



SONOPULS

Ultrasonic Homogenizer



Ultrasonic Homogenizer mini20

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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 familiarised 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 unauthorised 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.

Symbol	Significance	Explanation
	Danger	Identifies information that could signify a risk to life and limb, especially through electric shock, if not observed.
	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.
4	Operating sequence instructions	Identifies instructions that are to be followed in the described sequence.

Symbols used:

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1 Product description

The SONOPULS 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.

Product features:

- HF generator (1) in low-maintenance, robust plastic housing, with connections for the ultrasonic transducer (2).
- Operating and display panel (3) with LCD display (4)
- Ultrasonic transducer (5) with Start/Stop button (5a) and ventilation slits (5b)
- Probe (6)



Product features on the rear side of the HF generator:

- Mains switch (7)
- · Mains socket (8) with fuse holder
- Recessed grip with storage (9)



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 30 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 30 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 (AMPLICHRON[®] system), 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

SONOPULS 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 short-series 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)
- · Sonochemistry
- **IVD** SONOPULS 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

SONOPULS 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
- RoHS directive

in their currently valid versions.

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

1.4 Technical data

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

1.4.1 HF Generator (GM)

HF ultrasound frequency³ Frequency control⁴ Ultrasound operation type Time setting range Pulsation times⁵ ON (t_{ON}) / OFF (t_{OFF}) ultrasound control⁶ Amplitude setting range Power setting range HF power⁷, effective HF connection (ultrasonic converter) Energy display Mains supply Mains power consumption Program memory slots Interface Material (Housing) External dimensions Weight Protection class Degree of protection

approx. 30 kHz (AFC) automatic or search function continuous or pulsating 00:01 - 59:59 [mm:ss] or Continuous operation 0.1 - 60 s / 0.2 - 60 sAmplitude or power 10 - 100% in 1% steps 1-9 W in 0.1 W steps max 20 W Socket for round plug (MEDISNAP plug) in kJ 115 ... 230 V~ (± 10 %). 50/60 Hz max. 25 W 9 infrared (RS-232, half-duplex) plastic (ASB)/metal (AI) 250 × 155 × 257 mm (W × H × D) 2 ka Class I IP 30 according to DIN 60529



Protected against access by instruments to dangerous components, protected against solid foreign bodies with a diameter of 2.5 mm or larger No protection against penetration of water

2 Depending on the operating conditions and production tolerances as well as the probe types used, the actual value of the resonance or ultrasonic frequency can deviate from the specified value.

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

4 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 acoustic 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.

- 5 Pulse period duration = $t_{ON} + t_{OFF}$
- 6 Amplitude/power control: see chapter 3.2.3
- 7 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.

	Environmental conditions pursuant to EN 61 010)-1
	Overvoltage category:	II
	Degree of contamination:	2
	Permissible relative humidity up to 31 °C:	80 %
	Permissible relative humidity up to 40 °C:	50 %
	Permissible ambient temperature:	5 to 40 °C
	Altitude:	up to 2000 m above sea level
	No dewing allowed.	
	Only for indoor operation.	
IVD	Specifications for use as a medical device	
	Name:	Ultrasonic Homogenizer
	UMDNS nomenclature (ECRI / DIMDI):	17-125
	Purpose:	homogenizing, emulsifying, cell disruption and suspension
	Medical device pursuant to	
	Directive 98/79/EC for in-vitro diagnostics:	other IVD
	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 (section 5):	Not required
Technical safety controls (section 6):	No specifications
Technical measurement controls (section 11):	N/A

e-procurement

e-cl@ss: HD device classification: 32-08-02-02 HD accessories classification: 32-08-92-03

1.4.1.1 Electromagnetic ambient conditions (EMC)

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

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1.4.2 Technical data, Ultrasonic converter UW

Transformation principle	piezoelectric
Ultrasonic frequency ²	approx. 30 kHz
Material	titanium/plastic (POM)
External dimensions	Dia. 50 mm, h = 160 mm
Connecting line	2.5 m, push-pull round plug (MEDISNAP plug)
Weight	260 g
Degree of protection	IP 30 according to DIN 60529, see also chapter 1.4.1
Hand key	Start/stop function

Environmental conditions, see chapter 1.4.

1.4.3 Remote control

The ultrasonic homogenizer has an infrared interface (RS-232, half-duplex) and can be applied by the user for

- remote monitoring of the operation data.
- · remote control of the process cycle.

The protocol and command set for the infrared interface (application information) are provided by the manufacturer on request.

For communication, a commercially available infrared adapter (RS-232) 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.



Note:

Proper operation will depend on the length of the connection cable. If an extension is used, a length of 5 m may not be exceeded.

The WINPULS remote operation programme, for operating systems Windows 2000 and Windows XP, is provided optionally, see chapter 7.

Diverse additional functions such as protocol and batch functions allow for process control and quality control to be comfortably operated via PC.

The WINPULS remote operation programme is not part of the standard product range.

1.5 Warnings and safety precautions

General

- Keep the device and accessories out of the reach of children and also 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 authorised.
- · 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.

Operation

- · Observe ambient and set-up conditions, see chapter 1.4.
- Determine the mains voltage before connecting the HF generator. Only connect the HF generator to a grounded socket.
- Fuse protection 10 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 vapours must be guaranteed. When using a sound proof box, the vapours 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 (\Rightarrow unstable operation, loss of power).



- Only the ultrasonic converter UW mini20 may be connected to the HF connection.
- · Do not operate the device without supervision.

IVD 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 in the vicinity of the homogenizer should be turned off operation may be disrupted.

Damages

- 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 authorised 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:

- 1 HF Generator GM mini20 with holder and mains cable NL 5 xx see delivery note
- 1 Ultrasonic transducer UW mini20
- 1 Probe
- 1 Tool set WZ 4
- 1 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,



Guard against moisture and wetness - risk of electric shock.

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

2.2.1 HF connection for the ultrasonic converter

The ultrasonic converter is connected to the HF generator by means of a push-pull round plug (MEDISNAP plug with lock). For connection hold the plug on the handle and position it so that guide lug and arrow marking point upwards. The plug can only be closed if the guide groove of the socket and the guide lug of the plug are positioned as shown in the illustration. Push the plug into the socket until it latches. To disconnect, hold the plug only at the handle, pull it back and remove the plug.



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

Operation is conducted from the operating and display panel on the front side of the HF generator:



1	LCD display	Display of the operating parameters and status information			
2	"START/STOP" button	Starting or stopping the ultrasound emission, ending functions, leaving the menu			
3	"PROG" button	Calling-up the sa	Calling-up the save options, moving within the menu (backward)		
4	Rotary knob	Setting the operating parameters (right/left, without dead stop)			
5	"MENU" button	Calling-up the list of editable operating parameters, moving within the menu (forward)			
6	Control LED	green light: blinking green: or red light: blinking red:	Ultrasound operation Remote control over the digital IR interface Error messages Warning messages		

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. Initialisation occurs automatically. The ultrasonic homogenizer will display the manufacturer's name, type designation, and the last-connected sonotrode [probe].



If the probe type displayed does not conform with the probe that is mounted, the correct probe type will have to be set before the next step using the rotary knob. By pressing the "START/ STOP" button, the menu switches into stand-by mode and the ultrasonic homogenizer is ready for operation. The parameters used during the last operation will be set again and displayed.

	AM 25%		ProgNo	5*
START	time	0:01:30		0:00:00
STOP	pulse	ØØØ.5s		0001.0s
	En	Ø.ØØØ kJ		

The mains switch can also be used for powering off.

When the HF generator is powered off, the memory contents are saved and become available again when the generator is powered on.

3.1.2 Explanation of the display fields



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). The editing mode is activated by pressing the "MENU" button. It is possible to switch between the individual parameters by repeatedly pressing the "MENU" button. 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.

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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]
- Operating mode for the ultrasound control [En]

The operating parameters "Energy" and "Elapsed sonication time" cannot be edited.

3.2.1 Sonication time [time]

A value of 9 hours, 59 minutes and 59 seconds (9:59:59) 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.

a) Set continuous operation [non-stop]



b) Set the sonication time

If a value of 59 minutes or seconds is exceeded when setting the time, or a shortfall occurs when setting back the time, the values for the set hours or minutes will change accordingly.



3.2.2 Pulsation [pulse]/1

In addition to the pulse turn-on time $t_{\rm E}$ and the pulse turn-off time $t_{\rm A}$, 2 additional operating modes can also be set:

off no pulsation or continuous sound

by hand key it is possible to pulse manually with the button on the ultrasonic transducer. Ultrasound operation will be active as long as the button on the ultrasonic transducer is pressed.

a) Setting the operating modes



b) Setting the time intervals

The maximum setting value is 600.0 s. The minimum setting value will depend on the type of device and ranges between 0.1 und 0.3 s.



/1 The pulse period is the sum of the turn-on and turn-off times $t = t_{F} + t_{A}$

3.2.3 Special functions

Additional functions are available within a second menu level. These can be accessed by pressing and holding the "MENU" button for approximately 2 seconds. Switching between these functions is accomplished in the manner already described. The menu level can only be exited by pressing the "START/STOP" button. In doing so, settings and function statuses are accepted and executed.



Check the ultrasonic transducer [probe check]

This function is used for quick verification as to whether the ultrasonic transducer is recognised by and can be correctly activated by the HF generator. After a change in probe or in operating conditions, it could be the case that the HF generator, for example, cannot synchronise with the ultrasonic transducer and issues an error message, e.g. Error 011. The HF frequency is reset to the base value and the function is restored if no device fault or other cause is present.

The set value is "off". In order to activate the function, set the parameter to "start" using the rotary knob, and then press the "START/STOP" button. See chapter 6.2.1 for additional information.

Search for resonance frequency [scan frequency]

This function is an expansion of the above-mentioned "probe check" function. In addition, a frequency scan is conducted in order to determine the correct ultrasound frequency for the ultrasonic transducer. Depending upon the probe used and the operating conditions, the frequency can fluctuate significantly, in some instances. When switched off, the HF generator saves the current frequency value and uses it as the start value when switched on again. If there are significant deviations in the current HF frequency, this can lead to malfunctions.

i) (

Note:

After a successful scan while in continuous operation (pulsation = off, time > 30 s), start with an amplitude setting of 50 % and check the operation. Next, set the desired value.

Setting the monitor contrast [contrast]

With this function, the monitor contrast can be adapted to the local light conditions. The contrast values range between 1 and 255, and can be set by turning the rotary knob. Smaller values result in a darker image and larger values result in a lighter image. The default value is 190.

Type of ultrasound regulation [operating mode]

Here you can define whether the ultrasonic homogenizer is to work with amplitude or power control.

ampl. \rightarrow Amplitude control = constant amplitude

Thanks to the direct data logging in the ultrasonic transducer (AMPLICHRON[®] system), the amplitude is precisely and quickly measured and set. In the process, the power output may fluctuate based on the physical state of the medium.

power \rightarrow power control = constant power output

The control variable is calculated based on the measured electrical HF power, and has a process-dependent time delay. Only the average of larger fluctuations is balanced. Depending on the physical state of the medium, the amplitude may fluctuate. This type of regulation cannot be recommended for reproducible results.

3.3 Loading / saving sonication programmes

The ultrasonic homogenizer possesses a working memory and 9 memory locations for sonication programmes.

In order to work with a sonication programme, it must first be loaded into the working memory. If changes in the operating parameters are made in the working memory, a * (asterisk) will appear after the program number [ProgNo]. If these changes need to be available later as samples, the current operating parameters may be saved on one of the 9 memory locations.

The memory management is called up with the "PROG" button and the content of the selected memory is displayed.

Am 50%		ProgNo <mark>1</mark>
time	Ø1:3Ø	00:00
pulse	ØØ.5s	Ø1.Øs

The sonication programmes can be individually selected using the rotary knob. Memory location 0 represents the working memory.

Loading the sonication programme

After selecting the desired sonication programme, the parameters are transferred to the working memory by pressing the "START/STOP" button, and they can be used or processed in that location.

Saving the sonication programme

In order to store the content of the working memory in the selected memory location, e.g. programme 2, press and hold the "PROG" button until a signal tone is heard. The saving process is now concluded and the new content is displayed. By pressing the "START/STOP" button you return to stand-by mode.

Am 50%	ProgNo	2
time	01:30	00:00
pulse	ØØ.5s	Ø1.Øs
o.k.	→	[start]

If you need to exit the memory management without making changes, you can either press the "MENU" button (termination of the mode) or set the programme number [ProgNo] to 0 and then press the "START/STOP" button (the working memory will overwrite itself).

3.4 Activating / deactivating the ultrasound

Ultrasound operation can be started and stopped by pressing the "START/STOP" button or the button on the ultrasonic transducer. Ultrasound operation ends once the target time has elapsed (if a time has been set), and a signal tone (long + short) is emitted. When the device is restarted, the displays for the elapsed sonication time and for the energy are set to zero.



In contrast to stand-by mode, ultrasound operation displays the actually-achieved value in bar graph form, in addition to the pre-set amplitude or power.



Notes:

- Depending upon the physical conditions, i.e. the viscosity of the sonicated medium and the thus-resulting control processes, a difference between the specified and the actual value, as well as a fluctuating display, may occur.
- The amplitude and the power can be changed at any time during ultrasound operation, using the rotary knob. All other operating parameters can only be edited while in stand-by mode (see chapter 3.2).
- If the ultrasound operation is manually interrupted before it reaches the activated target time, the display values for the elapsed sonication time and for the energy will be saved and will continue running upon restart. The display values can be reset to zero by pressing the "MENU" button and then pressing the "START/STOP" button.
- With the "non-stop" setting, the elapsed sonication time and energy must also be manually reset, if needed. Once the maximum displayable time has been reached and exceeded, the time display will start again at 0:00:00.
- If the maximum displayable energy value of 99999.99 kJ is exceeded, the display starts again at 0.000 kJ.
- The displayed value for energy is calculated based on the HF energy applied and can be used as an equivalent for the acoustic ultrasound energy under consideration of the efficiency.

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4 Use

4.1 Instructions for use

- Before each sonication, make sure that the ultrasonic homogenizer is in proper condition.
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 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 again and again. 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 setpoint 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 programme 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 programme 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	MS 1.5	MS 2.0	MS 2.5
Tip diameter	1.5 mm	2.0 mm	2.5 mm
Sonication volume	0.1 - 10 ml	0.25 - 20 ml	0.5 - 25 ml
Amplitude	65 μm _{ss}	70 µm _{ss}	72 µm _{ss}
Maximum permissible amplitude setting	90 %	100 %	100 %

4.3.1 Mounting and dismounting of the probes

To install or remove the probes, 2 spanners of type SW 10 (8 x 10) are needed. The spanners are included in the scope of delivery of the ultrasonic homogenizer.

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



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

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.



Work steps for mounting (see illustration)

- > Clean the coupling surface at the ultrasonic converter and check whether it is free of damage.
- > 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.

5.1 Cleaning and care

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:







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 check up.

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.

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, use a suitable surface disinfectant if needed. Afterwards, allow to dry off or wipe 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.

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

SONOPULS 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

6.2.1 Testing the ultrasonic transducer (probe check) – Error 011

The test is preferably conducted while the probe is acoustically uncoupled, i.e. the probe should not be immersed in the sonicating medium.



The ultrasound frequency depends on the probe, and the actual value may vary from the example presented here. After successful completion, the monitor display switches back to stand-by mode. Otherwise, an error message appears again.

6.2.2 Conducting a frequency scan (scan frequency) – Error 002/011/012

The conditions for execution are similar to those for conducting checks with the "probe check" function, see chapter 3.2.3.





The frequency scan is completed once fine-tuning has been successful, and the display switches back to stand-by mode.

Otherwise, an error message such as Error 012 appears again.



IMPORTANT

Only allow repairs to be conducted by authorised 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 black housing of the ultrasonic transducer and the connector made of titanium (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 recognised by the device and signaled by a red LED and an intermittent signal tone (3 times), and displayed with an error number, see the following table.

Error no.	Possible cause	Remedial action
002	Frequency setting not possible	Perform frequency scan. If the error occurs again, contact BANDELIN.
003	No power output, amplitude setting not possible	Error correction should only be carried out by BANDELIN. Send in the complete ultrasonic homogeniser.
004	Mains voltage fallen short of	Check mains connection, check fuse
011	No return signal from USC, USC or probe defective	- Check whether the probe has been mounted correctly = sufficiently tight
012	Error in frequency scan, no resonance frequency found, probe defective	 Check for damage: Horn/probe contact surfaces Horn/probe threads Probe radiation surface If needed, replace the USC/probe and then check its function. Use the "probe check" or "scan frequency" functions for this purpose. After successfully completing the frequency scan, do not restart operation until initialization is complete. In the event of failure, contact BANDELIN. Check for the surface of the surface of
014	Permissible internal operating temperature exceeded, ultrasonic homogenizer switches off	Allow the ultrasonic homogeniser to cool down for at least 10 minutes, if necessary use a temperature sensor to check that the operating temperature of the GM has dropped to < 50 °C.

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?	Is the connection from the ultrasonic transducer to the probe not secure?	- Using the tool supplied, separate parts from one another, clean the surfaces, and firmly screw together once again, see chapter 4.3.1.
	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.	
	slight?	- Polish the probe.
	some pitting?	 Mill the probe until flat, or grind (max. 1 mm).
	heavy?	- Replace the probe with new ones?
	Has liquid seeped in between the ultrasonic transducer and the probe?	 Dismount the probe, clean the mounting surfaces and threads, dry and check for evenness, remount the probe and tighten, see chapter 4.3.1.
	Is the threaded pin attachment on the titanium plate defective?	- Replace the probe, see chapter 4.3.1.
	Internal thread or mounting surface of the ultrasonic transducer defective?	- Send in for repair.
	Breakage in the h.f. cable of the transducer?	- Send in for repair.
	Wrong resonance frequency?	 Conduct frequency scan, see chapter 6.2 (search frequency).
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.

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6.4 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:

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

 Repairs/Maintenance department:

 Tel.:
 +49-(0)-30 - 768 80 - 13

 Fax:
 +49-(0)-30 - 76 88 02 00 13

E-mail: info@bandelin.com

In the event of returns, the General Terms and Conditions for Delivery and Payment of BANDELIN electronic GmbH & Co. KG apply.

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

6.4.1 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: www.bandelin.com - Service - Downloads ...

6.4.2 Software version display

In some cases it may be necessary to inform authorised skilled personnel or the manufacturer of the software version for the homogenizer.

After the HF generator is turned on (power switch) and initialisation is complete, press and hold the "PROG" button and press the "START/STOP" button simultaneously. An ultrasonic transducer must not be connected.



The software version provided here is an example, the actual specifications may differ.

7 Accessories

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

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

No-obligation telephone consultation:	Website:
+49-(0)-30 - 768 80 - 0	www.bandelin.com

7.1 Required accessories - not applicable -

7.2 Optional accessories

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

8 Consumable materials

No consumable materials are available for this ultrasound application.

9 Taking the unit out of service

The device must be disposed of appropriately, not with household waste.

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



- The device must be decontaminated before disposal. It can then be disposed of as electronic waste. If decontamination is incomplete / cannot be correctly performed, a material safety data sheet for the liquids used must be affixed to each device.
- Metal accessories such as probes or standard horns should be decontaminated and disposed of as metal waste.
- The packing is recyclable.

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Note:

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