nexus® Ultrasonic Surgical Aspirator System

Instructions for Use

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1. Overview

This Misonix neXus® Ultrasonic Surgical Aspirator System Instructions For Use manual describes how to use the system including the console, footswitch, handpieces, and accessories. Misonix recommends that you read and understand the instructions in this manual before using the system. Misonix also recommends that you read and understand the separate Instructions For Use manuals for the handpieces you purchased with the system [Misonix neXus® Standard Handpiece, Misonix neXus® SonaStar® (Long and Short) Handpiece, the Misonix neXus® Access™ Handpiece, and the SonaSter® Elite™ Handpiece] before using the system.

This Instructions For Use manual includes indications for use, contraindications, adverse effects, general safety statements, considerations during clinical use, console setup and use, cleaning, fault codes, indicators and troubleshooting, specifications, service, repair and technical correspondence, and repair, service, and replacement parts. Please refer to the table of contents.

1.1 Conventions

Table 1 Conventions on Warning and Cautions

Conventions on Warnings and Cautions	
WARNING	Denotes potentially dangerous situation that could result in death or serious injury to patient, operator, or staff.
CAUTION	A caution contains information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device.

Refer to Section 4.6 for symbols used on product labeling and in the Misonix neXus® IFUs.

1.2 Trademark Information

- Misonix®, neXus®, and neXus® BoneScalpel® are registered trademarks of Misonix, Inc.
- BoneScalpel Access™ and SonaStar Elite are trademarks of Misonix, Inc.
- ASP Enzol® and Prolystica® are registered trademarks of STERIS Corporation.
- CaviWipes™ is a trademark of Metrex Research LLC.

1.3 Principle of Operation

The Misonix neXus® Ultrasonic Surgical Aspirator System is comprised of a generator which converts mains voltage and frequency to a 22.5 kHz (neXus® Standard Handpiece), 23.0 kHz (neXus® BoneScalpel Access™ Handpiece, neXus® SonaStar® Long Handpiece and neXus® SonaStar® Short Handpiece), or 36.0 kHz (neXus® SonaStar Elite™ Handpiece) electrical signal depending upon the handpiece and accessories that are connected to the console. The generator feeds the electric signal to a piezoelectric transducer comprised of a ceramic crystal stack in the handpiece. The crystals vibrate at the output frequency, translating the electrical energy into mechanical vibration. A titanium horn amplifies the vibration and transmits the amplified vibration to a titanium probe tip. The titanium probe tip is the applied part that comes into contact with patient tissue. An integrated irrigation pump delivers an irrigation solution to the surgical site. An integrated aspiration system removes the fragmented, emulsified material and waste liquids from the area. Accessories include various horn/probe tips, irrigation & aspiration tubing sets, wrenches, and cleaning brushes. The system, with the Misonix neXus® SonaStar® Long, Short, and Elite Handpieces may also be combined with electrosurgery using optional RF surgery interface components.

1.4 Part Numbers

Part number	Part Description	Market
100-21-0000	Handpiece Kit (boneScalpel or SonicOne OR)	EEU and US
100-21-0001	Standard Handpiece	EEU and US
100-22-0000	BoneScalpel Access (BSA) Handpiece Kit	US only
100-22-0001	BoneScalpel Access (BSA) Handpiece	US only
100-24-0000	Handpiece Kit (Short) Sonastar	EEU and US
100-24-0001	Short Handpiece (Sonastar)	EEU and US
100-25-0000	Handpiece Kit (Long) Sonastar	EEU and US
100-25-0001	Long Handpiece (Sonastar)	EEU and US
100-26-0000	Sonastar Elite (SSE) Handpiece Kit	US only
100-26-0001	Handpiece (Sonastar Elite)	US only

2. Indications and Contraindications

2.1. Indications for Use

The Misonix Inc. **neXus®** Ultrasonic Surgical Aspirator System is intended for the fragmentation, emulsification and aspiration of both soft and hard (i.e.bone) tissue. The indications for use for the Misonix **neXus® Standard Handpiece, SonaStar® Long Handpiece** and **Short Handpiece, BoneScalpel Access™ Handpiece, and SonaStar Elite™ Handpiece** in combination with the appropriate single-use disposable kits accessory configurations are charted below.

Table 2.1: Indications for Use by handpiece and probe kit accessory combination

Standard Handpiece	
BoneScalpel® Probe and Tubeset Configurations	**SonicOne® Probe and Tubeset Configurations**

Indicated for use in the fragmentation, emulsification, and aspiration of soft and hard (e.g., bone) tissue in the following surgical specialties:
• **Neurosurgery**
• **Gastrointestinal and Affiliated Organ Surgery**
• **Urological Surgery**
• **Plastic and Reconstructive Surgery**
• **General Surgery**
• **Orthopedic Surgery**
• **Gynecology**
  ○ **External genitalia** - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primary and metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts
  ○ **Abdominal area** - any abnormal growth, cystic or solid, benign, or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus except as contraindicated for uterine fibroids.
• **Thoracic Surgery**
Limited pulmonary reception such as segmetectomies, nonanatomical subsegmentectomies and metastatectomies.
• **Wound Care**
The neXus® Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.
	Indicated for use in the fragmentation, emulsification, and aspiration of soft and hard tissue (i.e., bone) in the following surgical specialties:
	• **Wound Care**
	The neXus® Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.
	• **Plastic and Reconstructive Surgery**

Table 2.1: Indications for Use by handpiece and probe kit accessory combination (continued).

BoneScalpel® Access™ Handpiece, Probe and Tubeset Configurations	**SonaStar® and SonaStar Elite™ Handpieces, Probes and Tubeset Configurations**

Indicated for use in the fragmentation, emulsification, and aspiration of soft and hard (e.g., bone) tissue in the following surgical specialties:
• **Neurosurgery**
• **Gastrointestinal and Affiliated Organ Surgery**
• **Urological Surgery**
• **Plastic and Reconstructive Surgery**
• **General Surgery**
• **Orthopedic Surgery**
• **Gynecology**
  ○ **External genitalia** - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primary and metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts
  ○ **Abdominal area** - any abnormal growth, cystic or solid, benign, or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus except as contraindicated for uterine fibroids.
• **Thoracic Surgery** - Limited pulmonary reception such as segmetectomies, nonanatomical subsegmentectomies and metastatectomies.
	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**
	  ○ Including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy
	• **Urological Surgery**
	  ○ Including removal of renal parenchyma during nephrectomy or partial nephrectomy
	• **Plastic and Reconstructive Surgery**
	• **General Surgery**
	  ○ Including removal of benign or malignant tumors or other unwanted tissue in open or minimally invasive general surgical procedures
	• **Orthopedic Surgery**
	• **Gynecological Surgery except as contraindicated for uterine fibroids.**
	• **Thoracic Surgery**
	• **Laparoscopic Surgery –**
	  ○ Including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy
	• **Thoracoscopic Surgery**
	The system may also be combined with electrosurgery using optional RF surgery interface components.

2.2. Intended Use Environment

The Misonix neXus® Ultrasonic Surgical System is intended to be used in hospital OR suites, ambulatory surgery suites, or surgical clinic environments.

CAUTION Special Skills Training Requirements

- Rx ONLY CAUTION: United States Federal law restricts this device to sale by or on the order of a physician or health care practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device; Not applicable in the European Union.
- The neXus® Ultrasonic Surgical Aspirator System is to be used by an appropriately trained and licensed healthcare practitioner.
- All health care institution personnel are to be trained in the healthcare institution's procedures for universal precautions for bloodborne pathogens and the use of appropriate PPE.

2.3. Contraindications

- The Misonix neXus® Ultrasonic Surgical Aspirator System probe tips are not indicated for and should not be used for direct contact with cardiac tissue (direct cardiac application).
- 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.
- The Misonix neXus® Ultrasonic Surgical Aspirator System is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

3. Adverse Effects

See separate Handpiece Instructions For Use (IFU) documents for Adverse Effects:

- Document #: 100-24-1000 – neXus® SonaStar ® Handpiece (Short & Long) Instructions for Use (IFU)
- Document #: 100-21-1000 – neXus® Standard Handpiece Instructions for Use (IFU)
- Document #: 100-22-1000 – neXus® BoneScalpel Access™ Handpiece Instructions for Use (IFU)
- Document #: 100-26-1000 – neXus® Sonastar Elite™ Handpiece Instructions for Use (IFU)

WARNING Probe tip temperatures may exceed the tissue necrosis point if insufficient irrigant is present at the probe tip-tissue interface. For hard tissue removal, always use the maximum irrigation flowrate that does not affect the surgical field of view, or impact surgical technique. Additional external irrigation, e.g., by administering sterile saline with a syringe over the distal probe tip portion, may be necessary for removal of very dense, hard osseous structures.

WARNING Tissue necrosis may result if probe tip is not moved relative to tissue. A continuous, lateral sweeping motion is recommended in order to minimize contact duration with the ultrasonic probe tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert probe tip frequently.

4. General Safety Statements

WARNING — The neXus® Ultrasonic Surgical Aspirator System is an electro-mechanical device, which under certain circumstances could present an electrical shock hazard to the operator and/or patient. Please read the Instructions For Use manual thoroughly and follow directions stated herein to assure maximum safety during operation. This manual shall be kept in close proximity to the system for easy referral when needed.

WARNING — The neXus® Ultrasonic Surgical Aspirator 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 — Special Skills Training Requirements

- United States Federal law restricts this device to sale by or on the order of a physician or health care practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device; Not applicable in the European Union.
- The neXus ® Ultrasonic Surgical Aspirator System is to be used by an appropriately trained and licensed healthcare practitioner.
- All health care institution personnel are to be trained in the healthcare institution's procedures for universal precautions for bloodborne pathogens and the use of appropriate PPE.

4.1 EMC Statement

The neXus® Ultrasonic Surgical Aspirator System is designed and tested to comply with FCC regulations for conducted and radiated emissions under 47 Part 18 Subchapter J and to comply with IEC 60601-1-2 and BS EN 60601-1-2: Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests.

CAUTION — 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 Instructions For Use manual.

WARNING — 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 neXus, including the cables supplied with the neXus Otherwise degradation of the performance of this equipment could result.

WARNING — The use of accessories, handpieces 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.

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

4.2 Electromagnetic Compatibility Guidance

(In accordance with EN/IEC 60601-1-2:2014)

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.

Table 4.1 Guidance & manufacturer's declaration on electromagnetic emissions (EN table 201)

Guidance and Manufacturer's Declaration – Electromagnetic Emissions (Table 201)		
The neXus® Ultrasonic Surgical Aspirator System is intended for use in the electromagnetic environment specified below. The customer or the user of the neXus® Ultrasonic Surgical Aspirator System should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The neXus® Ultrasonic Surgical Aspirator 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 neXus® Ultrasonic Surgical Aspirator 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 4.2 Manufacturer's declaration on electromagnetic emissions (EN table 201)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Table 202)			
The neXus® Ultrasonic Surgical Aspirator System is intended for use in the electromagnetic environment specified below. The customer or the user of the neXus® Ultrasonic Surgical Aspirator 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	o ±8 kV contact o ±2 kV, ±4 kV, ±8 kV, ±15 kV air	o ±8 kV contact o ±2 kV, ±4 kV, ±8 kV, ±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	o ±2 kV for power supply lines o ±1 kV for input/output lines	o ±2 kV for power supply lines o ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	o ±0.5 kV, ±1 kV line to line o ±0.5 kV, ±1 kV, ±2 kV line to ground	o ±0.5 kV, ±1 kV line to line o ±0.5 kV, ±1 kV, ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Table 202)			
The neXus® Ultrasonic Surgical Aspirator System is intended for use in the electromagnetic environment specified below. The customer or the user of the neXus® Ultrasonic Surgical Aspirator System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T for 0,5 cycle 70 % U_T (30 % dip in U_T) for 25 cycles 0 % U_T (100 % dip in U_T) for 1 cycle 0 % U_T (100 % dip in U_T) for 5 sec	0 % U_T (100 % dip in U_T) for 0,5 cycle 70 % U_T (30 % dip in U_T) for 25 cycles 0 % U_T (100 % dip in U_T) for 1 cycle 0 % U_T (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 neXus® Ultrasonic Surgical Aspirator 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. NOTE If a fault notification on the GUI occurs, press the "X" button to exit the screen and initiate system reset.			

Table 4.3 List of cables

List of Cables		
Item	Cable Length	Type
Handpiece cable	15 ft | 4.6 m	shielded 2-conductor
Power cord	10 ft | 3.0 m	unshielded 3-conductor
Monopolar Hand Switch Cable	15.5 ft | 4.7 m	unshielded 3-conductor
Wired Footpedal (optional)	20 ft | 6.1 m	unshielded 2-conductor

Table 4.4 Guidance & manufacturer's declaration on electromagnetic immunity (EN table 204)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Table 204)			
The neXus® Ultrasonic Surgical Aspirator System is intended for use in the electromagnetic environment specified below. The customer or the user of the neXus® Ultrasonic Surgical Aspirator System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM Bands	3 Vrms 150 KHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the neXus® Ultrasonic System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.4\sqrt{P}$ 800 MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 Hz to 2.7 GHz 80% AM at 1Khz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1Khz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. 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.
Note 3: If a fault notification on the GUI occurs, press the "X" button to exit the screen and initiate system reset.

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 neXus® Ultrasonic Surgical Aspirator System is used exceeds the applicable RF compliance level above, the neXus® Ultrasonic Surgical Aspirator 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 neXus® Ultrasonic System.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4.5 Recommended separation distances (EN table 206)

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the neXus® Ultrasonic Surgical Aspirator System (Table 206)			
The neXus® Ultrasonic Surgical Aspirator System is intended for use in an electromagnetic environment in which radiated RF disturbances are con- trolled. The customer or the user of the neXus® Ultrasonic Surgical Aspirator System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the neXus® Ultrasonic Surgical Aspirator 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

Table 4.6 Characteristics of wireless footswitch receiver

Characteristics of Wireless Footswitch Receiver	
Frequency Band of reception	2400 – 2483.5Mhz
Preferred Frequency band of reception	No preference
Bandwidth of receiving section of the frequency bands	5Mhz
Frequency band of transmission	2400 – 2483.5Mhz
Frequency characteristics of the modulation	GPSK modulation
Effective radiated power	-2.22dBm (0.60mW) max, 1.3dBi antenna gain, -0.92dBm EIRP

4.3 Electrical Safety Statement

The neXus® Ultrasonic Surgical Aspirator System is designed and tested to comply with IEC 60601-1, UL 60601-1, and BS EN 60601-1: Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

WARNING The neXus® Ultrasonic Surgical Aspirator 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 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 The neXus® console automatically adjusts for the mains voltage and frequency. Confirm that the correct fuses are being used. Refer to Section 11.1 of this Instructions For Use manual for instructions on fuse replacement.

WARNING The neXus® Ultrasonic Surgical Aspirator System, including all accessories and components, is MR Unsafe. It must not be brought into the MR environment.

4.4 Environmental Statement

This equipment consists of materials that may be recycled if disassembled by a specialized company. Please observe local and federal regulations regarding the disposal of packing materials and old equipment.

Table 4.7: Environmental statement

Important Environmental Information for Users within the European Economic Area
The European Council Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), usually referred to as WEEE Directive, place responsibilities on the supplier and you, the purchaser/user to dispose of electrical and electronic equipment properly. One of the actions required for a supplier is to inform users of their obligations. The WEEE Directive requires that the EEE be disposed of at the end of its useful life in an environmentally responsible manner. The WEEE Directive requires that if replacing the EEE with a new equivalent product, the supplier shall collect the old item without cost to the user. In a similar fashion, Directive 2006/66/EC on Batteries requires that batteries be disposed of at the end of their useful life in an environmentally responsible manner. The Directive on Batteries requires that when replacing batteries with new or equivalent batteries, the supplier shall collect the old batteries without cost to the user.
If you wish to dispose of the EEE and/or the batteries without having the supplier replace them then they must not be mixed with unsorted municipal waste. You must ensure that the EEE and /or the batteries are disposed of at an authorized treatment facility. Details for special disposal procedures for EEE and/or batteries can be obtained from your local council. 

4.5 Summary of Safety Notices

Please read this section of the Instructions For Use 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, Inc. There are no service controls accessible to the user.

4.5.1 List of Warnings

- The neXus® Ultrasonic Surgical Aspirator 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.

- The neXus® Ultrasonic Surgical Aspirator 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.

- **Potential Burn Hazard**

    - neXus probes have a silicone and/or hard plastic sheaths. Compressing or bending the sheath may cause the sheath to contact the vibrating surface along the length of the probe or at the probe tip and may cause excessive heating, which may burn user or patient tissue at the surgical site.

    - Excessive loading of neXus probes at the surgical site may induce heating due to vibration and friction as target tissue is fragmented and emulsified. It is critical to manage the temperature of the probe by adjusting the irrigation, aspiration, and ultrasound settings, and surgical technique. Tissue necrosis may result if probe tip is not moved relative to tissue. A continuous, lateral sweeping motion is recommended in order to minimize contact duration with the ultrasonic probe tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert probe tip frequently.

    - Contact to vibrating elements like an extension and ultrasonic probe tip may cause burns and should be avoided by all means. The handpiece should only be held at the black handpiece housing area and/or the black hard sheath.

    - A protective silicone sleeve, included with certain probe tips, reduces the risk of thermal damage but does not eliminate it. Contact with the silicone sleeve should be avoided or kept brief with minimal amount of contact pressure. Pressure and extended exposure can still result in excessive frictional heat and cause burns.

    - Contact of the rigid or silicone sheaths with patient tissue under pressure, may create a burn hazard. Avoid contact of sheath elements with patient tissue under pressure.

    - Probe tip temperatures may exceed the tissue necrosis point if insufficient irrigant is present at the probe tip-tissue interface. For hard tissue removal, always use the maximum irrigation flowrate that does not affect the surgical field of view, or impact surgical technique. Additional external irrigation, e.g., by administering sterile saline with a syringe over the distal probe tip portion, may be necessary for removal of very dense, hard osseous structures.

    - For hard tissue applications, a minimum Irrigation setting of 20 is recommended to minimize or prevent thermal injury and/or tissue necrosis.

- 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. The 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.

- 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. Refer to the back label on the system console for line voltages and frequencies.

- Replacement fuses other than what is specified can cause a fire hazard. Use only as specified. Refer to Section 11.1 for replacement fuse specifications.

- Explosion Hazard: Never use the neXus® Ultrasonic Surgical Aspirator System in the presence of a flammable or explosive atmosphere, such as flammable anesthetics.

- The neXus® Ultrasonic Surgical Aspirator System and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits. Refer to Section 3 (Adverse Effects) of this IFU for exposure limit.

- Only use the neXus® Standard Handpiece with neXus® BoneScalpel® or neXus® SonicOne® OR Probe and Tubeset single-use disposable kits configurations for the indications for use charted in Section 2.1 for the neXus® Standard Handpiece.

- Only use the neXus® SonaStar® Long and Short Handpieces with neXus® SonaStar® Probe and Tubeset single-use disposable kits are listed below for the indications for use charted in Section 2.1 for the neXus® SonaStar® Handpieces.

- Only use the neXus® BoneScalpel Access™ Handpiece with neXus® BoneScalpel Access™ MIS Probe and Tubeset accessory kit configurations for the indications for use charted in Section 2.1 for the neXus® BoneScalpel Access™ Handpiece.

- Only use the neXus® SonaStart Elite™ Handpiece with the neXus® SonaStar Elite™ Probe and Tubeset accessory kit configurations for the indications for use charted in Section 2.1of the neXus® SonaStart Elite™ Handpiece.

- The neXus® SonaStar® Long and Short handpieces and the SonaStar Elite™ Handpiece may be combined with electrosurgery using an optional RF Monopolar fingerswitch cable. Refer to the neXus® SonaStar® Long and Short Handpiece or the SonaStar Elite™ Handpiece IFU for detailed instructions for using the RF Monopolar Handswitch cable and for monopolar cautery guidelines.

- The neXus® SonaStar® Long and Short Handpieces and the SonaStar Elite™ Handpiece can deliver RF energy via its attached probe tip when connected to a 3rd party electrosurgical generator using the RF Monopolar Handswitch Cable accessory. Misonix recommends use of the electrosurgical generators listed in the neXus® SonaStar® Long and Short Handpiece or the SonaStar Elite™ Handpiece IFU that have been validated for compatibility with the neXus® system.

- Tissue necrosis may result if probe tip is not moved relative to tissue. A continuous, lateral sweeping motion is recommended in order to minimize contact duration with the ultrasonic probe tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert probe tip frequently.

- Additional external irrigation, e.g., by administering sterile saline with a syringe over the distal probe tip portion, may be necessary for removal of very dense, hard osseous structures of the skull, when using the neXus® Ultrasonic Surgical Aspirator System accessories.

- Ultrasonic probe tips can break under excessive use in extreme conditions, e.g., when cutting for extended / duration in tight cavities with limited lateral motion. The probe tip could break into two or more fragments with the main fragment remaining attached to the handpiece. All fragments must be retrieved immediately from the surgical site. The fragments should be checked to ensure that no further pieces are missing. It is possible that a fragment is propelled outside of the surgical cavity. Diagnostic imaging, such as X-ray, must be used if a fragment cannot be found to confirm that the broken piece is outside of the surgical cavity.

- Breakage of ultrasonic probe tips will result in sharp edges that can be harmful to soft tissue even without activation of ultrasound. Probe tips can bend or deform before they actually break. Probe tips showing signs of deformation or cracking should be replaced immediately since probe tip breakage is otherwise imminent. Do not bend or twist the ultrasonic probe tips since it reduces the structural integrity and can result in probe tip breakage during use. Dispose of deformed or broken probe tips immediately in a biohazardous sharps container in accordance with your facility biological hazardous waste procedure.

- Do not operate pump with pump cover in raised position. Rollers might pinch loose clothing or fingers. Personal injuries may result.

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

- Heat is being generated at the probe tip/tissue interface. A continuous, lateral sweeping motion is recommended for general bone/tissue removal in order to minimize contact duration with the ultrasonic probe tip and minimize the temperature increase.

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

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

- 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 probe tip free from contact with any objects.

- Remove probe cover, ultrasonic probe tip and extension from the handpiece prior to cleaning and/or sterilization; otherwise, proper cleaning/sterilization may be inhibited.

- Probe and Tubeset single-use disposable kit components (probe tips, sheaths, tubing sets) are labeled with the international symbol for "do not reuse - single use only" (⊘). Discard these components following each surgical procedure in accordance with the hospital protocol for biohazardous waste. Probe tips are to be disposed of in a biohazardous sharps container. To prevent the risk of malfunction and transmission of disease, do not attempt to reprocess, clean, re-sterilize, and/or reuse these components.

- Immediately suspend operation if a persistent "Electrical Fault" appears on display and/or an Electrical Fault audible indicator sounds. Remove ultrasonic probe tip from surgical site. Turn Mains Power OFF. Do not touch any metallic parts of handpiece, extension, ultrasonic probe tip or generator while fault is indicated.

- 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.

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

- No modifications of this equipment are allowed except as noted for cleaning and sterilization. The user should return the system, accessories or components to Misonix or an authorized service center.

- The neXus® Ultrasonic Surgical Aspirator System, including all accessories and components, is MR Unsafe. It must not be brought into the MR environment.

4.5.2 List of Cautions

- Special Skills Training Requirements

  - ℞ ONLY Caution: United States Federal law restricts this device to sale by or on the order of a physician or health care practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device; Not applicable in the European Union.

  - The neXus® Ultrasonic Surgical Aspirator System is to be used by an appropriately trained and licensed healthcare practitioner.

  - All health care institution personnel are to be trained in the healthcare institution's procedures for universal precautions for bloodborne pathogens and the use of appropriate PPE.

- 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 Section 4.1 and 4.2 of this Instructions For Use manual.

- Portable and mobile RF communication equipment can affect medical electrical equipment. If RF equipment is in use monitor the neXus® Ultrasonic Surgical Aspirator System for proper function during procedure.

- The use of accessories, transducers and cables other than those specified by Misonix may result in increased RF emissions or decreased immunity to RF of the device. Use only Misonix branded equipment and accessories.

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

- This Misonix neXus® Ultrasonic Surgical Aspirator System Instructions For Use manual describes how to use the system including the console, footswitch, handpieces, and accessories. Misonix recommends that you read and understand the instructions in this manual before using the system. Misonix also recommends that you read and understand the separate Instructions For Use manuals for the handpieces you purchased with the system (Misonix neXus® Standard Handpiece, Misonix neXus® SonaStar® (Long and Short) Handpiece, and/or the Misonix neXus® Access™ Handpiece) before using the system.

- Ultrasonic energy is inhibited if excessive physical force is applied to the ultrasonic probe tip; use only enough force to guide the probe tip to the surgical site and to advance it through the tissue. Do not force the probe tip; allow the ultrasonic action to do the work.

- Insufficient irrigation and high probe tip pressure (loading) under extended exposure, e.g. in tight cavities, are to be avoided in hard tissue removal. It is recommended to withdraw and re-insert the ultrasonic probe tip repeatedly to re-establish adequate cooling and lubrication.

- Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal probe tip portion, may be necessary for removal of very dense, hard osseous structures of the skull, when using the neXus® Ultrasonic Surgical Aspirator System accessories.

- The single-use disposable probe and tubeset kits are intended for one procedure only. Do not attempt to reuse, clean or re-sterilize the single-use disposable probe and tubeset kit components.

- Do not place the soft silicone tube behind or in front of the rollers (latch removed in illustrations in Sections 7.4 of this Instructions For Use manual).

- Do not pinch the soft silicone tube when the latch is locked.

- Do not pinch barb fittings when closing the latch.

- Prime the irrigation tubing prior to use. At all times ensure that the irrigation flows towards the handpiece when footswitch is depressed. If irrigation is not flowing, cease use until flow is restored.

- The system check should always be done in advance of preparing patient for surgery to minimize risk to patient in case of system malfunction. Refer to Section 7.11 – System Check.

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

- The aspiration pinch valve and irrigation pump can create pinch points. Keep fingers away from these parts while operating unit. Use caution when assembling components.

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

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

- Only external surfaces of the console should be cleaned. Refer to Section 8 – Cleaning the neXus® system.

- Do not attempt to remove any panels in order to clean or disinfect internal surfaces.

- Do not immerse ultrasonic console, handpiece, irrigation pump or electric cables. These items are not sealed against liquids and damage to equipment will result.

- Improper use or adjustment of this device may invalidate the Misonix Warranty Agreement. Contact your authorized Misonix representative before attempting to troubleshoot this device in any manner other than those specified in this Instructions For Use manual. There are no user serviceable parts.

- The only user replaceable fuses are the two fuses located on the bottom rear of the unit. Replacement fuses must be identical in type, voltage rating and current rating to the original fuse. Refer to Section 11.1 for replacement fuse specifications.

- 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.

- 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.

- When using optional cart accessory, be sure to align the rubber feet on the bottom of the console with the indents in the cart base

- After extended periods of operation, the bottom of the console housing may become warm to the touch. This is normal. Do not touch the bottom of the console housing while in operation or shortly after operation.

- Loose probe tip/tissue contact upon an initial bone incision can cause a thin probe tip to resonate not only longitudinally but also transversely. This can cause a thin probe tip to break. It is necessary to engage bone actively and with a minimal probe tip pressure greater than zero in order to prevent the shattering.

- Contact of the ultrasonic probe tip or the exposed extension with metal, surgical instruments or other objects during ultrasound use must be avoided. Such contact can damage the ultrasonic components very easily and may result in compromised performance, including failure. Discard any extensions or probe tips that show signs of damages like gouges, nicks or fractures. External aspiration may be used but it is recommended that a plastic suction probe tip should be used when in proximity with the probe tip.

- Adequate air circulation is needed to cool electronic components inside of the unit. Do not block the cooling fan at the console rear or the air vents on the console bottom. Do not place the unit on a towel, foam or other soft surface since the material may block the air vents. Blocking these vents may cause unit to overheat and malfunction or create a shock hazard. A clear drape can be used to protect the console front panel but do not cover the pump housing or other console portions.

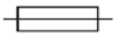
- The neXus® system should be fully tested and inspected prior to each procedure. The console, footswitch, handpieces, all cables and accessories should be examined for proper appearance and condition.

- The neXus® system will alert the user if the batteries in the footswitch are low. Replace batteries immediately following the procedure.

- All periodic maintenance is to be performed by the health care institution's (hospital OR suites, ambulatory surgery suites, or surgical clinic environment) technical staff, trained staff member, or by a Misonix authorized technical personnel. Under normal conditions, the filter should be changed at 6-month intervals.

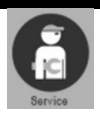
4.6 Explanation of Symbols

Table 4.6: Symbol Definitions

Symbol	Description
	Caution: Consult accompanying documents
	Caution: Do Not operate with cover in the raised position
	Protective earth ground
	Equipotentiality connection
	Disposal to be com- pliant with EN 50419 (WEEE directive)
EC REP	Authorized representative
	Type BF Applied Part
	Power Standby
CE 0482	Misonix CE number
	Classified by UL
SN	Serial Number
REF	Catalog number
	AC Voltage
	Fuse
	Manufacturer
	Date of Manufacture
	Country of Origin
	Do not use if packaging is damaged
	Contents are latex-free
Rx ONLY	Restricted to sale by or on the order of a physician only
LOT	Lot or batch code
	Do Not expose to Temperatures greater than indicated
	Do Not expose to Humidity greater than indicated
	MR Unsafe

Symbol	Description
	Single sterile barrier system
	Sterilized using Ethylene Oxide
	Unique Device Identification is specific to a manufacturer and a device
	Identifies product as a medical device
	Single use (do not re-use)
	Do not re-sterilize
	Non-sterile medical device

Graphic Images	Description
	Wireless Footswitch not activated
	Wireless Footswitch or Flush button activated
	Wired Footswitch connected (not activated)
	Wired Footswitch activated
	Wireless Footswitch connected to console
	Footswitch Not connected to Console, Flashing “X”
	Low Footswitch Battery
	Enable Mode Active
	Standby Mode Active
	Dynamic Tissue Control (DTC) Enabled
	Dynamic Tissue Control (DTC) Disabled
	Preset Mode Active
	Linear Mode Active
	Vacuum System On
	Vacuum System Off
	Irrigation System
	Lap/Endo Mode Off
	Lap/Endo Mode On
	Exit button to return to the Main screen
	System Information

Graphic Images	Description
	Service Mode
	Footswitch Settings
	System Reset Button
	Fast Flush, Off State
	Fast Flush, On State
	Initiate Priming Cycle
	Pause Priming Cycle
	Resume Prime Irrigation
	Skip Priming Cycle
	Handpiece Not Connected
	Handpiece Connected
	Tubeset Not Connected
	Tubeset Connected
	Irrigation Pump Door Open
	Irrigation Pump Door Closed
	Settings

5. Considerations During Clinical Use

WARNING The neXus® Ultrasonic Surgical Aspirator System and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits. Refer to Section 3 of this Instructions For Use manual for exposure limits.

WARNING neXus probes have a silicone or hard plastic sheath. Compressing or bending the sheath may cause the sheath to contact the vibrating surface of the probe along the length of the probe or at the probe tip and may cause excessive heating, which may burn user or patient tissue at the surgical site.

WARNING Excessive loading of neXus probes at the surgical site may induce heating due to vibration and friction as target tissue is fragmented and emulsified. It is critical to manage the temperature of the probe by adjusting the irrigation, aspiration, and ultrasound settings, and surgical technique. Tissue necrosis may result if probe tip is not moved relative to tissue. A continuous, lateral sweeping motion is recommended in order to minimize contact duration with the ultrasonic probe tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert probe tip frequently.

WARNING Contact to vibrating elements like an extension and ultrasonic probe tip may cause burns and should be avoided by all means. The handpiece should only be held at the black handpiece housing area and/or the black hard sheath.

WARNING A protective silicone sleeve, included with certain probe tips, reduces the risk of thermal damage but does not eliminate it. Contact with the silicone sleeve should be avoided or kept brief with minimal amount of contact pressure. Pressure and extended exposure can still result in excessive frictional heat and cause burns.

WARNING Contact of the rigid or silicone sheaths with patient tissue under pressure, may create a burn hazard. Avoid contact of sheath elements with patient tissue under pressure.

CAUTION After extended periods of operation, the bottom of the console housing may become warm to the touch. This is normal. Do not touch the bottom of the console housing while in operation or shortly after operation.

5.1. Hard Tissue Applications/Use (e.g., BoneScalpel® Standard Handpiece or BoneScalpel Access™ Handpiece)

5.1.1 neXus® Standard Handpiece with neXus® BoneScalpel® Probe and Tubing Set Single Use, Disposable Kits

Recommended Settings

The following settings are general guidelines and should be adjusted based on indication, anatomy, pathology and surgeon's preference.

Table 5.1.1: Hard Tissue, Standard Handpiece Recommended Settings

Tissue Effect	[1]Amplitude Setting	[2]Flow Setting
Highest	100	100
Standard (Default)	70	70
Lowest	5	5
1 – At Amplitude Setting = 0, ultrasound is disabled 2 – The lowest flow setting is 5.		

- A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in tissue necrosis.
- A lower amplitude setting in combination with higher irrigation would reduce the potential for tissue necrosis.
- The various disposable attachments (i.e. blades, shavers, probes, etc.) are considered the applied part.

5.1.2 neXus® BoneScalpel Access™ Handpiece with neXus® BoneScalpel Access™ MIS 20mm Blade and Tubing Set Single Use, Disposable Kits

Recommended Settings

The following settings are general guidelines and should be adjusted based on indication, anatomy, pathology, and surgeon's preference.

Table 5.1.2: Hard Tissue, BoneScalpel Access™ Handpiece with MIS 20mm Blade and Tubing Set

Tissue Effect	[1]Amplitude Setting	[2]Flow Setting
Highest	100	100
Standard (Default)	70	70
1 – At Amplitude Setting = 0, ultrasound is disabled 2 – The lowest recommended flow setting is 20.		

- A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in tissue necrosis.
- A lower amplitude setting in combination with higher irrigation would reduce the potential for tissue necrosis.
- The various disposable attachments (i.e., blades, Shavers, probes, etc.) are considered the applied part.

5.1.3 neXus® BoneScalpel Access™ Handpiece with neXus® BoneScalpel Access™ MIS Shaver and Tubing Set Single Use, Disposable Kits

Recommended Settings

The following settings are general guidelines and should be adjusted based on indication, anatomy, pathology, and surgeon's preference.

Table 5.1.3: Hard Tissue, BoneScalpel Access™ Handpiece with MIS Shaver and Tubing Set Recommended Settings

Tissue Effect	[1]Amplitude Setting	[2]Flow Setting	Aspiration Setting
Highest	100	100	100
Standard (Default)	70	70	50
1 – At Amplitude Setting = 0, ultrasound is disabled 2 – The lowest recommended flow setting is 20.			

- A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in tissue necrosis.
- A lower amplitude setting in combination with higher irrigation would reduce the potential for tissue necrosis.
- The various disposable attachments (i.e., blades, Shavers, probes, etc.) are considered the applied part.

WARNING Probe tip temperatures may exceed the tissue necrosis point if insufficient irrigant is present at the probe tip-tissue interface. For hard tissue removal, always use the maximum irrigation flowrate that does not affect the surgical field of view, or impact surgical technique. Additional external irrigation, e.g., by administering sterile saline with a syringe over the distal probe tip portion, may be necessary for removal of very dense, hard osseous structures.

WARNING For hard tissue applications, a minimum Irrigation setting of 20 is recommended to minimize or prevent thermal injury and/or tissue necrosis.

WARNING Tissue necrosis may result if tip is not moved relative to tissue. A continuous, lateral sweeping motion is recommended in order to minimize contact duration with the ultrasonic tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert tip frequently.

WARNING Additional external irrigation, e.g., by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures of the skull, when using the neXus® Ultrasonic Surgical Aspirator System accessories.

CAUTION Ultrasonic energy is inhibited if excessive physical force is applied to the ultrasonic tip; use only enough force to guide the tip to the surgical site and to advance it through the tissue. Do not force the tip; allow the ultrasonic action to do the work.

Tip Limitations During Bone Removal

Both the ultrasonic tip and the extension (horn, where applicable) are vibrating at a high frequency and are thus exposed to extreme mechanical stresses, especially when cutting bone.

WARNING Ultrasonic tips can break under excessive use in extreme conditions, e.g. when cutting for extended duration in tight cavities with limited lateral motion. The tip could break into two or more fragments with the main fragment remaining attached to the handpiece. All fragments must be retrieved immediately from the surgical site. The fragments should be checked to ensure that no further pieces are missing. It is possible that a fragment is propelled outside of the surgical cavity. Diagnostic imaging, such as X-ray, must be used if a fragment cannot be found to confirm that the broken piece is outside of the surgical cavity.

WARNING Breakage of ultrasonic tips will result in sharp edges that can be harmful to soft tissue even without activation of ultrasound. Tips can bend or deform before they actually brake. Tips showing signs of deformation or cracking should be replaced immediately since tip breakage is otherwise imminent. Do not bend or twist the ultrasonic tips since it reduces the structural integrity and can result in tip breakage during use. Dispose of deformed or broken tips immediately in a biohazardous sharps container in accordance with your facility biological hazardous waste procedure.

CAUTION Insufficient irrigation and high tip pressure (loading) under extended exposure, e.g., in tight cavities, are to be avoided in hard tissue removal. It is recommended to withdraw and re-insert the ultrasonic tip repeatedly to re-establish adequate cooling and lubrication.

CAUTION Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures of the skull, when using the neXus® Ultrasonic Surgical Aspirator System accessories.

CAUTION Loose tip/tissue contact upon an initial bone incision can cause a thin tip to resonate not only longitudinally but also transversely. This can cause a thin tip to break. It is necessary to engage bone actively and with a minimal tip pressure greater than zero in order to prevent the shattering.

CAUTION Contact of the ultrasonic tip or the exposed extension with metal, surgical instruments or other objects during ultrasound use must be avoided. Such contact can damage the ultrasonic components very easily and may result in compromised performance, including failure. Discard any extensions or tips that show signs of damages like gouges, nicks, or fractures. External aspiration may be used but it is recommended that a plastic suction tip should be used when in proximity with the probe tip.

5.2 Soft Tissue Applications / Use (e.g., with SonaStar Handpieces)

5.2.1 neXus® SonaStar® Long or Short Handpiece with neXus® SonaStar® Probe and Tubing Set Single Use, Disposable Kits.

Aspiration probes are typically used for soft tissue removal. Tissue excision and fragmentation are achieved through cavitation and other mechanical and hydrodynamic effects.

Recommended Settings
The following settings are general guidelines and should be adjusted based on indication, anatomy, pathology, and surgeon's preference.

Table 5.2.1: Soft Tissue, SonaStar® Long or Short Handpiece Recommended Settings (*Dynamic Tissue Control* (DTC) Disabled)

Tissue Effect	[1]Amplitude Setting	[2]Flow Setting	[3]Aspiration Setting
Highest	100	100	100
Standard (Default)	50	50	50
Lowest	5	5	5
1 – At Amplitude Setting = 0, ultrasound is disabled 2 – The lowest flow setting is 5 3 – The lowest aspiration setting is 5			

- A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in tissue necrosis.
- A lower amplitude setting in combination with higher irrigation would reduce the potential for tissue necrosis.
- The various disposable attachments (i.e., blades, Shavers, probes, etc.) are considered the applied part.

Table 5.2.2: Soft Tissue, SonaStar® Long or Short Handpiece Recommended Settings (*Dynamic Tissue Control* (DTC) Enabled)

Tissue Effect	**DTC Setting**	**Amplitude Setting**	**Flow Setting**	**Aspiration Setting**
Highest	1	100	100	100
Standard (Default)	1	50	50	50
Lowest	6	5	5	5

* At Amplitude setting 0, ultrasound is disabled. The lowest Flow and Aspiration setting is 5.

- A high amplitude setting combined with a low DTC setting results in more aggressive tissue removal.
- A low amplitude setting combined with a high DTC setting results in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in tissue necrosis.
- A lower amplitude setting in combination with higher irrigation would reduce the potential for tissue necrosis.
- The various disposable attachments (i.e. aspiration probes, etc…) are considered the applied part.

5.2.2 neXus® SonaStar Elite™ (SSE) Handpiece with neXus® SonaStar Elite™ (SSE) Probe and Tubing Set Single Use, Disposable Kits

Aspiration probes are typically used for soft tissue removal. Tissue excision and fragmentation are achieved through cavitation and other mechanical and hydrodynamic effects.

Recommended Settings

The following settings are general guidelines and should be adjusted based on indication, anatomy, pathology and surgeon's preference.

Table 5.2.3: Soft Tissue SonaStar Elite™ Handpiece Recommended Settings (*Dynamic Tissue Control* (DTC) Disabled)

Tissue Effect	[1]Amplitude Setting	[2]Flow Setting	[2]Aspiration Setting
Highest	100	100	100
Standard (Default)	60	25	60
Lowest	5	5	5

1 – At Amplitude Setting = 0, ultrasound if disabled
2 – The lowest flow setting is 5
3 – The lowest aspiration setting is 5

* At Amplitude setting 0, ultrasound is disabled. The lowest Flow and Aspiration setting is 5.

- A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in tissue necrosis.
- A lower amplitude setting in combination with higher irrigation would reduce the potential for tissue necrosis.
- The various disposable attachments (i.e. aspiration probes, etc…) are considered the applied part.

Table 5.2.4: Soft Tissue SonaStar Elite™ Handpiece Recommended Settings (*Dynamic Tissue Control* (DTC) Enabled)

Tissue Effect	DTC Setting	Amplitude Setting	Flow Setting	Aspiration Setting
Highest	1	100	100	100
Standard (Default)	1	60	25	60
Lowest	6	5	5	5

* At Amplitude setting 0, ultrasound is disabled. The lowest Flow and Aspiration setting is 5.

- A high amplitude setting combined with a low DTC setting results in more aggressive tissue removal.
- A low amplitude setting combined with a high DTC setting results in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in tissue necrosis.
- A lower amplitude setting in combination with higher irrigation would reduce the potential for tissue necrosis.
- The various disposable attachments (i.e. aspiration probes, etc…) are considered the applied part.

5.3. Wound Debridement Applications

5.3.1 neXus® Standard Handpiece with neXus® SonicOne® OR Probe and Tubing Set Single Use, Disposable Kits

Debridement probes are typically used for contact wound debridement. Tissue excision and fragmentation are achieved through cavitation and other mechanical and hydrodynamic effects.

Recommended Settings
The following settings are general guidelines and should be adjusted based on indication, anatomy, pathology and surgeon's preference.

Table 5.3.1: Wound Debridement, Standard Handpiece Recommended Settings

Tissue Effect	[1]Amplitude Setting	[2]Flow Setting
Highest	100	100
Standard (Default)	70	70
Lowest	5	5
1 – At Amplitude Setting = 0, ultrasound is disabled 2 – The lowest flow setting is 5.		

- A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in tissue necrosis.
- A lower amplitude setting in combination with higher irrigation would reduce the potential for tissue necrosis.
- The various disposable attachments (i.e., debridement probes, etc.…) are considered the applied part.

For Cautions and Warnings, refer to Section 4.5

6. System Components

6.1 Reusable, Non-Sterile Console Components and Accessories

The main reusable system components include the console, footswitch, handpieces, some housings, power cord, cart, IV pole, cleaning brushes, wrenches, filters, suction canister, and sterilization trays. Reusable console components and quantities included with the system may change over time, please check with your Misonix representative for the most current configuration.

6.2 Single Use, Sterile Components

There are a variety of single-use sterile components for the neXus® Ultrasonic System. The components include various neXus® Sterile, Single Use Probe and Tubing Set Kit configurations and other accessories. Please ask your Misonix representative for the latest catalog of available products.

7. Console Setup and Use

7.1. Installation

Upon delivery of the console, perform a visual inspection of the shipping container and all system components for obvious shipping damage prior to use. Retain the shipping container and immediately notify the shipping carrier of any damages found. To lift the console, place hands underneath the base of the unit.

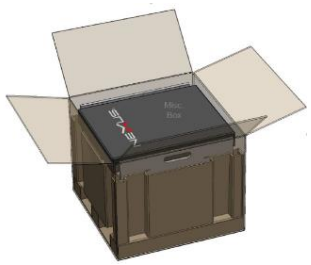


Figure 7.1 : Console Shipping Package

Major Items included:

Table 7.1.1: Console Shipping Package Contents

REF Number	Description	QTY
100-10-0000	Console	1
100-50-0000	Wireless Footswitch w/toe loop and batteries	1
100-11-0000	Irrigation Pole	1
100-40-0000	Aspiration Pump/Canister Tubing	1
100-10-0001	Suction Canister Ring	1
100-10-0010	Power Cord U.S.A. & Mexico	1
100-92-0000	Filter Assembly w/Filter Tubing	1

WARNING The neXus® console automatically adjusts for the mains voltage and frequency. Confirm that the correct fuses are being used. Refer to section 11.1 in instructions for fuse replacement.

Table 7.1.2: Operating Conditions

Operating Conditions	
Operating conditions	• Temperature 13 - 30°C (55 - 86°F) • Relative humidity 20 - 90% (non-condensing) • Altitude -91m (-300ft) to 3000m (9842 ft)

The console can be placed on an appropriate table or cart outside of the sterile field. Please check with your Misonix representative for purchase of the Misonix cart for the neXus® Ultrasonic Surgical Aspirator System, Part Number 100-80-0000.

CAUTION Adequate air circulation is needed to cool electronic components inside of the unit. Do not block the cooling fan at the console rear or the air vents on the console bottom. Do not place the unit on a towel, foam or other soft surface since the material may block the air vents. Blocking these vents may cause unit to overheat and malfunction or create a shock hazard. A clear drape can be used to protect the console front panel but do not cover the pump housing or other console portions.

7.2 Initial Setup Connect the Power Cord

1. The rear of the console features a receptacle for the power cord. Insert the power cord into the receptacle so that it is firmly seated.

2. Install the IV Pole into the IV Pole receptacle. The IV Pole is keyed so that it can be installed in only one direction with the irrigation bag hanging away from the top of the console.

3. Install the Suction Canister Holder. Ensure the Suction Canister Holder is firmly seated so that it can adequately support and secure the Suction Canister.

4. Install the supplied aspiration tubing from the Suction Canister to the Vacuum Filter. Section 7.4 sets up the irrigation and aspiration lines to the Canister and the IV bag.

NOTE: IV bag should be 1000ml or less

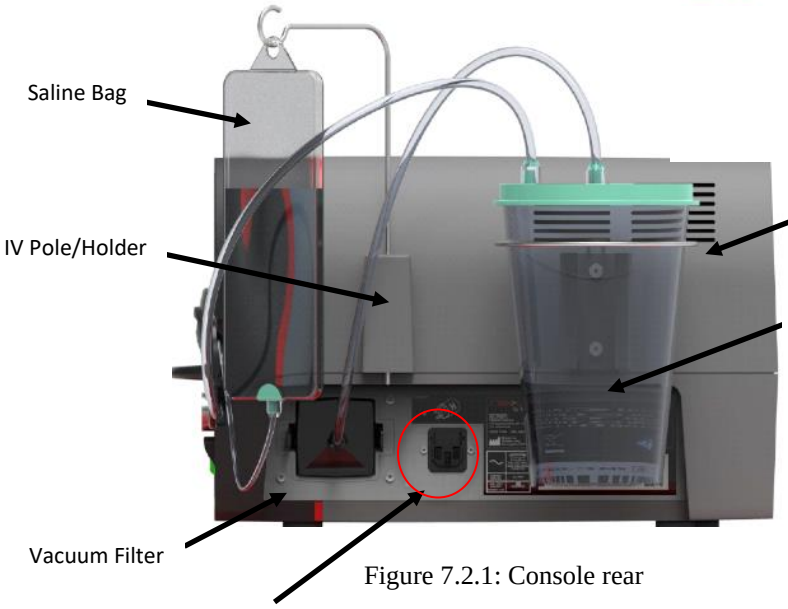
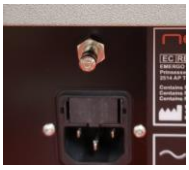
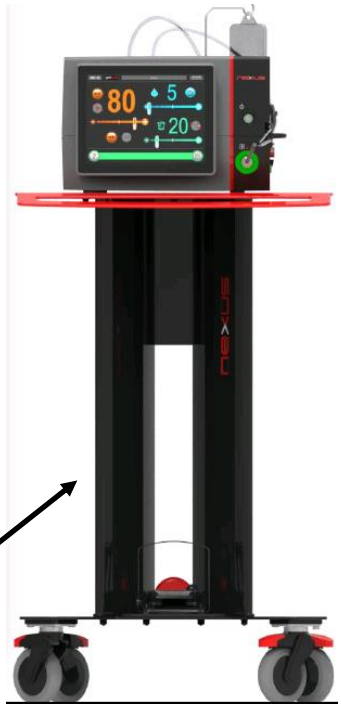


Figure 7.2.1: Console rear



Power Cord Inlet and equipotentiality terminal.
Potential equalization connector makes the connected equipment potential equal (ref IEC 60601-1)



CAUTION When using optional cart accessory, be sure to align the rubber feet on the bottom of the console with the indents in the cart base.

CAUTION Do not transport the neXus® console with the IV bag attached to the IV pole.

5. Obtain the wireless footswitch and place it in the vicinity of the console.

   NOTE: The wireless footswitch is factory paired to the console. Confirmation that the footswitch is connected and communicating with the console can be found in section 7.13.

7.3 Power Up and Setup

The front of the console features a receptacle for the handpiece cable. A large color LCD touchscreen provides the user interface to adjust the main functions of the console. The side of the console features magnetic receptacles where disposable tubing pucks are seated to orient the tubing correctly to the irrigation pump and aspiration valve.

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

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

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

7.3.1 Startup Screen

Plug the power cord into a hospital grade outlet. Plug the other end of the power cord into the rear of the console. Be sure that during use there is sufficient room necessary to disconnect the cord from the console for mains disconnection.

WARNING 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 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. Refer to the back label on the system console for line voltages and frequencies. The splash Screen is the first thing you see upon power up. This screen will progress to the Setup Screen within 5 seconds (see section 7.3 for powering down).

Figure 7.3.1 Startup Screen

7.3.2 Setup Screen

The Setup Screen provides assistance in connecting the Handpiece and Tubing to the Console.

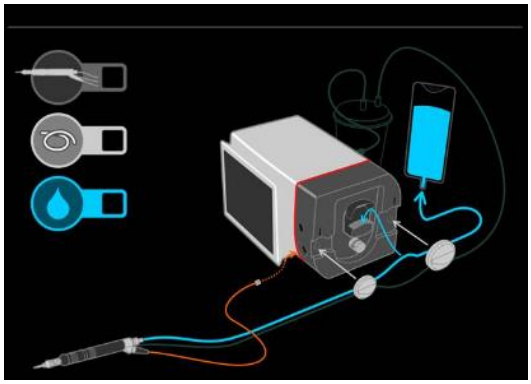


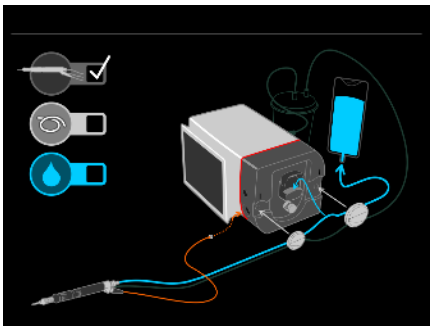
Figure 7.3.2 Setup Screen

7.3.3 Handpiece Connection

The handpiece receptacle is keyed in order to facilitate proper connection. The red dot on top of the receptacle must be in line with the corresponding red dot on the handpiece cable. The handpiece receptacle will turn from blue to green, with an audible click, and the Setup Screen will check the handpiece graphics box to indicate the handpiece is correctly connected. The handpiece connection allows the neXus® console to differentiate between handpieces automatically.

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

- **neXus® Standard Handpiece**



No Handpiece Connected

Handpiece Properly Connected

Figure 7.3.3 Handpiece Connection Status, Standard

- **neXus® SonaStar® Long, neXus® SonaStar® Short, neXus® BoneScalpel Access™ Handpiece(s), , neXus® Sonastar Elite™**

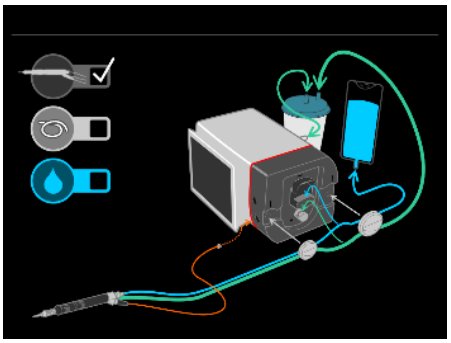


Figure 7.3.3.2 Handpiece Connection Status, Sonastar/Sonastar Elite™/BoneScalpel Access™

7.4 Tubing Connection

- **Tubing Puck Installation**

Connect the disposable tubing pucks as shown below. The pucks are magnetic, so when they are in close proximity to the space the puck will seat. This allows the irrigation and aspiration tubing to be aligned with the opening of the irrigation pump and pinch valve accordingly.

The LEDs on the side of the console will change from blue to green when the pucks are properly positioned. Furthermore, a check mark will appear next to the Tubing icon on the screen.

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

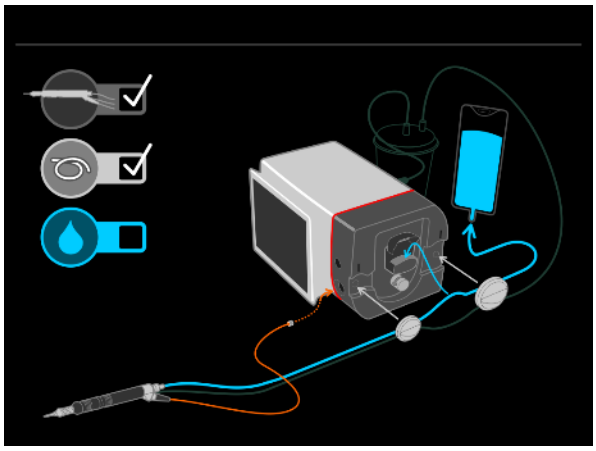


Figure 7.4.1.1 neXus® Standard Handpiece Tubing Connected

- **Irrigation & Aspiration Tubing Installation**

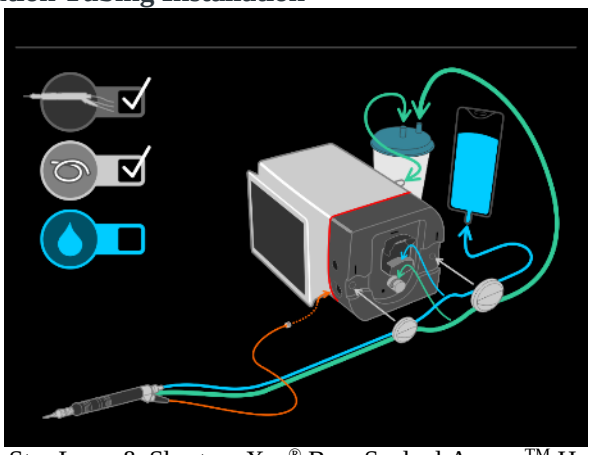


Figure 7.4.1.2 neXus® SonaStar Long & Short, neXus® BoneScalpel Access™ Handpiece, neXus® SonaStar Elite™ Handpiece Tubing Connected

- **Irrigation Tubing Installation**

CAUTION:

- Do not place the soft silicone tube behind or in front of the rollers (latch removed in illustrations)
- Do not pinch the soft silicone tube when the latch is locked.
- Do not pinch barb fittings when closing the latch.

Open the irrigation pump cover and seat the irrigation tubing so that it is centered to the pump rollers and aligned with the "V" slot as shown below. Close the pump cover taking care not to pinch your fingers in the closure. The LED light above the pump cover will turn from blue to green and the blue water symbol box on the screen will be checked indicating a correct connection followed by the Priming screen.

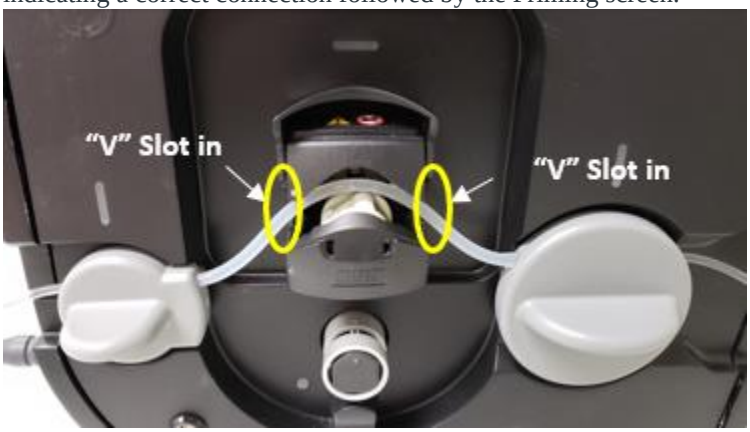


Figure 7.4.2.1.1 Irrigation Tubing Installation

- **Aspiration Tubing Installation**

Figure 7.4.2.2 Standard Handpiece

Figure 7.4.2.3 SonaStar Long, Short, Elite, SonicOne

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

- **Connection to Canister and IV bag**

For neXus® SonaStar® applications connect the aspiration tubing of the handpiece to the "Patient" port of the Suction Canister.

For all handpiece applications connect the irrigation tubing to the IV bag.

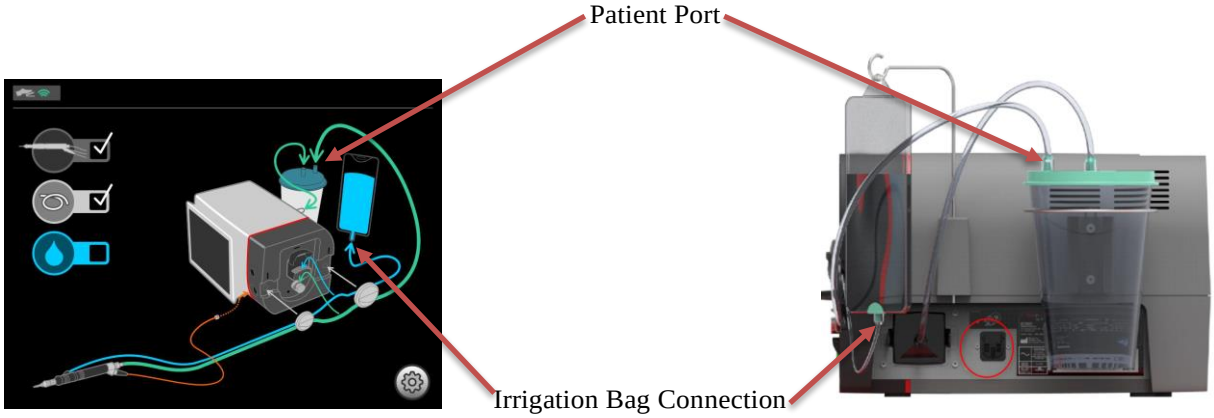


Figure 7.4.2.5 Aspiration and Irrigation Tubing Connections

7.5 Handpiece Assembly & Disassembly

See separate Handpiece IFU's for assembly and disassembly instructions as follows::

- Document #: 100-24-1000 – neXus® SonaStar ® Handpiece (Short & Long) Instructions for Use (IFU)
- Document #: 100-21-1000 – neXus® Standard Handpiece Instructions for Use (IFU)
- Document #: 100-22-1000 – neXus® BoneScalpel Access™ Handpiece Instructions for Use (IFU)
- Document #: 100-26-1000 – neXus® Sonastar Elite™ Handpiece Instructions for Use (IFU)

7.6 Priming Irrigation Tubing

Proper irrigation with sterile saline ensures cooling of handpiece and vibrating elements, cooling and lavage of the surgical site, and lubrication of bone/probe tip interface for hard tissue removal. The active ultrasonic probe remains cold when not in contact with tissue. However, when a probe tip contacts tissue heat is generated. The heat increases with applied probe tip pressure or amplitude. Irrigation needs to be applied at the probe tip/tissue interface to mitigate this temperature rise. Most ultrasonic probe tips feature an integrated irrigation channel. The irrigation is expelled through a jet nozzle at the probe tip. Active probe tip surfaces are being cooled directly.

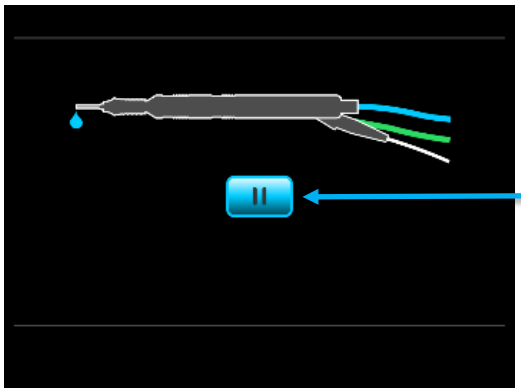


Figure 7.6.1 Priming Screen

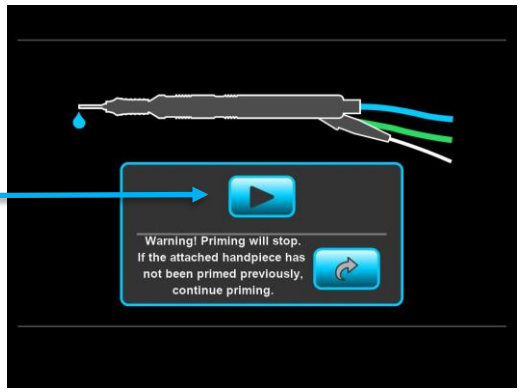


Figure 7.6.2 Prime Active/Pause Priming Screen

CAUTION Prime the irrigation tubing prior to use. At all times ensure that the irrigation flows towards the handpiece when footswitch is depressed. If irrigation is not flowing, cease use until flow is restored.

PRIMING BUTTONS	**FUNCTION**
	Initiates priming cycle. When the cycle is complete the Main screen automatically appears.
	Pauses the priming cycle. Pressing it again resumes the priming cycle.
	Skips priming cycle. Caution: Irrigation tubing needs to be primed prior to use. Not doing so can damage the probe/probe tip

Figure 7.6.3 Priming Button Definitions

7.7 Main Screen with a neXus® Standard Handpiece
(e.g., neXus® BoneScalpel® or neXus® SonicOne® Applications)

The Main Screen allows control of the main system functions such as Amplitude, Irrigation Flow and Aspiration (optional). Information on system status and set points for ultrasound amplitude, irrigation flow rate and aspiration with respective controls. Additional controls for ultrasound enable/ standby are provided on the display panel.

- **Default Main Screen with a neXus® Standard Handpiece (e.g., neXus® BoneScalpel® or neXus® SonicOne® Applications)**

Pressing the Flush Button, on the Footswitch, activates irrigation only.

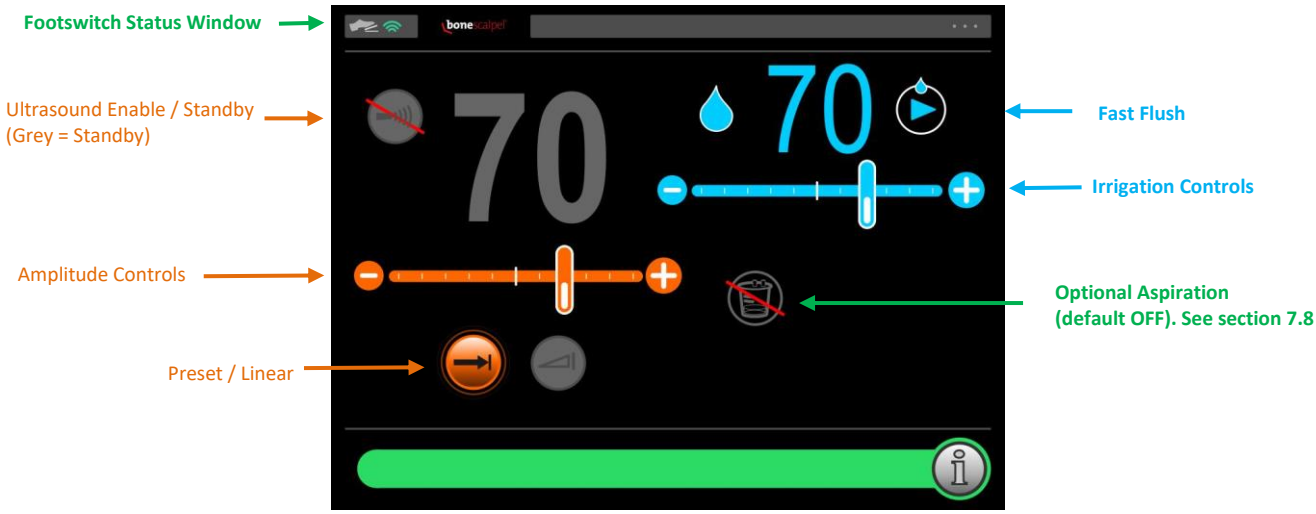


Figure 7.7.1 Default Main Screen (Standard Handpiece) with Ultrasound Disabled

- **Enabling Ultrasound Control with a neXus® Standard Handpiece (e.g., neXus® BoneScalpel® or neXus® SonicOne® Applications)**

Pressing the ultrasound Enable button, changes the amplitude setting from grey to orange. In this mode ultrasound is ready for activation via footswitch. Pressing the footswitch when the setting is orange activates ultrasound and irrigation.

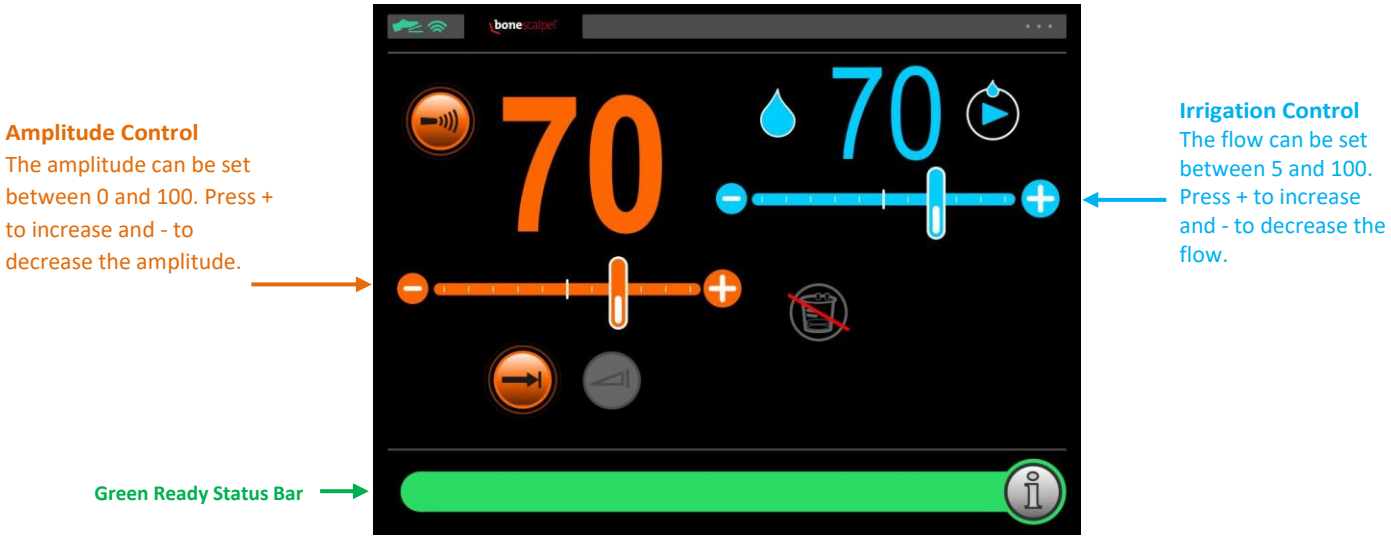
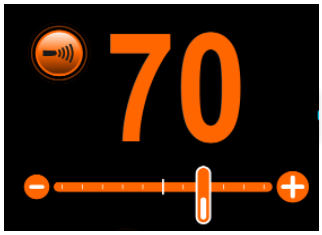


Figure 7.7.2 Default Main Screen (Standard Handpiece) with Ultrasound Enabled

- **System Controls; Amplitude, Irrigation & Aspiration (e.g., neXus® BoneScalpel® or neXus® SonicOne® Applications)**

  - ***Amplitude Controls***

    The **ORANGE** display controls amplitude. The ultrasonic probe tip engages the target area in linear strokes at a rate of approximately 22,500 cycles per second. During each cycle the probe tip elongates from resting to maximum position, contracts back over resting and to minimum position and elongates back to its resting point. The peak-to-peak amplitude or stroke distance can be adjusted by changing the Amplitude from setting 0-100. This is the main parameter to control the rate of tissue removal. A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal. Amplitude and thus removal rate may alter with size and geometry of the ultrasonic probe tip.

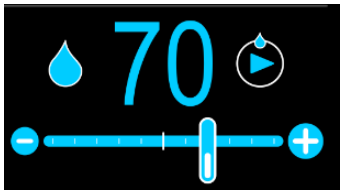
    Amplitude can be adjusted by any of the following methods:
    1. Tapping the "+" or "- "icons, each tap results in an incremental adjustment of 5.
    2. Touching the slider bar icon and moving right to left, while remaining contact with the screen.
    3. Touching a single point along the scale bar, resulting in a direct adjustment to that position.

    Preset / Linear Controls:

    1. Preset Mode – In this mode, vibration is available immediately at the user specified setting when the footswitch is depressed (i.e., on/off, no variability).
    2. Linear Mode - In this mode, the vibration setting varies from 0 to the user preset setting as a linear function of the amount of footswitch travel (i.e., gas pedal, user varied control).

  - ***Irrigation Controls***

    The **BLUE** display controls Irrigation. Proper irrigation with sterile saline ensures:
    1. Cooling of handpiece and vibrating elements
    2. Cooling and lavage of the surgical site
    3. Lubrication of bone/probe tip interface for hard tissue removal

    The active ultrasonic probe remains cold when not in contact with tissue. However, when a probe tip contacts tissue heat is generated. The heat increases with applied probe tip pressure or amplitude. Irrigation needs to be applied at the probe tip/tissue interface to mitigate this temperature rise. Most ultrasonic probe tips feature an integrated irrigation channel. The irrigation is expelled through a jet nozzle at the probe tip. Active tip surfaces are being cooled directly.

    Irrigation can be adjusted by any of the following methods:
    1. Tapping the "+" or "- "icons, each tap results in an incremental adjustment of 5.
    2. Touching the slider bar icon and moving right to left, while remaining contact with the screen
    3. Touching a single point along the scale bar, resulting in a direct adjustment to that position

    Flush Control: When the FLUSH button is pressed, irrigation pump operates at the Flush flow rate.
    1. Pressing it again stops the flow rate.

7.8 Main Screen with a neXus® SonaStar® Handpiece

(e.g., neXus® SonaStar® Short or neXus® SonaStar® Long Handpiece Applications)

The Main Screen allows control of the main system functions such as Amplitude, Irrigation Flow and Aspiration. See section 5.2 for recommendations on set points for ultrasound amplitude, irrigation flow rate and aspiration. Additional controls for ultrasound enable/ standby are provided on the display panel.

- **Default Main Screen with a neXus® SonaStar® Handpiece (e.g., neXus® SonaStar® Short or neXus® SonaStar® Long Handpiece Applications)**

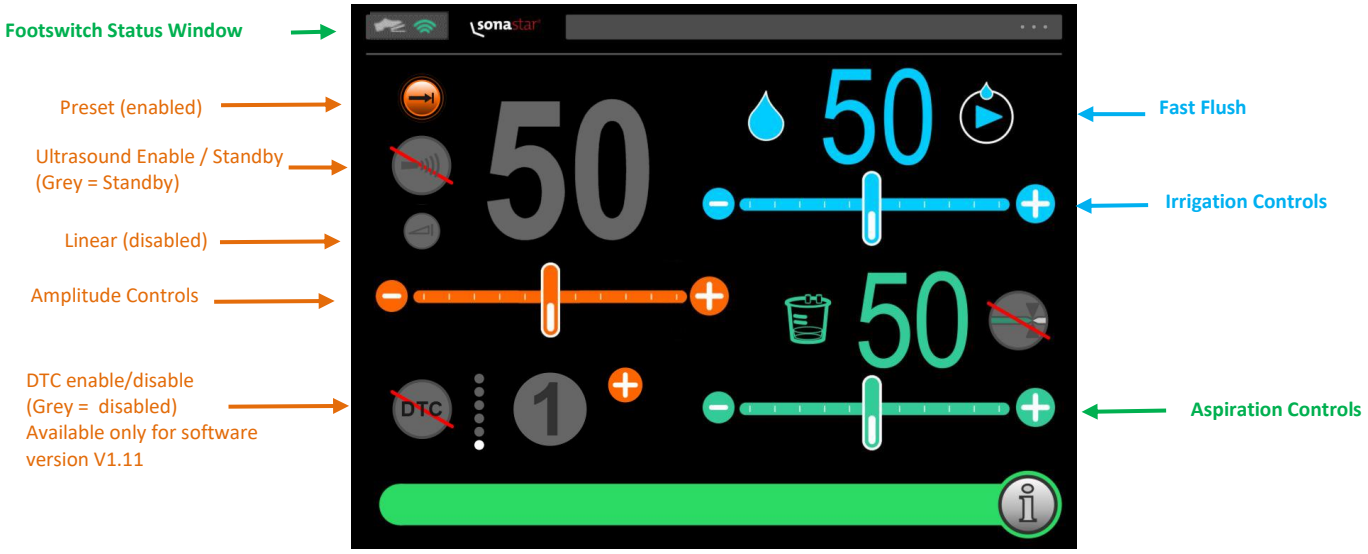


Figure 7.8.1 Default Main Screen (SonaStar Handpieces) with Ultrasound Disabled

- **Enabling Ultrasound Control with a neXus® SonaStar® Handpiece (e.g., neXus® SonaStar® Short or neXus® SonaStar® Long Handpiece Applications)**

Pressing the ultrasound Enable button, changes the amplitude setting from grey to orange. In this mode ultrasound is ready for activation via footswitch. Pressing the foot pedal when the setting is orange activates ultrasound and irrigation.

Figure 7.8.2 Default Main Screen (SonaStar Handpieces) with Ultrasound Enabled

- **Enabling *Dynamic Tissue Control* (DTC) with a neXus® SonaStar® Short or neXus® SonaStar® Long Handpiece**

  The neXus system provides a pulsed ultrasound feature called Dynamic Tissue Control or DTC. This is a pulsed ultrasound mode of operation for fine control of the tissue removal rate. Pressing the DTC button enables Dynamic Tissue Control. The color of the button will go from Grey to Orange. In this mode pulsed ultrasound is ready for activation via footswitch. Pressing the "+" and "-" buttons allows the user to change the DTC settings from 1 to 6 (refer to Table 7.8 below). Pressing the foot pedal when the setting is orange activates ultrasound and irrigation. Aspiration is active when the footpedal is either pressed or released.

DTC Control:
The Tissue Control can be set between 1 and 6. Press + to increase and - to decrease the setting.

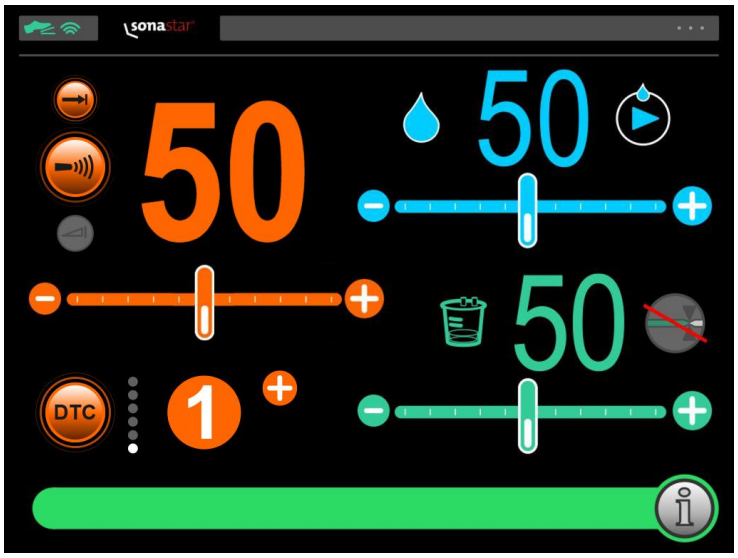


Figure 7.8.3 Default Main Screen with Ultrasound and DTC Enabled

- **System Controls; Amplitude, Irrigation & Aspiration (e.g., neXus® SonaStar® Short or neXus® SonaStar® Long Handpiece)**
  - ***Amplitude Controls***

    For Amplitude controls see Section 7.7: System Controls; Amplitude, Irrigation & Aspiration (e.g., neXus® BoneScalpel® or neXus® SonicOne® Applications).

  - ***DTC Controls***

    The ORANGE display below the vibration section is a user optional mode of operation called "*Dynamic Tissue Control*". This mode of operation pulses the ultrasound to reduce motional amplitude for fine control of tissue removal. Pressing the DTC button enables Dynamic Tissue Control. The color of the button will go from Grey to Orange. Pressing the "+" and "-" buttons allows the user to change the DTC settings from 1 to 6. Refer to Table 7.8. In combination with the DTC settings, the tissue removal effect can be adjusted by changing the Amplitude, Irrigation, and/or Aspiration settings. Lower Amplitude and Aspiration settings will result in a slower tissue removal rate. See Table 5.2.3 for recommended settings if DTC is enabled.

DTC Setting	Tissue Effect
Off (grey)	Fastest removal rate
1	Slightly decreased removal rate
2	Removal rate less than setting 1
3	Removal rate less than setting 2
4	Removal rate less than setting 3
5	Removal rate less than setting 4
6	Slowest removal rate

Table 7.8: DTC Settings vs. Tissue Effects

- ***Irrigation Controls***

  For Irrigation controls see Section 7.7: System Controls; Amplitude, Irrigation & Aspiration (e.g., neXus® BoneScalpel® or neXus® SonicOne® Applications).

- ***Aspiration Controls***

  The **GREEN** display indicates the aspiration or vacuum level set by the user. The vacuum level may be adjusted by pressing the "+" or "-" on the green slider below the numeric indicator on the screen. 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 1.5 inch Hg (38 mm Hg) for delicate, tissue removal applications.

  The aspiration function varies slightly, based upon user preferences:

- When the pedal on the footswitch is depressed, vacuum is available up to the preset level. When the footswitch is released, the pinch valve is activated and the vacuum at the probe tip ceases for a very short time period, allowing the safe removal of the probe tip from the surgical site. Subsequently, the vacuum is reactivated for approximately 2.5 minutes.

- When the FLUSH button on the Main screen or on the footswitch is pressed, the pinch valve is closed and there is no vacuum present at the probe 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 probe tip.

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

- When in LAP and in Standby mode (footswitch not depressed), vacuum is available up to the preset level. 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.

7.9 Main Screen with a neXus® SonaStar Elite™ Handpiece

The Main Screen allows control of the main system functions such as Amplitude, Irrigation Flow, Aspiration, and optional *Dynamic Tissue Control* (DTC). See Table 5.2.2 for recommendations on set points for ultrasound amplitude, irrigation flow rate , aspiration, or optional *Dynamic Tissue Control* (DTC). Additional controls for ultrasound enable/ standby are provided on the display panel.

- **Default Main Screen with a neXus® SonaStar Elite™ Handpiece**

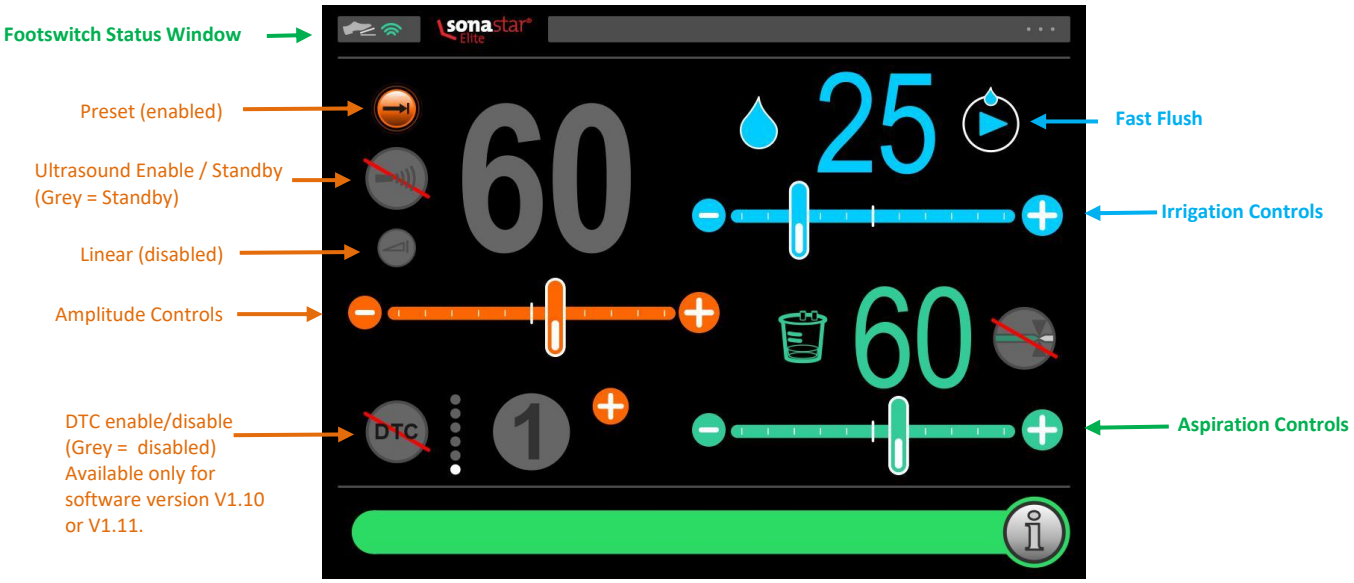


Figure 7.9.1 Default Main Screen with Ultrasound Disabled

- **Enabling Ultrasound Control with a neXus® SonaStar Elite™ Handpiece**

Pressing the ultrasound Enable button, changes the amplitude setting from grey to orange. In this mode ultrasound is ready for activation via footswitch. Pressing the foot pedal when the setting is orange activates ultrasound and irrigation. Aspiration is active when the footpedal is either pressed or released.

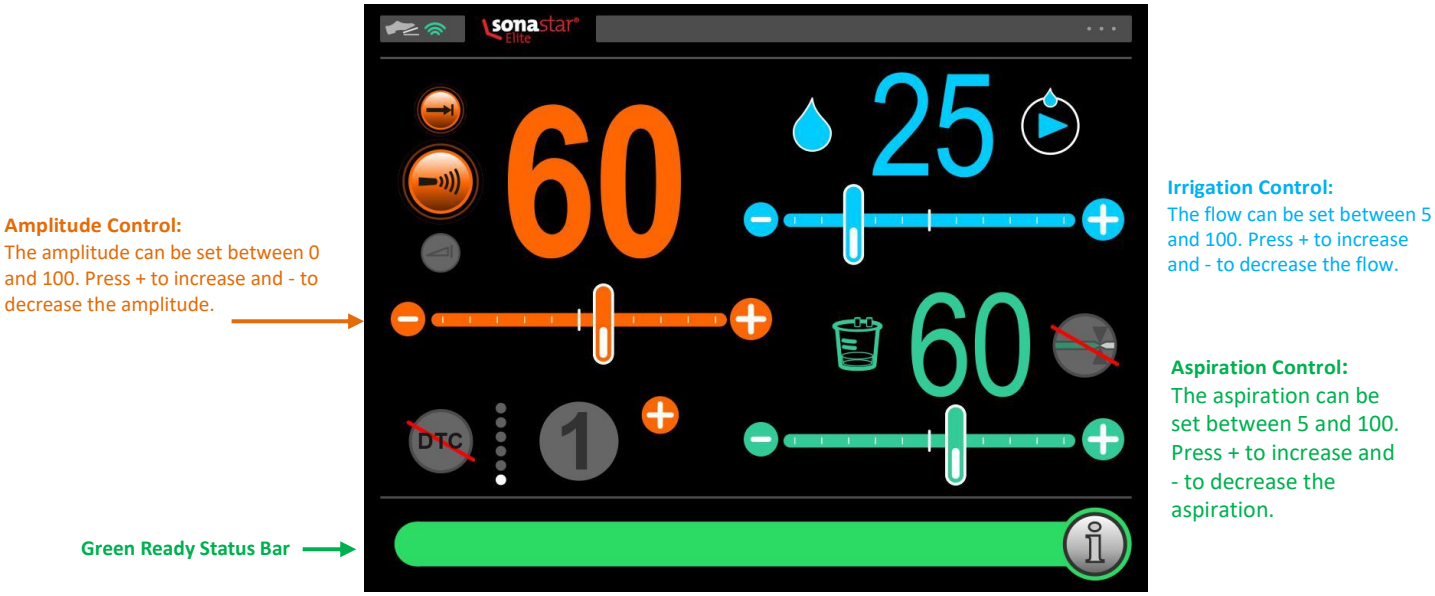


Figure 7.9.2 Default Main Screen with Ultrasound Enabled

- **Enabling *Dynamic Tissue Control* (DTC) with a neXus® SonaStar Elite™ Handpiece**
  The neXus system provides a pulsed ultrasound feature called Dynamic Tissue Control or DTC. This is a pulsed ultrasound mode of operation for fine control of the tissue removal rate. Pressing the DTC button enables Dynamic Tissue Control. The color of the button will go from Grey to Orange. In this mode pulsed ultrasound is ready for activation via footswitch. Pressing the "+" and "-" buttons allows the user to change the DTC settings from 1 to 6 (refer to Table 7.9 below). Pressing the foot pedal when the setting is orange activates ultrasound and irrigation. Aspiration is active when the footpedal is either pressed or released.

DTC Control:
The Tissue Control can be set between 1 and 6. Press + to increase and - to decrease the setting.

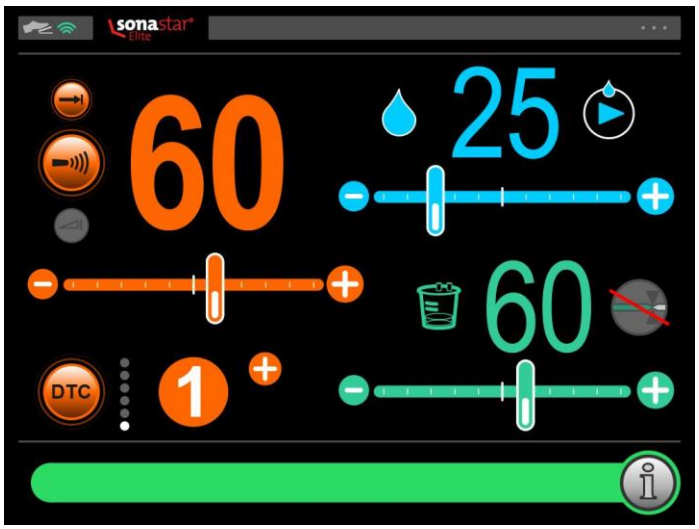


Figure 7.9.3 Default Main Screen with Ultrasound and DTC Enabled

- **System Controls; Amplitude, DTC, Irrigation & Aspiration**
  - ***Amplitude Controls***
    For Amplitude controls see Section 7.7: System Controls
  - ***DTC Controls***
    The ORANGE display below the vibration section is a user optional mode of operation called "*Dynamic Tissue Control*". This mode of operation pulses the ultrasound to reduce motional amplitude for fine control of tissue removal. Pressing the DTC button enables Dynamic Tissue Control. The color of the button will go from Grey to Orange. Pressing the "+" and "-" buttons allows the user to change the DTC settings from 1 to 6. Refer to Table 7.9. In combination with the DTC settings, the tissue removal effect can be adjusted by changing the Amplitude, Irrigation, and/or Aspiration settings. Lower Amplitude and Aspiration settings will result in a slower tissue removal rate. See Table 5.2.3 for recommended settings if DTC is enabled.

DTC Setting	Tissue Effect
Off (grey)	Fastest removal rate
1	Slightly decreased removal rate
2	Removal rate less than setting 1
3	Removal rate less than setting 2
4	Removal rate less than setting 3
5	Removal rate less than setting 4
6	Slowest removal rate

Table 7.9: DTC Settings vs. Tissue Effects

  - ***Irrigation Controls***
    For Irrigation controls see Section 7.7: System Controls
  - ***Aspiration Controls***
    For Irrigation controls see Section 7.8: System Controls.

7.10 Main Screen with a neXus® BoneScalpel Access™ Handpiece (e.g., neXus® BoneScalpel Access™ Applications)

The Main Screen allows control of the main system functions such as Amplitude, Irrigation Flow and Aspiration. See Section 4.4 for recommendations on set points for ultrasound amplitude, irrigation flow rate and aspiration. Additional controls for ultrasound enable/standby are provided on the display panel.

- **Default Main Screen with a neXus® BoneScalpel Access™ Handpiece (e.g., neXus® BoneScalpel Access™ Applications)**

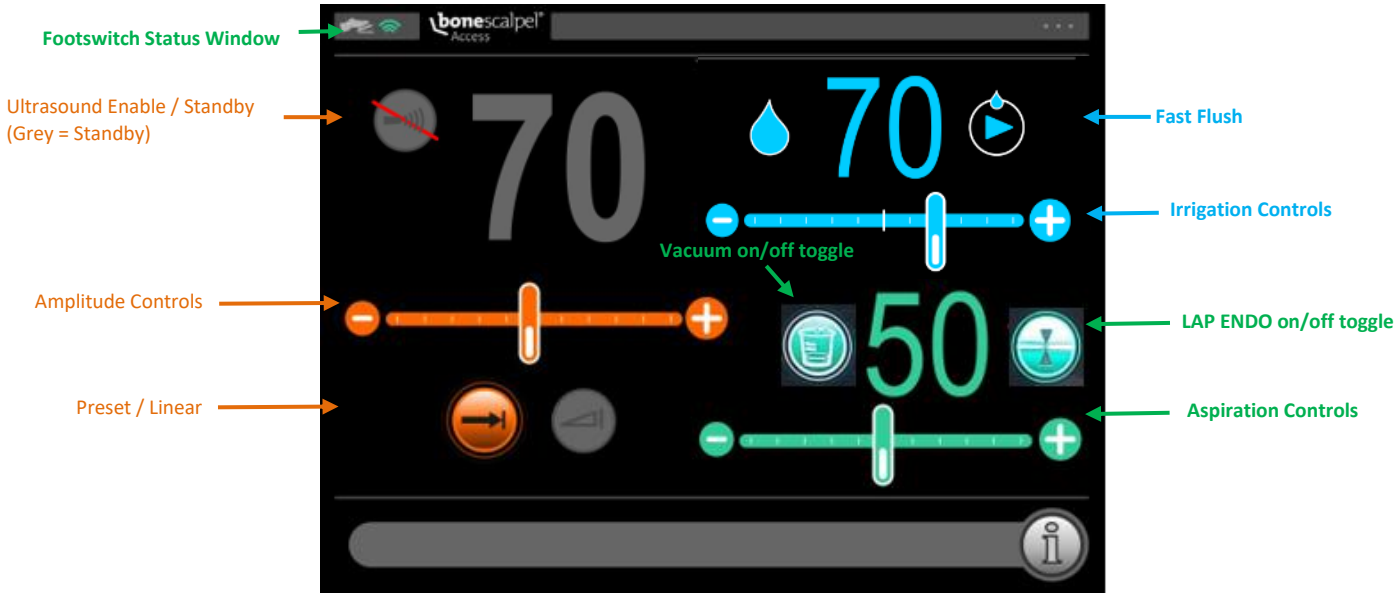


Figure 7.10.1 Default Main Screen (BoneScalpel Access Handpiece) with Ultrasound Disabled

- **Enabling Ultrasound Control with a neXus® BoneScalpel Access™ Handpiece (e.g., neXus® BoneScalpel Access™ Applications)**

Pressing the ultrasound Enable button, changes the amplitude setting from grey to orange. In this mode ultrasound is ready for activation via footswitch. Pressing the footswitch when the setting is orange activates ultrasound and irrigation.

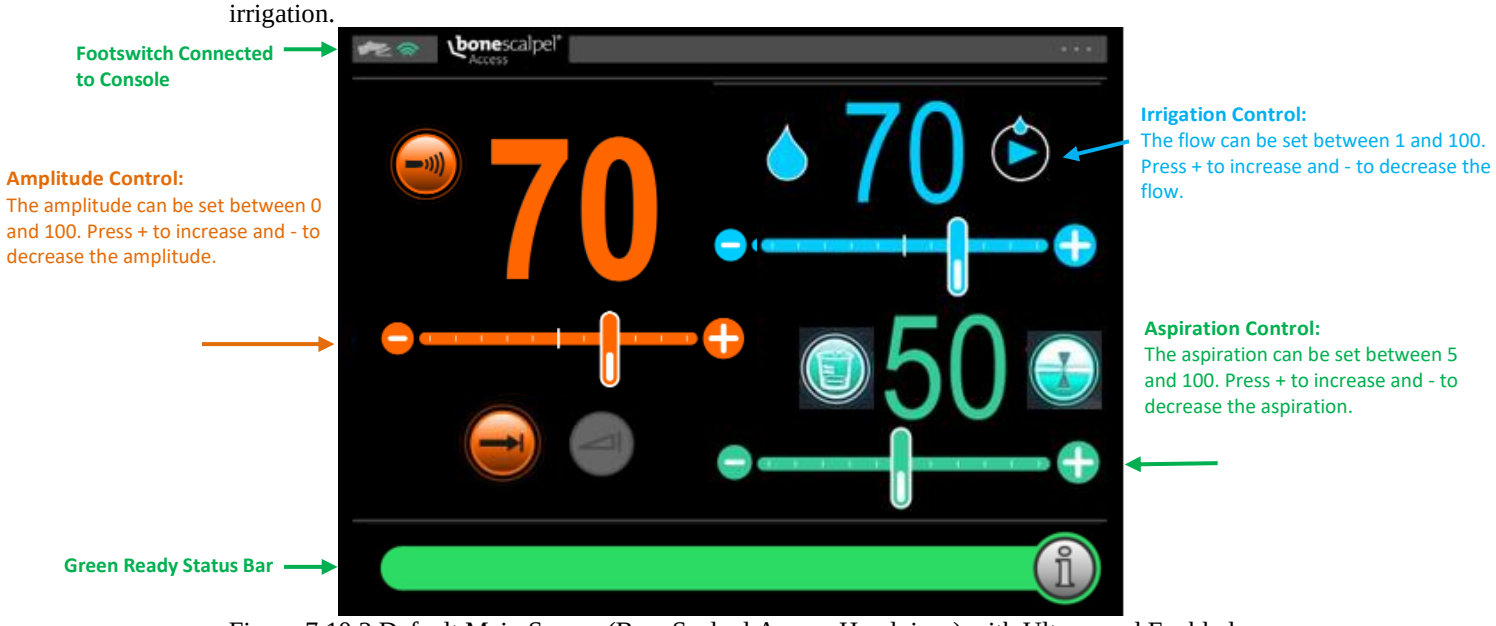


Figure 7.10.2 Default Main Screen (BoneScalpel Access Handpiece) with Ultrasound Enabled

- **System Controls; Amplitude, Irrigation & Aspiration (e.g., neXus® BoneScalpel Access™ Applications)**

  - ***Amplitude Controls***

    For Amplitude controls see Section: System Controls; Amplitude, Irrigation & Aspiration (e.g., neXus® BoneScalpel® or neXus® SonicOne® Applications).

  - ***Irrigation Controls***

    Irrigation can be adjusted by any of the following methods:

    1. Tapping the "+" or "- "icons, each tap results in an incremental adjustment of 1 from 1 to 20 and increments of 5 from 20 to 100.
    2. Touching the slider bar icon and moving right to left, while remaining contact with the screen
    3. Touching a single point along the scale bar, resulting in a direct adjustment to that position

  - ***Aspiration Controls***

    The aspiration system is on by default. Pressing the Vacuum canister icon shuts the aspiration system off. Refer to BoneScalpel Access Handpiece Instructions for Use for when to activate/deactivate aspiration as well as recommendations for settings.

    The **GREEN** display indicates the aspiration or vacuum level set by the user. The vacuum level may be adjusted by pressing the "+" or "- "on the green slider below the numeric indicator on the screen. At the maximum setting of '100', approximately 25 inches Hg (635 mmHg) at sea level is available at the canister. At the minimum setting '5', the vacuum is less than 2.0-inch Hg (51 mm Hg) for delicate, tissue removal applications.

    LAP/ENDO Mode is on by default  and the vacuum line is pinched. When the footswitch is depressed, the pinch valve opens to provide vacuum to the probe tip and allow the ablated tissue to be aspirated into the vacuum canister. Upon release of the pedal on the footswitch, the pinch valve closes. In this mode, 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.

    When LAP/ENDO mode is off,  and the pedal on the footswitch is depressed, vacuum is available up to the preset level. When the footswitch is released, the pinch valve is activated and the vacuum at the probe tip ceases for a very short time period, allowing the safe removal of the probe tip from the surgical site. In this mode, after 2.5 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.

    When the FLUSH button on the Main screen or on the footswitch is pressed, the pinch valve is closed and there is no vacuum present at the probe 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 probe tip. If in LAP/ENDO mode, when the FLUSH button is released, the valve re-opens for a short period of time and then closes.

7.11 Mode Selection & Functionality

Table 7.11: Operational Mode Selection

Operational Mode	Icon and Description	Function & Purpose
Preset Mode	 Preset Mode is ON  Preset Mode is OFF	This icon allows the user to enable/disable the Preset mode. In this mode, vibration is available immediately at its user setting.
Linear Mode	 Linear Mode is ON  Linear Mode is OFF	This icon allows the user to enable/disable the Linear mode. In this mode, the vibration setting varies from 0 to the preset user setting as a linear function of the amount of footswitch travel (i.e., gas pedal)
Lap/Endo Mode	 LAP/ENDO Mode is ON  LAP/ENDO Mode is OFF	This icon allows the user to enable/disable the LAP/ENDO mode. In this mode the aspiration tubing is being pinched to prevent the loss of insufflation. When the footswitch is depressed, it opens for tissue removal into the canister.
DTC Mode	 DTC Mode is ON  DTC Mode is OFF	This icon allows the user to enable *Dynamic Tissue Control* (DTC) which is a pulsed ultrasound mode of operation for fine control of the tissue removal rate.

7.12 System Check

After preparing the system for use, a System Check should be performed prior to use ensuring proper functionality. Upon success completion of the System check, as described below, the neXus® Ultrasonic Surgical Aspirator System is now ready for use.

Table 7.12: Console System Check

System Check	
Enable Ultrasound	Switch to Enable Mode using enable/standby button. Confirm that Amplitude setting is Orange.
Depress footswitch	Direct ultrasonic probe tip toward suitable reservoir to collect irrigation. Depress footswitch.
Confirm Function	Irrigation is pumped from console towards handpiece. A beep is briefly heard. Ultrasonic probe tip emits buzzing sound and irrigation exits probe tip as fine spray.
Release footswitch	Release footswitch. Ultrasound and Flow output stop.
Function Confirmed	System is now ready for use.
Function NOT confirmed	Console alerts of a Fault or does not respond as expected. Refer to troubleshooting section for next steps.

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

WARNING Heat is being generated at the probe tip/tissue interface. A continuous, lateral sweeping motion is recommended for general bone/tissue removal in order to minimize contact duration with the ultrasonic probe tip and minimize the temperature increase.

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

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

WARNING 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 probe tip free from contact with any object

7.13 Software Version Information

The following steps may be performed to view the software that is installed on your system. The Software Version Information may be obtained from both the Setup screen and the Mains Screen.

From the Main screen press the System Information icon.

From the Setup screen press the Settings icon followed by the System formation icon.

Table 7.13: Software Versions related to User Features

User Feature	Software Version	Version Information
Software Update Capability	V1.6	GUI: 01.06.0882 ACC: 01.06.0882 DSP: 01.06.0178
Wired Footpedal	V1.7	GUI: 01.07.0933 ACC: 01.06.0882 DSP: 01.06.0178
BoneScalpel Access™ Handpiece	V1.8	GUI: 01.08.0952 ACC: 01.08.0952 DSP: 01.08.0204
SonaStar Elite™ Handpiece	V1.9	GUI: 01.09.0967 ACC: 01.09.0967 DSP: 01.09.0227
Dynamic Tissue Control for SonaStar Elite™ Handpiece	V1.10	GUI: 01.10.1324 ACC: 01.10.1324 DSP: 01.10.0338
Adds Dynamic Tissue Control for SonaStar® Short or neXus® SonaStar® Long Handpiece	V1.11	GUI: 01.10.1327 ACC: 01.10.1327 DSP: 01.10.0362

Note: Each software version is backward compatabile

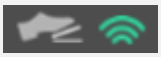
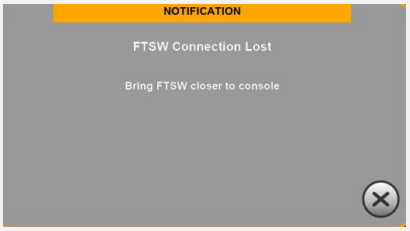
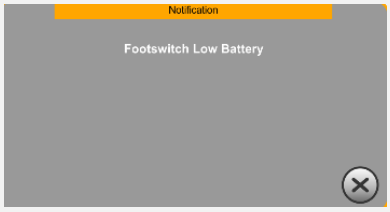
7.14 Footswitch Connectivity & Functionality

- **Wireless Footswitch Functionality and Features**

The neXus® system offers users a wireless footswitch option to activate its core functions(e.g., Ultrasound, Irrigation, and Aspiration). The console monitors the communication with the footswitch at all times. If communication is lost an alert appears on the screen (see Troubleshooting Section: Wireless Footswitch Connection Lost Notification). The footswitch is powered with one “AA” alkaline battery. If the battery is low, an alert will appear on the screen. (See Troubleshooting Section: Wireless Footswitch Connection Lost Notification). For battery replacement see section 11.3.

- **Wireless Footswitch Connectivity**
  The console monitors the status of the wireless footswitch at all times. A window is provided in the corner of the main and setup screen to alert the user of its status.

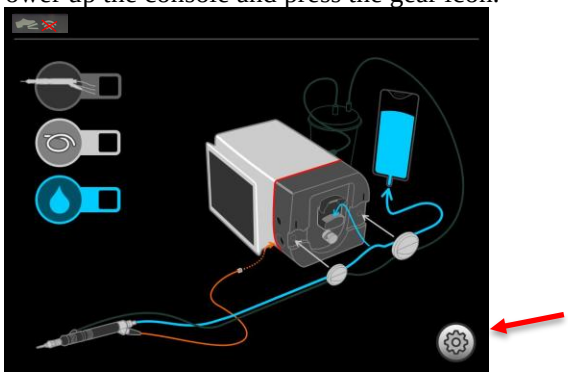
Table 7.14.1: Wireless Footswitch Connectivity Icons and Descriptions

STATUS ICONS	DESCRIPTION
	Footswitch **IS** communicating with the console
	Footswitch is **NOT** communicating with the console (Flashing X and audible beep)
FOOTSWITCH CONNECTION LOST ON-SCREEN NOTIFICATION 	(For when on Main screen only) Footswitch is **NOT** Communicating with Console. Bring footswitch closer to the console or replace battery.
	Footswitch is pressed, Vibration is active. A one-time audible beep will be heard.
LOW BATTERY ON-SCREEN NOTIFICATION  **FOLLOWED BY** 	Low Footswitch Battery. **Caution**: Change batteries immediately following procedure

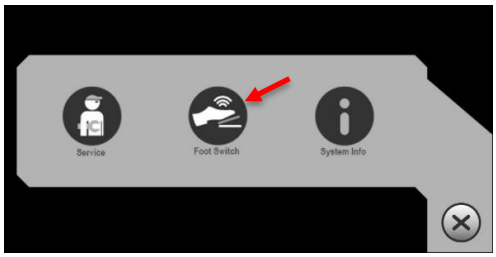
- **Pairing the Wireless Footswitch to the Console**

  The neXus® footswitch is paired to the console prior to delivery to the end customer. If a replacement footswitch is required or footswitch needs to be re-paired to the console, the following steps are required to pair the footswitch.

  Power up the console and press the gear icon.



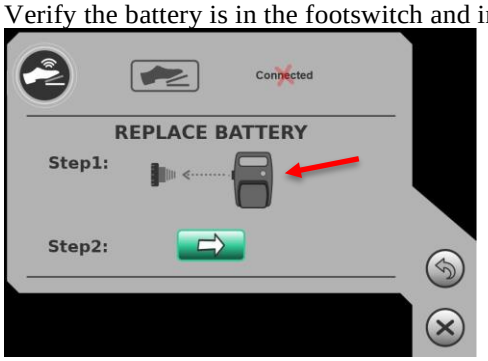
  Press the Footswitch icon.



  If this screen appears, no further action is required. Footswitch is connected to the console.

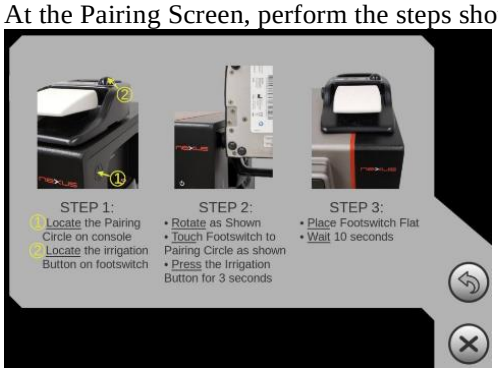
  If the screen below appears, replace battery (Standard AA Battery), verifying proper orientation (refer to image on bottom of the footswitch). If the screen above appears after replacing the battery, no further action is required. Footswitch is connected to the console. If the screen below remains after replacing the battery, press the arrow to advance to the Start Pairing screen.

  Verify the battery is in the footswitch and in the proper orientation.



Press the arrow to advance to the pairing process for additional instructions.

At the Pairing Screen, perform the steps shown within 30 seconds.



Once pairing has been successfully completed, there will be a green “(insert check mark symbol). Once that is confirmed, press the “X” in the lower right corner to exit back to the Setup screen.

- **Wired Footswitch Connectivity**

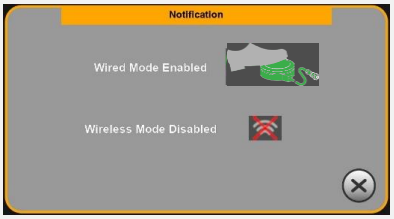
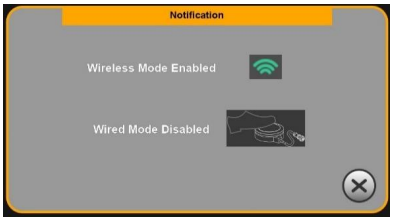
  The Wired Footswitch is an optional accessory for the neXus® console (part number 100-51-0000). The Wired Footswitch may be connected to the receptacle on the side of the console as shown below. A one-time Notification is provided to alert the user on which footswitch is enabled with the system. Also, an icon is provided in the corner of the main screen to alert the user of its status. As an optional accessory, the neXus® system may use a wired Footswitch to activate its core functions (e.g., Ultrasound, Irrigation, and Aspiration) to their preset settings. The wired footswitch does not separately activate Irrigation Fast Flush. This Footswitch must be used with software GUI version 01.07.XXXX or above where XXXX are any 4-digits. See System Information screen for the software version installed in your console (see section 7.13 for accessing System Information).

Figure 7.14.1 Wired Footswitch

- **Wired Footswitch Notifications**

  The console monitors the status of the Footswitch at all times. When the wired Footswitch is either connected or disconnected, a Notification window is provided to indicate which Footswitch is active. In addition, once clearing the notification, an icon is shown in the corner of the main and setup screens to alert the user of its status.

Table 7.14.2 Wired Footswitch Notifications

WIRED FOOTSWITCH NOTIFICATION / ICONS	DESCRIPTION
	The Notification screen alerts the user that the Wired Footswitch is connected and ready and the Wireless footswitch is disabled.
	The Notification screen alerts the user that the Wired Footswitch is disabled, and the Wireless footswitch is enabled.
	Wired Footswitch connected to the console and pedal not pressed.
	Footswitch is pressed. Vibration is active. A one-time audible beep will be heard.

- **Connecting the Wired Footswitch to the Console**
  The Wired Footswitch is connected to the port located on the side of the console (see below). The connector on the console and wired Footswitch is keyed so that it can only be connected in the orientation shown.

Figure 7.14.3 Wired Footswitch Connection to Console

7.15 Console Disassembly

The neXus® console can be placed into "Power Standby" by pressing and holding the power button on the front panel. In this mode, the screen is turned off and power is in standby. Pressing again "wakes up" the display and starts the setup sequence. If the device is already setup, the Priming screen shall appear. To completely tear-down the console, follow the steps in the table below.

Table 7.15.1 Console Disassembly

Console Disassembly Procedure (Note: Steps can be done in ANY order)	
Remove power	Unplug Mains power cord from the rear of the console.
Remove Handpiece Cable	Pull cable connector from receptacle on console front.
Remove Tubing	Open pump cover. Remove tubing from pump compartment. Disconnect tubing from irrigation source (i.e. Saline Bag / Bottle) and canister (if applicable.

Figure 7.15.1 Console Power Button

8. Cleaning the neXus® System

8.1 Console & Footswitch Cleaning

Table 8.1.1 Console & Footswitch Cleaning

Console and Footswitch	
Wipe Surfaces	• Misonix recommends the use of EPA certified CaviWipes® or an equivalent quaternary ammonium compound surface cleaning and disinfection wipe. Please follow the manufacturer's instructions for surface cleaning and disinfection of hard nonporous surfaces including, without limitation, the use of Personal Protection Equipment (PPE) for bloodborne pathogens. Dispose of the used wipes in accordance with local regulations regarding the disposal of biological hazardous waste. • Dispose of cloth or paper with contaminated waste.

CAUTION Only external surfaces of the console should be cleaned. Do not attempt to remove any panels in order to clean or disinfect internal surfaces.

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

8.2 Cleaning and Sterilization of neXus® Handpieces and Reusable Accessories

See the separate Handpiece IFU's for cleaning and sterilization of neXus® handpieces prior to use:

- Document #: 100-24-1000 – neXus® SonaStar® Handpiece (Short & Long) Instructions for Use (IFU)
- Document #: 100-21-1000 – neXus® Standard Handpiece Instructions for Use (IFU)
- Document #: 100-22-1000 – neXus® BoneScalpel Access™ Handpiece Instructions for Use (IFU)
- Document #: 100-26-1000 – neXus® Sonastar Elite™ Handpiece Instructions for Use (IFU)

8.3 Sterile, Single-Use, Disposable neXus® Probe and Tubeset Kit Components

All neXus® sterile, single-use, disposable neXus® probe and tubeset kits are labeled single use must not be reused. Reuse of these kits or kit components could result in severe patient injury or death.

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

WARNING Single-use items (probe tips, sheaths, tubing sets) are marked with the international symbol for "do not reuse - single use only" (Ⓧ). Discard these items following each surgical procedure in accordance with the hospital protocol for biohazardous waste. Probe tips are to be disposed of in a biohazardous sharps container. To prevent the risk of malfunction and transmission of disease, do not attempt to reprocess, clean, re-sterilize, and/or reuse these items.

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

9. Faults, Indicators & Troubleshooting

The neXus® Ultrasonic Surgical Aspirator System provides both visual and audible alert signals when the system is not functioning properly. The fault system can issue either a "Notification" or "System Reset" Fault.

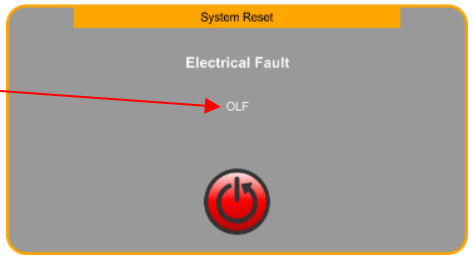
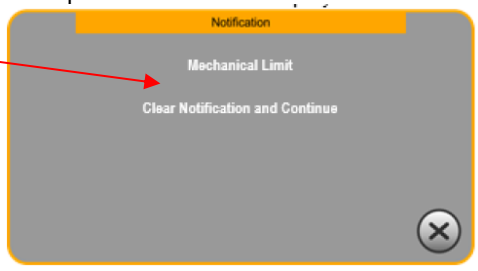
The neXus® Ultrasonic Surgical Aspirator System has multiple fault groups including the following:

- Electrical Faults
- Mechanical Faults
- Power Supply Faults
- Communication Faults
- Temperature Faults
- Footswitch Faults
- Handpiece Faults
- Vacuum Faults/Notifications

Faults on the neXus® system can result in a notification, allowing for correction and dismissal. Or faults can require a system reset.

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

Table 9.0: Types of Faults and Indicators

Fault Type	Fault Indicator	Fault Action
System Reset Fault Codes; Varies depending on the particular fault. **See below Note for "POST" fault code	Example screen:  Fault screen also triggers a pulsed, audible indicator.	System functions automatically disabled. Press the System Reset Button. System reboots; "neXus®" splash screen appears followed by the Priming screen. Priming screen may be skipped. *Skipping priming screen returns user to the Main screen.
Notification Message here depends on the particular fault	Example screen:  Fault screen also triggers a pulsed, audible indicator.	System functions remain enabled. Press the Exit button to return to the Main screen.

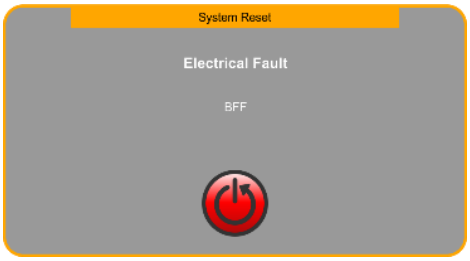
*Caution: Skipping priming screen can only be performed if the tubing was previously primed.

**The neXus® runs through a diagnostic self-test upon power up. If "POST" XXXXX is seen on the screen (where XXXX is a custom fault code) a Power-On Self-Test Failure has occurred. The only corrective action will be to press the system reset button on the fault screen to reboot the system.

9.1 Electrical Faults

The console monitors the electrical output at all times and faults in cases where the electrical connections to the handpiece are compromised. A System Reset screen is displayed together with an audible indicator. Ultrasound and Irrigation are deactivated.

Table 9.1: Electrical Faults

Fault Type	Fault Screen	Fault Action
System Reset **Electrical Fault** **Possible Fault codes:** ILF BFF VLF OCF SCF	Example screen:  	System functions automatically disabled. Pressing the System Reset Button reboots the system. "neXus" splash screen appears followed by the Priming screen. Priming screen may be skipped. *Skipping priming screen returns user to the Main screen.
Possible Cause	**Corrective Action**	
ILF: Damaged console or Handpiece	Press the System Reset Button and try again. If problem persists, replace handpiece and try again. If corrective action steps above are followed and fault continues, the console may need to be replaced.	

WARNING Immediately suspend operation if a persistent Electrical Fault appears on display and/or an Electrical Fault audible indicator sounds. Remove ultrasonic probe tip from surgical site. Do not touch any metallic parts of handpiece, extension, ultrasonic probe tip or generator while fault is indicated.

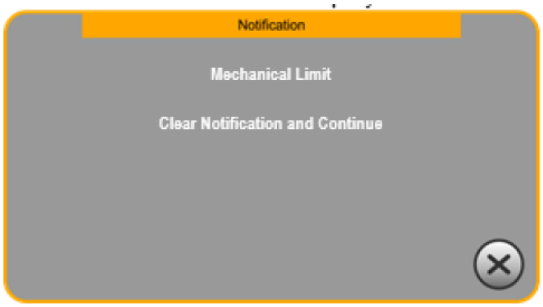
WARNING Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth. Install plug and receptacles as per local regulations before 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 If a Mains Power fuse fails after replacement when the unit is reactivated, discontinue use of the device and contact an authorized Misonix representative.

9.2 Mechanical Faults

The console monitors the ultrasonic output at all times and alerts in cases of overload or malfunction of the vibrating elements (handpiece, extension and ultrasonic probe tip). A Notification is displayed together with an audible indicator as long as the footswitch is depressed. Probe tip overload can occur during hard tissue removal when applying excessive probe tip pressure or facing strong tissue resistance, e.g. from thick cortical bone. This can lead to stalling of the ultrasonic probe tip. Follow the corrective action below.

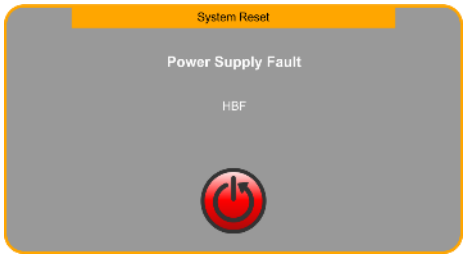
Table 9.2: Frequency Fault Notification

Fault Type	Fault Screen	Fault Action
Notification **Frequency Fault**		System functions remain enabled while Notification is displayed.
Possible Cause	**Corrective Action**	
Probe tip Overload	Reducing probe tip pressure will automatically clear the Notification without releasing the footswitch or release footswitch and try again. If problem persists, use higher amplitude setting as required.	
Loose or damaged component	Release footswitch and Set ultrasound to STANDBY  . Remove silicone sleeve (if applicable) and probe cover. Inspect extension probe and ultrasonic probe tip for damage. Replace if necessary. Otherwise re-tighten extension probe and probe tip using the correct wrenches. Set ultrasound to ENABLE  and continue procedure.	
Defective Handpiece	If corrective action steps above are followed and fault continues, the handpiece may need to be replaced.	

9.3 Power Supply Faults

The console monitors the internal power supplies at all times and faults in cases when they are compromised. A System Reset screen is displayed together with an audible indicator. Ultrasound and Irrigation are deactivated.

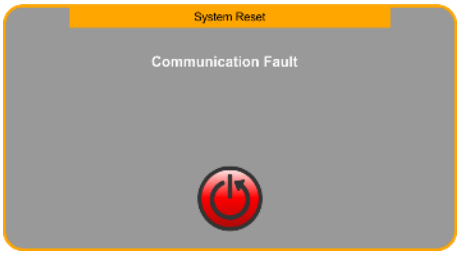
Table 9.3: Power Supply Faults

Fault Type	Fault Screen	Fault Action
System Reset **Power Supply Fault** **Possible Fault Codes;** CSF LVF HVF RSF HBF PFEW	Example screen:  	System functions automatically disabled. Pressing the System Reset Button reboots the system. "neXus®" splash screen appears followed by the Priming screen. Priming screen may be skipped. *Skipping priming screen returns user to the Main screen.
Possible Cause	**Corrective Action**	
Damaged console	Press the System Reset Button and try again. If corrective action steps above are followed and fault continues, the console may need to be replaced.	

9.4 Communication Faults

The console monitors the internal microprocessors at all times and faults in cases when they are not communicating properly. A System Reset screen is displayed together with an audible indicator. Ultrasound and Irrigation are deactivated.

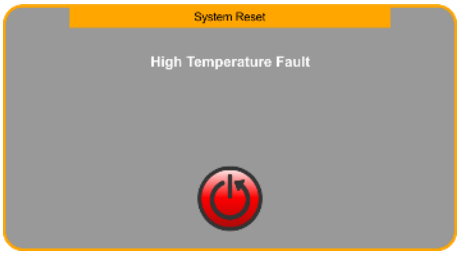
Table 9.4: Communication Faults

Fault Type	Fault Screen	Fault Action
System Reset **Communication Fault** **Possible Fault Codes;** CF1 CF2 CF3 CF4 CF5 CF6	Example Screen  	System functions automatically disabled. Pressing the System Reset Button reboots the system. "neXus®" splash screen appears followed by the Priming screen. After connecting the handpiece, the priming screen may be skipped. *Skipping priming screen returns user to the Main screen.
Possible Cause	**Corrective Action**	
Damaged console	Press the System Reset Button and try again. If corrective action steps above are followed and fault continues, the console may need to be replaced.	

9.5 Temperature Faults

The console monitors the internal temperature at all times and faults in cases where the temperature is too high. A System Reset screen is displayed together with an audible indicator. Ultrasound and Irrigation are deactivated.

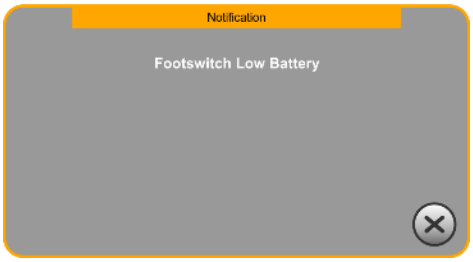
Table 9.5: Temperature Faults

Fault Type	Fault Screen	Fault Action
System Reset **High Temperature Fault** **Possible Fault Code;** HTF	Example Screen  	System functions automatically disabled. Pressing the System Reset Button reboots the system. "neXus" splash screen appears. followed by the Priming screen. After connecting the handpiece, the priming screen may be skipped. *Skipping priming screen returns user to the Main screen.
Possible Cause	**Corrective Action**	
1. Blowers failed or 2. Air vents underneath display or in the rear are blocked	Inspect that the vents under the display and in the rear of the console are not blocked. Press the System Reset Button and try again. If corrective action steps above are followed and fault continues, let the unit cool down and try again. If fault persists, the console may need to be replaced.	

9.6 Footswitch Faults

- **Footswitch Low Battery Notification**
  The footswitch is powered with an "AA" alkaline battery. If the battery voltage is too low the console will issue a low battery notification. The system remains active and the procedure is uninterrupted. Thee batteries should be replaced immediately following the procedure.

Table 9.6.1: Low Battery Notification

Fault Type	Fault Screen	Fault Action
Notification **Footswitch Low Battery** 	 	System functions remain enabled. Pressing the Exit button returns to the Main screen.
Possible Cause	**Corrective Action**	
Low battery	Press the Exit Button and continue procedure. Replace battery immediately following the procedure.	

- **Wireless Footswitch Connection Lost Notification**

The footswitch for the neXus console uses wireless RF technology. If the wireless connectivity is lost, the console will display a fault notification. As a result, the console functionality will be disabled.

Table 9.6.2: Footswitch Connection Lost Notification

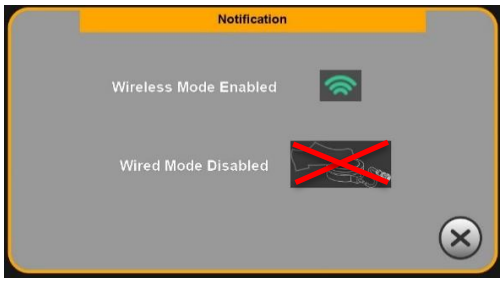
Fault Type	Fault Screen	Fault Action
Notification Footswitch Connection Lost	 Followed by Flashing red X and an audible beep. 	System functions remain enabled. Pressing the Exit button returns to the Main screen.

Possible Cause	Corrective Action
1. Footswitch out of range 2. Interruption in Wireless communication 3. No battery or dead battery (The more likely cause) 4. Not paired with console (Least likely cause) 5. Footswitch failure	Follow these corrective actions in order. DO NOT immediately try to re-pair footswitch to console. 1. Bring the footswitch closer to the console. The footswitch shall be less than 15 feet from the console. 2. Press the Exit Button "X" and wait 10-20 seconds to see if footswitch **automatically** reconnects to the console. If connected, the icon will change to green. 3. If problem persists, replace the battery. Observe Wi-Fi symbol again to determine if footswitch re-connects to console. If connected, the icon will change to green. 4. If problem persists, re-pair the footswitch to the console (see Section 7.13 for Pairing steps). 5. If corrective action steps above are followed and fault continues, the footswitch may need to be replaced or connect a Wired Footswitch to the console. Contact Misonix Service Center.

- **Wired Footswitch Connection Lost Notification**

The wired Footswitch, when connected to the console, is always monitored. If the connectivity is lost, the console will display a fault notification. As a result, the console functionality will automatically change to wireless footswitch mode of operation (see section 7.13).

Table 9.6.3: Wired Footswitch Connection Lost Notification

Fault Type	Fault Screen	Fault Action
Notification **Wired Footswitch Connection Lost**	 Followed by audible beeping.	System functions remain enabled. Pressing the Exit button returns to the Main screen and re-enables the wireless footswitch
Possible Cause	**Corrective Action**	
1. Wired Footswitch connector damaged 2. Wired Footswitch cable damaged	Follow these corrective actions in order. DO NOT immediately try to re-pair footswitch to console. 1. Disconnect cable and re-connect to the console 2. Recycle power to the console 3. If corrective action steps above are followed and fault continues, the Footswitch is defective. Locate the wireless footswitch, check that the battery is installed. Follow steps in Section 7.13 if necessary.	

9.7 Handpiece Faults

The console has the ability to recognize the handpiece that is connected to the console. If the handpiece cannot be recognized, the console will display a fault notification. As a result, the console functionality will be disabled.

Table 9.7.1: Unrecognized Handpiece Notification

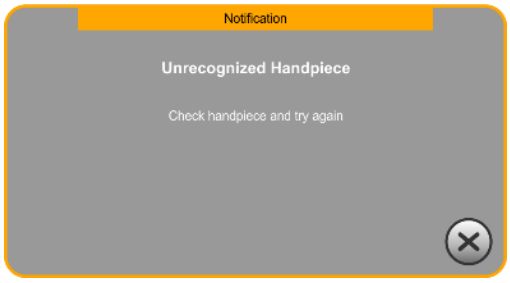
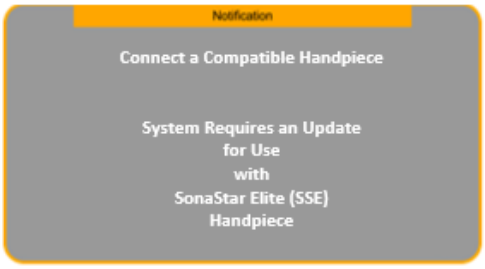
Fault Type	Fault Screen	Fault Action
Notification **Unrecognized Handpiece**		System functions automatically disabled. Pressing the Exit button returns to the Main screen.
Possible Cause	**Corrective Action**	
Damaged Handpiece or System Software may not support the handpiece in use	Unplug the handpiece. Plug handpiece back in, press the Exit Button . If corrective action steps above are followed and fault continues, either the handpiece may need to be replaced or system software not compatible with handpiece. Refer to Table in section 7.12 for required software version.	

Table 9.7.2: Handpiece Incompatibility Notification

Fault Type	Fault Screen	Fault Action
Notification **Handpiece** **Incompatibility**		System functions automatically disabled. Remove handpiece and connect a compatible handpiece.
Possible Cause	**Corrective Action**	
SSE Handpiece not compatible with console	Unplug the SSE handpiece. Plug a compatible handpiece into the console. Clear the notification. If use with an SSE handpiece is required, send the console to Misonix for an update.	

9.8 Vacuum Faults / Notifications

The console has the ability to monitor certain parts of the vacuum system. A vacuum fault can either result in a Notification or a System Reset.

Table 9.8.1: Vacuum Fault, Notification

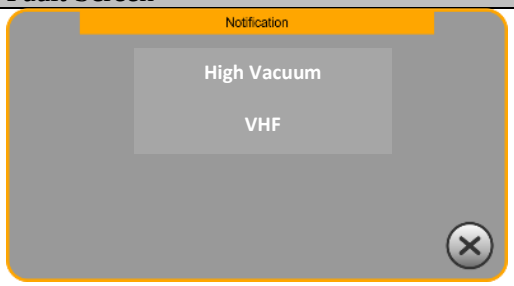
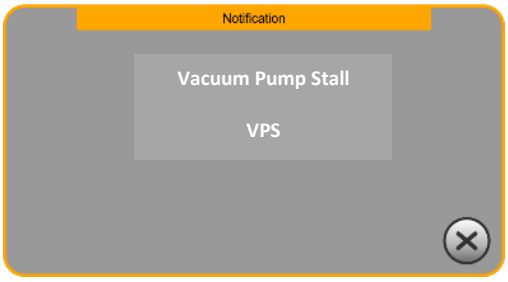
Fault Type	Fault Screen	Fault Action
Vacuum Notifications	 OR 	System functions remain enabled. Pressing the Exit button returns to the Main screen.
Possible Cause	**Corrective Action**	
1. External filter blocked or restricted. 2. Damaged console	1. Press the Exit button “X” and try again. 2. Replace the external filter. 3. If fault persists, the console may need to be replaced.	

Table 9.8.2: Vacuum Fault, System Reset

Fault Type	Fault Screen	Fault Action
Vacuum Fault **Fault Codes;** VZF	Example Screen 	System functions automatically disabled. Pressing the System Reset Button  reboots the system.
Possible Cause	**Corrective Action**	
Damaged console	1. Press the System Reset Button  and try again. 2. If corrective action steps above are followed and fault continues, the console may need to be replaced.	

9.9 Aspiration Troubleshooting

Table 9.9: Troubleshooting – Insufficient Aspiration

Lack of Aspiration	
Symptoms • Irrigation not removed from surgical field • No tissue removal from the surgical field	
Possible Cause	Corrective Action (Refer to section 7.4)
Clogged filter	Replace vacuum filter located in the rear of the console.
Aspiration lines not properly connected	Check all aspiration line connections; Handpiece, filter, canister
Cracked Canister	Replace canister

9.10 Irrigation Troubleshooting

Table 9.10: Troubleshooting – Insufficient Irrigation

Lack of Irrigation	
Symptoms • No spray from probe tip when ultrasound is engaged • No flush fluid available • Unexpected temperature rise at operative site • Unexpected temperature rise of handpiece	
Possible Cause	Corrective Action (Refer to section 7.4)
1. Closed or empty fluid bag	Set ultrasound to STANDBY. Check fluid bag and tubing clamp. Replace fluid bag if necessary.
2. Tubing not connected	Set ultrasound to STANDBY. Check tubing connections. Check mounting in pump head. Close pump cover until locked.
3. Tubing obstructed or defective	Set ultrasound to STANDBY. Check tubing for kinking, restrictions or leaks. Replace tubing if necessary. Check mounting in pump head. Close pump cover until locked.
4. Tubing installed in reverse	Set ultrasound to STANDBY. Open pump cover. Reposition the tubing in direction of flow. Close pump cover until locked.
6. Pump defect	Set ultrasound to STANDBY. Open pump cover. Check if pump rollers are rotating when depressing footswitch. Replace console if they don't.

WARNING Tip temperatures may exceed the tissue necrosis point if insufficient irrigant is present at the probe tip-tissue interface. For hard tissue removal, set the irrigation and the aspiration to levels that ensure irrigant is observed coming out from the probe tip. Additional external irrigation, e.g., by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures.

WARNING Do not operate pump with pump cover in raised position. Rollers might pinch loose clothing or fingers. Personal injuries may result.

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

10. Specifications

Table 10 Console Specifications

Console Specifications	
Classification	Class 1 Type BF Applied Part
Power input, Voltage	100-240VAC
Power input, Current	5A
Power input, Frequency	50/60Hz
Power input, Fuses	5 amp, 250V high breaking capacity fuse Use only as directed in Section 11.1 of this Instructions For Use manual.
Power Cord	10ft (3m) Use only supplied power cord with hospital grade plug for US, Canada
Ground leakage current	500 µA (max.)
Vibration System	Continuous Wave Frequency 22.5Khz
Wireless Footswitch Wired Footswitch	IPX8, internally powered IPX8
Console	IPX1
Operating conditions	Temperature 13-30°C (55-86°F) Relative humidity 20-90% (non-condensing) -91m (-300ft) to 3000m (9842ft)
Shipping/storage conditions	Temperature: -20 to 50°C (-4 to 122°F) Relative humidity: 15-90% (non-condensing)
Dimensions – Console w/o canister	11.5” H x 16” W x 17” D | 292mm H x 406 mm W x 432mm D
Weight – Console	45 lbs | 20.4 kg
Dimensions – Console w/Cart	51.5” H x 25.5” W x 27.5” D | 1308mm H x 648 mm W x 699mm D
Weight – Console w/Cart	95 lbs | 43.1 kg

11. Service, Repair and Technical Correspondence

WARNING 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 The neXus® console automatically adjusts for the mains voltage and frequency. Confirm that the correct fuses are being used. Refer to section 11.1 in instructions for fuse replacement.

WARNING The neXus® Ultrasonic Surgical Aspirator 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

11.1 Fuse Replacement

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

WARNING Replacement fuses other than what is specified can cause a fire hazard. Use only as specified.

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

Table 11.1.1 Console Fuse Specifications

	Fuse Specifications			
Line Voltage	Manufacturer	Manufacturer P/N	Rating	Description
100-240 VAC, 50/60 Hz	Littlefuse	0216005.HXP	250V @ 5A	Fast Acting, 1.5kA High Breaking capacity

Table 11.1.2 Console Fuse Replacement

Fuse Replacement (The fuse holder is located on the console rear)		
Disconnect the power cord from the rear of the console		
Remove Fuse Holder	Pinch the tab on each side of the fuse holder. 	 Pull fuse holder out.

Fuse Replacement (The fuse holder is located on the console rear)	
Replace Fuses and reinsert holder into socket	Replace both fuses as specified above and insert holder into the socket. A click shall be heard. 
Connect power cord to the rear of the console	neXus Splash screen shall appear followed by the setup screen

11.2 Filter Replacement

11.2.1 Periodic Maintenance

The filter should be changed at 6-month intervals.

CAUTION All periodic maintenance is to be performed by the hospital's technical staff, trained OR staff member or by a Misonix Inc. authorized technical personnel. Under normal conditions, the filter should be changed at 6-month intervals. For any user location that requires aspiration, date applied to filter shall be 6 months from installation.

11.2.2 Replacing the External Filter

Disconnect the aspiration line from the filter. Push in both tabs inward toward the filter as shown and pull out from the console. Reverse procedure to reinstall.

Figure 11.2.1: Push Tabs inward

Figure 11.2.2: Pull out filter

11.3 Footswitch Battery Replacement

The Wireless footswitch is powered by one “AA” alkaline battery. Replace with only NEW battery.

CAUTION The neXus® device will alert the user if the battery in the footswitch is low. Replace batteries immediately following the procedure.

Open the battery compartment by turning the cap counterclockwise. Remove the battery and reinstall new “AA” battery.

CAUTION The polarity is indicated on the rear of the footswitch. Assure the battery is installed in proper polarity.

Re-tighten cap to footswitch housing by rotating clockwise. Turn until the cap is tight to the housing.

Figure 11.3.1: Remove Battery Cap

Figure 11.3.2: Remove Battery

Figure 11.3.3: Battery polarity

12. 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.

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

CAUTION 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 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.

WARNING No Modifications of this equipment is allowed except as noted for cleaning and sterilization. The user should return to Misonix or an authorized service center.

WARNING The neXus® Ultrasonic Surgical Aspirator 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.

Important Notice

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

Company Name: Misonix, Inc.
Website: www.Misonix.com
Email: POR@MISONIX.COM
Phone: 631-694-9555 / 800-694-9612
Address: 1938 New Highway
Farmingdale, NY 11735

By returning any material to Misonix, Inc. 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.

Do not return any material for which such certification cannot be made without prior approval from Misonix, Inc. The correct return address should read as follows:

Misonix
Medical Service Department
*RMA #
1938 New Highway
Farmingdale, NY 11735

*Request an RMA# by emailing POR@MISONIX.COM
