

Leica Autostainer XL (ST5010)

Automated slide stainer



Instructions for Use
English

Order No.: 14 0456 80101 - Revision 0

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



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.

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



Leica Biosystems Nussloch GmbH
Heidelberger Strasse 17 - 19
69226 Nussloch
Germany
Tel.: +49 - (0) 6224 - 143 0
Fax: +49 - (0) 6224 - 143 268
Web: www.LeicaBiosystems.com

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1 Important Information

1. Important Information

General information

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. They must be read carefully prior to startup and use, and must always be kept near the instrument.

If additional requirements for accident prevention and environmental protection apply in the country of operation, these Instructions for Use must be supplemented by appropriate instructions to ensure compliance with such requirements.

Make sure to read all of these Instructions for Use before you work on or operate the instrument.



Warning

Be sure to comply with the safety instructions and warnings in (→ p. 12 – 2. Safety). Be sure to read these notes even if you are already familiar with the operation and use of other Leica products.

1.1 Symbols in the text and their meaning

Symbol:



Title of the symbol:

Warning

Description:

Warnings appear in a white box and are marked by a warning triangle.

Symbol:



Title of the symbol:

Note

Description:

Useful tips, i.e. important information for the user, appear in white boxes and are marked by an information symbol.

Symbol:

→ "Fig. 7 - 1"

Title of the symbol:

Item number

Description:

Numbers in parentheses refer to item numbers in illustrations or to the illustrations themselves.

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:

Consult Instructions for Use

Description:

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

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.

Symbol:



Title of the symbol:

Description:

WEEE Symbol

The WEEE (**W**aste **E**lectrical and **E**lectronic **E**quipment) symbol, indicating separate collection of electrical and electronic equipment, consists of a crossed-out wheeled bin (§ 7 ElektroG).

Symbol:



Title of the symbol:

Description:

CE Label

The CE marking is the manufacturer's declaration that the medical product meets the requirements of the applicable EC directives and regulations.

Symbol:



Title of the symbol:

Description:

UKCA Label

The UKCA (UK Conformity Assessed) marking is a new UK product marking that is used for goods being placed on the market in Great Britain (England, Wales and Scotland). It covers most goods which previously required the CE marking.

Symbol:



Leica Microsystems (UK) Limited
Larch House, Woodlands Business Park, Milton Keynes
England, United Kingdom, MK146FG

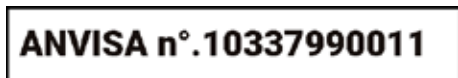
Title of the symbol:

Description:

UK Responsible Person

The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations.

Symbol:



Title of the symbol:

Description:

ANVISA Identification number

The National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – ANVISA) is responsible for the registration of medical devices in Brazil and assigns a unique 11-digit identification number to each device, according to specific resolutions.

Symbol:



Title of the symbol:

Description:

Caution

Indicates that caution is necessary when operating the device or control close to where the symbol is placed or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

Symbol:



Title of the symbol:

Description:

Caution – Moving parts

Label is attached on the transport arm. It indicates a risk of collision between the transport arm and any operator working within the instrument while the transport arm is moving.

Symbols:**Title of the symbol:**

Caution – Toxic chemicals / Flammable substances

Description:

Labels are attached inside the instrument below the fixation of the hood (in the middle).

The first label indicates that toxic chemicals are inside the instrument. Do not handle solution vessels unless properly protected.

The second label indicates that there is a risk of fire because of flammable substances inside the instrument. Thus, avoid any source of ignition close to the instrument.

Symbol:**Title of the symbol:**

Caution – Hot surface

Description:

Two labels are attached close to the oven. They indicate a risk of burns because of hot surfaces. Do not touch these parts.

Symbol:**Title of the symbol:**

Caution – Risk of fire

Description:

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

Symbol:**Title of the symbol:**

Caution – Input voltage

Description:

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

Symbol:**Title of the symbol:**

Caution – Water supply and interfaces

Description:

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

Symbol:**Title of the symbol:**

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:**

Serial number

Description:

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

Symbol:**Title of the symbol:**








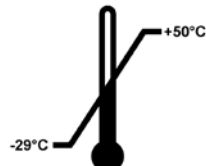
Article number

Description:

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

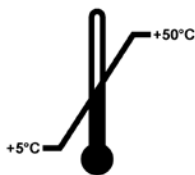
Symbol:**Title of the symbol:**

Alternating current

<p>Symbol:</p> 	<p>Title of the symbol: Description:</p>	<p>Manufacturing date Indicates the date when the medical device was manufactured.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Description:</p>	<p>Manufacturer Indicates the manufacturer of the medical product.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Description:</p>	<p>This way up Indicates correct upright position of the transport package.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Description:</p>	<p>Store dry Indicates a medical device that needs to be protected from moisture.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Description:</p>	<p>Country of Origin The Country of Origin box defines the country where the final character transformation of the product has been performed.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Description:</p>	<p>Fragile, handle with care Indicates a medical device that can be broken or damaged if not handled carefully.</p>
<p>Symbol:</p> 	<p>Title of the symbol: Description:</p>	<p>Stack limit The largest number of identical packages allowed to be stacked; "2" stands for the number of permitted packages.</p>
<p>Symbol:</p> <p>Transport temperature range:</p> 	<p>Title of the symbol: Description:</p>	<p>Temperature limit for transport Indicates the transport temperature limits to which the medical device can be safely exposed.</p>

Symbol:

Storage temperature range:

**Title of the symbol:**

Temperature limit for storage

Description:

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

Symbol:**Title of the symbol:**

Humidity limitation for transport and storage

Description:

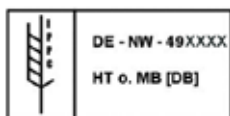
Indicates the range of humidity for transport and storage to which the medical device can be safely exposed.

Symbol:**Title of the symbol:**

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.

Symbol:**Title of the symbol:**

IPPC symbol

Description:

The IPPC symbol includes IPPC symbol

- Country code to ISO 3166, e.g. DE for Germany
- Regional identifier, e.g. NW for North Rhine-Westphalia
- Registration number, unique number beginning with 49.
- Treatment method, e.g. HT (heat treatment)

Symbol:**Title of the symbol:**

ON / STOP (Power)

Description:

ON: The electronic power supply is connected upon pushing the power switch.

STOP: The electronic power supply is disconnected upon pushing the power switch.

Label is attached close to the electronic power supply switch.

1.2 Instrument type

All information given in these Instructions for Use applies only to the instrument type indicated on the title page. A nameplate indicating the instrument serial number is attached to the rear side of the instrument. Precise data for the various versions is specified in (→ p. 19 – 3.3 Technical Data).

1.3 Intended purpose

The Leica Autostainer XL (ST5010) is an automated stainer specifically designed for staining of human tissue specimens in order to contrast cell formations and their components used for histological medical diagnosis by a pathologist, e.g. for cancer diagnosis.

The Leica Autostainer XL (ST5010) is designed for in vitro diagnostic applications.



Warning

Any use of the instrument that deviates from the intended purpose 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 purpose includes compliance with all inspection and maintenance instructions, along with the observance of all instructions in the Instructions for Use as well as the constant inspection of the reagents for storage life and quality. The Leica Autostainer XL (ST5010) carries out the specified staining steps automatically. The manufacturer assumes no liability for the staining results in the case that the staining steps and programs are entered incorrectly. Thus, the end user is independently responsible for self-created reagents or program entries.

1.4 User group

- The Leica Autostainer XL (ST5010) should be operated by trained laboratory personnel only.
- All laboratory personnel designated to operate the Leica Autostainer XL (ST5010) must read these Instructions for Use carefully and must be familiar with all technical features of the instrument before attempting to operate the Leica Autostainer XL (ST5010). The instrument is intended for professional use only.



Note

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

2. Safety

2.1 General 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:

- This instrument has been built and tested in accordance with the safety requirements for electrical equipment for measurement, control and laboratory use. 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.
- To maintain this condition and ensure safe operation, the user must observe all notes and warnings contained in these Instructions for Use.
- 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 permitted original Leica accessories may be used.
- In accordance with national rules and regulations, the operator may be obligated to provide long-term protection of the public water supply from contamination due to backflowing water from the building installation. In Europe, the protection device of the potable water installation to be connected is selected in accordance with the specifications of DIN EN 1717:2011-08 (information status August 2013).

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

Warnings – Handling reagents



Warning

- Exercise 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.
- The installation site must be well-ventilated. In addition, we highly recommend connecting the instrument to an external exhaust air extraction system. The chemicals to be used in the Leica Autostainer XL (ST5010) are flammable and hazardous to health.
- Do not operate the instrument in rooms with an explosion hazard.
- Use only reagents and consumables which are within their expiration date.
- 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.

2.2 Specific safety notes



Warning

Operating the instrument without adequate clothing

Personal injury

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



Warning

Breathing in vapors dangerous to health

Personal injury

- Connect the instrument to a laboratory air exhaust system using the dedicated hose (lengths of 2 m and 4 m available). Alternatively the instrument can be operated below a fume cupboard. This should be run in addition to the active carbon filter.



Warning

Contamination after accidental handling of reagents

Insufficient staining quality or complete loss of tissue

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



Warning

Vessels not cleaned or cleaned insufficiently before refilling with another reagent

Insufficient staining quality, tissue damage or loss of tissue

- Always clean the vessels thoroughly and regularly before refilling them (→ p. 40 – 6.2 Reagent vessels).



Caution

Inadequate manual loading of specimen slide holders into vessels

Loss of tissue and / or property damage because of crash due to automatized loading of another specimen slide holder into the same vessel

- Do not manually load specimen slide holders and start any movement of the transport arm



Caution

Lids not removed from vessel

Loss of tissue and / or property damage because of crash due to automatized loading of a specimen slide holder

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

2 Safety



Caution

Specimen slide holders are loaded unintentionally into exit drawer instead of the load drawer.

Delay of processing time / Damage or loss of tissue

- Always pay attention to load specimen slide holders into the load drawer (→ p. 36 – 5.9.4 [Loading specimen slide holders](#)).



Caution

Reagent filling level within vessels is insufficient

Loss of tissue and / or property damage because of crash due to automatized loading of a specimen slide holder

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



Caution

Water drainage not cleaned or cleaned insufficiently

Insufficient staining quality, loss of tissue or property damage

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



Caution

Specimen slide holders not unloaded in a timely manner from exit drawer

Delay of processing time / Damage or loss of tissue

- Unload the exit drawer in time, close the exit drawer and press **EXIT** (→ p. 36 – 5.9.5 [Unloading specimen slide holders from the exit drawer](#)).



Caution

Specimen slide holder processed with wrong program parameters

Damage or loss of tissue

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

3. Instrument Features

3.1 General description

The Leica Autostainer XL (ST5010) was developed with the goal of satisfying the quality requirements of modern laboratories:

- high specimen throughput,
- flexibility,
- safety.

The Leica Autostainer XL (ST5010) achieves its high throughput by means of a specimen slide transport system, which allows for simultaneous processing of up to 11 specimen slide holders, each with 30 slides.

The flexibility of Leica Autostainer XL (ST5010) permits simultaneous processing of specimen slide holders according to various staining protocols.

An oven is integrated into the instrument which accelerates drying of specimen slides. Optimized wash stations provide for rapid removal of reagent residue. The design of the specimen slide holders ensures minimal reagent displacement and prevents the reagents from being contaminated by liquid dripping into them and needing to be replaced prematurely.

The Leica Autostainer XL (ST5010) is safe to use and has an integrated system for extracting reagent vapors. The specimen slide holders are loaded and unloaded using two drawers.

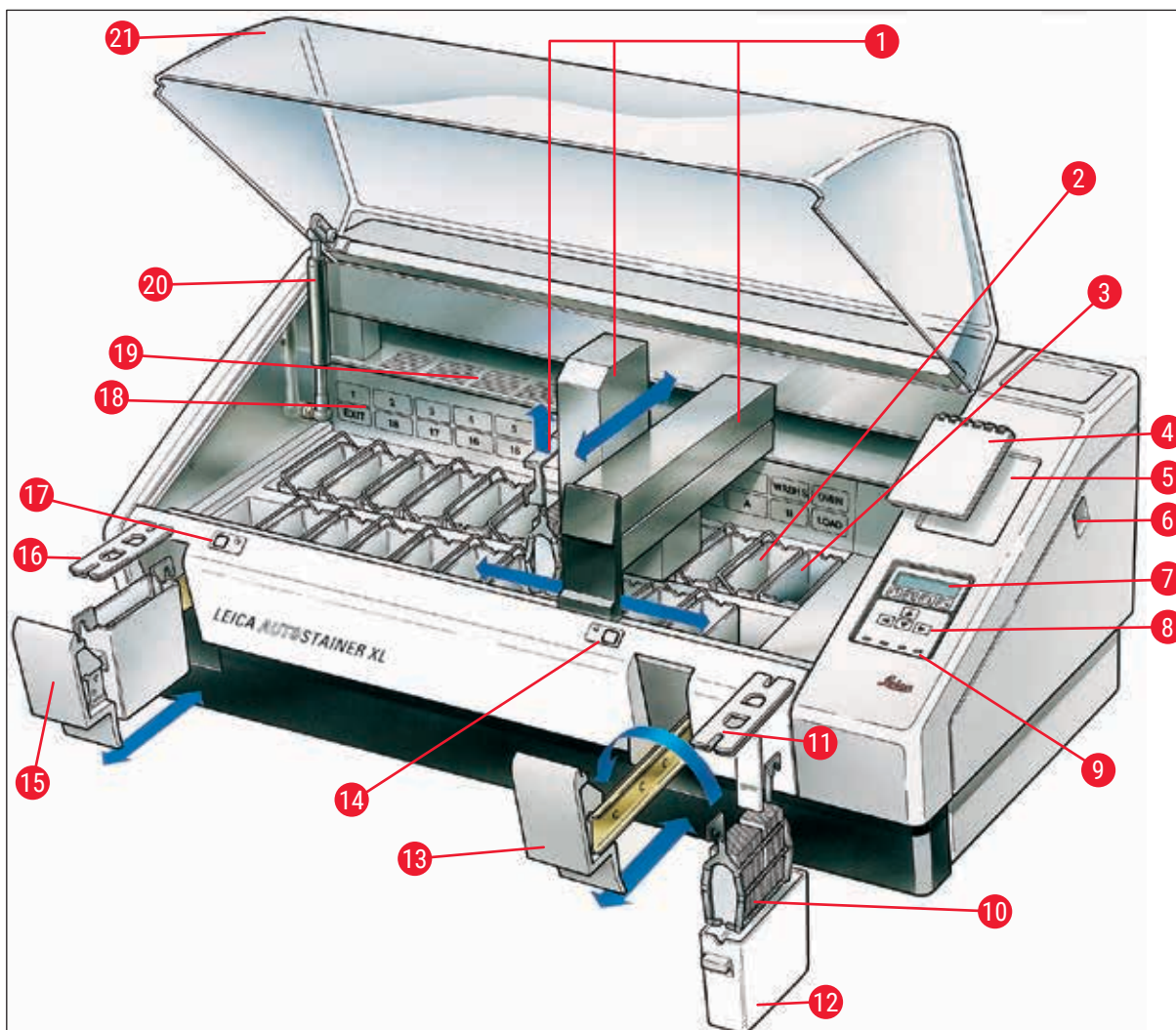


Fig. 1

Front side of instrument

1	Transport arm	12	Reagent vessel
2	Wash stations	13	Load drawer
3	Oven	14	LED indicator and key for load drawer
4	Notepad for staining protocols	15	Exit drawer
5	Recess for notepad	16	Cover with cut-outs (for vessel transportation)
6	ON/STOP switch	17	LED indicator and key for exit drawer
7	Display screen	18	Schematic diagram of the stations
8	Keypad	19	Cover plate
9	LED indicators	20	Lock for hood ¹⁾
10	Specimen slide holder	21	Hood
11	Container cover		

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

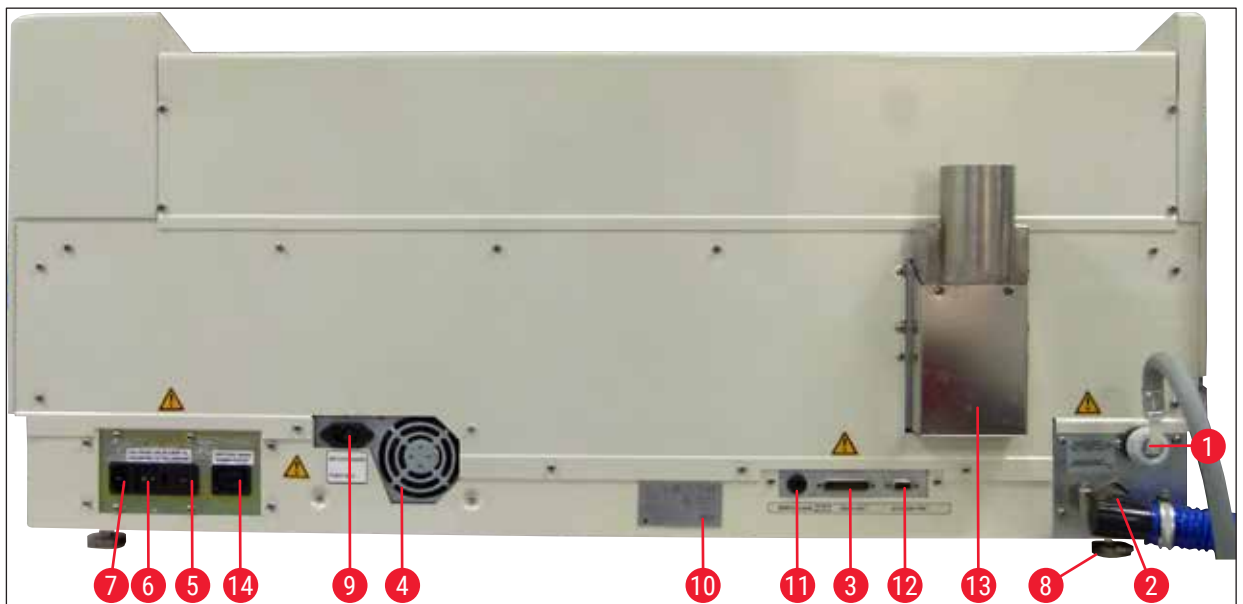


Fig. 2

Rear side of instrument

1	Water inlet	8	Feet, adjustable
2	Drain outlet	9	Switched mains power inlet
3	Serial port	10	Nameplate
4	Power supply (electronics)	11	Remote alarm socket, 30 V AC/1 A, 60 V DC/1 A
5	Voltage selector and fuses for heater	12	Accessory port
6	Power switch (ON/OFF)	13	Exhaust air duct
7	Power input	14	Switched mains power outlet

**Note**

The Serial port (→ Fig. 2-3) and the Accessory port (→ Fig. 2-12) are used by the certified Leica service technician to install the optional Leica TS5015 Transfer Station which connects the Leica Autostainer XL (ST5010) with a Leica CV5030 Robotic Coverslipper (→ 5.9.9 Operation as a workstation-12).

3 Instrument Features

3.2 Standard delivery – packing list



Note

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

Standard delivery:

Qty.	Designation	Order No.
1	Leica Autostainer XL (ST5010) basic unit (230-240 V / 50-60 Hz) (local power cord included)	14 0456 35136
	- or -	
1	Leica Autostainer XL (ST5010) basic unit (100-120 V / 50-60 Hz) (local power cord included)	14 0456 35340
1	accessories kit (0456 35660) consisting of:	
22	reagent vessels with lids	14 0475 33659
5	wash vessels, assy.	14 0456 35268
10	slide racks, 30 slides	14 0475 33750
2	covers with slots for reagent vessels	14 0475 34486
1	jumper cable, power supply	14 0411 34604
1	remote alarm connector	14 6844 01005
1	tubing band clamp	14 0422 31972
1	angular connecting nozzle for hose	14 0475 33669
1	V filter 3/4.	14 0456 36101
1	active carbon filter	14 0474 32273
1	filter cover	14 0456 35240
1	collecting tray for paraffin (heater) (inside the instrument)	14 0456 35216
1	staining protocol notepad (attached to instrument)	14 0456 35459
1	water supply hose with seal	14 0474 32325
1	drain hose	14 0475 35748
1	International bundle Instructions for Use (incl. English printout, any additional languages on a data storage device 14 0456 80200 and a reference manual as appendix, only in English (staining protocols, etc.))	14 0456 80001

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



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.

3.3 Technical Data

Dimensions (width x depth x height):	109 cm x 67 cm x 51 cm
Weight:	65 kg
Nominal supply voltages:	100-120V AC \pm 10 % or 230-240V AC \pm 10 %
Nominal frequency:	50-60 Hz
Power draw:	650 VA
Fuses:	5 x 20 mm, VDE / UL listed 100-120 V: quick acting fuse F 6.30 A L250 VAC 230-240 V; quick acting fuse F 3.15 A L250 VAC
Means of protection according to IEC 61010-1:	Class 1
Overvoltage category according to IEC 61010-1:	II
Pollution degree according to IEC 61010-1:	2
Degree of protection according to IEC 60529:	IP20
A-weighted noise level, measured at 1 m distance:	\leq 70 dB (A)
Remote alarm socket:	30 V AC/1 A – 60 V DC/1 A
Performance parameters	
Slide throughput	depending on selected protocol: max. 600 slides /h min. 200 slides /h
Loading capacity:	max. 11 specimen slide holders
Capacity of one specimen slide holder:	30 slides
Overall number of stations:	26
Reagent stations:	min. 18
Volume of reagent vessels:	450 ml
Overall number of water stations:	max. 5 (DI water optional)
Number of oven chambers:	1
Temperature of oven chamber:	Ambient temperature or +30 to +65 °C
Incubation time setting:	0 s to 99 min 59 s
Overall number of loading / unloading stations:	1 / 1
Capacity of nonvolatile storage:	15 programs with up to 25 steps
Integration:	Connection with CV5030 (coverslipper, optional)
Fresh water connection	
Hose material:	PVC
Hose length:	2.5 m
Connecting piece:	G3/8
Inner diameter:	10 mm
Outer diameter:	16 mm
Internal pressure:	Min. 1 bar / max. 6 bar
Required flow rate:	Min. 12 l/ min

Waste water connection

Hose material:	PVC
Hose length:	4 m
Inner diameter:	32 mm
Outer diameter:	36.8 mm

Exhaust air

Hose material:	PVC
Hose length:	2 m or 4 m
Inner diameter:	50 mm
Outer diameter:	60 mm
Exhaust performance:	22.4 m ³ /h
Exhaust extraction:	Active carbon filter and exhaust hose for connecting with an external exhaust system

Ambient conditions

Operating temperature:	15 to 35 °C
Operating relative humidity:	20 % to 80 %, non-condensing
Operating altitude:	Max. 2000 m above sea level
Storage temperature:	+5 to +50 °C
Storage relative humidity:	10 % to 85%, non-condensing
Transport temperature:	-29 °C to +50 °C
Transport relative humidity:	10 % to 85%, non-condensing

4. Installing the Instrument

This chapter provides instructions on how to install the Leica Autostainer XL (ST5010). It also includes a diagram and detailed description of the instrument's components. The procedure for replacing the active carbon filter for protection against reagent vapors is outlined as well.

4.1 Installation site requirements

- Required hard surface: 1.09 x 0.67 m²
- The laboratory bench must be of sufficient bearing capacity relating to the instrument and must have a rigid surface.
- The device is intended for indoor use only
- The next power socket must not be further away than the length of the power cord (2.5 m). Use of an extension cord is not allowed.
- The instrument needs to be connected to a grounded power supply socket.
- Use only the provided power cord intended for the local power supply
- The instrument must not be installed below any air conditioning system
- Any shaking, direct sunlight and significant current fluctuations need to be avoided
- Proper function is ensured only if a minimum distance of 10 cm is respected towards all walls and any other fixtures
- The instrument needs to be installed in a way that allows easy access to the power switch and the power plug at the rear side.
- Operation is not allowed in any areas exposed to explosion hazards
- The installation site needs to be protected against electrostatic discharges
- The installation site needs to be well ventilated because chemicals used within the instrument are highly flammable and unhealthy
- Connect the instrument to a laboratory air exhaust system using the dedicated hose (lengths of 2 m and 4 m available). Alternatively the instrument can be operated below a fume cupboard. This should be run in addition to the active carbon filter.
- Please consider that the active carbon filter supports only filtration of hazardous vapors (Xylene)
- The situation at the installation site may vary significantly and depends on existing ventilation, emissions of other installed devices, the use of solvents, the volume of the room, etc.
- It is the responsibility of the laboratory owner / laboratory operator to not exceed the legal maximum permissible values and to take all measures at the working places regarding the solvent vapors. This includes also corresponding documentation.
- The operator of the instrument needs to make sure that sufficient ventilation is ensured and the active carbon filter is replaced within the required interval.
- The voltage selector and other internal components are preset by the manufacturer to meet the power requirements of the respective country of destination.



Warning

The user must not alter the voltage selector setting.

- The Leica Autostainer XL (ST5010) must be connected to a laboratory water tap with a pressure reducer.

4 Installing the Instrument

4.2 Setting up the instrument



Warning

Inadequate lifting and transportation of the instrument

Injury of persons and/or property damage

- Do not try to lift the instrument with less than 4 persons.
- Grab the instrument under the frame at all corners and lift it evenly.

1. Grip the instrument with at least 4 persons at all corners and evenly lift the instrument.
2. Place the instrument onto the bench (→ p. 21 – 4.1 Installation site requirements).
3. Pull off plastic cover.
4. Check whether all accessories have been delivered as per your order.

4.3 Connections on the instrument

4.3.1 Power supply



Warning

- Before connecting the device to the power supply, it is essential to compare the connection data on the nameplate with the local power supply.
- The instrument must be connected to a grounded power socket. Use ONLY the power cord provided, which is intended for the local power supply.

- Connect the power cable to the power input (→ Fig. 2-7).
- Connect the power supply jumper cable to the switched mains power outlet (→ Fig. 2-14) and switched mains power inlet (→ Fig. 2-9).

How to switch on:

1. Plug the power plug into the power socket.
2. Set the **ON/STOP** switch on the right side of the instrument to **STOP**.
3. Set the **ON/OFF** switch on the rear side of the instrument to **ON**.
4. Set the **ON/STOP** switch on the side to **ON**.

✓ The instrument will emit 3 short beeps and the **Main Menu** will be displayed.

When the instrument is not in use, set the **ON/STOP** switch on the side to **STOP**.

The **ON/OFF** switch on the rear side of the instrument should be left **ON**.



Warning

The instrument must never be operated without the power supply jumper cable.
The instrument must be connected to a grounded power socket.

4.3.2 Water supply



Warning

In order to ensure the functionality of hose assemblies and not to shorten their service life due to additional stresses, the following must be observed:

- Do not put the hose assembly into operation if there is visible damage.
- Hose lines must be installed in such a way that they are not obstructed in their natural position and movement.
- Hose lines must not be subjected to tensile, torsional and compressive stresses during operation unless they are specially designed for this purpose.
- Hose lines must be protected against damage due to mechanical, thermal or chemical effects.
- All detachable connections must be checked for tightness prior to the operation of the instrument.

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



Note

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

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

4.4 Battery backup – UPS (optional)

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

A compact UPS can be connected easily as shown in (→ Fig. 3) via the power supply jumper cable.

The UPS should be designed for an output of 200 VA for a duration of 5 minutes. However, the UPS will not maintain operation of the oven.

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

4 Installing the Instrument

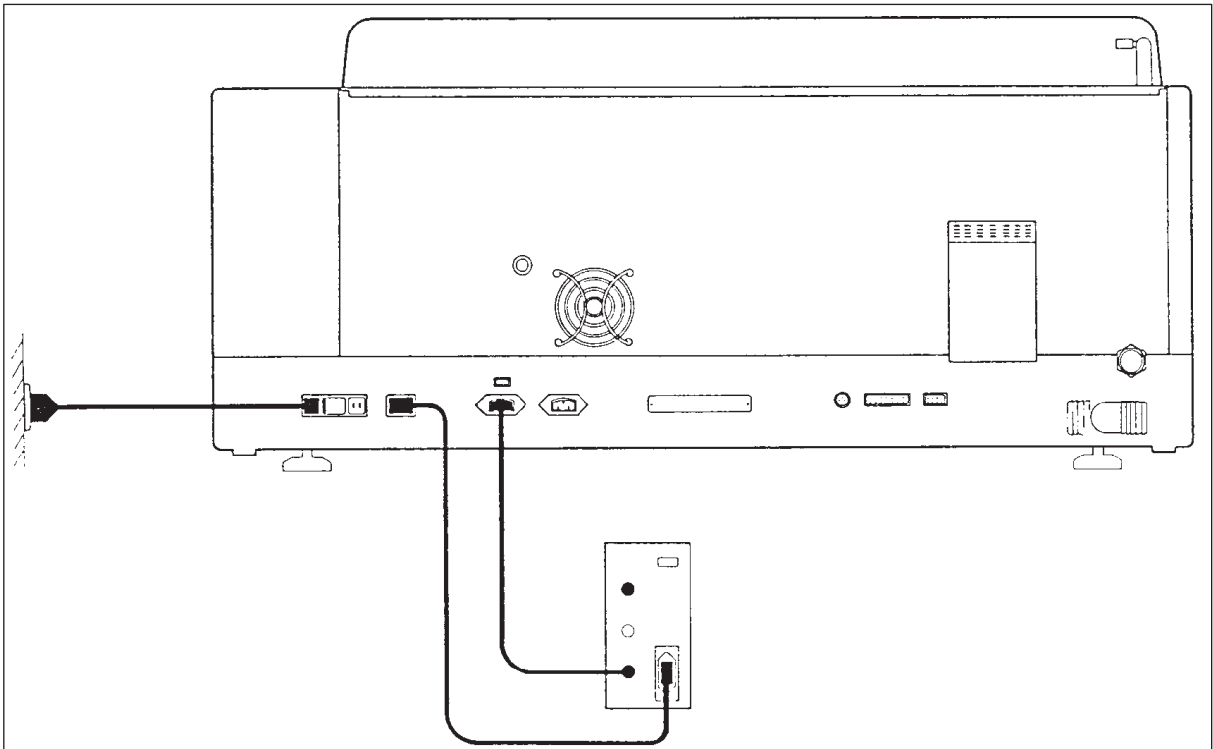


Fig. 3

4.5 Remote alarm (optional)

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



Note

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

Ensure that the instrument is still turned ON and press any key to turn off sound of the alarm. If the power failed during a staining run, you may first need to turn the ON/STOP switch on the side to STOP and then back to ON.

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

The remote alarm must be designed for 30 V AC/1 A, 60 V DC/1 A.

Connect the remote alarm to the connection socket on the rear side of the instrument using a phono jack (6.25 mm).

4.6 Vacuum extraction system for reagent vapors

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

To change the filter, remove the cover plate over the filter (→ Fig. 1-19). Use the straps provided to remove the filter. Put in a new filter and reattach the cover.

4.7 Oven

Put the wax tray on the oven floor.

5 Operating the Instrument

5. Operating the Instrument

Introduction

This chapter describes how to operate Leica Autostainer XL (ST5010). It includes information on how to use the function keys and displays in the control panel. It also describes how to create and edit programs as well as how to stain specimen slides.

Leica Autostainer XL (ST5010) offers many features not found in other stainers. In particular, the specimen slide holders are loaded and unloaded not by opening the cover, but by means of drawers. Once the instrument is able to accept a new specimen slide holder, the LED by the load drawer lights up. After a specimen slide holder has been loaded, the LOAD key must be pressed for the instrument to begin the staining run. Similarly, if the staining run for a specimen slide holder has finished, the LED by the exit drawer lights up. After the specimen slide holder has been removed, the EXIT key must be pressed so that the instrument knows this has been done. Programs can be ended at any station. However, if the exit drawer is not the program's last step, then the LCD will display which station to unload the holder from. In this case, the instrument's cover will have to be opened to remove the holder.

The Leica Autostainer XL (ST5010) can accept a new specimen slide holder as soon as the LOAD LED on the load drawer lights up. This makes it possible to process up to 11 specimen slide holders simultaneously.

Each specimen slide holder can be processed according to any of the 15 programs, provided that the corresponding reagents are available and the program chosen is compatible (no conflicting sequence) with the programs already being used.

Operation

The Leica Autostainer XL (ST5010) is operated using the control panel, the LOAD and UNLOAD keys and corresponding LEDs, and audible signals.

5.1 The control panel

The control panel consists of an LCD, the keypad and four LEDs.

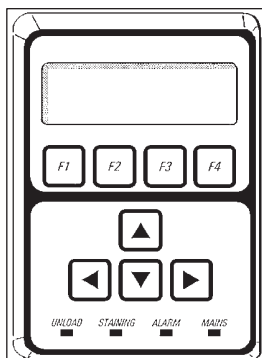


Fig. 4

The display

The display has a backlit LCD with four lines. The fourth line is usually reserved for commands associated with the function keys [F1] to [F4]. A flashing cursor appears under the settings that the user can change.

The keypad

The membrane keypad incorporates 4 function keys and 4 arrow keys. The function keys perform the actions that appear immediately above them in the fourth line of the display. The arrow keys move the cursor in the direction indicated. They are also used to select digits and other settings.



Note

Contact with solvents, use of sharp instruments or excessive force may damage the membrane keypad.

The LED indicators

The four LEDs are located below the arrow keys and have the following functions: The UNLOAD LED (yellow flashing) indicates that a specimen slide holder has been fully processed and is ready to be removed from a station (except the exit drawer). The staining LED (yellow) is lit when staining is in progress. The alarm LED (red) indicates that a malfunction has occurred. The power LED (green) signals that the power supply voltage is available (ON/OFF switch and ON/STOP switch are both switched ON).

LOAD and EXIT keys and indicators

The LOAD and EXIT keys and associated LED indicators are located adjacent to the load and exit drawers. For more information, see (→ p. 36 – 5.9.4 Loading specimen slide holders) and (→ p. 37 – 5.9.7 Interrupting staining).

Audible signals

There are four different audible signals:

- Short single beep: Sounds when a key is pressed.
- Short double beep: Wrong key pressed or error message received.
- Long double beep: Operator action required to remove a fully processed holder.
- Continuous tone: Indicates a malfunction.

5.2 Main menu

When the ON/STOP switch has been turned ON, the Main Menu appears and the instrument beeps 3 times.

Autostainer XL	V2.00			
Main Menu				
Stain	Edit	SetUp	PC	

Autostainer XL	V2.00			
Hauptmenü				
Färben	Programme erstellen	Geräteparameter	PC	

The instrument has the following operating modes:

- Stain: To stain the specimen slides.
- Edit: To create, view or change programs.
- SetUp: To set or change parameters such as oven temperature and how many times the specimen slide holder moves up and down (dips) in a reagent station.
- PC: For service use only.

5.3 Menu overview

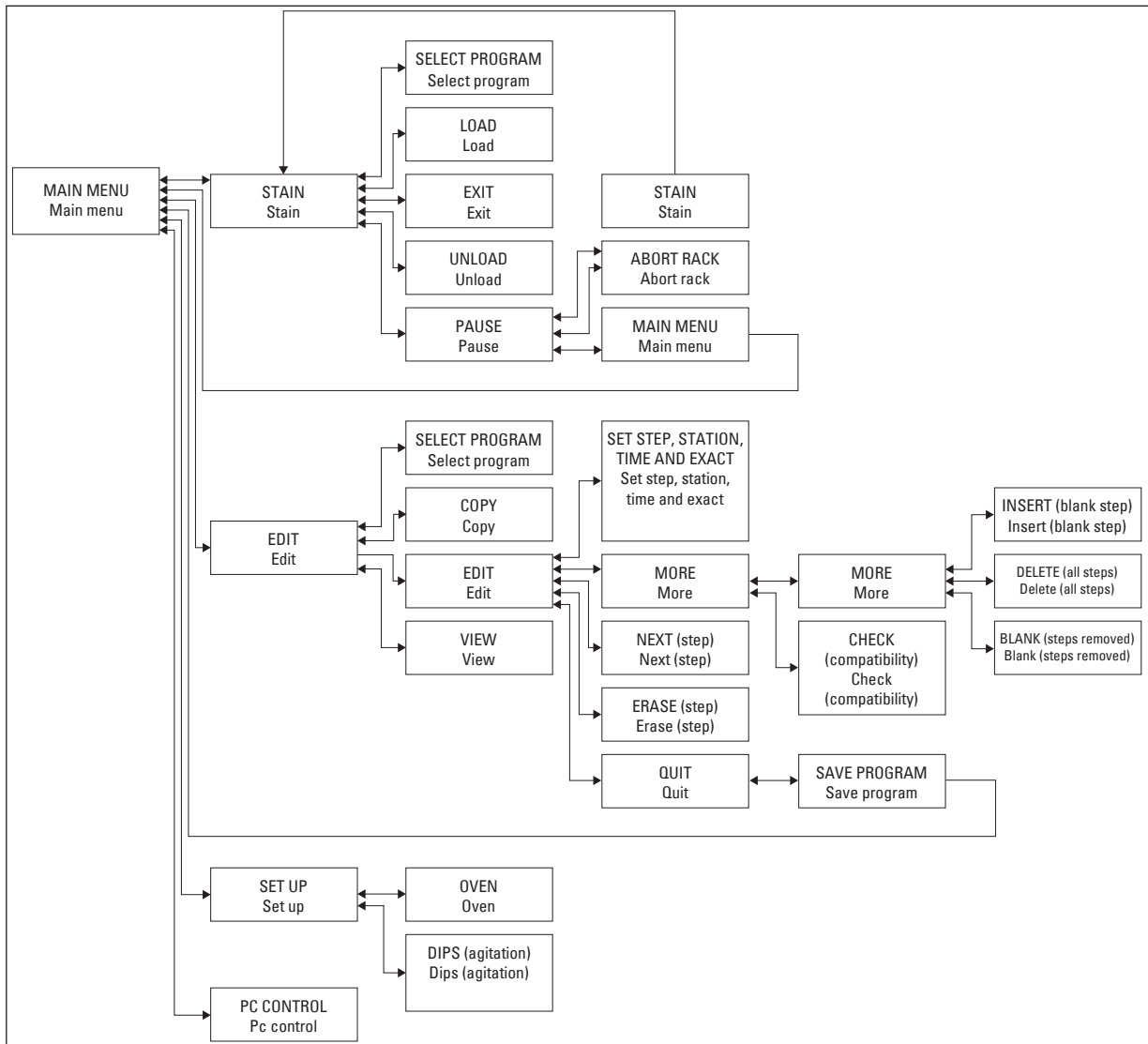


Fig. 5

5.4 Editing programs

The Leica Autostainer XL (ST5010) can store up to 15 programs, numbered consecutively from 1 to 15. Programming is easy. The user is guided through a menu and enters all information via the keypad.



Caution

Specimen slide holder processed with wrong program parameters

Damage or loss of tissue

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

A program consists of 25 steps, some of which may be blank. A step consists of the following information:

- The step number
- The station
- The incubation time (immersion time)
- Whether or not the specified incubation time must be adhered to exactly.

The step number defines the order in which the stations are used. The incubation time is the time the specimen slide holder is fully immersed in a station.

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





Warning

Programs assigned to specimen slide holders currently being processed cannot be altered, neither can steps be copied into them.

The menu overview ([→ p. 28 – 5.3 Menu overview](#)) provides an overview of the programming structure.









5.4.1 Entering program steps

1. Press **[F2]** Edit in the Main Menu.
2. Select the desired program using the  and  keys.
3. Press **[F2]** Edit.

✓ The first step of the program is displayed under the following headings:

- step: the step number,
- stn: the station number or name,
- time: the incubation time in minutes and seconds,
- exact: whether or not the incubation time is critical.

5 Operating the Instrument

4. Move the cursor under the step number and use the  and  keys to call up steps 1 to 25 of the program. Alternatively, press **[F2]** Next to move to the next step.
5. To enter the appropriate information, use the  and  keys to position the cursor beneath the appropriate heading. Scroll through the existing information or alter the digits using the  and  keys.
Enter the program details and, after each item of a step is completed, use the  and  keys to move to the next heading.



Warning

An incubation time of 00:00 means that this step will be omitted.

6. Repeat items 4 and 5 until the program is complete.



Warning

If the specimen slide holder needs to end up in the exit drawer, enter this as the last step.

7. Save the program (→ p. 31 – 5.4.5 Saving a program).

5.4.2 Deleting program steps

Information contained in a step may be deleted, leaving a blank step.

1. Select the program (see items 1 to 3 (→ p. 29 – 5.4.1 Entering program steps)).
2. Select the step to be deleted (see item 4, (→ p. 29 – 5.4.1 Entering program steps)).
3. Press **[F3]** Erase.
Then the step is left blank.
You may enter new details for the step, if desired.
4. Save the program (→ p. 31 – 5.4.5 Saving a program).

5.4.3 Inserting a blank step into a program

This function is used to insert an additional step into an existing program.

1. Call up the program (see items 1 and 2 (→ p. 29 – 5.4.1 Entering program steps)).
2. Press **[F2]** Edit.
3. Select the step number where the new (blank) step is to be inserted.
4. Press **[F1]** More.
5. Press **[F1]** More.
6. Press **[F1]** Insert.
7. If you wish to proceed, press **[F1]** Yes.
A blank step is inserted now at the step selected under item 3.



Note

The steps following the blank step will be renumbered. Step 25 is lost when a blank step is inserted.

8. Continue editing the program.
9. Save the program (→ p. 31 – 5.4.5 Saving a program).

5.4.4 Removing blank steps from a program

This function is used to remove blank steps left by deleting one or more program steps.

- ① Steps will then be renumbered in the same sequence as in the original program.
- 1. Select the program (see items 1 and 2 (→ p. 29 – 5.4.1 Entering program steps)).
- 2. Press **[F2]** Edit.
- 3. Press **[F1]** More.
- 4. Press **[F1]** More.
- 5. Press **[F3]** Blank.
- 6. Press **[F1]** Yes to continue. The blank steps are removed and the subsequent steps are renumbered.
- 7. Save the program (→ p. 31 – 5.4.5 Saving a program).

5.4.5 Saving a program

When the program is complete, save it as follows:

- 1. From the **Edit Program** screen, press **[F4]** Quit. You now have the options of saving the edited program **[F1]**, leaving the program as it was before the changes were made **[F2]**, or continuing to edit the program **[F4]**.
- 2. Press **[F1]** to save the program, or
- 3. Press **[F2]** to leave the program unchanged, or
- 4. Press **[F4]** to continue editing the program.

5.4.6 Deleting a program

This function is used to delete all steps in a program.

- 1. Select the program (see items 1 and 2 (→ p. 29 – 5.4.1 Entering program steps)).
- 2. Press **[F2]** Edit.
- 3. Press **[F1]** More.
- 4. Press **[F1]** More.
- 5. Press **[F2]** Delete.
- 6. Press **[F1]** Yes to continue.
- 7. To save the program (which now contains no steps), see above.

5.4.7 Copying a program

This function is used to copy a program into another program number.

- 1. Select a corresponding program (see items 1 and 2 (→ p. 29 – 5.4.1 Entering program steps)).
- 2. Press **[F1]** Copy.

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Note

If an empty program has been selected, a corresponding message appears in the display.

- Using the and keys, select the program number into which the program is to be copied.
- Press **[F1]** Copy.



Note

If the selected program number is not blank, a corresponding message appears in the display.
If the selected program number is assigned to a specimen slide holder currently being processed, copying is not allowed and a corresponding message appears in the display.

A confirmatory message will be momentarily displayed if the copy is successful.

- If you wish to copy the program into another program number, repeat items 3 and 4.
- Press **[F4]** Cancel to exit this routine

5.4.8 Viewing a program

To view a program:

- Select the program (see items 1 and 2 (→ p. 29 – 5.4.1 Entering program steps)).
- Press **[F3]** View.
Up to four steps can be viewed simultaneously. Use the and keys to view other steps.
- Press **[F4]** to return to the previous screen.

5.4.9 Checking the compatibility of programs

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

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

However, the instrument carries out this calculation automatically.

- Select the program (see items 1 and 2 (→ p. 29 – 5.4.1 Entering program steps)).
- Press **[F2]** Edit.
- Press **[F1]** More.
- Press **[F2]** Check.
- Using the and keys, select the program number to be checked for compatibility.
- Press **[F2]** Check.
A message appears in the display to inform you of whether or not the programs are compatible.

7. If the programs are not compatible, an explanation will be given. Press **[F4]** to continue.
8. Repeat items 5 and 6 to check the compatibility with other programs.
9. Press **[F4]** to return to the program selected under item 1.

**Note**

In many cases, incompatibility of staining protocols can be traced to assignment of the wash stations. Therefore, these stations can be selected by the user.

(→ p. 50 – 11.3 Compatible staining programs) gives some examples of staining protocols that are compatible with each other.

5.5 User-adjustable parameters

The Leica Autostainer XL (ST5010) has multiple parameters that pertain to operation of the instrument regardless of the selected program. These parameters can be set by the user (refer also to (→ p. 48 – 11.1 Adjustable parameters)):

- Oven temperature.
- Number of up/down movements (dips) of a specimen slide holder within a station.
- Time for one complete movement up and down (dip).
- Time for the process to remove a specimen slide holder from a station.
- Time for the process to insert a specimen slide holder into a station.

5.6 Oven

The oven temperature can be set between 35 and 65 °C, or the oven can stay turned OFF.



**Note**

The oven operates during the entire staining process with the respectively specified temperature setting, even if it is not used.

To set, view or change this setting:

1. Press **[F3]** SetUp in the **Main Menu**.
The current setting appears in the first line of the display.

To alter this setting:

2. Press **[F1]** Oven.
3. Press **[F1]** to turn the oven ON, or press **[F2]** to turn the oven OFF, or use the  and  keys to alter the programmed oven temperature.
4. Press **[F4]** to return to the **SetUp** screen.

The new oven setting will now be displayed.

5. Press **[F4]** to return to the **Main Menu**.

5 Operating the Instrument

5.7 Up/down movement (dips)

The number of times the specimen slide holder moves up and down (dips) after being inserted into a station can be set to OFF, in the range 1 - 20 or continuous.



Note

If continuous movement was selected, then only one specimen slide holder from the instrument can be processed at a time.

To view or change this setting:

1. Press **[F3]** SetUp in the **Main Menu**.
Then the current setting appears in the second line of the display.
To alter this setting:
2. Press **[F2]** Dips.
3. Press **[F1]** to turn the dips ON, or
Press **[F2]** to turn the dips OFF, or
Use the **↑** and **↓** keys to alter the number of dips.
4. Press **[F4]** to return to the **SetUp** screen.
The new setting for the number of dips is displayed.
5. Press **[F4]** to return to the **Main Menu**.



Note

The time for one complete movement up and down (dip) is set in the menu (Setup/Move).
Use the selected time as a guide when setting the number of dips.
If the incubation time for a selected number is too short, only the number of dips that fit into the specified incubation time will be done.

5.8 Number of up/down movement (dips)

You can set the number and duration of dips of the specimen slide holder to suit the duration and special requirements of the staining run (→ p. 48 – 11.1 Adjustable parameters).

To view or change this setting:

1. Press **[F3]** SetUp in the **Main Menu**.
2. Press **[F3]** Move.
The current setting appears as the number of seconds for each individual movement operation, that is, the total duration for dips and the duration for unloading and loading each holder.
3. To change the values, press **[F1]** Dip, **[F2]** Up or **[F3]** Down to position the cursor under the appropriate value.
4. Use the **↑** and **↓** keys to alter the setting.
5. Repeat steps 3 and 4 as required.
6. Press **[F4]** to return to the **SetUp** screen.
7. Press **[F4]** to return to the **Main Menu**.

5.9 Staining

This chapter discusses how to stain specimen slides.

The Leica Autostainer XL (ST5010) can accept a new specimen slide holder as soon as the load drawer is empty. Then the specimen slides are stained according to the program selected for the respective holder. Different programs may be used simultaneously, provided they are compatible. The method for checking compatibility is described on ([→ p. 32 – 5.4.9 Checking the compatibility of programs](#)).

5.9.1 Reagent vessels

Reagent vessels can be individually removed for filling. Each vessel holds 450 ml. The filling level mark is on the inside. After being filled, they are put in the instrument at the position designated in the corresponding programs.

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

A schematic drawing of the individual stations is inside the instrument on the back panel ([→ Fig. 1-18](#)). Make sure that the vessels are inserted correctly and that all handles are folded to the correct side so that they do not obstruct transport of the specimen slide holders. Lids are provided to reduce evaporation of solvent while the reagent vessels are not in use. The vessels of the load and exit drawers can also be filled with a reagent, if desired. However, the instrument will not monitor the incubation times in these two stations.

5.9.2 Wash system

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



Note

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

To use the wash station, slowly open the water tap in the lab all the way. The flow control valve in the Leica Autostainer XL (ST5010) limits the flow rate in the wash stations to an optimum value of 8 liters/minute.



Note

If the flow rate drops below this value for any reason, the wash period specified in the program may have to be extended.

5.9.3 Water-saving function

The Leica Autostainer XL (ST5010) has a water-saving function that stops the flow of water when none of the wash stations is in use and the reagent residue has been flushed out of them.

5.9.4 Loading specimen slide holders

Specimen slide holders are inserted into the instrument only via the load drawer, which is on the front right side of the instrument. Reach several fingers into the recess on the underside of the drawer, release the lever by gently pushing it up and pull the drawer out as far as it will go.

To load a specimen slide holder:

1. Press **[F1]** Stain in the **Main Menu**.
The instrument will take a few seconds to initialize.



Note

If a holder is already loaded, then the Abort menu will be displayed. Press **[F1]** Stain to continue.

2. Select the required program number using the **↑** and **↓** keys.
Check to see whether the load drawer is actually empty (the **[LOAD]** LED will be lit). Open the drawer and insert the specimen slide holder, ensuring that it is positioned correctly. Close the drawer.
3. Press the **[LOAD]** key.
If the program is compatible with the programs already in use, then the **[LOAD]** LED will turn off and the specimen slide holder will be processed using the selected program, otherwise a message will appear in the display and the holder will not be processed.
4. To load additional specimen slide holders, repeat items 2 and 3.



Note

If the instrument is in the midst of processing a specimen slide holder, there may be a delay before processing of additional holders begins.

5.9.5 Unloading specimen slide holders from the exit drawer



Caution

Specimen slide holders not unloaded in a timely manner from exit drawer

Delay of processing time and damage of tissue

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

When a specimen slide holder is in the exit station, the **[EXIT]** LED will be on and the beeper will sound every 30 seconds.

To unload from the exit drawer:

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

**Note**

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



5.9.6 Unloading specimen slide holders from other stations

If the final step in a program is not the exit drawer, the **[UNLOAD]** LED on the control panel will flash when processing of the holder is complete.

To unload:

**Note**

For unloading, below steps must be carried out as quickly as possible. In the case of delays, the staining quality of other samples within the device may be negatively impacted.

1. Press **[F1]** Unload.
A confirmatory message will appear in the display while the transport arm completes its current operation. Then the station number of the fully processed specimen slide holder will be displayed.
2. Select the station number of the holder to be removed using the  and  keys (if more than one holder is completed), or
3. Press **[F4]** Cancel if you do not wish to unload the holder. Then the instrument will resume processing.
4. Press **[F1]** Unload.
Open the lid and remove the specimen slide holder.
5. Press **[F1]** Done.
6. Repeat items 2 to 5 to remove other fully processed holders.

5.9.7 Interrupting staining

Staining can be interrupted:

- To edit a program not currently being used for staining;
- To change the general instrument parameters (**SetUp**);
- To allow access to the instrument to check/change reagents;
- To abort staining of one or more specimen slide holders.

To interrupt a staining run:

1. Press **[F4]** Pause in the **Abort** screen.

5 Operating the Instrument



Note

If staining is interrupted, incubation times during the pause will not be identical to those in the selected program(s).

If no specimen slide holders are loaded, then the **Main Menu** will be displayed.

2. To cancel processing of a holder, ([→ p. 38 – 5.9.8 Aborting the processing of a specimen slide holder](#)).
3. Press **[F1]** Stain to continue staining, or
4. Press **[F4]** Main Menu to return to the **Main Menu**.
You may now edit programs not currently in use or change the general instrument parameters (**SetUp**).

To resume staining, press **[F1]** in the **Main Menu**.

5.9.8 Aborting the processing of a specimen slide holder

To abort the processing of a specimen slide holder:

1. Press **[F4]** Pause in the **Staining** screen.
2. Press **[F2]** Abort rack.
3. Using the **[↑]** and **[↓]** keys, select the station containing the holder for which you want to abort processing.
4. Press **[F2]** Abort.
5. Remove the holder as instructed. Press **[F1]** Done to confirm.
6. To abort the processing of other holders, repeat items 3 to 5.
7. Press **[F4]** Cancel to exit the **Abort** screen.
8. Press **[F1]** to continue staining or press **[F4]** to return to the **Main Menu**.

5.9.9 Operation as a workstation

The Leica Autostainer XL (ST5010) can be operated as a workstation together with a Leica CV5030 Robotic Coverslipper robotic coverslipper. This enables an interruption-free workflow from the staining process up to the removal of the finished coverslipped slides.

An optional Leica TS5015 Transfer Station is available for this purpose ([→ p. 48 – 11.2 Consumables and accessories](#)).



Note

- The optional Leica TS5015 Transfer Station and connection of a Leica CV5030 Robotic Coverslipper to the Leica Autostainer XL (ST5010) may be installed subsequently only by a Leica-certified service technician.
- The operation as a workstation is described in detail in the Instructions for Use of the Leica CV5030 Robotic Coverslipper

6. Care and Cleaning



Warning

- 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 hoods and housing using mild commercial, pH-neutral household cleaners. The finished surfaces are not resistant to solvents and xylene substitutes!
- The plastic reagent vessels of the rinsing water and reagent stations 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.
- Liquid must not come into contact with the electrical connections or get inside the instrument or in the housing below the transport arms.
- When using cleaning agents, observe the manufacturer's safety instructions and the laboratory regulations valid in the country of operation.
- The transport arm contains sensitive electronic components, therefore do not use any liquid in this area. Wipe clean only.

- Clean the interior stainless steel surfaces with a detergent and then rinse them with water. Clean the transport arm surfaces by wiping them with a damp cloth.
- The drainage system may be cleaned using a denture cleaner to inhibit bacterial growth. Flush well with water afterwards. Painted exterior surfaces can be cleaned with a mild detergent and then wiped with a damp cloth.



Note

Do not use solvent on the outer surfaces, particularly the control panel and the cover!

- Carefully wipe the control panel with a damp cloth.

6.1 Wash vessels



Note

- The wash vessels are to be regularly checked for calcification, visible, microbiological deposits of bacteria, fungi, algae and permeability. Lime residue can be removed using a mild vinegar-based cleaning solution. Finally, rinse off the vessels with clear water until the cleaning agent residue has been removed.



Warning

- O-rings need to be checked for damage. Replace damaged O-rings with new ones (→ p. 48 – 11.2 Consumables and accessories).
- After cleaning the rinsing water vessels and before inserting them into the instrument again, the connecting piece to the water inlet system must be checked for correct positioning on the O-ring.
- If O-rings are left in the instrument when removing a wash vessel, remove them carefully with pincers and stick them back onto the connection port.
- If an O-ring is missing or positioned incorrectly, the wash vessels must not be put back into position after cleaning, because otherwise there is a danger of the priming function being defective during the staining process.
- After attaching or correcting the position of the O-ring, lubricate it.
- Then the wash vessels can be put back into their position.
- Do not reinsert wash vessels without O-ring or with a damaged O-ring! If an O-ring cannot be replaced immediately, the affected wash vessel must be removed from the instrument.
- Replace the missing/defective O-ring (s) and grease it. Put the wash vessel(s) back into the device.

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

6.2 Reagent vessels



Caution

Reagent vessels not cleaned or cleaned insufficiently

Damage or loss of tissue

- Clean reagent vessels regularly according the instruction.

- Clean with warm water and detergent.

6.3 Specimen slide holders

- Clean with household or laboratory detergent as needed.

6.4 Oven

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

6.5 Water drainage



Caution

Water drainage not cleaned or cleaned insufficiently

Insufficient staining quality, loss of tissue or property damage

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

1. To clean the water draining system, remove the rinsing water vessels and all surrounding reagent vessels.

2. The remaining reagent vessels have to be covered with lids.
3. Place one to two cleaning tablets with active oxygen (e.g. a denture cleaner) into the drain and dissolve in water to remove various residue (reagents, bacteria, fungi, algae).
4. Then, clean the entire curved drainage area inside the instrument with a long, flexible brush.
5. Check the flow by flushing thoroughly with water.
6. Put the vessels back in their original, defined positions.
7. Remove any lids from vessels before processing specimen slide holders into them.

6.6 Changing the active carbon filter

The active carbon filter (→ Fig. 6-3) installed in the instrument helps reduce the amount of reagent vapors in the exhaust air. The life cycle of the filter can fluctuate strongly depending on intensity of use and the reagent configuration of the instrument. Therefore, replace the active carbon filter regularly (every 2-3 months) and dispose of it properly in accordance with the laboratory regulations applicable in the country of operation.

It can be accessed and exchanged without tools.

To exchange the active carbon filter, proceed as follows:

1. Turn off the instrument.
2. Remove the cover plate (→ Fig. 6-1) by moving it up and out (→ Fig. 6-2).
3. Use the pull tabs (→ Fig. 6-4) to remove the filter (→ Fig. 6-5).
4. Insert the new filter (→ Fig. 6-6) so that the pull tabs can be reached after the filter is inserted fully and the article number (→ Fig. 6-8) printed on it is legible.
5. Note the insertion date for the filter element on the white label and stick the label next to the article number (→ Fig. 6-8).
6. The active carbon filter must be pushed in until you feel it make contact with the rear panel of the instrument (→ Fig. 6-7).
7. Reattach the coverplate (→ Fig. 6-9).

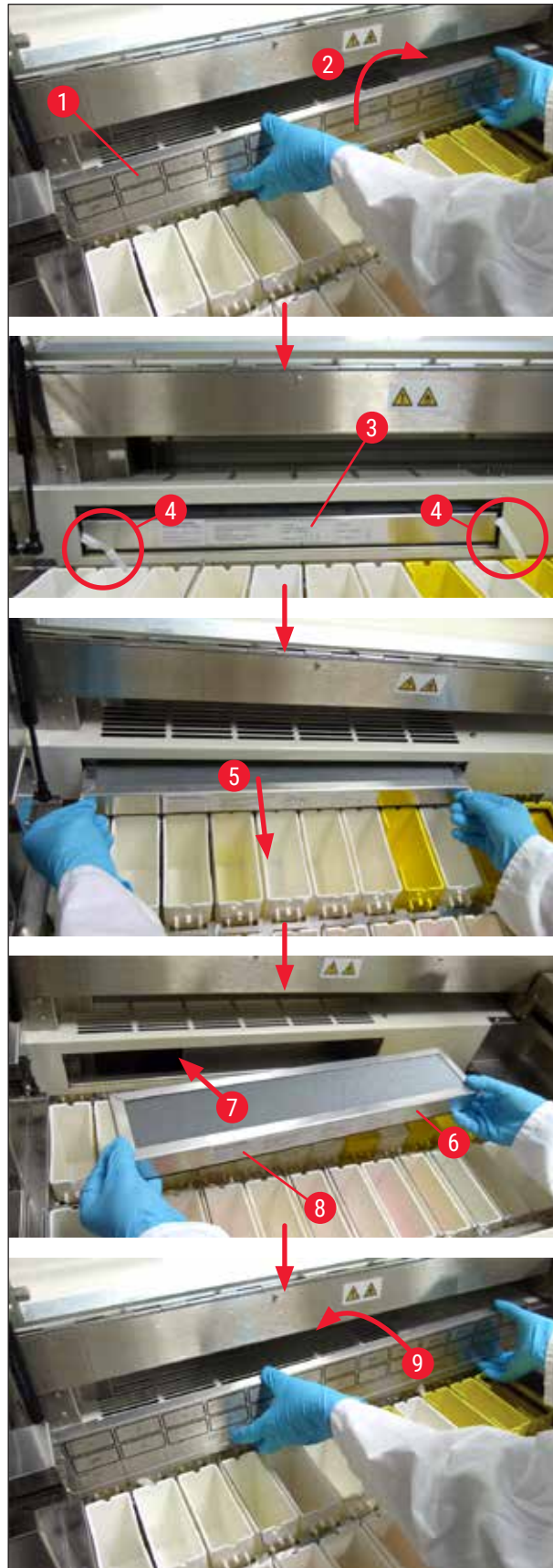


Fig. 6

7. Error Messages and Troubleshooting

Introduction

The Leica Autostainer XL (ST5010) has a system that continually monitors the instrument's functions. It displays a corresponding error message if any errors occur. If a minor error occurs during staining, the instrument will first attempt to correct the problem on its own. If this is unsuccessful, then a message appears and the instrument waits for the user to rectify the problem.

Some errors trigger an audible alarm. This alarm can be turned off by pressing **[F1] Quiet**.

If there is an error message, press **[F2] Pause** to pause staining.

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

7.1 Warning messages for instrument errors

Mains Power fail	This warning indicates a power failure. It appears only if a UPS is connected. For more details, (→ p. 23 – 4.4 Battery backup – UPS (optional))
Power Supply fail	The power supply device has failed and must be repaired.
Make sure that the head is free of obstruction	The transport arm for transferring the specimen slide holder is locked. The most frequent causes for this are: <ol style="list-style-type: none"> 1. The reagent vessel is inserted incorrectly 1. The handle is positioned incorrectly 2. The cover is still on the reagent vessel 3. The specimen slide holder is bent <p>The instrument immediately starts staining again after the problem is remedied</p>
Head stalled	Even after the attempt to resume staining, the head of the transport arm does not move. Eliminate all blockage and resume staining. If the problem does not go away, contact our after-sales service.
Fume system blocked	The drain opening on the rear side of the instrument is blocked. Eliminate blockage.
Oven failure	The oven is not working and has to be repaired. All other stations of the instrument are still working. Only drying of the specimen slides has to be done outside of the instrument.
Oven overheating	If this message appears, it is very likely that the oven is blocked. Make sure the slot in the oven floor is not blocked.
Remove obstruction and replace rack on hook	The specimen slide holder could have separated from the hook. Remedy the problem (e.g., the reagent vessel is inserted incorrectly) and put the holder back on the hook.

7.2 More information and warnings

7.2.1 During staining

Program (x) cannot be used for staining	Either the program in question contains no steps, or it consists only of blank steps or steps with the time set to 0.
Program (x) is not compatible with programs in us	The program in question is incompatible with a program assigned to one (multiple) specimen slide holder(s), which is (are) currently being processed. Processing of the specimen slide holder(s) must be finished before the program in question can be used. (→ p. 32 – 5.4.9 Checking the compatibility of programs)
Ensure a rack is in the Load drawer and close the drawer	The load drawer must be closed for the instrument to be able to remove a specimen slide holder from it.
Ensure the Exit drawer is empty and close the drawer	The exit drawer must be closed for the instrument to be able to insert a specimen slide holder for removal.

7.2.2 During editing of programs

Station (x) and Station (y) are in reverse order	This message appears when two programs are checked for compatibility. The stations in question are specified in the two programs in reverse order. Therefore the programs cannot be used in parallel.
The steps after Exit will be ignored	The Exit step is not the last program step. The steps specified after the Exit step are ignored.
Program (x) is in use for staining and cannot be altered	A program that is currently being used for staining cannot be altered. Copy the program to another program number and then edit it.

7.2.3 During SetUp

SetUp lost. Default SetUp used.	Programs and settings of the instrument parameters have been lost and must be reentered.
Battery backed RAM Failure! Service is required.	The internal memory has to be replaced. Contact the after-sales service responsible for you.
Caution: increasing dips might extend some station times	Increasing the number of up/down movements (dips) while specimen slides are being processed can result in lengthening of exactly defined incubation periods. If continuous up/down movement was selected, only one specimen slide holder can be processed at a time.

8. Warranty and Service

Warranty

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

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

Service information

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

The following information about the instrument is required:

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



Warning

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

9. Decommissioning and disposal**Caution**

The instrument or parts of the instrument must be disposed of according to existing applicable, local regulations. All objects contaminated with spilled reagents must be disinfected immediately with a suitable disinfectant to prevent spreading to other areas of the lab or to lab personnel.

Please refer to (→ p. 39 – 6. Care and Cleaning) and (→ p. 46 – 9. Decommissioning and disposal) for information about cleaning the Leica Autostainer XL (ST5010) stainer.

The instrument can be contaminated when using biohazardous specimens. Thorough disinfecting is required before re-commissioning or disposal (e.g. multiple cleaning steps, disinfection or sterilization). Dispose of the instrument in compliance with the applicable laboratory specifications.

Contact your Leica representative for more information.



Instrument components such as the computer, monitor, etc. that are labeled with the crossed-out dust bin are affected by the European Directive 2002/96/EC for Waste Electrical and Electronic Equipment (WEEE) of the European Parliament and the Council of January 27, 2003.

These objects must be disposed of via the collection points in accordance with the local regulations. More information on disposal of the instrument can be obtained from your local disposal company or your local Leica support staff.

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.

11. Appendix

11.1 Adjustable parameters

Parameter	Setting ex works	Variable	Range
Specimen slides per holder	N/A	N/A	0 - 30
Specimen slide holders in the instrument	N/A	YES	0 - 11
Stations			
Reagent stations	18	NO	0 - 18
Wash stations	5		0 - 5
Oven	1		1
Load drawer	1		1
Exit drawer	1		0 - 1
Programs	15	NO	15
Steps per program	25	NO	25 (Note: Some steps can be defined as blank)
Incubation time	N/A	YES	0 sec. - 59 min. 99 sec. (Note: Setting 0 seconds for a step will omit it)
Timing accuracy (exact)	N/A	YES	± 1 second (exact) 0 - "infinity" (not exact)
Oven temperature	N/A	YES	OFF / 30 - 65 °C
Up/down movements (dips)	N/A	YES	OFF / 1 - 20 / Continuous
Duration of an entire dip (in seconds)	2	YES	1 - 4
Unloading time per holder (in seconds)	9	YES	4 - 9
Loading time per holder (in seconds)	2	YES	2 - 4

11.2 Consumables and accessories



Note

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

Consumables

Active carbon filter	14 0474 32273
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Accessories

Leica TS5015 - transfer station	14 0506 38050
Baseplate for workstation	14 0475 37647
Specimen slide holders for special staining	14 0475 34524

Accessories	
Insert for special staining	14 0475 34525
Holder for large individual specimen slides	14 0456 27069
Specimen slide holders 30, metal	14 0456 33919
Wash vessel, assembly	14 0456 35268
Holding frame for a specimen slide holder	14 0456 35434
Slide rack 30 (specimen slide holder for 30 specimen slides)	14 0475 33750
Specimen slide holder for 30 specimen slides, Type Leica, plastic, 5 pcs.	14 0475 33643
Adapter Sakura (specimen slide holder 140474 33463)	14 0475 34515
Adapter Medite 20	14 0475 34516
Adapter Medite 30	14 0475 34517
Adapter Shandon	14 0475 34518
Adapter Microm 30	14 0475 34943
Reagent vessel, assembly, with lid and transport handle	14 0475 33659
Cover, without slots for reagent vessel	14 0475 34488
Cover, with slots for reagent vessel	14 0475 34486
Cover for 12 vessels, assembly	14 0475 33644
Holding bracket (stand for one reagent vessel)	14 0456 35445
Dummy plugs (sealing plugs for wash vessel)	14 0456 35393
Supply hose for rinsing water, 2.50 m, assembly with 3/4" connection	14 0474 32325
Outlet hose, 4 m	14 0475 35748
Exhaust adapter, assy.	14 0456 35435
Flexible tube, D-50 mm/2 m length	14 0422 31974
Flexible tube, D-50 mm/4 m length	14 0422 31975
Drip tray (wax collecting bowl for oven)	14 0456 35216
O-ring 3 x 2 mm FKM (O-ring for hook)	14 0253 35822
O-ring 7.65 x 1.78 FKM (O-ring for wash vessel)	14 0253 34214
V filter 3/4" 40/22 H6 (wax strainer).	14 0456 36101
Staining protocol block	14 0456 35459
Remote alarm device for exit drawer	14 0456 30906

11.3 Compatible staining programs

Reagent	Station	Program 1 H&E			Program 2 Papanicolaou		
		Step	Time	Exact	Step	Time	Exact
	Oven	1	10:00	Y			
Xylene	1	2	2:00	N			
Xylene	2	3	2:00	N			
100 % alcohol	3	4	2:00	N			
100 % alcohol	4	5	2:00	N			
70 % alcohol	5	6	1:00	N	1	1:30	N
Wash medium	Wash station 1	7	2:00	N	2	2:00	N
Hematoxylin	6	8	5:00	Y	3	3:30	Y
Wash medium	Wash station 2	9	2:00	N	4	2:00	N
HCl alcohol	7	10	0:02	Y	5	0:05	Y
Wash medium	Wash station 3	11	3:00	N	6	2:00	N
Scott's medium	8	12	3:00	Y	7	4:00	Y
Wash medium	Wash station 4	13	3:00	N	8	2:00	N
95 % alcohol	9				9	1:30	N
OG 6	10				10	2:00	Y
95 % alcohol	11				11	1:30	N
95 % alcohol	12				12	1:30	N
EA 50	13				13	2:30	Y
Eosin	14	14	2:00	Y			
95 % alcohol	15	15	0:30	Y	14	1:30	Y
100 % alcohol	16	16	2:00	N	15	1:30	Y
100 % alcohol	17	17	2:00	N	16	1:30	Y
100 % alcohol	18	18	2:00	N	17	1:30	Y
Xylene	Exit tank	19			18		



Note

Wash stations 1 to 4 (and the stations in between) are used in the same sequence in both programs. These two programs are compatible with each other, but not with the programs on ([→ p. 51 – Compatible staining programs](#)).

Compatible staining programs

Reagent	Station	Program 1 H&E			Program 5 Hx Counterstain		
		Step	Time	Exact	Step	Time	Exact
Oven		1	10:00	Y			
Xylene	1	2	2:00	N			
Xylene	2	3	2:00	N			
100 % alcohol	3	4	2:00	N			
100 % alcohol	4	5	2:00	N			
70 % alcohol	5	6	1:00	N			
Wash medium	Wash station 1	7	2:00	N			
Hematoxylin	6	8	5:00	Y	1	5:00	Y
Wash medium	Wash station 2	9	2:00	N	2	2:00	N
HCl alcohol	7	10	0:02	Y	3	0:02	Y
Wash medium	Wash station 3	11	3:00	N	4	3:00	N
Scott's medium	8	12	3:00	Y	5	3:00	Y
Wash medium	Wash station 4	13	3:00	N	6	3:00	N
Eosin	14	14	2:00	Y			
95 % alcohol	15	15	0:30	Y			
100 % alcohol	16	16	2:00	N	7	2:00	N
100 % alcohol	17	17	2:00	N	8	2:00	N
100 % alcohol	18	18	2:00	N	9	2:00	N
Xylene	Exit tank	19			10		

11.4 Glossary

CURSOR	A flashing cursor appears on the LCD under the parameters that the user can change.
DISPLACEMENT	The amount of REAGENT transferred by the SPECIMEN SLIDE HOLDER from one STATION to another.
EXACT IMMERSION	The IMMERSION TIME is kept at 1 second, exactly as programmed.
EXIT DRAWER	Drawer into which the instrument inserts the SPECIMEN SLIDE HOLDER for subsequent removal by the user.
EXTRACTION	Noxious REAGENT vapors are extracted by a fan using a filter.
HEAD	see TRANSPORT ARM
HOOK ON	Process in which the TRANSPORT ARM gets hooked on the SPECIMEN SLIDE HOLDER before PICKING UP.
IMMERSION TIME	The time that a SPECIMEN SLIDE HOLDER stays in a reagent STATION. It counts the time from the end of the LOWERING to the beginning of the PICKUP.
INCUBATION TIME	see IMMERSION TIME
INEXACT IMMERSION	The IMMERSION TIME is reached as programmed or extended to ensure compatibility with other, exactly defined times.
LCD	The LCD on the control panel.
LEDs	Light emitting diodes on the control panel and on the LOAD DRAWERS and EXIT DRAWERS.
LOAD DRAWER	Drawer into which the user inserts the SPECIMEN SLIDE HOLDER and from which this is removed by the TRANSPORT ARM for STAINING.
LOWERING	The SPECIMEN SLIDE HOLDER is inserted into a STATION by the TRANSPORT ARM.
OVEN	STATION with warm air flowing through it to dry the SPECIMEN SLIDES so that the tissue sections adhere to them.
PC	IBM-compatible personal computer
PICKING UP	The SPECIMEN SLIDE HOLDER is removed from a STATION with the TRANSPORT ARM in such a way that only minimal REAGENT DISPLACEMENT takes place in the process.
PROGRAM	Series of STEPS to which the SPECIMEN SLIDE HOLDER is subjected for STAINING in the instrument.
REAGENT	Chemicals used for STAINING.
REAGENT STATION	REAGENT-filled vessel, into which the SPECIMEN SLIDE HOLDERS are inserted.
SETUP	Parameter setting required for operating the instrument regardless of the program used, for example, the temperature of the OVEN and the number of UP/DOWN MOVEMENTS (DIPS).
SOLVENT	Organic liquid, such as xylene and ethanol
SPECIMEN SLIDE	Specimen slides made of glass 25 x 75 x 1 mm
SPECIMEN SLIDE HOLDER	Frame on which the SPECIMEN SLIDES sit to make for easier handling with the instrument.
STAINING	The process in which the tissue sections are stained.
STATION	Part on the inside of the instrument, where part of the STAINING occurs.

STEP	Defined by the STATION, IMMERSION TIME and time accuracy for a certain process in the STAINING process.
TRANSFER ARM	Device that moves in the x-, y- and z-directions for PICKING UP or LOWERING, MOVING UP/DOWN (DIPPING) and TRANSPORTING the SPECIMEN SLIDE HOLDERS from STATION to STATION.
UNHOOK	Process in which the TRANSPORT ARM separates from the SPECIMEN SLIDE HOLDER after the LOWERING or after the IMMERSION PROCESSES.
UNLOADING	Removal of a SPECIMEN SLIDE HOLDER from the EXIT DRAWER or from a station in which the STAINING run is ended.
UP/DOWN MOVEMENT	The SPECIMEN SLIDE HOLDER is moved up and down (dipped) after being inserted into a REAGENT STATION. The number of up/down movements (dips) can be programmed.
UPS (battery backup)	Uninterruptible power supply that allows STAINING to continue during brief power failures.
WASH STATION	Vessel through which water flows to wash REAGENT from a SPECIMEN SLIDE HOLDER and the SPECIMEN SLIDES in it.

www.LeicaBiosystems.com



Leica Biosystems Nussloch GmbH
Heidelberger Strasse 17 - 19
69226 Nussloch
Germany

Tel.: +49 - (0) 6224 - 143 0
Fax: +49 - (0) 6224 - 143 268
Web: www.LeicaBiosystems.com