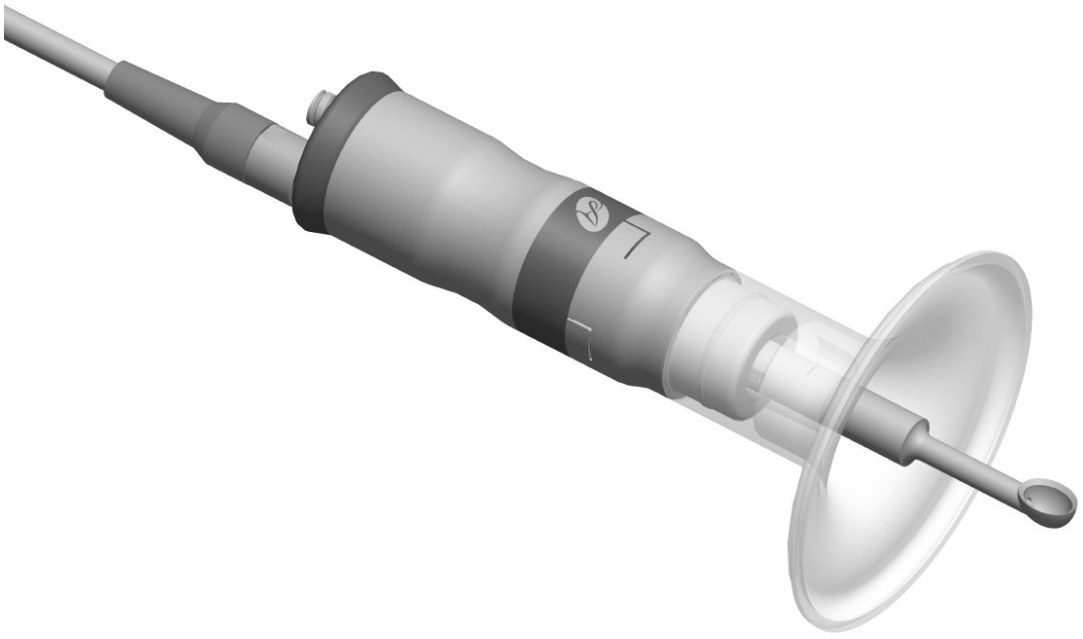
Arobella Medical, LLC

(((Sound Touch for Wound Care™)))

Qoustic Wound Therapy System™
Model - AR1000 Series

INSTRUCTIONS FOR USE

Read and understand instructions thoroughly before beginning treatment.



0000051 • Rev G • 01OCT08

The AR1000 Ultrasonic Wound Therapy System is referred to as the Qoustic Wound Therapy System™ or as the Qoustic Wound Therapy System™ - Model AR1000 Series throughout this document.

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SECTION 1 – DESCRIPTION / INDICATIONS FOR USE

Description: The Qoustic Wound Therapy System™ - Model AR1000 Series is designed for the selective dissection & fragmentation of tissues, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue), and cleansing irrigation of the site for the removal of debris, exudates, fragments, and other matter through the use of ultrasonic energy and/or fluid irrigation. This is accomplished by (1) selectively dissecting and fragmenting the unwanted tissue from the wound bed with the applicator tip (Qoustic Qurette™) activated by ultrasonic energy and (2) cooperatively cleansing the site of the separated and loosened fragments and debris with an irrigation wash of saline. This process is directed for single (1) treatment, and total recommended treatments shall be no more than three (3) times per week; typical treatment regimen is approximately two (2) weeks or more, depending on the size and nature/condition of the treated area as well as other subject dependent factors, but may be prescribed longer on the order of a physician.

Indication For Use: The Qoustic Wound Therapy System™ uses ultrasonic energy and/or fluid irrigation to selectively dissect & fragment tissue, perform wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue), and provide cleansing irrigation of the site for the removal of debris, exudates, fragments, and other matter on humans via direct contact.

U.S. FEDERAL LAW restricts this device to sale, distribution, and use solely by or on the order of a physician or other licensed practitioners in the state where the system is to be operated.

Sterile Saline: The Qoustic Wound Therapy System™ is to only be used with sterile saline, which is widely available for purchase from medical suppliers.

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SECTION 2 – SAFETY AND STANDARDS

2.1 SAFETY

Please review all safety advisories prior to operating this system (see SECTION 3 – WARNINGS AND PRECAUTIONS). This device is a Class I electrical safety device.

It is recommended that the user follow universal precautions, including the wearing of protective gloves, when operating the system.

U.S. FEDERAL LAW restricts this device to sale, distribution, and use solely by or on the order of a physician or other licensed practitioners in the state where the system is to be operated.

2.2 BIOCOMPATIBLITY

The Qoustic Wound Therapy System™ materials that come into contact with patients, comply with the applicable requirements of EN ISO 10993-1, according to their intended use. No negative reactions to these materials have been reported. This device does not contain, nor have in patient contact, any latex materials.

2.3 STANDARDS

The Qoustic Wound Therapy System™ - Model AR1000 Series and Accessories have been designed and manufactured to comply with the following voluntary, FDA-recognized standards:

- 21 CFR 1050.10 – Ultrasonic therapy products
- IEC 61847 Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics
- IEC 60601-1 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
- UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical electrical equipment, Part 1-2: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-4 Medical electrical equipment, Part 1-4: Programmable electrical medical systems
- FCC Part 18 - EMC Requirements
- CAN/CSA STD. C22.2 NO.601.1-M90 Medical Electrical Equipment - Part 1: General Requirements for Safety

The Qoustic Wound Therapy System™ has been designed and manufactured according to the following quality standards:

- 21 CFR 820 – Good Manufacturing Practices (GMP) / Quality System (QS) Regulation
- MDD 93/42/EEC – Medical Device Directive
- ISO 13485 – Quality management systems

2.4 LABEL AND ICON DESCRIPTION

The following table describes the purpose and location of safety labels on the device. Other important information is included if applicable.

Label/Symbol	IEC Publication	Description	Location on Device
	348	"CAUTION" - Consult accompanying document	Front and rear of generator
	417-878-02-02	Type B Equipment	Rear of generator

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SECTION 3 – WARNINGS AND PRECAUTIONS

Be sure to read and understand all warnings and instructions prior to use.

WARNING: U.S. Federal Law restricts these devices to sale, distribution and use by or on the order of a physician or other licensed practitioners in the state where the system is to be operated.

WARNING: Please use caution when choosing protective gloves because they are often composed of latex. Be certain to identify latex sensitive patients prior to exam. Carefully read the protective glove package labeling to verify the material used. Serious allergic reactions to latex have been reported and the user should be ready to react accordingly.

WARNING: Do not operate the system without a flow of saline (do not run dry). Only use sterile saline with the system. Do not use any other fluid with this device.

WARNING: Unauthorized modifications will void warranty and may cause harm to the patient or physician.

WARNING: The Disposable Shield (21) is designated for single-patient / single-treatment use only. Do not reuse as there is potential risk of contamination. Dispose according to local regulations regarding biohazard waste.

CAUTION: Always handle fluids with caution. In addition to warnings and instructions listed herein, follow all appropriate warnings and procedures associated with handling, transport and storage of electric and electronic devices.

CAUTION: Always handle the saline reservoir in a secure manner to minimize fluid spills and leaks. Do not over-pressurize the saline reservoir, either manually or with mechanical automated assistance, to minimize over-pressurization with the device and splatter of potentially biohazardous fluid during treatment.

CAUTION: Keep exposed skin clear of the active Qoustic Qurette™ tip unless under treatment.

CAUTION: Avoid uncontrolled contact with the Qoustic Qurette™ (12,13,14), Extender (15) or "Active" Parts of Qoustic Qurette™ Hand Piece (46) while ultrasonic energy is being applied or using the device without cooperatively supplying the saline solution to irrigate the area where applied. Risk of burns or other injury will result as the system can cut tissue or damage cells in which it comes into contact with or when operated without saline.

CAUTION: Do not activate or operate Hand Piece (9) without a Shroud (20 or 22) in place and in "Locked" position. Operating without a Shroud or operating with a Shroud in the "Unlocked" position may lead to burns or other injuries to the user.

CAUTION: Do not sterilize the hand piece in any way other than as recommended in Section 7.2. Performing any other sterilization methods (e.g. autoclave, ETO, etc.) will damage the hand piece and void all warranties on the device. **DO NOT AUTOCLAVE THE HAND PIECE.**

CAUTION: Do not attach or remove any components of the system with the system turned on.

CAUTION: Always check for signs of damage or mishandling prior to operating the system. If damage is suspected, turn off the equipment, do not use the equipment, and call for service.

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CAUTION: Attaching devices to the Hand Piece (9) or generator that are not referenced in these instructions may cause personal injury or malfunctioning of the system. Do not attach any devices to the generator or Hand Piece (9) that are not specifically recommended by Arobella Medical.

CAUTION: As with all electronic equipment, dropping the unit may cause damage. Handle the system with care. If damage is suspected, turn off the equipment, do not use the equipment, and call for service.

CAUTION: Do not immerse the Hand Piece (9) and/or Generator in liquid. Doing so may cause electrical shock to the patient and/or user. The Hand Piece is IPX4 and the Generator is IPX0.

CAUTION: Risk of electrical shock. Do not open. No user serviceable parts inside.

CAUTION: Please record any incurred treatment times prior to powering down the generator and/or switching to another Hand Piece (9).

CAUTION: Do not run each Hand Piece (9) over the designed duty cycle of 20% ON – 80% OFF over a period of 50 minutes. Running over the 20% ON duty cycle may lead to excessive heating, leading to possible injury of the patient and/or user and system malfunction.

CAUTION: Abort treatment with the system if typical Indications for Discontinuing Sharp Debridement apply.

CAUTION: Do not block the cooling intakes under the Generator's Front Panel (5, 6 &7) or the Cooling Fan Exhausts (44) on the back. Blocking these may lead to overheating and system malfunction.

CAUTION: Do not use wrenches other than those supplied with the system. Using other wrenches may lead to excessive torque and wear that may damage the system.

CAUTION: Users are strongly advised to wear Personal Protective Equipment (PPE) including sterile gloves while treating patients.

PRECAUTION: Always sterilize the patient contact components (i.e. Qoustic Qurette™ (12,13, or 14), Extender (15), Shroud (20 or 22), etc.) before each use of the device in accordance with the instructions provided in SECTION 7 - SERVICE AND CARE OF THE SYSTEM of this manual.

PRECAUTION: Every unit is calibrated prior to leaving the factory. If, however, you suspect your unit to be out of calibration, call for service before continued use.

CONTRAINDICATIONS: Typical Contraindications for Sharp Debridement apply when using the system.

CONTRAINDICATIONS: Do not use the system within 30 cm of any lifesaving electronic implants/prosthesis (i.e. pacemaker, pump, defibrillator, etc); on the lower back during pregnancy or over the pregnant uterus. Do not use the system at or near metal implants (e.g. artificial hip, bone screws, dental implants, etc).

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SECTION 4 – PRE AND POST PATIENT TREATMENT

4.1 PRETREATMENT

Arobella Medical, LLC recommends that the target treatment area (wound, burn, etc) should be cleaned of any excess medications, topical products, and/or wound exudate prior to use of the Qoustic Wound Therapy System™.

The use of local anesthesia is a decision to be made by the physician or licensed practitioner and patient on a case-by-case basis. The patient should not feel any significant pain or discomfort during the procedure. If there is onset of significant pain or discomfort, modify the procedure to prevent pain or abort treatment if "Typical Indications for Discontinuing Sharp Debridement" occur.

Arobella Medical, LLC recommends the use of disposable sterile 0.9% saline solution, supplied by the user in bag or bottle form, with the requisite tubing, valving, and connection for use with the system.

4.2 POST TREATMENT

Following the procedure, the physician and/or patient may wish to apply any medications, topical products, and/or other adjunct therapy to the treatment area, and then cover the area with a wound dressing. The patient may continue to apply any medications, topical products, and/or other adjunct therapies as well as the dressing, as needed, post treatment under the order of the physician.

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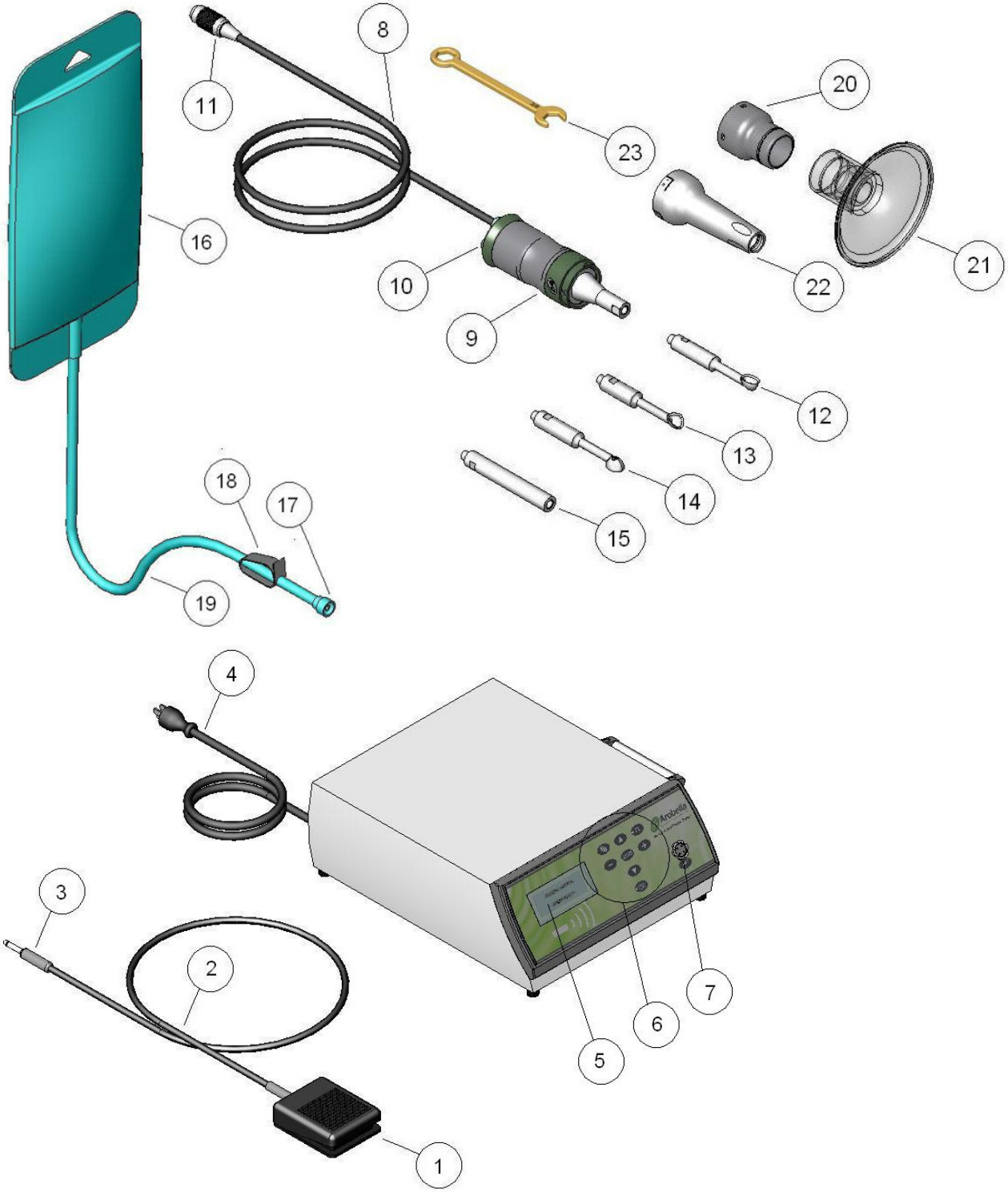
SECTION 5 – PREPARING THE SYSTEM FOR USE

5.1 SYSTEM DESCRIPTION

5.1.1 Figure 1 – System Components



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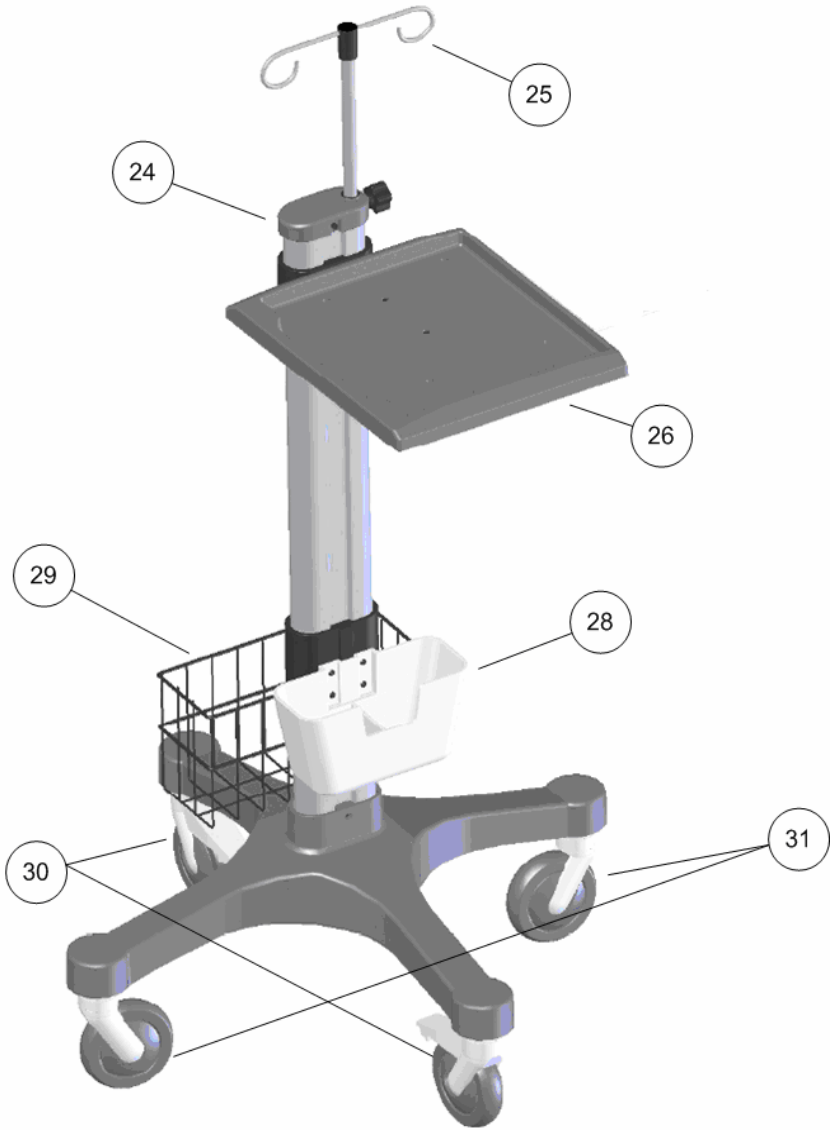
Legend - Figure 1

1. Foot Pedal Switch
2. Foot Pedal Cable
3. Foot Pedal Connector
4. AC Power Cable
5. Generator Display
6. Generator Keypad Controls
7. Generator Connector For Hand Piece
8. Hand Piece Cable
9. Qoustic Qurette™Hand Piece
10. Hand Piece Inlet Tube
11. Hand Piece Connector
12. Qoustic Qurette™, 10mm, Full (Type 1)
13. Qoustic Qurette™, 10mm, 50° Angle (Type 2)
14. Qoustic Qurette™, 10mm, 4mm Open (Type 3)
15. Extender, Qoustic Qurette™
16. Saline Reservoir (supplied by the user)
17. Saline Outlet Tubing Connector (supplied by the user)
18. Saline Outlet Tubing Valve (supplied by the user)
19. Saline Outlet Tubing (supplied by the user)
20. Qoustic Qurette™ Shroud (Type SWD - use with disposable)
21. Disposable Shield (For use with Type SWD Shroud)
22. Qoustic Qurette™ Shroud (Type SND - no disposable)
23. Wrench

5.1.2 Figure 2 – Cart and Components



Legend - Figure 2

24. System Cart
25. Height-Adjustable Dual Saline Bag Holder
26. Generator Shelf
27. <not used>
28. Front Storage Basket (height adjustable)
29. Rear Storage Wire Basket (height adjustable)
30. Swivel Casters With Brakes
31. Swivel Casters Without Brakes

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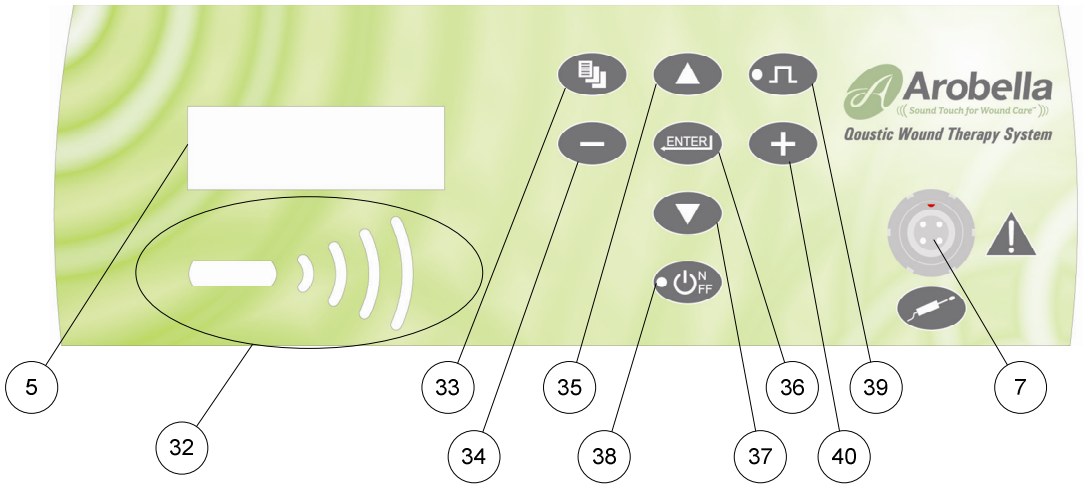
5.1.3 Figure 3 – Front Panel

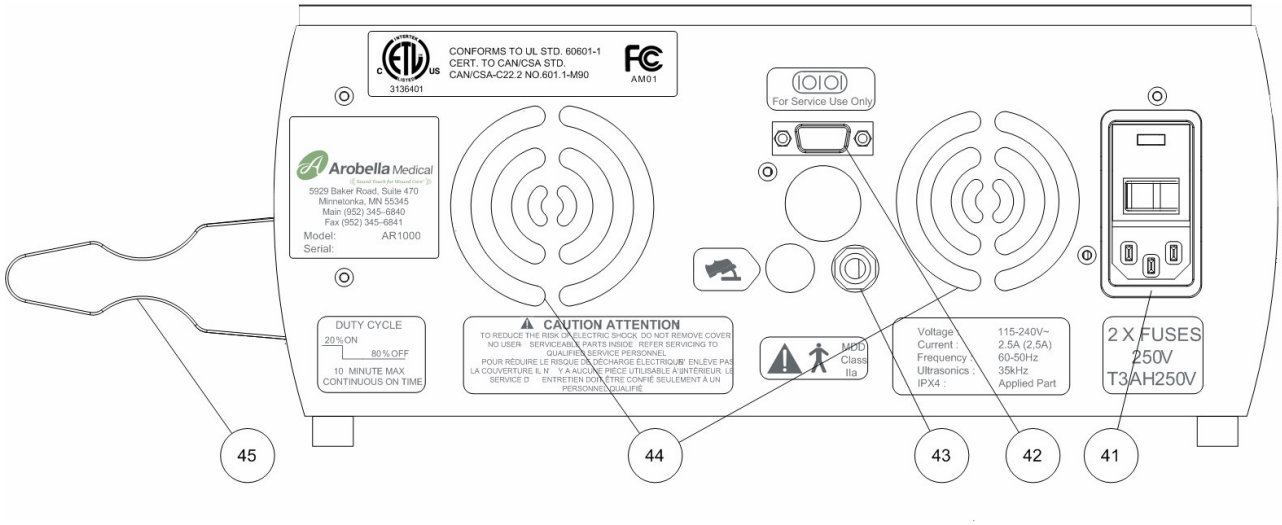


Legend - Figure 3

32. Active Hand Piece Indicator
33. Menu (configuration, versions, & other options)
34. Decrease Parameter
35. Scroll Up
36. Enter (i.e. confirm or accept)
37. Scroll Down
38. Activate Hand Piece (with active indicator)
39. Pulsed Mode Operation (with active indicator)
40. Increase Parameter

Generator Display (5) and Generator Connector For Hand Piece (7) shown for reference purposes.

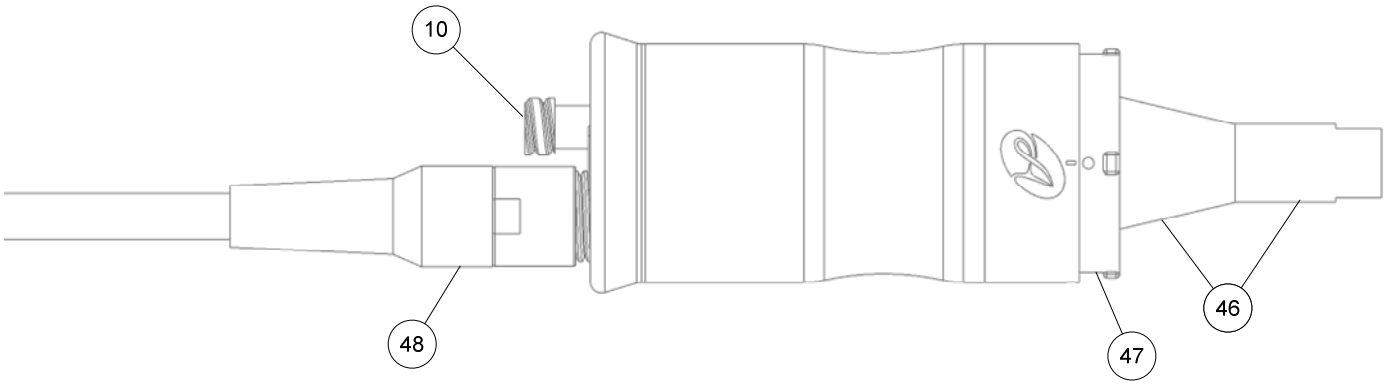
5.1.4 Figure 4 – Rear Panel



Legend - Figure 4

41. Power Switch / Connector For AC Power Cable / Fuses
42. Communication Port (for service use only)
43. Foot Pedal Port - Activate Hand Piece
44. Cooling Fan Exhausts (do not block during use)
45. Generator Handle / Hand Piece Cradle

Figure 5 – Qoustic Qurette™ Hand Piece



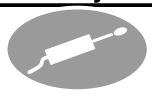
Legend - Figure 5

46. "Active" Parts of Qoustic Qurette™ Hand Piece
47. Qoustic Qurette™ Shroud Connection
48. Qoustic Qurette™ Hand Piece Strain Relief

Hand Piece Inlet Tube (10) shown for reference purposes.

5.1.5 Symbol Summary

The following table summarizes the function and location of symbols on the device.

Label/Symbol	Reference No.	Description/Function	Location on Device
	7	Generator Connector For Hand Piece	Front panel of generator
	39	Pulsed Mode - press to activate/deactivate	Front panel of generator
	33	Menu - press to open/exit main menu; cancel power adjustment	Front panel of generator
	35,37	Scroll - press to navigate menus	Front panel of generator
	34,40	Press to increase/decrease power percentage setting	Front panel of generator
	36	Enter - press to confirm/accept commands or power setting	Front panel of generator
	38	Activate Hand Piece - press to activate/deactivate hand piece	Front panel of generator
	43	Foot Pedal Port	Rear of generator
	42	Communication Port - service use only	Rear of generator

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5.2 PREPARING THE SYSTEM FOR USE

1. Plug one end of the AC Power Cable (4) into Connector For AC Power Cable (41) on the back of the generator, and plug the other end the AC Power Cable (4) into a standard, grounded electrical outlet (115-240V~ (VAC) / 50-60Hz).
2. Plug Connector (3) of the foot pedal into Connector (43) on the back of the generator. Place Foot Pedal Switch (1) in an appropriate location for ease-of-use and comfort of the user for accomplishing the treatment.
3. Steam sterilize each Qoustic Qurette™ & Extender (12, 13, 14, & 15) and Qoustic Qurette™ Shrouds (20 or 22) prior to each use. Please refer to sterilization instructions and/or recommendation in SECTION 7 - SERVICE AND CARE OF THE SYSTEM.
4. Wipe down the entire Hand Piece (9), Hand Piece Cable (8), and both Wrenches (23) with an FDA-approved liquid sterilant wetted cloth prior to each use. Please refer to sterilization instructions and/or recommendation in SECTION 7 - SERVICE AND CARE OF THE SYSTEM.
5. Connect Hand Piece Connector (11) to Connector For Hand Piece (7) on the generator.
6. Use sterile gloves when handling the sterile Qoustic Qurette™ (12, 13, or 14), the Extender (15), or the Shroud (20 or 22) to prevent contamination.
7. Connect Qoustic Qurette™ (12, 13, or 14) to either the Hand Piece (9) or the Extender (15) using both Wrenches (23) on the associated wrench notches; connect the Extender (15), if used, to the Hand Piece (9) using both Wrenches (23) on the associated wrench notches. **Firmly tighten to ensure proper operation.**

CAUTION: Do not use wrenches other than those supplied with the system. Using other wrenches may lead to excessive torque and wear that may damage the system.

8. Mount the appropriate Shroud (20 or 22) as shown in Figure 6, depending on the intended application. Make sure to lock the Shroud by aligning the line on the Qoustic Qurette™ Hand Piece (9) with the dot on the Shroud by turning and “snapping” it into place. If user selects Shroud Type SWD (20), remove Shield (21) from its packaging and mount in place as in Figure 7.

Figure 6 – Shroud Installation

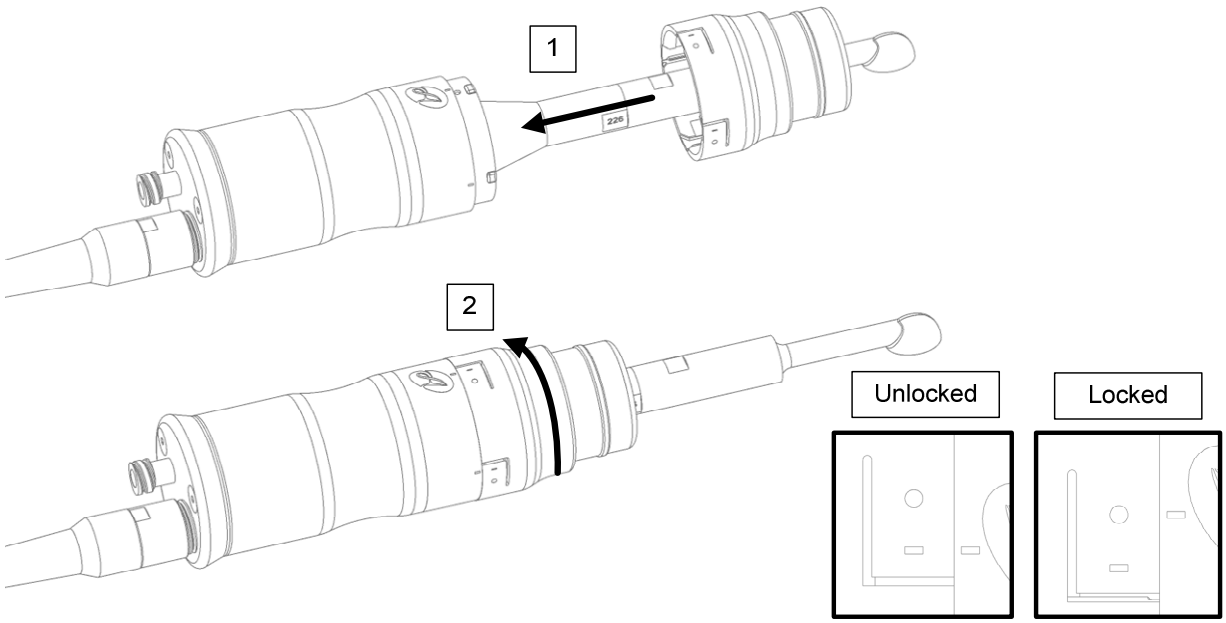

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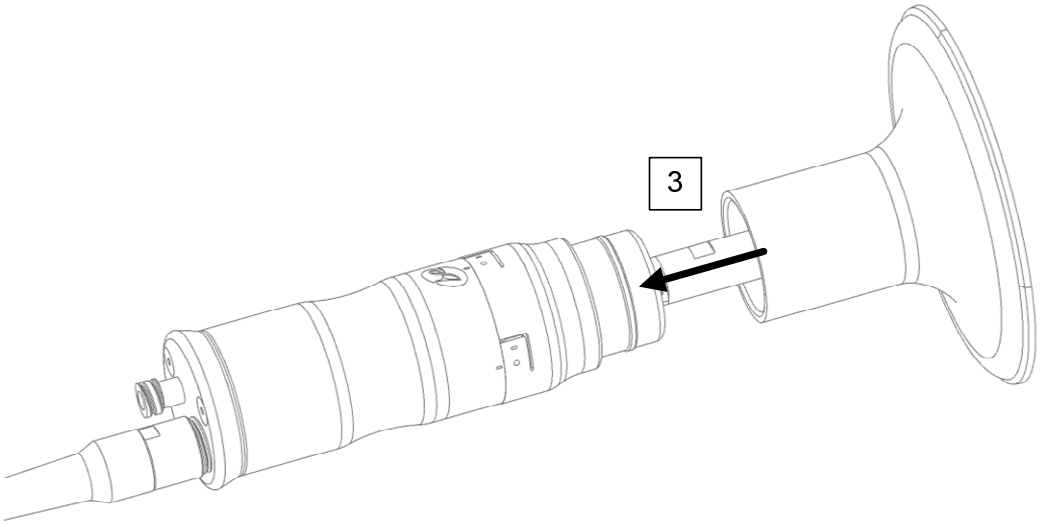
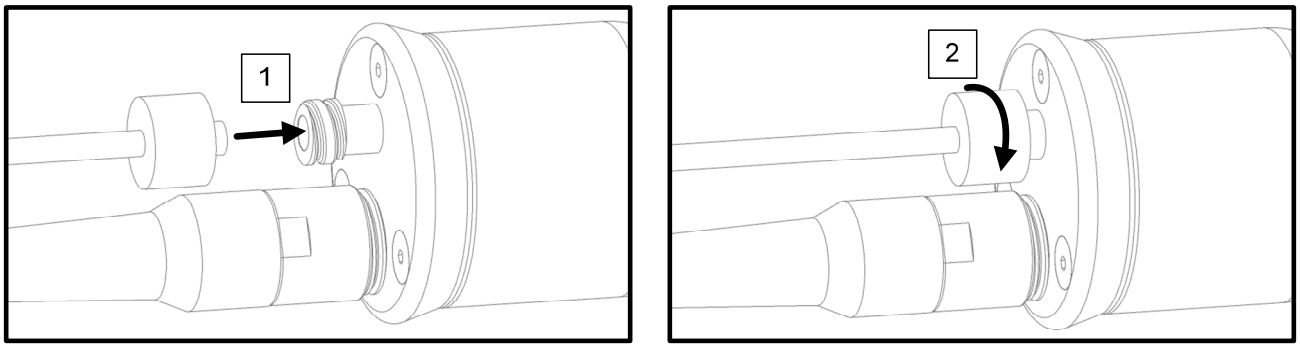
Figure 7 – Shield Installation (if applicable)



CAUTION: Do not activate or operate Hand Piece (9) without a Shroud (20 or 22) in place and in "Locked" position. Operating without a Shroud or operating with a Shroud in the "Unlocked" position may lead to burns or other injuries to the user.

9. Visually inspect the saline reservoir for any defects that may affect its performance and/or sterility. Discard if damaged and replace. Only use sterile, room temperature or cooler saline with the system. Use caution when inserting the cannula to prevent operator injury and/or damage of the saline reservoir.
10. Ensure that saline outlet tubing valve (18) is closed (i.e. no flow thru tubing from reservoir). Connect the saline reservoir Outlet Tubing Connector (17) to the Inlet Tube (10) located on the back of the hand piece as in Figure 8. Verify the connection is secure to avoid leaks.

Figure 8 – Saline Reservoir Connection



11. Turn on power to the system via the generator Power Switch (41) located on back of the generator.

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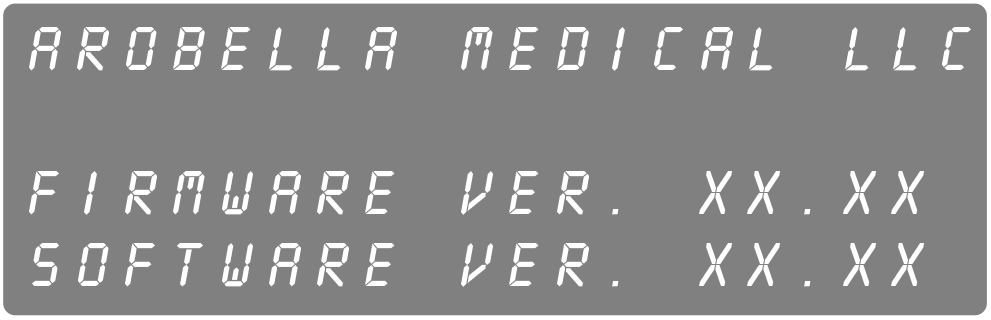
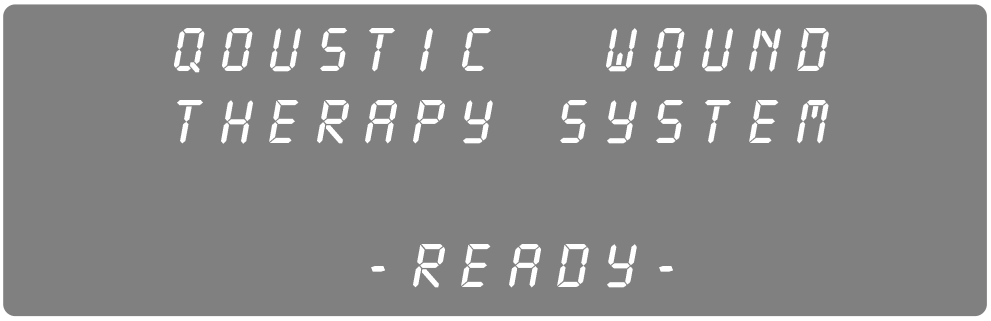
Verify power up; the Generator Display (5) should briefly read each screen as follows:



Followed by:



12. Depress either of the generator power adjustment controls, + or − (40 or 34), and the Generator Display (5) may read as follows:

13. Set the power level by depressing the power adjustment controls, + or − (40 or 34), to increase or decrease in 5% intervals to the recommended value (Power Level 50%) as shown:

14. Depress ENTER (36) to accept. The Display (5) should read:

15. The system is now ready to be used for treating patient's wound(s). Alternately, the system can be set to operate in preset pulsed mode by depressing PULSE (39).

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SECTION 6 – TREATING THE PATIENT

Please refer to Figure 3 in SECTION 5 – PREPARING THE SYSTEM FOR USE for reference in the functions of the Keypad Controls (6) of the generator.

CAUTION: Users are strongly advised to wear Personal Protective Equipment (PPE) including sterile gloves while treating patients.

6.1 HAND PIECE ACTIVATION AND DUTY CYCLE

1. With the generator power adjustment control set to its recommended value (50%), depress and release ACTIVATE (38) or Foot Pedal Switch (1) to produce ultrasonic energy at the Hand Piece (9). The Active Hand Piece Indicator (32) will light as in Figure 9 and the Generator Display (5) will indicate proper operation as follows:

Figure 9 – Active Hand Piece Indicator (32) Light Sequence

2. Both the treatment time and total time will increase in 1 second intervals until Hand Piece (9) ultrasonic activation has stopped by:
   a. Depressing and releasing the ACTIVATE (38) or Foot Pedal Switch (1).
   b. Reaching the maximum duty cycle time limit (total time of 10 minutes per 50 minutes).

   Each Qoustic Qurette™ Hand Piece (9) has a duty cycle of 20% ON and 80% OFF with a maximum continuous run time of 10 minutes. The generator will keep track of the active time versus the inactive time of the Hand Piece and not allow the system to run over the duty cycle.

   If additional treatment is required, power down the generator, replace the current Hand Piece (9) with another Hand Piece (9), and power up the generator.

CAUTION: Please record any incurred treatment times prior to powering down the generator and/or switching to another Hand Piece (9).

CAUTION: Do not run each Hand Piece (9) over the designed duty cycle of 20% ON – 80% OFF over a period of 50 minutes. Running over the 20% ON duty cycle may lead to excessive heating, leading to possible injury of the patient and/or user and system malfunction.

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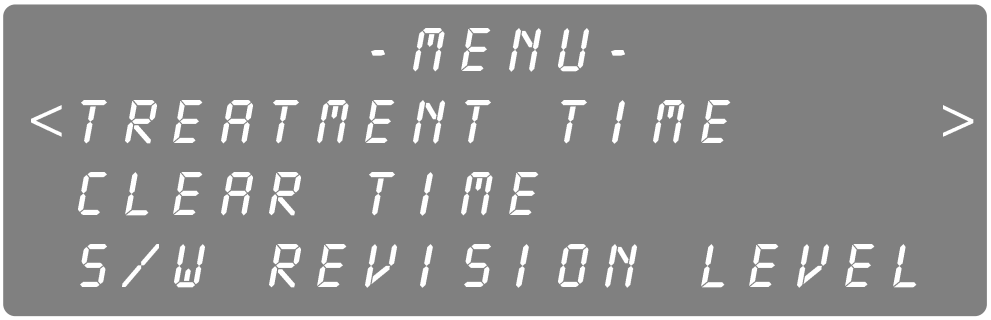
When deactivated, the Active Hand Piece Indicator (32) will turn off and the Generator Display (5) will indicate:

6.2 TREATMENT TIMER USE

1. Depress and release ACTIVATE (38) or Foot Pedal Switch (1) to start producing ultrasonic energy again at the Hand Piece (9). Again, the Active Hand Piece Indicator (32) will light and the Generator Display (5) will indicate proper operation as follows:

Note: Both the treatment time and total time will increase in 1 second intervals (but the total time will be incrementing, in absolute terms, from the end of the previous treatment cycle) until Hand Piece (9) ultrasonic activation has stopped. The number of treatments, up to five, will be displayed next to “TREAT.TIME”.

2. Depress ACTIVATE (38) or Foot Pedal Switch (1) to deactivate the Hand Piece (9). Depress MENU (33), and the display should read as follows:



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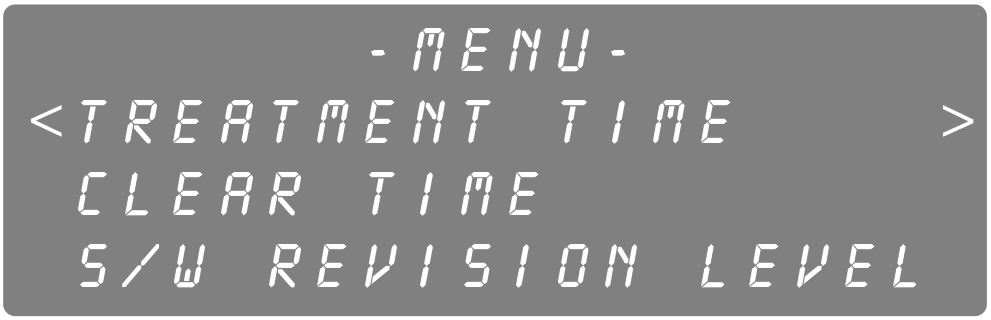
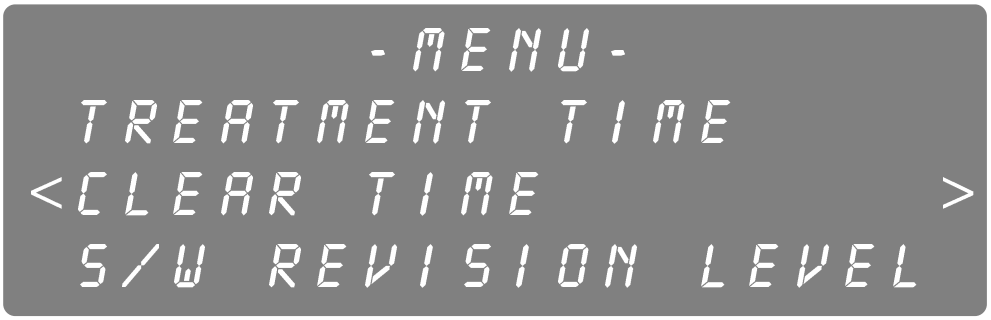
SCROLL UP (35)or SCROLL DOWN (37) to select “Treatment Time” and depress ENTER (36) to display treatment times accomplished on the patient, as shown in the example below:

Note: Only the last five treatment times are shown though the total time will reflect the sum of all the treatment times delivered.

3. Depress MENU (33) until the display reads as follows:



SCROLL UP (35) or SCROLL DOWN (37) to select “Clear Time”, as shown in the example below:



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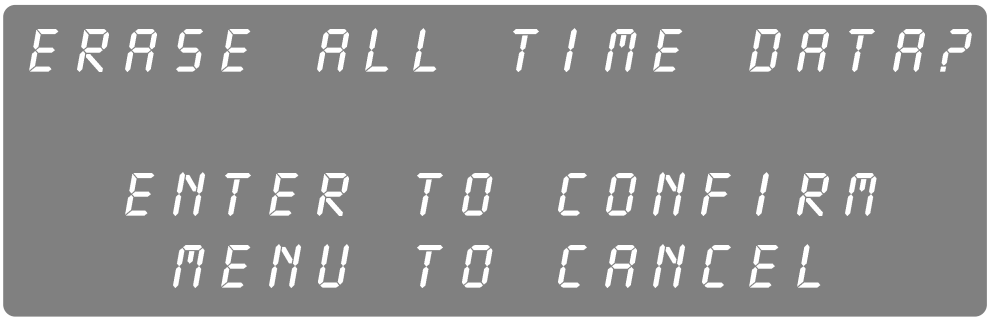
Depress ENTER (36), and the display should read as follows:



To erase all time data, press ENTER (36) to confirm. To cancel erasure of all time data, press MENU (33) to cancel.

4. Depress either of the generator power adjustment controls, + or − (40 or 34), to adjust Hand Piece (9) output power from 10% to the maximum of 100%. Depress ENTER (36) to confirm all changes in power level.

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6.3 TREATMENT TECHNIQUES

1. With the Hand Piece (9) active in the desired power level, initiate saline flow by opening Saline Outlet Tubing Valve (18). The Qoustic Qurette™ will begin to stream saline as it flows through to the orifice.
2. Treat the area as follows: With Hand Piece (9) active and saline flowing, apply the edge of any Qoustic Qurette™ (12, 13, or 14) to the edge of the wound or tissue area and translate into area being treated with or without a rolling scoop motion (as illustrated in Figures 10 & 11 below).

Figure 10 – Using Edge of Qoustic Qurette™ to Treat Wound/Tissue

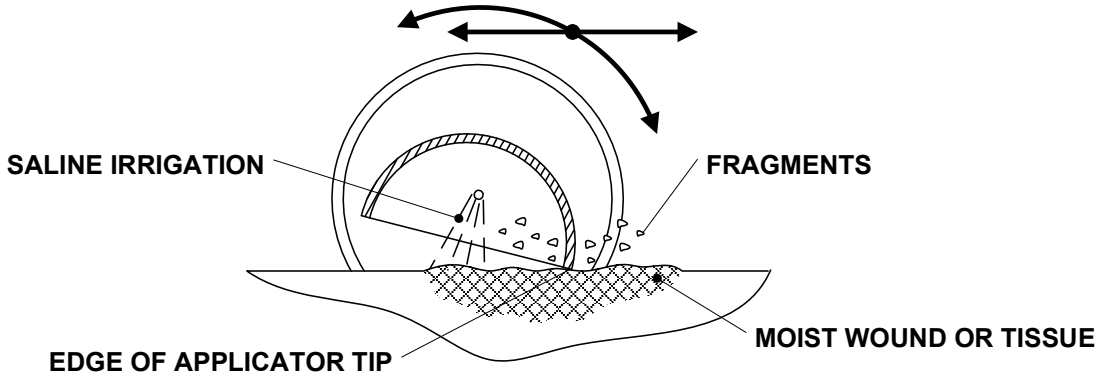
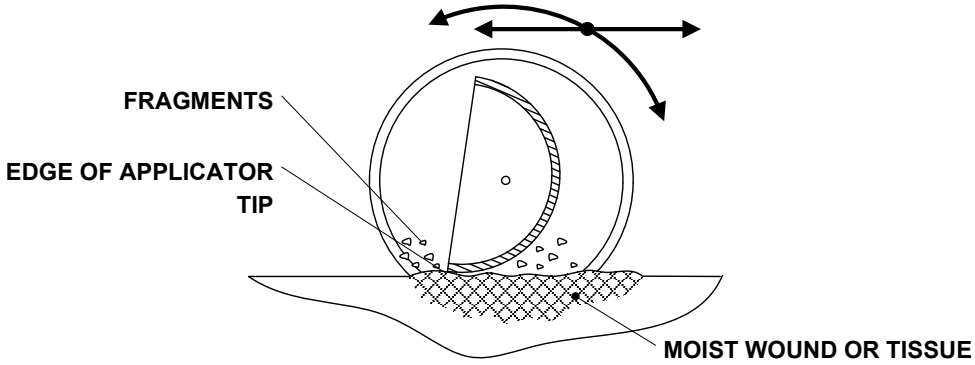


Figure 11 – Rotating Qoustic Qurette™ in Scooping Motion



Note: The back and sides of any Qoustic Qurette™ (12, 13, or 14) may be applied to wound or tissue so as to ultrasonically stimulate the area, as shown below in Figure 12. Cavitation of the wound can also be achieved by facing the open end of the Qoustic Qurette™ toward the wound with light contact, as in Figure 13.

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Figure 12 – Ultrasonic Stimulation of the Wound/Tissue

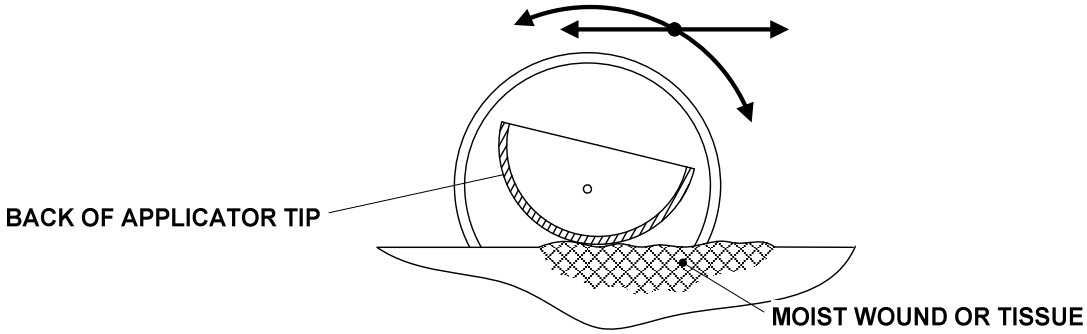
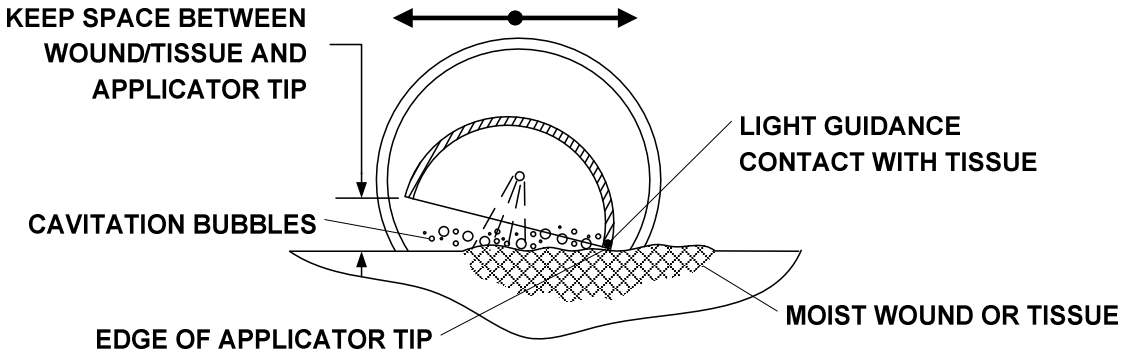


Figure 13 - Cavitation of the Wound/Tissue



Please keep these considerations in mind when applying the treatments indicated:

a. Vary the pressure and holding time according to the size and severity of wound or tissue area and treatment method being used (i.e. debridement versus volume removal).
b. Small areas should only require a very small amount of pressure to treat. Larger areas can be treated by applying the tip to the treatment area and moving around the entire area.
c. Areas that require removal of deeper tissue will require more pressure.
d. Only use as much pressure as needed for the wound or tissue area being treated.
e. Discontinue use if no saline is flowing (i.e. reservoir is empty, valve is closed, tubing is clogged, etc).

3. Repeat treatment as necessary to treat other wounds or tissues.

4. When treatment is done, cease saline flow by closing Saline Outlet Tubing Valve (18). Using the reverse operation from Figure 8 disconnect Saline Outlet Tubing Connector (17) from Hand Piece Inlet Tube (10). As applicable, dispose of Saline Reservoir (16), Saline Outlet Tubing (19), and Tubing Valve (18) according to local regulations regarding biohazard waste.

5. To switch between each Qoustic Qurette™ (12, 13, or 14), first confirm that the Hand Piece (9) is not activated, and if it is active, depress and release the ACTIVATE (38) or Foot Pedal Switch (1) to cease Hand Piece activation. Remove the Shroud/Shield (20/21 or 22) and use both Wrenches (23) to loosen, remove, replace, and tighten the alternate Qoustic Qurette™ (12, 13, or 14). Install Shroud/Shield (20/21 or 22) again and continue treatment by depressing and releasing the ACTIVATE (38) or Foot Pedal Switch (1).

6. Cease treatment by depressing and releasing the ACTIVATE (38) or Foot Pedal Switch (1). If appropriate, record treatment times prior to clearing time data or powering down the generator in preparation for next patient.

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SECTION 7 – SERVICE AND CARE OF THE SYSTEM

7.1 SERVICE & PREVENTIVE MAINTENANCE

There are no user-serviceable components within the system. Prior to first use each day, a thorough preventive maintenance inspection of the system is suggested. User-required preventive maintenance of the system includes:

1. Ensure all cabling is in good condition (i.e. not frayed, kinked, or damaged in any other way).
2. Ensure Hand Piece (9) and generator are intact and in good condition (i.e. not cracked, loose, or damaged in any other way).
3. All connectors (plugs and receptacles) on Hand Piece (9), Generator, Foot Pedal (1), and Power Cables (4, 2, & 8) are in good condition.
4. Ensure each Qoustic Qurette™ (12, 13, & 14) and Extender (15) are intact and in good condition (i.e. not cracked, chipped, discolored, or damaged in any other way). Discontinue use of any Qoustic Qurette™ (12, 13, or 14) and/or Extender (15) that is cracked, chipped, discolored, or damaged in any other way.
5. The system has dual fuses on the AC input, and if it fails to power up, one or more of the fuse may have blown. Check fuses just above AC Power Cable Connector (41) and, if blown, replace with type T3AH250V fuse(s).

CAUTION: If any or all of the above cases are true, please call for service immediately! Do not proceed to use the system!

7.2 CLEANING & STERILIZATION

Clean the system thoroughly prior to and after each treatment session either per the procedural steps that follow or in compliance with the approved infection control procedures of the end user site or facility for reprocessing the system. For guidance, please refer to ANSI/AAMI ST35:2003, “Safe handling and biological decontamination of medical devices in health care facilities and in non-clinical settings” (formerly designated as ANSI/AAMI TIR 10). Be sure to first verify power is off via the Power Switch (41) located on the rear of the generator. Use and/or continue to wear Personal Protective Equipment (PPE) during the cleaning process.

1. Disengage the Saline Output Tubing Connector (17) from Inlet Tube (10) of the Hand Piece (9) using the reverse operation of Figure 8 in SECTION 5 - PREPARING THE SYSTEM FOR USE. Dispose of Saline Outlet Tubing (19) and Tubing Valve (18) according to local regulations regarding biohazard waste.
2. If empty, dispose of the spent Saline Reservoir (16) according to local regulations regarding biohazard waste and replace with a new sterile Saline Reservoir (16) to continue treatment.
3. Remove Shroud/Shield (20/21 or 22) from the Hand Piece (9) and if used, dispose of the Disposable Shield (21) according to local regulations regarding biohazard waste.

WARNING: The Disposable Shield (21) is designated for single-patient / single-treatment use only. Do not reuse as there is potential risk of contamination. Dispose according to local regulations regarding biohazard waste.

4. Disconnect Qoustic Qurette™ (12, 13, or 14) and/or Extender (15) from the Hand Piece (9), using both Wrenches (23) provided, along the wrench notches of each, respectively.
5. Brush clean with an appropriate FDA-approved enzymatic cleaning agent to remove soil from the entire Hand Piece (9), Hand Piece Cable (8), Hand Piece Connector (11), both Wrenches (23), and the entire generator front panel and any other user accessed areas. Do a thorough cleaning, including any visible cracks/crevices and edges. (Some examples of enzymatic cleaners include Resinase A2X, Paradigm, Pandion, Spezyme GA300, or equivalent.)

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6. Dampen a clean cloth with an appropriate FDA-approved liquid sterilant used in the medical setting to achieve high level disinfection. Wipe down the entire Hand Piece (9), Hand Piece Cable (8), Hand Piece Connector (11), and both Wrenches (23). Make sure to have the Shroud (20 or 22) off of the Hand Piece (9) to wipe surfaces underneath. Thoroughly wipe all visible surfaces, including cracks/crevices and edges. Wipe down the entire generator front panel and any other user accessed areas, also thoroughly wiping all visible surfaces, including cracks/crevices and edges. Allow to air dry. (Some examples of liquid sterilant include Cidex OPA or equivalent.)
7. Fill the inner lumen with an appropriate FDA-approved liquid sterilant agent used in the medical setting via Inlet Tube (10) with a luer syringe and allow the sterilant to dwell for the duration recommended by the sterilant manufacture. Afterwards, drain and then flush with a 0.9% sterile saline rinse. Allow to air dry and cap the Inlet Tube (10) of the Hand Piece (9) between uses. (Some examples of liquid sterilant include Cidex OPA or equivalent.)

CAUTION: Do not sterilize the hand piece in any way other than as recommended in Section 7.2. Performing any other sterilization methods (e.g. autoclave, ETO, etc.) will damage the hand piece and void all warranties on the device. **DO NOT AUTOCLAVE THE HAND PIECE.**

8. Sterilize each used Qoustic Qurette™ (12, 13, or 14), the used Extender (15), the used Shroud (20 or 22) using a steam sterilizer. This should be performed in a manner that achieves an SAL (Sterility Assurance Level) of 10^{-6} when the components are either properly packaged in a steam sterilization pouch for a wrapped sterilization cycle or placed unpackaged for an unwrapped sterilization cycle. In either case, a steam sterilization verification/indication strip is required.

   The following table is summarized in part from the standard, ANSI/AAMI ST79:2006, for convenience of the user. For more detailed information, however, please refer to the above standard or to the steam sterilizer manufacturer's model specific recommendations.

Item	Gravity-Displacement		Dynamic-Air-Removal (Pre-Vac)	
	Exposure time at 132℃ (270℉)	Drying times	Exposure time at 132℃ (270℉)	Drying times
Wrapped instruments	15 minutes	15~30 minutes	4 minutes	20~30 minutes
Unwrapped instruments	3 minutes	0~1 minutes	3 minutes	N/A

Note: This table represents the variation in sterilizer manufacturer's recommendations for exposure at a particular temperature. For a specific sterilizer, consult only that manufacturer's recommendations.

PRECAUTION: The steam sterilizer must be monitored in a regulated validation and calibration program to assure proper functioning.

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SECTION 8 – TROUBLESHOOTING THE SYSTEM

8.1 GENERAL SYSTEM TROUBLESHOOTING

System Issue	Trouble Shooting Steps
System will not power up	Check to ensure AC power cable is properly connected. AC input fuse(s) may be blown. Check fuses just above AC Power Cable Connector (41) and if blown, replace with type T3AH250V fuse(s).
Hand piece whines when activated.	Verify Qoustic Qurette™ (12, 13, or 14) and/or Extender (15) is/are all properly connected. Tighten with both Wrenches (23) as needed. Verify Hand Piece Connector (11) is properly connected to the Connector (7) on the generator. If the Hand Piece (9) has been operating near the limits of the defined duty cycle, allow system to rest for a period of 40 minutes before proceeding to the next procedure or power down the generator to switch to another Hand Piece (9), if available.
Hand piece does not “Activate” when the Activate Hand Piece (38) button is pressed.	Verify that the active indicator light on the Activate Hand Piece (38) button is on. If it is not lit, press button again to activate making sure to fully depress the button. Verify the “wave” lights of the Active Hand Piece Indicator (32) are sequentially lighting up as in Figure 9. If only the horizontal bar is lit, the Hand Piece is active but cannot lock onto a frequency. Press the Activate Hand Piece (38) button to turn off. Disconnect and reconnect the Hand Piece Connector (11) to ensure proper connection and press Activate Hand Piece (38) button to activate. If the “wave” lights of the Active Hand Piece Indicator (32) are sequentially lighting up then the Hand Piece should be active and functioning correctly. If the Hand Piece (9) has been operating up to the limits of the defined duty cycle, the system may have shutdown and counting down thru a rest period of 40 minutes before proceeding to the next procedure. If further treatment is required, power down the generator and switch to another Hand Piece (9), if available.

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8.2 ERROR CODES

Error Code	System Message	Clearing The Error	Description Of Error
01	<!WARNING!> SYSTEM OVER TEMP PLEASE WAIT SEE MANUAL ERROR #01	Temperature Cooling	This error indicates that the generator internal temperature has increased above the upper limit set by the factory (approx. 75°C). To prevent generator damage, the system will cease operation until the generator reaches a safe temperature. If this error occurs more than once or does not clear after the system cools down, call for service.
02	<!WARNING!> TIME LIMIT REACHED PLEASE WAIT MM:SS SEE MANUAL ERROR #02	Wait for Timer Count Down on Display	This error indicates that the time limit for continual operation has been reached. This limit is set to 10 minutes of ON time for every 40 minutes of OFF time over a 50 minute period. The generator locks all functions out during this period and will return to the inactive screen after 40 minutes has elapsed. The PLEASE WAIT counts down the remaining time until the system is operational. If this error occurs under the 10 minutes of ON time for every 40 minutes of OFF time, call for service. If further treatment is required, power down the generator and switch to another Hand Piece (9), if available.
03	<!WARNING!> OUT OF FREQUENCY CHECK CONNECTIONS SEE MANUAL ERROR #03	Check Connections & Verify Qoustic Qurette™ / Extender is Tight; Depress ENTER (36)	This error indicates that the generator could not maintain the frequency lock required for resonance. The frequency stayed within the limits set in the system, but a frequency lock could not be attained. The CHECK CONNECTIONS line flashes. If error occurs 2 or more times sequentially and connections are correct and in good condition, the system may be out of calibration. Call for service. If further treatment is required, power down the generator and switch to another Hand Piece (9), if available.

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04	<!WARNING!> OUT OF FREQUENCY CHECK CONNECTIONS SEE MANUAL ERROR #04	Check Connections & Verify Qoustic Qurette™ / Extender is Tight; Depress ENTER (36)	This error indicates that the generator could not maintain the frequency lock required for resonance. The frequency was forced to sweep thru the limits set in the system for several cycles in an attempt to force a frequency lock until the maximum number of cycles was reached. The CHECK CONNECTIONS line flashes. If error occurs 2 or more times sequentially and connections are correct and in good condition, the system may be out of calibration. Call for service. If further treatment is required, power down the generator and switch to another Hand Piece (9), if available.
05	<!WARNING!> TEMP. SENSOR ERROR SEE MANUAL ERROR #05	Displays Message Then Clears Automatically	This error indicates that either the temperature sensor circuit has failed in an open condition or that the circuit is operating above 95°C. The fan will run continually to avoid overheating. Call for service immediately. This error will only appear during power-up; it will stay on the screen for 5 seconds after the splash screen and sound the alarm if the error is detected
06	<!WARNING!> TEMP. SENSOR ERROR SEE MANUAL ERROR #06	Displays Message Then Clears Automatically	This error indicates that either the temperature sensor circuit has failed in a short condition or that the circuit is operating below 5°C. The fan will run continuously. Call for service immediately. This error will only appear during power-up; it will stay on the screen for 5 seconds after the splash screen and sound the alarm if the error is detected
07-09	RESERVED	---	RESERVED

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10	<!WARNING!> SOFTWARE ERROR SYSTEM RESETTING SEE MANUAL ERROR #10	Displayed for 5 Seconds, Returns to Stand-by Mode	This error indicates that the software timed out and will be restarted automatically. Wait for system to restart and proceed as normal. If error occurs more than 2 times sequentially, call for service immediately.

If problem(s) persist after performing troubleshooting, please call for service through Arobella Medical (see contact information in SECTION 9 - MANUFACTURER AND TECHICAL SERVICE INFORMATION).

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SECTION 9 – MANUFACTURER AND TECHICAL SERVICE INFORMATION

The Qoustic Wound Therapy System™ and its accessories are manufactured by:
Arobella Medical, LLC
5929 Baker Road, Suite 470
Minnetonka, MN 55345

Final certification of the unit is also accomplished at Arobella Medical, LLC.

For service or replacement parts for the Qoustic Wound Therapy System™, please contact Arobella Medical, LLC at (952) 345-6840 or 1-866-WOUNDS-Ø (1-866-968-6370).

For technical questions and support for the Qoustic Wound Therapy System™, please contact Arobella Medical, LLC at (952) 345-6840 or 1-866-WOUNDS-Ø (1-866-968-6370).

SECTION 10 – SYSTEM SPECIFICATIONS

Generator Power Source:	115-240V~ (VAC), 2.5A, 50/60Hz
Power Output To Hand Piece:	<140 Watts
Fuses:	2 x 250V / 3A (T3AH250V)
Electrical Safety:	Class I
Amplitude:	0µm~75µm
Frequency:	35kHz (±3kHz)
Duty Cycle:	20% ON – 80% OFF, 10 min. max continuous on time
Storage/Transport Temperature:	-20 to 50℃ at a maximum relative humidity of 90% (non-condensing)
Operating Temperature:	0 to 40℃ at a maximum relative humidity of 90% (non-condensing)

Unit must be allowed to stabilize within specified operating temperature for a minimum of 24 hours prior to use.

END OF DOCUMENT

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