

Instructions for Use

Leica ST4020

Small Linear Stainer



Leica ST4020, English
Order No.: 14 0509 80101 RevJ

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

NOTE

The information, numerical data, notes and value judgments contained in this documentation 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 at the back of the instrument.

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Table of Contents

1.	Important Information	6
1.1	Symbols in the text and their meanings.....	6
1.2	Intended purpose.....	7
1.3	Qualification of personnel.....	7
1.4	Type.....	7
2.	Safety	8
2.1	Safety notes.....	8
2.2	Warnings.....	8
3.	Instrument Components and Specifications.....	11
3.1	Overview - instrument components	11
3.2	Instrument specifications.....	12
3.3	Functional description of components - system overview.....	13
3.4	Functional Areas of the Slide carrier	15
3.5	Standard delivery – packing list.....	16
3.6	Technical data.....	17
4.	Instrument Setup.....	19
4.1	Installation site requirements.....	19
4.2	Unpacking the instrument.....	19
4.3	Setup.....	21
4.4	Water Connection.....	22
4.5	Installing the rinsing water containers.....	22
4.6	Remedy if hose is too short.....	26
5.	Operation.....	27
5.1	Switching on the instrument.....	27
5.2	Control panel functions.....	27
5.3	Setting the Operating Parameters	29
5.4	Setting the rinsing water flow rate	32
5.5	Processing slides.....	33
5.5.1	Starting a staining run.....	34
5.5.2	Adding more slide carriers during a staining run.....	35
5.5.3	Temporarily pausing a staining run	36
5.5.4	Ending a staining run prematurely.....	37
5.5.5	Removing processed specimen slides.....	38

Table of Contents

6.	Cleaning and Maintenance	40
6.1	Cleaning the Instrument	40
6.2	Maintenance Instructions.....	41
7.	Troubleshooting	42
7.1	General	42
7.2	Alarms.....	42
7.3	Fault detection and correction list.....	43
7.4	Power failure	45
8.	Optional Accessories	46
8.1	Ordering information	46
9.	Warranty and Service	52
10.	Decontamination Certificate	53

1. Important Information

1.1 Symbols in the text and their meanings



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



Notes, i.e. important user information appears in a gray box and is marked by an information symbol .



Inflammable solvents and reagents are identified using this symbol.



This warning symbol on the device notifies users of the danger of electric shock. To avoid the risk of injury from electric shock, a panel bearing this marking, or this housing, must not be opened.



Samples processed on this instrument may be biohazardous. Appropriate safety procedures must be followed to prevent a biohazard.

RUN

Function keys to be pressed on the instrument are written in bold-print capital letters.

(5)

Numbers in parentheses refer to item numbers in illustrations.



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

Country of Origin: United States

Country of Origin: The Country of Origin box defines the country where the final character transformation of the product has been performed.



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.



In vitro diagnostic medical device: Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.



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



China RoHS: Environmental protection symbol of the China ROHS directive. The number in the symbol indicates the "Environment-friendly Use Period" of the product in years.



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Larch House, Woodlands Business Park, Milton Keynes
England, United Kingdom, MK14 6FG

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



Fragile, handle with care
Indicates a medical device that can be broken or damaged if not handled carefully.



Attention: 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.



WEEE Symbol: Indicates separate collection for WEEE – Waste of electrical and electronic equipment, consists of the crossed-out wheeled bin (§ 7 ElektroG).



Manufacturer: Indicates the manufacturer of the medical product.



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



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



Manufacturing date: Indicates the date when the medical device was manufactured.



UL Listing Mark: Indicates that UL experts have determined that a representative sample meets UL safety requirements and the manufacturer claims that the product continues to meet those requirements.



Keep dry
Indicates a medical device that needs to be protected from moisture.



This way up
Indicates correct upright position of the transport package.

1.2 Intended purpose

The Leica ST4020 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 ST4020 is designed for in vitro diagnostic applications.

Any other use of the instrument is considered improper!

1.3 Qualification of personnel

- The Leica ST4020 may be operated by trained laboratory personnel only.
- All laboratory personnel designated to operate the Leica instrument must read this Instructions for Use carefully and must be familiar with all technical features of the instrument before attempting to operate it.

1.4 Type

All information contained in this Instructions for Use applies solely to the instrument type listed on the cover page. A nameplate indicating the instrument serial number is attached to the rear side of the instrument.

2. Safety



The safety and caution notes in this chapter must be observed at all times. Be sure to read these instructions, even if you are already familiar with the operation and use of other Leica products.

2.1 Safety notes

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.

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 this Instructions for Use.



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.



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



**Material safety data sheets for reagents can be requested from the respective manufacturer of the chemical. Alternatively, they can be downloaded from the following website:
<http://www.msdsonline.com>**



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

2.2 Warnings

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

Hazards – safety regulations on the instrument itself



Warning labels on the instrument marked with a warning triangle indicate that the correct operating instructions (as defined in this Instructions for Use) must be followed when operating or replacing the item marked. Failure to adhere to these instructions may result in an accident, personal injury, damage to the instrument or accessory equipment.

Hazards – transport and installation



Once unpacked, the instrument may be transported only in an upright position. Place the instrument on a laboratory bench and align it horizontally. The instrument must not be placed in direct sunlight (e.g. next to a window). Avoid impacts, bright direct light, and excessive temperature fluctuations. 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. The instrument will automatically detect the voltage/frequency of the power source. The installation location must be well ventilated, and must contain no sources of ignition of any kind. The chemicals used in the Leica ST4020 are easily inflammable and hazardous to health. Do not operate the instrument in rooms with explosion hazard. Condensation water may form in the instrument, if there is an extreme difference in temperature between the warehouse and the installation site and if air humidity is high at the same time. In this case, a two-hour waiting period must be maintained before switching on the instrument.

Warnings – Handling reagents



Take care when handling solvents! Always wear rubber gloves and safety goggles when handling the chemicals used in this instrument. The reagents used can be both toxic and/or flammable. When disposing of spent reagents, observe the applicable local regulations and the waste disposal regulations of the company/institution in which the instrument is being operated. Do not smoke near the stainer or the reagents. The stainer should be operated under an extractor hood.

2. Safety

Warnings – Operating the instrument



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.

In the event of an emergency, switch off the power switch and unplug the instrument from the power supply.

The instrument must be positioned so that the connection socket and the power switch are easily accessible at all times.

The power supply cord must be routed so that it is not likely to be walked on or pinched by items placed on or against it.

Suitable protective clothing (lab coat, gloves, protective goggles) must be worn when working with reagents and specimen slides.

There is a danger of fire if an open flame (e.g. Bunsen burner) is used directly beside the instrument (solvent fumes). Therefore, keep all ignition sources at least 2 meters away from the instrument!

While the stainer is not in use, keep the reagent containers covered with the reagent cover provided with the stainer.

Warnings – Maintenance and cleaning



Before any maintenance, switch off the instrument and unplug it from power supply.

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, chlorine or xylene!

Clean the Hood and the housing with commercial mild household cleaning agents. The finished surfaces are not resistant to solvents!

Prevent liquids from entering the interior of the instrument while the instrument is being cleaned or during operation.

Do not use any attachments or accessories not recommended by the product manufacturer as such attachments and accessories may cause hazards, damage the instrument and void the warranty.

3. Instrument Components and Specifications

3.1 Overview - instrument components

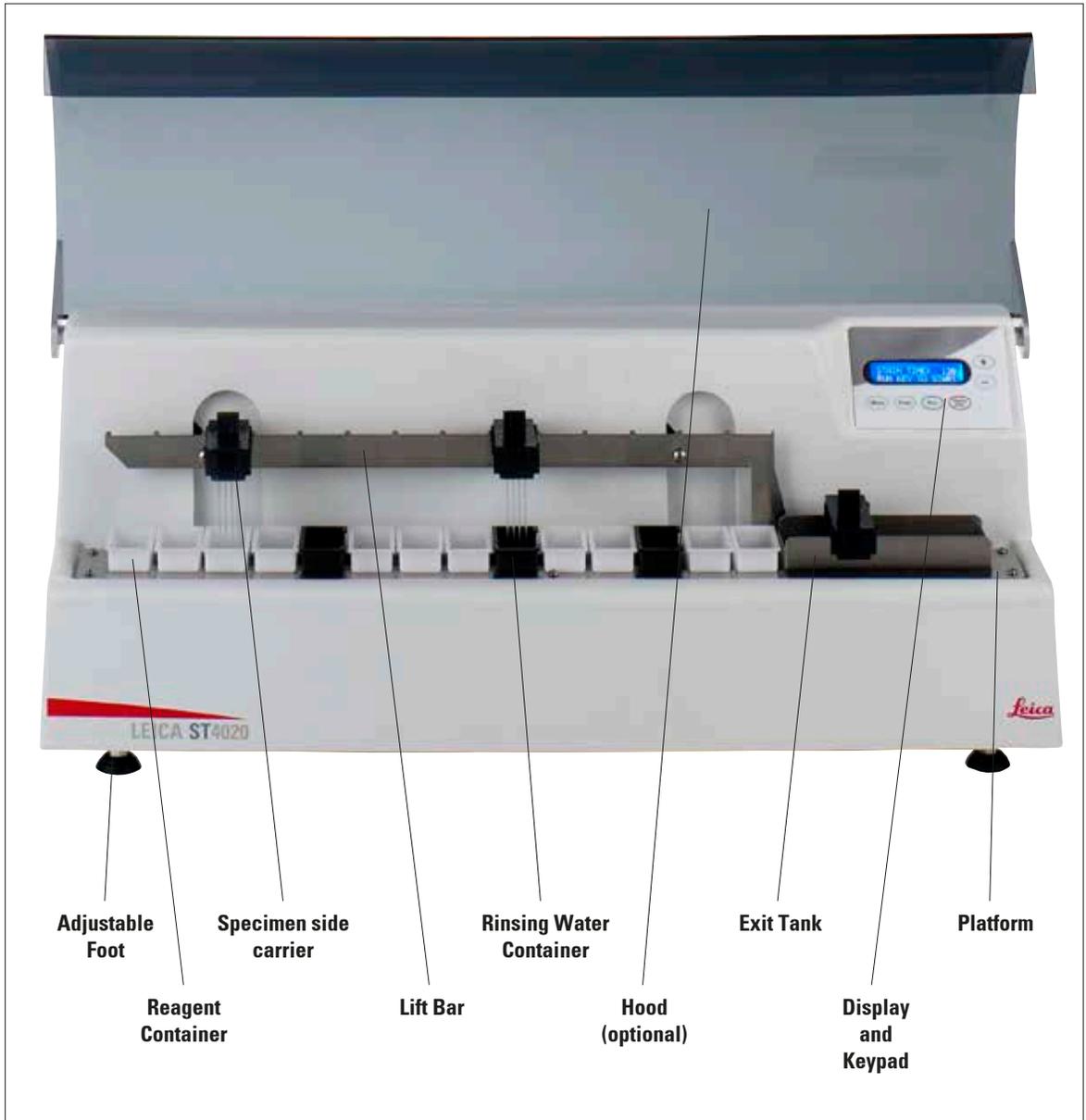


Fig. 2

3. Instrument Components and Specifications

Instrument rear view

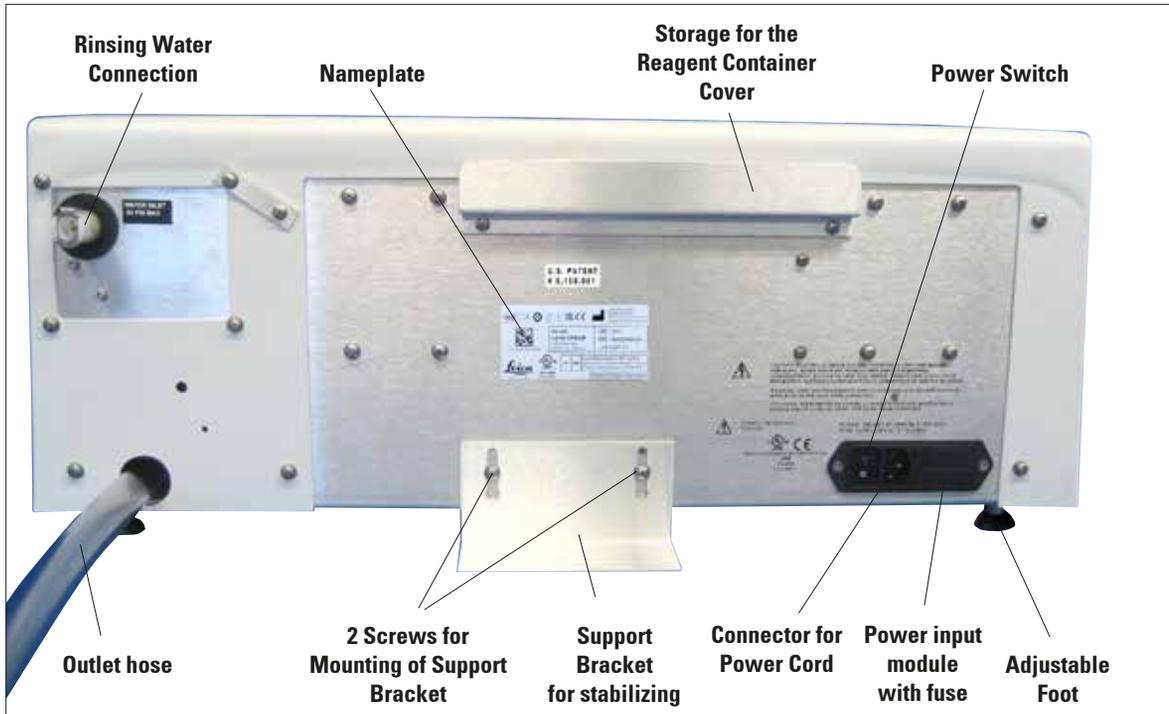


Fig. 3

3.2 Instrument specifications

The Leica ST4020 is an automatic linear stainer designed for stand-alone use, and can be used for staining frozen tissue sections in histology labs as well as anatomical pathology laboratories. It is ideal for use in staining samples from either Mohs technique laboratories or sections from frozen section laboratories or general surgical pathology. In addition, it is intended to be used in hematology, cytology, as well as performing routine H & E stains.

The user loads the slides in a carrier that can hold up to 4 slides at a time. The stainer provides 14 reagent stations that can be used as reagent stations or running rinse water stations and has an Exit Tank that can hold up to four processed slide carriers.

The slides will remain in each reagent station for a fixed programmable time that is applicable to all stations during staining. Station time, number of dips and start position are programmable.

3.3 Functional description of components - system overview

Figure 2 on page 10 shows an overview of the stainer.

The Leica ST4020 has the following functional areas:



Fig. 4

Keypad (14) with Display (13)

A membrane keypad with 6 keys allows the user to set up the processing parameters and also allows the user to start and stop the processing runs.

An LCD display consisting of two rows, each row 16 characters long, in which the progress of slide processing and the stainer's processing parameters are displayed. The user is directed to take various actions as necessary.

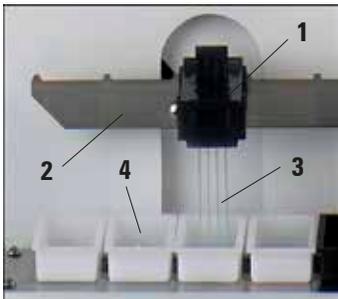


Fig. 5

Slide Carrier (1) and Lift Bar (2)

The user inserts the slides for staining (3) in the slots of the slide carrier (1). This is then placed onto the Lift Bar (2), by which it is transferred to the first reagent container.

The Lift Bar moves the slide carriers from one station to the next station and eventually deposits them in the exit tank.

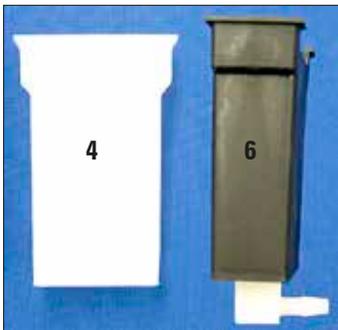


Fig. 6

Reagent container (4) and rinsing water container (6)

Each reagent container (4) can hold up to 50 ml of the reagent for staining and processing.

A total of 14 reagent and rinse containers (6) can be arranged to customize the stainer to carry out a specific staining protocol.

Each of the 14 processing positions must have either a reagent container or a rinse container present.

The rinse containers allow the slides to be subjected to running rinse water while the slides are being processed.

3. Instrument Components and Specifications

Functional description of the components (continued)



Fig. 7

Exit Tank (7)

The exit tank holds the processed slides. It can hold up to 4 slide carriers.

As soon as the exit tank is full, the stainer pauses processing until the slide carriers are removed.

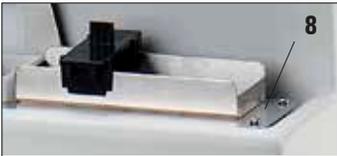


Fig. 8

Platform (8)

The platform holds the reagent containers, rinse containers and the exit tank in fixed locations to ensure the proper operation of the stainer. All 14 containers and the exit tank must be placed on the platform to ensure proper operation of the stainer.

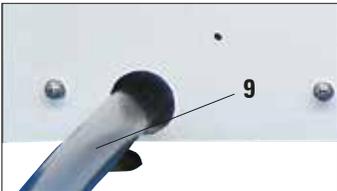


Fig. 9

Waste Water Drain Hose (9)

The waste water drain hose must always be inclined downwards so that the rinsing water drains into a collecting receptacle or drainage basin, and cannot collect in the stainer.

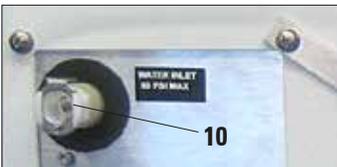


Fig. 10

Rinsing water supply (10)

A connection port for the rinsing water supply is located on the rear of the stainer. The necessary connecting hose with clamp is included in the equipment supplied.

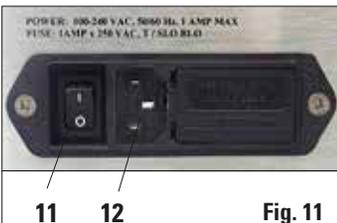


Fig. 11

Main Switch and (11) Connection to Power Supply (12)

The stainer is connected to the power supply (12) by the power supply cord, and activated with the main switch (11).

The instrument can be operated with alternating current at 100 to 230 Volt with a power frequency of 50/60 Hz.

3.4 Functional Areas of the Slide carrier

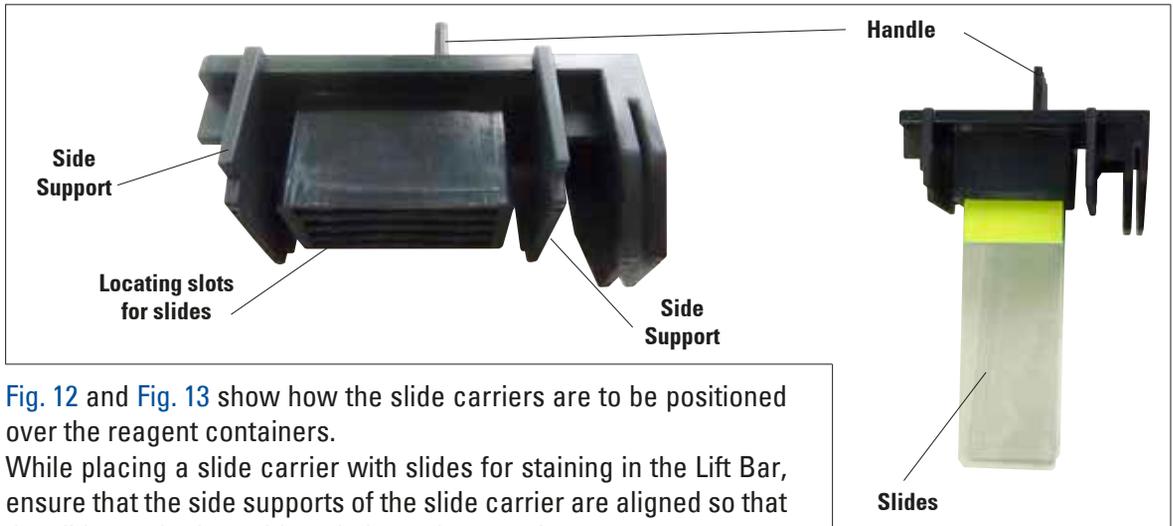


Fig. 12

Fig. 12 and Fig. 13 show how the slide carriers are to be positioned over the reagent containers. While placing a slide carrier with slides for staining in the Lift Bar, ensure that the side supports of the slide carrier are aligned so that the slide carrier is positioned above the container.

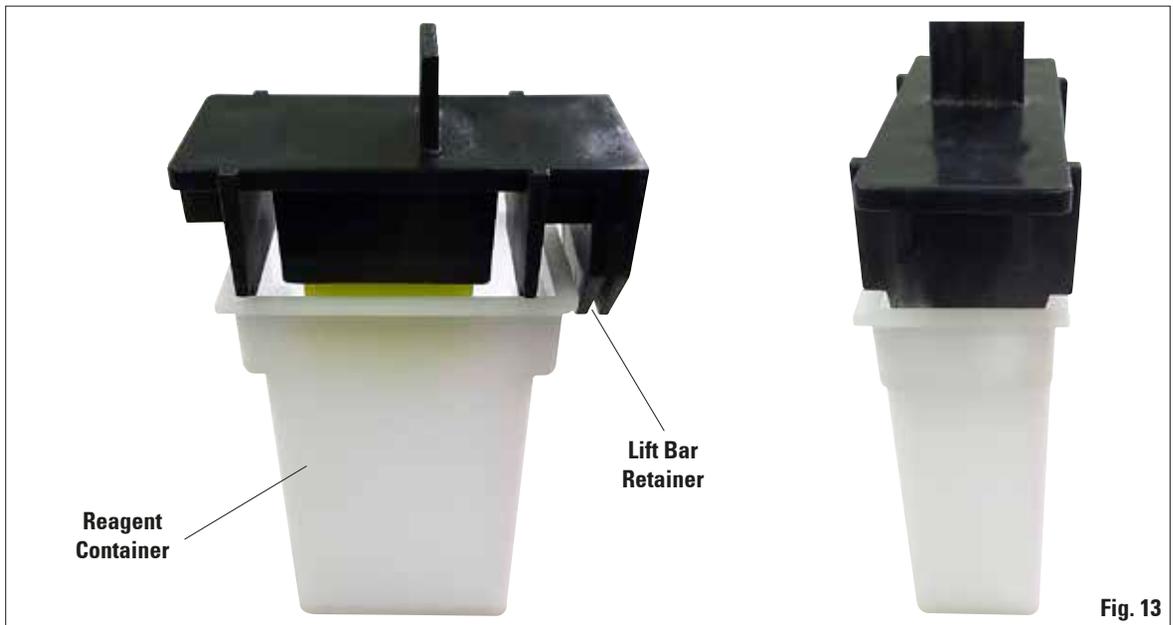


Fig. 13

3. Instrument Components and Specifications

3.5 Standard delivery – packing list

The Leica ST4020 standard delivery consists of the following items:

Qty	Designation	Order No.
1	Leica ST4020 basic unit	14 0509 46425
14	Reagent containers (white)	14 0509 46437
3	Wash stations (black)	14 0509 46441
3	Slide carriers	14 0509 46438
1	Water Inlet Hose Assembly (with hose connectors, 150 cm long, Ø 1/4")	14 0509 46532
1	Water drain hose 150 cm long (installed on the instrument)	14 0509 46445
1	Hose distributor to rinse stations Ø 1/8" (installed in the instrument)	14 0509 46533
1	Exit Tank	14 0509 46450
1	Set of tubings, fittings, tie wraps:	14 0509 46459
1	Water hose 40 cm long, Ø 1/8"	
3	in line fittings	
2	plugs	
10	tie wraps	
1	Support Bracket for Stabilizing	14 0509 46570
1	Cover for reagent container (made of metal)	14 0509 46442
1	Set of replacement fuses, consisting of	
2	Fuses 250 V, T 1.0 A	14 0509 46463
1	International bundle Instructions for Use (incl. English printout and additional languages on a data storage device 14 0509 80200)	14 0509 80001

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



Check the delivery carefully against the packing list, delivery note and your order. Should you find any discrepancies, please contact your Leica sales office without delay.

3.6 Technical data

Electrical specifications

Nominal supply voltage	100 – 240 V AC
Nominal supply frequencies	50 / 60 Hz
Mains supply voltage fluctuations	± 10 %
Power consumption	100 VA
Mains input fuses	T1A L 250 V AC

Dimensions and weight specification

Overall size of device in operating mode (width x depth x height, mm)	630 x 245 x 250
Height with hood open (mm):	430
Empty weight (without accessories, kg)	16
Overall weight (with accessories, kg)	19
Device weight including packaging (kg)	21

Environmental specification

Operating altitude (meters above sea level, min / max)	Up to a max. of 2000 m above sea level
Temperature (operation, min / max)	+15 °C to +30 °C
Relative humidity (operation, min / max)	20 % to 80 %, non-condensing
Temperature (transit, min / max)	-29 °C to +50 °C
Temperature (storage, min / max)	+5 °C to +50 °C
Relative humidity (transit / storage)	10 % to 85 %, non-condensing
Minimum distance to walls (mm)	250
Operating noise level	< 70 dB (A)
BTU (J/s)	100 J/s

Emissions and boundary conditions

Overvoltage category to IEC 61010-1	II
Pollution degree to IEC 61010-1	2
Means of protection to IEC 61010-1	Class 1
Degree of protection to IEC 60529	IP 20
Heat emission	100 J/s
A-weighted noise level, measured at 1 m distance	≤ 70 dB (A)

3. Instrument Components and Specifications

EMC class	Class B
Approvals	CE, cULus Listed
Throughput	
Specimen slides per hour	Depends on program structure and load
Loading capacity	Max. 4 slide carriers
Unload / storage capacity	14
Rack	
Slide rack capacity	4
Stations	
Total number of stations	14
Total number of reagent stations	14
Wash stations	max. 3 (than only 11 reagent stations are possible)
Reagent container volume	50 ml
Agitation	
Agitation performed	By lift bar
Agitation strokes	0 to 3 dips per station for dwell times > 4 s.
Wash stations	
Number of wash stations	3
Fresh water connection	
Hose length	1.5 m
Connection piece	1/4"
Wastewater connection	
Hose material	PVC
Hose length	1.5 m
Drain principle	Gravity

4.1 Installation site requirements

- The instrument requires an installation area of approx. 250 x 700 mm. A clearance of at least 25 cm must be left between the instrument and the closest wall or other instruments.
- If the stainer is to be operated with rinsing stations, fresh water and waste water connections must be no more than 1.2 m from the ports on the back of the instrument.
- It must be ensured that there is sufficient clear space (approx. 30 cm) above the instrument to allow unobstructed opening of the optional hood.
- Room temperature consistently between +10 °C and +30 °C.
- Relative air humidity maximum 80 %, non-condensing.
- Practically vibration-free floor. Avoid vibrations, direct sunlight and heavy variations in temperature.



- **The chemicals used in the Leica ST4020 are easily inflammable and hazardous to health.**
- **The installation site for the Leica ST4020 must be well ventilated, and there must be no ignition sources of any kind in the area.**
- **The instrument must not be operated in areas at risk of explosion.**

4.2 Unpacking the instrument

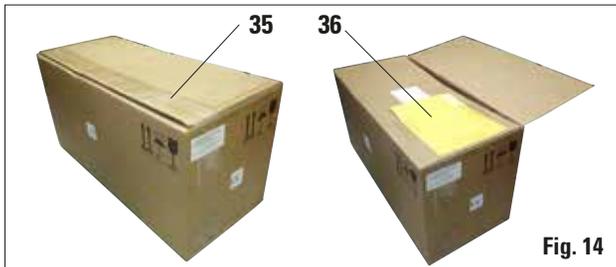


First check the shipment for external damages upon arrival. If it is evident that the shipment was damaged during transport, please make a claim to the carrier immediately.

- Detach the Instructions for Use from the outside of the package.
- Open the packaging.
- Remove foam material.
- Take out all accessories.
- Check the contents of the delivered pack against the order form to ensure that all components and accessories are included.

4. Instrument Setup

Unpacking the Instrument (continued)



These unpacking instructions only apply if the box is placed with the symbols  facing upwards for unpacking.

1. Detach the Instructions for Use from the outside of the box.
2. Cut through the packing tape (35) on the top edge of the box.
3. Remove the yellow envelope with "Documents of Conformity" (36) and keep it in a safe place.
4. Remove the accessory carton (37) and remove the packing material (39).
5. Use the molded foam pads (38) to pull the instrument out of the inside packaging and place it on a firm laboratory bench.
6. Pull the molded foam pads (38) away from the sides of the instrument. Remove the protective film (40) from the instrument.
7. Remove the cover of reagent container and the water hose from the bottom of the box.
8. The instrument must now be prepared for correct use in accordance with the instructions in the accompanying Instructions for Use - the first step is to align the instrument feet.



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



4.3 Setup

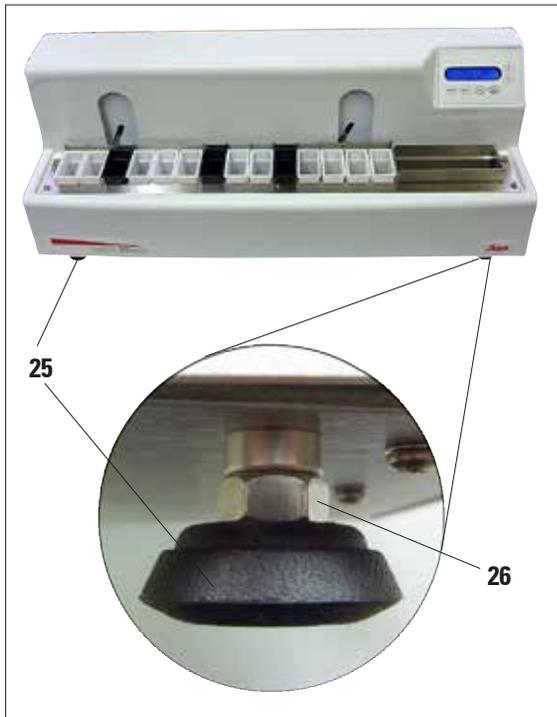


Fig. 19

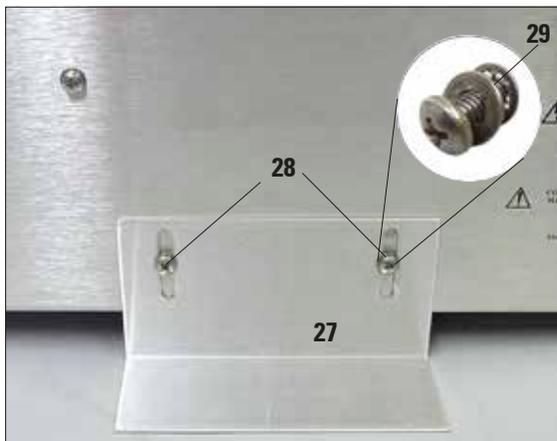


Fig. 20

Horizontal Alignment

For safe and accurate work, it is important that all instrument feet are in uniform contact with the installation surface.

The stainer is horizontally aligned at the factory. If a completely level or horizontal surface is not available at the installation site, the instrument must be realigned.

For this purpose, the instrument feet (25) are height-adjustable.

- For alignment, loosen the locknuts (26) using a size 11 open-end wrench.
- Adjust the instrument feet (25) until the instrument is in a stable position at the installation location according to requirements.
- Retighten the locknuts.

Mounting the Support Bracket

To ensure that the instrument cannot tip over when its keys are pressed, the support bracket (27) must be mounted on the rear.

- To do this, first unscrew the two Phillips head screws (28) with a screwdriver. Place them together with the two associated washers (29)
- Place the support bracket against the rear of the instrument (Fig. 20), reinsert but do not fully tighten the two screws.
- Press the support bracket down onto the support surface until a face of the plate lies flush with the bench surface. Tighten the plate in this position.

4. Instrument Setup

4.4 Water Connection

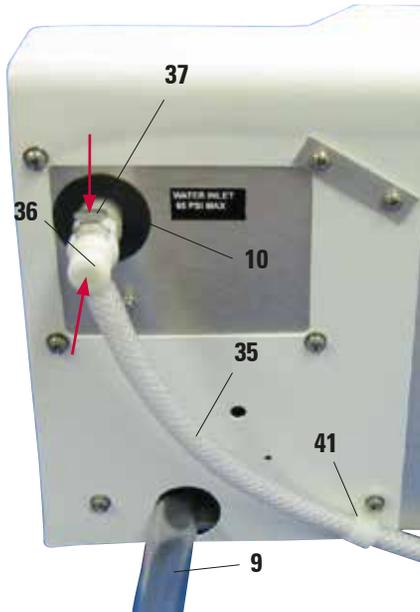


Fig. 21

- Run the drain hose (9) into a suitable collecting tank or waste basin. Make sure that the hose is not kinked and that the water is able to drain freely downwards.
- Then connect the rinsing water supply (35) to the stainer.
- To do this, push the connector (36) into the orifice (10) on the instrument until it clicks into place. To detach the hose, press on the plate (37) and pull the connector back.
- Secure the hose to the unit using the clamp (37) at the location shown in Fig. 21.
- Connect the other end of the hose to a suitable water tap. If necessary an optional connection kit can be used for this.
- Do not open the water inlet yet!
- Adjustment of the rinsing water flow rate is described in Chap. 5.4.

4.5 Installing the rinsing water containers

Up to three rinsing stations may be provided on the stainer. The rinsing water containers can be located at any of the 14 reagent stations.

The equipment supplied includes three hoses with Y-connectors. The cable ties on these Y-connectors must not be removed. Also, do not detach the Y-connectors from the associated hoses. Watertight, functional rinsing stations in accordance with the desired staining protocol can be set up with the aid of additional cable ties, hoses, plugs and connectors that are also included in the scope of delivery.



While the rinsing stations are being set up, it must be ensured that the rinsing water containers are positioned horizontally on the platform, and all hoses are lying horizontally on the bottom of the drainage tank, outside of the travel path of the Lift Bar. The rinsing water hoses must not be subjected to any kind of pulling or stretching stresses.

Installing the rinsing water containers (continued)

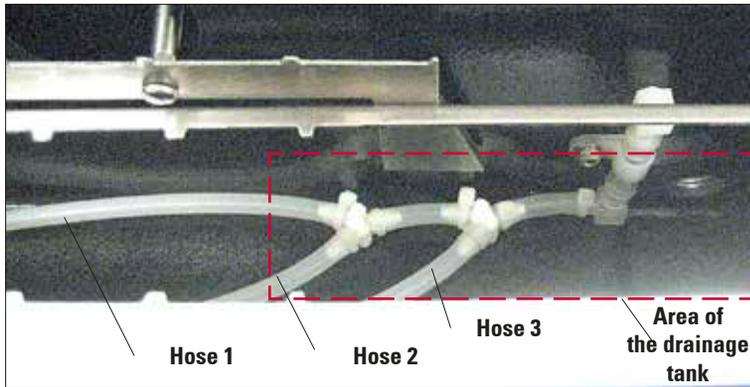


Fig. 22

Fig. 22 shows how the hoses are routed in the instrument.

If you want to work entirely without water, no further steps are necessary – simply do not connect a water supply line to the instrument.

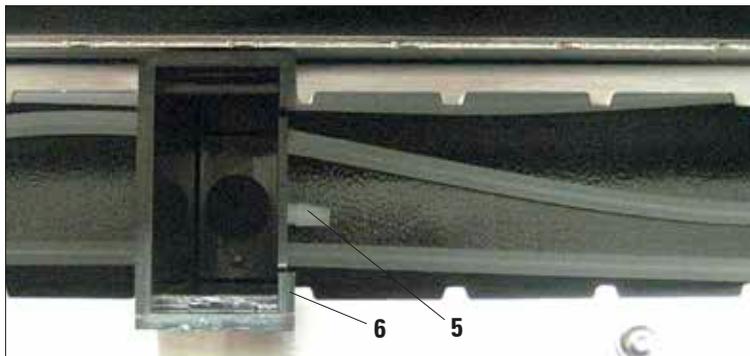


Fig. 23

Place the rinsing water containers (6) in the desired position on the platform. Start with the station closest to the drainage tank.

Insert the rinsing water container so that the hose connection (5) points to the exit tank (Fig. 23).

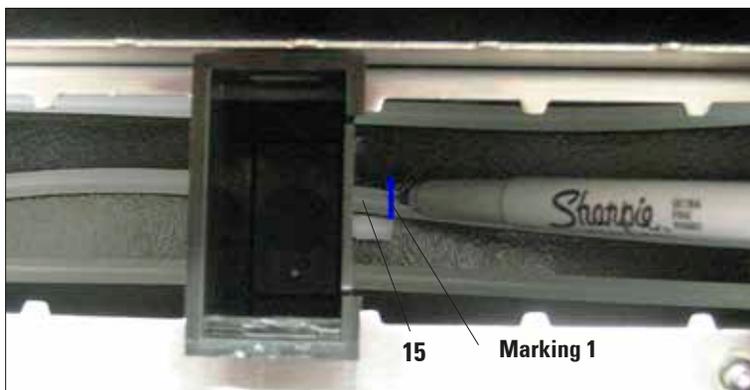


Fig. 24

The hose (15) should run level along the bottom of the instrument.

Mark the end of the hose that will connect to the rinsing water container.

This is "Marking 1".

4. Instrument Setup

Installing the rinsing water containers (continued)

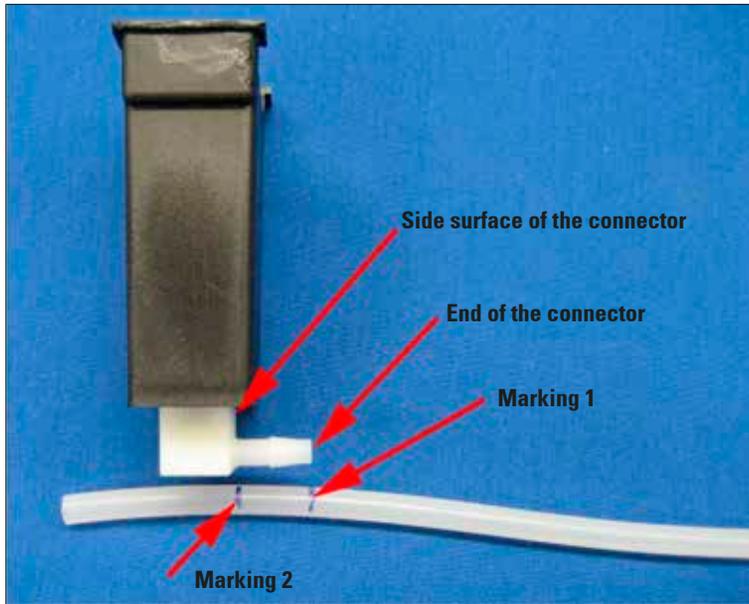


Fig. 25

- Now take the rinsing water container and the hose out of the stainer.
- Align marking 1 to the end of the connector and make a second marking ("Marking 2") to indicate the lateral surface of the connector (Fig. 25).
- Cut the hose off at Marking 2.

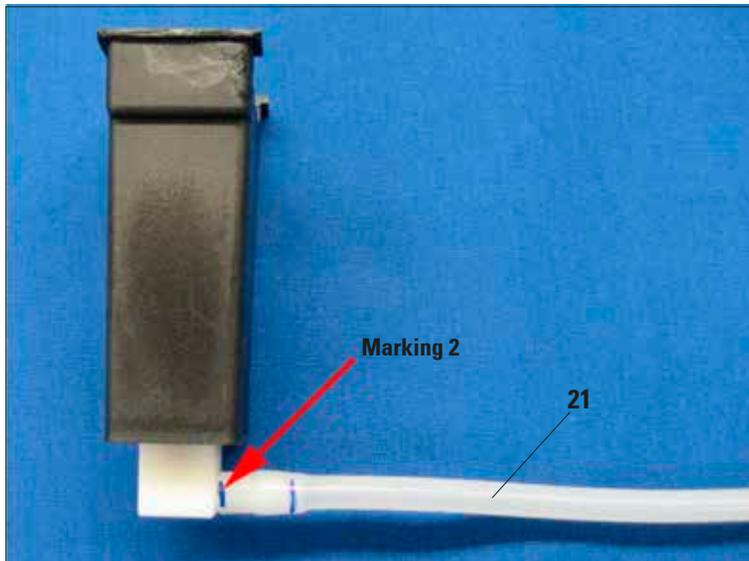


Fig. 26

- Then push the hose (21) fully onto the connector by twisting until the end of the hose is flush against the side surface of the connector (Fig. 26).
- If the hose is not pushed completely onto the connector, it may become detached as soon as the water supply is turned on.



Do not stretch tubing to fit on the fitting.

Installing the rinsing water containers (continued)

- Place the rinsing water container back in the desired position on the platform. Check that the rinsing water container is positioned horizontally on the platform.

If the hose is too long, the rinsing water container will tilt to the right; if it is too short, it will tilt to the left. If the rinsing water container is not positioned horizontally on the platform, it cannot be guaranteed that the stainer will function properly.



If the rinsing water container is not positioned horizontally on the platform, it cannot be guaranteed that the stainer will function properly.

- Repeat the steps described above for the other rinsing stations.

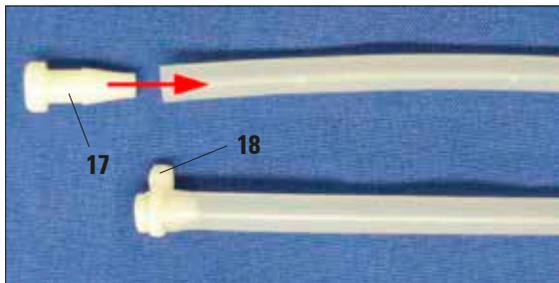


Fig. 27

If only one or two rinsing stations are required, the hoses that are not used must be sealed with a plug (17), see Fig. 27.

- To do this, twist and push the plug fully into the end of the hose, and then secure it with a cable tie (18).

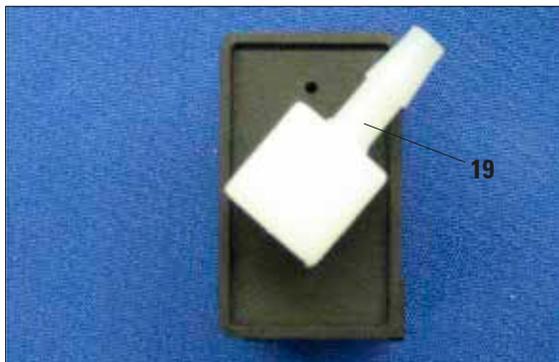


Fig. 28

If two rinsing stations are to be located immediately beside one another, the connector (19) for the left station must be aligned as shown in Fig. 28.

4. Instrument Setup

4.6 Remedy if hose is too short

If the hose (21) at one of the stations should be too short, or if a hose has been cut too short by mistake, the following remedy may help:

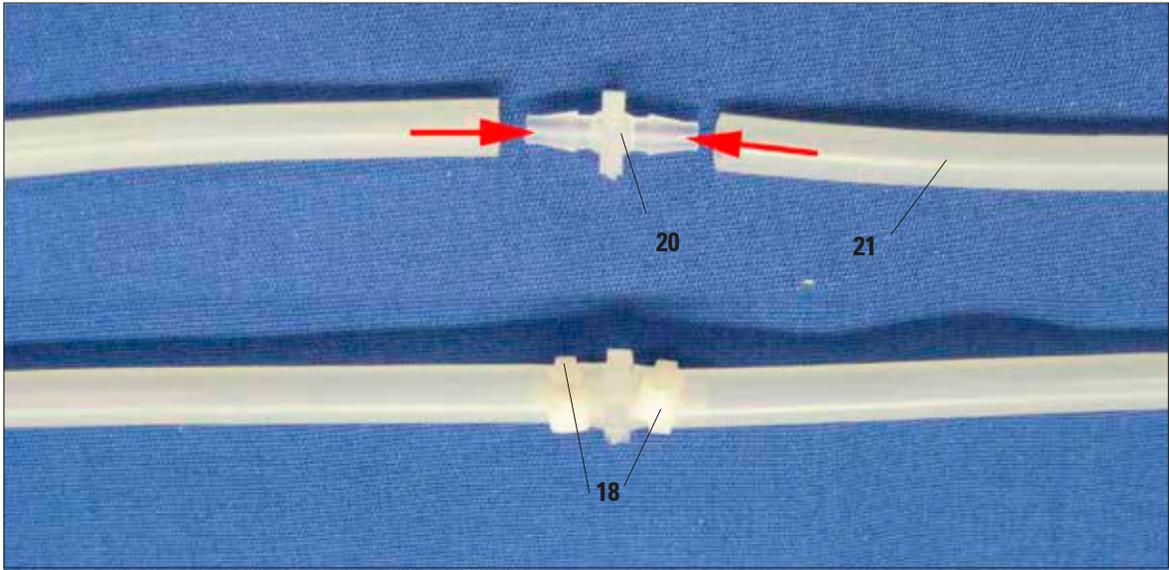


Fig. 29

- Cut the hose roughly in the middle between the Y-connector and the rinsing station.
- Use the extension connector (20) included with the package to attach an additional hose section (21) of the required length.
- To do this, measure the length of the hose again, and if necessary cut it to exactly the required length.
- Push both ends of the hose as far as they will go onto the extension connector, and then secure each hose with a cable tie (18).
- Finally, check again that the rinsing water container is positioned horizontally on the platform.

5.1 Switching on the instrument



The instrument **MUST** be connected to a grounded power socket. Only the power cord provided may be used, which is intended for the local power supply (socket). Do not interfere with the grounding function by using an extension cord without a ground wire. The AC socket used for the power supply must be close to the instrument and easily accessible.



Fig. 30

- Before plugging the instrument into the mains, make sure that the main switch (**11**) on the rear of the instrument is in the **OFF** ('0') position.
- Insert the correct power cord into the power input socket and connect to a power socket (**12**). If applicable, switch on the switch for the power socket.
- Then switch on the main switch on the instrument (**11**) (**ON** = 'I').

5.2 Control panel functions

The control panel consists of a membrane keypad with six pushbuttons, and a screen consisting of a two-line display, each line being 16 characters long.

This is used for controlling the functions of the instrument and for programming the software. The current state of the stainer and ongoing operations are displayed while a staining task is being processed.



Fig. 31

- The instrument will take a few seconds to initialize. During this time, the installed version of the software will be displayed on the monitor.
- Then, the Lift Bar performs a circular motion to ensure that the arm is in the correct position at the start of staining. The message **FINDING HOME...** is displayed on the screen.

5. Operation

Control panel functions (continued)

There are six pushbuttons on the control panel, and these are used to adjust the operating parameters and control the instrument.

The keys have been assigned the following functions:



The operating parameters can be displayed and checked with the **MENU** key.

Each time the **MENU** key is pressed, another one of the six operational parameters will be displayed.

Whenever a new setting is made, it will take effect immediately. Furthermore, since all settings are saved in memory, it will automatically be used the next time the system is powered up.



The operating parameter that is currently being displayed can be raised or lowered by pressing the **PLUS** ('+', increases the displayed value) and **MINUS** ('-', reduces the displayed value) keys respectively.

Pressing the **PAUSE/STOP** key allows the operator to exit the setup menu without changing the 1 parameter currently being displayed.



While running:

Pressing PAUSE/STOP once interrupts the current staining operation so that another slide carrier can be placed in the Lift Bar.

Pressing PAUSE/STOP twice (in quick succession) terminates the current program, and the system returns to idle mode.



If the **ENTER** key is pressed, the selected parameter is stored in the system.

The system returns to its idle mode whenever a new setting is entered, or whenever the user exits the setup menu by pressing the **PAUSE/STOP** key.



Pressing the **RUN** key starts a staining operation on the basis of the values shown in the display. At the same time, the flushing valve is activated, the display changes, and the timer appears, counting down to show the remaining processing time.

5.3 Setting the Operating Parameters

The process of adjusting the operational parameters is simple and direct.

When the system is "ON" and in the idle mode (that is, neither **RUNNING** nor in a **SETUP** mode), the operator may display and check the setup parameters by pressing the **MENU** key.

If the **ENTER** key is pressed, the selected parameter is stored in the system.

Pressing the **PAUSE/STOP** key allows the operator to exit the setup menu without changing the parameter currently being displayed.

Whenever a new setting is made, it will take effect immediately.

Furthermore, since all settings are saved in memory, it will automatically be used the next time the system is powered up.

The system returns to its idle mode whenever a new setting is entered, or whenever the user exits the setup menu by pressing the **PAUSE/STOP** key.

Processing time



The amount of time that the slides are immersed at each station can be varied from 2 to 300 seconds.

- When the **PLUS** or **MINUS** key is pressed ('+' or '-'), the staining time is altered in:
 - one second at a time in a range from 2 to 30 seconds,
 - five seconds at a time in a range from 30 to 60 seconds,
 - ten seconds at a time in a range from 60 to 300 seconds.
- After **ENTER** is pressed, the new processing time is activated, and this time is stored for future use.

5. Operation

Display Contrast



The contrast on the liquid crystal display can be adjusted according to the preferences of individual users.

- The adjustment range is between 1 and 15, 1 being the brightest setting.

Transfer Mechanism Calibration



The position at which the transfer movement is paused and processing started may be adjusted by pressing the **PLUS** or **MINUS** key ('+' or '-') followed by pressing the **ENTER** key.

- Pressing the Plus or Minus key changes the number of steps carried out by the stepping motor by 8. The minimum permitted value is 704, the maximum permitted value is 1000.
- After **ENTER** is pressed, the number of steps is stored. Also, the transfer mechanism advances to the next station, stopping when the selected number of steps has been taken.
- We recommend not altering the value adjusted at the factory.

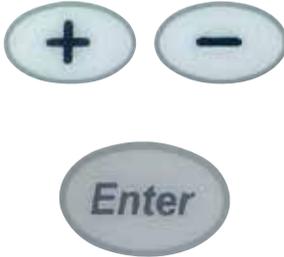
Number of Dips



The number of dips that are carried out for uniform staining can be set in a range from 0 to 3. Pressing the **PLUS-** or **MINUS** key changes the number of dips carried out by the instrument. After **ENTER** is pressed, the number of dips is stored.

If a value of 1, 2 or 3 has been selected, the system dips the slide carriers the corresponding number of times 2 seconds after it reaches a station if the processing time is longer than 4 seconds. All subsequent dip motions are carried out at intervals of 5 seconds each if the processing time is 4 seconds or more. If the processing time is less than 4 seconds, then no dips will occur, regardless of the setting selected.

Start position



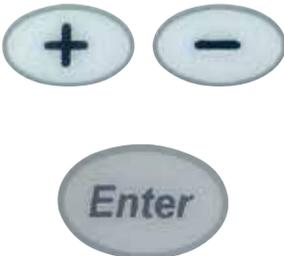
The start position has to be set if staining protocols that do not make use of all 14 staining positions are being run.

In order to make the processed slides available to the user at the exit tank in the least amount of time possible, a programmable start position feature has been added.

The user can specify which station is being used for the start position.

- For example, a protocol that requires only ten stations could use stations 5 through 14 rather than beginning at the first station. This puts the slides into the exit tank as soon as they leave the last process station. By specifying the start position as position 5, the user allows the system to issue its "reminder beep" at the correct time.
- Adjustment takes place using the **PLUS** or **MINUS** key. After **ENTER** is pressed, the selected start position is stored.
- This beep informs the operator that slides have reached the exit tank.

Run Forever



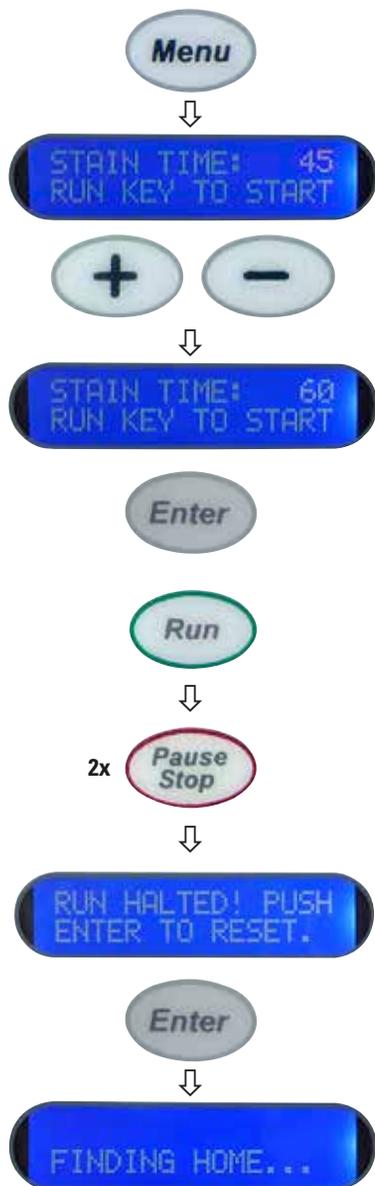
There are two settings, and these can also be set using the **PLUS** or **MINUS** keys.

- With a setting of "00," the stainer runs for as long as slide carriers are loaded into it and are undergoing the staining process.
- A beep sounds every time a slide carrier is ready. When 3 racks have reached the exit tank, a signal sounds 5 times.
- With the "01" setting, the stainer runs continuously whether it is loaded or not. A beep sounds every time a slide carrier is ready.
- Adjustment takes place using the **PLUS** or **MINUS** key. After **ENTER** is pressed, the selected start position is stored.

5. Operation

5.4 Setting the rinsing water flow rate

To set the flow rate for the rinsing water, proceed as follows:



- First set a staining time of 60 seconds. To do this, press **MENU** once, and then press the **PLUS** key repeatedly until a processing time of 60 seconds is displayed.
- Then press the **ENTER** key to confirm this processing time.
- Now press **RUN**. The countdown of station time will be displayed while the rinse water valve inside the unit activates.
- Now slowly open the water tap to which the supply hose is connected. Adjust the flow rate so that a sufficient amount of rinsing water flows into the rinsing water container and the rinsing water can drain off freely.



DO NOT adjust the flow rate too high. This can cause spills on the platform to the next stain station or can overflow the drain area of the stainer.

- Once the flow rate is adjusted properly, press the **PAUSE/STOP** key twice, and then press the **ENTER** key to reinitialize the mechanism when prompted by the instrument.

5.5 Processing slides

The Leica ST4020 is a relatively simple and trouble-free system. The user must inform the system via the keypad whenever slides are to be added to or removed from the stainer.

Directions as to how this is done appear in the following sections. Slides must be loaded and unloaded in the prescribed fashion.



Important!
Failure to follow the directions given here may result in improper or incomplete processing of slides.



Fig. 32

- The slide carrier must be prepared carefully, because if the Lift Bar is positioned incorrectly, it may not transport the slides properly.

There are two occasions when slides may be loaded onto the start position:

- before the start of processing, and
- after the start of processing.

In both cases, the slides will be immersed in the start position's reagent.

The user should be prepared to start or resume the staining run as soon as the slide carrier is in position, so that extra staining time may be kept to a minimum.

5. Operation

5.5.1 Starting a staining run

It is, of course, the user's responsibility to verify that each of the setup parameters (station time, number of steps, number of dips, etc.) is set to an acceptable value before slides are placed in the starting position and **RUN** is pressed.

Slides should not be loaded while the user is verifying setup parameters, because changing the number of steps ("transfer mechanism calibration") will cause the transfer mechanism to advance to the next position!

All parameters should be verified **BEFORE** loading the first set of slides.

A staining run cannot be started unless the stainer is in standby-mode.

In this mode, the system displays the process time and instructions to press the **RUN** key to start:



When the **RUN** key is pressed, the flushing valve is actuated, the display changes and the remaining processing time appears, counting downwards:

When a staining run is started by pressing the **RUN** key, the system receives the information that there are slides in the start position that are to be stained.



Note that the first station's process time begins as soon as the RUN key is pressed. This means that the slide carriers must be loaded in the start position immediately before the RUN key is pressed.

- The stainer will continue running until these slide carriers are transferred from station 14 to the exit tank.
- The current operation appears successively in the display.
- When the last slide carrier has been transferred to the exit tank, the system stops the process and returns to idle mode, unless more slides are inserted in the correct manner.

5.5.2 Adding more slide carriers during a staining run

The **PAUSE/STOP** function can be used to allow additional slide carriers to be placed in the instrument after processing has begun.

The following procedure should always be followed:



Please wait, and do not add any further slides!

This message is displayed until the slide carriers have been removed from a position by the Lift Bar and transferred to the next station.



If a staining run is already underway and more slide carriers are to be inserted, press the **PAUSE/STOP** key once.



Important!

Only press PAUSE/STOP ONCE!

If this key is pressed twice, the entire staining run will be aborted.

When:

LOAD SLIDES...

PRESS RUN

appears in the display, the new slide carriers must be inserted at the start position immediately, and the **RUN** key pressed.

As soon as the **RUN** key is pressed, the system resumes processing, and continues counting down the process time.



It should also be noted that the entire operation is interrupted until the RUN key is pressed again. The staining period is therefore lengthened by the time needed for insertion.

Therefore, the operator should be prepared to load the new slides as quickly as possible and should then press the **RUN** key quickly to avoid having all slides in the system spend extra time immersed.

5. Operation

5.5.3 Temporarily pausing a staining run



If the **PAUSE/STOP** and **RUN** keys are pressed in this order, the instrument receives the information that more slide carriers have been inserted at the start position.

The stainer continues operating until these slide carriers are transferred from station 14 to the exit tank.

If no other slides have been added in the meantime, it emits an audible signal to alert the operator that the staining run has been completed. A corresponding message appears in the display.



This procedure applies for inserting slide carriers after processing has begun, and must be followed under all circumstances.

Attempting to add slide carriers without pressing the PAUSE and RUN keys will result in the carriers not being transported to all of the stations, since the stainer will not know that additional slide carriers have been added!

Occasionally, it may be necessary to stop the system when it is processing slides. This too can be accomplished with the **PAUSE/STOP** key.

Staining can be interrupted,

- to allow access to the instrument if anomalies requiring such arise during staining.
- so that reagents can be checked, and changed if necessary.



Important!

The Lift Bar will complete the current cycle, and will move the slide carriers to the next station. Do not attempt to open the instrument until "LOAD SLIDES... PRESS RUN" appears in the display.

5.5.4 Ending a staining run prematurely

The role of the **PAUSE/STOP** key in loading additional slides was described in the previous chapter.

However, this key has a second function, that of terminating a staining run that has already been started.



It has been noted already that the **PAUSE/STOP** key should be pressed only **ONCE** when additional slides are to be loaded.

Because if the **PAUSE/STOP** key is pressed **TWICE**, processing is stopped. If this happens, the message opposite appears in the display.

- This means that the staining run has been aborted, and the instrument must be reset by pressing **ENTER**.



Important!
All slide carriers must be removed from the instrument, because all the information in the software has been reset.



- As soon as the user presses the **ENTER** key in this situation, the transfer mechanism returns to the home position. This is then the same situation as when the instrument is first switched on.
- The corresponding message appears in the display.
- As soon as the transfer mechanism reaches the start position, the stainer returns to idle mode; The same starting message is displayed after successful initialization that is displayed upon switching.

5. Operation

5.5.5 Removing processed specimen slides



To be able to loosen and remove stained specimen slides from the specimen slide carrier easily and safely, grip the individual slides in sequence carefully with two fingers, move them back and forth slightly and pull them out. Usually, only a few movements are necessary.



When handling specimen slides, safety gloves are to be worn at all times to avoid injury.

Removing processed slides means more than the mere physical act of removing slides. It also involves informing the instrument that slide carriers have been removed, so that the stainer may keep an up-to-date count of how many slide carriers are still in the system.

- Every time the system transfers a slide carrier from station 14 to the exit tank, an audible signal (beep) is emitted to inform the user that slides are available for removal.
- The system also increments its count of the number of slide carriers that are in the exit tank.
- The operator should remove processed slides as quickly as possible.
- The exit tank can hold up to four slide carriers. This enables the operator to remove the slides at a more convenient time.
- As soon as there are 3 slide carriers in the exit tank, the stainer emits a distinctive audible signal (5 beeps) to alert the operator.
- In this case, the slides should be removed immediately, **before** the counter in the system is set to 4;



Important!

As soon as there are four slide carriers in the exit tank, the stainer stops processing, because the exit tank cannot hold any more slides.

- It is often convenient to insert new slides for staining at the same time as the processed slides are being removed.

Removing processed slides (continued)

In this case it may be assumed that the operator normally removes all the stained slides from the exit tank every time new slides are loaded.

Of course, there will be times when slides are being removed but no additional slides are being loaded.

These two different situations are handled in the following ways:



1. To remove stained slides only:

- Take **ALL** of the slide carriers out of the instrument's exit tank.
- Press the **RUN** key once to start processing the loaded slide carriers.

2. To remove the carriers with stained slides and load fresh slide carriers:

- Press the **PAUSE/STOP** key once.
- Wait until the system prompts you to load the slides and press the **RUN** key.
- Place the new slide carriers in the system.
- Press the **RUN** key once.
- Remove **ALL** the slides from the exit tank.

6. Cleaning and Maintenance

6.1 Cleaning the Instrument



Prior to cleaning the instrument, always switch off power supply and unplug the power cord!

When using cleaners, comply with the safety instructions from the manufacturer and the labor-safety regulations at your laboratory.

Dispose of spent reagents in accordance with the laboratory guidelines in force in your country!

Wipe off spilled solvents (reagents) immediately! The Hood surfaces only have moderate resistance in the event of prolonged contact with solvents!

The painted surfaces and the control panel of the instrument are not resistant to xylene or acetone!

Do not use any of the following for cleaning the outside surfaces of the instrument: alcohol, detergents containing alcohol (window cleaner!), abrasive cleaning powders, solvents containing acetone or xylene!

No liquid must be allowed to come into contact with the electrical connections or get inside the instrument!

Instrument interior

Remove reagent containers and the exit tank. To clean the inner walls of the reagent containers and stainless steel inner walls of the exit tank, use a normal detergent and then rinse thoroughly with water.

Lift Bar

Wipe the surfaces of the Lift Bar with a damp cloth.

Instrument exterior

The outer surfaces can be cleaned with a mild detergent and wiped off afterwards with a damp cloth. Do not use any solvents for cleaning the outer surfaces and the Hood!

Slide carrier

Clean with domestic or laboratory cleaning agents as necessary.

Drain

The drain hose must periodically be checked for contamination, particularly by algae and bacteria, cleaned as necessary.

In order to prevent contamination by bacteria and algae, the drainage system can be flushed with a 5 % solution of sodium hypochlorite. However, metal parts must not remain in contact with this solution for prolonged periods (e.g., overnight). Flush thoroughly with water afterwards.

Cleaning the instrument (continued)

Reagent container and rinsing water container

The reagent and rinsing water containers must be cleaned regularly in order to achieve consistently good staining results.

They can also be cleaned in the dishwasher at a max. temperature of +65 °C. Any standard cleaning agent for laboratory dishwashers may be used.



Caution!

The stations must not be exposed to elevated temperatures (e.g. in industrial dishwashers, which operate at a temperature of +85 °C), because the heat can deform the stations!

6.2 Maintenance Instructions



Only authorized and qualified Leica service personnel may repair the instrument and access the instrument's internal components.

For your safety, never attempt to repair the instrument yourself.

Unauthorized repairs will render any claims under the warranty null and void. See also the section on "Warranty" in [Chap. 9](#) on this matter.

The instrument is basically maintenance-free.

To ensure trouble-free operation of the instrument over a long period of time, the following is recommended:

- Have the instrument checked at least once a year by a qualified service technician authorized by Leica.
- Enter into a service contract at the end of the warranty period. For more information, please contact your local Leica technical service center.

7. Troubleshooting



In the following table there is a list of the most common problems which can arise while working with the instrument, along with possible causes and troubleshooting procedures.

If faults occur that cannot be corrected with the recommended procedures, or if they occur again, Leica Service Support must be informed immediately.

7.1 General

The Leica ST4020 is equipped with a simple fault detection system, and can identify certain movement errors automatically.

- If an operation error is detected, the transfer mechanism will first stop moving.
- It will then back up a short distance, stop again, and then move forward in a second attempt to reach the desired position.
- If this error recovery attempt is successful, processing continues normally.

7.2 Alarms



- However, if the second attempt to reach the position for advancing the slide carriers is also unsuccessful, the system emits a continuous audible alarm.
- The message shown here also appears in the display.



- As soon as the **PAUSE/STOP** key is pressed, the system returns to the start position, reinitializes, and switches to idle mode.



- In this event, any staining run currently in progress is terminated and must be restarted.

7.3 Fault detection and correction list

Issue	Possible cause	Corrective action
<ul style="list-style-type: none"> The instrument cannot be started up 	<ul style="list-style-type: none"> The power supply cord is not plugged into wall outlet properly. The power supply cord is not plugged into the stainer properly. The power supply in the instrument is defective. 	<ul style="list-style-type: none"> Check the cable connections at both ends, replace the power supply cord if necessary. Inform Technical Service.
<ul style="list-style-type: none"> Display appears blue, but no text is visible. 	<ul style="list-style-type: none"> The contrast may have to be adjusted again. The control board in the instrument is defective. 	<ul style="list-style-type: none"> Adjust the contrast as described in Chapter 5.3. Inform Technical Service.
<ul style="list-style-type: none"> Unit powers up, but the transfer mechanism does not initialize. 	<ul style="list-style-type: none"> The main mechanism is jammed. The motor seems to turn, but the Lift Bar does not move because a belt is worn or broken, or a set screw on the motor has come loose. 	<ul style="list-style-type: none"> Check for visible external obstruction and remove as necessary.
<ul style="list-style-type: none"> The motor does not turn. 	<ul style="list-style-type: none"> Motor or control board defective. 	<ul style="list-style-type: none"> Inform Technical Service.
<ul style="list-style-type: none"> Keypad does not respond to key presses 	<ul style="list-style-type: none"> The keypad or the control board is defective. 	<ul style="list-style-type: none"> Inform Technical Service.

7. Troubleshooting

Issue	Possible cause	Corrective action
• Water does not flow.	• Water hose is not connected.	• Connect the water hose to the stainer and the tap.
	• Tap is not open.	• Turn on the tap.
	• The valve in the instrument is faulty (does not open) or the control board is defective.	• Inform Technical Service.
	• Flow restrictor is clogged.	• Replace flow restrictor.
• Water overflows at the rinse stations.	• Tap is open too far.	• Adjust the flow rate for the rinsing water at the tap as described in Chap. 5.4 .
	• The drain hose is clogged.	• The drain hose must not be kinked. • Check the drain hose for objects that might block it.
	• The drain hose is routed incorrectly, gradient insufficient.	• Place the drain hose so that water does not have to rise above the level of the drain fitting.

7.4 Power failure

- Check whether there is a general power failure (no power).
- Check whether the power plug is inserted correctly into the wall outlet and whether the wall outlet is switched on.
- Check whether the power cable is plugged into the socket on the instrument properly.
- Check whether the power switch is switched on correctly.
- Some instrument malfunctions / failures are caused by defective fuses. Check whether one or both secondary fuse(s) is/are faulty.



Before replacing a fuse, always switch the instrument off and unplug from power supply. Defective fuses may be replaced only with the replacement fuses supplied together with the instrument.

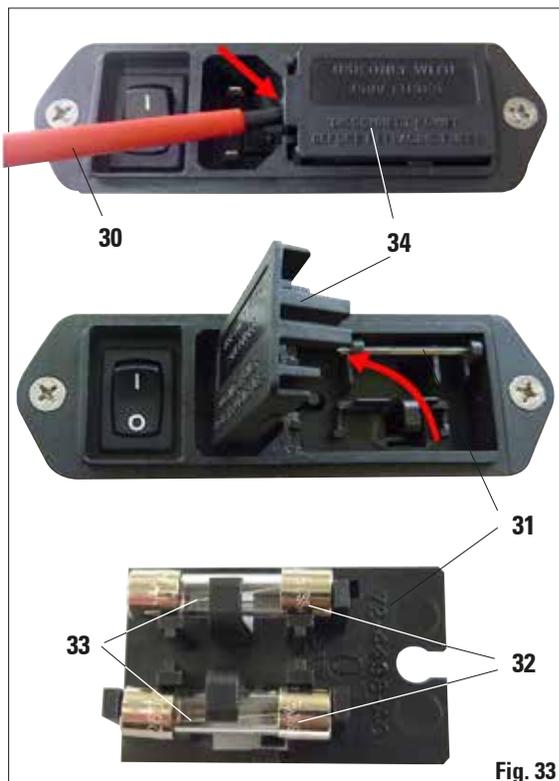


Fig. 33

To replace a fuse, proceed as follows:

- Using a screwdriver (30), carefully remove the fuse insert (34) on the rear side and flip upward.
- Remove the fuse insert (31) - it contains two fuses on the rear (32).
- Check that the thin wire (33) in the glass capillary of a fuse is intact. If not, the fuse must be replaced.



Before plugging the power cable back in and switching on the instrument, you must have identified and corrected the cause of the faulty fuse.

- Insert the fuse insert with the two fuses and start up the instrument again.

8. Optional Accessories

8.1 Ordering information

	Order No.
Reagent containers (6 in a pack)	14 0509 46437
Reagent containers (48 in a pack)	14 0509 46439
Slide Carriers (4 in a pack)	14 0509 46438
Slide Carriers (48 in a pack)	14 0509 46440
Wash station (1 container, 1 cleaning nozzle, 1 hose connector, 1 hose)	14 0509 46441
Hose for wash station (61 cm long, Ø 0.32 cm)	14 0509 46457
Tubing and Fitting Kit (1.22 m hose for wash station - Ø 0.32 cm, 2 Y-fittings, 3 in-line hose connectors, 2 plugs, 10 cable ties)	14 0509 46459
Hose for water inlet (with hose connector, in-line filter, 4 hose clamps and 2 brass fittings; 1.52 m long and Ø 0.64 cm reinforced hose)	14 0509 46443
Hose for water inlet (with hose connector, 2 hose clamps; 12.5 cm longer and Ø 0.64 cm reinforced hose, no in-line filter)	14 0509 46532
Adapter kit for connection to water taps (including 1.9 cm NPT external thread)	14 0509 46444
Drain hose (1.52 m long, Ø 1.50 cm), 0.32 cm cable tie	14 0509 46445
Exit Tank	14 0509 46450
Support Bracket for stabilization	14 0509 46570
Stabilizer bar	14 0509 46451
Reagent container cover (metal)	14 0509 46442
Optional plexiglass hood	14 0509 46478
Packaging (packing material, outer box, bubble wrap and accessory box) including packaging instructions	14 0509 46455
Outer box	14 0509 46456



Fig. 34

Reagent Containers

6 in a pack

Order-No. 14 0509 46437

48 in a pack

Order-No. 14 0509 46439

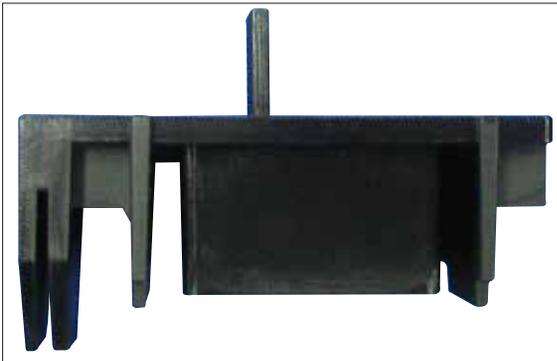


Fig. 35

Slide Carriers

4 in a pack

Order-No. 14 0509 46438

48 in a pack

Order-No. 14 0509 46440



Fig. 36

Wash Station

Consisting of:

1 container, 1 cleaning nozzle,

1 hose connector,

1 Hose

Order-No. 14 0509 46441

8. Optional Accessories



Fig. 37

Rinse Tubing

61 cm long, Ø 0.32 cm

Order-No. 14 0509 46457

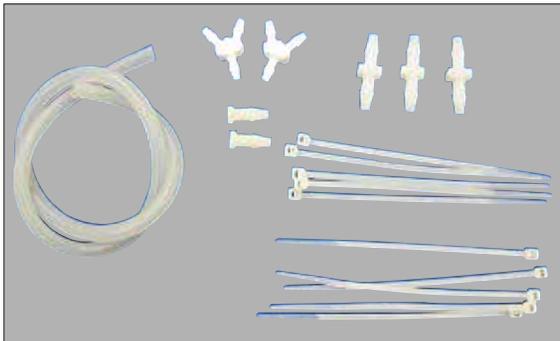


Fig. 38

Tubing and Fitting Kit

1.22 m hose for wash station - Ø 0.32 cm,
2 Y-fittings, 3 in-line pipe unions, 2 plugs,
10 cable ties

Order No. 14 0509 46459



Fig. 39

Water Inlet Hose Assembly

with hose connector, in-line filter,
4 hose clamps and 2 brass fittings;
12.5 cm long and Ø 0.64 cm reinforced hose

Order No. 14 0509 46443

8. Optional Accessories



Fig. 40

Water Inlet Hose Assembly

with hose connector,
2 hose clamps; 1.52 m long and \varnothing 0.64 cm rein-
forced hose, no in-line filter

Order No. 14 0509 46532

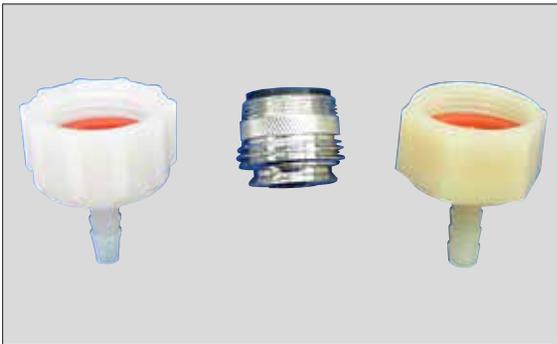


Fig. 41

Adapter kit for Water Inlet Hose Connection to Faucets

(including 1.9 cm NPT external thread)

Order No. 14 0509 46444

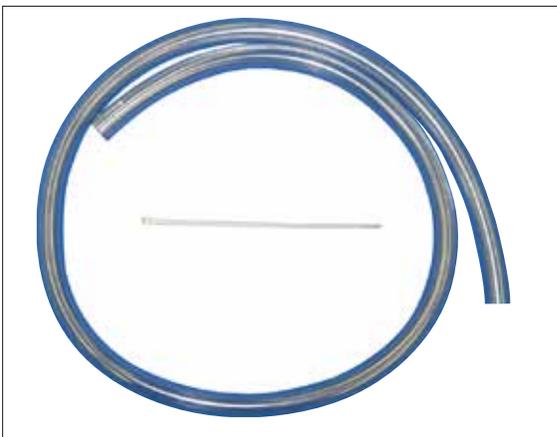


Fig. 42

Drain hose

1.52 m long, \varnothing 1.6 cm, 0.32 cm cable tie

Order No. 14 0509 46445

8. Optional Accessories

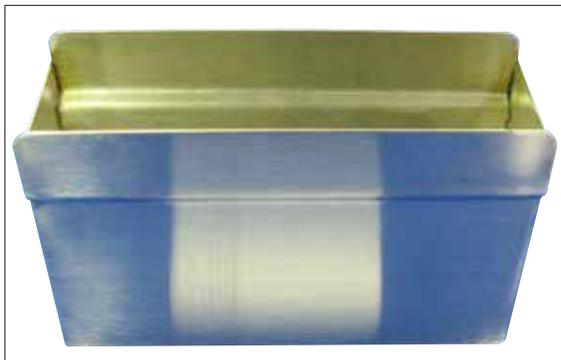


Fig. 43

Exit Tank

Order No. 14 0509 46450

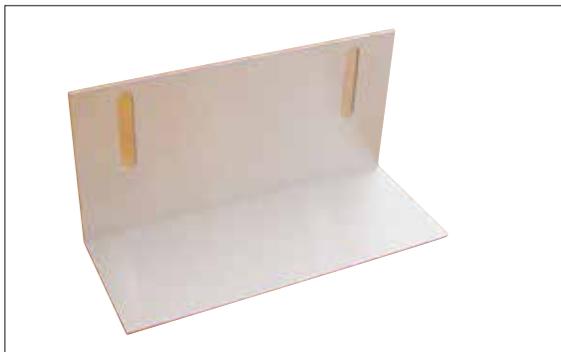


Fig. 44

Support Bracket

Order No. 14 0509 46570



Fig. 45

Stabilizer Bar

Order No. 14 0509 46451



Fig. 46

Reagent Container Cover,

metal

Order No. 14 0509 46442

8. Optional Accessories

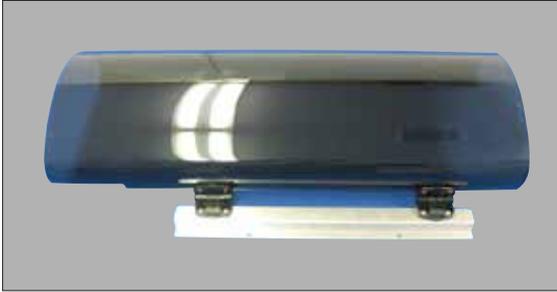


Fig. 47

Optional Plexiglas Hood

Order No. 14 0509 46478



Fig. 48

Packaging,

with foam, outer carton, bubble wrap, and accessory box) with packaging instructions

Order-No. 14 0509 46455



Fig. 49

Outer Carton Only

Order-No. 14 0509 46456

9. 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 technical specifications and/or agreed characteristics warranted.

The scope of the warranty is based on the content of the concluded agreement. The warranty terms of your Leica 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 service or spare parts, please contact your Leica representative or the Leica dealer where you purchased the unit.

Please provide the following information:

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

Decommissioning and disposal

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

10. Decontamination Certificate

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.

Note

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