02392

EN

Operating Instructions

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Contents

Dear Customer,
We are delighted that you have chosen this **ultrasound pain therapy device.**

Before using this device for the first time, please read the operating instructions carefully and keep them for future reference. The operating instructions form an integral part of the device. If the device is passed on to others, these operating instructions must also be passed on together with the device.

The manufacturer and importer do not accept any liability if the information in these operating instructions is not complied with.

If you have any questions about the device and about spare parts / accessories, contact the customer service department via our website:

www.dspro.de/kundenservice

Explanation of the Symbols

The following symbols are used in the operating instructions for the “ultrasound pain therapy device” or accessories:

Danger symbols: These symbols indicate dangers of injury. Read through the associated safety notices carefully and follow them.

Read the operating instructions before use

Type BF applied part

Manufacturer

SN

Specification of the serial number

EC REP

EU Representative

Only use indoors!

Direct current

CE 0123

Concordance with Directive 93/42 EEC

Energy efficiency class VI

Date of manufacture

Supplementary information

Protection class II device

Polarity of the coaxial connector (mains adapter)

Electrical and electronic devices must be properly disposed of in accordance with the WEEE Directive

IP22

Protection type

Explanation of the Signal Words

DANGER Warning of serious and life-threatening injuries.
WARNING Warning of *possible* serious and life-threatening injuries.
NOTICE Warning of damage to property.

Intended Use

- The device is intended to be used only on humans. Use the device exclusively for the applications described.
- This device is intended to be used for medical care at home.
- **The device is designed exclusively for personal use and must not be used for commercial purposes.**
- The device does not require any calibration, preventive inspection or maintenance measures.
- The device is not equipped with any parts that need to be maintained by the user.
- The device is protected against unauthorised use. Never modify the device without the manufacturer's approval. If you modify the device, suitable inspection and test procedures must be carried out in order to ensure that the device is still safe for use.
- All defects caused by improper handling or damage are excluded from the warranty. The same applies to normal wear and tear.

Indications

- Pain relief, muscle spasms and joint contractures
- Symptomatic relief of chronic persistent pain
- Post-traumatic and post-operative pain

Contraindications

If you have any health concerns, suffer from health problems or belong to a risk group, consult your doctor before using the device.

- The following people must **not use the device or do so only after consulting a doctor**:
  - people who wear a pacemaker or similar medical implants (e.g. a neurostimulation device);
  - people with heart disease or who suffer from epilepsy;
  - women who are pregnant, have just given birth or are breastfeeding;
  - people who suffer from infectious diseases or circulation problems;
  - people with incomplete skeletal growth;
  - people who have undergone an operation for which the treatment is not yet complete;
  - people with carcinogenic lesions;
  - people with malignant tumours;
  - people with haemorrhagic diathesis (strong bleeding propensity);
  - people with local inflammation;
  - people with tuberculosis;
  - people with septic inflammation;
  - people with diabetes mellitus;
  - people with osteoporosis;
  - people who have had a laminectomy;
  - people with an endoprosthesis / metal implant;
  - people with a thrombophlebitis and / or varicose veins;
  - patients with a fever (pyrexia).

- Do not use the device near to or on the following areas:
  - heart;
  - chest area for people who wear a pacemaker or similar medical implants;
  - brain tissue;
  - carotid sinus nerves;
  - carotid artery;
  - laryngeal or throat muscles;
  - after undergoing a laminectomy not over the affected area of the spine;
  - a healing fracture;
  - body parts with no feeling;
  - body parts with post-traumatic consequential damages;
  - numb body parts;
  - ossification centres (in the case of incomplete bone growth);
  - acute injuries and open wounds;
  - benign or malignant tumours;
  - eyes;
  - uterus;
  - testicles;
  - genital area.
- This device should not be used to alleviate symptomatic local pain, unless the cause of the illness is known or a pain syndrome has been diagnosed.
- The other contraindications include patients who are suspected to have illnesses for which it is advisable to avoid heat and fever for general medical reasons.
- If you experience pain or skin irritation during or after use of the device, stop using the device immediately and consult a doctor before using the device again.

Read Carefully Before First Use

Caution!

- Read, understand and follow the safety precautions and these operating instructions. You should be aware of the restrictions and risks which occur when using all ultrasound devices.
- Regularly find out information about all contraindications.
- The ultrasound device should be subjected to a routine check before each use to check whether all operating elements are working properly and in particular whether the intensity regulation adjusts the intensity of the ultrasound power that is emitted stably and correctly. You should likewise check whether the regulation of the treatment time actually ends the emission of the ultrasonic waves when the timer runs out.
  Check: Hold the device horizontally with the ultrasound head pointing upwards. Place a drop of water in the middle of the ultrasound head and switch the device on (see the “Operation” chapter). If the device functions correctly, the drop of water will move around the surface area of the ultrasound head or it might even disperse.

Safety Notices

- This device may be used by people with reduced physical, sensory or mental abilities or a lack of experience and / or knowledge if they are supervised or have received instruction on how to use the device safely and have understood the dangers resulting from failure to comply with the relevant safety precautions.
- The device may **not** be used by children. Children and animals must be kept away from the device and the connecting cable.
- Close supervision is required if the device is used by or in the vicinity of **children** or fragile people.
- **Children** should be supervised to ensure that they do not play with the device. No particular training is required to use this device.
- The device should only be used and stored out of the reach of **children** and animals.

- The device must always be disconnected from the mains power when left unattended and before cleaning it.
- The mains adapter contains a transformer. Do not replace the mains adapter with another adapter as this can be dangerous.
- In the interest of your own safety, check the device and the connecting cable for damage before each use. Only use the device if it is in good working order. If the connecting cable or device are damaged, contact the customer service department or your dealer as repairs can only be carried out with a special tool.
- Do not use a damaged device.
- Never try to repair the device yourself. This could cause serious injuries. Failure to follow this specification will cause the warranty to become void.

DANGER – Danger of Electric Shock

- Use the device only in closed rooms.
- Do not use the device in a wet environment (e.g. in a bathroom or near to a shower). Never immerse the device in water or other liquids.
- Penetration of liquids into the device should be prevented as this can cause a malfunction of the internal parts and thus entail a risk of injury to the user.
- Should the device fall into water, switch off the power supply immediately. Do not attempt to pull the device out of the water while it is still connected to the mains power!
- Never touch the device and the connecting cable with wet hands when the device is connected to the mains power.

WARNING – Danger of Injury

- **Danger of injury and suffocation!** Keep children and animals away from the device and packaging material.
- Danger of strangulation! Make sure that the connecting cable is always kept out of the reach of small children and animals.
- **Danger of burns from heated ultrasound head!**
  - Make sure that you do not hold the ultrasound head on one spot for too long. It must constantly be kept moving.
  - Make sure that you use a sufficient amount of ultrasonic gel.
  - The recommended length of use is no more than 15 minutes. Do not exceed this!
  - Allow the device to cool down for approx. 30 minutes after use before using it again.
  - Do not leave the device switched on without contact with the skin. There is a danger of overheating!
- Operating the device in a way other than the one described here or failure to follow the operating steps described here may cause dangerous ultrasound radiation to be released.
- The device must not be operated in the vicinity (i.e. within a radius of less than 1 metre) of short-wave or microwave ovens.
- Do not use a mobile phone while using the device.
- Do not use the device while you are connected to other medical devices.
- Do not use the device in an environment in which devices which deliberately release electromagnetic radiation without a shield are used.
- Disinfect the ultrasound head with a cloth soaked in alcohol before the device is used by another person. This prevents any transfer of skin infections or similar complaints.
- **Danger of tripping!** Lay the connecting cable in such a way that it does not present a trip hazard.

WARNING – Danger of Fire

- Do not use the device in rooms containing easily ignitable dust or poisonous and explosive fumes.
- Do not operate the device in the vicinity of combustible material.
- Do not cover the device during operation in order to prevent it from catching fire.

NOTICE – Risk of Damage to Material and Property

- Only connect the mains adapter to a properly installed plug socket. The plug socket must also be readily accessible after connection so that the connection to the mains can quickly be isolated. The mains adapter may only be connected to the mains voltage indicated on the rating plate. Only use suitable extension cables whose technical data matches that of the device and the mains adapter.
- Make sure that the connecting cable is not squashed, bent or laid over sharp edges and does not come into contact with hot surfaces. Do not wrap the mains cable around the mains adapter or device.
- Full disconnection from the mains power is only guaranteed once the mains adapter has been unplugged.
- Do not pull the mains cable but always the mains adapter to disconnect it from the mains power.
- Never pull or carry the device by the connecting cable.
- Remove the mains adapter from the plug socket if a fault occurs during operation or before a thunderstorm.
- Protect the device from heat, naked flames, direct sunlight, sub-zero temperatures, persistent moisture, wet conditions and impacts.

Product Description

The device has a round ultrasound head which is placed directly on the patient's skin and transmits ultrasonic waves. This involves applying an ultrasonic gel which optimises the transmission of the ultrasonic waves on the whole head. A frequency of 1 MHz is used in the ultrasound treatment.

The waves are generated by a piezoelectric effect which is caused by crystals vibrating inside the device head. The sonic waves which penetrate the skin cause the tissue to locally oscillate. This oscillation or cavitation can lead to local deep heating. The sonic waves can be used with continuous ultrasound or pulsed ultrasound.

As well as the potential heating, ultrasound can also be used to produce lots of other effects. An ultrasound treatment demonstrably promotes relaxation of the tissue, local blood flow and the breakdown of scar tissue. The increased blood flow can help to reduce local swelling and chronic inflammation. The intensity of the ultrasound can be adjusted to deliver the effect you want.

Before Initial Use

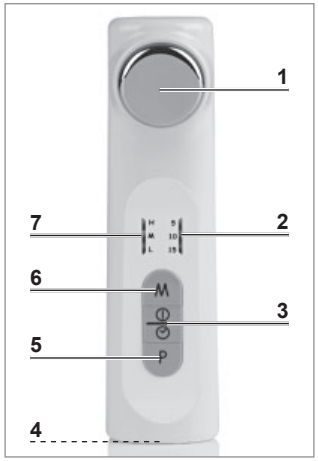
- Read through the operating instructions carefully to be able to take advantage of all the benefits of your new “ultrasound pain therapy device”. However, these operating instructions are not a substitute for consultation with your doctor.
- Make sure before using the device that all packaging materials have been removed and the device and accessories have no visible damage. If you are in any doubt, do not use the device and contact your dealer or the customer service department at the listed address.
- Before treating a patient, you should familiarise yourself with the operating steps in all available treatment modes and with the indications, contraindications, safety warnings and precautions. Make sure that there are no contraindications for the person who is to be treated. You should also make use of other sources of information about using ultrasonic waves.

Items Supplied

Check the items supplied for completeness and the components for transport damage. If you notice any damage, do not use the device, but contact the customer service department.

- Ultrasound pain therapy device (1 x)
- Mains adapter (1 x)
- Ultrasonic gel (1 x)
- Operating instructions (1 x)

Device Description



1 Ultrasound head
2 Timer indicator light (5, 10, 15)
3 Button : Switch device on / off / set operating time
Press 1 x: 5 minutes
Press 2 x: 10 minutes
Press 3 x: 15 minutes
Press 4 x: Switch off the device
4 Mains adapter socket
5 Button **P:** Switching Pulsed Ultrasound On / Off
6 Button **M:** Adjust sound intensity (ultrasound intensity)
7 Sound intensity indicator light (L, M, H)

Operation

PLEASE NOTE!

- **Use the device for no more than 15 minutes in one go and no more than 30 minutes daily on one body part.**
- Keep the ultrasonic gel clean. It must be free of dust, dirt or similar.

Ultrasonic gel is required to use the device to establish a connection between the skin and the device and thus ensure its effectiveness. A tube of ultrasonic gel is supplied with the device. Once this has been used up, use an ultrasonic gel with the CE mark from a pharmacy that is suitable for your needs. If you are unsure about possible incompatibilities, consult a chemist or physician.

1. Preparing the Treatment Area

Clean the skin in the area to be treated with soap or alcohol. If the skin is too hairy, trim or shave the hair to ensure optimum treatment.

2. Applying Ultrasonic Gel

Apply a generous amount of ultrasonic gel to the area of the body that is to be treated. The treatment area should be twice as large as the diameter of the ultrasound head. **IMPORTANT!** Never apply the ultrasonic gel directly to the ultrasound head.

The amount of ultrasonic gel is dependent on the size of the area of the body that is going to be treated. What is important is that the ultrasound head can glide effortlessly over the skin.

3. Installation

Connect the barrel connector of the mains adapter to the mains adapter socket of the device. Plug the mains adapter all the way into the plug socket.

4. Switching On

Press the  button once to switch on the device. The presettings are 5 minutes and light sound intensity (the indicator lights show the values “5” and “L”).

5. Setting the Operating Time

Press the  button to set the appropriate timer setting (5 / 10 / 15 minutes).

6. Setting the Sound Intensity

Press the **M** button to select the sound intensity (“**L**ow” / “**M**iddle” / “**H**igh”).

7. Switching Pulsed Ultrasound On / Off

Press the **P** button to activated pulsed ultrasound. Press the **P** button again to deactivate pulsed ultrasound and switch back to continuous ultrasound.

8. Application

Place the ultrasound head flat on the area of the body that has been wetted with ultrasonic gel and move it slowly and in a circular motion over the surface of the skin. Make sure that you cover the full treatment area evenly. **Please Note:** Switch off the device during breaks.

The circular movement should not be too slow so that no heat is produced, and not too fast so that the effectiveness of the treatment is not reduced. If the ultrasonic energy is not transmitted very well, we recommend applying more ultrasonic gel or repositioning the ultrasound head.

9. Switching Off

When the set time has elapsed, the device switches off automatically. However, you can switch the device off manually at any time by pressing the  button several times. The indicator lights go out, the device is now switched off. Disconnect the device from the mains power and let it cool completely.

Cleaning and Storage

PLEASE NOTE!

- Make sure that no water enters the device or is spilled over the device.
- Do not use any caustic or abrasive cleaning agents to clean the device. They may damage the surface.

- Make sure that the device has been disconnected from the mains and has cooled down.
- For cleaning, use a damp cloth to which you can apply a little detergent if necessary.
- Clean the contact surface immediately after every treatment and make sure that no residues of ultrasonic gel remain on the ultrasound head. Disinfect it from time to time with a cloth soaked in alcohol.
- Keep the device out of the reach of children and animals in a dry, clean place which is protected from direct sunlight when it is not in use. Do not leave it connected to the power supply.

FAQs

Do not use the device if is damaged or not working. Try to fix the problem using the table of FAQs. If the problem persists, contact the customer service department or your dealer as repairs can only be carried out with a special tool.

Never try to repair the device yourself!

Problem	Possible cause	Solution
Ultrasound does not work.	The device is not switched on.	Press the ⏻ button.
	The temperature of the ultrasound head is above 42 °C. The built-in temperature control function kicks in and automatically switches off the ultrasound.	Switch off the device and wait until it has cooled down. The device can only be used again once the temperature has fallen below 40 °C.
	The device is defective.	Contact the customer service department or a specialist dealer.
The device cannot be switched on.	The barrel connector has a weak contact or is not plugged correctly in the mains adapter socket of the device.	Connect the mains adapter again. If the problem persists, contact the customer service department or a specialist dealer.
	The connecting cable is defective.	Contact the customer service department or a specialist dealer.
	The device is defective.	Contact the customer service department or a specialist dealer.

Technical Data

Model number:	GL06
Reference article no. for customer service:	02392
Power:	max. 2.5 W
Weight of device:	250 g
Effective radiating area (ERA*):	4 cm^2 ± 20 %
Radiation type:	bundled
Sound frequency:	1 MHz ± 5 %
Mains connection:	UES12LCP-240050SPA Input: AC 100 – 240, 50 / 60 Hz; 0.5 A Output: DC 24.0 V, 0.5 A
Timer:	max. 15 minutes
Pulse duration:	L: 12.5%, M: 33%, H: 50% with pulsed ultrasound
Electric shock protection class:	Type B
Fluid ingress protection class:	IP22
Protection class:	II
Temperature range:	Operation: 0 – +40°C | Storage and transport: -20 – +55°C
Humidity:	Operation: 30 – 85% | Storage and transport: 20 – 90%
Air pressure:	Operation: 70 – 106 KPa | Storage and transport: 70 – 106 KPa
Product classification:	Not approved acc. to category AP or APG
Operating mode:	Continuous ultrasound / pulsed ultrasound
Dimensions:	approx. 61.5 mm (H) x 48 mm (W) x 175.5 mm (D)
Lifespan of the device:	3 years
ID of operating instructions:	Z 02392 M GM V1 1119

* Error on rating plate possible! A_{ER} indication on the rating plate corresponds to *ERA* indication in the operating instructions.

Subject to technical changes.

Disposal

Please dispose of the packaging material in an environmentally friendly manner and take it to a recycling centre.

Please note that this device is marked with the WEEE symbol on its left-hand side. The symbol denotes that the device may not be disposed of together with normal household waste but must be properly disposed of in accordance with the regulations for electronic waste.
If you have any questions on this, please contact your local waste disposal authority.

Safety and Performance Standards

The “ultrasound pain therapy device” has been developed in compliance with the highest safety and performance standards, including electromagnetic compatibility (EMC). The “ultrasound pain therapy device” meets the relevant requirements of the following regulations:

CE
0123

This device satisfies the requirements of the Medical Devices Directive 93/42/EEC in relation to medical devices.

Notices on EMC

Warning!

- Use of this device in the vicinity of or in combination with another device should be avoided as otherwise there may be malfunctions. If this should nevertheless be necessary, this device and the other device should be monitored to ensure that they work properly. If the indicator lights do not light up or flicker, this means that the device is not working properly.
- Do not change the cable without the manufacturer’s approval. The use of cables which have not been specified or provided by the manufacturer of the device may result in increased electromagnetic emissions or reduced electromagnetic interference immunity for this device and thus in malfunctions.

- Do not use in the vicinity of high-frequency surgical equipment which is switched on and RF-shielded rooms of an ME system for magnetic resonance imaging as the intensity of the electromagnetic interference is high there.
- Mobile RF communications devices (including peripherals such as antenna cables or external antennae) should only be used with a minimum gap of 30 cm from each part of this device, including the power cable. Otherwise the power of this device may decrease.

- If the device does not work in the ultrasound functional test (as specified in the “Read Carefully Before First Use” chapter) as a result of electromagnetic interference, it must not be used and an attempt should be made to use it in a different place.
- To maintain the basic safety and performance capacity with regard to electromagnetic interference for the expected lifespan, please take precautions if the place of use is in the vicinity of (i.e. less than 1.5 km from) AM, FM radio or television aerials.

The appliance is complied with the following emission and immunity standard, and test level:

Emissions Test Standard	**Compliance**
RF emissions CISPR 11	Group 1, Class B
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable

Immunity Test standard	IEC 60601-1-2 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV,±8 kV, ±5 kV air	±8 kV contact ±2 kV, ±4 kV,±8 kV, ±5 kV air
Electrical fast transient / burst IEC 61000-4-4	±2 kV, for power supply lines ±1 kV 100 kHz repetition frequency	±2 kV, for power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential lines ±0.5 kV, ±1 kV , ±2 kV common mode	±0.5 kV, ±1 kV differential lines Not Applicable
Voltage dips, interruptions and variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conducted RF IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz

NOTE: *UT is the a.c. mains voltage prior to application of the test level.*

Guidance and manufacturer's declaration – electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specification for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
	450	380 – 390	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800,	Pulse modulation 217 Hz	2	0.3	28
	870						
	930						
	1720	1700 – 1990	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

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The “ultrasound pain therapy device” is manufactured by:

Zero-Plus International Limited

Room1004,10/F, Join-In Hang Sing Centre, 71-75 Container Port Road, Kwai Chung, N.T., HK

The “ultrasound pain therapy device” is distributed by:

DS Produkte GmbH

Am Heisterbusch 1, 19258 Gallin, Germany

Customer service for medical questions: +49 (0) 38851 314337* (Mon – Fri, 8 am – midday)

Technical customer service: +49 (0) 38851 314650 * (spare parts, damage to device)

http://www.dspro.de/kundenservice

* Calls to German landlines are subject to your provider’s charges.

EC REP

EU representative in accordance with Directive 93/42 EEC:

Globalmind consumer electronics GmbH

Ernst-Mantius-Str. 11, 21029 Hamburg, Germany