Sonostat

User manual

The gbo Medizintechnik AG of has taken care in preparation of this manual, but makes no expressed or implied warranty of any kind and assume no responsibility for errors or omissions.

Part No.: 032-7-0015

Version: 1.2
Date of issue: 2014-12-09

Manufacturer:

gbo Medizintechnik AG
Kleiststraße 6
D-64668 Rimbach
Germany

Contents

Warnings and Notes

Warning!
Warnings which must be observed by all means!

Attention!
Observe the instructions for use!

Note!
Information that will facilitate the work.

1 Introduction

1.1 Intended use

Therapy with ultrasound.

1.2 Note concerning the operating personnel

The operation of the device must be performed only by trained medical professionals.

1.3 Description

The **Sonostat** is an ultrasonic therapy equipment for continuous and pulsed sound. All applications are easy and safe.
The ultrasonic waves are generated by means of the two main components of the generator and the treatment head. A distinction is three effects of ultrasound:

a) Mechanical effects (primary effect)
   By ultrasound, the mass particles experienced in sonicated tissue vibration and acceleration (= high frequency vibration massage).
b) Thermal effects (primary effect)
   In the environment of the sonicated tissue locally increases the respective temperature. Energy flow and temperature in the treated tissue is determined by absorption and reflection of ultrasound and is therefore highly tissue specific.
c) Piezoelectric effect (primary action)
   Under varying mechanical pressure electric potentials are induced in particular in bone, leading to an increase cell activity.

In addition: biological effects (secondary effects)
   Due to thermal and mechanical effects, biological effects, such as better membrane permeability, vasodilation achieved with resultant pain relief.

Ultrasound is successfully inserted through its mechanical, thermal, chemical and biological efficiency by:

- inflammatory rheumatic diseases of the musculoskeletal system
- traumatic affections such as contusions, sprains, contractures
- inflammatory diseases of the peripheral nerves, such as neuritis or neuralgia
- peripheral circulatory disorders.

By pulse operation of the application is extended. It can also acute inflammatory processes are treated specifically.

The **Sonostat** can apply ultrasonic frequencies of 1 and 3.3 MHz. Basically, the higher the ultrasonic frequency, the lower the penetration of the ultrasound. Accordingly, we recommend the use of 3.3 MHz at near-surface indications.

In addition the **Sonostat** offers indication programs. By selecting the desired indication, the appropriate therapy time, ultrasound power, frequency and constant or pulsed ultrasound are selected automatically.

2 Start of Operation

2.1 Unpacking, transport and installation

Check all components for external integrity after unpacking.
Handle all applicators with care. Do not let ultrasonic heads fall down.

The unit may be placed on any flat surface. It must not be placed on the floor. Keep a wall distance of at least 20 cm. The device should neither be placed in front of radiators nor should it be covered by pillows or blankets while in operation. The device is not made for outdoor operation.

The **Sonostat** corresponds to the regulations DIN EN 60601. It is a device of protection class I. Within the scope of the Medical Device Directive (MDD) the ultrasound therapy device belongs to class IIa.

Warning!
Note for use in the clinical area:

The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anesthesia departments, the possibility of an explosion cannot be excluded.

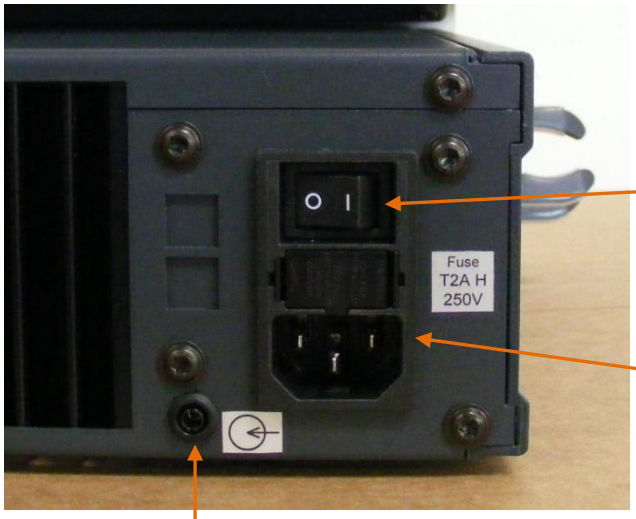
If the patient and/or the patient cable is directly exposed to a radiator of a medical device for high frequency heat therapy, damage of the device or danger to the patient cannot be excluded. As a rule, a clearance distance of 3 m is sufficient.

2.2 Connect and switching-on

The **Sonostat** is designed for connection to a mains voltage suitable from 100 to 240V and automatically adjusts to the correct mains voltage.
Independent of the mains voltage, the unit for power frequencies of 50 to 60 Hz is suitable.

Warning!
To avoid the risk of electric shock, this unit must be connected only to a supply with protective conductor!

Turn on the **Sonostat** with the power button on the rear panel.



ON/Off switch

AC power connector with fuse holder

Stimulation Input jack

The **Sonostat** is equipped with a SD card slot, located to the right of the display. This port is intended for service purposes only.

SD-Card reader

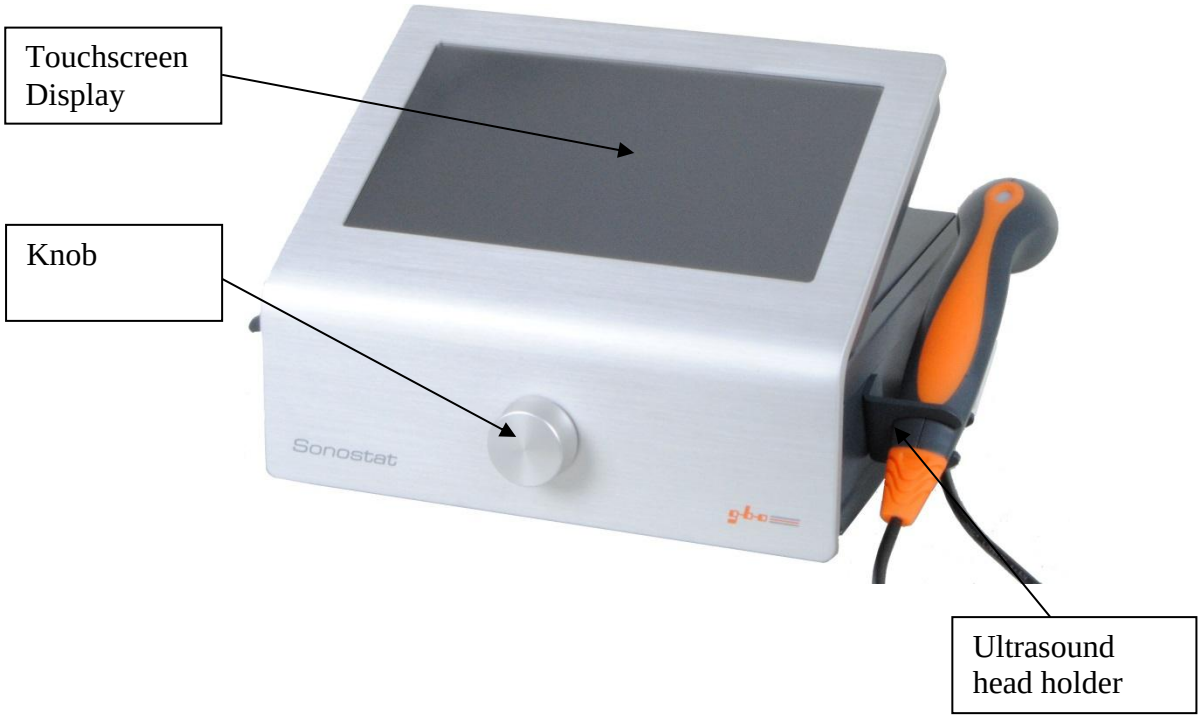
2.3 Placing out of operation

In order to place the device out of operation, just disconnect it from the mains power supply. No other measures need to be taken.

3 Operation

The **Sonostat** has a touchscreen display, a knob, an ON/OFF switch and sockets for two ultrasound heads.

The **Sonostat** is being operated via the control panel of the touch screen.



3.1 Overview

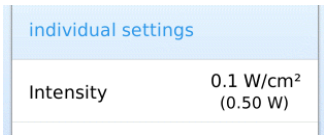
3.1.1 Touchscreen display

The touch screen should be operated with a distinct pressure of the fingertip. Sharp objects are unsuitable for operation and can damage the screen.

The individual panels (buttons) are clearly labeled. Visually accessible buttons are distinguished from non-use buttons.

3.1.2 Power regulator

The power regulator is located on the front panel and is used to adjust the ultrasonic power.



It is activated by pressing the “Intensity” control panel shown on the right. After activation, you can use the rotary encoder to set the desired ultrasonic power.
After a timeout of 3 seconds, the knob becomes inactive and must be released again before you may change the ultrasonic power.

3.1.3 The ultrasonic heads

The treatment heads can be connected to the right or left side of the device.

The treatment head has an LED lamp signaling the following states:

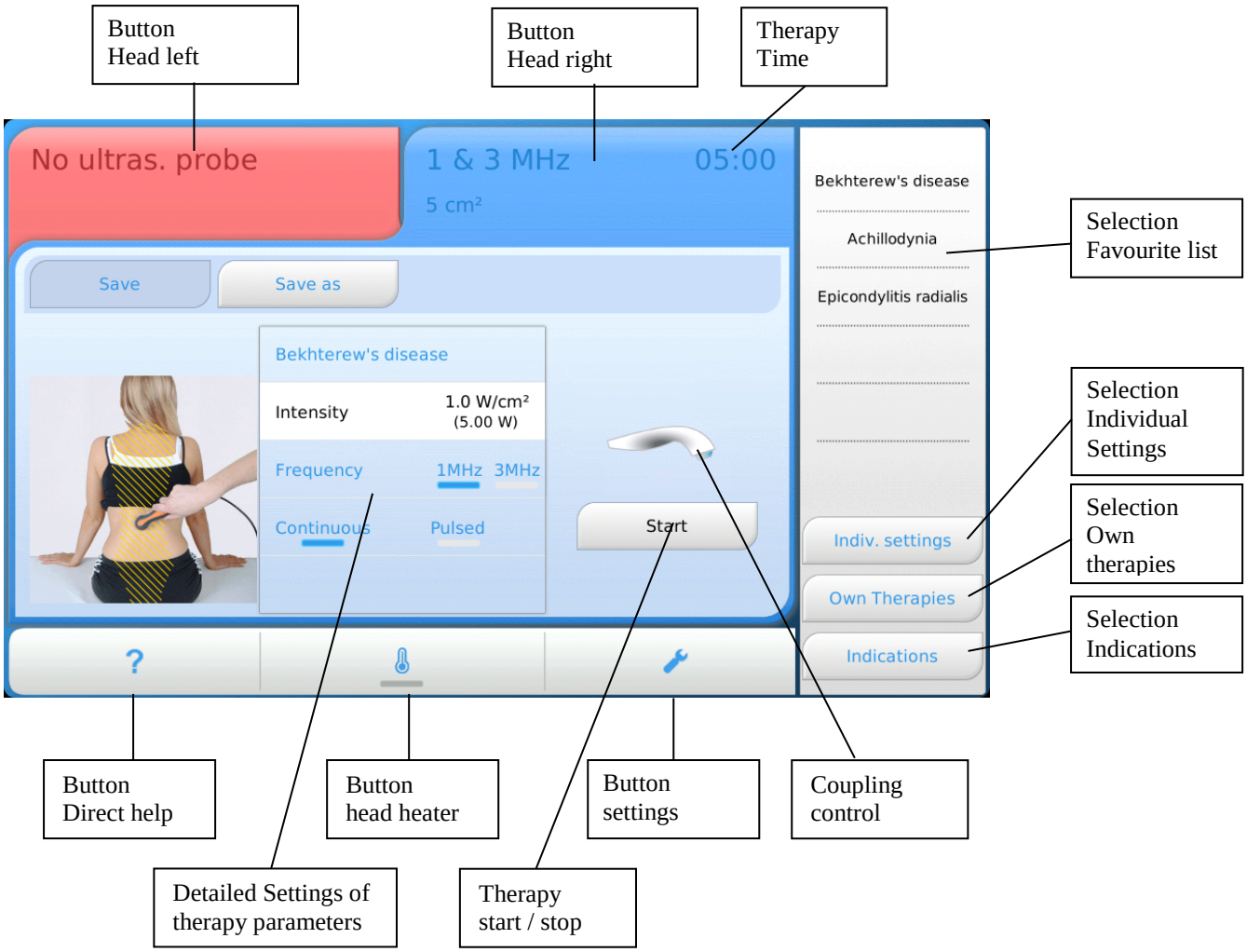
Importance	Color	Type
Head waiting for calibration	orange	on
Head during calibrated	blue	flashing
Head is calibrated and selected (= ready)	blue	on
Head is calibrated and not selected	--	off
Head not coupled	green	flashing
Head is coupled	green	on
Error in head	red	flashing

Warning!

- Always handle all applicators with care. Do not let ultrasonic heads fall down.
- Remove gel residues directly after treatment completely from the active metal surface of the ultrasound head.

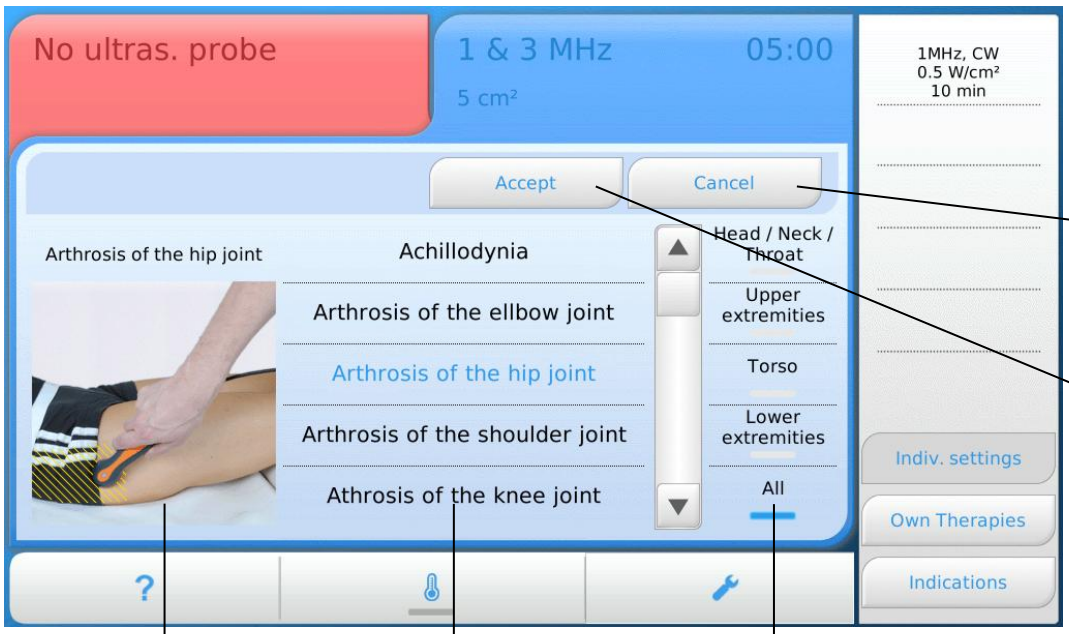
3.1.4 Panels Home screen

After power-up, and ready for operation, the device displays the home screen.



3.1.5 Panels selection indication

After pressing the button indications, the device displays the following screen.



Return to the Home screen without loading of the indication

Return to the Home screen with loading of the indication

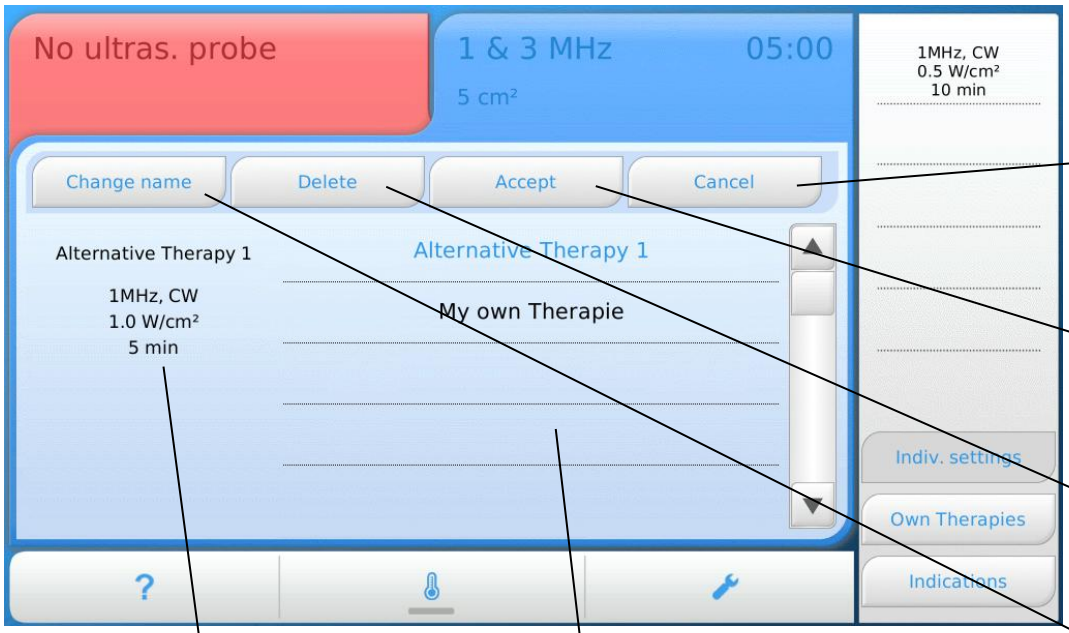
Indication image with hatched Treatment area

Indication list in alphabetical order

Range selection to restrict the list of indications

3.1.6 Panels choice own therapies

After pressing the button indications, the device displays the following screen.



Return to the Home screen without applying their own therapy

Return to the Home screen with assumption of the own therapy

Delete the selected entry

Rename the selected entry

Parameters for selected list entry

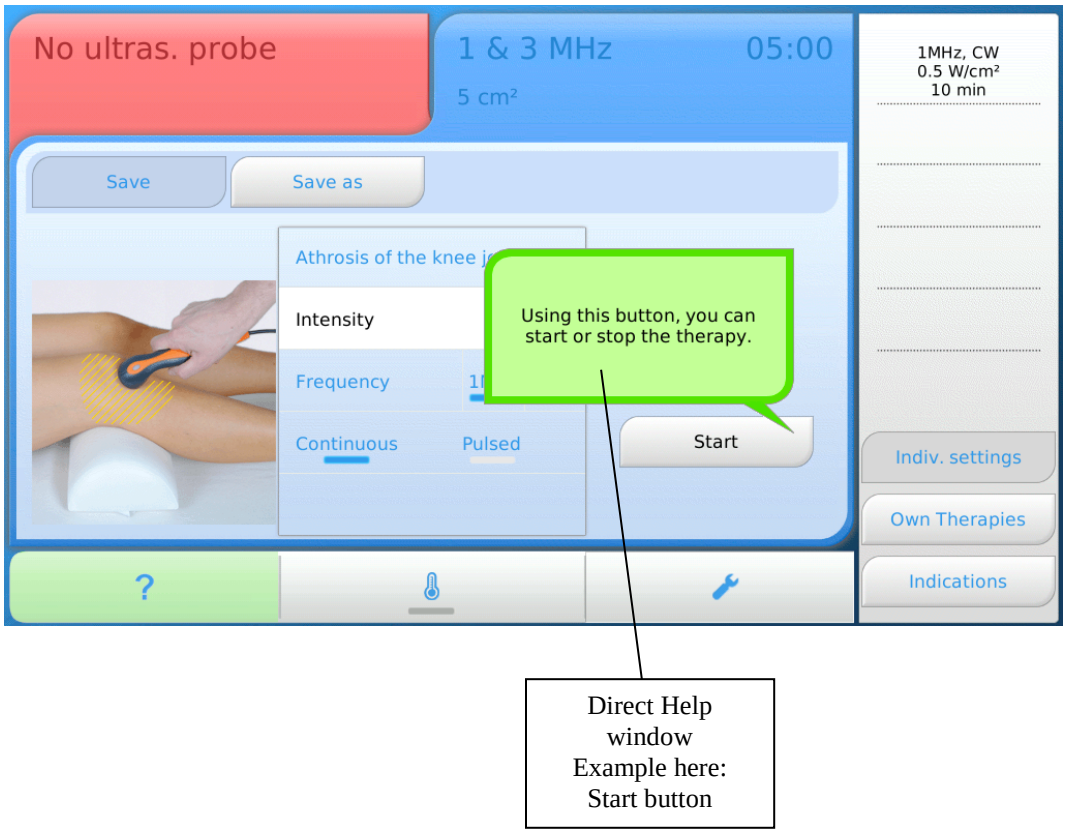
List of own therapies in alphabetical order

3.2 Direct help

The user is guided during use of Sonostat by the software. Due to the direct help the selected keys are explained directly on the screen.

To start the Direct help function, press the Button "?" on the screen and then press the button to which you want information. This opens an information window on the screen, which provides information about the selected key. The information window can be closed by pressing in the Help window.

In normal operation, selectable buttons are a light grey, keys that are not selectable are dark gray. If you press a button not selectable, automatically a message appears on the operation of this button on the screen.



Direct Help window Example here: Start button

3.3 Settings

Use the “Settings” key to access the setup menu of the **Sonostat**. In this menu, parameters such as languages, output of different sounds, i. e. for the end of treatment and various treatment parameters are defined.
The access to the service menu is also located in the settings menu.

Only if no therapy is active, you can switch to the setup menu.

The following items are available in the Settings menu:

Display	Setting the language, Calibration of the touch screen.
Audio	Setting the system sounds like the therapy end sound, error tone, etc. The sounds can be heard and assigned to the corresponding functions. The sound can also be disabled here. Additionally, it can be specified if the therapy end sound should be repeated for a certain period.
Therapy	Setting the relation between coupling and time count.
Service	Service area with access to service menu. The service is reserved for service partners and helps in the search for faults in the hardware. Version of the software. Change to factory settings.

4 Therapy

4.1 General guidelines for ultrasound therapy

The duration of treatment depends not only on the size of the body area being treated and the size of the treatment probe used, but also on the relative stage of the disease. Treatment with ultrasound lasting 5 minutes is usually sufficient for an average-size zone. With disorders accompanied by changes in the tissue structure, such as sclerodermatitis, arthrosis, etc., it is frequently advantageous to lengthen the exposure to about 10 minutes per field. Treatment zones extending over some length, such as courses of nerves, are divided up into several fields, which are exposed to ultrasound one after another for 5 (or 10) minutes.

The golden rule is: the more acute the process, the lower the intensity to be used, and the more chronic the process, the greater the intensity to be used. Take care with the dosage when beginning treatment. This is particularly advisable when treating the trunk of the body with ultrasound: don't forget that there may be sensitive organs close by *(see chapter 7* Contraindications*)*. The upper limit of the permissible intensity is generally signaled by the occurrence of periosteal pain, provided the patient does not exhibit any sensory disturbance. Treatment can be regarded as therapeutically appropriate when the intensity is such that a just detectable feeling of warmth is produced in the normally sensitive patient. Underdosage runs the risk of being ineffectual, and thus a waste of time.

The number of treatments required (carried out daily or each second day, depending on the circumstances) depends on how successful the treatments are. Usually only one or two further treatments are necessary after the symptoms subside. A total of 10 to 15 treatments generally suffices. Where improvement is only slow, continue therapy until a satisfactory result obtained. Even where there is an apparent worsening, we do not recommend giving up treatment before third or fourth sitting. If deterioration continues, it is advisable to check the diagnosis (e.g. slipped disk with sciatica, foci). It is frequently the case that structure-changing processes can be favorably influenced by an extended therapy of up to 40 treatment sessions.

4.2 Choice of therapy - by own therapy

It is possible to define your own therapy with the parameters ultrasonic frequency, pulse ratio and time, and save it under a self-defined name. These self-defined therapies can then be retrieved using the button own therapies.

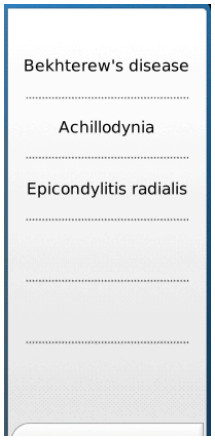
4.3 Choice of therapy - by indications

In **Sonostat** an indication menu is integrated. This provides a list of programs with pictures indication specifying parameters (ultrasound frequency, pulse ratio, intensity and time). This treatment parameters are indicative and recommendations are the responsibility of the treating physician.

4.4 Choice of therapy - by individual settings

With the button "Indiv. Settings" all parameters in the setting are changed as desired. The set therapy parameters may also be stored in the Favorites list.

4.5 Choice of therapy - from the favorites list



The Favorites list can be filled by the user as desired. Thus, the user defines the order of his frequently used therapies itself. Indications, own therapies and individual treatment settings may be transferred to the Favorites list. A simple push on the button loads the therapy from the favorite list as current therapy.

The Favorites list can be easily filled. Select a treatment from the list of indications, the list of own therapies or adjust the parameters individually. This therapy can be now stored by pressing and holding (≥2.5 seconds) on the relevant space of the favorites list. A no longer required entry can be easily deleted by push away to the right.

!!

Note!

After switching on the device the last used therapy is automatically loaded.

4.6 Operating a treatment

For this purpose move the applicator slowly and quietly through the skin. In this case the transducer should, whenever possible, be flat on the treatment area so that the ultrasound is well coupled.

If the Ultrasound head is coupled, the light in the treatment head is green lightning.
If the Ultrasound head is not coupled, the light in the treatment head is green flashing.

If the slide the applicator across the skin becomes worse and the skin is pulled, it is time to apply further gel.

!!

Note!

- The ultrasonic frequency can be set between 1 and 3 MHz.
- The frequency of the pulsed sound is 100 Hz pulse
- You can choose between continuous sound (100%) and pulsed sound with 50%, 30%, 20%, 10% and 5%.
- The coupling state of the transducer is indicated by a green LED on the transducer housing and through a graphical representation on the screen. In case of bad coupling of the transducer, the LED flashes green.

Warning!

- Do not forget contact gel!
- The transducer is careful to handle, since harsh external factors - such as impact or shock - can change its properties. We recommend an annual visual inspection for cracks that allow penetration of liquids, as well as to the integrity of the cable and connector.

	Performance for			
	5 cm^2 sound head		**2.5 cm^2 sound head**	
1 MHz	0.5 - 15 W	0.1 - 3 W/cm^2	0.1 - 7.5 W	0.1 - 3 W/cm^2
3 MHz	0.1 - 7.5 W	0.1 - 1.5 W/cm^2	0.1 - 3.75 W	0.1 - 1.5 W/cm^2

Table 1: Possible settings of ultrasonic power, step size is 0.1 W/cm^2

!!

Note!

- In the settings it can be specified if the therapy time is running or stopped when you lift the ultrasound head. (Coupling control)
- The ultrasound head is freely interchangeable. When the device is switched on or the ultrasound head is inserted, each head is calibrated individually.

4.7 Combination therapy with current stimulation

4.7.1 General information

The **Sonostat** may only be operated with the **Duodynator (touch)** of gbo Medizintechnik AG. When operating the **Sonostat** in combination with other than the above assumes gbo Medizintechnik AG no product liability and warranty.

!!

Note!

If another stimulation current device is connected, the combination according to EN 60601-1 has to be approved as a system.

The connection of the devices is performed by the connection of the current stimulator output to the input jack which is located on the back side of the **Sonostat**. The device's internal flow path is activated only for the selected ultrasound head.

Warning!

- **Observe the operating instructions of the connected electrical stimulation therapy device (Duodynator)!**
- The ultrasound therapy must not be operated with galvanic current due to the acidification of the contact gel.
- A current density of 2 mA/cm^2 should not be exceeded.
- Disable the current monitoring of the connected electrical stimulation therapy device, so that a smooth course of therapy is possible.
- If a multiple socket-outlet is used do not placed it on the floor.
- If a multiple socket-outlet is used do not connect any other devices expect the ones that belong to the system.
- If a multiple socket-outlet is used do not connect any other multiple socket-outlets or extension cords.

4.7.2 Procedure for combination therapy

1. Select the current form out of the current stimulation device.
2. Set the desired modifications.
3. White plugs has a positive polarity in the primary position, while the counter electrode - the metallic surface of transducer - is negative. Connect the white plug to the patient cable to the neutral electrode and the black one with the **Sonostat**.
4. Apply the neutral electrode.
5. Select the desired treatment head by pressing the button head left and head right.
6. Choose an own therapy, an indication or the individual setting on **Sonostat**.
7. Bring plenty of contact means to be sonicated area of the patient. Place the surface of the head under light pressure to the skin.
8. Set the current intensity so that the patient experiences a significant irritant effect on the stimulation current therapy unit by turning the intensity knob. If the patient feels a pain, reduce the stimulation current intensity.
9. Press the Start button at the **Sonostat** to begin ultrasonic treatment now.
10. Move the ultrasound head, under light pressure, with circular or straight even strokes on the area to be sonicated.
11. At the end of treatment the selected tone signal sounds. The power is automatically turned off and the ultrasonic intensity is automatically set to 0.0.
12. Clean the ultrasound head from the contact gel.
13. When the treatment time is expired electrotherapy device sounds the selected tone signal and the intensity is automatically set to 0.0.

!!

Note!

- Combination therapy should be performed only with biphasic currents.
- We recommend to select medium frequency currents for the combination therapy.
- Use a conductive electrode cream to ensure a flow of current.

5 Maintenance

Functionality, reliability and safety characteristics of the **Sonostat** are guaranteed only if the device is handled in accordance with the operating instructions. Safety control, maintenance work, repair work and modifications must only be carried out by the manufacturer or by service agents authorized by him. In case of a failure, parts which influence the safety of the device must only be replaced by original spare parts of the manufacturer. The electric installation must correspond to the requirements in accordance with VDE/IEC. **The device does not contain any parts which require maintenance work by the user.**

5.1.1 Safety checks

The device is subject to the provisions of the Medical Device Directive. The safety controls have to be carried out on the basis of this directive. Thereby, the operator regulation has to be observed in particular.

Irrespective of the legal rules or beyond the scope of the Medical Device Directive, it is mandatory to have the device checked at 12-months intervals by the manufacturer or by a maintenance service authorized by him.

The review must consist at least of the following criteria:

- Electrical safety check in accordance with the test plan of the manufacturer
- Review of the device and the probes in respect of external integrity
- Review of all display and operating elements in respect of damages
- Review of all inscriptions in respect of immaculate legibility
- Review of power cord and all probe connecting cables
- Functional check

5.2 Disposal of equipment and accessories

According to the WEEE Directive 2002/96/EG (waste electrical and electronic equipment) this device must not be disposed of with the domestic waste. The device must be returned to the manufacturer for disposal. The manufacturer is committed to guarantee the disposal of all devices marketed. This is also indicated by the WEEE sign (crossed out waste container).

5.3 Cleaning, Disinfection and care

5.3.1 Cleaning the unit

Clean the device with a clean, lint-free cloth dampened with water and mild detergent. Please do not use abrasive cleaners. Fingerprints on the display can be removed with a dry cloth or something isopropanol.

Warning!

- Do not hold the device under running water and do not use liquid cleaners!
- Before cleaning or disinfecting always pull out the mains plug from the wall outlet!

The **Sonostat** is suitable for wipe disinfection. It is important to ensure that no liquids get into the unit. Do not wet plugs or sockets. The device must not be sprayed for cleaning or disinfecting. The device and its accessories are not suitable for heat sterilization or sterilization with gases.

Take care when cleaning on external damage to the unit, the applicators and their supply lines. If necessary, inform an authorized service center

5.3.2 Disinfection of the ultrasound head

The ultrasonic transducers can be disinfected by spray / wipe disinfection. Spray on disinfectants, act and wipe with a cloth (Please follow the manufacturer's instructions).
We recommend for disinfection Bacillol AF of the company Bode.

6 Warnings and Safety Precautions

Warning!

- For patients with implanted electronic device electrical stimulation treatment is to be carried out only after having checked any risks.
- Turn off cellular phones and radiophones or place them in a distance of 3 m from the device.
- Cardiac pacemakers are extremely vulnerable. Here the therapy should only be carried out under continuous pulse and ECG control. The lower extremities may be treated without control.
- If the patient and/or the patient cable is in the direct range of a high-frequency, short-wave or micro-wave therapeutic device, damage to the device or an injury to the patient cannot be excluded. Please keep a clearance of 3 m.
- A simultaneous connection of the patient to a high-frequency surgery device can lead to burns under the electrical stimulus electrodes.
- The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anesthesia departments, the possibility of an explosion cannot be excluded.
- In all discernible malfunction, immediately contact gbo Medizintechnik AG or an authorized service center in conjunction.

7 Contraindications

Despite the low dosage is definite contraindications have emerged.

Warning!

Ultrasound should not be used in the following syndromes:

- Patients with implanted electronic devices
- Malignant tumors
- Oncological diseases at all stages
- Feverish conditions
- Active tuberculosis regardless of the stage and the localization
- Pregnancy
- Vascular disease of the extremities (thrombophlebitis, thrombosis, varicose veins)
- Disorders of coagulation of blood
- Changes in the skin, particularly in infectious diseases and Hautnaevi (birthmarks) and open wounds
- Inflammation of the skin (caused by cosmetics)
- Epilepsy

Warning!

In addition to these disease groups should endeavor to exclude certain organs of a direct sound. Are not directly sonicate

- Eyes, brain and spinal cord
- Laminectomy-related spinal incisions
- Anesthetized areas
- Heart and lungs
- **No sound** of cardiac segments with functional heart complaints.
- **No sound** of the epiphysis zones of children.
- Sexual organs
- Front of the neck: carotid artery and thyroid
- End prosthesis
- Body parts with silicone implants or metal implants
- not directly sonicate the larynx in the treatment
- not directly sonicate The thyroid gland in the treatment
- Heed warnings for general ultrasound treatment in this manual.

!!

Note!

- This list does not claim to be complete. In individual cases, always the doctor must decide about contraindications and treatment criteria.

- In all discernible malfunction, contact gbo Medizintechnik AG or an authorized gbo Medizintechnik AG service contact immediately.

8 Explanation of symbols used

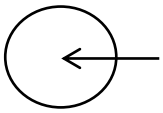
CE 0123 — CE - Conformity mark

 — Follow operating instructions!

 — Caution!

 — Output for ultrasound head

 — Application part of Type BF (floating).

 — Stimulation current input for combination therapy
Max. $120V_{eff}$, max. 100 mA_{eff}

 — This appliance is labeled in accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (waste electrical and electronic equipment WEEE). The disposal at the end of its useful life, the manufacturer accepts.

9 Technical data

Mains voltage and Frequency:	100 - 240 V 50-60 Hz	
Power consumption:	Max 120 VA	
Mains fuses:	T 2A H 250V	
Maximum Ultrasound Intensity:	3W/cm ² at 1 MHz, 1.5 W / cm ² at 3.3 MHz	
Accuracy of the output:	1 MHz: +0% / -20% all other frequencies: ± 20%	
Effective radiating area	5 cm² and 2.5 cm² ± 20%	
Pulse ratio:	CW, 5%, 10%, 20%, 30% and 50%	
Pulse sound frequency:	100 Hz ± 5%	
Ultrasonic frequency:	1 MHz ± 10% / 3.3 MHz ± 10%	
Applied part:	Titanium surface of the ultrasonic head	
Type of applied part:	BF	
Protection class of probe	IP X7	
Mode of operation:	Continuous operation	
Protection class:	I	
Protection class of housing:	IP X0	
Dimensions:	27 cm × 19.3 cm × 28 cm (W × H × D)	
Weight:	4.9 kg without accessories	
Display:	10.1 "TFT LCD with touch screen	
Environmental conditions:	Operation of the device:	Temperature range +10 ° C ... +35 ° C relative humidity 30 ... 75%
	Transport and storage:	Temperature range 5 ° C ... +50 ° C relative humidity <90%, non-condensing

On request, spare parts lists and circuit diagrams can be made available for repair technical personnel.

To maintain the leakage current limits it is not allowed to repair or replace components on the PCBs.

The IEC connector is used for all-pole disconnection from the mains.

gbo Medizintechnik AG reserves the right to change design and specifications without prior notice.

10 Accessories

Included accessories:

Sonostat 032-0-3000			Part no.
	1	Ultrasound head 5cm ²	032-0-3020
	1	Ultrasound gel 250 ml bottle	45-39-128EH725
	1	Power cord	027-4-6001
	1	User manual (English)	032-7-0015

Other accessories for the **Sonostat**:

Specification	**Article no.**
Ultrasound head 2.5 cm ²	032-0-3010
Equipment trolley basic rack	026-0-3000
Sonostat additional module	026-0-3050
Holder for ultrasound gel bottle	026-0-3020

The picture shows the trolleys for the **Sonostat**

It consists of the basic rack and the **Sonostat** additional module

!!

Note!

- Use only original accessories to ensure the safe operation of the appliance.
- The ultrasonic heads can be freely exchanged. The unit automatically adjusts itself to the relevant properties of the ultrasound head.

11 Troubleshooting

Each problem that occurs during operation of the unit will be shown in a message window on top of the display and will be accompanied by an acoustic tone. Most of the problems can be solved by the instructions displayed.

In general:

1. The malfunction is shown on the display.
2. An acoustic signal is heard.
3. Follow the instructions on the display.

Suggestions:

- Turn off the unit and turn it on again.
- If the error occurs again, the device is not functioning. Please contact a service authorized by the manufacturer.

Further errors

symptom	**cause and action**
The device cannot be switched on, no display is shown.	Please check the mains plugs and sockets. If necessary contact your service agent or the manufacturer.
No acoustic signal is heard. (End of therapy…)	Please check the settings of the acoustic sound in the menu. The volume must be greater than 0.

Please contact your service agent or the manufacturer if the problems cannot be solved by the measures mentioned above.

Please note that the unit must be placed on a plane horizontal surface. The device should neither be placed in front of radiators nor should it be covered with pillows or blankets while in operation. Do not cover the ventilation slots on the bottom of the unit either.

12 Appendix

Notes in accordance with EC directive and Medical Device Directive (MDD)

The **Sonostat** is a line-powered ultrasound-therapy device of the protection class **I**.

The device is in accordance with the EC directive for medical devices (93/42/EWG) and therefore carries the CE sign with the registration number of the notified body for medical devices. The according graphical symbol is placed on the type plate.

According to the MDD, **Sonostat** is a class **IIa** device.

The manufacturer is only responsible for the safety, operational reliability and functionality of the device if:

* the device is used in accordance with the instructions for use;
    * the electrical installation of the location where the device will be used meets the respective current requirements of electrical safety;
    * the device is not used in hazardous environments and humid locations;
    * mountings, amplifications, re-adjustments, modifications or repair works are carried out only by personnel authorized by the manufacturer;
    * the operator regulation of this EC directive is observed within the scope of MDD.

Technical support may be obtained by the manufacturer, dealers or service authorized by the manufacturer. The product's duration of life as scheduled by the manufacturer is 10 years.

Sonostat is an electronic device. For its disposal the according regulations for electronic devices have to be observed.

On request, the manufacturer will provide you with further technical descriptions for all repairable parts of the device, such as circuit diagrams, spare parts lists, and adjustment instructions as far as these are necessary for the qualified technical staff of the operator.

Comments on electromagnetic compatibility (EMC)
Medical, electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the accompanying documents. In particular medical, electrical devices may be influenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only when using accessories which are listed in the EC declaration of conformity. The usage of other accessories my cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be arranged physically close to other devices or stacked with other devices than current stimulation units of the brand gbo. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC-comments in the chapter "Warnings and Safety Precautions" of this manual as well as in the Technical Information on the next two pages.

In accordance with the EMC-regulations for medical products we are obliged by law to provide the following information.

Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions, CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2 (*)	Class A	
Voltage fluctuation/flicker emissions, IEC 61000-3-3 (*)	Complies	

(*) Note: For devices with a power consumption between 75 W and 1000 W only.

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD), IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_τ is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF, IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{eff}	$d=1,2\sqrt{P}$
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d=1,2\sqrt{P}$ for 80 MHz to 800 MHz $d=2,3\sqrt{P}$ for 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.			
Rated power of the transmitter (W)	**Separation distance according to the transmission frequency (m)**		
	150 kHz to 80 MHz $d=1,2\sqrt{P}$	**80 MHz to 800 MHz $d=1,2\sqrt{P}$**	**800 MHz to 2,5 GHz $d=2,3\sqrt{P}$**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

Index