BAUSCH+LOMB

Stellaris Elite™

vision enhancement system

Operator's Manual

For use with Stellaris Elite™ REF BL14455 and REF BL15455

Preface

Indications for Use

The Bausch + Lomb ***Stellaris Elite***™ vision enhancement system is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Bausch + Lomb ***Stellaris Elite***™ vision enhancement system configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

WARNING: ***Use only accessories approved, manufactured, or distributed by Bausch + Lomb that are designated for use with this system. Failure to do so may affect system performance and create hazards. Use of accessories approved, manufactured, or distributed by Bausch + Lomb on systems for which they are not designated may affect system performance and create hazards.***

Operator Profile

The Bausch + Lomb ***Stellaris Elite***™ vision enhancement system is intended for use only by qualified physicians, nurses, and other trained medical professionals.

The laser functionality is intended for use only by qualified physicians. If you are not a qualified physician, do not attempt to operate the laser system for any reason. Specific indications for Laser Modes are retinal photocoagulation and laser trabeculoplasty. Available delivery devices include the EndoProbe for intraocular Endolaser surgery and Laser Indirect Ophthalmoscope (LIO) for transpupillary laser delivery for patients treated in a supine position.

Contraindications

Use of accessories not designated by Bausch + Lomb for use with this equipment may result in serious permanent patient injury, adverse surgical outcome, or damage to the equipment, and may void warranty coverage. See page 1-1 for precautions relevant to patients with implantable defibrillators and cardiac pacemakers.

This manual contains precautions (Cautions, Warnings, Notes, etc.) throughout that should be observed when using this equipment. For safety's sake, please heed these precautions.

Reporting of Adverse Reactions

Any side effects, adverse events, product complaints, or device malfunctions that may affect safety, should be reported to the manufacturer and competent authority. Contact information can be found on www.bausch.com/contactus.

Patents

See patents.bausch.com for applicable US patents.

Power Outputs

COAG
BF
7.5 W, 0.274 A
100 Ω
1 MHz

U/S
BF
35 W
900 Ω
28.5 kHz

VITESSE
BF
250V
25 – 42 kHz

Training

Following system delivery at a surgical facility, Bausch + Lomb personnel or authorized representatives will provide on-site training to those who will operate the system. The training is essentially an on-site review of system startup, accessories and connections, priming and settings adjustment consistent with the instructions provided in the operator's manual. Subsequent training may be provided for new staff, when the system is upgraded, or as requested by the facility.

Manual Concept

Our goal is to provide you with the information you need, with minimal searching.

Chapter 1 provides information for a quick setup and answers general questions about the ***Stellaris Elite***™ vision enhancement system. Numerous pictures enhance understanding. Chapter 2 describes the connections to operate the system, including the Graphical User Interface and the Primary (Integrated) Foot Control. Chapter 3 describes information on how to customize the system to suit your particular needs. Chapter 4 details each function and feature, how to set up the function and its associated disposables, and how to interact with each function. Chapter 5 provides cleaning and sterilization information. Chapter 3-Chapter 5 are reference for questions of a technical nature. Chapter 6-Chapter 8 contain information that you may rarely need, such as unpacking, installing modules, system check-out, meanings of error messages, service information, and system specifications. **Make sure that you read and follow all safety precautions set forth in this manual. Information presented in this manual relating to surgical procedures is a suggestion only, and does not constitute any warranty of fitness or claim of responsibility, or undertaking of liability resulting from any surgical techniques practiced. The surgeon is ultimately responsible for determining the appropriate procedure for each patient.**

Note: *The user interface screens displayed in this manual may differ from what is on your system. While the information on the screens is the same, the depiction of the screens may change. The screen illustrations should not be used in place of the instructions in the manual.*

Symbols and Notes

The following are general definitions of the symbols and precautions used on this equipment and in this manual. See www.bausch.com/symbols for additional symbol information.

WARNING: ***Calls attention to an operating procedure, practice, or condition, which if disregarded or incorrectly performed, could result in serious and/or permanent injury to personnel and/or patients.***

CAUTION: ***Calls attention to an operating procedure, practice, or condition, which if disregarded or incorrectly performed, could result in damage to the product and/or equipment.***

Note: ***Calls attention to an operating procedure, practice, or condition providing essential information.***


Aiming beam


Aiming beam, blinking


Alternating Current

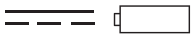

Always wear eye protection or face mask when installing or removing the lamp


Aspiration


Aspiration Cassette

Authorized representative in the European Community


Battery Condition Indicator


Battery Direct Current

Catalogue number


Caution


Caution or warning to consult accompanying documents to avoid patient or operator hazard.


CE Mark

Authorized Representative in Switzerland


Cloud

Consult operating instructions for use or consult operating electronic instructions for use


Date of manufacture


Dispose of Properly


Do not re-use

Do not resterilize

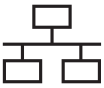

Do not use if package is damaged


Electrostatic-sensitive device


Electrosurgery, coagulation mode


Equipotential Ground

ETL Listed Number (Intertek)


Ethernet


Extrude

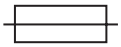

Eye


FCC


Fibre-optic handpiece


Fluid/Air Exchange


Frequency in Hertz


Fuse


Importer


Infusion bottle


Infusion Cassette


Irrigation


Irrigation/Aspiration


Laser

Laser Emergency Stop


Laser Indirect Ophthalmoscope

Laser Key Off

Laser Key On


Manufacturer

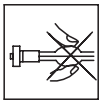
Medical device


Fee paid for waste management


Microscope Camera

Model number


Monitor


Never touch the silica glass bulb of the lamp with bare hands


Non Ionizing Electromagnetic Radiation

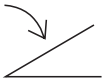
Non-sterile

Ω ohms
VA Volt Amps
A Amperes

Phacofragmentation

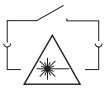
Phone

Prescription only (USA)



Primary (Integrated) Foot Control

Primary (Integrated) Foot Control ready



Remote interlock connector

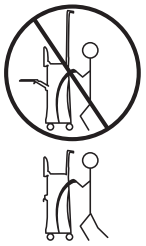
Serial number

Stellaris Elite™
vision enhancement system

Sterilized using ethylene oxide

Sterilized using irradiation

System Mass



Transport Tipping Hazard Symbol
See page 1-34

Type BF Applied Part

UK Conformity Assessed

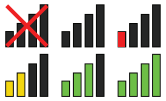
U/S vitrectomy

USB

Viscous Fluid Control

Vitrectomy

Warning: Hot surface



Wireless

Xenon

Xenon-Mercury

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1. Getting Started

1. Getting Started

1. Getting Started

This chapter is for people who have used this type of ophthalmic vision enhancement system before and want to use the system without reading large portions of the manual. It also provides information on setting up your ***Stellaris Elite***™ vision enhancement system and making the necessary connections.

WARNING: ***The use of flammable anaesthetics, flammable disinfectants, aerosol sprays, or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided unless the gaseous agents are sucked away and the liquid agents are fully dried or evaporated. Ensure the flammable liquids are not pooled beneath the patient drape.***

WARNING: ***Implantable defibrillators present a risk of injury if triggered by a fibrillatory event during intraocular surgery, due to involuntary motion by the patient. Patients being considered for intraocular procedures must be questioned to determine if they have such a device and, if so, the defibrillator manufacturer must be consulted to determine the appropriate action.***

WARNING: ***Electromagnetic interaction between the phacoemulsification (phaco) handpiece and an implanted cardiac pacemaker is unlikely, but cannot be ruled out. Patients should be questioned to determine if they have such an implant and, if so, the manufacturer of the implant should be consulted to determine the proper course of action.***

WARNING: ***All external wiring must be in accordance with local electrical code requirements and NEC Class II signaling system twisted wire with outer shield. The wire length must not exceed 20 meters (60 feet). The wire gauge must be 26 AWG to 12 AWG gauge, with ends stripped from 9 mm to 10 mm (3/8 in.). At no point should the wire be untwisted more than 5 cm (2 in.).***

WARNING: ***The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.).***

WARNING: ***Avoid skin-to-skin contact of the patient while using the bipolar output, using gauze or similar as needed.***

WARNING: ***Use of other high-frequency (HF) output equipment in the vicinity of the device or equipment failure could result in an unintended increase in the output power of the bipolar function.***

WARNING: ***Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade."***

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

WARNING: ***Care should be taken to prevent intraocular pressure changes that may cause damage to the patient's eye.***

CAUTION: ***Preventative scheduled maintenance is recommended once a year to ensure that the* Stellaris Elite™ *vision enhancement system meets its optimum performance, reliability and safety standards set by the manufacturer. The maintenance shall be done by a Bausch + Lomb certified individual only.***

Note: *The equipotentiality lug is provided to ground the system if the receptacle is not sufficient.*

Note: *Fluidic stability in the eye during surgery is crucial for safe and effective phacoemulsification (phaco) surgery. During phaco surgery, fluid is aspirated out of the eye through the phaco needle, and fluid is infused into the eye through the irrigation sleeve. Balancing these two flows maintains acceptable intraocular pressure throughout the surgical procedure.*

Factors that affect the aspiration rate through the phaco needle include the vacuum setting (mmHg), and the internal diameter of the needle and tubing. Factors that affect the infusion rate are the bottle height, incision size, and dimensions of the needle-sleeve interface.

The **Stellaris Elite™** *vision enhancement system provides vacuum settings up to 660 mmHg (Vacuum Fluidics Module (VFM)). The higher the vacuum setting, the higher the aspiration rate. Higher aspiration rates increase the risk of fluidic instability, which could lead to anterior chamber collapse during phacoemulsification or soft eye during posterior surgery. The maximum safe vacuum setting for each needle-sleeve combination depends on the surgical*

technique being performed and the surgeon's level of proficiency. It is the surgeon's sole responsibility to use the system settings to achieve optimal operating conditions.

Note: *If Infusion pressure is elevated an alarm will sound. Go to page 4-35: Fluid Tamponade for further detail.*

1.1. Components Shipped with the System

Before unpacking, inspect all packages for damage. Report any damage from shipping to the carrier. Before discarding packaging material, ensure all parts are accounted for. Smaller parts may be attached to packing materials. If shock label indicator on shipment carton is red, do not refuse shipment. Make notation on delivery receipt and inspect for damage. If damage is discovered, leave in original container and packaging and request immediate inspection from carrier within 3 days. Contact Bausch & Lomb Surgical Technical Support at:
1-636-226-3705 (Outside U.S.A.)
+49-05221-823-171 (Within Europe).

Standard components shipped with the system include:

- System Main Console
- Primary (Integrated) Foot Control with Battery
- Primary (Integrated) Foot Control Wall Charger
- Extra Foot Control Battery
- Primary (Integrated) Foot Control Backup Cable
- Operator's Manual (CD)
- System Power Cord
- Mayo Tray
- Foot Control Battery Charging Cradle
- Air Hose
- Zero Level Bottle Hanger
- Remote Control

Systems equipped with laser functionality also include two Laser Keys, one pair of safety glasses, and a Connectivity Kit (interlock keys, see page 6-4).

1.2. System Description

1.2.1 System Console

The ***Stellaris Elite***™ vision enhancement system's modular design enables easy upgrades as technology advances. The system consists of a main housing unit, a user interface screen, surgical modules, a Primary (Integrated) Foot Control, and an infrared remote control (for anterior application only, optional accessory). Handpieces, packs and other accessories are supplied separately. The ***Stellaris Elite***™ (BL15455) vision enhancement system with laser functionality ships with all essential laser accessories.

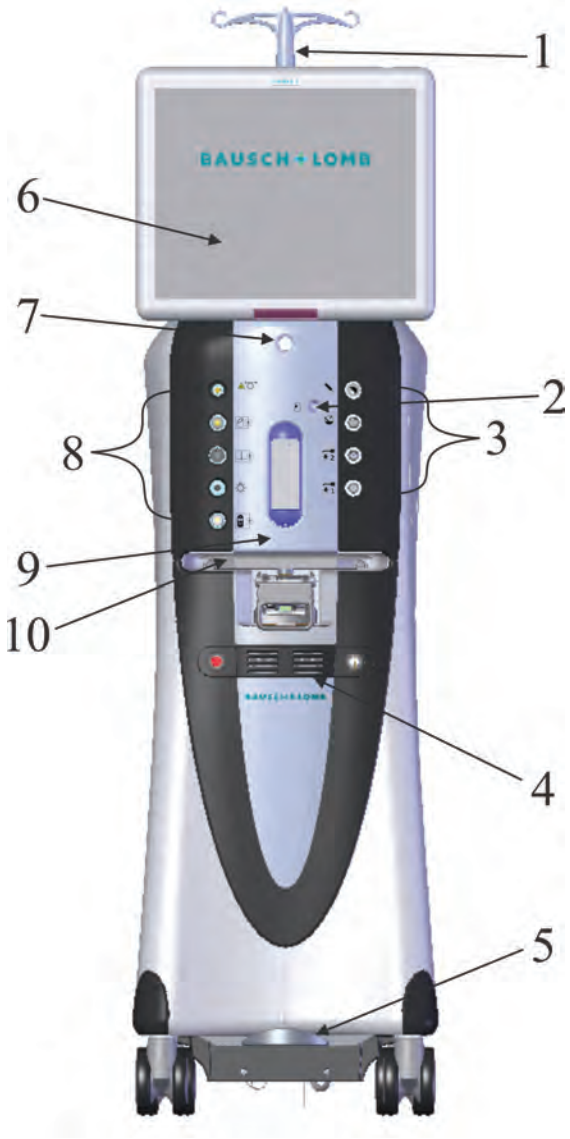


Figure 1.1. ***Stellaris Elite***™ **Posterior/Combined Configuration (with Laser Module)**

1. IV Pole. 2. Pneumatic Actuation Port. 3. Posterior Handpiece Connectors. 4. Laser.
5. One-Touch Wheel Locking. 6. User Interface screen. 7. System Switch "On/Off".
8. Handpiece Connectors. 9. Fluidic Module. 10. System Tray.

Your ***Stellaris Elite***™ vision enhancement system is easily upgraded to take advantage of future technology innovations. The primary interface with the system is a 19 inch, 5:4 aspect ratio color touch screen display. The display screen may be tilted 10 degrees forward and 15 degrees back, and swiveled 90 degrees to the right or left. The brightness of the display is controlled through the **More Screen A/V** (see page 2-19).

An infrared receiver, at the bottom of the display screen, interfaces with the remote control.

The computer system includes both audio and visual capabilities, which provide warning messages, alarms, and other audio indications, as well as allowing you to view setup screens, surgical settings, and video from a microscope camera. The volume is adjustable via the touch screen setting globes on the More Screen A/V tab.

Two USB ports on the back of the display allow you to save, load, and transfer your customized settings between systems.

There are two air outputs built into the system to provide filtered atmospheric air for anterior and posterior surgeries. A single port on the front of the system provides filtered atmospheric air for both Fluid/Air Exchange (F/AX) and Air Forced Infusion (AFI) for posterior and combined surgery. The port near the IV Pole on the back of the system provides air for Pressurized Infusion (PI) and Adaptive Fluidics in anterior surgery.

The system can be set for either gravity infusion (IV Pole) or infusion using pressurized air (AFI and PI, respectively) through the **More Screen Infusion Tab** or through the programming interface (see Chapter 3).

Both air output ports have lighted rings surrounding them. The ring light will be solidly lit if that function is active and within correct pressure range. If the pressure moves outside of the specified range, the ring will begin blinking. If the pressure remains outside the set range, an error message will appear on the screen.

Laser functionality is only available on the ***Stellaris Elite***™ (BL15455) vision enhancement system. The laser functionality is integrated and shipped with a new ***Stellaris Elite***™ (BL15455) vision enhancement system.

Service Life: The expected service life is 10 years.

1.2.2 Pack Compatibility with Older Systems

Posterior and Combined Procedure Packs designed for use on the older Stellaris posterior combined systems cannot be used on the new ***Stellaris Elite***™ PC. Likewise, Posterior and Combined Procedure Packs designed for use on the new ***Stellaris Elite***™ PC system should not be used on the older systems. In addition, ***Stellaris Elite***™ PC supports the use of anterior Adaptive Fluidics packs (see Adaptive Fluidics™ on page 4-53)

1.2.3 System Alarm

The ***Stellaris Elite***™ has one Low-Priority alarm with a Delayed harm effect. The single-alarm is activated immediately when the operator selects a tamponade pressure setting above 59 mmHg or 80 cmH_20. The elevated tamponade (elevated infusion) pressure is selected on the Graphical User Interface screen. Therefore, the operator's position is in front of the Stellaris system, within reach of its display, when the low priority alarm is activated. The alarm only occurs when the user sets a tamponade pressure above a preset point.

See manual Section 4 Air and Fluid Tamponade functions for detailed operation of the elevated infusion pressure low priority alarm.

1.3. Connections and Setup

WARNING: ***When using gravity infusion, the ophthalmic irrigation source shall be at or above the patient's eye level to avoid patient injury.***

WARNING: ***Do not add unapproved accessories that modify the effective IV Pole Height.***

WARNING: ***For optimum aspiration and reflux performance, the patient's eye must be at the same level as the* Stellaris Elite™ *vision enhancement system aspiration port on the fluid collection cassette. If this is not possible, use the patient eye level offset feature in the programming screen.***

Note: *The out-of-factory Wireless System Setup is "Disabled". Performing a software upgrade will also reset the Wireless System Setup to "Disabled". To set up wireless operation, see Wireless Primary (Integrated) Foot Control System Setup on page 1-51.*

This connections and setup section applies to systems without laser function only. For systems with laser functionality, see Laser Function on page 1-71.

The ***Stellaris Elite***™ vision enhancement system is pre-configured at the factory to minimize setup and installation requirements.

The power cable, Primary (Integrated) Foot Control and Ethernet connections are located at the lower rear of the system.

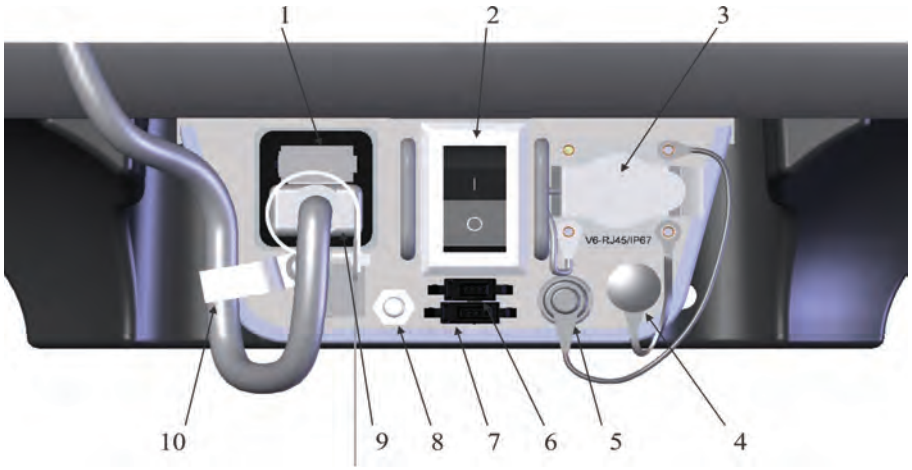


Figure 1.2. **Lower Rear of System (*Stellaris Elite*™ PC+L)**

1. Fuse Holder. 2. Main Power Switch, disconnects system from mains voltage. 3. Ethernet Port.
4. Secondary (LIO) Foot Control Port. 5. Primary (Integrated) Foot Control Backup Cable Port.
6. Microscope Filter Interlock. 7. Room Interlock. 8. Potential Equalization Connector.
9. Power Cord Input. 10. Power Cord Retention Clip.
Note: Systems without laser functionality will not have 4, 6, or 7.

Note: *Turning off the Main Power Switch will disconnect the system from mains.*

Primary (Integrated) Foot Control

The Primary (Integrated) Foot Control shipped with all systems contains a laser firing switch, and can use either wired or wireless communication. The first time the ***Stellaris Elite***™ vision enhancement system is used, you must use the wired connection to establish communication between the Primary (Integrated) Foot Control and the ***Stellaris Elite***™ vision enhancement system.

For wired communication, connect the Primary (Integrated) Foot Control backup cable from the back of the Primary (Integrated) Foot Control to the lower rear of the ***Stellaris Elite***™ vision enhancement system.

See page 1-43 for details on use of the Primary (Integrated) Foot Control.

Figure 1.3. **Primary (Integrated) Foot Control**.

Ethernet Cable (optional)

The Ethernet cable connects the ***Stellaris Elite***™ vision enhancement system with the Digital Media System (DMS) to provide video overlay function. If you have the optional DMS module, connect the Ethernet cable to the port at the bottom of the ***Stellaris Elite***™ vision enhancement system and the other end of the cable to the DMS.

When the Ethernet cable is not in use, install the attached protective cap into the open socket.

Compressed Air Connection

Connect the external air hose to the rear of the system as shown, and then to an appropriate air source.

WARNING: ***For optimum aspiration and reflux performance, the patient's eye must be at the same level as the* Stellaris Elite™ *vision enhancement system aspiration port. If this is not possible, use the patient eye level offset feature in the programming screen.***

To set up the ***Stellaris Elite***™ vision enhancement system:

a. Plug the power cord into the wall.

b. Turn on the power switch, located on the back of the bottom of the system console, and wait for the software to load.

c. Connect the Foot Control backup cable to the system to initiate wireless operation.

d. The battery in the Foot Control must charge at least overnight before it can be used wirelessly. To charge the battery, you can use one of three methods. See page 1-55. To use the system immediately, use the provided cable to connect the Primary (Integrated) Foot Control directly to the ***Stellaris Elite***™ vision enhancement system.

e. If you purchased the DMS, see DMS Operator's Manual for setup details.

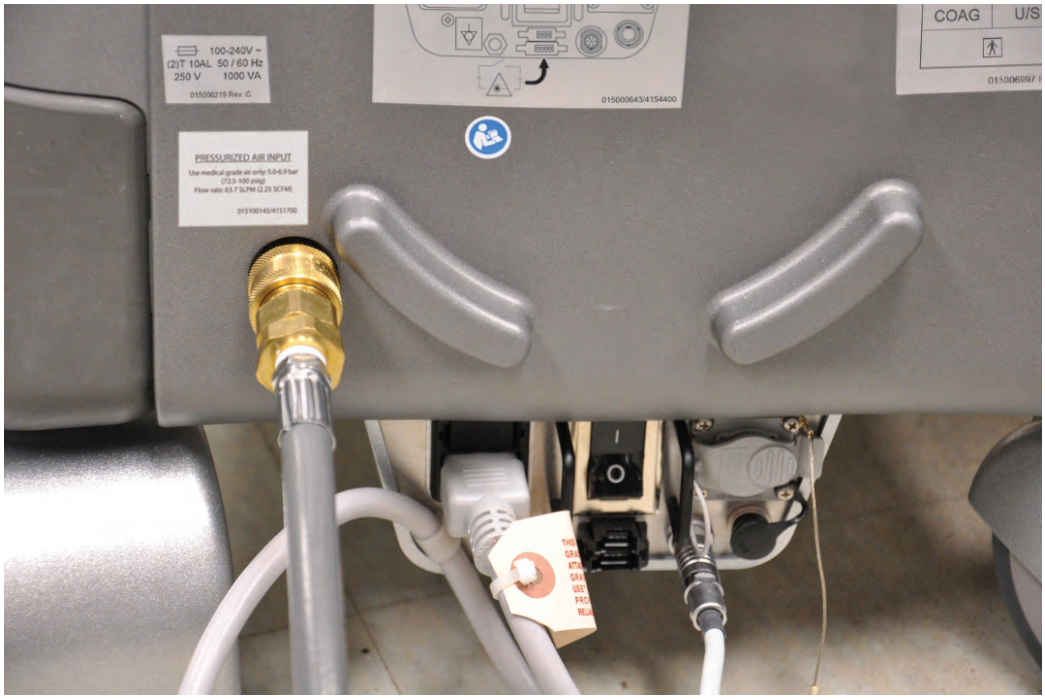


Figure 1.4. **Rear of system, showing air connection**.

Note: *The system requires filtered medical grade air or medical grade nitrogen, at 72.5 psig to 100 psig (500 kPa to 690 kPa or 5.0 bar to 6.9 bar) and a flow rate of 2.25 SCFM (63.7 SLPM).*

See 1.12. Foot Control on page 1-43 for a detailed description of Primary (Integrated) Foot Control operation.

1.4. Setting Up Your System

WARNING: ***The use of flammable anaesthetics, flammable disinfectants, aerosol sprays, or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided unless the gaseous agents are sucked away and the liquid agents are fully dried or evaporated. Ensure the flammable liquids are not pooled beneath the patient drape.***

WARNING: ***This system should only be operated by personnel who have been trained and are qualified to use this system.***

WARNING: ***Do not manually force the IV Pole downward if the system is on.***

WARNING: ***Do not modify the pole height or manually force the pole height, as this could cause an incorrect indication of the bottle height, leading to patient injury.***

WARNING: ***When using gravity infusion, the ophthalmic irrigation source shall be at or above the patient's eye level to avoid patient injury.***

WARNING: ***Do not add unapproved accessories that modify the effective IV Pole Height.***

CAUTION: ***Do not block air vents.***

Before the first use of the ***Stellaris Elite***™ vision enhancement system, connect the Primary (Integrated) Foot Control to the system with the Primary (Integrated) Foot Control backup cable provided with the system.

The following pages contain an overview for setup and use of your ***Stellaris Elite***™ vision enhancement system in a typical surgery without laser functionality. This information is intended for use by someone who is already familiar with this type of system.

Turning System On

Plug the power supply cord into the wall. Connect the compressed air hose to the system.

If desired, connect the Ethernet cable to the port at the bottom of the ***Stellaris Elite***™ vision enhancement system, and the other end to the optional DMS system for Video Overlay function.

Turn on the switch at the bottom of the system console.

WARNING: ***Ensure that the power cord is routed away from traffic areas to prevent accidental disconnection or tripping hazards.***

WARNING: ***Do not disconnect system from power while in use.***

CAUTION: ***Do not turn this switch off until the system has been properly shut down.***

Note: *Turning off the Main Power Switch will disconnect the system from mains.*

Connect the air supply to the back bottom of the system.

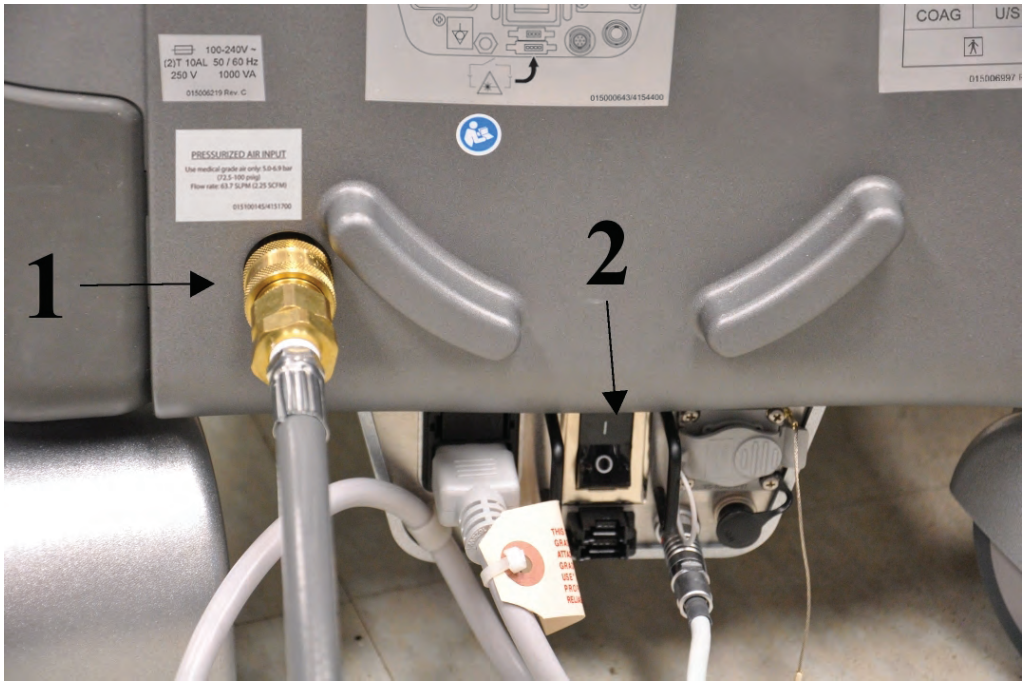


Figure 1.5. **Back bottom of system**.

1. Air hose connection. 2. Main Power Switch.

Note: *The system requires filtered medical grade air or medical grade nitrogen, at 72.5 psig to 100 psig (500 kPa to 690 kPa or 5.0 bar to 6.9 bar) and a flow rate of 2.25 SCFM (63.7 SLPM).*

Press the power button on the front of the system, and wait for the screen to come on and the software to load. The front power switch is brighter when the system is off, and dims when you turn the system on.

The ***Stellaris Elite***™ vision enhancement system performs a self-check each time the power is turned on. The system automatically checks its configurations for any changes since the last time it was turned on.

CAUTION: ***Observe system diagnostic messages when powering up system for first use each day and take appropriate action if required. Also observe first cassette priming or calibration, phaco/frag handpiece tuning and/or vitrectomy handpiece testing for correct completion.***

After the Primary (Integrated) Foot Control has been synchronized to the specific ***Stellaris Elite***™ vision enhancement system (see page 1-43), you may use wireless communication.

Note: *The out-of-factory Wireless System Setup is "Disabled". Software upgrade will also reset the Wireless System Setup to "Disabled". See System Setup Instructions on page 1-51 to configure Primary (Integrated) Foot Control to wireless operation.*

If you are going to use the Primary (Integrated) Foot Control in wireless mode, ensure the Foot Control battery is charged, then hold down any button on the Primary (Integrated) Foot Control until the green ready light comes on, indicating that communication has been initiated. This light will turn solid green when full communications have been established.

When the system check is completed following system power-up, the **Splash screen** will appear (see Figure 1.6 on page 1-14).

Note: *Following system shutdown, wait a minimum of 15 seconds before restarting the system. The system is fully shut down after the front panel power button light changes from dim to bright.*

Figure 1.6. **Opening Splash Screen**.

Once the software has finished loading, the **Select Procedure Screen** will appear, unless a default procedure has been set (see page 3-26).

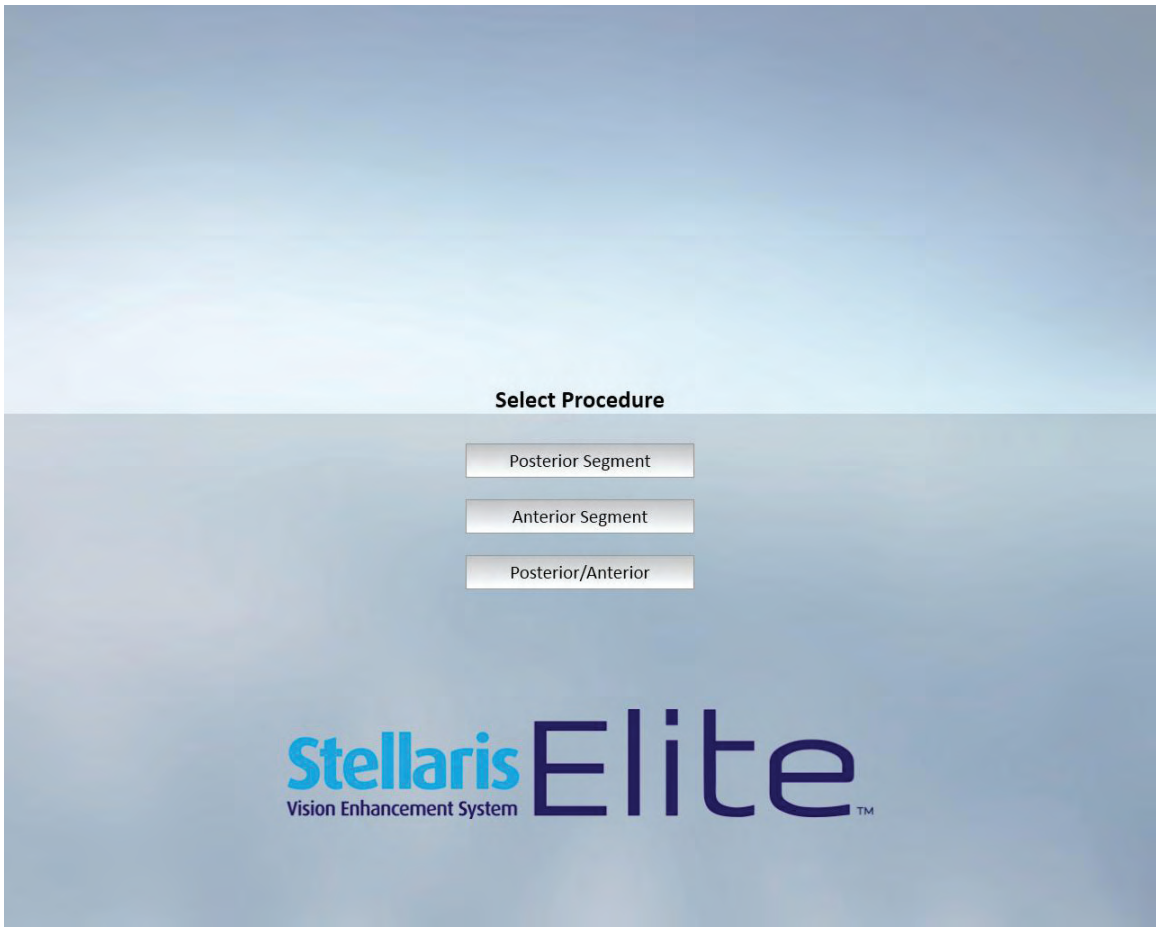


Figure 1.7. **Select Procedure Screen**.

A **Select Surgeon Screen** (as shown in Figure 1.8 on page 1-16) will appear when you select any type of procedure from the **Select Procedure Screen**.

If your system is programmed to default to either the Anterior Domain, Posterior Domain or the Combined Domain, the **Select Procedure Screen** will not appear, and the system will move directly to the **Select Surgeon Screen**, as shown in Figure 1.8 below.

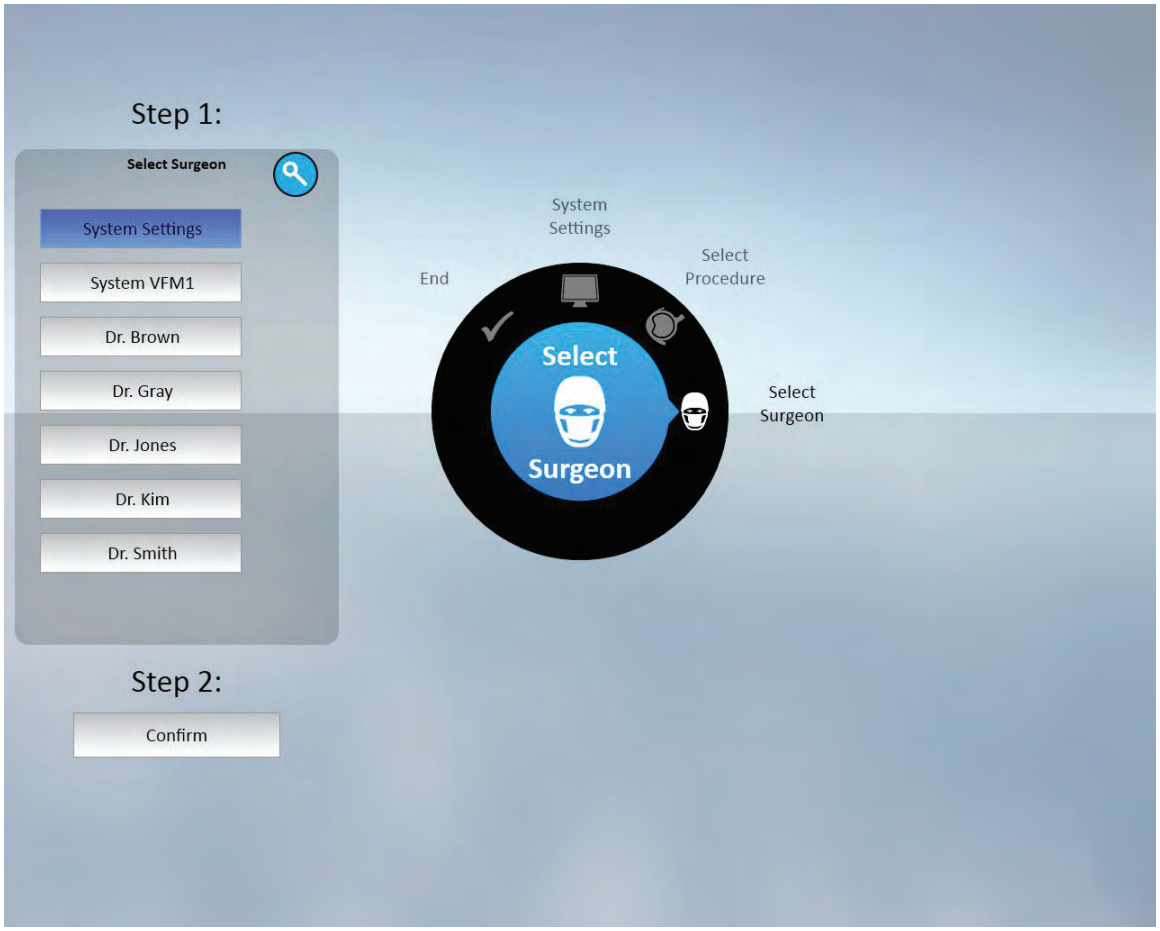


Figure 1.8. **Select Surgeon Screen**.

Select Surgeon

Touch the name of a surgeon on the list to highlight it, then select **Confirm** to load the parameters for that surgeon and advance to the **Setup Screen**.

Note: *A search function is available to filter the surgeon names list when selecting a surgeon file to load. If the **Confirm** button is not active, this indicates one or more modules were not detected in the system and further operation is not allowed.*

See page 3-17 to create a new surgeon preference file.

Setup Screen

The **Setup Screen** allows you to set certain procedure parameters, and prepare the system for surgical procedures.

The Insert Cassette option will be highlighted when you initially see this screen.

If desired, select the specific technique, needle, grade, vitrectomy gauge, extrude gauge, and fragmentation needle (Posterior Domain) for the current procedure.

Figure 1.9. **Anterior Domain Case Menu Screen**.

Figure 1.10. **Posterior Domain Case Menu Screen.**

Figure 1.11. **Combined Domain Case Menu Screen**.

Advance to the open pack step by selecting **Insert Cassette** from the **Clock Menu**.

1.5. Starting a New Procedure

The ***Stellaris Elite***™ vision enhancement system is user-friendly, and will highlight whichever step is next in a typical procedure. The steps shown on the display screen will vary slightly depending on which optional features are installed on your machine. On-screen instructions take precedence over information in this manual.

WARNING: ***Before beginning a procedure, ensure that there is sufficient volume of irrigation solution for the entire procedure.***

WARNING: ***Visually inspect all sterile barrier systems prior to opening to determine if breaches of integrity are present. If damaged, do not use.***

Note: *Ensure tube set connection is secure when connecting to the handpiece and system.*

1. Set up the sterile field

Open the disposable pack and drop contents onto a sterile surface.

Note: *Make sure to use the proper pack for the mode you are using. Packs will not work for other modes. The Packs are color-coded. Anterior packs are green and/or light blue. Posterior Packs and Combined Packs are color-coded by needle gauge: 20 gauge is gray, 23 gauge is green, 25 gauge is blue, and 27 gauge is purple.*

Attach the sterile screen drape by placing the drape over the top of the ***Stellaris Elite***™ vision enhancement system screen and secure with the adhesive strip to top, not the front, of the display as shown in the illustration below.

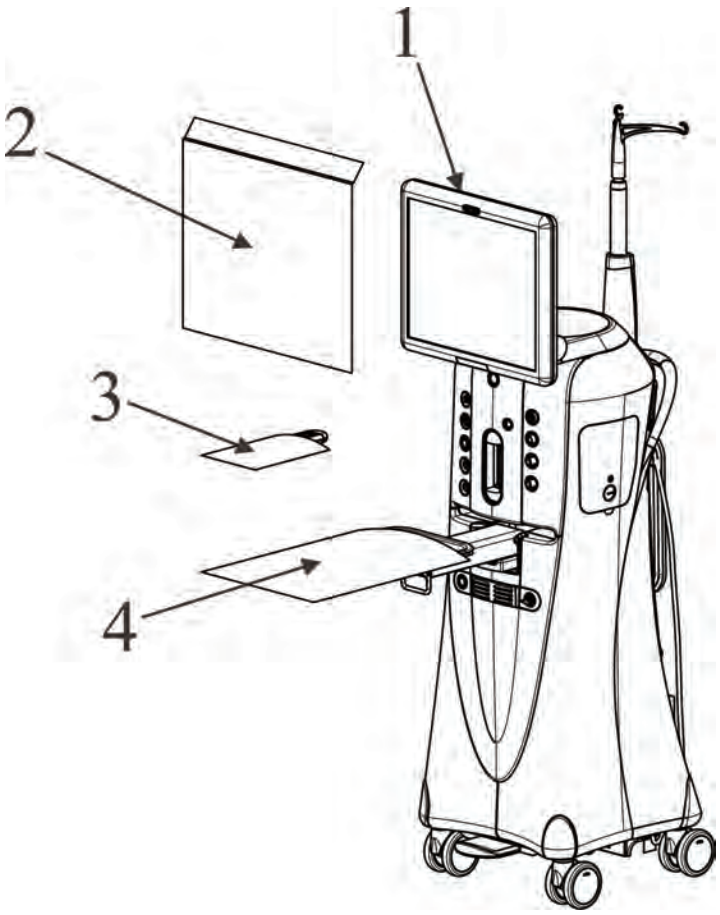


Figure 1.12. **Schematic diagram of Sterile Draping**.

1. Adhere screen drape on the top of the screen panel. 2. Screen drape. 3. Anterior Remote control drape. 4. Mayo Tray drape.

CAUTION: ***Do not exceed a maximum load of 3 lbs. when system tray is fully extended.***

2. Set Up Fluid Collection System

WARNING: ***Before beginning a procedure, ensure that there is sufficient volume of irrigation solution for the entire procedure.***

Insert the fluidics cassette into the slot on the front of the system and hold until it is automatically captured by the system. The cassette housing backlight will stop blinking and remain on when the system captures the cassette.

The system will automatically conduct a vacuum sensor and calibration check. Wait until the progress bar shows successful completion to proceed. If the system does not pass, corrective actions will be suggested. Following the successful cassette check, the screen will automatically advance to the Prime and Tune steps.

Adaptive Fluidics is a new fluidics function for phacoemulsification surgery during lens removal and I/A only. It is not available for anterior vitrectomy and all posterior phases. The new function is to be used with Adaptive Fluidics surgical packs. Please see page 4-53 for detailed information on Adaptive Fluidics, and page 2-30 for Adaptive Fluidics changes to the GUI.

3. Connect the proper accessories to the system for an Anterior, Posterior, or Combined procedure

Note: *If you are using a vented Air Forced Infusion (AFI) pack, make sure to connect the Fluid/Air Exchange filter to the F/AX port on the front of the machine.*

Detailed setup instructions for each configuration are provided in Chapter 4. Use the following list to navigate to the appropriate page and surgical setup instructions for the desired configuration.

Posterior Domain -

- Vitrectomy - See page 4-8
- Illumination - See page 4-24
- Fluid/Air Exchange - See page 4-32
- Viscous Fluid Injection - See page 4-37
- Viscous Fluid Extraction - See page 4-38
- Fragmentation - See page 4-41
- Laser Photocoagulation - See page 1-71

Anterior Domain -

- Irrigation/Aspiration - See page 4-45
- Phacoemulsification - See page 4-50
- Planned Anterior Vitrectomy - See page 4-57
- Unplanned Anterior Vitrectomy - See page 4-58

Coagulation -

- Fixed Coagulation - See page 4-64
- Linear Coagulation - See page 4-65

Combined Domain - See page 4-67

Note: *Ensure tube set connection is secure when connecting to the handpiece and system.*

Note: *Fragmentation uses the same power connection as the ultrasound handpiece. Only one function can be used at a time.*

Note: *If a linear coagulation in setup is enabled or a Primary (Integrated) Foot Control button is programmed for coagulation, begin by plugging in the coagulation cord.*

For on-screen instructions, select **Show Me Steps** from the **Prime and Tune Screen** and a list will appear, detailing the required steps and showing animations of how to perform each step. Multiple video sequences can be selected and played. Available videos include:

- Anterior Domain - Phaco, Vitrectomy
- Posterior Domain - Pressurized Infusion, Gravity Infusion, Coagulation, Vitrectomy, Fragmentation, VF Inject, VF Extract, Illuminator, Easy Prime, EndoProbe, LIO
- Combined Domain - Pressurized Infusion, Gravity Infusion, Coagulation, Vitrectomy, Fragmentation, VF Inject, VF Extract, Illuminator, Easy Prime, EndoProbe, LIO, Phaco, Anterior Vitrectomy

WARNING: ***The animations illustrate the steps, but do not represent sterile technique.***

4. Prime and Tune

Note: *The system will not provide feedback as to whether or not fluid is present during priming. Inspect tubing and confirm that it is filled with fluid and free of bubbles after each Prime and Tune. Repeat the priming process if the tubing is not adequately filled with fluid.*

When the cassette has been inserted and captured by the machine, and all accessories, tubing and handpieces have been connected, the system is ready for Prime and Tune. To proceed to the Prime and Tune phase, select the appropriate options for the domain in which you are operating. Available options are described below.

For Posterior Domain:

- Select the **Easy Prime** button from the **Prime and Tune Screen** to fill the left and right tubing with Balanced Salt Solution, and then perform a test of the pneumatic cutter. During this process, the gravity feed infusion IV pole will raise to 140 cm or lower if maximum ceiling height is set lower than 140 cm for the anterior. In the posterior/combined domains, IV pole will raise to the maximum ceiling height programmed for the system. With the air pressured infusion, the pressure will raise to 103 mmHg for posterior/combined domains.

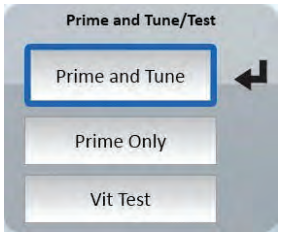
- Select the **Prime/Test Vit** button to activate the vacuum on right side aspiration line and test the pneumatic vitrectomy function. The handpiece tip must be submerged in Balanced Salt Solution during this process. After the line has been primed, this button will become **Test Vit**, which will activate the cutter test without aspiration.
- Select the **Prime/Tune U/S** button to activate aspiration on the left line and tune the fragmentation handpiece. The electric connector on the fragmentation handpiece must be inserted into the ***Stellaris Elite***™ vision enhancement system and the tip submerged in Balanced Salt Solution before this option is selected. After the line has been primed, this button will become **Tune U/S**, which will activate a shorter cycle of aspiration and tuning.
- Select the **Prime/Aux** button to activate aspiration to fill the left aspiration line with Balanced Salt Solution. After the first use, subsequent priming cycles will be slightly shorter.

For Combined Domain:

- Select the **Easy Prime** button from the **Prime and Tune Screen** to fill the left and right tubing with Balanced Salt Solution, and then perform a test of the pneumatic cutter. During this process, the gravity feed infusion IV pole will raise to 140 cm or lower if maximum ceiling height is set lower than 140 cm for the anterior. In the posterior/combined domains, IV pole will raise to the maximum ceiling height programmed for the system. With the air pressured infusion, the pressure will raise to 103 mmHg for posterior/combined domains.
- Select the **Prime/Test Vit** button to activate the vacuum on right side aspiration line and test the pneumatic vitrectomy function. The handpiece tip must be submerged in Balanced Salt Solution during this process. After the line has been primed, this button will become **Test Vit**, which will activate the cutter test without aspiration.
- The operation of the **Prime/Tune U/S** button differs, depending on which ultrasound handpiece is connected to the system.
  - Fragmentation Handpiece: Select the **Prime/Tune U/S** button to activate aspiration on the left line and tune the fragmentation handpiece. The electrical connector on the fragmentation handpiece must be inserted into the ***Stellaris Elite***™ vision enhancement system and the tip submerged in Balanced Salt Solution before this option is selected. After the line has been primed, this button will become **Tune U/S**, which will activate a shorter cycle of aspiration and tuning.
  - Ultrasound Handpiece: Select the **Prime/Tune U/S** button to initiate priming of the irrigation and left aspiration line, followed by tuning of the ultrasound handpiece and a vacuum test. During this process, the IV bottle will be raised to 140 cm or the system will use a pressure of 73 mmHg if AFI is used. The irrigation line and the aspiration line need to be connected to the ultrasound handpiece with the test chamber attached to the tip of the ultrasound handpiece. After the line has been primed, this button will change to **Tune U/S** which will activate a shorter cycle of aspiration and tuning without the vacuum test.
- Select the **Prime/Aux** button to activate aspiration to fill the left aspiration line with Balanced Salt Solution. After the line has been primed, subsequent priming cycles will be slightly shorter.

For Anterior Domain:

- Select the **Prime and Tune** button from the **Prime and Tune Screen** to initiate priming of the irrigation and left aspiration line, followed by tuning of the ultrasound handpiece and a vacuum test. During this process, the IV bottle will be raised to 100 cm or the system will use a pressure of 73 mmHg if AFI is used. The irrigation line and the aspiration line need to be connected to the ultrasound handpiece with the test chamber attached to the tip of the ultrasound handpiece. After the line has been primed, this button will change to **Tune Only** which will activate a shorter cycle of aspiration and tuning without the vacuum test.
- Select the **Prime Only** button from the **Prime and Tune Screen** to initiate priming of the irrigation and left aspiration line, followed by a vacuum test. The irrigation line and the aspiration line need to be connected to the ultrasound handpiece with the test chamber attached to the tip of the ultrasound handpiece. During this process, the IV bottle will be raised to 100 cm or the system will use pressure if AFI is used. After the line has been primed, the button will activate a shorter cycle of aspiration without the vacuum test.
- Select the **Prime/Test Vit** to activate aspiration and a test of the pneumatic cutter.
- In the anterior domain, the remote control can be used to activate functions in the “Prime and Tune” window of the setup screen. The remote control UP/DOWN buttons are used to move the arrow and select options in the “Prime and Tune” window:



“Prime and Tune” Window on Setup Screen

Figure 1.13. **Prime and Tune Window**.

1. Enter. 2. Up. 3. Down.

- Pressing the “Enter” button on the remote control activates the selected function as indicated by the arrow.

Once Prime and Tune is initiated by any of these options, a Cancel button will appear. Selecting the Cancel button will immediately stop the priming and tuning process.

When Prime and Tune is in progress, a progress bar at the lower left-hand corner is displayed to indicate the status of the Prime and Tune cycle.

If the system does not pass the Prime and Tune test, suggestions for corrective action will be displayed.

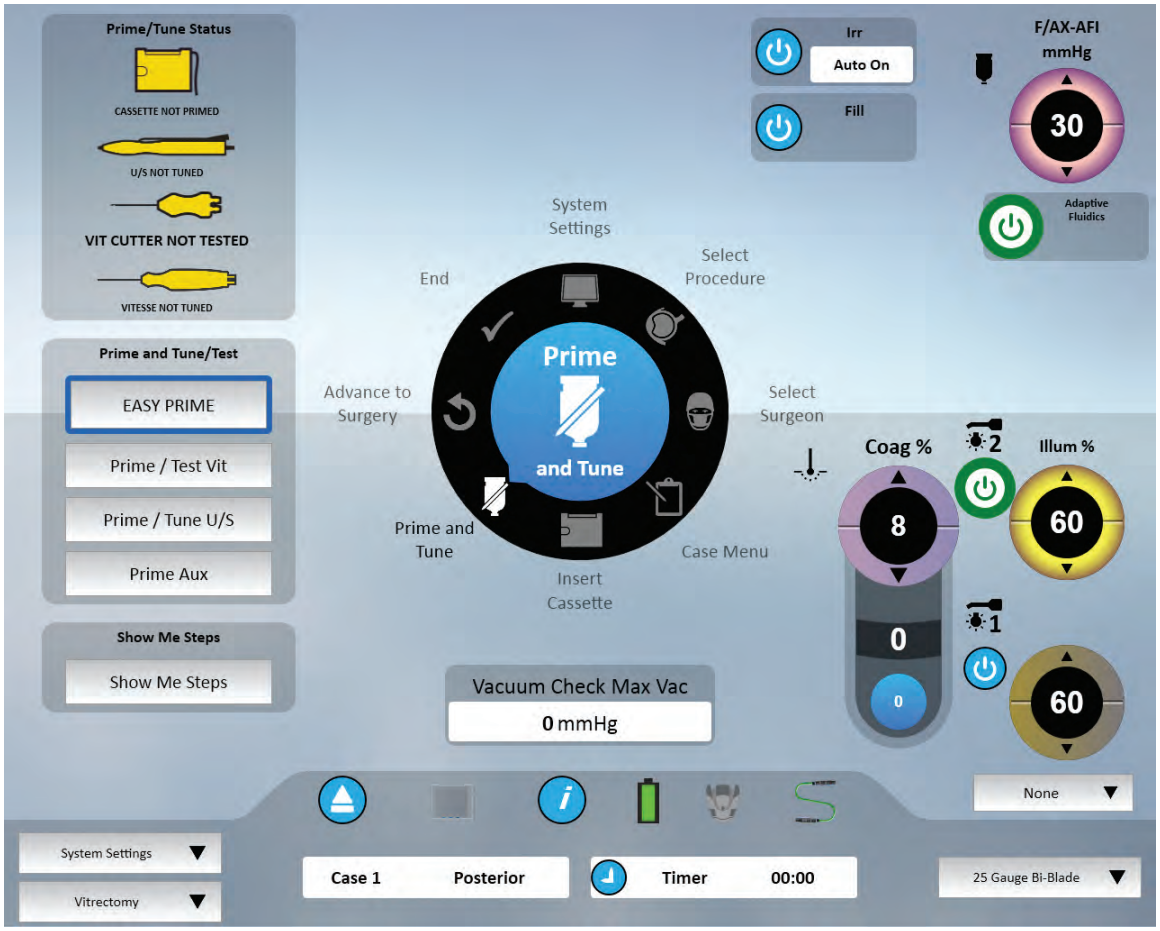


Figure 1.14. **Prime and Tune Screen. This is an example of a posterior domain screen**.

5. Advance to Surgery Phase

WARNING: ***Inadvertent activation of functions that are intended for priming or tuning handpieces while the handpiece is in the eye can create a hazardous situation that could result in patient injury.***

Once the system has been successfully primed and tuned, it will automatically move to the main surgical screen. Manually selecting **Advance to Surgery** produces the same result.

Note: *If the system is not primed and tuned, the aspiration, vitrectomy and ultrasound functions will be unavailable.*

1.6. Using Your System in Surgery

Default parameters and settings are saved in the surgeon preference file, but can be modified during a procedure using the on-screen controls and surgical settings screens (see page 2-6).

Your system will display the appropriate surgical screen for the current surgical mode. The interface is visibly different depending on the current operational mode. See Figure 1.15 for an example of a Posterior Surgical Screen, or Figure 1.16 for an example of an Anterior Surgical Screen or Figure 1.17 for an example of a Combined Surgical Screen. When the appropriate screen appears, your ***Stellaris Elite***™ vision enhancement system is ready for the surgical procedure to begin.

Figure 1.15. **Posterior Surgical Screen**.

Figure 1.16. **Anterior Surgical Screen**.

Figure 1.17. **Combined Surgical Screen**.

1.7. Concluding a Surgical Procedure

Select **End** from the **Clock Menu**. Confirm that you are ready to end the case and eject the cassette, and you will be reminded to close the clamps on the irrigation tube set. A similar **End** function is accessible from the **Setup Screen**.

WARNING: ***Make sure to close the Irrigation Clamp on the Irrigation Tube Set before pressing End Procedure or fluid may continue to flow from the handpiece and into the cassette.***

The system will then advance to the **End of Case Screen** (shown below), lower the IV Pole, and eject the cassette.

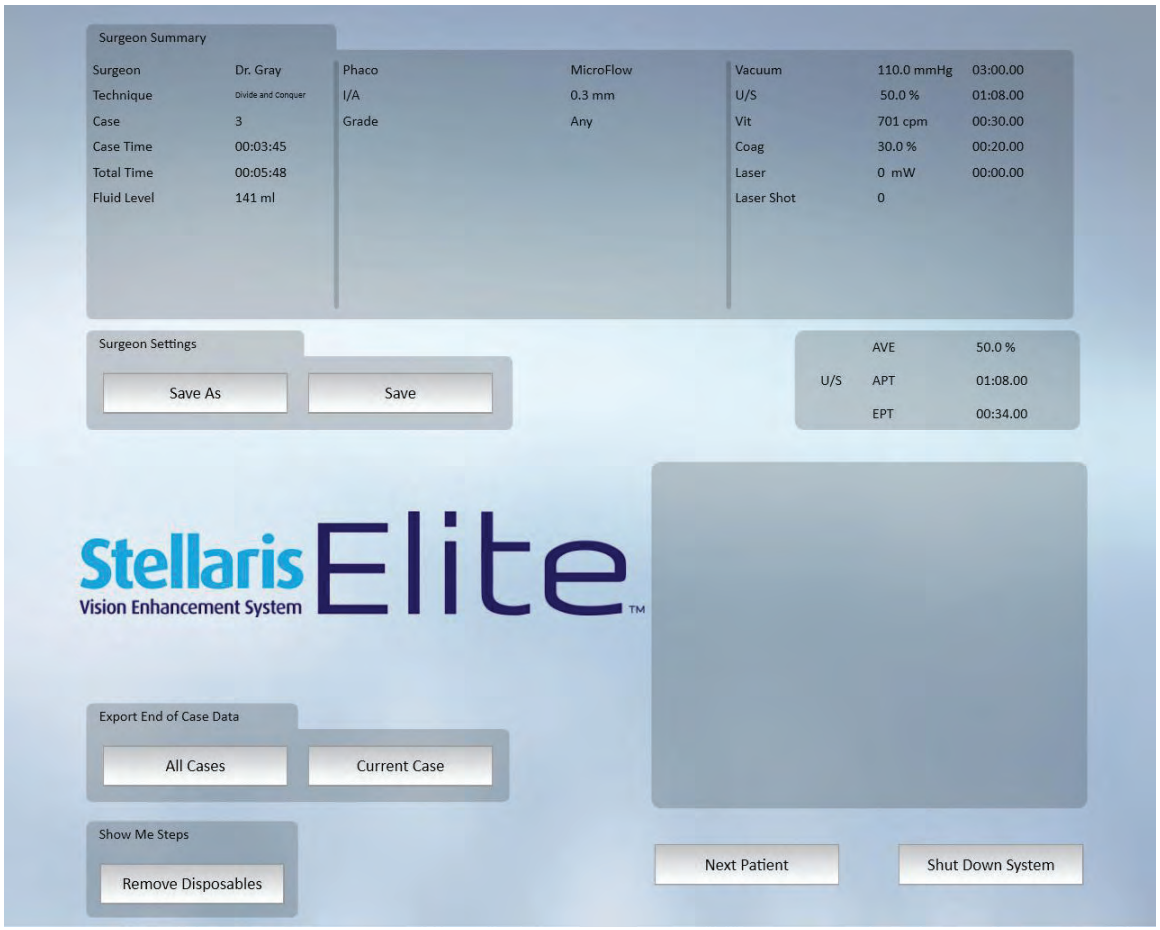


Figure 1.18. **Anterior End of Case Screen**.

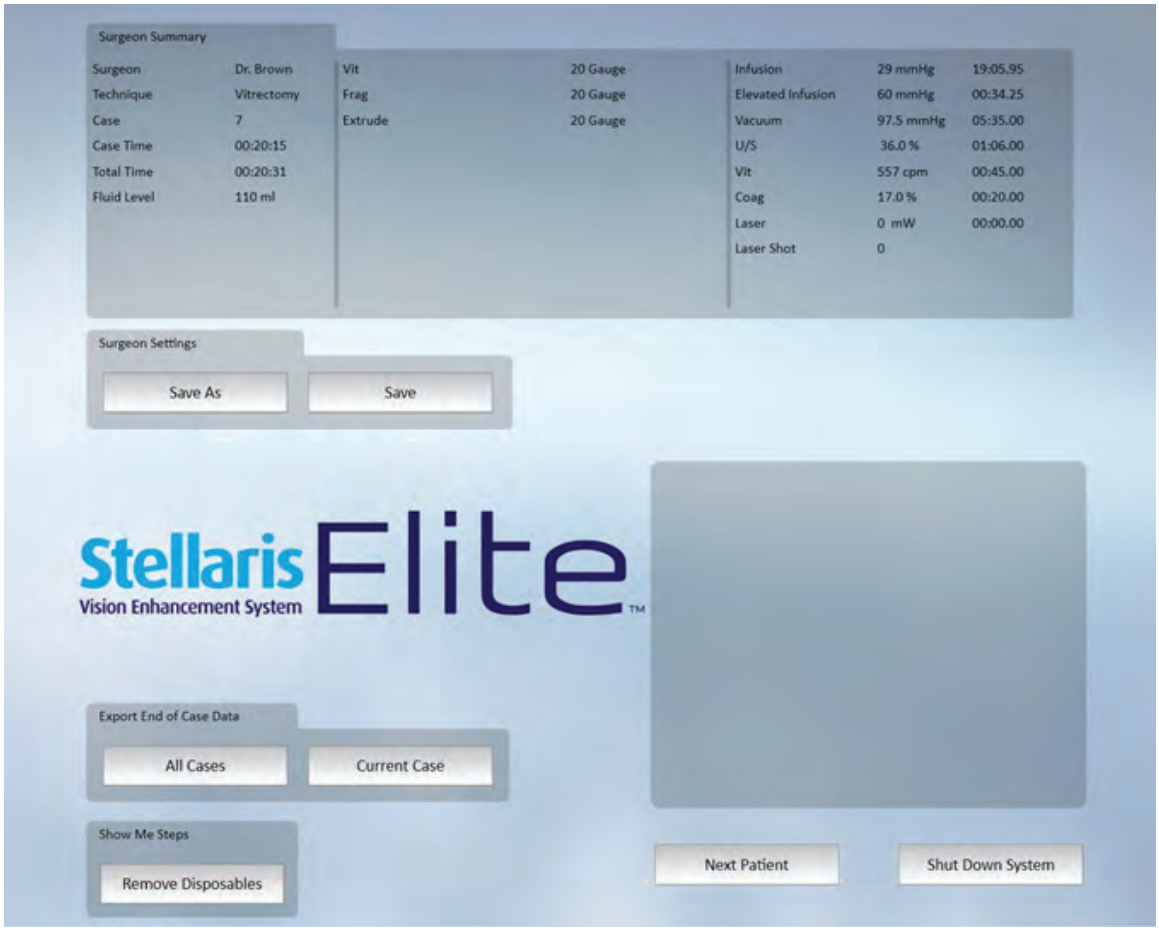


Figure 1.19. **Posterior End of Case Screen**.

Figure 1.20. **Combined End of Case Screen**.

Remove the fluidics cassette immediately.

Remove all disposables from the system. Select Show Me Steps, then **Remove Disposables** to see a list of which disposables need to be removed, and animations of how to remove each of them.

Selecting **End of Case Data** will capture the **End of Case** screen as an image. The stored **End of Case** screen images may be exported to a USB memory device.

Select **Next Patient** to return to the **Setup Screen** and prepare the machine for the next procedure, or select **Shut Down System** to power down the system.

Note: *On selecting **Shut Down System**, a message reminding you to charge the battery will be displayed.*

1.8. Shutting Down the System

CAUTION: ***Never turn the power switch off or disconnect the power without proper system shutdown. Equipment damage can occur.***

Although there is no maximum activation (on) time or minimum deactivation (off) time defined for the ***Stellaris Elite***™ system, Bausch + Lomb recommends the system to be shut down at the end of each surgical day. This allows for the system to perform self-check when powered on the next day and allows for refresh of system memory.

From the **System End** Screen, select **Shut Down System**. Select **Yes** to confirm shut down, or **No** to go back to the **End Screen**. The system may take a few minutes to shut down. The front panel light will glow brighter when shut down is complete.

When shutting down the system, make sure to recharge the Primary (Integrated) Foot Control, as described on page 1-55.

Note: *On selecting **Shut Down System**, a message reminding you to charge the battery will be displayed.*

1.9. Power Interruptions

If the ***Stellaris Elite***™ vision enhancement system requires continued operation during power main interruptions, the system should be powered from an uninterruptible power supply (not provided).

In the event the power source is interrupted causing the system to shut down, the cassette will be ejected automatically. Perform the steps listed below according to the type of surgery.

Anterior Segment surgery:
Remove the handpiece from the eye safely and pinch off the irrigation clamp to stop fluid flowing into the cassette.

Posterior Segment surgery:
Remove handpiece from the eye safely, and use sclera plugs to stop fluid leakage from the eye. Pinch off irrigation clamp only after sclera plugs have been inserted to prevent fluid leakage.

When the power supply resumes, reboot the system, insert the cassette, open the irrigation clamp and perform prime and tune according to the system setup procedures (see page 1-23). Remove the infusion cannula or clamp off the infusion line near the infusion cannula before Priming and Tuning the system.

WARNING: ***Do not Prime and Tune with the infusion line clamp in the open position and the infusion cannula attached to the eye. Remove the infusion cannula, or clamp off the infusion line clamp near the infusion cannula before priming and tuning the system.***

1.10. Moving Your System to Another Location

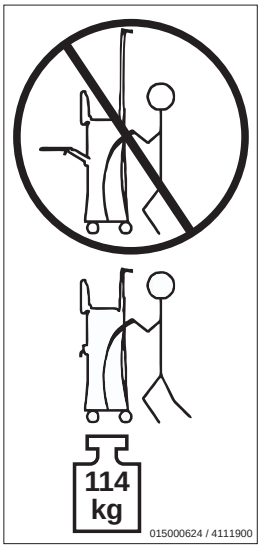
WARNING: ***Do not pull the system by the IV Pole.***

CAUTION: ***Do not transport or move your system from room to room or up an inclination unless you have followed the steps below.***

This unit is designed to provide mobility within the environment of the operating room.

Care must be taken as to avoid sloped floors greater than 5 degrees during use.

If you want to move your system to another location, follow the steps as listed below.



1. Power down normally by selecting “Shut Down” from the end of case screen or pressing and holding the front button for at least 8 seconds, ensuring the IV Pole is fully retracted.
2. Remove any objects from mat on top of unit.
3. Depressurize the compressed air supply that feeds your unit.
4. Disconnect the pneumatic air hose from the lower left corner (facing the rear end of the unit).
5. Store the tray all the way in the unit’s tray receptacle.
6. Fully close the front drawer.
7. Roll the power cord in its proper hooks at the rear end of the unit.
8. Place the Primary (Integrated) Foot Control on its dedicated hook, at the rear end of unit.
9. Remove the bottles and tube sets from the unit’s pole hanger and store separately from the unit.
10. Make sure no objects such as air hose, electrical cord, video cables, etc., lie in the moving path.
11. Disengage the front brake lever.

12. Always maneuver the unit using the handlebar designed for this purpose.

Note: *Do not store anything on top of the system.*

1.11. System Components

The ***Stellaris Elite***™ vision enhancement system has an advanced modular design with independent modules concealed in a uniquely designed exterior housing. The top level of the system is the user interface screen and computer unit. The surgical modules are concealed inside the main housing and strategically positioned to provide optimum user interaction and surgical functions. The Primary (Integrated) Foot Control is connected to the system by either wired or wireless connections.

WARNING: ***Use only handpieces, cables, tube sets and accessories manufactured or distributed by Bausch + Lomb that are designated for use with this system. Failure to do so may affect system performance and create hazards. Use of accessories manufactured or distributed by Bausch + Lomb on systems for which they are not designated may affect system performance and create hazards.***

WARNING: ***Manufacturers of cardiac pacemakers advise against use of bipolar cautery devices on patients with such implants. When conducting surgery on such a patient, a battery-powered thermal cautery may be used, or the manufacturer of the pacemaker should be consulted to determine appropriate steps to take in order to use the bipolar cautery function.***

WARNING: ***Manufacturers of implantable defibrillators recommend that these devices be temporarily disabled when using bipolar cautery on patients with implants. The surgeon should determine if the patient has such a device and consult the manufacturer for appropriate actions.***

User Interface Screen

The **User Interface Screen** is the way the user communicates with the system. See Chapter 2 for basic user interface controls. Technical specifications can be found in Chapter 8. A typical interface setup screen is shown below.

Figure 1.21. **Typical interface screen**.

System Console

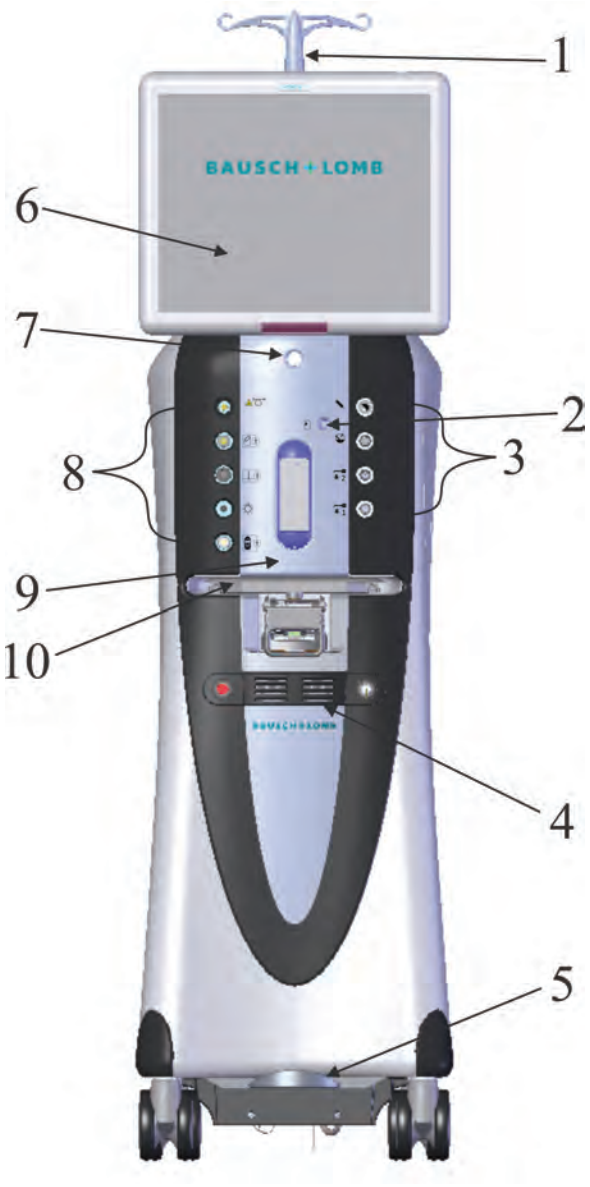


Figure 1.22. **Front of *Stellaris Elite*™ Posterior/Combined Configuration**.

1. IV Pole. 2. Pneumatic Actuation Port. 3. Posterior Handpiece Connectors. 4. Laser. 5. One-Touch Wheel Locking. 6. User Interface screen. 7. System Switch “On/Off”. 8. Handpiece Connectors. 9. Fluidic Module. 10. System Tray.

This is the main unit, which contains the connections for all handpieces, Mayo tray, Ethernet connection and system housing. On the rear of the main unit (see Figure 1.23 on page 1-38), near the IV Pole, are three buttons that move the IV Pole up, down or back to the preset height for the current mode of operation. The console also contains the power supply.

For systems left idle more than seven days, the Primary (Integrated) Foot Control must be charged for six hours before use to ensure proper operation.

CAUTION: ***To prevent loss of data, save data before the system shuts down.***

Figure 1.23. **Rear of *Stellaris Elite*™ Posterior/Combined Configuration**.

1. USB Port Access. 2. IV Pole Control Buttons. 3. Cord Wrap Hooks.
4. Primary (Integrated) Foot Control Hook. 5. Air Pressure Output connector.

The front of the system (see Figure 1.24 on page 1-39) contains multiple ports for connecting system accessories.

There are five ports on the left side of the system for connecting specific system accessories.

- The first port (1 in figure below) is for laser (if available, see page 1-71).
- The second port (2 in figure below) is for ultrasound (see page 1-40).

- The third port (3 in figure below) is for coagulation (see page 4-64).
- The fourth port (4 in figure below) is power for the LIO (available as distributed product, see page 1-76).
- The fifth port (5 in figure below) is for Vitesse (see page 4-14).

There are five ports down the right side of the system for connecting specific system accessories.

- The first port (6 in figure below) is for Viscous Fluid Injection & Aspiration.
- The second port (7 in figure below) is for Air Forced Infusion and Fluid/Air Exchange.
- The third port (8 in figure below) is for Lamp 2 and provides illumination (see page 1-66).
- The fourth port (9 in figure below) is for Lamp 1 and provides illumination with selectable filters (see page 1-66).
- The last port on the front of the panel (10 in figure below) is for Vitrectomy.

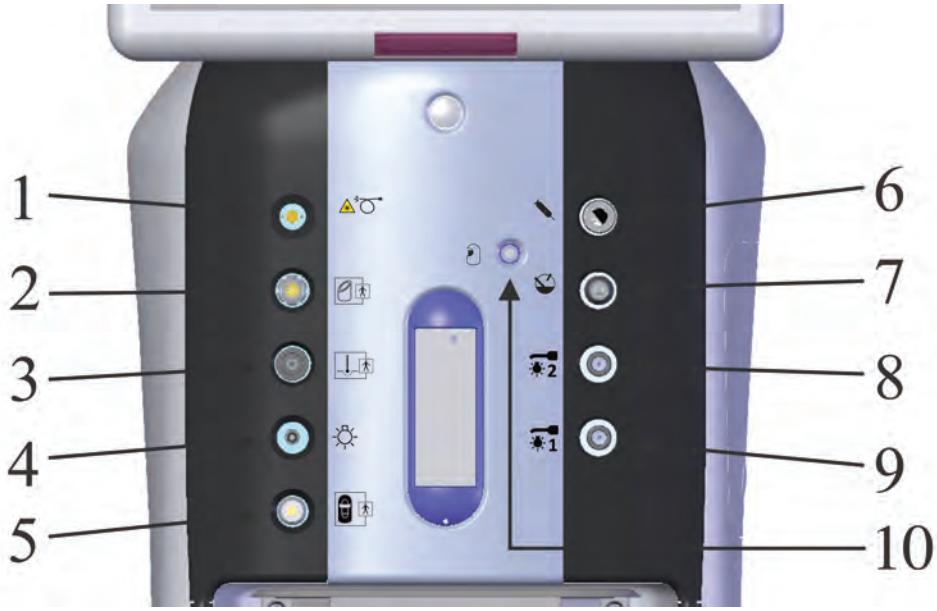


Figure 1.24. **Front panel with handpiece connectors**.

1. Laser (Optional Laser module only). 2. Ultrasound. 3. Coagulation. 4. Power to the lamp-type LIO. 5. Vitesse. 6. Viscous Fluid Injection and Aspiration. 7. AFI and F/AX. 8. Lamp 2 and provides illumination. 9. Lamp 1 and provides illumination with selectable filters. 10. Vitrectomy.

Systems without laser functionality (shown) will not have 1 or 4.

Ultrasound Functions (Phacoemulsification and Fragmentation)

WARNING: ***Manufacturers of implantable defibrillators recommend that these devices be temporarily disabled when using phacoemulsification systems on patients with these implants. This is especially important when using pulsed phaco modes of operation. Although the implanted devices are designed to reject electromagnetic interference, and Bausch + Lomb vision enhancement equipment is designed to minimize such interference, a chance interaction cannot be ruled out. Patients should be questioned to determine if they have such an implant and, if so, the manufacturer should be consulted to determine the proper course of action.***

The second port on the left side of the system is for ultrasound handpieces. These support phacoemulsification and fragmentation procedures in continuous, pulsed, and burst modes.

Coagulation

The third port on the left side of the system is for a coagulation handpiece which provides coagulation power in either Fixed or Linear modes. See page 4-62 for details of use and page 8-7 for technical specifications.

The front of the system contains a total of 10 ports for connecting system accessories. All ports should be utilized now with Vitesse.

Primary (Integrated) Foot Control

The Primary (Integrated) Foot Control contains the Foot Pedal and four programmable buttons, and provides the main interface between the user and the vision enhancement system for controlling most functions. The Primary (Integrated) Foot Control can be used in a wired or wireless mode. See page 1-43 for detailed instructions for its use and Chapter 8 for technical specifications.

Fluidics Function

This function uses a vacuum-based pump to control the output vacuum range from 0 mmHg to 660 mmHg, and uses a rigid 300 ml collection cassette with attached irrigation and aspiration tubing. Pneumatic vitrectomy supports both a Linear Cut Rate and a Fixed Cut Rate from 0 cuts per minute (CPM) to 7500 CPM. See page 4-6 for details of use and page 8-11 for technical specifications.

Illumination Function

The illumination function provides two light sources, both with an adjustable attenuator. More than 25 lumens output is available at maximum settings. With a xenon lamp in Lamp 1 location, any one of three color filters (yellow, green and amber) may be used. Both ports incorporate permanent filtration to reduce ultraviolet, violet, deep red and infrared light. See page 4-24 for details of use and page 8-12 for technical specifications, and page 1-66 gives additional guidance on output setting.

Air Compressor

The compressor provides air pressure to drive various pinch valves, Pressurized Infusion (Anterior domain), Air Forced Infusion (Posterior/Combined domains) and Fluid/Air Exchange. It also houses the air pump to drive the Viscous Fluid injection function and the venturi regulator for vacuum control. See Chapter 8 for technical specifications.

IV Pole

WARNING: ***Use of an IV Pole extension or other means of altering the bottle height may cause inaccurate setting displays resulting in serious permanent patient injury.***

WARNING: ***When using Pressurized Infusion with Balanced Salt Solution bottle hung on the system-automated IV pole, the actual intraocular pressure will be higher than the air pressure displayed in the machine. The actual intraocular pressure would be equal to air pressure combined with hydrostatic pressure created from the gravity force.***

CAUTION: ***Do not manually force the IV Pole or use the IV Pole as a handle.***

The ***Stellaris Elite***™ vision enhancement system IV Pole is an integral part of the system console. It can be directly moved up, down, or to a specific preset height by any of several methods. It can be controlled through the touch screen, Primary (Integrated) Foot Control (if programmed), remote control (optional accessory), or directly by using the buttons on the back of the system console. The IV Pole can also be pre-programmed to a certain height for various surgical modes. The system will not compensate if the bottle height is altered through the use of IV Pole extensions or other hardware not provided with the system.

To change the bottle height during surgery, use the up and down arrows on the IV Pole control section of the **Surgical Screen** (see page 2-27), or use the buttons on the back of the system console.

In the lowest (stowed) position and with a 500 ml bottle, the IV Pole will provide approximately 30 cm (12 in.) of infusion pressure, measured from the aspiration port to the middle of the Balanced Salt Solution drip chamber. This is an equivalent pressure (not Intraocular Pressure) of 22.4 mmHg. The IV Pole can extend to 140 cm (55 in.) high, an equivalent pressure of 102.74 mmHg.

To change the programmed bottle height settings for the current surgical mode, select the **More Screen Infusion Tab** (page 2-7) if in Posterior Mode, or the **More Screen Vacuum Tab** (see page 2-7), then select the **Infusion Tab** to change the actual height, preset height, or the maximum the IV Pole is allowed to reach.

The maximum IV Pole Height should be set when installing the ***Stellaris Elite***™ vision enhancement system in a particular medical facility. You can do this using the programming interface (see Chapter 3).

Remote Control (Anterior Domain Only, Optional Accessory)

CAUTION: ***The remote control is not waterproof and is not sterilizable. The remote control must be placed in a sterile cover prior to use in the sterile field.***

The remote control transmits an infrared signal to a receiver at the bottom of the touch screen. For critical functions you can activate a command directly through the remote control. The commands which may be given from each remote control button are shown in Figure 1.25.

The remote control is powered by two AA batteries, which should be replaced when the low battery light comes on. Access the remote control batteries by removing the battery cover on the back of the remote.

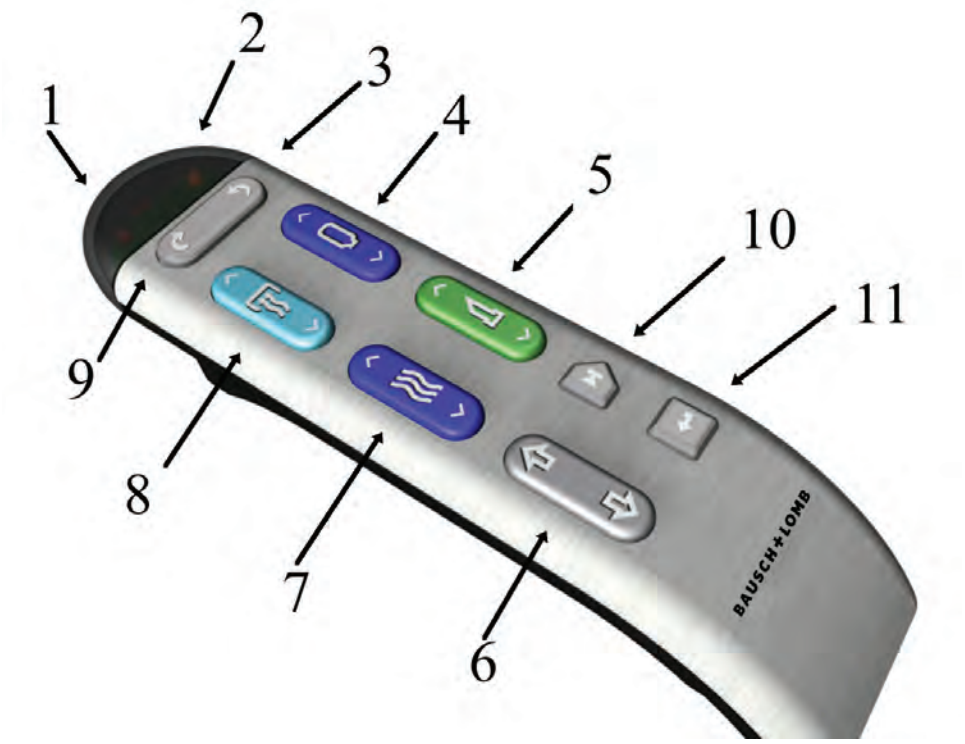


Figure 1.25. **Remote Control Functions**.

1. Low Battery Light. 2. Transmitting Signal Light. 3. Next Phase.
4. Bottle Height or Pressurized Infusion.
5. Phaco, Vitrectomy or Coagulation. 6. Up and Down. 7. Flow. 8. Vacuum. 9. Previous Phase.
10. Reserved for Future Use. 11. Enter.

In the anterior domain, the remote control can be used to activate functions in the “Prime and Tune” window of the setup screen. The remote control UP/DOWN buttons are used to move the arrow and select options in the “Prime and Tune” window. Pressing the “Enter” button on the remote control activates the selected function.

Note: *The batteries should be removed from the remote control if the system is to be idle for more than 30 days.*

Note: *It is your responsibility to dispose of batteries in a safe and environmentally-responsible manner in accordance with local regulations.*

Digital Media System (DMS) (Optional)

The DMS (if available) receives streaming of surgical settings from ***Stellaris Elite***™ and combines surgical video to provide overlay capability. See DMS Operator's Manual for setup details.

*Laser (***Stellaris Elite™** *BL15455 system only)*

See 1.14. Laser Function on page 1-71 for details on use of the laser function (if available).

1.12. Foot Control

The Foot Control is the main interface between the surgeon and the ***Stellaris Elite***™ vision enhancement system. The surgeon can control most of the available functions from the Primary (Integrated) Foot Control. The Primary (Integrated) Foot Control can be connected through a physical cable, or through a wireless Bluetooth connection. When the Primary (Integrated) Foot Control cable is not in use, make sure to install the attached protective caps into the cable ports.

This device complies with Part 15 of the FCC (U.S. Federal Communication Commission) Rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesired operation.

Summary of Wireless Specifications for Wireless Foot Controller

Item	Specification
Bluetooth version	V4.0 compliant
Operating frequency	2402.0 MHz to 2480.0 MHz (per FCC ID RFRMSR)
Operating distances	No minimum
Ranges	10 meters (maximum)
Wireless functions/ capabilities	Wireless functionality is the same as that in the wired configuration and is configurable by the user as described in Section 1.12.
FCC Compliance	Complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesired operation.

The ***Stellaris Elite***™ vision enhancement system is compatible with the Primary (Integrated) Foot Control. The Primary (Integrated) Foot Control contains a laser firing switch, and can use either wired or wireless communication. The foot control charger and battery are interchangeable.

Note: *In this manual, the term "Foot Control" will indicate information that applies to the Primary (Integrated) Foot Control.*

Figure 1.26. **Primary (Integrated) Foot Control**.

Figure 1.27. **Placement of Primary (Integrated) Foot Control During Storage**.

The Primary (Integrated) Foot Control contains an internal, rechargeable battery. The battery cover has the battery symbol on it.

The battery must be charged overnight prior to initial wireless use, or if the system is idle for more than seven days. Refer to the battery charging options section on page 1-55.

Foot Control Battery Replacement:

Note: *Replacing the battery when the system is powered up will disable the Primary (Integrated) Foot Control wireless setup. To re-enable wireless setup, see page 1-51.*

1. Place the Primary (Integrated) Foot Control upside down on a flat, dry surface.
2. Open the battery door by pressing the targets on the door toward the battery compartment and turn the two latches 90 degrees away from the center.
3. Remove the battery with two fingers holding on to the battery.

4. Before installing the replacement battery, check the battery electrical contacts to ensure they are clean and free of contamination.
5. Install the new battery.
6. Press the door toward the compartment and engage door latches to securely close the battery door.

Note: *Following system shutdown, wait a minimum of 15 seconds before restarting the system. The system is fully shut down after the front panel power button light changes from dim to bright.*

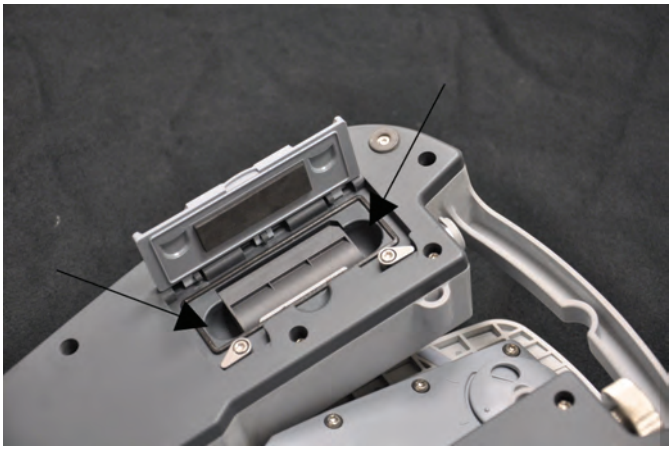


Figure 1.28. **Battery compartment with recess (arrows) to facilitate battery replacement**.

Note: *Be sure to securely close battery door.*

Note: *A battery must be installed in the Primary (Integrated) Foot Control at all times, while operating either wired or wireless, to ensure proper operation.*

LED Symbol for Battery on Primary (Integrated) Foot Control

Note: *The out-of-factory Wireless System Setup is "Disabled". Software upgrade will also reset the Wireless System Setup to "Disabled".*

Note: *Replacing the battery when the system is powered up will disable the Primary (Integrated) Foot Control wireless setup.*

Note: *The system setup is for enabling wireless functionality; it does not affect the wired functionality. The wired option is always available and active when connected.*

Note: *The system will disable wireless operation once it detects loss of wireless communication at the setup and surgery screens. Once wireless connectivity is lost, the wireless operation must be manually re-configured, using the system setup screens or the Action button on the last connectivity message. Irrigation/Infusion will be turned on if the wireless connection is lost.*

Note: *The system will disable wireless operation when the battery is replaced or removed while system is in surgical or setup screens. To configure system to wireless operation, see section on Wireless Primary (Integrated) Foot Control System Setup, page 1-51.*

The first time a Primary (Integrated) Foot Control is used, it must be connected via the backup cable to set the configuration. Once this is set, the Primary (Integrated) Foot Control will only communicate wirelessly with that specific system. To begin wireless operation, make sure the ***Stellaris Elite***™ vision enhancement system is on, then press any Primary (Integrated) Foot Control Button and wait for communication to be established, which may take up to 10 seconds.

The ready light, identified by the symbol below, will turn solid green when the Primary (Integrated) Foot Control is communicating wirelessly with the ***Stellaris Elite***™ vision enhancement system. During operation when system is not detecting Primary (Integrated) Foot Control wireless connection, the system will disable wireless operation. This happens when the system is in setup and surgery screens. To resume wireless operation, refer to the Wireless Primary (Integrated) Foot Control System Setup (page 1-51).

LED Symbol for Ready on Primary (Integrated) Foot Control

When not in use, the Primary (Integrated) Foot Control can be stored on the back of the ***Stellaris Elite***™ vision enhancement system.

In some operating configurations the surgeon can change surgical phases using the Primary (Integrated) Foot Control.

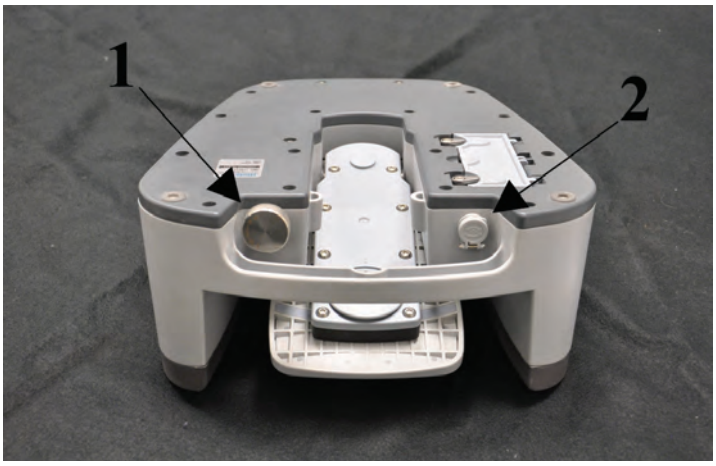


Figure 1.29. **Back of Primary (Integrated) Foot Control**.

1. Pedal Pitch Tension Adjustment Knob. 2. Backup Power Cord Connection.

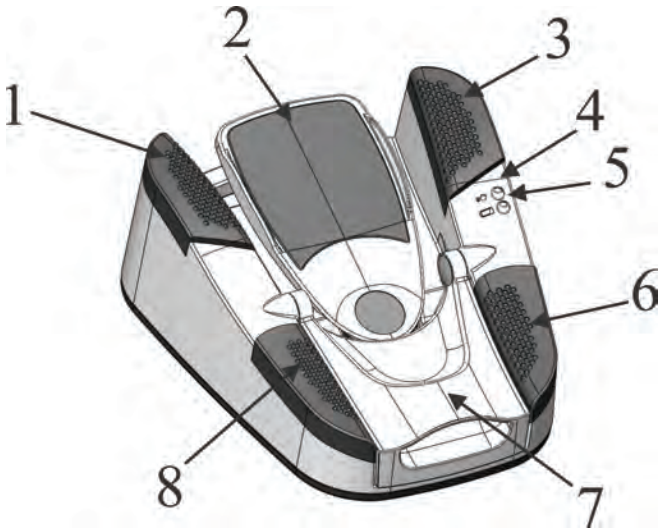


Figure 1.30. **Top of Primary (Integrated) Foot Control**.

1. Left Toe Button. 2. Foot Pedal. 3. Right Toe Button. 4. Wireless Indicator. 5. Battery Indicator. 6. Right Heel Button. 7. Laser Firing switch (cover closed) [not functional on the ***Stellaris Elite***™ Anterior systems]. 8. Left Heel Button.

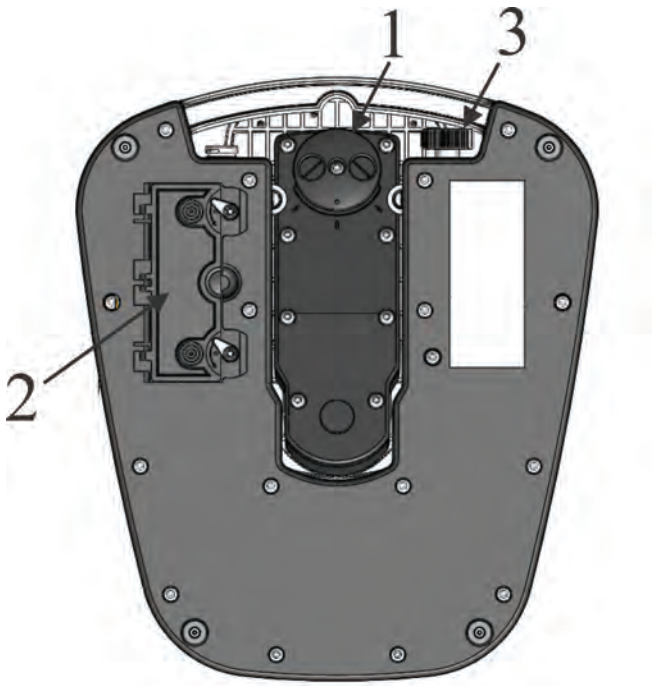


Figure 1.31. **Bottom of Primary (Integrated) Foot Control**.

1. Pedal Offset Switch. 2. Battery Compartment Door. 3. Pedal Pitch Tension Adjustment Knob.

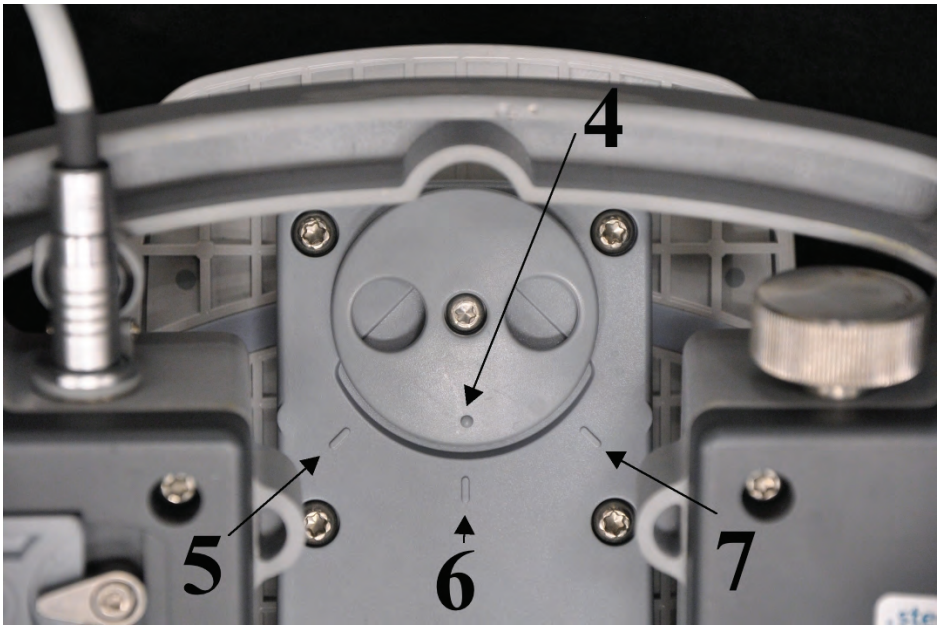


Figure 1.32. **Pedal Offset Switch Indicator (4) and Pedal Offset Positions (5, 6, and 7)**.

4. Pedal Offset Switch Indicator. 5. Left Offset (for system setup of left foot operation).
6. Center Position (for system setup for left or right foot).
7. Right Offset (for system setup for right foot operation).

Note: *The pedal offset switch indicator must align with either Left, Right or Center pedal offset position. Failure to align the indicator appropriately will cause the Primary (Integrated) Foot Control to become inoperable. Left or Right offset position selections strictly follow system software programming for Left or Right foot operations. For example, if the system is programmed to Right foot operation, the indicator (4) can only be set to Center (6) or Right Offset Position (7).*

Wireless Primary (Integrated) Foot Control System Setup

Note: *The out-of-factory Wireless System Setup is "Disabled". Software upgrade will reset the Wireless System Setup to "Disabled" also.*

To set up wireless operation, follow steps below:

Step 1: Select "Programming" from Setup or "Select Surgeon" screens.

Step 2: Select "System Setup" from the programming screen, as shown below.

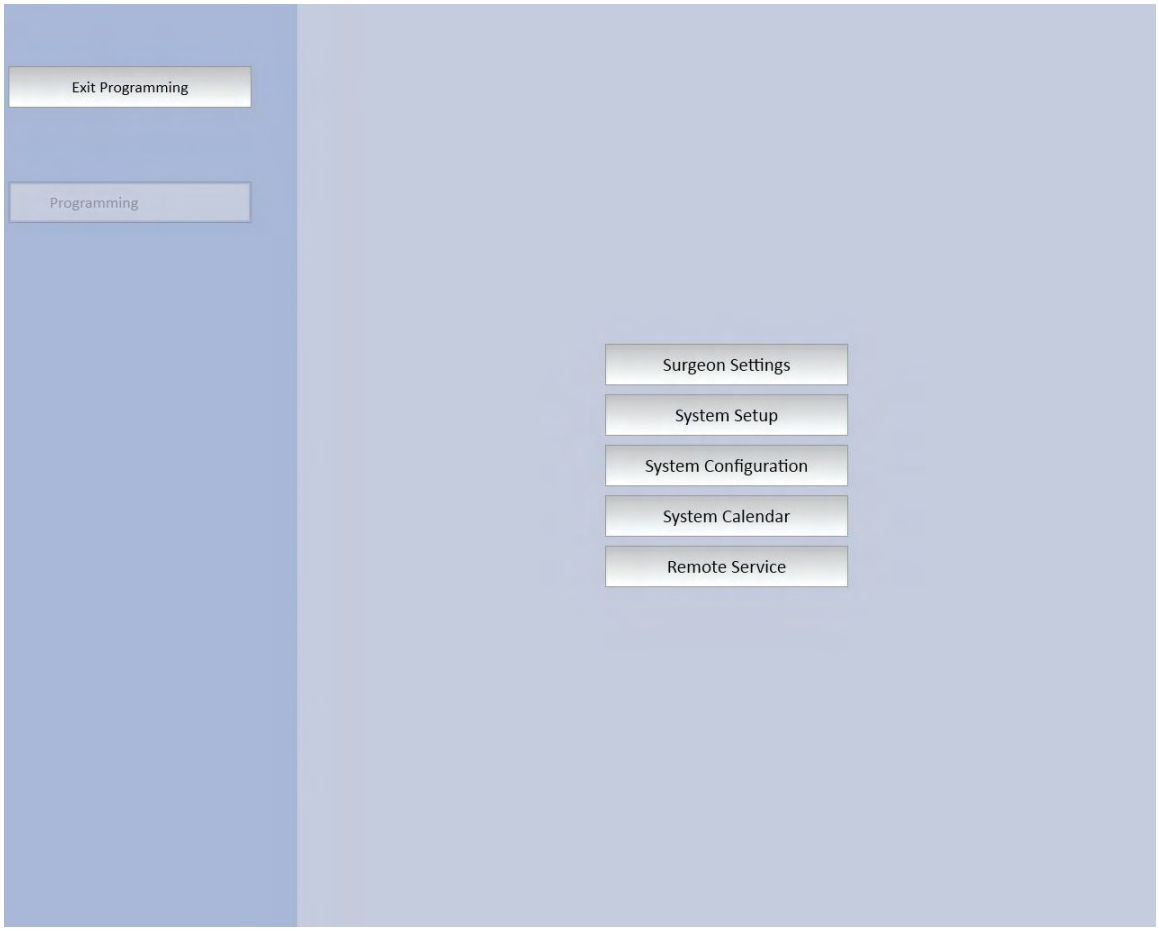


Figure 1.33. **Programming Screen**.

Step 3: Select "Primary (Integrated) Foot Control" tab from the System Setup screen.

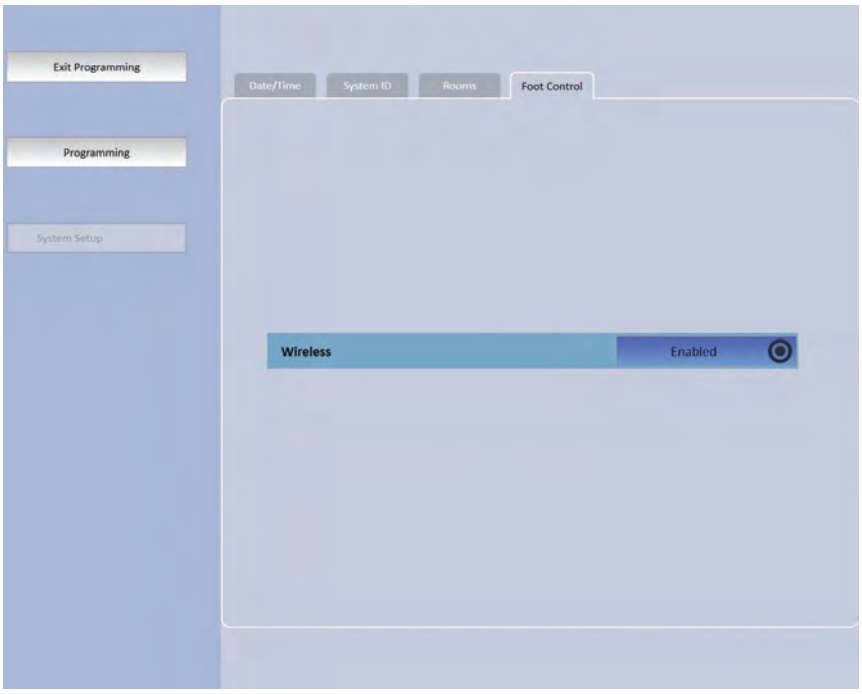


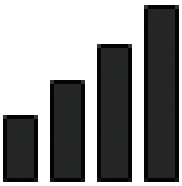
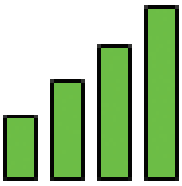
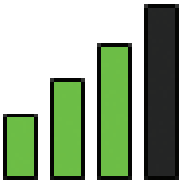
Figure 1.34. **System Setup Screen, Foot Control Tab**.

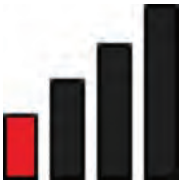
Step 4: Select Wireless “Enabled” or “Disabled” to configure Primary (Integrated) Foot Control connection mode.

Primary (Integrated) Foot Control Status and Wireless Signal Strength Meter Display

The status of Primary (Integrated) Foot Control operation is represented by an icon displayed next to the Foot Pedal activation status indicator. Wired connectivity is represented with a cable icon and the wireless connectivity is indicated with a signal strength meter icon. See table below:

Display Type	Primary (Integrated) Foot Control Setup	Status	Action
	Wired or Wireless	System detecting wired Primary (Integrated) Foot Control	No action required

Display Type	Primary (Integrated) Foot Control Setup	Status	Action
	Wired (Wireless disabled)	System NOT detecting wired connection. Possible cause: Primary (Integrated) Foot Control cable not connected.	Check Primary (Integrated) Foot Control cable connection. If Wireless System Setup is on “enabled,” wireless connection will be activated momentarily when system detects loss of wired connection. The wireless signal strength icon will be displayed indicating system is now in wireless operation.
	Wireless	System NOT detecting wireless connection signal. Possible cause: 1. Primary (Integrated) Foot Control wireless function has not been activated. 2. Wireless connectivity not functioning due to battery issue.	1. Initiate wireless Primary (Integrated) Foot Control connectivity by pressing one of the Primary (Integrated) Foot Control buttons momentarily, the left LED will light up. 2. Check battery if Primary (Integrated) Foot Control wireless function not established after Step 1.
	Wireless	System detecting Excellent signal strength.	No action required.
	Wireless	System detecting Good signal strength.	No action required.

Display Type	Primary (Integrated) Foot Control Setup	Status	Action
	Wireless	System detecting Moderate signal strength.	No action required.
	Wireless	System detecting Low signal strength.	No action required
	Wireless (System disabled wireless setup)	System lost wireless connection signal during procedure. System will automatically configure to wired operation. The icon remains until connected with Primary (Integrated) Foot Control cable or manually re-configures system to wireless configuration.	Connect Primary (Integrated) Foot Control backup cable to resume operation. Note: System will remain in wired configuration the next time system is powered up. To configure system to wireless operation, see section on Wireless Primary (Integrated) Foot Control System Setup, page 1-51.

Note: *Irrigation or infusion will be turned ON and other functions will be disabled when the system does not detect Primary (Integrated) Foot Control connectivity in surgical mode. Irrigation or infusion can be turned OFF from the touch screen.*

Battery Management

This symbol on the battery indicates that the product must be disposed of separately and safely. Therefore, it is your responsibility to dispose of this waste equipment by handing it over to a designated collection point or organization that specializes in the recycling of waste electrical and electronic equipment. The separate collection and recycling of waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects both human

health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local recycling office or electronic waste hauler.

CAUTION: Do not expose the battery to any fluids.

The battery, when fully charged, will last for 12 hours. You may rely on a single battery, or choose to keep one charging in a battery charging cradle (BL4393) while the other battery is being used.

Figure 1.35. **Foot Control battery Charging Cradle**.

Battery Charging Options

Note: *The battery should be removed from the Primary (Integrated) Foot Control if the system is to be idle for more than seven days.*

Note: *To maximize performance, the Primary (Integrated) Foot Control batteries (BL4390) should be rotated every two months. Upon removal, battery must be charged before it is stored.*

Note: *Use only Bausch + Lomb supplied wall chargers (BL4391), charging cradles (BL4393), and batteries (BL4390) with the* **Stellaris Elite™** *vision enhancement system.*

The Foot Control battery should be charged whenever the system is not in use. Any one of three methods can be used to charge the battery.

- With the system power cord plugged into the electric source and the Primary (Integrated) Foot Control connected to the system, the battery will be charged if the main power switch is turned ON. This charging method applies with or without the Graphical User Interface being turned ON. See Option 1 in Figure 1.36.
- The Primary (Integrated) Foot Control can be directly connected to the wall charger. Connect the wall charger cable into the back of the Primary (Integrated) Foot Control, into the same receptacle used for the backup cable. See Option 2 in Figure 1.36.

- With an extra battery and battery charging cradle, you can connect the wall charger cable to the battery charging cradle. A green light indicates the cradle is on, a second light is yellow when charging is in progress, and green when the battery charging is complete. Once the battery is fully charged, you can take it out of the cradle and replace the battery in the Primary (Integrated) Foot Control. See Option 3 in Figure 1.36.

Note: *When the Primary (Integrated) Foot Control is connected to the wall charger it will not communicate with the system and cannot be used in surgery.*

Note: *To connect the backup cable or wall charger to the Primary (Integrated) Foot Control, align the red dot of the connectors to the 12 o'clock position.*

Note: *The Primary (Integrated) Foot Control is only to be used with wall charger BL4391.*

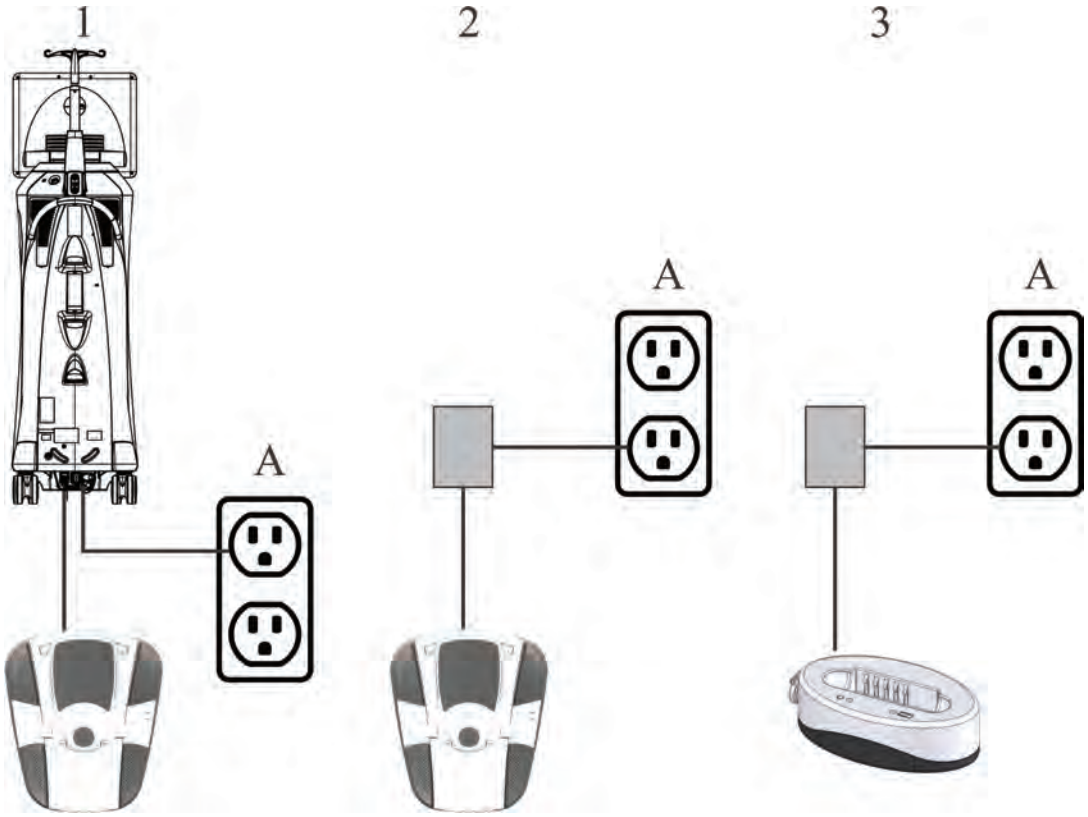


Figure 1.36. **Foot Control Battery Charging Options**.

1. Using Primary (Integrated) Foot Control Backup Cable.
2. Using Wall Charger. 3. Using Charging Cradle.
A = Electrical Power Source.

Note: *The battery charging cradle **MUST** be connected to the wall charger to charge the battery.*

Wireless communication is disabled when the backup cable is in place.

The ***Stellaris Elite***™ vision enhancement system will provide a warning message when the battery is nearing the end of its life. Call your customer service representative for a replacement battery. See Chapter 7 for a list of local Bausch + Lomb offices.

Primary (Integrated) Foot Control Operation

The Primary (Integrated) Foot Control has four side buttons, and a center Foot Pedal with two axes of movement to control two linear functions simultaneously. In addition, there is a laser firing switch at the heel resting area protected with a laser firing switch cover. To control two linear functions simultaneously, the Foot Pedal operates with both the pitch (up and down) and yaw (side to side) travel. The yaw movement simulates the side switches used on some systems, and can be set and programmed for left-foot or right-foot users. Reflux (if selected) is always activated by inward yaw displacement. The center Foot Pedal may be programmed to operate two linear functions simultaneously (Dual Linear control). The control of linear functions is proportional to the amount of Foot Pedal travel. See page 1-60 for description of linear control. In single linear mode, pitch controls the linear functions selected, and yaw movement provides on/off control in both directions. In Dual Linear mode, one linear function is controlled by pitch travel, and the other linear function is controlled by yaw travel. The table on page 1-63 shows the possible combinations of linear control.

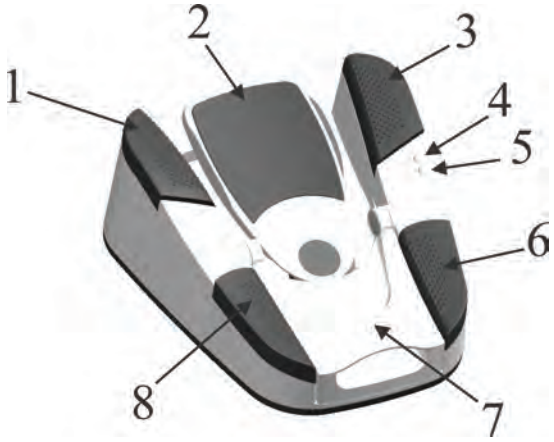


Figure 1.37. **Primary (Integrated) Foot Control, labeled**.

1. Left Toe Button. 2. Foot Pedal. 3. Right Toe Button. 4. Wireless Indicator. 5. Battery Indicator. 6. Right Heel Button. 7. Laser Button Cover. 8. Left Heel Button.

There are two lights on the Primary (Integrated) Foot Control itself. The top light on the right indicates that the wireless connection on the Primary (Integrated) Foot Control is active. This light will flash until communications are established with the system. When the light is non-flashing green, the Primary (Integrated) Foot Control is ready to be used wirelessly. The bottom light on the right indicates battery status, as described in the table below.

Color	Status
Green	More than one hour of battery life remains
Yellow	Battery is charging
Red and Blinking	Less than one hour of battery life remains

Note: *The GUI will provide an auditory and visual indication that less than one hour of battery life remains and requires engagement by the user for the condition to be dismissed. In addition to the GUI messaging, the red blinking LED (on the Foot Control) also indicates less than one hour of battery life, though it is out of the user's immediate line of sight.*

Basic Button Operation

Note: *Voice confirmation (if enabled) responds to Primary (Integrated) Foot Control and remote control operation. For surgical phase changes, voice confirmation also will be activated if changes are made through the touch screen.*

All four buttons on the Primary (Integrated) Foot Control are user programmable. They are initially set in the surgeon preferences file, and can be modified either through the programming interface (see Chapter 3), or in some cases through the **More Screen Foot Control Tab** (see page 2-13).

The **More Screen Foot Control Tab** is used to convey the current Foot Pedal configuration and status to the surgical team, and is accessed by selecting the More Screen button.

For a description of the laser firing switch, see page 1-76.

Foot Pedal

The Foot Pedal itself, located in the center of the Primary (Integrated) Foot Control, provides two axes of movement and thus allows simultaneous control of two system parameters. Both controls are programmable with respect to function and control parameters. In the pitch direction, the Foot Pedal will provide approximately 15° of up/down movement. In the yaw direction, the center pedal will provide approximately 10° of travel from center in both the left and right directions; however, the center (home) position may be set to be offset approximately 5° in either direction as explained on page 1-60. When released, the Foot Pedal will return to the home (up or center) position. The table on page 1-63 shows the possible combinations of control available. The programmable detents provide tactile feedback to the pitch movement when it moves between different regions.

Single Region Pitch Control (one detent position)

The pitch movement is programmed to provide linear control as a function of relative Foot Pedal displacement (e.g., 0° to 15° down corresponds to 0% to 100% output). Examples of single region pitch control are the linear coagulation function and linear vitrectomy function.

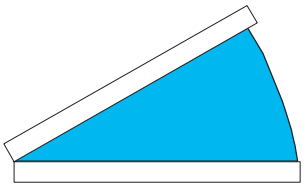


Figure 1.38. **Single Region Pitch Control**.

Two Region Pitch Control

There are two programmable regions (two detent positions). When programmed for linear control, the pitch movement is a function of relative Foot Pedal displacement in Region 2 (e.g., 5° to 15° down corresponds to 0% to 100% output). An example is Irrigation/Aspiration I/A control, where Region 1 is for irrigation, and Region 2 is for linear vacuum or flow.

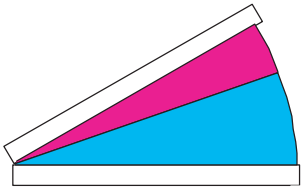


Figure 1.39. **Two Region Pitch Control**.

Three Region Pitch Control

There are three programmable regions (three detent positions). When programmed for linear control, pitch movement is a function of relative Foot Pedal displacement as shown below. An example is single linear ultrasound phases, where Region 1 is irrigation, Region 2 is fixed aspiration, and Region 3 is linear ultrasound power.

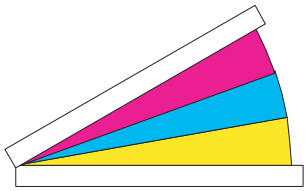


Figure 1.40. **Three Region Pitch Control**.

Programmable Yaw Positions

The Primary (Integrated) Foot Control may be set and programmed to give greater linear yaw movement for either right or left foot operation. Turn the Primary (Integrated) Foot Control over and adjust the Pedal Offset Switch to the left or right for preferred direction.

- Set and programmed for a right footed operator with the pedal home position offset to the left of center by approximately 5° to give approximately 15° of motion to the right and approximately 5° of motion to the left. See **Dual Linear Yaw Setup** description on page 1-61.
- Set and programmed for a left footed operator with the pedal home position offset to the right of center by approximately 5° to give approximately 15° of motion to the left and approximately 5° of motion to the right. See **Dual Linear Yaw Setup** description on page 1-61.
- Set and programmed for a right or left footed operator with the pedal home position in the center giving approximately 10° of motion in both directions.

The pedal offset switch indicator must align with either left, right or center pedal offset position. Failure to align the indicator appropriately will cause the Foot Control to become inoperable. Left or right offset position selections strictly follow system software programming for Left or Right foot operations. See page 1-50.

Single Linear Setup

In Fixed Cut **Vitrectomy Mode**, the outward yaw movement provides ON/OFF cutting control. Each successive outward movement toggles the programmed tool ON or OFF. In ultrasound mode, outward yaw control could be programmed to toggle between different ultrasound submodes. When the Foot Pedal is released, it returns to the center position. Inward yaw movement controls reflux.

Dual Linear Setup

The outward yaw movement provides linear control of the programmed function, relative to Foot Pedal displacement (e.g., 0° to 15° displacement corresponds to 0% to 100% output). When the Foot Pedal is released, it returns to the center position. Inward yaw movement controls reflux.

Yaw Control of Reflux

The Foot Pedal may be programmed for use with either the right or left foot. **Reflux** (if selected) is always activated by inward yaw displacement. For a right foot configuration, reflux is to the left (inward). For a left foot configuration, reflux would be to the right. **Reflux** may only be activated when aspiration is not activated.

Yaw Control of Ultrasound Submode

For single linear setup, the ultrasound submode sequence (if programmed) is activated by inward or outward yaw when the Foot Pedal is in Region 2 or Region 3. In a **Dual Linear Setup**, the yaw control of the ultrasound submode can only be activated (if programmed) by inward yaw when the Foot Pedal is in Region 2 or Region 3.

Yaw Control of Continuous Irrigation On/Off

This function is available in software version 5.3 and above. The system can be configured so that outward yaw turns continuous irrigation on/off. This function applies only to the Irrigation, Single Linear Phaco, and Irrigation/Aspiration (I/A) phases. This function can be enabled/disabled in two ways: 1. Customize Technique screen under the Foot Control tab. 2. Customize Phase screen under the Foot Control for Irrigation, Single Linear Phaco, and I/A. The system will notify users with voice confirmation when continuous irrigation is turned on or off using outward yaw in the Primary (Integrated) Foot Control.

Linear Coagulation Control

The control power is varied linearly from preset minimum to the preset limit. Power begins when entering Foot Pedal position 1 and ends at the completion of travel.

Note: *Due to compliance with 60601-2-2, position 1 will not start until approximately 35% of pedal travel is attained in the linear coagulation mode.*

Use of Laser Functions on Foot Controls

The ***Stellaris Elite***™ vision enhancement system can support up to two Foot Controls in simultaneous use. Either foot control can be used for either laser function, LIO or Endo. By default, the Primary (Integrated) Foot Control is selected for use when in an Endo mode, and the Secondary (LIO) Foot Control is selected for use in LIO modes.

Primary (Integrated) Foot Control (BL2295)

The laser firing switch is concealed in the heel resting area of the Primary (Integrated) Foot Control (BL2295). To access the laser firing switch, lift the safety cover. The door may be opened to any angle up to 45 degrees. To activate the laser, depress the laser firing switch. This is a momentary ON switch that automatically returns to the OFF position when released. In all Laser Modes, depressing the main pedal activates linear aspiration.

All four of the side buttons on the Primary (Integrated) Foot Control are user programmable. The buttons can be programmed using the **More Screen Laser Tab** to adjust laser power up, laser power down, toggle Single Shot/Repeat and toggle laser Standby/Ready.

Figure 1.41. **Primary (Integrated) Foot Control**.

1. Laser firing switch, under open Safety Cover.

Secondary (LIO) Foot Control (BL2296)

The Secondary (LIO) Foot Control has a main pedal, and one switch on either side. Pressing down on the pedal activates the laser.

The two side buttons on the Secondary (LIO) Foot Control increment laser power up and down, and are enabled through the **More Screen Laser Tab** (page 2-23), or the Phase Programming Screen (page 3-9).

The LIO (Secondary) Foot Control operates in wired mode only, and connects to the system to the right of the connection port for the Primary (Integrated) Foot Control.

Figure 1.42. **Secondary (LIO) Foot Control**.

See Chapter 3 for details on customizing your Foot control.

Center Primary (Integrated) Foot Control

Phase Type	Dual Linear Control	Region	Pitch	Yaw Out
Ultrasound	Disabled	R1	Irrigation	Next submode
		R2	Fixed aspiration	
		R3	Linear ultrasound	
	Disabled (Continuous Irrigation On/Off Activation in Yaw)	R1	Irrigation	Continuous Irrigation On in all positions
		R2	Fixed aspiration	
		R3	Linear ultrasound	Continuous Irrigation Off in R0 and R1
	Disabled (with Region 2 Linear Vacuum Enabled or aspiration control feature on)	R1	Irrigation	Next submode
		R2	Aspiration R2 minimum to fixed vacuum or vacuum limit	
		R3	Fixed aspiration & linear ultrasound	
	Disabled (with Region 2 Linear Vacuum Disabled or aspiration control feature off)	R1	Irrigation	Next submode
		R2	Linear Aspiration disabled	
		R3	Fixed aspiration & linear ultrasound	
	Aspiration on yaw (with Region 2 Linear Vacuum Disabled or aspiration control feature off)	R1	Irrigation	
		R2	Minimum aspiration	Linear aspiration
		R3	Linear ultrasound	
	Aspiration on yaw (with Region 2 Linear Vacuum Enabled or aspiration control feature on)	R1	Irrigation	
		R2	Aspiration R2 minimum to fixed vacuum or vacuum limit	To max. aspiration
		R3	Min. aspiration and linear ultrasound	
	Aspiration on Pitch	R1	Irrigation	
		R2	Linear aspiration	Linear ultrasound
	Dual Linear Ultrasound	R1	Irrigation	
		R2	Fixed Aspiration	
		R3	Linear U/S Function	Linear Ultrasound

Phase Type	Dual Linear Control	Region	Pitch	Yaw Out
Irrigation/ Aspiration	Disabled	R1	Irrigation	
		R2	Linear aspiration	
	Disabled (Continuous Irrigation On/Off Activation in Yaw)	R1	Irrigation	Continuous Irrigation On in all positions
		R2	Linear Aspiration	Continuous Irrigation Off in R0 and R1
Irrigation Only	Disabled	R1	Irrigation	
	Disabled (Continuous Irrigation On/Off Activation in Yaw)	R1	Irrigation	Continuous Irrigation
Anterior Vitrectomy	Disabled	R1	Irrigation	
		R2	Linear Aspiration & fixed vitrectomy when on	Cutter On/Off
	Aspiration on Pitch	R1	Irrigation	
		R2	Linear Aspiration	Linear Vitrectomy
	Aspiration on Yaw	R1	Irrigation	
		R2	Linear Vitrectomy	Linear Aspiration
Posterior Vitrectomy Auto On or Manual Infusion	Disabled (Fixed cut)	R1	Linear Aspiration and fixed cut vitrectomy when On	Cutter On/Off
	Disabled (Single cut)	R1	No Function	Single Cut
		R2	Linear Aspiration	Single Cut
	Aspiration on Pitch (Dual/Yaw Cut)	R1	No Function	Linear Cut
		R2	Linear Aspiration	Linear Cut
	Aspiration on Yaw (Dual/Yaw Vac)	R1	No Function	Linear
		R2	Linear Cut	Linear Aspiration
	Disable (co-linear)	R1	Linear Aspiration and Cut	Cutter On/Off

Phase Type	Dual Linear Control	Region	Pitch	Yaw Out
Posterior Vitrectomy Infusion Auto On/Off	Disabled (Fixed Cut)	R1	Irrigation On	Cutter On/Off
		R2	Linear Aspiration and fixed cut vitrectomy when On	
	Disabled (Single Cut)	R1	Irrigation On	Single Cut
		R2	Linear Aspiration	
	Aspiration on Pitch (Dual/Yaw Cut)	R1	Irrigation On	Linear Cut
		R2	Linear Aspiration	
	Aspiration on Yaw (Dual/Yaw Vac)	R1	Irrigation On	Linear Aspiration
		R2	Linear Cut	
	Disabled (Co-Linear)	R1	Irrigation On	Cutter On/Off
		R2	Linear Aspiration and Cut	
Extrude	N/A	R1	Linear Vacuum	Linear Coagulation if Programmed
Extrude Infusion Auto On/Off	N/A	R1	Irrigation On	
		R2	Linear Vacuum	
Fragmentation	Disabled (Linear Frag)	R1	Linear Vacuum	Toggle U/S Submode
		R2	Max Vacuum Linear U/S	
	Ultrasound on Yaw (Dual/Yaw US)	R1	Irrigation On	Linear U/S
Fragmentation Infusion Auto On/Off	Disabled (Linear Frag)	R1	Irrigation On	Toggle U/S submode
		R2	Linear Vacuum	
		R3	Max Vacuum Linear U/S	
	Ultrasound on Yaw (Dual/Yaw US)	R1	Irrigation On	Linear U/S
		R2	Linear Vacuum	

Phase Type	Dual Linear Control	Region	Pitch	Yaw Out
Viscous Fluid Control	Disable (Fixed Inject, Linear Inject, Fixed Extract or Linear Extract)	R1	Inject (Fixed), Inject (Linear), Extract (Fixed) or Extract (Linear)	N/A
	Aspiration on Yaw (Dual/Yaw Vac)	R1	No function or Irrigation On if infusion type Auto On/Off	Linear Vacuum
		R2	Inject (Linear)	
Linear Coagulation	N/A	R1	Linear Coagulation	N/A
Laser	All Laser Modes	R1	Linear Vacuum	N/A
Laser Infusion Auto On/Off	All Laser Modes	R1	Irrigation On	N/A
		R2	Linear Vacuum	

Note: *In Single Linear Phaco Phase, if the continuous irrigation activation in yaw on/off function is enabled, the ultrasound next submode on yaw function cannot be enabled. The continuous irrigation in yaw function must be disabled to enable the ultrasound next submode on yaw function.*

1.13. Illumination Function

Note: *The Illumination controls can be disabled through the* ***Illuminators Tab*** *on the* ***Customize Technique*** *programming screen (page 3-7).*

Note: *Illumination is not available while in LIO mode.*

General introduction to setting the correct light level

The guidelines provided in this section are based on ISO15752 and ISO15004-2.

The ***Stellaris Elite***™ vision enhancement system illumination system comes with a state of the art visualization module to enhance the surgeon's ability to see effectively during procedures. The output from the illumination probe can attain high-lumen levels if needed; is filtered to minimize hazardous light; and is very flexible, providing easy to access color filter options to enhance safety and tissue visibility.

As with any high-intensity illumination system used in the eye, care is needed during use to reduce potential for damage to intraocular tissues.

WARNING: ***The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at various output % settings is provided within the table entitled "Time to exceed 10 J/cm^2 weighted radiant exposure guideline" located on the following pages. Avoid concentrating the illumination output on a small area of the retina for prolonged periods of time due to the potential for photoretinitis and serious permanent patient injury. Set the illumination level to the minimum needed to perform the surgical procedure.***

There are two mechanisms by which harm can be induced:

- Photoretinitis - photochemical injury to the retina resulting from intense light exposure
- Thermal

In both cases the damage is caused by the intensity of light at a given point, normally called "irradiance" and usually measured as power per square centimeter. This means that the risk of harm is increased when the illumination probe is moved closer to the retina: at a distance of 5 mm from the retina the irradiance is about twice that of the probe at 7 mm.

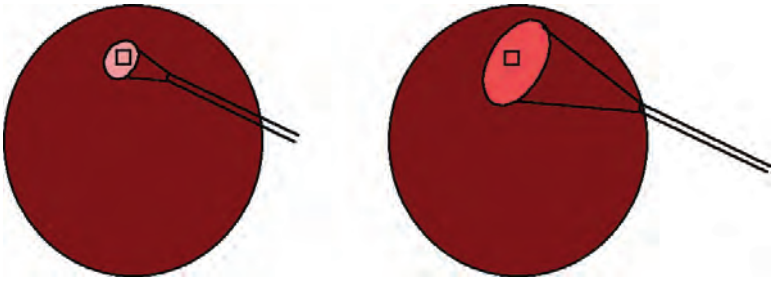


Figure 1.43. **Irradiance as a function of distance**.

For reference, the "lumens" output of an illumination probe is a measure of the total light output at the end of a fiber. For the same lumens output, a focal probe has a higher irradiance (and hence risk of harm) than a wide angle probe because the same total light output is concentrated into a smaller area on the retina. The lumens measurement also takes into account the sensitivity of the human eye to different wavelengths of light.

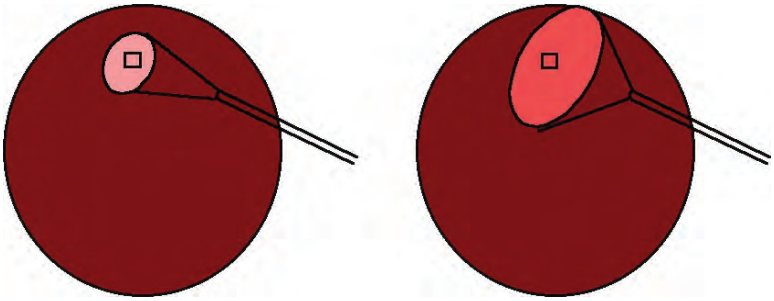


Figure 1.44. **Irradiance as a function of probe type**.

Photoretinitis

Sensitivity versus wavelength

The retina is more easily damaged by ultraviolet and violet-blue light than it is by light with longer wavelengths. The ***Stellaris Elite***™ vision enhancement system incorporates filters to remove ultraviolet light and violet light, but it is not possible to eliminate more of the phototoxic influence without significantly discoloring the light output.

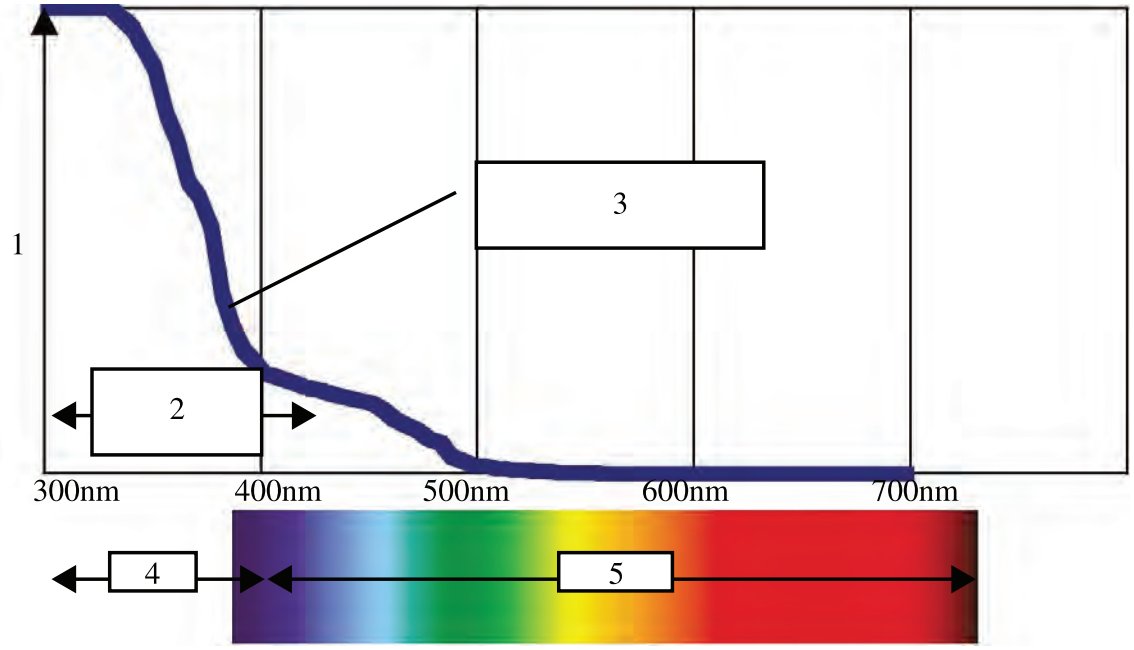


Figure 1.45. **Phototoxic sensitivity vs. light wavelength**.

1. Phototoxic sensitivity. 2. Filtered in ***Stellaris Elite***™. 3. Aphakic hazard weighting function. 4. UV. 5. Visible.

Note that the xenon lamp has a greater phototoxic effect than xenon-mercury for the same apparent brightness.

Time dependency

The risk of developing photoretinitis depends not only on the intensity of light, but also on the duration of the exposure, i.e. the total dose of intensity times duration must be limited to prevent damage. This applies to an uninterrupted beam at a particular point on the retina. Normal surgical procedures do not involve exposure to a single point on the retina, and movement of the light guide would be expected to extend the time before which photoretinitis might occur.

WARNING: ***The light emitted from this instrument is potentially hazardous (see third note below). The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at various outputs may exceed the safety guideline after the times listed in the table below when used with a Bausch + Lomb focal type probe:***

Time to Exceed 10 J/cm² Weighted Radiant Exposure Guideline, in Minutes, at a Working Distance of 15 mm								
Lamp Filter	Mercury				Xenon Mercury			
	None	Amber	Green	Yellow	None	Amber	Green	Yellow
Setting								
100%	29	>120	>30	>30	11	>90	18	16
60%	>40	>120	>70	>70	18	>120	>30	26
50%	>45	>120	>90	>80	20	>120	>30	>30
Default Setting								
40%	>70	>120	>90	>90	27	>120	>45	>40
30%	>90	>120	>120	>120	>30	>120	>60	>50
20%	>120	>120	>120	>120	>50	>120	>70	>70
10%	>120	>120	>120	>120	>90	>120	>120	>120

Note: *The data presented above is for 20 gauge focal illumination probes which are representative worst case. Focal fibers are true worst case due to spot size, therefore midfield and widefield probe time to phototoxicity is greater.*

Note: *The exposure from all light sources is cumulative and additive.*

Note: *If the intensity of any of the light sources is reduced to 50% of the maximum intensity, the exposure time for that light source to reach the exposure guideline is doubled. This linear relationship can be used to determine the approximate time to reach the exposure guideline for the combination of light sources at various intensity settings.*

Note: *The ISO 15004-2 weighted radiant exposure guideline is 10 J/cm².*

Note: *When using two lamps simultaneously at arbitrary settings, the formula for calculating the time to reach the exposure threshold with both lamps running is:*
tc = 1/[(s1 / t1,100)+(s2 / t2,100)] where:

tc = time to reach the threshold for the combination of the two lamps

s1 = (setting of Lamp 1 in %/100%)

s2 = (setting of Lamp 2 in %/100%)

t1,100 = time to reach the threshold with Lamp 1 at 100%

t2,100 = time to reach the threshold with Lamp 2 at 100%

Note: *The use of fibers with wider fields of illumination than focal probes at the same setting and working distance will increase the time before the guidance threshold is exceeded.*

Thermal

WARNING: ***High-intensity visible and infrared light is absorbed as heat in the retina. The* Stellaris Elite™ *includes filters to remove the unwanted infrared from the light output, but the visible light also contributes to the heat absorbed by the retina.***

ISO15004-2 advises limits to the thermal power density received by the retina (in W per cm²). Unlike photoretinitis, these limits are not time-related. With the high-intensity output of the ***Stellaris Elite***™ vision enhancement system, it is possible to exceed these limits with a focal probe at 100% output level with the probe close to the retina.

Color filters

For the lamp in position 1, the user may select one of three color filters that tint the light output to give improved visualization in certain circumstances according to surgeon preference.

The current pre-installed filter colors in the ***Stellaris Elite***™ illumination module are green, yellow and amber. Additional color options may become available later and at customers' request can replace any or all of the current colors.

1.14. Laser Function (Stellaris Elite™ *BL15455 system only)*

Note: *Laser functionality may or may not be available in your region. Even if available in your region, it may or may not be installed on your system.*

Note: *Calibration of the laser function should be performed annually, as described on page 6-3.*

Note: *The laser function is only available in Posterior/Combined modes.*

Potential Risks

WARNING: ***A risk of fire and/or explosion exists when the laser output is used in the presence of flammable materials, solutions or gases, or in an oxygen-enriched environment. Some materials - for example cotton wool saturated with oxygen - may be ignited by the high temperatures produced in normal use of the laser equipment. Flammable solutions used for cleaning or disinfecting, or solvents of adhesives, should be allowed to evaporate before the laser equipment is used. There is also danger of ignition of endogenous gases.***

WARNING: ***Do not remove protective covers, due to shock hazard and accessible laser radiation. Refer servicing to laser qualified personnel.***

WARNING: ***Do not attempt to operate the laser if you suspect it is not working properly. Only factory trained personnel should have access to the interior of the laser.***

WARNING: ***Since the aiming beam passes down the same delivery system as the treatment beam, it provides a good method of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, or its intensity is reduced or it looks diffused, this is a possible indication of a damaged or not properly working delivery system. If possible, try a different delivery device. If there is any doubt, contact Bausch + Lomb Global Product Support. See Chapter 7 for a list of service facilities.***

WARNING: ***Inspect the moveable microscope filter periodically before use to ensure there are no scratches or other damage, and that it is operating properly.***

WARNING: ***Remove all reflective hazards near the laser before operating the laser.***

WARNING: ***All support personnel who are present during laser treatment must wear appropriate laser protective eyewear.***

WARNING: ***The laser protective eyewear provided is not optimized for the aiming beam. DO NOT look directly into the aiming beam even with laser protective eyewear.***

WARNING: ***Never look directly into the fiber-optic cable which delivers the aiming or treatment laser beam, with or without laser safety eyewear.***

WARNING: ***Each delivery device has a proprietary connection that identifies its transmission characteristics. Devices made by other manufacturers cannot be guaranteed to work properly with this system and may result in either no operation or inaccurate laser delivery which could result in serious permanent patient injury.***

WARNING: ***The use of unapproved delivery devices may cause inaccurate laser delivery which could result in serious permanent patient injury. Use only approved delivery devices.***

WARNING: ***Careless handling of the fiber-optic cable, such as improperly inserting or securing the connector, or sharply bending the cable and/or the delivery system, could result in serious permanent patient or user injury.***

WARNING: ***There are potential hazards when inserting, sharply bending, or improperly securing the fiber-optic cable. Not following the recommendations of the manufacturer may lead to damage of the fiber or delivery system and/or harm to the patient or user.***

WARNING: ***The use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.***

WARNING: ***Position all laser delivery devices (LIO or EndoProbes) such that laser energy is never directed toward a door, window, or reflective surface.***

CAUTION: ***The Primary (Integrated) Foot Control, EndoProbe and LIO should be used within 2 meters of the* Stellaris Elite™ *vision enhancement system.***

CAUTION: ***Never leave the powered laser unattended. Before leaving, turn off the Laser Key switch, remove the Laser Key, and place it in a secure location.***

CAUTION: ***Never leave the laser in Ready state when not treating a patient.***

Note: *A laser safety officer should be appointed to supervise the installation and use of the system.*

Note: *The treating physician bears sole responsibility for determining the applicability of the laser system for any patient or condition, and for the clinical effects of any treatment delivered.*

Note: *See page 1-92 for a description of room interlocks, and page 6-4 for specific wiring instructions.*

Laser System Description

Photocoagulation in the posterior mode is accomplished with the ***Stellaris Elite***™ (BL15455) vision enhancement system Laser function. The treatment laser provides a visible green (532 nm CW, 2 W max.) class 4 laser for photocoagulation, and a class 2 diode aiming laser (635 nm CW < 1 mW max.). Laser energy is delivered into the eye through a fiber-optic delivery device. The low-power, red aiming laser is used before and (optionally) during the firing of the treatment laser.

The laser and the type of delivery device determine which clinical treatments can be performed with this system. The ***Stellaris Elite***™ vision enhancement system laser delivery devices are:

- ***Stellaris Elite***™ vision enhancement system Endolaser photocoagulation probes
- Laser Indirect Ophthalmoscope (LIO) for transpupillary delivery of laser energy

Photocoagulation is available when the laser function is installed and the vision enhancement system is operating in the posterior segment surgery mode. The laser function is accessible from the pre-programmed **Clock Menu**.

The laser panel is immediately below the instrument tray, and contains the red Emergency Laser Stop button and the Key Switch.

Figure 1.46. **Front Panel with Emergency Laser Stop button, air vents and Key Switch**.

A Laser Key switch prevents unauthorized use of the laser function. The laser will not operate unless the Laser Key is inserted and in the On position. The Laser Key may be turned on when the system is powered up, so it will be prepared for use. It will take the laser from 40 seconds to several minutes to reach its operating temperature.

The system will sound a laser tone when the laser is firing. There is a volume control for the laser active tone, but the tone cannot be turned off (see page 2-23).

The Emergency Laser Stop Button is a red button located on the front of the system. When pressed, laser emission immediately stops, all related circuits are disabled, and a message is displayed. When the message is cleared, the last status will read **Emergency Laser Stop**.

To re-enter Standby Mode, cycle the Laser Key off and on. The shot counter, laser total time and average power will be reset to zero. The current laser power setting, interval and duration will maintain their prior settings and the system will be in Standby Mode.

The laser delivery device connects to top, left port on the front of the system, as shown below.

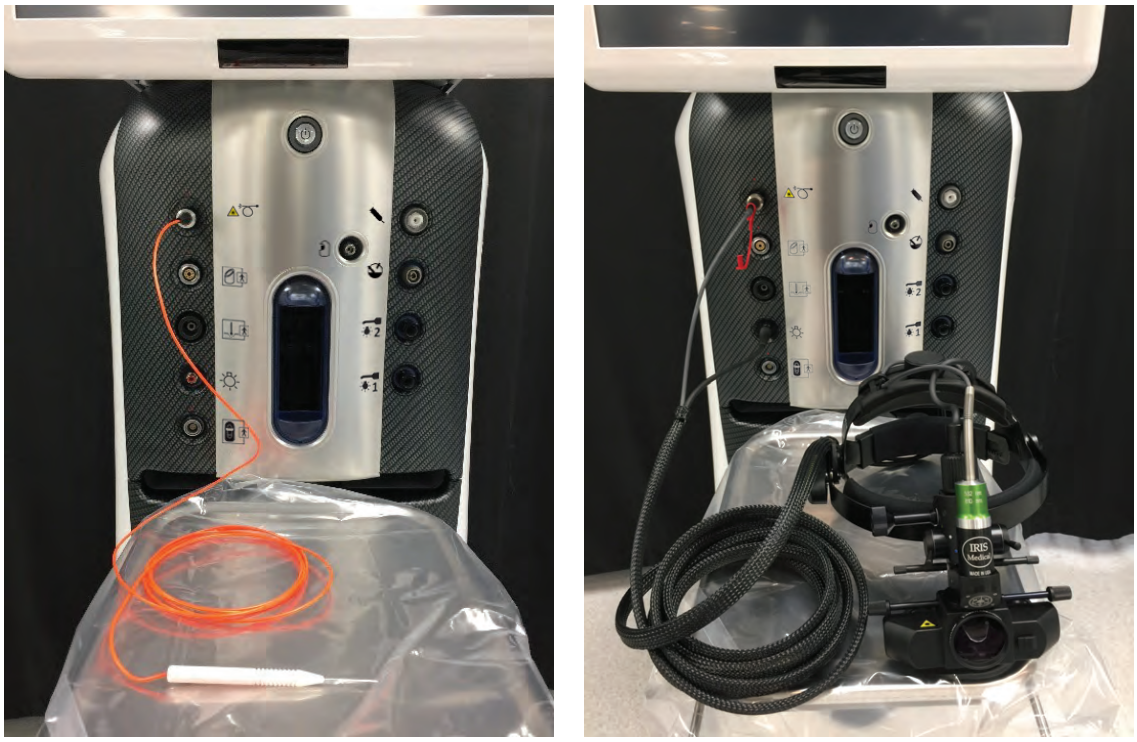


Figure 1.47. **Laser handpiece (left) and LIO (right) connected to system**.

System States

The ***Stellaris Elite***™ vision enhancement system laser has four possible states, as described below.

Laser System	Treatment Laser	Aiming Beam
Off	Disabled	Off
Standby	Disabled	On or Off
Ready	Ready to fire when Foot Pedal depressed	On
Treat	Actively Firing	On (default setting)

Note: *System settings can be changed to turn the aiming beam off when laser is firing.*

Operating Modes

The available surgical tools and modes are:

- Endo - Single Shot, Pulsed, and Continuous Modes
  The EndoProbe consists of a blunt intraocular needle, a handle, and a fiber-optic cable.

An Endo Submode is typically used during vitrectomy, to perform an Endophotocoagulation procedure to seal holes during treatment of retinal detachment, or to perform a panretinal photocoagulation in treatment of diabetic retinopathy.

- Laser Indirect Ophthalmoscope (LIO) (optional distributed product) - Single Shot and Pulsed Modes
  The LIO delivery device adds the treatment option of transpupillary retinal photocoagulation to the diagnostic indirect ophthalmoscope. It enables a physician to deliver laser energy to pathologies in the far periphery of the retina and to treat supine patients. A LIO is typically used for retinal photocoagulation of proliferative and nonproliferative diabetic retinopathy with pathology outside the arcades, retinal tears, lattice degeneration, and localized retinal detachments. For detailed information on the LIO, refer to the user manual as provided with the distributed product.

Note: *Illumination is not available while in LIO mode.*

Laser Foot Controls

The laser function is activated by pressing the laser firing switch on the Primary (Integrated) Foot Control or on the Secondary (LIO) Foot Control. Bausch + Lomb recommends using the Primary (Integrated) Foot Control with EndoProbes and the Secondary (LIO) Foot Control with the LIO. The treatment laser is activated by depressing the predefined laser firing switch on either Foot Control. See page 1-43 for instructions on Primary (Integrated) Foot Control use, setup and battery management.

The Secondary (LIO) Foot Control connects to the lower rear of the system. See Figure 1.2 on page 1-8.

At any given time, only one foot control can be programmed for laser firing. For Endo Submode, the default foot control is the Primary (Integrated) Foot Control. For LIO Submode, the default foot control is the Secondary (LIO) Foot Control.

Note: *Open and close the laser button door cover on the foot control to select and deselect the laser mode automatically, if the option is enabled. The option can be enabled in Surgical More Screen and in the programming.*

Figure 1.48. **Primary (Integrated) Foot Control, with laser firing switch protected by safety cover (open)**.

Figure 1.49. **Laser mode More Screen showing option to enabled/disabled Laser Mode with laser button door cover**.

Laser User Interface

The Laser Mode can be pre-programmed in the user file to be available in the surgical screen **Clock Menu**. When Laser Mode is selected, the surgical screen will display laser settings and system status (see Figure 1.50).

Figure 1.50. **Surgical Screen with Laser on, in Standby State**.

The submode menu appears adjacent to the Laser segment of the **Clock Menu**. The Aiming setting globe and Laser Power setting globe appear in the middle of the screen, just above and on either side of the Laser Status window. The Laser Status window includes the laser shot counter, a button to reset the counter, and the laser status button (toggles between Off, Standby, Ready, and Treat). There may also be a Shot Selector drop-down menu that toggles between Single Shot and Repeat (continuous) modes, as shown in the lower right corner of Figure 1.50.

If the surgeon's file has been programmed to include Laser Mode, the **Clock Menu** will display the Laser segment. Select the laser submode drop-down button to display list of laser submode options.

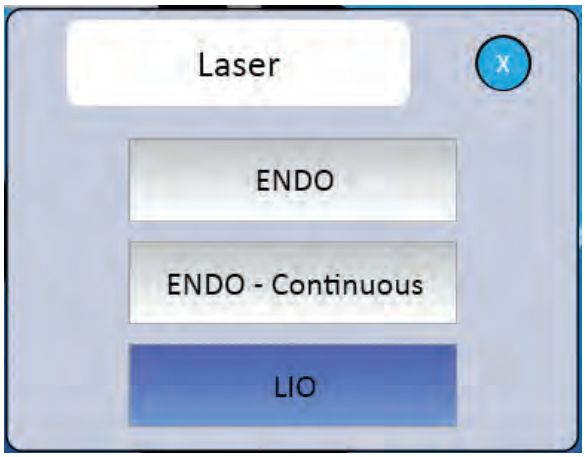


Figure 1.51. **Laser Submode Option List**.

The laser function parameters (Power and Duration) can be changed through the setting globes on the right side of the screen.

A touch button on the surgical screen, below the laser Interval setting globe, allows toggling between Single Shot and Repeat Modes. When set to Single Shot, pressing the laser firing switch will deliver a single laser pulse. When set to Repeat, pressing the laser firing switch will deliver a continuous series of laser pulses until the firing button is released. Alternately, the Primary (Integrated) Foot Control side buttons can be programmed to toggle between the two laser shot settings using the **More Screen Laser Tab** (page 2-23).

Note: *The numeric keypad is only accessible if that surgical function is not currently in use.*

The laser output power may be adjusted from 50 mW to 2000 mW for the Endo Submode, from 50 mW to 500 mW for Endo-Continuous Submode and from 50 mW to 1000 mW for LIO Submode using the up/down arrows:

The Laser duration and interval are adjustable from 10 ms to 3000 ms in steps of:

- 10 ms from 10 ms to 100 ms
- 50 ms from 100 ms to 500 ms
- 100 ms from 500 ms to 3000 ms

Note: *When operating the laser at high powers with a high duty cycle (ratio of the duration of each pulse to the sum of the duration and interval between pulses), if the acceptable thermal limit for laser operation is exceeded, the laser will stop firing and message LAS08 "Laser treatment mode is unavailable - see the laser status" will be displayed. The laser will automatically return to operating temperature. Follow the on-screen instructions to resume laser operation.*

The counter increments once for each laser pulse fired during the procedure. Selecting the clear button resets the counter to zero.

The status button to the right of counter indicates the current status of the laser: Off, Standby, Ready, Treat.

Figure 1.52. **Surgical Screen, Laser Endo Submode, Laser in Ready**.

Aiming Beam

The Aiming Beam controls, including the power setting and On/Off control button, are displayed just below and to the left of the center **Clock Menu**. The Aiming Beam is always on when the system is in Ready state, and is user-programmable to be either On or Off while the system is in Standby state, and On or Off during the treatment pulse, through the **More Screen Laser Tab** (page 2-23). These options can also be pre-programmed in the surgeon file.

The intensity of the Aiming Beam Tool is displayed as a percentage of full power (0.8 mW). This percentage may be changed using the Up/Down arrows on that control, in 5% increments. Selecting the displayed number will bring up a numeric keypad, on which you can enter an exact percentage.

LIO Lamp Tool

The LIO Lamp Tool settings are displayed to the left of the Aiming Beam Tool when Laser LIO Submode is selected. The window displays the LIO Lamp status (on/off) and its current power setting. The intensity of the LIO Lamp is displayed as a percentage of power from 5% to 100% in 5% increments. This percentage may be changed using the up/down arrows, or selecting the number brings up a keypad where you can enter an exact number.

The LIO Lamp Tool will be displayed if the LIO Submode is selected, even if there is no Laser Indirect Ophthalmoscope connected to the system.

Figure 1.53. **Surgical Screen, Laser LIO Submode, Laser in Standby**.

Figure 1.54. **System with LIO connected**.

The LIO Lamp cable connects to the port on the left side of the ***Stellaris Elite***™ vision enhancement system, second connector from the bottom.

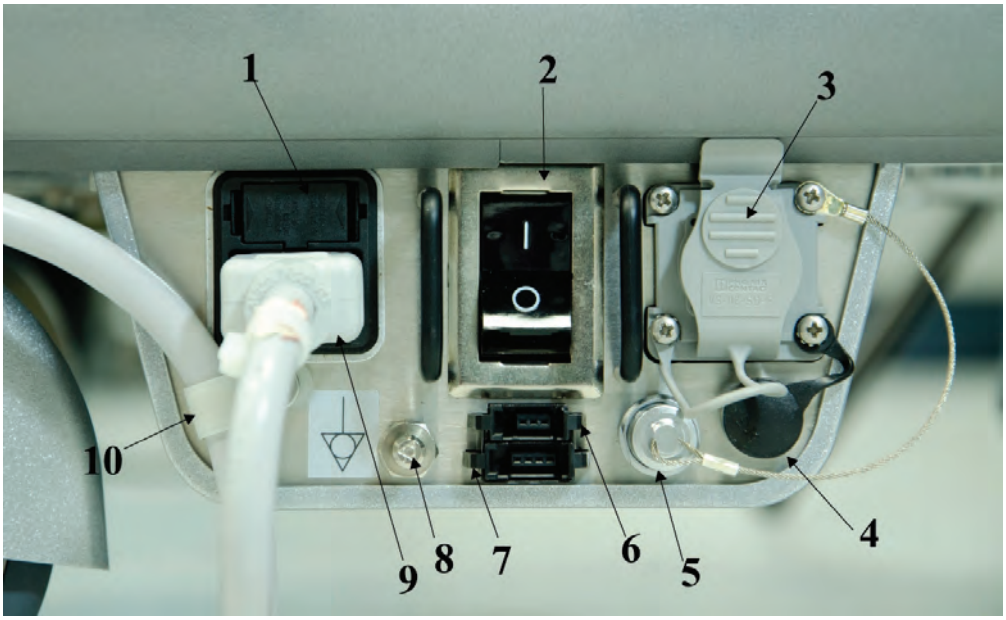


Figure 1.55. **Room Interlock (7) and Microscope Filter Interlock (6) ports**.

1. Fuse Holder. 2. Main Power Switch, disconnects system from mains voltage. See 60601-1, paragraph 8.6.7. 3. Ethernet Port. 4. Secondary (LIO) Foot Control Port. 5. Primary (Integrated) Foot Control Backup Cable Port. 6. Microscope Filter Interlock. 7. Room Interlock. 8. Potential Equalization Connector. 9. Power Cord Input. 10. Power Cord Retention Clip.

See page 6-4 for details on use of interlocks.

Figure 1.56. **Surgical Screen showing Laser LIO selected and Laser in Standby state. The LIO Lamp tool is displayed indicating LIO is connected**.

EndoProbe

WARNING: ***Avoid unnecessary illumination of the retina using the aiming beam.***

WARNING: ***Do not apply excessive stress to the EndoProbe to avoid product damage.***

WARNING: ***Avoid contact of the EndoProbe tip with other instruments because of the risk of uncontrolled scatter or damage to the EndoProbe.***

CAUTION: ***All products should be stored in a clean and dry environment.***

The Laser Endo Submode allows the user to deliver laser energy inside the eye with the laser EndoProbe. Contact your Bausch + Lomb representative for a list of available EndoProbes. Bausch + Lomb offers many EndoProbe configurations to meet user needs, in both straight and curved versions. Illuminating EndoProbes incorporate illumination to provide visualization and laser treatment. Aspirating EndoProbes incorporate aspiration to provide suction and laser treatment.

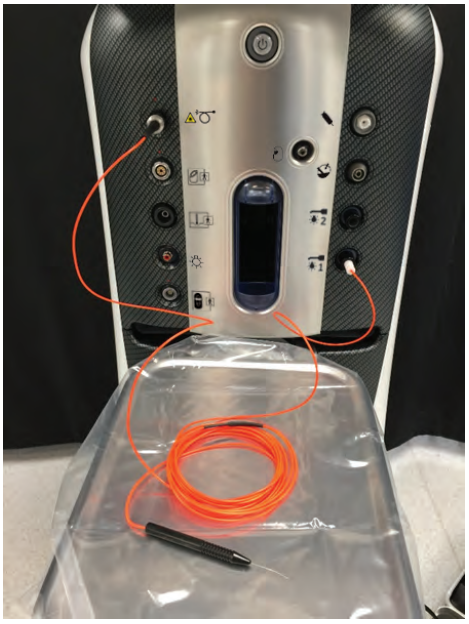


Figure 1.57. **System connected with Illuminating EndoProbe**.

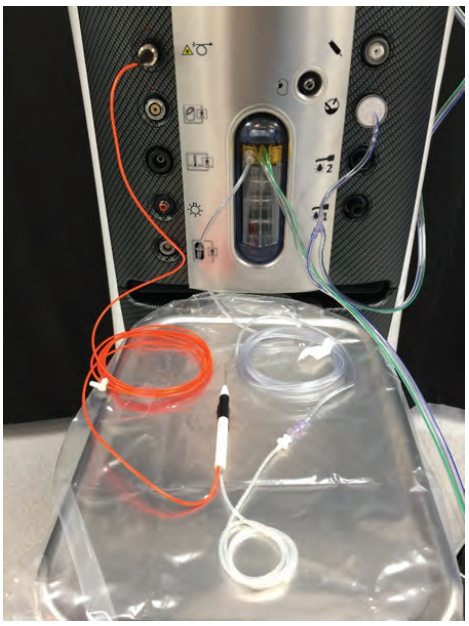


Figure 1.58. **System with Aspirating EndoProbe**.

EndoProbes are available in 20 gauge, 23 gauge, 25 gauge, and 27 gauge sizes.

Endo Submode Setup and Use

These procedures assume the system is properly connected and running in the Posterior or Combined domain, and that the system is at the Surgical Screen.

A. Ensure that the room interlock or the room interlock bypass key is connected to the system.

B. Ensure that the eye safety filter is installed in the microscope.
   - If a fixed filter is in use, connect the laser filter bypass key to the system.
   - If a two-position filter is in use, connect the interlock filter cable to the system.

C. Ensure all personnel in the operating room are wearing their laser protective eyewear.

D. Ensure the desired foot control is communicating with the system.

E. Remove the protective caps, and connect the EndoProbe delivery device. Tighten the connector finger tight only.

Note: *When attaching a delivery device to the fiber-optic port, do not overtighten the connector, or it will be difficult to disconnect. Therefore, only finger tighten this connection.*

F. Insert and turn the Laser Key clockwise, one quarter turn to power on the laser.

G. Select the **Laser Mode** from the **Clock Menu**.

H. Select the Laser Option List button to open the Laser Option List.

I. Select Endo or Endo-Continuous from the Laser Option List.

J. Open the laser firing switch cover, if using the Primary (Integrated) Foot Control.

K. Follow the prompts on the **Laser Status** window. After successfully performing all setup procedures, the system will be in Standby state.

L. Use the up/down arrows to adjust the power, duration and interval desired. The green laser Counter Reset command may be used to clear the pulse counter.

M. Select the Standby button to enter Ready state. When entering the Ready state, do not depress the laser foot button. The button will blink, and in about 3 seconds will provide audio feedback that the system is in the Ready state.

N. Press the firing button to activate the laser. Always toggle the laser to Standby state when not preparing to deliver the laser.

O. When finished, turn the Laser Key one quarter turn counterclockwise to power down the laser. Remove the Laser Key and secure it in a safe location.

For detailed instructions, select Show Steps Laser and a new screen will appear. Select Laser EndoProbe and a new tabbed screen will appear, detailing the required steps and showing animations of how to perform each step.

LIO Submode Setup and Use

These procedures assume the system is properly connected and running in the Posterior or Combined domain, and that the system is at the Surgical Screen.

Figure 1.59. **LIO Headset with Connections**.

A. Ensure that the room interlock or the room interlock bypass key is connected to the system.

B. Ensure that the microscope bypass key is connected to the system.

C. Ensure all personnel in the operating room are wearing their laser protective eyewear.

D. Ensure the desired laser Foot Control is communicating with the system.

E. Remove the protective caps, and connect the LIO delivery device and lamp to the ***Stellaris Elite***™ vision enhancement system. Tighten the connector finger tight only. Ensure that the LIO delivery device and lamp power cable are kept out of the sterile field.

Note: *When attaching a delivery device to the fiber-optic port, do not overtighten the connector or it will be difficult to disconnect. Therefore, only finger tighten this connection.*

F. Turn the Laser Key clockwise one quarter turn to power on the laser.

G. Select Laser Mode from the **Clock Menu**.

H. Select the Laser Option List drop-down menu to open the **Laser Option List**.

I. Select LIO from the **Laser Option List**.

J. Follow the prompts on the laser status window. After successfully performing all setup procedures, the system will be in Standby state.

K. Use the up/down arrows to adjust the power, duration and interval desired. The green laser Counter Reset command may be used to clear the pulse counter.

L. Select the Standby button to enter Ready state. When entering the Ready state, do not depress the laser foot button. The Standby button will blink, and in about 3 seconds will provide audio feedback that the system is in the Ready state.

M. Press the firing button to activate the laser. Always toggle the laser to the Standby state when not preparing to deliver the laser.

N. When finished, turn the Laser Key one quarter turn counterclockwise to power down the laser. Remove the Laser Key and secure it in a safe location.

CAUTION: ***After removing a delivery device, remember to attach the protective cap to the input end (that attaches to the system). The input end collects dirt and fingerprints, which can interfere with transmission of light and may destroy the fiber. Make sure to attach the caps on the delivery device and on the fiber-optic port after each treatment.***

For detailed instructions, select Show Me Steps and a new screen will appear. Select Laser LIO from the drop-down list and a tabbed screen will appear detailing the required steps and showing animations of how to perform each step.

Laser Safety Information

General Measures

Operating room personnel must wear adequate eye protection if they work within 4 m of the delivery end of the laser system while it is in ready or treat state. The NHZ for the EndoProbe as calculated per ANSI Z136.1 is 4 m using a beam divergence half angle of 4.5 degrees, an average aversion reflex time of 0.25 sec., and assuming that a (worst case) 2 W accidental boresight exposure.

All ancillary personnel who can be exposed to a laser beam directed out of the Laser Indirect Ophthalmoscope (LIO) must wear eye protection. The NHZ for the LIO as calculated per ANSI Z136.1, Table B6, is 20 m using an aversion reflex time of 0.25 sec., and assuming that a (worst case) 2 W accidental boresight exposure.

Protective Measures for the Green Treatment Beam

Protection for Physicians

WARNING: ***Eye safety filters protect the physician's vision from backscattered treatment laser light. Integral eye safety filters are permanently installed in the Laser Indirect Ophthalmoscope (LIO) delivery device at the factory. For Endolaser applications, a separate discrete eye safety filter assembly must be installed into each viewing path of the operating microscope. All eye safety filters have an optical density (OD protection of a minimum of 3.0) at the laser wavelength of 532 nm, which is sufficient to permit long-term viewing of diffuse 532 nm laser light at Class 1 levels.***

Protection for Ancillary Personnel

WARNING: ***To adequately protect the eyes of ancillary personnel within the Nominal Hazard Zone (NHZ) from both accidental intrabeam (boresight) viewing or long-term viewing of diffuse reflections of the treatment beam, all personnel must wear laser protective eyewear which offer a minimum OD protection of 3.5 or greater at the laser wavelength of 532 nm. Appropriate laser safety eyewear is permanently identified with the protection wavelength and OD.***

Protective Measures for the Red Aiming Beam

WARNING: ***The laser system allows adjustment of the power of the red aiming laser over a continuous range from 0 mW to a maximum power of < 1 mW. When set for maximum power, the red aiming laser generates Class 2 radiation, and staring directly into the beam can cause retinal damage.***

Reflective Hazards

WARNING: ***Laser beams reflected from specular surfaces can harm the eyes of the physician, the patient, or others. Any mirror or metal object which reflects the laser beam can constitute a reflection hazard. Make sure to remove all reflection hazards near the laser, and use nonreflecting instruments whenever possible. Be careful not to direct the laser beam at unintended objects.***

For questions in the U.S. regarding laser safety requirements or training refer to ANSI Z136.1 or contact the Laser Institute of America, http://www.lia.org or 1-800-345-2737, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826.

Compliance with FDA-Required Safety Features

The United States Food and Drug Administration (FDA), under Title 21 of the Code of Federal Regulations (CFR) Subchapter J, Part 1040, has established that all laser products distributed in the U.S. must incorporate specific laser safety features. This laser function complies with these regulations as follows:

- Protective Housing Safety Interlocks (21 CFR 1040.10 (f)(1))
  The Laser Module's internal housing prevents access to all unintended emission of laser radiation. Special tools are required to open the protective housing. The laser port is electronically interlocked so that no laser energy can be emitted without the correct connection of the delivery device.
- Safety Interlock (21 CFR 1040.10 (f)(2))
  An electronic interlock prevents the Laser Module from emitting laser energy if a delivery device is absent or incorrectly connected.

- Remote Interlock Connector (21 CFR 1040.10 (f)(3))
  A connection labeled with the Remote Interlock symbol on the power input module allows incorporation of external interlock switches or safety circuits (for example, a switch that will disable the laser whenever a hospital operating room door opens). The laser function will not operate unless the two pins in the Remote Interlock jack are electrically connected. A connector will be provided that can override this interlock.
  - If external interlocks will not be used, insert the connector.
  - If incorporating an external interlock, it must be connected to the system. When the external switch circuit opens, it will open the Remote Interlock circuit and automatically shut down all laser circuits within the module. The status display on the display will read “Room Interlock is open” to indicate that electrical continuity must be reestablished in the interlock circuit before treatment can resume. After the interlock circuit is closed, the system will re-initialize itself to Standby state. Power, pulse duration, interval, and the counter will return to the most recent settings. To resume treatment, simply press the Standby/Ready button to re-enter ready mode.
- Key Switch (21 CFR 1040.10 (f)(4))
  The module will only operate when the proper Laser Key is in place. The Laser Key cannot be removed while the Key Switch is in the “on” position.
- Laser Turn-On and Emission (21 CFR 1040.10 (f)(5))
  The module has a two-step laser sequence to turn on the laser. First, insert the Laser Key into the key switch on the front of the module and turn it clockwise to the ON position. This initiates a diagnostic sequence and initializes the control system. When the appropriate delivery device is attached, the Standby and status display for the specific delivery device will illuminate. During Standby state the control system withholds power from the laser system. When ready mode is selected, there will be a three-second delay before the ready mode is activated. The system will treat (deliver laser energy) only when in treat mode and one of the Laser Module compatible footswitches is activated. An audible tone is generated during delivery of laser energy. The volume of the tone can be adjusted, but it cannot be turned off.
- Laser Beam Attenuation (21 CFR 1040.10 (f)(6))
  The treatment laser does not emit continuously but is only energized when laser delivery is intended. Power is withheld from the laser system by a fail-safe combination of electronic elements until all requirements for emission are met and either laser Primary (Integrated) Foot Control is depressed. The aiming beam intensity is controlled by the aiming beam adjustment. Turn off the aiming beam by selecting the Aiming Beam tool on the user interface, and turning off the aiming beam.
- Location of Controls (21 CFR 1040.10 (f)(7))
  All laser controls for the module and delivery devices are located at a safe distance from the laser aperture.
- Viewing Optics (21 CFR 1040.10 (f)(8))
  The Laser Indirect Ophthalmoscope Plus contains an integral eye safety filter which ensures that any laser radiation returned to the physician’s eyes during clinical use does not exceed CDRH Class 1 limits. When using laser delivery devices that do not contain integral eye safety protection, the user interface will automatically prompt for confirmation that an eye safety filter is installed before treatment begins. If using an operating microscope with the module, an appropriate eye safety filter must be installed in the viewing path of the microscope. An appropriate eye safety filter will be designated with 532 nm. A list of acceptable filters is given in Chapter 6. When correctly installed, the appropriate eye safety filter will protect from potentially unsafe laser radiation (i.e., radiation which exceeds Class 1 limits) when looking into the microscope. Always confirm that the eye safety filter to be used with the module is marked for use with 532 nm laser light. The moveable safety filter

is electronically interlocked to the module via the SmartKey connector on the power input module to prevent the selection of ready mode when a safety filter is not installed.

- Manual Restart (21 CFR 1040.10 (f)(10))
  The module can tolerate minor power disruptions lasting only a few cycles without shutting down or changing the intensity of the laser beam. However, it immediately disables all laser circuits whenever the supply of electrical power fluctuates severely or the Remote Interlock circuit opens. To manually restart the system, let it finish the initialization sequence, and if the fault condition is no longer detected, the system will enter the Standby state. To begin operation of the laser, reset the power level and re-select ready mode. The system cannot deliver laser energy without the operator making these adjustments.
- Internal Power Monitor (21 CFR 1040.11 (1))
  The system reads the output laser power emitted from the delivery device. Two power monitors independently measure and verify the proper laser power before coupling it into the fiber-optic cable. If the power measurements from the two monitors vary, the system automatically enters the Call Service mode, and displays an error message. Press the button to return to the Standby state.
- Laser Safety Labels (21 CFR 1040.10 (g))
  All laser safety labels included on the system are illustrated in Chapter 8.

Additional Laser Safety Features

- Laser Turn-On Sequence: Emission of laser radiation requires the user to:
  (1) Insert the Laser Key and turn the lock from off to on.
  (2) Press the “Standby” button to change to “Ready” on the user interface. There is a three-second sequence in which the Primary (Integrated) Foot Control is locked out during which the module conducts a brief diagnostic sequence and initializes the control and safety circuitry.
  (3) Depress the predefined laser Foot Pedal to fire the laser. This sequence must be successfully completed and all connection requirements must be satisfied before laser energy can be emitted.
- Laser Primary (Integrated) Foot Control: When the system is in ready mode, the physician activates the treatment laser with either the Primary (Integrated) Foot Control or the Secondary (LIO) Foot Control. Both are watertight and shrouded for safety. Several safety features are incorporated into the laser Primary (Integrated) Foot Control circuit to prevent accidental emission of energy: dual signal lines to prevent accidental contact, two separate switches that must be closed in order to obtain laser emission, and it must be correctly installed. The system always tests for a properly connected footswitch before entering ready mode. An error message will be displayed if there is damage or an improper connection. Replace either Foot Control if it is damaged or if the cord becomes damaged or worn, or fails to make the proper connection. The module will not allow adjustment of the treatment settings while either laser firing switch is depressed.
- Emergency Laser Stop Button: The Emergency Laser Stop Button is a red button located on the front of the module. When pressed, laser emission immediately stops, all related circuits are disabled, and the system display reads “Emergency Laser Stop!” To re-enter Standby Mode, press the button again. The counter, pulse duration, and interval will be restored to their prior settings and the system will be in Standby Mode.
- Audio Tone: During laser emission, a distinct audible tone between 45 dBA and 65 dBA will sound. The volume can be turned down, but the tone cannot be turned off.

Compliance with FDA-Required Laser Safety Features (Summary)

- Protective Housing Safety Interlocks (21 CFR 1040.10 (f)(1))
- Safety Interlock (21 CFR 1040.10 (f)(2))
- Remote Interlock Connector (21 CFR 1040.10 (f)(3))
- Key Switch (21 CFR 1040.10 (f)(4))
- Laser Turn-On and Emission (21 CFR 1040.10 (f)(5))
- Laser Beam Attenuation (21 CFR 1040.10 (f)(6))
- Location of Controls (21 CFR 1040.10 (f)(7))
- Viewing Optics (21 CFR 1040.10 (f)(8))
- Manual Restart (21 CFR 1040.10 (f)(10))
- Internal Power Monitor (21 CFR 1040.11 (1))
- Laser Safety Labels (21 CFR 1040.10 (g))

Laser Interlocks

Two system interlocks are included in the ***Stellaris Elite***™ vision enhancement system. The system cannot be placed in Ready mode with an interlock open. If the system is in Ready mode or Treating (firing) and an interlock opens, the system will be placed in Standby Mode. The status display on the display will read "Interlock is open" to indicate that electrical continuity must be reestablished in the interlock circuit before treatment can resume. After the interlock circuit is closed, the system will re-initialize itself to Standby state. Power, pulse duration, interval, and the counter will return to the most recent settings. To resume treatment, simply re-enter ready mode.

Connecting the System to the Microscope Filter

Eye safety filters protect the physician's vision from backscattered treatment laser light. Integral eye safety filters are permanently installed in the Laser Indirect Ophthalmoscope (LIO) delivery device. For Endolaser applications, a separate discrete eye safety filter assembly must be installed into each viewing path of the operating microscope. All eye safety filters have an optical density (OD protection of a minimum of 3.0) at the laser wavelength of 532 nm sufficient to permit long-term viewing of diffuse 532 nm laser light at Class 1 levels.

The ***Stellaris Elite***™ vision enhancement system will not allow the laser to fire unless the microscope filter circuit is closed, either through wiring it to the filter or inserting a bypass key.

If you wish to incorporate the microscope filter interlock, connect the wires to your system. When your external switch circuit opens, it will open the Remote Interlock circuit and automatically shut down all laser circuits within the module. The status display on the ***Stellaris Elite***™ vision enhancement system will read "Filter Interlock is open" to remind you that you must reestablish electrical continuity in the interlock circuit before treatment can resume. After the interlock circuit is closed, the system will re-initialize itself to Standby state. Power, pulse duration, interval, and the counter will return to the most recent settings. To resume treatment, simply re-enter ready mode.

Adaptor Cable (BL3242) will be needed to use these filters with the system.

Remote Interlock Connector (21 CFR 1040.10 (f)(3))

The ***Stellaris Elite***™ vision enhancement system will not allow the laser to fire unless the Remote Interlock circuit is closed, either through wiring it to a facility interlock circuit or inserting a bypass key. A Remote Interlock connection gives you the opportunity to incorporate your own external interlock switch or safety circuit (for example, a switch that will disable the laser whenever a hospital operating room door opens).

If you wish to incorporate an external interlock, connect the wires to your own switch. When your external switch circuit opens, it will open the Remote Interlock circuit and automatically shut down all laser circuits within the module. The status display on the ***Stellaris Elite***™ vision enhancement system will read "Room Interlock is open" to remind you that you must reestablish electrical continuity in the interlock circuit before treatment can resume. After the interlock circuit is closed, the system will re-initialize itself to Standby Mode. Power, pulse duration, interval, and the counter will return to the most recent settings. To resume treatment, press the Standby/Treat button to select treatment mode.

A room safety light interface can be connected on the same circuit as the room interlock, and must interface to a 24V relay.

If you choose not to use the facility interlock, you may use a room interlock bypass.

Note: *Ensure both interlock bypass keys are inserted when you want to use the laser function.*

Laser Probes and Cables

The following laser accessories are distributed by and compatible with the ***Stellaris Elite***™ vision enhancement system (BL15455). Contact your local Bausch + Lomb sales representative for the most current listing of available laser accessories.

WARNING: ***MEDICAL DEVICE RE-USE STATEMENT***
If the single-use probe accessories listed below are reprocessed and/or re-used, Bausch + Lomb cannot guarantee the functionality, material structure, or cleanliness or sterility of the product. Re-use could lead to illness, infection and/or injury to the patient or user and in extreme incidents, death. The single-use probe accessories listed below are labeled as 'single-use' which is defined as a device intended to be used once only for a single patient.

WARNING: ***Laser probes (also referred to as EndoProbes) and their fiber-optic cables should be handled with care. The fiber-optic cable should not be tightly coiled, twisted or sharply bent to preclude damage to the fiber-optic. Failure to use care may damage the fiber and/or beam delivery system and may lead to harm of the patient or laser operator.***

SKU	Description
Laser Filters	
BL3236	Zeiss Fixed ESF
BL3240	Zeiss 2 Position Filter ESF
BL3245	Moeller Wedel Fixed ESF
BL3241	Leica 2 Position Filter ESF
BL3247	Leica 4-way Filter
BL3237	Leica Fixed ESF
BL3239	Laser Filter ESF Mount Topcon
BL3242	Adaptor for Fitting of 2 Position Filters
Laser Indirect Ophthalmoscopes	
BL2298	TruFocus LIO Premiere™ with LED Illumination
BL2296	Auxiliary Foot Pedal for LIO Use
Standard Laser Probes	
BL5290	20 gauge Standard Laser Probe Straight
BL5293	23 gauge Standard Laser Probe Straight
BL5295	25 gauge Standard Laser Probe Straight
Curved Standard Laser Probes	
BL5290C	20 gauge Standard Laser Probe Curved
BL5293C	23 gauge Standard Laser Probe Curved
BL5295C	25 gauge Standard Laser Probe Curved
Illuminated Laser Probes	
BL5290L	20 gauge Illuminated Laser Probe Straight
BL5293L	23 gauge Illuminated Laser Probe Straight
BL5295L	25 gauge Illuminated Laser Probe Straight
Curved Illuminated Laser Probes	
BL5290LC	20 gauge Illuminated Laser Probe Curved
BL5293LC	23 gauge Illuminated Laser Probe Curved
BL5295LC	25 gauge Illuminated Laser Probe Curved
Standard Aspirating Laser Probes	
BL5290ASPH	20 gauge Hard Tip Aspirating Laser Probe Straight
BL5293ASPH	23 gauge Hard Tip Aspirating Laser Probe Straight
Soft Tip Aspirating Laser Probes	
BL5290ASP	20 gauge Soft Tip Aspirating Laser Probe Straight
BL5293ASP	23 gauge Soft Tip Aspirating Laser Probe Straight
Synergetics Directional Laser Probes	
55.26	20 gauge Directional Laser Probe
55.26.23	23 gauge Directional Laser Probe
55.26.25, 55.26.25S	25 gauge Directional Laser Probe

SKU	Description
55.26.27	27 gauge Directional Laser Probe
Synergetics Extendable Directional Laser Probes	
55.26E	20 gauge Extendable Directional Laser Probe
55.26.23E	23 gauge Extendable Directional Laser Probe
55.26.25E	25 gauge Extendable Directional Laser Probe
Synergetics Inverted Directional Laser Probes	
55.36.23E	23 gauge Inverted Directional Laser Probe
55.36.25E	25 gauge Inverted Directional Laser Probe
Synergetics Directional™ II Laser Probes	
55.27	20 gauge Directional™ II Laser Probe
55.27.23	23 gauge Directional™ II Laser Probe
55.27.25	25 gauge Directional™ II Laser Probe
55.27.27	27 gauge Directional™ II Laser Probe
Synergetics Straight Laser Probes	
55.21	20 gauge Straight Laser Probe
55.21.23	23 gauge Straight Laser Probe
55.21.25S	25 gauge Straight Laser Probe
55.21.27	27 gauge Straight Laser Probe
Synergetics Curved Laser Probes *Adaptor is required for use with Stellaris Elite BL15455	
55.25.23	23 gauge Flexible Tapered Laser Probe
55.25.25	25 gauge Flexible Tapered Laser Probe
55.23	20 gauge TruCurve Curved Laser Probe, 37° Curve
55.23.23	23 gauge TruCurve Curved Laser Probe, 37° Curve
55.23.25	25 gauge TruCurve Curved Laser Probe, 37° Curve
55.23.27	27 gauge TruCurve Curved Laser Probe, 37° Curve
55.12	20 gauge Curved Laser Probe*, 22° Curve
Synergetics Illuminated Laser Probes* *Adaptor is required for use with Stellaris Elite BL15455 for the following illuminated laser probes	
55.69P	20 gauge Curved Fixed Extended Illuminated Laser Probe, 37° Curve
55.69.23P	23 gauge Curved Fixed Extended Illuminated Laser Probe, 37° Curve
55.69.25P	25 gauge Curved Fixed Extended Illuminated Laser Probe, 37° Curve
55.29	20 gauge Curved Maxillum™ Laser Probe, 37° Curve
55.62.23P	23 gauge Straight Fixed Extended Illuminated Laser Probe
55.62.25P	25 gauge Straight Fixed Extended Illuminated Laser Probe

SKU	Description
55.70.23P	23 gauge Flexible Tapered Illuminated Laser Probe
55.70.25P	25 gauge Flexible Tapered Illuminated Laser Probe
55.47.23P	23 gauge Illuminated Directional™ Laser Probe
55.47.25P	25 gauge Illuminated Directional™ Laser Probe
55.48.23P	23 gauge Illuminated Directional™ II Laser Probe
55.48.25P	25 gauge Illuminated Directional™ II Laser Probe

2. User Interface

2. User Interface

This chapter introduces you to the basic operation of the ***Stellaris Elite***™ vision enhancement system. The Anterior domain system allows the use of phacoemulsification, irrigation/aspiration, irrigation only and coagulation functions. The Posterior domain allows the use of posterior vitrectomy, Fluid/Air Exchange, coagulation, endoillumination, fragmentation, Air Forced Infusion, Viscous Fluid Control (VFC), and laser photocoagulator. The combined domain includes all functions from both domains.

2.1. Basic Interface Controls

Setting Globe

For a single valued function, a round setting globe will display the current value. The value can be incremented or decremented using the up and down arrows, or the value itself can be selected to activate the pop-up keypad (see page 2-4) and enter a value.

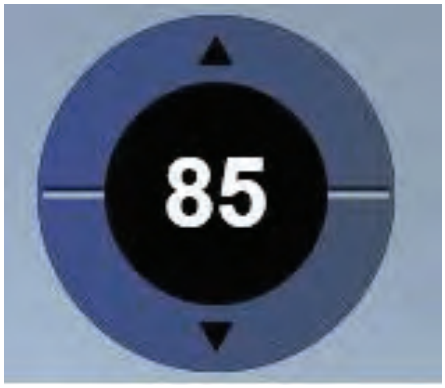


Figure 2.1. **Setting Globe**.

Setting Tube

This control allows you to set the limits of a system parameter. The current value is displayed in the center of the tube. The maximum allowed value, shown at the top of the tube, may be changed by using the increment and decrement buttons that appear immediately above and below the value, or by selecting the value itself to activate the pop-up keypad (see page 2-4) and enter a value. The minimum allowed value, located at the bottom of the tube, can be changed by selecting the value itself to activate the pop-up keypad (see page 2-4) and enter a value.

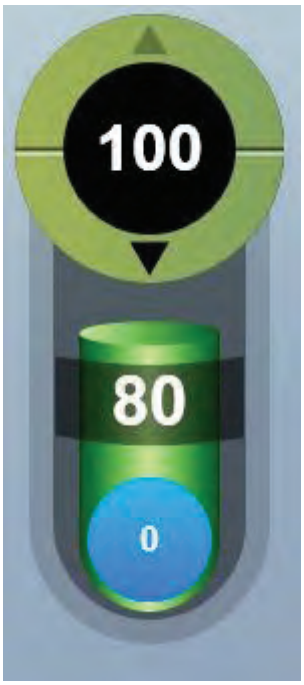


Figure 2.2. **Setting Tube**.

Command Button

This is a single button control which displays a command, and initiates that action when selected. No value is associated with this control and holding it down performs no additional function.

Figure 2.3. **Command Button**.

On/Off Button

This is a single round control, which is green when the associated function is on, and grey when it is off. Select the button to toggle between the two states.

Figure 2.4. **On/Off Button**.

Toggle Setting Button

This is a single button control on a labeled command button, which has a circle that is filled when the function is on, and unfilled when the function is off. Select the button to toggle between the two states.

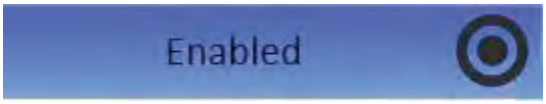


Figure 2.5. **Toggle Settings button**.

Option List

An Option List allows you to select one option from a list of available choices. Selecting the currently displayed option will cause a list to drop down. Only one option can be selected at a given time. Selecting one option automatically deselects others. Select close button (X) to close pop-up window without changing the current setting.

Figure 2.6. **Option Lists**.

Progress Bar

This graphic shows the progress of a procedure.

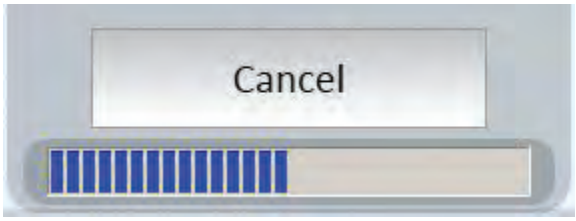


Figure 2.7. **Progress Bar**.

Typewriter Setting Button

This is a single button control, which when selected brings up a keyboard, through which you can enter alphanumeric text.

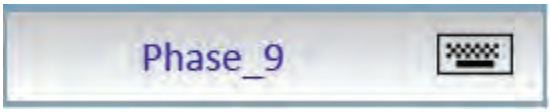


Figure 2.8. **Typewriter Setting Button**.

Numeric Keypad

Selecting a number on a setting globe brings up the numeric keypad. The keypad allows you to rapidly enter numerical surgical settings or change settings. Numbers are entered by touching the numeral, then selecting **Enter** to make the change. When a surgical function is active, the keypad is not available.

Figure 2.9. **Numeric Keypad**.

Keyboard

Sometimes you will need to enter alphabetic or numeric data into the ***Stellaris Elite***™ vision enhancement system. A keyboard similar to that shown below will appear, and you can touch the characters in order to enter them. Selecting the back arrow will delete the last character typed, and selecting **Clear** will delete all characters. Select **Enter** when you are done to save the entry and return to the previous screen (or advance to next level of programming screen).

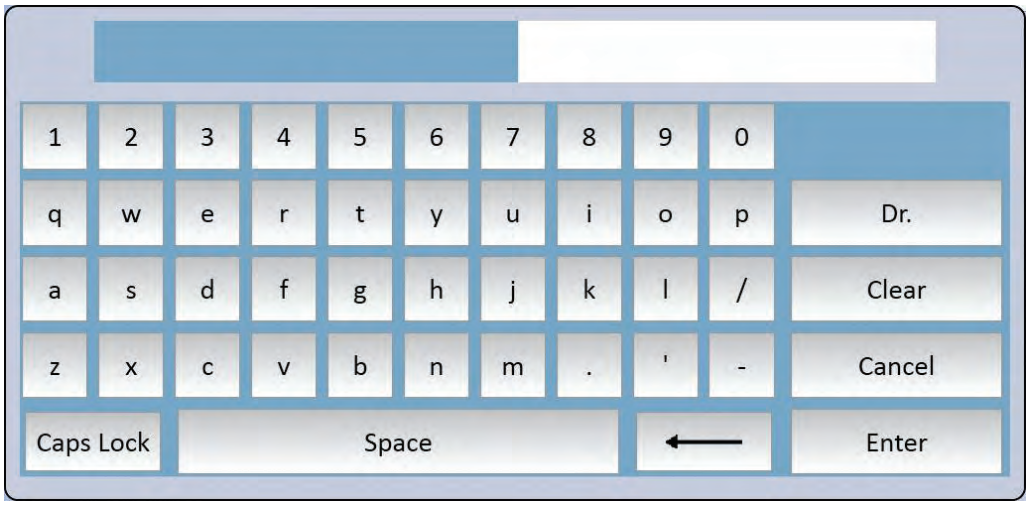


Figure 2.10. **Keyboard**.

Pop-Up Message Window

This type of window appears to display informational messages. Depending on the type of message, you may be required to take appropriate action before the system will continue. Nothing else can be done on the screen while a pop-up window is active. The surgeon may be able to continue with the procedure once the error has been rectified.

Figure 2.11. **Pop-Up Message Window**.

For some messages, suggested actions to resolve the condition appear. If more than one suggested action is available, pressing the **Next** button will cycle through all possible suggested actions. For some suggested actions, a button will appear that will initiate the suggested action.

2.2. Surgical More Screen

The **More Screen** allows easy access to all system parameters. The exact **More Screen** options available will depend on the current state and system settings. Select the **More Screen** button (shown below) to open the **More Screen**.

Figure 2.12. **More Screen Button**.

More Screen Tabs are available for Fluidics (Vacuum and Infusion), Ultrasound, Coagulation, Vitrectomy, Primary (Integrated) Foot Control, Laser, Audio/Visual and Messages.

Note: *Which **More Screen Tabs** are available at any given time depends on the current mode and other system parameters.*

More Screen Vacuum Tab

The **More Screen Vacuum Tab** shows the vacuum settings (minimum and maximum), **Primary (Integrated) Foot Control Mapping**, vacuum response setting (Global On/Off, response speed), and venting method (Global On/Off, Air or Fluid).

Figure 2.13. **More Screen Vacuum Tab**.

More Screen Infusion Tab

The **More Screen Infusion Tab** can show the current Infusion type (Pressurized or IV Pole) and Infusion Units, IV Pole Height (current setting and maximum allowed), Patient Eye Level, Irrigation Shut-Off Delay, Infusion Control (Auto On, Manual, Auto On/Off), Air Port (front/back) and Pressurized Infusion pressure settings, Irrigation Fill Time, and Balanced Salt Solution container type.

The IV Pole Height is the current distance between the aspiration port and the mid-point of the viewing port of the Balanced Salt Solution drip chamber. The maximum IV Pole Height is the highest setting the IV Pole will be allowed to reach, usually determined by the ceiling height and set at time of system installation. A zero-level bottle hanger (a standard component for ***Stellaris Elite***™ PC and PC+L configured for posterior and combined surgeries) allows the BSS drip chamber to be level with the aspiration port.

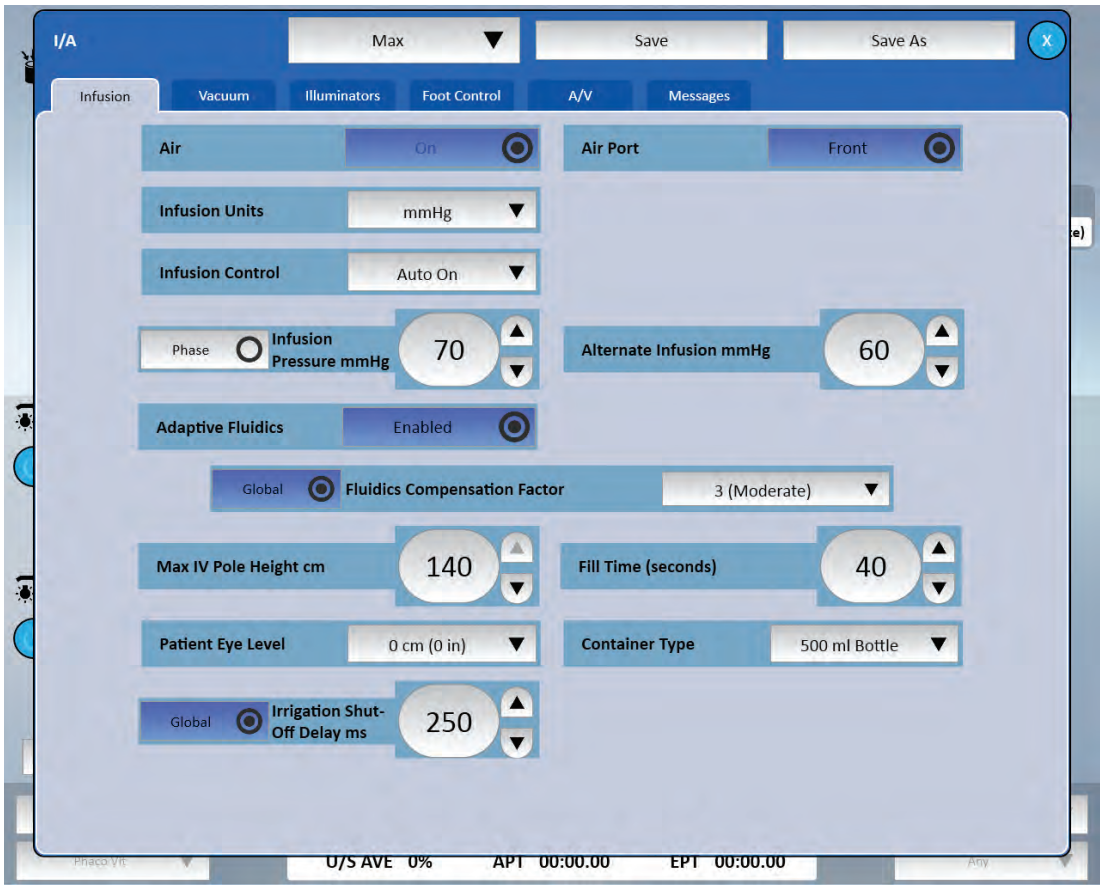


Figure 2.14. **More Screen Infusion Tab**.

Note: *The Air setting will only be shown on the surgical screen when Pressurized Infusion is selected.*

More Screen Ultrasound Tab

The **More Screen Ultrasound Tab** shows the current modulation status (Continuous, Pulsed, Single Burst, Fixed Burst, Multiple Burst) and power level. Depending on which type of ultrasound modulation you are using, you may also see number of pulses per second (PPS), duty cycle (DC), burst duration (BD), pulse interval (PI), waveform type, or waveform depth. You can add or delete up to three modulation submodes, and can adjust any of these settings.

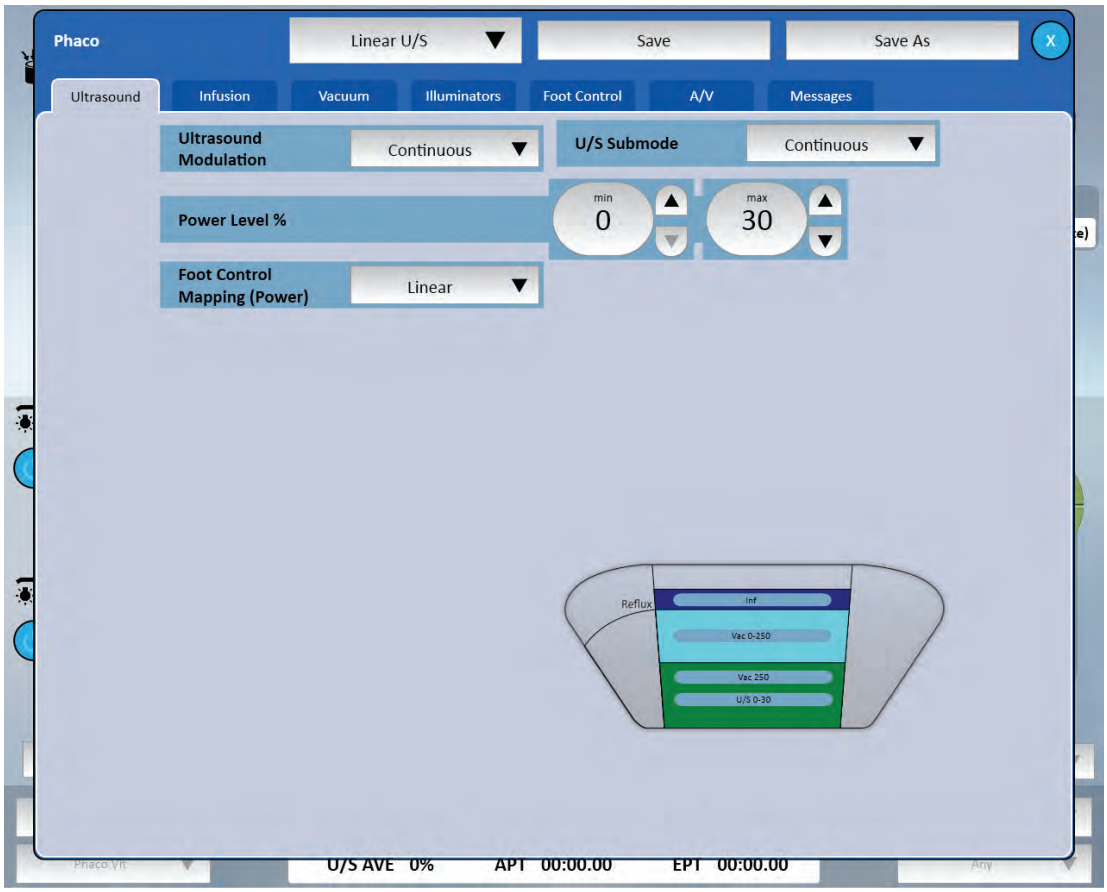


Figure 2.15. **More Screen Ultrasound Tab**.

More Screen Visc Tab

The **More Screen Visc Tab** shows the injection or extraction pressure (single value or min and max) and Foot Control Mapping (Linear, Front Loaded, Back Loaded). A surgeon-level setting controls whether units are displayed in psi or kPa (see Chapter 3).

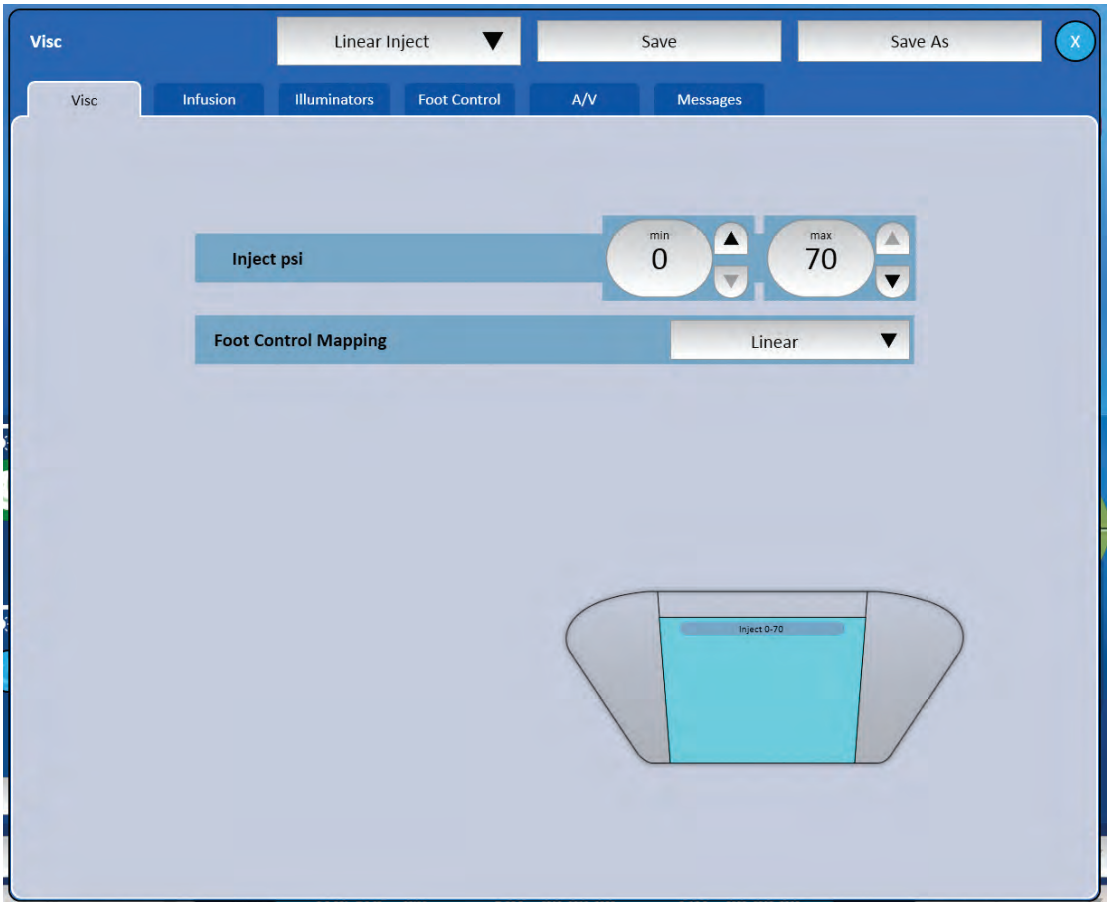


Figure 2.16. **More Screen Visc Tab**.

More Screen Coagulation Tab

The **More Screen Coagulation Tab** shows the current minimum and maximum power levels, and the **Primary (Integrated) Foot Control Mapping** mode. You can adjust either power level setting.

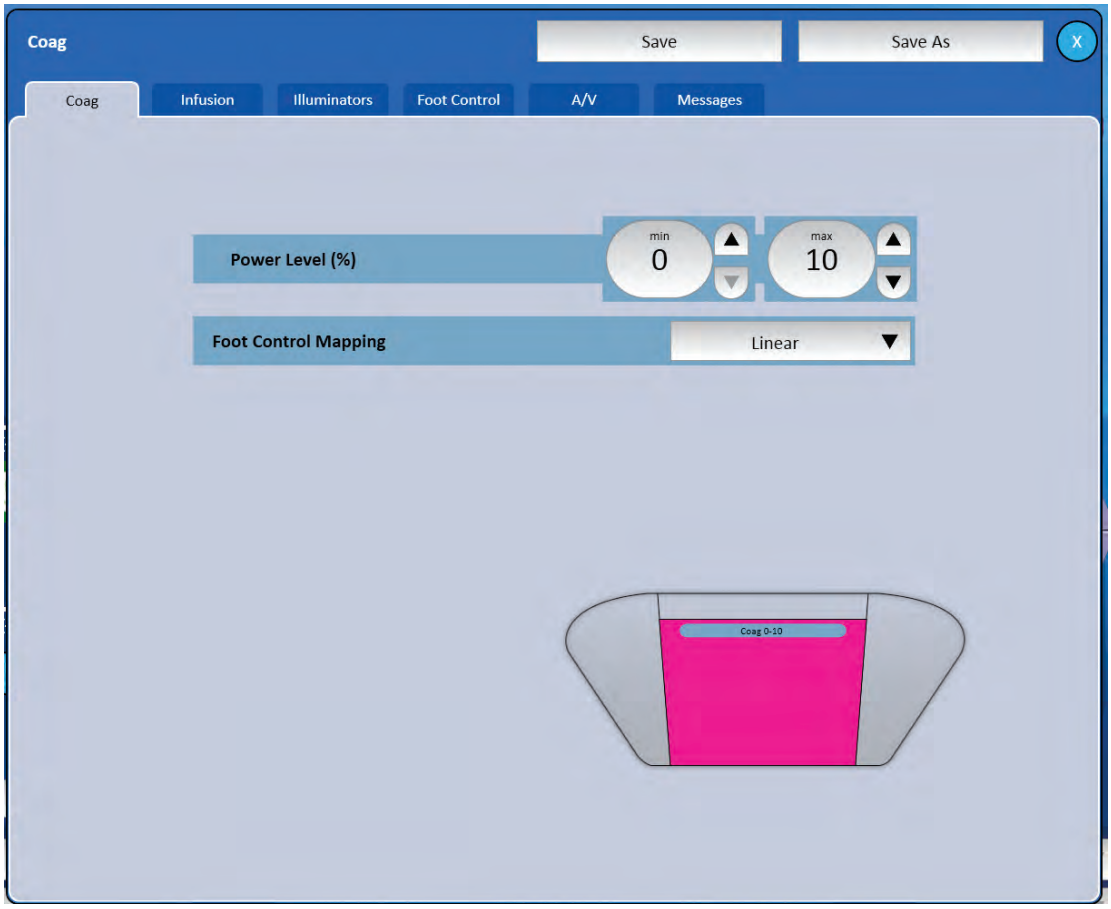


Figure 2.17. **More Screen Coagulation Tab**.

More Screen Vitrectomy Tab

The **More Screen Vitrectomy Tab** allows you to change the current subphase (Fixed Cut, Co-Linear Vit, Dual/Yaw Vac, Dual/Yaw Cut, Single Cut), the current settings for the minimum and maximum CPM (cuts per minute), and the current **Primary (Integrated) Foot Control Mapping** (if applicable).

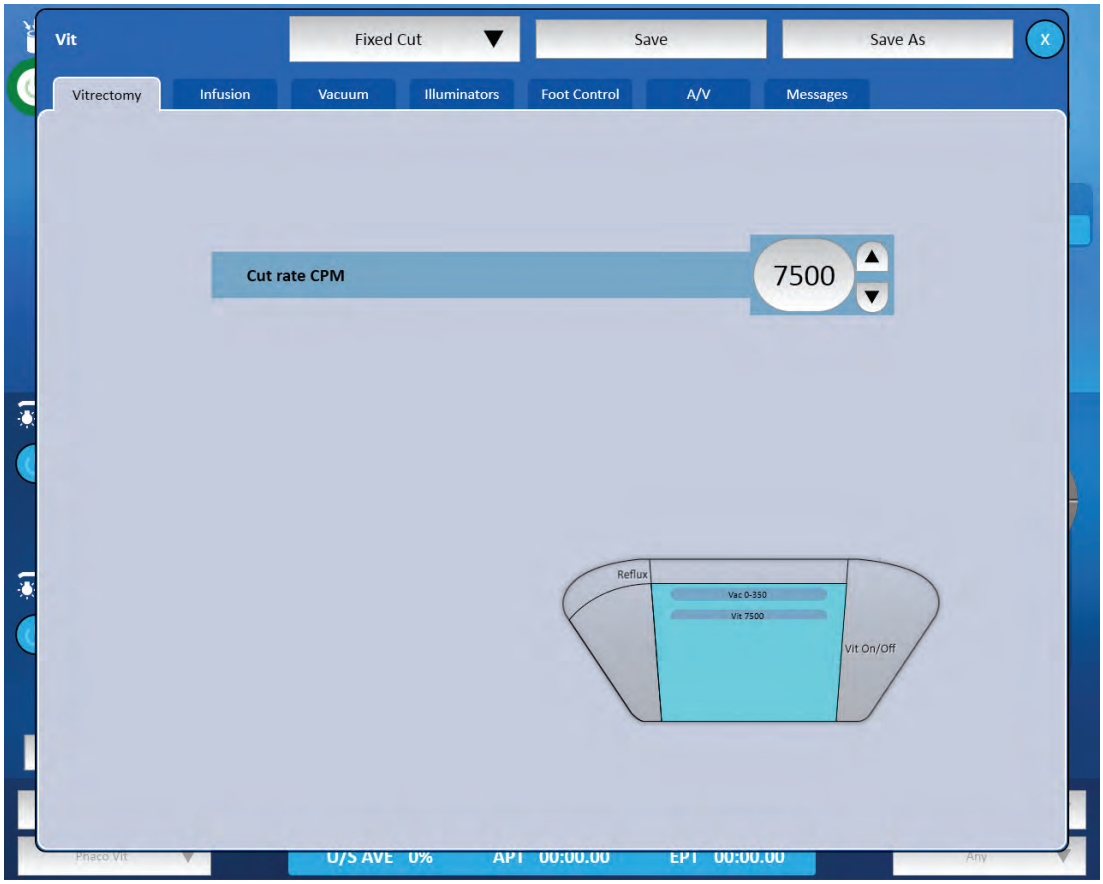


Figure 2.18. **More Screen Vitrectomy Tab**.

More Screen Foot Control Tab

The **More Screen Primary Foot Control Tab** has three subtabs that allow you to view and edit Settings, Regions, and the Status of the Primary (Integrated) Foot Control. These functions are described in detail in the Primary (Integrated) Foot Control section (see page 1-43).

The **Settings Subtab** shows the current functions assigned to each of the Primary (Integrated) Foot Control buttons, Next U/S (Ultrasound) Modulation on Yaw, Reflux on Yaw, Reflux Type, and Linear Coag in Setup. You can also load up to 4 custom sets of button settings using the **Custom** button.

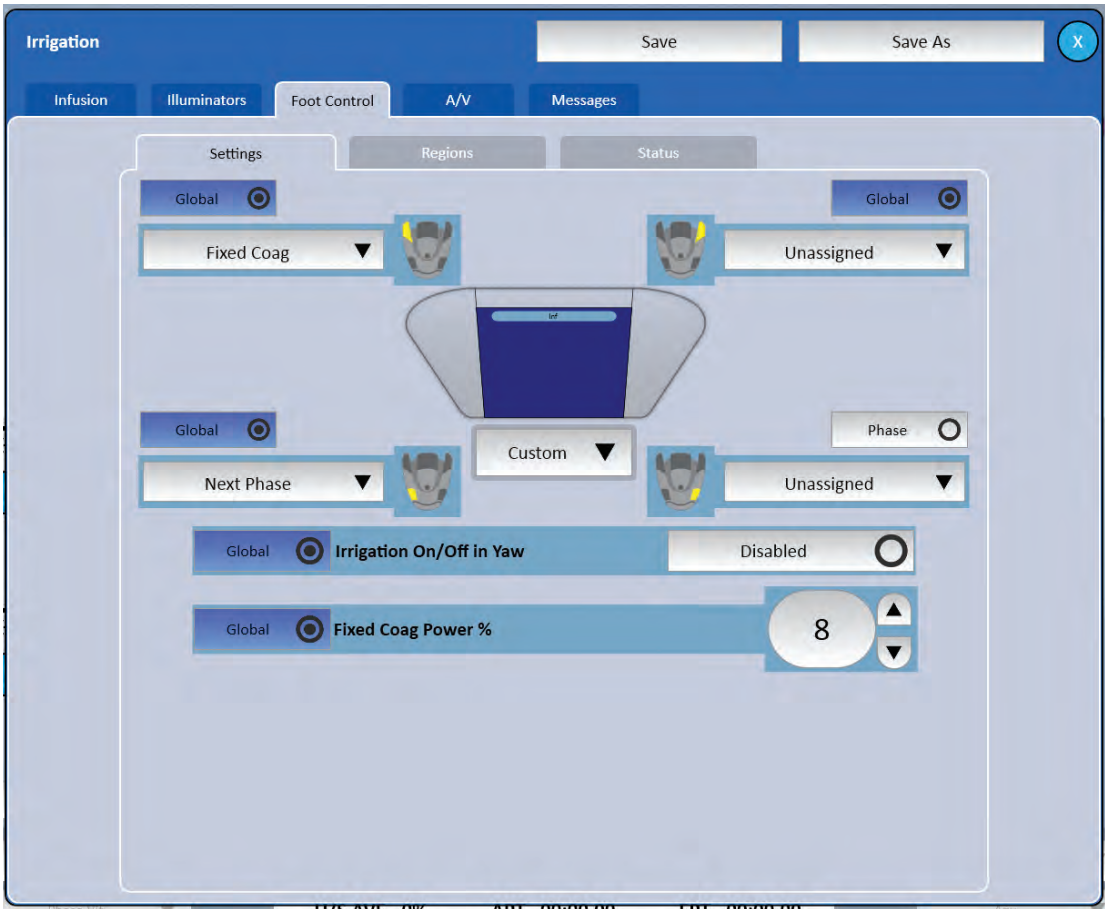


Figure 2.19. **More Screen Primary (Integrated) Foot Control Tab, Settings Subtab**.

The Continuous Irrigation feature available in software version 5.3 and above; (see Irrigation on page 4-43) can be activated in the More Screen Foot Controls Tab, Settings Subtab screen for Irrigation, Single Linear Phaco, and I/A Phases.

Figure 2.20. **Continuous Irrigation On/Off Activation in Yaw Enabled**.

Figure 2.21. **Continuous Irrigation On/Off Activation in Yaw Disabled**.

Figure 2.22. **Disabling Continuous Irrigation On/Off Activation in Yaw in the Single Linear Phaco Phase More Screen Foot Control Tab, Settings Subtab, Allows Ultrasound Modulation on Yaw**.

The **Regions Subtab** shows the current settings for right or left footed operation, mode change control, the Foot Pedal pitch regions and detent options. You can modify the starting depression position for each region.

Figure 2.23. **More Screen Foot Control Tab, Regions Subtab**.

The **Status Subtab** shows the current status of several Foot Pedal options, including communication status, battery status, and signal strength. These are informational only and not user editable.

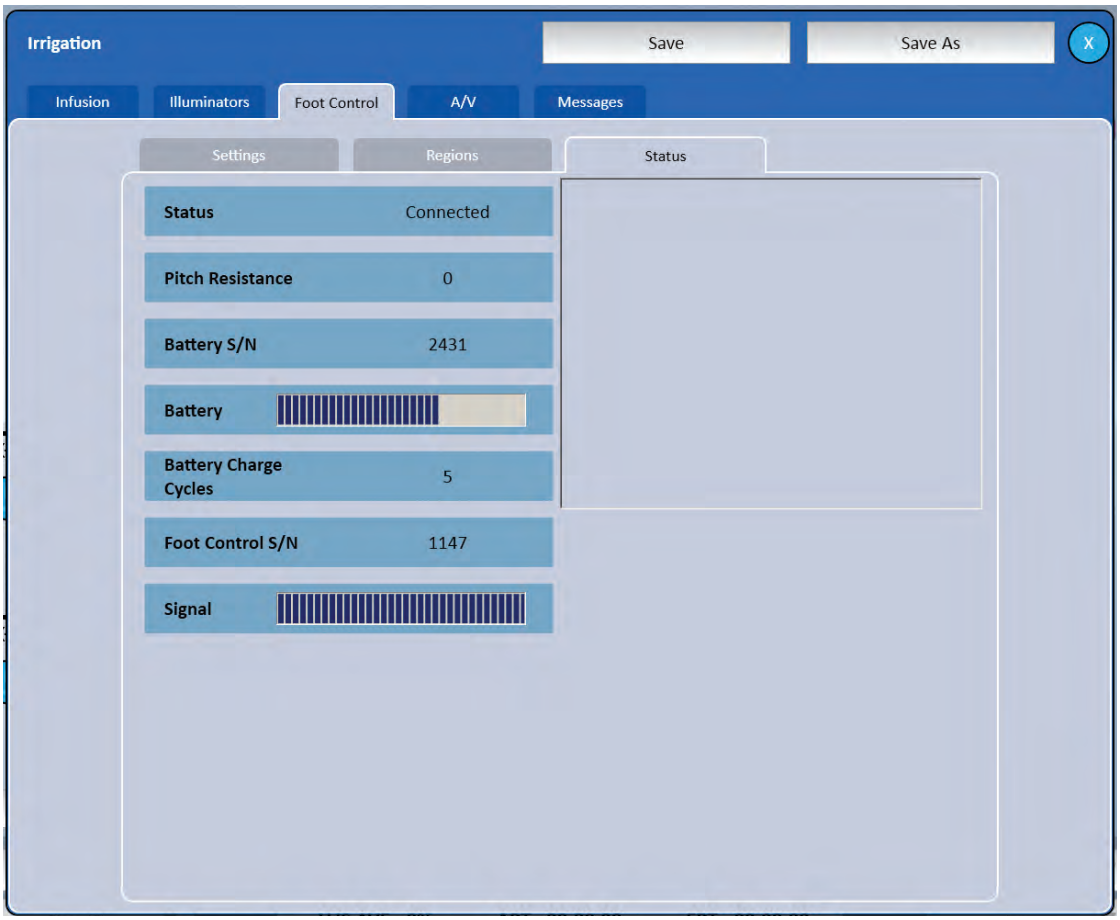


Figure 2.24. **More Screen Primary (Integrated) Foot Control Tab, Status Subtab**.

More Screen A/V Tab

The **More Screen A/V Tab** and its subtabs allow you to change many aspects of the audio and video display.

The **Audio Subtab** controls the master volume for the system, as well as the specific tone and volume used for Alert, Aspiration, Coagulation, Elevated Infusion, Irrigation Infusion, Key, Laser, Reflux, Occlusion, Timer, Ultrasound, Visc Inject, Vitesse Vitrectomy, and Voice Confirmation. The selected tone will be played when that function is active, and the frequency of the tone will change with the value of the function.

To change the tone selected for a particular function, select that function and it will appear at the top of the screen, along with a drop-down menu of all tones currently available for use. No tone may be used simultaneously by two functions, and some functions have a required tone.

Figure 2.25. **More Screen A/V Tab, Audio Subtab**.

Select the tone you want to change, then use the menu and arrows on the right side of the screen to select the tone used for that condition, and the volume at which the tone will be played. Only tones not currently in use for another condition will be displayed.

Voice Confirmation can also be enabled or disabled through this tab.

The **Display Tab** control allows you to adjust the display brightness, voice confirmation language, and to clear the average values and elapsed times for the surgical functions for this case.

Figure 2.26. **More Screen A/V Tab, Display Subtab**.

The **Video Overlay Subtab** allows you to select the language to be used for video overlays.

You can also set whether or not the system will display or combine the Video Overlay Format U/S Averages, or whether or not the system will combine settings information. By default, the U/S data is shown as three separate lines on the video overlay. If the U/S combine option is set to **Yes**, the display will appear on one line, which will step through the three values. Similarly, settings are normally displayed on four lines, but if the combine option is set to **Yes**, settings will appear on one line that will step through the values.

Finally, you can set the video overlay overscan in one-degree increments from 0% to 5%.

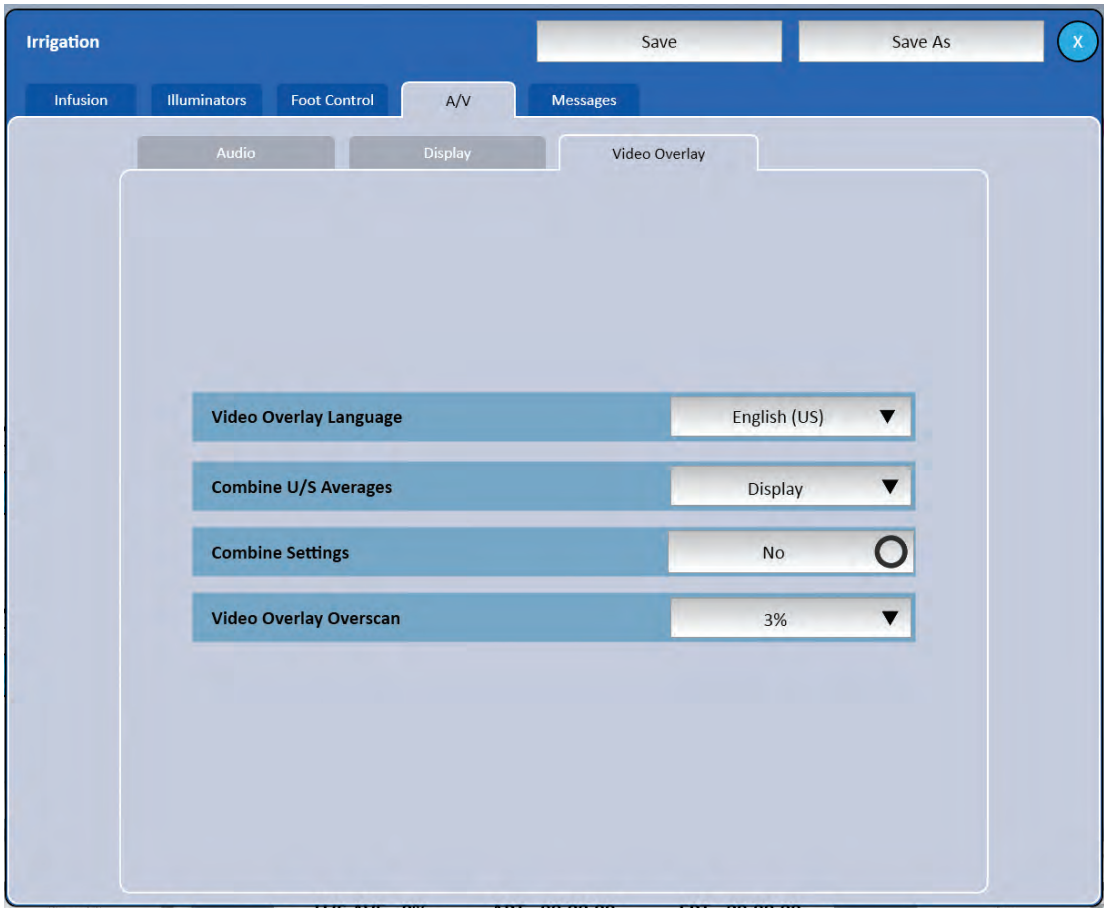


Figure 2.27. **More Screen A/V Tab, Video Overlay Subtab**.

More Screen Illuminator Tab

The **More Screen Illuminator Tab** allows you to enable or disable the upper and lower lamps and to set the current power and filter (none, amber, green tint, yellow tint).

The bottom section of the **More Screen Illuminator Tab** displays the type of bulb currently installed in each lamp and the number of hours of lamp life remaining.

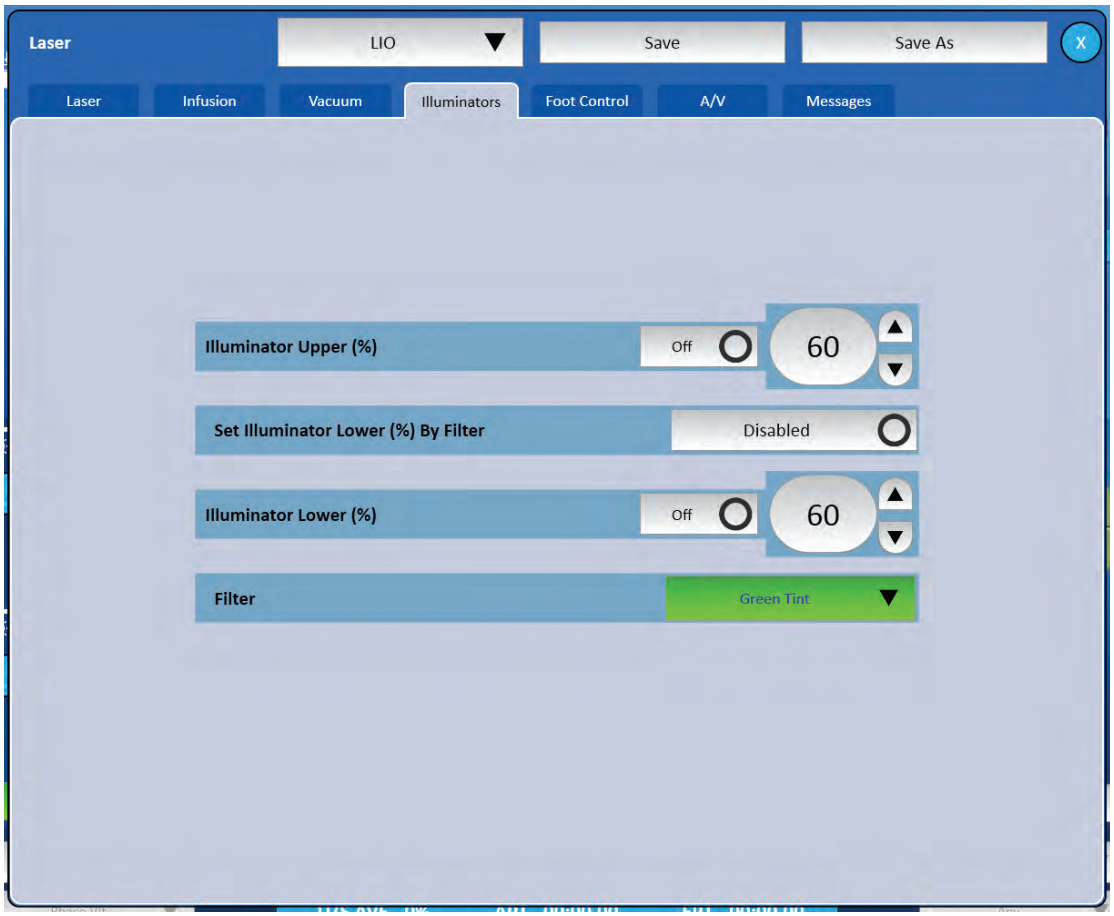


Figure 2.28. **More Screen Illuminator Tab**.

More Screen Laser Tab

The **More Screen Laser Tab** includes the Laser Power (mW), Laser Duration (ms), Aiming Beam in Standby (On/Off), Aiming Beam Intensity (%), Foot Pedal (Integrated Foot Pedal, Secondary Foot Pedal), Default Laser Shot (Single, Repeat), Aiming Beam During Pulse (On/Off), LIO (On/Off, %), and Laser Foot Control Buttons (Enabled, Disabled). Laser functionality is only available in posterior modes.

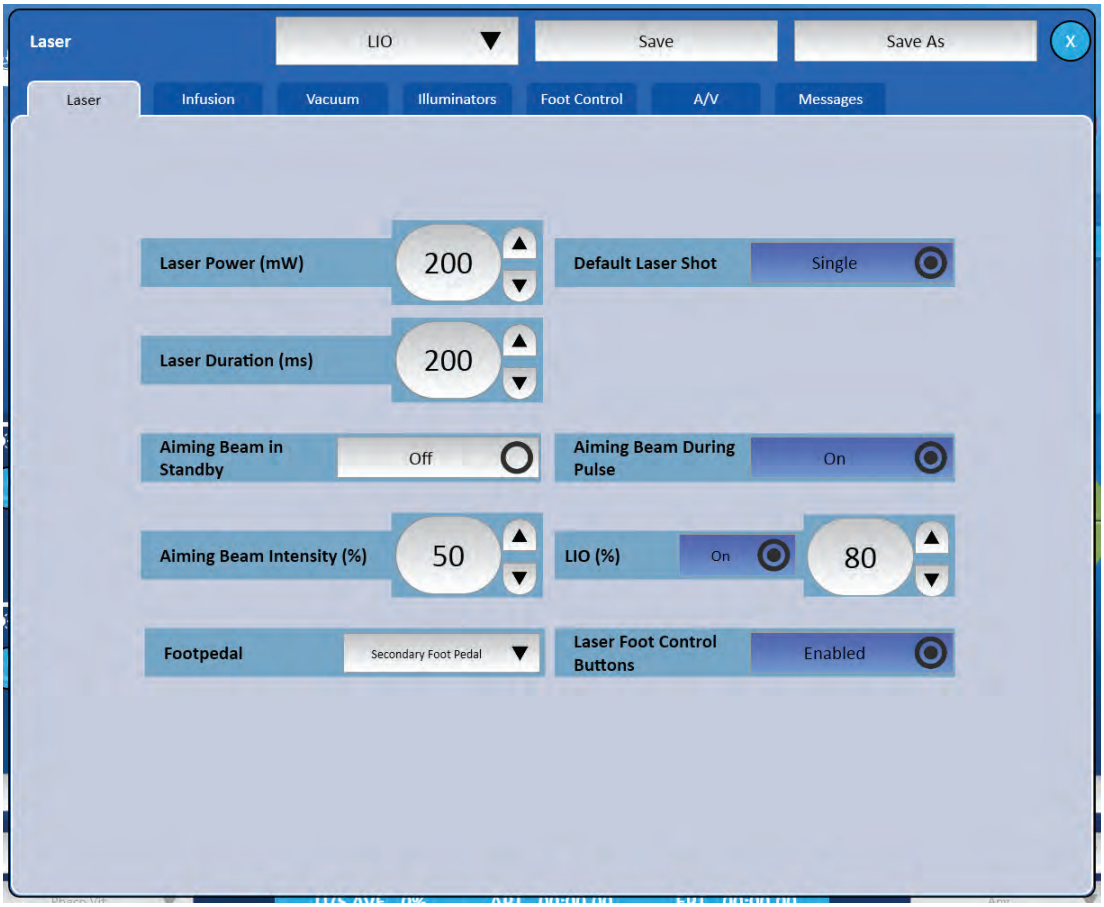


Figure 2.29. **More Screen Laser Tab**.

More Screen Vitesse Tab

The **More Screen Vitesse Tab** includes settings for Vitesse modulation, submode, power (minimum and maximum for linear mapping and maximum only for fixed), and foot control mapping.

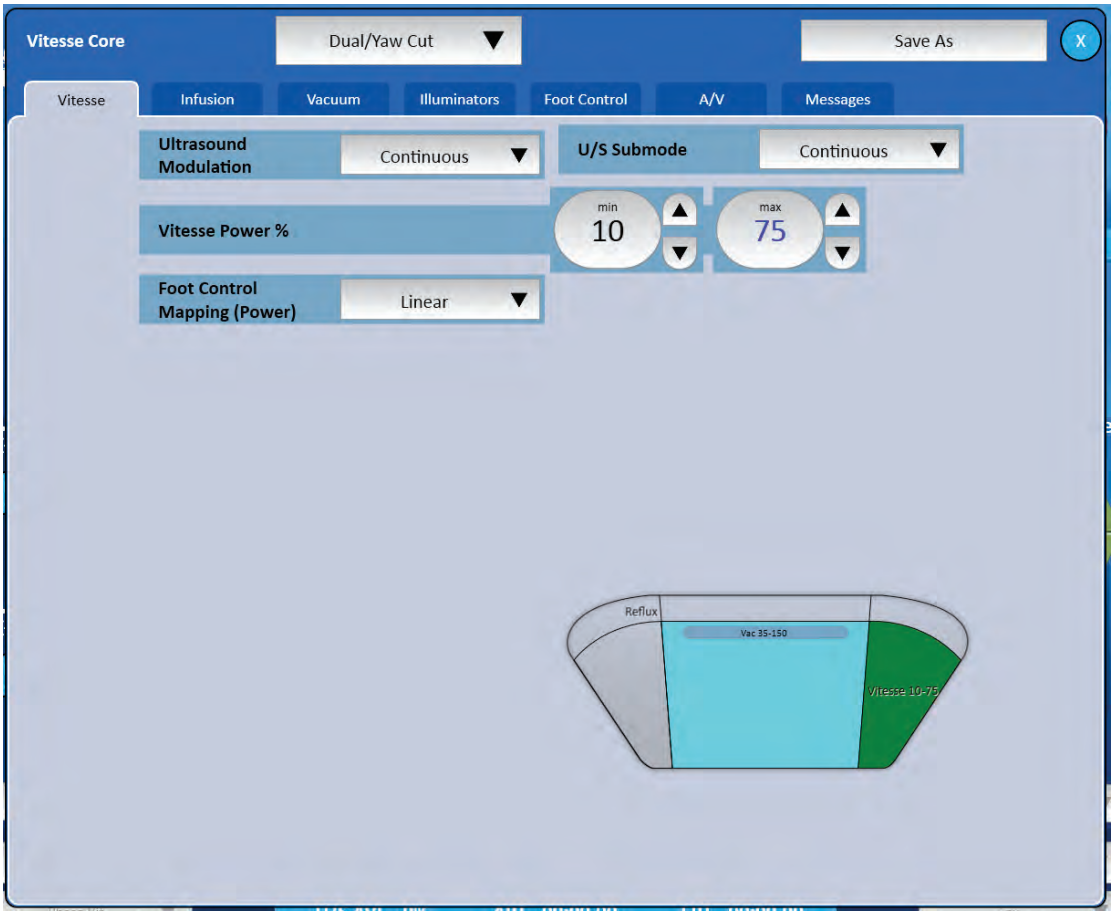


Figure 2.30. **More Screen Vitesse Tab**.

More Screen Messages Tab

The **More Screen Messages Tab** lists all system messages. You can scroll through the messages to see any issues that have arisen during the current case.

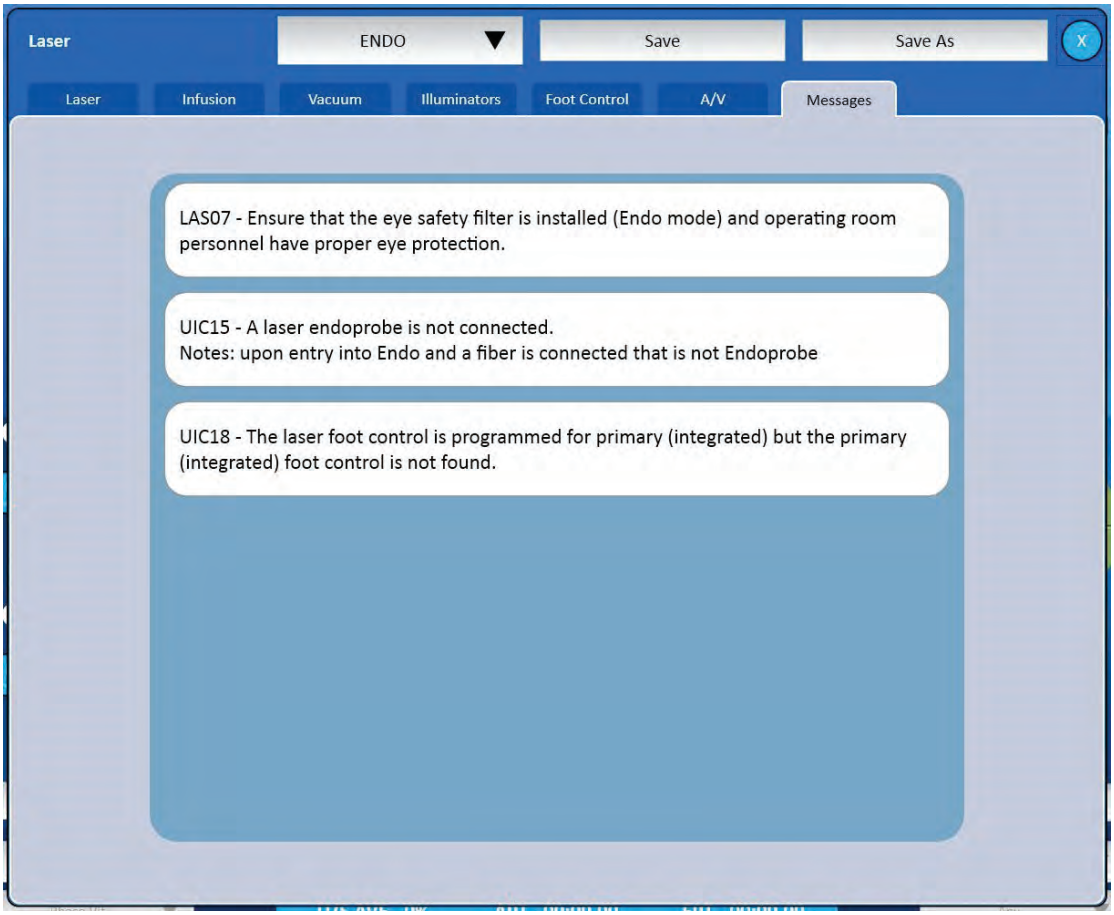


Figure 2.31. **More Screen Messages Tab**.

2.3. Surgical Screen Layout

The surgical screen is divided into four quadrants: the center of the screen displays the clock menu for procedure selection and navigation, and different settings and functional controls are displayed in the surrounding quadrants. The upper left corner displays the vacuum setting. The upper right corner displays the IV Pole Height setting, air pressure setting, irrigation function status, fill function for the surgical beaker, and Adaptive Fluidics status. The lower right corner shows the ultrasound (or coagulation) setting. The bottom of the surgical screen displays the status bar which provides the current value for a number of system parameters.

Note: *Voice confirmation (if enabled) responds to Primary (Integrated) Foot Control, remote control and on-screen buttons.*

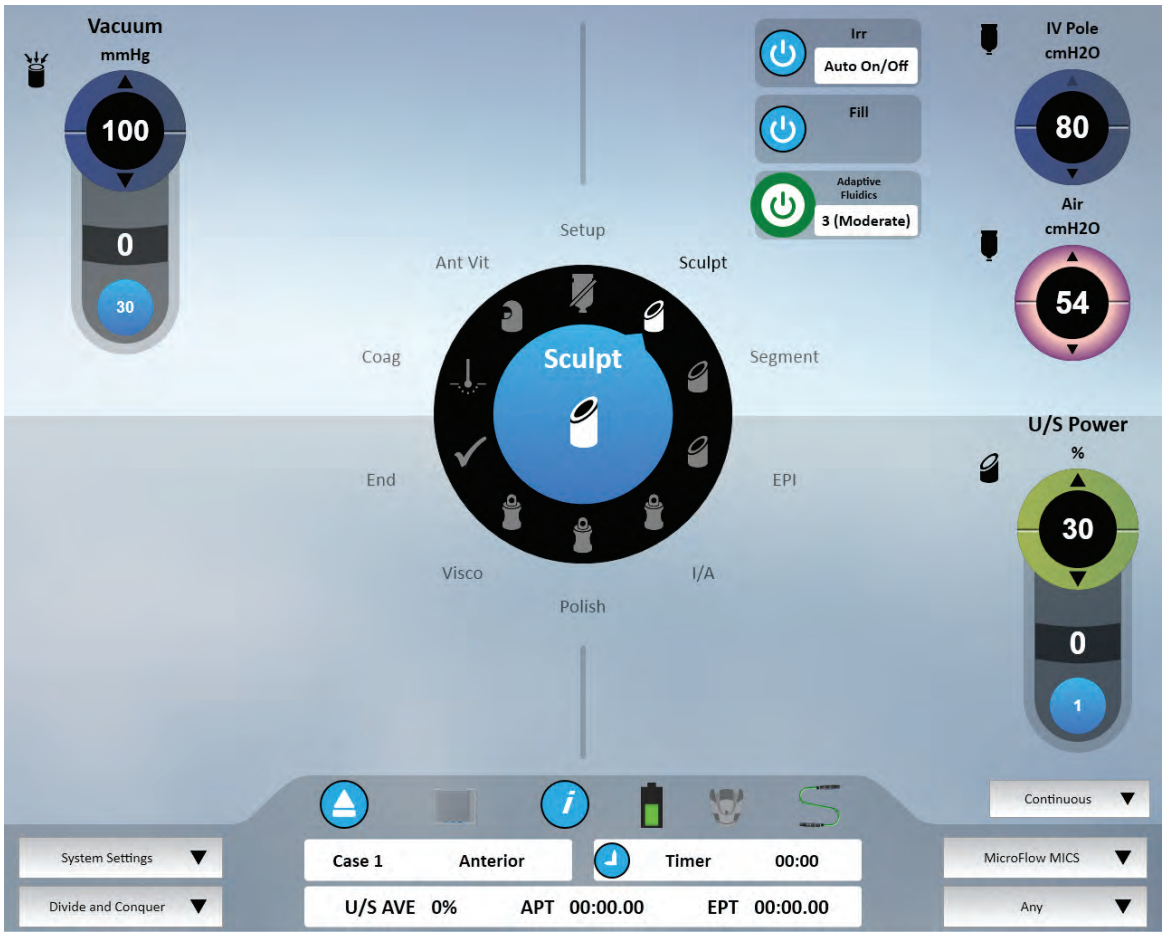


Figure 2.32. **Surgical Screen, Anterior Mode**.

Clock Menu

The round **Clock Menu** in the middle of the screen can display up to 12 phases or exceptions. The exceptions usually appear on the left side of the **Clock Menu**, against a darker background. These are user-defined to be any mode or phase type. The **Setup** and **End** are the system function keys in the **Clock Menu** to change from surgical display screen to **Setup** and **End** screens.

The main Surgical Screen will have a darker background when the system is in a posterior mode and a lighter background when it is in an anterior mode.

When the infusion type is Air Forced Infusion, the infusion pressure unit of measurement display can be toggled between cmH_2O and mmHg. Pressing the display unit button will change the displayed unit of measure.

See Chapter 3 for more details on customizing your system.

IV Pole

The upper right corner of the screen also displays the current setting for the IV Pole (in either mmHg or cmH_2O). You can use the up and down arrows to change the height, and the IV Pole will automatically move up and down to match the setting.

The On/Off button controls the continuous irrigation function by opening or closing the irrigation pinch valve in the fluidics system. Irrigation can be set to off, auto on, auto on/off. If the irrigation control is turned off, the function will still be managed by the Primary (Integrated) Foot Control; when the Foot Pedal enters Region 1, irrigation will commence.

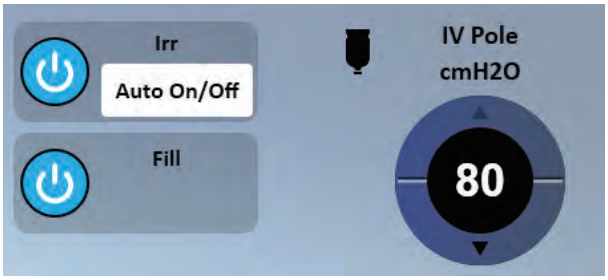


Figure 2.33. **IV Pole Controls**.

Selecting the fill button opens the pinch valves in the fluidics system for a user-programmable period of time. This function is useful for filling surgical beakers without overflow. The button shows the current state of the fill system (On or Off), and the fill control displays the time remaining for the fill operation.

Air Pressure

The Infusion Mode (Pressurized or IV Pole) is displayed and can be changed through the More Screen. Infusion control can be set to be manual, Auto On, or Auto On/Off.

If the Pressurized Infusion function is programmed in the surgeon file, the upper right corner of the screen displays the current setting of air pressure when the pump is not running. When the pump is switched on, the same area will display the actual output pressure. Below the setting display, there is an on/off button to control the air pump operation.

Ultrasound or Coagulation

The lower right corner of the screen displays either the Ultrasound or Coagulation status, depending on which mode is currently selected from the **Clock Menu**. The current setting is shown in the large setting globe, with a green background for ultrasound, or purple background for coagulation. The actual value is displayed in the middle of the settings tube.

When ultrasound is active, an option list control appears in the lower right corner, and selecting the button allows you to select from a list of pre-programmed ultrasound submodes. If you select pulsed ultrasound, the pulse per second (PPS) and duty cycle (DC) setting globes appear.

Vitrectomy and Vacuum

The upper left section of the screen shows status of the Vitrectomy and Vacuum functions, along with the setting globes to adjust them.

Vitesse Hypersonic Vitrectomy

The ***Stellaris Elite***™ GUI setup screen has been updated to provide one-touch **Easy Prime** to prime and tune the Vitesse handpiece for surgery. A color-coded Vitesse icon has been added to the upper left-hand portion of the screen to indicate Vitesse tune status. Detailed instructions for preparing the system and handpiece for priming and tuning are included in Prime and Tune on page 1-23. Users may also refer to the **Show Me Step** videos for animated instructions.

Once the system completes the **Easy Prime** cycle, the user interface controls will transition from the **Setup Screen** to the **Surgical Screen** (Figure 2.34) in preparation for surgery.

Figure 2.34. **Surgical Screen**.

The **Surgical Screen** user controls provide the capability to adjust the **Vacuum** settings from 0 mmHg to 660 mmHg, similar to the controls for the pneumatic vitrectomy cutter. The user controls also provide the capability to control cutting power expressed as a percent of the maximum power.

Coagulation (Fixed)

If one of the **Primary (Integrated) Foot Control Buttons** has been programmed to control coagulation, a small Coagulation setting globe will appear, showing the current maximum fixed setting for the coagulation function.

Status Bars

At the bottom of the screen, the status section displays the current value of a number of system parameters. The top section includes a cassette ejection button, fluid collection device fill level indicator, the More Screen button, as well as the Primary (Integrated) Foot Control battery level, Foot Control icon, and wireless signal strength indicators (see page 1-52). The current pitch region is shown, and circles around the top indicate yaw position. See page 2-13 for details on changing these settings, and the note on page 1-61.

The lower two lines in the status section show the following:

- Current Surgeon (editable)
- Current Technique (editable)
- Domain (Anterior)
- Case Number
- Timer
- U/S Average, APT, EPT
- Needle (editable)
- Grade (editable)

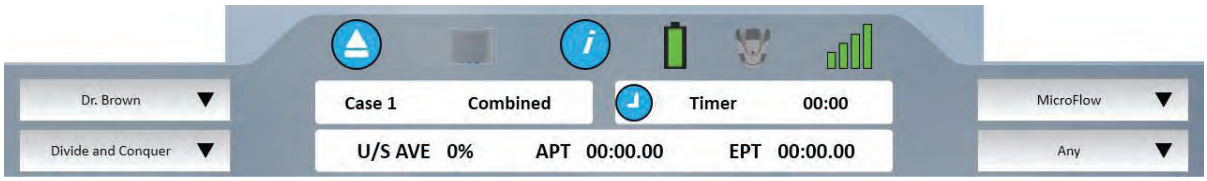


Figure 2.35. **Surgical Screen Status Bar**.

The More Screen button allows access to the **More Screens** for changing various system parameters.

Figure 2.36. **More Screen Button**.

Adaptive Fluidics™

Adaptive Fluidics is a new fluidics function for phacoemulsification surgery during lens removal and I/A only. Adaptive Fluidics is NOT available for anterior vitrectomy and all other posterior phases. Updates to the **More Screen** related to Adaptive Fluidics are detailed below.

- **Enable Function**
  - If the system is installed with ***Stellaris Elite***™ Software Rev 5.3 or higher, the Adaptive Fluidics function can be enabled from either surgeon file programming or the surgical **More Screen**.

To enable the Adaptive Fluidics function from the surgical **More Screen**:

1. Select **More Screen** button as shown in Figure 2.37.
2. Select the **Infusion** Tab on the pop-up screen to display infusion options.
3. Set **Infusion Type** to **Pressurized**, as shown in Figure 2.38.
4. Set **Adaptive Fluidics** to **Enabled**, as shown in Figure 2.38.
5. Adaptive Fluidics settings can be saved with the **Save Settings** command button.
6. The Adaptive Fluidics function can be turned on or off from the Surgical screen (Figure 2.39, Figure 2.40, Figure 2.41, and Figure 2.42).

Figure 2.37. **More Screen Button Located at the Lower Center Portion of the System Screen**.

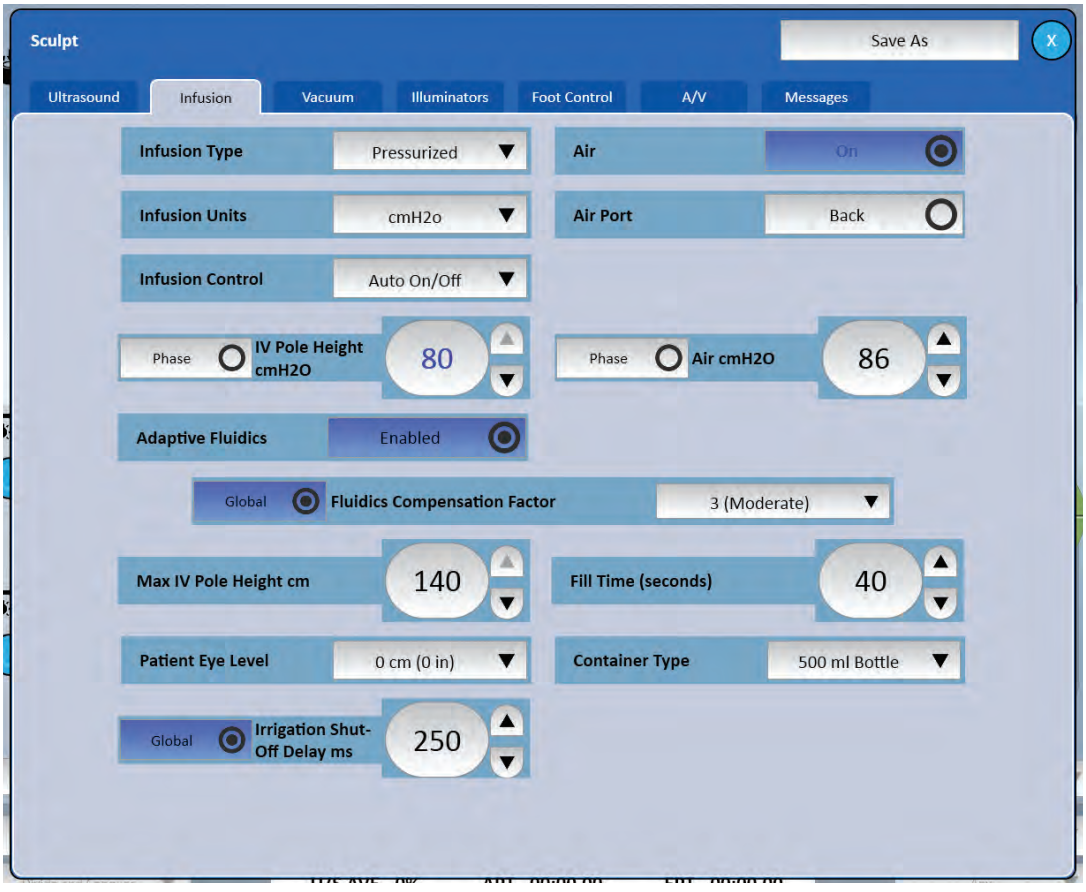


Figure 2.38. **More Screen Infusion Tab**.

Figure 2.39. **Anterior Surgical Screen with More Screen Button to Turn Adaptive Fluidics Function On/Off**.

Figure 2.40. **Combined Surgical Screen with More Screen Button to Turn Adaptive Fluidics Function On/Off**.

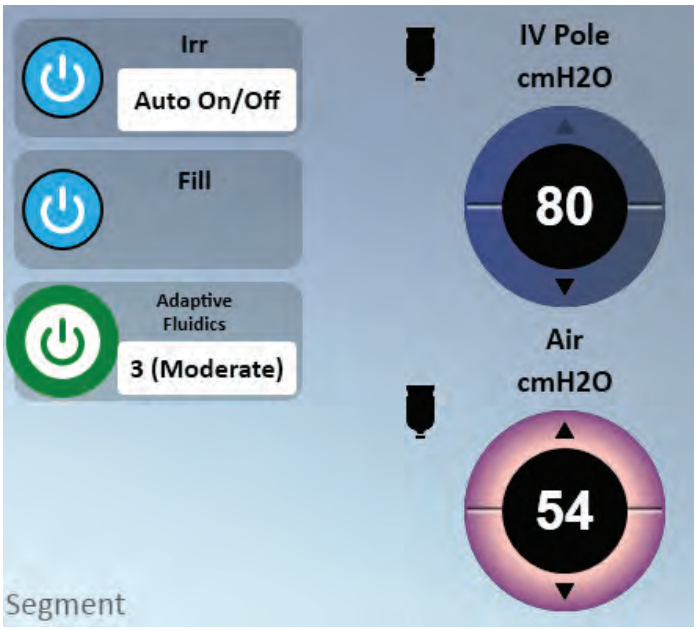


Figure 2.41. **Adaptive Fluidics Turned On**.

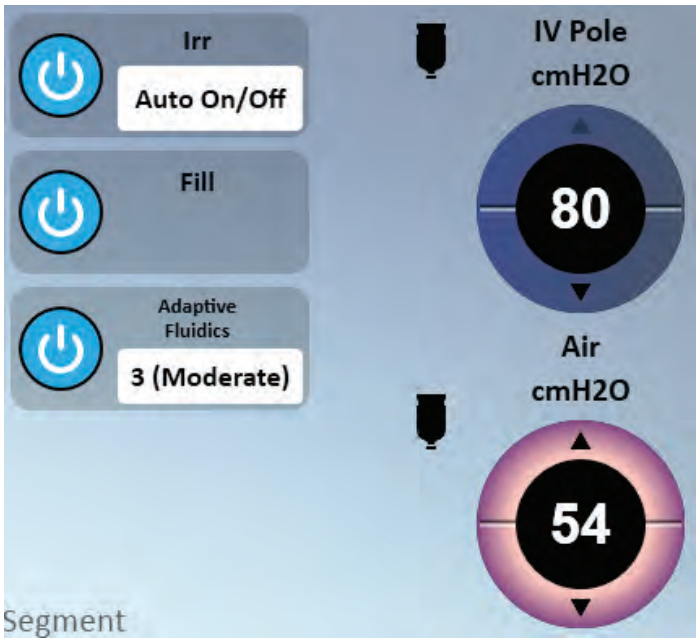


Figure 2.42. **Adaptive Fluidics Turned Off (Pressurized Infusion Remains On)**.

3. Customizing Your System

3. Customizing Your System

This chapter explains how to customize your ***Stellaris Elite***™ vision enhancement system to achieve maximum flexibility for your operating needs.

Note: *Surgical devices may not be operated during programming.*

Each surgeon using the ***Stellaris Elite***™ vision enhancement system can program the system to their own preferred operating configuration and instrument parameters. The **System Settings** system profile contains all available techniques. Several default surgeon preference files are pre-loaded on the system, and you may copy and modify any of them through the Programming interface. You can create, modify and back up surgeon setting preference files, as well as modify system parameters. The programming screens are organized as outlined in the diagrams below.

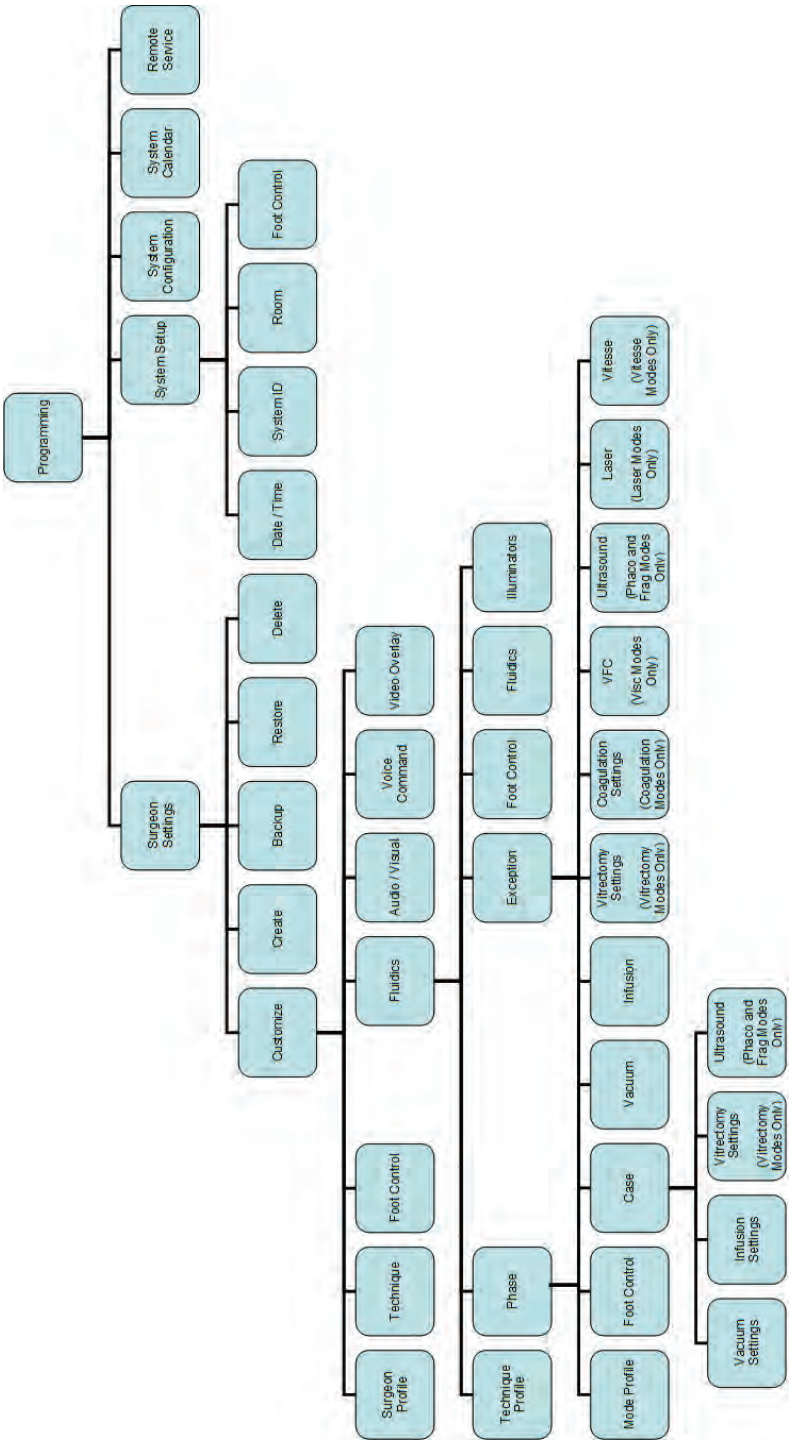


Figure 3.1. **Programming Screen Layout**.

To program system parameters, select **Programming** from main **Clock Menu** on the **Surgeon Level Programming Screen** or the **Setup Surgical Screen**.

The **Main Programming Screen** will appear, from which you can perform the following functions:

- Surgeon Settings
- System Setup
- System Configuration
- System Calendar
- Remote Service

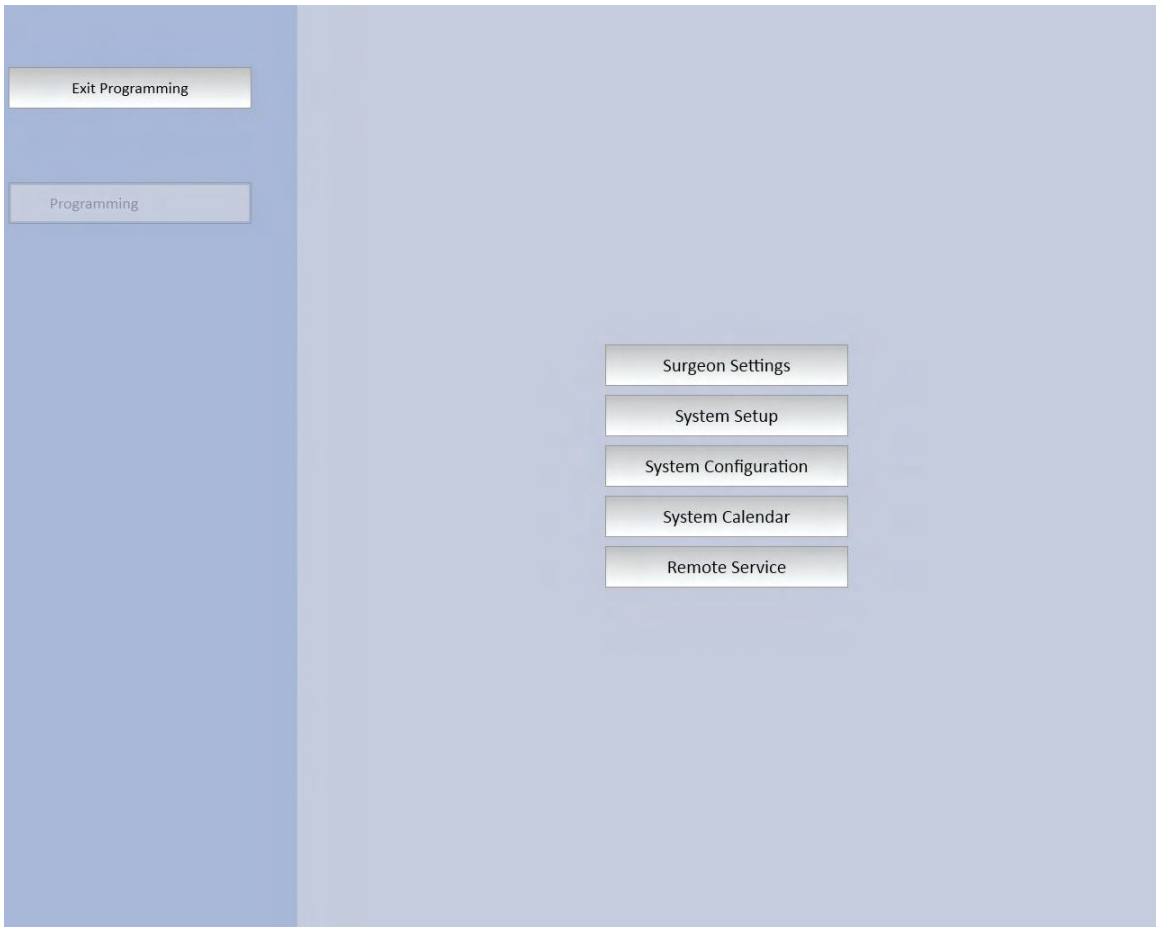


Figure 3.2. **Main Programming Screen**.

Each of these functions is described in more detail below.

At any time, you can select **Programming** to return to the **Main Programming Screen**, or **Exit Programming** to return to the **Surgeon Level Programming Screen** or the **Setup Surgical Screen**. In either case, the ***Stellaris Elite***™ vision enhancement system will ask if you want to save any changes you have made. Select **Yes** to save your changes and overwrite existing files, or **No** to discard your changes.

3.1. Manage Settings

Select **Surgeon Settings** from the **Main Programming Screen**, and a new screen will appear through which you can customize an existing surgeon's file, create a new surgeon preference file by copying from an existing one, back up files, restore files from a backup, or delete surgeon preference files.

A search function is available to filter the surgeon names list when selecting a surgeon file to copy.

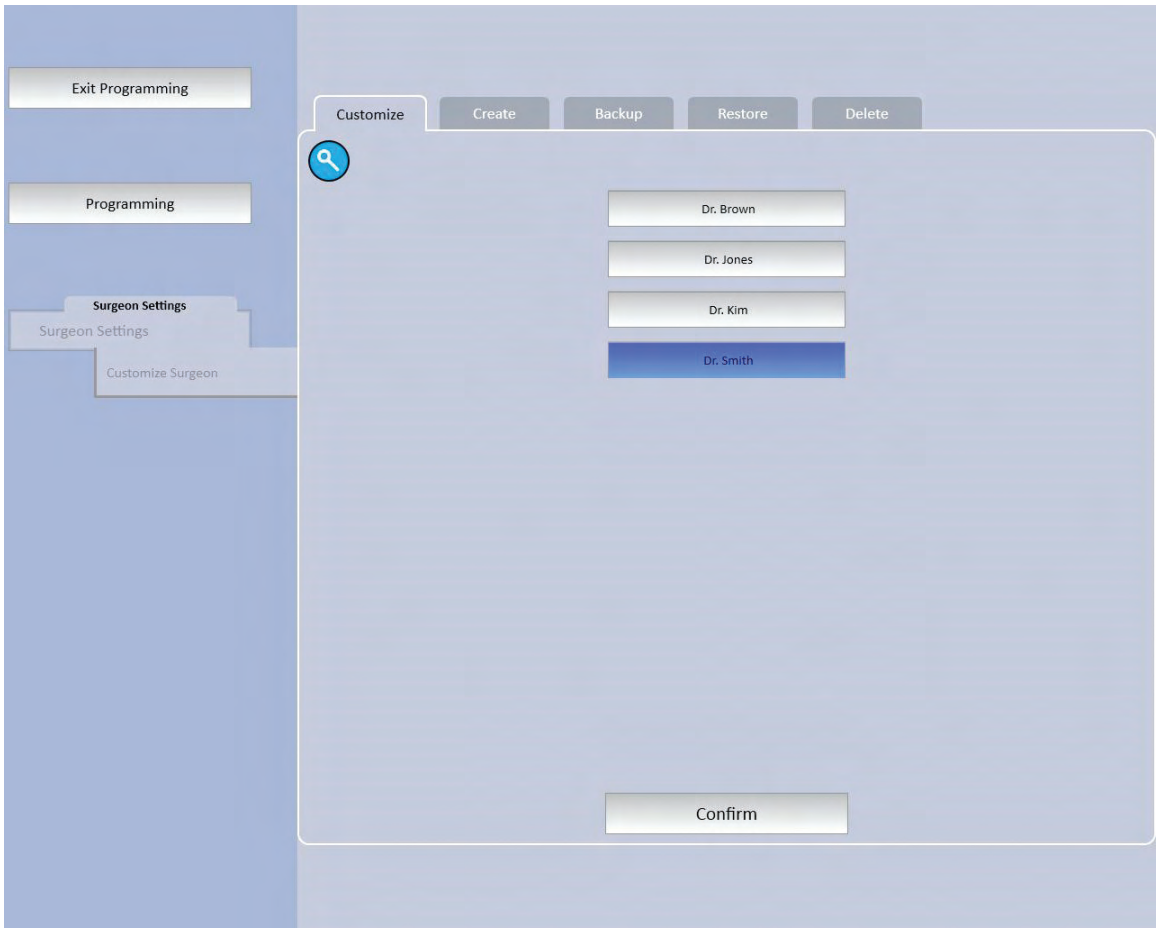


Figure 3.3. **Surgeon Settings Screen**.

Customize a Settings File

To change the settings for a currently existing preference file, select **Surgeon Settings** on the **Main Programming Screen**. A list of all surgeon preference files currently loaded on your ***Stellaris Elite***™ vision enhancement system will appear. Select the name of the surgeon file to be modified, then select **Confirm**. The **Surgeon Programming Screen** appears, with the file name along the left side of the screen, and tabs across the top (see page 3-6). These tabs are **Profile**, **Technique**, **Primary (Integrated) Foot Control**, **Fluidics**, **A/V**, and **Video Overlay**. Each tab allows you to make global changes to system parameters, and is described in detail below.

System parameters can be customized at different levels. Global settings take place at the Technique Level. Technique level settings can be overridden at the phase level. See the table at the end of this chapter for details on which options can be customized at which level.

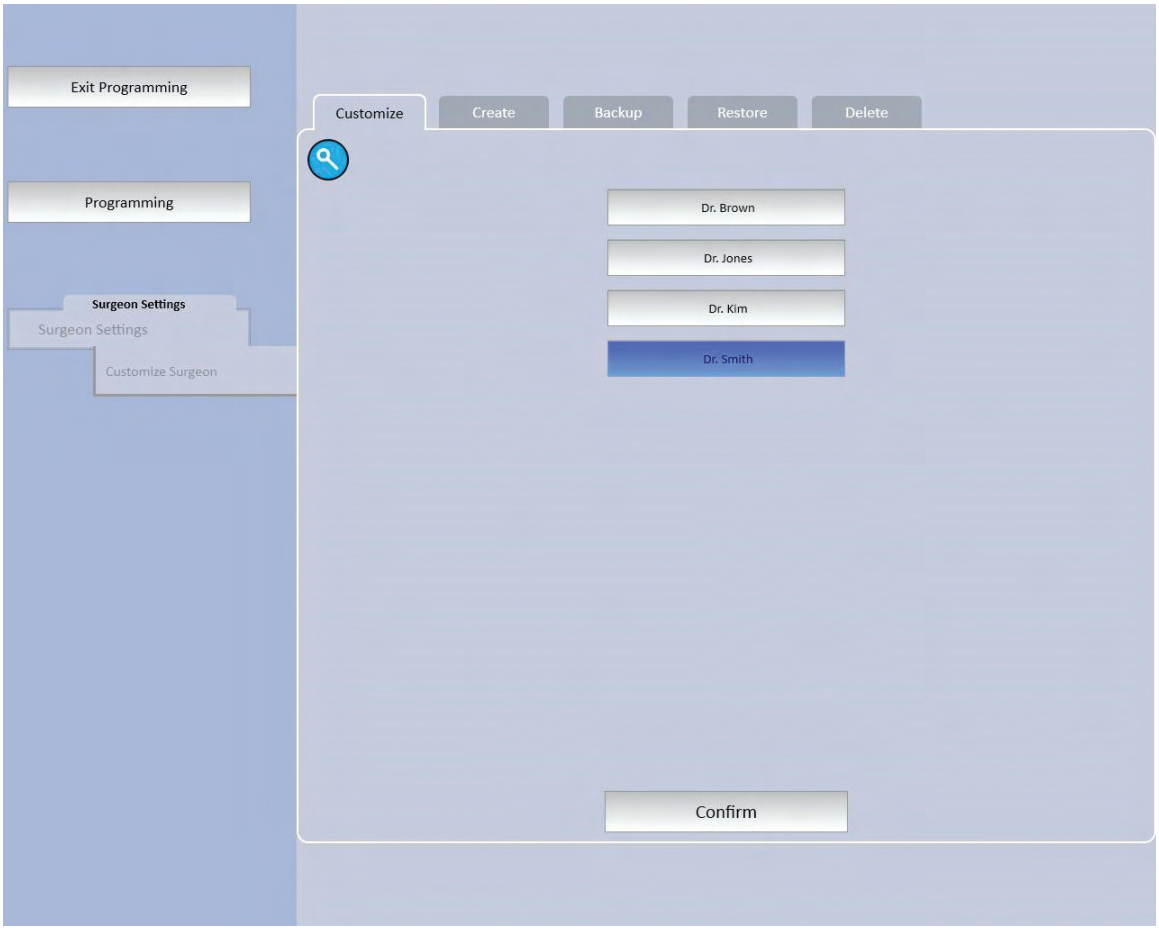


Figure 3.4. **Customize Tab on Surgeon Settings Screen**.

Customize Profile

To change the surgeon's name associated with a settings file, the default screen language, Viscous Fluid Injection Units (PSI, kPascal), enable or disable use of the remote control, or the surgeon password, select the **Profile Tab** on the **Surgeon Level Programming Screen**.

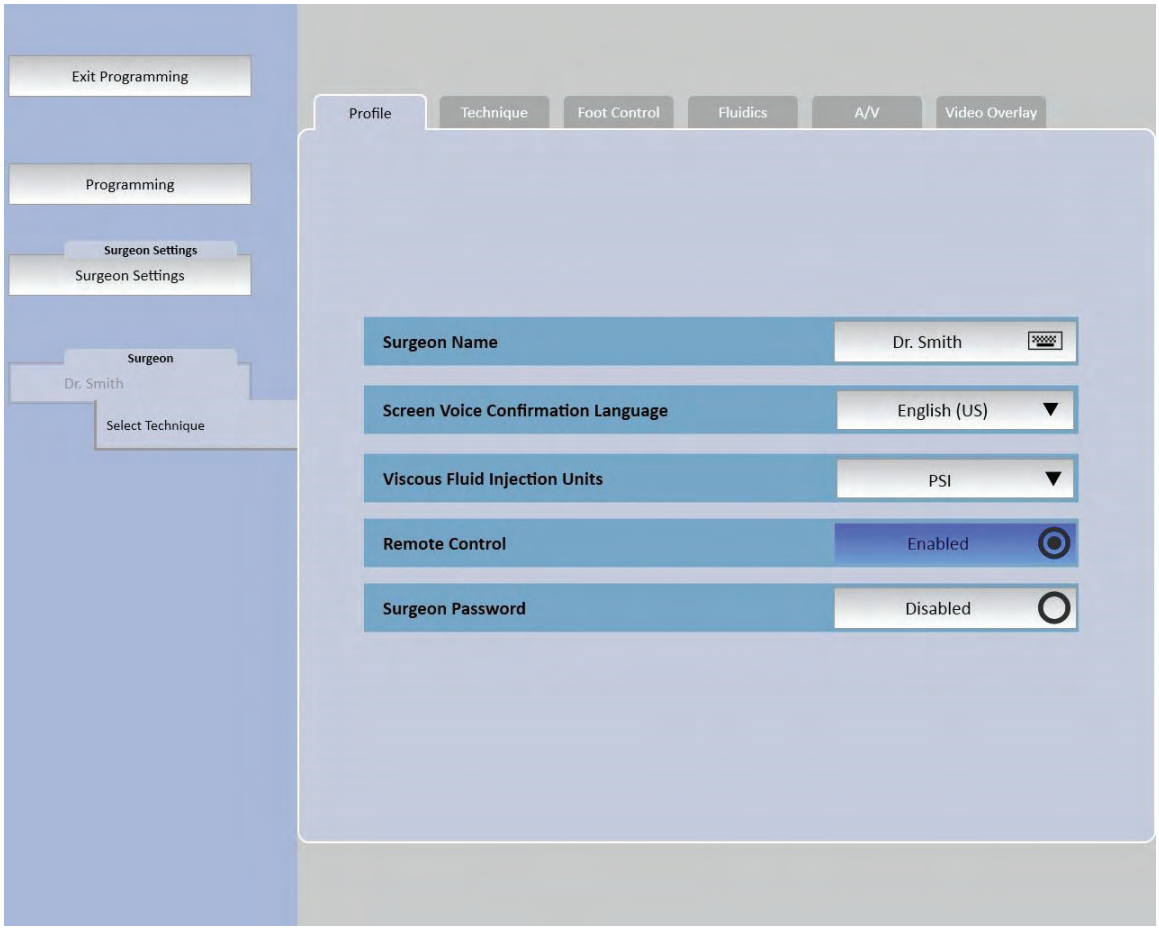


Figure 3.5. **Profile Tab on Surgeon Programming Screen**.

Customize Technique

To change the techniques available for a particular surgeon or modify their settings, select the **Technique Tab** on the **Surgeon Level Programming Screen**, and a list of currently defined techniques will appear. You can select any technique from the current list and use the **Move Up** and **Move Down** buttons to rearrange the order in which they appear. Select **Add** to add a new technique to the surgeon's list. Select a technique, then select **Delete** to remove it, or select **Customize** to continue programming that technique.

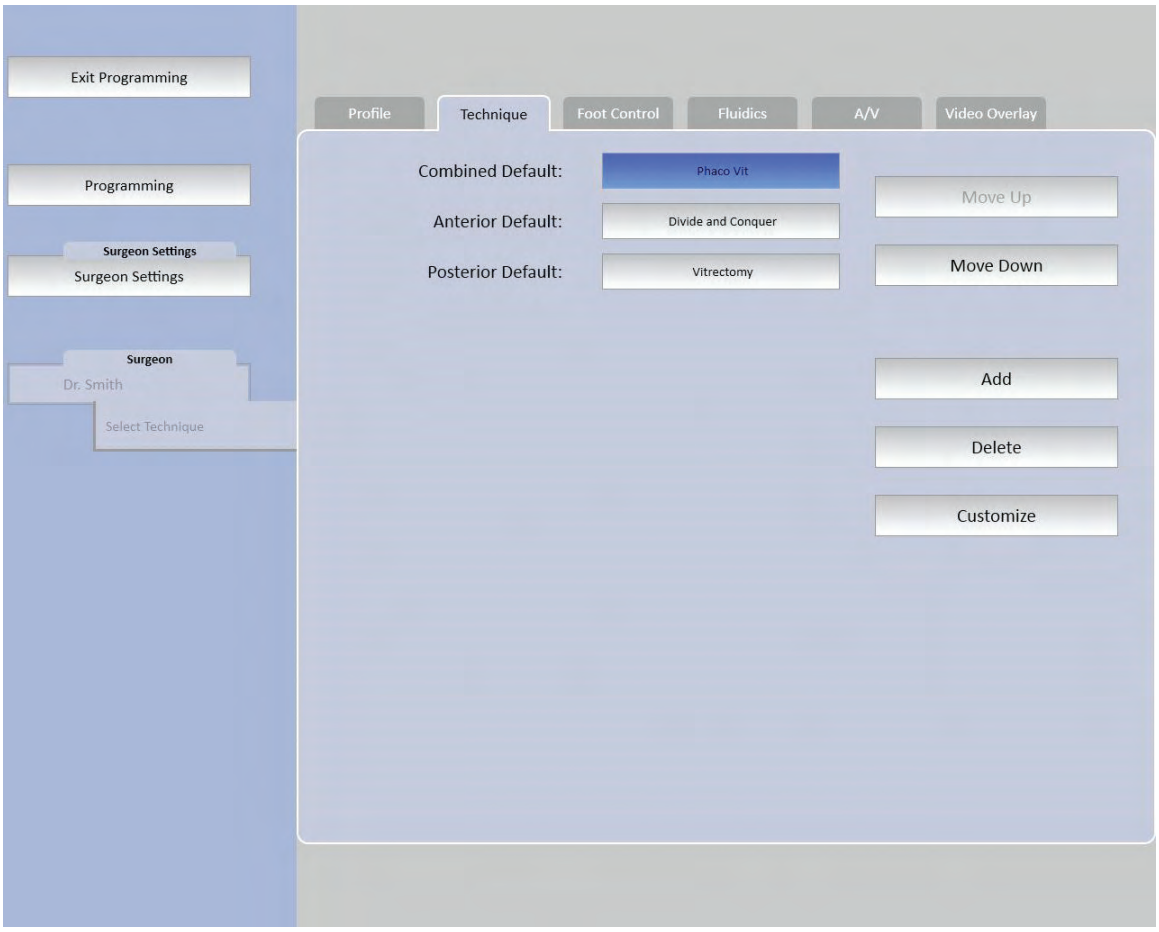


Figure 3.6. **Technique Tab on Surgeon Level Programming Screen**.

Surgeon Level Primary (Integrated) Foot Control, Fluidic, A/V and Video Overlay settings can also be controlled from the corresponding tab. Select the right-pointing arrow to show the Video Overlay tab.

To add a new technique to the list, select **Add**, then select any surgeon from the list that appears, and the techniques defined for that surgeon will appear. Select a technique and select **Confirm** to add that technique to the original list.

To change the settings for a particular technique, select the technique, then select **Customize**. The **Customize Technique Screen** will appear, with tabs for **Profile**, **Phases**, **Exceptions**, **Primary (Integrated) Foot Control**, **Fluidics**, and **Illuminators**. Various parameters may be adjusted through these tabs, as described below.

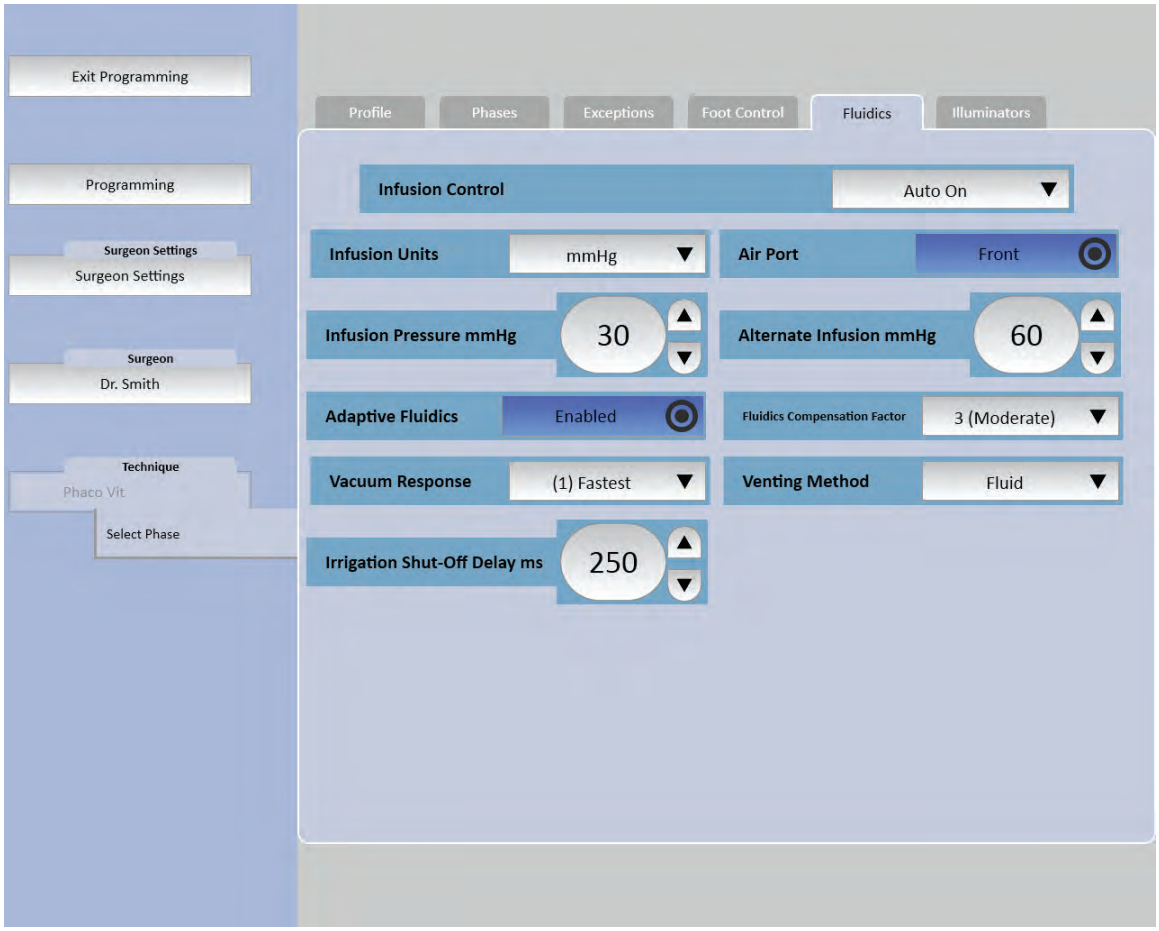


Figure 3.7. **Customize Technique Screen**.

- **Profile Tab**—Technique Name, Remote Control (Enable, Disable)
- **Phases Tab**—Each technique may include up to eight phases. The **Phases Tab** shows the name of the phase, and the mode for that phase. Phases can be added, deleted, or re-ordered. They may also be customized, as described below.
- **Exceptions Tab**—Each technique may include up to eight exceptions, for a total of no more than 12 phases and exceptions. Exceptions can be added, deleted, or re-ordered. They may also be customized, as described below.
- **Primary (Integrated) Foot Control Tab**—Primary (Integrated) Foot Control Button (four standard sets plus custom settings), enable/disable next ultrasound modulation on yaw, reflux on yaw, reflux type, fixed coag power, linear coag setup
- **Fluidics Tab**—Aspiration types (Vac: Vac Modes, Flow: Vac Modes, Flow: Flow Modes, Flow: All modes), Infusion Type (IV Pole, Pressurized), Infusion Units (mmHg or cmH_2O), Infusion Mode (Manual, Auto On, Auto On/Off), IV Pole Height, Vacuum Response, Venting Method (Air or Fluid), Irrigation Shut-Off Delay (ms), and Pressurized Infusion Settings
- **Illuminators Tab**—Illumination Controls (Enabled/Disabled), Upper lamp on/off and percent on, lower lamp on/off, percent on, and filter (none, amber, green, yellow), Display illuminator controls (anterior technique option only)

For combined techniques, Infusion Type, Infusion Units, F/AX pressure, Infusion pressure, Elevated Infusion pressure, and Elevated F/AX pressure settings are displayed. They are not displayed in anterior modes.

For anterior techniques, the IV Pole Height setting and Pressurized Infusion pressure setting are displayed.

Customizing Phases and Exceptions

Both Phases and Exceptions can be re-ordered and customized. Select a phase or exception from the list on the appropriate tab, and the **Customize** button will appear. Select **Customize**, and more options specific to that function will appear, and can be modified. These can include Phase Information, **Primary (Integrated) Foot Control** settings, Fluidics (Aspiration and Infusion), Ultrasound, Vitrectomy, and Coagulation settings. When you are done making changes, select **Exit Programming**. The system will ask you to confirm your changes before exiting.

Note: *The total number of surgery phases (normal and exception) cannot exceed 12. There must be at least one normal phase in each technique, and there can be no more than 8 exceptions.*

Note: *When you are in an anterior technique, and either Phaco or Irr/Asp phase, the Mode name setting will have a drop-down menu with default options.*

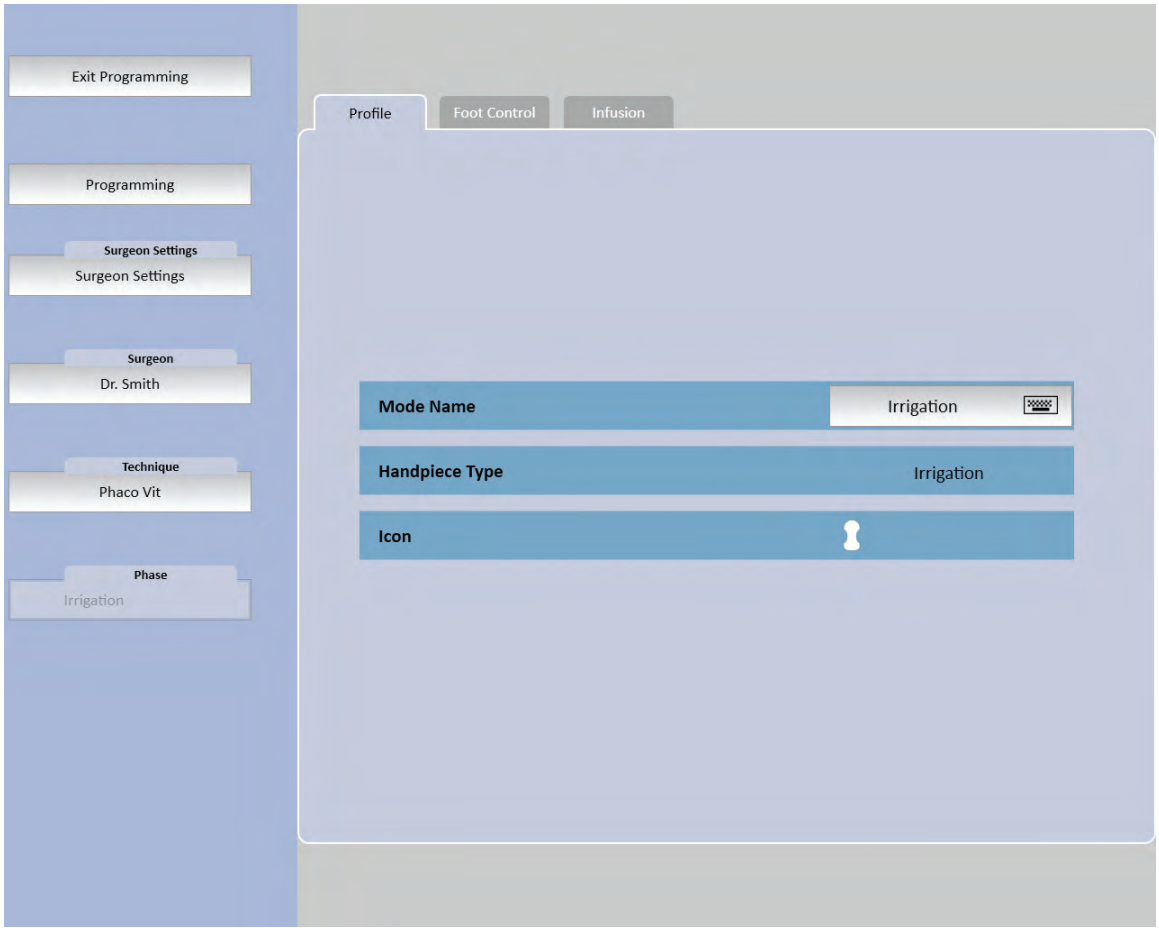


Figure 3.8. **Customize Phase Screen**.

Select **Customize**, and more options specific to that function will appear, and can be modified. These can include Profile, Primary (Integrated) Foot Control, Vacuum, Infusion, U/S Setting, U/S Waveform, Cut, Coagulation and Visc tab.

Which tabs are displayed depends on which mode you are in, and whether Customize Settings by Case is disabled or enabled, as detailed in the table below.

Mode	**Tabs Displayed on Phase Programming Screens**
***Customize Setting by Case* disabled**	
Anterior Vitrectomy Posterior Vitrectomy	Profile, Primary (Integrated) Foot Control, Vacuum, Infusion, Cut
Phaco Frag	Profile, Primary (Integrated) Foot Control, Vacuum, Infusion, U/S
I/A	Profile, Primary (Integrated) Foot Control, Vacuum, Infusion

Mode	Tabs Displayed on Phase Programming Screens
Irrigation	Profile, Primary (Integrated) Foot Control, Infusion
Viscous Fluid Control	Profile, Primary (Integrated) Foot Control, Visc
Viscous Fluid Control (Dual/Yaw Vac submode)	Profile, Primary (Integrated) Foot Control, Visc, Vacuum and Infusion
Extrude	Profile, Primary (Integrated) Foot Control, Vacuum, Coag (if Coag on Yaw is enabled), Infusion
Linear Coagulation	Profile, Primary (Integrated) Foot Control, Coag
Customize Settings by Case **enabled**	
Extrude	Profile, Primary (Integrated) Foot Control, Case
Posterior Vitrectomy	Profile, Primary (Integrated) Foot Control, Case
Phaco	Profile, Primary (Integrated) Foot Control, Case
Frag	Profile, Primary (Integrated) Foot Control, Case
I/A	Profile, Primary (Integrated) Foot Control, Case

When you are done making changes, select **Exit Programming**. The system will ask you to confirm your changes before exiting.

3.2. Surgeon Level Settings

To access the surgeon level settings, go to the **Programming** Screen, then select **Surgeon Settings**, the name of the surgeon file to be modified, then **Confirm**.

Customize Primary (Integrated) Foot Control

To modify the techniques and settings for the Primary (Integrated) Foot Control, select the **Primary (Integrated) Foot Control Tab** on the **Surgeon Level Programming Screen**. You can set the Primary (Integrated) Foot Control for right or left foot operation.

The **Mode Change Control** allows you to set the ***Stellaris Elite***™ vision enhancement system response when the Foot Pedal is activated and you change surgical modes. Options are Allow-Limit Pedal, Allow-Remap Pedal, Allow-No Limiting, and Not While Active.

The **Detent Control** determines what feedback the ***Stellaris Elite***™ vision enhancement system will give when changing Foot Pedal regions. This can be Disabled, Enabled for regions 1, 2 and 3 or Enabled for regions 2 and 3 only.

The **Region Setting globes** control at what percent depression at which each region begins.

A button is displayed that allows selection of Posterior Modes or Anterior Modes. When Posterior Modes is selected, the Foot Pedal region 1, 2 and 3 start positions are adjustable. The posterior mode start positions are used in the posterior domain and the posterior modes of the combined domain.

When Anterior Modes is selected, the Foot Pedal region 1, 2 and 3 start positions are adjustable. The anterior mode start positions are used in the anterior domain and the anterior modes of the combined domain.

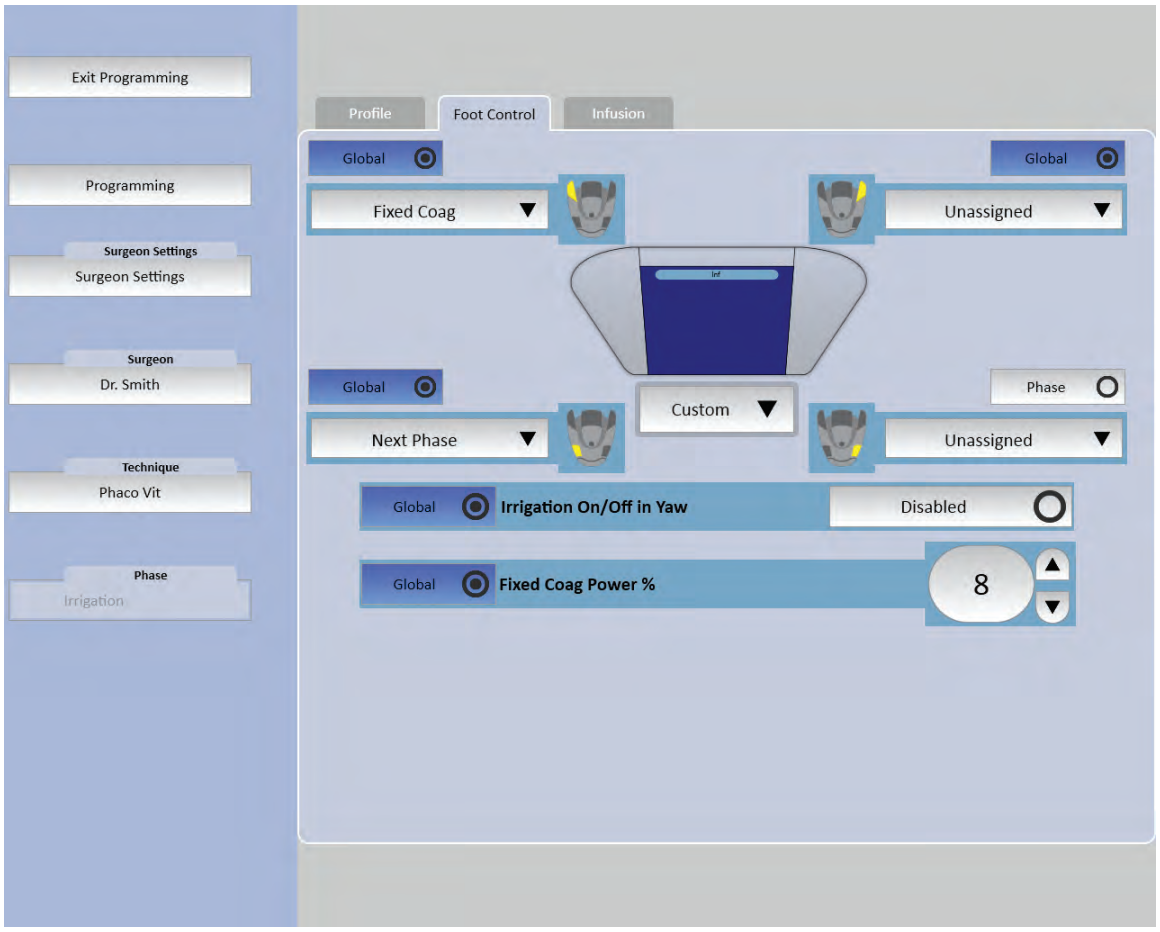


Figure 3.9. **Customize Primary (Integrated) Foot Control Screen**.

Customize Fluidics

To set the parameters for Fluidics functions, select the **Fluidics Tab** on the **Surgeon Level Programming Screen**. You can set the following options by selecting the current setting, and then selecting the new setting from the menu.

- **Container Type** (500 mL bottle, 500 mL Bag, 250 mL bottle)
- **Patient Eye Level** (relative to the aspiration port on the fluidics system)
- **Vitrectomy Gauge** (Any, 20 gauge, 23 gauge, 25 gauge, 27 gauge)
- **Frag Needle Gauge** (Any, 20 gauge, 23 gauge)
- **Extrude Gauge** (Any, 20 gauge, 23 gauge, 25 gauge, 27 gauge)
- **Phaco Needle** (Any, Standard, MicroFlow™, MicroFlow+, Thin Tip, MICS 1.8, Vortex, MicroFlow MICS)
- **I/A Tip Type** (Any, 0.3 mm, 0.5 mm)

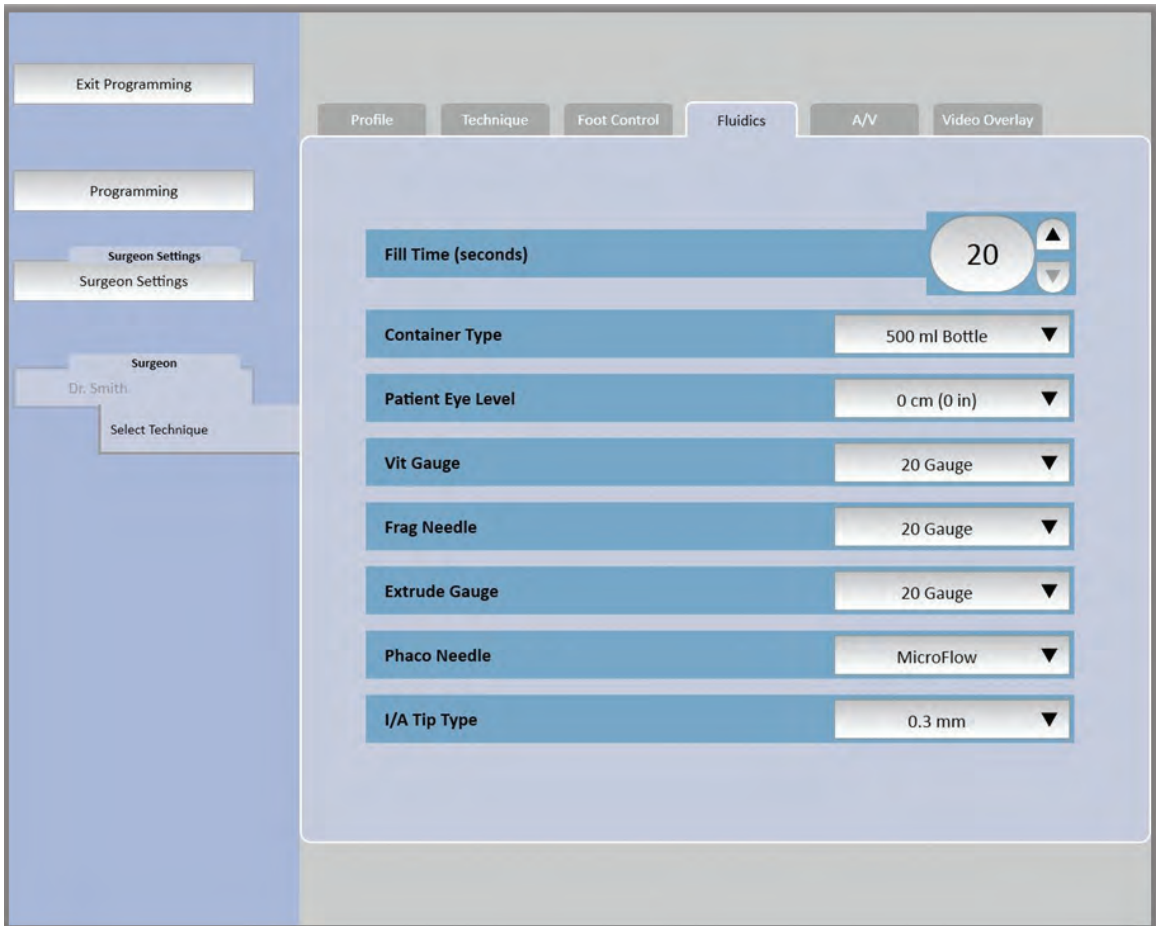


Figure 3.10. **Customize Fluidics Screen**.

Customize A/V (Audio/Visual)

To set the parameters for audio and visual functions, select the **A/V Tab** from the **Surgeon Level Programming Screen**. You can adjust both **Display Brightness** and **Master Volume** by using the setting globes on this screen. To change the tone or volume of a tone that is sounded for a particular condition, select the function from the list at the bottom of the screen, and that condition will appear in the change section in the middle of the screen. Select the desired tone from the option list, and use the setting globe to increase or decrease the volume.

Functions that can have a tone associated with them include:

- Alert (only volume can be adjusted)
- Aspiration
- Coagulation
- Elevated Infusion (only volume can be adjusted)
- Key (only volume can be adjusted)
- Irrigation Infusion
- Laser (only volume can be adjusted)
- Occlusion (Flow systems only)
- Reflux
- Ultrasound
- Timer
- Visc Inject
- Vitrectomy
- Voice Confirmation (Enabled or Disabled)

Note: *Only tones that are not currently in use by another function will be available for selection.*

Note: *Elevated Infusion, Key, Laser and Visc Inject are used for Posterior/Combined systems only. (***Stellaris Elite**™ *SKU BL14455 and SKU BL15455)*

Figure 3.11. **Customize A/V Settings Screen**.

Customize Video Overlay

To set the parameters for the DMS Video Overlay functions, select the **Video Overlay Tab** on the **Surgeon Level Programming Screen**.

Through this tab you can set whether or not the system will combine Video Overlay Format information (U/S Averages, settings). By default, the U/S data is shown as three separate lines on the video overlay. If the U/S display option is set to **Combine**, the display will appear on one line, which will step through the three values, or it may be set to **Display None**. Similarly, settings are normally displayed on four lines, and case information on two lines, but if the combine option is set to **Yes** they will appear on one line that will step through the values.

You can select the language to be used on the Video Overlay.

You can set the Video Overlay overscan rate from 0% to 5%.

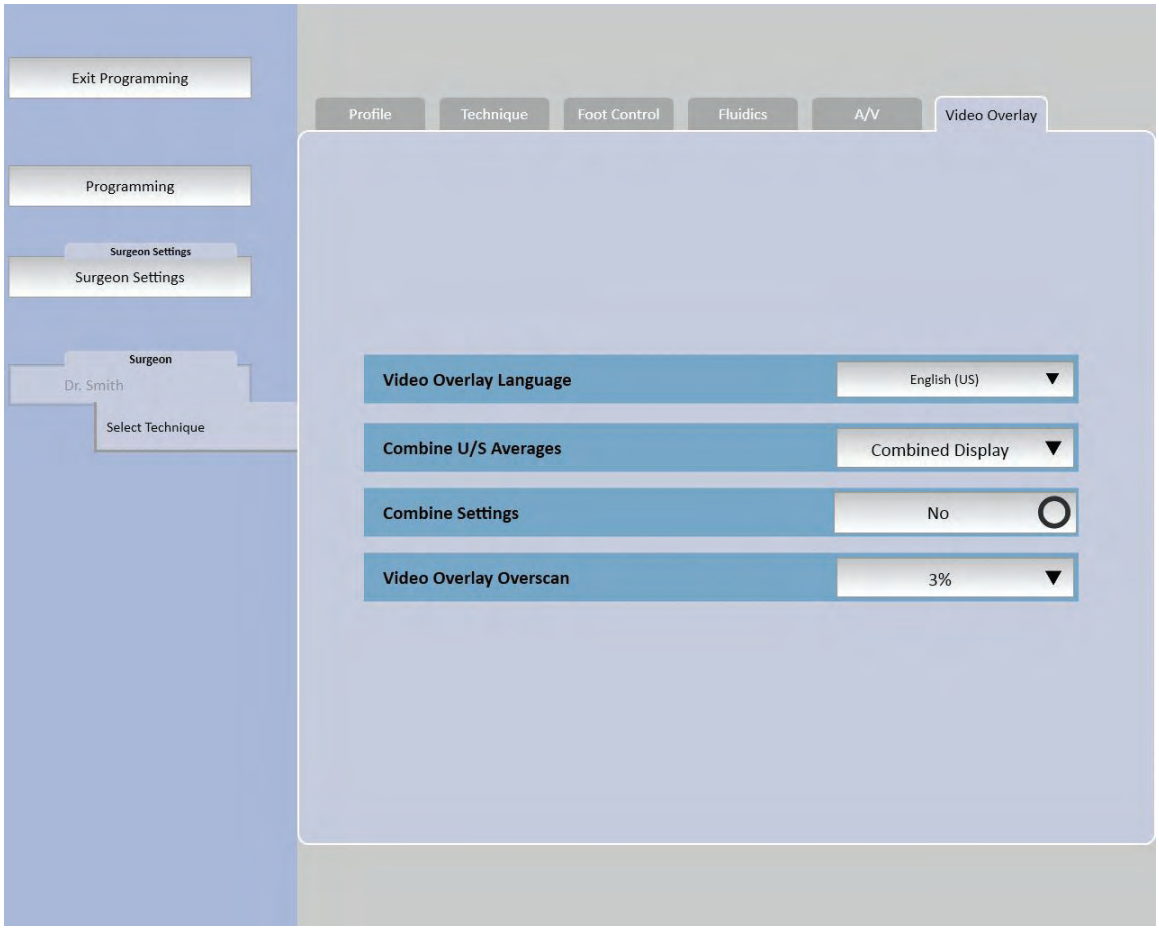


Figure 3.12. **Customize Video Overlay Screen**.

3.3. Manage Surgeon Files

Create a New Settings File

The system will come pre-loaded with several system files, including System Settings, System Vitesse, and System VFM1.

To create a new surgeon preference file, select the **Create Tab** from the **Surgeon Settings Screen**, then select the existing surgeon file which has settings most similar to the file you are going to create. Once you have highlighted a file, the techniques in that file will be listed on the right side of the screen. Select one or more techniques by touching them. Select a technique a second time to deselect it.

A search function is available to filter the surgeon names list when selecting a surgeon file to load.

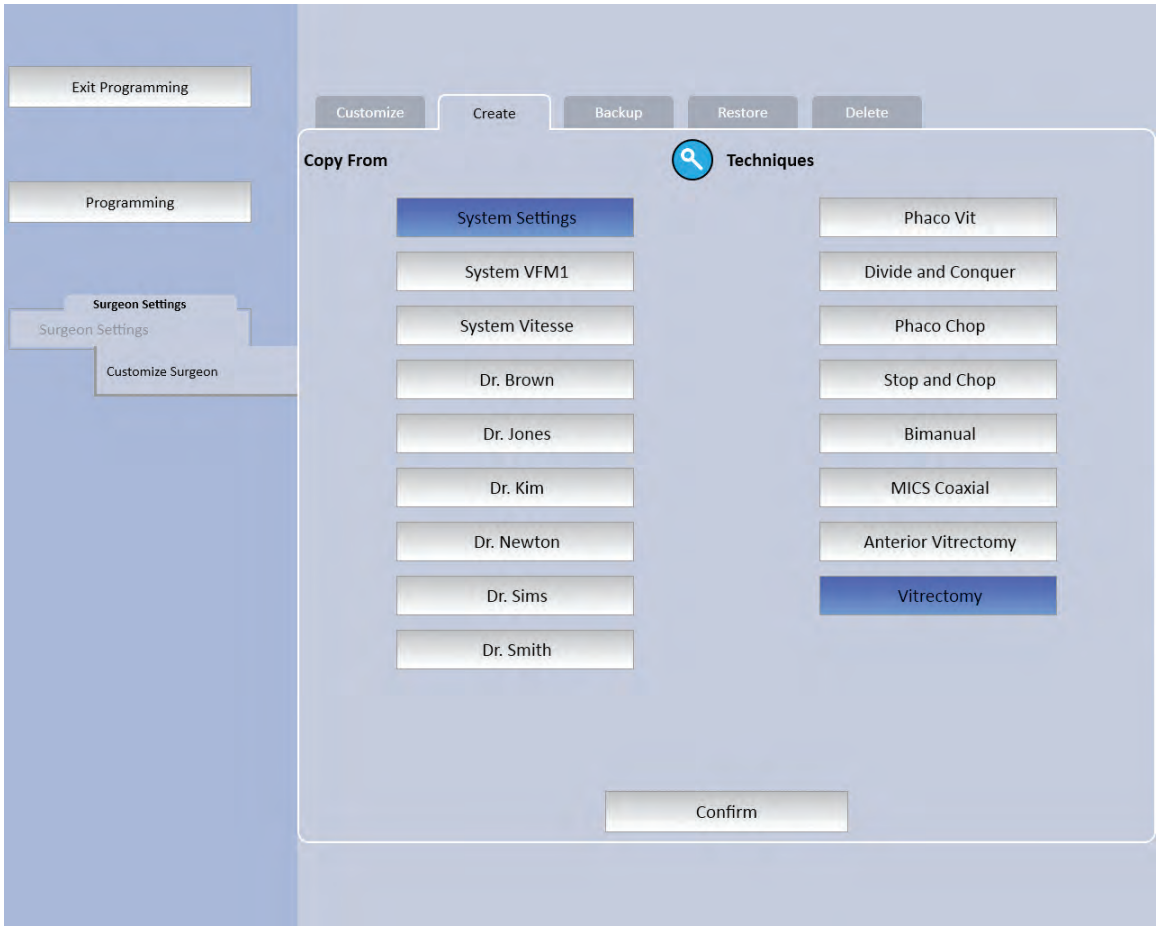


Figure 3.13. **Create New Settings File Screen**.

Once all the desired techniques are highlighted, select **Confirm** and a keyboard will appear, through which you can enter the name for the new surgeon file, then select **Enter**. The name of the new file will appear on the left side of the screen, and a new set of tabs (**Profile**, **Technique**, **Primary (Integrated) Foot Control**, and **Fluidics**) will appear across the top of the screen. These can be used to further customize the preference file (see page 3-8).

Back Up a Settings File

To back up an existing surgeon preference file to a USB memory device, select the **Backup Tab** from the **Manage Settings Screen**, then insert the device into one of the two USB ports behind the round sliding door on the back of the display panel. Select the file or files to be backed up, the location to which they should be backed up, and select **Confirm**. You must select the screen first, then insert device. The system will only recognize a USB device after this screen is selected.

To move a surgeon preference file from one system to another, use **Backup** on the first system to move the file to a USB drive, then **Restore** that file on the second machine (page 3-20).

Note: *Memory devices complying with either USB 1.1 or USB 2.0 standards are supported by the* **Stellaris Elite™** *vision enhancement system. Operations with other USB devices are* ***NOT*** *supported.*

Figure 3.14. **Backup Settings File Screen**.

Restore a Settings File

To restore an existing surgeon preference file from a USB memory device, select the **Restore Tab** from the **Manage Settings Screen**, then insert the device into one of the two USB ports on the back of the system console, behind the round sliding door. Make sure the **Restore Tab** is active at the top of the **Manage Settings Screen**, select the file or files to be restored, and select **Confirm**.

To move a surgeon preference file from one system to another, use **Backup** on the first system to move the file to a USB drive (page 3-18), then **Restore** that file on the second machine.

Note: *You must select the **Restore Settings File** screen first, then insert the device. The system will only recognize a USB device after this screen is selected.*

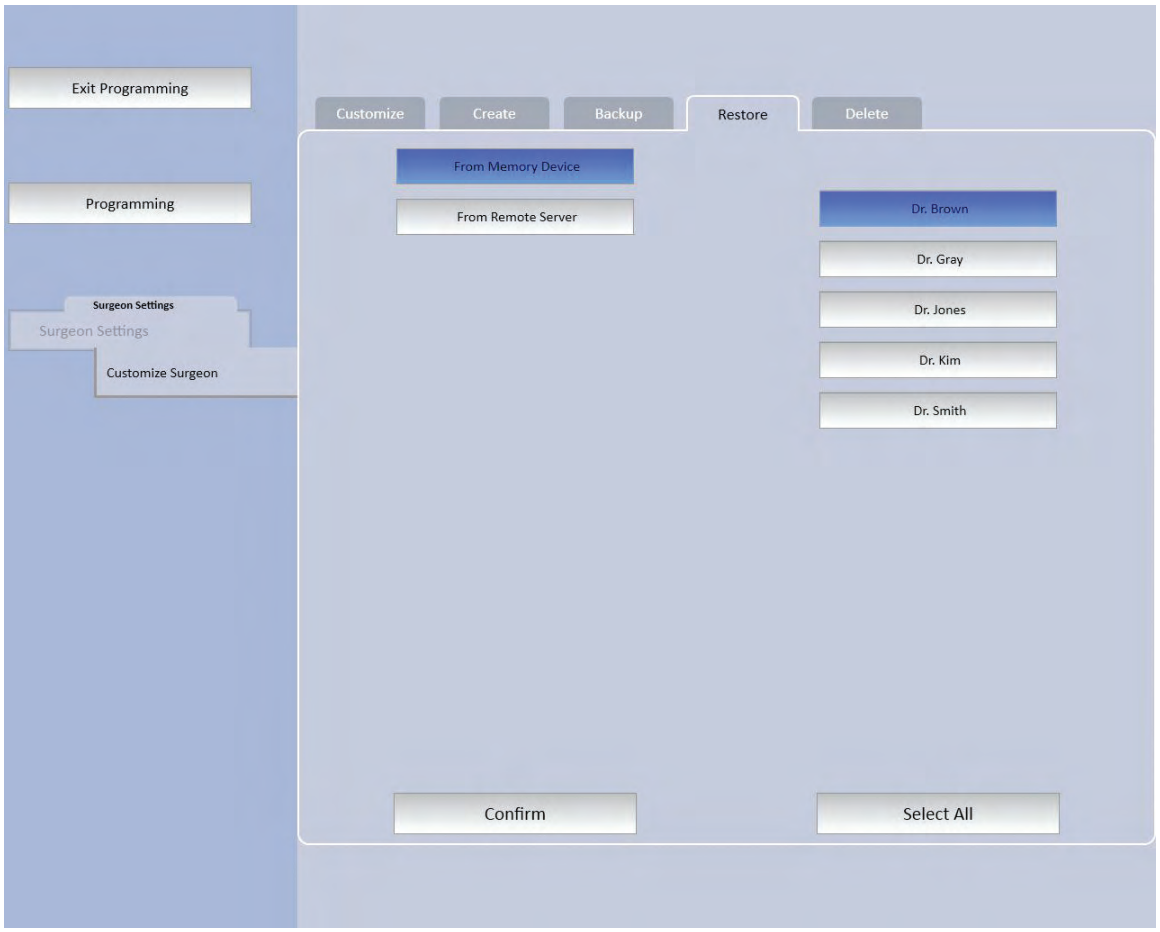


Figure 3.15. **Restore Settings File Screen**.

Delete a Settings File

To delete an existing surgeon preference file, select the **Delete Tab** from the **Manage Settings Screen**, select the file or files to be deleted, and select **Confirm**.

Figure 3.16. **Delete Settings File Screen**.

3.4. System Setup

Select **System Setup** from the **Main Programming Screen**, and a new screen will appear through which you can set the Date/Time for the system, view the System IDs, and set operating room parameters. Any changes you make here are implemented immediately.

Set Date, Time and Language

To change the system language, current date, time or format in which the time is displayed, select the **Date/Time Tab** at the top of the **System Setup Screen**. Select from the option list menus to change the default system language, month, day, year, clock format (12 or 24 hour), and current time in hours and minutes. Once all changes have been made, select **Confirm** at the bottom of the screen to make your changes effective immediately.

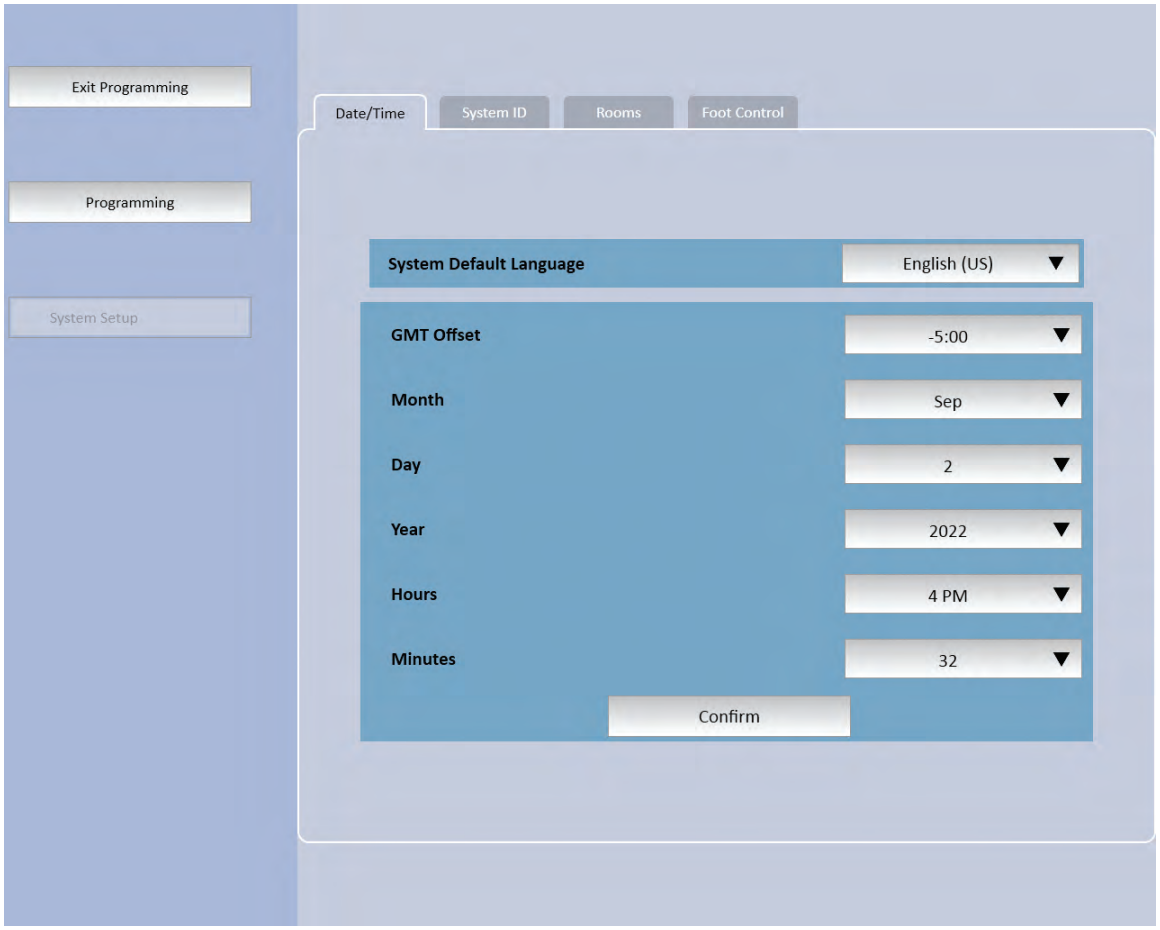


Figure 3.17. **Set System Date/Time Screen**.

System ID

To monitor or change the identifying names of your ***Stellaris Elite***™ vision enhancement system, select the **System ID Tab** at the top of the **System Setup Screen**. You can enter or update the account name and system name that have been assigned to your ***Stellaris Elite***™ vision enhancement system. You can view the system catalog number as well as its installation number, but these are not editable.

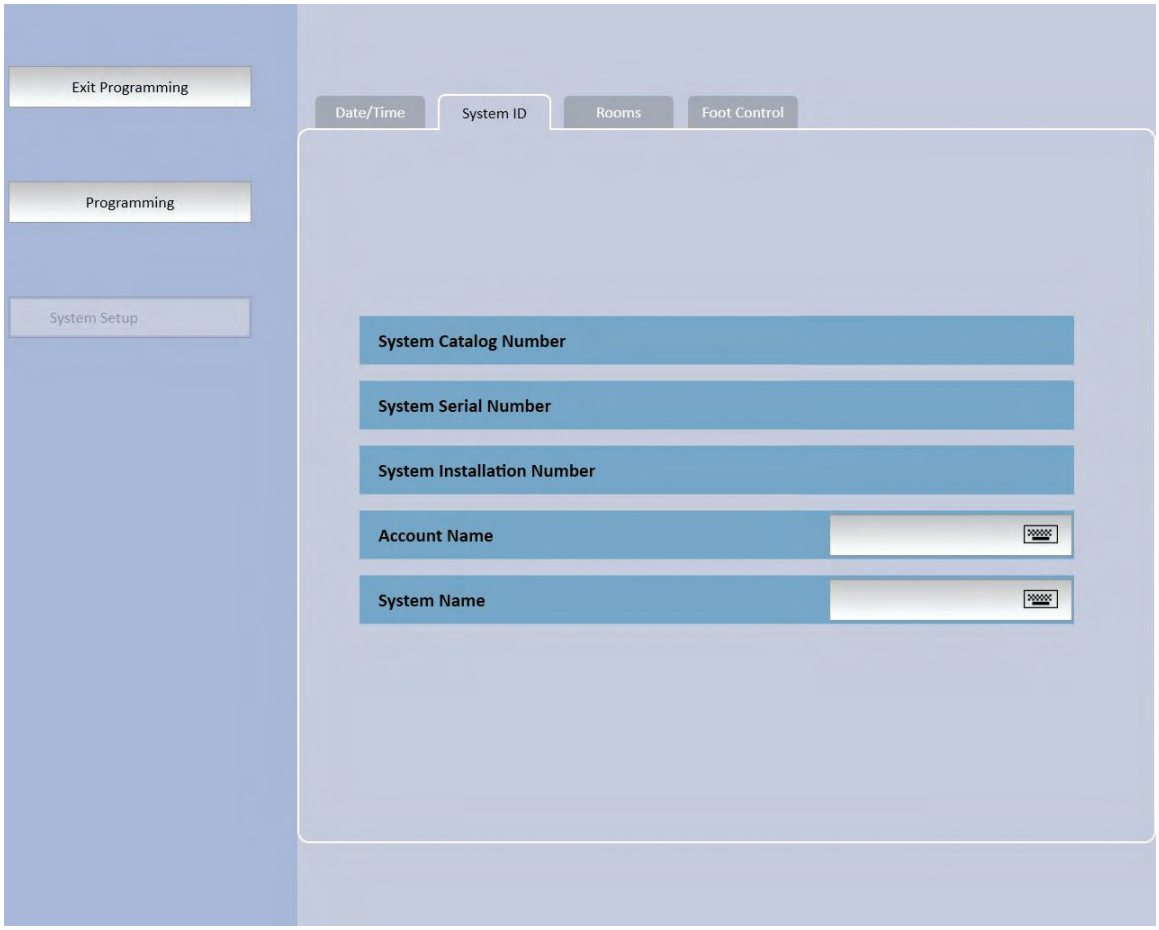


Figure 3.18. **System ID Screen**.

Rooms

To assign names to the operating rooms in which your ***Stellaris Elite***™ vision enhancement system is used, select the **Rooms Tab** at the top of the **System Setup Screen**, select any room button, and the keyboard will appear, where you can enter the name for that room. Select **Enter** and the room name will be saved. You can also set the **Maximum IV Pole Height** in centimeters, as measured from the aspiration port in the fluidics system, using the setting globe on this screen. This setting is to allow the system to be programmed to not hit the ceiling in a facility with ceilings lower than nine feet (2.75 meters).

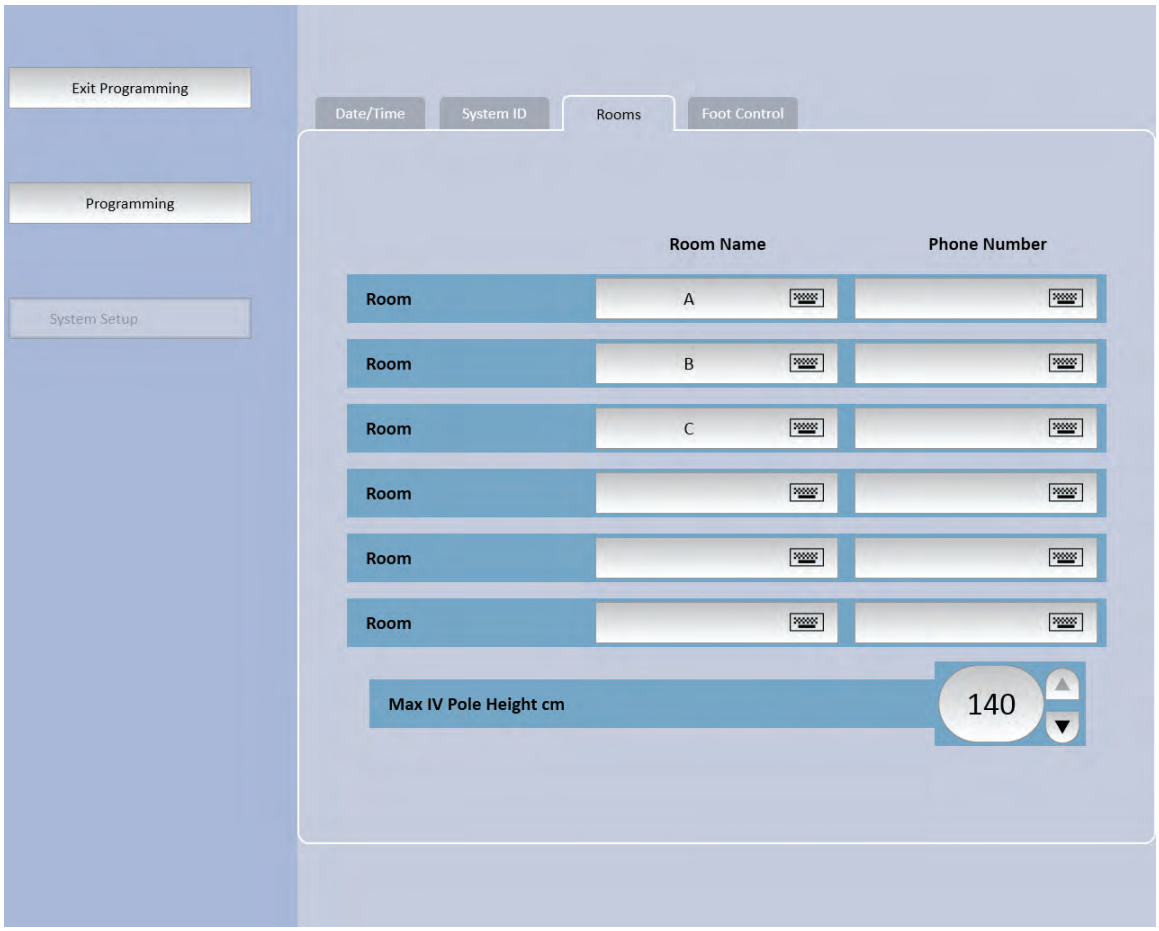


Figure 3.19. **Room Assignment Screen**.

Primary (Integrated) Foot Control

To change the way your ***Stellaris Elite***™ vision enhancement system connects to the Primary (Integrated) Foot Control, select the **Primary (Integrated) Foot Control Tab** at the top of the **System Setup Screen**. Select **Enabled** or **Disabled** to configure the connection mode.

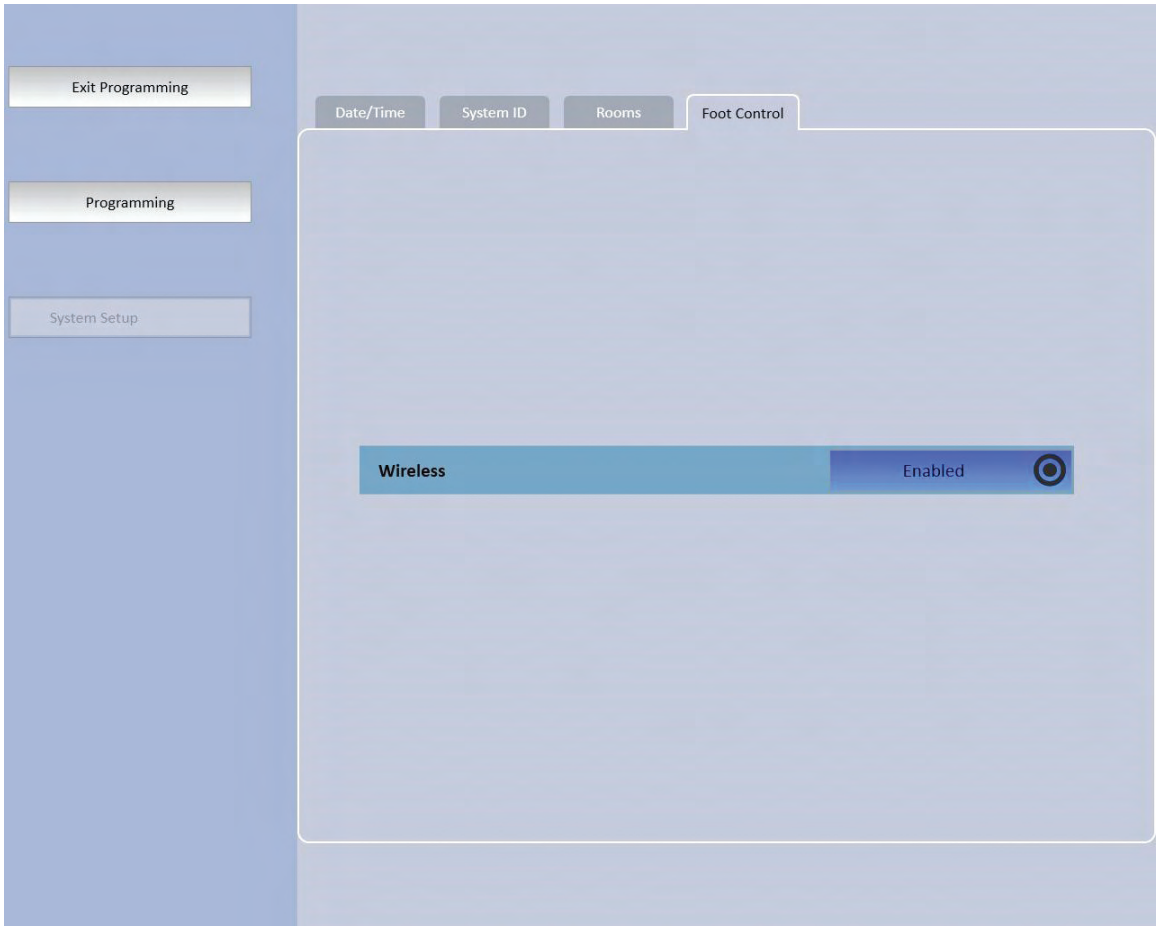


Figure 3.20. **Primary (Integrated) Foot Control Connectivity Screen**.

3.5. System Configuration

To see a detailed listing of the software and hardware configurations of your system, select **System Configuration** from the **Main Programming Screen**.

Software Options	
Surgical Functions	**Combined**
Fluidics Module	**HPM**
Laser Module	**Enabled**
Remote Service	**Enabled**

Module Configuration	Serial Number	Software Version	Hardware Version
User Interface Computer		5.105	2.1
Remote Control Receiver		1.12	2.1
Multimedia Center			
Foot Control Receiver	WFR00182	2.1	1.2
Foot Controller	WFC00108	1.0	1.0
Fluidics Module	PFM00250	3.0	2.0
Ultrasound Module	USM00222	1.34	1.0
IV Pole Controller	EIV00159	1.4	1.0
Compressor Module	PCM00111	3.0	1.0
Power Supply Module	SPS00099	1.2	2.0
Illumination Module	PIM00201	2.7	1.1
Laser Module	GLM00117	3.1	1.1

Figure 3.21. **System Configuration Screen**.

3.6. System Calendar

To set up your system to default to certain surgeon preference files and room numbers at certain times of the week, select **System Calendar** from the **Main Programming Screen**, and the **System Calendar Screen** will appear with three or four user-editable columns.

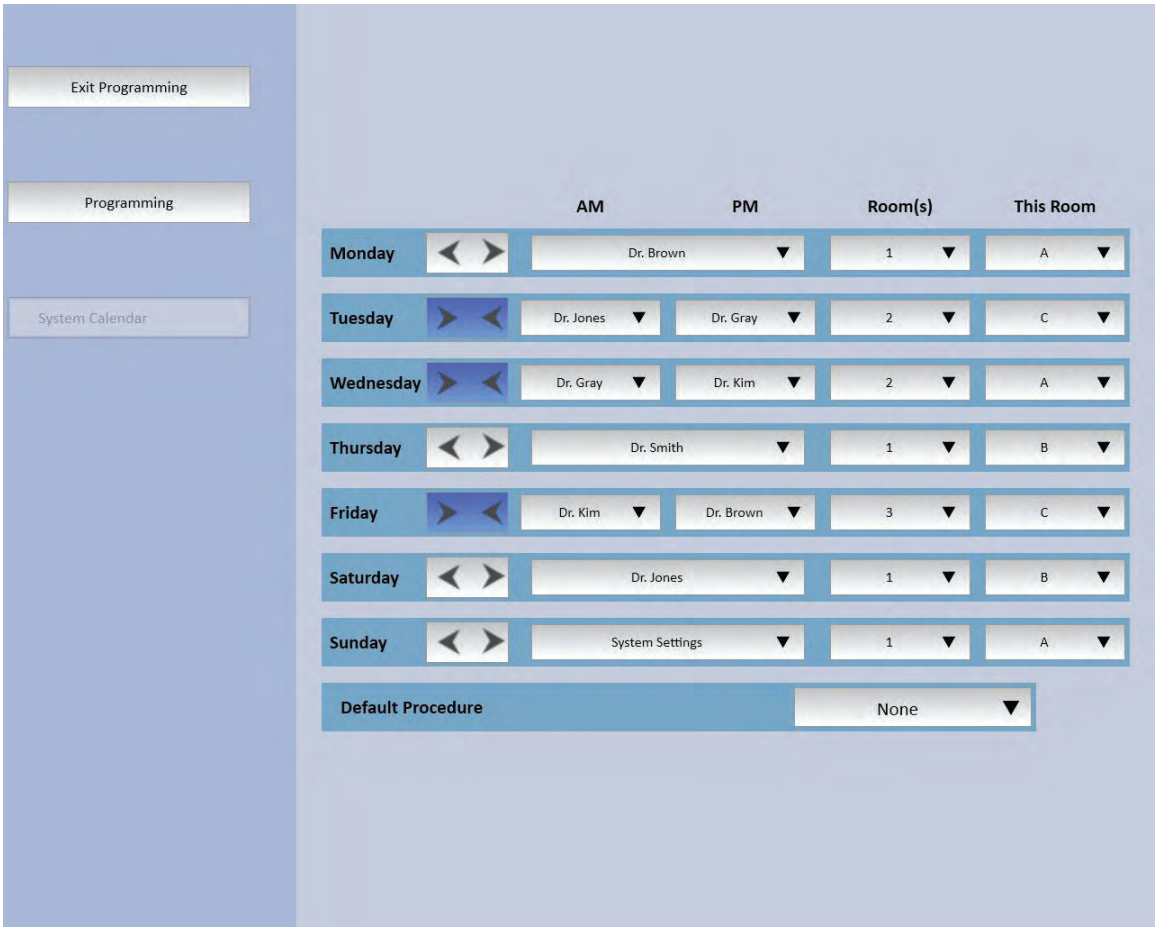


Figure 3.22. **System Calendar Screen**.

The second column, next to the listing of the days of the week, determines if the default surgeon applies to the full day, or if separate defaults will be applied to the morning and afternoon of that weekday. Select  to toggle between full day or morning and afternoon settings.

The third column contains option lists with the names of all the surgeon preference files currently available. Select a file from the list, and that will be the default file when the ***Stellaris Elite***™ vision enhancement system starts up at that time.

In the fourth column, select how many rooms that surgeon operates in, and in the fifth column select in which room number this ***Stellaris Elite***™ vision enhancement system is located. These settings determine how the case numbers will be incremented, to avoid duplicate case numbers for a single surgeon.

The Default Procedure menu allows selection of the default mode for the system. The Default Procedure menu will not be displayed in posterior only configuration systems.

3.7. Customization

The following tables detail which options can be customized at which level.

Audio and Visual Customization Settings

Parameter	Options/Ranges/Step Sizes			Level
Surgeon name	Typewriter data entry (32 characters max)			Surgeon
Screen/Voice language	English (U.S.), English (U.K.), Français, Deutsch, Italiano, Español, Português, Nederlands, Norsk, Svenska, Česky, Dansk, ελληνικά, Suomi, Magyar, 日本語, Polski, Русский, 中文			Surgeon
Password	Disabled and enabled			Surgeon
Display backlight brightness	20% to 100%, by 10%			Surgeon
System master audio volume	0% to 100%, by 5%			Surgeon
Tone Selection and Volume Control	Irrigation	No Tone, Tone 1-Tone 10 (0% to 100%)	By 5%	Surgeon
	Reflux			
	Ultrasound			
	Timer			
	Vacuum			
	Viscous			
	Vit			
	Vitesse			
	Bipolar	Tone 1-Tone 10 (20% to 100%)	By 5%	
	Occlusion	0% to 100%	By 5%	
	Key			
	Elevated Infusion Alarm	20% to 100%	By 5%	
	Laser			
	Alert - GUI Popup Messages			
Voice confirmation	Disabled and Enabled, volume: 0% to 100%, by 5%			Surgeon
Video overlay language	English (U.S.), English (U.K.), Français, Deutsch, Italiano, Español, Português, Nederlands, Norsk, Svenska, Česky, Dansk, ελληνικά, Suomi, Magyar, 日本語, Polski, Русский, 中文			Surgeon

Parameter	Options/Ranges/Step Sizes	Level
Video overlay display format	Ultrasound averages lines - Display, Display Combine, No Display Combine settings lines - No, Yes	Surgeon
Video overlay overscan allowance	0% to 5%, by 1%	Surgeon
Remote control	Disabled and Enabled	Surgeon
Technique name	Typewriter data entry	Technique

Case Customization Settings

Parameter	Options/Ranges/Step Sizes	Level
Phase name	Typewriter data entry (16 characters max)	Phase
Mode type	Phaco, irrigation/aspiration, irrigation, coagulation, anterior vitrectomy	Phase
Ultrasound Submode name	Typewriter data entry (24 characters max)	Phase
Customize Mode by case (applies only to Phaco and I/A modes)	Disabled and Enabled	Phase

Note: *Posterior Vitrectomy, Extrude, Frag, Viscous Fluid Control and Laser may be programmed on a* **Stellaris Elite™** *(BL11145) vision enhancement system. However, these functions can only be used on a* **Stellaris Elite™** *(BL14455 or BL15455) vision enhancement system.*

Foot Control

Parameter	Options/Ranges/Sizes	Level
Operation	Right Foot, Left Foot	Surgeon
Mode change control	Not While Active, Allow-Limit Pedal, Allow-Remap Pedal, and Allow-No Limiting	Surgeon
Detents	Disabled, Enabled (R1/R2/R3), Enabled (R2/R3)	Surgeon
Starting position	Region 1: 2% to 5%<R2 start, by 5% Region 2: 5%>R1 start to 5%<R3 start, by 5% Region 3: 5%>R2 start to 95%, by 5%	Surgeon
Linear Coagulation in Setup Mode	Disabled, Enabled	Technique
Switch assignment	Anterior techniques: Unassigned, next phase, previous phase, next U/S modulation submode, confirm settings, irrigation on/off, reflux, air on/off, vitrectomy cutting on/off, fixed coagulation, increase vacuum, decrease vacuum, increase air pressure, decrease air pressure, increase bottle height, decrease bottle height, increase U/S power, decrease U/S power, increase U/S pulse rate/duration, decrease U/S pulse rate/duration, increase U/S duty cycle/interval, decrease U/S duty cycle/interval, increase coagulation power, decrease coagulation power, increase vitrectomy cut rate, decrease vitrectomy cut rate Posterior and combined techniques: Unassigned, next phase, previous phase, next U/S / Vitesse modulation submode, confirm settings, infusion on/off, alternate infusion on/off, reflux, fixed coagulation, F/AX on/off, vitrectomy cutting on/off, increase vacuum, decrease vacuum, increase infusion pressure, decrease infusion pressure, increase F/AX pressure, decrease F/AX pressure, increase U/S power, decrease U/S power, increase U/S PPS/duration, decrease U/S PPS/duration, increase U/S DC/interval, decrease U/S DC/interval, increase coagulation power, decrease coagulation power, increase vitrectomy cut rate, decrease vitrectomy cut rate, increase viscous fluid pressure/vacuum, decrease viscous fluid pressure/vacuum, increase lower illuminator power, decrease lower illuminator power, lower illuminator on/off, increase upper illuminator power, decrease upper illuminator power, upper illuminator on/off, next illuminator filter, increase laser power, decrease laser power, pulse selection (Single Shot/repeat/continuous), laser mode (Standby/ready), Vitesse power up, Vitesse power down, Vitesse PPS duration up, Vitesse PPS duration down, Vitesse DC interval up, Vitesse DC interval down, Vitesse ON/OFF	Technique, Phase
Reflux Type	Anterior: Continuous, Single Low, Single High *Note: The Single Low and Single High settings require an Adaptive Fluidics with reflux bulb.* Posterior or Combined Domain: Continuous, Single High, Single Low	Technique, Phase

Parameter	Options/Ranges/Sizes	Level
Next Ultrasound Modulation on Yaw	Disabled, Enabled Note that for single linear Foot Pedal modes, the outward yaw motion would be used for next ultrasound modulation, and for dual linear Foot Pedal modes, the inward yaw motion would be used.	Technique, Phase
Fixed Coagulation Power Level	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5% Applicable if one of the Primary (Integrated) Foot Control buttons is programmed to activate fixed coagulation.	Technique, Phase
Dual Linear Control	Mode Level: U/S Modes: Disabled, Asp on Yaw, Asp on Pitch, Dual Linear U/S I/A Modes: Disabled, Dual Linear Flow (only for AFS fluidics if flow modes enabled) Vit Modes: Disabled, Asp on Pitch, Asp on Yaw, Dual Linear Flow (only for AFS fluidics if flow modes enabled)	Phase
Reflux on Yaw	Disabled/Enabled	Technique, Phase
Activate Continuous Irrigation on Yaw	Disabled and Enabled	Technique, Phase
Option to Auto-Select/Deselect Laser Mode with Opening/Closing of Laser Button Door	Disabled and Enabled	Technique

Fluidics

Parameter	Options/Ranges/Step Sizes	Level
Max IV Pole Height	80 cm to 140 cm, by 5 cm	System
Balanced Salt Solution Container Type	500 ml Bottle, 500 ml Bag, 250 ml Bottle	Surgeon
Patient Eye Level	-15 cm to +15 cm, by 1 cm	Surgeon
Default Ultrasound Tip Type	Standard, MicroFlow™, MicroFlow+, Thin Tip, MICS 1.8, Vortex, MicroFlow MICS	Surgeon
Default I/A Tip Type	0.3 mm, 0.5 mm	Surgeon
Default Vitrectomy Tip Type	20 Gauge, 23 Gauge, 25 Gauge, 27 Gauge	Surgeon
Default Extrude Gauge	20 Gauge, 23 Gauge, 25 Gauge, 27 Gauge	Surgeon
Default Frag Gauge	20 Gauge, 23 Gauge	Surgeon
Default Vitesse™ Gauge	23 Gauge, 25 Gauge	Surgeon
Default Anterior Vitrectomy Gauge	20 Gauge, 23 Gauge, 23 Gauge Bi-Blade	Surgeon
Fill Time	20 s to 120 s, by 5 s	Surgeon
IV Pole bottle height (Pressure)	30 cmH_2O to 140 cmH_2O by 5 cmH_2O 22 mmHg to 103 mmHg by 5 mmHg	Technique, Phase/Case
Irrigation Delay	100 ms to 3000 ms, steps of 50 ms. Also resolution of 50 ms even with calculator	Technique, Phase/Case
Vacuum Response	(1) Fastest, 2, 3, 4, (5) Slowest	Technique, Phase/Case
Vent Method	Fluid Venting, Air Venting	Technique, Phase/Case
Infusion Type	IV Pole, Pressurized	Technique
Infusion Units	cmH_2O, mmHg	Technique
Infusion Mode	Auto On, Auto On/Off, Manual *NOTE: Manual setting will operate as Auto On/Off in Anterior techniques or phases.*	Technique
Pressurized Infusion Pressure	Anterior Techniques: 0 mmHg to 20 mmHg, by 2 mmHg 20 mmHg to 150 mmHg, by 5 mmHg 0 cmH_2O to 204 cmH_2O, by 5 cmH_2O	Technique, Phase/Case

Parameter	Options/Ranges/Step Sizes	Level
Infusion Pressure	Posterior and Combined Techniques: Infusion Type = IV Pole 30 cmH_2O to 140 cmH_2O, by 5 cmH_2O 22 mmHg to 103 mmHg, by 5 mmHg Infusion Type = Pressurized Infusion 0 cmH_2O to 204 cmH_2O, by 5 cmH_2O 0 mmHg to 20 mmHg by 2 mmHg, 20 mmHg to 150 mmHg by 5 mmHg	Technique, Phase
Alternate Infusion Pressure	Posterior and Combined Techniques: Infusion Type = IV Pole 30 cmH_2O to 140 cmH_2O, by 5 cmH_2O 22 mmHg to 103 mmHg, by 5 mmHg Infusion Type = Pressurized Infusion 0 cmH_2O to 204 cmH_2O, by 5 cmH_2O 0 mmHg to 150 mmHg, by 5 mmHg	Technique
F/AX Pressure	0 mmHg to 20 mmHg, in steps of 2 mmHg 20 mmHg to 150 mmHg, in steps of 5 mmHg	Technique, Phase
Alternate F/AX Pressure	0 mmHg to 150 mmHg, in steps of 5 mmHg	Technique
Air Port	For use in Posterior/Combined techniques only. Front/Back	Technique
Adaptive Fluidics™	Disabled and Enabled	Technique, Phase/Case
Adaptive Fluidics™ CF	1(Lowest), 2(Low), 3(Moderate), 4(High), 5(Highest)	Technique, Phase/Case
Aspiration Type Posterior/Combined Domain VFM	Region 2 Linear Vacuum, (applies to Phaco modes only) Posterior, Combined, and VFM Techniques Disabled, Enabled	Phase/Case
Fixed vacuum level or linear vacuum maximum level, for vacuum modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 660 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case
Fixed flow level or linear flow maximum level, for flow modes	0 ml/min to 10 ml/min by 1 ml/min 10 ml/min to 30 ml/min by 2 ml/min 30 ml/min to 60 ml/min by 5 ml/min Minimum of 5 ml/min for U/S modes	Phase/Case
Fluidics - Fixed vacuum limit level or linear vacuum limit maximum level, for flow modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 650 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case

Parameter	Options/Ranges/Step Sizes	Level
Linear vacuum minimum level, for vacuum modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 660 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case
Region 2 minimum vacuum, for aspiration control feature vacuum modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 660 mmHg by 10 mmHg	Phase/Case
Linear flow minimum level, for flow modes	0 ml/min to 10 ml/min by 1 ml/min 10 ml/min to 30 ml/min by 2 ml/min 30 ml/min to 60 ml/min by 5 ml/min Minimum of 5 ml/min for U/S modes	Phase/Case
Region 2 minimum flow, for aspiration control feature flow modes with control on flow	0 ml/min to 10 ml/min by 1 ml/min 10 ml/min to 30 ml/min by 2 ml/min 30 ml/min to 60 ml/min by 5 ml/min	Phase/Case
Linear vacuum limit minimum level, for flow modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 650 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case
Region 2 minimum vacuum limit, for aspiration control feature flow modes with control on vacuum limit	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 650 mmHg by 10 mmHg	Phase/Case
Primary (Integrated) Foot Control mapping (for linear control)	Linear, Front Loaded, Back Loaded	Phase/Case
Pitch function for dual linear flow aspiration modes	Vacuum limit, Flow	Phase/Case
Primary (Integrated) Foot Control mapping (for yaw function linear control in dual linear aspiration flow modes)	Linear, Front Loaded, Back Loaded	Phase/Case

Ultrasound

Parameter	Options/Ranges/Step Sizes	Level
Ultrasound Modulation Type	Continuous Pulsed Single burst Fixed pulse Multiple burst Linear Power Linear Pulse Linear Power Linear Duty Cycle Dual Linear Multiple Burst Variable Power Multiple Burst Variable Power Linear Burst	Phase/Case
Fixed power level or linear power maximum level	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase/Case
Pulse rate for pulsed modes	1 PPS to 20 PPS by 1 PPS 20 PPS to 50 PPS by 5 PPS 50 PPS to 250 PPS by 10 PPS Subject to minimum on time of 2 ms and a minimum off time of 2 ms	Phase/Case
Duty cycle fixed or maximum for pulsed modes	5% to 95% by 5% Subject to minimum on time of 2 ms and a minimum off time of 2 ms	Phase/Case
Burst or pulse duration for burst modes or fixed pulse modes	2 ms to 20 ms by 2 ms 20 ms to 80 ms by 5 ms 80 ms to 600 ms by 20 ms	Phase/Case
Burst interval for fixed pulse modes	2 ms to 20 ms by 2 ms 20 ms to 80 ms by 5 ms 80 ms to 600 ms by 20 ms	Phase/Case
Maximum duty cycle for multiple burst modes	50% to 99% by 5% Subject to a minimum off time of 2 ms and a maximum off time of 1500 ms	Phase/Case
Waveform Ultrasound	Disabled, Enabled	Phase/Case
Linear control power minimum level	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase/Case
Minimum duty cycle for multiple burst modes	1% to 10% by 1% 10% to 30% by 2% 30% to 50% by 5% Subject to a minimum off time of 2 ms and a maximum off time of 1500 ms	Phase/Case
Primary (Integrated) Foot Control mapping (for linear control) - front loaded, linear, back loaded	Linear, Front Loaded, Back Loaded	Phase/Case

Parameter	Options/Ranges/Step Sizes	Level
Waveform Depth	25% to 100% by 5%	Phase/Case
Pulsed mode linear pulse rate minimum	0 PPS to 20 PPS by 1 PPS 20 PPS to 50 PPS by 5 PPS 50 PPS to 250 PPS by 10 PPS Subject to minimum on time of 2 ms and a minimum off time of 2 ms	Phase/Case
Pulsed mode linear duty cycle minimum	5% to 95% by 5% Subject to minimum on time of 2 ms and a minimum off time of 2 ms	Phase/Case
Burst mode linear duration minimum	2 ms to 20 ms by 2 ms 20 ms to 80 ms by 5 ms 80 ms to 600 ms by 20 ms	Phase/Case
Primary (Integrated) Foot Control mapping (for second ultrasound linear control)	Linear, Front Loaded, Back Loaded, Reverse Linear, Reverse Front Loaded, Reverse Back Loaded	Phase/Case

Vitesse Customization Settings

Parameter	Options/Ranges/Step Sizes	Level
Vitesse modulation type	Fixed Cut: Fixed Power, Fixed Power Fixed Pulse Co-Linear Vit, Dual/Yaw Cut, and Dual/Yaw Vac: Continuous, Pulsed, Linear PPS, or Linear DC Single Cut: Single	Phase
Power	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase
Pulse Rate	1 PPS to 20 PPS, by 1 PPS 20 PPS to 50 PPS, by 5 PPS 50 PPS to 250 PPS, by 10 PPS Subject to minimum on-time of 2 ms and a minimum off-time of 2 ms	Phase
DC for Pulsed Mode	5% to 95%, by 5% Subject to minimum on-time of 2 ms and a minimum off-time of 2 ms	

The pulse rate can be adjusted from 1 PPS to 250 PPS. Using the up and down arrows, PPS adjustment is made in steps of 5 PPS from 20 PPS to 50 PPS, and in steps of 10 PPS from 50 PPS to 250 PPS, subject to a minimum on-time of 2 ms and a minimum off-time of 2 ms (for pulsed modulation, the DC setting may limit the allowable PPS range). DC for pulsed modulation is adjustable from 5% to 95%. Using the up and down arrows, DC adjustment is made in steps of 5%, subject to a minimum on-time of 2 ms and a minimum off-time of 2 ms (for pulsed modulation, the PPS setting may limit the allowable DC range). Similar to other surgical modes in the Posterior and Combined Domains, the Vitesse surgical modes have programmable reflux capability with three setting options: Continuous, Single High, and Single Low.

Vitrectomy

Parameter	Options/Ranges/Step Sizes	Level
Fixed cut rate or linear cut rate maximum rate	Anterior System: 30 CPM to 100 CPM by 10 CPM, 100 CPM to 1000 CPM by 50 CPM, 1000 CPM to 2500 CPM, by 100 CPM Posterior System: 30 CPM to 100 CPM by 10 CPM, 100 CPM to 1000 CPM by 50 CPM, 1000 CPM to 2500 CPM, by 100 CPM	Phase
Linear cut rate minimum rate	Anterior System: 30 CPM to 100 CPM by 10 CPM, 100 CPM to 1000 CPM by 50 CPM, 1000 CPM to 2500 CPM, by 100 CPM Posterior System: 30 CPM to 100 CPM by 10 CPM, 100 CPM to 1000 CPM by 50 CPM, 1000 CPM to 2500 CPM, by 100 CPM	Phase
Primary (Integrated) Foot Control mapping	Linear, Front Loaded, Back Loaded, Reverse Linear, Reverse Front Loaded, Reverse Back Loaded	Phase

Coagulation

Parameter	Options/Ranges/Step Sizes	Level
Coag - Power level maximum level	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase
Power level minimum level	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase
Primary (Integrated) Foot Control mapping	Linear, Front Loaded, Back Loaded	Phase

Illuminator Settings (For Use on Posterior/Combined Systems only - BL14455 and BL15455)

Parameter	Options/Ranges/Step Sizes	Level
Display in Anterior Tech	Disabled, Enabled	Technique
Upper On/Off	On, Off	Technique
Upper Power	0% to 100% by 5%	Technique
Lower On/Off	On, Off	Technique
Lower Power	0% to 10% by 1% 10% to 40% by 2% 40% to 100% by 5%	Technique
Lower Filter	None, Amber, Green Tint, Yellow Tint	Technique
Set Illuminator Lower (%) By Filter	Disabled, Enabled	Technique

Extrude Mode Settings (For Use on Posterior/Combined Systems only - BL14455 and BL15455)

Parameter	Options/Ranges/Step Sizes	Level
Coag On Yaw	Enable/Disable	Phase
Max Power	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase
Min Power	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase
Foot Control Mapping	Linear, Front Loaded, Back Loaded	Phase

Viscous Fluid Control Settings

Parameter	Options/Ranges/Step Sizes	Level
Viscous Fluid Injection Pressure	0 to 20 psi, by 1 psi 20 to 70 psi, by 5 psi 0 to 140 kPA, by 10 kPA 140 to 483 kPA, by 20 kPA	Phase/Case
Viscous Fluid Extraction Vacuum	0 to 30 mmHg, by 1 mmHg 30 to 100 mmHg, by 5 mmHg 100 to 600 mmHg, by 10 mmHg	Phase/Case
Foot Control Mapping	Linear, Front-Loaded, Back-Loaded	Phase/Case

Laser Mode Settings (For Use on Posterior/Combined Systems only - BL15455 only)

Parameter	Options/Ranges/Step Sizes	Level
Power	Endo Submode 50 mW to 200 mW by 10 mW 220 mW to 500 mW by 20 mW (Additional Options: 250, 350, and 450) 550 mW to 1000 mW by 50 mW 1100 mW to 2000 mW by 100 mW Continuous Endo Submode 50 mW to 200 mW by 10 mW 220 mW to 500 mW by 20 mW (Additional Options: 250, 350, and 450) LIO Submode 50 mW to 200 mW by 10 mW 220 mW to 500 mW by 20 mW (Additional Options: 250, 350, and 450) 500 mW to 1000 mW by 50 mW	Phase
Duration	10 ms to 100 ms by 10 ms 100 ms to 500 ms by 50 ms 500 ms to 3000 ms by 100 ms	Phase
Interval	Minimum is current duration setting 10 ms to 100 ms by 10 ms 100 ms to 500 ms by 50 ms 500 ms to 3000 ms by 100 ms	Phase
Pulse Type	Endo - Single Shot, repeat Endo-Continuous - Single Shot, continuous LIO - Single Shot, repeat	Phase
Aiming Beam in Standby	On, Off	Phase
Aiming Beam in Pulse	On, Off	Phase
Aiming Beam Intensity	5% to 100% by 5%	Phase
Selected Foot Control	Primary (Integrated) or Secondary (LIO)	Phase
Dedicated Foot Control Buttons	Enabled, Disabled	Phase
LIO	On, Off	Phase
LIO Intensity	5% to 100% by 5%	Phase

4. Detailed Reference

4. Detailed Reference

This chapter provides a detailed reference for each system function and accessory.

WARNING: ***The use of flammable anaesthetics, flammable disinfectants, aerosol sprays, or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided unless the gaseous agents are sucked away and the liquid agents are fully dried or evaporated. Ensure the flammable liquids are not pooled beneath the patient drape.***

WARNING: ***The use of high infusion pressure may cause damage to the eye. It is the user's responsibility to ensure use of appropriate infusion pressure during the surgery.***

Note: *Ensure tube set connection is secure when connecting to the handpiece and system.*

4.1. Advanced Vacuum System Fluidics

WARNING: ***For optimum aspiration and reflux performance, the patient's eye level must be at the same level as (no more than 7 cm [3 in.] from) the* Stellaris Elite™ *vision enhancement system aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.***

The advanced vacuum fluidics creates aspiration using a venturi system driven by compressed air, which is connected to the machine by an air hose.

With your ***Stellaris Elite***™ vision enhancement system, the irrigation line from an inverted bottle of Balanced Salt Solution is integrated into the tubing manifold at the top part of the vacuum cassette. The delivery pressure of the Balanced Salt Solution is adjusted by varying the height of the bottle in relation to the patient's eye, or by air pressure injected into the bottle when Pressurized Infusion or AFI is used. On/off control of irrigation is accomplished through the touch screen interface or by the Foot Pedal (for modes with infusion type Auto On/Off).

As the cassette fills up, the system gives a **Cassette Nearing Full** warning. When the fluid level reaches the maximum capacity, the system gives a **Cassette Full** warning. After this second warning, the aspiration function will be disabled. You must replace the fluidics cassette with one that is either empty or nearly empty. No re-priming is required.

WARNING: ***Ensure the maximum capacity of the cassette is not exceeded as this could cause a hazardous situation to the patient.***

WARNING: ***Never intentionally modify handpieces or tips, including bending, cutting, or engraving, as they could break or malfunction.***

Note: **Stellaris Elite™** *vision enhancement system is designed with cassette identification feature. Use only cassette type that is similar to the selected software domain. System error messages will be displayed when wrong cassette type is inserted.*

Emptying Cassette

The ***Stellaris Elite***™ vision enhancement system's cassette can be emptied during operation by using the following instructions:

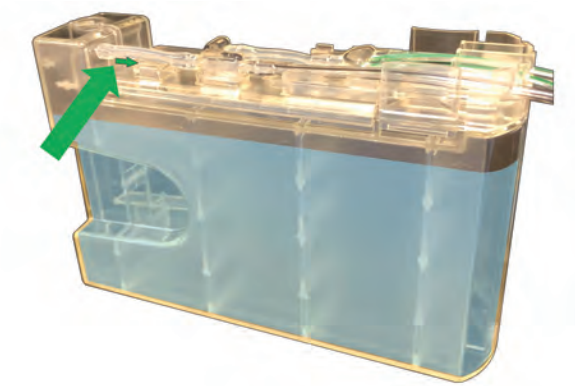
1. Stop operation and remove all handpieces from the eye.
2. Close **both** irrigation clamps (the clamp near the bottle and the clamp at the 2-way stopcock).

3. Select **Eject Cassette** from the surgical screen.

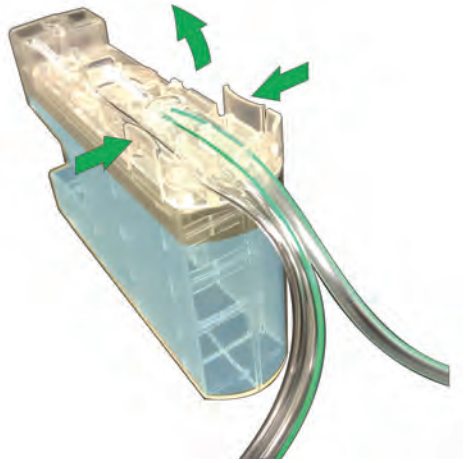
WARNING: ***Wear gloves before performing following instructions.***

4. Remove cassette from the system.

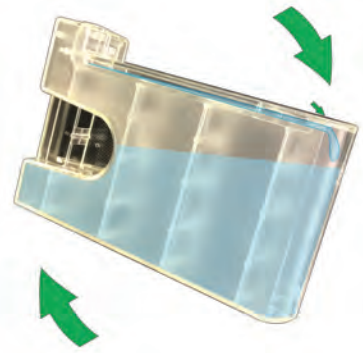
5. Detach the aspiration tubing that connects to the cassette. Hold aspiration tubing very close to the connector to facilitate removal (arrows).



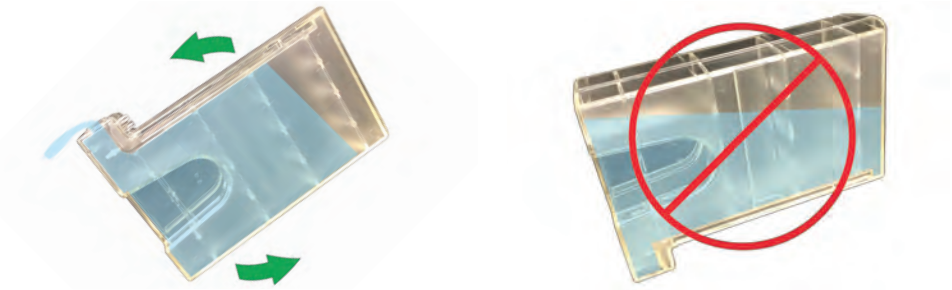
6. Press manifold to release latch to free it from the cassette (arrows).



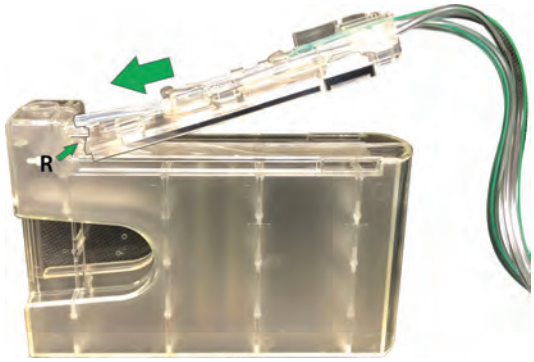
7. Tilt cassette backward approximately 20 to 30 degrees to drain fluids from the top compartment to the main cassette cavity.



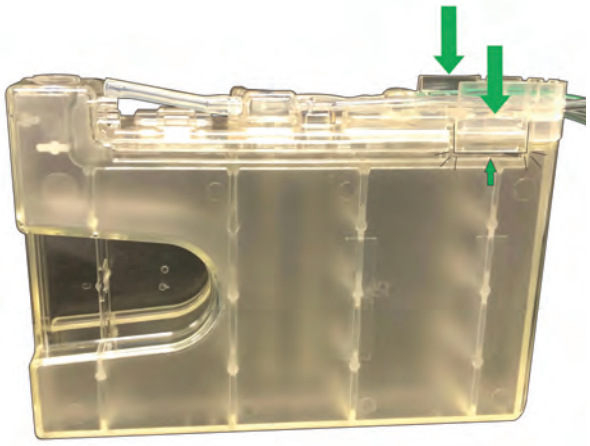
8. Drain fluid out of the cassette. Tilt cassette to drain fluid orderly. Do not shake or flip cassette.



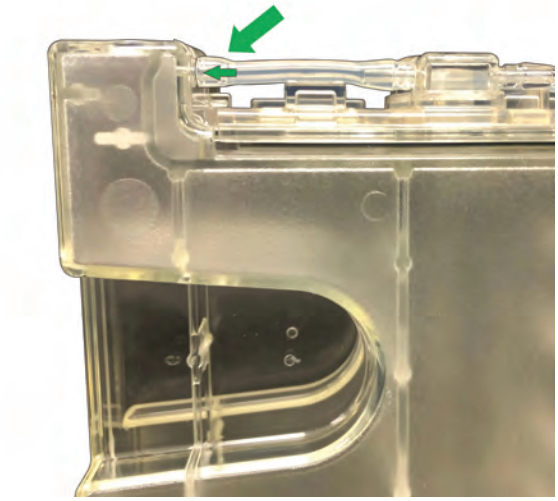
9. Assemble tubing manifold by first sliding the front end under the cassette retainer (R).



10. Press the manifold to engage manifold latch (arrows).



11. Connect aspiration tubing to the cassette connector.



12. Insert cassette to the system.
13. Release **both** irrigation clamps (the clamp near the bottle and the clamp at the 2-way stopcock).

14. Resume surgery once system passes vacuum check and surgical screen is displayed.

WARNING: ***Do not operate system with irrigation clamp closed.***

Note: *No re-priming is required.*

4.2. Posterior Functions

Posterior Vitrectomy Function

The ***Stellaris Elite***™ vision enhancement system vitrectomy function uses an external air source to drive the pneumatically operated guillotine type vitrectomy cutter that draws the vitreous material into the port. The vitreous material is then cut and aspirated into a disposable collection container through the attached tubing.

Vitrectomy Cutter Modes

The ***Stellaris Elite***™ vision enhancement system provides four vitrectomy cutter modes as described below. The cut rate may be adjusted from 30 CPM to 7500 CPM, with increments as shown in the table below, or to any specific value using the keypad.

Range	Step Size
30 CPM to 100 CPM	10 CPM
100 CPM to 1000 CPM	50 CPM
1000 CPM to 7500 CPM	100 CPM

Note: *Vitrectomy cut rate derating above 915 meters (3000 feet) altitude can be compensated with increased input pressure, not to exceed 6.9 bar (100 PSIG). See the Vacuum Fluidics Function Specification table in section 8.2 for derating specifications.*

Fixed Cut
Fixed cut is a single region pitch control mode, and vitreous cutting is activated the moment the Foot Pedal is depressed. The cut rate is fixed. Vacuum is proportional to Foot Pedal depression. Each successive outward yaw movement of the Foot Pedal toggles the cutter ON or OFF. If enabled, an audible tone will indicate cutter on (double beep) or cutter off (single beep). By default, the vitrectomy cutter is ON.

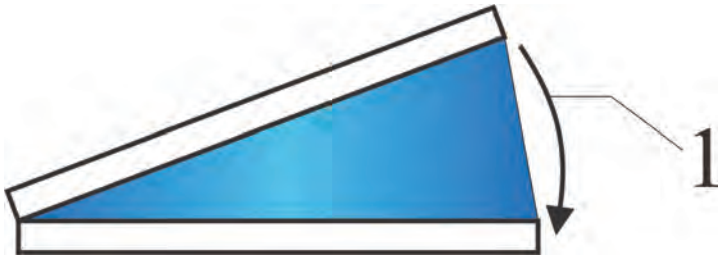


Figure 4.1. **Single region pitch control, Fixed cut, linear vacuum**.

Dual Linear Cut: Dual/Yaw Cut
Dual Linear cut uses two region pitch and yaw control. Pressing the Foot Pedal downward into Region 1 is necessary to activate cutting with outward yaw. Outward yaw while in Region 1 activates cutting without vacuum. Linear control of the cut rate is a function of Foot Pedal yaw displacement. Further depressing the Foot Pedal downward to Region 2 activates linear vacuum.

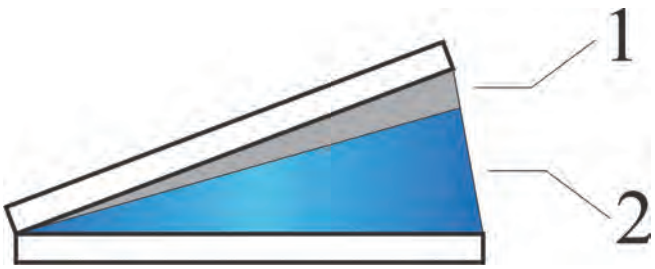


Figure 4.2. **Diagram showing two region pitch control programmed for Dual Linear Cut**.

1. Region #1 (no active function). 2. Region #2 Linear Vacuum.

The actual cut rate and vacuum level is displayed on the screen. When the Foot Pedal is released, it returns to center and the cutter is disabled. If enabled, an audible linear tone indicates cut rate and vacuum level; the pitch of the tone increases with increased cutter speed and vacuum level.

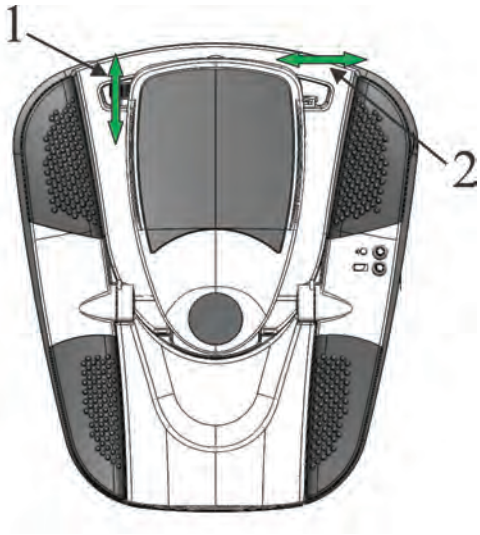


Figure 4.3. **Primary (Integrated) Foot Control Top View to Illustrate Dual/Yaw Cut Vitrectomy Programmed for Right Foot**.

1. Pitch Movement to control linear vacuum. 2. Outward Yaw to control linear cut.

Dual Linear: Dual/Yaw Vac

This is a two region pitch and yaw control mode. Pressing the Foot Pedal downward into Region 1 activates the vacuum with outward yaw. Outward yaw while in Region 1 activates the vacuum without cutting. Linear control of the vacuum is a function of Foot Pedal yaw displacement. Further depressing the Foot Pedal downward into Region 2 activates the linear cut rate.

The actual cut rate and vacuum level is displayed on the screen. When the Foot Pedal is released, it returns to center where both vacuum and the cutter are disabled. If enabled, an audible linear tone indicates the cut rate and vacuum level; the pitch of the tone increases with increased cutter speed and vacuum level.

Co-Linear Cut

For Co-Linear Cut mode, the Foot Pedal pitch movement simultaneously controls linear vacuum and linear cut rate. The downward pitch movement could be programmed to increment or decrement vacuum control.

Similarly, the downward pitch movement could be programmed to increment or decrement cut rate control. The range of vacuum level and cut rate is programmable. Each successive outward yaw movement of the Foot Pedal toggles the cutter ON or OFF. By default, the vitrectomy cutter is ON. If enabled, an audible tone will indicate vacuum level, cut rate, cutter on (double beep) or cutter off (single beep).

Single Cut
For Single Cut mode, the Foot Pedal pitch controls linear vacuum. Single cut will be activated when the Foot Pedal moves to 95%. Release the Foot Pedal back to at least 75% in order to have the subsequent single cut.

For all vitrectomy modes, reflux (if enabled) is activated by inward yaw movement of the Foot Pedal. The Primary (Integrated) Foot Control side button can also be programmed to activate reflux function.

WARNING: ***Never intentionally modify handpieces or tips, including bending, cutting, or engraving, as they could break or malfunction.***

Note: *Make sure the pack you are using is appropriate for the domain selected.*

Posterior Vitrectomy Setup and Use

WARNING: ***For optimum aspiration and reflux performance, the patient's eye level must be at the same level as (no more than 7 cm [3 in.] from) the* Stellaris Elite™ *vision enhancement system aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.***

1. Connect the compressed air source to the connector on the lower rear of the system.
2. Turn the power on and wait until the screen displays the Primary (Integrated) Foot Control or other system messages.
3. Acknowledge and close all messages.
4. To operate the Primary (Integrated) Foot Control wirelessly, press any button on the Primary (Integrated) Foot Control and wait until the ready light turns solid green. This indicates that wireless communication has been established.
5. If your system is programmed to default to either the Anterior Domain, Posterior Domain or the Combined Domain, the **Select Procedure Screen** will not appear, and the system will move directly to the **Select Surgeon Screen**, as shown in Figure 1.8.
6. Select **Posterior Segment**; the screen will transition to **Select Surgeon**. (Skip this step if the system is already displaying the **Select Surgeon Screen**.)
7. Select **Surgeon's Name** and select **Confirm** to transition to the **Insert Cassette** screen.

8. Open the posterior surgical pack with the following steps:

   a. Hold the bottom of the tray with one hand placing the thumb in the thumb notch. (Circulating Nurse)

   b. Tear open the Tyvek seal with the other hand toward the body. (Circulating Nurse)

   c. Transfer contents onto sterile field. (Circulating Nurse)

   d. Identify loose components from the pre-connected tubing set. (Scrub Nurse)

   e. Drape the system tray and screen with drapes provided. (Scrub Nurse)

   f. Arrange the pre-connected tubing set with cassette, bottle spike, air tubing filter and actuation connector toward the system front. The priming cup is placed at the other end with the tubing set in the middle as shown in the figure below. (Scrub Nurse)

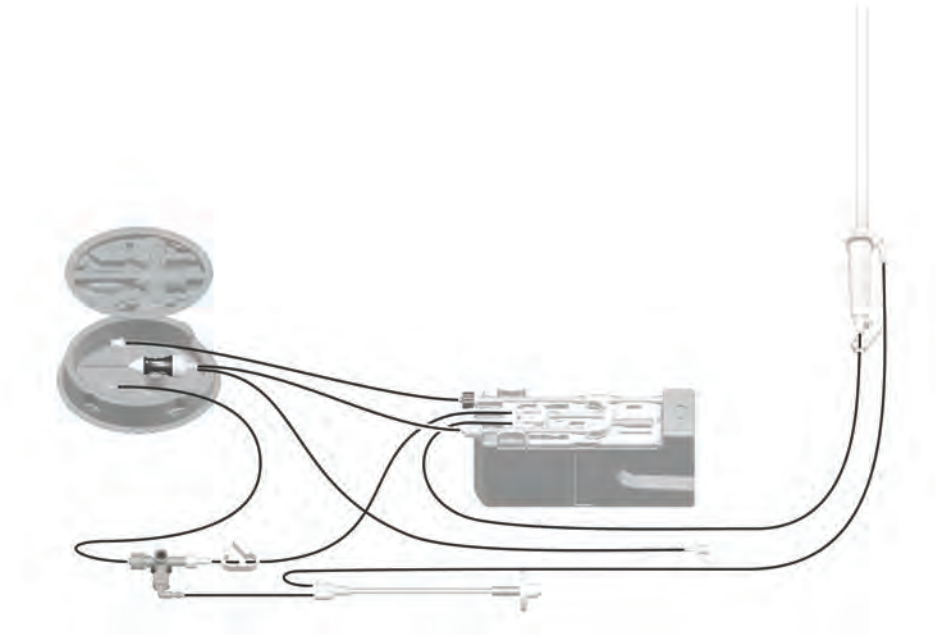


Figure 4.4. **Pre-connected Tubing set arrangement to facilitate setup**.

   g. Remove the tape to unbind all the tubing. (Scrub Nurse)

   h. Straighten the tube set and secure it, so it will not drop off the sterile surface. (Scrub Nurse)

   i. Remove the tape from the cassette to release the additional tubing that is tied to the cassette. (Scrub Nurse)

   j. Connect the air tubing filter to the system (second right connector). Ensure the air pump is on. (Scrub Nurse or Circulating Nurse)

   k. Connect the vitrectomy actuation line (blue stripe) to the system. (Scrub Nurse or Circulating Nurse)

l. Insert the fluidics cassette all the way in and hold until it is automatically captured by the system. The cassette housing backlight will stop blinking and remain on when the system captures the cassette. (Scrub Nurse or Circulating Nurse)

m. Pass the bottle spike and irrigation tubing to Circulating Nurse. (Scrub Nurse)

n. Spike and hang the Balanced Salt Solution bottle on the automated IV pole or the Zero Level hanger if using AFI. Squeeze and release the drip chamber until it is half filled with solution. (For AFI setup, use the spiking tool provided to puncture the rubber stopper on the bottle before inserting the metal cannula into the bottle.) (Circulating Nurse) See Figure 4.5.

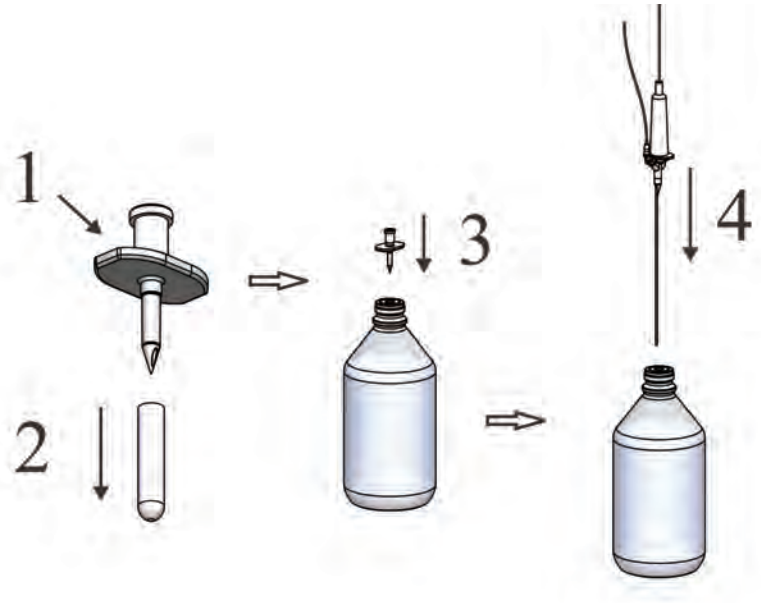


Figure 4.5. **AFI Setup instructions**.

1. Spiking tool. 2. Remove cover. 3. Spike bottle with spiking tool. 4. Spike AFI spike into the bottle.

o. Remove the tape on the priming cup. (Scrub Nurse)

p. Place the priming cup flat on the tray as in the figure below. (Scrub Nurse)

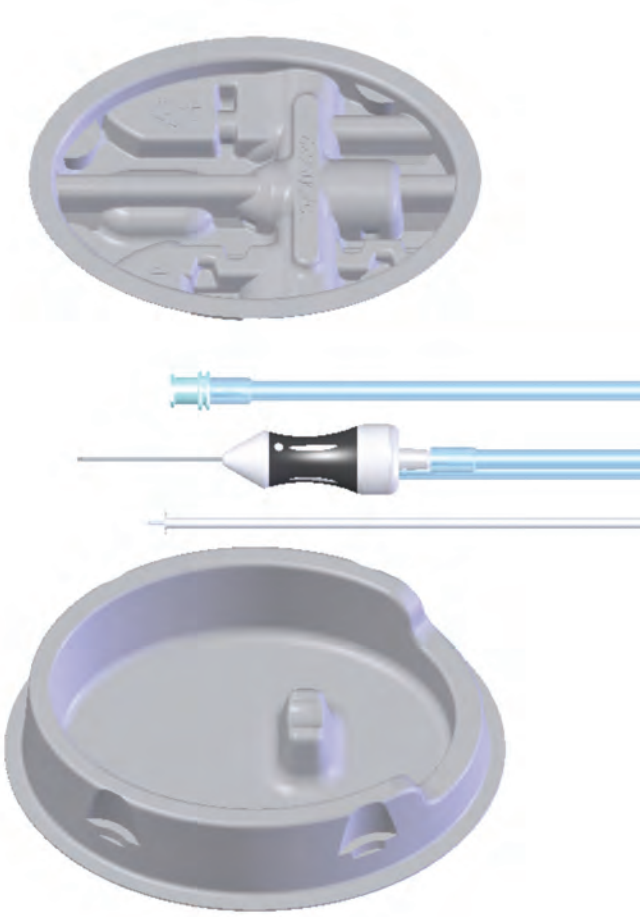


Figure 4.6. **Priming cup with infusion cannula, left aspiration and vitrectomy cutter attached**.

9. Select the first button from the **Easy Prime** selection menu to initiate the auto priming and vitrectomy cutter test sequence. (Scrub Nurse or Circulating Nurse)

Note: *The system will not provide feedback as to whether or not fluid is present during priming. Inspect tubing and confirm that it is filled with fluid and free of bubbles after each Prime and Tune. Repeat the priming process if the tubing is not adequately filled with fluid.*

There are three settings to control infusion On/Off in Posterior modes of surgery: “Manual”, “Auto On/Off”, “Auto On”.

- In Manual Infusion Mode, infusion is activated and deactivated by using the button on the GUI screen or one of the Primary (Integrated) Foot Control switches assigned to this function. Pressing the Foot Pedal into Region 1 will NOT start infusion.

Note: *When the system is in Manual Infusion Mode, pressing the Foot Pedal will not activate aspiration.*

Note: *When in an Anterior phase, manual infusion will operate as auto on/off.*

- In Auto On/Off Infusion Mode, infusion will be activated when the Foot Pedal is depressed into region 1 or beyond and will be deactivated when the Foot Pedal is released to region 0 for all aspirating modes. The GUI screen and a Primary (Integrated) Foot Control switch assigned to this function will toggle between "infusion always on" and "infusion On/Off" with the Foot Pedal. This infusion option is identical to the infusion control in all anterior modes.
- In Auto On Infusion Mode, infusion control is the same as in Manual Infusion Mode except that infusion will be activated as soon as the Foot Pedal is depressed into region 1 or beyond and will remain active when the Primary (Integrated) Foot Control pedal is released to region 0.

For all infusion control modes: Infusion, once started, cannot be turned off using either the GUI or the foot control switch while the Primary (Integrated) Foot Control pedal is in region 1 or beyond.

CAUTION: ***Make sure to remove vitrectomy cutter by pulling it away from the priming cup, without allowing the cutter needle to touch the priming tray.***

Note: *In all circumstances, the stopcock and tubing clamp may be used to stop infusion.*

Note: *The system will prime the left aspiration line, right aspiration line, cutter test, infusion line and the infusion cannula. Irrigation will be shut off and some Balanced Salt Solution will be left in the priming cup at the end of priming cycle. The system will transition to Surgical screen. Inspect the infusion line to ensure it is free of air bubbles. If there are bubbles in the infusion line, toggle* ***Irrigation On*** *from the screen and tap the line to purge it of the air bubbles. To turn irrigation off, use the tubing clamp or toggle* ***Irrigation Off*** *from the screen.*

ESA Use

The Entry Site Alignment (ESA) system is designed for posterior segment ophthalmic surgery. The system consists of the following components (see **Figure 4.7A**):

- Trocar Handle (1) with ESA Cannula Hub Assembly (2) preloaded
- Protective Tip Guard (3)

1. Use the "marker" end of the Trocar handle (1) to mark the eye in the surgeon's preferred location. (see **Figure 4.7B**).

2. Carefully remove the cap (3) covering the ESA Cannula. (see **Figure 4.7C**).

Note: *Hold the ESA with tip pointing up while removing the cap to prevent the ESA Cannula from sliding off.*

3. At the desired location, insert the Trocar until the cannula hub rests against the conjunctiva. Twist the handle, if necessary, to ease insertion. (see **Figure 4.7D**).

WARNING: ***Misplacement or over manipulation of the trocar during this step could result in serious patient injury.***

4. Slide the handle out of the ESA cannula, allowing the cannula to remain in place. (see **Figure 4.7E**). For the cannula to remain in place as the handle is withdrawn, it may be necessary to apply a counter force to the cannula hub.
5. Once the cannula is in place, the ESA cannulas may be used to insert an infusion line, insert a plug, or introduce instruments or other devices for surgical procedures.
6. Replace the protective tip guard (3) over the trocar needle.
7. At the end of the procedure, grasp each ESA cannula individually with forceps and gently remove.
8. Follow proper disposal procedures to discard the ESA components upon surgery completion.

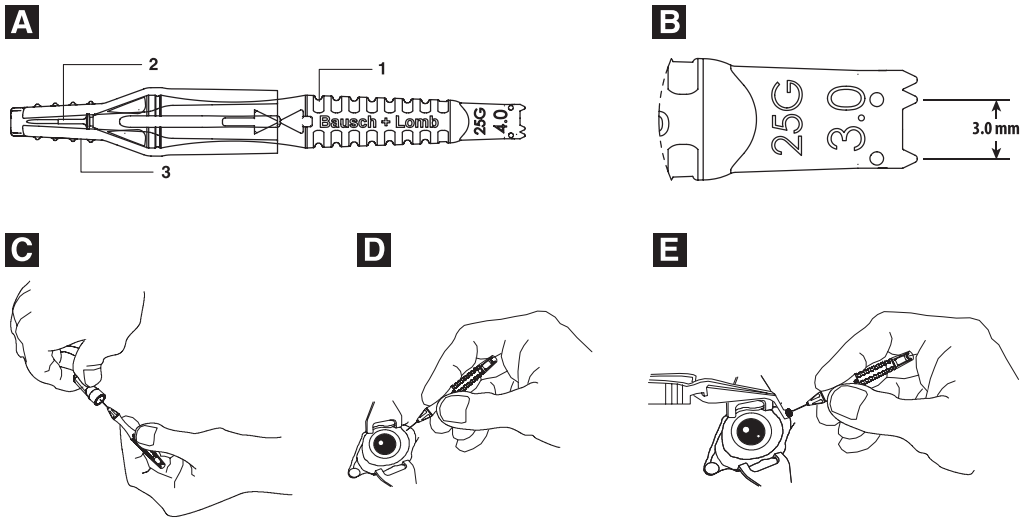


Figure 4.7. **ESA Usage**.

Vitesse™ Hypersonic Vitrectomy

WARNING: ***Do not place fingers on the needle during use.***

WARNING: ***Exercise great care when operating near the retina or other sensitive structures within the eye. When operating near the retina, begin with minimum effective Power and Vacuum settings and increase settings cautiously as needed. The Vitesse Low surgical phase setting may be used to assist.***

WARNING: ***Exercise care when using the Single High reflux setting near the retina to minimize the risk of retinal damage.***

WARNING: ***Use only the Entry Site Alignment (ESA) devices provided with the Vitesse™ handpiece pack (yellow trocar caps). Do not use any ESA with metal components to avoid particulate in the eye.***

WARNING: ***This product should only be used by a trained and registered physician.***

WARNING: ***Only use this product with Bausch + Lomb products and Bausch + Lomb vision enhancement systems. Use of this product with non-Bausch + Lomb products may affect system performance and create hazards.***

WARNING: ***Use of accessories manufactured or distributed by Bausch + Lomb on systems for which they are not designated may affect system performance and create hazards.***

WARNING: ***Contact with an implanted intraocular lens (IOL) while Vitesse™ ultrasound energy is activated may result in abrasion of the surface of the IOL. Physicians should use care when using Vitesse™ on patients with implanted IOLs.***

WARNING: ***Do not excessively flex the needle during use.***

WARNING: ***Bending of the needle can lead to needle damage and/or handpiece performance degradation.***

WARNING: ***Do not use any item in this pack if received in an unsatisfactory manner. Customer inquiries or concerns should be promptly directed to a Bausch + Lomb representative.***

WARNING: ***If needle port obstruction is suspected during use, use the reflux function (directed away from the retina or other eye structures) per the owner's manual to attempt to clear material that may be blocking the port.***

WARNING: ***If air bubbles are seen while using Vitesse™, it is recommended that you reduce the power and/or vacuum.***

WARNING: ***If the handpiece fails to operate at the commanded power settings or loses efficiency during use, retune the handpiece. To retune, hold the handpiece with the needle tip submerged in Balanced Salt Solution. Return to the Setup Screen and press the Tune Vitesse button to initiate the tuning sequence. Hold the handpiece until tuning completes. Do not allow the needle to contact any hard surface during priming and tuning.***

CAUTION: ***Failure to follow priming, tuning, and retuning instructions may result in a reduction in handpiece effectiveness.***

CAUTION: ***To avoid damage to handpiece internal components, do not submerge the front end of the handpiece body during priming and tuning.***

CAUTION: ***Do not allow the needle to contact any hard surfaces during priming and tuning.***

CAUTION: ***When using the Dual-Yaw mode, commanding power before activating vacuum may result in reduced performance of the handpiece.***

CAUTION: ***Only energize the Vitesse™ handpiece with the needle partially submerged in BSS, vitreous, or other liquids and maintain fluid flow or you may experience reduced performance of the handpiece.***

CAUTION: ***Using Vitesse™ at high power and low vacuum may reduce flow and result in reduced performance of the handpiece.***

The Vitesse™ handpiece is an accessory that is used on the ***Stellaris Elite***™ vision enhancement system to remove vitreous humor, lens tissue and other material from the posterior segment of the eye using ultrasound energy and aspiration during a typical or atypical surgery. The Vitesse™ handpiece pack is designed to be used with an appropriate Posterior or Combined Vitrectomy Pack, or Posterior or Combined Basic Pack, and appropriate accessories for posterior vitrectomy.

The Vitesse™ handpiece (Figure 4.8) is a vitreous cutting and aspiration device for the removal of vitreous humor, lens tissue and other material from the posterior segment of the eye during a typical or atypical surgery. Vitesse™ uses ultrasonic, harmonic (U/H) needle movement to generate vitreous cutting. Similar to the pneumatically operated, guillotine type vitrectomy cutter, the device draws vitreous to the port, then cuts and aspirates the vitreous out of the eye into a disposable fluid collection cassette through the attached tubing.

Figure 4.8. **Vitesse Handpiece**.

The Vitesse™ connector is the bottom port on the front left side of the ***Stellaris Elite***™, and is labeled as shown in Figure 4.9.

The Vitesse™ handpiece electrical plug connects to the connector port (Figure 4.9). The handpiece aspiration tubing (yellow stripe) connects to the right-hand aspiration connector on the fluid collection cassette.

Figure 4.9. **Vitesse™ handpiece plug and aspiration tubing connected to the *Stellaris Elite*™ vision enhancement system**.

The Stellaris Elite™ vision enhancement system GUI **Setup Screen** provides one-touch **EASY PRIME** functionality to prime and tune the Vitesse™ handpiece for surgery (Figure 4.10). A color-coded Vitesse™ icon on the upper left portion of the screen indicates the Vitesse™ tune status. Detailed instructions for preparing the system and handpiece for priming and tuning are included in the **Vitesse™ Posterior Vitrectomy Setup and Use** section below. Users may also refer to the **Show Me Steps** videos for animated instructions.

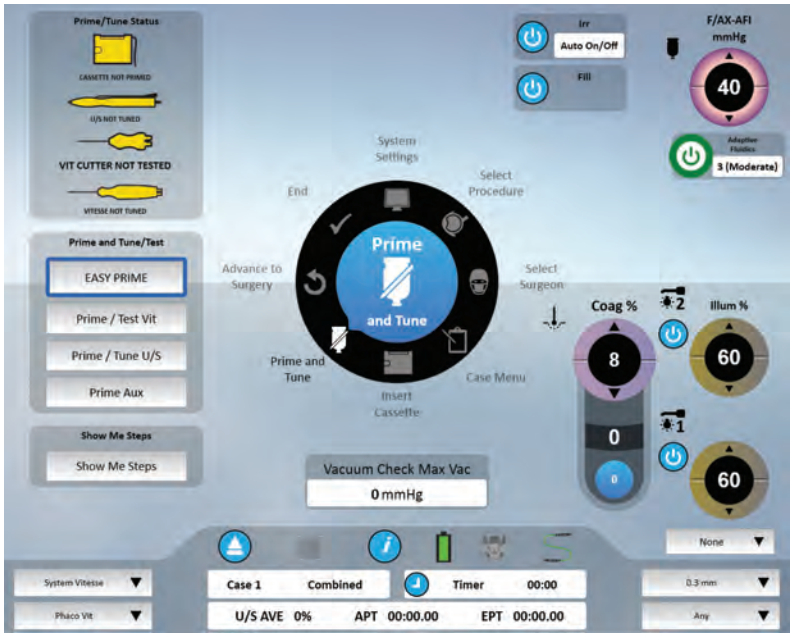


Figure 4.10. **Setup Screen**.

Once the system completes the **EASY PRIME** cycle, the user interface controls will transition from the **Setup Screen** to the **Surgical Screen** (Figure 4.11) in preparation for surgery.

Figure 4.11. **Surgical Screen, Combined Procedure**.

Figure 4.12. **Surgical Screen, Posterior Procedure**.

To adjust the numerical settings on the **Surgical Screen**, use the up and down arrows on the setting globe or setting tube to increase or decrease the setting or use the pop-up keypad to enter settings directly. (Refer to the Operator's Manual Section 2.1 for additional instructions for using the basic interface controls.)

Five surgical modes are included on the **Surgical Screen** for Vitesse™ operation: **Vitesse Core**, **Vitesse Vac**, **Vitesse Low**, **Vitesse Pulse**, **and Vitesse Medium**. These modes serve as a baseline to facilitate changing power and vacuum levels based on surgeon needs. The **Vitesse Core** mode provides starting default settings for vitreoretinal surgeries which may be adjusted further by the surgeon prior to each case. The **Vitesse Low** mode provides lower power and lower vacuum. The **Vitesse Vac** mode provides higher vacuum and a broad range of power. The **Vitesse Medium** mode provides default settings that are intermediate to the low and core settings. **Vitesse Pulse** adjusts the number of cycles of ultrasound power that occur during a one-second time interval. In Pulsed Mode, the handpiece is energized for the portion of each time interval as programmed by the Duty Cycle setting.

The user interface controls also provide surgical sub-modes for Vitesse™, similar to those for the pneumatic vitrectomy cutter: **Fixed Cut**, **Co-Linear**, **Dual/Yaw Cut**, **Dual/Yaw Vac**, **and Single Cut**. (Refer to the Operator's Manual Section 4.2 for a detailed explanation of vitrectomy sub-modes.)

The **Surgical Screen** user controls provide the capability to adjust **Vacuum** settings from 0 to 600 mmHg (a maximum of 660 mmHg is available as an option dependent on local registration of the product), similar to the controls for the pneumatic vitrectomy cutter. The user controls also provide the capability to control handpiece power expressed as **Vitesse Power** in percent (%). **Vitesse Power** can be adjusted from 0 to 100% of the full ultrasonic power of the handpiece. Using the up and down arrows, power adjustment is made in steps of 1% from 0-10%, steps of 2% from 10-30%, and in steps of 5% from 30-100%.

The Vitesse™ user controls incorporate ultrasound modulation, pulse rate (pulses per second [PPS]), and duty cycle (DC) controls similar to those for the phacoemulsification and fragmentation ultrasound handpieces.

The ultrasound modulation types available for the Vitesse™ surgical sub-modes are as follows:

Surgical Sub-Modes	Available Modulation Types
Fixed Cut	Fixed Power, Fixed Power Fixed Pulse
Co-Linear, Dual/Yaw Cut, Dual/Yaw Vac	Continuous, Pulsed, Linear PPS, Linear DC
Single Cut	Single Burst

The pulse rate can be adjusted from 1 to 250 PPS. Using the up and down arrows, PPS adjustment is made in steps of 1 PPS from 1 to 20 PPS, in steps of 5 PPS from 20 to 50 PPS, and in steps of 10 PPS from 50 to 250 PPS, subject to a minimum on-time of 2 ms and a minimum off-time of 2 ms (for pulsed modulation, the DC setting may limit the allowable PPS range).

The DC for pulsed modulation is adjustable from 5% to 95%. Using the up and down arrows, DC adjustment is made in steps of 5%, subject to a minimum on-time of 2 ms and a minimum off-time of 2 ms (for pulsed modulation, the PPS setting may limit the allowable DC range).

Similar to the other surgical modes in the Posterior and Combined domains, the Vitesse™ surgical modes have programmable reflux capability with three setting options: **Continuous**, **Single High**, and **Single Low**.

Vitesse Posterior Vitrectomy Setup and Use

1. Connect the compressed air source to the connector on the lower rear of the system.
2. Turn the power on and wait until the screen displays the Primary (Integrated) Foot Control or other system messages.
3. Acknowledge and close all messages.
4. To operate the Primary (Integrated) Foot Control wirelessly, press any button on the Primary (Integrated) Foot Control and wait until the ready light turns solid green. This indicates that wireless communication has been established.
5. The screen will display **Select Procedure**. (If your system is programmed to default to either the Anterior Domain or the Posterior/Combined Domain, the **Select Procedure Screen** will not appear, and the system will move directly to the Select Surgeon Screen, as shown in Figure 1.8 in the Operator's Manual.)
6. Select **Posterior Segment**; the screen will transition to **Select Surgeon**. (Skip this step if the system is already displaying the **Select Surgeon** screen.)
7. Select **Surgeon's Name** and select **Confirm** to transition to the **Insert Cassette** screen.
8. Open the posterior or combined surgical pack with the following steps:
    a. Hold the bottom of the tray with one hand. (Circulating Nurse)
    b. Tear open the Tyvek seal with the other hand toward the body. (Circulating Nurse)
    c. Pour contents onto sterile surface. (Circulating Nurse)

d. Identify loose components from the pre-connected tubing set. (Scrub Nurse)

e. Drape the system tray and screen with the provided drapes. (Scrub Nurse)

f. Arrange the pre-connected tubing set with cassette, bottle spike, air tubing filter, and actuation connector toward the system front. In a later step, the Vitesse™ priming tray will be placed at the other end with the tubing set in the middle as shown in Figure 4.13. (Scrub Nurse)

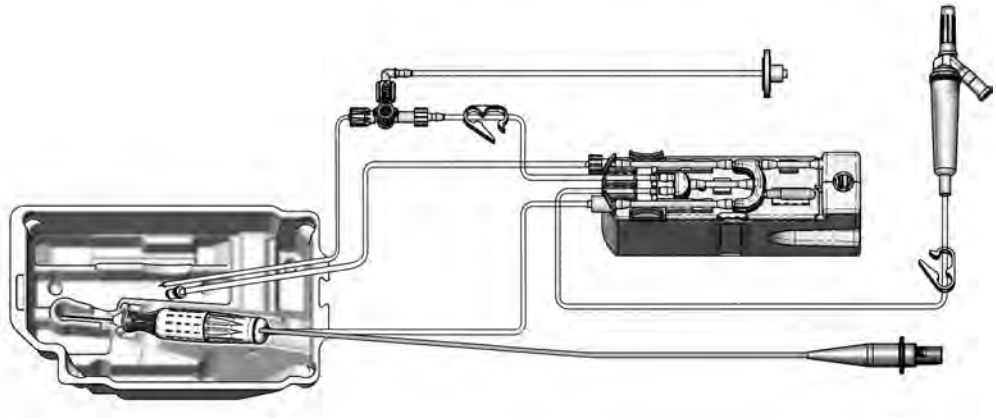


Figure 4.13. **Complete Vitesse™ tubing connections and setup**.

g. Remove the tape to unbind all the tubing. (Scrub Nurse)

h. Straighten the tube set and secure it, so it will not drop off the sterile surface. (Scrub Nurse)

i. Remove the tape from the cassette to release the additional tubing that is tied to the cassette. (Scrub Nurse)

j. Connect the air tubing filter to the system (second right connector). Ensure the air pump is on. (Scrub Nurse or Circulating Nurse)

k. If the surgical pack contains a pneumatic vitrectomy cutter, disconnect it from the cassette and set it aside. (Scrub Nurse)

l. If the surgical pack contains Entry Site Alignment (ESA) devices, remove and set aside. Only use the ESA devices provided with the Vitesse™ handpiece pack (yellow trocar caps) while using Vitesse™.

m. Insert the fluidics cassette all the way in and hold until it is automatically captured by the system. The cassette housing backlight will stop blinking and remain on when the system captures the cassette. (Scrub Nurse or Circulating Nurse)

n. Pass the bottle spike and irrigation tubing to the Circulating Nurse. (Scrub Nurse)

o. Spike and hang the Balanced Salt Solution (BSS) bottle on the automated I/V pole or the Zero Level hanger if using Air Forced Infusion (AFI). Squeeze and release the drip chamber until it is half filled with solution. (For AFI setup, use the spiking tool provided to puncture the rubber stopper on the bottle before inserting the metal cannula into the bottle.) (Circulating Nurse) See Figure 4.5 of the Operator's Manual.

p. If the surgical pack contains a priming cup, remove it and set it aside. (Scrub Nurse)

9. Open the Vitesse™ handpiece pack and perform the following setup steps:

a. Hold the bottom of the tray with one hand. (Circulating Nurse)

b. Tear open the Tyvek seal with the other hand toward the body. (Circulating Nurse)

c. Remove the enclosed tray insert containing the handpiece and accessories and place on a sterile surface, with the clear top section facing up. The tray insert can be removed from the tray either by pouring out or by lifting out, while ensuring no contact is made with the non-sterile top edge of the tray. (Circulating and Scrub Nurse)

d. Unfasten the handpiece electrical cable and plug from the outside top of the tray insert, remove tape, and connect the plug to the **U/H VIT** handpiece connector port on the left side of the Stellaris Elite™ vision enhancement system (bottom port). (Scrub Nurse)

e. Remove clear top section of the tray insert by removing any tape, unfastening the tab holding the top and bottom sections together, and then lifting off the top section. Discard the top section after removal. (Scrub Nurse)

f. Remove the package containing the ESA devices, and any other accessories from the bottom of the tray insert. Set aside for later use. (Scrub Nurse)

g. Carefully remove aspiration tubing coil (yellow stripe) from the bottom of the tray insert, without disturbing the handpiece. Remove any tape on the tubing coil. (Scrub Nurse)

h. Connect the aspiration tubing to the connector located on the right side of the fluid collection cassette. (Scrub Nurse)

i. Remove any remaining tape holding the handpiece in the tray insert. (Scrub Nurse)

j. To ensure effective system priming, tuning, and Vitesse™ operation, verify all tubing connections are made in accordance with Figure 4.13. For use of the **EASY PRIME** function, it is important that the infusion cannula and second aspiration line are positioned in the bottom of the tray insert, as shown in Figure 4.14. (Scrub Nurse)

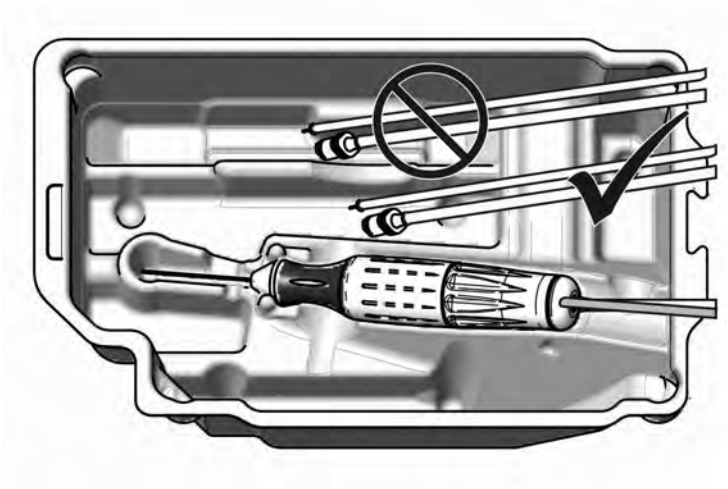


Figure 4.14. **Proper positioning of infusion and aspiration lines for effective Easy Prime operation**.

To prepare for priming and tuning, position the tray insert on the system mayo tray such that the handpiece needle is pointing away from the system. (Scrub Nurse)

10. Prime and tune the system and handpiece. For hands-free priming and tuning with the handpiece in the tray insert, select **EASY PRIME** on the **Setup Screen** or hold the handpiece with needle tip submerged in BSS. If the handpiece is held while priming and tuning, ensure the needle does not contact any hard surface during this process or the handpiece may fail to tune. Press the **EASY PRIME** button to initiate the auto priming and tuning sequence. Hold the handpiece until prime/tune completes. (Scrub Nurse)
11. (Optional) Installation and removal of the snap-on finger guard.

Note: *An optional snap-on finger guard may be included in the Vitesse™ handpiece pack to assist surgeons with avoiding inadvertent finger contact with the handpiece needle during Vitesse™ operation. Finger contact with the needle during use can lead to a frictional heating effect that may result in minor discomfort to the surgeon. The finger guard may help to reduce the chance of inadvertent needle contact and the resulting frictional heating.*

Figure 4.15. **Vitesse™ snap-on finger guard**.

a. The finger guard can be installed on the front of the handpiece, as shown in Figure 4.16. To ensure safe, effective installation, attach the finger guard with the needle pointed away from the hand, while avoiding finger contact with the needle. (Scrub Nurse)

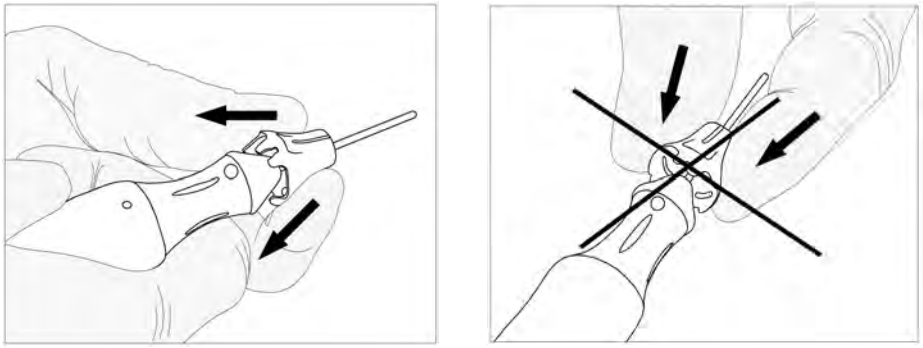


Figure 4.16. **Left: Safe, effective method for installing the finger guard; Right: Incorrect method**.

b. The finger guard can be removed from the handpiece, as shown in Figure 4.17. Carefully pull the finger guard off the front of the handpiece and rotate it such that the needle passes through the open slot on the finger guard. (Scrub Nurse)

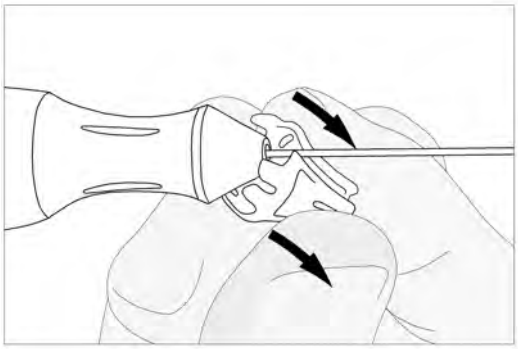


Figure 4.17. **Removal of the finger guard**.

Illumination Function

WARNING: ***Care should be taken to avoid concentrating the illumination output on a small area of the retina for unnecessarily prolonged periods of time, due to the potential for phototoxicity and serious permanent injury.***

CAUTION: ***Do not use lamps in damp locations, in areas of high humidity, or if condensation is likely to have formed; for example, immediately after moving from a cold location to a warm location.***

CAUTION: ***Do not block air vents.***

Note: *The surgeon should use the minimum illumination necessary to undertake the desired procedure.*

Fiber-optic illumination for intraocular viewing is accomplished with the ***Stellaris Elite***™ illumination function. The system contains two individually controlled light outputs, each with its own lamp. The standard configuration is a xenon lamp in the lower position (Lamp 1) and xenon-mercury lamp in the upper position (Lamp 2), but the instrument can be configured with either type of lamp in either position. The probe connector contains a shutter mechanism to prevent light leakage when the probe is not connected.

The light transmitted to the patient will have a spectral content between 435 nm and 650 nm.

Each lamp provides slightly different illumination, and the choice of which to use will be dependent on both surgeon preference and procedure type. The xenon lamp has a whiter light with a full spectrum. The xenon-mercury lamp has a greener light that has less blue light content than the xenon spectrum at the same perceived light level.

If a xenon lamp is installed in the lower position, the user may select one of three color filters (green, yellow, amber) to tint the light output to give improved visualization in certain circumstances.

The Primary (Integrated) Foot Control side button may be programmed to turn Lamp 1 or Lamp 2 on and off. There are three ways to map the illuminator settings to the Primary (Integrated) Foot Control:

1. Using the More Screen Foot Control Tab .
2. Programming the technique level Primary (Integrated) Foot Control settings.
3. Also in programming, overriding the technique level settings on the phase level Primary (Integrated) Foot Control settings screen.

Illumination Setup and Use

1. Connect the fiber-optic illuminator to the desired port (see Figure 1.24 Posterior). Push the connector into the port until the groove on the connector is aligned with the front surface of the port receptacle. See Figure 4.18. (Scrub Nurse or Circulating Nurse)

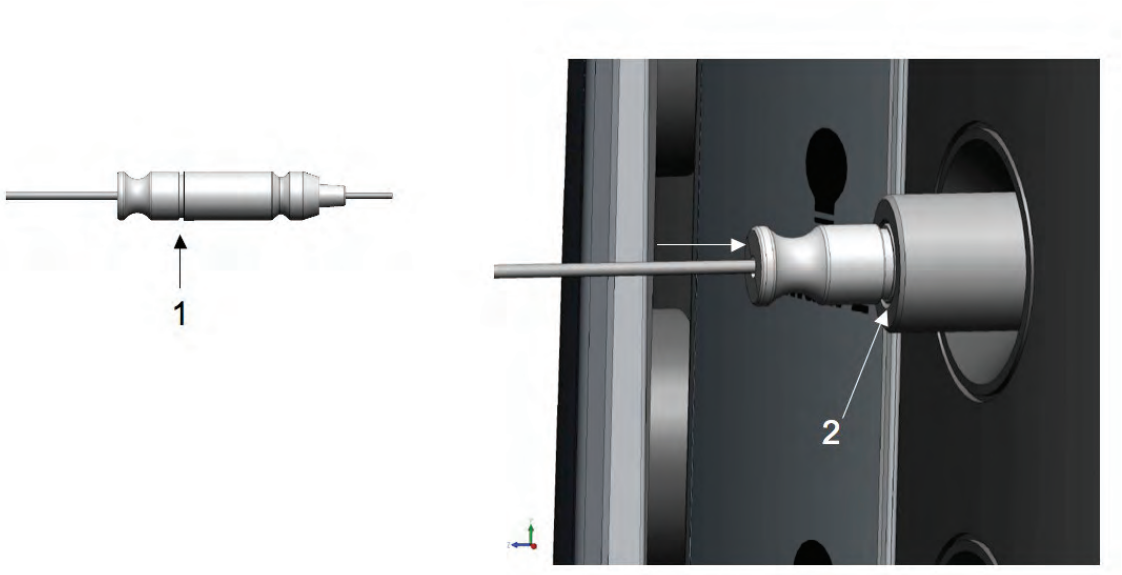


Figure 4.18. **Connecting Fiber-Optic Connector to the Illumination Port**.

1. Connector groove. 2. Connector groove align with port receptacle when it is properly connected.

2. To turn illumination on, select the **On/Off** button from the screen as shown in the figure below. (Scrub Nurse or Circulating Nurse)

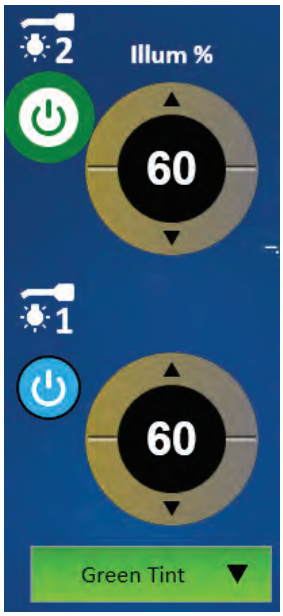


Figure 4.19. **Illumination Control.**

Illumination control showing a green ring around the **On/Off** button, which indicates the lower illumination port (right) is turned on. The filter button is below the **On/Off** button for the lower (right) lamp.

3. Use the on-screen control to adjust the intensity.

CAUTION: ***Never turn the illumination on and off rapidly.***

Note: *Lamp may take several minutes to complete the warm up, but can be used once the required intensity has been reached.*

4. Set the illumination output with the **Up/Down** buttons in the display tube. Click on the arrow to increase or decrease the output level, or click and hold to make larger changes.

Note: *Should the light source fail during use, the operator must switch the fiber-optic illuminator to the other lamp port. The burned-out lamp should be replaced before the next surgery.*

Illumination Filter Control

The lower lamp has three optional filters that can be used.

You can change the current filter using the touch screen display and Primary (Integrated) Foot Control (if programmed appropriately), or use the filter button on the surgical screen to toggle filter selection (none, amber, green, yellow). You can also select the filter from the **More Screen Illumination Tab**.

By default, the filter is set to **None**. To change this, edit your surgeon preferences file (see page 3-11).

The output level should be set in accordance to the guidance shown in the detail section on page 4-20.

Lamp Life Cycle

As the lamp ages, its operating voltage will naturally increase. In some cases, it may increase beyond an acceptable level before the normal number of operating hours have elapsed. In this case the ***Stellaris Elite***™ will prevent further use of the lamp to avoid the possibility of lamp rupture.

If the lamp takes longer than usual to strike, or fails to strike, this indicates the lamp is nearing the end of its life and a warning message may appear on the screen.

Each lamp has a maximum number of hours of life, and the system will provide a warning when that limit is near, and again once the limit has been reached. Once the limit has been reached, the lamp will remain on for the current surgery but once turned off will not turn on again and must be replaced.

The amount of lamp life remaining for each lamp is displayed in the **Illumination More Screen**. The display represents the remaining hours of lamp life. The Green area represents the amount of hours of life remaining prior to the user notification. The Yellow area represents the point that the user notification has been given, meaning that the lamp has a specific number of hours (15) until the indicated light bulb must be replaced.

Lamp Life

Xenon—400 hours, notification is at 15 remaining hours of lamp life.
Xenon-Mercury—500 hours, notification is at 15 remaining hours of lamp life.

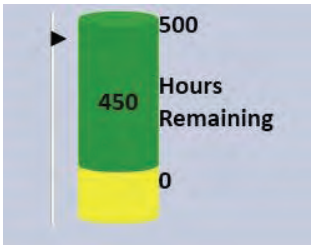


Figure 4.20. **Lamp Life Indicator**.

Lamp Replacement Procedure

WARNING: ***Always turn off the power supply before attempting to replace the lamps to avoid danger of burns, electric shock and eye damage from arc light.***

WARNING: ***Wear eye protection when installing or removing lamps.***

WARNING: ***Do not touch the glass lamp or the circuit board. Hold the assembly only by the outer metal housing.***

WARNING: ***Do not drop, scratch, or apply force to lamp, as the high pressure inside may cause the lamp to rupture.***

Note: *The* **Stellaris Elite**™ *will not work unless both lamps are fitted in place. If you remove a lamp you must replace it with another lamp or the system will not function.*

1. TURN OFF THE SYSTEM. Wait 20 minutes for the system to cool before attempting lamp replacement.
2. Open the lamp replacement access door on the side of the unit by placing a coin or flat head screwdriver into the slot and turning it counter-clockwise. The dot should be on the right, and the door should then lift off.

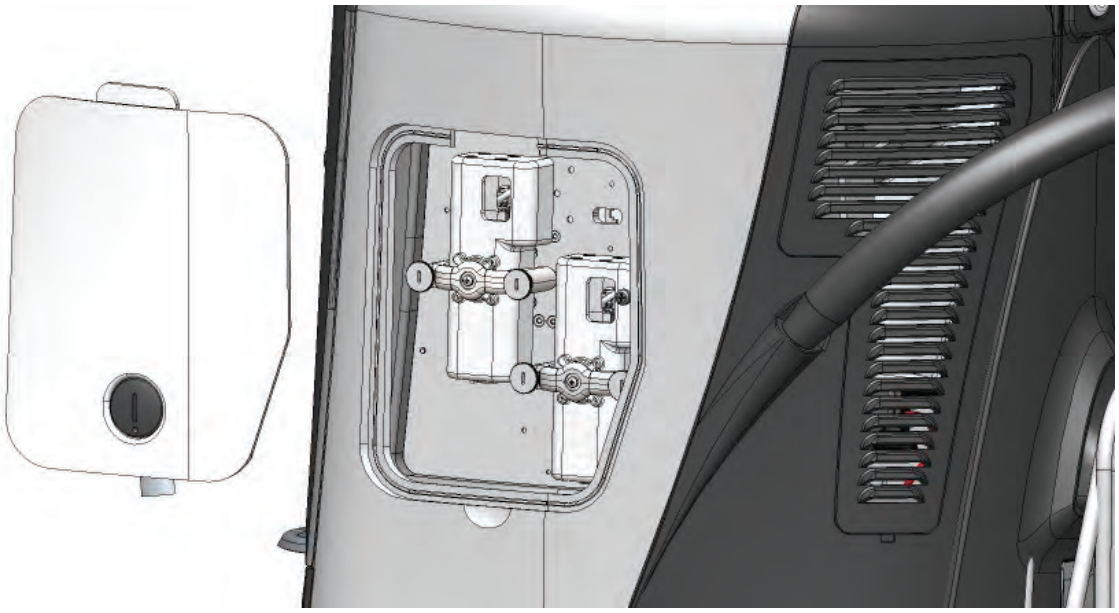


Figure 4.21. **System Side with Lamp Access Door Open**.

3. Identify the lamp that requires replacement: lower lamp = Lamp 1; upper lamp = Lamp 2.
4. Undo the two lamp fasteners by turning the two thumbscrews counterclockwise.

5. Carefully pull the lamp housing from the unit and dispose of according to applicable regulations.

Note: *Make sure to dispose of the old lamp properly. Lamps are filled with high pressure xenon gas or xenon and mercury gases. When disposing of the used lamp, take appropriate measures in compliance with applicable regulations regarding waste disposal, or entrust disposal to a licensed industrial waste disposal company. Be sure to comply with the regulations in your country, state, region or province to ensure the used lamp is disposed of legally and correctly.*

6. If the bulb is shattered and glass fragments are found, contact Bausch + Lomb service to remove them to prevent damage to the unit.

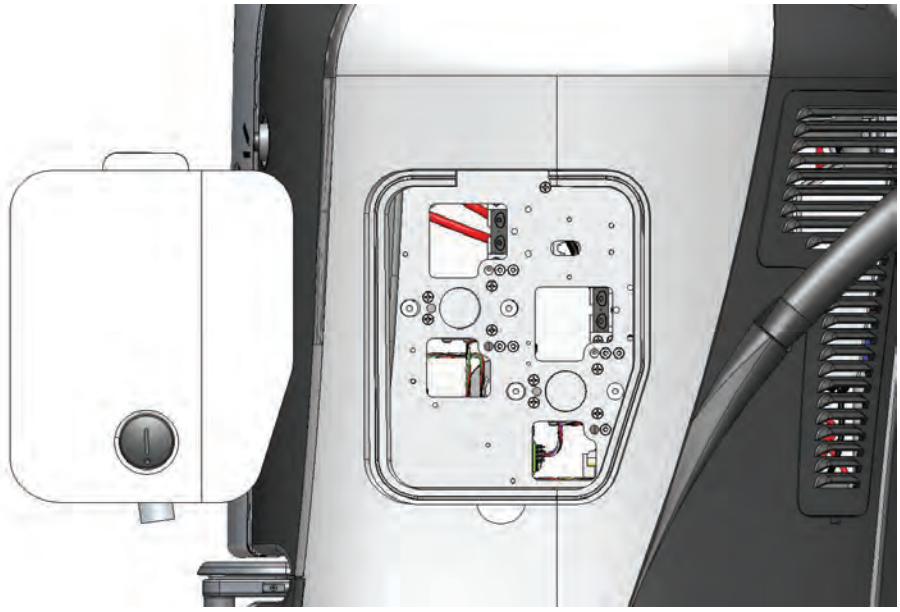


Figure 4.22. **Side of Unit with Lamps Removed, with Lamp Location and Orientation Shown**.

7. DON'T TOUCH THE LENS, LAMP CONNECTORS OR OTHER PARTS INSIDE THE SYSTEM.
8. Open the packaging for the replacement lamp (holding only the metal housing). BE CAREFUL NOT TO TOUCH ANY PART OF THE GLASS BULB OR CIRCUIT BOARD.

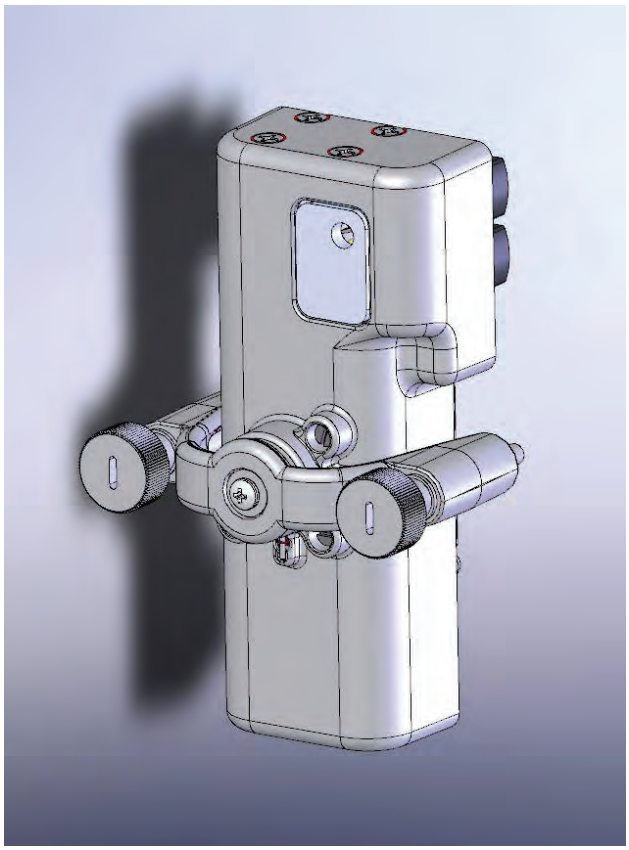


Figure 4.23. **Lamp Housing Exterior**.

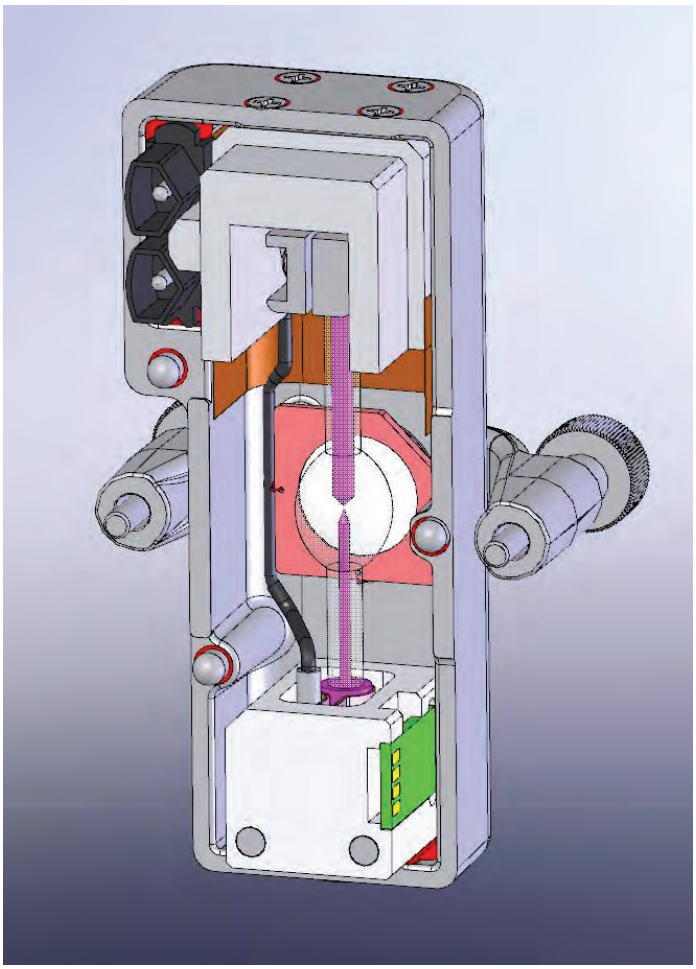


Figure 4.24. **Lamp Housing Interior**.

9. Align the replacement lamp housing with the hole, taking care to align the connectors on the top-right and bottom-left corners.
10. Push the replacement lamp housing firmly into place.
11. Screw the two lamp fasteners clockwise until tight (thumbscrews).

WARNING: RISK OF ARC EXPOSURE.

12. Prior to restoring power to the system, replace the access door on the side of the unit, and turn the slot clockwise. Make sure the dot is pointing down, indicating that the door is locked.
13. Turn on the system.
14. Check that the new lamp is recognized.

Note: *Make sure to dispose of the old lamp properly. Lamps are filled with high pressure xenon gas or xenon and mercury gases. When disposing of the used lamp, take appropriate measures in compliance with applicable regulations regarding waste disposal, or entrust disposal to a licensed industrial waste disposal company. Be sure to comply with the regulations in your country, state, region or province to ensure the used lamp is disposed of legally and correctly.*

Fluid/Air Exchange (F/AX) Function

The Fluid/Air Exchange function provides continuous air flow from a pneumatic pump located in the compressor. The air output connector must be used in the posterior mode for Fluid/Air Exchange. Air is filtered through a disposable filter. The Primary (Integrated) Foot Control side button may be programmed to turn Fluid/Air Exchange **On** or **Off**.

Fluid/Air Exchange Operation

The Fluid/Air Exchange mode is a posterior feature which provides the surgeon with the ability to instill a preset air pressure into the eye for Fluid/Air Exchange. It supports pressures up to 150 mmHg at flow rates up to 3.5 standard cubic feet (99 liters) per hour. The air pressure from the pump may be adjusted from 0 mmHg to 150 mmHg in 1 mmHg increments.

Fluid/Air Exchange Setup and Use

The Fluid/Air Exchange tubing is an integrated part of the pre-connected tubing set of the ***Stellaris Elite***™ procedure pack. The function shares the same air source as AFI. In the event the air pump is already on for AFI, all you need to do to activate Fluid/Air Exchange is switch the 2-way stopcock that is attached to the infusion cannula.

1. Set up the system for posterior vitrectomy (see page 4-8) or combined surgery (see page 4-67).
2. Select the **On/Off** button to turn on air pump. (Scrub Nurse or Circulating Nurse)

Note: *When the pump is turned on, the air pressure numeric display will transition to show actual pressure. When the pump is off, the display indicates the preset air pressure.*

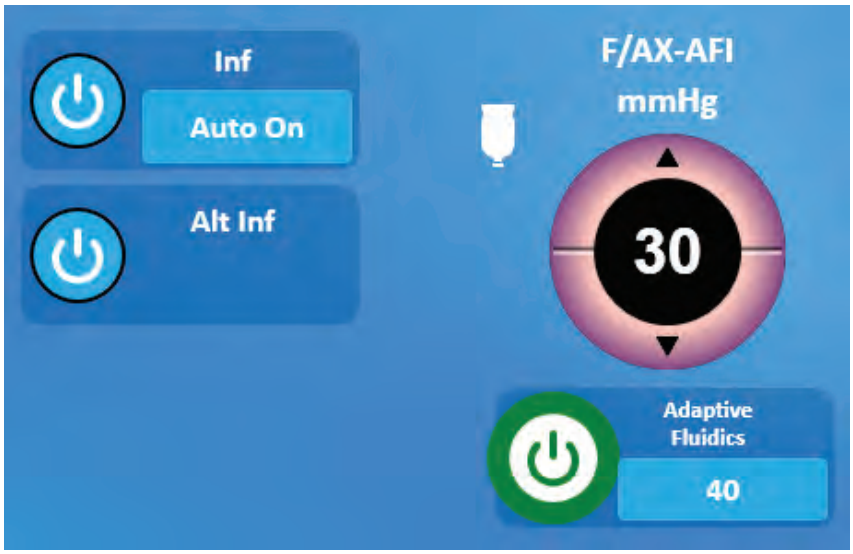


Figure 4.25. **A Green Ring on the On/Off Switch Indicates Air Pump Has Been Turned On**.

3. Select the up/down arrows to change the air pressure output. (Scrub Nurse or Circulating Nurse)
4. Turn the valve of the stopcock to stop the flow of irrigating solution and start the flow of air as shown in Figure 4.26 (top). (Scrub Nurse)

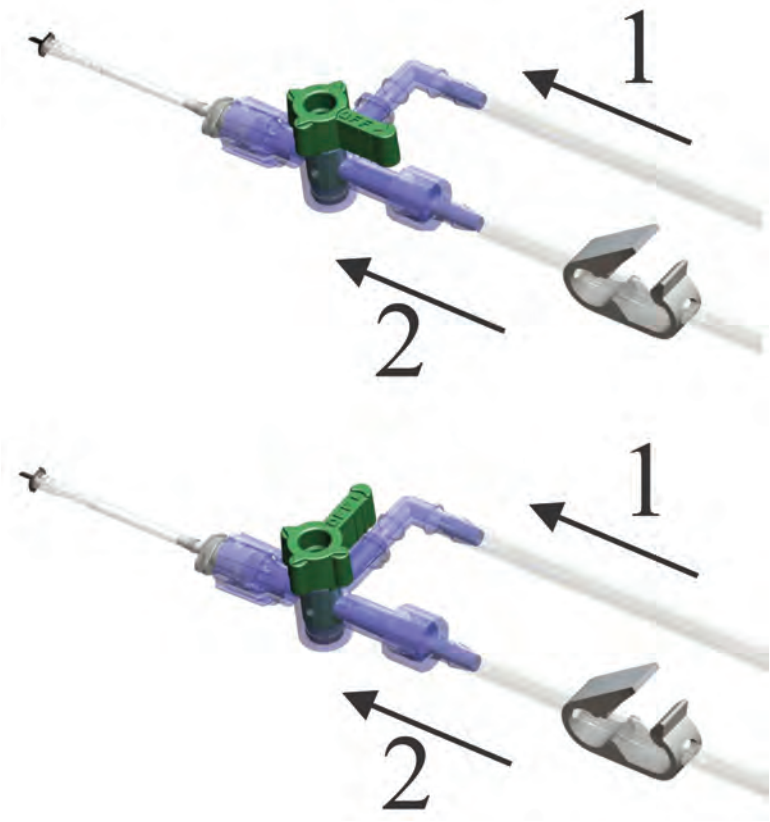


Figure 4.26. **The 2-way stopcock control of Fluid/Air Exchange**.
Top: On - Air flows into the eye.
Bottom: Off - Fluid flows into the eye.

1. Air. 2. BSS.

Tamponade

Air Tamponade

Air Tamponade is a function where the air pressure is temporarily elevated to a pre-programmed level during a Fluid/Air Exchange procedure. The pressure level for Air Tamponade is higher than pressure use during normal operation. The temporary increase of pressure is normally used to stop intraocular bleeding.

The Air Tamponade function may be enabled by the **Alt Inf On/Off** button on the display (see Figure 4.27), or the Primary (Integrated) Foot Control switch if it is programmed to control Alternate Infusion. Adjusting the air pressure above 59 mmHg will also enable Elevated Infusion. The tamponade pressure is displayed in the surgical screen and may be adjusted by selecting the numeric pressure display or using the touch screen **Up/Down** arrows. Air Tamponade would also be enabled whenever the Fluid/Air Exchange pressure level is raised above the programmed tamponade level.

When the function is enabled, a two bell auditory notification will sound every 30 seconds and an Elevated Infusion indicator on a yellow background is displayed, with an elapsed time counter, on the surgical screen to indicate the low priority alarm condition for elevated infusion.

An optional voice indication if enabled will state “Elevated Infusion On” at one minute intervals.

When **Alt Inf** is disabled or the Fluid/Air Exchange level is reduced below the tamponade level, the alarm condition is immediately ended when the infusion pressure is set below the tamponade level of 60 mmHg or 81 cmH_2O.

When **Alt Inf** is toggled **Off**, the Fluid/Air Exchange function status and pressure will return to the value it had prior to turning **Alt Inf On**, and the timer will be cleared from the screen if the pressure setting is reduced below 60 mmHg (81 cmH_2O).

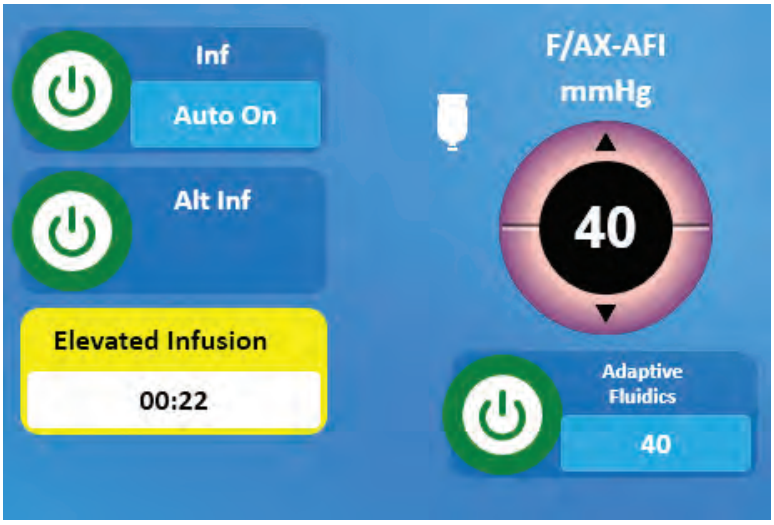


Figure 4.27. **Surgical Screen Displays Elevated Infusion Controls (Status On) and Timer**.

Fluid Tamponade

Similar to the Air Tamponade, Fluid Tamponade is a function where the fluid infusion pressure is temporarily elevated to a pre-programmed level. The Fluid Tamponade can be driven by pressurized air or gravity infusion.

The Fluid Tamponade function may be enabled by the **Alt Inf On/Off** button on the display, or the Primary (Integrated) Foot Control switch if it is programmed to control the Elevated Infusion. Adjusting IV Pole above 80 cm or pressurized infusion above 59 mmHg, will also enable Elevated Infusion. The tamponade pressure is displayed in the surgical screen and may be adjusted by selecting the numeric pressure display or using the touch screen **Up/Down** arrows. Fluid Tamponade would also be enabled whenever the Fluid/Air Exchange pressure level is raised or the IV Pole is adjusted above the programmed tamponade level.

When the function is enabled, a two bell auditory notification will sound every 30 seconds and an Elevated Infusion indicator on a yellow background is displayed, with an elapsed time counter, on the surgical screen to indicate the low priority alarm condition for elevated infusion.

An optional voice indication if enabled will state “Elevated Infusion On” at one minute intervals.

When **Alt Inf** is disabled or the Fluid/Air Exchange level is reduced below the tamponade level, the alarm condition is immediately ended when the infusion pressure is set below the tamponade level of 60 mmHg or 81 cmH_2O.

When **Alt Inf** is toggled **Off**, the air pressure and IV Pole will be set to the value it had prior to turning **Alt Inf On**, and the timer will be cleared from the screen if the pressure setting is reduced below 60 mmHg (81 cmH_2O).

The visual and auditory indicators provided when elevated infusion pressure is set above the stated limits constitutes a low priority alarm as prolonged use has the potential to induce blindness in the patient. It is triggered as soon as the feature is activated and will turn off immediately after the feature is deactivated. While the volume level can be adjusted, it cannot be turned off, see Section 3.

To program the Elevated Infusion pressure for Air Tamponade and Fluid Tamponade, go to the Technique Level Programming Fluidics tab to set desired pressure (see page 3-7). By default, the pressure is set at 80 mmHg and 100 cm.

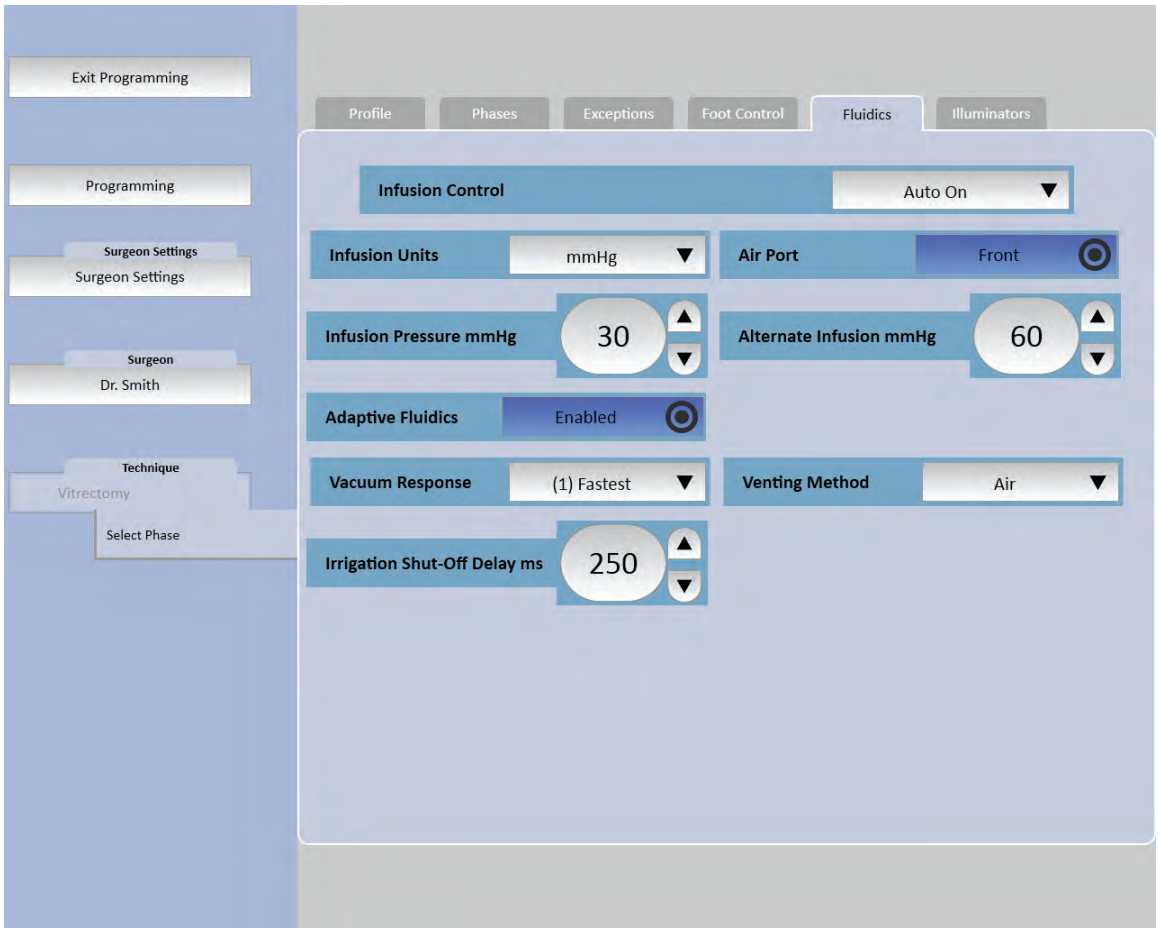


Figure 4.28. **Technique Programming Level Fluidics Screen with Air and Fluid Tamponade Settings**.

Viscous Fluid Control (VFC) Function

WARNING: ***The VFC is not intended for aspiration of BSS.***

The ***Stellaris Elite***™'s VFC function generates the required injection pressures and aspiration vacuums for injecting viscous fluids to, and aspirating viscous fluids from, the eye during posterior segment surgery. The Viscous Fluid function will deliver up to 72.5 psig (500 kPa, 5.0 bar) of pneumatic pressure to the disposable tube set. All other posterior system functions except fragmentation and vitrectomy may be operated simultaneously or in conjunction with this function.

Silicone Oil: When used in the injection mode, the system can inject up to 5 cc of 1000 centistoke to 7500 centistoke silicone oil at 24°C (75°F) in less than 6.25 minutes.

Viscous Fluid Injection: Setup and Use

1. Open a viscous fluid injection disposable pack and place contents on a sterile surface.
2. Connect the locking air connector on the tubing set to the ***Stellaris Elite***™ system (top-right connector, Figure 1.24).
3. Connect the syringe coupler of the Viscous Fluid tubing to the syringe filled with silicone oil. Twist the coupler to lock it securely to the syringe (see Figure 4.29).

WARNING: ***Ensure a black piston is in the syringe before connecting the syringe coupler to the syringe filled with silicone oil. Failure to do so will cause patient injury.***

4. Slowly turn the syringe upward so that the tip points toward the ceiling, allowing any air to move to the tip in one cohesive bubble.
5. While holding the syringe in the upright position, remove the syringe cap from the syringe and attach the 19 gauge Teflon cannula. (Teflon cannula is recommended for injection.)
6. Select **Visc Inject** from the Surgical Screen **Clock Menu** to perform the VFC injection procedure.
7. To evacuate air from the syringe, hold the syringe in the upright position and activate low injection pressure to force air out the tip of the cannula.
8. Remove the cannula cover before use.

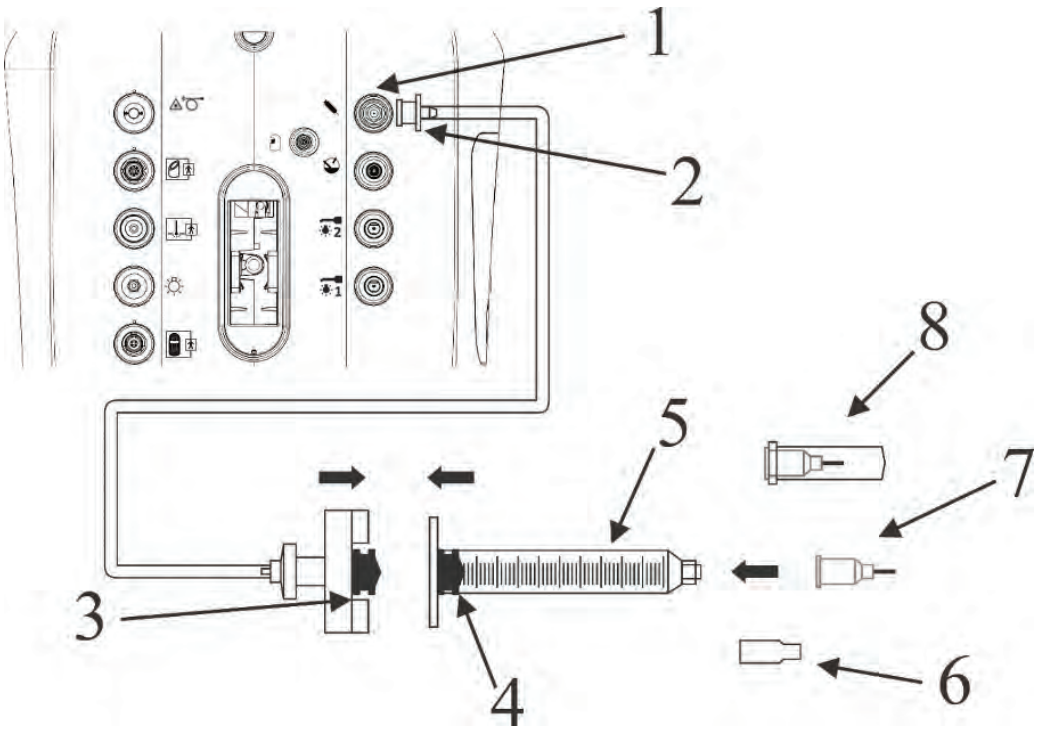


Figure 4.29. **Viscous Fluid Injection Setup**.

1. Viscous Fluid Port. 2. Air Tubing Connector. 3. Coupler. 4. Piston. 5. Syringe with Silicone Oil. 6. Syringe Cap. 7. 19 gauge Injection Cannula (for injection). 8. 19 gauge Extraction Cannula.

Viscous Fluid Injection: Operation Modes

Fixed Fluid Injection
The Foot Pedal is used to control the injection with a pre-programmed fixed pressure. The pressure level is set using the setting globes on the touch screen.

Linear Fluid Injection
Control of linear fluid injection is via the Foot Pedal. The injection pressure increases proportional to Foot Pedal travel from the minimum programmed setting to the maximum programmed setting. The minimum and maximum pressure levels are set using the touch screen.

Dual/Yaw Vac (Linear Fluid Injection, Linear Vacuum)
Linear fluid injection is actuated by depressing the Foot Pedal. Linear aspiration through the left aspiration line is actuated by an outward yaw movement of the center Foot Pedal. The minimum and maximum pressure levels are set using the touch screen.

Viscous Fluid Extraction: Setup and Use

1. Open a viscous fluid extraction disposable pack and place contents on a sterile surface.

2. Connect the locking air connector on the tubing set to the ***Stellaris Elite***™ system (top-right connector, Figure 1.24).
3. Remove the syringe cap (item 6 of Figure 4.29). (Must be completed before step 4)
4. Place the black piston into the syringe barrel and use the plunger to push the piston all the way down to the tip of the syringe. (Refer to Figure 4.30 and Figure 4.31.)

CAUTION: ***Ensure a black piston is in the syringe before connecting the syringe coupler to the syringe. Failure to do so will cause fluid to be aspirated into the system's electronic components.***

5. Connect the syringe coupler of the Viscous Fluid tubing to the empty syringe. Twist the coupler to lock it securely to the syringe. (Refer to Figure 4.32.)
6. Connect the extraction needle to the syringe. The 19-gauge steel needle is suitable for this application.
7. Remove the cannula cover (8) before use.
8. Select **Visc** from the Surgical Screen **Clock Menu** to perform the VFC extraction procedure. A drop-down menu will appear with different inject or extract submode options.

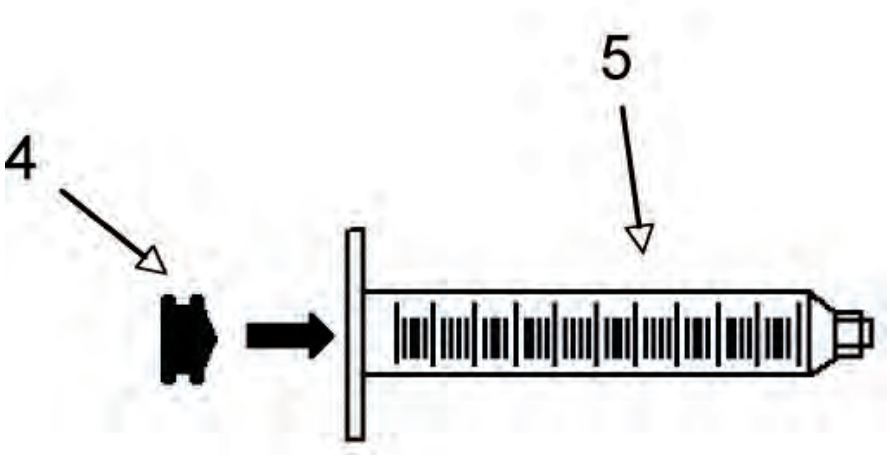


Figure 4.30. **Viscous Fluid Extraction Setup**.
Inserting Piston (4) into the Empty Syringe (5).

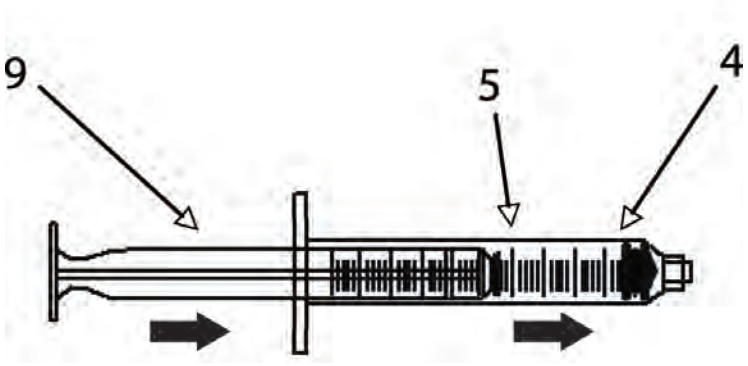


Figure 4.31. **Viscous Fluid Extraction Setup**.
Use Plunger (9) to Push Piston (4) to the End of the Empty Syringe (5).

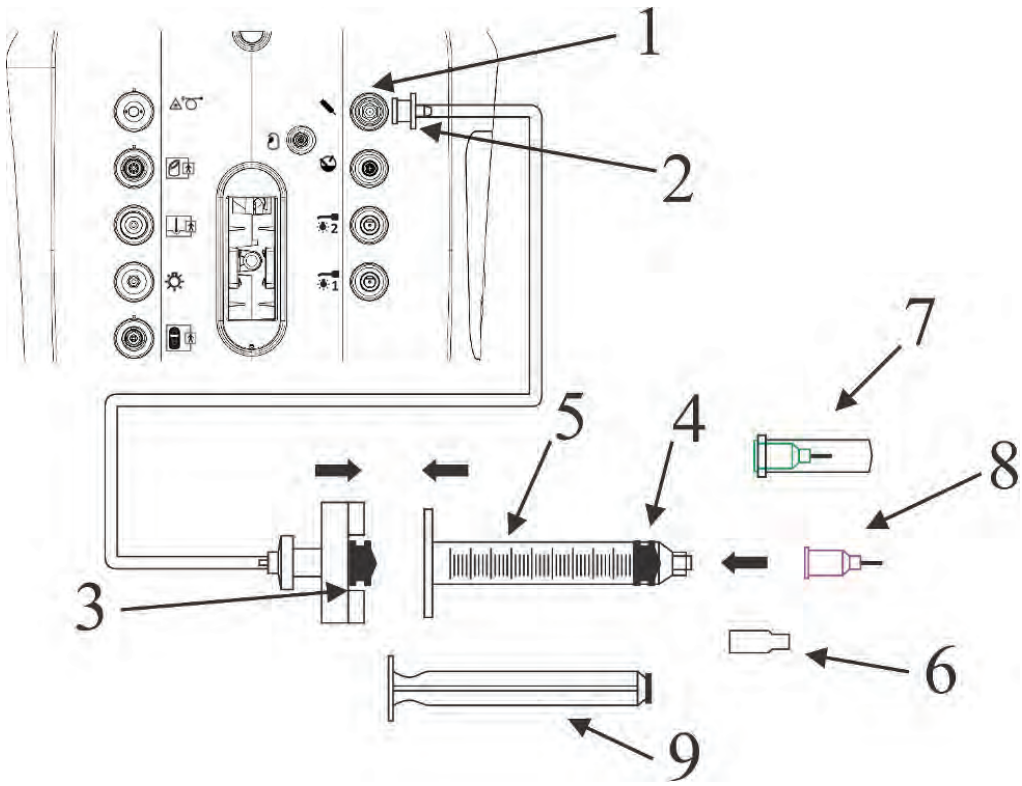


Figure 4.32. **Viscous Fluid Extraction Setup**.

1. Viscous Fluid Port. 2. Air Tubing Connector. 3. Coupler. 4. Piston. 5. Empty Syringe. 6. Syringe Cap. 7. 19 gauge Teflon Cannula. 8. 19 gauge Extraction Cannula. 9. Plunger.

Viscous Fluid Extraction: Operation Modes

Fixed Extract
Extraction is activated when the Foot Pedal is depressed. Aspiration pressure is fixed and pre-programmed through the touch screen user interface.

Linear Extract
Extraction is controlled via the center Foot Pedal. The extraction vacuum increases proportional to Foot Pedal travel from the minimum programmed setting to the maximum programmed setting. The minimum and maximum vacuum are set using the touch screen.

Fragmentation

The ***Stellaris Elite***™ Fragmentation function provides ultrasound emulsification and vacuum for lens removal from the posterior segment of the eye.

WARNING: ***During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.***

Fragmentation Setup and Use

WARNING: ***A loose needle may lead to improper tuning and could cause shedding of metal fragments into the eye, which can result in serious permanent patient injury.***

Note: *Fragmentation uses the same power connection as the ultrasound handpiece. Only one function can be used at a time.*

Note: *Prior to setting up Fragmentation, the* **Stellaris Elite**™ *has to be set up for Posterior Vitrectomy or Combined surgery.*

Note: *Specific instructions for cleaning and sterilization included with a handpiece or accessory take precedence over these instructions.*

1. Set up the system for posterior vitrectomy (page 4-8) or combined surgery (page 4-67).
2. Ensure the screen is displaying the **Prime and Tune** Setup screen.

3. Connect the handpiece electrical connector to the connector on the machine. (Scrub or Circulating Nurse)
4. Thread and firmly secure the single-use fragmentation needle onto the fragmentation handpiece using a needle wrench. (Scrub Nurse)
5. Connect the clear aspiration line to the fragmentation handpiece. (Scrub Nurse)
6. Hold the handpiece with tip submerged into BSS. (Scrub Nurse)

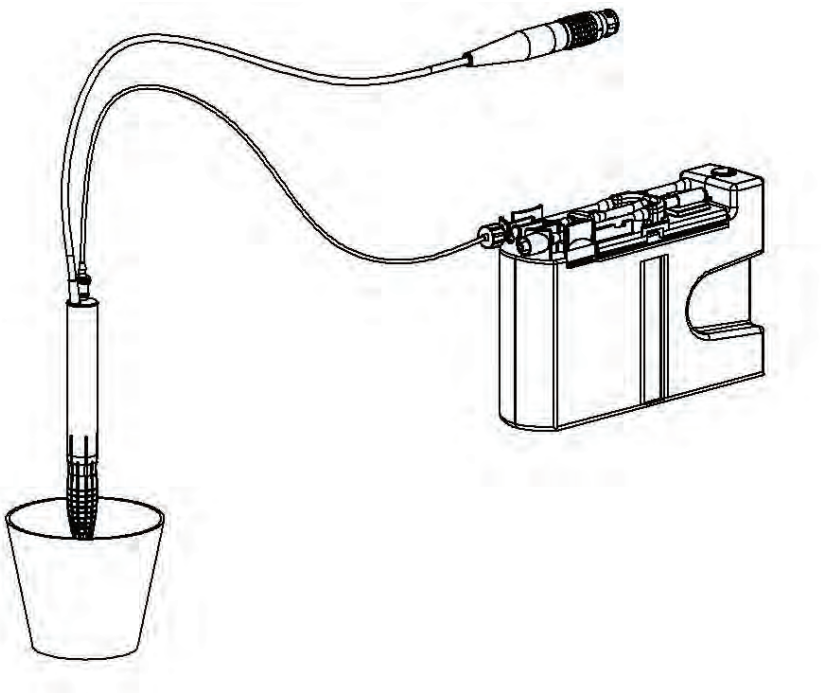


Figure 4.33. **Hold Frag Piece with Tip Submerged into Water During Priming and Tuning**.

7. Select **Prime/Test U/S** to initiate the autopriming and tune ultrasound sequence. Hold the handpiece until prime and tune completes and the system transitions to the **Surgical Screen**. (Scrub or Circulating Nurse)
8. Select **Frag mode** from the **Clock Menu** to perform the fragmentation procedure. (Scrub or Circulating Nurse)

Fragmentation Modes

The ***Stellaris Elite***™ provides two Fragmentation modes with adjustable ultrasound power and vacuum control. Refer to the table on page 3-35 on ultrasound customization for information on the available vacuum range and options on ultrasound modulations. Detailed description of Ultrasound modulations such as Pulse, Burst and Duty Cycle are provided in the Ultrasound Functions section in the Anterior Domain Section, page 4-43.

Linear Frag
Linear Frag submode provides linear vacuum in Foot Pedal Region 1 and fixed maximum vacuum and linear ultrasound in Foot Pedal Region 2. The outward yaw in any Foot Pedal region controls ultrasound **On/Off**.

Dual/Yaw U.S. Frag
This submode provides linear vacuum control on Foot Pedal pitch, and linear ultrasound on outward yaw in Foot Pedal Region 1.

4.3. Anterior Functions

Irrigation

Irrigation is part of the fluidics system, providing continuous fluid flow to compensate for fluid aspirated out of the eye. Irrigation on/off is controlled by the pinch valve, which is opened when the Foot Pedal is pressed and closed when the Foot Pedal is released.

An Irrigation-only mode is available, in which the Foot Pedal controls irrigation on/off. The **Fill Button** on the **Surgical Screen** opens the irrigation control valve for 20 seconds to facilitate collection of irrigation solution into a surgical container.

Irrigation/Aspiration (I/A) Function

Note: *Do not pull the tubing taut — it must be allowed to have a droop or sag between the cassette and the handpiece.*

Note: *Whenever the cassette is ejected from the system console, keep the handpiece above the level of the cassette port.*

The Advanced Vacuum Function provides vacuum levels from 0 mmHg to 660 mmHg in 1 mmHg increments depending upon the mode of operation. Aspiration limits are set via the touch screen, the remote control, or the Primary (Integrated) Foot Control buttons (if programmed).

In I/A mode, irrigation is activated in Region 1 of Foot Pedal travel, and both irrigation and aspiration are activated in Region 2 of Foot Pedal travel.

Capsule Polish

The capsule polish function is typically accomplished with a lower vacuum setting than standard settings. These settings may be customized to allow quick entry into a lower vacuum level as explained in Chapter 3.

Viscoelastic Removal

The viscoelastic removal function provides different settings for the doctor's convenience. These settings may be customized to allow quick entry into a specific vacuum level as explained in Chapter 3.

Venting

The Vacuum Flow Fluidics system provides the surgeon with either air or fluid venting options to free an occluded tip when the Foot Pedal is released. When air venting is selected, the residual vacuum is vented to atmospheric pressure, and when fluid venting is selected, it is vented to a positive pressure equal to the bottle height head pressure. Venting automatically occurs every time the Foot Pedal travels back to region 1.

Reflux

Aspiration of fluid to the collection cassette occurs via the handpiece and a tube set. Reflux applies a momentary reverse pressure through the aspiration line to clear the aspiration port of lodged material.

The ***Stellaris Elite***™ vision enhancement system is designed for use with continuous reflux or pulse reflux. If enabled, the reflux feature is activated by inward movement of the Foot Pedal in all aspiration modes.

Continuous Reflux
Reflux pressure is based on irrigation pressure.

Pulse Reflux
Reflux is created by the momentary activation of a plunger on the reflux bulb.

Pulse reflux is only available with Adaptive Fluidics built with reflux bulb and combined procedure cassette.

Vacuum Response

Vacuum response refers to the amount of time required to obtain the desired aspiration level. A fast response value instructs the system to achieve the desired aspiration level in the shortest amount of time; similarly, slow indicates that the time to achieve the desired aspiration will be significantly longer. The response can be changed through the programming interface (see Chapter 3) or the **More Screen** (see page 2-7). The Advanced Vacuum System has five levels of vacuum response setting, with one being the fastest response and five being the slowest response.

Primary (Integrated) Foot Control of Irrigation/Aspiration

As the Foot Pedal is initially pressed, the irrigation control valve will open to allow irrigation into the eye.

Once irrigation has been initiated and the Foot Pedal has been depressed approximately five degrees (or as programmed), a momentary increase in Foot Pedal resistance will be noted, signifying the transition from Region 1 to Region 2 and the start of aspiration. Aspiration increases proportional to Foot Pedal travel, with the maximum level being set via the **Max Vacuum** input on the touch screen. You can program Region 2 to provide either fixed or linear vacuum control. The **Actual Vacuum** display will indicate the current aspiration level.

If enabled, an audible linear tone will indicate aspiration. The pitch of the tone increases with increased aspiration.

Irrigation/Aspiration Setup

WARNING: ***For optimum aspiration and reflux performance, the patient's eye level must be at the same level as (no more than 7 cm [3 in.] from) the* Stellaris Elite™ *vision enhancement system's aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.***

WARNING: ***Ensure the handpiece and accessories are sterilized before use as specified.***

Note: *Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.*

1. Turn Power on.
2. Press any button on the Primary (Integrated) Foot Control and wait until the ready light turns solid green, indicating wireless communication has been established.
3. Select **Surgeon's Name** and select **Confirm**.
4. Open the disposable package and insert the fluidics cassette all the way in and hold until it is automatically captured by the system. The cassette housing backlight will stop blinking and remain on when the system captures the cassette.
5. After the vacuum test completes, the **Setup Screen** will display with **Prime and Tune** as the highlighted function.
6. Spike the Balanced Salt Solution container and hang it at the desired height.

   Additional step if pressurized infusion is used:

   Connect the Air Tubing Line to the vent port at the bottle spike and the other end with air filter to the **Stellaris Elite**™ *air output connector. Switch on the air pump from the system setup screen (use the control in the upper right-hand corner of the screen). The output connector will remain lit when it is at commanded pressure, and blink on and off when it is not at the commanded pressure.*
7. Connect tubing to the I/A handpieces. Select **Show Me Steps** for animated setup guide, if necessary.
8. Ensure the irrigation clamp is open and toggle **Irrigation Off** to turn the flow on and allow irrigation to fill the tubing up to the handpieces.
9. Fill the test chamber with irrigating solution, then slide over the tip of the handpiece.
10. Select **Prime Only**. A vacuum test is part of the priming cycle.
11. After successful priming and tuning, the Main Surgical Screen will be displayed.

The external components of your system are now ready. Continue to set the operating parameters.

Note: *Hold the handpiece tip towards the ceiling while priming the irrigation line to ensure all air has been removed.*

I/A Use

1. Select the I/A mode on the **Clock Menu**.
2. Use the setting globes to set the desired aspiration vacuum.
3. The system is now ready for Irrigation/Aspiration.

Note: *See Chapter 5 for cleaning and sterilization requirements when surgery is completed.*

Ultrasound Function

Phacoemulsification refers to the process of ultrasonic disintegration of the lens using a vibrating needle operating at a frequency above the audible range, in the anterior chamber of the eye.

Ultrasound Power

The ultrasound display allows you to adjust maximum ultrasound power pulses per second (PPS), duty cycle (DC), pulse duration, and pulse interval. Both the current setting and the actual value are shown on the **Surgical Screen** display. The status bar (see page 2-30), visible at the top center of the surgical screen, might display the average ultrasound power (AVE), actual phaco time (APT), and effective phaco time (EPT), depending on system settings.

The AVE display is internally calculated as the arithmetic average of all phaco power used since last reset. The APT display indicates the time in minutes and seconds that phaco power has been energized since last reset. The EPT is derived from multiplication of AVE and APT. Use the **More Screen A/V Tab** (see page 2-19) to reset the phaco timer and average. The timer is also reset when you select **Next Patient** on the **End of Case Screen**.

Pulse Mode Ultrasound

Pulse mode ultrasound power may be adjusted from 0% to 10% in 1% increments, 10% to 30% in 2% increments, and 30% to 100% in 5% increments using the up/down setting globes, Primary (Integrated) Foot Control buttons, or remote, and in 1% increments using the keypad. Pulse output control is programmable from 1 to 250 pulses per second in 1 PPS increments.

The pulse rate control does not adjust the ultrasound power. The control adjusts the number of cycles of ultrasound power that occurs during a one second time interval. In **Pulsed Ultrasound Mode**, the ultrasound handpiece is energized for the portion of each time interval as programmed by the **Duty Cycle** setting.

Burst Mode Ultrasound

Burst mode ultrasound is an anterior only mode to provide minimal ultrasound energy. Ultrasound is applied in either single or multiple bursts using a fixed power or in fixed bursts using a linear control of power. The burst duration can range from 2 ms to 600 ms.

When single burst mode is selected, a burst of ultrasound energy is emitted when the Primary (Integrated) Foot Control is pressed to 90% of the linear control position, and is reset when the pedal is released to less than 90% of the linear control position.

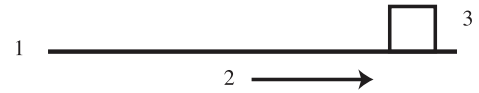


Figure 4.34. **Burst Mode Ultrasound**.

1. Single Burst. 2. Pedal Position. 3. Power.

When fixed pulse mode is selected, the pulse duration and interval may be selected with the screen settings.

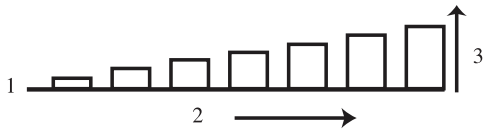


Figure 4.35. **Fixed Pulse Ultrasound**.

1. Fixed Pulse. 2. Pedal Position. 3. Power.

The ultrasound power is controlled by the linear control position of the Foot Pedal.

When multiple burst mode is selected, a sequence of bursts of ultrasound energy is emitted. The time interval between bursts is controlled by the linear control position of the Foot Pedal. When the pedal reaches full travel in the linear control, the ultrasound energy is limited by the **Max Duty Cycle** setting.

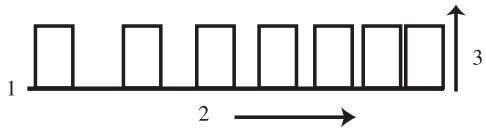


Figure 4.36. **Multiple Burst Mode Ultrasound**.

1. Multiple Burst. 2. Pedal Position. 3. Power.

Ultrasound Submode

Up to three sets of ultrasound modulation settings may be stored with each ultrasound mode. Primary (Integrated) Foot Control activation of the submode sequence may be enabled or disabled. Submodes can be toggled with the Primary (Integrated) Foot Control heel switch or by Foot Pedal outward yaw motion in Region 2 or 3, depending on how the system has been programmed.

The options to change submodes with the Primary (Integrated) Foot Control are:

- Either the left side button pair or the right side button pair may be grouped to change submodes to the next submode (toe) or previous submode (heel)
- Any of the four Primary (Integrated) Foot Control buttons may be assigned to advance to the next submode (when ungrouped)
- The outward yaw switch may be enabled to advance to the next submode (in any region) (for single linear modes)
- The inward yaw switch may be enabled to advance to the next submode (in any region) (for dual linear modes with reflux disabled)
- The inward yaw switch may be enabled to advance to the next submode (in Region 2/3) (for dual linear modes with reflux enabled)

Ultrasound Tuning

The ultrasound handpiece must be tuned with the needle installed before using. Select **Prime and Tune** on the **Setup Screen**.

Description of Ultrasound Modes

The application of ultrasound power may be fixed or linear. Linear power is proportionally controlled by the Foot Pedal between zero and the maximum limit set on the console.

Ultrasound power may be adjusted from 0% to 10% in 1% increments, 10% to 30% in 2% increments, and 30% to 100% in 5% increments using the up/down setting globes, Primary (Integrated) Foot Control buttons, or remote, and in 1% increments using the keypad. The ultrasound output will be activated at the minimum programmed power level as the Foot Pedal moves into the active ultrasound region, and will increase to the maximum programmed output as a function of linear Foot Pedal travel.

Single Linear Ultrasound Mode with Fixed Aspiration

Once irrigation has been initiated and the Foot Pedal has been depressed approximately five degrees (or as programmed), an increase in Foot Pedal resistance will be noted, signifying the transition from Region 1 to Region 2 and the start of aspiration. Fixed aspiration will be developed at the selected aspiration level. The screen will display the actual amount of aspiration at any given time.

Ultrasound power is activated in Region 3 of Foot Pedal travel. Another momentary increase in Foot Pedal resistance will be noted (if detents are enabled) signifying the transition from one Region to the next and the

start of ultrasound power. Ultrasound power will be initiated and controlled as a function of Foot Pedal travel in Region 3. The next ultrasound submode may be selected (if enabled) by moving the Foot Pedal in the outward yaw direction.

Single Linear Ultrasound Mode with Linear Aspiration

Once irrigation has been initiated and the Foot Pedal has been depressed approximately five degrees (or as programmed), an increase in Foot Pedal resistance will be noted, signifying the transition from Region 1 to Region 2 and the start of aspiration. Aspiration will increase from 0 to the fixed level in proportion to Foot Pedal travel in Region 2. The screen will display the actual amount of aspiration. Aspiration will remain at the fixed level in Region 3.

Ultrasound power is activated in Region 3 of Foot Pedal travel. Another momentary increase in Foot Pedal resistance will be noted, signifying the transition from one region to the next and the start of ultrasound power. Linear ultrasound power will be initiated and controlled as a linear function of Foot Pedal travel in Region 3. Pulsed ultrasound may be toggled on/off by moving the Foot Pedal in the outward yaw direction.

Note: *If single or multiple burst mode is selected, position 3 (or outward yaw movement) does not control ultrasound power, but rather the burst interval (for multiple burst) or nearly full travel initiates and resets the single burst (see page 4-50).*

Dual Linear Ultrasound Mode with Aspiration in Yaw (Fixed Minimum Vacuum in Region 2)

Once irrigation has been initiated and the Foot Pedal has been depressed approximately five degrees (or as programmed), an increase in Foot Pedal resistance will be noted, signifying the transition from Region 1 to Region 2 and the start of aspiration. The minimum set aspiration will be developed in Region 2. Linear aspiration to the maximum setting will be controlled by outward yaw Foot Pedal travel. The screen will display the actual amount of aspiration.

Ultrasound power is activated in Region 3 of Foot Pedal travel. Another momentary increase in Foot Pedal resistance will be noted, signifying the transition from one region to the next and the start of ultrasound power. Linear ultrasound power will be initiated and controlled as a linear function of Foot Pedal travel in Region 3 (see note).

Dual Linear Ultrasound Mode with Aspiration in Yaw and Linear Aspiration (Linear Vacuum in Region 2)

Once irrigation has been initiated and the Foot Pedal has been depressed approximately five degrees (or as programmed), an increase in Foot Pedal resistance will be noted, signifying the transition from Region 1 to Region 2 and the start of aspiration. Aspiration will increase from zero to the **minimum** level in proportion to Foot Pedal travel in Region 2. Linear aspiration to the maximum setting will be controlled by outward yaw Foot Pedal travel. The screen will display the actual amount of aspiration.

Ultrasound power is activated in Region 3 of Foot Pedal travel. Another momentary increase in Foot Pedal resistance will be noted, signifying the transition from one region to the next and the start of ultrasound power. Linear ultrasound power will be initiated and controlled as a linear function of Foot Pedal travel in Region 3.

Note: *If single or multiple burst mode is selected, position 3 (or outward yaw movement) does not control ultrasound power, but rather the burst interval (for multiple burst) or nearly full travel initiates and resets the single burst.*

Dual Linear Ultrasound Mode with Aspiration in Pitch

Irrigation is activated by Region 1 of Foot Pedal travel. As the Foot Pedal travels through Region 1, the irrigation pinch valve will open to apply irrigation to the eye.

Aspiration is activated by Region 2 of Foot Pedal travel. A momentary increase in Foot Pedal resistance will be noted, signifying the transition from Region 1 to Region 2 and the start of aspiration. In Region 2, linear aspiration will be developed at the selected aspiration level. The screen will display the actual amount of aspiration.

Linear ultrasound power will be initiated and controlled as a linear function of outward yaw Foot Pedal travel in position 2.

Dual Linear Ultrasound

Dual Linear Ultrasound mode allows control of two ultrasound parameters, one on pitch and one on yaw. In these modes, position 1 provides irrigation, position 2 provides fixed aspiration or fixed aspiration with aspiration control feature enabled, and position 3 pitch and yaw movements provide linear control of two ultrasound parameters. Modes are available for controlling power and pulse rate (pulsed), power and duty cycle (pulsed), duration and duty cycle (multiple burst), power and duration (multiple burst), and power and duty cycle (multiple burst).

Phacoemulsification Setup

WARNING: ***Never intentionally modify handpieces or tips, including bending, cutting, or engraving, as they could break or malfunction.***

WARNING: ***Do not touch an activated ultrasonic handpiece tip, as injuries could occur.***

WARNING: ***A loose needle may lead to improper tuning and could cause shedding of metal fragments into the eye, which can result in serious permanent patient injury.***

WARNING: ***For optimum aspiration and reflux performance, the patient's eye level must be at the same level as (no more than 7 cm [3 in.] from) the* Stellaris Elite™ *vision enhancement system aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.***

WARNING: ***The ultrasound handpiece, needle, and irrigation sleeve must be sterilized before performing these steps.***

Note: *Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.*

1. Turn Power on.
2. Press any button on the Primary (Integrated) Foot Control and wait until the ready light turns solid green, indicating wireless communication has been established.
3. Select **Surgeon's Name** and select **Confirm**.
4. Open disposable package and insert the cassette all the way in and hold until it is automatically captured by the system. The cassette housing backlight will stop blinking and remain on when the system captures the cassette. The vacuum test starts automatically.
5. After vacuum test completes, the **Setup Screen** will appear with **Prime and Tune** as the highlighted function.
6. Spike the Balanced Salt Solution container and hang it at the desired height.

   Additional step if pressurized infusion is used:

   Connect the Air Tubing Line to the vent port at the bottle spike and the other end with air filter to the **Stellaris Elite**™ *vision enhancement system air output connector. Switch on the air pump from the system setup screen; the control is at the upper right-hand of the screen. The output connector will remain lit when it is at commanded pressure, and blink on and off when it is not at the commanded pressure.*
7. Connect tubing to ultrasound handpiece. Select **Show Me Steps** for animated setup guide if necessary.
8. Plug the handpiece connector to the machine (second connector from the top on the left side).
9. Thread and firmly secure the ultrasound needle onto the ultrasound handpiece using a needle wrench.
10. Thread the irrigation sleeve over the ultrasound needle so that the holes in the irrigation sleeve are placed approximately 1 mm from and perpendicular to the bevel of the ultrasound needle (increase to approximately 1.5 mm for denser cataracts). For MICS needles, assemble sleeve as shown. Balanced

Salt Solution wetting of the sleeve prior to assembly is advised to assist assembling the irrigation sleeve to the needle.

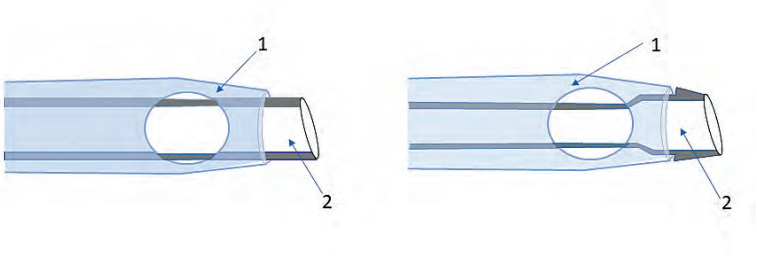


Figure 4.37. **Irrigation Sleeve and Needle** (Left: Needle without ramp, Right: Needle with ramp)

1. Irrigation Sleeve. 2. Needle.

WARNING: ***When installing irrigation sleeve on phaco handpiece, avoid scratching the inner surface of the sleeve with the needle tip. Inadvertent scratching of the sleeve's inner surface may create silicone particulate that may appear during surgery.***

11. Ensure the irrigation clamp is open and toggle **Irrigation Off** to turn flow on, and allow the flow to fill the irrigation tubing up to the handpieces. (See page 2-27 for details on the irrigation flow button.) Activate the Fill button to turn flow on for 20 to 120 seconds. The duration is user-defined.
12. Fill the test chamber with irrigating solution, then slide over the tip of the handpiece.
13. Select **Prime and Tune**. A vacuum test is part of the priming cycle.
14. After successful priming and tuning, the **Main Surgical Screen** will appear.

The external components of your system are now ready. Continue to set the operating parameters.

Note: *The system will not provide feedback as to whether or not fluid is present during priming. Inspect tubing and confirm that it is filled with fluid and free of bubbles after each Prime and Tune. Repeat the priming process if the tubing is not adequately filled with fluid.*

Phacoemulsification Use

WARNING: ***During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.***

WARNING: ***The ultrasound needle must be properly installed and not defective, and the irrigation and aspiration lines must be properly connected.***

Note: *Hold the handpiece tip towards the ceiling while priming the irrigation line to ensure all air has been removed.*

You have connected the external components of your ***Stellaris Elite***™ vision enhancement system. Now you are ready to set the operating parameters.

1. From the **Main Surgical Screen**, select the desired surgical mode from the **Clock Menu**.
2. Use the setting globes to set the desired aspiration level and the ultrasound maximum power. Set the desired number of PPS for pulsed ultrasound.

Note: *Ensure all air bubbles are cleared from lines during priming. Once the system has been primed, ultrasound tuning will begin automatically, and ultrasound tone will sound. When complete, the* ***Main Surgical Screen*** *will appear.*

Note: *As a matter of operator convenience, priming is automatically canceled when tuning has been completed or canceled. Re-tune if either the handpiece or ultrasound needle is changed.*

3. Press the Foot Pedal to begin ultrasound operation. Aspiration and ultrasound power will be applied as the Foot Pedal enters their pre-programmed regions (as described in page 1-43).
4. The **Actual Vacuum** displays the vacuum being used in relation to the maximum setting. The **Actual U/S** progress bar displays amount of ultrasound power being used in relation to the maximum setting. The **Elapsed Time** display indicates the time in minutes and seconds that ultrasound power has been energized.

Note: *See Chapter 5 for cleaning and sterilization requirements when surgery is completed.*

Adaptive Fluidics

Features

If the system is installed with ***Stellaris Elite***™ Software Rev 5.3 or higher, the Adaptive Fluidics function can be enabled from either surgeon file programming or the surgical **More Screen**. Please refer to page 2-30 for additional details related to the GUI for Adaptive Fluidics.

- **New Fluidics Function**
  - Adaptive Fluidics is a fluidics function for phacoemulsification surgery during lens removal and I/A only.
  - It is not available for anterior vitrectomy.
- **Surgical Packs**
  - The new function is to be used with Adaptive Fluidics surgical packs.
- **Fluidic Stability**
  - Adaptive Fluidics maintains fluidic stability inside the eye by linking variable infusion pressure to the real-time surgeon-commanded vacuum level. The variable infusion pressure is generated by pressurized air in the BSS bottle.

Adaptive Fluidics Setup (with Anterior Adaptive Fluidics Packs)

1. Turn Power on.
2. Press any button on the Foot Control. Wait until the ready light changes to solid green, indicating wireless communication has been established.
3. Select **Anterior Segment**.
4. Select **Surgeon's Name**, and then select **Confirm**.
5. Open disposables pack and insert fluid collection system as follows:
   a. Insert the fluidics cassette completely.
   b. Hold the fluidics cassette until it is automatically captured by the system.
   c. The cassette housing backlight will stop blinking and turn solid when the system captures the cassette.
6. Insert the spike into the BSS bottle, following the steps listed in Figure 4.38.

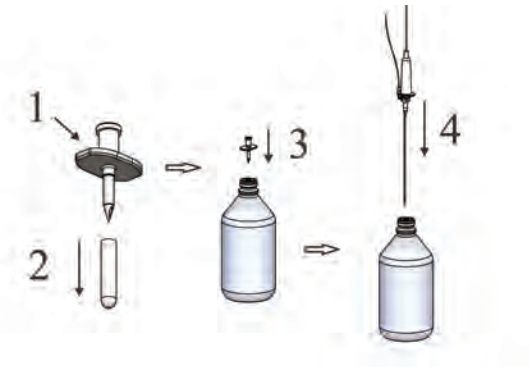


Figure 4.38. **Steps for Inserting Spike into BSS Bottle**.

1. Spiking tool. 2. Remove cover. 3. Spike bottle with spiking tool. 4. Insert spike into the bottle.

7. Squeeze and release the drip chamber until it is half filled with solution.
8. Hang the bottle at the desired BH.

9. Connect the air tubing with filter to the air output connector at the back of the system (Figure 4.39).

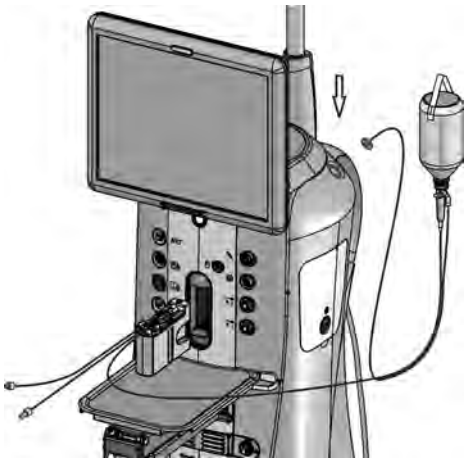


Figure 4.39. **Air Tubing Connected to the Back of the System**.

10. Ensure **Adaptive Fluidics** and **Pressurized Air** are switched on.
    a. The output connector LED ring will remain lit when it is at the commanded pressure, and blink when it is not at the commanded pressure.
11. Ensure the irrigation clamp is open, connect the irrigation and aspiration lines to the handpiece, and select **Prime and Tune**. Select **Show Me Steps** for animated setup guide.
12. After successful prime and tune, the system will transition to the surgical screen.

Note: *Adaptive Fluidics is not available for anterior vitrectomy procedures.*

Baseline Infusion Pressure (BIP) Settings

The use of Adaptive Fluidics does not require changes to the vacuum settings, needle/sleeve, tubing types, or surgical techniques. Changes are only required to BIP settings for Adaptive Fluidics use. The BIP is the starting infusion pressure when vacuum is 0 mmHg. During surgery, the infusion pressure will increase proportionally to the commanded vacuum level.

It is the user's prerogative to determine the appropriate BIP setting to optimize the surgical outcome. The following calculation method is a guide to determine the BIP when transitioning to Adaptive Fluidics:

$$BIP = Existing\ Infusion\ Setting - Bottle\ Height\ (mmHg) - (\frac{Vacuum\ Setting}{11})$$

WARNING: ***Turning Adaptive Fluidics ON or OFF requires the user to check and adjust the infusion settings in each surgical phase throughout the user file.***

Compensation Factor (CF) Settings
There are five levels of CF settings for Adaptive Fluidics. The default CF setting is level three. Higher CF settings provide higher intraocular pressure (IOP) compensation when the vacuum is activated. A higher CF setting could be used to sustain anterior chamber stability in the event of abnormal/unexpected substantial fluid leakage through the incision.

Reflux with Adaptive Fluidics Surgical Packs
When operating Adaptive Fluidics using surgical packs which have a built-in reflux bulb on the cassette, the user has access to more Reflux options. The options can be selected from the Foot Control More Screen (Figure 4.40).

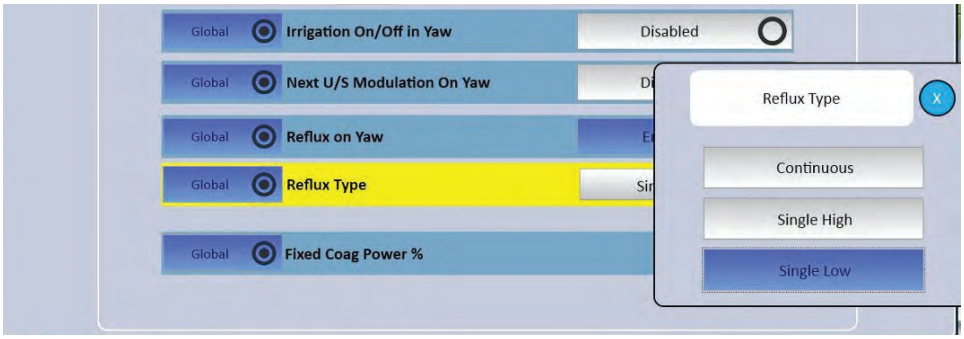


Figure 4.40. **Reflux Options Selection from More Screen**.

Reflux Types

- **Continuous:** Reflux pressure is based on irrigation pressure.
- **Single High:** Reflux is created by the momentary activation of a plunger on the reflux bulb.
- **Single Low:** Similar to Single High reflux with lower pressure.

Reflux activation can be programmed with Inward Yaw of the Foot Pedal and also on any of the Foot Control buttons.

Anterior Vitrectomy Function

The ***Stellaris Elite***™ vision enhancement system supports a pneumatic vitrectomy cutter, which uses pressurized air to drive the guillotine-type vitrectomy cutter. The Advanced Vacuum System provides aspiration to draw the vitreous material into the port, where it is then cut and aspirated through the flexible tubing into the disposable collection container.

Anterior Vitrectomy Cutter Modes

The Advanced Vacuum System provides two vitrectomy cutter modes:

Fixed Cut
Pneumatic cutter: The control may be adjusted to provide a fixed cutting speed from 30 cuts per minute (CPM) to 7500 CPM.

Dual Linear Cut
Pneumatic cutter: The control may be adjusted to provide a linear cutting speed from 30 CPM to 7500 CPM. The Foot Pedal yaw is used to achieve dual linear function.

The cut rate may be adjusted from 30 CPM to 7500 CPM, with increments as shown in the table below, or to any specific value using the keypad.

Range	Step Size
30 CPM to 100 CPM	10 CPM
100 CPM to 1000 CPM	50 CPM
1000 CPM to 7500 CPM	100 CPM

Planned Anterior Vitrectomy Setup

WARNING: ***For optimum aspiration and reflux performance, the patient's eye level must be at the same level as (no more than 7 cm [3 in.] from) the* Stellaris Elite™ *vision enhancement system aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.***

1. Turn Power on.
2. Press any button on the Primary (Integrated) Foot Control and wait until the ready light turns solid green, indicating wireless communication has been established.
3. Select **Surgeon's Name** and select **Confirm**.
4. Open the disposable phaco package and insert the fluidics cassette all the way in and hold until it is automatically captured by the system. The cassette housing backlight will stop blinking and remain on when the system captures the cassette.
5. Spike the Balanced Salt Solution container and hang it at the desired height.

   If pressurized infusion is used:

   Connect the Air Tubing Line to the vent port at the bottle spike and the other end with air filter to the **Stellaris Elite**™ *vision enhancement system air output connector. Switch on the air pump from the system setup screen; the control is at the upper right-hand of the screen. The output connector will remain lit when it is at commanded pressure, and blink on and off when it is not at the commanded pressure.*
6. Ensure the irrigation clamp is open, connect the irrigation and aspiration lines together, and select **Prime**. Select **Show Me Steps** for animated setup guide if needed.
7. Open the vitrectomy cutter pack; connect the tubing and the actuation line to the pneumatic port on the ***Stellaris Elite***™ vision enhancement system.
8. Apply a pinch clamp (not supplied) at the end of the irrigation line to shut off irrigation flow when using the vitrectomy cutter without irrigation. Do not close the clamp on the irrigation line.
9. Ensure the irrigation clamp is opened and the tip is immersed in irrigation solution, then select **Vit Test**.

10. After successful test, select **Advance to Surgery** and the **Main Surgical Screen** will appear.

Planned Anterior Vitrectomy Use

1. Select **Vit** from the **Clock Menu**. **The Show Me Steps** animated setup guide will appear.
2. Use the setting globes to set the desired vacuum level and cut rate.
3. For Fixed cut vitrectomy, yaw the Foot Pedal outward to toggle the cutter on and off, and depress the Foot Pedal for aspiration. An audio tone will signify cutter operation (if enabled). Fixed cut rate is activated in Foot Pedal Region 2.
4. For Linear cut vitrectomy, activate the cutter by outward yaw travel of the Foot Pedal in Region 2.
5. For Reflux (if enabled), rotate the Foot Pedal inward.

Unplanned Anterior Vitrectomy Setup

In the event anterior vitrectomy is needed during phaco surgery:

1. Select the **Vitrectomy** mode from the **Clock Menu**. The **Show Me Steps** animated setup guide will appear. Select **Close** to close the animated setup guide.
2. Open the appropriate vitrectomy cutter pack.

   For the pneumatic cutter, connect tubing and the actuation line to the pneumatic port on the ***Stellaris Elite***™ vision enhancement system.
3. Ensure that the irrigation clamp is open and the tip is immersed in irrigation solution. Select **Setup**, then **Pneumatic Vit Test**. Select **Show Me Steps** for animated setup guide if needed.
4. After a successful test, select **Advance to Surgery** and select the **Vit** phase from the **Clock Menu**.

Primary (Integrated) Foot Control of Anterior Vitrectomy Mode

As the Foot Pedal is initially pressed, the irrigation control valve will open to allow irrigation into the eye.

Once irrigation has been initiated and the Foot Pedal has been depressed approximately five degrees (or as programmed), a momentary increase in Foot Pedal resistance will be noted, signifying the transition from Region 1 to Region 2 and the start of aspiration. Aspiration increases proportional to Foot Pedal travel, with the maximum level being set via the **Max Vacuum** input on the touch screen. Region 2 will provide linear control of aspiration. The **Actual Vacuum** display will indicate the current aspiration level.

If enabled, an audible linear tone will indicate aspiration. The pitch of the tone increases with increased aspiration.

For Fixed Cut vitrectomy mode, vitreous cutting is activated in Region 2. The cut rate is fixed. Each successive outward yaw movement toggles the cutter ON or OFF. If enabled, an audible tone will indicate cutter on (double beep) or cutter off (single beep).

For Dual Linear Cut mode, outward yaw movement provides linear control of the cut rate as a function of Foot Pedal displacement once it is within Region 2. The actual cut rate is displayed on the screen. When the Foot

Pedal is released, it returns to center and the cutter is disabled. If enabled, an audible linear tone indicates cut rate, and the pitch of the tone increases with increased cutter speed.

Reflux (if enabled) is activated by inward yaw movement of the Foot Pedal.

By default, the vitrectomy cutter is On.

Pressurized Infusion

WARNING: ***When using Pressurized Infusion with Balanced Salt Solution bottle hung on the system automated IV pole, the actual intraocular pressure will be higher than the air pressure displayed in the machine. The actual intraocular pressure would be equal to air pressure combined with hydrostatic pressure created from the gravity force.***

WARNING: ***When using air pressured infusion, hang the bottle so that the drip chamber is close to patient eye level.***

Note: *Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.*

The Pressurized Infusion function infuses a preset air pressure to pressurize the Balanced Salt Solution bottle. The pressure generated would force Balanced Salt Solution into the eye to maintain a preset intraocular pressure (IOP). The air pressure is generated by a compressor in the system and air is infused into the bottle through air tubing. The use of Pressurized Infusion function would replace the gravity infusion that depends on bottle height. The preset air pressure may be adjusted from the system screen display.

Enable Pressurized Infusion Function

To enable Pressurized Infusion function from **Surgical More Screen**:

1. Select the More Screen button.
2. Select the Infusion Tab of the pop-up screen.
3. Select Infusion type of Pressurized Infusion.
4. The Pressurized Infusion settings and function can be saved through **Save Settings** command button.

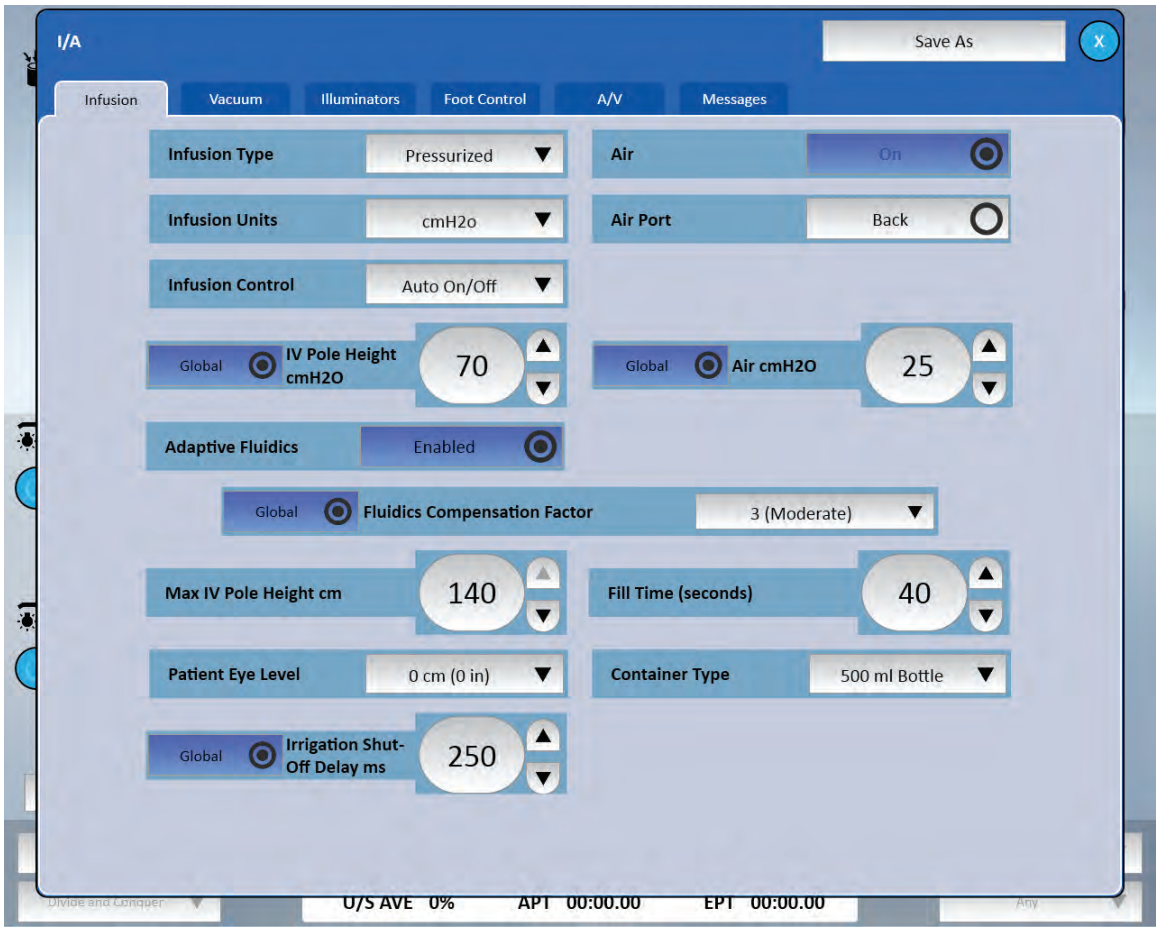


Figure 4.41. **More Screen, Infusion Tab (Anterior Domain)**.

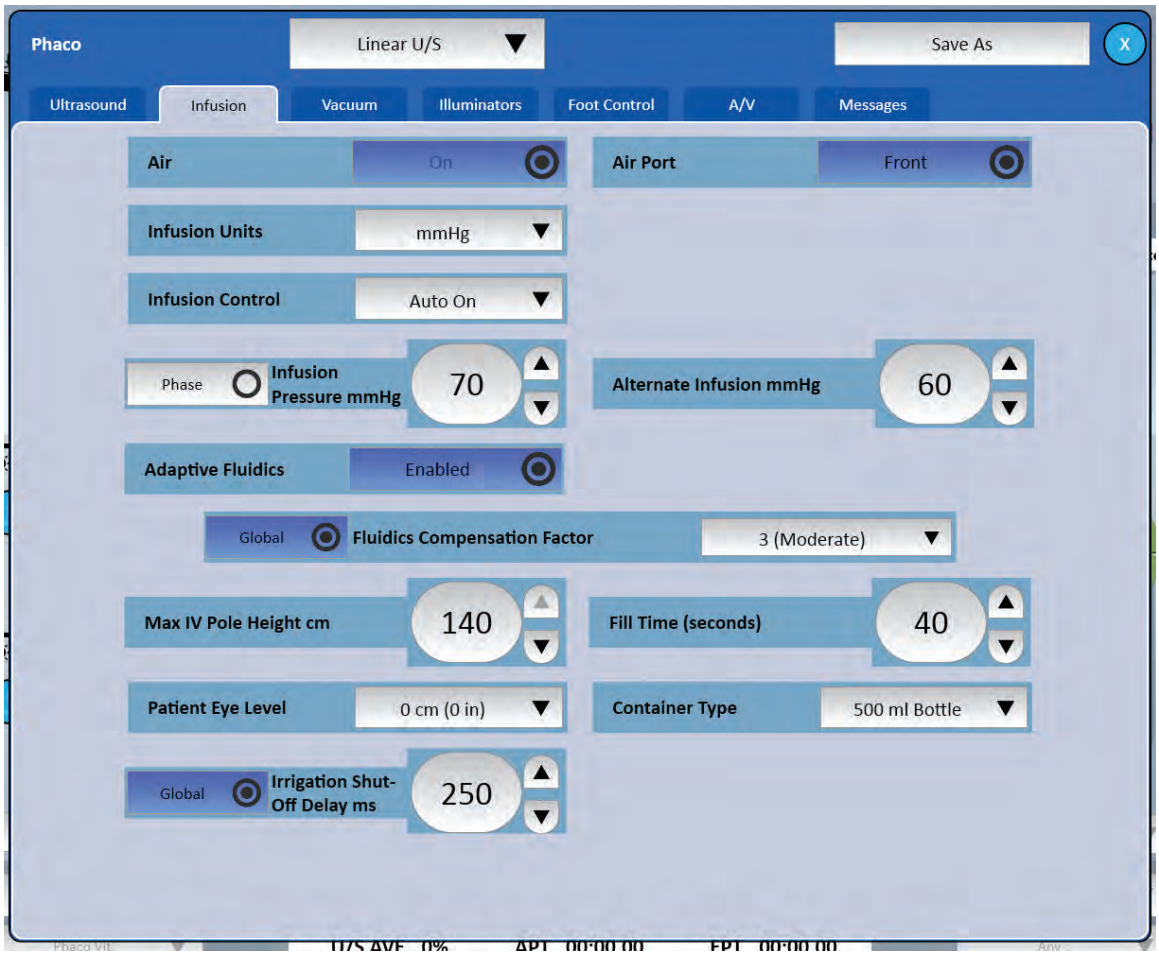


Figure 4.42. **More Screen, Infusion Tab (Combined Domain)**.

Pressurized Infusion Setup

1. Remove the filter cap (A) from the bottle spike venting port that comes with the system disposable pack in Figure 4.43.
2. Connect the Air Tubing Line male connector to the bottle spike venting port (A) in Figure 4.43.
3. Connect the Air Tubing Line filter to the vision enhancement system air source (B) in Figure 4.43.
4. Spike and hang the bottle on the hanger at the desired bottle height.
5. Use the up and down arrows to select the desired air pressure.
6. Turn On the air pump by selecting the **Off** button below the setting display. Selecting the same button again will turn off the pump.

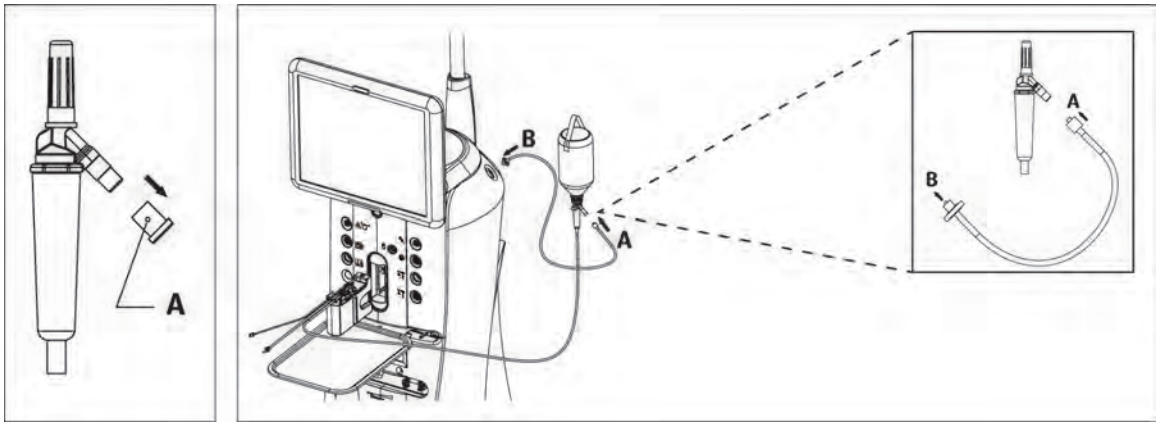


Figure 4.43. **Pressurized Infusion Setup**.

Note: *If the infusion type is set to "Pressurized Infusion", the pump will come on when a cassette is captured and the vacuum check completes.*

4.4. Coagulation Function (Posterior & Anterior Modes)

WARNING: ***Check the coagulation power level when changing between extraocular and intraocular cauterization.***

WARNING: ***Use only bipolar handpieces and cables designed and manufactured or distributed by Bausch + Lomb that are designated for use with this system. Failure to do so may affect system performance and create hazards. Use of accessories manufactured or distributed by Bausch + Lomb on systems for which they are not designated may affect system performance and create hazards.***

WARNING: ***Failure of HF surgical equipment could result in an unintended power output increase.***

WARNING: ***The patient leads should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused bipolar handpieces should be stored in a location that is isolated from the patient.***

WARNING: ***When the device and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating high-frequency current limiting devices are recommended.***

CAUTION: ***All bipolar accessories must be rated for an operating voltage of at least 120V.***

Note: *If Linear Coagulation is enabled or a Primary (Integrated) Foot Control button is programmed for coagulation, begin by plugging in the coagulation cord.*

Note: *No neutral electrode is required for use of the bipolar function.*

Note: *The output power selected should be as low as possible for the intended purpose.*

Note: *For explanation of Dual Linear Primary (Integrated) Foot Control see page 1-57.*

Bipolar coagulation is accomplished with the ***Stellaris Elite***™ vision enhancement system Coagulation Function. Bipolar forceps or pencil handpieces are used as electrodes. Coagulation power may be adjusted from 0% to 100% of the output power using the up/down arrow keys. The available coagulation modes are:

Fixed coagulation mode
Provides an adjustable output between 0% and 100%. Power levels are set via setting globe control. Fixed coagulation may be actuated by any Primary (Integrated) Foot Control button, if programmed. Fixed coagulation remains activated as long as the button remains depressed.

Linear coagulation mode
Provides an adjustable output between 0% and 100%. Power levels are set via setting globe control. Linear Coagulation is selected from the **Clock Menu** on the **Main Surgical Screen**. Linear coagulation is actuated by depressing the Foot Pedal, if it has been programmed to provide linear control as a function of angular Foot Pedal displacement.

Fixed Coagulation Setup and Use

WARNING: ***Ensure the handpiece and accessories are sterilized before use.***

WARNING: ***Cables to the surgical electrodes should be positioned such that contact with the patient or other leads are avoided.***

Note: *See Chapter 5 for cleaning and sterilization requirements when surgery is completed. Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.*

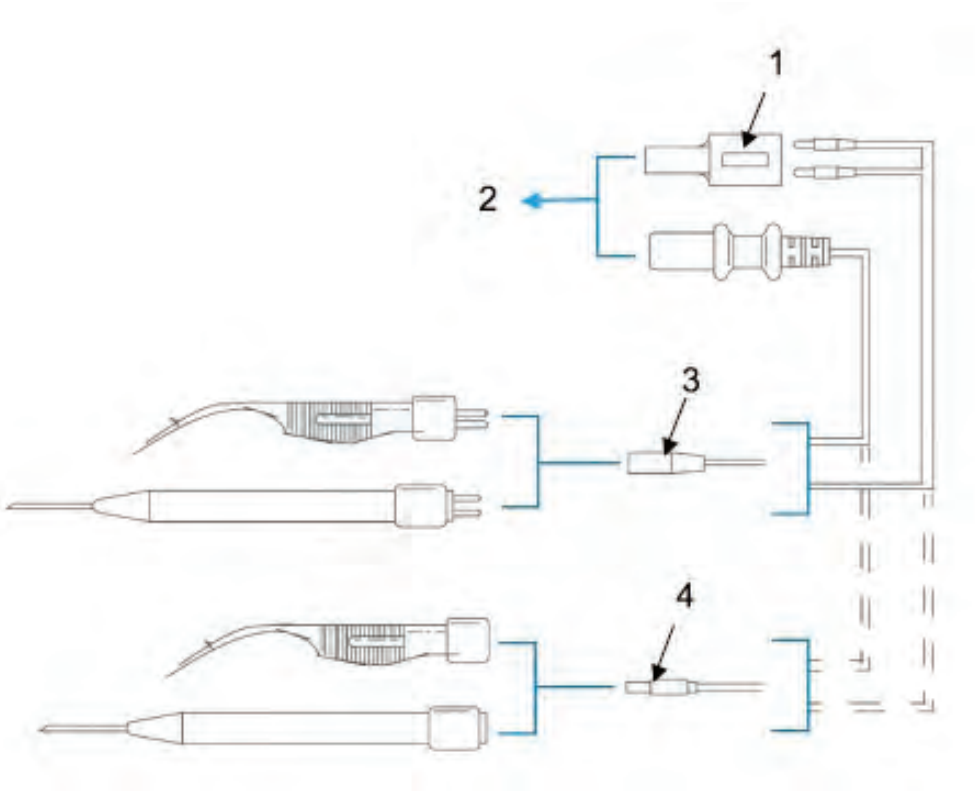


Figure 4.44. **Fixed Coagulation Handpiece setup**.

1. Adaptor CX9404. 2. To system coagulation connector.
3. 2-pin connector style. 4. Lemo connector style.

1. Connect the desired bipolar forceps or pencil to its cable. You may need to use an adapter.
2. Connect the bipolar cable to the coagulation connector.

3. Use the setting globes to adjust the percentage of coagulation power desired.
4. The fixed coagulation function is activated by pressing the programmed Primary (Integrated) Foot Control switch. When the switch is released, the function will deactivate. Fixed coagulation mode is accessible during the system setup.
5. If programmed, a tone will signify bipolar coagulation operation.

Linear Coagulation Setup and Use

WARNING: ***Ensure the handpiece and accessories are sterilized before use as specified.***

Note: *Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.*

Note: *See Chapter 5 for cleaning and sterilization requirements when surgery is completed.*

Note: *Due to compliance with 60601-2-2, position 1 will not start until approximately 35% of pedal travel is attained in the linear coagulation mode.*

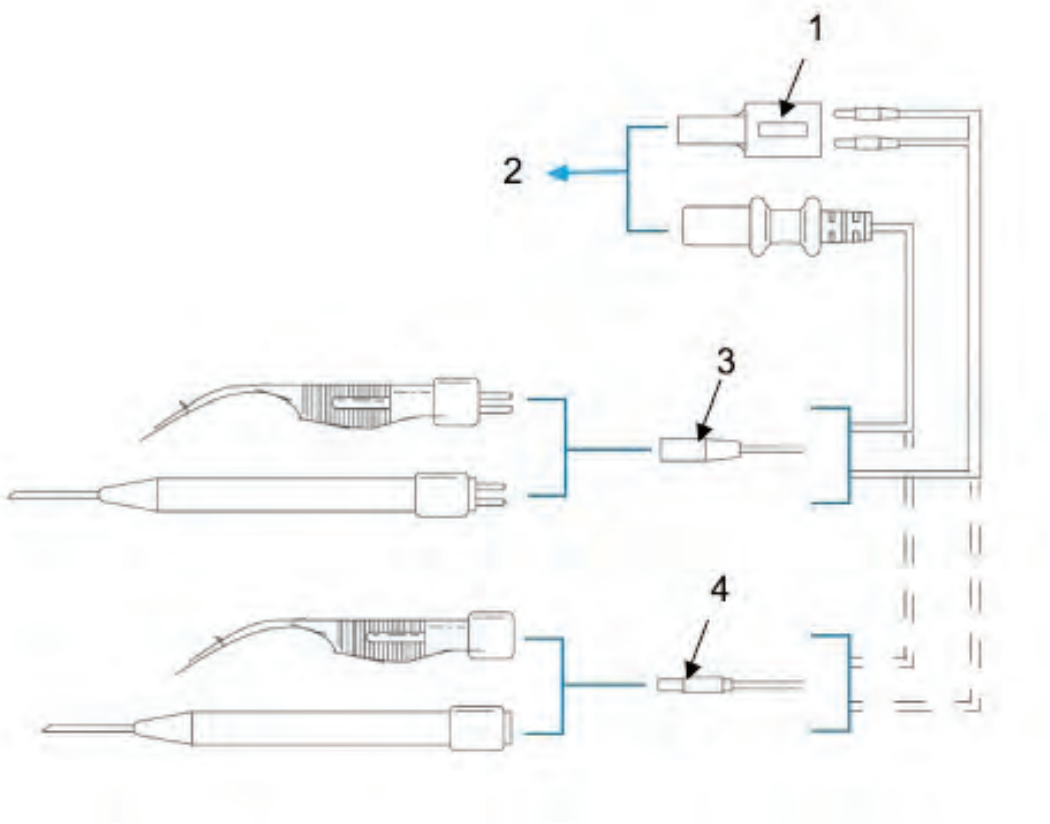


Figure 4.45. **Linear Coagulation Handpiece Setup**.

1. Adaptor CX9404. 2. To system coagulation connector.
3. 2-pin connector style. 4. Lemo connector style.

1. Connect the desired bipolar forceps or pencil to its cable. The use of an adapter may be necessary.
2. Connect the bipolar cable to the coagulation electrical connector, if required.
3. Select Coag from the **Clock Menu**.
4. Use the setting globes to adjust the **Max Coagulation** power desired.
5. The linear coagulation function is actuated by the Foot Pedal, if programmed. The **Actual Coagulation** progress bar will display the amount of coagulation power being used in relation to the maximum setting.
6. A tone will signify bipolar coagulation operation if programmed.

4.5. Combined Domain

The ***Stellaris Elite***™ PC and PC with Laser systems that are configured to support combined procedures allow users to perform both posterior and anterior segment surgeries with the dedicated software interface and packs. Select **Posterior/Anterior Segment** in the **Select Procedure** startup screen to begin. The Posterior/Anterior Domain user interface allows the user to perform all the posterior and anterior functions from a single surgical screen and cassette pack.

Note: *Make sure the pack you are using is appropriate for the domain selected.*

Combined Procedure Setup and Use

WARNING: ***For optimum aspiration and reflux performance, the patient's eye level must be at the same level as (no more than 7 cm [3 in.] from) the* Stellaris Elite™ *vision enhancement system aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.***

Note: *Specific instructions for cleaning and sterilization included with any handpiece or accessory take precedence over these instructions.*

1. Connect the compressed air source to the connector on the lower rear of the system.
2. Turn the power on and wait until the screen displays the Primary (Integrated) Foot Control or other system messages.
3. Acknowledge and close all messages.
4. To operate the Primary (Integrated) Foot Control wirelessly, press any button on the Primary (Integrated) Foot Control and wait until the ready light turns solid green. This indicates that wireless communication has been established.
5. The screen will display **Select Procedure**. (If your system is programmed to default to either the Anterior Domain or the Posterior/Combined Domain, the **Select Procedure Screen** will not appear, and the system will move directly to the **Select Surgeon Screen**, as shown in Figure 1.8.)
6. Select **Posterior/Anterior Segment**, and the screen will transition to the **Select Surgeon Screen**. (Skip this step if the system is already displaying the **Select Surgeon Screen**.)
7. Select **Surgeon's Name** and then **Confirm** to transition to the **Insert Cassette** screen.
8. Open the combined surgical pack with the following steps:
    a. Hold the bottom of the tray with one hand with the thumb placed in the thumb notch. (Circulating Nurse)
    b. Tear open the Tyvek seal with the other hand toward the body. (Circulating Nurse)

c. Transfer contents onto sterile field. (Circulating Nurse)

d. Identify loose components from the pre-connected tubing set. (Scrub Nurse)

e. Drape the system tray and screen with drapes provided. (Scrub Nurse)

f. Arrange the pre-connected tubing set with cassette, bottle spike, air tubing filter and actuation connector toward the system front. The priming cup is placed at the other end with the tubing set in the middle as shown in the figure below. (Scrub Nurse)

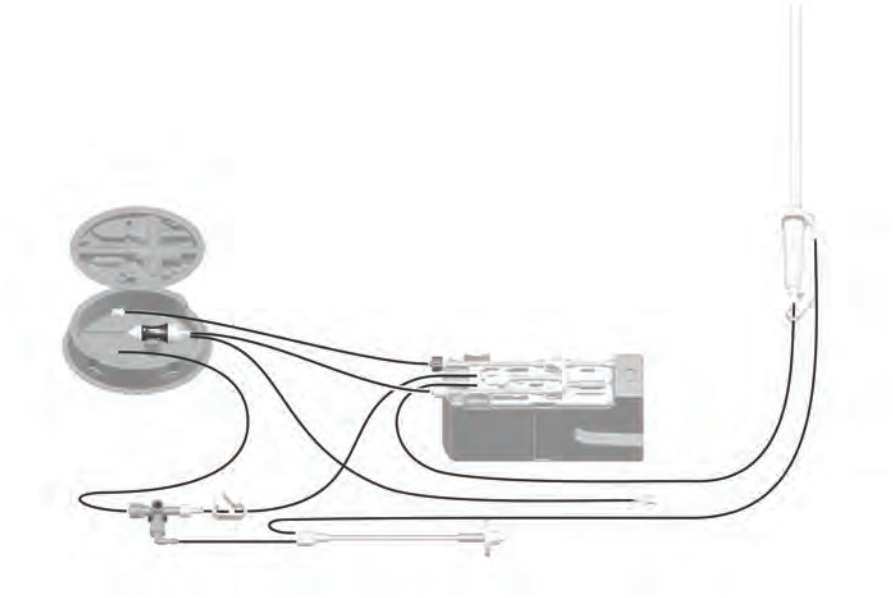


Figure 4.46. **Pre-connected tubing set**.

g. Remove the tape to unbind all the tubing. (Scrub Nurse)

h. Straighten the tube set and secure it so it will not drop off the sterile surface. (Scrub Nurse)

i. Insert the fluidics cassette all the way in and hold until it is automatically captured by the system. The cassette housing backlight will stop blinking and remain on when the system captures the cassette. (Scrub Nurse or Circulating Nurse)

j. Connect the air tubing filter to the system (second connector down, on the right side of the machine). Ensure the air pump is on. (Scrub Nurse or Circulating Nurse)

k. Connect the vitrectomy actuation line (blue stripe) to the system. (Scrub Nurse or Circulating Nurse)

l. Pass the bottle spike and irrigation tubing to Circulating Nurse. (Scrub Nurse)

m. Spike and hang the Balanced Salt Solution container on the automated IV pole or the Zero Level hanger if using AFI. Squeeze and release the drip chamber until it is half filled with solution. (For AFI setup, use the spiking tool provided to puncture the rubber stopper on the bottle before inserting the metal cannula into the bottle.) (Circulating Nurse). See Figure 4.5.

n. Remove the tape on the priming cup. (Scrub Nurse)

o. Place the priming cup flat on the tray as in the figure below. (Scrub Nurse)

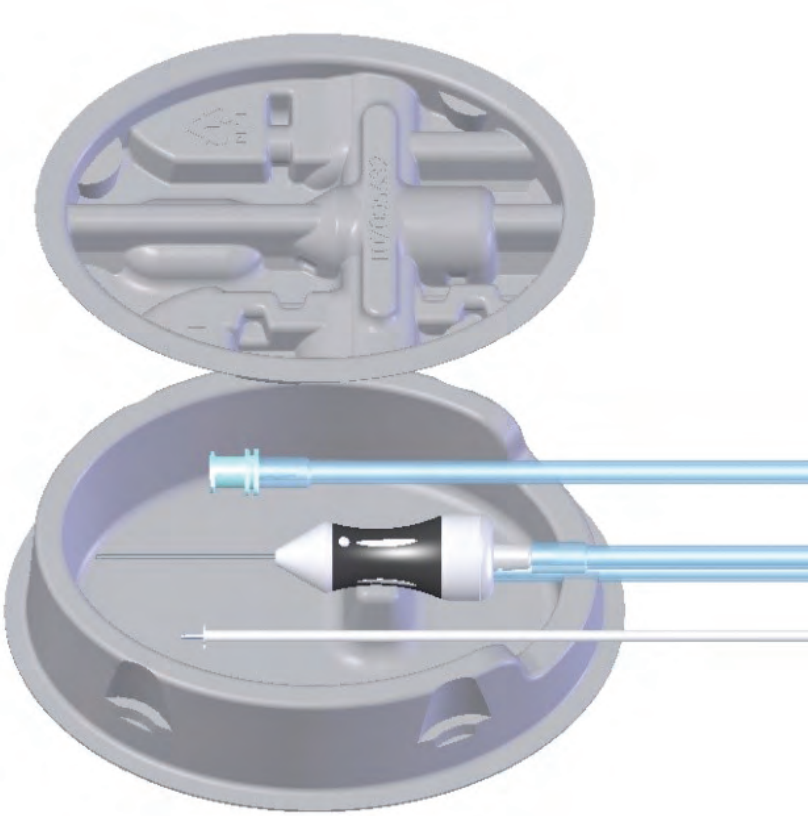


Figure 4.47. **Priming cup with infusion cannula, left aspiration and vitrectomy cutter attached**.

9. Select the first button from the **Easy Prime** selection menu to initiate the auto priming and vitrectomy cutter test sequence. (Scrub Nurse or Circulating Nurse)

Note: *The system will not provide feedback as to whether or not fluid is present during priming. Inspect tubing and confirm that it is filled with fluid and free of bubbles after each* ***Prime and Tune****. Repeat the priming process if the tubing is not adequately filled with fluid.*

The posterior section setup is now complete.

Anterior Segment Setup

1. Remove the second aspiration line from the priming cup and connect to the phaco handpiece.
2. Remove the irrigation line from the 2-way stopcock and connect it to the phaco handpiece. See Show Me Steps for animated setup guide if necessary.

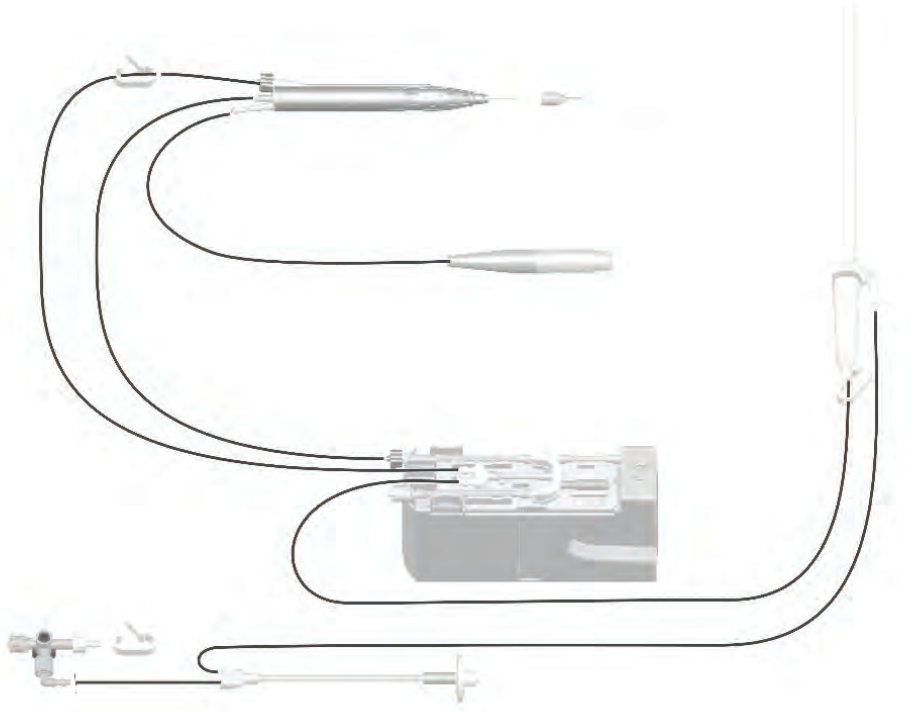


Figure 4.48. **Connecting tubing to the phaco handpiece**.

1. Phaco Handpiece. 2. Phaco Needle. 3. Irrigation sleeve. 4. Test Chamber. 5. Connect to U/S connector. 6. Connect to Vit actuation port. 7. Connect to air pressure port.

3. Plug the handpiece connector to the machine (second connector from the top, U/S port).
4. Thread and firmly secure the ultrasound needle onto the ultrasound handpiece using a needle wrench.
5. Slide the irrigation sleeve over the ultrasound needle so that the holes in the irrigation sleeve are placed approximately 1 mm from and perpendicular to the bevel of the ultrasound needle (increase to approximately 1.5 mm for denser cataracts). For MICS needles, assemble sleeve as shown in Figure 4.37. Balanced salt solution of the sleeve prior to assembly is advised to assist assembling the irrigation sleeve to the needle.

WARNING: ***When installing irrigation sleeve on phaco handpiece, avoid scratching the inner surface of the sleeve with the needle tip. Inadvertent scratching of the sleeve's inner surface may create silicone particulate that may appear during surgery.***

6. Toggle the **Irrigation Off** button to turn flow on, and allow the flow to fill the irrigation tubing up to the handpieces. See page 2-27 for details on the irrigation flow button. Activate the Fill button with turn flow on for 20 to 120 seconds. The duration is user-defined.
7. Fill the test chamber with irrigating solution, then slide over the tip of the handpiece.
8. Select Prime and Tune. A vacuum test is part of the priming cycle.

After successful priming and tuning, the **Main Surgical Screen** will appear.

Adaptive Fluidics is a fluidics function for phacoemulsification surgery during lens removal and I/A only. It is not available for anterior vitrectomy and all posterior phases. The function is to be used with **Adaptive Fluidics** surgical packs. This function is also available for combined procedure using combined surgical packs that come with a vented BSS spike (AFI packs). Please see page 4-53 for detailed information on **Adaptive Fluidics**, and page 2-30 for **Adaptive Fluidics** changes to the GUI.

5. Cleaning and Sterilization

5. Cleaning and Sterilization Requirements

This chapter provides instructions for cleaning the ***Stellaris Elite***™ vision enhancement system, and for cleaning and sterilization of the reusable accessories.

WARNING: ***Do not reprocess single-use instruments.***

WARNING: ***Do not use this procedure for any items other than those described within this manual.***

CAUTION: ***Preventative scheduled maintenance is recommended once a year to ensure that the* Stellaris Elite™ *vision enhancement system meets its optimum performance, reliability and safety standards set by the manufacturer. The maintenance shall be done by a Bausch + Lomb certified individual only.***

5.1. Routine Cleaning

WARNING: ***Do not reprocess single-use instruments.***

WARNING: ***Disconnect AC power before cleaning the system.***

CAUTION: ***To preserve the surface finish, avoid the use of abrasive cleaners. If possible, clean spots before they dry.***

Bausch + Lomb tested the following products, and found that they can be used on all external surfaces of the ***Stellaris Elite***™ vision enhancement system. Use of any substance not listed is at the user's own risk.

- Isopropyl alcohol (70%)
- Mild soap and water

You should wipe the external surfaces of the ***Stellaris Elite***™ vision enhancement system, Primary (Integrated) Foot Control and remote control with a soft cloth moistened with cleaning solution on a weekly basis while the ***Stellaris Elite***™ vision enhancement system is disconnected from any power supply. Avoid applying any

cleaner directly to the display (apply to cloth sparingly). Remove all traces of the cleaning solution with a cloth dampened with clean water, and dry the surfaces with a lint-free cloth.

You should clean the fluid level detection lens (Figure 5.1) every three months with a 4 x 4 in. gauze pad and isopropyl alcohol.

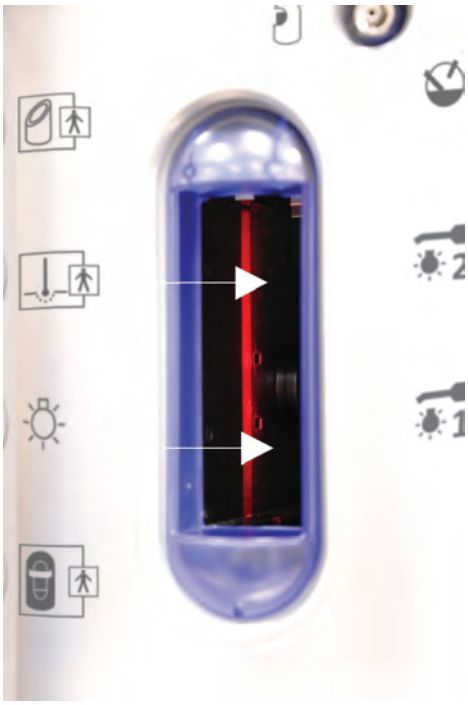


Figure 5.1. **Fluid Level Detection Lens**.

Gently swab the electrical connectors with an alcohol swab weekly, taking care to avoid excessive quantities of cleaning solution around the ports. Do not reconnect to power until the ports have completely dried.

5.2. Reusable Accessories

All ***Stellaris Elite***™ vision enhancement system requirements for cleaning and sterilization of reusable accessories are located within the accessory Reprocessing Instructions. Accessories may include bipolar coagulation accessories, irrigation and irrigation/aspiration handpieces, ultrasound handpieces and accessories.

5.3. Laser Protective Eyewear

Use isopropyl alcohol, or soap and water to clean the lenses of the goggles. Rinse with warm water and air-dry. DO NOT USE ANY OTHER CLEANING SOLVENTS. Laser protective eyewear should be stored at room temperature.

6. Troubleshooting

6. Troubleshooting

This chapter contains procedures for identifying and resolving problems that may occur with your ***Stellaris Elite***™ vision enhancement system.

CAUTION: ***Preventative scheduled maintenance is recommended once a year to ensure that the* Stellaris Elite™ *vision enhancement system meets optimum performance, reliability and safety standards set by the manufacturer. The maintenance shall be done by a Bausch + Lomb certified individual only.***

Note: *Other than main fuses, power cords, and lamps (PC systems only), this system contains no parts that are serviceable by the user. All maintenance shall be done by a Bausch + Lomb certified individual only.*

6.1. User Troubleshooting

- If possible, try a known good handpiece or connector to isolate the issue.
- If the aspiration line becomes clogged, and it cannot be cleared using reflux, remove the handpiece from the eye and clear the aspiration port of lodged material.
- If ultrasound calibration fails, check connections and needle, then attempt calibration a second time. If calibration fails twice, change to a known good handpiece and attempt to calibrate again. If a known good handpiece fails calibration, or if assistance is needed to determine if the original handpiece is defective, contact the Global Product Support (see Chapter 7).

6.2. Power Issues

WARNING: ***For continued protection of operators and patients from electrical and other hazards, replace fuses only with the same type and rating as defined in the service instructions.***

WARNING: ***For continued protection of operators and patients from electrical hazards, only replace the mains power cord with a Bausch + Lomb-specified replacement.***

If you flip the main power switch and no power is sent to the system (i.e., the Standby power switch does not light up, there is no faint fan noise from the lower rear of the system, etc.) there may be a bad fuse. First check

that the rest of the operating suite has power, the cord is still plugged in, and the wall outlet is still supplying proper power.

If the power supply chain appears to be intact, you may have a blown fuse. A blown fuse is usually noticeable after removal from the system by obvious discoloration within the fuse and/or an obviously broken fuse-wire within the fuse.

Fuse Replacement

The ***Stellaris Elite***™ vision enhancement system has 2 user-replaceable fuses. If an over-current condition should occur which opens these fuses, they must be replaced with fuses of the same type and rating as the original fuses (see specifications table in Chapter 8).

A blown fuse may be indicated when you are using a known good outlet, and no power is sent to the system when you flip the main power switch to on (i.e., the Standby power switch is not lit up, no faint fan noise from the lower rear of the system, etc.).

A blown fuse is usually noticeable after removal from the system by obvious discoloration within the fuse and/or an obviously broken fuse-wire within the fuse.

Note: *If damage is apparent to either fuse, both should be replaced to ensure proper operation.*

a. Remove the power cord from the ***Stellaris Elite***™ vision enhancement system. The presence of the power cord will physically prevent the removal of the fuse drawer.

b. Using a flat-blade screwdriver, turn the fuse holder counter-clockwise, and pull outward. One style of fuse holder will come partially out and the fuse will drop out. On the other style, the fuse is retained by clips on the back.

c. Replace the fuses, reinstall the fuse holder and lock it by turning clockwise.

d. Snap the fuse drawer back into place.

e. Replace the cord and the system should be ready to run again.

Fuse Holder Location

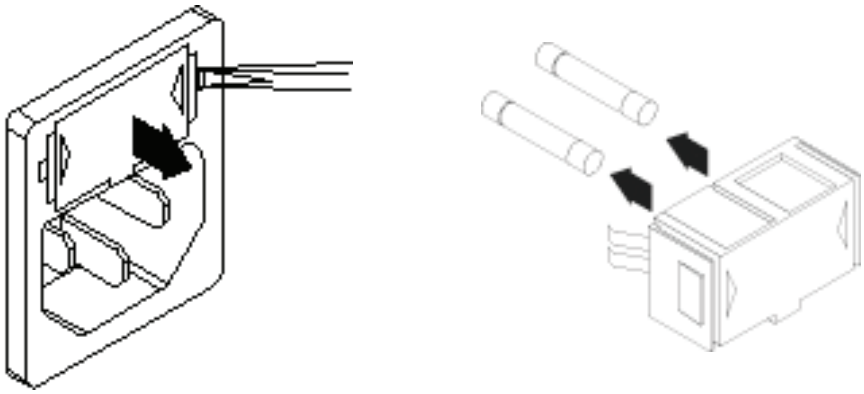


Figure 6.1. **Fuse Holder Location**.

6.3. Laser Calibration Verification (*Stellaris Elite*™ BL15455 only)

The ***Stellaris Elite***™ vision enhancement system Laser function should have its output verified annually. An external power meter is used to measure the actual power delivered through the delivery devices. The ***Stellaris Elite***™ vision enhancement system also displays the power delivered from the selected delivery device. Bausch + Lomb recommends using an annually calibrated laser power meter system (e.g. Thorlabs S142C laser power sensor and compatible meter head) with a previously unused EndoProbe.

To measure the power:

A. Wear appropriate eye protection.

B. Connect a known good EndoProbe to the laser port.

C. Prepare the ***Stellaris Elite***™ vision enhancement system and enter the laser Endo mode.

D. Select laser power to the value on the chart below.

E. Select 50 ms exposure Duration and 50 ms Repeat Interval (50% duty cycle).

F. Select Treat mode and turn the aiming beam on.

G. Direct the end of the EndoProbe into the power meter so that the aiming beam diameter is 2 mm to 4 mm in diameter and centered in the meter.

H. Depress the footswitch, measure the delivered power, and record this value. Make sure to select the correct wavelength (532 nm) and range as needed on the power meter.

I. Repeat steps D through H for each value on the chart.

J. If a reading falls outside the minimum/maximum value shown (+/-20%), recheck the test setup, the power meter, the placement of the device into the meter, and the delivery device. If possible, test with another delivery EndoProbe. If the system is still out of calibration, it must be returned for service (see 7.1. Service Information on page 7-1).

Display	Meter Reading	Date	Minimum @ 50% duty cycle	Maximum @ 50% duty cycle
50			20	30
350			140	210
2000			800	1200

6.4. Laser Interlocks (*Stellaris Elite*™ BL15455 only)

Room Interlock & Safety Light Instructions

The ***Stellaris Elite***™ vision enhancement system includes a 3M, 37104-B122-00E MB, 4-pin yellow insulation displacement plug for user termination of a room interlock and/or a room laser safety light. This connector accepts 22 and 24 AWG wire with outer diameters from 1.0 mm to 2.0 mm. Bausch + Lomb recommends Alpha 79052 if additional wire is needed.

The door interlock circuit is in pins 1 and 2 of the connector. A normally open mechanical switch should be used in the door frame, with a closed circuit when the door is closed and an open circuit when the door is open. Connect one side of the switch to pin 1 and the other side of the switch to pin 2.

CAUTION: Do not interface this circuit to any external power.

If you are not installing a door interlock but will use a Laser Safety Light, use a short piece of 22 AWG wire to connect pins 1 and 2.

The Room Laser Safety Light circuit is in pins 3 and 4 of the connector. It is a normally open relay contact that is closed when the laser is enabled. The circuit will support any lamp that uses less than 2A at 24 VDC. If the lamp is less than 50W DC, connect pin 3 of the connector to the lamp source voltage, and pin 4 of the connector to the high side of their lamp. An additional wire will be needed from the low side of the lamp to the ground side (or return) of the power supply.

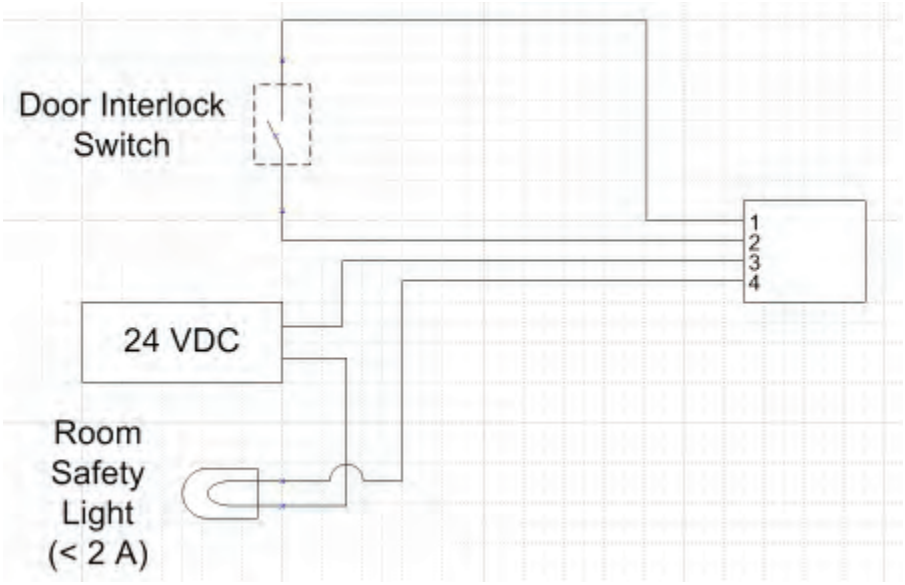


Figure 6.2. **Wiring Diagram for Room Interlock**.

If your lamp uses more power (is greater than 50W DC or AC power), a dry contact relay and DC Power supply must be installed with the lamp. In this case, the higher voltage or circuit that powers the lamp must go through the switching contact of the relay, and the lower voltage power supply must be used as the source voltage for pin 3, as shown below.

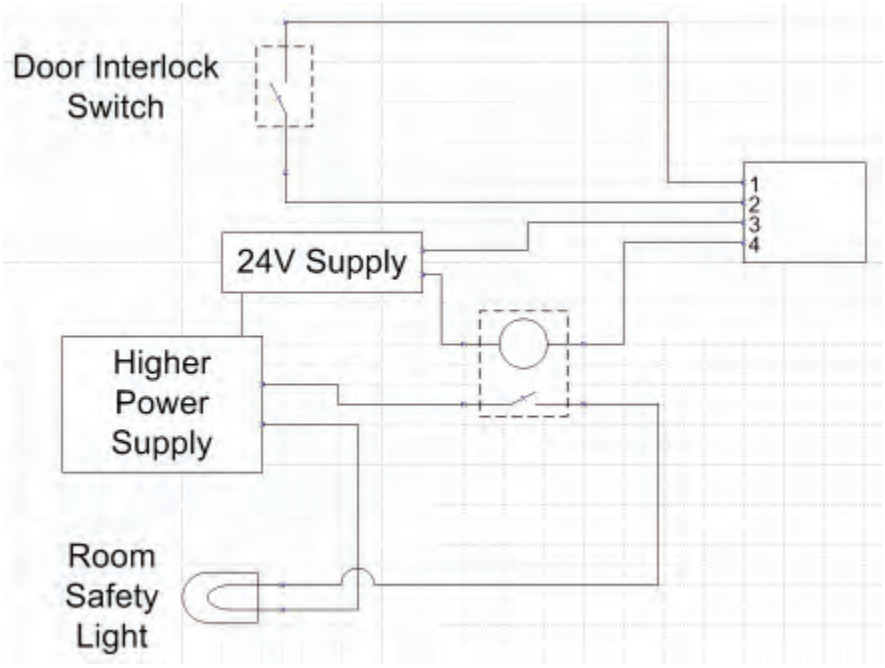


Figure 6.3. **Wiring Diagram for Room Interlock with Dry Connection**.

After inserting all the wires into the connector, use pliers to press the yellow block into the black body mating the insulation displacement blades. Insert the plug into the 4-pin port on the Power Input Module of the ***Stellaris Elite***™ vision enhancement system.

Microscope Filter Interlocks

The ***Stellaris Elite***™ vision enhancement system includes a 3M, 37103-A124-00E MB, and a 3-pin green insulation displacement plug for user termination of a Removable Microscope Filter (RMF). This connector accepts 22 and 24 AWG wire with outer diameters from 1.0 mm to 2.0 mm. Bausch + Lomb recommends Belden 9533 if additional wire is needed. To terminate this plug, you will need the wiring definition of your RMF.

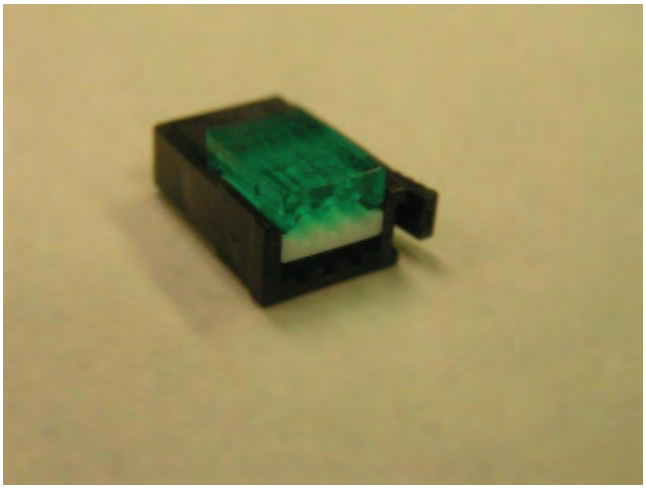


Figure 6.4. **Interlock Connector**.

Note: *Users with a microscope equipped with a 2-position laser safety filter for use with a Millennium Microsurgical System should call Bausch + Lomb for a BL3242 adapter.*

1. If your RMF is only 2 wires with a mechanical switch between them, trim the two wires to a matched length and insert into the back of the connector body into pins 2 and 3.

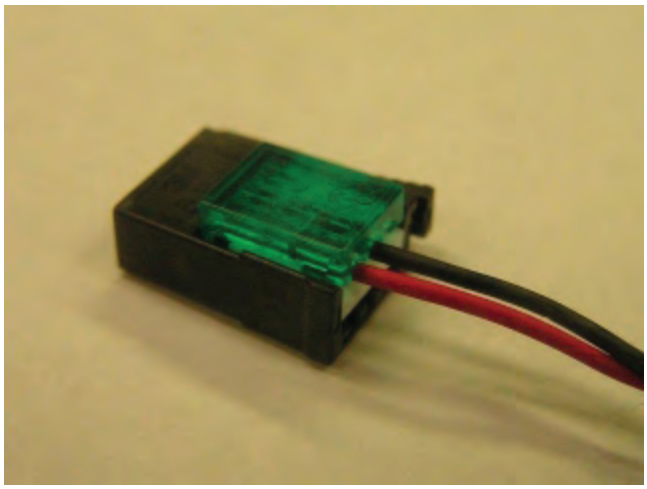


Figure 6.5. **Interlock Switch with Two Wires**.

2. If your RMF is 3 wires (identified as power, switch, and ground), trim the wires to a matched length and insert into the back of the connector body with power in pin 1, switch in pin 2, and ground in pin 3.
3. If your RMF is 4 wires (identified as power, switch 1 and switch 2 or switch ground, and ground), use a multimeter to verify 4 ohms or less between the 2 grounds. Once verified, follow step 2 above, leaving one of the two ground wires unconnected. If the voltage cannot be verified, cut off 2 inches from the 2 grounds, strip a ¼" off three of the wires and create a Y by soldering them together, then continue with step 2 above.
4. For any other RMF configuration call Bausch + Lomb for assistance (see page 7-1).
5. After inserting the wires into the connector, use a standard set of pliers to press the green block into the black body, mating the insulation displacement blades.

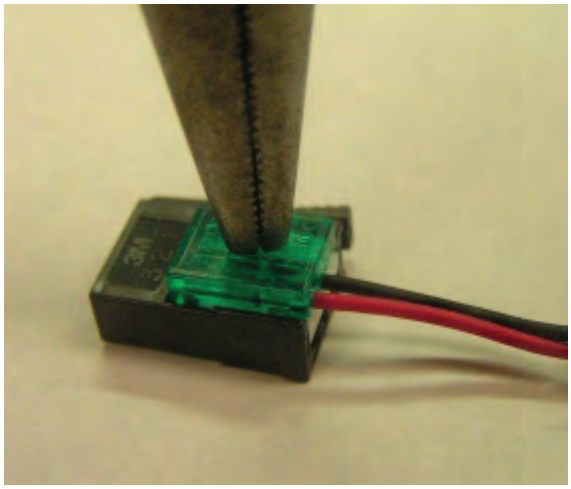


Figure 6.6. **Interlock Closure**.

6. Finally, insert the plug into the 3-pin port on the Power Input Module of the ***Stellaris Elite***™ vision enhancement system.

6.5. System Messages

All system messages displayed by the user interface are uniform in their appearance. However, the message box will have a red border if a safety-related condition is present. When an event occurs, the system will sound a tone and display a pop-up window with the appropriate message displayed. The pop-up window may provide a choice of options for proceeding, but no other action may be taken while a message box is active.

Messages and suggested corrective actions are shown in the following tables.

Message Prefix	Trouble Area
BPS	Power supply module, refer to page 6-9.
CPX	Compressor module, refer to page 6-10.
EIV	IV Pole module, refer to page 6-12.
LAS	Laser module, refer to page 6-35.
LM	Light module, refer to page 6-31.
RCR	Remote control receiver module, refer to page 6-13.
UIC/PRT	User interface computer module, refer to page 6-14.
USM	Ultrasound module, refer to page 6-17.
VFM	Vacuum fluidics module, refer to page 6-21.
WFC	Wireless Primary (Integrated) Foot Control module, refer to page 6-27.
WFR	Wireless Primary (Integrated) Foot Control Receiver module, refer to page 6-31.

Power Supply Module Messages

ID	Type	Message	Suggested Action
BPS02	Caution	The power supply was not detected in the system. Surgical mode is not available.	Call your product service representative.
BPS03	Caution	The power supply software version is not compatible with this software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.
BPS04	Caution	The power supply has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
BPS05	Caution	The power supply has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
BPS07	Informational	The power module temperature is higher than expected.	Confirm that the bottom and lower rear areas of the system are not blocked from free air flow. Call your product service representative if this problem persists.
BPS08	Caution	The power module is at an over temperature condition. System shutdown is imminent.	Confirm that the bottom and lower rear areas of the system are not blocked from free air flow. Call your product service representative if this problem persists.
BPS09	Caution	The power module output is low. System functions may not be available.	Call your product service representative if this problem persists.
BPS12	Informational	A back-up battery was detected in the power supply. This feature is no longer supported. Surgical mode is not available.	Call your product service representative if this problem persists.

Compressor Module Messages

ID	Type	Message	Suggested Action
CPX01	Caution	The compressor module was not detected in the system. Surgical mode is not available.	Call your product service representative.
CPX02	Caution	The compressor module software version is not compatible with the system software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.
CPX03	Caution	The compressor module has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
CPX04	Caution	The compressor module has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
CPX05	Caution	The air pressure output is lower than commanded.	Check that the air line tubing is connected tightly to the system. Check that there are no leaks in the air line and that the air line tubing is connected tightly to the pack components. Call your product service representative if this problem persists.
CPX06	Caution	The air pressure output is higher than commanded.	*P/C Domains*: Disconnect the air tubing from the system and switch to gravity infusion setup. *Anterior Domain*: Change the bottle and switch to gravity infusion setup. Call your product service representative if this problem persists.
CPX07	Caution	The internal air pressure system cannot reach the full pressure expected.	*PC Systems BL14455 and BL15455 Only*: Increase input pressure to nominal pressure of 85 psi (5.9 bars). Call your product service representative if this problem persists.
CPX08	Caution	The internal vacuum pump has failed.	Call your product service representative if this problem persists.

ID	Type	Message	Suggested Action
CPX09	Caution	The internal vitrectomy air pressure is low.	*PC Systems BL14455 and BL15455 Only*: Increase input pressure to nominal pressure of 85 psi (5.9 bars). Call your product service representative if this problem persists.
CPX10	Caution	Viscous fluid injection pressure is low.	*PC Systems BL14455 and BL15455 Only*: Check that the VFI tubing is connected tightly to the system and to the other pack systems. Call your product service representative if this problem persists.
CPX11	Caution	Viscous fluid injection pressure is high.	Call your product service representative if this problem persists.
CPX12	Caution	Viscous fluid extraction vacuum is low.	*PC Systems BL14455 and BL15455 Only*: Check that the VFI tubing is connected tightly to the system and to the other pack systems. Call your product service representative if this problem persists.
CPX13	Caution	Viscous fluid extraction vacuum is high.	Call your product service representative if this problem persists.
CPX14	Informational	External supply pressure is low.	*PC Systems BL14455 and BL15455 Only*: Increase input pressure to nominal pressure of 85 psi (5.9 bars).
CPX15	Caution	The internal air pressure supply to the vacuum fluidics module is low. The vacuum fluidics module may not function properly.	*PC Systems BL14455 and BL15455 Only*: Increase input pressure to nominal pressure of 85 psi (5.9 bars). Call your product service representative if this problem persists.
CPX19	Caution	The vitrectomy cutter input pressure is high. The vitrectomy cutter function is not available.	Call your product service representative if this problem persists.
CPX20	Caution	The internal air pressure supply to the vacuum fluidics module is high. The vacuum fluidics module may not function properly.	Call your product service representative if this problem persists.
CPX22	Caution	The internal air pressure system pressure is higher than expected.	Call your product service representative if this problem persists.
CPX23	Informational	External supply pressure is high.	*PC Systems BL14455 and BL15455 Only*: Decrease input pressure to 85 psi (5.9 bars).

ID	Type	Message	Suggested Action
CPX24	Informational	The compressor module has failed the pressure sensors power up test.	Ensure that the front and back air ports are not connected to tubing and shut down the system by selecting the 'End' icon, confirming any prompts, and then selecting the 'Shutdown System' button on the End screen. Following system shut down, restart the system. Close this message and then complete this action or use the 'Shut Down System' button on this message. Call your product service representative if this problem persists.

IV Pole Module Messages

ID	Type	Message	Suggested Action
EIV01	Caution	The IV Pole controller was not detected in the system. Surgical mode is not available.	Call your product service representative.
EIV02	Caution	The IV Pole controller software version is not compatible with the system software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.
EIV03	Caution	The IV Pole controller has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
EIV04	Caution	The IV Pole controller has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
EIV05	Caution	The IV Pole position cannot be determined.	Command the IV Pole to the minimum bottle height position using the down arrow or the numeric keypad for the IV Pole bottle height setting on the surgical screen. Close this message and then complete this action or use the 'Lower IV Pole' button on this message. Call your product service representative if this problem persists.

ID	Type	Message	Suggested Action
EIV07	Caution	The IV Pole is not detecting the home position switch or the IV Pole motor may have failed.	Call your product service representative if this problem persists.
EIV08	Caution	The IV Pole panel button sensors have failed or the buttons have been activated continuously since being powered on.	Ensure that the IV Pole back panel buttons are not activated. Confirm proper operation of the IV Pole back panel buttons. Call your product service representative if this problem persists.

Remote Control Receiver Module Messages

ID	Type	Message	Suggested Action
RCR01	Caution	The remote control receiver was not detected in the system. Surgical mode is not available.	Call your product service representative.
RCR02	Caution	The remote control receiver software version is not compatible with the system software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.
RCR03	Caution	The remote control receiver has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
RCR04	Caution	The remote control receiver has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
RCR05	Informational	Possible interference with remote control receivers. Remote control function may not be available.	Turn off or dim room lights. Certain types of room lighting may cause this type of interference. Call your product service representative if this problem persists.
RCR06	Informational	The remote control battery level is low. Remote control function may not be available shortly.	Replace the remote control battery at your earliest convenience. Call your product service representative if this problem persists.

User Interface Computer (UIC) Module Messages

ID	Type	Message	Suggested Action
UIC01	Informational	The IV Pole height has been limited to the maximum ceiling height. The IV Pole height range is {X}-{Y} {cm | mmHg}.	Go to Infusion More screen or programming function to reset max IV Pole Height. Close this message to complete this action or use the 'Set Max IV Pole Height' button on this message.
UIC03	Informational	Phase/Mode change not allowed while surgical functions are in use.	Change Phase/Mode while surgical functions are not in use.
UIC04	Caution	Initialization of surgical system failed. Surgical mode not available.	Power down the system by selecting the 'End' icon, confirming any prompts, and then selecting the 'Shutdown System' button on the End screen. Following system shut down, restart the system. Close this message and then complete this action or use the 'Shut Down System' button on this message. Call your product service representative if this problem persists.
UIC06	Informational	Cassette type does not match procedure type. Do you want to change to the matching procedure type?	Press Yes for a {anterior, posterior, combined} procedure, or Press No to eject the cassette.
UIC07	Informational	Cassette type does not match procedure type.	Please insert a posterior cassette.
UIC08	Informational	Incorrect ultrasound handpiece connected.	Please plug in a {Phaco, Frag} handpiece, or try a different ultrasound handpiece.
UIC09	Informational	Priming/Tuning/Vitrectomy cutter testing is in progress.	Please wait for Priming/Tuning/ Vitrectomy cutter testing to complete.
UIC13	Informational	Surgeon File Is Not Usable due to loss of database integrity. Try a system default setting file.	None
UIC14	Informational	Posterior and Combined Techniques Only: The IV Pole and AFI are both engaged. Please confirm that the AFI bottle is at patient eye level.	None
UIC15	Informational	A laser endoprobe is not connected.	Connect an EndoProbe.
UIC16	Informational	A laser Laser Indirect Ophthalmoscope (LIO) is not connected.	Connect an LIO.
UIC17	Informational	A laser module is not installed; laser functions will not be available.	Call your product service representative.

ID	Type	Message	Suggested Action
UIC18	Informational	The laser foot control is programmed for primary (integrated) but the primary (integrated) foot control is not found.	Change the laser Foot Control to secondary (LIO) via the info screen. Connect the Primary (Integrated) Foot Control.
UIC19	Informational	The laser foot control is programmed for secondary (LIO) but the secondary (LIO) foot control is not connected.	Connect the secondary (LIO) Foot Control. Change the laser Foot Control to primary (integrated) via the info screen.
UIC20	Caution	A loss of audio feedback processing has been detected. System may not be providing audio feedback.	Power down the system by selecting the 'End' icon, confirming any prompts, and then selecting the 'Shutdown System' button on the End screen. Following system shut down, restart the system. Close this message and then complete this action or use the 'Shut Down System' button on this message. Call your product service representative if this problem persists.
UIC21	Caution	The system requires restarting due to an internal error, Please perform the following 1. Select "Shutdown" to initiate system shutdown. 2. If system does not shut down in 30 seconds, power off the system by pressing and holding the power button at the front panel 3. Restart system after 1 minute. Call your product service representative if this problem persists.	None
UIC22	Informational	Anterior module installed is not compatible with Vitesse; Vitesse functions will not be available.	Call your product service representative.

ID	Type	Message	Suggested Action
UIC23	Informational	This technique was programmed with the Adaptive Fluidics feature enabled, but this feature is not available with the current system hardware and/or software options configuration. Check and adjust the infusion settings in each surgical phase during this procedure.	Call your product service representative. A compatible software version must be installed.
UIC24	Informational	This technique was programmed with the Adaptive Fluidics feature enabled. When this feature is used with the anterior cassette, confirm that the vented long bottle spike is inserted. Select Yes to confirm the vented bottle spike is in use, or select No to turn Adaptive Fluidics off.	Turn Adaptive Fluidics off. Check and adjust the infusion settings in each surgical phase during this procedure.
UIC27	Caution	Exercise care when using the Single reflux types near the retina with the Vitesse handpiece. Position the Vitesse handpiece at a distance to the retina that is equal to or greater than the size of the optic disc when using the Single reflux types, especially the Single High reflux type.	Set Reflux Type to Single Low. Close the message and then complete this action or use the Single Select Low Reflux Button on the message. Select Continue to continue with Single High Reflux selected.
User Interface Prompt Messages			
PRT1	Prompt	Press Yes to confirm turning off pressurized infusion.	N/A
PRT2	Prompt	Please allow setup functions to complete and turn off all surgical functions before entering the Programming mode.	N/A
PRT3	Prompt	This mode change will turn off/on surgical functions and load new settings! (i.e. Alternate Infusion, Fluid Air Exchange, Air, Illuminators) Are you sure you want to change modes?	N/A
PRT4	Prompt	1) Close the Irrigation Clamp. 2) Press yes to end case.	N/A
PRT5	Prompt	This mode change will turn off Alternate Infusion. Are you sure you want to change modes?	N/A
PRT10	Prompt	Are you sure you want to Shut Down the System?	N/A

ID	Type	Message	Suggested Action
PRT11	Prompt	Clamp the irrigation line, then Press Yes to eject the cassette.	N/A
PRT12	Prompt	Press Yes to confirm turning on or off Adaptive Fluidics. Check and adjust infusion settings in each surgical phase throughout this procedure.	N/A

Ultrasound Module Messages

ID	Type	Message	Suggested Action
USM01	Caution	The ultrasound module was not detected in the system. Surgical mode is not available.	Call your product service representative.
USM02	Caution	The ultrasound module software version is not compatible with the system software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.
USM03	Caution	The ultrasound module has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
USM04	Caution	The ultrasound module has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
USM05	Informational	The ultrasound handpiece is not connected or detected.	Please plug in the {Phaco, Frag} handpiece. The ultrasound connector indicator light is flashing. If the handpiece is not detected, unplug the handpiece and try another {Phaco, Frag} handpiece. Call your product service representative if this problem persists.
USM06	Informational	The ultrasound handpiece has not been tuned.	Select ‘Setup’, then select ‘Prime/ Tune’ or ‘Tune Only’ button. Close this message and then complete this action or select the ‘Prime/Tune’ button on this message.

ID	Type	Message	Suggested Action
USM08	Informational	The ultrasound handpiece has failed the tuning process.	Ensure ultrasound needle is properly tightened, the handpiece is sufficiently cooled, and the connector is dry. Select the 'Prime/Tune' or 'Tune Only' button again to repeat the handpiece tuning process. Close this message and then complete this action or use the 'Prime and Tune' button on this message. Unplug the handpiece and try another ultrasound handpiece. Select the 'Prime/Tune' or 'Tune Only' button again to repeat the handpiece tuning process. Close this message and then complete this action or use the 'Prime and Tune' button on this message. Call your product service representative if this problem persists.
USM09	Informational	The ultrasound handpiece may have failed or may be failing.	Unplug the handpiece and try another ultrasound handpiece. Select the 'Prime/Tune' or 'Tune Only' button again to repeat the handpiece tuning process. Close this message and then complete this action or use the 'Prime and Tune' button on this message. Call your product service representative if this problem persists.
USM10	Caution	Coagulation circuit may have failed, potential coagulation output over-voltage condition.	Unplug the bipolar handpiece and cord and try another bipolar handpiece and cord. Call your product service representative if this problem persists.
USM11	Caution	Coagulation circuit may have failed, potential uncommanded or incorrect coagulation output.	Unplug the bipolar handpiece and cord and try another bipolar handpiece and cord. Call your product service representative if this problem persists.

ID	Type	Message	Suggested Action
USM15	Informational	Unable to read ultrasound handpiece data. Attempt to tune the handpiece to confirm proper operation.	Ensure ultrasound needle is properly tightened, the handpiece is sufficiently cooled, and the connector is dry. Select the 'Prime/Tune' or 'Tune Only' button again to repeat the handpiece tuning process. Close this message and then complete this action or use the 'Prime and Tune' button on this message. Unplug the handpiece and try another ultrasound handpiece. Select the 'Prime/Tune' or 'Tune Only' button again to repeat the handpiece tuning process. Close this message and then complete this action or use the 'Prime and Tune' button on this message. Call your product service representative if this problem persists.
USM16	Informational	The ultrasound module fan has failed. The ultrasound handpiece cannot be tuned or operated.	Power down the system by selecting the 'End' icon, confirming any prompts, and then selecting the 'Shutdown System' button on the End screen. Following system shut down, restart the system. Close this message and then complete this action or use the 'Shut Down System' button on this message. Call your product service representative if this problem persists.
USM17	Informational	The Vitesse handpiece is not connected or detected.	Plug in the Vitesse handpiece. The ultrasound connector indicator light is flashing. If the handpiece is not detected, unplug the handpiece and try another Vitesse handpiece. Call your product service representative if this problem persists.
USM18	Informational	The Vitesse handpiece has not been tuned.	Select the 'Setup' icon, and then select the 'Easy Prime' or 'Tune Vitesse' button. Close this message and then complete this action or select the 'Prime / Tune' button on this message.

ID	Type	Message	Suggested Action
USM19	Informational	The Vitesse handpiece has failed the tuning process.	Unplug the handpiece and try another Vitesse handpiece. Select the Prime/Tune Vitesse or Tune Vitesse button again to repeat the handpiece tuning process. Close this message and then complete this action or use the Prime/Tune Vitesse button on this message. Call your product service representative if this problem persists.
USM20	Informational	The Vitesse handpiece may have failed or may be failing.	Unplug the handpiece and try another Vitesse handpiece. Select the Prime/Tune Vitesse or Tune Vitesse button again to repeat the handpiece tuning process. Close this message and then complete this action or use the Prime/Tune Vitesse button on this message. Call your product service representative if this problem persists.

Vacuum Fluidics Module Messages

ID	Type	Message	Suggested Action
VFM01	Caution	The vacuum fluidics module was not detected in the system. Surgical mode is not available.	Call your product service representative.
VFM02	Caution	The vacuum fluidics module software version is not compatible with the system software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.
VFM03	Caution	The vacuum fluidics module has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
VFM04	Caution	The vacuum fluidics module has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
VFM05	Caution	The vacuum fluidics module does not have valid factory calibration data. Surgical mode is not available.	Call your product service representative to replace or calibrate the vacuum fluidics module.
VFM07	Informational	The cassette vacuum check is in progress.	Please wait for the cassette vacuum check to complete.
VFM08	Informational	The cassette vacuum check has failed.	Eject the cassette using the ‘Eject Cassette’ icon button in the status display and then re-insert the cassette to retry the cassette vacuum check. Close this message and then complete this action or use the ‘Eject Cassette’ button on this message. Eject the cassette using the ‘Eject Cassette’ icon button in the status display and then replace the cassette with a new cassette. Close this message and then complete this action or use the ‘Eject Cassette’ button on this message. Call your product service representative if this problem persists.
VFM09	Informational	System priming has not been completed.	Select the ‘Setup’ icon, then select the ‘Prime’ or ‘Prime and Tune’ button to complete the system priming. Close this message and then complete this action or use the ‘Prime’ or ‘Prime and Tune’ button on this message.

ID	Type	Message	Suggested Action
VFM11	Informational	System priming has failed.	Check irrigation and aspiration tubing connections for leaks. Check that the test chamber is forming a tight seal around the handpiece. Select the 'Setup' icon, then select the 'Prime' or 'Prime and Tune' button to complete the system priming. Close this message and then complete this action or use the 'Prime' or 'Prime and Tune' button on this message. Eject the cassette using the 'Eject Cassette' icon button in the status display and then load a new pack. Close this message and then complete this action or use the 'Eject Cassette' button on this message. Call your product service representative if this problem persists.

ID	Type	Message	Suggested Action
VFM13	Informational	The cassette is nearly full.	*P/C Domains*: At the soonest convenient time, empty the cassette. To empty the cassette: 1. Clamp the infusion line. 2. Select the eject cassette icon. 3. Empty the cassette. 4. Re-insert the cassette. 5. Open the infusion clamp. Refer to operator's manual for detailed instructions to detach tubing manifold from the cassette. *Anterior Domain*: At the soonest convenient time, empty the cassette. To empty the cassette: 1. Clamp the irrigation line. 2. Replace the test chamber on the handpiece. 3. Select the eject cassette icon. 4. Empty the cassette. 5. Re-insert the cassette. 6. Open the irrigation clamp 7. Remove the test chamber from the handpiece. Refer to operator's manual for detailed instructions to detach tubing manifold from the cassette. Eject the cassette using the 'Eject Cassette' icon button in the status display and then load a new pack. Close this message and then complete this action or use the 'Eject Cassette' button on this message. Call your product service representative if the cassette is not nearly full and this message persists.

ID	Type	Message	Suggested Action
VFM14	Caution	The cassette is full.	*P/C Domains*: Empty the cassette. To empty the cassette: 1. Clamp the infusion line. 2. Select the eject cassette icon. 3. Empty the cassette. 4. Re-insert the cassette. 5. Open the infusion clamp. Refer to operator's manual for detailed instructions to detach tubing manifold from the cassette. *Anterior Domain*: Empty the cassette. To empty the cassette: 1. Clamp the irrigation line. 2. Replace the test chamber on the handpiece. 3. Select the eject cassette icon. 4. Empty the cassette. 5. Re-insert the cassette. 6. Open the irrigation clamp 7. Remove the test chamber from the handpiece. Refer to operator's manual for detailed instructions to detach tubing manifold from the cassette. Eject the cassette using the 'Eject Cassette' icon button in the status display and then load a new pack. Close this message and then complete this action or use the 'Eject Cassette' button on this message. Call your product service representative if the cassette is not full and this problem persists.

ID	Type	Message	Suggested Action
VFM15	Caution	The vitrectomy cutter output pressure is low. Vitrectomy cutter may not be cutting.	Check that the vitrectomy cutter tubing is connected tightly. Select the 'Setup' icon, then select the 'Vit Test' button. Close this message and then complete this action or select the 'Vit Test' button on this message. Replace the vitrectomy cutter. Select the 'Setup' icon and then select the 'Vit Test' button. Close this message and then complete this action or select the 'Vit Test' button on this message. Call your product service representative if this problem persists.
VFM17	Informational	Please insert the cassette.	None
VFM18	Informational	Unrecognized cassette.	Please re-insert the cassette or try a different cassette. Call your product service representative if this problem persists.
VFM19	Caution	A Vacuum Fault has occurred.	Eject the cassette using the 'Eject Cassette' icon button in the status display and then load a new pack. Close this message and then complete this action or use the 'Eject Cassette' button on this message. Call your product service representative if this problem persists.
VFM20	Informational	Reflux is not available – Reflux cannot be activated when aspiration is active.	To activate reflux, release the Foot Pedal to a non-aspirating position and activate the inward yaw reflux command or the button programmed for reflux.
VFM21	Informational	Reflux is not available – too many reflux pulses have been activated, aspiration must be commanded again to reset the reflux function.	Press the Foot Pedal to activate a short period of aspiration before re-activating reflux.
VFM22	Informational	Aspiration is not available – the Foot Pedal started in the inward yaw position when pressed to activate aspiration or the foot control button programmed for reflux is activated.	Release the Foot Pedal to home position and ensure the Primary (Integrated) Foot Control button programmed for reflux is not activated. Press the Foot Pedal into the aspiration region again to obtain aspiration.

ID	Type	Message	Suggested Action
VFM23	Informational	Aspiration is not available – in Manual infusion mode, infusion is set to OFF.	Set Manual mode infusion to ON. Close this message and then complete this action or use the 'Infusion On' button on this message.
VFM24	Informational	The cassette was not captured – the fluid level sensor could not be read.	Clean and dry the fluid level detection lens inside the cassette capture slot on the right side (red blinking light) as recommended in the Operator's Manual, and insert the cassette again. Call your product service representative if this problem persists.
VFM26	Informational	The fluid level sensor could not be read.	Without ejecting the cassette, gently push it back into the module. This message will clear automatically once the fluid level sensor can be read successfully. Clean and dry the fluid level detection lens inside the cassette capture slot on the right side (red blinking light) as recommended in the Operator's Manual, and insert the cassette again. Eject the cassette using the 'Eject Cassette' icon button in the status display and then replace the cassette with a new cassette. Close this message and then complete this action or use the 'Eject Cassette' button on this message. Call your product service representative if this problem persists.
VFM27	Informational	Aspiration is not available - Pressurized infusion is commanded OFF.	Set pressurized infusion to ON. Close this message and then complete this action or use the 'Infusion On' button on this message.

Primary (Integrated) Foot Control Module Message

ID	Type	Message	Suggested Action
WFC01	Informational	The foot control battery has exceeded 300 charge cycles. The foot control battery may not provide power for the entire day.	If the battery does not provide power for the full day, replace the battery. Use the Primary (Integrated) Foot Control cable to connect the Primary (Integrated) Foot Control to the system. Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system.
WFC02	Caution	The foot control does not have valid factory calibration data. Surgical mode is not available.	Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system. Call your product service representative to have the Primary (Integrated) Foot Control calibrated.
WFC03	Informational	The foot control is programmed for right footed operation, but is set up for left footed operation.	Change the Primary (Integrated) Foot Control home position switch selector located underneath the pedal to the center position or left-side biased for right footed operation or to the center position or right-side biased for left footed operation. Confirm the correct surgeons' settings file is loaded. If incorrect, return to the Setup Select Surgeon screen to select the correct settings file. Close this message and then complete this action or select the 'Select Surgeon' button on this message.

ID	Type	Message	Suggested Action
WFC04	Informational	The foot control is programmed for left footed operation, but is set up for right footed operation.	Change the Primary (Integrated) Foot Control home position switch selector located underneath the pedal to the center position or left-side biased for right footed operation or to the center position or right-side biased for left footed operation. Confirm the correct surgeons' settings file is loaded. If incorrect, return to the Setup Select Surgeon screen to select the correct settings file. Close this message and then complete this action or select the 'Select Surgeon' button on this message.
WFC05	Caution	The foot control center pedal or button sensors have failed or the foot control has been activated continuously since being powered on.	Reposition the Primary (Integrated) Foot Control and ensure that the center pedal and buttons are not activated. Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system. Change the Primary (Integrated) Foot Control home position switch selector located underneath the pedal to the center position or left-side biased for right footed operation or to the center position or right-side biased for left footed operation. Call your product service representative if this problem persists.

ID	Type	Message	Suggested Action
WFC08	Informational	The system is not detecting the wireless foot control.	Initiate wireless Primary (Integrated) Foot Control connectivity by pressing one of the Primary (Integrated) Foot Control buttons momentarily, the left LED will light up. Use the Primary (Integrated) Foot Control cable to connect the Primary (Integrated) Foot Control to the system. Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system. Call your product service representative if this problem persists.
WFC09	Caution	The foot control software version is not compatible with the system software version. Surgical mode is not available.	Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system. Call your product service representative. A compatible software version must be installed.
WFC10	Informational	Foot control detected on wired cable connection.	Please wait while the Primary (Integrated) Foot Control configuration completes.
WFC11	Informational	Foot control configuration on wired cable connection has completed successfully.	You may disconnect the Primary (Integrated) Foot Control cable and operate the Primary (Integrated) Foot Control wirelessly.
WFC12	Informational	Foot control configuration on the wired cable connection has failed.	Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system. Call your product service representative if this problem persists.
WFC13	Caution	The foot control battery charge level is low.	Use the Primary (Integrated) Foot Control cable to connect the Primary (Integrated) Foot Control to the system. If the battery does not provide power for the full day, replace the battery.

ID	Type	Message	Suggested Action
WFC14	Caution	The foot control battery is nearly discharged and may be insufficient to complete the case.	Use the Primary (Integrated) Foot Control cable to connect the Primary (Integrated) Foot Control to the system. If the battery does not provide power for the full day, replace the battery.
WFC16	Caution	The foot control spring has failed; the foot control center pedal is disabled.	Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system. Call your product service representative if this problem persists.
WFC17	Caution	The foot control battery has exceeded 300 charge cycles and the battery is nearly discharged. The foot control may stop functioning unless the battery is replaced immediately.	Immediately replace the battery to ensure Primary (Integrated) Foot Control functionality. Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system.
WFC18	Informational	The system is not detecting the wired foot control.	Use the Primary (Integrated) Foot Control cable to connect the Primary (Integrated) Foot Control to the system. Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system. Call your product service representative if this problem persists.
WFC19	Caution	The system has lost communications with the wireless foot control, wireless function is disabled.	Go to the programming function to re-enable wireless communication. Close this message and then complete this action or use the ‘Re-enable Wireless’ button on this message. Connect the Primary (Integrated) Foot Control cable to continue surgery.

ID	Type	Message	Suggested Action
WFC20	Caution	The system has lost communications with the wired foot control.	Check the Primary (Integrated) Foot Control cable connection. Replace the Primary (Integrated) Foot Control with another Primary (Integrated) Foot Control. Use the wired cable connection to initially pair the new Primary (Integrated) Foot Control with the system. Call your product service representative if this problem persists.
WFC21	Informational	Charge the foot control battery before next use.	Charge the Primary (Integrated) Foot Control battery before next use.

Primary (Integrated) Foot Control Receiver Module Messages

ID	Type	Message	Suggested Action
WFR01	Caution	The foot control receiver was not detected in the system. Surgical mode is not available.	Call your product service representative.
WFR02	Caution	The foot control receiver software version is not compatible with the system software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.
WFR03	Caution	The foot control receiver has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
WFR04	Caution	The foot control receiver has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.

Illumination Module Messages

ID	Type	Message	Suggested Action
LM01	Caution	The light module was not detected in the system. Surgical mode is not available.	Call your product service representative.
LM02	Caution	The light module software version is not compatible with the system software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.

ID	Type	Message	Suggested Action
LM03	Caution	The light module has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
LM04	Caution	The light module has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
LM05	Caution	The upper illuminator bulb is near end of life.	*PC Systems BL14455 and BL15455 Only*: Use the lower illumination source. Replace the upper illuminator bulb at your earliest convenience (requires system shutdown).
LM06	Caution	The lower illuminator bulb is near end of life.	*PC Systems BL14455 and BL15455 Only*: Use the upper illumination source. Replace the lower illuminator bulb at your earliest convenience (requires system shutdown).
LM07	Caution	The illuminator temperature is too high. The illuminators have been turned off.	Call your product service representative if this problem persists.
LM09	Caution	The upper illuminator bulb has failed.	*PC Systems BL14455 and BL15455 Only*: Use the lower illumination source. Replace the upper illuminator bulb at your earliest convenience (requires system shutdown).
LM10	Caution	The lower illuminator bulb has failed.	*PC Systems BL14455 and BL15455 Only*: Use the upper illumination source. Replace the lower illuminator bulb at your earliest convenience (requires system shutdown).
LM11	Caution	The illuminator filter control has failed.	Call your product service representative if this problem persists.
LM12	Caution	The upper illuminator brightness control has failed.	Call your product service representative if this problem persists.
LM13	Caution	The lower illuminator brightness control has failed.	Call your product service representative if this problem persists.

ID	Type	Message	Suggested Action
LM14	Caution	The upper illuminator bulb type is not valid.	*PC Systems BL14455 and BL15455 Only*: Use the lower illumination source. Replace the upper illuminator bulb at your earliest convenience (requires system shutdown). Call your product service representative if this problem persists.
LM15	Caution	The lower illuminator bulb type is not valid.	*PC Systems BL14455 and BL15455 Only*: Use the upper illumination source. Replace the lower illuminator bulb at your earliest convenience (requires system shutdown). Call your product service representative if this problem persists.
LM16	Caution	The upper illuminator fan has failed. Illuminators will be turned off in 5 minutes if the fan failure persists.	Call your product service representative if this problem persists.
LM17	Caution	The lower illuminator fan has failed. Illuminators will be turned off in 5 minutes if the fan failure persists.	Call your product service representative if this problem persists.
LM18	Caution	The upper illuminator has a bulb ballast error and cannot be used. It will be turned off in 30 seconds.	Call your product service representative.
LM19	Caution	The lower illuminator has a bulb ballast error and cannot be used. It will be turned off in 30 seconds.	Call your product service representative.
LM20	Caution	The upper illuminator bulb voltage is high.	*PC Systems BL14455 and BL15455 Only*: Use the lower illumination source. Replace the upper illuminator bulb at your earliest convenience (requires system shutdown).
LM21	Caution	The lower illuminator bulb voltage is high.	*PC Systems BL14455 and BL15455 Only*: Use the upper illumination source. Replace the lower illuminator bulb at your earliest convenience (requires system shutdown).
LM23	Caution	The illuminator ballast fan has failed. The illuminators will be turned off in 30 seconds.	Call your product service representative if this problem persists.

ID	Type	Message	Suggested Action
LM24	Caution	The upper illuminator bulb is at end of life. Lamp will be disabled when turned off.	*PC Systems BL14455 and BL15455 Only*: Use the lower illumination source. Replace the upper illuminator bulb at your earliest convenience (requires system shutdown).
LM25	Caution	The lower illuminator bulb is at end of life. Lamp will be disabled when turned off.	*PC Systems BL14455 and BL15455 Only*: Use the lower illumination source. Replace the upper illuminator bulb at your earliest convenience (requires system shutdown).
LM26	Caution	The illuminator temperature is too high. The illuminators will be turned off in 2.5 minutes if the fan failure persists.	Call your product service representative if this problem persists.
LM27 And LM28	Informational	Note that the level of light output being requested should be used with awareness of exposure time and proximity to the retina. Limiting exposure to less than a guideline value of 10 J/cm^2 helps maintain the retinal tissue. At the requested setting, this dose level may be exceeded in less than 30 minutes with the Bausch & Lomb focal light probe positioned 15mm from the retina. Do you want to continue?	None

ID	Type	Message	Suggested Action
LM27 Page 2 And LM28 Page 2	Informational	The time to reach the exposure guidelines will vary with: 1) Filter selection - Value reached within the 30 minutes with the following settings: a) White - 60% b) Green - 68% c) Yellow - 88% d) Amber - 100% 2) Distance from the retina 3) Light dispersing probes Consult the User Manual for additional information. Do you want to continue?	None

Laser Module Messages

ID	Type	Message	Suggested Action
LAS01	Caution	The laser module was not detected in the system. Surgical mode is not available.	Call your product service representative.
LAS02	Caution	The laser module software version is not compatible with the system software version. Surgical mode is not available.	Call your product service representative. A compatible software version must be installed.
LAS03	Caution	The laser module has failed to respond to a settings command. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
LAS04	Caution	The laser module has reset. The module settings have been re-sent to the module.	Call your product service representative if this problem persists.
LAS05	Caution	The laser module emergency stop has been pressed.	Cycle the Laser Key switch to deactivate emergency stop.

ID	Type	Message	Suggested Action
LAS06	Caution	A laser module malfunction has occurred, malfunction code XX (where XX is the code).	Cycle the Laser Key off and then on. Call your product service representative if this problem persists.
LAS07	Caution	Ensure that the eye safety filter is installed (Endo mode) and operating room personnel have proper eye protection.	None
LAS08	Informational	Laser treatment mode is unavailable – see the laser status.	None
LAS09	Informational	Laser not in treatment mode.	Select the laser mode button to enter ready mode.
LAS10	Caution	Laser has failed to deliver the commanded power.	Cycle the Laser Key off and then on. Call your product service representative if this problem persists.

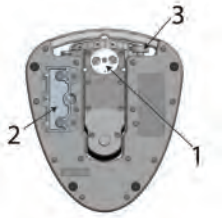
Internal Application Messages

The system requires restarting due to an internal error, please perform the following:

1. Select **Shut Down System** to initiate system shutdown.
2. If system does not shut down after 30 seconds, power off the system by pressing and holding the power button on the front panel.
3. Restart system after one minute.

Call your product service representative if this problem persists.

Additional Troubleshooting Guide

	Symptom	Potential Cause	Corrective Action
1	Primary (Integrated) Foot Control lost Pitch control of Region 2, 3 and Yaw. Pitch could only control Irrigation On/Off. The four side buttons function normally.	The Foot Pedal Offset switch not properly engaged. System not detecting if Foot Pedal is offset to Left, Right or Center. See page 1-50.  1. Pitch Tension Adjustment. 2. Battery Door. 3. Offset Adjustment.	Check Offset switch at the back of the Foot Pedal, ensure switch is fully engaged to the Left, Right or Center.
2	Primary (Integrated) Foot Control does not automatically transition to wireless operation after disconnecting the Primary (Integrated) Foot Control backup cable.	The Primary (Integrated) Foot Control does not automatically transition to wireless operation every time the backup cable is disconnected.	Following the disconnection of backup cable, initiate wireless Primary (Integrated) Foot Control connectivity by pressing one of the Primary (Integrated) Foot Control buttons. The right LED light would light up within 10 seconds; indicating wireless connection is ready.
3	System not reading cassette fluid level correctly.	The cassette was not fully inserted. This can occur if the cassette is inserted slowly and captured in a position that affects the performance of the fluid level sensor. This may also occur if the cassette is inserted too fast and released before the capture mechanism captures the cassette at the optimum position.	Eject cassette and reinsert. To ensure cassette is properly positioned in the system, firmly insert the cassette until it snaps in place.

	Symptom	Potential Cause	Corrective Action
4	No or low infusion with Pressurized Infusion function.	System displays actual pressure correctly and air is coming out of the air output connector. If problem persists with the all of the above corrective actions, stop using Pressurized Infusion and call service.	1. Air tubing or irrigation tubing may be kinked. Check air tubing and irrigation tubing for kink or pinch. 2. The air tubing pathway may be obstructed. Ensure new air tubing is used. Otherwise, replace with new tubing. 3. Preset pressure may be set too low. Increase air pressure setting to desired level.
5	System shutdown, cassette ejected and irrigation running into cassette/ cartridge and handpiece.	Power supply cut off from the source or power cable is accidentally unplugged from the wall.	1. Stop surgery and remove handpiece from the eye. 2. Close irrigation clamp to stop fluid flow into the cassette/cartridge and handpiece. 3. Replace test chamber to the handpiece that is connected to the tubing. 4. Reboot system, prime and tune handpiece when power supply resumes (make sure to open irrigation clamp before starting to re-prime and tune system).
6	Remote Control not working with good or new batteries.	Remote firmware not responding to key inputs.	Corrective action: Reset the device by removing the batteries and waiting for at least one minute before re-installing the batteries.

6.6. System Configurations, Replacement Parts, and Medical Device Accessories

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

Use of non-approved medical device accessories including procedure packs or replacement parts may affect system performance. The unauthorized modification or alteration of the equipment, or the use of non-approved medical device accessories, or replacement parts with the equipment shall relieve Bausch + Lomb from any warranty, service obligation or other liability for damages to, or failure of, the equipment caused by such unauthorized acts.

Approved medical device accessories will be appropriately labeled as Manufactured By, Manufactured For, or Distributed By Bausch & Lomb Incorporated. For a complete list of approved accessories please consult your local Bausch + Lomb catalog or contact your local Bausch + Lomb representative.

Applied Parts (non-energized) include: vitrectomy cutters, illumination probe, I/A handpieces, and various ophthalmic surgical items such as needles, entry site alignment, laser probes etc.

Applied Parts (energized) include: reusable phaco or fragmentation handpiece or fragmentation handpiece, bipolar forceps, Vitesse handpiece.

Stellaris Elite™ System List

Category	SKU	Description
System	BL11145	***Stellaris Elite***™ Anterior System
System	BL14455	***Stellaris Elite***™ Posterior/Combined System
System	BL15455	***Stellaris Elite***™ Posterior/Combined System with Laser

Anterior Device Accessories

Category	SKU	Description
Accessory	BL3170	Ultrasound Phaco Handpiece
Accessory	BL3379	***Stellaris***™ Ultrasound Handpiece Tray

Posterior Device Accessories

Category	SKU	Description
Miscellaneous	BL4360	Alternate Mayo Tray - Metal Bracket
Miscellaneous	BL4364	Alternate Mayo Tray - Plastic Bracket
Miscellaneous	BL4363	***Stellaris***™ ***PC*** Zero Level Bottle Hanger

Category	SKU	Description
Miscellaneous	BL5280	Dual Infusion Kit
Accessory	BL3270	Fragmentation Handpiece
Accessory	BL2295	Primary (Integrated) System Foot Control
Accessory	BL2296	Secondary (LIO) Foot Control
Accessory	BL2394	Elite Primary (Integrated) System Foot Control

Replacement Parts

Category	SKU	Description
Miscellaneous	BL4351US	System Power Cord, United States
Miscellaneous	BL4351EUR	System Power Cord, Europe
Miscellaneous	BL4351UK	System Power Cord, United Kingdom
Miscellaneous	BL4351ITL	System Power Cord, Italy
Miscellaneous	BL4351SWI	System Power Cord, Switzerland
Miscellaneous	BL4351CHI	System Power Cord, China
Miscellaneous	BL4352	Fuses, AC Input, User Replaceable
Miscellaneous	BL4361	Dust Cover
Miscellaneous	BL4390	Primary (Integrated) Foot Control Battery
Miscellaneous	BL4391	Primary (Integrated) Foot Control Wall Charger (without adapter)
Miscellaneous	BL4393	Primary (Integrated) Foot Control Charging Cradle
Miscellaneous	BL4394	Primary (Integrated) Foot Control Backup Cable
Miscellaneous	CX7120	Universal Maintenance Kit
Module	BL2271	532 nm Laser module
Accessory	BL3320	Xenon Lamp Assembly
Accessory	BL3321	Xenon-Mercury lamp assembly
Accessory	BL2273	Anterior module with laser connection ports
Accessory	BL3234	Laser On/Off keys
Accessory	BL3235	532 Laser safety glasses
Accessory	BL3244	Kit, Interlock Bypass Connectors
Accessory	BL3246	LIO Lamp Replacement

Refer to Laser Function Section 1.14 of manual for listing of medical device laser accessories.

Table of Cables

Cable	Maximum Length
BL3170 Ultrasound handpiece	84"
BL4351US, Power Cable United States	180"
BL4351UK, Power Cable Great Britain	180"
BL4351EUR, Power Cable General Europe	180"
BL4351ITL, Power Cable Italy	180"
BL4351SWI, Power Cable Switzerland	180"
BL4351CHI, Power Cable China	98"
BL4394 Primary (Integrated) Foot Control Backup Cable	144"
BL2296 Secondary (LIO) Foot Control Cable	192"
BL3270 Frag Handpiece	84"
S2050B Autoclavable Bipolar Cord	144"
CX9400 Bipolar Cord	144"
CX9430 Bipolar Cord with Lemo	144"
CX9404 Bipolar Cord	144"
BL4394 Primary (Integrated) Foot Control Power Cable	144"

7. Service and Warranty

7. Service and Warranty

7. Service and Warranty

This chapter contains instructions on how to contact Bausch + Lomb to obtain service on your ***Stellaris Elite***™ vision enhancement system, as well as warranty and environmental information.

CAUTION: ***Preventive scheduled maintenance is recommended once a year to ensure that the* Stellaris Elite™ *vision enhancement system meets its optimum performance, reliability and safety standards set by the manufacturer. The maintenance shall be done by a Bausch + Lomb certified individual only.***

Note: *Other than main fuses, power cords, and lamps (PC systems only), this system contains no parts that are serviceable by the user. All maintenance shall be done by a Bausch + Lomb certified individual only.*

7.1. Service Information

Technical Assistance

Assistance for ***Stellaris Elite***™ vision enhancement system is available from Global Product Support:

Bausch & Lomb Incorporated
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122 USA
Attention: Global Product Support Department

https://www.bausch.com/ecp/for-your-practice/surgical-support/surgical-product-support

- For product support **within the USA** call the 24-hour telephone line 1-800-338-2020 or fax 1-636-226-3070.
- For product support from **outside the USA** either call 1-636-226-3535, send a fax to 1-636-226-3070, or contact your local Bausch + Lomb Product Support Representative (listing of local offices starts on page 7-3).

Please organize your material before calling or writing for technical support. Please have the following information ready:

- Customer account number
- Name of function, handpiece, etc. that needs service
- Model number (REF #) and serial number (SN#) of ***Stellaris Elite***™ vision enhancement system, located on the label on the back panel
- Date of purchase

- Date of awareness
- Date of event
- Occurrence stage
- Medical intervention Yes/No. If Yes, please describe.
- Description of problem, listing all observable symptoms and characteristics, and details of occurrence. Was patient involved at time of occurrence?

Returns

To return a ***Stellaris Elite***™ vision enhancement system and/or system assembly or component to Bausch + Lomb for service, a **return authorization number must be obtained** from your local Product Support team prior to returning any unit for repair or calibration. The following information must accompany all returned units:

- Customer account number
- Customer name, address, and telephone number
- Name of function, handpiece, etc. that needs service
- Model number (REF #) and serial number (SN#) of ***Stellaris Elite***™ vision enhancement system, located on the label on the back panel
- Date of purchase
- Description of the problem or service desired. List all observable symptoms and characteristics, and details of occurrence. Was patient involved at time of occurrence?
- Return authorization number assigned by our Global Product Support specialist
- Contact name and phone number if additional information is required
- Date of awareness
- Date of event
- Occurrence stage
- Medical intervention Yes/No. If Yes, please describe.

Ship or otherwise return the part, transportation and insurance prepaid, to your local Bausch + Lomb International Facility unless otherwise instructed.

For accessories and disposable handpieces, contact your local Bausch + Lomb representative to determine applicable return policies for your local market.

Bausch + Lomb International Facilities

* Indicates Global Product Support Numbers

Argentina

Bausch & Lomb Argentina S.R.L.
Avenida Del Libertador 174 piso 12
B1638BEN- Vicente López.
Provincia de Bs As. Argentina
Teléfonos
(54911) 4718-4200

Australia

Bausch + Lomb Australia Pty Ltd
Level 2, 12 Help Street
Chatswood, NSW 2067 Australia
Tel: 1800 251 150
eMail: anztservice@bausch.com

Austria

Bausch + Lomb GesmbH
SURGICAL
Hintzerstraße 5 / Top 2
1300 Wien
Austria
Tel: 0800 / 241015
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Bausch & Lomb Pharma S.A
Avenue du Haras, 156
1150 Woluwe-Saint-Pierre
Belgium
Tel : +32 3 280 82 71
*Tel: +33 4 67 12 30 68
*Fax: +33 4 67 12 30 66

Bermuda

Bausch & Lomb Bermuda Office
Gibbons Bldg.
P.O. Box 1154
Hamilton, HM EX Bermuda
Tel: 441-295-1044
Fax: 441-292-6140

Brazil

BL Industria Otica LTDA.
Rua Dona Alzira, 139
91110-010, Porto Alegre, RS, Brazil
Tel: 55-51-3393-2000
Fax: 55-51-3393-2100

BL Industria Otica LTDA.
Av Eng° Luiz Carlos Berrini, 1700 -15°andar
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7.2. Environmental Protection

Accessories such as disposable packs, handpieces, and tubing will be contaminated with human tissue fragments and bodily fluids during the surgical process. These should be handled and disposed of in accordance with current biomedical procedures.

The system and accessories and Primary (Integrated) Foot Control may, in use, become contaminated with fluids from the operating field and should be treated as biohazards and therefore need to be decontaminated.

When discarding any major component of the system, use local market techniques for disposal of standard electronic components and equipment.

7.3. Warranty Information

Stellaris Elite™ *vision enhancement system Warranty*

Bausch & Lomb Incorporated warrants, for the benefit of the purchaser only, that the ***Stellaris Elite***™ vision enhancement system, when delivered, will conform to the manufacturer's then current version of the published specifications for the device in all material respects and shall be free from defects in material or workmanship for a period of twelve (12) months from the date of delivery when properly installed, maintained and used for its intended purpose and in accordance with all manufacturer's instructions.

The exclusive remedy for any breach of this Warranty, and Bausch + Lomb's only responsibility therefore, shall be, at Bausch + Lomb's option, the repair or replacement of the non-conforming defective equipment or component thereof. Non-conforming or defective parts may be either repaired or replaced with new, refurbished, or remanufactured parts at Bausch + Lomb's sole discretion. Any such non-conforming or defective parts, which are replaced by Bausch + Lomb, will become the property of Bausch + Lomb. Any service or replacement part provided under this Warranty may be supplied by Bausch + Lomb or any of its affiliates or authorized service providers, at Bausch + Lomb's sole discretion. Any claim based on this Warranty must be submitted to Bausch + Lomb, in writing, within the twelve (12) month warranty period which commences on the date of delivery.

Bausch + Lomb reserves the right to deny warranty coverage, and shall have no responsibility to repair or replace any non-conforming or defective equipment or component under this warranty if (a) the ***Stellaris Elite***™ vision enhancement system is not maintained and operated in accordance with all manufacturer's instructions, (b) the non-conformity or defect arises from, or is related to, any service or maintenance of the equipment, or component(s) thereof, provided by persons other than Bausch + Lomb or its authorized service representatives, (c) the non-conformity or defect arises from, or is related to, any spare or replacement part(s) or component(s) or any consumable or disposable products or parts which are used in the operation of the equipment or its components other than those purchased from, installed by or approved for use by Bausch + Lomb or its authorized service representatives, (d) the ***Stellaris Elite***™ vision enhancement system has been altered, neglected, abused or misused, (e) the ***Stellaris Elite***™ vision enhancement system has been relocated, reinstalled or taken apart by any person other than Bausch + Lomb or its authorized service representative, (f) the non-conformity or defect arises from, or results from, any damage to the ***Stellaris Elite***™ vision enhancement system or its components occurring subsequent to delivery, or (g) the non-conformity or defect is not reported to Bausch + Lomb in writing within the twelve (12) month warranty period. This Warranty does not apply to normal wear and tear or disposable components used in connection with the ***Stellaris Elite***™ vision enhancement system.

BAUSCH + LOMB EXCLUDES AND DISCLAIMS ALL OTHER WARRANTIES OR REPRESENTATIONS RELATING TO THE *Stellaris Elite*™ vision enhancement system WHETHER EXPRESS, IMPLIED OR ARISING BY OPERATION OF LAW, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL BAUSCH + LOMB BE LIABLE FOR, AND IT SPECIFICALLY DISCLAIMS RESPONSIBILITY FOR, ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL OR EXEMPLARY DAMAGES OR EXPENSES ARISING OUT OF THE PURCHASE OR USE OF THE *Stellaris Elite*™ vision enhancement system OR THIS WARRANTY, EVEN IF BAUSCH + LOMB HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, DAMAGE OR EXPENSE. THE LIABILITY OF BAUSCH + LOMB TO THE PURCHASER OR ANY USER FOR ANY CLAIM

RELATED TO THE *Stellaris Elite*™ vision enhancement system OR THIS WARRANTY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE OF THE *Stellaris Elite*™ vision enhancement system PAID TO BAUSCH + LOMB.

Handpiece Warranty

Bausch + Lomb warrants ultrasonic handpieces against defects in materials and workmanship under normal use for the minimum period of twelve (12) months from the date of delivery unless otherwise specified on your sales tender or contract. If any such defect occurs within the warranty period, contact Bausch + Lomb to return the handpiece for replacement. Bausch + Lomb will, as its sole obligation under this warranty, and at its sole discretion, replace the defective handpiece with either a new or repaired/refurbished handpiece. All replacement handpieces are covered for the balance of the warranty period remaining on the original handpiece. Bausch + Lomb will arrange for replacement at no charge. Loss or damage in return shipment to Bausch + Lomb shall be at purchaser's risk.

The warranty shall not apply to, and Bausch + Lomb shall not be responsible for, any loss arising in connection with the purchase or use of any handpiece which has been repaired or altered in any way so as, in Bausch + Lomb's judgment, to affect its reliability or which has been subject to misuse, negligence or accident, or which has had the serial or lot number altered, defaced or removed, or which has been used otherwise than in accordance with the instructions furnished by Bausch + Lomb. Bausch + Lomb neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with the sale of such handpieces.

BAUSCH + LOMB DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OTHER THAN THOSE EXPRESSLY SET FORTH IN THE APPROPRIATE PRODUCT LABELING OR USER INFORMATION MANUAL. IN NO EVENT WILL BAUSCH + LOMB BE LIABLE FOR ANY INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH THE PURCHASE OR USE OF ITS PRODUCTS.

Code Project Open License (CPOL)

Use of the ***Stellaris Elite***™ vision enhancement system constitutes the user's acceptance and agreement to the terms of The Code Project Open License (CPOL) 1.02, a copy of which is available at http://www.codeproject.com/info/cpol10.aspx, for certain Executable Files and Source Code embedded in the ***Stellaris Elite***™ vision enhancement system, specifically with respect to an Advanced WPF Localization Library, written by Jecho Jekov.

Post-Warranty Information:

When the Manufacturer's Warranty expires, Bausch + Lomb is pleased to offer Service Agreements that provide the assurance that customers are seeking in managing equipment performance and budgeted service expense. Contact your local Bausch + Lomb sales or service representative for service agreement programs.

CAUTION: ***Bausch + Lomb is the only authorized service organization for Bausch + Lomb ultrasonic handpieces. Bausch + Lomb does not recommend having your ultrasonic handpiece repaired by third-party service organizations and assumes no responsibility or liability for the function, safety or operation of any handpiece repaired or serviced by anyone other than the Bausch + Lomb service organization.***

Return Policy:

Bausch + Lomb will, within the return period as specified on your invoice, from the date of invoice, accept return of this product for a full refund less any handling and shipping charges incurred by Bausch + Lomb. Customer must call their local Bausch + Lomb customer service representative to request a Return Good Authorization prior to expiration of the return period. It is the Customer's responsibility to properly pack all items being returned. A restocking charge of 15% of the purchase price listed on the invoice for the product, in addition to any refurbishment, handling and shipping charges, may be assessed for any return received after the return period but not greater than 180 days of the invoice date.

Handpiece Disclaimer

Bausch + Lomb is the only authorized service organization for the Bausch + Lomb handpiece. Bausch + Lomb does not recommend having your handpiece repaired by third-party service organizations and assumes no responsibility or liability for the function or safety of operation of any handpiece repaired or serviced by anyone other than the Bausch + Lomb service organization.

8. Specifications

8. Specifications

8.1. Environmental and Physical Specifications

Note: *This device contains items which may be classified as waste electrical or electronic equipment. Please dispose of the equipment according to local requirements.*

This symbol indicates that the product must be disposed of separately and safely. Therefore, it is your responsibility to dispose of this waste equipment by handing it over to a designated collection point or organization that specializes in the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local recycling office or electronic waste hauler.

Essential Performance: Maintenance of static irrigation pressure in the eye is considered essential performance of the system. Other surgical functions (Aspiration pressure, Diathermy power, Diathermy frequency, Illumination output, Ultrasonic velocity of Tip, Vitrectomy probe cut rate, and Laser output of the working beam) are considered critical functions that are tested similarly and guaranteed to have their output free from: incorrect numeric values, production of excessive output, unintended transient or permanent changes to assigned values, unintended activation of function or laser firing, and unwanted output in the event of power loss or system reset but are not essential performance as non-function does not create an immediate hazardous situation for the patient or operator.

Note: *In the context of essential performance, any EMC related impact could lead to a delay of surgery with the system continuous irrigation to maintain inner ocular pressure based on the current bottle height. After the EMC disturbance has passed, the system will need to be restarted, the cassette re-inserted, the handpieces primed and tuned prior to continuing surgery.*

Environmental Specifications

Parameter	Specifications
Electrical Input	Detachable international power cord Universal Input (100-240 VAC, 50/60 Hz, 1000 VA) Equipotential grounding stud Fuse Set BL4352—includes (2)T 10AL, 250V slow-blow (5 mm x 20 mm) fuses
Temperature	Ambient Operating Temperature: 10°C to 40°C (50°F to 104°F) Ambient Storage/Transport Temperature: -20°C to 60°C (-4°F to 140°F)
Humidity	Operating Humidity: 30% to 70% Relative Storage/Transport Humidity: 10% to 98% Non-Condensing
Altitude	Operates as rated up to 3,000 feet above sea level. See the Vacuum Fluidics Function Specification table in section 8.2 for derating specifications.
Shock/Vibration	Passes ISTA 3A and 3H
Air Input	Filtered medical grade air or medical grade nitrogen, at 72.5 psig to 100 psig (500 kPa to 690 kPa or 5.0 bar to 6.9 bar) and a flow rate of 2.25 SCFM (63.7 SLPM).

Physical Specifications

Parameter	Specifications
Stellaris Elite™ vision enhancement system (excluding IV Pole and handle)	122 cm (H) x 45.7 cm (W) x 45.7 cm (D) 48 in. (H) x 18 in. (W) x 18 in. (D) 162.5 cm (64 in.) from floor to top of IV Pole Approximate Weight: 230 lbs. (114 kg) Recommended Tray Capacity: 12 lbs. (5.4 kg)

Equipment Classifications

Type of Protection Against Electrical Shock	Class I
Degree of Protection Against Electrical Shock	Type BF
Degree of Protection Against Water Ingress	Ordinary
Mode of Operation	Continuous
Electromagnetic Compatibility (EMC)	Class A

Electromagnetic Compatibility

For Electromagnetic Compatibility (EMC) details please refer to document 41539XX.

A complete line of accessories for the ***Stellaris Elite***™ vision enhancement system and other surgical instruments are available from Bausch + Lomb. Contact your Bausch + Lomb sales representative for detailed information.

WARNING: ***The use of accessories and cables other than those specified by Bausch + Lomb in the table below may result in increased electromagnetic emissions or decreased immunity to external electromagnetic radiation, resulting in decreased patient safety.***

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

Note: *The* **Stellaris Elite**™ *vision enhancement system includes functions that use high-frequency signals for treatment, including bipolar coagulation and pulsed phaco. As with all systems using high-frequency signals, interference may occur between the bipolar function or the pulsed phaco function and other equipment. If any physiological patient sensors are to be used in conjunction with the* **Stellaris Elite**™ *vision enhancement system, the phaco and bipolar circuits should be activated briefly prior to contact with the patient while the sensor operator is monitoring the output of the sensor. If there is noise observed on the sensor, the operator may adjust the sensor according to the instructions of the sensor manufacturer.*

When phaco or bipolar functions and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.

In all cases, monitoring systems incorporating high-frequency current limiting devices are recommended. Properly equipped monitors are usually identified as having "electrosurgery interference suppression" or "ESIS" options.

8.2. Primary System Specifications

Computer Unit Specifications

Parameter		Specification
Display Assembly	Display	Technology: Flat Panel, Liquid crystal display (TFT LCD) full color Size: 19" diagonal Pixels: 1280 x 1024 Physical Adjustment: Tilt: +15° up and -10° down Swivel: 90° left and 90° right Brightness: Controlled via touch screen
	Touch Screen	Technology: Resistive Analog Size: Approximately 19" diagonal active area Environmental: Chemical resistant to cleaning solutions Drip proof bezel
Computer Assembly	Motherboard	Technology: IBM Compatible, Pentium or better
	Computer hardware	Hard Drive or Solid State Drive Two Audio Speakers Two USB ports Ethernet port

Primary (Integrated) Foot Control Specifications

Parameter	Specification
General	External components and housing are corrosion resistant Watertight housing Wireless control (10 m standard range) Corded, low voltage connection to system Non-skid base 4 gray-colored function switches Wall Charger 3.6v battery (lithium) Battery charging cradle
Physical	13.8 cm, 5.44 in. (H) 30.1 cm, 11.83 in. (W) 34.8 cm, 13.72 in. (L) Weight 3.9 kg, 8.6 lbs.
Center pedal: Pitch	Linear on/off
Center pedal: Yaw	Left On/Off (simulated) Right On/Off (simulated) Left Linear Right Linear
Function switches	Increase/decrease On/Off Function
Center pedal: Pitch	Motion: Pitch (up/down) Automatic return to up position Detent: (2) programmable as to position, may be enabled or disabled Control: Provides primary linear function or on/off
Center pedal: Yaw	Motion: Yaw (Left/Right) Automatic return to center Detent: (1) center detent Non-programmable control: Provides secondary linear function in primary yaw direction and on/off control in secondary yaw direction, may be physically set for greater linear movement
Function switches	Motion: Momentary Push-button Control: Provides programmable increment/decrement or on/off control of assigned function
Laser Flip Up Door	Open (enables firing button)/Closed (disables firing button) See Laser Module Specifications Table
Laser Firing Button	On/Off See Laser Module Specifications Table

Remote Control Unit Specifications (Anterior Only)

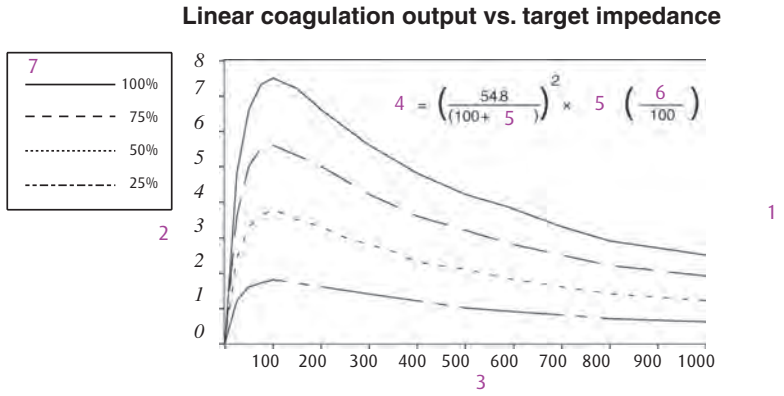
Parameter	Specification
General	Wireless pointing device providing line of sight operation using an IR transmitter
	Provides operation up to 15 feet from display console
	Powered from standard AA battery (batteries)
	Low battery indicator
	Transmit indicator
	Splash-proof (IPX2)
	Illuminated keys
Aspiration (ASP)	Vacuum Level Increase/Decrease Air consumption Increase/Decrease
IV Pole	Up Down
Phase	Next Phase
	Previous Phase
Ultrasound Power (U/S), Vitrectomy, Coagulation	Increment Decrement (shared button)
Tab	Future Use
Enter	Activate selected type
Parameter increment/ decrement	Select Prime and tune/test type

IV Pole Specification

Parameter		Specification
General		Automated Provides two (2) bottle hooks
Operation Parameters	Capacity	Capable of lifting two 500 ml glass bottles of Balanced Salt Solution
	Travel	Range of 110 cm (43.3 in.) (30 cm to 140 cm, 13.8 in. to 55 in. from aspiration port)
	Speed	10.6 cm/sec. (4 in./sec.)
	Control	Controlled via touch screen entry, remote control, Primary (Integrated) Foot Control, or directly via buttons on the back of the system
	Positioning	Relative from home sensed position

Coagulation Function Specifications

Parameter		Specification
Coagulation Connections	Connector	Single, Floating BF Connection Coaxial connector
	Cords	United States—Banana Jack Cord, Banana Jack to Coaxial adapter International—Reusable Coaxial Cord
Modes of Operation		
Operating Parameters	Linear Mode	Maximum Output Range: 7.5 Watts, 0.274 A Nominal @ 100 ohms Frequency: 1 MHz nominal Maximum Peak Open Circuit Voltage = 120V Range: Programmable from 0% to 100% in 1% increments Control: Linear control of coagulation power via the Foot Pedal
	Fixed Control	Maximum Output Range: 7.5 Watts, 0.274 A Nominal @ 100 ohms Frequency: 1 MHz nominal Maximum Peak Open Circuit Voltage = 120V Range: Programmable from 0% to 100% in 1% increments Control: On/Off control via the Foot Pedal



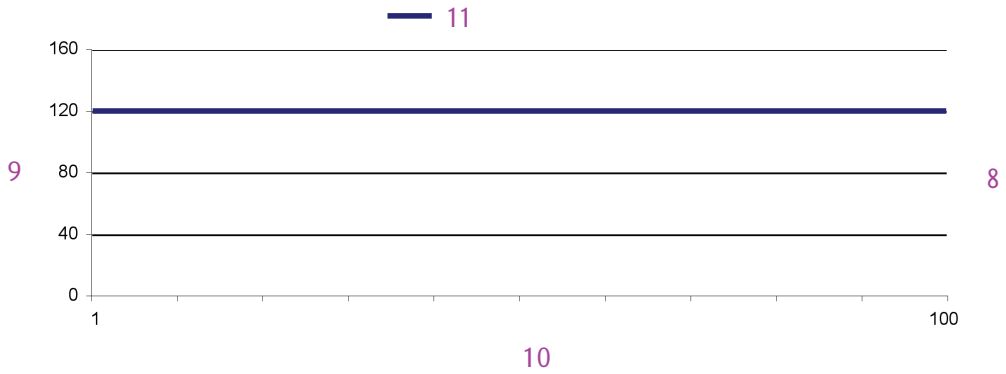


Figure 8.1.

1. Bipolar Power vs. Load. 2. Power (watts). 3. Load (ohms). 4. Power out. 5. Load. 6. Setting. 7. Settings. 8. Maximum Possible Peak Coagulation Output Voltage at all Output Control Settings and Both Modes. 9. Peak Output (V). 10. Output Control Setting (%). 11. Linear and Fixed Control.

Ultrasound Function Specifications

Parameter	Specification
Special Features	Ultrasound Time: System records and displays ultrasound time in 0.01 second increments Tuning: System provides one step tuning. Self-adjusts to resonant frequency of handpiece Probe Present: System provides a probe present detection system Wave form ultrasound available
Connection	Type: Floating BF Connection
Modes of Operation	Continuous ultrasound Pulsed ultrasound Fixed pulse ultrasound Single burst ultrasound Multiple burst ultrasound Dual Linear Ultrasound Linear Power, Linear Pulse ultrasound Linear Power, Linear Duty Cycle ultrasound Dual Linear Multiple Burst ultrasound Variable Power Multiple Burst ultrasound Variable Power Linear Burst ultrasound

Ultrasound Mode Specifications

Parameter	Specification
Continuous Ultrasound Mode	Maximum Power: 35 Watts @ approx. 900 ohms Frequency: 28.5 kHz nominal Range: 0% to 100% power in 1% increments Ultrasound Waveform: Disabled/Enabled (throughout) Control: Linear power control via the Foot Pedal Nominal phaco handpiece tip stroke at 100% power setting with DP8230 Microflow™ needle is 130 um at 28.5 kHz.
Pulsed Ultrasound Mode	Maximum Power: 35 Watts @ approx. 900 ohms Frequency: 28.5 kHz nominal Range: 1 to 250 pulses per second Duty Cycle: 5% to 95% in 1% increments
Single Burst Ultrasound Mode	Maximum Power: 35 Watts @ approx. 900 ohms Frequency: 28.5 kHz nominal Range: 80 ms to 600 ms. burst width Control: Single burst at end of pitch or yaw travel
Fixed Pulse Ultrasound Mode	Maximum Power: 35 Watts @ approx. 900 ohms Frequency: 28.5 kHz nominal Duration: 2 ms to 600 ms Interval: 2 ms to 600 ms Control: Linear power control via the Foot Pedal. Burst duration and interval as selected.
Multiple Burst Ultrasound Mode	Maximum Power: 35 Watts @ approx. 900 ohms Frequency: 28.5 kHz nominal Range: 2 ms to 600 ms. burst width Maximum Duty Cycle*: 50% to 99% in 1% increments Minimum Duty Cycle*: 1 - 50% in 1% increments Waveform: Enabled (Rise Time 2), Disabled (Rise Time 1) Control: 1 burst at minimum duty cycle at start of linear control region. Interval decreases until maximum duty cycle is commanded at end of linear control region. *Actual Duty Cycle Range is limited by the Burst Width Setting

Vacuum Fluidics Function Specifications

Parameter		Specification
Aspiration	General	Provides Cassette Full, Near-Full and Continuous Fluid Level Sensing Programmable vacuum response curves
	Modes of Operation	Linear control of vacuum Fixed, On/Off control of vacuum Dual Linear Modes: Pitch or Yaw
	Operating Parameters	I/A mode: 0 mmHg to 660 mmHg Phaco: 10 mmHg to 660 mmHg Vitrectomy: 0 mmHg to 660 mmHg Extrude: 0 mmHg to 660 mmHg Vacuum Control: 1 mmHg increments
Irrigation		Gravity feed from I/V bottle with pinch valve On/Off control via Foot Pedal
Reflux	Control	Gravity feed from I/V bottle Modes: Continuous, Pulsed Activated via the Primary (Integrated) Foot Control
Vitrectomy	Linear Cut Rate Mode Operating Parameters	Range: 30 to 7500 cuts per minute Control: Linear control of cut rate via the Foot Pedal
	Fixed Cut Rate Mode Operating Parameters	Range: 30 to 7500 cuts per minute Cut rate is derated no more than 20% above 3000 feet (915 meters) altitude Control: On/Off control of cut via the Foot Pedal
The system will provide minimum aspiration of 660 mmHg at sea level. A derating of 24.3 mmHg per 1000 feet up to 9000 feet (2745 m). The vacuum rise time, with an empty cassette, shall not increase more than 25% above 1.6 seconds per 1000 feet up to 9000 feet (2745 m).		

Viscous Fluid Control Specifications

Parameter	Specification
Injection Mode	Pressure: 70 psi (482.6 kPa, 4.8 bar)
Extraction Mode	Vacuum: Between 5 mmHg to 660 mmHg in 10 mmHg increments

Fluid/Air Exchange, Pressurized Infusion and Air Forced Infusion Specifications

Parameter	Specification
Output	0.1 micron hydrophobic filtered air
Pressure	150 mmHg or 203 cmH_2O maximum air pressure
Flow Rate	Up to 4.8 standard cubic feet per hour (2.25 L/min)
Safety	System includes pneumatic shut-off valve in case of power loss

Illumination Specifications

Parameter	Specification
Modes of Operation	Independent Illumination and control of either port
Lamp Type	Xenon and Xenon-Mercury
Output	Light output from a single port is minimum 25 lumens using standard 20 gauge probe
Safety Filter	Both ports incorporate permanent filtration to reduce ultraviolet, violet, deep red and infrared light
Control	0-100% control range, 1% resolution
Color Filtration	None, Green, Yellow, Amber (only available on Port 1 when a xenon lamp is installed)

Laser Module Specifications

Parameter		Specification
Laser Connections	Connector	Connector Single, Floating BF Connection
	Ground Leakage Current	< 200 µA 115V 60 Hz < 300 µA 230V 50 Hz < 500 µA 250V 60 Hz
Electrical Power Consumption	Low Power	150 W
	Standby	250 W
	Treat	300 W

Parameter	Specification
Safety Interlocks	Room Interlock, Key Switch, Laser Turn-On and Emission Indicator, Emergency Off, Microscope eye safety filter interlock
Cooling	Internal whisper fans, operating on demand
Temperature Range	Operating: 10°C to 35°C (50°F to 95°F) Storage: -20°C to 60°C (-4°F to 140°F)
Relative Humidity	Operating: 30%-70%, noncondensing Storage: 10%-98%
Shock/Vibration	Passes IEC601-1, MIL-STD-810D, and ISTA Procedure 2A
Surgical Submodes	LIO Mode, EndoProbe Mode, Continuous Endo Mode
Laser Operating Modes	Disabled, Stabilization, Reduced Cooling, Standby, Treatment, Deliver Pulse

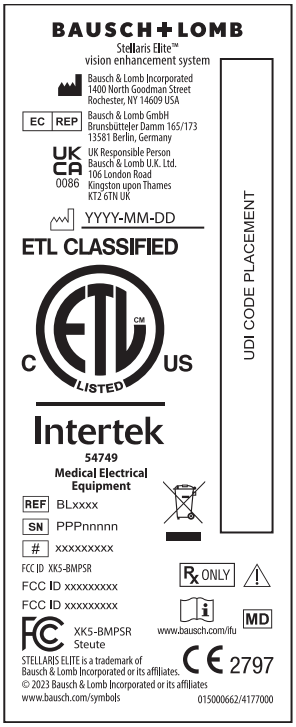
Feature	Description
Treatment Laser	Fixed 532 nm +/- 3 nm Treatment Laser: Diode-pumped, frequency-doubled, solid-state laser
Laser delivery device connector	Industry standard SMA 905 connection with delivery device detection via a resistor in the delivery device connector Connection located above the sterile field Connector backlit to make it visible in a darkened room Back light will be on when in a Laser Mode or when the key is turned on, and will blink to indicate no or incorrect delivery device is connected
Endo Single Shot mode	Single Shot 10 ms to 3000 ms 50 mW to 2000 mW
Endo Pulsed mode	Duration 10 ms to 3000 ms Interval 10 ms to 3000 ms 50 mW to 2000 mW
Endo Continuous (paint mode)	Continuous mode for up to 1 minute of firing 50 mW to 500 mW

Feature	Description
LIO Single Shot	Single Shot 10 ms to 3000 ms 50 mW to 1000 mW
LIO pulsed mode	Duration 10 ms to 3000 ms Interval 10 ms to 3000 ms 50 mW to 1000 mW
Aiming beam	635 nm +/- 5 nm Red diode laser adjustable from 0 mW to 0.8 mW Coincidental with treatment laser to ensure accurate targeting
Aiming beam modes	Standby Mode - Aiming Beam On/off Ready mode - Aiming Beam On Treatment Mode - Continuous On or On/Off during pulse treatment
Laser fire tone	2 kHz, 45 dBA to 65 dBA adjustable
Primary (Integrated) Foot Control	Laser firing button integrated into ***Stellaris Elite***™ vision enhancement system Primary (Integrated) Foot Control, with wired and wireless modes of operation All system functionality accessible from the integrated Primary (Integrated) Foot Control Laser firing button is located under a flip up door General purpose toe and heel buttons can be assigned laser functions Laser power up, power down, Standby/Ready toggle, Single/Repeat toggle, in addition to standard functions IPX7 rating (water and dust proof)
Secondary (LIO) Foot Control	Dedicated Secondary (LIO) Foot Control (wired) for laser functions only Designed to be easily moved when using a LIO headset, but remain in place and stable when firing the laser Can be used in all Laser Modes (Endo and LIO) Laser power adjustment via side buttons, which can be programmed for Standby/Ready toggle or Single/Repeat toggle. Default setting is for buttons to adjust laser power - right is increase, left is decrease. Side buttons can be disabled via the GUI. IPX7 rating (water and dust proof)

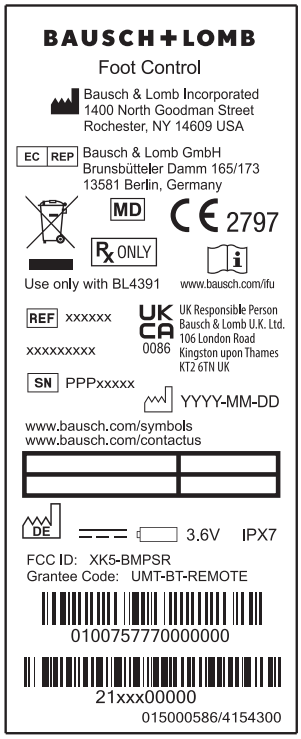
Feature	Description
GUI integration	Laser control, Aspiration control, Infusion control, Illumination control, all accessible in Endo and Continuous Submodes Illumination is not available while in LIO mode
Laser setting	Preset increment and decrement values for up and down buttons (power duration and interval) or the ability to enter an exact setting
User presets	Laser default settings power, interval and duration by mode can be stored by the user in ***Stellaris Elite***™ vision enhancement system surgeon preference file
Audio feedback	Active Laser Mode (Endo, LIO) Active laser state (Laser Standby or Ready mode) Current laser settings Laser setting changes via either Primary (Integrated) Foot Control Language of voice selectable
Movable filter interface	System interlock interface to a 2-position microscope filter Connector available to adapt existing 2-position filters to system Adapter available for backwards compatibility to Millennium 2-position filters. (BL3242) • Bausch + Lomb part number CX5996 IRIDEX 30494 WILD • Bausch + Lomb part number CX5595 IRIDEX 30493 ZEISS Key included with each system to be used when a fixed filter is in use
Room interlock	System room interlock Smart key included when used in a room without a room interlock connection Connector available to adapt existing room interlock
Room safety light	System interface to control a room laser safety light Light will be commanded on when Laser Key is on Connector available to adapt existing safety interlock

Feature	Description
Laser Key	Conveniently located on front of system for easy access Two Laser Keys supplied Key On initiates system warm up Key On illuminates EndoProbe connection back light (blinks until probe is connected)
Emergency stop button	Conveniently located on front of system Backlit to be clearly visible in a darkened room Off when the Laser Key is off On when the Laser Key is on Blinking if the emergency stop function is active. (Cycling the Laser Key will clear emergency stop.)
LIO	LIO lamp power connector conveniently located on front of system Connector backlit to be clearly visible in a darkened room System will automatically detect if an LIO device is connected LIO power output for a 6.3V 10W bulb
EndoProbes	Full line of EndoProbes in 20, 23, 25 gauge Proprietary illuminating probe connects directly with ***Stellaris Elite***™ vision enhancement system illumination module
Microscope safety filter	> 3.0 OD at 532 nm required
Eye protection	1 set of user goggles supplied > 3.5 OD at 532 nm
System LIO compatibility requirements	Industry standard SMA 905 connection with LIO device detection resistor fiber ≥ 150 micron 532 nm, 50 mW to 1000 mW Laser light input 100 micron spot size with a NA of 0.08 RCA Style Illumination power connector Illumination Power output 6.3V 10W user variable

8.3. System Labels

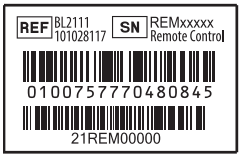


Main System Label



Primary (Integrated) Foot Control Label

Large Remote Control Label



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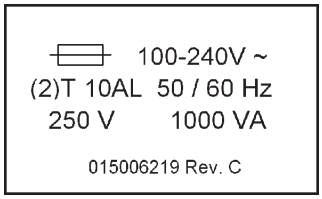
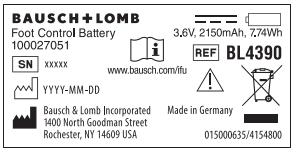
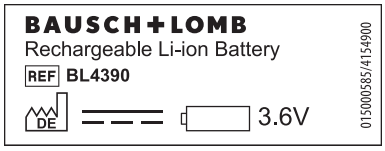


System Power and Fuse Label



Primary (Integrated) Foot Control Battery Label

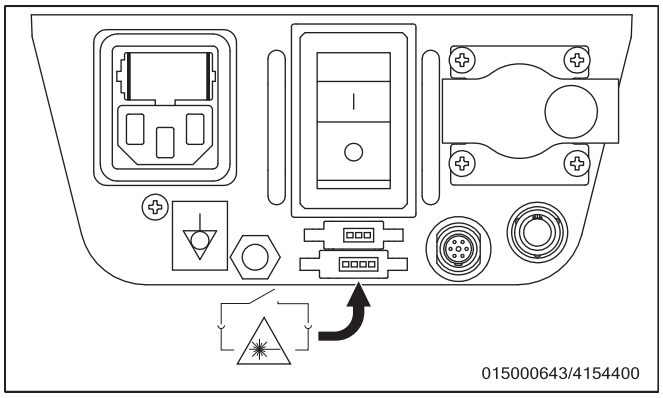


Primary (Integrated) Foot Control Battery Compartment Label

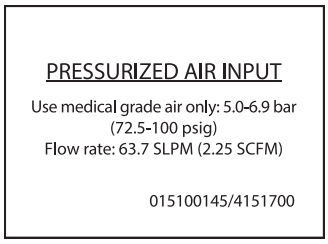
Xenon Lamp Label

Xenon-Mercury Lamp Label

Compliance Label



Interlock Connections



Pressurized Air Input Label

9. Glossary

9. Glossary

Adaptive Fluidics

Adaptive Fluidics is a new fluidics function for phacoemulsification surgery during lens removal and I/A only. Adaptive Fluidics is NOT available for anterior vitrectomy and all other posterior phases. Adaptive Fluidics maintains fluidics stability inside the eye by linking variable infusion pressure to the real-time surgeon-commanded vacuum level.

AFI

Air Forced Infusion. Refers to the use of pressurized air to create necessary pressure for infusion of fluid into the eye. The ***Stellaris Elite***™ vision enhancement system AFI requires the use of the bottle spike with metal tube to supply air pressure and venting.

A/V

Audio/Visual settings that include screen display, tone, volume and video display.

Burst Mode Ultrasound

An intermittent ultrasound modulation with ultrasound duration and rest-time controlled linearly with Primary (Integrated) Foot Control. Ultrasound power is fixed.

Case

Settings relating to instrument gauge, needle type, cataract hardness or pathology.

Detent

Tactile feedback in ***Stellaris Elite***™ vision enhancement system Primary (Integrated) Foot Control to alert user when Foot Pedal is moved from one region to another.

DMS

Digital Media System provides video overlay where real time system settings are displayed simultaneously on the surgical screen and/or projected on external monitors or video recording devices.

Domain

System functionality and setup that provides a group of functions related to either anterior, posterior or combined surgery.

Dual Linear

Primary (Integrated) Foot Control feature that controls various surgical functions with two axes of Foot Pedal movement. Both axes allow linear control of surgical functions relative to the pitch and yaw movement of the Foot Pedal.

Elevated Infusion

Refers to temporary use of higher than normal infusion pressure during posterior surgery. In ***Stellaris Elite***™ vision enhancement system, Elevated Infusion is defined as pressure above 60 mmHg for air infusion or above 81 cmH_2O for fluid infusion.

End Case

Describes the conclusion of surgery. A touch screen button in the ***Stellaris Elite***™ vision enhancement system graphical user interface would conclude a surgery and transition system to the **End of Case** screen.

Extrude

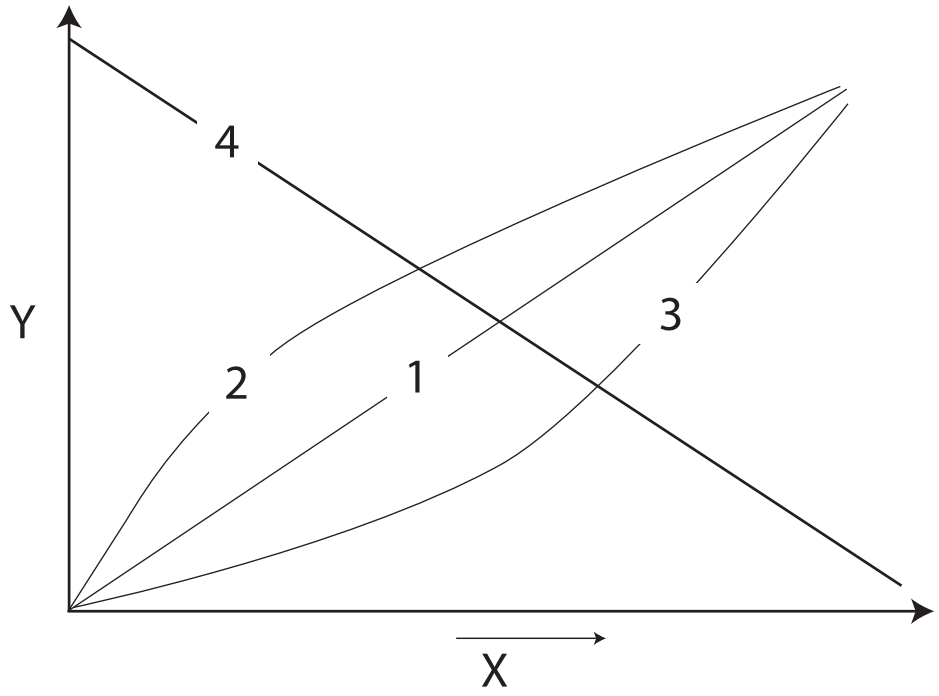
A surgical mode that aspirates fluid out of the eye. Selecting the Extrude mode activates vacuum from the left aspiration line to be used during the procedure.

Fluid/Air Exchange

F/AX. A surgical procedure to replace fluid in the eye with atmospheric air. The process involves injecting air with a specific pressure and an extrusion cannula to evacuate the fluid.

Foot Control Mapping

The correspondence between Foot Pedal linear movement and surgical function activation. Primary (Integrated) Foot Control mapping options are linear (1), front loaded (2), back loaded (3) or reverse linear (4). X = Foot Pedal movement from home position and Y = Surgical function energy level. (see diagram below)



Foot Control Switches

Four active pressable areas surrounding the ***Stellaris Elite***™ vision enhancement system Foot Pedal. The two upper switches are referred to as toe switches and the two lower switches are referred to as heel switches.

Gravity Infusion

Infusion derived from pressure created by hanging the fluid bottle at a certain height above the patient's eye level.

Infusion

Similar to irrigation, particularly referring to fluid use for posterior segment surgery. In addition to fluid, atmospheric air infusion can also be used in posterior surgery.

Irrigation

Refers to flow of fluid use in the surgery. Irrigation flows out of surgical handpieces into the eye through tubing to maintain intraocular pressure.

Mode/Phase

It is a subset of the Technique level setting. It describes the surgical phase that provides a specific function. Example 1: Vitrectomy mode provides vitreous removal functions derived from vitreous cutting and aspiration. Example 2: Phaco mode provides lens removal functions derived from lens emulsification and aspiration. ***Stellaris Elite***™ allows up to 12 different modes to be programmed in each Technique setting.

Modulation

Ultrasound settings with a unique characteristic, such as pulsed, burst, or waveform.

More Screen

Secondary menu-driven graphical user interface screen that allows the user to adjust surgical settings. The More Screen is hidden during normal operation and can be accessed from the main screen when needed.

Patient Eye Level

The vertical distance from patient eye level to the aspiration ports of the ***Stellaris Elite***™ vision enhancement system. ***Stellaris Elite***™ system has a feature to adjust patient eye level offset if the patient eye level is not at the same level as the aspiration port. The offset range is -15 cm to +15 cm.

Phase

See Mode.

Pitch

Up and down movement of Foot Pedal.

Pressurized Infusion

Similar to AFI, pressurized air is used to drive irrigation into the eye for anterior surgery.

Programming Level

Describes the ***Stellaris Elite***™ vision enhancement system system settings hierarchy. The hierarchy is System, Surgeon, Technique, Mode/Phase, Sub-mode and Case levels.

Pulse Mode Ultrasound

An intermittent ultrasound pulse modulation with fixed rate. Ultrasound power is linearly controlled with the Primary (Integrated) Foot Control.

Reflux

Momentary reversal of fluid flow towards the handpiece. Reflux pressure is generated from the irrigation bottle or mechanical plunger.

Rise Time

Speed with which system generates commanded ultrasound level. The ***Stellaris Elite***™ vision enhancement system has ultrasound rise times 1 and 2. Rise time 1 is traditional power control where ultrasound is ramped up to demanded level instantaneously. Rise time 2 ramps up phaco power gradually.

Sub-mode

Different Primary (Integrated) Foot Control options or settings within a surgical mode/phase. Examples of Vitrectomy sub-modes are Fixed Cut, Co-Linear Vit and Single Cut.

Surgeon Level

It is the second highest programming level, after the System level setting, in the ***Stellaris Elite***™ vision enhancement system system hierarchy. Typical Surgeon level settings are language, Primary (Integrated) Foot Control settings, audio-visual feedback and units of measurement.

Technique Level

Refers to surgical settings within the Surgeon level programmed either for anterior, posterior or combined surgery. It is a subset of the Surgeon level setting. The ***Stellaris Elite***™ vision enhancement system includes a list of default techniques settings, and individual users can create new techniques using the default techniques as a template.

Tone

System audio feedback specific to surgical functions and energy level.

Vacuum Response

Speed with which system generates commanded vacuum level. The ***Stellaris Elite***™ vision enhancement system has a vacuum response range of 1 to 5 (1 = fastest).

Video Overlay

Feature that simultaneously projects system settings on the surgical video screen.

Viscous fluid

Refers to high viscosity fluids. Normally refers to silicone oil use in posterior segment surgery.

Vitesse Handpiece

The Vitesse handpiece is an accessory that is used on the ***Stellaris Elite***™ PC configuration to perform hypersonic vitrectomy in the posterior segment of the eye.

Volume

System audio feedback output level.

Waveform

Ultrasound modulation where power delivery is software controlled to simulate a sinusoidal wave pattern.

Xenon lamp

A type of lamp used in the ***Stellaris Elite***™ vision enhancement system to provide endoillumination. It contains pure xenon gas and emits whiter light with a full spectrum.

Xenon-Mercury lamp

A type of lamp used in the ***Stellaris Elite***™ vision enhancement system to provide endoillumination. It contains xenon gas and small amounts of mercury metal, and emits greener light.

Yaw

Side to side movement of Foot Pedal.

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