sonastar®

Instructions For Use

Models with serial #'s that begin with FHF
SYSTEM-M300
SYSTEM-M360
SYSTEM-M380

MISONIX®
BETTER MATTERS™

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1. General Safety Statements

WARNING 1.1 The SonaStar system is an electro-mechanical device, which under certain circumstances, could present an electrical shock hazard to the operator and/or patient. Please read manual thoroughly and follow directions stated herein to ensure maximum safety during operation. This manual shall be kept in close proximity to the system for easy referral when needed.

WARNING 1.2 The SonaStar system is intended to be used in various types of invasive, surgical procedures. There may be indirect danger to the patient should the device fail during the procedure. It is recommended that the facility follows its back-up equipment protocols.

CAUTION 1.1 Federal law restricts this device to be sold only to or on the order of a licensed healthcare practitioner.

1.1. Summary of Safety Notices: Warnings, Cautions and Notes

Please read this section of the manual carefully. It contains a summary of all precaution, warning and caution statements contained in the manual. However, the user is advised to read the entire manual and operate the device only in accordance with all of the instructions contained herein.

Servicing of this device should only be performed by qualified technicians authorized by Misonix, LLC. There are no service controls accessible to the user.

Conventions on Warnings, Cautions and Notes	
WARNING	Denotes potentially dangerous situation that could result in death or serious injury to patient, operator or staff.
CAUTION	Denotes potentially dangerous situation that could result in moderate injury to patient, operator or staff.
NOTE	Indicates potential hazard that may result in product damage.

Table 1.1 Conventions on warnings, cautions and notes

List of Warnings

WARNING 1.1 The SonaStar system is an electro-mechanical device, which under certain circumstances, could present an electrical shock hazard to the operator and/or patient. Please read manual thoroughly and follow directions stated herein to ensure maximum safety during operation. This manual shall be kept in close proximity to the system for easy referral when needed.

WARNING 1.2 The SonaStar system is intended to be used in various types of invasive, surgical procedures. There may be indirect danger to the patient should the device fail during the procedure. It is recommended that the facility follows its back-up equipment protocols.

WARNING 1.3 The SonaStar system generates high voltages within the console itself and the connected handpiece. To avoid injury, the console should never be operated before ensuring that its cover is properly closed and not tampered with. Do not attempt to remove or disassemble the cover. There are no user-serviceable parts inside the console. All service should only be performed by an authorized Misonix representative. No modification of this equipment is required.

WARNING 1.4 Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cord to remove it from the receptacle.

WARNING 1.5 Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch on the console rear panel is set to the local voltage setting and ensure that the correct fuses are being used. Refer to Section 12.1 on instructions for fuse replacement.

WARNING 1.6 Explosion Hazard: Never use the SonaStar system in the presence of a flammable or explosive atmosphere, such as flammable anesthetics.

WARNING 1.7 The Sonastar system, including all accessories and components, is MR unsafe. It must not brought into the MR environment.

WARNING 6.1 Use only sterilization cycles specified in this user manual. Do not use any other sterilization cycles. Improper sterilization can lead to handpiece or accessory damage, patient injury, or death.

WARNING 6.2 Improper connection of the handpiece cable may present a shock hazard. Confirm that handpiece connector is dry prior to plugging it in.

WARNING 6.3 During system check, make sure the tip of the handpiece is free from contact with any object. Allowing contact with the tip may result in damage and/or personal injury.

WARNING 6.4 Inadvertent or improper foot pedal depression can cause possible injury to the patient, surgeon, or operating room staff, and can cause product damage. Place foot pedal where it is highly visible and labels can be clearly seen.

WARNING 6.5 Do not lay the handpiece on the patient when not in use. When not in use, keep the handpiece on a dry, non-conductive surface with the tip free from contact with any objects.

WARNING 6.6 Make sure that the handpiece is properly positioned at the tissue site before the footswitch is depressed. Once the Preset or Linear key has been chosen, any inadvertent activation of the footswitch will initiate vibration. DO NOT TOUCH tip while activated.

WARNING 6.7 Never activate Vibration or electrosurgery while using the cleaning stylet. Tip damage and operator, patient, or staff injury may result.

WARNING 7.1 Improper assembly of Single-Use Monopolar Handpiece Cable to endcap can expose potentially dangerous electrosurgery voltage. Always make sure the Single-Use Monopolar Handpiece Cable socket is firmly and fully engaged onto the pin in the endcap.

WARNING 7.2 Ensure that the aspiration tubing is fully seated onto the Aspiration Port in the base of handpiece.

WARNING 7.3 Remove all housing components, silicone elbow, silicone sleeve and ultrasonic tip from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.

WARNING 8.1 Saline leakage through handpiece housing can cause a hazard when electrosurgery is energized. Always make sure the handpiece housing parts are properly assembled, with mating parts firmly in contact.

WARNING 9.1 Single-use items should be discarded following each surgical procedure according to hospital protocol for disposal of bio contaminated wastes. **Do not attempt to reuse or re-sterilize any single-use items. Dispose of ultrasonic tips in a sharps container.**

WARNING 9.2 All reusable handpiece parts and accessories must be properly cleaned and sterilized before each use as per instructions contained in this manual. Failure to do so may lead to infections, which can ultimately cause patient death.

WARNING 9.3 Misonix LLC has validated all cleaning and sterilization cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the SonaStar System and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilization if they differ from the procedures as outlined in this manual.

WARNING 10.1 If a Mains Power fuse fails after replacement when the unit is reactivated, discontinue use of the device and contact an authorized Misonix representative.

WARNING 10.2 Portable and mobile RF communication equipment (including peripherals such as antennas) should be no closer than 30 cm (12 inches) to any part of the console, including the cables supplied with the console Otherwise degradation of the performance of this equipment could result.

WARNING 10.3 The use of accessories, transducers and cables other than those specified or provided by Misonix may result in increased electromagnetic emissions or decreased immunity of the device and may result in improper operation. Use only Misonix branded equipment and accessories.

WARNING 10.4 Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

List of Cautions

CAUTION 1.1 Federal law restricts this device to be sold only to or on the order of a licensed healthcare practitioner.

CAUTION 1.2 This device is considered medical electrical equipment. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this operator's manual.

CAUTION 3.1 The SonaStar system and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits.

CAUTION 4.1 Never operate the handpiece without proper irrigation. Irreparable damage to the handpiece and probe may result if adequate irrigation is not provided to the probe tip.

CAUTION 6.1 Adequate air circulation is needed to cool electronic components inside of the unit. Do not block the cooling fans located on the lower console rear. Blocking these vents may cause unit to overheat and malfunction or create a shock hazard.

CAUTION 6.2 It is strongly advised that a sterile backup handpiece be readily available in the operating room as insurance against any contamination or malfunction of the handpiece used during surgery.

CAUTION 6.3 All reusable system components like handpiece, torque wrench and torque fixture are supplied **NON-STERILE**. All items intended for use in the sterile field must be cleaned and sterilized as per the indicated instructions before first clinical use and before every subsequent clinical use.

CAUTION 6.4 The "Vacuum" port of the suction canister should contain a positive shut off float. The aspiration pump connection should be made only to the *VACUUM PORT* to prevent overflow contamination.

CAUTION 6.5 All items intended for use in the sterile field must be cleaned and sterilized as per indicated instructions in Chapter 9 before each clinical use.

CAUTION 6.6 The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.

CAUTION 6.7 If COAG is to be performed, the Single-Use Monopolar Handpiece Cable must be introduced in the sterile field, because the cable is supplied sterile, and is NOT AUTOCLAVABLE. DO NOT RE-STERILIZE THE SINGLE-USE MONOPOLAR HANDPIECE CABLE.

CAUTION 6.8 Aspiration tissue release valve and irrigation pump can create pinch points. Keep fingers away from these parts while operating unit. Use caution when assembling components.

CAUTION 6.9 Incorrect routing of irrigation tubing will result in no flow of irrigating solution to the tip; this may cause damage to handpiece.

CAUTION 6.10 The system check should always be done in advance of preparing the patient for surgery to minimize risk to patient in case of system malfunction.

CAUTION 6.11 Simultaneous use of a standard monopolar device with ultrasound can create sparking and possible tip damage.

CAUTION 6.12 Vibrating tip contact with hard objects can cause tip damage.

CAUTION 6.13 If a fault occurs, suspend operation of handpiece and unit. Determine the cause of the problem and its solution by consulting the troubleshooting tables found in section 10 of this manual.

CAUTION 6.14 DO NOT use any electrosurgical device that exceeds a peak electrosurgical output of 3.5KV. Misonix recommends staying within the limits prescribed by the electrosurgical generator's user manual for the type of procedure being performed, up to a maximum power setting of 70 W. Generally, the lowest setting that proves effective for the procedure being performed should be used.

CAUTION 6.15 Use of a separate monopolar instrument at electrosurgery settings greater than 70 W while simultaneously touching the handpiece probe to tissue can induce faults and possible system damage.

CAUTION 6.16: Remove the batteries if the SonaStar is not likely to be used for long period of time

CAUTION 7.1 Be careful not to damage the tip when sliding the torque wrench over the tip. System failure may result from scratches or damage to the tip when vibration is active.

CAUTION 7.2 Use only properly calibrated torque wrench. Send torque wrench to Misonix for calibration every twelve months.

CAUTION 9.1 Use manual cleaning techniques only. Do not use ultrasonic cleaners or automated washers to clean the handpiece as both methods could damage handpiece.

CAUTION 9.2 Be certain to clear debris from all internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving.

CAUTION 9.3 Do not immerse ultrasonic console, handpiece, irrigation pump, remote footswitch, IR receiver or electric cables. These items are not sealed against liquids and damage to equipment will result.

CAUTION 10.1 Improper use or adjustment of this device may invalidate the Misonix, LLC warranty agreement. Contact your authorized Misonix, LLC representative before attempting to troubleshoot this device in any manner other than those specified in this manual. There are no user serviceable parts.

CAUTION 12.1 The only user replaceable fuses are the two fuses located on the bottom rear of the unit and the one located on the top rear of the unit. Replacement fuses must be identical in type, voltage rating and current rating to the original fuse.

CAUTION 12.2 Use only genuine replacement parts from Misonix. Use of parts furnished by other sources may result in patient or operator injury or system malfunction and will void any applicable warranty.

CAUTION 12.3 When returning items, before using loose packing materials, such as foam pellets, shredded paper or similar, be sure to wrap the component(s) separately in plastic bags, film or other protective wrapping.

List of Notes

NOTE 4.1 For proper operation, the console and wireless footswitch must have the same frequency code number. Refer to Section 5.4 for more details.

NOTE 4.2 A second torque wrench is highly recommended to allow system usage during wrench calibration. See section 9.7 for more information on wrench calibration.

NOTE 4.3 It is highly recommended to have backups of all single- use items available in case of unforeseen events.

NOTE 5.1 In addition to their normal function, the Preset or Linear keys can also be used to reset the unit after a fault condition has been displayed and corrected (or overridden).

NOTE 5.2 When a footswitch function is activated, if the activation LED does not illuminate on the top of the console (see Figure 5.7, #2), plug the Remote IR receiver into its receptacle at the console rear and place it within direct line of sight with the footswitch. The Remote IR receiver can be moved closer to the wireless footswitch or linked directly to it to improve signal reception as needed.

NOTE 6.1 The SonaStar system should be fully tested and inspected prior to each procedure. The console, footswitch, handpieces, all cables and accessories should be examined for proper appearance and condition.

NOTE 6.2 The IV pole should be positioned to yield continuous flow and visibility, but elevated IV bag position is not necessary to achieve flow.

NOTE 6.3 The sterile wire stylet, torque wrench and torque fixture should be retained with the handpiece in the sterile field.

NOTE 6.4 The handpiece, torque wrench and torque fixture should be sterilized prior to starting assembly according to Method 2.

NOTE 6.5 When assembling aspiration tubing, be sure there are no kinks or blockages along the entire tubing's length. Be sure the cuff end of the aspiration tubing is not deformed at its connection to the patient port on the aspiration canister.

NOTE 6.6 If there is a high pitched squealing noise after pressing the Setup key, turn the power switch off and check that the tip is torqued properly. If it was, there may not have been adequate irrigation fluid at the tip. Turn the unit back on and depress the flush pedal again making certain there is irrigation at the tip, then press the Setup key.

NOTE 6.7 The tissue release valve should be checked for proper operation by activating Flush. If irrigation flow is immediately aspirated prior to reaching the operative site, proper tubing routing and tissue release valve operation should be checked.

NOTE 7.1 Do not attempt to tighten or loosen handpiece components by holding the handpiece case. Always place the handpiece into the torque fixture and use the torque wrench when tightening or un-tightening the tip. Do not over-tighten the tip.

NOTE 7.2 Monopolar Handpiece Cable is supplied sterile and is NOT sterilizable.

NOTE 8.1 The SonaStar system has been designed for use with monopolar COAG using a Misonix approved electrosurgical generator. CUT mode has NOT been approved for use with the SonaStar. DO NOT use this mode with the SonaStar.

NOTE 8.2 Do not clean the tip with abrasive or metallic materials, as damage to the tip may result in device failure.

NOTE 9.1 Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage.

NOTE 10.1 The following tables do not attempt to anticipate all possible failures. Any fault not listed in the tables must be referred to an authorized Misonix, LLC technical representative.

NOTE 12.1 The SonaStar is configured for a specific electrical input (line) at the factory before shipment, and is not intended to be configured or changed in the field except by Misonix authorized technical personnel. The unit may only be used with the electrical input originally intended.

1.2. EMC Statement

The SonaStar system is designed and tested to comply with FCC regulations for conducted and radiated emissions under Part 18 Subchapter J. and to comply with IEC EN60601-1-2: 2014 guidelines for EMC.

CAUTION 1.2 This device is considered medical electrical equipment. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this operator's manual.

WARNING 10.2 Portable and mobile RF communication equipment (including peripherals such as antennas) should be no closer than 30 cm (12 inches) to any part of the console, including the cables supplied with the console Otherwise degradation of the performance of this equipment could result.

WARNING 10.3 The use of accessories, transducers and cables other than those specified or provided by Misonix may result in increased electromagnetic emissions or decreased immunity of the device and may result in improper operation. Use only Misonix branded equipment and accessories.

WARNING 10.4 Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Electromagnetic Compatibility Guidance (in accordance with EN/IEC 60601-1-2:2014)

Guidance And Manufacturer's Declaration – Electromagnetic Emissions (Table 201)		
The SONASTAR SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of SONASTAR SYSTEM should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SONASTAR 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 SONASTAR SYSTEM is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 1.2 Guidance & manufacturer's declaration on electromagnetic emissions (EN table 201)

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. 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.

Guidance And Manufacturer's Declaration – Electromagnetic Immunity (Table 202)			
The SONASTAR SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the SONASTAR SYSTEM should assure 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 ○ ±2kV, ±5kV, ±8kV, ±15 kV air	○ ±8 kV contact ○ ±2kV, ±5kV, ±8kV, ○ ±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	○ ±0.5 kV, ±1 kV line to line ○ ±0.5 kV, ±1 kV, ±2 kV line to ground	○ ±0.5 kV, ±1 kV line to line ○ ±0.5 kV, ±1 kV, ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	○ ±1 kV differential mode ○ ±2 kV common mode	○ ±1 kV differential mode ○ ±2 kV common mode	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	100 % dip in U_T for 0,5 cycle 70 % U_T (30 % dip in U_T) for 25 cycles 100 % dip in U_T for 1 cycles 100 % dip in U_T for 5 sec	100 % dip in U_T for 0,5 cycle 70 % U_T (30 % dip in U_T) for 25 cycles 100 % dip in U_T for 1 cycles 100 % dip in U_T for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SONASTAR SYSTEM requires continued operation during power mains interruptions, it is recommended that the powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field 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 AC mains voltage prior to application of the test level.			

Table 1.3 Guidance & manufacturer's declaration on electromagnetic immunity (EN table 202)

List of Cables		
Item	**Cable Length**	**Type**
Handpiece Cable – both CE and SS	17' | 5.2m	shielded multi-conductor
Remote IR Receiver Cable	18' | 5.5m	shielded multi-conductor
AC Main Power Cord	10' | 3.1m	unshielded 3-conductor

Table 1.4 List of cables

Guidance And Manufacturer's Declaration – Electromagnetic Immunity (Table 204)			
The SONASTAR SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the SONASTAR SYSTEM should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the SONASTAR SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 2.3\sqrt{P}$ 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 deter-mined 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: 
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 absorption 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 SONASTAR SYSTEM is used exceeds the applicable RF compliance level above, the SONASTAR 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 SONASTAR SYSTEM. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 1.5 Guidance & manufacturer's declaration on electromagnetic immunity (EN table 204)

Recommended Separation Distances Between Portable And Mobile RF Communications Equipment And The SONASTAR SYSTEM (Table 206)			
The SONASTAR SYSTEM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SONASTAR SYSTEM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SONASTAR SYSTEM below, according to the maximum output power of the communications equipment.			
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** $d = 2.4\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.76
1	1.2	1.2	2.4
10	3.8	3.8	7.6
100	12	12	24
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 separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 1.6 Recommended separation distances (EN table 206)

1.3 Electrical Safety Statement

The SonaStar System is designed and tested to Standard UL 60601-1 as well as IEC 60601-1.

WARNING 1.3 The SonaStar system generates high voltages within the console itself and the connected handpiece. To avoid injury, the console should never be operated before ensuring that its cover is properly closed and not tampered with. Do not attempt to remove or disassemble the cover. There are no user-serviceable parts inside the console. All service should only be performed by an authorized Misonix representative. No modification of this equipment is required.

WARNING 1.4 Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cord to remove it from the receptacle.

WARNING 1.5 Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch on the console rear panel is set to the local voltage setting and ensure that the correct fuses are being used. Refer to Section 12.1 on instructions for fuse replacement.

WARNING 1.6 Explosion Hazard: Never use the SonaStar system in the presence of a flammable or explosive atmosphere, such as flammable anesthetics.

1.4 Environmental Statement

This equipment consists of materials that may be recycled if disassembled by a specialized company. All equipment shall be disposed at the end of life in accordance to local requirements. Please observe local and federal regulations regarding the disposal of packing materials and old equipment.

Important Environmental Information for Users within the European Economic Area
The European Parliament did enforce new regulations developed in 2005 concerning the disposal medical electrical and electronic equipment. The regulations, called Directives, place responsibilities on the supplier and you, the purchaser/user. One of the actions required is to inform users of their obligations. The device has been assessed in accordance with the European Parliament Directive 2002/96/EC on Waste Electrical and Electronic Equipment, usually referred to as WEEE Directive. The WEEE Directive requires that the device be disposed of at the end of its useful life in an environmentally responsible manner. Similar requirements have been applied to refrigerators for some time. The WEEE Directive requires that if replacing the device with a new equivalent product, that supplier shall collect the old item without cost to the user.
If you wish to dispose of the device without replacing it then the device must not be mixed with unsorted municipal waste. The crossed-out wheeled bin symbol on the unit label or packaging, and repeated below, indicates this requirement.    Disposal Symbol, disposal to be compliant with EN 50419 You must ensure that the device is disposed of at an authorized treatment facility; details can be obtained from your local council.
Your role is critical and will help to ensure the Earth's resources are maintained and that as much re-useable and recyclable material as possible is processed. It will also ensure that the landfill volume requirements are kept at a minimum and that hazardous materials are not buried thereby providing potential future problems for the environmental and human health.

Table 1.7 Environmental statement

1.5 FCC Statement

This complies with FCC regulations for conducted and radiated emissions under FCC Part 18.

1.6 Trademark Information

Misonix®, SonaStar® and OsteoSculpt® are registered trademarks of Misonix, LLC, Farmingdale, NY

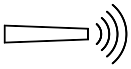
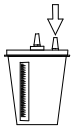
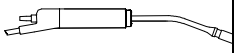
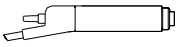
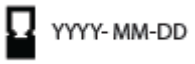
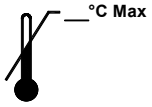
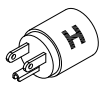
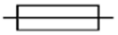
ASP Enzol® and Prolystica® are registered trademarks of STERIS Corporation, Mentor, OH

Force FX™ and Valleylab™ are trademarks of Covidien AG, Switzerland

ConMed System 2400™ and System 2700™ are trademarks of ConMed Corporation, Utica, NY

Erbe® is a registered trademark of Erbe Elektromedizin GmbH, Tübingen, Germany

1.7 Explanation Of Symbols

Console Related Symbols					
Symbol	**Description**	**Symbol**	**Description**	**Symbol**	**Description**
IP68	Footswitch protected against immersion		Danger: High Voltage. No not remove cover. Contact service personnel.		Mains Power ON
	Not for use in the vicinity of flammable anesthetics, oxygen or volatile solvents		Caution: Consult accompanying documents		Mains Power OFF
	Amplitude setting		Caution: Pinch hazard		Protective earth ground
	Handpiece vacuum		Curved extended handpiece		Short straight handpiece
	System Fault		Type B equipment		Disposal to be compliant with EN 50419 (WEEE directive)
	Do not reuse		Sterilized using Ethylene Oxide		Restricted to sale by or on the order of a physician only
	Do not use if packaging is damaged		Sterilized using Gamma Irradiation		Authorized representative in the European community
	Contents are latex-free		Use by date indicated	REF	Catalog number
	Do not expose to temperatures greater than indicated		Lot or batch code		Handpiece irrigation
	Must use hospital grade power cord only		Fuse		Manufacturer

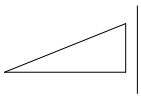
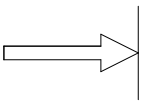
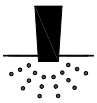
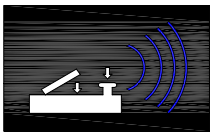
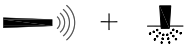
CE 0482	Misonix CE number	CLASSIFIED C UL US	Classified by UL		Setup
	Remote IR receiver	Handpiece This Side	Handpiece faces this side- Marking on Torque wrench	Remove	Remove probe tip
Torque	Tighten probe tip		Linear Mode		Preset Mode
	Elapsed time		Vibration		Lap Mode
	Replace wireless footswitch batteries		Coagulation		Signal transmission, Footswitch activated
	Flush irrigation		Vibration + coagulation	~	AC Mains Voltage
	Do not resterilize		Non-sterile device		Single sterile barrier system with protective packaging inside
	Date of Manufacture	UDI	Unique Device Identification is specific to a manufacturer and a device	MD	Identifies product as a medical device
	MR Unsafe				
	Reusable. Do Not Discard				

Table 1.8 Explanation of symbols

2. Indications And Contraindications

2.1. Indications

The SonaStar Ultrasonic Aspirator System is indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery
- Thoracoscopic Surgery

The system may also be combined with electrosurgery using optional RF surgery interface components.

The SonaStar system is to be operated by surgeons / physicians licensed to practice in the fields covered by the stated indications for use.

CAUTION 1.1 Federal law restricts this device to be sold only to or on the order of a licensed healthcare practitioner.

2.2. Contraindications

The SonaStar ultrasonic surgical aspirator system is not indicated for and should not be used for cardiac surgery and any procedure in the proximity of the heart.

The irrigation pump is not indicated for and should not be used for the administration of parenteral fluids, infusion of drugs, or for any life sustaining purposes.

This Sonastar ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

3. Adverse Effects

CAUTION 3.1 The SonaStar system and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits.

Limits For Airborne Acoustic Exposure		
Minimum Operating Distance (from operator's or patient's ear)		**Maximum Exposure Period (within a 24 hour period)**
12"	30 cm	Not to exceed 9 minutes
24"	60 cm	Not to exceed 90 minutes
> 24"	> 60 cm	Not to exceed 240 minutes

4. Principle of Operation

4.1. Ultrasonic Theory

The Ultrasonic Aspirator achieves surgical fragmentation and excision of tissue by high frequency vibration of the titanium tip connected to the handpiece. The application of the vibrating tip to the tissue results tissue ablation.

Once the contact has been established between the tip and the target tissue, two ablation effects are noted: (1) The most prominent effect is cavitation. The rapid motion of the tip towards and away from the target area causes localized pressure waves within the tissue, inducing the rapid formation and collapse of vapor pockets around cells that have a high water content. The collapse of the vapor pockets results in tissue rupture/ablation. (2) Vacuum at the tip ensures tip/tissue contact during, at least a portion of, each vibration cycle.

4.2. System Overview

The SonaStar Ultrasonic Aspirator is designed for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in numerous surgical specialties (see Section 2.1 for specific details). The SonaStar is a fully self-contained console with built-in irrigation, aspiration and vibration functions. The handpiece, connected to a microprocessor based console, work together to provide precise surgical tissue ablation and removal. The SonaStar, can also be combined with an approved electrosurgical unit, to facilitate tissue penetration and fragmentation.

Figure 4.1 SonaStar System

Curved Extended Handpiece
Short Straight Handpiece

Figure 4.2 SonaStar Handpiece

4.2.1. Irrigation System

Irrigating solution is provided to the distal end of the tip to suspend fragmented particles, prevent clogging of the aspiration system and to cool the tip and handpiece. The irrigating solution (sterile IV) is routed from the IV bag (or equivalent), through an irrigation pump, to the tip of the handpiece.

CAUTION 4.1 Never operate the handpiece without proper irrigation. Irreparable damage to the handpiece and probe may result if adequate irrigation is not provided to the probe tip.

4.2.2. Aspiration System

Irrigation fluid and fragmented tissue particles are continuously aspirated through the hollow titanium tip and the aspiration canal of the handpiece, through the disposable tubing to a collection canister. A self-contained suction pump provides the vacuum source. Aspiration level is controlled from the front panel, with a maximum setting of '100' corresponding to availability of approximately 25 inches Hg (635 mmHg) at sea level, measured at the canister. At the lowest aspiration setting, a suction level of less than 0.5 inche of Hg is available for meeting the most delicate tissue removal requirements.

4.2.3. Vibration System

Tissue fragmentation is achieved upon contact with the vibrating handpiece tip. The high frequency oscillation of the tip is powered by an ultrasonic generator within the console, which provides current to a piezoelectric transducer housed within the handpiece. Electrical energy is converted to mechanical motion in the transducer, causing the titanium tip of the handpiece to vibrate longitudinally at approximately 23,000 cycles per second. The amplitude of the tip is a function of the vibration level setting. At full or '100' vibration setting, the standard tip's amplitude (displacement) is approximately 300 microns when used with the Curved Extended handpiece and approximately 225 microns when used with the Short Straight handpiece. Amplitude will vary with the use of other probes on each handpiece.

4.2.4. Standby Mode

Upon completion of the initial system setup or following release of the footswitch pedal, the system automatically switches to a Standby mode. Vibration is not active at any time in the Standby Mode.

- Immediately after set up is complete, the vacuum system is active at the user preset level for approximately 5 minutes and the irrigation function is active for 20 seconds at a minimal level. Neither function requires the footswitch to be depressed.
- After the system has been used, and the foot switch pedal has been released, the vacuum system is active at the user preset level for approximately 5 minutes and the irrigation function is active for 2 minutes at a minimal level. If Lap mode is enabled, the vacuum is present at the tip for 15 seconds, but irrigation is inactive.
- In either case, the full system function can easily be reactivated, to the preset user settings, by stepping on the footswitch. Additionally, after 5 minutes of inactivity (when the footswitch has not been depressed), vacuum goes into the Suspend mode (see section 4.2.5).

4.2.5. Suspend Mode

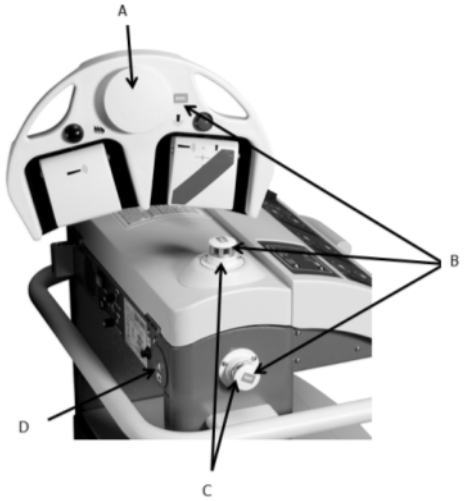
Once the system has remained in a Standby mode for more than 5 minutes (i.e. the footswitch has not been depressed), the system will go into a Suspend mode. In the Suspend mode, the vacuum pump (the only function previously working in Standby mode) will turn off. The system can be easily reactivated by stepping on any footswitch pedal.

4.2.6. Wireless Footswitch

An infrared, multi-pedal, wireless footswitch communicates, via infrared signals, with two integrated IR receivers and an optional remote IR receiver. The first integrated IR receiver is mounted on the top of the SonaStar console, the second, on the console left side, above the handle bar. Together they facilitate wireless communications in the standard operating room environment. Occasionally, the O.R. interior or the arrangement of surgical equipment can diffuse or interfere with the wireless IR signal. In these cases it is recommended to use the remote IR receiver. The remote IR receiver is connected, via its cable to the console rear and placed on the floor in direct line of sight with the wireless footswitch. In cases of moderate signal strength it is sufficient to place the remote IR receiver next to the console. The remote IR receiver can be moved closer or even mechanically linked to the wireless footswitch (see image below) to improve reception of the IR signal as needed. The remote IR receiver will function with any frequency code number.

Figure 4.3 Wireless Footswitch and Remote IR Receiver shown separately and linked

NOTE 4.1	For proper operation, the console and wireless footswitch must have the same frequency code number. Refer to Section 5.4 for more details.



A Footswitch wireless transmitter
B Red frequency labels (last digits must match)
C Integrated IR Dome receivers
D Receptacle for remote IR receiver

Figure 4.4 Wireless Footswitch and Console with integrated IR receivers (top and left side)

4.3. Reusable System Components

The following reusable system components are required for performing procedures. They can be ordered as a system or individually.

Console Configurations and Reusable Accessories	
SYSTEM – M360-0* SYSTEM – M360-1* SYSTEM – M360-2* SYSTEM – M360-3* * Last digit indicates the wireless frequency	SonaStar System (110/115/120/220/230V Systems) Includes generator console, wireless footswitch, remote IR receiver, autoclavable torque wrench, autoclavable torque fixture (2), IV pole, handpiece brush (3) probe brushes (3), vacuum canister, vacuum canister ring, suction tubing, power cord and instructions for use Choice of two of the following: • SonaStar Short Straight Handpiece (CFSX6-H321) • SonaStar Curved Extended Handpiece (CFSX6-H322)
SYSTEM – M380-0* SYSTEM – M380-1* SYSTEM – M380-2* SYSTEM – M380-3* * Last digit indicates the wireless frequency	SonaStar System (240V System) Includes generator console, wireless footswitch, remote IR receiver, autoclavable torque wrench, autoclavable torque fixture (2), IV pole, handpiece brush (3) probe brushes (3), vacuum canister, vacuum canister ring, suction tubing, power cord and instructions for use Choice of two of the following: • SonaStar Short Straight Handpiece (CFSX6-H321) • SonaStar Curved Extended Handpiece (CFSX6-H322)
SYSTEM – M300-0* SYSTEM – M300-1* SYSTEM – M300-2* SYSTEM – M300-3* * Last digit indicates the wireless frequency	SonaStar System (100/200 V System) Includes generator console, wireless footswitch, remote IR receiver, autoclavable torque wrench, autoclavable torque fixture (2), IV pole, handpiece brush (3) probe brushes (3), vacuum canister, vacuum canister ring, suction tubing, power cord and instructions for use Choice of two of the following: • SonaStar Short Straight Handpiece (CFSX6-H321) • SonaStar Curved Extended Handpiece (CFSX6-H322)
CFSX6-H321	SonaStar Short Straight, 23 kHz Handpiece which includes: long and short front housings 
CFSX6-H322	SonaStar Curved Extended, 23 kHz Handpiece which includes a front housing assembly 
CFSX3-M200-0* CFSX3-M200-1* CFSX3-M200-2* CFSX3-M200-3* * Last digit indicates the wireless frequency	SonaStar 2- Pedal Footswitch (electrosurgery compatible) Frequency 0 Frequency 1 Frequency 2 Frequency 3 
CFSM6-T222	Autoclavable Torque Fixture: Compatible with CFSX6-H321 and CFSX6-H322
CFSM2-T018	Autoclavable Torque Wrench: Compatible with CFSX6-H321 and CFSX6-H322

CFSX3-M201	Remote IR Receiver
E0702ABC07	IV Pole
CFSM5-T101	Suction tubing, 3 ft. length, compatible with CFSM5-C136
CFSM5-C136	Suction Canister
CFSS2-F019	External Vacuum Filter is intended for all SonaStar consoles.
CFSS2-F219	External Vacuum filter with attached suction tubing and quick connect fitting - For use on consoles with serial #'s that begin with FHF
CFSS2-F025	Internal Vacuum Filter
CFSS2-F115	Activated Carbon Filter with attached suction tubing and quick connect fitting
E- BRUSET	Handpiece and Probe Brush Set (3 large and 3 small), set

Table 4.1 Console Configurations and Reusable Accessories

Components and quantities included with the system may change over time, please check with your Misonix representative for the most current configuration.

4.4. Single-use, Sterile Components

At least one tube set, suction tubing and canister must be available for each surgical procedure. The tube set includes both aspiration and irrigation tubing. The aspiration tubing has a larger lumen; the irrigation tubing has an end section with a yellow line and luer lock.

Tube Sets- Single Use	
MXA-HF	Tube set, sterile, High Flow, 1 box= 5 pcs. For use on consoles with serial #'s that begin with FHF and Handpieces with the serial number designation of 3 digits- 2 digits (XXX-YY)
MXA-PA	SonaStar Tube Set, 1 box= 5pcs For use on consoles with serial #'s that begin with FLV and Handpieces with the serial number designation that begins with an E and followed by 4-5 digits, no dashes (EXXXXX)

Table 4.2 Tube Sets and Suction accessories

- **The MXA-HF Tube Sets are NOT compatible with older style handpieces (handpieces that have a gray aspiration port and serial #'s that are 5 digits in length with no dashes XXXXX)**
- **The MXA-PA Tube Sets will fit on the new style handpieces (handpieces that have a blue aspiration port and serial #'s that are 5 digits in length, separated by a dash XXX-YY) but will have significantly lower flow rates as compared to MXA-HF.**

Please contact Misonix directly if you have any questions regarding compatibility issues.
There are a variety of ultrasonic tips (Applied Part) available for the SonaStar system. Please ask your Misonix representative for the latest catalog of available tips. Ultrasonic tips are supplied sterile and are for single use only.

Sonastar Tips	
MXA-D212	1.9mm Standard Procedure Pack
MXA-D214	1.6mm Micro Procedure Pack
MXA-D216	1.1mm Precision Procedure Pack
MXA-D218	1.9mm Standard Long Curved+ Procedure Pack
MXA-D224	1.1mm Precision Long Curved Procedure Pack
MXA-D226	1.6mm Micro Long Curved Procedure Pack
MXA-D228	1.9mm Standard Long Curved Procedure Pack

MXA-D230	1.9mm Standard Notched Procedure Pack
MXA-D232	1.9mm Standard Deep Access Probe
MXA-D234	2.6mm Macro Procedure Pack
MXA-L002*	2.0mm Laparoscopic Probe Procedure Pack
MXA-S002	Standard Short Osteosculpt® Procedure Pack
MXA-S004	Long Curved Micro Osteosculpt® Procedure Pack

*- MXA-L002 Laparoscopic probe can be used up to 6 times

4.5. Optional Accessories for Monopolar COAG

To perform monopolar COAG, the following items are needed. (See Chapter 8 for more information on use of COAG):

1) Approved electrosurgical generator, see Section 8.1.
2) Appropriate umbilical cable, see Table 4.2.
3) Single-Use Monopolar Handpiece Cable, see Table 4.2.

Accessories for Monopolar COAG	
CFSM6-C140	Valley Lab Force 2 Electrosurgery Generator Umbilical Cable – reusable, each
CFSM6-C141	Conmed, Sabre 2400 & Model 7500 Electrosurgery Umbilical Cable – reusable, each
CFSM6-C142	Erbe ICC 300 Electrosurgical Generator Umbilical Cable – reusable, each
CFSM4-M100	8mm Monopolar RF Cable Connector – reusable, each
CFSM5-D050	Single-Use Monopolar Handpiece Cable (5-pack), 1 box

Table 4.2 Accessories for Monopolar COAG

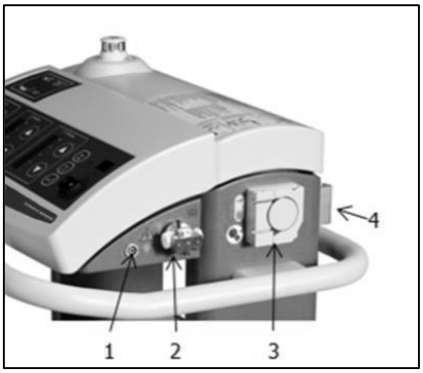
5. Console - Receptacles, Controls and Indicators

The main controls, indicators and connection points for the SonaStar Ultrasonic Surgical Aspiration System are described in this chapter. Color coding has been used to simplify control of the three functional subsystems within the SonaStar System.

Color	Function
Yellow	-Designates **Irrigation**
Green	-Designates **Aspiration**
Blue	-Designates **Vibration**

Table 5.1 Color Coding and Functions on the SonaStar Console

5.1. Side Panel Receptacles



1 Handpiece Connector
2 Tissue Release Valve
3 Irrigation Pump
4 IV Pole block

Figure 5.1 SonaStar (side view)

The side of the console features a cable connection or the handpiece (1), insertion connection for the aspiration tubing (2), pump for the irrigation tubing (3) and the IV pole (4) (see Figure 5.1).

(1) Handpiece Connector - The handpiece receptacle is keyed in order to facilitate connection. The red dot on

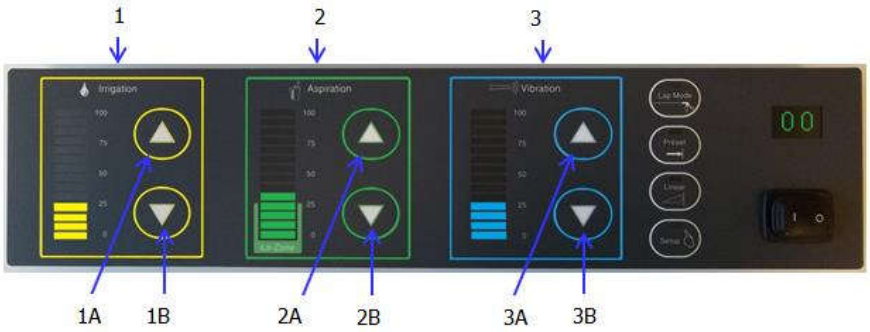
the receptacle must be in line with the corresponding red dot on the handpiece cable.

(2) Tissue Release Valve – This is a pinch-off valve through which the suction tubing is routed. During standard operation (vibration footswitch depressed), it is open and then closes for ½ second when the footswitch is released, shutting off suction to the tip. When Lap Mode is being used (when the footswitch is not pressed), the tubing is pinched off to prevent the loss of insufflation. Again, when vibration footswitch is depressed it opens for tissue removal into canister. This valve also pinches off the suction line during flush mode to allow irrigation to be delivered to the operative site without being immediately aspirated.

(3) Irrigation Pump – A peristaltic pump is used to deliver the irrigating solution from the IV bag to the handpiece tip. The irrigation tubing is connected to the IV set and routed clockwise around the pump rotor. The pump provides a fixed high flow rate to the handpiece when the Flush button is activated and a user defined flow rate during vibration. No irrigation flow is present when the COAG button is depressed. Following footswitch release, the pump will continue to deliver irrigant for two minutes before coming to a complete stop. During Lap Mode, the pump stops immediately following footswitch release and irrigation is ceased.

5.2 Front Panel Controls

The Console front features a large panel that allows visualization and adjustment of all of the system parameters (Setup, Function Mode, Irrigation, Aspiration, Vibration), and the display of error notifications.



1 Irrigation level display & controls
1A Irrigation control - increase Pulse setting
1B Irrigation control - decrease

2 Aspiration level display & controls
2A Aspiration control - increase Pulse setting
2B Aspiration control - decrease

3 Vibration level display & controls
3A Vibration control - increase
3B Vibration control - decrease

Figure 5.2 Front Panel Controls

(1) Irrigation Level Display & Controls: The yellow bar graph display indicates the irrigation flow setting. The flow rate may be adjusted by pressing the "Increase" ▲ (1A) or "Decrease" ▼ (1B) buttons located to the right of the illuminated scale. In order to optimize cooling and prevent clogging, a minimum setting of 25 is recommended. A single display bar is illuminated at the user preset level when the footswitch is not depressed.

When either the ***Vibration*** *or* ***Vibration + COAG*** footswitch pedal is depressed, all of the display bars, up to the preset level, are illuminated, indicating that the Irrigation feature is active at that preset level. The minimum irrigation flow rate that may be achieved is approximately 2cc/min and the maximum achievable irrigation flow rate is approximately 14cc/min.

When the ***FLUSH*** button is depressed, all the display bars are illuminated with the top 2 bars blinking to indicate to the user that this irrigation level is higher than the maximum irrigation level that would be obtained if the vibration pedal was depressed. Regardless of the user setting, when the FLUSH button is depressed, the irrigation flow rate is >25cc/min. In addition, the FLUSH feature also temporarily pinches off the suction line to allow maximum irrigation delivery to the surgical site.

When the ***COAG*** button is depressed, the irrigation pump is inactive and the bar graph displays a single bar at the preset level.

When any foot pedal is released, irrigation will continue to flow at a rate of approximately 2cc/min for 2 minutes. This is to clear the aspiration line and to keep the handpiece cool.

In Lap Mode, the Irrigation feature operates the same as above except when the footswitch is released, the irrigation immediately stops.

During Setup mode, the irrigation pump operates at a high flow rate to prime the irrigation line of the tube set.

(2) Aspiration Level Display & Controls: The green bar graph display indicates the vacuum level set by the user. The vacuum level may be adjusted by pressing the "Increase" ▲ (2A) or "Decrease" ▼ (2B) buttons located to the right of the illuminated scale. At the maximum setting of '100', approximately 25 inches Hg (635 mmHg) at sea level is available at the canister. At the minimum setting '0', the vacuum is less than 0.5 inch Hg (12.7 mm Hg) for delicate, tissue removal applications.

The display bars will illuminate up to the preset level when vacuum is available at the tip (except when in Suspend mode). When a single display bar is illuminated, it indicates that the aspiration feature is ready at the user preset level but vacuum is not present at the tip.

The aspiration function varies slightly, based upon user preferences:

- When either the Vibration or Vibration + COAG pedals are depressed, vacuum is available up to the preset level. The bar graph illuminates up to the preset level signifying that the vacuum is present at the tip. When the foot pedal is released, the tissue release valve is activated and the vacuum at the tip ceases for a very short time period, allowing the safe removal of the tip from the surgical site. Subsequently, the vacuum is reactivated for approximately 5 minutes.

- When the COAG button is depressed, the aspiration is active as described above. However, when the COAG button is released, vacuum continues to the tip for approximately 5 minutes.

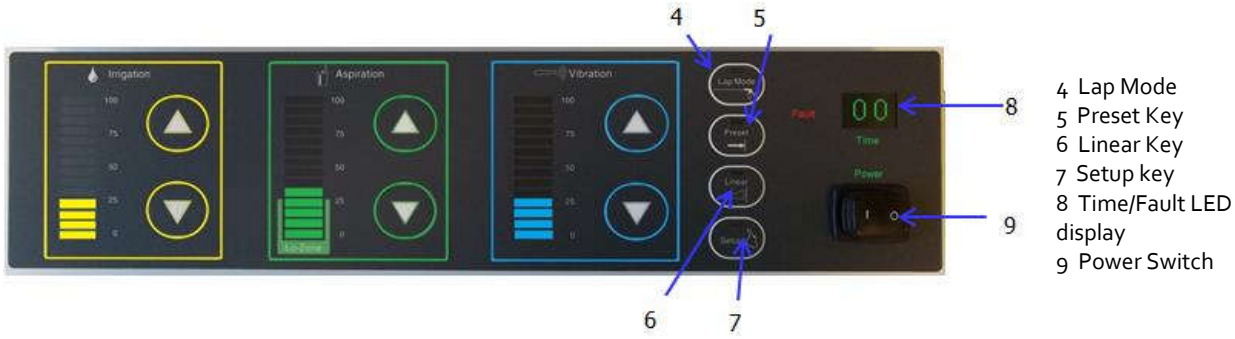
- When the FLUSH button is depressed, the tissue release valve is closed and there is no vacuum present at the tip. This is to prevent the irrigation fluid from immediately being aspirated before reaching the surgical site. When the FLUSH button is released, the valve re-opens allowing vacuum to be present at the tip.

- When the LAP Mode has been chosen, the aspiration system works as described above for each function. When the footswitch is depressed, the tissue release valve opens to provide vacuum to the tip and allow the ablated tissue to be aspirated into the vacuum canister. Upon release of the Vibration or Vibration + COAG pedal, the pinch valve closes quickly (for less than a second) to allow the tip to release tissue and be safely removed from the surgical site. It then re-opens, providing vacuum at the preset level to the tip for approximately 15 seconds. After 15 seconds, the pinch valve closes again and vacuum is no longer available at the tip, thus preventing insufflated gases from escaping the body. The system is now in a Standby mode and can be reactivated by pressing any pedal/button on the footswitch.

- When in Standby mode (footswitch not depressed), vacuum is available up to the preset level. The bar graph illuminates up to the preset level signifying that this level is available at the tip. After 5 minutes of footswitch inactivity (Standby mode), the system will go into a Suspend Mode in which aspiration is not active. The aspiration feature can be re-activated by depressing any footswitch pedal.

(3) Vibration Level Display & Controls: The blue bar graph display indicates the vibration level set by the user. The vibration level may be adjusted by pressing the "Increase" ▲ (3A) or "Decrease" ▼ (3B) buttons located to the right of the illuminated scale. The excursion (displacement) at the tip is a function of the vibration setting. At the maximum setting of '100', the tip excursion (displacement) is approximately 300 microns for the Curved Extended Handpiece and approximately 225 microns for the Short Straight Handpiece.

The single display bar illumination shows the user preset level when the footswitch is not depressed. When the Vibration or Vibration + COAG footswitch is depressed in Preset mode, the vibration level is available immediately at its user preset level. The bar graph will illuminate up to the preset level signifying that the vibration is active at that level. In Linear mode, the vibration level is controlled by the amount that the footswitch is depressed (i.e. gas pedal). In this mode the vibration level varies from 0 to the user preset level as a linear function of the amount of footswitch travel.



4 Lap Mode
5 Preset Key
6 Linear Key
7 Setup key
8 Time/Fault LED display
9 Power Switch

Figure 5.3 Power, Setup and Mode Keys

(4) Lap Mode Key: is selected when performing minimally invasive procedures (laparoscopic procedures). The Lap Mode key works as a toggle switch, press to set/press to cancel. A LED indicator illuminates when Lap Mode is enabled. In this mode the tissue release valve is controlled in a manner that prevents the insufflated gases from escaping the body when the system is in standby mode.

Once the vibration footswitch is depressed, the tissue release valve opens to allow the ablated tissue to be aspirated into the vacuum canister. Once the footswitch is released, aspiration is stopped for less than a second to release any tissue, then aspiration will continue for 15 seconds. After that, the tissue release valve closes and there is no vacuum at the tip. This mode may be used in conjunction with the Preset and Linear modes of operation.

(5) Preset Key: works as a toggle switch and allows the end user to enable/disable the preset mode. A LED indicator illuminates when the mode is enabled. The LED will flash to indicate that a selection is required. Canceling the key function places the system in Standby. During Setup mode, the Preset key is inoperable. The Preset Key is also used to clear a fault, which is indicated by flashing. For additional details regarding the use of the Preset mode, please refer to Section 5.2, paragraph (3).

(6) Linear Key: works as a toggle switch and allows the end user to enable/disable the linear mode. A LED indicator illuminates when the mode is enabled. The LED will flash to indicate that a selection is required. Canceling the key function places the system in Standby. During Setup mode, the Linear key is inoperable. The Linear Key is also used to clear a fault, which is indicated by flashing. For additional details regarding the use of the Linear mode, please refer to Section 5.2, paragraph (3).

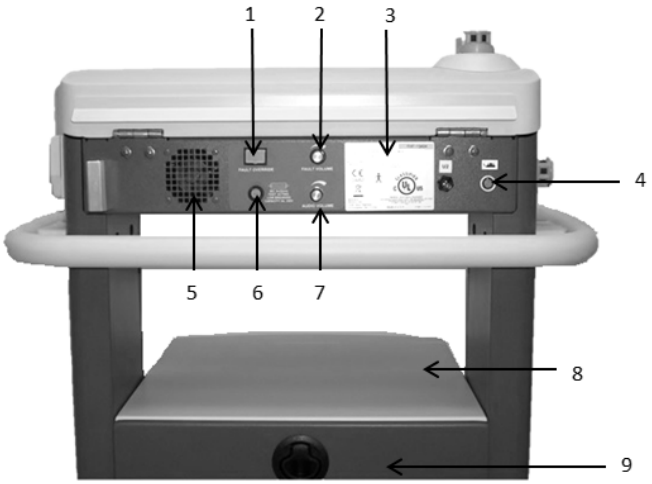
NOTE 5.1 In addition to their normal function, the Preset or Linear keys can also be used to reset the unit after a fault condition has been displayed and corrected (or overridden).

(7) Setup Key - A key used to initiate self-testing following initial system power-up. When the power switch is first turned on, the Setup key LED flashes to indicate that the Setup key must be pressed to initiate the system self-test procedure. Please make sure that the system has been set up properly according to Chapter 6, including handpiece connection. Pressing the key will initiate testing of the vibration system to verify that the handpiece tip is properly tightened and that the handpiece is functioning properly. During this test, the vibration, irrigation and aspiration displays will ramp up and back down. All three subsystems will be tested simultaneously and an end-of-test beep will be heard when completed. The Setup LED will extinguish upon completion of the procedure and the Lap Mode, Preset and Linear LEDs will flash to prompt the user that a selection is required.

(8) Time/Fault two-digit LED display: Provides indication of the vibration on accumulated time in minutes. The timer may be reset by a "power down, power up" sequence. This readout will also display error codes (i.e. E2) in the event of a fault condition (see Table 10.2 for a detailed description of the error codes). A backlit "Time ⏳ " LED illuminates as long as a fault has not occurred. Whenever a fault condition exists, a backlight "Fault 🔔 " LED is illuminated. If the fault is cleared, the backlit LED turns off. If the fault is bypassed, the backlit LED flashes, indicating that the fault was overridden.

(9) Power Switch - Mains power ON/OFF switch for the unit. Backlit LED above the switch illuminates to indicate that the unit is turned on.

5.3 Rear Controls, Labeling, Storage and Receptacles



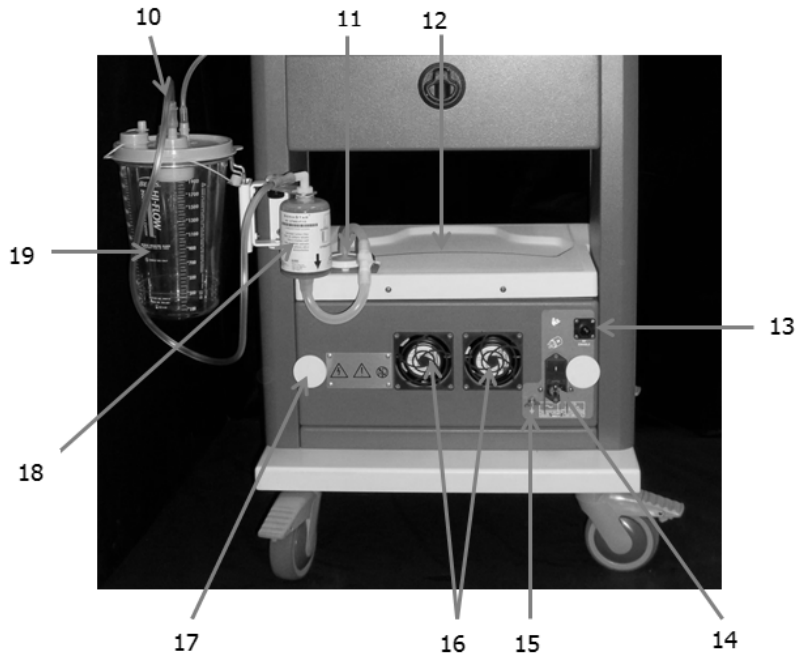
1 Fault Override Button
2 Fault Volume Control Knob
3 Rating Plate with Serial Number
4 Receptacle for remote IR receiver
5 Fan
6 Fuse
7 Audio Feedback Volume Control Knob
8 Electrosurgical Unit Shelf
9 Storage Compartment Drawer

Figure 5.4 Upper Console rear

The rear of the console features control knobs for secondary system functions, labeling, storage and receptacles.

1) Fault Override Button : Overrides a non-critical fault (i.e. E3) and allows continued use of the Ultrasonic Aspirator, see Section 4 for more details.
2) Fault Volume Control Knob: Controls the volume of the audio indicator when a fault condition occurs.
3) Rating Plate: Includes serial number
4) Receptacle for Remote IR receiver: This is where the remote IR receiver would be connected to the console, if required.
5) Fan
6) Fuse: Location of fuse F3, see section 12.1, page 62 for details on fuse replacement.
7) Audio Feedback Volume Control Knob: Controls the volume (down to zero level) of the audible alert tone heard when the vibration footswitch is depressed during Preset or Linear operation.
8) Electrosurgical Unit Shelf: If used, electrosurgical unit can be stored on this shelf.
9) Storage Compartment Drawer: Can be used to hold accessories such as the remote IR receiver. Accessible from

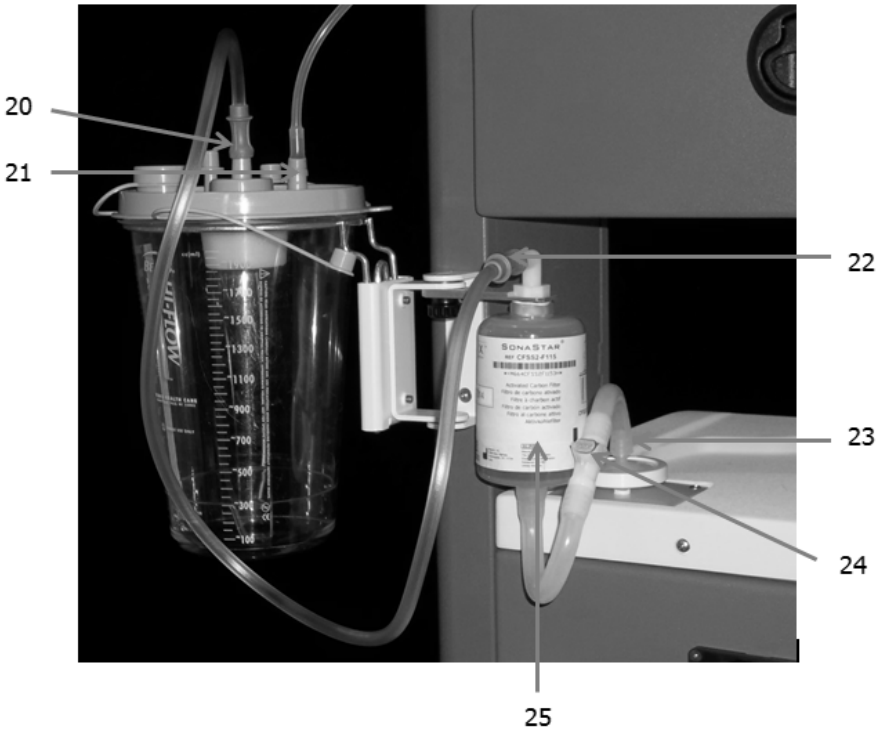
the rear.



10 Suction Tubing Connection Port
11 External Aspiration Filter Assembly
12 Footswitch Storage Shelf
13 Electrosurgery Umbilical Connector
14 Power Cord Receptacle
15 Equipotential Grounding Lug
16 Fans
17 Power Cord Brackets (2)
18 Carbon Filter Assembly
19 Suction Canister

Figure 5.5 Lower Console (rear view)

10) Suction tubing connection port: Primary vacuum connection from the carbon filter to the "vacuum" port on the suction canister.
11) External Aspiration Filter Assembly: External (visible) and internal vacuum filters. See Section 9.6, page 54.
12) Footswitch Storage Shelf
13) Electrosurgery Umbilical Connector: provides for connection to a Misonix-approved electrosurgical unit. See Chapter 8 for more details.
14) Power cord receptacle: Location of Fuses - F1 and F2 (see Section 12.1 for replacement).
15) Equipotential Grounding Lug
16) Fans
17) Power Cord Brackets (2): for wrapping the power cord when the unit is not in use.
18) Carbon Filter Assembly: The filter assembly protects the vacuum pump and should be used for all procedures. See
19)
20) Figure 5.6 for more details.
21) Suction Canister: Mounts on securing bracket for collection of aspirated fluid and tissue. A vacuum hose connects the canister suction port to the aspiration filter assembly. The handpiece is connected to the canister patient port via the aspiration tube (larger bore tube) of the tube set. See
22)
23) Figure 5.6 for more details.



20 Vacuum Port Tubing Connection

21 Handpiece Tubing Connection

22 Carbon Filter Suction Tubing Connection

23 External Vacuum Filter Tubing Connection

24 Carbon Filter Tubing Quick Connect

25 Activated Carbon Filter With Attached Tubing

Figure 5.6 Lower Console rear view (canister/filter connections)

24) Vacuum port tubing connection: One end of the 3 ft. suction tubing is connected to the vacuum port of the canister.

25) Handpiece tubing connection: The distal end of the handpiece tubing is connected to the patient port of the canister.

26) Carbon filter suction tubing connection: The other end of the 3 ft. suction tubing is connected to the plastic elbow fitting on the top of the carbon filter.

27) External vacuum filter tubing connection: The filter is supplied with a permanently attached short length of suction tubing that has a quick connect fitting on the other end.

28) Carbon filter tubing quick connect: The flexible tubing segments that are connected to the carbon filter (25) and the external vacuum filter (23) have the matching parts of a quick connect coupling, installed at their free ends. Aspiration line continuity is established by inserting the male side of the quick connect coupling (on the external vacuum filter) into the corresponding female end of the tubing attached to the carbon filter.

29) Activated carbon filter with attached tubing: The activated carbon filter is supplied with an elbow connector and an attached length of suction tubing with a quick connect fitting on the end.

5.4 Wireless System Receptacles, Controls and Indicators

1 Low Footswitch Battery Indicator
2 Footswitch Activation Indicator

Figure 5.7 Wireless System Indicators (located on top of unit)

1) Low Footswitch Battery Indicator: Illuminates if wireless footswitch battery is low.

2) Footswitch Activation / Signal Transmission Indicator: Illuminates when wireless footswitch pedal or button is depressed and signal is received by console.

NOTE 5.2 When a footswitch function is activated, if the activation LED does not illuminate on the top of the console (see Figure 5.7, #2), plug the Remote IR receiver into its receptacle at the console rear and place it within direct line of sight with the footswitch. The Remote IR receiver can be moved closer to the wireless footswitch or linked directly to it to improve signal reception as needed.

5.4.1 Wireless Footswitch

1 Flush Irrigation Button
2 Transmitter Dome
3 Footswitch Frequency Code
4 Coagulation Only Button
5 Vibration Only Foot Pedal
6 Vibration and Coagulation Foot Pedal

Figure 5.8 Wireless Footswitch

The wireless footswitch enables the operator to activate and control the system functions remotely without physically connecting a cable to the generator. The footswitch functions are:

- Vibration - When the footswitch pedal (5) is depressed, the ultrasound will be activated on the SonaStar. The mode of operation is determined by the user setting – Preset or Linear. Please refer to section 5.2 for more details.
- FLUSH - When the footswitch button (1) is depressed, the irrigation fluid (physiological saline) will be supplied to the tip's distal end at a rate >25cc/min.

When used with an electrosurgery unit: The SonaStar can only activate the COAG function if an authorized electrosurgery unit is connected via an umbilical cable connector, available from Misonix.

- COAG - When the footswitch button (4) is depressed, the COAG function will be activated on the electrosurgical unit via the umbilical cable connected to an authorized electrosurgical unit.
- Vibration + COAG - When the footswitch pedal (6) is depressed, the ultrasound and the COAG functions will be activated simultaneously as long as the electrosurgery system is connected via the umbilical cable.

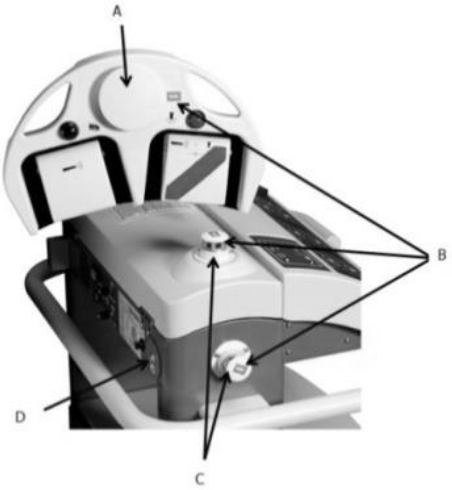
Upon release of a footswitch function a "STOP" command is sent to the console, disabling the function. The footswitch activation LED on the top of the console may continue to illuminate for a short period of time after

footswitch release; this is normal.

If the footswitch signal is blocked or otherwise interrupted, activation will cease after approximately 2 seconds.

Please refer to Figure 5.10 starting on 29 for a chart that summarizes the functions of aspiration, irrigation and vibration based upon the of the functions of the footswitch, i.e. Vibration, Vibration + COAG, Flush and COAG.

Four coded wireless frequencies are available to independently allow the use of multiple systems located in the same transmitting/receiving distance. The IR receivers and the wireless footswitch have color coded labels with numbers that end in either 0, 1, 2, 3, as shown in Figure 5.9. *For proper footswitch /receiver communication, the numbers on the labels must have the same last digit.* The remote IR receiver does not have a color coded label and will function as required for all four coded wireless frequencies.



A Footswitch Wireless Transmitter
B Red Frequency Labels (Last Digits Must Match)
C Integrated IR Dome Receivers
D Receptacle For Remote IR Receiver

Figure 5.9 Wireless Footswitch Receivers/Frequency Labels and Receptacle

CAUTION 6.16: Remove the batteries if the SonaStar is not likely to be used for long period of time.

Standard Operation – Foot Pedal Functions			
	Irrigation	**Aspiration**	**Vibration**
Vibration Foot Pedal			
Foot Pedal depressed	• All of the display bars, up to the preset level, are illuminated. • Irrigation is active at that preset level. • Irrigation flow rates: Min: ~ 2cc/min, Max: ~14cc/min	• The bar graph illuminates up to the preset level signifying that vacuum is present at the tip.	• Preset Mode: Vibration is available immediately at its user preset level. The bar graph will illuminate fully up to the preset level. • Linear mode: Vibration setting varies from 0 to the user preset level as a linear function of the amount of footswitch travel (i.e. gas pedal).
Foot Pedal released	• Irrigation will continue to flow at a rate of approximately 2cc/min for 2 minutes.	• Vacuum at the tip ceases for a very short time period (for less than a ½ second). • The vacuum is reactivated to the tip very quickly and will remain active for ~5 minutes, unless the footswitch is reactivated.	• Vibration ceases.
Vibration + COAG Foot Pedal			
Foot Pedal depressed *Note: If connected to electrosurgery system, RF will be active*	• All of the display bars, up to the preset level, are illuminated. • Irrigation is active at that preset level. • Irrigation flow rates: Min: ~ 2cc/min, Max: ~14cc/min	• The bar graph illuminates up to the preset level signifying that vacuum is present at the tip.	• Preset Mode: Vibration is available immediately at its user preset level. The bar graph will illuminate fully up to the preset level. • Linear mode: Vibration setting varies from 0 to the user preset level as a linear function of the amount of footswitch travel (i.e. gas pedal).
Foot Pedal released	• Irrigation will continue to flow at a rate of ~2cc/min for 2 minutes.	• Vacuum at the tip ceases for a very short time period (for less than a ½ second). • The vacuum is reactivated to the tip very quickly and will remain active for ~5 minutes.	• Vibration ceases.
FLUSH Button			
Button depressed	• All display bars are illuminated with the top 2 bars blinking; indicating irrigation level is higher than the maximum level. • Regardless of setting, the flow rate is >25cc/min.	• The tissue release valve is closed and there is no vacuum present at the tip.	• No vibration available.
Button released	• Irrigation will continue to flow at a rate of ~2cc/min for 2 minutes.	• When the FLUSH button is released, valve re-opens allowing vacuum to be present at the tip, for up to 5 minutes.	• No vibration available.
COAG Button			
Button depressed *Note: If connected to electrosurgery system, RF will be active*	• No irrigation • Bar graph displays a single bar at the preset level.	• Vacuum is available up to the preset level.	• No vibration available.
Button released	• Irrigation will continue to flow at a rate of ~2cc/min for 2 minutes.	• Vacuum continues to the tip for ~5 minutes.	• No vibration available.

Figure 5.10 Summary Table of Irrigation, Aspiration and Vibration Functions during Operation

Lap Mode – Foot Pedal Functions			
	Irrigation	**Aspiration**	**Vibration**
Vibration			
Foot Pedal depressed	• All of the display bars, up to the preset level, are illuminated. • Irrigation is active at that preset level. • Irrigation flow rates: Min: ~ 2cc/min, Max: ~14cc/min	• The bar graph illuminates up to the preset level signifying that vacuum is present at the tip.	• Preset Mode: Vibration is available immediately at its user preset level. The bar graph will illuminate fully up to the preset level. • Linear mode: Vibration setting varies from 0 to the user preset level as a linear function of the amount of footswitch travel (i.e. gas pedal).
Foot Pedal released	• Irrigation immediately stops	• The pinch valve closes quickly and the vacuum ceases (< ½ second) to allow the tip to release tissue and safely removed. • Valve re-opens, providing vacuum at the preset level to the tip for ~15 seconds, then closes.	• Vibration ceases.
Vibration + COAG			
Foot Pedal depressed *Note: If connected to electrosurgery system, RF will be active*	• All of the display bars, up to the preset level, are illuminated. • Irrigation is active at that preset level. • Irrigation flow rates: Min: ~ 2cc/min, Max: ~14cc/min	• The bar graph illuminates up to the preset level signifying that vacuum is present at the tip.	• Preset Mode: Vibration is available immediately at its user preset level. The bar graph will illuminate fully up to the preset level. • Linear mode: Vibration setting varies from 0 to the user preset level as a linear function of the amount of footswitch travel (i.e. gas pedal).
Foot Pedal released	• Irrigation immediately stops	• The pinch valve closes quickly and the vacuum ceases (< ½ second) to allow the tip to release tissue and safely removed. • Valve re-opens, providing vacuum at the preset level to the tip for ~15 seconds, then closes.	• Vibration ceases.
FLUSH Button			
Button depressed	• All display bars are illuminated with the top 2 bars blinking; indicating irrigation level is higher than the maximum level. • Regardless of setting, the flow rate is >25cc/min.	• The tissue release valve is closed and there is no vacuum present at the tip.	• No vibration available.
Button released	• Irrigation will continue to flow at a rate of ~2cc/min for 2 minutes.	• When the FLUSH button is released, the valve re-opens allowing vacuum to be present at the tip for 15 seconds. Vacuum pump stays on for up to 5 minutes	• No vibration available.
COAG Button			
Button depressed *Note: If connected to electrosurgery system, RF will be active*	• No irrigation • Bar graph displays a single bar at the preset level.	• Vacuum is available up to the preset level.	• Vibration not active
Button released	• No irrigation	• Vacuum continues to the tip for 15 seconds.	• No vibration available.

6. System Set-up

6.1. Installation

Upon delivery perform a visual inspection of the shipping container(s) and all system components for obvious shipping damages. If any damages are found, retain the shipping container and immediately notify the shipping carrier of any damages found.

Care should be taken to stay within the recommended operating conditions (see Table 11.1).

Space Requirements

The width and depth dimensions for the SonaStar are shown below. For enhanced accessibility to the SonaStar and convenience to the user, an open space, enough for a person to walk around, is required. The power cord length is 10 feet (3.1 m), the Remote IR Receiver cable is 18 feet (5.5 m) long and the handpiece cable 17 feet (5.2 m) in length.

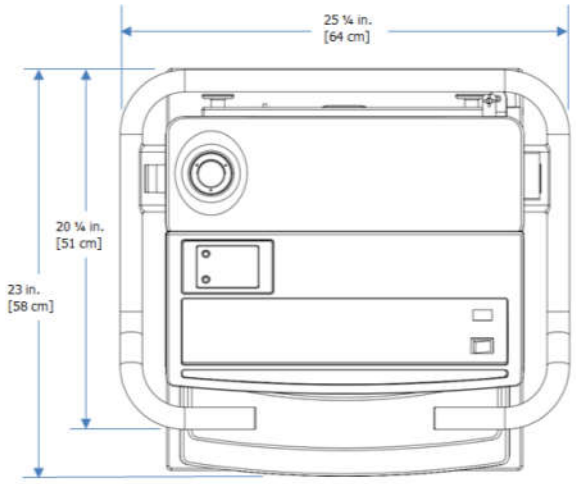


Figure 6.1 Top View System dimensions

CAUTION 6.1	Adequate air circulation is needed to cool electronic components inside of the unit. Do not block the cooling fans located on the lower console rear. Blocking these vents may cause unit to overheat and malfunction or create a shock hazard.
WARNING 1.5	Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch on the console rear panel is set to the local voltage setting and ensure that the correct fuses are being used. Refer to Section 12.1 on instructions for fuse replacement.

Electrical Requirements

Electrical requirements for the Ultrasonic Aspirator will vary, depending on the country in which it is to be used. Check the identification label on the rear of the unit for the electrical specifications (refer to Table 11.1, page 60 for specific details).

6.1.1. Equipment List

Please refer to sections 4.3 through 4.4 for a complete list of the SonaStar System components and accessories, including items to perform monopolar COAG.

6.2 Pre-Operative Preperation

For operation of the SonaStar system, the following items are required:

- System console with Wireless footswitch
- IV Bag (500mL is recommended)
- IV Administration Set, Macro Drip
- Suction Canister (1200-2000 cc recommended)
- Suction Tubing
- Remote IR Receiver
- Optional if COAG electrosurgery will be performed: 8 mm adapter and Umbilical Cable
- Sterile Tube set
- Sterile Procedure Tray for available options)Sterile Torque Wrench and Torque Fixture
- Two sterile handpieces (one for the operations, second as a backup)
- Optional if electrosurgery will be performed: Sterile, single-Use Monopolar Handpiece Cable

CAUTION 6.2 It is strongly advised that a sterile backup handpiece be readily available in the operating room as insurance against any contamination or malfunction of the handpiece used during surgery.

NOTE 6.1 The SonaStar system should be fully tested and inspected prior to each procedure. The console, footswitch, handpieces, all cables and accessories should be examined for proper appearance and condition.

NOTE 6.2 The IV pole should be positioned to yield continuous flow and visibility, but elevated IV bag position is not necessary to achieve flow.

CAUTION 6.3 All reusable system components like handpiece, torque wrench and torque fixture are supplied **NON-STERILE**. All items intended for use in the sterile field must be cleaned and sterilized as per the indicated instructions before first clinical use and before every subsequent clinical use.

CAUTION 6.4 The "Vacuum" port of the suction canister should contain a positive shut off float. The aspiration pump connection should be made only to the *VACUUM PORT* to prevent overflow contamination.

6.3 Console Set-up – Part I (In the Non-Sterile Field)

Console Set-up | Part I	
Position the SonaStar	Roll system to the desired location in the OR
Switch Mains Power OFF	Set Mains Power switch on console front panel to OFF.
Connect IV-pole	Connect IV-pole to receptacle in console rear.
Connect Electrical Power	Connect power cord to receptacle on console rear and to wall outlet.

Table 6.1 Console Set-up - Part I

6.4 Handpiece Assembly

The handpiece can be assembled with the procedural pack components either prior to the procedure (Method 1) or in the sterile field (Method 2). If COAG electrosurgery is to be performed, the Single-Use Monopolar Handpiece Cable must be introduced in the sterile field, because this cable is supplied sterile and is NOT sterilizable.

Please refer to Chapter 7 for specifics on the handpiece assembly and disassembly. Once the handpiece has been assembled, continue with part II of the Console Set Up.

CAUTION 6.5 All items intended for use in the sterile field must be cleaned and sterilized as per indicated instructions in Chapter 9 before each clinical use.

CAUTION 6.6 The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.

WARNING 6.1 Use only sterilization cycles specified in this user manual. Do not use any other sterilization cycles. Improper sterilization can lead to handpiece or accessory damage, patient injury, or death.

6.4.1 Method 1 – Handpiece to be assembled PRIOR to procedure in non-sterile field

Method 1 - Handpiece assembled PRIOR to procedure in non-sterile field- Pre sterilization | Part I	
Remove Procedure Pack components	Lay components out on a clean area.
Assemble Handpiece	Assemble as per instructions described in Chapter 7.
Connect Tubing to Handpiece	Open tubing pack. Connect large diameter tubing to the blue aspiration port at the center of the back of the handpiece. Connect the small diameter tubing to the port located towards the front of the handpiece. Attach cable to tubing with clips. The large O-ring, included in some procedural packs, can be slid over the handpiece and placed towards the distal end to hold the irrigation tubing in place if desired.
Prepare Handpiece for Sterilization	Before sterilization, the irrigation and aspiration tubing must be disconnected from handpiece. For an assembled CE handpiece, the housing must be gapped (pulled apart) between the silicone elbow and Housing Tip Assembly to allow proper sterilization.
Sterilize Handpiece and accessories	Sterilize handpiece assembly, torque wrench, torque fixture, tubing and wire stylet as described in Chapter 9.

Table 6.2 Handpiece Assembly Prior to Procedure - Part I

Following Sterilization, the remaining steps are to be performed in the sterile field:

Method 1 - Handpiece assembled PRIOR to procedure in non-sterile field- Post sterilization | Part II	
Open sterilization tray	**Sterile Person** to remove components and lay them out in the sterile field.
Connect Handpiece together	**Sterile Person** to close housing on CE handpiece (where previously separated) between the silicone elbow and Housing Tip Assembly. Confirm that it is aligned correctly.
Reconnect the tubing to the Handpiece	**Sterile Person**: Connect large diameter tubing to the blue aspiration port at the center of the back of the handpiece. Connect the small diameter tubing to the port located towards the front of the handpiece. Attach cable to tubing with clips. The large O-ring, included in some procedural packs, can be slid over the handpiece and placed towards the distal end to hold the irrigation tubing in place if desired.
Make connections to the console in non-sterile field	**Sterile Person** will pass the connector end of the handpiece cable, the flared end of the aspiration tubing and the luer fitting end of the irrigation tubing from the sterile field to the non-sterile person who will connect to the console. Continue with instructions found in Table 6.5.
OPTIONAL: (if RF will be used)	
Connect Monopolar Handpiece Cable	**Sterile Person** If electrosurgery is to be used, open the sterile monopolar handpiece cable and plug the single use, monopolar cable small socket end into the electrosurgical pin receptacle located in the rear cap of the handpiece (as shown on page 41). The cable may be secured using the clips supplied with the aspiration/irrigation tube set. Pass the other end of the cable to the non-sterile person for attachment to the electrosurgery unit as described in Chapter 8.

Table 6.3 Handpiece Assembly Prior to Procedure - Part II

NOTE 6.3 The sterile wire stylet, torque wrench and torque fixture should be retained with the handpiece in the sterile field.

CAUTION 6.7 If COAG is to be performed, the Single-Use Monopolar Handpiece Cable must be introduced in the sterile field, because the cable is supplied sterile, and is NOT AUTOCLAVABLE. DO NOT RE-STERILIZE THE SINGLE-USE MONOPOLAR HANDPIECE CABLE.

6.4.2 Method 2 – Handpiece assembly in the sterile field

NOTE 6.4 The handpiece, torque wrench and torque fixture should be sterilized prior to starting assembly according to Method 2.

WARNING 6.1 Use only sterilization cycles specified in this user manual. Do not use any other sterilization cycles. Improper sterilization can lead to handpiece or accessory damage, patient injury, or death.

Method 2 – Handpiece assembly in the sterile field	
Prepare components	**Non Sterile Person**: Prepare all sterile components (sterilization tray containing handpiece components, tubing set and procedure pack) to be passed into the sterile field for use.
Assemble Handpiece	**Sterile Person**: Receive the sterilization tray and procedure pack into the sterile filed via standard OR procedures. Assemble handpiece as per instructions in Chapter 7.
Connect Tubing to Handpiece	**Non Sterile person:** Open the sterile tubing package and aseptically pass the tubing set into the sterile field. **Sterile Person**: Connect large diameter tubing to the blue aspiration port at the center of the back of the handpiece. Connect the small diameter tubing to the port located towards the front of the handpiece. Attach cable to tubing with clips. The large O-ring, included in some procedural packs, can be slid over the handpiece and placed towards the distal end to hold the irrigation tubing in place if desired.
Make connections to the console in non-sterile field	**Sterile Person** will pass the connector end of the handpiece cable, the flared end of the aspiration tubing and the luer fitting end of the irrigation tubing from the sterile field to the non-sterile person who will connect to the unit. Continue with instructions found in Table 6.5.
OPTIONAL: (if RF will be used)	
Connect Monopolar Handpiece Cable	**Sterile Person** If electrosurgery is to be used, open the monopolar handpiece cable and plug the single use, monopolar cable small socket end into the electrosurgical pin receptacle located in the rear cap of the handpiece (as shown on page 41). The cable may be secured using the clips supplied with the aspiration/irrigation tube set. Pass the other end of the cable to the non-sterile person for attachment to the electrosurgery unit as described in Chapter 8.

Table 6.4 Handpiece Assembly in the Sterile Field

NOTE 6.3 The sterile wire stylet, torque wrench and torque fixture should be retained with the handpiece in the sterile field.

CAUTION 6.7 If COAG is to be performed, the Single-Use Monopolar Handpiece Cable must be introduced in the sterile field, because the cable is supplied sterile, and is NOT AUTOCLAVABLE. DO NOT RE-STERILIZE THE SINGLE-USE MONOPOLAR HANDPIECE CABLE.

6.5 Console Set-up – Part II (In the Non-Sterile Field)

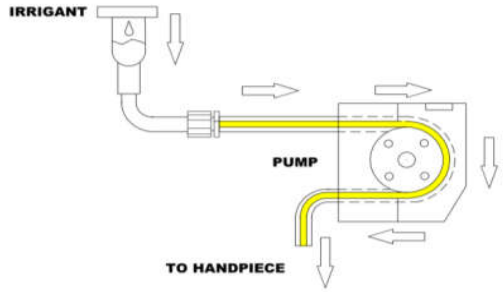
Console Set-up | Part II	
Hang IV bag/bottle	Extend the IV pole and hook the IV bag/bottle on to it.
Connect IV Administration Set	IV administration set should be connected to the last segment of the yellow striped irrigation tubing. Be sure to leave the protective cap on the end of the IV spike.
Spike IV Bag	Remove the protective cap from the IV spike. Spike the IV bag, attaching the administration set to the IV bag. Open the roller clamp all the way.
Connect Handpiece	Attach cable connector receptacle on system side panel. Align red dot on cable connector with red dot on receptacle. Push cable connector into place.
Open pump gate	Open the pump gate by pressing the lever on top of the gate on the right hand side.  Press here to open Figure 6.2 Open irrigation pump gate
Thread tubing through irrigation pump	The tube set consists of two, different size lumens. The smaller diameter tubing, with the yellow stripe and luer lock located at one end, is used for irrigation. The larger diameter tubing is used for aspiration. Route the yellow striped section of the tubing clockwise around the irrigation pump head (see Figure 6.3), following the direction indicated below, ensuring that the luer lock end of the tubing . Route the yellow striped section of the tubing clockwise around the irrigation pump (see) following the direction indicated below, making sure that the luer lock end of the tubing is connected to the IV spike. Pull the section of the irrigation tubing with yellow stripe that attaches to the IV line, taut. **While keeping the tubing taut**, close the pump gate. The flow of irrigant will follow the clockwise rotation of the pump head.  Figure 6.3 Direction of Irrigant Flow
Insert tubing into tissue release valve	Install the aspiration tubing (larger diameter tubing) section (delineated by the two green markers) into the tissue release valve. For easy installation, pull tubing taut prior to inserting into the valve.
Connect tubing to canister	Connect the cuff end of the aspiration tubing to the "Patient" port of the suction canister. Cap all unused ports.
Install the carbon filter (if required)	If the carbon filter is not already installed or has been removed, it must be placed in position. Refer to Section 0, page 55 for more details.
Connect umbilical cable (if RF will be used)	Connect reusable umbilical cable from SonaStar system to Electrocautery unit. Refer to Table 8.2 for additional details.
Position Footswitch	Position the footswitch in a convenient location for use during procedure. Footswitch may be placed in a clear plastic bag to keep clean.
Connect IR receiver (if required)	Connect the remote IR receiver cable to the corresponding receptacle at the console rear. Place the remote IR receiver on the floor in direct line of sight to the wireless footswitch.

Table 6.5 Console set-up - Part II

The SonaStar System is now ready for the system check

NOTE 6.2	The IV pole should be positioned to yield continuous flow and visibility, but elevated IV bag position is not necessary to achieve flow.
WARNING 6.2	Improper connection of the handpiece cable may present a shock hazard. Confirm that handpiece connector is dry prior to plugging it in.
CAUTION 6.4	The "Vacuum" port of the suction canister should contain a positive shut off float. The aspiration pump connection should be made only to the *VACUUM PORT* to prevent overflow contamination.
CAUTION 6.8	Aspiration tissue release valve and irrigation pump can create pinch points. Keep fingers away from these parts while operating unit. Use caution when assembling components.
NOTE 6.5	When assembling aspiration tubing, be sure there are no kinks or blockages along the entire tubing's length. Be sure the cuff end of the aspiration tubing is not deformed at its connection to the patient port on the aspiration canister.
CAUTION 6.9	Incorrect routing of irrigation tubing will result in no flow of irrigating solution to the tip; this may cause damage to handpiece.

6.6 Perform System Check

CAUTION 6.10	The system check should always be done in advance of preparing the patient for surgery to minimize risk to patient in case of system malfunction.
WARNING 6.3	During system check, make sure the tip of the handpiece is free from contact with any object. Allowing contact with the tip may result in damage and/or personal injury.
NOTE 6.6	If there is a high pitched squealing noise after pressing the Setup key, turn the power switch off and check that the tip is torqued properly. If it was, there may not have been adequate irrigation fluid at the tip. Turn the unit back on and depress the flush pedal again making certain there is irrigation at the tip, then press the Setup key.

System Check	
Turn Power On	Switch the power button on top front section of SonaStar to the ON position. The setup LED will be flashing. Make sure handpiece tip is free from contact with anything, that the tubing is not tangled or kinked.
Test Footswitch	Make sure "Low Battery" LED on top of console is not illuminated. If illuminated, please refer to Table 10.1 on replacing the 3 x AA batteries before continuing. Have another staff member depress any pedal or button function of the footswitch. Observe the blue blinking footswitch activation LED on top of the console. This indicates that the connectivity is good.
Perform the System Set Up	Press the FLASHING Setup key. Total time for system check is approximately 45-50 seconds.
Aspiration, Irrigation and Vibration Function Confirmed	During the System check, the SonaStar will go through three different tests: Test 1: The Setup LED will stop blinking and remain illuminated. Ultrasound will be at a low level and the Vibration display will illuminate up to '25' for a few seconds. While the Vibration is at '25', Irrigation LEDs ramp from minimum to maximum, while the speed of the irrigation pump increases. Test 2: The ultrasound will stop and the Vibration display returns to 1st bar. The Irrigation pump will run at a very high speed and the irrigation bar graph will fully illuminate, with the top 2 LED bars flashing. The tissue release valve will close and remain closed for approximately 9 seconds, while the Aspiration LEDs ramp up (the LEDs may oscillate up and down as the levels change). Test 3: After the Aspiration test, the tissue release valve opens and priming continues for 30 seconds. Vibration goes to '40' for a few seconds and then stops. Once completed, an audible tone will heard and the following can be observed: • Irrigation, Aspiration and Vibration LEDs will be illuminated at the minimum settings. • Lap Mode, Preset and Linear buttons will be flashing. • The Setup LED is off. • Irrigation pump will remain ON for 20 seconds after the completion of Setup.
Functions NOT confirmed	Fault Status indicator will illuminate and an error code will appear in the digital display. Refer to troubleshooting section for next steps.

Table 6.6 System check

NOTE 5.2	When the foot pedal on the footswitch is depressed, if the activation LED does not illuminate on the top of the console (see Figure, #2), plug the Remote IR receiver into its receptacle at the console rear and place it within direct line of sight with the footswitch. The Remote IR receiver can be moved closer to the wireless footswitch or linked directly to it to improve signal reception as needed.
CAUTION 4.1	Never operate the handpiece without proper irrigation. Irreparable damage to the handpiece and probe may result if adequate irrigation is not provided to the probe tip.
NOTE 6.7	The tissue release valve should be checked for proper operation by activating Flush. If irrigation flow is immediately aspirated prior to reaching the operative site, proper tubing routing and tissue release valve operation should be checked.
WARNING 6.4	Inadvertent or improper foot pedal depression can cause possible injury to the patient, surgeon, or operating room staff, and can cause product damage. Place foot pedal where it is highly visible and labels can be clearly seen.

The SonaStar System is now ready for use. Refer to Section 1 for General Safety Statements, Section 2 for Indications And Contraindications, Section 3 for Adverse Effects and Section 4 for Use of Main System functions.

6.7 Operative Use of System

Once system setup has been completed, the SonaStar is ready for use by the surgeon.

Set Up System for Operative Use	
Select Operating Levels	Select the desired operating levels for all functions.
Irrigation (YELLOW)	Press the increase/decrease button (▲/▼) until desired level is reached. Be sure to increase the irrigation setting when increasing the vibration setting. Refer to section 5.2 for details.
Aspiration (GREEN)	Press the increase/decrease button (▲/▼) until desired level is reached. Refer to section 5.2 for details.
Vibration (BLUE)	Press the increase/decrease button (▲/▼) until desired level is reached. Refer to section 5.2 for details.
Enable Lap Mode Function (Optional)	If performing a laparoscopic procedure, press the flashing Lap Mode key to enable the function. When enabled, LED is constantly on. See page 23 for more details.
Choose Vibration Mode and Enable	Press the desired control function for the procedure; Preset or Linear. When enabled, the chosen mode's LED is constantly on if enabled. An audible tone will be heard when the footswitch is depressed, with the tone level corresponding to vibration level.
Preset Mode	When the footswitch is depressed it will activate the vibration at the preset level.
Linear Mode	Depressing footswitch will vary the vibration level in proportion to how far the pedal is depressed (like a gas pedal), up to the user selected level.
Begin Procedure	Press the footswitch to begin system operation.

Table 6.7 System Set Up

WARNING 6.5	Do not lay the handpiece on the patient when not in use. When not in use, keep the handpiece on a dry, non-conductive surface with the tip free from contact with any objects.
WARNING 6.6	Make sure that the handpiece is properly positioned at the tissue site before the footswitch is depressed. Once the Preset or Linear key has been chosen, any inadvertent activation of the footswitch will initiate vibration. DO NOT TOUCH tip while activated.

During operation, the vibration, irrigation and aspiration levels may all be adjusted through their corresponding Increase (▲) or Decrease (▼) keys.

The digital display indicates the accumulated time in which vibration has been activated since system power-on. The time clock resets whenever the system is powered off.

If a FAULT condition occurs during the operation of the Ultrasonic Aspirator, the vibration and irrigation will

automatically deactivate. An error code will be displayed along with the fault indicator light and an audible fault indicator. Remove the handpiece from the surgical site and refer to the troubleshooting chapter (Chapter 10, page 57) to diagnose and correct the fault or refer to the label on top of the console. To reset the system after correcting the fault, press either the Preset or Linear key.

To prevent clogging of the aspiration lines, it is recommended periodically to briefly immerse the tip in sterile solution to clear the tubing. If a clog does occur, a sterile wire (or the supplied stylet) tip can be inserted into the distal end of the tip to dislodge the clog.

CAUTION 6.11	Simultaneous use of a standard monopolar device with ultrasound can create sparking and possible tip damage.
CAUTION 6.12	Vibrating tip contact with hard objects can cause tip damage.
CAUTION 6.13	If a fault occurs, suspend operation of handpiece and unit. Determine the cause of the problem and its solution by consulting the troubleshooting tables found in section 10 of this manual.
CAUTION 6.14	DO NOT use any electrosurgical device that exceeds a peak electrosurgical output of 3.5KV. Misonix recommends staying within the limits prescribed by the electrosurgical generator's user manual for the type of procedure being performed, up to a maximum power setting of 70 W. Generally, the lowest setting that proves effective for the procedure being performed should be used.
CAUTION 6.15	Use of a separate monopolar instrument at electrosurgery settings greater than 70 W while simultaneously touching the handpiece probe to tissue can induce faults and possible system damage.
WARNING 6.7	Never activate Vibration or electrosurgery while using the cleaning stylet. Tip damage and operator, patient, or staff injury may result.

6.8 Post-Operative Procedure

Once the procedure has been completed, the system can be prepared for storage.

Post-Operative Tear Down and Storage Procedure	
Remove any residuals in tip and handpiece	Sterile person should immerse the tip of the handpiece in 100 cc of sterile solution and aspirate full volume. This removes residual blood and tissue fragments from inside tip and handpiece.
Turn the unit off	Press the power OFF switch.
Disconnect the remote IR receiver (if used)	Unplug the connector from the rear of the SonaStar system.
Remove handpiece from sterile field	Sterile person should pass handpiece and all accessories outside the sterile field for disassembly.
Disconnect tubing from handpiece	Disconnect irrigation and aspiration tube and discard according to hospital's Biohazard Protocol.
Disassemble handpiece	Follow detailed instruction in Sections 7.5 & 7.6 on how to properly disassemble the handpiece and associated components.
Disconnect monopolar handpiece cable (if used)	Disconnect single use monopolar handpiece cable and discard according to hospital's biohazard procedure.
Clean handpiece	Clean the handpiece according to directions found in Section 9.2.
Clean and store footswitch and remote IR receiver	Wipe down the footswitch and handpiece as per Section 9.2. Place footswitch on the lower part of the console and the IR receiver in the drawer for storage.
Disconnect vacuum hose	Disconnect the suction canister from the vacuum hose. Replace the caps over the open "patient" and "vacuum" ports on the suction canister. Discard the suction canister as per Hospital's Biohazard Protocol.
Wipe down console	Wipe down the SonaStar system as per Section 9.2.
Remove IV pole	Remove IV pole by lifting straight up. Store IV pole in drawer for future use.
Store power cord	Coil the power cord around the brackets at the rear of the unit.

Table 6.8 Post-Operative Console Tear-Down and Storage

7. Handpiece Assembly and Disassembly

The SonaStar System can be used with two different handpieces (short straight or curved extended) along with a variety of tip configurations to perform different applications. The tip choice is determined by the type of target tissue. Please refer to Section o prior to handpiece assembly to determine which method of handpiece assembly will be used (Preassembly outside of the sterile field or complete assembly in the sterile field).

7.1. Items Required for Handpiece Assembly

Prior to assembling the handpiece, have the following items available:

- Handpiece to be assembled (Short Straight or Curved Extended)
- Handpiece tip housing assembly
- Procedure Tray
- Tube Set
- Torque wrench
- Torque Fixture
- Single-Use Monopolar Handpiece Cable pack (if needed)

7.2. Handpiece Inspection

Perform an inspection of the handpiece and all components prior to assembly. Then prepare the procedure tray and necessary items that are provided with the unit. See Chapter 7 for details on assembly options (Preassembly outside of the sterile field or complete assembly in the sterile field).

Handpiece Inspection	
Inspect Handpiece	Inspect the handpiece housing and cable for any visual cracks. Inspect the front metallic portion for surface damage like nicks, gouges and cracks. Inspect the threads for signs of damage or excessive wear. Replace if damaged.
Inspect Mating Surface	Inspect mating face of handpiece and ultrasonic tip to verify that it is clean and dry.

Table 7.1 Handpiece inspection

CAUTION 6.3 All reusable system components like handpiece, torque fixture and torque wrench are supplied industrially cleaned, but **NON-STERILE**. All items intended for use in the sterile field must be cleaned and sterilized as per the indicated instructions before first clinical use and before every subsequent clinical use.

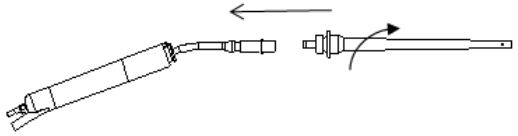
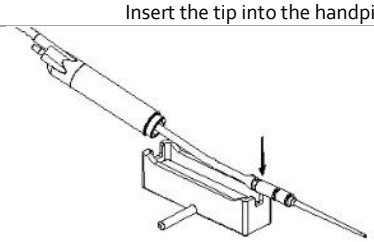
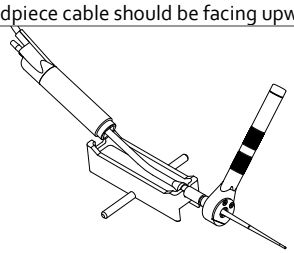
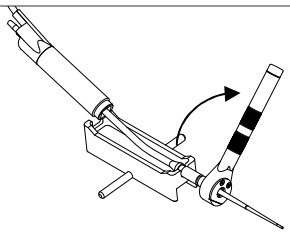
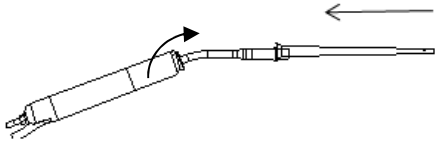
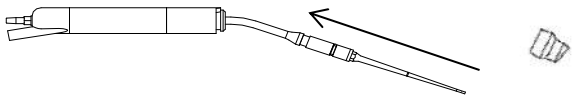
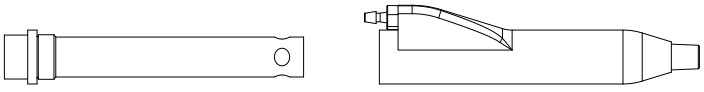
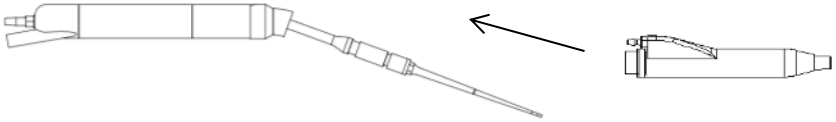
CAUTION 6.4 All items intended for use in the sterile field must be cleaned and sterilized as per indicated instructions in Chapter 9 before each clinical use.

CAUTION 6.5 The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.

NOTE 7.1 Do not attempt to tighten or loosen handpiece components by holding the handpiece case. Always place the handpiece into the torque fixture and use the torque wrench when tightening or un-tightening the tip. Do not over-tighten the tip.

7.3. Handpiece Assembly – Curved Extended Handpiece (CE)

Perform an inspection of the handpiece and all components prior to assembly. Then prepare the procedure tray and necessary items that are provided with the unit. See Chapter 7 for details on assembly options (Preassembly outside of the sterile field or complete assembly in the sterile field).

Handpiece Assembly – Curved Extended (CE) Handpiece		
1. Install the tip	 Insert the tip into the handpiece and hand tighten turning clockwise.	
2. Place handpiece into torque fixture	 Handpiece cable should be facing upward	Place hand over torque fixture and hold handpiece securely down in torque fixture to tighten ultrasonic tip.
3. Tighten the ultrasonic tip	 Slide torque wrench over tip, ensuring that text "Handpiece this side" faces the handpiece	 Rotate clockwise until two clicks are heard. Remove wrench.
4. Install the Mid-Housing	 Slide the Front Housing onto the handpiece and then tighten by turning clockwise.	
5. Mount silicone elbow	 Snap silicone elbow onto Mid-Housing and align with notch on silicone elbow	
6. Replace O-ring (if required)	Slide the small O-ring over the probe and into the groove of the front driver. Replacement of this O-ring is not required for each use. Replace only if O-ring becomes worn or damaged. Medical grade silicone lubricant may be used to lubricate this O-ring.	
7. Assemble housing tip assembly	 Screw together the inner and outer sleeves	
8. Install the rigid housing tip assembly	 Push the rigid tip assembly onto the silicone elbow until the silicone elbow makes contact with the shoulder of the rigid Housing tip assembly.	

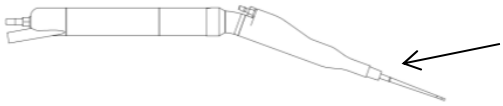
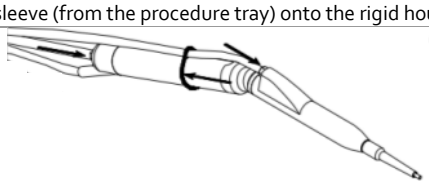
9. Install the silicone sleeve	 Install the silicone sleeve (from the procedure tray) onto the rigid housing tip assembly.
10. Attach the silicone tubing and o-ring	 Attach the smaller diameter tubing to the aspiration port on the front housing. Attach the larger diameter tubing to the blue connector on the rear of the handpiece. Slide the black o-ring over the handpiece up to the mid-section to secure the tubing.

Table 7.2 Short Straight Handpiece assembly

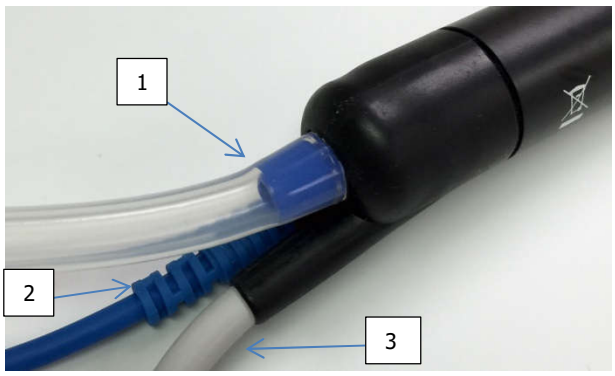
The handpiece is now ready for use and can be connected to the SonaStar System.

Figure 7.1 Fully assembled Curved Extended handpiece

7.4. Electrosurgery Connector Assembly

The electrosurgery connector is located on the rear cap of the handpiece, adjacent to the cable strain relief.
For electrosurgery capability, plug the appropriate end of the Single-Use Monopolar Handpiece Cable into the handpiece end, as shown in
Figure 7.2

WARNING 7.1	Improper assembly of Single-Use Monopolar Handpiece Cable to endcap can expose potentially dangerous electrosurgery voltage. Always make sure the Single-Use Monopolar Handpiece Cable socket is firmly and fully engaged onto the pin in the endcap.
WARNING 7.2	Ensure that the aspiration tubing is fully seated onto the Aspiration Port in the base of the handpiece.
NOTE 7.2	Monopolar Handpiece Cable is supplied sterile and is NOT sterilizable.



1. Aspiration Port with tubing connected
2. Single-Use Monopolar Cable connected
3. Ultrasound Power Cable

Figure 7.2 SonaStar Handpiece with Monopolar Cable Connection

7.5. Handpiece Disassembly – Short Straight Handpiece (SS)

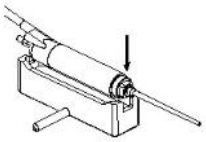
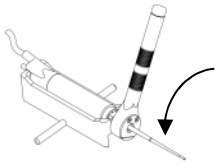
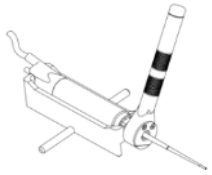
Handpiece Disassembly – Short Straight (SS) Handpiece		
1. Remove the o-ring from the handpiece and disconnect the tubing from the handpiece connector and the aspiration port		
2. Remove the silicone/rigid sleeve from the front housing		
3. Remove the plastic front housing from the handpiece (front housing varies based upon tip selection)		
4. Remove the tip	 Place the handpiece into the torque fixture (cable should be facing upward).	
5. Loosen the ultrasonic tip	 Slide torque wrench over tip, ensuring that text "Handpiece this side" faces the handpiece.	Rotate counter clockwise to loosen the tip. Remove wrench. 
6. Remove the Tip	Hand loosen and remove the tip by turning counter clockwise.	

Table 7.3 Short Straight Handpiece Disassembly

WARNING 7.3 Remove all housing components, silicone elbow, silicone sleeve and ultrasonic tip from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.

7.6. Handpiece Disassembly – Curved Extended Handpiece (CE)

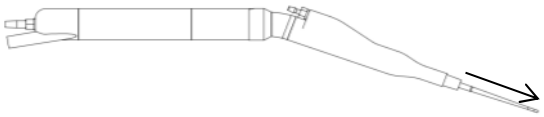
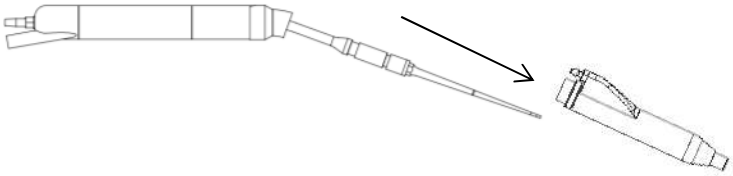
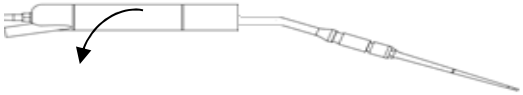
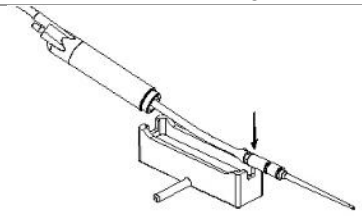
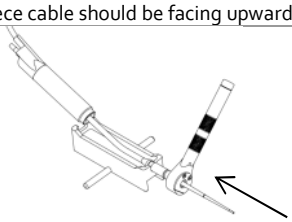
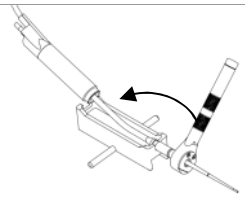
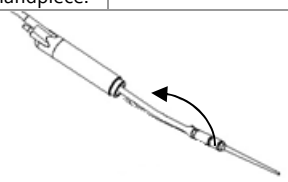
Handpiece Disassembly – Curved Extended (CE) Handpiece		
1. Remove the o-ring from the handpiece and disconnect the tubing from the handpiece connector and the aspiration port		
2. Remove the silicone sleeve	 Remove the silicone sleeve from the rigid housing tip assembly.	
3. Remove the rigid housing tip assembly	 Pull the rigid housing tip assembly from the silicone elbow (do not discard).	
4. Disassemble housing tip assembly	 Unscrew the inner sleeve from the outer sleeve and separate from housing (do not discard).	
5. Remove silicone elbow	 Pull the silicone elbow from the handpiece (do not discard).	
6. Remove the Mid-Housing	 Turn the front housing counter clockwise and slide over the tip to remove (do not discard).	
7. Place handpiece into torque fixture	 Handpiece cable should be facing upward.	
8. Loosen the ultrasonic tip	 Slide torque wrench over tip, ensuring that text "Handpiece this side" faces the handpiece.	 Rotate counter clockwise until the tip is loosened. Remove wrench.
9. emove the tip	 Hand loosen and remove the tip by turning counter clockwise.	

Table 7.4 Short Straight Handpiece Disassembly

8. Monopolar COAG Guidelines

8.1. Background

The SonaStar system is designed to the delivery of RF energy via its instruments, from approved electrosurgical units. Although these electrosurgery units support bipolar and monopolar instruments, as well as CUT and COAG modes, the SonaStar is designed for use in monopolar COAG mode ONLY. CUT mode cannot be accessed when delivering RF energy through the SonaStar instrument to the target tissue.

The RF energy is delivered via a cable connecting the SonaStar HP to the RF generator, through the handpiece and the probe, where it contacts tissue. The patient is fitted with one or more ground pads, as per common monopolar electrosurgery practice.
This chapter will outline the interface of the SonaStar with the electrosurgical generator. For detailed instructions, guidelines, cautions, and indications, consult the appropriate electrosurgical generator user's manual.

Currently the following electrosurgical generators are approved for use with the SonaStar:

- ValleyLab™ Force 2 Electrocautery Unit
- ValleyLab Force FX™ Electrosurgical Generator
- Conmed® System 2400™ Electrosurgical Generator
- Conmed System 7500™ Electrosurgical Generator
- Erbe™ ICC 300

Figure 8.1 Console with Force 2 Electrosurgical Generator

NOTE 8.1 The SonaStar system has been designed for use with monopolar COAG using a Misonix approved electrosurgical generator. CUT mode has NOT been approved for use with the SonaStar. DO NOT use this mode with the SonaStar.

The items needed for interfacing a SonaStar system with an approved electrosurgical device are listed below, in Table 8.1

Accessories for Monopolar COAG			
REF	**Description**	**Cross Reference**	**Type**
CFSM6-C140	Valley Lab Force 2 Electrosurgery Generator Umbilical Cable	2	Reusable
CFSM6-C141	Conmed, Sabre 2400 & Model 7500 Electrosurgery Umbilical Cable	2	Reusable
CFSM6-C142	Erbe ICC 300 Electrosurgical Generator Umbilical Cable	2	Reusable
CFSM4-M100	8mm Monopolar RF Cable Connector	not shown	Reusable
CFSM5-D050	Single-Use Monopolar Handpiece Cable (5-pack)	5	Single Use

Table 8.1 Monopolar COAG interface accessories

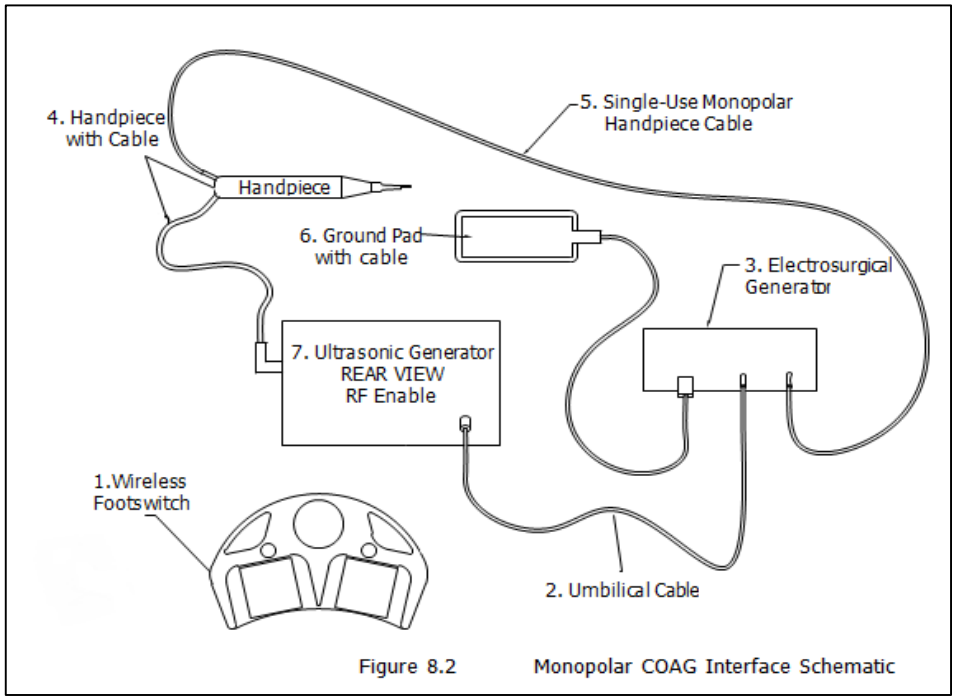
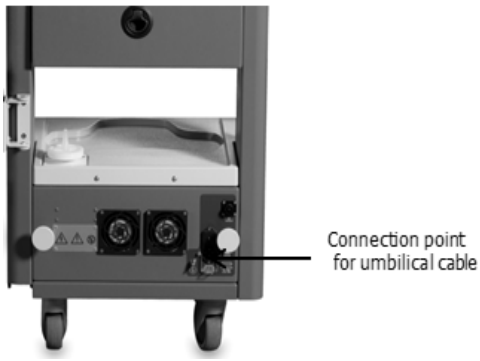


Figure 8.2 Monopolar COAG Interface Schematic

1 Wireless Footswitch
2 Umbilical Cable
3 Electrosurgical Generator
4 Handpiece with Cable
5 Single-use Monopolar Handpiece Cable
6 Ground Pad w/ Cable
7 Ultrasonic Generator

8.2. Preparing the System for Monopolar COAG Use

Consult the user manual supplied with the electrosurgery unit for operating instructions, safety guidelines, and setup. To enable monopolar COAG through the SonaStar handpiece, perform the following steps:

Cable Attachment for Monopolar COAG Function		
1. **Plug appropriate umbilical cable into SonaStar**	 Plug cable into rear of SonaStar console.	Refer to Table 8.1 for list of available cables.
2. **Plug umbilical cable into electrosurgery unit**	 Plug the other end of the cable into the footswitch connector typically located on the rear of the electrosurgery system.	For example: On the Force 2 generator, attach the cable to the footswitch connector marked "Monopolar Footswitch" on the back of the unit (see image to the left). Other units connect in a similar manner; consult documentation supplied with these umbilical cables.

3.	**Connect monopolar handpiece cable to handpiece**	 **Sterile Person** will plug the single-use, blue monopolar handpiece cable's small socket end onto the electrosurgical pin receptacle in the rear cap of the SonaStar handpiece. Refer to Table 6.4 and Table 6.5 for details.	The cable may be secured to the tube set using the clips (not shown) supplied with the aspiration/irrigation tube set.
4.	**Connect monopolar handpiece cable to electrosurgery unit**	 **Sterile person** will pass the other end of the cable to the non-sterile. Non sterile person will plug this end into the appropriate 4 mm monopolar receptacle (1) on the electrosurgical generator. (8 mm adapter may be required for connection – see Table 8.1).	(1)Monopolar Cable Connection (2)Ground Pad connection Force 2 front connections are shown to the left. Other units connect in a similar manner.
5.	**Connect ground pad cable**	Connect the ground pad cable to the electrosurgical generator (2) and attach to the patient as per the electrosurgical generator's instruction found in the user manual.	

Table 8.2 Connecting an Electrosurgical System to perform Monopolar COAG

The electrosurgical generator may now be powered and used as per manufacturer's guidelines.

8.3. Using Monopolar COAG with the SonaStar System

Refer to the user manual supplied with the electrosurgical generator for all settings, conventions, and safety guidelines. Setup the electrosurgical generator interface with the footswitch as per section 8.2.

- To use the COAG feature, the COAG button atop the SonaStar footswitch may be depressed for COAG only operation, or the VIBRATION + COAG pedal on the right-hand side of the footswitch may be depressed for simultaneous operation.
- Misonix recommends staying within the limits prescribed by the electrosurgical generator's user manual for the type of procedure being performed, up to a maximum power setting of 70 W. Generally, the lowest setting that proves effective for the procedure being performed should be used.
- During activation of the COAG button, there is no irrigation present at the tip. When the VIBRATION + COAG pedal is activated, irrigation will flow to the tip at the user preset level.

CAUTION 6.14	DO NOT use any electrosurgical device that exceeds a peak electrosurgical output of 3.5KV. Misonix recommends staying within the limits prescribed by the electrosurgical generator's user manual for the type of procedure being performed, up to a maximum power setting of 70 W. Generally, the lowest setting that proves effective for the procedure being performed should be used.
WARNING 8.1	Saline leakage through handpiece housing can cause a hazard when electrosurgery is energized. Always make sure the handpiece housing parts are properly assembled, with mating parts firmly in contact.

- During electrosurgery use, the tip may develop eschar buildup. To maximize efficiency, the tip should be wiped clean with a sterile pad and alcohol. Briefly activating vibration with the tip immersed in sterile saline will also clean the tip and flush the vacuum system lines.
- After use, the system may be disassembled and the Single-Use Monopolar Handpiece Cable should be disposed of as per Hospital's Biohazard Protocol. *The umbilical cable is reusable and should NOT be discarded.*
- Follow the electrosurgical generator manufacturer's guidelines for dismantling and storing the unit.
- Proceed to the next section to prepare the footswitch and associated components for storage (See section 6.8).

NOTE 8.2	Do not clean the tip with abrasive or metallic materials, as damage to the tip may result in device failure.

9. Cleaning, Sterilization and Maintenance

1. Misonix recommends the use of CaviWipes1™ or equivalent surface disinfectant wipes. Please follow the manufacturer's instructions for surface cleaning and disinfection including without limitation, the use of Personal Protection Equipment (PPE) for bloodborne pathogens. Dispose of wipes with contaminated wastes.

9.1. Disassembly

Handpiece Disassembly
Disassemble all handpiece components in reverse order of assembly. Please refer to Section 7.5 and 7.6 for disassembly post use.

Dispose of Single-Use Items
The following items are considered single use items and must not be reused. Reuse of these items could result in severe patient injury or death.

- Tube Set
- Ultrasonic Tip
- Silicone Sleeve
- Wire Stylet

Once used, dispose of above items in accordance with standard hospital procedures for disposal of bio contaminated wastes.

WARNING 7.2	Remove sleeve, front housing, and ultrasonic tip from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.
WARNING 9.1	Single-use items should be discarded following each surgical procedure according to hospital protocol for disposal of bio contaminated wastes. **Do not attempt to reuse or re-sterilize any single-use items. Dispose of ultrasonic tips in a sharps container.**

9.2. Cleaning

Misonix LLC has validated the cleaning procedures outlined below.

Misonix continually updates its sterilization and cleaning instructions as required. For the latest instructions and reuse recommendations please refer to the *Reuse Instructions* found in the *Downloads* section under www.misonix.com/sonastar/.

WARNING 9.2	All reusable handpiece parts and accessories must be properly cleaned and sterilized before each use as per instructions contained in this manual. Failure to do so may lead to infections, which can ultimately cause patient death.
WARNING 9.3	Misonix LLC has validated all cleaning and sterilization cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the SonaStar System and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilization if they differ from the procedures as outlined in this manual.

Clean And Disinfect Reusable Items
The following items are considered reusable items and should be cleaned as recommended (see Table 9.3 for part numbers):

- Handpiece
- Housing Components*
- Torque Fixture
- Torque Wrench
- Gray, Silicone Elbow Connector on the CE Handpiece

*Includes Rigid Front Sleeve found on Curved Extended Handpiece only.

9.2.1 Manual Cleaning Procedure

Wrenches	
Wash & Brush	6 Wash items with hot water mixed with an enzymatic detergent such as ASP Enzol® or Steris Prolystica® according to standard hospital protocol. Follow manufacturer's directions for preparing solutions. 7 Wrenches may be fully immersed. 8 Brush all passages at least four (4) times from FRONT to REAR, rotating the brushes during insertion and inserting the brushes fully. This ensures clearing of debris from the internal passages. 9 Item's exterior surface can be cleaned using a standard soft bristle cleaning brush.
Rinse	10 Rinse item under warm running water for a minimum of 1 minute to clear soap residue.
Dry	11 Dry item fully with absorbent towel or paper. Dispose of cloth or paper in accordance with Hospital practices for contaminated wastes.
Inspect	• Inspect wrenches and remove any item which shows signs of damage (cracks, gouges, fractures etc.). Mark damaged items clearly to prevent future use before disposal.

Table 9.1 Cleaning of wrenches

Handpiece, Front Housing and CE Rigid Front Sleeve and Silicone Connector*	
Wipe Cable	12 Wipe cable with cloth or absorbent paper moistened with an enzymatic detergent such as ASP Enzol® or Steris Prolystica®. Follow manufacturer's directions for preparing solutions. Clean all surfaces of bloodstains and obvious signs of contamination.
Brush & Wash	13 Wash and brush handpiece and/or accessories with hot water mixed with an enzymatic detergent such as ASP Enzol® or Steris Prolystica®. Follow manufacturer's directions for preparing solutions. 14 The handpiece cannot be immersed. 15 Brush all passages at least four (4) times from FRONT to REAR, rotating the brushes during insertion and inserting the brushes fully. This insures clearing of debris from the internal passages. • Through-hole diameters of handpiece components: o Handpiece Lumen (both): 3.2mm (.13") o Housing Tip assemblies (CE): 5.8 - 12.7mm (.23" - .50") o Silicone Elbow (CE): 12.7 - 17.7mm (.50" - .70") o Irrigation Connector: 1.5 - 2.2mm (.06" - .09") o Mid-Housing (CE): 11.4 - 16.7mm (.45" - .66") o Plastic Front Housing (Irrigation Housing SS): 16 Brush the cavity surrounding the electrosurgery pin molded in the rear (proximal) end of the handpiece cavity which is 1.3mm (0.05") x 10.1mm (0.40") in addition to any other cavities visible on the handpiece. 17 The item's exterior surface can be cleaned using a standard soft bristle cleaning brush.
Rinse	18 Rinse item under warm running water for a minimum of 1 minute to clear soap residue. **19 Repeat brush-wash-rinse procedure at least 4 times.**
Dry	20 Dry item fully with absorbent towel or paper. Dispose of cloth or paper in accordance with Hospital or Clinic practices for contaminated wastes.
Inspect	21 Inspect handpiece and cable and remove any item which shows signs of damage (cracks, gouges, fractures etc.). Mark damaged items clearly to prevent future use before disposal.
Post-Cleaning	Inspect all items for cleanliness and damage following cleaning and prior to terminal sterilization.

**Rigid Front Sleeve and Silicone Connector available on Curved Extended Handpiece only.*

Table 9.2 Cleaning of handpiece

CAUTION 9.1 Do not use ultrasonic cleaners to clean the handpiece as this method could damage handpiece.

CAUTION 9.2 Be certain to clear debris from all internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving.

CAUTION 9.3 Do not immerse ultrasonic console, handpiece, irrigation pump, remote footswitch, IR receiver or electric cables. These items are not sealed against liquids and damage to equipment will result.

9.2.2 Automated Wash Procedure

<table>
<tr><th colspan="2">Handpiece, Front Housing, Wrenches and CE Rigid Front Sleeve and Silicone Connector*</th></tr>
<tr><td>Point of Use</td><td>Immediately following procedure perform the following:
22 Flush handpiece lumen with minimum 100 mL of saline to clear the bore of debris.
23 Wipe all reusable devices to remove visible blood and debris.

CAUTION: DO NOT use saline to wet the tray and tray contents before transport to the decontamination processing area.

NOTE: If transport to the decontamination processing area is delayed, cover the tray with a damp cloth or spray the tray and its contents with a pre-cleaning foam. The pre-cleaning foam will minimize the drying of soil and facilitate later decontamination processing.</td></tr>
<tr><td>Pre-Cleaning</td><td>24 The following should be performed on a disassembled handpiece:
25 Remove the probe and disassemble all housing components.
26 Prepare neodisher® MediClean forte at 3.9 mL per liter of water (5/8 oz. per gallon water). Water should be lukewarm (<40°C, <104°F).
27 Use a tight-fitting brush dipped in the prepared cleaning solution to clean the cavity surrounding the electrosurgery pin molded in the proximal end of the handpiece in addition to any other cavities visible on the handpiece.
28 Use a tight-fitting brush dipped in the prepared cleaning solution to clean the lumen of the handpiece by inserting the brush fully through the lumen until visible from the other side a minimum of four times, rotating the brush as it is inserted.
29 Rinse all residual soap from the handpiece under warm running water for a minimum of one minute.
30 Visually inspect internal and external surfaces of the handpiece including the pin cavity and repeat the above steps as required until all visible debris and staining are removed.</td></tr>
<tr><td>Automated Wash and Disinfection</td><td>Place the handpiece and all reusable components and accessories into the washer; position all lumened devices to allow for drainage.

Process the handpiece and all reusable components and accessories using the following cycle parameters:

<table>
<tr><th>Phase</th><th>Time*</th><th>Parameters</th><th>Detergent Type and Concentration</th></tr>
<tr><td>Pre-Wash 1</td><td>2 minutes</td><td>Cold tap or purified water</td><td>None</td></tr>
<tr><td>Wash 1</td><td>2 minutes</td><td>≥65.5°C (150°F)</td><td>neodisher® MediClean forte 2mL/L (¼ oz. / gallon)</td></tr>
<tr><td>Rinse 1</td><td>1 minute</td><td>Hot tap water</td><td>None</td></tr>
<tr><td>Disinfection</td><td>1 minute</td><td>≥90°C (194°F)</td><td>None</td></tr>
<tr><td>Drying</td><td>6 minutes</td><td>≥98.8 °C (210°F)</td><td>None</td></tr>
</table>
*Durations listed are minimum acceptable. Longer durations than those specified for cleaning and disinfection are acceptable.</td></tr>
<tr><td>Post-Cleaning</td><td>Inspect all items for cleanliness and damage following cleaning and prior to terminal sterilization.</td></tr>
</table>

**Rigid Front Sleeve and Silicone Connector available on Curved Extended Handpiece only.*

Table 9.3 Cleaning of Handpiece and Wrenches

9.2.3 Cleaning of console, footswitch and IR receiver

1. Misonix recommends the use of CaviWipes1™ or equivalent surface disinfectant wipes. Please follow the manufacturer's instructions for surface cleaning and disinfection including without limitation, the use of Personal Protection Equipment (PPE) for bloodborne pathogens. Dispose of wipes with contaminated wastes.

Console, Footswitch and IR receiver	
Wipe Surfaces	31 Wipe console, footswitch and IR receiver with cloth or absorbent paper moistened with an enzymatic detergent such as ASP Enzol® or Steris Prolystica®. Follow manufacturer's directions for preparing solutions. Clean all surfaces of bloodstains and obvious signs of contamination. 32 Dispose of cloth or paper with contaminated waste.

Table 9.4 Cleaning of console, footswitch and IR receiver

9.3. Sterilization of Reusable Sterile Field Components

Reusable, Autoclavable Components	
CFSX6-H321	SonaStar Short Straight 23 kHz Universal Handpiece
CFSX6-H322	SonaStar Curved Extended 23kHz Handpiece
CFSM2-T018	Autoclavable Torque Wrench
CFSM2-T222	Autoclavable Torque Fixture
CFSM6-H175	Aspiration Front Housing for Curved Extended Handpiece
CFSM6-H183	Aspiration Long Front Housing for Short Straight Handpiece
CFSM6-H185	Aspiration Front Housing for Short Straight Handpiece
CFSM6-H190	Laparoscopic Rigid Sheath for Short Straight Handpiece
CFSS2-S148	Silicone Elbow for Curved Extended Handpiece
MXA-L002	SonaStar, 1.9 mm Standard, Laparoscopic Probe, long*

Table 9.3 Autoclavable components *MXA-L002 Laparoscopic Probe can be used up to 6 times.

NOTE 9.1 Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage.

Sterilization methods and terminology are bades on ANSI/AAMI ST81 and EN ISO 17664:2004 standards.

9.3.1 For Handpiece Disassembled

For sterilizing the Curved Extended (CE) or Short Straight (SS) Handpiece in a DISSASSEMBLED condition, the probe, tubing, and housing should be removed from the handpiece. Please refer to Section 7.3 for more details.

With Misonix Sterilization Tray

	132°C (270°F)	134-137°C (274-279°F)
Configuration	Items placed in Misonix Sterilization Tray MXA-TRAY or MXA-TRAY-2[1]	Items placed in Misonix Sterilization Tray MXA-TRAY or MXA-TRAY-2[1]
Cycle	Prevacuum	Prevacuum
Preconditioning Pulses	4	4
Minimum Exposure Time	8 minutes*	4 minutes*
Minimum Dry Time	30 minutes	30 minutes

Items Wrapped – No Tray Used

	132°C (270°F)	**134-137°C** (274-279°F)
Configuration	Items wrapped, NO TRAY[2]	Items wrapped, NO TRAY[2]
Cycle	Prevacuum	Prevacuum
Preconditioning Pulses	4	4
Minimum Exposure Time	4 minutes*	3 minutes*
Minimum Dry Time	45 minutes	30 minutes

Table 9.4 Steam sterilization cycles

[1]Tray wrapped in Kimberly Clark KC300 KIMGUARD sterilization wrap.

[2]NO TRAY. Wrapped in Kimberly Clark KC300 or KC600 KIMGUARD sterilization wrap.

*Exposure time can be increased up to a maximum of 18 minutes to comply with local requirements and/or recommendations of the World Health Organization (WHO), Robert Koch Institute (RKI), etc. Misonix Inc reusable medical devices are able to sustain such sterilization cycles.

9.3.2 For Handpiece Assembled

For sterilizing the curved extended (CE) or short straight (SS) handpiece in ASSEMBLED condition, the probe and housing should be assembled to the handpiece. Please refer to Table 6.2 for more details. In addition, the tube set must be removed from the handpiece, and the housing of the CE handpiece must be gapped (pulled apart) between the silicone elbow and Housing tip assembly to allow proper sterilization.

	132°C (270°F)	**134-137°C** (274-279°F)	**134-137°C** (274-279°F)
Sterilization Method	Moist Heat (Autoclave)	Moist Heat (Autoclave)	Moist Heat (Autoclave)
Configuration	Items wrapped, NO TRAY[1]	Items wrapped, NO TRAY[1]	Items wrapped, NO TRAY[1]
Cycle	Prevacuum	Prevacuum	**GRAVITY**
Preconditioning Pulses	3	3	N/A
Minimum Exposure Time	12 minutes	8 minutes	40 minutes
Minimum Dry Time	5 minutes	5 minutes	5 minutes

[1]NO TRAY. Wrapped in Kimberly Clark KC300 or KC600 KIMGUARD sterilization wrap.

9.4. Deviations from Decontamination, Cleaning And Sterilization Instructions

Misonix LLC has validated all cleaning and sterilization cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the SonaStar System and related accessories be followed. It is the responsibility of the user to validate procedures for cleaning and/or sterilization of this device or any accessories used with it, if they differ from the procedures as outlined in this manual.

Should the user wish further information or instructions regarding any aspect of cleaning or sterilizing procedures, please contact Misonix LLC or an Authorized Representative.

9.5. Moving the Unit

Before moving the SonaStar within the hospital, please perform the following procedures:

1. Disconnect all plugs and coil the power cord around the brackets at the rear of the unit.
2. Locate the wireless footswitch and remove the remote IR receiver. Place the footswitch on the bottom shelf of the console. The IR receiver can be placed in the accessory drawer.
3. Do not attempt to use the IV pole as a support when moving the unit. If the unit must be removed from the hospital, it should be prepared and secured for transfer by a qualified technical person.

9.6 Periodic Maintenance

All periodic maintenance is to be performed by the hospital's technical staff, trained OR staff member or by a Misonix, LLC authorized technical personnel.

1. Change both the internal and external aspiration filters, and the activated carbon filter at 6-month intervals, under normal conditions. Despite the similar appearance of the internal and external filters, they are distinct. Refer to Table 4.1 for the proper replacement part number.

Figure 9.1: ***External Filter Installed***

Figure 9.2: ***Internal Filter Assembly***

2. If the external aspiration filter appears soiled, change immediately. If not, poor aspiration will be experienced. Treat as a contaminated part.

9.6.1 Replacing the External Filter

Replacing the External Filter (CFSS2-F019)	
Remove the existing External Filter	Unscrew the External Vacuum Filter counter-clockwise by hand.
Install the new External filter	Remove the External Filter from the packaging. Screw-in clockwise the External Filter by hand.

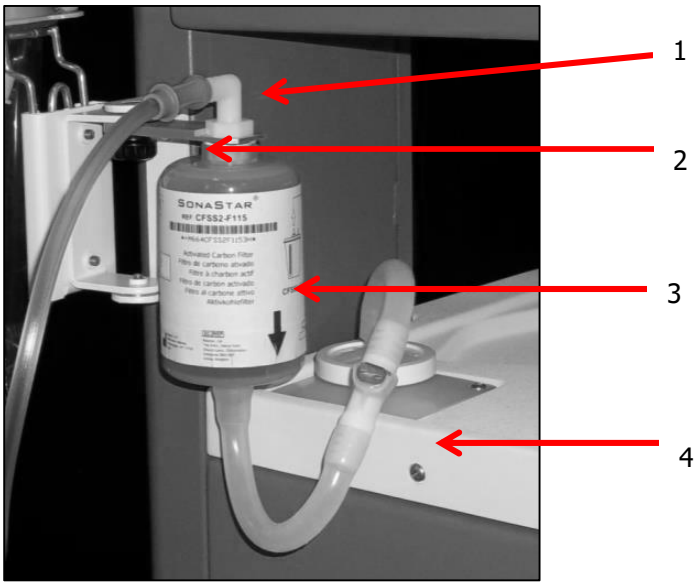
9.6.2 Replacing the Internal Filter

Replacing the Internal Filter (CFSS2-F025)	
Remove the existing Internal Filter	Use the Phillips screwdriver to remove 4 screws securing the Vacuum Filter Union to the top of the Base Assembly and lift up the Vacuum Filter Union. Remove the vacuum tube connected to the manifold. Remove the cable clamp and disconnect the tube from the Internal Vacuum Filter. Use pliers, if necessary. Unscrew the Internal Vacuum Filter from the Vacuum Filter Union.
Install the new Internal Filter	Remove the Internal Filter from the packaging. Apply Teflon® tape to the thread on the Internal Filter that connects to the brass fitting. Reverse the above "Removal" procedure.

3. The Torque Wrench (CFSM2-T018) should be returned to Misonix for recalibration every 12 months, regardless of use. Please contact Misonix for details. Refer to Chapter 12 for additional information on how to return products for repair/calibration.
4. In the wireless footswitch, three "AA" batteries require change with new alkaline batteries when red LED indicator light is illuminated on the top of console.

9.6.3 Replacing the Activated Carbon Filter

Included with your SonaStar system is an activated carbon filter assembly and tubing. The filter assembly protects the vacuum pump and should be used for all procedures. It is recommended that the carbon filter is to be changed at 6 month intervals under normal conditions.



1 Plastic elbow fitting
2 Filter mounting bracket
3 Activated carbon filter
4 Quick connect coupling

Figure 9.1 Carbon Filter Assembly

Replacing the Activated Carbon Filter	
Remove the existing carbon filter	Press the quick connect fitting located between the carbon filter and the vacuum filter to disconnect the carbon filter. While holding the plastic elbow fitting with one hand, twist the carbon filter counterclockwise until it is free from the mounting bracket.
Install the new carbon filter	Remove the filter from the packaging. Place the plastic elbow connector into the filter mounting bracket, directing its open end towards the canister. Place the two o-rings on the threaded portion of the elbow connector, proximal to the mounting bracket. Position the threaded end of the elbow connector against the carbon filter's threaded port. Slowly and carefully turn the filter in a clockwise direction (when looking from the bottom up), until the filter is securely tightened against the elbow connector.
Connect the suction tubing	Attach one end of the suction tubing to the elbow connector located on the top of the filter assembly – see Figure 9.1, #1. Connect the other end of the suction tubing to the vacuum port (center port) on the suction canister – see Figure 5.6, page 26.
Connect the carbon filter to the external filter	Using the quick connect fittings, insert the connector on the external vacuum filter tubing into the connector on the carbon filter tubing, see Figure 5.6, page 26.

Table 9.5 Replacing the Activated Carbon Filter

10. Troubleshooting

The SonaStar is equipped with self-test routines which monitor system operation. If a system malfunction is detected, the FAULT light illuminates  and an error code appears on the digital display. Should a fault occur, consult Table 10.1 and Table 10.2 in this chapter.

NOTE 10.1 The following tables do not attempt to anticipate all possible failures. Any fault not listed in the tables must be referred to an authorized Misonix, LLC technical representative.

10.1. Possible Malfunctions, Not Associated with an Error Code

Possible system symptoms, indicating a malfunction, that do not generate an error code are listed below. If the corrective action listed in the table does not solve the problem, contact your authorized Misonix, LLC service representative.

Problem	Corrective action
System does not power on	• Check power outlet • Check fuses F1, F2 and F3 on rear panel.
No ultrasonic vibration	• Check footswitch. • Verify Footswitch Actuation LED indicator illuminates. If no illumination refer to Footswitch Actuation LED indicator section below. • Make sure either Preset or Linear has been pressed and that its mode indicator is on. • Check handpiece cable and connection. • Replace handpiece.
No aspiration	• Use stylet to remove clog. • Immerse tip in fluid and check that fluid collects in canister. • Check fluid collection in canister. • Make sure that unused ports on the suction canister are covered with caps, and that the canister is not damaged. • Check tubing and connections to and from suction canister for secure fitting. • Make sure there are no kinks in tubing. • Check vacuum coming out of vacuum filter. If weak, change aspiration filter assembly. • Check that the internal and external filter are not clogged. • Ascertain that "tissue release" valve functions (opens and closes) properly during system test. • Canister overflow (hydrophobic filter clogged or blocked).
No irrigation	• Make sure IV tubing roller clamp is in the open flow position. • Make sure bag or bottle has fluid. • Check for kinks in tubing. • Check that irrigation pump is rotating and tubing is properly installed. Yellow striped section of the tubing should be routed clockwise as shown in Table 6.7.
No footswitch actuation LED indicator	• Check "Low Battery" Indicator on top of console, if battery indicator is red; change three (3) AA batteries in wireless footswitch battery compartment on bottom of footswitch. • Reorient or relocate the footswitch to stop signal from being blocked by surrounding table or equipment. • Connect Remote IR Receiver; place near footswitch or hook into footswitch as required. • Turn equipment in vicinity off to isolate other equipment from interfering with wireless signal.

Table 10.1 Troubleshooting

10.2. Error Code Messages

Error code messages may appear on the digital display and can be attended to by hospital staff. Upon correction of the problem, the system may be reset by pressing the Linear or Preset key, and operation is resumed.

Error Code Messages		
Error Code	**Possible Cause**	**Corrective action**
E1 - Tip problem		
	No water at tip	• Point handpiece down, depress flush pedal until water emerges from the tip.
	Overloaded tip	• Avoid applying excessive pressure to the tip.
	Clogged tip	• Check system for clogs and dislodge using wire stylet. Immerse tip in fluid, depress flush pedal and check if irrigation fluid collects in the canister.
	Tip not torqued properly	• Re-torque tip. • Check for debris or wear at the connection between the tip and handpiece.
	Handpiece housing improperly assembled	• Recheck assembly according to Section 0.
	Damaged tip	• Replace tip.
	Handpiece problem	• Replace handpiece.
E2 – Handpiece Problem		
	Handpiece not properly connected	• Ensure that the handpiece is properly connected.
	Leakage current detected by handpiece circuit	• Could occur if using electrosurgery. Confirm electrosurgical unit settings below 70W. • In case of repeated failures replace handpiece.
	Handpiece problem	• Replace handpiece.
E3 – Handpiece / Irrigation / Electronics Problem		
	Handpiece tip excursion problem.	• Re-torque tip. • Change tip. • Change handpiece.
	Low/High irrigation flow	• Check irrigation tubing for proper loading into pump, jams, and kinks. Ensure pump is rotating.
	Electronics Problem	• If error re-occurs contact your Misonix, LLC service representative.
E4 – Not Used		
E5 – Not Used		
E6 – Handpiece Connection Fault		
	Handpiece not properly connected	• Check handpiece connection.
	Handpiece problem	• Replace handpiece.

Table 10.2 Error Code Messages

10.3. Clearing Faults

A fault should be cleared using the following method:

1. Fix the problem indicated by the fault (see Table 10.1 and Table 10.2).
2. Clear the fault on the front panel by pressing either the Preset or Linear keys, which will be blinking.
3. When the fault has been cleared, the system will be in Standby mode and will retain the original settings prior to the fault.

4. The fault indicator bell should cease. If it does not, either the fault has not been corrected, or it cannot be cleared in this manner. In this case the system should be powered-down for at least 15 seconds, then restarted.

10.4. Overriding faults

Most errors should be cleared using the method outlined in Section 0. However, some persistent E3 error codes may be overridden by using the following method, **provided that the fault is not critical.**

1. Press the Fault Override button on the rear panel – see Figure 5.4.
2. The fault indicator bell should cease. If it does not, the fault cannot be cleared in this manner.
3. If the system can still function, operation will resume, reverting to the previous user settings, but operation may be impaired based upon the reason for the fault.
4. In either case, the Fault status indicator will continue to flash until the system is powered-down and restarted.
5. When the operation is completed, be sure to call Misonix, LLC Customer Service Department.

WARNING 1.4	Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cord to remove it from the receptacle.
CAUTION 10.1	Improper use or adjustment of this device may invalidate the Misonix, LLC warranty agreement. Contact your authorized Misonix,LLC representative before attempting to troubleshoot this device in any manner other than those specified in this manual. There are no user serviceable parts.
WARNING 10.1	If a Mains Power fuse fails after replacement when the unit is reactivated, discontinue use of the device and contact an authorized Misonix representative.

For all other malfunctions please contact Misonix or a Misonix authorized representative for service.

11. Specifications

Console Specifications	
Power input	• 100/110/115/120 VAC, 4 Amps, 50/60Hz • 200/220/230/240 VAC, 2 Amps, 50Hz *Must be configured to customer requirements during assembly at factory*
Operating frequency	23 kHz
Ground leakage current	300 µA (max.)
Modes of Operation	Setup mode: System setup Standby mode: Irrigation & Aspiration active Linear mode: Linear Vibration, Irrigation & Aspiration active Preset mode: Preset Vibration, Irrigation & Aspiration active Lap Mode: Preset or Linear Vibration, Irrigation & Aspiration active Suspend Mode: Aspiration pump shuts down
Irrigation pump	Peristaltic pump Pump flow rate • Minimum 1-3 cc/min. and Maximum 9-14 cc/min. • 25 cc/min., flush • 2 cc/min., 2 minutes following deactivation of footswitch (non Lap Mode)
Vacuum pump	Minimum vacuum level less than 0.5" Hg Maximum vacuum level 25" Hg
Generator	IPX 0
Power cord length	10 ft. | 3.1m
Operating conditions	Temperature 55-86°F (13-30°C) Relative humidity 15-90% (non condensing) -91m (-300ft) to 3000m (9840ft) . Note; higher altitudes may require custom calibration
Shipping/storage conditions	Temperature: -4-122°F (-20-50°C) Relative humidity: 15-90% (non condensing)
Shelf Dimensions	16" W x 16" D | 40.6 cm x 40.6 cm
Shelf capacity	35 lb. | 15.9 kg
System Dimensions	40" H x 25" W x 19" D | 102 cm H x 63.5 cm W x 48 cm D
System Weight	120 lb. | 54.5 kg

Table 11.1 Console specifications

Wireless Footswitch Specifications	
Range	Up to 40', with 360° transmission Infrared 870nm
Latency	200 milliseconds
Footswitch	IP 68
Functions	● Vibration (Linear and Preset) ● Flush ● Vibration (Linear and Preset) + COAG ● COAG
Battery Type	3 AA alkaline cells
Battery Life	150 hours at 50% duty cycle
Dimensions	14.0" W x 10.0" D x 3.0" H
Current consumption (Stand-By)	250µa
Weight	5.5 lb. (with three AA batteries installed)

Table 11.2 Footswitch specifications

Handpiece Specifications	
Short Straight Handpiece	
Operating frequency	23 kHz
Maximum stroke amplitude	Approximately 225 microns (with standard tip).
Cable length	17' | 5.2 m
Dimensions	4.8" L (without probe) x 0.8" D | 13 cm x 2.0 cm
Weight with tip	3.2 oz. | 91 g
Curved Extended Handpiece	
Operating frequency	23 kHz
Maximum stroke amplitude	Approximately 300 microns (with standard tip).
Cable length	17' | 5.2 m
Dimensions	9.5" L (without probe) x 0.8" D | 24.1 cm x 2.0 cm
Weight with tip	4.16 oz. | 118 g

Table 11.3 Handpiece specifications

Remote IR Receiver Specifications	
Cable Length	18.0' (5.5m)
Dimensions	5.0" diameter (nom) (14.6cm x 2.0 cm)
Weight	2.0 lb.

Table 11.4 Remote IR Receiver specifications

12. Service, Repair and Technical Correspondence

WARNING 1.4 Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cord to remove it from the receptacle.

NOTE 12.1 The SonaStar is configured for a specific electrical input (line) at the factory before shipment, and is not intended to be configured or changed in the field except by Misonix authorized technical personnel. The unit may only be used with the electrical input originally intended.

12.1. Fuse Requirements

To check and/or replace the fuses on the unit, turn the unit off and disconnect the power cable. The voltage and current rating of each of the three fuses is marked on the rear panel next to the fuse. Please refer to the chart below for fuse requirements.

CAUTION 12.1 The only user replaceable fuses are the two fuses located on the bottom rear of the unit and the one located on the top rear of the unit. Replacement fuses must be identical in type, voltage rating and current rating to the original fuse.

WARNING 1.5 Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch on the console rear panel is set to the local voltage setting and ensure that the correct fuses are being used. Refer to page 63 for instructions on fuse replacement.

100/110/115/120VAC Systems

Fuse	Fuse Type	Fuse Rating	LITTLEFUSE Part Number	Location on Rear of Console
F1	5x20 mm Fast-Acting	6.3A, 250V	021706.3	Bottom
F2	5x20 mm Fast-Acting	6.3A, 250V	021706.3	Bottom
F3	3AG Fast-Acting	5A, 250V	312005	Top

200/220/230/240 VAC Systems

Fuse	Fuse Type	Fuse Rating	LITTLEFUSE Part Number	Location on Rear of Console
F1	5x20 mm Time Delay	3.0A, 250V	0239003	Bottom
F2	5x20 mm Time Delay	3.0A, 250V	0239003	Bottom
F3	3AG Fast-Acting	5A, 250V	312005	Top

Table 12.1 Console fuse specifications

Fuse Replacement F1 and F2 are inside the Fuse Drawer, which is inserted inside the Power Receptacle in back of the Base Assembly. F3 is located in the Fuse Holder in the Top Rear portion of the console.	
Switch Console OFF	Switch console OFF and disconnect power cord.
To replace F1 and F2	Located on rear bottom of console.
Remove Fuse Drawer	  Insert a small flat-blade screwdriver into bottom of the Fuse Drawer to release it and remove the Fuse Drawer.
Replace Fuses	Replace fuse F1 and F2.
Reinstall Fuse Holder	Insert Fuse Drawer into Power Receptacle. Listen for click to ensure the Fuse Drawer is secure.
To replace F3	Located on top rear side of unit.
Remove Fuse	  Use a small flat-blade screwdriver to push in the fuse holder and turn counter-clockwise. Remove the fuse holder with the fuse.
Replace Fuse	Replace fuse F3 and place into the fuse holder.
Reinstall Fuse Holder	Insert the fuse holder into the back of the Controller Assembly and use a small flat-blade screwdriver to push in and turn clockwise.

Table 12.2 Fuse replacement

12.2. Repair, Service and Replacement Parts

All requests for repairs and replacement parts should be directed to Misonix or an authorized Misonix representative. Always provide model and serial number of malfunctioning items.

Only persons authorized by Misonix LLC and qualified by education and experience in electrical test methods can perform repairs to the SonaStar unit.

When returning items include model, serial number, RMA number, as well as purchase order number on all documents. Always include a completed Declaration of Decontamination, prepay return shipping and specify method of shipment.

CAUTION 12.2 Use only genuine replacement parts from Misonix. Use of parts furnished by other sources may result in patient or operator injury or system malfunction and will void any applicable warranty.

CAUTION 12.3 When returning items, before using loose packing materials, such as foam pellets, shredded paper or similar, be sure to wrap the component(s) separately in plastic bags, film or other protective wrapping.

12.3. Important Notice

Please contact Misonix with any questions regarding the specifications, use, sterilization, limitations or maintenance of the SonaStar System:

Misonix, LLC

Web	www.misonix.com
Email	sales@misonix.com
Phone	+1.631.694.9555 / 1-800-694-9612
Fax	+1.631.694.9412
Address	1938 New Highway Farmingdale, NY 11735 U.S.A.

Any serious incident occurring in relation to the SonaStar System should be reported to Misonix, LLC (using the contact information listed above) and the competent authority of the Member State in which the user is established.

By returning any material to Misonix, LLC the customer or the customer's agent must certify that any and all materials so returned are or have been rendered free of any hazardous or noxious matter or radioactive contamination and are safe for handling under normal repair shop conditions. Please include the signed Declaration of Decontamination (available by contacting Misonix) with all products returned to Misonix.

Do not return any material for which such certification cannot be made without prior approval from Misonix, LLC

The correct return address should read as follows:

MISONIX (Misonix, LLC)
Service Department
RMA # _____
1938 New Highway
Farmingdale, New York 11735
U.S.A.

Please contact Misonix for a list of other authorized service centers.

The authorized EC representative is

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CE 0482

+1.631.694.9555 Phone +1.631.694.3285 fax

1938 New Highway, Farmingdale, N.Y. 11735, U.S.A.

MISONIX.COM | NASDAQ SYMBOL. MSON