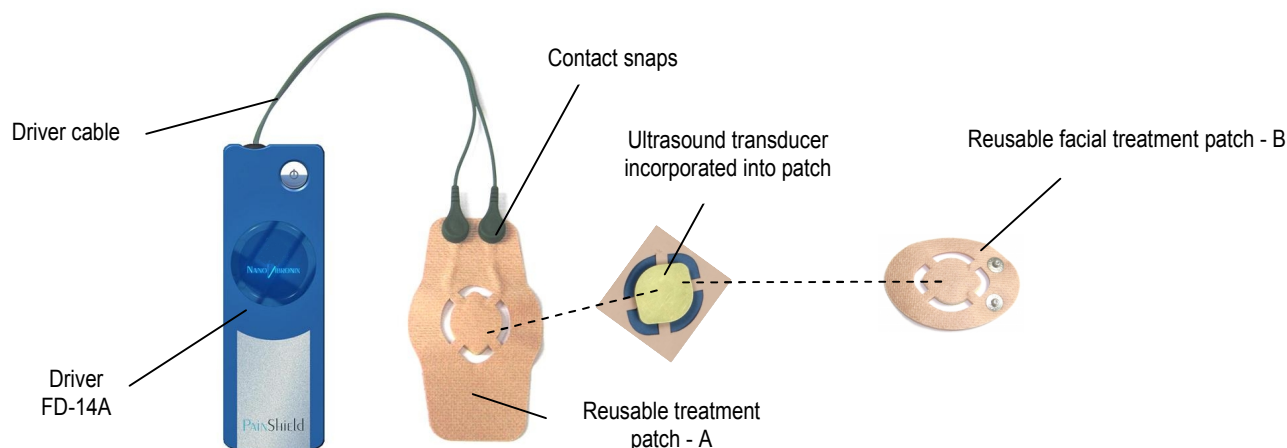


PainShield®

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



The 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 improvement of localized blood circulation. The ultrasonic waves are generated by a unique transducer incorporated into a treatment patch. There are two types of the patches: Reusable treatment patch – A and Reusable facial treatment patch – B. The treatment patch should be placed on the 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 \pm 0.001 Hz
Output voltage:	12 V
Rechargeable battery:	Lithium-ion (full charging time ~ 6 h)
Dimensions:	113 mm (h) x 39.4 mm (w) x 12.6 mm (h)
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
- Pregnant women should be treated only with physician consent.



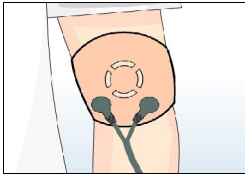

Precautions

- In children, it is preferable to avoid usage over the epiphyseal growth plate area.
- Following a laminectomy when major tissue removal has occurred
- Over anesthetic areas
- When hemorrhagic diathesis is present

General warnings and precautions

- Treating of children should be done under adult supervision.
- Following treatment, some redness might occur in the treated area. The redness should resolve naturally within a few hours.
- Do not place the treatment patch directly on open wound.
- The safety and effectiveness of PainShield has not been determined 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 or other surgical implants.

PainShield® – Instruction for use

<p>1. Ensure that the treatment area is clean, dry and free of wounds or other lesions. Remove the protective liner from the treatment patch.</p>		<p>2. Place the ultrasonic transducer (the metal part in the center of the treatment patch) over the pain source or next to it and tighten the patch to the skin.</p>	
<p>3. Following treatment patch placement, connect it to the PainShield device using the snaps at the end of the connecting cable.</p>		<p>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.</p>	

Removal and storage of the treatment patch

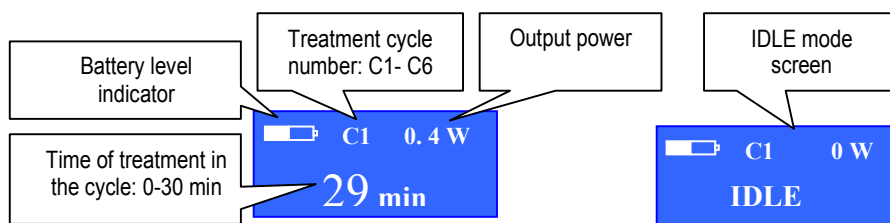
Reusable patch (A) – gently remove the patch from the skin. Moist the sticky area of the patch with water and put the protective liner back and store it in its original package.

Reusable facial patch (B) – gently remove the patch from the skin. Moist the sticky area of the patch with water and put the protective liner back and store it in its original package.

Pain Shield driver screens



Device is turned On



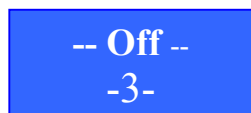
Treatment screen indicates treatment phase.

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 server is activated. For returning to normal screen, press shortly the ON/ OFF button.

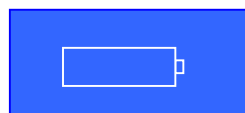
It is possible to turn the device off at any time by pressing the ON / OFF button and hold it during 2 seconds.



Device is turning Off



Treatment patch is disconnected or damaged



Battery discharged and requires charging



Charging in progress

Approvals and compliance with standards

FDA 510 K cleared
IEC 60601-1; IEC-60601-2

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