User instructions

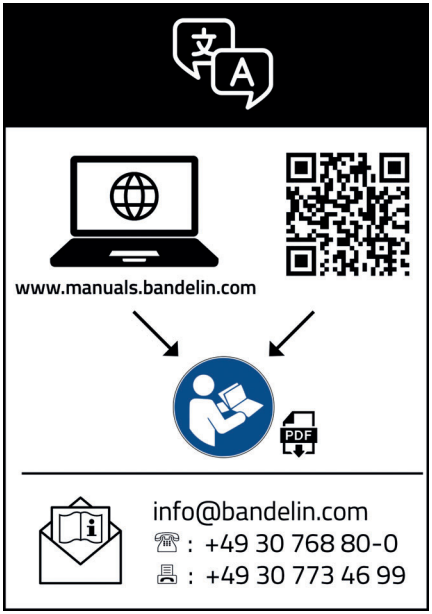
BANDELIN
Ultraschall seit 1955

BactoSonic

Ultrasonic special bath

Ultrasonic bath BS 14

6366-007 en/2022-09



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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.
IVD	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 transducers, 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.

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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.

IVD In this connection, the ultrasonic bath is classified in accordance with Regulation 2017/745/EU **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.

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1.3 CE conformity

The units satisfy the CE marking criteria in the European Union:

- 2017 / 746 / EU – IVD Regulation
- 2011 / 65 / EU – RoHS Directive

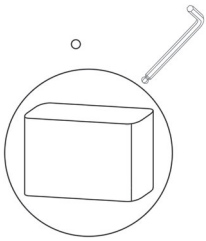
in their currently valid versions.

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

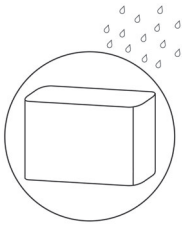
1.4 Technical data

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/1:	800 W
Frequency	40 kHz
Ultrasonic nominal output:	200 W_{eff}
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



Protected against access by instruments to dangerous components, protected against solid foreign bodies with a diameter of 2.5 mm or larger



Protected from dripping water up to 15° from its vertical axis

/1 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.

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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%
Altitude:	up to 2000 m above sea level

No dewing.
Only for indoor operation.

IVD **Specifications for use as a medical device**

Name:	Ultrasonic bath
EMDN nomenclature:	V0799
Purpose:	See chapter 1.2.
Classification according to Regulation 2017/745/EU for in-vitro diagnostic equipment:	class A
Type, model, serial number, year of manufacture:	See type plate on the rear side for information

The ultrasonic bath has been inspected pursuant to norms currently in effect and is to be installed and put into operation pursuant to EMC directions.

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

Startup on location, functional check and personnel training (section 4):	not required
Technical safety controls, (STK, section 11):	no specifications
Technical measurement controls, (MTK, section 14):	not applicable

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.
It may generate radio interferences or disrupt the operation of devices nearby. It may be necessary to take remedial measures such as realigning the device or a 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.

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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.

IVD Advice for the medical field

- The ultrasonic bath is exclusively intended for use by medical skilled personnel.

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

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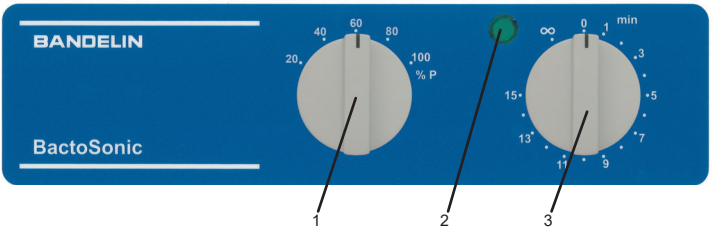
2.3 Start-up

- 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 chapter 5.
  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.
- 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:

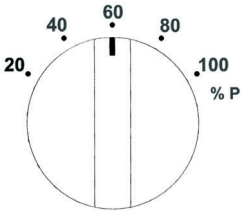


1 Power control knob (power selection switch)
2 Green control light (ultrasound in operation)
3 Turning knob for ultrasound ON / OFF with preset time

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_{eff}



Note

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

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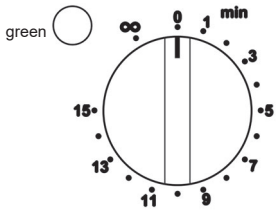
3.1.2 Ultrasound

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.

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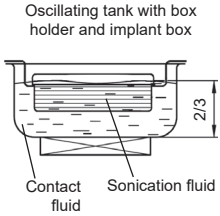
4 Use

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.

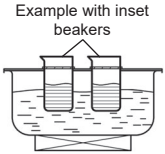
For additional instructions and queries regarding this process, please send an E-mail to info@ bactosonic. com.

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.



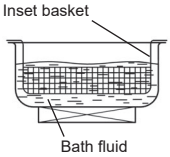
Indirect sonication in inset beakers is to be additionally conducted for special applications:

- 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.



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4.1 Instructions for use

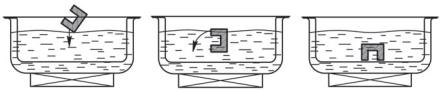
Instructions - filling

- 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[/2].
- 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.

/2 MILLNER, R.: Wissenspeicher Ultraschalltechnik, Fachbuchverlag publishing house, Leipzig 1987

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4.2 General application

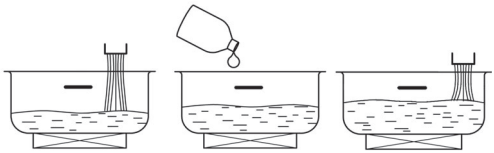
Step 1: Fill oscillating tank

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

Indirect sonication

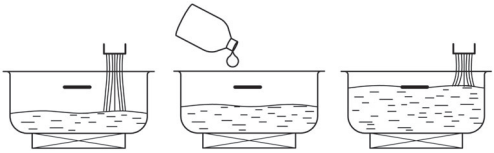
When using aggressive acidic liquids (e.g., sulfuric acid, hydrochloric acid), we recommend using alkaline contact liquid such as 5% TICKOPUR R 33.

- 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

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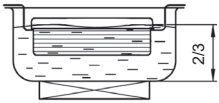
Step 3: Insert objects to be treated

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

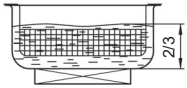
Oscillating tank with box holder and implant box



- ➢ 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

Oscillating tank with inset basket



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.

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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.

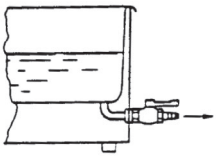
- Switch off the ultrasound.
- Remove the inset beaker and/or basket from the tank and safely set down atop a level surface.

  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.



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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.

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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.

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, use a suitable surface disinfectant if needed. Afterwards, allow to dry off 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 ± 20 %).

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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 ...

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.

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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

7.1 Required accessories

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

Implant boxes:
Air-tight containers of different volumes, e.g. Lock & Lock.

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

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

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 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 for 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 packing is recyclable.

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10 Key words

A

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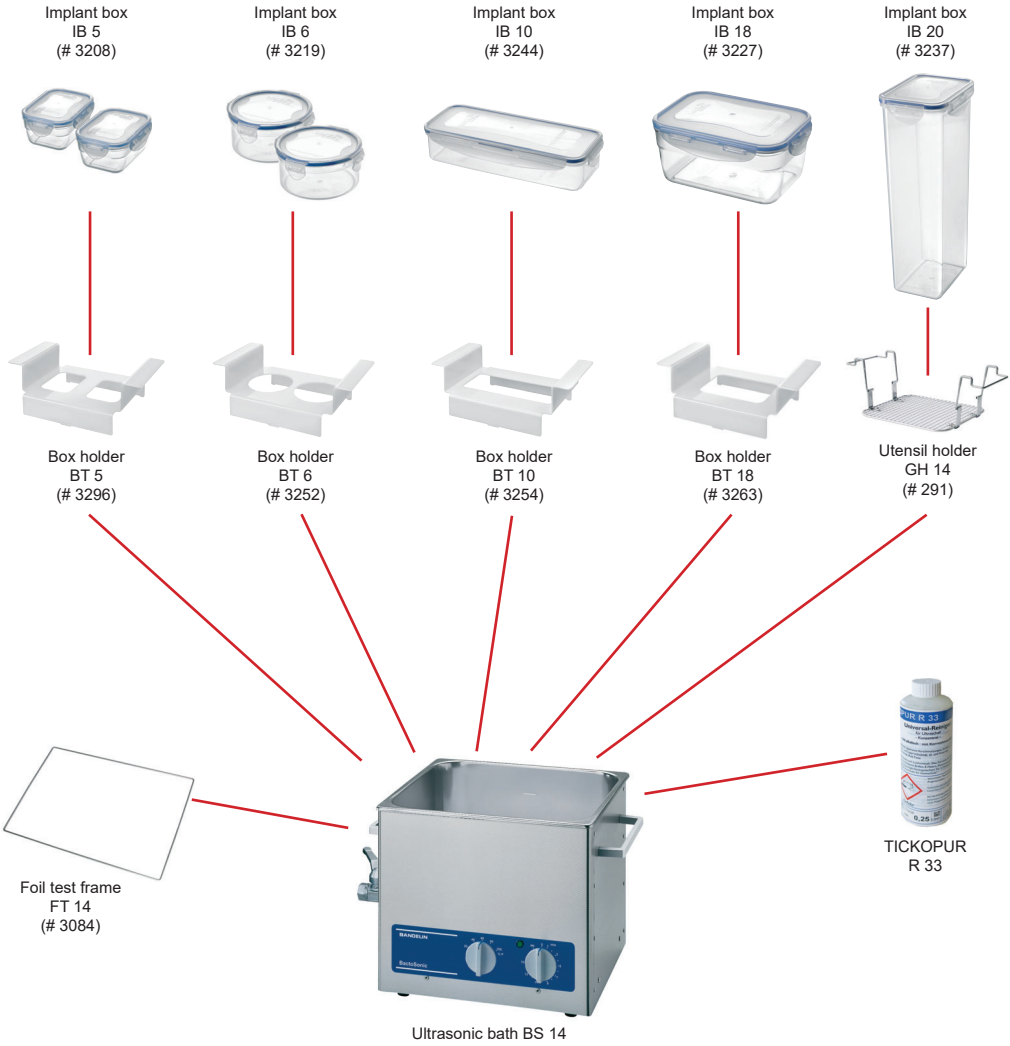
A Scope of supply BactoSonic 14.2



B Optional accessories

	Inset basket K 14, made of stainless steel, sieve cloth. Protects objects to be cleaned and prevents damages to the tank bottom. Optimum ultrasound transmission.
	Lid D 514, made of stainless steel, for use with inserted basket. Protects from exterior contamination. Condensation water is discharged in the oscillating tank. Sound-absorbing

Information

BANDELIN
Ultraschall seit 1955

Foil test

Function testing of an ultrasonic bath

A foil test[1] is recommended for testing ultrasonic baths. This should 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 for demonstrating the intensity and distribution of cavitation in an ultrasonic bath. It involves stretching aluminium foil over a foil testing frame, which will be perforated or destroyed to a certain degree by cavitation, depending on sonication time.

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

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

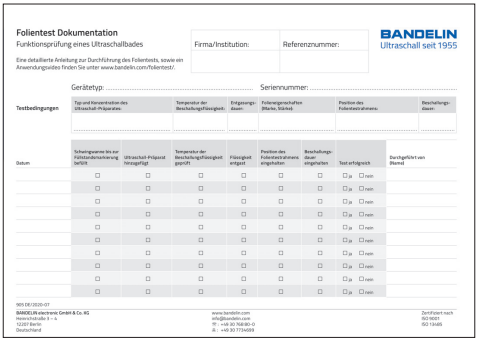
Fluid for the foil test:
In order to obtain a sufficiently strong cavitation effect, the foil test also requires the surface tension of the water used to be reduced using surfactant preparations.
We recommend the following ultrasonic agents:

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 determined from the perforated surface of the foils.
The perforated areas of all foils should have approximately the same extent and distribution – the results are never identical. Consistency of process validation, e.g. for treatment of medical devices, can only be ensured by regular foil tests.

As documentation of the test results, the following document templates can be used.
A PDF for downloading and a usage video are available at http://bandelin.com/folientest/.



Folientest Dokumentation
Funktionsprüfung eines Ultraschallbades

Eine detaillierte Anleitung zur Durchführung des Folientests, sowie ein Anwendungsvideo finden Sie unter www.bandelin.com/folientest/.

Firma/Institution: | Referenznummer:

BANDELIN Ultraschall seit 1955

Gerätetyp: ..... Seriennummer: .....

Testbedingungen	Typ und Konzentration des Ultraschall-Präparates	Temperatur der Beschallungsflüssigkeit	Entgasungs-dauer	Folieneigenschaften (Marke, Stärke)	Position des Folientestrahmens	Beschallungs-dauer

Datum	Schwingwanne bis zur Füllstandsmarkierung befüllt	Ultraschall-Präparat hinzugefügt	Temperatur der Beschallungsflüssigkeit geprüft	Flüssigkeit entgast	Position des Folientestrahmens eingehalten	Beschallungs-dauer eingehalten	Test erfolgreich	Durchgeführt von (Name)
	☐	☐	☐	☐	☐	☐	☐ ja ☐ nein	
	☐	☐	☐	☐	☐	☐	☐ ja ☐ nein	
	☐	☐	☐	☐	☐	☐	☐ ja ☐ nein	
	☐	☐	☐	☐	☐	☐	☐ ja ☐ nein	
	☐	☐	☐	☐	☐	☐	☐ ja ☐ nein	
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	☐	☐	☐	☐	☐	☐	☐ ja ☐ nein	

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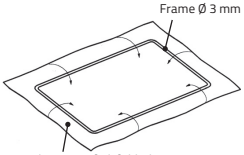
Zertifiziert nach
ISO 9001
ISO 13485

Foils can also be suitably archived (scanning, photos, etc.). This allows the foils to be compared at any time.

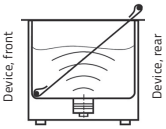
1 Investigations on test procedures for ultrasonic cleaners. IEC/TR 60886 (1987-03)

Conducting the foil test

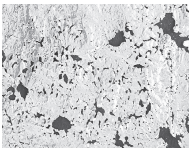
1. Fill oscillating tank to the filling level mark with water and an appropriate ultrasonic agent, in the concentration specified by the manufacturer.
2. Degas the liquid (see user instructions)
3. Stretch aluminium foil (household foil, 10 µm to 25 µm thick) over the foil testing frame.
   Depending on the tank size, it is possible that the frame will protrude outside the tank.
   It is sufficient to cover the submerged portion of the frame with foil.



4. With the ultrasound switched off, position or fix the foil-wrapped frame at an angle across the middle of the oscillating tank (see video).



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 may be up to 3 minutes.
6. Switch off the ultrasound, take the foil out and let it dry.
7. The foil must be perforated, see photo. Otherwise, we recommend having the device checked by the service department at BANDELIN electronic GmbH & Co. KG.



8. Archiving of foil with test date and serial number of the ultrasonic bath. The foil test document template can also be completed and archived.
9. After the test, the oscillating tank must be thoroughly rinsed out to remove any loose foil particles.

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 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	3222	DL 156 BH, DT 156/BH, RK 156/BH
FT 14	3084	DL 510 H, DL 512 H, DL 514 BH, DT 510/H/H-RC, DT 512 H, DT 514H/BH/BH-RC, DT 510 F, RK 510/H, RK 512 H, RK 514/H/BH, ZE 514/...DT
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
FT 42	3224	TRISON (TE 3000)
FT 45	3204	DT 1050 CH, RK 1050/CH

Suitable foil testing frames can be ordered from BANDELIN electronic GmbH & Co. KG.
The foil testing frames are suitable for a wide range of tank dimensions. Aluminium foil is also required for conducting the test, but this is not included in the delivery.

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