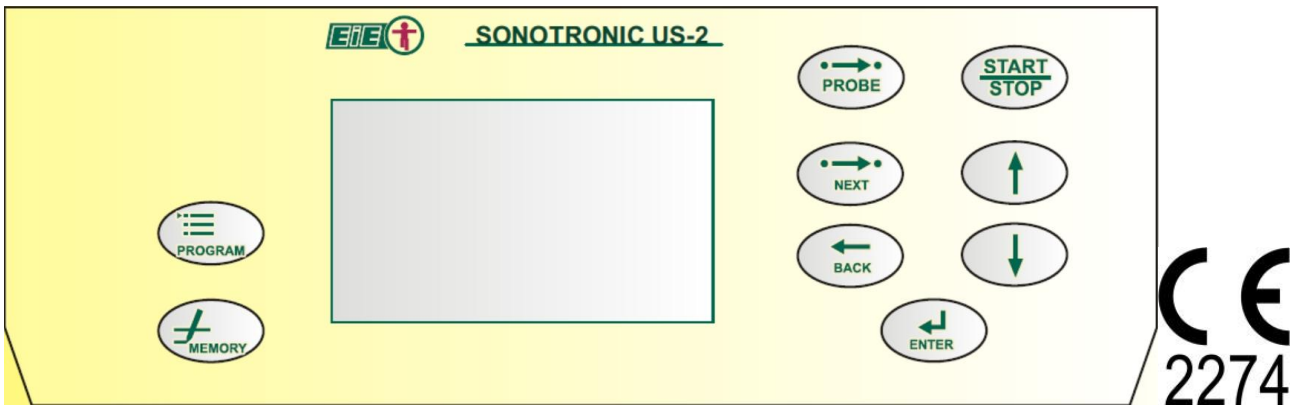
SONOTRONIC US-2

Ultrasound therapy



INSTRUCTIONS FOR USE

NOTICE! PROTECT THE MANUAL FROM LOSS.
THIS MANUAL IS PART OF THE EQUIPMENT

NUMBER: .....

In the case of loss, instructions are sold after this number is given.

Digitally signed by Cobzari-Țurcan Rodica
Date: 2025.10.02 20:38:00 EEST
Reason: Validated Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Series: 2025-02/A

MANUFACTURER: ***Elektronika i Elektromedycyna M.Lewandowski Sp.J.***
05–402 OTWOCK, ul. Zaciszna 2, tel./fax +48 22 779 42 84; tel. +48 22 710 08 39
www.eie.com.pl **e–mail: office@eie.com.pl**

MANUFACTURER: ***Elektronika i Elektromedycyna M.Lewandowski Sp.J.***
05–402 OTWOCK, ul. Zaciszna 2, tel./fax +48 22 779 42 84; tel. +48 22 710 08 39
www.eie.com.pl e–mail: office@eie.com.pl

WARRANTY CARD

Name and model of the product: **SONOTRONIC US-2**

Serial number ..... Date of production.....

Warranty period: 24 months from the date of purchase.

Conditions of warranty:

1. The selling party is obliged to deliver the fully fit equipment to the customer.
2. Warranty card is valid only with the date of sale stamped and signed by the seller.
3. Exploitation of the product must be conducted according to the instructions for use.
4. All warranty and post–warranty repairs will be done by the manufacturer or by the authorised and qualified service.

The warranty does not cover:

1. Accessories which are subject to the natural wear and tear in the route of exploitation (electrodes, cables, bands, pads, sacks, eyewear, etc.).
2. Mechanical damages which did not rise from the fault of the producer.
3. Damage to cables (cracks, breaking and the like), which can happen under the intensive exploitation.
4. Occurrence of up to 2 bad pixels on graphic display.
5. Necessary periodic technical tests.

The warranty ceases to be valid in the case of:

1. Expiry of the warranty period.
2. Lack of required periodic technical tests.
3. Repairs done by the user or an unqualified service.
4. Non-observance of correct exploitation as described in the instructions for use.

All customer complaints should be sent to the above address.

.....

Stamp and signature of the manufacturer

.....

Date of purchase

.....

Stamp and signature of the seller

Confirmations of technical service

TABLE OF CONTENTS

I. APPLICATION

I.1. Meaning of symbols used in this manual.

WARNING: This symbol indicates that it is absolutely necessary to acquaint with and remember the following information regarding safety of use of the device. Failure to consider such warnings may cause deterioration of health or even death.

IMPORTANT: This symbol indicates essential advice helping to prevent the damage of the device or equipment as well as the important general information.

NOTICE: This symbol indicates useful hints making the operating of the device easier.

I.2. Intended purpose of the device

SONOTRONIC US-2 is intended for use in professional healthcare facilities by a qualified physiotherapy technician.
SONOTRONIC US-2 is a modern, microprocessor controlled unit for ultrasound therapy (a colour graphic screen with touch panel). It can work with various types of ultrasound heads.
A detailed description of the therapeutic indications can be found in chapter **Błąd! Nie można odnaleźć źródła odwołania.** "MEDICAL DESCRIPTION".

WARNING: Any treatment with SONOTRONIC US-2 should be performed carefully by a qualified physiotherapy technician.

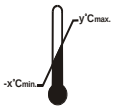
WARNING: The manufacturer takes no responsibility for using this device in violation of the instructions for use recommendations, especially if the obligatory servicing is neglected or the device is used by the unqualified staff.

WARNING: The ultrasound heads (applicators, probes) are calibrated and dedicated to an individual device. Using the heads with other devices without the calibration can result in using wrong treatment parameters. DO NOT use the heads with another device without previous calibration by the manufacturer.

IMPORTANT: Device is an electrical device like a TV-set, radio or hair dryer so the operator should observe the basic safety precautions:
- do not pour water or other liquids on the device
- do not open the device's case
- do not cover the ventilation vents
- do not expose the device to shaking, moisture or dust.

NOTICE: The device has pre-programmed average treatment parameters for typical diseases (PROGRAM function) and has the option of their individual adjustment. You can also save settings of treatment parameters individually selected by the operator (MEMORY function).

I.3. Other symbols used on the device

ON THE DEVICE			
CE	CE mark	MD	Medical device
UDI	Unique device identifier		Manufacturer
	Date of manufacture	SN	Serial number
REF	Catalogue number		Caution
	Electrical device type B		Fuse
	Consult instructions for use or consult electronic instructions for use		Equipment should be disposed of according to the regulations for disposing of electrical devices
ON THE PACKAGE			
	Maximum allowed temperature range		Keep dry
	The maximum allowable load on the package		This side up

II. TECHNICAL SPECIFICATION

II.1. Nominal operating conditions

- Heating time — 1 min
- Time of continuous work — 24 h
- Power supply (single phase) — ~230 V 10%, 50 Hz, 50 VA
- Insulation class — I type B
- Ambient temperature — 10°C ÷ 40°C
- Relative humidity — 30% – 75%
- Atmospheric pressure — 780-1060 hPa

II.2. Additional specifications

- Internal treatment clock — 30s ÷ 30 min
- Dimensions — 335 x 270 x 125 mm
- Weight (without accessories) — 2,7 kg

II.3. Technical data – ultrasound

NOTICE: The ultrasonic powers below are given with accuracy ± 20%.

NOTICE: Times and frequencies below are given with accuracy ± 10%.

NOTICE: In modulating mode of operation, the maximum continuous power density must not be exceeded.

SU-1 treatment head

- effective treatment area — 1,33 cm^2
- maximum continuous power — 2,5 W/cm^2
- ultrasound frequency — 1 MHz or 3,3 MHz
- work mode — continuous or pulsed
- type of beam — collimated
- ingress protection code — IPX7
- BNR — < 6:1

SU-5 treatment head

- effective treatment area — 5 cm^2
- maximum continuous power — 2,5 W/cm^2
- ultrasound frequency — 1 MHz or 3,3 MHz
- work mode — continuous or pulsed
- type of beam — collimated
- ingress protection code — IPX7
- BNR — < 6:1

SUP-6 treatment head

- effective treatment area — 6x3 cm^2
- ultrasound frequency — 1 MHz or 3,3 MHz
- power density (continuous mode) — 0,1 ÷ 2,5 W/cm^2
- peak power density (modulated mode) — 0,1 ÷ 2,5 W/cm^2
- type of beam — collimated
- ingress protection code — IPX7
- BNR — < 6:1

Device parameters

- max. continuous power — 12,5 W
- pulse frequency — 10 – 150 Hz
- working modes — continuous or pulsed
- duty factor — 5 – 100%
- internal treatment clock — 30 s ÷ 30 min

II.4. EMC requirements

This equipment requires special attention for EMC environment conditions and must be installed according to the information given below. The user should provide such conditions for proper functioning of the equipment.

EMC emission resistance

Subject	EMC Standard or Examination Method	Resistance test level Professional health care facility environment and home health care environment
Port on the casing		
ESD	PN-EN 61000-4-2:2011	± 8 kV contact, ± 2; 4; 8; 15 kV by air
RF radiation	PN-EN 61000-4-3:2014	10 V/m rms before modulation) 80 MHz – 2,7 GHz , modulation: 80% AM, 1kHz
Proximity RF fields from wireless radio equipment	PN-EN 61000-4-3:2014	p. 8.10 of the Standard (Table 9)
AC. Mains Port		
Fast transients (BURST)	PN-EN 61000-4-4:2013	± 2 kV, freq. 100 kHz
SURGES	PN-EN 61000-4-5:2014	Line to line ± 0,5 kV, ± 1 kV Line to earth ± 0,5 kV, ± 1kV, ± 2 kV
Disturbances conducted and induced from RF fields	PN-EN 61000-4-6:2014	3 V (rms before modulation) 0,15 – 80 MHz, 6 V (rms before modulation) in the ISM band and in the radiofrequency bands 0,15 and 80 MHz, modulation: 80% AM and 1 kHz
Voltage drops DIP	PN-EN 61000-4-11:2007	0% U_T; 0,5 T in 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º
		0% U_T; 1 T; and 70% U_T; 25 T; single phase 0º
Supply breaks		0% U_T; 250 T
Magnetic fields of the supply mains frequency	PN-EN 61000-4-8:2010	30 A/m 50 Hz

*) Radiation of stationary radio transmitters should not exceed the above declared levels.

Disturbances may be observed close to devices marked with the following label:

Emission levels for the professional medical care company and environment of the domestic medical care			
Subject	**Applied Standard**	**Allowed levels and /frequency bands MHz**	
Harmonics of current	PN-EN 61000-3-2:2014	The device meets the requirements of the Standard and due to small power does nod require any testings.	
Fluctuations of voltage and light flickering	PN-EN 61000-3-3:2013	The device meets the requirements of the Standard and due to small power does nod require any testings.	
Conducted RF emission	PN-EN 55011:2016 Group 1, Class B	66 dBµV (quasipeak.) 56 dBµV (avr.)	0,15 - 0,5
		56 dBµV (quasipeak.) 46 dBµV (avr.)	0,5 - 5
		60 dBµV (quasipeak.) 50 dBµV (avr.)	5 - 30
Radiated RF emission	PN-EN 55011:2016 Group 1, Class B	**Elecrical field at 10 m distance**	
		30 dBµV/m (quasipeak.)	30-230
		37 dBµV/m (quasipeak.)	230-1000

Cables used with the device:

- cables connecting the ultrasound head to the device up to 2 m
- mains cable up to 1,8 m

IMPORTANT: Using cables exceeding the limits may cause increased emission or lower resistance of the device.

IMPORTANT: Telecommunication equipment using radio frequencies may affect operation of this device.

Working environment: Health care facilites and domestic medical care environments.

II.5. Storage and transportation conditions

The device with accessories should be stored in the original packaging observing the following conditions:

- ambient temperature 5°C ÷ 40°C
- relative humidity up to 85% condensation-free
- atmospheric pressure 780-1060 hPa

The device with accessories should be transported in the original packaging observing the following conditions:

- ambient temperature -10°C ÷ 45°C
- relative humidity up to 95% condensation-free
- atmospheric pressure 780-1060 hPa

NOTICE: Do not expose the device or accessories to outdoor weather conditions.

III. ACCESSORIES

III.1. Equipment supplied with the device

- mains cable 1 pcs
- T-0,315AL, 250V fuse 2 pcs
- instructions for use 1 pcs
- gel for ultrasound treatments 0.5L (if an ultrasound head is ordered with a device)

III.2. Basic accessories

Basic accessories – ultrasound:

- Ultrasonic applicator (head) 1,3 $cm^{2:}$ **SU-1**
- Ultrasonic applicator (head) 5 $cm^{2:}$ **SU-5**
- Ultrasonic applicator (head) 6x3 $cm^{2:}$ **SUP-6**

III.3. Connecting the device with accessories

The control device allows you to perform the treatments of individual therapies with the appropriate equipment. Without accessories, the device is not applicable.
For ultrasound treatments, at least one ultrasound applicator is needed.

IV. PREPARING OF THE DEVICE FOR USE

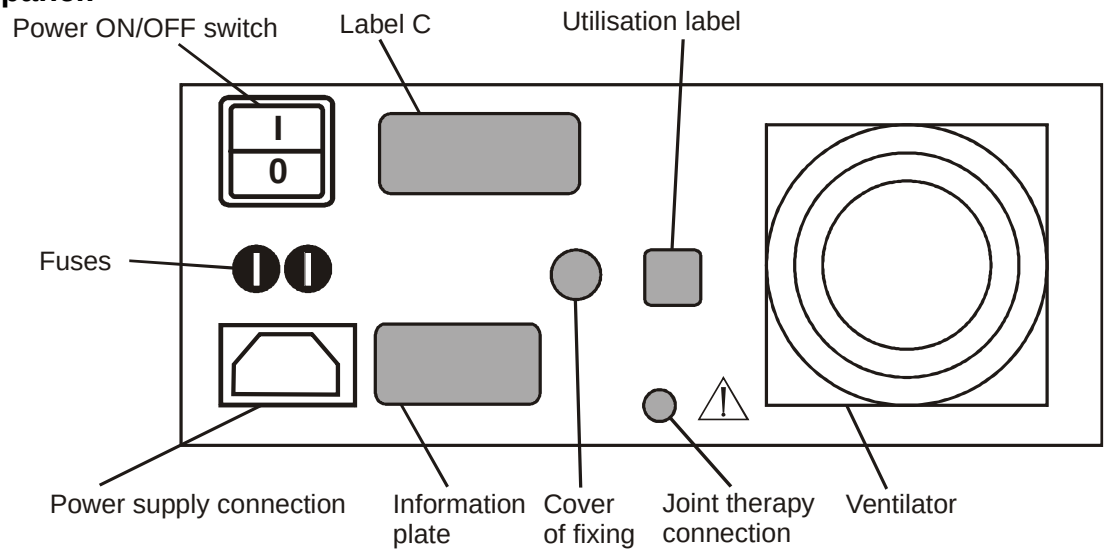
WARNING: Thoroughly read the instructions for use before using the device.

1. If the device was for some time in temperature below 0ºC (e.g. in transport) it should be unpacked and left in room temperature for about 4-8 hours. Only then it can be plugged into mains and switched on.
2. The device should be placed in such a place that connected cables (especially the mains cables) are not exposed to pulling or tearing by persons passing by. Such a situation may expose people to an electric shock and the equipment to damage or destruction.
3. It is recommended to remove the protective sticker from the display. Gently lever up the sticker with your nail and remove it. Leaving the sticker on may impair the vision of the display.

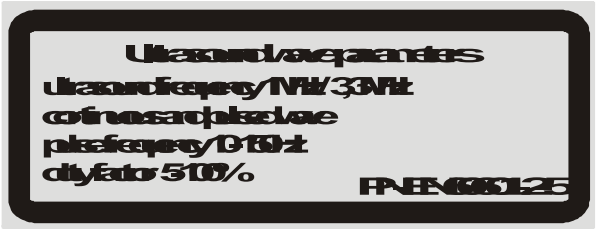
   IMPORTANT: The ultrasound heads are calibrated and dedicated to an individual device. Using an non-calibrated ultrasound probe can result in using inaccurate parameters, which may lead to usage of too high power. Please contact the manufacturer for calibration of the ultrasound probe (for example coming from another device or newly bought).

IV.1. Labels' placement

Back panel:



Labels C on the back panel



IV.2. Recommended workplace organization

The control unit should be positioned firmly in the workplace before treatment: on a table, desk or trolley, near the mains socket ~230 V 10% 50 Hz. The device should be placed at a suitable height which allows easy manipulation of controls on the front panel. Sunlight, or other bright light may dim the screen and decrease LEDs visibility, so the front panel should not be lit with direct light.

It is recommended that the workplace organization allow for easy and uninterrupted access to all controls and accessories. Special care must be taken to put the mains and connecting cables aside from the area where people move as this may cause accidental stumbles or pulling of the cable. Between treatments, the cables should be put aside safely not to be pressed or broken by a drawer or cabinet doors.

NOTICE: In particular, care should be taken to ensure easy access to the power switch (on the rear panel of the device).

IV.3. Connection of cables and treatment applicators

IMPORTANT: Plug has an automatic lock protecting it from falling off from the socket (when connecting one should hear a "click"). The plug fits the socket only in the position with the arrow symbol up. When disconnecting, one should gently pull the plug out, but strong enough to unlock it, avoiding to turn the plug around while in the socket. When disconnecting, the plug should be held near the socket, avoid pulling the plug by the cable, otherwise the cable may be broken.

IV.4. Switching on

IMPORTANT: This device is manufactured with the insulation of class I. Connect the device to the socket with grounding pin.

IMPORTANT: Before switching on the POWER button connect treatment probes to the sockets in front of the device.

The device is turned on by the POWER button on the back panel into position “I”.

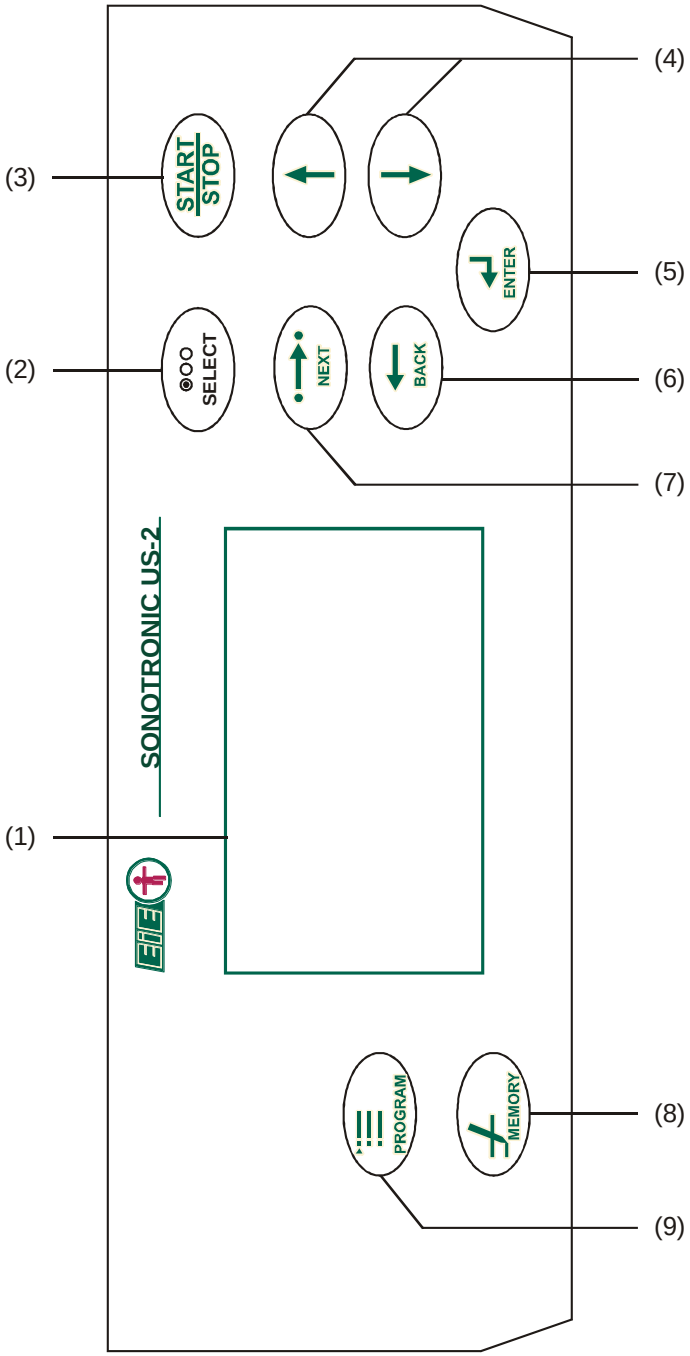
V. OPERATION AND HANDLING OF THE DEVICE

WARNING: All treatments using SONOTRONIC US-2 should be performed carefully by a qualified physiotherapy technician. Otherwise, the therapeutic effects may be limited and the patient and staff may be exposed to health risks.

NOTICE: A number in parentheses, ex. (10) used in the test refers to a corresponding number on the front panel in the drawing in part V.1. „Front panel description”.

NOTICE: In this chapter, if the character “+” accompanies a button icon, it means that two respective buttons should be pressed simultaneously.

V.1. Front panel description



No.	Symbol	Description	
1		Colour LCD screen with touch panel	
2		Change of the type of therapy	
3		Turn ON / OFF the treatment	
4		Parameter value setting	Increase value of the parameter
			Decrease value of the parameter
5		Accept the choice	
6		Move to menu for additional functions or return to the previous screen	
7		Go to next item on the screen	
8		Individual sets of parameters saved by the user	
9		Pre-programmed parameter sets for various treatments	

V.2. Preparation for treatment

V.2.1. Connection of applicators

Before turning on the device, therapeutic probes and cables should be connected as described in IV.3. „Connection of cables and treatment applicators”.

V.2.2. Switching on

WARNING: All treatments using SONOTRONIC US-2 should be performed carefully by a qualified physiotherapy technician. Otherwise, the therapeutic effects may be limited and the patient and staff may be exposed to health risks.

WARNING: In the case of abnormal functioning of the device, which may result in danger to an operator or a patient, stop the treatment immediately and proceed as in chapter VI. „Maintenance”.

IMPORTANT: Before switching on check the condition of the cables. If they are damaged, call for a qualified maintenance technician to repair them.

IMPORTANT: This device is manufactured with the insulation of class I. Connect the mains supply cable to the socket at the back of the device, and plug the cable into the wall socket with a grounding pin.

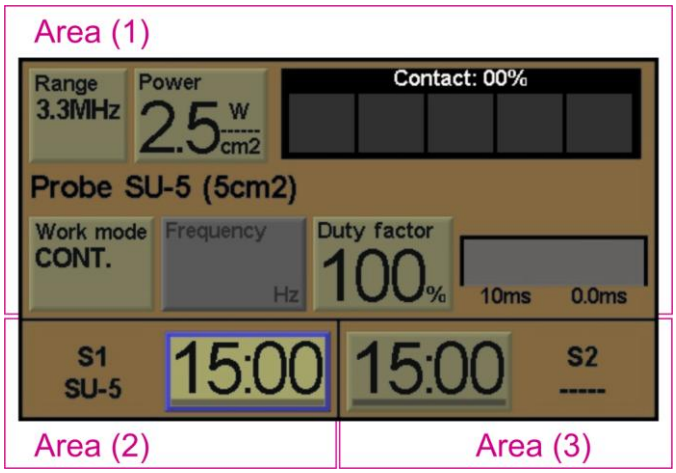
NOTICE: Do not bend the cables at acute angles and do not wind them up tight, because they can be damaged.

WARNING: The ultrasound heads are calibrated and dedicated to the individual device and should only be used with the device they were calibrated for. Do not use the heads that are not calibrated with a given device, instead send them to the manufacturer for calibration. The heads without proper calibration may not work properly or may show inaccurate parameters.

V.3. Information presented by the device

V.3.1. Main screen

After turning on the device the screen for editing treatment parameters shows up. Fields that cannot be changed are coloured in grey.



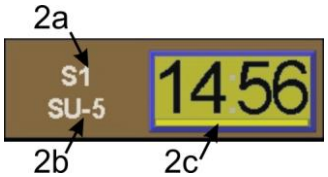
There are 3 main areas on the screen:

(1) – parameters area
(2) – applicator 1 area
(3) – applicator 2 area

In areas (2) and (3) the times of treatment and the type of detected applicator, or the kind of the selected current are displayed. When there is no probe in a channel, the sign „-----" is displayed. The probe chosen for edition / current is indicated by blue frame around timer. Treatment parameters are displayed in area (1).

V.3.2. Applicator areas

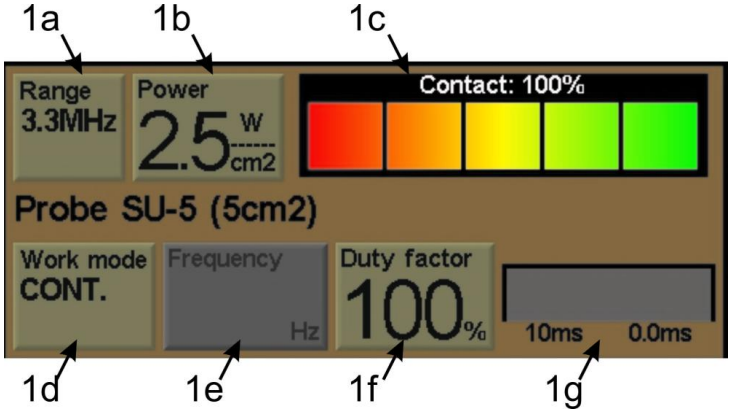
Areas (2) and (3) are connected to applicators' related sockets.



There are the following fields in these areas:

(2a): Related socket symbol („S1" – socket 1., „S2" – socket 2.)
(2b): Type or lack of applicator („SU-5", „SU-1", „SUP-6" „-----")
(2c): Time of treatment for a given applicator

V.3.3. Parameter screen



Area (1) shows treatment parameters for chosen applicator and allows for editing them. There are following fields:

(1a): parameter: ultrasound frequency [MHz]
(1b): parameter: power density [W/cm^2]
- for continuous work mode it is peak value and mean value at the same time
- for impulse work mode it is peak value
  Mean value is the product (ratio) of peak value and duty factor

(1c): graphic representation of the degree of treatment head contact with the patient's body
(1d): parameter: work mode (continuous / pulsed)
(1e): parameter: pulse frequency (for pulsed mode)
(1f): parameter: duty factor for pulsed mode [ratio: duration of pulse to the repetition period]
(1g): graphic representation of pulsed mode [first number is the pulse time, second the break time]

V.4. Performing treatments

V.4.1. Range of regulation of treatment parameters

Definitions:

$P_{constant}$ – constant power density [W/cm^2]
P_{peak} – peak power density [W/cm^2]
duty – duty factor [%]

Ranges of regulation of treatment parameters (for all ultrasound heads):

- Acoustic frequency 1 MHz or 3,3 MHz
- Treatment time t = 30 s ÷ 30 min.
- Continuous work mode:
  - Power density $P_{constant} = P_{peak}$ = 0,1 ÷ 2,5 W/cm^2
- Pulse work mode:
  - Peak power density P_{peak} = 0,1 ÷ 3,0 W/cm^2 **[*]**
  - Impulse frequency 10 – 150 Hz
  - Duty factor 5 – 100% **[*]**

[*] **NOTICE:** In case of pulse work mode only the peak power density is shown. Mean power density (constant) depends on duty factor as follows:

$P_{constant}$ = Ppeak * duty/100

Maximum peak power density is limited by the condition $P_{constant} \leq$ 2,5 W/cm^2.
The same condition limits the maximum of duty factor.
NOTICE: The device calculates values very precisely, but they are shown rounded on the screen. It is not an error.

V.4.2. Choosing the applicator

You can choose the applicator by:

- touching the screen in related applicator field (treatment timer)
- pressing the button PROBE, which changes the applicator for the next one

Chosen applicator is indicated by blue frame highlight. Its parameters are shown in area (1).

NOTICE: Changing the applicator may take up to 1 second. You have to wait until the applicator is changed.

V.4.3. Selection of parameter

We can choose a parameter in one of the two ways:

- pressing with a finger on the LCD in the field of the desired parameter
- repeatedly pressing NEXT, which consecutively selects parameters.

The parameter chosen for edition is marked by pulsating brightness.

V.4.4. Changing the parameter value

Regulation (change of value) is done only with buttons ↑ and ↓ on the keyboard. Longer pressing of any of the two keys gives a fast change. In some parameter numeric fields there is a strap at the bottom showing the presently chosen value compared to its limits.

NOTICE: The device calculates the parameter values very precisely. However, the displayed setting values are rounded off accordingly. This is not an error.

V.4.4.1 Steps of change of parameters

Power: one step is 0,1 W/cm^2
Treatment time: one step is 30 s
Pulse frequency: one step is 1 Hz
Duty factor: one step is 5%.

V.4.5. Work modes

Continuous work mode means uninterrupted in ultrasound wave emission.
Pulsed work mode means that ultrasound wave is interrupted at given frequency (pulse frequency) and duty factor. Duty factor is a proportion of emission time to span of repetition of pulses.

V.4.6. Treatments in water

Treatment heads are suited for treatments in water.
Treatment heads may be immersed in water up to 2/3 of their length.

IMPORTANT: Do not soak applicator's cable in water.

V.4.7. Starting treatment

In order to start a treatment first set the parameters and then press START/STOP. The signalling diode on the probe lights up, timer on it starts counting down and the state of connection of the applicator with the patient is shown.
WARNING: Remember to put the treatment gel on the applicator head.

V.4.8. Monitoring the contact applicator/patient

The device controls state of connection between the front of the treatment head and the patient. It is shown on the screen in percentage. This indication is approximate; it does not show the exact area of contact.

If the contact indication is equal to or higher than 50%, time of treatment is counted down.
If there is no contact (or lower than 50%), then:

- ultrasound emission is stopped (but the treatment is not terminated)
- treatment time is not counted down
- sound signal starts and light diode on the applicator starts flickering
- state of connection is still monitored
- if there is no connection for 1 minute, treatment is stopped and a relevant message shown

If the contact is restored the treatment is automatically continued.
Weak contact may result e.g. from:

- too weak tightening of the treatment head with the patient
- treatment head is touching too small area of the patient's body
- lack of or too little amount of treatment gel
- too much patient hair in the treatment area on the body

V.4.9. Termination of treatment

Treatment ends in one of the following cases:

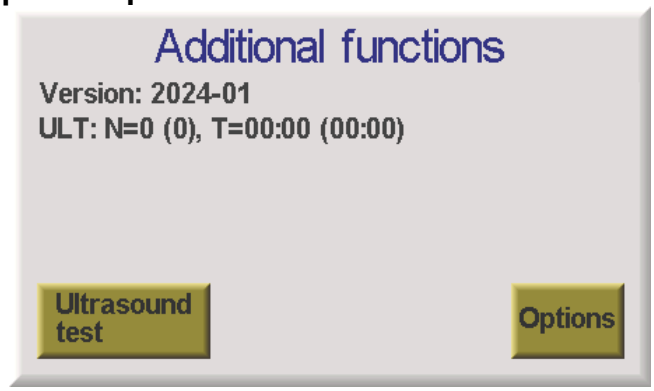
- Time of treatment runs out.

Then the signal diode on the applicator turns off, the timer background turns green and the end of treatment sound signal starts, which may be stopped by pushing any button.

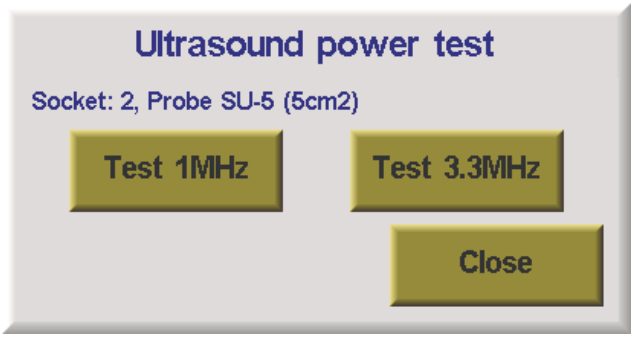
- Pressing the button START/STOP
- Longer than 1 minute break of the contact applicator/patient
- Malfunction was detected in the device or in the applicator – treatment is stopped automatically (individual situations are specified in p. V.8. “Information given by the unit during work”).

When the end of treatment results from malfunction, the suitable information appears on the screen and shall stay on until OK is pressed. Necessary actions to remove malfunction should be taken, depending on the kind of malfunction. Assistance of a qualified maintenance technician may be required.

V.4.10. Ultrasonic applicator power test



- There will be additional functions of the device. One of them is the ultrasonic test. Press the **“Ultrasound test”** button.
- To run the power test, select the ultrasonic applicator under test, position it with its forehead upward and drip water, quite a lot, but so that it does not run off the forehead.



- To run the power test, select the first frequency and observe the effect. Then add water again and select the second frequency. If the probe is working properly, most of the water should be vaporized. The effect is stronger for a frequency of 1 MHz.

V.5. PROGRAM function (build-in treatment parameters)

PROGRAM is a pre-programmed collection of optimal sets of device parameters suitable for selected illnesses. When the button PROGRAM is pressed, a list of programmed illnesses appears on the screen (arranged according to illness type):

A list of indications is displayed according to the selected treatment.

Use ↑ ↓ buttons or touch the screen to choose the item. Alternatively you may press the screen and while pressing move your finger up or down for browsing through the list.

The selection is confirmed by pressing "Choose" on the screen or by pressing the ENTER button. You may discontinue using PROGRAM function by pressing BACK or PROGRAM button at any moment.

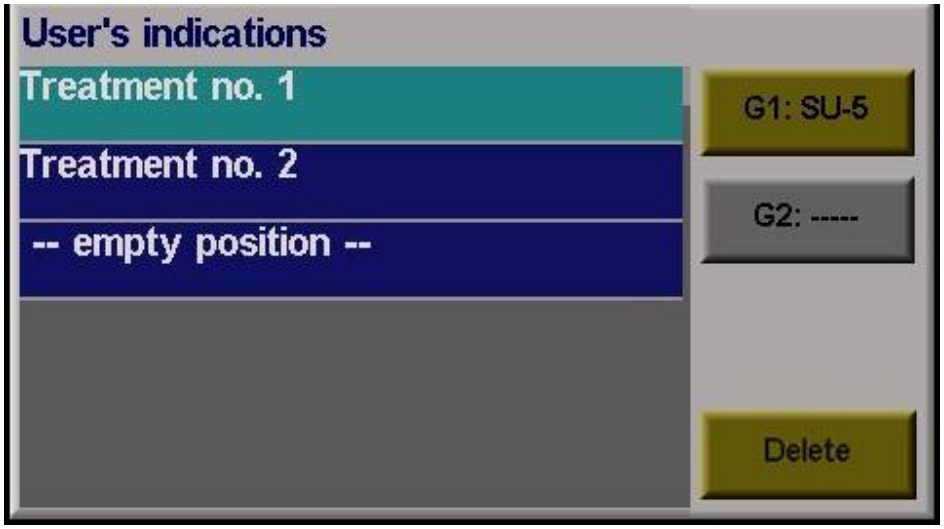
NOTICE: If no applicator is connected or a treatment is currently active in a channel, then the buttons for program selection are not active for this channel.

V.6. MEMORY function (user's own parameters)

This function allows saving parameters' values which aremost often used by the user. You may assign them to illnesses or patient names.

V.6.1. Reading the previously saved settings from MEMORY

You can use the treatment previously saved in MEMORY by pressing MEMORY button. The list of saved items will show up on the screen.



Use ↑ ↓ buttons or touch the screen to choose the desired item. Alternatively you may press the screen and, while keeping pressed, move your finger up or down to browse through the list.

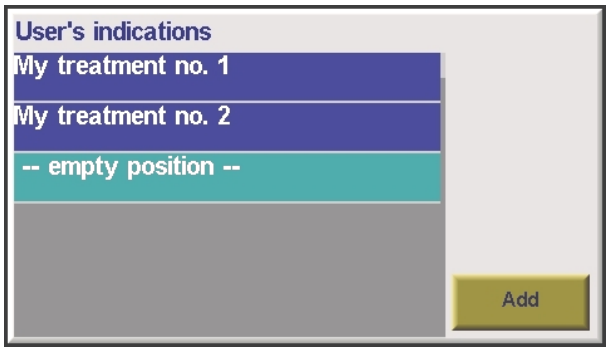
The selection is confirmed by pressing one of the buttons on the screen to the right of the list, indicating for which applicator the parameters programmed for a given disease are to be set.

You may resign from using the MEMORY function by pressing BACK or MEMORY button at any moment.

V.6.2. Saving treatment parameters in MEMORY

To save treatment parameters in **MEMORY**:
choose treatment parameters when the device is in the edition mode

- press MEMORY; the list of saved items appears on the screen
- Using ↑ ↓ buttons or touching the screen chose the item "--empty position--"



- press ADD button – the window for entering the description shows up

- you may change the position of the cursor with ↑ ↓ buttons or by touching the screen
- description of the item is entered with the keyboard shown on the screen
- tabs at the lower end of the keyboard mean:
  - CAPS – capital letters on/off
  - SPACE – inserting space
  - BACKSPACE – deleting of last symbol to the left of the cursor
  - NEWLINE – adding new line after the cursor

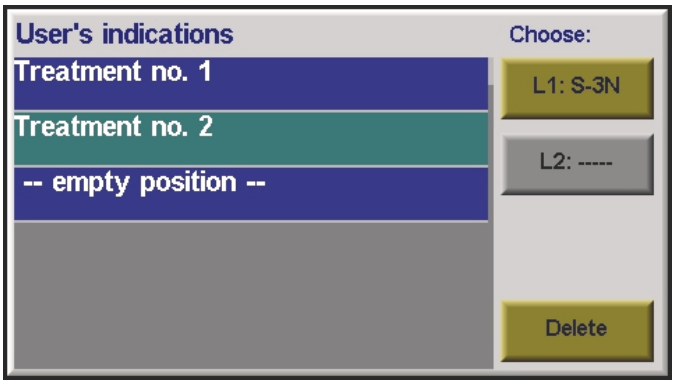
When ready, the description is confirmed by pressing ENTER.

You may discontinue using **MEMORY** function by pressing BACK or MEMORY button at any moment**.**

V.6.3. Deleting an item from MEMORY

In order to delete an item from **MEMORY** do the following:

- choose item in the list which is to be deleted - with ↑ ↓ buttons or touching the screen

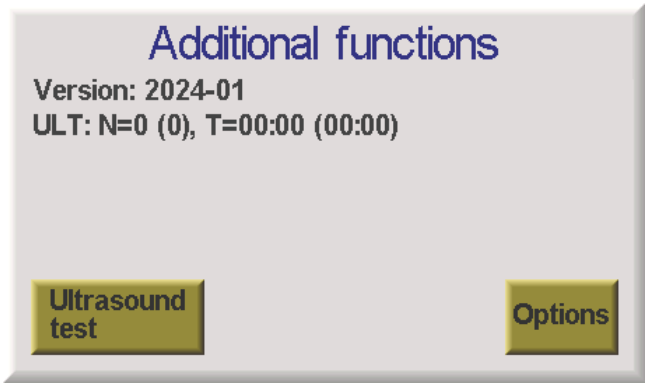


- press **DELETE** on the screen; a window will appear with a request for confirmation

- press YES to delete item or NO to quit deleting

V.7. Additional functions

Press BACK button to access the additional device functions (from the main parameter edition screen).

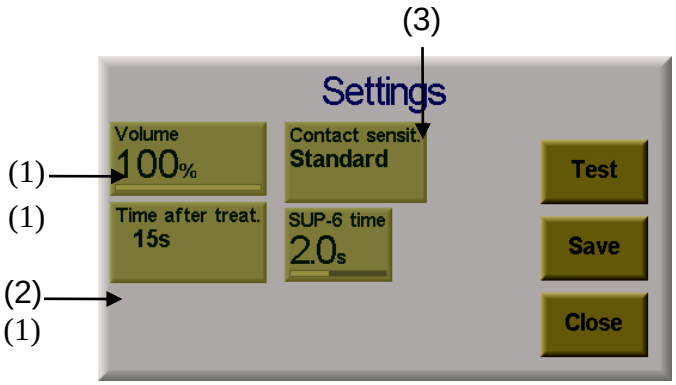


You may use them to do the following:

- check the software version
- check the number of performed treatments
  The Numbers and times after the '=" sign concern the period since the date of manufacturing, while the ones provided with parentheses are counted since the last service.
- Set the sound signal parameters (including the end of treatment signal)

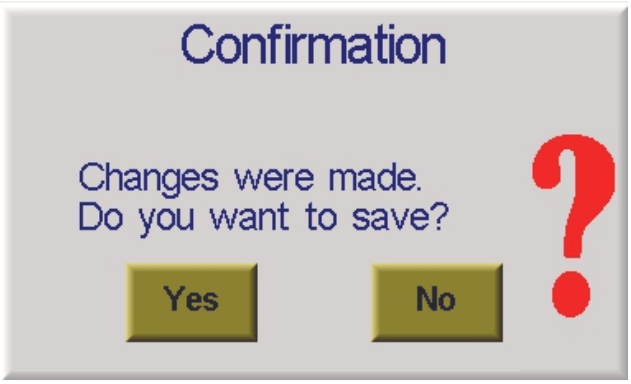
V.7.1. Setting (Options)

Pressing „Options" on the "Additional functions" screen calls up the following window:



Description of the fields:
(1) Setting the sound volume 0 –100%.
(2) Time of the sound signal after the end of treatment (choose from list):
15 s, 30 s, 1 min, 2 min, not terminated
(3) Detection sensitivity of the probe/body acoustic contact during the ultrasound treatment
To check up the sound volume press the **Test** key.
The settings chosen should be accepted with the **Save** key.

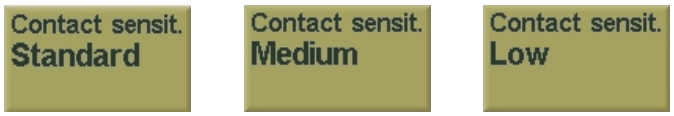
To exit the setting window press the **Close** or BACK key. If there were any changes made that have not been saved, the request for confirmation will appear:



V.7.2. Setting the sensitivity of the ultrasound applicator contact detection

The choice is by indicating the chosen field and pressing keys ↑ ↓.

The field can be chosen directly on the display, or by means of the key NEXT
The "standard" setting is the most sensitive, it can be changed into less sensitive "medium" and "low" levels.



The "medium" level is half less sensitive than "standard". The "low" level is a quarter of the "standard" level. Lowering sensitivity helps to avoid frequent pauses during treatment because of temporary loss of contact.

To exit the setting window press the **Close** or BACK key. If there were any changes made that have not been saved, the request for confirmation will appear:

V.8. Information given by the unit during work

During treatment, the unit constantly monitors the parameters of the treatment. When an error is detected, all treatments are stopped and one of following messages is shown on the screen.

- Malfunction of the fan:

- Ultrasound: the applicator non-operational

- Ultrasound: No contact of the ultrasound head with the patient's body

This messages can be closed by pressing **OK** and then the device automatically switches over to the parameter edition mode.

NOTICE: Most frequent cause of fault is disconnection or break in applicator's cable. When the error occurs please check the connection of all cables in the sockets on both sides and search for possible damages of the cables.

If this does not help, you have to contact an authorised service.

V.9. Helpful general information

- A comment on using the touch screen:

  IMPORTANT: Use the touch screen with care, because the screen is not resistant to hits or scratches. In particular, do not hit it with sharp objects (like pen or nails). The strength necessary for activating a „button" on the screen is similar to that used when pressing the external keyboard.

- The device detects the type of applicator connected.
- The device is designed for a continuous use. It is not necessary to switch it off during breaks between treatments.
- Treatment can be stopped in the following conditions:
  - after the set treatment time has elapsed
  - when there is no contact between the device and the head
  - after 60 seconds of no contact between the head and the patient
  - in the event of a power failure
  - after pressing the START/STOP button

V.10. Safety of treatments

WARNING: In the event of any serious incident related to the use of a device, it is essential to report this information to the manufacturer and to the relevant competent authority of the Member State dealing with the safety of medical devices. In Poland, such an authority is:

Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych
Al. Jerozolimskie 181C, 02-222 Warsaw
e-mail: incydenty@urpl.gov.pl
fax: +48 (22) 492 11 29

WARNING: It is necessary to interview the patient about the contraindications against the treatment, before the treatment is started.

WARNING: Before starting treatment it is necessary to make sure the patient has no blood flow disturbances or metal objects in the treatment area. Otherwise internal burns may occur resulting from the tissue density change when blood flow is limited (especially periosteum burn by a "standing wave" effect).

WARNING: In case of untypical device behaviour, which may be dangerous to the patient or staff, stop the treatment immediately and follow the guidelines of the chapter VI. „Maintenance".

WARNING: To avoid the risk of electric shock, the appliance must be connected to a mains supply with a protective earthing connection.

WARNING: No modifications may be made to the unit.

WARNING: It is forbidden to use ECG gel as connecting agent for the treatment head.

WARNING: The use of the therapy for patients under the age of 8 years is possible following a positive specialist medical opinion.

IMPORTANT: Treatment applicators (probes and heads) should be protected from shocks and mechanical damage. Applicator damage may be not visible from outside and may result in faulty work.

IMPORTANT: Operating the device in close proximity (up to a few metres) to a source of short-wave or microwave therapy may cause the output signal to be unstable and the device to malfunction.

IMPORTANT: Care should be taken not to transfer bacteria from one patient to another or to the staff. Pay attention to the hygiene of patients and staff. Applicators and eyewear must be properly cleaned and disinfected with proper agent (70% solution of ethyl alcohol or a suitable disinfectant is recommended).
The application of the agent should be checked up in the manufacturer's datasheet. It is also advised to put it to test on a small area of a probe and check on the possible damage after some time (e.g. after 24 hours).

IMPORTANT: During treatment with ultrasound head a small part of vibration may be transmitted to holding part of the applicator and to therapist's hand. This exposure is very low and should have no significant effects. Sometimes therapists complain about ailments resulting from work with ultrasound treatment heads but it possibly results from work physiology of hand. People who work long time with ultrasound heads should avoid limb overuse and possible desecration formation. We advise working more with shoulder and systematic relieving of the tension of wrist.

NOTICE: The device must be switched off by setting the power switch in the position „O" after daily treatments.

VI. MAINTENANCE

NOTICE: The addresses of authorised service are available at the manufacturer's office (see: the cover of this manual).

VI.1. Checking the proper operation of the device

- The unit should be periodically checked every 12 months throughout the time of exploitation.
- The checking can be done only by the manufacturer or authorised service having a manufacturer's certificate.
- The periodical technical tests should be made at the user's workplace, because the work environment of the unit has to be checked.

IMPORTANT: If the device fell down, before the next switching on call for the authorised service to inspect the device. There may be invisible damages that can bring about a faulty operation.

VI.2. Proper working environment

Observing the recommendations given below will help keep the device in good technical condition and will assure a long and undisturbed use.

- Power supply mains should be checked systematically, there should be no breaks, sparking or similar disturbances.
- Equipment should not work in humid environment or one with steam, salts, sulphides etc. in the air. Pay attention there are no any rooms for inhalation, hydrotherapy, pools or similar if in vicinity. If you cannot avoid such situation, the room with electrotherapy equipment must be insulated from such influences.
- Work environment should not be dusted or littered, because the fan may get blocked by the accumulated dust and dirt. Break-down of the device may occur, similarly to a PC computer. This may be avoided by systematic (e.g. once a

month) cleaning of the fan with a vacuum-cleaner (see VI.1. „Checking the proper operation of the device").

- The device should not be heated by an external radiator, heater, direct sunlight etc. Overheated electric devices may break down.

VI.3. Repairs

Should any faulty operation occur, the equipment ought to be delivered to an authorised service having a manufacturer's certificate for such repairs or directly to the manufacturer for check up or repair.

If the mains switch indicating that the device is switched on is not illuminated, have the fuse, located on the rear panel of the device (a spare fuse is provided) checked and replaced if necessary by a qualified service technician.

IMPORTANT: All repairs can be performed only by the manufacturer or authorised service.

NOTICE: When sending equipment to the service or manufacturer, remember to enclose all cables and accessories used with the unit and also a detailed description of failure (conditions of work, features of error etc.), your address and contacts (phone, e-mail).

NOTICE: Check the service authorization certificate for it may not be authorized to conduct specific controls or repairs.

VI.4. Maintenance and cleaning

The device should be cleaned of accumulating dirt.

- At least once a month clean the fan on the back panel and ventilating holes at the bottom of the device. Turn the power off and remove dust with a vacuum-cleaner, keeping the muzzle for at least 1 min at the apertures.
- Clean the device with a soft moistened cloth or sponge, but not too wet, not to let water inside.

NOTICE: Do not use paint or varnish solvents to clean the device.

VI.5. Maintenance of applicators

IMPORTANT: The device, and especially applicators, should be protected from shocks, hits and falling which may result in mechanical damage.

IMPORTANT: Periodically (for example everyday before starting treatment) check up the applicator cables for damage. The repairs of the ultrasound cable should be done by an authorised service. For other damages: see p. VI.3. „Repairs".

After each treatment the treatment head should be cleaned of gel and dried with soft cloth. Then after drying it should be disinfected with gauze or cotton slightly moistened with 70% solution of ethyl alcohol. Next treatment may be started after the agent/alcohol dries out. This procedure prevents the microorganism transmission between patients.

VI.6. Disposal of the warn out equipment

- Predicted exploitation time of the device is 10 years, provided that it is properly used and maintained according to user's manual and put to periodic technical service.
- After this time the device may be still used as long as it is serviced by the authorised service according to its condition. It can be further used if approved by the authorized service or by the manufacturer. Especially service intervals can be shortened in comparison to the nominal ones.

- After the exploitation time is over or end of usage, the device should be handed over for disposal to a company dealing with disposal of electronic equipment, in accordance with current legislation, in accordance with current legislation.

VII. MEDICAL DESCRIPTION

WARNING: Recommendation of this manual are of general nature. They should be adjusted individually to every patient.

WARNING: In doubts consult a doctor of appropriate speciality.

WARNING: Treatments with Sonotronic US-2 must be done by a qualified physiotherapist under the supervision of a medical doctor. Otherwise the therapy effects may be limited and the patients may be exposed to the risk of health deterioration.

WARNING: Treatments must be conducted according to the instructions for use and all safety recommendations.

VII.1. Intended patient group

The Sonotronic US-2 can be used with patients of all ages, taking into account the counterindications listed below in p. VII.3. „Contraindications".

VII.2. Indications

VII.2.1. Basic indications for ultrasound therapy

- Rheumatology and musculoskeletal disorders
  - Osteoarthritis
  - Osteoarthritis of the hip joint
  - Osteoarthritis of the knee joint
  - Ankylosing spondylitis (Bechterev's disease)
  - Fibromyalgia
  - Lower back pain
  - Sciatica
- Orthopedics and sports medicine
  - Pain syndromes such as:
    - Spinal pain syndromes
    - Tennis elbow
    - Shoulder pain
    - Myofascial pain
  - Heel bone spurs
  - Achilles tendonitis
  - Condition after an injury to the ankle joint
  - Lateral epicondylitis
  - Tendonitis
  - Adhesive capsulitis
  - Tendinopathy
  - Quervain's tendon sheath inflammation
  - Carpal tunnel syndrome
- Dentistry and oral disorders
  - Temporomandibular joint pain and trismus
  - Masticatory myalgia
- Dermatology and tissue regeneration
  - Treatment of bedsores
  - Venous leg ulcers
  - Shin ulceration
- Neurological disorders

VII.3. Treatment of nodules in multiple sclerosisContraindications

VII.3.1. Contraindications to ultrasound therapy

- Cancers and conditions after their surgical removal (consent of an oncologist required)
- Pregnancy
- Bleeding disorders
- Circulatory failure
- Heart arythmia
- Pacemaker
- Peripheral blood supply disorders
- Thrombophlebitis
- Acute inflammatory processes and febrile conditions
- Severe general condition and exhaustion
- Incomplete bone growth
- Conditions after X-ray therapy
- The presence in the tissues of metal foreign bodies
- Severe vegetative neurosis
- Unexplained neuralgia
- Advanced vascular calcification
- Skin changes, especially in the course of infectious diseases
- Generalized atherosclerosis and atherosclerotic conditions of the limbs
- Bronchiectasis
- Gastrointestinal bleeding

Ultrasound must not be used for safety reasons in some areas of the body: the area of the heart and cardiac segment, lungs, parenchymal organs of the abdominal cavity, brain, testicles, eyes, bones, and especially epiphyses in children and adolescents, the area of the medulla oblongata (the maximum height of sounding is the C4 segment of the cervical spine) and areas adjacent to the area where the laminectomy (excision of the vertebral arch) was performed. The clusters of lymph nodes - armpits, elbows, popliteal and groin must not be treated also.

VII.4. Side effects

Side effects that have been reported during ultrasound therapy include burns, the appearance of blisters on the skin, rashes and swelling, tingling, pain, difficulty moving, and tinnitus. If cavitation is too intense, cell death and internal bleeding can occur.

VIII. METHODOLOGY OF TREATMENTS

WARNING: Treatments with SONOTRONIC US-2 must be done by a qualified physiotherapist. Otherwise the therapy effects may be limited and the patients and the staff may be exposed to the risk of health damage.

NOTICE: Treatments must be conducted according to the user's manual and especially all safety recommendations described in it must be observed.

VIII.1. Methodology of ultrasound treatment

In ultrasound therapy, it is customary to use a frequency of 1 MHz for deeper tissues and 3 MHz for surface tissues, in accordance with half-depth rule. From the point of view of the methodology of performing the procedure, the appropriate selection of this parameter is crucial for its effectiveness. In practice, each ultrasound treated area must be assessed for the depth of the target tissue, the abundance of surrounding tissue, and the proximity of the bone. The values given in the table of indications are the proposed base values, but each person applying ultrasound should individually select all treatment parameters, including the carrier frequency.

IX. LITERATURE

1. Kiwerski J.: „Rehabilitacja medyczna”. PZWL 2005
2. Kwolek A.: Rehabilitacja medyczna. Urban & Partner, 2003
3. Straburzyński G., Starburzyńska–Lupa A., "Fizjoterapia", PZWL, Warszawa 2003
4. Łazowski J.: Podstawy fizykoterapii. AWF Wrocław 2002
5. Mika T., Kasperczyk W.: Fizykoterapia. PZWL, 2001
6. Straburzyński G., Straburzyńska-Lupa A.: Medycyna Fizykalna. PZWL, Warszawa 2000
7. Nowotny J.: Podstawy fizjoterapii. Część II. AWF Katowice 2000
8. "Balneologia Polska" Tom XXXIV Zeszyt 1–4 – Instytut Medycyny Uzdrowiskowej – Poznań 1992
9. Knoch H., Knauth K. „Leczenie ultradźwiękami“ PZWL Warszawa 1984

(oryginał „Therapie mit Ultraschall“ VEB Gustav Fischer Verlag, Jena 1977)

Please fill in the following questionnaire. Your opinions are very helpful in fulfilling your expectations concerning our equipment.

USER'S QUESTIONNAIRE

Please pick your answer and mark it with an X.

Device's type	**US-2**	**Device's number**	

No	**Question**
1.	How do you grade therapeutic effectiveness of the device in its treatments compared with similar devices of different producers?

Very low		Low		Average		Good		Very good	

2.	What is the reliability of the device during use?

Very unreliable		unreliable		Average		Rather reliable		Reliable	

3.	How do you grade easiness of operating this device?

Very difficult		Difficult		Average		Easy		Very easy	

4.	Does the device meet expectations?

Very poorly		Poorly		Average		Highly		Very highly o	

5.	Is the information provided in the instructions for use and on the device clear and does it provide the necessary information??

Very poor		Poor		Average		Good		Very good	

6.	If the instrument has been serviced (repaired) please evaluate the quality of the service:

Very poor		Poor		Average		Good		Very good	

Has not been serviced	

Can the ease of use be improved? If so, how?

Yes		No		I cannot decide	

.....

.....

Can the content of the instructions be improved? If so, what should be changed?

Yes		No		I cannot decide	

.....

.....

Please enter which conditions are most frequently treated:

THERAPY	**DISEASE**
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....

What kind of another therapy would you like to use in your work?

a/.....
b/.....
c/.....

Other notes on the use of the device:

.....
.....
.....

Please name the position of the person filling in this questionnaire:

.....

Please name the kind of place at which the device is used::

Hospital	Outpatients clinic	Physiotherapy room	Home visits	Sanatorium	Other (please name)

Thank you for filling in this questionnaire.
Pease send filled questionnaire by e-mail: malew@eie.com.pl
or by post: EiE, 05–402 Otwock, ul. Zaciszna 2, Poland