btt

Mewak

Faster Fracture Healing

Instructions For Use

CLINICIAN MANUAL

BTT01-055-00
Rev3-03/2012

BTT Melmak Development & Production GmbH
Gewerbegebiet 16
82399 Raisting
Germany
Tel. +49 (0)8807 923922
Fax +49 (0)8807 8806
Email: info@melmak.com
www.melmak.com

MANUFACTURED FOR:

Biomedical Tissue Technologies Pty Ltd (BTT)
342 Chisholm Road
Auburn NSW 2144
Tel.: +61 2 8717 7940
Fax: +61 2 8717 7999
www.biottech.com

(All enquiries regarding the Melmak device and support should be first directed to your local Melmak Distributor.)

Symbols

	Manufacturer BTT Melmak Development & Production GmbH Gewerbegebiet 16, D-82399 Raisting, Germany
	Order Number
	The CE mark indicates conformity with European Council of directive concerning Medical Devices (93/42/EEC)
	Serial Number
	Keep dry
	Batch Number of the Product
	Follow Manual
	Type BF
	Protection Class II
	HF-Transmitter
	Non Sterile
	EU: Not for general Waste For details of how to dispose these items please contact your local waste agency or your local Melmak Distributor
	C-Tick
	Service Sticker
	Connector with Electrostatic discharge (ESD) – Attention: follow manual

Table of Contents

1 Introduction

The Melmak Device is a Low Intensity Pulsed Ultrasound Device (LIPUS). LIPUS devices have been clinically found to support and accelerate the healing process of fresh fractures and non-unions.

The Melmak Device is intended for non-invasive use only, and should only be used as prescribed by a Physician or other Health Professional for its intended use.

Treatment is carried out for 20 minutes, once a day. Patients should treat themselves at approximately the same time each day.

1.1 Indications and Intended Use

The Melmak Device is indicated for the treatment of fresh bone-fractures and established non-unions excluding treatment of the skull and the vertebral column. The location and type of fracture will influence results.

This non-invasive treatment can only be prescribed by a Physician or other Health Professional.

1.2 Use with Internal Fixation

The Melmak Device can be used in the presence of metal screws and plates.

1.3 Contra-indications

There are no known Contra-indications to the use of the Melmak Device.

1.4 Complications

There have been no known adverse reactions or medical complications related to the use of the Melmak Device.

1.5 Warnings

Whilst use of the Melmak Device may be of clinical benefit, evidence of safety and effectiveness has not been established in the following:

1.5(i) Non-union

- For the treatment of fractures of the vertebrae or skull
- In the skeletally immature

1.5(ii) Fresh Fracture

- For the treatment of fractures of the vertebrae or skull
- All fracture types
- In the skeletally immature
- Reduced fractures which remain substantially displaced
- For pregnant and breast feeding women
- For use in pathological fractures due to bone pathology or malignancy
- For complex fractures requiring surgical intervention to reduce and stabilise

- For use in patients with vascular disease or somatosensory dysfunction
- For use in patients with any neurological disorders which may affect the general wellbeing of the person, including any condition leading to nutritional deficiency
- For use in patients taking various medications including phosphonate therapy, steroids and cardiac medication
- If using for greater than the recommended 20 minutes per day
- For use outside the recommended clinical parameters, including prolonged use beyond prescribed guidelines

1.6 Precautions

Whilst use of the Melmak Device may be of clinical benefit, evidence of safety and effectiveness has not been established in the following:

1.6(i) Non-Union

- Reduced fractures which remain substantially displaced. The Melmak Device will not correct any displacement.
- For pregnant and breast feeding women
- For complex fractures requiring surgical intervention to reduce and stabilise
- If using for greater than the recommended 20 minutes per day
- For use outside the recommended clinical parameters, including prolonged use beyond prescribed guidelines

1.6(ii) Fresh Fracture

- Reduced fractures which remain substantially displaced. The Melmak Device will not correct any displacement.
- For pregnant and breast feeding women
- For complex fractures requiring surgical intervention to reduce and stabilise
- If using for greater than the recommended 20 minutes per day
- For use outside the recommended clinical parameters, including prolonged use beyond prescribed guidelines

1.7 General Precautions

Mobile phones may cause interference. Please keep mobile phones at a safe distance from the Melmak Device during a treatment.

The Melmak Device is a medical electrical device and needs special precautions regarding electromagnetic compatibility (EMC) and must be installed according to EMC information.

People with cardiac pacemakers should get clearance from their physician prior to use.

Some individuals may be susceptible to the following:

- a potential allergic reaction to the coupling gel
- mild swelling
- muscle spasm at treatment site
- pain
- mild erythema

If any of these occur the individual should cease use of the Melmak Device and seek medical attention immediately.

1.8 Safety Instructions

The Melmak Device is intended for non-invasive use only, and should only be used as prescribed by a Physician or other Health Professional for it's intended use.

The Operating Guide must be followed accurately. The Melmak Device is to be used only with Melmak specified and supplied equipment and not in combination with other devices.

For external use only.

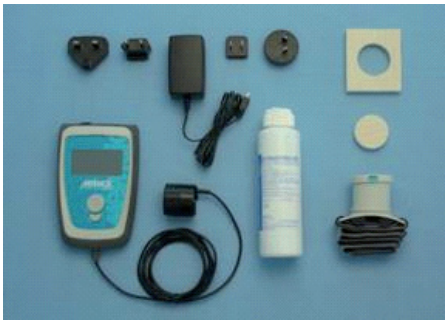
The Melmak Device is to be operated and stored under dry conditions.

For any queries please contact your local Melmak Distributor.

2 Melmak Device (LIPUS)

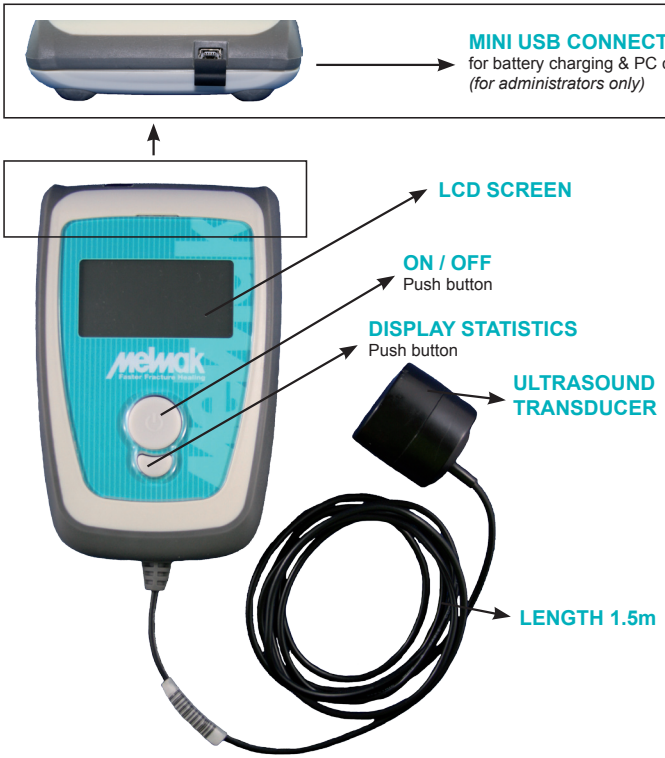
2.1 Components

The following components are part of your Melmak Device shipment.



2.1(i) Control Unit and Transducer

Tested and validated for 1500 treatments. This model Transducer transmits a low intensity, high frequency pulsed ultrasound signal through the patient's skin to the fracture site to be treated.



2.1(ii) Accessories

ULTRASOUND GEL
250 gram bottle. Gel must be applied to 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

CLINICIAN SOFTWARE CD

USB CABLE *(for clinician use only)*
Used for charging Melmak Device via PC or for connection to PC for set up or data logging. Length 1m. *(Consider references to USB cable & charging via PC).*

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.

INSTRUCTIONS FOR USE MANUAL
Operation instructions

3 Operating Guide

3.1 Before a Treatment

The Melmak Device is a battery operated device, it will need to be charged prior to use using a country specific adaptor.

3.1(i) Rechargeable Battery and USB connection

The Melmak Device Control Unit is powered by a non-replaceable, rechargeable Lithium-Ion (Li-On) battery pack. A medical grade battery charger with inbuilt USB connector is used to charge the internal battery. Country specific adaptor must be used.

The USB mini connector on the top edge of the Melmak Device is used for charging and for connection to a PC for data logging.

All functions of the Melmak Device will be disabled if the device is not charged. The voltage level of the battery pack is constantly monitored by the Control Unit while operating and the voltage level is displayed on the LCD.

When the battery voltage falls below the critical battery level during a treatment session, in addition to flashing, the LCD will also show "Lo bAt" signal. When the "Lo bAt" signal is present, the current treatment will be completed but further treatments will not be possible until the Melmak Device is recharged.

During the charging process, the LCD will show the letter "P" and the animated battery symbol will be displayed.

During the charging process, the Melmak Device cannot be operated.

3.1(ii) Audio Feedback

A high frequency audible sound is generated to give feedback when:

- Pressing any button
- If gel is required, 3 short beeps, repeated approximately every 3 seconds
- At the completion of a treatment, alarm will sound 6 short beeps
- Low battery level is detected

3.1(iii) LCD Screen

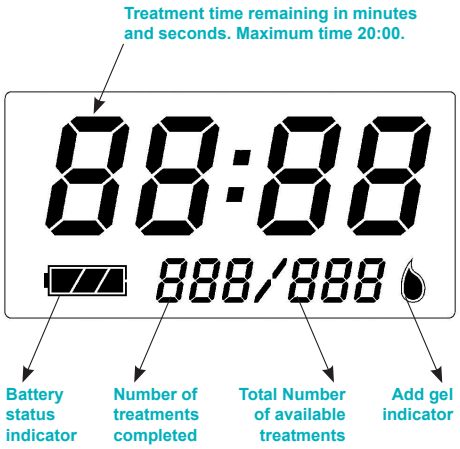


Figure 1: Display showing all symbols

3.1(iv) Error Symbols and Message Displayed on LCD Screen

The Control Unit monitors the Transducer status and gel level continuously during the 20 minute treatment cycle. The treatment will be interrupted if an error mode occurs. In this case the error message will be displayed as follows:

- INSUFFICIENT GEL "💧"
  If insufficient gel is detected before or during a treatment cycle, the Control Unit will suspend the treatment cycle unit until sufficient gel is applied. The Control Unit will generate three audible beeps every 3 seconds and will display a flashing drop symbol "💧" in the lower right corner of the display. If sufficient gel is not applied within 2 minutes after error symbol is displayed the device will automatically switch off.
- LOW BATTERY "Lo bAt 🔋"
  Once the Control Unit detects a low battery level this will be displayed with the following message: "Lo bAt" and the flashing battery symbol "🔋" displayed in the lower left corner of the display, indicating battery needs to be charged. The low battery status allows you to finish the current treatment but will not allow for further treatments to be performed until the battery is recharged. Pressing and releasing the ON/OFF button will light the display for 5 seconds and then switch off the device.
- TRANSDUCER FAULT "Err"
  If the Control Unit detects a Transducer fault, the treatment cycle will be interrupted until the Transducer fault is rectified. The following error message will be displayed: "Err". This message will be displayed for 1 minute and then the device will switch off. If an error message is displayed please contact your local Melmak Distributor.
- NO ALLOCATED TREATMENTS REMAINING "- - - -"
  

  Once all treatments allocated to the Control Unit are used the following error message will be displayed "- - - -". If above error is displayed please contact your local Melmak Distributor.

3.1(v) ON/OFF Push Button

The ON/OFF Push Button on the Control Unit allows the patient to start and terminate a treatment cycle.

STARTING A TREATMENT SESSION
(Gel must be placed on the ultrasound head to enable transmission of ultrasound signal from the ultrasound Transducer across the skin to the fracture site)

- Pressing and releasing the ON/OFF Push Button will start a 20 minute treatment session. The Control Unit will generate a short beep and the LCD will be lit for 5 seconds. The 20 minute count down timer will commence counting down.

Figure 2: Example of display on the LCD at the start of a treatment session

END OF A TREATMENT SESSION

- When the countdown timer reaches zero, the treatment is completed and a short audible beep will be heard. The LCD will show the following for 20 seconds and then switch off.

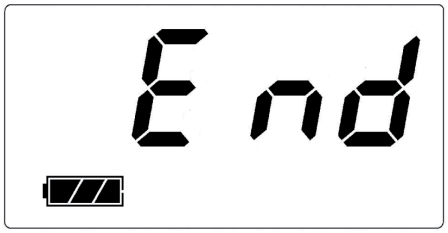


Figure 3: Example of LCD at the end of a 20 minute treatment

TERMINATING A TREATMENT

- Pressing and holding the ON/OFF Push Button for 4 seconds or longer during a treatment will stop the treatment session.
- If the treatment has gone over 16 minutes of the 20 minute treatment session, the Control Unit will register the treatment as a valid session. The Control Unit will generate a short audible beep and the display will continue to show "End" for 20 seconds and then switch off.
- If the treatment session has gone for less than 16 minutes, the Control Unit will not register the treatment session as a valid cycle and the Control Unit will generate a short beep for 2 seconds and the LCD will show "0:00" for 4 seconds.

3.1(vi) Display Statistics Push Button

The Display Statistics Push Button is only operational when a treatment is in progress.

The Statistics-button enables the patient to:

- Switch on the back light by pushing and releasing the button once.
- Receive information about the number of treatments completed and the programmed number of treatments by pushing and releasing the button a second time. This will be displayed by the following message in the lower right corner of the display 34/ 150, indicating 34 completed treatments and the total number of programmed treatments 150.

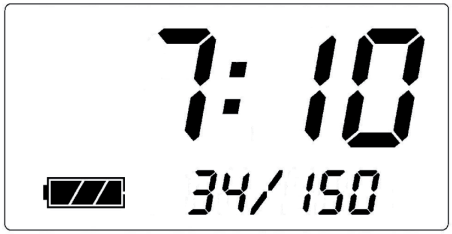


Figure 4: Example of the display on the LCD when the Display Statistics Push Button is pressed and released second time while the backlight is enabled

3.1(vii) Transducer Monitoring

The Control Unit will monitor the Transducer status and gel level continuously throughout the 20 minutes treatment session.

TRANSDUCER FAULT

- If the Control Unit detects a Transducer fault, the Control Unit will suspend the treatment session until the Transducer fault is rectified. The Melmak Device may need to be returned to your local Melmak distributor for diagnostic tests and potential repair.
- The LCD will display following error signal "Err" for 1 minute and then switch off.
- Pressing and releasing the ON/OFF Push Button will switch off the Control Unit immediately.

INSUFFICIENT GEL

- If insufficient gel is detected during the treatment cycle, the Control Unit will suspend the treatment until sufficient gel is applied to Transducer head.
- The Control Unit will generate 3 audible beeps every 3 seconds and will display a flashing "💧" symbol.

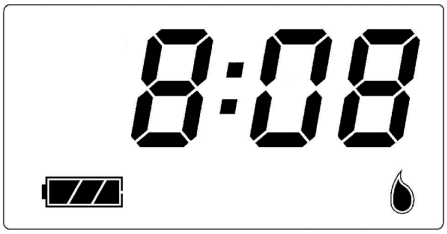


Figure 5: Example of the display on LCD when insufficient gel is detected

- The Control Unit will apply the gel sensing signal for 2 minutes. If the insufficient gel condition persists at the end of the 2 minute time period, the Control Unit will reset the 20 minute treatment session timer and will not register the treatment as a valid treatment.
- If the insufficient gel condition is not rectified for another minute, i.e. 3 minutes after the low gel condition is detected, the Control Unit will switch off.
- Pressing and releasing the ON/OFF Push Button or the Display Statistics Push Button has no effect while "💧" is being displayed.

3.2 Clinician Software Program

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.

The minimum system requirements are:

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

3.2(i) PC Connection to Control Unit via USB Port

The same USB mini connector that is used to recharge the battery also allows the Control Unit to be connected to a Personal Computer (PC) for configuration and data management.

When the Control Unit is connected to the PC with the PC-Based clinician software program activated, the battery will be charged and the Control Unit will establish communication with the program. The LCD will display as in Figure 6.

Figure 6: Example of the display on LCD while battery is being charged and communication is established with the clinician software program

3.2(ii) Data Management

The Management Software enables you to allocate a pre-set number of treatments to your patient.

The Melmak Device has been tested and validated to deliver 1500 treatments in total.

If you choose to use the management software, the following patient/data information is required to be 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

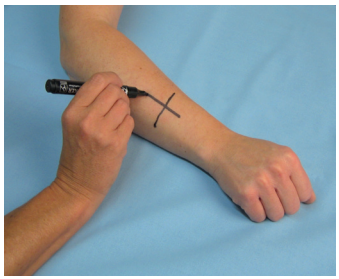
The following patient data/record can be downloaded from the Control Unit to the PC when required:

- 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 sessions
- Length of treatments if >= 16 minutes

4 Application Guide

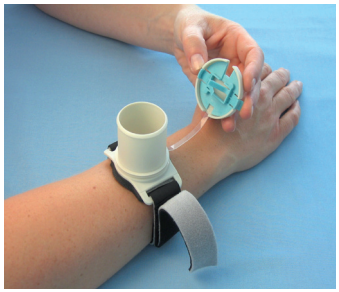
4.1 Non-Cast Application

1. Before starting, Physician has to mark on skin an "X" over fracture site, to ensure accurate placement of Transducer holder for every treatment. Patient/Clinician will need to ensure this point is reproducible for each treatment. An indelible marker may assist.



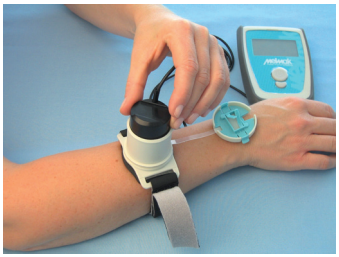
2. Place strap with Transducer holder over fracture site and stabilise securely using the Hook and Loop fasteners. It is vital that Transducer holder be held securely over site to be treated, to ensure Transducer is accurately positioned.

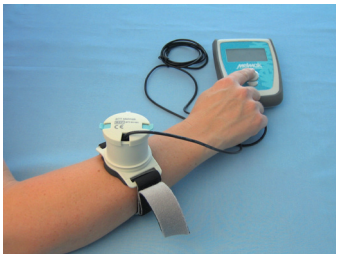
3. Open Transducer holder by pushing two turquoise tabs on either side of Transducer holder towards centre.



4. Hold Transducer and place a small amount of ultrasound gel on the Transducer face, approximately 1.5cm diameter.

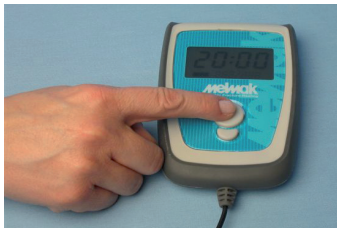
Place ultrasound Transducer through Transducer holder. Ensure cable is routed through cut out on cap and secure by closing cap.





The spring mechanism on the cap provides light pressure to the Transducer. It ensures good contact to the gel and skin over the treatment area for ultrasound transmission.

5. Press ON/OFF button to start treatment. Timer will illuminate and count down from 20 minutes and then turn off automatically.



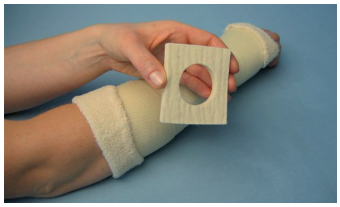
AFTER TREATMENT HAS COMPLETED

6. Undo strap and remove Transducer head from treatment site. Clean gel from Transducer head, strap and skin with soft cloth. Pack Melmak device into carry case for safe keeping.

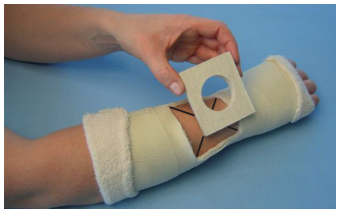
4.2 Cast Application A USING STRAP TO ATTACH

1. Physician to determine location of fracture site. Mark an "X" on the cast.

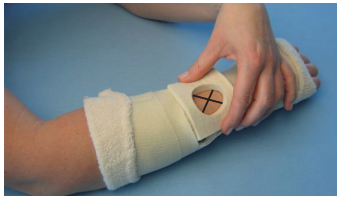
2. Place felt pad on cast. Remove round plug and ensure the "X" is the centre of the hole. Trace outline of the square felt pad on the cast.



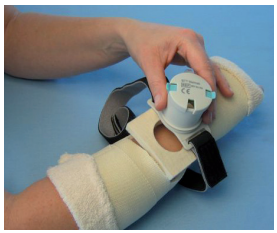
3. Remove the marked area with a cast saw. The cast padding and stockinette are then cut to show the skin underneath.



4. Insert the felt pad into the cast window. You may need to remove some layers of the square felt pad to ensure the pad is the same thickness as the cast, and if necessary cut to fit hole.



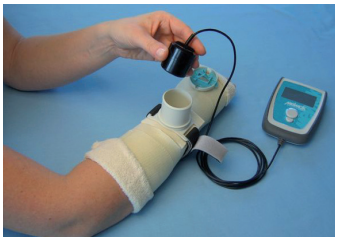
5. Place strap with Transducer holder over fracture site and stabilise securely by using the Hook and Loop fasteners. Foam pad may or may not be needed to assist with fit. Cut foam as necessary to assist with fit.

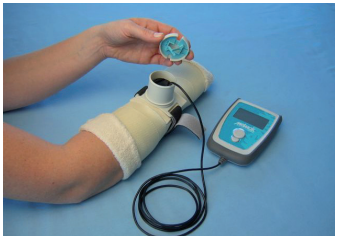


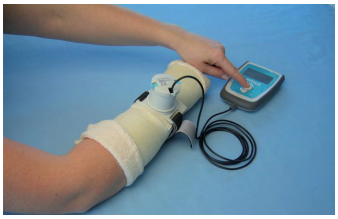
6. Open Transducer holder by pushing two turquoise tabs on either side of Transducer holder towards centre.

7. Hold Transducer and place a small amount of Transducer gel on the Transducer face. Approximately 1.5cm diameter.

8. Position the Transducer in the window of the cast directly over the fracture site. Ultrasound gel must be touching the skin. Close cap to secure.



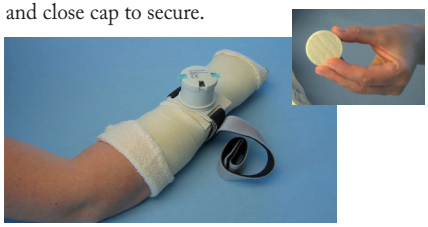




9. Press ON/OFF button once to begin treatment. Timer will illuminate and count down from 20 minutes and then turn off automatically.

10. Remove Transducer head from treatment site. Clean gel from Transducer head, strap and skin with a soft cloth.

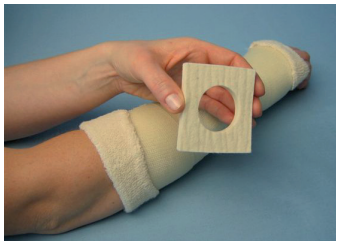
11. Place the round felt plug into the cast window and close cap to secure.



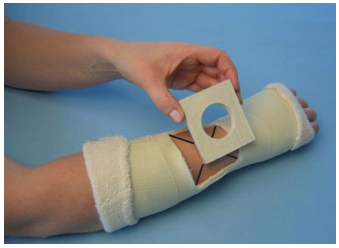
4.3 Cast Application B INCORPORATION OF TRANSDUCER HOLDER INTO CAST

1. Physician to determine location of fracture site. Mark an "X" on the cast and on the skin if the cast is not already applied.

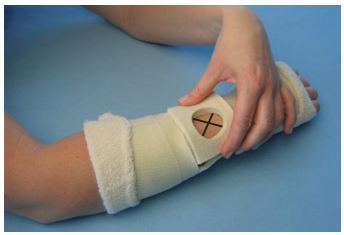
2. Place felt pad on cast. Remove round plug and ensure the "X" is the centre of the hole. Trace outline of the square felt pad on the cast.



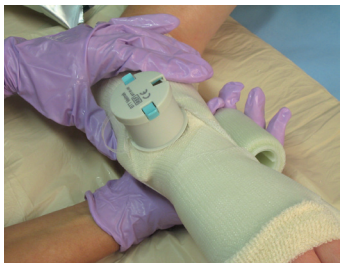
3. Remove the marked area with a cast saw. The cast padding and stockinette are then cut to show the skin underneath.



4. Insert the felt pad into the cast window. You may need to remove some layers of the square felt pad to ensure the pad is the same thickness as the cast, and if necessary cut to fit hole.



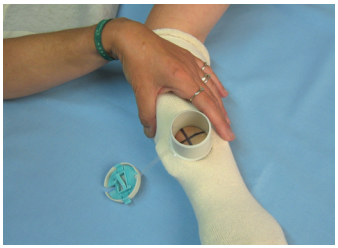
5. Place Transducer holder over fracture site and felt pad. As per picture incorporate into cast using a roll of cast tape. Ensure cast tape goes over corners of Transducer holder to secure.

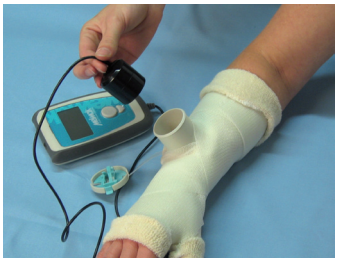


6. Open Transducer holder by pushing two turquoise tabs on either side of Transducer holder towards centre.

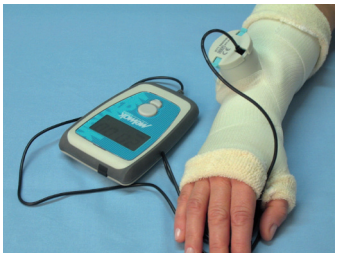
7. Hold Transducer and place a small amount of Transducer gel on the Transducer face. Approximately 1.5cm diameter.

8. Position the Transducer in the window of the cast directly over the fracture site.



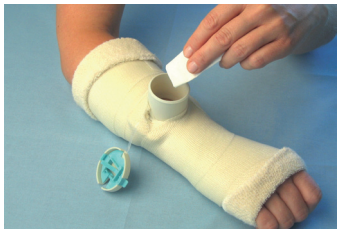


Ultrasound gel must be touching the skin. Close cap to secure.

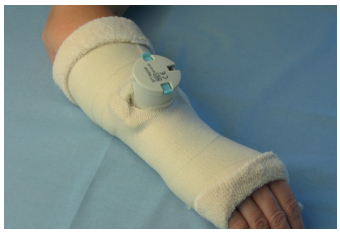


9. Press ON/OFF button once to begin treatment. Timer will illuminate and count down from 20 minutes and then turn off automatically.

10. Remove Transducer head from treatment site. Clean gel from Transducer head, strap and skin with a soft cloth.



11. Place the round felt plug into the cast window and close cap to secure.



5 Care and Maintenance

5.1 Care and Cleaning of the Melmak Device

The Melmak Device must be used according to the following instructions:

- The Melmak Device is only to be used according to the intended use mentioned in this manual.
- Please read this manual very carefully and only operate and handle the Melmak Device according to these instructions.
- The Melmak Device must only be used with Melmak supplied and specified equipment. The Melmak device must not be used in combination with other devices.

  Warning: Using other than Melmak specified cables and accessories may negatively affect electromagnetic compatibility performance.
- Never use cleaning agents or solvents to clean device, its components or accessories. For cleaning use only a soft moist cloth or soft paper towel or tissue.
- The Melmak Device must be operated under dry conditions. The Melmak Control Unit must never be exposed to liquid.
- Please check the Melmak Device and its components after each treatment for any damage. Never use a damaged or broken device or component. In case of damage contact your local Melmak Distributor.
- Do not open and do not try to repair or modify the Melmak Device.
- **Warning:** Do not touch Connector pins marked with the following symbol "  ". Connections between these pins must not be conducted without using specified Electrostatic Discharge (ESD) Safety precautions.
  - -> Using procedures to avoid electrostatic charging (e.g. conducting flooring, non-synthetic clothing)
  - -> Discharging of the own body to ground or large metallic items
  - -> Connection to ground by wristband
- **Warning:** The Melmak Device is not to be stored or located close to other electrical equipment.
- Use only the charger and the accessories supplied by your local Melmak Distributor to avoid any increase in emissions or interference resistance by the Melmak device.
- All staff including e.g. medical engineers and nursing staff are recommended to receive explanation and training in ESD procedures.
- The minimum specifications of ESD precautionary procedure training are:
  - -> Introduction into physical basics of electrical charging and the danger of destroying electrical functionality of devices.
  - -> Methods to avoid electrical charging and explanation for necessity of grounding.
- Please **contact your local Melmak Distributor in case of any questions or concerns**.

5.2 Disposal of Melmak Device

Disposal of electrical waste is an important environmental issue. Disposal of this device should not be treated like household waste.

Please contact your local Melmak Distributor for information on correct disposal of your Melmak Device.

To minimise environmental impact, components of this device will be recycled where possible.

5.3 Warranty and Statutory Rights

The Melmak product is covered by a 2 year limited warranty. Please contact your local Melmak Distributor for full warranty terms. In addition, the Melmak product may be covered by specific statutory rights in your jurisdiction. To find out details of any statutory rights you may have (for e.g. under any consumer guarantees) please contact your local Melmak Distributor.

Do not try to repair or modify your Melmak Device. This will void your warranty.

5.4 Enquiries

For any questions, concerns or assistance please contact your local Melmak Distributor.

5.5 Servicing

Return your Melmak Device to your local Melmak Distributor for a technical service once a year in order to ensure optimum performance of the device and the intended therapeutic response.

On the rear of the Melmak electronic control unit you find the following service sticker "  " indicating the mandatory date for next service.

5.6 Melmak Service and Support Centres

5.6(i) European Authorised Representative

BTT MELMAK DEVELOPMENT & PRODUCTION GMBH
Gewerbegebiet 16
82399 Raisting
Germany
Phone: +49 (0)8807/ 92 39 22
Fax: +49 (0)8807/ 88 06
www.melmak.com

5.6(ii) Australian Representative

BIOMEDICAL TISSUE TECHNOLOGY PTY LTD (BTT)
342 Chisholm Road
Auburn NSW 2144
Phone: +61 (0)2 8717 7940
Fax: +61 (0)2 8717 7999
www.biotech.com

6 Technical Information

6.1 Control Unit Specification

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

6.2 Battery Charger Specification

- Input Voltage: 100 - 240 VAC
- Input Current: <0.5 A RMS Max
- Input Frequency: 47 - 63 Hz
- Output Voltage: 5.0 V, No Load to Full Load, No Minimum Load Required
- Output Current: 1.0 A
- Output Power (Rated): 5 W Max

6.3 Information about Electro-Magnetic-Compatibility (EMC)

6.3(i) Guidelines and Manufacturer's Declaration - Electro-Magnetic Emission

<table>
<tr><td colspan="3">The Melmak Device is destined for the use under the circumstances listed below. The customer and the user of the Melmak device may ensure that the device will be operated in such a surrounding.</td></tr>
<tr><th>Transient emissions measuring</th><th>Correlations</th><th>Electro-Magnetic
Environment – Guideline</th></tr>
<tr><td>HF emission according to CISPR 11</td><td>Group 1</td><td>The Melmak Device applies HF-Energy for internal function only. Therefore the HF-Emission is very low and it's unlikely, that it will interfere with other electronic devices nearby.</td></tr>
<tr><td>HF emission according to CISPR 11</td><td>Class B</td><td rowspan="3">The Melmak Device is a Device which is for the use in every facility including residential areas and those connected to the public power supply, supplying buildings made for living.</td></tr>
<tr><td>Emission of harmonic according to IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Emission of voltage variation / Flicker according to IEC 61000-3-3</td><td>Agreed</td></tr>
</table>

6.3(ii) Guidelines and Manufacturer's Declaration - Electro-Magnetic Stability

The Melmak device is destined for the use under the circumstances listed below. The customer and the user of the Melmak device may ensure, that the device will be operated in such a surrounding.

Stability Tests	IEC 60601-Test Level	Correlations Level	Electro-Magnetic Environment - Guidelines
Discharge static electricity (ESD) according to IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors may consist of wood or concrete or ceramic tile. If the floor consists of synthetic material, the relative humidity has to be at least 30%.
Fast transients / Bursts according to IEC 61000-4-4	± 2 kV for power line ± 1 kV for input- and output-lines (not applicable)	± 2 kV for power line ± 1 kV for input- and output-lines (not applicable)	The quality of the supply voltage should be up to the standard of a typical business- or hospital-environment.
Surge Voltages (Surges) according to IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV common-mode voltage (not applicable)	± 1 kV push-pull voltage ± 2 kV common-mode voltage (not applicable)	The quality of the supply voltage should be up to the standard of a typical business- or hospital-environment.
Voltage drops, short time interruption and variations of supply voltage according to IEC 61000-4-11	< 5% U_T (> 95% voltage drop of UT) for ½ of Period 40% U_T (60% voltage drop of UT) for 5 Periods 70% U_T (30% voltage drop of UT) for 25 Periods < 5% U_T (> 95% voltage drop of UT) for 5 s	< 5% U_T (> 95% voltage drop of UT) for ½ of Period 40% U_T (60% voltage drop of UT) for 5 Periods 70% U_T (30% voltage drop of UT) for 25 Periods < 5% U_T (> 95% voltage drop of UT) for 5 s	The quality of the supply voltage should be up to the standard of a typical business- or hospital-environment. If the user of the Melmak Device requires continuous function even at interruptions of the power supply, it's recommended to operate the Melmak Device with an independent power supply or a battery.
Magnetic Field at supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the supply frequency should be up to the standard of a typical business- or hospital-environment.

Note: U_T = alternating voltage before application of test levels

6.3(ii) Guidelines and Manufacturer's Declaration - Electro-Magnetic Stability (continued)

The Melmak device is destined for the use under the circumstances listed below. The customer and the user of the Melmak device may ensure, that the device will be operated in such a surrounding.

Stability Tests	IEC 60601-Test Level	Correlations Level	Electro-Magnetic Environment - Guidelines
			Portable and mobile walkie-talkies may not be operated in a lower distance to the Ultrasound-Therapy device, including the wires, than according to the recommended security distance, determined by the following equation: **Recommended Security Distance:**
conducted HF-transient according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1{,}16 * \sqrt{P}$
radiated HF- transient according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}16 * \sqrt{P}$ for 80 MHz to 800 MHz $d = 2{,}33 * \sqrt{P}$ for 800 MHz to 2,5 GHz P = actual power output of sender (S) expressed as in Watt (W) according to the information of the sender manufacturer d = recommended security distance expressed as in Meter (m) The field intensity of static transmitter may be for all frequencies according to an investigation on site[a] lower than the correlations level[b]. In the vicinity of device labelled with the following sign, interferences are possible. 

Note 1 At frequencies of 80 MHz and 800 MHz the higher frequency range is valid

Note 2 These guidelines may not be applicable in all cases. The electromagnetic parameter propagation will be influenced by absorption and reflection of buildings, subjects or people.

a The wave band of static senders, e.g. the base station of a Mobile Telephone and mobile walkie-talkies, amateur radio operation devices, AM- and FM- Radio- and TV-Stations can in theory not be determined in advance. In order to investigate the electro-magnetic environment concerning static senders, a survey of the site has to be considered. If the determined field intensity on site, where the Melmak device will be operated, exceeds the above mentioned correlations level, the Melmak device has to be monitored, in order to verify the designated function. If unusual characteristics will be determined, additional action may be required, e.g. a different orientation or a different location of the Melmak device.

b For frequency range from 150kHz to 80MHz the field intensity may be lower than 10V/m.

6.3(ii) Guidelines and Manufacturer's Declaration - Electro-Magnetic Stability (continued)

The Melmak device is destined for the use in an electro-magnetic environment, where the HF-transient is controlled. The customer or user of the Melmak device can help to avoid electro-magnetic inferences by keeping the minimum distance (see below) between portable and mobile HF-Telecommunication Devices (Senders) and the Melmak device – dependent on the output power of the communication device:

Actual Power Output of Sender (W)	Security Distance dependent on Transmitter Frequency (m)		
	150 kHz to 80 MHz $d = 1{,}16 * \sqrt{P}$	80 MHz to 800 MHz $d = 1{,}16 * \sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}33 * \sqrt{P}$
0,01	0,116	0,116	0,23
0,1	0,366	0,366	0,73
1	1,16	1,16	2,33
10	3,66	3,66	7,36
100	11,6	11,6	23,3

For transmitter, who's actual power output is not mentioned in the chart above, the recommended security distance d (m) can be determined by using the equation belonging to the corresponding column.

P = actual power output of sender (S) expressed as in Watt (W) according to the information of the sender manufacturer.

Note 1 At frequencies of 80 MHz and 800 MHz the higher frequency range is valid
Note 2 These guidelines may not be applicable in all cases. The electromagnetic parameter propagation will be influenced by absorption and reflection of buildings, subjects or people.

6.3(iii) Declaration of Conformity

KONFORMITÄTSERKLÄRUNG / *DECLARATION DE CONFORMITE / DECLARATION OF CONFORMITY / DICLARATIONE DE CONFORMITA*

Wir / Nous / We / Noi

Name + Adresse der Firma: Nom + adresse de l'entreprise: Name + address of manufactuer: Nome + indorizzo della ditta:	*BTT Melmak Development & Production GmbH* *Gewerbegebiet 16* *D- 82399 Raisting Germany*

erklären in alleiniger Verantwortung, dass

déclarons sous notre propre responsabilité que
declare on our own responsibility that
dichiariamo sotto propria responsabilitá che

das Medizinprodukt le dispositif médical the medical device il dispositivo medico	Name / nom / name / nome	*Melmak Ultraschallgerät*
	Typ / type ou modél/type or model / tipo o modello	*Melmak*
	Los oder- Serien Nr. / no . de lot d'echantillons ou de serie / lot or serial number / no. di lot campione o serie	
	ggf. Herkunft + Stückzahl / source et nombre d'exemplaires / sources and numbers of items / fonte e numero di esamplari	
	Klasse und MDD Regel / ckasse et MDD règlement / class and MDD rule / classificatione e MDD regola	*IIa – Regel 9*

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG und 2007/47/EG entspricht.

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE (ou 90/385/CEE) qui le concernait.
meets all the provisions of the Directive93/42/EEC (or 90/385/EEC) which apply to him.
addempie a tutte le exigenze della Direttiva 93/42/CEE (opure 90/385/CEE) che lo riguardano.

Angewandte harmonisierte Normen: Normes harmonisées appliquées Applied harmonized standards Norme armonizzate applicate	*EN 980 ; EN 1041 ; EN ISO 10993-1 ; EN ISO 10993-3 ; EN ISO 10993-10 ; EN ISO 10993-11 ; EN ISO 10993-18 ; EN ISO 13485 ; EN ISO 14155-1, -2 ; ISO TR 14969; DIN EN ISO 14971; ISO 15223; DIN EN ISO 17050; EN 60601-1, -1-6, -2-5;*
Angewandte nationale Normen: Normes nationales appliquées Applied harmonized standards Norme nazionali applicate	*n.a.*
Andere normative Dokumente: Autres documents normatifs Other normative documents Altri documenti normativi	*n.a.*
Benannte Stelle (falls zutreffend) Organisme notifié (le cas échéant) Notified body (if applicable) Organo notificato (se il caso)	*mdc medical device certification GmbH* *Registration # 0483* *Kriegerstrasse 6; D-70191 Stuttgart; Germany*
Konformitätsbewertungsverfahren Procèdure d'évaluation de la conformité Conformity assessment procedure Procedimento d'evaluazione della conformita	*Anhang V, Abschnitt 3*
Laufzeit der Konformitätserklärung Durée de la declaration de conformité Duration of this declaration of conformity Durata di diclaratione de conformita	*01.01.2011 – 01.08.2016*

Raisting, 09/11/2011 — Ort, Datum / lieu, date / place, date / luogo, data

Name und Funktion / nom et fonction / name and function / nome e funzione

If you have further questions or require additional information,
please contact your local Melmak Distributor:

Local Distributor Label Here