



Leica TP 1020

Automatic Tissue Processor



Instruction Manual

Leica TP1020 V2.4 English – 08/2009

Always keep this manual near the instrument!

Read carefully prior to operating the instrument!



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For the instrument serial number and year of manufacture, please refer to the name plate at the back of the instrument.

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Symbols used in this manual and their meaning



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



Notes, i.e. important user information appear in a grey box and are marked by an information symbol .

(5)

Figures in brackets refer to item nos. in drawings.

ENTER

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

Qualification of personnel

- The Leica TP1020 may be operated only by trained laboratory personnel.
- The instrument may be operated only according to the instructions contained in this manual.

Designated use

The instrument has been designed so that it is safe to use by the operator as well as for processing specimens - provided that it is operated according to the present instruction manual.

The Leica TP1020 is a modular automated tissue processor designed for the following laboratory applications:

- fixation
- dehydration
- paraffin wax infiltration of histological tissue specimens.

The Leica TP1020 must be operated exclusively with the reagents listed in chapter 15.2.

The instrument may be operated only according to the instructions contained in this manual.



Any other use of the instrument is considered improper!

Failure to adhere to these instructions may result in an accident, personal injury, damage to the instrument or accessory equipment.

Instrument type

All information provided in this manual applies only to the instrument type indicated on the title page.

A name plate indicating the instrument serial number is attached to the back of the instrument.



Fig. 1

1. Important information



**Make sure to comply with the safety instructions and warnings in this chapter.
Make sure to read these instructions, even if you are already familiar with the operation and use of other Leica products.**

Safety instructions

This instruction manual includes important information related to the operating safety and maintenance of the instrument and it is an important part of the product.

This instrument has been built and tested in accordance with the following safety regulations on electrical measuring, control, regulating and laboratory devices.

In order to maintain this condition and to ensure safe operation, the operator must observe the instructions and warnings contained in this instruction manual.



If additional requirements on accident prevention and environmental protection exist in the country of operation, this instruction manual must be supplemented by appropriate instructions to ensure compliance with such requirements.



**For current information about applicable standards, please refer to the CE declaration of conformity on our Internet site:
www.leica-microsystems.com**



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

Warnings

The safety devices installed in this instrument by the manufacturer only constitute the basis for accident prevention. Primarily responsible for accident-free operation is above all the institution which owns the instrument and, in addition, the designated personnel who operates, services or repairs the instrument.

To ensure trouble-free operation of the instrument, make sure to comply with the following instructions and warnings.

Transport and installation



- Keep in mind **Chapter 3, 'Technical data'**!
- During transport, keep the instrument up-right!
- When transporting the instrument, do not lift it up by the carousel cover!
- This instrument may not be operated in hazardous locations!
- Attention: the voltage selector is factory preset. Before connecting the instrument to the mains make sure the correct setting matching your laboratory's power supply has been selected. The socket for connecting the mains cable, located at the rear of the instrument is sealed with an adhesive tape which indicates the factory preset voltage for your particular instrument.
- Connecting the instrument to the mains with the voltage selector set at a wrong value can cause severe damage to the instrument!
- When adjusting the voltage selector setting, the instrument must be disconnected from the mains.
- The instrument may only be connected to the mains with the cable supplied together with the instrument and it may only be connected to grounded sockets.

Operating the instrument



- The carousel may not be rotated manually! Severe damage will result from doing so!
- Caution when lowering the carousel! Keep your fingers out of the space between the container lid and the upper rim of the container!
- Caution! In case of a power failure, the carousel automatically descends into a station.
- Instruments equipped with vacuum function may only be operated with the aluminium containers supplied together with the instrument.
- While operating the instrument, no liquid may enter in contact with any of the electrical connections or the interior of the instrument.
- Make sure to observe the level indicators on the reagent and paraffin stations.
- Warning! Use caution when handling solvents! Make sure the premises are adequately ventilated! Explosion hazard!
- Spilled reagents have to be wiped away immediately. In case of long-term exposure, the instrument surfaces are only conditionally resistant to solvents.
- Always observe worker's protection rules and use adequate protective gear (gloves, laboratory coats).

2. Safety

Operating the instrument (continuance)



- The heated wax baths may only be used with paraffin. Under no circumstances may they be filled with solvents. When solvents heat, a highly explosive mixture builds up!
- Caution! The interior containers of the paraffin stations become very hot when the heating function is activated! Do not touch the gray upper rim of the containers with your hands! Risk of injury!
- Caution when handling hot paraffin! Risk of injury!

Cleaning



- Before cleaning the instrument, disconnect the mains switch.
- Caution! The interior containers of the paraffin stations become very hot when the heating function is activated! Do not touch the gray upper rim of the containers with your hands! Risk of injury!
- Caution when handling hot paraffin! Risk of injury!
- When cleaning the instrument, no liquid may enter in contact with any of the electrical connections or the interior of the instrument.
- Spilled reagents have to be wiped away immediately. In case of long-term exposure, the instrument surfaces are only conditionally resistant to solvents.
- To clean the painted surfaces, the container platform and the control panel, do not use solvents containing acetone or xylene; neither use abrasive cleaning powders! Only mild household detergents may be used! The lacquered surfaces and the control panel are not resistant to xylene or acetone!

Maintenance



- For purposes of maintenance or repair, the instrument may only be opened by service technicians authorized by Leica.
- Before exchanging the fuses, switch off the mains switch and unplug the instrument!
- Burnt-out fuses may only be replaced by fuses of the same type and specification. For appropriate brands and specifications, see Chapter 4 'Technical Data'.

Paraffin stations



- If the excess temperature repeatedly - please call Leica Technical Service. **DO NOT** continue to use the paraffin station.
 - Check if the paraffin station works trouble-free.
- Use of defective paraffin stations has to be discontinued for safety reasons!

Activated carbon filter (optional accessory)



- **Warning! Fire hazard!** It is important that the activated carbon filters are changed at factory recommended intervals. If a filter becomes saturated with solvent, there is a potential fire risk!

3. Instrument components and specifications

3.1 Technical Data

Type	TP1020
Approvals	UL / cUL / VDE
Electrical data	
Nominal voltage	100 / 120 / 230 / 240 V AC $\pm 10\%$
Rate frequency	50 - 60 Hz
Mains fuses (type MDA; manufacturer: Bussmann)	2 x T 10 A, UL-approved
Nominal capacity	700 VA

Classifications according to IEC-1010/EN61010-1:

Protective class	I
Pollution degree	2
Overvoltage installation category	II
Heat emission (max.)	700 J/s

Working temperature range:	5 °C - 40 °C
Relative humidity of air	80%, non-precipitating

Dimensions

Carousel lid	820 mm Ø
Height	595 - 780 mm
Pitch diameter of rollers	610 mm Ø

Weight

Net weight (including accessories)	60 kg
Net weight, including packaging material	116 kg

Paraffin stations

Quantity:	2 (optionally 3)
Capacity:	1.8 l
Nominal voltage / rated frequency:	230 V AC, 50-60 Hz
Nominal capacity per station:	150 VA
Temperature setting range:	45 °C - 65 °C ± 3 K
Excess temperature disconnection:	85 °C ± 5 K

3. Instrument components and specifications

Technical Data (continuance)

Reagent stations

Quantity: 10 (9 when 3rd paraffin station is installed)

Capacity: 1.8 l

Tissue basket

Quantity: 1 (optionally 2)

Capacity: 100 cassettes (optionally: 200)

Programs

Quantity: 9, freely selectable

Programmable infiltration time per station: up to 99 hours 59 minutes

Delayed start time of processing: up to 9 days

Dripping time: 60 seconds

Vacuum function (types 2 and 4)

Pressure difference 500 hPa maximum (appr. 0.5 bar)

3. Instrument components and specifications

3.2 Description of the instrument

The Leica TP1020 is an automatic tissue processor used for the fixation, dehydration and infiltration of histological tissue samples with fixatives, alcohol, solvents and paraffin wax.

The reagent stations numbered 1 - 10 are used to contain reagents. Station 10 may be replaced with an optional third paraffin wax bath. Stations 11, 12, and if used 10, are heated, temperature controlled wax baths that can be filled with either wax pellets or molten paraffin wax.

Embedding cassettes used to hold the tissue samples, are placed into the tissue basket. The basic instrument is designed for a single tissue basket. An optional second basket can be added. The basket, or baskets, are moved clockwise from station to station.

To ensure thorough infiltration the basket containing the tissue samples is agitated, by moving up and down, at each station. This function can be switched off at any time.

During processing as the tissue basket moves from station to station there is a delay period of sixty (60) seconds during which time the basket is suspended above the station. This ensures that there is minimal reagent carryover from station to station.

All instrument functions are activated through the control panel. Real time is displayed via LCD. The instrument can be operated in manual and automatic processing mode. Automatic processing is controlled via 9 different programs which can be individually set up, altered and edited.

If a power failure occurs, the specimens are protected from drying out - even when overnight processing has been selected, since in case of a power failure the tissue basket will always be immersed into a station. Once mains power is restored, processing will be resumed where it had been interrupted. After a long-term power failure, critical excess immersion time in a station will be visually displayed.

The Leica TP1020 has been designed to comply with the strict UL and VDE safety regulations. It is manufactured under a quality system in compliance with ISO9001.

3.3 Standard delivery

The Leica TP1020 is available in 4 different versions:

Type 1 - Basic instrument

Type 2 - Basic instrument with vacuum function

Type 3 - Basic instrument with fume control system

Type 4 - Basic instrument with vacuum function and fume control system

The basic instrument comes with the following accessories:

12 glass Beakers with holder	14 0422 42545
2 paraffin containers	14 0422 30665
1 standard tissue basket	14 0422 30585
2 set of replacement fuses (2 x T 10,0 A)	14 0600 00759
1 set of mains cables	14 0411 45754
- 1 power cord „D“	14 0411 13558
- 1 power cord „USA-C-J“	14 0411 13559
- 1 power cord „UK“ ST/BU F-5A	14 0411 27822
1 screwdriver 5,5 x 200	14 0170 10702
1 crank handle (mounted)	14 0222 30663
1 instruction manual for Leica TP1020	14 0422 80001

Types 2 and 4 - instead of glass beakers, these instruments are supplied with:

10 aluminum containers with holders

Vacuum function and fume control system are not available as a retrofitting option.

All types can also be retrofitted with a third paraffin bath at station 10 (optional accessory).

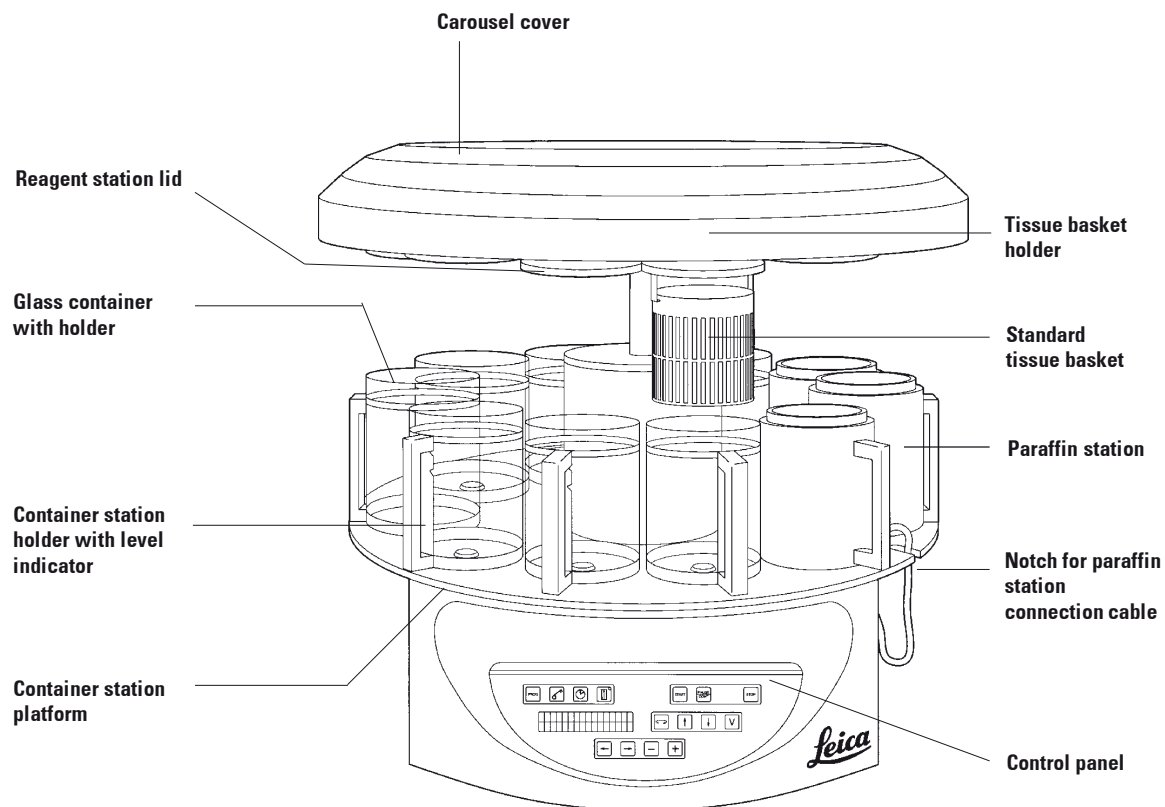


You will find the standard accessories and - in case you ordered them - further parts in the upper portion of the packing box. Compare the delivered parts with the packing list and your actual order.

If you find any discrepancies, please contact your local Leica sales organization immediately.

3. Instrument components and specifications

3.3 General overview Leica TP1020 - Type 1 with additional paraffin station (optional accessory)



3. Instrument components and specifications

General overview Leica TP1020 - Type 1 with additional paraffin station (optional accessory, continuance)

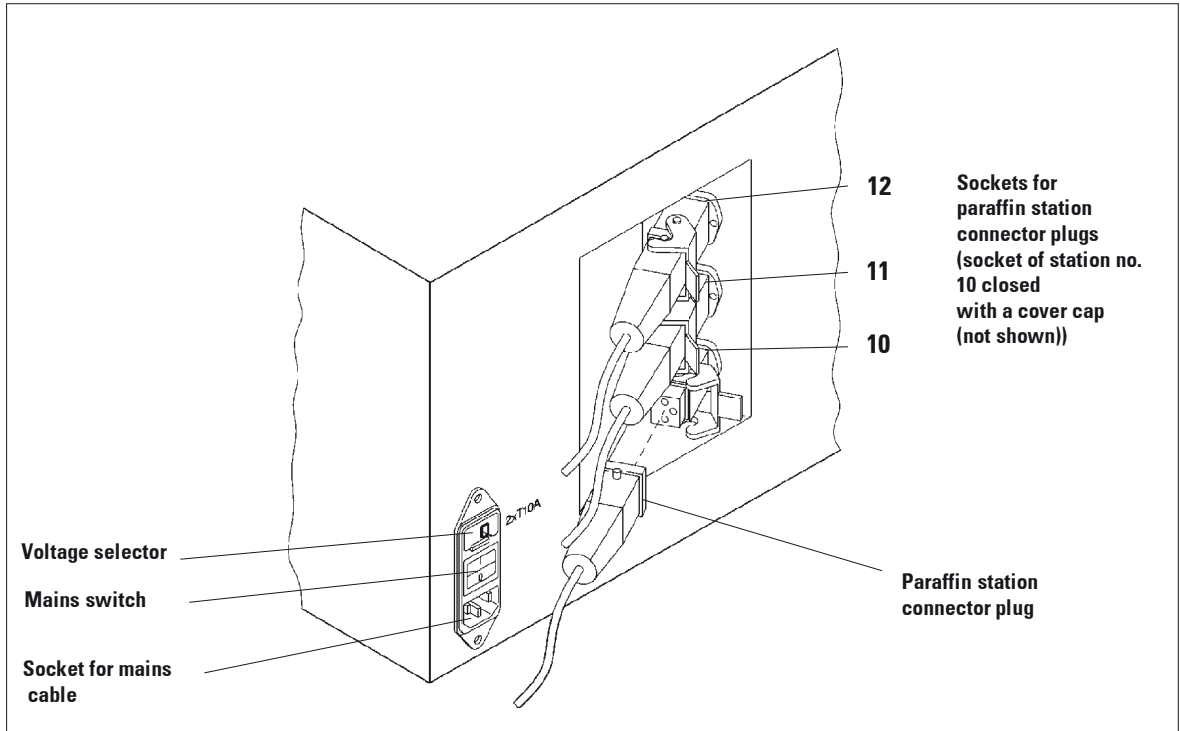


Fig. 3 - TP 1020 - rear side

3. Instrument components and specifications

3.4 General overview Leica TP1020 - Type 3

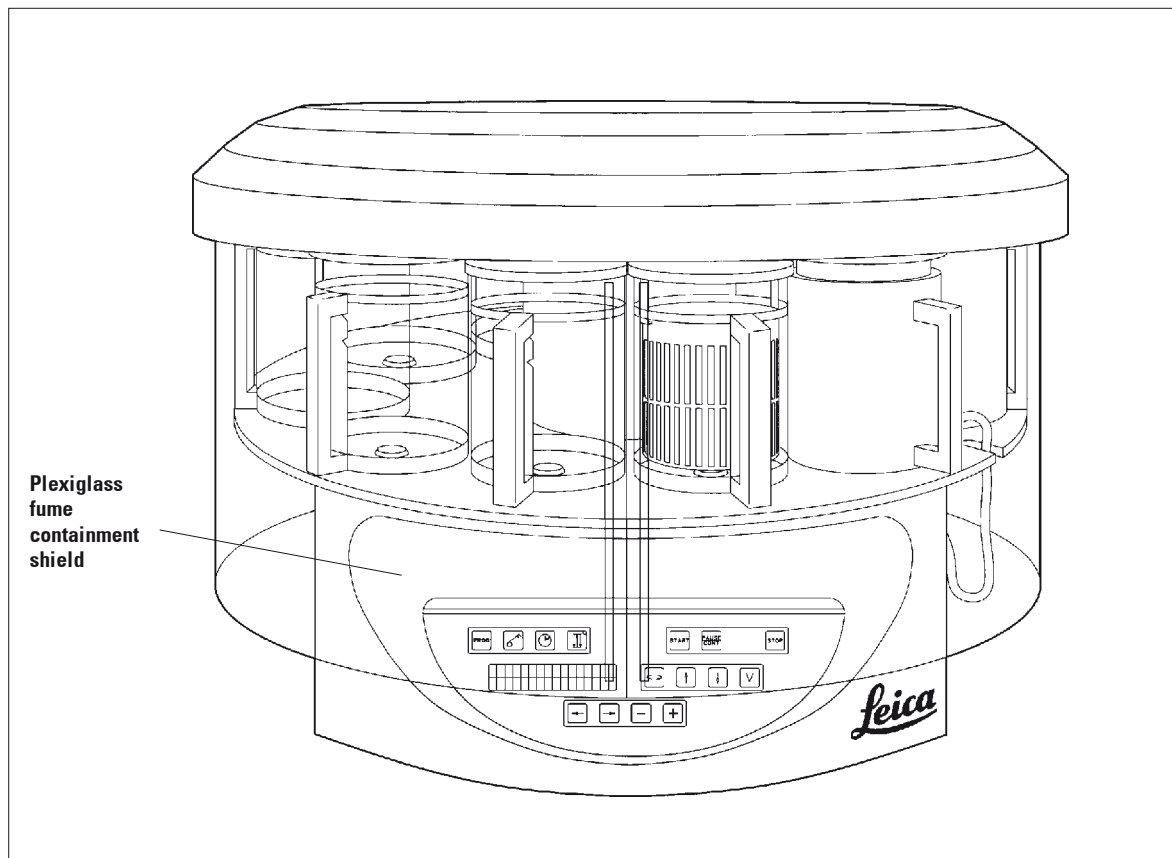


Fig. 4

General overview Leica TP1020 - Type 3 (continuance)

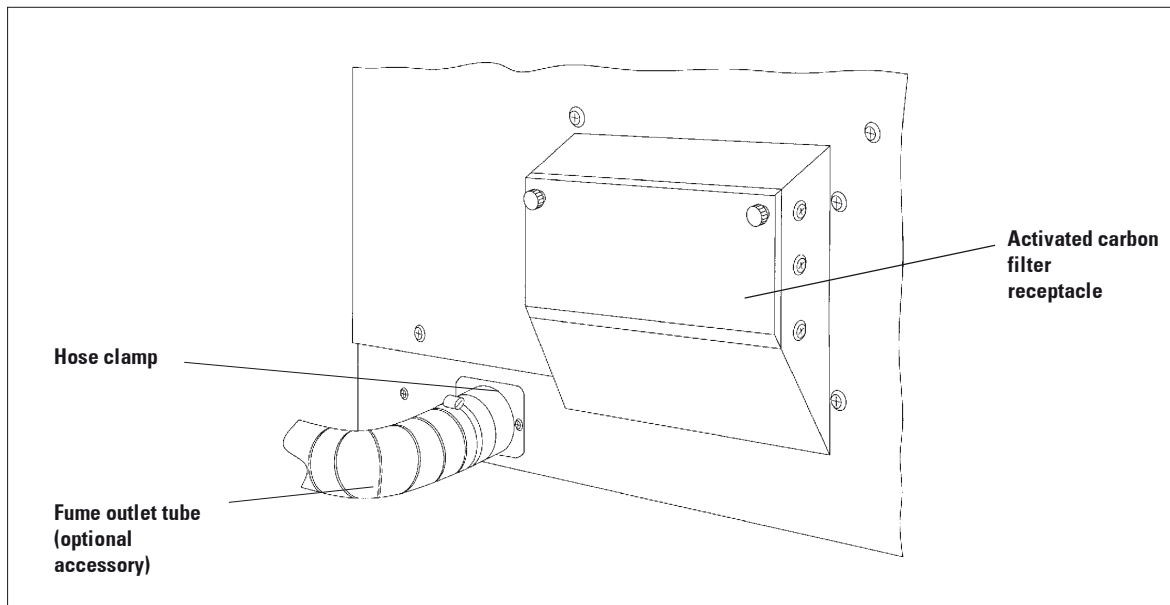


Fig. 5

3. Instrument components and specifications

3.5 Accessories supplied together with the instrument

3.5.1 Standard tissue basket

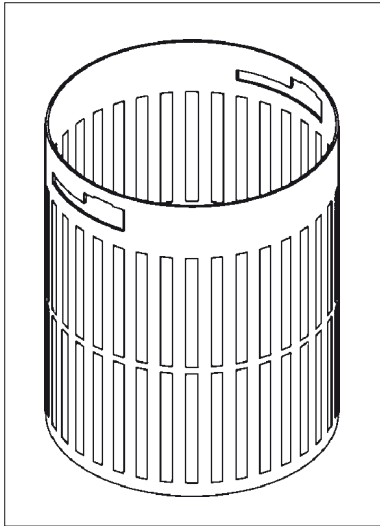


Fig. 6

Capacity: 100 cassettes

Tissue cassettes are loosely arranged in the basket.

3.5.2 Glass beaker with holder



Fig. 7

Capacity: 1.8 l

Reagent containers consist of a glass beaker inserted into a metal holder with handle.

Two marks in the metal holder serve as minimum and maximum level indicators.

When filling the container the level of liquid should not be below the minimum or above the maximum level indication mark.

3.5.3 Aluminum container with holder

(standard outfit in instruments with vacuum function or available as optional accessory for other types)

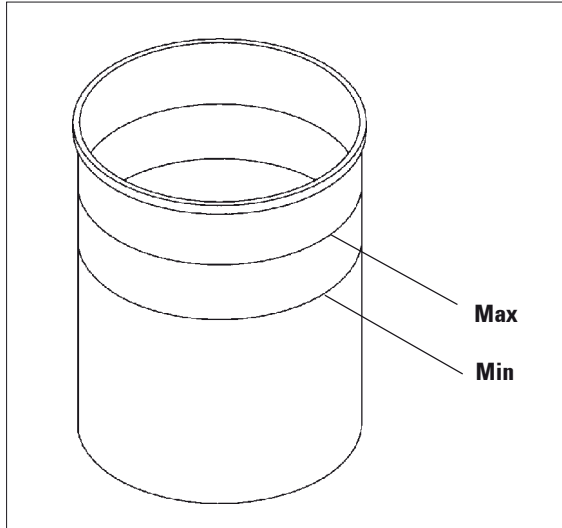


Fig. 8

Capacity: 1.8 l

Instruments equipped with vacuum function are supplied with aluminum containers instead of glass containers.

In aluminum containers the level indications marks are located on the inside of the container.

When filling the container make sure the filling level is not below the minimum or above the maximum level indication mark.

3. Instrument components and specifications

3.5.4 Paraffin station

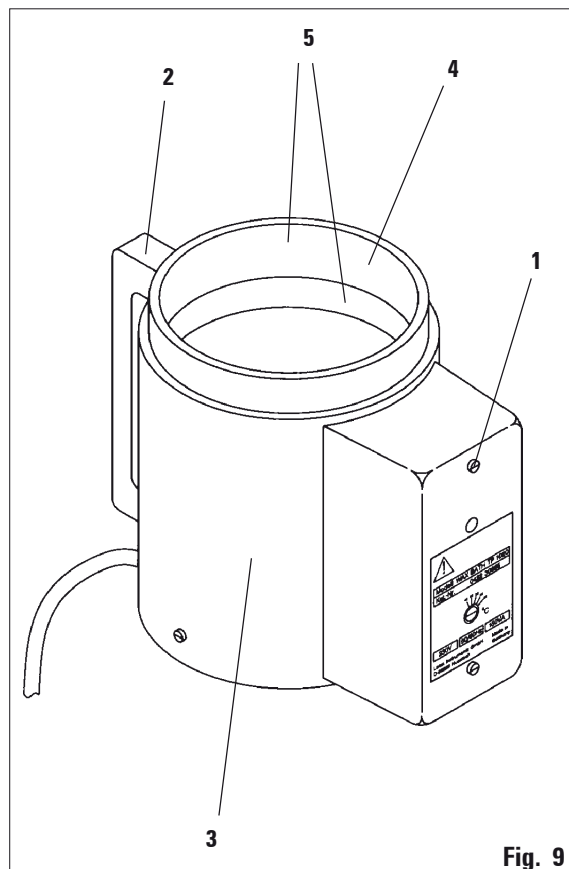


Fig. 9

Capacity:	1.8 l
Nominal voltage:	230 V AC
Rated frequency:	50 - 60 Hz
Nominal capacity (heating):	150 VA
Temperature setting range:	45 - 65 °C ± 3 K
Excess temperature switch-off mechanism:	85 °C ± 5 K



Empty the wax baths completely before the paraffin cools! When cooling down, the paraffin contracts, which can cause damage to the wax bath.



If the actual temperature rises above the range of normal working temperature, an excess temperature switch-off mechanism responds. The paraffin station heating is disconnected. The yellow signal lamp is extinguished. Use of the paraffin station can be resumed only after a cooling down period. For cooling down, disconnect the paraffin station connector plug from the socket at the rear of the instrument, or switch off the main switch.

The paraffin stations are equipped with heating. While the heating is functioning, the yellow pilot lamp lights. The handle (2) is insulated. The paraffin container (3) is also insulated to ensure that there is no risk of injury.



Caution! The interior containers of the paraffin stations become very hot when the heating function is activated! Do not touch the gray upper rim of the containers with your hands! Risk of injury!

The inside of the interior container (4) is coated with Teflon. The interior container gets very hot. It has minimum and maximum level indicator marks (5).



If the excess temperature switch-off mechanism reacts several times, call Technical Service without delay. In those cases, use of the paraffin station in question has to be discontinued immediately!

4.1 Unpacking



Check the packaging material for visible damage. If obviously there is damage, please contact your freight forwarder immediately.

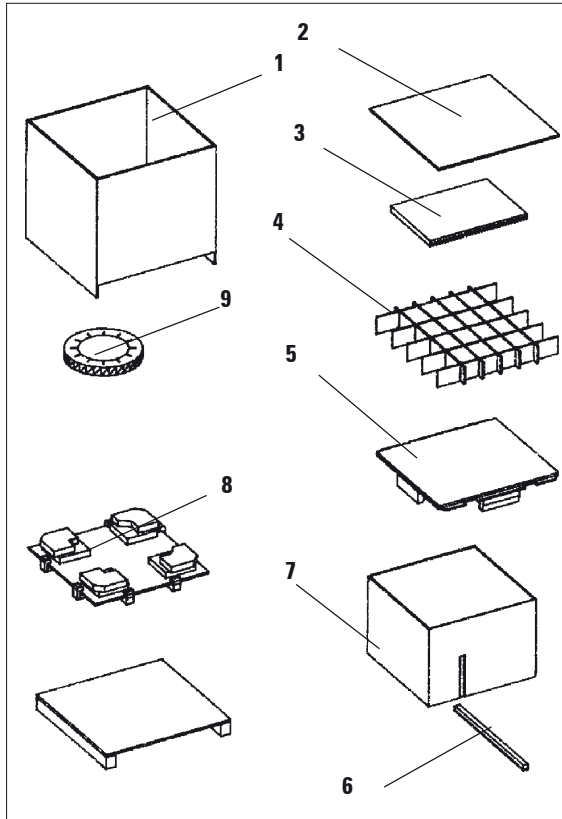


Fig. 10

- Loosen the 3 screws on the upper and lower ends of each of the four sides of the transport box (1).
- Remove the wooden lid (2).
- Remove the sponge rubber mat (3).
- Remove the instruction manual and the packing list.
- Remove all accessories of the individual compartments of the cardboard grid (4).
- Remove the cardboard grid (4).
- Remove the intermediate bottom (5).
- Take away the wooden crate (1) moving it upwards.
- Remove the wooden ledge (6) from the interior box (7).
- Remove the interior box (7) in an upward movement.

4. Setting up the instrument

4.1 Unpacking (continuance)



When transporting the instrument, do not lift it up by the carousel cover!

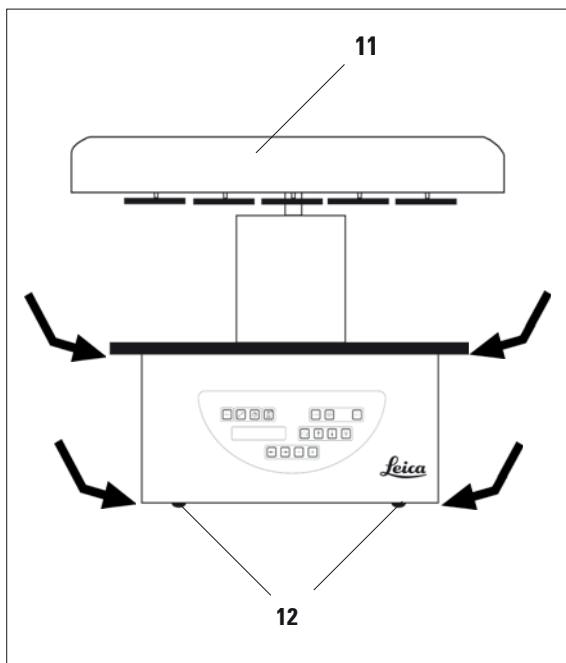


Fig. 11

- To lift up the instrument take it by the reagent container platform or by the lower end of the housing (Fig. 11) and lift it from the base plate (8).
- Install the instrument on a stable laboratory bench.

Four rollers (12) under the instrument housing permit rotating the instrument on the bench.

- Remove the sponge rubber transport safety device (9) from under the carousel cover.



For further secure transport of the instrument we recommend you keep the original packaging material.

4.2 Requirements at the installation site



Because of the quantity of solvents used for processing and the solvent concentrations that build up, for the instrument versions without fume control system (containment shields and activated carbon filter) we recommend installation in the laboratory's fume hood.



This instrument may not be operated in hazardous locations!

The installation site has to fulfill the following conditions:

- Stable and plane installation surface.
- Minimum installation surface dimensions: 850 x 850 mm.
- Stable ambient temperature of +5 °C to +40 °C.
- Relative humidity: 80 % maximum.

Necessary conditions for electrical connection

- Grounded wall outlet near enough so it can be reached with the mains cable supplied together with the instrument.



If you wish to install the basket holder for a second tissue basket, you should do that now. For mounting instructions, see Chapter 13 'Optional accessories'.

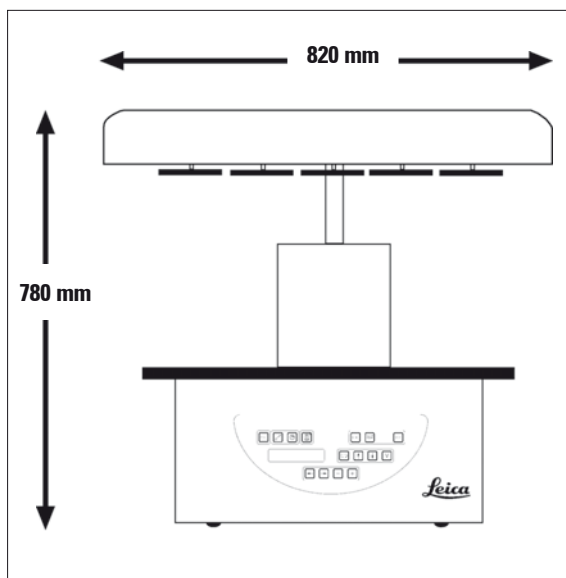
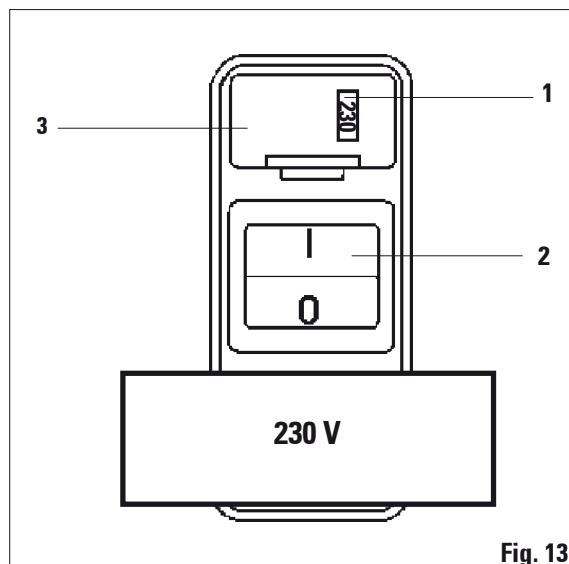


Fig. 12

4. Setting up the instrument

4.3 Electrical connection

4.3.1 Checking the voltage selector setting



The voltage selector is located in a shell (3) above the mains switch (2) at the rear of the instrument. The actual selected voltage can be seen in the window (1).

- Check if the setting showing in the window (1) corresponds to the nominal voltage in your laboratory.
- Remove the adhesive tape.

If the setting is correct proceed at [8.1.3](#).

If the setting does not correspond to the nominal voltage in your laboratory, the voltage selector **MUST** be adjusted to match your laboratory's electrical setting prior to connecting the instrument to the mains.



Attention: the voltage selector is factory preset. Before connecting the instrument to the mains make sure the correct setting, matching the nominal voltage of your laboratory's power supply, has been selected. The socket for connecting the mains cable, located at the rear of the instrument, is sealed with an adhesive tape which indicates the factory preset voltage for your particular instrument. Connecting the instrument to the mains with the voltage selector set at a wrong value can cause severe damage to the instrument!

4.3.4 Adjust the voltage selector



When adjusting the voltage selector setting, the instrument must be disconnected from the mains.

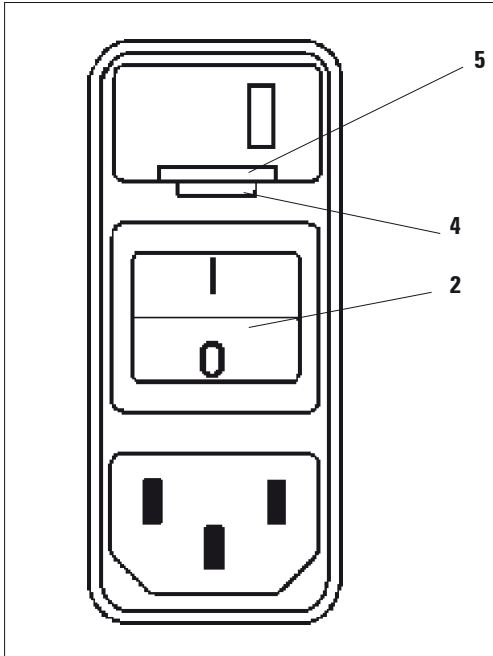


Fig. 14

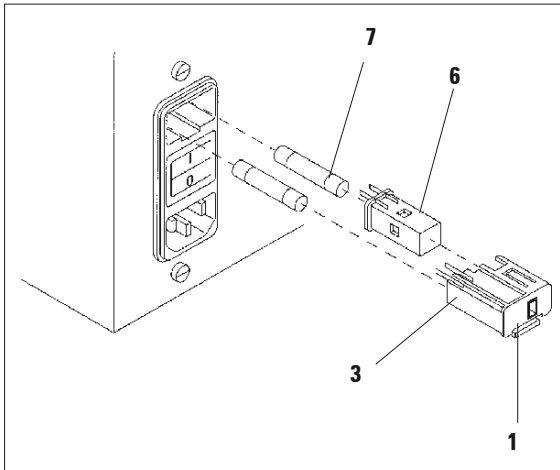


Fig. 15

- Insert the small screw driver (4) into the smaller one of the two notches at the lower end of the lock (5) using the screw driver as a lever.
- Remove the shell (3).
- Remove the voltage selector (6) from the shell (3) and reinsert it so that the correct voltage selection can be seen in the window (1) of the shell.
- Insert the voltage selector shell (3) together with the voltage selector (6) and fuses (7) back into the receptacle in the instrument and press lightly until it locks.
- Check again if the right setting shows in the window (1).

4. Setting up the instrument

4.3.3 Connecting the mains cable



The instrument is supplied together with various country-specific mains cables.



The instrument may only be connected to the mains with the cable supplied together with the instrument and it may only be connected to grounded sockets.

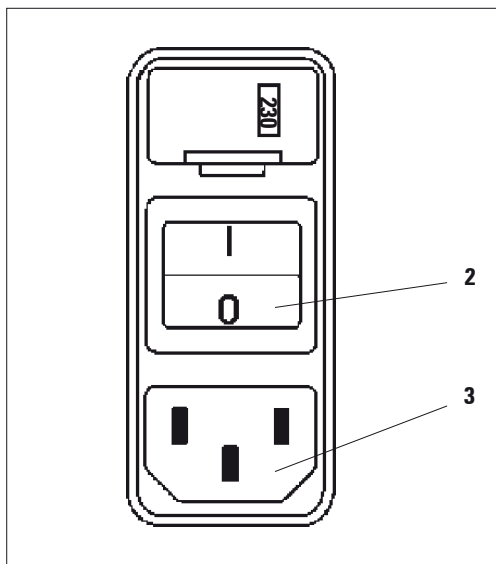


Fig. 16

- Before connecting the mains cable check if the mains switch (2) at the rear of the instrument is disconnected ('O').
- Out of the selection of cables, select the one with the plug that fits into your laboratory's wall outlets.
- Connect the mains cable to the corresponding socket (8) at the rear of the instrument and plug the mains cable into the wall outlet.

The instrument is ready to be switched on.

4. Setting up the instrument

4.6 Installing the accessories

- Press ARROW UP to lift the carousel.

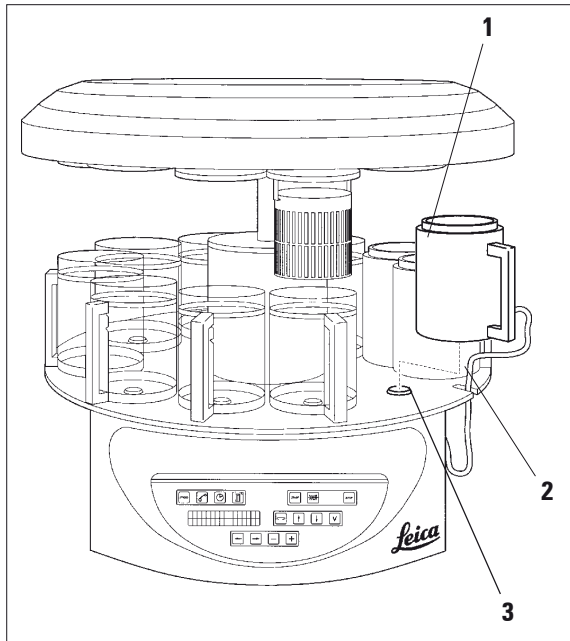


Fig. 17

4.6.1 Installing the paraffin stations



The Leica TP1020 basic instrument is delivered with two paraffin stations (no. 11 and 12). Optionally a third wax bath can be connected to station no. 10.

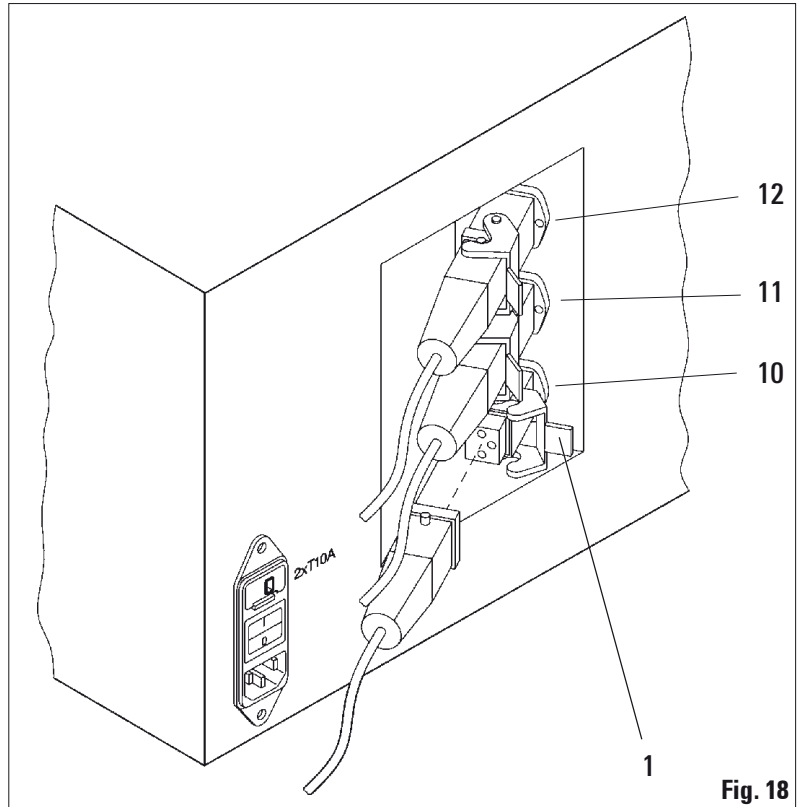
- Insert the paraffin station connection cable (1) in the notch (2) in the platform and mount the paraffin station onto the station holder (3).

4.6.2 Connecting the paraffin stations



The connection plugs of each paraffin station has to be inserted into the corresponding socket number at the rear of the instrument.

- Rotate the instrument so that the sockets are easily accessible.
- Insert plug number 12 into socket number 12.
- Insert plug number 11 into socket number 11.
- Lock clip (1) at each plug.



Before connecting a third paraffin bath to station no. 10, the cover cap has to be removed. Finally, the standard instrument configuration has to be altered accordingly. For detailed instructions, see [Chapter 10 'Altering instrument standard configuration'](#).

4. Setting up the instrument

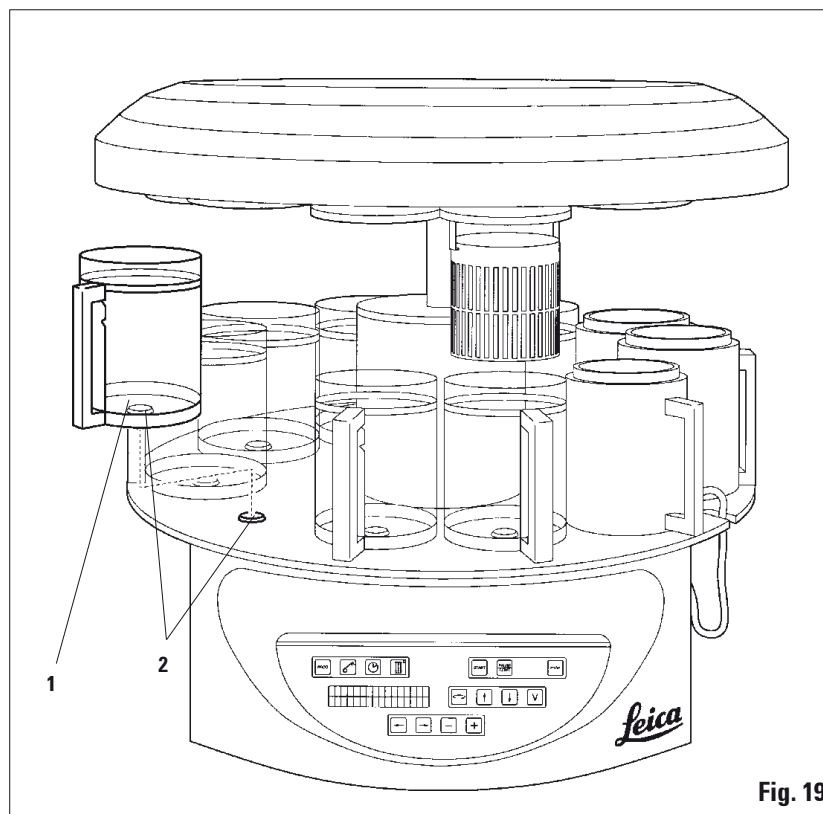
4.6.3 Fixing the paraffin station connection cables (instruments with fume control system only)



Instruments with fume control system are equipped with a plexiglass fume containment shield which consists of two parts. To ensure the fume containment shields can be freely rotated and displaced as required without being obstructed by the paraffin station connection cables, two magnetic clamps are provided on each of the cables to attach the cables to the housing.

After having mounted and connected the paraffin stations, place the magnetic clamps on the side wall of the housing so that the cables are fixed in a position that ensures free movement of the fume containment shields.

4.6.4 Installing the reagent stations



Mount the reagent containers (1) (glass or aluminum) onto the station holders (2) of the platform as shown in Fig. 19.

Fig. 19

Control panel

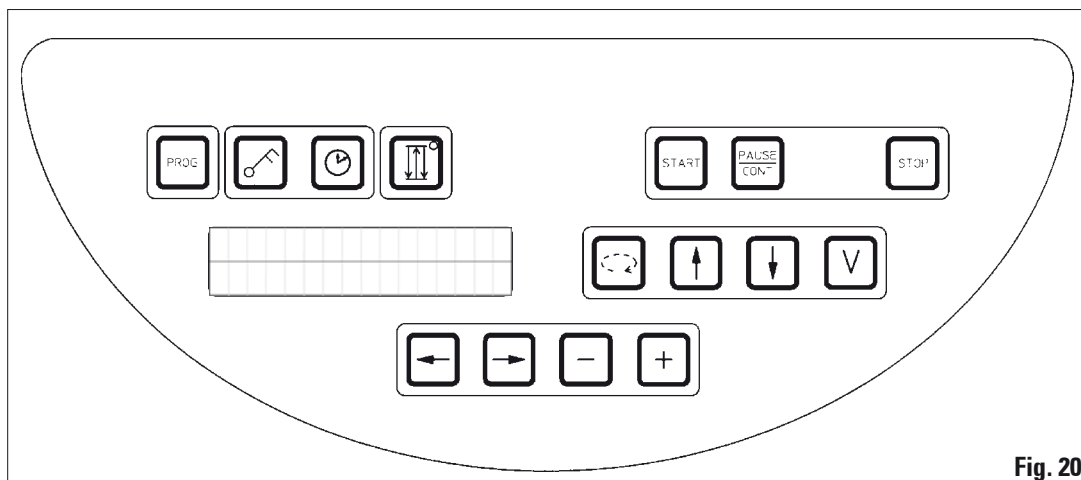


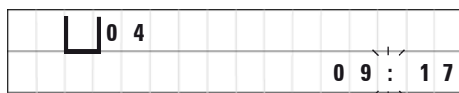
Fig. 20

The control panel is an easy-care key pad.

The individual keys are organized in four functional groups. Pressing any key will be acknowledged by an audible signal. This function can be disconnected if required ([see Chapter 15](#)).

Display

The display is a two-line LCD indication, each line with 16 single characters. When the instrument is on, the display is always illuminated.



Tissue basket



Processing station



The display will indicate in which station the tissue basket is located. At the same time the display also reads real time (24 hour clock). The colon between hours and minutes is blinking.

The display shows all tissue processing parameters as well as the individual programs. Tissue baskets and processing station are displayed with symbols.

In addition to programming features other useful data is displayed; such as program duration and end of processing. Also displayed are warning codes (W:01 - W:06) to ensure trouble-free processing, and error codes (E:01 - E:03) which indicate instrument or data entry errors.

5. The user interface

Key functions

Programming, control panel locking, time setting, up-and-down movement of the tissue basket



Programming button 'PROG'

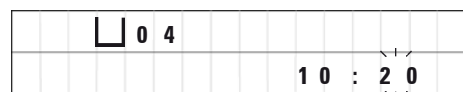
To call and quit the programming mode, in which programs are set up, edited and altered, and to display a program which is currently activated.

Lock button 'KEY'.

To lock all control panel functions as protection against accidental changes of programmed parameters.

- To activate and quit the lock function, press 'KEY' for 5 seconds.

The display reads 'LOCKED'.



After 10 seconds the display returns to standard reading.

All key functions with the exception of the locking key itself are now locked. Non of the key functions can be activated. When pressing any key, the display will always read 'LOCKED' for 10 seconds.

- To unlock the key functions, press 'KEY' again for 5 seconds.

All key functions will return to normal.

'CLOCK' symbol button



To set the time and to indicate the total duration, start time and expected end of automatic tissue processing programs.

The display differentiates between indication of time (real time, start time when working with delayed starting function, end time) - which is indicated through hyphens and colon - and indication of duration (holding time of the tissue basket in a particular station, total duration of process) - which is indicated through the letters 'd' and 'h'.



'THREE ARROW' button for carousel up and down movement

The 'THREE ARROW' button is used to start and stop the carousel (tissue basket) up and down movement. When this function is activated, the tissue basket is lifted and lowered in three-second intervals within the processing stations. This ensures a uniform mixing of all liquids and an optimized tissue infiltration.

This function is automatically activated when a an automatic processing cycle is started.

It can be switched off and back on at any time, also when no processing cycle is running.

With the function being activated, the green diode in the 'THREE ARROW' button is lighted.

- To switch off the function, press the 'THREE ARROW' button.

The diode is extinguished; the function is switched off. It can, however, be turned back on at any time.

- To reactivate the function press the 'THREE ARROW' button once again.



If the tissue basket is located in a paraffin bath that contains solid paraffin, the instrument disconnects the up/down function automatically.

5. The user interface

Start, pause, resume, stop and abort automatic tissue processing cycles



'START' button

To immediately start processing or to insert delayed starting parameters for automatic processing after having selected a program.



'PAUSE/CONT' button

To pause and resume an automatic processing cycle.



When the function is activated, the display reads 'PAUSE'. In addition, 5 minutes after last pressing a button, a double sound signal will remind the user that processing is still paused. This signal will repeat itself every 5 minutes until the automatic processing cycle is resumed.

		0	1		V	A	C		0	h	1	2
P 4	P	A	U	S	E							

When automatic processing is paused, the buttons for manual processing become functional, so that e.g. the tissue basket can be lifted out of the station to add tissue samples or to unload them for further/special processing.

The pause period is terminated by pressing the 'PAUSE/CONT' button. The processing cycle is resumed and the remaining immersion time for that station is completed without interruption.



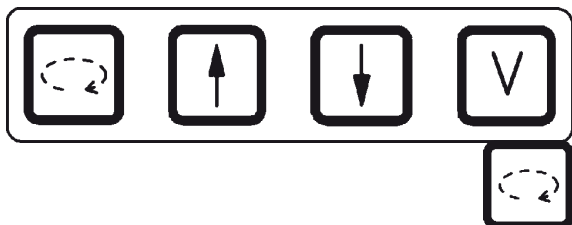
'STOP' button

To immediately stop the carousel up and down movement (press once) or to abort a processing cycle in progress (press twice).

		0	1		V	A	C		0	h	5	5
P 8	S	T	O	P	?							

The display reads 'STOP?'.

Manual processing keys



While the carousel is moving, the display reads 'WAIT!' and two blinking arrows indicate the direction of the movement. Only when the carousel has completely come to a halt, this indication will disappear from the display.

These buttons are only functional in the manual processing mode and while an automatic processing mode is paused, via the 'PAUSE/CONT' button.

'CIRCLE ARROW' button to rotate the carousel

To move the tissue basket to the next station. Rotation is only clockwise and while the carousel is in the upper end position.

'ARROW UP' and 'ARROW DOWN' button for vertical carousel movement

Lift and lower respectively the carousel to withdraw the basket from a processing station or insert a basket into a processing station.



To halt an up or down movement while still in progress, push one of the two buttons again. The movement will stop immediately when pressing the button.



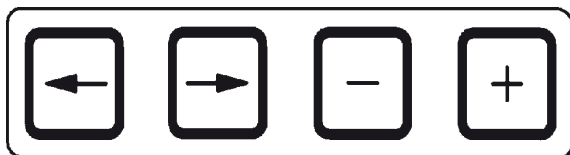
'V' button for vacuum function (types 2 and 4)

To connect / disconnect the vacuum function in the manual processing mode.



The Leica TP1020 is available with and without a vacuum function. The instrument versions without vacuum functions do not have the 'V' button in the control panel; however it is not functional and the letter 'V' is not displayed. Of course a vacuum function cannot be activated with the 'V' buttons in those cases.

5. The user interface



These buttons are equipped with a repeat function.

If one of the **ARROW** is pressed for a while, the cursor jumps to the respectively next data entry position.

If one of the **PLUS / MINUS** buttons is pressed for a while, the displayed numerical value is continuously increased or decreased.



The Leica TP 1020 is available with and without a vacuum function. The instrument versions without vacuum functions do have the 'V' button in the control panel; however it is not functional and the letter 'V' is not displayed. Of course a vacuum function cannot be activated with the 'V' buttons in those cases.

Programming mode buttons

These buttons are used to enter or alter parameters when programming.

ARROW LEFT / ARROW RIGHT buttons (cursor)

To move the cursor in the direction of the arrow to the respectively next data entry position.

- When pressing one of the **ARROW** buttons, the cursor jumps to the next data entry position in the direction of the arrow.
- To switch lines press **ARROW LEFT**.

PLUS / MINUS buttons

To modify the parameter in the position where the cursor is located.

- To increase the numerical value, press **PLUS**.
- To decrease the numerical value, press **MINUS**.
- To change the number of baskets from 1 to 2, press **PLUS**.
- To change the number of baskets from 2 to 1, press **MINUS**.
- To change the station number press **PLUS** or **MINUS** respectively.
- To switch on the vacuum function (types 2 and 4) push **PLUS**.
- To deactivate the vacuum function (types 2 and 4), press **MINUS**.

6.1 General description**Example of a one-basket-program**

Station	Reagent	VAC	Time
1	Formalin	V	1h00
2	Formalin	V	1h00
3	Alcohol 70%	V	1h30
4	Alcohol 80%	V	1h30
5	Alcohol 96%	V	1h30
6	Alcohol 100%	V	1h00
7	Alcohol 100%	V	1h00
8	Alcohol 100%	V	1h00
9	Xylene	V	1h30
10	Xylene	V	1h30
11	Paraffin	V	2h00
12	Paraffin	V	2h00

Programs are created step by step in the programming mode. Programming parameters have to be entered for each station individually. For that purpose, the cursor is moved to the corresponding data entry position with the ARROW buttons. The actual parameters are entered with the PLUS / MINUS keys. All entered parameters are memorized immediately.

The TP1020 has a memory capacity of 9 programs. Each program can be set up and edited by the user.

Programs nos. 6 to 9 have already been set up ex works. Programs nos. 6 and 7 contain a short-term or long-term program for one tissue basket each. Programs nos. 8 and 9 contain a short-term or long-term program for two tissue baskets each. These programs can be edited.

6. Programming the instrument

6.1.1 Special characteristics of two-basket programs

Example of a two-basket-program

Station	Reagent	VAC	Time
1	Formalin	-	2h00
2	Formalin	-	2h00
3	Alcohol 70%	-	2h00
4	Alcohol 80%	-	2h00
5	Alcohol 96%	-	2h00
6	Alcohol 100%	-	2h00
7	Alcohol 100%	-	2h00
8	Xylene	-	2h00
9	Xylene	-	2h00
10	Paraffin	-	2h00
11	Paraffin	-	2h00
12	Paraffin	-	2h00

In one-basket programs, for every processing station a different infiltration time can be selected.

However, in two-basket programs infiltration time is the same for every processing station. Basket no. 1 starts in station no. 2 and basket no. 2 starts to be processed in station no. 1.

If a one-basket program is modified into a two-basket program by adding a basket, the instrument automatically selects station no. 2 as starting container. At the same time the infiltration time for all stations is selected the same as the infiltration time for the actually displayed station. These changes alter the previous one-basket program permanently.

If the second basket is deleted, the starting container and the infiltration times remain as set for the two-basket program. They have to be reentered as desired for each individual station.

6. Programming the instrument




6.2 Setting-up / editing programs

6.2.1 Selecting programming mode



- To select the programming mode, push the PROG key.

The following parameters are displayed:

- Number of baskets  or  ,
- Number of processing station  1 - 12,
- Vacuum 'ON' or 'OFF',
- Tissue infiltration time in the displayed station '0 h 50 min',
- Program number 'P1 - P9',
- Programming mode 'PROG'.

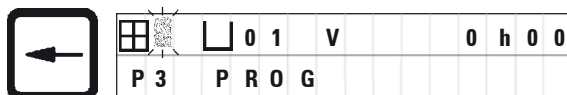
The cursor blinks at the program number.

6.2.2 Selecting the program



- Select the program number you wish to edit with the PLUS or MINUS buttons.

6.2.3 Selecting the number of baskets



- Push the ARROW LEFT button to move the cursor to the upper line.

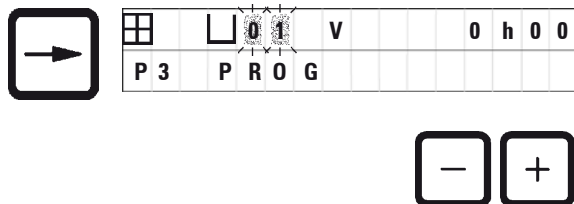
The cursor blinks next to the first basket symbol.

- To increase the number of baskets from 1 to 2, press PLUS.
- To decrease the number of baskets from 2 to 1, press MINUS.

With this, the infiltration for the tissue baskets will be the same in all stations.

6. Programming the instrument

6.2.4 Selecting the starting station

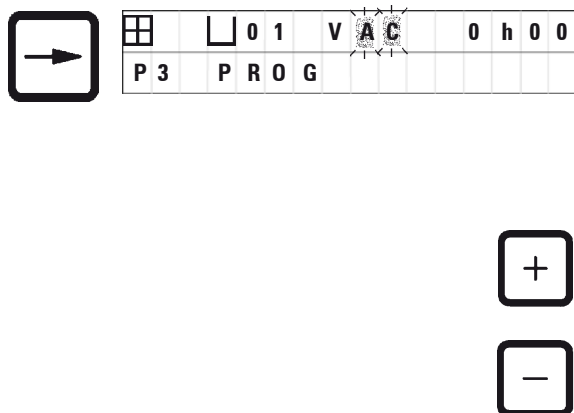


- Press ARROW RIGHT to move the cursor to the next entry position.

The cursor blinks at the station number data entry position.

- Select the desired station number by pressing PLUS or MINUS.

6.2.5 Activating the vacuum function (instruments with vacuumfunction only)



- Press ARROW RIGHT to move to the next entry position.

The cursor blinks at the two positions next to the 'V' for vacuum function.

- Select the desired station number by pressing PLUS or MINUS.
- To activate the vacuum, press PLUS.
- To deactivate the vacuum, press MINUS.



The Leica vacuum accessories for enhanced tissue infiltrations may ONLY be used with aluminium containers. Glass beakers used in combination with the vacuum accessories have a high hazard potential when damaged!

6.2.6 Selecting infiltration times per station



☐	☐	0	1	V	AC	0	h	0	0
P 3	P	R	O	G					



- Press ARROW RIGHT to move to the next entry position.

The cursor blinks at the hour entry digits.

- Press PLUS or MINUS respectively to enter the hours.
- To move the cursor to the next digit for data entry, push the ARROW RIGHT key.

The cursor flashes on both digits destined for entering the minutes.



☐	☐	0	1	V		0	h	0	0
P 3	P	R	O	G					

- Press PLUS or MINUS to enter the minutes.

Setting range: 0 hrs. 05 min to 99 hrs. 59 min.,



For stations you wish to leave out of your program, select an infiltration time of 0 h 00 min.



☐	☐	0	3	V		0	h	0	0
P 3	P	R	O	G					



In two-basket programs infiltration time is the same for all stations!

Press ARROW RIGHT to quickly jump to the next station for entering the desired parameters (vacuum and infiltration time). Press PLUS/MINUS to enter the desired parameters.

6. Programming the instrument

6.2.7 Displaying total program duration

Once a program is set up, total run time can be displayed.

☐	☐	0	1	V	A	C		2	h	0	0
P	7	T	O	T	A	L		1	d	0	0



- Press CLOCK to display the total run time of the program.

The total duration displayed here is 1 day, 0 hours and 12 minutes.



- To quit the total run time indication, press CLOCK.



While you are in the programming mode, you cannot start a program. Prior to starting a program, you must quit the programming mode.

9.2.8 Leaving the programming mode

To end programming you have to leave the programming mode.



- Press PROG to quit programming.



Warning! Use caution when handling solvents! Make sure the premises are adequately ventilated! Explosion hazard!

Always observe worker's protection rules and use adequate protective gear (gloves, laboratory coats).

While operating the instrument, no liquid may enter in contact with any of the electrical connections or the interior of the instrument.



To remove and reinstall the reagent and paraffin containers, the instrument can be rotated thus ensuring easy access to all stations at any time.

7.1 Filling the reagent stations

- Lift the carousel cover.
- Fill all stations with the corresponding reagents. Make sure to observe the minimum and maximum level indication marks.



**Spilled reagents have to be wiped away immediately.
In case of long-term exposure, the instrument surfaces are only conditionally resistant to solvents.**

- Mount every container onto the station holder at the corresponding station.



The container rims and sealing rings of the lids always have to be clean. The lids have to close tightly - otherwise larger amounts of solvent fumes will escape and, in instruments with vacuum function, vacuum will not be generated.

7. Preparations for tissue processing

7.2 Filling the paraffin stations



The heated wax baths may only be used with paraffin. Under no circumstances may they be filled with solvents. When solvents heat, a highly explosive mixture builds up!

Caution! The interior containers of the paraffin stations become very hot when the heating function is activated! Do not touch the gray upper rim of the containers with your hands! Risk of injury!

Caution when handling hot paraffin! Risk of injury!

Altering the standard working temperature



Factory-set standard working temperature is 65 °C (70 °C on the special paraffin station model that is resistant to chloroform).

When working with paraffin that has a melting point below 58 °C, the instrument working temperature can be readjusted with the corresponding setting screw.

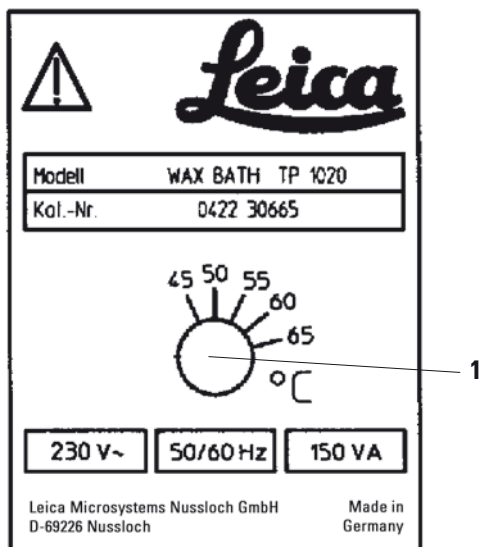


Fig. 21

- Use a screw driver to turn the setting screw (1) to the desired value.

If you find that the paraffin does not melt completely after lowering the working temperature, slightly readjust again.

Altering the standard working temperature (continuance)



Do not overfill the paraffin stations! Make sure the paraffin level is not below the minimum or above the maximum level indicator.

- To fill the paraffin stations, use wax pellets or paraffin which has already been liquefied.



When filling the station, make sure the paraffin level is not below the minimum level in which case there is a risk that not all specimens will be entirely immersed in paraffin and thus will not be infiltrated completely.



It may take several hours to liquefy solid paraffin. Make sure to calculate the waiting time! When refilling wax pellets, again make sure to observe the waiting time for complete liquefaction.

- Place the paraffin station onto the corresponding station holder and push the cable into the notch at the edge of the platform.

Check for each paraffin station whether it is actually installed at same station number it is connected to at the rear of the instrument.



When filling the station, make sure the paraffin level is not below the minimum level in which case there is a risk that not all specimens will be entirely immersed in paraffin and thus will not be infiltrated completely.

7. Preparations for tissue processing

7.3 Inserting the tissue basket



Use caution when lowering the carousel! Keep your fingers out of the space between the container lid and the upper rim of the container!

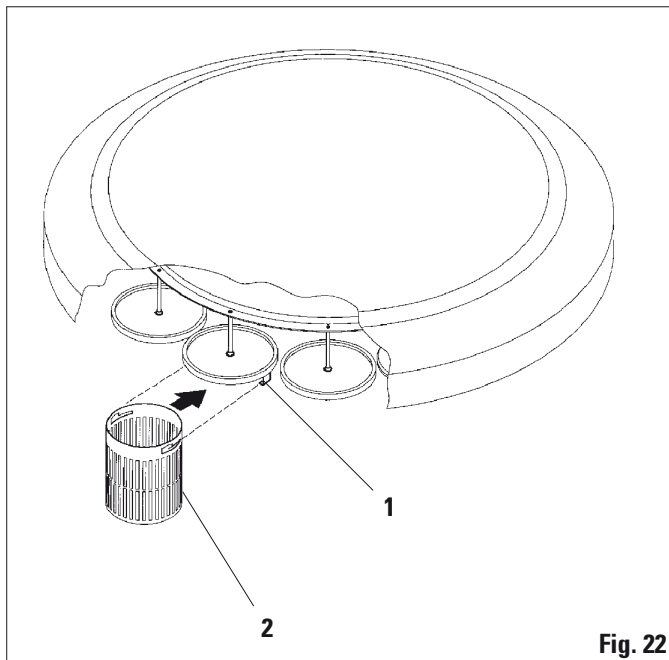


Fig. 22

- Fill the tissue cassettes or capsules into the tissue basket.

To hook in the tissue basket(s), the basket holder(s) should not be located over a paraffin station.

- Lift the carousel in the manual processing mode.
- Rotate the carousel so the basket holder (1) is located above the starting container for basket 1.
- Hook the tissue basket (2) into the basket holder as shown.
- Lower the basket into the starting container in the manual processing mode or start an automatic processing cycle.



The carousel may not be rotated manually! Severe damage will result from doing so!

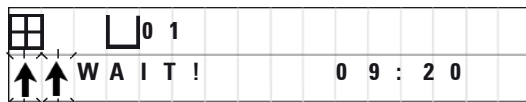
When working in the manual mode, all carousel movements are activated through the corresponding function keys on the control panel.

7. Preparations for tissue processing

Inserting the tissue basket (continuance)



While the carousel is moving, the display reads 'WAIT!' and shows two blinking arrows which indicate the direction of movement in each particular case. When the carousel has completely come to a halt, this indication will disappear from the display.



To avoid reagent carryover as far as possible in the manual mode, allow for a sufficient dripping time.

8. Operating the instrument in the manual processing mode

8.1 Lifting and lowering the tissue basket



The carousel may not be rotated manually! Severe damage will result from doing so!



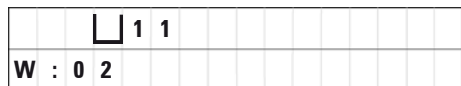
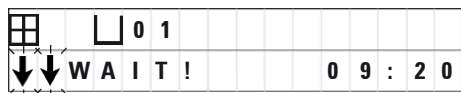
Pressing the corresponding button, the basket can be lifted out of a station or lowered into one.

- To lift the basket, press ARROW UP.
- To lower the basket, press ARROW DOWN.

The up or down movement is carried out entirely and a corresponding message is displayed while the action is in progress.

- To interrupt an up or down movement, before it is completed, press one of the two ARROW keys again.

As soon as you press the button, the movement will stop.



If one of the warning codes W:01 - W:03 (see Chapter 13) is displayed while you try to lower the basket into one of the paraffin stations, check whether the paraffin is actually liquefied.

If yes, you may carry on and lower the basket into or lift it out of the station.

8. Operating the instrument in the manual processing mode

Lifting and lowering the tissue basket (continuance)



If yes, you may carry on and lower the basket into or lift it out of the station.

- To lower the basket press KEY and ARROW DOWN simultaneously.



Or

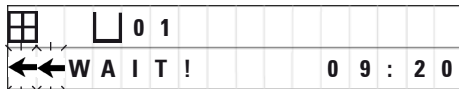
- To lift the basket, press KEY and ARROW UP simultaneously.

8.2 Moving the tissue basket to the next station



To transport the tissue basket from one station to the next, the CIRCLE ARROW button has to be pressed. The movement can only be carried out in single steps and clockwise.

- Press CIRCLE ARROW.



The basket is moved to the next station. 'WAIT!' and two blinking arrows, indicating in which direction the basket is moving, are displayed. The carousel will stop when the basket is above the next station without lowering the basket into the station.



- To move on to the next station, press CIRCLE ARROW again.

8. Operating the instrument in the manual processing mode

8.3 Activating the vacuum function (instruments with vacuum function only)



The Leica TP1020 is available in different types, with or without vacuum function. Instruments without vacuum function also have the 'V' button for vacuum on the control panel, however this key is not functional. 'V' is not displayed. Of course in those instruments, vacuum cannot be applied or ventilated via the 'V' button.



Instruments equipped with vacuum function may only be operated with the aluminum containers supplied together with the instrument.

In the manual processing mode, pressing a button activates / deactivates the vacuum function.



- Press 'V' to activate vacuum.

☐	☐	0	3	V	A	C						
							0	9	:	1	7	

The display reads 'VAC' (vacuum). The pump noise diminishes while vacuum is generated.



- To deactivate the vacuum, press 'V' again.

☐	☐	0	3											
		W	A	I	T	!				0	9	:	1	8

'VAC' disappears from the display. The vacuum is deactivated.

While the container is being ventilated, a slight hissing noise can be heard. Only after the station has been completely ventilated can the tissue basket be lifted out of it.

9.1 Starting a program



A program can either be started immediately or at a later point in time using the delay function.

9.1.1 Immediate start



- To start a program, press START.



The program on display is always the last one that has been in use. All corresponding parameters are displayed, such as number of baskets, starting position (station number), vacuum on/off, and infiltration time of the basket in the starting container. Therefore, check the parameters on display and decide if you actually wish to start the displayed program. Otherwise select another program.

The cursor blinks at the program number data entry position.

For a program to be selectable for use, at least one infiltration time for one processing station must have been set.

☐	☐	0	1	V	A	C	1	h	0	0
W	:	0	5							



- To start a program, press START.
- Select the desired program number by pressing PLUS or MINUS.



- To start the selected program immediately, press START again.

9. Operating the instrument in the automatic processing mode

Immediate start (continuance)



The warning codes W:04 - W:06 (see Chapter 4) are displayed for programs of less than 8 hours duration from start until the basket reaches the first paraffin station. Check if the available amount of time is sufficient for the paraffin to liquefy completely. If this is not ensured, fill the paraffin stations with liquid paraffin.



- Select the desired program number by pressing PLUS or MINUS.
- To start the selected program immediately, press START again.



The warning codes W:04 - W:06 (see Chapter 4) are displayed for programs of less than 8 hours duration from start until the basket reaches the first paraffin station. Check if the available amount of time is sufficient for the paraffin to liquefy completely. If this is not ensured, fill the paraffin stations with liquid paraffin.



+



- To override the warning codes and start processing, press KEY and START simultaneously.
- To override the warning codes and start processing, press KEY and START simultaneously.

After the drain time of 60 seconds, the carousel will automatically move to the programmed starting position.

9. Operating the instrument in the automatic processing mode

Immediate start (continuance)

		0 9	V A C	-	-	h	-	-
P 4						0 9	:	1 7

While the basket is being moved, the display reads the numbers of the container stations the carousel is rotating past. Instead of the infiltration time 'h' will be displayed.

As soon as the basket has arrived at the programmed starting station, it will be lowered into that station.



From that point on, the remaining infiltration time of the basket in the current station is displayed. While processing time is running, the display reading is updated in one-minute intervals; i.e. you can always see exactly the remaining infiltration time for each station.

9.1.2 Delayed start



The delay function enables you to start a program e.g. during the weekend, so it will be completed by the time you return to work on Monday.



		0 1	V A C	1	h	0 0
P 4						0 9 : 1 9

Select starting time

- Press START.

The program which was used last is displayed. Decide whether you want to start that particular program or select another one.

- To enter the desired starting time, press ARROW RIGHT.

The display reads START and the cursor blinks at the data entry position for the days of delay.

0 = Start at the same day (= today),

1 = Start the next day (= tomorrow),

2 = Start in two days (= the day after tomorrow)

...etc..

9. Operating the instrument in the automatic processing mode

Delayed start (continuance)



<div><div></div><div></div><div></div><div></div></div>		<div><div></div><div></div></div>	0	1	V	A	C		<div><div></div><div></div></div>	1	h	0	0	
P	4	S	T	A	R	T	<div><div></div><div></div></div>	0	-	0	0	:	0	0

<div><div></div><div></div><div></div><div></div></div>		<div><div></div><div></div><div></div><div></div></div>	0	1	V	A	C		1	h	0	0	
P	4	S	T	A	R	T	1	-	1	9	:	3	0



☐		0	1					-	-	h	-	-
P	4							1	6	:	3	0



☐		☐	0	1		V	A	C		1	h	0	0		
P	4				E	N	D		2	-	0	9	:	4	8

- Press PLUS / MINUS to enter the number of days.
- Press ARROW to move the cursor to the data entry position for the hours.
- Press PLUS / MINUS to enter the number of hours.
- To move the cursor to the digits destined for entering the minutes, push the ARROW key.
- Press PLUS / MINUS to enter the number of minutes.

The program shown here would be started the next day at 7.30 PM.

- To activate the delay function press START. Once the delay function has been activated, the tissue basket will move immediately to the selected starting container.

While the basket is waiting in the starting container for the actual program to start, the display reads '- - h - -'.

When pressing CLOCK the display switches from real time indication to reading the selected starting time and the resulting end time.

Display end of processing time
To check if the programmed starting time leads to an acceptable end of run time:

- Press CLOCK

In the example shown here the end of processing would be the day after next at 9.48 AM.

9. Operating the instrument in the automatic processing mode

Delayed start (continuance)

Edit and change starting time (when using the delayed starting function)



- Press CLOCK again.
- Check the selected starting time and if necessary change it as appropriate to achieve the desired end or run time.



The warning codes W:04 - W:06 (see Chapter 7) are displayed for programs of less than 8 hours duration from start until the basket reaches the first paraffin station. Check if the available amount of time is sufficient for the paraffin to liquefy completely. If this is not ensured, fill the paraffin stations with liquid paraffin.



+



- To override the warning codes and start processing, press KEY and START simultaneously.

The program will be started at the selected delay time.



- To quit the display indication, press CLOCK again.

9. Operating the instrument in the automatic processing mode

Locking the key functions



To protect program settings against unintended deletion or alterations, the key functions of the control panel can be locked.



- To lock the panel, press KEY for 5 seconds.

'LOCKED' will be displayed.

After 10 seconds the display will return to standard reading. Every time a button is pressed, 'LOCKED' will be displayed again.



- To unlock the control panel functions, press KEY again for 5 seconds.

9. Operating the instrument in the automatic processing mode

9.2 Editing and altering programs while a processing cycle is in progress



Programs can be edited and changed while a processing cycle is in progress. All programs can be edited and changed with the exception of the program currently in progress. A program in progress can be displayed but not changed.



- Activate the programming mode.
- Select a program.

To verify and/or change the selected parameters,

- Move the cursor to the station number entry position (ARROW RIGHT / LEFT = cursor buttons)
- Modify the station number pressing PLUS or MINUS and thus edit, and if necessary alter, step by step all station parameters.



**All modifications are saved immediately.
The program currently in progress cannot be changed!**



- Press PROG to quit programming.

9.3 Display end of processing time



While a processing cycle is in progress, it is possible to display the expected end of run time.

- To display end of run time, press CLOCK.

9. Operating the instrument in the automatic processing mode

Display end of processing time (continuance)



☐	☐	0	1					0	h	5	0
P	7			E	N	D		1	-	1	0 : 3 8



In the example shown here end of processing would be the next day at 10.38 AM.

- To quit the end of run indication, press CLOCK again.

'PAUSE' is displayed.

While a processing cycle is in progress, it is possible to display the expected end of run time.

- To display end of run time, press CLOCK.

In the example shown here end of processing would be the next day at 10.38 AM.

- To quit the end of run indication, press CLOCK again.

9.4 Pausing a process



☐	☐	0	1	V	A	C		0	h	1	2
P	4	P	A	U	S	E					

A tissue processing run can be paused, e.g. to add samples, and then be resumed.

- To pause a run, press PAUSE/CONT.

'PAUSE' is displayed.



While a run is paused, 'PAUSE' will be displayed continuously.

In addition, 5 minutes after last pressing a key, a double sound signal reminds the user the run is still paused. The sound signal will recur in 5 minute intervals until processing is resumed.

When in 'PAUSE', the buttons for manual operation become functional, e.g. to lift the tissue basket out of a station to add specimens. The carousel can also be rotated to move the basket to any processing station - see 'Operating the instrument in the manual processing mode'.

9. Operating the instrument in the automatic processing mode

9.5 Resuming a paused process



- To reassume processing press PAUSE/CONT again.

Pressing this key will lower the basket into the station. Processing continues as programmed.

While a run is paused, the infiltration time count-down in the actual station will also be interrupted. When processing is resumed, the remaining infiltration time in the station will be carried out without interruption. Thus, the end of run time of a process will be postponed by the length of time the process was paused.

The display reading will automatically be updated, showing the new end of run time.

9.6 Stopping or aborting a process



		0	1	V	A	C		0	h	5	5
P	8	S	T	O	P	?					

If there is an emergency, an automatic processing cycle can be stopped immediately and - in a subsequent step - entirely aborted.

- To stop a processing cycle in progress press STOP.

The carousel up-and-down movement stops immediately.

The display reads 'STOP?'.



		0	1	V	A	C		0	h	5	5
P	8						1	0	:	1	9

With this the instrument is asking you whether you really want to abort the processing cycle currently in progress?

- To resume processing, press START.

Processing will continue as programmed.

9.8 Remove the specimens

- Lift the carousel.
- Allow for the tissue basket to drain in that position.
- Lift the tissue basket slightly with your hand and pull it out of the basket holder in a horizontal movement.
- Lower the carousel.

9.9 Finishing your daily work





Due to the relatively long time paraffin requires to melt, the instrument should not be turned off routinely after finishing the day's last processing cycle.

- Check the filling level and quality of the liquid in each station (reagent and paraffin stations) and refill or exchange completely if necessary.
- Clean the rims of all stations and the seal of each lid.
- Wipe the control panel clean.
- Press KEY to lock the panel and that way protect program settings against accidental alteration or misuse.

10. Warning and error codes - troubleshooting

10.1 Warning codes

		0 4													
W :	0 3														



Solid paraffin takes several hours to melt. Please keep this in mind and make sure to switch on the instrument early enough so the paraffin will be molten and ready for use when necessary.

The warning codes W:01 - W:06 may be displayed.

W:01, W:02, W:03 - paraffin in station no. 10, 11, 12 still solid.

W:04, W:05, W:06 - paraffin in station no. 10, 11, 12 may still be solid when basketno. 1 arrives

When these warning codes are displayed, a short sound signal (very short sound - very short sound) is emitted and repeated in 5 minute intervals.

W:01 - W:03 are displayed by the processing cycle upon occurrence, e.g. when the basket is due to be immersed into a paraffin station as programmed.

W:04 - W:06 are displayed immediately when starting an automatic processing cycle of less than 8 hours duration from start until the basket reaches the first paraffin station.



oder



- To quit warning codes W:01 - W:03 press any key.
- To lower or lift the tissue basket press KEY and ARROW UP or ARROW DOWN simultaneously.

10. Warning and error codes - troubleshooting

Warning codes (continuance)



W:01 - W:03 block the transport of the tissue basket to the paraffin station no. 10, 11 or 12. If you know though that the paraffin is actually liquefied, you can immerse the tissue basket into or remove from one of the paraffin stations manually.



- To override the warning codes W:04, W:05 and W:06 press KEY and START simultaneously to start processing.

Code	Possible root cause	Troubleshooting
Warning code W:01, W:02, W:03 in manual processing mode	Paraffin in stations 10/11/12 still solid.	<ul style="list-style-type: none">- To quit the warning code, press any key.- Check if the paraffin is really molten.- If you find that the paraffin is molten, pause the automatic processing cycle and -in the manual processing mode - by pressing KEY and the corresponding ARROW button lower the basket into the paraffin station or lift it out of the paraffin station.
Warning code 'W:04' 'W:05' 'W:06' when starting an automatic processing cycle.	Total duration of program from start until the basket reaches the first paraffin station is less than 8 hours. Paraffin in stations 10/11/12 possibly still solid upon arrival of tissue basket.	<ul style="list-style-type: none">- Check if there is sufficient time for the paraffin to liquefy completely until the basket arrives at the paraffin station.- If this is not ensured, fill the paraffin station with molten paraffin.- To override / quit the warning code, press KEY and START simultaneously.

10.2 Error codes



To indicate a series of malfunctions, the error codes E:01 to E:013 are displayed.

Three consecutive and very short sound signals that are repeated every 10 seconds reinforce the visual error code.

- To quit the error codes, press any key.

Code	Possible root cause	Troubleshooting
Error code 'E:01'	Cache memory defective	Call Technical Service
Error code 'E:03' - 'E:04' - 'E:05'	Drive malfunction	<ul style="list-style-type: none"> - Switch off the main switch and next switch it back on. Try again. - Call Technical Service Call Technical Service
	Clock component defective	<ul style="list-style-type: none"> - Connect paraffin station.
Error code 'E:07'	<ul style="list-style-type: none"> - Paraffin station not connected. 	<ul style="list-style-type: none"> - Check if paraffin station is connected to the appropriate socket. Correct if necessary.
Error code 'E:08' (Paraffin station 1)	<ul style="list-style-type: none"> - Paraffin station possibly connected to wrong socket. 	<ul style="list-style-type: none"> - Disconnect the paraffin station connection plug from the socket at the rear of the instrument.
Error code 'E:09' (Paraffin station 2)	<ul style="list-style-type: none"> - Excess temperature switch-off mechanism has responded. 	Let paraffin station cool down. Reconnect paraffin station
Error code 'E:10' (Paraffin station 3)		If the yellow pilot lamp lights, use of the paraffin bath may be continued.
	<ul style="list-style-type: none"> - Paraffin station defective. - Control unit defective. 	<ul style="list-style-type: none"> - Exchange paraffin station. - Call Technical Service.

10. Warning and error codes - troubleshooting

List of error codes (continuance)

Error code 'E:11'	Loss of processing data (current process).	<ul style="list-style-type: none">- Press any key to confirm error message; 'ABORT' will be displayed; processing cycle will be aborted.- Restart processing cycle.- If the same problem recurs, call Technical Service.
Error code 'E:12'	Loss of program settings.	<ul style="list-style-type: none">- Press any key to confirm error message; 'ABORT' will be displayed; processing cycle will be aborted.- Restart processing cycle.- If the same problem recurs, call Technical Service.
Error code 'E:13'	Erroneous data entry for delayed start function (e.g. desired starting time would be earlier than current real time.)	<ul style="list-style-type: none">- Correct erroneous data entry.

10. Warning and error codes - troubleshooting

10.3.1 'POWER FAILURE' and 'WRONG STATION' messages

☐	☐	0	1							0	h	4	7
P O W E R F A I L U R E													



In case of a power failure the carousel is lowered immediately into the station where the tissue basket happens to be located when the power failure occurs. Once mains power is restored processing will be resumed as programmed. Possible impairment of the processing cycle through the interruption is displayed.

☐	☐	0	1							0	h	1	6
W R O N G S T A T I O N													

'POWER FAILURE' is displayed when mains power is restored after a power failure, but only if the processing cycle in progress has been impaired by the power failure.

The display reading is accompanied by a sound signal which intends to attract the user's attention to the malfunction so he/she can take appropriate measures to rescue the specimens.

The upper line of the display shows the surplus time the basket remained immersed, and the station number where it was immersed due to the power failure. In the example shown here the infiltration time in station no. 3 was exceeded by 47 minutes.

If, due to the power failure, the basket is lowered into a station which is not part of the program (programmed infiltration time '0 h 00 min'), instead of 'POWER FAILURE' the message 'WRONG Station' is displayed. In addition, when mains power is restored, an uninterrupted sound signal is emitted.

The upper line of the display shows how long the basket remained in the wrong station due to the power failure. In the example shown here the basket remained in station no. 4 for 16 minutes.

By pressing any key the display reading will switch back to normal and the sound signal will be turned off.

Once mains power is restored, processing will be reassumed as programmed. The basket will be moved from the wrong station to the next station that is part of the current program.

10.3.2 Measures to remove specimen material in case of prolonged power failure



In case of a prolonged power failure the tissue can be removed from the instrument manually and also be relocated to the next station by entirely manual operation.

- Switch off the mains switch.
- Remove the crank handle (1) from the clip and insert it into the access port (2) on the left side of the instrument.

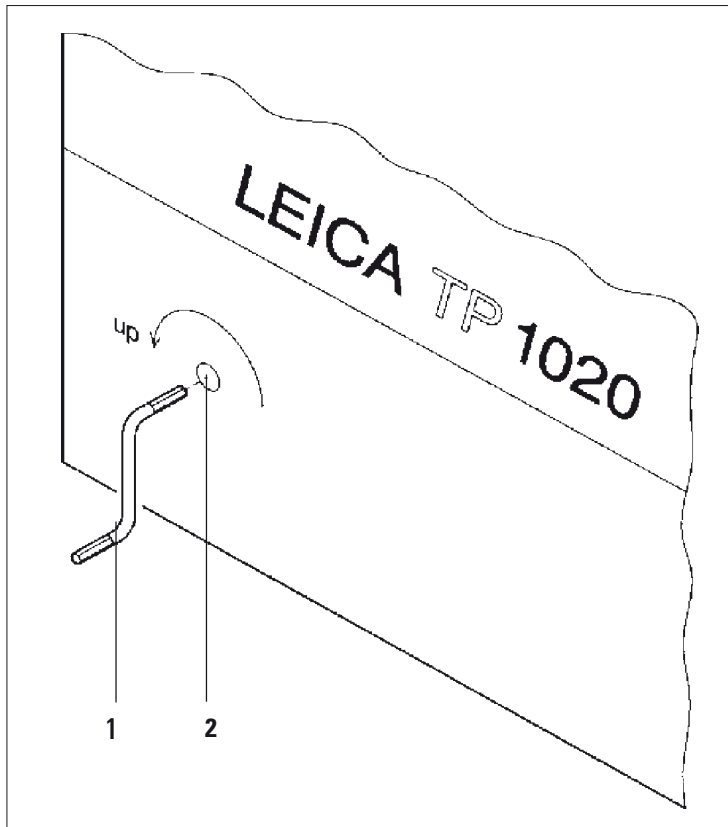


Fig. 23

Removing the tissue basket

- Lift the carousel rotating the crank handle in the direction of the arrow until the lower end of the basket is above the rim of the processing station.
- Hang on to the crank handle to keep it securely in its position and remove the tissue basket.

10. Warning and error codes - troubleshooting

Warning and error codes - troubleshooting (continuance)



Caution when lowering the carousel! Keep your fingers out of the space between the container lid and the upper rim of the container!

When you release the crank handle, the carousel will start to slowly descend.

Manual relocation to the next station

- Rotating the crank handle in the direction of the arrow, lift the carousel upwards until there is a notable resistance to the rotating movement.

When you release the crank handle, the carousel will be lowered into the next processing station.

Skipping stations

To skip one or more processing stations, hold on to the crank handle to avoid that the basket will actually be lowered into the station.

- Next, lift the carousel again with the crank handle until you notice resistance to the rotating movement.

To lower the basket into the station, release the crank handle.

When using the manual transporting option, infiltration times for all stations have to be user-controlled.

- To resume processing once mains power has been restored, switch on the mains switch.

After mains power is restored the software recognizes any manual station changes that have occurred during the power failure. When mains power is back, the program is resumed as originally set up.

10.4 'ABORT' message



'ABORT' is displayed after quitting an error code emitted due to instrument malfunction. When confirming such an error message processing is aborted.

At this point processing can be restarted from the beginning. To skip the stations that had already been covered during the previous aborted run proceed as follows:



- Press START.
- To start the currently displayed program, press START again.



This will cause the instrument to step by step move the basket to the programmed starting station. Before reaching that position:



- Press PAUSE/CONT to switch to the manual processing mode.



- Press CIRCLE ARROW to move the basket to the station where processing was aborted.



- Press ARROW DOWN to lower the basket.



- To leave the manual processing mode, press PAUSE/CONT again.

Processing will then continue where it had previously been aborted.

11. Cleaning

- Lift the carousel in the manual processing mode.
- Remove all station containers from the platform.



Spilled reagents have to be wiped away immediately. In case of long-term exposure, the instrument surfaces are only conditionally resistant to solvents.

Caution! The interior containers of the paraffin stations become very hot when the heating function is activated! Do not touch the gray upper rim of the containers with your hands! Risk of injury!

Caution when handling hot paraffin! Risk of injury!

- Disconnect the paraffin station plugs, slightly lift the paraffin station lids and remove the paraffin containers.
- Lower the carousel in the manual processing mode.



Before cleaning the instrument, disconnect the mains switch.

To clean the painted surfaces, the container platform and the control panel, do not use solvents containing acetone or xylene; neither use abrasive cleaning powders!

Only mild household detergents may be used! The lacquered surfaces and the control panel are not resistant xylene or acetone!

- Remove residual paraffin from the station holders, lid seals and lid holders.
- Use a soft plastic spatula for removing the paraffin.



Vor der Reinigung Gerät mit dem Netzschalter ausschalten!

Zum Reinigen der lackierten Flächen, der Behälterplattform und des Bedienfelds keine acetone- und xylolhaltigen Lösemittel oder Scheuermittel verwenden!

Nur milde handelsübliche Haushaltsreiniger benutzen! Die lackierten Flächen und das Bedienfeld sind nicht xylol- oder acetonebeständig!



When cleaning the instrument, no liquid may enter in contact with any of the electrical connections or the interior of the instrument.

- Use a moist cleaning cloth to clean platform, lacquered instrument surfaces and control panel.
- Clean the rims of the glass or aluminum reagent containers and of the paraffin containers.



The glass and aluminum containers are dishwasher-proof.

- Take the glass or aluminum containers out of the beaker carriers and wash them in the dishwasher.
- Fill the paraffin and reagent containers and put them back into place.
- Reconnect the paraffin station plugs.
- Switch on the mains switch.

Cleaning the plexiglass fume containment shields of instruments with fume control system

- Use a soft plastic spatula for removing residual paraffin from the surface of the shields to avoid scratches.
- Apply some alcohol or xylene on a cloth and wipe off the surfaces previously cleaned with the plastic spatula.
Do not allow xylene or alcohol to react on the surfaces!

12. Maintenance

12.1 Allgemeine Wartungshinweise



For purposes of maintenance or repair, the instrument may only be opened by service technicians authorized by Leica.

Overall, the instrument can be considered maintenance-free. To ensure its trouble-free functioning over a prolonged period of time, we still recommend:

- Have a preventive maintenance done once a year by a service engineer authorized by Leica.
- Once your warranty period expires, we recommend to purchase a Leica Service Contract. For details please contact your local Leica Service Organization.
- Mop up spilled reagents immediately.
- Clean the instrument on a daily basis ([see Chapter 11 'Cleaning'](#)).
- Once a month, lift the carousel cover to its upper end position, clean the carousel axle with a cleaning cloth and subsequently apply a thin coat of machine oil.
- Never attempt any repairs on the instrument or paraffin stations on your own - by doing so you will lose any warranty claims!

12.2 Paraffin stations

12.2.1 Altering the standard working temperature



Factory-set standard working temperature is 65 °C. The paraffin station heating will automatically switch on when the actual temperature of the paraffin is 5 °C below standard working temperature.

When working with paraffin that has a melting point below 58 °C, the instrument working temperature can be readjusted with the corresponding setting screw

- Use a screw driver to turn the setting screw (1) to the desired value.

If you find that the paraffin does not melt completely after lowering the working temperature, slightly readjust again.

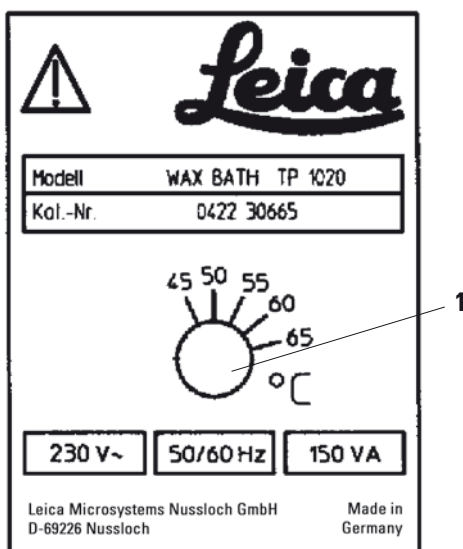


Fig. 24

12. Maintenance

12.2.2 Reset after excess temperature shutdown



If the actual temperature rises above the range of normal working temperature, an excess temperature switch-off mechanism responds. The paraffin station heating is disconnected. The yellow signal lamp is extinguished.

Use of the paraffin station can be resumed only after a cooling down period. For cooling down, disconnect the paraffin station connector plug from the socket at the rear of the instrument, or switch off the main switch.

- Disconnect the paraffin station connector plug from the socket at the rear of the instrument.
- Wait for the paraffin station to cool.



Check if the paraffin station works trouble-free. Use of defective paraffin stations has to be discontinued for safety reasons!

Operational test

- Plug the paraffin station back in.
- Check whether the yellow pilot lamp lights when heating is activated.
- Wait until the paraffin is completely molten. The set standard working temperature has been reached when the pilot lamp goes out.
- Measure if the actual temperature of the paraffin corresponds to the standard working temperature.

If there is any doubt whether the paraffin station is functioning trouble-free, it has to be exchanged.

12.3 Replacing the fuses



Before exchanging the fuses, switch off the mains switch and unplug the instrument! Burnt-out fuses may only be replaced by fuses of the same type and specification. For appropriate brands and specifications, see [Chapter 3 'Technical Data'](#).

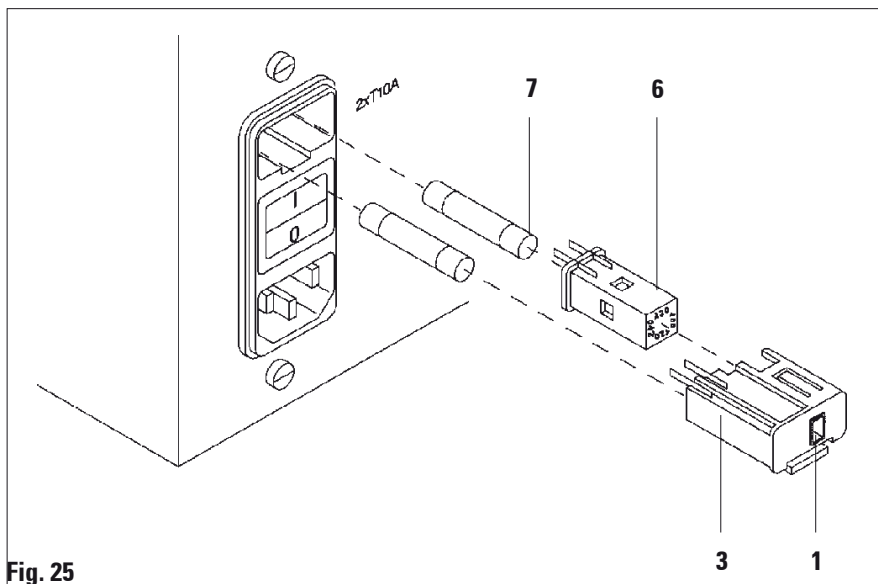


Fig. 25

The fuses are located in the voltage selector shell (3).

- Remove the shell (3) as described in [Chapter 4.3.4 'Adjust voltage selection'](#).
- Remove the fuses (7).
- Insert replacement fuses of the same type.

The currently selected voltage can be seen in the small window (1) in the voltage selector shell.

- Insert the voltage selector shell together with the fuses back into the receptacle in the instrument and press lightly until it locks.
- Check if the setting that shows in the window (1) corresponds to the nominal voltage in your laboratory.

13. Optional accessories

13.1 Three-level tissue basket

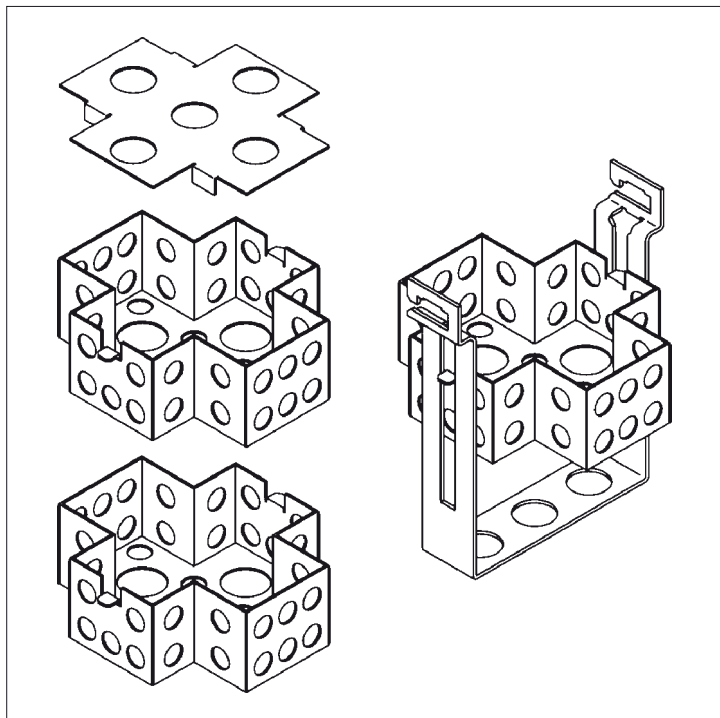


Fig. 26

Capacity: 20 cassettes per level.

The three-level tissue basket consists of a holder (1) in which the three levels (2) for the cassettes are stacked. The upper level is closed with a lid (3).

13.2 Basket removal device

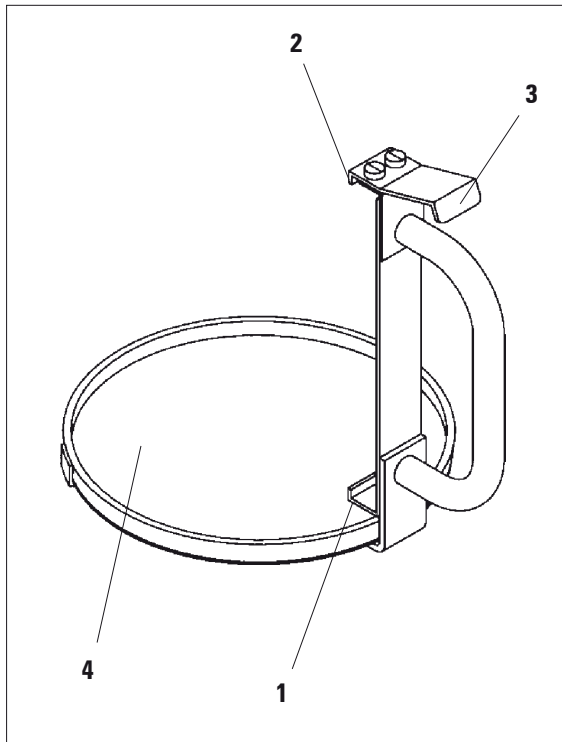


Fig. 27

The basket removal device with drip tray makes it easy to remove the hot dripping tissue basket at the end of the processing cycle. The rubber insert (4) of the drip tray can be removed for cleaning.

- Grasp the basket removal device at the black handle and insert the dripping tray under the tissue basket.
- Insert the metal hook (1) under the notch at the bottom of the tissue basket.
- To lift the hook (2), press the spring (3) downwards with your thumb.
- Lock the hook (2) into the upper rim of the tissue basket and release the spring.
- Lift the basket slightly and remove it from the basket holder in a horizontal movement.

13. Optional accessories

13.3 Basket holder for second tissue basket



To increase the specimen throughput the instrument can be retrofitted with a basket holder for a second tissue basket.

A second tissue basket (standard or three-level type) has to be ordered separately.

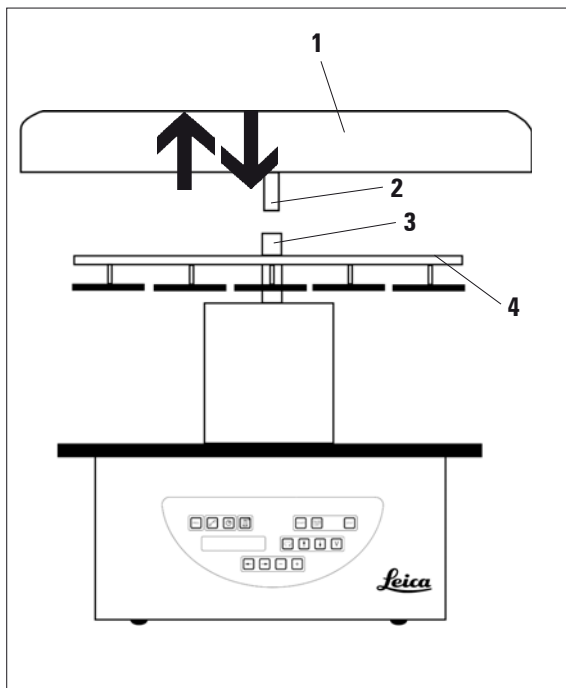


Fig. 28

Standard delivery

1 basket holder for second tissue basket

1 paraffin station

1 station holder for paraffin station

Basket holder for second tissue basket (continuance)

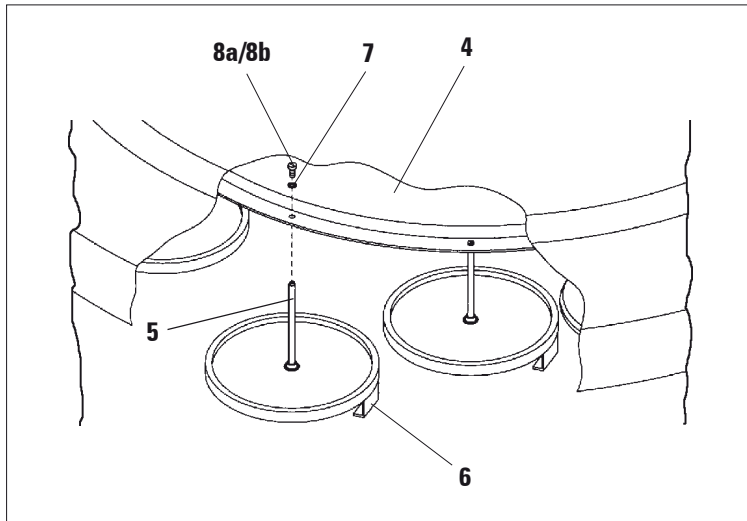


Fig. 29

Installing the second basket holder

- Rotate the carousel cover counterclockwise until it can be removed from the axle (3) in an upward movement.

The second basket holder is installed at position 2. For installation, the station lid with rod which is located in position 2 has to be removed first.

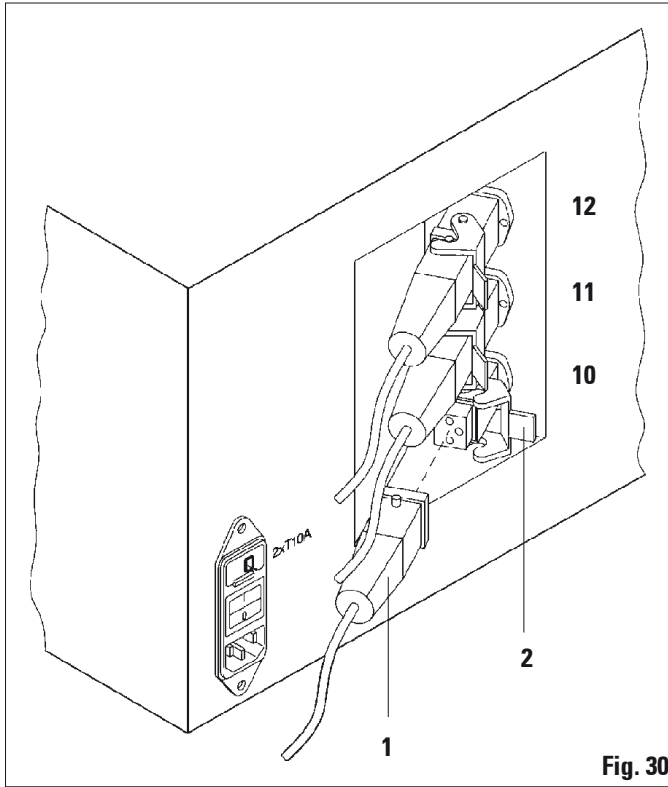
- Clutch the rod (5) with a pair of tongs and release the slotted screw (8a) on the upper side of the disc (4).
- Insert the rod (5) of the second basket holder in the bore on the bottom of the disc (4). Adjust the holding device (6) for the second basket in the same way as the holding device in position 1 and hold it in that position.
- Put the locking washer (7) around the bore in disc (4).
- Insert the Allen screw (8b) into the bore from above and tighten with an Allen key no. 3.
- Insert the hub (2) of the carousel cover (1) from above into the axle (3) of the center piece.
- To secure hold on to the disc (4) and rotate the carousel cover clockwise.

13. Optional accessories

Basket holder for second tissue basket (continuance)



The instrument standard configuration will then have to be changed accordingly to acknowledge that a third paraffin station has been connected - [see Chapter 15](#).



Installing the station holder

- Use a screw driver to lift the reagent station holder out of the platform.
- Insert the paraffin station holder and drive in with a plastic hammer.

Connecting the third paraffin station

- Pull off the cover cap from the socket no. 10.
- Insert the plug (1) of the third paraffin station into socket no. 10 and secure with the clip (2).

13.4 Connecting the fume outlet tube (optional accessory for instruments with fume control system)



Via a solvent resistant fume outlet tube (which is available in a length of 2 or 4 meters), the instrument can be connected to a central fume extraction system. The fume outlet tube can also be used to conduct solvent fumes outside a building.

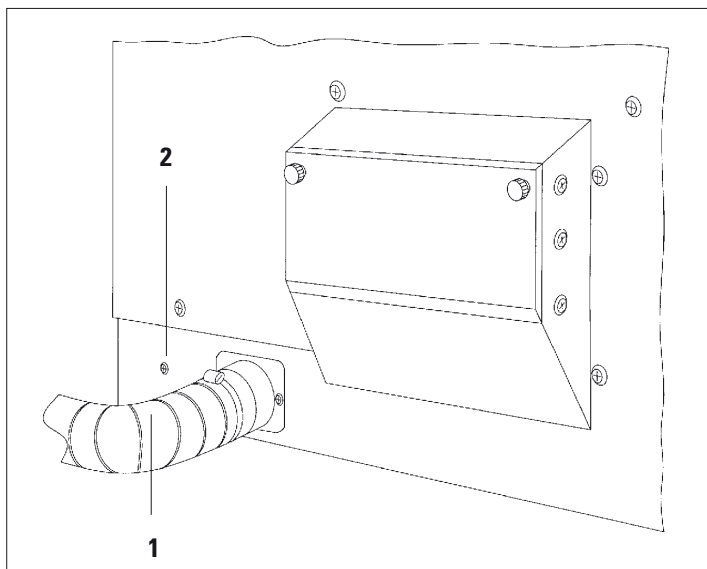


Fig. 31

Installing the fume outlet tube

- Put the tube (1) over the connecting piece on the left side of the housing and fasten by means of the hose clamp (2) that is supplied with the instrument.

13. Optional accessories

13.5 Inserting the activated carbon filters

(optional on instruments with fume control system)



Instruments with fume control system can be equipped with two activated carbon filters. One filter is specific to formaldehyde, whilst the other takes up other solvents. The working life of the activated carbon filters is dependent on the reagent concentrations actually used, instrument running time and ambient temperature.

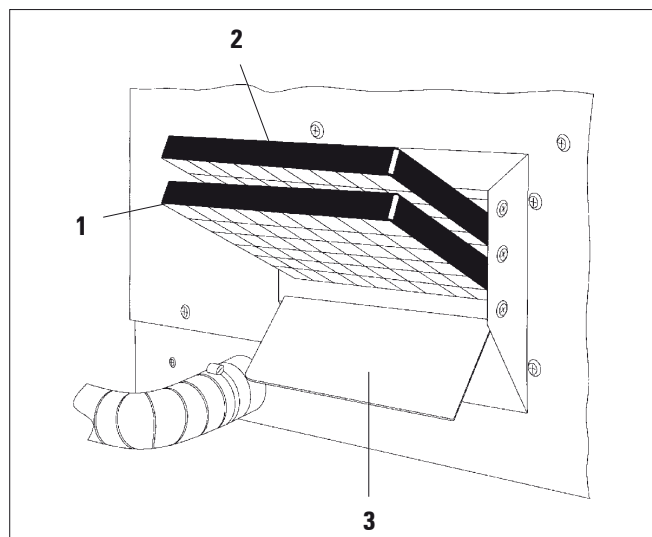


Fig. 32

- Unpack the filters.
- To open the lid (3) of the receptacle on the left side of the instrument, loosen the two knurled knobs.
- Fold down the lid (3).
- Insert the activated carbon filter for other solvents (1) in the lower guide rail and push until it is completely inserted.
- Insert the activated carbon filter for formaldehyde (2) in the upper guide rail and push until it is completely inserted.
- Fold up the lid and lock by tightening the two knurled knobs.



Warning! Fire hazard! It is important that the activated carbon filters are changed at factory recommended intervals. If a filter becomes saturated with solvent, there is a potential fire risk!

14.1 TP 1020 Automatic tissue processor**Type 1 - Basic instrument**

Standard loading capacity with standard tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 30543
Double loading capacity with standard tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 31418
Double loading capacity with three-level tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 31419

Type 2 - Basic instrument with vacuum function

Standard loading capacity with standard tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 30536
Double loading capacity with standard tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 31414
Double loading capacity with three-level tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 31415

Type 3 - Basic instrument with fume control system

Standard loading capacity with standard tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 30537
Double loading capacity with standard tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 31416
Double loading capacity with three-level tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 31417

Type 4 - Basic instrument with vacuum function and fume control system

Standard loading capacity with standard tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 30535
Double loading capacity with standard tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 31412
Double loading capacity with three-level tissue basket	100/120/230/240 V, 50-60 Hz	14 0422 31413

Retrofitting kits for double loading capacity (operation with two tissue baskets)

Basket holder for 2nd tissue basket, paraffin station, station holder for paraffin station	14 0422 32156*
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* **A second tissue basket (standard tissue basket or three-level tissue basket) is not included in the retrofitting kit and has to be ordered separately.**

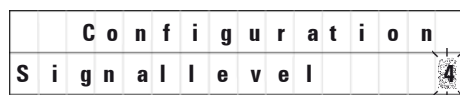
14. Ordering information

14.2 Accessories

Standard tissue basket	14 0422 30585
Three-level tissue basket	14 0422 30547
Single-level compartment for three-level tissue basket	14 0422 30622
Lid for three-level tissue basket	14 0422 30623
Basket removal device with drip tray	14 0422 30637
Glass container, 1.8 l capacity	14 0424 60429
Beaker carrier	14 0422 30671
Aluminum container, 1.8 l capacity	14 0422 32166
Station holder for paraffin station	14 0422 30571
Paraffin station, 1.8 l (230 V)	14 0422 30665
Paraffin station (resistant to chloroform) 1.8 l, adjustable up to 70 °C	14 0422 32001
Screw driver for paraffin station	14 0170 10702
Fume outlet tube (solvent resistant) 2 m	14 0422 31974
Fume outlet tube (solvent resistant) 4 m	14 0422 31975

15. Appendix

15.1 Altering the instrument standard configuration



For this menu item four different settings can be selected. Setting 4 is factory preset. Setting 1 is the lowest level. The next higher level always contains all the parameters of the next preceding level plus the additional signals as listed on this page.

The instrument has a factory-set standard configuration which can be modified by the user if desired.

Modifications can be done in the configuration menu, which consists of 4 different menu items:

- Signal level 1 - 4
- 3. Wax bath?
- ProgPreset?
- SystemReset?

Editing the configuration menu

- Switch off the mains switch.
- Switch the mains switch back on. While the display still reads 'TP1020 V x.xx' press PROG for a short while.

The first configuration menu item is displayed.

Modifying the configuration

Signal level = Setting of the desired type and frequency of sound signal

Level 1 = sound signal in case of power failure and malfunctions.

Level 2 = level 1 + sound signal in case of interrupt ion, warning code and end of program.

Level 3 = level 2 + sound signal when confirming warning codes and error codes.

Level 4 = level 3 and sound signal every time a button is pressed.

- To change the setting, press the PLUS / MINUS keys.

Altering the instrument standard configuration (continuance)



- For the next menu item, press the CURSOR button.

The next standard setting is displayed.



		C	o	n	f	i	g	u	r	a	t	i	o	n	
3	.	w	a	x		b	a	t	h	?			Y	E	S

3. Wax bath = do you wish to use a third paraffin station?



In station no. 10 you can install a third paraffin bath instead of the reagent station. If you do so, you have to modify the configuration menu accordingly; otherwise the instrument will not function properly.

If you change from a three paraffin stations operation mode back to two paraffin stations, you have to go back and readjust the configuration menu.



- To change the setting, press the PLUS / MINUS keys.

- Press CURSOR to get to the next menu item.

The next standard setting is displayed.



		C	o	n	f	i	g	u	r	a	t	i	o	n	
P	r	o	g		P	r	e	s	e	t	?			N	O

ProPreset? = Set programs no. 6 - 9 to factory preselected standard values?

15. Appendix

Altering the instrument standard configuration (continuance)



Programs no. 6 - 9 come with a number of factory preset standard values; however these may be altered by the user.

Standard setting is 'NO'.

- To change the setting, press the PLUS key.

When answering 'YES', programs no. 6 - 9 are set to standard values and programs no. 1 - 5 are deleted.

- Press CURSOR to get to the next menu item.

The next standard setting is displayed.



		C	o	n	f	i	g	u	r	a	t	i	o	n
S	y	s	t	e	m	R	e	s	e	t	?	Y	E	S



A system reset will set real time to 0.00 and maximum heating time for the paraffin stations to 8 hours. The 'Sound Signal Level' setting and the number of paraffin baths selected in the standard configuration menu will remain unaltered by a system reset.

SystemReset? = Reset a number of settings to standard value

Standard setting is 'NO'.

- To change the setting, press the PLUS key.

When answering 'YES' the system clock is set at 0:00 and the maximum heating time for the paraffin wax baths is set at 8 hours. No other settings are altered.

Leaving the configuration menu

- To leave the configuration menu, press PROG.



15.2 Reagents appropriate for use with the instrument

The following reagents are safe for use with the TP1020:

Fixation

Formalin, buffered or unbuffered
Picric acid

Dehydration

Ethanol
Isopropyl alcohol
Methanol
Butyl alcohol
Industrial alcohol

Clearing

Xylene and xylene substitutes
Toluene
Benzene
Chloroform
Trichlorethane
Acetone

Paraffin

Paraffin



Using other than the reagents listed below can cause damage to the instrument or to parts of the instrument.

15. Appendix

15.4 Factory-set programs

Program No. 6 - 1 basket			
Station	Reagent	VAC	Duration
1		V	0h15
2		V	0h15
3		V	0h15
4		V	0h15
5		V	0h15
6		V	0h15
7		V	0h15
8		V	0h15
9		V	0h15
10		V	0h15
11	Paraffin	V	0h15
12	Paraffin	V	0h15

Program No. 8 - 2 baskets			
Station	Reagent	VAC	Duration
2		V	0h15
3		V	0h15
4		V	0h15
5		V	0h15
6		V	0h15
7		V	0h15
8		V	0h15
9		V	0h15
10		V	0h15
11	Paraffin	V	0h15
12	Paraffin	V	0h15

Factory-set programs (continuance)

Program No. 7 - 1 basket

Station	Reagent	VAC	Duration
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1		V	1h00
2		V	1h00
3		V	1h00
4		V	1h00
5		V	1h00
6		V	1h00
7		V	1h00
8		V	1h00
9		V	1h00
10		V	1h00
11	Paraffin	V	1h00
12	Paraffin	V	1h00


Program No. 9 - 2 basket

Station	Reagent	VAC	Duration
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2		V	1h00
3		V	1h00
4		V	1h00
5		V	1h00
6		V	1h00
7		V	1h00
8		V	1h00
9		V	1h00
10		V	1h00
11	Paraffin	V	1h00
12	Paraffin	V	1h00

15. Appendix

Leica TP1020 - Programming Worksheet

Program No. _____ Name: _____ Date: _____ Written by: _____					
Station	Reagent	VAC		Duration	Notes
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11	Paraffin				
12	Paraffin				

Leica TP1020 - Programming Worksheet

Program No. _____ Name: _____ Date: _____					
Station	Reagent	VAC		Duration	Notes
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11	Paraffin				
12	Paraffin				

16. 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.

Technical service information

If you require technical service or replacement parts, please contact your Leica sales representative or dealer who sold the product.

Please provide the following information:

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

Decommissioning and disposal

The instrument or parts of the instrument must be disposed of in compliance with the local laws.



We herewith declare, in exclusive responsibility, that the

Leica TP1020 Automatic Tissue-Processor

was developed, designed and manufactured to conform with the

- European council Directive 2006/95/EG of the European Parliament and of the Council (Low Voltage)
- European council Directive 2004/108/EG of the European Parliament and of the Council (electromagnetic compatibility) and
- European council Directive 98/79/EC of the European Parliament and of the Council (in-vitro diagnostic medical devices)

The following harmonized standards were applied:

- **EN 61010-1: 2001 + A1:2002 + A2:2004**
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- **EN 61010-2-101: 2003**
Safety requirement for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostics (IVD).
- **EN 61010-2-0101: 2002**
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2: Particular requirements for laboratory equipment for the heating of materials.
- **EN 61326: 2006 + A1:2008**
Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- **EN 14971: 2007**
Medical devices - Application of risk management to medical devices
- **EN 591: 2001**
Instruction for use for in vitro diagnostic instruments for professional use
- **EN ISO 132485: 2003 + A1:2007**
Medical devices - Quality management systems - Requirements for regulatory purposes.

In addition, the following in-house standards were applied:

- **DIN EN ISO 9001: 2001.**

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March 13, 2008

Anne De Greef-Safft
President Biosystem Division

