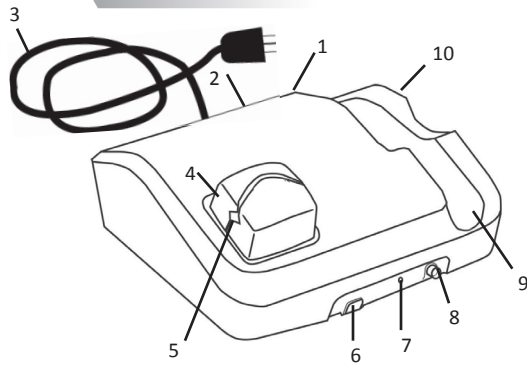




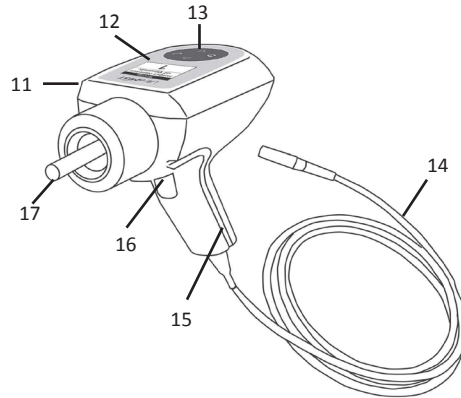
**PLEASE READ INSTRUCTIONS BEFORE USE.**

**Caution:** Rx Only. This medical device is to be operated by a healthcare professional in accordance with the instructions for use.

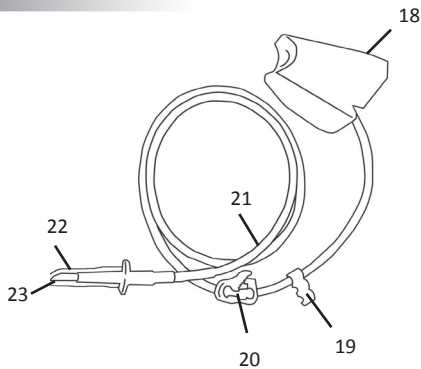
**Generator**



**Treatment Wand**



**Applicator**



**Other Materials Required**

- 0.9% Normal Saline 100cc - 1000cc bag
- Germicidal wipes for cleaning/disinfecting
- Absorbent pads

**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 Light	17 Treatment Wand Tip	
8 Treatment Wand Connector		
9 Treatment Wand Cradle		
10 USB Port/Cover		

## DESCRIPTION & INDICATIONS FOR USE

**Description:** The UltraMIST™ System delivers low frequency ultrasound to the treatment site using a noncontact saline mist.

**Indications for Use:** The MIST Therapy System produces 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; over areas of malignancies.

**Potential Complications:** Tingling, redness.

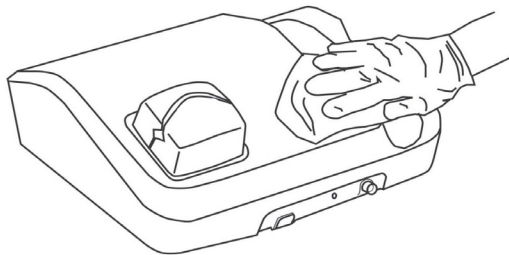
## PREPARING THE PATIENT FOR TREATMENT WITH THE ULTRAMIST SYSTEM

- 1 Collect all required materials (generator, treatment wand, applicator, IV saline, germicidal wipes, absorbent pads and gloves).
- 2 Use facility approved Infection Control Procedures throughout the treatment session.
- 3 Treatment with the UltraMIST System will require a clean environment.
- 4 Depending on the wound location, position the patient in a comfortable position for treatment.
- 5 Remove soiled dressings and discard all contaminated materials (gloves, dressings, pads) prior to UltraMIST treatment.
- 6 Place an absorbent pad under the portion of the patient being treated to collect the saline runoff.
- 7 Measure the area of the wound to be treated.

## CLEANING THE ULTRAMIST SYSTEM

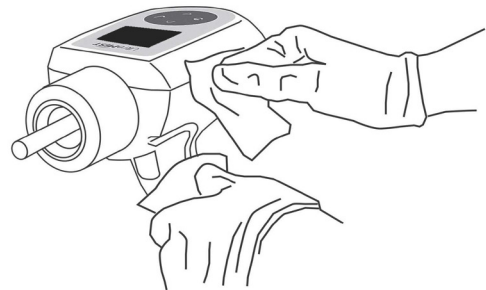
Clean the UltraMIST System prior to and after each treatment session with the Power Switch in the “off” position.

1



Prior to treatment, clean the entire system using facility approved infection control procedures.

2

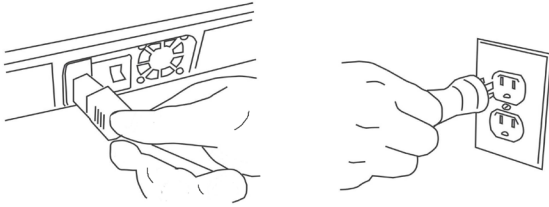


Do not sterilize the treatment wand including tip with steam, ETO, radiation, gas/plasma, or cold sterilants. After completion of the UltraMIST treatment, repeat the cleaning process.

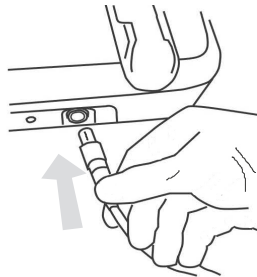
**WARNING:** The UltraMIST applicator is designed as a single patient-use disposable unit to avoid contamination. Do not re-sterilize or reuse applicators. Re-using the applicator and/or saline may result in infection and degraded performance.

PREPARING THE ULTRAMIST™ SYSTEM

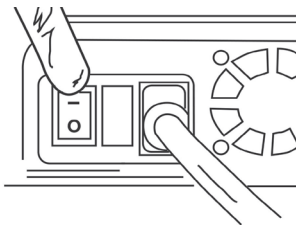
- 1 With the power switch in the 'off' position, plug the supplied generator power cord into the back of the generator and into an electrical outlet.



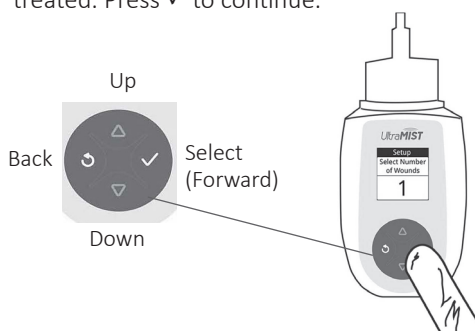
- 2 Ensure the treatment wand cable is attached and fully seated to the front of the generator by aligning the red mark on the cable with the red mark on the connector.



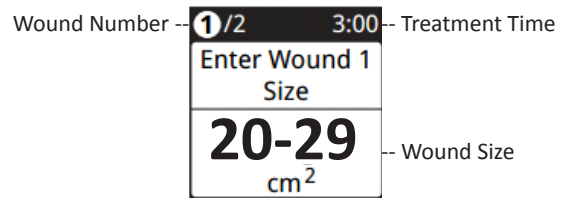
- 3 Turn the power switch located on the back of the generator to the 'on' position.



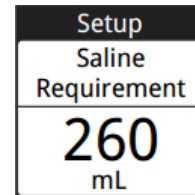
- 4 After the self-test is completed, use the key pad on the treatment wand to select the number of wounds to be treated. Press ✓ to continue.



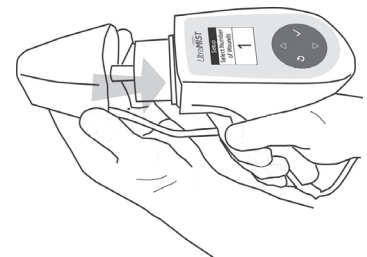
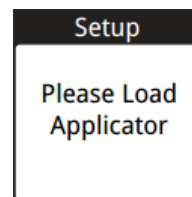
- 5 Use the keypad to enter the size of each wound to be treated per the screen prompts.



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



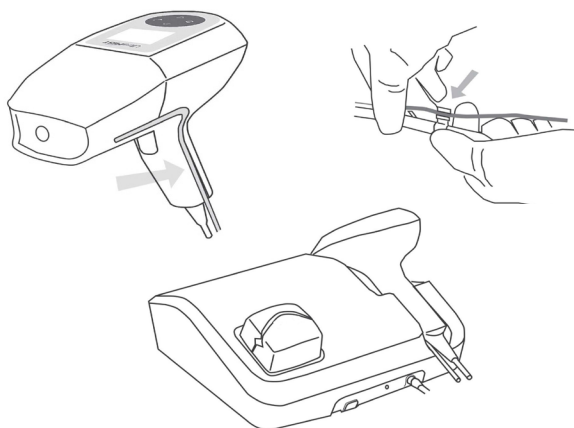
- 7 The display screen will ask for the applicator to be loaded. Remove applicator from packaging and press the applicator onto the treatment wand. Ensure the applicator is fully seated prior to use with the metal tip visible in the center.



*Note: After the set up is complete, DO NOT remove the applicator until the treatment has been fully concluded. This is a single use product that once removed will need to be replaced with a new applicator.*

PREPARING THE ULTRAMIST™ SYSTEM

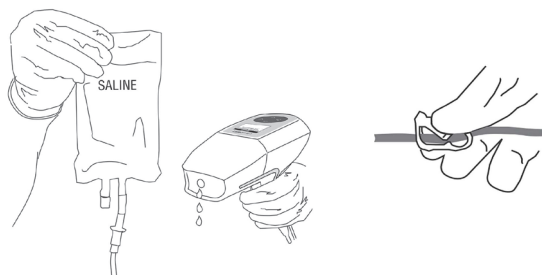
- 8 Insert applicator tubing into the treatment wand tubing channel and attach the tubing clip to the treatment wand cable. Place treatment wand in cradle once completed.



- 9 Remove saline bag from outer packaging. Remove the protective cover from applicator tubing spike and from saline bag port. Insert spike fully into saline bag.



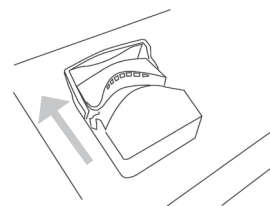
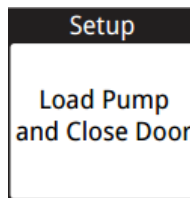
- 10 Allow the saline to run through the applicator tubing until saline is noted at the distal tip. Close the tubing clamp.



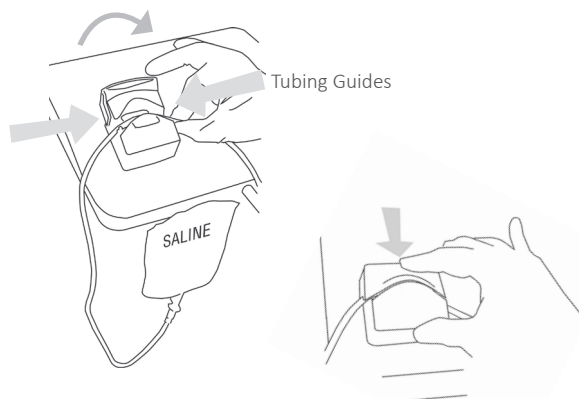
- 11 If utilizing the adjustable hook, position generator near the edge of a flat work surface (i.e. tabletop or cart). Extend the hook beyond the edge and attach the saline bag. Adjust position as necessary so the saline bag hangs freely and the generator is stable.



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

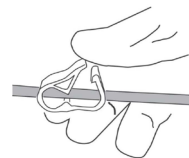


- 13 Loop the applicator tubing from the saline bag through the saline pump from left to right, center on tubing guides, and close the pump door. Leave enough tubing to allow the saline bag to hang freely with the majority of the tubing between the pump and treatment wand.

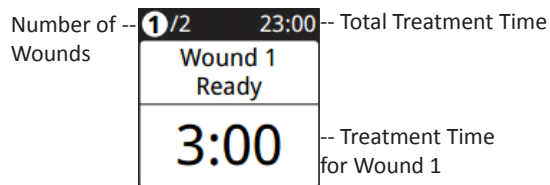


- 14 Open the tubing clamp. Saline will not flow until the treatment on/off button is initiated.

*Note: Saline will only flow in conjunction with ultrasound delivery.*



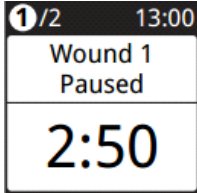
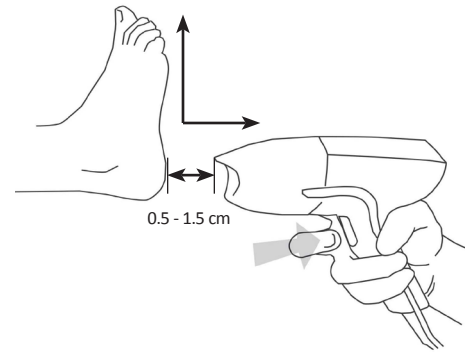
The system is now set up and ready for treatment.



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.

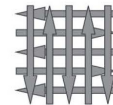
2 Depress and release the treatment on/off button (trigger) on the treatment wand handle. This will initiate both the saline flow and ultrasound delivery. The treatment timer will start to count down on the display.



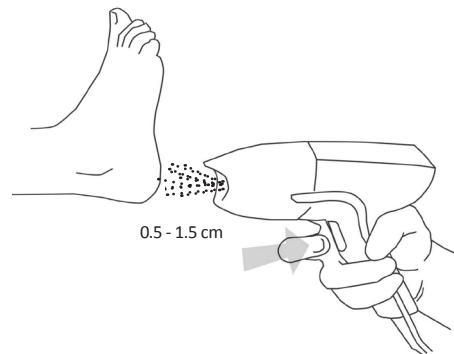
*Note: You may pause treatment by depressing and releasing the treatment on/off button. The treatment timer will be paused until restarted.*

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



4 Audible (gurgling) and surface visual 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.

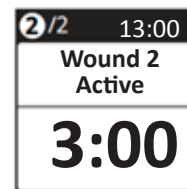


*Note: It is important to maintain a 0.5 to 1.5 cm (0.2 – 0.6 inch) distance from the leading edge of the applicator to the treatment area at all times to maximize therapeutic effect.*

5 Continue treatment until 3 audible tones sound indicating the end of treatment time. The ultrasound and saline 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.

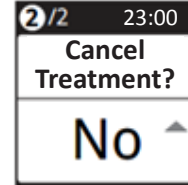
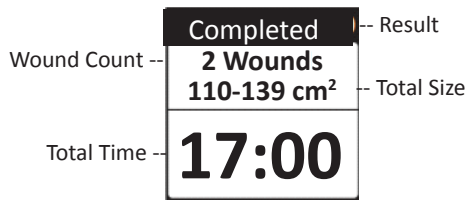
*Note: if at anytime during the treatment it is determined additional time will be required, use the up/down buttons to add time in increments of 1 minute. Press ✓ to continue.*



TREATING THE PATIENT WITH THE ULTRAMIST™ SYSTEM

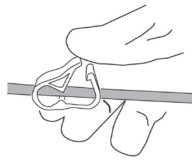
- Once all the wounds are completed, the summary screen will be displayed.

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 treatment summary screen will appear.

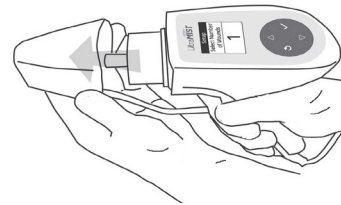


ULTRAMIST™ SYSTEM SHUTDOWN PROCEDURE

- Turn power switch to off. Clamp the tubing with the pinch clamp. There may be saline remaining in the bag which is normal depending upon the size of the wound being treated.



- Remove the tubing from the treatment wand channel and pump, remove the applicator from the treatment wand and saline bag from adjustable hook and discard. Follow facility approved biohazard disposal procedures.



Use the facility’s approved infection control procedures to clean the system.

USB PORT

- The generator USB port is designed for the following:
  - Download encrypted performance data to a Celleration approved USB drive for troubleshooting purposes
  - Upload software upgrades from a Celleration 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.

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

- Accessing USB Port
  - Remove Treatment Wand from Generator cradle and set aside
  - Turn Generator over
  - Using a coin or flathead screw driver, rotate the lock 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 lock clockwise a quarter to lock the door in place

## COMMON ERRORS (noted on display screen)

#	ERROR	CAUSE	SOLUTIONS
008	OVERHEAT	Treatment wand temperature has exceeded the allowed limit	<p>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</p> <p>20 minutes is the expected maximum treatment time after periods of system inactivity.</p> <p>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.</p> <p>DO NOT TURN OFF SYSTEM during cool down (this will require a replacement of the applicator)</p>
200	INVALID REPLACE APPLICATOR	Applicator has been previously used and should be replaced	Replace applicator
201	REPOSITION APPLICATOR	Applicator not positioned properly on treatment wand	Adjust current applicator properly on treatment wand
202	MAX USE REPLACE APPLICATOR	Applicator has been used for the maximum time period allowed	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
For errors not listed or more details, refer to the Troubleshooting section of the Instructions for Use or contact Celleration 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 Celleration 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 its in the “on” position
	Treatment wand is not connected to the generator	Insert or re-insert treatment wand cable into connector or generator
SINGLE KEY ON KEYPAD NOT FUNCTIONING	Mechanical failure	Call Celleration Customer Service
ALL KEYS ON KEYPAD NOT FUNCTIONING	System software error	Shut down system by turning off power and then restart. If error continues, call Celleration Customer Service
OVERHEAT	Treatment wand temperature has exceeded the allowed limit	<p>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</p> <p>20 minutes is the expected maximum treatment time after periods of system inactivity.</p> <p>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.</p> <p><b>DO NOT TURN OFF SYSTEM</b> during cool down (this will require a replacement of the applicator)</p>
ERROR MESSAGE ON DISPLAY SCREEN	An error has occurred	Refer to the common errors table to determine appropriate action. If error continues, note the contents of the error message and call Celleration Customer Service



## TROUBLESHOOTING

PROBLEM	CAUSES	SOLUTIONS
NO SALINE OR INSUFFICIENT SALINE IS COMING OUT OF APPLICATOR	Wound ready screen is not visible on display screen	Complete set up process until wound ready 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
	Saline pump door is open	Close pump door
	Tubing is not properly loaded in the saline pump	Load tubing into saline pump using tubing guides and 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 saline bag	Ensure spike and saline bag are fully mated
SALINE 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 saline to accumulate inside applicator	Turn applicator tip downward to allow excess saline 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 qualified service personnel.

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 - Never depress treatment on/off button without applicator in place.

Always have the applicator properly seated and tubing clamp open when activating the treatment on/off button.

**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.

**ULTRAMIST™ PRODUCT SPECIFICATIONS**

<b>SAFETY REQUIREMENTS</b>	Meets requirements of IEC 60601-1, 3rd Edition ETL listed as 'Conforms to UL 60601-1' Reference file: 3055920
<b>ELECTRONIC COMPATIBILITY SYSTEM CLASSIFICATION</b>	Meets the requirements of IEC 60601-1-2 and FCC Part 18 Class II equipment Type BF applied parts
<b>STERILIZATION METHOD IPX RATING</b>	Gamma Sterilization (applicators only) Generator: IP21 Treatment Wand: IP22
<b>INPUT DETACHABLE POWER CORD</b>	100-240 VAC; 50-60Hz 125V, 10A UL or equivalent listed for hospital grade. Note: this Class II equipment does not rely on grounding from power cord as means of insulation.
<b>CURRENT FUZE</b>	2.0A T2AL250V
<b>OPERATING AND STORAGE CONDITIONS</b>	Operating: Temperature: 15° to 25° C Atmospheric Pressure: 700 to 1060 mmHg Applicator/System Transport and Storage: Temperature: -25° to 75° C Relative Humidity: 30% to 75% (non-condensing)
<b>ACOUSTIC OUTPUT POWER</b>	Operating Frequency: 40 Khz ± 1 Khz Maximum Unintentional Ultrasound Energy: ≤ 100mW/cm <sup>2</sup> Tip Displacement Range: 65µm ± 10µm

**TECHNICAL SERVICE**

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

PHONE: 1-866-307-MIST (6478)

ADDRESS: 6321 Bury Drive, Suite 15, Eden Prairie, MN 55346

WEBSITE: [www.Celleration.com](http://www.Celleration.com)

EMAIL: [customerservice@celleration.com](mailto:customerservice@celleration.com)

























FREQUENTLY USED FUNCTIONS OF THIS SYSTEM

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 control panel	Allows full set up of treatment parameters
Treatment ON/OFF Button	Front treatment wand handle	Controls ultrasound and saline on and off

Note: No parts of the UltraMIST System are serviceable during use or by user.

EXPLANATION OF SYMBOLS

 Fragile, Handle with Care	 Consult Instructions for Use	<b>IPXX</b> Ingress Protection	 Do Not Dispose in Municipal Waste
 This End Up	 Manufacturer	 ETL Symbol	<b>REF</b> Catalog Number
 Keep Dry	 Date of Manufacture	 Class II Equipment	 Up
 Recycle	<b>LOT</b> Lot Number	<b>STERILE R</b> Sterilized Using Irradiation	 Down
<b>EC REP</b> Authorized Representative in the European Community	Rx Only Prescription Use Only Device	 Type BF Applied Part	 Back
<b>CE</b> CE Mark	 Do Not Reuse	<b>SN</b> Serial Number	 Select
 Temperature Limit	 Use-By Date	 Caution, Refer to Accompanying Documents	 On/Off
 Open	 Closed	 Do Not Allow Fingers to Contact Moving Parts	 Do Not Resterilize

## 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 assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - 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 UltraMIST System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:  <b>Warning:</b> This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the UltraMIST System or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
<i>Ref. IEC 60601-1-2:2007 §5.2.1.1</i>		

## 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 <sup>2</sup> , 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 <sup>2</sup> , 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.
<i>Ref. TR-75143 on file at Celleration</i>		

**FEDERAL COMMUNICATIONS COMMISSION (FCC) USER INFORMATION**

The UltraMIST System has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receivers.
- Connect the equipment into and outlet on a different circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio.TV technician for help.



6321 Bury Drive Suite 15  
Eden Prairie, MN 55346

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fax: 952.224.8750  
customer service: 866.307.MIST (6478)

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web: [www.celleration.com](http://www.celleration.com)  
patent information: [www.Celleration.com/company/IP](http://www.Celleration.com/company/IP)