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PREFACE

Intended Audience

This operator’s manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the CUSA® Clarity Ultrasonic Surgical Aspirator System only.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

Trademark Acknowledgments

Integra, the Integra logo, CUSA, and Tissue Select are registered trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries. ShearTip, MicroTip, and CUSA Quick Connect are trademarks of Integra LifeSciences Corporation or its subsidiaries. Sani-Cloth is a trademark of Professional Disposables International, Inc. neodisher is a trademark of Chemische Fabrik Dr. Weigert GmbH & Co. KG. All other trademarks and trade names are the property of their respective owners.
Manufacturer

Integra LifeSciences (Ireland) Limited
IDA Business & Technology Park
Sragh
Tullamore, County Offaly, Ireland

Integra LifeSciences Corporation
Plainsboro, NJ 08536 USA; 1-800-997-4868

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Patent Information

U.S. Patents 6,499,358; 8,118,823; 8,518,066; 9,421,027; additional patent(s) pending.

Overview of Manual

This operator’s manual describes how to use the CUSA Clarity Ultrasonic Surgical Aspirator System. It presents the CUSA Clarity as a system that includes a console, handpieces, and accessories. It describes:

• The system and its functions
• The console, its subsystems, and its components
• The handpiece and its components
• How to setup and use the console
• How to assemble and use the handpiece with the system
• How to disassemble the handpiece
• How to clean components of the system
• How to sterilize components of the system
System Features

The CUSA Clarity system includes several important components and features:

- Console with touchscreen interface
- Cart
- 36 kHz handpiece
- A variety of surgical tips that attach to the handpiece:
  - Sterile, single-use tips
  - Non-sterile, extended use tips (EUT)
- Tissue Select® feature, which increases the selectivity of the surgical tip, allowing greater control and precision

Intended Uses of this Manual

When you receive your CUSA Clarity system, we recommend that you read and understand all of this operator’s manual before using the system. Also, use the manual for:

- Reference - When you need specific information on a task.
- Training - When training new personnel to use the system.

Conventions Used in this Guide

To draw immediate attention to matters of importance, this manual presents Warnings, Cautions, and Notes

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
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<tbody>
<tr>
<td>Indicates a potentially hazardous situation that, if not avoided, could result in serious injury or death.</td>
</tr>
</tbody>
</table>

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<tr>
<th>CAUTION</th>
</tr>
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<tbody>
<tr>
<td>Indicates a hazardous situation that, if not avoided, could result in product damage.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>NOTE</th>
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<tbody>
<tr>
<td>Indicates additional information.</td>
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</table>
SECTION 1
Patient and Operating Room Safety

Indications for Use

The CUSA® Clarity Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable.

The CUSA® Clarity Ultrasonic Surgical Aspirator is indicated for use in:

- Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses:
  - Gastrointestinal and Affiliated Organ Surgery - including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor heptectomy.
  - Urological surgery - including removal of renal parenchyma during nephrectomy or partial nephrectomy.
  - General Surgery - including removal of benign or malignant tumors or other unwanted soft tissue in open or minimally invasive general surgical procedures.
  - Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor heptectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy.
Contraindications

The device is not indicated for and should not be used for the removal of uterine fibroids.

Intended Users

You should use the CUSA Clarity system only in a surgical environment by qualified medical professionals trained in the use of this equipment.

This system must be set up/disassembled by operating room (OR) staff (for example, surgical nurse, neuro technician). The OR staff is also likely to operate the device controls. The handpiece and footswitch are controlled by the surgeon.

**WARNING**

It is the responsibility of the Healthcare Facility to ensure that intended users of CUSA Clarity system are appropriately trained in the use of this equipment.

Safety Information

The safe and effective use of ultrasonic surgery depends to a large degree on factors solely under the control of the operator. Only medical professionals that are properly trained in the use of ultrasonic equipment should operate the CUSA Clarity system. It is important that medical professionals read, understand, and follow the operating instructions supplied with this equipment.

Before starting any surgical procedure, medical professionals should be familiar with the medical literature, complications, and hazards of using ultrasonic surgery in that procedure.
Warnings and Cautions

To promote the safe use of the CUSA Clarity system, this section lists the warnings and cautions that appear throughout this operator’s manual. To operate this equipment with maximum safety, it is important to read, understand, and follow the instructions in these warning and cautions.

Patient and Operating Room Safety

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

**WARNING**
Operating the CUSA Clarity system outside of the specified environmental conditions may result in injury to the patient and/or user, or equipment damage, which may result in a delay in patient treatment.

**WARNING**
No modification of this equipment is allowed.

**WARNING**
Single-use devices are for single patient use only. Do not reprocess or re-use.

**WARNING**
Ignoring alarms on the CUSA Clarity system while continuing to use the system may result in injury to the patient and/or user, or equipment damage.

**WARNING**
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
**WARNING**
When the handpiece is connected to a CUSA Clarity system that is powered on, but the handpiece is not in use, keep the handpiece away from the patient. Place the handpiece on a sterile, flat, dry, nonconductive, and highly visible surface.

**WARNING**
When the handpiece is powered on, contact of the tip with a hard surface (for example: a metal instrument, tray, staples, clips, instruments, and so on) may damage the tip of the handpiece.

**WARNING**
Do not use a damaged handpiece with the CUSA Clarity system. This may result in injury to the patient or user.

**WARNING**
The handpiece and handpiece accessories (tip, flue, stylet and nosecone) must be sterile before surgical use.

**WARNING**
To avoid injury to the user, keep fingers away from the peristaltic pump and pinch valve.

**WARNING**
Touching the tip of the handpiece by the user, while the handpiece is powered on, may result in personal injury.

**WARNING**
To avoid injury or damage to equipment, place system in standby prior to changing tip or clearing a clog.
| WARNING | **Potential Burn Hazard** - CUSA Clarity tips utilize a silicone flue. Compressing the flue against the side of the vibrating surface along the length of the tip may cause excessive heating, which may burn the adjacent tissue of the surgical site. |
| WARNING | Excessive loading of CUSA Clarity tips at the surgical site may induce heating due to vibration and acoustic power transmissions. Thermal management of the surgical site with the aid of the appropriate irrigation and aspiration settings is essential. |
| WARNING | If the aspiration tubing and contamination guard are not connected to the correct canister ports, the system may not work. |
| WARNING | Avoid excessive lateral loading of CUSA Clarity tips. This may result in injury to the patient and/or user, or equipment damage. |
| WARNING | Avoid contacting bone with the CUSA Clarity tips. |
| WARNING | Do not use the sterile torque wrench for more than one surgical procedure. Reprocessing may damage the torque wrench. |
| WARNING | Before use, sterilize the torque base in the sterilization tray with the handpiece. |
**WARNING**

**Explosion Hazard** - Do not use the CUSA Clarity system in the presence of flammable anesthetics or other volatile solvents.

**WARNING**

**Electric Shock Hazard** - Always unplug the CUSA Clarity system before cleaning it.

**WARNING**

**Electrical Shock Hazard** - Do not remove cover. Refer servicing to authorized service personnel.

**WARNING**

The minimum aspiration level setting is 10%. This ensures proper handpiece cooling and performance. Insufficient aspiration may cause premature handpiece or tip failures and may induce heat exchange with the patient or user, and cause tissue burns.

**WARNING**

For continued protection against fire and electrical hazard, replace fuse only with same type and rating. Refer to “Power Input and Fusing” on page A-4.

**WARNING**

Do not allow fluids to enter the console.

**WARNING**

When testing the handpiece, do not allow the tip to come in contact with any person or object during tip activation. Contact may result in injury to the patient and/or user, or handpiece tip damage.

Contact with any object or person may cause the test to fail.

**WARNING**

Do not power up the handpiece without performing a prime cycle (that is, irrigation fluid must flow from the distal tip of the handpiece). Failure to prime the handpiece could result in permanent damage to the handpiece (internal and/or external components) and may induce heat exchange with the patient and/or user, and cause tissue burns.
### Warnings and Cautions

<table>
<thead>
<tr>
<th>WARNING</th>
<th>If the packaging for a sterile accessory is damaged, do not use the sterile accessory.</th>
</tr>
</thead>
<tbody>
<tr>
<td>WARNING</td>
<td>To ensure sterility, assemble sterile handpiece and tip in the sterile field only.</td>
</tr>
<tr>
<td>CAUTION</td>
<td>Read the instructions, warnings, cautions, and notes provided with the CUSA Clarity system before use; otherwise, injury to the patient and/or user, or equipment damage may result.</td>
</tr>
<tr>
<td>CAUTION</td>
<td>During surgery, under maximum loading conditions, CUSA Clarity system has an ultrasonic duty cycle of 10 minutes on, 5 minutes off.</td>
</tr>
<tr>
<td>CAUTION</td>
<td>Before surgery, apply the brake locks to all wheels on the cart (if using the optional Integra cart) to stop the wheels from rolling.</td>
</tr>
<tr>
<td>CAUTION</td>
<td>When using the console without a cart, prior to surgery, place the console on a solid surface. The surface must be flat, non-slip, and free from obstruction.</td>
</tr>
</tbody>
</table>
**CAUTION**
To avoid product damage, always use the torque base to hold the handpiece while using the torque wrench to tighten or loosen the tip. Avoid over torqueing the tip.

**CAUTION**
Do not use sterilization methods involving temperatures in excess of 134ºC as this may damage the handpiece.

**CAUTION**
Product damage may result if you do not follow the instructions described in the cleaning section.

**CAUTION**
To move the console up or down a ramp, use two or more people.

**CAUTION**
High frequency surgical equipment can affect the function of medical electrical devices such as ultrasonic aspirators. When using monopolar high frequency surgical equipment simultaneously with the CUSA Clarity system, contact between the activated monopolar electrosurgery instrument and the CUSA Clarity surgical tip could affect system functionality. Avoid contact between the CUSA Clarity surgical tip and an activated monopolar surgical instrument.
## Classification and Console Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tr>
<td><img src="image" alt="Follow Instructions for Use" /></td>
<td>Follow Instructions for Use</td>
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<td>MR Unsafe</td>
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<tr>
<td><img src="image" alt="This equipment meets type Cardiac Floating (CF) safety standards" /></td>
<td>This equipment meets type Cardiac Floating (CF) safety standards</td>
</tr>
<tr>
<td><img src="image" alt="High Voltage Warning" /></td>
<td>High Voltage Warning</td>
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<td><img src="image" alt="Ground Stud Marking" /></td>
<td>Ground Stud Marking</td>
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<td><img src="image" alt="System Power On/Off" /></td>
<td>System Power On/Off</td>
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<td><img src="image" alt="Handpiece Connector" /></td>
<td>Handpiece Connector</td>
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<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
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<tr>
<td><img src="image" alt="Amplitude Pedal" /></td>
<td>Amplitude Pedal</td>
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<td><img src="image" alt="Fast Flush Pedal" /></td>
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<td><img src="image" alt="Dispose in accordance with WEEE regulations" /></td>
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<td>Symbol</td>
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<td><img src="image" alt="Non-pyrogenic" /></td>
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<td>Do not re-use</td>
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<td>Sterilized using ethylene oxide</td>
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<td><img src="image" alt="Do not re-sterilize" /></td>
<td>Do not re-sterilize</td>
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<td><img src="image" alt="Temperature limitations" /></td>
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<td>Humidity limitations</td>
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<tr>
<td><img src="image" alt="This product is not manufactured with Dry Rubber or Natural Rubber Latex" /></td>
<td>This product is not manufactured with Dry Rubber or Natural Rubber Latex</td>
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<td><img src="image" alt="Lot number" /></td>
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<tr>
<td><img src="image" alt="Expiration date" /></td>
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<td><img src="image" alt="Keep dry" /></td>
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<tr>
<td><img src="image" alt="Non-sterile" /></td>
<td>Non-sterile</td>
</tr>
<tr>
<td><img src="image" alt="Recyclable packaging" /></td>
<td>Recyclable packaging</td>
</tr>
<tr>
<td><img src="image" alt="Rx ONLY" /></td>
<td>Caution: Federal law restricts this device to sale by or on the order of a physician</td>
</tr>
<tr>
<td><img src="image" alt="Consult Instructions for Use" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="image" alt="Product complies with the requirements of directive 93/42/EEC" /></td>
<td>Product complies with the requirements of directive 93/42/EEC</td>
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SECTION 2

Introduction to the System

In this section:
• Overview, page 2-1
• CUSA® Clarity System, page 2-2
• Handpiece, page 2-6
• Tissue Select® Feature, page 2-7
• Sterilization of Handpieces and Accessories, page 2-11

Overview

CAUTION
Read the instructions, warnings, cautions, and notices provided with the CUSA® Clarity system before use. Otherwise, injury to the patient or user or equipment damage may result.

This section provides general information about the CUSA Clarity Ultrasonic Surgical Aspirator System: what it is, what it does, and how it works. It also describes the handpiece functions, configurations, and the sterilization requirements for the handpiece and accessories.
CUSA Clarity System

The CUSA Clarity system is an ultrasonic surgical aspirator system that allows a surgeon to remove tissue efficiently and selectively. It performs three functions:

- **Fragmentation**: When the vibrating tip of the handpiece comes into contact with the tissue, the cells of the tissue break apart or “fragment”.

- **Irrigation**: Irrigation fluid from a user-supplied saline bag or Lactated Ringer’s solution is transferred to the distal tip of the handpiece.

- **Aspiration (Suction)**: Draws or “aspirates” irrigation fluid, fragmented tissue, and other material through the distal end of the surgical tip to the user-supplied canister.

**NOTE**

All three functions may occur at the same time.
The system includes the following items:

**Components:**

- **Console:** houses electronics, pumps, and mechanical parts. It includes a touch screen that allows you to control the functions of the system.
- **Cart:** provides a secure platform for the console. It has a handle and locking casters to facilitate movement and provide storage for the footswitch and power cord.
- **Handpiece:** a hand-held surgical device with a tip that is applied to patient tissue.
- **Footswitch:** a device connected to the console that includes two pedals used to control the ultrasonic power and irrigation fluid.
- **Torque Base:** a device that holds the handpiece to tighten or loosen a tip with the torque wrench.
- **Contamination Guard:** the filter and tubing that connects between the canister and the console. This assembly filters any remaining particulate matter or moisture, preventing them from entering the vacuum pump.
- **Sterilization Tray:** a tray for steam sterilizing the handpiece (including the cable and connector), tip pack components, and torque base.
- **Canister:** a container that stores the used irrigation fluid, fragmented tissue, and other aspirated materials. (User Supplied)
- **Irrigations Fluid Bag:** can be saline or Lactated Ringer’s solution (User supplied)
CUSA Clarity System

- **Accessories:**
  - **CUSA Quick Connect™ Cartridge and Tubing Set:** the sterile tubing and cartridge kit includes the aspiration tubing (aspirates away used irrigation fluid, fragmented tissue, and other materials to the canister), irrigation tubing (provides irrigation to the surgical site during the surgical procedure), and a cartridge (connects the tubing to the console). The kit is designed for single patient use and must be disposed of after surgery.
  - **Single Use Tip Pack:** the single-use tip pack contains a tip, flue, nosecone, and stylet. The stylet is used to remove tissue blockage from the tip and/or handpiece. You can remove the stylet from the packaging and put it aside within the sterile field for later use. The pack is designed for single patient use and must be disposed of after each surgery.
  - **Extended Use Tip (EUT) Pack:** the EUT pack contains a single tip, five nosecones, five flues, and five stylets. The tip must be sterilized and may be used up to five times. Each nosecone, flue, and stylet must be sterilized before use and must be disposed of after each use.
  - **Torque Wrench:** the torque wrench is designed for single-use and must be disposed of after each surgery.
  - **Specimen Trap:** a device that attaches to the canister to trap waste.
  - **Cleaning Brush:** a brush that is used to clean the internal pathway of the handpiece and tip.

**Fragmentation**

**Electromechanical Operation**

The console supplies the high-frequency handpiece with an alternating voltage signal at 36,000 cycles per second (36 kHz). This voltage is directed to opposite poles of a stack of piezoelectric ceramic discs, which are fastened to the metallic body inside the handpiece. The resulting oscillating electric field causes the discs to vibrate, and this vibration is transmitted down the length of the metallic body and into the surgical tip. The slender, tapered shape of the surgical tip focuses this vibrational energy, causing tissue fragmentation.

**Irrigation**

The system transfers irrigation fluid from a user-supplied IV saline or Lactated Ringer’s solution to the distal tip of the handpiece. Sterile irrigation fluid flows from an IV set (bottle or bag and IV administration tubing) to a variable speed peristaltic pump.
The pump:

- Moves fluid at 2 to 20 mL/min; default flow is 3 mL/min. Use the adjustment slider (move the slider up/down on the **Irrigation** column on the touch screen) to increase or decrease the irrigation flow in 1 mL/min increments.

- Accelerates to a Fast Flush speed, pumping at 25 mL/min ± 0.5 mL/min. The Fast Flush pedal on the system footswitch activates the Fast Flush feature.

The pump pushes the fluid through the manifold irrigation tubing to a flue, a sleeve surrounding the vibrating tip. As the irrigation fluid passes through the flue, it cools the tip.

When the fluid reaches the distal end of the tip, as much as 99% of it passes through two pre-aspiration holes in the tip, preventing fluid pooling in the sterile field and continually clearing the suction system. Fluid that does not pass through the pre-aspiration holes irrigates the surgical site and suspends fragmented tissue.

**Aspiration (Suction)**

Aspiration enables Constant Tissue Contact, the consistent, tangible contact between tip and tissue which is essential in efficient tissue resection.

A vacuum pump in the console provides nominally 640 mmHg maximum dead head vacuum at sea level. Use the adjustment buttons (move the slider up/down on the **Aspiration** column on the touchscreen display) to increase or decrease the suction from 10 to 100% in 5% increments; default is 60%.

The suction, which produces an air stream moving toward the vacuum pump, pulls irrigation fluid, fragmented tissue, and other materials through the distal end of the surgical tip. From the tip, the aspirated materials pass through the handpiece and manifold suction tubing into the suction canister. From the suction canister, the air stream continues to flow through a contamination guard that filters any remaining particulate matter or moisture, preventing them from entering the vacuum pump.

The accuracy of the vacuum level in the aspiration tubing at the port of the handpiece is ± 66 mmHg and never less than 30 mmHg.

A suction pinch valve on the front of the console opens when the system is on, and closes to stop suction when:

- Priming the irrigation system
- Pressing the Fast Flush pedal
- Releasing the amplitude pedal in Run Status (in this case, the pinch valve closes for approximately one second, then re-opens).
- Releasing the amplitude pedal in the on demand aspiration mode (this suction stoppage prevents depletion of the pneumoperitoneum).

When the system is powered off, the suction pump remains off and the suction pinch valve remains closed. Use the pinch value button on the front of the suction pinch valve to open the valve manually.
Touchscreen Display

After the system is set up and powered on it provides power to the handpiece used during ultrasonic surgery and to the footswitch. The footswitch contains two pedals that allow the user to control the ultrasonic power and fast flush of irrigation fluid. The user can control amplitude, irrigation and aspiration levels during surgery using the scales and buttons on the touchscreen display. For more detailed information about the touchscreen display, see “Touchscreen Display and Functions” on page 4-1.

Handpiece

The CUSA Clarity handpiece is a hand-held surgical device. It houses a transducer that vibrates at an ultrasonic frequency, transferring the vibrations to a hollow titanium tip.

When applied to patient tissue, the vibrating tip provides the desired surgical effect – the fragmentation and removal of specific tissue.

The handpiece connects to the console by a handpiece cable and by the CUSA Quick Connect Cartridge and Tubing Set. The disposable CUSA QuickConnect Cartridge and Tubing Set consists of a tube for sterile irrigation fluid, which the console pumps to the handpiece, and a tube for aspiration as well as a cartridge that aligns the tubes with the console. Clips on the aspiration tubing fasten the tubing to the handpiece cable.

Handpiece Functions

Together, a handpiece and CUSA Clarity console form an ultrasonic surgical aspirator system. This system has three functions:

- Fragmentation
- Irrigation
- Aspiration (Suction)

All three functions can occur at the same time.
**Handpiece Configurations**

The CUSA Clarity system includes a high frequency handpiece.

**NOTE**

The high frequency handpiece operates within a frequency range and 36 kHz is a representative value. See the “Technical Specifications” on page A-3 for the frequency range.

**Handpiece Tips**

A variety of handpiece tips are available. Tips vary in internal diameter and length. For information on the tips available, see “Tip Specifications” on page A-2.

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**Tissue Select® Feature**

Tissue Select® allows the surgeon to maintain a high fragmentation rate while increasing selectivity and control at the surgical site.

The benefits of Tissue Select are:

- Gives surgeon greater control and precision when resecting near critical structures
- Enhances tissue selectivity while maintaining fragmentation capability. The power to the site is limited while strength and efficacy in tissue removal are still provided.
- Provides maximum tissue selectivity
- Gives surgeon superior tactile feedback

**Fragmentation**

Fragmentation occurs when the vibrating tip comes into contact with tissue. As the tip begins to move toward tissue, it accelerates, then impacts and penetrates the tissue. The acceleration, impact, and penetration produce a combination of direct mechanical forces and hydrodynamic pressures that burst cells.

Several variables affect the fragmentation rate. Most are functions of the CUSA Clarity system:

- Amplitude (tip excursion—the total distance the tip travels): greater amplitude results in greater fragmentation rate
- Aspiration has several functions:
  - It draws tissue toward the vibrating tip and creates constant tissue contact.
Tissue Select Feature

- It removes irrigation and fragmentation debris from the surgical site.
- If there is no suction or low suction, tissue contact does not occur, resulting in minimal tissue fragmentation and increased tissue temperature.
- Tip acceleration: produces the peak forces and pressures that fragment tissue.
- Tip cross-sectional area at the tip-tissue contact site

These variables also affect tactile feedback, what the surgeon’s hand feels when using the handpiece.

Inherent Tissue Selectivity

With all other variables remaining constant, the tip does not fragment all tissue types equally effectively. Another variable, tissue strength, affects fragmentation rate.

- “Low strength” soft tissues that are easiest to fragment include the brain and most organs. Older, partially dried tissues are also easy to fragment. “High strength” strong tissues that are most difficult to fragment include vessel structures, tendons, ligaments, healthy skin, and organ capsules.
- Strength increases and fragmentation rate decreases with tissue containing greater collagen, elastin, or both (collagen type, quantity, and organization affect cell structural quality).

Tissue strength also affects tactile feedback. The surgeon can feel a difference between the tip contacting low strength tissue and the tip contacting high strength tissue. As the tip works through low strength tissue, the surgeon feels a smooth, rhythmic sensation from the handpiece. When the tip contacts high strength tissue, it feels like it is “bouncing off” the tissue. Also, the smooth, rhythmic sensation becomes rougher. To avoid fragmenting high strength tissue, the surgeon must apply less pressure to the tip or move the tip away from the tissue. To continue fragmenting high strength tissue, the surgeon must manually apply more pressure.

Continued manual pressure on the footswitch pedals could result in unintentional damage to critical structures. Using the Tissue Select feature, the CUSA Clarity system can help the surgeon avoid these problems when dissecting near critical structures.

Increasing Tissue Selectivity

It is possible to increase the inherent selectivity resulting from variations in tissue strength while maintaining amplitude, tip acceleration, and suction. This increase in selectivity results from reducing the adaptive power that drives the tip. Remember: The ultrasonic generator delivers
electrical power (which is directly related to the acoustic power present at the tip, which results in fragmentation) to the handpiece. Consider the power delivered to the handpiece in three terms:

- **Initial power**: the quantity of power necessary to drive the tip vibration in air; that is, no contact with tissue.
- **Adaptive power**: the power necessary to maintain tip vibration under load (in contact with tissue). When the tip encounters load, a feedback loop in the system senses the additional load and provides additional power to maintain tip vibration.
- **Maximum power**: the greatest power output the console can provide. Maximum power is the sum of initial and adaptive power.

**A Common Misunderstanding of the Amplitude Setting**

It has been common practice to decrease the amplitude setting when encountering critical structures. The reasoning behind this practice is that the lower amplitude setting results in slower fragmentation rate and greater selectivity, thus greater control to help avoid damage when dissecting near the critical structures. Consider this reasoning more carefully:

- **True**: Decreasing the amplitude setting also decreases the fragmentation rate.
- **True**: Because the fragmentation rate is slower, the surgeon has a little more time to move the tip away from a critical structure before damaging it; therefore, the surgeon *seems* to have greater selectivity and control.
- **False**: The surgeon gains greater selectivity, thus greater control and precision, when dissecting near critical structures.

Why does the decrease in amplitude not give greater selectivity and control? Decreasing the amplitude does not greatly affect the adaptive power. Decreasing the amplitude leaves plenty of adaptive power.

When the tip contacts critical structures, it still has more than enough power to fragment them if the surgeon applies pressure or prolongs the tip-tissue contact. Therefore, decreasing the amplitude setting gives the following results:

- Reduced fragmentation ability
- Reduced fragmentation rate
- Little increase in selectivity
- Little reduction in adaptive power
Tissue Select Settings

Ultrasonic energy is inherently selective. It fragments soft tissue more easily than collagen-rich tissue. **Tissue Select** is a safety setting unique to the CUSA systems that allows the surgeon to increase selectivity and safety without sacrificing procedure speed. Tissue Select limits power when the tip encounters a blood vessel, providing a wider margin of safety in preserving the vessel.

**Tissue Select** has 5 settings:

<table>
<thead>
<tr>
<th>Level of Selectivity</th>
<th>Fragmentation Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Off (Default)</td>
<td>Maximum power</td>
</tr>
<tr>
<td>1 Low</td>
<td>Slightly decreased tissue removal rate, increased tissue selectivity and tactile feedback</td>
</tr>
<tr>
<td>2 Medium</td>
<td>Further decreased tissue removal rate, increased tissue selectivity and tactile feedback</td>
</tr>
<tr>
<td>3 High</td>
<td>Slowest tissue removal rate, maximum selectivity and tactile feedback</td>
</tr>
<tr>
<td>4 Maximum</td>
<td></td>
</tr>
</tbody>
</table>

**Standard Operation**

Power is continuous. The console provides ample adaptive power, as necessary to maintain amplitude under heavy load.

**Tissue Select High or Maximum Setting Operation**

Both adaptive power and amplitude are reduced.
- When the tip encounters strong tissue, it will not be fragmented at all due to reduction in amplitude.
Sterilization of Handpieces and Accessories

You must sterilize the CUSA Clarity handpiece with steam before use. Some of the CUSA Clarity system accessories are sterile, single-use items. Other accessories are reusable. You must sterilize all reusable accessories with steam before use.

The table below describes the sterilization requirements for the handpiece and accessories. For information on the sterilization parameters and sterilization procedure for the handpieces and accessories, see “Assembling the System Prior to Use” on page 6-1.

<table>
<thead>
<tr>
<th>Item</th>
<th>Initially Sterile</th>
<th>Reusable / Requires Sterilization by the User</th>
<th>Validated Number of Sterilizations Cycles</th>
<th>Sterilization Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece</td>
<td>No</td>
<td>Yes</td>
<td>200</td>
<td>Steam</td>
</tr>
<tr>
<td>Torque Base</td>
<td>No</td>
<td>Yes</td>
<td>200</td>
<td>Steam</td>
</tr>
<tr>
<td>Torque Wrench</td>
<td>Yes</td>
<td>No</td>
<td>Single Use</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>CUSA Quick Connect Cartridge and Tubing Set</td>
<td>Yes</td>
<td>No</td>
<td>Single Use</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Single Use Tip Pack (all items)</td>
<td>Yes</td>
<td>No</td>
<td>Single Use - One time prior to use</td>
<td>Steam</td>
</tr>
<tr>
<td>EUT Tip Pack (all items)</td>
<td>No</td>
<td>Tip: Yes</td>
<td>5 (EUT tip only)</td>
<td>Steam</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All other items: No (not reusable; but require sterilization prior to use)</td>
<td>Flue, styllet and nosecone - one time prior to use</td>
<td></td>
</tr>
</tbody>
</table>

**WARNING**

Single-use devices are for single patient use only. Do not reprocess or re-use.
Sterilization of Handpieces and Accessories

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SECTION 3

Console Components

In this section:
• Overview, page 3-1
• Console Features, page 3-2
• Console – Front Panel, page 3-4
• Console – Rear Panel, page 3-5

Overview

This section describes the console for the CUSA® Clarity Ultrasonic Surgical Aspirator System. It provides an overview of the console and a description of each major console subsystem and its components.
Console Features

The figure illustrates the console on the optional cart. The components are described in the table.
## Console Features

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>① Console Body</td>
<td>Houses the electronics, pumps, and mechanical parts. It includes a touchscreen that allows you to control the functions of the system.</td>
</tr>
<tr>
<td>② Handpiece Connector</td>
<td>Connector to plug in the surgical handpiece.</td>
</tr>
<tr>
<td>③ Contamination Guard</td>
<td>The filter and tubing that connects between the canister and the console. This assembly filters any remaining particulate matter or moisture, preventing them from entering the vacuum pump.</td>
</tr>
<tr>
<td>④ Canister Holder</td>
<td>Holder for user-supplied aspiration canister.</td>
</tr>
<tr>
<td>⑤ AC Mains Connector and Cable</td>
<td>Cable that plugs into a wall receptacle to provide power to the system.</td>
</tr>
<tr>
<td>⑥ Footswitch</td>
<td>A device connected to the console that includes two pedals used to control the amplitude and irrigation fluid.</td>
</tr>
</tbody>
</table>
Console – Front Panel

The figure illustrates the front view of the console. The components are described in the table.

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>① Power Button</td>
<td>Powers the system on and off.</td>
</tr>
<tr>
<td>② Handpiece Cable Connector</td>
<td>Connects the handpiece to the console.</td>
</tr>
<tr>
<td>③ Contamination Guard Connector</td>
<td>Connects the contamination guard filter to the console.</td>
</tr>
<tr>
<td>④ Suction Pinch Valve</td>
<td>When closed, the valve pinches off suction flow to the handpiece when:</td>
</tr>
<tr>
<td></td>
<td>• Priming the handpiece with irrigation fluid</td>
</tr>
<tr>
<td></td>
<td>• Pressing the Fast Flush pedal</td>
</tr>
<tr>
<td></td>
<td>• Releasing the amplitude pedal in Run Status</td>
</tr>
<tr>
<td></td>
<td>• Releasing the amplitude pedal in the on demand aspiration mode</td>
</tr>
<tr>
<td></td>
<td>When the system is powered off, the suction pinch valve remains closed.</td>
</tr>
<tr>
<td></td>
<td>Use the suction pinch valve release button to open the valve.</td>
</tr>
<tr>
<td>⑤ Suction Pinch Valve Release Button</td>
<td>Opens the suction pinch valve manually.</td>
</tr>
<tr>
<td>⑥ Irrigation Door</td>
<td>Open to connect cartridge. Protects irrigation pump head.</td>
</tr>
</tbody>
</table>
Console – Rear Panel

The figure illustrates the rear view of the console. The components are described in the table.

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>① System Fan Vent</td>
<td>Fan keeps internal system cool.</td>
</tr>
<tr>
<td>② Potential Equalization Terminal</td>
<td>For use in locations where Potential Equalization Conductors are used.</td>
</tr>
<tr>
<td>③ Footswitch Cable Connector</td>
<td>Connects the footswitch to the console.</td>
</tr>
<tr>
<td>④ AC Power Cord Connector</td>
<td>Connects the system to the Mains power supply. A safety feature prevents the power cord from being accidentally unplugged.</td>
</tr>
<tr>
<td>⑤ Fuses</td>
<td>Protect the system from electrical overloads. Refer to “Power Input and Fusing” on page A-4.</td>
</tr>
<tr>
<td>⑥ Labels</td>
<td>Displays the console model number, serial number and regulatory approvals.</td>
</tr>
<tr>
<td>⑦ USB Connector</td>
<td>Used for service</td>
</tr>
<tr>
<td>⑧ I.V. Pole</td>
<td>Supports the sterile irrigation fluid container. The pole must be raised to use it. The pole can be lowered when not in use. The safe working load for the I.V. pole is 2 kg.</td>
</tr>
</tbody>
</table>
Intentional Blank
Touchscreen Display and Functions

In this section:
- Overview, page 4-1
- Touchscreen Layout, page 4-1
- Alarm Indicators, page 4-4
- Ultrasonic Control Scale Adjustments, page 4-5
- Footswitch and Aspiration Modes, page 4-6

Overview

This section describes the touchscreen display (or “touchscreen”) layout and the behavior during system startup and operation of the CUSA® Clarity System.

Touchscreen Layout

The touchscreen consists of the following screens:
- Main
- Setup Tasks
- Settings
- Online Help
Main Screen

To access the Main Screen, press the Main Screen button from any other screen.

The Main Screen contains ultrasonic control scales for amplitude, Tissue Select®, aspiration, and irrigation, slide buttons for the footswitch and aspiration modes, and buttons to open the setup tasks, settings, and online Help screens.
Setup Tasks Screen

To access the Setup Tasks screen, press the Setup/Standby button on the Main Screen. The Setup Tasks screen is displayed when the system is powered on.

The Setup Tasks screen contains the setup tasks for the footswitch, handpiece, and cartridge, for priming the system, and for testing the handpiece.

Press the help icon next to the task to access specific information about that task.

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Footswitch Setup (see page 8-2)</td>
<td>4</td>
<td>Start Prime Button (see page 10-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Handpiece Setup (see page 8-3)</td>
<td>5</td>
<td>Start Test Button (see page 10-4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Cartridge Setup (see page 8-4)</td>
<td>6</td>
<td>Main Screen Button (see page 4-2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Settings Screen

The Settings screen contains:

- **Language**—Setting for the touchscreen language
  
  Available languages are: English, French, Italian, German, Spanish, Dutch, Japanese, Chinese (Traditional), Chinese (Simplified), Korean, Russian, Danish, Polish, Finnish, Portuguese (Brazilian), Portuguese (European), Swedish, Norwegian, Czech, and Croatian.

- **System Information**—Provides the software, IB firmware, UM firmware, UC firmware, and operating system version numbers, and the device serial number. There is also a **Extract Log** button to download system log files for service help.

- Handpiece hours of use

This screen is accessed by the Settings button.
Online Help

The online Help screen provides basic information on setting up, operating, troubleshooting, disassembling, and cleaning.

This screen is accessed by the Online Help button.

Alarm Indicators

The CUSA Clarity System activates an alarm to indicate a technical problem with the system. All alarms on the CUSA Clarity System are technical, low-priority alarms, for example, mechanical or equipment-related. There are no physiological alarms on the CUSA Clarity system.

When the system activates an alarm, it:

- Displays a System Error screen with the description of the alarm and a resolution
- Sounds a two-beep alarm tone every 20 seconds

Refer to the Alarm Descriptions section on 13-2 for information on how to clear alarms.

It is recommended that when the CUSA Clarity System is set up for surgery, make sure that the touchscreen is clearly visible to the surgeon in the event of an alarm. Remove any obstructions that may block the surgeon’s view of the touchscreen.

**WARNING**

Ignoring alarms on the CUSA Clarity system while continuing to use the system may result in injury to the patient and/or surgical personnel, or equipment damage.
Ultrasonic Control Scale Adjustments

On the main screen, white ultrasonic control scale adjustment arrows ① and the selected values ② are shown for amplitude, Tissue Select, aspiration, and irrigation settings.

Adjusting the Ultrasonic Control Scale Values

To adjust the ultrasonic control scale values:

1. Select the ultrasonic control scale adjustment arrow.

2. Slide the arrow up to increase the value or down to decrease the value.

   The selected value displays above the control scale.

   When the Amplitude pedal is pressed, the amplitude scale border is highlighted and a feedback bar displays next to the Amplitude control scale to show that the handpiece is running.

   When the Fast Flush pedal is pressed, the Irrigation scale border is highlighted to show Fast Flush is active.

Control Scale Values

The ultrasonic control scale values are:

- **Amplitude**: scale ranges from 10 to 100% in selectable increments of 5%; default value is 60%.

- **Tissue Select**: scale ranges from Off (0), Low (1), Medium (2), High (3) to Maximum (4); default value is Off. Maximum (4) provides maximum selectivity, not maximum power.

- **Aspiration (Suction)**: scale ranges from 10 to 100% in selectable increments of 5%; default value is 60%.
Footswitch and Aspiration Modes

- **Irrigation**: scale ranges from 2 to 20 mL/min in selectable increments of 1 mL/min; default value is 3 mL/min.

When using the CUSA® Clarity ShearTip™ for fibrous tissue resection, Integra recommends using a minimum irrigation setting of 7mL/min. The irrigation setting should be adjusted based on the requirements of the specific procedure.

**Ultrasound Active Indicators**

*When ultrasonics is active*:

- The border around the Amplitude Control Scale is highlighted in yellow, and:
- A yellow Amplitude Indicator bar rises to the left of the Amplitude Control Scale, which represents the actual amplitude of the tip.
- When Tissue Select is 0-Off, 1-Low, or 2-Medium, this yellow bar will be the same height as the Amplitude Control Scale adjustment arrow.
- When Tissue Select is 3-High, or 4-Maximum, this yellow bar will be slightly lower than the Amplitude Control Scale adjustment arrow, because these settings also reduce amplitude.

**Footswitch and Aspiration Modes**

Footswitch Mode

The **Footswitch Mode** ① controls the level of power to the handpiece from pressure applied to the footswitch.

The footswitch mode values are:

- **Standard** (default): The handpiece operates at the amplitude level set on the touch screen, regardless of the pressure you place on the amplitude pedal.

  **NOTE**: The default setting changes to the last setting after initial use

- **Proportional**: The handpiece operates according to how much pressure you place on the amplitude pedal, that is, the more you press the pedal, the higher the resulting amplitude up to the level set on the touch screen.
**Aspiration Mode**

The Aspiration Mode controls the flow of suction from the handpiece. The aspiration mode values are:

- **Constant** (default): Constant suction and irrigation is provided to the handpiece at the level set on the touch screen.
- **On Demand**: Suction and irrigation is only provided to the handpiece when you activate the Amplitude pedal on the footswitch.

**Selecting the Modes**

To select the footswitch and/or aspiration mode, slide the Footswitch Mode (1) button and/or Aspiration Mode button right or left to the desired value.
Handpiece Components

In this section:
• Overview, page 5-1
• Components of Assembled Handpieces, page 5-2
• Additional Handpiece Components, page 5-4

Overview

This section describes the components of an assembled handpiece, the physical characteristics, and functions. It also describes the components needed to assemble the handpiece.
Components of Assembled Handpieces

The handpiece body contains:
- Transducer to convert electric energy into mechanical motion
- Aspiration port to connect the aspiration tubing to the handpiece

The handpiece cable contains:
- Electric wires (deliver electric power from console to drive the handpiece)
- Connector that attaches the handpiece cable to the console

The connecting body serves as the connecting point for the tip and transfers the vibrations from the transducer to the tip.
Components of Assembled Handpieces

Tip

The tip is a hollow titanium tube that touches patient tissue. When active, the tip vibrates at an ultrasonic frequency, causing it to fragment tissue. The tip has two pre-aspiration holes ①, one on either side, which help to keep the tip clear and provide better visibility at the surgical site.

Threads ② on the end of the tip are for attaching the tip to the connecting body of the handpiece.

The tip is sterile and single use when in a sterile tip pack or can be used up to five (5) times if it is an extended use tip (EUT).

For more information on various tip diameters and lengths, see Tip Specifications, page A-2.

Nosecone

The single-use nosecone attaches to the handpiece, covers the connecting body, and holds the flue in place. It is sterile in a single use tip pack and nonsterile in an EUT pack.

Integrated O-rings

The o-rings are integrated into the nosecone. They provide stability for the nosecone and prevent fluid leaks into the connecting body.
Additional Handpiece Components

Flue

The single-use flue is a translucent silicone tube tapered at one end that provides a sleeve over the tip. Irrigation fluid flows through an irrigation connection tube at one end of the flue and down the tip to the surgical site.

The single-use flue is sterile in a single use tip pack and nonsterile in an EUT pack.

Each tip size requires a tip-specific flue; therefore, you will find the tip-specific flue packaged with the appropriate tip.

Additional Handpiece Components

These components are essential in assembling a handpiece.

CUSAR® Clarity Ultrasonic Surgical Aspirator System Operator’s Manual
**Additional Handpiece Components**

**Aspiration Tubing**
- Aspirates away used irrigation fluid, fragmented tissue, and other aspirated materials to the canister
- Connects to the aspiration port at the base of the handpiece, passes through the suction pinch valve, and connects to the aspiration port on the canister
- Contains a small clip to attach to the handpiece cable

**Irrigation Tubing**
- Provides irrigation during the surgical procedure
- Connects to the flue, passes over the peristaltic pump, and connects to a standard IV bag, which can be hung on the console’s IV pole

**Cartridge**
- Connects the aspiration and irrigation tubing to the console

**WARNING**
Single-use devices are for single patient use only. Do not reprocess or re-use.

**Torque Wrench (Sterile)**

The single-use sterile torque wrench is used to attach or remove a tip to the handpiece.
Additional Handpiece Components

**Torque Base (Sterilizable)**

The reuseable torque base is used to hold the handpiece securely in place while using the torque wrench to attach or remove a tip. The torque base is sterilizable.

For information on sterilizing the torque base, see Sterilization Tray Packaging, page 11-16.
SECTION 6
Assembling the System Prior to Use

In this section:
• Overview, page 6-1
• Assembling the Console and Cart, page 6-2
• Attaching the Power Cord, page 6-3

Overview

This section describes how to assemble the console and cart, and to attach the power cord.
Assembling the Console and Cart

1. Place the console on the cart by aligning the four (4) feet on the bottom of the console with the four (4) indentations on the cart.

2. Make sure the console is seated on the top of the cart.
3. Under the top of the cart, insert and turn counter-clockwise the provided screw.

Attaching the Power Cord

1. Plug the power cord into the back of the console.
2. Plug the plug end into the wall receptacle.

**NOTE**
Make sure you position the console so that you can quickly access the power cord in case you need to disconnect it.

**WARNING**
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
Assembling the Console and Cart

Intentional Blank
In this section:
• Overview on page 7-1
• Quick Reference: Setting Up in the Sterile Field on page 7-2
• Assembling the Handpiece in the Sterile Field on page 7-3

Overview

This section describes the steps for setting up the CUSA® Clarity System in the sterile field. It begins with the arrival of the sterilized handpiece and accessories in the operating room. It ends with the handpiece ready to be connected to the console.
Quick Reference: Setting Up in the Sterile Field

1. Attaching a Tip on page 7-3.
2. Attaching the Nosecone and the Flue on page 7-5.
3. Attaching the Tubing on page 7-7.

**WARNING**

Do not use a damaged handpiece with the CUSA Clarity system. This may result in injury to the patient or user.
Assembling the Handpiece in the Sterile Field

Attaching a Tip

1. Thread a tip onto the handpiece connecting body by turning the tip clockwise until it is finger tight.

Place the torque base on a flat surface or in the designated spot in the sterilization tray.

**WARNING**

Before use, sterilize the torque base in the sterilization tray with the handpiece.

For EUT use, the tip must be sterilized before use and may be used up to five times. Each nosecone, flue, and stylet must be sterilized before use and must be disposed of after each use.

2. Place the handpiece into the torque base as shown and make sure that the 2 flat metal sides of the handpiece fit snugly in the metal slot at the end of the base.
3. Hold the handpiece in the base and place the torque wrench (color side towards handpiece) over the tip.

4. Rotate the torque wrench clockwise until it clicks twice.

**CAUTION**
To avoid product damage, always use the torque base to hold the handpiece while using the torque wrench to tighten or loosen the tip. Avoid over torqueing the tip.

**NOTE**
Keep the torque wrench and base in the sterile field in case you need to change a tip during the procedure and for disassembly after surgery.
Attaching the Nosecone and the Flue

1. Slide the larger end of the nosecone over the tip and slide it down over the neck of the handpiece making sure the white dots are aligned.

2. Rotate the nosecone clockwise until it locks into place and the white dot on the nosecone aligns with the white dot on the body of the handpiece.
   Make sure the white dots are aligned on the nosecone and handpiece.

3. Slide the flue onto the nosecone base along the tip.
   Remove stylet from the flue and put it aside in the sterile field if needed to clear the tip during surgery.
4. Make sure that the flue is aligned with the pre-aspiration holes at the distal end of the tip.

NOTE

If the pre-aspiration holes are completely covered, most of the irrigation fluid may be aspirated back through the handpiece, impairing cavitation, thus reducing tissue ablation efficacy.
**Attaching the Tubing**

1. Open the CUSA Quick Connect™ Cartridge and Tubing Set using proper sterile technique.

2. Pick up the larger loop of the irrigation and aspiration tubing set to be brought into the sterile field and assembled to the handpiece.
3. Place the cartridge and smaller loop of the irrigation and aspiration tubing set aside until it is time to connect it to the console.

4. Attach the aspiration tubing to the aspiration port at the base of the handpiece.
5. Attach the irrigation tubing to the Luer lock fitting on the handpiece flue.
6. Push the irrigation tubing into the clip at the base of the handpiece.

**NOTE**
If needed, the clip can be rotated to minimize strain on the user’s wrist.

7. Clip the handpiece cable to the aspiration tubing using clips available along the aspiration tubing.

**NOTE**
Handpiece cable is not intended to be inserted into the clip at the base of the handpiece.

8. Keep sufficient tubing and cable in the sterile field to allow you to reposition the console.

9. Pass off the cartridge and smaller loop of the irrigation and aspiration tubing set and handpiece cable connector outside of the sterile field for attachment to the console.
Overview

This section describes the steps for setting up the CUSA® Clarity System in the non-sterile field.

**CAUTION**
Before surgery, apply the brake locks to all wheels on the cart (if using the optional Integra cart) to stop the wheels from rolling.

**CAUTION**
When using the console without a cart, prior to surgery, place the console on a solid surface. The surface must be flat, non-slip, and free from obstruction.

Quick Reference: Setting Up in the Non-Sterile Field

1. Powering Up the System, page 8-2
2. Attaching the Footswitch, page 8-3
3. Attaching the Handpiece, page 8-3
4. Connecting the Tubing Set, page 8-4
Assembling the Handpieces

The handpiece must be assembled in a sterile area, see System Setup in the Sterile Field, page 7-1.

**WARNING**

To ensure sterility, assemble sterile handpiece and tip in the sterile field only.

---

**Console Setup (Non-Sterile)**

**Powering Up the System**

Press the **System Power On/Off** button on the console (Classification and Console Symbols, page 1-9). The console sounds a startup tone.

**NOTE**

The purpose of the startup tone verifies that the audio alarms are functioning correctly. If this tone does not sound during the startup process, contact Integra for service.
Attaching the Footswitch
Align the red dot on the footswitch cable connector with the red dot on the footswitch port on the rear of the console and plug in the footswitch cable.

Attaching the Handpiece
After the handpiece cable connector is passed out from the sterile field, align the red dot on the handpiece cable connector with the red dot on the handpiece port on the front of the console and plug in the handpiece cable.
Connecting the Tubing Set

NOTE
Make sure the handpiece and contamination guard have been properly set up and connected. See the contamination guard instructions for use for information.

1. Place the canister into the canister holder.
2. Open the cartridge door, insert the cartridge, and slide the cartridge down.

WARNING
To avoid injury to the user, keep fingers away from the peristaltic pump and pinch valve.
3. Close the cartridge door.

4. Connect the contamination guard to the vacuum port of the canister.

**WARNING**
If the aspiration tubing and contamination guard are not connected to the correct canister ports, the system may not work.

**NOTE**
Since there are several brands of canisters, the canister may appear different than in the picture above.

Make sure the contamination guard is in place and check expiration date.

**NOTE**
Contamination guard must be replaced every six months or when the color changes.

**WARNING**
If the aspiration tubing and contamination guard are not connected to the correct canister ports, the system may not work.
5. Connect the aspiration tubing to the patient port of the canister.

![Diagram showing connection of aspiration tubing to canister]

**NOTE**
Make sure the remaining ports on the canister are covered.

6. From the rear of the console, lift the IV pole straight up.

![Diagram showing lifting of IV pole]
7. Rotate the IV pole hook 180 degrees to the left until you feel it lock into place.

8. Hang the irrigation fluid bag on the IV pole hook. Use saline or Lactated Ringer’s solution.
9. Remove cover from the IV spike end of the irrigation tubing.
10. Spike the irrigation fluid bag with the end of the irrigation tubing.

11. Make sure the irrigation tubing is securely attached to the irrigation fluid bag.
Operating the System

In this section:

• Overview on page 9-1
• Quick Reference: Operating the System on page 9-2
• Priming the System on page 9-2
• Testing the Handpiece on page 9-4

Overview

This section describes the procedures for operating the CUSA® Clarity System for surgery. The system must be properly setup before using it. For specified environmental conditions for operation of the system, see “Environment” on page A-5.

WARNING

Operating the CUSA Clarity System outside of the specified environmental conditions may result in injury to the patient and/or user, or equipment damage, which may result in a delay in patient treatment.

If the system is not setup, see:

1. “System Setup in the Sterile Field” on page 7-1.
2. “System Setup in the Non-Sterile Field” on page 8-1.
Quick Reference: Operating the System


Check Connections

On the Setup Tasks screen, make sure the footswitch, handpiece and cartridge have a green check mark.

If not, select the ? to view further information.

NOTE
The footswitch (page 8-3), handpiece (page 8-3), and tubing set (page 8-4) connections must be completed prior to priming the system.

Priming the System

During the prime cycle, the system pumps irrigation fluid from the irrigation bag through the irrigation tubing to the handpiece tip. The prime cycle takes less than one minute (approximately).

NOTE
Priming the system is required to operate the handpiece.

Start Prime

To start priming the system:

1. On the Setup Tasks screen, select the Start Prime button.
2. Make sure the irrigation tubing is filled with irrigation fluid, and the irrigation fluid flows from the tip.

**NOTE**
The prime cycle ends automatically; however, if necessary, the cycle may be stopped at any time by selecting the Stop Prime button.

3. If fluid does not flow from the tip after one prime cycle, select the Start Prime button again.

If irrigation fluid does not flow from the handpiece tip after several prime cycles, see “Irrigation Troubleshooting” on page 13-5.

**Stop Prime**
To stop priming the system, during the priming cycle, select the Stop Prime button (the Start Prime button changes to a Stop Prime button during the priming cycle).
Testing the Handpiece

During the test cycle, the system verifies the handpiece is working properly by automatically increasing tip amplitude to 100% and then decreasing it to 0%. The test cycle takes about 4 seconds (approximately).

After the test cycle completes, the Setup Tasks screen displays either Pass or Fail and a Details button. Select the Details button to display the Detailed Test Results screen with the test results. If the test failed, the Detailed Test Results screen provides the error(s) and solution(s). For additional troubleshooting information, see “Troubleshooting the System” on page 13-1.

NOTE

The footswitch, handpiece, and cartridge connections must be made and a priming cycle completed prior to performing the test.

NOTE

The handpiece must be tested prior to use to ensure proper function.

Start Test

To start testing the handpiece:

1. On the Setup Tasks screen, select the Start Test button.
2. If the test fails:
   a. Remove the tip and then re-attach with the torque wrench and base, and re-run the test. If the error continues to persist, attach a new tip with the torque wrench and base, and re-run the test.
   b. If the error continues to persist after replacing the tip, replace the entire handpiece.
   c. Re-run the test.
3. If the test passes, press the **Main Screen** button.

After testing the system, a Details button displays. Press this button to view the following detailed test results.

**Detailed Test Results**
- **Tip Frequency Optimization** - Finds the best frequency for the tip
- **Amplitude Test** - Measures how close the handpiece is to maximum amplitude and provides a score from 0 to 100%. The score must be greater than or equal to 50% to pass the test

**System Ready for Use**

Press the **Main Screen** button to begin surgical use.

For a description of the settings, see “**Section 4 Touchscreen Display and Functions**” on page 4-1.
Testing the Handpiece

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SECTION 10

Changing Tips in the Sterile Field During a Surgical Procedure

In this section:

• Overview on page 10-1
• Quick Reference: Changing Tips on page 10-1
• Changing a Tip on page 10-2

Overview

This section describes the procedures for changing tips during surgery while in the sterile field.

Quick Reference: Changing Tips

1. Put the system in standby.
2. “Removing the Used Tip” on page 10-2.
4. Test and prime the handpiece again.
Changing a Tip

The contents of the Single Use Tip Packs are sterile and for single-use only. Unused items of the single use tip packs can be re-sterilized once.

The contents of Extended Use Tip (EUT) Packs are non-sterile. An EUT can be sterilized up to five times. EUT nosecones, flues and stylets are single-use only.

If you intend to attach an EUT tip in the sterile field, make sure the EUTs nosecones, and flues are sterile before introducing them into the sterile field.

Putting the system in Standby

To avoid any unwanted activation of the system during tip change which may result in user injury, put the system in standby mode before starting by pressing “Setup / Standby” button on the main screen.

Removing the Used Tip

1. Remove the irrigation tubing from the clip at the base of the handpiece.
2. Remove the irrigation tubing from the Luer fitting on the handpiece flue.

3. Slide the flue off of the nosecone base.

4. Twist off the nosecone counter-clockwise until it unlocks.
5. Slide the nosecone off the tip.

6. Place the handpiece on the torque base as shown and make sure that the 2 flat metal sides fit snugly in the metal slot at the end of the base.

7. Hold the handpiece in the base and place the torque wrench (color side towards handpiece) over the tip.

CAUTION
To avoid product damage, always use the torque base to hold the handpiece while using the torque wrench to tighten or loosen the tip. Avoid over torqueing the tip.
8. Rotate the torque wrench counter-clockwise.

9. Unthread the tip from the handpiece connecting body by turning the tip counter-clockwise by hand.

10. Discard the flue and nosecone in compliance with hospital policy for contaminated waste.
Assembling the New Tip on the Handpiece

1. Open new sterile tip pack.
2. Thread a tip onto the handpiece connecting body by turning the tip clockwise until it is finger tight.

3. Place the torque base on a flat surface or in the designated spot in the sterilization tray.
4. Place the handpiece on the torque base as shown and make sure that the 2 flat metal sides fit snugly in the metal slot at the end of the base.

5. Hold the handpiece in the base and place the provided torque wrench (color side towards handpiece) over the tip.
WARNING
Before use, sterilize the torque base in the sterilization tray with the handpiece.

CAUTION
To avoid product damage, always use the torque base to hold the handpiece while using the torque wrench to tighten or loosen the tip. Avoid over torquing the tip.

6. Rotate the torque wrench clockwise until it clicks twice.

Remove the handpiece from the torque base.

7. Slide the larger end of the nosecone over the tip and slide it down over the neck of the handpiece making sure the white dots are aligned.

8. Rotate the nosecone clockwise until it locks into place and the white dot on the nosecone aligns with the while dot on the body of the handpiece.

Make sure the white dots are aligned on the nosecone and handpiece.
Changing a Tip

9. Slide the flue onto the nosecone base along the tip.

10. Make sure that the flue is aligned with the pre-aspiration holes at the distal end of the tip.

**NOTE**

If the pre-aspiration holes are completely covered, most of the irrigation fluid may be aspirated back through the handpiece, impairing cavitation, thus reducing tissue ablation efficacy.
11. Attach the irrigation tubing to the Luer lock fitting on the handpiece flue.
12. Push the irrigation tubing into the clip at the base of the handpiece.

**NOTE**
If needed, the clip can be rotated to minimize strain on the user’s wrist.

**NOTE**
Handpiece cable is not intended to be inserted into the clip at the base of the handpiece.

13. Prime the irrigation and test the handpiece before starting to use the handpiece again by pressing “start prime” and “start test”.
SECTION 11

Disassembling, Cleaning, and Sterilizing the System

In this section:
• Overview on page 11-1
• Quick Reference: Disassembling the System on page 11-1
• Quick Reference: Cleaning the System on page 11-2
• Disassembling the System on page 11-2
• Cleaning the System on page 11-11
• Sterilizing the System on page 11-14
• Sterilization Parameters on page 11-16

Overview
This section describes how to disassemble the system and clean the console, handpiece, and components.

Quick Reference: Disassembling the System

4. “Detaching the Contamination Guard” on page 11-10
Disassembling the System

CUSAn Clarity Items to Keep and Discard After a Surgical Procedure

<table>
<thead>
<tr>
<th>Keep</th>
<th>Discard</th>
</tr>
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<tbody>
<tr>
<td>Handpiece</td>
<td>Nosecone</td>
</tr>
<tr>
<td>Contamination Guard</td>
<td>Flue</td>
</tr>
<tr>
<td>EUTs (with less than 5 uses)</td>
<td>EUTs (after 5 uses)</td>
</tr>
<tr>
<td>Torque Base</td>
<td>Tip Stylet</td>
</tr>
<tr>
<td>Footswitch</td>
<td>Torque Wrench</td>
</tr>
<tr>
<td>Power Cord</td>
<td>CUSA Quick Connect™ Cartridge and Tubing Set</td>
</tr>
<tr>
<td>Sterilization Tray</td>
<td>Aspiration Canister</td>
</tr>
<tr>
<td></td>
<td>Irrigation Supply</td>
</tr>
<tr>
<td></td>
<td>Specimen Trap (if used)</td>
</tr>
<tr>
<td></td>
<td>Single Use Tip</td>
</tr>
</tbody>
</table>

Disassembling the Handpiece

1. Remove the irrigation tubing from the clip at the base of the handpiece.
2. Remove the handpiece cable from the aspiration tubing clips.

3. Remove the aspiration tubing from the aspiration port at the base of the handpiece.
Disassembling the System

4. Remove the irrigation tubing from the Luer fitting on the handpiece flue.

5. Slide the flue off of the nosecone base along the tip.

6. Twist off the nosecone counter-clockwise until it unlocks.
7. Slide the nosecone off the tip.

8. Place the handpiece on the torque base as shown and make sure that the 2 flat metal sides fit snugly in the metal slot at the end of the base.

9. Hold the handpiece in the base and place the torque wrench (color side towards handpiece) over the tip.

**CAUTION**

To avoid product damage, always use the torque base to hold the handpiece while using the torque wrench to tighten or loosen the tip. Avoid over torquing the tip.
Disassembling the System

10. Rotate the torque wrench counter-clockwise.

11. Unthread the tip from the handpiece connecting body by turning the tip counter-clockwise by hand.

12. Discard the items (listed in the table in “CUSA® Clarity Items to Keep and Discard After a Surgical Procedure” on page 11-2) in compliance with hospital policy for contaminated waste.
Disassembling the Console

1. Detach the aspiration tubing from the patient port on the canister.

2. Disconnect the contamination guard tubing from the vacuum port of the canister.

NOTE

The contamination guard should not be removed from the console unless it is time to replace it (every six months or when the color changes).
3. Open cartridge door, if necessary press the pinch valve button, and remove the cartridge from the console by sliding it up.

4. Detach the handpiece cable from the console by gently pulling on the handpiece cable connector in the handpiece port on the front of the console.
5. Unplug the power cord from the wall receptacle and the console.

6. Disconnect the footswitch cable connector from the back of the console.

7. Discard the used/contaminated items in compliance with hospital policy for contaminated waste. Please reference the table “CUSA® Clarity Items to Keep and Discard After a Surgical Procedure” on page 11-2.
Detaching the Contamination Guard

NOTE
The contamination guard should not be removed from the console unless it is time to replace it (every six months or when the color changes).

1. Detach the handpiece cable from the console by gently pulling on the handpiece cable connector in the handpiece port on the front of the console.

2. Discard the contamination guard in compliance with hospital policy for contaminated waste.

Powering Down the System

Press the **Power** button on the front of the console. The touchscreen will go dark. Do not unplug power cord until system has powered down.
Cleaning the System

**WARNING**

_Electric Shock Hazard_ - Always unplug the CUSA Clarity System before cleaning it.

**CAUTION**

Product damage may result if you do not follow the instructions described in the cleaning section.

Cleaning the Touchscreen

Make sure to the console is unplugged before cleaning it. Clean the touch screen with a lint-free wipe and a cleaner, such as window/glass cleaner, eyeglass cleaner, or a quaternary ammonia disinfectant.

**NOTE**

Do not wipe the touch screen with a sponge because it may scratch the surface.

**NOTE**

Never apply cleaner directly to the touch screen.

Cleaning the Console and Cart

1. Unplug the power cord from the wall receptacle and the console.
2. Clean the surface with a lint-free wipe soaked with one of the following:
   - 70% IPA
   - Super Sani-Cloth®
   - Sani-Cloth® Bleach
3. Make sure the surfaces remain visibly wet for a minimum of two (2) minutes, then air dry.

**WARNING**

Do not allow fluids to enter the console.
4. Clean the wheels at the base of the system cart to ensure that the four anti-static wheels function correctly.

**NOTE**

Make sure that the surface of the wheels is free from dirt and dust. Make sure that the surface is completely dry before using the system again.

---

**Cleaning the Handpiece, EUT, and Torque Base**

The handpiece, extended use tips, and torque base may be cleaned by either the manual cleaning or autowash cycle process prior to sterilization. For Sterilization Parameter, see “**Sterilizing the System**” on page 11-14.

**Manual Cleaning**

1. Use the provided cleaning brush to clean out the internal channels of both the handpiece and tip. Continue to pass the brush through the tip and handpiece until it comes out clean.

**NOTE**

Make sure to keep the handpiece cable connector dry.

2. Clean the exterior of the handpiece and tip with a lint free cloth soaked with warm water and a non-alkaline detergent.
3. Use the cloth to manually clean the junction where the tip attaches.
4. Rinse the entire handpiece and tip thoroughly with water and dry with a soft cloth.

**Autowash Cycle:**

Before auto washing, use the provided cleaning brush to thoroughly clean the internal channels of the handpiece and tip. Continue to pass the brush through the tip and handpiece until it comes out clean.

In a Steelco DS50 DRS or equivalent washer/disinfector, perform a prewash cycle of 5 minutes, then clean using a 1% solution of alkaline detergent (neodisher® MediClean forte or equivalent, final pH between 10.0-11.5) for 10 minutes at 60°C (140°F), disinfect for 10 minutes at 93°C (199.4°F), and dry for 20 minutes.
Cleaning the Footswitch

1. Disconnect the footswitch from the console.

2. Wipe it clean.

3. If the footswitch is contaminated with blood or fluid:
   a. Immerse the footswitch in warm water containing detergent or disinfectant.
   b. Rinse the footswitch with clean water.

   **NOTE**
   Make sure to keep the connector dry.

4. Allow the footswitch to drain after rinsing.

Sterilization Tray Cleaning

Use a neutral detergent to clean the tray.

**NOTE**
Do not clean the sterilizer tray with abrasives. Product damage will result.
Sterilizing the System

Packaging the Handpiece and Components for Sterilization

The handpiece and components need to be packaged for sterilization.

Integra provides a sterilization tray for steam sterilization of the CUSA Clarity handpiece. This tray protects the handpiece during sterilization and during transfer to the sterile field. The handpiece and components must be cleaned prior to sterilization, see “Cleaning the Handpiece, EUT, and Torque Base” on page 11-12.

Sterilization Tray Layout

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>①</td>
<td>Handpiece</td>
<td>⑤</td>
</tr>
<tr>
<td>②</td>
<td>Handpiece Cable Posts</td>
<td>⑥</td>
</tr>
<tr>
<td>③</td>
<td>Handpiece Connector</td>
<td>⑦</td>
</tr>
<tr>
<td>④</td>
<td>Nosecone</td>
<td>⑧</td>
</tr>
</tbody>
</table>
**Most Common Sterilization Tray Configuration**

![Diagram of Most Common Sterilization Tray Configuration]

**EUT Sterilization Tray Configuration**

![Diagram of EUT Sterilization Tray Configuration]
1. Place the handpiece in the appropriate slot ① and align it with the outline on the bottom of the tray.

2. Wrap the handpiece cable around the posts ②.

3. Place the handpiece connector in the appropriate slot ③ and align it with the outline on the bottom of the tray.

4. Optional. Place the nosecone in the appropriate slot ④ and align it with the outline on the bottom of the tray.

5. Optional. Place the flue ⑤ anywhere on the bottom of the tray.

6. Place the torque base in the appropriate slot ⑥ and align it with the outline on the bottom of the tray.

7. Optional. Place the Extended Use Tips (up to 3) in the appropriate slots ⑦ and align them with the outline on the bottom of the tray.

8. Put on the lid ⑧ on the sterilizer tray.

9. Close and latch the lid.

**Sterilization Parameters**

The CUSA Clarity handpiece and components must be sterilized with steam.

**Sterilization Tray Packaging**

The handpiece and components can be packaged in the sterilization tray either:

- **Wrapped**—Sterilization tray double wrapped in hospital CSR material
- **Flash (Unwrapped)**—Sterilization tray unwrapped

The cycles below are acceptable for sterilizing the CUSA Clarity handpiece and components

<table>
<thead>
<tr>
<th>Packaging</th>
<th>Temp</th>
<th>Type</th>
<th>Time</th>
<th>Dry Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wrapped</strong></td>
<td>132°C (269.6°F)</td>
<td>Prevac</td>
<td>4 min</td>
<td>30 min</td>
</tr>
<tr>
<td></td>
<td>134°C (273.2°F)</td>
<td>Prevac</td>
<td>3 min</td>
<td>30 min</td>
</tr>
<tr>
<td></td>
<td>134°C (273.2°F)</td>
<td>Prevac</td>
<td>18 min</td>
<td>30 min</td>
</tr>
<tr>
<td><strong>Flash (Unwrapped)</strong></td>
<td>132°C (269.6°F)</td>
<td>Prevac</td>
<td>4 min</td>
<td>None</td>
</tr>
</tbody>
</table>
Sterilizing the Handpiece and Components with Steam

Sterilizing the handpiece with steam depends on the following factors:

- Temperature
- Exposure time
- Population and resistance of resident bioburden
- Method of air removal from the autoclave

Use the validated steam sterilization cycle parameters in these instructions. If you deviate from this recommended method of sterilizing, it is your Health Care Facility’s responsibility to validate the deviation. For sterilizing the handpiece with steam, do not exceed 134°C (273.2°F).

**CAUTION**

Do not use sterilization methods involving temperatures in excess of 134°C (273.2°F) as this may damage the handpiece.
Sterilization Parameters

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In this section:

• Overview on page 12-1
• Quick Reference on page 12-2
• Handpiece Maintenance on page 12-2
• Handling and Transporting of the System on page 12-3
• Storage of the System and Accessories on page 12-3
• Disposal of the Equipment on page 12-4
• Return Equipment for Service on page 12-4
• Integra Service Centers on page 12-6

Overview

This section describes routine maintenance tasks for the system. Biomedical Engineering at the facility should perform these tasks. It also describes handling and storage information for the system, and information on returning equipment to Integra for service.

Annual preventive maintenance and testing is required to inspect for any possible wear that will degrade your CUSA® Clarity System’s essential performance or operation. Being proactive in your CUSA Clarity preventive maintenance program ensures your equipment will run at optimal capability for longer, allowing you to get the most from your tissue ablation device, protecting your patients, users, and your financial investment.

**WARNING**

No modification of this equipment is allowed.
**WARNING**

*Electrical Shock Hazard* - Do not remove cover. Refer servicing to authorized service personnel.

---

**Quick Reference**

The following chart lists routine maintenance tasks, when you perform each task, and the equipment on which you perform them.

<table>
<thead>
<tr>
<th>When</th>
<th>Equipment</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily or when used</td>
<td>Console</td>
<td>Clean and wipe dry.</td>
</tr>
<tr>
<td>Daily or when used</td>
<td>Footswitch</td>
<td>Clean the footswitch.</td>
</tr>
<tr>
<td>Every 6 months, or when filter changes color</td>
<td>Contamination Guard</td>
<td>Replace the contamination guard. Write either the installation date or the expiration date on the guard.</td>
</tr>
<tr>
<td>After 50 hours of use, or 200 surgical procedures, whichever comes first</td>
<td>Handpiece</td>
<td>Return handpiece to Integra and replace with a new handpiece.</td>
</tr>
</tbody>
</table>

---

**Handpiece Maintenance**

**Return and Replace the Handpiece**

The handpiece has been validated to 50 hours of ultrasonic usage (i.e. with foot pedal depressed) and 200 procedures. To ensure optimal performance, it is recommended that you replace the handpiece once it reaches 50 hours or 200 procedures, whichever comes first. The tracking of ultrasonic usage hours and the recommendation to replace the handpiece are to support patients and users by following the recommendations outlined in the FDA Guidance Document issued March 17, 2015, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” and by complying with applicable international standards.

To view the hours of use, with the handpiece connected, go to the **Settings** screen (see “Settings Screen” on page 4-3).

Integra recommends that you retain a spare, sterile handpiece for every surgical procedure.
Handling and Transportation of the System

If you need to move/relocate the CUSA Clarity Ultrasonic Surgical Aspirator System within the environment of the Healthcare Facility, note the guidelines below:

Before moving the console:

- Power off the system.
- Unplug the power cord from the wall receptacle and secure it.
- Disconnect the handpiece.
- Disconnect and remove the irrigation fluid bag.
- Lower the IV pole.
- Secure any loose objects. Make sure there are no loose objects placed on the top of the console.
- Secure the footswitch and cord.

When moving the console (if attached to a cart):

- Push the cart using the handle.
- Do not run while pushing the console and cart.
- Use an elevator to move the console between floors of a building. Never use a stairwell.
- Do not attempt to lift the console while attached to the cart.

**CAUTION**

To move the console up or down a ramp, use two or more people.

Storage of the System and Accessories

**Console**

- Make sure the system is clean. Store the system in a low traffic area that is free of dirt, blood, water, and other contaminants.
- Contamination guard may be stored with console if it is not expired.
- Store the system at an ambient temperature between -20°C (-4°F) and 60°C (154°F).

**Console with Cart**

- Wrap footswitch cord around cart and store footswitch in cart basket.
- Wrap power cord around cart.
- Make sure the system is clean. Store the system in a low traffic area that is free of dirt, blood, water, and other contaminants.
- Contamination guard may be stored with console if it is not expired.
- Store the system at an ambient temperature between -20°C (-4°F) and 60°C (154°F).

**Handpiece**
- Store the handpiece and torque base in the sterilizer case according to your facility’s policy.
- Store the system at an ambient temperature between -20°C (-4°F) and 60°C (154°F).

**Footswitch**
You do not need to disconnect the footswitch from the console except for maintenance or service. When you are not using CUSA Clarity System, secure the footswitch cord.

**Disposal of the Equipment**

The CUSA Clarity Ultrasonic Surgical Aspirator System console, handpiece, and footswitch are considered electrical equipment and must be disposed of in accordance with regional regulation hospital protocols.

**Return Equipment for Service**

Before you return CUSA Clarity equipment, call your Integra representative for help. If the representative tells you to send the equipment to Integra, first obtain a Return Authorization Number, then clean the equipment, and ship it to Integra for service.

**Obtaining a Return Authorization Number**

Call the Integra Service Center for your area (refer to Integra Service Centers in this section) to obtain a Return Authorization Number. Have the following information ready when you call:
- Hospital/clinic name/customer number
- Telephone number
- Department/address, city, state, and zip or postal code
Return Equipment for Service

- Model number
- Serial number
- Description of the problem
- Type of repair to be done

Attach a tag with this same information to the equipment when you ship it for service.

Returning the Console

Clean the console and touchscreen before you package it for shipping.

NOTE

To avoid product damage, use proper packaging materials and packing procedures when preparing the console for shipment. Failure to return product in this manner may void your warranty.

For instructions on packing the console properly, contact your Integra representative.

Returning the Handpiece

Clean and sterilize the handpiece before you package it for shipping.

Package the handpiece to protect the handpiece and handpiece cable connector from damage.

Package each handpiece in a separate packaging container.

Ordering Replacement Parts

The following replacement parts may be ordered from Integra:

- I.V. Pole
- Power Cord
- Footswitch
- Contamination Guard

When ordering replacement parts for equipment, include the following information:

- Model number (located on the CUSA Clarity console rear panel)
- Serial number (located on the CUSA Clarity console rear panel)
Integra Service Centers

US Service Center
Integra Neurosciences
5965 Pacific Center Blvd
Suite 705
San Diego, CA 92121
Tel: 800-815-1115 Option 5
Fax: 858-455-5874
E-mail: SanDiegoServiceCenter@Integralife.com

Europe, Middle East and Africa Service Center
Integra Neurosciences GmbH
Halskestrasse 9
Ratingen 40880
Germany
Tel: +49 2102 5535 6150
Fax: +49 2102 942 4872
E-mail: emea.techservice@integralife.com

Asia Pacific Service Center
Integra NeuroSciences Pty. Ltd.
Unit 3, 24-30 Winterton Road
CLAYTON, VIC. 3168, Australia
Tel: +613 85400400
Fax: +613 95400004
E-mail: service@integralife.com.au
In this section:
• Overview on page 13-1
• Extracting Log Files on page 13-2
• Technical Messages on page 13-3
• Aspiration Troubleshooting on page 13-5
• Irrigation Troubleshooting on page 13-5

Overview

This section describes troubleshooting procedures for the CUSA® Clarity system. It describes how to extract log files and resolve an alarm message on the system.
Extracting Log Files

1. From the **Main Screen**, press the **Settings** button.
2. Press **System Information**.
3. Attach a USB drive to the USB connector on the rear of the console.

**NOTE**
The external USB drive should be a FAT, FAT32, exFAT or NTFS formatted drive. Other file formats are not supported.

4. Press the **Extract Log** button.

**NOTE**
When the extraction is complete, a message to remove the USB drive displays.

5. Remove the USB drive.

### Alarm Descriptions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Cause</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| Low Aspiration     | The console has measured the aspiration level to be too low to be functioning properly. | - Check tubing connections and routing  
                     |                                                                       | - Replace tubing set if problem persists  |
| Handpiece Failure  | A fault has occurred reading or writing to the handpiece memory chip. | - Disconnect and reconnect handpiece  
                     |                                                                       | - Replace handpiece if problem persists  |
| Footswitch Failure | A footswitch wiring or connection fault has been detected.            | - Disconnect and reconnect footswitch  
                     |                                                                       | - Replace footswitch if problem persists  |
| Console Overheating| A high temperature has been measured within the console. The console will automatically shut off. | Contact Integra Service  |
### Amplitude Troubleshooting

<table>
<thead>
<tr>
<th>Condition</th>
<th>Cause</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Console Failure (Recoverable)</td>
<td>A fault has occurred when restoring the previously used settings or service information; default values may be used.</td>
<td>System is usable, but notify Integra Service</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Console Failure</td>
<td>A fault condition has been detected within the console. Restart console, contact Integra Service if problem persists</td>
</tr>
</tbody>
</table>

### Technical Messages

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fan Failure</td>
<td>Contact Integra Service</td>
</tr>
<tr>
<td>Low Battery</td>
<td>System is usable, but notify service</td>
</tr>
</tbody>
</table>

### Amplitude Troubleshooting

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| Amplitude Indicator bar not equal to selected amplitude, or pulsing erratically | - On Tissue Select® 3-High, or 4-Maximum, Amplitude Indicator is always lower than selected amplitude.  
- During aggressive tissue fragmentation, small amplitude drops may briefly occur.  
- If Amplitude Indicator is persistently low or erratic:  
  - Stop vibration; allow handpiece to cool.  
  - Return to Setup screen and repeat handpiece test. |
<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| Ineffective fragmentation (due to frequency drift - temperature dependence) | 1. Go into standby.  
2. Run handpiece test to update the frequency optimization. |
| No fragmentation while using CUSA Clarity in conjunction with a monopolar electrosurgery system | 1. Go into standby.  
2. Press Start Prime.  
3. Press Stop Prime.  
4. Press Start Test.  
5. Press Main Screen. |
| Low or no aspiration                                                      | 1. Check aspiration at the end of the tip to make sure the aspiration is being delivered to the distal end of the tip.  
2. Check tubing and connections for leaks.  
3. Verify connections to canister.  
4. Utilize the stylet to clear the clog. |

**NOTE**

To avoid tip blockage during surgery flush with saline solution in between uses. This removes debris before it can dry and block the tip while it is not in use.

**WARNING**

To avoid injury or damage to equipment, place system in standby prior to changing tip or clearing a clog.
**Aspiration Troubleshooting**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| Excessive aspiration in On Demand aspiration mode | • Remove and re-install the cartridge to make sure the tubing is in the pinch valve.  
• Press the pinch valve button to open and close the valve 3 to 5 times to ensure the valve closes completely.  
• Replace cartridge set.  
• Contact Integra Service. |
| Difficulty with removing cartridge | • If the system is powered on, lift the cartridge door and remove cartridge.  
• If the system is powered down, press the pinch valve to remove the cartridge. |

**Irrigation Troubleshooting**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| Insufficient irrigation | • Check tubing connections and routing for leaks or blockages.  
• Check the handpiece is fully primed and irrigation fluid is visible at the flue.  
• Replace tubing set. |
| Fast flush not working | • Make sure On Demand aspiration mode is not selected.  
• Make sure the amplitude pedal is not pressed. |
MR Safety Information

In this section:
• Overview on page 14-1
• Use of the CUSA Clarity System in the MR environment 14-2

Overview

This section describes the MR safety information of the CUSA® Clarity Ultrasonic Surgical Aspirator System.
MR Safety Information

Use of the CUSA Clarity System in the MR Environment

**WARNING**

The CUSA Clarity Ultrasonic Surgical Aspirator System, including all accessories and components, is MR Unsafe. It must not be brought into the MR environment.
### Technical Specifications

**Console**

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>CUSA® Clarity Console without Cart</th>
<th>CUSA Clarity Console with Cart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>49.3 cm (19.5 in)</td>
<td>1.33 m (52.5 in)</td>
</tr>
<tr>
<td>Width</td>
<td>34.9 cm (13.75 in)</td>
<td>57.2 cm (22.5 in)</td>
</tr>
<tr>
<td>Depth</td>
<td>45.7 cm (18 in)</td>
<td>64.8 cm (25.5 in)</td>
</tr>
<tr>
<td>Weight</td>
<td>29.5 kg (65 lbs)</td>
<td>81.5 kg (179.6 lb)</td>
</tr>
<tr>
<td>Cable Length</td>
<td>5 m (196.85 in)</td>
<td>5 m (196.85 in)</td>
</tr>
</tbody>
</table>

**Footswitch**

<table>
<thead>
<tr>
<th>Dimensions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>5.5 cm (2.2 in)</td>
</tr>
<tr>
<td>Width</td>
<td>19.5 cm (7.7 in)</td>
</tr>
<tr>
<td>Length</td>
<td>22 cm (8.66 in)</td>
</tr>
<tr>
<td>Cable Length</td>
<td>6.25 m (24.5 ft)</td>
</tr>
</tbody>
</table>
## Tip Specifications

<table>
<thead>
<tr>
<th>Tip</th>
<th>Length (mm) [in]</th>
<th>Inside Dimension (mm) [in]</th>
<th>Outside Dimension (mm) [in]</th>
<th>Amplitude (peak to peak) (µm) [in]</th>
<th>Weight (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Curved Extended MicroTip™</td>
<td>121.5 [4.783]</td>
<td>1.6 [0.062]</td>
<td>2.0 [0.077]</td>
<td>160 to 206 [0.0063 to 0.0081]</td>
<td>7.8</td>
</tr>
<tr>
<td>Curved Extended MicroTip™ Plus</td>
<td>192.7 [7.588]</td>
<td>1.6 [0.062]</td>
<td>2.0 [0.077]</td>
<td>127 to 163 [0.0050 to 0.0064]</td>
<td>9.5</td>
</tr>
<tr>
<td>Standard Tip</td>
<td>45.7 [1.800]</td>
<td>2.0 [0.078]</td>
<td>2.6 [0.101]</td>
<td>127 to 163 [0.0050 to 0.0064]</td>
<td>1.3</td>
</tr>
<tr>
<td>Curved Extended Standard Tip</td>
<td>114.4 [4.505]</td>
<td>2.0 [0.078]</td>
<td>2.6 [0.101]</td>
<td>127 to 163 [0.0050 to 0.0064]</td>
<td>7.4</td>
</tr>
<tr>
<td>Curved Extended ShearTip™</td>
<td>120.5 [4.743]</td>
<td>1.6 [0.062]</td>
<td>2.3 [0.092]</td>
<td>160 to 206 [0.0063 to 0.0081]</td>
<td>7.9</td>
</tr>
<tr>
<td>Extended Use Curved Extended MicroTip</td>
<td>121.5 [4.783]</td>
<td>1.6 [0.062]</td>
<td>2.0 [0.077]</td>
<td>160 to 206 [0.0063 to 0.0081]</td>
<td>7.8</td>
</tr>
<tr>
<td>Extended Use Curved Extended Standard Tip</td>
<td>114.4 [4.505]</td>
<td>2.0 [0.078]</td>
<td>2.6 [0.101]</td>
<td>127 to 163 [0.0050 to 0.0064]</td>
<td>7.4</td>
</tr>
</tbody>
</table>
### Subsystems

#### Ultrasonic

<table>
<thead>
<tr>
<th>Frequency</th>
<th>35.55 - 36.25 kHz (frequency range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Tip Amplitude (High Frequency Handpiece)</td>
<td>Up to 210 microns</td>
</tr>
</tbody>
</table>

#### Fluidic System

<table>
<thead>
<tr>
<th>Irrigation Rate</th>
<th>The irrigation rate display shows digits 2 to 20.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The irrigation rate is approximately:</td>
</tr>
<tr>
<td></td>
<td>• Normal = 2 to 20 ml/min</td>
</tr>
<tr>
<td></td>
<td>• Fast Flush = 25 ml/min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Suction System</th>
<th>Up to 640 mm (25.2 in) mercury at the pump intake at sea level.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• The suction level is lower at higher altitudes.</td>
</tr>
</tbody>
</table>

### Handpiece

#### Dimensions

<table>
<thead>
<tr>
<th>Length</th>
<th>13.03 cm (5.13 in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>2.41 cm (0.95 in)</td>
</tr>
<tr>
<td>Weight</td>
<td>71 g (0.15 lb)</td>
</tr>
<tr>
<td>Cable Length</td>
<td>463.3 cm (182.4 in)</td>
</tr>
</tbody>
</table>

#### Frequency

<table>
<thead>
<tr>
<th>High</th>
<th>36 kHz</th>
</tr>
</thead>
</table>
## Electrical Requirements

### Power Input and Fusing

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Voltage</strong></td>
<td>100-240V~</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>50-60Hz</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>480VA</td>
</tr>
<tr>
<td><strong>Phases</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Fuses</strong></td>
<td>5A, Type T, 1500A IR, 250V, 5mm x 20mm, ceramic body</td>
</tr>
</tbody>
</table>

**NOTE**

Only the exact fuse type and rating is to be used. Littelfuse 0215005.HXP, 2 fuses required per console.

### Power Cords

#### United States and Canada:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Meets hospital grade</strong></td>
<td>UL817</td>
</tr>
<tr>
<td><strong>Cord</strong></td>
<td>3 x 16AWG 5 Meters Color White</td>
</tr>
<tr>
<td><strong>Console Connector</strong></td>
<td>C13 IEC 60320-1 V-Lock</td>
</tr>
<tr>
<td><strong>Plug</strong></td>
<td>NIMA 5-15 Straight</td>
</tr>
</tbody>
</table>

#### Other Countries:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cord</strong></td>
<td>3 x 1mm² 5 Meters Color Black</td>
</tr>
<tr>
<td><strong>Console Connector</strong></td>
<td>C13 IEC 60320-1 V-Lock</td>
</tr>
<tr>
<td><strong>Plug variation by country:</strong></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>AS3112, Straight</td>
</tr>
<tr>
<td>Brazil</td>
<td>NBR 14136, Straight</td>
</tr>
<tr>
<td>China</td>
<td>GB2099, Straight</td>
</tr>
<tr>
<td>Europe</td>
<td>CEE 7/ XVII, Straight</td>
</tr>
<tr>
<td>Italy</td>
<td>CEI 23-50, Straight</td>
</tr>
<tr>
<td>Japan</td>
<td>JIS 8303, Straight</td>
</tr>
<tr>
<td>South Africa</td>
<td>SANS 164-1, Straight</td>
</tr>
<tr>
<td>Switzerland</td>
<td>SEV Typ 12, Straight</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>BS 1363, 13A fused, Angled</td>
</tr>
</tbody>
</table>

Only use Integra approved power cords.
**WARNING**

Explosion Hazard - Do not use the CUSA Clarity System in the presence of flammable anesthetics or other volatile solvents.

**WARNING**

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

**Maximum Low Frequency Leakage**

<table>
<thead>
<tr>
<th>Current Type</th>
<th>Leakage Current</th>
</tr>
</thead>
<tbody>
<tr>
<td>Touch current</td>
<td>&lt;500µA</td>
</tr>
<tr>
<td>Patient leakage current</td>
<td>&lt;50µA</td>
</tr>
</tbody>
</table>

**Environment**

**Duty Cycle**

Under maximum loading conditions, the CUSA Clarity console is suitable for ultrasonics activation times of 10 minutes on, 5 minutes off.

The system requires a minimum of one hour exposure at its operating temperature range before you use it.

See the EMC Information section, page A-6 for further information on environmental conditions.

**Electromagnetic Interference**

The CUSA Clarity system console minimizes electromagnetic interference to other equipment used in the operating room. The system complies with the requirements of IEC 60601-1-2: 2014 Fourth Edition.

**Moisture**

- **Console Ingress Protection Rating**: IPX1

**Operating**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature range</td>
<td>10°C (50°F) to 35°C (95°F)</td>
</tr>
<tr>
<td>Humidity range</td>
<td>30 to 85%, relative humidity, non-condensing</td>
</tr>
<tr>
<td>Atmospheric pressure range</td>
<td>70 kPa to 106 kPa (10.15 to 15.38 psi)</td>
</tr>
</tbody>
</table>

**Storage and Shipping**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature range</td>
<td>-20°C (-4°F) to 60°C (140°F)</td>
</tr>
<tr>
<td>Humidity range</td>
<td>15 to 85% relative humidity, non-condensing</td>
</tr>
</tbody>
</table>

**NOTE**

Other devices in the operating room may generate electromagnetic interference. Use caution in locating equipment within the room to reduce the electromagnetic interference.
Voluntary Standards

The CUSA Clarity system meets the following standards:

- **ANSI/AAMI ES60601-1:2012** Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
- **CSA C22.2 No. 60601-1:2012** Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
- **IEC 60601-1-6:2010+AMD1:2013** Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- **IEC 60601-1-8:2006+AMD1:2012** Collateral Standard - General requirements for alarm systems in Medical Electrical Equipment

Statutory and Regulatory Classification

- Class II (FDA) Medical Device (General Controls and Special Controls)
- Class IIb (EU)
- Class III (EU)
- Class 4 (Canada)

EMC Information

**NOTE**

The CUSA Clarity system should not be used adjacent to or stacked with equipment other than the equipment specified in the CUSA Clarity Ultrasonic Surgical Aspirator System Operator’s Manual. If adjacent or stacked use is necessary, the CUSA Clarity system should be observed to verify normal operation in the configuration in which it will be used.

The use of accessories, other than the accessories specified in this manual, may result in increased emissions or decreased immunity of the CUSA Clarity system.
**Guidance and Manufacturer’s Declarations**

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The CUSA Clarity 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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>The CUSA Clarity system is suitable for use in a hospital environment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonics emissions</td>
<td>Not Applicable</td>
<td>Not applicable for hospital environments</td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The CUSA Clarity system is intended for use in the electromagnetic environment specified below. The customer or the user of the CUSA Clarity system should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>IMMUNITY Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>± 6 kV contact (3rd ed.) ± 8 kV contact (4th ed.) ± 8 kV air (3rd ed.) ± 15 kV contact (4th ed.)</td>
<td>± 8 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>± 2 kV for power supply lines ± 1 kV for input / output lines</td>
<td>± 2 kV for power supply lines ± 1 kV for input / output lines</td>
<td>Mains power quality should be that of a typical hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>± 1 kV line(s) to line(s) ± 2 kV line(s) to earth</td>
<td>± 1 kV line(s) to line(s) ± 2 kV line(s) to earth</td>
<td>Mains power quality should be that of a typical hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11</td>
<td>&lt; 5% $U_T$ (&gt;$95%$ dip in $U_T$) for 0.5 cycle &lt; 40 % $U_T$ (&gt;$60%$ dip in $U_T$) for 5 cycles &lt; 70 % $U_T$ (&gt;$30%$ dip in $U_T$) for 25 cycles &lt; 5% $U_T$ (&gt;$95%$ dip in $U_T$) for 5 s</td>
<td>&lt; 5% $U_T$ (&gt;$95%$ dip in $U_T$) for 0.5 cycle &lt; 40 % $U_T$ (&gt;$60%$ dip in $U_T$) for 5 cycles &lt; 70 % $U_T$ (&gt;$30%$ dip in $U_T$) for 25 cycles &lt; 5% $U_T$ (&gt;$95%$ dip in $U_T$) for 5 s</td>
<td>Mains power quality should be that of a typical hospital environment. If the user of the CUSA Clarity system requires continued operation during power mains interruptions, it is recommended that the CUSA Clarity system be powered from an uninterruptible power supply.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m (3rd ed.) 30 A/m (4th ed.)</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.</td>
</tr>
</tbody>
</table>

**NOTE:** $U_T$ is the a.c. mains voltage prior to application of the test level.
### Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The CUSA Clarity system is intended for use in the electromagnetic environment specified below. The customer or the user of the CUSA Clarity system should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>IMMUNITY Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF Immunity</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz (3rd and 4th ed.)</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 Vrms in ISM and amateur radio bands (4th ed.)</td>
<td>6 Vrms in ISM and amateur radio bands</td>
</tr>
<tr>
<td>Radiated RF Immunity</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz (3rd ed.) 80 MHz to 2.7 GHz (4th ed.)</td>
<td>3 V/m 80 MHz to 2.7 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 V/m 80 MHz to 2.7 GHz</td>
<td></td>
</tr>
</tbody>
</table>

Where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and \( d \) is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey\(^a\), should be less than the compliance level in each frequency range\(^b\).

Interference may occur in the vicinity of equipment marked with the following symbol:

\[ d = 1.2 \sqrt{P} \]

\[ d = 1.2 \sqrt{P} \]

\[ d = 2.4 \sqrt{P} \]

80 MHz to 800 MHz

800 MHz to 2.7 GHz

\( \sqrt{P} \)

\( \sqrt{P} \)

\( \sqrt{P} \)

\[ \text{At 80 MHz and 800 MHz, the higher frequency range applies.} \]

\[ \text{These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.} \]
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 CUSA Clarity system is used exceeds the applicable RF compliance level above, the CUSA Clarity system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the CUSA Clarity system.

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

### Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the CUSA Clarity System

The CUSA Clarity system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CUSA Clarity system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CUSA Clarity system as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated Maximum Output Power of Transmitter W</th>
<th>Separation Distance According to Frequency of Transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>( d = 1.2, \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12 m</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38 m</td>
</tr>
<tr>
<td>1</td>
<td>1.2 m</td>
</tr>
<tr>
<td>10</td>
<td>3.8 m</td>
</tr>
<tr>
<td>100</td>
<td>12 m</td>
</tr>
</tbody>
</table>

For transmitters rated at maximum output power not listed above, the recommended separation distance \( d \) in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
Integra LifeSciences Corporation and its wholly owned subsidiaries ("Integra") warrant to Integra authorized distributors and to the original purchaser only that each new Integra® CUSA® Clarity Ultrasonic Surgical Aspirator System ("CUSA Clarity") is free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of delivery ("Warranty Period") by Integra to the original purchaser, but in no event beyond the expiration date stated on any product labeling (hereinafter the Warranty Period). For the purpose of products sold by Integra through an Integra-authorized distributor, “original purchaser” shall mean the purchaser of Integra products to whom an Integra-authorized distributor first sells the product. The original purchaser is hereinafter referred to as Customer.

1.1. Coverage. During the Warranty Period, Integra shall provide free-of-charge service and maintenance consistent with the provisions of Section 3 of this Warranty, so that the Equipment conforms to the specifications defined in the CUSA Clarity Operator’s Manual, as such Operator’s Manuals may be modified by Integra from time to time (the “Specifications”).

1.2. Exclusions. The Warranty shall not apply in any manner to service or maintenance of the Equipment, or to replacement of its parts, with respect to:

(i) use of Equipment with any tips, flues, and cartridge and tubing sets and accessories other than those manufactured by Integra LifeSciences;
(ii) defects arising out of materials or parts provided, modified, or designed by anyone other than an authorized Integra service agent (the “Integra Service Agent”);
(iii) defects emanating from improper or negligent installation, storage, or use of the Equipment or any component thereof, including but not limited to operating the Equipment not in accordance with instructions provided in the Operator’s Manual;
(iv) defects arising from improper or negligent cleaning or sterilization methods or improper maintenance of the Equipment;
(v) defects resulting from repairs or service of the Equipment provided other than by Integra or its authorized representatives;
(vi) defects arising from accidental damage to the Equipment, acts of God, electrical power damage, equipment malfunction, unusual stress, unreasonable operating procedures, or abnormal or extreme operating conditions; and

(vii) normal wear and tear.

Service, Repairs and Replacement

2.1 Service and Repairs. All service and repairs covered by this Warranty may be referred to hereinafter as “in-warranty repairs,” and all service and repairs not covered by this Warranty may be referred to as “out-of-warranty repairs.” Integra’s sole obligation for in-warranty repairs shall be to make all necessary adjustments and repairs in accordance with this Warranty. Integra shall charge Customer at Integra’s then-standard rates for any out-of-warranty repair performed by Integra.

2.2 Equipment Replacement. The defective Equipment or part thereof that is replaced in accordance with the Warranty shall be the property of Integra. Integra reserves the right to fill spare parts requests using refurbished sub-assemblies provided that such sub-assemblies are functionally equivalent to new sub-assemblies and carry the same warranty as the replaced sub-assemblies.

2.3 Notification. In order to avail itself of its rights under the Warranty, Customer or Integra authorized distributors, must immediately notify Integra of any defects and provide Integra every opportunity to inspect and remedy defects.

Repair Parts and Services

3.1 Included under the Warranty are the following services:

3.1.1 Consoles. Integra or its distributor, when authorized for this purpose, shall, if possible, perform on-site repair of consoles and where not possible or otherwise decided at the sole discretion of Integra, Integra or its distributor shall arrange and pay to ship the affected Equipment to the designated repair facility. Integra or its distributor authorized for this purpose shall repair the affected Equipment or replace a console by a new or refurbished console (at the discretion of Integra), that shall carry the same remaining warranty as the original equipment.

3.1.2 Handpieces. Integra shall repair or replace any defective handpieces covered by the Warranty by a new or refurbished handpiece (at the discretion of Integra) that shall carry the same remaining warranty as the original equipment.
3.2 Modifications to Covered Equipment. From time to time, at its sole discretion, Integra may propose modifications to the covered Equipment and to the Specifications for the Equipment. Subject to Customer’s approval and at its sole expense, the Customer may request Integra to make such modifications to the covered Equipment and to the Specifications. Integra shall make such modifications for the Customer, which modifications may include the installation of new parts in the Equipment, at a price equal to the then-current list price for such modifications, as such list price is established by Integra in its sole discretion.

Quality Control

4.1 Customer shall maintain reasonable standards of quality control, operations, procedures, safety testing and inspection of Equipment to ensure that unnecessary service or maintenance is not required hereunder.

4.2 Customer shall provide a technical counterpart to Integra’s Service Agent for assistance in Integra’s telephonic diagnosis of the malfunction with the Equipment. Customer shall reasonably accept Integra’s determination whether a repair or service is an in-warranty repair or an out-of-warranty repair.

Limitation of Liability

5.1 Integra’s only responsibility under the warranties described in Section 1 shall be repair or replacement, at Integra’s option and election, of any Integra product (or part thereof) that Integra reasonably determines to be covered by this warranty and to be defective in workmanship or materials. Repair or replacement of products under this warranty does not extend the warranty period.

THE WARRANTIES DESCRIBED IN SECTION 1 HEREOF ARE EXCLUSIVE AND ARE GIVEN AND ACCEPTED IN LIEU OF ALL OTHER WARRANTIES OF INTEGRA OR ITS SERVICE AGENTS WITH RESPECT TO THE QUALITY, PERFORMANCE AND OPERATION OF THE EQUIPMENT, WRITTEN OR ORAL, EXPRESSED OR IMPLIED, AND WHETHER OR NOT ATTRIBUTABLE TO SERVICE PERFORMED PURSUANT TO THE WARRANTY. INTEGRA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE EQUIPMENT OR THE SERVICES, DIAGNOSES, ADVICE, ASSISTANCE OR PARTS TO BE TENDERED PURSUANT TO THE WARRANTY, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, USAGE OR TRADE OR OTHERWISE, OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS.
Further, this warranty shall not apply to, and Integra shall not be responsible for, any loss arising in connection with the purchase or use of any Integra product that has been repaired by anyone other than an authorized Integra service representative or altered in any way so as, in Integra’s sole judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used other than in accordance with the instructions furnished by Integra.

IN NO EVENT SHALL INTEGRA, ITS AFFILIATES, ASSIGNEES OR SERVICE AGENTS BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA PRODUCT, OR OF LOSS OF USE, REVENUE OR PROFIT, WHETHER ARISING IN CONTRACT OR IN TORT, BY VIRTUE OF THE WARRANTY OR ANY PERFORMANCE OR BREACH BY INTEGRA, ITS AFFILIATES, ASSIGNEES OR SERVICE AGENTS HEREUNDER OR PURSUANT HERETO.

5.2 Customer agrees that, notwithstanding the technical assistance provided pursuant to the Warranty by Integra or its representatives, Customer shall be fully responsible for all treatments performed or attempted with the Equipment.

INTEGRA MAKES NO REPRESENTATION OR WARRANTY AS TO THE EFFICACY OF THE EQUIPMENT OR OF THE TECHNICAL ASSISTANCE TO BE RENDERED BY INTEGRA, ITS AFFILIATES, ASSIGNEES OR SERVICE AGENTS, FOR PURPOSES OF THE PARTICULAR TREATMENT THAT CUSTOMER UNDERTAKES TO PERFORM FOR THIRD PARTIES. Moreover, Customer shall not make any claim against Integra or any of its affiliates, assignees or representatives with respect to the efficacy of the Equipment or of said technical assistance or with respect to any claims by third parties related to any treatment undertaken by Customer.

5.3 Force Majeure. Notwithstanding anything to the contrary herein contained, if the performance of the Warranty by Integra or Customer or any obligation of Integra or Customer hereunder is prevented, restricted or interfered with by reason of fire, explosion, act of God, labor disputes or accidents affecting performance under the Warranty, or war, mobilization, civil commotions, blockade or embargo, or any future law, regulation, ordinance or requirement of any government or regulatory agency or any other act, whatsoever similar to those above enumerated, or any other circumstance being beyond the reasonable control of Integra or Customer, then and in that event Integra or Customer, as the case may be, shall promptly notify the other party hereto of the resulting difficulties therefrom, and any of the foregoing events shall excuse any performance required under the Warranty.