Operating Instructions

BANDELIN
Ultraschall seit 1955

TRISON 4000

High-power ultrasonic bath

TRISON 4000 Xi R

Valid for all TRISON 4000 Si/Xi R/L and SONOBOARD TRISON R/L ultrasonic baths with software versions starting at 2.0.0 and images version 2.0.1

6416-009 GB/2021-04

CE

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General

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

The instructions are part of the scope of delivery and are to be stored near the device for later reference. This also applies if the device is transferred to others.

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

The warnings and safety precautions (Section 1.9) are always to be followed during use.

The manufacturer will not assume any responsibility for the device's safety or proper functioning in the event of improper handling or usage contrary to the intended purpose. Unauthorised alterations/modifications will render both the warranty claim and the CE conformity null and void.

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

Symbols used:

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

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Table of Contents

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Informative annexes

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1 Product description

The TRISON ultrasonic tank primarily consists of the TRISON Base control unit, the ultrasonic oscillating tank, and the ultrasound generator.
The mains connection is made via the mains supply switch.
Special accessories or other inset beakers are also required for operation.

The TRISON ultrasonic bath is also available as a ready-to-use "SONOBOARD TRISON" set in a functional cabinet.
In the following, the term "TRISON ultrasonic bath" will stand for both the model to be mounted in an existing work plate and also for the "SONOBOARD TRISON" ready-to-use set.

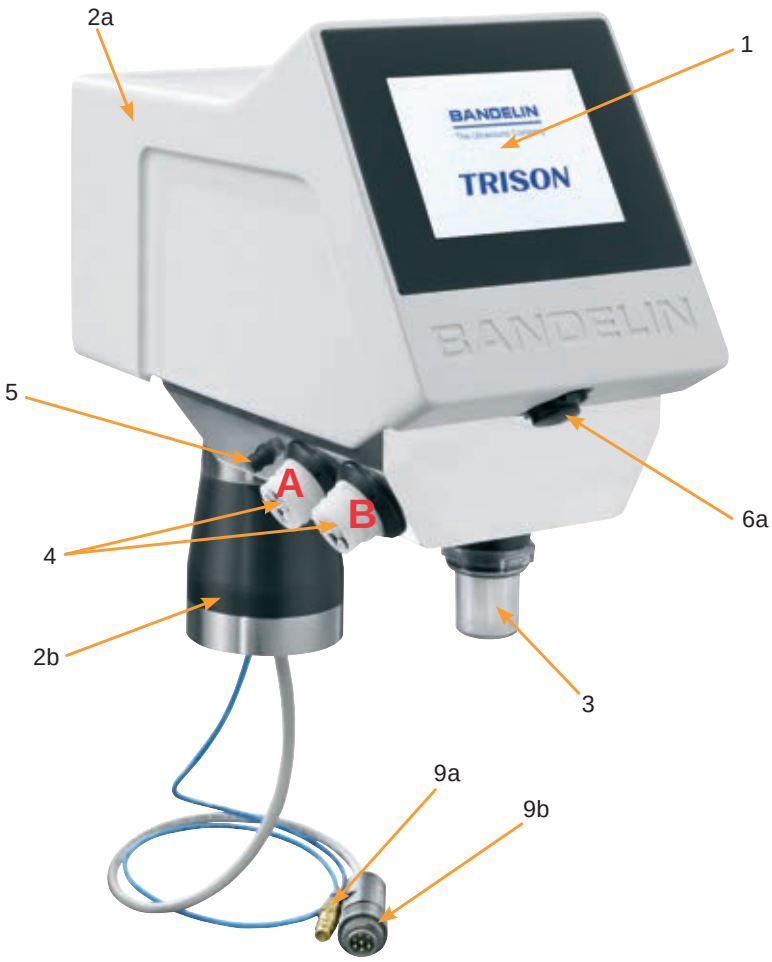
1.1 TRISON Base control unit

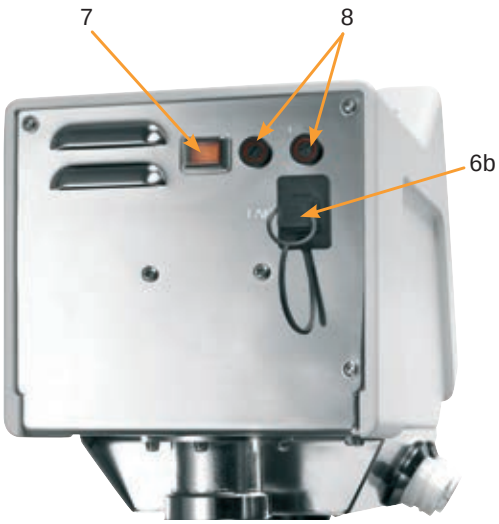
TRISON Base TB 4000 R/L control unit with rinsing function for robotic and MIS instruments. The base is available in both right- and left-handed variants, as indicated by the letters "R" or "L" in the type designation.
The exact type specification and serial number are found on the type plate.

Product features:

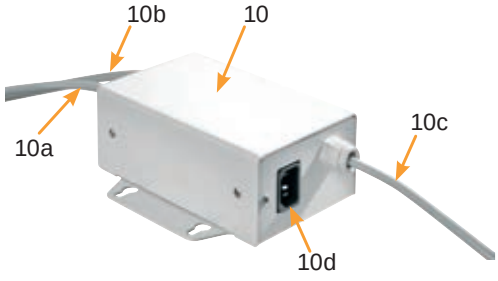
- Touchscreen (1)
- Easy-to-clean plastic housing (2a) atop a rotary base (2b)
- Replaceable filter (3) for capturing dislodged contamination
- Connectors (4) for hose couplings (TRISON Twist & Rack)
- Connector for TRISON Twist (5) or temperature sensor
- USB interface (6a) and Ethernet interface (6b) for logging
- Mains switch (7)
- Fuses (8)
- Connectors for compressed air (9a) and electricity (9b)
- Mains supply switch (10) for setting on a level surface or for suspension, with connectors for the mains (10a), TRISON Base (10b), ultrasound generator (10c), and a second ST control unit if required (10d)

Based on example of a
TRISON Base TB 4000 R





Mains supply switch
NW 3000



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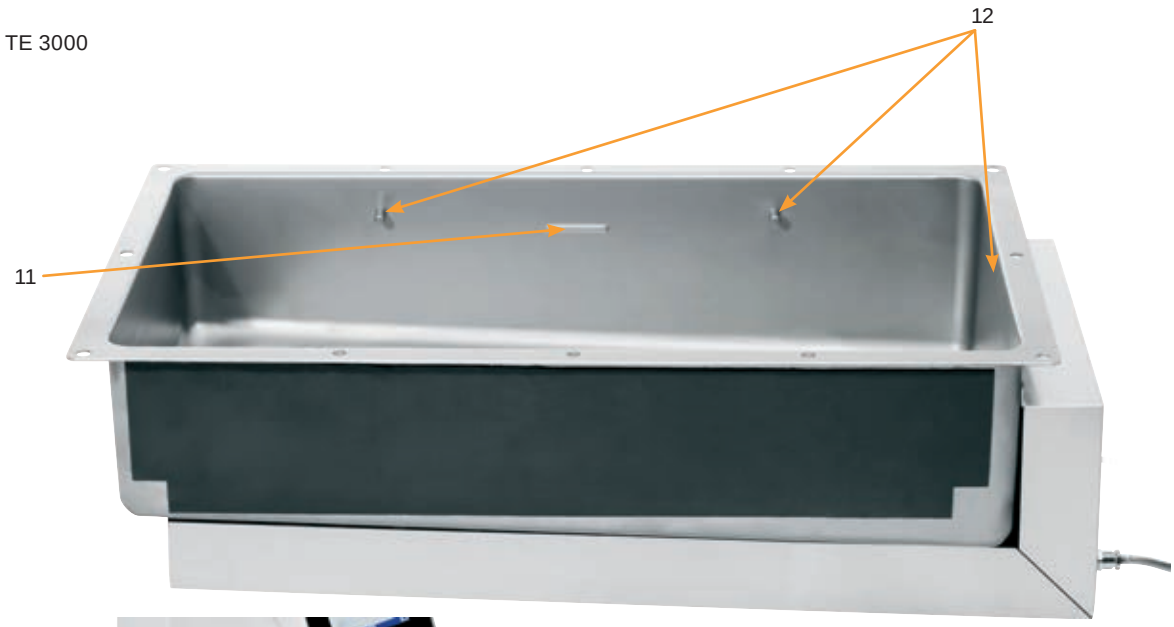
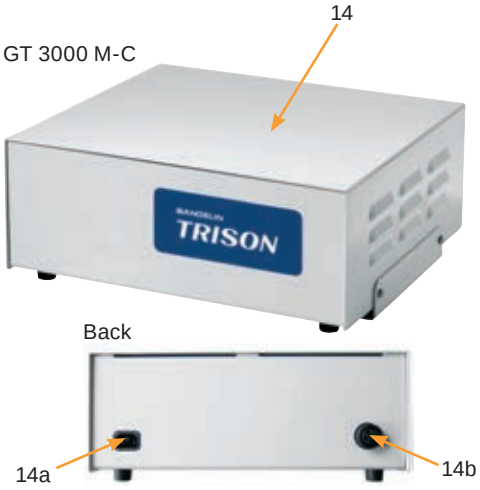
1.2 Ultrasonic oscillating tank with ultrasound generator

The TE 3000 ultrasonic oscillating tank has been especially developed and adapted for robotic instruments. A specially adapted ultrasound generator GT 3000 M-C is supplied for operation of the tank.
The exact type specification and serial number are found on the type plate.

Product features:

- Stainless steel oscillating tank with transducer on the tank bottom and side, ultrasonic frequency 38 kHz
- Filling level mark for safe filling (11)
- Basket mounts (12) for special accessories
- Outlet for drain set to enable fast draining of the bath liquid (13)
- Ultrasound generator (14) for setting on a level surface or for suspension, with mains panel connector (14a) for mains cable, and HF connection (14b) for TE 3000





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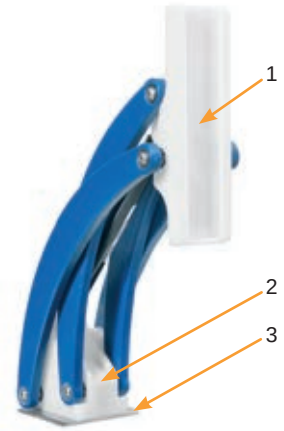
1.3 Special accessories

Special accessories have been developed to fit in the ultrasonic bath, customised to the respective application:

TRISON Twist with pivot-mounted arm, TRISON Lift for robotic instruments, and TRISON Rack for MIS instruments.

1.3.1 TRISON Lift pivot-mounted arm for TRISON Twist

The TRISON Twist for robotic instruments can be swivelled into the oscillating tank using the TRISON Lift TL 4000 pivot-mounted arm, which is mounted on the work surface behind the ultrasonic oscillating tank.
It can be used together with the TRISON Twist Si and Xi.



Product features:

- Head section (1) with guide and rack for both TRISON Twists
- Base (2) with guide for affixing to the base plate (3), firmly screwed-in to the work plate

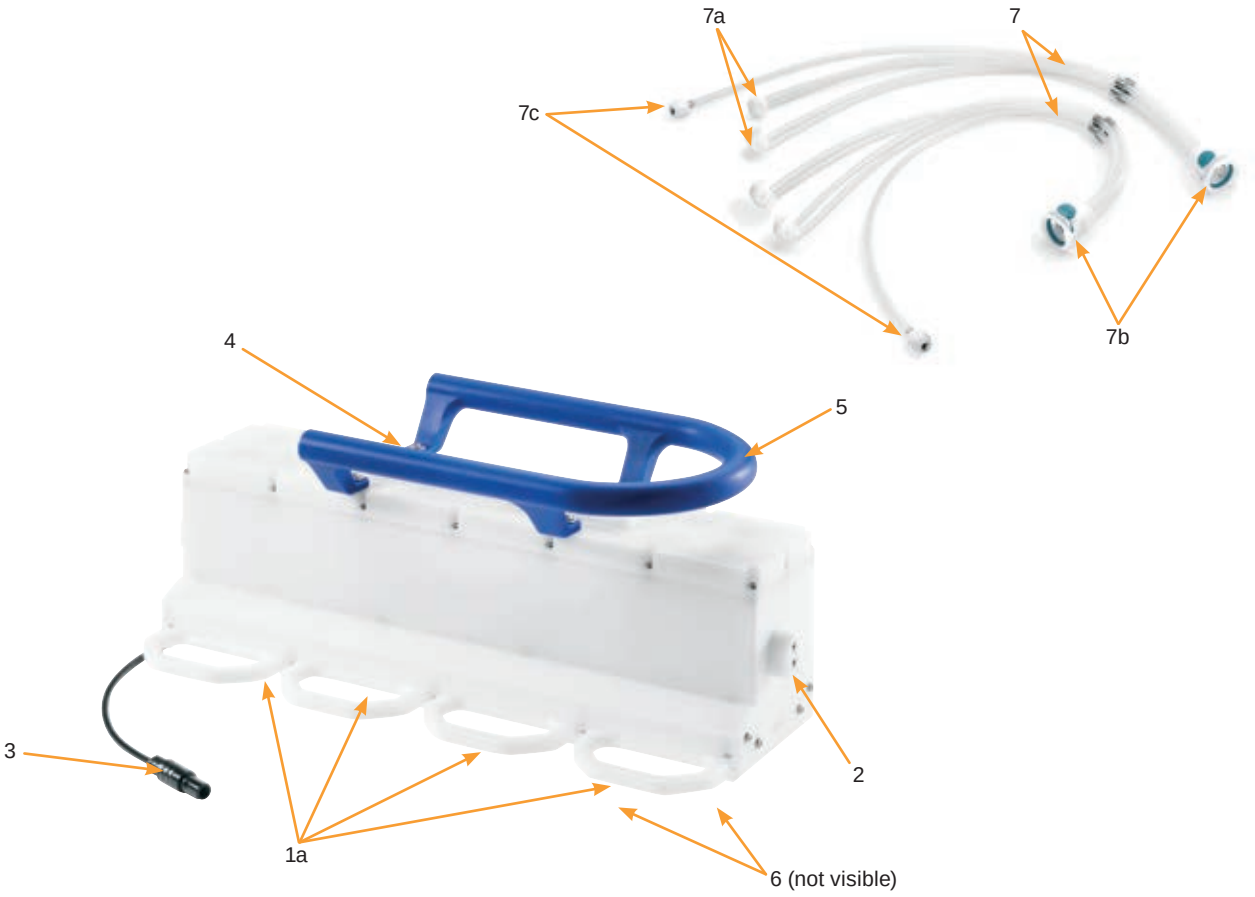
1.3.2 TRISON Twist moving device for robotic instruments

With its special mounts, the TRISON Twist TT 4000 Si or Xi moving device can accommodate up to 4 Si or Xi robotic instruments and turn the instrument tips at the same time as they are being rinsed. This means that all surfaces/joints/cavities are cleaned, even those that are hard to reach by hand. The Twist is available in both left-handed and right-handed versions (matching the TRISON Base).
The exact type specification and serial number are found on the type plate.

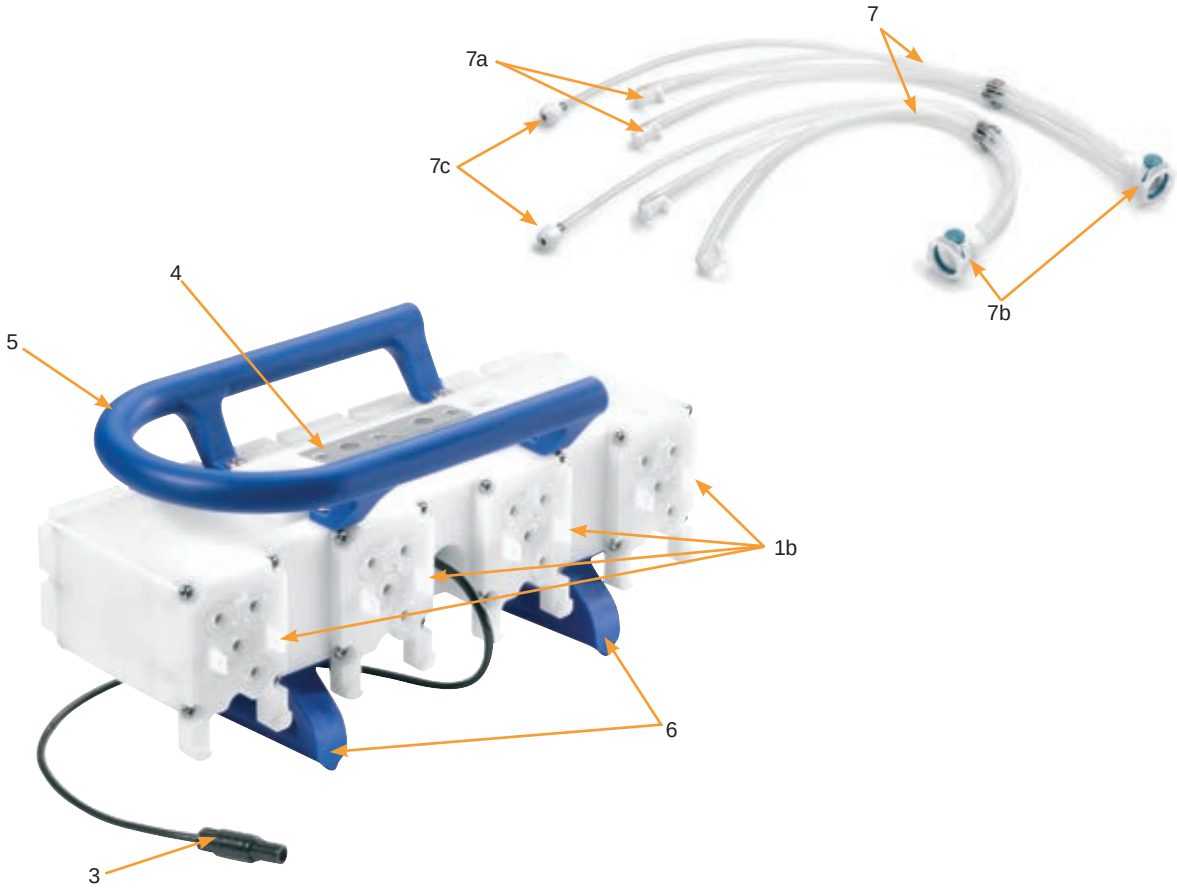
Product features for TT 4000 Si and TT 4000 Xi:

- 4 mounts for the corresponding instruments, with push handles for the TT 4000 Si (1a), and with guiding pins for the TT 4000 Xi (1b)
- Bearings (2) suitable for the ultrasonic oscillating tank (only for Si)
- Plug (3) for connection to the TRISON Base
- Connector (4) with guide for affixing to the TRISON Lift
- Handle (5) and legs (6)
- Hose set (7) with rinsing plugs (7a), couplings (7b) for connection to the TRISON Base and return flow (7c) with lowering weight

TT 4000 Si for Si robotic instruments



TT 4000 Xi for Xi robotic instruments



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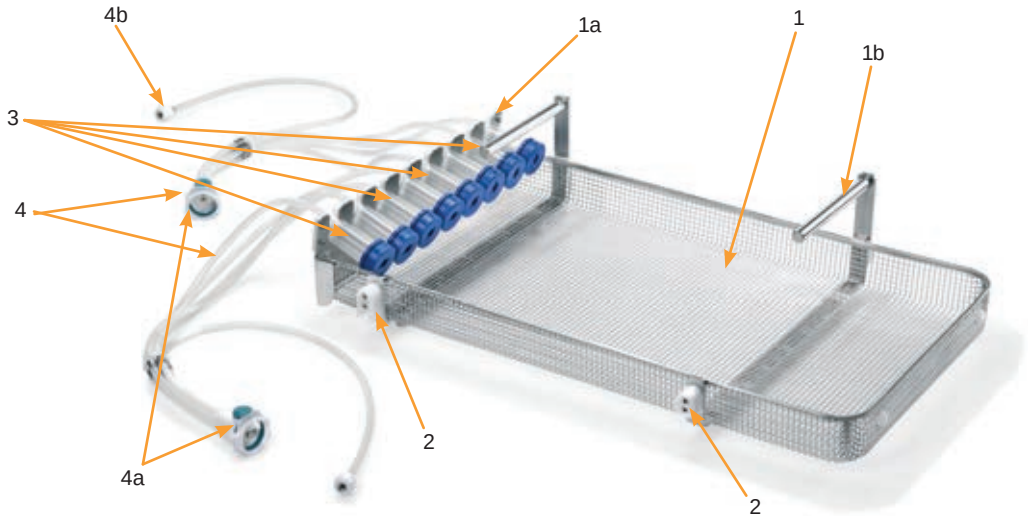
1.3.3 TRISON Rack special basket for MIS instruments

The TRISON Rack TR 3001 R special basket can accommodate up to 8 MIS instruments thanks to its special comb.
It is available in both right- and left-handed variants, as indicated by the letters "R" or "L" in the type designation.

Product features:

- Basket (1) with comb bar (1a) and handles (1b)
- Bearings (2) suitable for the ultrasonic oscillating tank
- 8 adapters (3) to connect the instruments, detachable from the comb bar
- Hose set (4) with couplings (4a) to connect to the TRISON Base and return flow (4b) with lowering weight

TRISON Rack
TR 3001 L



TRISON Rack
TR 3001 R

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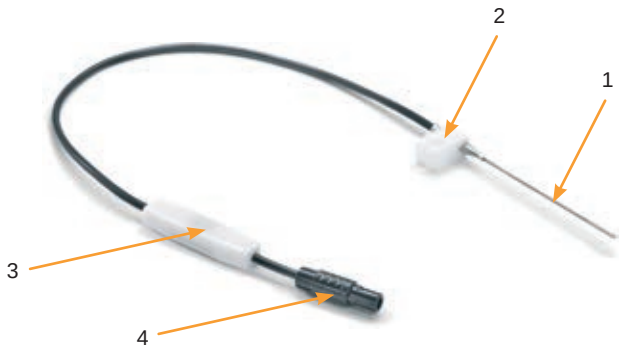
1.3.4 Temperature sensor

The temperature sensor TM 4000 is used for monitoring the temperature of the bath liquid during cleaning of standard instruments (program: Standard).
It is plugged into a basket holder of the on the drain side of the oscillating tank and connected to the TRISON Base for power supply.

Product features:

- Sensor immersion sleeve (1)
- Clamp (2) for attachment to a basket mount of the oscillating tank
- LED display (3)
- Plug (4) for connection to the TRISON Base



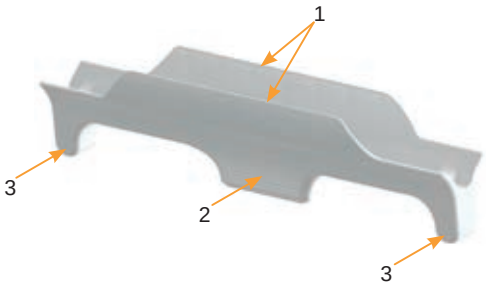
1.3.5 Twist spacer Xi

The spacers are accessories for the TRISON Twist 4000 Xi when cleaning EndoWrist Xi Staplers.
2 spacers in the scope of delivery.

The spacers are attached to the feet of the TRISON Twist Xi and thus raise positioning of the Twist. This prevents possible contact between the instruments and the tank bottom, thus preventing damage.

Product features:

- Clip (1) for attachment to the Twist
- Handle (2) for easier handling
- Feet (3)



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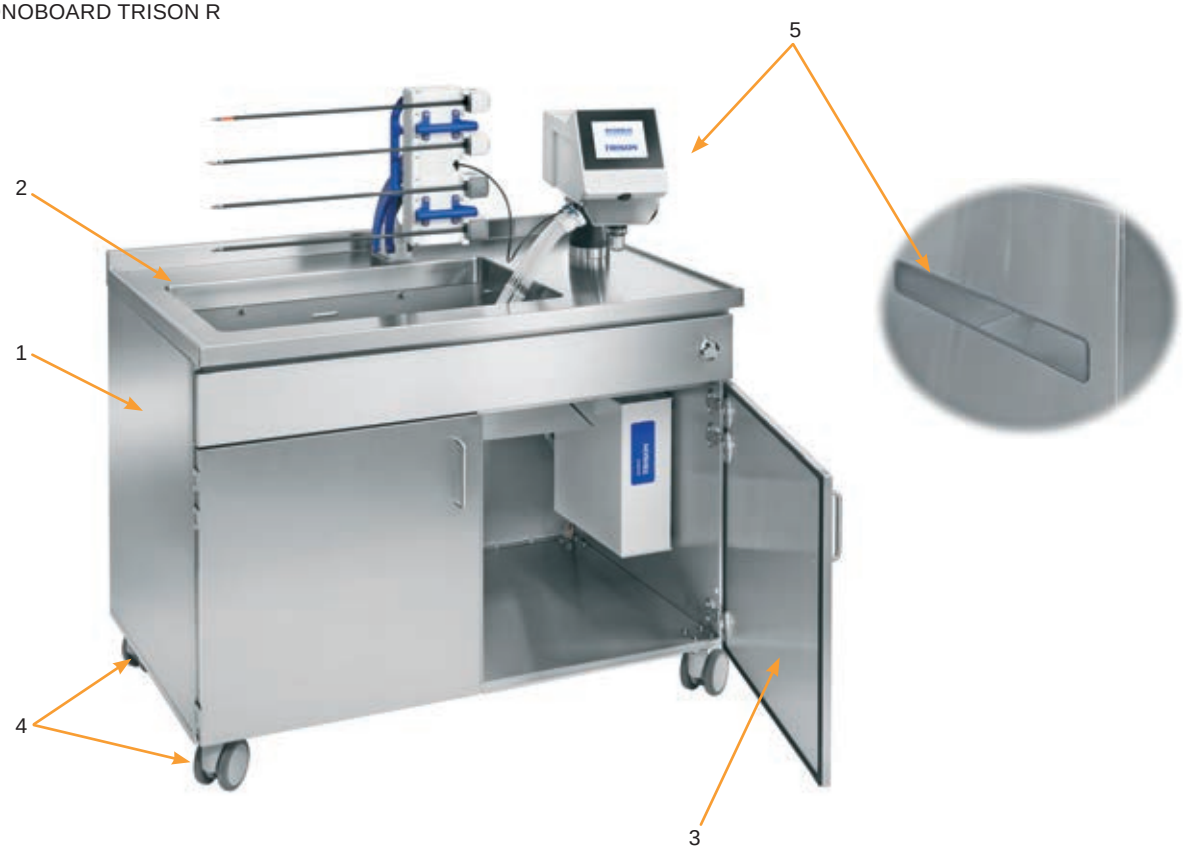
1.4 SONOBOARD TRISON functional cabinet

The SONOBOARD functional cabinet is available in both right- and left-handed variants, as indicated by the letters "R" or "L" in the type designation.

Product features:

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

Based on example of a
SONOBOARD TRISON R



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1.5 Mode of operation

Principle of ultrasonic cleaning

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

Cleaning, rinsing and movement of robotic instruments in the TRISON Twist

On the TRISON Twist, up to 4 robotic instruments with diameters of 5 or 8 mm can be rinsed on the inside and simultaneously moved at their tips during sonication.
The instruments are snapped onto the TRISON Twist and each of them is connected through two hoses to the TRISON Base's rinsing circuit.
The cleaning program first conducts a filling and soaking of the instruments for 30 minutes, using a cleaning agent, in order to loosen up or dissolve organic residue. The control housing and shaft of each instrument are rinsed and tested for flow-through in subsequent ultrasonic cleaning. Instruments that were not rinsable during the cleaning process, e.g. due to clogging, are reliably identified by the integrated continuity test and specified on the monitor.

The sonication time is permanently programmed for 30 min.

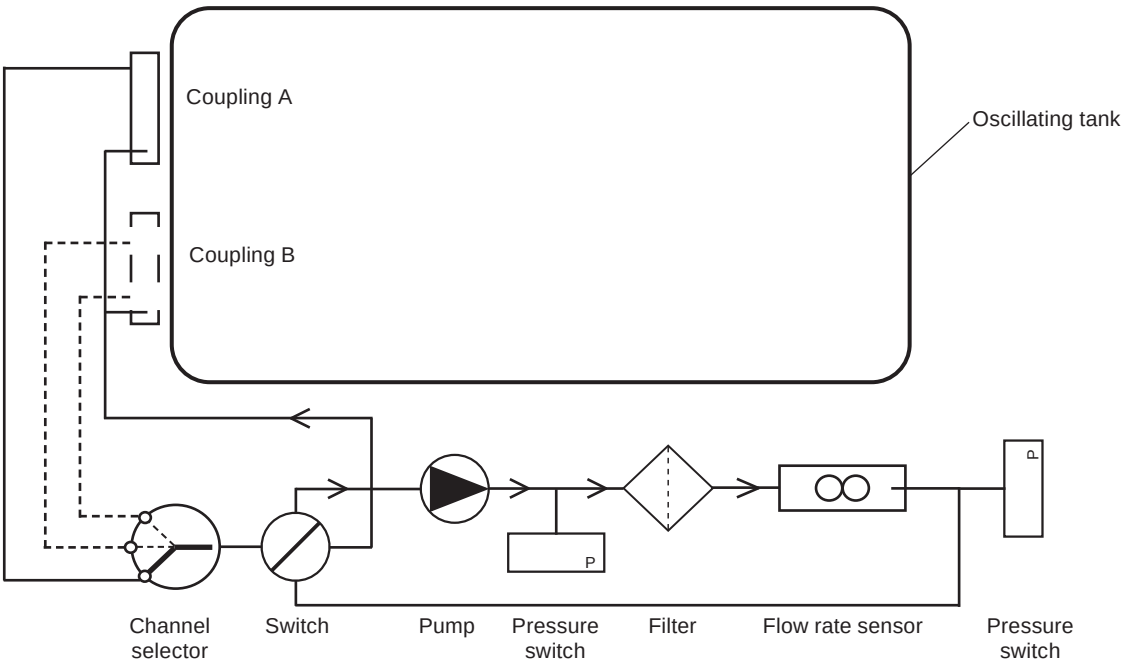
Cleaning and rinsing of MIS instruments/cleaning of standard instruments in the TRISON Rack

During sonication, up to 8 rinsable MIS instruments with exterior diameters of 3 to 10 mm can be rinsed from the inside in the TRISON Rack. Each instrument is hooked up to its assigned adapter and connected to the rinsing cycle of the TRISON Base. Rinsing is conducted using a suction process at the distal end of the instruments. Soiling is always evacuated in the direction opposite to that in which it entered. The remaining lumen of the respective instruments is not contaminated any further by this soiling. The interior of the shaft of every instrument is rinsed and tested individually for flow-through. Instruments that were not rinsable during the cleaning process, e.g. due to clogging, are reliably identified by the integrated continuity test and specified on the monitor. "Non-continuity" of an instrument is declared if the flow-through rate is less than 2 ml/s.

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

The sonication time for each instrument can be set by the user according to the cleaning and/or disinfection agent used (default value 15 min).

TRISON functional diagram:



1.6 Intended purpose

1.6.1 Use of the devices

TRISON ultrasonic baths use the physical effect of high-frequency ultrasound in aqueous liquids in order to clean re-processable medical instruments. Their main application is the gentle, intensive cleaning of rinsable robotic and MIS instruments. Simple standard instruments can also be effectively cleaned in ultrasonic baths. Sonication is conducted using water and an agent suitable for use with ultrasound. In order to use the device as intended, an ultrasound-permeable insert basket or an appliance suitable for positioning the instruments during sonication is also required.

IMPORTANT!

Ultrasonic baths are operated in the context of further steps required to meet the requirements for hygiene in the reprocessing of medical devices in accordance with applicable national regulations. TRISON ultrasonic baths are class I medical devices in accordance with Directive (EU) 2017/745 and must be operated accordingly.

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1.6.2 Indications, contraindications, side effects of the devices

1.6.2.1 Indications/areas of application

- Physically, TRISON ultrasonic baths are especially suited for the cleaning of objects made of metal, glass or hard plastics. Hard-to-access spots, surfaces, corners and openings can be conveniently reached through ultrasound.
- Medical instruments can be cleaned by TRISON ultrasonic baths as part of manual processing, and before or after machine processing, with:
  - o Sonication and simultaneous rinsing of the instrument shafts, as well as simultaneous movement of the instrument tools for daVinci Si/daVinci Xi robotic instruments using the TRISON Twist
  - o Sonication and simultaneous rinsing of instrument shafts for MIS instruments with outer diameters of 3 to 10 mm using the TRISON Rack
  - o Sonication of standard instruments in suitable baskets/devices
- The information supplied by the instrument manufacturer specifies whether the instruments are suited for ultrasonic cleaning.

1.6.2.2 Contraindications/exclusions

- Lenses, camera systems, light cables, mirrors, or objects made of or containing elastic materials (e.g. catheters, respiratory system functional parts, flexible endoscopes) are not suitable for sonication, or are only suitable under certain conditions. The information supplied by the instrument manufacturer specifies whether the instruments are suited for ultrasonic cleaning.
- TRISON ultrasonic baths are not suitable for cleaning and/or disinfection of contact lenses.
- The sonication of combustible liquids in TRISON ultrasonic baths is not permitted.
- Indirect sonication is not permitted in TRISON ultrasonic baths.
- Wearers of medical implants (e.g. implants with electrical or electromotor function) must observe the safety instructions in Section 1.8.

Note:

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

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1.6.2.3 Possible side effects/limitations

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

1.6.3 User group

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

1.7 CE conformity

The ultrasonic bath is declared as a medical device and satisfies the CE-marked criteria for the European directives:

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

in their currently valid versions.

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

1.8 Technical data

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

Ambient conditions pursuant to EN 61 010-1

Overvoltage category:	II
Degree of contamination:	2
Permissible ambient temperature:	15 to 35°C
Permissible relative humidity up to 31°C	80%
Permissible relative humidity up to 40°C:	50 %
Altitude:	up to 2,000 m above sea level

No condensation allowed.
For indoor operation only.

Specifications for use as a medical device

Name:	Ultrasonic bath
UMDNS nomenclature (ECRI/DIMDI):	14-263
Purpose:	see Section 1.6.
Classification (pursuant to Medical Devices Directive (EU) 2017/745, Annex VIII):	Class I; active, non-invasive, non-implantable medical device
Type, model, serial number, year of manufacture:	See type plates for information

The ultrasonic bath has been inspected according to applicable standards and must be installed and operated according to EMC directions; see Section 1.8.2.

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

On-site commissioning, function check and personnel instruction (§ 4):	not required
Technical safety control (STK) (§ 11):	Every 2 years by the manufacturer or authorised skilled personnel
(DIN EN 62353/VDE 0750)	
Technical measurement controls (§ 14):	N/A

Ultrasonic oscillating tank

Type:	**TE 3000**
Internal dimensions: (L×W×H)	770 × 420 × 165/190* mm
External dimensions: (L×W×H)	900 × 480 × 245/275* mm
Material:	Stainless steel, welded
Operating volume:	35.0 l
Weight:	24 kg
Protection class:	IP 20 according to DIN EN 60529 (see Section 1.8.1)
Protection class:	I
Drain set:	G 1½

* tilted tank bottom

Ultrasound generator

Type:	**GT 3000 M-C**
Mains supply:	230 V~ (± 10 %) 50/60 Hz
Ultrasonic frequency:	38 kHz
Fuse:	4× F2A
Ultrasonic peak power:	3040 W**
Ultrasound output:	760 W
Current consumption:	3.3 A
External dimensions: (L×W×H)	360 × 310 × 142 mm
Weight:	4 kg
Protection class:	I
Protection class:	IP 20 according to DIN EN 60529 (see Section 1.8.1)

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

TRISON Base control unit

Type:	**TB 4000 R or TB 4000 L**
External dimensions (incl. rotary base):	370 × 190 × 380 mm (L×W×H)
Current consumption:	0.2 A
Output:	35 W
Compressed air connection:	Coupling plug: NW 7.2 (without connection hose) Input pressure: 5 ... 9 bar, ISO 8573-1 [7:4:4]
Fuses:	2 × F 3.15 A
Interfaces:	USB (front side), Ethernet RJ45 (on the rear side)
Protection class:	IP 22 according to DIN EN 60529 (see Section 1.8.1)
Operating elements:	Touchscreen, mains switch
Protection class:	I
Temperature monitoring	16 ... 45°C
Cleaning pressure:	~ 1 bar
Back-up battery:	3 V lithium metal battery, CR2032
Weight:	9.1 kg

Mains supply switch

Type:	**NW 3000**
External dimensions:	220 × 60 × 145 mm (L×W×H) 300 × 60 × 145 mm (L×W×H) – with cable
Mains supply	230 V~ (± 10 %) 50/60 Hz
Current consumption:	0.005 A
Output:	1 W
Mains fuse:	10 A
Connections:	– Approx. 1.2 m mains cable with safety plug for connection to the mains. (drill hole Ø 60 mm required) – Approx. 1.0 m mains cable with IEC socket for connection to the ultrasound generator. – Approx. 1.4 m mains supply line with flange socket for connection to the control unit.
Protection class:	IP 20 according to DIN EN 60529 (see Section 1.8.1)
Protection class:	I
Weight:	1.1 kg

TRISON Lift

Type:	**TL 4000**
External dimensions, (L×W×H)	240 × 95 × 350 mm
Material:	Stainless steel, POM and PU (polyurethane)*
Weight:	Approx. 3 kg

* Maximum operating temperature +50 °C (no thermal disinfection or sterilisation).

TRISON Twist

Type:	**TT 4000 Si**	**TT 4000 Xi**
External dimensions, without TRISON Lift without instruments: (L×W×H) in mm	405 × 205 × 190	345 × 160 × 175
Material:	Stainless steel, POM and PU (polyurethane)*	
Rotation speed:	Approx. 6 rpm	Approx. 6 rpm
Voltage:	24 V / 5 V	24 V / 5 V
Current consumption:	0.63 / 0.03 A	0.63 / 0.03 A
Output:	15 / 0.15 W	15 / 0.15 W
Weight: without instruments	Approx. 5 kg	Approx. 4 kg
Protection class:	IP 68**	IP 68**

* Maximum operating temperature +50 °C (no thermal disinfection or sterilisation).

** Only valid for the moving device. The mains connector is not waterproof and must not be submerged.

TRISON Rack

Type:	**TR 3001 R / TR 3001 L**
External dimensions, (L×W×H)	640 × 405 × 150 mm
Material:	Stainless steel and POM*
Max. load up to:	10 kg
Weight:	4.1 kg

* Maximum operating temperature +50 °C (no thermal disinfection or sterilisation).

Temperature sensor

Type:	**TM 4000**
External dimensions (L×W×H) in mm	400 × 20 × 20
Material:	Stainless steel, POM and PU
Measuring range:	1 ... 60°C
Voltage:	24 V
Current consumption:	1.2 mA
Output:	989 mW
Weight:	Approx. 50 g
Protection class:	IP 68*

* Only valid for sensor immersion sleeve. The mains connector is not waterproof and must not be submerged.

Twist spacer Xi

Type:	**Spacer Xi**
Material:	PU
Dimensions (L×W×H):	138 × 23 × 32 mm
Weight:	21 g each

SONOBOARD functional cabinet

Type:	**FS 1200 TR / TL**
External dimensions, incl. casters (L×W×H):	1200 × 700 × 930 mm
Material:	Stainless steel
Weight, complete*:	180 kg

* Functional cabinet including TRISON 4000

Note:

The TRISON 4000 Xi ultrasonic bath is included in the SONOBOARD TRISON set.

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1.8.1 Degrees of protection according to DIN EN 60529

IP 20

Protected to prevent fingers from accessing dangerous parts.
Protected against solid foreign bodies with a diameter of 12 mm or larger.

Not protected against ingress of water.

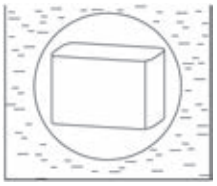
IP 22

Protected to prevent fingers from accessing dangerous parts.
Protected against solid foreign bodies with a diameter of 12 mm or larger.

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

IP 68

Protected to prevent access to dangerous parts with a wire.
Dustproof.



Protected against the effects of long-term submersion in water.

1.8.2 Electromagnetic compatibility (EMC)

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

1.9 Warnings and safety instructions

General

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

Operation and transport

- Observe ambient and set-up conditions, see Section 1.8.
- Never operate the oscillating tank without the cover on the oscillating systems!
- Only turn on the generator if the ultrasonic oscillating tank is connected (HF cable) – never run the generator without a load.
- Only plug in the ultrasonic bath to an outlet with a grounded socket.
- Do not operate the ultrasonic oscillating tank without liquids.
- Do not use a rubber plug or stand pipe on the oscillating tank outlet!
- Do not place or lay any objects on the tank bottom, accessories must be used, see Section 7.

- Do not immerse any parts of the body (e.g. hands, feet) or living organisms (animals or plants) in the oscillating tank; in particular, do not make contact with the bath liquid during ultrasound operation. Danger: Ultrasound has a cell-destroying effect.

- In the event of continuous activity within a 2 m radius, adequate hearing protection must be used. Danger: Hearing impairment possible during operation if not wearing hearing protection – the typical ultrasound cavitation noise can be very uncomfortable.
- Do not operate the ultrasonic bath while unattended.
- TRISON Twist with TRISON Lift:
  - Do not touch moving parts during operation.
  - The TRISON Twist may only be lowered/raised using the handle provided for this purpose.
- Only move the SONOBOARD TRISON ultrasonic bath when it is empty.

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Advice for the laboratory and medical field

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

Damages and defects

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

Battery

- The TRISON Base control unit contains a back-up battery. (3 V lithium metal battery, type CR2032). Battery replacement is not anticipated!
- Heed the separate instructions for battery disposal when the ultrasonic bath is decommissioned! See Section 9.
- Never dispose of the battery in household waste, and never dispose of it while charged or by throwing it in the fire! There are risks of explosion and leakage in the event of improper use.
- Do not open/deform the battery. Leaking chemicals could cause injury! In the event of contact with the skin or eyes, rinse and flush out with plenty of water and seek medical care!

2 Preparation

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

2.1 Scope of delivery

The scope of delivery is listed in the delivery note.

2.2 Setup/assembly

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

Multi-part ultrasonic bath

The installation of the components of the TRISON ultrasonic bath must be conducted by authorised skilled personnel, under reference to the installation instructions.

SONOBOARD TRISON

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

- Compressed air connection with a minimum of 5 bar, maximum of 9 bar. In order to protect the components operated by compressed air, it is recommended that a suitable filter be installed upstream.
- Power supply: Grounded socket outlet 230 V~ (± 10%) 50/60 Hz
- Suitable filling fitting (spray, spigot, dosing unit)
- Outlet for emptying the ultrasonic oscillating tank
- Ethernet interface for documentation/record-keeping (recommended). Alternatively, a USB connector is available on the control unit.

At the place of operation, engage the locking brakes on the front swivelling casters to secure the SONOBOARD TRISON against accidental movement.

Note:

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

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2.3 Commissioning and basic settings

- Thoroughly rinse the ultrasonic bath oscillating tank with water before its first use.
  Note:
  All outer surfaces (and also the inner walls of the oscillating tank) are covered with an oily preservative in order to protect the surface during transport and storage. This should be removed with a suitable cleanser before commissioning, see Section 5.
- Connect the TRISON Base to the mains switch for testing.
  If the touchscreen lights up, the connection is correct.

Note:

If the Ethernet cable is not connected or if there is no network connection, an error message will appear on the touchscreen after approx. 13 sec. This will disappear automatically and the ultrasonic bath will perform an automatic restart.
In order to initialise a network connection, the Ethernet cable must be plugged in before turning on the device, or before the ultrasonic bath is turned off and on again.

- It is recommended that a foil test be conducted as part of quality assurance prior to the first use.
  This test is to be saved for later comparison, see Section 6.2.
- Place the TRISON Rack or Twist in the ultrasonic oscillating tank. Place lid on top.

IMPORTANT!

Required basic settings must also be entered in the system prior to the first use.

2.3.1 Basic settings

The required data are:

- Operating volume of the connected ultrasonic bath:
  Only important for the duration of the degassing!
- Treatment time for the “MIS” program:
  Only important for the duration of cleaning of MIS instruments!
- Runtime for the "Robotics" program:
  The duration of the soaking and cleaning phase for the robotic instruments can be set.

Incorrect or false values shall be the responsibility of the user.

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The standard settings are:

– 35 litres (corresponding to a TE 3000)
– 15 minutes (corresponding to STAMMOPUR DR 8, see Section 7.3)
– 30 minutes soaking and 30 minutes cleaning in the robotics process

Change standard settings for operating volumes and MIS instruments:

➢ Check the operating volume and the duration of treatment under *Settings/User/Process data* and correct if necessary.

➢ Next, exit this menu by pressing the Home key.

Change standard settings for robotic instruments:

➢ Check the runtimes under *Settings/System/Robotic duration* and correct if necessary.

Note:

A password is required to change these settings. This can be requested from BANDELIN.

➢ Next, exit this menu by pressing the Home key.
The basic settings are completed and saved.

➢ Turn the ultrasonic bath off again.

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2.3.2 Additional user settings

If required, the time and date can be checked and corrected under *Settings/System/Time/Date*. The current display is on the top right-hand side of the Home menu.

The device does not switch automatically between CET and CEST; this switch must be performed manually as described above.

In *Settings/Users ...* the screen contrast can also be set and the institution entered.

3 Operation

3.1 Operating elements

The device is operated via the touchscreen. The operating program will guide you with clear instructions through the individual steps.

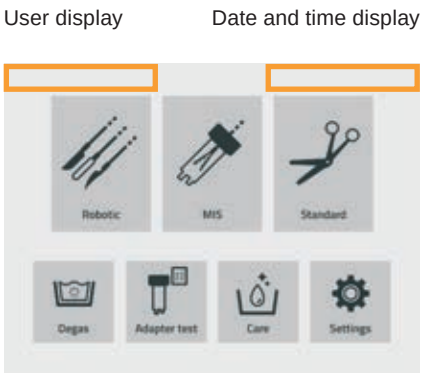
Caution!

Do not use force when pressing on the touchscreen. Do not use your thumbs to press the buttons.

Home menu:

The central screen is the Home menu.
All important programs and sub-menus can be accessed from here; the program returns to this menu after every cleaning.

The date and time (on delivery: CET or CEST) and the registered user (default setting: empty) are also shown in the Home menu.
If needed, the data can be adjusted by going to:
Settings/System/TIme/Date or
Settings/User/Institution
The specifications are also saved in the protocols.



Setup of operating screens:

Brief instructions or information on the action to be carried out

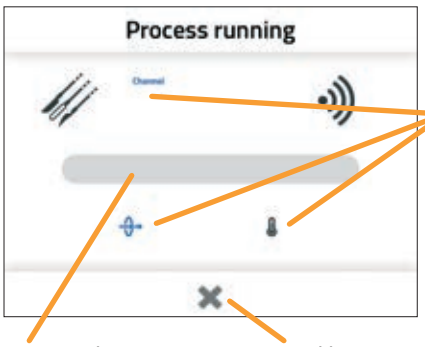
Illustration of the action

Navigation bar

- The Next key ▸ is used to proceed only when all instructions have been followed.
- The Back key ◂ is used to return to the previous screen.
- The Home key ⌂ takes you back to the Home menu.

Setup of process screens:

If a process has started, a progress bar will appear to show the status of the process. A Cancel key is displayed in the navigation bar in place of the Home button and makes premature termination of the ongoing process possible if required (not recommended).



Various process indicators, e.g. number of the currently rinsed channel, flow-through rate, temperature ok or not ok

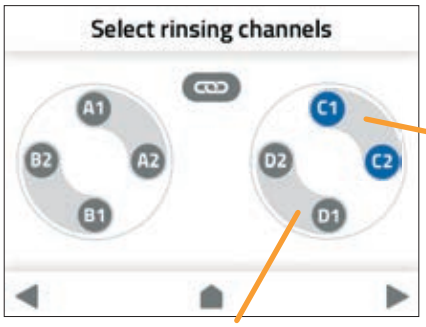
Progress bars

Cancel key

Setup of selection screens:

Similar selection screens appear in the various cleaning programs. Here, the mounted/ connected rinsing channels must be selected or set for the program. If nothing is selected, the program will be unable to start.

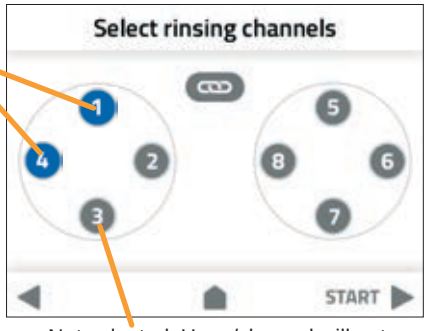
Example from the robotics program:



Selected: Loaded/connected hose/ channel

Not selected: Hose/channel will not be rinsed during the current program

Example from the MIS program:



Selected: Loaded/connected hose/ channel

Not selected: Hose/channel will not be rinsed during the current program

Note:

In the Maintenance menu and for the adapter test, rinsing channels can only be selected or deselected as couplings – individual selection is not possible.

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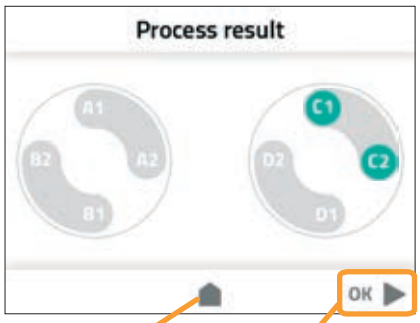
Setup of results screens:

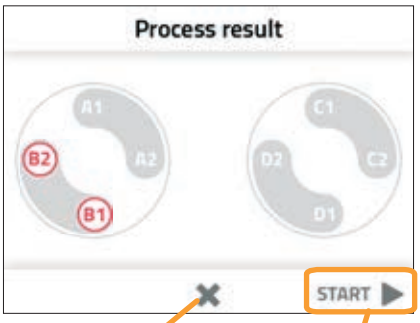
After cleaning, the Results screens display whether any rinsing channels or instruments were non-continuous and, if so, which ones. In this case, a decision must be made as to whether the affected instruments should undergo cleaning again, or should be processed manually and separately.

Example from the robotics program:



Return to Home menu

Instrument on hoses C1/C2 continuous, cleaning concluded

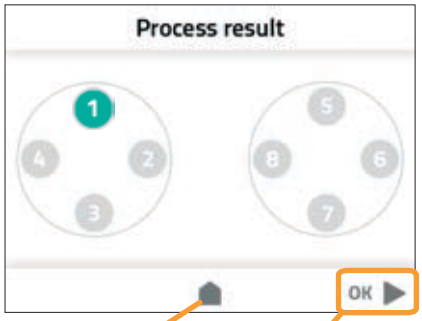


Return to Home menu

Instrument on hoses B1/B2 not continuous, cleaning not completed

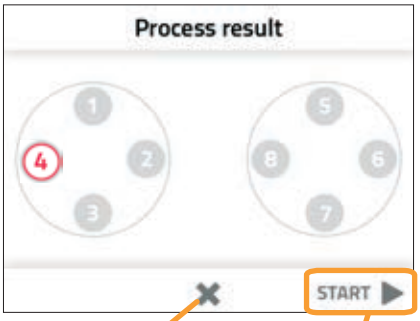
Repeat cleaning on non-continuous instruments?

Examples from the MIS program:



Return to Home menu

Instrument on hose 1 continuous, cleaning concluded



Return to Home menu

Instrument on hose 4 not continuous

Repeat cleaning on non-continuous instruments?

3.2 Signals on the touchscreen

Colours and symbols

Colours and symbols are used on the screens to underscore information:

Signal	Type	Explanation
"orange"	Arrows, numerals	Work steps and sequences of movement
"green"	Keys	Positive, error-free result
"red"	Keys	Negative result
"yellow"	Warning triangle	Warning notice, can be skipped
"red"	Warning triangle	Error message, action required
"light grey"	Keys	Inactive buttons
	Symbol	Test (of a value) = OK
	Symbol	Test (of a value) = False
	Symbol	Flow rate during cleaning
	Symbol	Temperature during cleaning
	Symbol	Channel number during cleaning
	Key	Return to Home menu
	Key	In the general program sequence = Next In case of an error message = OK
	Key	In the general program sequence = Back
	Key	In process or in case of error message = Abort In case of an error message = Ignore
	Key	Starts the process

Key operation

Correct key operation on the control panel is acoustically identified by a signal tone (beeping).

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3.3 Connection/removal of the instruments

3.3.1 Robotic instruments

Robotic instruments are connected to the TRISON Twist. To connect them, use the hose set with rinsing plugs, see Section 1.3.2.

IMPORTANT when cleaning EndoWrist Staplers:

The daVinci instruments EndoWrist Stapler 45 Xi and EndoWrist stapler 45 Si can also be cleaned in the TRISON ultrasonic bath. Special accessories are available:

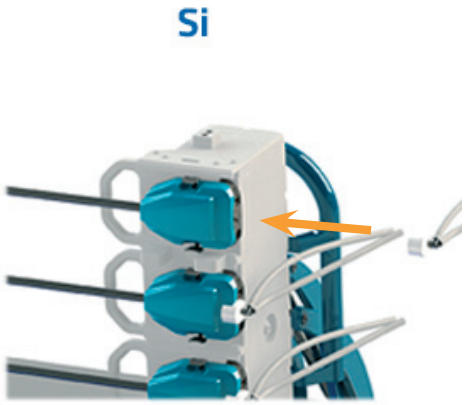
- For cleaning the EndoWrist Stapler 45 Xi, the TRISON spacer Xi on the TRISON Twist 4000 Xi must be used. Treating the EndoWrist Stapler 45 Xi without the spacer can damage the instrument and the TRISON oscillating tank.
- For cleaning the EndoWrist Stapler 45 Si, two individual Luer connection plugs must be connected to the hose set of the TRISON Twist 4000 Si.

Generally speaking, due to larger dimensions, the instruments can only be connected to TRISON Twist Xi or TRISON Twist Si in one of the two central positions. In addition, only one EndoWrist Stapler 45 per process run is permitted.

The instrument moving function of the EndoWrist Stapler 45 in the TRISON ultrasonic bath is limited, as it can only be completely released by the robot arm itself. This means that the shaft or distal end cannot be rotated. In addition, the stapler instruments are significantly stiffer, overall, than other daVinci instruments.
Visual control after cleaning and manual post-cleaning may be necessary.

3.3.1.1 Connection of Si instruments to the TRISON Twist TT 4000 Si

- Hold the TRISON Twist by the handle and rotate it into the top position.
- If necessary, open the push handles, place the robotic instruments in the TRISON Twist mounts and ...
- ... secure them once again with the push handles. This will hold the instruments in place and prevent them from floating to the surface.
- **Only when cleaning a Si Stapler:**
  Observe the note for Luer plugs – see next page.
- Connect the rinsing plugs to the robotic instruments and press firmly.
- Hold the TRISON Twist by the handle and lower it into the ultrasonic bath (lower position, see images below).
- **Connect the couplings to the TRISON Base** (see Section 3.3.3).



Removal of the instruments:

Follow the reverse order.
After cleaning a Si Stapler: Unplug the individual Luer connector and replace with the original rinsing plug.

TRISON Twist Si positions:

Top position
(assembly, rinsing plug connection)

Bottom position
(sonication)

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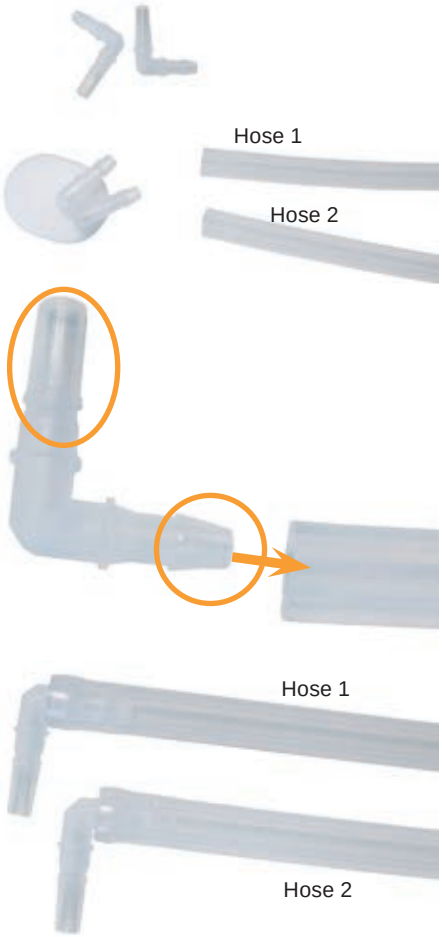
Replace rinsing plugs with individual Luer connectors for Si Staplers:

- Pull off the existing rinsing plug on any pair of hoses and replace it with individual Luer connection plugs (separate accessories, see Section 7.2).

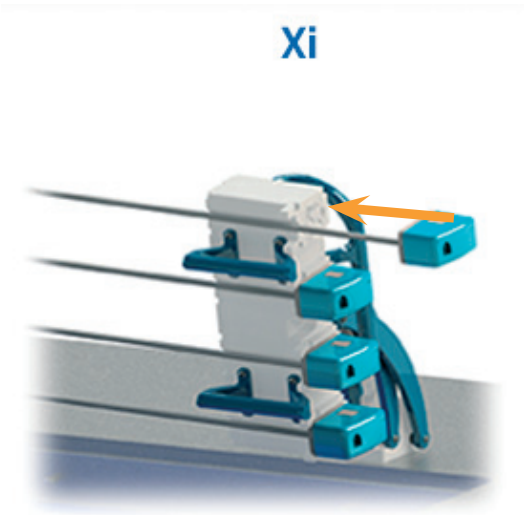


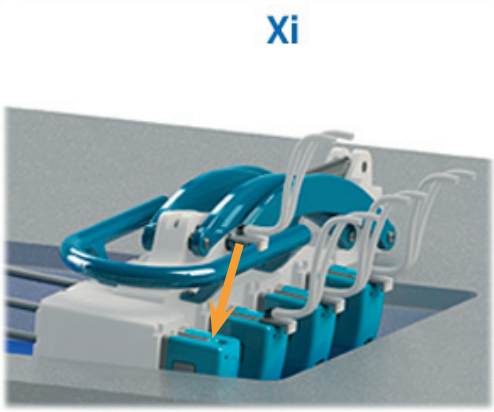
IMPORTANT Note the insertion direction of the Luer connector plugs: insert the short side into the hose as pictured.

- Then connect a Luer connector plug to hose 1 on the rinsing connection 1 and a Luer connector plug to hose 2 on the rinsing connection 2 of the Stapler.

3.3.1.2 Connection of Xi instruments to the TRISON Twist TT 4000 Xi

- Hold the TRISON Twist by the handle and rotate it into the top position.
- Press/latch the robotic instruments onto the guide lugs in the TRISON Twist mounts. Careful handling!
- **Only when cleaning an Xi Stapler:**
  Attach Twist spacer Xi to the feet of the Twist – see next page.
  Insert the rinsing plug into the Stapler and press firmly.
- Hold the TRISON Twist by the handle and lower it to the middle position. Connect the rinsing plugs to the instruments and press firmly.
- Hold the TRISON Twist by the handle and lower it into the ultrasonic bath (lower position).
- **Connect the couplings to the TRISON Base** (see Section 3.3.3).

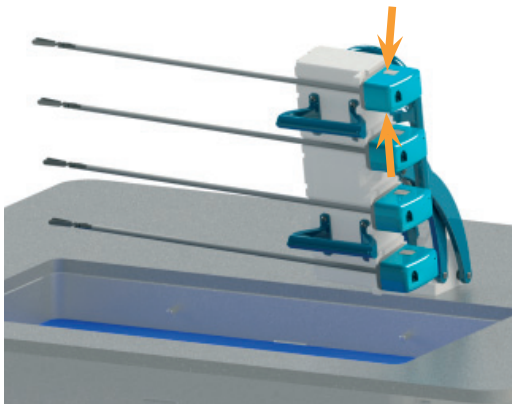




Removal of the instruments:

... Follow the reverse order.

- In order to remove the instruments, press the appropriate locking buttons on the instrument.



TRISON Twist Xi positions:

Top position
(assembly)

Middle position
(rinsing plug connection)

Bottom position
(sonication)

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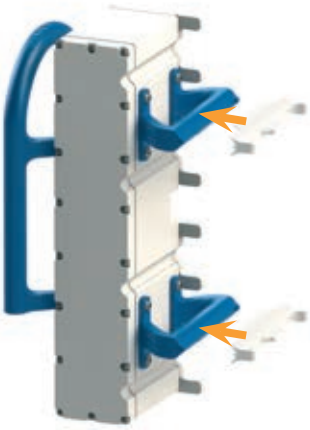
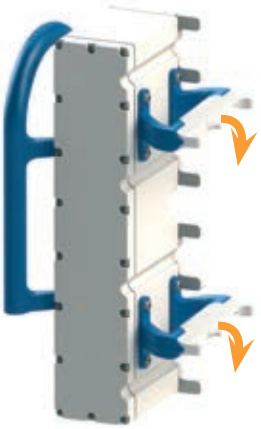
Mounting/storage of the Twist spacer Xi

- For use, the spacers are clicked onto the TRISON Xi feet.
  To remove the spacers, unscrew them sideways on the grooved handle.
- If no EndoWrist Stapler 45 Xi is being cleaned, the spacers can be attached to the handle of the TRISON Xi.
  To remove, slide the spacer backwards off the handle.

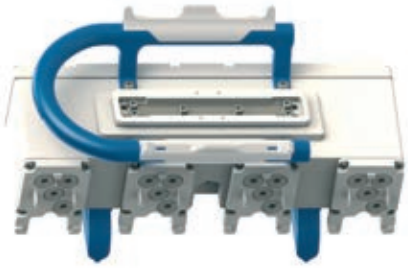
Attaching for use

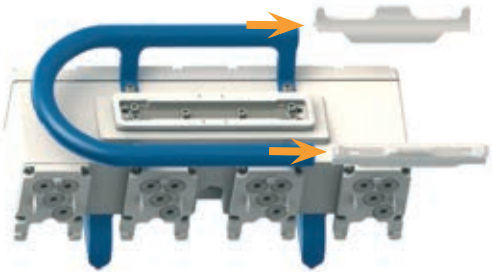


Removal after use



Storage/removal





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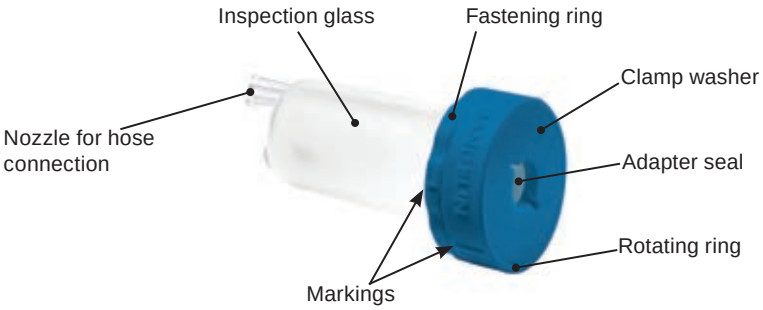
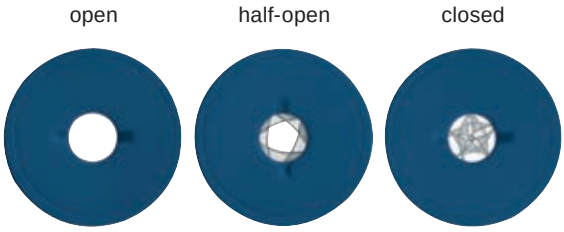
3.3.2 Rinsable MIS instruments

Rinsable MIS instruments are connected to the TRISON Rack. To do so, use the hose set with the adapters, see Section 1.3.3.

Setup of an adapter:

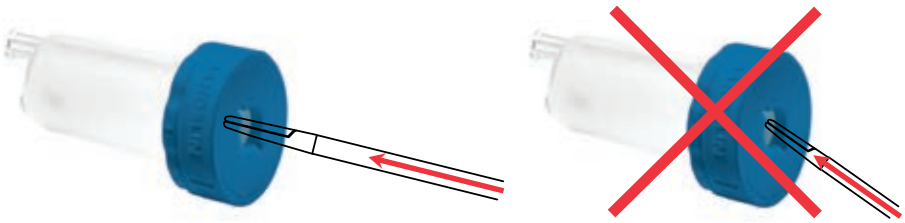


Adapter settings:

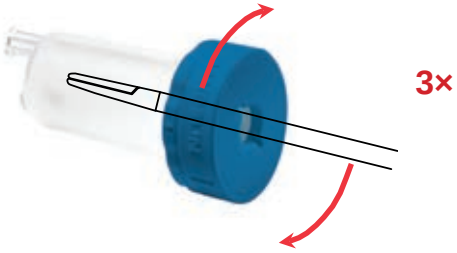


Connecting the instruments:

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



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



Important!

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

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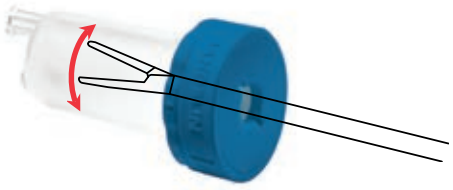
➢ Next, open the movable parts on the tip of the instrument in order to also guarantee optimum cleaning in that area.

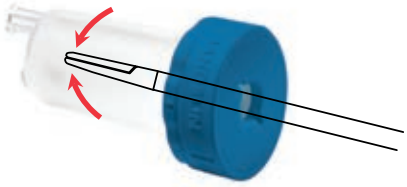


➢ Check for correct positioning of the adapter in the comb bar; if needed, reaffix the nozzle in the comb bar. The nozzle with the hose connection must be on top.

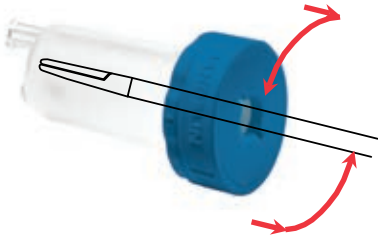
➢ Place the TRISON Rack in the ultrasonic bath and **connect the couplings** (see Section 3.3.3).

Removal of the instruments:

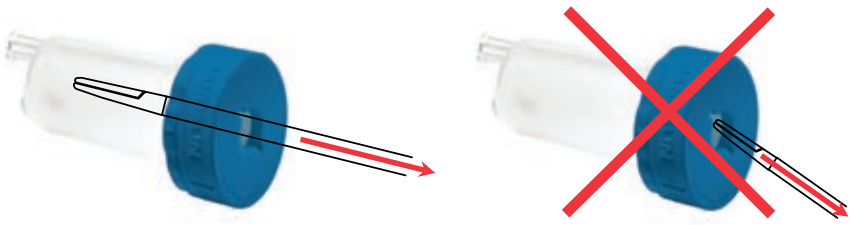
➢ First, close the movable parts on the tip of the instrument.



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



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



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3.3.3 Establishing connections to the TRISON Base

Connect couplings

For a rinsing operation, the special baskets must be connected with the TRISON Base.

➢ Always connect both couplings of the hose sets by pressing down the release button on the couplings and attaching the coupling until it engages.

Note:

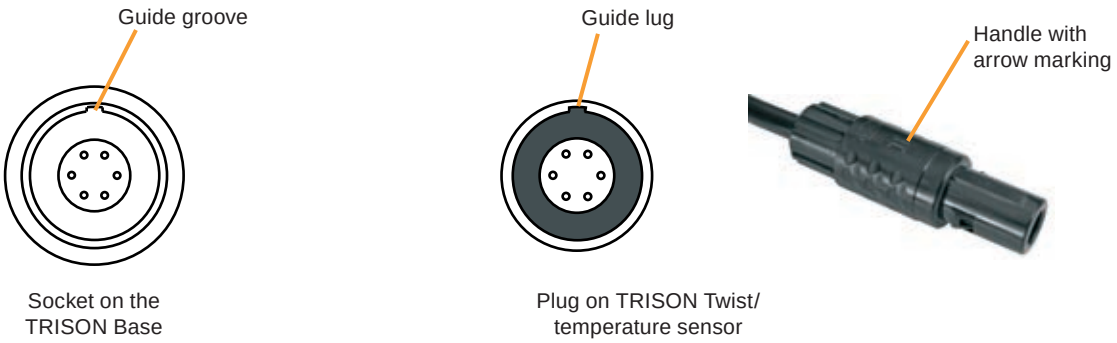
The couplings are coded (“A” or “B”) and therefore cannot be confused.

Important:

Before starting with the cleaning process, both “RL” returns (one per coupling) must be placed loosely in the oscillating tank. This will pump the rinsing fluid back into the ultrasonic oscillating tank in a circuit.

Connect TRISON Twist or temperature sensor

The connection between TRISON Twist/temperature sensor and TRISON Base is established via a push-pull circular plug with locking mechanism.
To connect, hold the plug from the handle and position it in such a way that the guide lug and arrow point upwards.
The plug can only be connected if the socket's guide lug and the plug's guide lug are positioned uniformly on the TRISON Base, see image. Insert the plug into the socket until it clicks into place.
In order to unplug the connection, hold the plug from the handle only and not from the cable, pull it back and remove the plug.



Caution:

- Do not twist the plug or insert it forcefully. Damage may lead to a short circuit!
- The plug is not waterproof.

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Tip:

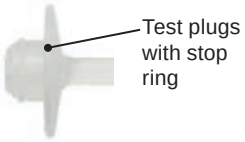
Time can be saved by filling an additional basket while the first basket is being used.

3.4 Connecting/removing the adapter testing strips

Connecting the testing strips:

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

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



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

Removing the testing strips:

- ➢ Pull the test plugs from the adapters.

3.5 Opening and closing the outlet

The outlet of the oscillating tank is operated using the drain set turning knob.

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

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3.6 Attachment/removal of the TRISON Lift

If the TRISON Lift is not needed, it can be easily removed without tools and stored in a different location. It can be reattached just as easily.

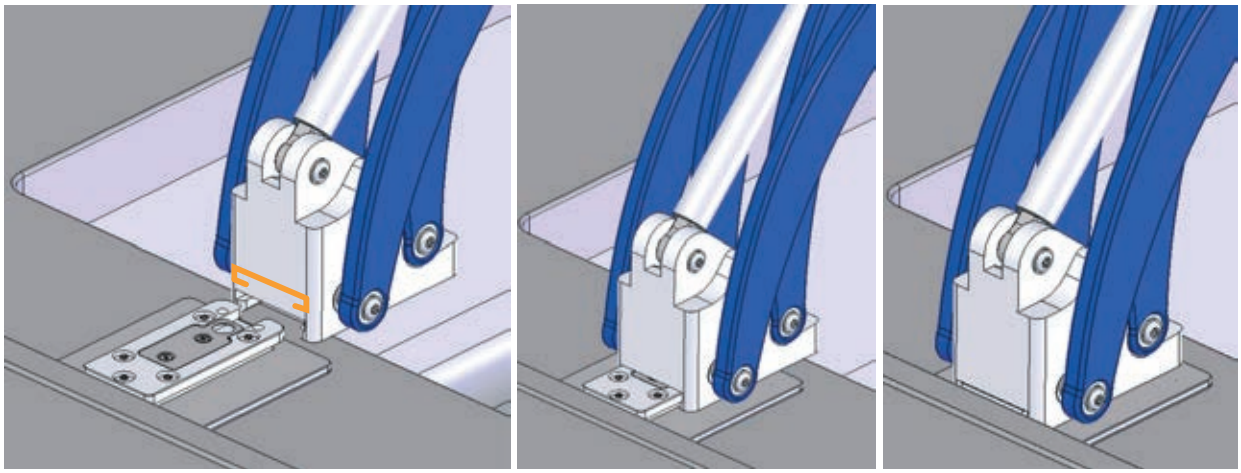
Removal:

- Before the TRISON Lift is removed, remove the TRISON Twist.
- From the base, pull the Lift directly forward (i.e. in the direction of the ultrasonic oscillating tank).
- Then store it in a clean, dry location.

Attachment:

- Push the TRISON Lift straight backwards at the base, using the glide on the base plate, until the stop is reached and it clicks into place.
- A TRISON Twist can then be mounted.

View:
As seen from the rear



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3.7 Mounting/removal of the TRISON Twist

If the TRISON Twist Si or Xi is not needed, it can be easily removed without tools and stored in a different clean and dry location. It can be reattached just as easily.

Important:

The plug on the TRISON Twist must not be submerged!
If the plug comes into contact with liquids it must be blown out with compressed air and allowed to dry completely.

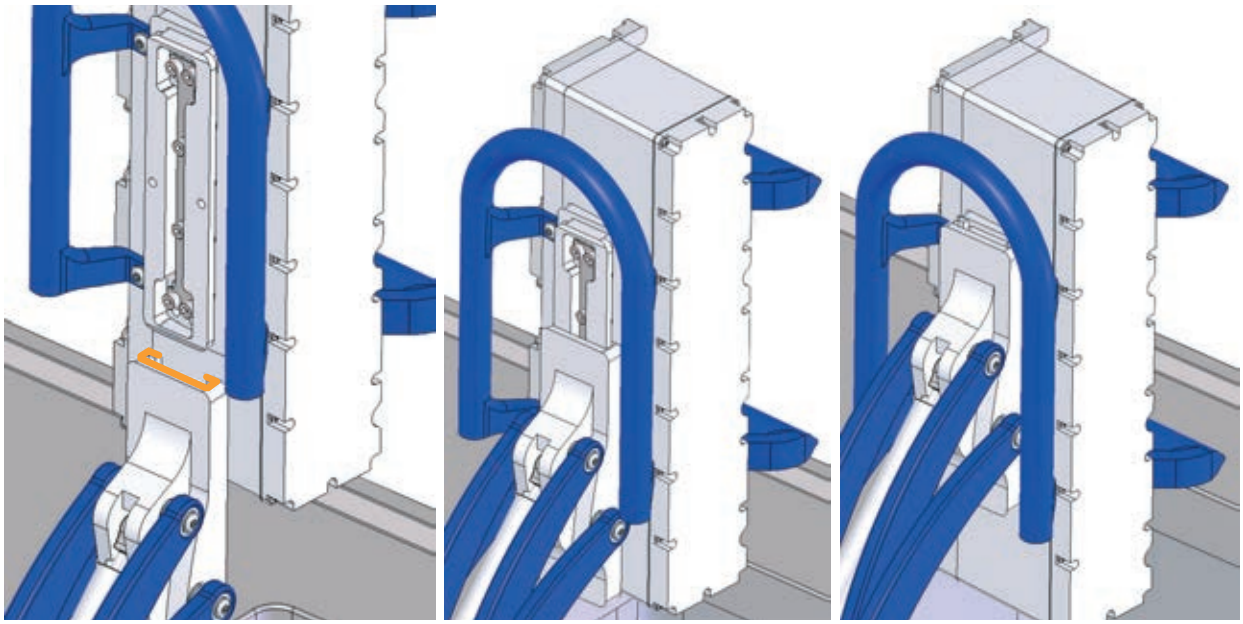
Removal:

- Before the TRISON Twist Si or Xi is removed, withdraw all instruments.
- Undo all connections between the TRISON Base and TRISON Twist (push-pull plug and hose connections).
  Hold the plug in your hand and protect it from liquid.
- Hold the TRISON Twist by its handle and pull directly upwards.
- Then store it in a clean, dry location.

Attachment:

- Hold the TRISON Twist Si or Xi by its handle. Using its guide, slide it straight downward into the head of the TRISON Lift, until the dead stop is reached and it clicks into place.
- Then the TRISON Twist can be loaded with the instruments.

View:
As seen from the rear



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3.8 Protocols

After the completion of each cleaning procedure, a protocol is prepared and filed in the internal memory. This memory can save and manage up to 50 protocols.

Depending on the cleaning program, the protocols will vary in content and are provided with corresponding names:

Cleaning protocol for
Robotic instruments “17_0030R”

BANDELIN TRISON
SN: 7800.00102011.001
protocol cleaning: Robotic Instruments # 1
user:

robotic shortened: true
skipped soaking: true
skipped temperature warning: false
diameter: 8
retake cleaning: false

selected channels: A B C D
clogged channels: -
start: 06:05 / 12.05.2017 / 24°C
end: 06:23 / 12.05.2017 /24°C
---
working hours pump: 0:15
bath volumen (l): 35

Cleaning protocol for
MIS instruments “17_0010M”

BANDELIN TRISON
SN: 7800.00102011.001
protocol cleaning: MIS Instruments # 1
user:

MIS duration (s): 900
retake cleaning: false
skipped temperature warning: false

selected channels: 1 2 3 4 5 6 7 8
clogged channels: -
start: 06:36 / 12.05.2017 / 25°C
end: 06:55 / 12.05.2017 / 25°C
---
working hours pump: 0:35
bath volume (l): 35

Cleaning protocol for
Standard instruments “17_0001S”

BANDELIN TRISON
SN: 7800.00102011.001
protocol cleaning: Simple Instruments # 1
user:

duration (s): 120

start: 11:20 / 08.03.2017
end: 11:22 / 08.03.2017
---
working hours pump: 0:0
bath volume: 35

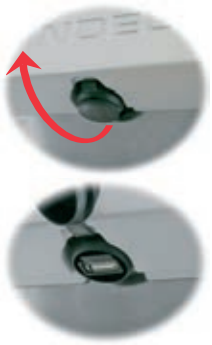
The name of an individual protocol uses its year of creation and a consecutive number for the process conducted. This is followed by a code letter indicating the cleaning program.

Important:

If the maximum number of data (max. 50 protocols) is exceeded, an error may occur in the internal data administration. Therefore, protocols must be retrieved at regular intervals, i.e. these protocols must be saved on another data storage medium and be deleted from the TRISON Base.

3.8.1 Opening and closing of the USB interface

The USB interface is located below the touchscreen.



Opening/closing of
the USB interface

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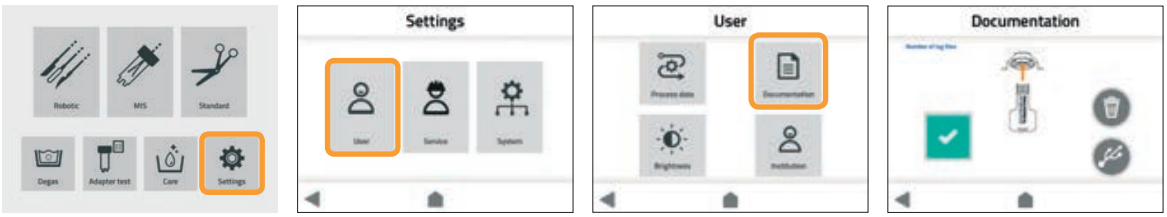
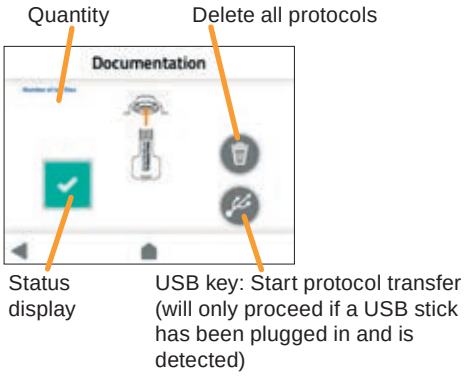
3.8.2 Copying/retrieving protocols via USB interface

The saved protocols may be retrieved, when required, by going to *Settings/User/Documentation*.



The number of saved protocols is displayed on the upper left-hand corner.
After inserting the USB stick, the detected hardware appears in a field in the upper right. Press the “USB” key on the bottom right in order to copy the protocols onto the USB stick.



Important:

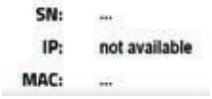
- After copying, the data is automatically deleted from the internal memory.
- Always close the interface cover(s) after use.

3.8.3 Copying/retrieving protocols via Ethernet interface

The IP address that is assigned by the DHCP server can be found, if required, under *Settings/System/Information*.

The IP address is only available when the Ethernet connection is established.
For this to happen, the corresponding cable must be plugged in before the TRISON Base is turned on, see Section 1.1 if needed.

If a connection is not established, the message "not available" will appear.



Calling up the protocols

The protocols can be called up in an installed browser (PC).
Enter the IP address in the address bar, and confirm with Enter.

Example of protocols saved in the TRISON Base:

By clicking "delete" (with left mouse click), the protocol will be deleted.

The saved protocol can be viewed by left-clicking on "view".
By right-clicking on "view", a pull-down menu will appear.
By selecting "Save target as...", the protocol can be saved on a storage medium.

Note:

Detailed information on interface communications via Ethernet can be obtained from the manufacturer upon request.

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3.9 Connecting/analysing the temperature sensor

The TM 4000 temperature sensor must be connected to the TRISON Base in order to operate; see Section 3.3.3.
The sensor immersion sleeve must be fastened to a front basket mount of the oscillating tank with the clamp.

Important:

- Functioning is only guaranteed if the plug is connected and the immersion sleeve for the sensor has been immersed.
- The plug on the temperature sensor must not be submerged!
  If the plug comes into contact with liquids it must be blown out with compressed air and allowed to dry completely.

Assessment

The LED display of the temperature sensor should be positioned clearly visible next to the TRISON Base, as this is used for evaluation by optical signals.

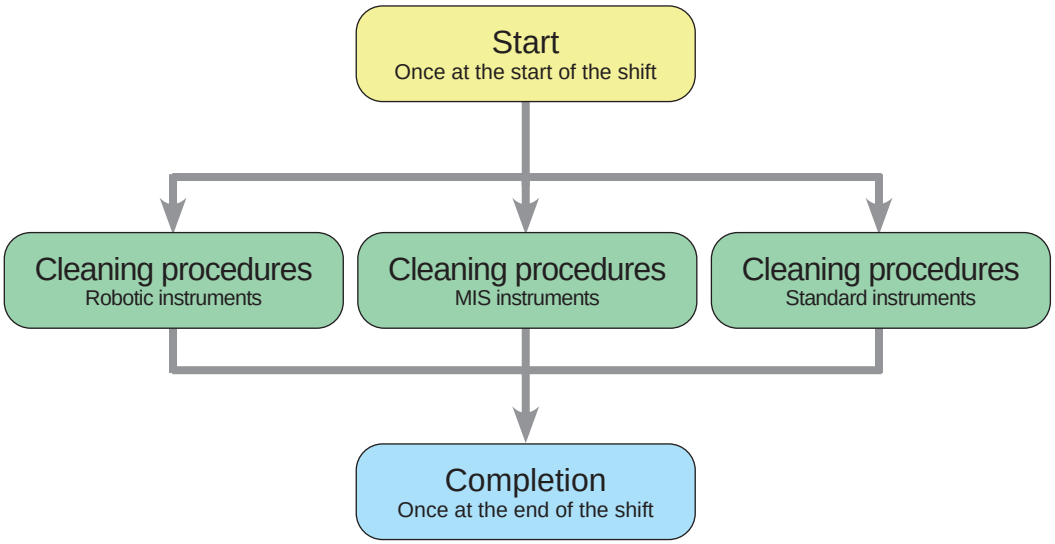
- Green – permanently lit:
  Ready for operation, temperature OK
- Red – permanently lit:
  Ready for operation, bath temperature too low
- No display:
  Internal error (e.g. sensor defective)
- Red – flashing:
  Ready for operation, bath temperature too high
- Orange – flashing:
  Sensor not immersed

Note:

The temperature sensor is only used/evaluated with the “Standard” program.
With the two other programs, the temperature is monitored by the internal temperature sensor and displayed by the TRISON Base.

4 Application

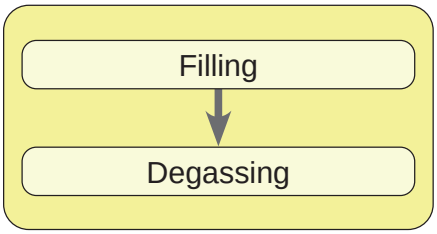
The TRISON ultrasonic bath is designed for multi-shift operation in a medical establishment. As many cleaning procedures as desired can be conducted within a single shift, according to the following procedure:



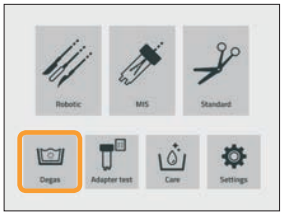
The coloured work steps are explained next.

4.1 Start – preparation of the ultrasonic bath

Preparation of the ultrasonic bath is to be conducted once at the start of a shift, or after every change of bath liquid.
The following work steps are required:



Turning on



- Turn on the TRISON Base from the mains switch. A welcome screen will appear for approx. 2 seconds, then the Home menu appears.
- Press the "Degas" button and follow the instructions on the touchscreen.

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Filling

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

Important!

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

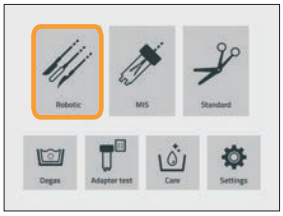
Degassing

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

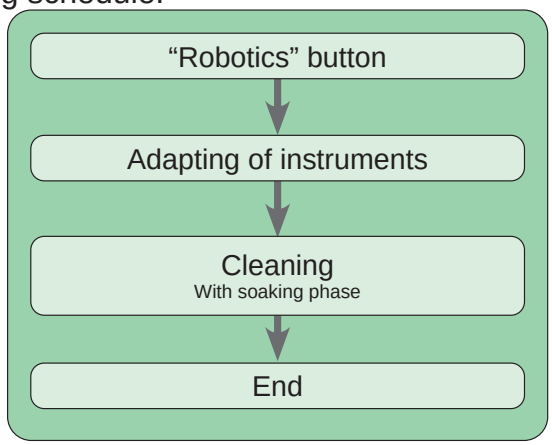
The cavitation noise changes during the degassing process. Loud degassing noises disappear toward the end of the degassing process and the ultrasonic bath appears to work more quietly.
However, a lower noise level does not mean a reduction in ultrasonic power. Instead, it signifies the end of the degassing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

4.2 Cleaning

4.2.1 Robotic instruments

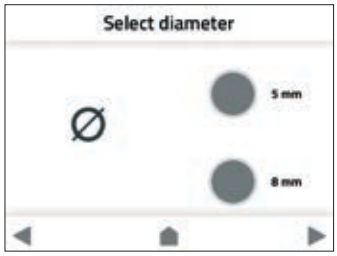


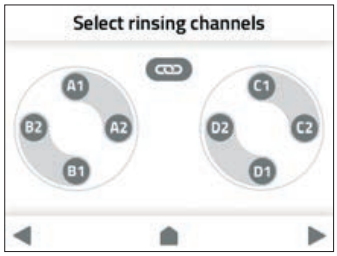
Rinsable robotic instruments are cleaned according to the following schedule:



Adapting the instruments

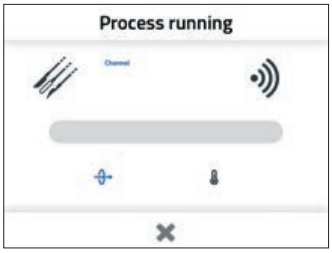
- ➢ Connect the instruments to the TRISON Twist and lower into the ultrasonic oscillating tank (see Section 3.3.1). Observe the following:
  - Only clean instruments that have been approved by their manufacturer for ultrasonic cleaning.
  - Do not clean any damaged instruments.
  - The instruments must be fully covered with liquid.
- ➢ Connect couplings, see Section 3.3.3.
  If the Twist is not connected, an error message appears.
- ➢ Set the smallest available instrument diameter.
- ➢ Select only the occupied rinsing channels (see Section 3.1).
  The numbering of the channels can be found on the hoses.
  Do not select unused channels.
- ➢ Start cleaning.





Cleaning operation

The cleaning operation takes place automatically and includes a preliminary soaking phase[1] (without ultrasound or instrument movement).
Note: The instruments do not move uniformly during operation and, if sluggish, they can only be moved to a limited extent!



At the end, an overview indicates which instruments were successfully rinsed (shown in green) and which were "non-continuous" (shown in red), see also Section 3.1.

1 Required treatment time for enzymatic cleaners (agents).

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Caution!

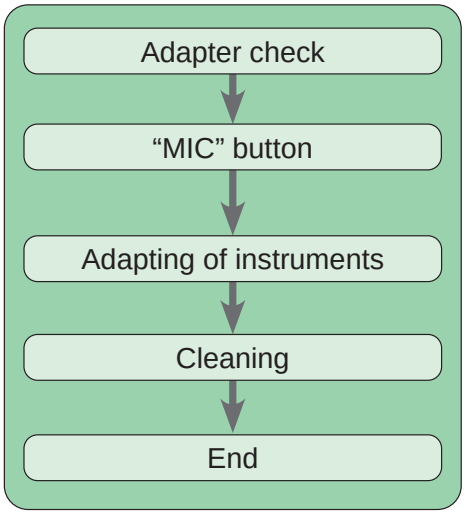
“Non-continuous instruments” have not been treated! They may be cleaned again, or removed individually and stored separately. Non-continuous instruments must undergo another cleaning, or be processed separately.

End

After removal, the instruments are to be rinsed intensively using water of at least drinking quality. Demineralised water should be used for the final rinsing. Continue to treat instruments in accordance with the hygiene plan, German KRINKO recommendations, or other respectively applicable national regulations (e.g. continued machine treatment in a cleaning and disinfection device, drying, function control, sterilisation).
Once the cleaning process is completed, a protocol is saved and can be accessed later via the interfaces. See Section 3.8.
Before every subsequent cleaning, it is necessary to check whether the bath liquid needs to be replaced.

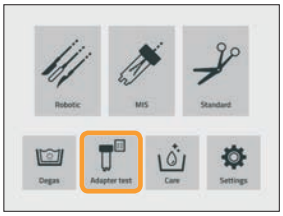
4.2.2 MIS instruments

Rinsable MIS instruments are cleaned according to the following schedule:



Adapter check

Important:



Before every cleaning of MIS instruments, an adapter check should be performed, since seals in the TRISON Rack are subject to process-related wear (ultrasound, opening, closing).

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

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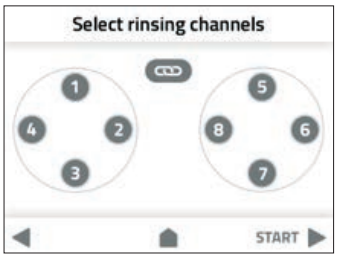
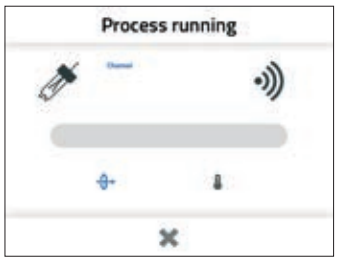
Adapting the instruments

- Properly prepare the instruments before cleaning in the TRISON ultrasonic bath and **rinse on the inside and outside with cold water (of at least drinking quality)**.
- Connect the instruments to the adapter on the TRISON Rack and lower into the ultrasonic oscillating tank (see Section 3.3.2). Observe the following:
  - Only clean instruments that have been approved by their manufacturer for ultrasonic cleaning.
  - Do not clean any damaged instruments.
  - Disassemble instruments that can be taken apart as much as possible. When doing so, heed the manufacturer's instructions. Remove sealing caps/seals and place them loosely in the basket, open up valves, remove the Luer cap from instruments with a lateral rinsing connection.
  - Fragile parts must not be touching each other. If needed, use special placement accessories such as silicone knob mats, see Section 7.
  - The instruments must be fully covered with liquid.
- Only select the rinsing channels that are equipped (see Section 3.1). The numbering of the channels can be found on the hoses. Do not select channels that are not in use (tip: the cleaning duration will be shorter as a result).
- Start cleaning.



Cleaning

The cleaning operation is conducted automatically.
At the end, an overview indicates which instruments were successfully rinsed (shown in green) and which were "non-continuous" (shown in red), see also Section 3.1.



Caution!

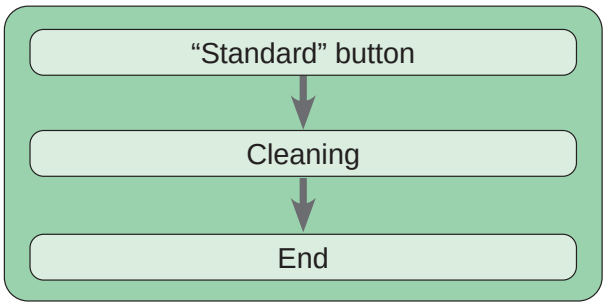
“Non-continuous instruments” have not been cleaned! They may be cleaned again, or removed individually and stored separately. Non-continuous instruments must undergo another cleaning, or be processed separately.

End

After removal, the instruments are to be rinsed intensively using water of at least drinking quality. Demineralised water should be used for the final rinsing. Continue to handle instruments in accordance with the hygiene plan, German KRINKO recommendations, or other applicable national regulations (e.g. drying, function control, sterilisation).
Once the cleaning process is completed, a protocol is saved and can be accessed later via the interfaces. See Section 3.8.
Before every subsequent cleaning, it is necessary to check whether the bath liquid needs to be replaced.

4.2.3 Standard instruments

Simple (non-rinsable) instruments such as scissors and forceps are cleaned according to the following procedure:



➢ Place instruments loosely in the basket. The adapter/hoses are not needed and the couplings do not need to be plugged in.

When laying down the instruments, observe the following:

- Only process instruments that have been approved by their manufacturer for ultrasonic cleaning.
- Do not treat any damaged instruments.
- Hinged instruments, e.g. forceps or scissors, should be fully opened or disassembled.
- Place the more heavily soiled side facing downward.
- In the case of hollow areas, ensure that the air can escape.
- Space instruments evenly apart, do not stack them. Overloading the basket will reduce the ultrasound effect (the ultrasound will be absorbed).
- Fragile parts must not be touching each other. If needed, use special placement accessories such as silicone knob mats, see Section 7.
- The instruments must be fully covered with liquid.

➢ For temperature monitoring during cleaning, the temperature sensor must be inserted, see Section 3.9.

➢ Set the sonication time for the cleaning.

➢ Start cleaning.

End

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

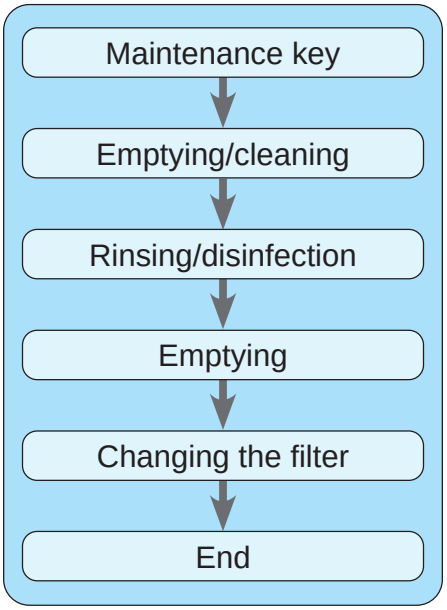
Once the cleaning process is completed, a protocol is saved and can be accessed later via the interfaces. See Section 3.8.

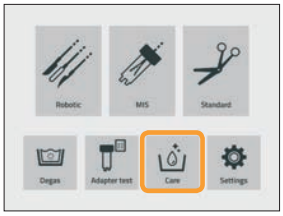
Before every subsequent cleaning, it is necessary to check whether the bath liquid needs to be replaced.

4.3 Completion – post-processing of the ultrasonic bath

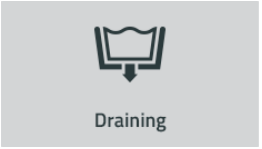
Once sonication is completed, it is necessary to check whether the bath liquid needs to be replaced. According to general recommendations, cleaning solutions must be replaced immediately in the event of visible soiling, or at least once every working day. In the case of disinfecting solutions, the useful life according to manufacturer specifications must be observed.

In connection with a replacement of the bath liquid, post-processing of the ultrasonic bath must also be conducted according to the following procedure, in order to restore the device to a perfectly hygienic condition.





Emptying/cleaning



- ➢ Access the "Draining" submenu.
- ➢ Open the outlet and allow the oscillating tank to drain completely. In doing so, observe the information regarding disposal of the bath liquid agent used. See below for additional instructions.
- ➢ Thoroughly rinse the oscillating tank and wipe it out/wipe it down with a soft cloth. Proceed in the same way with all accessories, e.g. the TRISON Twist.
- ➢ Connect the hose set with couplings to the TRISON Base and hang the rinsing plug or adapter, together with the returns, in the oscillating tank.
- ➢ Continue to follow the instructions on the touchscreen to enable the hoses in/on the device to pump until empty.

Notes:

All aqueous agents made by DR. H. Stamm GmbH are prepared in accordance with the regulations of the German Washing and Cleansing Agents Act, are biodegradable and may be disposed of in the wastewater as working solutions, see Section 7.3. Disinfection and cleaning agents that become contaminated during use are considered "waste material" pursuant to the German Waste Act (AbfG) and may not be taken back by the manufacturer. In any case, the statutory provisions and regulations of municipal wastewater plants must be complied with. Information is provided by municipal wastewater plants as well as by environmental agencies.

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Rinsing/disinfection

Important!

If an agent that has no disinfecting properties is used during sonication, the TRISON Base and accessories must be disinfected using a disinfection agent listed by the VAH (Association for Applied Hygiene)! Otherwise, rinsing the device will be sufficient.

Disinfection of the device

- ➢ Enter the "Disinfection" submenu.
- ➢ Close the outlet. Fill the oscillating tank with water of at least drinking quality and add a suitable agent.

Important!

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

- ➢ Place the TRISON Twist or Rack in the ultrasonic oscillating tank.
- ➢ Connect the hose set with couplings to the TRISON Base and hang the rinsing plug or adapter, together with the return, in the ultrasonic oscillating tank.
- ➢ On the screen, set the treatment time for the agent used and start the disinfection process.
- ➢ Once the disinfection process is completed, empty out the oscillating tank completely as described previously.
- ➢ Finally, conduct a simple rinse (see next Section) in order to remove the rest of the disinfecting solution used.

Simple rinsing of the device

- ➢ Call up the "Rinsing" submenu.
- ➢ Close the outlet. Fill the oscillating tank with water of at least drinking quality. Do not use any chemical additives!
- ➢ Place the TRISON Twist or Rack in the ultrasonic oscillating tank.
- ➢ Connect the hose set with couplings to the TRISON Base and hang the rinsing plug or adapter, together with the return, in the ultrasonic oscillating tank.
- ➢ Start the rinsing process.
- ➢ Once the rinsing process is completed, empty out the oscillating tank completely as described previously.

Filter replacement/end

- ➢ Call up the "Replacing filter" submenu and replace the filter cartridge, see Section 6.1.1.
- ➢ Turn off the ultrasonic bath.

5 Cleaning and maintenance of the ultrasonic bath

To achieve an optimum lifespan for the TRISON ultrasonic bath, cleaning and maintenance are to be conducted regularly. The following instructions are for manual cleaning and care of the exterior.

CAUTION!

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

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

5.1 Cleaning and care

Ultrasonic oscillating tank

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

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

TRISON Base/SONOBOARD functional cabinet

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

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TRISON Lift, TRISON Twist and TRISON Rack

- Remove and clean the TRISON Lift regularly (or disinfect it as well); for this purpose, it can be placed in the ultrasonic bath, e.g. during post-processing of the ultrasonic bath, see Section 4.3. Next, rinse thoroughly with water, wipe dry with a soft towel and attach once again to the work plate.
- Special accessories such as the TRISON Twist, TRISON Rack and temperature sensor should also be cleaned (or disinfected) during post-processing of the ultrasonic bath, see Section 4.3.

Important:
The plug on the TRISON Twist or temperature sensor must not be submerged!
If the plugs come into contact with liquids, they must be blown out with compressed air and allowed to dry completely.

5.2 Disinfection

- If contaminated medical instruments are treated in the ultrasonic bath, hygienic safety after application is important. An automatic procedure for chemical disinfection of the ultrasonic bath and accessories (TRISON Twist, TRISON Rack, TRISON Lift) must therefore be conducted, if required, as part of the post-processing, see Section 4.3. Thermal disinfection or sterilisation of the device components is not permitted, see also Section 1.8.
- In order to prevent any cross-contamination as a result of the colonisation of microorganisms, especially along the tank edge and in the drain outlet area, but also on the operator panel, these areas are to be regularly cleaned and disinfected with a suitable surface disinfectant, i.e. one that is at least bactericidal, yeasticidal and partially virucidal.

5.3 Warehousing/storage

If not in use for long periods of time, the TRISON ultrasonic bath should be disconnected from the mains (pull the mains plug of the mains supply switch from the power outlet).
The lid should be put on in order to protect the ultrasonic oscillating tank from outside contamination.

6 Maintenance and repair

6.1 Maintenance

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

daily	monthly	every 2 years	Part/object/remark
X			Post-processing, including replacement of the liquid and of the filter cartridge (see Section 4.3 or 6.1.1)
	X		TRISON Rack Replace adapter seals (see Section 6.1.2)
		X	Maintenance of the ultrasonic bath: Contact Customer Service or the manufacturer.
		X	Replace hose sets All hoses and couplings on the rack, or all rinsing plugs with hoses and couplings on the twist.

The operator is responsible for planning and documenting maintenance.
Appropriate maintenance lists (sample copies) are found at the end of these operating instructions, see Annex B.

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6.1.1 Replacing filter cartridge

During post-processing and in the event of a prematurely clogged filter, a prompt to replace the filter will appear on the touchscreen.

In the event of a persistent error message, the filter cartridge can be replaced – the pump will stop during this error message.
After replacement, the error message must be acknowledged.

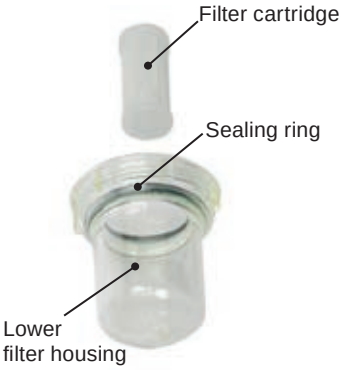
The filter cartridges are suitable for backwashing. The filter cartridges can be used multiple times with appropriate, thorough backwashing.

Removing the filter cartridge:

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

Inserting a new filter cartridge:

- ➢ Insert open side (straight) of the filter cartridge into the head piece.
- ➢ Check if the sealing ring is in place.
- ➢ Re-screw the lower filter housing.



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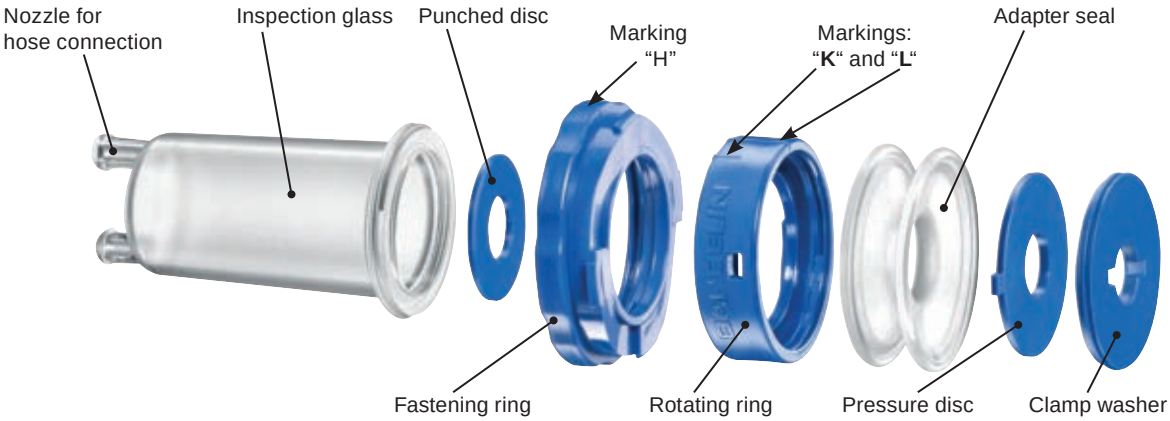
6.1.2 Replacing the adapter seal (TRISON Rack)

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



Disassembling the adapter seal:

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

Fitting the new adapter seal:

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

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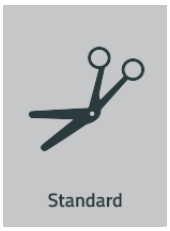
6.2 Function checks

Checking the touchscreen

- Turn on the ultrasonic bath – the touchscreen must light up.
- The touchscreen should respond to the pushing of buttons and the relevant screens must appear.

Checking operation of the ultrasonic bath

The output can be checked using a standard wattmeter. It is to be inserted between the mains plug, the mains supply switch, and the power outlet.

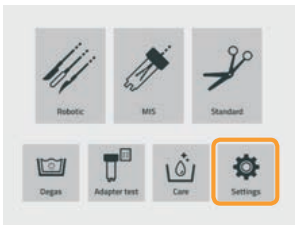


- Turn on the ultrasonic bath.
- Fill the ultrasonic oscillating tank with liquid.
- Only the ultrasound needs to be turned on for this check. Select “Standard” and start.
- Compare the value displayed with the corresponding value in the technical data (Section 1.8) (tolerances ± 10 %).

Check the ultrasound effect

A foil test is recommended for verification.
A suitable foil test frame is included in the scope of delivery. Household aluminium foil is used to conduct the test. Next, a comparison is made with previously-generated foils. As a departure from the detailed information in the annex (which is intended for simple standard ultrasonic baths), please note the following special instructions for the TRISON:

After turning on the device, the test can be conducted by going to *Settings/Service/Foil test*.



Important:

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

Note:

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

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Checking the rinsing and/or moving function

The most complex cleaning program (“Robotic”) is to be used for checking both functions.

- Turn on the ultrasonic bath.
- Fill the ultrasonic oscillating tank with liquid.
- Select the “Robotic” program and connect the TRISON Twist to the control unit. Continue pressing the “Next” key until the channel selector appears (specify 8 mm instrument diameters). Select all channels and start. Skip the following soaking phase by pressing the “Start” key. Allow the rinsing program to run for approx. 5 min. During this time, check the following functions:

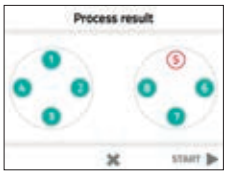
Rinsing function:
On hoses A1, B1, etc., water should run out visibly during the return cycle. A flow-through of approx. 350 ml/min should be displayed.

Moving function:
Movement must be visible on the TRISON Twist moving device at the slots. If needed, connect a test instrument to make the movement recognisable.

6.3 Malfunction/fault analysis

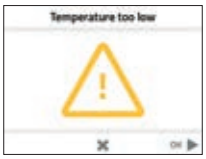
TRISON ultrasonic baths are designed for high reliability. A possible malfunction due to a defective component cannot be fully ruled out, however. Mechanical defects, e.g. on the adapters, hoses, etc., are also possible due to wear or improper use.
The following overview of possible sources of error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

Error	**Possible cause(s)**	**Measure(s)**
Instruments do not move uniformly	The movement has been programmed to be intentionally chaotic. The actuating force is limited, thus sluggish instruments can only be moved to a limited extent.	None
The TRISON Base cannot be turned on (display remains dark)	TRISON Base connected to the mains?	Check the mains connection, see the installation instructions.
	Mains switch correctly activated?	Check that the mains switch is lit up.
	Fuses defective?	If needed, Replace fuses, see Section 6.4.3.
No displays or incomprehensible displays	TRISON Base defective?	Can only be rectified by the manufacturer.

Error	Possible cause(s)	Measure(s)
Touchscreen does not react to pressing of keys	Keys not pressed correctly?	Control option: An acoustic signal is emitted.
	Touchscreen defective?	Can only be rectified by the manufacturer.
TRISON Base freezes on the welcome screen?	Has it been turned on and off too quickly?	No error. The start screen appears for approx. 10 sec. Turn off the ultrasonic bath and turn it back on after 10 sec.
	Ethernet cable not plugged in?	No error. The ultrasonic bath restarts after approx. 10 sec.
	SD card defective?	Can only be rectified by the manufacturer.
Progress bars freeze?	Software or hardware defective?	Turn off the base and turn it back on after 10 sec.
		Can only be rectified by the manufacturer.
Repeats negative process result on the same channel (example 5)  without a plausible cause being recognisable	Are instruments in this channel not covered with liquid?	If needed, fill with liquid up to the filling level mark.
	Adapter or coupling incorrectly connected/mounted?	Check the plug connection of the adapter and coupling. If needed, disconnect and reconnect, see Section 3.3
	Clogging in the hose system of the TRISON Base?	Interchange the instruments. If a different channel is now affected, the instrument itself is not continuous.
		Use a new hose set.
		Can only be rectified by the manufacturer.
Repeated negative process result on all channels	Are instruments not covered with liquid?	If needed, fill with liquid up to the filling level mark.
	TRISON Rack: Adapter incorrectly connected/ mounted?	Check adapters and adapter connections, see Section 6.1.2.
	Blockage/defect in the TRISON Base rinsing circuit?	Can only be rectified by the manufacturer.
Ultrasonic bath oscillates weakly, unevenly or noise is too loud	Overloaded with objects to be cleaned (instruments)?	Remove a few parts.
	Irregular sounds?	No error.
	Defective oscillating system or ultrasound generator?	Conduct a foil test and compare it to the first test (conducted during commissioning).
		Request a test sheet and allow authorised, skilled personnel to conduct test. If an error is detected, the ultrasonic oscillating tank should be returned to the manufacturer for repair.

Error	Possible cause(s)	Measure(s)
Unsatisfactory cleaning results	Degassing not conducted?	Always conduct degassing during the preparation.
	Insufficient amount of disinfection and/or cleaning agent used?	Repeat treatment with a proven disinfection and/or cleaning agent such as STAMMOPUR DR 8.
	Instruments stored in contaminated condition for too long?	Repeat cleaning or store and treat instruments separately.

Warning and error screens

Error	Possible cause(s)	Measure(s)
	Ongoing process was interrupted.	The Back button discards the cancellation. The Next key confirms the interruption and the software returns you to the Home menu.
	The temperature of the bath liquid is higher than the critical value. Notes: Protein coagulates starting at a temperature of >45°C. The message appears once this temperature is reached. The working temperature should lie between 20 and 40°C.	Allow the liquid to cool down or exchange part or all of it. Then fill up with cold liquid (water and dosed agent). Press Cancel to return to the Home menu. Press the Forward key to skip this message.
	The temperature of the bath liquid is too low.	Exchange part or all of the liquid (at least 20 °C hot). Press Cancel to return to the Home menu. Press the Forward key to skip this message.
	The program “Robotic” has started, but the TRISON Twist is not connected.	Connect the Twist. Press Cancel to return to the Home menu. Press the Forward key to skip this message.
	Maximum number of protocols has been reached.	Copy the protocols to a USB stick and/or delete them, see Section 3.8. Press Cancel to return to the Home menu. The Next key can be used to jump directly to the "Documentation" menu.
	Maintenance interval has been reached.	The device must undergo its 2-year maintenance, see Section 6. Press Cancel to return to the Home menu. The Next key can be used to jump directly to the “Information” menu.

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Error	Possible cause(s)	Measure(s)
	Filter is clogged.	Replace filter cartridge, see Section 6.1.1.
	Filter cartridge not installed correctly.	Check filter, see Section 6.1.1.
	Pressure sensor defective.	Can only be rectified by the manufacturer.
	Compressed air not connected.	Check that the coupling for the compressed air connection is correctly plugged in. If needed, disconnect and reattach it.
	Compressed air not set correctly.	Check that the correct pressure is present, see Section 1.8.
		Can only be rectified by the manufacturer.
	Switch defective.	Can only be rectified by the manufacturer.

6.4 Repairs and service

If errors or defects are ascertained during the function check and cannot be rectified, the ultrasonic bath may no longer be used. In such cases, please contact the supplier, customer service, or the manufacturer:

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

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

E-mail:
info@bandelin.com

Returns are subject to the General Conditions of Delivery and Payment of BANDELIN electronic GmbH & Co. KG In addition, the ultrasonic bath must be cleaned and decontaminated (if necessary), see the following Section.

6.4.1 Customer service

For on-site repairs, you can contact the customer centre of
MMM Münchener Medizin Mechanik GmbH, Hauptstraße 2, 92549 Stadlern, Germany.
Service hotline: 01805 666 112

6.4.2 Certificate of Decontamination

If the ultrasonic bath is sent back to the manufacturer for repairs (with accessories, if applicable), the form "Certificate of Decontamination" must be filled out and affixed to the packaging in a visible spot on the outside.
If this form has not been filled out, we reserve the right to refuse receipt of the package in order to protect our employees.

The form can be downloaded as a PDF file from our website:
www.bandelin.com/Downloads ...

6.4.3 Replacing fuses

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

Caution!

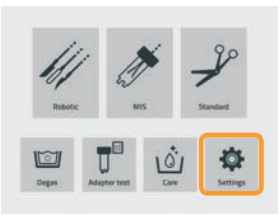
- Only authorised skilled personnel may replace the fuses.
- Pull the mains plug before replacement.
- The fuse values are listed under "Technical Data" (Section 1.8).

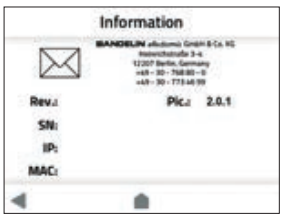
6.4.4 Determining the software version

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

Determining the software version

The software version can be found, if required, under *Settings/System/Information*.





Note:
The blank fields here are filled out by the software and only appear when the unit is functional.

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7 Accessories

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

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

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

Website:
www.bandelin.com

7.1 Required accessories

Do not place or lay any objects directly on the tank bottom.
Exceptions to this rule are special baskets and basket holders designed by BANDELIN in such a manner that they do not lay in the cavitation field and do not damage the tank bottom.

Description	Code No.
TT 4000 Si R TRISON Twist moving device for robotic instruments, type “Si," suitable for a right-handed base	7820
TT 4000 Si L TRISON Twist moving device for robotic instruments, type “Si," suitable for a left-handed base	7920
TT 4000 Xi R TRISON Twist moving device for robotic instruments, type “Xi," suitable for a right-handed base	7821
TT 4000 Xi L TRISON Twist moving device for robotic instruments, type “Xi," suitable for a left-handed base	7921
TR 3001 R TRISON Rack special basket for MIS instruments, with comb bar on right; suitable for a right-handed base;	7631
TR 3001 L TRISON Rack special basket for MIS instruments, with comb bar on left; suitable for a left-handed base	7731
K 29 EM Insert basket for standard instruments	688
KT 3000 Z Basket holder for inset basket K 29 EM	7761

7.2 Optional accessories

Description	Code No.
SM 1000 MC Silicone knob mat – for protective, contact-free keeping of fragile parts during cleaning, suitable for the TRISON Rack.	3313
FT 42 Foil test frame	3224
TM 4000 Temperature sensor – when cleaning standard instruments	7741
Luer mains connector plug for cleaning an EndoWrist Si Stapler	7847
Twist spacer Xi for cleaning an EndoWrist Xi Stapler	7763
D 4000 A-R made of plastic; suitable for a right-handed base;	7955
D 4000 A-L made of plastic; suitable for a left-handed base;	7956

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7.3 Agents

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

For rinsable robotic instruments, BANDELIN recommends:

the use of an enzymatic cleaner satisfying the specifications of the instrument manufacturer.

For rinsable MIS instruments and standard instruments, BANDELIN recommends:

the use of the STAMMOPUR concentrates STAMMOPUR DR 8 and STAMMOPUR R, by DR. H. Stamm GmbH, which have been especially developed for ultrasound use and which utilise the ultrasound optimally.

IMPORTANT!

It is necessary to ensure that the agent used is aldehyde-free and does not feature any proteopectic properties.

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

Caution:

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

We do not offer a guarantee for damage to the ultrasonic bath or to the objects to be treated (instruments) caused by the use of inadequate disinfection and cleaning agents.

7.3.1 STAMMOPUR DR 8
Disinfection and cleaning agent

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

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

Application:

	TE 3000
2%	Total filling volume 35 l (= 34.3 l water + 700 ml STAMMOPUR DR 8)
3%	Total filling volume 35 l (= 33.95 l water + 1.05 l STAMMOPUR DR 8)

Order information:

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

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

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

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7.3.2 STAMMOPUR R instrument cleaner

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

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

Application:

	TE 3000
2%	Total filling volume 35 l (= 34.3 l water + 700 ml STAMMOPUR R)

Order information:

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

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

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

8 Consumable materials

Description	PU	Code No.
EF 1001 Filter cartridges for TRISON Base	30 units 100 units	3365 3366
AD 1000 Adapter seal for TRISON Rack	8 units 24 units	3361 3354
ADT 1000 Adapter with seal for TRISON Rack	1 unit 8 units	7770 3359
SLS 3000 TT Hose set with couplings for TRISON Twist Si	1 unit	3363
SLS 4000 TT Hose set with couplings for TRISON Twist Xi	1 unit	3362
SLS 3000 TR Hose set with couplings for TRISON Rack (without adapter)	1 unit	3364
APB 3000 Adapter testing strips for TRISON Rack (consisting of 2 × 4 test plugs)	1 unit	7771

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9 Decommissioning

The device must be disposed of properly – not in household waste.

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

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

Environmentally-appropriate disposal of the battery

The battery contained in the TRISON Base control unit must be professionally removed as described below. It must be disposed of in discharged condition, at waste battery collecting station.

Caution!

- Only authorised skilled personnel may remove the battery!
- Pull the mains plug before removal!

Removal instructions:

➢ Disconnect any connections from the TRISON Base control unit to the TRISON mains supply switch and to the compressed air supply. If needed, dismount the control unit from the work plate. See the installation instructions for additional information.

➢ Remove the screws alongside the plastic cover. Then pull the cover carefully upwards/forwards, and loosen the connectors between the cover and subshell.

➢ The battery is located on the circuit board, on the inner side of the plastic cover.

10 Keyword index – not applicable –

A Foil test

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/.

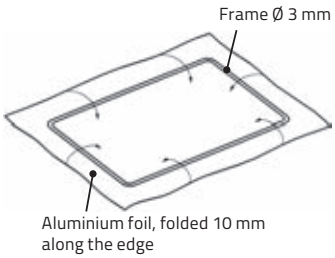
Foils can also be suitably archived (scanning, photos, etc.). This allows the foils to be compared at any time.

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

BANDELIN
Ultraschall seit 1955

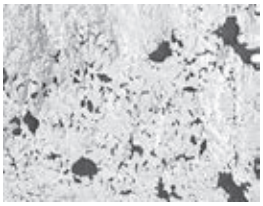
Conducting the foil test

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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🖷 + 49 30 773 46 99

B Maintenance lists

Maintenance list/daily

- **Replace filter cartridge on the TRISON Base**

Date	Signature

Maintenance list/monthly

- **Replace adapter seals on the TRISON Rack**

Date	Signature

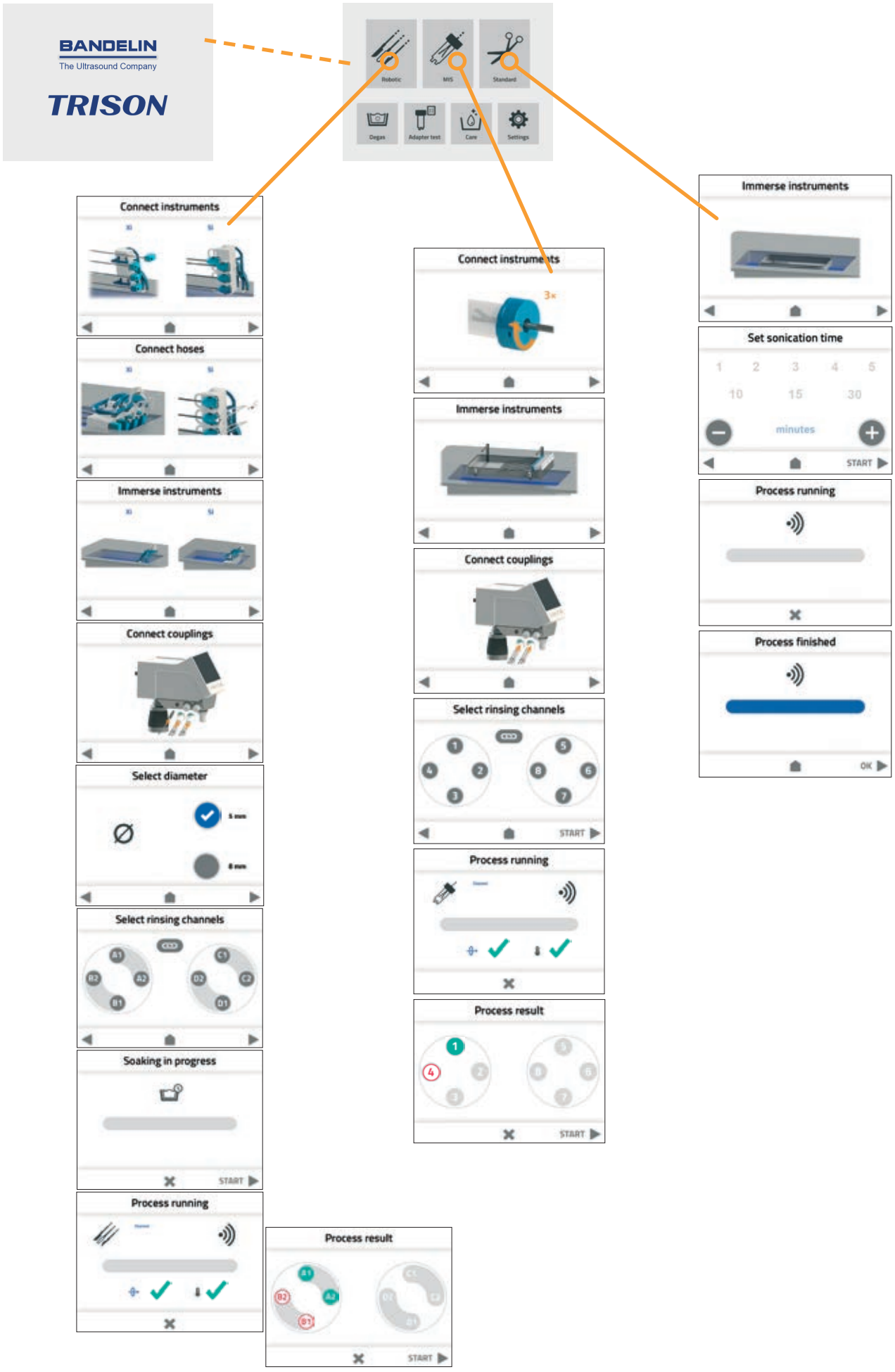
Maintenance list/every 2 years

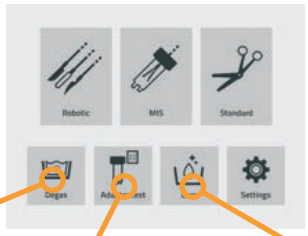
- **Ultrasonic bath – maintenance**
- **Replace hose set (TRISON Twist or Rack)**

Date	Manufacturer's receipt	Signature

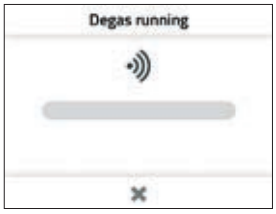
C Screen displays

Sequence without interruptions.

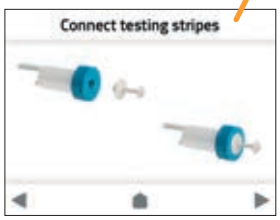



Robotic
MIS
Standard
Degas
Settings

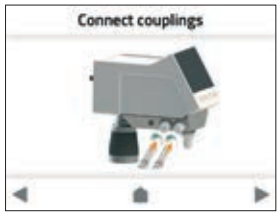

Fill the tank
START

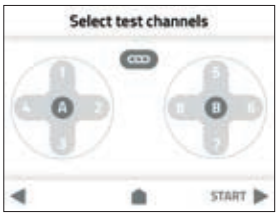

Degas running

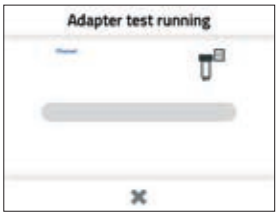

Degas finished
OK

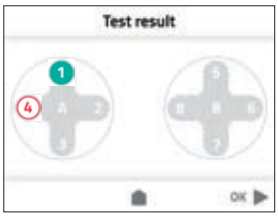

Connect testing stripes

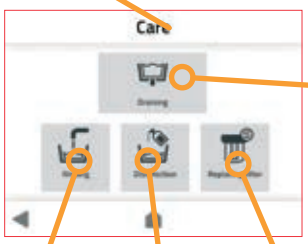

Immerse adapter


Connect couplings

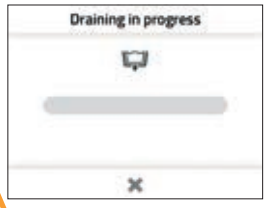

Select test channels
START

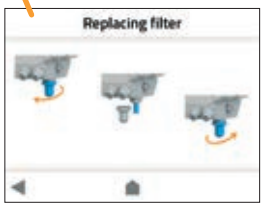

Adapter test running


Test result
OK

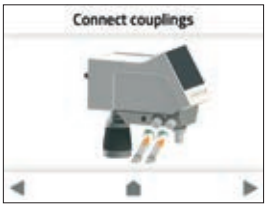

Care


Clean the tank
START


Draining in progress

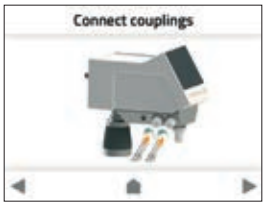

Replacing filter


Fill the tank


Connect couplings

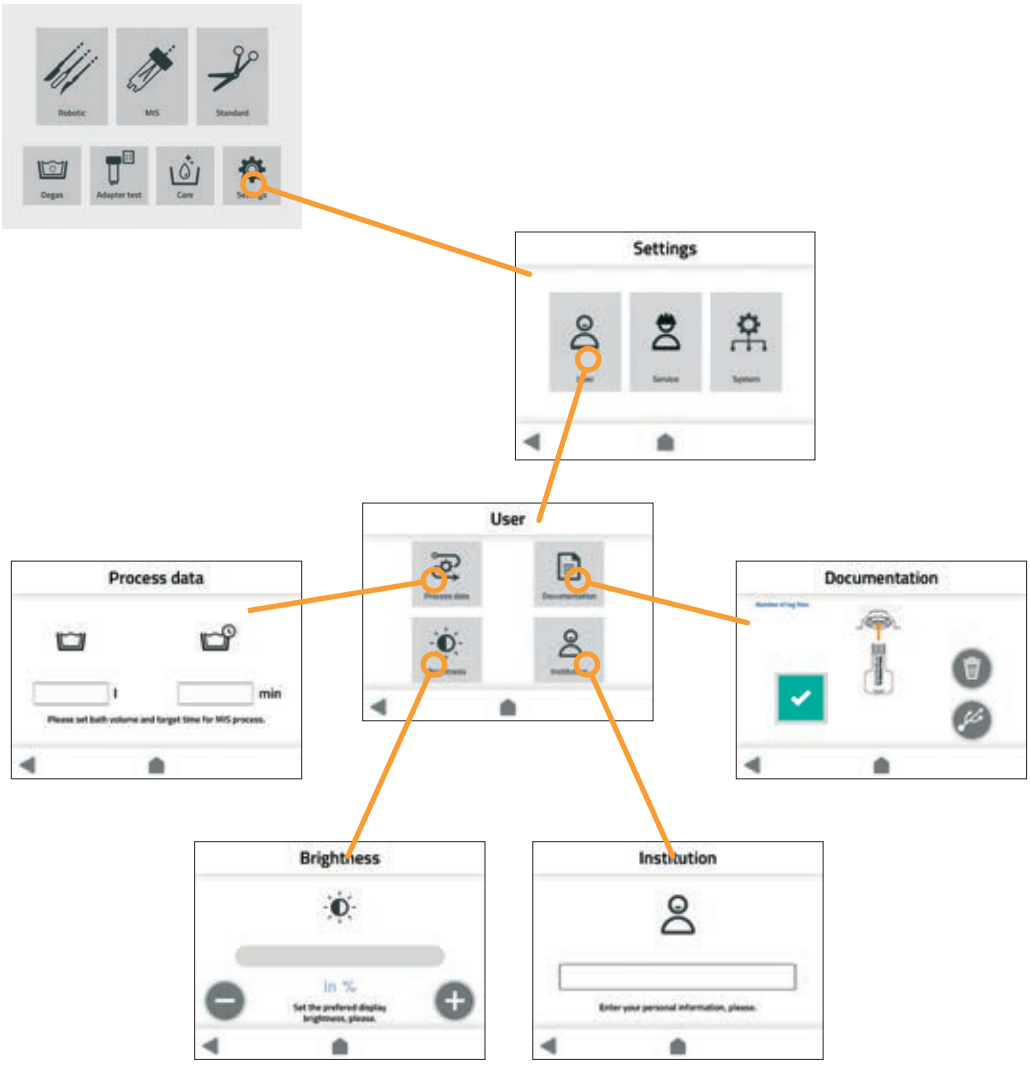

Rinsing in progress

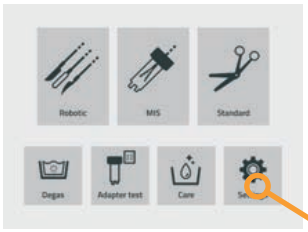

Fill the tank

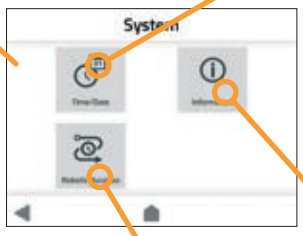

Connect couplings

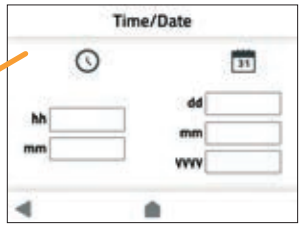

Set treatment duration
5
10
15
20
30
45
60
minutes
START

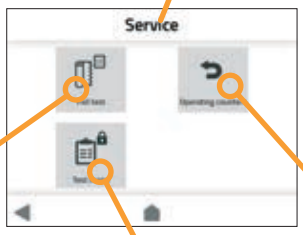

Disinfection in progress


Robotic
MIS
Standard
Degas
Adapter test
Care
Settings
Settings
Service
System
User
Process data
Documentation
Process data
l
min
Please set bath volume and target time for MIS process.
Documentation
Brightness
in %
Set the prefered display brightness, please.
Institution
Enter your personal information, please.

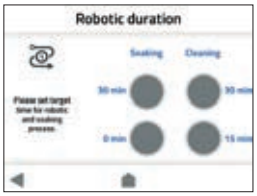








Test menu – password-protected:
Only available to autho-rised skilled personnel



Resetting – password-protected:
Only available to autho-rised skilled personnel

Note:

The operating instructions in this and other languages, as well as further information, can be found on the enclosed CD.