Helping a faster recovery

Melmak

Faster Fracture Healing

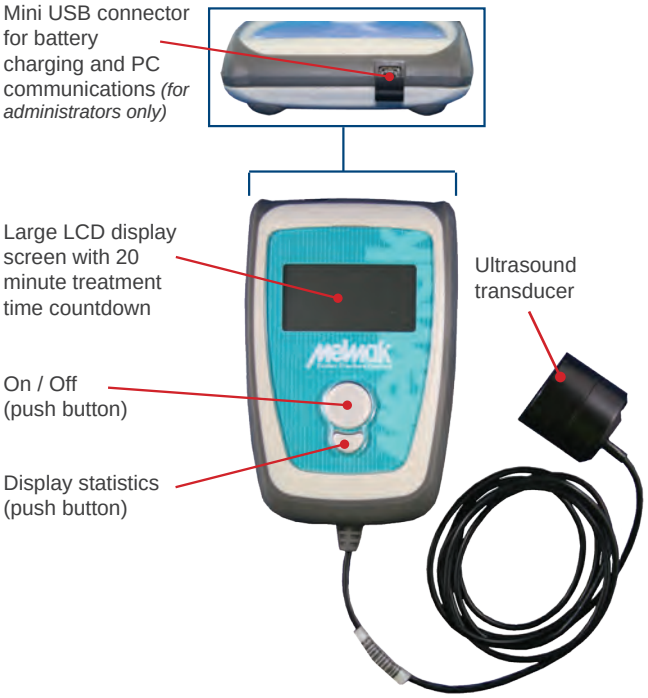
btt

How does the Melmak ultrasound device work?

The Melmak Device delivers low intensity, high frequency, pulsed ultrasound to the fracture site. Studies using commercially available LIPUS devices have demonstrated this form of ultrasound upregulates healing.

The Melmak Device is applied to the fracture site 20 minutes every day.

Features



- ✓ Delivers low intensity pulsed ultrasound 30mW cm^2
- ✓ On screen patient compliance information
- ✓ Multi-use device
- ✓ Rechargeable battery with battery recharge indicator
- ✓ Clinician software

Product Specifications

Ultrasound Frequency **f**: 1.5 ± 5% MHz	Power Input P_{in}: 1.1 ± 0.6 W
Modulating Burst Width t_p: 200 ± 10% µs	Beam Non-Uniform Ration R_{BN}: < 6
Repetition Rate **REF**: 1.0 ± 10% KHz	Waveform: Pulsed
Acoustic Power P_1: 116mW	Effective Acoustic Radiating Area A_{er}: 3.88 cm^2
Spatial Average - Temporal Average (SATA) I_e: 30 ± 30% mW/cm^2	Duty Factor **DF**: 5
Spatial Average - Temporal Maximum (SATM) I_m: 116 ± 30% mW/cm2	Time Average Intensity: 6
Power Supply – Lithium Ion Rechargeable Battery: 3.7 DCV nominal	Weight (Control Unit including Transducer): approximately 285 g

Clinical Studies

STUDY	OUTCOME MEASURES	RESULTS	TECHNICAL SPECIFICATIONS OF LIPUS DEVICE
Pilla et al, Non-invasive low-intensity pulsed ultrasound accelerates bone healing in the rabbit. *The Journal of Orthopaedic Trauma*, Vol 4, No 3, 1990: pp 246-253	Acceleration of fracture healing	Ultrasound treated bone as strong in torsion as intact fibulae, increased periosteal reaction	➤ f = 1.5 MHz ➤ t_p = 200 µs ➤ REF = 1 KHz ➤ I_e = 30 mW/cm²
Walsh et al, Effect of Low Intensity Pulsed Ultrasound on Healing of an Ulna Defect Filled with a Bone Graft Substitute. *Journal of Biomedical Materials Research Part B: Applied Biomaterials,* 86B, 2008: pp 74–81	Rate of healing of bone defect	LIPUS resulted in more new bone growth at wk 4 and 12 compared to control and increased VEGF expression	➤ f = 1.5 ± 5% MHz ➤ t_p = 200 ± 10% µs ➤ REF = 1 ± 10% KHz ➤ I_e = 30 ± 30% mW/cm²
Walsh et al, Effects of low-intensity pulsed ultrasound on tendon-bone healing in an intra-articular sheep knee model. *The Journal of Arthroscopic and Related Surgery*, Vol 23, No 2 (February), 2007: pp 197-204	Rate of healing at tendon/bone junction	LIPUS resulted in improved ability to withstand increased load at tendon/bone junction	➤ f = 1.5 MHz ➤ t_p = 200 µs ➤ REF = 1 KHz ➤ I_e = 30 mW/cm²
Siska et al, External adjuncts to enhance fracture healing: What is the role of ultrasound? *Injury Journal*. 2008 Oct.39 (10): pp 1095-1105	Effect of LIPUS on rate of fracture healing	Safe, practical and effective treatment	➤ f = 1.5 MHz ➤ t_p = 200 µs ➤ REF = 1 KHz ➤ I_e = 30 mW/cm²
Busse et al, The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis. *CMAJ.* 2002 Feb 19;166(4): pp 437-441	Time to fracture healing	LIPUS may significantly reduce the time to fracture healing for fractures treated non operatively	➤ f = 1.5 ± 5% MHz ➤ t_p = 200 ± 10% µs ➤ REF = 1 ± 10% KHz ➤ I_e = 30 ± 30% mW/cm²

Melmak Ultrasound Device Specifications

➤ Resonant Frequency	f = 1.5 MHz
➤ Signal Pulse Duration	t_p = 200 µs
➤ Pulse Repetition Rate	REF = 1 KHz
➤ Spatial Average Intensity	I_e = 30 mW/cm²
➤ Waveform	Puls = Pulsed

This Schedule lists some examples of clinical studies that have been carried out on low intensity pulsed ultrasound systems (LIPUS) such as the EXOGEN® product. (EXOGEN® is the registered trade mark of Exogen, Inc). The studies have not utilised a Melmak LIPUS device.

Clinician Software

Melmak Device administrators have access to a proprietary PC-based Clinician Software program used to upload and download information to and from the Melmak Control Unit.

- ► Ability to allocate a preset number of treatments to your patient.
- ► Tested and validated to deliver 1500 treatments in total.
- ► Programmed into the Control Unit at the start of the treatment program:
  - Patient ID
  - Number of Treatments for the above patient
  - Date (DD/MM/YYYY) synchronised to PC date
  - Time (HH:MM:SS) synchronised to PC time
- ► Download from the Control Unit to the PC when required:
  - Patient ID
  - Number of Completed Treatments (or partial treatments of greater than 3 minutes)
  - Number of Treatment Sessions
  - Time and Date of each of the Treatment Session
  - Length of treatments

Minimum System Requirements

- Operating System: Microsoft Windows XP / Vista / 7
- 1GB of RAM
- 500 MB of hard drive space
- Minimum screen resolution 1280 x 1024
- Keyboard and mouse
- Unoccupied USB port

RENTAL & PURCHASE OPTIONS AVAILABLE

Melmak
Faster Fracture Healing

Accessories

Ultrasound Gel
250ml bottle. Gel must be applied to ultrasound transducer head prior to all treatment to enable ultrasound signal to pass from transducer through skin to the fracture site. Only use Gel supplied by your local Melmak distributor.

Assembled Transducer Holder & Strap
Used to position ultrasound transducer over fracture site.

Felt
For cast application.

Battery Charger
(including adaptors)
USB Cable is used for charging the internal non-replaceable battery of the Melmak Device. Length 1.8m. For international use multiple adaptors are supplied.

CLINICIANS PACK

Clinician Software

Software and Clinician Manuals

USB Cable
Used for charging the Melmak Device via PC or for connection to PC for set up or data logging. Length 1m.

Product Codes

Code	Description
MLK-MEL-3011-00	Melmak Fracture Healing System with Single Transducer (with Soft Bag)
BTT-BTT01-101	Melmak Transducer Holder Assembly
BTT-BTT01-008-00	Melmak Polyester Padded Carry Cases Size 32 x 30 x 10cm
BTT-BTT01-033	Plug Pack USB Travel Adaptor (inc. Worldwide Input Plug Kit 4pcs) inc. Ferrites
BTT-BTT01-040	Transducer Strapping
BTT-BTT01-041	Felt Pads 75 x 65 x 10mm
BTT-BTT01-042	Foam - Large Shaped 56 x 49.4mm. Thickness 10 mm and Self-Adhesive for Transducer Holder
NTF-METGEL250	Ultrasound Gel 250ml

btt Rehacare

RehaCare Pty Ltd

PO Box 71, Cherrybook NSW 2126
Australia
P: 1300 653 522
E: sales@rehacare.com.au
W: www.rehacare.com.au

BTT01-083-00
Rev8-11/2014