

**TISSUE PROCESSOR
STP 420 D**

INSTRUCTION MANUAL

CERTIFICATION

MICROM International GmbH certifies that this instrument has been tested and checked carefully. Its technical data was verified before shipment to be in accordance with the published specifications.

The instrument complies with applicable international safety regulations.

WARRANTY

This MICROM product is warranted against defects in material and workmanship for a period of 1 year. Parts which prove to be defective during the warranty period will be repaired or replaced free of charge by MICROM International GmbH. No other warranty is expressed or implied. Unauthorized modification or repair by third party persons will void the warranty.

The warranty will expire in case of improper or wrong use of the instrument and in case the warning and precautionary messages are not observed. MICROM International GmbH is not liable for any occurring damage.

Errors and omissions excepted. Subject to amendment and improvement without further notice.

This instruction manual will be supplied together with each instrument. Further copies can be ordered at the nearest MICROM sales office by giving the serial number of the instrument, the number of the instruction manual and the date of issue.

This instruction manual is available in the following languages:

German:	387790
English:	387791
French:	387792
Spanish:	387793

Dear Customer,

Before putting the instrument into operation, please read these operating instructions carefully to familiarize yourself with its proper operation and functions.

MICROM serial number:.....

Please check the MICROM serial number on the type plate, which is placed on the rear side of your instrument and enter this number here. This way, questions and service can be handled faster.

Instruction Manual no. 387791

Issued on June 02, 2006

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EC Certificate of Conformity

Name and address of the manufacturer: MICROM International GmbH
Robert-Bosch-Straße 49
D-69190 Walldorf

Product designation: STP 420 D
Type reference: STP 420 D

The designated product complies with the laid down regulation:

**DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 27 October 1998
on in vitro diagnostic medical devices**

The designated product complies with the EC regulations by strictly observing the following norms:

DIN EN ISO 14971:2001-03

Medical devices - Application of risk management to medical devices (ISO 14971:2000).

DIN EN 61010-1:2002-08

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements (IEC 61010-1:2001).

IEC 61010-2-101:2003-09

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for In-Vitro-Diagnostic-(IVD)-Medical instruments.

DIN EN 61010-2-081:2002-12

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes (IEC 61010-2-081:2001).

DIN EN 61010-2-010:1995-03

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials (IEC 61010-2-010:1992, modified); German version EN 61010-2-010:1994

DIN EN 61326:2004-05

Electrical equipment for measurement, control and laboratory use - EMC requirements (IEC 61326-1:1997 + IEC 61326-1/A1:1998 + IEC 61326-1/A2:2000 + Annexes E & F of IEC 61326:2002 + Corrigendum:2002); German version EN 61326-1:1997 + EN 61326/A1:1998 + EN 61326/A2:2001 + EN 61326/A3:2003

DIN EN ISO 9001:2000

Quality management systems - Requirements (ISO 9001:2000)



Hans Heid
Managing Director

Walldorf, 24 August 2004

PART 1 IMPORTANT INFORMATION

1-1 SAFETY PRECAUTIONS AND SYMBOLS

The installation and routine use of the STP 420 D is easy and safe if the instructions in this manual are being observed.



Note:

Special instructions regarding operation of the instrument.



Warning:

Special precautionary measures to prevent damage to equipment. For a long lifetime of the equipment, please observe these instructions carefully.



Caution – general danger spot:

The instruction manual must strictly be observed whenever this symbol is visible on the instrument. Do not override safety features built into this instrument.



Biohazard:

Warning of biological danger.



Chemicals:

Warning of unhealthy or irritating substances.



Hot surface:

Some surfaces of the instrument become hot during the intended use. They are marked with this warning symbol. Touching these surfaces may cause burns.



Separate taking back of electrical and electronic instruments in the countries of the European Union:

This is to be applied in the countries of the European Union and other European countries with a separate collecting system within the waste management.

This product, being an electro and/or electronic instrument, must be treated separately within the waste management process (WEEE).

SAFETY PRECAUTIONS AND IMPORTANT INFORMATION**CAUTION!**

The operator's safety is affected, when the instrument is not operated in accordance with this instruction manual.

Please observe the following general precautions during operation of this instrument. Failure to comply with these precautions violates safety standards and the intended use of the instrument. MICROM International GmbH is not liable for misuse of the instruments and failure to comply with basic safety requirements.

INSTRUMENT GROUNDING

To avoid injury from electrical current, the instrument must be connected with the protective earth. The instrument is equipped with a three wire ground plug. The power outlet must be connected to the protective earth and must meet the International Electrotechnical Commission (IEC) regulations. Do not cut, deform or remove any of the prongs from the power cord. Do not use with an extension cord.

CAUTION: MAINS VOLTAGE

Never remove instrument covers during operation. Component replacements as well as adjustments must only be made by trained service personnel. Unplug the unit before removing or opening the covers.

CAUTION WHEN CLOSING THE PROCESSING CHAMBERS

Do not attempt to operate the unit with an object caught in the lid, a lid does not close properly, a damaged lid, hinge, latch or sealing surface. Please care for the correct function of the locking mechanism and cleanliness as well as for the correct seat of the seal inside the lid.

CAUTION – NOTIFY A SERVICE TECHNICIAN!

Notify an authorized service technician if a problem or suspected problem occurs. Proper servicing is required for continued compliance with applicable safety precautions.

DANGER IN FLAMMABLE ENVIRONMENT

The instrument must not be operated in the presence of flammable gases.

HAZARD OF BIOLOGICAL DANGER

Specimens used during the intended operation of the instrument might potentially be infectious. For this reason, it is recommended to observe the general laboratory regulations concerning protection against danger of infection.

Information on decontamination media, their use, dilution and effective range of application can be read in the Laboratory Biosafety Manual : 1984 of the World Health Organization.

HAZARD OF MALFUNCTION

To avoid the hazard of malfunction of an instrument, it must only be operated in a controlled electromagnetic environment. This means that transmitters such as mobile phones must not be operated in their close vicinity. In case of malfunctions and/or service work, please turn off the instrument and contact your local dealer.

WARNING OF UNHEALTHY OR IRRITATING SUBSTANCES

During the intended use, smallest amounts of irritating aerosols might occur. For this reason, please care for sufficient ventilation. To avoid negative effects on your health while in direct contact with the reagents or its residues, always wear respective safety clothing (e.g. protective glasses, laboratory gloves).

WASTE DISPOSAL

All debris and waste as well as infectious and radioactive contaminated material from operation must be disposed of in accordance with the respective regulations of the lab. Disinfection and cleaning liquids as well as section waste must be disposed of according to the respective regulations for special waste! Reagents must be disposed of according to the respective Safety Data Sheets of the manufacturer!

1-2 INTENDED USE

The Tissue Processor STP 420 D from MICROM is a highly efficient microprocessor-controlled instrument that automates tissue sample preparation for laboratory testing. The instrument is used for the

fixation, dehydration, clearing and infiltration (with paraffin)

of tissues.

Only skilled or specially trained personnel must operate the Tissue Processor.

The listed and marked safety measures as well as the regulations and hygiene measures of your lab must strictly be observed.

The STP 420 D must only be operated with the reagents listed in part 2-4.

The STP 420 D incorporates a number of protection features as well as sophisticated software controls. In case of a power failure or other problems during the infiltration process it is thus guaranteed that the specimens remain undamaged and the infiltration can be completed successfully.

The instrument must be installed and instructed by an authorized representative. All warranties and guarantees are null and void, should the instrument be installed by a third party. Please inform MICROM International GmbH or your local, authorized representation to fix a date for the initial turn-on and for instructions.



Fig. 1

2 INTRODUCTION

2-1 DESCRIPTION AND OVERVIEW OF THE STP 420 D

The Tissue Processor STP 420 D from MICROM is a microprocessor-controlled instrument that automates tissue sample preparation for laboratory testing. The Tissue Processor fixes, dehydrates, clears and infiltrates tissue samples and incorporates:

- a main processing chamber with rotating basket carrier (rotary chamber);
- a second processing chamber (biopsy chamber);
- ten reagent stations, four paraffin stations and two cleaning stations for the automatic cleaning process;
- a storage capacity of processing protocols, which are only limited by the storage capacity of the fixed disk, with an unlimited number of steps. Each step can independently be programmed concerning processing temperature and pressure, vacuum or pressure/vacuum cycles;
- variable processing times for each station;
- a closed exhaust system, allowing operation free from odors due to a condensation container (water filter bottle) and active charcoal filter;
- a possible connection for a network and a modem for remote diagnostics.

Tissue processing protocols, which are exactly tailored to the needs of individual laboratories as well as to their special quality controls, can be elaborated.

Unlimited number of routine or special tissue processing protocols, which are only limited by the storage capacity, can be entered and stored for easy recall or editing. Protocols can be set for fixed duration and fixed ending times. The MICROM STP 420 D also features delay programming for weekend or overnight runs.

Operation as well as programming is prompted by easy-to-follow menu displays and entered using the clearly designed touch screen. Protocols are easily changed if laboratory requirements change.

To monitor protocols, the instrument displays progress messages during each step of the tissue processing run. A summary report can be viewed after the run. When attached to a printer, the STP 420 D also prints information on programmed settings, date and time for each step, system messages that occur during the run as well as reagent and paraffin usage status.

To process tissues, samples are placed in cassettes and loaded in sample baskets. The specimens can be loaded into up to six baskets with lids. Each basket holds up to 60 cassettes if arranged in organized form. If a basket is filled non-organized, the basket might hold up to approx. 40 cassettes. Up to six organized baskets may be processed in a single run. The baskets are placed into the rotary chamber. The user selects the menu button for the rotary chamber to start the desired protocol.

Processing starts after the system checks critical operating functions (the so-called self-test). Messages appear during a run to show which step the instrument is performing and the time elapsed in the protocol. The display also shows whether the process chamber is being filled or drained for each step. Any error messages and relevant protocol data are displayed and can be printed in a summary report, even after a protocol run has been completed.

The system automatically prompts the operator to start a programmed clean cycle for the process chamber at the end of any run that includes paraffin steps.

Exhaust fumes and particles which are ecologically harmful are confined in the instrument through a water bottle and an active charcoal filter ventilations system.

Total overview STP 420 D

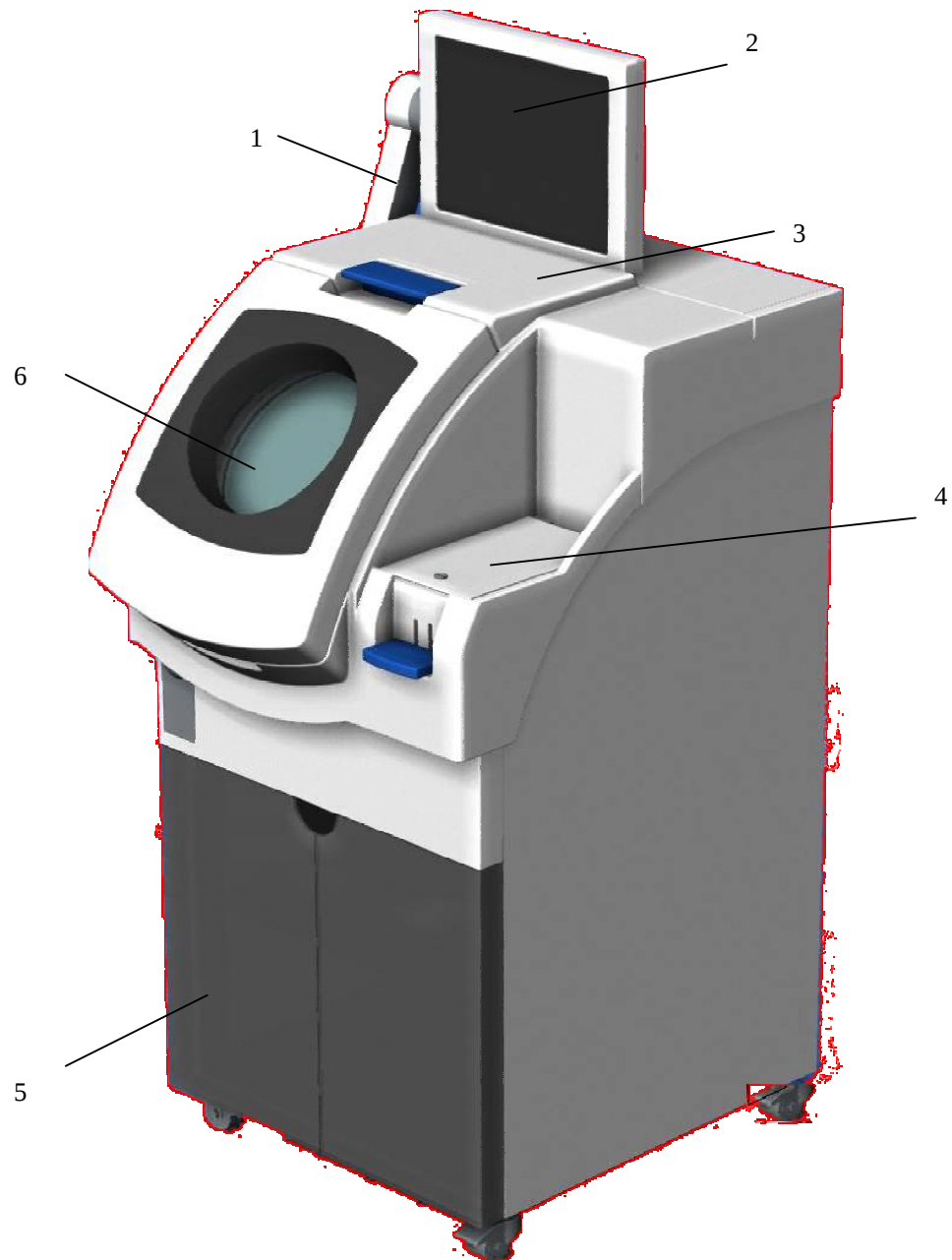


Fig. 2

1 = Movable arm for touch screen
2 = Touch screen
3 = Paraffin reservoir

4 = Biopsy chamber
5 = Reagent reservoir
6 = Rotary chamber

The Tissue Processor STP 420 D has these primary features:

- a monitor (touch screen)
- two temperature-controlled process chambers
- a heated paraffin reservoir with four paraffin stations
- a storage containment for bottles with ten reagent stations and two cleaning fluid stations
- an enclosed exhaust filter and a water container for filtration
- an acoustic alarm
- a connection for a computer network (LAN)
- a parallel printer interface for an IBM compatible printer
- a serial connection
- two PS-2 interfaces for a PC keyboard or a mouse
- a 3,5" disk drive
- a battery buffered protocol and data memory
- a battery supported emergency system to secure the specimens in case of a power failure

2-2 ACCESSORIES**2-2-1 STANDARD EQUIPMENT**

The Tissue Processor STP 420 D is supplied with the following standard equipment:

	Cat. no.
7 baskets for organized or bulk fill	
7 basket lids	
14 reagent bottles	
1 power cord	
1 instruction manual	387791
1 hexagon key for manually opening the rotary chamber in case of a power failure	
1 hose with connection for the automatic filling/emptying of reagent bottles	
1 bottle for emptying the water filter bottle	

**Note:**

Please check all delivered parts with the delivery note and with your order. In case of a missing part, please contact your local MICROM sales office immediately!

2-2-2 FACTORY DEFAULT SETTINGS

Feature	Setting
Date format	TT/MM/JJ
Paraffin temperature	60°
Default selections for a protocol:	
drain time:	20 sec.
pressure/vacuum	OFF
Default passwords:	
User (routine user)	no password required
Supervisor	Supi

**Note:**

When entering the passwords, please note the correct capital and/or small letters!

2-3**TECHNICAL SPECIFICATIONS TISSUE PROCESOR STP 420 D**

Volume rotary chamber: approx. 13,3 l
 Actual filling volume rotary chamber: 3 l
 Volume biopsy chamber: 2,0 l
 Actual filling volume biopsy chamber: 1 l
 Volume remote fill tank: approx. 5,3 l

Filling or infiltration during low pressure: -0,7 bar
 Emptying or infiltration during over pressure: +0,35 bar

Chamber temperature during infiltration: ambient temperature up to 65°C
 Chamber temperature during cleaning and paraffin steps: 50°C up to 65°C

Paraffin containers:
 Paraffin temperature: 45°C up to 65°C
 Volume per container: 5,3 l

Process chambers:
 Over pressure: +0,35 bar
 Low pressure: -0,7 bar

Transportation and storage conditions

Storage
 temperature range: -20°C up to +50°C

Operating conditions: +5°C up to +35°C (at a max. rel. humidity of 60%)
 altitude up to 2000 m M.S.L.
 for indoor use only
 floor loading requirements: 350 kg/m²

Max. pressure: 0,35 bar = 35 kPa < 50 kPa

Power requirements: 100...115V, 10A, 50...60Hz, +/-10%
 220...240V, 5A, 50...60Hz, +/-10%

Internal protection

Primary circuits: mains switch fuse unit Q1 T15AH

Secondary circuits:**Supply board A2:**

Trafo T1 secondary:		F1..... T20A
Main circuit for heatings	P24.1	F2..... 16AFF
		F3..... 16AFF
Pump P1:	P24.3	F4..... 5 A
Valve and lock for lid – supply	P24.2	F5..... 6,3 AFF
Controller	P24.8	F6..... 1 AFF
Turning valve V1	P24.5	F7:..... 6,3AFF
Turning valve V2	P24.6	F8..... 6,3AFF
Rotary motor R7	P24.7	F9..... 6,3AFF

Continued on page -2

Power board A3:

Instrument fan	M1/M2	F1.....	0,1 AFF
Rotary chamber fill/drain tube heating	R21	F2.....	1 AFF
Paraffin drain heating	O12	F3.....	1 AFF
Rotary chamber heating, lower front	R12	F4.....	3,15 AFF
Rotary chamber heating lower	R15	F5.....	10 AFF
Rotary chamber heating upper	R28.1	F6.....	8 AFF
Biopsy chamber heating	B12/B13	F7.....	10AFF
Paraffin container heating 1	O6.1	F8.....	5 AFF
Paraffin container heating 2	O6.2	F9.....	5 AFF
Paraffin container heating 3	O6.3	F10.....	5 AFF
Paraffin container heating 4	O6.4	F11.....	5 AFF
Valve unit	V5/V6	F12.....	5 AFF
Magnetic valve remote fill tank	P40	F13.....	1 AFF
Magnetic valve biopsy chamber	B24	F14.....	1 AFF
Magnetic valve pressure	P31	F15.....	1 AFF
Magnetic valve rotary chamber	P32	F16.....	1 AFF
Magnetic valve vacuum	P30	F17.....	1 AFF
Locking magnet biopsy chamber	B24	F18.....	1 AFF
Magnetic valve reserve 1		F19.....	1 AFF
Magnetic valve reserve 2		F20.....	1 AFF

Pollution degree: 2
 Overvoltage category: II
 Sound pressure: 50 dB(A)

Dimensions: wide 639 mm x high 1503 mm x deep 635 mm
 Working height: 848 mm
 Level paraffin bottles: 1079 mm
 Entire height with monitor: 1503 mm

Weight (empty): 200 kg
 (with operating media): 260 kg

All temperatures refer to an ambient temperature of +20°C!

2-4 ACCEPTABLE REAGENTS

The following reagents are to be used with the STP 420 D:

Fixatives

Formalin
Buffered or non-buffered formalin substitutes

Dehydrants

Ethanol
Isopropanol
Methanol
Butanol
Denatured industrial alcohols

Clarifiers

Xylene
Xylene substitutes

Paraffins

Paraffins with melting points between 55°C and 58°C

Clearants

Xylene (no Xylene substitute!!)
Ethanol
Isopropanol
Methanol
Industrial alcohols
Water



Caution:

Reagents which are not listed here can cause damage to the instrument. Do not use acetone, benzene or trichlorethan!

PART 3 OPERATING INSTRUCTIONS

3-1 Setting up the STP 420 D



Warning:

The instrument must only be transported while in upright position!

Unpacking the STP 420 D:

- Carefully inspect the shipping packaging for any signs of shipping damage as soon as it is delivered. Do not open the packaging. Contact the delivery carrier immediately to report any damage. Also contact MICROM International GmbH or your local dealer as soon as possible.

The instrument must be installed and instructed by an authorized representative. All warranties and guarantees are null and void, should the instrument be installed by a third party. Please inform MICROM International GmbH or your local, authorized representation to fix a date for the initial turn-on and for instructions.

Carrying the instrument by means of a carrying device:

The carrying device, consisting of two parts, is used to transport the instrument over stairs in a slightly slanted position:

- For this, fasten the larger one of the two parts to the rear wall by means of screws (see fig. 4).
- Tilt the instrument by approx. 45° and fasten the smaller part onto the lower side of the instrument by means of screws (fig. 4).
- Lifting and carrying is carried out via the bars of the upper and lower carrying device.

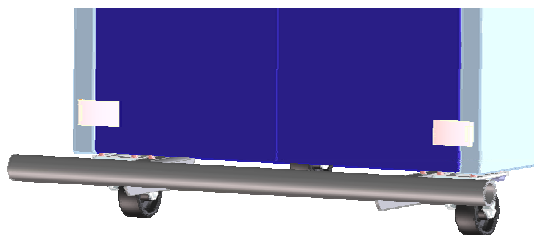


Fig. 3

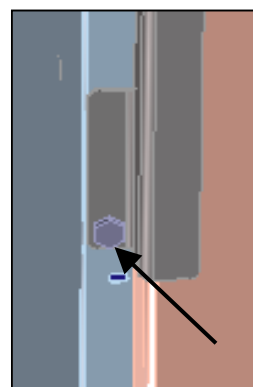
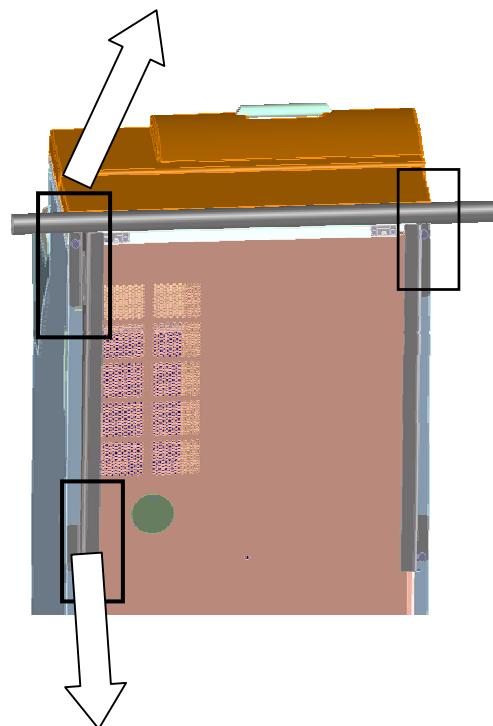
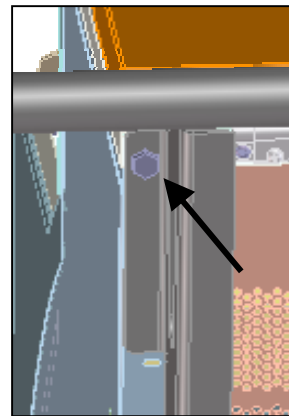


Fig. 4

Carrying the instrument by means of carrying belts:

The transportation of the instrument over stairs is carried out via a carrying belt:

- Lead the carrying belts through the rollers (fig. 3) on the lower side of the instrument.

**Warning:**

When carrying the instrument and/or during the transportation, no pressure should be exercised onto the side walls and/or front and rear side of the instrument.

Transporting the instrument by means of a lifting instrument:

- When transporting the instrument by means of a lift-truck or a fork lift truck, place the forks on the lower side of the instrument between the rollers.

**Warning:**

Please note that the instrument does not get in a tilt position. For this reason, persons should secure a stable position of the instrument on the right and left side.

Moving the instrument on rollers:

The instrument is equipped with four rollers (fig. 3), which are suitable for an even floor.

- When moving the instrument, keep the instrument on the right and left side and push it.

Site of installation

- Please select the site of installation in a way that the mains switch is accessible at any time.
- Flammable liquids are used for tissue processing, so install the STP 420 D Tissue Processor in a location free from sparks or open flame.
- Set the instrument on a stable, flat table top large enough to match the instrument's dimensions.
- Avoid vibrations, direct exposure to sunlight and heavy temperature variations.
- The instrument has an exhaust system with internal fume control. Placement near a fan or exhaust vent is not necessary for safe operation.
- To guarantee a sufficient ventilation, the following distances to walls or other instruments must be observed: rear side: 30 cm, left side: 30 cm, right side: 20 cm.
- Connection for printer and mains fuse connection as well as a disk drive are placed on the left side of the instrument. Leave enough space on that side for easy access to the panel.
- The room of installation must be ventilated with a ventilation opening of at least 10 x 10 cm or an air volume of at least 10 m³/h.
- The max. heat emission in the room of installation is 1200 W. The user must take care for a corresponding carrying-off of the heat.

Electrical requirements

A suitable power supply is needed for optimal operation. Emergency power is also recommended.

- The Tissue Processor is equipped with a 1,5 m power cord which is equipped with a three-wire ground plug.

Optional interfaces:

- On the left side of the instrument, there is a connection for a modem (fig. 5.1). With this modem, remote diagnostics and remote control of individual functions of the instrument are possible.
- A printer can be connected to the parallel interface LPT1 (fig. 5.2).
- An external mouse can optionally be connected to the PS-2-interface (fig. 5.3)
- An external keyboard can optionally be connected to the PS-2-interface (fig. 5.4)
- A LAN-network can be connected to the socket (fig. 5.5).
- Fig. 5.6 and 5.7 are USB-interfaces.
- Disks for data storage can be inserted into the disk drive (fig. 5.8) (please see part 3-5-5).

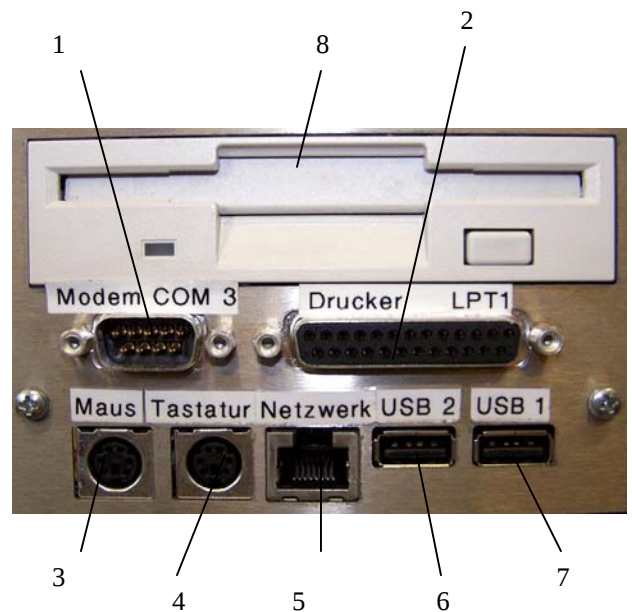


Fig. 5

3-2 INITIAL TURN-ON



Note:

The kind of the used examination materials and all special conditions for their processing, pre-treatment and, if necessary, storage as well as instrument controls for correct and safe operation is in the responsibility of the operator.

The operator is also responsible for special equipment and materials and/or reagents for the operation of the instrument.



Warning:

Before turning on the instrument for the first time, please check if the power requirements indicated on the type plate correspond to the power supply voltage being used. Whenever turning on the instrument, the operator must convince himself of the proper condition of the instrument.

Filling the reagent bottles with reagents (see part 3-4):

- Before starting the staining process, fill the bottles, according to the pre-defined bath plan, with the corresponding reagents.
- The reagent bottles are marked with two filling lines (fig. 6). The lower mark corresponds to 3,8 l (1 US gallon), the upper one is for 5 l (1,32 US gallons).
- In case the instrument is operated with one chamber only, filling up the bottles to the lower mark is sufficient.
- In case the instrument is operated with two chambers simultaneously, fill to the upper mark.
- Moreover, when creating a reagent list, a limit how often a reagent may be used, can be entered (see part 3-5-3).

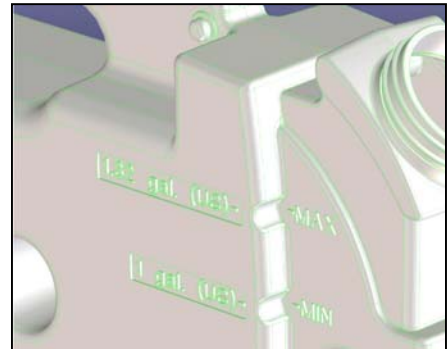


Fig. 6

3-2-1 TURNING ON AND/OR OFF THE INSTRUMENT

Turning on:

- First, turn on the power switch on the left side of the instrument.



Note:

The following starting process is accompanied by the various text messages of the Linux operating system.

Afterwards, the so-called starting screen appears (fig. 16).

- The symbol of the melting timer might occur in the upper right status window, after a longer break.
- It means that the paraffin stations are ready for operation only after the paraffin has been melted completely.
- Now, the instrument is ready for operation.



Fig. 7

Turning off:

- Turn off the power switch on the left side of the instrument.

3-2-2 PARAFFIN CONTAINERS

The Tissue Processor STP 420 D has four paraffin containers, which are placed in the upper area of the instrument behind the processing chambers.

- Open the paraffin lid (fig. 8.1) to have access to the containers.
- The paraffin containers are constantly heated as long as the instrument is supplied with voltage.
- Heating is carried out from below and via heating tubes also from the side walls of the containers as well as from inside via the star-shaped heating elements (fig. 9.2).
- Due to this large heating, the paraffin can be melted rapidly. Melting of the entire volume takes approx. 4 h max.
- For cleaning the drain sieve or for removing objects that have fallen into the containers by mistake, the drain sieves together with the central heating elements can be removed from the container via the upper cover cap.



Caution:

Do not operate the instrument, when the heating elements have been removed!

3-2-2-1 FILLING THE PARAFFIN CONTAINERS

- Open the paraffin lid (fig. 8.1) to be able to fill the paraffin containers from above.
- First, however, insert the central heating elements.
- Fill the respective container with paraffin pellets to the upper edge.
- After approx. 2 h, again fill in pellets to the upper edge.
- After approx. 4 h, the entire paraffin is melted.
- It is absolutely necessary to check again for a sufficient filling height. If needed, refill again.

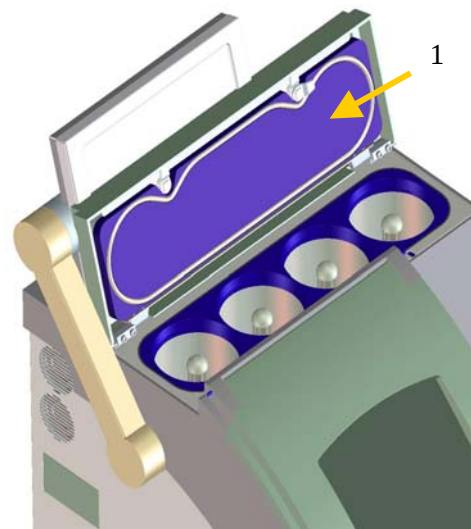


Fig. 8

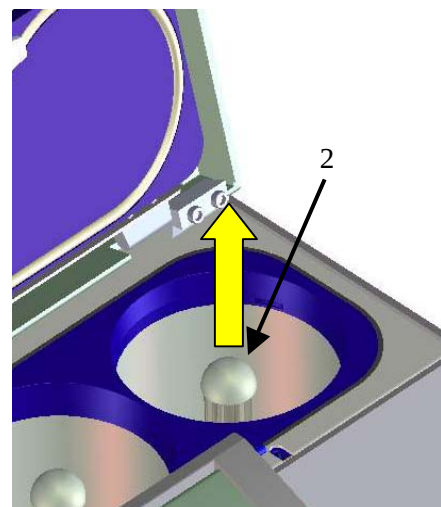


Fig. 9

3-2-2-2 EMPTYING THE PARAFFIN CONTAINERS

Emptying the paraffin containers is carried out on the front side of the instrument above the reagent stations.

- Place a suitable container for collecting the hot paraffin in front of the instrument.
- Open the protective cover (fig. 10.2).
- Pull out the drain tube (fig. 10.1) completely and turn the drain opening downwards and note that the container is below the opening.
- Open the desired paraffin tap (P1, P2, P3, P4).
- Completely empty the paraffin container and let it drip for a short time so that there is no paraffin inside the drain tube any more.
- Close the paraffin tap again.
- Slowly push the drain tube backwards, while still keeping the opening over the container.
- Shortly before the stop, turn the drain opening upwards and slowly push the tube backwards completely.
- Close the protective cover (fig. 10.2).

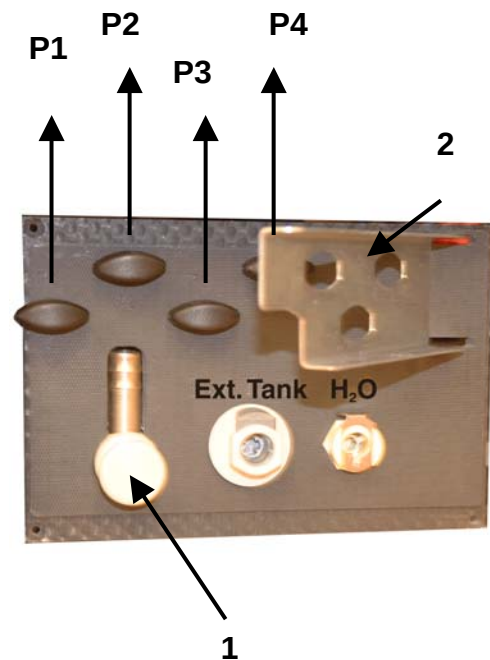


Fig. 10

3-2-3 HANDLING, STORAGE AND VENTILATION OF REAGENTS



Chemicals:

Reagents must be used according to the safety data sheets of the respective manufacturer!!

Handling of reagents:

The reagents, which are used for the instrument, must be handled according to the respective lab regulations.

- It is not suggested to manually refill combustible reagents inside the room of operation.
- **Combustible reagents must be filled or emptied as follows:**
 - a) in an external, suitable room or
 - b) on the instrument via a separate container by using the remote fill/drain function.

Storage of reagents:

- The reagents inside the reagent bottles must be transported in a way that the lock of the bottles is higher than the rear side of the bottle.
- Reagents must be stored in an external, suitable room according to the respective applicable lab regulations.

3-2-4 FILTER SYSTEM

The filling and emptying process in the STP 420 D is based on a vacuum, which is generated inside the process chamber via an integrated pump, during the filling process.

This way, air, which is charged with the vapors of the used reagents, is sucked from the chamber. This air is not directly released into the ambient air, however, it is separated from the solvent vapors in a two-step procedure.

- For this, the pumped air is guided through a condensation bottle (fig. 11.1) which is filled with water. The water-soluble constituents of the vapors, e.g. alcohol are completely condensed in this bottle.
- Afterwards, the air is additionally guided through a large active charcoal filter (fig. 11.2), which filters the still remaining vapors.

For a sufficient filtering effect, the respective replacement intervals must strictly be observed:

- **Water filter bottle:** after 5 program runs or once a week
- **Active charcoal filter:** after approx. 6 months



Note:

Either filter element can only result in best filtering performance, when observing the replacement intervals!



Fig. 11

3-2-4-1 EMPTYING THE FILTER WATER

The filling height of the water inside the bottle can be checked on the right side of the instrument in an oval window (fig. 13).

Emptying the water filter bottle:

- First open the rear cover and remove the screw cap of the filter bottle (fig. 11.3).
- Open the glass doors of the reagent cabinet and place a suitable collecting container, which is able to collect approx. 2 l of liquids, in front of the instrument.
- Place the open end of the attached drain hose into the container and connect the connecting piece on the connection **H₂O** (fig. 12). Firmly press it until it locks.



Caution:

It is absolutely necessary to note that the end of the hose is already placed in the collecting container, as the filter water starts to drain immediately after the connecting piece has been locked!

- Let the used filter water drain into the container until the filter bottle is completely empty.
- Unlock the drain hose by pressing the metal piece (fig. 12.) on the connection and pull it off.
- This way, the connection is automatically closed again.
- The used filter water must be disposed of according to the respective lab regulations.

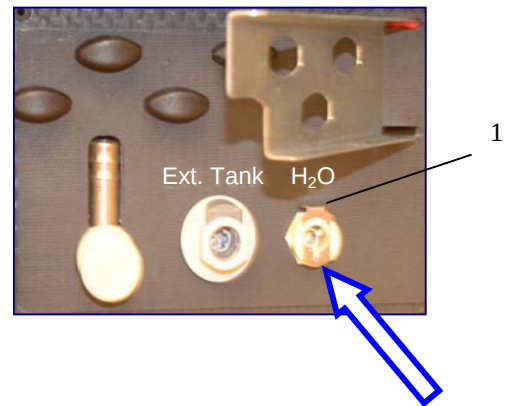


Fig. 12

3-2-4-2 FILLING WITH FILTER WATER

The filling height of the water inside the bottle can be checked on the right side of the instrument in an oval window (fig. 13).

Filling the water filter bottle:

- Insert a suitable funnel into the opening of the water filter bottle (fig. 14.3) and fill in clean tap water until the water level can be seen in the lower area of the window (fig. 13).



Caution:

Fill the water filter bottle only until the lower area of the window (see arrow in fig. 13), as the contents of water inside the filter bottle increases due to the filtering effect. As soon as the level can be seen in the upper area of the window, it is absolutely necessary to completely replace the filter water.

- Again insert the cap screw (fig. 14.3) onto the water filter bottle and tilt the rear cover again towards the front.

3-2-4-3 REPLACING THE ACTIVE CHARCOAL FILTER CARTRIDGE

The active charcoal filter cartridge has an effective lifetime of approx. 6 months. Afterwards, it must be replaced completely.

- For this, open the cover behind the paraffin containers with an upward movement.
- Vigorously pull off the filter cartridge on the cover cap and replace it with a new one.



Caution:

When inserting the new filter cartridge, please note that the new one locks correctly in the new instrument!

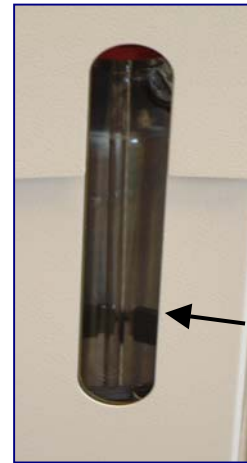


Fig. 13



Fig. 14

3-3 BASIC OPERATIONAL RULES

3-3-1 FUNCTIONS OF THE TOUCH SCREEN

Operation of the STP 420 D Tissue Processor is carried out via a PC based user interface. The PC is integrated in the instrument.

Presentation on the monitor is realized by the operating system "LINUX". As graphical surface library the "KDE" system is used.

- When turning on the instrument, the integrated PC will automatically be started as well.
- This way, the user interface is also started and is available for the user within a few minutes.
- The STP 420 D can be operated completely via the colored touch screen.
- It is not necessary to connect a mouse or a keyboard. However, in case one of them is connected, the other one must be connected as well.



Note:

If the word "click" is used for entries in this manual, entries via the mouse or by touching the buttons on the touch screen are identical.



Caution:

During routine operation it is not necessary for the operator to have direct access to the operating system and its functions. However, it is possible (e.g. for maintenance work) to have access to all functions of the operating system. Non-skilled personnel should not alter those settings in order to not impair the functions of the Tissue Processor.



Note:

All screen indications have an integrated help function (fig. 15), which refer to the respective functions that are shown (context-sensitive). The help function offers in text form a description of the selection possibilities. It can be called by pressing the question mark on the right lower side of the screen. To turn off the help function, press the question mark again.



Fig. 15

3-3-2 USER PROFILE

Four levels of user access are available:

- Locked 
- User 
- Supervisor 
- Technician 

On the access level "**Locked**" no operation is possible during a protocol run:

- All functions are locked.
- To avoid wrong entries via the touch screen, the instrument returns into this access level after a protocol has been started with the first step.

On the access level "**User**" all operations for a normal protocol run are possible, e.g.:

- Calling of pre-defined protocols.
- Opening of chambers to add specimens.
- Closing of protocols, however, **not** altering of protocols.

On the access level "**Supervisor**", it is possible to define protocols and reagents.

On the access level "**Technician**" access to all the functions of the instrument is possible as well.

- All hardware functions can be checked here and instrument parameters can be altered.



Caution:

Unintended operations on this level may result in malfunctions and damage to the instrument.



Note:

The user levels "Supervisor" and "Technician" are protected by passwords. When changing the levels, the password of the respective level is required.

3-3-3 TOUCH SCREEN DESIGN



Fig. 16

3-3-3-1 STATUS WINDOW

In the upper right corner of the screen different symbols are shown concerning the condition of the instrument:

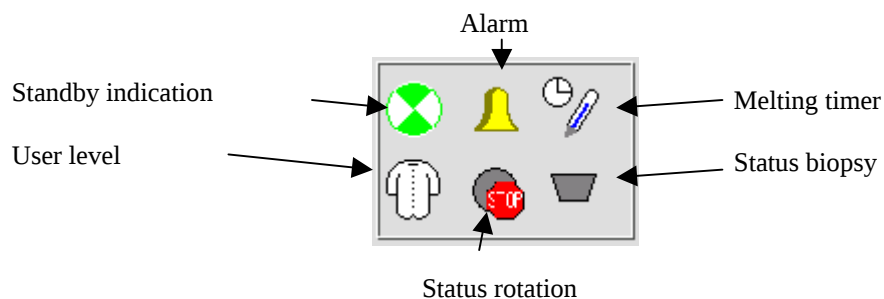


Fig. 17

- A **rotating "wheel"** (fig. 18.1) is placed in the upper left corner of the status window. This wheel is turning and is used as a symbol for the communication between the user interface and the control.
- After having started the instrument, the wheel icon is shown in blue.
- When the instrument is ready for operation, the icon turns from blue to green.
- A **bell** is placed beside this symbol (fig. 18.2).
- At the same time, it is used as a button to reset an alarm situation.
- In addition to the warning messages, an acoustic warning sounds through the integrated loudspeaker.
- Press this symbol, to turn it off.
- On the right side in the upper line of the status window, there is the indication for the **melting timer** (fig. 18.3) and the **signal indication for a voltage breakdown**.
- During the heating phase of the paraffin, the respective icon is shown there. It symbolizes a clock and a thermometer.
- As long as this picture is being displayed, paraffin is not available for processing tissue specimens.
- In case of a voltage breakdown, the symbol for a plug is shown instead.
- In the lower line on the left side of the status window, there is an indication for the current user level (fig. 18.4).
- Beside this, there are the status indications (fig. 18.5 and 18.6) for the **rotary** and **biopsy chambers**.
- Whenever a protocol runs, the symbol of the respective chamber is shown.
- Additionally, a "stop sign" is shown when canceling the protocol.
- A "hand symbol" is shown when the chamber is opened during a run, e.g. reloading of specimens.

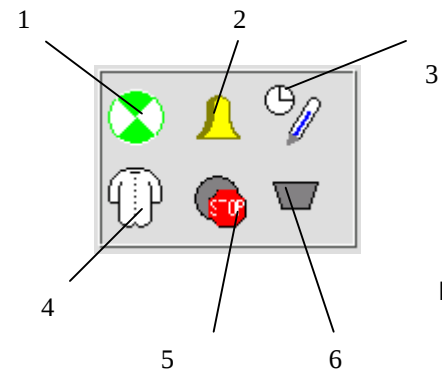


Fig. 18



3-3-3-2 COMMAND BUTTONS

Six soft buttons (fig. 19) for the main functions of the instrument are placed below the status window:

- **Rotation:** functions for calling rotation protocols
- **Biopsy:** functions for calling biopsy protocols
- **Reagents:** reagent management and setup, functions for loading and drain stations
- **Diagnosis:** all hardware diagnostic functions for the service technician. Appropriate knowledge is absolutely necessary here!! Every user is allowed to use this menu, e.g. to print or to export Log-file. Alterations or testing functions are only allowed for "Technicians"!
- **Setups:** different settings that can be entered by the user
- **Help:** context-sensitive help functions
- Depending on the screen contents and user status, the functions alter.
- If the instrument is in stand-by mode and no protocol is running, the soft buttons have the function of quick start buttons. They can be allocated to the protocols which are used very often.



Fig. 19

Structure of the screen:

- The rest of the screen is used for the indication of text and processes.
- It consists of a sequence of different pictures which are shown depending on the selected function. Detailed explanations will follow below.
- At the lower rim of the screen, there is a message line. The last message of the instrument together with the respective time is always shown there.

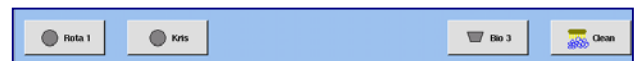


Fig. 20

10:41:01 Leeren der Rotationskammer in Station 6 ("alcohol abs.1") gestartet

- A complete message protocol with all message codes can be recalled via the diagnostic function.

3-3-4 USING THE TOUCH SCREEN

Operation of the entire instrument is carried out by the user via the touch screen. For normal operation, it is not necessary to connect a keyboard or a mouse.

To enter numbers and letters, two different input fields (fig. 21 and 22) are available:

- This input field (fig. 21) is shown for entering numbers.
 - The title bar indicates which parameter must be entered.
 - The input field checks the entered value for limits which are valid for the current input.
 - In case of an invalid value, the number is shown in red and the input field cannot be quit via "Enter".
 - Use the button "<" to delete the entered number.
-
- Letters and numbers can be entered via this input field (fig. 22), e.g. protocol names or reagent names.
 - Passwords can also be entered via this field.
 - When entering the password, the entered characters are replaced by stars "*" on the screen for higher security.
 - Compared with a common keyboard, the shift function between small and capital letters has a "caps lock" function, i.e. the button "Shift" remains active until it is deleted or loosened.

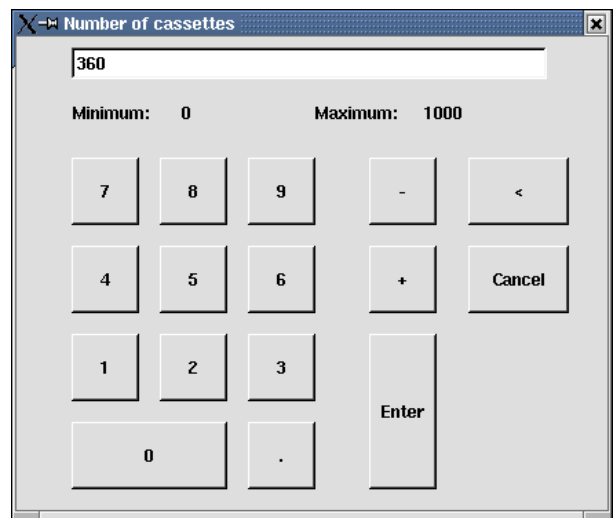


Fig. 21



Fig. 22

3-3-5 SETTING THE STP 420 D TO THE LOCAL TIME

- To adjust the inner system time to the local time, please select the submenu "Language" in the setting menu. The opposite screen is shown (fig. 23).
- Press the button **Select Time** and another window is shown (fig. 24). All settings concerning the respective weekday, date, hour and minute can be made.
- Confirm the settings by entering OK.

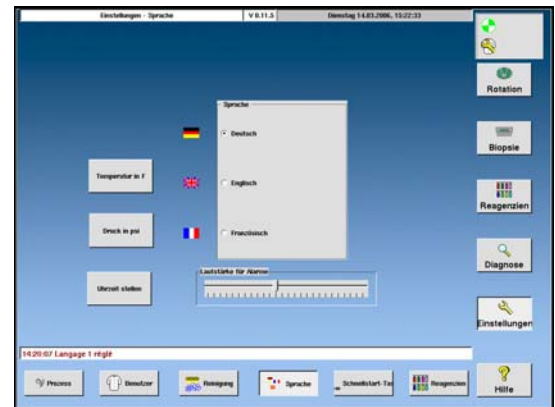


Fig. 23

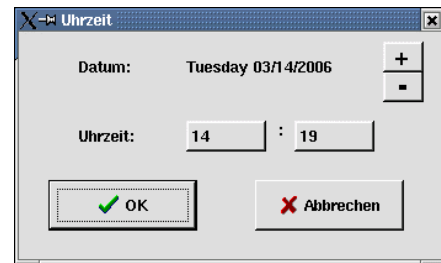


Fig. 24

3-3-6 SETTING THE LANGUAGE

To adjust the respective language, please choose from the following languages:

German
English
French

- For this, select the submenu "Language" in the setting menu.
- Tip on the respective language and all indications and messages on the screen are shown in the respective language without having to restart the instrument (fig. 25).
- Please wait for approx. 10 sec. before entering new settings. This way, the system has enough time to adjust itself accordingly.



Fig. 25

3-3-7 VOLUME CONTROL

- To adjust the system volume, please select the submenu "Language" in the setting menu.
- The opposite indication (fig. 26) is shown on the screen.
- The volume of alarm and signal sounds can be adjusted via the slider.
- Sliding to the left side decreases the volume.
- Sliding to the right side increases the volume.

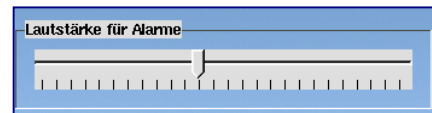


Fig. 26

3-3-8 SETTING THE INDICATION OF THE PRESSURES

- To adjust the indication of the pressure values, please select the submenu "Language" in the setting menu.
- The opposite indication (fig. 27) is shown on the screen.
- Via the button **Pressure in psi**, the indication can be switched over from unit **psi** to **mbar**.



Fig. 27

3-3-9 SETTING THE TEMPERATURE UNIT

- To adjust the indication of the temperature value from **Celsius** to **Fahrenheit**, please select the submenu "Language" in the setting menu.
- The opposite indication (fig. 28) is shown on the screen.
- Via the button **Temperature in F** the indication of the temperature can be shown either in **Celsius** or in **Fahrenheit**.



Fig. 28

3-4 REPLACING REAGENTS

Replacing the reagents can be carried in two different ways:

1. Manual emptying and filling of the reagent bottles
2. Automatic emptying and filling of the reagent bottles by the instrument

3-4-1 MANUAL EMPTYING AND FILLING OF THE REAGENT BOTTLES (CLASSIC WAY)

- To remove the reagent bottle, press the button on the front side of the bottle (fig. 29). In doing so, pull the bottle towards the front (fig. 30).
- Via the well-shaped handle, the bottle can easily be transported to a suitable place for emptying it.
- Remove the cap and empty the used reagent into an intended waste container.
- After having emptied the container, clean it with a suitable cleaning agent, if necessary.
- Afterwards, rinse it thoroughly with water.



Warning:

When filling with fresh reagent, please note that the required filling levels are observed. For this, the reagent bottles are marked with two fill level markings. On the left side, US gallons are shown and on the right side liters are shown (fig. 31).

- In case only one program is to be started either in the rotary or in the biopsy chamber and a parallel run of the chambers is not intended, filling up to somewhat above the MIN marking (3,8 l/1 US gallon) is sufficient.
- In case a parallel run of the two chambers should be carried out, filling up to the MAX marking (5 l/1,32 US gallons) is absolutely necessary.

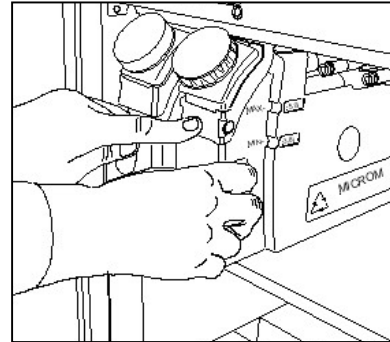


Fig. 29

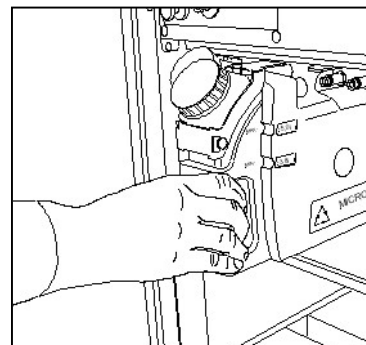
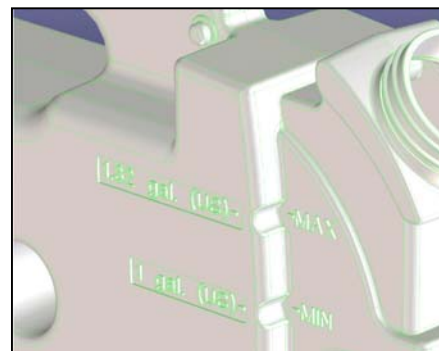


Fig. 30



31

The integrated reagent management system monitors the consumption of reagents and may request you to replace reagents.

- To inform the system on the reagent replacement, tip on the respective reagent container on the screen.
- This container symbol is then marked with a thicker frame.
- Then just press the button "Delete counter" (fig. 32).
- This way, all consumption counters for this reagent are reset.
- The filled reagent bottle can be inserted into its respective position again.
- In doing so, please note that the bottle is completely inserted into its end position. A click can be heard.
- Only then a trouble-free operation can be guaranteed!!



Fig. 32

3-4-2 AUTOMATIC EMPTYING AND FILLING OF THE REAGENT BOTTLES

Emptying:

- For the automatic emptying a suitable waste container, which is large enough, must be placed directly in front of the instrument.
- Then insert the attached hose with the connecting piece on the connection "Ext. Tank" (fig. 33) and place the end of the hose into the waste container.
- The emptying process can now be carried out automatically.
- For this, briefly tip onto the reagent, which is to be replaced, on the screen.
- It is then marked with a thicker frame.
- Then press the button "Empty" (fig. 34).



Fig. 33

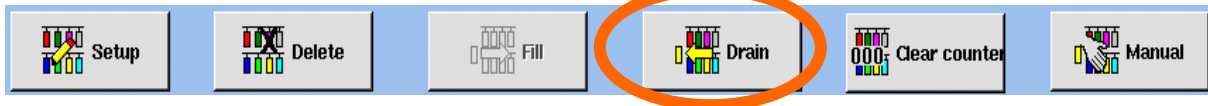


Fig. 34

- A safety interrogation is shown once more on the screen, asking if the end of the hose has really been put in a suitable waste container.
- Confirm it with "OK".
- The used reagent is then pumped into the waste container.



Warning:

Never remove the hose from the waste container as long as the emptying process is still active on the screen.

Filling:

- After the emptying process of the reagent bottle has completely been finished, place a bottle with fresh reagent close to the instrument.
- Insert the attached hose with the connecting piece on the connection "Ext. Tank" (fig. 33) and place the end of the hose into the store container.
- Check if the station, which is to be filled, is still enabled (can be seen on the thicker frame around it).
- Then press the button "Fill".

**Warning:**

Never remove the hose from the external store container, before the filling process has been finished on the screen.

- After the filling process has been finished, the reagent station can be used and the consumption counter of the reagent management system is automatically reset.

3-4-3 EMPTYING THE PARAFFIN CONTAINERS

Emptying the paraffin containers is carried out on the front side of the instrument above the reagent stations.

- Place a suitable container for collecting the hot paraffin in front of the instrument.
- Open the protective cover (fig. 35.2).
- Pull out the drain tube (fig. 35.1) completely and turn the drain opening downwards and note that the container is below the opening.
- Open the desired paraffin tap (P1, P2, P3, P4).
- Completely empty the paraffin container and let it drip for a short time so that there is no paraffin inside the drain tube any more.
- Close the paraffin tap again.
- Slowly push the drain tube backwards, while still keeping the opening over the container.
- Shortly before the stop, turn the drain opening upwards and slowly push the tube backwards completely.
- Close the protective cover (fig. 35.2).

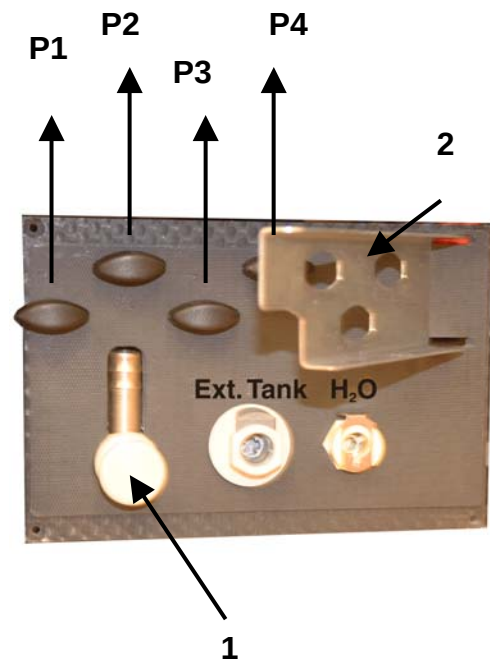


Fig. 35

3-5 STARTING PROTOCOLS

- A protocol of the STP 420 D consists of a sequence of one or more protocol steps.
- One protocol step each stands for the treatment of tissue specimens with one reagent.
- The sequence of the protocol steps results from the desired processing sequence of the tissue specimen.
- This way, as many protocol steps as you like can be entered for a protocol.
- Depending on the different necessities, a various number of different protocols can be filed in the instrument for both the rotary chamber and the biopsy chamber.



Note:

Generally, the number of possible protocols is only limited to the storage capacity, which is available on the fixed

disk.

3-5-1 TIME CONTROL OF PROTOCOLS

- Normally a protocol is processed in a way that it will have been finished after the end of the defined processing time plus the necessary additional times for refilling reagents, heating up process and the pressure built-up.
- However, it might be desirable to carry out a specimen processing over night.
- However, the specimens should not be stored inside the hot paraffin all night, but the additional time should be used for added fixation of the specimens.
- For these protocols, a fixed end time can be defined. At this fixed end time, the protocol is to be finished.
- A waiting step is defined in the protocol, which is used to get all available left-over time, so that the last protocol step is finished at the programmed end time.

3-5-2 PROTOCOL EXECUTION

To start pre-defined protocols, please select the corresponding chamber via the function line on the right side of the screen. If no protocol is being processed, a list of all pre-defined protocols is shown.

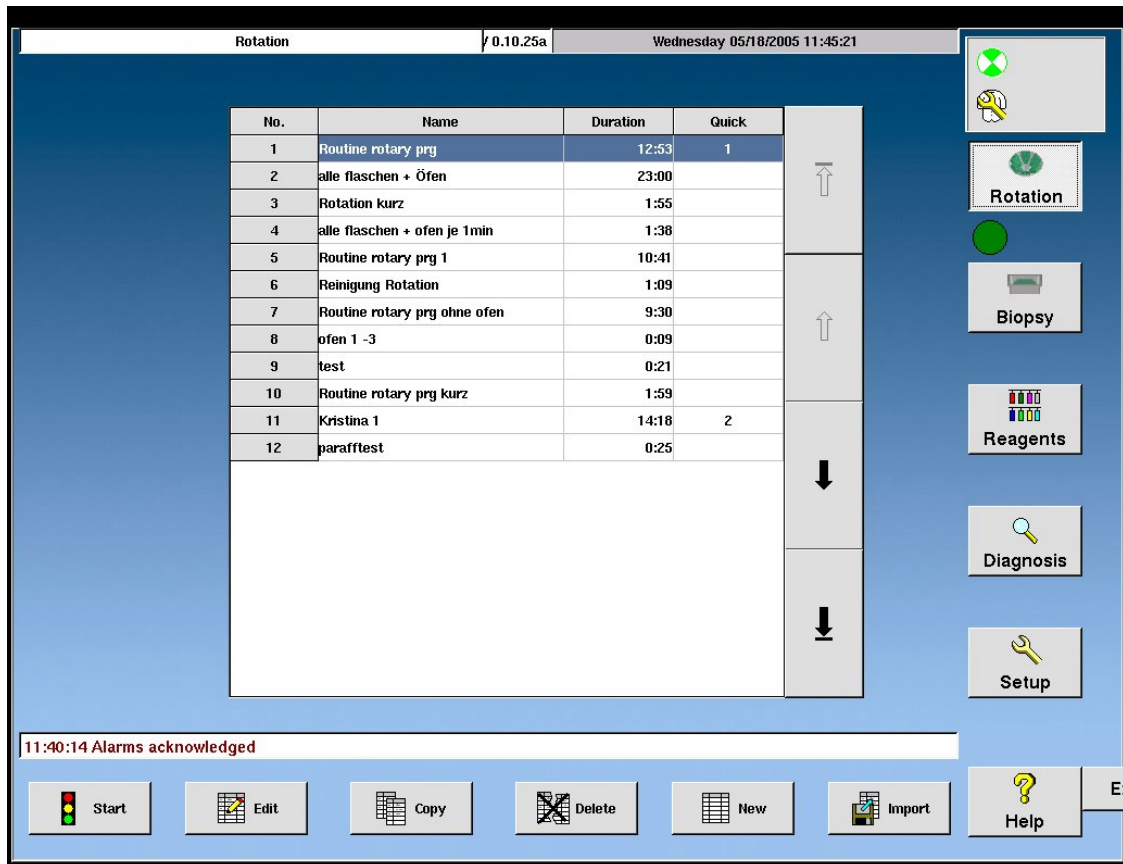


Fig. 36

At the lower side, the buttons are switched according to the respective functions.

When logging-in as a supervisor or technician, more functions are available:



Fig. 37

In the function "Indications", a list (fig. 37) is shown on the screen showing all protocol steps of the selected protocol.

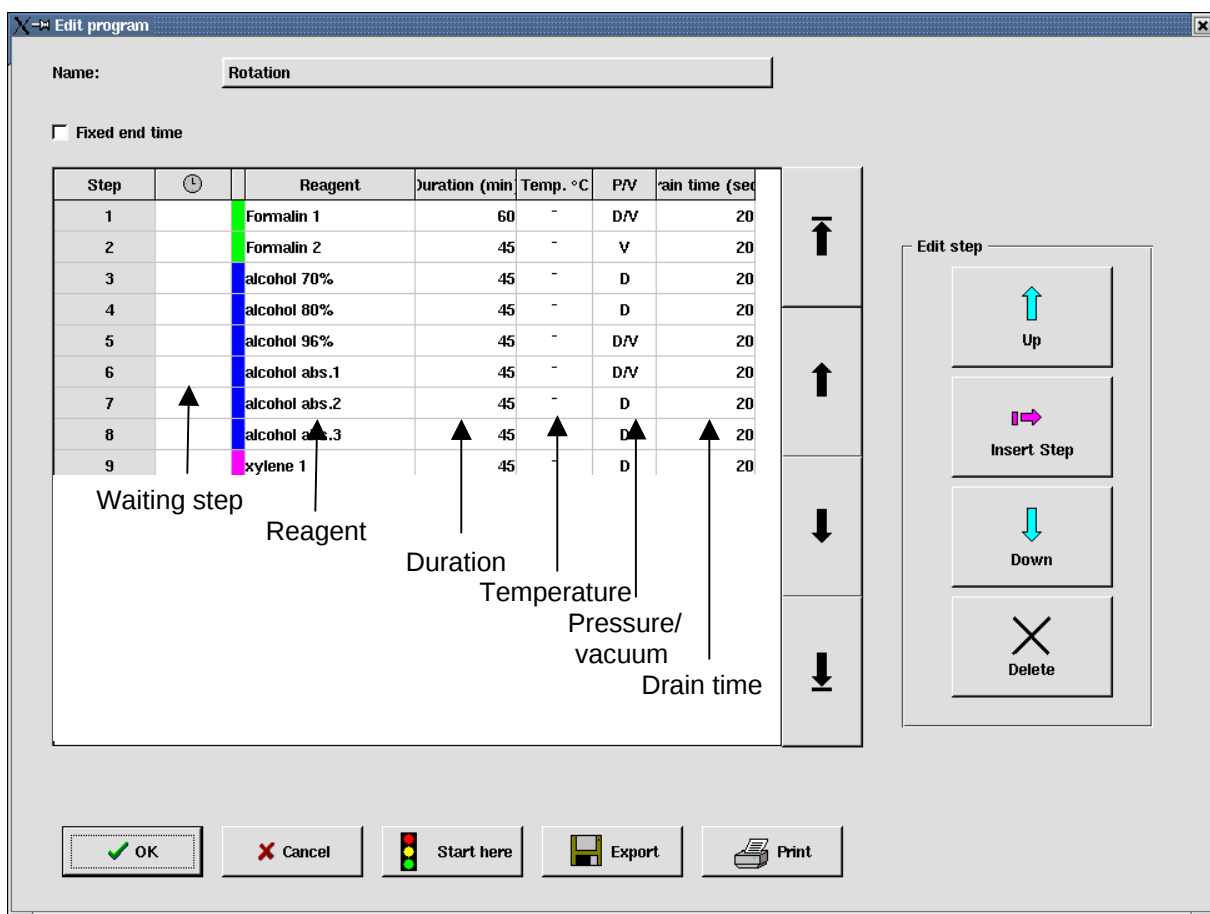


Fig. 38

In the upper line the protocol name is shown as well as the pre-defined fixed end time, if the check button has been set.

List with all protocol steps (fig. 36):

- **Waiting step:** The clock in this column means that, if a fixed end time has been defined, the protocol waits in this step. It will take as long as the protocol will have been finished at the pre-defined end time of the last protocol step.
- **Reagent:** The reagent which is used for this protocol step is shown here. In front of the reagent, the color of the used reagent group is shown.
- **Duration:** The duration of the defined protocol step is shown here.
- **Temperature:** The temperature inside the chamber during a certain protocol step is shown here. *For paraffins, please note the minimum temperature!!*
- **Pressure/vacuum:** For a specimen processing, it is possible to build up an over or low pressure or alternating pressure inside the chamber during the protocol step.
- **Drain time:** The time that is to be taken into consideration for draining the chamber.

**Note:**

The routine user cannot alter a protocol, only the function "Cancel" is active.

Starting a protocol:

- Press the "Start" button.

**Note:**

The expected end time of the protocol is indicated on the screen taking into consideration the heating and reagent changing times.

- Press "Yes" to start the protocol. It starts immediately and runs according to the defined times.
- Press "No" to be able to enter a different end time of the protocol. This setting has the same effect as a definition of a fixed end time in a protocol, i.e. the protocol remains in a pre-defined waiting step a little bit longer.

**Note:**

In case date and time are chosen so that a protocol run is no longer possible, the end date will automatically be postponed to the next day.

- If no waiting step has been defined in a protocol, the last protocol step is used as a waiting step.
- Thus, there will be no negative effects on the protocol run.

Additionally, the status of the reagents will be checked prior to a protocol start.

- When reagents have passed their defined lifetime, a corresponding warning message appears on the screen.
- However, the protocol can still be started.
- It is recommended to replace the reagent with a new one.

**Note:**

Should pre-defined reagents, which are not available in the instrument, be used in a protocol, an error code is shown and the protocol will be cancelled.

Following the reagent check, the pressure is tested as well:

- For this, a brief vacuum and overpressure is applied to the chamber. If chambers are not closed properly, an error code will be shown.
- After these preparatory tests have been carried out, the protocol will be started in its first step.
- To avoid operating errors, the touch screens switches to "Locked".
- The indication on the screen switches to the process indication (fig. 40).

There are two different forms of display on the screen (fig. 40 and 41): as graphics and as a table. Within the graphics (fig. 40) the list of the protocol steps is shown in the upper right corner as a small image.

The remaining part of the image shows a diagram of the process inside the instrument with reagents, paraffin containments and chambers. Filling and draining processes are displayed by a respective animation inside the tubing.

To switch between the two different forms of indication, press the left function button in the lower line ("Table"/"Graphics") (fig. 39).



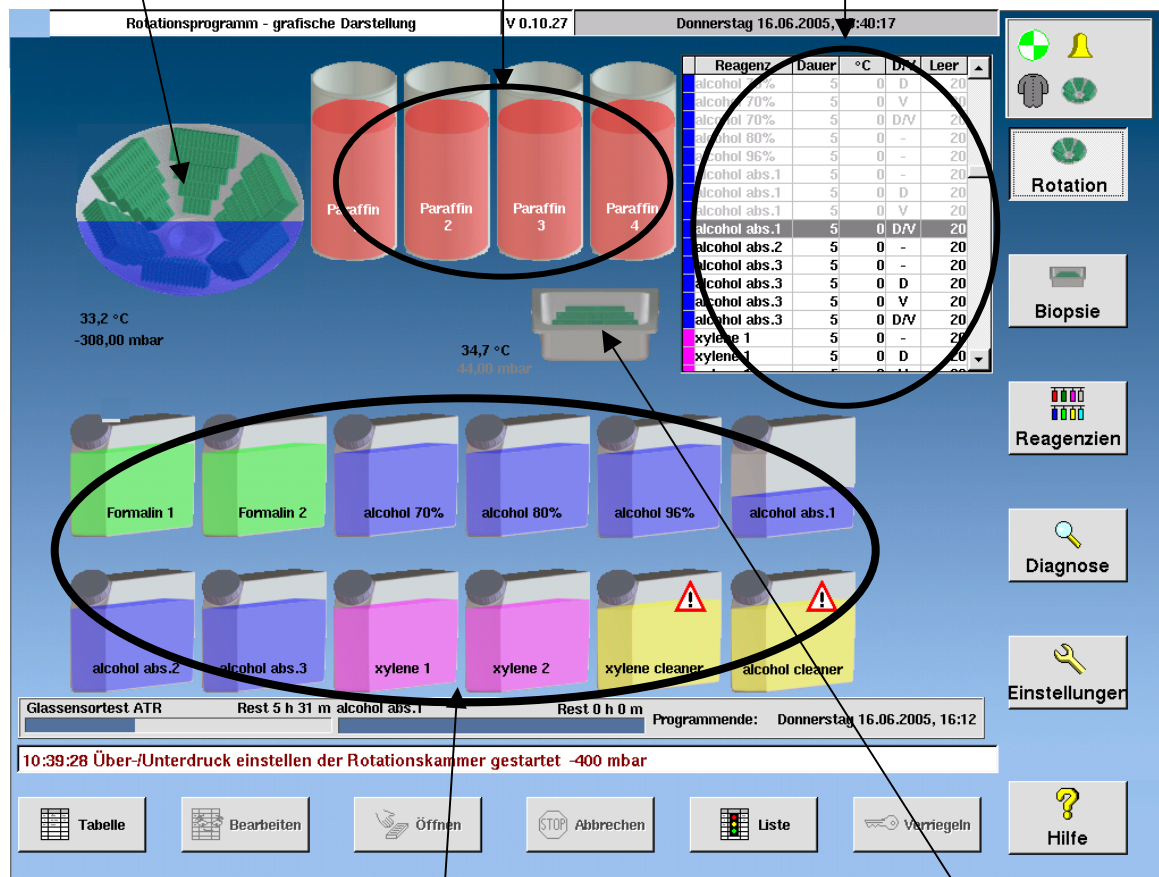
Fig. 39

Graphical display

Rotary chamber

Paraffin containments

Protocol



Stations

Biopsy chamber

Fig. 40

The current status of the protocol is shown in a tabular form (fig. 41).

The screenshot displays the 'Rotation program - table' window. At the top, it shows 'V 0.11.3' and the date/time 'Tuesday 01/24/2006 6:15:02'. The main table lists 14 steps of a protocol, each with a color-coded reagent, duration, remaining duration, temperature, P/V status, and drain time. To the right of the table are several icons and buttons: a green circle with a white cross, a green circle with a white 'V', a 'Rotation' button, a 'Biopsy' button, a 'Reagents' button, a 'Diagnosis' button, and a 'Setup' button. At the bottom, there is a status bar showing 'Rotation' and 'Rest 11 h 39 m', and a 'Program end: Tuesday 01/24/2006, 17:54'. Below the status bar, a red text box indicates '6:14:36 over-/under-pressure rotation chamber started -200 mbar'. At the very bottom, there is a row of buttons: 'Graphics', 'Edit', 'Open', 'Cancel', 'List', 'Lock', and 'Help'.

Step	Reagent	Duration min	Rem. duration min	Temperature °C	P/V	Drain sec
1	Formalin 1	60		0.0	D/V	20
2	Formalin 2	45		0.0	V	20
3	alcohol 70%	45		0.0	D	20
4	alcohol 80%	45		0.0	D	20
5	alcohol 96%	45		0.0	D/V	20
6	alcohol abs.1	45		0.0	D/V	20
7	alcohol abs.2	45		0.0	D	20
8	alcohol abs.3	45		0.0	D	20
9	xylene 1	45		0.0	D	20
10	xylene 2	45		0.0	V	20
11	Paraffin 1	36		60.0	D	20
12	Paraffin 2	45		60.0	D	20
13	Paraffin 3	39		60.0	D	20
14	Paraffin 4	42		60.0	D	20

Rotation Rest 11 h 39 m Program end: Tuesday 01/24/2006, 17:54

6:14:36 over-/under-pressure rotation chamber started -200 mbar

Graphics Edit Open Cancel List Lock Help

Fig. 41

In either form of image (graphics, fig. 40 and table, fig. 41) there is an indication showing the progress of the protocol:

- For this, the following is shown on the screen: on the left side there is a progress bar informing on the protocol run; in the middle there is a progress bar informing on the respective protocol step; and on the right side you can see the planned end time of the protocol.

While a protocol is being processed, the following functions are available for the user during routine operation (fig. 42):

- Changing from graphics and table (function button, left side) and vice versa.
- Opening the chamber for reloading specimens etc. and continuing the protocol.
- Canceling of protocols.
- Indication of the list of defined protocols.
- Locking the screen = changing to the level "Locked".

In this user mode, it is possible to modify the parameters reagents, time, temperature, pressure/vacuum and drain time of the steps which have not yet been processed.

- This means, e.g. if a running protocol is in the step 2, protocol step 3 as well as the following steps can still be altered.
- However, it is not possible to insert or delete protocol steps. Neither is it possible to alter the current step.
- Alterations made to a running protocol are not stored permanently. They are only valid for the current protocol run.



Note:

The functions for opening and canceling a protocol are provided with safety interrogations.

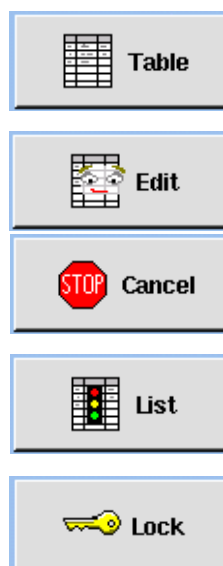


Fig. 42

- When opening the rotary chamber, the entire reagent, if it is a combustible reagent, inside the chamber is pumped off. Atmospheric pressure is adjusted.
- Afterwards, the chamber is unlocked.
- To show that the protocol has not been interrupted, the symbol of the chamber in the upper status corner is overlapped by a hand symbol.
- After having inserted the specimens, continue the protocol via the button "Continue" in the current step.
- In case the order "Open" is given during the pumping process of a reagent, the chamber will of course be filled with the next reagent when continuing the process.
- After the end of the pre-defined time of the last protocol step, the specimens will remain in the reagent.
- The button "Cancel" changes to "Finish".
- Click on this button to start the final pumping of the reagent and to release the chamber for opening.



3-5-3 REAGENT MANAGEMENT

A list of the reagents used in your respective lab is the basis for a well functioning reagent management.

During the installation of the instrument, this reagent list must be created.

- For this, select the button "Reagents" on the right side (fig. 43).
- Afterwards, select "Setup" in the lower function line (fig. 43).
- The list with the already defined reagents is shown and can be used for protocols.



Fig. 43

Reagent setup / 0.10.25a Wednesday 05/18/2005 11:44:07

Name	Reagent Group	Cassettes until change	Cycles until change	Days until change	Cassettes until cleaning	Cycles until cleaning	Days until cleaning
alcohol 70%	Dehydration	16960	16960	16960			
alcohol 80%	Dehydration	1111	111	111			
alcohol 96%	Dehydration	16960	16960	16960			
alcohol abs.1	Dehydration	16960	16960	16960			
alcohol abs.2	Dehydration	16960	16960	16960			
alcohol abs.3	Dehydration	16960	16960	16960			
alcohol cleaner	Cleaning alcohol	2000	10	20			
Formalin 1	Fixation	16960	16960	16960			
Formalin 2	Fixation	16960	16960	16960			
Paraffin 1	Paraffin	16960	16960	16960	16960	16960	34464
Paraffin 2	Paraffin	16960	16960	34464	16960	34464	10000
Paraffin 3	Paraffin	16960	16960	16960	16960	34464	10000
Paraffin 4	Paraffin	16960	16960	16960	34464	34464	34464
xylene 1	Clearing	16960	16960	16960			
xylene 2	Clearing	16960	16960	10000			
xylene cleaner	Cleaning xylene	2000	10	20			

11:40:14 Alarms acknowledged

Management Edit New Delete Export Print Help

Rotation Bopsy Reagents Diagnosis Setup

Fig. 44

- The list of the defined reagents can be edited via the lower buttons (fig. 44).



Note:

For safety reasons, alterations in the list can only be made when no protocol is running. Functions which are not yet available are shown in gray.

- To insert a new reagent into the list and open it for editing, press the button "New" (fig. 44).
- To delete a selected reagent from the list, press the button "Delete" (fig. 44).

**Note:**

However, only reagents, which are not defined as a station in the instrument, can be deleted. In case a reagent cannot be deleted, please check in the reagent management, if this reagent is assigned to a station.

- Via the button "Edit", the currently selected reagent is opened for editing purposes (fig. 45).
- In the upper line, please enter the description of the reagent.
- Click here to open the already known input field for text entries.
- Below that, a selection is shown to which group the reagent is to be assigned to.

**Note:**

The assignment to a group is necessary for the validity of defined protocols, as some reagents are not miscible with others. This could lead to malfunctions due to reagent carryovers, if the necessary sequence of the processing steps are not observed. Due to this assignment, the instrument is able to check if the reagent sequence corresponds to a logical protocol run.

- The two special reagent groups "Cleaning " and "Valve cleaning" describe two reagent groups which are used for cleaning the chambers and the turning valves. Which reagent is used for them, results from the protocol runs.

**Caution :**

Via the checkbox "Explosive" (fig. 46.1), it can be defined whether special safety measures for avoiding explosions by evaporation must be observed when working with the reagent. This must be especially observed when locking the chambers during a protocol run.

Fig. 45

46

- On the screen "Edit" (fig. 47), there are definitions for the shelf life of the reagents.
- Limiting values on the number of cassettes, number of cycles and the number of days can be defined.
- Limiting values are maximum values for how long a reagent can be used.
- When surpassing one of these limits, a warning message is shown on the screen.

**Note:**

In addition, limiting values for the regeneration of paraffin can be entered.

The list of defined reagents can be exported onto a disc for backup purposes.

- For this, please insert a disc with MS-DOS format and activate the button "Export".
- The data is filed in a file "Reagents.CSV".
- Via the button "Print", the list of the defined reagents can be printed on a connected printer.

Fig. 47

3-5-4 CREATING A PROTOCOL

As described before, a protocol consists of a sequence of one protocol step at least. One individual protocol step consists of the definition of:

- reagent to be used
 - immersion time
 - pressure or vacuum
 - temperature
 - emptying time
- Chose a chamber (rotary or biopsy) (fig. 48).
 - Press the button "New" (fig. 48) to be able to create a new protocol.
 - This new protocol can then be edited via "Edit" (fig. 48).
 - It is also possible to copy an existing protocol via the button "Copy" and use or modify it via "Edit" (fig. 48).
 - Press the button "Delete" to delete the selected protocol (fig. 48).



Note:

If a protocol is already running in the selected processing chamber, these functions can be reached via the overview of the already defined protocols by using the button "List".

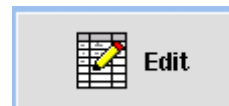
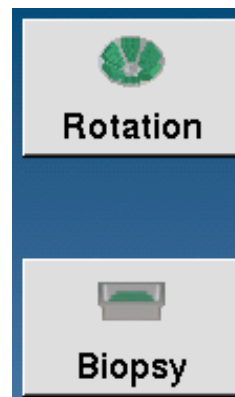


Fig. 48

The dialog for creating protocols is opened.

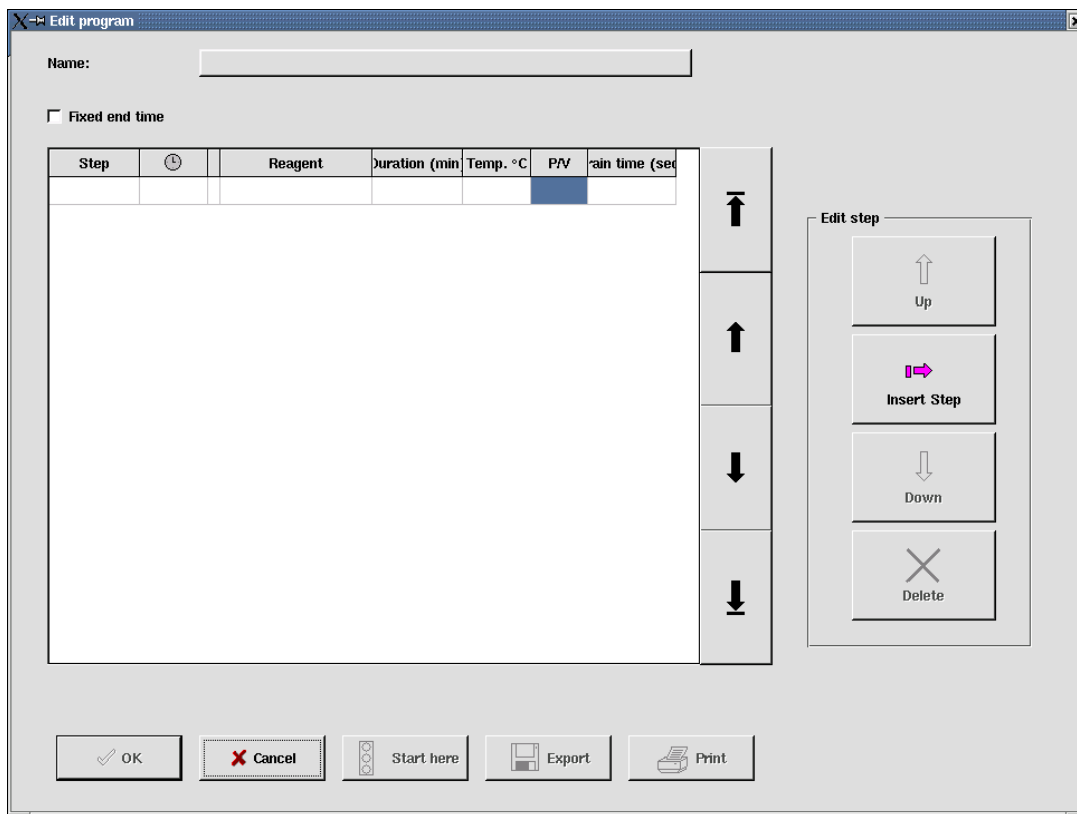


Fig. 49

- In addition to the already known buttons, there are buttons (fig. 49) on the right rim for replacing, inserting and deleting steps.
- At the lower rim of the table, there is always an additional blank line allowing additional protocol steps when clicking on.
- Click to an entry in the table to open a mask. Here a defined and existing reagent can be selected (fig. 50).
- In general, the number of protocol steps is unlimited.

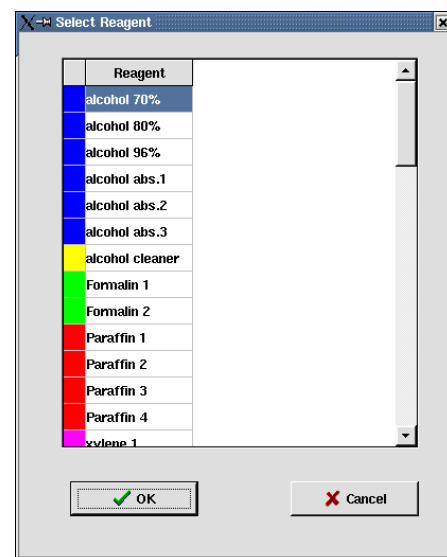


Fig. 50

After having entered a step this way, the parameters can be altered. Click on the individual cells of the line to adjust them:

- **Waiting time:** Click on this cell to define the step as a waiting step. Please note that only one step can be defined as a waiting step.
- **Time:** Click on this cell to open a mask for the entries of numbers. Here the processing time in minutes can be set for this step. One step must take at least one minute. Max. time is practically unlimited.
- **Temperature:** The temperature in degree Celsius is entered. A "0" means that this step is not heated at all. The maximum value is the default parameter for the maximum paraffin temperature of 65°C.
- **P/V:** Here a special entry mask (fig. 51) opens up for the selection of the pressure. Processing under ambient pressure, under defined over pressure, defined low pressure or pressure/vacuum change can be pre-selected. The pressure values, which are used, are defined as system parameters and cannot be altered by the routine user for safety reasons.
- **Drain time:** Here a prolonged drain time can be set to achieve even less carry-over into the next reagent (fig. 52).
- This way, a protocol step has been created.
- When defining a reagent in a protocol step, a new empty line is created simultaneously to permit the entry of the next protocol step.

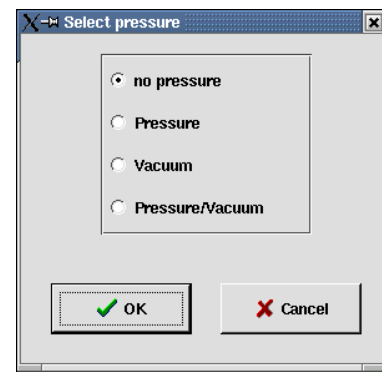


Fig. 51

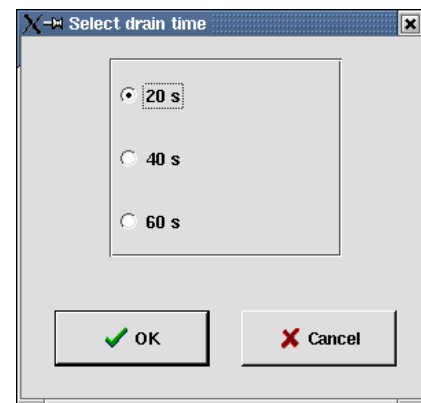


Fig. 52

- Above the table beside "Name:" there is a button, which is empty when a new protocol is defined (fig. 53)
- Click on it to open an entry box for the protocol name.
- Below the protocol name, it is possible to enter a fixed end time.
- When all protocol steps are defined, store the protocol with "OK".
- In doing so, the validity of the protocol is checked, e.g. whether the parameters are logical, whether the reagents are located in a correct logical sequence.
- Only when possible errors are eliminated, the protocol can be stored.

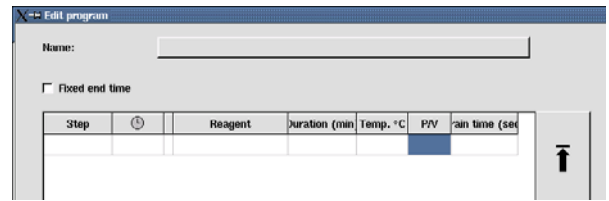


Fig. 53

3-5-5 EXPORTING AND IMPORTING OF PROTOCOLS

For data security and for the transportation of protocols from one instrument to the other, protocols can be exported onto discs. For this, please use 3.5" standard discs, which are formatted with MS-DOS.

- To export and/or store a copy of a protocol onto an inserted disc, press the button "Export" on the screen (fig. 54).
- The protocol is filed as a CVS file on the disk which can then be read or evaluated by using a spread-sheet program, e.g. Microsoft Excel.
- The protocol name is used as the file name.
- A defined protocol is imported from the disk via the button "Import" in the indication of the protocol list.
- A file select box is shown. Select a file.
- To import a protocol, press "OK". In case of a defective file, the importing process is cancelled.
- When importing a protocol, the protocol name is used as the file name.
- This way, it is possible to alter the file name on the disc for archiving purposes without loosening the protocol name in the system.



Fig. 54

3-5-6 ASSIGNMENT TO STATIONS

The reagents, which have been defined in the list, can be assigned to the individual stations.

- When needed, please change to the window "Reagent management".



Note:

Alterations can only be carried out, if no protocol is being processed in the chambers.

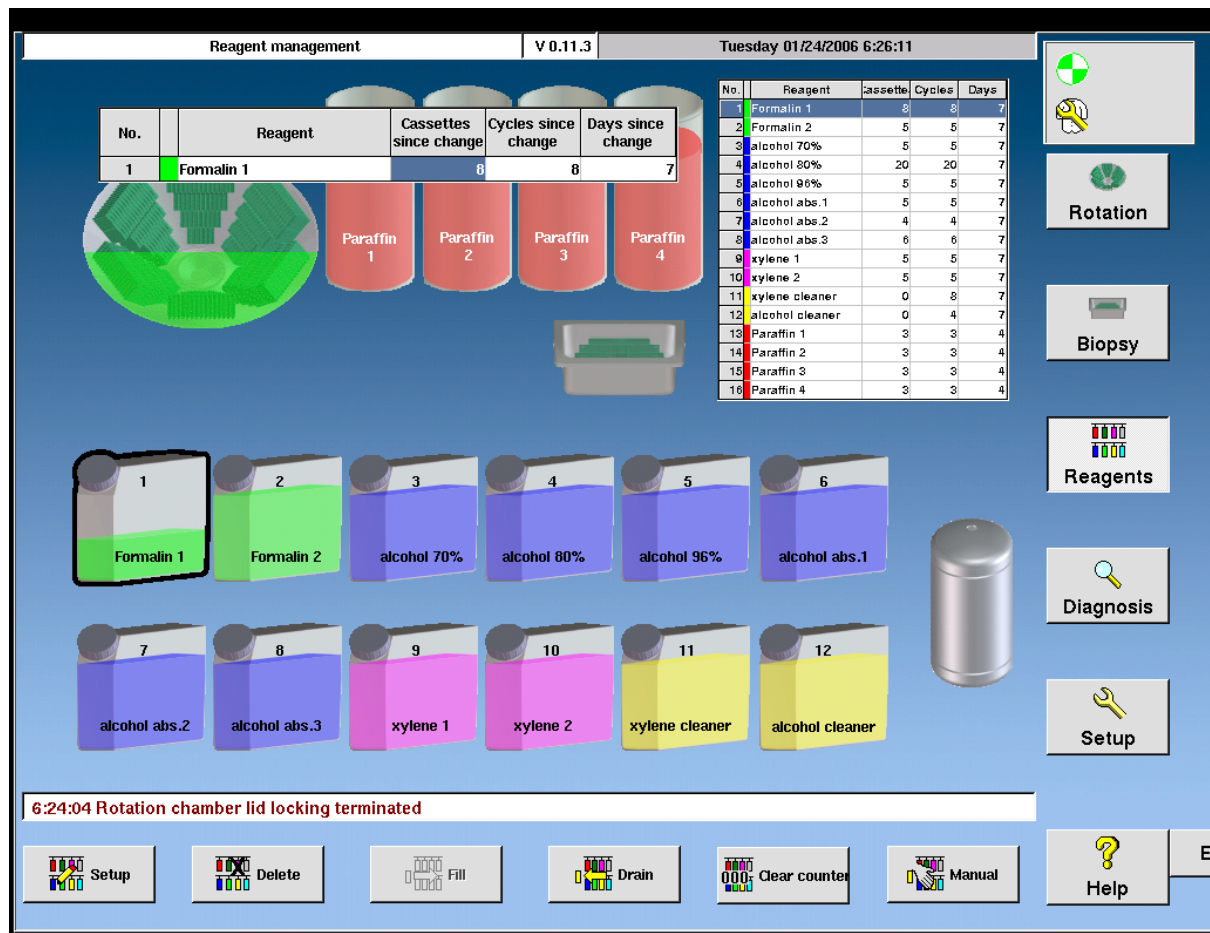


Fig. 55

- Select the respective station on the touch screen to activate the respective function.
- This way, the button function in the lower function line changes accordingly.



Fig. 56

For an empty station, which no reagent has been assigned to, only one reagent can be assigned:



Fig. 57

- Activate the button "Reagent" to receive the list of the defined reagents.
- By selecting a reagent and clicking on "OK" in this list, a reagent is assigned to the station.
- Afterwards, the station can be filled with the corresponding reagent.
- Filling can be carried out either via the function "automatic filling" or via manually replacing the canister.
- For the automatic filling process, insert the suction hose of the instrument into a container with the reagent which is to be filled.
- After safety interrogation and/or selection of the station and condition of the station, the reagent is filled into the station via an integrated remote fill tank.
- In doing so, the liquid is pumped from the container into the remote fill tank and then filled into the station.
- This procedure allows filling/emptying of stations with slight restrictions, also during a protocol run.
- In case the automatic filling function is not used, the reagent bottle can be removed manually. It can be emptied/filled outside the instrument.
- To inform the reagent management on this procedure, press the button "Manual". The bottle symbol changes from "Empty" to "Full" or vice versa.
- It is also possible to empty a station via the "Empty" button.
- This way, the contents of a station is emptied into a collecting container which must have been placed under the drain before.
- Emptying is also carried out via the remote fill tank.

When selecting a paraffin container, the allocation changes:



Fig. 58

Following functions are available:

- Regeneration of the paraffin
- Deleting the expiry counter
- Manual emptying for new definition of the container
- For the **regeneration** of the paraffin, a special protocol is started in the rotary chamber. The entire paraffin is treated at an increased temperature with vacuum. This way, residues of other reagents are to be evaporated.
- Via the function "**Expiry counter**", the expiry counter of the selected paraffin is reset, e.g. after having refilled fresh paraffin.
- For the new definition of the paraffin container, the container must first be emptied virtually. For this, press the button "**Manual**". This way, the allocation of the paraffin container to another paraffin can be altered.

PART 4 ERROR MESSAGES AND REMOVAL

4-1 ERROR MESSAGES ON THE SCREEN

- Whenever a message appears on the screen during operation, check it with regard to its cause.
- Before using the instrument again, first rectify the error on the instrument or on the condition of the reagents.
- In case of filling errors, clean the sieves in the rotary and/or biopsy chambers.
- Moreover, in case of filling errors, check the reagent bottles and/or paraffin containers for correct filling height.

**Caution:**

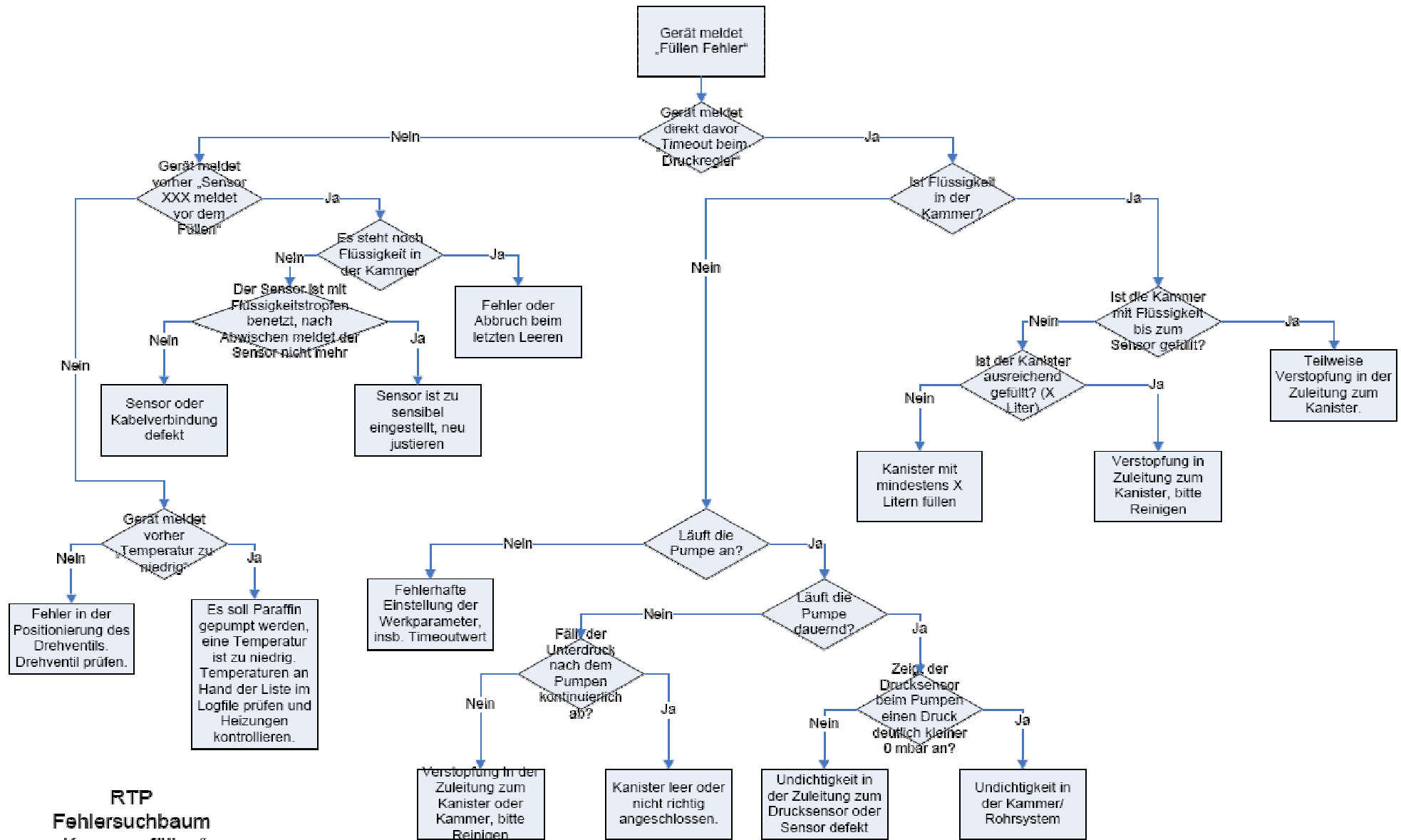
Make sure that any irregularities are clarified before a program start!

**Note:**

If the user has any doubt on the efficiency of his error removal, please contact the corresponding service person or our

factory!

4-2 POSSIBLE ERROR SOURCES – CAUSE AND REMEDY



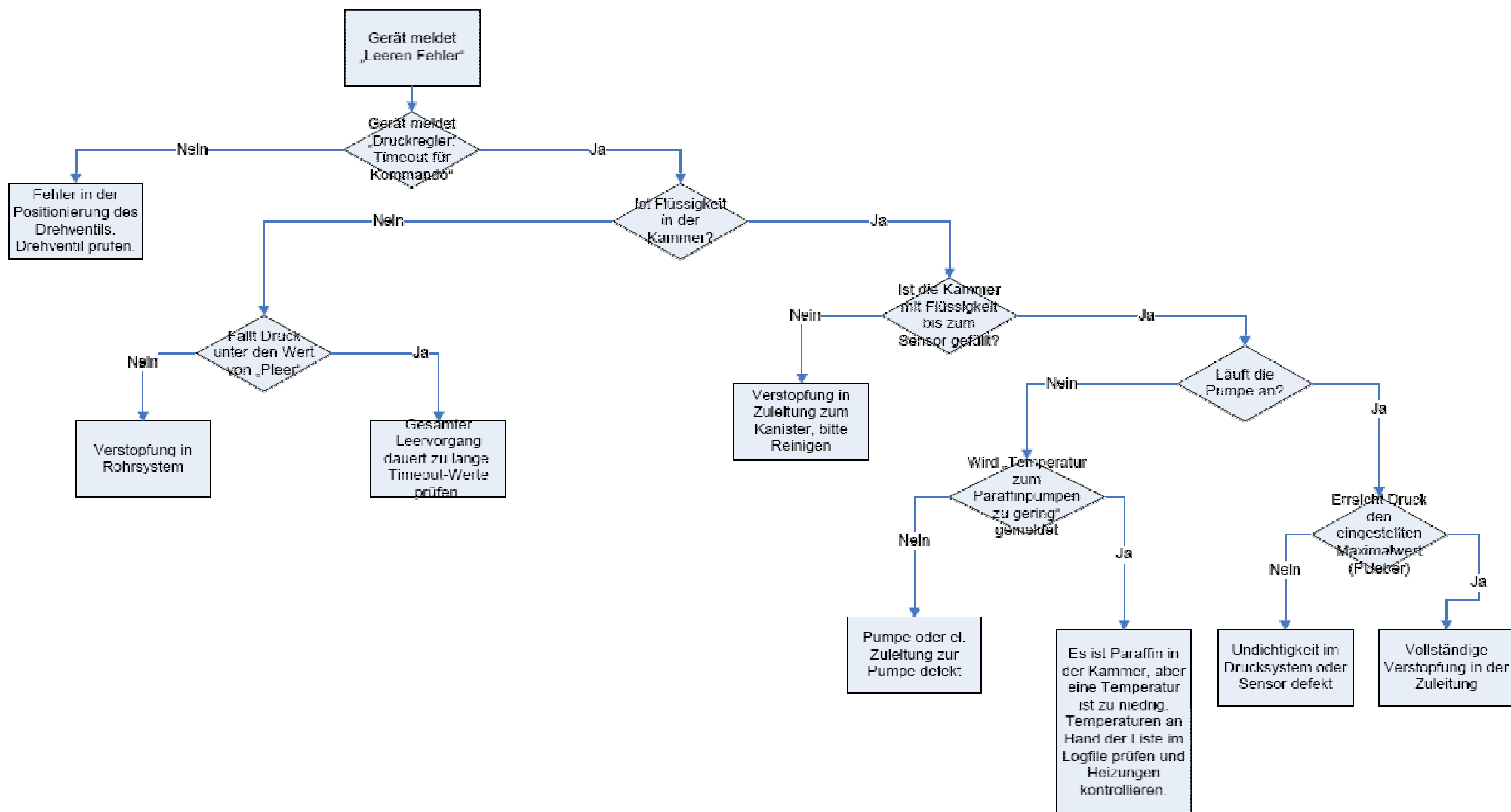
RTP
Fehlersuchbaum
„Kammer füllen“

MICROM International GmbH
 Robert-Bosch-Str. 49

D-69190 Walldorf

English - 387791

Diagnostic tree: Empty error



4-3 CURRENTLESS STATE

In case a currentless state occurs during a program run (e.g. power failure), all running process functions are maintained for a period of 5 minutes. This also includes the draining off, possibly the spinning inside the rotary chamber and the re-filling of the specimen chambers with the subsequent reagents.

In case, the currentless state exceeds 5 minutes, possibly started reagent transfers are properly terminated. Afterwards, the instrument is shut down and partly turned off. The internal power supply monitors the power connection to turn on the instrument automatically when power is resumed and to continue the interrupted programs. When doing so, a melting timer, which runs in the background, monitors that the solidified paraffin will be completely melted before it is pumped into the chamber.

Opening while in currentless state:

- In case, the instrument is in a currentless state, please remove the specimens to be able to continue a manual infiltration process.



Caution:

When the process is interrupted, an overpressure or vacuum might prevail in the chamber, which might result in a possible hazard for the user (in case of an overpressure) or in an unsuccessful attempt of opening the chamber (in case of a vacuum). Before opening the respective chamber, please activate the emergency ventilation!

Biopsy chamber:

Before opening the biopsy chamber in a currentless state, ventilate it.

- For this, insert the attached hexagonal key or another pin-shaped object into the lower hole on the left side of the instrument. Keep it pressed for approx. 10 sec. (fig. 59).
- A biopsy chamber locked for operation is now unlocked during the currentless state and can now easily be opened manually by lifting the locking mechanism (fig. 60).

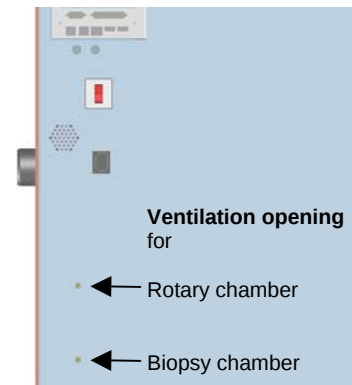


Fig. 59

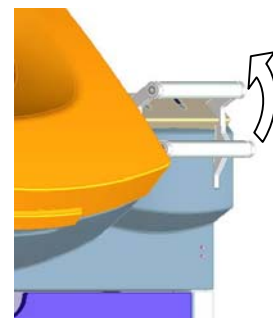


Fig. 60

Rotary chamber:

Before opening the rotary chamber in a currentless state, ventilate it.

- For this, insert the attached hexagonal key or another pin-shaped object into the upper hole on the left side of the instrument. Keep it pressed for approx. 10 sec until the ventilation sound is no longer audible (fig. 59).
- Then insert the attached hexagonal key into the hole from the left side below the lid of the rotary chamber (fig. 61).
- The ball-shaped head of the key must be inserted in a way that the hole of the guide plate engages with the hexagon screw (fig. 62).
- Then turn the key to the left side until the lid can be opened. Try to open it after each rotation.
- After a successful opening, DO NOT continue to turn further!

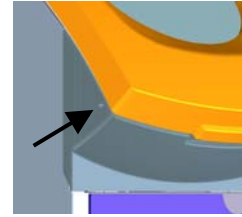


Fig. 61

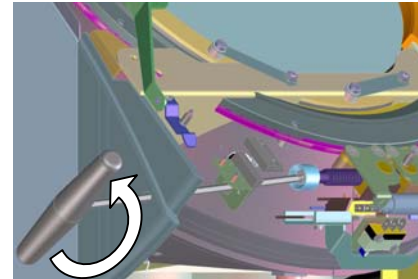


Fig. 62

PART 5 MAINTENANCE AND CARE

5-1 CLEANING

Cleaning cycle in the rotary and biopsy chambers:

- After paraffin steps the rotary and biopsy chambers must be cleaned from paraffin waste by running a cleaning cycle.
- After a program run, a new start is only possible after having carried out a cleaning cycle.
- During a pre-defined cleaning cycle, paraffin waste dissolves and remains in the cleaning liquids.
- They must be replaced after frequent usage.
- For cleaning purposes we recommend to use Xylene and water/alcohol-mixture (50:50).

Cleaning of the outside of the instrument:

Cleaning and care of the instrument should be performed daily.

Please proceed as follows:

- Turn off the mains switch of the instrument.
- Remove coarse paraffin waste with a plastic scraper.
- Clean the instrument by using commercially available cleaning agents and a smooth cloth.
- Economically use the cleaning agent so that it does not drip into the instrument or the screen.



Note:

For the outer cleaning of the instrument and the accessories use mild domestic cleaners. Do not use aggressive cleaning agents and solvents such as abrasive agents, as the paint and plastic parts might be damaged.



Note:

As a permanent protection against the danger of fire, the installed fuses must be replaced with equivalent ones in case of an error.

5-2 MAINTENANCE

Routine maintenance by an authorized service technician twice a year:

To secure process safety of the instrument, it is recommended that a **routine maintenance** be performed by a trained service technician **twice a year**.

Service contract:

MICROM offers a service contract which guarantees that your instrument is always in perfect condition. For more information, please contact the nearest MICROM sales office.



Note:

We strongly recommend to not carry out repair by yourself. All warranties and guarantees would then be null and void!

Repair work must only be carried out by an authorized service technician.



Warning:

Parts must only be checked or replaced by Microm or its authorized representatives!!

PART 6 CONDITIONS FOR THE TRANSPORTATION OF THE INSTRUMENT

6-1 RETURNING THE INSTRUMENT FOR REPAIR OR ROUTINE MAINTENANCE

Repair or maintenance work are normally carried out at the site of installation. If this is not possible for some specific reasons, the instrument can be returned to MICROM. The contact address can be found at the beginning of this instruction manual.

- To guarantee a trouble-free function of the instrument after transportation, please note the below-mentioned measures for transportation preparations.
- In addition, the conditions for storage and transportation as mentioned in part 2-3 must be observed during the entire transportation.



Biohazard:

Please also note the precautionary measures described in our safety precautions concerning biological hazards!

Measures for taking out of operation:

- Remove all tissue cassettes.
- Carry out a cleaning cycle with empty baskets.
- Empty the reagents.
- Empty the paraffin.
- Empty the water filter bottle.
- Turn off the mains switch of the instrument.
- Unplug the unit.
- Appropriately dispose of all liquids according to the safety data sheets and/or the respective applicable lab regulations.

The user must care for a clean and safe condition of the instrument when returning it to an appropriate service provider.

**For transportation outside closed buildings,
please observe the following measures:**

- Remove all tissue cassettes.
- Carry out a cleaning cycle with empty baskets.
- Empty the reagents.
- Empty the paraffin.
- Empty the water filter bottle.
- Turn off the mains switch of the instrument.
- Unplug the unit.
- Appropriately dispose of all liquids according to the safety data sheets and/or the respective applicable lab regulations.
- Pack the instrument into the original packaging as it offers best pre-conditions for transportation without damage.



Note:

If the original packaging is no longer available, please contact your local MICROM representation.

6-2 DISPOSAL OF THE INSTRUMENT AFTER FINAL SHUTDOWN

After the final shutdown of the instrument, we recommend to contact a local recycling company for the disposal according to the national applicable regulations.



To be applied in the countries of the European Union and other European countries with a separate collecting system within the waste management.

The marking of the product and/or the respective literature indicates that, after its final shutdown, it must not be disposed of together with ordinary domestic waste.

- Please dispose of your instrument separately from other waste to not harm our environment and/or human health by uncontrolled waste disposal.
- Recycle your instrument to support the sustainable recycling of material resources.
- **Industrial users** should contact their suppliers and observe the conditions of the contract. This product must not be disposed of together with other commercial waste.
- **Please contact your supplier!!**

Appendix C: Examples for a routine protocol for the rotary chamber

Step	⌚	Reagent	Duration (min)	Temp. °C	P/V	rain time (sec)
1		Formalin 1	60	-	D/V	20
2		Formalin 2	45	-	V	20
3		alcohol 70%	45	-	D	20
4		alcohol 80%	45	-	D	20
5		alcohol 96%	45	-	D/V	20
6		alcohol abs.1	45	-	D/V	20
7		alcohol abs.2	45	-	D	20
8		alcohol abs.3	45	-	D	20
9		xylene 1	45	-	D	20
10		xylene 2	45	-	V	20
11		Paraffin 1	36	60.0	D	20
12		Paraffin 2	45	60.0	D	20
13		Paraffin 3	39	60.0	D	20
14		Paraffin 4	42	60.0	D	20

Example for a biopsy protocol

Step	⌚	Reagent	Duration (min)	Temp. °C	P/V	rain time (sec)
1		Formalin 1	30	-	D	20
2		Formalin 2	15	-	V	20
3		alcohol 70%	15	-	D	20
4		alcohol 80%	15	-	D/V	20
5		alcohol 96%	15	-	D	20
6		alcohol abs.1	15	-	V	20
7		alcohol abs.2	15	-	D	20
8		alcohol abs.3	20	-	D	20
9		xylene 1	15	-	D	20
10		xylene 2	20	-	D/V	20
11		Paraffin 1	25	60.0	D	20
12		Paraffin 2	20	60.0	D	20
13		Paraffin 3	20	60.0	D	20
14		Paraffin 4	30	60.0	D	20