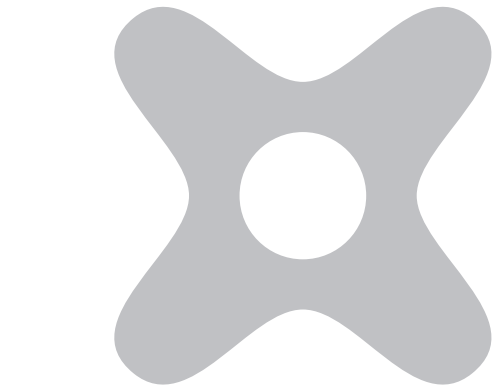

Directions for Use

sam Model 551

Product Support **1-888-202-9831**

Contents

1. Introduction

Thank you for choosing **sam**! This manual contains general instructions for operation, application, precautions, and maintenance. In order to obtain maximum life and efficiency from the **sam X1** 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 one hour. It operates at a preset frequency and time. Applicators are applied and secured to the surface of the body using convenient **sam** Ultrasound Coupling Patches.

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 X1** Long Duration Ultrasound Device. Know the limitations and hazards associated with using any ultrasound device. Observe the precautionary and operational information on the device. Periodically review the operation procedures and safety precautions outlined in this manual. The patient is an intended operator of this device.

1.2. USA: 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 X1** Long Duration Ultrasound Device is intended for home use 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 in circulation.

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 painful or too hot at any point during treatment, turn off the device and remove the device from the skin.
- If any pain or burning is felt during treatment, remove the device.
- ALWAYS administer treatment using a new **sam** Ultrasound Coupling Patch. Use one **sam** Ultrasound Coupling Patch per applicator. Use of the **sam X1** Ultrasound Applicator without a new **sam** Ultrasound Coupling Patch MAY RESULT IN BURN and/or REPEATED SHUTOFF of the **sam X1** Applicator.
- The **sam X1** Device should be kept out of the reach of children.
- **DO NOT** apply the **sam X1** Applicator with alternative coupling media as a replacement for the **sam** Ultrasound Coupling Patch. Use of alternative coupling media in lieu of the **sam** Ultrasound Coupling Patches 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 Patch.
- Applicators and **sam** Ultrasound Coupling Patches are not sterile. **DO NOT** apply this device over an open wound or inflamed skin.

- **DO NOT** use the **sam** Ultrasound Coupling Patch if the **sam** Ultrasound Media is dried out. Indications of a dried out Patch 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 Patch 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 Patch, 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 IP22 . 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. **DO NOT** shower, bathe, or swim with device.
- 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.
- Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.
- Keep out of reach of children and pets. Small parts are a choking hazard. To avoid injury or product damage due to tripping, strangulation, entanglement, ensure wires are secured.
- DO NOT open or modify any component of the **sam X1** Device. Hazards such as shock, burn or inappropriate functionality can result from unauthorized modification of the **sam X1** Device.
- **DO NOT** service or maintain the **sam X1** device while in use.
- Use of the **sam X1** 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.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such

use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **sam X1** Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

PRECAUTIONS

- Only recharge the **sam X1** Device using the **sam X1** 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 Pontroller 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 as damage may result.
- Prevent potential electromagnetic or other interference. **DO NOT** open the **sam X1** device or connect the device or components of the device to any non-**sam X1** 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 X1 Device

4.1. PRESET TREATMENT

The **sam X1** Device is preconfigured to provide continuous ultrasonic output at a preset frequency, intensity, and time which cannot be modified by the user.

4.2. SAM ULTRASOUND APPLICATORS

The **sam X1** Ultrasound Applicators serve as the ultrasound transducers of the **sam X1** 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 X1 is designed to work with the human body and maximize the safe and effective delivery of long-duration therapeutic ultrasound. Each **sam X1** Applicator is equipped with closed-loop continuous temperature monitoring which maintains treatment site temperatures below 44°C during normal operation.

4.4. **sam** ULTRASOUND COUPLING PATCHES

The **sam X1** Device utilizes ultrasound coupling Patches which are manufactured with ultrasound coupling media sealed inside. The ultrasound coupling Patches ARE REQUIRED to secure the **sam** Applicators to the body.

4.5. BATTERY OPERATION

Powered by a rechargeable lithium polymer battery, the **sam** Device utilizes a battery-operated power controller which delivers one hour of therapy on a single charge.

5. sam X1 Components

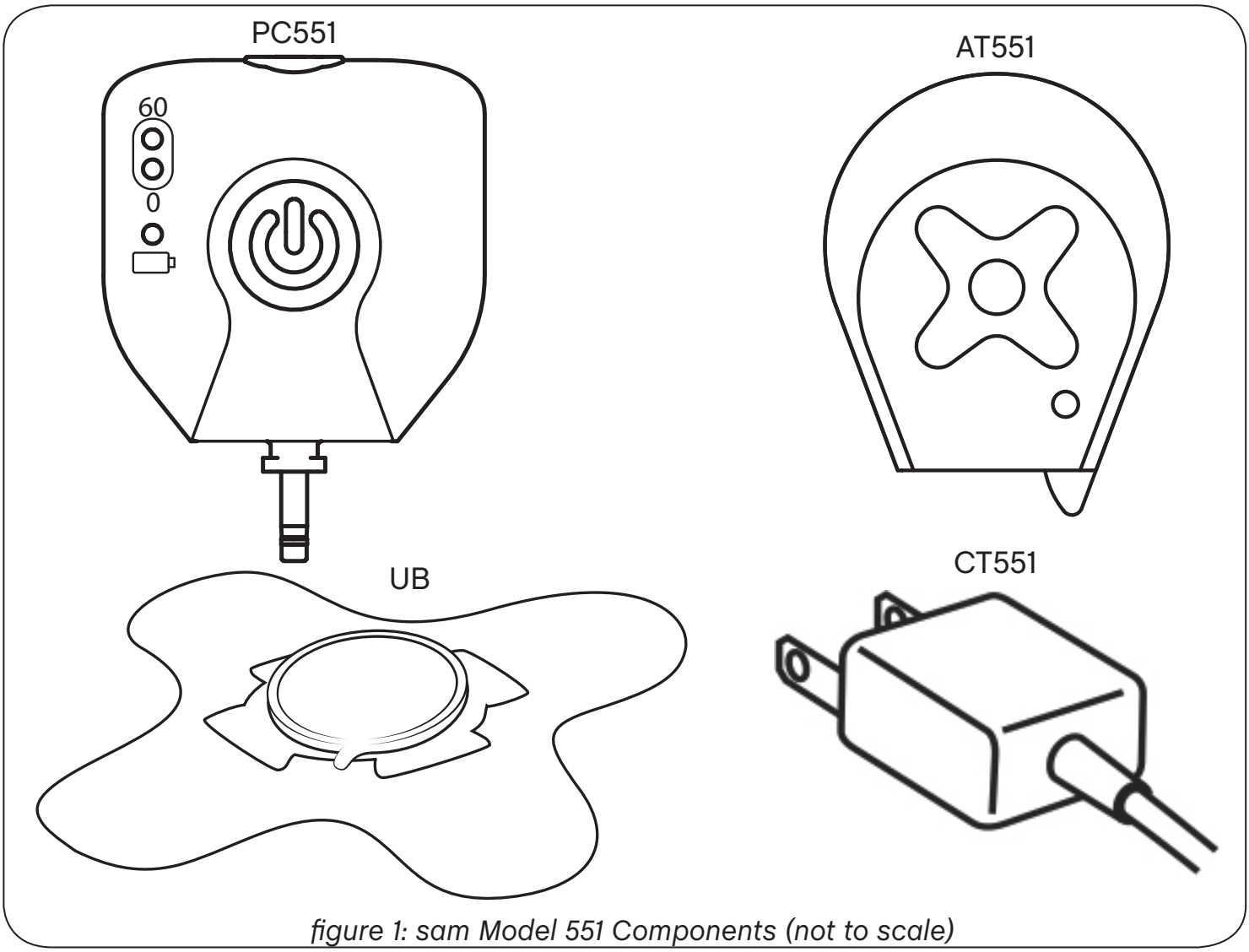

figure 1: sam Model 551 Components (not to scale)

sam MODEL 551 COMPONENTS

AT551:	Ultrasound Applicators
UB:	Ultrasound Coupling Patches
PC551:	Power Controller
CT551:	Electrical Charger
OM551:	User Manual
QS551:	Quick Start Guide

6. Operator Interface

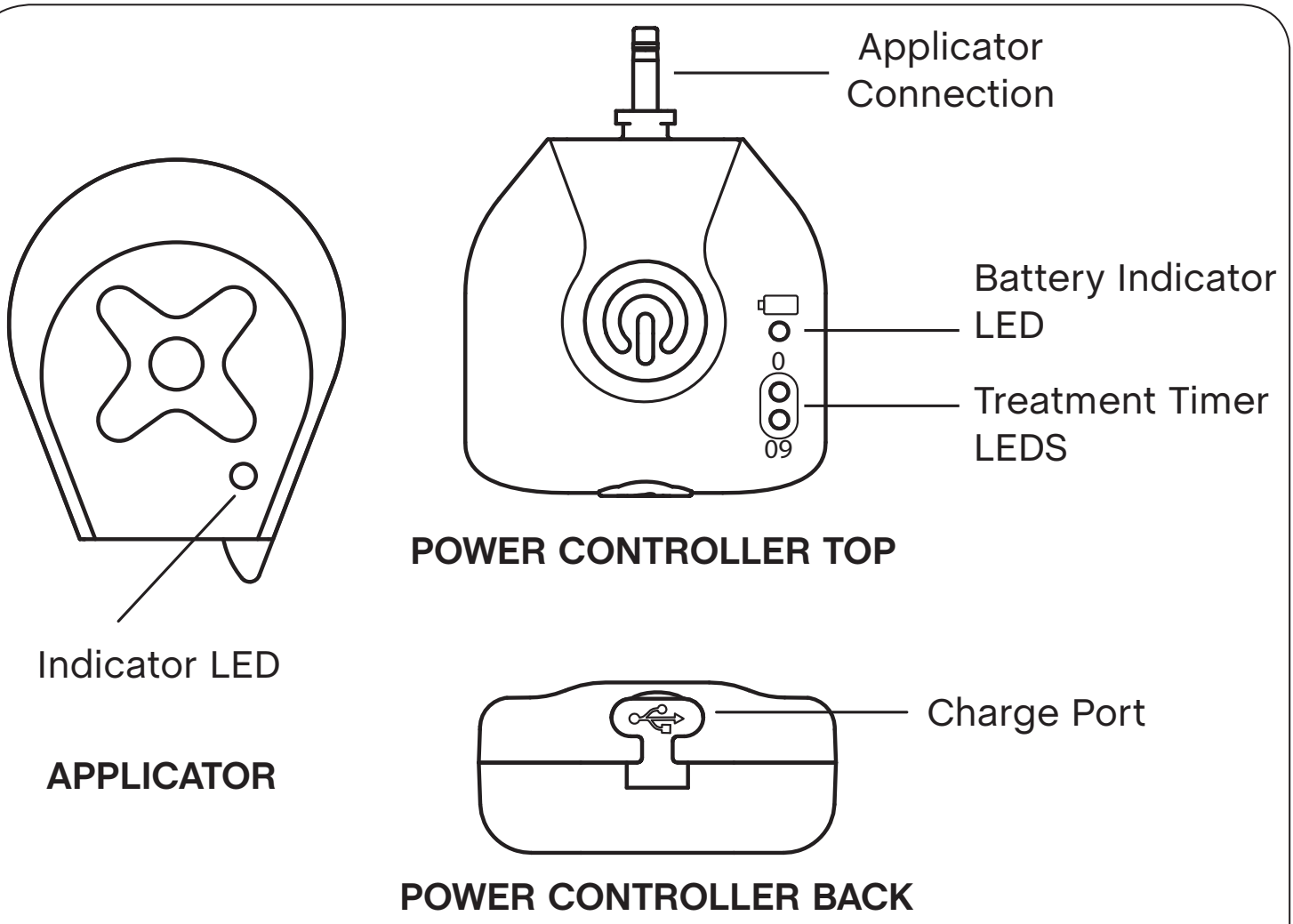

figure 2: sam Interface Components

7. LED Display

The **sam X1** Device contains Light Emitting Diode (LED) displays that indicate the functions of the device (see Figure 2). The front face of the **sam X1** Power Controller contains a power button that turns on power to the applicator.

7.1. POWER CONTROLLER BATTERY INDICATOR LED

Color of Indicator LED	Meaning
Opaque (absence of light)	Charger is not attached
Red	Power Controller is charging
Green	Power Controller is fully charged

7.2. TREATMENT TIMER LEDS

The green LEDs count down at 15 minute intervals.

Treatment Timer LED	Meaning
Green	Power controller is delivering power. Note – ***Ultrasonic energy is generated only when the Power Controller is connected to the sam Applicator***
Two Solid LEDs	The timer is set for 60 minutes
One blinking green LED one solid green LED	15 minutes have passed and 45 with minutes remain
One Opaque LED with one solid Green LED	30 minutes have passed, 30 minutes remain
One blinking green LED	15 minutes remain

7.3. 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.
Red (accompanied by vibration)	**sam** Sensing Mode. ***No Ultrasonic energy is being generated from this Applicator while this light is illuminated***

8. Initial Setup Instructions

Remove the **sam X1** Device components (Figure 1) from the packaging and inspect for any damage that may have occurred during shipment. Charge the device for up to 2 hours or until the Power Controller Indicator LED is Green. The **sam X1** Device arrives only partially charged due to generally accepted shipping practices.

8.1. CHARGING THE POWER CONTROLLER

The **sam X1** *device must be charged fully prior to each use.*

A. Peel back the dust cover on the bottom of the **sam X1** Power Controller and plug the micro USB end of the **sam X1** Electrical Charger into the charging port.

B. Plug the electrical charger into a 120/230 VAC wall outlet. The **sam X1** Power Controller indicator LED will be red. When the device is fully charged the indicator LED will change to green.

C. To disconnect from the mains power supply, unplug the wall charger from the outlet.

figure 3A

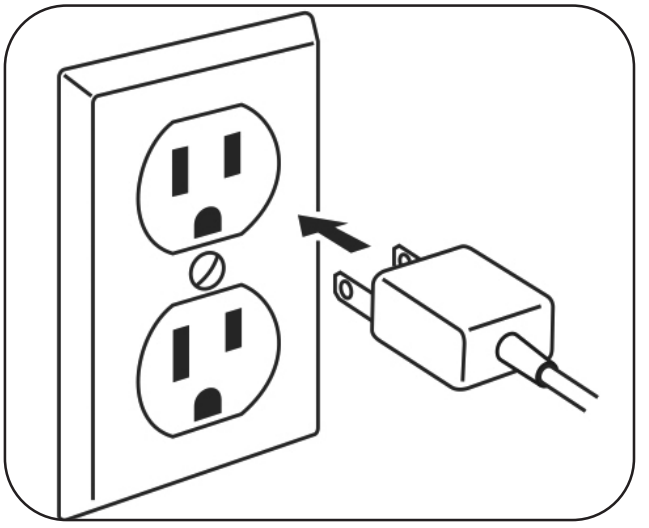

figure 3B

9. Treatment Options

9.1. TREATMENT DURATION

The **sam X1** Long Duration Ultrasound Device provides ultrasound therapy at a preset frequency, intensity, and time. The maximum treatment duration setting on the **sam** Device is one hour.

The **sam** Device cannot be used while charging.

9.2. TREATMENT LOCATIONS

Figures 4 and 5 depict examples of device placement on two treatment locations. Figure 4A and 4B illustrates using the **sam X1** device with one applicator on the shoulder and knee. Figure 5A and 5B illustrates using the **sam X1** 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.

9.3. ONE OR TWO APPLICATORS

The **sam X1** 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.

When using two **sam X1** Applicators and two **sam** Ultrasound Coupling Patches simultaneously, the **sam** Ultrasound Coupling Patches should be positioned so that their footprints do not overlap.

9.4. PLACEMENT EXAMPLES

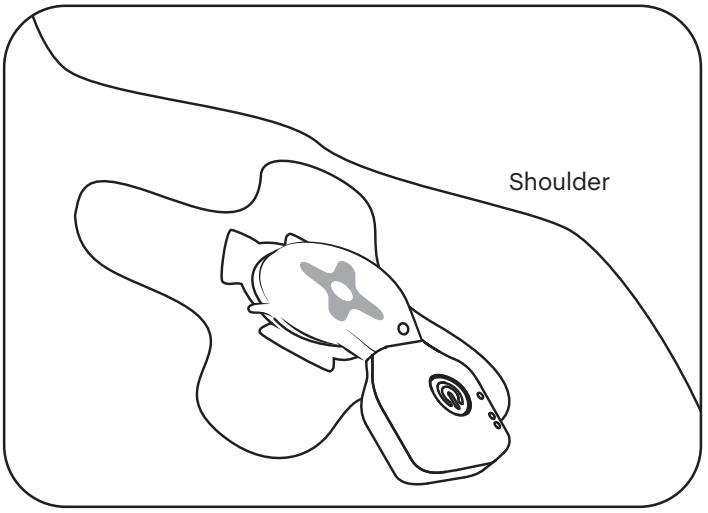

figure 4A: Single Shoulder Application

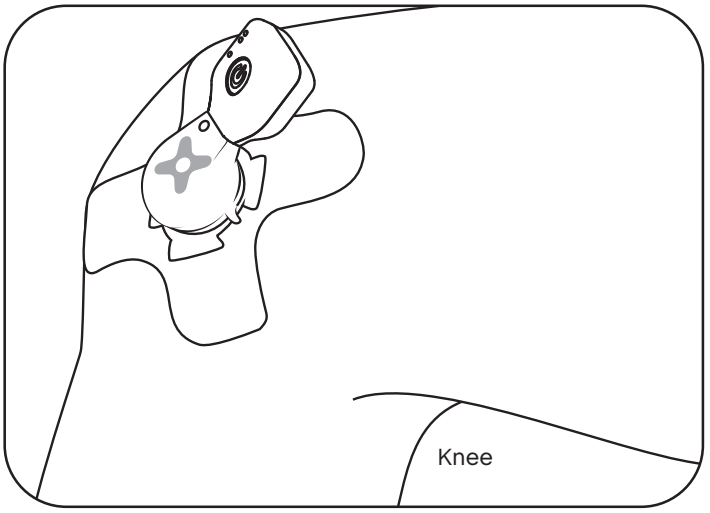

figure 4B: Single knee Application

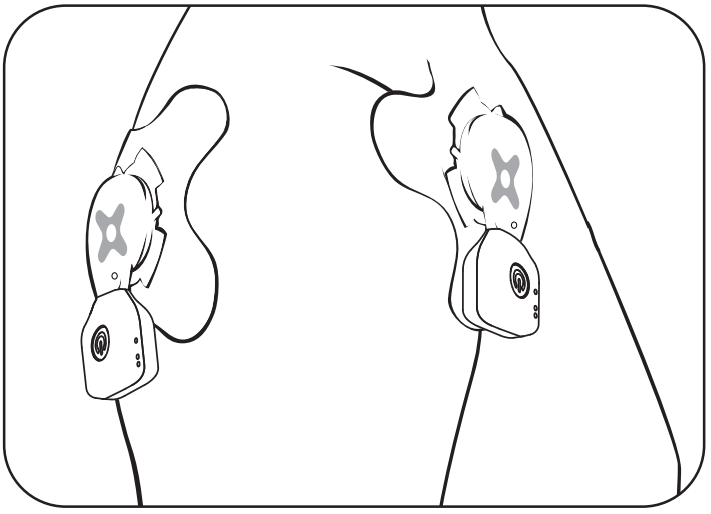

figure 5A: Dual Shoulder Application

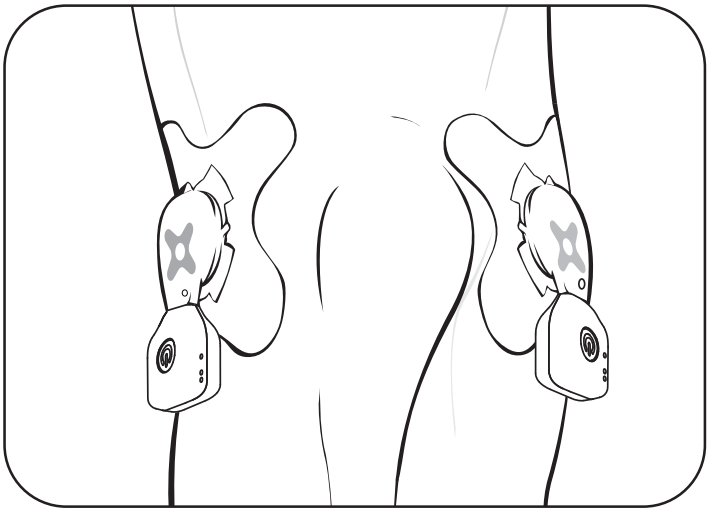

figure 5B: Dual Knee Application

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

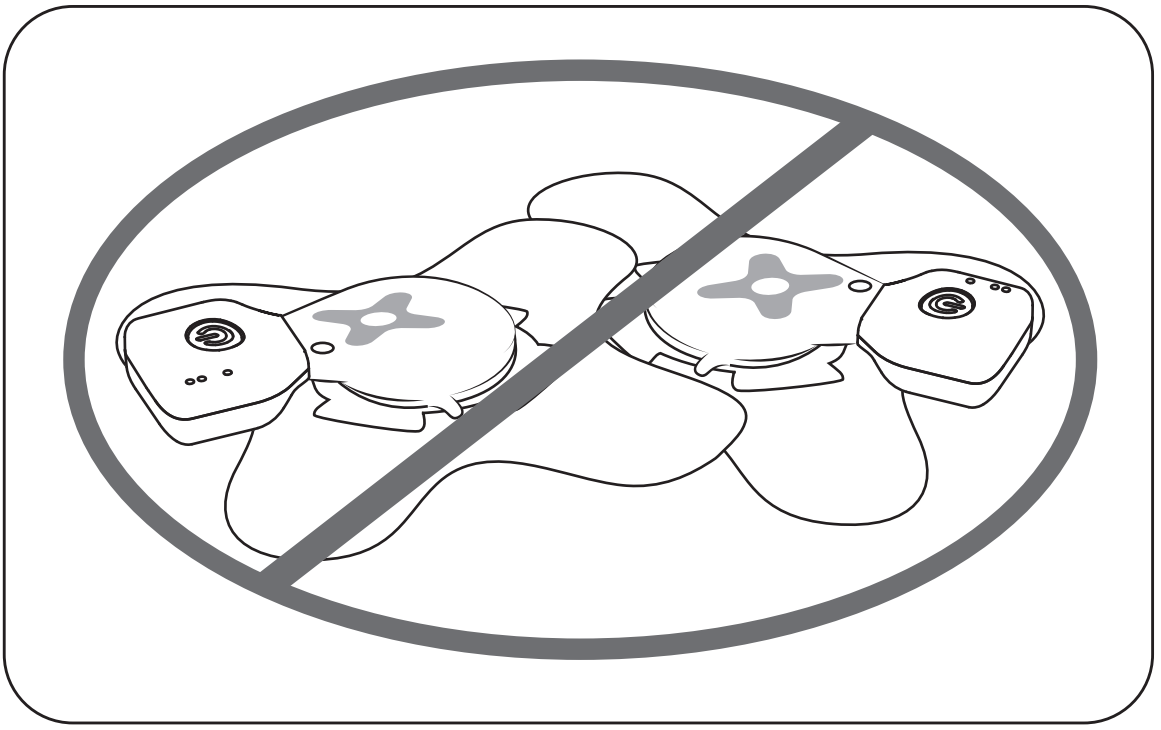

figure 6: NO Patch Overlap

10. Application Instructions

10.1. CHECK DEVICE CHARGE

A. Check to make sure the Power Controller holds enough charge to provide the desired duration of treatment.

10.2. CONNECT APPLICATOR TO POWER CONTROLLER

A. Insert the Power Controller Connector into the matching cavity at the base of the Applicator at a 45 degree angle (Figure 7A).

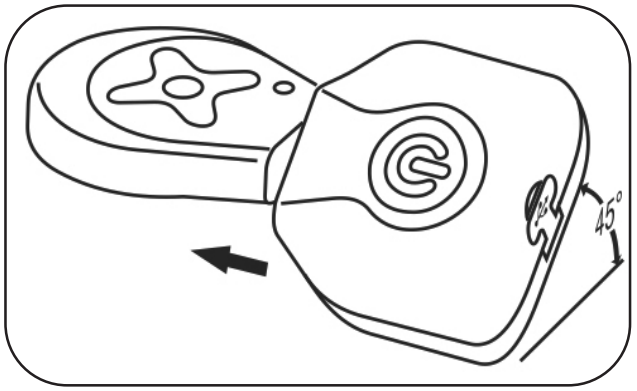

figure 7A: Insert Power Controller wire at 45⁰ angle

B. ***Gently*** twist the power controller clockwise until the Applicator edge is flush with the Power Controller (Figure 7B).

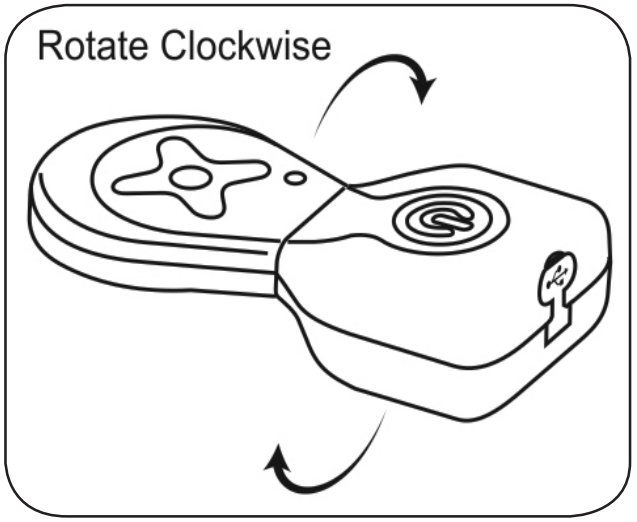

figure 7B: Gently twist until flush

10.3. ATTACH APPLICATOR TO PATCH

A. Remove the circular foil seal from the top of the Patch to reveal the coupling media within the gel cup (Figure 8A).

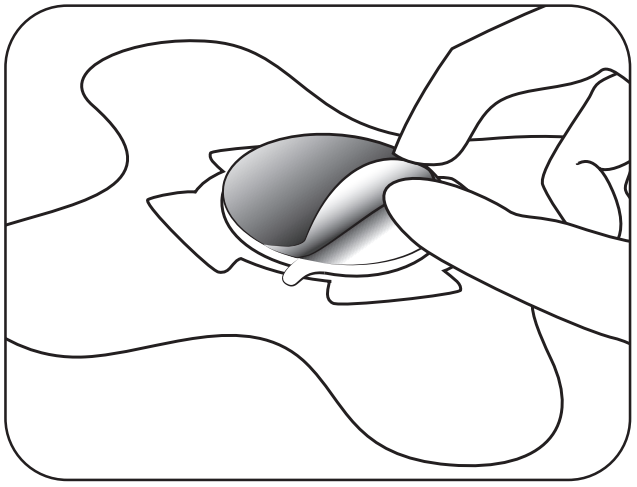

figure 8A: Removing Foil Seal

B. While supporting the edges of the cup with your fingers, align the applicator, face down, above the cup and coupling media (Figure 8B).

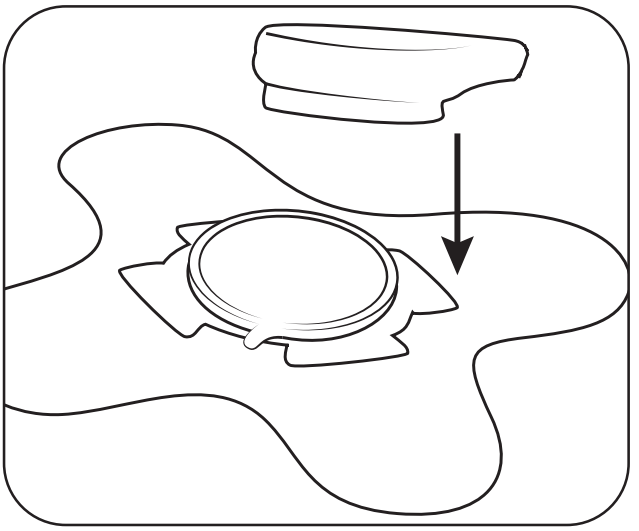

figure 8B: Attach Applicator

C. While continuing to support the edges of the cup, firmly press the applicator down onto the center of the gel cup until a clicking noise is heard or clicking sensation is felt (Figure 8C).

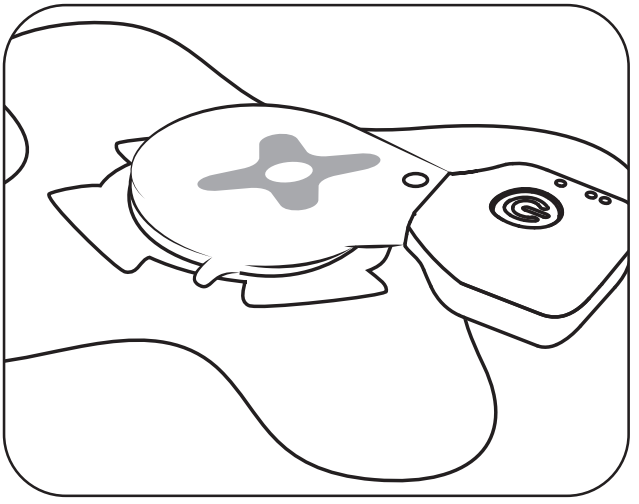

figure 8C: Press Applicator down

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

Note: When the Applicator is pressed down onto the gel cup, keep your fingers on the back of the Patch, keeping them on the edges of the cup and NOT at the center of the gel reservoir.

Note: 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 Patch.

10.4. APPLY ULTRASOUND COUPLING PATCH TO TREATMENT LOCATION

A. Hold the Applicator so the bottom of the Patch faces up. Remove the circular foil seal, revealing the gel.

B. Remove the paper liner, revealing the Patch adhesive (Figure 9).

   i. Add more **sam** Coupling Gel as needed.

C. Turn the Patch over and adhere the Patch to the desired treatment location (Figure 10).

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

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

Note: When applying Patches, both sides of the ultrasound coupling gel 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.

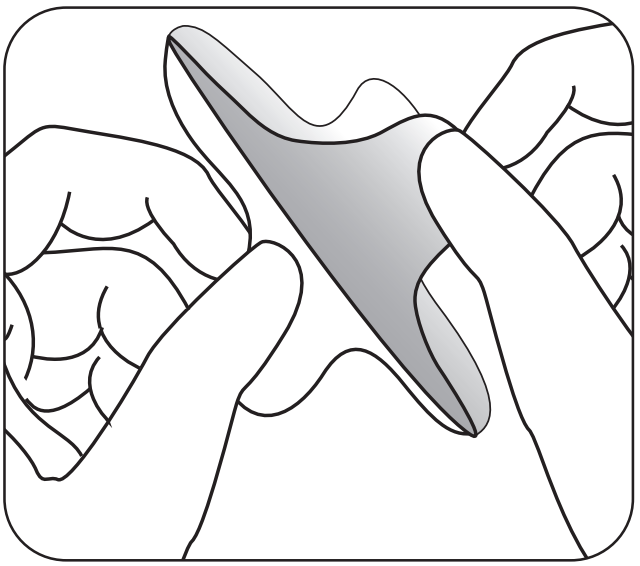

figure 9: Removing Paper Liner

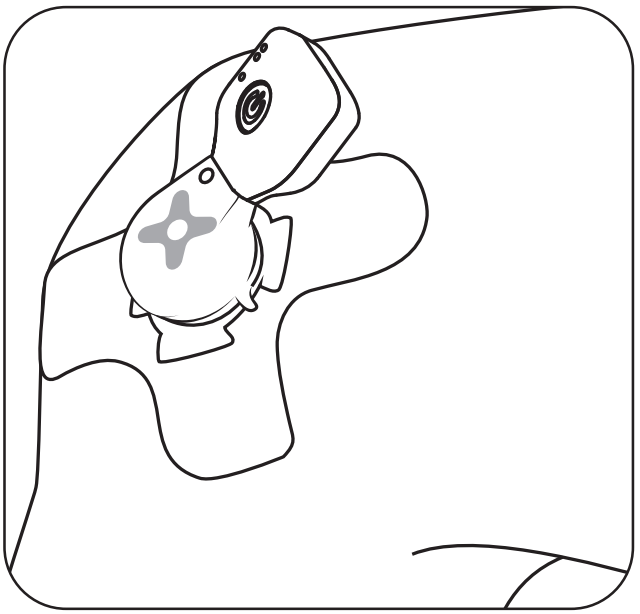

figure 10: Adhere Patch to Site

10.5. TURN THE DEVICE ‘ON’

A. Press and hold the *Power Button* on the **sam X1** Power Controller for at least 1 second to turn the device ‘ON’ (Figure 11).

   i. As confirmation that the device is ‘ON’, the LEDs on the **sam X1** Power Controller will illuminate and the indicator LED on the Applicator will illuminate blue.

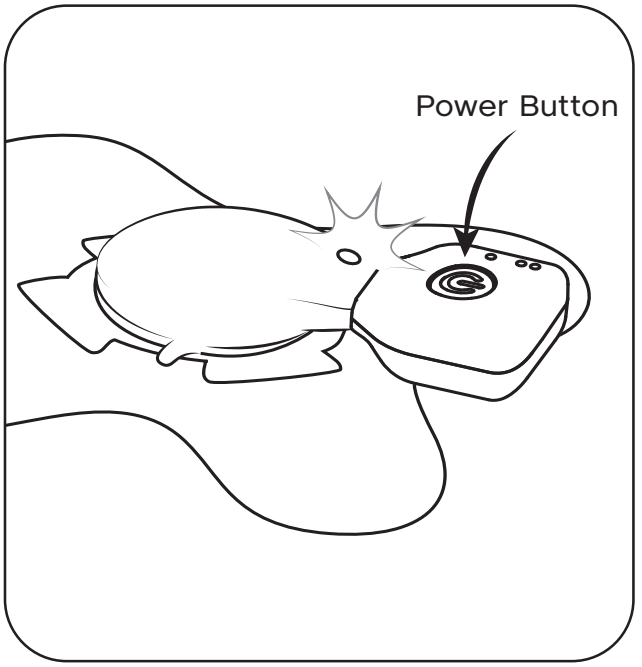

figure 11: Press Power Button

10.6. TREATMENT DELIVERY

Treatment will be delivered for one hour. The treatment timer LEDs will count down in 15 minute increments as treatment progresses. Upon completion, the device will automatically shut off Press the Power Button to manually power ‘OFF’ the device.

Warning:
ALWAYS keep the* sam X1 *Power Controller within easy reach so that power may be ceased at any time.

11. Device Power Down and Removal

11.1. POWER OFF THE POWER CONTROLLER

Press the Power Button on the **sam X1** Power Controller to turn the device 'OFF' (See Figure 11).

11.2. REMOVE DEVICE FROM SKIN

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

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

C. Discard the used **sam** Patches.

11.3. CLEAN THE APPLICATORS

Clean any residual ultrasound coupling media off of the applicator and off of the skin. See section 13 for 'Cleaning and Maintenance' details.

11.4. RECHARGE THE DEVICE

Connect the **sam X1** Power Controller to the **sam X1** Electrical Charger for recharging. Prior to the next use, allow up to 2 hours to recharge the battery to 100% charge. See section 8 for charging instructions.

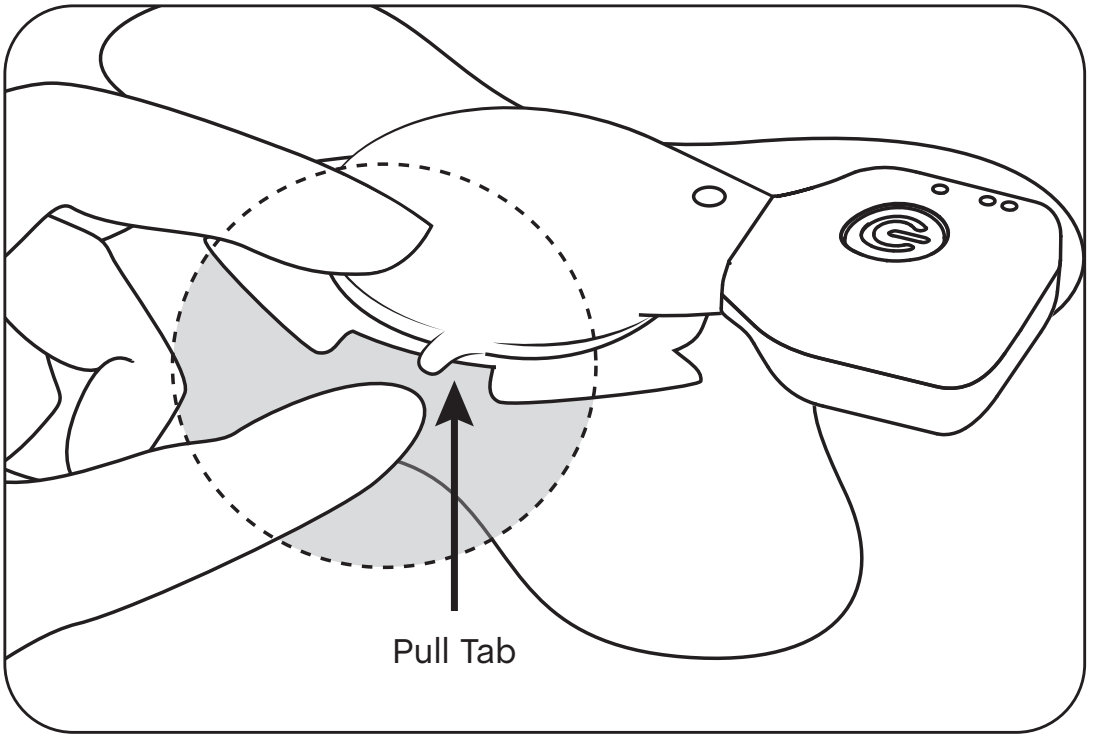

figure 12: Removing Applicator

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

12. Modes of Operation

12.1. ON MODE

To turn the device 'ON' press and hold the Power Button for at least 1 second. The treatment timer LED will be displayed on the control panel (see section 7: LED Display). The Applicator indicator LED will be displayed on the attached Applicator (See Figure 2, page 10). The connected Applicator will emit ultrasound energy immediately upon the **sam X1** Power Controller entering the 'ON' mode of operation. A powered **sam X1** Applicator will always emit ultrasonic energy unless it enters the **sam** Sensing Mode or the treatment duration concludes.

12.2. OFF MODE

When the device is 'OFF', the LEDs on the applicator will not be illuminated, the LEDs on the **sam X1** Power Controller 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 felt by the patient.

12.3. 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 X1** 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 X1 *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 X1 *to disable and remain disabled throughout the therapy session.

12.4. END OF TREATMENT MODE

At the end of treatment, all displays (battery indicator, treatment timer, and applicator LEDs) will be inactive. All ultrasound emissions from the applicator will cease. Clean the device (see section 13: Cleaning and Maintenance). Recharge the Power Controller.

13. Cleaning and Maintenance

The exterior of the **sam X1** Power Controller and 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(s) 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.

14. Storage & Operating Conditions

14.1. STORAGE

Store the **sam X1** device in the following conditions:

Temperature: 5-57°C;

Humidity: 10-80%;

Atmospheric pressure range: 700-1060 hPa

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

Temperature: 5-30°C;

Humidity: 10-80%;

Atmospheric pressure range: 700-1060 hPa

14.2. OPERATION

Only operate the **sam X1** device in the following conditions:

Temperature: 1-44°C;

Humidity: 10-80%;

Atmospheric pressure range: 700-1060 hPa

if stored above 44°C, allow 2 hours for the sam device to return to room temperature prior to powering on the device.

Caution: Do not keep the device in extreme hot or cold temperatures (above 50°C or below 0°C). Do not leave the* sam X1 *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. Do not expose the device to high heat or humidity sources such as fireplaces or humidifiers which can degrade performance.

14.3. IP RATING

IP22 - the **sam** X1 device is protected from touch by fingers and objects greater than 12 mm. It is protected from water spray less than 15 degrees from vertical.

Caution: 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.

15. Disposal of Waste Products

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

Old, damaged or expired **sam** X1 Power Controllers and Applicators should be recycled or returned to the manufacturer for proper disposal.

16. 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)
	Use only with
W	Watts, ultrasonic power
MHz	Frequency in megahertz
ERA	Effective radiating area
BNR	Beam non uniformity ratio

	Use by date
	Temperature limitation
	Humidity limitation
SN	Serial number
REF	Catalogue/Reorder Number
LOT	Lot Number
	Atmospheric Pressure limitation
V_o	Output Voltage
P	Acoustic Power
I_e	Average Intensity
f_{awf}	Frequency

B. SPECIFICATIONS

The **sam X1** device does not contain microprocessor or software to control function

Maximum Acoustic Power Output	0.65 W ±20% per transducer (Applicator) 1.3 W ±20% for 2 transducers (Applicators)
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 ±20 %
Maximum Treatment Duration	1 hour

Other Electrical Ratings for the **sam X1** device Components

Electrical Charger (Model SINGOF-10U-050200)

Input Voltage	100-240 V, 50/60 Hz
Input Current	0.12-0.3 A

Output Voltage	4.75-5.25 V DC
Output Current	2.0 A
Max Output Power	10.5 W

Power Controller

Output Voltage	3.7 V DC ±10%
Max Output Amperes	700 mA
Battery Protection Max Voltage: 4.2 V Min Voltage: 3.1 V	Max Current: 2 Amps
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

C. NOTICE OF COMPLIANCE, CALIBRATION AND OPERATIONAL PERIOD

The **sam X1** device meets performance standards under 21 C.F.R. § 1050.10 - PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS. The **sam X1** device meets IEC 60601-1, 3.1 ed. (2012); IEC 60601-1-11 (2015) Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, IEC 60601-1-2, 4 ed. (2014-02); Medical Electrical Equipment, General Requirements for Safety; Electromagnetic Compatibility. The **sam X1** device is calibrated to provide 3 MHz ±20% ultrasound at 0.65 W ±20% per ultrasound Applicator.

Operational Period and Service Life:

The **sam X1** Power Controller is intended to maintain calibration for up to 300 charging cycles and each ultrasound Applicator is intended to withstand 1,500 hours of run time over a two year service life, after which the system should be recycled or returned to the manufacturer for proper disposal.

D. TECHNICAL INFORMATION

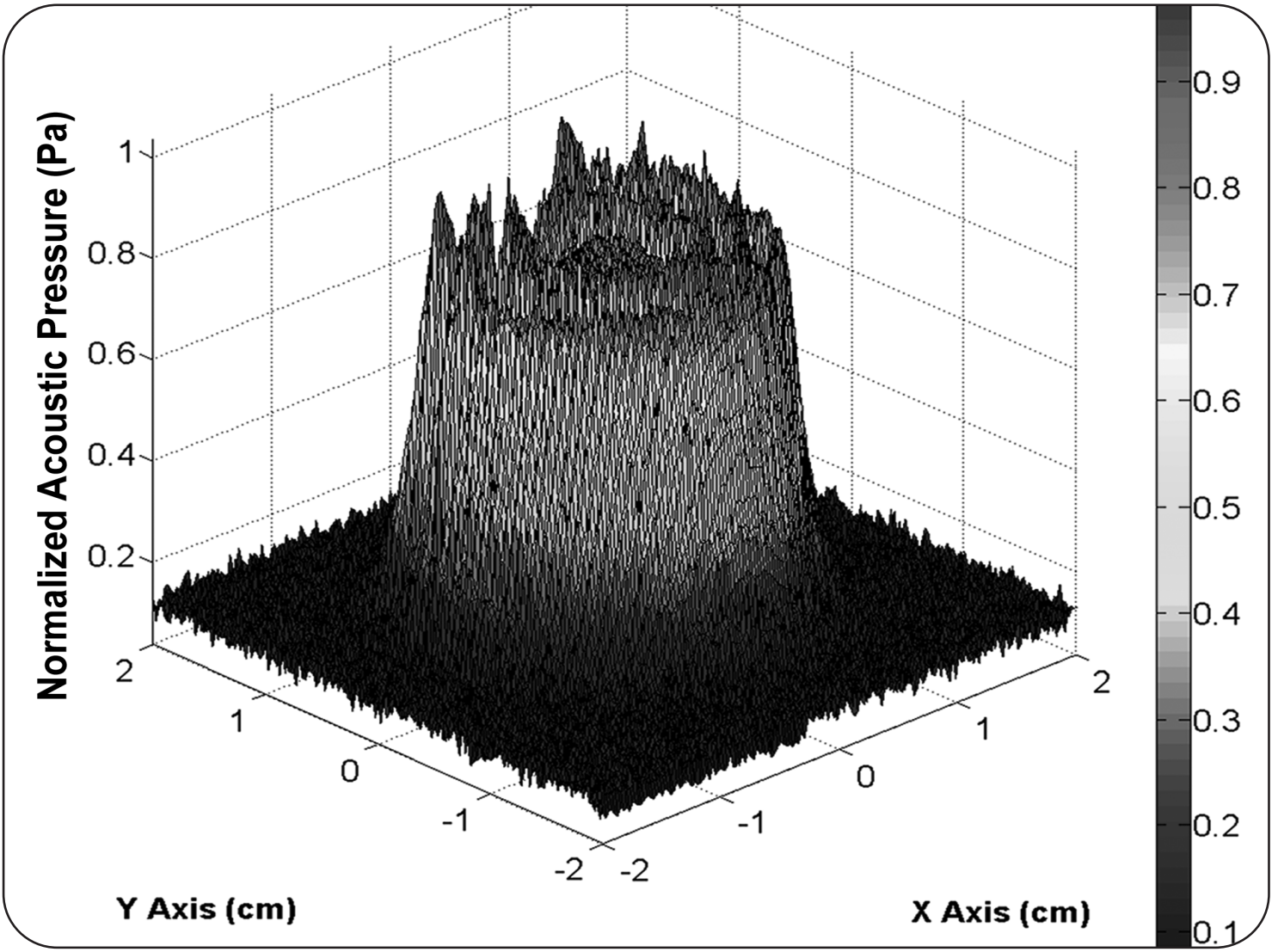

figure A. Ultrasound Field Scan Across Applicator Face

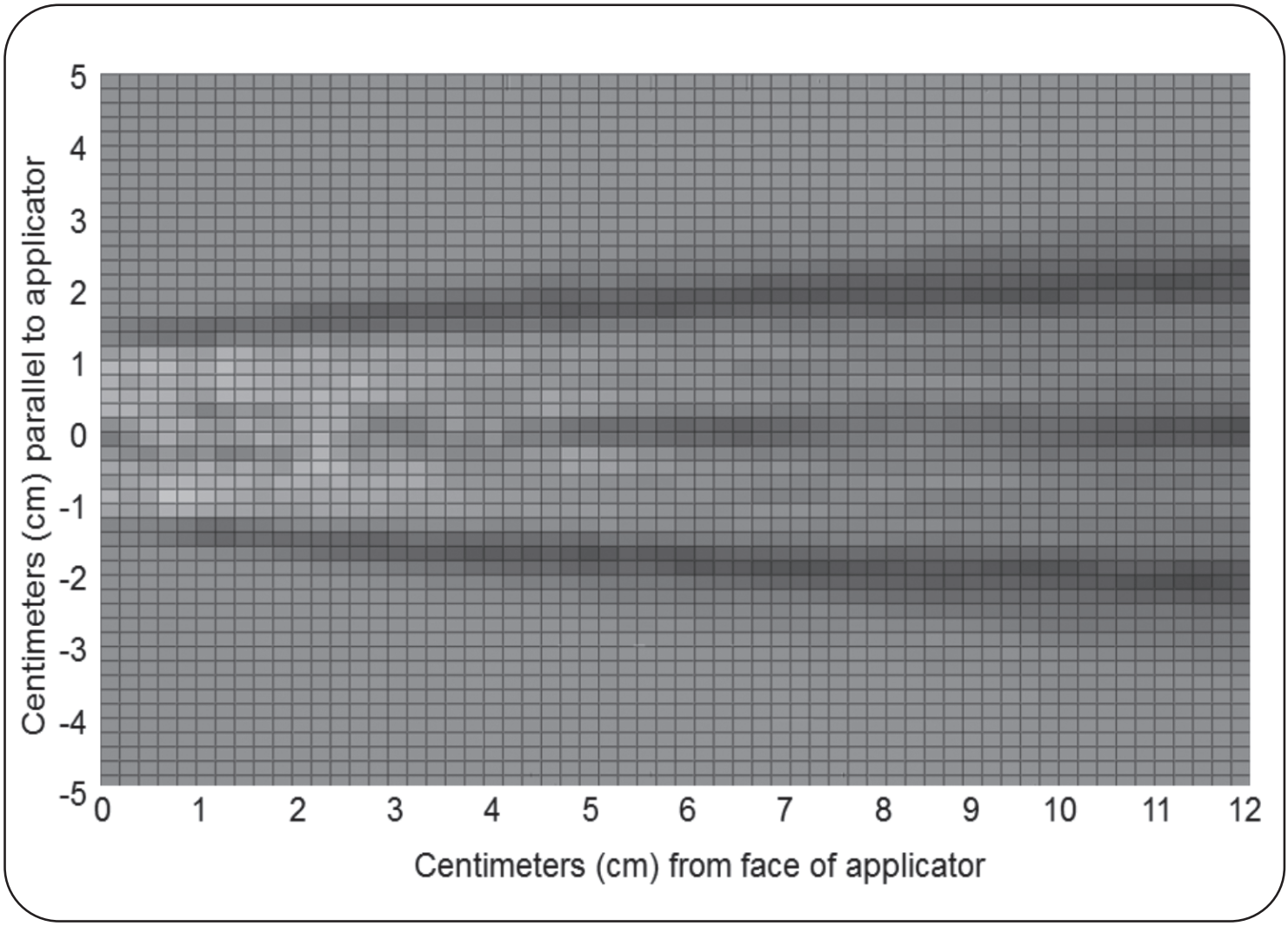

figure B. Ultrasound Field Scan Away From the Applicator Face

E. ELECTRICAL IMMUNITY AND EMISSIONS

The following components of the **sam X1** Long Duration Ultrasound Device are compliant with the requirements of IEC 60601-1-2 ed 4.0 (2014-02):

sam Model 271

	Cable Length
AT551: Ultrasound Applicators	N/A
PC551: Power Controller	N/A
CT271: Electrical Charger	59. inches ±.4

Guidance and Manufacturer's Declaration – Emissions

Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The **sam X1** 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	**sam X1** 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 concrete IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	2kV Mains 100kHz repetition f_{awf}	±2kV Mains 100 kHz repetition f_{awf}	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	±.5V Differential ±2kV Common	±.5kV Differential Common N/A (no ground)	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips/Interruption healthcare IEC 61000-4-11	0% U_T for 0.5 Cycle 0% U_T for 1 Cycle 70% U_T for 25/30 Cycles 0% U_T for 250/300 Cycles	0% U_T for 0.5 Cycle 0% U_T for 1 Cycle 70% U_T for 25/30 Cycles 0% U_T for 250/300 Cycles	Mains power quality should be that of a typical home environment. If the user of the **sam X1** requires continued operation during power mains interruptions, it is recommended that **sam X1** be powered from an uninterruptible power supply or battery.
Power Frequency 50Hz Magnetic Field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be that of a typical home. healthcare environment

Guidance and Manufacturer's Declaration – Immunity

The **sam X1** 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 **sam X1** by no less than the distances calculated/ listed below:
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V ISM ameteur radio bands	(V1) = 3 V	D = (1.2)(Sqrt P) 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	(E1) = 10 V/m	D = (1.2)(Sqrt P) 80 to 800 MHz D=(2.3)(Sqrt 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 or marked with the symbol 

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 X1** device complies with the requirements of IEC 60601-1-2:2014 (EMC Collateral Standard) including the E-field susceptibility requirements at 10 V/m, at frequencies from 80 MHz to 2.7 GHz. However, even at this level of device immunity, certain transmitting devices (diathermy, electrocautery, security systems (e.g., anti-theft (a.k.a. EAS)), metal detectors, cellular phones, two-way radios, cordless phones, paging transmitters, RFID devices, etc.) emit radio frequencies that could interrupt **sam X1** operation if operated in a range too close to the **sam X1** device. Users and practitioners should be aware of possible radio frequency interference if portable devices are operated in close proximity to the **sam X1** device. Some RF emitters might not be visible and the device can potentially be exposed to fields from these RF emitters without the user's awareness. If abnormal performance is observed, additional measures may be necessary such as reorienting or relocating **sam X1**. The user of **sam X1** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and **sam X1** of 12 in (30 cm).
The device is MR Unsafe. Keep it outside the MRI scanner room.

F. WARRANTY

ZetrOZ Systems offers a 1-year manufacturer's warranty for the **sam X1** device. If the **sam X1** device fails due to defects in material or workmanship, ZetrOZ Systems, at its discretion, will:

1. REPAIR the **sam X1** device OR

2. REPLACE the **sam X1** device with another **sam X1** device

THIS LIMITED WARRANTY AND ANY IMPLIED WARRANTIES THAT MAY EXIST UNDER STATE LAW APPLY ONLY TO THE ORIGINAL PURCHASER OF THE **sam X1** 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.

If assistance is needed in setting up, using or maintaining the **sam X1** device, or to report unexpected operation events or warranty issues, contact the manufacturer

ZetrOZ Systems, LLC
56 Quarry Road
Trumbull, CT 06611 USA
Tel. 888-202-9831
E-mail: Info@samrecover.com

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 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. 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. The Applicator is not staying secured during treatment.	Turn off the device. Remove the **sam** Ultrasound Coupling Patch from the applicator. Replace with new **sam** Ultrasound Coupling Patch. See section 11.3 for gel cup application instructions.
5. 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 X1** 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 X1** to disable and remain disabled throughout the therapy session.

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