NANOVIBRONIX™

PainShield® MD

User Manual

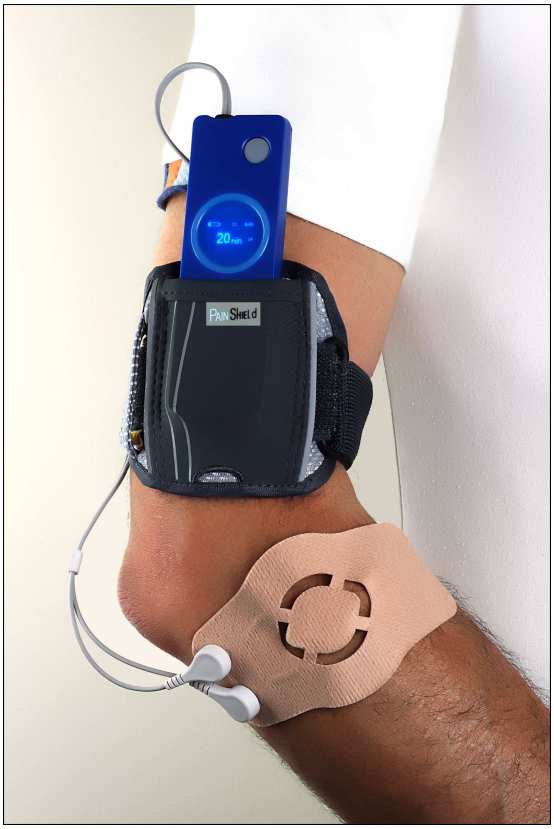

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Table of Contents

General Information

Introduction to ultrasound

Ultrasound is a form of acoustical vibration occurring at frequencies above the 20 kHz perception limit of the human ear. Ultrasound therapy effectiveness depends on transmitting pressure and displacement waves through body tissues. Since the body is composed of a variety of tissue types, the penetration depth will depend on the thickness of each tissue in the pathway of the ultrasound beam.

Therapeutic ultrasound is produced through a reverse piezoelectric effect. Electric signals produced by the driver are delivered to an electrode that is in contact with the piezo electric element. The signal applied to the piezo element surface produces mechanical vibrations, or the so-called reverse piezoelectric effect.

The ultrasound power is expressed in watts (W). The average intensity in watts per square centimeter (W/cm^2) is obtained by measuring the total output of the ultrasound transducer and dividing it by the effective area of the radiating surface.

High frequency waves (megahertz range) are absorbed rapidly with consequent reduction in penetration. Conversely, lower frequencies (kilohertz range) support wave penetration and may lead to greater energy deposition.

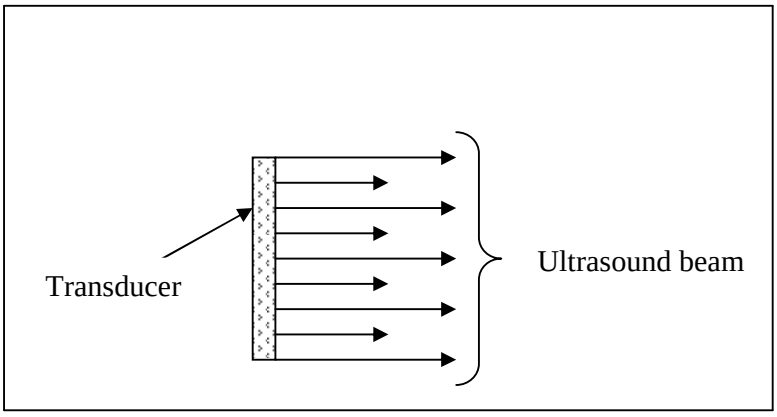


Figure 1 Principal scheme of ultrasound beam radiation

The PainShield® MD Device

Ultrasound energy has been widely used to treat pain and muscle spasms and to temporarily improve local circulation. In addition, ultrasound has been used to treat post-operative pain and for physiotherapy.

PainShield MD applies ultrasound energy through a treatment patch that is placed at, or close to, the center of the painful area. The user may feel minor warmth at the treatment patch site during the treatment period. PainShield MD should be used under the prescription of a physician or physical therapist.

PainShield MD is comprised of two elements: a treatment patch that contains the transducer which delivers ultrasound waves and a portable battery-operated driver unit.

Definitions

Driver	Electronic unit providing the electrical signals to the ultrasound transducer.
Ultrasound Transducer	Piezoelectric element, incorporated in the treatment patch, which converts the electrical signals into ultrasound treatment energy.
Treatment patch	Self-adhering patch, incorporating the ultrasound transducer that comes in direct contact with the treatment area.
Charger	Device for recharging the battery within the driver.

Symbols

	Type BF applied part		CE mark
	Do not reuse	**SN**	Serial number
	Caution, consult accompanying documents		LOT
	Manufacturer		Rated frequency or rated frequency range(s) (Hz)
	Separate collection for electrical and electronic equipment		Authorized representative in the European Community
	Use by YYYY-MM-DD or YYYY-MM	**BNR**	Beam nonuniformity ratio
0.4W	Power output 0.4 watts	**ERA**	Effective radiating area
CW	Continuous wave	**W**	Watt 1W = 1000mW
mW/cm^2	Milliwatt per square centimeter	**cm^2**	Square centimeter
kHz	Kilohertz 1 kHz = 1000 Hz	**Rx only**	Caution: 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 that person practices to use or order the use of the device.

Important General Safety Cautions and Notices

This product was designed and manufactured to ensure maximum safety of operation. It should be operated and maintained in strict compliance with the safety precautions, warnings and operating instructions contained in this manual.

The product in whole or in part shall not be modified in any way. No part should be replaced with components or parts other than with those supplied by NanoVibronix.

PainShield MD is a stand-alone device and should not be connected to any other device/system except to its own accessories.

Servicing, repairs and opening of the device may be carried out only by authorized personnel.

- PainShield MD is classified as internally powered, continuous operation ordinary equipment with a disposable type BF applied part. The device is not intended for use in the presence of flammable mixtures.
- The PainShield MD device is not waterproof and therefore should not be immersed in water or other liquid.
- Do not clean the device during charging, or while the unit is switched on.
- Do not wear or operate while bathing or showering.
- The PainShield MD device should be used only in the manner described in this User Manual.
- PainShield MD device should not be used while in charging mode.
- Does not use if the driver or any part of the equipment appears to be damaged.
- Since the driver contains a rechargeable lithium-ion battery:
  - Do not disassemble
  - Do not heat above 100°C
  - Do not incinerate or expose device to water.

Clinical Information

Caution: 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 that person practices to use or order the use of the device.

Indications for Use

PainShield MD diathermy device 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

- Do not use in patients with cancer and bone metastases.
- Do not apply over bone growth centers until bone growth is complete.
- Do not apply directly on the eye.
- Do not apply directly over ischemic tissues in individuals with vascular disease.
- Do not use in patients who are pregnant over the uterus.

Precautions

- Do not place the treatment patch directly on an open wound.
- In children, it is preferable to avoid usage over the epiphyseal growth plate area.
- Use with caution following a laminectomy when major tissue removal has occurred.
- Use with caution over anesthetic areas or areas of impaired skin sensitivity.
- Use with caution when hemorrhagic diathesis is present.
- Treatment of children should be performed under adult supervision.
- The safety and effectiveness of PainShield MD has not been established in patients who are being treated by, or who have received, other medical devices including but not limited to pacemakers, electrical stimulators, radiofrequency generators, surgical meshes, Intra-Uterine Devices (IUDs), or other surgical implants.
- Following treatment, some redness might occur in the treated area. This redness should resolve on its own within a few hours.

If the redness persists, or if you experience a rash, itching, pain, swelling or any other abnormality, immediately stop using the device and consult with your medical professional.

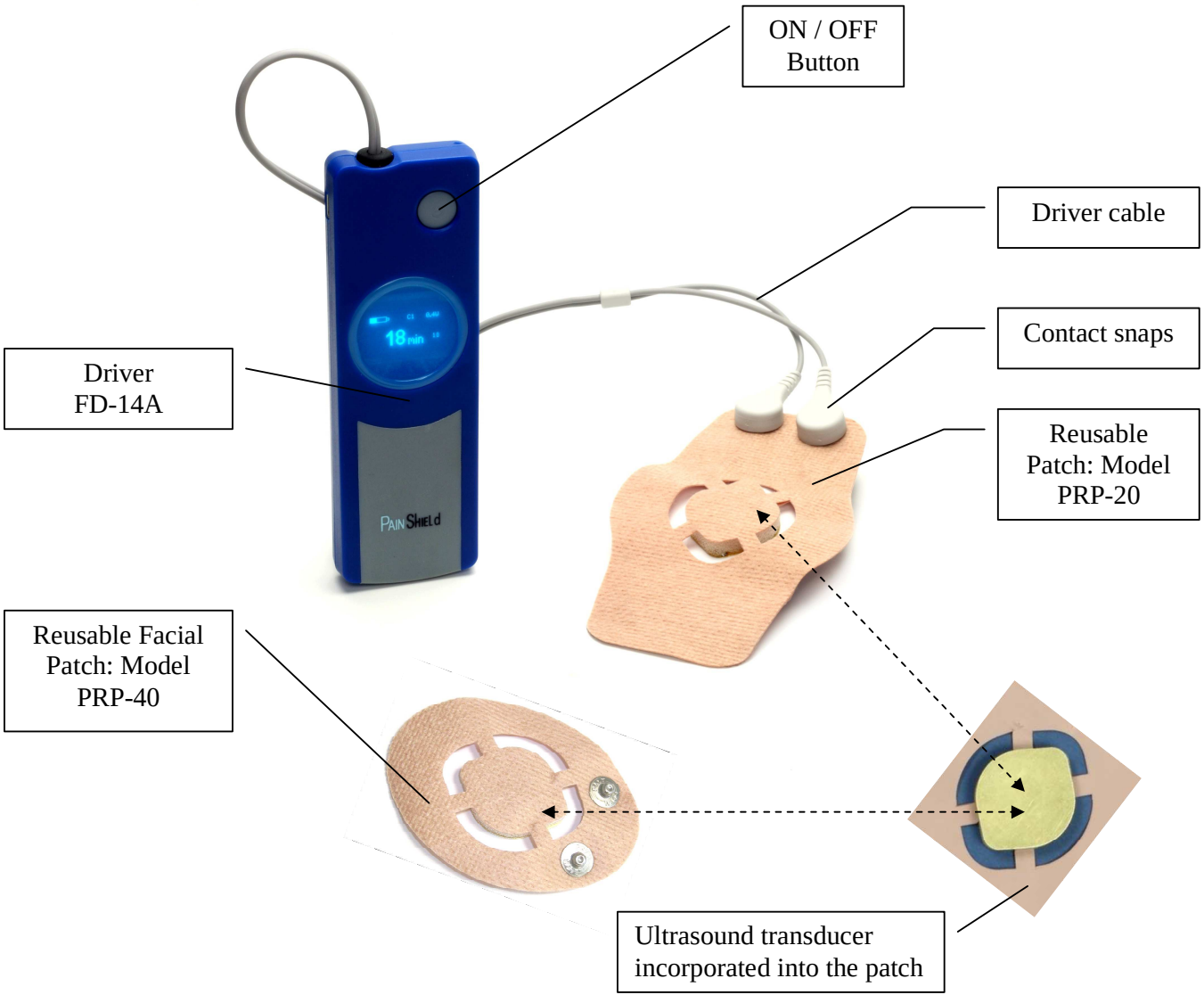
- The safety and effectiveness of this device in pregnant women or children has not been established.
- Use with caution in patients who have experienced adverse reactions to other forms of ultrasound.

General Description

The PainShield MD device produces ultrasonic waves for the relief of pain and muscle spasms, and for improvement of local circulation. The device includes a rechargeable battery-powered driver unit that connects with a cable to a treatment patch. The ultrasonic waves are generated by a transducer that is incorporated into the treatment patch. The treatment patch should be placed on or next to the desired treatment area. For maximal effectiveness, the transducer should be in full contact with the skin.

Two treatment patch types are available for use: The Reusable Patch (Model PRP-20) and the Reusable Facial Patch (Model PRP-40).

PainShield MD Device



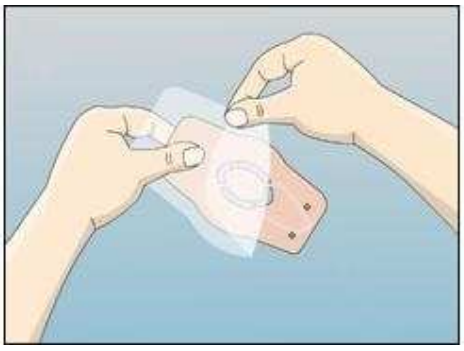
PainShield MD Operation

Pre-Use Preparations

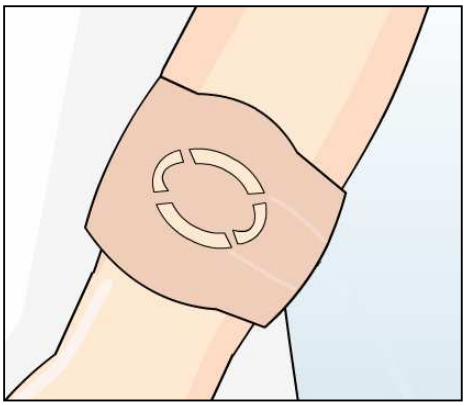
1. Ensure that the driver is charged. If required, charge according to instructions (see page 15).
2. Prior to attaching the treatment patch to the skin, ensure that the designated area is clean and dry.
3. Remove excess hair from the area prior to patch application.
4. Carefully cut open the pouch containing the treatment patch. Keep the pouch to store the patch between uses.

Using PainShield MD treatment patch

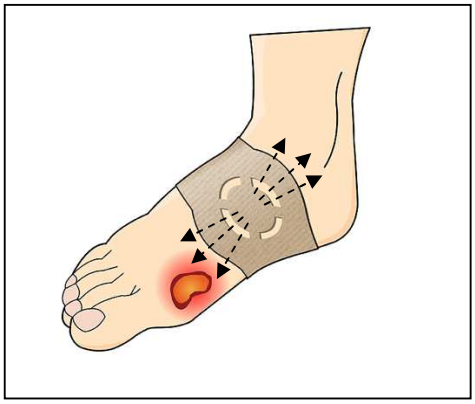
1. Remove the transparent protective liner from the treatment patch. Save the liner to protect the patch during storage after patch use.



2. Attach the treatment patch to the skin with the adhesive side down over, or as close to, the area where the pain is most intense.
   Ensure that the ultrasound transducer is in full contact with the skin.



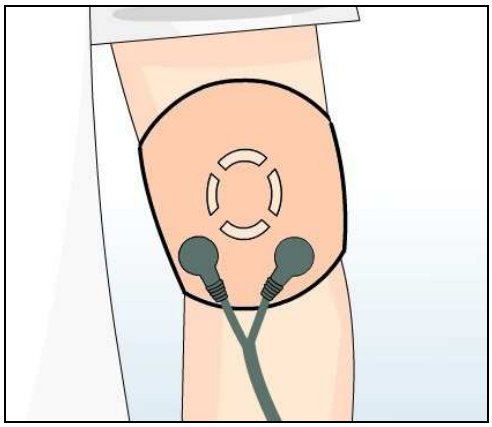
Treatment patch placed directly over the location of pain.



Due to the oval shape of the transducer, ultrasound waves mainly propagate directionally as per illustration.

Place the treatment patch directly over the location of the pain. If skin integrity is compromised in that area, place the patch on healthy skin with long edge of the oval ultrasound transducer adjacent to the lesion (see illustration).

3. Connect the patch to the cable from the driver using the snap connectors. It does not matter which connector connects to which terminal on the patch.



4. Press the ON/OFF button on the driver for about 2 seconds until you hear a beeping sound indicating that the device is turned on. The driver requires a few seconds to initialize and then displays the information screen.
5. PainShield MD delivers ultrasound therapy for 6 ½ hours, after which it turns off automatically. During treatment, a screen saver is activated. To return to the normal information screen, briefly press the ON/OFF button.
6. It is possible to turn off the device at any time by pressing the ON/OFF button and holding it for 2 seconds.

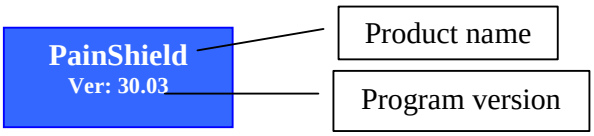
The reusable patch (Model PRP-20) may be used a number of times because of its hydrogel adhesive that may be refreshed. The reusable patch can be used as long as the patch and ultrasound transducer remain firmly adherent to the treatment area.

The reusable facial patch (Model PRP-40) provides the same treatment as the PRP-20 treatment patch, but has a smaller adhesive area and is intended for use when adhesion area is limited, such as facial application for patients with Trigeminal Neuralgia (***See additional details in Appendix I).***

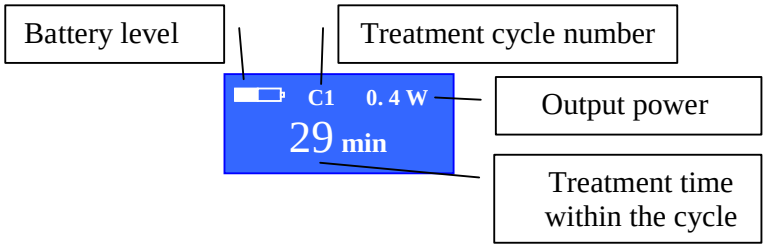
For both patches, following therapy, first disconnect the cable snaps from the patch and then gently remove the patch from the skin. Once fully removed, lightly moisten the hydrogel portions of the patch using a small amount of water, then place the patch on the transparent protective liner and store it in its original pouch.

PainShield MD User Interface (Screens)

1. Driver turned on



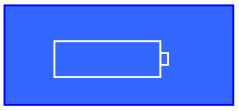
2. Active mode



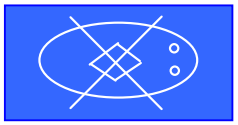
Treatment screen indicates treatment phase.
Each cycle has an active period of 30 minutes followed by an inactive (IDLE) period of 30 minutes.
The PainShield MD is active for 6 ½ hours and then it shuts down automatically.
During treatment, a screen saver is activated. To return to normal screen, briefly press the ON/OFF button.
It is possible to turn the device off at any time by pressing the ON/OFF button and holding it for 2 seconds.

3. IDLE mode

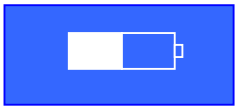
4. Battery is discharged and requires charging



5. Treatment patch is disconnected or damaged



6. Charging in progress



7. Driver is turning off

Charging the PainShield MD Driver

1. When the battery is discharged, the on-screen battery icon blinks and a beeping sound indicates that the battery requires recharging. It is advisable to charge the driver prior to each use, in order to assure 6 ½ hours of activation.
2. Turn the driver off by pressing the ON/OFF button. Disconnect the patch from the driver before charging. Connect the charger to the driver socket and plug the adaptor into a wall outlet.
3. The battery icon on the driver screen indicates that battery charging is in progress.
4. Complete charging process takes approximately 2 hours.
5. When the battery is fully charged, the on-screen battery indicator will remain illuminated.

CAUTION! PainShield MD should not be used while charging.

CAUTION! Use the original charger only.

Signals and Alarms *(see device view on page 10)*

Signal or Alarm	***What it Means***
The driver screen is lit.	The device is working properly.
The patch indicator on the screen flashes and an audible alert is heard.	The treatment patch is not connected properly or it has been damaged and should be replaced.
The battery indicator on the screen flashes and an audible alert is heard.	Low battery – Recharging is required.
The battery indicator on the screen is filling up sequentially.	The driver is being charged.
The battery indicator on the screen is full and is lit continuously.	Charging is complete.
The driver screen is not lit.	The driver is turned off.

Specifications

Driver model FD-14A

Frequency	90 kHz ± 0.001 Hz
Voltage output	12 V p-p
Current output	Up to 0.3 A rms
Rechargeable battery:	Lithium-ion (full charging time ~ 2 h)
Dimensions:	125 mm (h) x 39.4 mm (w) x 12.6 mm (d)
Weight:	~ 70 g
Housing:	ABS

Treatment patch

Model and type	**Reusable PRP-20**	**Reusable Facial PRP-40**
Acoustic power:	0.4 W	0.4 W
Frequency	90 kHz ± 0.001 Hz	90 kHz ± 0.001 Hz
Beam non uniformity ratio (BNR)	6:1	6:1
Active treatment area ERA	6 cm^2	6 cm^2
Adhesive area	33 cm^2	25 cm^2
Dimensions	120 mm x 70 mm x 6 mm	75 mm x 55 mm x 6 mm
Weight	10 g	6 g
Color	Beige	Beige
Usage	Multiple uses (Approximately 7 treatment sessions)	Multiple uses (Approximately 7 treatment sessions)

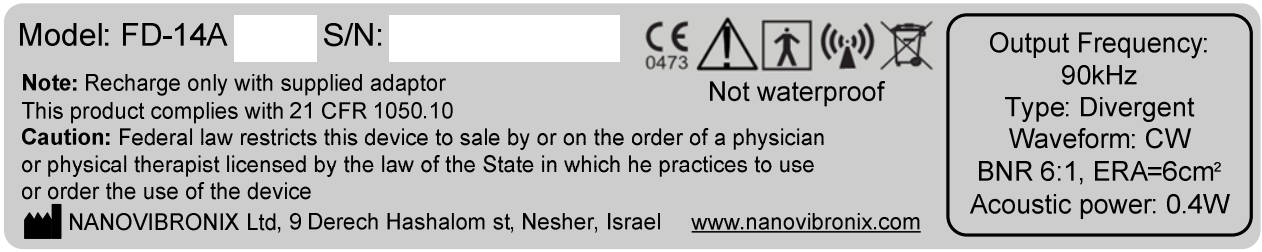
Charger

Voltage input:	100-240 V ac, ~ 138mA, 50/60 Hz
Output:	5V dc, 1A

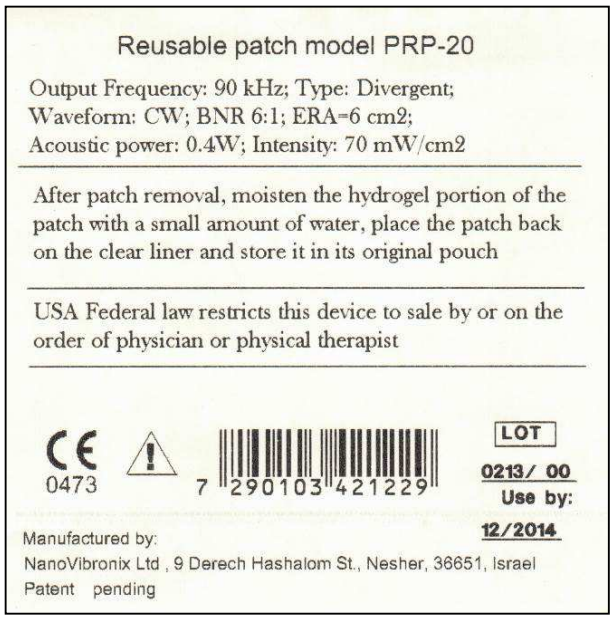
Note: Use an appropriate adaptor for local mains.

Labels

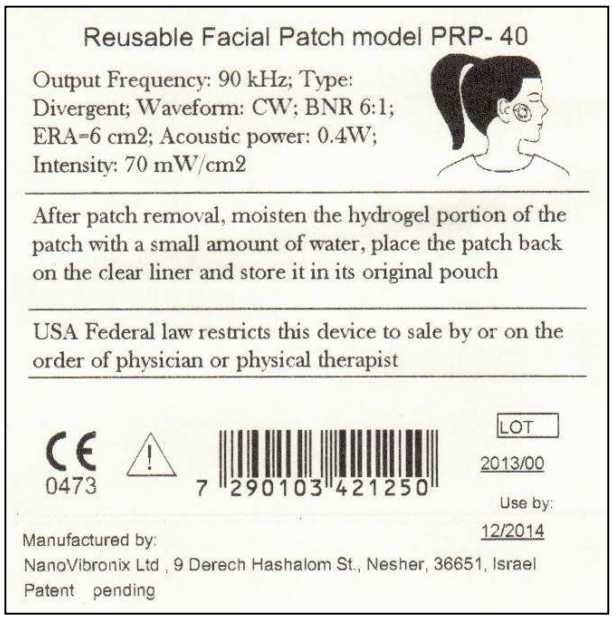
PainShield MD driver label



Reusable treatment patch label



Reusable facial treatment patch label



Electrical Hazards

- Do not attempt to open the PainShield MD device, to remove any of its panels, or to open any covers.
- When recharging, always use the charger which was supplied with the device.
- Do not plug the device in for recharging when barefoot or with moisture on your hands**.**
- Do not immerse in water or other liquid.
- Do not wear or operate while bathing or showering.

Electromagnetic Compatibility

PainShield MD complies with IEC 60601-1-2 EMC standard for medical devices. PainShield MD is suitable for use in an electromagnetic environment, as per the limits and recommendations described in the tables hereafter:

- Emission Compliance Level & Limits (Table 1).
- Immunity Compliance Level & Recommendations to Maintain Equipment Clinical Utility (Table 2 and Table 3).

Note: This system complies with above mentioned EMC standard when used with supplied power supply.

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 device 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. The PainShield MD is predominantly intended for use with an appropriate power supply.
Harmonic emissions, IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IES 61000-3-3	Complies	

Table 1 - PainShield MD Electromagnetic Emission.

Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
PainShield MD device is intended for use in the electromagnetic environment specified below. The customer or the user of the PainShield MD device 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 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.
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 device during continued operation will not be affected by power mains interruptions, since PainShield MD is battery powered. During system charging, it is recommended that PainShield MD device be powered by an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a. c. mains voltage prior to application of the test level.			

Table 2 - PainShield MD Electromagnetic Immunity.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The PainShield MD device is intended for use in the electromagnetic environment specified below. The user of the PainShield MD device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 3 Vrms 80MHz to 2.5GHz	[*V*1] V [*E*1] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PainShield MD, 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 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 MD is used exceeds the applicable RF compliance level above, the PainShield MD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PainShield MD. [b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than [*V*1] V/m			

Table 3 - PainShield MD Electromagnetic Immunity (Continued)

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the PainShield MD device

The PainShield MD device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the PainShield MD device 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. *V*1 is COMPLIANCE LEVEL for the IEC 61000-4-6 test and *E*1 is the COMPLIANCE LEVEL for the IEC 61000-4-3 test. *V*1 and *E*1 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.

Table 4 - Recommended Separation Distances

Product Classification

Low risk device classification:

CE Mark - Class II a
FDA Clearance - Class II
Health Canada License - Class II

Compliance with Standards

IEC 60601-1:2001; IEC 60601-2:2001
ISO 10993

Storage and Maintenance

Store PainShield MD device under the following conditions:
Temp: 0-40 °C; Humidity: 20-85%.
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 mixtures.

Treatment Patch Shelf life

According to expiration date, printed on the patch package label.

Operational period

The driver is intended to undergo up to 400 charging cycles.
The reusable treatment patch should be used for approximately 7 treatment sessions.

Cleaning

The driver unit can be wiped with disinfecting medical wipes.

CAUTION! Do not use solvents (such as acetone), as they may damage the product.

Troubleshooting

(See also Signals and Alarms – page 15)

Problem	Required action
The battery icon on the screen is blinking and an audible alarm is heard.	Low battery – charging is required.
A patch icon is displayed on the screen and an audible alarm is heard.	Patch is either disconnected or non-functional - check that the driver cable is connected correctly to the patch's snaps or replace the treatment patch. Before patch replacement, turn the driver off.
The cable snaps connectors are loosened when connected to the patch.	Please contact the NanoVibronix local representative.

Frequently Asked Questions

Question	Answer
Can I put the patch over an open wound?	The patch should never be placed on an open wound; it should be placed on the healthy skin nearby the wound.
I do not feel anything during the treatment procedure. Is the device working properly?	The PainShield MD ultrasound waves are not felt and may produce, during treatment, only slight warming at the treatment patch site.
How can I order additional patches?	Please contact NanoVibronix or its local distributor.
How do I place the patch correctly?	The user should ensure that the ultrasound transducer is placed directly on healthy skin over the source of pain and that the treatment patch is in full contact with the skin.
How can I extend reusable patch usage?	After patch removal, moisten the hydrogel portion of the patch with a small amount of water, place the patch back on the clear plastic liner and store it in its original packaging
When will I feel relief?	Pain reduction could begin as early as 30 minutes after treatment and up to several hours or days. PainShield MD is believed to work by improving blood flow to muscles and tissues that are in spasm and by normalizing nerve activity.
Should I discontinue other therapies while using PainShield MD?	You may feel that you can reduce your use of opioids, analgesics and other prescription or non-prescription medications. You should consult with

	your doctor or other medical professional any time you feel you need to make any changes in your medical treatment.
Can PainShield MD be used with physical therapy?	Yes. PainShield MD is perfectly suited to be used in concert with a program of physical therapy and can be used in between therapy sessions.
Do I need to program PainShield MD or to change any settings?	No. The only control is the ON/OFF button. PainShield MD is simple to use and requires no programming or selection of settings.
Do I need to use an ultrasound gel under the PainShield MD patch?	No. You should not use ultrasound gel with PainShield MD.
Will I feel any vibrations or shocks from the device when it is on?	Other than mild warmth from the metal transducer in the center of the patch you will feel no vibrations or electric shocks.

Service

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

Addresses

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Appendix I

Application of Reusable Facial Patch for Trigeminal Neuralgia

PainShield MD use should start gradually with the first and second treatments lasting 2 and 4 hours, respectively, during day time. Subsequent treatments should be administered for 6 ½ hours on a daily basis and may be performed overnight, with the PainShield MD removed upon wakening.

1. Connect the PainShield MD cable to the patch snaps. See Fig.1

2. Remove the protective liner from the facial patch. See Fig.1

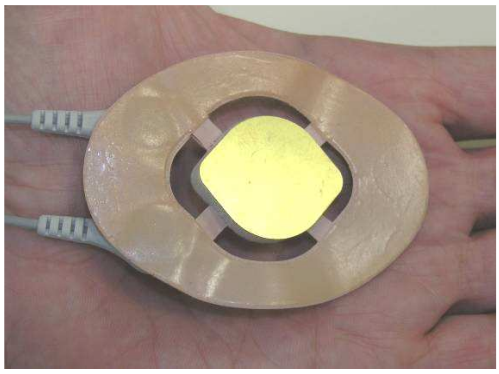

Fig. 1

3. Place and adhere the facial patch so that it is abutted next to a bony prominence in the painful region; such as the zygomatic arch (cheek bone) in V2 pain or the lower mandible area (lower jaw bone) in V3 pain (See Fig. 2). In cases when local sensitivity makes patch application painful, the treatment patch should be applied on the forehead on the non-painful side.

Fig. 2

4. Turn the PainShield MD ON.

Notes:

- Ensure that ultrasound transducer (flat metal part of the treatment patch) is in full contact with the skin.
- When used overnight, use a wrap type dressing (e.g. Nexcare 3M Athletic Wrap) to secure the patch and wrap twice around the head (Fig. 3).

The treatment patch is effective for 50 hours of use and should be used for up to 7 treatment sessions.

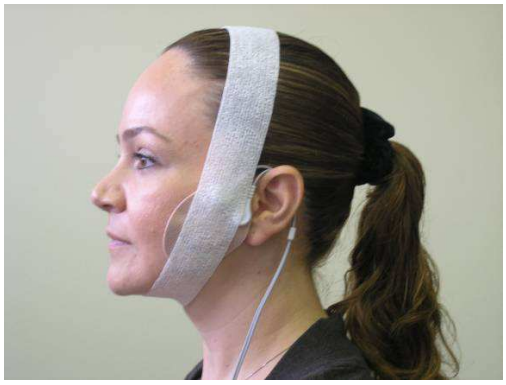

Fig. 3

Notes: