

## BactoSonic®

Ultrasonic special bath for the gentle removal of biofilms



Ultrasonic bath BS 14

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## General

The equipment, the accessories and the preparations are to be used in accordance with the user 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.










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

The warnings and safety precautions (chapter 1.5) 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 expire.

If Service is required, please contact the specialist dealer in charge or the manufacturer.

### Symbols used:

Symbol	Significance	Explanation
	Danger	Identifies information that, if not observed, could signify a risk to life and limb, especially as a result of electric shock.
	Caution	Identifies information that is to be observed and adhered to without fail, to prevent damage to the device and danger to the user.
	Warning	Warning of hot surface
	Important	Identifies information that is important for execution.
	Note	Identifies information provided for explanatory purposes.
	In vitro diagnostics information	Identifies information that is important for in vitro diagnostics applications.
	Do not grip inside	For health reasons, touching the oscillating fluid is prohibited.
	Wear ear protectors	For health reasons, standing for long periods of time in the vicinity of the device without ear protectors is prohibited.
	Operating sequence instructions	Identifies instructions that are to be followed in the described sequence.

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# 1 Product description

Power-reduced "BactoSonic" ultrasound special bath with diverse implant boxes, box holders and other accessories. The type specification and serial number are found on the type plate on the rear side of the ultrasonic bath.

## Product features:

- Stainless steel oscillating tank (1) with high-grade PZT high-performance ultrasonic systems, ultrasound frequency 40 kHz
- Time switch for 1-15 min and continuous operation (2)
- Power selection switch (3) for 20-100%
- Filling level mark for safe filling (4)
- Compact, easy-to-clean stainless steel housing (5)
- Rubber feet for safe positioning (6)
- With ball valve (7) for easy draining of the bath fluid and handles (8)



## 1.1 Mode of operation

BactoSonic ultrasonic baths use the effect of cavitation. Under their oscillating tank bottoms they contain piezoelectric transducers, the energy of which is transferred to the bath fluid with ultrasound frequency as mechanical oscillations. As a result, microscopically small bubbles are continuously formed in the bath fluid, which release energy upon imploding and generate local micro currents. This process is called cavitation.

Compared to other ultrasonic baths, sonication in the BactoSonic is conducted using low-frequency ultrasound at low intensity within the cavitation threshold range. In doing so, the adhesiveness of the biofilm to the implant surface is altered by active micro currents, shear forces and oscillating cavitation bubbles to such an extent that it detaches. Resulting cavitation events possess so little energy, however, that they do not cause any significant damage to cell structures and the microorganisms released are available for the subsequent analysis.

BactoSonic ultrasonic baths are efficiently supported by SweepTec® automatic frequency control. SweepTec® immediately balances load-dependent working point fluctuations to the optimal working point using fast frequency modulation. This produces an especially homogeneous and uniform ultrasound field in the bath volume for constantly reproducible results.

## 1.2 Purpose

### Gentle separation of biofilms (main application)

The BactoSonic ultrasonic bath may be used to detach biofilms gently from the surface of infected implants, as part of the scientifically-funded "Processing of implants using sonication methods". The microorganisms that are obtained in this manner are available for analysis following cultivation and make a prompt differential diagnosis possible in the event of implant infections.



In this connection, the ultrasonic bath is classified in accordance with Directive 98/79/EC **on medical devices as an in vitro diagnostic device** and is to be treated as such.

Sonication is always carried out in connection with a suitable preparation that is added to the bath liquid. In order to use the device as intended, the implant boxes and box holders supplied are further needed to collect the implants and place them in the oscillating tank during sonication (indirect sonication). Only in this manner is the optimum diffusion of the ultrasound guaranteed. The ultrasonic bath is operated from the front. The operation is usually carried out on a table.

### Further possible applications.

As an alternative to its main application, the BactoSonic ultrasonic bath may also be used for the gentle and intensive cleaning of objects of diverse shapes, types and sizes and to support chemical processes, e.g., during the preparation and treatment of samples. Accessories additional to those included in the scope of supply may be required, depending on the application, to guarantee proper sonication.



### Caution

The user is fully responsible for the employment of suitable treatment and lab processes together with the BactoSonic.

## 1.3 CE conformity

Ultrasonic baths are declared as IVD products and satisfy the CE marking criteria for the European Directives:

- "IVD" directive
- "Low-voltage directive"
- "Electromagnetic compatibility" directive

in their currently valid versions.

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

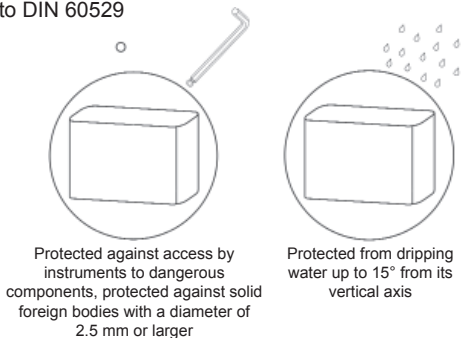
## 1.4 Technical data

Ultrasonic baths are interference-free and CE -marked.

Safety: EN 61010-1,

EMC: EN 61326-1

Serial number (SN):	see type plate on the rear side
Oscillating tank:	Stainless steel
Interior dimensions:	325 × 300 × 150 mm (L × W × D)
Working fill capacity:	9.5 L
Outlet:	G ½ (valve)
Ultrasonic peak power <sup>1/</sup> :	800 W
Frequency	40 kHz
Ultrasonic nominal output:	200 W <sub>eff</sub>
Power selection switch:	adjustable to 20, 40, 60, 80 and 100%
Mains supply:	230 V~ (± 10 %) 50/60 Hz, (115 V upon request), mains cable length 2 m
Current consumption:	0.9 A
Fuses:	F3, 15A
Weight (net):	14 kg
Protection class:	Class I
Degree of protection:	IP 32 according to DIN 60529



<sup>1/</sup> In order to improve the effect, the ultrasound is modulated whereby, depending upon the ultrasonic bath, a 4-fold -ultrasonic nominal output value is yielded as ultrasonic peak power.



### **Ambient conditions according to EN 61 010-1**

Overvoltage category:	II
Degree of contamination:	2
Permissible ambient temperature:	5 to 40°C
Permissible relative humidity up to 31°C:	80%
Permissible relative humidity up to 40°C:	50%
No dewing.	
Only for indoor operation.	

#### **1.4.1 Electromagnetic ambient conditions (EMC)**

The device was tested to DIN EN 61326-1 for electromagnetic compatibility (EMC) and complies with the requirements for class B devices according to EN 55011.  
It is suitable for use in facilities and areas which are directly connected to a public low-voltage supply network, e.g. medical laboratory facilities.

## 1.5 Warning and safety precautions

### General

- Keep the ultrasonic bath out of the reach of children and of 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 treated, 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.
- Move the ultrasonic bath only when it is empty.
- Empty the ultrasonic bath only while turned off.
- Ultrasonic baths adhere to prescribed EMC limit values, such that it can be assumed that the electromagnetic radiation emanating from the units is harmless to humans. However, 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 is to be obtained from the implant manufacturer.

### Operation

- Observe ambient and set-up conditions, see chapter 1.4.
- Only plug in the ultrasonic bath to an outlet with a grounded socket.
- Do not operate the ultrasonic bath without fluids.
- Do not stand or lay any objects on the tank bottom, accessories must be used, see chapter 7.
- Do not immerse any parts of the body (e.g., hands, feet) or living beings (animals or plants) into the tank; in particular, do not immerse them in the bath fluid during ultrasound operation.  
Danger: Ultrasounds have a cell-destroying effect.
- In the event of continuous activity within a 2 m radius, adequate hearing protection must be worn. Danger: Hearing disturbances during operation when not wearing hearing protection – the typical ultrasound cavitation noise can be very uncomfortable.
- Do not leave the ultrasonic bath running while unattended.



### Damages

- If damage to the ultrasonic bath is detected, do not connect the ultrasonic bath to the mains.
- In the event of defect, disconnect the mains plug immediately.
- Repairs are only to 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 damages. If any damages or defects are found, these are to be immediately notified in writing to the transportation company and to the supplier.

Before startup, the ultrasonic bath is to be left to stand at its operating location for 2 hours so that it may adapt to the ambient conditions.

### 2.1 Scope of delivery

- 1 Ultrasonic bath – see delivery note
- 1 Ball valve with hose, packaged separately with sealing tape and assembly instructions
- 1 User instructions
- 2 Implant boxes IB 5 (# 3208) compatible with 1 Box holder BT 5 (# 3296)
- 2 Implant boxes IB 6 (# 3219) compatible with 1 Box holder BT 6 (# 3252)
- 1 Implant box IB 10 (# 3244) compatible with 1 Box holder BT 10 (# 3254)
- 1 Implant box IB 18 (# 3227) compatible with 1 Box holder BT 18 (# 3263)
- 1 Implant box IB 20 (# 3237) compatible with 1 Utensil holder GH 14 (# 291)
- 1 Bottle (250 ml) TICKOPUR R 33 and
- 1 Foil test frame FT 14 (# 3084)

Additional accessories according to order – see delivery note



#### **IMPORTANT!**

All accessories are provided with non-sterile packing!

### 2.2 Set-up / assembly

- Place the ultrasonic bath atop a firm, level and dry surface. In doing so,
  - observe the maximum weight of the ultrasonic bath, including fluid.  
Net weight, see technical data chapter 1.4.



- Do not block the air supply below the ultrasonic bath.
  - Guard against moisture and wetness – risk of electric shock.
- Install the ball valve, hose socket and hose, which are included in the delivery, pursuant to the enclosed assembly instructions.

2.3 Start-up

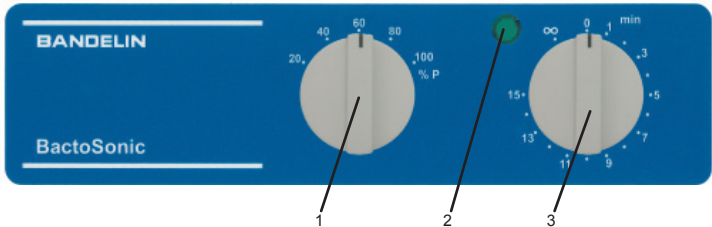


- Thoroughly rinse the ultrasonic bath's oscillating tank with water before its first use.  
Implant boxes:  
Prior to initial usage and when reprocessing, the implant boxes are to be prepared according to the instructions attached!
- Verify that the operating button on the right-hand side is in the "off" position, then connect the ultrasonic bath to the mains (grounded socket).
- Conduct function test – briefly plug in the ultrasound (maximum of 1 to 2 seconds), a hissing noise should be heard. Then switch device 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 appendix for information.
- If applicable, hang accessories in the ultrasonic bath and place lid on top.

3 Operation

3.1 Operating elements

The ultrasound and the power are operated from the front:

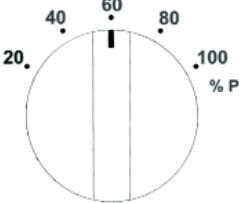


- 1 Power control knob (power selection switch)
- 2 Green control light (ultrasound in operation)
- 3 Turning knob for ultrasound ON / OFF with preset time

3.1.1 Power selection switch

The power is controlled through the integrated power selection switch.

Adjustable power settings	20% P	= 40 W
	40% P	= 80 W
	60% P	= 120 W
	80% P	= 160 W
	100% P	= 200 W
HF power		max. 200 W <sub>eff</sub>



Note

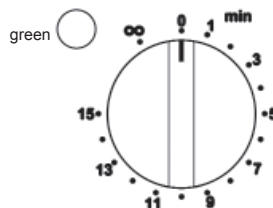
- For foil tests, for degassing and cleaning, etc., of the bath fluid, the power selection switch must be set to 100% P.

### 3.1.2 Ultrasound

The ultrasound is operated through the turning knob (time switch).

#### Timed operation:

- Turn knob to the right → range of time 1 - 15 minutes
  - Green control light flashes.
  - Once the time has elapsed, the time switch will automatically turn off.
- By turning the knob back, the operating time will be shortened, i.e. the ultrasonic bath will be turned off.



#### Continuous operation:

- Turn knob to the left → Setting ∞
  - Green control light flashes.
  - The ultrasonic bath will not turn off automatically, to switch it off turn the knob right, back to "0".



#### Notes

- While turned off, the ultrasonic bath may remain connected to the mains. It can be disconnected from the mains by pulling the mains plug out.
- An "engaging" of the time switch is barely felt if mains voltage is not present, e.g. if the mains plug is disconnected or the fuse is blown. The time switch only works if mains voltage is present.

### 3.2 Ultrasound signals - not applicable -

### 3.3 Miscellaneous functions - not applicable -

## 4 Use

The correct handling of the ultrasonic bath is described in the following. The process for sonication of implants is to be conducted in accordance with the enclosed, scientifically-based "Diagnostics of implant infections via sonication" process instructions. These also include bibliographical references to such processes.

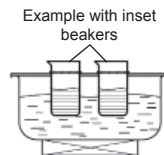
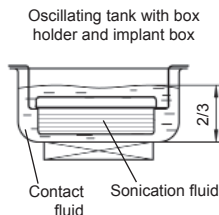
The preparation of the implant boxes is to be conducted pursuant to the enclosed "Implant boxes" preparation instructions.

For additional instructions and queries regarding this process, please send an E-mail to [info@bactosonic.com](mailto:info@bactosonic.com).

Depending on the application, the implants are sonicated **indirectly** in the implant boxes supplied or in other sample vessels, which are positioned in special holders in the contact liquid within the oscillating tank, in order to detach the biofilms.

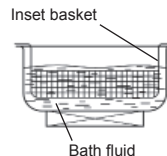
**Indirect** sonication in inset beakers is to be additionally conducted for special applications:

- Sonication of sample fluids.
- Use of chemically aggressive fluids (e.g., using acids as cleaning agents).
- Removal of chemically aggressive soiling (e.g., cleaning of developing machine racks).
- Removal of abrasive soiling (e.g., polishing pastes, quartz, sand).



### Remarks on direct sonication

For all other applications, sonication may be conducted directly. For this purpose, the objects to be treated are placed in a basket and hung inside the oscillating tank which is filled with bath liquid.



## 4.1 Instructions for use

### Instructions - filling

- Verify that the ball valve is closed.
- The ultrasound must be turned off.
- Do not fill oscillating tank with hot water. Maximum filling temperature: 50°C.
- Water of at least drinking quality must be used to fill the oscillating tank.
- Water without additives is not suited for sonication. BANDELIN recommends the TICKOPUR or STAMMOPUR preparations.
- Only use distilled or deionised water without additives in inset beakers or insert tubs.
- The fill level must always be at or slightly above the filling level mark.  
A low fill level will damage the ultrasonic bath!
- Do not use any combustible fluids (e.g., benzine, solvents) or chemicals that contain chloride ions or that separate (some disinfection agents, household cleaners and dish detergents) for sonication in the stainless steel tank.
- When working with aggressive preparations in inset beakers or insert tubs: Prevent the contact fluid or stainless steel surfaces from being sprayed. If necessary, replace the contact fluid, clean the surfaces and wipe dry.
- When using preparations, the safety instructions included in the respective product leaflets are fundamentally to be adhered to.
- Replace used sonication fluids, do not refresh them by adding more fluids.



### Notes - Inserting objects

- Fully remove air bubbles from cavities (e.g., blind holes).

#### Indirect sonication

Fully remove possible air bubbles from underneath the vessels.



### Notes - Temperature

- Warmed-up fluids intensify the ultrasound effect.  
Experience has shown that the best results are obtained with a bath temperature of 50 bis 60 °C. At higher temperatures, the effect of the ultrasound cavitation decreases, however<sup>/2</sup>.
- Ultrasound energy warms up the bath fluid (even without additional heating). The temperature of the bath fluid can increase rapidly if the ultrasound is active for long periods of time and/or the oscillating tank is covered.  
Therefore, control the temperature when treating temperature-sensitive components.
- To protect the electronic components inside the ultrasonic bath, the ultrasound output is reduced upon reaching a critical temperature in order to inhibit a further increase in the interior temperature.
- The fluid in the oscillating tank must not exceed a maximum operating temperature of 100°C.

## 4.2 General application

### Step 1: Fill oscillating tank

The oscillating tank is filled with water and a suitable preparation to reduce the surface tension, see chapter 7.3.

#### Indirect sonication

When using aggressive acidic liquids (e.g., sulfuric acid, hydrochloric acid), we recommend using alkaline contact liquid such as 5% TICKOPUR R 33.

- Fill 1/3 of oscillating tank with water.
- Add surfactant.
- Fill carefully, avoid as much as possible the formation of foam.  
The oscillating tank must be filled contingent upon the inset beaker since inset beakers displace the contact liquid.



#### Direct sonication

- Fill 1/3 of oscillating tank with water.
- Add dosed preparation to the oscillating tank. See appendix for dosage information.
- Fill carefully up to the filling level mark, avoid as much as possible the formation of foam.



### Step 2: Degassing the fluid

Freshly-filled bath fluid or fluid that has remained in the oscillating tank for a longer period of time must be degassed prior to use. See also chapter 4.3.1.

- Remove basket and other accessories from the oscillating tank.
- Place lid on top.
- Set the power selection switch to 100% P.
- Switch ultrasound on for 10 min, see chapter 3.1.2



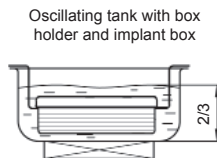
### Step 3: Insert objects to be treated

For optimal diffusion of the ultrasound and protection of the oscillating tank, nothing should be in contact with the bottom of the bath during sonication. Implant boxes and other inset beakers must be stored in the supplied box holders or similar accessories. Suitable baskets are to be used for placement of objects to be cleaned, see chapter 7.

Before every sonication it is necessary to check whether the sonication fluid needs to be cleaned or replaced.

#### Indirect sonication

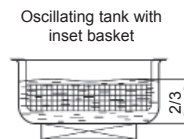
- Hang the box holder in the oscillating tank and fill it with implant boxes/inset beakers.
- Fill box/inset beaker, in doing so please note:
  - It is possible to treat multiple sample vessels with different fluids at the same time.
  - When treating small quantities of combustible fluids, the country-specific guidelines/regulations that are currently in effect are to be observed.
- Place the box/inset beaker on the holder, in doing so please note:
  - Immersion depth of the box is min. 2 cm.
  - Control fill level (contact liquid).
  - Remove air bubbles below the box.



#### Direct sonication

Place the objects to be cleaned in the appropriate accessories, in doing so please note:

- Evenly distribute parts, do not stack them.
  - An overloading of the basket or inset beaker reduces the ultrasound effect (the ultrasound is absorbed).
  - Place the more heavily soiled side facing downward.
  - Parts with joints are to be fully opened before placing inside.
  - Delicate parts are not to come into contact with one another - for positioning, use special accessories such as silicone knob mats if necessary, see chapter 7.
  - Due to the design, the ultrasound effect is weaker on the outlet side. Heavily contaminated objects should not be placed in the basket over the outlet.
- Hang the inset basket with the goods to be treated or place the basket holder in the oscillating tank and the inset basket on the basket holder.
  - Verify that the objects to be treated are fully covered by fluid.
  - With every object inserted, the fill level is to be monitored.



#### Step 4:        **Ultrasound - operation**

Fundamentally, the sonication time is to be as short as possible in order to protect the objects to be treated and the oscillating tank.

- Place lid on top.
- Set the desired sonication time, see chapter 3.1.2.

#### Step 5:        **Removing treated objects**

After sonication, the objects are to be removed from the ultrasonic bath. Allowing them to remain any longer in the bath fluid may damage them.

- Switch off the ultrasound.
- Remove the inset beaker and/or basket from the tank and safely set down atop a level surface.
- Depending on the length of sonication, the beakers/objects may be hot!
- After the cleaning processes, rinse the treated objects with water of at least drinking quality. Visually review the sonication results.
- Before the next sonication, verify the service life (see chapter 4.3.2) of the bath fluid. Heed the specifications of the preparation manufacturer. If necessary, empty the oscillating tank.

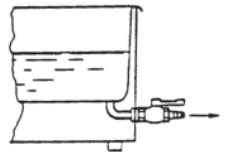


#### Step 6:        **Empty the oscillating tank.**

Layers of contamination on the tank bottom reduce the ultrasonic output.

The oscillating tank is to be emptied after a long period of use or sonication of heavily soiled objects, see chapter 4.3.2.

- Pull the mains plug out.
  - Do not place the ultrasonic bath in the sink.
  - Empty the oscillating tank by placing the ball valve handle in the direction of discharge to open outlet.
  - After emptying the oscillating tank, rinse it thoroughly. Then dry with a soft cloth.
- For further care instructions, see chapter 5.



## **4.3 Further information**

### **4.3.1 Degassing**

Degassing the bath fluid 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 fluid (e.g., oxygen) are reduced through degassing and the ultrasound effect is thus significantly improved.

The cavitation noise changes during degassing, loud degassing noises disappear at the end of the degassing process, the ultrasonic bath appears to work more quietly.

A lower noise level, however, does not mean a reduction in ultrasonic power. It rather means the end of the degassing process and an improvement in the ultrasound effect.

### **4.3.2 Disposal of sonication fluids**

The working solution is disposed of pursuant to the specifications of the product leaflet and the label. All aqueous preparations of DR H. STAMM GmbH are prepared pursuant to the regulations of the Washing and Cleansing Agents Act, are biodegradable and may be added to sewerage as working solutions. Strongly acidic and strongly alkaline fluids are to be previously neutralised pursuant to technical data sheet specifications. The manufacturer specifications for the corresponding preparations are to be observed.

If the solution contains after use substances that are dangerous to water, e.g., oils, heavy metal compounds, etc., it must be prepared once the limit values are exceeded (removal of contaminants) or disposed of as special rubbish.

Disinfection and cleaning agents that become contaminated when used are considered "waste material" pursuant to the Waste Act (AbfG) and may not be taken back by the manufacturer.

In every case, the statutory provisions and regulations of municipal wastewater plants are to be adhered to. Information is provided by municipal wastewater plants as well as by environmental agencies.

## 5 Cleaning and maintenance of the ultrasonic bath

To achieve an optimum lifespan for the ultrasonic bath, cleaning and maintenance are to be conducted regularly.



### CAUTION!

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



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

**A guarantee will not apply to damages caused by the use of unsuitable disinfection agents or detergents.**

### 5.1 Cleaning and care

#### Oscillating tank

The 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 through the movement of the fluid, therefore

- Rinse the oscillating tank with water thoroughly and frequently and dry using a soft cloth.
- Regularly remove residue from the edges of 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.
- Rust particles from the water pipe system and metal residue from cleaning processes can penetrate the passive protective layer of the stainless steel, "activating" the stainless steel to begin rusting. The extraneous rust produces localised corrosion of the stainless steel. For this reason, immediately remove small rust stains with a soft cloth and a commercial stainless steel cleaning product without abrasive additives. Remove metal parts such as screws, filings, etc., from the oscillating tank.

#### Housing

- Do not use any abrasive cleaners, only commercial care products without abrasive additives.
- Housing is to be wiped off only from the outside with a moist cloth; afterwards, allow to dry alone or wipe dry.

### 5.2 Disinfection

Oscillating tank and housing are to be regularly cleaned and disinfected pursuant to the hygiene plan using a VAH-certified or effective surface disinfectant.

Accessories such as holders and baskets should be processed regularly in a cleaning and disinfection unit.

### 5.3 Positioning / Storage

During long periods of non-use, the ultrasonic bath is to be stored in a cool, dry location. The lid should be placed on top in order to protect the oscillating tank from outside contamination.

## **6 Maintenance and repair**

### **6.1 Maintenance**

To achieve a consistent sonication quality, the ultrasonic bath is to be inspected at regular intervals.

#### **6.1.1 Inspection of ultrasonic power**

Execution of a foil test with the enclosed frame FT 14.

The procedure is described in the enclosed "Foil test" document (appendix C).

Customary aluminium foil is used to conduct the foil test.

The power selection switch is to be set to 100% P for the test.

Next, a comparison is made with the initial foil included with the ultrasonic bath.

#### **6.1.2 Maintenance conducted by the manufacturer – every 2 years**

The maintenance is conducted by the manufacturer. It especially includes a recalibration of the power parameters and technical safety controls.

For information on shipment of the ultrasonic bath, see chapter 6.4.

### **6.2 Functional checks**

#### **Checking the control lights**

- pursuant to chapter 3.1.2.

#### **Monitoring the ultrasound**

The function can be checked using a standard wattmeter. It is to be inserted between the ultrasonic bath's power plug and the power outlet.

- Fill the oscillating tank with fluid, see chapter 4.2.
- For monitoring purposes, the power selection switch is to be set to 100% P and the ultrasound is to be switched on. Next, the value displayed is to be compared with the corresponding value in the technical data (chapter 1.4) (tolerances  $\pm 20\%$ ).

## 6.3 Error analysis

Ultrasonic baths are robustly constructed and designed for a high level of reliability. Nevertheless, the possibility of a malfunction due to a defective component can never be fully discounted.

The following overview of possible sources of error should serve as an aid for error detection and elimination.

- Ultrasonic bath oscillates weakly, unevenly, or noise is too loud:
  - Has fluid been properly degassed?                      ⇒ Treat for 15 min.
  - Is it overloaded with objects to be treated?            ⇒ Remove a few parts.
  - Uneven noises (wobbling)                                ⇒ No error – slightly adjust the filling level of the fluid.
- Slight erosion visible on the bottom of the bath?    ⇒ Natural wear.  
Ultrasonic bath OK.

Any malfunctions are to be communicated in writing to the manufacturer.

## 6.4 Repairs and service

Repair work may only be carried out by authorised, qualified personnel or by the manufacturer. If the ultrasonic bath has to be sent to the manufacturer for maintenance, or if errors or defects are ascertained and are impossible to rectify, the ultrasonic bath may no longer be used. In such a case, please contact the supplier or the manufacturer:

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

Repairs/Maintenance department:  
Tel.: +49-(0)-30 – 768 80 – 13  
Fax: +49-(0)-30 – 76 88 02 00 13

E-mail:  
info@bandelin.com

In the case of returns, the general terms and conditions for delivery and payment of BANDELIN electronic GmbH & Co. KG shall apply.

In addition, the ultrasonic bath is to be cleaned and decontaminated (if necessary), see the following chapter.

### 6.4.1 Decontamination certificate

If the ultrasonic bath is sent back to the manufacturer for repairs (with accessories, as the case may be), the form "Certificate of Decontamination" is to 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 from the Internet as a PDF file:

[www.bandelin.com / Service / Download ...](http://www.bandelin.com / Service / Download ...)

A sample copy can be found in appendix D.

## 6.4.2 Exchanging fuses



### CAUTION!

Repair work may only be carried out by authorised, qualified personnel or by the manufacturer. The manufacturer assumes no liability for unauthorised interventions on the ultrasonic bath!



### **The mains plug must be pulled out before opening the ultrasonic bath!**

There is a risk of electric shock from live parts in the ultrasonic bath!

- Empty ultrasonic bath.
- Turn over ultrasonic bath.
- Loosen the screws around the casing.
- Carefully remove the base plate.
- If required, carefully separate the electrical plug connections between the base plate with generator circuit board and the casing with oscillating tank.
- Exchanging fuses:
  - The fuses are located on the generator circuit board.
  - After inspection, exchange only the defective fuses.
  - Replacement fuses are located on the base plate.
- Assembly in reverse order.

## 7 Accessories

The proper accessories facilitate use of the ultrasound and also protect the oscillating tank and objects to be treated.

BANDELIN offers a broad range of accessories, see appendix.

Additional information may be obtained from our supplier, our sales representatives or from our website.

No-obligation telephone consultation:  
+49-(0)-30 – 768 80 – 0

Internet:  
[www.bandelin.com](http://www.bandelin.com)

### 7.1 Required accessories

Implant boxes and box holders are part of the scope of delivery, for more information see appendix A.

### 7.2 Optional accessories

Additional accessories such as baskets, basket holders, positioning lids with inset beakers, etc., are available for applications that diverge from the main application "Detachment of biofilms". For more detailed information, please see appendix B.

Do not stand or lay any objects directly on the tank bottom.

Exceptions to this rule are special baskets and basket holders (e.g., K 6 and SH 7) that have been designed by BANDELIN in such a manner that they do not lie in the cavitation field and do not damage the tank bottom.

### 7.3 Preparations

Special preparations, i.e., preparations that are cavitation-conducive, biodegradable, easily disposable, gentle to the material and long-lasting, are required for use of the ultrasound.

BANDELIN recommends the TICKOPUR and STAMMOPUR concentrates from DR. H. STAMM GmbH, which have been specially developed for ultrasound applications and which utilise the ultrasound optimally.

Additional information may be obtained from our supplier, our sales representatives or from our website.

No-obligation telephone consultation:  
+49-(0)-30 – 768 80 – 280

Internet:  
[www.dr-stamm.de](http://www.dr-stamm.de)



#### IMPORTANT!

- When using preparations, the safety instructions on the label and in the respective product leaflets must be adhered to.
- Keep the preparations 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 preparations and do not allow them to come into contact with the eyes or skin.
- Preparations in powder form may only be used fully dissolved.



## 8 Consumable materials - not applicable -

## 9 Taking the unit out of service

If the ultrasonic bath no longer works, it must be disposed of appropriately. Some electrical components are considered to be toxic waste.



## 10 Key words

### A

Accessories	6, 7, 10, 11, 12, 16, 17, 20, 22, 24
Air bubbles	15, 17

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## U

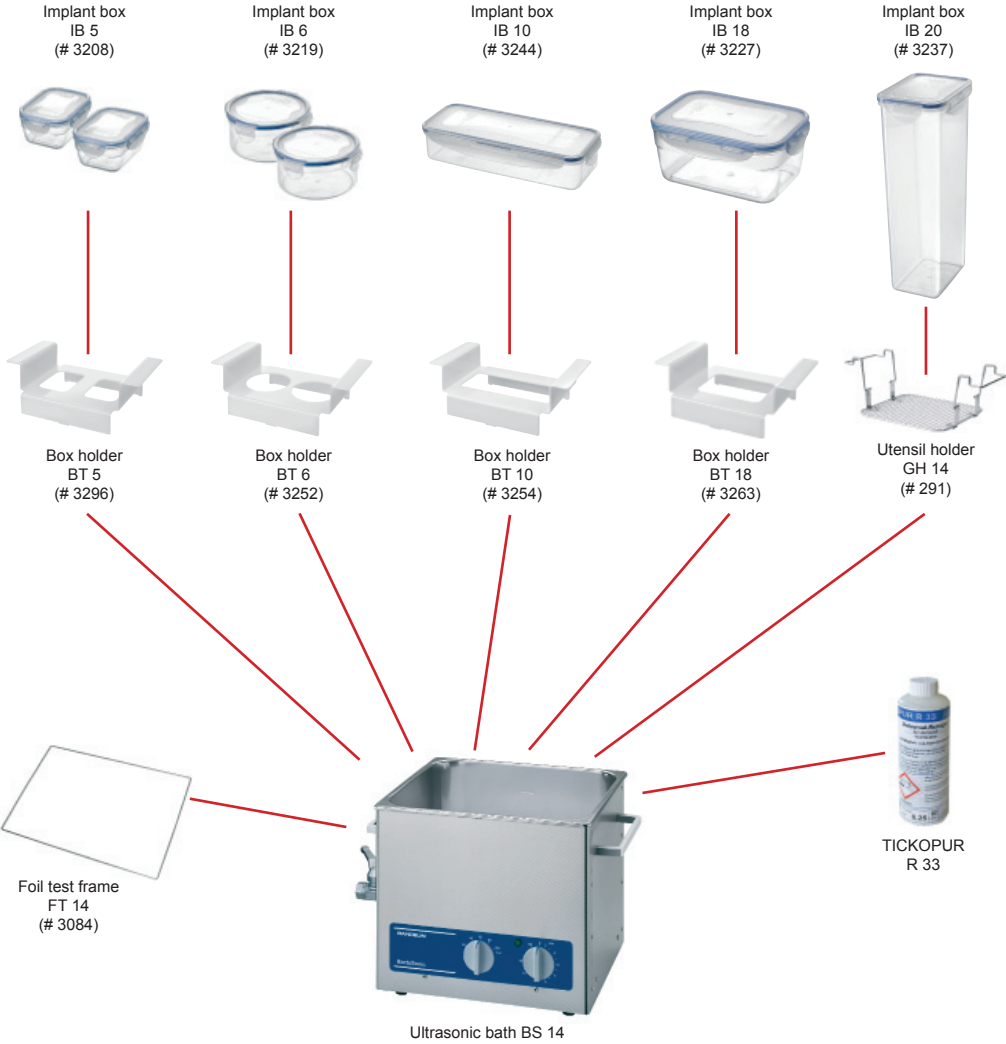
Ultrasonic bath	6, 7, 8, 10, 11, 12, 13, 14, 15, 18, 19, 20, 21, 22, 23, 25
Ultrasonic output	15, 18, 19, 21
Ultrasonic peak power	8
Ultrasound application	24
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Ultrasound effect	15, 17, 19
Ultrasound energy	15
Ultrasound frequency	6
Ultrasound operation	10, 18, 20
Utensil holder	11

## W



Wetness	11
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**A      Scope of supply BactoSonic® 14.2**



**B      Optional accessories**

 A rectangular stainless steel basket with a fine sieve cloth mesh. It has two small handles on opposite sides.	<p><b>Inset basket K 14,</b> made of stainless steel, sieve cloth. Protects objects to be cleaned and prevents damages to the tank bottom. Optimum ultrasound transmission.</p>
 A flat, rectangular stainless steel lid with a central black knob. It has several small holes along its edges.	<p><b>Lid D 514,</b> made of stainless steel, for use with inserted basket. Protects from exterior contamination. Condensation water is discharged in the oscillating tank. Sound-absorbing</p>

### Information

### Foil test

#### Testing of ultrasonic baths

A foil test<sup>1</sup> is recommended for testing ultrasonic baths. It is to be conducted upon initial startup, and at regular intervals thereafter (e.g. every 3 months). The frequency of testing is the responsibility of the user.

The foil test is a simple procedure to demonstrate the intensity and distribution of cavitation in an ultrasonic bath. To do so, aluminium foil is stretched over a foil test frame. It is perforated or destroyed to a certain degree by cavitation, depending on the duration.

For purposes of reproducibility, it is **important that the test conditions remain constant**:

- Fill level in the oscillating tank (¾)
- Temperature of tank contents
- Degassing time, if needed (degassing 5 to 30 min. before the test, depending on the tank contents)  
Time may need to be extended with acidic cleaning solutions.
- Frame positioning
- Foil properties (thickness, surface)
- Sonication time
- Concentration and type of ultrasound preparation

Foils can be archived in a suitable way (scanning, photos, etc.) This allows the foils to be compared at any time. The perforated areas of all foils should have approx. the same dimensions and distribution – the results are never identical. A process validation, e.g. for the treatment of medical products, can only be achieved by conducting regular foil tests.

To execute the foil test, different foil test frames FT can be ordered from the manufacturer (for a fee). The foil test frames are suitable for a wide range of tank dimensions. Aluminium household foil is also required to conduct the test and is not included in the delivery.

Film: <http://bandelin.com/folientest/>.

#### Fluid for the foil test

In order to obtain an adequately strong cavitation effect, the 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:  
STAMMOPUR DR 8, STAMMOPUR R, TICKOMED 1, TICKOPUR R 33, TICKOPUR R 30, TICKOPUR TR 7

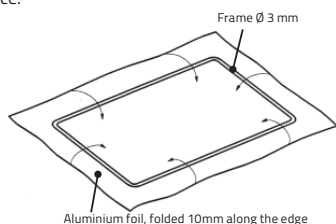
If none of these preparations is available, a neutral or mildly alkaline preparation that does not destroy aluminium may be used. The preparation must be approved by the manufacturer for use in ultrasonic baths.



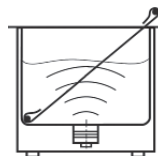
<sup>1</sup> Investigations on test procedures for ultrasonic cleaners. IEC/TR 60886 (1987-03)

### Conducting the foil test

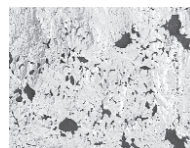
1. Fill 2/3 of the oscillating tank with water and a suitable ultrasound preparation in the dosage specified by the manufacturer.
2. Degas the liquid: < 10 l - 10 min and > 10 l - 30 min (see user instructions.)
3. Stretch aluminium foil (household foil with a thickness of 10 µm to 25 µm) over the wire frame (stainless steel). Depending on the tank size, it is possible that the frame protrudes from the tank.  
Covering the portion of the frame that is submerged will suffice.



4. With the ultrasound switched off, place the foil-wrapped wire frame diagonally inside the oscillating tank, adjust if necessary.



5. Switch on the ultrasound and 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 can last up to 3 minutes.
6. Switch off the ultrasound, take the foil out and let it dry.
7. The foil must be perforated, otherwise contact the manufacturer.



8. Archive it together with testing date and the serial number of the ultrasonic bath.
9. After the test, the oscillating tank must be thoroughly rinsed out to remove any loose foil particles.

Type	for interior tank dimensions in mm (L x W x H)		Order No.	for
	from	to		
FT 1	190 × 85 × 60		3190	DT 31/H, DT 52/H RK 31/H, RK 52/H
FT 4	240 × 140 × 80	300 × 150 × 150	3074	DL 102 H, DL 255 H, DT 100/H, DT 102H/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	500 × 140 × 100	500 × 140 × 150	3222	DL 156 BH, DT 156/BH, DT 1028 F RK 156/BH
FT 14	280 × 234 × 80	325 × 300 × 300	3084	DL 510 H, DL 512 H, DL 514 BH, DT 510/H/H-RC, DT 512 H, DT 514/H/BH/BH-RC, RK 510/H, RK 512 H, RK 514/H/H/BH, ZE 514/...DT
FT 36	510 × 300 × 200/220		3673	ZE 1031/1032/...DT
FT 37	600 × 400 × 200/220		3674	ZE 1058/1059/...DT
FT 38	650 × 400 × 140/160		3672	MC 1001/E
FT 40	500 × 300 × 80	500 × 300 × 300	3094	DL 1028 H, DT 1028/H/CH, RK 170 H, RK 1028/H/C/CH, RK 1040
FT 42	700 × 420 × 160/190		3224	TRISON (TE 3000)
FT 45	600 × 400 × 200	600 × 400 × 200	3204	DT 1050 CH, RK 1050/CH

<p><b>Certificate of Decontamination</b></p>
<p><b>!!! CAUTION!!!</b></p> <p><b><i>This form must be visibly affixed to the outside of the package!</i></b></p>

This "Certificate of Decontamination" is meant to provide occupational safety and health maintenance for our employees pursuant to the "Infection Protection Act" and trade association accident prevention regulations.

Please understand that we can only initiate work operations when this Certificate has been submitted.

Before sending the unit back to us for inspection/repair, the unit and accessories must be cleaned pursuant to current laws and regulations and, if necessary, must also be disinfected with a surface disinfection agent listed by the VAH.

Device type: \_\_\_\_\_

Serial No.: \_\_\_\_\_

Accessories: \_\_\_\_\_

Device / accessories ...	
are not contaminated:	<input type="checkbox"/>
were cleaned before shipping?	<input type="checkbox"/>
are free from toxic matter?	<input type="checkbox"/>
have been decontaminated and/or disinfected and no longer pose a health risk?	<input type="checkbox"/>

With what type of toxic materials did the device / accessories come into contact?

Corrosive	<input type="checkbox"/>	Biologically hazardous (e.g., microorganisms)	<input type="checkbox"/>
Toxic	<input type="checkbox"/>	Radioactive	<input type="checkbox"/>
None	<input type="checkbox"/>		



# Certificate of Decontamination

**!!! CAUTION!!!**

***This form must be visibly affixed  
to the outside of the package!***

## Legally binding statement

I/we hereby confirm that the device and accessories found in this package have been cleaned and/or disinfected pursuant to current laws and regulations and that the information provided in this declaration is correct and complete:

Company /

Institution: \_\_\_\_\_

Street and  
number: \_\_\_\_\_

Postal code, city: \_\_\_\_\_

Department: \_\_\_\_\_

Name: \_\_\_\_\_

Telephone,  
extension: \_\_\_\_\_

Fax: \_\_\_\_\_

## **Reason for return:**

Thank you, in this  
way you help us to  
reduce costs.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Company stamp

**Note:**

The user instructions in this and other languages, as well as further information, are available on the supplied CD.