strictly follow the loading instructions provided by the software.
- Double-check all containers for correct placement on the carrier.

Use of Tubes

- For sample and reagent tubes, use the appropriate carriers (strip racks) according to the following list.

Tab. 6-1 *Racks for sample and reagent tubes*

Strip rack	Tube diameter, outside
with black insert	10 mm
with blue insert	12 to 13 mm
without insert (white)	15 to 16 mm

Note: *For parameters other than listed here, choose the strip rack the tubes best fit in and make sure they do not jam. The deviations in diameter must be adapted within the Application Software.*

- In each rack, use tubes of one size only. Tube height and diameter must be identical for all tubes.

ATTENTION

Make sure that all tubes are positioned correctly in the carrier and touch the rack bottom, otherwise liquid level detection and clot detection might not work properly.

ATTENTION

Incorrect identification of the carrier (strip rack).
The carrier barcode is associated with the corresponding tube size. Therefore, the carriers are not handled correctly if the inserts are exchanged.

- Do not change the strip rack inserts.
- Do not exchange the carrier barcode flags.

Note: *The filling level of tubes, troughs and containers must not exceed 80% to avoid spillage during PosID reading.*

Tab. 6-2 *Minimum inner diameter for primary sample tubes*

Tip type	Tube diameter, inside
Fixed tips	7 mm

6.3.4.3 Preparation of Samples

Visually inspect the samples before pipetting. They must be free of:

- Clots
- Foam
- Droplets on the tube wall

For this purpose we strongly recommend that you centrifuge the samples before pipetting. After the sample collection wait for at least 10 minutes before centrifuging the sample.

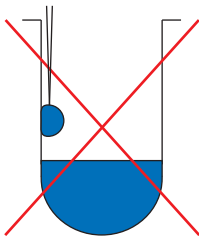


Fig. 6-4 *Droplet on wall*

- Maximally fill the sample tubes to 80%.
- The sample tubes must not contain any additional (non-conductive) inserts or have covers.
- When using monovettes with plunger, the plunger must first be retracted fully and only then be broken off. This method ensures a good contact to the worktable (liquid detection).
- If pipetting from gel monovettes is intended, make sure you use only sample tubes with a sufficient amount of supernatant.

Note: *For further information on sample preparation, please refer also to the recommendations given by your manufacturer and by the WHO.*

6.3.4.4 Connecting Liquid Containers

When connecting liquid containers, also pay attention to the maintenance instructions given in section 7.3.7 “Liquid Containers”, 2 7-17.

Tubing from Pressure Relief Valve

If your instrument is equipped with FWO/SPO/MPO, pay attention to the following:

Note: *To minimize the contamination risk, Illumina recommends you to connect the bypass tubing from the pressure relief valve to the waste container (not back to the system liquid container).*

ATTENTION

Liquid handling problems due to air in the liquid system

- If you direct the bypass tubing from the pressure relief valve back to the system liquid container, make sure that the bypass liquid flow does not cause bubbles in the system liquid.
- Separate the bypass tubing and the aspiration tube in such a way that no air bubbles can be aspirated.

Wash Station/Waste Tubing

Installing the Waste Tubing

When installing the waste tubing, pay attention to the following:

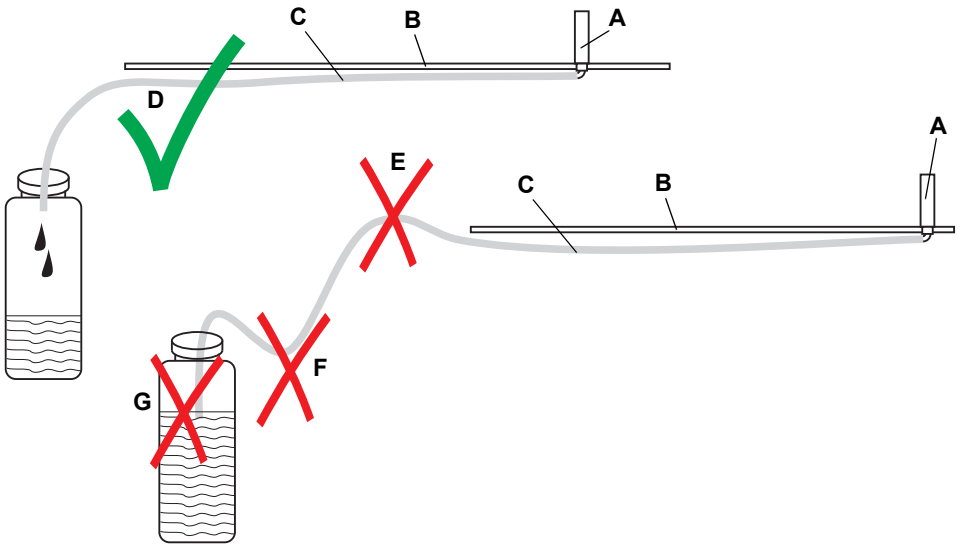


Fig. 6-5 *Correct and disadvantageous course of waste tubing*

Correct installation of waste tubing

A *Wash station*
B *Worktable*
C *Waste tubing*
D *Correct course of waste tubing*

Incorrect installation of waste tubing

E *Rising waste tubing*
F *Sagging waste tubing*
G *Waste tubing reaching into liquid*

ATTENTION

Liquid spillage on the worktable.
To prevent overflow of the wash station the waste tubing must be routed in such a way that the back pressure is as low as possible.

- The waste tubing must not be longer than necessary.
- The waste tubing must not be kinked or squeezed (reduction of clear cross section).
- The waste tubing must not rise after wash station (back pressure).
- The waste tubing must not sag (back pressure).
- The lower end of the waste tubing must not be in the liquid (back pressure).

6.3.5 Checks and Terminating Tasks

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Empty/clean the waste container	See section 7.3.7 “Liquid Containers”, 2 7-17

Performing the Checks and Tasks

1. Check if the run has been terminated without any error (check for error messages).
2. Empty and clean the reagent troughs.
3. Empty and clean the waste container and rinse it with ethanol.
   Refer to cross references above.

6.3.6 Switching the Instrument Off

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Maintenance tasks	See chapter 7 “Preventive Maintenance and Repairs”, 2 7-1

Before switching the instrument off, some maintenance tasks might need to be performed, e.g. tip cleaning.
Refer to cross references above.
Except in an emergency situation, switch the instrument off only after an application is completed.

To switch the instrument off:

1. Press the power ON/OFF switch and keep it pressed for at least 2 seconds.

ATTENTION

Wait until the status light in the power switch is off (for approx. 10 sec.) before switching the instrument on again.

6.3.7 When a Crash Occurred

When a crash occurred, consult chapter 8 “Troubleshooting”, 2 8-1 for possible corrective measures. Also check the log files generated by the application software.

ATTENTION

After a harsh crash some components of the instrument may be out of alignment or even defective.

- If a harsh crash occurred, contact your local service organization to have the instrument checked.

RoMa Crash

After a crash with the RoMa, check the gripper and the RoMa alignment.

6.4 Maintenance

Make sure that your instrument and devices are in a faultless state. Regular maintenance guarantees the high accuracy and precision you require and at the same time minimizes downtime of instrument and devices. For detailed descriptions of the maintenance tasks, refer to 7 “Preventive Maintenance and Repairs”, 2 7-1 in this Operating Manual - Document # 1000000110155 v00.

7 Preventive Maintenance and Repairs

Purpose of This Chapter

This chapter gives instructions on all maintenance work to be performed in order to keep the Infinium LiHa and Infinium RoMa in good working condition.

In addition to this, adjustment and repair jobs the operator can carry out by himself/herself are explained.

Principle

Only operate the Infinium LiHa and Infinium RoMa when it is in good working condition. Strictly observe the maintenance instructions as set out in this manual. To achieve specified performance and reliability of the instrument, regularly carry out the maintenance and cleaning tasks.

In case of any problems and for inquiries contact the local service organization.

Additional Documents

In the **Infinium LiHa and Infinium RoMa Daily/Weekly Maintenance Checklist**, the maintenance work that has been carried out can be recorded to be kept in the **Infinium LiHa and Infinium RoMa Maintenance and Service Logbook**.

7.1 Tools and Consumables

7.1.1 Cleaning Agents

WARNING

Working with cleaning agents may be hazardous.

- Always observe the safety measures given by the manufacturer.

WARNING

Fire hazard.

- Do not use flammable liquids without supervision by the operator.
- Take measures to prevent electrostatic discharge.

ATTENTION

Strong detergents can dissolve carrier and worktable surface coatings.

- For cleaning the instrument, use alcohol or water as cleaning agents.

Commercially Available Cleaning Agents

Tab. 7-1 *Commercially available cleaning agents*

Agent	Description	Manufacturer	Part No.
Contrad 70[a)]	Surface active cleaning agent	Decon Labs Inc., USA www.deconlabs.com	Please contact the manufacturer
Contrad 90[a)] Contrad 2000[a)]	Surface active cleaning agent	Decon Laboratories Limited, UK www.decon.co.uk	Please contact the manufacturer
Decon 90[a)]	Surface active cleaning agent	Decon Laboratories Limited, UK www.decon.co.uk	Please contact the manufacturer
Bacillol Plus	Alcoholic, disinfection agent, free of formaldehyde, for surface cleaning	Bode Chemie, Hamburg www.bode-chemie.de	Please contact the manufacturer
DNAzap	Cleaning agent for surfaces contaminated with nucleic acids	Ambion www.ambion.com	Please contact the manufacturer
SporGon	Disinfectant	Decon Laboratories www.deconlabs.com	Please contact the manufacturer
Liqui-Nox	Weak detergent	Alconox www.alconox.com	Please contact the manufacturer

a) These are identical products; are hereafter called Decon / Contrad

Cleaning Agents Specifications

Tab. 7-2 Cleaning agents specifications

Agent	Specification
Water	Distilled or deionized water
Alcohol	70% ethanol or 100% isopropanol (2-Propanol)
Decon / Contrad	Liquid concentrate, for dilution with water (normally 2%, 5% in case of severe contamination)
Weak detergent	e.g., Liqui-Nox
Disinfectant	e.g., Bacillol plus, SporGon
Surface disinfectant	All disinfectants except: Lysetol FF, SporGon
Base	e.g., 0.025–0.25 mol/l NaOH
Bleach	0.5% to 3% sodium hypochlorite

Instrument Parts and Cleaning Agents

Tab. 7-3 Cleaning agents application

Instrument part	Cleaning agent
Liquid system, including waste system	Water, alcohol, weak detergent, base Suitable for flushing are: Bleach, Decon / Contrad, Terralin protect
Worktable	Water, alcohol, weak detergent, disinfectant, base, bleach
Housing	Water, alcohol, surface disinfectant
Metal parts	Water, alcohol, disinfectant
Carriers	Water, alcohol, weak detergent, disinfectant **Use**: Decon / Contrad for surface cleaning only **Do not use**: Decon / Contrad, Bleach, SporGon as cleaning bath for carriers (damage to aluminum)
Racks	Water, alcohol, weak detergent, disinfectant
Gripper	Water, alcohol, weak detergent, disinfectant
Tips	Water, alcohol, weak detergent, disinfectant, base
Safety panels	Water, alcohol, disinfectant, suitable for acrylic glass
Disposable tip cones	Alcohol
PosID scanner head laser beam output window	Alcohol
Arm guide, arm guide roller of arms	Do not use any agent
Z-rod	Do not use any agent

Note: *After use of weak detergents, base or bleach, thoroughly clean with water and wipe dry to totally remove the cleaning agent and obtain normal operating conditions.*

Cleaning

Cleaning Tissue	Use a lint-free tissue together with the appropriate cleaning agent.

7.2 Maintenance Schedule

Note: *To ensure a good working condition of the instrument a half-yearly or yearly (depending on configuration) maintenance carried out by a Illumina authorized field service engineer (FSE) is recommended.*

Maintenance Record

Note: *In order to be able to track all maintenance performed on the Infinium LiHa and Infinium RoMa over the whole lifetime, the periodic maintenance must be recorded as follows:*

- *Fill in the necessary data in the form "Infinium LiHa and Infinium RoMa Daily/ Weekly Maintenance Checklist".*
- *File the form in the "Infinium LiHa and Infinium RoMa Maintenance and Service Logbook".*

Maintenance Tables

The maintenance tables are divided according to the frequency the corresponding maintenance task must be periodically performed. For example, there are tables for:

- Daily maintenance
- Weekly maintenance
- Half-yearly maintenance

Example and Explanations

Example for a maintenance table, followed by explanations:

Tab. 7-4 *Example (e.g. daily maintenance)*

Instrument/Component	Maintenance Task	Reference
Part A	Clean thoroughly	Water with weak detergent
Part B	Check adjustment of component C	Refer to section X.X.X, 🗎 Y-Z

- Instrument/Component
  - Specifies the instrument or one of its individual components on which a maintenance task must be performed.
- Maintenance Task
  - States briefly what maintenance must be performed on the instrument/ component mentioned before.
- Reference
  - Gives additional information, e.g. on means, tools, etc. that are necessary to perform the maintenance task mentioned before.
  - Contains references to the sections in this manual or to other documents where the corresponding instructions can be found.

General Guideline

Note: *The daily and weekly maintenance schedule described here is a general guideline. The schedule and the cleaning agents may have to be adapted to your special laboratory conditions and depending on your application.*

7.2.1 Maintenance: Immediate Maintenance

If the instrument is leaking, switch it off immediately and eliminate the source of leakage. Refer also to section 7.3.1.1 "Checking for Leaks", 🗎 7-10.

7.2.2 Maintenance Table: Daily Maintenance

At Beginning of Day

Tab. 7-5 *Daily maintenance in chronological order*

Instrument/ Component	Maintenance Task	Reference
Liquid system	Check for leakage	See section 7.3.1.1 “Checking for Leaks”, 🗎 7-10
	Check the tubing connections and tighten, if necessary	See figure in 7.3.1 “Liquid System”, 🗎 7-10
Tips	Clean	See section 7.3.3 “Fixed Tips of LiHa”, 🗎 7-15
	Check for damage	See section 7.3.3 “Fixed Tips of LiHa”, 🗎 7-15
System liquid container	Make sure that it is full	-
Waste container	Make sure that it is empty	-
Plate Washer	Flush with distilled or deionized water	Refer to Washer Manual
Liquid system	Flush	See section 7.3.1.2 “Flushing the Liquid System”, 🗎 7-12
	Check for air bubbles	See section 7.3.1.2 “Flushing the Liquid System”, 🗎 7-12
RoMa	Visually check grippers for deformities and damage	Call Illumina customer service if they are not in order

During Day

Tab. 7-6 *Daily maintenance during the day*

Instrument/ Component	Maintenance Task	Reference
Liquid system	Flush prior to each application run	See section 7.3.1.2 “Flushing the Liquid System”, 🗎 7-12

At End of Day

Tab. 7-7 *Daily maintenance at end of day in chronological order*

Instrument/ Component	Maintenance Task	Reference
Tips	Clean inside and outside	See section 7.3.3 “Fixed Tips of LiHa”, 7-15
	Clean standard tips	Caustic soda solution (1% NaOH)
	Check all tubing, tubing connections, syringes	See section 7.3.1.1 “Checking for Leaks”, 7-10
Carriers and racks	Clean using a detergent or antiseptic solution	See section 7.3.9 “Positive Identification (PosID)”, 7-19
Worktable	Clean	See section 7.3.5 “Worktable”, 7-17
Safety panel	Clean	See section 7.3.6 “Safety Panels”, 7-17
Wash station	Clean using a detergent or antiseptic solution	See section 7.3.4 “Wash Station”, 7-16
System liquid container	Rinse with water and fill up	
Waste container	Clean using a detergent or antiseptic solution	See section 7.3.7 “Liquid Containers”, 7-17
Waste tubing	Clean using a detergent or antiseptic solution	
RoMa standard	Clean gripper fingers using alcohol or acetone	–
Plate washer	Leave filled with deionized water overnight	–
Liquid system	Check for leakages after every 8 hours of operation	See section 7.3.1.1 “Checking for Leaks”, 7-10
	If liquids other than water are used as system liquid, flush with deionized water	See section 7.3.1.2 “Flushing the Liquid System”, 7-12

7.2.3 Maintenance Table: Weekly Maintenance

Weekly Maintenance

Tab. 7-8 *Weekly maintenance*

Instrument/Component	Maintenance Task	Reference
Liquid system	Clean	See section 7.3.1.3 “Cleaning the Liquid System”, 7-13
System liquid container	Empty and clean	See section 7.3.7 “Liquid Containers”, 7-17
Waste container	Empty and clean	See section 7.3.7 “Liquid Containers”, 7-17
Liquid handling arm, Robotic manipulator arm	Clean front arm guide	See section 7.3.10 “Arm Guide”, 7-21
PosID	Clean laser output window and “No Tube” sensor	See section 7.3.9 “Positive Identification (PosID)”, 7-19
	Clean PosID working area of the worktable (abrasion)	Lint-free cloth and alcohol

Note: *The weekly maintenance should be performed on the last working day of each week.*

7.2.4 Maintenance Table: Yearly Maintenance

Every twelve Months

Tab. 7-9 *Yearly maintenance*

Instrument/Component	Maintenance Task	Reference
LiHa	Liquid handling performance verification testing with QC Kit (optional)	See section 7.4.1 “Liquid Handling Performance Verification Testing”, 7-22
Complete Infinium LiHa and Infinium RoMa	Clean system	Call Illumina customer support to perform the task.
Frontal arm guide	Clean	Call Illumina customer support to perform the task.
Worktable	Visually inspect worktable grids for wear and replace if necessary.	Call Illumina customer support to perform the task.
LiHa	Visually inspect moving parts, especially Y-belt, for wear and replace faulty parts. Check parts for abrasion; wipe wear debris off, if necessary.	Call Illumina customer support to perform the task.

Tab. 7-9 *Yearly maintenance*

Instrument/Component	Maintenance Task	Reference
LiHa; support tubing	Check condition of mesh (must not be broken). Check if support tubing ends lock firmly in their seats. Replace defective support tubing.	Call Illumina customer support to perform the task.
RoMa	Visually inspect moving parts, especially Y-belt, for wear and replace faulty parts. Check parts for abrasion; wipe wear debris off, if necessary.	Call Illumina customer support to perform the task.
RoMa; Z-rod	Clean	Call Illumina customer support to perform the task.
Liquid system, diluters	Replace syringe	Call Illumina customer support to perform the task.
Liquid system, diluters	Replace 3-way valve	Call Illumina customer support to perform the task.
LiHa	Replace fixed tips	Refer to the “Infinium LiHa and Infinium RoMa Operating Manual”
Liquid system	Replace aspirating tubing	Call Illumina customer support to perform the task.
Liquid system	Replace interconnecting tubing	Call Illumina customer support to perform the task.
Liquid system	Replace pipetting tubing	Call Illumina customer support to perform the task.
Liquid system	Check and replace waste tubing, if necessary.	Call Illumina customer support to perform the task.
X-rail	Clean and apply thin layer of grease	Call Illumina customer support to perform the task.
Complete Infinium LiHa and Infinium RoMa	Perform tests according to form “Preventive Maintenance”	Call Illumina customer support to perform the task.

Note: *Depending on your system configuration there are other parts not described in this chapter, which have to be exchanged during regular service maintenance procedures. Please contact your local service organization, for further information on maintenance tasks and schedule of your system.*

7.3 Maintenance Tasks

WARNING

Automatically moving parts.
Injuries (crushing, piercing) possible if the safety panels are not in place.

- Always switch off the instrument for maintenance tasks or to clean the instrument surfaces, e.g. worktable, instrument panels etc.
- Never clean the instrument while it is switched on.

7.3.1 Liquid System

7.3.1.1 Checking for Leaks

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Chemical resistance of the tubing material	See section 3.3.3 “System Liquid Requirements”, 2 3-8
Flushing the liquid system	See section 7.3.1.2 “Flushing the Liquid System”, 🗎 7-12
Lock nut tightening	See section 7.3.3 “Fixed Tips of LiHa”, 🗎 7-15
Syringe and plunger lock screw tightening	See section 7.3.2 “Syringe”, 🗎 7-14

The liquid system is leaking

- if liquid droplets are hanging on the fixed tips before the instrument is switched on or when it is in stand-by mode.
- if the syringes are leaking, e.g. liquid accumulates around the diluters before the instrument is switched on or when it is in stand-by mode.
- if there are drops on the worktable.

Leakages in the liquid system can also be caused by an empty liquid system or by aggressive liquids. When using aggressive liquids, take into account the chemical resistance of the tubing material.
Refer to cross references above.

Instructions

If the system is leaky, do the following:

1. Make sure that the system liquid container is full.
2. Tighten the lock nut.
   Refer to cross references above.
3. Tighten syringe and plunger lock screw.
   Refer to cross references above.
4. Flush the liquid system until all air is removed.
   Refer to cross references above.
5. Observe the tips for 1 minute.
   If no droplets are formed, the liquid system is tight.
6. If the system is still leaky, remove the top cover of the instrument by loosening the two outer screws.
7. Tighten the tubing connections (A) according to the figure:

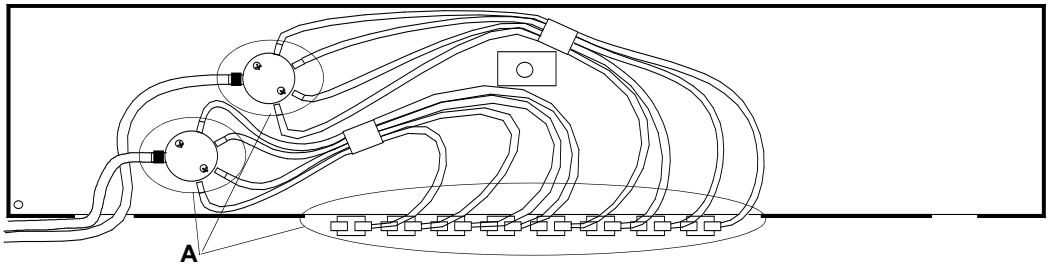


Fig. 7-1 *Tubing connections (top view of instrument)*

8. Flush the liquid system.
   Refer to cross references above.
9. Observe the tips for 1 minute.
   If no droplets are formed, the liquid system is tight.
10. If the system is still leaky, call your local Illumina service organization.

ATTENTION

A leaking liquid system causes pipetting inaccuracy and cross-contamination.

- Never operate the Infinium LiHa and Infinium RoMa if the liquid system is leaking.

7.3.1.2 Flushing the Liquid System

When to Flush

If the liquid system has been stationary overnight, outgassing results in air bubbles present in the liquid system. Even during a run air bubbles may remain in the liquid system. Therefore, flushing the liquid system is recommended before each application run.

Flush Procedure

To flush the liquid system:

1. Make sure that the system liquid container is full.
2. Switch on the instrument and start the IAC software.
3. Flush the liquid system by clicking **Sys Wash** in the IAC software.
4. During flushing, carefully observe the tubing. If necessary, gently move the tubing to make sure all air bubbles are removed.
5. If there are still air bubbles in the tubing, repeat steps 3 - 4.

ATTENTION

Air bubbles in the liquid system cause pipetting inaccuracy.

- Never operate the Infinium LiHa and Infinium RoMa with air bubbles in the liquid system.

7.3.1.3 Cleaning the Liquid System

Cleaning the Liquid System

To prevent growth of micro-organisms in the liquid system, we recommend cleaning the liquid system once a week. Depending on your application you can fill the system with one of the following agents (water is used as system liquid):

- Mild detergent
- Weak acid and base in sequence
- Disinfectant

Note: *If a system liquid other than de-ionized water is used, clarify the suitability of the cleaning agents with the manufacturer.*

To fill the liquid system and allow the agent to react, proceed as follows:

1. Place the tubing in a bottle with the cleaning agent and flush the liquid system twice.
   Refer to cross references above.
2. Allow the cleaning agent to react for at least 10 minutes.
3. Place the tubing in a bottle with distilled or de-ionized water and flush the liquid system twice.
   Refer to cross references above.
4. Flush the liquid system eight times with system liquid.
   Refer to cross references above.

7.3.2 Syringe

Cross References

By the continuous up and down movements of the syringes during operation, the syringe and plunger lock screws might get loose if these elements were not tightened properly. This may result in leakage of the liquid system.

To avoid this problem, proceed as follows:

Tightening Syringe and Plunger Lock Screws

1 Manually tighten the plunger lock screw and the syringe screw before switching the Infinium LiHa and Infinium RoMa on.

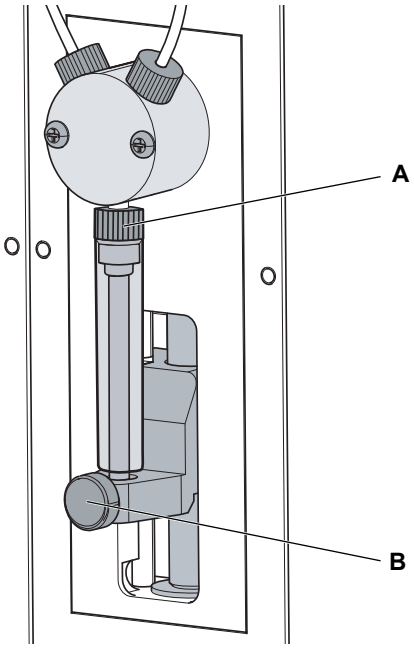


Fig. 7-2 *Syringe and valve*

A *Syringe screw* ***B*** *Plunger lock screw*

2 If leakages still occur, replace the syringe or the syringe cap. Refer to cross references above.

7.3.3 Fixed Tips of LiHa

ATTENTION

Electrostatic discharge can damage the liquid detector.

- Discharge yourself electrically through contact with an earthed object before touching the tips.

WARNING

Pipetting tubing and tips can be contaminated.

- Decontaminate the instrument and assure appropriate safety measures.

WARNING

Pipetting tips can cause injuries.

- Avoid contact with the pipetting tips and contact with aerosols when accessing the worktable, by wearing adequate protective clothing.

Checking Fixed Tips for Damage

Visually inspect the before switching on the instrument. Make sure that the tips are not bent. If the tip is damaged or the tip is bent, the tip must be replaced (call Illumina Support).

ATTENTION

Bent tips or damaged tip coating cause pipetting inaccuracy and liquid detection errors.

- Never work with damaged or bent tips.

ATTENTION

Handle tips with extreme care at all times.

- Do not use bent tips or tips with damaged coating. Replace them.
- If a tip is to be reinstalled, do not remove the lock nut from the tip.
- Always hold the tip at its upper end, avoiding contact with the coated surface whenever possible.

7.3.4 Wash Station

Note: *Always make sure that the wash station is installed in the correct grid position when it has been removed. If the grid position has changed, verify the corresponding definitions in the application software.*

7.3.4.1 Cleaning the (Standard) Wash Station

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Clean worktable	See section 7.3.5 “Worktable”, 🗎 7-17

The wash station can come in contact with reagents and samples. If a spillage occurred, the wash station needs to be removed from the worktable for cleaning.

Clean the wash station as follows:

1 Wipe the surface of the wash station with a suitable cleaning agent (e.g. water, alcohol, disinfectant) to remove any spilled reagent.

Note: *Do not use bleach to clean the wash station and do not clean it in a laboratory washing machine.*

2 If necessary, rinse the wash station and clean it additionally with water or alcohol.

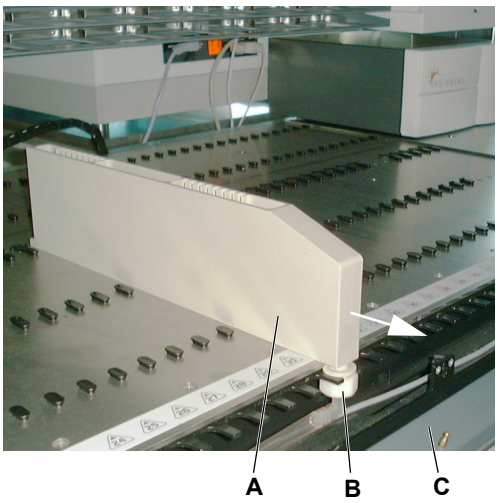


Fig. 7-3 *Wash station*

If necessary, remove the wash station from the worktable.

1 Open the front access panel (C).

2 Loosen the nut (B).

3 Pull the wash station (A) to the front (see arrow).

4 Clean the wash station as described above.

5 Clean the worktable.
Refer to cross references above.

6 Reinstall the wash station on the worktable.
Make sure that the wash station is pushed all the way back to the stop during installation.

7.3.5 Worktable

WARNING

Possible worktable damage

- Only clean the worktable with small amounts of cleaning agent, e.g. with a damped cloth.
- Do not spill cleaning agent on the worktable.

Cleaning the Worktable

Perform the following procedure to clean the pipetting instrument's worktable:

1. Remove all racks and carriers from the worktable.
2. Wipe the surface of the worktable with a suitable cleaning agent (e.g. alcohol, disinfectant) to remove any spilled reagent.
3. If necessary, additionally clean with water.

7.3.6 Safety Panels

Cleaning the Safety Panels

Perform the following procedure to clean the safety panels.

- Wipe the inner and outer surface of the safety panels with a suitable cleaning agent, e.g. water, alcohol or disinfectant, to remove any spilled reagent or sample.
- If necessary, additionally clean the surface with water or alcohol.

7.3.7 Liquid Containers

System Liquid Container

To prevent deposition of crystals and growth of micro-organisms in liquid containers, clean all liquid containers at least once a week. Make sure to allow solvents (e.g. ethanol) to evaporate before filling reagents into the containers again.

Waste Container

Clean the waste container at least once a day.

WARNING

Contamination through waste liquid, if the containers are installed wrongly.

- Make sure not to mix up the system liquid container and the waste container.

7.3.8 Carriers and Racks

WARNING

Potentially infectious
Instrument parts may be contaminated with potentially infectious materials.

- Follow basic biohazard precautions
- Wear appropriate personal protective equipment, such as gloves, lab coats and protective eye wear

Cleaning Carriers and Racks

Racks and carriers can come in contact with reagents and samples, which must be removed.

Perform the following procedure to clean the carriers and racks.

1. Remove all carriers and racks from the Infinium LiHa and Infinium RoMa worktable.

   The wash station can be cleaned on the worktable.
2. Before cleaning, remove the barcode labels from the carriers, if possible.
3. Wipe the surface of the racks, carriers and the gripper with a suitable cleaning agent (e.g. water, alcohol, disinfectant) to remove any spilled reagent.

   If you have not removed the labels on the carriers and racks, make sure not to damage them with the cleaning agent.

Note: *Do not use bleach to clean the carriers and racks and do not clean them in a laboratory washing machine.*

4. If necessary, rinse the carriers and racks and clean them additionally with water or alcohol.
5. Replace the barcode labels and make sure to put them back to their original position.
6. Return the carriers and racks to the Infinium LiHa and Infinium RoMa worktable.

Note: *If barcode labels are damaged or contaminated, replace them immediately.*

7.3.9 Positive Identification (PosID)

WARNING

Fire hazard, if heated parts are cleaned with flammable agents.

- Allow the PosID to cool down before cleaning.

ATTENTION

The laser output window of the PosID barcode scanner must be perfectly clean at all times. Even slight soiling may cause errors.

- For cleaning, avoid abrasive substances.
- Do not scour the surface. Use a soft, clean tissue.

Barcode Scanner

To clean the laser output window of the barcode scanner, proceed as follows:

WARNING

Laser light (CLASS 2 LASER PRODUCT).

- Do not stare into beam nor into its reflections on the worktable.
- Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- Ensure appropriate FDA regulatory actions have been taken for any Class II laser products.

1 Check if the barcode scanner (A) is in vertical position and if the laser output window is accessible as shown in the figure below.

If this is not the case, initialize the PosID.

ATTENTION

Damage to the barcode scanner drive if the position of the barcode scanner is forced manually.

- Do not attempt to rotate the barcode scanner manually.
- Use the initialization routine to run the barcode scanner into maintenance position.

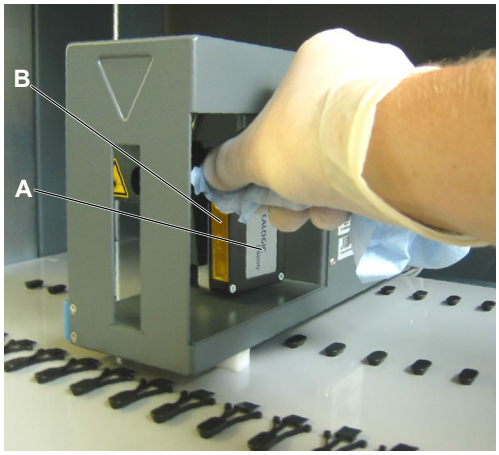


Fig. 7-4 PosID barcode scanner

2 Switch the instrument off.

3 Remove the carriers in front of the PosID to gain access to the PosID.

4 Visually check the laser output window (B) for cleanliness.

5 Moisten a lint-free tissue with alcohol and clean the output window, if necessary.

"No Tube" Sensor

To clean the "No Tube" sensor, proceed as follows:

1 Switch the instrument off.

2 Remove the carriers in front of the PosID to gain access to the PosID.

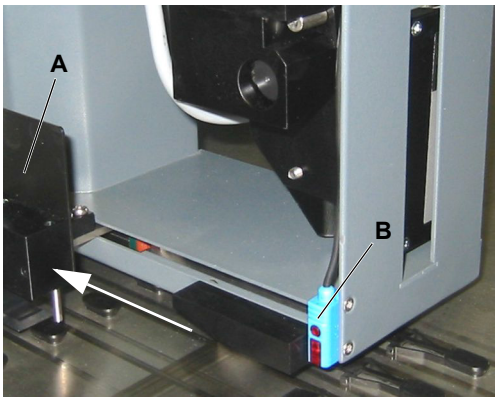


Fig. 7-5 PosID "No Tube" sensor

3 Slide the PosID gripper (A) back to gain access to the "No Tube" sensor (B).

4 Moisten a lint-free tissue with alcohol and clean the front surface of the "No Tube" sensor.

7.3.10 Arm Guide

The following description is applicable to:

- Liquid handling arm (LiHa)
- Robotic manipulator arm

Cleaning the Arm Guide

In order to avoid uneven movements of the arm, use a cotton tab or a lint-free tissue on a screwdriver to clean the arm guide roller and a lint-free tissue to thoroughly clean the arm guide rails.

Note: *Do not use alcohol or solvents to clean the arm guide. Do not use grease on the arm rails.*

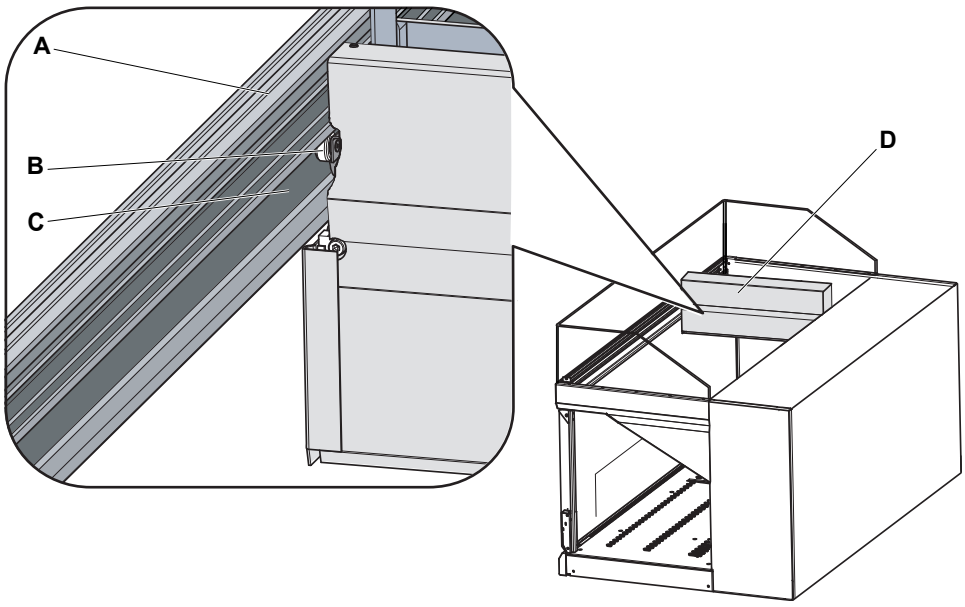


Fig. 7-6 *Arm guide and roller*

A	*Arm guide*	***C***	*Arm rail*
B	*Arm guide roller*	***D***	*Arm*

7.4 Precision and Function Tests

7.4.1 Liquid Handling Performance Verification Testing

QC Kit

For details about the QC Kit refer to the QC Kit manuals (see 1.1 “Reference Documents”, 2 1-2) and the website https://support.illumina.com/content/dam/illumina-support/documents/documentation/chemistry_documentation/infinium_assays/infinium/infinium-assay-lab-setup-and-procedures-11322460-03.pdf

7.5 Decontamination

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Safety information on decontamination	See section 2.8 “Decontamination Declaration”, 2 2-13
Commercially available agents	See section 7.1 “Tools and Consumables”, 7-1

Agents

Note: *The selection of the appropriate decontamination agent depends on the contamination degree and the kind of contaminant.*

Decontamination can be performed with the following agents:

- Bleach 0.5% to 3%
- 70% ethanol + 30% H_2O

Commercially Available Agents

For commercially available agents that can be used for decontamination or disinfection, refer to cross references above.

Hints Concerning Decontamination

In order to remove protein residues in the tubing and tips, flush the liquid system periodically with weak acid, followed by base. Alternatively, use the above mentioned commercially available agents.

Certain agents can be used as system liquid additives. Most of the immunological assays will not be affected by them.

Elimination of Nucleic Acid Residues

Nucleic acid residues in standard tips and pipetting tubing can usually be eliminated by means of wash or decontamination cycles with a 3% bleach solution.

Appropriate commercially available agents (e.g. DNAzap) are used to keep the pipetting area (worktable, carriers etc.) free of interfering nucleic acids.

8 Troubleshooting

Purpose of This Chapter

This chapter helps to resume operation after a minor problem has occurred with the Infinium LiHa and Infinium RoMa. It lists possible occurrences, their probable cause and suggests how to remedy the problem.

Which Errors can the Operator Correct?

The troubleshooting table below lists possible malfunctions and errors of the Infinium LiHa and Infinium RoMa. The operator is enabled to correct some of those problems or errors by him/herself. For this, appropriate corrective measures are listed in the column “Corrective measures”.

The elimination of more complicated malfunctions or errors is usually performed by the Illumina FSE according to separate instructions. In this case, reference to the FSE is made.

8.1 Troubleshooting Table

Trouble-shooting by the Operator

The following table lists problems and errors and gives instructions on how to eliminate them:

Tab. 8-1 *Troubleshooting table*

Problem, error	Possible cause	Corrective measures
Problem, error on instrument level		
System liquid leakage	Tubing and/or tubing connections not tight Syringe is leaking	Switch off instrument immediately Perform decontamination and/or maintenance
Communication error	Power not ON Power/communication interrupted No communication	Switch on instrument Check cable and plug Switch off instrument and PC, wait until the status lamp is dark, switch on instrument and PC
	X, Y or Z-drive or PosID scanner head blocked	Check for obstacles
Initialization error	Arms can not initialize	Make sure that the arms can move freely, i.e. that their movement range is not obstructed by other objects.
	Hardware defective	Contact your local service organization
Front safety panel does not unlock properly	Mechanical failure of the door locks	Contact your local service organization

Tab. 8-1 Troubleshooting table (cont.)

Problem, error	Possible cause	Corrective measures
Front safety panel does not lock properly	Mechanical failure of the door locks	Switch off the instrument. Contact your local service organization
Problem, error on liquid handling arm (LiHa) and tips		
Positioning error	X, Y or Z-drive blocked Crash Hardware defective	Check for obstacles Check container, rack and carrier positions Contact your local service organization See “Carrier Positioning”, 6-11
Problem, error on Positive Identification, PosID		
Positioning error	Hardware defect	Contact your local service organization
Barcode not read	Barcode label not facing barcode scanner	Check container position on carrier See 3.4.3, 2 3-13
	Bad barcode label quality	Check with new barcode label See 3.4.3, 2 3-13
	Barcode type not according to specifications	Check if barcode type is permissible See 3.4.3, 2 3-13
	Barcode label position not according to specifications	Check barcode label position on container See 3.4.3, 2 3-13
	Barcode type not specified in software	Check the settings in the application software
	Laser output window dirty	Clean output window See 7.3.9, 7-19
Alignment barcode on barcode flag not read	PosID adjustment/setup not correct	Contact your local service organization
Carrier or tube presence not detected	“No Tube” sensor dirty	Clean “No Tube” sensor See 7.3.9, 7-19
Unusual noise during movement	Worn out or damaged parts	Contact your local service organization
Problem, error on robotic manipulator arm, RoMa Standard		
Microplate not picked up	No microplate on carrier Cannot pick up microplate	Put microplate on carrier Set gripper position Clean grippers
Unusual noise during arm movement	Worn or damaged parts	Contact your local service organization

Tab. 8-1 *Troubleshooting table (cont.)*

Problem, error	Possible cause	Corrective measures
Problem, error on wash station		
Overflow of wash station	Waste tube is below liquid surface in the waste container	Use a wash container with fixed wash tubing inlet
	Algae block the wash station	Clean the wash station
	Waste tubing kinked	Check tubing for kinks

9 Shutdown, Transport and Storage

Purpose of This Chapter

This chapter instructs how to shut down the Infinium LiHa and Infinium RoMa, how to pack it for storage or transport, and specifies the storage and shipping conditions.

9.1 Shutdown

9.1.1 Instrument

Since the material processed by the Infinium LiHa and Infinium RoMa is not known to Illumina, detailed information on how to dispose of it cannot be given here.

WARNING

Chemical, biological and radioactive hazards can be associated with the waste material from the process run on the Infinium LiHa and Infinium RoMa.
Treat these substances and disposables, such as wash liquid, etc. in accordance with good laboratory practice guidelines.

Inquire about appropriate collecting points and approved methods of disposal in your country, state or region.
When disposing of operating material of the Infinium LiHa and Infinium RoMa the relevant national and regional laws, directives and recommendations must be followed.

To shut down the instrument for a long period:

1. Empty the liquid system and thoroughly clean and decontaminate all liquid system components.
2. Save data and exit application software and instrument software.
3. Press the power **ON/OFF switch** for 2 seconds to switch the instrument off.
   The status lamp turns off.

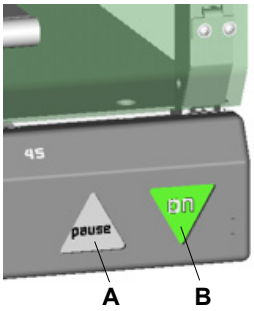


Fig. 9-1 *Power Switch*

A *Pause button* ***B*** *Power ON/OFF switch*

Note: *Wait until the status lamp is off before switching the instrument on again.*

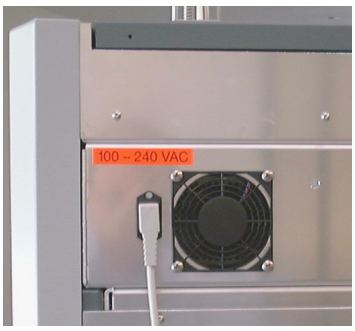


Fig. 9-2 *Power cord/mains socket*

4 Unplug the power cord from the power supply at the rear of the instrument.

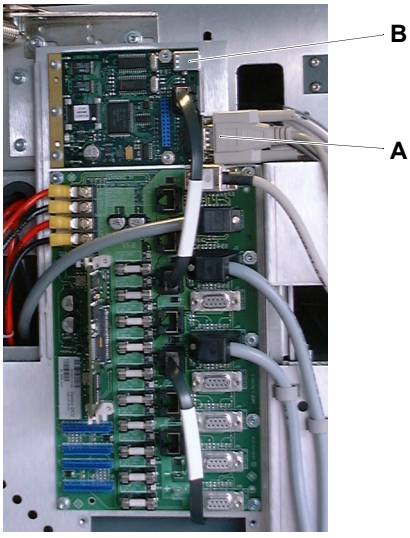


Fig. 9-3 *RS232 interface on Optibo PCB*

A *RS232 interface connector* ***B*** *USB connector*

5 Disconnect the instrument from the PC.

6 If desired, unplug the interface cable from the USB port on the Te-CU board behind the left access door.

Or Disconnect the RS-232 interface cable from the Te-CU board.

7 Clean and, if necessary, decontaminate the entire instrument.

9.1.2 Reporting

1 Fill out a copy of the decontamination form and place it with the instrument.

2 Record the shut down in the appropriate CRM.

9.2 Transport

WARNING

Lifting or moving the instrument can cause serious injuries

- Injuries to the back due to overload can occur
- Injuries can be caused due to a falling instrument
- Lifting or moving the instrument must be correctly prepared and may only occur under the direction of a qualified Illumina person

ATTENTION

Lifting or moving the instrument can cause damage due to unsecured parts

- Lifting or moving the instrument must be correctly prepared and may only occur under the direction of a qualified Illumina person only

Transport

The transport of the instrument may be done under direction of a qualified Illumina service person only. Due to the heavy weight, trained relocation staff is needed to lift the instrument.

9.2.1 Unpacking

The unpacking of the instrument may be done by a qualified Illumina service person only.

Packaging materials

The instrument packaging has been designed to prevent damage to instrument and parts during normal transport conditions.
Keep the packaging materials for future use.

ATTENTION

Do not remove the transport moorings before the instrument is in its final operating position.

9.2.2 Packaging

The packaging of the instrument may be done by a qualified Illumina service person only.

Packaging materials

Use original packing material that has been designed to prevent damage to instrument and parts under normal transport conditions.

Guarantee

All Illumina guarantees are void if the instrument is not correctly prepared by qualified Illumina service personnel for transport.

9.3 Storage

Cross References

List of cross references to information provided in other sections:

Subject	Reference
Storage conditions	See section 3.2.4 “Environmental Conditions”, 2 3-6
Packaging	See section 9.2.2 “Packaging”, 9-4

Protect the instrument against dust and debris with a cover. For long term storage, pack the instrument in its original packing.
Store all manuals and the “Maintenance and Service Logbook” with the instrument.

10 Disposal

Purpose of This Chapter

This chapter includes regulatory information about recycling that needs to be followed.

NOTICE

Recycling in accordance with applicable legal regulations!
Observe the laws applicable in your country for recycling.

10.0.1 Local Requirements European Union

EC Directive WEEE

The European Commission has released the Directive on Waste Electrical and Electronic Equipment (WEEE; 2012/19/EU).
Since August 2005, producers have been responsible for taking back and recycling electrical and electronic equipment.

Tab. 10-1 *Electrical and electronical equipment waste logo*

Marking	Explanation
	Negative environmental impacts associated with the treatment of waste. • Do not treat electrical and electronic equipment as unsorted municipal waste. • Collect waste electrical and electronic equipment separately.

10.0.2 Local Requirements People's Republic of China

Marking for the Restriction of the Use of Hazardous Substances in Electronic and Electrical Products

Required Product Information

The People's Republic of China Electronic Industry Standard SJ/T11364-2014 "Marking for the Restriction of the Use of Hazardous Substances in Electronic and Electrical Products" requires the marking for the restriction of the use of hazardous substances in electronic and electrical products.

Product Marking

In accordance with the requirements specified in SJ/T11364-2014, all electronic and electrical Illumina products sold in the People's Republic of China are labeled with a marking for the restriction of the use of hazardous substances.

Tab. 10-2 Marking for the restriction of the use of hazardous substances

Marking	Explanation
	This marking indicates that this electronic product contains certain hazardous substances and can be safely used during the environment-friendly use period, but it shall enter the recycling system after the environment-friendly use period.

11 Spare Parts and Accessories

Contact your local service representative for information on spare parts.

11.1 Software

Tab. 11-1 *Software*

No.	Plain Text Designation	p/n	Label Designation
1	Illumina Automation Control	-	IAC 6.3.1

11.2 Documentation

Tab. 11-2 *Documentation*

No.	Plain Text Designation	p/n	Label Designation
1	Infinium LiHa and Infinium RoMa Operating Manual	-	Not for sale

11.3 Infinium LiHa and Infinium RoMa Basic Accessories Kit

Tab. 11-3 *Infinium LiHa and Infinium RoMa basic accessories kit*

No.	Plain Text Designation	p/n	Label Designation
1	Infinium LiHa and RoMa Accessory Kit	-	Not for sale: KIT ACCESSORY INFINIUM ILLUMINA *SCREWDRIVER 4.5/1.5*90 MM BRASS PLT.NI* *SCREWDRIVER SIZE 2 WORKTABLE MOUNTING* *SET WRENCH HEXAGON* *WRENCH HEXAGON 0.71*

11.4 Carriers, Racks, Troughs

11.4.1 Carriers for Microplates

Tab. 11-4 *Carriers for microplates*

Plain Text Designation	Label Designation	Width[a)]	Reference
Carrier for microplates, RoMa, 3 pos., landscape orientation	CARRIER MTP 3POS. ASSY ROMA ILLUMINA	6 150 mm (5.9 in.)	See Fig. 11-1 , 🗎 11-2

a) Number or grid positions the carrier occupies

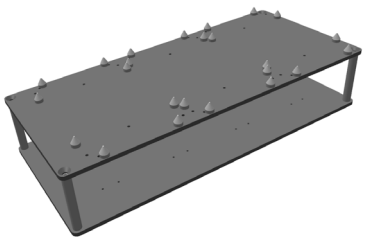


Fig. 11-1 *Carrier for 3 microplates landscape*

11.4.2 Carriers for Tubes

Tab. 11-5 *Tube carriers*

Plain Text Designation	p/n	Label Designation	Width[a)]	Reference
Carrier for tubes, 16 mm, 6 x 16 pos. Set of 6 carriers	-	RACK STRIP 16 POS. TUBE 16MM 6 PCE.	1 25 mm (0.98 in.)	See Fig. 11-2 , 11-3

a) Number or grid positions the carrier occupies

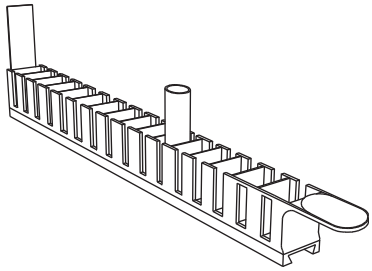


Fig. 11-2 *Carrier for tubes (example for 16 tubes)*

11.4.3 Wash Stations

Tab. 11-6 *Wash/waste stations*

Plain Text Designation	p/n	Label Designation	Width[a)]	Reference
Wash/waste station standard, PP 8 wash positions shallow at rear 1 waste position at center 8 wash positions deep at front	-	WASHSTATION GENESIS 8+8POS.WIDTH 1 CAR.	1 25 mm (0.98 in.)	See Fig. 11-3 , 11-4

a) Number or grid positions the carrier occupies

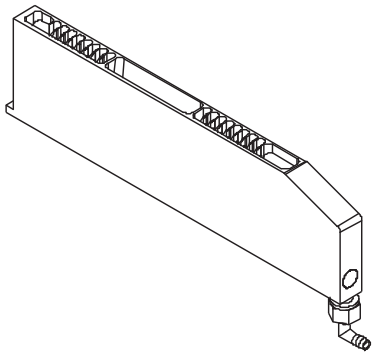


Fig. 11-3 *Wash/waste station, standard*

11.5 Tips and Accessories

Contact your local service representative for information on other accessories.

12 Customer Support

Purpose of This Chapter

This chapter informs you how to contact us in case help is needed.

How to get Help

Illumina and its representatives maintain a fully trained staff of technical specialists around the world. For any technical question, contact the nearest Illumina representative.

12.1 Contacts

Technical Assistance

For technical assistance, contact the Illumina technical support:
Website: www.illumina.com
E-Mail: techsupport@illumina.com

Illumina customer support toll-free telephone number:

Country/Region	Telephone
North America	+1.800.809.4566
Australia	+1.800.775.688
Austria	+43 800006249 +43 19286540
Belgium	+32 80077160 +32 34002973
China	400.066.5835
Denmark	+45 80820183 +45 89871156
Finland	+358 800918363 +358 974790110
France	+33 805102193 +33 170770446
Germany	+49 8001014940 +49 8938035677
Hong Kong, China	800960230
Ireland	+353 1800936608 +353 016950506
Italy	+39 800985513 +39 236003759
Japan	0800.111.5011

Netherlands	+31 8000222493 +31 207132960
New Zealand	0800.451.650
Norway	+47 800 16836 +47 21939693
Singapore	+1.800.579.2745
South Korea	+82 80 234 5300
Spain	+34 911899417 +34 800300143
Sweden	+46 850619671 +46 200883979
Switzerland	+41 565800000 +41 800200442
Taiwan, China	00806651752
United Kingdom	+44 8000126019 +44 2073057197
Other countries	+44.1799.534000