The purpose of this manual is to provide instructions for use and a technical description, including general product specifications and guidance for troubleshooting, for the UltraMIST System.

Caution: Rx Only. Federal law restricts this device to sale by or on the order of a licensed practitioner. This medical device is to be operated only by a healthcare professional in accordance with the instructions for use.

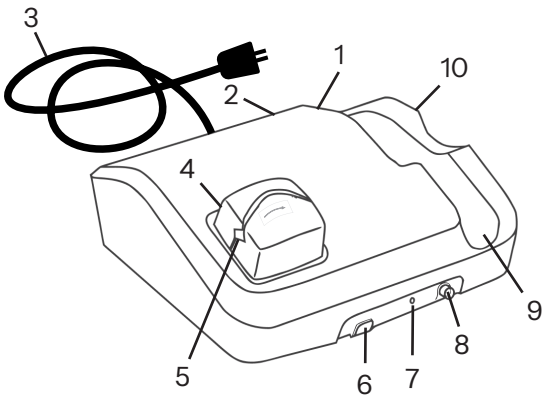
TABLE OF CONTENTS

SYSTEM COMPONENTS

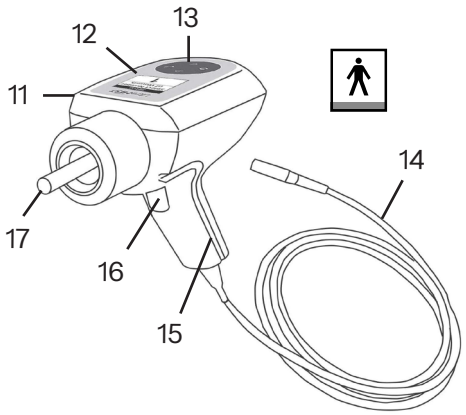
The UltraMIST System consists of the following commercially available components:

- CP-80030 UltraMIST System (Generator plus Treatment Wand),
- CP-80031 UltraMIST Generator (includes power cord),
- CP-80033 UltraMIST Treatment Wand, and
- CP-80040 UltraMIST Applicator.

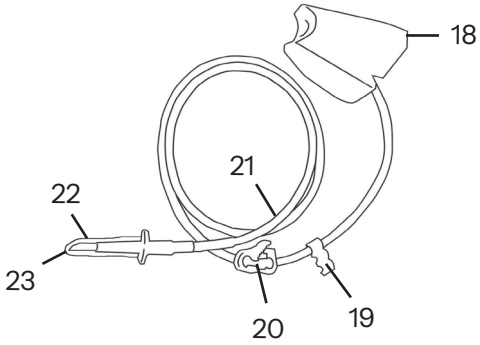
Generator Model# CP-80031



Treatment Wand Model# CP-80033



Applicator Model# CP-80040



Other Materials Required

- Fluid (e.g. saline) 100cc - 1000cc bag or bottle
- Germicidal wipes for cleaning/disinfecting
- Absorbent pads
- Appropriate PPE-personal protective equipment (e.g. gloves)

UltraMIST System

GENERATOR	TREATMENT WAND	APPLICATOR
1. Generator	11. Treatment Wand	18. Applicator
2. Power Switch (Back of Generator)	12. Display Screen	19. Tubing-Cable Clip
3. Generator Power Cord	13. Keypad	20. Tubing Clamp
4. Peristaltic Pump	14. Treatment Wand Cable with Connector	21. Infusion Tubing
5. Tubing Guides	15. Tubing Channel	22. Tubing Spike
6. Adjustable Hook	16. Treatment ON/OFF Button (trigger)	23. Tubing Spike Protective Cover
7. Indicator LED Light	17. Treatment Wand Transducer Tip	
8. Treatment Wand Connector		
9. Treatment Wand Cradle		
10. USB Port/Cover		

SYSTEM DESCRIPTION

The UltraMIST System uses ultrasound to atomize fluid (e.g. saline) and deliver energy to the treatment site. The generated mist acts as the medium for transmitting ultrasonic energy to the treatment site. The UltraMIST System consists of the following components: the Generator (with provided power cord), Treatment Wand (including the transducer), and a single-use disposable sterile Applicator.

SYSTEM

UltraMIST is a system that requires all three components (Generator, Treatment Wand, and Applicator) for proper therapy delivery. Both the Generator and Treatment Wand may be used for multiple treatments using a single use Applicator for each patient therapy.

The operator is trained on the use of the System prior to delivering therapy to patients. The system is not fully automated and requires that the user select the appropriate parameters for treatment based on the tissue injury (size, shape/configuration/position). Delivery of the therapy requires skill in positioning and manipulation of the Treatment Wand relative to the tissue requiring therapy. Recommended treatment times are presented to the user based on treatment area, and the user may select the recommended times or modify them based on experience and the wound being treated.

GENERATOR

The Generator is connected to an available wall power supply and controls the transducer output and graphic user interface by communicating with the Treatment Wand via the connector/cable interface. Using a microprocessor and appropriate hardware components, the Generator communicates with the Treatment Wand via the connector/cable interface. The primary function of the Generator is to convert electricity from the wall power supply mains (i.e. typical electrical outlet) and deliver the appropriate energy, voltage, current, and frequency required by the transducer to resonate at a fixed displacement. The Generator also receives additional information from the Treatment Wand including commands for delivery of the energy (on/off) and other system information including, but not limited to, error and alert codes.

The Generator has a USB data port that may be accessed (behind a protective cover) for the downloading of system information (does NOT include any protected information as defined by HIPAA) and uploading of system firmware. The uploaded and downloaded data is encrypted preventing access from unauthorized sources. The USB port is not available to connect with other devices such as printers etc.

TREATMENT WAND

The Treatment Wand is the primary interface between the user and the system allowing for the operator to input information and to monitor the therapy procedure. The Treatment Wand houses the ultrasonic transducer, a display screen and user-actuated keypad. The Treatment Wand is connected to the Generator via a hard wired cable and polarized medical grade connector. The transducer housed in the Treatment Wand is a classic Langevin, or sandwich style acoustic horn/stack consisting of a solid titanium horn (two-stage, full-wave design), piezoelectric lead zirconium titanate (PZT) ceramics, electrodes, leads, and a tail mass assembled together under axial pressure and designed to resonate at a frequency of 40 kHz when properly electrically excited. Using the piezoelectric effect, the acoustic horn converts electrical input from the Generator to mechanical output, in this case ultrasonic pressure waves. The piezoelectric ceramics expand and contract axially with changes in electrical input causing the horn to vibrate axially with the expansion and contraction of the piezoelectric ceramic. The horn vibrates at 40 kHz with a tip displacement of 65 µm, thereby creating longitudinal pressure waves.

A display and keypad (user interface) on the top of the Treatment Wand steps the user through set-up, allows for treatment selection and programming, and shows the user time remaining in the selected treatment. If an error code is generated during the course of operation, the message will be shown on the Treatment Wand display. No clinical diagnostic information is captured, generated, or displayed by the system. A "trigger switch" is provided for initiating and stopping treatment. Once the operator has successfully attached the Applicator to the Treatment Wand and input the appropriate information/parameters, treatment may be initiated by actuating the trigger. The system provides feedback to the user via the display screen indicating the treatment time remaining. Upon reaching the completion of the therapy the user will be required to remove and dispose of the Applicator prior to initiation of more treatments on other patients.

APPLICATOR

The Applicator is a sterile single-use disposable component used for management of sterile fluid (e.g. saline). The Applicator mounts on the end of the Treatment Wand and connects via tubing spike to a user provided fluid supply source. Fluid viscosity should be similar to saline. The fluid is channeled, metered, and pumped through the Applicator tubing via a peristaltic pump. The fluid is presented to the ultrasonic horn via an orifice in the Applicator. The ultrasonically vibrating horn thereby creates an atomized fluid (i.e. mist) through which the ultrasound is transmitted to the wound.

SYSTEM DESCRIPTION CONTINUED

A number of features present in the UltraMIST System were designed to improve usability of the device over the previous system. These features include a Treatment Wand that is lighter weight with a textured grip for stability if fluid is present in the grip area, better visibility of the patient's wound due to the profile of the Treatment Wand / Applicator combination, and a Treatment Wand that has the majority of its weight centered over the user's hand for ease of handling during a patient treatment. If a problem is detected by the UltraMIST system, an alarm will be generated, and the System will de-energize the acoustic output power and peristaltic pump terminating the therapy. An error code will be displayed to assist in determining the error.

The user should refer to the Troubleshooting section to assist in determining whether the problem requires servicing. If the error cannot be determined and resolved, the user should contact SANUWAVE Customer Service at the number listed on the last page of this manual.

PLEASE READ INSTRUCTIONS BEFORE USE

INDICATIONS FOR USE

Description: The UltraMIST System delivers low frequency ultrasound to the treatment site using a non-contact fluid (e.g. saline).

The UltraMIST Treatment Wand is a Type BF applied part.

Indications for Use: MIST Systems (including UltraMIST) produce a low energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of fibrin, yellow slough, tissue exudates and bacteria.

CONTRAINDICATIONS & POTENTIAL COMPLICATIONS

Contraindications: Do not use near electronic implants/prosthesis (e.g. Near or over the heart or over the thoracic area if the patient is using a cardiac pacemaker); on the lower back during pregnancy or over the pregnant uterus or over areas of malignancies.

Potential Complications: Tingling, redness.

TREATMENT FREQUENCY

Frequency of Treatment: Frequency of patient treatment is to be determined by the treating physician after appropriate patient evaluation. Good clinical practice dictates re-evaluation of the wound at routine intervals by a qualified healthcare professional. If no improvement is noted, the use of this therapy should be reconsidered.

SERIOUS INCIDENTS/ADVERSE EVENTS REPORTING

Any adverse event that has occurred in relation to the device should be reported immediately to the manufacturer (SANUWAVE Inc.) by contacting Customer Service by phone **(+1-800-545-8810)** or email **(customerservice@SANUWAVE.com)**. SANUWAVE will notify the relevant competent authorities..

PREPARING THE PATIENT FOR TREATMENT WITH THE ULTRAMIST SYSTEM

1. Collect all required materials (Generator, Treatment Wand, Applicator, fluid, germicidal wipes, absorbent pads and PPE). Fluid viscosity should be similar to saline.
2. Use approved Infection Control Procedures throughout the treatment session.
3. Treatment with the UltraMIST System will require a clean environment using proper Clean Technique to reduce transmission of pathogenic organisms.
4. Depending on the wound location, position the patient in a comfortable position for treatment.
5. Remove soiled dressings and discard all contaminated materials (PPE, dressings, pads) prior to UltraMIST treatment.
6. Place an absorbent pad under the portion of the patient being treated to collect fluid runoff.
7. Measure the area of the wound to be treated.

CLEANING THE ULTRAMIST SYSTEM

Select from the list of approved cleaning agents below to clean the UltraMIST System.

APPROVED CLEANING AGENTS

The following products may be used with a cloth or sponge:

- Bleach, diluted per manufacturer's instructions
- 70% isopropyl alcohol

The following premoistened wipe products may be used:

- Clorox Healthcare® Bleach Germicidal Wipe
- Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipe
- Clorox Healthcare® VersaSure Cleaner Disinfectant Wipe
- PDI® Sani-Cloth® AF3 Germicidal Disposable Wipe
- PDI® Sani-Cloth® Bleach Germicidal Disposable Wipe
- PDI® Sani-Cloth® Plus Germicidal Disposable Wipe
- PDI® Super Sani-Cloth® Germicidal Disposable Wipes
- Metrex® CaviWipes1™ Disinfecting Towelettes
- Palmero Health Care DisCide® Ultra Disinfecting Towelettes

Cleaning agents not on the approved list may contain chemicals that are known to damage the plastic of the UltraMIST System. Damage due to use of cleaning and/or disinfecting products not included on the approved list is not covered by the warranty or service contract. If you are unsure of the suitability of a particular product, please contact SANUWAVE Customer Service at +1-800-545-8810 for more information.

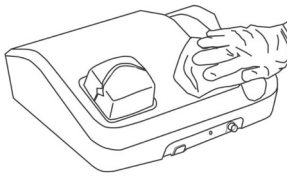
Use of iodine-based products may cause staining of the Treatment Wand and Generator enclosure material and is not recommended.

Do not spray cleaning solutions directly into openings on the device. Use only recommended cleaning solutions and follow manufacturers' recommendations. Use only soft cloths or sponges. Never use sharp objects (e.g. fingernails, paper clips, or needles), or abrasive brushes/pads to clean any part of the system. Allow to dry before use.

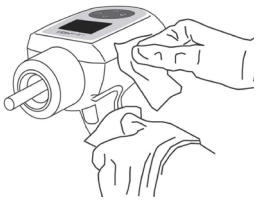
To extend the life of the system, after use of an approved cleaning agent per manufacturer's instructions, wipe with a damp cloth to remove any remaining residue.

Clean the UltraMIST System prior to and after each treatment session with the Power Switch in the "off" position.

1 Prior to treatment, clean the entire system using an approved cleaning agent and following approved Infection Control Procedures.



2 Do not sterilize the Treatment Wand including tip with steam, ETO, radiation, gas/plasma, or cold sterilants. After completion of the UltraMIST treatment, repeat the cleaning process.

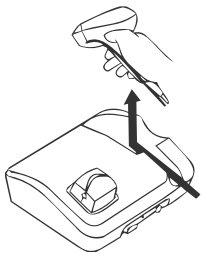


WARNING: The UltraMIST Applicator is designed as a single patient-use disposable unit to avoid contamination. Do not resterilize or reuse Applicators. Re-using the Applicator and/or fluid may result in infection, degraded performance, and voids warranty.

TREATMENT WAND REMOVAL/STORAGE

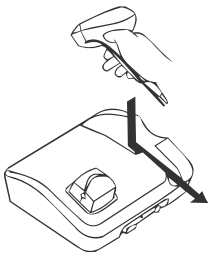
Removal

Slide Treatment Wand toward the back of the generator and up.



Storage

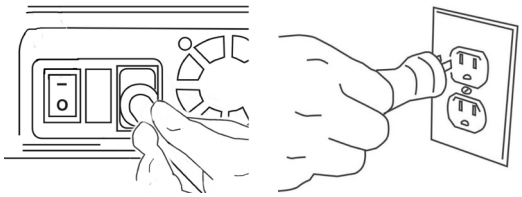
Slide Treatment Wand into cradle.



PREPARING THE ULTRAMIST SYSTEM

1

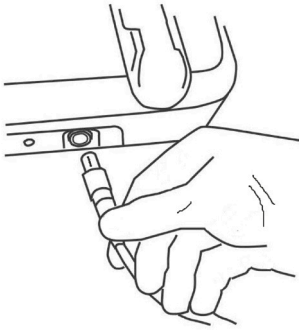
With the power switch in the "off" position, plug the supplied generator power cord into the back of the generator and into an electrical outlet.



CAUTION: Do not place the Generator power connections near an obstruction that prevents either removal of the power cord connection to the Generator or its power cord wall plug.

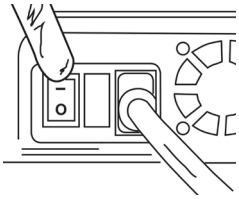
2

Ensure the Treatment Wand cable is attached and fully seated to the front of the generator by aligning the red mark on the cable with the red mark on the connector and gently pushing in. Do NOT twist or force connector into place.



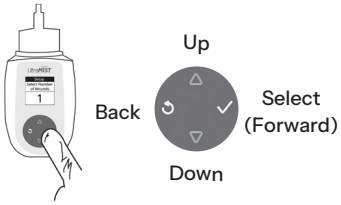
3

Turn the power switch located on the back of the generator to the "on" position.



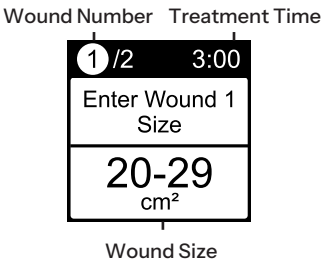
4

After the self-test is completed, use the keypad on the Treatment Wand to select the number of wounds to be treated. Press ✓ to continue.



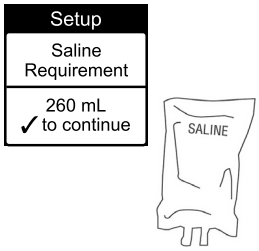
5

Use the keypad to enter the size of each wound to be treated per the screen prompts.



6

The total fluid requirement for the combined treatment area is displayed (approximately 100 mL for every 25 cm²). Select the appropriate fluid bag/bottle size. Press ✓ to continue.



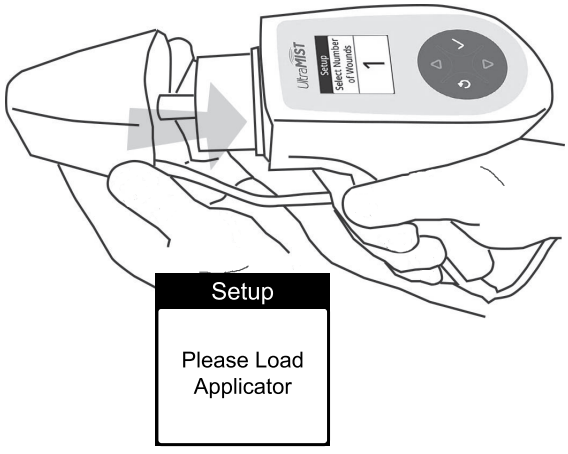
NOTE: One applicator is required for each 60 minutes of treatement time.

7

The display screen will ask for the Applicator to be loaded. Remove Applicator from packaging and press the Applicator onto the Treatment Wand, being careful not to pinch tubing. Ensure the Applicator is fully seated prior to use with the metal tip visible in the center.

Note: After the setup is complete, DO NOT remove the Applicator until the treatment has been fully concluded. This is a single use product that will need to be replaced for treatment on the next patient.

WARNING: Do not depress the treatment on/off button if an Applicator is not in place.

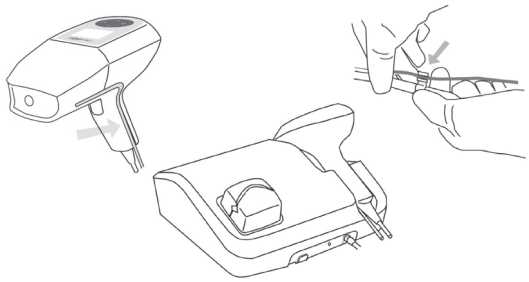


Preparing the UltraMIST System continued on next page

PREPARING THE ULTRAMIST SYSTEM

8

Insert Applicator tubing into the Treatment Wand tubing channel and attach the tubing clip to the Treatment Wand cable. Place Treatment Wand in cradle once completed.



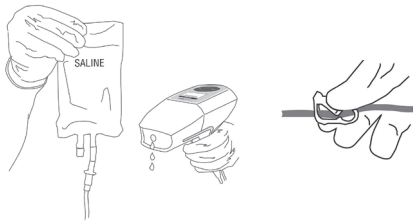
9

Remove fluid source from outer packaging. Remove the protective cover from Applicator tubing spike and from fluid source port. Insert spike fully into fluid source.

Note: When using a bottle as a fluid source: Place the bottle/ cup where it will not spill, place the spike in the bottom of the bottle, do not invert the bottle.

10

Ensure the tubing clamp is open. Squeeze the bag to run fluid through the tubing until fluid is noted at the distal tip of the Applicator. Close the tubing clamp.

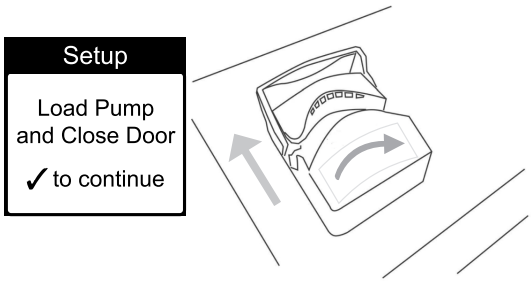


11

If utilizing the adjustable hook, position generator near the edge of a flat work surface (i.e. tabletop or cart). Extend the hook beyond the edge and attach the fluid bag. Adjust position as necessary so the fluid bag hangs freely and the generator is stable.

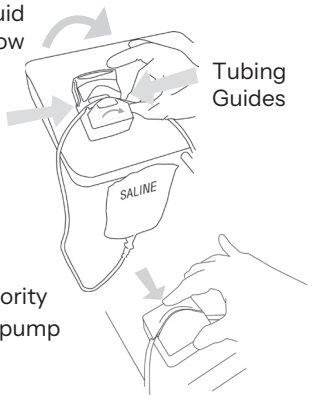
12

The display screen will ask for the pump to be loaded. Open the pump door.



13

Loop the Applicator tubing from the fluid source through the pump from left to right, center on tubing guides, and close the pump door. Leave enough tubing to allow the fluid source to hang freely with the majority of the tubing between the pump and Treatment Wand.



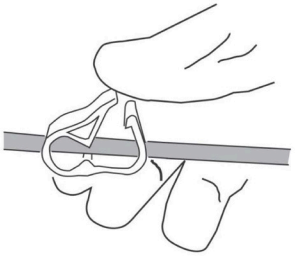
14

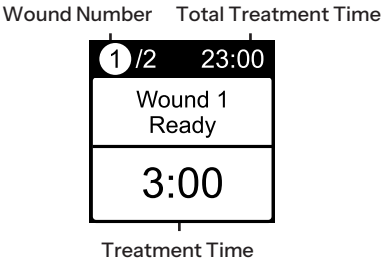
Open the tubing clamp. Fluid will not flow until the treatment on/off button is initiated.

Note: Fluid will only flow in conjunction with ultrasound delivery.

Note: When using a bottle as the fluid source: Press the treatment on/off (trigger) button (refer to the figure in step 1 on the next page) and observe fluid flow. Once the mist becomes visible, press the treatment on/off button to pause the fluid flow. Press the up arrow one time to add a minute to the treatment time.

The system is now set up and ready for treatment



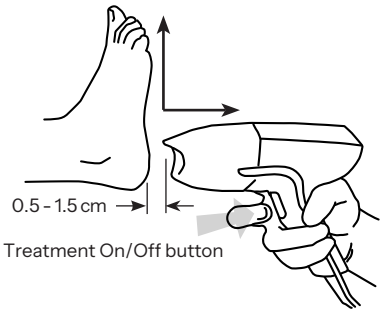


TREATING THE PATIENT WITH THE ULTRAMIST SYSTEM

1

The Treatment Wand should be oriented so that it is perpendicular to the wound with the leading edge of the Applicator approximately 0.5 to 1.5 cm (0.2–0.6 inches) from the wound.

Note: Avoid contact of the Treatment Wand or Applicator to the wound bed to prevent patient discomfort or irritation.



2

Depress and release the treatment on/off button (trigger) on the Treatment Wand handle. This will initiate both the fluid flow and ultrasound delivery.
The treatment timer will start to count down on the display.

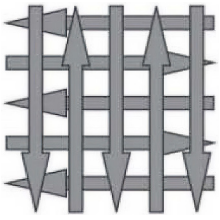
Note: You may pause treatment by depressing and releasing the treatment on/off button. The treatment timer will be paused until restarted.

Screen Saver

NOTE: While in pause mode, once the system goes to the screen saver, there is a 15-minute pause limit. If the system reaches the pause limit, the Applicator will be invalidated and cannot be reused. Press ✓ to go back to the treatment screen before the pause limit is reached.

3

The UltraMIST System will begin to deliver the ultrasound through a continuous mist. Move the Treatment Wand vertically across the wound using multiple passes. Follow this by moving the Treatment Wand horizontally across the wound using multiple passes. The Treatment Wand should be moved across the wound using slow, even strokes.



Spray Pattern

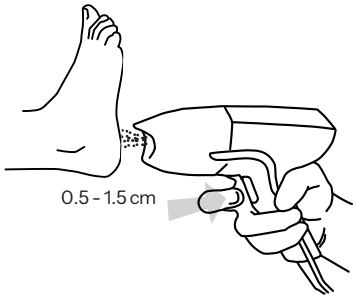
WARNING: Do not allow the Treatment Wand or Applicator to contact the patient's skin directly.

4

Audible (gurgling) and visual surface bubbling may occur. This is normal when moving back and forth through the recommended treatment range.

For best results, the Treatment Wand should be perpendicular to the wound and parallel to the floor during treatment.

Note: It is important to maintain a 0.5 to 1.5 cm (0.2–0.6 inch) distance from the leading edge of the Applicator to the treatment area at all times to maximize therapeutic effect.



5

Continue treatment until 3 audible tones sound indicating the end of treatment time. The ultrasound and fluid will automatically stop, ensuring accurate treatment time for the wound size selected.

If there is more than one wound to treat, the next wound screen will appear. Press the treatment on/off button to start treating the next wound.

Note: If at any time during the treatment it is determined additional time will be required, use the up/down buttons to add time in increments of 1 minute. Press ✓ followed by pressing the treatment on/off button (trigger) to continue treatment. Exceeding 60 minutes of total treatment time will require an additional applicator.

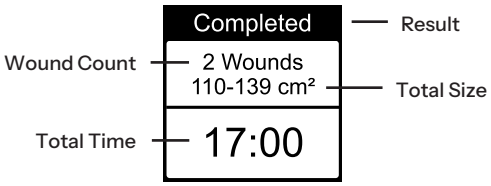
In-between wounds, if the system is paused for more than 15 minutes after the screen saver appears, the applicator will be invalidated. Press the ✓ to go back to the next wound screen before the pause limit is reached.

Treating the Patient continued on next page

TREATING THE PATIENT WITH THE ULTRAMIST SYSTEM

6

Once all the wounds are completed, the summary screen will be displayed.

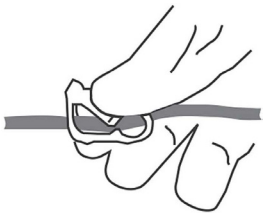


Note: To cancel a treatment at any time press the back button. The "Cancel Treatment" screen will appear. Use the up down buttons to select "yes" or "no" then press select. If you cancel treatment, the Applicator will be invalidated and the treatment summary screen will appear. Do not cancel treatment until finished treating all wounds are for this session, otherwise a new Applicator will be required to continue treatment.

ULTRAMIST SYSTEM SHUTDOWN PROCEDURE

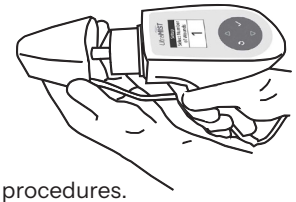
1

Turn power switch to off. Clamp the tubing by closing the tubing clamp. There may be fluid remaining in the bag which is normal depending upon the size of the wound being treated.



2

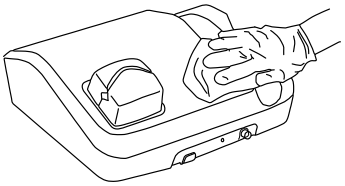
Remove the tubing from the Treatment Wand channel and pump, remove the Applicator from the Treatment Wand and fluid source and discard following approved biohazard disposal procedures.



3

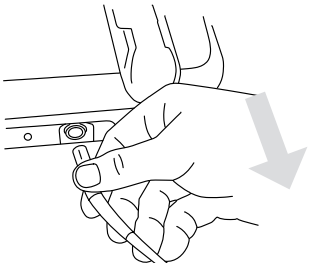
Use approved Infection Control Procedures to clean the system. Refer to page 5 for a list of approved cleaning agents.

Suggestion: Use separate cleaning wipes for the (1) metal transducer, (2) Treatment wand and cable, (3) Generator, (4) power cord, and other accesories.



4

Optional: Disconnect Treatment Wand by sliding back the metal connector ring. Do not pull on rubber connector cover or cord.



USB PORT

1

The generator USB port is designed for the following:

- Download encrypted performance data to a SANUWAVE approved USB drive for troubleshooting purposes
- Upload software upgrades from a SANUWAVE provided USB drive

Specific instructions for use of the port will be provided when required.

Note: System does not collect and/or store patient specific data. All data is encrypted to prevent usage by unauthorized personnel.

2

Accessing USB Port:

- Remove Treatment Wand from generator cradle and set aside
- Turn generator over
- Using a coin or flathead screwdriver, rotate the screw counterclockwise a quarter turn to unlock and remove the cover
- To replace the cover, position it over the port, then using a coin or flathead screwdriver, rotate the screw clockwise a quarter to lock the door in place

WARNING: DO NOT ATTACH ANY UNAPPROVED USB DRIVES, CABLES, OR EQUIPMENT TO THE PORT AS IT MAY INTERFERE WITH OPERATION OF THE DEVICE.

Troubleshooting continued on next page

COMMON ERRORS/ALERTS (noted on display screen)

#	ERROR	CAUSE	SOLUTIONS
205	FREQUENCY SLIP	Transducer wand tip has come in contact with tissue	Press ✓ to continue treatment Ensure Treatment Wand tip does not come into contact with tissue
129	IMPEDANCE ERROR	Transducer wand tip has come in contact with tissue creating impedance outside the normal range	Press ✓ to continue treatment Ensure Treatment Wand tip does not come into contact with tissue
		The transducer tip is pointed up and fluid is accumulating in a well	Point the tip downward to drain fluid
		Mechanical interference between the transducer and Applicator	Ensure that the Applicator is properly seated on the Treatment Wand without interfering with the transducer Ensure that the transducer is free of debris and clean with an approved wipe as required
200	INVALID REPLACE APPLICATOR	Applicator has been previously used and should be replaced Turning off the system after starting a treatment.	Replace Applicator
201	REPOSITION APPLICATOR	Applicator not positioned properly on Treatment Wand during the first 60 sec of treatment	Adjust Applicator properly on Treatment Wand
202	MAX USE REPLACE APPLICATOR	Applicator has been used for the maximum time period allowed (60 minutes).	Replace with new Applicator to continue
203	NOT READING APPLICATOR	Applicator is not being sensed by Treatment Wand	Properly align the Applicator on the Treatment Wand Replace with new Applicator
204	OVERHEAT	Treatment Wand temperature has exceeded the allowed limit	The system alarm for overheating indicates that the ultrasound is being turned off as a preventive measure and does not indicate a malfunction of the system 20 minutes is the expected maximum treatment time after periods of system inactivity. The overheat screen will automatically begin to count down the minutes required to cool the system. Once this completes, the “paused treatment” screen will appear and the treatment can now be completed. DO NOT TURN OFF SYSTEM during cool down (this will require a replacement of the Applicator)

For errors/alerts not listed or more details, refer to Appendix A or contact SANUWAVE Customer Service for further information.

INDICATOR LIGHT (located on front of generator)

RED	An error has occurred - refer to the Troubleshooting section for more details
GREEN	Electrical/System Power On, System Ready and Functioning

TROUBLESHOOTING

PROBLEM	CAUSES	SOLUTIONS
SYSTEM WILL NOT TURN ON	System not plugged in and/or power cord not properly seated in the generator outlet on back of instrument	Ensure power cord is plugged in and properly seated with one end attached to the generator and the other end to the power outlet
	Power is not being delivered to outlet	After power is delivered to outlet, turn system on
	Fuse is missing or blown on system	Call SANUWAVE Customer Service
NO POWER TO TREATMENT WAND (NO SCREEN DISPLAY)	System is not turned on	Toggle power switch located on back of system to ensure it's in the "on" position
	Treatment Wand is not connected to the generator properly	Turn power off Remove Treatment Wand cable from generator by pulling back on the metal collar to release the lock (Never pull on the white rubber coating) If cable is damaged or wire is exposed then call SANUWAVE Customer Service If debris is in a connector, then blow into connector to remove debris Fully re-insert Treatment Wand cable into generator connector Turn power on
KEYS ON KEYPAD NOT FUNCTIONING	System software error, Electrical failure, Mechanical failure	Shut down system by turning off power and then restart. If error continues, call SANUWAVE Customer Service.
OVERHEAT	Treatment Wand temperature has exceeded the allowed limit	The system alarm for overheating indicates that the ultrasound is being turned off as a preventive measure and does not indicate a malfunction of the system. 20 minutes is the expected maximum treatment time after periods of system inactivity. The overheat screen will automatically begin to count down the minutes and seconds required to cool the system. Once this completes, the "paused treatment" screen will appear and the treatment can now be completed. DO NOT TURN OFF SYSTEM during cool down (this will require a replacement of the Applicator)
ERROR/ALERT MESSAGE ON DISPLAY SCREEN	An error/alert has occurred	Refer to the common errors table to determine appropriate action. If error continues, note the contents of the error message and call SANUWAVE Customer Service

Troubleshooting continued on next page

TROUBLESHOOTING

PROBLEM	CAUSES	SOLUTIONS
NO FLUID OR INSUFFICIENT FLUID IS COMING OUT OF APPLICATOR	Wound active screen is not visible on display screen	Complete set up process until wound active screen is seen on display
	Treatment on/off button not pressed for treatment to begin	Ensure system power is on and press treatment on/off button
	Fuse is missing or blown on system	Call SANUWAVE Customer Service
	Pump door is open	Ensure tubing does not interfere. Close the pump door
	Tubing is not properly loaded in the pump	Ensure that tubing is loaded with fluid flow following arrow, with fluid from the fluid source entering left side of pump and fluid exiting the right side of pump to Treatment Wand Ensure tubing is not pinched by pump door Close pump door
	Tubing is clamped	Open clamp and press treatment on/off button
	Tubing is kinked or knotted	Unkink or remove knot from tubing
	Treatment Wand tip is not properly aligned in center of Applicator	Ensure the Applicator is positioned correctly with Treatment Wand tip located in center of Applicator opening and fully seated on the Applicator housing
	Tubing spike not fully mated with bag	Ensure spike and fluid bag are fully mated
	Bottle as fluid source: Spike tip is in air	Ensure that the spike tip is in the fluid
	Bottle as fluid source: Spike cap is on the spike	Ensure that the spike cap is removed
FLUID LEAKING AROUND APPLICATOR	Treatment Wand tip is not properly aligned in center of Applicator	Ensure the Applicator is positioned correctly with Treatment Wand tip located in center of Applicator opening
	Treatment Wand position during treatment caused fluid to accumulate inside Applicator	Turn Applicator tip downward to allow excess fluid to drain, continue treatment
DAMAGED APPLICATOR	Damaged in shipment	Replace with new Applicator
OPEN OR DAMAGED STERILE APPLICATOR PACKAGE	Damaged in shipment	Replace with new Applicator

WARNINGS

CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

Risk of electric shock – Do not remove cover or loosen cable connections. Refer servicing to Sanuwave or Sanuwave authorized service provider.

Do not use the UltraMIST System in oxygen enriched environments.

Do not use if Treatment Wand or cables show evidence of deterioration or damage.

Discard disposable Applicator components appropriately.

Risk of burns – Do not touch the metal tip of the Treatment Wand during operation.

Do not depress the treatment on/off button if an Applicator is not in place.

Do not aim the mist at eyes/ears or use on wounds near the eyes/ears without proper eye/ear protection.

Do not allow the Treatment Wand or Applicator to contact the patient's skin directly.

Use of the UltraMIST System on uncovered surgical wounds should only be performed under the order of a physician.

PRECAUTIONS

Treatment effectiveness may be diminished if any of the following occur:

- The Applicator is not fully engaged, aligned and securely attached to the Treatment Wand.
- The distance between the leading edge of the Applicator and the wound is greater than 1.5 cm (0.6 inches).
- The Treatment Wand is not held perpendicular to the wound.

Infection or suspected infection of the wound should be evaluated by the physician for appropriate intervention

Use of proper Clean Technique is essential to limit the risk of transmission of pathogenic organisms.

Use of iodine-based products may cause staining of the Treatment Wand and Generator enclosure material and is not recommended.

If a product is damaged or suspected to be damaged in any way it should not be used for a patient treatment.

If an Applicator sterile barrier is breached or suspected to be breached in any way then the Applicator should not be used for a patient treatment.

ULTRAMIST PRODUCT SPECIFICATIONS

APPROXIMATE SIZE AND WIGHT	12" x 10" x 7.5" (with Treatment Wand in cradle) 8–10 lbs.
SAFETY REQUIREMENTS	ETL Listed Conforms to ANSI AAMI Std ES60601-1 & IEC Std 60601-1-6 Certified to CSA Std C22.2 No. 60601-1 Intertek Reference file: 5029304
ELECTROMAGNETIC COMPATIBILITY	Meets the requirements of IEC 60601-1-2 and FCC 47 CFR Part 15
SYSTEM CLASSIFICATION	Class II equipment Type BF applied parts
STERILIZATION METHOD	Gamma Sterilization (Applicators only)
IPX RATING	Generator: IP21 Treatment Wand: IP22
INPUT **DETACHABLE POWER CORD**	100–240 VAC; 50–60 Hz 125V, 10A UL or equivalent listed
CURRENT **FUSE**	2.0 A T2AL250V
OPERATING CONDITIONS	Operating Temperature: 15° to 25° C (59°F to 77°F) Operating Relative Humidity: 30% to 75% (non-condensing) Atmospheric Pressure: 700 to 1060 hPa
SHIPPING/STORAGE CONDITIONS	Applicator/System Transport & Storage Temperature: -25° to 60° C (-3°F to 40°) Applicator/System Transport & Storage Relative Humidity: 85% Maximum (non-condensing) Atmospheric Pressure: 600 to 1060 hPa
ACOUSTIC OUTPUT POWER	Operating Frequency: 40 KHz ± 1 KHz Tip Displacement Range: 65 µm ± 10 µm Maximum Unintentional Ultrasound Energy: < 100 mW/cm²

FREQUENTLY USED FUNCTIONS

Operation of the UltraMIST System is limited to the following:

CONTROL	LOCATION	FUNCTION
Power ON/OFF Button	Back panel of generator	Controls power to the system
Keypad	Treatment Wand control panel	Allows full set up of treatment parameters
Treatment ON/OFF Button	Front Treatment Wand handle	Controls ultrasound and fluid on and off

HISTORY SCREENS

USE HISTORY

To obtain data on the system usage, turn on the system using normal procedure then press the back button for 2 seconds. A treatment history screen will appear that provides the total treatment for the system.

ERROR LOG

To obtain data on the system usage, turn on the system using normal procedure then press the back button for 2 seconds. A treatment history screen will appear that provides the total treatment for the system. Use the down arrow to advance to the error log. The first screen provides the most recent 6 errors. Use the down arrow button again to move to the screen with an additional 6 errors.

TECHNICAL SERVICE

For technical questions about the operation of the UltraMIST System contact SANUWAVE Customer Service:

PHONE	+1-800-545-8810
ADDRESS	9600 W 76th St, Eden Prairie, MN 55344 USA
WEBSITE	www.ultramist.com
EMAIL	customerservice@sanuwave.com

EXPLANATION OF SYMBOLS

- Fragile, Handle with Care
- This End Up
- Keep Dry
- Recycle
- Non-Ionizing Radiation
- Do Not Resterilize
- Temperature Limits
- Humidity Limits
- Pressure Limits
- Consult Instructions for Use
- Manufacturer
- Date of Manufacture
- LOT Lot Number
- RX Only Prescription Use Only Device
- Do Not Reuse
- Use-By Date
- Open
- Closed
- IPXX Ingress Protection
- ETL Symbol
- Class II Equipment
- STERILE R Sterilized Using Irradiation
- Type BF Applied Part
- SN Serial Number
- Caution, Refer to Accompanying Documents
- Do Not Allow Fingers to Contact Moving Parts
- Do Not Dispose in Municipal Waste
- REF Catalog Number
- Up
- Down
- Back
- Select
- On/Off
- Fluid Flow Direction

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTRONIC EMISSIONS

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

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIROMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The UltraMIST System 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 A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	
Ref. IEC 60601-1-2:2014 +AMD1:2020 §5.2.2.1(a)		

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycles at 50 Hz at 0, 45, 90, 135, 180, 225 and 315° Phase	0% U_T for 0.5 cycles at 50 Hz at 0, 45, 90, 135, 180, 225 and 315° Phase	Mains power quality should be that of a typical commercial or hospital environment. If the user of the UltraMIST System requires continued operation during power mains interruptions, it is recommended that the UltraMIST System be powered from an uninterruptible power supply or battery.
	0% U_T for 1 cycle at 50 Hz at 0° Phase	0% U_T for 1 cycle at 50 Hz at 0° Phase	
	70% U_T for 25 cycles at 50 Hz at 0° Phase	70% U_T for 25 cycles at 50 Hz at 0° Phase	
	0% U_T for 250 cycles at 50 Hz at 0° Phase	0% U_T for 250 cycles at 50 Hz at 0° Phase	
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity continued on next page

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (CONTINUED)

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Proximity magnetic fields IEC 61000-4-39	65 A/m at 134.2 kHz, 2.1 kHz Pulse Modulation 7.5 A/m at 13.56 MHz, 50 kHz Pulse Modulation	65 A/m at 134.2 kHz, 2.1 kHz Pulse Modulation 7.5 A/m at 13.56 MHz, 50 kHz Pulse Modulation	Proximity magnetic fields should be that of a typical commercial or hospital environment.
Immunity to proximity fields from RF wireless communications equipment	Table 9 from IEC 60601-1-2:2014 +AMD1:2020	Table 9 from IEC 60601-1-2:2014 +AMD1:2020	N/A
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the UltraMIST System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \sqrt{P}$ P=150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz Where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms (In ISM Bands) 150 kHz to 80 MHz	6 Vrms (In ISM Bands) 150 kHz to 80 MHz	
Radiated RFI EC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptions and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the UltraMIST System is used exceeds the applicable RF compliance level above, the UltraMIST System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UltraMIST System.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity continued on next page

RECOMMENDED SEPARATION BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE ULTRAMIST SYSTEM

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

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptions and reflection from structures, objects, and people.

WARNING: The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by SANUWAVE as replacement parts for internal components, may result in increased emissions or decreased immunity of the UltraMIST System.

WARNING: The UltraMIST System may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

The UltraMIST System needs special precautions regarding EMC and needs to be put into service according to the EMC information provided in the accompanying documents.

Portable and mobile RF communications equipment can affect the UltraMIST System.

The UltraMIST System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the UltraMIST System should be observed to verify normal operation in the configuration in which it will be used.

The UltraMIST System does not have essential performance characteristics as defined in IEC 60601-1-2, Clause 5.2.2.1g.

GUIDANCE AND MANUFACTURER'S DECLARATION - RADIATION EMISSIONS

EMISSIONS TEST	COMPLIANCE	RADIATION GUIDANCE
Maximum Acoustic Output Power	Complies	The UltraMIST System requirement for the Maximum Acoustic Output Power is that the measured value be less than 3W/cm^2, which is a requirement established by the World Health Organization for acoustic safety. The actual output is significantly less than the above limit, which is considered to be safe.
Sidewall Radiation	Complies	The UltraMIST System requirement for Sidewall Radiation is that the measured value be less than 100mW/cm^2, which is a requirement established by the World Health Organization for acoustic safety. The actual output is significantly less than the above limit, which is considered to be safe.
Ref. TR-75144 on file at SANUWAVE		

FEDERAL COMMUNICATIONS COMMISSION (FCC) USER INFORMATION

The UltraMIST System has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15, Subpart B:2025 FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

ACCESSORIES/TRANSDUCERS/CABLES	LENGTH	SPECIFICATION
Ultrasonic Transducer	N/A	AS-55061
Transducer Cable Power	1.8 m	PC-50178

The UltraMIST System utilizes vicinity-coupled radio frequency identification (RFID) that is compliant with ISO / IEC 15693, and communicates with a 13.56 MHz carrier frequency and 423.75 kHz subcarrier frequency with Amplitude-shift keying (ASK) modulation. Functions of the RFID in the UltraMIST System include: determine the presence of an UltraMIST Applicator, determine if an Applicator is valid/invalid, and invalidate an Applicator after use.

The acceptable Quality of Service is defined as follows:

- Compliance to ISO / IEC 15693
- Interrogation every 500 milliseconds
- Read / write range of 5–50 mm

No patient identification data is collected, stored, or communicated with this System.

RFID	
Transmit Power	< 200 mW
Transfer Power to Tag	< 50 mW
Carrier Frequency	13.56 MHz
Subcarrier Frequency	423.75 kHz
Modulation	ASK – 100%
Data Rate	26.48 kbps
Data Flow	Command and response using transmit FIFO
Protocol	ISO/IEC 15693
Security	Encryption; 128 bit

ULTRAMIST SERVICE AND SYSTEM CHECKS

There is no recommended preventative maintenance or service interval for the UltraMIST System. The servicing of the UltraMIST System should only be performed by authorized and trained SANUWAVE service personnel. There are no interchangeable or detachable parts related to the function of the system that can be replaced by anyone other than trained SANUWAVE service personnel.
In addition, none of the following will be available as all repairs are to be made at SANUWAVE: circuit diagrams, component part lists and descriptions, calibration instructions or other information designed to assist service personnel in repairs (NOTE: this does not include UltraMIST System software updates, power cords, or fuses).

Please contact a SANUWAVE Customer Service Representative to arrange for servicing your System.

Software updates may be performed by either SANUWAVE field personnel or trained customers as appropriate. Instructions for upgrading will be provided as required.

There is currently no recommendation that the UltraMIST undergo a functional verification at any specific interval. The checklist in Appendix B has been provided for users who have internal institutional procedures requiring periodic review of equipment on site that can be performed by the user. If damage or abnormal operation is noticed do not continue to use the UltraMIST System and contact SANUWAVE Customer Service for diagnostic and repair.

WARNING: Do not modify this equipment without authorization of the manufacturer!

DISPOSAL

The UltraMIST System excluding the Applicator should be returned to SANUWAVE upon end of its service life.

Do not dispose of the UltraMIST System as unsorted municipal waste.

The UltraMIST System should be handled as electronic waste and/or electrical equipment waste according to the institution's disposal policies. If the UltraMIST System is to be returned, please contact SANUWAVE Customer Service for return instructions.

SANUWAVE, Inc.

9600 W 76th St,
Eden Prairie, MN 55344 USA

Customer Service

+1-800-545-8810
Email: customerservice@SANUWAVE.com
Web: www.ultramist.com
Pat.: www.ultramist.com/IP

APPENDIX A: ERROR/ALERT CODES

TREATMENT WAND

In order to more quickly identify the origin of an error, the error codes will be divided based on device:

- 001–099 Treatment Wand
- 100–199 Generator
- 200–299 Applicator
- 1000–1099 Bootloader

If users experience errors with Applicators, SANUWAVE requests return of the potentially defective Applicator for analysis when possible. Please save Applicators and record lot number on Applicator pouch.

Discuss return with customer service at +1-800-545-8810 or customerservice@SANUWAVE.com

CODE	DESCRIPTION	EXPLANATION	POSSIBLE CAUSES	SOLUTION
1	13V POWER RAIL OUT OF RANGE	Treatment Wand power out of spec	Component Failure, poor internal cable connection	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
3	RFID COMMUNICATION ERROR	Unable to communicate with RFID antenna	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
4	RFID WRITE FAILURE	Unable to write data to Applicator	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
5	RFID LOCK FAILURE	Attempt to lock the RFID data failed	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
6	EEPROM SPI COMMUNICATION ERROR	Unable to write to EEprom	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
7	EEPROM DATA CRC FAILURE	EEprom contents are corrupt	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
10	GENERATOR COMMUNICATION TIMEOUT	No message from generator to Treatment Wand	Broken Treatment Wand cable, poor cable connection in generator or poor cable connection in Treatment Wand	Remove and reinsert Treatment Wand cable. If error persists, call SANUWAVE Customer Service
11	GENERAL GENERATOR COMMUNICATION FAILURE	Message from generator cannot be processed	Software programming error	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
12	TIMEOUT WAITING FOR GENERATOR TO SEND BOOT COMPLETE PACKET	No message from generator indicating generator boot complete	Generator board not programmed, bootloader corrupt or broken Treatment Wand cable	Reinsert Treatment Wand cable. Try a different Treatment Wand if possible. Call SANUWAVE Customer Service if error continues.
13	TIMEOUT WAITING FOR GENERATOR TO SEND POST COMPLETE PACKET	Generator did not finish its POST	Broken Treatment Wand cable	Reinsert Treatment Wand cable. Try a different Treatment Wand if possible. Call SANUWAVE Customer Service if error continues.
14	SOFTWARE TIMER FAILED TO START	Timer resource limit exceeded	Software programming error	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
15	EVENT QUEUE IS FULL	Software event limit exceeded	Software programming error	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
16	OUTGOING PACKET QUEUE IS FULL	Software message queue limit exceeded	Software programming error	Shut down and restart the system. If error persists, call SANUWAVE Customer Service

GENERATOR

The following table outlines the errors that can originate from the Generator. All errors/alerts will cause the Ultrasonic driver and pump to be disabled.

CODE	DESCRIPTION	EXPLANATION	POSSIBLE CAUSES	SOLUTION
100	+24V POWER RAIL OUT OF RANGE	Voltage is outside of working limits	Dip in voltage when pump starts or electrical component tolerance stackup issue	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
101	−24V POWER RAIL OUT OF RANGE	Voltage is outside of working limits	Dip in voltage when pump starts or electrical component tolerance stackup issue	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
102	5V POWER RAIL OUT OF RANGE	Voltage is outside of working limits	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
103	DISTRIBUTION IC OVERLOAD	Faulty component. Unable to turn on power to the Treatment Wand	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
104	TRANSDUCER OP AMP OVERLOAD	Faulty component. Unable to turn on power to the Transducer	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
107	DAC HW FAILURE	Unable to set Transducer power within limits	Component Failure	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
109	RTC LOW BATTERY	Battery less than 2.5 V	End of battery life	Call SANUWAVE Customer Service. Press OK to continue
110	RTC COMMUNICATION FAILURE	Real time clock unable to keep time	Electrostatic discharge event	Press OK and continue
112	TW COMMUNICATION TIMEOUT	Communication between Treatment Wand and generator is interrupted	Treatment Wand may have been disconnected at the base of the generator while power was on, or the connection was not complete before the power was turned on.	Shut down system. Disconnect and visually inspect the connection between the Treatment Wand cable and generator. Reconnect cable and restart system. If error persists, call SANUWAVE Customer Service.
114	RESONANT FREQUENCY NOT FOUND	Transducer displacement out of range	Debris on Transducer, Applicator not positioned properly (in contact with Transducer) or Transducer assembly malfunction	Clean Transducer, inspect for mechanical interference with Applicator. If error persists, call SANUWAVE Customer Service
115	WATCHDOG RESET	Microcontroller idle for more than 1.6 sec	Possible programming error	Shut down and restart the system. If error persists, call SANUWAVE Customer Service
116	TRANSDUCER CURRENT OUT OF RANGE	Transducer current out of range	Debris on Transducer, Transducer out of calibration or mechanical shock causing Transducer performance change	Clean Transducer, inspect for mechanical interference with Applicator. If error persists, call SANUWAVE Customer Service
117	TRANSDUCER VOLTAGE OUT OF RANGE	Transducer voltage out of range	Debris on Transducer, Transducer out of calibration or mechanical shock causing Transducer performance change	Clean Transducer, inspect for mechanical interference with Applicator. If error persists, call SANUWAVE Customer Service

CODE	DESCRIPTION	EXPLANATION	POSSIBLE CAUSES	SOLUTION
121	PUMP FEEDBACK SPEED ERROR	Peristaltic pump rollers are not functioning or are meeting too much resistance to operate at the proper speed	IV tubing may be improperly or incompletely threaded across the rollers or a foreign object impeding rollers	Shut down system. Remove tubing from peristaltic pump. Check for any foreign debris on tubing and inside the pump. Rethread the tubing across the rollers ensuring the fluid source is being fed from the left to right. If error persists, call SANUWAVE Customer Service
122	PERISTALTIC PUMP 24V CURRENT SENSE FAILURE	The peristaltic pump is not operating properly	Peristaltic pump may have shut down due to excess force either from a foreign object jamming inside or component failure	Shut down system. Remove tubing from peristaltic pump. Visually inspect the peristaltic pump for physical damage. If damage exists, contact SANUWAVE Customer Service. Also check for any foreign debris on tubing and inside the pump. If foreign objects or debris are found inside the pump, remove them, and restart treatment.
123	TW COMMUNICATION TIMEOUT	Message not received from Treatment Wand to Generator.	Broken Treatment Wand cable, poor cable connection in generator or poor cable connection in Treatment Wand	Shut down system. Disconnect and visually inspect the connection between the Treatment Wand cable and generator. Reconnect cable and restart system. If error persists, call SANUWAVE Customer Service.
124	GENERAL TREATMENT WAND COMMUNICATION FAILURE	A message from the Treatment Wand cannot be handled	Software programming error	Call SANUWAVE Customer Service
125	FLASH DATA CRC FAILURE	Memory contents are corrupt	Software programming error and/or component failure	Call SANUWAVE Customer Service
126	OUTGOING PACKET QUEUE IS FULL	Software message queue limit exceeded	Software programming error	Call SANUWAVE Customer Service
127	USB IC OVERLOAD	Faulty component. Unable to turn on power to the USB port	Component Failure	Call SANUWAVE Customer Service
128	TRANSDUCER FREQUENCY RANGE ERROR	Transducer Frequency Out of Range	Vibration of the horn is being impeded by: debris on Transducer, Applicator touching horn, pooling of fluid (e.g. saline) around base of horn and/or damage to the horn.	Clean Transducer of any foreign debris, inspect for mechanical interference with Applicator and reposition as needed, and/or drain excess fluid (e.g. saline) by tipping the horn perpendicular to the floor. If error persists, call SANUWAVE Customer Service.
129	TRANSDUCER IMPEDANCE RANGE ERROR	Treatment Wand vibration is being impeded	Vibration of the horn is being impeded by: debris on Transducer, Applicator touching horn, pooling of fluid (e.g. saline) around base of horn and/or damage to the horn.	Clean Transducer of any foreign debris, inspect for mechanical interference with Applicator and reposition as needed, and/or drain excess fluid (e.g. saline) by tipping the horn perpendicular to the floor. If error persists, call SANUWAVE Customer Service.

APPLICATOR

The following table outlines the errors that can originate from the Applicator.

CODE	DESCRIPTION	EXPLANATION	POSSIBLE CAUSES	SOLUTION
200	INVALID APPLICATOR	The Treatment Wand detects a used Applicator	The Applicator has been used in a previous treatment.	Replace with a new Applicator.
201	USER REMOVED APPLICATOR DURING TREATMENT	This occurs if the Treatment Wand can no longer sense Applicator during the first 60 sec of use.	Will occur if a user removes an Applicator during an active treatment session.	Reposition Applicator on Treatment Wand and continue treatment.
202	APPLICATOR USED MORE THAN 60 MINUTES	This occurs when an Applicator reaches its maximum use of 60 minutes of treatment time.	Applicator has reached maximum use of 60 minutes.	Replace Applicator
203	APPLICATOR RFID DATA ERROR	Treatment Wand is unable to read the Applicator	Applicator may not be fully seated onto the Treatment Wand, an impediment (such as debris) is between the Treatment Wand's sensor and the Applicator's software chip and/or a component failure.	Clean Transducer of foreign debris and reposition Applicator on Treatment Wand. If error persists, call SANUWAVE Customer Service.
204	OVERHEAT TRANSDUCER	A temperature sensor inside the Treatment Wand has reached a heat threshold.	When a heat threshold has been reached, the system will automatically initiate a 5 minute cool down period before allowing the treatment to continue.	DO NOT TURN OFF System. Allow the system to complete its 5 minute cool-down and then resume treatment.
205	FREQUENCY SLIP	The system is unable to maintain its target operating frequency.	Vibration of the horn is being impeded by: debris on Transducer, Applicator touching horn, pooling of fluid around base of horn and/or damage to the horn.	Clean Transducer of any foreign debris, inspect for mechanical interference with Applicator and reposition as needed, and/ or drain excess fluid by tipping the horn perpendicular to the floor. If error persists, call SANUWAVE Customer Service.
206	OVERHEAT – HANDLE	A temperature sensor in the Treatment Wand handle has reached a heat threshold.	When a heat threshold has been reached, the system will automatically initiate a 5 minute cool down period before allowing the treatment to continue.	DO NOT TURN OFF System. Allow the system to complete its 5 minute cool-down and then resume treatment.
207	OVERHEAT – TREATMENT WAND BOARD	A temperature sensor attached to the Treatment Wand board has reached a heat threshold.	When a heat threshold has been reached, the system will automatically initiate a 5 minute cool down period before allowing the treatment to continue.	DO NOT TURN OFF System. Allow the system to complete its 5 minute cool-down and then resume treatment.
208	OVERHEAT – GENERATOR	A temperature sensor inside the generator has reached a heat threshold.	When a heat threshold has been reached, the system will automatically initiate a 5 minute cool down period before allowing the treatment to continue.	DO NOT TURN OFF System. Allow the system to complete its 5 minute cool-down and then resume treatment.

BOOTLOADER

The following table outlines the errors that can originate from the Applicator.

CODE	DESCRIPTION	EXPLANATION	POSSIBLE CAUSES	SOLUTION
1000	FAILED TO LAUNCH TREATMENT WAND APPLICATION FIRMWARE	Treatment Wand software is not running.	A hardware issue has occurred.	Call SANUWAVE Customer Service
1001	TREATMENT WAND NOT PROGRAMMED WITH APPLICATION FIRMWARE	Treatment Wand software is not running.	Treatment Wand memory corruption or device was not properly programmed.	Call SANUWAVE Customer Service
1002	GENERATOR NOT FOUND	Connection between Treatment Wand cable and generator is incomplete/faulty. Communication between generator and Treatment Wand is being interrupted.	If the Treatment Wand cable connector wasn't fully inserted into the generator when the treatment was initiated or the cable was disconnected during a treatment an intermittent connection may exist.	Turn off the system. Disconnect and reconnect the cable ensuring it is fully inserted. Restart the system. If the error persists, contact SANUWAVE Customer Service.
1003	GENERATOR BOOTLOADER NOT FOUND	Connection between Treatment Wand cable and generator is incomplete/faulty. Communication between generator and Treatment Wand is being interrupted.	If the Treatment Wand cable connector wasn't fully inserted into the generator when the treatment was initiated or the cable was disconnected during a treatment an intermittent connection may exist.	Turn off the system. Disconnect and reconnect the cable ensuring it is fully inserted. Restart the system. If the error persists, contact SANUWAVE Customer Service.
1004	GENERAL SERIAL COMMUNICATION ERROR	Software communication packet is full	Possible programming error	Call SANUWAVE Customer Service
1005	TREATMENT WAND POWER-ON RESET ERROR	Unexpected Treatment Wand reset.	Possible programming or hardware error	Call SANUWAVE Customer Service

NOTE: No patient data is stored on the Applicators, or the equipment. The generator retains only usage data which can be retrieved for analysis by SANUWAVE technical support upon request.

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APPENDIX B: ULTRAMIST® SYSTEM CHECK OUT

ULTRAMIST® SYSTEM CHECK OUT PROCEDURE

Serial Numbers (fill in)	Generator:	Treatment Wand:

INSPECT	SYSTEM CHECK (Circle all that apply)	Circle Response		Appropriate	
Power Cord	Damaged (fraying insulation, exposed wires, bent plug, etc.)	YES	NO	PASS	REJECT
Generator	Damaged (cracked case, broken case seal, dents, broken or missing cradle, etc.)	YES	NO	PASS	REJECT
	Labels (3 labels on the back of Generator) – present and readable	YES	NO	PASS	REJECT
Peristaltic Pump	Damaged (broken or missing pump door, cracked cover, rollers do not rotate, etc.)	YES	NO	PASS	REJECT
	Labels (one label behind pump) – present and readable	YES	NO	PASS	REJECT
Treatment Wand	Damaged (broken case, broken seal, cable pulled out, etc.)	YES	NO	PASS	REJECT
	Labels (one label underside) – present and readable	YES	NO	PASS	REJECT
	Keypad damaged (missing all or part of keypad, symbols not readable, not securely connected to Treatment Wand, etc.)	YES	NO	PASS	REJECT
	Lens damaged (missing all or part of lens, scratched, dented, unreadable, etc.)	YES	NO	PASS	REJECT
	Transducer tip damaged (bent, dented, etc.)	YES	NO	PASS	REJECT
	Treatment Wand cable damaged (pulled out from handle, cracked insulation, exposed wires, damaged lemo connector/pins, etc.)	YES	NO	PASS	REJECT
TURN SYSTEM POWER ON		Circle Response		Appropriate	
Preparing for treatment	Generator power switch easily flips on	YES	NO	PASS	REJECT
	Verify indicator light on front of Generator is on and green	YES	NO	PASS	REJECT
	You hear 3 audible tones on start up	YES	NO	PASS	REJECT
	Start-up screen is noted on Treatment Wand display screen	YES	NO	PASS	REJECT
	Treatment Wand Display is clear and easy to read	YES	NO	PASS	REJECT
	Press the four keypad buttons on the Treatment Wand to ensure they function, and you hear a single tone each time you press	YES	NO	PASS	REJECT
	Check for fluid leaks from Applicator or Applicator tubing connections during setup. There should be no fluid leaks with the tubing installed in the pump.	YES	NO	PASS	REJECT
	Applicator installation – the Treatment Wand ultrasonic metal tip should be nearly flush with the front port opening of the Applicator	YES	NO	PASS	REJECT
TURN SYSTEM POWER ON		Circle Response		Appropriate	
Treatment Wand	Select Wound 1, input wound size 10 cm – 19 cm, confirm amount of fluid required is displayed	YES	NO	PASS	REJECT
	Energize the system by pressing the treatment button on the Treatment Wand handle	YES	NO	PASS	REJECT
	Confirm a fluid mist is flowing from the end of the Treatment Wand tip.	YES	NO	PASS	REJECT
	When the system completes the treatment verify three audible tones are heard	YES	NO	PASS	REJECT

Additional Notes (Document any damage or issues not noted above)

_____

_____

CHECK OUT SUMMARY

Are all items marked as PASS	YES	NO (Contact SANUWAVE)

NAME (PLEASE PRINT): _____ **DATE:** _____

SIGNATURE: _____