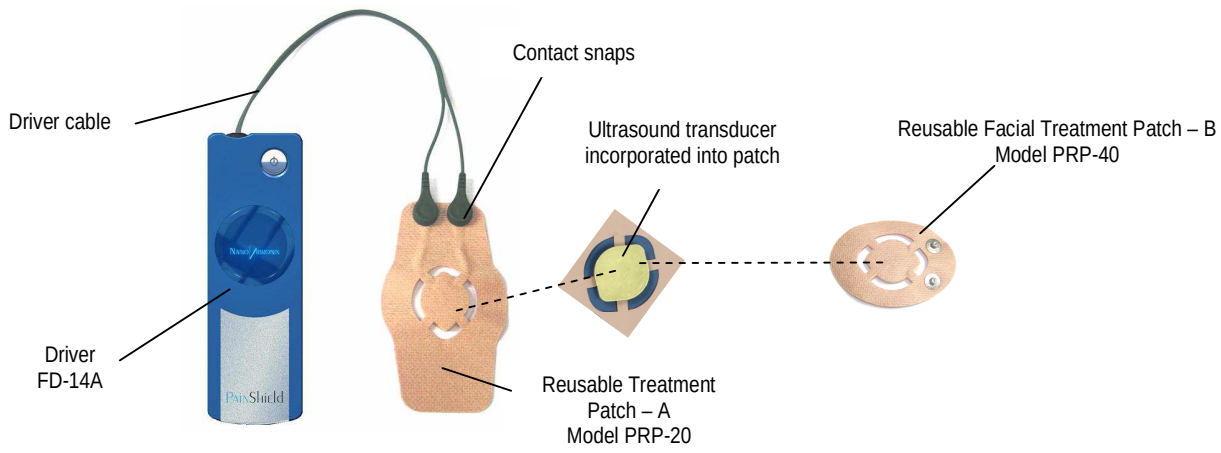
PainShield® MD Instructions for Use

Attention – this guide provides the basic principles of operation for the PainShield® MD device. It is not intended to replace the complete User Manual. Please read the complete manual (PSUM003) before using PainShield MD and make sure that you understand all aspects of PainShield MD operation.



PainShield MD is a microprocessor controlled therapeutic ultrasound device that produces low-frequency, low-intensity ultrasonic waves for the relief of pain, muscle spasm and joint contractures. The ultrasonic waves are generated by a unique transducer incorporated into a treatment patch. There are two types of patches: Reusable Treatment Patch – A and Reusable Facial Treatment Patch – B. The treatment patch should be placed on intact skin at the desired treatment area or adjacent to it. **For maximal effectiveness – ensure that the ultrasonic transducer is in full contact with the skin.**

Pain Shield MD model FD-14A specifications

Frequency range:	90 kHz ± 0.001 Hz
Output voltage:	12 V
Rechargeable battery:	Lithium-ion (full charging time ~ 2 h)
Dimensions:	125 mm (h) x 39.4 mm (w) x 12.6 mm (d)
Weight:	Driver ~ 70 g ; patch ~ 10 g
Acoustic power:	0.4 W

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.
- The safety and effectiveness of this device in pregnant women or children has not been established.
- 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.
- Treatment of children should be performed under adult supervision.
- Following treatment, some redness might occur in the treated area. The redness should resolve naturally 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.
- Use with caution in patients who have experienced adverse reactions to other forms of ultrasound.
- The PainShield MD parts are not waterproof. Do not expose it to water or any other liquid.
- The device contains Lithium-ion batteries. Do not discard as typical waste. Do not hold the device near water or fire sources.
- For further explanations on symbols, icons and storage instructions please refer to the PainShield User manual (PSUM006).

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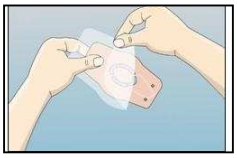
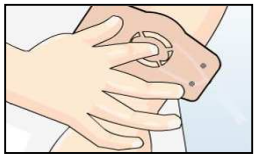
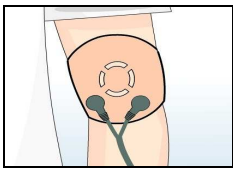
1. Ensure that the treatment area is clean, dry and free of wounds or other lesions. Remove excess hair. Carefully cut open foil pouch and keep to store patch between uses. Remove the protective liner from the treatment patch and keep liner for storing patch between uses.		2. Attach the treatment patch to the skin with the adhesive side down over the area where the pain is most intense or adjacent to the treated wound. Ensure that the ultrasound transducer is in full contact with the skin.	
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.	

Removal and Storage of the Treatment Patch

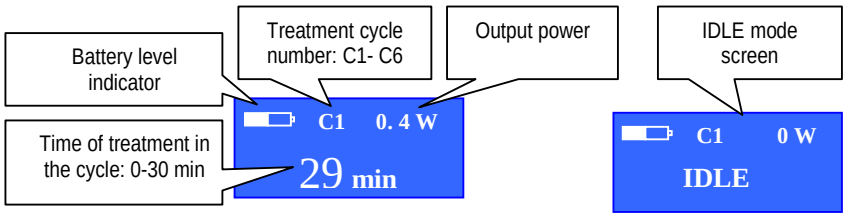
The reusable patch (Model PRP-20) may be used multiple times because of its hydrogel adhesive that may be refreshed. The reusable patch can be used as long as the patch and ultrasound transducer remain firmly adherent to the treatment area.

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.

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.

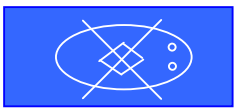
Pain Shield Driver Screens

Device is turned on

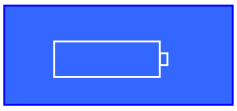


Treatment screen indicates treatment phase.
Each cycle has an active period of 30 minutes followed by an inactive (IDLE) period of 30 minutes.
PainShield MD operates for 6.5 hours, after which it turns off automatically.
During treatment, a screen saver is activated. To return to normal screen, press shortly the ON/ OFF button.
It is possible to turn the device off at any time by pressing the ON/OFF button and holding it for 2 seconds.

Device is turning off



Treatment patch is disconnected or damaged



Battery discharged and requires charging

Charging in progress

Approvals and Compliance with StandardsFDA 510(k) cleared
CE Mark – Class IIa
Health Canada License – Class II
IEC 60601-1; IEC-60601-2
ISO 10993

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