NANOVIBRONIX®
Therapeutic Waves in Motion

PAINSHIELD® MD

User Manual

Cat. # PSUM003 Ver. 12 (USA)

CE 1282

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NanoVibronix Inc.,
525 Executive Boulevard,
Elmsford, N.Y. 10523, USA
Tel.: 1 (914) 233-3004
Fax: 1 (914) 376-6111
Email: info@nanovibronix.com
Website: www.nanovibronix.com

EC REP

Authorized representative in the European Community:
CEpartner4U BV,
Esdoornlaan 13,
3951 DB Maarn,
The Netherlands
Tel.: +31.343.442.524
Mobile: +31.6.516.536.26
Fax: +31.343.442.162
office@CEpartner4U.nl

Table of Contents

1 Introduction

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

The PainShield® MD uses ultrasound therapy for the relief of acute or chronic pain and muscle spasms.

The PainShield® MD was developed as a next generation wearable ultrasound system which transforms conventional therapeutic ultrasound technology into a small and portable ultrasound therapy system. It is designed to work with the human body and maximize the safe and effective delivery of long-duration therapeutic ultrasound.

Simple to administer and operate on a broad range of body types, the PainShield® MD allows the delivery of ultrasound treatment for up to 6.5 hours. It operates at a preset frequency of 90 kHz and is available with patches in two sizes. The patch is applied and secured to the surface of the body using the incorporated adhesive hydrogel coating.

1.1 General Safety

Thoroughly read and understand the precautionary and operating instructions before attempting to operate the PainShield® MD. Know the limitations and hazards associated with using any ultrasound device. Observe the precautionary and operational labels on the product. Periodically review the operation procedures and safety precautions outlined in this manual.

1.2 Prescription Use Only

CAUTION

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.

2 Indications for Use

The 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

In suitable cases the PainShield® MD improves local blood circulation and reduces pain.

3 Safety

3.1 Contraindications

The PainShield® MD is not for use in the following cases:

- Patients with cancer and bone metastases in the 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 centers until bone growth is complete

3.2 Warnings

WARNING

- Do not use the PainShield® MD in the presence of flammable materials and liquids. The PainShield® MD is classified as internally-powered, intermittently-operated, ordinary equipment with a disposable type BF applied part.
- Do not immerse any part of the PainShield® MD in water or any other liquid.
- Use the PainShield® MD only as instructed in this manual.
- Do not use any part of the PainShield® MD that appears damaged.
- Do not modify the PainShield® MD in any way.
- Do not replace any part of the PainShield® MD with components or parts other than those supplied by NanoVibronix.
- Do not connect the PainShield® MD to any device/system other than the parts supplied with it.

CAUTION

- Charge the PainShield® MD only with the supplied charger.
- Do not attempt to open or remove the cover of the PainShield® MD.
- The lithium ion rechargeable battery in the PainShield® MD must not be disassembled, heated above 100 degrees Celsius, incinerated, or exposed to water.

3.3 Precautions

- Use with caution in the following cases:
  - Following a laminectomy involving major tissue removal
  - In patients susceptible to bleeds
  - Over anesthetized areas of impaired skin
- Treatment of children should be performed under adult supervision.
- In children, avoid use over the epiphyseal growth plate area.
- The safety and effectiveness of the PainShield® MD 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.

4 Product Features

4.1 Preset Treatment

The PainShield® MD is preconfigured to provide intermittent ultrasonic output at a preset frequency of 90 kHz and a low intensity neither of which can be modified by the user.

When the PainShield® MD is ON, it alternates automatically between 2 phases:

- Active phase—the PainShield® MD delivers 30 minutes of ultrasound therapy.
- Idle phase—the PainShield® MD is idle for 30 minutes.

1 active phase + 1 idle phase = 1 cycle.

The PainShield® MD automatically switches OFF after 6.5 hours, at which point the battery should be recharged.

4.2 Battery Operation

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

You can switch the PainShield® MD OFF manually at any time.

4.3 PainShield® MD Patches

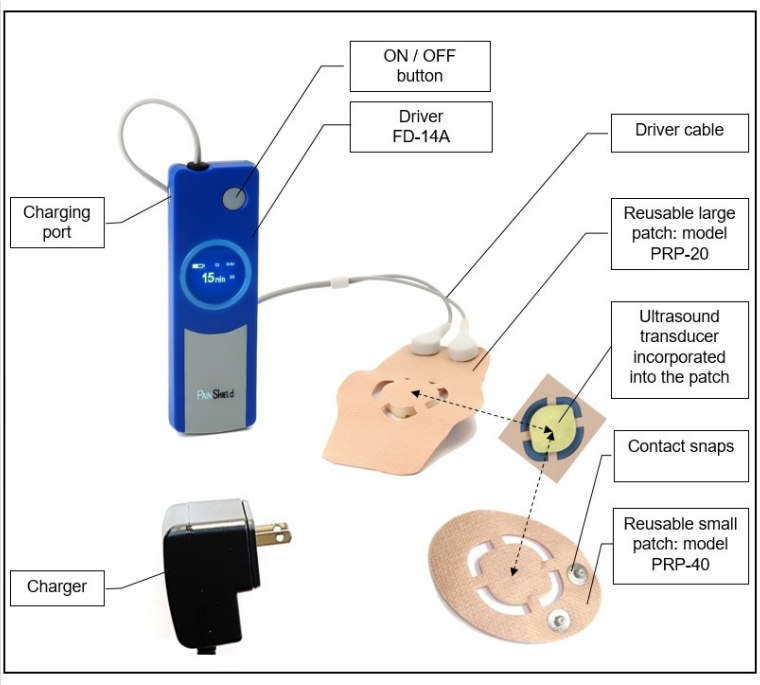
The PainShield® MD hydrogel adhesive patch secures the transducer to the affected area. The transducer converts energy to ultrasonic therapeutic waves.

The patch is reusable and can be used approximately 7 times provided the hydrogel layer is kept from drying.

The patches come in two sizes to better fit application in various body areas:

Large patch - Model PRP-20	120 mm x 50 mm x 6 mm
Small Patch - Model PRP-40	75 mm x 55 mm x 6 mm

5 Product Components



The PainShield® MD has two components: a treatment patch and a driver. A charger is included.

5.1 The PainShield® MD Treatment Patch

The reusable treatment patch comes in a pouch which also serves for storing the patch between treatment sessions.

The patch comes in two sizes: a larger size (Model PRP-20) and a smaller size (Model PRP-40). The smaller size should be used when the larger size is inconvenient (e.g. Achilles tendon treatment). The two patch types differ only in size.

One side of the patch is protected by a transparent liner. Under the liner the patch has a layer of adhesive hydrogel. The liner is removed before treatment,

and the side of the patch with hydrogel is placed on the skin. When the patch is removed from the skin, the liner is replaced to protect the hydrogel coating.

The transducer in the center of the patch is the active element that converts electric signals to ultrasound waves.

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

The reverse side of the patch has two snap contacts for connecting the driver cable.

5.2 The PainShield® MD Driver

The driver supplies electrical signals to the transducer in the patch. It has the following parts:

- Built-in rechargeable battery
- Charging port
- Connection cable
- ON/OFF button
- Operational screen display

6 Operation

6.1 Charging the Driver

When the battery is fully charged, the driver has an operating life of 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 verify that it is fully charged.

To charge the driver:

1. Connect the mini USB plug of the supplied charger to the driver's charging port.
2. Plug the charger into a wall 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.

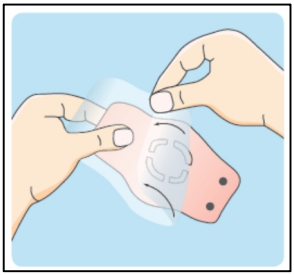
6.2 Preparing the Treatment Area

1. Remove excess hair from the treatment area.
2. Clean the treatment area thoroughly with soap and water or an alcohol prep pad.
3. Dry the treatment area.

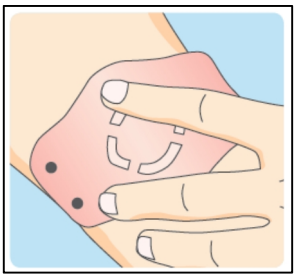
6.3 Applying the Patch

Apply the patch over the area of the most intense pain or next to the wound.

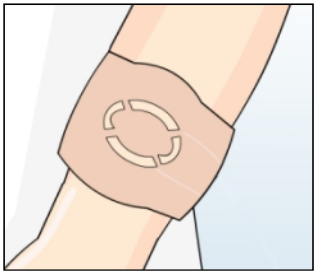
1. Carefully cut open the pouch containing the patch. Save the pouch for storing the patch between treatment sessions.
2. Connect the driver cable to the two snap contacts on the patch.
3. Remove the transparent protective liner from the patch. Save the liner for protecting the patch during storage.



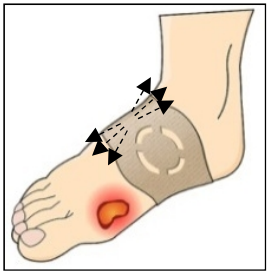
4. Place the patch on the area of treatment over healthy skin. The hydrogel adhesive attaches the patch to the skin.



5. If the skin is broken, place the patch on adjacent healthy skin as illustrated below.

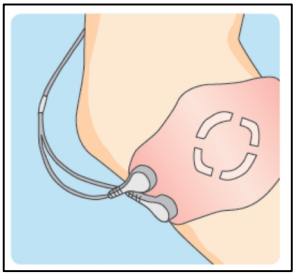


Over painful area



Next to wound

6. Make sure that the ultrasonic active element is in full contact with the skin.



Note: To ensure full contact of the active element with the skin, particularly when using the smaller patch or during prolonged use,

consider using a wrap-type dressing (e.g. 3M™ Coban™ Self-Adherent Wrap, supplied with the kit).

6.4 Applying Therapy

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

To switch the driver ON:

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

To switch the driver OFF:

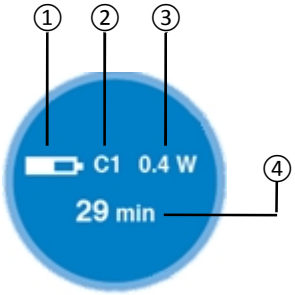
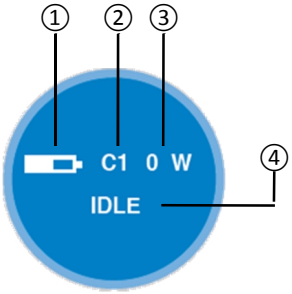
- Press the ON/OFF button until you hear the shut-off beep.

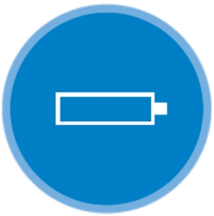
Note: Briefly pressing the ON/OFF button refreshes the information screen. The screen saver is replaced by the information screen.

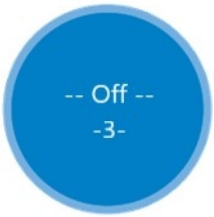
6.5 Monitoring the PainShield® MD

The driver screen displays information on the functioning of the PainShield® MD. The table below explains the symbols and text that may be displayed on the screen at various times.

Symbols/Text Displayed	Explanation
	Manufacturer name (displayed briefly when you switch ON the driver)

Symbols/Text Displayed	Explanation
	Product name Software version number (displayed briefly in the interval before the information display appears)
	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.
	Working mode information (IDLE phase) 1. Battery indicator 2. Treatment cycle number 3. Output power 4. The PainShield® MD is in IDLE phase.
	Screensaver during working mode (automatically replaces the information screen after 3 minutes) The PainShield® MD is ON. To refresh the display of information, briefly press the ON/OFF button.

Symbols/Text Displayed	Explanation
	The battery is discharged and requires recharging.
	Charging mode information The battery icon fills gradually to show charging progress.
	<u>Screensaver in Charging Mode</u> The display is dimmed and keeps scrolling vertically. To refresh the display of information press the ON/OFF button briefly (that is, for less than 2 seconds).
	The treatment patch is damaged or not connected to the driver.

Symbols/Text Displayed	Explanation
	The driver is switching OFF Switching off takes 3 seconds. The number indicates how many seconds to complete shut off.

6.6 Removing the Patch

1. Unsnap the driver cable from the patch.
2. Gently lift the patch off the skin.
3. Moisten the hydrogel layer with a little water.
4. Replace the clear patch protective liner.
5. Return the patch to its pouch.

CAUTION Do not leave the patch unpackaged in a dry place. It will lose its hydration and will no longer adhere to the skin. .

7 Frequently Asked Questions

Question	Answer
How do I place the patch correctly?	Place the patch on clear, dry healthy skin with the ultrasound active element over the source of pain and in full contact with the skin.
Do I need to use an ultrasound gel under the PainShield® MD patch?	You do not need to use ultrasound gel with the PainShield® MD.
Can I put the patch over an open wound?	The patch should never be placed on an open wound; it should be placed on healthy skin near the wound.
Will I feel any vibrations or shocks from the PainShield® MD when it is on?	Other than mild warmth from the metal active element in the center of the patch 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.
When will I feel relief?	Pain reduction could begin as early as 30 minutes after treatment and last up to several days. The PainShield® MD works by improving blood flow to muscles and tissues that are in spasm and by normalizing nerve activity.
How can I extend patch reusability?	After patch removal, moisten the hydrogel layer of the patch with a little water, replace the clear protective liner, and store the patch in its original pouch. Do not leave the patch unpackaged in a dry place. It will lose its hydration and will no longer adhere properly to the skin.
How can I order additional patches?	Please contact NanoVibronix or your local distributor.
Can the PainShield® MD be used with physical therapy?	Yes. The PainShield® MD is perfectly suited for use in conjunction with a program of physical therapy and can be used in between therapy sessions.

8 Product Care

Store the PainShield® MD under the following conditions:

- Temp: 10 °C to 27 °C (50 °F to 80 °F);
- Humidity: 40% to-60%.

The driver is intended to undergo up to 400 charging cycles.

The life expectancy of the driver is 5 years, subject to replacement batteries by the manufacturer.

To clean the driver use disinfectant medical wipes. Do not use solvents (such as acetone) as they may damage the product.

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.

After patch removal, moisten the hydrogel layer with a little water, replace the protective liner, and store the patch in its original pouch.

Do not leave the patch unpackaged in a dry place. It will lose its hydration and will no longer adhere properly to the skin.

You can use the patch for approximately 7 treatment sessions.

The treatment patch expiration date is printed on the patch pouch label. Do not use the patch after its expiration date.

A faulty unit which is under the warranty period can be sent to NanoVibronix for replacement.

Appendix A: Electromagnetic Compliance

Table 1: PainShield® MD Electromagnetic Emission

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
PainShield® MD is intended for use in the electromagnetic environment specified below. The customer or user of the PainShield® MD should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic Environment – Guidance
RF emissions, CISPR 11	Group 1	The PainShield® MD 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® MD is not directly connected to the Public Mains Network.
Harmonic emissions, IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions IES 61000-3-3	Complies	

Table 2: PainShield® MD Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
PainShield® MD is intended for use in the electromagnetic environment specified below. The customer or user of the PainShield® MD should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transfer/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial environment.

Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic Environment – Guidance
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T* (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. The use of the PainShield® MD during continued operation will not be affected by power mains interruptions, since the PainShield® MD is battery powered. During system charging, it is recommended that the PainShield® MD be powered by an uninterruptible power supply.
*U_T is the A/C mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 3 Vrms 80MHz to 2.5GHz	[V1] V [E1] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PainShield, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic Environment – Guidance
			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PainShield is used exceeds the applicable RF compliance level above, the PainShield should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PainShield.

b Over the frequency range 150 kHz to 80 MHz, field strength should be less than [V1] V/m

Table 3: PainShield® MD Recommended Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the PainShield® MD			
The PainShield® MD is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the PainShield® MD can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PainShield® MD as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter, m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ Separation Distance, meters	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$ Separation Distance, meters	800 MHz to 2.5 GHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$ Separation Distance, meters
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.7	23.33
For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer. V1 is COMPLIANCE LEVEL for the IEC 61000-4-6 test and E1 is the COMPLIANCE LEVEL for the IEC 61000-4-3 test. V1 and E1 are in V/m. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix B: Specifications

Driver model FD-14A

Frequency:	90 kHz ± 0.001 kHz
Voltage output:	12 V p-p
Current output:	Up to 0.3 A RMS
Rechargeable battery:	Lithium-Ion, 3.7V, 1200mAh (full charging time ~ 2 h)
Dimensions:	113 mm (L) x 39.4 mm (W) x 12.6 mm (h)
Weight:	Approximately 70 g
Housing:	ABS

Treatment patch

	Model PRP-20	Model PRP-40
Acoustic power:	0.4 W	0.4 W
Frequency:	90 kHz ± 0.001 kHz	90 kHz ± 0.001 kHz
Beam Non Uniformity Ratio (BNR)	6:1	6:1
Effective radiating area (ERA)	6 cm^2	6 cm^2
Adhesive area	33 cm2	25 cm^2
Dimensions	120 mm x 50 mm x 6 mm	75 mm x 55 mm x 6 mm
Weight	10 g	6 g
Color	Beige	Beige
Reuse	Approximately 7 times	Approximately 7 times

Charger

Voltage input:	100-240 VAC, ~ 138 mA, 50/60 Hz
Output:	5 VDC, 1 A

Note: Use an appropriate adaptor for local mains.

Appendix C: Labels

Figure 1 and Figure 2 show the PainShield® MD labels.

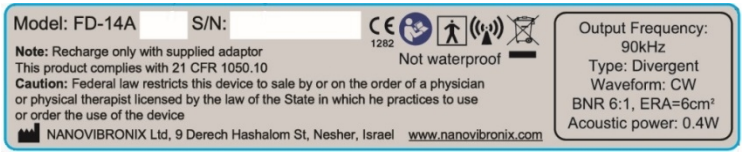


Figure 1: Driver Label

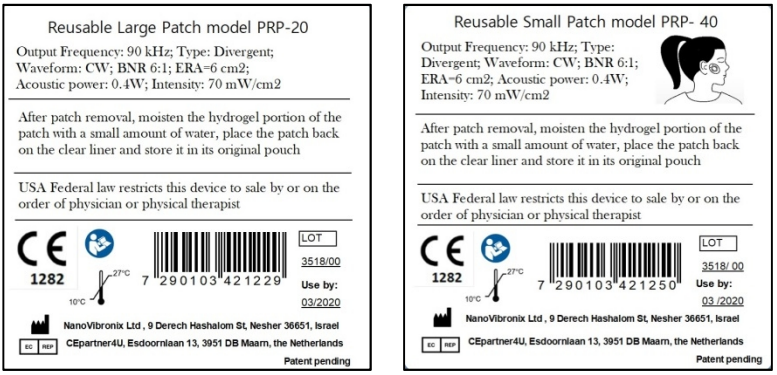


Figure 2: Patch Labels

Appendix D: Symbols

	CE mark
	Refer to instruction manual/ booklet
	Type BF applied part
	Rated frequency or rated frequency range(s) (Hz)
	Separate collection for electrical and electronic equipment
	Manufacturer
	Temperature limits
EC REP	Authorized representative in the European Community
LOT	LOT
BNR	Beam nonuniformity ratio
S/N	Serial number
ERA	Effective radiating area
W	Watt (1W = 1000mW)
0.4W	Power output 0.4 watts
CW	Continuous wave
mW/cm^2	Milliwatt per square centimeter
cm^2	Square centimeter
kHz	Kilohertz (1 kHz = 1000 Hz)

Appendix E: Warranty

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

The liability of NanoVibronix under this warranty is limited to the repair or replacement (at NanoVibronix's choice) of any allegedly defective part or parts under warranty by NanoVibronix at its expense. The defective driver shall 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, accident, (including but not limited to fire, water, explosion, smoke, or vandalism) or which has not been operated in compliance with NanoVibronix instructions of 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.