Model **sam**-12
Ultrasonic
Diathermy
Device

Directions
for Use

Contents

1. Introduction

Thank you for choosing the **sam** Ultrasonic Diathermy Device! This manual contains general instructions for operation, application, precautions, and maintenance. In order to obtain maximum life and efficiency from the **sam** Device and to assist in the proper operation of the device, please read and understand this manual thoroughly. This device is only to be used as directed in this manual.

sam was developed as a next generation wearable ultrasound therapy system which combines miniaturization technology into a small and portable ultrasound therapy system. It is designed to work with the human body and maximize the safe and effective delivery of long-duration therapeutic ultrasound. Simple to administer and operate on a broad range of body types, **sam** allows the delivery of ultrasound treatment for up to four hours. It operates at a preset frequency and allows the use of up to two applicators simultaneously. Applicators are applied and secured to the surface of the body using convenient **sam** Ultrasound Coupling Bandages.

The specifications put forth in this manual were in effect at the time of publication.

1.1. GENERAL SAFETY

Thoroughly read and understand the precautionary and operating instructions before attempting to operate the **sam** Ultrasonic Diathermy Device. Know the limitations and hazards associated with using any ultrasound device. Observe the precautionary and operational decals placed on the device. Periodically review the operation procedures and safety precautions outlined in this manual.

1.2. PRESCRIPTION USE ONLY

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which he/she practices to use or order the use of the device.

This device complies with 21 C.F.R. § 1050.10

2. Indications for Use

The **sam** Ultrasonic Diathermy Device is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures and the local increase of circulation.

The **sam** Ultrasonic Diathermy Device is a prescription use device. **sam** should only be administered and monitored by a licensed healthcare practitioner.

3. Safety

3.1. CONTRAINDICATIONS

Contraindications for the use of ultrasound include:

- Over an area of the body where a malignancy is known to be present
- Over the eyes
- Over or near growth centers until bone growth is complete
- Over the reproductive organs
- Over the pregnant uterus
- Over a healing bone fracture
- On the thoracic area if the patient is using a cardiac pacemaker
- Over an active implanted medical device such as an implanted deep brain stimulation device
- On the brain, spinal cord, or large subcutaneous peripheral nerves
- Ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result

3.2. WARNINGS

- If the treatment is reported as painful or too hot at any point during treatment, turn off device and remove the device from the skin.
- Instruct the patient to inform the practitioner if the patient feels any pain or burning during treatment.
- Instruct the patient how to turn off the **sam** Device and remove the **sam** Applicator if the patient feels any pain or burning during treatment.
- If the *Lock Switch* is in the locked position it must be placed in the unlocked position to disable the power. Locking the treatment settings is optional and not required for treatment.
- ALWAYS administer treatment using a new **sam** Ultrasound Coupling Bandage. Use one **sam** Ultrasound Coupling Bandage per applicator. Use of the **sam** Ultrasound Applicator without a new **sam** Ultrasound Coupling Bandage MAY RESULT IN BURN and/or REPEATED SHUTOFF of the **sam** Applicator.
- The **sam** Device should be kept out of the reach of children.

- **DO NOT** apply the **sam** Applicator with alternative coupling media as a replacement for the **sam** Ultrasound Coupling Bandage. Use of alternative coupling media in lieu of the **sam** Ultrasound Coupling Bandages may reduce the effectiveness of treatment, lead to automatic shutoff of the applicator, or cause a burn.

- **DO NOT** administer treatment if the applicator is not connected to a **sam** Ultrasound Coupling Bandage.

- Applicators and **sam** Ultrasound Coupling Bandages are not sterile. **DO NOT** apply this device over an open wound or inflamed skin.

- **DO NOT** use if the **sam** Ultrasound Coupling Bandage if the **sam** Ultrasound Media is dried out. Indications of a dried out bandage include: the cup is not full of gel, there is dry residue or film in the cup, or there is any cut, break, or opening in the bandage or seals.

- **DO NOT** apply directly over a bone that is near the skin surface.

3.3. PRECAUTIONS

Precaution should be taken when using the device:

- Over an area of the spinal cord following a laminectomy, i.e. when major covering tissues have been removed

- On patients with hemorrhagic diatheses

- Over areas where metal prosthesis or other metallic implants are embedded in tissue which may form a reflective surface to the ultrasound energy causing unintended irradiation of tissue and excessive heating

- Over an acute infection or sepsis

- On patients with peripheral artery disease

- Over a deep vein thrombosis

- Over an anesthetized area or in conjunction with a condition that causes impairment of sensation, such as caused by chemotherapy

- When using the **sam** Ultrasound Coupling Bandage, ensure the top and bottom seals have been completely removed before attaching the applicator to the skin

3.4. INFLAMMABLE GASES AND ANESTHETICS

- Warning: Explosion hazard if used in the presence of flammable anesthetics, open flame, or oxygen-rich environment

3.5. ELECTRONICS AND BATTERY

WARNINGS

- This device is rated IPX-0; therefore, it is **Not Waterproof**. **DO NOT** apply a direct stream of any liquid onto the device, submerge the device, or allow any liquid to pool on the surface of the device. **DO NOT** use if device has been submerged in water.

- This device contains a rechargeable lithium-ion battery. **DO NOT** disassemble, **DO NOT** heat above 100°C, **DO NOT** incinerate or expose to water and **DO NOT** ingest.

- The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased electrical immunity of the equipment or system.

- DO NOT open or modify any component of the **sam** Device. Hazards such as shock, burn or inappropriate functionality can result from unauthorized modification of the **sam** Device.

- Use of the **sam** Device around electromagnetic interference may negatively affect the output performance and safety of the device. Do not use the device if any abnormal functionality occurs.

PRECAUTIONS

- Only recharge the **sam** Device using the **sam** Electrical Charger. Use with any other recharging device may result in damage to the system and void all warranties.

- When not in use, power 'OFF' the device to protect the functionality of the components.

- Avoid dropping the applicator or power controller and avoid scratching the lens of the applicator. Rough handling may reduce the device's acoustic output power, thereby reducing the effectiveness of therapy.

- The power controller and applicators should be routinely checked for cracks and other damage before each use to determine that the device functions normally.

- **DO NOT** place the device in a location where the power charging cord could be a trip hazard.

- **DO NOT** use sharp objects such as a pencil point or ball point pen to operate the buttons on the control panel as damage may result.

- Prevent potential electromagnetic or other interference. **DO NOT** open the **sam** Device or connect the device or components of the device to any non-**sam** part. Keep the device clean and make sure no exposed non-insulated wires are visible. If damage is present, **do not** administer treatment.

4. Features of the sam Device

4.1. PRESET TREATMENT

The **sam** Device is preconfigured to provide continuous ultrasonic output at a preset frequency and intensity which cannot be modified by the user. The user can set the treatment duration to be 1, 2, 3, or 4 hours.

4.2. sam ULTRASOUND APPLICATORS

The **sam** Ultrasound Applicators serve as the ultrasound transducers of the **sam** Device. The applicators offer low-profile design with light emitting diode (LED) on/off notification. The ergonomic plastic housing and smooth contours provide enhanced comfort.

4.3. sam SENSING

sam is designed to work with the human body and maximize the safe and effective delivery of long-duration therapeutic ultrasound. Each **sam** Applicator is equipped with closed-loop continuous temperature monitoring which maintains treatment site temperatures below 44°C during normal operation. See section 13.4 on page 24 for more information.

4.4. sam ULTRASOUND COUPLING BANDAGES

The **sam** Device utilizes ultrasound coupling bandages which are manufactured with ultrasound coupling media sealed inside. The ultrasound coupling bandages ARE REQUIRED to secure the **sam** Applicators to the body.

4.5. BATTERY OPERATION

Powered by a rechargeable lithium-ion battery, the **sam** Device can provide 4 hours of therapy on a single battery charge.

4.6. LOCK SWITCH

The **sam** Power Controller Module includes a slide lock switch that allows the locking of treatment settings so that they cannot be inadvertently modified during a 1 – 4 hour treatment session. Locking the **sam** Power Controller Module will disable both the treatment time toggle button and the power ON/OFF button. To disable the device or modify treatment time once in locked mode, the lock switch must be moved to the unlocked position. Similarly, the device cannot be turned on while in locked mode and must be unlocked first. The use of the locking feature is OPTIONAL.

5. sam Components

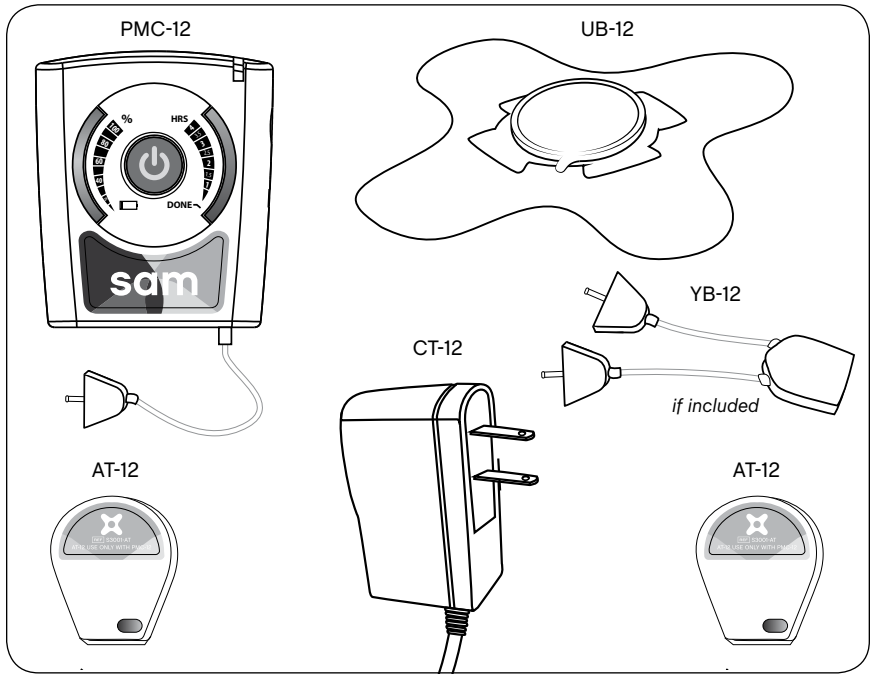

figure 1: sam Model-12 Components

sam MODEL 12 COMPONENTS

AT-12:	Ultrasound Applicators
UB-12:	Ultrasound Coupling Bandages
OM-12:	User Manual
PMC-12:	Power Controller Module
CT-12:	Electrical Charger
YB-12:	Y-branch Adapter

6. Operator Interface

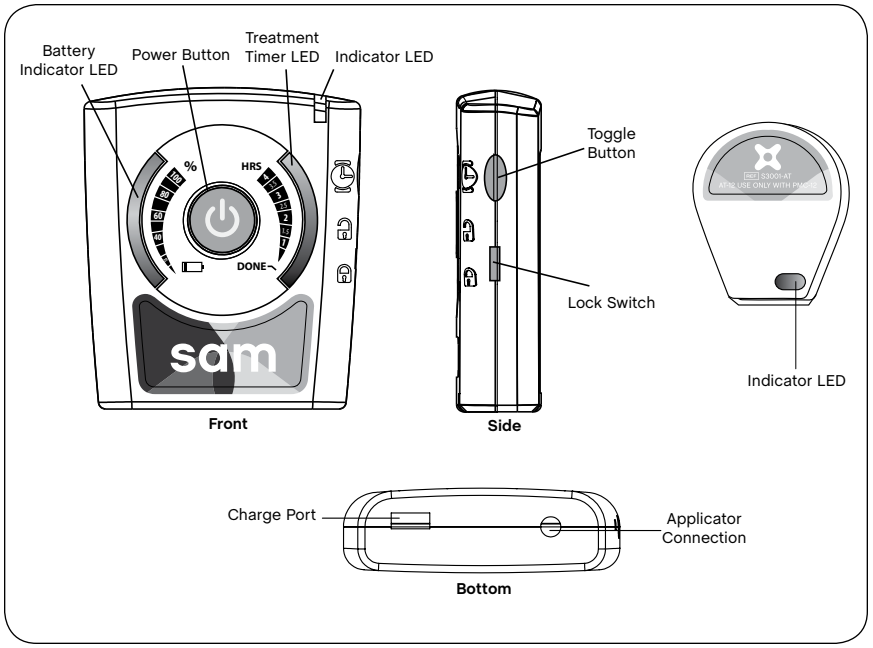

figure 2: sam Interface Components

7. Accessories

The **sam** Device may be used with any of the following accessories:

sam Belt Clip
sam Armband
sam Carrying Case

**** Additional sam Ultrasound Coupling Bandages may be obtained by contacting the manufacturer***

8. LED Display

The **sam** Device contains Light Emitting Diode (LED) displays that indicate the functions of the device (see Figure 2).

8.1. POWER CONTROLLER INDICATOR LED

The Indicator LED provides power, charging and error checking information.

Color of Indicator LED	Meaning
Opaque (absence of light)	Power Controller is OFF. No power is being generated
Blue	Power Controller is ON. Note – ***Ultrasonic energy is generated only when the Power Controller is connected to the sam Applicator(s)***
Green	Power Controller battery is fully charged
Amber	Power Controller battery is charging
Red	Too many applicators are attached. A maximum of two applicators may be attached to a single power controller at any time

Table 1. Power Controller LED Color Definitions

8.2. CONTROL PANEL

The front face of the **sam** Power Controller Module contains a control panel. The LEDs on the control panel are divided into a field for *Battery Indicator* and a field for *Treatment Timer.* The operator is able to make selections by pressing the *Power Button* and the *Toggle Button.*

Color of Battery Indicator LED*	Meaning
Red Only	Low Battery, Re-Charge required
Blinking Red	Re-Charge required
Amber	Power Controller is partially charged
Green	Power Controller fully charged
*These lights remain on for 4 seconds and subsequently turn off	

Table 2. Battery Indicator LED Color Definitions

Treatment Time Indicator LED	Meaning
Blue	Treatment time remaining. Treatment timer is set in one hour increments and will count down in 30 minute increments
Amber	Treatment complete. This single “done” light will activate only when a treatment cycle has completed and will remain illuminated for 8 hours, then turn off

Table 3. Treatment Time Indicator LED Color Definitions

8.3. APPLICATOR INDICATOR LED

LED Color	Meaning
Opaque (absence of light)	Applicator is not receiving power
Blue	Applicator is receiving power from the Power Controller. Ultrasonic energy is being generated at all times this light is illuminated
Red (accompanied by vibration)	**sam** Sensing Mode. ***No Ultrasonic energy is being generated from this applicator while this light is illuminated***

Table 4. Applicator LED Color Definitions

9. Initial Setup Instructions

Remove the **sam** Device components (Figure 1) from the packaging and inspect for any damage that may have occurred during shipment. Charge the device for up to 6 hours or until the Power Controller Indicator LED is Green. The **sam** Device arrives only partially charged due to generally accepted shipping practices.

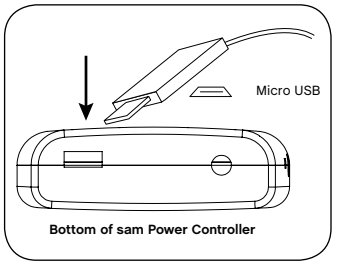

figure 3A

9.1. CHARGING THE POWER CONTROLLER MODULE

A. Plug the micro USB end of the **sam** Electrical Charger into the charging port on the bottom of the **sam** Power Controller.

B. Plug the electrical charger into a 120/230 VAC wall outlet. The **sam** Power Controller Module indicator LED will be amber. When the device is fully charged the top right indicator LED will change from amber to green.

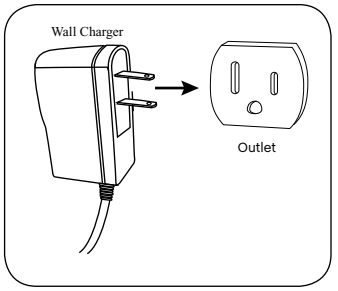

figure 3B

10. Treatment Options

10.1. TREATMENT DURATION

The **sam** Ultrasonic Diathermy Device provides ultrasound therapy at a preset frequency and intensity. The user can program the treatment duration to be 1, 2, 3, or 4 hours. The maximum treatment duration setting on the **sam** Device is 4 hours. Treatment duration should be set to the minimum increment required for effective therapy. Due to individual differences in skin type and tolerance, it is recommended to begin with a 1 hour treatment. Increase treatment duration in subsequent applications only as tolerated. Maximum usage time is 4 hours per day per treatment area.

The **sam** Device may be used while charging. Charging the device during treatment has no impact on device frequency or intensity output settings. If using **sam** while charging, position the device in such a way that the charger cable is easily removed from the power controller module if needed.

10.2. TREATMENT LOCATIONS

Figures 4 and 5 depict examples of device placement on two treatment locations. Figure 4A and 4B illustrates using the **sam** Device with one applicator on the shoulder and knee. Figure 5A and 5B illustrates using the **sam** Device with two applicators on the shoulder and knee. When determining treatment location, consider that the maximum diathermic effect will occur directly under the applicator face; therefore, placing the applicator near or directly over the target area while following all warning and cautionary instructions is advised.

Note: These figures are examples and are not intended to be the suggested or only allowable applicator configurations for those body locations.

Warning: Do Not apply directly over a bone that is near the skin surface.

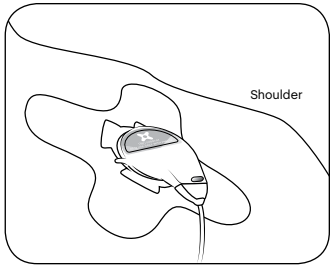

figure 4A: Single Shoulder Application

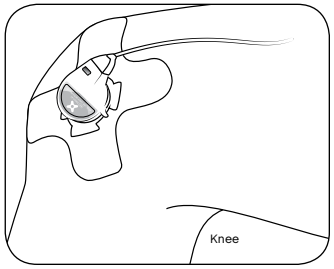

figure 4B: Single knee Application

10.3. ONE OR TWO APPLICATORS:

The **sam** Device may be used with one or two applicators simultaneously. The decision to use one or two applicators is dependent on the size and anatomical area of treatment. Using two applicators allows a larger area of tissue to receive ultrasound treatment. For example, large anatomical regions, such as the shoulder could benefit from two applicators, whereas smaller treatment areas such as the forearm may only require one.

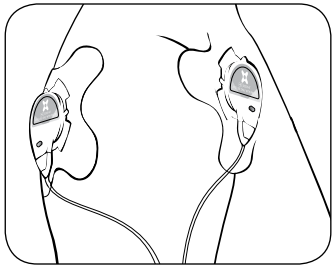

figure 5A: Dual Shoulder Application

10.3.1. SINGLE-APPLICATOR MODE

Connect the power controller wire to a single applicator by inserting the power controller wire jack into the matching cavity at the base of the applicator. The port for the power controller wire is described as '*Applicator connection*' on the Power Controller drawing shown in Figure 2, page 10.

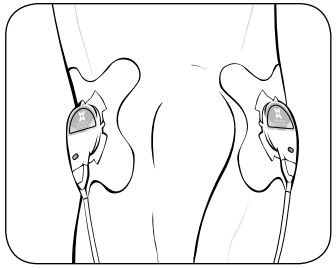

figure 5B: Dual Knee Application

10.3.2. DUAL-APPLICATOR MODE

The Y-adapter (optional) may be used to power two Applicators simultaneously. As shown in Figure 8, connect the Y-adapter directly to the Power Controller wire and then connect each Applicator to a wire jack at the other end of the Y-adapter.

When using two **sam** Applicators and two **sam** Ultrasound Coupling Bandages simultaneously, the **sam** Ultrasound Coupling Bandages should be positioned so that their footprints do not overlap.

Caution: DO NOT overlap sam Ultrasound Coupling Bandages (Figure 6).

Caution: DO NOT use the Y-adapter when using only one applicator for treatment.

Caution: Do NOT attach more than one Y-adapter to the sam Device.

Note: If two applicators will be used, two sam Ultrasound Coupling Bandages (one for each applicator) and the Y-adapter must be used for the treatment.

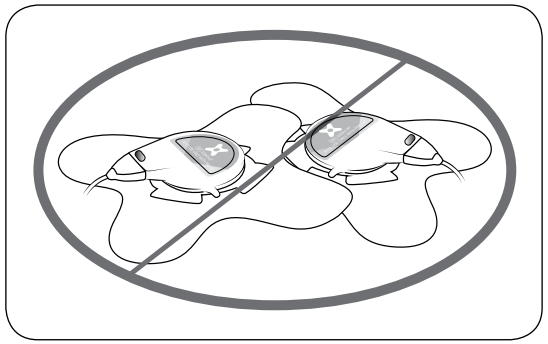

figure 6: NO Bandage Overlap

11. Application Instructions

11.1. CHECK DEVICE CHARGE

A. To prevent accidental activation during shipping, the device will arrive to the user in the 'locked' position. To unlock the device, slide the *Lock Switch* on the **sam** Power Controller 'up' into the 'unlocked' position (Figure 7A).

B. Check to make sure the Power Controller holds enough charge to provide the desired duration of treatment. Press the *Toggle Button* on the **sam** Power Controller to view the battery indicator lights (Figure 7B). The lights will illuminate to show how much battery life is remaining in the device. If the device is not fully charged it may not be able to deliver treatment for 4 hours. The device will only permit the user to set a treatment duration for which the battery charge is capable of fulfilling.

   i. To check the treatment duration for which the battery charge is capable of fulfilling, simply continue to press the *Toggle Button* sequentially to view all timer settings allowed by the current battery charge. See section 9 for charging instructions.

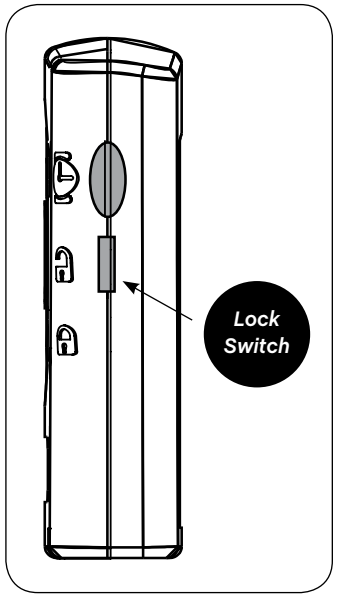

figure 7A: Check Device Charge

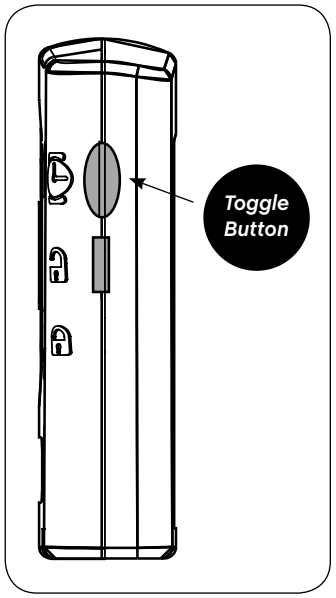

figure 7B: Check Device Charge

11.2. CONNECT APPLICATOR TO POWER CONTROLLER

**** If using 2 applicators: first connect the Y-adapter directly to the power controller wire jack and then connect each applicator to a wire jack at the other end of the Y-adapter (Figure 8*).***

A. Insert the *power controller wire* into the matching cavity at the base of the applicator at a 45 degree angle (Figure 8A).

B. ***Gently*** twist the wire jack clockwise until the applicator edge is flush with the wire jack (Figure 8B).

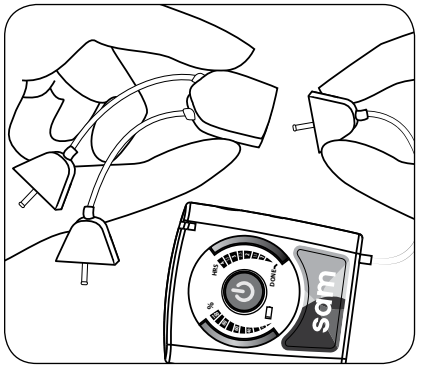

figure 8: Connecting Y-Adapter*

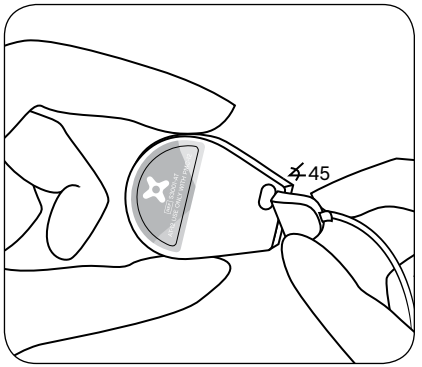

figure 8A: Insert power controller wire at 45⁰ angle

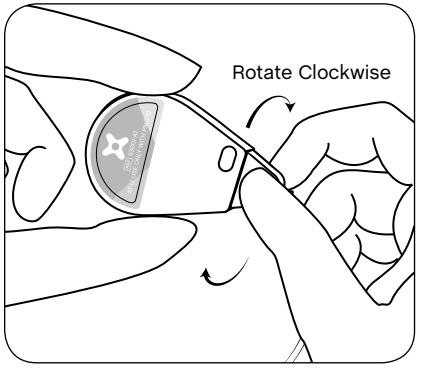

figure 8B: Gently twist to Lock

11.3. ATTACH APPLICATOR TO BANDAGE

A. Remove the circular seal from the top of the bandage to reveal the coupling media within the gel cup (Figure 9A).

B. Attach the applicator, face down, into the coupling media (Figure 9B).

C. Firmly press the applicator down onto the center of the gel cup until a clicking noise is heard or clicking sensation is felt (Figure 9C).

If using dual applicators, repeat these steps with the second applicator and the second bandage.

Note: When the applicator is pressed down onto the gel cup, do not be concerned if coupling media flows out the edges of the gel cup. Wipe any excess coupling media away with a tissue or towel.

Note: Ensure the applicator is fully attached to the bandage.

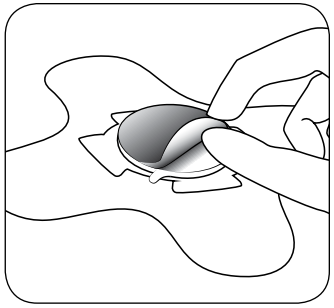

figure 9A: Removing Foil Seal

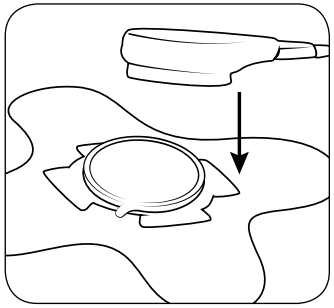

figure 9B: Attach Applicator

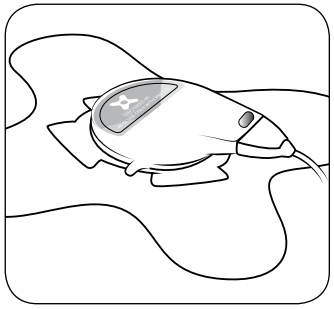

figure 9C: Press Applicator Down

11.4. APPLY ULTRASOUND COUPLING BANDAGE TO TREATMENT LOCATION

A. Hold the applicator so the bottom of the bandage faces up. Remove the paper liner from the back of the bandage, revealing the bandage adhesive (Figure 10A).

i. The circular seal should peel off the bottom of the gel cup along with the paper bandage liner. If it does not peel with the paper, be sure to peel away the circular seal so the coupling media is completely uncovered.

ii. Add more **sam** Coupling Media as needed.

B. Turn the bandage over and adhere the bandage to the desired treatment location (Figure 10B).

i. The **sam** Coupling Media must be in direct contact with the skin.

If using dual applicators, repeat these steps to adhere the second bandage and applicator to the second treatment site.

Note: When applying bandages, both sides of the ultrasound coupling media should be uncovered. One side should be in contact with the skin. The other side should be in contact with the face of the applicator.

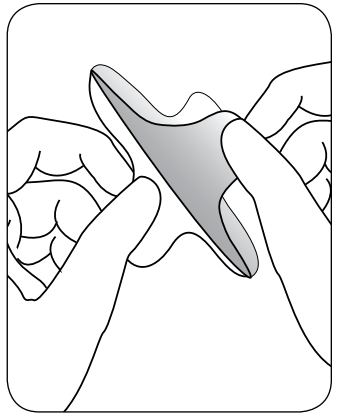

figure 10A: Removing Paper Liner

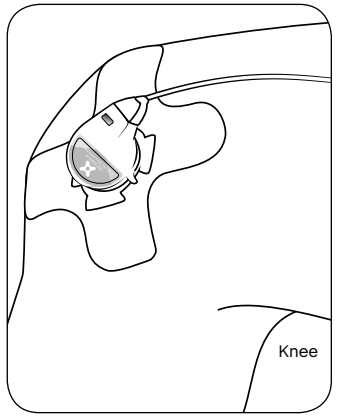

figure 10B: Adhere Bandage to Site

11.5. TURN THE DEVICE 'ON'

A. Check to make sure the *Lock Switch* is in the 'unlocked' position (Figure 11A).

B. Press and hold the *Power Button* on the **sam** Power Controller for at least 1 second to turn the device 'ON' (Figure 11B).

   i. As confirmation that the device is 'ON', the LEDs on the **sam** Power Controller will illuminate blue (treatment timer and indicator LEDs) and the indicator LED on the applicator will illuminate blue.

   ii. The battery indicator LEDs will remain 'ON' for about 4 seconds after turning 'ON' the device.

   iii. The treatment timer LEDs and blue indicator LEDs (power controller and applicator) will remain 'ON' for the duration of treatment.

C. Press the *Toggle Button* to select 1, 2, 3 or 4 hour treatment duration (as allowed by current battery charge) (Figure 11C).

   i. If the *Toggle Button* is pressed up to the 4 hour setting and a decreased treatment time is desired, pressing it again will return the treatment timer to the 1 hour setting.

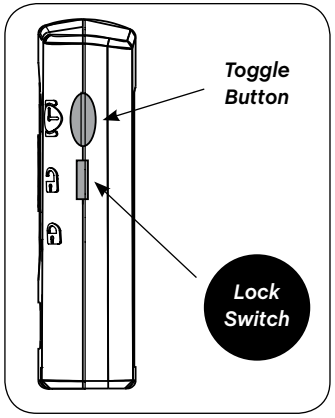

figure 11A: Slide to Unlocked Position

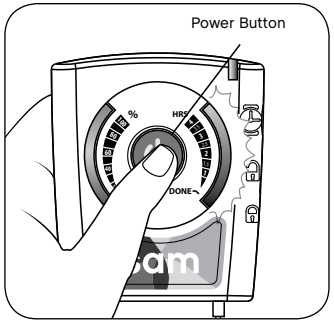

figure 11B: Press Power Button

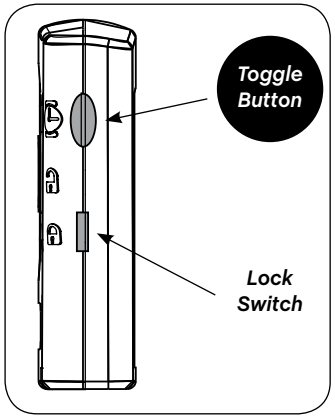

figure 11C: Select Duration

11.6. PREVENT UNINTENTIONAL SHUTOFF

Once satisfied with the treatment settings, the settings may be locked to prevent unintentional shutoff during treatment by sliding the *Lock Switch* down into the 'locked' position as indicated by the symbols on the **sam** Power Controller (see Figure 11A). In this state the settings cannot be changed until the *Lock Switch* is moved back to the 'unlocked' position.

Note: The system is not required to be locked in order to operate. Always be aware of how to disable a locked device. Always notify the patient if their device is locked.

11.7. TREATMENT DELIVERY

Treatment will be delivered for the duration set by the user. The treatment timer LEDs will count down in 30 minute increments as treatment progresses. Upon completion, the device will automatically shut off and the 'treatment complete' LED will illuminate for approximately 8 hours before turning off. See section 12 for how to manually power 'OFF' the device.

Warning: If the sam Lock Switch is in the locked position, the sam Power Button will not turn off the device until the sam Lock Switch is placed into the unlocked position.

Warning: ALWAYS instruct the patient to alert the practitioner in the event of discomfort during treatment.

Warning: As an additional safety measure, ALWAYS instruct the patient how to turn off the sam Device and remove the sam Applicator in the event of discomfort or emergency.

Warning: ALWAYS keep the sam Power Controller within easy reach so that power may be ceased at any time.

12. Device Power Down and Removal

12.1. POWER OFF THE POWER CONTROLLER

Move the *Lock Switch* up to the 'unlocked position' (if locked) then press and hold the *Power Button* on the **sam** Power Controller ***for at least 1 second*** to turn the device 'OFF' (See Figure 11B for device diagram).

12.2. REMOVE DEVICE FROM SKIN

A. Remove the bandage(s) from the skin.

B. Remove the applicator from the **sam** Ultrasound Coupling Bandage by pulling the tab on the side of the gel cup. This unlocks the cup from the applicator (See Figure 12).

C. Throw away the **sam** Bandages.

Warning: NEVER use a sam Ultrasound Coupling Bandage for more than one use. Misuse of sam Ultrasound Coupling Bandages or use for more than the intended treatment duration MAY RESULT IN BURN OR REPEATED SHUTOFF of the applicator.

12.3. CLEAN THE APPLICATORS

Clean any residual ultrasound coupling media off of the applicator and off of the skin. See section 14 for 'Cleaning and Maintenance' details.

12.4. RECHARGE THE DEVICE

Connect the **sam** Power Controller to the **sam** Electrical Charger for recharging. Prior to the next use, allow up to 6 hours to recharge the battery to 100% charge. See section 9 for charging instructions.

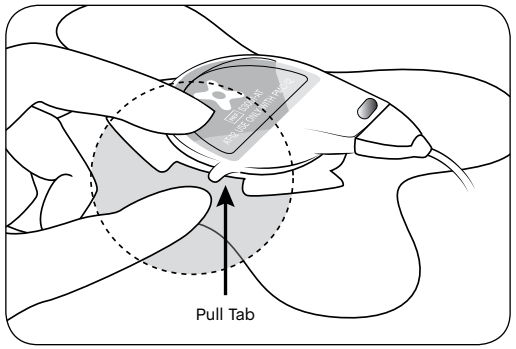

figure 12: Removing Applicator

13. Modes of Operation

13.1. ON (UNLOCKED) MODE

To turn the device 'ON', first ensure the Lock Switch is in the unlocked position as indicated by the unlocked symbol on the **sam** Power Controller Module. Press and hold the *Power Button* for at least 1 second. Press the *Toggle Button* on the right side of the **sam** Power Controller Module to set the treatment duration. The treatment duration may be set for 1, 2, 3 or 4 hours. The battery indicator LED and treatment timer LED will be displayed on the control panel (see section 8: LED Display). The applicator indicator LED will be displayed on each attached applicator (See Figure 2, page 10). Each connected applicator will emit ultrasound energy immediately upon the **sam** Power Controller Module entering the 'ON' mode of operation. The **sam** Applicator will emit ultrasonic energy whether the device is locked or unlocked (locking is optional). A powered **sam** Applicator will always emit ultrasonic energy unless it enters the **sam** Sensing Mode or the treatment duration concludes.

13.2. ON (LOCKED) MODE

Once the device is powered 'ON', the user may lock the control panel settings by sliding the *Lock Switch* on the **sam** Power Controller Module to the 'locked position' as indicated by the lock symbol on the **sam** Power Controller Module. This will prevent the device from unintentional shutoff during treatment. While locked, the *Power Button* and the *Toggle Button* cannot be modified. The **sam** Applicator will emit ultrasound whether the device is locked or unlocked. To change the treatment duration or turn the power off, simply slide the *Lock Switch* to the 'unlocked position' as indicated by the symbols on the **sam** Power Controller Module then press the desired user button.

Warning: If the Lock Switch is in the locked position, the Power Button will not turn off the device until the Lock Switch is placed into the unlocked position. Locking the treatment settings is not required.

13.3. OFF MODE

When the device is 'OFF', the LEDs on the applicator will not be illuminated, the LEDs on the **sam** Power Controller Module will not be illuminated, and no ultrasound energy will emanate from the device. Always turn the device 'OFF' when not in use or if pain or uncomfortable heating is indicated by the patient.

13.4. SAM SENSING MODE

In the event that the treatment site underneath the applicator reaches the temperature threshold, the applicator will pause ultrasound output and vibrate once with a red LED notification to signify that the device has begun a cooling or rest cycle. **sam** Applicator will automatically resume treatment with a blue LED notification after the site has cooled.

Warning: Should the patient ever report discomfort or a painful sensation from the site under the sam Applicator, the applicator should be removed immediately.

Caution: At no time during treatment should the applicator be covered by thick insulating material such as a coat, blanket or sports wrap. This may cause sam to disable and remain disabled throughout the therapy session.

13.5. END OF TREATMENT MODE

At the end of treatment, an amber-colored "Treatment Complete" LED will illuminate on the **sam** Power Controller Module and all other displays (battery indicator, treatment timer, indicator LED, and applicator LEDs) will be inactive. All ultrasound emissions from the applicator will cease. The "Treatment Complete" LED will remain illuminated for approximately 8 hours after completion of therapy, at which point it will time out and turn off. To set the **sam** Device for a new treatment, remember to move the lock switch to the unlocked position and assess whether the **sam** Device requires recharging.

14. Cleaning and Maintenance

The exterior of the **sam** Power Controller and the applicator surfaces may be cleaned with a soft cloth, tissue, or towel and one of the following cleaning agents: mild detergent and water or disinfecting medical wipes.

Caution: Properly clean the applicator between treatments.

Caution: The device is not waterproof. Do not apply a direct stream of liquid onto the device, submerge the device, or allow any liquid to pool on the surface of the device.

Caution: DO NOT USE: Phenolic-based disinfectants, quaternary ammonium, chlorine-based disinfectants, solvent-based cleaners, or abrasive materials. Doing so may damage the plastic housing and void the warranty.

15. Storage & Operating Conditions

15.1. STORAGE

Store the **sam** Device in the following conditions:

Temperature: 5-57 °C;
Humidity: 10-80%;
Atmospheric pressure range: 700-1060 hPa

Store the **sam** Ultrasound Coupling Bandages in the following conditions:

Temperature: 5-30 °C;
Humidity: 10-80%;
Atmospheric pressure range: 700-1060 hPa

15.2. OPERATION

Only operate the **sam** Device in the following conditions:

Temperature: 1-44 °C;
Humidity: 10-80%;
Atmospheric pressure range: 700-1060 hPa

Caution: Do not keep the device in extreme hot or cold temperatures (above 50°C or below 0°C). Do not leave the sam Device in a hot or freezing car. Do not leave the device in direct sunlight for extended periods. UV light may damage or discolor the device.

16. Disposal of Waste Products

sam Ultrasound Coupling Bandages are one time use and may be disposed of in regular sanitation trash. No special disposal procedures are necessary.

Old, damaged or expired **sam** Power Controller Modules and applicators should be recycled or returned to the manufacturer for proper disposal.

17. Appendix

A. SYMBOLS

	Consult User Manual/Instructions for Use
	Manufacturer/Date of Manufacture
	Lithium-ion battery inside
	Class BF Applied Part
	Do not use if package is damaged
	Do not reuse
	Non-ionizing radiation
	Separate collection for electrical and electronic equipment. Must not be disposed of in unsorted municipal waste.
	Caution, consult accompanying documents
	Diverging beam
	Continuous wave (CW)
W	Watts, ultrasonic power
MHz	Frequency in megahertz
ERA	Effective radiating area
BNR	Beam non uniformity ratio
	Use by date
	Temperature limits
	Humidity limitation
SN	Serial number
REF	Catalogue/Reorder Number
LOT	Lot number

B. SPECIFICATIONS

The **sam** Device does not contain microprocessor or software

Maximum Acoustic Power Output	0.65 W ±20% per transducer 1.3 W ±20% for 2 transducers
Maximum Intensity	0.132 W/cm^2 ±20%
Frequency	3 MHz ±20%
Duty Cycle	100% - continuous wave
Beam Form	Wide Beam – 5 degree diverging lens
Individual Transducer Dimension	5 cm^2 emitting surface area (circular)
BNR	<5:1
ERA	6 cm^2
Maximum Treatment Duration	4 hours

Other Electrical Ratings for the **sam** Device Components

Electrical Charger (Model GS2U-006-050-A)

Input Voltage	100-240 V, 50-60 Hz
Input Current	0.2 A
Output Voltage	5 V DC
Output Current	1.2 A
Max Output Power	6 W

Power Controller

Output Voltage	3.7 V DC ±10%
Max Output Amperes	700 mA
Battery Protection	Max Current: 2 Amps Max Voltage: 4.2 V Min Voltage: 3.1 V
Cable Voltage Rating	300 V
Cable 20°C Resistance:	94/km

Applicator

Input Voltage:	3.7 V DC ±10%
Ultrasound Frequency:	3 MHz ±20%
Ultrasonic Output Power:	1 Transducer: 0.65 W ±20% 2 Transducers Together: 1.3 W ±20%
Max Input Current:	400 mA

Y-Adapter

Voltage Rating	300 V
20°C Resistance	94/km

C. NOTICE OF COMPLIANCE, CALIBRATION AND OPERATIONAL PERIOD

The **sam** Device meets performance standards under 21 C.F.R. § 1050.10 - PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS. The **sam** Device meets IEC 60601-1, 3 ed. (2012); IEC 60601-1-2, 3 ed. (2007); Medical Electrical Equipment, General Requirements for Safety; Electromagnetic Compatibility. The **sam** Device is calibrated to provide 3 MHz ±20% ultrasound diathermy at 0.65 W ±20% per ultrasound applicator.

Operational Period:
The **sam** Power Controller Module is intended to maintain calibration for up to 300 charging cycles and each ultrasound applicator is intended to withstand 1500 hours of run time, after which the system should be recycled or returned to ZetrOZ, Inc. for proper disposal.

D. TECHNICAL INFORMATION

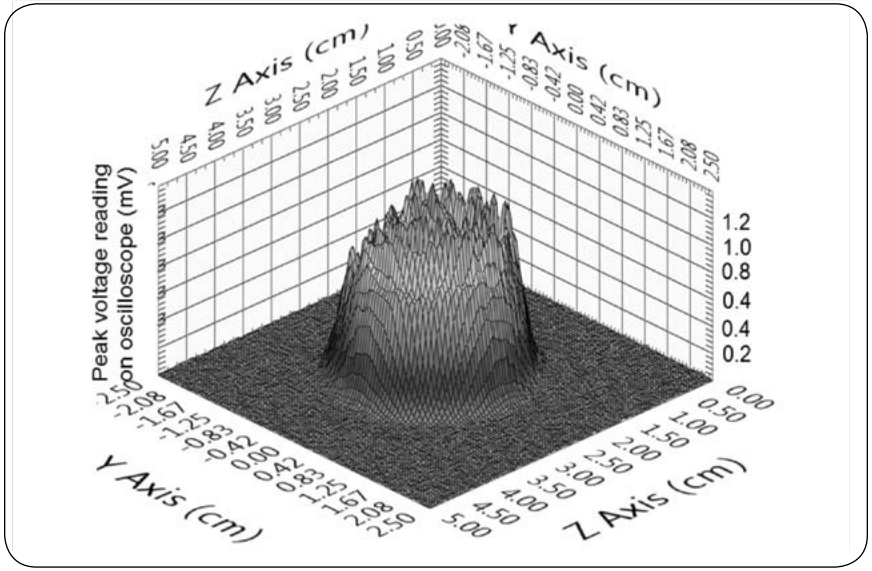

figure A. Ultrasound Field Scan Across Applicator Face

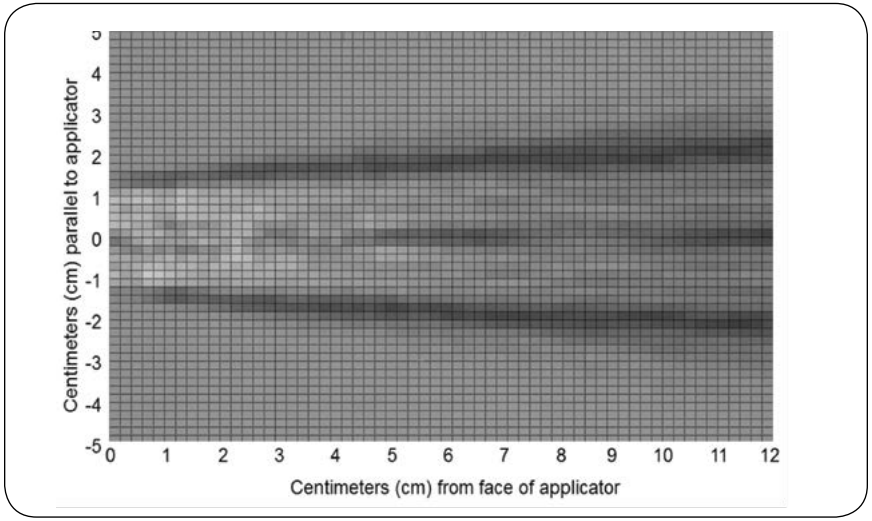

figure B. Ultrasound Field Scan Away From the Applicator Face

E. ELECTRICAL IMMUNITY AND EMISSIONS

The following components of the **sam** Ultrasonic Diathermy Device are compliant with the requirements of IEC 60601-1-2 ed 3.0 (2007-03):

sam Model 12

	Cable Length
AT-12: Ultrasound Applicators	
UB-12: Ultrasound Coupling Bandages	
PMC-12: Power Controller Module	48 inches ±1.2
CT-12: Electrical Charger	60 inches ±2.0
YB-12: Y-branch Adapter	8 inches ±.6 x 2

Guidance and Manufacturer's Declaration – Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The **sam** 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 CISPR 11	Class B	The **sam** is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3		

Guidance and Manufacturer's Declaration – Immunity All ME Equipment and ME Systems

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 610000-4-4	2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential Common N/A (no ground)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **sam** requires continued operation during power mains interruptions, it is recommended that the **sam** be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from the **sam** by no less than the distances calculated/listed below:
Conducted RF	3 Vrms	(V1) = 3 Vrms	D = (3.5/V1)(Sqrt P)
IEC 61000-4-6	150 kHz to 80 MHz		150 kHz to 80 MHz
Radiated RF	3V/m		D = (3.5/Eq)(Sqrt P)
IEC 61000-4-3	80 MHz to 2.5 GHz	(E1) = 3 V/m	80 to 800 MHz D=(7/E1)(Sqet P) 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strength from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Recommended Separation Distances between portable and mobile RF Communications equipment and the sam ME Equipment and ME Systems that are NOT Life-supporting

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

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz	Separation (m) 80 to 800MHz	Separation (m) 800MHz to 2.5GHz
	D=(3.5/V1)(Sqrt P)	D=(3.5/E1)(Sqrt P)	D=(3.5/E1)(Sqrt P)
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1.0	1.1667	1.1667	2.3333
10.0	3.6894	3.6894	7.3785
100.0	11.667	11.667	23.333

F. WARRANTY

ZetrOZ, Inc. offers a 1-year manufacturer's warranty for the **sam** Device. If the **sam** Device fails due to defects in material or workmanship, ZetrOZ, Inc., at its discretion, will:

1. REPAIR the **sam** Device OR
2. REPLACE the **sam** Device with another **sam** Device

THIS LIMITED WARRANTY AND ANY IMPLIED WARRANTIES THAT MAY EXIST UNDER STATE LAW APPLY ONLY TO THE ORIGINAL PURCHASER OF THE **sam** DEVICE AND ARE NON-TRANSFERABLE.

Extent of Limited Warranty
This limited warranty does not cover damages due to external causes, including, without limitation, accident, usage not in accordance with product instructions, misuse, neglect, alteration or repair.

G. TROUBLESHOOTING

Question or Problem	Solution
1. How to determine if the device is delivering treatment	As confirmation that the device is delivering ultrasound, the LEDs on the Power Controller will illuminate blue (treatment timer and indicator LEDs) and the indicator LED on the applicator will illuminate blue. See section 8 on LED Display.
2. The device isn't turning ON and the buttons aren't working	Ensure the power controller lock switch is in the UNLOCKED position. If the device still fails to power ON/OFF or toggle treatment duration, contact the manufacturer with serial and model number details.
3. The indicator LED on the Applicator does not illuminate when the device is turned ON	Ensure that the applicator is fully connected to the power controller wire jack and/or the Y-adapter wire jack. If recently in **sam** Sensing Mode, ensure that the applicator has had time to reach normal operating temperature and the indicator LED on the applicator has turned from red back to blue. If the applicator LED still fails to illuminate blue, contact the manufacturer with serial and model number details.
4. How to observe the Battery level during treatment	The Battery Indicator display can only be viewed when the device is powered ON or OFF by pressing the *Power Button,* or when the *Toggle Button* is pressed. (See section 11.1) The lights remain illuminated for approximately 4 seconds after the device is turned ON or OFF. The Battery Indicator LEDs do not remain illuminated during treatment. The treatment duration is indicated by the blue treatment timer LEDs (See section 8 on LED display).

G. TROUBLESHOOTING

Question or Problem	Solution
5. The Applicator is not staying secured during treatment	Turn off the device. Remove the **sam** Ultrasound Coupling Bandage from the applicator. Replace with new **sam** Ultrasound Coupling Bandage. See section 11.3 for gel cup application instructions.
6. The Applicators are vibrating and red	The device has entered '**sam** Sensing Mode' (See section 13.4) Each **sam** Applicator is equipped with closed-loop continuous temperature monitoring which maintains treatment site temperatures below 44°C during normal operation. In the event that the treatment site underneath the applicator reaches the temperature threshold, the applicator will pause ultrasound output and vibrate once with a red LED notification that the device has begun a cooling or rest cycle. **sam** will automatically resume treatment with a blue LED notification after the site has cooled. **Caution:** At no time during treatment should the applicator be covered by thick insulating material such as a coat, blanket or sports wrap. This may cause **sam** to disable and remain disabled throughout the therapy session.

sam

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