



# Operating instructions

# **SONOREX**

High-performance ultrasonic baths



#### Valid for:

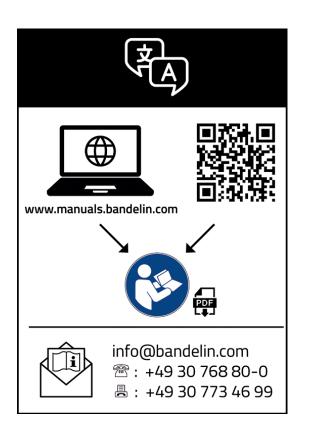
ZE 1031, ZE 1031 DT

ZE 1032, ZE 1032 DT

ZE 1058, ZE 1058 DT

ZE 1059, ZE 1059 DT





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Certified to ISO 9001 and ISO 13485



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# 1 About these operating instructions

These operating instructions contain information that is necessary and useful in order to use the device safely and efficiently.

- Read these operating instructions before using the device.
- Pay particular attention to section **2 Safety**.
- If you pass this device on to someone else, provide these operating instructions with it.
- Should these operating instructions leave any questions unanswered, please contact your specialist dealer or BANDELIN. Notes on service can be found in section **6.4 Repairs**.

In the event that the translation cannot be understood, the German original version of BANDELIN must be followed.

BANDELIN assumes no responsibility or liability for damage caused by improper handling or use.

Illustrations are exemplary and not to scale. Decorations not included with delivery.

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# 2 Safety

# 2.1 Using the device

You can use the device for the following applications:

- Ultrasonic cleaning of objects of various shapes, types and sizes
- Homogenisation, emulsification
- Rapidly degassing liquids
- Sonochemical applications, e.g., for generating radicals or for improved substance transport
- Preparing samples for analysis

A solution of water and a special agent for ultrasound application is used as the sonication fluid. Refer to chapter **5.2 Sonication fluid** for information on the sonication fluid. Goods to be treated may not be placed on the bottom of the ultrasonic oscillating tank. They must be placed in the sonication fluid in an insert basket or another suitable container. An overview of suitable accessories can be found in chapter **10 Accessories**. In the event of stains, discolouration, rust deposits or similar, special

detergents and indirect sonication can be used to ensure thorough cleaning.

The device must not be operated without supervision.

### 2.2 Use in medical field

The medical purpose of the device is to clean instruments. Ultrasonic cleaning is carried out as part of further necessary steps to reprocess medical devices. Please observe hygiene requirements in accordance with the applicable regulations. The device is a Class I medical device according to Regulation (EU) 2017/745.

EMDN nomenclature: Z12011302

### Indications/areas of application

Medical instruments can be cleaned in the device as part of manual reprocessing as well as before or after machine reprocessing. The specifications from the instrument manufacturer provide information about its suitability for ultrasonic cleaning.

#### Contraindications/exclusions

- Optical equipment, camera systems, light guides, mirrors or objects made from or with elastic materials (e.g., catheters, ventilator system functional parts, flexible endoscopes) are either not suitable or are only conditionally suitable for sonication. The specifications from the relevant manufacturer provide information about suitability for ultrasonic cleaning.
- The device is not suitable for cleaning and disinfecting contact lenses.
- Direct sonication of flammable liquids is not permitted.



#### Possible side effects/restrictions

- Ultrasound does not disinfect. However, processes such as chemical disinfection can be accelerated in the device.
- Surfaces can be mechanically attacked by cavitation erosion and coatings can be detached.

#### Intended users

The device may be used by persons who are qualified and have received instruction for their work, for example, in the reprocessing of instruments.

Being pregnant is not a contraindication to operating the device.

# 2.3 Obligation to report serious incidents

Report serious incidents to BANDELIN electronic GmbH und Co. KG and the competent authority.

### 2.4 Avoidance of cross-contamination and infections

If you use the device in the medical field, clean and disinfect the device's surfaces on a regular basis with a surface disinfectant which is at least bactericidal, levurocidal and, to a limited extent, virucidal disinfection agent to avoid cross-contamination. Prepare accessories such as holders, carriers or baskets in a washer-disinfector (WD).

At higher temperatures, vapours and aerosols contaminated with impurities from the goods to be treated may rise from the device. This can lead to infections and illnesses. When cleaning medical instruments, avoid bath temperatures above 40°C. If necessary, use a lid, an extraction system or protective equipment.

# 2.5 Keep away from children

Children may not detect hazards emanating from the device. Therefore, keep the device away from children.

### 2.6 Risk of electric shock

The device is an electrical device. Failure to follow safety rules can result in a life-threatening electric shock.

- Never let the device become wet. Keep the surface and operating elements clean and dry.
- Only empty the device when it is switched off.

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- Disconnect the device from the mains before any cleaning or maintenance.
- Only connect the device to a socket with an earthed protective contact that matches the protective contact of the device's plug.



#### WARNING

### Note for unit with type E+F jack:

Combination with socket type K (especially common in Denmark) is not permitted.

- If you discover a defect in the device, unplug it immediately. Do not connect a faulty device to the mains.
- Only have repairs carried out by the manufacturer. See chapter 6.4 Repairs.
- Position the ultrasonic bath so that it is possible to disconnect the mains connection without difficulty.

# 2.7 Damage to health due to ultrasonic noise

The typical ultrasonic noise produced during a procedure can be perceived as very unpleasant. Remaining within a radius of 2 m for a long period of time may cause you to suffer damage to your health.

- Wear suitable hearing protection.
- Use a lid to reduce noise.

## 2.8 Danger due to high temperatures

The device, the ultrasonic fluid and the goods to be treated may become hot during operation. Touching them may cause burns.

Ultrasound heats the sonication fluid even without additional heating. Very high temperatures can occur during prolonged ultrasound operation.

- Observe the treatment times recommended by the manufacturer of the ultrasonic agent. Do not leave the ultrasound on for longer than necessary.
- Do not reach into the sonication fluid by hand. Remove goods to be treated using the insert basket or forceps.
- Allow the goods to be treated to cool before touching them.

Non-aqueous liquids can heat up many times faster than water. A possible flashpoint can be reached and exceeded after a very short period of sonication. In the case of fluids with high boiling points, the bath temperature can rise to over 120 °C due to the energy supplied by the ultrasound.

This can lead to fires and severe burns.

• Do not use combustible, explosive or non-aqueous liquids (e.g., petrol, solvent) or mixtures with combustible liquids (e.g., alcoholic solutions) directly in the stainless steel ultrasonic oscillating tank.



Small amounts of combustible liquids in sample vessels can be indirectly sonicated.
 Before exposing combustible liquids to sonication, familiarise yourself with the necessary safety measures and applicable regulations when handling these liquids.

### 2.9 Danger due to ultrasound

Strong ultrasound, like that produced in the device, destroys cell structures. If a body part is immersed in the sonication fluid during operation, this can damage both the skin and the internal tissue.

The fingers' periosteum can become damaged.

- Do not reach into the sonication fluid during operation.
- Never expose living things to ultrasound.

## 2.10 Danger due to agents used

Agents used in the device can be toxic or corrosive. They can irritate eyes, skin and mucous membranes. The vapours and aerosols can also be dangerous.

- Wear gloves and goggles when handling dangerous agents.
- Do not ingest the agents and avoid bringing them into contact with eyes or skin. Avoid bending over very close to the device in order to avoid vapours coming into contact with your eyes or inhaling the vapours.
- Place a lid on the device during operation. In the event of dangerous vapours, use an extraction system.
- Observe the information on the label and in the safety data sheet of the agent.
- Keep agents away from children and untrained persons.

## 2.11 Disposing of sonication fluid

Dispose of the sonication fluid according to the instructions of the manufacturers of the ultrasonic agents used. The recommended ultrasonic agents belonging to the TICKOPUR, TICKOMED and STAMMOPUR product series from DR. H. STAMM GmbH are biodegradable in accordance with the provisions of Regulation (EC) No. 648/2004 (Detergents Regulation). If necessary, the sonication fluid must be neutralised before disposal.

Depending on the type of contamination, substances hazardous to water, e.g., oils or heavy metal compounds, may have been introduced into the sonication fluid during cleaning. If the limit values for these substances are exceeded, the sonication fluid must be treated or disposed of as hazardous waste.

Observe local sewage regulations.

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# 2.12 Erosion of the ultrasonic oscillating tank

The surface of the ultrasonic oscillating tank is subject to erosion. How quickly this erosion takes place depends on how the device is used. The erosion leads to leakage points in the oscillating tray. This allows bath liquid to enter the interior of the device. Moisture on electrical components can cause an electric shock or fire.

• Do not use the device if you notice a leak. Disconnect the mains plug immediately. Empty the ultrasonic oscillating tank.

You can extend the service life of the ultrasonic oscillating tank by observing the following information:

- Replace sonication fluid which is visibly contaminated by particles.
- Only use demineralised water (aqua purificata) with an ultrasound-compatible agent.
- Do not use chemicals that contain or release chloride ions in the ultrasonic oscillating tank. This is the case with some disinfectants, household cleaners and dishwashing detergents. Chloride ions cause corrosion on stainless steel.
- Only use the device with accessories that are suitable for the device and the goods to be treated, e.g., a basket. Do not place any goods to be treated on the bottom of the ultrasonic oscillating tank directly. An overview of suitable accessories can be found in chapter **10** Accessories.

# 2.13 Preventing damage to the device

- Only use aggressive agents in inset beakers or insert tubs. When working with aggressive agents, avoid splashing into the contact liquid or onto the stainless steel surface. Replace contaminated sonication fluid immediately. Clean surfaces and wipe them dry.
- Do not operate the device without sonication fluid in the ultrasonic oscillating tank. The fill level must be at or just above the filling level mark.

### 2.14 Interference with wireless communication

The device may interfere with wireless communication devices in close proximity, such as:

- Mobile phones
- Wi-Fi devices
- Bluetooth devices

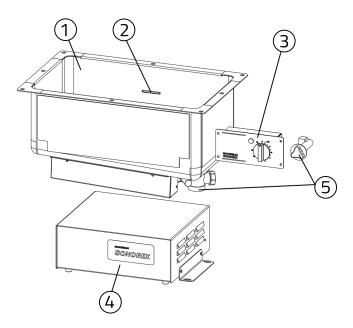
If a wireless device malfunctions, move it further away from the device.

The device complies with the requirements for Class B devices according to EN 55011.



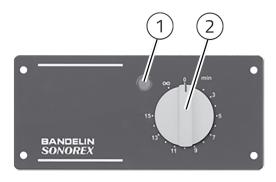
# 3 Design and function

# 3.1 Overview



- 1 Ultrasonic oscillating tank
- 2 Filling level marking
- 3 Control panel (depending on the model; control panel ST 15.1 or control panel ST 30.1 DT)
- 4 Ultrasonic generator
- 5 Outlet (optional; here, Viega fitting)

# 3.2 Control panel for control unit ST 15.1

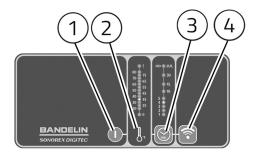


- 1 Green indicator light lighting up means: ultrasound is switched on
- 2 Turn knob for adjusting the sonication duration

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## 3.3 Control panel for control unit ST 30.1 DT



- 1 On/Off button to switch the device on/off
- 2 Temperature scale
- 3 Button for adjusting the sonication time with time scale
- 4 Start/Stop button for the ultrasound

### 3.4 Function

The device uses cavitation triggered by low-frequency ultrasound. Piezoelectric transducers are located on the underside of the ultrasonic oscillating tank. The ultrasonic generates strong pressure fluctuations in the sonication fluid. Cavitation bubbles are formed at the pressure minima. At higher ambient pressure around the bubbles, they collapse very quickly. This creates strong local micro-currents on the surfaces of the exposed objects. This removes contamination from the surface of the objects. Dirt particles are transported away and fresh sonication fluid flows in.

SONOREX devices use SweepTec®, a technology in which the ultrasonic frequency often changes based on the operating frequency. The optimal operating frequency depends on the load, fill level, temperature and type of sonication fluid. The operating frequency can deviate significantly from the nominal frequency. SweepTec® creates a particularly homogeneous ultrasonic field in the bath volume to ensure optimal results at all times.



# 4 Set-up/assembly

The device was assembled by authorised specialist personnel based on the assembly instructions.

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# 5 Operation

### 5.1 Direct and indirect sonication

Objects can be sonicated directly or indirectly in the device.

**Direct sonication** is the standard procedure. The goods to be treated are introduced into the ultrasonic oscillating tank with suitable accessories, e.g. a basket. There, they are in direct contact with the sonication fluid.

**Indirect sonication** is used in the following cases:

- Application of chemically aggressive or combustible liquids
- Application of deionised water without additives
- Removal of chemically aggressive contamination
- Removal of stains, discolouration and rust deposits with acidic agents

The objects or fluids to be sonicated are introduced into the contact liquid via an inset beaker to allow the ultrasound to be transmitted in the ultrasonic oscillating tank. The contact liquid in the ultrasonic oscillating tank must contain a surfactant agent.

For accessories suitable for direct and indirect sonication, see chapter 10 Accessories.

### 5.2 Sonication fluid

A solution made of water and a special ultrasonic agent is used as the sonication fluid. Drinking water or fully demineralised water (aqua purificata) can be used as water. Water without any additive is unsuitable for sonication. Use of aqua purificata without an ultrasonic agent will result in increased erosion of the ultrasonic oscillating tank. The ultrasonic agent used must be cavitation conducive, biodegradable, easy to dispose of, gentle to material and long-lasting. BANDELIN recommends ultrasonic agents belonging to the TICKOPUR, TICKOMED and STAMMOPUR product series from DR. H. STAMM GmbH.

- Telephone consultation: +49 30 76880-280
- Website: www.dr-stamm.de

Observe the instructions of the ultrasonic agent's manufacturer regarding dosing. The necessary amount of ultrasonic agent and water can be found in the dosage table.

10 I ready-to-use solution, 2.5%

Calculation of the agent:  $\frac{101 \times 2.5 \%}{100 \%} = 0.251$ 

Calculation of the water quantity: 10 I - 0.25 I = 9.75 I



### 5.3 Sonication time

#### **NOTICE**

### Danger of damage to the goods to be treated

Excessive sonication can damage the surface of the goods to be treated.

- Choose the shortest possible sonication time.

The optimal sonication time depends on a number of factors:

- Type and concentration of the agent
- Temperature of the sonication fluid
- Type of contamination
- Type of goods to be treated, especially materials

Observe the specifications of the agent's manufacturer for the recommended sonication time. At the start, choose the shortest possible sonication time to protect the goods to be treated and the ultrasonic oscillating tank. Check the result. Extend the sonication time if the result is insufficient.

### 5.4 Pour in sonication fluid



### **CAUTION**

### Risk of scalding!

- Do not fill the ultrasonic oscillating tank with hot water
- Maximum filling temperature: 50 °C

### **NOTICE**

### Damage due to condensate in the device

At high humidity, condensation forms inside the device when cold water is poured in.

Do not fill the ultrasonic oscillating tank with cold water at high humidity.

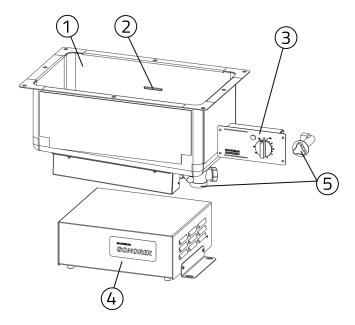
#### **NOTICE**

If you are using a powdered agent, do not put it directly into the ultrasonic oscillating tank.

- Mix a powdered agent in another container before placing it in the ultrasonic oscillating tank.
- Do not put the agent in the ultrasonic oscillating tank until it has dissolved completely.

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- 1 Ultrasonic oscillating tank
- 2 Filling level marking
- 3 Control panel (depending on the model; control panel ST 15.1 or control panel ST 30.1 DT)
- 4 Ultrasonic generator
- 5 Outlet (optional; here, Viega fitting)

### Requirements

- The process must be closed.
- Ultrasound must be switched off.

#### Procedure for direct sonication

- 1. Fill 1/3 of the ultrasonic oscillating tank with water.
- 2. Dose the agent for the sonication fluid into the ultrasonic oscillating tank. See chapter **9 Dosing table**.
- 3. Fill up to the filling level mark with water, avoiding foaming.

#### Procedure for indirect sonication

- 1. Fill 1/4 of the ultrasonic oscillating tank with water.
- 2. Dose the agent for the contact liquid into the ultrasonic oscillating tank. See also information on the insert tub.
- Fill with water, see also information on the insert tub.Take displacement through the insert tub into account. And avoid foaming.
- 4. The insert tub must be filled with the sonication fluid until it stops floating. The insert tub must also be filled at least until the objects to be treated are covered with sonication fluid.



#### Result

» The device is ready to be switched on.

# 5.5 Switching sonication on and off – ST 15.1

### Requirements

- The ultrasonic oscillating tank is filled.
- The mains plug is plugged into an earthed wall socket.

#### **Procedure**

- 1. If present, place the lid on the ultrasonic bath.
- Rotate the turning knob for the ultrasound duration to the desired duration or to the ∞ symbol for continuous operation.
  - » The ultrasound is switched on. The ultrasonic noise can be heard.
  - » The green indicator lamp lights up.
  - » If the turning knob is not set to ∞, it will move slowly in the anti-clockwise direction, indicating the remaining sonication duration. As soon as it reaches "0", the ultrasound will switch off.
- 3. To switch off sonication, rotate the turning knob for the ultrasound duration to "0".
  - » The green indicator lamp will go out.

### i Information

- You can rotate the turning knob in both directions.
- You can extend, shorten or switch off sonication at any time.
- The time switch only works when the device is connected to the mains voltage. Without mains voltage, it is difficult to feel when the turning knob is locked.

# 5.6 Switching sonication on and off – ST 30.1 DT

#### Requirements

- The ultrasonic oscillating tank is filled.
- The mains plug is plugged into an earthed wall socket.

#### **Procedure**

- 1. If present, place the lid on the device.
- Press the On/Off button to turn on the device.

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- 3. Press the button to configure the sonication time until you reach the desired sonication time or the ∞ symbol for continuous operation appears.
- 4. Press the Start/Stop button.
  - » The ultrasound is switched on. The ultrasonic noise can be heard.
  - » The LEDs display the remaining sonication time second by second.
- 5. To switch off sonication, press the Start/Stop button.

### i Information

- As soon as only the "0" LED lights up, the ultrasound will switch off automatically. In continuous operation, the green LED next to the ∞ symbol will remain lit up. The ultrasound does not switch off automatically.
- You can extend, shorten or switch off sonication at any time.
- If no button has been pressed for more than 12 hours, the device will switch off automatically.
- The temperature cannot be configured. However, the current temperature is indicated by a yellow LED.
- The red "!" LED will flash if the temperature exceeds 40 °C.

# 5.7 Degassing sonication fluid

Sonication fluid that has been freshly poured in or that has remained in the ultrasonic oscillating tank for a longer period of time must be degassed before use. Degassing the sonication fluid increases the effect of the ultrasound.

- Cover the ultrasonic oscillating tank with the lid, if present.
- To degas, switch on the ultrasound. The degassing time is:
  - Sonication fluid volume up to 10 litres:
     10 minutes
  - Sonication fluid volume over 10 litres:
    30 minutes

# i Information

During degassing, the ultrasonic noise becomes quieter. This means that the ultrasound effect is increasing.



## 5.8 Adding goods to be treated

To achieve a good result, observe the following information when adding goods to be treated:

- Before each sonication process, check to ensure the sonication fluid is not contaminated. If there is visible contamination, replace the sonication fluid.
- The sonication fluid must be degassed. See chapter **5.7 Degassing sonication fluid**.
- The sonication fluid must be preheated to the desired temperature before you insert objects.
- Use suitable accessories, such as a basket. Do not place objects on the bottom of the ultrasonic oscillating tank directly. For sensitive objects, use a silicone base pad. See chapter 10 Accessories.
- Insert objects and spread them out. Do not stack them. Sensitive objects must not touch other objects.
- The ultrasound must be switched off while inserting objects.
- Check the filling level. Goods to be treated must be completely covered with liquid. Inset beakers for indirect sonication must be immersed at least 2 cm below the surface of the contact liquid.
- Remove air bubbles from cavities. Rotate the objects accordingly. Remove air bubbles under inset beakers. The ultrasound is only effective where liquid is in contact with the goods to be treated or the inset beaker.
- Place the more contaminated side downwards. Insert objects with joints (e.g., scissors, tongs) in an open state so that the sonication fluid is able to cover the entire surface optimally.
- Distribute the instruments in the insert basket.
   Do not overload the insert basket.
   Make sure that the instruments are open and disassembled if applicable.

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### 5.9 Removing goods to be treated



#### **WARNING**

#### Risk of burns

The sonication fluid, goods to be treated, the surface of the device and accessories can be very hot.

- Do not touch the surface of the device or accessories such as the lid. Do not reach into the sonication fluid.
- Allow the goods to be treated to cool before touching them.

Switch off the ultrasound before removing goods to be treated.

Do not remove goods to be treated by hand. Carefully remove, for example, the insert basket containing the goods to be treated and place it on a flat surface.

Rinse the goods to be treated with clear water.

Do not leave goods to be treated in the sonication fluid for too long. This can damage the objects.

# 5.10 Emptying the ultrasonic oscillating tank

Contamination on the bottom of the ultrasonic oscillating tank reduces the power of the ultrasound.

If the sonication fluid is visibly contaminated, empty and clean the ultrasonic oscillating tank. Observe the information provided by the manufacturer of the agent on the service life of the sonication fluid.

Fully replace used sonication fluid. Do not replenish it by topping up the dose.

#### Procedure

- 1. Switch off the ultrasound.
- 2. Open the outlet.
- 3. Rinse the ultrasonic oscillating tank thoroughly.
- 4. Wipe the device dry with a soft cloth.
- 5. If necessary, disinfect the device with a suitable surface disinfectant.



# 5.11 Enabling and disabling continuous operation – ST 30.1 DT

To avoid continuous operation being accidentally switched on, you can lock this function.

### Requirement

• The mains plug is unplugged.

#### **Procedure**

Press and hold the button to adjust the sonication time. At the same time, plug the mains plug into the mains socket.

» The yellow "1 min" LED will light up.



### Information

You can enable continuous operation in the same way. The green LED next to the ∞ symbol will light up to confirm this.

# 5.12 Troubleshooting

#### Malfunctions

Error	Possible causes	Troubleshooting
Ultrasound effect too low, loud noises	<ul> <li>Sonication fluid contains gases</li> <li>There are too many goods to be treated in the ultra- sonic oscillating tank</li> </ul>	<ul> <li>Degassing the sonication fluid; see chapter</li> <li>5.7 Degassing sonication fluid</li> <li>Reduce the number of goods to be treated</li> </ul>
Unsteady noises (wobbling)	<ul> <li>Incorrect filling level in the ultrasonic oscillating tank</li> </ul>	<ul> <li>Slightly change the fill level of the sonication fluid in the ultrasonic oscillating tank Pay attention to the minimum filling level and correct dosing of the agent.</li> <li>Vary the position of the goods to be treated</li> </ul>

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### 6 Maintenance

# 6.1 Cleaning and caring for the device

### Cleaning the housing of the ultrasonic generator

- Wipe the housing with a damp cloth. Wipe it dry with a soft cloth.
- Do not use abrasive cleaning agents; only use care products free from abrasive additives.
- If necessary, disinfect the housing with a suitable surface disinfectant.

### Caring for the ultrasonic oscillating tank

Impurities in the ultrasonic oscillating tank accelerate its wear, can lead to corrosion and reduce the ultrasonic effect. Please therefore observe the following information:

- Rinse the ultrasonic oscillating tank thoroughly with water after each use. Wipe it dry with a soft cloth.
- Remove edges and residues with a stainless steel cleaning product free from abrasive additives.
- Do not use steel wool, scratches or scrapers to clean the ultrasonic oscillating tank.
- Metal parts and rust particles in the ultrasonic oscillating tank cause corrosion. Please therefore avoid leaving any metal parts in the ultrasonic oscillating tank. If rust stains are visible, remove them immediately with a soft cloth and a stainless steel cleaning product without abrasive additives.

# 6.2 Testing

#### **NOTICE**

### Damage to the device

- Only carry out checks on the device when it is filled.

If one of the tests does not lead to the desired result, contact the service team. See chapter **6.4 Repairs**.



### Checking indicator lamp - ST 15.1

Check the function of the indicator lamp.

- Briefly switch on the ultrasound.
  - » The green indicator lamp will remain on as long as the ultrasound is switched on.

### Checking indicator lamp - ST 30.1 DT

### Requirement

• The device must be switched off.

#### **Procedure**

- 1. Press and hold the Start/Stop button and press the On/Off button.
  - » All LEDs will light up briefly one after the other. Then all LEDs will light up at the same time.
- 2. Press the Start/Stop button twice.
  - » The most recently configured sonication time will then be displayed again on the time scale. The "O" LED will light up on the temperature scale (if present).
  - » The device is ready for use again.

### Checking the power to the ultrasound

The power can be checked with a wattmeter between the mains plug of the device and the socket.

#### **Procedure**

- 1. Fill the ultrasonic oscillating tank with water.
- 2. Switch on the ultrasound. Take the power reading. Switch off the ultrasound again.
- 3. Compare the readings with the technical data. See chapter 8 Device information.

The measured values may deviate from the values in the technical data by no more than ± 20%.

### Checking ultrasonic effect

Check the effect of the ultrasound during set-up and at regular intervals. Testing is recommended every 3 months.

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# 6.3 Performing the foil test

A foil test should be carried out before first use and at regular intervals, e.g., every 3 months. This serves to ensure a consistent effect on the part of the ultrasound. You are responsible for how often this test is performed.

The foil test is a simple method for displaying the intensity and distribution of cavitation in a device. This done by inserting aluminium foil stretched over a foil test frame. Depending on the duration of sonication, this is perforated or destroyed to a certain extent by cavitation.

In order to be able to compare results, it is **important that the conditions of the foil test are** always the same:

- Filling the ultrasonic oscillating tank up to the filling level mark
- Temperature of the sonication fluid
- Duration of degassing
- Positioning of the frame
- Foil type (brand, thickness)
- Sonication time
- Type and concentration of the ultrasonic agent

### Liquid for the foil test

In order to obtain sufficiently strong cavitation, the boundary surface tension of the water used must also be reduced for the foil test with the help of 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 agents are available, a neutral or mildly alkaline, non-aluminium-destroying agent should be used. The agent must be approved by the manufacturer for use in a device.



#### Test result and documentation

While always maintaining the same test conditions, the test result must be assessed based on the perforated area of the foils. The perforated areas of the foils should always have approximately the same spread and distribution – they are never congruent. A constant process check, e.g. when reprocessing medical devices, is only possible with regular foil tests.

You can download a documentation template here for documenting the test results:

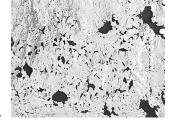
https://bandelin.com/folientest/ You will also find an application video there.



The foils can also be archived in a suitable way (scan, photo, etc.). This makes it possible to compare the foils at any time.

#### Performance of the foil test

- 1. Fill the ultrasonic oscillating tank with water and a suitable ultrasonic agent in the dosage specified by the manufacturer up to the filling level mark.
- Degas the sonication fluid.See chapter 5.7 Degassing sonication fluid.
- 3. Tension the aluminium foil (household foil 10 µm to 25 µm thick) on the foil test frame. Depending on the size of the tank, the frame may protrude. It is sufficient to cover the part of the foil test frame that is covered by the sonication fluid.
- 4. Place the covered foil test frame diagonally in the middle of the ultrasonic oscillating tank. If necessary, fix it in place.
- 5. Switch on the ultrasound. Sonicate the foil for at least 1 minute until visible perforation or pitting occurs. For more stable foils (thicker or coated), the sonication time can be up to 3 minutes.
- 6. Switch off the ultrasound. Take out the foil test frame. Remove the aluminium foil from the foil test frame and allow it to dry.
- The foil must be perforated, see picture. Otherwise, we recommend having the unit checked by the service team of BANDELIN electronic GmbH & Co. KG: See chapter 6.4 Repairs.
- 8. Archive the foil with the test date and serial number of the device. The documentation template for the foil test can also be filled in and archived.
- 9. Rinse the ultrasonic oscillating tank thoroughly to remove loose foil particles.



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Suitable foil test frames can be ordered from BANDELIN electronic GmbH & Co. KG. The foil test frames are designed for a wide range of tank dimensions. Aluminium foil is also required for the test procedure; this is not included in the scope of delivery.

Туре	Ord. no.	for
FT 36	3673	ZE 1031/1032/ DT
FT 37	3674	ZE 1058/1059/ DT



### 6.4 Repairs

Contact the specialist dealer or the manufacturer during the warranty period.

Only have repairs carried out by qualified personnel authorised by the manufacturer or by the manufacturer itself.

The manufacturer assumes no liability for unauthorised interventions on the device.



### **WARNING**

#### Health hazard due to contaminated device

- Decontaminate the device before shipping if it has come into contact with hazardous substances.

If the device needs to be repaired, send it to the manufacturer.

Clean the device before sending it.

Decontaminate the device if it has come into contact with toxic, corrosive, radioactive or biohazardous substances. Clean and decontaminate the accessories you send.

Download the "decontamination certificate" form here:

https://www.bandelin.com/downloads



Fill out the form and attach it so as to be clearly visible on the outside of the packaging. Acceptance will be refused without a completed form.

Send the unit to the following address:

BANDELIN electronic GmbH & Co. KG Heinrichstr. 3–4 12207 Berlin Germany

+49 30 76880-2674 service@bandelin.com

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# 7 Disposal



### **WARNING**

#### Health hazard due to contaminated device

- Decontaminate the device before disposal if it has come into contact with hazardous substances.
- Also decontaminate accessories before disposal.

Dispose of the device properly as electrical waste if it can no longer be used. Do not dispose of the device in the household waste. Observe local regulations for the disposal of electrical waste.

The oscillating elements contain sintered ceramics made of lead zirconium titanate.

- EC no. 235-727-4
- CAS no. 12626-81-2

This use is permitted in accordance with RoHS Directive 2011/65/EU, Annex III, Exception 7c. l.

Dispose of accessories as metal scrap or as plastic waste according to the material used.



# 8 Device information

# 8.1 Technical data

### Ultrasonic generator

Operating voltage:  $230 \text{ V} \sim (\pm 10\%) 50/60 \text{ Hz}$   $115 \text{ V} \sim (\pm 10\%) 50/60 \text{ Hz}$ 

Protection class:

Degree of protection: IP 20

Ultrasonic frequency: 35 kHz

Ultrasonic bath	Туре	Ultrasonic peak power/ Rated power	Current consumption		Fuse	
			230 V	115 V	230 V	115 V
		[W]	[A]			
ZE 1031/DT	GT 503 M-C	1200/300	1.4	2.8	F2A	F4A
ZE 1032/DT	GT 504 M-C	1760/440	2.0	4.0	F2A	F4A
ZE 1058/DT	GT 1003 M-C	2400/600	2.7	5.4	F4A	F8A
ZE 1059/DT	GT 1003 M-C	2400/600	2.7	5.4	F4A	F8A

### Dimensions and weights – ultrasonic generator

Ultrasonic bath	Туре	External dimensions (L x W x H)	Weight
		[mm]	[kg]
ZE 1031/DT	GT 503 M-C	360 × 310 × 142	3.5
ZE 1032/DT	GT 504 M-C	360 × 310 × 142	3.5
ZE 1058/DT	GT 1003 M-C	360 × 310 × 142	3.6
ZE 1059/DT	GT 1003 M-C	360 × 310 × 142	3.6

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### Dimensions and material – ultrasonic oscillating tank

Cable: 2 m long, AMP CPC plug

Degree of protection: IP 30

Material: Stainless steel, 2 mm, welded

Outlet: Bead 1 1/2"

Ultrasonic bath	Туре	Internal dimensions (L x W x H)	Operating volume	External dimensions (L x W x H)
		[mm]	[1]	[mm]
ZE 1031/DT	TE 1031	510 × 300 × 200/220	20	570 × 360 × 270/290
ZE 1032/DT	TE 1032	510 × 300 × 200/220	20	570 × 404 × 270/290
ZE 1058/DT	TE 1058.2	600 × 400 × 200/220	32	660 × 460 × 270/290
ZE 1059/DT	TE 1059	600 × 400 × 200/220	32	660 × 504 × 270/290

The TE 1032 and TE 1059 ultrasonic oscillating tanks have piezoelectric oscillating systems on the underside as well as on one side.

### Dimensions and material – rinsing tank

For each ultrasonic oscillating tank, there is a rinsing tank of the same size, with no piezoelectric oscillating systems.

Material: Stainless steel, 2 mm, welded

Outlet: Bead 1 1/2"

Suitable for ultrasonic bath	Rinsing tank Type	Internal dimensions (L x W x H)	Operating volume	External dimensions (L x W x H)
		[mm]	[1]	[mm]
ZE 1031/DT	SW 31 Z	510 × 300 × 200/220	20	570 × 360 × 205/225
ZE 1032/DT	SW 31 Z	510 × 300 × 200/220	20	570 × 360 × 205/225
ZE 1058/DT	SW 58 Z	600 × 400 × 200/220	32	660 × 460 × 205/225
ZE 1059/DT	SW 58 Z	600 × 400 × 200/220	32	660 × 460 × 205/225

The technical data of the SONOBOARD standard correspond to those of the ZE 1058 DT, which is delivered already pre-installed in a functional cabinet ready for operation.



#### Control unit ST 15.1

Time switch: 1 to 15 min. and continuous operation

Fuse: G 5×20 6.3 A, medium time-lag

Degree of protection: IP 30

Connections: 2-m-long mains cable for mains connection (mains plug)

2-m-long mains cable for connection to the ultrasonic generator

(mains plug)

#### Control unit ST 30.1 DT

Digital time switch: 1, 2, 3, 4, 5, 10, 15, 30 min., continuous operation, temperature display

Fuse: G 5×20 6.3 A, medium time-lag

Degree of protection: IP 30

Connections: 2-m-long mains cable for mains connection (mains plug)

2-m-long mains cable for connection to the ultrasonic generator

(mains plug)

1 × temperature sensor socket (incl. temperature sensor with 2-m cable)

### 8.2 Ambient conditions

Overvoltage category:

Degree of contamination: 2

Permissible ambient temperature: 5... 40 °C

Permissible relative humidity up to 31 °C: 80% (non-condensing)

Permissible relative humidity up to 40 °C: 50% (non-condensing)

Altitude: < 2000 m above sea level

For indoor operation only

# 8.3 CE conformity

The device is a medical device and fulfils the CE marking criteria of the European Union:

- 2017/745/EU MDR
- 2011/65/EU RoHS Directive

The declaration of conformity can be requested from the manufacturer, stating the serial number.

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# 9 Dosing table

		Disinfection and intensive cleaning	Cleaning	Thorough clean- ing <sup>/1</sup>
		<b>Directly</b> oscillati	•	<b>Indirectly</b> in the oscillating tank
		STAMMOPUR DR 8	STAMMOPUR R	STAMMOPUR GR
		2%	2%	5%
Disinfection and cleaning time	[min]	5	3 – 10	2 – 15
Application temperature	[°C]	max. 40	20 – 60	50 – 60
TE 1031/TE 1032				
Filling quantity up to the filling level mark	[1]	20.0	20.0	15.0
Concentrate	[ml]	400	400	750
Water	[1]	19.6	19.6	14.2
TE 1058/TE 1059				
Filling quantity up to the filling level mark	[1]	32.0	32.0	-
Concentrate	[ml]	640	640	-
Water	[1]	31.3	31.4	-
Ordering information				
Order number	2 litres	972	934	938
Order number	51	974	989	969
Order number	10	6028	6029	6031

Please note the product information attached to the cleaning agents used and the instructions for use, dosage and treatment time.

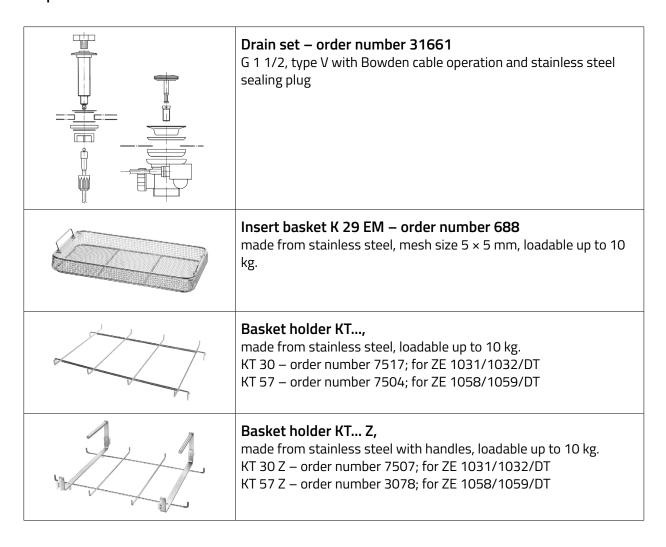
<sup>/1/</sup> Filling volume up to the filling level mark:

Recommended filling quantity in the plastic insert tub = until the tub no longer floats in the contact liquid of the ultrasonic oscillating tank. Make sure that the goods to be treated are completely covered with sonication fluid in the tank.



### 10 Accessories

### Required accessories



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# Optional accessories

<b>Lid D,</b> D 30 – order number 7522; for ZE 1031/1032/DT D 57 – order number 7520; for ZE 1058/1059/DT
Lid D 1031 G – order number 3229 for ZE 1031/1032/DT with gas spring and EPDM gasket Lid D 1058 G – order number 3232 for ZE 1058/1059/DT with gas spring and EPDM gasket
Silicone base pad SM 29 – order number 178 for K 29 EM For use in baskets, for gentle and contact-free cleaning of sensitive parts, such as micro-instruments
Fixing clamps FE 12 – order number 117 A set of 2 large and 5 small clamps for fixing flexible goods to be treated to the bottom of the basket
Insert tub CW 28-0 – order number 717 made from plastic with lid suitable for ZE 1031/DT and ZE 1032/DT
Foil test frame FT made from stainless steel FT 36 – order number 3673; for ZE 1031/1032/DT FT 37 – order number 3674; for ZE 1058/1059/DT



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