NANO VIBRONIX™
Curing through prevention

Pain Shield ™ MD

User Manual

Cat. # PSUM003
Ver. 03 (USA)

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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 actually 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.

Ultrasonic power is expressed in watts (W), or watts per square centimetre (W/cm^2). Average intensity (W/cm^2) is obtained by measuring the total output of the applicator (in watts) and then divided by the size of the effective radiating area of the applicator.

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.

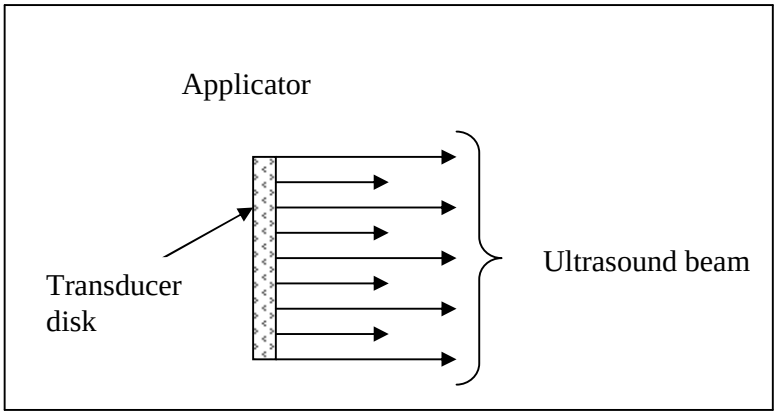


Figure1. Principal schema of Ultrasound beam radiation

The PainShield Device

Ultrasonic diathermy is known to treat pain, muscle spasms and to provide temporary improvement in local circulation. In addition, ultrasound has been used to treat post operative pain and for physiotherapy.

PainShield MD applies ultrasound energy through an Applicator that is placed at the epicenter of the pain. The user may feel minor warmth at the Applicator site during the treatment period. PainShield MD should be used under the prescription of a physician or physiotherapist.

The PainShield MD is comprised of two elements: an Applicator that delivers ultrasound waves and a portable Driver unit that is battery operated.

Definitions

Driver:	Electronic unit that provides the electrical signals to the transducer incorporated into the treatment patch.
Ultra sound transducer	Piezoelectric element which converts the electrical signals into ultrasound waves.
Applicator	Treatment patch with incorporated ultrasound transducer that comes in direct contact with the treatment area. Two variants are available: single attachment or reusable applicator.
Single attachment applicator	A treatment patch intended for single attachment and can be used for several treatments, until removal.
Reusable applicator	A treatment patch intended for multiple treatments by a single patient.
Charger:	Device for battery recharging.

Symbols

	Class 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
	Used by YYYY-MM-DD or YYYY-MM	**BNR**	Beam non uniformity ratio
0.4W	Power output 0.4 watts	**ERA**	Effective radiating area
CW	Continues wave	**W**	Watts
mW/cm^2	Miliwatt (s) per square centimeter, 1W=1000mW	**cm^2**	Square centimeters
kHz	1Kilohertz =1000 Hz		

Important Notices

WARNING!	The unit 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.
WARNING!	PainShield MD device is not waterproof and therefore should not be immersed in water or other liquid.
WARNING!	Do not place the treatment patch directly over an open wound.
ATTENTION!	PainShield MD device should be used by the order of a physician.
ATTENTION!	Following treatment, some redness might occur in the treated area. The redness should naturally be resolved after a couple of hours.
ATTENTION!	PainShield MD device should not be used while in charging mode.
CAUTION!	PainShield MD device should be used only in the manner described in this User Manual.
CAUTION!	The device contains rechargeable Lithium-ion batteries: • Do not disassemble • Do not heat above 100°C • Do not incinerate or expose device to water
CAUTION!	Treating of children should be done under adult supervision.

Clinical Information

Intended 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

- Cancer and bone metastases
- Over bone growth centers until bone growth is complete
- Directly on the eye
- Directly over ischemic tissues in individuals with vascular disease

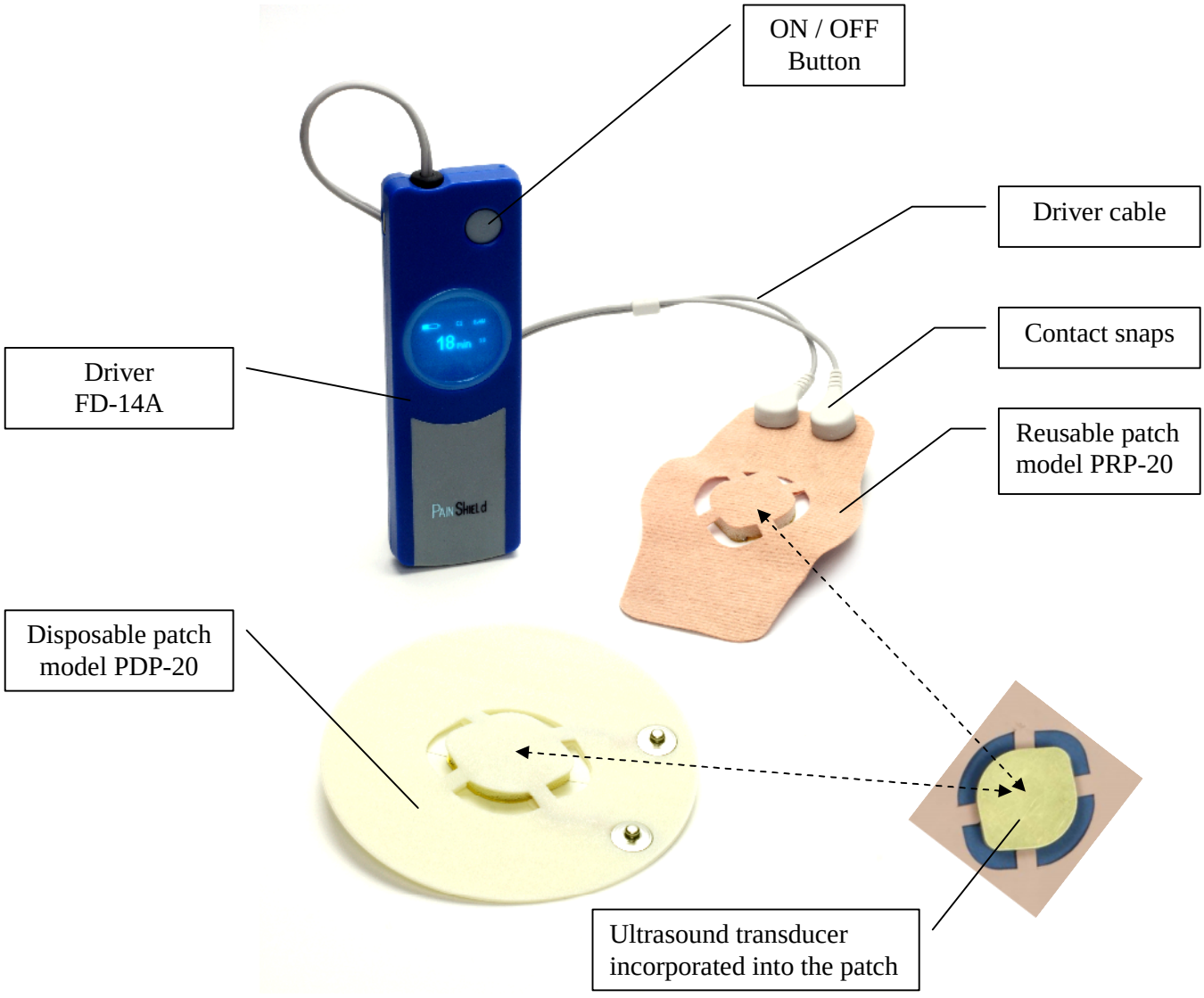
Precautions

- In young children it is preferable to avoid usage over the epiphyseal growth plate area.
- When hemorrhagic diathesis is present.
- Pregnant women should be treated only with physician consent

General Description

The Pain Shield MD device produces low frequency, low intensity ultrasonic waves for the relief of pain, muscle spasm and improvement of local circulation. The device includes a rechargeable battery powered driver unit that connects with a cable to an applicator. The ultrasonic waves are generated by a transducer that is incorporated into the applicator. The applicator should be placed on or next to desired treatment area. For maximal effectiveness – the transducer should be in full contact with the skin.
Two applicators are available for use: Single attachment patch and Reusable patch.

PainShield MD device



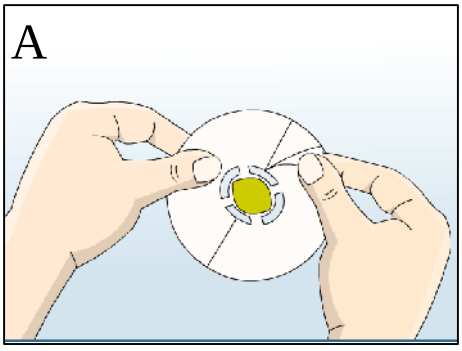
PainShield MD Operation

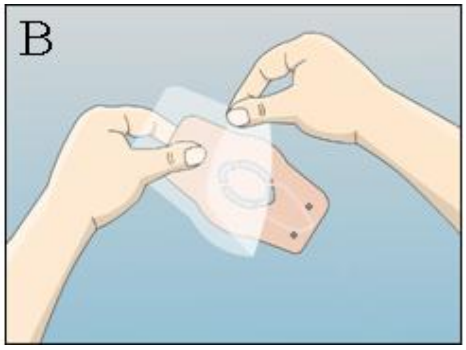
Pre-Use Preparations

1. Ensure that the driver is charged. If required, charge according to instruction (See page 13).
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

Using PainShield MD Applicator

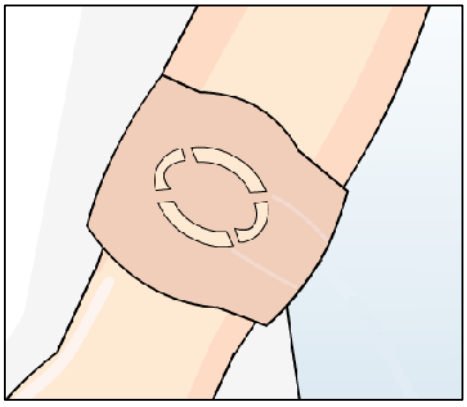
1. Remove the protective layer from the single attachment (A) or reusable (B) treatment patch, respectively. The protective layer of single attachment patch can be disposed of, while the layer of reusable treatment patch will be reused for storing.



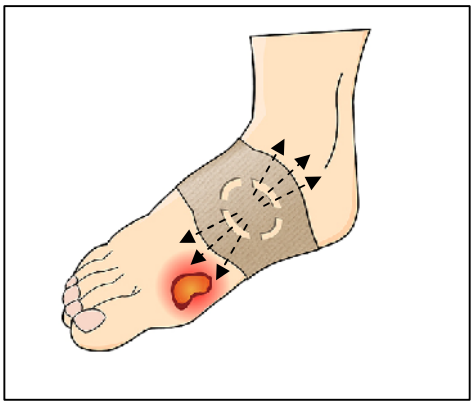


2. Attach the treatment patch to the skin over the area where the pain is most intense or adjacent to the treated wound.
   Ensure that ultrasound transducer is in full contact with the skin.

The patch is attached to the skin



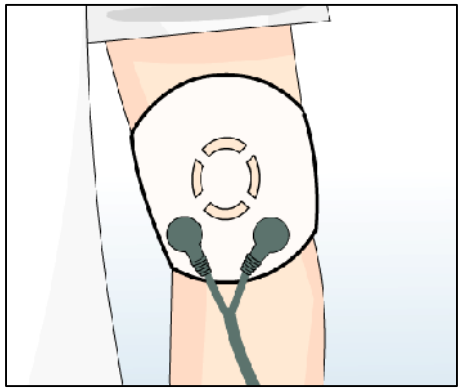
Treatment patch placed directly over the location of the pain.



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 oval edge of the active element adjacent to the lesion (see illustration).

3. Connect driver cable to the treatment patch snaps.



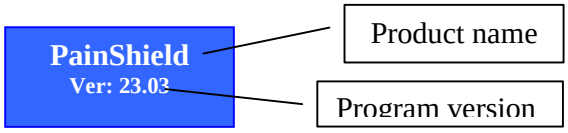
4. Press the ON/OFF button at the upper side of the device for about 2 seconds till you hear a beeping sound to turn the device on.
5. Pain Shield is active for 6.5 hours and then it shuts off automatically. During treatment, a screen server is activated. For returning to normal screen press shortly the ON/OFF button.
6. It is possible to shut off the device at any time by pressing the ON/OFF button and hold it during 2 seconds.

The single attachment patch can be used as long as the patch remains adherent to the treatment area. Before each treatment connect the cable to the patch snaps. After the patch has been removed, it should be disposed of. Never pull the single use patch away from the skin by pulling on the cable. To remove the patch, first disconnect the cable snaps from the patch and then gently remove the patch from the skin (using alcohol to dissolve the adhesive).

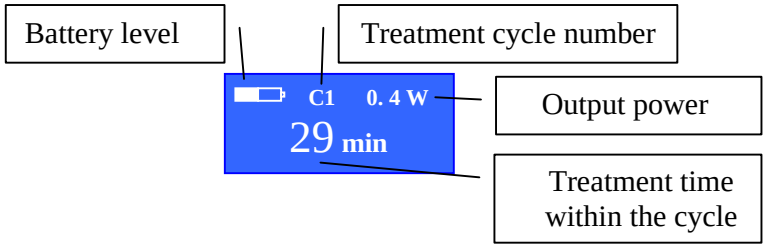
The reusable patch may be used multiple times due to a hydro gel adhesive that may be refreshed. Gently moisten the hydro gel portions of the patch using water before storage. It should then be placed back on the transparent protective layer. Once this is done the patch can be stored in its original silver pouch.

PainShield MD user interface (screens)

1. Driver turned on

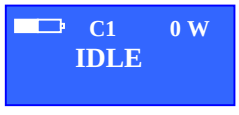


2. Active mode

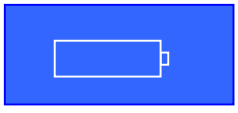


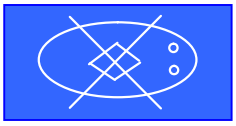
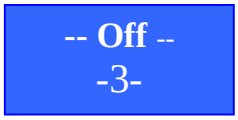
Treatment screen indicates treatment phase.
Each cycle has an active period of 30 min. followed by an IDLE period of 30 min.
The PainShield is active for 6.5 hours and then it shuts down automatically.
During treatment, a screen saver is activated. For returning to normal screen, press shortly the ON/ OFF button.
It is possible to turn the device off at any time by pressing the ON / OFF button and hold it during 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 battery recharging is required.
   It is advised to charge the driver prior to each use, in order to assure 6.5 hours of activation.
2. Turn driver off, by pressing ON/OFF button. After 1 minute connect the charger to the driver socket and then plug the adaptor to the wall outlet.
3. Battery icon on the driver screen will indicates battery charging process.
4. Complete charging process takes approximately 5 hours.
5. When the battery is fully charged, the on the screen battery indicator will stay constantly lit.

CAUTION! PainShield MD should not be used while charging.

CAUTION! Use original charger only

Switch and Alarms (see the device view on the page 9)

- The driver screen is lit – the device is working properly.
- The Patch indicator on the screen flashes and an audible alert is heard – 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 lits continuously – charging is completed.
- 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 ~ 6 h)
Dimensions:	113 mm (h) x 39.4 mm (w) x 12.6 mm (h)
Weight:	~ 70 g
Housing:	ABS
Holding accessories (optional):	Hanging strip / pouch

Applicator

Patch model and type	**Reusable PRP-20**	**Single attachment PDP-20**
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	40 cm^2
Dimensions	120 mm*50 mm*6 mm	Ø100 mm
Weight	10 g	5.6 g
Color	Beige	White
Usage	Multiple uses by a single patient (Approx. 4-5 treatment sessions)	Single-attachment; can be reused for several treatments, until removal

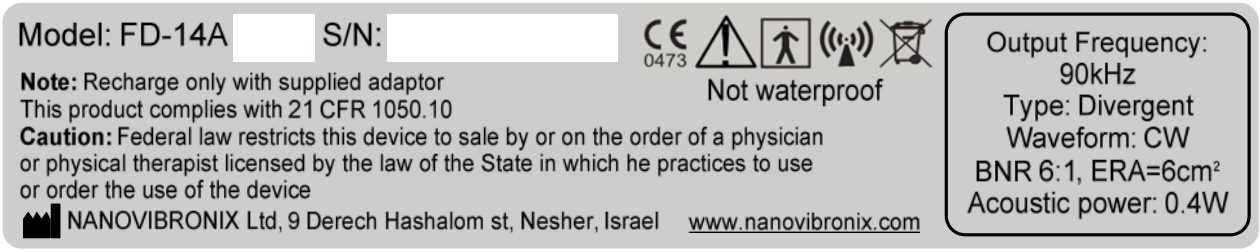
Charger

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

Note: use an appropriate adaptor for local mains

Labels

PainShield MD driver's label



Single attachement treatment patch label

Reusable treatment patch label

Safety Measures

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 then the originals 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.

CAUTION! Cleaning of the device, should not take place during charging.

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

Product classification

Low risk device classification:
CE mark-Class II a
FDA clearance- 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.

Patch Shelf life

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

Operational period

The Driver is intended undergo up to 300 charging cycles.
The single attachment treatment patch can be reused until removal from the skin.
The reusable treatment patch is effective for 40-50 hours of use and should not be used for more than 10 treatment sessions.
Before storage moisten the hydro gel portion of the patch with a small amount of water. Then place the patch back on the clear plastic liner. Once this is done the patch can be stored in its original silver pouch.

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

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

Frequently Asked Questions

Question	Answer
Can I use the single attachment treatment patch again, as it looks like new?	No, the single attachment patch is designed for a single attachment and can be reused for several treatments, until removal
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 health skin nearby the wound
I do not feel anything during the treatment procedure. Is the device working properly?	The PainShield ultrasound waves are not felt and may produce, during treatment, only slight warming at the Applicator site
How I can order additional patches?	Please contact NanoVibronix' local representative
How do I place the patch correctly?	The user should ensure that ultrasound transducer is placed directly on healthy skin over the source of pain and the applicator is in full contact with the skin
How I can extend reusable patch usage?	After patch removal, moisten the hydro gel 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 **Do not use alcohol for reusable hydro gel patch removal**
How can I easily remove the single attachment treatment patch?	Use disinfecting medical wipes to dissolve the single attachment patch adhesive.
Can I use additional bandage for patch attachment?	**Not recommended**. The bandage can remove hydro gel portions from the patch.

Addresses

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