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LEICA BIOSYSTEMS HISTOCORE PEARL INSTRUCTIONS FOR USE MANUAL

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HistoCore PEARL

Tissue Processor

Instructions for Use
English
Order No.: 14 0493 80101 - Revision D
Always keep this manual with the instrument.
Read carefully before working with the instrument.

CE

Version 1.3, Revision D - 08.2018

The information, numerical data, notes and value judgments contained in this manual represent the current state of scientific knowledge and state-of-the-art technology as we understand it following thorough investigation in this field.
We are under no obligation to update the present manual periodically and on an ongoing basis according to the latest technical developments, nor to provide our customers with additional copies, updates etc. of this manual.

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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 used in the text and their meanings

	Danger: Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injuries.
	Warning: If this danger is not avoided, then this may result in death or serious injury.
	Caution: Indicates an potentially hazardous situation which, if not avoided, could result in death or serious injury.
	Note: Indicates information which are important but not related to any risk.
1	Item numbers for numbering illustrations.
→ "Fig. 7 - 1"	Numbers in red refer to item numbers in illustrations.
Save	Software symbols that have to be pressed on the input screen are displayed as bold, gray text.
	Manufacturer
REF	Order number
SN	Serial number
	Manufacturer date
	Observe the Instructions for Use
	Caution, consult the instructions for use for cautionary information.
	Caution, consult the instructions for use for cautionary information.
IVD	In vitro diagnostics (IVD) medical device
CE	This product fulfills the requirements of the EU directives.

Symbol for labeling electrical and electronic equipment in accordance with Section 7 of the German Electrical and Electronic Equipment Act (ElektroG). ElektroG is the law regarding the sale, return and environmentally sound disposal of electrical and electronic equipment.

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

Symbol for alternating current

PE terminal

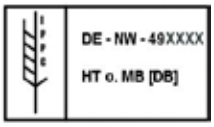
Power on

Power off

This warning symbol indicates the surfaces on the instrument that are hot during operation.
Avoid direct contact to prevent risk of burning.

Biohazard warning

Solvents and reagents that are inflammable are marked with this symbol.



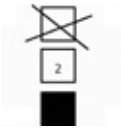
IPPC symbol

- Country code in accordance with ISO 3166, e.g. DE for Germany
- Regional identifier, e.g. HE for Hessen
- Producer/treatment provider code, unique assigned number starting with 49
- Treatment code, e.g. HT (heat treatment), MB (methyl bromide), and possibly DB (debarked).

The package contents are fragile and must be handled with care.

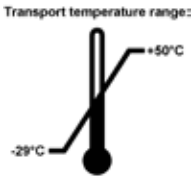
The package must be kept in a dry environment.

Do not stack.

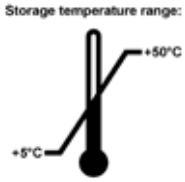


Maximum of 3 stacked layers (only for the accessory box).

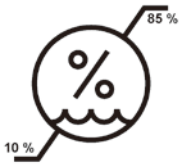
Indicates the correct upright position of the package.



Indicates the temperature range permitted for transporting the package.
Minimum -29 °C
Maximum +50 °C



Indicates the temperature range permitted for storing the package.
Minimum +5 °C
Maximum +50 °C



Indicates the humidity range permitted for storing and transporting the package.
minimum 10 % r.H.
maximum 85 % r.H.

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.

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.

This product fulfills the requirements of the CAN/CSA-C22.2 No. 61010.

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 PEARL is designed to enable tissue processing, performing all steps from fixation to wax infiltration. It is normally processed in sequential mode, which means that the instrument is strictly using one bottle after the other.
The HistoCore PEARL is a tissue processor for the following laboratory applications:

- Fixation
- Dehydration
- Infiltration with intermedium
- Paraffin infiltration

of histological tissue specimens.
The HistoCore PEARL must be operated exclusively with the reagents listed in the section of Compatible reagents (→ P. 20 – 3.4 Compatible reagents).

Caution

Any other use of the instrument is considered Off Label use.

Failure to observe these instructions may result in an accident, personal injury, damage to the instrument, accessories or specimens.

Proper and intended use includes compliance with all inspection and maintenance instructions, along with the observance of all instructions in the Instructions for Use.

1.4 Qualification of personnel

- The HistoCore PEARL must be operated by trained laboratory personnel 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.

Caution

- All information messages displayed on the touchscreen must be read and observed at all times.
- 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 protective devices located on the instrument and the accessories must not be removed or modified. Only qualified service personnel authorized by Leica Biosystems may repair the instrument and access its internal components.
- The instrument has been designed and constructed with the latest state-of-the-art technology and according to recognized standards and regulations with regard to safety technology. Operating or handling the instrument incorrectly can place the user or other personnel at risk of injury or can cause damage to the instrument or other property. The instrument must be used only as intended and only if all of its safety features are in proper working condition. Malfunctions which could impede safety must be remedied immediately.
- Only original spare parts and permitted original accessories can be used.
- If the instrument is to be returned to Leica Biosystems for repair, it must be cleaned and decontaminated in the appropriate manner. For details, please see (→ P. 101 – 10. Decontamination Confirmation).

Note

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.

Note

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

Note

For current information about applicable standards, please refer to the CE declaration for the instrument and to our Internet site:

http://www.LeicaBiosystems.com

2.2 Warnings

The safety 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 repair 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

Caution

Markings on the instrument showing the warning triangle indicate that the correct operating instructions (as defined in the Instructions for Use) must be followed when operating or replacing the item marked. Failure to observe to these instructions may result in an accident, personal injury, damage to the instrument, accessories or specimens.

Caution

Some instrument surfaces become hot during operation. They are marked with this warning label. Touching these surfaces may cause burns.

2.2.2 Transport and Installation

Caution

- Once unpacked, the instrument must be transported only in an upright position.
- Follow the unpacking instructions carefully to avoid damage to the instrument!
- Prior to every transport in which it is possible for the instrument to be shaken, tilted, or lifted, it must be cleaned including the tubing, paraffin baths and reagent bottles – otherwise the interior of the instrument can be severely damaged.
- Plug the instrument only into a grounded power socket. Make sure an obligatory use of a CB (Circuit breaker).
- Severe damage may occur if the instrument is connected to a power supply voltage other than that to which it shows on the nameplate.
- The installation location must be well-ventilated; there should be no ignition sources there of any kind. The chemicals to be used in the HistoCore PEARL are both flammable and noxious.
- Do not operate the instrument in rooms with explosion hazard.
- Extreme temperature fluctuations between storage facility and setup site as well as high humidity may cause condensation to form. If this is the case, wait at least two hours before switching on the instrument. Failure to comply with this may cause damage to the instrument.

2.2.3 Operating the instrument

Caution

- The instrument can only be operated by trained laboratory personnel. It must only be operated for the purpose of its designated use and according to the instructions contained in the Instructions for Use.
- Failure to observe the instructions specified by the manufacturer may result in damage to the protection provided by the instrument.
- Pre-installed Leica Biosystems programs are validated based on Leica Biosystems consumables and reagents.
- Before using the instrument, run the Bottle Check function to check the connections of the reagent bottles. Make sure that they are properly connected. Prevent any leaks or blockages.
- Before opening the retort when a program is in progress, always press the pause button so that the retort is ventilated or vented.
- After refilling/replacing reagent bottles, make sure the reagent bottles caps are closed tightly.
- The reagent bottles must be properly pushed home into the connection manifolds at the rear inner wall of the reagent module.
- Failure to plug the reagent bottles into the manifold correctly will interrupt the program process and may also result in spilling of reagents.
- Fixing solutions that contain mercury salts, acetic acid, or picric acid can cause corrosion on metal components.
- When there is a potential exposure to the infective material and/or toxic vapor, please wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment.

Caution

In exceptional situations (e.g. accidental reagent spills), it may be necessary to wear a respirator. This depends on the specific local ambient temperature, room volume, additional load, ventilation rate etc. In case of doubt, the laboratory owner/operator must carry out a local measurement to prove that applicable maximum workplace concentrations are not exceeded. Measurements performed of maximum workplace concentrations that occur at an air change rate of 8 times per hour and a room temperature of 40 °C, room volume of 18 m^3 and reagent temperature of 45 °C have shown that limit values are exceeded for short periods during the step when specimens are loaded in formalin. At lower ambient temperatures and/or larger room volumes in the laboratory or higher ventilation rates, the workplace concentration will be less. The exact concentration values can only be measured locally. The limits were complied with in all operating states.

Caution

The electromagnetic environment should be evaluated prior to operation of the instrument. Do not use this instrument in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

Note

Material safety data sheets can be obtained from the supplier of the chemicals.

If using Leica branded reagents, MSDS are available on-line at

http://www.LeicaBiosystems.com

2.2.4 Handling reagents

Caution

- To prevent damage to the instrument, use only the reagents listed in Chapter 3.4 (→ P. 20 – 3.4 Compatible reagents)!
- Do not use acetone, benzene, chloroform and trichlorethane on HistoCore PEARL.
- When disposing of spent reagents, observe the applicable local regulations and the waste disposal regulations of the company/institution in which the instrument is being operated.
- Do not clean reagent bottles in a dishwasher; the reagent bottles are NOT dishwasher-proof.

Caution

- Reagents used for tissue processing can be both toxic and/or flammable. Take care when handling reagents! Always wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment.
- Keep the instrument away from fire and heat.

Caution

Use caution when handling paraffin or removing the specimens/baskets from the retort – molten paraffin is hot and may cause burns. Also, avoid personal contact with paraffin baths and retort walls – they can be hot as well.

Caution

- When handling fixation, dehydration or clearing reagents (e.g. Formalin, ethanol, xylene, etc.), wear Personal Protective Equipment (lab coat, protective goggles, respirator, rubber gloves, etc.).
- When handling infiltration reagents (e.g. paraffin, etc.), wear Personal Protective Equipment (lab coat, protective goggles, respirator, safety gloves, etc.).

Caution

- For toxic reagents, such as fixation reagents (e.g. Formalin), clearing reagents (e.g. xylene), store them in a cool, ventilated warehouse/safe cabinet, and keep them away from fire and heat. When handling the toxic reagents, wear personal protective equipment (lab coat, protective goggles, respirator, rubber gloves, etc.).
- For flammable reagents, such as dehydration reagent (e.g. absolute ethanol, diluted ethanol, etc.), infiltration reagents (e.g. paraffin), store them in a cool, ventilated warehouse/safe cabinet, and keep them away from fire and heat. When handling the flammable reagents, wear personal protective equipment (lab coat, protective goggles, respirator, rubber gloves/safety gloves, etc.).

2.2.5 Cleaning and maintenance

Caution

- Do not clean the instrument with solvents containing acetone or xylene. No liquid may be spilled into the internal components of the instrument – neither during operation nor during cleaning.
- When using cleaners, please comply with the safety instructions of the manufacturer and the laboratory safety regulations.
- Check the condensate bottle at least once a week and empty it.
- If the instrument is not to be used for a long time, drain out the reagent and paraffin. Use deionized water to clean the formalin bottle and water bottle, and dry; use ethanol to clean the ethanol bottle, xylene bottle and paraffin baths, and dry; use ethanol to wipe clean the instrument exterior.

2.3 Safety features on the instrument

The HistoCore PEARL tissue processor is equipped with safety functions and with sophisticated software control mechanisms. These ensure that the specimens remain undamaged in the event of a power failure or other malfunction during the program and that the program is completed successfully.

2.3.1 Overpressure protection

- When the power is switched off, the pressure air pump and valves default to a safe condition (retort vented, no pressure generation).
- In addition, there is a relief valve that vents all excess air pump output to atmosphere.

2.3.2 Overcurrent protection

Overcurrent conditions are protected against by the main fuse overcurrent protection.

2.3.3 Overheating protection

The heat limiter protects the instrument against the abnormally high temperature.

3. Instrument Components and Specifications

3.1 Overview

Instrument components

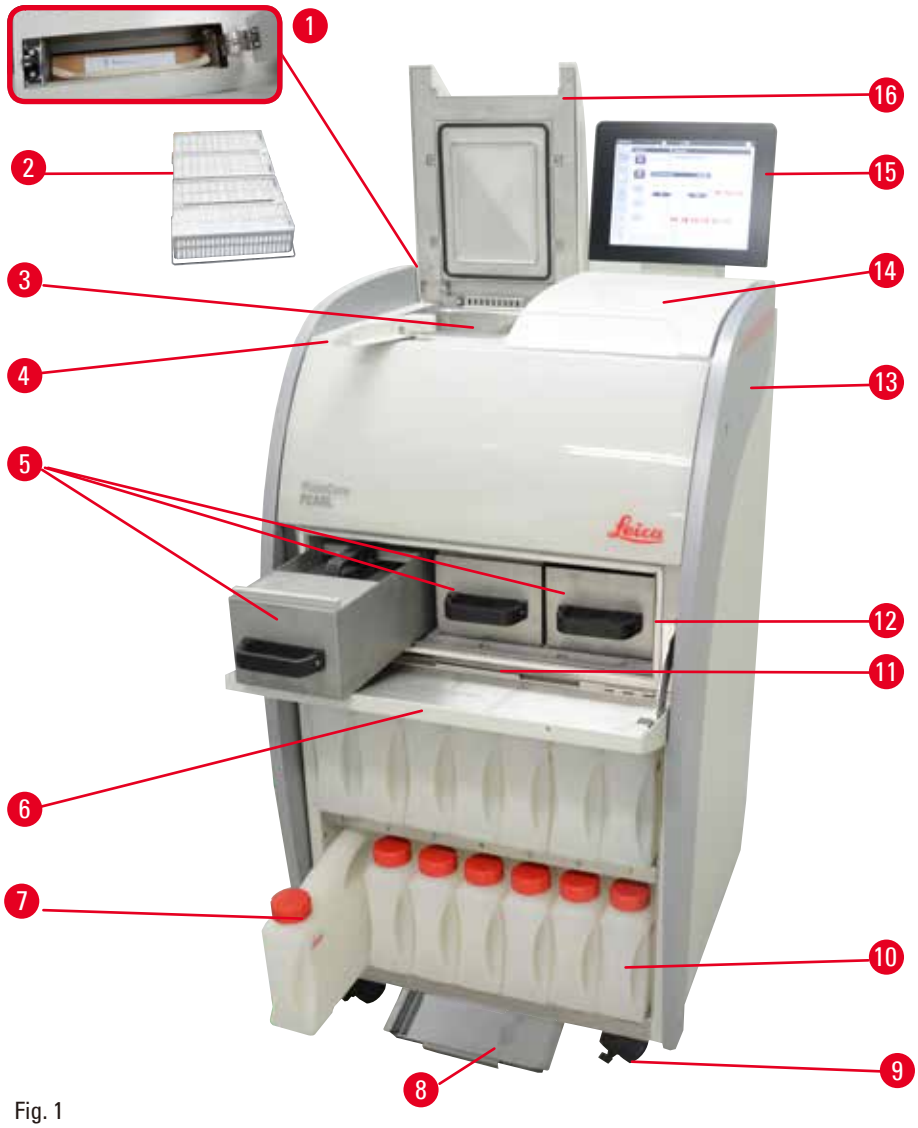


Fig. 1

1	Active carbon filter	9	Caster
2	Specimen baskets	10	Condensate bottle (1)
3	Retort	11	Paraffin drip tray
4	Lid latch knob	12	Paraffin oven
5	Paraffin baths (3)	13	Basic instrument
6	Paraffin oven cover	14	Counter area
7	Reagent bottles (13)	15	Display
8	Bottom tray	16	Retort lid

Rear panel

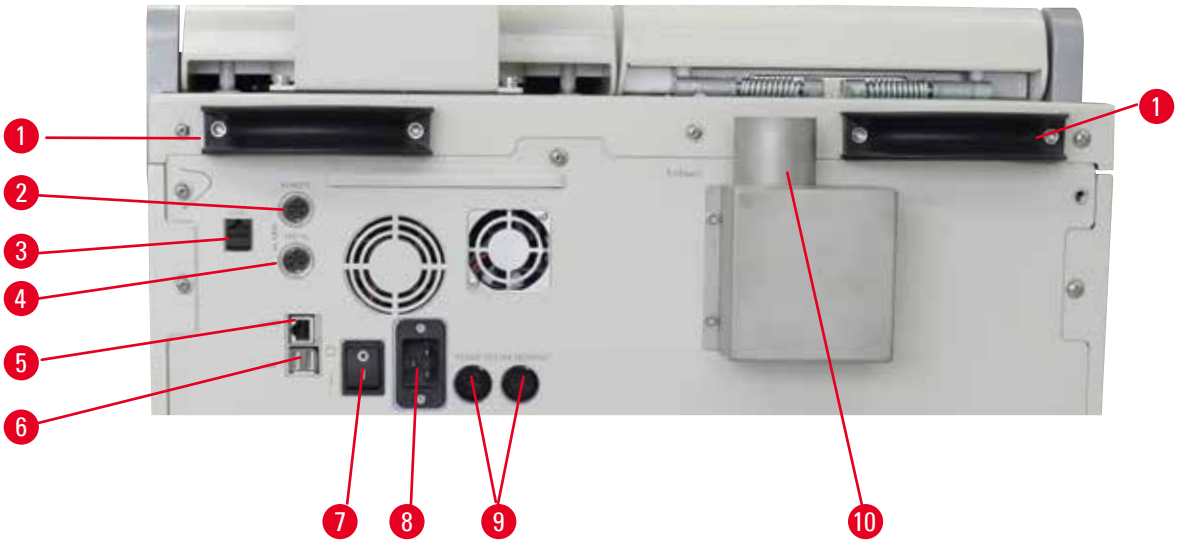


Fig. 2

1	Handles for moving the instrument (2)	6	USB ports (2)
2	Remote alarm connection	7	Main power switch (ON/OFF)
3	Network connection 1 (LAN 1) for service	8	Power supply input
4	Local alarm connection	9	Fuses
5	Network connection 2 (LAN 2) for RemoteCare	10	Exhaust interface

Note

The USB ports are for memory sticks only. Do not connect any other type of USB device to the instrument.

3.2 Main features of the instrument

- The HistoCore PEARL is equipped with an LCD touch screen. Multilingual user interface and graphic display of the program flow (dashboard) are for clarifying all menu steps.
- The HistoCore PEARL can be operated using customized or pre-installed, validated tissue processing programs. There are 3 pre-installed, non-editable programs available, including 1 Cleaning program, 1 Overnight and 1 Biopsy.
- 10 processing programs are freely configurable with up to 14 steps (temperature; time; reagent; pressure/vacuum options).
- Reagent Management System (RMS) enables the users to monitor the usage of reagents per number of cassettes, cycles or days.
- The quick start system enables the users to start each program immediately from the Favorite program panel (max. 5 programs).
- The number of cassettes, number of processing cycles, days since the last change and the reagents to be replaced can be displayed according to the customized settings of the RMS.

- Three paraffin baths are used for the tissue infiltration, each with a max. capacity of 3.5 L of liquid paraffin. The paraffin baths can be easily removed for cleaning simply by pulling them out. The paraffin drip tray is used to collect any spilled paraffin.
- Harmful reagent vapors are continuously suctioned back from the retort into the instrument and filtered even after the retort is opened, e.g. to reload cassettes or baskets. The instrument uses an active carbon filter. In addition, it is recommended to connect the instrument to an external vacuum extractor via a separate port on the rear of the instrument.
- The retort is capable of holding up to 200 standard cassettes depending on whether it is operated with one or two baskets.
- RemoteCare Internet connection between the instrument and the Service Support Team enables optimized service through monitoring of the instrument and its functions.
- The user can transfer all processing programs and logs via USB.
- Access to the instrument can be limited via a multilevel password protection system.
- The user can utilize the Bottle Check function to ensure connecting status of reagent bottles.
- In the event of a power failure, the alarm system is triggered off. The HistoCore PEARL will provide recovery measures after interruption.
- In the event of an error, an alarm is sound immediately. The system will retry first to recover, if this is unsuccessful the instrument will then fill the retort with a safe reagent to ensure the safety of specimens if no operation is taken on the display in 15 minutes.
- Three alarm modes: instrument alarm, local alarm and remote alarm, enable the customers to be alerted whenever necessary.

3.3 Technical Data

General	
Nominal supply voltages	100 to 120 V AC or 220 to 240 V AC
Nominal frequency	50/60 Hz
Main Fuses	2 melting fuses, 32 x 6.3 mm, UL-approved T15 A 250 VAC
Nominal power	1650 VA
Operating temperature range	+10 °C to +35 °C
Transport temperature range	-29 °C to +50 °C
Storage temperature range	+5 °C to +50 °C
Transport and storage relative humidity	10 % to max. 85 % non-condensing
IEC 61010 classification	Pollution degree 2 Overvoltage installation category II
Operating elevation	Up to a max. of 2000 m above sea level
A-weighted noise level	< 70 dB (A)
Local/remote alarm relay	30 V DC, maximum 1 A
Air-liquid system pressure range	-40 kPa to +40 kPa
Dimensions and weights	
Dimensions, unpacked (W x D x H), in mm	600 x 710 x 1320
Empty weight, unpacked	Max. 140 kg

Dimensions and weights	
Weight, packed	Max. 175 kg
Paraffin baths	
Number of paraffin baths	3
Capacity	Max. 3.5 L per paraffin bath
Support paraffin melting point	50 °C - 64 °C
Melting time	50 °C - 64 °C, 12 hours
Temperature settings range	50 °C - 70 °C
Retort	
Capacity	Max. 200 cassettes
Temperature (paraffin)	50 °C - 70 °C
Temperature (processing reagents)	Ambient temperature or 35 °C to 60 °C
Temperature (cleaning reagents)	Ethanol 62 °C, Xylene 67 °C
Reagent bottles	
Reagent bottles	11 (in reagent cabinet)
Condensate bottle	1
Cleaning bottles	2
Bottle volume	Max. 3.5 L
Reagent Management System (RMS)	
RMS	• Processing program: Cassettes/Cycles/Days • Cleaning program: Cycles/Days
Access levels	
Access levels	• Standard User • Supervisor • Service
Password status	• Supervisor • Service
Type of password	Alphanumeric, freely selectable

Hardware and Software

- Color LCD touchscreen.
- User-friendly, interactive software.
- Two USB 2.0 ports, DC 5V.
- Alarm system with two alarm sockets (for local alarm and remote alarm).
- Smart error-handling for specimen protection.

Capacities
• 10 freely configurable programs and 2 pre-installed programs, each consisting of up to 11 reagent and 3 paraffin processing steps.
- Time per program step: 0 to 99 hours, 59 minutes.
- Delay time: max. 7 days.
• Up to 200 cassettes can be processed simultaneously.
• 1 cleaning program for the retort.
• 11 reagent bottles.
• 2 cleaning bottles.
• 1 condensate bottle.
• 3 paraffin baths.
• Reagent temperature selectable from 35 °C to 60 °C or ambient temperature, depending on the reagent.
• Paraffin temperature selectable from 50 °C to 70 °C.
• Cleaning temperature of 62 °C (ethanol) or 67 °C (xylene).

3.4 Compatible reagents

Caution

Use of the HistoCore PEARL is permitted with the reagents specified in this section only. These reagents must be validated before use, i.e. tissue processing with patient tissue for diagnostics, by the laboratory itself according to the local or regional accreditation requirements.

Reagents other than these listed here may cause severe damage to the components of the instrument.

Acetone, benzene, chloroform and trichlorethane must NOT be used.

The following reagents may be used in the HistoCore PEARL:

Fixatives	Dehydration	Clearing	Xylene Replacement
1. Formalin (buffered or unbuffered)	1. Ethanol 2. Isopropanol 3. Methanol-Isopropanol mixture (50% Methanol)	1. Xylene 2. Toluene*	1. Surgipath Sub-x 2. Sakura Tissue Tek Tissue Clear 3. Thermo Scientific Shandon Xylene Substitute

* Before using these reagents, please obtain information from Leica Biosystems or the supplier about required preventive measures.

Note

Fixatives containing mercuric salts, acetic or picric acid will corrode metallic components in the instrument and shorten instrument life.

If you choose to work with such fixatives, change the processing water at least every 600 cassettes or 3 cycles, to minimize the damage.

In addition, we recommend regular preventive maintenance by Leica Biosystems Technical Service.

Caution

Reagents other than these listed here may damage components of the instrument. Do not use acetone, benzene chloroform and trichlorethane in the instrument.

3.5 Recommended reagent handling

- The recommended temperature for Formalin is 37 °C.
- The recommended temperature for processing water is ambient temperature.
- The recommended temperature for processing ethanol and xylene is 45 °C.
- The temperature for cleaning xylene in the cleaning cycle is 67 °C.
- The temperature for cleaning ethanol in the cleaning cycle is 62 °C.
- The use of formalin reagents containing zinc chloride can cause corrosion of the instrument.

3.5.1 Cycle for changing reagents

Station	Reagent	*Week 1/ 5 Cycles	Week 2	Week 3	Week 4
1	**Formalin**	Refresh each 600 cassettes/ 3 cycles	Refresh each 600 cassettes/ 3 cycles	Refresh each 600 cassettes/ 3 cycles	Refresh each 600 cassettes/ 3 cycles
2	**Processing water**	Refresh each 600 cassettes/ 3 cycles	Refresh each 600 cassettes/ 3 cycles	Refresh each 600 cassettes/ 3 cycles	Refresh each 600 cassettes/ 3 cycles
3	**70 % Ethanol**	Refresh	Refresh	Refresh	Refresh
4	**80 % Ethanol**	Refresh	Refresh	Refresh	Refresh
5	**95 % Ethanol**	Refresh with 100% and move to Station 8	Refresh with 100% and move to Station 8	Refresh with 100% and move to Station 8	Refresh with 100% and move to Station 8
6	**100 % Ethanol**	Move to Station 5	Move to Station 5	Move to Station 5	Move to Station 5
7	**100 % Ethanol**	Move to Station 6	Move to Station 6	Move to Station 6	Move to Station 6
8	**100 % Ethanol**	Move to Station 7	Move to Station 7	Move to Station 7	Move to Station 7
9	**Xylene**	Refresh and move to Station 11	Refresh and move to Station 11	Refresh and move to Station 11	Refresh and move to Station 11

Station	Reagent	*Week 1/ 5 Cycles	Week 2	Week 3	Week 4
10	**Xylene**	Move to Station 9	Move to Station 9	Move to Station 9	Move to Station 9
11	**Xylene**	Move to Station 10	Move to Station 10	Move to Station 10	Move to Station 10
P1	**Paraffin**	Refresh and move to Station P3	Refresh and move to Station P3	Refresh and move to Station P3	Refresh and move to Station P3
P2	**Paraffin**	Move to Station P1	Move to Station P1	Move to Station P1	Move to Station P1
P3	**Paraffin**	Move to Station P2	Move to Station P2	Move to Station P2	Move to Station P2
12	**Cleaning xylene**	Refresh	Refresh	Refresh	Refresh
13	**Cleaning ethanol**	Refresh	Refresh	Refresh	Refresh

* On the condition that the instrument is running not more than 5 overnight program cycles per week, and not exceeding 200 cassettes per cycle.

Note

Do not reuse contaminated dehydrants as cleaning ethanol. The contaminated dehydrants will cause salts to crystallize on the retort's internal surfaces and the level sensor.

4. Initial Operation

4.1 Installation site requirements

- The instrument requires an installation area of approximately 700 x 800 mm.
- The substrate must have a sufficient load capacity and rigidity with respect to the weight of the instrument.
- The instrument is designed for indoor use only.
- The instrument must be installed in a place that ensures an easy disconnection from the power supply. The power cable must be in a place that can be easily reached.
- No extension cable can be connected.
- The instrument MUST be connected to a grounded power socket.
- Use only one of the provided power cables that is intended for the local power supply.
- Avoid vibrations, direct sunlight and heavy variation in temperature.

Caution

The chemicals used in the HistoCore PEARL are easily inflammable and hazardous to health. Therefore the installation location must be well ventilated, and must contain no open flames. The room in which the instrument is located must not be used as a permanent station for people. Otherwise the room must be equipped with an exhaust device.

The installation location must be protected against electrostatic discharge.

Do not operate the instrument in rooms with explosion hazard.

To ensure proper function of the instrument, it must be set up while maintaining a minimum distance of 10 cm from walls and furniture.

4.2 Standard delivery - packing list

Note

To prevent damage to the instrument or specimens, only accessories and spare parts authorized by Leica Biosystems can be used.

Quantity	Part description	Order No.
1	HistoCore PEARL instrument	14 0493 50667
1	Display module	14 0493 50642
14	Reagent bottle assembly	14 0493 50465
1	Paraffin drip tray	14 0493 50570
1	Bottom tray	14 0493 55572
1	Bottle label	14 0493 50467
2	Basket assembly	14 0493 51403
1	Paraffin scraper	14 0393 53643
1	Maintenance kit, consists of	14 0493 53391
	10 O-rings	14 0493 51361
	1 Lubricant, Molykote 111, 100g	14 0336 35460
	10 Seal bottle cap, normal	14 0461 36136

Quantity	Part description	Order No.
1	Additional reagent bottle assembly	14 0493 53393
1	Funnel	14 0493 55900
2	Connector male 5-pole	14 0493 51429
1	Instructions for Use (printed English with language CD 14 0493 80200)	14 0493 80001

The country specific power cord needs to be ordered separately. Please find a list of all power cords available for your device on our website www.LeicaBiosystems.com within the product section.

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 and installation

Caution

The packaging has two indicators (→ "Fig. 3-14") (→ "Fig. 3-15") 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.

Caution

At least TWO persons are required when unpacking the instrument.

If the instrument is moved over stairs, please call your local Leica Biosystems Technical Service, who can safely transport it with appropriate equipment.

Caution

DO NOT use the handles on the rear panel to carry, as they are not designed to bear the weight, but only for rolling the instrument.

Unpacking the instrument

- ⓘ Before unpacking the instrument, read the unpacking instructions carefully. They are attached to the outside of the transport packaging.
- ⓘ Sufficient surface area is required for unpacking the instrument. The distance to the nearest wall must be at least 1 m on the side and rear. On the front, the distance must be at least 3 m, as the HistoCore PEARL is rolled from the pallet in this direction.
- ⓘ Bring the instrument package as close as possible to the final installation location.

1
2
3
4
14
15
6
5
7
8
9
Front
Leica
KIPPINDIKATOR
OPEN
SPERR
LINIE
SHOCKDOT
WARNING
HANDLE WITH CARE

Fig. 3

1. Remove the straps (→ "Fig. 3-1"), then the cover (→ "Fig. 3-2").
2. Unfasten 3 plastic locks (→ "Fig. 3-3") on the front side and remove the carton wall (→ "Fig. 3-4").
3. Remove the compression strap (→ "Fig. 3-5").
4. Remove the molded foam (→ "Fig. 3-6") on the top of the instrument.
5. Remove the top plastic dust cover (→ "Fig. 3-7") from the instrument, and fold carefully the lower plastic dust cover (→ "Fig. 4-8") under the pallet (→ "Fig. 4-9").
6. Unfasten 4 screws (→ "Fig. 4-10") and remove the wooden transport anchor (→ "Fig. 4-11").
7. Pull out the two rails (→ "Fig. 4-12") from beneath the instrument by pulling them towards you.
8. Hook these rails into the groove on the left and right (→ "Fig. 4-13") of the pallet so that they are flush with the wooden board that holds the instrument.

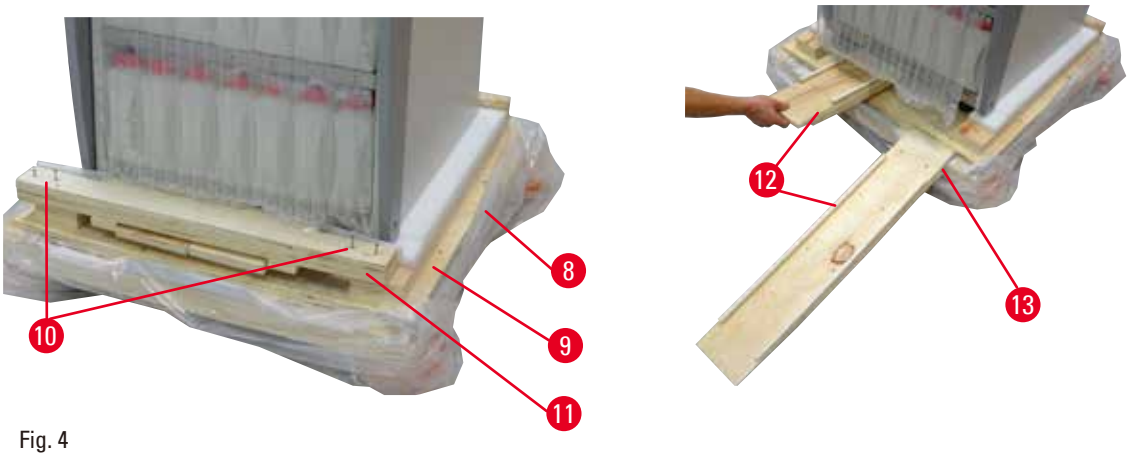


Fig. 4

9. Push the instrument from the pallet.

Caution

The instrument casters move very easily. The empty weight of the HistoCore PEARL is 140 kg! Therefore, it is mandatory to have at least TWO persons hold the instrument when it is rolled off the pallet via the ramp.

» When moving the instrument down from the pallet, one person should support it by the outer top corners using both hands; the other person holds the rear of the instrument securely by both handles (→ "Fig. 5"). Do not support the instrument on the fragile glossy plexiglass area (→ "Fig. 5-1").

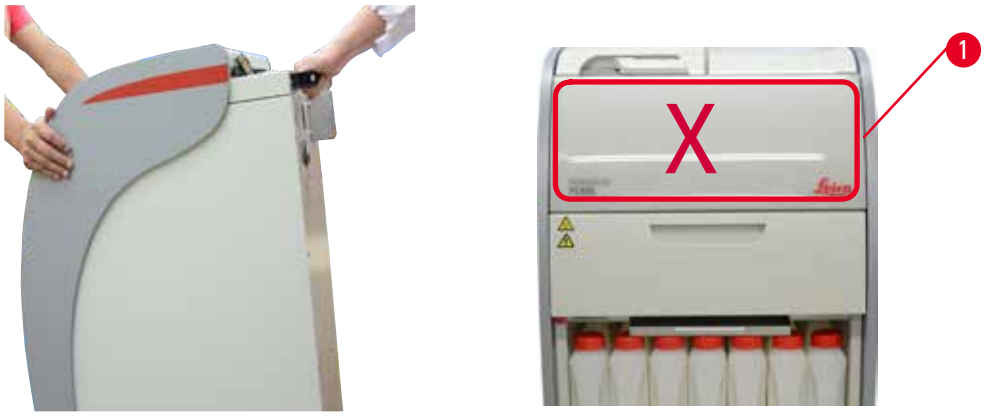


Fig. 5

10. Bring the instrument to its final location and lock the casters.
11. Remove the transport anchors.

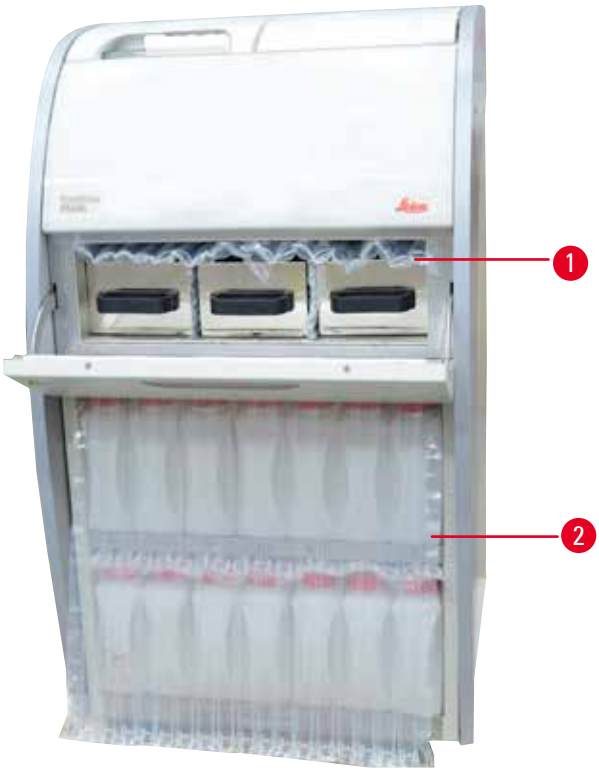


Fig. 6

» Remove the packaging (→ "Fig. 6-1") from behind the paraffin oven door along with the packaging (→ "Fig. 6-2") covering the reagent bottles.

12. Check the instrument and accessories for any visible transport damage. All accessories are located in the small package box.

1	Additional reagent bottle	6	Maintenance kit, Paraffin scraper, Reagent bottle labels
2	Alarm connector	7	Basket assembly
3	Display module	8	Paraffin drip tray
4	Funnel	9	Bottom tray
5	Power cord		

Note

During unpacking, make sure to keep the accessory box in the upright direction as indicated by the transportation symbol on the packaging box. Otherwise, the accessories could fall out and become damaged.

Note

The packaging must be retained for the duration of the warranty period. To return the instrument, follow the instructions above in reverse order.

4.4 Basic instrument/hardware

4.4.1 Installing the Display

Installing the display

ⓘ The display is located along with all other accessories in the small packaging box.

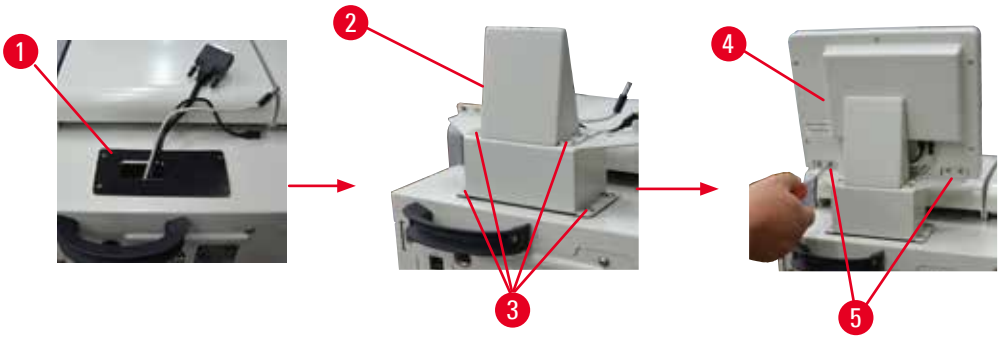


Fig. 7

1. Install the rubber pad (→ "Fig. 7-1") on the instrument.
2. Guide the cables of three terminals (power supply, USB port and display cable) through the hole on the bracket and then install the bracket (→ "Fig. 7-2") by fastening 8 screws at two sides. (→ "Fig. 7-3").
3. Plug in three terminals (power supply, USB port and display cable) on the bottom of the display (→ "Fig. 7-4").
4. Install the display by fastening 4 screws at the back of the instrument (→ "Fig. 7-5") using spring washers and flat washers.

4.4.2 The retort

Open/Close the retort

- Turn the handle as shown in the below figure (→ "Fig. 8") and lift here (→ "Fig. 8-1") to open the retort. Do not try to pry the handle.
- To seal the retort, push the handle back to the place with strength.

Fig. 8

The open/close status of the retort is displayed on the screen (→ P. 74 – Retort status).

Caution

Because of the hot surface, wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment, and keep your distance when opening the retort lid, particularly if the reagents are heated. Also avoid breathing in the vapors.

Level sensor and retort sieve

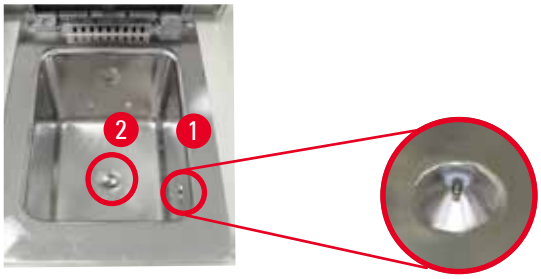


Fig. 9

There is a level sensor (→ "Fig. 9-1") located at the right side wall of the retort. It prevents the retort from being overfilled or insufficiently filled.
There is a retort sieve (→ "Fig. 9-2") at the bottom of the retort. Install the sieve by inserting and rotating it clockwise.

4.4.3 Active carbon filter

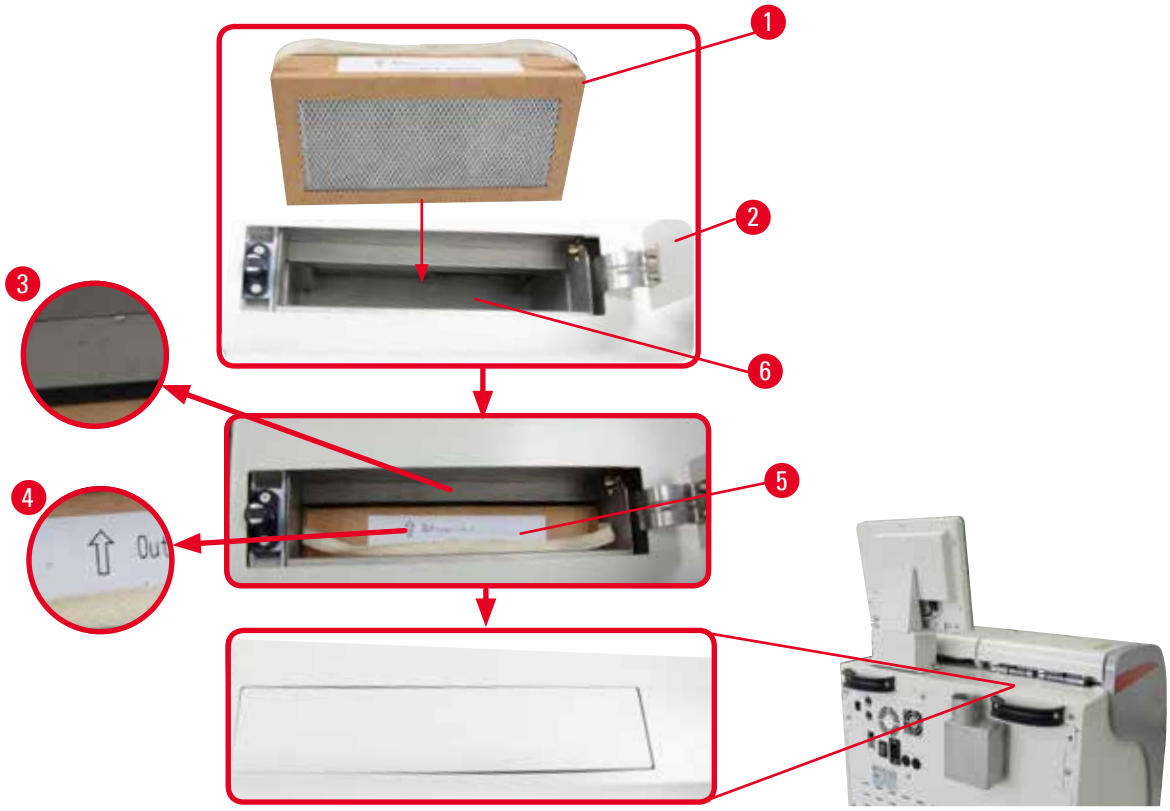


Fig. 10

Inserting/Replacing the active carbon filter

1. To insert/replace the active carbon filter (→ "Fig. 10-1"), press and open the top cover (→ "Fig. 10-2") behind the retort lid.

Caution

Putting hand in the active carbon filter container (→ "Fig. 10-6") may cause injury.

2. For the first time to insert the active carbon filter, make sure that the arrows on the filter (→ "Fig. 10-4") and on the instrument (→ "Fig. 10-3") are at the same direction, and then push the new filter in as far as it will go. The date on which the filter has been inserted can be marked on the label (→ "Fig. 10-3") on the front side.
3. Close the top cover.

The instrument will calculate the time the active carbon filter has been in use.

- When the time exceeds the warning threshold, a warning pops up, reminding you to replace a new active carbon filter.
- When the time exceeds the alarm threshold, the alarm rings with a warning message.

For how to set the warning/alarm threshold of the active carbon filter, see (→ P. 56 – 5.2.8 Maintenance).

Note

The exhausted vapors from the instrument is harmful. The active carbon filter must be in use.

The active carbon filter is only an additional measure to minimize harmful vapors in the area surrounding the instrument. Ventilation of the workroom is required in any case. The filter replacement is dependent on the frequency of using the instrument, but at least it needs to be replaced after 45 - 60 days.

Note

The used carbon filter contains harmful fumes. Dispose of it with proper care according to the existing applicable local regulations.

4.4.4 External exhaust system

The instrument has been designed so that it can be connected to an external exhaust device. The optional delivery includes the "Extraction tube" (→ P. 97 – 8. Ordering information) for this purpose. It is recommended to use an external exhaust system.

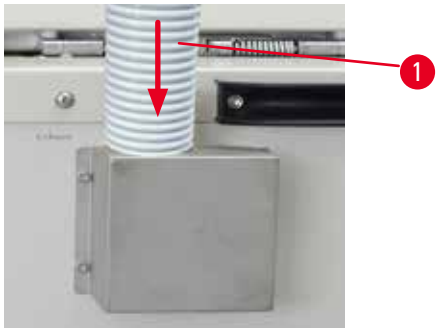


Fig. 11

Attach one end of the extraction tube (→ "Fig. 11-1") to the upwards-pointing tube of the flange and push it down as far as it will go. Connect the other end of the extraction tube with the external exhaust station.

Caution

Even if the instrument is connected to an external exhaust device, the active carbon filter provided must remain in use.

4.4.5 Counter area

Fig. 12

To the right of the retort in front of the display, there is a counter area (→ "Fig. 12-1"). The flat area can be used for setting down the prepared specimens and baskets removed from the retort. However, we recommend also covering the counter area with a silicone pad (→ "Fig. 12-2"). For ordering information of the silicone pad, see (→ P. 97 – 8. Ordering information). To avoid reagent dripping, it is recommended to use a container on the silicone pad to hold the baskets.

Caution

The specimens and baskets may drop down if they are not set down at the flat area of the counter.

4.4.6 Cassette baskets

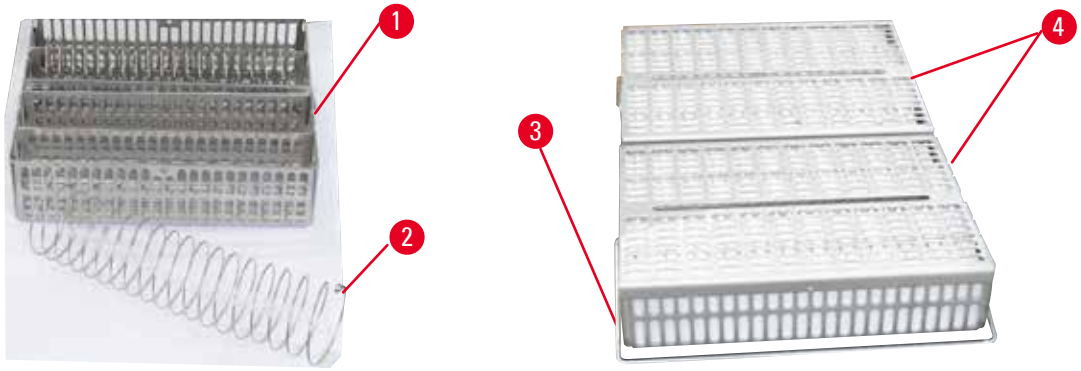


Fig. 13

- The above figure (→ "Fig. 13") shows the standard stainless steel basket (→ "Fig. 13-1").
- The dividing spiral (→ "Fig. 13-2") is used to align the cassettes in the basket accurately.
- As shown with the dividing spiral, the standard basket can be filled with up to 80 specimen cassettes. Without a dividing spiral, the cassettes can be packed in more tightly, so that a maximum of 100 cassettes can fit in the basket.
- Each metal basket has a movable handle (→ "Fig. 13-3") for inserting and removing it from the retort.
- The lid (→ "Fig. 13-4") is added onto the baskets after being filled.
- Up to 2 baskets can be inserted into the retort and processed simultaneously.

Caution

Only clean baskets can be used for tissue processing.

Note

It is recommended to use Leica Biosystems predefined/validated consumable (cassettes).

Note

Do not add more than 200 cassettes into the retort during processing.

Note

HistoCore PEARL basket can be used in ASP6025.

4.4.7 The display

Fig. 14

- The HistoCore PEARL is programmed and operated via a color LCD touchscreen.
- A screen saver will turn off the screen display if no key has been pressed for 30 minutes. Press any part of the touchscreen to restore the screen. After having been restored, the on-screen functions will be non-operational for a few seconds to avoid accidental touch of any keys.
- The touchscreen is fastened to a stable base with four screws. All terminals are protected from contact with reagents. The touchscreen itself is resistant to all reagents used in the instrument. Despite this, avoid any reagent contamination to the screen. Immediately wipe any reagent splashes!

4.4.8 The paraffin baths

Fig. 15

- The instrument has three heated paraffin baths, each with a max. capacity of 3.5 L of liquid paraffin. They are located over the reagent cabinet.
- The individual paraffin baths can be pulled out (→ "Fig. 15-1") for filling and can also be removed from the paraffin oven for cleaning.

Caution

Be careful of the paraffin oven cover hinges. Open and close the oven cover only using the supplied handle (→ "Fig. 15-2"). Do not place fingers in the areas shown in the above figure (→ "Fig. 15-3").

Caution

Never attempt to forcefully remove the paraffin baths when the instrument is cold. Doing so can damage the instrument.

Caution

Proceed slowly and carefully when pulling out a paraffin bath—never jerk it out. The paraffin inside is hot and can cause burns. The paraffin baths surfaces, handles and covers are also hot, therefore always wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment, and proceed carefully.

Caution

Before use or after maintenance, check the paraffin baths to make sure there is no leakage.

- The baths need to be filled with liquid paraffin manually. It is also possible to fill with pellets - the melting time then is approximately 12 hours or 15 hours dependant on the paraffin bath temperature setting.

- All paraffin baths have two handles (→ "Fig. 16-1") for pulling out and carrying. Two covers (→ "Fig. 16-2") (→ "Fig. 16-3") provide for better thermal insulation and prevent the liquid paraffin from spilling out when being pulled out.

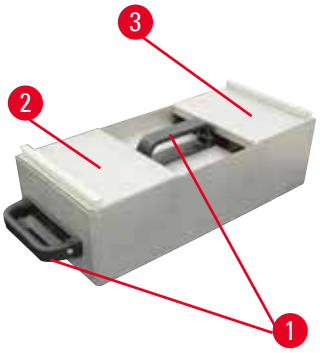


Fig. 16

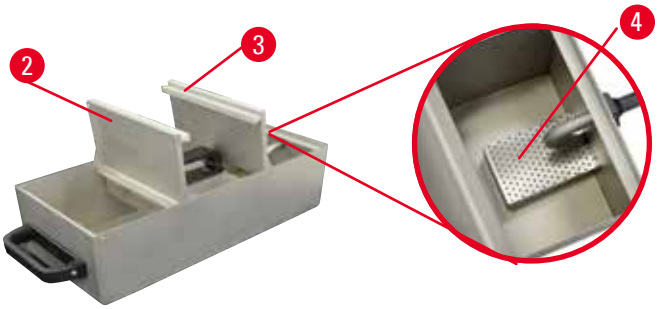


Fig. 17

- When pulling out a bath, both the front and the rear cover can be folded upwards each other (→ "Fig. 17") to facilitate filling and cleaning.
- The maximum and minimum filling levels are located on the interior walls. Make sure that the paraffin level is between these two marks.
- There is a filter (→ "Fig. 17-4") located in each paraffin bath, which can be taken out for easy cleaning.

4.4.9 The paraffin drip tray

Fig. 18

- The paraffin drip tray (→ "Fig. 18") is located below the paraffin oven. It collects paraffin that have overflowed.
- The paraffin drip tray must be regularly checked and cleaned. To do so, pull the paraffin drip tray out by the handle and empty it.

4.4.10 Reagent cabinet with reagent bottles

Fig. 19

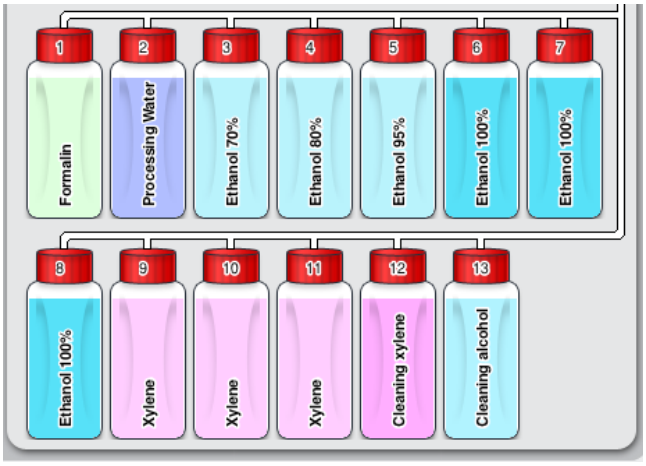


Fig. 20

- The 13 white plastic reagent bottles are located together with the condensate bottle (→ "Fig. 19-1") in the reagent cabinet under the 3 paraffin baths (→ "Fig. 19"). The numbering of the bottle positions are silk-screened on ribs of the reagent carbinet (→ "Fig. 19-2").
- The simulated reagent bottles are designated "1" to "13" on the top with the reagent name in the middle, and are displayed on the screen (→ "Fig. 20").
- All reagent bottles have a max. capacity of 3.5 L . The maximum (3.5 L) and minimum (3.3 L) fill levels for filling are embossed on the front of each bottle.

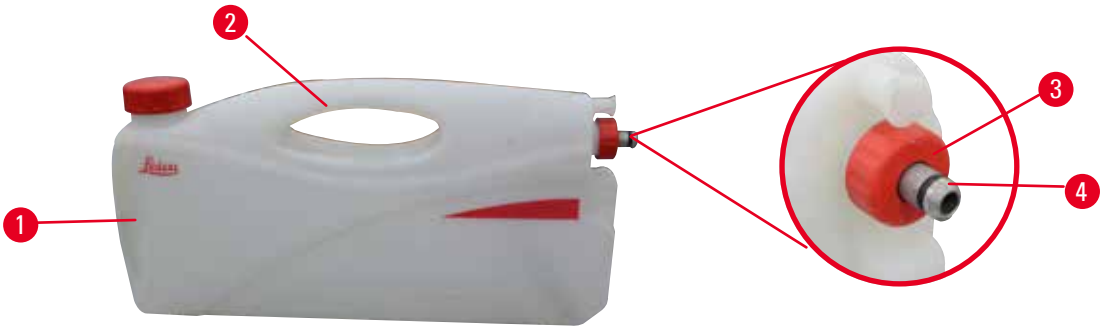


Fig. 21

Pulling out a reagent bottle

1. Grasp the front handle (→ "Fig. 21-1") and pull out half of the bottle.
2. Grasp the top handle (→ "Fig. 21-2") and pull out the full length of the bottle.

Inserting a reagent bottle,

» When inserting a reagent bottle, always ensure that the retaining ring (→ "Fig. 21-3") is tightened and the connection port is pushed into place with a click sound (→ "Fig. 21-4").

Caution

Before use or after maintenance, make sure the reagent bottles are properly connected.

Note

Only HistoCore PEARL reagent bottles can be used.

Note

The connection port must be pushed into place with a click sound, thus ensuring an optimum fit in the reagent cabinet.

Condensate bottle

- The condensate bottle (→ "Fig. 19-1") has the exact same shape and connection design as a reagent bottle.
- It captures and collects condensate that forms in the system. A mark for the maximum level is on the front side.
- Regularly check and empty the condensate bottle (→ P. 90 – Emptying the condensate bottle).

4.4.11 The bottom tray

Fig. 22

The bottom tray is located below the reagent cabinet (→ "Fig. 22-1"). It collects reagents that have overflowed or spilled. The bottom tray volumn is approximately 4 L.
The bottom tray must be regularly checked for signs of reagents that have leaked. To do so, use one hand to pull the bottom tray out by the handle until you see the etched number, 20 cm; use the other hand to support the tray from the bottom. Then pull out the whole bottom tray and empty it.

Caution

Dispose of waste reagent with care according to local regulations and the waste management policy of the company or institution.

4.4.12 Adhesive labels for reagent bottles

- The standard delivery of the HistoCore PEARL includes adhesive labels for the reagent bottles in the reagent cabinet. They can be used to mark the groups of the reagent bottles.
- Ensure the surface on the reagent bottles are clean and dry; then apply the label and press on firmly—especially at the edges.
- The labels are resistant to the reagents used in the instrument.
- The station number can be noted on the label as well as the date when the reagent specified in the color table was commissioned.

4.5 Alarm functions

Note

In the instrument, states can occur that require the attention of, or a decision on the part of, the user. In the simplest case, these are confirmations for continuing in the processing program. In addition, however, during continuous monitoring of the hardware, errors can be identified that must be eliminated as soon as possible for a running program to be finished successfully. Correspondingly, all messages are classified according to their severity.

The HistoCore PEARL is equipped with 3 different alarm functions:

Instrument alarm

This instrument alarm is generated from within the instrument itself for all alarm messages.

Local alarm

This alarm is external to the instrument, e.g. in the office of the instrument operator. The local alarm is used when the instrument cannot continue with the current program or operation because of a problem.

Remote alarm

This alarm is also external to the instrument. If installed, it can be connected to a remote alarm system that sends an alarm message to the person responsible for after-hours problems.
The remote alarm is only generated when the instrument cannot continue with a program.

Note

The remote alarm will still operate even if the local alarm is not installed.

Connecting the local and remote alarm system

Note

Both local and remote alarm options are relays that are voltage-isolated from the rest of the instrument. When an error condition occurs, the relevant alarm circuit closes. The remote alarm device connected to the instrument must be rated at less than 1 A. A maximum voltage of 30 V DC may be present.

Caution

Connection of an external alarm system (local and remote alarm) is absolutely necessary for preventing damage or loss of tissue samples in the event of a malfunction.

Fig. 23

Fig. 24

The alarm systems for the local alarm and remote alarm are connected via a 5-pin male M16 connector (Amphenol T3360001U as a reference for cable diameter 4-6mm).

The maximum values of the alarm system connected to the instrument must not exceed 30V DC, max. 1A.
Local alarm: socket (1) (→ "Fig. 23-1")
Remote alarm: socket (2) (→ "Fig. 23-2")
Each alarm is connected to the plug (6) as follows:
Shared terminal: pin (1) (→ "Fig. 24")
Normally open contact: pin (3) (→ "Fig. 24")
Normally closed contact: pin (2) (→ "Fig. 24")
Pin (4) (→ "Fig. 24") and pin (5) (→ "Fig. 24") shall be short-circuited.

4.6 Connecting the power supply

Caution

Observe the following instructions carefully to prevent damage to the instrument.

The instrument MUST be connected to a grounded power socket. The power plug must be easily accessible so that it can be pulled out if required.

The instrument is supplied with a set of different power cords. Use only the power cable that matches the local power supply (outlet).

Do not use an extension cable!

Caution

Check the nameplate on the rear of the instrument to ensure that the instrument delivered is designed for the required voltage.

Severe damage may occur if the instrument is connected to a power supply voltage other than that to which it was originally set.

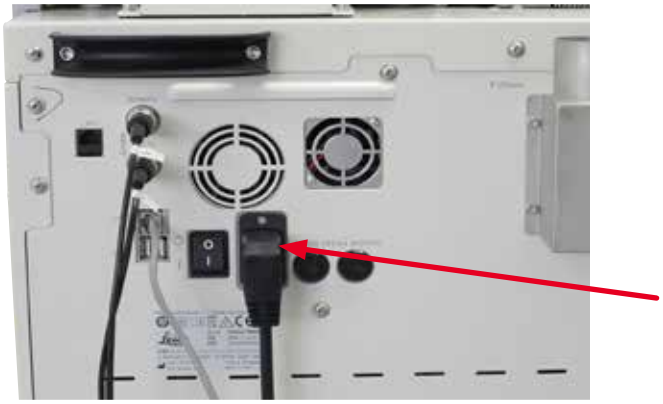


Fig. 25

4.7 Switching the instrument on

Caution

The instrument MUST be connected to a grounded power socket.

For additional electrical fuse protection, we recommend connecting the HistoCore PEARL to a socket with a residual current circuit breaker.

Switching the instrument on

1. Connect the power cable to the power socket. If applicable, switch on the switch for the power socket.
2. Switch On the ON/OFF switch on the rear panel of the instrument.
3. After being switched on, the instrument will take a few minutes to initialize (→ "Fig. 26").

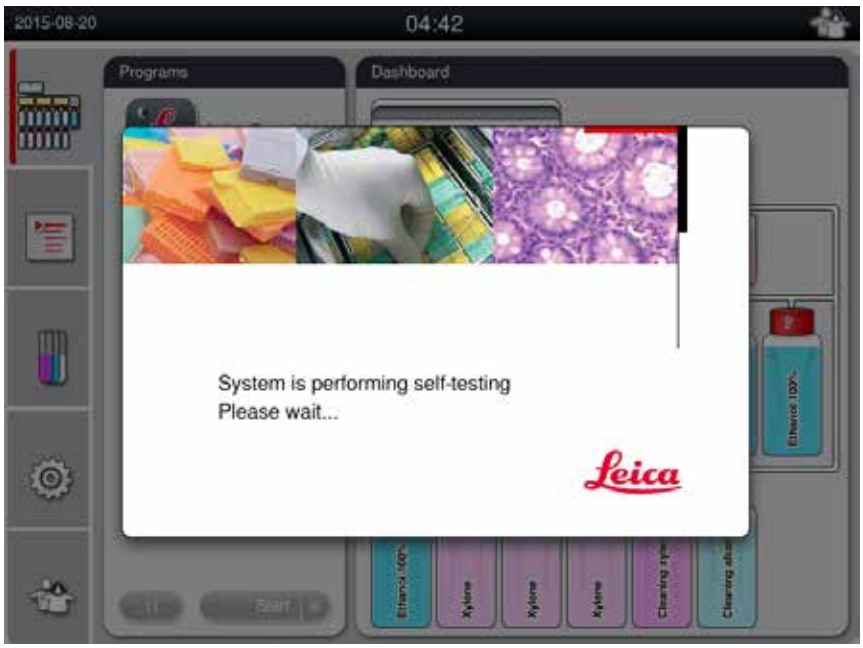


Fig. 26

4. After that, the application window (→ "Fig. 27") will be displayed, which consists of the status bar (→ "Fig. 27-1") and the main window (→ "Fig. 27-2") .

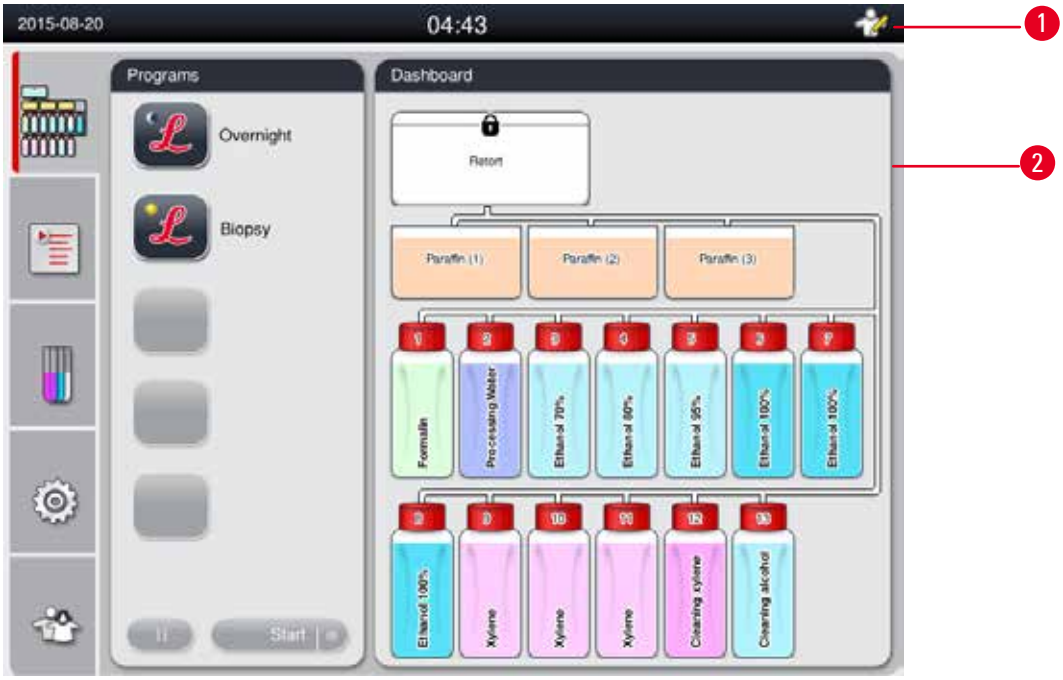


Fig. 27

Screen saver

A screen saver will turn off the screen display if no key has been pressed for 30 minutes. Press any part of the touchscreen to restore the screen.
After having been restored, the on-screen functions will be non-operational for a few seconds to avoid accidental touch of any keys.

Note

When a program is running and the screen saver is active, the message "In processing" is displayed on the screen.

4.8 Touchscreen functions

The HistoCore PEARL is operated via a touchscreen.

Status Bar

Fig. 28

On the status bar the following information is displayed.

- Current date (→ "Fig. 28-1"). To set the current date, see (→ P. 50 – 5.2.3 Date/Time) .
- Current time (→ "Fig. 28-2"). To set the current time, see (→ P. 50 – 5.2.3 Date/Time) .
- RemoteCare connection symbol (→ "Fig. 28-3").
- Active user level symbol, which have three levels, Standard user (default level) (→ "Fig. 28-4"), Service (→ "Fig. 28-5"), Supervisor (→ "Fig. 28-6"). To switch between the user levels, see Access levels (→ P. 47 – 5.1 Access levels).
- Error button (→ "Fig. 28-7"). For more information, see (→ P. 43 – Message boxes).
- Warning button (→ "Fig. 28-8"). For more information, see (→ P. 43 – Message boxes).
- Program running status (→ "Fig. 28-9").

Main window

The main window is displayed as a tabbed pane (→ "Fig. 29-1") with a working area (→ "Fig. 29-2").

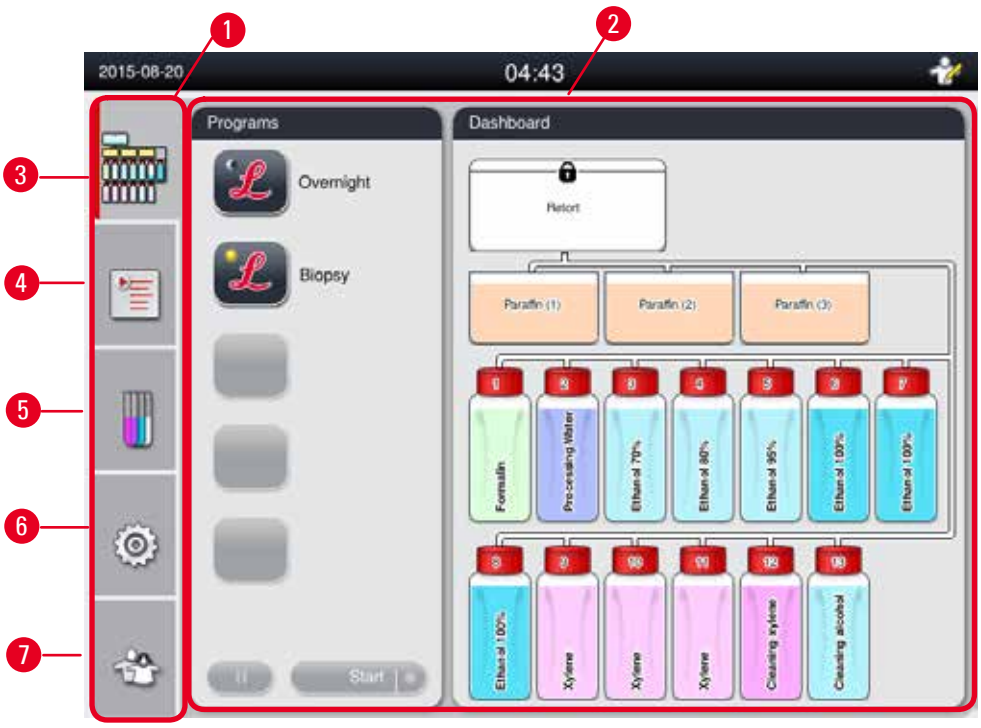


Fig. 29

The tabbed pane has five tabs, vertically stacked along the left side of the main window and correspond to a menu access bar.

- Dashboard (→ "Fig. 29-3") - select the program; view the status of reagents; start/pause/abort the program, and view the program running status.
- Programs (→ "Fig. 29-4") - view, edit and create new programs; select the favorite program.
- Reagents (→ "Fig. 29-5") - view the reagent groups; view, edit and create new reagents; view and edit reagents in the stations; view and edit reagent status in the status; view and change RMS modes.
- Settings (→ "Fig. 29-6") - edit user settings, manage data and access the service software.
- User (→ "Fig. 29-7") -switch the user mode and change the password.

For more information, see (→ P. 47 – 5. Operation).

Message boxes

The system delivers messages in three different severity levels.

- Information (→ "Fig. 30-1")
- Warning (→ "Fig. 30-2")
- Error (→ "Fig. 30-3")

Each message is displayed on the screen as shown below (→ "Fig. 30"). The message must be confirmed with OK, Yes, or No. If an error occurs, a warning or error symbol will appear in the status bar. Press the symbol and read the message carefully. Some of the messages can be cleared from the pop-up window, but they are still recorded and kept in the log files. For the messages that cannot be cleared, the warning or error symbol will remain present in the status bar until the error is resolved by a trained service engineer.

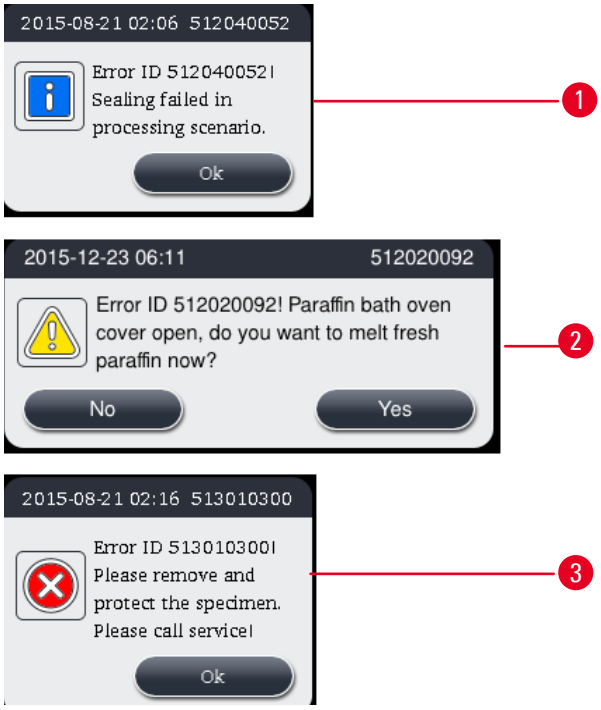


Fig. 30

Virtual keyboard

Fig. 31

The keyboard (→ "Fig. 31") is displayed any time text needs to be entered.

- The keyboard headline tells you what kind of text to enter.
- 30 characters can be entered into each entry field, however sometimes not all characters entered can be displayed.

Important keys

Keys	Description
ESC	Escape.
OK	Confirm.
⇧	Switch between upper/lower case letters.
#...@	Switch between letters/numbers and special characters.
◁	Jump over the previous character.
▷	Jump over the next character.
⌫	Delete the previous character.

Buttons

Fig. 32

The enabled button is highlighted (→ "Fig. 32-1"); the disabled button is grayed out (→ "Fig. 32-2").

Fig. 33

- Page up (→ "Fig. 33-1")
- Page down (→ "Fig. 33-2")
- To top line (→ "Fig. 33-3")
- To end line (→ "Fig. 33-4")

4.9 Switching off the instrument

If the instrument must be completely switched off or disconnected from the power supply, please follow these steps.

Fig. 34

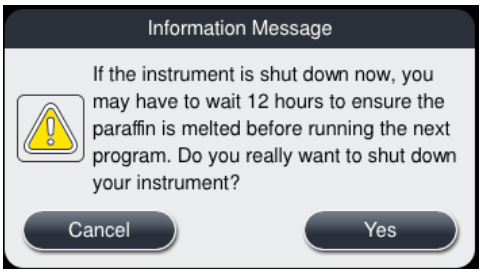
Switching off the instrument

Caution

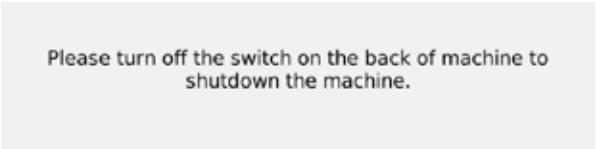
Do not switch off the instrument while a program is running.

ⓘ Only supervisor or service user level can access the shut down button.

1. Press the settings icon (→ "Fig. 34-1").
2. Press the icon of **Maintenance** (→ "Fig. 34-2").
3. Press **Shutdown** button (→ "Fig. 34-3"). The following message pops up. Please note that the waiting hours in the message is dependant on the settings of the paraffin melting point.



4. Press Yes.
5. When the following message appears, switch off the instrument with the ON/Off switch at the rear panel of the instrument.



Caution

The HistoCore PEARL is to be switched off completely in this way only. Otherwise, severe damage to the instrument's hardware and loss of data can occur.

Note

When the instrument is switched off by directly turning off the ON/OFF switch, the alarm will be triggered.

4.10 Moving the instrument

Caution

Before moving, switch off the instrument.

Before moving the instrument, the power cord must be disconnected from the power supply and the instrument is cooled down.

Before moving the instrument, make sure that no paraffin is in paraffin baths or the paraffin drip tray, and the paraffin oven cover is closed to protect paraffin baths from dropping during transportation. Or remove the paraffin baths from the instrument. The retort lid must be sealed as well.

To avoid dropping of the filled reagent bottles and damage to the reagent bottles or connectors, the reagent bottles must be empty or removed while moving.

Moving the instrument

1. Release the casters of the instrument.
2. Hold the handles at the rear panel and push the instrument to its new location.
3. Lock the casters after the instrument has reached the final position.

5. Operation

5.1 Access levels

The HistoCore PEARL has three access levels. The user level symbol (→ "Fig. 35-1") is displayed at the upper right corner of the touchscreen.

- Standard user (→ "Fig. 35-3") - The Standard user is the default user level when you log on the instrument. It does not require a password. The Standard user can work with limited funtions, such as running programs, viewing results, setting the status of reagents as empty or full, etc. The function buttons that can not be accessed by the Standard user are grayed out.
- Supervisor (→ "Fig. 35-4") - The Supervisor can perform all Standard user functions, and additionally create programs and perform the initial setting functions. The function buttons that can not be accessed by the Supervisor are grayed out.

Note

The system will be automatically switched from Supervisor back to Standard user if no operation is performed within 10 minutes.

- Service (→ "Fig. 35-5") - For service personnel only.

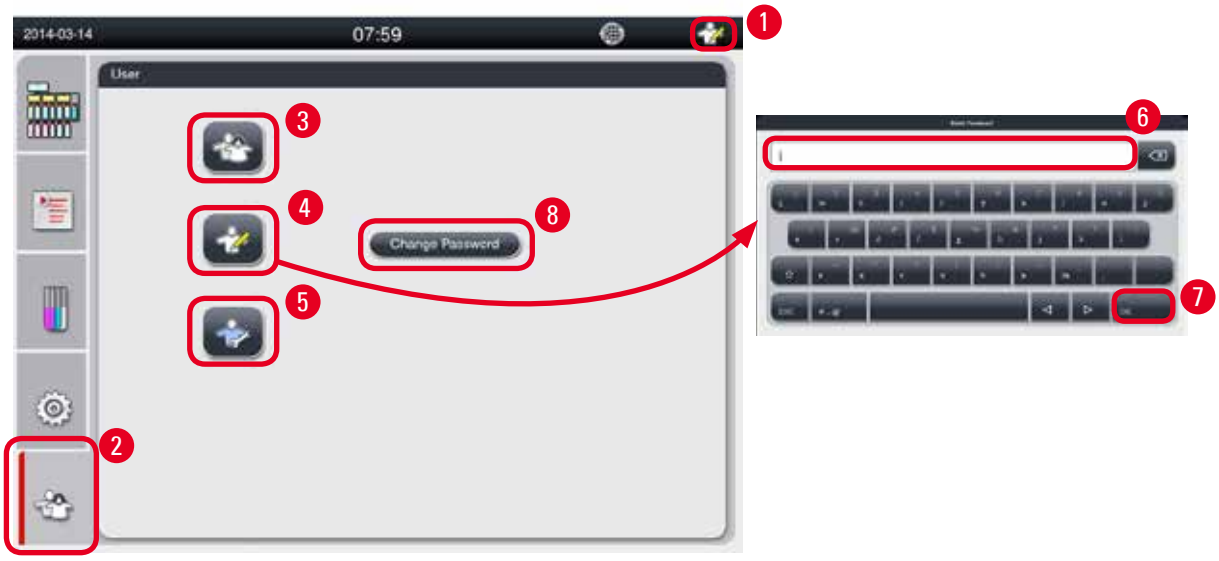


Fig. 35

Switching from Standard user to Supervisor

1. Press the icon of Standard user (→ "Fig. 35-2").
2. Press the icon of Supervisor (→ "Fig. 35-4") and the virtual keyboard appears.
3. Enter the default password, Histocore.
4. Press OK (→ "Fig. 35-7") and the Supervisor symbol appears in place of Standard user.

Changing password

Follow these steps to change the password of the Supervisor level.

1. Press Change Password (→ "Fig. 35-8"), and the virtual keyboard appears.
2. Enter current password and press OK.

3. Enter new password and press OK.
4. Enter the new password again to confirm, and press OK.
5. The password is changed.

Note

To reset the password in case it has been forgotten, contact your local service representative.

5.2 Setting up system

From the start screen, press the settings icon (→ "Fig. 29-6").
The settings menu has the following sub-menus: Languages, Regional Settings, Date/Time, Alarm, Installation, System Setup, Data Mgm., Maintenance, Event View and Network.

5.2.1 Languages

Fig. 36

Setting the Language

ⓘ Only Supervisor and Service user level can edit the system language.

1. Press the icon of Languages (→ "Fig. 36-1").
2. Select a language from the list (→ "Fig. 36-2").
3. Press Save (→ "Fig. 36-3").

5.2.2 Regional Settings

View and edit the temperature unit, the format of the date and the time.

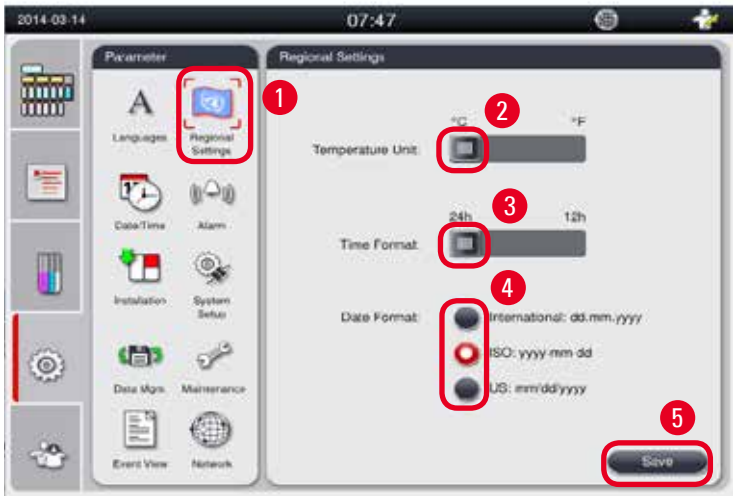


Fig. 37

Setting the Regional Settings

ⓘ Only Supervisor and Service user level can edit it.

1. Press the icon of **Regional Settings** (→ "Fig. 37-1").
2. Set the temperature unit, °C or °F, by pressing the two ends (→ "Fig. 37-2").
3. Set the time format, 24h or 12h, by pressing the two ends (→ "Fig. 37-3").
4. Toggle between the International format, ISO format or US format (→ "Fig. 37-4").
5. Press **Save** (→ "Fig. 37-5").

5.2.3 Date/Time

View and edit the date and the time.

Note

It is important to set the date and time correctly so that programs start and end at the correct time and on the correct day.

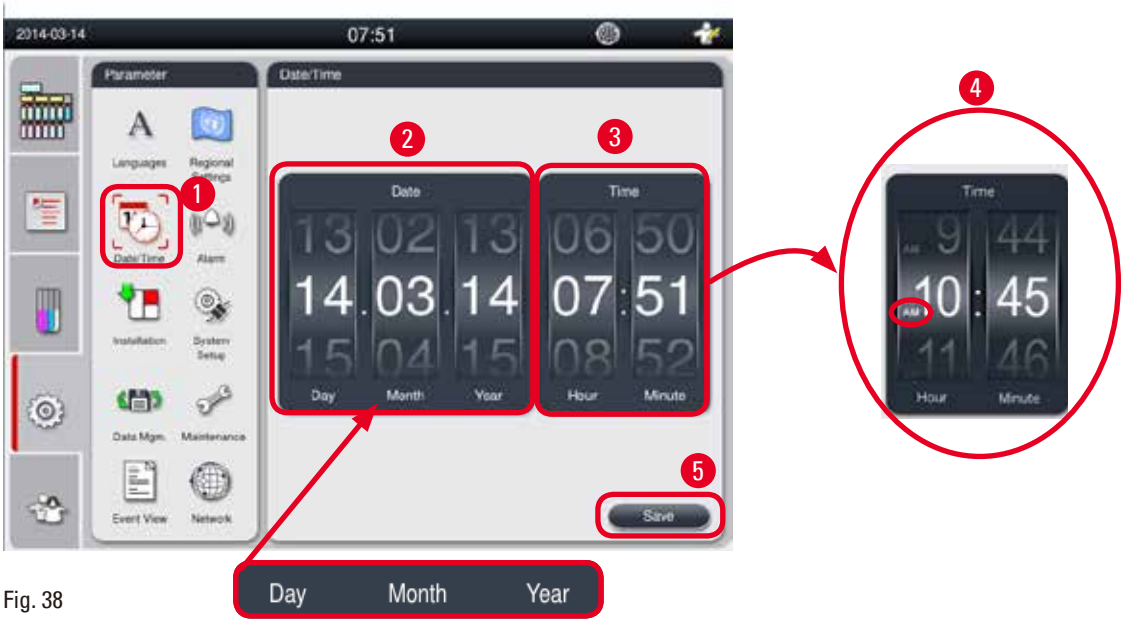


Fig. 38

Setting the Date/Time

ⓘ Only Supervisor and Service user level can edit it.

1. Press the icon of Date/Time (→ "Fig. 38-1").
2. Set the date by scrolling the wheels (→ "Fig. 38-2").

Note

The date sequence is Day-Month-Year.

3. Set the time by scrolling the wheels (→ "Fig. 38-3"). If the time format is set to 12h in the Regional Settings, the time scroll wheel uses AM and PM (→ "Fig. 38-4").

» The local time and date can only be changed to the value within 24h deviation from the current one.

4. Press Save (→ "Fig. 38-5").

5.2.4 Alarm

Set alarm sound for the Information, Warning and Error messages.

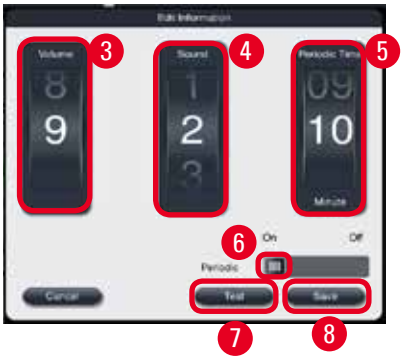


Fig. 39

Setting the Alarm

ⓘ Only Supervisor and Service user level can edit it.

1. To set the alarm for the Information, press the icon of **Alarm** (→ "Fig. 39-1").
2. Press Edit (→ "Fig. 39-2").
3. Set the volume (→ "Fig. 39-3") from weak to strong, ranging from 0-9. If it is set to 0, the alarm is muted.
4. Select one type of the sound from six sounds provided (→ "Fig. 39-4").
5. Set the periodic time (→ "Fig. 39-5"), ranging from 0-10 minutes. For example, if it is set to 5 minutes, the alarm rings one time per 5 minutes. If the periodic time is set to 0, the alarm rings continuously. The periodic time can be set to On or Off by using the slider (→ "Fig. 39-6"). If it is set to Off, the periodic time is disabled.
6. Press **Test** (→ "Fig. 39-7") to play the select sound at the selected volume for 1 cycle.
7. Press **Save** (→ "Fig. 39-8").
8. To set the alarm for the Warning, repeat from steps 2 to 7.
9. To set the alarm for the Error, repeat steps 2, 3, 4, 6 and 7. Please noted that the volume range for Error is 2-9, and the periodic time is not changeable.

5.2.5 Installation

View the Instrument name, Serial number and Software version.

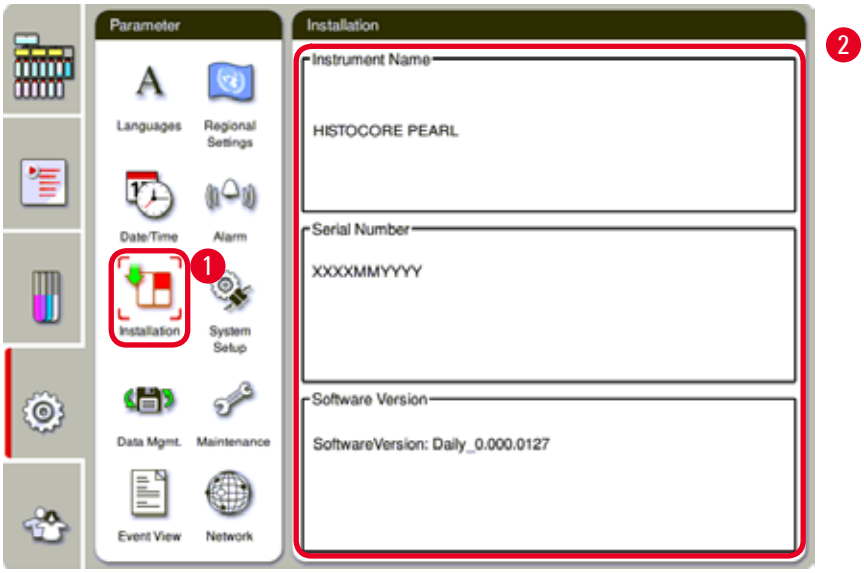


Fig. 40

Viewing the Installation

» Press the icon of **Installation** (→ "Fig. 40-1"), and the Instrument name, Serial number and Software version are displayed on the right (→ "Fig. 40-2").

5.2.6 System Setup

Setting the paraffin bath temperature

Fig. 41

Setting the paraffin bath temperature

ⓘ Only Supervisor and Service user level can edit it.

1. Press the icon of System Setup (→ "Fig. 41-1").
2. Set the paraffin bath temperature, ranging from 50°C - 70°C in 1°C increments (→ "Fig. 41-2"). The temperature unit and range is dependant on the settings in Regional Settings (→ P. 48 – 5.2.2 Regional Settings).
3. Press Save (→ "Fig. 41-4").

Note

It is recommended to set the paraffin baths temperature 2 °C higher than the maximum paraffin melting point provided in the paraffin manufacturer's specification. Otherwise, the paraffin that is not completely melted may cause a blockage in the air/liquid system.

If the paraffin baths temperature is set to above 64 °C, the melting time will take longer, approximately 15 hours.

If the paraffin bath temperature is set from a higher value to a lower value, an error code pops up. When it occurs, restart the instrument using the On/Off button on the back panel. If any error appears after the restart, please retry after several minutes. If the problem persists, call your local service representative.

Bottle Check function

The Bottle Check function checks the following:
- The connections between the reagent bottles and the instrument for leaks and blockages;
- Whether the reagent bottles are filled or insufficient.

To start the Bottle Check function, press the **Bottle Check** button (→ "Fig. 41-3").
Follow the instructions on the pop-up messages. If the Bottle Check is completed successful, the instrument is ready to start a program. If the Bottle Check fails, follow the instructions on the pop-up messages. If the Bottle check is interrupted, for example by the power failure, restart the Bottle Check when the power is restored.

5.2.7 Data management

Note

The instrument only supports the USB disk with FAT32 format.

User export

Fig. 42

With this function, the data relating to the instrument can be transferred to a USB disk.
The following data is saved.
- Customized programs, information of reagents status, group, station, and RMS. These information will be compressed to "HISTOCOREPEARL_User_(SerialNumber)_(Time).lpkg". The ".lpkg" file can not be viewed by the user, but can be used for service to do troubleshooting or diagnosis.
- Event reports. These information will be compressed to "HISTOCOREPEARL_User_(SerialNumber)_(Time).zip". The ".zip" file can be viewed by the user.

User export

ⓘ Make sure that no program is running.

1. Insert a USB disk in one of the USB ports on the instrument and press the icon of **Data Mgm.** (→ "Fig. 42-1").
2. Press **User Export** (→ "Fig. 42-2") .
3. A display on the screen shows that data is currently being copied while the files are being transferred. When all data has been successfully transferred, a completion message appears.

Note

If the exporting fails, restart the exporting.

Service export

With this function, configuration files and all log files can be exported to a USB disk. These files will enable your responsible service organization to evaluate and resolve potential instrument issues. In case of errors, you might be requested to remotely provide these exported files to your service engineer or customer support.

Service export

ⓘ Make sure that no program is running.

1. Insert a USB disk in one of the USB ports on the instrument and press the icon of **Data Mgm.** (→ "Fig. 42-1").
2. Press **Service Export** (→ "Fig. 42-3").
3. A display on the screen shows that data is currently being copied while the files are being transferred. When all data has been successfully transferred, a completion message appears.

Import

With this function, the file of "HISTOCOREPEARL_User_(SerialNumber)_(Time).lpkg" can be imported from a USB disk to the instrument.
From the ".lpkg" file, the following information is imported- the customized programs, information of reagents group and station.

Importing data from a USB

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can perform this.

1. Insert a USB disk in one of the USB ports on the instrument and press the icon of **Data Mgm.** (→ "Fig. 42-1").
2. Press **Import** (→ "Fig. 42-4").

3. Select the file that is to import. A display on the screen shows that data is currently being copied while the files are being transferred. When all data has been successfully transferred, a completion message appears.

Update software

Updating software

ⓘ Only Supervisor and Service user levels can perform this whilst there is not a program currently running.

1. Insert a USB disk with the according SW update data in one of the USB ports on the instrument, or connect the instrument to the RemoteCare server, and press the icon of **Data Mgm.** (→ "Fig. 42-1").
2. Press **SW Update** (→ "Fig. 42-5"). Or press **Remote SW Update** (→ "Fig. 42-6") after the RemoteCare server is connected and the button is activated.
3. A display on the screen shows that data is currently being copied while the files are being transferred. When all data has been successfully transferred, a completion message appears.

Note

If power failure occurs when updating the master software, restart the instrument. When the power restores, check whether the software update has completed successfully or not.

If the software update is successful, a message box pops up to indicate the update has been successful once the master software has restarted.

If the software update fails, there will not be a message box appear when the master software restarts. Please restart the software update to finish updating the software.

5.2.8 Maintenance

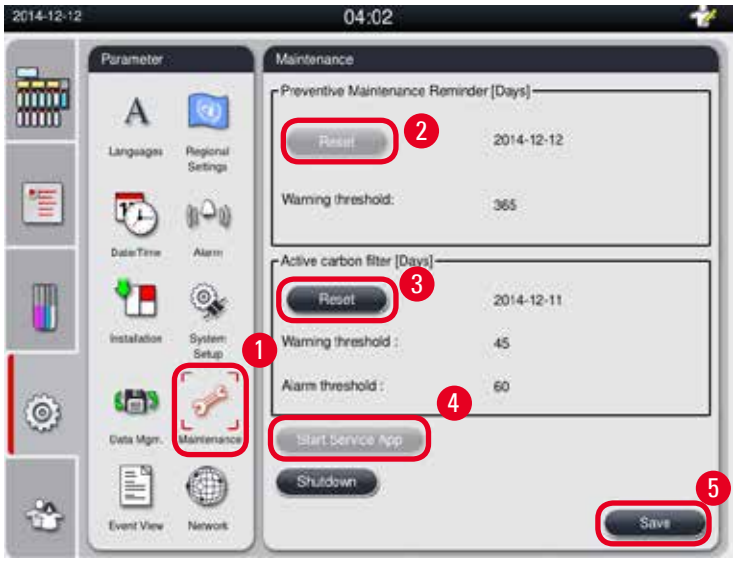


Fig. 43

Preventive maintenance reminder

The instrument calculates the operation time , including the idle time. When the time exceeds the warning threshold, the warning symbol presents in the status bar, and a warning message pops up on the screen, reminding you to contact your service provider to perform a preventive maintenance.

It can only be reset by the Service User by pressing the **Reset** button (→ "Fig. 43-2").

Caution

Only qualified service personnel authorized by Leica Biosystems can do the yearly preventive maintenance.

Active carbon filter

The instrument calculates the time of the active carbon filter in use. When the time exceeds the default warning threshold, a warning pops up, reminding you to replace a new active carbon filter. When the time exceeds the default alarm threshold, the alarm rings with a warning message.

Reset the active carbon filter

ⓘ The default warning threshold is 45 days. The default alarm threshold is 60 days. Validate your actual threshold before use.

ⓘ Only Supervisor and Service user level can perform this.

1. Press **Maintenance** (→ "Fig. 43-1").
2. Press **Reset** (→ "Fig. 43-3").
3. Press **Save** (→ "Fig. 43-5").

Start Service App

The **Start Service App** button (→ "Fig. 43-4") is for Service User only .

5.2.9 Event view

View daily run log file.

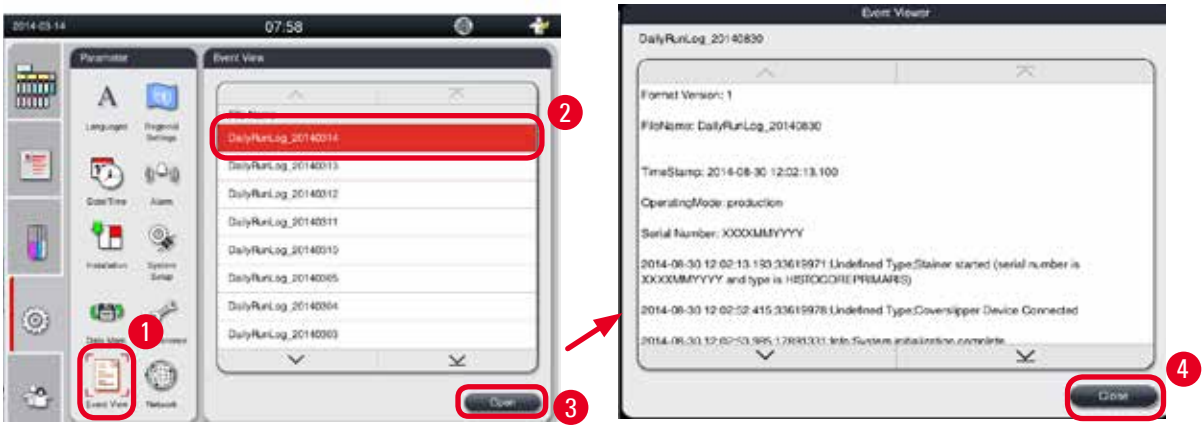


Fig. 44

Viewing log file

1. Press **Event View** (→ "Fig. 44-1").
2. Select a log file you want to view (→ "Fig. 44-2").
3. Press **Open** (→ "Fig. 44-3"), and the Event Viewer window pops up.
4. Press **Close** (→ "Fig. 44-4") to close the Event Viewer window.

5.2.10 Network

View and edit remote care parameters.

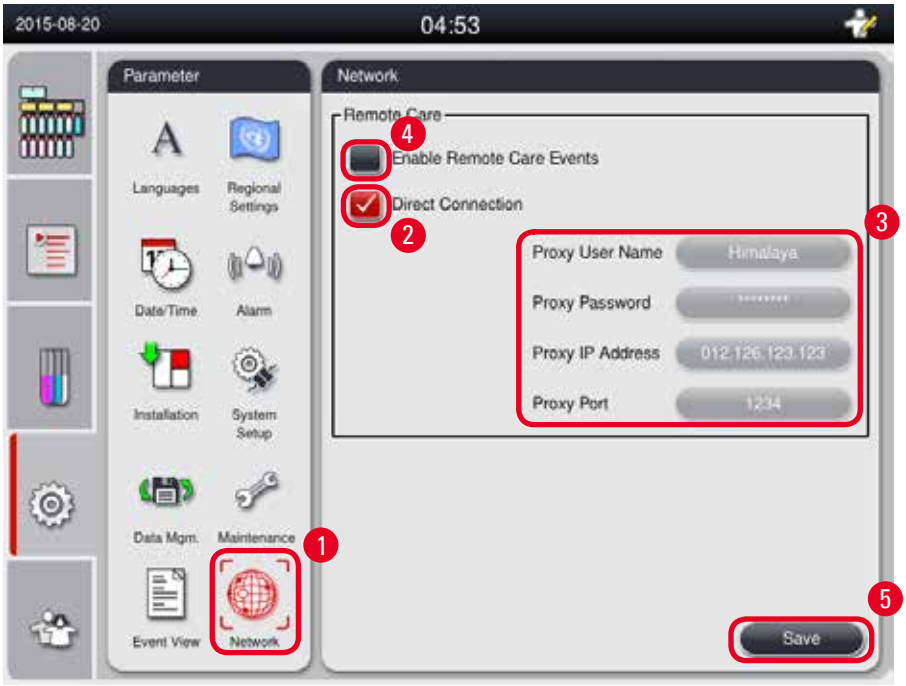


Fig. 45

- Checkbox “Enable RemoteCare Events”(→ "Fig. 45-4"): The check box “Enable RemoteCare Events” only affects instrument events sent to the RemoteCare server. If checked, the instrument will actively send events to the server. If not checked, it will not send any events. This is the standard setting. The RemoteCare server can remotely request events or (with permission of the customer) trigger software updates no matter if box is checked or not.
- Checkbox “Direct Connection” (→ "Fig. 45-2"): The check box “Direct Connection” determines whether a direct connection to the Leica RemoteCare service or to a “proxy server” shall be used. If the instrument shall connect the RemoteCare server directly, please check the “Direct Connection” check box. If selected, the proxy settings underneath it will be greyed out. This is the standard connection method. If a proxy server shall be used, uncheck the “Direct Connection” checkbox and set the proxy parameters (Proxy User Name, Proxy Password, ProxyIP Address and Proxy Port).

Editing Remote Care parameters

ⓘ Only Supervisor and Service user level can edit Remote Care parameters whilst there is not a program running.

ⓘ Make sure that the instrument is connected to the network.

1. Press **Network** (→ "Fig. 45-1").
2. Uncheck **Direct Connection** (→ "Fig. 45-2"), and the proxy parameters fields are enabled (→ "Fig. 45-3").
3. Edit the parameters.
4. Check **Enable Remote Care Events** (→ "Fig. 45-4").
5. Press **Save** (→ "Fig. 45-5").

5.3 Reagents

5.3.1 Reagent status

This window is to display the current reagent status of the stations. Reagent stations can be marked as full or empty here.
The following is displayed.

- **Station** - 1-13 bottles, 3 paraffin baths
- **Reagent**
- **Exchange date**
- **Status** - Full/Empty
- One of the following columns based on the RMS mode settings

-- **Cassettes since change** - Cassettes processed since last change. It is displayed if the RMS mode is set to be Cassettes.
-- **Cycles since change** - Cycles processed since last change. It is displayed if the RMS mode is set to be Cycles.

Note

For the Cleaning reagent, the cycle number is recorded as 1 cycle after the whole Cleaning program is completed.

-- **Exchange date** - Days since last change. It is displayed if the RMS mode is set to be Days.
-- **Expiry Date**. It is displayed if the RMS mode is set to be Days.

-- No column is displayed if the RMS mode is set to be Off.
When the reagents are expired, the texts in the fields are highlighted with red.

Fig. 46

Note

After filling a bottle manually the bottle must be defined as Full.

Editing reagent status

ⓘ Make sure that no program is running.

1. Press Status (→ "Fig. 46-1").
2. Select a reagent. The selected row is highlighted with red (→ "Fig. 46-2").
3. Press Set as Empty (→ "Fig. 46-3"), or Set as Full (→ "Fig. 46-4"), or Reset Data (→ "Fig. 46-5") as needed.
4. A message pops up, asking if you want to run a Bottle Check or not. When editing the paraffin status, no messages will pop up.

Note

If the instrument is in heating, the Bottle Check function is disabled for about 30 minutes.

5. The reagent status is updated both in this window and on the Dashboard.

5.3.2 Groups

In the Groups window you can select the colors to be used for each reagent group in the program display.
8 reagent groups are displayed:

- 6 Processing reagent groups: Fixation; Water; Dehydration, diluted; Dehydration, absolute; Clearing; Paraffin;
- 2 Cleaning reagent groups: Cleaning solvent; Cleaning ethanol.

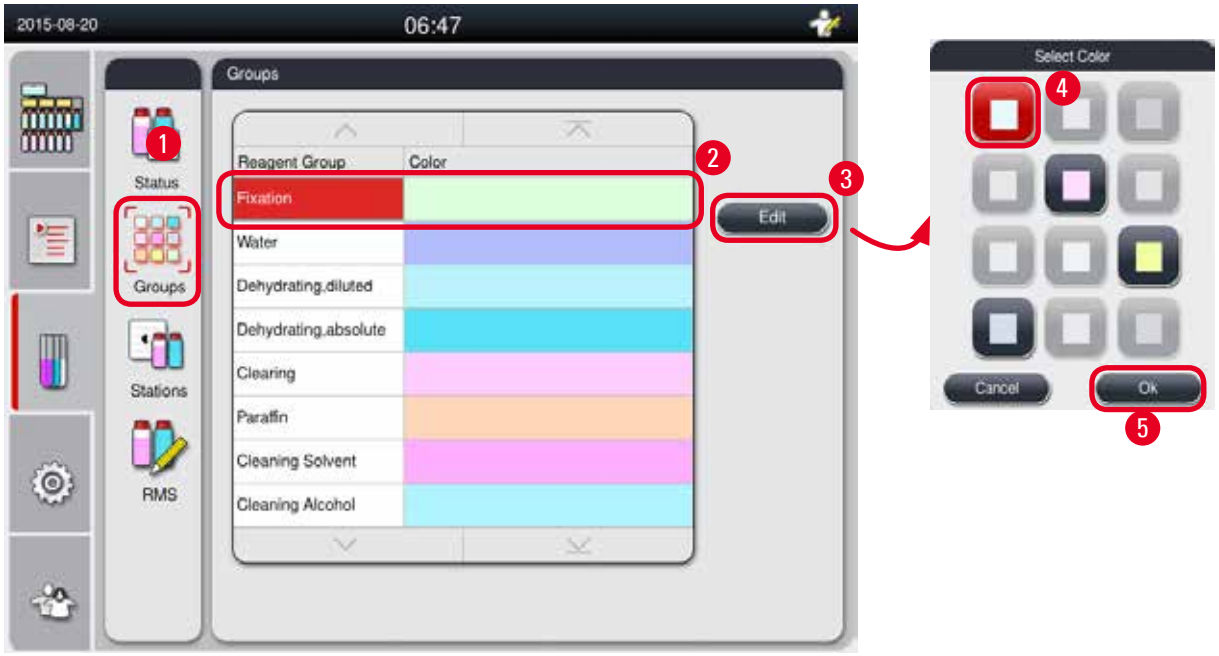


Fig. 47

Editing the color of a reagent group

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can edit the color.

1. Press Groups (→ "Fig. 47-1").
2. Select the group in the table (→ "Fig. 47-2").
3. Press Edit (→ "Fig. 47-3"), and the color palette pops up. The system provides 12 predefined colors.
4. Select a color (→ "Fig. 47-4").
5. Press OK (→ "Fig. 47-5").

✓ The new color will be used on all stations to represent the reagent.

5.3.3 Stations

This window shows a list of all stations with the allocated reagents defined in the instrument.

Allocation of the reagents

- Stations 1 – 11 can only be assigned to specimen processing reagents (other than paraffin).
- Station 12 can only be assigned to a cleaning solvent.
- Station 13 can only be assigned to a cleaning ethanol.
- Station 14 is the condensate bottle.

- Paraffin baths can only be used for paraffin.

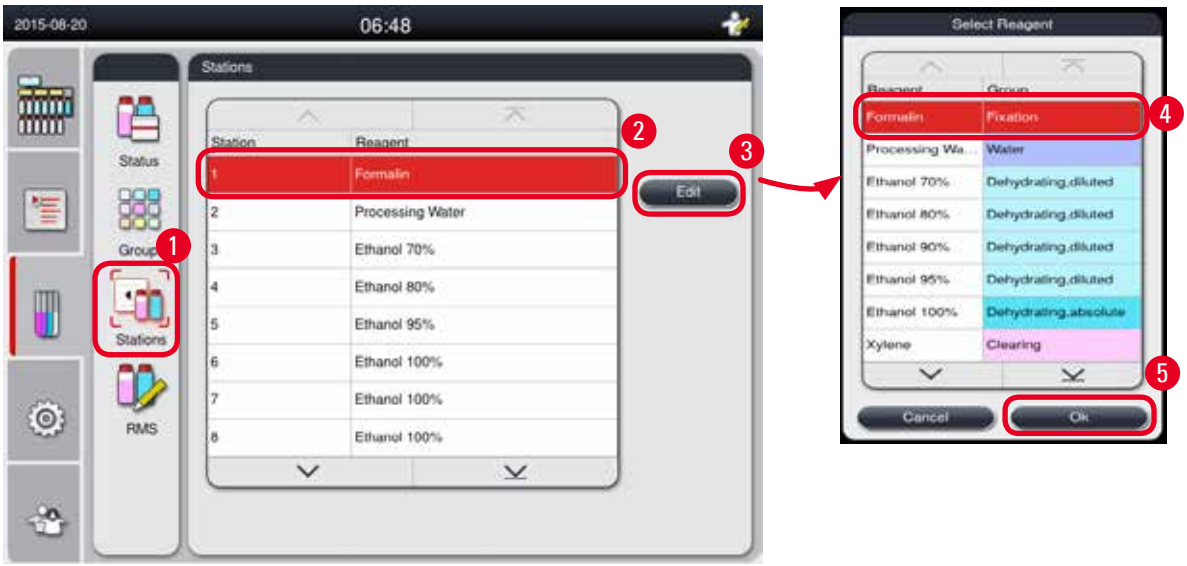


Fig. 48

Editing the stations

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can edit the stations.

1. Press Stations (→ "Fig. 48-1").
2. Select a station in the table (→ "Fig. 48-2").
3. Press Edit (→ "Fig. 48-3"), and the reagent list pops up.
4. Select a reagent (→ "Fig. 48-4"). To remove the reagent from a station, select None.
5. Press OK (→ "Fig. 48-5").

5.3.4 RMS

The HistoCore PEARL has a Reagent Management System (RMS) that ensures optimized reagent consumption and the best possible tissue processing results. The Reagent Management System is controlled via warning threshold values that display the reagent replacement. For each reagent, a value of this type can be defined depending on the use.

RMS mode

The RMS is divided into 2 groups, Processing Reagents and Cleaning Reagents.
For Processing Reagents, the following 4 modes are available.
- Off- The RMS mode of the processing reagents turns off.
- Cassettes - Number of processed cassettes
- Cycles - Number of cycles (1 processed program = 1 cycle)
- Days - Days until changing the reagent

For Cleaning Reagents, the following 3 modes are available.
- Off- The RMS mode of the cleaning reagents turns off.

- Cycles - Number of cycles (1 processed program = 1 cycle)
- Days - Days until changing the reagent

The RMS is enabled by entering warning threshold values for one of these parameters specified above and is displayed in the reagents Status.

Note

If the RMS is set to be Off, the reagent consumption status can not be monitored, which may impact the tissue processing quality. The pre-installed programs can not run, either.

Note

If additional cassettes were added to the retort during processing and the quantity is beyond the RMS threshold, the program would continue and a reminder message would appear on the screen at the end of the program.

Reagent warning messages

If the RMS is enabled, the following indicates that the warning threshold values have been exceeded.

- The exceeded bottle turns to red and blinks. The operator is notified that the reagent has exceeded and can replace this reagent before the program starts. However it is possible to start the program if logged in at Supervisor level. Always replace the reagents when the threshold is reached.
- The exceeded bottle turns to red and flashes at the end of a program (after the cleaning). You can go directly to the reagent Status window.
- The reagent status highlights the exceeded values in red in the table.

Caution

Longer than the recommended use of cleaning reagents can cause paraffin blockage in reagent tubes.

Changing the threshold value to more than recommonded, may impact the tissue processing quality.

Threshold Value

Reagent	ReagentGroup	Cassette	Cycle	Day
Formalin	Fixation	600	/	/
Processing water	Water	600	/	/
Diluted ethanol	Dehydrating, diluted	1000	/	/
Absolute ethanol	Dehydrating, absolute	1000	/	/
Xylene	Clearing	1000	/	/
Paraffin	Paraffin	1000	/	/
Cleaning xylene	Cleaning solvent	/	5	/
Cleaning ethanol	Cleaning ethanol	/	5	/

Setting the RMS

Fig. 49

Editing the RMS

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can edit the RMS.

1. Press **RMS** (→ "Fig. 49-1").
2. Select a reagent (→ "Fig. 49-2").
3. Select a RMS mode (→ "Fig. 49-3") .

Note

The above figure (→ "Fig. 49") is provided as an example only and shows steps of how to edit the RMS of a processing reagent. To edit the RMS of a cleaning reagent, select a RMS mode in the cleaning reagent setting area.

4. Press **Edit** (→ "Fig. 49-4"), and the **Edit Reagent** window pops up.
5. To change the reagent name, press the reagent name button (→ "Fig. 49-5"). To change the warning threshold value, press the button (→ "Fig. 49-6").
6. Press **OK** (→ "Fig. 49-7").

✓ The warning threshold value on the **Status** window is updated.

Adding a new reagent

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can edit the RMS.

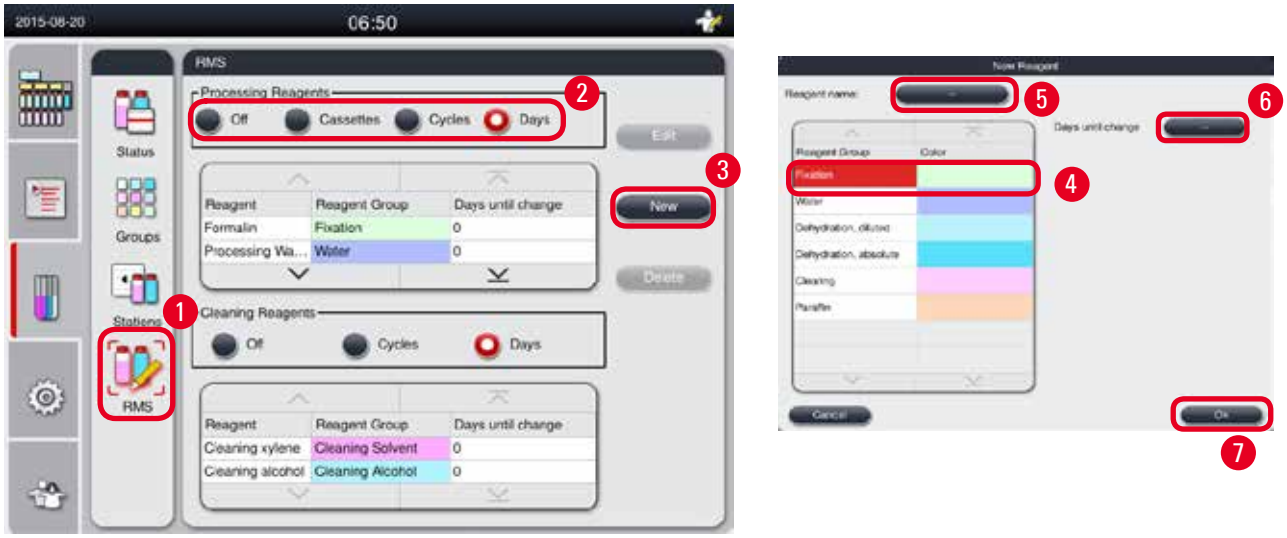


Fig. 50

1. Press **RMS** (→ "Fig. 50-1").
2. Select a RMS mode (→ "Fig. 50-2") .

Note

The above figure (→ "Fig. 50") is provided as an example only and shows steps of how to add a processing reagent. To add a cleaning reagent, select a RMS mode in the cleaning reagent setting area.

3. Press **New** (→ "Fig. 50-3"), and the **New Reagent** window pops up.
4. Select a reagent group (→ "Fig. 50-4").
5. Enter a name for the new reagent (→ "Fig. 50-5"). Enter the warning threshold value (→ "Fig. 50-6"). Please refer to the warning threshold value (→ P. 63 – Threshold Value) , otherwise the tissue processing quality may be impacted.
6. Press **OK** (→ "Fig. 50-7").

✓ The new reagent is displayed on the **Status** window.

Deleting a reagent

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can edit the RMS.

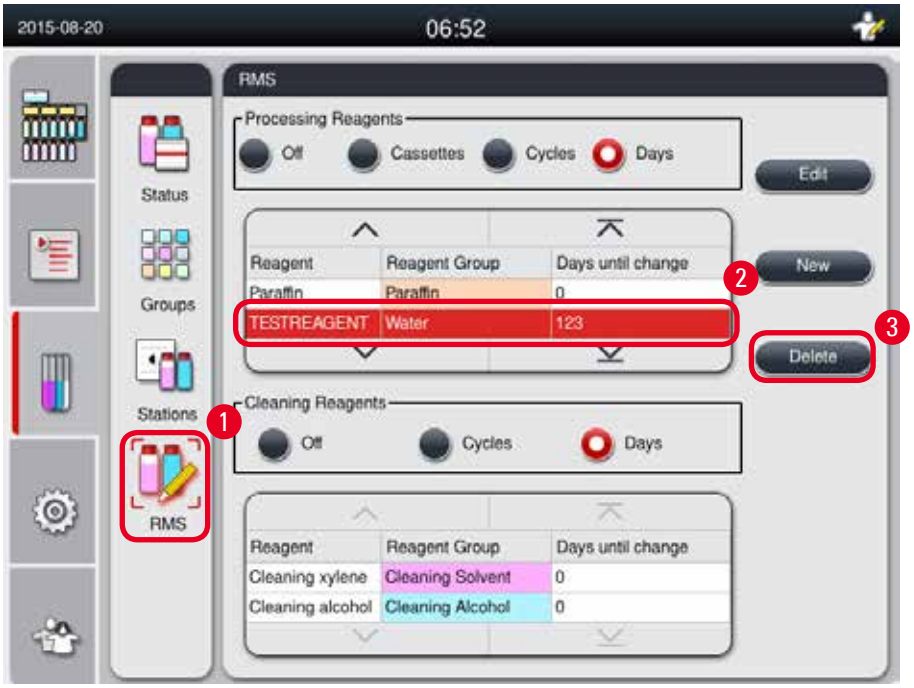


Fig. 51

1. Press **RMS** (→ "Fig. 51-1").
2. Select the reagent that you want to delete (→ "Fig. 51-2").
3. Press **Delete** (→ "Fig. 51-3"). A confirmation message box pops up.
4. Press **Yes**.

5.4 Program

The Program list shows all programs defined in the HistoCore PEARL.
These programs include
- 1 Cleaning program
- 2 pre-installed programs, Overnight and Biopsy
- Up to 10 customized programs created by users at the Supervisor level.

At the Standard user level or when a program is running, the menu Program is in view mode.
At the Supervisor or Service level, and if no program is running, the menu Program is in edit mode.
The customized programs can be added, deleted or edited by Supervisor.

Note

HistoCore PEARL is normally used in sequential mode, which means that the instrument uses one bottle after the other.

Note

The pre-installed processing programs and Cleaning program are preset and listed on the top of the user programs. They cannot be renamed, edited or deleted.

The pre-installed programs can be copied. The copied program is renamed automatically. For more information, see below section (→ P. 67 – Creating a new program).

5.4.1 Adding/Editing programs

Caution

All customized processing programs and RMS (Reagent Management System) have to be validated by the user before running the program, i.e. tissue processing with patient tissue for diagnostics, according to the local or regional accreditation requirements.

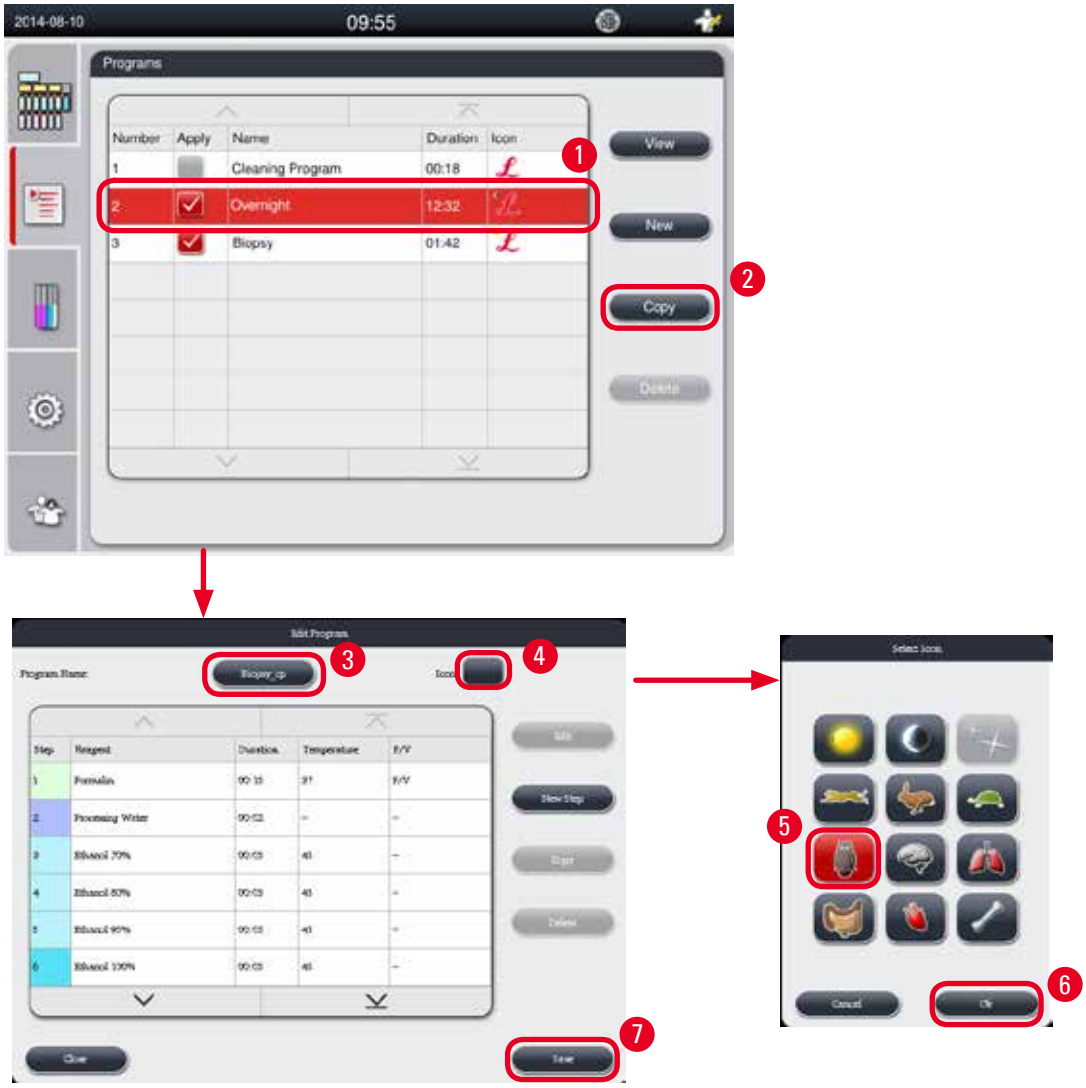


Fig. 52

Creating a new program

ⓘ Make sure that no program is running.

ⓘ Make sure that the number of programs is less than 10.

ⓘ Only Supervisor and Service user level can create/edit/delete customized programs.

1. In the Program window (→ "Fig. 52") , select a program (→ "Fig. 52-1") as similar as possible to the program you wish to create. (This minimizes the number of editing steps).

2. Press **Copy** (→ "Fig. 52-2") to copy the selected program. The **Edit Program** window pops up. The new program will have the same name as the program copied, however, the suffix "_cp" will be added to indicate the change. For example, if the "Biopsy" is copied, the new program is named as "Biopsy_cp".

Note

The word "Leica" (not case sensitive) is not allowed to appear in a user program name.

3. Press the program name (→ "Fig. 52-3") if you want to change the name. The virtual keyboard pops up. Enter a new name and press **OK**.

Note

The program name can not exceed 20 characters and can not consist of all spaces.

4. Press the icon button (→ "Fig. 52-4"). The **Select Icon** window pops up.
5. Select an icon (→ "Fig. 52-5").
6. Press **OK** (→ "Fig. 52-6").
7. Check the steps of the program. If no change is to be made, press **Save** (→ "Fig. 52-7") and the new program is displayed at the end of current program list. If changes are to be made to program steps, go on with steps in Editing program steps.

Editing a program step

The program steps are displayed in the order in which they are carried out. For each program, up to 14 steps can be defined.
The reagents of adjacent steps must be compatible. See below figure (→ "Fig. 53").

Processing Program

Current Step	Previous Step						
Compatible	None(clean retort)	Fixation	Water	Dehydration, diluted	Dehydration, absolute	Clearing	Paraffin
Fixation	✓	✓	x	x	x	x	x
Water	✓	✓	✓	x	x	x	x
Dehydration, diluted	✓	x	✓	✓	x	x	x
Dehydration, absolute	✓	x	✓	✓	✓	x	x
Clearing	✓	x	x	x	✓	✓	x
Paraffin	✓	x	x	x	x	✓	✓

Cleaning Program

Cleaning Program	Retort Residue						
Run the following cleaning step in this sequence	None(clean retort)	Fixation	Water	Dehydration, diluted	Dehydration, absolute	Clearing	Paraffin
Cleaning Solvent	x	x	x	x	x	x	✓
Cleaning Alcohol	x	x	x	x	x	✓	✓
Dry Step	x	x	x	x	x	✓	✓

Fig. 53

The following characteristics of each program step can be edited:
- Duration of step.
- Reagent temperature .
- Pressure/Vacuum type (Pressure, Vacuum, Pressure/Vacuum, Ambient).

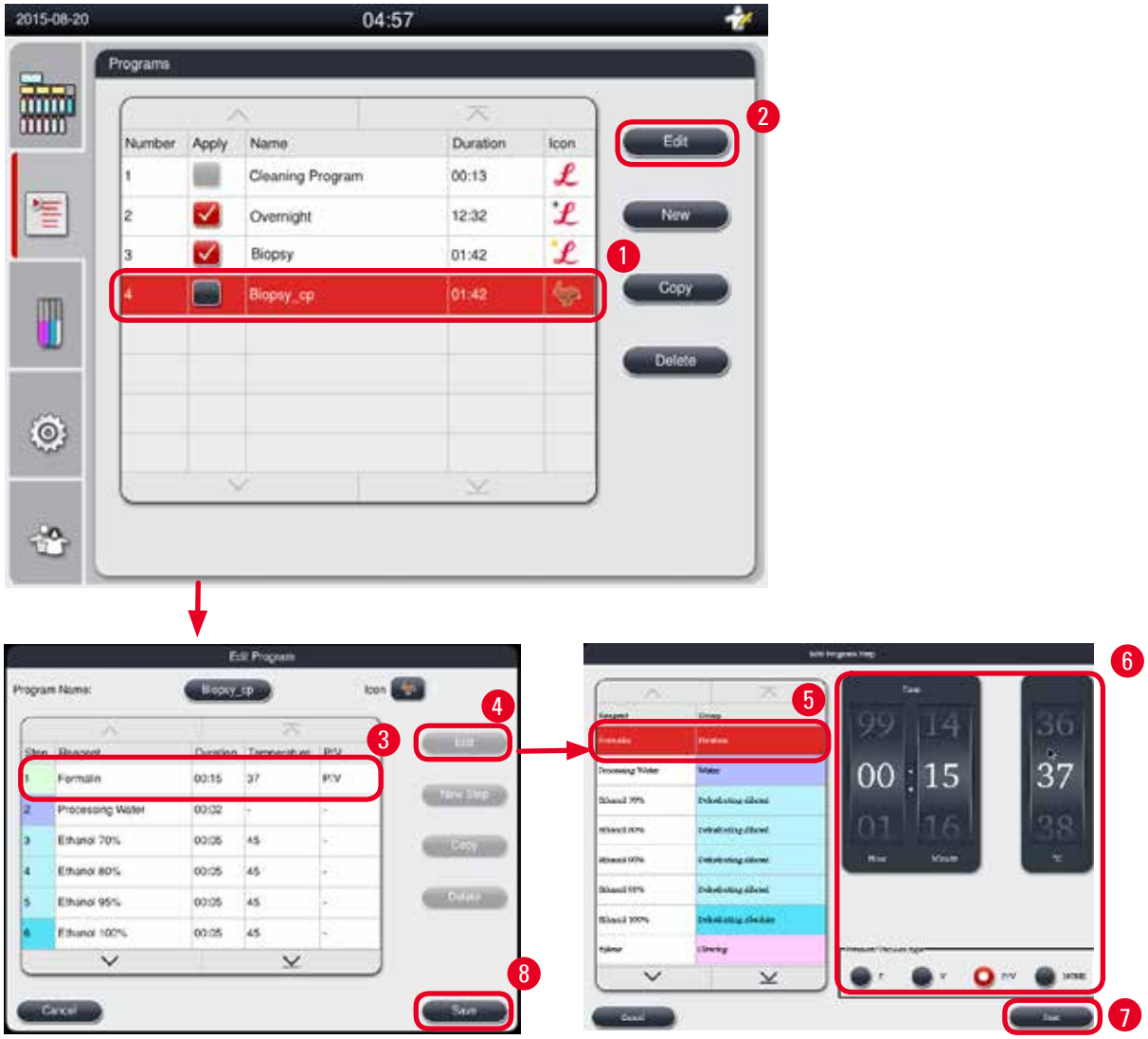


Fig. 54

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can create/edit/delete a program step.

1. Select the program that is to be changed (→ "Fig. 54-1") and press **Edit** (→ "Fig. 54-2"). The **Edit Program** window pops up.
2. Select the step that is to be changed (→ "Fig. 54-3") and press **Edit** (→ "Fig. 54-4"). The **Edit Program Step** window pops up.
3. Make sure that the step which is to be changed is selected (→ "Fig. 54-5"). Set the duration of the time, the temperature and the Pressure/Vacuum type (→ "Fig. 54-6").

Note

To change the temperature unit, see Regional Settings (→ P. 48 – 5.2.2 Regional Settings).

4. Press **Save** on the **Edit Program Step** window (→ "Fig. 54-7").
5. To continue to edit other steps, repeat from Step 2 to Step 4. Otherwise, go to Step 6.

6. Press Save on the Edit Program window (→ "Fig. 54-8").

Adding a new program step

ⓘ Make sure that no program is running.

ⓘ Make sure that the program has less than 14 steps.

ⓘ Only Supervisor and Service user level can create/edit/delete a new program.

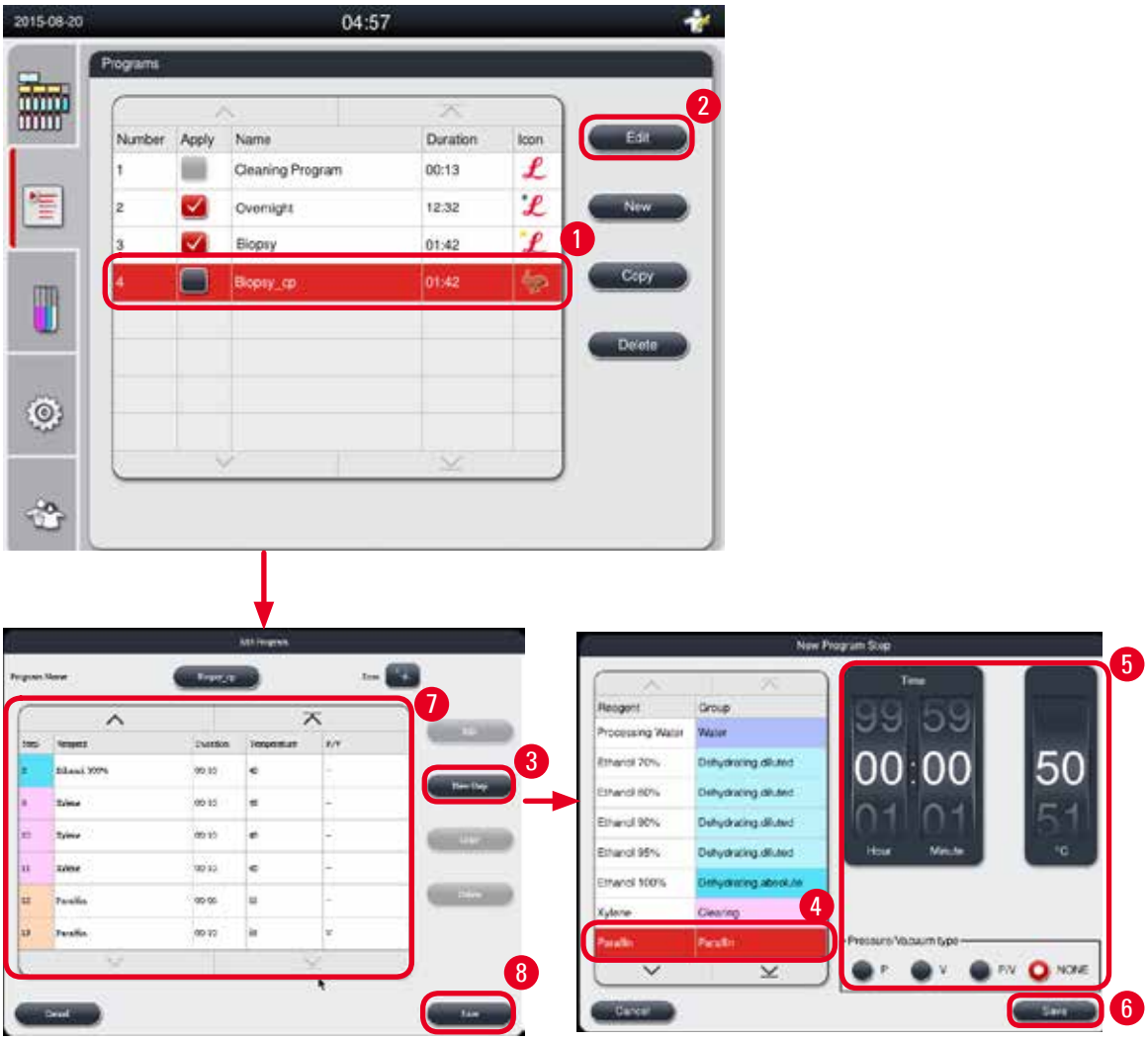


Fig. 55

1. Select the program that is to be changed (→ "Fig. 55-1") and press Edit (→ "Fig. 55-2"). The Edit Program window pops up.
2. Press New Step (→ "Fig. 55-3"). The New Program Step window pops up.

3. Select a reagent (→ "Fig. 55-4"). Set the duration of the time, the temperature and the cycle type (→ "Fig. 55-5").

Note

The tissue quality would be deteriorated by prolonged soaking time in ethanol.

4. Press **Save** on the **New Program Step** window (→ "Fig. 55-6"), and the new step is displayed in the list on the **Edit Program** window (→ "Fig. 55-7").
5. To continue to add more steps, repeat from Step 2 to Step 4. Otherwise, go to Step 6.
6. Press **Save** on the **Edit Program** window (→ "Fig. 55-8").

Deleting a program step

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can create/edit/delete a new program.

Fig. 56

1. Select the program that is to be changed (→ "Fig. 56-1") and press **Edit** (→ "Fig. 56-2"). The **Edit Program** window pops up.
2. Select the step (→ "Fig. 56-3") that you want to delete, and press **Delete** (→ "Fig. 56-4"). The confirmation message box pops up.
3. After you confirm deleting the step, press **Save** (→ "Fig. 56-5").

Deleting a program

ⓘ Make sure that no program is running.

ⓘ Only Supervisor and Service user level can create/edit/delete a new program.

Fig. 57

1. Select the program that is to be deleted (→ "Fig. 57-1") and press **Delete** (→ "Fig. 57-2"). The confirmation message box pops up.
2. Press "Yes" to delete the selected program.

5.4.2 Favorite programs

Favorite programs are displayed on the Program List Panel on the dashboard. Up to 5 programs can be selected as favorite programs.

Setting a favorite program

ⓘ Only Supervisor and Service user level can set a program as a favorite program.

Fig. 58

To set a program as a favorite program, check the box before the program name (→ "Fig. 58-1").

5.5 Dashboard

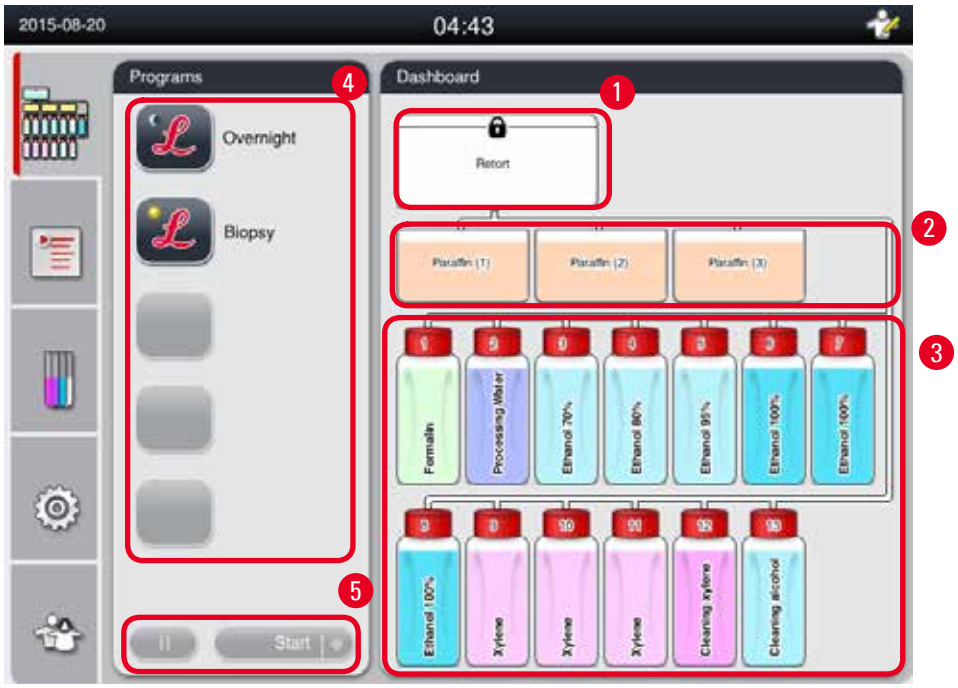


Fig. 59

On the dashboard displays the retort status (→ "Fig. 59-1"), paraffin baths status (→ "Fig. 59-2"), reagents status (→ "Fig. 59-3"), a list of favorite programs (→ "Fig. 59-4") and program running status, buttons of start/pause/abort (→ "Fig. 59-5"), and shows the seal/unseal status of retort lid.

Retort status

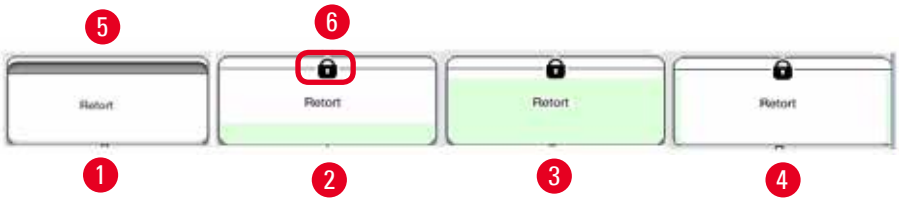


Fig. 60

The retort is filled with the reagent group color that the reagent in the retort belongs to.
The retort has the following status:

- Empty (→ "Fig. 60-1") - The retort is empty and clean.
- Partially filled (→ "Fig. 60-2") - The retort is sucking/draining a reagent.
- Full (→ "Fig. 60-3") - The retort is full.
- "U" form filled (→ "Fig. 60-4") - The retort is empty, but contaminated by a previous reagent.
- Unsealed (→ "Fig. 60-5")/Sealed (→ "Fig. 60-6")

A filling animation is displayed when the retort is filling/draining reagents. The retort filling grows from empty to full during sucking; the retort filling decreases from full to empty during draining.

Caution

Do not open the retort when the program is running. It may damage the specimens.

Paraffin baths status

Fig. 61

The paraffin baths are filled with paraffin group color, and named with Paraffin (1), Paraffin (2) and Paraffin (3).
The paraffin baths have the following status:

- Empty (→ "Fig. 61-1") - The paraffin bath is empty.
- Partially filled (→ "Fig. 61-2") - The retort is sucking/draining the paraffin.
- Full (→ "Fig. 61-3") - The paraffin bath is full.
- Blinking (→ "Fig. 61-4") - The paraffin is expired, when the RMS is on.
- Not displayed - The paraffin bath is not used in the selected program.

A filling animation is displayed when the retort is sucking/draining paraffin. Paraffin bath filling decreases from full to empty, when the retort is sucking the paraffin; paraffin bath filling grows from empty to full, when the retort is draining the paraffin back.

Reagent bottle status

Fig. 62

The reagent bottles are filled with reagent group colors, and named from No.1 to No.13.
The reagent bottles have the following status:

- Empty (→ "Fig. 62-1") - The reagent bottle is empty.
- Partially filled (→ "Fig. 62-2") - The retort is sucking/draining a reagent.
- Full (→ "Fig. 62-3") - The reagent bottle is full.
- Blinking (→ "Fig. 62-4") - The reagent is expired, when the RMS is on.
- No bottle shown in the place - The bottle is not used in the selected program.

A filling animation is displayed when the retort is sucking/draining a reagent. Reagent bottle filling decreases from full to empty, when the retort is sucking a reagent; reagent bottle filling grows from empty to full, when the retort is draining the reagent back.

Pipe connection

Fig. 63

When the retort is sucking a reagent from one station, the connection from the station (paraffin baths and reagent bottles) to the retort is highlighted, with the pipe filled with the reagent group color (→ "Fig. 63-1"). An animation shows the reagent going out of the station and into the retort. When the retort is draining the reagent back to the station, the connection from the retort to the station is highlighted, with the pipe filled with the reagent group color. An animation shows the reagent going out of the retort and into the station.

Program list panel

Fig. 64

Program list panel is displayed when no program is running (→ "Fig. 64-1"). It is switched to the program running panel after a selected program starts (→ "Fig. 64-2").
If a program is selected, the program icon and name is highlighted (→ "Fig. 64-3").
Maximum 5 favorite programs can be shown in the program list panel. For how to set a program as a favorite program, see (→ P. 72 – 5.4.2 Favorite programs).

5.6 Reagent handling

Caution

Always replenish reagents via the reagent bottle and paraffin via the paraffin bath.

Do not add reagents or paraffin directly into the retort. Doing so will cause an overflow from reagent bottles or paraffin baths during filling or draining which could result in instrument malfunction or potentially a fire accident.

5.6.1 Filling/draining reagents

Caution

The following steps should only be carried out by trained laboratory personnel, experienced in handling reagents.

Always wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment, when handling the reagents used in this instrument.

Reagents used for tissue processing can be both toxic and/or flammable.

Caution

Dispose of waste reagent with care according to local regulations and the waste management policy of the company or institution.

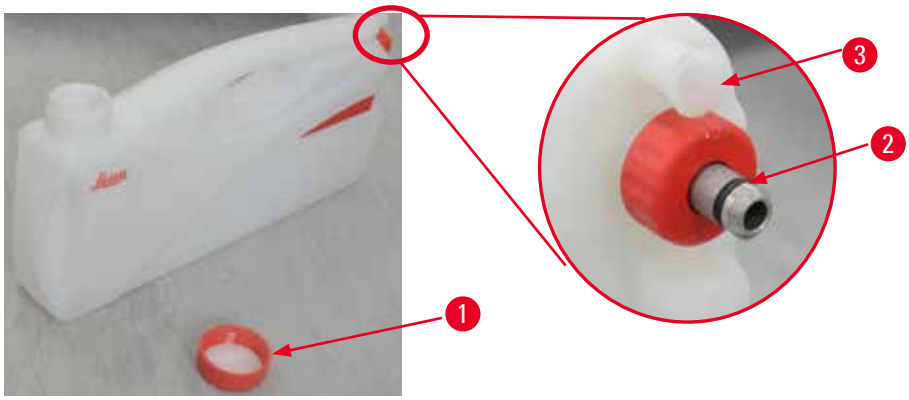


Fig. 65

Changing the reagents

ⓘ Never replace reagents or fill empty reagent bottles while a process is running. This can result in severe damage to the instrument.

ⓘ Make sure that the reagent bottles are placed in the correct position according to the reagent definition on the display. For reagent positions, see (→ P. 21 – 3.5.1 Cycle for changing reagents).

1. Remove the reagent bottle from the reagent cabinet and unscrew the bottle cover (→ "Fig. 65-1").
2. Drain the used reagent into a bulk container.
3. Clean the reagent bottle sufficiently before refilling.
4. Refill the reagent bottle. The maximum and minimum fill levels for filling are embossed on the front of each bottle. Use a funnel for clean filling.

Note

Check the reagent level in the reagent bottle on flat ground. To do so, keep your eye-sight and the reagent level at the same level, and make sure that the volume of the reagent is not either more than the max. level or lower than the min. level. The insufficient reagent may cause the specimen to dry out due to the specimen not being covered by sufficient reagents.

5. Place the filled reagent bottle back in the reagent cabinet. When inserting the reagent bottle, always make sure that the retaining ring (→ "Fig. 65-2") is securely tightened and the connection port (→ "Fig. 65-3") clicks into the back panel correctly.
6. In the reagent status window, reset the data. For more information, see (→ P. 59 – 5.3.1 Reagent status).

5.6.2 Filling/refilling paraffin

There are two marks on the interior wall of the paraffin bath that display the maximum and minimum filling level when filled with paraffin. The level must be between these marks. The paraffin bath can be filled with paraffin pellets, paraffin blocks or liquid paraffin.

If the paraffin baths temperature is set to below 64 °C, or at 64 °C, the melting time is approximately 12 hours. If the paraffin baths temperature is set higher than 64 °C, the melting time takes longer, approximately 3 additional hours. For setting the paraffin baths temperature, see (→ P. 53 – 5.2.6 System Setup).
For each paraffin bath, 2.8 kg-3.0 kg of the paraffin pellets are required.
Fill the paraffin bath to the brim with pellets. The paraffin will need to be topped up with additional pellets within 6 hours.
Make sure that the paraffin has completely melted after being replaced, prior to use.

Note

If pellets were added 6 hours after the initial paraffin refill, they may not be melted completely before use and an error message would be triggered which may cause the instrument to stop heating.

Caution

If the pellets were added, make sure that the paraffin is completely melted before starting a program.

Refilling paraffin

1. Open the paraffin oven cover. A message pops up on the screen, and asks if you want to refill the paraffin.
2. Press Yes, the system will calculate the melting time. If it is to run a processing program, make sure that the time length before the paraffin step is longer than 12 hours. If the time length is less than 12 hours, the Formalin step will be delayed so that the melting time of 12 hours is completed. If the melted paraffin is added, press No, and the system will not calculate the melting time. You must check the melting status of the paraffin, prior to use.

Caution

Press Yes first on the pop-up message box before adding the solid paraffin.
There is a risk of blocking the instrument if the paraffin is not completely melted.

3. Pull the paraffin bath out from the paraffin oven.

Caution

Proceed slowly and carefully when pulling out or removing a paraffin bath—never jerk it out. The paraffin inside is hot and can cause burns. The paraffin baths surface are also hot, therefore always wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment during exchanging or adding paraffin.

4. Drain the used paraffin into a bulk container and then refill the bath. The maximum and minimum levels for filling is in the interior wall of the paraffin bath.

Note

Remove the residue of the paraffin or dirts before refilling the paraffin.

5. Place the filled paraffin bath back in the paraffin oven. When inserting the paraffin bath, always make sure that it slides back through the sliding slot and connects into the back panel correctly.

Note

It is recommended to refill the paraffin bath one by one.

6. In the reagent status window, reset the data. For more information, see (→ P. 59 – 5.3.1 Reagent status).

Note

If the paraffin baths are refilled with paraffin of different melting points, empty and clean the paraffin baths and the filter. After refilling, reset the melting point of the paraffin baths, for more information, see the section of System Setup (→ P. 53 – 5.2.6 System Setup) .

5.7 Starting a program

Before a program can be started, a number of conditions must be met. The following steps are essential in order to be able to start a program.

Caution

- Before switching the instrument on, visually check the instrument and accessories for any damages possibly caused during transportation or moving the instrument. Do not operate the instrument and contact your local service representative if you find or suspect any damage.
- Before processing patient tissue samples after transportation or moving the instrument, perform a test run to ensure the suitability of the instrument and the program used. Either use a pre-installed program or combine this activity with the validation of your own protocols. Only process patient tissue samples for diagnostic purpose, after all above checks have been performed successfully. If any of the previous steps failed, contact your local service representative.

Caution

The pre-installed programs, the customized processing programs and RMS (Reagent Management System) have to be validated by the user before running the program, i.e. tissue processing with patient tissue for diagnostics, according to the local or regional accreditation requirements.

Caution

Check the reagent levels and the paraffin levels before starting a program. To do so, keep your eye-sight and the reagent/paraffin level at the same level, and make sure that the volume of the reagent/paraffin is not either more than the max. level or lower than the min. level. The insufficient reagent/paraffin may cause the specimen to dry out due to the specimen not being covered by sufficient reagents/paraffin. Check that the reagent bottles and paraffin baths are correctly inserted.

Caution

Never leave a paraffin bath empty. The absence of the paraffin may cause incorrect heating to the paraffin bath.

Caution

Make sure that the simulation of the reagent bottles on the display and the reagent bottles in the reagent cabinet are correctly matched.

Caution

Check that the retort sieve is correctly installed at the bottom of the retort, then make sure that the retort lid is sealed before a program starts.

Starting a program

1. Make sure that the correct paraffin melting temperature has been set in the system settings (→ P. 54 – 5.2.6 System Setup).
2. It is recommended to run the Bottle Check after the reagents are refreshed. For how to run a Bottle Check, see the section of System Setup (→ P. 53 – 5.2.6 System Setup).

Caution

- Not running Bottle Check function may cause tissue damage due to blockage or leakage, or lack of reagents.
- If the retort is contaminated by the reagents/paraffin, the Bottle Check function will be disabled to avoid tube blockage.
- Before running the Bottle Check, make sure that the retort is empty, clean and dry. Otherwise, the contamination in retort may occur and impact the tissue processing quality.

3. Put the baskets in the retort.

Note

Use the basket during processing. Do not put the specimens into the retort directly.

Carefully handle the specimens and place into a cassette to avoid dropping into the retort sieve holes.

4. Select a program in the program list panel. The selected program name and the icon are highlighted. Please double check that the highlighted program is the correct program that you want to run. Then press Start. The system reserves time for melting paraffin. The Start button on the pop-up message will be disabled for Standard User access. If the paraffin is already completely melted and you wish to start the program immediately, you must first switch to the Supervisor account, the Start button will then be enabled. Follow the messages on the pop-up window to proceed.

Caution

- Make sure that the paraffin in the paraffin baths are completely melted before pressing the Start button. Failure to do so could lead to paraffin blocking the liquid system

5. If RMS is set On and Cassette mode is selected, the following box pops up (→ "Fig. 66").

Fig. 66

6. Select the cassette number and press OK. The End Time of Program window (→ "Fig. 67") pops up. The default end time (→ "Fig. 67-1") for the selected program is shown.

Fig. 67

7. Set the day and the time (in 24-hour format) (→ "Fig. 67-2") on which you want the program to end.

Note

The date sequence is Day-Month-Year.

8. Press OK (→ "Fig. 67-3").

Note

If the first reagent in the program belongs to the fixation group, programs can be started up to 7 days in advance. If the program is ended at a defined date/time, the delay step is lengthened accordingly.

» Or if you do not set the end time, press ASAP (→ "Fig. 67-4") and then press Run (→ "Fig. 67-3"). The program starts. The Dashboard is switched to the program running panel.

Note

After press ASAP, the Endtime field (→ "Fig. 67-1") is displayed as ASAP, and the OK button changes to Run.

Caution

Monitor the instrument during Pre-checking and formalin soaking in the retort, in case any message pops up.

Caution

Do not open the retort lid or remove reagent bottles/paraffin oven cover/paraffin baths when a program is running, unless a system message indicates to do so. Doing so may cause damage to the instrument or trigger an error message.

Caution

Do not open the retort lid or unplug any reagent bottle whilst the instrument is paused or resuming.

Caution

Whilst a program is running, if you want to remove the specimens from thte retort or add specimens to the retort, press the pause button.

Loaded specimens/baskets must not be higher than the level sensor, to ensure that they will always be covered by reagent.

Note

If you want to add more cassettes when the program is running and the tissue is soaking in Formalin, pause the program and make sure to wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment to add the cassettes. The Standard user can only pause the program at the first 3 steps, and abort the program at the first step. The Supervisor can pause or abort the program at any step.

After pausing, please be aware of the finish time of the processing program.

If the RMS is set to be in Cassettes mode, input the number of the newly-added cassettes. The number can not be 0, and the total number of the cassettes in the retort can not exceed 200.

If no cassette is added, press Cancel.

Press the Start button to continue the program, and make sure that the retort lid is sealed after cassettes are added.

Program running panel

Below figure (→ "Fig. 68") is the dashboard panel while a program is running.

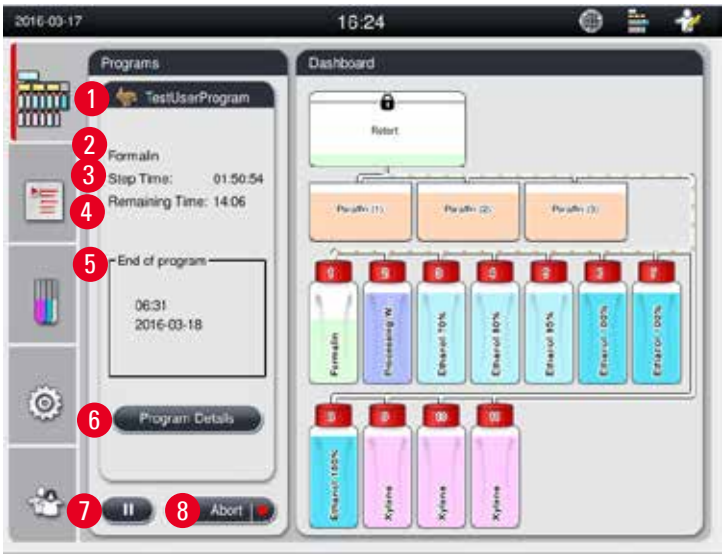


Fig. 68

Fig. 69

- The icon and name of the program which is running (→ "Fig. 68-1")
- The name of the step which is running (→ "Fig. 68-2")
- The step remaining time (→ "Fig. 68-3"). The step time is the total time of filling, soaking/infiltration and draining.
- The program remaining time (→ "Fig. 68-4")
- The end date and time (→ "Fig. 68-5")
- **Program Details** button (→ "Fig. 68-6"). Press **Program Details** to view the program details (→ "Fig. 69").
- Pause button (→ "Fig. 68-7"). At the Standard user level, the pause button is only enabled during the first 3 program steps; at Supervisor/Service level, the pause button is enabled at any time within the program.
- **Abort** button (→ "Fig. 68-8")/**Abort Program** button (→ "Fig. 69-10"). At the Standard user level, the **Abort** button is only enabled during the first program step; at Supervisor/Service level, the **Abort** button is enabled at any time within the program.

- Current step (→ "Fig. 69-9") is highlighted with red. The duration column is showing only the soaking/ infiltration time.
- Close button (→ "Fig. 69-11"). Press Close to close the program details window.

Note

The Step time (→ "Fig. 68-3") and the Remaining time (→ "Fig. 68-4") may not match at the last step. The instrument may carry out self calibrating during this time.

Caution

Always wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment, if it is necessary to open the retort whilst a program is running.

Note

When it is necessary to pause the program, press the pause button and wait till the current step (filling or draining) finishes. When the Start button is enabled, operate the instrument then, for example, open the retort lid to remove the cassettes. To continue with the program, press Start.

If the pause time exceeds 15 minutes, the program cannot be resumed. Please press the "OK" button, then press the "Abort" button to abort the program.

Caution

Make sure that the retort lid is sealed when the program starts.

Do not open the retort lid when a program is running.

5.8 Ending a program

When a program is completed, a message pops up , indicating that "The program is finished. Would you like to drain the paraffin?" Press OK, and the instrument starts to drain the paraffin.
After the paraffin is drained, another message pops up, indicating that you can take out the basket.
After the basket is taken out and the retort lid is sealed, the third message box pops up, indicating that the retort is contaminated and please run the Cleaning program. Insert the empty baskets and run the Cleaning program.

Caution

The baskets are hot. Wear gloves when taking out the baskets.

5.9 Pre-installed program

Caution

The permanently installed programs described below have to be validated before use, i.e. tissue processing using patient tissue for diagnostics, by the laboratory itself based on tissues that are not intended for diagnostics and in accordance with local or regional accreditation requirements.

Note

The default Overnight program is suitable for standard size tissue and the default Biopsy program is suitable for biopsy size tissue. Do not mix different size tissues in the default Overnight or Biopsy Programs.

Overnight (approximately 13 hours)

Step	Reagent	Duration	Temperature	P/V
1	Formalin	1:00	37	P/V
2	Processing Water	0:02	-	-
3	Ethanol (70%)	0:40	45	-
4	Ethanol (80%)	0:40	45	-
5	Ethanol (95%)	0:40	45	-
6	Ethanol (100%)	1:00	45	-
7	Ethanol (100%)	1:00	45	-
8	Ethanol (100%)	1:00	45	-
9	Xylene	1:00	45	-
10	Xylene	1:00	45	-
11	Xylene	1:00	45	-
12	Paraffin	1:00	65	V
13	Paraffin	1:00	65	V
14	Paraffin	1:30	65	V

Biopsy (approximately 2 hours 40 minutes)

Step	Reagent	Duration	Temperature	P/V
1	Formalin	0:15	37	P/V
2	Processing Water	0:02	-	-
3	Ethanol (70%)	0:05	45	-
4	Ethanol (80%)	0:05	45	-
5	Ethanol (95%)	0:05	45	-
6	Ethanol (100%)	0:05	45	-
7	Ethanol (100%)	0:05	45	-
8	Ethanol (100%)	0:10	45	-
9	Xylene	0:10	45	-
10	Xylene	0:10	45	-
11	Xylene	0:10	45	-
12	Paraffin	0:05	65	-
13	Paraffin	0:05	65	-
14	Paraffin	0:10	65	V

Fig. 70

Note

The Duration is the time of soaking/infiltration.

The two pre-installed programs above cannot be edited or deleted, they can be copied.

6. Cleaning and maintenance

6.1 Cleaning program

Caution

Do not use the Cleaning program for reprocessing as the Dry step will damage the tissue.

Note

The Cleaning program is a pre-installed program.

The Cleaning program cannot be edited, copied or deleted.

The Cleaning program is offered automatically when an infiltration program has been completed. In this case, a retort cleaning cycle MUST be carried out; this function cannot be canceled.

Use only the recommended reagents.

Cleaning program (full-step: approximately 1.5 hours))

Step	Reagent	Time (min)	Cycle	Temp. (°C)	Pressure/Vacuum
1	Cleaning xylene	10*	7	67	Ambient
2	Cleaning ethanol	3*	3	62	Ambient
Dry step:	Empty retort				
3	Vacuum step	10		80	Vacuum
4	Ventilation step	20		Ambient	Ambient

* Indicating the duration of soaking.

Running Cleaning program

The Cleaning program skips any steps not required to complete the cleaning of the retort.

- If the last step of a processing program is Formalin, Processing Water or Ethanol, the Cleaning Program will not run after the processing program completes.
- If the last step of a processing program is Xylene or Paraffin, the cleaning program will run after the program completes.

Caution

Do not open the retort lid during the Dry step of the cleaning program.

Caution

Do not pull the reagent bottles when the cleaning program is running. It may cause damage to the instrument or trigger an error reporting.

Caution

Do not load unprocessed specimens or wet baskets into the retort prior to running a cleaning program. Formalin and water residue can flow into the reagent bottle/paraffin bath from the last step of the previous processing cycle.

If you have inadvertently loaded unprocessed specimens into the retort and have started a cleaning program, stop the program, remove the unprocessed specimens and finish the cleaning program. Replace all the processing reagents and paraffin before doing any further processing.

Caution

Baskets can be cleaned together in the retort. ONLY completely cleaned baskets can be used for tissue processing. After a maximum of 5 cleaning cycles, cleaning xylene and cleaning ethanol must be replaced.

Neither drip trays nor other objects can be cleaned using the HistoCore PEARL Cleaning program!

- After you touch the **OK** button, a message appears indicating that before the cleaning is started the retort must be empty and all specimens have to be removed.
- When all necessary conditions have been satisfied, press the **Start** button. Wait about 8 seconds, and the cleaning program starts. The procedure is displayed graphically on the Dashboard.
- After the cleaning program has been completed, a message appears on the screen if the temperature in the retort is high. Open the retort lid and wait for a few minutes to let it cool down.

Cleaning reagent warning message

If RMS is enabled, the following indicates that the warning threshold values have been exceeded.

- The exceeded bottle turns to red and flashes. The operator is notified that the reagent has exceeded and can replace this reagent before the program starts. However, it is also possible to start the program despite this at Supervisor level.
- The exceeded bottle turns to red and flashes at the end of a program (after the cleaning). You can go directly to the reagent **Status** window.
- The reagent status highlights the exceeded values in red.

Caution

Follow the RMS reminder. Continuously reusing the expired cleaning reagents may lead to bad quality of the Cleaning program and may cause damage to the instrument or trigger an error reporting.

6.2 General instrument cleaning

6.2.1 Daily cleaning and maintenance

Instrument exterior

Clean the housing (including the instrument exterior, display, retort lid, counter area, etc) and the ground if contaminated by reagent. Wipe with a damp lint-free cloth moistened with mild detergent and dry.

Caution

Do not use solvents on painted surfaces, warning labels or the touchscreen.

To avoid scratching the surface of the instrument only the paraffin scraper that is supplied with the instrument should be used for cleaning – Do not use metal tools!

Cleaning the retort lid

Remove paraffin from the inside of the retort lid with the plastic scraper provided. Thoroughly remove all paraffin deposits from around the lid seal.

Caution

Only use the plastic scraper provided when cleaning the retort lid and seal to avoid damage to the retort lid seal. Do not damage the edges of the seal with the scraper.

Cleaning the retort

- Wipe the retort using a lint-free cloth moistened with solvent (xylene or ethanol) or mild detergent.
- Remove residues of paraffin and reagent from the retort inside wall higher than the reagent level area and the area around the retort (→ "Fig. 71") after each cleaning program.

Fig. 71

- Make sure that the air vent holes at the top front of the retort are not dirty.

Cleaning the level sensor

Note

The level sensor must be cleaned of all residue (reagents and paraffin).

Use a lint-free cloth to clean the level sensor.

Checking the bottom tray

Caution

Some of the reagents used in the HistoCore PEARL are hazardous to health. Therefore always wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment, when handling them.

The bottom tray must be inspected regularly for signs of leaking reagents. It is recommended to do this after the processing program and cleaning program has been completed, before any leaking reagent has a chance to evaporate.
To check the bottom tray, use one hand to pull the bottom tray out by the handle until you see the etched number, 20 cm; use the other hand to support the tray from the bottom. Then pull out the whole bottom tray.

Cleaning the paraffin drip tray

Caution

Use care with paraffin - risk of burning when removing the paraffin drip tray due to liquid paraffin.

- Pull out the paraffin drip tray. Empty the paraffin drip tray with the supplied scraper.
- If necessary place it in the laboratory oven (on cellulose) and clean with xylene substitute.

6.2.2 Weekly cleaning and maintenance

Cleaning the paraffin baths

Caution

Work carefully and wear gloves!
Be careful as the walls of the paraffin baths are very hot and may cause burns!

- Wipe the paraffin baths and the lids using a lint-free cloth moistened with solvent (xylene or paraffin remover).
- The lid can be removed for cleaning purposes.
- If they are very dirty, remove the paraffin filters from the paraffin baths. Clean, dry, and reinsert them.
- The paraffin bath seals must be replaced yearly. Contact Leica Biosystems Technical Service for the replacement service.

Emptying the condensate bottle

The condensate bottle must be taken out, emptied and reinserted weekly. This should be done sooner if a prompt to that effect is issued by the software.

Caution

Dispose of waste solvents with care according to local regulations and the waste management policy of the company or institution.

Cleaning the retort sieve

Use ethanol or xylene to clean the sieve located at the bottom of the retort. For convenience, the sieve may be taken out to remove all solid dirt.

Note

Make sure that nothing falls into the drain hole when the sieve is removed for cleaning purpose.

Checking the retort lid seal

Regularly check the retort lid seal for damage. If the seal is damaged, it must be replaced without delay. The retort lid sealing must be inspected at least once a year. Contact Leica Biosystems Technical Service for the inspection/replacement service.

Cleaning the display

Clean the screen using a lint-free cloth.

Note

The touchscreen may be triggered during cleaning. Clean the touchscreen whilst there is not a program currently running.

6.2.3 Monthly cleaning and maintenance

Replacing the active carbon filter

- The life of the active carbon filter will depend on the reagent types used and the frequency of vacuum cycles.
- The filter should be replaced every 45 - 60 days (45 days, warning threshold; 60 days, alarm threshold). After replacing the filter, open the maintenances menu to reset the filter threshold. For additional information, see (→ P. 56 – 5.2.8 Maintenance).

Note

When inserting the new filter, make sure that the arrows on the filter and on the instrument are in the same direction. It is inserted with the correct side up, as specified on the label on the front side of the filter, see (→ P. 30 – 4.4.3 Active carbon filter) for detailed information.

Cleaning the reagent bottle

- Empty and clean the reagent bottles, using a bottle brush in warm water. Wait till they dry and rinse the reagent bottles with corresponding reagents.

Note

The level can be identified by simply looking through the reagent bottles if these are cleaned regularly to remove clinging contamination.

Caution

Never clean reagent bottles in an automatic dishwasher.

The reagent containers are NOT dishwasher-proof!

Care of reagent and condensate bottle seals.

- To ensure easy removal of the reagent and condensate bottles, lubricate the O-ring seals on the plug-in nozzles with the O-ring lubricant supplied.
- Refill and reconnect the bottles once cleaned. Make sure the bottle lids are tight and the bottles are properly seated in their home position at the rear of the reagent module.

Caution

The reagent bottles must be properly engaged in the home position in the connection manifolds at the rear inner wall of the reagent module. Failure to correctly plug reagent containers into the manifold will cause an interruption to the processing run and may result in spilling of reagents.

- While the reagent bottles are outside of the reagent cabinet, wipe the stainless steel inner walls of the reagent cabinet with a lint-free cloth moistened with a mild detergent.

Cleaning the paraffin oven

Caution

Switch off the instrument before cleaning the paraffin oven.

Work carefully and wear chemical protective clothing, protective goggles, respirator, rubber gloves and all other necessary personal protective equipment!

Be careful as the walls of the paraffin oven are very hot and may cause burns!

- Wipe the paraffin oven using a lint-free cloth.
- Check the paraffin oven cover seal and clean it with a lint-free cloth.

6.2.4 Recommended cleaning reagents

The following reagents can be used for external (the top, sidewalls and the front) cleaning of the instrument.

- 1% HCl Ethanol
- Paraffin remover (i.e. Medite)
- Aqua Dest. Desinfection (Incidin)
- Paraguard (Polyscience)

6.3 Checklist for regular maintenance

Step	Daily	Weekly	Monthly	Every 2 months
Clean the outer surfaces of the instrument by a soft lint-free cloth with recommended cleaning reagents (→ P. 92 – 6.2.4 Recommended cleaning reagents).	√			
After each retort cleaning program, wipe the retort and lid dry.	√			

Step	Daily	Weekly	Monthly	Every 2 months
Check the level sensor and clean it.	√			
Check the bottom tray.	√			
Clean the paraffin drip tray.	√			
Check the paraffin level and refill if necessary.	√			
Check the fill levels of the reagent bottles.	√			
Check that the reagent bottles are connected securely in the ports.	√			
Remove paraffin residue from the interior surface of the paraffin baths. Check the filter of the paraffin baths.		√		
Check and empty the condensate bottle. Clean the inlet openings.		√		
Check the retort sieve for tissue or paraffin residue.		√		
Check the retort lid seal and clean it.		√		
Clean the display.		√		
Check the status of the active carbon filter.			√	
Clean the reagent bottles from the inside. Lubricate the O-rings of the reagent bottles and check them for damage. Make sure that the shutter caps of the reagent bottles and the O-rings fit correctly and are tight.			√	
Check the paraffin oven cover seal. Clean the paraffin oven.			√	
Replace the active carbon filter.				√

7. Troubleshooting

7.1 Troubleshooting

When a problem occurs with the HistoCore PEARL, take the following steps to diagnose the problem:

1. Read the error message(s).
2. Follow the instructions on the message.
3. Check the Run Log for any messages that indicate the nature of the failure. If the failure occurred during a program run, check the Run Log for an indication of whether the failure occurred during the fill, processing or drain cycles, and the station in use at the time.

7.2 Power failures

If there is evidence of a power failure to the instrument:

- Verify that the power plug is plugged into the socket and that the socket is switched ON.
- Verify that the power switches on the rear of the instrument (adjacent to the power lead) is switched ON.
- Disconnect the instrument from the power supply, take out the main fuses and check them for continuity. In case of discontinuity, replace them with fuses of the correct value, reinsert them and reconnect the power cable. For how to replacing the fuse, see (→ P. 96 – 7.4 Replacing a fuse).

Note

If you cannot identify the problem by carrying out the above listed steps, call Leica Biosystems Technical Service.

Caution

If the instrument detects a power failure, the heaters and the display are immediately switched off.

The objective in case of power failure is to secure the tissue samples in a currently running program. The main emphasis is on the safety of the tissue samples, not the speed of processing.
In the event of a power failure, local alarm and remote alarm are triggered off.
After the power is restored, a message box is displayed, instructing the user to take out the specimens. If no operation is taken to the instrument with 5 minutes after the message box appears, the system starts reheating and the specimens are then safeguarded by filling the retort with a safe reagent.
If the power can not be restored in time, remove the specimens and put them into a corresponding safe reagent. Check which bottle is running when the power fails. After the power is restored, check if the paraffin is melted or not, set a program and reprocess the specimens.

Note

The property of a safe reagent is that the specimen can stay in it for a long time without being damaged. An individual safe reagent is assigned to each program step/reagent group.

Current step	Safeguard in safe reagent
Fixation	Fixation
Processing water	Fixation
Diluted ethanol	Fixation, diluted ethanol
Absolute ethanol	Diluted, fixation, absolute ethanol
Xylene	Xylene (heating off)
Paraffin	Paraffin (heating on)

If no program is running when a power failure is detected, after the power is restored, the instrument is in standby.

7.3 Malfunctions in the program sequence

7.3.1 Safe reagent

Maintaining the specimen in a safe state is the primary concern during a malfunction.
A safe specimen state is initiated following any power outage or malfunction where the processing program cannot be automatically finished. A processing program that has been started and cannot be finished automatically leads to a safe specimen state being initiated. The safe reagent process ends with one of the following results.

- Safe reagent filling process has been completed successfully. The specimens are being protected by safe reagent.

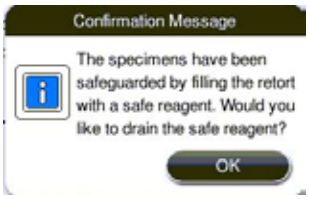


Fig. 72

- Safe reagent filling process is finished but with warning information, which means the safe reagent may be insufficient.

Caution

Open the retort lid and visually check the safe reagent level in the retort. If the safe reagent level is insufficient, close the retort lid and drain the reagent, then fill the safe reagent bottle to sufficient.

Fig. 73

- Safe reagent filling process fails. Please call service.

Fig. 74

7.3.2 Crash or freeze of master software

Follow below steps to protect the specimens.

1. Take out specimens from the retort.
2. Restart the instrument. If the problem still exists, call Leica Biosystems Technical Service.

7.4 Replacing a fuse

Caution

Before replacing a fuse, switch the instrument off and pull out the power plug.
Use ONLY the fuses with correct value.
Fuse rating: T15 A, 250 V AC

Fuse Order No.: 14049354395

Fig. 75

Replacing a fuse

ⓘ A suitable flat-head screwdriver must be used to prevent damage to the fuse holders.

1. Unscrew the two fuse holders (→ "Fig. 75-1") at the rear panel of the instrument with a flat-head screwdriver and check for damage.
2. Remove the defective fuse from the holder and replace it with a new one.
3. Install the fuse holders back to the rear panel with the flat-head screwdriver.

8. Ordering information

Description	Order No.
Bottle label	14049350467
Basket assembly	14049351403
Paraffin scraper	14039353643
Maintenance kit	14049353391
Reagent bottle assembly	14049350465
Funnel, 255 mm, D=250 mm	14047643631
Connector male 5-pole	14049351429
Extraction tube	14049544881
Silicone pad	14049350559
Active carbon filter 200X100mm 36mm	14049350629
Main control fuse	14049354395

Reagent bottle label kit

Order No: 14049353389

Fig. 76

Paraffin scraper

Order No: 14039353643

Fig. 77

Maintenance kit

Order No: 14049353391

Fig. 78

Funnel

Order No: 14049355900

Fig. 79

Extraction tube

Order No: 14049544881

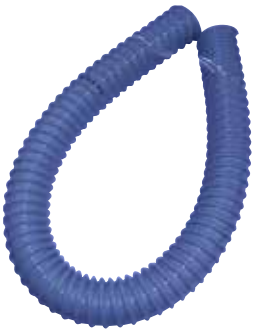


Fig. 80

Optional silicone plate kit

Order No: 14049353396

Fig. 81

Active carbon filter

Order No: 14049350629

Fig. 82

9. Warranty and Service

9.1 Warranty

Leica Biosystems Nussloch GmbH guarantees that the contractual product delivered has been subjected to a comprehensive quality control procedure based on the Leica Biosystems in-house testing standards, and that the product is faultless and complies with all technical specifications and/or agreed characteristics warranted.
The scope of the warranty is based on the content of the concluded agreement. The warranty terms of your Leica Biosystems sales organization or the organization from which you have purchased the contractual product shall apply exclusively.

9.2 Service information

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

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

9.3 Decommissioning and disposal

The instrument or parts of the instrument must be disposed of according to existing applicable, local regulations.

10. Decontamination Confirmation

Every product that is returned to Leica Biosystems or that requires on-site maintenance must be properly cleaned and decontaminated. You can find the dedicated template of the decontamination confirmation on our website www.LeicaBiosystems.com within the product menu. This template has to be used for gathering all required data.

When returning a product, a copy of the filled and signed confirmation has to be enclosed or passed on to the service technician. The responsibility for products that are sent back without this confirmation or with an incomplete confirmation lies with the sender. Returned goods that are considered to be a potential source of danger by the company will be sent back at the expense and risk of the sender.

www.LeicaBiosystems.com

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