HistoCore SPECTRA CV

Coverslipper

Instructions for Use
English

Order No.: 14051480101 - Revision A

Always keep these instructions near the instrument.
Read carefully before working with the instrument.

CE

Version 1.2, Revision A - 05.2018

The information, numerical data, notes and value judgments contained in this Instructions for Use 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 Instructions for Use periodically and on an ongoing basis according to the latest technical developments, nor to provide our customers with additional copies, updates etc. of this Instructions for Use.

To the extent permitted in accordance with the national legal system as applicable in each individual case, we shall not be held liable for erroneous statements, drawings, technical illustrations etc. contained in this Instructions for Use. In particular, no liability whatsoever is accepted for any financial loss or consequential damage caused by or related to compliance with statements or other information in this Instructions for use.

Statements, drawings, illustrations and other information regarding the contents or technical details of the present Instructions for Use are not to be considered warranted characteristics of our products.

These are determined only by the contract provisions agreed between ourselves and our customers.

Leica reserves the right to change technical specifications as well as manufacturing processes without prior notice. Only in this way is it possible to continuously improve the technology and manufacturing techniques used in our products.

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

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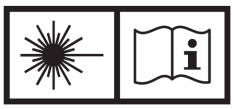
1. Important Notes

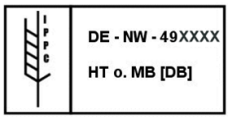
1.1 Symbols and their meanings

Symbol:	**Title of the symbol:**	Hazard warning
	**Description:**	Warnings are displayed in a white field with an orange title bar. Warnings are identified by a warning triangle.
Symbol:	**Title of the symbol:**	Note
	**Description:**	Notes, i.e. important information for the user, are displayed in a white field with a blue title bar. Notes are identified by a notification symbol.
Symbol:	**Title of the symbol:**	Item number
→ "Fig. 7 – 1"	**Description:**	Item numbers for numbering illustrations. Numbers in red refer to item numbers in illustrations.
Symbol:	**Title of the symbol:**	Software designations
Supervisor	**Description:**	Software designations that have to be displayed on the input screen are displayed as bold, gray text.
Symbol:	**Title of the symbol:**	Function key
Save	**Description:**	Software symbols that have to be pressed on the input screen are displayed as bold, gray and underlined text.
Symbol:	**Title of the symbol:**	Keys and switches on the instrument
Main switch	**Description:**	Keys and switches on the instrument that are supposed to be pressed by the user in various situations are displayed as bold, gray text.
Symbol:	**Title of the symbol:**	Attention
	**Description:**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
Symbol:	**Title of the symbol:**	Warning, hot surface
	**Description:**	Instrument surfaces which become hot during operation are marked with this symbol. Avoid direct contact to prevent risk of burning.

Symbol:	**Title of the symbol:**	Manufacturer
	**Description:**	Indicates the manufacturer of the medical product.
Symbol:	**Title of the symbol:**	Date of manufacture
	**Description:**	Indicates the date when the medical device was manufactured.
Symbol:	**Title of the symbol:**	CE Compliance
	**Description:**	The CE marking is the manufacturer's declaration that the medical device meets the requirements of the applicable EC directives.
Symbol:	**Title of the symbol:**	CSA Statement (Canada/USA)
	**Description:**	The CSA test mark means that a product has been tested and fulfills the applicable safety standards:
Symbol:	**Title of the symbol:**	In vitro diagnostic medical device
	**Description:**	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
Symbol:	**Title of the symbol:**	China ROHS
	**Description:**	Environmental protection symbol of the China RoHS directive. The number in the symbol indicates the "Environment-friendly Use Period" of the product in years. The symbol is used if a substance restricted in China is used in excess of the maximum permitted limit.
Symbol:	**Title of the symbol:**	WEEE symbol
	**Description:**	The WEEE symbol, indicating separate collection for WEEE - Waste of electrical and electronic equipment, consists of the crossed-out wheeled bin (§ 7 ElektroG).
Symbol:	**Title of the symbol:**	Alternating current
		
Symbol:	**Title of the symbol:**	Article number
	**Description:**	Indicates the manufacturer's catalog number so that the medical device can be identified.

Symbol:	**Title of the symbol:**	Serial number
	**Description:**	Indicates the manufacturer's serial number so that a specific medical device can be identified.
Symbol:	**Title of the symbol:**	Consult instructions for use
	**Description:**	Indicates the need for the user to consult the instructions for use.
Symbol:	**Title of the symbol:**	ON (Power)
	Description:	The power supply is connected upon pushing the Power switch.
Symbol:	**Title of the symbol:**	OFF (Power)
	**Description:**	The power supply is disconnected upon pushing the Power switch.
Symbol:	**Title of the symbol:**	Warning, risk of electric shock
	**Description:**	Instrument surfaces or areas which become energized during operation are marked with this symbol. Therefore, direct contact is to be avoided.
Symbol:	**Title of the symbol:**	Caution: danger of crushing
		
Symbol:	**Title of the symbol:**	Flammable
	**Description:**	Inflammable reagents, solvents and cleaning agents are marked with this symbol.
Symbol:	**Title of the symbol:**	Observe the laser beam warning and Instructions for Use
	**Description:**	The product uses a class 1 laser source. The safety notes for handling lasers and the Instructions for Use must be observed.

Symbol:



Title of the symbol: IPPC symbol

Description: The IPPC symbol includes:

- IPPC symbol
- Country code in accordance with ISO 3166, e.g. DE for Germany
- Regional identifier, e.g. HE for Hesse
- Registration number, unique number beginning with 49
- Treatment method, e.g. HT (heat treatment)

Symbol:

Title of the symbol: Fragile, use with care

Description: Indicates a medical device that can be broken or damaged if not handled carefully.

Symbol:

Title of the symbol: Store dry

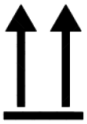
Description: Indicates a medical device that needs to be protected from moisture.

Symbol:

Title of the symbol: Do not stack

Description: Stacking of the transport package is not allowed and no load should be placed on the transport package.

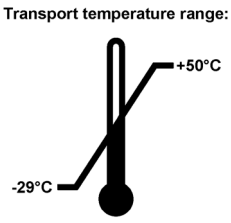
Symbol:



Title of the symbol: This way up

Description: Indicates correct upright position of the transport package.

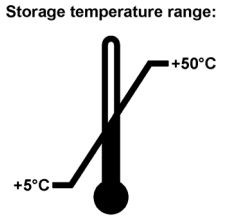
Symbol:



Title of the symbol: Temperature limit for transport

Description: Indicates the temperature limits for transport to which the medical device can be safely exposed.

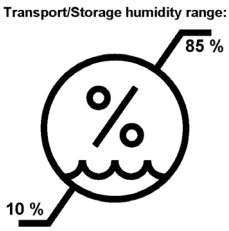
Symbol:



Title of the symbol: Temperature limit for storage

Description: Indicates the temperature limits for storage to which the medical device can be safely exposed.

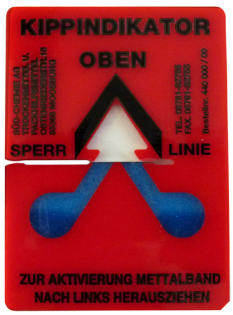
Symbol:



Title of the symbol: Humidity limitation for transport and storage

Description: Indicates the range of humidity for transport and storage to which the medical device can be safely exposed.

Appearance:



Indication: Tilt indicator

Description: 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.

Note

- When delivering the instrument, the recipient must check that the tilt indicator is intact. The responsible Leica representative must be notified if the indicator has been triggered.
- The Instructions for Use are accompanied by a bound "RFID Registration" supplemental sheet. This supplemental sheet contains country-specific information for the user about the meaning of the RFID symbols and registration numbers available on the packaging or the HistoCore SPECTRA CV nameplate.

1.2 Instrument type

All information provided in these Instructions for Use applies only to the instrument type indicated on the title page. A nameplate (→ Fig. 1) indicating the instrument serial number is attached to the rear side of the instrument. The figure below (→ Fig. 1) is provided as an example only and shows a valid nameplate for this instrument.

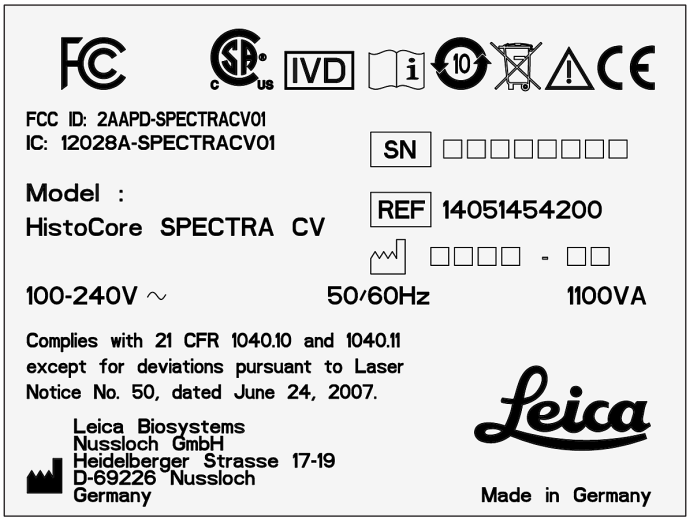


Fig. 1

1.3 User group

- The HistoCore SPECTRA CV must only be operated by authorized personnel comprehensively trained in using lab reagents and their application in histology.
- 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.

1.4 Intended use

The HistoCore SPECTRA CV is a fully automated coverslipper that is used to apply mounting media between the slide and coverglass. Then a coverglass is applied in order to preserve conserve the specimen and to create a uniform visual surface for microscopic research on histological and cytological tissue samples for medical diagnostics (e.g. cancer diagnostics).

This instrument may be operated only in conjunction with the coverglasses and mounting media approved by Leica.

Warning

Any use of the instrument that deviates from the designated use is considered improper. Failure to adhere to these instructions may result in an accident, personal injury, damage to the instrument or accessory equipment. Proper and intended use includes compliance with all inspection and maintenance instructions, along with the observance of all notes in the Instructions for Use as well as the constant inspection of the media being used for storage life and quality.

1.5 Copyright – Instrument software

The software installed and used on the HistoCore SPECTRA CV is subject to the following license agreements:

1. GNU General Public License Version 2.0, 3.0
2. GNU Lesser General Public License 2.1
3. additional software not licensed under the GPL/LGPL

The complete license agreements for the first and second items in the list can be found on the provided language CD (→ P. 19 – 3.1 Standard delivery – packing list) in the **Software Licenses** directory.

Leica Biosystems provides a complete machine-readable copy of the source code to every third party in compliance with the agreements of the GPL/LGPL applicable for the source code or of the other applicable licenses. To contact us, go to www.leicabiosystems.com and use the corresponding contact form.

2. Safety

2.1 Safety notes

Warning

- 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 instruments.
- The protective devices located on the instrument and the accessories must not be removed or modified.
- Only qualified service personnel authorized by Leica may repair the instrument and access its internal components.

Residual risks:

- 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 death or can cause damage to the instrument or property.
- The instrument may be used only as intended and only if all of its safety features are in proper working condition.
- If malfunctions occur that can impede safety, the instrument must be put out of operation immediately and the responsible Leica service technician must be notified.
- Only original spare parts and approved original Leica accessories may be used.
- Electromagnetic compatibility, emitted interference and immunity to interference are applicable, as are the requirements in accordance with IEC 61326-2-6. The requirements in accordance with IEC 61010-1, IEC 61010-2-101, IEC 62366 and ISO 14971 with regard to safety information are applicable.

These Instructions for Use include important instructions and information related to the operating safety and maintenance of the instrument. The Instructions for Use are an important part of the product, and must be read carefully prior to startup and use and must always be kept near the instrument.

Note

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

The instrument's EC Declaration of Conformity can be found on the Internet at:

http://www.LeicaBiosystems.com

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 these Instructions for Use.

Warning

- The presence of malware on the system can lead to uncontrolled system behavior. Ensuring that the behavior of the instrument conforms to specifications is no longer possible in this case! If the user suspects malware is on the system, the local IT department must be notified immediately.
- You must make sure that any data loaded onto the instrument is free of viruses. No anti-virus software is provided.
- The instrument is only suited for integration in a firewall-protected network. Leica shall not assume any liability for errors due to integration in an unprotected network.
- ONLY technicians trained and permitted by Leica can connect a USB input device (mouse/keyboard, etc.). This also applies to the network connection, which is to be used only together with Remote Care (service diagnostics).

In the interest of specimen safety, the HistoCore SPECTRA CV indicates when it is necessary for the user to intervene using on-screen messages and audible signals. Therefore, the HistoCore SPECTRA CV robotic coverslipper requires that the user is within hearing distance during operation.

Warning

The product uses a class 1 laser source.

Attention, laser radiation! Do not look into the beam! This can cause injury to the retina of the eye.

Warning

LASER RADIATION - DO NOT
STARE INTO BEAM
ISO 60825-1: 2014
P<1 mW, λ = 630 to 670 nm
Pulse duration = 500 µs
Class 1 laser product

2.2 Hazard 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, make sure to comply with the following notes and warnings.

Please note that electrostatic discharges can result due to direct or indirect contact with the HistoCore SPECTRA CV.

Warning

Markings on the instrument surface showing the warning triangle indicate that the correct operating instructions (as defined in these Instructions for Use) must be followed when operating or replacing the item marked. Failure to adhere to these instructions may lead to accidents causing personal injury and/or damage to the instrument or accessories or destroyed, unusable specimens.

Warning

Certain surfaces of the instrument are hot during operation under normal conditions. They are marked with this warning sign. Touching these surfaces without suitable safety measures can cause burns.

Warnings - Transport and installation

Warning

- The instrument must only be transported in an upright position.
- The empty weight of the instrument is 110 kg; therefore, four qualified persons are required to lift or carry the instrument!
- Use non-skid gloves to lift the instrument!
- A Leica service technician must carry out any transport, installation or possible move of the instrument.
- Retain the instrument packaging.
- Place the instrument on a sturdy laboratory bench (load capacity 150 kg/m^2) and adjust it to a horizontal position.
- A Leica service technician must re-level and recalibrate the instrument after any transport.
- Prevent the instrument from being exposed to direct sunlight.
- Only connect the instrument to a grounded power socket. Do not interfere with the grounding function by using an extension cord without a ground wire.
- Exposure to extreme temperature changes between storage and installation locations and high air humidity may cause condensation inside the instrument. If this is the case, wait at least two hours before switching on the instrument.
- The installation of the instrument at the area of use and a possible transport to a new location can only take place with the help of a Leica service technician.
- A Leica service technician must carry out the restart of the instrument.

Warnings – Handling reagents

Warning

- Caution when handling solvents and mounting media!
- Cover the reagent vessels during instrument pauses to avoid evaporation of the filled reagent. Caution! Reagent vapors (e.g. xylene) can be irritating.
- Always wear protective clothing suitable for laboratory use, as well as rubber gloves and safety goggles when handling the chemicals and mounting medium used in this instrument.
- The installation site must be well-ventilated. Alternatively, the instrument can be connected to an external exhaust air extraction system. The chemicals to be used in the HistoCore SPECTRA CV are flammable and hazardous to health.
- Do not operate the instrument in rooms with an explosion hazard.
- 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.
- Reagent vessels must always be filled outside of the instrument in compliance with the safety information.
- Danger of explosion and potential respiratory tract irritation due to flammable, evaporative reagents in the oven.

Warnings – Operating the instrument

Warning

- The instrument may be operated by trained laboratory personnel only. It must only be operated for the purpose of its designated use and according to the instructions contained in these Instructions for Use. Antistatic protective clothing made from natural fibers (e.g. cotton) should be worn when working with the instrument.
- When working with the instrument, wear suitable protective clothing (lab coat, safety goggles and gloves) for protection against reagents and potentially infectious micro-biological debris.
- In the event of an emergency, shut down the Main switch (→ Fig. 2-8) and unplug the instrument from the Power supply (→ Fig. 3-2) (circuit breaker in accordance with EN ISO 61010-1).
- For severe instrument faults, the warning and error messages on the screen must be followed. Samples located in the process must be removed from the instrument immediately. The user is responsible for the safe further processing of the samples.
- There is a fire hazard if work with an exposed flame (e.g. Bunsen burner) is carried out in the direct vicinity of the instrument (solvent vapors). Therefore, keep all ignition sources at least 2 meters away from the instrument!
- Be absolutely certain to operate the instrument with the active carbon filter, technical ventilation system and an exhaust air hose, as using the instrument may result in the formation of solvent vapors that are both flammable and hazardous to health, even when the instrument is used as intended!
- The user must stay within earshot during the operation in order to react immediately during instrument malfunctions.

Note

For instrument fume control, Leica recommends a delivery volume of 50 m^3/h and an 8x air exchange rate (25 m^3/m^2h) in the lab.

Warning

- Personal protective clothing in the form of a respirator must be worn when working directly with reagent vessels that contain solvents.
- Opening the hood when one or more coverslipping process(es) are active causes delays, since no transport movements take place during this time. Tissue samples might dry out.
- Make sure to keep the instrument cover closed while processing is active. Leica assumes no liability for loss of quality caused by opening the instrument hood during processing.
- ATTENTION when closing the hood: Crushing hazard! Do not reach into the swivel range of the hood!
- Liquid must not get behind covers or in gaps while operating or cleaning the instrument.

Warnings - Cleaning and Maintenance

Warning

- The instrument should always be cleaned after the end of work, but BEFORE the instrument is shut down. An exception from this is cleaning the interior (→ P. 111 – 7.2.4 Interior cleaning). We recommend cleaning while the instrument is shut down.
- When cleaning the instrument, wear suitable protective clothing (lab coat, cut-resistant gloves and safety goggles) to protect from reagents and potentially infectious micro-biological debris.
- When using cleaners, please comply with the safety instructions of the manufacturer and the laboratory safety regulations.
- Do not use any of the following for cleaning the outside surfaces of the instrument: alcohol, detergents containing alcohol (glass cleaners), abrasive cleaning powders, solvents containing acetone, ammonia, chlorine, or xylene!
- Clean the hood and housing using mild commercial, pH-neutral household cleaners. The finished surfaces are not resistant to solvents and xylene substitutes!
- The plastic reagent vessels can be cleaned in a dishwasher at a maximum temperature of +65 °C. Any standard cleaning agent for laboratory dishwashers may be used. Never clean the plastic reagent vessels at higher temperatures since higher temperatures can cause the reagent vessels to become deformed.

2.3 Safety features on the instrument

Warning

- Make sure to keep the hood closed whenever coverslipping processes are active. Leica assumes no liability for loss of quality caused by opening the hood during processing.
- If the hood of the instrument is opened, the movements are stopped for safety reasons as soon as the slide currently being coverslipped is finished being coverslipped in order to avoid any risk of specimen damage due to collision with moving parts.
- Opening the hood when one or more coverslipping process(es) is/are active causes delays in the respective processing steps since no transport movements take place for this time frame.

3. Instrument Components and Specifications

3.1 Standard delivery – packing list

Qty		Designation	Order No.
1		HistoCore SPECTRA CV basic instrument	14 0514 54200
4		Rack for 30 slides* (3 pcs. per package)	14 0512 52473
1		Handle for rack for 30 slides* (yellow, 3 pcs. per package)	14 0512 52476
1		Handle for rack for 30 slides* (light blue, 3 pcs. per package)	14 0512 52477
1		Handle for rack for 30 slides* (red, 3 pcs. per package)	14 0512 52480
1		Handle for rack for 30 slides* (white, 3 pcs. per package)	14 0512 52484
2		Label cover S	14 0512 53748
2		Label cover, blank	14 0512 47323
2		Reagent vessel, assembly, each consisting of 1 pc.:	14 0512 47086
		Reagent vessel	14 0512 47081
		Reagent vessel cover	14 0512 47085
		Reagent vessel handle	14 0512 47084
1		Prime bottle, assembly, consisting of:	14 0514 53931
	1	Lab bottle, 150 ml	14 0514 56202
	1	Screw cap	14 0478 39993
	1	Prime bottle insert	14 0514 57251
	1	28x3 mm O-ring	14 0253 39635
1		Cleaning bottle	14 0514 57248
1		Needle cleaning container, kit (2 pcs., as reserve)	14 0514 54195
3		Rack storage rails for the unload drawer	14 0514 55967
1		Exhaust air hose set, consisting of:	14 0514 54815
	1	Exhaust air hose, 2 m	14 0422 31974
	1	Hose clamp	14 0422 31973
1		Pair of cut-resistant gloves, size M	14 0340 29011
1		Tool kit HistoCore SPECTRA CV, consisting of:	14 0514 54189
	1	Screwdriver, 5.5x150	14 0170 10702
	1	Leica brush	14 0183 30751
	2	T16A fuse	14 6000 04696
1		Active carbon filter set, consisting of:	14 0512 53772
	2	Active carbon filter	14 0512 47131
4		Suction cups (as reserve)	14 3000 00403
2		Waste trays	14 0514 49461
1		Instructions for Use, printed (German/English, with language CD 14 0514 80200)	14 0514 80001

*OT = slide

The country-specific power cable must be ordered separately. A list of all power cables that are available for your instrument can be found on our website www.LeicaBiosystems.com in the Product area.

Note

The delivered components must be carefully compared against the packing list, delivery note, and your order. Should you find any discrepancies, please contact your Leica sales office without delay.

3.2 Technical data

Nominal supply voltages:		100–240 V AC ±10 %
Nominal frequency:		50/60 Hz
Power draw:		1100 VA
Fuses:		2 x T16 A H 250 V AC
IEC 1010 classification:		Protection class 1
Pollution degree in accordance with IEC61010-1:		2
Overvoltage category in accordance with IEC61010-1:		II
Exhaust air:	Hose length:	2000 mm
	Inner diameter:	50 mm
	Outer diameter:	60 mm
	Exhaust performance:	30 m^3/h
Exhaust extraction:	Active carbon filter and exhaust hose for connecting with an external exhaust system.	
Heat emission:		1100 J/s
A-weighted noise level, measured at 1 m distance:		< 60 dB (A)
Connections:		
1 x RJ45 Ethernet (rear):	RJ45 - LAN (external data management)	
1 x RJ45 Ethernet (front):	Only for service purposes	
2 x USB 2.0 (front):	5 V/500 mA (service & data storage)	
International protection class:		IP20
1st parameter = Protected against fixed foreign bodies with a diameter ≥ 12.5 mm		
2nd parameter = No protection against water		
Ambient conditions:		
Operation:	Temperature:	+18 °C to +30 °C
	Relative humidity:	20 % to 80 %, non-condensing
	Operating elevation:	Up to a max. of 2000 m above sea level
Storage:	Temperature:	+5 °C to +50 °C
	Relative humidity:	10 % to 85 %, non-condensing
Transport:	Temperature:	-29 °C to +50 °C

	Relative humidity:	10 % to 85 %, non-condensing
HistoCore SPECTRA CV Dimensions and weights:	Dimensions (length x depth x height):	Hood closed: 690 x 785 x 585 mm Hood opened: 690 x 785 x 943 mm
	Empty weight (without reagents and accessories):	110 kg
Workstation dimensions and weights (HistoCore SPECTRA CV and HistoCore SPECTRA ST):	Dimensions (length x depth x height):	Hood closed: 2044 x 785 x 585 mm Hood opened: 2044 x 785 x 943 mm
	Empty weight (without reagents and accessories):	295 kg
Performance:	Usable slides:	In accordance with DIN ISO 8037-1 (76 mm x 26 mm)
	Coverglass cartridge capacity:	Exclusively Leica consumables with 300 coverglasses per magazine
	Coverglasses:	Exclusively Leica consumables. Available size: 50 mm x 24 mm, thickness: No. 1 In accordance with ISO 8255-1
	Mounting medium application quantity:	Preset value corresponding to coverglass size. Fine adjustment by users possible.
	Types of mounting media:	Exclusively Leica consumables: X1 mounting medium
	Capacity of mounting medium bottle:	At least 1600 slides
	Racks:	Leica rack for 30 slides
Factory settings:	Mounting medium application volume:	0 (→ P. 60 – 5.8.6 Volume calibration)
	Oven temperature:	40 °C (not changeable)
	Oven step:	Enabled
	Date format:	International (DD.MM.YYYY)
	Time format:	24 h
	Language:	English

Note

When using an external uninterruptible power supply (UPS), it should be designed for an output of at least 1100 VA and ensure operation over a time frame of at least 10 minutes.

3.3 General overview - front view

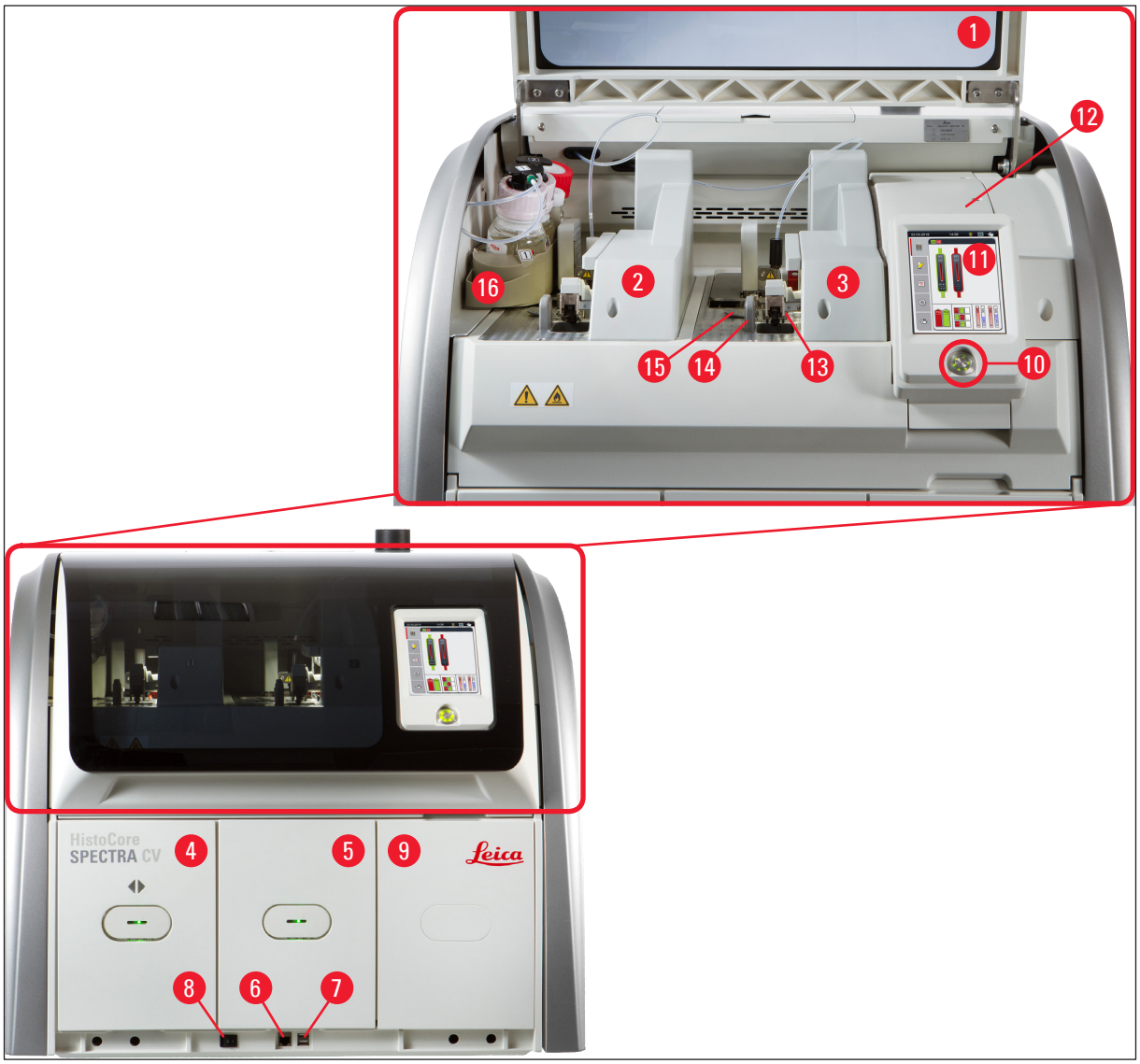


Fig. 2

1	Instrument cover	**9**	Access to oven
2	Left coverslip line L1	**10**	Operating switch
3	Right coverslip line L2	**11**	Screen with user interface
4	Load drawer	**12**	Fuses
5	Unload drawer	**13**	Pick&Place module
6	Service access	**14**	Waste tray
7	USB slot	**15**	Coverglass cartridge
8	Main switch	**16**	Bottle sledge

3.4 General overview - rear view

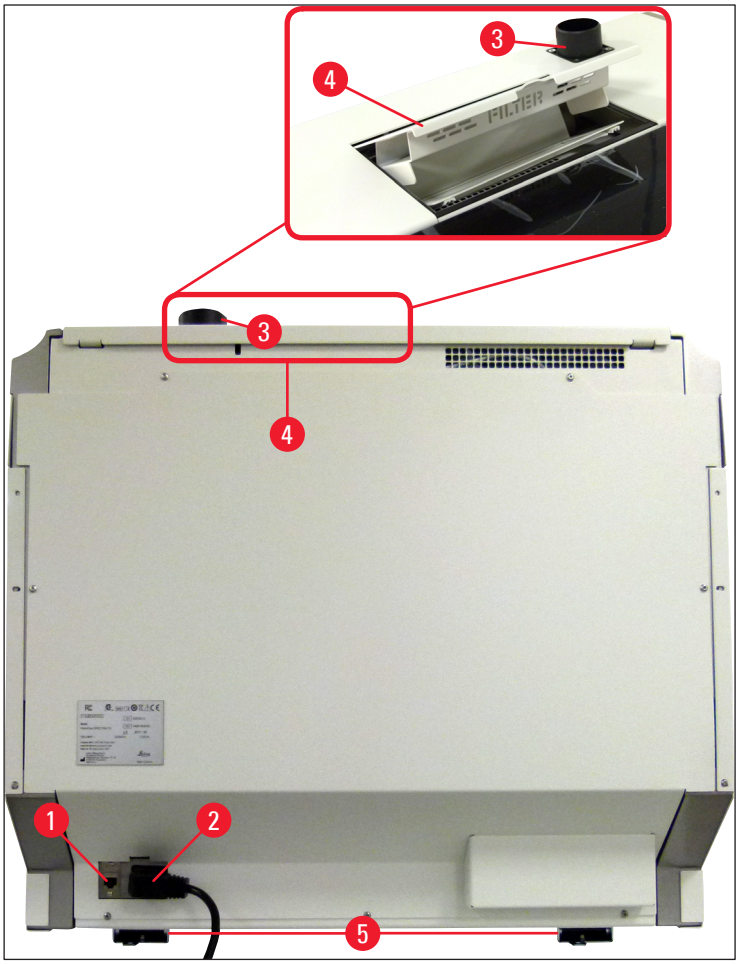


Fig. 3

1	Network connection (Remote Care)	**4**	Access to active carbon filter
2	Power supply	**5**	Height-adjustable instrument feet
3	Exhaust air connection		

3.5 General overview - inside view

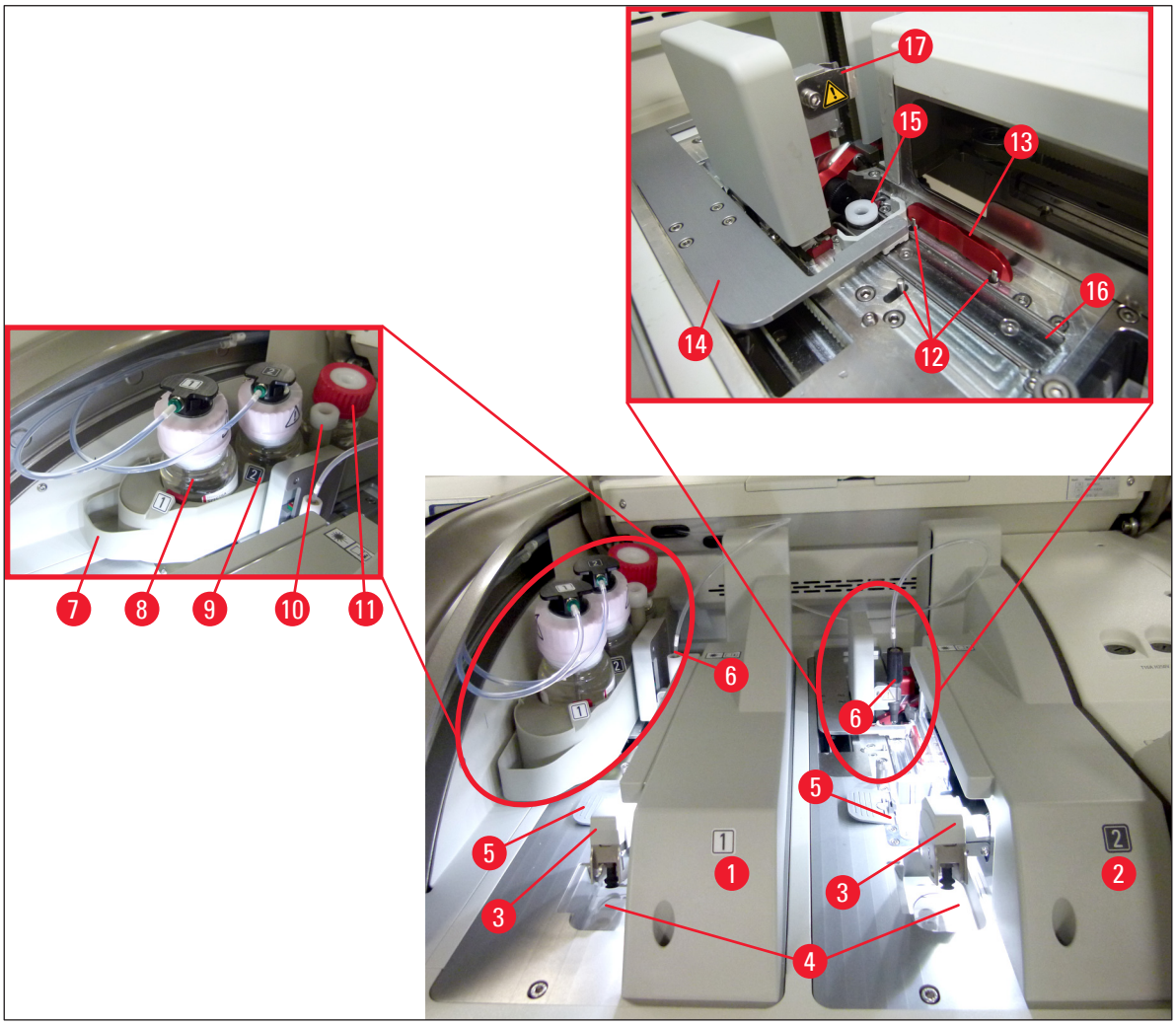


Fig. 4

1	Left coverslip line L1	**10**	Parking location
2	Right coverslip line L2	**11**	Prime bottle
3	Pick&Place module	**12**	Alignment pins
4	Waste tray	**13**	Red bar
5	Coverglass cartridge	**14**	Shifter and shifter tongue
6	Needle	**15**	Needle cleaning container
7	Bottle sledge	**16**	Coverslipping position of the slide
8	Mounting medium bottle L1	**17**	Needle holder
9	Mounting medium bottle L2		

4. Installation and Instrument Setup

4.1 Installation site requirements

Note

- Installation, adjustment and level alignment of the instrument are carried out as part of the instrument installation by a service technician certified by Leica only.
- The level orientation is done using a level and by adjusting the height-adjustable instrument feet (→ Fig. 3-5).
- Use 4 qualified persons when lifting the instrument. Grab under the frame at all corners and lift evenly.

Warning

Failure to level the instrument correctly may result in instrument malfunctions. Slides may slide out of the rack during the necessary transport movements.

- Ensure that there is a vibration-free floor and sufficient clear space (approx. 1.10 m) above the laboratory bench to allow unobstructed opening of the hood.
- It is the user's responsibility to make sure that a compatible electromagnetic environment is maintained so that the instrument can work as intended.
- Condensation water may form in the instrument if there is an extreme difference in temperature between the storage location and the installation site and if air humidity is high at the same time. A waiting time of at least two hours must be observed each time before switching on. Failure to comply with this may cause damage to the instrument.
- Stable, exactly horizontal and level laboratory bench at least 1.00 m wide (2.20 m when operating as a workstation) and 0.80 m deep.
- The counter area must be designed for handling loads of at least 150 kg/m^2, vibration-free and level.
- Fume hood at a max. 2.0 m distance from the instrument.
- The instrument is suitable for operation in indoor areas only.
- The operating location must be well-ventilated and have an air exhaust.
- A grounded power supply socket must be available at a maximum distance of 3 m.

Warning

- A connection to an external exhaust system, a technical room ventilation system and an integrated exhaust system with an active carbon filter reduce the concentration of solvent vapor in the room air. The active carbon filter must be used for connecting to an external exhaust system as well (→ P. 121 – 7.2.15 Changing the active carbon filter). Compliance with this is mandatory.
- The instrument operator bears responsibility for complying with workplace limits and the measures necessary for this, including documentation.

4.2 Electrical connection

Warning

- Use only the power cable provided, which is intended for the local power supply.
- Before connecting the instrument to the power supply, make sure that the Main switch on the bottom front of the instrument (→ Fig. 2-8) is in the OFF ("0") position.

1. Connect the power cable to the power input socket on the rear panel of the instrument (→ Fig. 5-1).
2. Plug the power plug into a grounded power socket.
3. Switch on the Main switch (→ Fig. 2-8).

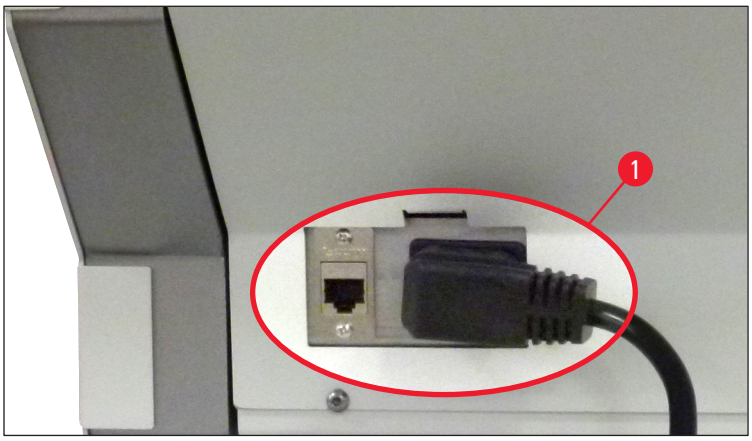


Fig. 5

4. After a short period of time, the Operating switch lights up orange. Once the software has finished starting up, the switch lights up red (→ Fig. 6-1) and the instrument is in standby mode.
5. The Operating switch can then be operated.

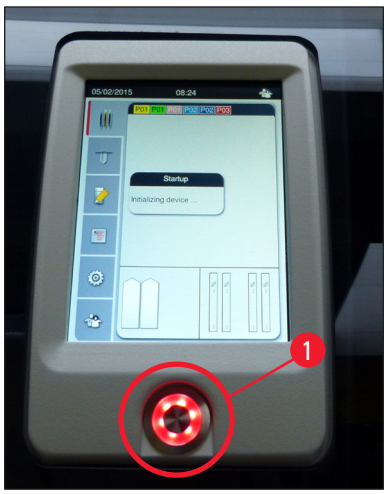


Fig. 6

4.2.1 Internal battery

- The HistoCore SPECTRA CV has a high-performance internal battery to bridge short-term power failures (< 3 s.). This enables processing to continue without interruption during a short-term power failure.
- The software detects if the power failure lasts longer than 3 sec. and initiates a controlled shutdown of the instrument (→ P. 139 – 8.2 Power failure scenario and instrument failure).

Note

- The internal battery has to be recharged when initializing the instrument after a power failure. The user is notified of the charging process by a note on the screen. Once the charging process has finished, the information message goes away automatically and the software prompts the user to check if there are any racks still in the instrument and to remove them by hand if necessary. The user confirms the removal of the rack by pressing the Ok button. Then the instrument restarts.
- The internal battery has to be charged if the instrument has been disconnected from a power supply for a prolonged time. For this purpose, connect the instrument to the socket and switch on the Main switch (→ Fig. 2-8). The charging time is approx. 30 minutes.

4.2.2 Using an external uninterruptible power supply (UPS)

An interruption of processing can be avoided in the event of a temporary power failure by connecting a battery-buffered uninterruptible power supply (UPS) (→ Fig. 7-1).

The UPS should enable an output of at least 1100 VA for the duration of 10 minutes.

The UPS must be designed for operating voltage at the installation location. The connection is carried out by connecting the HistoCore SPECTRA CV power cable to the UPS power output socket. The UPS is connected to the power socket in the lab.

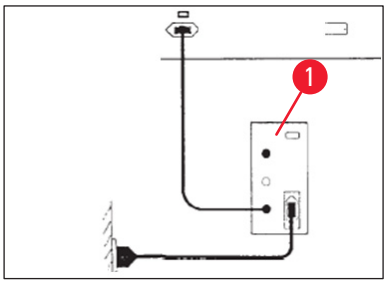


Fig. 7

Warning

The UPS power cable must always remain in the power socket in the lab, even in the event of a power outage. Otherwise grounding of the instrument cannot be ensured!

4.3 Exhaust air connection

» Connect one end of the exhaust air hose (→ Fig. 8-1) to the exhaust air connection (→ Fig. 3-3) on the top side of the instrument using the hose clamp (→ P. 19 – 3.1 Standard delivery – packing list) included in the standard scope of delivery (→ Fig. 8-2). Connect the other end to an exhaust air device installed at the lab.

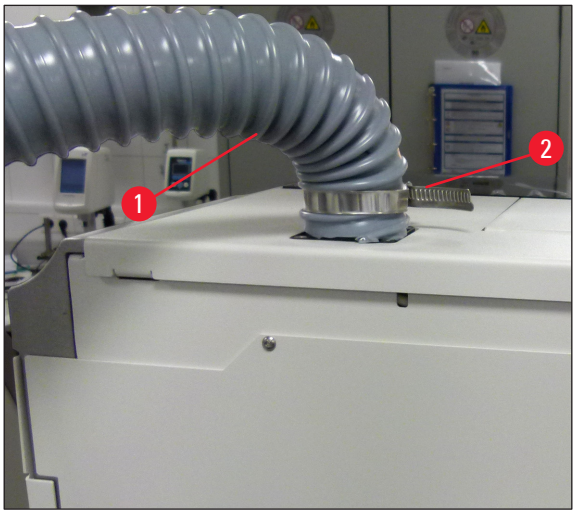


Fig. 8

Warning

The active carbon filter must be used for connecting to an external exhaust system as well (→ P. 121 – 7.2.15 Changing the active carbon filter). Compliance with this is mandatory.

4.4 Installing the accessories

4.4.1 Fit the drawer inserts into the unload drawer

Note

The load and unload drawers can be manually opened while the system's power is turned off.

1. Manually pull the unload drawer until it stops.
2. For a simplified fitting of the inserts, the unload drawer can be further opened. For this purpose, raise the red retaining lever (→ Fig. 9-3) that moves the unload drawer completely out of the instrument and carefully fold it downwards.
3. Insert the three inserts (→ Fig. 9-1) into the compartments (→ Fig. 9-2) in the unload drawer.

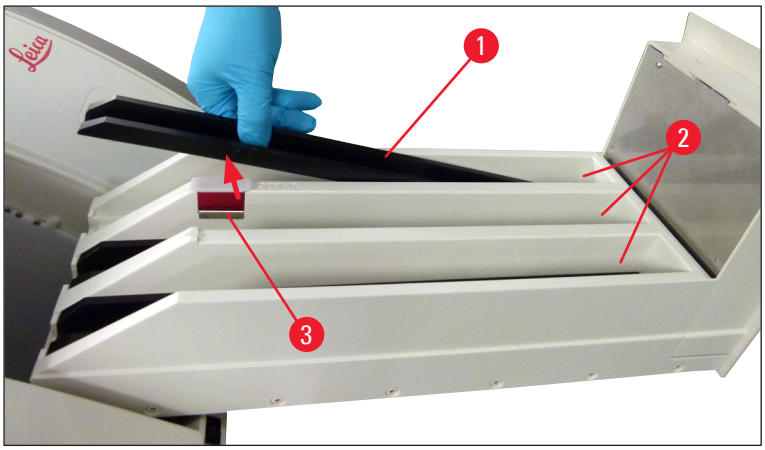


Fig. 9

4. Finally, lift the unload drawer and slide it back in the instrument.

4.4.2 Inserting the waste tray

» Remove the waste tray (→ Fig. 10-1) from the packaging and insert it into the instrument at the recess (→ Fig. 10-2) provided.

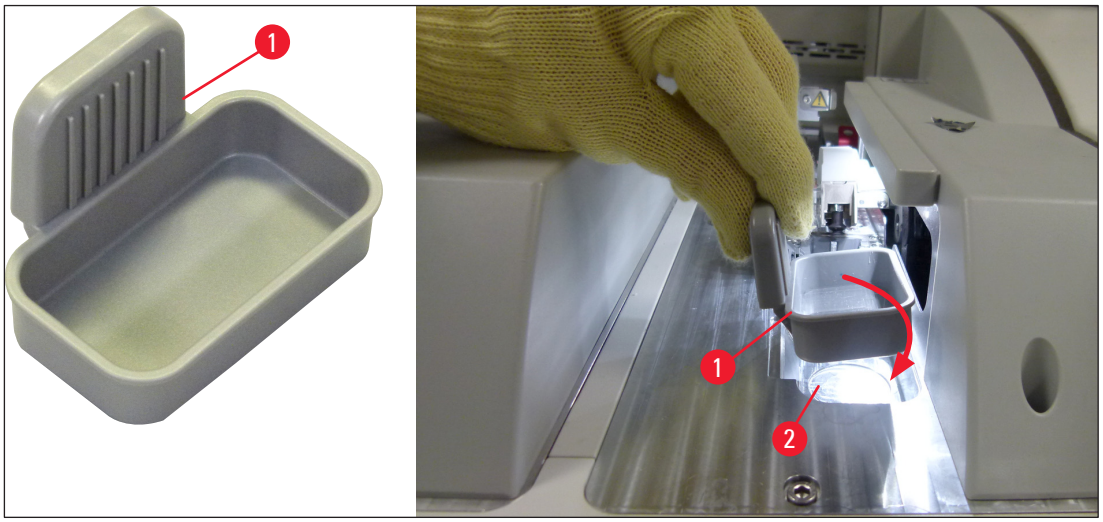


Fig. 10

4.4.3 Filling and inserting the needle cleaning container

Warning

The safety notes for reagent handling must be observed!

- Caution when handling solvents!
- Always wear suitable lab protective clothing, as well as gloves and safety goggles, when handling reagents.
- Always fill or drain needle cleaning containers outside of the instrument in compliance with safety information to avoid or reduce the risk of spilling reagents.

Note

- The needle cleaning container is used for holding the needle during instrument breaks. Immersing the needle in the filled solvent prevents the needle from becoming stuck and allows it to remain permeable.
- A filled needle cleaning container must be used in both coverslip line L1 and L2.
- Before inserting the needle cleaning container, make sure that the complete unit for the needle cleaning container (→ P. 115 – 7.2.9 Removing the complete unit of the needle cleaning container) has been fixed in both coverslip lines during initial installation.
- Do not leave the needle in the rest position for longer than necessary in order to prevent drying out.

1. Switch on the instrument (→ P. 31 – 4.5 Switching on and shutting down the instrument).
2. Switch to the **Module Status** (→ P. 74 – 5.11 Module status) and press the **Prime/Clean** button of coverslip line L1 or L2 in order to lift the respective needle holder.
3. Move the shifter (→ Fig. 11-1) into a position that enables access to the slot for the needle cleaning container (→ Fig. 11-2).
4. Remove the needle from the holder and plug into the parking location (→ Fig. 4-10).
5. Remove the needle cleaning container (→ Fig. 11-3) from the packaging and fill with xylene to the bottom edge of the cap, outside of the instrument (→ Fig. 11-5).
6. Following this, plug the needle cleaning container in the slot and press downwards until it clicks into place.
7. Remove the needle from the parking location and plug it back into the holder (→ Fig. 88).

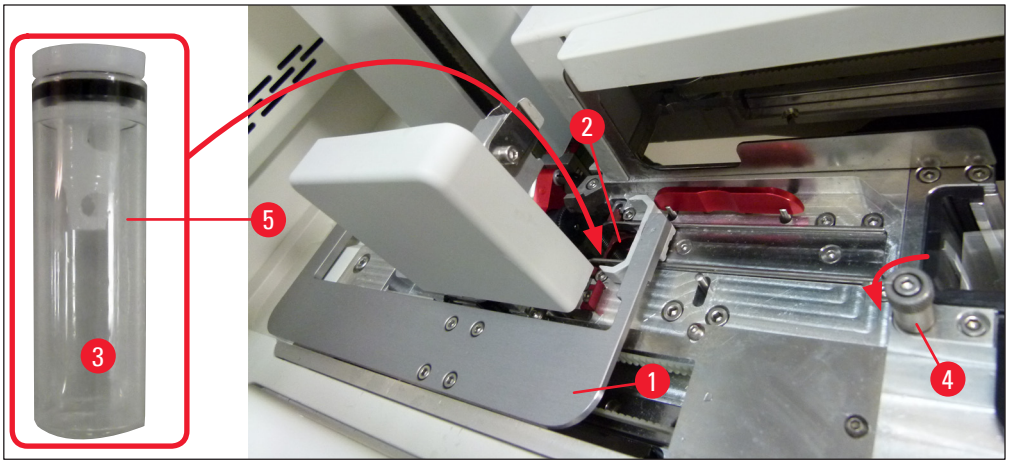


Fig. 11

Note

- If it is impossible to lift the needle cleaning container by rotating the knurled screw clockwise (it might be clogged with residual mountant), it can be removed as described in (→ P. 115 – 7.2.9 Removing the complete unit of the needle cleaning container).
- The needle has a notch (→ Fig. 88-3) that fits exactly in the holder. The Attention symbol (→ Fig. 88-4) on the holder (→ Fig. 88-2) indicates to the user that utmost care is required when inserting the needle into the holder. The needle must be inserted straight and all the way in order to make sure that no negative impact on the samples arises during processing.

4.5 Switching on and shutting down the instrument

Warning

The instrument must be connected to a grounded power socket. For additional electrical fuse protection, connecting the HistoCore SPECTRA CV to a socket with a residual current circuit breaker (RCCB) is recommended.

Note

- The needle cleaning container must be filled with solvent (→ P. 30 – 4.4.3 Filling and inserting the needle cleaning container), since otherwise initialization cannot be successfully performed.
- During the instrument setup or if no consumables (mounting medium and coverglass) have been added, the modules are displayed in the display as empty (→ Fig. 23).

1. Switch the **Main switch** on the front of the instrument (→ Fig. 2-8) to **ON** ("I").
2. Fill the needle cleaning container with a sufficient amount of solvent (→ P. 30 – 4.4.3 Filling and inserting the needle cleaning container).
3. A few seconds after switching on the **Main switch**, the **Operating switch** is illuminated in orange (→ Fig. 12-1). The software's start process ends when the **Operating switch** is illuminated in red.

Note

Pressing the **Operating switch** in the orange phase does not start the instrument.

Switching on and shutting down the instrument in workstation mode

Warning

If the HistoCore SPECTRA CV is operated together with a HistoCore SPECTRA ST as workstation (→ P. 105 – 6.7 Workstation operation), a message is always displayed upon switching on the HistoCore SPECTRA CV. This information message instructs the user to ensure that the reagent vessels in the load drawer are sufficiently filled (→ P. 39 – Correct fill level of the reagent vessels) and the covers have been removed. Note the information message and confirm with **OK**. Failure to observe this information message this may lead to a loss of specimen and instrument faults.

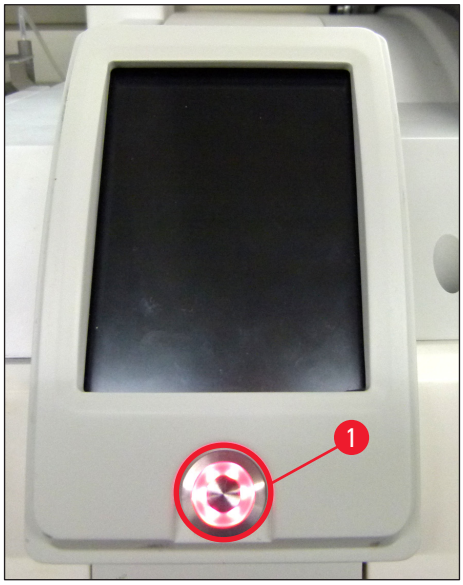


Fig. 12

4. To start the instrument, now press the illuminated in red **Operating switch** (→ Fig. 12-1); an audible signal sounds.
5. During initialization, a verification of all stations (**fill level scan**) is carried out automatically. Furthermore, the level of the needle cleaning containers is checked during operation approximately every 4 hours.
6. The **Operating switch** is illuminated in green whenever the instrument is ready to start.
7. After completing the initialization phase, the **Main menu** (→ Fig. 13) appears on the screen.

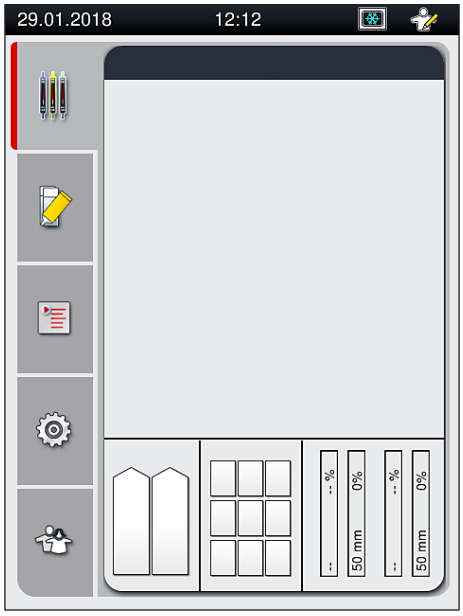


Fig. 13

Shutting down the instrument

1. To switch the instrument into standby mode (e.g. overnight), remove all racks from the instrument and then press the **Operating switch** (→ Fig. 12-1) twice. It then illuminates in red.

Note

If there is a rack in the instrument while the **Operating switch** is pressed, the user receives an information message indicating that the instrument cannot be shut down until the rack is no longer in the process or no longer present in the instrument. Any processing in progress is continued.

2. For cleaning and maintenance, switch off the instrument at the **Main switch** and also observe the instructions in (→ P. 109 – 7.1 Important notes about cleaning this instrument).

4.6 Refilling consumables

Warning

- Only original consumables that have been verified by Leica may be used (→ P. 160 – Consumables) in order to avoid instrument faults.
- Caution when handling solvents!
- Always wear protective clothing suitable for laboratory use, as well as rubber gloves and safety goggles when handling the chemicals used in this instrument.
- Only clean reagent vessels should be used (→ P. 121 – 7.2.16 Cleaning reagent vessels in the load drawer).
- Always fill or drain reagent vessels and the needle cleaning container outside of the instrument in compliance with safety information to avoid or reduce the risk of spilling reagents into other reagent vessels and onto interior instrument components.
- Proceed carefully and thoroughly when filling or draining and follow the respective applicable laboratory specifications. Remove spilled reagents immediately. If a reagent vessel in the load drawer has been contaminated, cleaning and refilling it is mandatory.

Note

- Validated coverglass (→ P. 71 – 5.9.4 Properties of the coverglass) and a validated mounting medium (→ P. 70 – 5.9.3 Properties of the mounting medium) are available for the HistoCore SPECTRA CV. Ordering information: (→ P. 160 – Consumables).
- If fewer than 300 slides are coverslipped per day on an ongoing basis, the HistoCore SPECTRA CV can also be operated with just a single coverslip line. In this configuration, do not fill any consumables (mounting medium, coverglass) in the unused coverslip line. Please note: Each time a rack is inserted into the load drawer, the software indicates to the user that there are missing consumables in the unused line. Confirm each of the respective information messages with **OK**.
- A check and a scan of the consumables is always performed after the hood has been closed.

4.6.1 Inserting a coverglass cartridge

Note

- Validated coverglass (→ P. 71 – 5.9.4 Properties of the coverglass) are available for the HistoCore SPECTRA CV. The coverglasses are only available packaged in magazines. The magazines are automatically read by the instrument when inserted and the data is sent to the consumables management system (CMS) (e.g. number and size).
- Only original coverglass that has been verified by Leica may be used (→ P. 160 – Consumables) in order to avoid instrument faults.
- The packaging should not be opened until immediately before inserting the coverglass cartridge into the instrument. This prevents a possible sticking of the coverglass due to humidity.
- An RFID chip is integrated into the coverglass cartridge, which ensures that the consumables management system (CMS) is given reliable information about the coverglass used (size and remaining amount).

Warning

Before inserting the coverglass cartridge (→ Fig. 14-1), remove both the packaging foam (→ Fig. 14-2) and the silica gel packet (→ Fig. 14-3).

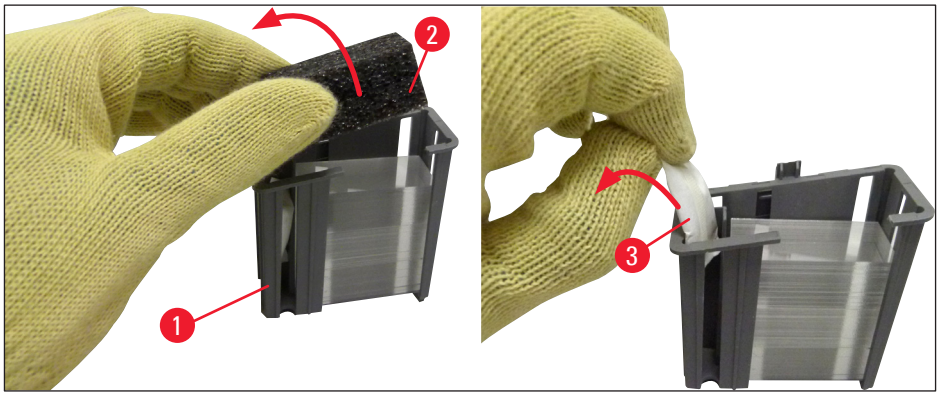


Fig. 14

1. Open the hood.
2. The Pick&Place module is located above the waste tray.
3. Unpack the coverglass cartridge (→ Fig. 14-1) and remove the foam insert (→ Fig. 14-2) and silica gel packet (→ Fig. 14-3).
4. Insert the coverglass cartridge (→ Fig. 15-1) into the slot of the coverglass cartridge (→ Fig. 15-2).
5. Close the instrument hood.
6. The coverglass cartridge data is imported and the **Module Status** (→ Fig. 23) is updated.