nexus® Ultrasonic

Surgical Aspirator System

# Instructions for Use

# Table of Contents

# 1. 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 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

1. U.S. federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.
2. The neXus system is to be used by an appropriately trained and licensed healthcare practitioner.
3. Prior to using the neXus system, all healthcare practitioners are to be trained in the institution's procedures for blood borne pathogen (BBP) universal precautions, including the use of appropriate personal protection equipment (PPE).

## 1.1. 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 IEC60601-1-2: 2014 for emissions and immunity.

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 operator's 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.

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

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

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions (Table 201) | | |
|---|---|---|
| The neXus Ultrasonic Surgical Aspirator System is intended for use in the electromagnetic environment specified below. The customer or the user of neXus Ultrasonic Surgical Aspirator System should ensure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| | | |
| RF emissions<br>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<br>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<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Complies | |

Table 1.1 Guidance & manufacturer's declaration on electromagnetic emissions (EN table 201)

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Table 202) | | | |
|---|---|---|---|
| The 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<br>o ±2 kV, ±4 kV, ±8 kV, ±15 kV air | o ±8 kV contact<br>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<br>o ±1 kV for input/output lines | o ±2 kV for power supply lines<br>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<br>o ±0.5 kV, ±1 kV, ±2 kV line to ground | o ±0.5 kV, ±1 kV line to line<br>o ±0.5 kV, ±1 kV, ±2 kV line to ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0 % $U_T$ (100 % dip in $U_T$ for 0,5 cycle<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br>0 % $U_T$ (100 % dip in $U_T$) for 1 cycles<br>0 % $U_T$ (100 % dip in $U_T$) for 5 sec | 0 % $U_T$ (100 % dip in $U_T$) for 0,5 cycle<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br>0 % $U_T$ (100 % dip in $U_T$) for 1 cycles<br>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.<br>NOTE If a fault notification on the GUI occurs, press the "X" button to exit the screen and initiate system reset. | | | |

Table 1.2 Guidance & manufacturer's declaration on electromagnetic immunity (EN table 202)

| 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-conducter |
| Monopolar Hand Switch Cable | 15.5 ft \| 4.7 m | unshielded 3-conducter |

Table 1.3 List of cables

| 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<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz<br>6Vrms in ISM Bands | 3 Vrms<br>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.<br><br>Recommended separation distance<br><br>d = 1.2√P<br><br>d = 1.2√P 80 MHz to 800 MHz<br><br>d = 2.4√P 800 MHz to 2.7 GHz |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 Hz to 2.7 GHz<br>80% AM at 1Khz | 3 V/m<br>80 MHz to 2.7 GHz<br>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).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.<br>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 1.4 Guidance & manufacturer's declaration on electromagnetic immunity (EN table 204)

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

Table 1.5 Recommended separation distances (EN table 206)

| 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 |

Table 1.6: Characteristics of Wireless footswitch receiver

## 1.2. Electrical Safety Statement

***The neXus Ultrasonic Surgical Aspirator System is designed and tested to comply with UL 60601-1 and EN 60601-1.***

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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 10 in instructions for fuse replacement.

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## 1.3. 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.

| Important Environmental Information for Users within the European Economic Area |
|---|
| The European Council Directive 2002/96/EC on Waste Electrical and Electronic Equipment (EEE), 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.<br><br>The WEEE Directive requires that the EEE be disposed of at the end of its useful life in an environmentally responsible manner.<br><br>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.<br><br>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.<br><br>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.<br>  |

Table 1.7: Environmental statement

## 1.4. Summary of Safety Notices

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

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

| Conventions on Warnings andCautions | |
|---|---|
| **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. |

Table 1.8: Conventions on warnings and cautions.

## 1.4.1 List of **Warnings**

- 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 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.
- 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.
- 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.
- 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.
- 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 of this IFU for exposure limit.
- Only use the Standard Handpiece with BoneScalpel or SonicOne OR probe accessory kit configurations for the indications for use charted in Section 2.1 for the Standard Handpiece.
- Only use the SonaStar Long and Short Handpieces with SonaStar probe accessory kit configurations for the indications for use charted in Section 2.1 for the SonaStar Handpieces.
- The SonaStar Long and Short Handpieces may combined with electrosurgery using an optional RF Monopolar fingerswitch cable. Refer to the SonaStar Handpiece IFU for detailed instructions for using the RF Monoplar Handswitch cable and for monopolar cautery guidelines.
- The neXus Long or Short Handpieces 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 Table 4.5 of the SonaStar Long and Shot Handpiece IFU that have been validated for compatibility with the neXus system.
- Tip and irrigation temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal, set the irrigation flow rate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 70, a minimum flow setting of 70% should be used. 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.
- 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.
- Contact with vibrating elements like extension and ultrasonic tip may cause burns and should be avoided by all means. The handpiece should only be held at the black housing area. An optional, protective silicone sleeve, included with certain 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.

- 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.
- 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.
- 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.
- 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 tip/tissue interface. A continuous, lateral sweeping motion is recommended for general bone/tissue removal in order to minimize contact duration with the ultrasonic tip and minimize the temperature increase.
- During system check, make sure the tip of the handpiece is free from contact with any object. Allowing contact with the tip may result in damage and/or personal injury
- 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 tip free from contact with any objects.
- Remove probe cover, ultrasonic tip and extension from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.
- Single-use items (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. 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, resterilize, and/or reuse these items.
- Immediately suspend operation if a persistent Electrical Fault appears on display and/or an Electrical Fault audible indicator sounds. Remove ultrasonic tip from surgical site. Turn Mains Power OFF. Do not touch any metallic parts of handpiece, extension, ultrasonic 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 is allowed except as noted for cleaning and sterilization. The user should return to Misonix or an authorized service center.

## 1.4.2 List of **Cautions**

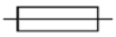
- Special Skills Training Requirements
    - U.S. federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.
    - The neXus Ultrasonic Surgical Aspirator System is to be used by an appropriately trained and licensed healthcare practitioner.
    - Prior to using the neXus system, all healthcare practitioners are to be trained in the institution's procedures for blood borne pathogen (BBP) universal precautions, including the use of appropriate personal protection equipment (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 this operator's 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 may result in increased emissions or decreased immunity of the device. Use only Misonix branded equipment and accessories.
- When used adjacent to the other electrical equipment, the console should be observed to verify normal operation in the configuration in which it will be used.
- This Instructions for Use Manual provides instructions on using the neXus Console. Refer to the Standard Handpiece Instructions for Use Manual or the SonaStar Long and Short Handpiece Instructions for Use Manual respectively prior to using either of the handpieces.
- 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.
- 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.
- 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.
- The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.
- 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.
- 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.
- 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.
- 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 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. Do not attempt to remove any panels in order to

clean or disinfect internal surfaces.

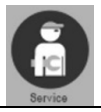
- Do not immerse ultrasonic console, handpiece, irrigation pump or electric cables. These items are not sealed against liquids and damage to equipment will result.
- Improper use or adjustment of this device may invalidate the Misonix, Inc. Warranty agreement. Contact your authorized Misonix, Inc. representative before attempting to troubleshoot this device in any manner other than those specified in this 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.
- 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 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.
- 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.
- 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 device 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 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.

## 1.5. Explanation of Symbols

Table 1.5.1: Symbol Definitions

| Symbol | Description |
|---|---|
|  | Caution:<br>Consult accompanying documents |
|  | Caution: Do Not operate with cover in the raised position |
|  | Protective earth ground |
|  | Equipotentiality connection |
|  | Disposal to be com- pliant with<br>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 Manufacturer |
|  | Do not use if packaging is damaged |
|  | Contents are latex-free |
| $R_x$ 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 |

| Graphic Images | Description |
|---|---|
|  | Wireless Footswitch not activated |
|  | Wireless Footswitch or Flush button activated |
|  | Wired Footpedal connected (not activated) |
|  | Wired Footpedal activated |
|  | Wireless Footswitch connected to console |
|  | Footswitch Not connected to Console, Flashing “X” |
|  | Low Footswitch Battery |
|  | Enable Mode Active |
|  | Standby Mode Active |
|  | 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 |

| Graphic Images | Description |
|---|---|
|  | Irrigation Pump Door Closed |
|  | Settings |

# 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 Standard Handpiece in combination with BoneScalpel® and SonicOne® OR probe kit accessory configurations and the indications for the SonaStar® long and short handpiece in combination with SonaStar® probe kit accessory configurations are charted below.

| **NEXUS INDICATIONS FOR USE BY HANDPIECE AND PROBE KIT ACCESSORY COMBINATION** | | |
|---|---|---|
| **Standard Handpiece** *for use with BoneScalpel® and Sonic One®* | | **Long and Short Handpiece** *for use with SonaStar®* |
| **Indications for Use BoneScalpel ®** | **Indications for Use SonicOne ®** | **Indications for Use SonaStar®** |
| Indicated for use in the fragmentation and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties:<br>• **Neurosurgery**<br>• **Gastrointestinal and Affiliated Organ Surgery**<br>• **Urological Surgery**<br>• **Plastic and Reconstructive Surgery**<br>• **General Surgery**<br>• **Orthopedic Surgery**<br>• **Gynecology**<br>**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<br>**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.<br>• **Thoracic Surgery**<br>Limited pulmonary reception such as segmetectomies, nonanatomical subsegmentectomies and metastatectomies.<br>• **Wound Care**<br>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 and aspiration of soft and hard tissue (i.e. bone) in the following surgical specialty:<br>• **Wound Care**<br>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.<br>• **Plastic and Reconstructive Surgery** | Indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties:<br>• **Neurosurgery**<br>• **Gastrointestinal and Affiliated Organ Surgery**<br>• **Urological Surgery**<br>• **Plastic and Reconstructive Surgery General Surgery**<br>• **Orthopedic Surgery**<br>• **Gynecological Surgery except as contraindicated for uterine fibroids.**<br>• **Thoracic Surgery**<br>• **Laparoscopic Surgery**<br>• **Thoracoscopic Surgery**<br>The system may also be combined with electrosurgery using optional RF surgery interface components. |

## 2.2. Intended Use Environment

- Operating room environment

## 2.3. Contraindications

2.2.1 The 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).

2.2.2 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.

2.2.3 The neXus Ultrasonic Surgical Aspirator System device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

# 3. Adverse Effects

| Limits For Airborne Acoustic Exposure | | |
|---|---|---|
| Distance from operator's or patient's ear | | Maximum Exposure Period Within a 24 hour period |
| 3" - 24" | 8 cm – 60 cm | 28 minutes |
| > 24" | > 60 cm | 287 minutes |

Table 3.1: Limits For Airborne Acoustic Exposure

WARNING The neXus Ultrasonic Surgical Aspirator System and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits.

WARNING Tip and irrigation temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal, set the irrigation flow rate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 70, a minimum flow setting of 70 should be used. 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 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.

# 4. 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 for exposure limits.

WARNING Contact to vibrating elements like extension and ultrasonic tip may cause burns and should be avoided by all means. The handpiece should only be held at the black housing area. A protective silicone sleeve, included with certain 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.

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.

## 4.1 Hard Tissue Applications/Use (e.g. BoneScalpel Applications)

***Recommended Settings***

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

| 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<br>2 – The lowest flow setting is 5, Refer to specifications table for applicable flow rate. | | |

Table 4.1: Hard Bone setting Recommendations

- 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.
- Bone shaving tips tend to require a lower amplitude than cutting blades.

WARNING Tip and irrigation temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal, set the irrigation flow rate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 70, a minimum flow setting of 70 should be used. 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 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) 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.

---

## 4.2 Wound Debridement Applications / Use (e.g. SonicOne applications)

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.

| 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<br>2 – The lowest flow setting is 5 | | |

Table 4.2: Wound Debridement Setting Recommendations

- 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.

---

## 4.3 Soft Tissue Applications / Use (e.g. SonaStar Applications)

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.

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

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

Table 4.3: Soft Tissue Setting Recommendations

- 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.

# 5. System Overview

## 5.1. Principle of Operation

The neXus Ultrasonic Surgical Aspirator System is comprised of a generator which converts mains voltage and frequency to a 22.5 kHz (Standard Handpiece) or 23.0 kHz (SonaStar Short & Long 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.

## 5.2. Reusable, Non-Sterile Components

| System Components | |
|---|---|
| neXus console; including an IV pole, power cord, peristaltic pump, filter, and instructions for use | 1 ea. |
| neXus Standard Handpiece Kit (i.e. Bonescalpel or SonicOne O.R. Applications) | 1 ea. |
| neXus SonaStar Handpiece Kit (i.e. Long or Short Handpiece for Sonastar Applications) | 1 ea. |
| neXus Wireless Footswitch | 1 ea. |
| neXus Wired Footswitch (optional, part number 100-51-0000) | 1 ea. |
| neXus Cart (optional, part number 100-80-0000) | 1 ea. |

Table 5.2: Reusable System Components

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

For the cleaning and sanitization of the console, footswitch, and cart Misonix recommends the use of EPA certified CaviWipes® or equivalent quaternary ammonium compound surface disinfectant wipe. Please follow manufacturer's instructions for surface cleaning and disinfection of hard non-porous 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 wipes.

Refer to the handpiece IFU's for cleaning and sterilization procedures for the reusable handpiece parts and accessories.

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.

## 5.3. Single Use, Sterile Components

There are a variety of single-use sterile components for the neXus Ultrasonic System. The components include various tips, tubing, and other accessories. Ultrasonic tips & tubing are supplied in a combined, sterile package, and are for single use only. Please ask your Misonix representative for the latest catalog of available products.

# 6. Console Setup and Use

## 6.1. 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.

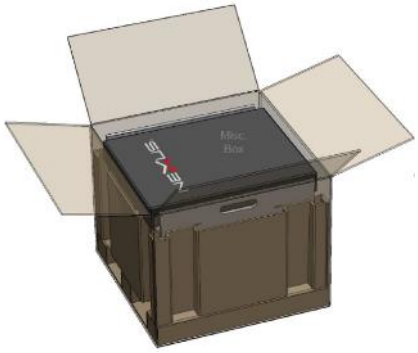


Figure 6.1 : Console Shipping Package

Major Items included:

| 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 |

Table 6.1.1: Console Shipping Package Contents

WARNING The neXus console automatically adjusts for the mains voltage and frequency. Confirm that the correct fuses are being used. Refer to section 10.1 in instructions for fuse replacement.

Care should be taken to stay within the general operating conditions.

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

Table 6.1.2: Operating Conditions

The console can be placed on an appropriate table or cart outside of the sterile field.

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.

## 6.2. Initial Setup

6.2.1 Connect the Power Cord. 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.

6.2.2 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.

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

6.2.4 Install the supplied aspiration tubing from the Suction Canister to the Vacuum Filter.
Section 6.4.2.3 sets up the irrigation and aspiration lines to the Canister and the IV bag.

NOTE: IV bag should be 1000ml or less

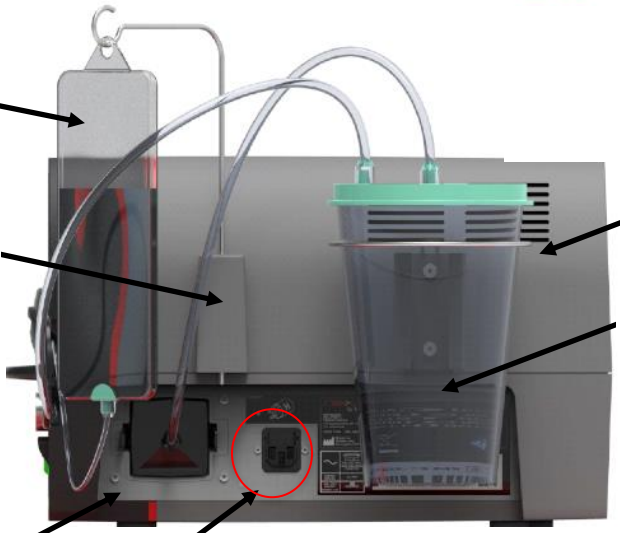
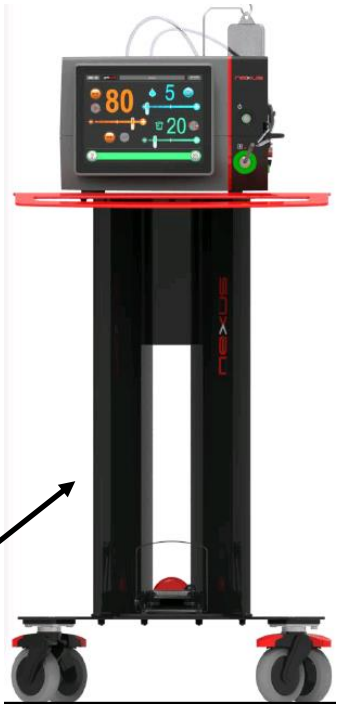
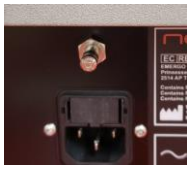



Figure 6.2.1: Console rear




Optional Cart Accessory (part number 100-80-0000)



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.

6.2.5 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 6.11.

## 6.3 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. |

### *6.3.1 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 6.12 for powering down).

Figure 6.3.1 Startup Screen

### *6.3.2 Setup Screen*

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

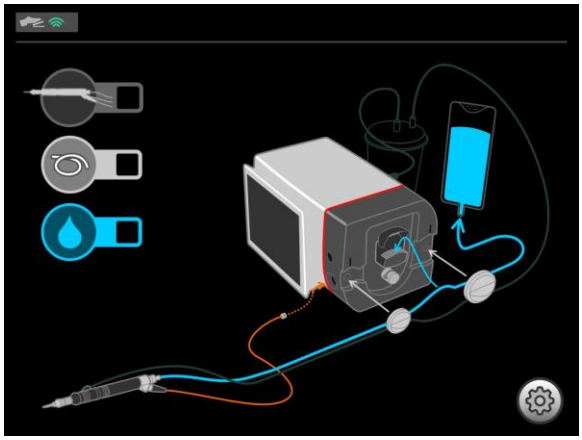


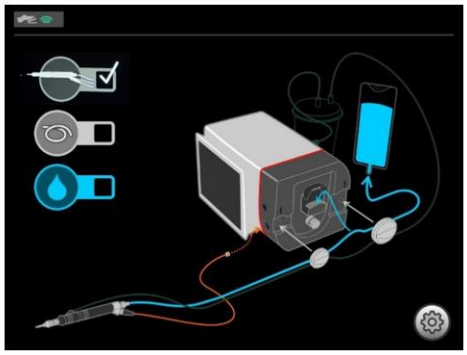
Figure 6.3.2 Setup Screen

### *6.3.3 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 audiable 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 Standard Handpieces and SonaStar 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.

6.3.3.1 Standard Handpiece



No Handpiece Connected

Handpiece Properly Connected

Figure 6.3.3.1 Handpiece Connection Status, Standard

6.3.3.2 SonaStar Long & Short Handpiece(s)

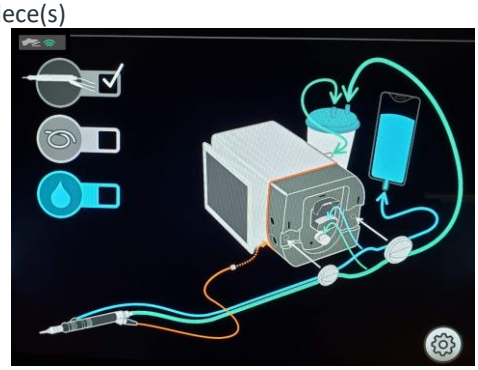


Figure 6.3.3.2 Handpiece Connection Status, Sonastar

# 6.4 Tubing Connection

### *6.4.1 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 tip; this may cause damage to the handpiece.

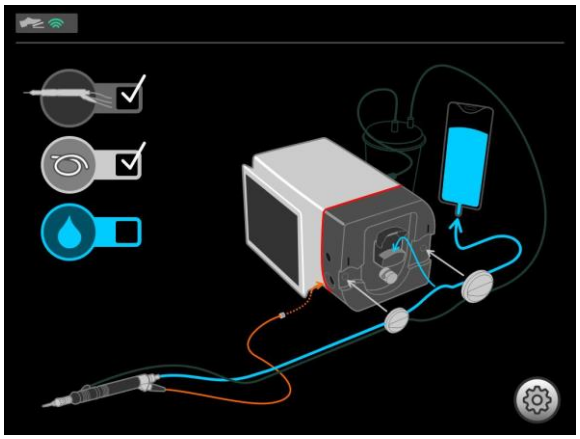


Figure 6.4.1.1 Standard Handpiece Tubing Connected

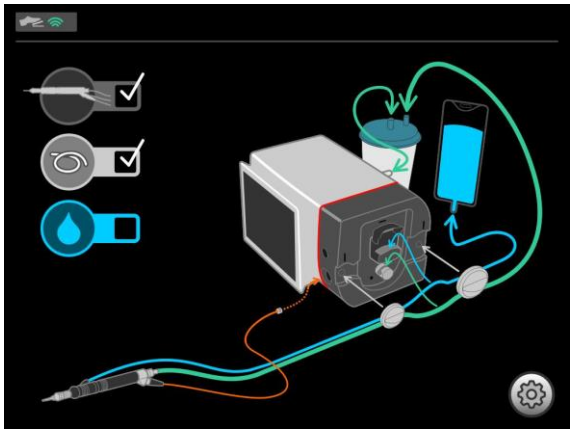


Figure 6.4.1.2 Long & Short Handpiece Tubing Connected

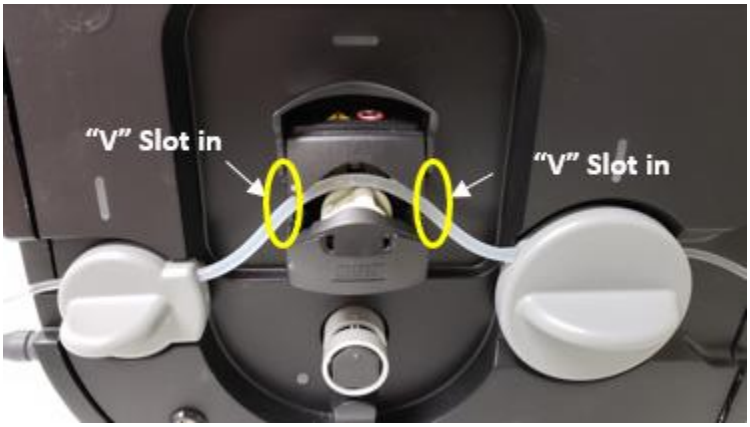
### *6.4.2 Irrigation & Aspiration Tubing Installation*

6.4.2.1 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.




6.4.2.2 Aspiration Tubing Installation


Figure 6.4.2.3 Standard Handpiece Tubing Connected


Figure 6.4.2.4 SonaStar Handpiece Tubing Connected

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.

6.4.2.3 Connection to Canister and IV bag

For SonaStar applications connect the aspiration tubing of the handpiece to the "Patient" port of the canister. For both SonaStar and Standard handpiece applications connect the irrigation tubing to the IV bag.

## 6.5 Handpiece Assembly & Disassembly

See separate Handpiece IFU's:

- Document #: 100-24-1000 - Sonastar Handpiece (Short & Long) Instructions For Use (IFU)
- Document #: 100-21-1000 - Standard Handpiece Instructions For Use (IFU)

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

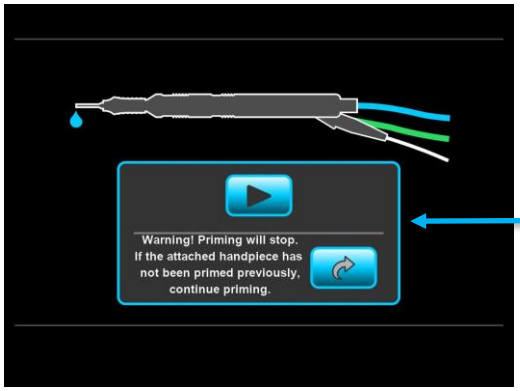



Figure 6.6.1 Priming Screen

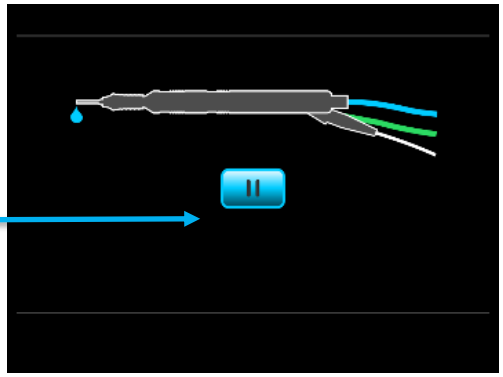


Figure 6.6.2 Prime Active/Pause Priming Screen

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.<br><br>Caution: Irrigation tubing needs to be primed prior to use. Not doing so can damage the probe/tip |

Figure 6.6.3 Priming Button Definitions

## 6.7 Main Screen with a Standard Handpiece (e.g. BoneScalpel or SonicOne)

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.

### *6.7.1 Default Main Screen with a Standard Handpiece (e.g. BoneScalpel or SonicOne)*

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

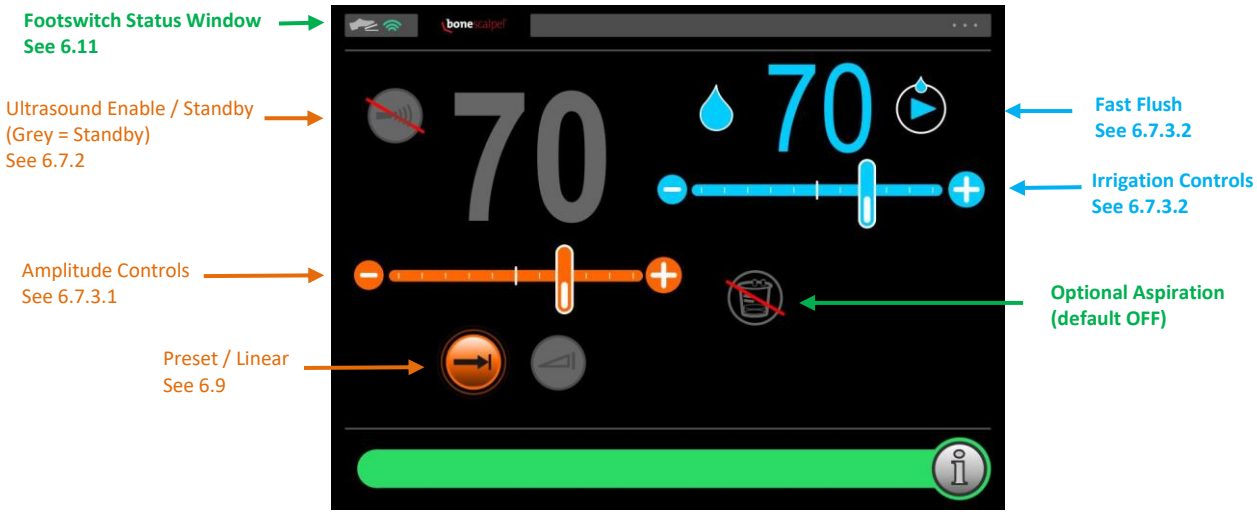



Figure 6.7.1 Default Main Screen (Standard Handpiece) with Ultrasound Disabled

### *6.7.2 Enabling Ultrasound Control with a Standard Handpiece (e.g. BoneScalpel or SonicOne)*

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.

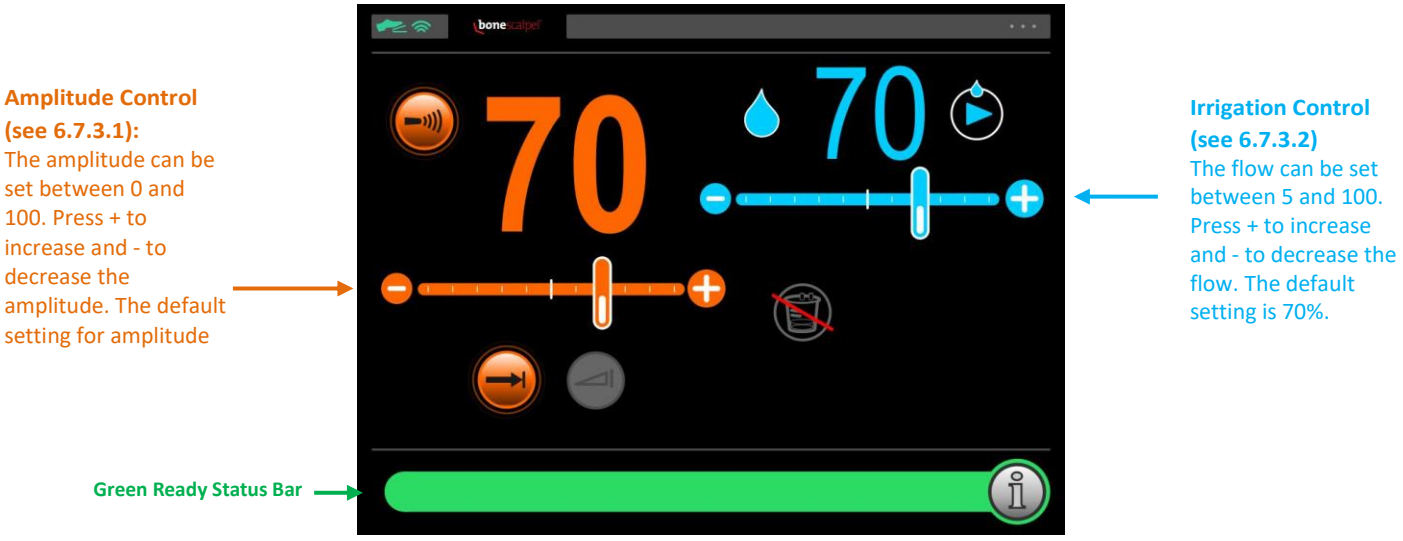
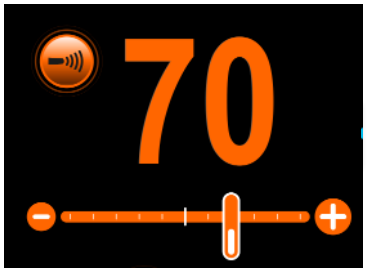



Figure 6.7.2 Default Main Screen (Standard Handpiece) with Ultrasound Enabled

### *6.7.3 System Controls; Amplitude, Irrigation & Aspiration (e.g. BoneScalpel or SonicOne)*

#### *6.7.3.1 Amplitude Controls*




The ORANGE display controls amplitude. The ultrasonic tip engages the target area in linear strokes at a rate of approximately 22,500 cycles per second. During each cycle the 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 tip.

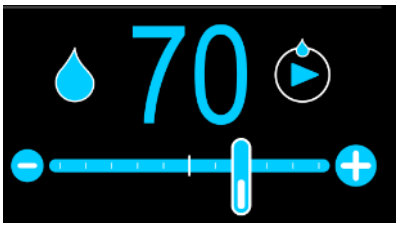
Amplitude can be adjusted by any of the following methods:

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:

- Preset Mode – In this mode, vibration is available immediately, at the user specified setting, when the footswitch is depressed (i.e. on/off, no varability).
- 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).

#### *6.7.3.2 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/tip interface for hard tissue removal

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

#### *6.7.3.3 Aspiration Controls*

Pressing the  icon enables the aspiration system. For aspiration controls see section 6.8.3.3.

Aspiration 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

## 6.8 Main Screen with a Sonastar Handpiece (e.g. SonaStar Short or SonaStar Long)

The Main Screen allows control of the main system functions such as Amplitude, Irrigation Flow and Aspiration. See section 4.3 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.

### *6.8.1 Default Main Screen with a SonaStar Handpiece (e.g. SonaStar Short or SonaStar Long)*

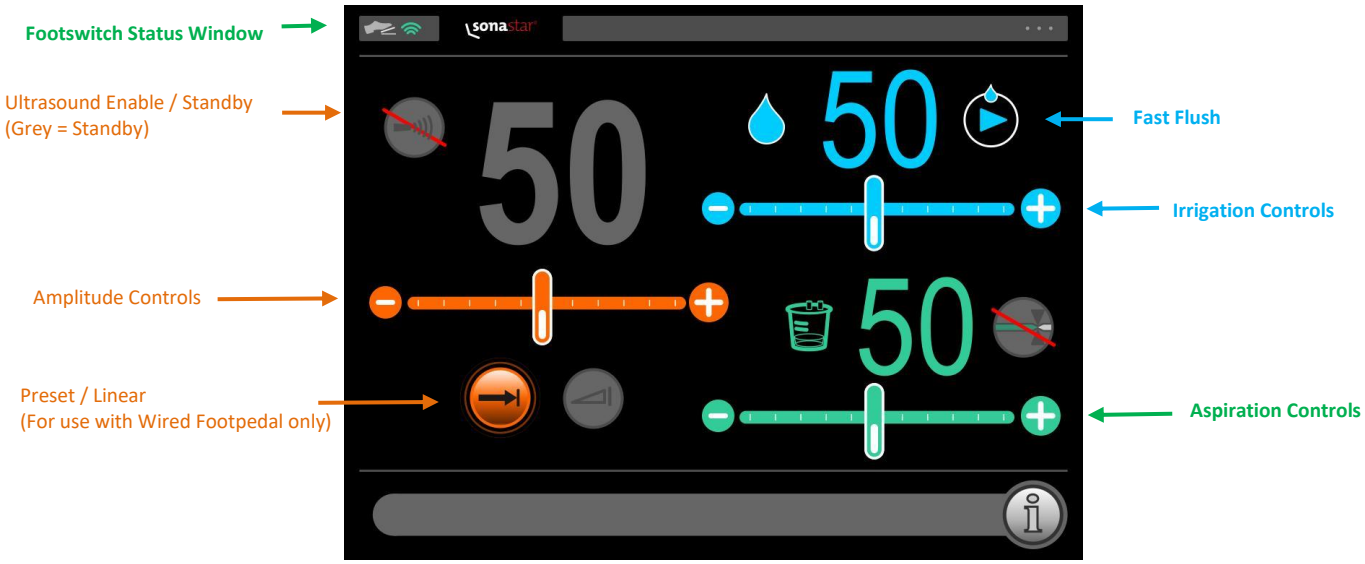



Figure 6.8.1 Default Main Screen (Sonastar Handpiece) with Ultrasound Disabled

### *6.8.2 Enabling Ultrasound Control with a SonaStar Handpiece (e.g. SonaStar Short or SonaStar Long)*

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.

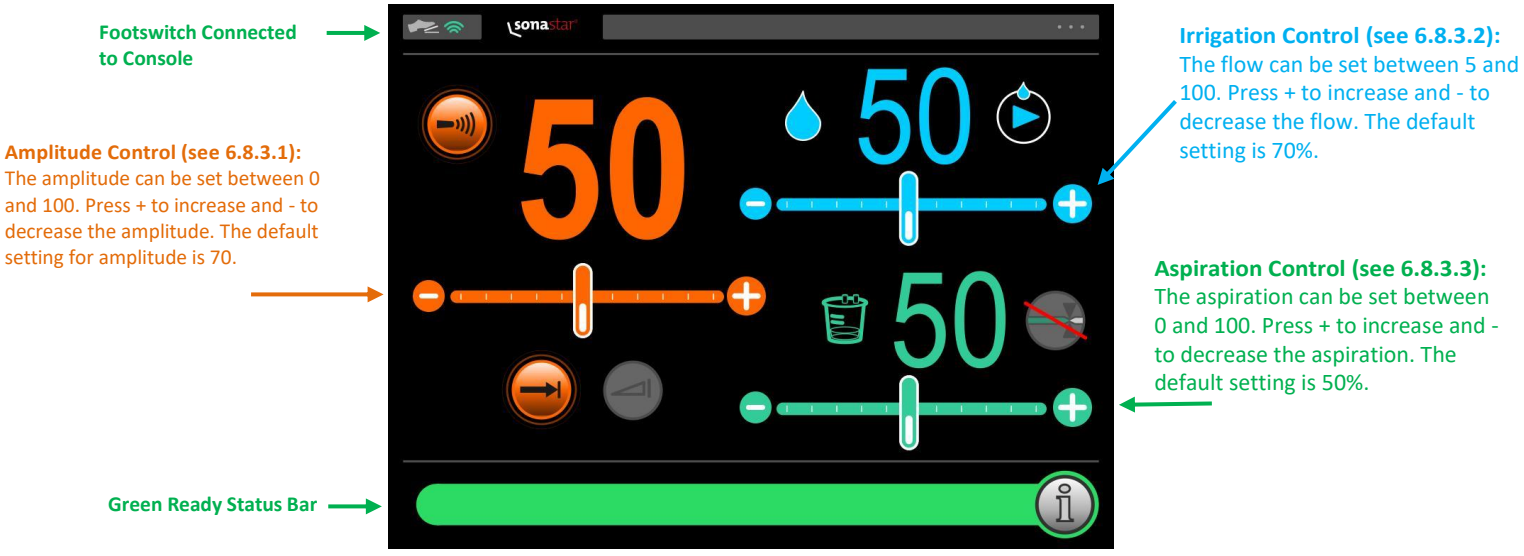



Figure 6.8.2 Default Main Screen (Sonastar Handpeice) with Ultrasound Enabled

### *6.8.3 System Controls; Amplitude, Irrigation & Aspiration* *(e.g. BoneScalpel or SonicOne)*

#### *6.8.3.1 Amplitude Controls*

For Amplitude controls see section 6.7.3.1

#### *6.8.3.2 Irrigation Controls*

For Irrigation controls see section 6.7.3.2

#### *6.8.3.3 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 '5', 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 tip ceases for a very short time period, allowing the safe removal of the tip from the surgical site. Subsequently, the vacuum is reactivated for approximately 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 tip. This is to prevent the irrigation fluid from immediately being aspirated before reaching the surgical site. When the FLUSH button is released, the valve re-opens allowing vacuum to be present at the tip.

- When the LAP/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 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 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 tip for approximately 15 seconds. After 15 seconds, the pinch valve closes again and vacuum is no longer available at the tip, thus preventing insufflated gases from escaping the body. The system is now in a Standby mode and can be reactivated by pressing 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.

## 6.9 Mode Selection & Functionality

| Operational Mode | Icon and Description | Function & Purpose |
|---|---|---|
| Preset Mode |  Preset Mode is ON<br>  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<br>  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<br>  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. |

Table 6.9: Operational Mode Selection

## 6.10 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.

| System Check | |
|---|---|
| Enable Ultrasound | Switch to Enable Mode using enable/standby button. Confirm that Amplitude setting is Orange. |
| Depress footswitch | Direct ultrasonic tip toward suitable reservoir to collect irrigation. Depress footswitch. |
| Confirm Function | Irrigation is pumped from console towards handpiece.<br>A beep is briefly heard.<br>Ultrasonic tip emits buzzing sound and irrigation exits tip as fine spray. |
| Release footswitch | Release footswitch.<br>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. |

Table 6.10: Console System Check

| | |
|---|---|
| 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 tip/tissue interface. A continuous, lateral sweeping motion is recommended for general bone/tissue removal in order to minimize contact duration with the ultrasonic tip and minimize the temperature increase. |
| WARNING | During system check, make sure the tip of the handpiece is free from contact with any object. Allowing contact with the tip may result in damage and/or personal injury |
| WARNING | 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 tip free from contact with any object |

## 6.10.1 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.

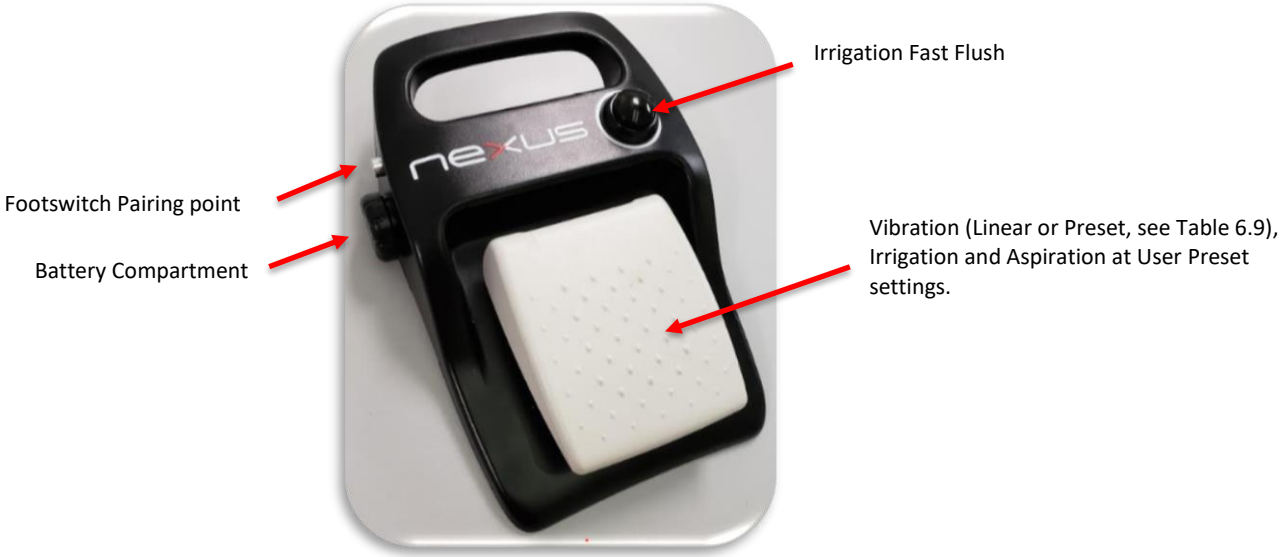
From the Main screen press the System Information  icon

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

## 6.11 Footswitch Connectivity & Functionality

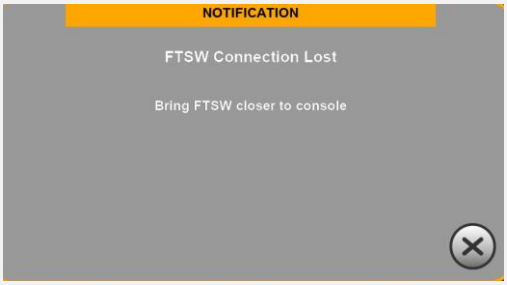
### 6.11.1 Wireless Footswitch Functionality and Features

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 8.6.2). The footswitch is powered with one “AA” alkaline battery. If the battery is low, an alert will appear on the screen. (see Troubleshooting section 8.6.1). For battery replacement see section 10.3.




#### 6.11.1.2 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.

| STATUS ICONS | DESCRIPTION |
|---|---|
|  | Footswitch **IS** communicating with the console |
|  | Footswitch is **NOT** communicating with the console<br><br>(flashing X and audible beep) |
| **FOOTSWITCH CONNECTION LOST ON-SCREEN NOTIFICATION**<br>  | (For when on Main screen only)<br><br>Footswitch is **NOT** Communicating with Console.<br><br>Bring footswitch closer to the console or replace battery. |

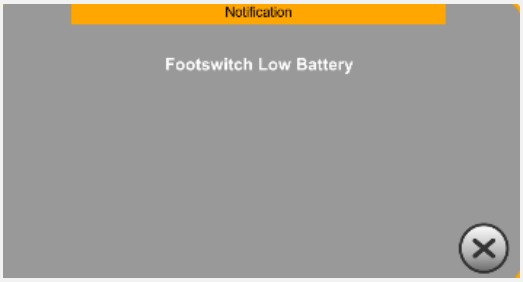
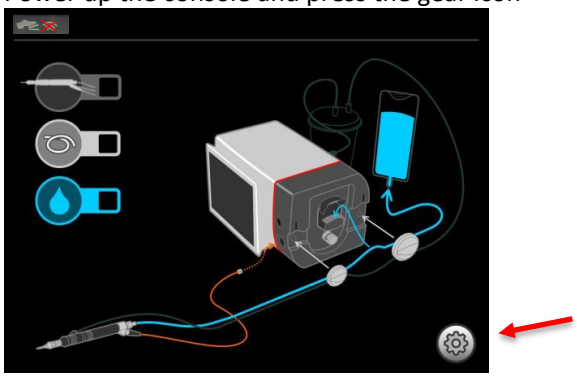
| | |
|---|---|
|  | Footswitch is pressed, Vibration is active. A one-time audible beep will be heard. |
| **LOW BATTERY ON-SCREEN NOTIFICATION**<br>  <br><br>**FOLLOWED BY**<br>  | Low Footswitch Battery.<br><br>**Caution**: Change batteries immediately following procedure |

Table 6.11.1: Wireless Footswitch Connectivity Icons and Descriptions

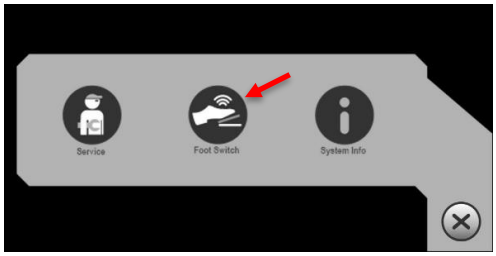
### 6.11.1.3 Pairing the Wireless Footswitch to the Console

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.

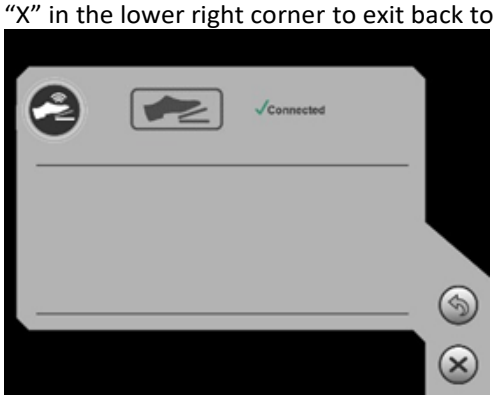

If the screen below appears, replace battery (Standard AA Battery), verifying proper orientation (refer to image on bottom of the footswitch). If the screen above appears after replacing the battery, no further action is required. Footswitch is connected to the console. If the screen below remains after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


Press the arrow to advance to the pairing process for additional instuctions


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.

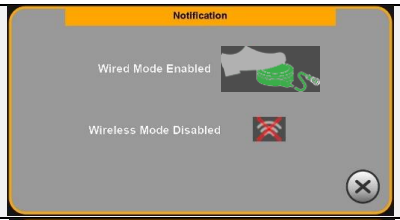



### 6.11.2 Wired Footpedal Connectivity

The Wired Footpedal is an optional accessory for the neXus console (part number 100-51-0000). The Wired Footpedal 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 optinal accessory, the neXus system may use a wired footpedal 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 footpedal must be used with software GUI version 01.07.XXXX where XXXX are any 4-digits. See System Information screen for the software version installed in your console (see section 6.10.1 for accessing System Information).

#### 6.11.2.1 Wired Footpedal Notifications

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

| WIRED FOOTPEDAL NOTIFICATION / ICONS | DESCRIPTION |
|---|---|
|   | The Notification screen alerts the user that the Wired Footpedal is connected and ready and the Wireless footswitch is disabled. |
|   | The Notification screen alerts the user that the Wired Footpedal is disabled and the Wireless footswitch is enabled. |

| | |
|---|---|
|  | Wired Footpedal connected to the console and pedal not pressed. |
|  | Footpedal is pressed. Vibration is active. A one-time audible beep will be heard. |

#### 6.11.2.3 Connecting the Wired Footpedal to the Console

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


Wired Footpedal Connection to Console

## 6.12 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 disassemble the console, follow the steps in the table below.

| Console Disassembly Procedure (Note: Steps can be done in ANY order) | |
|---|---|
| Remover 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). |

Table 6.12.1 Console Disaassembly

# 7. Cleaning Console

Follow manufacturer's directions for preparing solutions. Misonix recommends the use of EPA certified CaviWipes® or equivalent quaternary ammonium compound surface disinfectant wipe. Please follow manufacturer's instructions for surface cleaning and disinfection of hard non-porous 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 wipes.

## 7.1 Console & Footswitch Cleaning

| Console and Footswitch | |
|---|---|
| Wipe Surfaces | • Follow manufacturer's directions for preparing solutions. 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.<br>• Dispose of cloth or paper with contaminated waste. |

Table 7.1.1 Console & Footswitch Cleaning

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

WARNING Single-use items (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. 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.

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.

## 7.2 Single-Use Item Disposal

All items marked single use must not be reused. Reuse of these items 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.

# 8. 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 manual. There are no user serviceable parts.

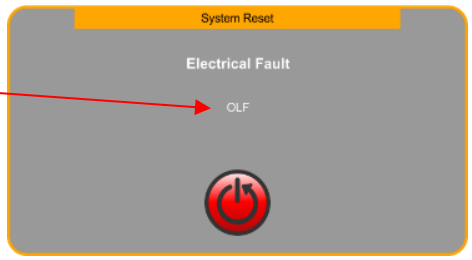
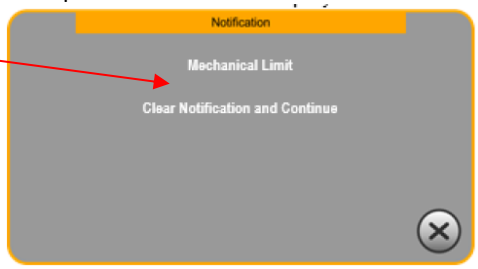
| Fault Type | Fault Indicator | Fault Action |
|---|---|---|
| System Reset<br><br>Fault Codes;<br>Varies depending on the particular fault.<br><br>**See below Note for “POST” fault code | Example screen:<br>  <br><br>Fault screen also triggers a pulsed, audible indicator. | System functions automatically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

**Table 8.0: Types of Faults and Indicators**

*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.

# 8.1 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.

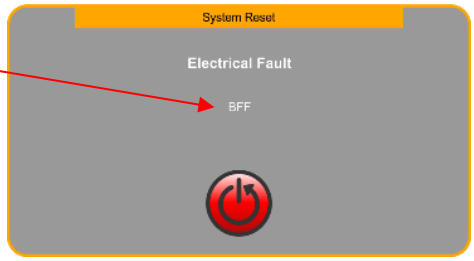
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **System Reset**<br>**Electrical Fault**<br><br>**Possible Fault codes:**<br>ILF<br>BFF<br>VLF<br>OCF<br>SCF | Example Screen<br>  <br> | System functions automatically disabled.<br><br>Pressing the System Reset Button reboots the system.<br>"neXus" splash screen appears followed by the Priming screen.<br><br>Priming screen may be skipped.<br>*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.<br>If problem persists, replace handpiece and try again.<br>If corrective action steps above are followed and fault continues, the console may need to be replaced. | |

**Table 8.1: Electrical Faults**

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

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# 8.2 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 tip). A Notification is displayed together with an audible indicator as long as the footswitch is depressed. Tip overload can occur during hard tissue removal when applying excessive tip pressure or facing strong tissue resistance, e.g. from thick cortical bone. This can lead to stalling of the ultrasonic tip. Follow the corrective action below.

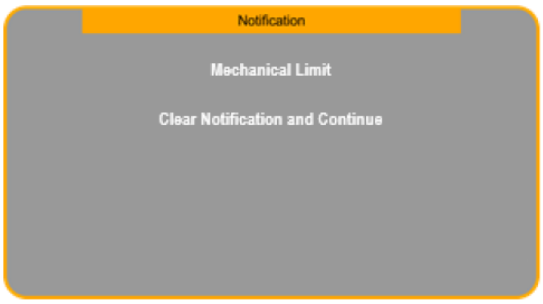
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **Notification**<br>**Frequency Fault** |  | System functions remain enabled while Notification is displayed. |
| **Possible Cause** | **Corrective Action** | |
| Tip Overload | Reducing tip pressure will automatically clear the Notification without releasing the footswitch or release footswitch and try again.<br>If problem persists, use higher amplitude setting as required. | |
| Loose or<br>damaged component | Release footswitch and Set ultrasound to STANDBY  .<br>Remove silicone sleeve (if applicable) and probe cover.<br>Inspect extension probe and ultrasonic tip for damage. Replace if necessary.<br>Otherwise re-tighten extension probe and 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. | |

**Table 8.2: Frequency Fault Notification**

## 8.3 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.

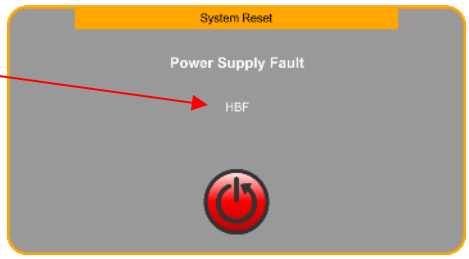
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **System Reset**<br>**Power Supply Fault**<br><br>**Possible Fault Codes;**<br>CSF<br>LVF<br>HVF<br>RSF<br>HBF<br>PFEW | Example Screen<br>  <br> | System functions automatically disabled.<br><br>Pressing the System Reset Button reboots the system. "neXus" splash screen appears followed by the Priming screen.<br><br>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.<br>If corrective action steps above are followed and fault continues, the console may need to be replaced. | |

**Table 8.3: Power Supply Faults**

## 8.4 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.

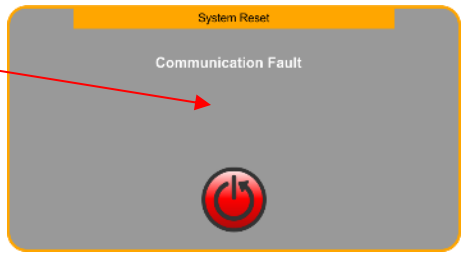
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **System Reset**<br>**Communication Fault**<br><br>**Possible Fault Codes;**<br>CF1<br>CF2<br>CF3<br>CF4<br>CF5<br>CF6 | Example Screen<br>  <br> | System functions automatically disabled.<br><br>Pressing the System Reset Button reboots the system. "neXus" splash screen appears. If the handpiece is connected, the Priming screen will appear.<br><br>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.<br>If corrective action steps above are followed and fault continues, the console may need to be replaced. | |

**Table 8.4: Communication Faults**

## 8.5 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.

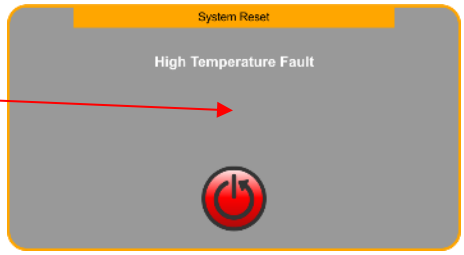
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **System Reset**<br>**High Temperature Fault**<br><br>**Possible Fault Code;**<br>HTF | Example Screen<br>  | System functions automatically disabled.<br><br>Pressing the System Reset Button reboots the system. "neXus" splash screen appears. If the handpiece is connected, the Priming screen will appear.<br><br>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<br>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.<br>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. | |

**Table 8.5: Temperature Faults**

## 8.6 Footswitch Faults

### 8.6.1 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. The batteries should be replaced immediately following the procedure.

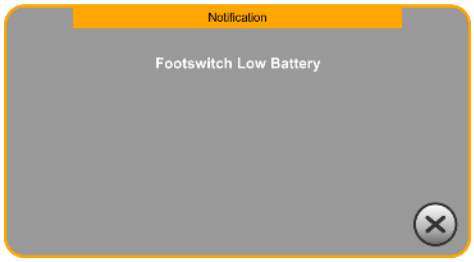
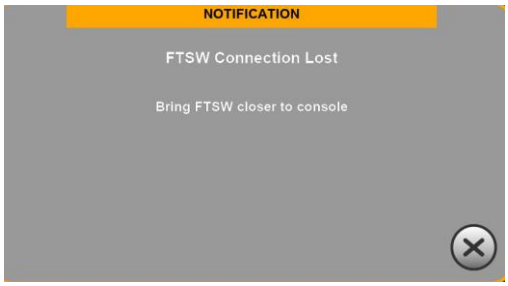
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **Notification**<br>**Footswitch Low Battery**<br>  |  | System functions remain enabled.<br><br>Pressing the Exit button returns to the Main screen. |
| **Possible Cause** | **Corrective Action** | |
| Low battery | Press the Exit Button and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

**Table 8.6.1: Low Battery Notification**

### 8.6.2 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.

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

| Possible Cause | Corrective Action |
|---|---|
| 1. Footswitch out of range<br><br>2. Interruption in Wireless communication<br><br>3. No battery or dead battery (the more likely cause)<br><br>4. Not paired with console (least likely cause)<br><br>5. Footswitch failure | Follow these corrective actions in order. DO NOT immediately try to re-pair footswitch to console.<br><br>1. Bring the footswitch closer to the console. The footswitch shall be less than 15 feet from the console.<br><br>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.<br><br>3. If problem persists, replace the battery. Observe wifi symbol again to determine if footswitch re-connects to console. If connected, the icon will change to green.<br><br>4. If problem persists, re-pair the footswitch to the console (see section 6.11.3 for Pairing steps).<br><br>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 (see section 6.11.4). Contact Misonix Service Center. |

**Table 8.6.2: Footswitch Connection Lost Notification**

### 8.6.3 Wired Footpedal Connection Lost Notification

The wired footpedal, 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 6.11.1).

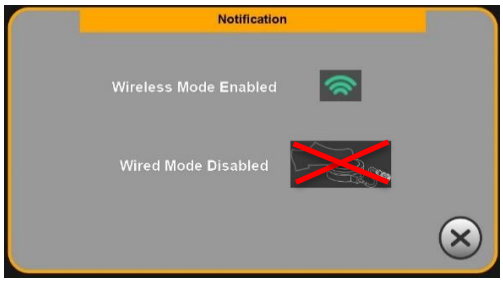
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **Notification**<br>**Wired Footpedal Connection Lost** |  <br>Followed by audible beeping. | System functions remain enabled.<br><br>Pressing the Exit button returns to the Main screen and re-enables the wireless footswitch |
| **Possible Cause** | **Corrective Action** | |
| 1. Wired Footpedal connector damaged<br><br>2. Wired Footpedal cable damaged | Follow these corrective actions in order. DO NOT immediately try to re-pair footswitch to console.<br><br>1. Disconnect cable and re-connect to the console<br><br>2. Recycle power to the console<br><br>3. If corrective action steps above are followed and fault continues, the footpedal is defective. Locate the wireless footswitch, check that the battery is installed. Follow steps in section 6.11.1.2 if necessary. | |

**Table 8.6.3: Wired Footpedal Connection Lost Notification**

## 8.7 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.

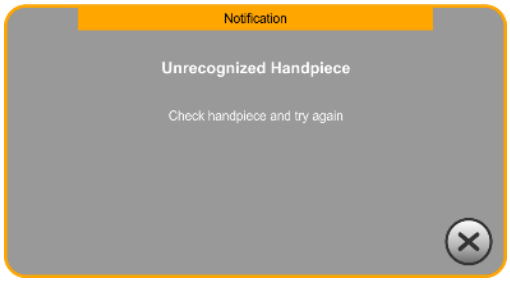
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **Notification**<br>**Unrecognized Handpiece** |  | System functions remain enabled.<br><br>Pressing the Exit button returns to the Main screen. |
| **Possible Cause** | **Corrective Action** | |
| Damaged Handpiece | Unplug the handpiece. Plug handpiece back in, press the Exit Button .<br>If corrective action steps above are followed and fault continues, the handpiece may need to be replaced. | |

**Table 8.7: Unrecognized Handpiece Notification**

## 8.8 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.

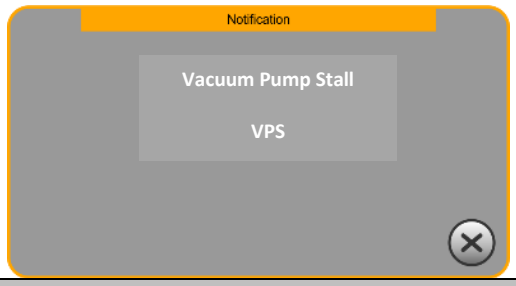
| Fault Type | Fault Screen | Fault Action |
|---|---|---|
| **Vacuum Notifications** |  <br>OR<br>  | System functions remain enabled.<br><br>Pressing the Exit button returns to the Main screen. |
| **Possible Cause** | **Corrective Action** | |
| 1. External filter blocked or restricted.<br><br>2.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

**Table 8.8.1: Vacuum Fault, Notification**

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

**Table 8.8.2: Vacuum Fault, System Reset**

## 8.9 Aspiration Troubleshooting

| Lack of Aspiration | |
|---|---|
| Symptoms<br>• Irrigation not removed from surgical field<br>• No tissue removal from the surgical field | |
| Possible Cause | Corrective Action<br>(refer to section 6.4.2.2 and 6.4.2.3) |
| 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 |

**Table 8.9: Troubleshooting – Insufficient Aspiration**

## 8.10 Irrigation Troubleshooting

| Lack of Irrigation | |
|---|---|
| Symptoms<br>• No spray from tip when ultrasound is engaged<br>• No flush fluid available<br>• Unexpected temperature rise at operative site<br>• Unexpected temperature rise of handpiece | |
| Possible Cause | Corrective Action<br>(refer to section 6.4.2.1) |
| 1. Closed or empty fluid bag | Set ultrasound to STANDBY.<br>Check fluid bag and tubing clamp. Replace fluid bag if necessary. |
| 2. Tubing not connected | Set ultrasound to STANDBY.<br>Check tubing connections.<br>Check mounting in pump head. Close pump cover until locked. |
| 3. Tubing obstructed or defective | Set ultrasound to STANDBY.<br>Check tubing for kinking, restrictions or leaks. Replace tubing if necessary.<br>Check mounting in pump head. Close pump cover until locked. |
| 4. Tubing installed in reverse | Set ultrasound to STANDBY.<br>Open pump cover. Reposition the tubing in direction of flow. Close pump cover until locked. |
| 5. Pump defect | Set ultrasound to STANDBY.<br>Open pump cover. Check if pump rollers are rotating when depressing footswitch. Replace console if they don't. |

**Table 8.10: Troubleshooting – Insufficient Irrigation**

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WARNING Tip and irrigation run-off temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal, set the irrigation flow rate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 70, a minimum flow setting of 70 should be used.

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

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

# 9. Specifications

| Console Specifications | |
|---|---|
| Classification | Class 1<br>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<br>Use only as directed in section 10 |
| Power Cord | 10ft (3m)<br>Use only supplied power cord with hospital grade plug for US, Canada |
| Ground leakage current | 500 µA (max.) |
| Vibration System | Continuous Wave<br>Frequency 22.5Khz |
| Wireless Footswitch<br>Wired Footpedal | IPX8, Internally powered<br>IPX8 |
| Console | IPX1 |
| Operating conditions | Temperature 13-30°C (55-86°F)<br>Relative humidity 20-90% (non-condensing)<br>-91m (-300ft) to 3000m (9842ft) |
| Shipping/storage conditions | Temperature: -20 to 50°C (-4 to 122°F)<br>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 |

**Table 9.1 Console Specifications**

# 10. 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 10 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

## 10.1 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.

| | 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 10.1 Console Fuse Specifications

| 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. |
| 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 | |

Table 10.2 Console Fuse Replacement

## 10.2 Filter Replacement

### 10.2.1 Periodic Maintenance

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.

### 10.2.2 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 10-1: Push Tabs inward

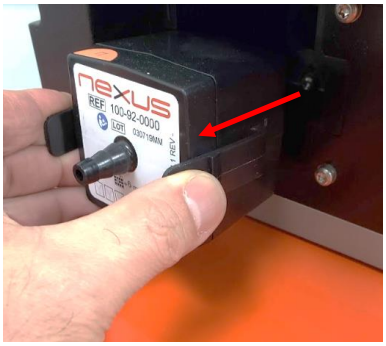


Figure 10-2: Pull out filter

## 10.3 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 are low. Replace batteries immediately following the procedure.

Open the battery compartment by turning the cap counter clockwise. 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 10-3: Remove Battery Cap

Figure 10-4: Remove Battery


Figure 10-5: Battery polarity

# 11. 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.

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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.

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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.

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# 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: Sales@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

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

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The authorized EC representative is:

CE 0482 EC REP

EMERGO EUROPE
Prinessegracht 20
2514 AP The Hague
The Netherlands

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