Operating Instructions

BANDELIN
Ultraschall seit 1955

SONOMIC

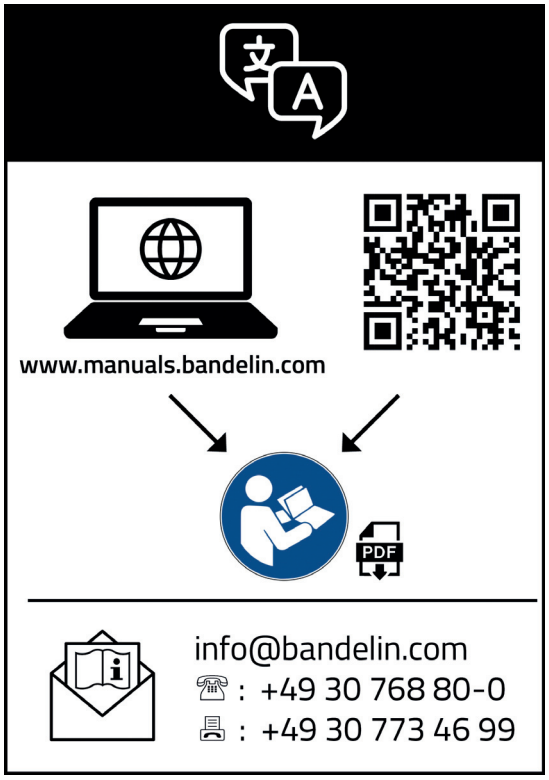
High-performance ultrasonic baths

Ultrasonic bath
MC 1001

Multi-part ultrasonic bath
MC 1001 E

Valid for all SONOMIC ultrasonic baths and SONOBOARD MIC with software versions starting at 1.5x and serial numbers starting at xxxx.00063019.yyy.

6376-007 en/2024-02



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General

The device, the accessories and the agents are to be used in accordance with the operating instructions and/or the product information.

The instructions are part of the scope of delivery and are to be stored in the vicinity of the device for later reference. This also applies if possession of the device is transferred elsewhere.

Before the device is put into operation, these instructions are to be read carefully and completely in order for the user to become familiarised with all functions.

The warnings and safety precautions (Section 1.6) are always to be followed during use.

The manufacturer will not assume any responsibility for the device's safety or functional ability in the event of improper handling or usage contrary to the intended purpose. In the event of unauthorised alterations/modifications, both the warranty claim and the CE conformity will become void.

If service is required, please contact the authorised specialist dealer, customer service, or the manufacturer.

Symbols used:

Symbol	Meaning	Explanation
	Danger	Denotes information that, if not observed, could pose a risk to life and limb, especially as a result of electric shock.
	Caution	Denotes information that must be observed and complied with in order to prevent damage to the device or injury to the user. When device parts are labelled with this symbol, the documentation must be referred to.
	Important	Identifies information that is important for execution.
	Note	Identifies explanatory information.
	Medical note	Identifies information that is important for medical use.
	Do not reach inside	For health reasons, touching the oscillating liquid is prohibited.
	Wear hearing protection	For health reasons, spending long periods of time in the vicinity of the device without hearing protection is prohibited.
➢	Instructions	Identifies instructions that must be followed in the described sequence.

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Informative annexes

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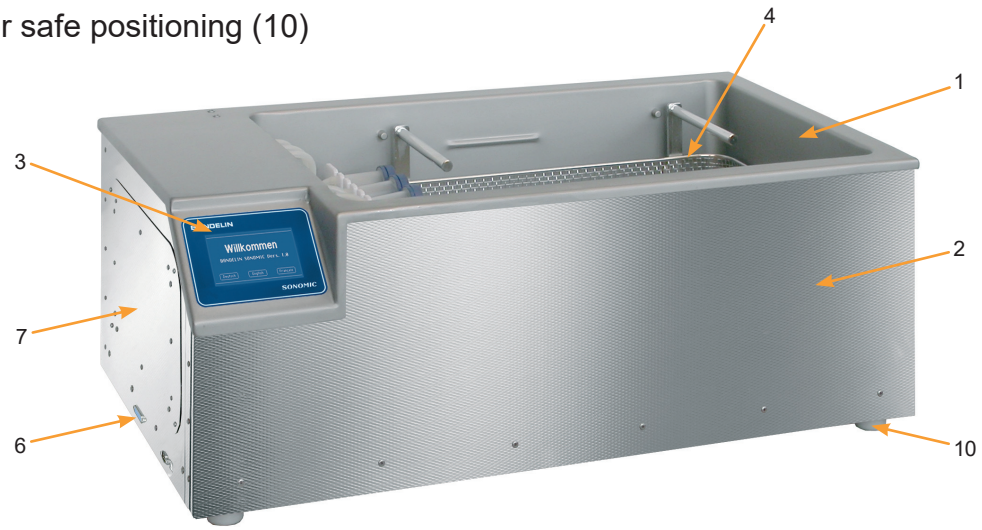
1 Product description

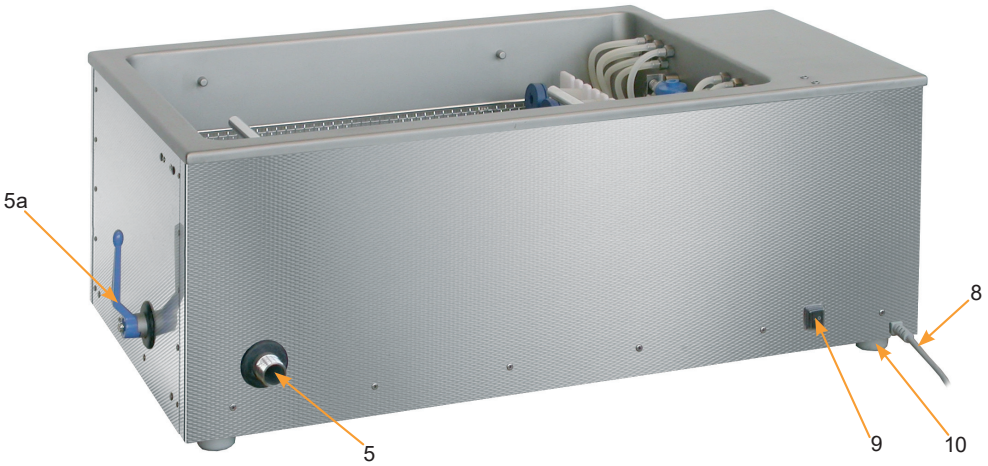
The SONOMIC is an ultrasonic bath with rinsing function for MIS instruments.
It is available as a compact or multi-part ultrasonic bath. The exact type specification and serial number are found on the type plate.
The multi-part SONOMIC ultrasonic bath is also manufactured as a ready-to-use "SONOBOARD MIC" set in a functional cabinet.
In the following, the term “SONOMIC ultrasonic bath” is used for all variants.

Product features for compact ultrasonic bath MC 1001:

- Stainless steel oscillating tank (1) with oscillating systems, ultrasonic frequency 40 kHz. For more details see page 8
- Compact, easy-to-clean stainless steel housing (2)
- Touchscreen (3)
- Special basket (4) with adapters for connection of instruments; for more details see page 9
- Outlet (5) with ball valve (5a) for quick draining of the bath liquid
- Various interfaces (6) for record keeping
- Maintenance cover (7)
- Mains cable (8) mains switch (9)
- Rubber feet for safe positioning (10)



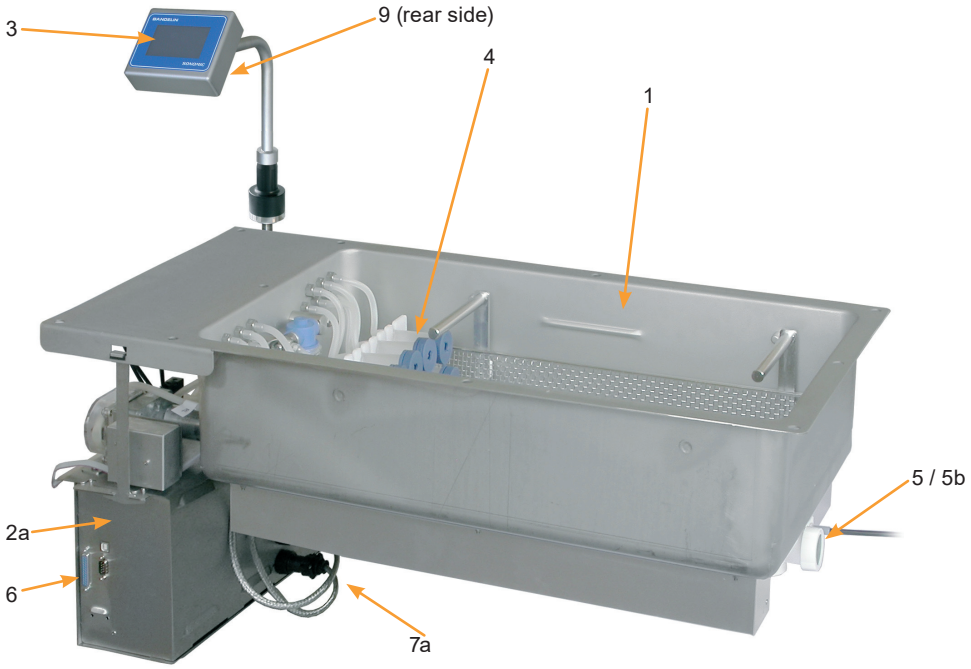
Front view



Rear view

Product features of the multi-part ultrasonic bath MC 1001 E:

- Stainless steel oscillating tank (1) with high-quality oscillating systems, ultrasonic frequency 40 kHz For more details see page 9
- Separate ultrasonic generator with rinsing module for hanging in the oscillating tank (2a)
- Separate control unit with touchscreen (3) – swivelling
- Special basket (4) with adapters for connecting the instruments. For more details see page 9
- Outlet (5) with drain set (5b) for fast draining of the bath liquid
- Various interfaces (6) for record keeping
- Connections for the oscillating tank and heating (7a)
- Cold device socket (8a) for mains connection, connections for control unit (8b), mains switch (9)



Front view

Rear view

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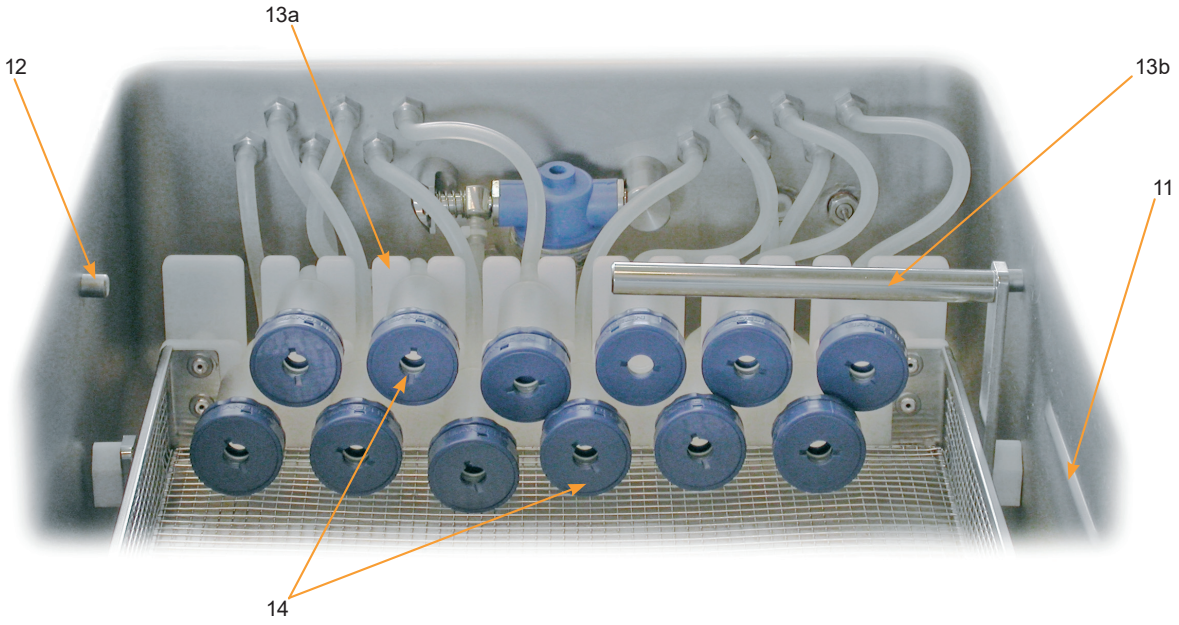
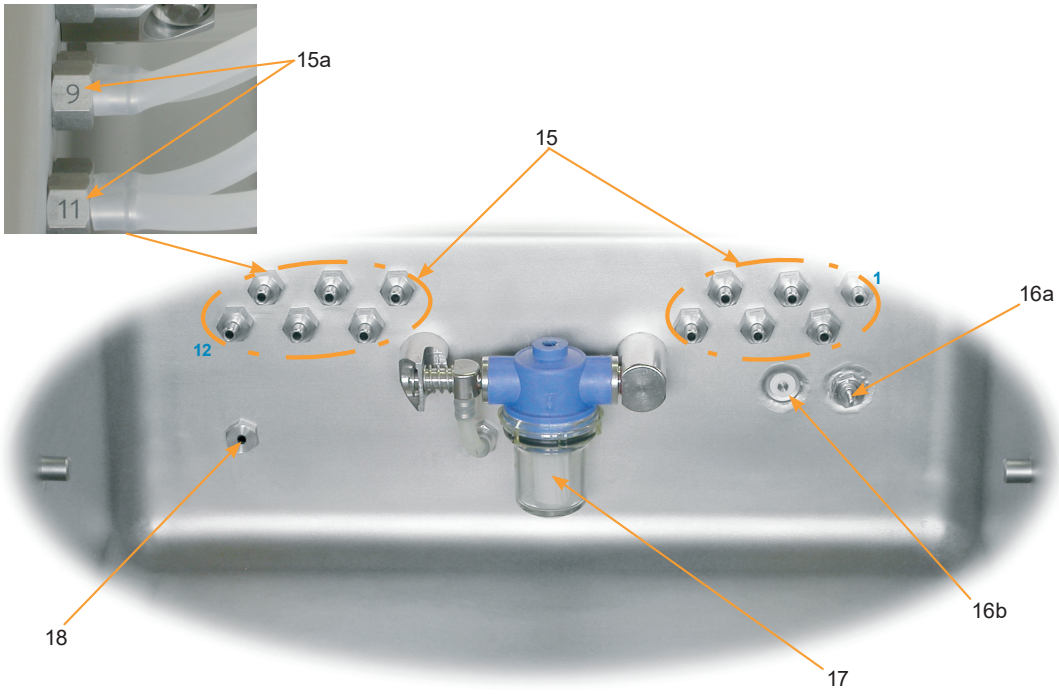
Details of the oscillating tank

- Filling level mark for safe filling (11)
- Basket mounts (12) for special basket (4) with comb bar (13a) and handles (13b)
- 12 adapters (14) to connect the instruments
- Labelled connector sockets (15 and 15a) for channels 1-12
- Liquid sensors for process control – temperature sensor (16a) and fill level sensor (16b)

  Exchangeable filter (17) for reception of cast-off contamination
- Return flow opening (18) for return transport into the oscillating tank





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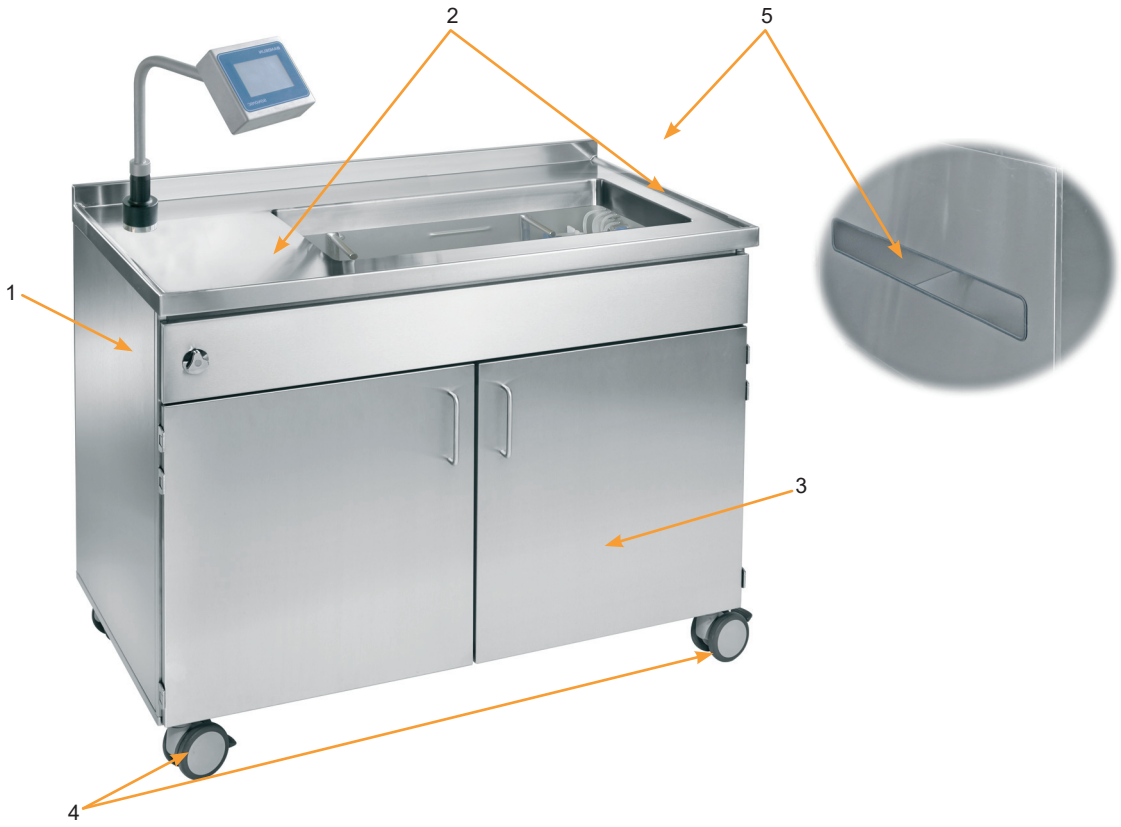
1.1 SONOBOARD MIC functional cabinet

The SONOBOARD MIC functional cabinet is only available in a left-handed variant, as indicated by the letter "L" in the type designation.

Product features:

- Stable, easy-care stainless steel body (1)
- Easy-care stainless steel work plate with upstand (2)
- Double-walled doors (3)
- Easy-run swivel-casters (4), with locking brakes at the front
- Recess (5) for utility connections in rear wall



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1.2 Mode of operation

Principle of ultrasonic cleaning

SONOMIC ultrasonic baths use the effect of cavitation. Under the tank bottom they contain piezoelectric transducers, the energy of which is transferred to the bath liquid as mechanical oscillations with ultrasonic frequency. As a result, microscopically small bubbles are continuously formed in the bath liquid, releasing energy upon imploding and generating local microcurrents. This process is called cavitation. During the cleaning process, this causes contamination to be positively blasted from the hard surfaces of the objects being processed. At the same time, dirt particles are dispersed and fresh bath liquid flows in.
SONOMIC ultrasonic baths are efficiently supported by SweepTec automatic frequency control. SweepTec immediately balances load-dependent working point fluctuations using fast frequency modulation around the optimal working point. This produces an especially homogeneous and uniform ultrasound field in the bath volume for constantly reproducible results.

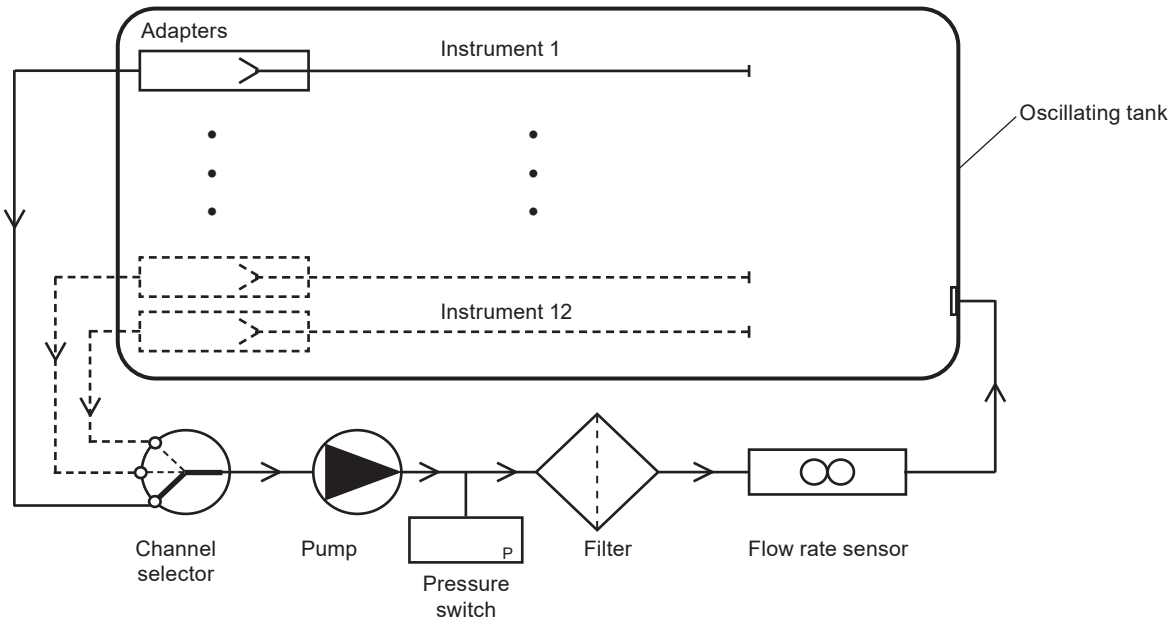
Rinsing of MIS instruments/cleaning of standard instruments

During sonication, up to 12 rinsable MIS instruments with exterior diameters of 3-10 mm can be rinsed from the inside in the SONOMIC ultrasonic bath.
Each instrument is connected to an assigned adapter and linked to the rinsing cycle. Rinsing is conducted using a suction process at the distal end of the instruments. Soiling is always evacuated in the direction opposite to that in which it entered. The remaining lumens of the instruments are not further contaminated with these contaminants. The interior of the shaft of every instrument is rinsed and tested individually for flow-through. Instruments that were not rinsable during the cleaning process, e.g. due to clogging, are securely identified by the integrated patency test and specified on the monitor. "Non-patency" of an instrument is declared when the flow-through rate is less than 2 ml/s.

Non-rinsable standard instruments such as scissors and forceps are placed in the special basket or a similar basket and are not connected to the adapters – the adapters remain open.

The ultrasound disinfection and cleaning cycle per instrument is programmed for a total treatment time of 5 min using a disinfecting agent suitable for use with ultrasound.

Functional diagram:



1.3 Intended purpose

1.3.1 Use of the devices

SONOMIC ultrasonic baths use the physical impact of high-performance ultrasound in aqueous liquids to clean reprocessed medical instruments. Their main application is the gentle, intensive cleaning of rinsable MIS instruments. Simple standard instruments can also be effectively cleaned in ultrasonic baths.
Sonication is conducted using water and an agent suitable for use with ultrasound.
In order to use the device as intended, a SONOMIC special basket or an appliance suitable for positioning the objects during sonication is also required.

IMPORTANT!
Ultrasonic baths are operated following the additionally required steps that satisfy requirements for hygiene in the reprocessing of medical devices, in accordance with applicable national regulations. SONOMIC ultrasonic baths are Class I medical devices pursuant to regulation (EU) 2017/745 and must be operated accordingly.

1.3.2 Indications, contraindications, side effects of the devices

1.3.2.1 Indications/areas of application

- Physically, SONOMIC ultrasonic baths are especially suited for the cleaning of objects made of metal, glass or hard plastics. Hard-to-access spots, surfaces, corners and openings can be conveniently reached through ultrasound.
- Medical instruments can be cleaned by SONOMIC ultrasonic baths as part of manual processing, and before or after machine processing.
    - o Sonication and simultaneous rinsing of instrument shafts for MIS instruments with outer diameters of 3 to 10 mm
    - o Sonication of standard instruments

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- The information supplied by the instrument manufacturer specifies whether the instruments are suited for ultrasonic cleaning.

1.3.2.2 Contraindications/exclusions

- Lenses, camera systems, light cables, mirrors, or objects made of or containing elastic materials (e.g. catheters, respiratory system functional parts, flexible endoscopes) are not suitable, or are only conditionally suitable for sonication. The information supplied by the instrument manufacturer specifies whether the instruments are suited for ultrasonic cleaning.
- SONOMIC ultrasonic baths are not suitable for cleaning and/or disinfection of contact lenses.
- The sonication of combustible liquids in SONOMIC ultrasonic baths is not permitted.
- Indirect sonication is not permitted in SONOMIC ultrasonic baths.
- Wearers of medical implants (e.g. implants with electrical or electromotor function) must observe the safety instructions in Section 1.6.

Note:

Pregnancy is not a contraindication for the use/operation of ultrasonic baths.

1.3.2.3 Possible side effects/limitations

- Processes such as chemical disinfection can be accelerated (time-shortened) in SONOMIC ultrasonic baths. Ultrasound alone does not disinfect.
- Cavitation erosion can cause surfaces to be mechanically corroded and their coatings to dissolve.
- In the event of steam formation, the SONOMIC ultrasonic baths must be operated with a lid.
- Ultrasound warms up the bath liquid even without additional heating.

1.3.3 User group

SONOMIC ultrasonic baths are intended for commercial use, e.g. in a reprocessing unit for medical devices (AEMP). The ultrasonic baths must be used by medical or equivalent skilled personnel.

1.4 CE conformity

The ultrasonic bath is declared as a medical device and satisfies the CE marking criteria for the European Union:

– Medical Device Regulation
– Low-Voltage Directive
– Electromagnetic Compatibility Directive
– RoHS Directive

in their currently valid versions.

A declaration of conformity can be requested from the manufacturer by providing the serial number.

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1.5 Technical data

The ultrasonic bath is interference-free and marked with CE.
Safety: EN 61010-1,
EMC: EN 61326-1

	Ultrasonic bath MC 1001	**Multi-part ultrasonic bath MC 1001 E:**
Material:	Stainless steel; oscillating tank 2 mm	Stainless steel; oscillating tank 2 mm
External dimensions (L×W×H): without lid and outlet	900 × 510 × 325 mm	855 × 475 × 380 mm
Internal dimensions (L×W×H):	650 × 400 × 160/170 mm	650 × 410 × 160/170 mm
Usable internal dimensions: (basket)	520 × 340 mm	
Weight:	38 kg (with basket and lid) 65 kg (filled with liquid)	36 kg (with basket and lid) 64 kg (filled with liquid)
Contents:	42.5 l	43.5 l
Operating volume: (filling level mark)	27.0 l	27.5 l
Outlet:	internal: outlet ¾", ball valve external: threaded sleeves G ¾	G 1½ fitting, with turning knob and stainless steel plugs
Protection class:	IP 20 – see below	–
Mains supply	230 V~ (± 10 %) 50/60 Hz, cable length 2 m 115 V~ (± 10 %) 50/60 Hz – only MC 1001	
Heating power: (maintenance heating)	400 W	
Ultrasonic frequency:	40 kHz	
Ultrasonic peak power:	2400 W	
Rated ultrasonic output	600 W*	
Current consumption (230 V), max.:	3 A	
Max. Power consumption:	680 W	
Fuses: relay circuit board Generator circuit board	2 × F 3.15 A 2 × F 4 A each	
Energy consumption:	1.49 kWh**	
Monitored temperature range	15-40°C	
Interfaces for protocol output	parallel and serial for connection to a receipt printer or PC	
Protection class:	I	

* In order to improve the effect, the ultrasound is modulated, resulting in the rated ultrasonic output being increased 4-fold as ultrasonic peak power.

** 10 cycles, incl. preparation and post-processing

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SONOBOARD functional cabinet

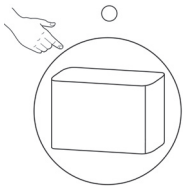
Type:	FS 1200 ML
External dimensions, incl. casters (L×W×H):	1200 × 700 × 930 mm
Material:	Stainless steel 1.4301
Weight, complete*:	193 kg

* Functional cabinet including MC 1001 E

Note:

The SONOBOARD MIC set includes the SONOMIC MC 1001 E ultrasonic bath.

More detailed information regarding the degree of protection pursuant to DIN EN 60529:



Protected against access with fingers to dangerous parts
Protected against solid foreign bodies with a diameter of 12 mm or larger

Not protected against ingress of water.

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Ambient conditions pursuant to EN 61 010-1

Overvoltage category:	II
Degree of contamination:	2
permissible ambient temperature:	15 to 35°C
Permissible relative humidity up to 31°C:	80%
Permissible relative humidity up to 40°C:	50%
Altitude:	up to 2000 m

No condensation allowed.

For indoor operation only.

Specifications for use as a medical device

Designation:	Ultrasonic bath
EMDN nomenclature:	Z12011302
Purpose:	See Section 1.3.
Classification (in acc. with regulation (EU) 2017/745, Annex VIII):	Class I; active, non-invasive, non-implantable medical device
Type, model, serial number, year of manufacture:	See type plate on the rear side for information

The ultrasonic bath has been inspected according to applicable standards and must be installed and operated according to EMC directions; see Section 1.5.1.

Specifications pursuant to the German Medical Devices Operator Ordinance (MPBetreibV):

Commissioning at location, functional check and personnel training (Section 4):	Not required
Technical safety check (STK, Section 11):	Every 2 years by manufacturer, customer service or authorised skilled personnel
(DIN EN 62353 / VDE 0750) Technical measurement controls (MTK, Section 14):	Not applicable

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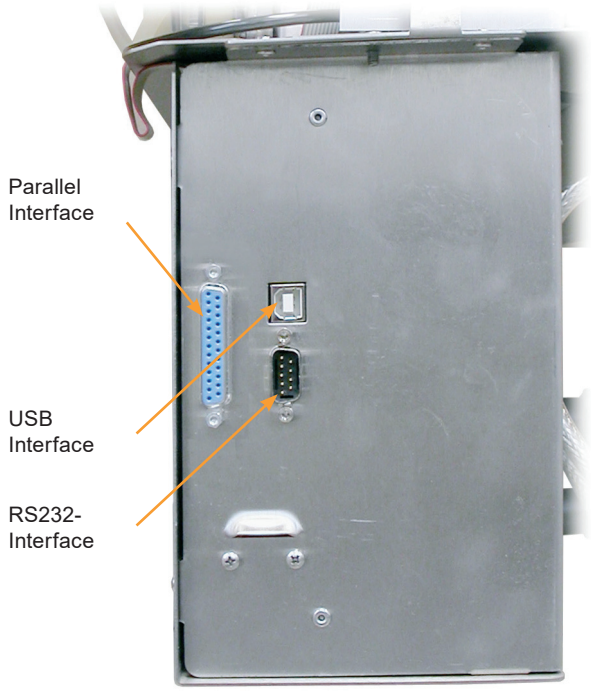
1.5.1 Electromagnetic compatibility (EMC)

The device has been checked for electromagnetic compatibility (EMC) in accordance with DIN EN 61326-1 and meets the requirements for Class B devices in accordance with EN 55011.
It is suitable for use in institutions and other areas that are directly connected to a public low-voltage power supply, e.g., medical laboratory facilities.
It may generate radio interference or disrupt the operation of devices nearby. It may be necessary to take remedial measures such as realigning the device or reconfiguring the ultrasonic bath or the shield.
During operation, portable or mobile HF communication systems in the vicinity of the ultrasonic bath should be turned off – their operation may be disrupted.

1.5.2 Interfaces

There are three data interfaces available for issuance of a reprocessing protocol, on the ultrasonic bath MC 1001 on the right-hand side and on the multi-part ultrasonic bath MC 1001 E on the front side of the ultrasound generator.



The parallel and RS 232 interfaces are designed for direct connection to a receipt printer. A PC is preferably connected to the RS 232 interface or to the USB interface.

After reprocessing, the same data is found on all three interfaces, including:

- Description, serial number
- Cycle counter
- Bath temperature
- Result of the reprocessing mode

The interfaces can be used simultaneously.

The devices, cables and PC programs required for communication are not part of the scope of delivery and are the user's responsibility. The manufacturer only guarantees the proper functioning of the interface.

Note:

Detailed information regarding the interfaces, protocol and connection assignment of usable cables and printers can be obtained from the manufacturer, upon request, in German or English.

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1.6 Warnings and safety instructions

General

- Keep the ultrasonic bath out of the reach of children and persons who have not been instructed in its operation by reference to these instructions.
- We will not offer a guarantee for damages to the ultrasonic bath or oscillating tank, or to the objects to be processed, as a result of use of inadequate disinfection agents or detergents.
- Keep the surface of the ultrasonic bath and operating elements clean and dry.
- Do not expose the ultrasonic bath to corroding influences.
- Accessories (special basket, adapter, etc.) are not suitable for thermal disinfection/ sterilisation due to the materials used.
- Ultrasonic baths adhere to prescribed EMC limit values, such that it can be assumed that the electromagnetic radiation emanating from the devices is harmless to humans. A binding statement for wearers of implants can only be made at the place of work and together with the implant manufacturer. In case of doubt, information regarding the allowable electromagnetic exposure level should be obtained from the implant manufacturer.

Operation and transport

- Observe ambient and set-up conditions, see Section 1.5.

- Never operate the ultrasonic bath without a cover for the oscillating systems (MC 1001 E) or the base plate (MC 1001)!

- Only turn on the ultrasound generator of the built-in MC 1001 E if the oscillating tank has been connected (HF cable) – never run the ultrasound generator without a load.
- Only plug in the ultrasonic bath to an outlet with a grounded socket.
- Do not operate the ultrasonic bath without liquids.
- Do not use a rubber plug or stand pipe on the oscillating tank outlet!
- Do not place or lay any objects on the tank bottom, accessories must be used, see Section 7.

- Do not immerse any parts of the body (e.g. hands, feet) or living beings (animals or plants) into the oscillating tank; in particular, do not immerse them in the ultrasonic fluid during ultrasound operation. Danger: Ultrasound has a cell-destroying effect.

- In the event of continuous activity within a 2 m radius, adequate hearing protection must be used. Danger: Hearing impairment possible during operation if not wearing hearing protection – the typical ultrasound cavitation noise can be very uncomfortable.
- Do not operate the ultrasonic bath while unattended.
- Only move the ultrasonic bath/SONOBOARD when it is empty.
- Empty the ultrasonic bath only upon prompting by the operating program.

Advice for the laboratory and medical field

- The ultrasonic bath is exclusively intended for use by medical skilled personnel.
- When handling contaminated instruments, adhere to the relevant personnel protection regulations (e.g. protective clothing, protective goggles, appropriate gloves).
- When cleaning instruments, follow the instructions of the instrument manufacturer.
- Ultrasonic cleaning is especially suited for instruments made of stainless steel and hard plastics. Do not process lenses, camera systems or optical cables with ultrasound.
- A combined disinfection and cleaning of medical instruments in the ultrasonic bath is only possible with the use of special agents (with the corresponding microbiological certificates). Ultrasound alone will not disinfect them!
- Operate the ultrasonic bath with a lid, or below/atop a suctioning system.
- Any incidents during operation of the ultrasonic bath which result, could have resulted, or might result in severe injury or even the death of a person must be immediately notified to the manufacturer and to the user’s competent authorities.

Damages and defects

- If damage to the ultrasonic bath is detected, do not connect the ultrasonic bath to the mains.
- In the event of defects, disconnect the mains plug immediately.
- Repairs may only be conducted by authorised skilled personnel or by the manufacturer.
- Defective parts may only be replaced with original parts.

2 Preparation

Carefully unpack the ultrasonic bath and accessories and inspect them for completeness or possible transportation damage. Any identified damage or defects must be communicated immediately and in writing to the transportation company and to the supplier.
Before operation, the ultrasonic bath should be allowed to stand for 2 hours at its operating location so that it can adjust to the ambient conditions.

2.1 Scope of delivery

1 Ultrasonic bath, cf. table

1 Operating instructions

Additional accessories as ordered – see delivery note

Component		Ultrasonic bath MC 1001		Multi-part ultrasonic bath MC 1001 E: or SONOBOARD MIC	
		Description	Code No.	Description	Code No.
Set		MC 1001	3315	MC 1001 E	3345
Oscillating tank		integrated		TE 1001 E	3371
Ultrasonic generator with rinsing module		integrated		GT 1001 E	3370
Control unit		integrated		ST 1001 E	337201
Adapter (complete with seal and hose)	12×	ADS 1000	3351	ADS 1000	3351
Basket		K 1001 MC	3324	K 1001 MC	3324
Adapter testing strips	2×	APB 1000	3358	APB 1000	3358
Reducer		G 1 on G ¾		–	
Elbow hose screw connection		G 1 with seal		–	
Hose (made of PVC)		19 mm, 1 m long		–	
Mains cable with plug		firm		loosely enclosed	
Cable ties	2× 3×	–		A 017 A 140	
Outlet		Ball valve ¾ integrated		Drain set G 1½ partially pre-mounted	
Filter cartridges	30×	EF 1001	3365	EF 1001	3365
Adapter seals	12×	AD 1000	3353	AD 1000	3353
Assembly chips	5×	enclosed		enclosed	
Functional cabinet		–		FS 1200 ML (for SONOBOARD MIC)	

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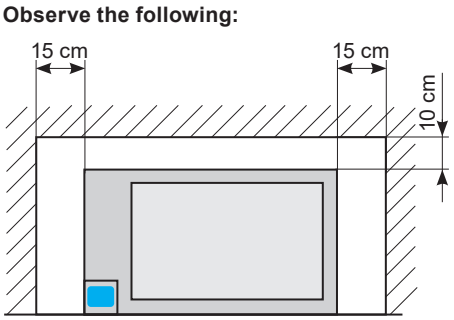
2.2 Setup/assembly

The ultrasonic bath must be positioned in such a way that disconnection from the power supply is easily possible.

Ultrasonic bath MC 1001



➢ Place the ultrasonic tank atop a firm, level and dry surface. In doing so,

- observe the maximum weight of the ultrasonic bath, including liquid (filled 80 kg).
  For net weight, see technical data in Section 1.5.
- do not block the air supply below the ultrasonic bath.
- guard against moisture and wetness – risk of electric shock.

➢ Connect enclosed hose with the outlet stud of the ultrasonic bath. To do so, wrap the enclosed sealing tape around the threaded sleeves multiple times (approx. 10x), toward the right, then screw on the reducer. While tightening the elbow hose screw connection, hold the reducer firmly in place using a spanner (SW 36). Do not back off the reducer by screwing it toward the left, as doing so will destroy the sealing action of the sealing tape. Lay the sloped hose end loosely for draining.
A fixed installation must be conducted by an installer.

Multi-part ultrasonic bath MC 1001 E

The installation of the multi-part ultrasonic bath must be conducted by authorised skilled personnel, under reference to the installation instructions.
If the ultrasonic bath comes with a drain set, this must be installed in accordance with the supplied installation instructions.
Ultrasonic oscillating tanks are generally short-circuited for transport.
Before commissioning, remove the short-circuit jumper on the ultrasonic oscillating tank or HF connection.

SONOBOARD MIC

Once utilities have been connected, SONOBOARD MIC is ready for use. Setup must be in the vicinity of the following connections:

- Power supply: See type plate
- Suitable filling fitting (spray, spigot, dosing unit)
- Outlet for emptying the ultrasonic oscillating tank

Engage the locking brakes on the front casters to secure SONOBOARD MIC from accidental movement.

Note:

The control unit can be pivoted out of the functional cabinet. When planning the installation, at least 250 mm of clearance must be added to the external dimension.

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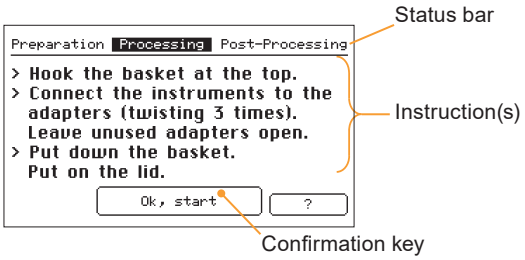
2.3 Commissioning

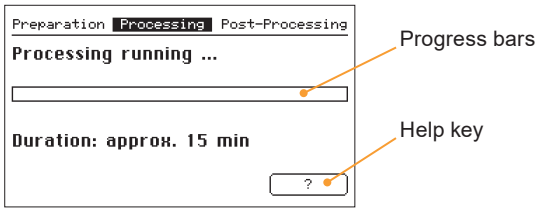
- Thoroughly rinse the ultrasonic bath's oscillating tank with water before its first use.
  Note:
  In order to protect the surface during transport and storage, all outer surfaces (and also the inner walls of the oscillating tank) are covered with an oily preservative. This should be removed with a suitable cleanser before first use, see Section 5.
- Verify that the mains switch is in the “0” position, then connect the ultrasonic bath to the mains (grounded socket).
- Connect the ultrasonic bath to the mains switch for testing. If the touchscreen is lit, the connection is correct. Set the desired language on the welcome screen. Turn the ultrasonic bath off again.
- It is recommended that a foil test be conducted as part of quality assurance prior to the first use.
  This test is to be saved for later comparison. See Section 6.2 for additional information.
- Insert the special basket in the oscillating tank (comb bar on the left). If the adapter with hoses is not yet connected, please connect.
  Note: First connect the lower row of adapters.
- Next, put on the lid or close the hinged lid.

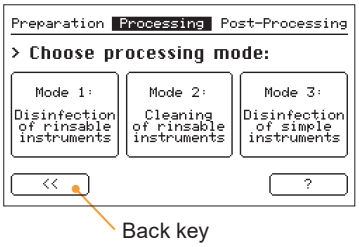
3 Operation

3.1 Operating elements

The device is operated via the touchscreen. The operating program will guide you with clear instructions through the individual steps. See Annex C for an overview of the operating program.







- Instructions must be carried out one after the other.
- Only once all instructions on the touchscreen have been carried out may the Confirmation key be pressed to continue.
- The Help key is used to obtain additional information (help texts).
- The Back key is used to return to the previous screen.

3.2 Signals on the touchscreen

Symbols

In some screens, symbols are used to underscore the information:

Symbol	Explanation
☑	Positive, error-free result
⊗	Negative result
⚠	Error message

Key operation

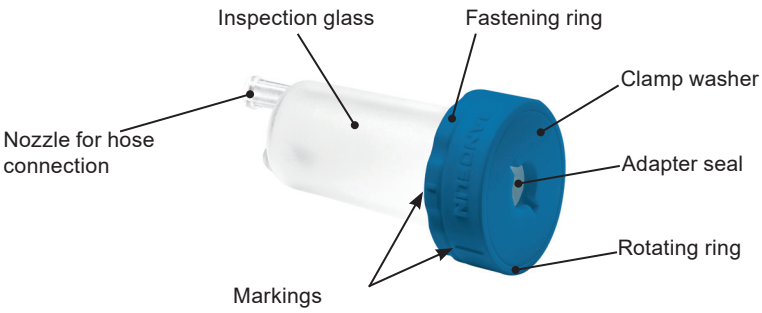
Correct key operation is visually identified by a reversing of the key colours, and it is acoustically identified by a signal tone (beeping).

Caution!

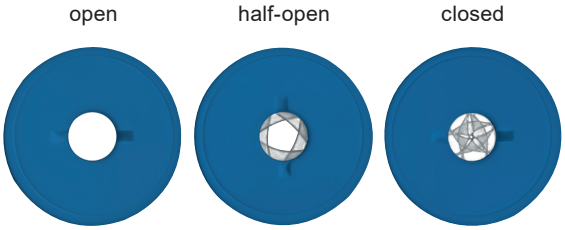
The touchscreen may not be pressed on forcibly. Do not use your thumbs to press the keys.

3.3 Connection and removal of the instruments

Setup of an adapter:



Adapter settings:



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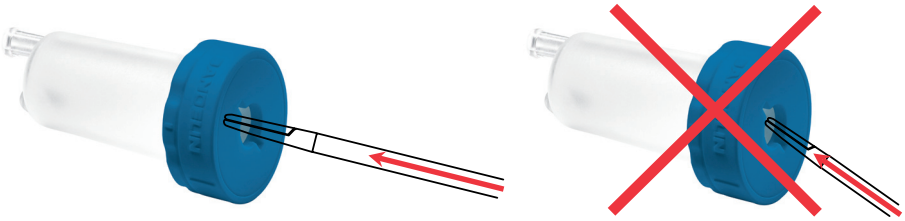
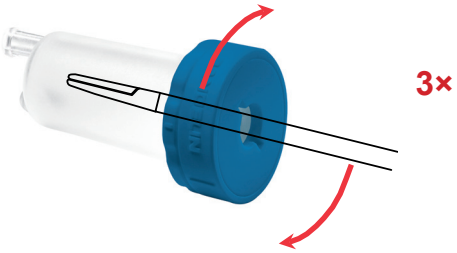
Connecting the instruments:

- First place the lower adapters on the comb bar to make handling easier.
- Check whether the adapter is fully opened.
- Slide the closed instrument all the way into the adapter, in the direction of the arrow, until the movable part on the tip of the instrument is fully visible in the inspection glass. **Do not damage the adapter sealing**, e.g. by inserting the instrument in a crooked manner.



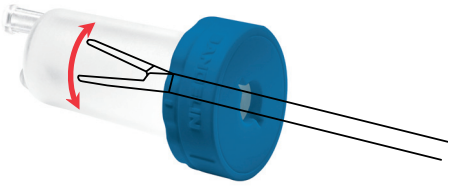
- Close the adapter. To do so, turn the rotation ring in a clockwise direction until it clicks (tensioning of the adapter seal). After **clicking 3×** (clicking noise), it is certain that the adapter sealing has been correctly sealed.



Important!

Click a maximum of 4 × (the markings will then align once again); additional clicking could cause damage to the adapter sealing.

- Next, open the movable part on the tip of the instrument in order to also guarantee optimum cleaning in that area.



- Check for correct positioning of the adapter in the comb bar; if needed, reaffix the nozzle in the comb bar. The nozzle with the hose connection must be on top.

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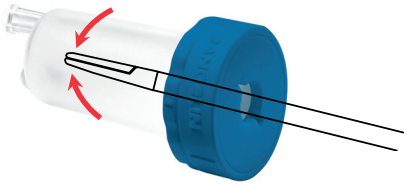
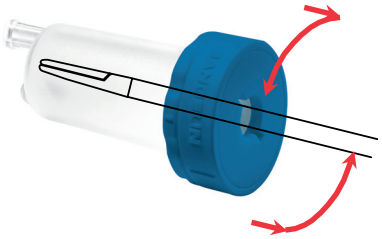
Removal of the instruments:

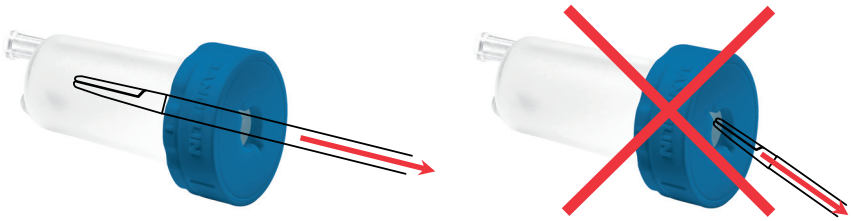
➢ First, close the movable parts on the tip of the instrument.



➢ Open the adapter. To do so, pull out the rotation ring somewhat and allow it to snap back (if needed, turn carefully in a counter clockwise direction). Repeat this process several times until the marking on the fastening ring aligns with the short marking on the rotation ring.



➢ The instrument can now be carefully pulled out of the adapter.
Do not damage the adapter seal.



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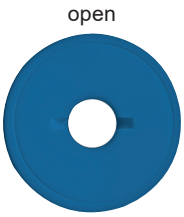
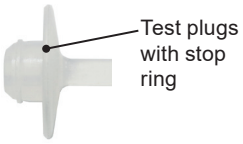
3.4 Connecting/removing the adapter testing strips

Connecting the testing strips:

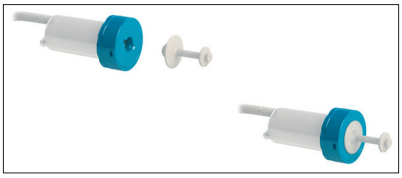
- ➢ Check whether all adapters are fully opened.
- ➢ Push the test plugs all the way to the stop ring in the adapters. Otherwise, it is not possible to conduct a correct adapter check.



- ➢ Do not leave any adapter apertures open, since the ultrasonic bath will otherwise prompt for a replacement of the adapter seals.



- ➢ Do not additionally close/twist (click in place) the adapters.
- (➢ Check for correct positioning of the adapter in the comb bar; if needed, affix new nozzles in the comb bar.)



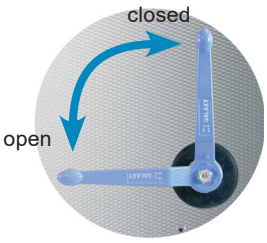
Removing the testing strips:

- ➢ Pull the test plugs from the adapters.

3.5 Opening and closing the outlet

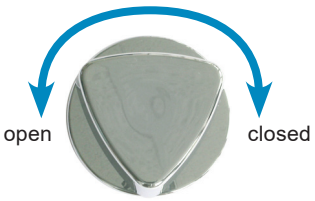
The oscillating tank outlet is operated using an integrated ball valve (on ultrasonic bath MC 1001), or a turning knob on the drain set (on multi-part ultrasonic bath MC 1001 E/ SONOBOARD MIC).

Ultrasonic bath MC 1001



Ball valve to open or close the outlet.

Multi-part ultrasonic bath MC 1001 E/ SONOBOARD MIC



Turning knob to open or close the outlet.
Depending on design, at the front or on top of the work plate

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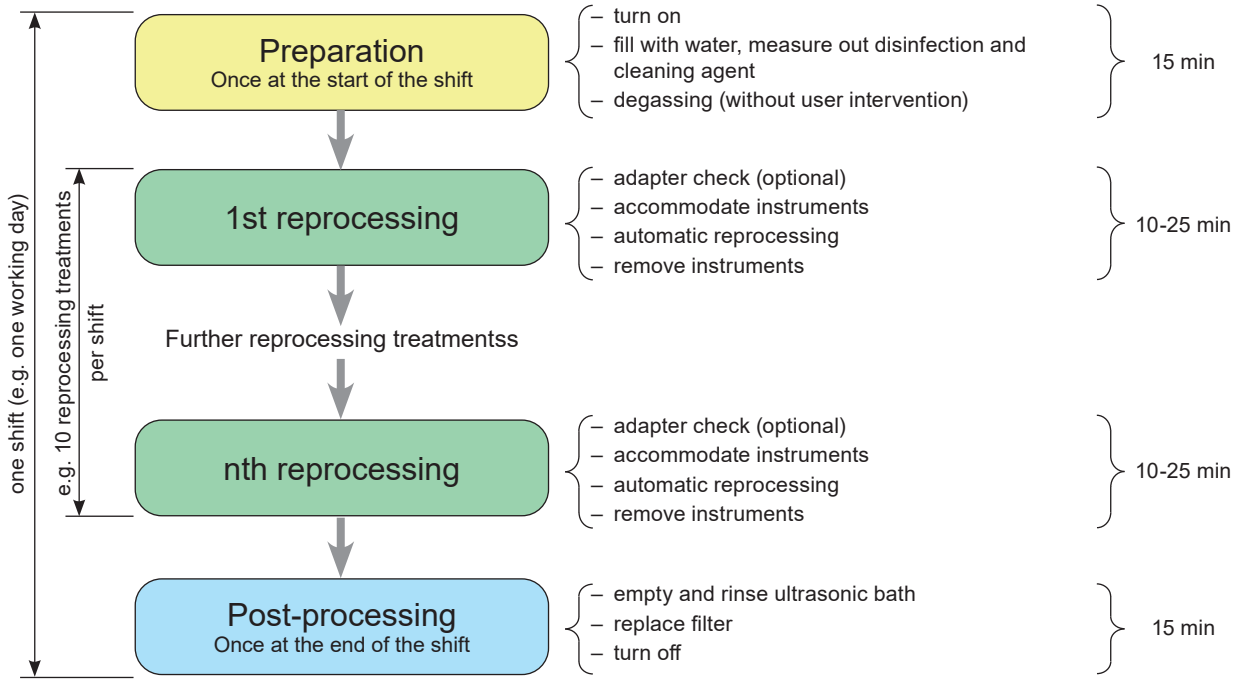
4 Application

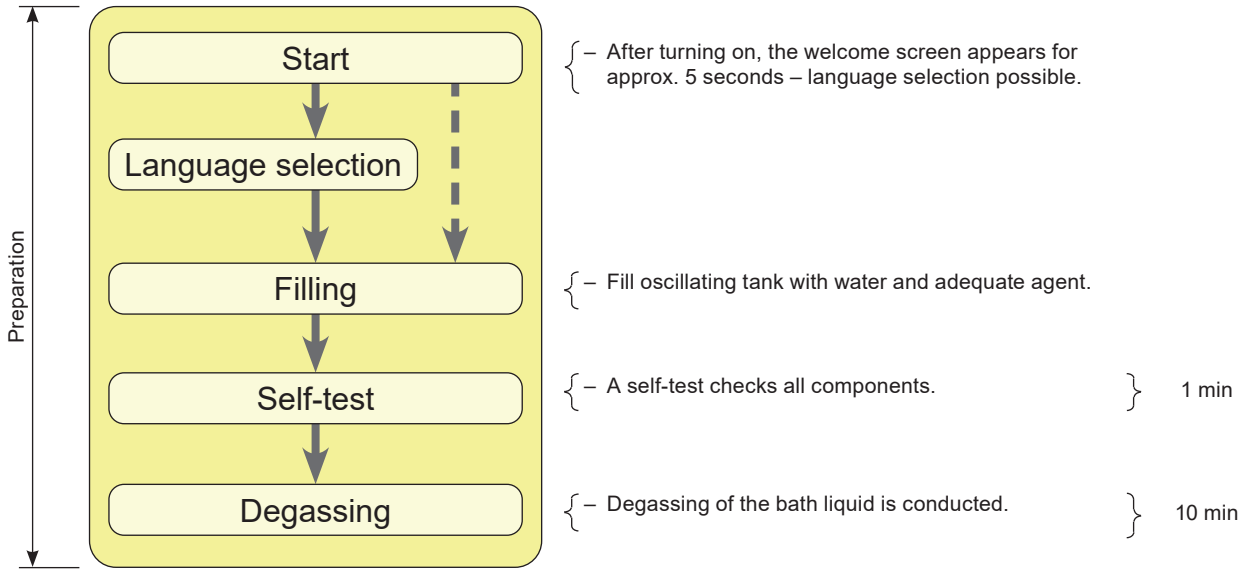
The SONOMIC ultrasonic bath is designed for multi-shift operation in a medical establishment. A shift generally consists of 8 hours including preparation, multiple reprocessing treatments and post-processing.



The coloured work steps are explained in the following.

4.1 Preparation of the ultrasonic bath

Preparation of the ultrasonic bath is to be conducted once at the start of a shift, or after every change of bath liquid.



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Start/language choice

➢ Turn on the SONOMIC's mains switch. The welcome screen will appear for approx. 5 s. Within this time, the language can be selected if necessary by pressing the appropriate key. If no key is pressed, the ultrasonic bath will start using the last setting.

➢ In the next selection menu, press the "Start" key and follow the instructions on the touchscreen.

Filling

To prepare the ready-for-use solution, you may only use water that is microbiologically at least of drinking quality.
For an optimal ultrasound effect, the filling temperature of the water should lie between 18 and 25°C. In addition, a suitable cleaning and disinfection agent should be added to the water in the oscillating tank, see Section 7.3.

Important!

- Verify that the outlet is closed.
- Do not fill oscillating tank with hot water (> 40°C). The filling temperature should be between 18 and 25°C.
- Fully replace used liquids, do not refresh them by adding more liquids. Follow the manufacturer's dosing instructions.
- Distilled or deionised water without additives is unsuitable for cleaning directly in the ultrasonic oscillating tank.
- Do not use any combustible liquids (e.g. benzine, solvents) or chemicals that contain chloride ions or that separate (some disinfectants, household cleaners, and dish detergents), for sonication in the stainless steel tank.
- The compatibility between the instrument and the agent is to be verified on the basis of the respective manufacturer's specifications.
- Working with chemically aggressive agents is strictly prohibited!

Self-test

The ultrasonic bath activates all components successively and verifies the data communication. Any errors are displayed on the touchscreen in the form of error codes. Additional information can be found in the Annex.

Degassing

Degassing the bath liquid increases the ultrasound effect.
Freshly-filled fluid or fluid that has remained in the oscillating tank for a longer period of time must be degassed prior to use. Gases released in the liquid (e.g. oxygen) are reduced through degassing, thus significantly improving the ultrasound effect.

The cavitation noise changes during degassing, loud degassing noises fade away at the end of the degassing process and the ultrasonic bath appears to work more quietly. However, a lower noise level does not mean a reduction in ultrasonic power. Instead, it signifies the end of the degassing process and an improvement in the ultrasound effect.

Note

Bath liquid with an excessively low filling temperature (<20°C) will be heated after degassing.

4.2 Reprocessing of instruments

In order to reprocess the instruments, there are 3 different programs (modes) to choose from:

Mode 1:

Cleaning and chemical disinfection of rinsable MIS instruments
15 minute rinsing program with sonication, especially for combined cleaning and disinfection solutions, used, for example, with STAMMOPUR DR 8.

Mode 2:

Cleaning of rinsable MIS instruments
10 minute rinsing program with sonication especially for cleaning solutions without disinfecting effect, used, for example, with STAMMOPUR R.

Mode 3:

Cleaning and chemical disinfection of simple (non-rinsable) instruments
5 minutes sonication without rinsing function, especially for a combined cleaning and disinfection solution.

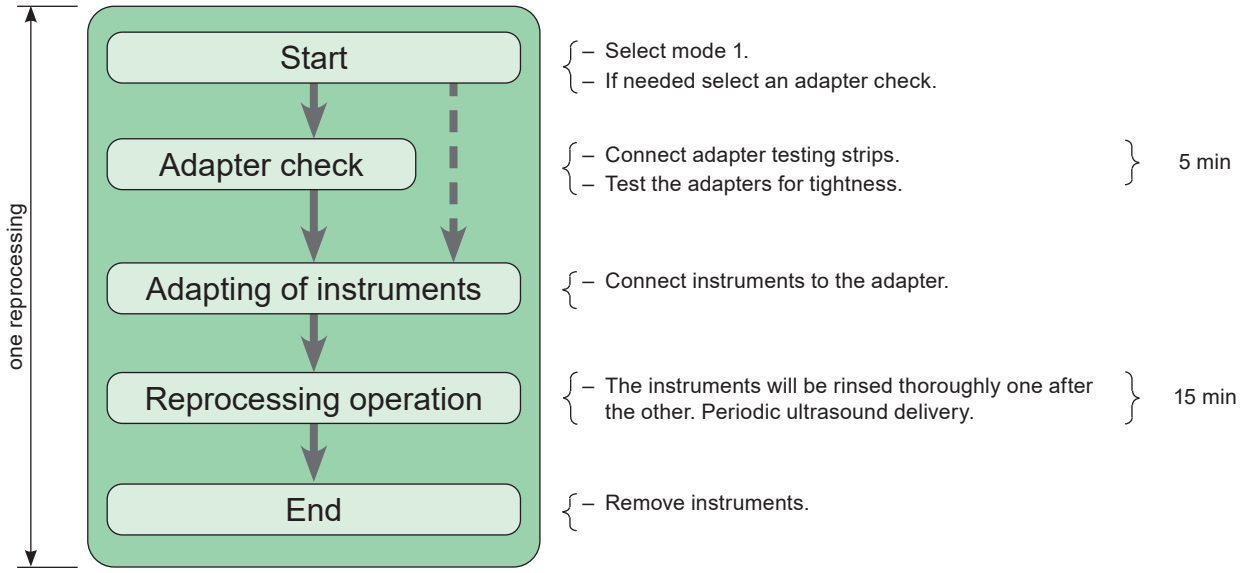
The instruments are connected to the adapters for reprocessing modes 1 and 2.
The included seals guarantee a secure, complete seal on the outer sheath of the instruments, which is indispensable for subsequent rinsing.
In order to exclude defective seals, modes 1 and 2 will be invoked for an adapter check before every reprocessing, since the adapter seal is subject to process-related wear (ultrasound, opening, closing). Defective or leaking adapters are identified once the test is completed.
The adapter check is not required in mode 3 as the adapters remain open throughout the sonication.

Note on temperature and fill level monitoring

The SONOMIC controls the temperature and fill level of the liquid in the bath prior to every reprocessing.
If the temperature is outside the permissible range of 20 to 40°C, or if the fill level falls below the sensor's permissible range, this is shown through respective warning messages on the touchscreen.
Further information is provided in Section 6.3.

4.2.1 Mode 1:

In mode 1, rinsable MIS instruments are reprocessed according to the following procedure:



Start

- ➢ After preparation, select mode 1 in the “Choose reprocessing mode” prompt on the screen.
- ➢ Then follow the instructions on the touchscreen.

Adapter check

- ➢ When prompted, insert the adapter testing strips included with delivery into the adapters, see Section 3.4.
- ➢ Continue following the instructions on the touchscreen.
- ➢ If indicated, replace the defective adapter seal(s), see Section 6.1.2.

Adapting the instruments

- ➢ Properly prepare the instruments before reprocessing in the SONOMIC and rinse **on the inside and outside with cold water (of at least drinking quality)**.
- ➢ Connect the instruments to the adapters (see Section 3.3).
  Unused adapters should be left open.

When laying down the instruments, observe the following:

- Only reprocess instruments that have been approved by their manufacturer for ultrasonic cleaning.
- Do not reprocess any damaged instruments.
- Disassemble instruments that can be taken apart as much as possible. When doing so, heed the manufacturer's instructions. Remove sealing caps/seals and place them loosely in the special basket, open up valves, remove the Luer cap from instruments with a lateral rinsing connection.

- Do not place instruments directly on the tank bottom. The basket prevents damage to the instruments and tank bottom.
- Space instruments evenly apart, do not stack them. An overloading of the basket will reduce the ultrasound effect (the ultrasound is absorbed).
- Fragile parts must not be touching each other. If needed, use special placement accessories such as silicone knob mats, see Section 7.
- The instruments must be fully covered with liquid.

Reprocessing operation

The reprocessing operation takes place automatically. At the end, instruments that could not be rinsed through are individually displayed on the touchscreen as “non-continuous"

Caution!

“Non-continuous instruments” have not been processed! They are to be individually removed according to the indication on the touchscreen, and stored separately. Non-continuous instruments must undergo further reprocessing, or be processed separately.

End

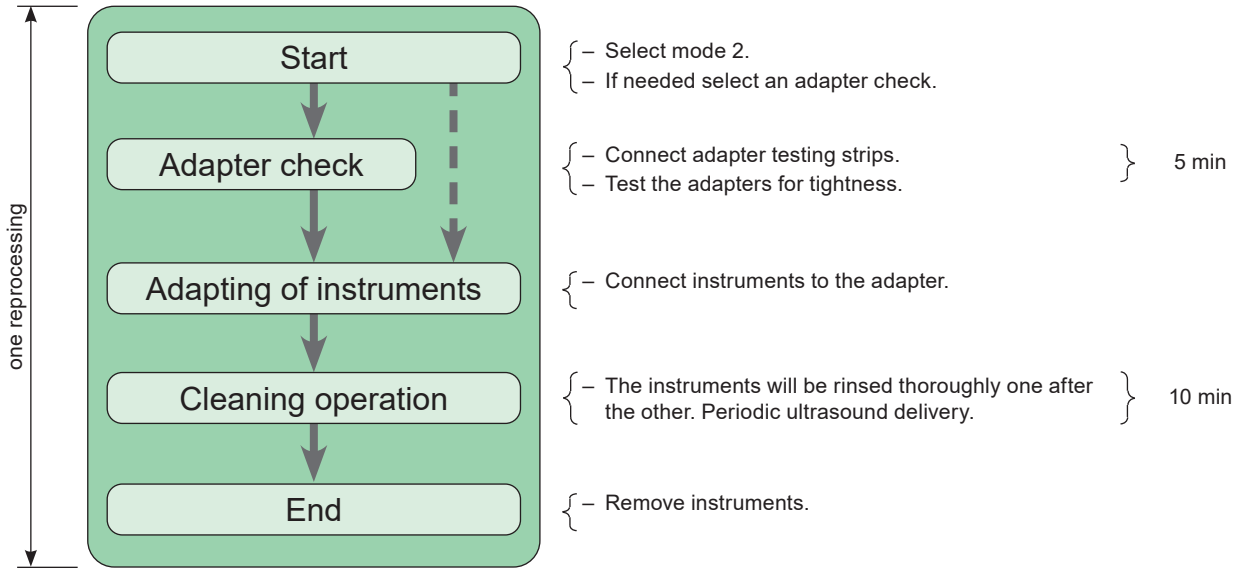
After removal of the instruments, these are to be intensively rinsed using water of at least drinking quality. Demineralised water should be used for the final rinsing. Continue to handle instruments in accordance with the hygiene plan, German KRINKO recommendations, or other respectively applicable national regulations (e.g. drying, function control, sterilisation).

After reprocessing, a report will be issued by the interfaces if a receipt printer or PC is connected (Section 1.5).

Before every subsequent reprocessing, it is necessary to check whether the bath liquid needs to be replaced.

4.2.2 Mode 2

In mode 2, rinsable MIS instruments are processed according to the following procedure:



Start

- ➢ After preparation, select mode 2 in the “Choose reprocessing mode” prompt on the screen.
- ➢ Then follow the instructions on the touchscreen.

Adapter check

- ➢ When prompted, insert the adapter testing strips included with delivery into the adapters, see Section 3.4.
- ➢ Continue following the instructions on the touchscreen.
- ➢ If indicated, replace the defective adapter seal(s), see Section 6.1.2.

Adapting the instruments

- ➢ Properly prepare the instruments before cleaning in the SONOMIC and rinse **on the inside and outside with cold water (of at least drinking quality)**.
- ➢ Connect the instruments to the adapters (see Section 3.3).
  Unused adapters should be left open.

When laying down the instruments, observe the following:

- Only clean those instruments that have been approved by their manufacturer for ultrasonic cleaning.
- Do not clean any damaged instruments.
- Disassemble instruments that can be taken apart as much as possible. When doing so, heed the manufacturer's instructions. Remove sealing caps/seals and place them loosely in the special basket, open up valves, remove the Luer cap from instruments with a lateral rinsing connection.
- Do not place instruments directly on the tank bottom. The basket prevents damage to the instruments and tank bottom.

- Space instruments evenly apart, do not stack them. An overloading of the basket will reduce the ultrasound effect (the ultrasound is absorbed).
- Fragile parts must not be touching each other. If needed, use special placement accessories such as silicone knob mats, see Section 7.
- The instruments must be fully covered with liquid.

Cleaning operation

The cleaning operation is conducted automatically. At the end, instruments that could not be rinsed through are individually displayed on the touchscreen as “non-continuous"

Caution!

“Non-continuous instruments” have not been cleaned! They are to be individually removed according to the indication on the touchscreen, and stored separately.
Non-continuous instruments must undergo another cleaning, or be cleaned separately.

End

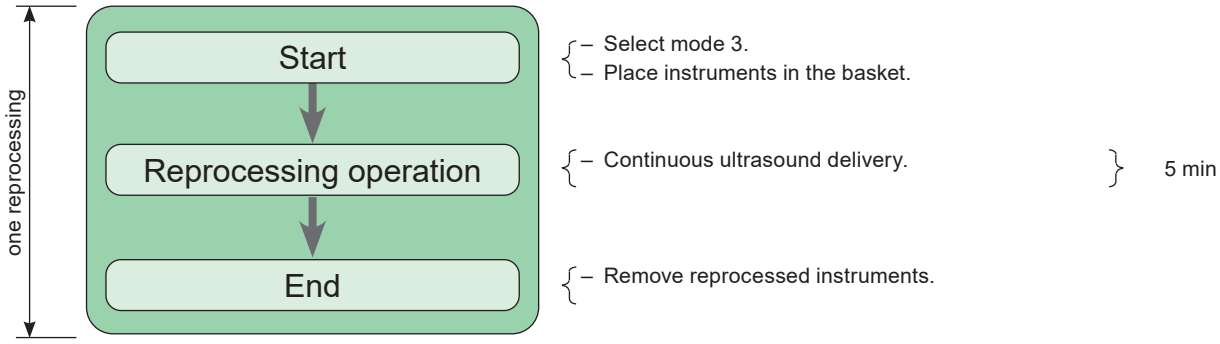
After removal of the instruments, these are to be intensively rinsed using water of at least drinking quality. Demineralised water should be used for the final rinsing. Continue to handle instruments in accordance with the hygiene plan, German KRINKO recommendations, or other respectively applicable national regulations (e.g. drying, function control, sterilisation).

After completion of cleaning, a protocol will be issued by the interfaces if a receipt printer or PC is connected (Section 1.5).

Before every subsequent reprocessing, it is necessary to check whether the bath liquid needs to be replaced.

4.2.3 Mode 3

In mode 3, simple (non-rinsable) instruments such as scissors and forceps are reprocessed according to the following procedure:



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Start

- ➢ After preparation, select mode 3 in the “Choose reprocessing mode” prompt on the screen.
- ➢ Then follow the instructions on the touchscreen.

The instruments are loosely placed in the basket and not connected to the adapters – the adapters remain open. An adapter check is not conducted in this reprocessing mode.

When laying down the instruments, observe the following:

- Only process instruments that have been approved by their manufacturer for ultrasonic cleaning.
- Do not reprocess any damaged instruments.
- Do not place instruments directly on the tank bottom. The basket prevents damage to the instruments and tank bottom.
- Fully open or disassemble tongs or scissors.
- Place the more heavily soiled side facing downward.
- In the case of hollow areas, ensure that the air can escape.
- Space instruments evenly apart, do not stack them. An overloading of the basket will reduce the ultrasound effect (the ultrasound is absorbed).
- Fragile parts must not be touching each other. If needed, use special placement accessories such as silicone knob mats, see Section 7.
- The instruments must be fully covered with liquid.

The **reprocessing operation** takes place automatically.

End

After removal of the instruments, these are to be intensively rinsed using water of at least drinking quality. Demineralised water should be used for the final rinsing. Continue to handle instruments in accordance with the hygiene plan, German KRINKO recommendations, or other respectively applicable national regulations (e.g. drying, function control, sterilisation).

After reprocessing, a report will be issued by the interfaces if a receipt printer or PC is connected (Section 1.5).

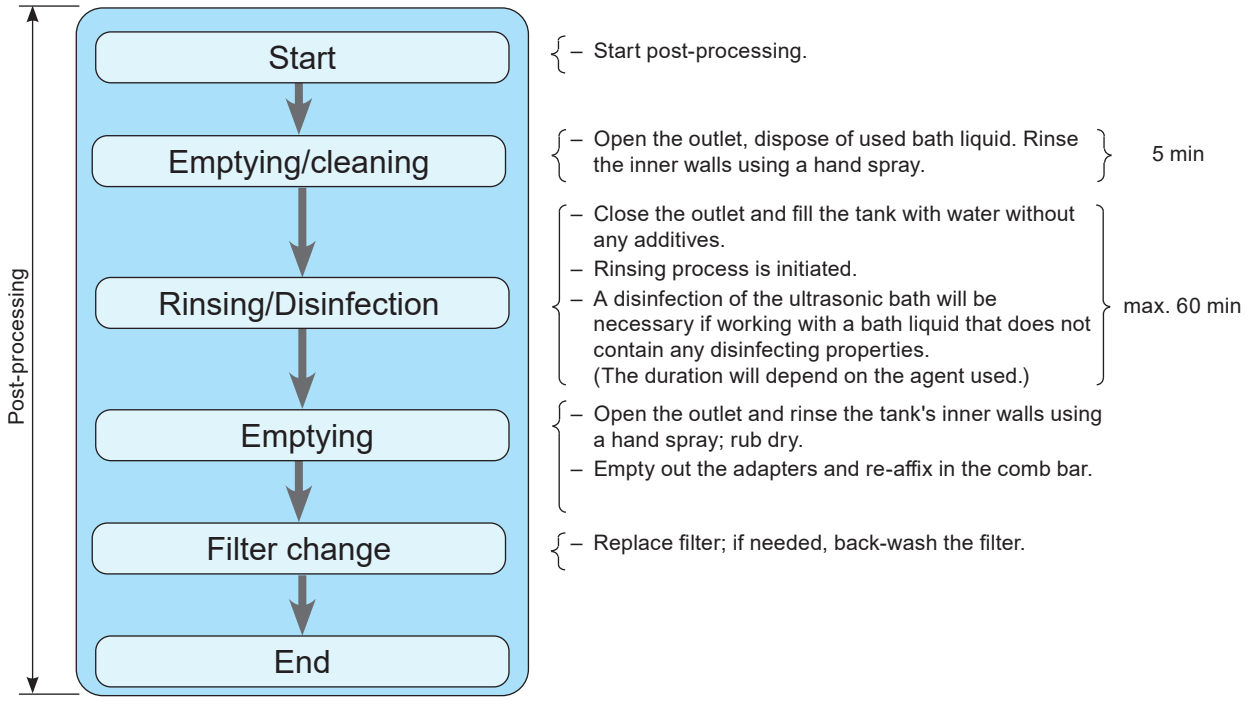
Before every subsequent reprocessing, it is necessary to check whether the bath liquid needs to be replaced.

4.3 Post-processing of the ultrasonic bath

Post-processing of the ultrasonic bath is to be conducted for reasons of hygiene prior to turning off the ultrasonic bath each time, and in the case of used bath liquid. This guarantees an effective cleaning action, and the ultrasonic bath is handed over to the next shift in clean, hygienic condition.

Cleaning solutions must be replaced immediately in cases of visible contamination, but at least once every working day. In the case of working solutions with a disinfecting agent, longer resting times are permissible if the manufacturer can verify, through expert reports, that the effectiveness of e.g. STAMMOPUR DR 8, remains present over a longer time period, even in the case of visible blood contamination, see Section 7.3.1. The manufacturer specifications regarding the service life must be observed.

Furthermore, the oscillating tank must be mechanically cleaned and, if applicable, disinfected, every working day to prevent biofilms.



Start

- ➢ To start the post-processing, respond to the “Start additional reprocessing?” prompt by pressing “No.”
- ➢ Follow the instructions on the touchscreen (see Annex for additional information).

Emptying

The working solution is disposed of pursuant to the specifications in the product leaflet and the label supplied by the manufacturer of the agents employed. All aqueous agents made by DR H. STAMM GmbH are prepared pursuant to the regulations of the German Washing and Cleansing Agents Act, are biodegradable and as working solutions may be disposed of in the wastewater. Strongly acidic and strongly alkaline liquids are to be previously neutralised pursuant to technical data sheet specifications. The manufacturer's specifications for the respective agents should be observed.
During cleaning, materials hazardous to water such as oils, heavy metal compounds, etc., depending on the type of contamination, may enter the working solution. If the limit values are exceeded, the working solution must be reconditioned (removal of contaminants) or be disposed of as toxic waste.
Disinfection and cleaning agents that become contaminated when used are considered "waste material" pursuant to the German Waste Act (AbfG) and may not be taken back by the manufacturer. In other countries, the relevant supplementary/deviating national regulations must be observed.
In every case, the statutory provisions and regulations of municipal wastewater plants must be adhered to. Information is provided by municipal wastewater plants as well as by environmental agencies.

Rinsing/disinfection

Following reprocessing modes 1 and 3 (used bath liquid = disinfection solution):
Here, all parts in the ultrasonic bath that came in contact with the disinfection and cleaning agent, and thus with the contamination, are thoroughly rinsed with water.
Following reprocessing mode 2 (used bath liquid = cleaning solution):
In addition to the rinsing, a disinfection is also initiated here. If prompted, a suitable disinfection agent (dosed according to manufacturer specifications) should be added to the filled water.

IMPORTANT!

It is important to carefully verify the compatibility of the agent used here to any previous agents or agents to be used in the future, e.g. in the cleaning and disinfection device! If necessary, consult with the manufacturer.

For the duration of the disinfection, 3 minutes should be added to the treatment time of the disinfection agent to allow for the safe rinsing of all channels. Therefore:

“Total disinfection duration” in mins = treatment time of the agent + 3 min

After reaching the total duration, the disinfection will be individually ended by the operator, or automatically after 60 mins.
At the end, rinse thoroughly with water of at least drinking quality.

Filter replacement/end

- The filter cartridge must be exchanged, see Section 6.1.1.
- Switch off the ultrasonic bath.
  In case of an extended period of non-use of the ultrasonic bath, it is recommended for hygienic reasons that an additional "pump out" be run. To do so, turn on the ultrasonic bath, go to the main menu and select the "Shutdown" key. Ignore the prompt to fill the oscillating tank and press the "Start rinsing" key. Any residual water present will be pumped out. Next, wipe out/wipe down the oscillating tank with a soft cloth.
- At the end, put on the lid to protect the tank interior from being contaminated from outside.

5 Cleaning and maintenance of the ultrasonic bath

To achieve an optimum lifespan for the ultrasonic bath, cleaning and maintenance should be conducted regularly. An automatic cleaning process is thus conducted 1 x daily as part of post-processing, see Section 4.3. Following are instructions for manual cleaning and care.

CAUTION!

Disconnect the ultrasonic bath from the mains before any cleaning/maintenance.

Do not rinse or immerse the ultrasonic bath in water and do not expose it to splash water.

5.1 Cleaning and care

Oscillating tank

The ultrasonic oscillating tank of an ultrasonic bath is a wear part.
It is continuously exposed to cavitation during ultrasound operation. Dirt particles remaining in the tank abrade and damage the tank surface due to the movement of the liquid, therefore

- Rinse the oscillating tank with water thoroughly and frequently and dry using a soft cloth.
- Regularly remove residue and scum from the oscillating tank using a commercial stainless steel cleaning product without any abrasive additives.
- Do not use steel wool, scrapers or graters for cleaning/maintenance.
- Metal particles that remain on the stainless steel surface as well as rust particles from the water pipe system penetrate the passive protective layer of the stainless steel. The stainless steel is "activated" in this process and it begins to rust. This extraneous rust produces localised corrosion of the stainless steel. For this reason, remove metal parts such as screws, filings, etc. from the oscillating tank, and immediately remove rust stains using a soft cloth and a commercial stainless steel cleaning product without abrasive additives.

Housing (MC 1001 or individual parts of the MC 1001 E)/SONOBOARD functional cabinet

- Wipe the housing only from the outside with a moist cloth; if needed, use a suitable surface disinfectant, then allow to dry or rub dry.
- Do not use abrasive cleaners, only use commercially-available care products without scouring agents.

5.2 Disinfection

- If contaminated medical instruments are cleaned in the ultrasonic bath, hygienic safety after application is important. An automated process for chemical disinfection of the ultrasonic bath and accessories is thus conducted 1 x daily as part of post-processing in accordance with reprocessing mode 2, see also Section 4.3. Thermal disinfection or sterilisation of the device components is not allowed.
- In order to avoid any cross-contamination as a result of the colonisation of microorganisms, especially along the tank edge and in the drain outlet area, but also on the operator panel, these areas are to be regularly cleaned and disinfected with a suitable surface disinfectant, i.e. one that is at least bactericidal, yeasticidal and partially virucidal.

5.3 Warehousing/storage

During longer terms of non-use, the ultrasonic bath should be disconnected from the mains (pull the mains plug from the power outlet).
The lid should be put on in order to protect the ultrasonic oscillating tank from outside contamination.

6 Maintenance and repair

6.1 Maintenance

The maintenance intervals provided assume daily use of the ultrasonic bath.

daily	monthly	after approx. 1,000 operating hours	every 2 years	Part/object/remark
X				Post-processing, including replacement of the liquid and of the filter cartridge (see Section 4.3 or 6.1.1)
	X			Replace adapter seals (see Section 6.1.2)
		X		Replacement of the hose in the pump by authorized specialist personnel, customer service or the manufacturer.
			X	Servicing by authorised specialist personnel, customer service or the manufacturer.

The operator is responsible for planning and documenting maintenance.
Appropriate maintenance lists (sample copies) are found at the end of these operating instructions.
The preservation heating does not require servicing.

6.1.1 Changing filter cartridge

During post-processing and in the event of a prematurely obstructed filter, a prompt for a filter exchange will appear on the touchscreen.
The filter cartridge can be replaced if the oscillating tank is full. To do so, the filter housing should always be fully removed from the tank so that the filtered-out contamination does not re-contaminate the tank bath during the exchange of filter unit.

The entire filter housing is fixed by a spring to the support, and can be removed by compressing the spring. Please ensure that the sealing rings on the connections do not get lost.

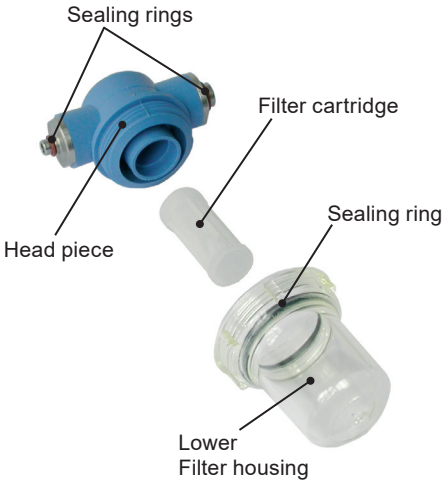
The filter cartridges are suitable for backwashing. The filter cartridges can be used multiple times with appropriate, thorough backwashing.

Removing the filter cartridge:

- ➢ Unscrew the lower filter housing (transparent).
- ➢ Pull out the filter cartridge from the head piece.
- ➢ Thoroughly rinse all housing parts with water.

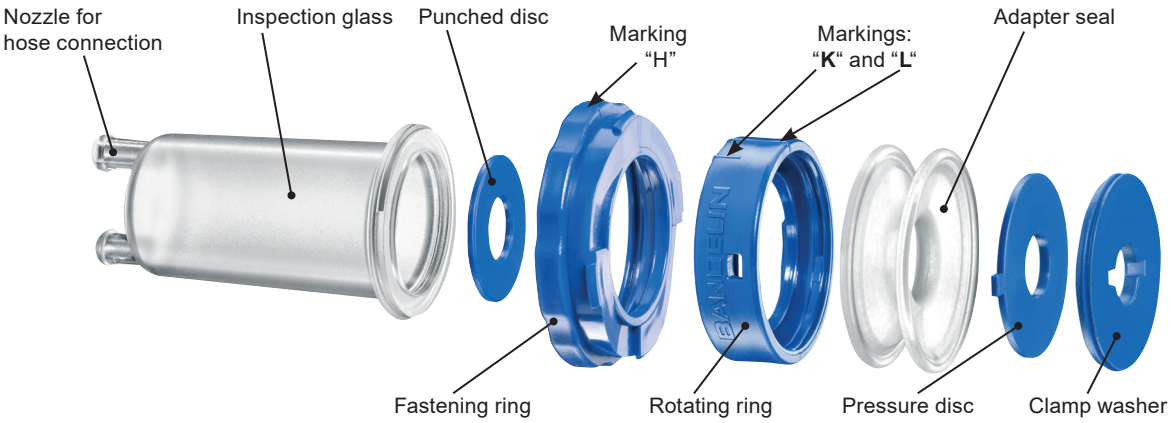
Inserting a new filter cartridge:

- ➢ Insert open side (straight) of the filter cartridge into the head piece.
- ➢ Verify that all sealing rings are present.
- ➢ Re-screw the lower filter housing.



6.1.2 Replacing the adapter seal

The adapter seals must be replaced every 4 weeks (approx. 500 reprocessing cycles). If the equipment does not pass the adapter check, all identified adapter seals must also be replaced and the 4-week service life restarted.
In order to replace the adapter seal, the adapter must be dismantled and reassembled. To do so, an assembly chip is required as a tool.



Disassembling the adapter seal:

- Take the adapter out of the comb bar and pull off the hose.
- Unscrew the clamp washer using the assembly chip.
- Remove the pressure washer.
- Then unscrew the conjoined rotating and fastening rings from the inspection glass.
- Pull out the defective/used adapter seal.
- Separate the rotating and fastening rings. To do so, align the “H” marking on the fastening ring and the “L” marking on the rotating ring, then pull both rings apart.
- Remove the punched disc from the inspection glass (click).
- Thoroughly rinse all detached adapter parts with water.

Fitting the new adapter seal:

- Press the punched disc into the inspection glass (snap-in).
- Interlock the fastening and rotating rings. To do this, the “H” marking on the fastening ring and the “L” marking on the rotating ring must be aligned.
- Insert one half of the adapter seal through the hole of both rings. In this position, the adapter seal should be loose and not wedged.
- Firmly screw both rings together with the seal onto the inspection glass.
- Turn the rotating ring somewhat, so that the “H” marking on the fastening ring and the “K” marking on the rotating ring face each other.
- Insert the pressure disc nose first (smooth side facing outwards) and hand tighten the clamp washer using the assembly chip. In the process, firmly hold the rotating and fastening rings in place – the markings must not fall out of alignment!
- Mount the hose on the nozzle for the hose connection, and reaffix the adapter in the comb bar.

6.2 Function testing

Checking the touchscreen

- ➢ Turn on the ultrasonic bath – the touchscreen must light up.
- ➢ The touchscreen should respond to the pushing of buttons and the relevant screens must appear.
- ➢ The press of a key is confirmed through a change in key colour and a beep.

Testing the device function

After being turned on, the SONOMIC ultrasonic bath conducts a self-test with a corresponding fault analysis as part of preparation, see Section 4.1 and/or the Annex. Further functional checks are only possible as part of servicing by authorised skilled personnel, customer service or the manufacturer.

Checking operation of the ultrasonic bath

The functioning can be checked using a standard wattmeter. This is to be inserted between the ultrasonic bath mains switch and the power outlet.

- ➢ Turn on the ultrasonic bath.
- ➢ Fill the ultrasonic oscillating tank with liquid.
- ➢ Start reprocessing mode 3 for a check.
  Compare the value displayed with the corresponding value in the technical data (Section 1.5) (tolerances ± 20%).

Check the ultrasound effect

For monitoring, we recommend the performance of a foil test.
A suitable frame for the foil test can be requested from the manufacturer. Household aluminium foil is used to conduct the test. Next, a comparison is made with previously-generated foils.
As a departure from the detailed information in the Annex (which is intended for simple standard ultrasonic baths), please note the following special instructions for the SONOMIC:

- ➢ Turn on the ultrasonic bath.
- ➢ Fill the ultrasonic oscillating tank with liquid.
- ➢ Conduct degassing (10 min).
- ➢ Start reprocessing mode 3 (5 min) for a check.

Important:

After the foil test, the ultrasonic oscillating tank must be thoroughly rinsed so that no aluminium residue remains on the inside.

Note:

A measurement procedure is described in DIN SPEC 40170:2013-11 (measurement and evaluation of the cavitation noise).

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6.3 Malfunction/fault analysis

SONOMIC ultrasonic baths are designed for high reliability. A possible malfunction due to a defective component cannot be fully ruled out, however. Mechanical defects, e.g. on the adapters, hoses, etc., are also possible due to wear or improper use.
The following overview of possible sources of error should serve as an aid for error detection and elimination.

Error	Possible cause(s)	Measure
Ultrasonic bath cannot be turned on (display remains dark)	Is ultrasonic bath plugged in to power supply?	If needed, Connect ultrasonic bath to power supply.
	Mains switch correctly activated?	Check that the mains switch is in position "I".
	Main fuse faulty?	If needed, Replace the building fuse, see Section 6.4.3.
No displays or incomprehensible displays	Blinking progress bars?	No error, the ultrasonic bath is preparing itself for operation. This can last up to 1 minute.
	Touchscreen defective?	This can only be rectified by a service technician or the manufacturer.
Touchscreen does not react to pressing of keys	Keys not pressed correctly?	Control option: When activated, the buttons change colour (dark = key activated). An acoustic signal is emitted.
	Key activated correctly but the ultrasonic bath does not react?	Wait approximately 10 s, some functions require some time. If the ultrasonic bath does not react after 10 s, turn it off and turn it on again after another 10 s.
	The ultrasonic bath only reacts to the "Help" key?	Turn off the ultrasonic bath and turn it back on after 10 sec.
	Touchscreen defective?	This can only be rectified by a service technician or the manufacturer.
Message "Filter obstructed" reappears even when a new filter cartridge has been installed	Filter installed incorrectly?	Check the filter housing and insert, see Section 6.1.1
	Flow rate sensor defective?	This can only be rectified by a service technician or the manufacturer.
Message "Instrument in channel ... non-patent" reappears for the same channel, with no identifiable plausible cause	Are instruments in this channel not covered with liquid?	If needed, If needed, fill with liquid up to the filling level mark.
	Adapter incorrectly connected/ mounted?	Check adapters and adapter connections, see Section 6.1.2
	Obstruction in the ultrasonic bath's hose system?	This can only be rectified by a service technician or the manufacturer.
Message "Instrument in channel ... non-patent" reappears for all channels, with no identifiable plausible cause.	Are instruments not covered with liquid?	If needed, If needed, fill with liquid up to the filling level mark.
	Adapter incorrectly connected/ mounted?	Check adapters and adapter connections, see Section 6.1.2
	Obstruction in the ultrasonic bath's hose system?	This can only be rectified by a service technician or the manufacturer.
	Flow rate sensor defective?	This can only be rectified by a service technician or the manufacturer.

Error	Possible cause(s)	Measure
Message "Insufficient liquid..." reappears	Is the level sensor soiled?	Clean the surface of the sensor in the oscillating tank.
	Correct dosing of the bath liquid?	Level sensor measures the conductance (≥ 300 µS). If required, increase the concentration or use tap water to prepare the bath liquid, see Section 4.1.
	Is level sensor defective?	This can only be rectified by a service technician or the manufacturer.
Unsatisfactory reprocessing results	Degassing not conducted?	Always conduct degassing during the preparation.
	Insufficient amount of cleaning and disinfection agent used?	Repeat reprocessing with a well-tested disinfection and cleaning agent such as STAMMOPUR DR 8.
	Instruments stored for too long in contaminated state?	Repeat reprocessing or store instruments separately and reprocess manually.
Ultrasonic bath oscillates weakly, unevenly or noise is too loud	Overloaded with objects to be cleaned (instruments)?	Remove a few parts.
	Irregular sounds?	No error.
	Defective oscillating system or ultrasound generator?	Conduct a foil test and compare it to the first test (conducted during commissioning).
		Request a test sheet and allow authorised, skilled personnel to conduct test. If an error is detected, the ultrasonic oscillating tank should be returned to the manufacturer for repair.
Does the ultrasonic bath crash on the welcome screen?	Has it been turned on and off too quickly?	No error. Turn off the ultrasonic bath and turn it back on after 10 sec.

Further error messages are displayed directly on the touchscreen – see Annex.

6.4 Repairs and service

If errors or defects are ascertained during the functional check, and if it is impossible to rectify such errors, the ultrasonic bath may no longer be used. In such cases, please contact the supplier, customer service or the manufacturer:

BANDELIN electronic GmbH & Co. KG
Heinrichstrasse 3-4
12207 Berlin
Germany

Repair service:
Tel.: +49 (0)30 7688 013
Fax: +49 (0)30 7688 0200 13

E-mail:
info@bandelin.com

In the event of returns, the General Terms and Conditions for Delivery and Payment of BANDELIN electronic GmbH & Co. KG apply. In addition, the ultrasonic bath must be cleaned and decontaminated (if necessary), see the following Section.

6.4.1 Customer service

For repairs on site, please contact directly the customer headquarters for
MMM Münchener Medizin Mechanik GmbH, Hauptstraße 2, 92549 Stadlern, Germany.
Service hotline: 01805 666 112

6.4.2 Certificate of Decontamination

If the ultrasonic bath is sent back to the manufacturer for repairs (with accessories, if applicable), the form "Certificate of Decontamination" must be filled out and affixed to the packaging on the outside, in a visible spot.
If this form has not been filled out, we reserve the right to refuse receipt of the package in order to protect our employees.
The form can be downloaded as a PDF file from our website:
www.bandelin.com/Downloads...

6.4.3 Replacing fuses

Six fuses are built into the SONOMIC ultrasonic bath, which respond to defects or overload. If a fuse has blown, the ultrasonic bath will no longer function (touchscreen remains dark). In general, the ultrasonic bath is defective and must be sent to customer service or the manufacturer for repair.

Caution!

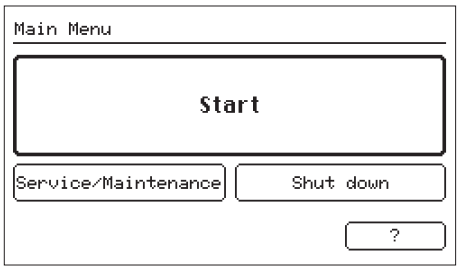
- Only authorised skilled personnel may open the ultrasonic bath and replace the fuses.

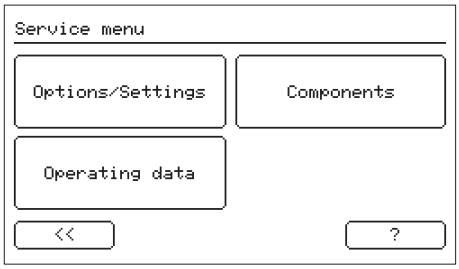
6.4.4 Determining the software version and operating data

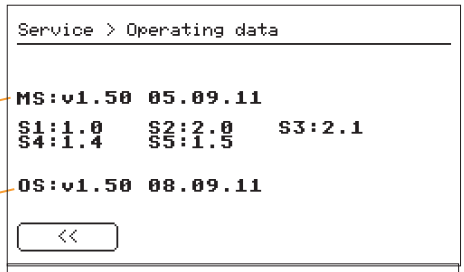
In some cases it may be necessary to inform authorised skilled personnel or the manufacturer of the software version and other operating data of the ultrasonic bath.

Determining the software version:

- Turn on the ultrasonic bath. The welcome screen will appear for 5 s.
- Click the “Service/Maintenance” key on the main menu after the welcome screen.
- Then click the “Operating data” key.
- Take a photograph of the screen and send the photograph.
- Press the “<<” key twice and then the "Shut down" key.
- Turn the ultrasonic bath off again.





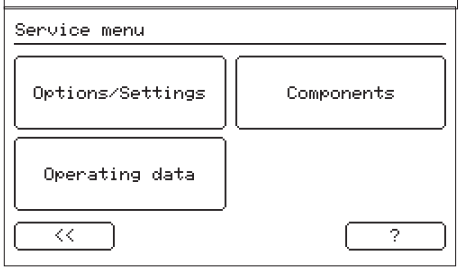


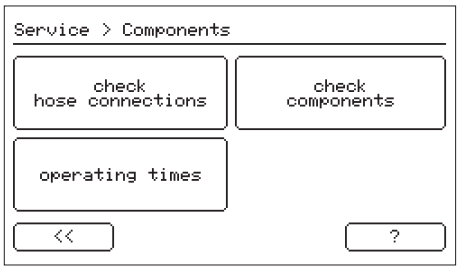
Software version of the controls

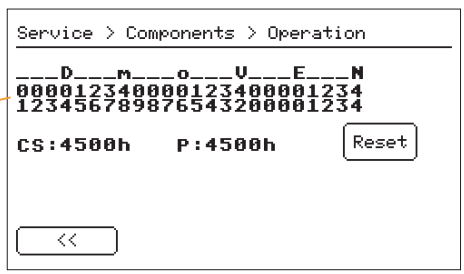
Software version of the operation

Determining operating data:

- Turn on the ultrasonic bath. The welcome screen will appear for 5 s.
- Click on the “Service/Maintenance” key on the main menu after the welcome screen (see above).
- Then press the "Components" and "Operating times" keys.
- Take a photograph of the screen and send the photograph.
- Press the "<<" key three times and then the "Shut down" key.
- Turn the ultrasonic bath off again.







Length of operation

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7 Accessories

The proper accessories facilitate use of the ultrasound and also protect the oscillating tank and instruments.

BANDELIN offers a wide range of accessories.
Additional information may be obtained from our supplier, our sales representatives or from our website.

No-obligation telephone consultation:
+49 (0)30 7688 00

Website:
www.bandelin.com

7.1 Required accessories

See scope of delivery, Section 2.1.

7.2 Optional accessories

Description	Code No.
D 1001 MC Non-hinged lid – plastic (for MC 1001 E/SONOBOARD MIC)	3312
D 1001 G Hinged lid – stainless steel with gas spring (for ultrasonic bath MC 1001)	3310
D 1001 GE Hinged lid – stainless steel with gas spring (for multi-part ultrasonic bath MC 1001 E/ SONOBOARD MIC)	3326
SM 1000 MC Silicone knob mat for gentle and contact-free accommodation of fragile parts during reprocessing.	3313
SONOBOARD FS 1200 M/L Functional cabinet for multi-part ultrasonic bath MC 1001 E	3346

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7.3 Chemical agents

Special cleaning and disinfecting agents that are ultrasound-compliant, i.e. they are cavitation-conducive, biodegradable, easily disposable, gentle to the material and long-lasting, are required for use of the ultrasound. Water without any additives does not clean and/or disinfect.

For the SONOMIC ultrasonic bath, BANDELIN recommends using the concentrates STAMMOPUR DR 8 and STAMMOPUR R of DR. H. Stamm GmbH, which have been especially developed for ultrasound use and which optimally support the ultrasound.

IMPORTANT!

The processing times for SONOMIC ultrasonic bath have been defined for a treatment time of 5 minutes with ultrasound use, in agreement with the recommended STAMMOPUR concentrates. If a different disinfection and cleaning agent is used, it is important to ensure an equivalent treatment time!
Furthermore, it is necessary to ensure that the agent used is aldehyde-free and does not feature any proteopectic properties.

The use of powder-based disinfecting and cleaning agents is not recommended since they may cause severe damage (e.g. obstructions) to the ultrasonic bath's cable ducts and to instruments after a long treatment time when not fully dissolved, due to a concentration of active oxygen. When using powder-based agents, ensure that they have dissolved completely in the bath liquid!

Caution!

- When using agents, the safety instructions included on the labels and in the respective product leaflets and safety data sheets are fundamentally to be adhered to.
- Keep the agents out of the reach of children and also of persons who have not been instructed in their use by reference to the product information.
- Do not ingest or inhale the agents and do not allow them to come into contact with the eyes or skin.

We do not offer a guarantee for damage to the ultrasonic bath or to the objects to be processed (instruments), arising from the use of inadequate disinfection and cleaning agents.

7.3.1 STAMMOPUR DR 8 instrument disinfection and intensive cleaning

STAMMOPUR DR 8 has been specially developed for disinfection during simultaneous intensive cleaning in the ultrasonic bath. It enables very short ultrasonic treatment times and possesses a very high material compatibility. Highly-sensitive instruments are especially protected in this manner.

STAMMOPUR DR 8	Aldehyde-free, chlorine-free and phenol-free concentrate for disinfection and intensive cleaning mildly alkaline, pH 9.9 (1%) Application 1-3% Bactericidal, yeasticidal, virucidal against vaccinia, BVDV, papovavirus, adenovirus, HBV, HCV, HIV, avian flu – A-Virus H5N1 VAH-certified

Application:

	Ultrasonic bath MC 1001	Multi-part ultrasonic bath MC 1001 E/ SONOBOARD MIC
2%	Total filling volume 27 l (= 26.5 l water + 540 ml STAMMOPUR DR 8)	Total filling volume 27.5 l (= 27.0 l water + 550 ml STAMMOPUR DR 8)
3%	Total filling volume 27 l (= 26.19 l water + 810 ml STAMMOPUR DR 8)	Total filling volume 27.5 l (= 26.67 l water + 830 ml STAMMOPUR DR 8)

Order information:

PU	Code No.
2 l	972
5 l	974
10 l	6028

Minimum order quantities:
6×2 litres, 2×5 litres or 2×10 litres

Additional information regarding STAMMMOPUR DR 8 can be obtained from the Product Information and Safety Data Sheet, to be downloaded from www.dr-stamm.de.

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7.3.2 STAMMOPUR R instrument cleaner

STAMMOPUR R is a cleaning agent for thorough intensive cleaning of medical instruments and devices in an ultrasonic bath. It allows for short ultrasonic cleaning times, protecting especially sensitive instruments in the process. STAMMOPUR R is suitable for all materials used in Medicine.

STAMMOPUR R	Phosphate-free concentrate for cleaning instruments Mildly alkaline, pH 9.6 (1%) Application 2%

Application:

	Ultrasonic bath MC 1001	Multi-part ultrasonic bath MC 1001 E/ SONOBOARD MIC
2%	Total filling volume 27 l (= 26.5 l water + 540 ml STAMMOPUR R)	Total filling volume 27.5 l (= 27.0 l water + 550 ml STAMMOPUR R)

Order information:

PU	Code No.
2 l	934
5 l	989
10 l	6029

Minimum order quantities:
6×2 litres, 2×5 litres or 2×10 litres

Additional information regarding STAMMMOPUR R can be obtained from the Product Information and Safety Data Sheet, to be downloaded from www.dr-stamm.de.

8 Consumable materials

Description	PU	Code No.
EF 1001 filter cartridges	30 pieces 100 pieces	3365 3366
AD 1000 adapter seal	12 pieces 24 pieces 36 pieces	3353 3354 3355
ADS 1000 Adapter with seal	1 piece 12 pieces	3350 3351
APB 1000 Adapter test band (consisting of 2 × 6 test plugs)	1 piece	3358

9 Decommissioning

The device must be disposed of appropriately, not with household waste.

Disposal must be conducted in accordance with the Waste, Electrical and Electronic Equipment Directive 2012/19/EU.
Any supplementary/deviating national regulations must be observed.

- The device must be decontaminated before disposal. It can then be disposed of as electronic waste. If decontamination is incomplete/cannot be correctly performed, a material safety data sheet noting the liquids used must be affixed to each device.
- Metal accessories such as the lid or basket should be decontaminated and disposed of as metal waste.
- Plastic accessories such as insert baskets, silicone knob mats or lids must be decontaminated and disposed of.
- The packaging is recyclable.

10 Keyword index – not applicable –

A Foil test

Information

BANDELIN
Ultraschall seit 1955

Foil test

Function testing of an ultrasonic bath

Before the first use and at regular intervals, e.g. every 3 months, a foil test should be conducted. This serves to ensure the consistent effect of the ultrasound. The frequency with which these tests are carried out is your responsibility.
The foil test is a simple procedure to demonstrate the intensity and distribution of cavitation in an ultrasonic bath. It involves stretching aluminium foil over a foil test frame. This frame will be perforated or destroyed to a certain degree by cavitation, depending on the sonication time.
In order to compare the results, it is **important for the conditions of the foil test to always remain the same:**

- Filling the oscillating tank to the filling level mark,
- Temperature of the sonication fluid,
- Degassing time,
- Frame positioning,
- Foil type (brand, thickness),
- Sonication time,
- Type and concentration of the ultrasound preparation.

Fluid for the foil test

In order to obtain a sufficiently strong cavitation effect, the foil test also requires the surface tension of the water used to be reduced using surfactant preparations.
We recommend the following ultrasound preparations:

- TICKOPUR R 33,
- TICKOPUR R 30,
- TICKOPUR TR 7,
- TICKOMED 1,
- STAMMOPUR R,
- STAMMOPUR DR 8.

If none of these products are available, a neutral or mildly alkaline product that does not destroy aluminium may be used. The product must be approved by the manufacturer for use in ultrasonic baths.

Test results and documentation

Assuming constant test conditions, the test result is evaluated based on the perforated surfaces of the foils. The perforated surfaces of all foils should have approximately the same reach and distribution – they are never identical. Consistency of process validations, e.g. for the treatment of medical devices, can only be ensured through regular foil tests.

To document the test results, you can download a documentation template here:

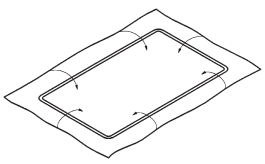
https://bandelin.com/folientest/

Here you will also find an application video.

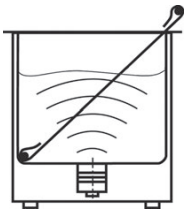
Foils can also be archived if done in a suitable manner (scanning, photos, etc.). This allows foils to be compared at any time.

Conducting the foil test

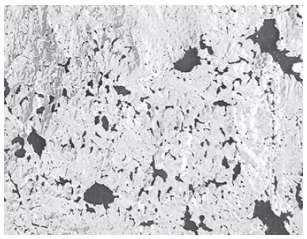
1. Fill the oscillating tank to the filling level mark with water and a suitable ultrasound preparation, in the concentration specified by the manufacturer.
2. Degas the sonication fluid.
3. Stretch aluminium foil (household foil, 10 µm to 25 µm thick) over the foil test frame. Depending on the tank size, it is possible that the frame will protrude outside the tank. Covering the part of the foil test frame that is covered by the sonication fluid will be enough.



4. Place the covered foil test frame diagonally in the centre of the oscillating tank. Fasten it if necessary.



5. Switch on the ultrasound. Sonicate the foil for at least one minute until visible perforations or holes are produced. With sturdier foils (thicker or coated ones), the sonication time may be up to 3 minutes.
6. Switch off the ultrasound. Remove the foil test frame. Remove the aluminium foil from the foil test frame and allow it to dry.
7. The foil must be perforated, see image. Else, we recommend having the device checked by the Service department at BANDELIN electronic GmbH & Co. KG.



8. Archive the foil with the test date and serial number of the ultrasonic bath. The foil test document template can also be completed and archived.
9. Rinse the oscillating tank thoroughly to remove any detached foil particles.

You can order suitable foil test frames from BANDELIN electronic GmbH & Co. KG. The foil test frames are configured for a wide range of tank dimensions. Aluminium foil is additionally required to perform the test as it is not included in the delivery.

Type	Order no.	for
FT 1	3190	DT 31/H, DT 52/H, RK 31/H, RK 52/H
FT 4	3074	DL 102 H, DL 255 H, DT 100 / H, DT 102 H /H-RC, DT 103, DT 106, DT 255 /H /H-RC, RK 100 /H, RK 102 H, RK 103, RK 106, RK 255 /H
FT 6	3222	DL 156 BH, DT 156 /BH,
FT 14	3084	DL 510 H, DL 512 H, DL 514 BH, DT 510 /H /H-RC, DT 512 H, DT 514 H /BH / BH-RC, DT 510 F, RK 510 /H, RK 512 H, RK 514 /H /BH, ZE 514/...DT, RM 16.2 U /UH
FT 36	3673	DT 1028 F, ZE 1031/1032/ ...DT
FT 37	3674	DT 1058 M, ZE 1058/1059/ ...DT
FT 38	3672	MC 1001/E
FT 40	3094	DL 1028 H, DT 1028 /H /CH, RK 170 H, RK 1028 /H /C / CH, RK 1040, RM 40.2 U /UH
FT 42	3224	TRISON (TE 3000)
FT 45	3204	DT 1050 CH, RK 1050 /CH, RM 75.2 U /UH

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🖷 + 49 30 773 46 99

Zertifiziert nach
ISO 9001
ISO 13485

B Maintenance lists

Maintenance list/daily

- **Change filter cartridge**

Date	Signature

Maintenance list/monthly

- **Replace adapter seals**

Date	Signature

Maintenance list/every 1,000 hours

- **Replace pump hose**

Date	Signature

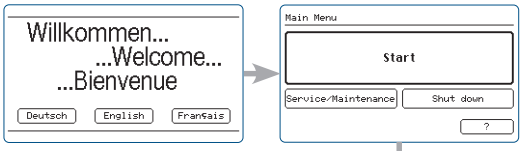
Maintenance list/every 2 years

- **Replace water-carrying hoses**
- **Maintenance of the ultrasonic bath**

Date	Signature

C Screenshots with explanations starting with version 1.5x

Order of reprocessing/cleaning without interruption:



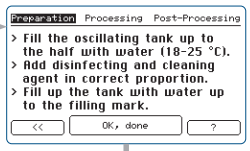
When the mains switch is actuated, the touchscreen begins to light up and the welcome screen appears for approx. 5 seconds. During this time, the language can be selected using the selection buttons.

Start: Start instrument preparation (initial preparation, preparation, post-processing).

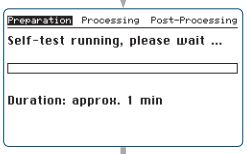
Service/Maintenance: For maintenance work by authorised skilled personnel, customer service or the manufacturer.

Shut down: Turning off the device (incl. the possibility of rinsing the unit).

Start

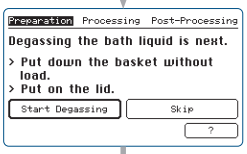


The bath must be filled to the fill line in accordance with the instructions.



The device performs an internal functional check.
All the components are turned on briefly and checked.

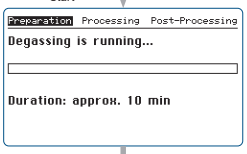
A progress bar and the approximate total time required are displayed.
The progress bar changes according to the attained status.



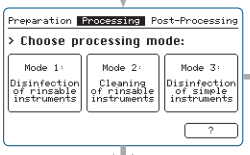
Freshly filled liquid must be degassed for an effective ultrasound effect.
To do so:
Lift the basket off the basket mounts and place it past them on the tank bottom. The lid should be put on to reduce noise. Further information on degassing can be found in Section 4.1.

Note: Degassing will not start if the filling level is below the filling level sensor.

Start



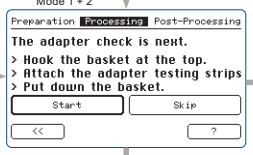
The degassing is performed.
If the temperature of the bath liquid is <20°C, the heating may need to be turned on to attain the requisite minimum temperature.
A further heating phase follows the degassing, if necessary.



Selection of the required reprocessing mode.
(See also Section 4.2.)

Mode 3

Mode 1 + 2



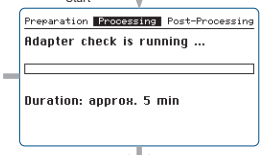
Skip check

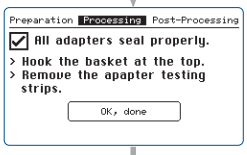
The adapter seals are subject to process-related wear (ultrasound, opening, closing).
For this reason, an adapter check is expressly recommended for modes 1 and 2.

The adapter check is not required in mode 3.

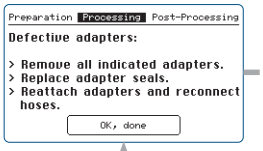
Hang the basket on the basket mounts.
The supplied adapter testing strips should be inserted in the adapters with their plugs. Do not leave any adapters open.

Start

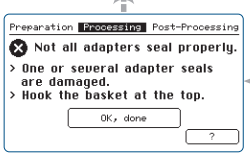




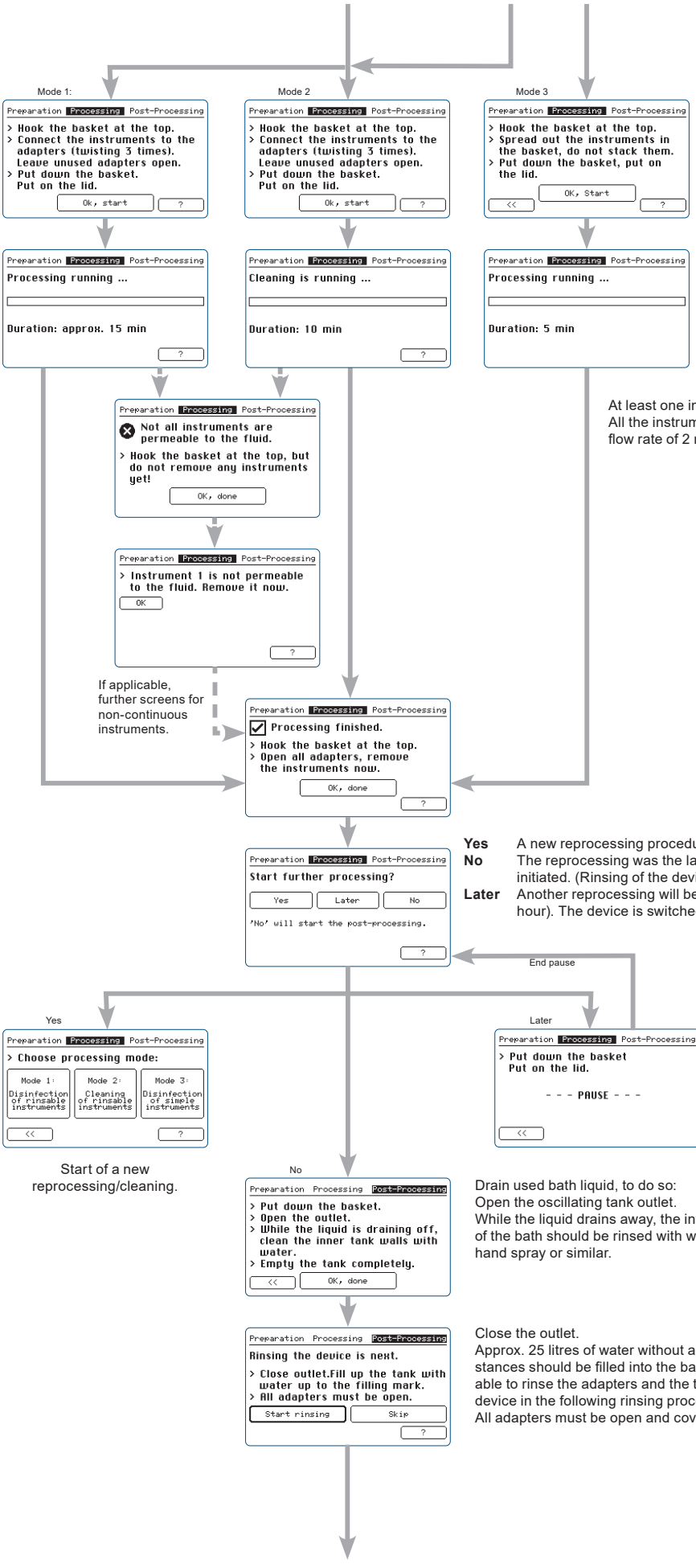
The adapter check finished without any errors.



Replace the seals on the identified adapters, see Section 6.1.2.
If the message appears again, perform a visual inspection of the adapters. Be attentive to correct screw connections, tight hose connections and tears/ damage to the adapters. Replace defective adapters.



The unit did not pass the adapter check – at least one seal is defective.



Mode 1 and 2: Hang the basket on the basket mounts in order to connect the instruments to the adapters (3x clicks, Section 3.3).
If needed, affix the adapters in the comb bar.
Leave unused adapters open so that no error message appears.
Mode 3 Leave all adapters open.

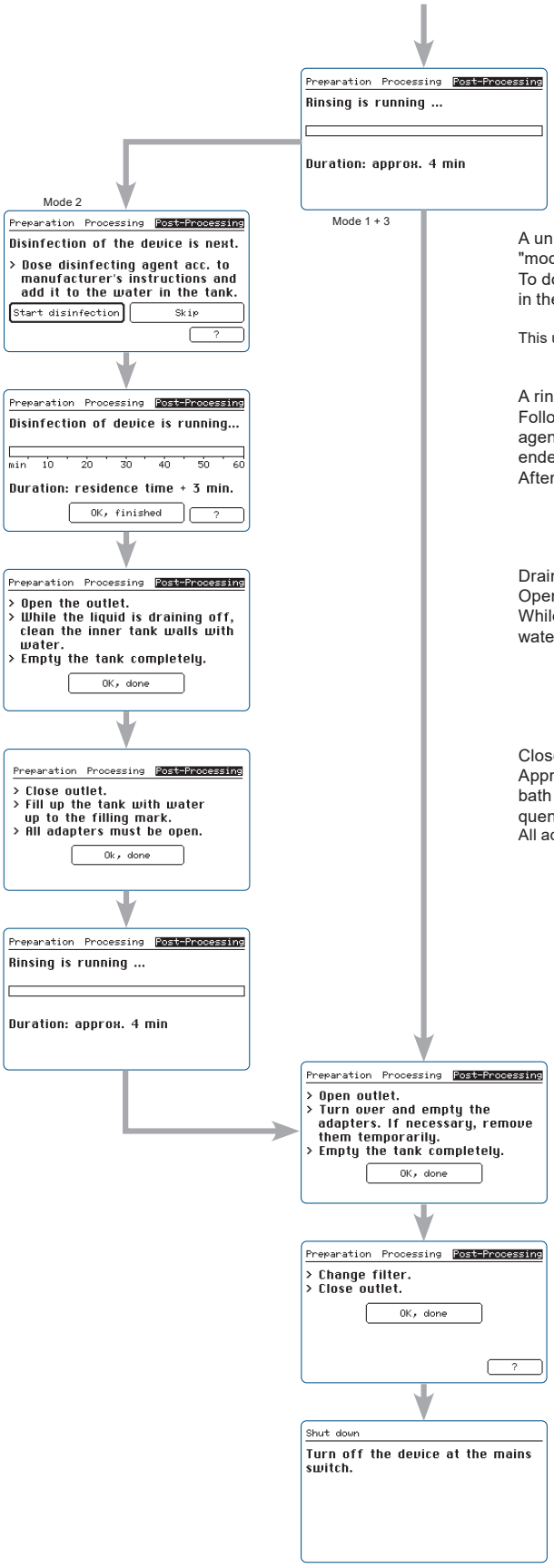
Use silicone knob mats for gentle placement of the instruments, see Section 7.2

At least one instrument could not be rinsed.
All the instruments that failed to attain the minimum flow rate of 2 m/s are shown below.

Yes A new reprocessing procedure will start immediately.
No The reprocessing was the last one for this shift. Post-processing is initiated. (Rinsing of the device)
Later Another reprocessing will be performed on the same day (e.g. in one hour). The device is switched to Pause mode for this purpose.

Drain used bath liquid, to do so:
Open the oscillating tank outlet.
While the liquid drains away, the interior walls of the bath should be rinsed with water using a hand spray or similar.

Close the outlet.
Approx. 25 litres of water without additional substances should be filled into the bath in order to be able to rinse the adapters and the tubes inside the device in the following rinsing procedure.
All adapters must be open and covered with liquid.



A unit disinfection with subsequent water rinsing should be performed following "mode 2" (cleaning without disinfection).
To do so: add a suitable disinfectant agent at the appropriate dosage for the water in the bath according to the manufacturer's specifications.

This unique "loop" is not conducted following modes 1 or 3.

A rinse is performed at the same time during the unit disinfection.
Following attainment of the prescribed exposure time of the disinfectant agent and 3 min rinsing time for all channels, the unit disinfection should be ended independently.
After 60 mins it ends automatically.

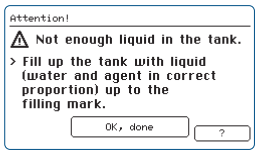
Drain the disinfectant solution, to do so:
Open the oscillating tank outlet.
While the liquid drains away, the interior walls of the bath should be rinsed with water using a hand spray or similar.

Close the outlet.
Approx. 25 litres of water without additional substances should be filled into the bath in order to rinse the adapters and the tubes inside the device in the subsequent rinsing procedure, thereby removing any disinfectant solution residue.
All adapters must be open and covered with liquid.

Draining the rinsing fluid, to do so:
Open the oscillating tank outlet.
While the liquid drains away, the interior walls of the bath should be rinsed with water using a hand spray or similar.
Pour out the adapters and then hang the adapters back in the comb bar.

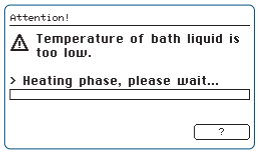
The filter should be exchanged after every shift to avoid becoming prematurely obstructed during reprocessing, see Section 4.3.

Error messages:



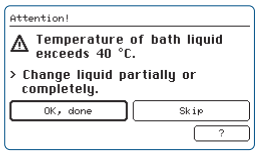
As a result of condensation or following several reprocessing treatments, the filling level may fall below the fill line and even below the filling level sensor.
This error message can be avoided by checking the filling level prior to the start of each reprocessing.
Dosed disinfection and cleaning liquid should be filled up.
The error is also displayed if the conductivity of the bath liquid is too low, see Section 6.3.

Numerous, heavily contaminated instruments can obstruct the filter
prematurely (prior to end of shift). Information on exchanging the filter can be found in Section 6.1.1.
The filter cartridge can be changed when the oscillating tank is filled. Wear disposable gloves when doing so.



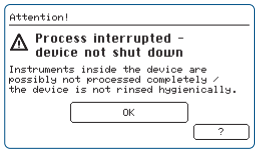
The temperature of the liquid is too low for an effective ultrasound effect and it is heated until it attains the minimum temperature (approx. 20°C).

Ultrasound and heating are turned on.
The program then continues automatically.



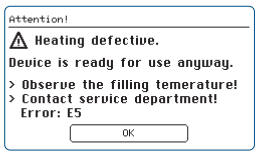
The liquid temperature is too high. Allow the liquid to cool down or exchange part or all of it. Then fill up with cold liquid (water and dosed agent).

Notes:
Protein coagulates starting at a temperature of >40°C. The message appears once this temperature is reached.
The working temperature should lie between 20 and 40°C.



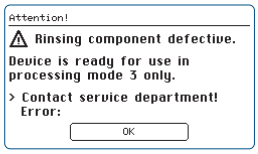
A power cut occurred or the mains switch was actuated during one of the processes (preparation, reprocessing, post-processing).

If instruments are present in the device, they must be treated again accordingly.
In other cases, it is recommended that the device be rinsed. To do so, the "Shutdown" key should be pressed in the subsequent main menu, and the subsequent question answered with "Yes".



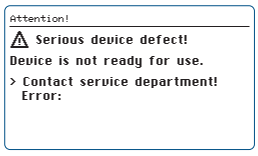
The heating is defective. The device can still be used nevertheless.
When filling the device, observe the filling temperature of 18-25°C.

Inform the Service department or manufacturer of the error, see Section 6.4.



One of the components required for rinsing is defective.
The device can now only be operated in mode 3 (simple sonication without rinsing function).

Inform the Service department or manufacturer of the error, see Section 6.4.

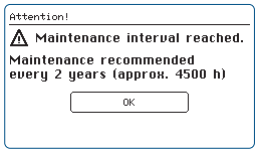


The device is defective and cannot be used further.

Contact the Service department or manufacturer, see Section 6.4.

Error codes and their meaning:

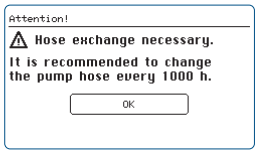
E1	Generator circuit board 1
E2	Generator circuit board 2
E3	Temperature board
E4	Relay circuit board
E5	Heating
E6	Flow rate sensor
E7	Pump
E8	Channel selector



The screen is displayed once the maintenance interval for the device has been attained (~4500 operating hours).

Perform maintenance, contact the Service department or manufacturer if necessary, see Section 6.1.

Following the maintenance, the screen is no longer displayed (until the next maintenance date).



After 1,000 operating hours for the pump, the screen is displayed for one additional operating hour.

Replace the pump hose, contact the Service department or manufacturer if necessary, see Section 6.1.