

Instructions for use




















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1. Symbols

Symbols displayed on the product, on the package and/or used in this manual:

 WARNING! / CAUTION! Indicates a hazardous situation that, if not avoided, could result in death or serious injury.	 Manufacturer
 Consult the instructions for use	 Temperature range
 Medical device	 Disposal / Do not dispose of with normal waste.
 Health Industry Bar Code (in accordance with HIBC Standard)	 This way up
 Type or model	 Keep away from sunlight
 Catalogue number	 Fragile, handle with care
 Lot	 Keep dry
 Manufacturing date	 GS1 data matrix for logistic purpose
 Ultrasonic bath	

2. Introduction



About this manual

This manual contains the Instructions for Use of the W&H U-Son ultrasonic cleaning baths, and important information about installation and operation safety, maintenance and use.

This manual is an essential part of the product and should always accompany the product when it is sold or transferred.

Failure to comply with the provisions given in this manual may cause damage to people, animals or property, and will impair the product warranty.

Keep these Instructions for Use for future reference.

The Instructions for Use updated to the latest version are always available at www.wh.com.



For your safety and the safety of your patients

The purpose of this manual is to provide you with information about U-Son cleaning baths to ensure:

- proper installation and set-up;
- optimal use;
- safe and reliable operation;
- compliance with regular maintenance and servicing requirements.



Please carefully read the safety information in Chapter 3!

Intended use of the product

Ultrasonic bath is intended for cleaning invasive and non-invasive medical devices by the emission of high frequency soundwaves. The device is intended for professional use only.



Responsibility of the manufacturer

The manufacturer may not be held responsible for damage caused by improper use or installation.

The manufacturer can only accept responsibility for the safety, reliability and performance of the product when the product itself is installed, used and serviced in accordance with the provisions given in this Instructions for Use.

Servicing by unauthorized persons invalidates all claims under warranty and any other claims.

All drawings, images and texts contained in this manual are the sole property of the manufacturer.


All rights reserved. Even partial duplication of drawings, images or text is strictly prohibited.

All information contained in this document is subject to change without prior notice.

Conformity

CONFORMITY TO EUROPEAN REGULATIONS, STANDARDS AND DIRECTIVES

The device conforms with the following Regulations, Standards and Directives:

Standards, Regulations, Directives	Description
	Medical Device Regulation (MDR) / Regulation (UE) n. 2017/745 for medical devices. Class I devices, in accordance with the Rule 1 – ANNEX VIII of the above Regulation
2012/19/EU	Waste Electrical and Electronic Equipment Directive (WEEE)
IEC 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use, general requirements
IEC 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements; general requirements

3. General information and safety advice



GENERAL SAFETY ADVICE

The product is intended for indoor use only.

Do not switch the device ON if the package is damaged.

Do not operate the device in presence of explosive or flammable gases, vapours, liquids or solids.

Install the device on a flat, stable and hard surface, capable of bearing the weight of the device, the tools/objects that are placed inside for washing and the relevant liquid. Handle it with care.

Do not remove the rubber feet as they are designed to reduce vibrations and to provide free ventilation space below the device.

Place on hard surfaces only. Do not place on soft pads as this might reduce the free ventilation space.

Installation must be carried out by an authorized technician only.

Install the device in a well-ventilated space, away from sources of heat and moisture, not subject to dust accumulation.

Do not start the device if: the power cable or plug has been damaged, the device does not operate properly, or has been damaged, or has fallen. Risk of electric shock, fire or other.

Do not attempt to repair the device personally and do not tamper the device. For any repairs always contact the W&H after-sales service. Repairs, maintenance or service must be carried out by service technicians authorized by the manufacturer and using genuine spare parts only.

Do not immerse the mains cable or plug into the water. Keep the mains cable away from hot surfaces.

Do not allow the mains cable to hang from tables or other furniture edges.

Do not remove the name plate or any label from the device.

Use the power cord set provided by the manufacturer only.

Do not lift and carry the device when it is full of liquid. The handles have been designed exclusively for lifting and carrying the device only when it is empty and disconnected from the power socket.

In case of transport:

- Completely drain the water tank.
- Allow the tank to cool down .
- Use original or appropriate packaging.

Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.

ELECTRICAL CONNECTION

The electrical power supply to the device must fulfil all applicable standards in the Country of use, and must comply with the data label on the back of the product.

The device is intended for the residential use and requires a suitable circuit breaker and a residual-current device. All protection devices must be certified according to applicable standards.

Ensure that the wall socket used is properly grounded.

Use the power cord set provided by the manufacturer only. Connect it to the appliance inlet in the back of the device, and then to the wall socket.

Connect the power cord in such a way that it may be easily disconnected from the device and/or from the wall socket.

After installation, run the ultrasound operational test as described on page 17.

Operation safety advice



Make sure that the electric plug has been disconnected before filling the tank. Any accidental liquid spillage could cause a short circuit or electrocution and would therefore be dangerous for the operator.

Check that the device has not been damaged. Do not use the device if it has visible or known damage; if in doubt consult the retailer or the manufacturer directly.

Change the cleaning solution regularly, for better cleaning results and to prevent damage to the device.

Always fill the tank with cleaning solution to the level mark, and always check the level so that it does not drop 1 cm below the level mark. Failure to comply may cause transducer and/or heater damage.

Don't operate the device dry.

This device must operate with water-based solutions only, either slightly acidic or slightly alkaline for ultrasonic treatments.

Do not use substances such as petrol, benzol or benzene, or other harmful or explosive or flammable solvents. Only use solutions suitable for the type of work to be performed.

Check that the drain tap, if present, is fully closed before pouring the cleaning solution into the tank.

Do not use chloride - or glutaraldehyde – based disinfectants, nor any other kind of acid or highly alkaline solutions. These chemicals corrode the tank to perforation, causing leaks of the cleaning solution onto the internal components and consequently bad operation and hazardous conditions.

Aggressive liquids or materials that could damage the tank should be placed in a special beaker which is then placed in the tank containing water which transmits the ultrasonic waves to the beaker and hence to the solution it contains. Remember not to rest the glass beaker on the bottom of the tank.

If you use cleaning agents that are susceptible of releasing potentially toxic or corrosive substances, follow the safety and operation advice provided by the manufacturer of the cleaning agent. To prevent releasing of potentially toxic or corrosive substances, micronized by the ultrasonic waves, use an extractor hood.

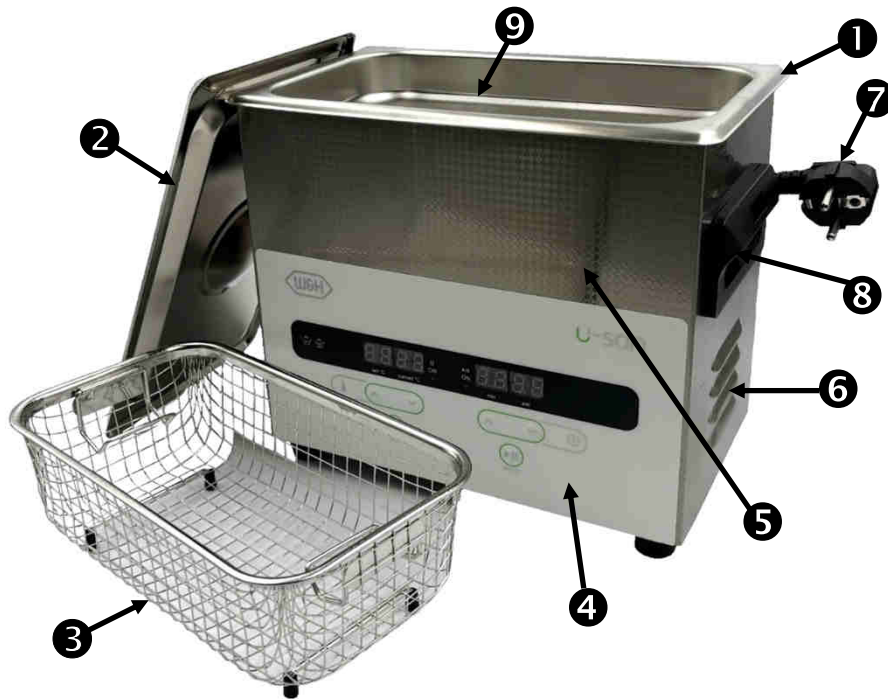
Ensure the **ventilation grids on the side and on the bottom** of the device are free from objects and obstructions.

Do not place your hands in the tank during operations.

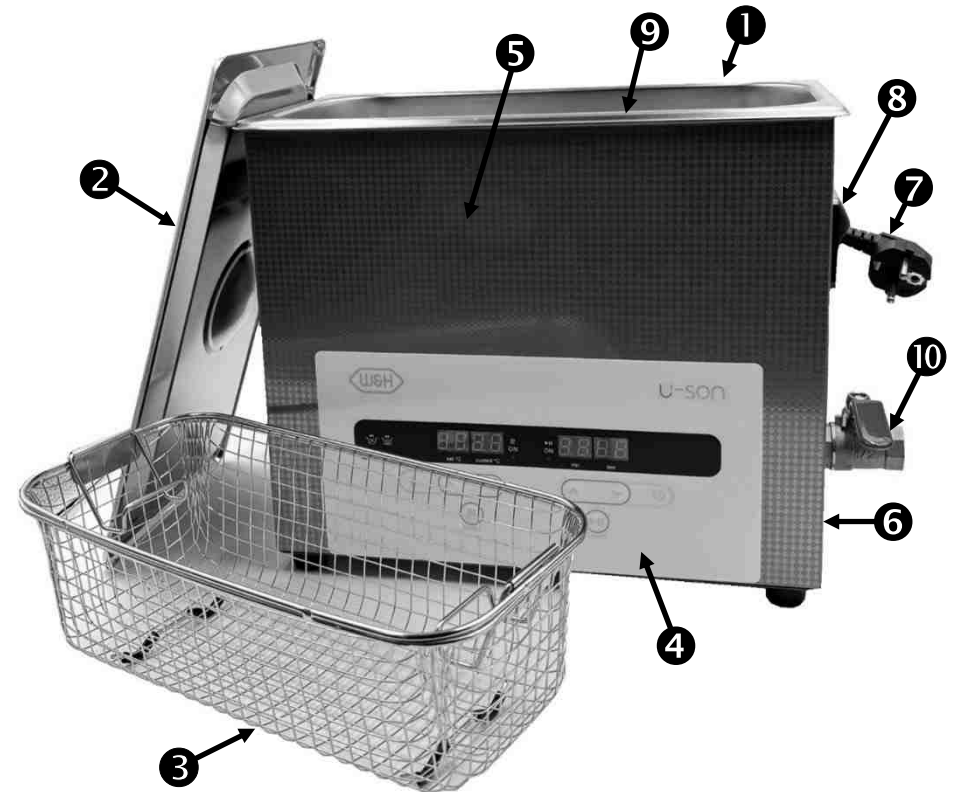
Always operate the device with the basket in place. Never lay objects on the bottom of the tank directly.

4. Contents of the packaging

3 LITRE VERSION



6 LITRE VERSION



- | | |
|----------------------------|--------------------------|
| ① - Stainless steel tank | ⑥ - Air intake grids |
| ② - Stainless steel lid | ⑦ - Mains cable |
| ③ - Stainless steel basket | ⑧ - Handles |
| ④ - Control panel | ⑨ - Operating level mark |
| ⑤ - Stainless steel case | ⑩ - Drain tap |

Contents of the packaging



Stainless steel basket (3-Litre or 6-Litre)

Used to:

- support the objects during operation
- let the objects drip into the tank after washing



Stainless steel lid

Use the stainless steel lid to cover the ultrasonic tank, both during treatments and when the device is not in use.

The steel lid helps reducing the heating time and the emission of fog and micronized particles from the liquid surface.

When removing the lid, take care not to drip any condensed liquid on objects that might be damaged by it.

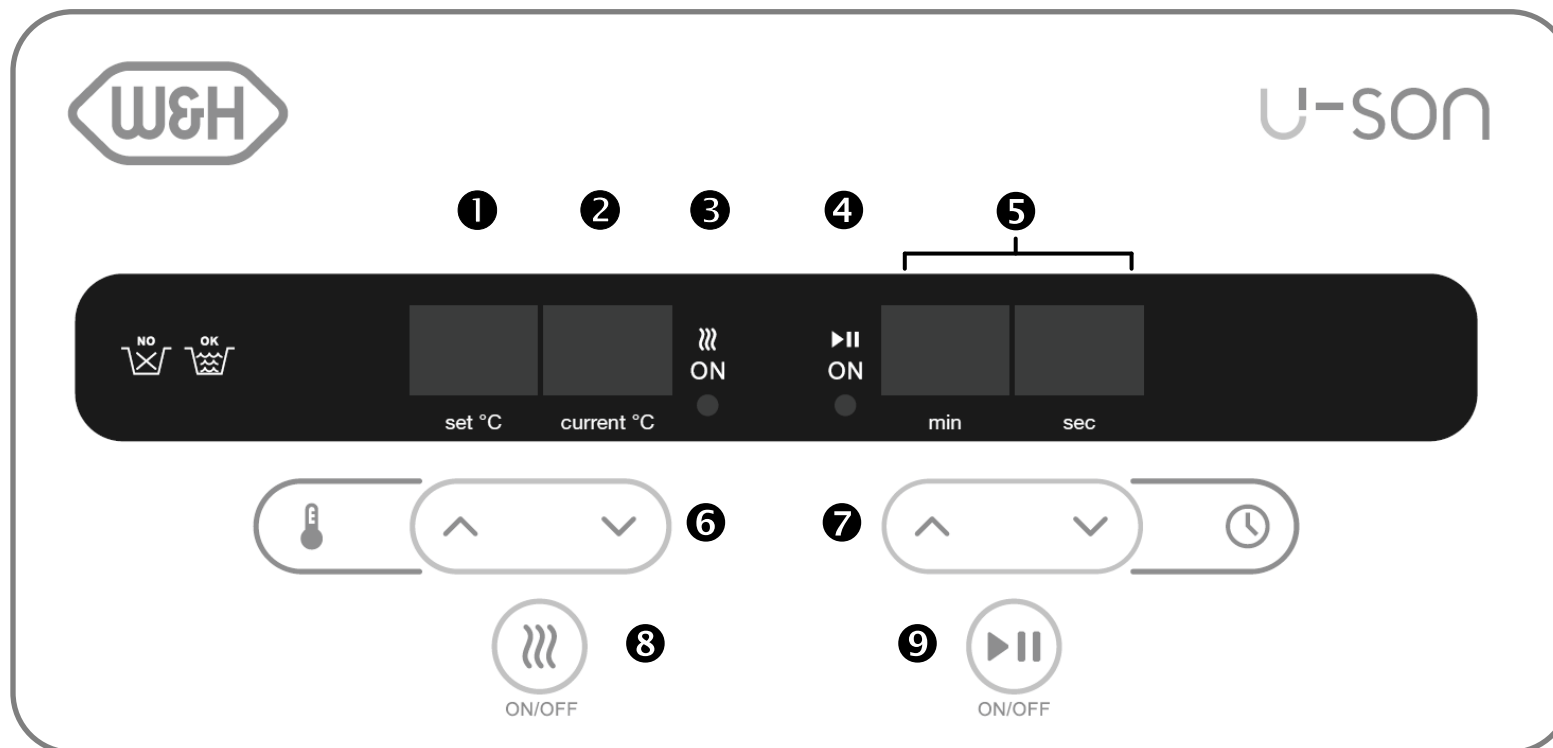


Drain tap with fitting and hose (for 6 Litre version only)



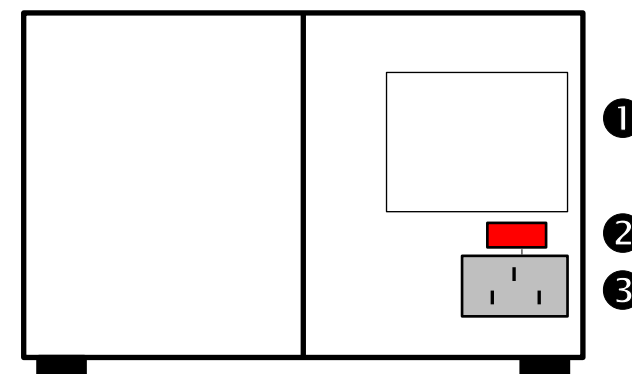
Power cord

5. Control panel



Front panel

- ❶ - Displays the temperature setting for the built-in heater.
- ❷ - Displays the current cleaning temperature.
- ❸ - Heating element On/Off indicator light.
- ❹ - Ultrasound Start/Stop indicator light.
- ❺ - Displays the set cleaning time
(during operation: displays the residual cleaning time).
- ❻ - Increases or decreases (by 1 °C) the cleaning temperature.
- ❼ - Increases or decreases (by 1 min) the cleaning time.
- ❽ - Heating On/Off button.
- ❾ - Ultrasound Start/Stop button.



Rear side

- ❶ - Device rating plate.
- ❷ - Mains switch.
- ❸ - Power supply appliance inlet.

6. Operating instructions

ABOUT ULTRASOUND

Ultrasound consists of vibrations similar to sound waves, but with frequencies which are too high to be audible to the human ear. The upper frequency limit of the human ear ranges approximately from 10 kHz to 18 kHz (it decreases with the increase of age).

W&H ultrasound cleaning devices operate at a frequency of about 40 kHz.

All W&H devices consist of a high frequency generator supplying one or more transducers (the number depends on the model) that are connected to the stainless steel tank. The high-frequency generator produces a continuous signal at a frequency of 40 kHz, and pilots the transducers which transform the electrical signal into a mechanical vibration.

This vibrational energy is transmitted to the liquid in the tank at high frequency. These pressure and vacuum oscillations create a huge quantity of microbubbles in the liquid which, by imploding in extremely rapid succession, transfer their impact energies to the surface to be cleaned. This is known as “cavitation” and provides an efficient and safe cleaning method in a reduced time.

USEFUL ADVICE AND SUGGESTIONS

Water-soluble dirt may be washed using water only. Just add a small quantity of cleaning agent for better and faster results. Use water suitable for medical environments

If you use a cleaning agent, refer to the instructions given by the manufacturer of it for the type of dirt it is suitable for, and for the dilution ratio.

Do not overload the device. Preferably arrange the objects on the base of the rectangular basket, place the latter in the tank and proceed with the cleaning. Too many objects cleaned at the same time reduce the efficiency of the ultrasound cleaning.

Cleaning very dirty objects: use longer cleaning times, heating the cleaning liquid according to the object to be cleaned and to the cleaning agent manufacturer's instructions.

Cleaning solution replacement frequency: to ensure good cleaning results, change the detergent solution often, especially if it is used to clean surgical instruments.

Object shape and size: there are no special recommendations for the shape of objects to be cleaned, however avoid cleaning particularly heavy and large objects in the tank. The liquid must always cover the entire object.

After cleaning, it is recommended to rinse the instruments with tap water, reverse osmosis water or distilled water.

Operating instructions

DEGASSATION

If you are using the device for the first time, or the cleaning solution has been changed, the cleaning solution must be degassed:

- 1) Fill the tank to the level mark with cleaning solution. Do not put any object in the tank.
- 2) Switch the device ON by pressing the mains power switch [❷]. The cleaning temperature display [❶] will show 40 °C (default temperature), while the cleaning time displays [❸] will show 05 min 00 sec" (default time).
- 3) Set the cycle time to 10 minutes by repeatedly pressing the buttons [❹],
- 4) Start the degassing cycle by pressing the ULTRASOUND START/STOP button [❺]; the indicator lights [❸ and ❹] light up, to show that both the ultrasound emitters and the heater are ON now.
- 5) If the set temperature is reached during the cycle, the heater and the relevant indicator light will turn OFF automatically.
- 6) At the end of the set time, the cycle stops automatically: the cleaning solution is now degassed.

PREPARATION OF THE OBJECTS TO BE CLEANED

The objects must rest on the basket, without overlapping to prevent rubbing and scratching.

Small objects, that might fall through the basket grid, should be put into glass beakers filled with cleaning solution.

Never put objects in direct contact with the tank bottom.

TEMPERATURE SETTING

The temperature that is set by the user is the temperature that is reached under the effect of the built-in electric heater. The maximum settable value is 40°C.

When the set temperature is reached, the heater is switched OFF automatically, but the temperature of the cleaning solution will go on increasing slowly, due to the heating effect of ultrasound.



Temperatures above 45°C might make blood and other proteins harden and more difficult to be removed.

When the instruments to be cleaned have blood or protein residuals, keep the heating function OFF, and set the cycle time to a value that makes you sure that the temperature does not rise over 45°C under the sole ultrasound effect.

Operating instructions

RECOMMENDATIONS BEFORE LAUNCHING A CLEANING CYCLE

- Fill the tank to the requested level using an already – degassed cleaning agent (see DEGASSATION on previous page). The water used for the cleaning solution must be suitable for use in medical environment.
- Let the tank temperature drop below the recommended starting temperature (see table next page) and, in any case, below 40°C to prevent overheating.
- The temperature during the cleaning cycle will raise for the combined effects of the heating function and the ultrasound emission.
- To remove traces of blood and/or protein, make sure that the temperature remains below 45 °C.
- The tank must be filled to the operating level mark [●], and shall never drop 1 cm below that level.
- Never lay the objects on the bottom of the tank, because this might damage it. Always use the stainless steel basket.

RECOMMENDED PRODUCTS

- **Cleaning:** for cleaning all kind of medical instruments, we recommend **W&H BePro Cleaner TE**, which is a neutral trienzymatic detergent, specific for automated reprocessing of medical, surgical and dental instruments.

Purchasing REF number: 19500200 (5-litre canister), suggested dilution 6%.

- **Disinfection:** when disinfection is required, we recommend **W&H BePro Disinfectant I**, which is a powerful disinfectant concentrate for medical and dental instruments.

Purchasing REF number: 19500106 (2-litre bottle), suggested dilution 2%.



Always use CE-marked detergents suitable for ultrasonic cleaning.
Always follow the cleaning product manufacturer's instructions.



Do not overlap instruments to prevent rubbing and scratching.

Do not put parts in direct contact with the bottom of the tank; use the basket to keep the instruments suspended.

The device releases vapour, fog and micronized particles from the cleaning bath. If the cleaning agent is flammable, toxic, corrosive or dangerous for any reason, suitable measures must be taken, to prevent contamination of people or the environment. These measures may consist of warning signs, closed furniture, extractor hoods, personal protection equipment.

Operating instructions

CLEANING CYCLE

- 1) Open the stainless steel lid.
- 2) Check the cleaning solution level. The cleaning solution must be already degassed (see DEGASSATION paragraph), should reach the level mark and cover the instruments completely.
- 3) Switch the device ON by pressing the mains power switch [②]. The set temperature displays [①/②] will show 40 °C (default temperature), while the set cleaning time displays [⑤] show “05:00” (default time).
- 4) Put the instruments to be cleaned into the basket.
- 5) Put the basket with the instruments into the tank. Use the side hooks to suspend the basket: The basket shall not settle on the tank bottom.
- 6) Using the buttons [⑥] and [⑦], set the temperature and the cycle time according to the type of dirt to be removed, the objects to be cleaned and the cleaning solution in use.
Never switch the heating nor the ultrasound ON without liquid: risk of burning the electric heater and damaging the entire device.
- 7) If requested by the cleaning conditions, switch the heating ON by pressing the HEATING ON/OFF button [③]. The Heating element indicator light [③] will light up.
- 8) Start the cycle by pressing the ULTRASOUND ON/OFF button [⑨]. The ultrasound will start and the heating will remain ON until the set temperature is reached. The time display [⑦] will start counting down. The cycle will end at the end of the programmed time.
- 9) Check visually the cleaning results. Repeat the cycle with more severe parameters, if necessary.

NOTE: during the cleaning cycle, even though the heating is OFF the temperature will go on rising slowly due to the heating effect of ultrasound.

RECOMMENDED CLEANING PARAMETERS with W&H BePro Cleaner TE			
TYPE OF DIRT	Temperature	Time	Concentration
Persistent / stubborn dirt	30°C	15 minutes	6%
Light dirt	Reduce the parameters above according to the type of dirt to be removed. This will save time and minimize the energy consumption and the environmental impact.		
Dirt containing blood or proteins (*)	Heater OFF Starting temperature less than 25°C	15 minutes	6%

(*) When the objects to be cleaned are contaminated with blood, proteins or other substances that are susceptible to coagulation, the temperature must remain below 45°C to prevent coagulation and consequent dirt hardening.

7. Maintenance, spare parts, consumables, accessories

ORDINARY MAINTENANCE

Switch the device OFF and disconnect the mains cable before carrying out any maintenance operation. Check regularly the housing, the tank, the control panel, the mains switch and the mains cable for damage to prevent electrical accidents.

Cleaning is the only maintenance operation normally required.

It must be performed with the device switched off, the tank empty and the power cord disconnected. **Do not use solvents nor flammable substances.** Only use mild detergents for cleaning the inside of the tank and a soft dry cloth for cleaning the outside parts such as the control panel and casing.

Do not leave deposits of dirt inside the tank, especially if your model is fitted with a liquid drain device.

If the liquid outlet hole is obstructed by dirt residues, clean it with a suitable tool.



Before making any operation, ward off unauthorized personnel from the working area.

Dispose of the degraded or dirty cleaning solution according to the regulations in force in the country of use.

SPARE PARTS, ACCESSORIES, CONSUMABLES		
DESCRIPTION	PART NUMBER	
	3 LITRE	6 LITRE
Stainless steel basket	A803513X	A803514X
Glass beaker kit, including: <ul style="list-style-type: none">- 2 beakers (250 ml each for 3 litre version, 400 ml each for 6 litre version)- 1 Stainless steel beaker holder- 2 suspension rings	19725001	19725000
Beakers (2 pieces + 2 gaskets)	19725003	19725002
BePro Cleaner TE (Neutral trienzymatic detergent for automated reprocessing of surgical and dental instruments)	19500200 (5 – litre canister)	
BePro Disinfectant I (disinfectant concentrate)	19500106 (2-litre bottle)	

8. Diagnostic

CHECKS AND ACTIONS

Note: for any problems not listed in the table below, contact technical service.

Description	Possible causes	Checks and actions
No functions; indicator lights off.	Burned fuse	Contact the technical service.
	Mains cable failure or disconnected.	Check the electric power at the wall plug and check that the mains cable is properly plugged.
	Failure in the building electric system.	
	Mains cable has been damaged / cut.	Replace the mains cable.
	Electronic damage.	Contact the technical service.
The device works, the heating is ON, but the temperature rise rate is just about 1°C per minute or less.	Heater failure.	Contact the technical service.
The device doesn't clean the instruments/objects.	The cleaning time and/or temperature set weren't enough.	Increase the cleaning time and/or temperature and repeat the washing cycle.
	There is no or not enough cleaning solution in the tank.	Fill the tank with water or cleaning solution. The liquid must cover the whole surface of the instruments and reach the operating level mark of the tank.
	Too little or no detergent added.	Add the correct type and quantity of detergent according to the type of dirt to be removed.
The device works, but there is a noticeable decrease in ultrasonic power.	There is no liquid or not enough liquid in the tank.	Fill the tank with water or detergent. The water/detergent must cover the whole surface of the instruments and reach the operating level mark of the tank.
	The cleaning temperature is too low.	Increase the cleaning temperature and repeat the washing cycle.
	New non-degassed liquid.	Carry out the DEGASSATION procedure.

Continues on next page

Diagnostic

Description	Possible causes	Checks and actions
The device works, but there is a noticeable decrease in ultrasonic power.	Inappropriate detergent.	Use the correct type of detergent according to the type of dirt to be removed.
	Dirty liquid in the tank.	Drain the dirty liquid from the tank and replace it with new liquid.
	Dirt residues deposited on the bottom of the tank.	Clean the tank with hot water and/or mild detergents.
	Basket overloaded.	Don't overload the basket with too many instruments/objects to clean; repeat the cleaning cycle with less instruments/objects.
	Transducer or electronic failure.	Run the ultrasound operational test as described below. If the test fails, contact the technical service.

ULTRASOUND OPERATIONAL TEST

- Cut three small pieces of food-grade aluminum foil, approximately 10 x 20 cm each.-
- Prepare the ultrasound tank (degassed, to temperature and with the right percentage of detergent).
- Immerse the first "sheet" in the centre of the tank and the other two ones at five centimetres from the walls.
- Turn on the ultrasound waves for ten minutes.
- Remove the aluminum sheets and inspect them: if all sheets have been perforated and "wrinkled" the same way, this means that the ultrasound is working properly.

9. Technical data

Description	Technical data	
Commercial name:	U-SON	
Tank capacity:	3 l	6 l
Supply voltage:	230V – 50/60 Hz	
Input power - current:	250 W – 1 A	380 W – 1.7 A
Overvoltage category	II	
Fuse rating and size	F 10 A - 250 V – size 5 x 20	
Environment pollution	Degree 2	
Usage environment	Indoor	
Storage temperature – rel. humidity	From -20 to 60 °C / 0-90% (with empty tanks)	
Heating power:	100 W	150 W
Weight (kg):	2.6	3.5
External dimensions (mm):	W: 265 H: 220 D: 165	W: 325 H: 280 D: 180
Tank dimensions (mm):	W: 240 H: 100 D: 135	W: 300 H: 150 D: 150
Timer range (min):	1÷20	
Temperature adjustment range (°C):	20÷40	
Number of transducers:	2	3
Working conditions:	Temperature from 5 to 40 °C; rel. humidity 80% up to 31 °C with linear decrease up to 50% at 40 °C	
Max. installation altitude	3000 m asl	

10. Disposal

DISCONNECTION FROM ENERGY SOURCES

1. Drain the tank.
2. Switch the device OFF by pressing by the “Main power switch” [②].
3. Disconnect the mains cable.

OBLIGATIONS AND RECOMMENDATIONS RELATED TO DISPOSAL

The crossed-out wheelie bin symbol on the equipment or its packaging indicates that the product, at the end of its life, must be collected separately from other waste.

- Separate the various components according to the materials they are made of.
- Drop the device with a company that specializes on the recycling of related products
- Do not abandon the device in unsecured places.
- Always refer to current/applicable laws and rules in the country of use.



MATERIALS

The product is mainly built from metals, plastic and electric / electronic components.



Manufacturer

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U-Son CE ENG Instructions for Use - Rev 00

Subject to alterations

05/05/2025

Authorized service Partners

A list and a map with your nearest W&H service partner are available at **<http://wh.com>**