User Manual

PAINSHIELD® MD

USA

NanoVibronix Inc.
525 Executive Boulevard
Elmsford
N.Y. 10523
USA

T +1 [914] 233 3004
F +1 [914] 376 6111

NanoVibronix Ltd,
9 Derech Hashalom St
Nesher 3665112
Israel

T +972 4 8200581
F +972 4 8202794

EC REP

CEpartner4U BV
Esdoornlaan 13
3951 DB Maarn
The Netherlands

T +31 343 442 524
M +31 6 516 536 26
F +31 343 442 162
office@CEpartner4U.com

info@nanovibronix.com
www.nanovibronix.com

NANOVIBRONIX® Therapeutic Waves in Motion

PAINSHIELD® MD

Contents

This manual contains general instructions for the operation, application and care of PainShield®. To obtain maximum life and efficiency from PainShield® and to assist in its proper operation, please read and understand this manual thoroughly. PainShield® is to be used only as directed in this manual.

PainShield® uses ultrasound therapy for the relief of acute or chronic pain and muscle spasms. It was developed as a next generation wearable ultrasound system which transforms conventional therapeutic ultrasound technology into a small and portable ultrasound therapy unit. It is designed to work along with the human body and maximise the safe and effective delivery of a long- duration therapeutic effect.

PainShield® is simple to use and operates on a broad range of body areas, allowing the delivery of ultrasound treatment for up to 6.5 hours, at a preset frequency of 90 kHz. Treatment is delivered via an ultrasound actuator, which is applied and secured to the surface of the body using single-use adhesive patches.

PAINSHIELD® ESSENTIAL PERFORMANCE 1.1

PainShield® produces low frequency, low intensity ultrasonic waves for the relief of pain, muscle spasm and improvement of local circulation. The ultrasonic waves are generated by a transducer that is incorporated into the actuator.

GENERAL SAFETY 1.2

Thoroughly read and understand the safety and operating instructions before attempting to operate the PainShield®. This user manual should be retained for future reference.

PRESCRIPTION USE ONLY 1.3

Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which he/she practices to use or order the use of the device.

CONTENTS 1.4

The PainShield® MD includes the following items:

- PainShield Driver.
- Actuator with its connecting cable
- 30 disposable patches
- Lanyard.
- Power supply charger.

2.1 INDICATIONS FOR USE

PainShield® MD is required to be prescribed by a licensed healthcare provider.

The PainShield® MD is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as:

- Pain.
- Muscle spasms.
- Joint contractures.

CONTRAINDICATIONS 3.1

PainShield® is contraindicated for use in the following cases:

- Patients with cancer and bone metastases under treatment area.
- Directly on the eye.
- Directly over an open wound.
- Directly over ischemic tissues in individuals with vascular disease.
- Over the uterus in pregnant patients.
- Over bone growth centres until bone growth is complete.

WARNINGS 3.2

- Do not use PainShield® in the presence of flammable materials or liquids. PainShield® is classified as an internally powered, intermittently-operated, ordinary equipment with a disposable type BF applied part.

- Do not immerse any part of PainShield® in water or any other liquid.
- Refer to Appendix A for information on maintaining basic safety with regard to electromagnetic disturbances of PainShield®.
- The PainShield® is not MRI compatible and therefore, should be removed before entering the MRI suite.
- Use PainShield® only as instructed in this manual.
- Do not use the PainShield® driver or accessories if they appear to be damaged.
- Do not modify PainShield® in any way.

3.3 CAUTIONS

- PainShield® has no user serviceable parts. If it is not operating correctly, contact the local representative of NanoVibronix. No part of the PainShield® system should be replaced with components or parts other than those supplied by NanoVibronix.
- Do not connect PainShield® to any device or system other than the parts supplied with it.
- Charge the PainShield® driver only with the supplied charger.
- Do not attempt to open or remove the cover of the PainShield® driver.
- The Lithium-Ion rechargeable battery in the PainShield® driver must not be disassembled, heated above 100 degrees Celsius, incinerated, or exposed to water.
- Be aware of the actuator cable which can get caught or wrapped around a person's body and lead to potential injury or restrict blood flow.
- Use of PainShield® adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, observe the PainShield® system to verify it is operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by NanoVibronix could result in increased electromagnetic emissions or decreased electromagnetic immunity of this medical device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be no closer than 30 cm (12 inches) to any part of the PainShield® system during operation. The performance of PainShield® may be affected.

PRECAUTIONS 3.4

Use PainShield® with caution in the following areas:

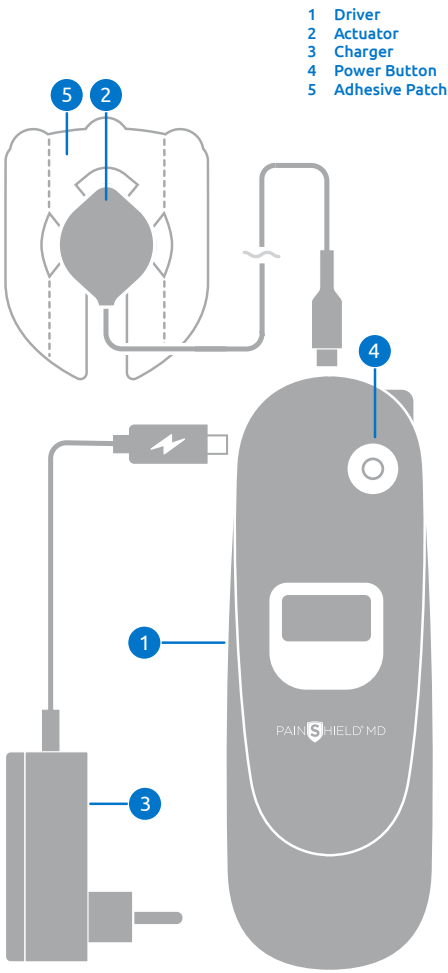
- Following a laminectomy involving major tissue removal.
- In patients susceptible to bleeds.
- Over anesthetised areas of impaired skin.
- Treatment of children should be performed under adult supervision.
- In children, avoid use over the epiphyseal growth plate area.
- Use caution when removing the actuator patch from the skin after use.

The safety and effectiveness of PainShield® has not been established in patients who are or have been treated by other medical devices including but not limited to:

- Pacemakers.
- Electrical stimulators.
- Radiofrequency generators.
- Surgical meshes.
- Intra-Uterine devices (IUDs).
- Other surgical implants.

When the actuator is applied in a location you are lying on you may experience slight redness of the skin, which will resolve in a few hours.

PainShield® has three components:
A Treatment Actuator ❷ Adhesive Patches ❺
and a Driver ❶ A charger ❸ is also included.



THE PAINSHIELD® TREATMENT ACTUATOR 4.1

The treatment actuator incorporates an ultrasonic transducer and connects to the driver with a cable.

The transducer is the active element that converts electric signals to ultrasound waves.

For effective treatment, the transducer must be in full contact with the skin.

PAINSHIELD® ADHESIVE PATCHES 4.2

The adhesive patches secure the actuator to the affected area.

THE PAINSHIELD® DRIVER 4.3

The driver that supplies electrical signals to the actuator. It has the following parts:

- Built-in rechargeable battery.
- Charging port.
- Actuator port.
- ON/OFF button.
- Operation screen display.

5.1 OPERATING CYCLE

PainShield® is preconfigured to provide intermittent ultrasonic output at a pre-set frequency which cannot be modified by the user.

When in ON mode, the PainShield® alternates between 2 phases:

- Active phase — PainShield® delivers 30 minutes of ultrasound therapy.
- Idle phase — PainShield® is idle for 30 minutes.
- 1 active phase + 1 idle phase = 1 cycle.

PainShield® counts the number of cycles, which is displayed as "C1" to "C6" and automatically switches to OFF mode after 6.5 hours.

The battery should be recharged following use.

5.2 BATTERY OPERATION

Powered by a rechargeable lithium-ion battery, PainShield® can provide approximately 6.5 hours of continuous therapy on a single battery charge. After 6.5 hours, PainShield® automatically switches off, and the battery must be recharged.

You can switch PainShield® to OFF mode manually at any point of time.

The internal battery can undergo greater than 500 full charge cycles. The operational time may decrease over time.

When not in use, it is recommended to store the driver with 50% charge on the battery.

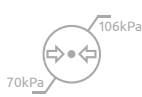
STORAGE CONDITIONS 6.1

PainShield® storage conditions:

	**5 - 40°c**
	**10 - 80%**
	**70 - 106 kPa**

ENVIRONMENTAL OPERATING CONDITIONS 6.2

The recommended environmental operating conditions are:

	**5 - 35°c**
	**10 - 80%**
	**70 - 106 kPa**

6.3 THE DRIVER

The life of the driver is dependent on the battery use, refer to section 5.2. To clean the driver use 70/30 IPA or disinfectant medical wipes. Do not use solvents, such as acetone, as they may damage the product.

Do not immerse any part of PainShield® in water or any other liquid.

The driver is flame resistant according to UL-94HB. It does not contain flammable materials and will not accelerate a fire. The driver is not intended for use in the presence of flammable liquids.

Use the actuator with a new patch for each treatment session.

A faulty unit which is still under warranty, can be sent to NanoVibronix for replacement. Refer to Appendix D for conditions of warranty.

The driver does not contain recyclable material.

6.4 THE ACTUATOR

It is recommended to replace the actuator after 30 treatments.

New actuators can be ordered from NanoVibronix or your local distributor.

6.5 THE PATCH

Do not use the patch more than once, as this may affect performance.

CHARGING THE PAINSHIELD® DRIVER 7.1

When the battery is fully charged, the PainShield® can be used without mains power connection for approximately 6.5 hours.

Charge the driver in accordance with the following guidelines:

- Charge the driver only with the supplied charger.
- Therapy is not available while the driver is being charged.
- Before first use, remove the driver from its packaging and place on charge.

To charge the driver:

1. Connect the USB-C plug of the supplied charger to the driver's charging port.
2. Plug the charger into a mains power outlet.

When the driver begins to charge, the screen lights up brightly and displays the battery icon:

After approximately 1 minute, the screen dims. To refresh the display, briefly press the ON/OFF button. During charging the battery icon fills gradually.

Charging takes about 2 hours. When the battery is fully charged, the battery icon appears full.

7.2 PREPARING THE TREATMENT AREA

1. Remove excess hair from the treatment area.
2. Clean the treatment area thoroughly with soap and water or an alcohol wipe.
3. Ensure the treatment area is dry and free from any creams or oils which could affect the adherence of the actuator patch.

7.3 PREPARING THE ACTUATOR AND PATCH FOR USE

1. Remove the actuator from it's packaging and connect the actuator plug into the driver socket, ensuring the plug is correctly orientated in relation to the socket, and make sure the plug is fully inserted and secured. *(fig.1)*

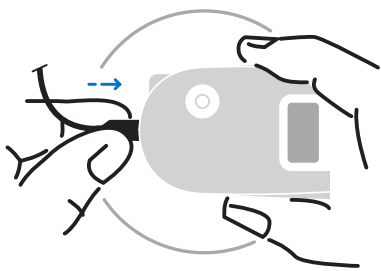


fig.1

2. Take adhesive patch. Remove the protective layer from an adhesive pad, taking care to remove the central piece first as illustrated below. *(fig.2)*

fig.2

❸ Place the actuator on the exposed adhesive at the centre of the patch, with the metal transducer facing up and the wire aligned with the open notch in the patch. *(fig.3)*

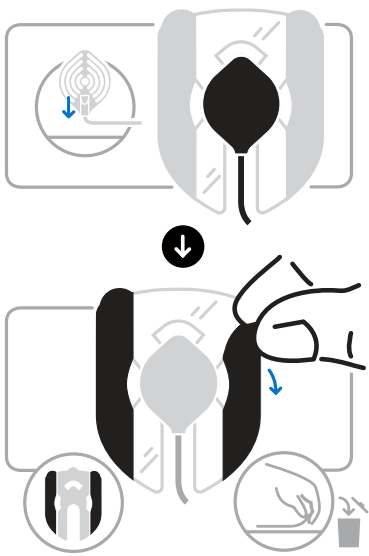


fig.3

4 Attach the actuator patch to the skin, with the adhesive side down over the area where the pain is most intense. (*fig.4)*

fig.4

5 If the skin is broken or if the pain is located near a joint, attach the actuator to the flat healthy skin area adjacent to the source of pain. Be sure to place the actuator within 10cm (4 inches) of the affected area to ensure the pain source is within the treatment area

Operation 7

APPLYING THERAPY 7.4

Use the ON/OFF button to switch the driver ON and OFF.

To switch the driver ON:

- Press and hold the ON/OFF button until you hear a beep, and the NanoVibronix logo appears on the screen.

Note: Briefly pressing the ON/OFF button refreshes the information screen. The screen saver is replaced by the information screen.

To switch the driver OFF:

- Press and hold the ON/OFF button until you hear the shut-off beep.

7.5 PAINSHIELD® DISPLAYS

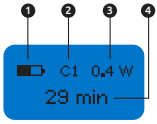
The information below explains the symbols and text that may be displayed on the driver display during normal functioning of the PainShield® at various times.

Manufacturer name

Displayed briefly when you switch ON the driver.

Product name
Software version number

(Displayed during device initiation).



Working mode information
(ACTIVE phase)

1. Battery indicator
2. Treatment cycle number (C1 to C6)
3. Output power.
4. Time elapsed since the beginning of the current ACTIVE phase.

Screensaver : In Charging Mode

The display is dimmed and keeps scrolling vertically.

To refresh the display of information, press the ON/OFF button for less than 2 seconds.

Screensaver : In Working Mode
(Automatically replaces the information screen after 3 sec)

PainShield® is ON.

To refresh the display, briefly press the ON/OFF button.

Communication Error

The actuator is not connected to the driver, or damaged.

Switching off

Switching off takes 3 seconds. The number indicates how many seconds to complete shut off.

REMOVING THE ACTUATOR PATCH 7.6

1. Use caution when removing the actuator patch from the skin.
2. Gently remove the patch from the actuator avoiding applying tension to the wire.

Important: Do not reuse the adhesive patch as this may affect the performance.

7.8 REPLACING THE ACTUATOR

It is recommended to replace the actuator after 30 treatments.

New actuators can be ordered from NanoVibronix or your local distributor.

1. Switch OFF the PainShield® driver to prevent the driver from sounding an alert when it is disconnected from the actuator.
2. Hold the driver in one hand and the actuator cable plug in the other hand and pull apart. *(fig.6)*

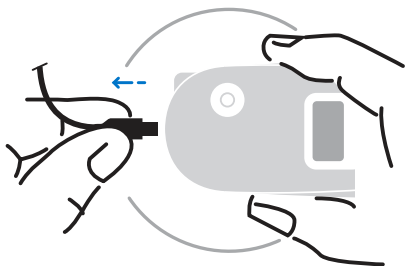


fig.6

3. Connect the new actuator cable plug into the driver socket, making sure to orient the plug correctly in relation to the socket, and that the plug is fully inserted and secured. (*fig.7)*

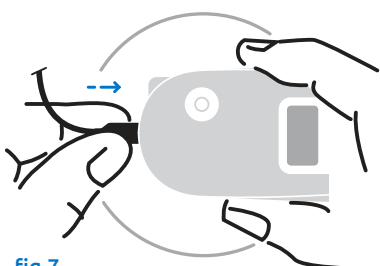


fig.7

TROUBLESHOOTING 7.7

Issue or Problem
The device does not turn on.

Solution
Charge the driver using the supplied charger for 2 hours. If issue is not resolved, contact the NanoVibronix local distributor.

Issue or Problem
The actuator is not staying secured to the skin during treatment.

Solution
Turn off the device. Remove the actuator patch (See 7.7). Replace with a new adhesive patch (See 7.3).

Issue or Problem
An empty battery icon is displayed on screen and an audio alert is played.

Solution
The battery requires recharging (See 7.1).

Issue or Problem
The screen displays actuator disconnection status icon, and an audio alert is played.

Solution
The actuator is not connected to the driver or damaged. Reconnect the actuator to driver. If the problem remains, replace with new actuator (See 7.8).

Question
How do I place the actuator correctly?

Answer
Place the actuator on clean, dry, healthy skin over or close to the source of pain and in full contact with the skin.

Question
Do I need to use an ultrasound gel under the PainShield® actuator?

Answer
You do not need to use ultrasound gel with the PainShield®.

Question
Can I put the actuator over an open wound?

Answer
The actuator should never be placed on an open wound; it should be placed on healthy skin near the wound.

Question
Will I feel any vibrations or shocks from PainShield® when it is on?

Answer
Other than mild warmth from the metal active element in the actuator you will feel no vibrations or shocks.

Following treatment, some redness might occur in the treated area. This redness resolves on its own within a few hours?

Question
When will I feel relief?

Answer
Pain reduction could begin as early as 30 minutes after treatment and last up to several days. PainShield® works by improving blood flow to muscles and tissues that are in spasm and by normalizing nerve activity.

Question
How can I order additional actuators and patches?

Answer
Please contact NanoVibronix or your local distributor.

Question
Can PainShield® be used with physical therapy?

Answer
Yes. PainShield® is perfectly suited for use in conjunction with a program of physical therapy and can be used in between therapy sessions.

Frequently Asked Questions 8

Appendix

PAINSHIELD® ELECTROMAGNETIC EMISSION 9.1

Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PainShield® D 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 PainShield® 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 fluctuations/ flicker emissions IEC 61000-3-3	Complies	

9.2 PAINSHIELD® ELECTROMAGNETIC IMMUNITY

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD), IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 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 SIP/ SOP lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line (Class II ME equipment)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % UT for 0.5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	0 % UT for 0.5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. The user of the PainShield® during continued operation not depend from power mains interruptions, because PainShield® powered from a batteries. During system charging is recommended that the PainShield® be powered from an uninterruptible power supply.
Power frequency magnetic field, IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the AC mains voltage prior to application of the test level.

PAINSHIELD® ELECTROMAGNETIC IMMUNITY 9.1

Table 3

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz) and amateur bands (1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz)	[V] = 3 Vrms [V] = 6 Vrms
Proximity fields from RF wireless communications equipment	10 V/m 80 MHz to 2.7 GHz	[E] = 10 V/m
	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	

9.2 PAINSHIELD® DRIVER & ACTUATOR SPECIFICATIONS

PainShield® Driver

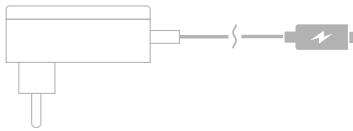
Frequency	90 kHz ± 0.001 kHz
Voltage output	12 V p-p
Current output	Up to 0.3 A RMS
Rechargeable battery	Lithium-Ion, 3.7 V, 1250 mAh (full charging time ~ 2 h)
Dimensions	137 mm (L) x 47 mm (W) x 21 mm (H)
Weight	Approximately 85 g
Housing	ABS

PainShield® Actuator

Acoustic power	0.4 W
Frequency	90 kHz ± 0.001 kHz
Beam Non-Uniformity Ratio (BNR)	6:1
Effective Radiating Area (ERA)	6 cm²
Dimensions	35 mm (L) x 27 mm (W) x 6 mm (D)
Weight	Approximately 12 g
Reuse	30 applications

PAINSHIELD® CHARGER SPECIFICATIONS 9.2

PainShield® Charger



Voltage input	100-240 VAC, 0.4-0.2A, 50/60 Hz
Output	5 VDC, 2.4 A

Note: Use an appropriate adaptor for local mains.

PAINSHIELD® PRODUCT CLASSIFICATIONS 9.2

Classification & Compliance

Product classification

Low risk device classification: CE Mark - Class IIa / FDA Clearance - Class II

9.3 PAINSHIELD® SYMBOL INDEX

	Refer to instruction manual/booklet
	Type BF applied part
	Rated frequency or rated frequency range(s) (Hz)
	The product must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substance, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner. Consult your municipal authority or your dealer for information about disposal.
	Manufacturer
	Date of Manufacture: YYYY-MM-DD
	CE Mark
	Authorized representative in the European Community
	Part number
	LOT
	Serial Number
0.4W	Power output 0.4 watts
BNR	Beam Non-uniformity Ratio
ERA	Effective Radiating Area
kHz	Kilohertz (1 kHz = 1000 Hz)

IP22	IP rating per IEC 60529
CW	Continuous Wave
mW/ cm²	Milliwatt per centimeter squared
cm²	Centimeter squared
W	Watt (1W = 1000mW)
℞ Only	21 CFR 801.109/ Prescription devices. US Federal law restricts this device to sale by or on the order of a physician or physical therapist licensed by the law of the State in which he practices to use or order the use of the device.

9.4 PAINSHIELD® WARRANTY

NanoVibronix warrants that the PainShield® driver will be defect-free for a period of one year from product date of purchase.

The liability of NanoVibronix under this warranty is limited to the replacement (at NanoVibronix's choice) of any allegedly defective part or parts under warranty by NanoVibronix and at its expense. The defective driver should be returned to NanoVibronix accompanied by a notice that describes the nature of the problem.

This warranty shall not apply to a product which has been subject to misuse, unauthorized use, negligence or accident (including but not limited to fire, water, explosion, smoke, or vandalism), or which has not been operated in compliance with NanoVibronix instructions for use.

Without derogating from the above, this warranty is void, if at any time anyone other than NanoVibronix authorized personnel removes the product casing and/or attempts to make any internal changes, removals, attachments or additions to the product or its components.

Notes

20-100-0004
Ver 06

info@nanovibronix.com
www.nanovibronix.com

NANOVIBRONIX® Therapeutic Waves in Motion

PAINSHIELD® MD