Instructions for Use

UP400 AE

Ultrasonic Homogenizer





Ultrasonic Homogenizer UP400

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topsonics accepts no responsibility or liability for damages caused by improper handling or usage contrary to the intended purpose.

The documentation was prepared with great care. Liability for indirect or direct damages arising because of incomplete or erroneous information in this documentation, as well as in its delivery and usage, is excluded.

Your new ultrasonic homogenizer has been designed, built and tested to assure maximum operator safety. However, no design can completely protect against improper use that may lead to bodily injury and/or property damage. For total safety and equipment protection, read the instruction manual carefully before attempting to operate this equipment.

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General

The equipment, the accessories and the preparations are to be used in accordance with the Instructions for Use and/or the product information.

The instructions are part of the scope of delivery and are to be stored in the vicinity of the device for later reference. This also applies if possession of the device is transferred elsewhere.

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

The warnings and safety precautions (section 1.5) are always to be followed during use.

The manufacturer will not assume any responsibility for the device's safety or functional ability in the event of improper handling or usage contrary to the intended purpose. In the event of unauthorized alterations/modifications, both the warranty claim and the CE conformity will be void.

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

Symbols used:

Symbol	Significance	Explanation					
A	Danger	High voltage is present in the generator (power supply), convertor and high frequency cable. There are no user-serviceable parts inside any of these devices. Do NOT attempt to remove the generator cover or convertor case.					
\triangle	Caution	Identifies information that is to be observed and adhered to without fail, to prevent damage to the device and danger to the user. When device parts are labelled with this symbol, reference must be made to the documentation.					
	Warning	Warning of hot surface.					
!	Important	Identifies information that is important for execution.					
í	Note	Identifies information provided for explanatory purposes.					
IVD	In vitro diagnostics information	Identifies information that is important for in vitro diagnostics applications.					
+	Medical note	Identifies information that is important for medical use.					
	Do not grip inside	For health reasons, touching the oscillating fluid is prohibited.					

	Wear hearing protection	For health reasons, standing for long periods of time in the vicinity of the device without hearing protection is prohibited.
>	Operating sequence instructions	Identifies instructions that are to be followed in the described sequence.
	Caution	A Turn Off When Not In Use Sign is a helpful tool to help protect the health and safety of personnel, and is not a replacement for required protective measures for lessening or removing hazards.
	Warning	Exposed fan belt drive. Can cause severe injury or death. Turn off power and lockout before servicing.
	Danger	Electrical shock or burn hazard. Turn off power supplying this equipment before working inside.

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Inspections

Your new TOP ultrasonic homogenizer was thoroughly inspected, tested and carefully packed before leaving the factory. Prior to unpacking, carefully inspect the shipping carton for any evidence of damage. Claims for loss or damage sustained in transit, must be made to the shipping company.

Unpack the unit from its shipping carton and check the contents against the packing list. Before disposing of the packing material, check it carefully for small items. Report any missing components to support immediately.

Visually inspect all external controls, indicators and surfaces to detect any damage in transit. If damage has occurred, contact your carrier within 48 hours of delivery date. DO NOT OPERATE DAMAGED EQUIPMENT. Retain all packing materials for possible future shipments.

Placement of Equipment

Place the device in an area that is free from excessive dust, dirt, water and explosive or corrosive fumes. A fan maintains safe operating temperature in the generator by circulating air over the electronic components. Therefore, the generator must be placed so that the air intake grills on the rear and lower panels are not blocked. DO NOT place unit on a soft surface such as a towel or foam, which may compress and block the lower grill. Place unit on a hard smooth surface only. Clean and inspect the air intake grill periodically, to insure it is free from dust and debris.

1 Product description

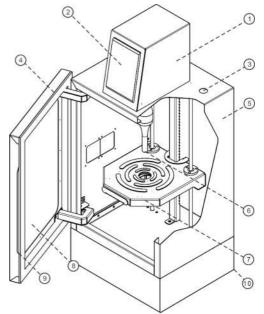
The topsonics ultrasonic homogenizer is essentially made up of two components: the HF generator, the ultrasonic transducer, and the working tip (probe). The individual components can be varied using a multitude of options and accessories. The type specification and serial number are found on the type plate.

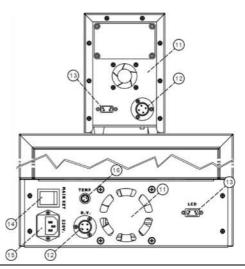
1-1-1 Product features:

- HF generator (1) in low-maintenance, robust metal housing, with connections for the ultrasonic transducer (3).
- Operating and display panel (2) with LCD display
- Sound insulation compartment (4)
- All-metal body (5)
- Inside the device and Ultrasonic transducer (6)
- Holder (7)
- Tow-layer transparent polyester to reduce sound (8)
- Device handles (9)
- Electronic part of the device (10)

1-1-2 Product features on the rear side of the HF generator and electronic part of the device:

- Cooling fan (11)
- Ultrasonic transducer probe ports (12)
- LCD ports (13)
- On/off button (14)
- Fuse and Mains socket (15)
- Temperature port (16)





1-1 Mode of operation

The HF generator transforms the absorbed mains energy (mains frequency 50 or 60 Hz) into high-frequency energy with a frequency of 20 kHz. Thanks to the ultrasonic transducer that is connected to the HF generator, the high-frequency energy of the HF generator is converted into ultrasound and thus into mechanical energy. This takes place with an efficient and robust PZT ultrasonic oscillating system. Thus, mechanical deflections with a similar frequency of 20 kHz, which are transferred into the sonication medium as ultrasound waves with a high power intensity, are generated on the tip of the probe. The amplitude is held constant by the ultrasonic transducer, independently from the applied load, using a signal feedback as long as the maximum power allowed is not exceeded. Thanks to these measures, the reproducibility of the process parameters is guaranteed and validation of the process is supported.

Probes are mounted on the ultrasonic transducer. These work as mechanical transformers and enable a multiple mechanical amplification of the ultrasound amplitude at the tip.

1-2 Purpose

topsonics ultrasonic homogenizers generate high-performance ultrasound with high intensities and ultrasonic amplitudes, which are transferred into liquid media through working tools known as probes. They are used in laboratories, clinics, and in industrial research, and in the process, they perform versatile tasks during sample preparation in Quality Assurance, scientific experiments, analyses, and in pilot or shortseries manufacture.

- Application examples:
- Cell disruption for paternity tests
- Cell disruption (extraction of microorganisms, tissue cells)
- Homogenizing of liquids
- Emulsifying hard-to-mix liquids
- Dispersing of agglomerates
- Accelerating chemical reactions
- Degassing of fluids
- Sample preparation in environmental analytics (wastewater tests, soil samples)
- Sono-chemistry



topsonics ultrasonic homogenizers are also used for in-vitro diagnostic lab procedures, to procure information from the handling of organic materials with ultrasound. Therefore, they are classified and treated in accordance with the Directive 98/79/EC on in-vitro diagnostic medical devices.

1-3 CE conformity

topsonics ultrasonic homogenizers are declared as IVD products and satisfy the CE marking criteria for the European Directives:

- IVD directive
- Low-voltage directive
- Electromagnetic compatibility directive in their currently valid versions.

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

1-4 Technical data

topsonics ultrasonic homogenizers are interference-free and marked with a: Safety: EN 61010-1, EMC: EN 61326-1

1-4-1 HF Generator (GM)

Power supply	230 V ~ 50/60 Hz
HF ultrasound frequency ¹	approx. 20 kHz±1 kHz
Frequency control ²	automatic or search function
Ultrasound operation type	pulsating
Time setting range	01:00 – 30:00 [mm:ss]
Pulsation times ³ ON (t_{on}) / OFF (t_{off})	1 - 20 s / 2 - 10 s
Ultrasound control	Amplitude or power
Amplitude setting range	0 - 100% in 1% steps
Power setting range	0-400 W in 1 W steps
HF power ⁴ , effective	max. 400 W
Temperature sensor	PT-100 with SS 316 cover $(\pm 1 \text{ °C})$
Measurable temperature	0-87 °C
Mains supply	220-230 V~ (± 10 %), 50/60 Hz
Mains power consumption	max. 400 W
Program memory slots	5
Interface	Wi-Fi (with android application) and colorful touch screen
Material (Housing)	Metal by electrostatic color
Package dimension	<u>???????????</u>
External dimensions	$301 \times 282 \times 603 \ mm \ (L \times W \times H)$
Weight	20 Kg
Protection class	Class I
Degree of protection	IP 30 according to DIN 60529

³ Pulse period duration = $t_{ON} + t_{OFF}$

⁴ HF power: In the case of amplitude control, the HF power necessary for the desired probe amplitude is dependent on the viscosity of the medium. To avoid damage to the HF generator and converter, the power is limited to the maximum permissible peak value. With very viscous media, this can result in failure to reach the desired amplitude.

¹ Depending on the operating conditions and production tolerances, the actual value of the ultrasonic frequency can deviate from the given value by +5 %/-7 %.

 $^{^2}$ Frequency control: The HF generator can perform automatic search of resonance frequency and frequency adjustment in an ongoing operation. Reasons for changes of resonance frequency are, for example, heating of the ultrasonic converter and probe, change in acous- tic load due to viscosity changes and also installation of another probe. Through the automatic frequency, a frequency drift during operation is corrected. The optimal work frequency is found with the resonance frequency scan, such as after a probe change.

tops	onics Instruction of Ultrasonic homogeneity 	enizer U400 🔸
	Environmental conditions pursuant to EN 61 010- Overvoltage category: Degree of contamination: Permissible relative humidity up to 31 °C: Permissible relative humidity up to 40 °C: Permissible ambient temperature: No dewing allowed. Only for indoor operation.	1 II 2 80 % 50 % 5 to 40 °C
IVD	Specifications for use as a medical device Name: UMDNS nomenclature (ECRI / DIMDI): Purpose:	Ultrasonic Homogenizer 17-125 homogenizing, emulsifying, cell disruption and suspension
	Medical device pursuant to	

Wedical device pursuant to	
Directive 98/79/EC for in-vitro diagnostics:	Category 5 device (miscellaneous)
Type, model, serial number, year of manufacture:	See type plate on the generator for information

The homogenizer has been inspected pursuant to norms currently in effect and is to be installed and put into operation pursuant to EMC directions; information in this respect is found in the appendix.

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

Commissioning on site, functional check	
and personnel instruction:	Not required
Technical safety controls:	No specifications
Technical measurement controls:	N/A

Electromagnetic ambient conditions (EMC)

The device was tested to DIN EN 61326-1 for electromagnetic compatibility (EMC) and complies with the requirements for class B devices according to EN 55011.

It is suitable for use in facilities and areas, which are directly connected to a public low-voltage supply network, e.g. medical laboratory facilities.

1-4-2 Technical data, Ultrasonic converter UW

An ultrasonic transducer is located on its electronics section of device.

Transformation principle	piezoelectric
Ultrasonic frequency	approx. 20 kHz
Material	titanium

1-4-3 Remote control

The ultrasonic homogenizer has a Wi-Fi interface with 802.11b standard and can be applied by the user for

- Remote monitoring of the operation data.
- Remote control of the process cycle.

The manufacturer on request provides the protocol and command set for the Wi-Fi interface (application information).

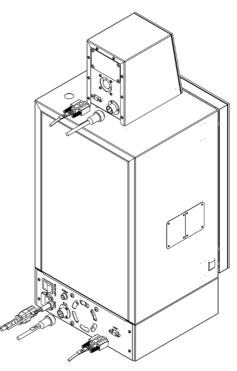
For communication, a commercially available Wi-Fi can be used. The program-related implementation required for communication is the responsibility of the user and is not supported by the manufacturer.

The manufacturer only guarantees proper functioning of the interface.

Optical access is located on the bottom of the housing with direction of view to the left (seen from the front side). For a secure connection, the infrared adapter must be positioned according to illustration.

The 802.11b standard has a maximum raw data rate of 11 Mbit/s, and uses the same media access method defined in the original standard. 802.11b products appeared on the market in early 2000, since 802.11b is a direct extension of the modulation technique defined in the original standard. The dramatic increase in throughput of 802.11b (compared to the original standard) along with simultaneous substantial price reductions led to the rapid acceptance of 802.11b as the definitive wireless LAN technology.

Devices using 802.11b experience interference from other products operating in the 2.4 GHz band. Devices operating in the 2.4 GHz range



include microwave ovens, Bluetooth devices, baby monitors, cordless telephones, and some amateur radio equipment.

1-5 Warnings and safety precautions

1-5-1 General

- Keep the device and accessories out of the reach of children and of persons who have not been instructed in their operation by reference to these instructions.
- The use of the device or parts thereof on humans or animals is not authorized.
- Keep the HF generator and operating elements clean and dry.
- Do not expose the unit to corroding influences.
- When working with the device, please observe hygiene instructions pursuant to chapter 5.2.
- The connection of any type of power or voltage sources to signal inputs or outputs is forbidden.
- All plug connections (such as for ultrasonic transducers, foot switches) may only be plugged or unplugged while the device is turned off.
- The HF generator and ultrasonic transducer may only be transported separately.
- The homogenizers adhere to prescribed EMC limit values, such that it can be assumed that the electromagnetic radiation emanating from the units 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 is to be obtained from the implant manufacturer.

1-5-2 Operation

- Observe ambient and set-up conditions see <u>chapter 1.4</u>.
- Determine the mains voltage before connecting the HF generator. Only connect the HF generator to a grounded socket.
- Fuse protection 3 A (main circuit breaker).
- The metallic ultrasonic transducer system must not be turned inside the black housing of the ultrasonic converter. This would destroy the ultrasonic transducer system and its electrical connections. The plastic clamping ring must not be loosened.
- Before each startup, check that the probe is firmly positioned; if necessary, tighten the probe (see chapter 4.3.1).
- Do not touch any oscillating parts during operation! Damage to health is possible.
- Do not touch the sonication vessels with the oscillating probe probes and vessels could be damaged.
- Warning, risk of splashing!
- This is especially the case with small sample quantities and when immersing oscillating probes.

- Do not use combustible solvents in open reaction vessels since the operating safety of the homogenizer could be compromised. Safe extraction of combustible vapors must be guaranteed. When using a soundproof box, the vapors cannot escape.
- Before any mounting or dismounting (chapter 4.3.1) of probes, turn off the device and disconnect the ultrasonic transducer from the HF generator.
- Only use the prescribed tool for mounting and dismounting (see appendix B).
- Do not use any bent probes (\Box unstable operation, loss of power).
- Liquids must not penetrate the inside of the ultrasonic transducer.
- Only the ultrasonic converter UW mini20 may be connected to the HF connection.
- Do not operate the device without supervision.
- Advice for the medical and laboratory field
- The homogenizer is exclusively intended for use by skilled medical personnel.
- It may generate radio interferences or disrupt the operation of devices nearby. It may be necessary to take remedial measures such as realigning the device or reconfiguring the homogenizer or the shield.
- During operation, portable or mobile RF communication systems near the homogenizer should be turned off operation may be disrupted.

Advice for the medical and laboratory field

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1-5-3 Damages

IVD

- If damage to the homogenizer is detected, do not connect the homogenizer to the mains.
- In the event of malfunction, disconnect the mains plug immediately.
- Repairs are only to be conducted by authorized skilled personnel or by the manufacturer.
- Defective parts must only be replaced with original parts or parts of the same quality!

2 **Preparation**

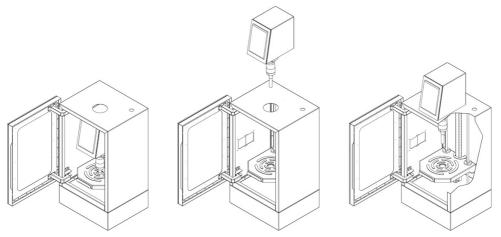
Carefully unpack the HF generator, ultrasonic transducer and accessories, and inspect them for completeness or possible transportation damages. If any damages or defects are found, these are to be immediately notified in writing to the transportation company and to the supplier. Before startup, the ultrasonic bath is to be left to stand at its operating location for 2 hours so that it may adapt to the ambient conditions.

2-1 Scope of delivery

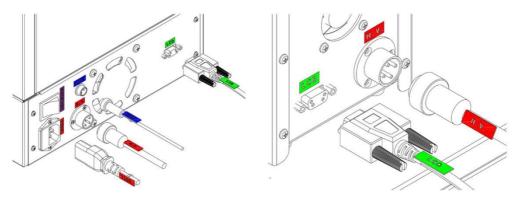
- The scope of delivery will depend on the size of the order. However, it will generally include the following parts:
- One HF Generator GM mini20 with holder and mains cable see delivery note
- One Ultrasonic transducer UW mini20
- One Probe
- One Instructions for Use
- Additional accessories according to order see delivery note

2-2 Set-up / assembly

- > Place the HF generator atop a firm, level and dry surface. In doing so,
 - Do not group it or stack it over other electric or non-electric devices.
 - Guard against moisture and wetness risk of electric shock.
- During delivery, a probe is already firmly screwed to the corresponding ultrasonic transducer. Other probes are mountable. To do so, see instructions in chapter 4.3.
- Screw together the supplied probe with the ultrasonic transducer, see chapter 4.3.1.
- Connect the ultrasonic transducer to the HF generator see the following chapter.
- > Verify that the power switch is in the "0" position.
- > Connect the generator to a suitable type to a grounded socket.



To assemble the device, first unboxing the device and get the electronic part of the device. According to the figure above, the electronic part of the device should set on the top of the box. After that, the process of installing the electronics and horn wires is as follows.



The wires and ports of the device have labels that are separated by name and color. Each wire and port that has the same name and color, must be connected to each other. In this way, the assembly can be completed easily.

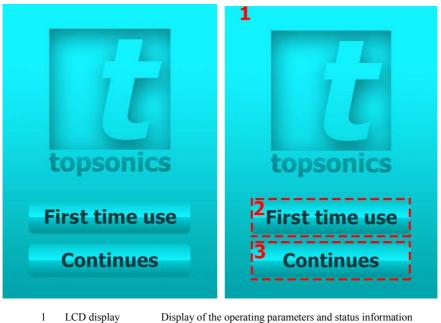
2-3 Start-up

- > Check the firm positioning of the probe and, if needed, clean thoroughly before first use.
- > Connect the HF generator to the mains (grounded socket) and switch on.
- Set the probe type (see chapter 3.1.1)
- Conduct a function test pursuant to chapter 6.2.1.

3 Operation

3-1 Operating elements

When the device is turned on, the display panel on the front side of the HF generator shows the following figure.



- 2 "First time use" At the first use of the device, you can use this option to learn how to operate the device
- 3 "Continues" You enter the main program environment by touching this option.

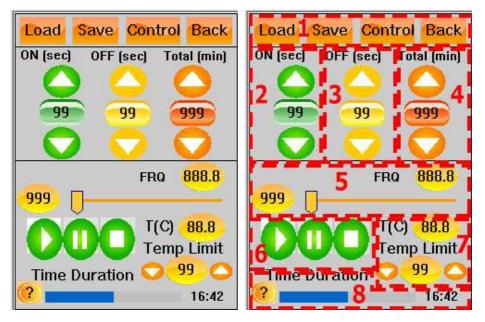
3-1-1 Turning the homogenizer on/off

The homogenizer is turned on using the power switch on the rear side of the HF generator. After turning on, the LCD display must light up. Initialization occurs automatically. The ultrasonic homogenizer will display the manufacturer's name, first time use and continues buttons.

3-1-2 Explanation of the display fields

3-1-2-1 Main page

The figure below is the home screen of the screen where you can change the settings of the device and launch the device.



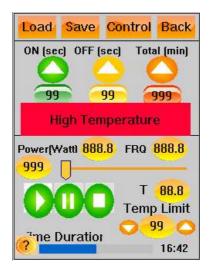
The settings for this page are as follows:

- 1 Load, save, control and back buttons, to save and restore settings, see a control unit and back to menu
- 2 Set the time of active mode on each pulse
- 3 Set the time of passive mode on each pulse
- 4 Set the total time of operation
- 5 Set the power (frequency)
- 6 Operation buttons
- 7 Temperature settings
- 8 Timeline

3-1-2-2 High temperature dialogue

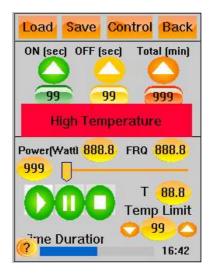
If the temperature is greatly increased, the screen will look similar to the figure below, and warns of an excessive increase in temperature.

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3-1-2-3 License dialogue

The first time the device is turned on, it is necessary to enter the license number of the device inside control panel. If the license number is invalid or not entered, the home page will be as follows.



3-1-2-4 Control panel

By tapping the control button on the main screen, we will enter this page (in figure below). On control panel page, information about the latest usage of the device, the administration page and the system information page are visible.

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23:36 15/12/17 Administration System Info								
Time	Time Date Duration							

3-1-2-5 Administration

The following figure shows the administration page, this page has device information, serial numbers and license number. The open or closed door status can also be checked on this page. If the sensor is encountered with a problem, this section is recognizable.

Power Ty 9999					
Clear Lo	g Do	or Check			
System S	ettings	Ma×Out	9.99		
	3	MinOut	9.99		
Drv.Serial	99999	99999	T.Sensor		
Gen.Serial	99999	99999	MLX		
Install	9999	/ 99 /	99		
Lic.ID	9999	t 9999	Save		
Repair	9999	/ 99 /	´ 99		
PerCode	9999		Save		

topsonics	♦ Instruction of Ultrasonic homogenizer U400									
3-1-2-6	Syst	em inf	formation							
			Lic ID 8888							
			Gen.Ser	8888	8888					
			Drv.Ser	8888	8888					
			Install	9999 /	99 / 9	9 🍅				
			WIFI SIE	AE	BCDEF	GH				
			WIFI PAS	s AE	BCDEF	GH				
					Save	Wifi				
				Syste	m Settin	gs				

3-2 Setting the operating parameters

With the exception of the amplitude and power, the operating parameters can only be set while in stand-by mode (idle mode). In the marked area (inverse view) of the selected parameter, the desired value is set by turning the rotary knob. By pressing the "START/STOP" button, the editing mode is exited.

The following operating parameters can be set:

- Default values for the amplitude or power [Am or Pw]
- Default values for the sonication time [time]
- Default values for the pulsation of the ultrasound (turn-on and turn-off time) [pulse]
- Limit value for the temperature monitoring [...°C]

In each of sections 2 through 7, values change with the touch of a triangle shapes. In addition, by touching the number display, you can change the number on the virtual keyboard. With the appearance of a virtual keyboard, a green area is displayed at the top of the screen that showing the minimum and maximum values. Values outside these numbers are not acceptable.

The function of the buttons in this section is as follows:

Button	Operation
Enter	Verify and apply the amount entered
Esc	Exit without Changes
Clr	Clear all values
Del	Clear one digit

After changing the values, by pressing the "START" button, device will start.

3-2-1 Sonication time [time]

A value of 30 minutes can be set as the maximum sonication time. If the set value is exceeded during ultrasound operation, the sonication will stop. The specification "non-stop" is equivalent to unlimited continuous operation until operation is ended by pressing the "START/STOP" button.

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3-2-2 Save programs

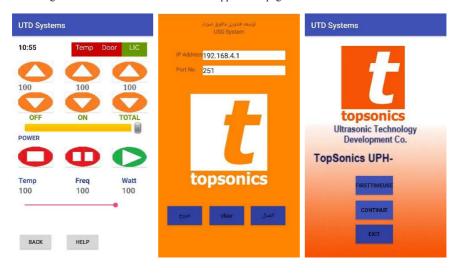
To save the settings for later use, changes will be saved by pressing the "SAVE" button. By pressing this button, the virtual keyboard screen is displayed. You must enter the storage slot number between one and five slots.

3-2-3 Load programs

The program saved in the previous step can be retrieved at this stage. For this purpose, by pressing the "LOAD" button, you can select one of the saved slots.

3-3 Android interface application

The UI for the Android operating system is available on our site. This software connects to the homogenizer device using the Wi-Fi protocol (chapter 1.3). The way it works is similar to the user interface of homogenizer device. The screenshots of the application pages are listed below.



4 Use

4-1 Instructions for use

- Before each sonication, make sure that the ultrasonic homogenizer is in proper condition.
 - The ultrasonic converter is held with the hand when performing sonication. Care must be taken that the ventilation slits are not covered. Before the end of sonication, the ultrasonic converter is hung again in the holder at the HF generator.



Caution! In continuous operation, the ultrasonic converter can heat up considerably.

- Do not touch the sonication vessels with the oscillating probe probes and vessels could be damaged.
- The recommended immersion depth for probes is 2 10 mm, depending on the set amplitude or power, to avoid suctioning and addition of air. If addition of air is desired, immerse the probe as little as necessary. With higher immersion depths and/or sonication of liquids with high viscosities, the probe is more strongly energized. The result is that the preset amplitude (power) might no longer be reachable, especially at higher settings (> 50%). The reason is that the HF generator can no longer provide the required power.
- When producing emulsions, the probe should be immersed to the level of the interface between the liquids to be mixed.



- Do not use combustible solvents in open reaction vessels since the operating safety of the homogenizer could be compromised.
- In order to shut down the device, disconnect it from the mains (pull the plug).

Remarks on cavitation formation

Compared to those of the larger ultrasonic homogenizers, the amplitudes for SONOPULS mini20 are much lower, especially for small amplitude or power settings. This can result in no initiation of cavitation, although the probe is oscillating correctly, or cavitation formation breaks off repeatedly. Stimulation for cavitation formation can be improved, such as of immersing the probe before starting ultrasound operation or by choosing a probe with larger diameter of the tip. If these activities are not successful, the set point for amplitude or power must be increased.

4-2 General use

Before starting use, the important instructions under chapter 4.1 are to be heeded!

Step 1 : Check the ultrasonic transducer

- > Verify that all connecting cables and couplings are correctly connected.
- > The probe type must conform to the sonication volume, see table in chapter 4.3.
- > The probe must be clean, faultless, and firmly mounted.

Step 2 : Prepare the sonication

- Prepare the sonication medium.
- Position the sonication vessel below the ultrasonic transducer in such a manner that the probe does not come in contact with the vessel.
- Set the immersion depth for the probe (approx. 2 10 mm).

Step 3 : Turn on the homogenizer

- > Turn on the homogenizer with the power switch.
- All saved data and settings will be loaded. Check the settings and load a different programmed if necessary, see chapter 3.3.

Step 4 : Activate the ultrasound

- Select a small amplitude at the start to prevent any splashing onto the ultrasonic transducer. Observe the maximum-allowed amplitude, see chapter 4.3.
- Activate the ultrasound

Warning, risk of splashing!

This is especially the case with small sample quantities and when immersing oscillating probes.

Step 5 : Remove the sample

After sonication, the probes are to be removed from the medium. Leaving them in the sonicating medium for a longer time can cause damage to the probe.

- > Once the programmed or time setting has elapsed, the delivery of ultrasound ends automatically.
- > If continuous sonication has been set, the ultrasound delivery must be stopped manually.
- > Remove the probe from the sonicating medium.

Step 6 : Clean the probe

In order to prevent contamination with other sonicating media, probes are to be thoroughly cleaned after every sonication, see chapter 5.2.

- Turn off the homogenizer with the power switch.
- Clean the probe and check the wear on the sound emitting surface at regular intervals, see chapter 5.1.

4-3 Selection of suitable probe

Detailed information on the individual probes can be found in the separate product information.

Probe	<mark>MS 13</mark>
Tip diameter	<mark>13 mm</mark>
Sonication volume	<mark>100-1500 ml</mark>
Amplitude	<mark>65 µт_{ss}</mark>
Maximum permissible amplitude setting	<mark>100 %</mark>

4-3-1 Mounting and dismounting of the probes

To install or remove the probes, two spanners of type SW 10 (8 x 10) are needed. The spanners are included in the scope of delivery of the ultrasonic homogenizer or are supplied together with the probe.

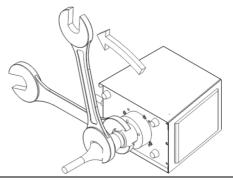
> Do not mechanically burden the probes during installation danger of bending.



> Before mounting the probes, the HF generator must be switched off or the ultrasonic converter separated from the HF generator.

4-3-1-1 Work steps for disassembly (see illustration)

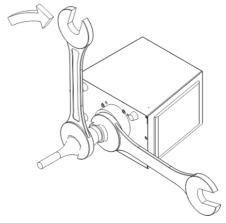
- Place the ultrasonic converter on a level surface, e.g. tabletop.
- Push the spanner with width 10 at the coupling piece into the guide grooves.
- Turn the ultrasonic converter and spanner to the left so that the other end of the spanner lies on the surface and the coupling piece can no longer be turned to the left.



- > Now push the spanner with width 8 into the guide grooves of the probe.
- > Then unscrew the probe. In doing so, firmly hold the spanner at the coupling piece.

4-3-1-2 Work steps for mounting (see illustration)

- > Clean the coupling surface at the ultrasonic converter and check whether it is free ofdamage.
- > Place the ultrasonic converter on a level surface, e.g. tabletop.
- > Push the spanner with width 10 at the coupling piece into the guide grooves.
- Turn the ultrasonic converter and spanner to the right so that the other end of the lies on the surface and the coupling piece can no longer be turned to the right.
- Screw in the probe hand-tight.
- Now push the spanner with width 8 into the guide grooves of the probe.
- Then firmly screw on the probe. In doing so, firmly hold the spanner at the coupling piece.



If the coupling surface is damaged at the coupling piece or probe or if the screw coupling between the coupling piece and the probe is not firm enough, a malfunction can occur (Error 011 or 012).

5 Cleaning and maintenance of the homogenizer

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

CAUTION!



Always disconnect the homogenizer from the mains before performing cleaning/maintenance.



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

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

5-1 Cleaning and care

5-1-1 Probes

All probes are subject to process-related wear, which leads to erosion on the sound-emitting surface and thus to a reduction in power.

In the case of frequent use, it is recommended that a supply inventory of probes be kept. The following images show examples of the course of erosion on the probe surface:



New and unused surface



Erosion still permissible, plate can be polished



Pitting started



Erosion limit exceeded, replacement necessary

The surface of the probe can be refinished by the manufacturer only, if the probe is qualified for after checkup.

5-1-2 Cleaning/disinfection of the ultrasonic converter

Cleaning and disinfecting can be done by wiping.

- Use only products on a aqueous, alcoholic or peroxide base to clean and disinfect.
- The ultrasonic converter may be wiped off.
- Spraying or immersing in water for cleaning purposes is not permitted.
- The push-pull round plug of the ultrasonic converter must not come into contact with water and must be protected.
- Do not use any abrasive cleaning agents (scouring liquid, etc.) or blades, scrapers, etc. to clean the ultrasonic converter, since the metal or plastic surface can be damaged.

5-1-3 HF generator

- Before cleaning, disconnect the HF generator from the power supply.
- Do not spray off the HF generator, immerse it on water, and do not subject it to spray water only wipe it off from the outside with a damp cloth, and then let it dry or rub it dry.
- Do not use abrasive cleansers, use only commercially available polishers without any abrasive additive.
- Housing is to be wiped off only from the outside with a moist cloth; afterwards, allow drying alone or wiping dry.

5-2 Treatment of contaminated parts in the ultrasonic transducer, vessels and accessories pertaining to the medical field

When working with ultrasonic homogenizers, the sonicating parts, vessels and other accessories (e.g. stands, mounting tools) could be contaminated with microorganisms or toxicologic agents and lead e.g. to cross-infections. Disinfection and/or cleaning is required.

In the event of incorrect or irregular disinfection and cleaning, contamination is possible, especially at the connecting points (e.g. between probe and ultrasonic transducer) and at the sound-emitting surfaces (see chapter 5.1, Wear).

Therefore, the sonicating parts (such as the probes), vessels and accessories are to be disinfected and cleaned, and dismounted for this purpose if necessary, after every use.

In the event of toxic contamination, the applicable regulations and provisions of the BGR 250/ TRBA 250 are especially to be observed.

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The disinfection and cleaning should be performed regularly by the operator, if applicable in accordance with the hygiene plan and using a VAH-certified or effective surface disinfectant.



Note:

Additional information and provisions locally applicable at the user's/operator's site are to be observed.

5-3 Warehousing / storing

During extended periods without use, the homogenizer should be stored in a cool, dry place. The ultrasonic transducer should be covered in order to protect the electronics from outside contamination.

6 Maintenance and repair

6-1 Maintenance

topsonics homogenizers are maintenance-free.

Aside from the process-dependent cavitation erosion on the sound-emitting surface of the probes, no other homogenizer parts are subject to wear. Worn out or faulty probes can be replaced following the instructions in chapters 4.3.1.

The devices are calibrated at the time of delivery. A control of the calibration is only required after repairs, and is only conducted by the manufacturer.

6-2 Functional checks

See also chapter 3.2.3 for description and operation



IMPORTANT

Only allow repairs to be conducted by authorized skilled personnel! Kindly inform us in writing of any malfunctions – use the enclosed questionnaire.



Important information

Before each repair, turn off the device and disconnect the plug from the mains! Defective parts may only be replaced with original parts.

The electronic housing and the ultrasonic transducer (ultrasonic oscillating system) may not be turned against each other. The ultrasonic oscillating system and its electrical connections would be damaged as a result.

6-3 Error analysis

Errors may arise

- on the plug connections
- on the ultrasonic transducer
- on the probes
- on the HF generator

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

Mechanical defects of the HF connector sockets, the plug connectors, the ultrasonic transducer, etc. are also possible as a result of frequent use or even incorrect handling, e.g. by dropping them.

Critical faults are recognized by the device and signaled by a red LED and an intermittent signal tone (3 times), and displayed with an error number, see next page.

6-4 General device errors

Error	Possible cause	Remedial action
Device cannot be switched on? (display without function)	No power Mains cable loose or faulty?	 Check the plug connection for firm positioning. Check the cable for continuity or, if needed, exchange the mains connector.
	Device fuse tripped?	 Exchange the fuses The fuses are located in the panel-mounted plug on the rear side of the generator, see chapter 1. (2 fuses: F2A)
	Main fuse faulty?	- Exchange the main fuse.

Little or no ultrasonic power?	Probe faulty?	 Check the probe and threaded pins for cracks, if necessary remove and replace. □ Ensure that the surfaces are clean and smooth, see chapter 4.3.1
	Check for erosion on the probe - see chapter 5.1.	4.3.1.
	slight?	- Polish the probe a bit.
		 Mill the probe until flat, or grind (max. 0.5 mm). This action would be a little risky, must be done by carefully.
	heavy?	- Replace the probe with new ones
	Has liquid seeped in between the ultrasonic transducer and the probe? Is the threaded pin attachment on the titanium plate defective?	 Dismount the probe, clean the mounting surfaces and threads, dry and check for evenness, remount the probe and tighten, see chapter 4.3.1.
	Internal thread or mounting surface of the ultrasonic transducer defective?	Replace the probe, see chapter 4.3.1.Send in for repair.
	Wrong resonance frequency?	 Probably the mechanical section must be repaired, Contact the local agency.
Significant heating in the vicinity of the mounting surfaces between the ultrasonic transducer – probe?	Sonicating parts (ultrasonic transducer and probe) not mounted firmly enough? Are mounting surfaces of the sonicating parts soiled?	- Dismount the respective parts, clean the surfaces and firmly retighten, see chapter 4.3.1.

If it is not possible to rectify the fault using these short instructions, please contact your local specialist dealer or write us to the address below.

6-5 Repairs and service

If you identify errors or defects that cannot be rectified, use of the homogenizer must be halted. In such a case, please contact the supplier or the manufacturer:

topsonics company	Tehran, iran
Repairs/Maintenance department:	E-mail: info@topsonics.com
Tel.:	+98-21-66065887, +98-9123830551

In the event of returns, the General Terms and Conditions for Delivery and Payment of topsonics apply. In addition, the homogenizer is to be cleaned and decontaminated (if necessary), see the following chapter.

6-5-1 Decontamination certificate

If the homogenizer is sent back to the manufacturer for repairs (with accessories, if applicable), the form "Certificate of Decontamination" is to be filled out and affixed to the packaging on the outside, in a visible spot.

If this form has not been filled out, we reserve the right to refuse receipt of the package in order to protect our employees.

The form can be downloaded from the Internet as a PDF file: <our website> - Service - Downloads... A sample copy can be found in appendix.

7 Accessories

The proper accessories facilitate use of the ultrasound and protect the device and materials used at the same time.

topsonics offers a broad range of accessories, see appendix. Additional information may be obtained from our supplier, our sales representatives, or from our website.

7-1 Required accessories

- not applicable -

7-2 Optional accessories

Pos.	<mark>Order</mark> no.	Designation
<mark>1</mark>	<mark>3639</mark>	Probe MS 1.5
<mark>2</mark>	<mark>3654</mark>	Probe MS 2.0
<mark>3</mark>	<mark>3652</mark>	Probe MS 2.5

7-3 Preparations

- not applicable -

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Consumable materials

- not applicable -

Taking the unit out of service

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



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10 Key words

Α

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Decontamination - Master copy

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

This "Certificate of Decontamination" is intended to secure the occupational health and safety of our employees pursuant to the Protection against Infection Act and trade association accident prevention regulations.

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

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

Serial number: Accessories: Device / accessories are not contaminated: were cleaned before shipping: are free from toxic matter: have been decontaminated and/or disinfected and no longer pose a health risk:	Device type:		
Device / accessories are not contaminated: were cleaned before shipping: are free from toxic matter:	Serial number:		
Device / accessories are not contaminated: were cleaned before shipping: are free from toxic matter:			
are not contaminated: were cleaned before shipping: are free from toxic matter:	Accessories:		
are not contaminated: were cleaned before shipping: are free from toxic matter:			
were cleaned before shipping: are free from toxic matter:	Device / accessories .		T
are free from toxic matter:	are not contaminated:		
	were cleaned befo	re shipping:	
have been decontaminated and/or disinfected and no longer pose a health risk:	are free from toxic	matter:	
	have been deconta	aminated and/or disinfected and no longer pose a health risk:	

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

Corrosive Toxic Biologically hazardous (e.g. microorganisms)



Radioactive

Certificate of Decontamination

! ! ! CAUTION ! ! ! This form must be visibly affixed to

the outside of the package!

Legally binding statement

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

Company / Institute:	
Street and number:	
Postal code, city:	
Department:	
Name:	
Telephone, extension:	Fax:
Reason for return:	
Thank you, in this way you help us to _	
reduce costs.	