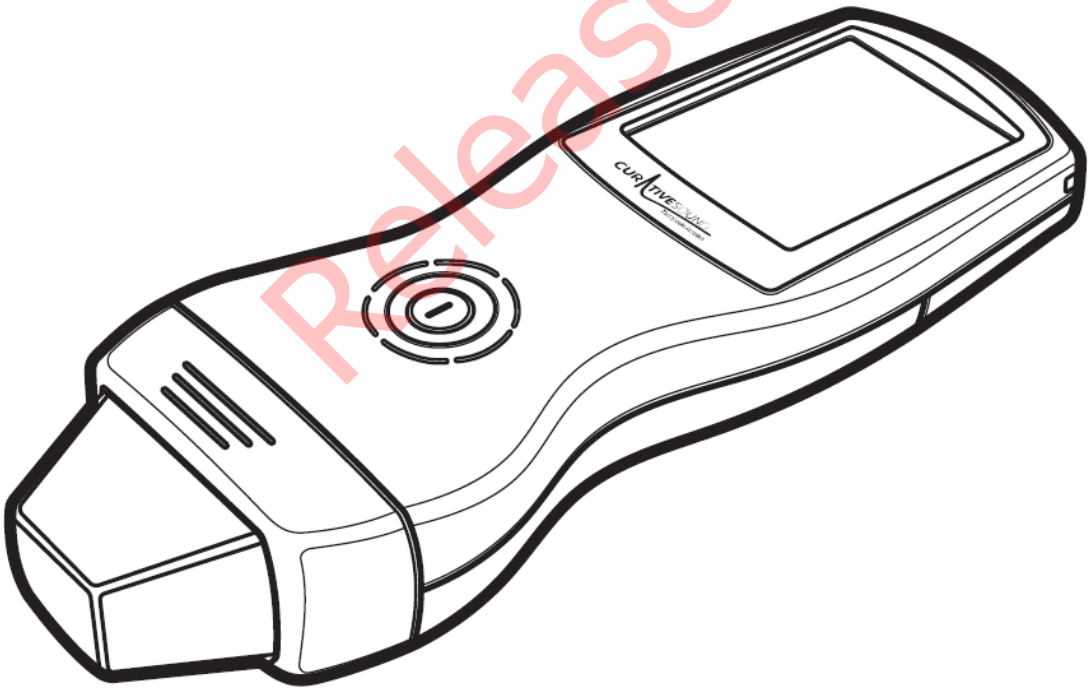
Instructions for Use

CS-Pro MED®

Class II

(US-510(k) – K250779)



Revision D, 11/04/2025

Caution: Federal law restricts this device to sale by or on the order of a physician.

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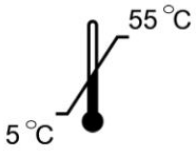
Glossary

Symbols Used in this Document

 NOTE	This symbol indicates articles in which additional information and hints about the respective circumstances are given.
	Warning: read the user manual
 WARNING	A warning indicates a situation which, if not avoided, could result in death or severe injury.
 WARNING	This symbol implies risks and hazards associated with hazardous high voltage. It means a potentially imminent danger to life, in which the electric shock may cause sudden cardiac arrest, severe burning, severe respiratory problems, hematoma, or, in the worst case, potential death.
 CAUTION	A caution indicates a situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the CS-Pro MED device or other property.

Symbols Used on Product Labels

Symbol	Meaning	Ref. ID
	Refer to the instruction manual/booklet	M002
	Manufacturer	3082

	Date of manufacturer	2497
	Temperature	0632
	Keep Dry	0626
	Serial Number	2498
	Type B Applied Part	5840

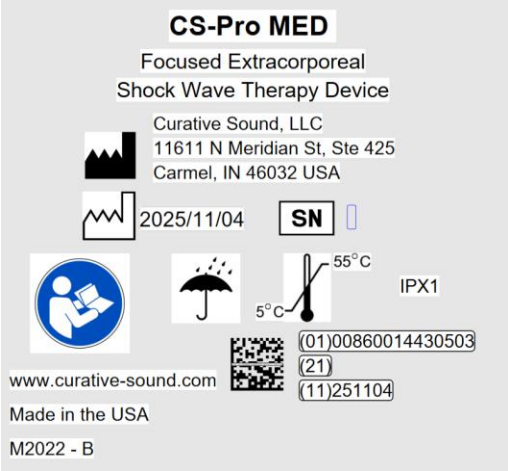
General Warning and Safety Instructions

	**Inappropriate Application of Shock Waves!** Extracorporeal shock wave treatments must always be administered by trained staff. Only the trained user is authorized to administer shock waves. The device must be operated in accordance with national regulations for shock wave devices. All treatments and operation of the device must be carried out in accordance with this manual.
	**Air-Filled Interfaces in Shock Wave Path!** Do not apply shock waves to air-filled areas of the body, i.e., intestines or lungs. Shock waves are rapidly dispersed through an air-filled interface, which can cause bleeding and other harmful side effects.
	**Danger of Infection!** Always clean and disinfect the device before any therapy procedure is initiated and after a therapy procedure is terminated. Use an approved disinfectant. Do not spray the disinfectant directly on the device. Use a sponge or a lint-free cloth.

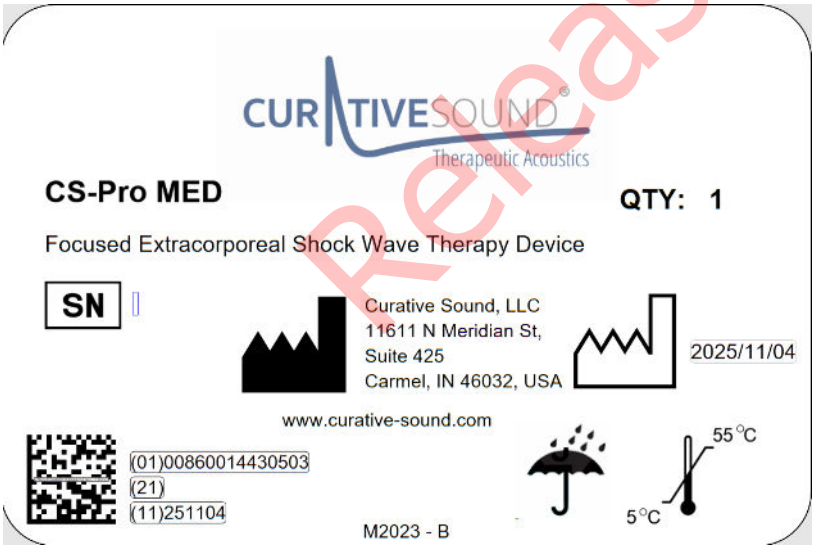
 WARNING	**Cardiac Arrhythmia during Treatment!** If a patient experiences cardiac arrhythmia during treatment, shock wave administration must be terminated.
 WARNING	**Neodymium Magnets!** The standoff is attached with strong neodymium magnets and should be kept a safe and long distance away from individuals with pacemakers or implanted heart defibrillators.
 WARNING	**Avoid Air Bubbles in Shock Wave Path!** The severity of tissue damage or hematomas depends on the total energy and energy density applied. The standoff should be in excellent contact with the patient's skin to prevent energy loss and hematoma development. Always use ultrasound gel and ensure there are no air bubbles between the surface of the standoff and the skin. Always use biocompatible ultrasound gel (ISO 10993-1/5/10 certificate). Any feedback from a patient during the procedure should be considered and the device parameters updated, if necessary.
 WARNING	**Danger of High Electrical Voltage!** Be careful not to come into contact with electrical voltage!
 WARNING	**Non-authorized Modification of Device, Applied Parts, and Accessories!** The device, applied parts, and accessories may not be modified without the manufacturer's prior authorization or approval.
 WARNING	**Lithium-Ion Batteries Present!** The CS-Pro MED is equipped with two 8.5 Wh lithium-ion batteries. It is important to note that lithium-ion batteries may pose a risk of fire or explosion if they are damaged or not used properly. Rechargeable lithium cells can be dangerous for consumers without proper safety measures. Do not heat them above 80°C. Always use the supplied battery charger. Before traveling, remove the batteries from the device and store them securely in their designated locations in the carrying case. Additionally, before flying, check the airline’s policy regarding lithium-ion batteries.

General Label for Product and Accessories

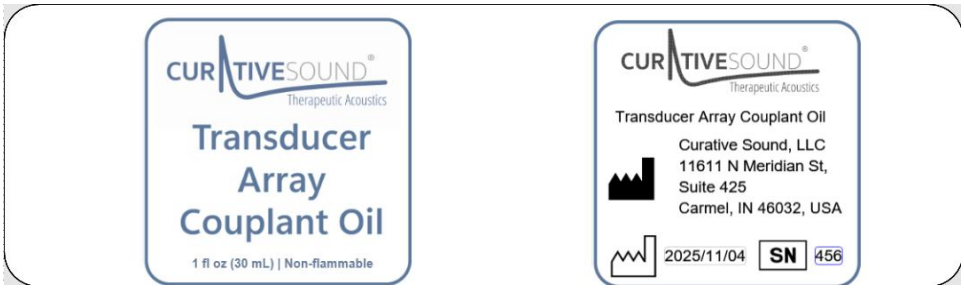
1. Label of the CS-Pro MED Handheld Device



2. Label of the Packaging Box



3. Front and Back Labels of the Transducer Array Couplant Oil Bottles



4. Label of the 2mm Standoff Assembly

5. Label of the 5mm Standoff Assembly

6. Label of the 10mm Standoff Assembly

7. Label of the 20mm Standoff Assembly

8. Label of the 30mm Standoff Assembly

1. Introduction

This manual instructs the user on properly using and operating the CS-Pro MED model. Please read these instructions carefully before starting treatment. The user must thoroughly understand the information presented in this manual and inform the patient of all risks associated with the treatment. Additionally, the device must be regularly maintained according to these instructions.

2. Device Information

2.1. Indications for Use

The CS-Pro MED is intended to provide acoustic shock waves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule but without bone exposure. The CS-Pro MED is indicated for adults (22 years and older) and diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.

2.2. Contraindications

A contraindication indicates a situation in which the device should not be used.

- The CS-Pro MED device contains strong neodymium magnets. Do not use the CS-Pro MED device in patients with pacemakers or implantable defibrillators.
- Do not use the CS-Pro MED device in patients who are using devices that are sensitive to electromagnetic radiation.
- Do not use the CS-Pro MED device in women who are confirmed or suspected to be pregnant.
- Do not use the CS-Pro MED device close to the reproductive system in females of childbearing potential. The application of shock waves to this patient population could result in irreversible damage to the female reproductive system and to the unborn fetus in an undiagnosed pregnancy.
- Do not use the CS-Pro MED device to treat vertebrae, skull bones, and ribs.
- Do not apply shock waves to internal air-filled organs (especially lungs).
- Do not use the CS-Pro MED device to treat infected pseudoarthrosis in the acute state.
- Do not use the CS-Pro MED device to treat patients with tumors.
- Do not use the CS-Pro MED device for the treatment of patients with severe coagulation disorders or patients taking blood-thinning medication.
- Do not use the CS-Pro MED device for extracorporeal acoustic wave lithotripsy.
- Do not use the CS-Pro MED device to treat patients younger than 22 years.

- Do not apply shock waves on large nerves.
- Do not apply shock waves on large vessels.
- Never use this device on children, the unconscious, or anyone who cannot give verbal consent or warnings about pain.
- Do not apply shock wave treatment on the chest or back.
- Do not apply shock wave treatment on the esophagus.
- Do not apply shock wave treatment on the ears.
- Do not apply shock wave treatment on the head.
- Do not apply shock wave treatment on the spinal column.
- Do not use in the presence of unexplained pain.
- All other contraindications mentioned in scientific literature.

2.3. Warnings

- The CS-Pro MED device may only be used by trained healthcare professionals with adequate medical and technical experience in shock wave treatments.
- The use of this device may cause undesirable heart reactions. The patient must be continuously observed during the treatment.
- If a patient experiences cardiac arrhythmia during treatment or a kind of uneasy feeling, shock wave delivery should be terminated.
- If a patient reports significant or unexpected pain, immediately stop the treatment and consult a physician.
- Avoid possible bruising. Use caution when determining a patient's sensitivity level.
- Shock wave treatment should not be administered to any patients who:
  - Are female patients who are nursing or actively lactating;
  - Are on dialysis;
  - Has a foot ulcer that involves osteomyelitis before initial treatment (Note: To rule out osteomyelitis on the foot, an x-ray of the foot in 3 views should be performed);
  - Has evidence of a prior ulcer in the same area as the target ulcer;
  - Has a target ulcer that has decreased in volume by 50% or more;
  - Has multiple foot ulcers that are connected by fistulas or has an ulcer(s) that is within 5 cm of the target ulcer;
  - Has a target ulcer that tunnels into wound tracks which cannot be fully visualized from the wound surface;
  - Has active cellulitis either at the site of or in the surrounding area of the target ulcer;
  - Has a target ulcer that has visually purulent exudates or that has malodorous exudates on examination;

- Has peripheral vascular disease, per Doppler Ultrasound, requiring vascular surgery intervention;
- Requires off-loading for the foot intended for study application for a reason other than for a target ulcer on the plantar surface of the foot;
- Has had a lower extremity revascularization procedure (e.g., percutaneous transthoracic angioplasty, vein graft bypass, etc.) within eight weeks of initial treatment;
- Has active Charcot foot;
- Has had a surgical procedure to correct biomechanical abnormalities (e.g., lengthening of the Achilles tendon, correction of hammer toe, correction of Charcot foot) within eight weeks of the first session;
- Has had a deep vein thrombosis within six months;
- Has clinical evidence of lymphedema;
- Has had chemotherapy within 60 days;
- Has a life expectancy < 2 years;
- Has had treatment of the target ulcer with growth factors, prostaglandin therapy, negative pressure, or vasodilator therapy within two weeks;
- Is receiving > 10 mg of steroid therapy per day (includes topicals, inhalers, etc);
- Has sickle cell anemia;
- Has a known immunodeficiency disorder to include, but not be limited to, Acquired Immunodeficiency Syndrome (AIDS), Human Immunodeficiency Virus (HIV), etc.;
- Has received radiation treatment within 120 days;
- Has received treatment with immunosuppressants or biologically active cellular products, e.g., Apligraf®, Dermagraft®, etc., within sixty (60) days;
- Has received treatment with acellular (collagen-based) products, e.g., Alloderm®, Integra®, etc., within 30 days;
- Has a current history of substance abuse (current is defined as within 120 days);
- Has a history of major systemic infections requiring hospitalization within 3 months;
- Has a current malignancy or a history of malignancy within the past five years, except for basal cell carcinoma that has been treated with local excision and is no longer present;
- Has a physical or mental disability or geographical concerns (e.g., residence not within reasonable travel distance) that would inhibit compliance with the recommended treatment protocol.

2.4. Cautions

Potential effects associated with shock wave treatments include those listed below:

- There is a potential for discomfort when using the device on bony surfaces.
- Use of this device may be painful or cause bruising or cavitation.
- Always protect patients and medical personnel with appropriate protection measures, such as probe covers, sterile drapes, and sterile ultrasound gel.

2.5. Adverse Events

- Transient moderate increase in pain
- Redness and swelling
- Hematoma and petechial hemorrhage
- Headaches and fainting during extracorporeal acoustic wave treatments
- Short-term hypoesthesia
- Nausea during therapy
- Tingling during therapy

2.6. Treatment Protocol

The recommended protocol is to deliver 1,000 to 3,000 shock waves per treatment session. However, the health care provider must use their best judgment for the patient based upon anatomy and treatment area.

	Review the indications and general contraindications before beginning the treatment.
 WARNING	Information for the Patient – The patient must be informed precisely and completely about the risks of the treatment.
 WARNING	Applying more than 3,000 pulses per treatment in a single session to a single target treatment area may increase the risk of bruising or cavitation.

	Take frequent breaks in treatment and move the CS-Pro MED device continuously to prevent bruising or cavitation. Always move the device over the treatment zone. Shock waves concentrated in one area may lead to bruising or cavitation. Cavitation is the formation of vapor cavities in a liquid, small liquid-free zones ("bubbles" or "voids") that are the consequences of forces acting upon the liquid. It usually occurs when a liquid is subjected to rapid changes in pressure that cause the formation of cavities in the liquid where the pressure is relatively low. Cavitation could lead to tissue damage.
	Device overheating may occur due to improper coupling, transducer malfunction, etc. Discontinue use if the device or standoff is too hot for the physician or patient to tolerate.
	**Avoid Air Bubbles in the Scope of the Shock Waves!** Ensure that the Transducer Array Couplant Oil between the array and the elastomeric standoff does not contain air bubbles. If air bubbles appear in the couplant oil, a small amount of couplant oil can be added and spread across the array surface with a clean finger to ensure there are no remaining air bubbles.
	Continuously move the device over the treatment area and restrict the number of shock waves concentrated in one location.
	**Treatment Parameters!** Energy Flux Density, Pulse Repetition Frequency, and Shock Count should be applied according to the recommended protocols. Any feedback from the patient should be considered and device parameters updated, if necessary.
	**Danger of Infection!** The bare standoff must never come into direct contact with skin injuries or abscesses. Otherwise, infectious material can contaminate the standoff, and/or the standoff may infect the wound.
	**Energy Absorption!** During treatment, shock waves are attenuated during passage through the patient's tissue. Additional energy is absorbed by bone that is in the pathway of the shock waves.

 NOTE	**Hearing Protection** The sound level emitted by the CS-Pro MED device treatment is no greater than 58 dbA at 0.25 meters. At this noise level, hearing protection is not required to be worn by the user or the patient to prevent hearing loss.

Typical Course of Treatment and Protocol Recommendations:

Chronic Diabetic Foot Ulcers

Recommended Treatment Protocol
In addition to standard of care procedures, apply ESWT as follows: • Standoff: 2mm / 5mm / 10mm, dependent on the depth of the ulcer • EFD: 0.20 / 0.19 / 0.18, dependent on the standoff used • Repetition Frequency: 6 - 10 Hz • # of Shocks: 1,000 – 3000, dependent on the size of the ulcer • # of Treatments: Twice per week for 3 weeks for a total of 6 treatments • Final follow up: 6 months

2.7. Device Description

2.7.1. Overview

The CS-Pro MED is a state-of-the-art, portable handheld device that produces high-pressure, focused, acoustic shock waves. It was designed to provide healthcare professionals with an effective and easy-to-use device for administering the latest and most advanced focused Extracorporeal Shock Wave Therapy (ESWT) treatment. Focused ESWT is an evidence-based therapy used across multiple orthopedic and wound healing indications. Focused acoustic shock waves trigger a biological healing response in tissue by the shear and pressure forces they produce.

2.7.2. Device Kit

A sturdy, hard-shell carrying case **(1)** contains the CS-Pro MED device **(2)** and five standoffs **(3)** used to change the focal depth of the shock wave energy in the tissue. The kit also contains two Li-ion batteries **(4)**, a battery charger **(5)**, and a battery charger power supply **(6)**. A squeeze bottle **(7)** contains a special couplant oil which is applied between the standoff and transducer array to ensure the optimal transfer of shock wave energy from the device transducer array through the standoff. (Additionally, water-based ultrasound gel must also be applied to the treatment area to ensure the transfer of shock wave energy into the tissue.) A wrist

strap **(8)** can be used to prevent accidental dropping of the device during use. A shoulder strap for the case is also provided (not shown).

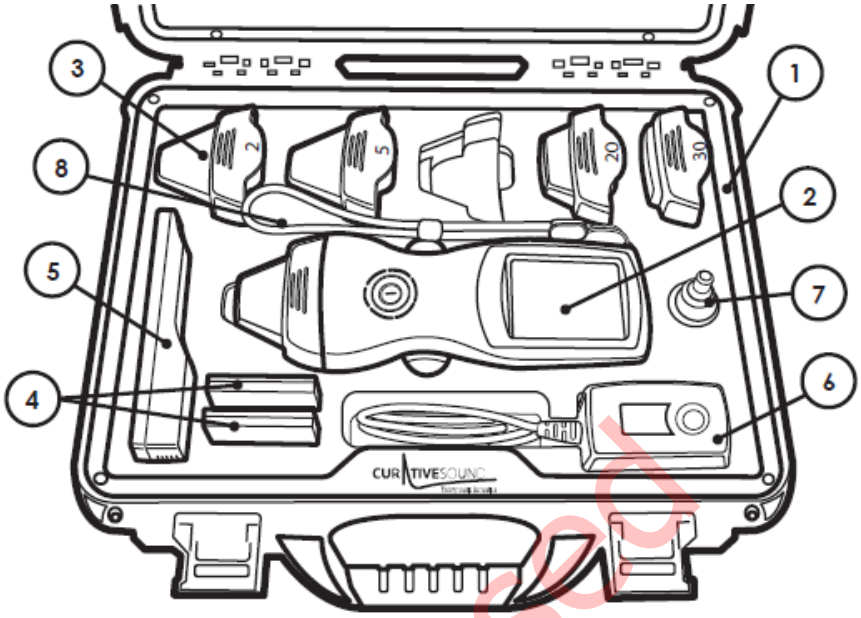


Figure 1: Components of the CS-Pro MED device

CAUTION	**Store Packaging** After unpacking the device, store the CS-Pro MED transport box safely. To protect the device, it must only be shipped in this transport box.

2.7.3. User Interface

The CS-Pro MED device is simple and easy to operate. The user interface comprises a large, round tactile button **(9)** surrounded by an LED light ring **(10)**. The button has multiple functions. Pressing and holding the button for 3 seconds powers the device on. The LEDs will slowly rotate during this step, and the Curative Sound logo will appear on the display. Once the device is powered on, a momentary "press and release" of the button will start or stop the generation of shock waves. The light ring and display are continuously illuminated when the device is powered on. When shock waves are generated, the LEDs rotate at the pulse repetition frequency, and an audible clicking will be heard. At the completion of the treatment session, the device will automatically stop treatment when the preset Shock Count is reached. The shock count can be reset, and the treatment can continue at another location, if necessary.

The CS-Pro MED device also features a 2.8" color touchscreen display **(11)**. Soft buttons on the display are used to change energy levels, set and reset the number

of shock waves to be administered, and change the pulse repetition frequency. Information such as the number of shock waves generated and the focal depth of the shock wave energy in tissue is also shown on the display. Once powered on, pressing and holding the button for 3 seconds will produce a power-off confirmation on the display, with a soft button that can be used to power off the device.

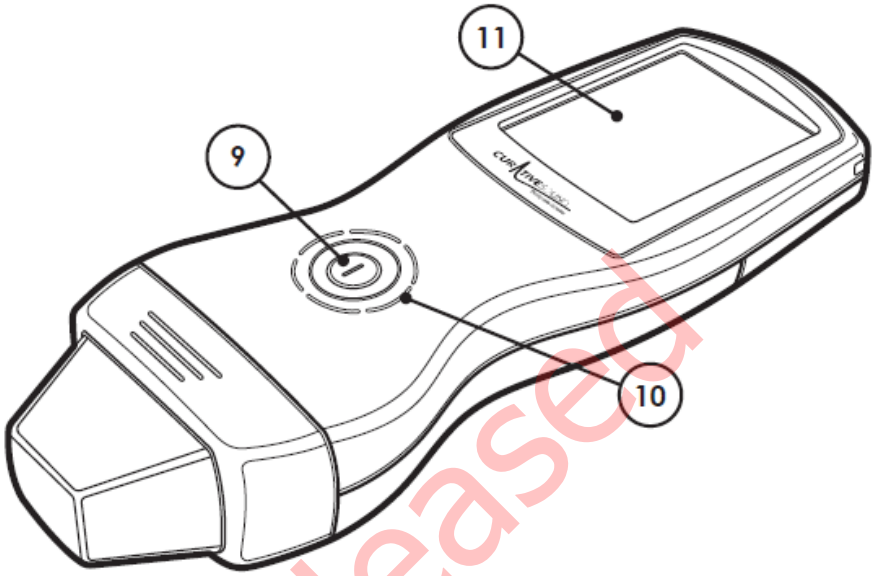
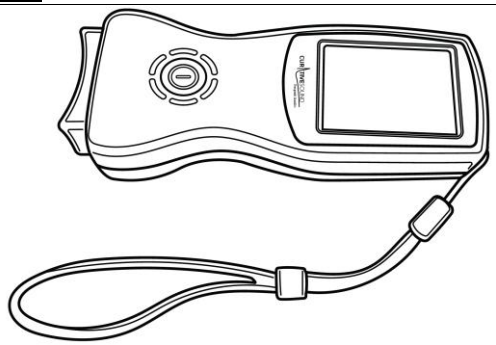


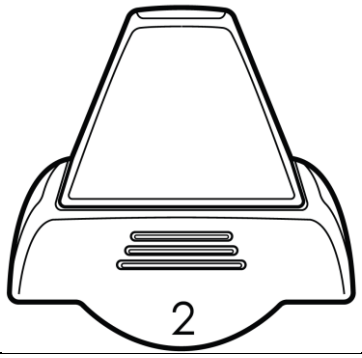
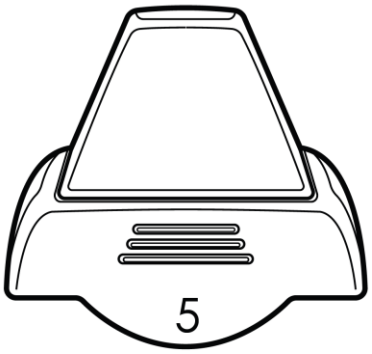
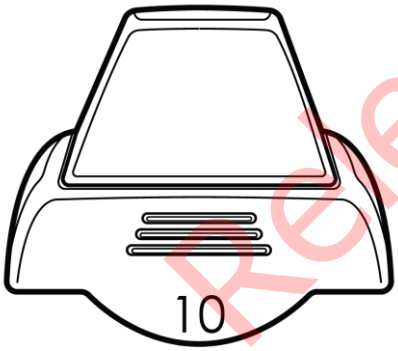
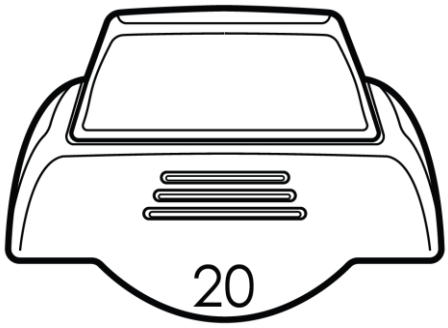
Figure 2: Top view of the CS-Pro MED device

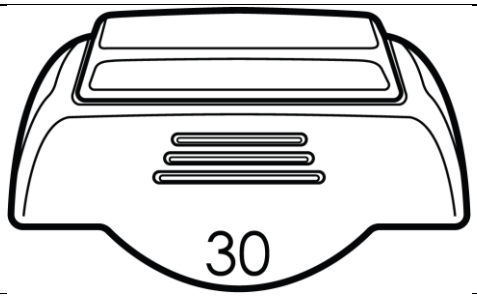
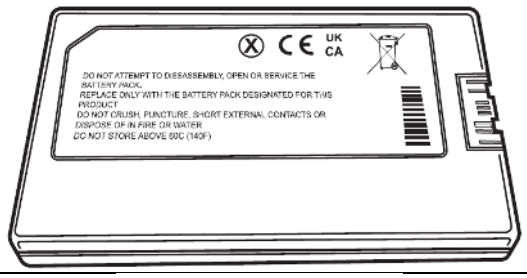
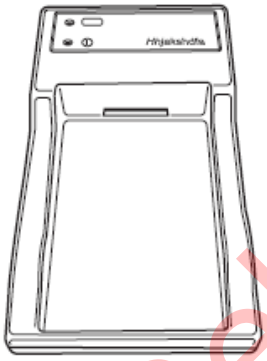
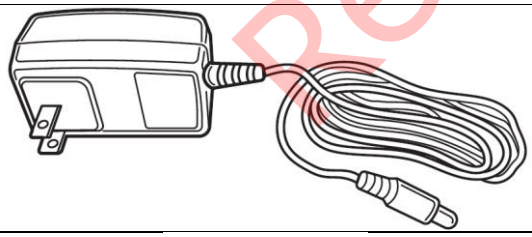
3. Set-up Instructions

1. Remove the CS-Pro MED device from the carrying case.

CS-Pro MED and Accessories

Part	Description	Quantity
	CS-Pro MED Handheld Unit	1

	2 mm Standoff	1
	5 mm Standoff	1
	10 mm Standoff	1
	20 mm Standoff	1

	30 mm Standoff	1
	Lithium-ion Battery	2
	Battery Charger	1
	Battery Charger Power Supply	1
	Transducer Array Couplant Oil	1

	Shoulder Strap	1
	Ultrasound Gel	1
	Instruction for use	1

Table 1: CS-Pro MED and accessories

2. Open the battery door **(12)** and install a fully charged battery.

WARNING	**Battery Installment!** Only a trained individual should install the battery. Improper battery installation increases the risk of harmful events, such as damage to the device and its functionality.

3. From the case, select the standoff with the focal depth specified by the therapy protocol. The focal depth is shown on the back of each standoff **(13)** in millimeters.

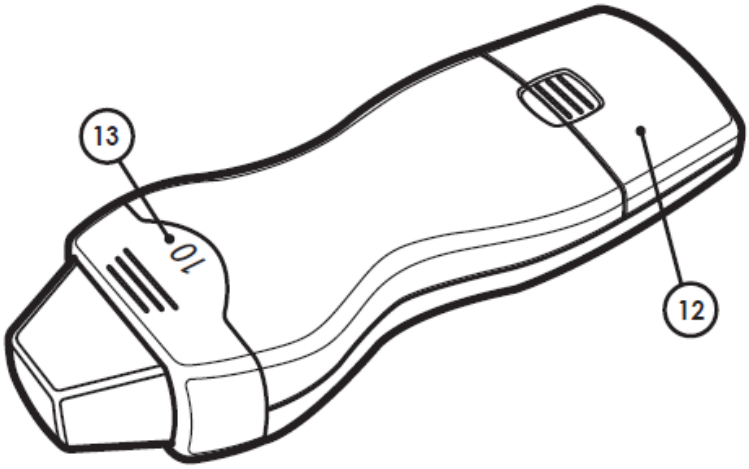


Figure 3: Bottom view of the CS-Pro MED device

4. Remove the dust cover **(14)** from the standoff and store the dust cover in the case. Note that the purpose of the dust cover is to keep the standoff surface that contacts the transducer array clean and free from dust and debris.

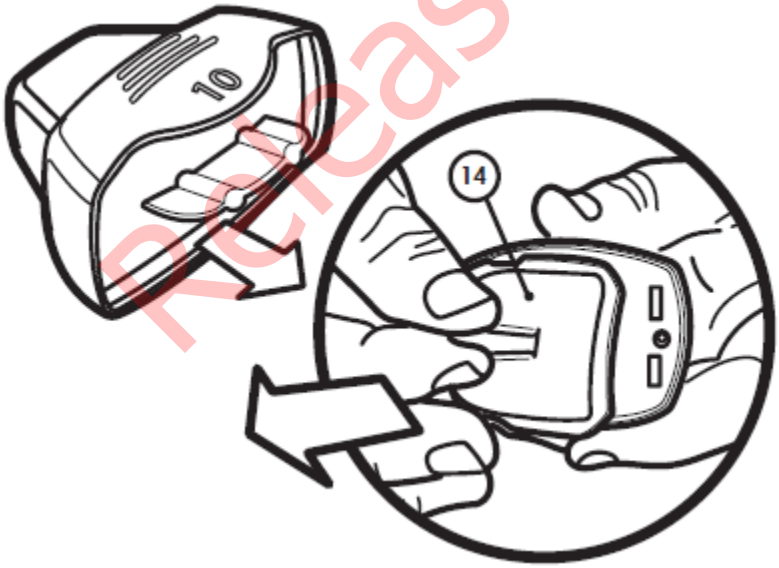


Figure 4: Removing the dust cover from the standoff

5. To transfer shock wave energy internally from the transducer array to the standoff, a thin film of the transducer array couplant oil must be present between those two surfaces. If the device has sat dormant for more than 3 days or when the standoff is being changed, check to ensure the transducer array's smooth concave surface **(15)** appears wet and shiny. If not, carefully apply and spread a drop of couplant oil to the array surface, as shown with a lint-free cloth or a clean fingertip. Additionally, whenever the standoff is removed from the device, wipe off any excess oil that has settled onto the plastic walls of

the standoff. This will keep couplant oil from getting on other device surfaces or inside the carrying case.

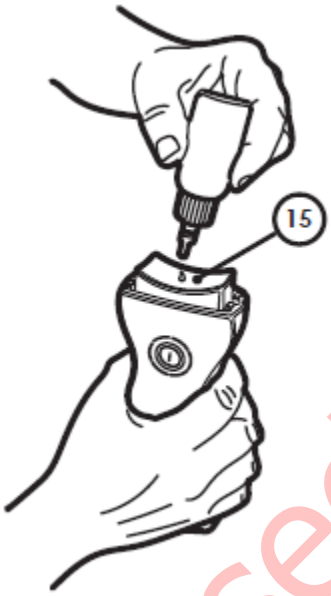


Figure 5: Applying Transducer Array Couplant Oil

WARNING	**Transducer Array Couplant Oil!** Never apply petroleum-based products as couplant oil on the standoff. Doing so will damage the standoff polymer and void the warranty.

6. Place the appropriate standoff onto the CS-Pro MED device.

WARNING	**Neodymium Magnets!** The standoff is attached with strong neodymium magnets and should be kept a safe and long distance away from individuals with a pacemaker or an implanted heart defibrillator.

4. Operating Instructions

4.1. Setting the Device Parameters

1. To “Power On” the device, press and hold the tactile button for 3 seconds until the start-up sequence is completed and the LED light ring and display become illuminated.

2. The device electronics will automatically identify the installed standoff, and the focal depth will be shown on the display (16). This is the same number shown on the back of the standoff.

⚠ CAUTION	**Appropriate Focal Depth** Ensure that the focal depth is correct for the protocol to be administered.

3. Check the battery charge level icon **(17)** shown on the display. Change the battery if necessary. A fully charged battery should power the device for at least 20 typical therapy sessions over the course of about 4 hours.

4. The Pulse Repetition Frequency **(18)** can be varied depending on the protocol and can be changed by pressing the "Req Freq" soft button on the display. A screen with "+" and "-" soft buttons will appear, which can be used to change the Pulse Repetition Frequency between 2 and 12 Hz. 10 Hz is commonly used in many protocols.

5. Use the "ENERGY" soft button (19) on the display to set the energy flux density (mJ/mm^2) as specified in the protocol. (See additional discussion below.)

6. Use the "Shock Set" soft button (20) on the display to set the number of shock waves to be delivered to a treatment area.

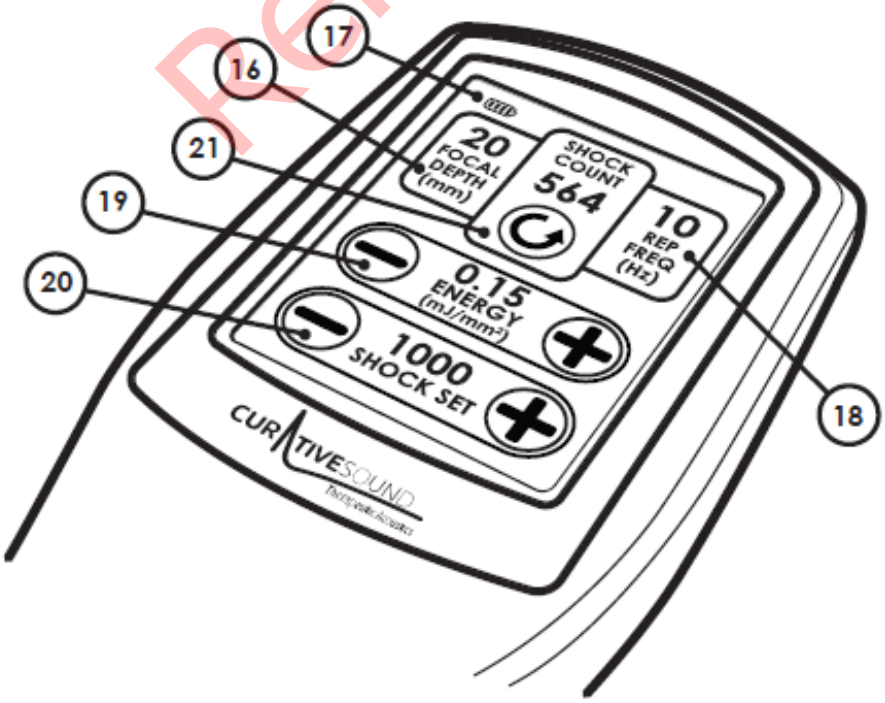


Figure 6: LCD screen showing the changeable device parameters

Function Test

Before treating with the CS-Pro MED, perform a functional test by holding the device away from the patient and pressing the tactile button to generate approximately 10 shock waves. Press the arrow on the Shock Count to reset the shock count to zero.

The functional test is successful if the shock count registers the number of shock waves that are released from the device and if the user hears the audible clicking noise associated with the release of the shock waves.

The functional test has failed if either the shock count does not register the number of shock waves that were released from the device or if the user fails to hear the audible clicking noise associated with the release of the shock waves.

4.2. Shock Wave Treatment

1. The location of shock wave delivery during treatment must be determined by the healthcare professional based on anatomical knowledge, patient history, medical imaging findings, and the location of the wound to be treated.
2. Mark the region for coupling on the skin of the patient.
3. Ensure the patient is prepared for the treatment and that the CS-Pro MED device has been cleaned according to the cleaning instructions outlined in this manual.
4. The patient should be instructed to either sit or lie down for the duration of the treatment.
5. Adjust the device parameters according to the treatment protocol that is being followed.
6. Prepare a single ultrasound probe cover by dispensing a packet of ultrasound gel into the bottom of the probe cover.

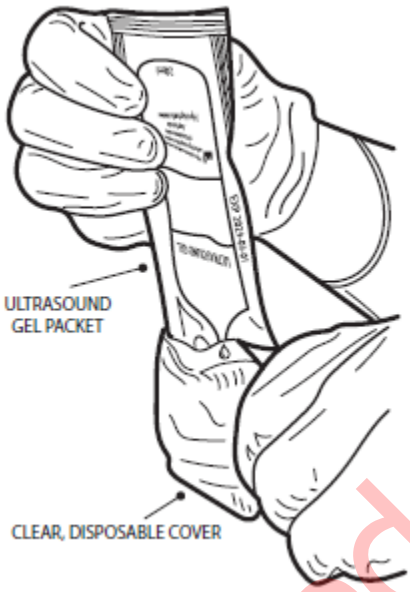
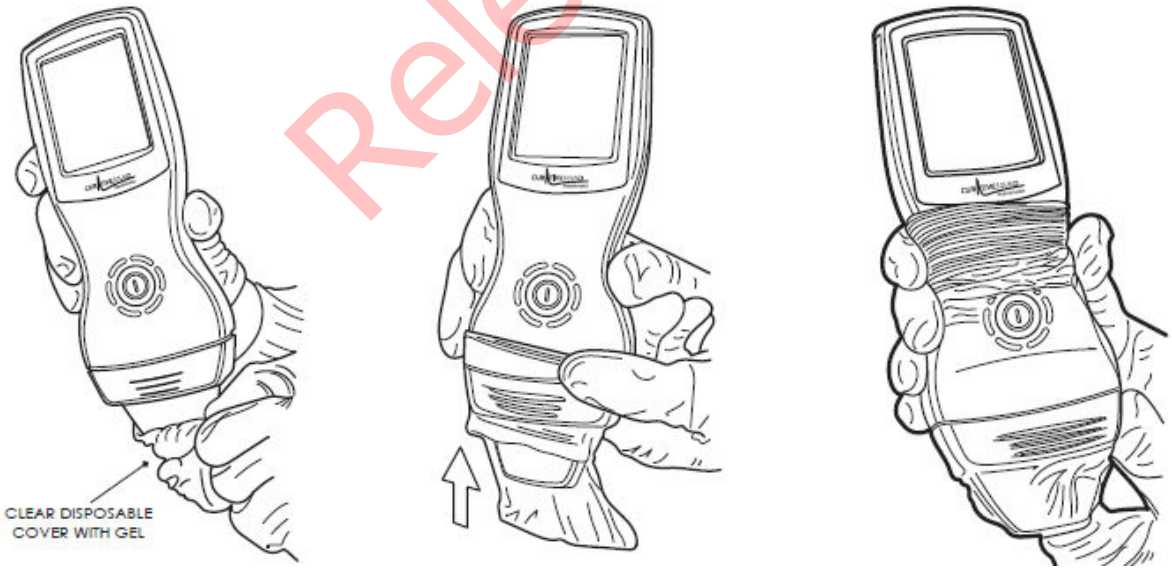


Figure 7: Dispensing ultrasound gel into the probe cover

7. Place the CS-Pro MED device into the probe cover so that the standoff is oriented toward the bottom of the cover and covered by the ultrasound gel.



Figures 8, 9, and 10: Placing CS-Pro MED device into the probe cover

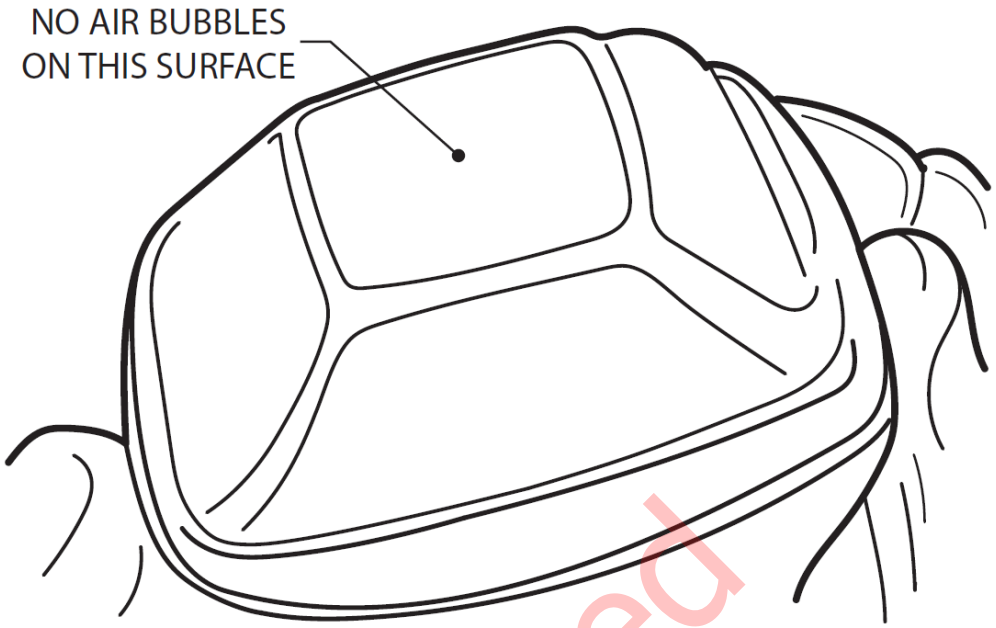
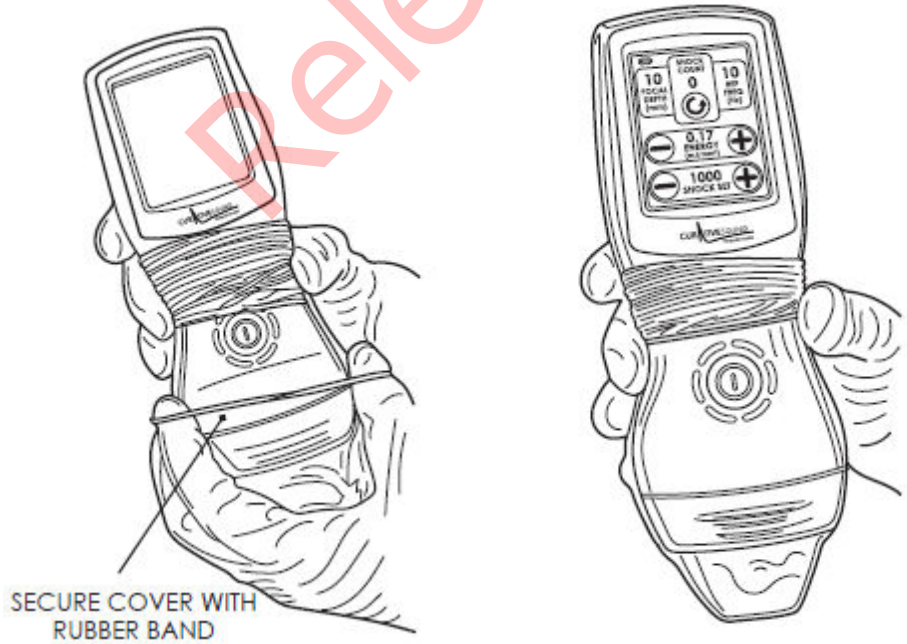


Figure 11: Probe cover installed over the device standoff

8. Secure the probe cover around the CS-Pro MED with the provided rubber band or ligature.



Figures 12 and 13: Placing the rubber band around the CS-Pro MED

 WARNING	**Air Bubbles in Ultrasound Gel!** Ensure no trapped air bubbles exist in the ultrasound gel between the probe cover and the CS-Pro MED standoff. Air bubbles reduce the transfer of shock waves into the patient's tissue.
 WARNING	**Probe Cover and Ultrasound Gel!** A probe cover and ultrasound gel must be used during the treatment protocol to prevent infection.
 WARNING	**Danger of Infection!** The bare standoff must never come into direct contact with the wound area. Infectious material may contaminate the standoff and lead to future infection.

9. Apply **sterile** ultrasound gel to the wound area to be treated.

10. Carefully cover the wound and sterile ultrasound gel with a **sterile** incise drape (3M Steri-Drape or equivalent). Ensure the drape covers the skin around the wound by at least 5 cm in all directions.

11. Apply ultrasound gel on top of the sterile incise drape.

 CAUTION	**Use of Ultrasound Gel** To ensure effective transmission of shock wave energy to the tissue, ultrasound gel must be applied in three areas: 1) On the tip of the standoff within the probe cover; 2) On the wound's surface beneath the sterile drape (Must be **sterile** ultrasound gel) and 3) On the outer surface of the sterile drape directly between the sterile drape and the probe cover.

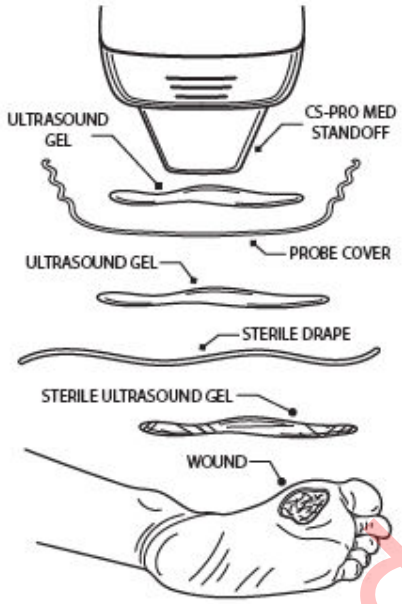
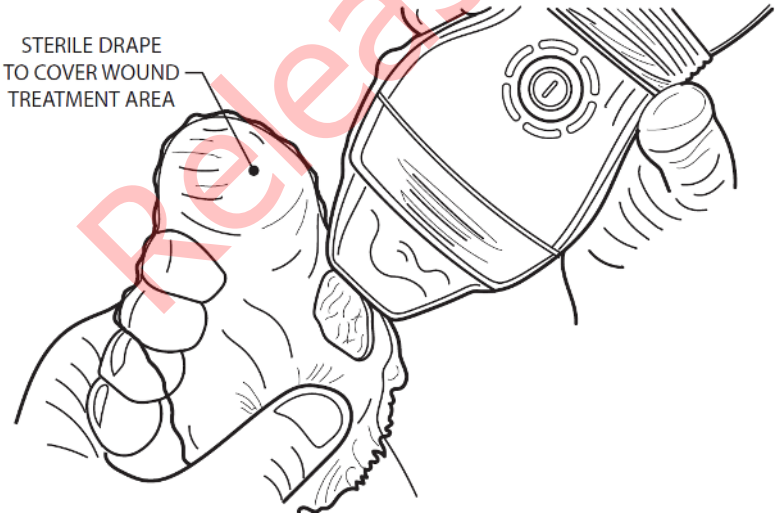


Figure 14: Layers of ultrasound gel and protective drape and cover.

12. Place the end of the covered standoff perpendicularly against the area to be treated.



Figures 15: Proper setup for conducting treatment using the CS-Pro MED on a diabetic foot ulcer (right).

CAUTION	**Application of Shock Waves** Hold the device perpendicular to the skin and use plenty of ultrasound gel during treatment. Therapeutic shock wave energy will not travel through air or air bubbles.

13. A momentary press of the tactile button starts or stops the generation of shock waves. Apply shock waves by moving the standoff against the patient with gentle pressure

using a slow, circular motion. Shock waves will be generated until the counter, "Shock Count," equals "Shock Set" or until the healthcare professional presses the tactile button.

14. At the point where "Shock Count" equals "Shock Set" and the device stops, the healthcare professional can either press the reset soft button **(21)** or press the tactile button again to change the "Shock Count" back to zero and move to another treatment area to repeat the process or conclude the treatment.

4.3. Power Down Procedure

1. Power down the device by pressing and holding the tactile button for 3 seconds. Complete this action by pressing the confirmation soft button on the display **(22)**. The total number of shock waves, firmware revision level, and device serial number are displayed on the screen before power down.

2. Remove and discard the probe cover.

3. Wipe off the standoff and product housing contact areas to remove any remaining ultrasound gel (see cleaning instructions below), then return the device to the carrying case.

4. The standoff can be left on the device or removed and placed in the case with the dust cover reinstalled.

5. The battery should be removed if the device is to be stored for an extended period.

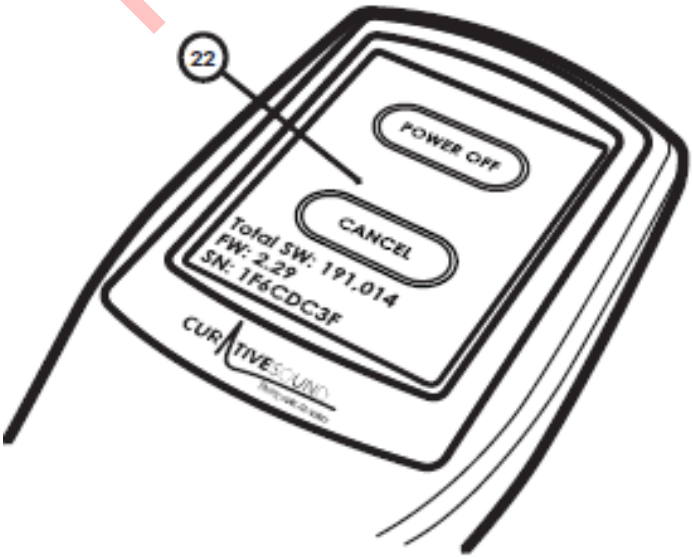


Figure 16: Power down screen

 WARNING	**High Voltage Components!** NEVER open the CS-Pro MED's housing. The device contains high-voltage components that could cause serious injury. Never use the device if the housing is damaged and exposes any of the electronics.

4.4. Charging the Battery

1. Place the charger on a flat, level surface away from sources of heat and moisture.
2. Plug the DC connector from the power supply into the rear of the charger and the other end of the cord into an AC power outlet. The charger will illuminate with a green LED.
3. Slide the battery into the charger so that the electrical contacts on the battery mate fully with the electrical contacts on the charger. The green LED will change from green to orange, indicating that the battery is charging. The orange LED will change to green once the battery is fully charged.
4. The charging time for a fully discharged battery is approximately four hours.

 CAUTION	**Battery Charger Fault Condition** If the LED becomes red, a fault condition has occurred. Ensure that the charger is not overheated due to being covered or placed in direct sunlight. If so, let the charger cool and try again. If problems persist, contact the manufacturer at service@curative-sound.com.

5. Emergency Procedures

If a hazardous incident occurs, power down the CS-Pro MED device and remove the battery. Protect the device from restarting and call authorized service personnel to repair it.

6. Cleaning Instructions

The CS-Pro MED should be cleaned and disinfected regularly. Use customary inorganic and non-flammable disinfectant (such as CaviWipes®) and follow the respective instructions. Use a cloth or a sponge. Do not spray the disinfectant directly onto the device. Wipe with circular motions over the surface of the CS-Pro MED.

6.1. Maintenance

Maintenance and inspections are to be performed by authorized service personnel only.

WARNING	**Electric Shock Hazard!** Never open the CS-Pro MED's housing. The high-voltage power supply circuits utilized by extracorporeal shock wave devices produce voltages capable of causing serious injury or death from electric shock.
WARNING	**Non-Authorized Maintenance Work!** Only authorized service personnel are allowed to perform maintenance work on the CS-Pro MED device. Any other intervention will be considered non-authorized, with all the consequences resulting from this fact.

6.2. Storage

For extended downtime, the battery and standoff should be removed from the CS-Pro MED device, and all components should be stored within the carrying case. The carrying case should be stored in a temperature-controlled environment.

CAUTION	**Minimum and Maximum Storage Temperatures** The CS-Pro MED device must be stored in a temperature-controlled environment. Storing it outside of the documented storage temperature range (e.g., in a hot car) may impact its effectiveness.

Storage Temperature:	5 - 55°C (41 - 131°F)
Storage Humidity:	5 – 98%, no condensation

Table 2: Storage conditions for CS-Pro MED

6.3. Disposal of the Device

The CS-Pro MED device must not be disposed of as regular garbage. Comply with local laws regarding the disposal of medical devices.

The manufacturer can advise on the disposal or return of the CS-Pro MED.

7. Technical, Electrical, and EMC

7.1. Technical Specs

The following figure shows the focal point and pathway the shock waves take into the patient's tissue.

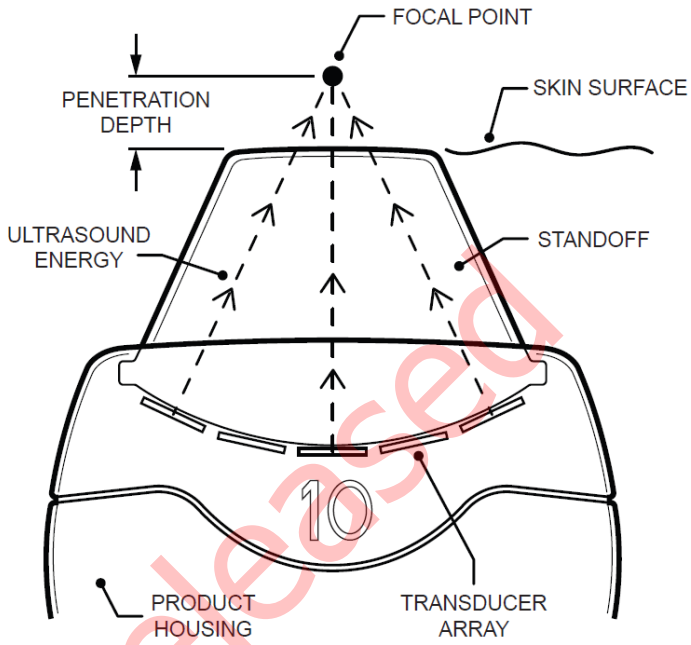


Figure 17: CS-Pro MED transducers, standoff, and focal point within patient tissue

Energy Flux Density (mJ/mm^2) Values Per Standoff

	Standoff				
Energy Level	2	5	10	20	30
Level 1	0.03	0.02	0.02	0.03	0.04
Level 2	0.06	0.05	0.05	0.06	0.07
Level 3	0.10	0.09	0.08	0.08	0.10
Level 4	0.13	0.12	0.11	0.12	0.14
Level 5	0.16	0.15	0.14	0.15	0.17
Level 6	0.20	0.19	0.18	0.19	0.22

Table 3: Energy Flux Density calculated per IEC 61846:1998

Peak Compressional Pressure (MPa) Values Per Standoff

	Standoff				
Energy Level	2	5	10	20	30
Level 1	16.61	12.82	15.13	21.07	27.31
Level 2	49.30	44.14	46.21	45.81	46.85
Level 3	62.35	57.56	51.76	47.34	46.82
Level 4	74.40	68.48	62.41	58.70	58.71
Level 5	80.19	74.57	69.33	66.04	66.43
Level 6	82.16	76.48	70.59	67.25	68.32

Table 4: Peak Compressional Pressure calculated per IEC 61846:1998

Peak Rarefactional Pressure (MPa) Values Per Standoff

	Standoff				
Energy Level	2	5	10	20	30
Level 1	-6.31	-5.94	-5.84	-7.19	-7.86
Level 2	-9.70	-9.31	-9.30	-9.60	-10.38
Level 3	-12.23	-11.58	-10.93	-11.06	-12.08
Level 4	-14.37	-13.99	-13.46	-13.87	-14.93
Level 5	-15.51	-15.37	-14.98	-15.74	-16.91
Level 6	-17.17	-17.01	-16.45	-17.52	-19.09

Table 5: Peak Rarefactional Pressure calculated per IEC 61846:1998

Positional Precision Per Standoff

	Standoff				
Positional Precision	2	5	10	20	30
Focal Target (mm)	2	5	10	20	30
Precision (mm)	±1	±1	±1	±1	±1

Table 6: Positional Precision calculated per IEC 61846:1998

Position and Size of Focal Volume Per Standoff

	Minimum Setting	**Typical Setting**	**Maximum Setting**
Standoff	10	10	30
Energy Setting	1	4	6
Fx -6dB (mm)	1.32	1.30	2.43
Fy -6dB (mm)	1.78	1.73	2.52
Fz -6dB (mm)	7.06	4.85	15.65
V -6dB (mm^3)	8.69	5.71	50.18
Fx -6dB (mm)	1.32	1.30	2.43

Table 7: Position and Size of Focal Volume calculated per IEC 61846:1998

Energy Per Pulse (mJ) Values Per Standoff

	Minimum Setting	**Typical Setting**	**Maximum Setting**
Standoff	10	10	30
Energy Setting	1	4	6
Ef -6dB (mJ)	0.05	0.20	0.26
Ef 5MPa (mJ)	0.08	0.94	1.20

Table 8: Energy per Pulse calculated per IEC 61846:1998

Dimensions/Weight

CS-Pro MED Device	Device in Carrying Case w/ Accessories
8” x 3” x 1 ¾” (203 x 76 x 44.5 mm)	14.3” x 11.1” x 4.7” (36.3 x 28.2 x 11.9 mm)
14.4 oz (0.41 Kg)	8.2 lbs (3.7 kg)

Table 9: Dimensions and weight of CS-Pro MED

Operation

Energy Flux Density Range:	0.02 – 0.22 mJ/mm^2
Pulse Repetition Frequency:	2-12 Hz
Shock Wave Focal Depths:	2, 5, 10, 20, 30 mm
Effective Focal Range (-6dB):	0 – 35 mm
Effective Therapeutic Range (5 MPa):	0 – 60 mm
Sound Output During Use:	58 dBA @ 0.25 m
Battery Life:	>4 Hours
Battery Charge Time:	4 Hours
Reliability:	>5,000,000 shock waves before recalibration
Carrying Case:	IPX7 Ingress, Mil Spec Certified

Table 10: Operating specifications of the CS-Pro MED

Shock Wave Characteristics

Energy Flux Density:	0.22 mJ/mm^2
Peak Positive Pressure:	69 MPa
Peak Negative Pressure:	-19 MPa
Rise Time (10% - 90%):	3 ns
Compressional Pulse Duration:	54 ns
Fx $_{5\ MPa}$ – Therapeutic Width (5 MPa):	18 mm
Fy $_{5\ MPa}$ – Orthogonal Therapeutic Width (5 MPa):	24 mm
Fz $_{5\ MPa}$ – Therapeutic Width (5 MPa):	60 mm
Fx $_{-6\ dB}$ – Therapeutic Width (-6 dB):	1.32 mm

Fy $_{-6\ dB}$ – Orthogonal Therapeutic Width (-6 dB):	1.78 mm
Fz $_{-6\ dB}$ – Therapeutic Width (-6 dB):	7.06 mm
Af - Cross Sectional Area (-6 dB):	1.82 mm^2
Therapeutic Volume (5 MPa):	2025 mm^3 (approx.)
V - Focal Volume (-6 dB):	8.69 mm^3
Ef $_{5\ MPa}$ – Derived Focal Acoustic Pulse Energy (5 MPa):	1.2 mJ
Ef $_{-6\ dB}$ – Derived Focal Acoustic Pulse Energy (-6 dB):	0.26 mJ

Table 11: Shock wave characteristics measured per IEC 61846:1998 with 30 mm standoff at the maximum energy setting

Acoustic Wave Generator

- The coupling to the treatment area occurs via an elastomeric standoff.
- Principle: Piezoelectric. The shock wave is caused by the discharge of high-voltage transducers.

Operation and Display Elements

- LCD screen on the front of the device to control device parameters.
- Power on/off and generation of shock waves controlled by a tactile button on the front of the device

Expected Service Life

The CS-Pro MED has an expected service life of 5 million shock waves or five years from the date of manufacture, as seen on the device's label.

Conditions for Operation

Temperature:	5 - 37°C (41 - 98°F)
Humidity:	5% - 95%, no condensation

Table 12: Operating conditions for CS-Pro MED

7.2. Electromagnetic Compatibility (EMC)

Electronic medical equipment is subject to special precautions regarding EMC (Electromagnetic Compatibility). They must be installed and used in accordance with EMC regulations, as detailed below. The CS-Pro MED is intended for use in the

environment indicated below. Please ensure the CS-Pro MED is operated in such an environment.

 WARNING	**Essential Requirements!** The CS-Pro MED has two essential requirements. 1. The CS-Pro MED must not display incorrect energy values. 2. The CS-Pro MED must not unintentionally release shock waves. If the CS-Pro MED is interrupted by electromagnetic interferences (even if it is certified to IEC 60601-1-2), it may: 1. Display the incorrect energy values, or 2. Unintentionally release shock waves. If either occurs, stop treatment and power down the device.
 NOTE	The CS-Pro MED is intended for use in an electromagnetic environment in which high-frequency (HF) interferences are controlled. You can help reduce electromagnetic interference by obtaining the minimum safe distance between mobile HF telecommunication devices (transmitters) and the CS-Pro MED. This distance depends on the output power of the communication device specified in the table below.
 CAUTION	**Electromagnetic Interactions** If the device is combined with other electrical equipment, the entire configuration must be in accordance with IEC 60601-1-1. Consult a specialist if in doubt. The CS-Pro MED may not be used in the vicinity of or with other equipment in a stacked arrangement. If it is unavoidable to stack the device in close proximity to other equipment, the CS-Pro MED should be carefully observed to detect any adverse effects among the devices installed in the stacked arrangement.
 WARNING	**RF Communication Devices!** Portable radio frequency (RF) communications equipment (such as radios, including their accessories, such as antenna cables and external antennas) should not be used closer than 30 cm away from the manufacturer's designated parts and wiring of the CS-Pro MED. Failure to do so may reduce the device's effectiveness.
 CAUTION	**Communication Devices and Portable Radios** Portable HF communication devices can affect medical electrical equipment. Portable radios should not be used in close proximity to the CS-Pro MED, including all cables that may be affected up to the recommended safe distance, which is calculated from the transmitter frequency used.

CAUTION	**AM, FM, and TV Antennas** Observe the CS-Pro MED's essential requirements if the device is used closer than 0.9 miles (1.5 km) from an AM, FM, or TV antenna. If the CS-Pro MED: 1. Displays the incorrect energy values, or 2. Unintentionally releases shock waves, due to electromagnetic interferences from the antennas, stop treatment and power down the device. The device must be relocated to prevent electromagnetic interference from affecting the essential performance of the CS-Pro MED device.
WARNING	**Devices Sensitive to HF Technology!** The CS-Pro MED used HF technology for internal functions. Devices sensitive to electromagnetic interference (cardiac pacemakers, etc.) should not be operated within close proximity to the CS-Pro MED device.
CAUTION	**Interferences** In this environment, interferences are possible from devices that carry the symbol for non-ionizing electromagnetic radiation.  Non-ionizing Electromagnetic Radiation Symbol

Tables 13, 14, 15, and 16 contain information about HF interference by the manufacturer.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The CS-Pro MED is intended for use in the electromagnetic environment specified below. The customer or the user of the CS-Pro MED should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1 Class B	The CS-Pro MED uses RF energy only for internal functions. Therefore, the RF emissions are very low and are not likely to interfere with nearby electronic equipment. Due to its emission characteristics, the device is allowed to be used in industrial areas, hospitals, and the home healthcare environment (CISPR 11, Class B).

		The user may change the position or realign the device. The CS-Pro MED complies with CISPR 11 except for the triggering and release of shock waves (according to IEC 60601-2-36).	
Test Description	**Standard – Specification IEC 60601-1-2:2014**	**Compliance Level IEC 60601-1-2:2014**	**Test Result for CS-Pro MED**
Radiated Emissions	EN 55011:2009+A1:2010	Class B 30 MHz – 1 GHz	

Table 13: Electromagnetic Radiation Testing

Immunity Test	**Standard – Specification IEC 60601-1-2:2014**	**Test Level IEC 60601-1-2:2014**	**Test Result for CS-Pro MED**
Electrostatic Discharge	IEC 61000-4-2:2008	Contact discharge: ± 8kV Air discharge: ± 2kV, ± 4kV, ± 8kV, ± 15kV	
Radiated RF EM Fields	IEC 61000-4-3:2010	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	
Proximity Fields from RF Wireless Communications Equipment	IEC 61000-4-3:2010	See Table 10.	
Rated Power Frequency Magnetic Fields	IEC 61000-4-8:2009	30 A/m 50 Hz	
Proximity Magnetic Fields	IEC 61000-4-39:	See Table 11.	

Table 14: Electromagnetic Immunity Testing

Test Frequency	Frequency Band	Transmitter Service	Modulation	Maximum Power Rating	Distance	Disturbance test level per IEC 60601-1-2:2014
[MHz]	[MHz]	-	-	[W]	[m]	[V/m]
385	380 bis 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27

450	430 bis 470	GMRS 460, FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2.0	0.3	28
710	704 bis 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 bis 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2.0	0.3	28
870						
930						
1720	1700 bis 1990		Pulse modulation 217 Hz	2.0	0.3	28
1845						
1970						
2450	2400 bis 2570		Pulse modulation 217 Hz	2.0	0.3	28
5240	5100 bis 5800		Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Table 15: Test requirements for disturbance test of CS-Pro MED vs. HF wireless communication devices and safety distances between mobile HF telecommunication devices and the CS-Pro MED

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5

Table 16: Test specifications for immunity to proximity magnetic fields

7.3. Standards

The CS-Pro MED device is designed and manufactured with the following international standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-2-36
- IEC 62304
- IEC 62366
- IEC 62366-1
- ISO 10993-1
- ISO 13485
- ISO 14971
- ISO 15223-1

8. Troubleshooting

Only authorized service personnel may repair the device in the case of an error. Alternatively, the device can be returned to the manufacturer for repair.

 WARNING	**High Voltage!** A fault diagnostic must only be completed by an authorized service personnel. The device contains high voltage within.

The CS-Pro MED device has a detailed error message system. Occurring errors are displayed in clear text (see the section below on Error Messages). The following table contains possible errors without an error message.

Error	Reason	Action
The device cannot be powered on	The battery is insufficiently charged.	Remove the battery and replace it with a charged battery.
	The battery is not connected correctly.	Remove and re-install the battery.
	Internal error in the power supply	Contact manufacturer at: service@curative-sound.com.

Table 17: Troubleshooting issues

Error Messages

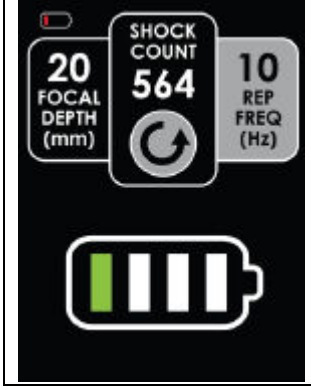
If an error occurs, the LCD screen may display an error message and accompanying error code.

Figure 18: Error code message

If an error code occurs, please stop using the device and contact the manufacturer at service@curative-sound.com.

User Information

During normal operation, the LCD screen displays information that is important for the user to notice to ensure the optimal performance of the CS-Pro MED device. The images and descriptions are shown in the table below.

Image	Description	Action
	**Standoff Missing** Message presented when attempting to start the shock sequence without the standoff properly connected.	Press the Return soft button to clear the message and properly attach the standoff.
	**Low Battery A** Screen presented after power on or idle screen when battery reaches critically low level.	Remove the battery and replace it with a battery with a sufficient charge level.
	**Low Battery B** Screen presented while shock is running and the battery reaches a critically low level.	CS-Pro MED will power down after the shock sequence is complete. Remove the battery and replace it with a battery with a sufficient charge.

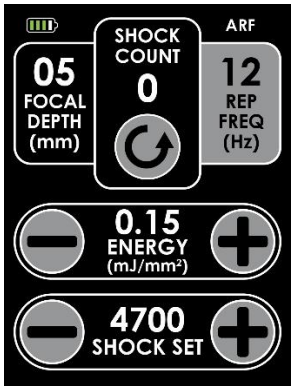
	**Adaptive Rep Frequency (ARF)** Icon in top right corner of screen presented if device automatically places itself in Adaptive Rep Frequency mode.	Under extreme conditions, such as extended use in a hot environment at the maximum Rep Freq and Energy settings, the CS-Pro MED may automatically reduce the shock wave repetition frequency. This ensures the device always delivers the Energy value shown on the display. When this occurs, an ARF will be shown at the top of the display and the sound of the shock wave generation will slow down slightly.

Table 18: User information displayed on the LCD screen

9. Additional Information

9.1. Ordering

To order consumables, accessories, or spare parts online, visit:

https://www.curative-sound.com

To order service, repair, or maintenance, use the same web address or email:

service@curative-sound.com

Product requiring service can be returned to:

Curative Sound, LLC
Warranty & Service Department
11611 N. Meridian Street, Suite 425
Carmel, IN 46032 USA

9.2. Registration of Device

At the earliest convenience, please register the CS-Pro MED device on the Curative Sound website using the QR code shown below:

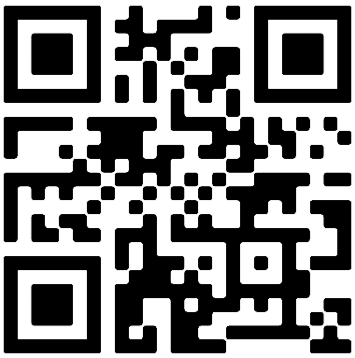


Figure 19: QR code to Curative Sound registration page

9.3. Product Liability and Warranty

During the one-year warranty period from the date of product delivery to the end customer, defects will be remedied at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship. The warranty does not extend to wear parts such as the elastomeric standoff. The customer shall bear transport costs and the risk of loss during shipping.

WARNING	**Unauthorized Modifications!** Modifications to the device are not permitted. Any unauthorized opening, repair, or modification of the device by unauthorized personnel will relieve the manufacturer of its liability and responsibility for safe system operation. This will automatically void the warranty even before the end of the warranty period.
CAUTION	**Exposure to Excessive Temperatures** Extended exposure to temperatures above 55°C or below 5°C will void the warranty. Do not leave the device in a hot vehicle for extended periods.
CAUTION	**Transducer Array Couplant Oil** Only use Curative-Sound-approved transducer array couplant oil on the standoff. The use of petroleum-based oil will void the warranty.

Warranty claims will only be accepted if the device is returned in its complete and original state, cleaned, and in the case. Missing components will be replaced subject to charge. Accessories also sent will be checked and, if necessary, replaced after they have been assessed.

The standoff is considered a wear part and is excluded from warranty claims.

 NOTE	If warranty service work cannot be completed within five business days, the customer will be provided with a loaner unit, subject to service pool unit availability. If the device to be serviced is not under warranty, a loaner unit may be rented while repairs are being made.

9.4. Transport

To prepare for transport, remove the battery from the CS-Pro MED device and place it and all accompanying parts within the supplied carrying case.

 CAUTION	**Transport** To avoid transport damage, transport the CS-Pro MED only in the carrying case provided by the manufacturer.

9.5. Return for Service

Returning to Curative Sound, LLC for service

To send the CS-Pro MED back for service, refer to the section on Transport. Package the device in the transport box and close the lid.

Instructions for Use
CS-Pro MED device

Manufacturer
Curative Sound, LLC
11611 N. Meridian Street, Suite 425
Carmel, IN 46032
Tel.:
Internet: https://www.curative-sound.com
E-Mail: service@curative-sound.com