

HistoCore CHROMAX ST

Automated Slide Stainer



Instructions for Use
English

Order No.: 14 0486 80101 - Revision A

Always keep this manual with the instrument.
Read carefully before working with the instrument.

CE

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For the instrument serial number and year of manufacture, please refer to the nameplate on the back of the instrument.



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1. Important Information

1.1 Symbols and their meanings

Symbol:



Title of the symbol:

Danger

Description:

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injuries.

Symbol:



Title of the symbol:

Warning

Description:

If this danger is not avoided, then this may result in death or serious injury.

Symbol:



Title of the symbol:

Caution

Description:

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

Symbol:



Title of the symbol:

Note

Description:

Indicates information which are important but not related to any risk.

Symbol:

→ Fig. 7-1

Title of the symbol:

Item number

Description:

Item numbers for numbering illustrations. Numbers in red refer to item numbers in illustrations.

Symbol:

Admin

Title of the symbol:

Software designations

Description:

Software designations that have to be displayed on the input screen are displayed as bold, gray text.

Symbol:

Save

Title of the symbol:

Function key

Description:

Function keys to be pressed on the instrument are displayed as bold, gray and underlined text.

Symbol:

Power switch

Title of the symbol:

Keys and switches on the instrument

Description:

Keys and switches on the instrument that are supposed to be pressed by the user in various situations are displayed as bold, gray and underlined text.

Symbol:



Title of the symbol:

Manufacturer

Description:

Indicates the manufacturer of the medical product.

Symbol:



Title of the symbol:

Manufacturing date

Description:

Indicates the date when the medical device was manufactured.

Symbol:



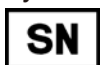
Title of the symbol:

Article number

Description:

Indicates the manufacturer's catalog number so that the medical device can be identified.

Symbol:



Title of the symbol:

Serial number

Description:

Indicates the manufacturer's serial number so that a specific medical device can be identified.

Symbol:












Title of the symbol:

Consult Instructions for Use

Description:

Indicates the need for the user to consult the Instructions for Use.

<p>Symbol: </p>	<p>Title of the symbol: CE Compliance Description:</p>	<p>The CE marking is the manufacturer's declaration that the medical product meets the requirements of the applicable EC directives and regulations.</p>
<p>Symbol: </p>	<p>Title of the symbol: Country of Origin Description:</p>	<p>The Country of Origin box defines the Country where the final character transformation of the product has been performed.</p>
<p>Symbol: </p>	<p>Title of the symbol: UKCA Description:</p>	<p>The UKCA (UK Conformity Assessed) marking is a new UK product marking that is used for goods being placed on the market in Great Britain (England, Wales and Scotland). It covers most goods which previously required the CE marking.</p>
<p>Symbol: </p>	<p>Title of the symbol: UKRP Description:</p>	<p>The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations.</p>
<p>Symbol: </p>	<p>Title of the symbol: WEEE Symbol Description:</p>	<p>The WEEE symbol, indicating separate collection for WEEE – Waste of electrical and electronic equipment, consists of the crossed-out wheeled bin (§ 7 ElektroG).</p>
<p>Symbol: </p>	<p>Title of the symbol: Caution Description:</p>	<p>Indicates the need for the user to consult the Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.</p>
<p>Symbol: </p>	<p>Title of the symbol: Caution – Moving parts Description:</p>	<p>Label is attached on the transport arm. It indicates a risk of collision between the transport arm and any operator working within the instrument while the transport arm is moving.</p>
<p>Symbol: </p>	<p>Title of the symbol: Caution – Toxic chemicals/Flammable substances Description:</p>	<p>Labels are attached inside the instrument below the fixation of the hood (in the middle).</p> <p>The first label indicates that toxic chemicals are inside the instrument. Do not handle solution containers unless properly protected.</p> <p>The second label indicates that there is a risk of fire because of flammable substances inside the instrument.</p> <p>Thus, avoid any source of ignition close to the instrument.</p>
<p>Symbol: </p>	<p>Title of the symbol: Caution – Hot surface Description:</p>	<p>Two labels are attached close to the oven. They indicate a risk of burns because of hot surfaces. Do not touch these parts.</p>
<p>Symbol:</p>	<p>Title of the symbol: Biohazard</p>	



Symbol:

Title of the symbol: Caution – Risk of crushing
Description: Reminds users to be careful to open/close the hood.



Symbol:

Title of the symbol: Caution – Risk of fire
Description: Label is attached at the rear of the instrument close to the fuse. It indicates a risk of fire in case that no or inappropriate fuses are used. For continued protection against the risk of fire replace only with appropriate fuses as indicated on the instrument.



Symbol:

Title of the symbol: Caution – Input voltage
Description: Label is attached at the rear of the instrument above the switched mains power inlet. It indicates that the unit is wired either for 100-120 VAC or 230-240 VAC (depending on your order). Do not change wiring or voltage selection on your own but contact qualified Leica Biosystems service personnel in this case.



Symbol:

Title of the symbol: Caution – Water supply and interfaces
Description: Labels are attached at the rear of the instrument close to the serial port and the water supply connections. They indicate that both Instructions for Use and – if applicable – any inscription on the instrument must be observed.



Symbol:

Title of the symbol: Caution - Laser light
Description: Label is attached close to the slides counting sensor.



Symbol:

Title of the symbol: China ROHS
Description: Environmental protection symbol of the China RoHS directive. The number in the symbol indicates the "Environment-friendly Use Period" of the product in years. The symbol is used if a substance restricted in China is used in excess of the maximum permitted limit.



Symbol:

Title of the symbol: PE terminal



Symbol:

Title of the symbol: **ON/OFF** (Power)
Description: In position of power on/off



"I" = ON

"O" = OFF





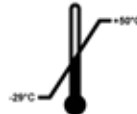
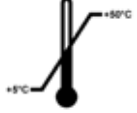



Symbol:

Title of the symbol: Stand-by



Symbol:

Title of the symbol: Fragile, handle with care

	<p>Description: The package contents are fragile and must be handled with care.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Store dry Description: The package must be kept in a dry environment.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Stacking limitation Description: Maximum number of identical packages that may be stacked, where 1 stands for the number of permitted packages.</p>
<p>Symbol:</p> 	<p>Title of the symbol: This way up Description: Indicates the correct upright position of the package.</p>
<p>Symbol:</p> <p>Transport temperature range:</p> 	<p>Title of the symbol: Temperature limit for transport Description: Indicates the temperature range permitted for transporting the package.</p>
<p>Symbol:</p> <p>Storage temperature range:</p> 	<p>Title of the symbol: Temperature limit for storage Description: Indicates the temperature range permitted for storing the package.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Humidity limitation for transport and storage Description: Indicates the humidity range permitted for storing and transporting the package.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Shockdot Impact Indicator Description: In the Shockwatch system, the shock dot shows impacts or shocks that are above a specified intensity through red colouration. Exceeding a defined acceleration (g value) causes the indicator tube to change colour.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Tilt indicator Description: Tip-n-Tell indicator to monitor whether the shipment has been transported and stored in upright position according to your requirements. With a pitch of 60° or more, the blue quartz sand flows into the arrow-shaped indicator window and sticks there permanently. Improper handling of the shipment is immediately detectable and can be proven definitively.</p>
<p>Symbol:</p>	<p>Title of the symbol: Recycle symbol</p>

**Description:**

Indicates the item can be recycled where correct facilities exist.

1.2 Instrument type

All information provided in these Instructions for Use applies only to the instrument type indicated on the cover page. A nameplate indicating the instrument serial number is attached to the rear side of the instrument.

1.3 Intended use

The HistoCore CHROMAX ST Automated Slide Stainer is a laboratory instrument.

The HistoCore CHROMAX ST Automated Slide Stainer is a stainer for laboratory applications and intended for the preparation of histological and cytological tissue samples. This product is used for staining of cells, tissue samples, etc. before pathological analysis.

**Warning**

- Any use of the instrument that deviates from the designated use is considered improper. Failure to adhere to these instructions may result in an accident, personal injury, damage to the instrument or accessory equipment. Proper and intended use includes compliance with all inspection and maintenance instructions, along with the observance of all instructions in the Instructions for Use as well as the constant inspection of the reagents for storage life and quality. The HistoCore CHROMAX ST Automated Slide Stainer carries out the specified staining steps automatically. The manufacturer assumes no liability for the staining results in the case that the staining steps and programs are entered incorrectly. Thus, the end user is independently responsible for self-created reagents or program entries.

1.4 Qualification of personnel

The HistoCore CHROMAX ST Automated Slide Stainer must be operated by trained laboratory personnel only. The instrument is intended for professional use only.

All laboratory personnel designated to operate this instrument must read these Instructions for Use carefully and must be familiar with all technical features of the instrument before attempting to operate it.

2. Safety

2.1 Safety notes

The Instructions for Use includes important information related to the operating safety and maintenance of the instrument.

The Instructions for Use is an important part of the product, and must be read carefully prior to startup and use and must always be kept near the instrument.

This instrument has been built and tested in accordance with the safety requirements for electrical equipment for measurement, control, and laboratory use.

To maintain this condition and ensure safe operation, the user must observe all notes and warnings contained in the Instructions for Use.

The safety and caution notes in this chapter must be observed at all times.

Be sure to read these notes even if you are already familiar with the operation and use of other Leica Biosystems products.

The Instructions for Use must be appropriately supplemented as required by the existing regulations on accident prevention and environmental safety in the operator's country.



Warning

- The protective devices on both instrument and accessories may neither be removed nor modified. Only authorized and qualified service personnel may repair the instrument and access the instrument's internal components.



Note

For current information about applicable standards, please refer to the CE Declaration of Conformity and UKCA Certificates on our Internet site:
<http://www.LeicaBiosystems.com>.

The device is designed to be used in a basic electromagnetic environment.

2.2 Warnings

The protective devices installed in this instrument by the manufacturer only constitute the basis for accident prevention. Operating the instrument safely is, above all, the responsibility of the owner, as well as the designated personnel who operate, service or clean the instrument. To ensure trouble-free operation of the instrument, be sure to comply with the following instructions and warnings.

2.2.1 Markings on the instrument itself



Warning

Failure to follow the correct operating instructions (as defined in the Instructions for Use) of the corresponding markings and warning triangles on the instrument.

Serious injury of persons and/or damage to instrument, accessories or specimen.

- Pay attention to the markings on the instrument and strictly follow operating instructions described in the Instructions for Use when operating or replacing the item marked.

2.2.2 Transport and installation



Warning

Inadequate lifting and transportation of the instrument

People injury and/or property damage

- The instrument must only be transported in an upright position.
- Do not try to lift the instrument with less than 4 persons.
- Wearing non-skid gloves, grab the instrument under the frame at all corners and lift it evenly.
- It is recommended to commission a transport company to transport, install or (where applicable) relocate the instrument.



Warning

The adjustable feet are not adjusted properly during installation, and the instrument is tilted.

Damage of sample due to the overflow of the liquid in the internal reagent/wash container.

- Place the instrument on a stable and level laboratory bench.
- Adjust the instrument to a level position if it is tilted.

2.2.3 Operating the instrument



Warning

Operating the instrument without adequate clothing

People injury

- Always wear protective clothing suitable for laboratory use, as well as rubber gloves and safety goggles when handling the chemicals used in this instrument.
- Always follow your laboratory safety regulations.



Warning

Handling infectious specimens without adequate clothing

People injury

- Always wear protective clothing suitable for laboratory use, as well as rubber gloves and safety goggles when handling infectious specimens used in this instrument.
- Always follow your laboratory safety regulations.

**Warning**

Breathing in vapors dangerous to health

People injury

- The active carbon filter must be in use. In addition, connect the instrument to an external exhaust system using the dedicated hose (lengths of 2 m and 4 m available), or operate the instrument below a fume cupboard.
- The reagent containers must be covered when not using the instrument to prevent the unnecessary evaporation of the reagents.
- Users must verify compliance with the workplace limit values when work is done with hazardous materials.

**Warning**

Assign incompatible reagents to adjacent stations.

Impaired of sample/poor staining quality

- Do not assign incompatible reagents to adjacent stations.

**Warning**

Reach into the swivel range of the hood when opening or closing the hood

People injury - fingers or hands crushed

- Do not reach into the swivel range of the hood when opening or closing it.

**Warning**

Inadequate manual loading of racks into reagent containers

Damage of sample and/or property damage because of crash due to automatized loading of another rack into the same reagent container

- Do not manually load racks and start any movement of the transport arm.

**Warning**

Lids not removed from reagent containers

Damage of sample because of crash due to automatized loading of a rack

- Always make sure that any lids are removed before initiating any transport to the affected reagent containers.

**Warning**

Reagent filling level within reagent containers is insufficient

Impaired of sample/Poor tissue quality

- Check the filling level of the reagent containers regularly and clean and/or refill if required.
- Cover unused reagent containers to minimize evaporation.

2 Safety



Warning

Racks not unloaded in a timely manner from the **EXIT** drawer

Damage of sample

- Unload the **EXIT** drawer in time, close the **EXIT** drawer and press **EXIT**.



Warning

Rack processed with wrong program parameters

Damage of sample

- Always double-check program parameters of user-defined programs before you start processing.



Warning

LOAD and **EXIT** drawers opened while the transport arm operates in the drawer area

Damage of sample

- Do not open the **LOAD** drawer or **EXIT** drawer when the transport arm is operating in the drawer area.



Warning

Taking out the rack during processing and colliding with the transport arm

People injury

- Be careful when opening the hood to take out the rack during processing.



Warning

Label adhesive/Labels on slide not solvent-resistant. Identification of the sample is no longer possible

Damage of sample

- The stickers and/or labels used on the specimen slides must be resistant to the solvents used in the instrument.
- When printable labels or handwritten labels are used on the rack handles and the specimen slides, they must be checked for solvent resistance prior to use.



Caution

Directly look at the light source of the scanner when it is working.

People injury

- Never look at the light source of the scanner when it is working.

2.2.4 Handling reagents



Warning

Contamination after accidental handling of reagents

Impaired of sample/Poor tissue quality

- If you have accidentally contaminated reagents, e.g., because a reagent has dripped into another reagent container, always follow your local regulations. Focus on saving the tissue first. Dispose any contaminated reagents and clean the affected reagent containers thoroughly.

**Caution**

User left during changing reagents and failed to enter correct reagent information, including lot number, expiration date, etc. when returned.

Impaired sample/Poor tissue quality

- Enter correct reagent information when changing reagents.
- Check entered reagent information before next step, especially after interruptions.

2.2.5 Cleaning and Maintenance**Warning**

Reagent containers not cleaned or cleaned insufficiently before refilling with another reagent

Impaired of sample/Poor tissue quality

- Always clean the reagent containers thoroughly and regularly before refilling them.

**Warning**

Water drainage not cleaned or cleaned insufficiently

Damage of sample/People injury

- Check and clean the draining system regularly for correct flow.

**Warning**

- In accordance with national rules and regulations, the operator may be obligated to provide long-term protection of the public water supply from contamination due to backflowing water from the building installation.

3 Instrument Components and Specifications

3. Instrument Components and Specifications

3.1 Overview

3.1.1 Instrument components

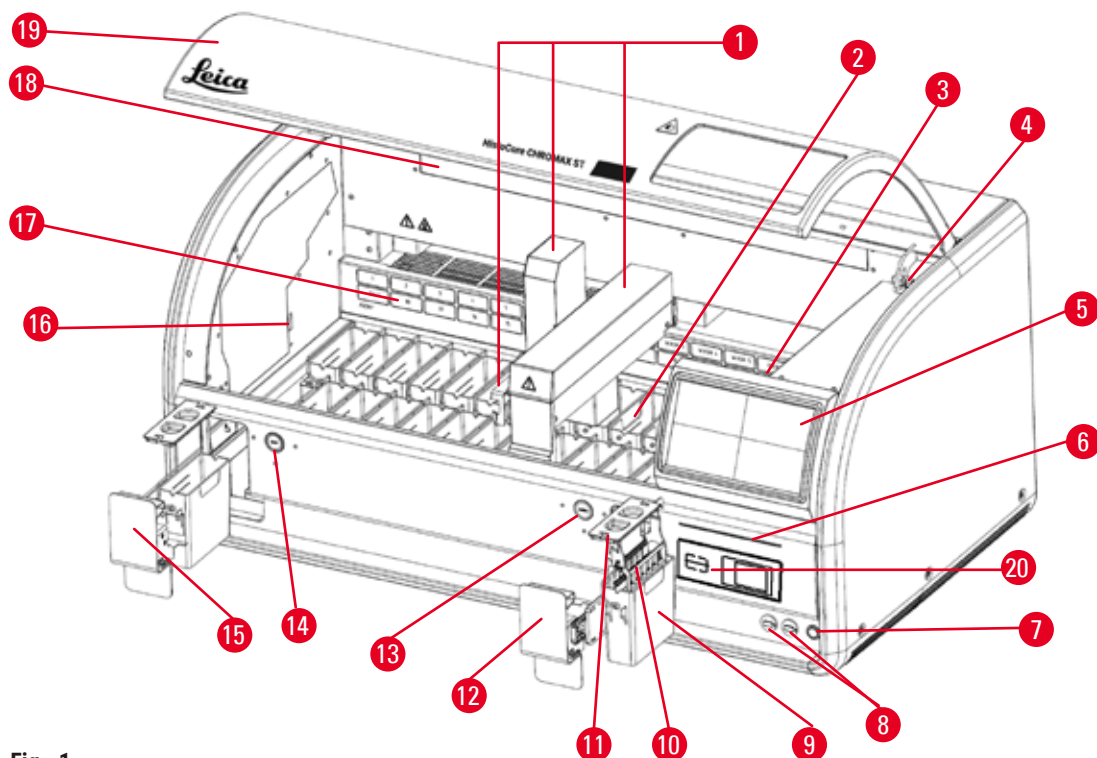


Fig. 1

- | | |
|--------------------------------|---|
| 1. Transport arm | 12. Load drawer |
| 2. Wash stations | 13. LED indicator and key for LOAD drawer |
| 3. Oven | 14. LED indicator and key for EXIT drawer |
| 4. Lock for hood ¹⁾ | 15. EXIT drawer |
| 5. Touch screen | 16. Slides counting sensor |
| 6. LED strip | 17. Back plate (the active carbon filter is inside), which is with the schematic diagram of the stations on it. |
| 7. Stand-by switch | 18. Lighting |
| 8. Two USB ports | 19. Hood |
| 9. Reagent container | 20. Barcode scanner |
| 10. Rack | |
| 11. Container cover | |

¹⁾The lock for the hood contains a gas pressure spring. This part can wear out. In case of weakening holding force, please contact our after-sales service and ask for replacement.

3.1.2 Rear panel

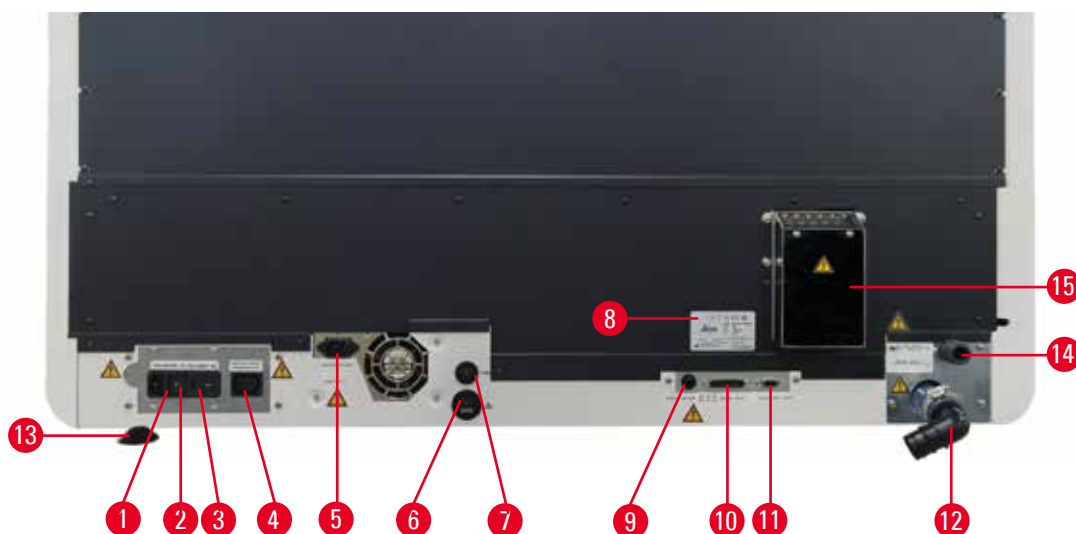


Fig. 2

- | | |
|--------------------------|------------------------------------|
| 1. Power input | 8. Nameplate |
| 2. Power switch (On/Off) | 9. Remote alarm socket |
| 3. Fuses | 10. Serial port (service computer) |
| 4. Power output | 11. Accessory port |
| 5. Power supply input | 12. Drain outlet |
| 6. Network connection | 13. Feet, adjustable |
| 7. USB port | 14. Water inlet |
| | 15. Exhaust port |

3.2 Main features of the instrument

The HistoCore CHROMAX ST Automated Slide Stainer gives you the confidence to generate standardized results. It is

- Versatile
- Robust
- And has a Standardized Staining Management System

The flexible HistoCore CHROMAX ST Automated Slide Stainer can process multiple protocols on one systems.

A user friendly and intuitive interface with visualized workflows, available in multiple languages, an optimized preinstalled protocol, as well as a reagent expiration reminder, help users to quickly understand the functions of the instrument and to produce high-quality stained slides while reducing manual recording and errors.

A built-in staining management system automatically documents each step of the staining protocol to standardize your laboratory procedure.

3 Instrument Components and Specifications

The HistoCore CHROMAX ST Automated Slide Stainer has an integrated system for extracting reagent vapors. The racks are loaded and unloaded using two drawers.

The HistoCore CHROMAX ST Automated Slide Stainer is equipped with a barcode scanner. The scanner is mounted right under the main display and embedded inside the scanning area. Both infrared sensor module and optical sensor module are integrated. There is a special motion sensor of the scanner which only activates the scanning and illumination functions while the to-be-scanned object approaches.

The sensor embedded on the scanner can automatically adjust the illumination intensity in terms of the light intensity reflected from codes.

3.3 Technical data

Electrical specifications	
Nominal supply voltage	230-240 VAC
Nominal supply frequency	50-60 Hz
Mains supply voltage fluctuations	± 10%
Power consumption	650 VA
Mains input fuses	5 x 20mm, 2 x F 3.15 A L250VAC
Dimensions and weight specification	
Overall size of device in operating mode (Width x Depth x Height, mm)	1136 mm x 670 mm x 550 mm (close hood)
Overall size serial packaging (Width x Depth x Height, mm)	1310 mm x 820 mm x 920 mm
Empty weight (without accessories, kg)	88 kg
Overall weight (with accessories, kg)	97 kg
Device weight including packaging (kg)	147 kg
Environmental specification	
Operating altitude (meters above sea level) (min/max)	Up to 2000 m above sea level
Temperature (operation) (min/max)	15 °C to 35 °C
Relative humidity (operation) (min/max)	20% to 80%, non-condensing
Temperature (transit) (min/max)	-29 °C to +50 °C
Temperature (storage) (min/max)	5 °C to 50 °C
Relative humidity (transit/storage)	10% to 85%, non-condensing
Minimum distance to walls (mm)	100 mm
Operating noise level	≤70 dB (A)
BTU (J/s)	2217.89 BTU/h (650 J/s)
Emissions and boundary conditions	
Overvoltage category to IEC 61010-1	II
Pollution degree to IEC 61010-1	2
Means of protection to IEC 61140	Class I
Degree of protection to IEC 60529	IP20
A-weighted noise level, measured at 1 m distance	≤70 dB (A)
EMC class	Class A

Throughput	
Specimen slides per hour	240 (with Leica's pre-installed protocol)
Loading capacity	1
Unload/storage capacity	1
Rack	
Slide rack capacity	30 slides
Stations	
Total number of stations	26
Total number of reagent stations	18
Wash stations	5
Reagent container volume	Max. 470ml
Drawer	
Load stations	1
Unload stations	1
Oven	
Number of oven stations	1
Temperature of oven chamber	30 ~ 65 °C
Wash stations	
Number of wash stations	5
Flow rate	8 l/m
Staining protocols	
Permanent memory capacity	100
Max no. of steps/program	25
Step duration	00 sec. ~ 99 min. 59 sec.
Fresh water connection	
Hose material	PVC
Hose length	2.5 m
Connection piece	G3/8
Inner diameter	10 mm
Outer diameter	16 mm
Internal supply pressure	Min. 1 bar/max. 6 bar
Required flow rate	Min. 12 l/min
Wastewater connection	
Hose material	PVC
Hose length	4 m
Inner diameter	32 mm
Outer diameter	36.8 mm
Drain principle	Gravity flow

Exhaust air	
Hose material	PVC
Hose length	2 m or 4 m
Inner diameter	50 mm
Outer diameter	60 mm
Exhaust performance	22.4 m ³ /h
Exhaust extraction	Active carbon filter and exhaust hose for connecting with an external exhaust system
Other specifications	
Basic instrument height (open hood) (W x D x H)	1136 mm x 670 mm x 870 mm
LCD (W x D x H)	235 mm x 5 mm x 143 mm
Slides counting accuracy% (within 300 slides)	<ul style="list-style-type: none"> • 99% for load dry slide to empty load drawer • 99% for load slide to load drawer with alcohol • 99% for load watery non-adhesive slide to empty load drawer • 97% for load watery adhesive slide to empty load drawer
Laser class	Class 1

4. Setting up the Instrument

4.1 Installation site requirements

- Required hard surface: 1.16 x 0.67 m²
- The laboratory bench must be of sufficient bearing capacity relating to the instrument and must have a rigid surface.
- The device is intended for indoor use only.
- The next power socket must not be further away than the length of the power cord (2.5 m). Use of an extension cord is not allowed.
- The instrument needs to be connected to a grounded power supply socket.
- Use only the provided power cord intended for the local power supply.
- The instrument must not be installed below any air conditioning system.
- Any shaking, direct sunlight and significant current fluctuations need to be avoided.
- Proper function is ensured only if a minimum distance of 10 cm is respected towards all walls and any other fixtures.
- The instrument needs to be installed in a way that allows easy access to the power switch and the power plug at the rear side.
- Operation is not allowed in any areas exposed to explosion hazards.
- The installation site needs to be protected against electrostatic discharges.
- The installation site needs to be well ventilated because chemicals used within the instrument are highly flammable and unhealthy.
- Connect the instrument to a laboratory air exhaust system using the dedicated hose (lengths of 2 m and 4 m available). Alternatively the instrument can be operated below a fume cupboard. This should be run in addition to the active carbon filter.
- Please consider that the active carbon filter supports only filtration of hazardous vapors (Xylene).
- The situation at the installation site may vary significantly and depends on existing ventilation, emissions of other installed devices, the use of solvents, the volume of the room, etc.
- It is the responsibility of the laboratory owner/laboratory operator to not exceed the legal maximum permissible values and to take all measures at the working places regarding the solvent vapors. This includes also corresponding documentation.
- The operator of the instrument needs to make sure that sufficient ventilation is ensured and the active carbon filter is replaced within the required interval.
- The voltage selector and other internal components are preset by the manufacturer to meet the power requirements of the respective countries of destination.
- The instrument must be connected to a laboratory water tap with a pressure reducer.

The instrument can be connected to glass coverslippers of Leica. For details, please refer to the IFU of glass coverslippers available on www.Leicabiosystems.com

4.2 Standard delivery - packing list

Quantity	Part description	Order No.
1	HistoCore CHROMAX ST instrument	14 0486 77888
1	Accessories kit, consisting of:	14 0486 60036
21	Reagent containers assembly	14 0486 60063
5	Wash containers assembly	14 0486 60064
1	Load container assembly	14 0486 60038
10	Plastic rack 30 slides	14 0486 59732
1	Jumper cable, power supply	14 0411 34604
1	Remote alarm connector	14 6000 04778
1	Tubing band clamp	14 0422 31972
1	Angular connecting nozzle for hose	14 0475 33669
1	V filter 3/4	14 0456 36101
1	Active carbon filter	14 0486 60073
1	Filter cover	14 0456 35240
1	Collecting tray for paraffin (heater) (inside the instrument)	14 0456 35216
1	Water supply hose with seal	14 0474 32325
1	Drain hose	14 0475 35748
1	Instructions for Use (printed English with language CD 14 0486 80200)	14 0486 80001

If the supplied local power cord is defective or lost, please contact your local Leica representative.

**Note**

- Please check all delivered parts against the packing list and against your order to verify whether the delivery is complete. Should you find any discrepancies, please contact your Leica Biosystems sales office without delay.

4.3 Unpacking instructions

**Warning**

- The packaging has two indicators, ShockDot Impact Indicator and Tilt Indicator, that indicate improper transport. When the instrument is delivered, check this first. If one of the indicators is triggered, the package was not handled as prescribed. In this case, please mark the shipping documents accordingly and check the shipment for damage.

**Warning**

Inadequate lifting and transportation of the instrument

People injury and/or property damage

- The instrument must only be transported in an upright position.
- Do not try to lift the instrument with less than 4 persons.
- Wearing non-skid gloves, grab the instrument under the frame at all corners and lift it evenly.
- It is recommended to commission a transport company to transport, install or (where applicable) relocate the instrument.

**Warning**

The adjustable feet are not adjusted properly during installation, and the instrument is tilted.

Damage of sample due to the overflow of the liquid in the internal reagent/wash container.

- Place the instrument on a stable and level laboratory bench.
- Adjust the instrument to a level position if it is tilted.



Fig. 3

1. Remove the straps (→ Fig. 3-1), then the carton wall (→ Fig. 3-2).

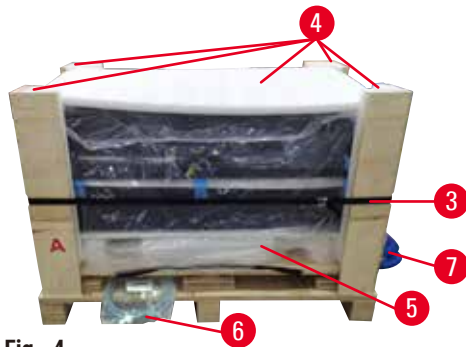


Fig. 4

2. Remove the compression strap (→ Fig. 4-3), then the molded foam around the instrument (→ Fig. 4-4).
3. Remove the dust cover (→ Fig. 4-5).
4. Remove the water supply hose (→ Fig. 4-6) and the drain hose (→ Fig. 4-7).



Fig. 5

5. Unfasten screws (→ Fig. 5-5) at 4 corners of the instrument. To do so, reach the screws under the base panel (→ Fig. 5-8) using a wrench.
6. Grip the instrument with at least 4 persons at all corners and evenly lift the instrument.
7. Place the instrument onto the bench.
8. Open the hood of the instrument and check whether all accessories have been delivered as per your order.

**Note**

- The transport carton and included retaining elements should be kept in case a return shipment is necessary later. To return the instrument, follow the instructions above in reverse order.

4.4 Water connections

Connect the water hose to the water connection on the rear side of the instrument. Attach the other end of the hose to the cold-water tap. The hose has a 3/4" connector. Then slowly turn the tap on all the way.



Note

- The water filter must be in place when the water hose is connected, otherwise water can leak out.

Connect the drain hose to the discharge nozzle on the rear side of the instrument.

Before setting up the instrument every day, check the water inlet to the instrument and turn it on.

4.5 Air exhaust system for reagent vapors



Warning

Breathing in vapors dangerous to health

People injury

- The active carbon filter must be in use. In addition, connect the instrument to an external exhaust system using the dedicated hose (lengths of 2 m and 4 m available), or operate the instrument below a fume cupboard.
- The reagent containers must be covered when not using the instrument to prevent the unnecessary evaporation of the reagents.
- Users must verify compliance with the workplace limit values when work is done with hazardous materials.

Active carbon filter

Fumes are extracted through the active carbon filter, which must be changed every three months (with average usage).

To change the active carbon filter, remove the back plate (→ Fig. 1-17). Use the straps provided to remove the active carbon filter. Put in a new one and reattach the cover plate.

Connecting to the external exhaust system

Connect one end of the exhaust air hose to the exhaust port (→ Fig. 2-15) at the rear side of the instrument. Connect the other end to an exhaust air device installed in the lab.

4.6 Oven

Put the paraffin tray on the oven floor.

4.7 Battery backup – UPS (optional)

An interruption of the staining process can be avoided in the event of a temporary power failure by connecting an uninterruptible power supply (UPS).

A compact UPS can be connected easily as shown below (→ Fig. 6) via the power supply jumper cable.

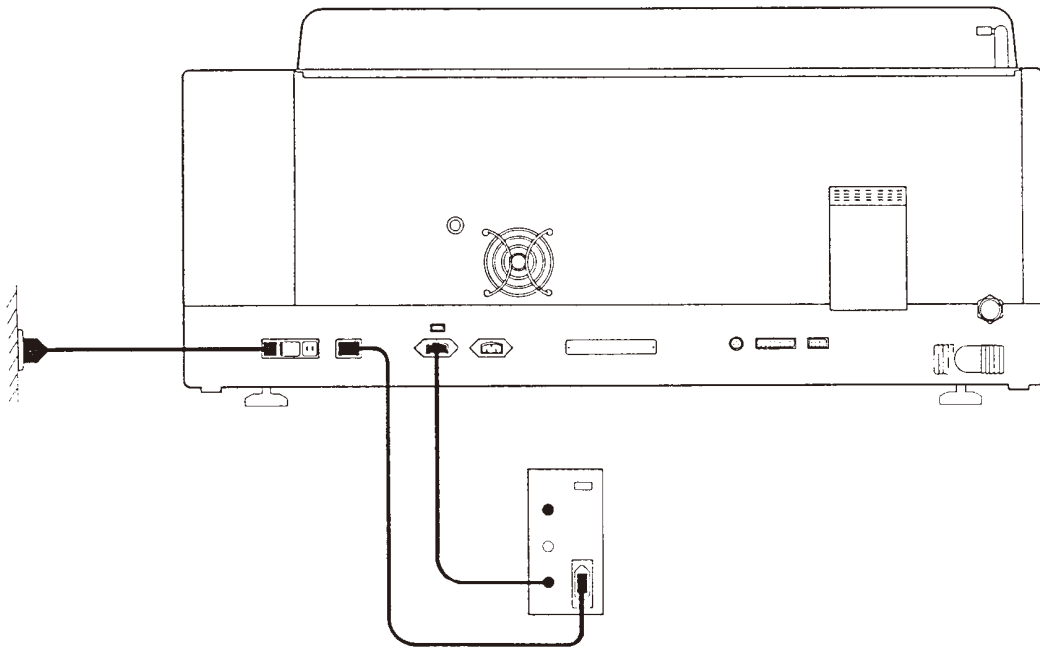


Fig. 6

The UPS should be designed for an output of 650 VA for a duration of 10 minutes. However, the UPS will not maintain operation of the oven.

The UPS must be designed for power supply voltage at the installation location. Your distributor will gladly recommend a UPS that is suitable for you.

4.8 Remote alarm (optional)

The optional remote alarm is an interlock relay that is voltage-isolated from the rest of the instrument. When there is an alarm condition (a major operational malfunction or a power failure during a staining run with a UPS connected), the alarm circuit closes and the alarm sounds.



Note

- If you need a remote alarm that sounds even if there is a power failure, you have to use a battery-operated remote alarm.

Ensure that the instrument is still turned on and confirm the message to turn off sound of the alarm. If the power fails during a staining run, you may first need to turn the Stand-by switch on the front side to Off and then back to On.

The remote alarm will only operate during a power failure if a UPS is connected. For details on how to connect a remote alarm, contact your distributor.

The remote alarm must be designed for less than 1 A and a maximum of 50 V.

4 Setting up the Instrument

Connect the remote alarm to the remote alarm socket (→ Fig. 2-9) on the rear side of the instrument using a phono jack (6.25 mm).

4.9 Switching on/off

Switching on

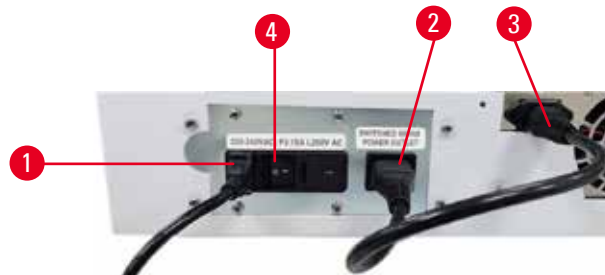


Fig. 7

1. Connect the power cable to the power input (→ Fig. 7-1).
 2. Connect the power supply jumper cable to the power supply output (→ Fig. 7-2) and power supply input (→ Fig. 7-3).
 3. Plug the power plug into the power socket.
 4. Make sure that the switch (→ Fig. 1-7) on the front side of the instrument is at the Off position, and then set the On/Off switch (→ Fig. 7-4) on the rear side of the instrument to On.
 5. Push down the switch on the front side to the On position and the instrument takes a few seconds to initialize.
 6. After the initialization completes successfully, the log-in window is displayed and the lighting lights up.
 7. Log in the system as the Admin (→ p. 31 – 5.2.2 Initial log-in). The **Status** screen is displayed and the transport arm starts moving to do a self-test.
- ✓ After the self-test completes successfully, the instrument emits ringing sound and the system is ready for operation.

LED strip

The LED strip (→ Fig. 1-6) on the front of the instrument indicates the instrument working status.

- LED off: mains power is off.
- LED on: mains power is on.
- LED in white light: there is no instrument error.
- LED flashing in white light: staining paused.
- LED in red light: the instrument has an error.

Switching off

1. When there is no program running, press the shut-down button on the touch screen. The following screen appears.



Fig. 8

2. Confirm with **OK**.
3. Press the switch on the front side to Off position. The On/Off switch on the rear side of the instrument should be left On.

Restart after long time shut-down

If no longer uses the instrument due to maintenance or disposal, the user must first switch off the power supply and then remove the power cable, ensuring that it is stored correctly. In addition, the user must clean the instrument surface, and empty the reagent containers and wash containers. If an exhaust hose is fitted, it must be removed.

If the instrument is to be restarted, refit the original power cable, and check the integrity of the instrument components and parts, making sure there are no impurities in the reagent containers and wash containers. If there is an exhaust hose, install it as per the instructions. Check the water inlet to the instrument and turn it on.

4.10 Moving the instrument



Warning

Inadequate lifting and transportation of the instrument

People injury and/or property damage

- The instrument must only be transported in an upright position.
- Do not try to lift the instrument with less than 4 persons.
- Wearing non-skid gloves, grab the instrument under the frame at all corners and lift it evenly.
- It is recommended to commission a transport company to transport, install or (where applicable) relocate the instrument.

Before moving the instrument, empty the reagent containers and wash containers, and make sure there is no residual reagent or water inside the instrument. Switch off the instrument. The power cord must be disconnected from the power supply and the instrument is cooled down.

5 Operation

5. Operation

5.1 User interface - overview

The HistoCore CHROMAX ST is programmed and operated via a color touchscreen. The screen appears as follows (→ Fig. 9) after switching on. The pre-installed bath layout is shown.

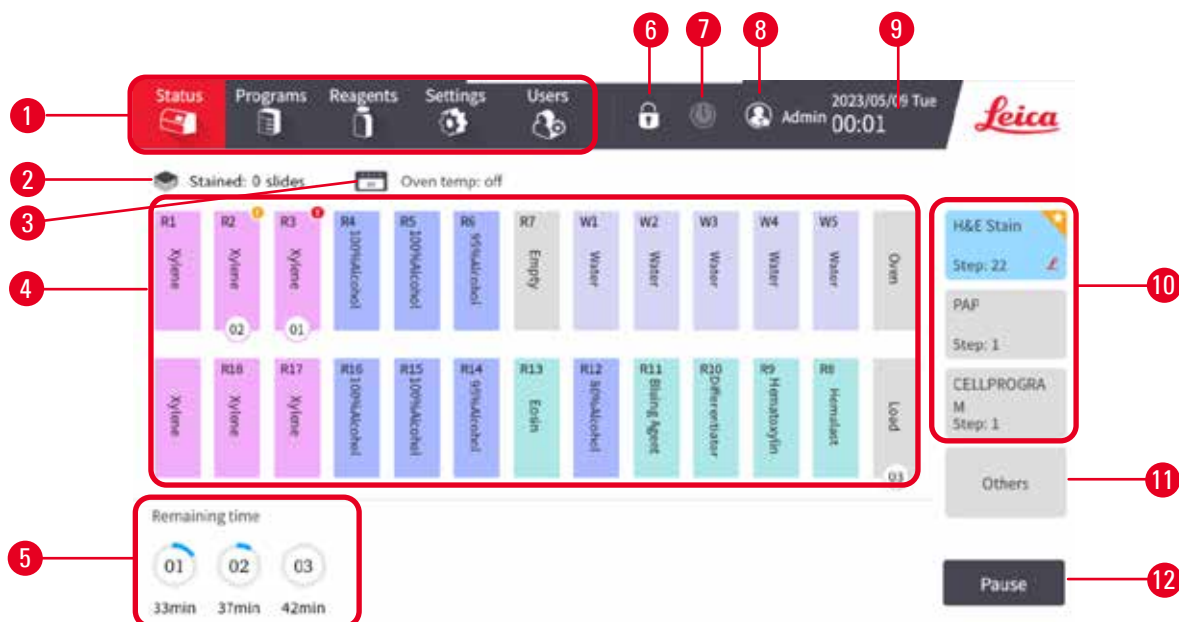


Fig. 9

5.1.1 Elements of the Status screen

- 1 Main menu - include 5 tabs: Status, Programs, Reagents (Reagent Management System RMS), Settings and Users
- 2 The number of the slides stained with Hematoxylin. For how to set up the reagent expiry thresholds and the reminder of the reagent expiry, refer to Station Management (→ p. 35 – 5.4.2 Station management)
- 3 Oven temperature when the oven is set to be On. When the oven is set to be Off, it shows as Off. (→ p. 33 – Oven)
- 4 Bath layout (→ p. 29 – Bath layout)
- 5 Running racks by number sequence (→ p. 29 – Rack status). Press a rack icon to view the detailed information for each rack (→ p. 48 – 5.6.6 Viewing the running information during staining).
- 6 Lock/Unlock button (→ p. 31 – 5.2.5 Locking/Unlocking the screen)
- 7 Shut-down button (→ p. 26 – Switching off)
- 8 Current user name (→ p. 30 – 5.2 User management)
- 9 Local time and date (→ p. 32 – Time)
- 10 Favorite programs list with active program highlighted in blue. (→ p. 41 – 5.5.4 Setting favorite programs)
- 11 Button for selecting more programs
- 12 Pause/Continue button

5.1.2 Process Status screen

Bath layout



Fig. 10

- 1 Station number
- 2 Reagent expiry reminder flag:
 - Yellow icon indicates that the reagent is to expire (→ p. 35 – 5.4.2 Station management).
 - Red icon indicates that the reagent expired (→ p. 35 – 5.4.2 Station management).
- 3 Reagent name (→ p. 36 – 5.4.3 Reagent management)
- 4 Reagent color (→ p. 36 – 5.4.3 Reagent management)
- 5 Position of the numbered staining rack, and color for the completion status

Rack status



Fig. 11

- 1 Rack numbering: starts from 01 every day.
- 2 Abort button - press the button to abort the running rack once the system has been paused (→ p. 49 – 5.7 Interrupting staining).
- 3 Show the real-time remaining processing time of the rack.

5.1.3 Keyboards

Keyboards appear as needed to allow you to enter texts and numbers. There are two types: alphanumeric (text and numbers) and numeric (numbers only). The keyboards are analogous to a computer keyboard with on-screen buttons.



Fig. 12

- | | |
|---|--|
| 1. Text window | 5. Clear - remove all characters |
| 2. Texts and numbers | 6. Caps Lock - select upper or lower case |
| 3. OK and Enter - confirm the entry | 7. Shift - select upper or lower case |
| 4. Back Space - remove the last character | 8. Cancel - exit without saving |

5.2 User management

This menu can be used to create and edit the user accounts.

5.2.1 Access levels

There are three access levels, Operator, Supervisor and Admin.

During the operation, the enabled buttons are highlighted and the disabled buttons are grayed out.

Operator

Operators can use the completely configured instrument for all routine applications, such as viewing/ selecting program, running/pausing/aborting staining, changing reagent, viewing running information. Operators can not modify programs and settings.

Supervisor

Supervisors have the same access options as the operators, and more access options, such as changing the bath layout, reagent management, program management, and instrument settings.

Admin

The admin account is configured at the factory. The Admin has the same access options as the supervisors, and more access options, that are user management and locking/unlocking the touch screen.

5.2.2 Initial log-in

The Admin account and its password are configured at the factory, which can be used to create new accounts. The default password is Admin1234. The password can be changed after the initial log-in.

To change the Admin's password, proceed as follows.

1. Press the **Users** tab.
2. Select the default account and press the **Edit** button.
3. Using the keyboard, enter **Admin1234**, then enter the new password twice and confirm with **Save**.

5.2.3 Adding/Editing/Deleting a user account

- ① The account name cannot duplicate an existing user name or contain the word "Leica". The length of the user name shall be shorter than 30 characters. The password shall have at least 6 characters mixed with numbers and English letters.

Adding a user account

1. Press the **Users** tab.
2. Press **New**.
3. Enter the user name and the password. Choose an access level from the drop-down list.
4. Press **Save**.


Editing a user account

1. Press the **Users** tab.
2. Select a user account from the table and press **Edit**.
3. Change the user name and the password. Choose an access level from the drop-down list.
4. Press **Save**.

Deleting a user account

1. Press the **Users** tab.
2. Select a user account from the table and press **Delete**.
3. Press **OK** in the prompted confirmation dialog box.

5.2.4 Logout

1. Press the user-name icon  **Admin**.
2. Select **Switch user** or **Logout**, and proceed with the next action of choice.

5.2.5 Locking/Unlocking the screen

The Admin can lock/unlock the touch screen. When the touch screen is locked, the system displays the last screen before locking. The unlock window will pop up when a user click the locked touch screen.

5 Operation

5.3 Settings

Press the **Settings** tab to open the **Settings** menu. Basic instrument and software settings can be configured in this menu.

5.3.1 General setting

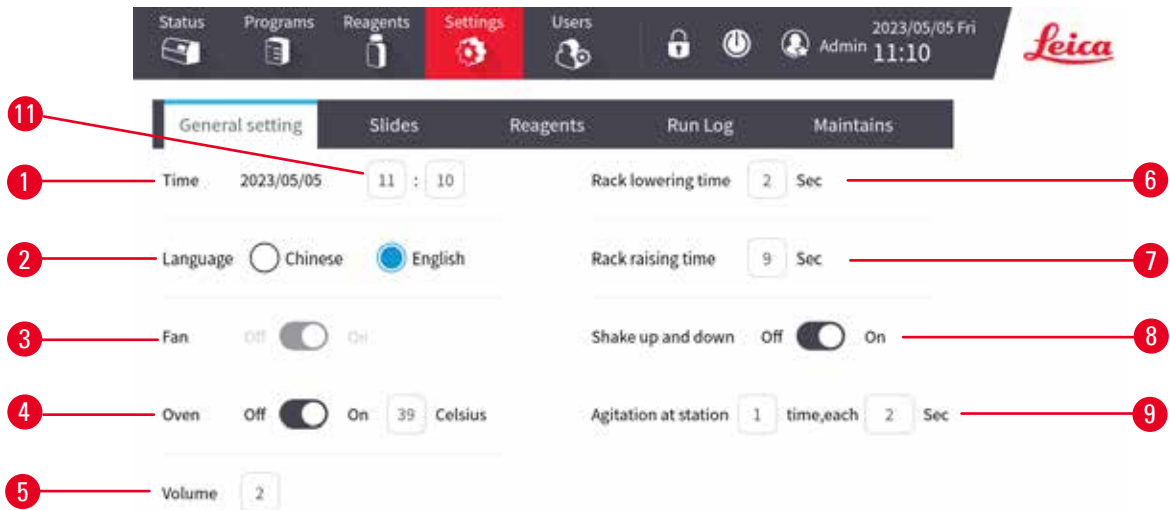


Fig. 13

Time

- ① All user levels have the access.

Press the edit button (→ Fig. 13-11) in the line and modify the hour and minute. The user can only modify the time once in a day. The value range that can be changed of 'Hour' is ± 1 . The value range that can be changed of 'Minute' is 0 to 59. The date cannot be modified.

Language

- ① All user levels have the access.

The default interface language (→ Fig. 13-2) is English. Users can select other languages in this interface.

Fan

- ① All user levels have the access.

Press the two ends to turn on or turn off the exhaust fan (→ Fig. 13-3).

When the oven is set to be **On**, the exhaust fan will be automatically turned on, even though it might be set to be **Off**.

Oven

- ① Supervisor and Admin have the access.

Press the two ends to turn on or turn off the oven (→ Fig. 13-4).

When the oven is set to be On, enter the temperature between 30 °C to 65 °C and confirm with **OK**. The actual oven temperature value is shown on the **Status** screen (→ Fig. 9-3). The system turns off the oven automatically when actual oven temperature is abnormal, and an error message pops up for the oven failure.

Alarm volume

- ① Supervisor and Admin have the access.

Set the volume (→ Fig. 13-5) from weak to strong, ranging from 2 to 9, and confirm with **OK**.

Rack lowering time

- ① Supervisor and Admin have the access.

Set the **Rack lowering time** (→ Fig. 13-6) from 2 to 4 seconds and confirm with **OK**.

Rack raising time

- ① Supervisor and Admin have the access.

Set the **Rack raising time** (→ Fig. 13-7) from 4 to 9 seconds and confirm with **OK**.

Up/Down movements (dips)

- ① Supervisor and Admin have the access.

Press the two ends to turn on or turn off the Up/Down movements (→ Fig. 13-8). When the Up/Down movements are set to be On, fill in the continuous times (from 1 to 20 times) and the duration of an entire dip (from 1 to 4 seconds) (→ Fig. 13-9).

The time for one complete movement up and down (dip) is set in the adding a new program (→ p. 39 – [Adding a new program](#)).

If the staining time for a selected number is too short, only the number of dips that fit into the specified staining time will be done.

5.3.2 Slide counting report

Slides in each rack to be stained are counted by the system (→ p. 46 – [5.6.5 Loading racks](#)). Press **Slides** tab to view the latest 3 years' slide counting number by day or by month.

Press **Export** button to export the slide counting report.

5 Operation

5.3.3 Reagent exchange report

Press **Reagents** tab to view the latest 3 years' reagent exchange information by month.

Press **Export** button to export the reagent exchange report.

5.3.4 User run log report

Press **Run log** tab to view the intermediate and completion status of protocols by day, for the last 3 years.

5.3.5 Maintains

Press **Maintains** tab to view the versions of the installed software and the firmware and the instrument serial number.

To export the log, press **Export**.

The Leica-authorized service staff can access to more functions for diagnostics and repairs to the HistoCore CHROMAX ST.

5.4 RMS (Reagent Management System)

Press the **RMS** tab to open the **RMS** menu.

5.4.1 Reagent information

Press **Reagents** to view reagent information.

Station	Reagent	ValidDays	ValidSlides	StainedDays	StainedSlides	Date	EXP	Operator
Load	Empty	N/A	N/A	N/A	N/A	N/A	N/A	N/A
R1	Xylene	N/A	N/A	5	0	23/04/21		Admin
R2	Xylene	N/A	N/A	5	0	23/04/21		Admin
R3	Xylene	N/A	998	5	1023	23/04/21	23/03/02	Admin
R4	100%Alcohol	N/A	N/A	0	0	23/04/26	25/04/26	Admin
R5	100%Alcohol	N/A	N/A	5	1023	23/04/21	23/03/02	Admin
R6	95%Alcohol	N/A	N/A	0	0			
R7	Empty	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Fig. 14

The reagent information includes: Reagent color (→ Fig. 14-1), Station number (→ Fig. 14-2), Reagent name (→ Fig. 14-3), Max days (→ Fig. 14-4), Max slides (→ Fig. 14-5), Stained days (→ Fig. 14-6), Stained slides (→ Fig. 14-7), Exchange date (→ Fig. 14-8), Expiration date (→ Fig. 14-12) and Operator (→ Fig. 14-9).

The Stained days and Stained slides are displayed in red color (→ Fig. 14-10) if the reagent in this station expired.

The field for max days or max slides is displayed as N/A (→ Fig. 14-11) if the Max days or Max slides are not set.

Once the real-time date is beyond the expiration date, the date will turn into red (→ Fig. 14-13) to remind the user that the corresponding reagent has expired.

5.4.2 Station management

Press **Station** to configure stations.

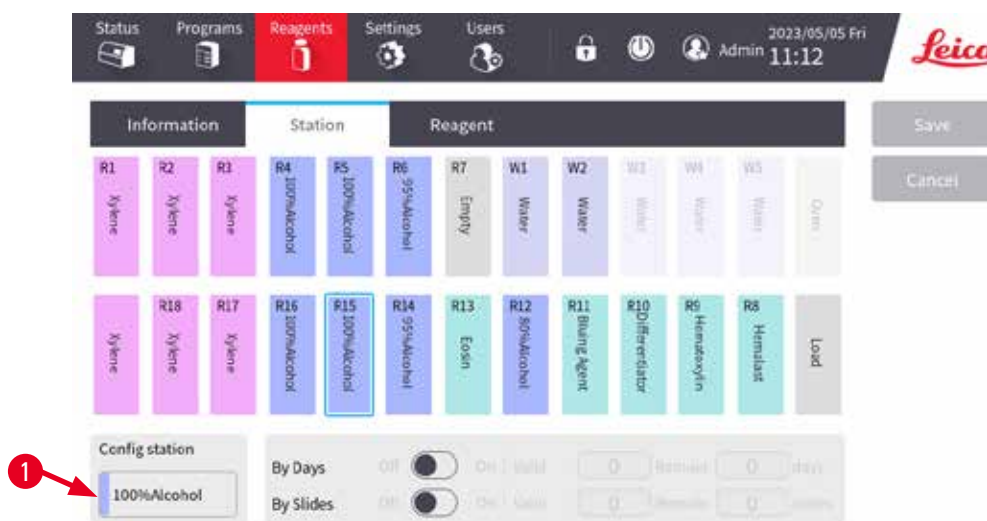


Fig. 15

The system is configured with the pre-installed bath layout. It is for Leica pre-installed program. Admins can change the bath layout.

The three reagent stations next to the load drawer can be set as the inner buffer stations. The inner buffer stations can be used to store three racks ready for staining. The inner buffer stations must be continuous, which means there cannot be non-inner buffer station between two inner buffers or between the inner buffer and the load drawer.

The two washing stations, W1 and W2, can be set as reagent stations. The Oven station and W3/W4/W5 washing stations cannot be changed.

The reagent expiry reminder can be set by days and/or by slides on this screen. The reagent expiry reminder warns you that the replacement of a reagent is necessary. When it is enabled, the expiry status flag (→ Fig. 10-2) appears on the bath layout if a reagent expires soon or expired.

5 Operation

To change the bath layout and/or set the reagent expiry reminder, proceed as below.

1. Select the station.
2. Click the Reagent station icon (→ Fig. 15-1). The reagent list screen appears.
3. Select a reagent and press **Select**.
4. Set the reagent expiry thresholds and reminders. The reagent expiry thresholds are maximum days and/or maximum slides. The reagent expiry reminders are remaining days and/or remaining slides.
5. Save the change to the select station.

5.4.3 Reagent management

Press **Reagents** to enter the Reagent Management System to configure the reagent list.

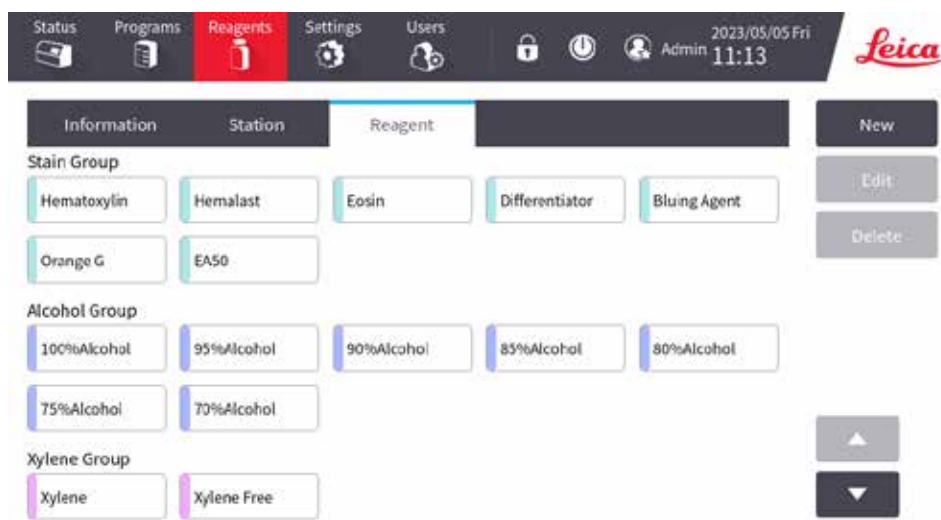


Fig. 16

There are pre-installed reagents in the system. The pre-installed reagents are used in Leica pre-installed program, including:

- Staining reagents: HemaLast, Hematoxylin, Eosin
- Differentiator, Bluing Agent, Orange G, EA50
- Ethanol: 100% Ethanol, 95% Ethanol, 90% Ethanol, 85% Ethanol, 80% Ethanol, 75% Ethanol, 70% Ethanol
- Xylene: Xylene, Xylene free
- Other: Ammonia, 1% alcohol hydrochloride, distilled water, water, saturated lithium carbonate, 0.5% alcohol hydrochloride

The pre-installed reagents cannot be deleted or edited.

User-defined reagents can be added to the reagent list.

To add a new reagent, proceed as below.

1. Press the **Reagents** tab, then press **Reagent**. Press **New**.

2. Input the reagent name. The new reagent name cannot duplicate the pre-installed reagent name and cannot contain 'LEICA' characters. The name cannot be longer than 30 characters.
3. Select a reagent group.
4. Save the reagent.

5.5 Programs

Press the **Programs** tab to open the **Programs** menu.

Programs list

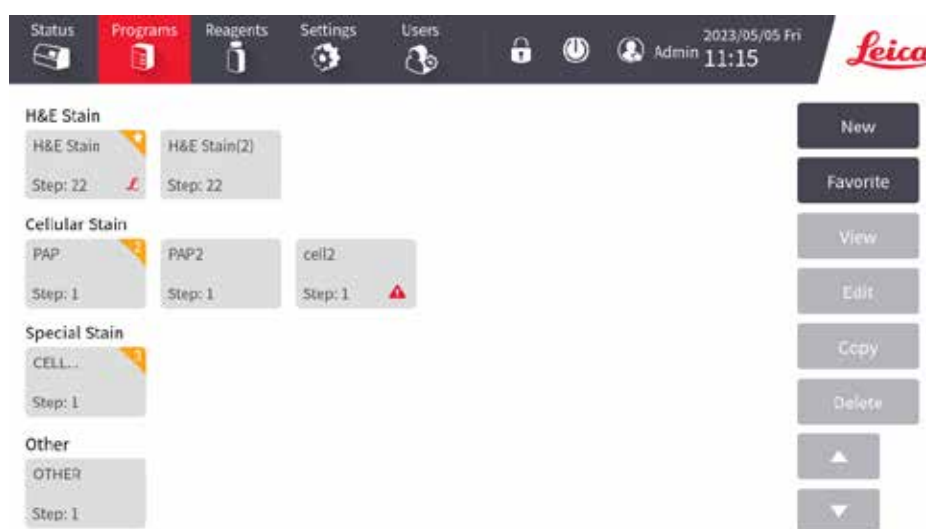


Fig. 17

The HistoCore CHROMAX ST has one pre-installed program (→ p. 51 – 5.10 Pre-installed program), and can store up to 99 user-defined programs. By default, the programs fall into four categories: H&E staining, Cytology staining, Special staining and Others.

Program icon

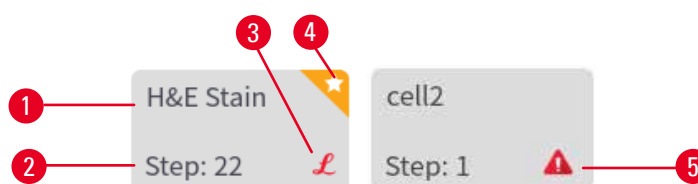


Fig. 18

A program icon includes:

- Program name (→ Fig. 18-1)
- Total steps number of a program (→ Fig. 18-2)
- Label "L" for Leica pre-installed programs (→ Fig. 18-3)

5 Operation

- Numbered yellow flag for favorite programs (→ Fig. 18-4). The default program is labelled with a star icon.
- Red icon (→ Fig. 18-5) indicates that the program is not valid.

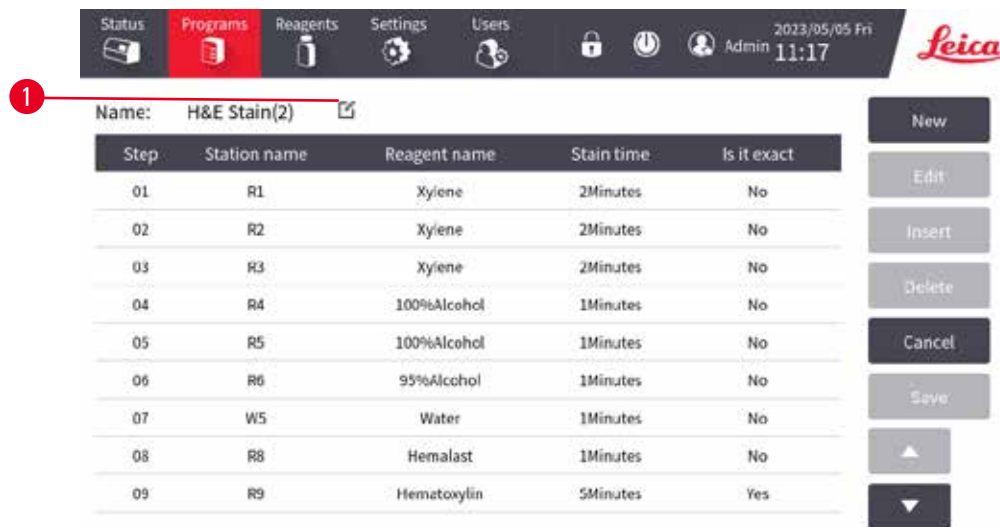


Fig. 19

Overview of program steps

A program contains up to 25 steps. A step consists of the following information:

- the step number
- the station
- the reagent
- the staining time (min./sec.), ranging from 0 min. 0 sec. to 99 min. 59 sec.
- Whether the staining time is to be achieved exactly or not

The step number defines the order in which the stations are used. The staining time is the time the rack is fully immersed in a station.

Times may overlap when multiple racks are being processed simultaneously, therefore the steps requiring precise adherence to the specified dwell time are designated as exact in the program. Therefore, staining times at these steps have priority and are adhered to with an accuracy of ± 1 second. Racks that are in a step that was designated not exact are processed further as soon as the transport arm is available for that.

5.5.1 Leica staining programs (pre-installed)

- Leica staining programs are preinstalled at the factory and have had their function and staining properties tested. They ensure consistent staining quality for a specified number of slides.
- Leica staining programs are labeled with a letter "L".
- The individual program steps of the Leica staining program cannot be edited or deleted.

5.5.2 User-defined staining programs

- Leica does not provide testing nor a warranty for user-defined programs.
- The testing of these staining programs using the respectively used reagents and adjusted temperatures must be carried out in the lab by the user. To do so, the staining result has to be checked with a specimen cycle (trial sections) before the program is used for patient specimens for clinical diagnostics.

5.5.3 Adding/Viewing/Editing/Copying/Deleting a program



Warning

Assign incompatible reagents to adjacent stations.

Impaired of sample /poor staining quality.

- Do not assign incompatible reagents to adjacent stations.

Adding a new program

1. Press the **Programs** tab, then press **New** button.
2. Select one program group and confirm with **OK**.
3. Enter a program name and confirm with **OK**. The program name cannot duplicate the pre-installed program name or contain the word "Leica". The length of the program name shall be shorter than 50 characters.
4. Select the station (→ Fig. 20-1), staining time (→ Fig. 20-2) and whether the staining time is exact or not (→ Fig. 20-3). Then confirm with **OK**.

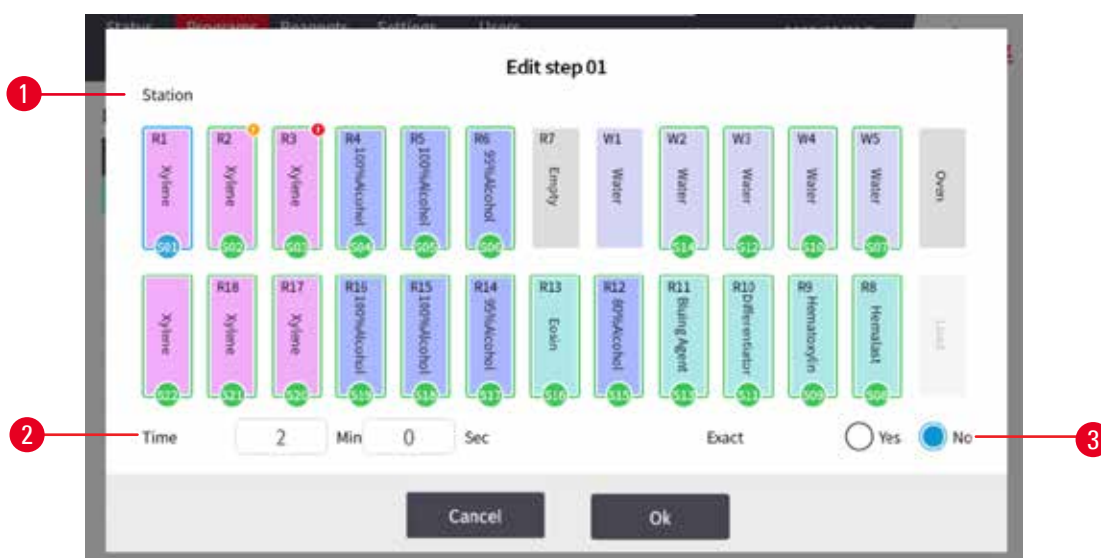


Fig. 20

5. Press **Add** button. Repeat step 4 until the program is complete.
6. Save the program.

**Note**

- When the instrument is set as a workstation, the last step of the program must be set to the **EXIT** drawer.

Inserting a step into a program

1. Press the **Programs** tab, and select the program that is to be modified. Then press **Edit** button.
2. Select the step number where the new step is to be inserted, and press **Insert**.
3. Enter the steps details (→ Fig. 20) and confirm with **OK**.

✓ The steps following the new step will be renumbered.

4. Save the program.

Removing a step from a program

1. Press the **Programs** tab, and select the program that is to be modified. Then press **Edit** button.
2. Select the step number which is to be deleted. Press **Delete** and confirm with **OK**.

✓ The selected steps are removed and the subsequent steps are renumbered.

3. Save the program.

Editing a program name

1. Press the **Programs** tab, and select the program that is to be modified. Then press **Edit** button.
2. Press the edit icon (→ Fig. 19-1) beside the program name.
3. Edit the program name using the keyboard and confirm with **OK**.
4. Save the program.

Saving a program

When the program is complete, save it as follows:

1. From the edit program screen (→ Fig. 19), you now have the options of saving the edited program, leaving the program as it was before the changes were made, or continuing editing the program.
2. Press **Save** to save the program, or
3. Press **Cancel** to leave the program unchanged, or
4. Select steps and press **New** or **Edit** to continue editing the program.

Viewing a program

To view a program:

1. Press the **Programs** tab, and select the program that is to be viewed.
2. Press **View**.
3. Press **Return** to go back to the program list screen.

Copying a program

1. Press the **Programs** tab, and select the program that is to be copied.
2. Press **Copy**.
3. Enter the program name and confirm with OK. The program is listed in the same group of the copied program.
4. Press **Edit**, if you want to do further modification.

If the selected program is assigned to a rack currently being processed, copying is not allowed and a corresponding message appears on the touch screen.

Deleting a program

1. Press the **Programs** tab, and select the program that is to be deleted.
2. Press **Delete** and confirm with **OK**.

5.5.4 Setting favorite programs

Supervisor can set three favorite programs which will be visible in the status screen. The first favorite program will be labeled with a yellow star and is the default program (→ Fig. 9-10). The default program will be automatically set active after each rack loading step. Favorite programs two and three will be visible on the status screen and need to be selected before loading a respective rack.

If no default program is needed, please leave the first favorite program empty.

The pre-installed program is set as the first favorite program in the factory.

To set a favorite program, proceed as below.

1. Press the **Programs** tab, and press **Favorite**.
2. Press one of the **Favorite** program fields.
3. Select a program from the program list.
4. Save the favorite program.

5.5.5 Checking the compatibility of programs

This function is used to check whether two programs can be run simultaneously. Programs cannot be run in parallel if they would need to control two identical stations defined as "exact" simultaneously, or if they contain two identical stations in reverse order, as in the following example:

Program 1	Program 2
Station 1	Station 1
Station 2	Station 2
Station 3	Station 3

However, the instrument carries out this calculation automatically.

5.6 Staining



Warning

Rack processed with wrong program parameters

Damage of sample

- Always double-check program parameters of user-defined programs before you start processing.



Warning

Handling infectious specimens without adequate clothing

People injury

- Always wear protective clothing suitable for laboratory use, as well as rubber gloves and safety goggles when handling infectious specimens used in this instrument.
- Always follow your laboratory safety regulations.

The HistoCore CHROMAX ST has the loading capacity of 11 racks at a time with up to 30 slides each. It can accept a new rack as soon as the load drawer is empty and the **LOAD** key is lit up. Then the specimen slides are stained according to the program selected for the respective holders. Different programs may be used simultaneously, provided they are compatible. The method for checking compatibility is described on (→ p. 41 – 5.5.5 [Checking the compatibility of programs](#)).

5.6.1 Reagent containers

Reagent containers can be individually removed for filling. Each container holds up to 450 ml. The maximum and minimum filling levels are on the inside. When filling the reagent, make sure that the volume of the reagent is not either more than the max level or lower than the min level.

Water containers and reagent containers have different shapes and colors. Water containers are blue and reagent containers are white. After being filled, they are put in the instrument at the position designated in the corresponding programs.

The yellow reagent container is specified for the load drawer. Make sure that it is inserted into the load drawer with the handle folded on the right side.

To make the containers easier to identify, a label can be inscribed or attached on the side directly above where the handle is connected.



Warning

Label adhesive/ Labels on slide not solvent-resistant. Identification of the sample is no longer possible.

Damage of sample

- The stickers and/or labels used on the specimen slides must be resistant to the solvents used in the instrument.
- When printable labels or handwritten labels are used on the rack handles and the specimen slides, they must be checked for solvent resistance prior to use.

A schematic drawing of the individual stations is inside the instrument on the back plate (→ Fig. 1-17). Make sure that the containers are inserted correctly and that all handles are folded to the correct side so that they do not obstruct transport of the racks. Lids are provided to reduce evaporation of solvent while the reagent containers are not in use. The containers of the **LOAD** and **EXIT** drawers can also be filled with a reagent, if desired. However, the instrument will not monitor the immersion times in these two stations.

5.6.2 Filling reagents



Warning

Operating the instrument without adequate clothing

People injury

- Always wear protective clothing suitable for laboratory use, as well as rubber gloves and safety goggles when handling the chemicals used in this instrument.
- Always follow your laboratory safety regulations.



Warning

Reach into the swivel range of the hood when opening or closing the hood

People injury - fingers or hands crushed

- Do not reach into the swivel range of the hood when opening or closing it.



Warning

Reagent filling level within reagent containers is insufficient

Impaired of sample / Poor tissue quality

- Check the filling level of the reagent containers regularly and clean and / or refill if required.
- Cover unused reagent containers to minimize evaporation.



Warning

Contamination after accidental handling of reagents

Impaired of sample / Poor tissue quality

- If you have accidentally contaminated reagents, e.g., because a reagent has dripped into another reagent container always follow your local regulations. Focus on saving the tissue first. Dispose any contaminated reagents and clean the affected reagent containers thoroughly.

Before filling reagents, make sure that the bath layout on the screen is correct. Fill the reagents following the bath layout. Any deviation can lead to undesired staining results.



Caution

Looking at the light source of the scanner when it is working.

People injury

- Never look at the light source of the scanner when it is working.

5 Operation



Caution

User left during changing reagents and failed to enter correct reagent information, including lot number, expiration date, etc. when returned.

Impaired sample/Poor tissue quality

- Enter correct reagent information when changing reagents.
- Check entered reagent information before next step, especially after interruptions.



Note

- Reagent containers must always be filled outside of the instrument in compliance with the safety information.



Fig. 21

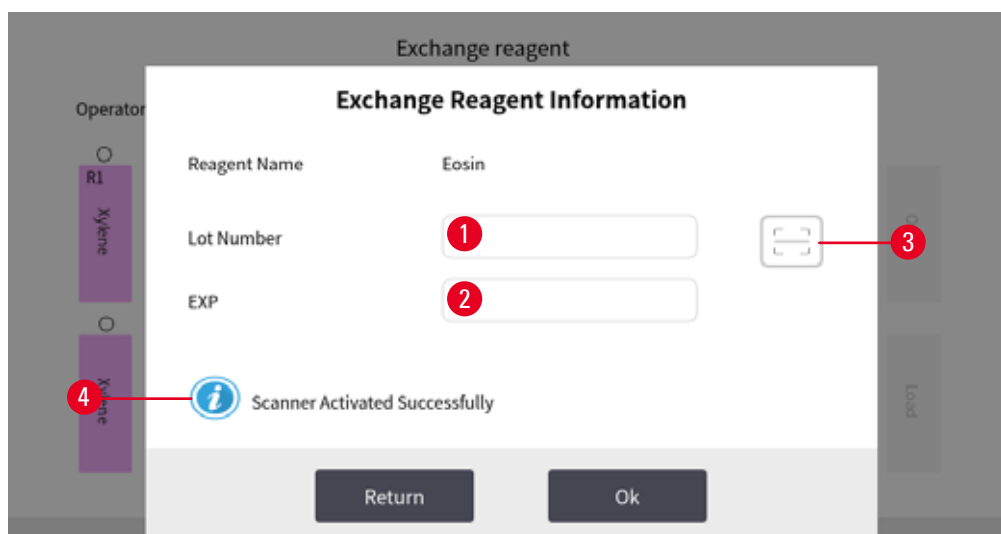


Fig. 22

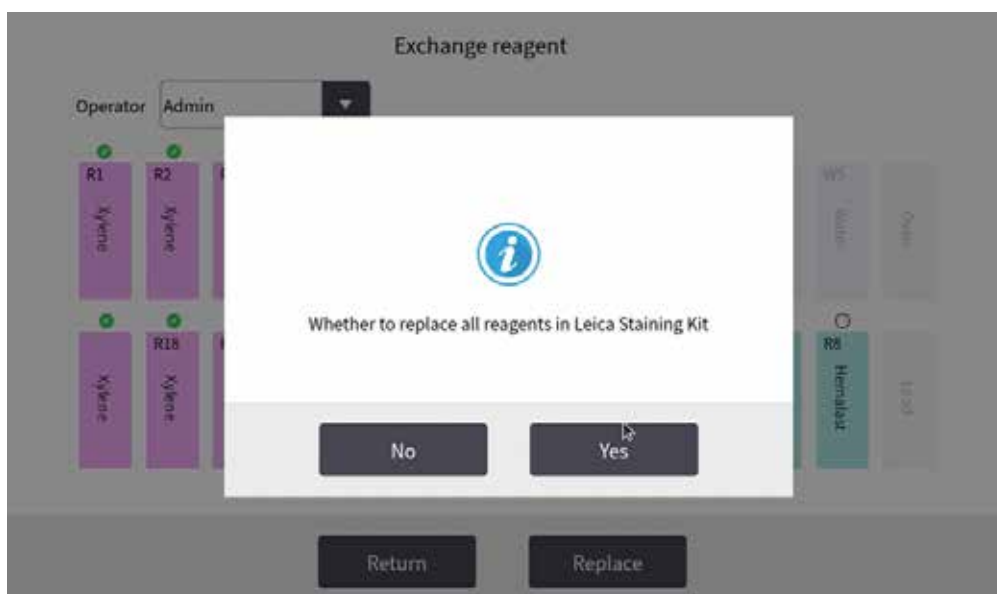


Fig. 23

Filling reagents

To fill the reagents, proceed as below.

1. Press the station icons. The **Exchange reagent** screen (→ Fig. 21) is displayed.
2. Check the Operator name (→ Fig. 21-1). Using the dropdown option to change the operator if needed.
3. Press the station (→ Fig. 21-2) that is to be filled in. The stations to be filled are marked with ticks (→ Fig. 21-3) on the top right corner. Press the **Replace** button. Only stations with the same reagents could be selected at the same time. Two ways could be used for recording reagent information:
 - a. Enter the lot number (→ Fig. 22-1) and the expiration date (→ Fig. 22-2) through the keyboard;
 - b. Press the scanning window (→ Fig. 22-3) to activate the scanner. Once the scanner is activated, it shows: **Scanner Activated Successfully**; see Fig. (→ Fig. 22-4).

Place the reagent bottle with the corresponding bar code. Scan the codes on the reagent packaging at a distance of 15 to 20 cm, right in front of the LED scanner in the lower right corner of the instrument. Entering the reagent information is optional and the reagent information can be updated manually after scanning.



Note

The scanner cannot be turned off once it is activated in **Exchange reagent** page. The illumination of the scanner is distance inductive and can only be activated within 15 to 20 cm. The green aiming line can help the operator to target the valid scanning area.

5 Operation

4. Fill the reagent containers outside of the instrument with the corresponding reagents and set it back in the correct position in the instrument. The reagent level must be below the maximum filling level mark.

The steps of filling Leica Staining Kit and reagents of other brands are similar. The difference is that a page will appear when Leica reagents are selected (→ Fig. 23). By pressing **No** button, users can replace the reagents one by one as the steps above. By pressing **Yes** button, users can replace the whole Leica Staining Kit at one time. That is to say all 5 Leica reagents will be updated simultaneously with the corresponding info in RMS (exchange date, exchanger, expired date).



Note

Meanwhile, the scanner would be turned off automatically till the operator activating it again.

5. Confirm filling by pressing the **Replace** button on the screen. The screen returns to the Replace the reagent screen. The background of the tick turns to green.
6. Repeat step 3 to 4 for stations that are to be filled.
7. Press **Return** button and go back to the **Status** screen.

5.6.3 Wash system

Before setting up the instrument every day, check the water inlet to the instrument and turn it on.

The wash system consists of five flow-through wash stations, each capable of holding one rack. Water is supplied through the opening in the container floor and drains through the cut-out at the upper left edge.

The floor of the station has a locating pin, which means the station can be used only in one direction. Be careful when removing or inserting wash containers, because using excessive force may damage the seals. Wet the O-ring before inserting the wash station.

To use the wash station, slowly open the water tap in the lab all the way.

If the flow rate drops below 8 liters/minute for any reason, the wash period specified in the program may have to be extended.

5.6.4 Water-saving function

The instrument has a water-saving function that stops the flow of water when none of the wash stations are in use and the reagent residue has been flushed out of them.

5.6.5 Loading racks



Warning

Rack processed with wrong program parameters

Damage of sample

- Always double-check program parameters of user-defined programs before you start processing.

**Warning**

Inadequate manual loading of racks into reagent containers

Damage of sample and / or property damage because of crash due to automatized loading of another rack into the same reagent container

- Do not manually load racks and start any movement of the transport arm.

**Warning**

Lids not removed from reagent containers

Damage of sample because of crash due to automatized loading of a rack

- Always make sure that any lids are removed before initiating any transport to the affected reagent containers.

**Warning**

LOAD and **EXIT** drawers opened while the transport arm operates in the drawer area.

Damage of sample

- Do not open the **LOAD** drawer or **EXIT** drawer when the transport arm is operating in the drawer area.

Racks are inserted into the instrument only via the load drawer, which is on the front right side of the instrument. Reach fingers into the recess on the underside of the drawer, release the lever by gently pushing it up and pull the drawer out as far as it will go. The yellow reagent container is specified for the load drawer, which is designed to ensure the proper loading of the rack. Insert the container into the load drawer with the handle folded on the left side. Load the rack in the load drawer with the colored handle facing you, so that the slides counting function and RMS can work properly. Failure to use in accordance with this regulation may result in harmful radiation exposure. Avoid direct eye exposure while the system is counting the slides. Non-professionals may not alter the laser supply voltage or current or perform other operations that will increase the output power without permission.

To load a rack and start a program:

1. Check whether a program is selected already (highlighted in blue). If needed, select the program for the next rack. Select the program in the favorite program list. Or press **Others...** to select a program from the program menu.
2. Check to see whether the load drawer is actually empty (the **LOAD** LED will be lit). Open the drawer and insert the rack, ensuring that it is positioned correctly. Close the drawer.
3. Press the **LOAD** key. If the program is compatible with the programs already in use, then the **LOAD** LED will turn off and the rack will be processed using the selected program, otherwise a message will appear in the display and the holder will not be processed.

**Note**

- The **LOAD** button LED on means that the system accepts loading a new rack. The **LOAD** button LED off means that the system does not accept loading a new rack.

4. To load additional racks, repeat step 2 to 3. If the instrument is in the midst of processing a rack, there may be a delay before processing of additional holders begins.

5 Operation

If the pre-defined program is to run, the system counts the slides in the racks before the staining program starts. The slide counting starts when the transport arm moves from the load drawer to R1 station. After the slide counting finishes, the transport arm moves back to the top of R1 station.

Use HistoCore CHROMAX ST racks to avoid wrong slide counting.

5.6.6 Viewing the running information during staining

Press the rack icon (→ Fig. 9-4) to view the running information of each rack during staining.

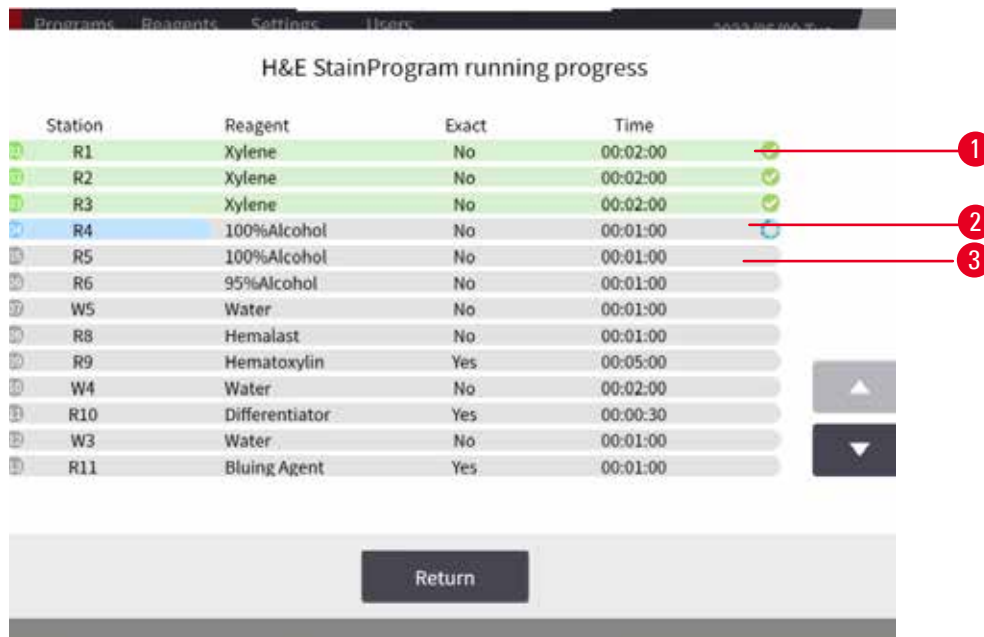


Fig. 24

The steps status include completed (→ Fig. 24-1), ongoing (→ Fig. 24-2) and not yet started (→ Fig. 24-3).

5.6.7 Unloading racks from the EXIT drawer



Warning

Racks not unloaded in a timely manner from the **EXIT** drawer

Damage of sample

- Unload the **EXIT** drawer in time, close the **EXIT** drawer and press **EXIT**.



Warning

LOAD and **EXIT** drawers opened while the transport arm operates in the drawer area.

Damage of sample

- Do not open the **LOAD** drawer or **EXIT** drawer when the transport arm is operating in the drawer area.

When a rack is in the EXIT station, the **EXIT** LED will be on and the ring will sound every 30 seconds.

To unload from the **EXIT** drawer:

1. Open the **EXIT** drawer carefully and remove the holder. Alternatively, you can remove the entire reagent container including the holder and replace it with another.
2. Close the drawer and press the **EXIT** key. Then the LED will go out.

**Note**

- If the **EXIT** key is not pressed, the instrument will be unable to finish processing other holders that require this station.

5.6.8 Unloading racks from other stations

**Warning**

Taking out the rack during processing and collide with the transport arm.

People injury

- Be careful when opening the hood to take out the rack during processing.

If the final step in a program is not the **EXIT** drawer, a message pops up on the screen to indicate that the processing is complete. Open the hood and remove the rack as quickly as possible. Then press OK.

The **EXIT** key does not light up in this case.

**Note**

- For unloading racks from other stations, the racks must be carried out as quickly as possible. In the case of delays, the staining quality of other samples within the instrument may be negatively impacted.

5.7 Interrupting staining

Staining can be interrupted:

- To edit a program not currently being used for staining;
- To change the general instrument settings;
- To allow access to the instrument to check reagents;
- To abort staining of one or more racks.

To interrupt a staining run:

1. Press **Pause** in the **Status** screen.
2. To cancel processing of a holder, press the cancel icon on the rack icons, or edit programs not currently in use, or change the general instrument settings.
3. Press **Continue** to continue staining.

5.8 Aborting the processing of a rack

To abort the processing of a rack:

1. Press **Pause** in the **Status** screen. The LED strip flashes.
2. To cancel the processing of a rack, press the cancel icon on the rack icons.
3. A confirm window will pop up. Press **Ok** to continue the abort process. Press **Cancel** to cancel the abort process.
4. Open the hood and carry out the rack as quickly as possible.
5. Close the hood and press **Continue** to continue staining.

5.9 Replacing reagents



Warning

Reagent containers not cleaned or cleaned insufficiently before refilling with another reagent

Impaired of sample / Poor tissue quality

- Always clean the reagent containers thoroughly and regularly before refilling them.



Caution

Looking at the light source of the scanner when it is working.

People injury

- Never look at the light source of the scanner when it is working.



Caution

User left during changing reagents and failed to enter correct reagent information, including lot number, expiration date, etc. when returned.

Impaired sample/Poor tissue quality

- Enter correct reagent information when changing reagents.
- Check entered reagent information before next step, especially after interruptions.

When the reagent expiry reminder (→ Fig. 10-2) appears on the station, the reagents must to be replaced.

For replacing the reagent, see (→ p. 43 – 5.6.2 Filling reagents).

5.10 Pre-installed program

H&E Staining program

Step	Station	Reagent	Time (min: sec)	Exact
1	LOAD	N/A	0:00	N/A
2	1	Xylene	2:00	No
3	2	Xylene	2:00	No
4	3	Xylene	2:00	No
5	4	100% Ethanol	1:00	No
6	5	100% Ethanol	1:00	No
7	6	95% Ethanol	1:00	No
8	Water Rinse 5	Water Rinse	1:00	No
9	8	HistoCore SPIRIT™ Hemalast	1:00	No
10	9	HistoCore SPIRIT™ Hematoxylin	5:00	Yes
11	Water Rinse 4	Water Rinse	2:00	No
12	10	HistoCore SPIRIT™ Differentiator	0:30	Yes
13	Water Rinse 3	Water Rinse	1:00	No
14	11	HistoCore SPIRIT™ Bluing Agent	1:00	Yes
15	Water Rinse 2	Water Rinse	1:00	No
16	12	80% Ethanol	1:00	No
17	13	HistoCore SPIRIT™ Eosin	0:45	Yes
18	14	95% Ethanol	1:00	Yes
19	15	100% Ethanol	1:00	Yes
20	16	100% Ethanol	1:00	Yes
21	17	Xylene	1:00	No
22	18	Xylene	1:00	No
23	EXIT	Xylene	N/A	N/A

6. Cleaning and Maintenance

Clean the interior stainless steel surfaces with a detergent and then rinse them with water. Clean the transport arm surfaces by wiping them with a damp cloth.

The transport arm contains sensitive electronic components, therefore do not use any liquid in this area. Wipe clean only.

The drainage system may be flushed with 5% sodium hypochlorite to inhibit bacterial growth. However, metal parts must not be in contact with this solution for prolonged periods (such as overnight). Flush well with water afterwards. Painted exterior surfaces can be cleaned with a mild detergent and then wiped with a damp cloth.

Do not use solvent on the outer surfaces, particularly the touch screen and the hood!

Carefully wipe the control panel with a damp cloth.

6.1 Wash containers

Remove the wash containers and clean them with detergent. Reagent and rinsing water containers can be cleaned in a dishwasher, at a maximum temperature of 65 °C, using a standard, commercially available detergent for lab dishwashers. The handles can remain attached to the various containers during this process.

6.2 Reagent containers



Warning

Reagent containers not cleaned or cleaned insufficiently before refilling with another reagent

Impaired of sample / Poor tissue quality

- Always clean the reagent containers thoroughly and regularly before refilling them.

Clean with warm water and detergent.

6.3 Racks

Clean with household or laboratory detergent as needed.

6.4 Oven

Regularly check the paraffin tray on the oven floor and clean it if you find excessive paraffin residue.

Clean the oven when it is cool.

6.5 Water drainage



Warning

Water drainage not cleaned or cleaned insufficiently

Damage of sample / People injury

- Check and clean the draining system regularly for correct flow.

1. To clean the water draining system, remove the rinsing water containers and all surrounding reagent containers.
2. The remaining reagent containers have to be covered with lids.
3. Remove the drainage sieve and clean it if necessary.
4. Place one to two cleaning tablets with active oxygen into the drain and dissolve in water to remove various residue (reagents, bacteria, fungi, algae).
5. Then, clean the entire curved drainage area inside the instrument with a long, flexible brush.
6. Check the flow by flushing thoroughly with water.
7. Insert the drainage sieve again, and put the containers back in their original, defined positions.
8. Remove any lids from containers before processing racks into them.

6.6 Cleaning and Maintenance Schedule



Note

- The instrument must be switched off before cleaning.

Daily

- Touch screen: clean with a lint-free cloth.
- Outside surface: clean with a soft cloth and mild detergent.
- Do not use any of the following for cleaning the outside surfaces of the instrument: xylene, acetone, solvents containing xylene or acetone, scouring powders, and cleaning fluids containing ethanol.

Weekly

- Wash containers: can be cleaned in the lab dish washer (not over 65 °C).
- Reagent containers: can be cleaned in the lab dish washer (not over 65 °C).
- Drain outlet/hose: check for dirt, algae; flush with 5% sodium chloride.
- Paraffin collecting tray: check in the oven.
- Interior stainless steel: clean with detergent and rinse with water.
- Transport arm: with slightly moistened cloth.

Monthly

- Glass cover for the slides counting sensor: clean with ethanol using a lint-free cloth gently
- Strainer(v-filter): check for dirt.
- Air vent holes of fan: vacuum clean.
- Tap water inlet hose connection
- Activated carbon filter: change every 3 months.
- Electrical connections

7. Troubleshooting

The HistoCore CHROMAX ST has a system that continually monitors the instrument's functions. It displays corresponding error messages if any errors occur. If a minor error occurs during staining, the instrument will first attempt to correct the problem on its own. If this is unsuccessful, then a message appears and the instrument waits for the user to rectify the problem.

Some errors trigger an audible alarm. This alarm can be turned off by confirming on the screen.

If there is an error message, press Pause to pause staining.

Error messages and their meanings are listed on the following pages.

7.1 Warning messages for instrument errors

Mains power fail	This warning indicates a power failure. It appears only if a UPS is connected. For more details, refer to (→ p. 24 – 4.7 Battery backup – UPS (optional))
Power supply fail	The power supply device has failed and must be repaired.
Make sure that the head is free of obstruction	The transport arm for transferring the rack is locked. The most frequent causes for this are: <ol style="list-style-type: none"> 1. The reagent container is inserted incorrectly. 2. The handle is positioned incorrectly. 3. The cover is still on the reagent container. 4. The rack is bent. <p>The instrument immediately starts staining again after the problem is remedied.</p>
Head stalled	Even after the attempt to resume staining, the head of the transport arm does not move. Eliminate all blockage and resume staining. If the problem does not go away, contact the customer service.
Fume system blocked	The drain opening on the rear side of the instrument is blocked. Eliminate blockage.
Oven failure	The oven is not working and has to be repaired. All other stations of the instrument are still working. Only drying of the specimen slides has to be done outside of the instrument.
Oven overheating	If this message appears, it is very likely that the oven is blocked. Make sure the slot in the oven floor is not blocked.
Remove obstruction and replace rack on hook	The rack could have separated from the hook. Remedy the problem (e.g., the reagent container is inserted incorrectly) and put the holder back on the hook.

7.2 More information and warnings

7.2.1 During staining

Ensure a rack is in the Load drawer and close the drawer	The load drawer must be closed for the instrument to be able to remove a rack from it.
Ensure the EXIT drawer is empty and close the drawer	The EXIT drawer must be closed for the instrument to be able to insert a rack for removal.

Slides number is 0, the instrument will run staining continuously

The slides counting number is 0. The most frequent causes for this are:

- Load a non-HistoCore CHROMAX ST rack.
- Load the HistoCore CHROMAX ST rack in a wrong direction.
- Slides counting module is broken.
- The glass cover of the slides counting module is contaminated.
- The rack light barrier is broken.

7.2.2 During SetUp

SetUp lost. Default SetUp used. Programs and settings of the instrument parameters have been lost and must be reentered.

Battery backed RAM Failure! Service is required. The internal memory has to be replaced. Contact customer service.

Caution: increasing dips might extend some station times. Increasing the number of up/down movements (dips) while specimen slides are being processed can result in lengthening of exactly defined immersion periods. If continuous up/down movement was selected, only one rack can be processed at a time.

7.3 Power failures

The instrument restarts as soon as the power supply is restored.

During initialization, the instrument software issues a series of messages and instructions to you, which provide you with information about the power failure and instruct you regarding how to proceed.

You can cancel or resume the staining process software using the displayed assistance.

If the power supply is not restored for a long time:

1. Press the Stand-by switch at the front panel of the device to shift to the Off mode.
2. Remove the rack hooked on the transport arm/tilted on the reagent container immediately to avoid reagents contamination.
3. Move the transport arm to sideways (for example, the right end position beside the LOAD drawer).
4. You should decide if you want to continue all processing racks manually according to the duration of power failure.

8. Ordering Information

Part description	Order No.
Active carbon filter	14 0486 60073
Leica TS5015 - transfer station	14 0506 38050
TS-SPIRIT	14 0486 60055
Racks for special staining	14 0475 34524
Insert for special staining	14 0475 34525
Holder for large individual specimen slides	14 0456 27069
Wash station, assembly	14 0486 60064
Plastic rack 30 (rack for 30 specimen slides)	14 0486 59732
Reagent container, assembly, with lid and transport handle	14 0486 60063
Cover, without slots for reagent container	14 0486 60068
Cover for 12 reagent containers, assembly	14 0475 33644
Dummy plugs (sealing plugs for wash container)	14 0456 35393
Supply hose for rinsing water, 2.50 m, assembly with 3/4" connection	14 0474 32325
Outlet hose, 4 m	14 0475 35748
Exhaust air hose, 2 m, assembly including adapter for fume hood	14 0475 35762
Exhaust air hose, 4 m, assembly including adapter for fume hood	14 0475 35763
Drip tray (wax collecting bowl for oven)	14 0456 35216
O-ring 3 x 2 mm FKM (O-ring for hook)	14 0253 35822
O-ring 7.65 x 1.78 FKM (O-ring for wash container)	14 0253 34214
V filter 3/4" 40/22 H6 (wax strainer)	14 0456 36101
Staining protocol block	14 0456 35459
Remote alarm device for EXIT drawer	14 0456 30906
China Power Cord GB2099 (10A) C13	14 0411 57007

A1. Decontamination Confirmation

Any product that is to be returned to Leica Biosystems or serviced on site must be properly cleaned and decontaminated. The associated decontamination certificate template can be found on our website www.LeicaBiosystems.com. This template must be used to enter all required data.

If a product is returned, a copy of the completed and signed decontamination certificate must either be enclosed or handed over to a service technician. The user shall be responsible for products that are returned without a completed decontamination certificate or with a missing decontamination certificate. Return shipments that are classified by the company as a potential hazard source will be returned to the sender at his/her own expense and risk.

A2. Warranty and Service

Warranty

Leica Biosystems Nussloch GmbH guarantees that the contractual product delivered has been subjected to a comprehensive quality control procedure based on the Leica in-house testing standards, and that the product is faultless and complies with all warranted technical specifications and/or agreed-upon characteristics.

The scope of the warranty is based on the contents of the contract concluded. The warranty terms of your Leica sales organization or the organization from which you have purchased the contractual product shall apply exclusively.

Service information

If you are in need of technical customer support or spare parts, please contact your Leica representative or the Leica dealer where you purchased the instrument.

The following information about the instrument is required:

- Model name and serial number of the instrument.
- Location of the instrument and name of a contact person.
- Reason for the service call.
- Date of delivery.



Warning

To prevent damage to the instrument and specimens, only those accessories and spare parts that have been authorized by Leica may be installed or used with the instrument.

Physical life

The physical life of the equipment is 7 years. Physical life of this product is determined according to actual situation after launching product in local market. Users have to maintain the product according to the requirements of the Instructions for Use and have to ensure that the product can be used safely and effectively.

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Version 1.0, Revision A - 08.2023