
# ManaFuse®

## INSTRUCTIONS FOR USE

Non-Invasive Bone Growth Stimulator


### Customer Service

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Email: support@manamed.com
Web: www.ManaMed.com

### Manufactured By:

ManaMed, LLC  2612 Sirius Dr., Denton, TX 76208


MD

REF MFUSE01



TD-MFUSE01-IFU Rev A

MANAMED
Recovery activated.

ManaFuse®

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# USER GUIDE

ManaFuse®

See accompanying documents / User's Manual.

℞ only CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

CONTENTS: ManaFuse Device, Transducer, Coupling Gel, Strap with Cap, Manual

## INDICATIONS FOR USE

The ManaFuse system is indicated for the non-invasive treatment of established non-unions excluding skull and vertebra, and for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature adult individuals when these fractures are orthopedically managed by closed reduction and cast immobilization.

The ManaFuse provides non-invasive therapy for only select non-unions (excluding skull and vertebra) and for accelerating the healing time of fresh fractures (tibia and radius). ManaFuse transmits a low-intensity ultrasound signal to the patient's fracture site through ultrasound gel. The patient will experience little or no sensation while in ultrasound mode. In clinical studies, low-intensity pulsed ultrasound has been shown in-vivo to produce protein and growth fractures that are important to bone healing. A non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.

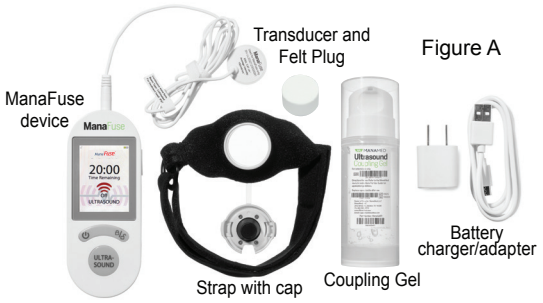
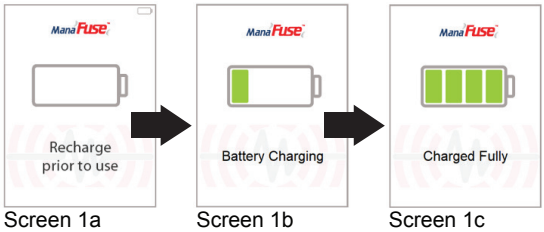



Figure A

The patient can administer treatment at home, work, or the clinical setting, or as prescribed by the physician. The ManaFuse comes in a carrying case and consists of one ManaFuse device, felt plug, a transducer, coupling gel, charger, and a strap. All items needed to treat your fracture or non-union can be verified in Figure A. If any part is missing, please contact ManaMed at 888-508-0712 or email support@manamed.com.

### Charge the battery before use

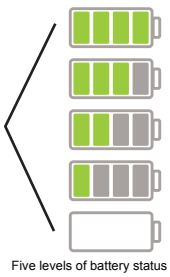



Screen 1a Screen 1b Screen 1c

Fully charge the ManaFuse device before your first use. The Micro-USB plug end of the charger cord plugs into the bottom of the device. The other end plugs into the adapter which plugs into a wall outlet. The charger requires a standard US 120 VAC, 60Hz, household electrical outlet. When the battery is insufficient to perform a 20 minute treatment session, the ManaFuse display will provide an alert to recharge prior to use (Screen 1a). Plug the power supply adapter to the wall socket and connect the charging port of the device to the power supply adapter using the provided charging cable. The BATTERY icon on the device's display keeps flashing or steady, depending on the state of the charge. When the battery is charging, the BATTERY icon will keep flashing (Screen 1b). Once the battery is fully charged, the BATTERY icon will become solid (Screen 1c). Note: The device cannot be used when it is being charged.

### Display Symbols and Descriptions

| Symbol | Name | Description |
|---|---|---|
| | Low Battery | The battery is low and needs to be charged prior to use. |
| | Battery Status | Shows how much charge is left in the battery. |
| | Calendar Broken Star | A 20-minute treatment was not completed on this calendar day. |
| | Calendar Star mark | A 20-minute treatment was completed on this calendar day. |
| | Calendar Double Star mark* | Two-20 minute treatments were completed on this calendar day. |
| | Calendar Double Checkmark Plus* | Three or more 20-minute treatments were completed on this calendar day. |
| | Ultrasound Symbol | Flashes during use to indicate that treatment is being delivered. |
| 20:00 | Countdown Timer | Counts down from 20 minutes to show treatment time remaining. |
| | Treatment Complete | Automatically displays when count-down timer reaches zero to show that treatment is complete. |
| | Lock Symbol | Locks the buttons to prevent unintended operation. |
| | Unlock Symbol | Unlock the buttons to operate the device. |



Five levels of battery status

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## Step 1: Use of Ultrasound function:

Your physician/doctor may have marked your non-union or fracture site with an 'X', or may have installed the cap in your cast over the treatment site. This is the spot to place the transducer to treat your non-union or fracture by using ultrasound. Contact your physician/doctor if you are not sure where to treat your non-union or fracture.

Screen 5a

Screen 5b

Screen 5c

### Set Date and Time

After the above steps are done, you can press the ON/OFF button on the device to turn it on: After showing the following display screen (Screen 5a) for 2 seconds, the device will then show the next screen (Screen 5b) of Date and Time Setup automatically. Follow the instructions on the screen to set the time and date, and you will see the "Set Successfully" message (Screen 5c). Note: The Date and Time Setup screen will only appear for the first time the device is powered on.

After the date and time are set, the device will automatically proceed to the ultrasound calendar/summary (Screen 5d) for 5 seconds. Clicking the + or – button on the right side of the device can show different months. Note: The screen of Ultrasound calendar/summary will appear each time when the device is turned on, or by clicking ON/OFF after the device is on.

Screen 5d

Screen 5e

Screen 5f

After the calendar/summary screen (Screen 5d), the device will automatically proceed to the ultrasound standby screen (Screen 5e). Follow the instructions on this screen, add ultrasound gel on the transducer applicator, and click the ULTRASOUND button to start the ultrasound function (Screen 5f). The 20 minute treatment cycle has begun. To avoid unintended operation, the device will automatically be locked after 60 seconds, or you can click the Lock/Unlock button to lock the device (Screen 5g).

After the 20-minute timer counts down to zero, you will see a "Treatment Completed" screen (Screen 5h). This means a 20-minute treatment of Ultrasound is complete. The device will turn off automatically after 20 seconds (alternatively, you can press and hold the ON/OFF button to turn off the device). Please be aware that you still can press and hold the ON/OFF button to turn off the device, even though the device is locked.

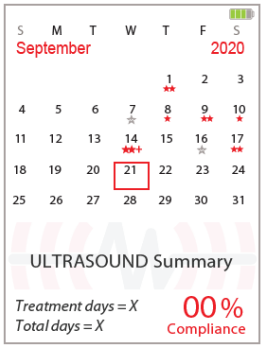
Screen 5g

Screen 5h

### Data Record

Your daily use time of Ultrasound is recorded, as shown on the following Screen 6a. When a 20-minute treatment is completed, a red star symbol will show on the calendar date. When two 20-minute treatments are completed, two red star symbols will show on the calendar date. When three or more 20-minute treatments are completed, two red star symbols and one plus sign will show on the calendar date. When a 20-minute treatment is started but not completed, a grey star symbol will show on the calendar date.

Please refer to the above section of "Use of Ultrasound function" for how to view the data recorded. It is worth noting that no patient information (such as name) is recorded and stored.



Screen 6a

# USER GUIDE (continued)

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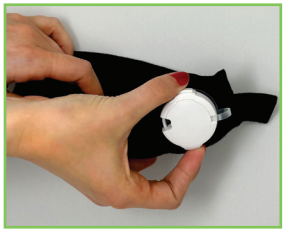
Read prior to use.

1. If not already connected, connect the transducer cable at the top of the ManaFuse device.

2. Grasp the strap with the cap facing upwards and thread the strap's end through the loop's bottom.



3. Press the sides of the cap to release and open.

4. Arrange the strap so the cap is directly aligned with the fracture, as directed by your healthcare provider.

5. Fasten the strap firmly using the hook-and-loop mechanism.

6. Take off the cap from the gel bottle, grasp the transducer by the cable under the head, and dispense one pump of gel onto the surface.

7. Place transducer so the gel faces down in the transducer holder.

8. Position the transducer making sure the gel is touching skin.

9. Position the cap's notch in line with the transducer cord and close securely. Put the cap back on the gel bottle.


10. Press the left Power button to power on the ManaFuse device.


11. Press the Ultrasound button to start 20 minute treatment.

12. After treatment, open cap and gently remove transducer.

13. Carefully remove all residual gel from skin with a cloth. Remove any excess gel from transducer with a soft cloth. Do not use any cleaning fluid.

14. Remove any excess gel from transducer holder with a soft cloth. Do not use any cleaning fluid.

15. Remove any excess gel from transducer holder cap with a soft cloth.

16. To charge device, insert the power cord into the bottom of ManaFuse and plug other end into outlet.

BUILT INTO CAST VERSION: • If you have a cast, your doctor or nurse will remove the cap from the strap and install it for you. The steps below will be performed by a medical professional.

1. Your medical professional will peel off adhesive backing from off-white square pad and stick to bottom of transducer holder. They will then insert assembly into stockinette.

2. Your medical professional will insert round felt plug to hold transducer holder in place.

3. Your medical professional will apply one layer of synthetic cast material, then place mesh square onto plastic port to ensure solid construct.

4. Your medical professional will place the transducer cap onto the transducer holder.

ON CAST VERSION: • If you have a cast, your doctor or nurse will remove the cap from the strap and install it for you. The steps below will be performed by a medical professional.

1. Position strap over the transducer holder to secure it over the cast window.

2. Insert the felt plug, with the tab up, back into the cap. This plug helps prevent swelling in the cast when you are not using ManaFuse.

# MANAFUSE LABEL SYMBOLS

The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the ManaFuse as replacement parts, may result in increased emissions or decreased immunity of the ManaFuse.

This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.

Type BF Applied Part. The transducer, shown in Figure A (Top diagram, this page) is an applied part.

IFU - Consult instructions for use.

Rx only CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

SN: Serial Number

REF: Part Number

MD: Medical Device

# SYMBOL GLOSSARY

For an explanation of symbols, please refer to https://www.manamed.com/glossary/symbol-glossary.pdf

# USER MAINTENANCE

- Contains no serviceable parts.
- Inspect the unit and all components for any damage that may have occurred during shipping or general handling prior to each use (for example, frayed or cut charging cord, cracked plastic housings, etc.).
- Refer to image of ManaFuse for description of all components.
- Do not attempt to connect the power supply if any damage is noticed.
- Avoid subjecting the unit to shocks, such as dropping the device.
- Battery is not replaceable; replacement units are available through customer service. Contact ManaMed via email at support@manamed.com to receive replacement instructions for any damaged items.

# STORAGE AND TRANSPORT

For optimal battery performance, ManaFuse should be transported and stored between 14°F and 113°F (-10°C and 45°C). If stored or transported in temperatures outside of this range, allow ManaFuse to come to room temperature for at least one hour prior to operating. Keep ManaFuse in its carrying case during storage and transport. Store away from sources of heat and direct sunlight.

Normal working atmospheric pressure: 70kPa~106kPa.

Store and transport ambient humidity: 30%-90%.

# DISPOSAL

This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.

# USING THE AC ADAPTER/ BATTERY CHARGER

IMPORTANT: Charge device before first use.

WARNING: Use only the charger provided by ManaMed. The use of chargers or charging cables, other than those supplied, may result in increased radio frequency emissions or decreased electromagnetic immunity of the ManaFuse device which may cause it to stop working. The use of the wrong charger can also cause excessive heat, damage to the circuit, and shorten the life of the battery.

CHARGING: Plug in the power supply adapter to the wall socket using the plug located at the bottom end of the device. The BATTERY icon on the device will keep flashing or steady, depending on the state of the charge. When the battery is charging, the BATTERY icon will keep flashing. Once the battery is fully charged, the BATTERY icon will become solid.

Note: The device cannot be used when it is being charged.

# CLEAN AFTER TREATMENT

- Use two fingers to squeeze the cap tabs together to open the cap cover, and take out the ultrasound head; Wipe and clean the ultrasound gel on the ultrasound head with a soft cloth or paper towel;
- Wipe and clean the ultrasound gel in the cap with a soft cloth or paper towel.

# CLEANING AND CARE

DEVICE: To clean the device, wipe it with a soft cloth. Do not use cleaning agents or solvents on any of the components of the system.

TRANSDUCER APPLICATOR: After the treatment is completed, wipe the transducer applicator with a soft cloth or paper towel to remove the ultrasound gel.

Unit must be completely dry prior to use. To ensure this, leave the device in the OFF position and disconnected from the wall outlet for at least 30 minutes (and as long as necessary for the unit to dry completely) after cleaning.

- Do not use hair dryer to accelerate drying.
- Do not place the device on top of or in front of portable or stationary radiators to accelerate drying.
- Do not use cleaning agents or solvents.

# PURPOSE OF DEVICE

The ManaFuse is a portable and rechargeable prescription device. It is intended to be used in the home or clinical/hospital setting by or under the direction of a medical professional.

# CONTRAINDICATIONS

There are no known contraindications.

# WARNINGS

The safety and effectiveness of this device has not been established for:

• Fractures with post-reduction displacement of more than 50% (i.e., fractures in which the opposing broken bone ends are out of alignment by more than one half of the width of the bone).

• The ManaFuse device is MR Unsafe. The device may be damaged and presents a projectile hazard in this environment.

• Pathological fractures due to bone pathology or malignancy (fractures due to disease).

• Pregnant or nursing women.

• Individuals with thrombophlebitis (blood clot in a vein), vascular insufficient (poor blood supply), abnormal skin sensitivity (very sensitive skin), sensory paralysis (lack of sensation), alcoholism and/or nutritional deficiency.

• Individuals receiving steroid, anticoagulant, prescription non-steroidal anti-inflammatory, calcium channel blocker and/or diphosphonate therapy. Individuals using these therapies were excluded from the studies because of the possible effects of these therapies on bone metabolism.

• Do not use to treat non-unions or fractures of the vertebra and the skull.

• Individuals lacking skeletal maturity.

• Fresh fracture locations other than the distal radius (end of the large bone in the forearm) or tibial diaphysis (middle 80% of the large bone in your lower leg).

• Fresh fractures that are open Grade II or III (fractures with large wounds) or that require surgical intervention with internal or external fixation (screws and/or plates used to hold your broken bones in place) or that are not sufficiently stable for closed reduction (manipulation of the fracture without surgery) and cast immobilization (cast treatment).

# PRECAUTIONS

• The ManaFuse device will not correct or alter post-reduction (when your fracture is initially set and placed in a cast) aspects of a fracture such as displacement, angulation or malalignment.

• The transducer, strap and gel are not sterile and should not be placed on an open wound.

• The operation of active, implantable devices, such as cardiac pacemakers, may be adversely affected by close exposure to the ManaFuse device. The physician should advise the patient, or other person in close proximity during treatment, to be evaluated by their attending cardiologist or implant physician before starting treatment with the ManaFuse device.

• The cords pose a risk for strangulation. Keep out of reach of children.

• Cell phones, televisions, and other devices using radio frequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer and unique medical emitters such as electrocautery, electrosurgical units, and diathermy equipment may cause interference. Don't use the ManaFuse device closer than 15 cm (6 inches) from these electromagnetic (EM) emitters.

• The safety and effectiveness of the ManaFuse device for use of more than one daily 20-minute treatment period has not been studied.

• Check the transducer and the transducer cord before starting treatment. If there are any signs of damage, do not use the device and call Customer Service at 888-508-0712.

• When choosing a treatment site, ensure that the site selected allows for full contact of the transducer face with the skin. Failure to do so may result in the transducer being only partially coupled to the skin. This may reduce the effectiveness of the ManaFuse device in treating the fracture.

• Only the region of the fracture within the effective radiating area (3.88 +/- 20% square cm (cm2) ) of the transducer is likely to benefit from the ManaFuse device's treatment. Therefore, the physician and patient should take care in appropriately placing of the device over the fracture site.

• Placement of the transducer directly over internal fixation may result in the treatment signal being partially or fully blocked and may reduce the effectiveness of the ManaFuse device in treating the fracture.

• When choosing a treatment site, the transducer shall be positioned such that the ultrasound beam is not impeded by any internal fixation which is directly in line with the fracture site (i.e., not directly over metal plating). This may require placement of the transducer on the opposite side of the limb or perpendicular to the fracture line. Correct placement should be confirmed using radiographic and/or anatomical markers by a health care provider during the fitting of the device. The ManaFuse device's site of application should be marked onto the patient's skin with an indelible marker to guide future transducer placements.

# COMPLICATIONS

Reported adverse events in the literature include skin sensitivity (most common), localized pain, swelling, tenderness, or device failure (failure to heal). Heckman et al. 1994 reported that one (1) patient undergoing active treatment, complained of muscle cramping."

# ULTRASOUND GEL

Ultrasound gel is provided for use with ManaFuse. Patients are instructed to place gel on the transducer applicator every time you use ManaFuse. This gel allows the ultrasound signal to reach the depths of the treatment site through your skin. If the transducer applicator is not properly applied, the patient will receive an alert from the device. For the best result, only use the gel supplied. Verify the gel expiration date, located above the QR code on the bottle. If you need more gel, please email ManaMed at Support@ManaMed.com or contact your DME supplier. The gel is sourced from Hony Medical Co., Ltd. (Reference Gel #K221999).

Caution: Some patients may experience mild skin irritation to the gel. If you feel your skin is sensitive to the gel, you may change the gel to mineral oil safe for home health use, glycerin, or a different FDA-cleared ultrasound gel.

# QUANTITY OF TREATMENT AND FREQUENCY OF USE

ManaFuse should be used for 20 minutes per day or as prescribed by your doctor. It is very important to follow your physician/doctor's protocol to get the full medical benefit of the treatment. It is up to your doctor when your fracture has successfully healed. Some fractures may take longer to heal than others. If you have concerns about your treatment or fracture, please contact your doctor directly. The device is a single patient reusable device. This device is prescription only and may not be used without a physician's order.

# EXPECTED SERVICE LIFE

The expected service life of ManaFuse and its accessories is 343 treatments (6860 minutes). Once ManaFuse delivers 343 treatments, it will not provide further treatment.

# TECHNICAL SPECIFICATIONS

Ultrasound frequency: 1.5 +/- 5% MHz
Ultrasound modulating signal burst width: 200 +/- 10% microsecond (µs)
Ultrasound Repetition Rate: 1.0 +/- 10% kilohertz (kHz)
Ultrasound Duty Factor: 20%
Ultrasound effective radiating area (ERA): 3.88 +/- 20% square cm ($cm^2$)
Ultrasound Temporal Average Power: 117 +/- 30% milliwatts (mW)
Ultrasound spatial average temporal avg. (SATA): 30 +/- 30% $mW/cm^2$
Ultrasound beam non-uniformity ratio (BNR): 4.0 maximum
Ultrasound beam type: Collimated
Battery: 3.7 VDC Lithium-ion battery, 2750mAh
Input Voltage (USB) of battery charger: 5.0 VDC, 1A max.

The essential performance of ManaFuse includes the following:

- Free from the display of incorrect numerical values (numbers) associated with the ultrasound/stimulation therapy
- Free from the production of unwanted ultrasound/stimulation output
- Free from the production of excessive ultrasound/stimulation output
- Free from the production of unintended or excessive transducer surface temperature

# TECHNICAL DATA

## SPECIFICATIONS:

Dimensions: 14cm x 5.6cm x 2.4cm
Weight: Approx. 0.17 kg

## SYSTEM OPERATING ENVIRONMENT:

Temperature: +10°C (50°F) to +40°C (104°F)
Humidity: 30%-75%. Keep dry.
Normal working atmospheric pressure: 70kPa~106kPa

Source of Power: DC 5 V or Internal Battery (3.7 volt Li-ion battery)

BATTERY CHARGE: Takes approximately 4 hours (from depleted state).

BATTERY RUN TIME: Approximately 10 hours

## CAUTION:

Charge batteries using only the power source provided by ManaMed.

## POWER SUPPLY:

Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 5 V @ 1 Amp)
Use only UL/60601-1 approved power supplies from ManaMed for use in hospital settings.

## INGRESS PROTECTION:

ManaFuse device: IP22, Transducer: IPX7 The first digit indicates the enclosure's protection against solid objects. A rating of 2 indicates protection against fingers or similar objects. The second digit indicates the enclosure's protection against liquids. A rating of 2 indicates protections against dripping water when tilted at 15°. A rating of 7 indicates protection against immersion up to 1m.

# ADVERSE EVENTS

Unlike conventional (physical therapy) ultrasound devices, ManaFuse is incapable of producing harmful temperature increases in body tissue[28]. The ultrasound output intensity of ManaFuse is 30 mW/cm2 and is typically only 1% to 5% of the output intensity of conventional therapeutic ultrasound devices. The ultrasound intensity is comparable to diagnostic ultrasound (1 to 50 mW/cm2), such as the intensities used in obstetrical sonogram procedures (fetal monitoring). In addition, there is no evidence of non-thermal adverse effects (cavitation). Reported adverse events in the literature include skin sensitivity (most common), localized pain, swelling, tenderness, or device failure (failure to heal). Heckman et al. 1994 reported that one (1) patient undergoing active treatment complained of muscle cramping.

# LIMITED WARRANTY

ManaMed ("Seller") warrants that the original purchaser ("Purchaser") of its ManaFuse purchased by the Purchaser directly from Seller ("Device") that the Device confirms to Seller's manufacturing specifications. The warranty will be three years for the date of purchase. In the event of a breach of this warranty, with a 30-day written notice, Seller will, at its sole option, either repair or replace the Device or issue a refund at the original purchase price. This warranty is null and void if the Device is resold or a transfer of the Device by Purchaser to any other person or entity. Seller expressly disclaims any and all other warranties, either expressed or implied, relating to the system or its performance, including, without limitation, any implied warranty of merchantability and any implied warranty of fitness for a particular purpose. This limited warranty does not cover damages due to eternal causes, including, without limitation, accident, usage not in accordance with product instructions, misuse, neglect, alteration, or repair.

# TRAVEL

Check with your airline regarding recommendations for packing and traveling with the ManaFuse device. The device contains rechargeable lithium-ion batteries that are not serviceable or removable.

# TROUBLESHOOTING

ManaFuse will alert you by displaying an alert screen if something is not working properly. See the following table for common alerts and problems and what to do if you get an alert or problem. If you get any other problem, do not try to fix ManaFuse by yourself, contact customer service at

| Alert / Problem | What does this mean? | What should I do? |
|---|---|---|
|  Contact Manufacturer | Contact customer service: ManaFuse will display the yellow "Contact manufacturer" screen when detecting that it is not working properly. | Call customer service at 888-508-0712. Do not try to fix ManaFuse by yourself. |
|  Recharge prior to use | Low battery: ManaFuse will display the "Low Battery" screen, when the battery level is very low. You are not able to start treatment or view history. | You must charge ManaFuse. Plug ManaFuse into a power source with the provided charger. |
| Blank screen, and ManaFuse does not turn on. | The battery may be completely discharged or the ManaFuse device has malfunctioned. | Plug ManaFuse into a power source with the provided charger and fully charge its battery. If ManaFuse still does not respond, contact customer service at 888-508-0712. |
| The battery area on ManaFuse or the battery charger gets excessively warm. | The battery or charger may be malfunctioning. | Stop charging ManaFuse and contact customer service at 888-508-0712. |

# CLINICAL STUDIES AND INFORMATION

The ManaFuse device has been designed to have technical features/device output, patient populations, intended use and indications for use which are similar to a previously approved product.[1] Therefore, the device is expected to perform similarly with regards to safety and performance. The following clinical data collected in support of the US FDA approval[1] for the prior product is therefore being presented in support of the ManaFuse device. Please note that the clinical studies leveraged to support the safety and effectiveness of the ManaFuse device may not necessarily be applicable to patients of all races and ethnicities. Such demographic details were not provided in the referenced clinical studies.

## Treatment of Nonunion Fractures

### Study Design

Three prospectively designed studies, undertaken in the USA, Germany, and the Netherlands, were submitted to the FDA[1] as the basis for approval of the ManaFuse Bone Healing System to treat established nonunions. The studies had a self-paired control design with each nonunion case serving as its own control, and with the prior treatment result of failed orthopedic care as the control compared to ultrasound as the only new treatment. The criterion for the definition of nonunion cases was the minimum time from fracture of nine months. The primary efficacy outcome was healed due to EXOGEN Ultrasound Bone healing system treatment, as judged clinically (no pain upon palpation or weight bearing) and radiographically (3 out of 4 cortices bridged).

### Clinical Results

Analyzing the data from Germany, the completed cases had a healed rate of 86% (64/74) with a mean time to a healed fracture of 163±9.4 days. The median heal time was 142 days with a range of 53 to 375 days. The mean fracture age for the healed cases was 494 days with a range of 257-6011 days. The scaphoid nonunion heal rate of 33% (2/6) was attributable to the three scaphoid nonunion failures that were all more than 10 years in fracture age and, therefore, were very difficult and challenging cases. Cases with metal surgical fixation present during EXOGEN Ultrasound Bone healing system treatment such as those with ORIF (Open Reduction Internal Fixation) and those cases with intramedullary rods had an 88% (21/24) and 100% (16/16) healed rate, respectively. The results of this nonunion paired design clinical study established the safety and efficacy of the EXOGEN Ultrasound Bone healing system in treating nonunions. This includes cases that had long fracture ages of up to five years but suggests that nonunions with of over five years duration may have a decreased response to ultrasound treatment. The results are summarized in Table 1. Nolte et al.,[2] reporting on the Netherlands study, confirmed the 86% (25/29) success rate and showed the average heal time to be around five months without additional intervention. Average nonunion fracture age was 61 weeks. There were high success rates seen with atrophic and oligotrophic non-unions (80% and 92% respectively) where some biological deficiency may contribute to the original nonunion. Additionally the application of EXOGEN Ultrasound Bone healing system to hypertrophic nonunions, which might usually be considered as requiring revised treatment to correct fracture instability, was successful in 80% of cases. Success was seen for a range of bones, all types of typical primary fracture management, and across all patient age ranges. For the United States study, the completed cases group had an 82% (352/429) heal rate.

### Other Nonunion Studies

Frankel and Mizuno[3] in their analysis of the 1,546 USA patient nonunion registry demonstrated that for patients with risk factors that may impair fracture healing, such as alcoholism, smoking, diabetes, vascular problems, or steroid use, there was no significant change in the effectiveness of the EXOGEN Ultrasound Bone healing system. High success rates were achieved for all bones, regardless of fracture age, but there was a trend towards higher success rates and faster healing with earlier intervention.

Strauss and Gonya[4] described the effects of low-intensity pulsed ultrasound on two difficult cases of Charcot nonunions with multiple prior failed surgical procedures. Both cases healed within 5.5 months when treated with the combination of low-intensity pulsed ultrasound and intramedullary fracture nailing.

Duarte et al.[5] presented data from one of the largest cohorts of patients treated with low intensity pulsed ultrasound (1996). 380 nonresponding delayed and non-unions (averaging 14 months old) were treated with the EXOGEN Ultrasound Bone healing system and achieved an 85% success rate across a range of bones.

Romano et al.[6] reported on prospective longitudinal studies in infected non-unions and pseudoarthrosis respectively, suggesting high success rates with low intensity pulsed ultrasound in both situations.

A number of clinical studies have explored the use of low-intensity pulsed ultrasound in non-union fractures with instrumented fixation, fragility fracture or bone infection. The results have been demonstrated to be comparable to non-union healing rates in patients without these particular confounding factors. The heal rate among the subject patient populations was 80% (578/719) for instrumented fractures[2, 8-19] 92% (145 of 158) for fragility fractures[20], and 80% (47/59) for infected fractures[2, 11, 15, 21-22] for a combined heal rate of 82%.

# Acceleration of Conservatively Treated Fresh Distal Radius Fractures

## Study Design

Placebo-controlled, randomized, double-blind multi-center study with the prospectively defined primary end-point of a combination of clinical and radiographic healing (4 out of 4 cortices bridged as judged by the blinded principal investigator). Sixty one fractures with conservatively treated cancellous radial fractures were randomized into the EXOGEN treated and control groups (Kristiansen et al.[23]).

## Patient Population and Demographics

The demographics of the trial participants were comparable across treatment and control groups with regard to age, sex, fracture characteristics, interval between fracture and change to: treatment of fracture, and duration of follow-up. Race and ethnicity of trial participants were not provided. Results of this study may not necessarily be applicable to patients of all races and ethnicities.

## Evaluation Schedule

Treatment was started within seven days of the fracture, and patients instructed to use the device until the 10 week follow-up visit. Duration of immobilization in the cast was determined by the site investigator. Patients were scheduled to return for follow up at 1, 2, 3, 4, 5, 6, 8, 10, 12 and 16 weeks.

## Clinical Results

EXOGEN treatment accelerated healing by 38% (61±3.4 days in the active group versus 98±5.2 days in the control group; $p<0.0001$). The effect of EXOGEN pulsed low-intensity ultrasound on fracture reduction during healing was also assessed. The subset of fractures which were satisfactorily reduced having presented with at least 10 degrees of negative volar angulation were analyzed. The active group demonstrated significantly smaller loss of reduction compared to the placebo group ($p<0.01$).

# Acceleration of Conservatively Treated Fresh Tibial Fractures

## Study Design

Placebo-controlled, randomized, double-blind multi-center study with the prospectively defined primary endpoint of a combination of clinical and radiographic healing (3 out of 4 cortices bridged as judged by the blinded principal investigator). Sixty seven patients with conservatively treated closed or Grade I open, cortical diaphyseal tibia fractures were randomized into the EXOGEN® (SAFHS® Model 2A) treated and control groups (Heckman et al.[24]).

## Patient Population and Demographics

The demographics of the trial participants were comparable across treatment and control groups with regard to age, sex, fracture characteristics, interval between fracture and treatment of fracture, duration of follow-up, and days to start weight-bearing. Race and ethnicity of trial participants were not provided. Results of this study may not necessarily be applicable to patients of all races and ethnicities.

## Evaluation Schedule

Treatment was started within seven days of the fracture, and continued for 20 weeks or until the clinical investigator judged the fracture to have healed. All patients were scheduled for follow-up radiographs at 4, 6, 8, 10, 12, 14, 20, 33 and 52 weeks after the fracture. Clinical follow-up evaluations were performed at the time of any cast change (usually at 6 and 10 weeks) and at the follow-up visit when radiographic evaluation indicated the fracture had healed sufficiently to allow removal of the cast.

## Clinical Results

EXOGEN treatment induced a 38% acceleration in achieving the prospectively defined primary endpoint of a combination of clinical and radiographic healing (96±4.9 days in the active group versus 154±13.7 days in the control group; $p = 0.0001$).

## Analysis of Fresh Fracture Studies

Cook et al.[25] retrospectively studied the tibial and distal radius fracture data of Heckman et al.[24] and Kristansen et al.[23] to analyze the impact of low-intensity pulsed ultrasound on the incidence of delayed unions, and on the healing time of smokers. Significant reductions in time to healing of tibial shaft fractures were observed in the active ultrasound treatment group with casting versus the casting only placebo control group (a 41% reduction for those who smoked, $p<0.006$; a 26% reduction for nonsmokers, $p<0.05$). Similarly, the distal radius fractures treated with the ultrasound device also showed decreases in healing time compared to placebo control group (51% faster active healing rate in smokers, $p<0.003$; 34% faster active healing in nonsmokers, $p<0.0001$).

Heckman et al.[24] reported similar results in a group of tibial fractures treated with the ultrasound device as compared to placebo control. There was a statistically significant decrease in the time to clinical healing (86 +/- 5 days vs. 114 +/- 10.4 days, $p=0.01$) and also a significant decrease in the time to overall clinical and radiographic healing (96 +/- 4.9 days vs. 154 +/- 13.7 days, $p=0.0001$).

# Table 1: Efficacy Results for SAFHS® Treated Completed Cases*

| | Categorical Variable Prior to Start of SAFHS® Treatment | Total | Healed | Failed | %Healed | p-value* |
|---|---|---|---|---|---|---|
| 1 | **Gender:** Female | 30 | 28 | 2 | 93% | 0.19 |
| | Male | 44 | 36 | 8 | 82% | |
| 2 | **Age:** <17 | 1 | 1 | 0 | 100% | 0.52 |
| | 18-29 | 12 | 9 | 3 | 75% | |
| | 30-49 | 32 | 27 | 5 | 84% | |
| | 50-64 | 21 | 19 | 2 | 91% | |
| | >65 | 8 | 8 | 0 | 100% | |
| 3 | **Weight:** <65kg. | 12 | 11 | 1 | 92% | 0.65 |
| | 65-80 kg. | 35 | 31 | 4 | 89% | |
| | >80kg | 27 | 22 | 5 | 81% | |
| 4 | **Fracture Age:** | | | | | 0.001 |
| | 256-356 days | 20 | 19 | 1 | 95% | |
| | 366-730 days | 27 | 24 | 3 | 89% | |
| | 731-1826 days | 17 | 16 | 1 | 94% | |
| | >1827 days | 10 | 5 | 5 | 50% | |
| 5 | **Total No. Surgical Procedures Combining and All Subsequent Interventions:** | | | | | 0.16 |
| | 0 | 20 | 15 | 5 | 75% | |
| | 1 | 15 | 12 | 3 | 80% | |
| | 2 | 24 | 23 | 1 | 96% | |
| | 3 or more | 15 | 14 | 1 | 93% | |
| 6 | **Prior Days without Surgery (Days from Last Surgical Procedure SAFHS® start):** | | | | | 0.03 |
| | < 82 | 9 | 9 | 0 | 100% | |
| | 83-365 | 39 | 34 | 5 | 87% | |
| | 366-730 | 12 | 12 | 0 | 100% | |
| | >731 | 14 | 9 | 5 | 64% | |
| 7 | **Bone:** | | | | | 0.03 |
| | Tibia/Tibia-Fibula/Fibula | 28 | 26 | 2 | 93% | |
| | Femur | 13 | 12 | 1 | 92% | |
| | Radius/Radius-Ulna/Ulna | 7 | 6 | 1 | 86% | |
| | Humerus | 6 | 5 | 1 | 83% | |
| | Metatarsal | 4 | 4 | 0 | 100% | |
| | Other Foot Bones (calcaneus) | 1 | 1 | 0 | 100% | |
| | Ankle* | 2 | 1 | 1 | 50% | |
| | Scaphoid | 6 | 2 | 4 | 33% | |
| | Other Hand Bones (metacarpal) | 1 | 1 | 0 | 100% | |
| | Other (4-clavicle, 1-pelvis, 1-rib) | 6 | 6 | 0 | 100% | |
| | *Tibio-talar arthrodesis | | | | | |
| 8 | **Long Bone vs. Other Bones:** | | | | | 0.02 |
| | **Long Bones** | 59 | 54 | 5 | 92% | |
| | -28 tibia | | | | | |
| | -13 femur | | | | | |
| | -7 radius | | | | | |
| | -6 humerus | | | | | |
| | -4 metatarsal | | | | | |
| | -1 metacarpal | | | | | |
| | **Other Bones** | 15 | 10 | 5 | 67% | |
| | -1 calcaneus | | | | | |
| | -4 clavicle | | | | | |
| | -1 pelvis | | | | | |
| | -1 rib | | | | | |
| | -6 scaphoid | | | | | |
| | -2 ankle | | | | | |
| 9 | **Displaced at the Start of SAFHS® Therapy:** | | | | | 1.00 |
| | Missing | (5) | (2) | (3) | | |
| | No | 56 | 50 | 6 | 89% | |
| | Yes | 13 | 12 | 1 | 92% | |
| 10 | **Long Bone Type: Only for Long Bones Cases:** | | | | | 0.05 |
| | Missing | (5) | (3) | (2) | | |
| | Metaphyseal | 8 | 6 | 2 | 75% | |
| | Diaphyseal | 46 | 45 | 1 | 98% | |
| 11 | **Initial Fracture Type:** | | | | | 0.16 |
| | Missing | (4) | (2) | (2) | | |
| | Closed | 40 | 34 | 6 | 85% | |
| | Open | 22 | 21 | 1 | 95% | |
| | Arthrodesis | 2 | 1 | 1 | 50% | |
| | Osteotomy | 6 | 6 | 0 | 100% | |
| 12 | **Fixation Present at Start of and During SAFHS® Treatment** | | | | | |
| | IM Rod; Only for Long Bone Cases (N=59) | | | | | |
| | No | 43 | 38 | 5 | 88% | |
| | Yes | 16 | 16 | 0 | 100% | 0.31 |
| | Open Reduction, Internal Fixation (ORIF) | | | | | |
| | No | 51 | 44 | 7 | 86% | |
| | Yes | 24 | 21 | 3 | 88% | 1.00 |
| | External Fixation; Only for Long Bone Cases (N=59) | | | | | |
| | No | 50 | 46 | 4 | 92% | |
| | Yes | 9 | 8 | 1 | 89% | 0.58 |
| | Conservative (Cast, Splint, Brace) | | | | | |
| | No | 59 | 52 | 7 | 88% | |
| | Yes | 16 | 13 | 3 | 81% | 0.44 |
| | IM Rod, or ORIF, or External Fixation, or Conservative | | | | | |
| | No | 11 | 8 | 3 | 73% | |
| | Yes | 64 | 57 | 7 | 89% | 0.16 |
| 13 | **Prior Failed Lithotripsy Therapy:** | | | | | 1.00 |
| | No | 73 | 63 | 10 | 86% | |
| | Yes | 2 | 2 | 0 | 100% | |
| 14 | **Smoking Status:** | | | | | 0.47 |
| | Missing | (2) | (2) | (0) | | |
| | Never Smoked | 34 | 31 | 3 | 91% | |
| | Stopped Smoking Prior to SAFHS® Start | 10 | 8 | 2 | 80% | |
| | Smoke at the SAFHS® Start | 28 | 23 | 5 | 82% | |
| 15 | **Nonunion Type:** | | | | | 0.57 |
| | Missing | (22) | (17) | (5) | | |
| | Atrophic | 41 | 36 | 5 | 88% | |
| | Hypertrophic | 11 | 11 | 0 | 100% | |

*Two-sided exact p-value, Fisher's exact test, testing homogeneity of strata.

## Conclusions Drawn from the Studies

The information provided provides reasonable assurance of the safety and effectiveness of the ManaFuse device for the noninvasive treatment of established nonunions (except skull and vertebra), fresh, closed, posteriorly displaced distal radius fractures and fresh, closed, or Grade I open tibial diaphysis fractures. Clinical studies leveraged to support the safety and effectiveness of the ManaFuse device may not necessarily be applicable to patients of all races and ethnicities. Such demographic details were not provided in the referenced clinical studies.



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# ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES - RF EMISSIONS CLASS B

The ManaFuse is a portable and rechargeable prescriptive device.

Warning: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

**GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS**

The ManaFuse is intended for use in the electromagnetic environment specified below.
The customer or the user of the ManaFuse should assure that it is used in such an environment.

| Emissions Tests | Compliance | Electromagnetic Environment Guidance |
|---|---|---|
| RF Emissions CISPR11 | Group 1 | ManaFuse uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR11 | Class B | ManaFuse is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions IEC 61000-3-2 | Class A | |
| Voltage Fluctuations IEC 61000-3-3 | Complies | |

**GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY**

The ManaFuse is intended for use in the electromagnetic environment specified below.
The customer or the user of the ManaFuse should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ±8kV contact<br>±15kV air | ±8kV contact<br>±15kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical Fast Transient/Burst IEC61000-4-4 | ±2kV for power supply lines<br>±1kV for input/ output lines | ±2kV for power supply lines<br>±1kV for input/ output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC61000-4-5 | ±1kV differential mode<br>±2kV common mode | ±1kV differential mode<br>±2kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11 | <5%$U_T$ (>95% dip in $U_T$) for 0.5 cycle<br>40%$U_T$ (60% dip in $U_T$) for 5 cycles<br>70%$U_T$ (30% dip in $U_T$) for 25 cycles<br><5%$U_T$ (>95% dip in $U_T$) for 5 seconds | <5%$U_T$ (>95% dip in $U_T$) for 0.5 cycle<br>40%$U_T$ (60% dip in $U_T$) for 5 cycles<br>70%$U_T$ (30% dip in $U_T$) for 25 cycles<br><5%$U_T$ (>95% dip in $U_T$) for 5 seconds | Mains power quality should be that of a typical commercial or hospital environment. If the user of the ManaFuse requires continued operation during power mains interruptions, it is recommended that the ManaFuse be powered from an uninterrupted power supply or a battery. |
| Power Frequency (50/60Hz) Magnetic Fields IEC61000-4-8 | 30 A/m at 50 or 60 Hz | 30 A/m at 50 or 60 Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

NOTE: $U_T$ is the a.c mains voltage prior to application of the test level.

# ELECTROMAGNETIC COMPATIBILITY (EMC)
# TABLES - RF EMISSIONS CLASS B (continued)

## GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The ManaFuse is intended for use in the electromagnetic environment specified below.
The customer or the user of the ManaFuse should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Conducted RF<br><br>IEC61000-4-6 | 3Vrms<br><br>150 kHz to 80 MHz | 3Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the ManaFuse, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = 1.2\sqrt{P}$ 150 KHz to 80 MHz<br>$d = .35\sqrt{P}$ 80 MHz to 800 MHz<br>$d = .70\sqrt{P}$ 800 MHz to 2.5 GHz<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF<br><br>IEC61000-4-3 | 3 V/m<br><br>80 MHz to 2.5 GHz | 10 V/m | |

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to the fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ManaFuse is used exceeds the applicable RF compliance level above, the ManaFuse should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ManaFuse.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

## RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE ManaFuse

The ManaFuse is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ManaFuse can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ManaFuse as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|---|
| | 150 KHz to 80 MHz<br>$d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = .35\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = .70\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.