PAINSHIELD®

Product Spec & Clinical Information Sheet

DRIVER

ACTUATOR

Ultrasound frequency
90 kHz

Output Power
400 mW (milliwatts)

Effective radiating area
6 cm²

Acoustic Power
0.4 watts

Ultrasound Intensity
about .0667 W/cm²

**low-dose low-intensity ultrasound therapeutic range = <1 W/cm²*

Xin Z, Lin G, Lei H, Lue TF, Guo Y. Clinical applications of low-intensity pulsed ultrasound and its potential role in urology. Transl Androl Urol. 2016 Apr;5(2):255-66. doi: 10.21037/tau.2016.02.04. PMID: 27141455; PMCID: PMC4837316.

INTENDED USE

Use of low-intensity ultrasound to generate deep heat within the body tissues for the purpose of treating musculoskeletal conditions.

TREATMENT

Alternates between 2 phases

- active phase = 30 minutes of ultrasound therapy
- idle phase = idle for 30 minutes
- 1 active phase + 1 idle phase = 1 cycle

The device automatically shuts off after 6.5 hours

INDICATIONS FOR USE

Intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of:

- **relief of pain**
- **muscle spasms**
- **joint contractures**

CONTRAINDICATIONS

- **patients with cancer and bone metastases under treatment area**
- **directly on the eye**
- **directly over an open wound**
- **directly over ischemic tissues in patients with vascular disease**
- **over the uterus in pregnant patients**
- **over bone growth centers until bone growth is complete**

PRODUCT INFO

Manufactured by NanoVibronix, Inc.

FDA REGISTRATION

Product code: PFW
Class: II
Regulation #: 890.5300
Ultrasonic Diathermy for use in applying deep heat
510k #: K081075