

BAUSCH + LOMB

Stellaris[®] *PC*


Vision Enhancement System




Operator's Manual

B+L

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Indications for Use

The Bausch + Lomb *Stellaris*® *PC* Vision Enhancement System device 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 phacofragmentation (coaxial or bimanual), irrigation/ aspiration, bipolar diathermy, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations.



WARNING: *Use only Bausch + Lomb approved disposable packs, tubing sets and Bausch + Lomb handpieces designated for use with this system. Safety may be degraded if accessories not meant for the system are connected.*

User Profile

The Bausch + Lomb *Stellaris*® *PC* Vision Enhancement System is intended for use only by qualified physicians and nurses.

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, which may not be covered by warranty. See page 1-1 for precautions relevant to patients with implantable defibrillators and cardiac pacemakers.

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

Patents

The Bausch + Lomb *Stellaris*® *PC* Vision Enhancement System is covered by the following patents: 5,331,951; 5,370,602; 5,388,569; 5,910,139; 5,964,746; 5,991,142; 6,045,527; 6,055,458; 6,081,122; 6,083,195; 6,106,512 and 6,203,516; additional patents pending. Foreign and other patents may also apply.



Trademarks

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The *Bluetooth*® word mark and logos are owned by the Bluetooth SIG, Inc.

Other brands and product names used are trademarks of their respective owners.

Power Outputs

COAG	U/S
 BF	 BF
7.5 W	35 W
100 Ω	900 Ω
1 MHz	28.5 kHz

Training

Following system installation at a surgical facility, Bausch + Lomb personnel will provide on-site training to users who will operate the system. The training includes system startup, accessories and connections, priming and settings adjustment consistent with the instructions provided in this user manual. Subsequent training is provided for new staff, when the system is upgraded, or as requested by the facility.

Manual Concept

Bausch + Lomb designs manuals to give you the information you need when you need it, without having to search for it.

This manual is organized so that in the first chapter you will find enough information to quickly get up and running, and get answers to general questions about the **Stellaris® PC** Vision Enhancement System. We have included plenty of pictures so you can grasp concepts quickly. Be sure to read Chapter 2 to become familiar with the **Graphical User Interface** and the Foot Control. These are your connections to operate the system. Chapter 3 describes information on how to customize the system to suit your particular needs. Chapter 4 has detailed information about 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. These chapters are meant to serve as a reference to questions of a more technical nature. Chapter 6 through 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 depending on configuration. While the information is the same, the depiction may change. The 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.



DANGER: *Calls attention to an operating procedure, practice, or condition, which if disregarded or incorrectly performed, could result in imminent explosion hazard and risk of death or serious injury.*



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.*





Consult operating instructions.



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

Preface

	Direct Current		Alternating Current
	Equipotential Ground		Foot Control
	Remote Control Reception Indicator (Foot Control On/TruLink® Customer Support Network Access)		Battery
	Dispose of Properly		Battery Condition Indicator
	Serial Number		Manufacturer
	Authorised Representative in the European Community		Date of Manufacture
	Non Ionizing Electromagnetic Radiation		Caution: Consult Accompanying Documents
H_z	Frequency in Hertz		Type BF Applied Part
	Fuse		Coagulation
	Microscope Camera		High Speed Vitrectomy
	Ethernet		Ultrasound
	Monitor	Ω	Ohms
	Stellaris® PC Vision Enhancement System.	VA	Volt Amps
	USB	A	Amperes

Posterior Functions



F/AX

Fluid/Air Exchange



Illum 1

Illumination



Visc

Viscous Fluid Control



21 CFR 801.109 (b)
Caution: Federal (USA)
law restricts this device to
sale by or on the order of a
physician



Member Green Dot Scheme



**NO
LATEX**

No Latex



Caution: Consult
Accompanying Documents



EtO gas sterilized



Gamma Irradiation Sterilized



**DO NOT
REUSE**

Do Not Reuse



Do Not Re-Sterilize



Do Not Use If Damaged



Transport Symbol.
See page 1-30.



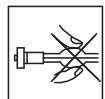
Always wear eye protection or face mask when installing or removing the lamp



Warning: Hot surface



Electrostatic-sensitive device



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



Xenon



Xenon-Mercury

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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® PC* Vision Enhancement System and making the necessary connections.



DANGER: *Do not use this device in the presence of flammable anaesthetics.*



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 gage must be 26 AWG to 12 AWG gage, with ends stripped from 9 mm to 10 mm (3/8 inch). At no point should the wire be untwisted more than 5 cm (2 inches).*



WARNING: *Patient not to come in contact with earthing metal parts.*



WARNING: *Avoid skin-to-skin contact.*



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.*



Note: *Preventative scheduled maintenance is recommended once a year to insure that the Stellaris® PC 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.*

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, assure all parts are accounted for. Smaller parts may be attached to packing materials.

Standard components shipped with the system include:

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

1.2. Connections and Setup



WARNING: *For optimum aspiration and reflux performance, the patient's eye must be at the same level as the Stellaris® PC Vision Enhancement System aspiration port. 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 setup wireless operation, see Wireless Foot Control Operations System Setup on page 1-46.

The **Stellaris® PC** Vision Enhancement System is pre-configured at the factory to minimize setup and installation requirements.

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

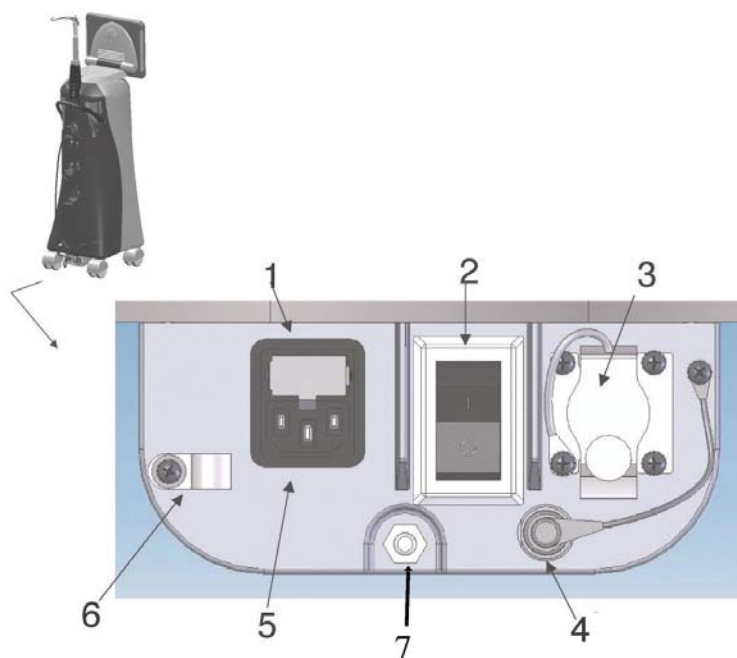


Figure 1.1. Lower Rear of System.

1. Fuse Holder.
2. Main Power Switch, disconnects system from mains voltage. See IEC 60601-1, paragraph 8.6.7
3. Ethernet Port. 4. Foot Control Backup Cable Port.
5. Power Cord Input. 6. Power Cord Retention Clip. 7. Potential Equalization Connector.

**Note:**

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

Foot Control

The Foot Control can use either wired or wireless communication. The first time the ***Stellaris® PC*** Vision Enhancement System is used, you must use the wired connection to establish communication between the Foot Control and the ***Stellaris® PC*** Vision Enhancement System.

For wired communication, connect the Foot Control backup cable from the back of the Foot Control to the lower rear of the ***Stellaris® PC*** Vision Enhancement System.

Ethernet Cable (optional)

The Ethernet cable connection only applies to a ***Stellaris® PC*** Vision Enhancement System with ***TruLink®*** Customer Support Network enabled, when you intend to upload system information to the Bausch + Lomb Global Service Support server. No Ethernet cable is supplied with the system.

If you plan to use the ***TruLink®*** Customer Support Network, connect an Ethernet cable from the back of the ***Stellaris® PC*** Vision Enhancement System to the wall network port before powering up the system, and disconnect it after the system is powered down.

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.

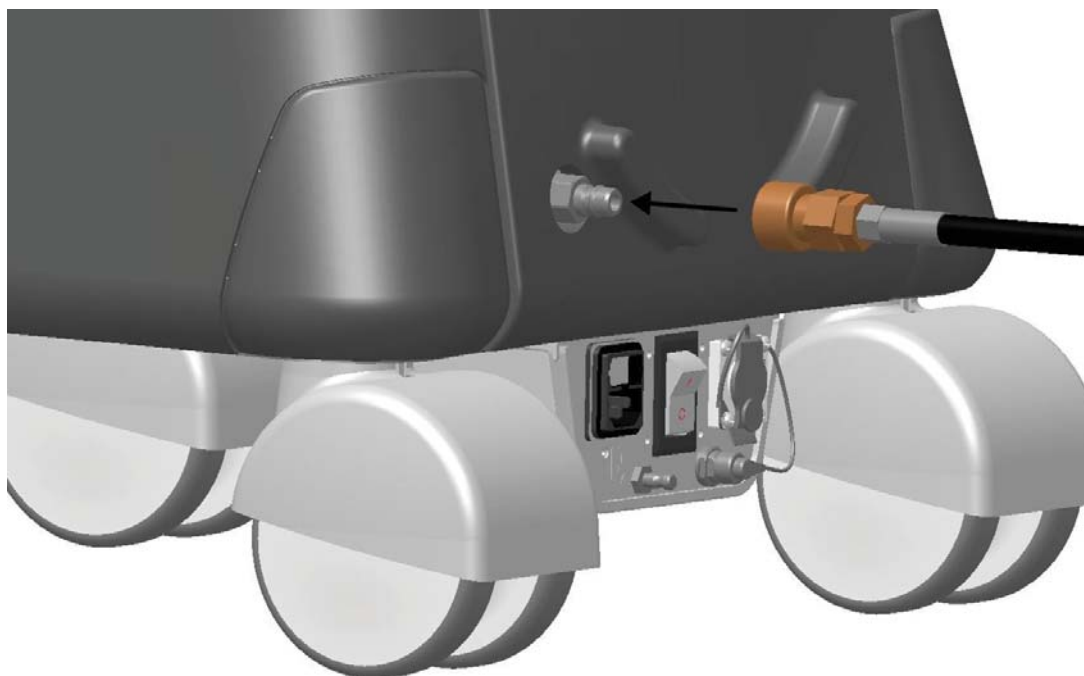


Figure 1.2. Back bottom of system.



Note:

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

1.3. System Description

The **Stellaris® PC** Vision Enhancement System has a modular design which enables it to be easily upgraded to take advantage of advances in technology. The system consists of a main housing unit which contains a user interface screen and the surgical modules, and a Foot Control, infrared remote control (for anterior application only, optional accessory). Handpieces, packs and other accessories are supplied separately.



Figure 1.3. *Stellaris® PC* Vision Enhancement System

Your Stellaris® PC Vision Enhancement System was designed to be easily upgraded to take advantage of future technology evolution. It includes an 19 inch, 5:4 aspect ratio color touch screen display which is the primary interface between you and your system. The display console 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 A/V More Screen (see page 2-28).

At the bottom of the screen is an infrared receiver which 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 spin buttons on the A/V More Screen.

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

A single port on the front of system provides filtered atmospheric air for both Fluid/Air Exchange (F/AX) and Air Forced Infusion (AFI) for posterior and combined surgery.

There are two air outputs built into the system, to provide filtered atmospheric air for anterior and posterior surgeries. The front port provides air for both Fluid/Air Exchange and Air Forced Infusion in posterior and

combined surgery. The port near the IV Pole on the back of the system provides air for Pressurized Infusion (PI) in anterior surgery.

The system can be set for either gravity infusion or infusion using pressurized air (AFI and PI, respectively) through the Infusion Tab of the More Settings Screen 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.

1.4. Setting Up Your System



DANGER: *Do not use in the presence of flammable anaesthetics, disinfectants, aerosol sprays, or in an oxygen rich atmosphere.*



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.*



CAUTION: *Do not block air vents.*



Note: *Do not add unapproved accessories that modify the effective IV pole height.*

1 Getting Started

Before the first use of the **Stellaris® PC** Vision Enhancement System, connect the Foot Control to the system with the Foot Control backup cable provided with the system.

The following pages contain an overview for setup and use of your **Stellaris® PC** Vision Enhancement System in a typical cataract surgery. 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® PC** Vision Enhancement System, and the other end to the hospital network port. If you have the optional MMC system, this cable should be connected to the MMC, and the MMC in turn connected to the hospital network port. Refer to page 1-39 for detailed MMC setup instructions.

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.*



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



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

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



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.*

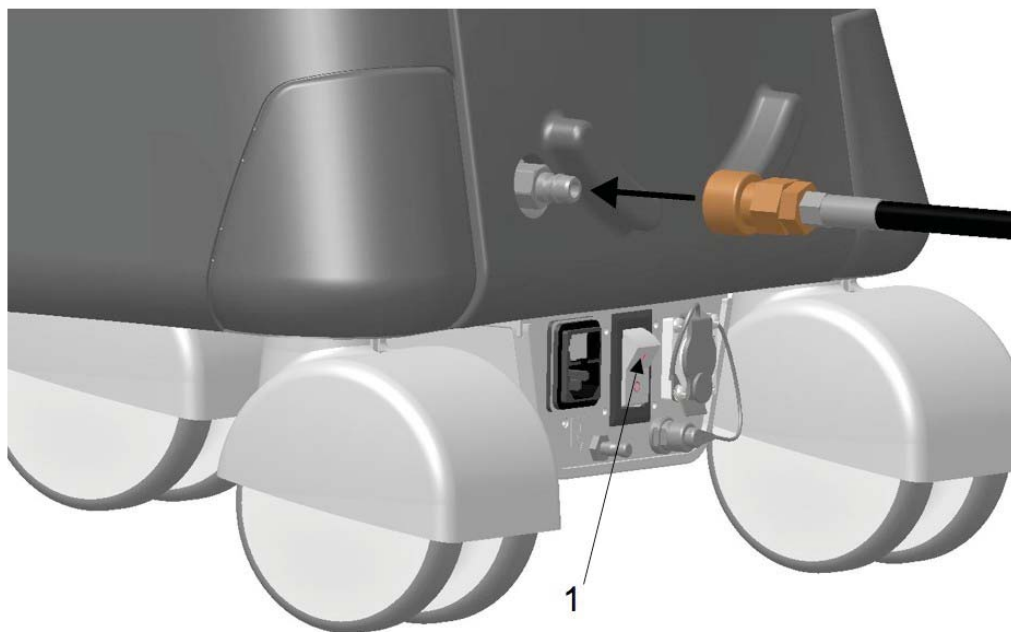


Figure 1.4. Back bottom of system.

1. Main Power Switch.



Note:

The system requires filtered medical grade air or medical grade nitrogen, at 72.5 to 100 psig (500 to 690 kPa or 5.0 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 animation to finish. The front power switch is brighter when the system is off, and dims when you turn the system on.

The **Stellaris® PC** 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.



Note:

When turning the system on for the first use of the day, pay close attention to any warning messages that appear on the screen and address any issues.

After the Foot Control has been synchronized to the specific **Stellaris® PC** Vision Enhancement System. (See page 1-40), you may use wireless communication.

1 Getting Started



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 1-46 to configure Foot Control to wireless operation.

If you are going to use the Foot Control in wireless mode, ensure the Foot Control battery is charged, then hold down any button on the 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 1.5 on page 1-10).



Note:

Following system shut down, 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 1.5. Opening Splash Screen.

Once the software has finished loading, the Select Procedure screen will appear as shown below.



Figure 1.6. Select Procedure Screen.

A Select Surgeon Screen (as shown in Figure 1.7 on page 1-12) 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 1.7 below.

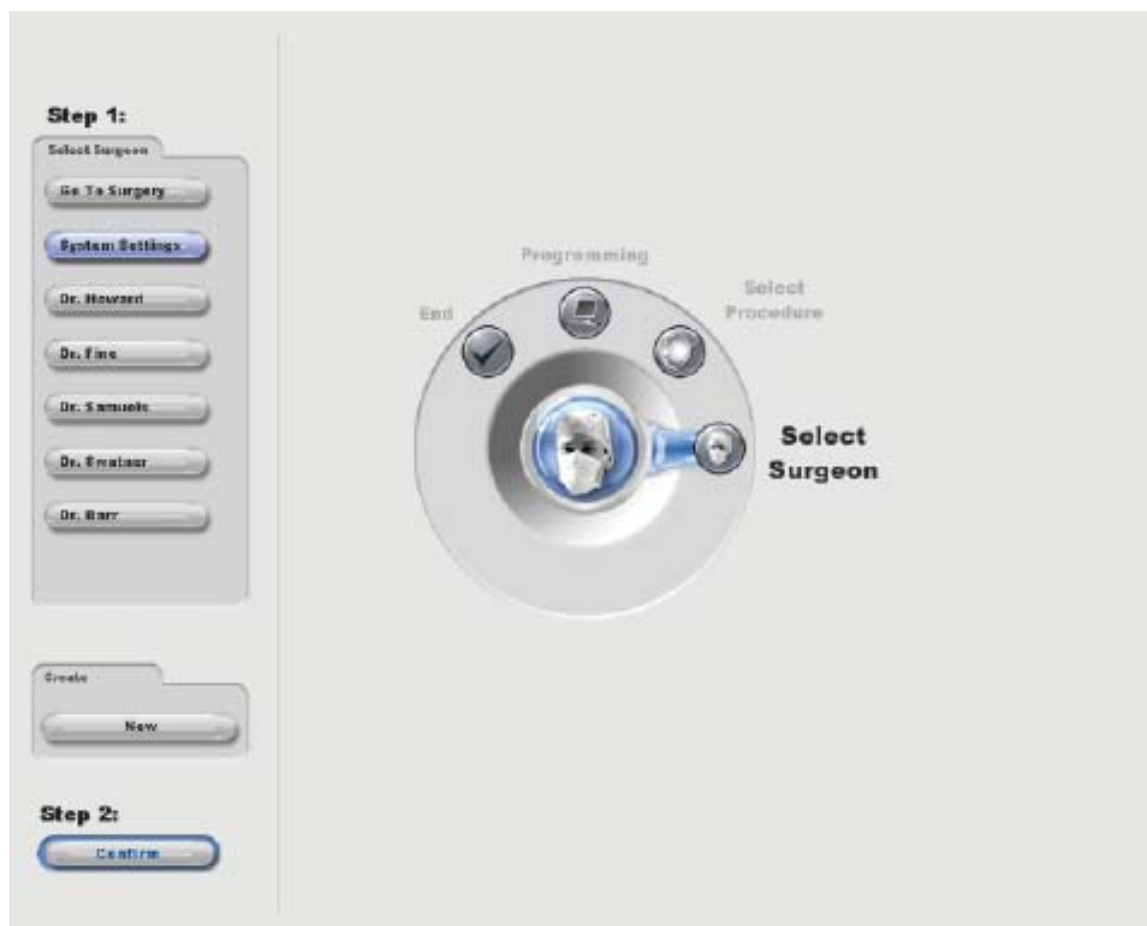


Figure 1.7. Select Surgeon Screen.

Select Surgeon

Selecting **Go To Surgery** option will advance the system to the Setup Screen, using the system's default parameters.

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:

*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.*

To set up default parameters for a new surgeon instead of using an existing surgeon's file, select **Create New**. This will allow you to setup a file for a new surgeon, using parameters from an existing surgeon as a template.

Setup Screen

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

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

If desired, select **Select Room** (Anterior Only) and choose the case number, number of operating rooms being used by the surgeon, and the particular operating room to be used.

If desired, select **Select Case** (Anterior) or Case Menu (Posterior and Combined) and choose the specific technique, needle, grade and pathology (Anterior Domain) or vitrectomy gauge, fragmentation needle (Posterior Domain) for the current procedure. The appearance of this screen will differ for the three possible domains, as shown in Figure 1.8.



Figure 1.8. Anterior Domain Select Case Screen.

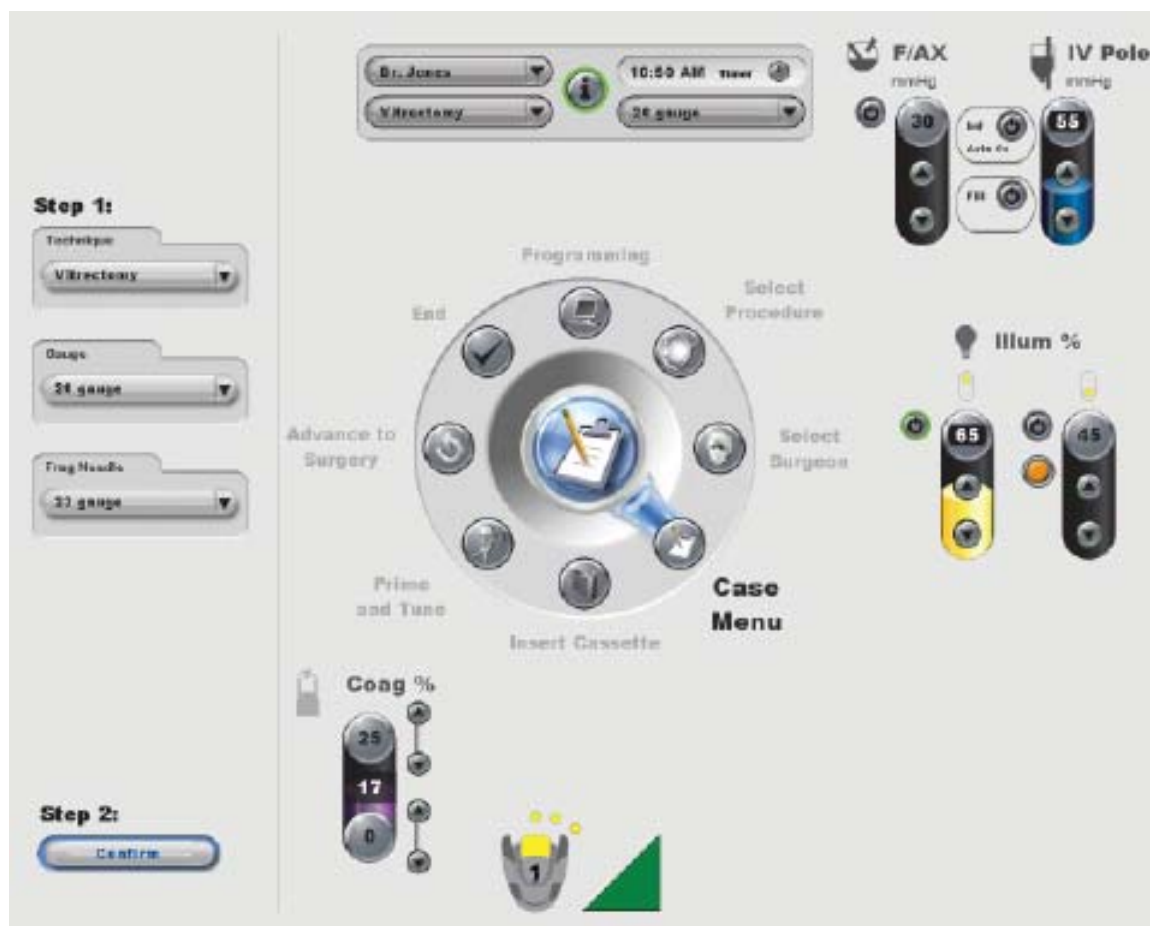


Figure 1.9. Posterior Domain Case Menu Screen.

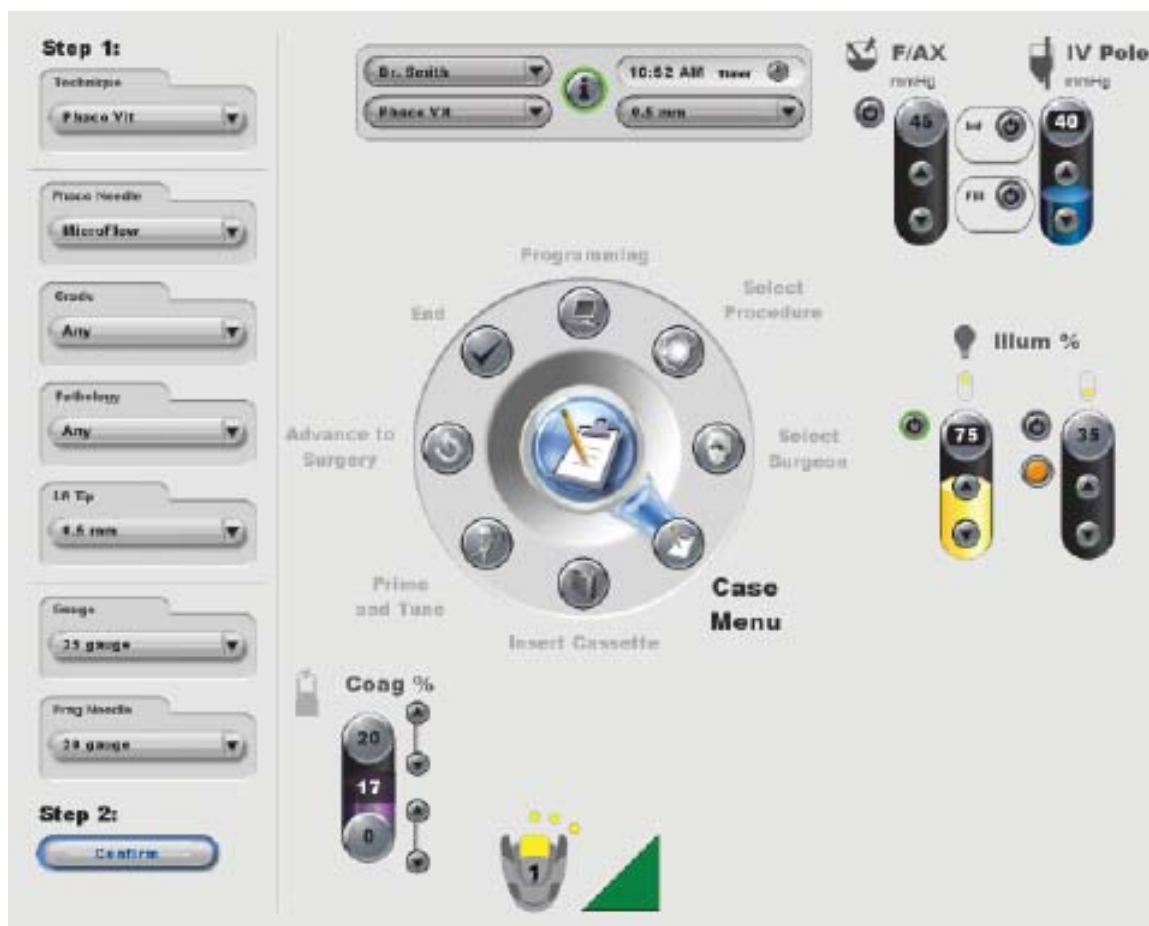


Figure 1.10. Combined Domain Case Menu Screen.

Advance to the open pack step by selecting **Open Pack Insert Cassette** (Anterior Domain) or **Insert Cassette** (Posterior or Combined Domain) from the clock menu.

1.5. Starting a New Procedure

The *Stellaris*® PC 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.*



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 g is black, 23 g is green, and 25 g is blue.*

Attach the sterile screen drape by placing the drape over the top of the *Stellaris*® PC Vision Enhancement System screen and secure with the adhesive strip to top, not the front, of the display as shown in the illustration below.

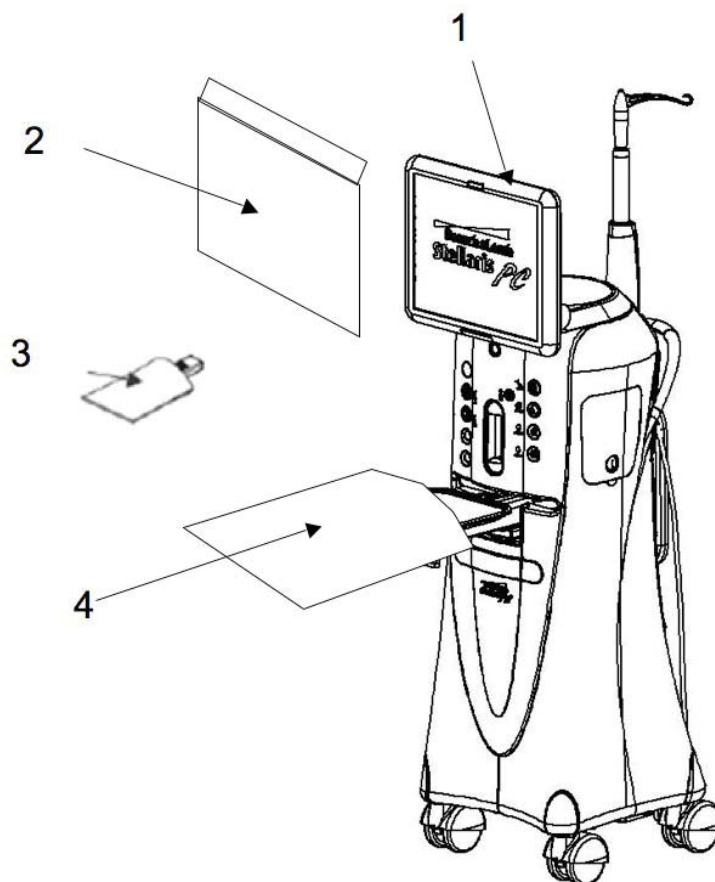


Figure 1.11. Schematic diagram of sterile draping.

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

2. Setup Fluid Collection System



Note:

Ensure sufficient volume of irrigation solution is available for the procedure. The level should be monitored during the 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.

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 4-7
- Illumination - See page 4-12
- Fluid/Air Exchange - See page 4-19
- Viscous Fluid Injection - See page 4-24
- Viscous Fluid Aspiration - See page 4-25
- Linear Fluid Injection, Linear Vacuum - See page 4-27
- Fragmentation - See page 4-28

Anterior Domain -

- Irrigation/Aspiration - See page 4-31
- Phacoemulsification - See page 4-37
- Planned Anterior Vitrectomy - See page 4-40
- Unplanned Anterior Vitrectomy - See page 4-41

Coagulation -

- Fixed Coagulation - See page 4-47
- Linear Coagulation - See page 4-48

Combined Domain - See page 4-50



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 set up is enabled or a 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 tabbed screen will appear, detailing the required steps and showing animations of how to perform each step.



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 BSS solution, and then perform a test of the pneumatic cutter. During this process, the gravity feed infusion I/V pole will raise to 100 cm or lower if maximum ceiling height is set lower than 100 cm for the anterior. In the posterior/combined domains, I/V pole will raise to the maximum ceiling height programmed for the system. With the air pressured infusion, the pressure will raise to 73 mmHg for anterior domain and 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 BSS 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® PC Vision Enhancement System and the tip submerged in BSS 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 BSS. After the first use, subsequent priming cycles will be slightly shorter.

1 Getting Started

For Combined Domain:

- Select the **Easy Prime** button from the Prime and Tune screen to fill the left and right tubing with BSS solution, and then perform a test of the pneumatic cutter. During this process, the gravity feed infusion I/V pole will raise to 100 cm or lower if maximum ceiling height is set lower than 100 cm for the anterior. In the posterior/combined domains, I/V pole will raise to the maximum ceiling height programmed for the system. With the air pressured infusion, the pressure will raise to 73 mmHg for anterior domain and 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 BSS 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® PC Vision Enhancement System and the tip submerged in BSS 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 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 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 BSS. 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 a pressure of 73 mmHg 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 **Pneumatic Vit test** 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:



-
- Pressing the “Enter” button of 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.

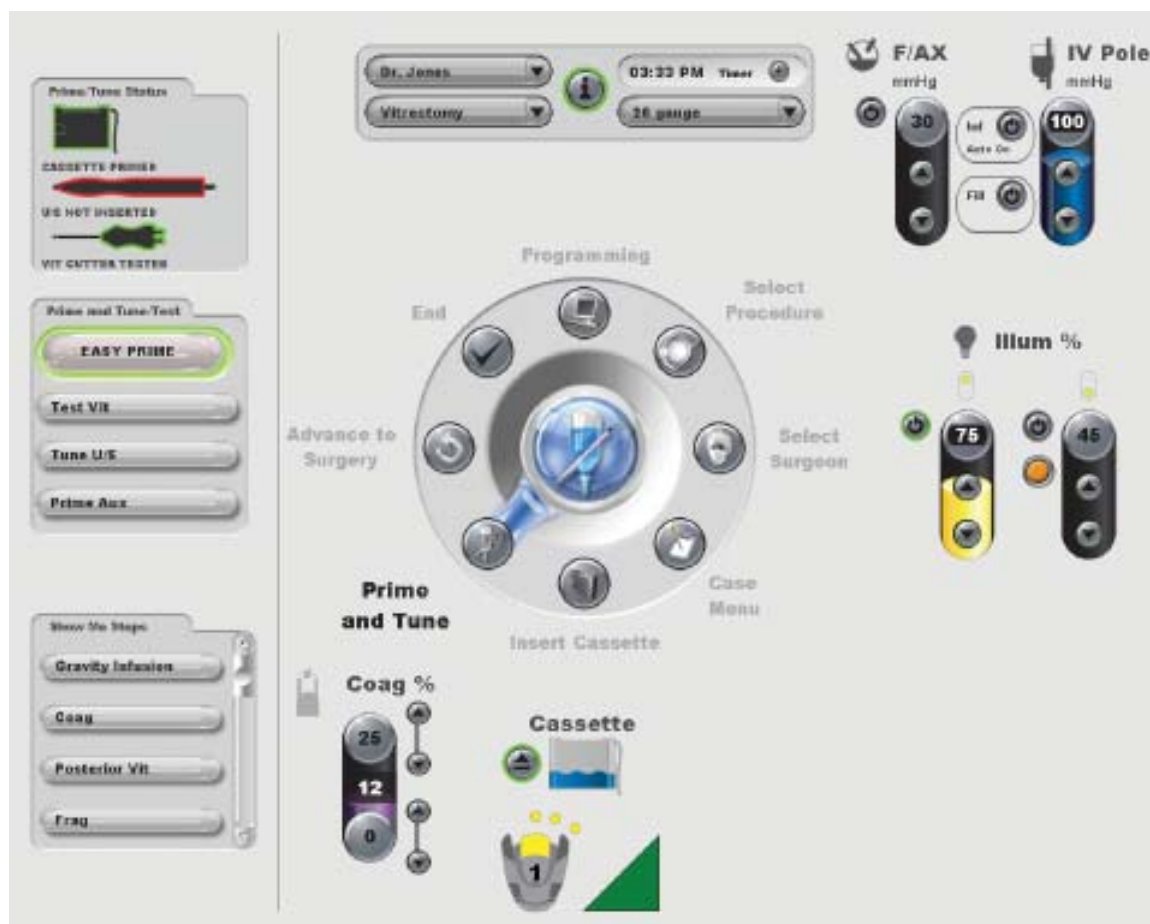


Figure 1.12. Prime and Tune Screen. This is an example of a posterior domain screen.

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 pop-up screens (see page 2-7).

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 1.13 for an example of a Posterior Surgical Screen, see Figure 1.14 for an example of an Anterior Surgical Screen, and Figure 1.15 for an example of a Combined Mode Surgical Screen. When the appropriate screen appears, your *Stellaris® PC Vision Enhancement System* is ready for the surgical procedure to begin.



Figure 1.13. Posterior Surgical Screen.



Figure 1.14. Anterior Surgical Screen



Figure 1.15. 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 administration tube set. A similar End function is accessible from the Setup Screen.



WARNING: *Make sure to close the Irrigation Clamp on the Administration 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 1.16. Anterior End of Case Screen.

Date: 7/1/2009
 Time: 04:57:44 PM

Surgeon Summary

Dr. Jones

Wrecklessy

23 gauge Yt

23 gauge Freq

Start of Case	4:47:19 PM
End of Setup	4:58:29 PM
End of Case	4:57:44 PM
Total Time	00:10:24
Case Time	00:08:23

	Average	Time
Yt	828 apm	06:40.69
Vacuum	282.8 mmHg	06:07.19
U/S	52.3 %	05:14.79
Coag	13.4 %	05:16.19
Infusion	78	06:47.89
Blowdoff Infusion	<18	05:38.29
Fluid Level	174 ml	

Surgeon Settings

Save
Save As



Shut Me Down

Remove Disposables

Next Patient

Shut Down System

Message Log

Figure 1.17. Posterior End of Case Screen.



Figure 1.18. Combined End of Case Screen.

Remove the fluidics cassette immediately.

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

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.

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.*

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.

If you have the *TruLink*® Customer Support Network option enabled, the system will ask if you want to upload system data to the Enterprise Server. Ensure the Ethernet cable is connected from the port at the bottom of the *Stellaris*® PC Vision Enhancement System to the hospital network port before attempting to upload data. The system will send diagnostic data (no patient data is transferred), then shut down when finished.

When shutting down the system, make sure to recharge the Foot Control, as described on page 1-51.

1.9. Power Interruptions

If the *Stellaris*® PC 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 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, 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 a cassette, open the irrigation clamp and perform prime and tune according the system setup procedures (see page 1-19).

1.10. Moving Your System to Another Location



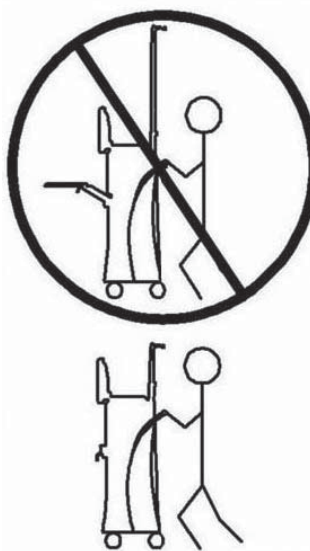
WARNING: *Do not transport or move your system from room to room or up an inclination unless you have followed the steps below.*

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 angle during use.

Before transporting the unit from room to room or for any more extensive moving, follow the basic safety instructions:

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 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 handle bar designed for this purpose.



Note: *Do not store anything on top of the system, and do not pull the system by the IV pole.*

1.11. System Components

The *Stellaris*® PC 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 Foot Control is connected to the system by either wired or wireless connections.



WARNING: *Use only handpieces, cables, tube sets and accessories designated by Bausch + Lomb for use with this system.*



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.

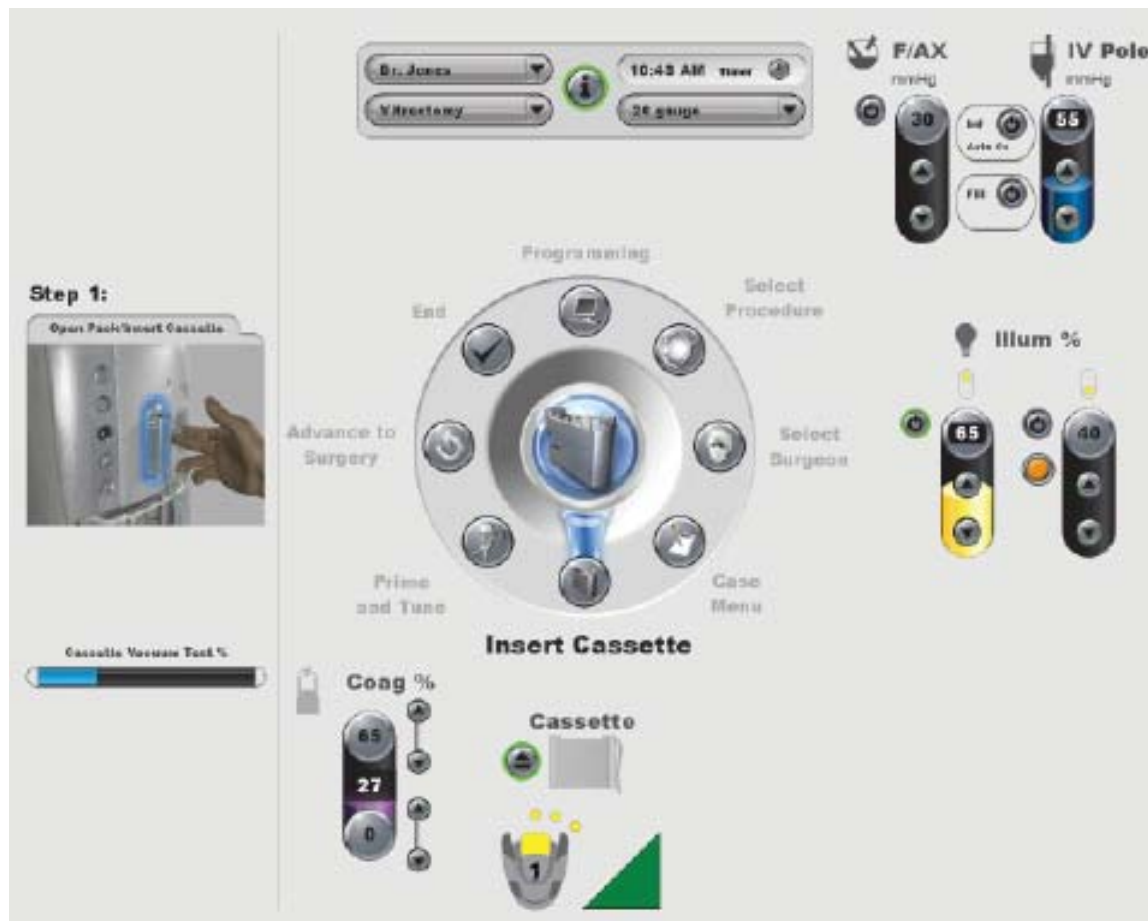


Figure 1.19. Typical interface screen.

System Console

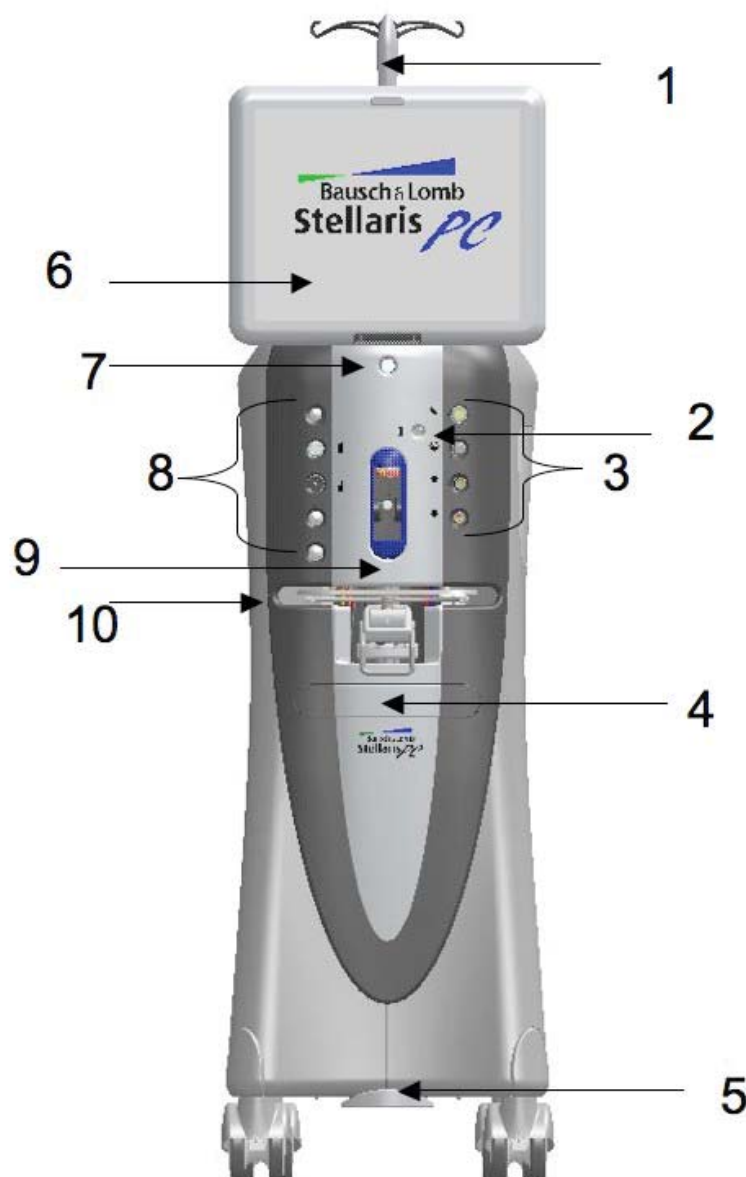


Figure 1.20. Front of Stellaris PC system.

- 1. IV Pole. 2. Pneumatic Actuation Port. 3. Posterior Handpiece Connectors. 4. Drawer.
- 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 1.21 on page 1-34), 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.

1 Getting Started

For systems left idle more than seven days, the 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.

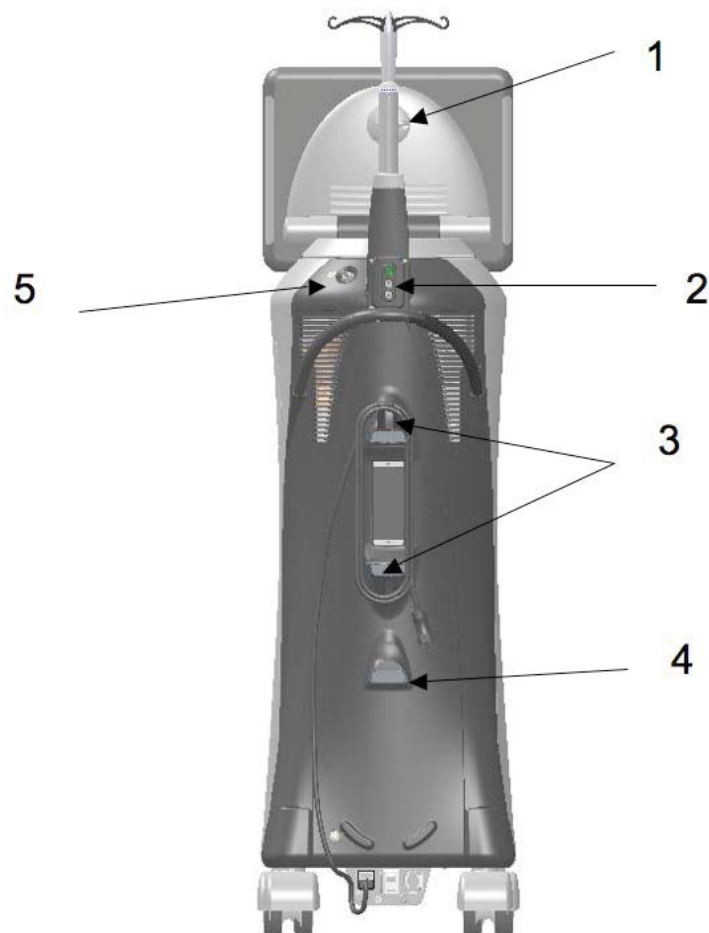


Figure 1.21. Stellaris PC System Rear View.

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

The front of the system (see Figure 1.22 on page 1-35) contains multiple ports for connecting system accessories. There are five ports down the left side of the system, of which only the second and third are active. The second port is for ultrasound handpieces (phacoemulsification and fragmentation) and the third port is for coagulation (see page 1-35). The remainder are reserved for future use.

The single port at the top of the cassette housing provides air pressure to drive the pneumatic vitrectomy cutter.

There are 4 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 1-61)

The fourth port (9 in figure below) is for lamp 1 and provides illumination with selectable filters. (See page 1-61)



Figure 1.22. Front panel with handpiece connectors.

1. Reserved for future use. 2. Ultrasound. 3. Coag. 4. Reserved for future use. 5. Reserved for future use.
6. VFC. 7. F/AX and AFI 8. Lamp 2. 9. Lamp 1.

Ultrasound Functions (Phacoemulsification and Fragmentation)



WARNING: *Manufacturers of implantable defibrillators recommend that these devices be temporarily disabled when using phacoemulsification or 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 4-46 for details of use and page 8-13 for technical specifications.

The front of the system contains a total of ten ports for connecting system accessories. Only some ports are active, the remainder are reserved for future use.

Foot Control

The Foot Control contains the Footpedal and four programmable buttons, and provides the main interface between the user and the vision enhancement system for controlling most functions. The Foot Control can be used in a wired or wireless mode. See page 1-40 for detailed instructions for its use and page 8-10 for technical specifications.

Fluidics Function

This function uses a vacuum-based pump to control the output vacuum range from 0 to 600 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 to 5000 cpm. See page 4-5 for details of posterior use and page 8-17 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 4-11 for details of use and page 8-18 for technical specifications. page 1-61 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: *This system is to be used in either air pressured infusion mode or IV Pole mode but never both together as high intraocular pressures may result.*



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

The **Stellaris® PC** 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, 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 though 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 2-39), 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 BSS 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 **Fluidics More Settings Screen** (page 2-32) if in Posterior Mode, or the **Vacuum Fluidics More Settings Screen** (See page 2-19), 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® PC** 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 1.23 on page 1-38.

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.

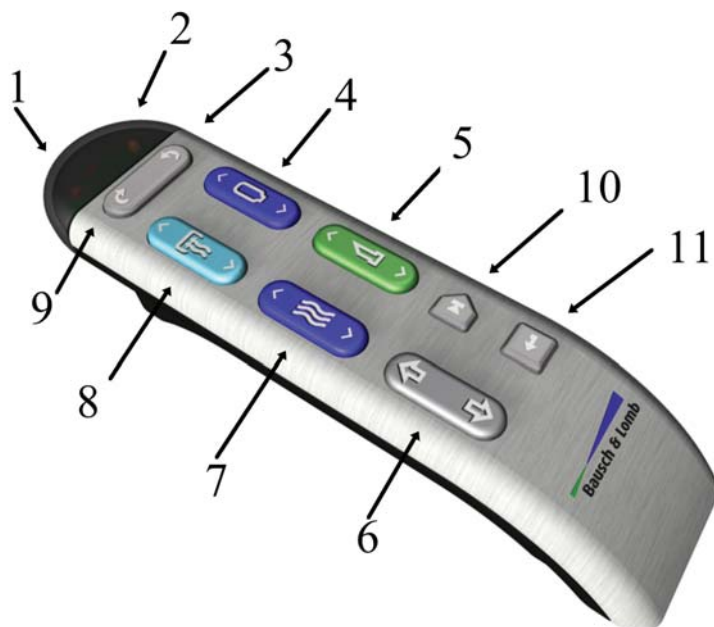


Figure 1.23. Remote Control functions.

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

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.

TruLink® Customer Support Network Remote Access (optional)

The *TruLink®* Customer Support Network feature improves system reliability by supporting remote diagnostics and performance analysis. System performance data, but no patient data, is collected by the *Stellaris® PC* Vision Enhancement System throughout the surgical day. Upon system shut down, that information can be sent to Bausch + Lomb secure servers through an encrypted, point to point connection. This allows Bausch + Lomb to analyze system performance, help you remotely (where this service is available), and proactively service the system. Surgeon preference files can also be transmitted, to provide a secure off-site backup.

The Ethernet cable that is used to transfer the data can be permanently connected to the *Stellaris® PC* Vision Enhancement System, or it can be connected at the end of each surgical day just before shutting down, and then disconnected to move or store the *Stellaris® PC* Vision Enhancement System. Upon shutdown from the End of Surgery screen, the system will offer a prompt to **Send data to TruLink**. If you agree, make sure that the Ethernet cable is connected to the designated port and follow instructions. After updating, the system will shut down automatically.

Multimedia Center (MMC) (optional)

The MMC (if available) provides streaming video on the surgical screen and microscope overlay capability. The MMC supports NTSC and PAL format composite video and S-video, or a FireWire digital camera.

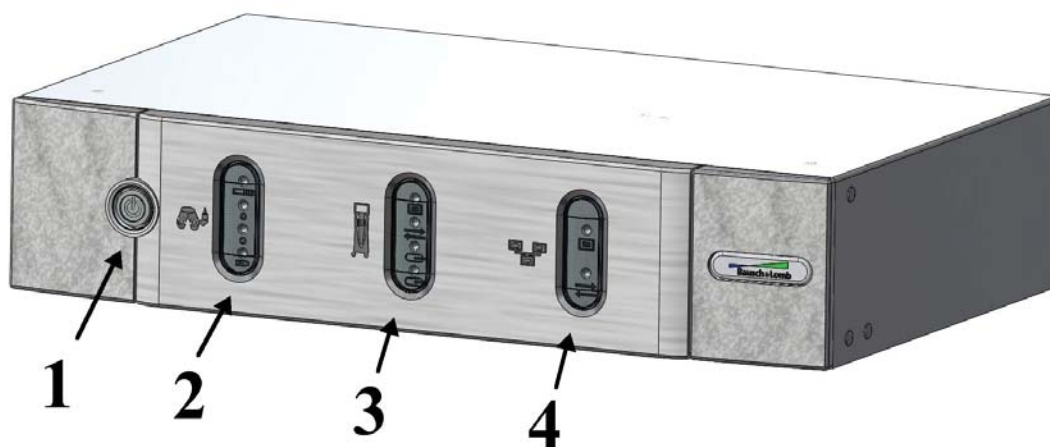


Figure 1.24. Multimedia Center (MMC) (optional).

1. Main Power Switch.
2. Connection Indicator LED from Stellaris® PC Vision Enhancement System.
3. Connection Indicator from microscope camera.
4. Connection Indicator LED to TruLink® Customer Support Network.

Data is transferred between the MMC and the *Stellaris® PC* Vision Enhancement System through an Ethernet cable that runs from the back of the MMC system to the Ethernet port on the bottom of the system. Whenever the MMC is on and connected and the *Stellaris® PC* Vision Enhancement System is in surgical mode, the

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current video image will appear on screen in the center of the **Clock Menu**. You can touch the video image itself to toggle between small and large display sizes. You can also touch the outer edge of the video display to toggle between the video display itself and an animation showing the effect of the handpiece in the eye for the currently selected phase.

If the system has the optional MMC, the *TruLink*® Customer Support Network can be activated by connecting the Ethernet port on the MMC to a designated Internet-enabled network connection and enabling the *TruLink*® Customer Support Network data download upon shutdown or Remote Access function (if available in your area) on the *Stellaris*® *PC* Vision Enhancement System.



Note:

*An off-the-shelf Ethernet cable may be used with the **Stellaris**® *PC* Vision Enhancement System to establish or restore connections.*



Note:

The MMC is not intended for diagnostic purposes.

Before installing the Multimedia Center, please take note of the following:

- Multimedia Center must be installed outside of the sterile field.
- Do not place BSS bottles or other containers of fluid on top of the Multimedia Center.
- The AC power source for the Multimedia Center must have a Ground Fault Interrupt.

1.12. Foot Control

The Foot Control is the main interface between the surgeon and the *Stellaris*® *PC* Vision Enhancement System. The surgeon can control most of the available functions from the Foot Control. The Foot Control can be connected through a physical cable, or through a wireless *Bluetooth* connection. When the 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.



Figure 1.25. Placement of Foot Control During Storage.

The 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 1-51.

Foot Control Battery Installation Guide:



Note:

Replacing the battery when the system is powered up will disable the foot control wireless set up. To re-enable wireless set up, see page 1-46.

1. Place the 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.

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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 shut down, 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.

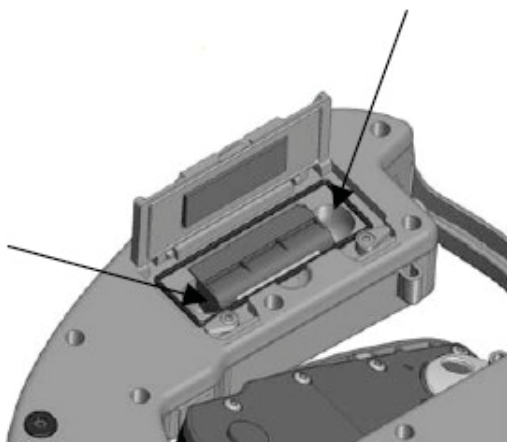


Figure 1.26. Battery compartment with recess (arrows) to facilitate battery replacement.



Note:

Be sure to securely close battery door.



Note:

A battery must be installed in the Foot Control at all times, while operating either wired or wireless, to insure proper operation.

The first time a Foot Control is used, it must be connected via the back up cable to set the configuration. Once this is set, the Foot Control will only communicate wirelessly with that specific system. To begin wireless operation, make sure the **Stellaris® PC** Vision Enhancement System is on, then press any Foot Control Button and wait 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 Foot Control is communicating wirelessly with the **Stellaris® PC** Vision Enhancement System. During operation when system is not detecting 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 Foot Control Wireless System setup section.



LED Symbol for Ready on **Foot Control**

When not in use, the Foot Control can be stored on the back of the *Stellaris*® *PC* Vision Enhancement System.

In some operating configurations the surgeon can change surgical phases using the Foot Control.

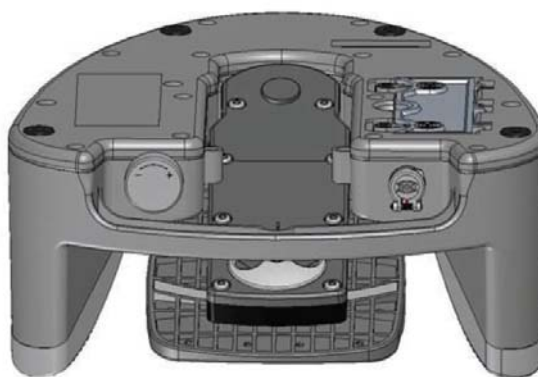


Figure 1.27. Back of Foot Control.

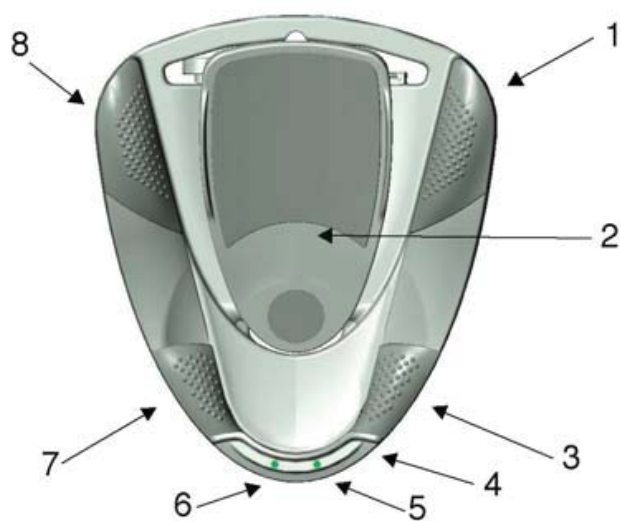


Figure 1.28. Top of Foot Control.

1. Right Toe Button. 2. Footpedal. 3. Right Heel Button. 4. Indicator Lights. 5. Right LED (Wireless).
6. Left LED (Battery). 7. Left Heel Button. 8. Left Toe Button.

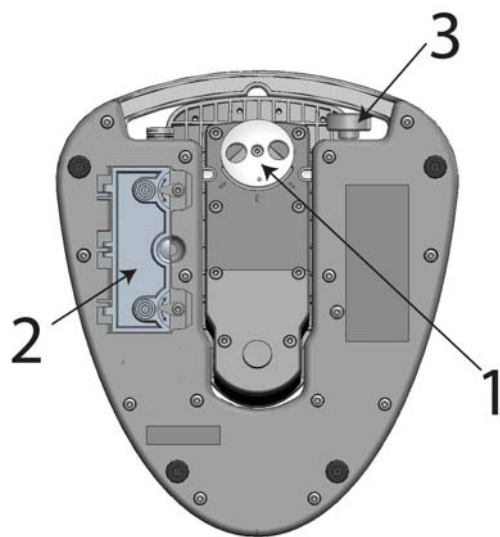


Figure 1.29. Bottom of Foot Control.

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

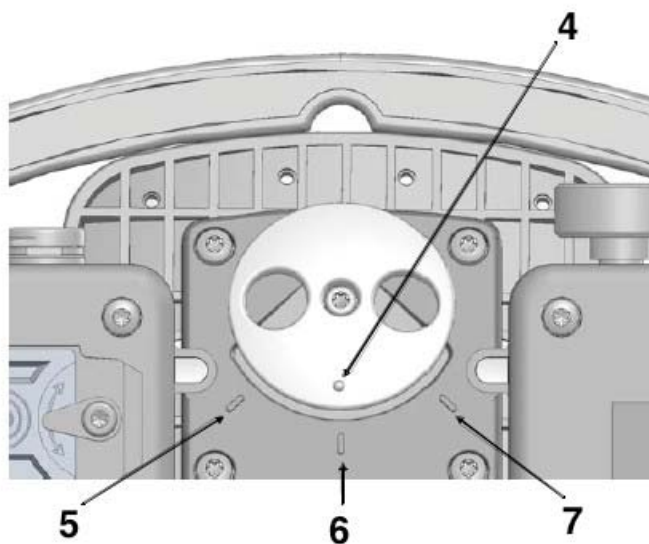


Figure 1.30. Pedal Offset Switch Indicator (4) and Pedal Offset Positions (5, 6, and 7).

- 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 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) only.

Wireless Foot Control Operations System Setup



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

To setup 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.

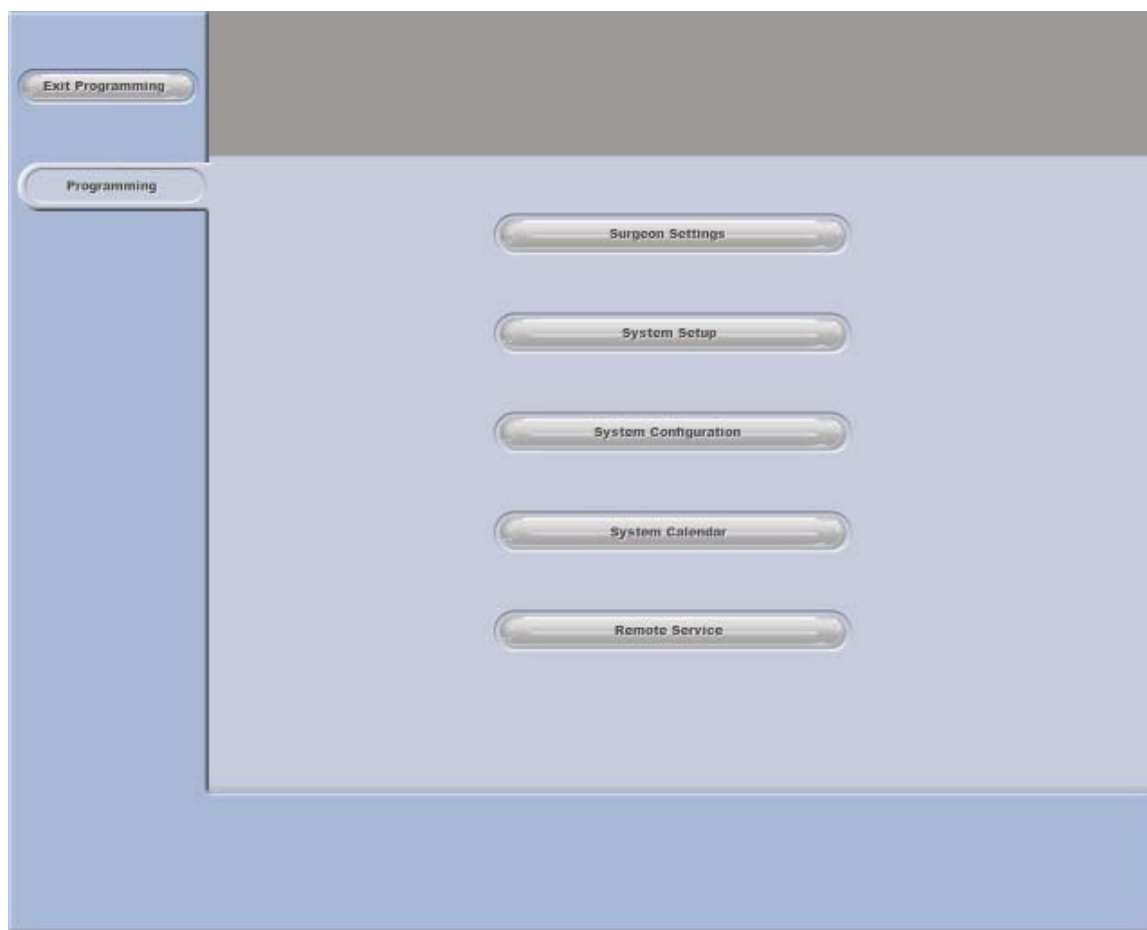


Figure 1.31. Programming Screen.

Step 3: Select “Foot Control” tab from the System Setup screen. (Arrow in image below).

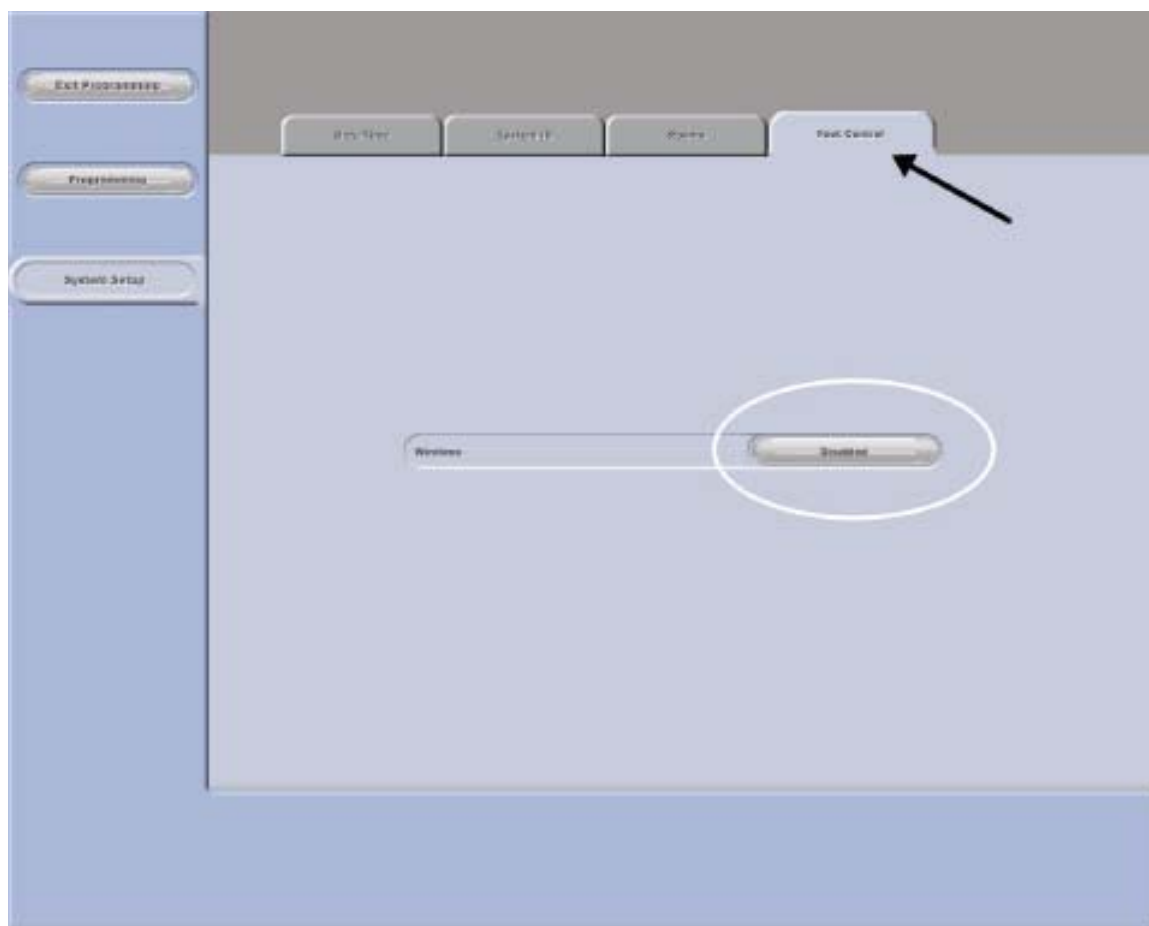


Figure 1.32. System Setup Screen.

Step 4: Select Wireless “Enabled” or “Disabled” to configure foot control connection mode. (Circled in image above.)



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.



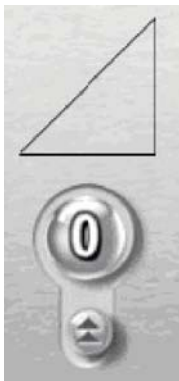






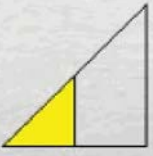

Note:

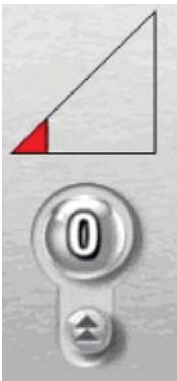

The system will disable wireless operation once it detects a loss of wireless connection at the setup and surgery screens. Changing the battery at the setup and surgery screens will also disable the wireless system setup.

Foot Control Status and Wireless Signal Strength Meter Display

The status of foot control operation is represented by icons display at the lower portion of the screen above 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	Foot Control Setup	Status	Action
	Wired or Wireless	System detecting wired Foot Control	No action required
	Wired (Wireless disabled)	System NOT detecting wired connection. Possible cause: Foot Control cable not connected	Check 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. Foot Control wireless function has not been activated. 2. Wireless connectivity not functioning due to battery issue.	1. Initiate wireless Foot Control connectivity by pressing one of the foot control buttons momentarily, the left LED will light up. 2. Check battery if Foot Control wireless function not established after Step 1.

Display Type	Foot Control Setup	Status	Action
 	Wireless	System detecting Excellent signal strength	No action required
 	Wireless	System detecting Good signal strength	No action required
 	Wireless	System detecting Moderate signal strength	No action required

Display Type	Foot Control Setup	Status	Action
	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 Foot Control cable or manually re-configures system to wireless configuration.	Connect 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 Foot Control System Setup, page 1-46.



Note:

Irrigation or infusion will be turned ON and other functions will be disabled when the system does not detect 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.

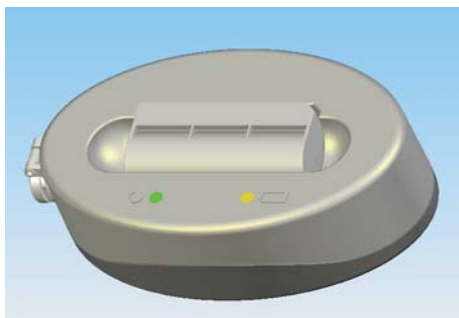


Figure 1.33. Foot Control Battery Charging Cradle.

Battery Charging Options



Note:

The battery should be removed from the Foot Control if the system is to be idle for more than seven days.



Note:

To maximize performance, the 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), adapters (BL4392US, BL4392UK, BL4392EU, BL4392AUS, BL4392ROW), and batteries (BL4390) with the **Stellaris®** PC 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 in to the electric source and the 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 1.34
- The Foot Control can be directly connected to the wall charger. Connect the wall charger cable into the back of the Foot Control, into the same receptacle used for the backup cable. See Option 2 in Figure 1.34.

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- 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 Foot Control. See Option 3 in Figure 1.34.



Note:

When the 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 Foot Control, align the red dot of the connectors to the 12 o'clock position.



Note:

The Foot Control is only to be used with wall charger BL4391.

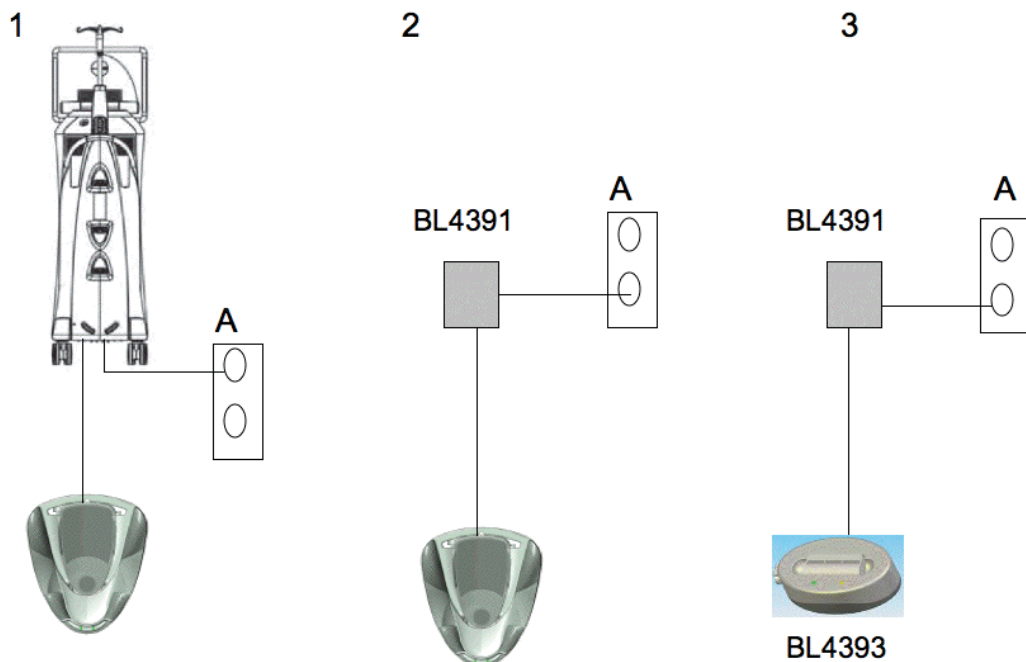


Figure 1.34. Foot Control Battery Charging Options.

1. Using Foot Control back up cable. 2. Using wall charger BL4391. 3. Using charging cradle BL4393.

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® PC** 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.

Foot Control Operation

The Foot Control has four buttons and a center footpedal which has two axes of movement, to control two linear functions simultaneously. The footpedal 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 footpedal may be programmed to operate two linear functions simultaneously (Dual Linear control). The control of linear functions is proportional to the amount of footpedal travel. See page 1-57 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 1-59 shows the possible combinations of linear control.

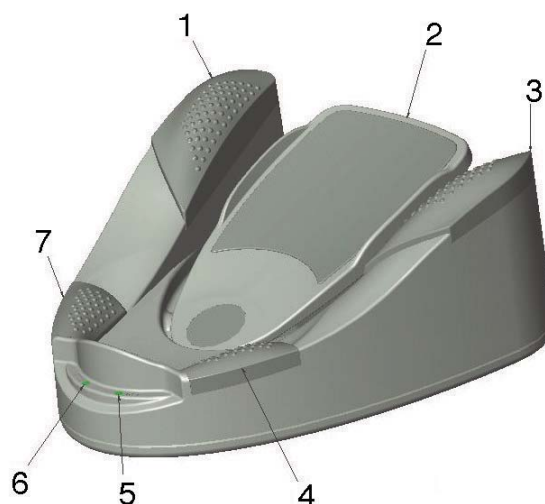


Figure 1.35. Foot Control, labeled.

1. Left Toe Button. 2. Footpedal. 3. Right Toe Button. 4. Right Heel Button. 5. Right LED (Wireless).
6. Left LED (Battery). 7. Left Heel Button.

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

Color	Status
Green	More than one hour of battery life remains

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


Basic Button Operation



Note:

Voice confirmation (if enabled) responds to 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 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 **Foot Control More Setting Screen** (see page 2-24).

The Foot Control **More Settings Screen** is used to convey the current footpedal configuration and status to the surgical team. In anterior domains, it is displayed by selecting the **Foot Control More Button**, which is the below the Footpedal status icon on the bottom of the **Main Surgical Screen** and Setup Screen. In the posterior and combined domains, the **Foot Control More Settings Screen** is displayed by selecting the More Settings Screen  button.

Footpedal

The footpedal itself, located in the center of the 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 footpedal 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 1-56. When released, the footpedal will return to the home (up or center) position. The table on page 1-59 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 footpedal 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 fixed cut vitrectomy function.

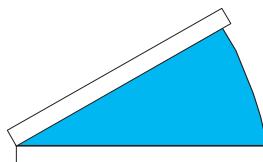


Figure 1.36. Single Region Pitch Control.

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 footpedal displacement in Region 2 (e.g., 5° to 15° down corresponds to 0% to 100% output). An example is I/A control, where Region 1 is for irrigation, and Region 2 is for linear vacuum or flow.

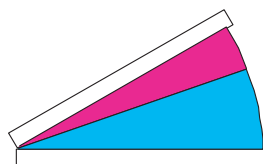


Figure 1.37. Two Region Pitch Control.

Three Region Pitch Control

There are three programmable regions (three detent positions). When programmed for linear control, pitch movement is a function of relative footpedal 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.

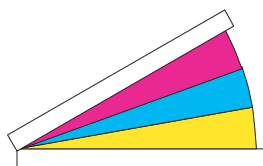


Figure 1.38. Three Region Pitch Control.

Programmable Yaw Positions

The Foot Control may be set and programmed to give greater linear yaw movement for either right or left foot operation. Turn the 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 Control** below.
- 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 Control** below.
- 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.

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) only. Refer to Figure 1.39 on page 1-57.

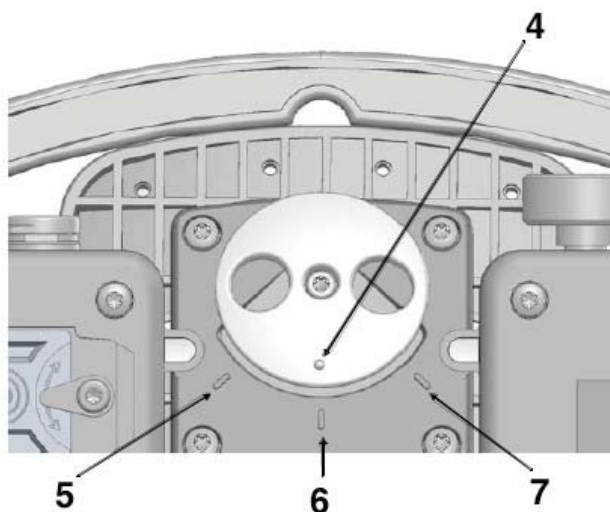


Figure 1.39. Pedal Offset Switch Indicator (4) and Pedal Offset Positions (5, 6, and 7).

- 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).

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 footpedal 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 footpedal displacement (e.g., 0° to 15° displacement corresponds to 0% to 100% output). When the footpedal is released, it returns to the center position. Inward yaw movement controls reflux.

Yaw Control of Reflux

The footpedal 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 footpedal 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 footpedal is in Region 2 or Region 3.

Linear Coagulation Control

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



Note:

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

Center Foot Control

Phase Type	Dual Linear Control	Region	Pitch	Yaw Out
Ultrasound	Disabled	R1	Irrigation	Next submode
		R2	Fixed aspiration	
		R3	Linear ultrasound	
	Disabled (with aspiration control feature on)	R1	Irrigation	Next submode
		R2	Aspiration R2 minimum to fixed vacuum or vacuum limit	
		R3	Fixed aspiration & linear ultrasound	
	Aspiration on yaw	R1	Irrigation	Linear aspiration
		R2	Minimum aspiration	
		R3	Linear ultrasound	
	Aspiration on yaw & aspiration control feature on	R1	Irrigation	To max. aspiration
		R2	Aspiration R2 minimum to fixed vacuum or vacuum limit	
		R3	Min. aspiration and linear ultrasound	
	Aspiration on Pitch	R1	Irrigation	Linear ultrasound
		R2	Linear aspiration	
	Dual Linear Ultrasound	R1	Irrigation	
		R2	Fixed Aspiration	
		R3	Linear U/S Function	Linear Ultrasound
Irrigation/aspiration	Disabled	R1	Irrigation	
		R2	Linear aspiration	
Irrigation Only	Disabled	R1	Irrigation	

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Phase Type	Dual Linear Control	Region	Pitch	Yaw Out
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	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
Coagulation	Disabled	R1	Linear Coagulation	

1.13. Illumination Function

General introduction to setting the correct light level

The guidelines provided in this section are based on ISO15752:2000(E), ISO15004-2:2007(E) and ISO/DIS 15752.

The *Stellaris® PC* 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. 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.

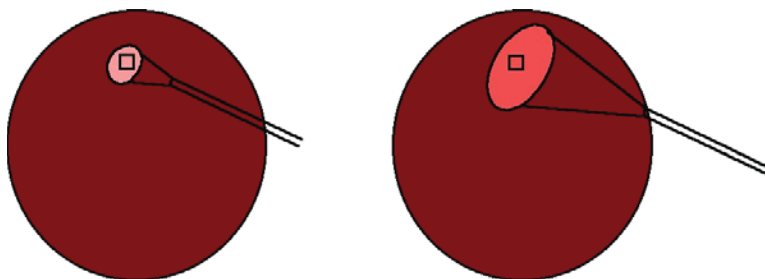


Figure 1.40. Irradiance as a function of distance.

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.

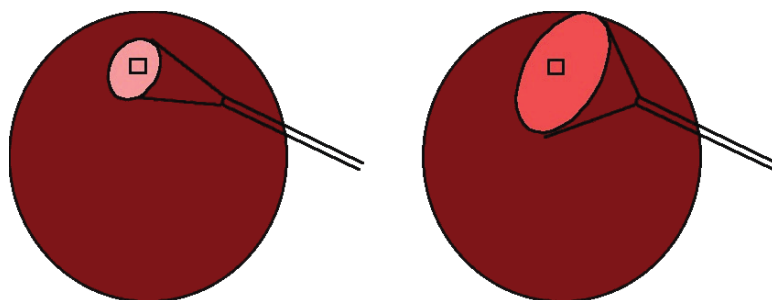


Figure 1.41. Irradiance as a function of probe type

Photoretininitis

Sensitivity verses wavelength

The retina is more easily damaged by ultra-violet and violet-blue light than it is by light with longer wavelengths. The *Stellaris® PC* Vision Enhancement System incorporates filters to remove ultra-violet light and violet light, but it is not possible to eliminate more of the phototoxic influence without significantly discoloring the light output.

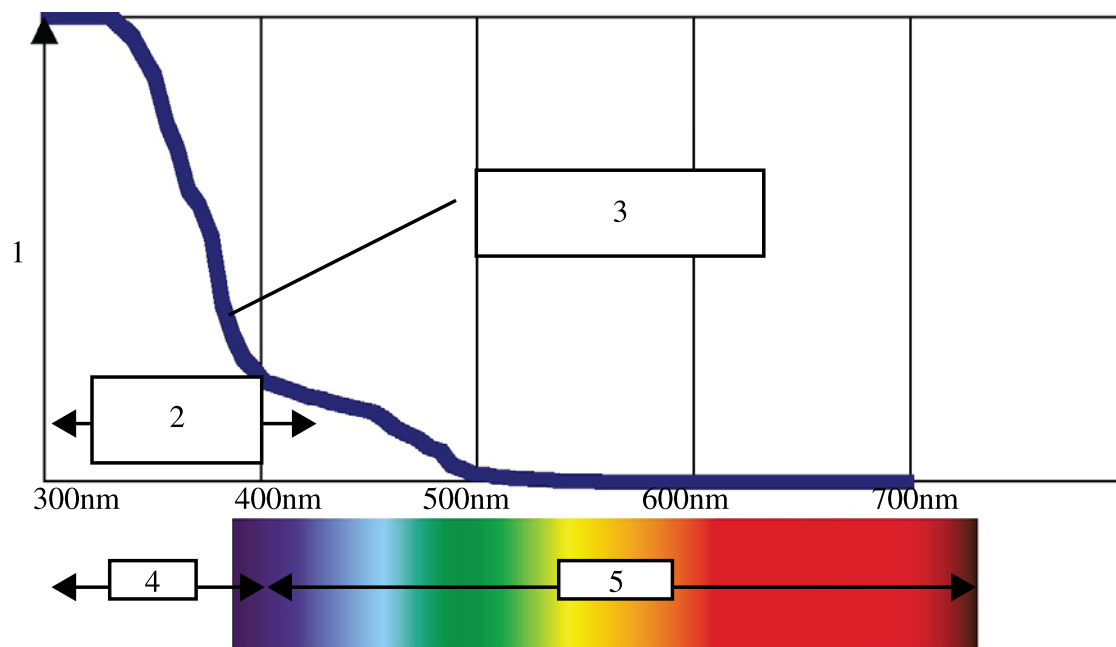


Figure 1.42. Phototoxic sensitivity vs. light wavelength

1. Phototoxic sensitivity 2. Filtered in Stellaris PC 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.



CAUTION: *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/cm ² weighted radiant exposure guideline, in minutes, at a working distance of 15 mm.								
Lamp Filter:	Mercury				Xenon			
	None	Amber	Green	Yellow	None	Amber	Green	Yellow
Setting: 100%	36	>120	42	54	18	>120	20	26
60%	61	>120	70	90	30	>120	34	44
50%	73	>120	83	108	36	>120	41	53
40% Default Setting	91	>120	104	>120	45	>120	51	66
30%	>120	>120	>120	>120	60	>120	68	88
20%	>120	>120	>120	>120	90	>120	102	>120
10%	>120	>120	>120	>120	>120	>120	>120	>120



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 time to reach the exposure guideline for the combination of light sources at various intensity settings.*



Note: *The ISO 15004-2:2007 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

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$s1 = (\text{setting of lamp 1 in \%} / 100\%)$

$s2 = (\text{setting of lamp 2 in \%} / 100\%)$

$t1,100 = \text{time to reach the threshold with lamp 1 at 100\%}$

$t2,100 = \text{time to reach the threshold with lamp 2 at 100\%}$



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

High intensity visible and infrared light is absorbed as heat in the retina. The **Stellaris® PC** Vision Enhancement System includes filters to remove the unwanted infrared from the light output but the visible light also contributes to the heat absorbed by the retina.

ISO15004-2:2007 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 PC 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 PC 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 with new ones as desired.

1.14. Multimedia Center (MMC) (optional)

The Multimedia Center (MMC) is used to overlay the surgical parameters output from the *Stellaris® PC* Vision Enhancement System to the video image of the surgical site captured by the operating microscope camera. The combined image is output to a video monitor and/or a video recorder to be displayed and stored for future use.

The MMC is NOT intended for diagnostic purposes.

Installation

Assure all equipment is turned off before making any connections. Position the MMC on a flat surface near the video monitor and/or recorder to be used.



WARNING: *The MMC is not to be placed inside the patient environment.*



CAUTION: *Do not place the MMC on devices that radiate heat.*



CAUTION: *The MMC may be damaged if fluids are spilled on the outer enclosure.*

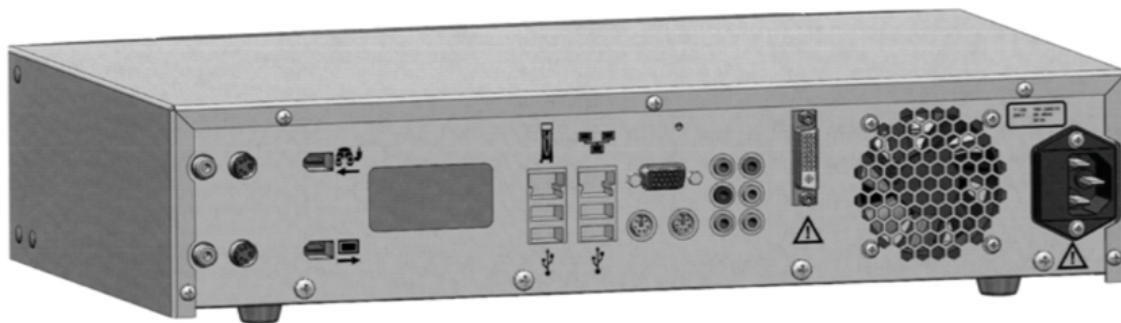


Figure 1.43. Multimedia Center (MMC) rear panel.

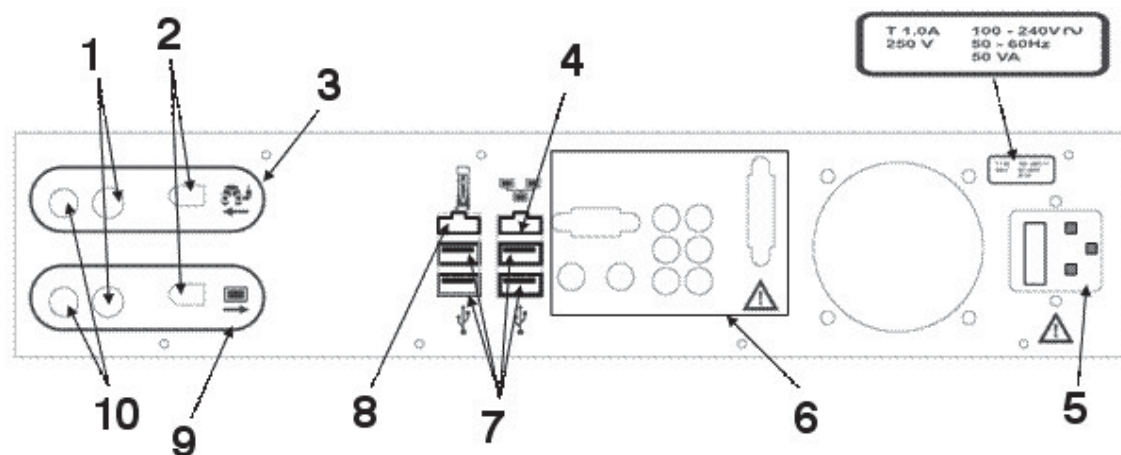


Figure 1.44. Labeled MMC Rear.

- 1. S-Video. 2. FireWire. 3. Input from Microscope camera.
- 4. Ethernet/TruLink® Customer Support Network Connector. 5. Power Input. 6. For Service Only.
- 7. USB Ports For Service Only. 8. Input from Stellaris® PC Vision Enhancement System.
- 9. Output to Display Monitor. 10. Composite Video.

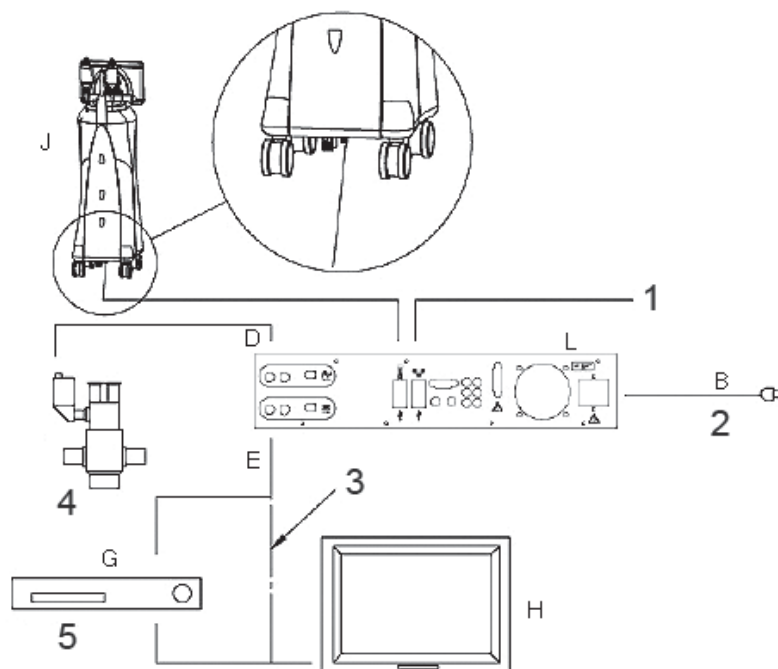


Figure 1.45. MMC connections.

- 1. Internet/Intranet Connection 2. AC Electrical Power Source 3. Optional Connection Without Recording Device 4. Video Camera (Not Supplied) 5. Optional Recorder (Not Supplied)

1. Connect the detachable power cord (B) to the MMC and plug it in to the AC power source.



WARNING: *Do not plug the MMC into multiple portable socket outlets or extension cords.*

2. Connect the video input cable (D) from the surgical microscope camera to the VIDEO IN connector (use the included RCA Plug to BNC Jack adapter if necessary) or S-VIDEO IN connector of the MMC (L).



WARNING: *The surgical microscope camera must be medical grade.*



Note:

The VIDEO IN connector requires that the camera output impedance be set to NORMAL or 75 OHMS if the camera has a switch setting or adjustment for output impedance.

3. Using the video output cable (E) provided with the MMC, connect the COMPOSITE VIDEO OUT or S-VIDEO OUT from the MMC (L) to the user supplied video monitor (H). If desired, the video cassette recorder (G) (per manufacturer's instructions for that equipment) may be connected between the MMC and monitor using user supplied cables. Use the included RCA Jack to BNC Plug adapter if necessary. The video monitor must be connected to the MMC before the MMC is powered up. If the MMC is powered up with no monitor or recorder connected, the video output with the overlay may not appear. The MMC must be powered down and powered up again with the monitor connected.



Note:

The COMPOSITE VIDEO OUT output must be used if the input video signal is connected via the COMPOSITE VIDEO IN connector. The S-VIDEO OUT output must be used if the input video signal is connected via the S-VIDEO IN connector.



WARNING: *The VCR and/or Monitor connected to the MMC must be medical grade or plugged into a medical grade isolation transformer.*

4. Attach the Ethernet cable on the back of the **Stellaris® PC** Vision Enhancement System Computer Unit (J). Attach the other end of the data communications cable to the Ethernet connector of the MMC (L) labeled with the **Stellaris® PC** Vision Enhancement System icon.



WARNING: *Connecting the MMC data communication cable to equipment other than the Stellaris® PC Vision Enhancement System may cause damage to both systems.*

5. Turn on the microscope camera and the video recorder and/or monitor.

User Interface

This chapter introduces you to the basic operation of the *Stellaris® PC* 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 seven different functions: posterior vitrectomy, Fluid/Air Exchange, coagulation, endoillumination, fragmentation, Air Forced Infusion and viscous fluid control. The combined domain includes all function from both domains.

2.1. Posterior & Combined Domain Interface Controls

Push Bar

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



Figure 2.1. Sample Push Button.

Option List


The Option List allows you to select an option. A small  next to a setting indicates that additional choices are available, and selecting the currently displayed option will bring up a list. Only one option can be selected at a given time. Selecting one option automatically deselects others.



Figure 2.2. Sample Option List.

Test Tube Display and Control

This control allows you to set the upper and lower limits of a system parameter.

For a linear setting, the maximum value is shown at the top of the tube, and the minimum value is shown at the bottom of the tube. The number in the middle of the tube shows the current value of that setting. The maximum and minimum values for that parameter may be increased or decreased by selecting the up and down arrows next to each of the numbers, respectively.

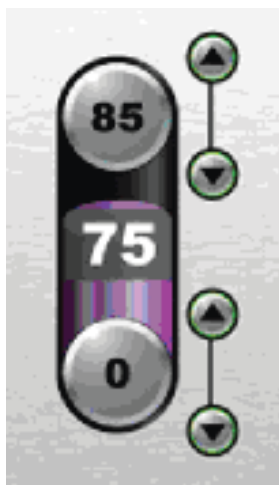


Figure 2.3. Sample Test Tube Display and Control for ranged parameters.

For a system parameter that has a fixed value instead of a range, the value on the top of the tube will represent the current setting when that function is not active, and the actual value when the function is active. Arrows on the tube itself will allow you to increase or decrease the value of the parameter.



Figure 2.4. Sample Test Tube display for fixed value parameters.

On/Off Button

A small on/off button will be displayed on the screen near the function indicator. A green ring around the button indicates the function is on, while no ring indicates the associated function is off.



Figure 2.5. On/Off button.

Progress Bar

This graphic shows the progress of execution of a command.



Figure 2.6. Sample Progress Bar.

Numeric Keypad

Touching the numeric display on a test tube button brings up the numeric keypad. The keypad allows you to rapidly enter numerical surgical settings or change settings. Enter a number by touching the proper numeral(s), then selecting **Enter** to make the change. When a surgical function is active, the keypad for settings associated with that function will be disabled.

If you are entering data into the numeric keypad and activate the Foot Control, the numeric keypad will disappear.

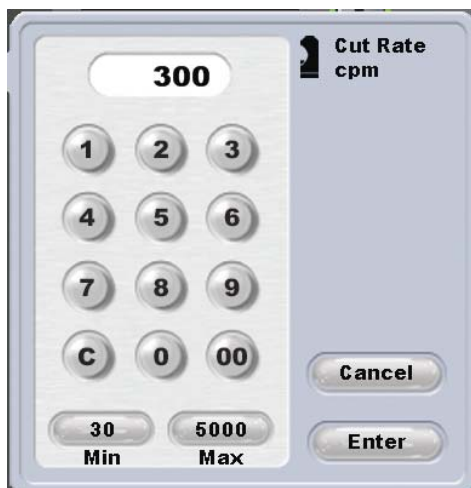


Figure 2.7. Numeric Keypad.

Keyboard

Sometimes you will need to enter alphabetical or numeric data into the *Stellaris*® *PC* 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.



Figure 2.8. Keyboard.

Character Lengths

When naming functions, there is a limit to the number of characters that can be used. That limit is the lesser of the number of characters in the table below, or the number of characters displayable in the corresponding area on the screen.

Function	Maximum Characters
Mode	8
Technique	20
Submode	20
Pathology	20
Surgeon	30

Eject Cassette

To eject the fluidics cassette, select the upward pointing arrow to the left of the cassette icon, shown below.

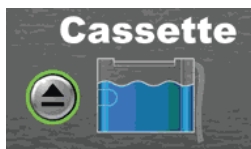


Figure 2.9. Eject Cassette button.

Foot Control Indicator

The image of the Foot Control on the screen shows the status of the Foot Control Operation. The yellow dots indicate that the Footpedal Yaw is activated. The numeric display on the pedal indicates the Footpedal position.



Figure 2.10. Foot Control Indicator.

Pop-Up Message Window

This type of window displays error and warning messages. You should take the appropriate action before continuing system operation. Nothing else can be done on the screen while a pop-up window is on the screen. The surgeon may be able to continue with the procedure once the error has been rectified.

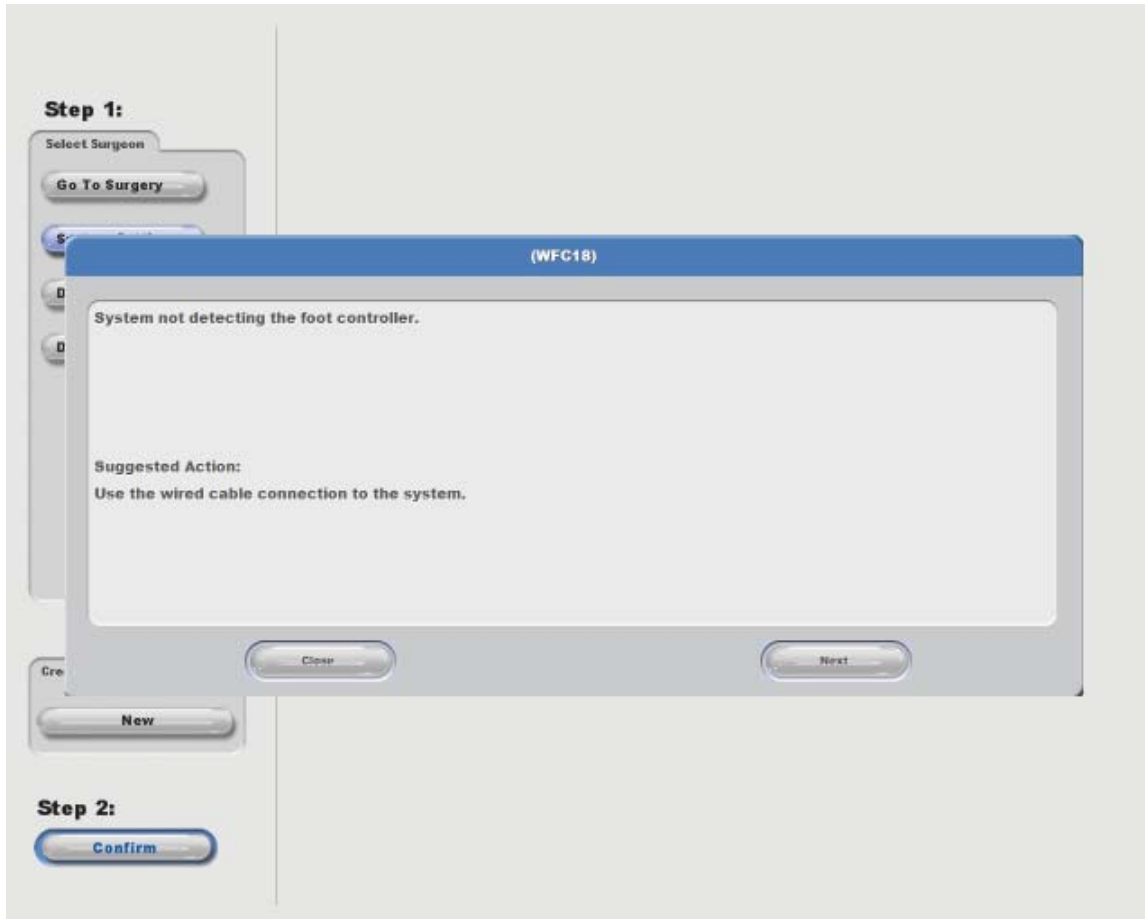



Figure 2.11. Sample Pop-Up Message Window.

For each message displayed, suggested actions to resolve the condition are displayed. If more than one suggested action is available, pressing the **Next** button will cycle through all possible suggested actions. Pressing the **Close** button will remove this window.

2.2. Posterior and Combined Domain Surgical Information More Settings Screens

More Settings Screens allow easy access to all system parameters.

In the posterior and combined domains, pressing the More Settings Screen button  will cause a tabbed window (the More Settings Screen) to appear, through which system settings and parameters can be changed. The specific More Settings Screen options available at any given time will depend on the current surgical domain and phase, as detailed in the table below.

If a setting has been changed in a More Screen, the text will be blue (instead of black) to highlight the modification. Once the change is saved, the text will turn black.

Posterior and Combined Domain Modes	Tabs Displayed on More Settings Screen	
Setup with Linear Coagulation	Coag, Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.12.
Setup without Linear Coagulation	Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.13.
Vitrectomy	Cut, Vacuum, Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.14.
Anterior Vitrectomy	Cut, Vacuum, Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.15.
Phaco	U/S, Vacuum, Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.16.
Frag	U/S, Vacuum, Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.17.
Viscous Fluid Control	Visc, Infusion, Illuminators, Foot Control, A/V, Messages. When the Dual/Yaw Vac submode is selected on the popup, the Vacuum tab is also displayed.	Figure 2.18.
Extrude	Vacuum, Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.19.
I/A	Vacuum, Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.20.
Irrigation	Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.21.
Linear Coagulation	Coag, Infusion, Illuminators, Foot Control, A/V, Messages	Figure 2.22.



Each More Settings Screen has a dropdown submode selection window , as well as Save, Save As and Cancel () buttons. Selecting **Save As** allows you to save the new parameters to a particular surgeon, technique and gauge file.



Figure 2.12. Setup Screen with Linear Coagulation function active.

The screenshot displays a medical device setup interface with a dark blue header bar containing 'Save As', 'Save', and a close button. Below the header is a tabbed menu with 'Infusion', 'Illuminators', 'Foot Control', 'A/V', and 'Messages'. The 'Infusion' tab is active, showing various settings panels. The 'Infusion Units' panel has a dropdown set to 'mmHg'. The 'Infusion Pressure mmHg' panel has a value of 30. The 'Irrigation Delay ms' panel has a value of 250. The 'Surgeon Settings' panel includes 'BSS Container Type' (500 ml Bag), 'Patient Eye Level' (0), 'Air Port' (Front), and 'Posterior Infusion Type' (Auto On). The 'System Settings' panel has 'Max IV Pole Height cm' set to 140. The 'Technique Settings' panel includes 'Infusion Type' (IV Pole), 'F/AX mmHg' (30), 'Elevated Infusion mmHg' (44), and 'Elevated F/AX mmHg' (60). All numerical values are displayed in circular buttons with up/down arrows.

Section	Parameter	Value
Infusion	Infusion Units	mmHg
	Infusion Pressure mmHg	30
	Irrigation Delay ms	250
Surgeon Settings	BSS Container Type	500 ml Bag
	Patient Eye Level	0
	Air Port	Front
	Posterior Infusion Type	Auto On
System Settings	Max IV Pole Height cm	140
Technique Settings	Infusion Type	IV Pole
	F/AX mmHg	30
	Elevated Infusion mmHg	44
	Elevated F/AX mmHg	60

Figure 2.13. Setup Screen without Linear Coagulation function active.

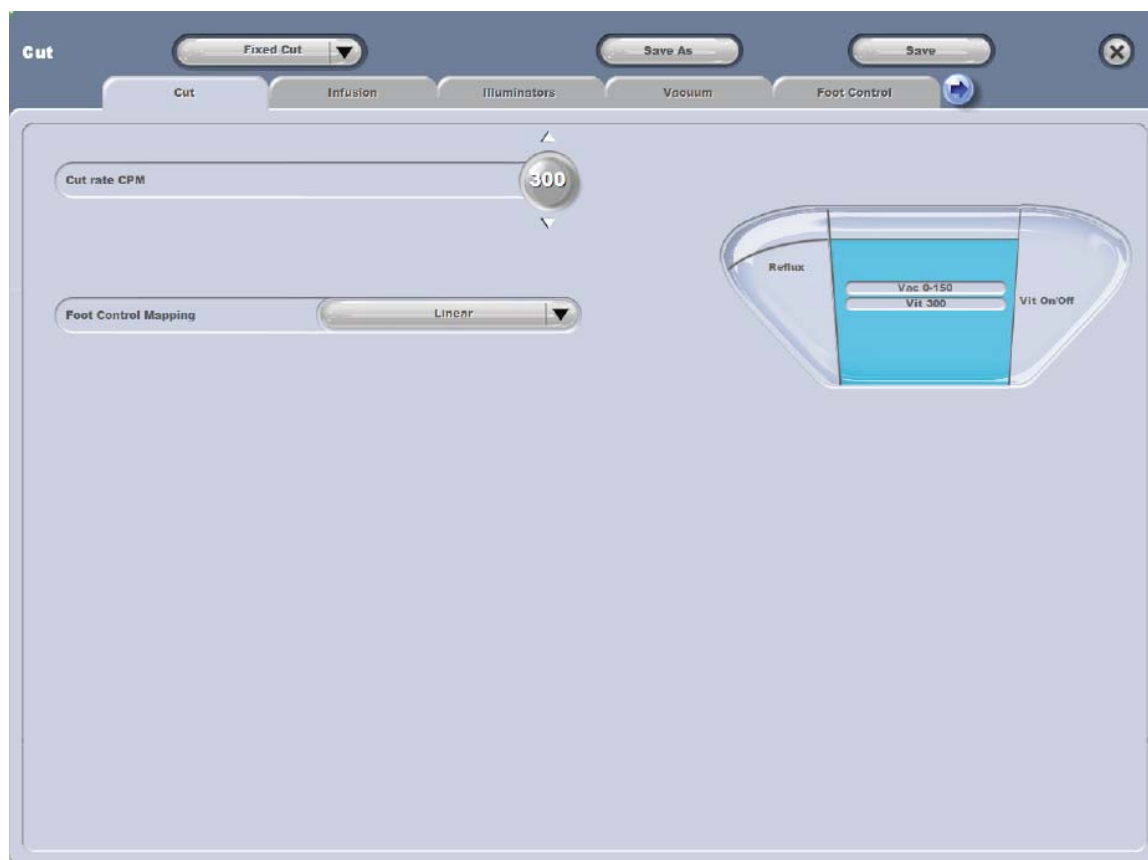


Figure 2.14. Vitrectomy Cut More Settings Screen tab.

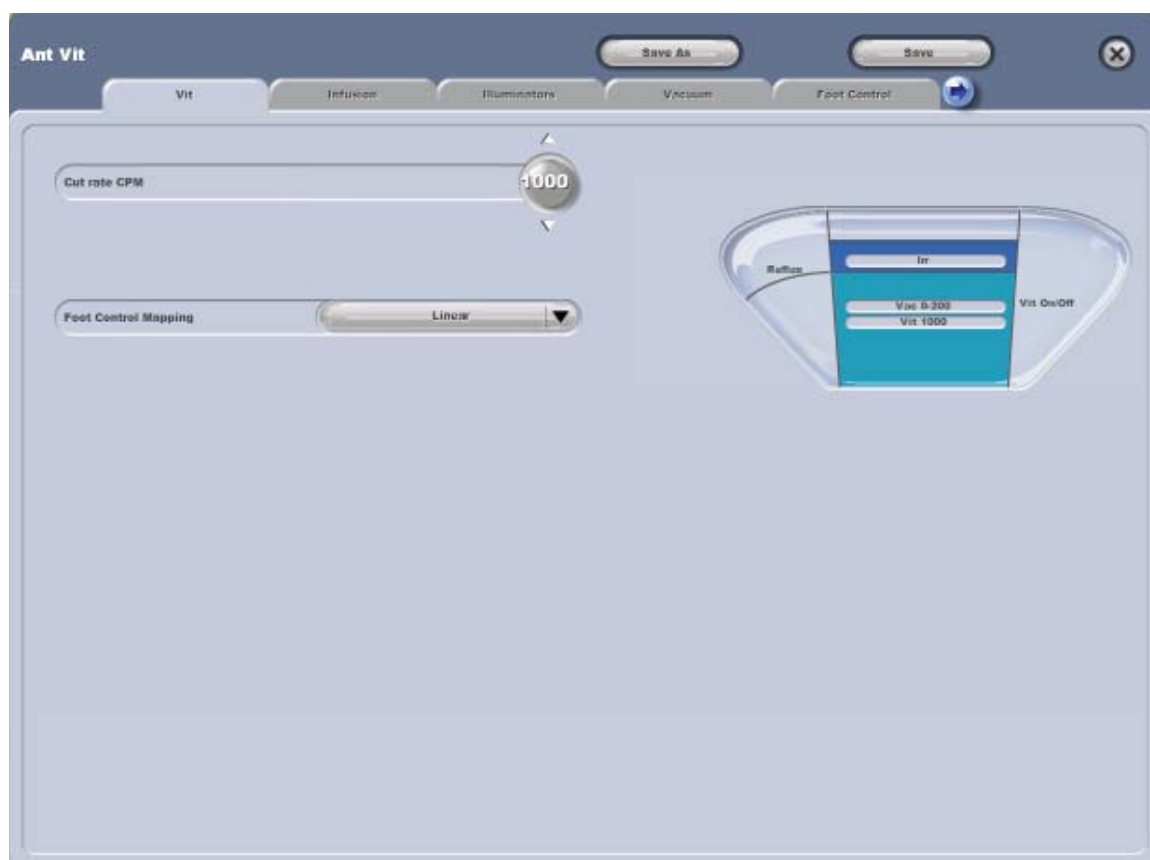


Figure 2.15. Anterior Vitrectomy More Settings Screen tab.

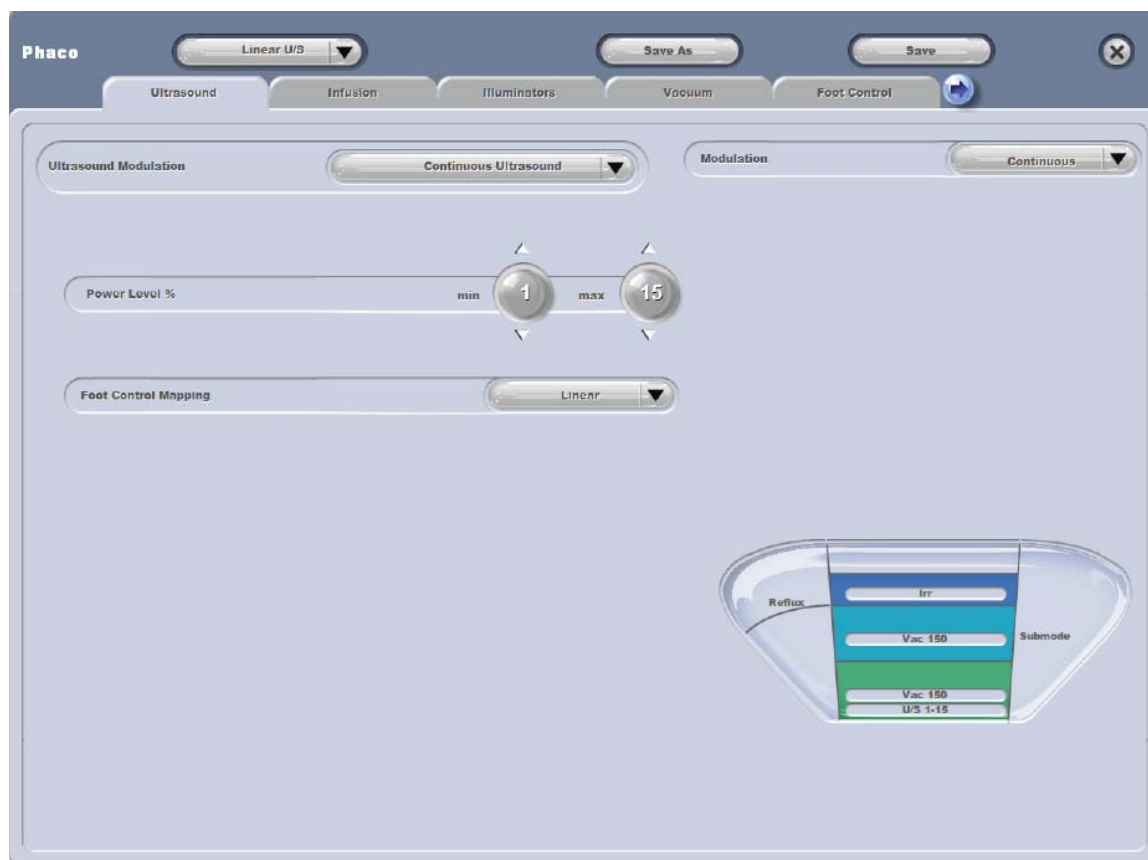


Figure 2.16. Phaco More Settings Screen tab.

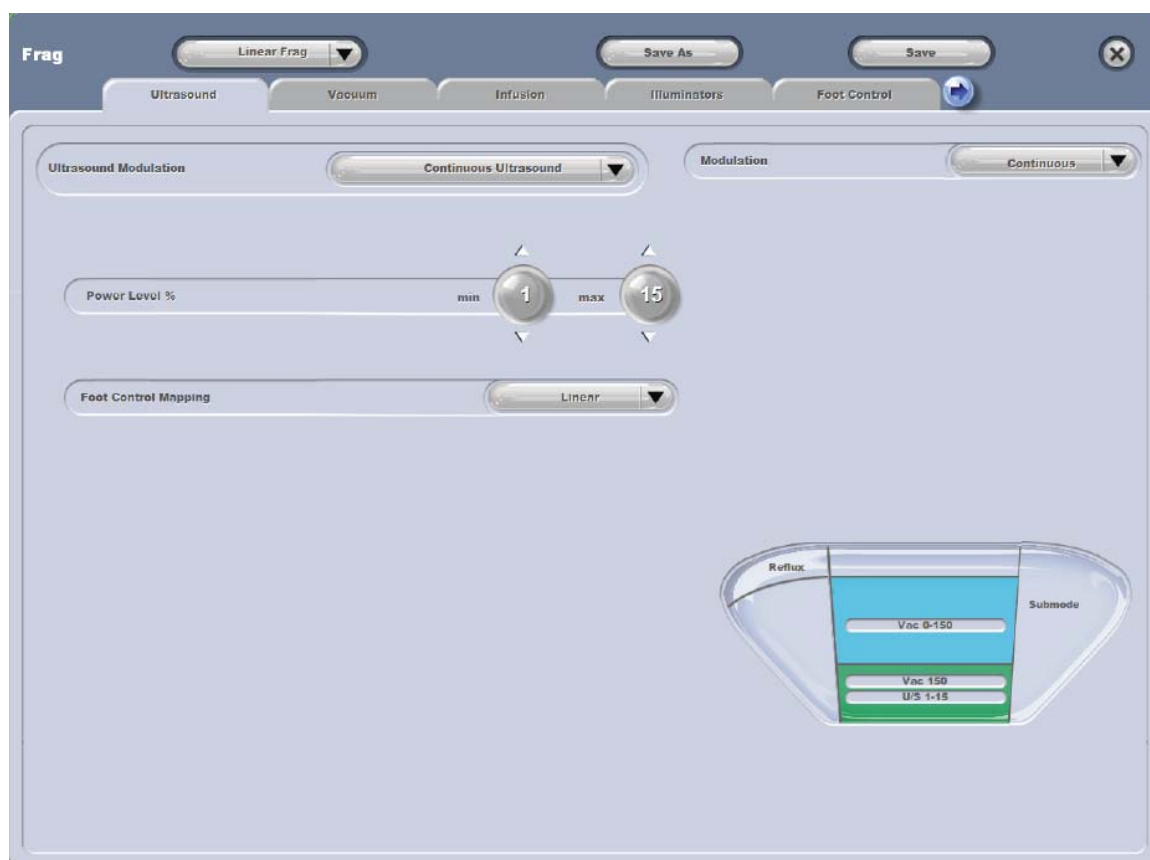


Figure 2.17. Ultrasound More Settings Screen tab for Fragmentation.

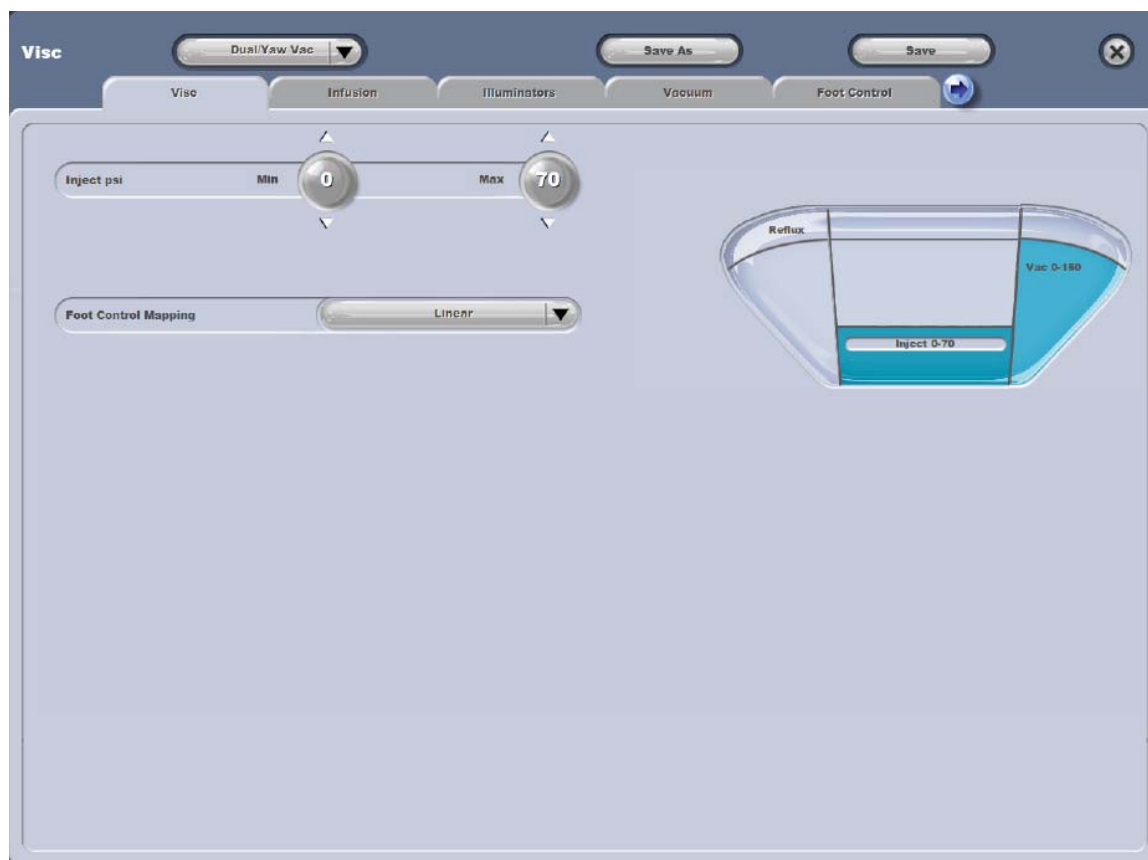


Figure 2.18. Viscous Fluid Control More Settings Screen tab.

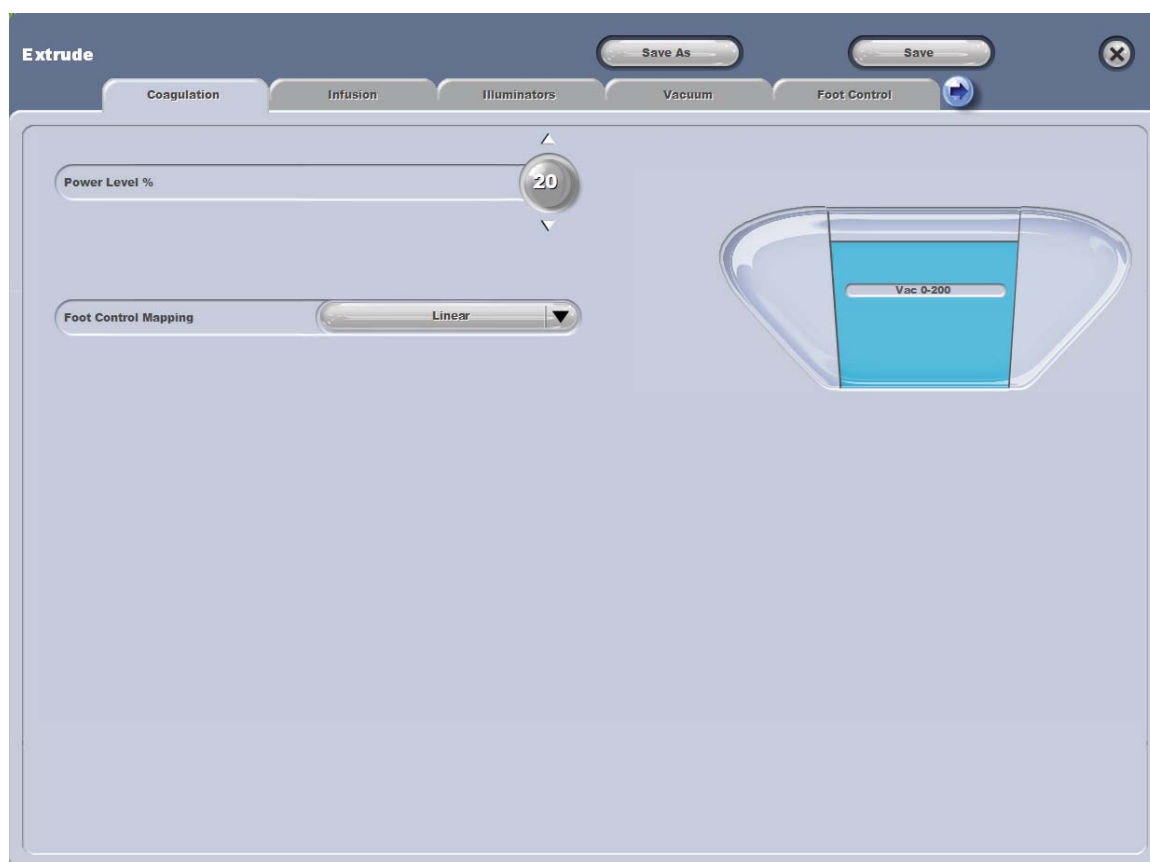


Figure 2.19. Extrude More Settings Screen tab.

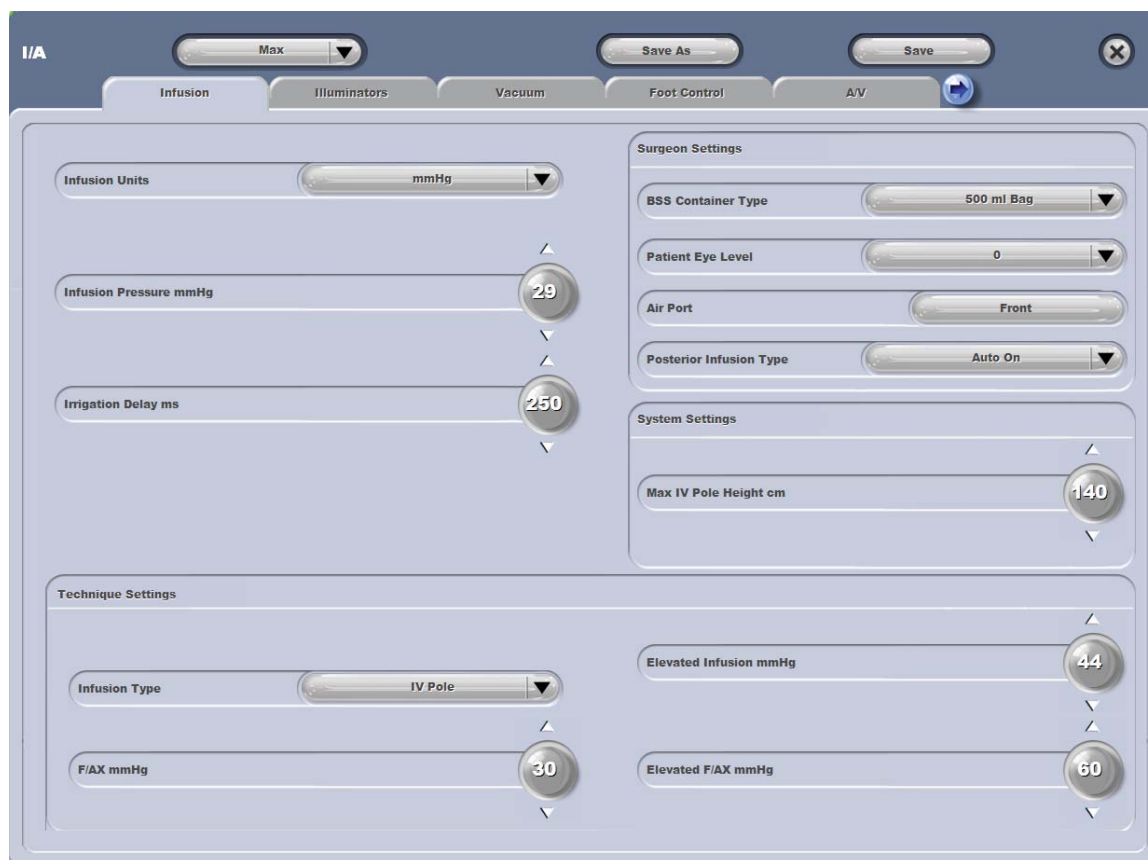


Figure 2.20. I/A More Settings Screen tab.



The screenshot displays the 'Irrigation' settings screen with a dark blue header bar. The header contains the title 'Irrigation' on the left, and 'Save As' and 'Save' buttons on the right, along with a close button (X). Below the header is a tabbed interface with five tabs: 'Infusion' (selected), 'Illuminators', 'Foot Control', 'A/V', and 'Messages'. The main content area is divided into several sections. On the left, under the 'Infusion' tab, there are three settings: 'Infusion Units' set to 'mmHg', 'Infusion Pressure mmHg' set to 33, and 'Irrigation Delay ms' set to 250. On the right, there are two sections: 'Surgeon Settings' and 'System Settings'. 'Surgeon Settings' includes 'BSS Container Type' set to '500 ml Bag', 'Patient Eye Level' set to 0, 'Air Port' set to 'Front', and 'Posterior Infusion Type' set to 'Auto On'. 'System Settings' includes 'Max IV Pole Height cm' set to 140. At the bottom, there is a 'Technique Settings' section with four settings: 'Infusion Type' set to 'IV Pole', 'Elevated Infusion mmHg' set to 44, 'F/AX mmHg' set to 30, and 'Elevated F/AX mmHg' set to 60. All settings are displayed with a slider control and a numerical value.

Section	Setting	Value
Infusion	Infusion Units	mmHg
	Infusion Pressure mmHg	33
	Irrigation Delay ms	250
Surgeon Settings	BSS Container Type	500 ml Bag
	Patient Eye Level	0
	Air Port	Front
	Posterior Infusion Type	Auto On
System Settings	Max IV Pole Height cm	140
Technique Settings	Infusion Type	IV Pole
	Elevated Infusion mmHg	44
	F/AX mmHg	30
	Elevated F/AX mmHg	60

Figure 2.21. Irrigation More Settings Screen tab.

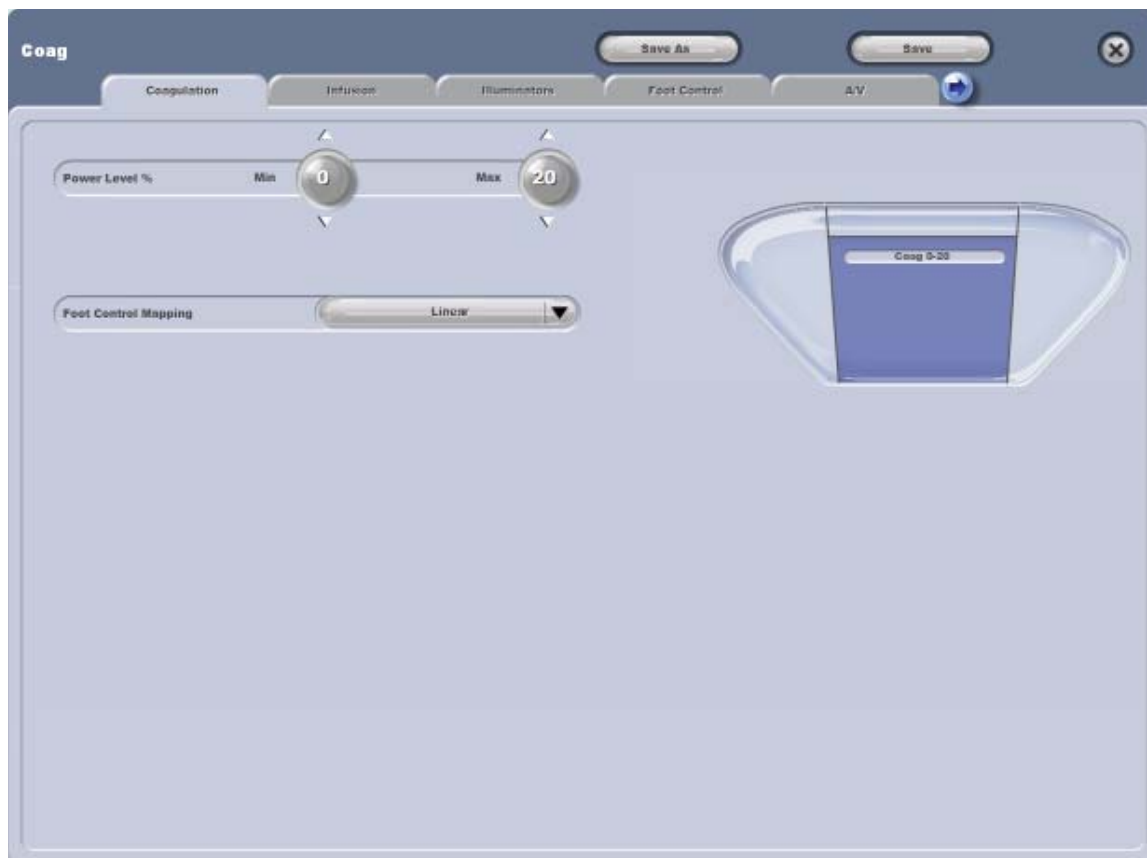


Figure 2.22. Linear Coagulation More Settings Screen tab.

Vacuum More Settings Screen Tab

The Vacuum More Settings Screen tab has options that control the maximum and minimum vacuum allowed, venting, method, and mapping of these options to the Foot Control.

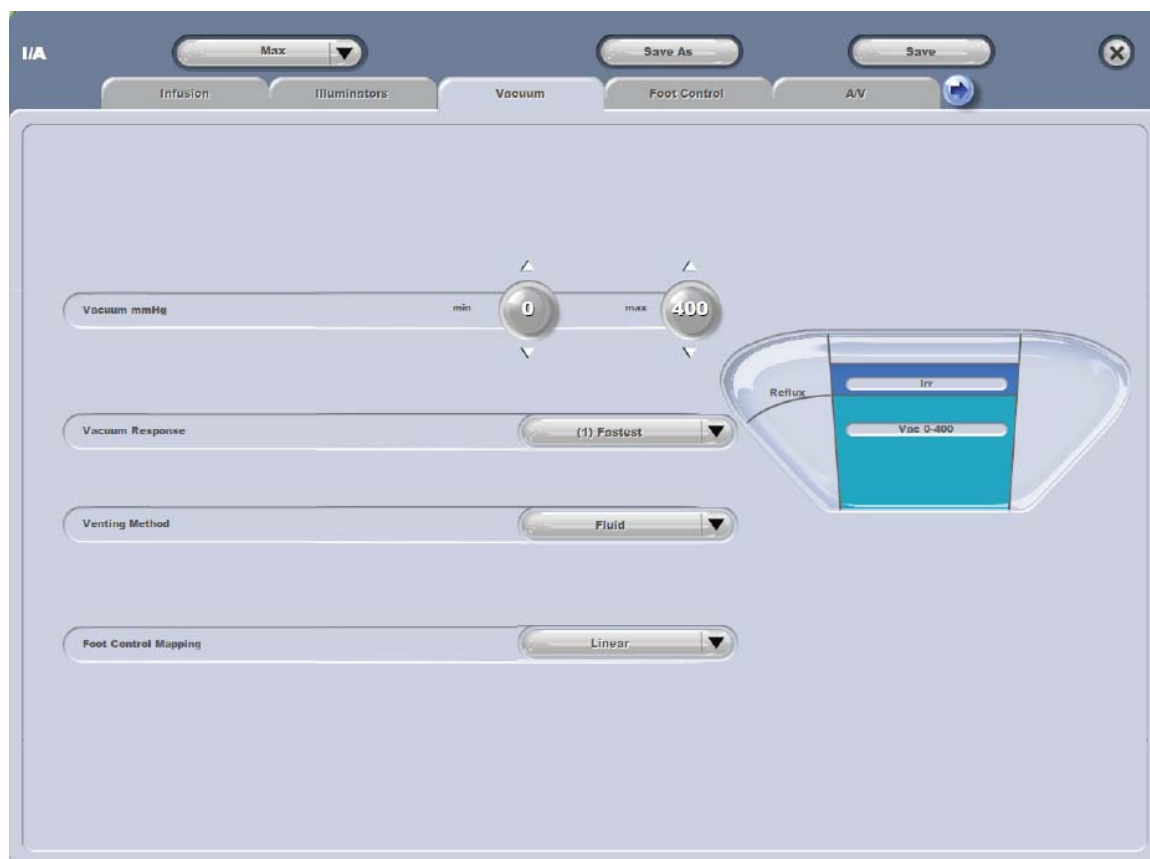


Figure 2.23. Vacuum More Settings Screen Tab.

Ultrasound More Settings Tab

The Ultrasound More Settings Screen tab shows the current modulation status and power level. Depending on which type of ultrasound you are currently using, you may also see power level, number of pulses per second (PPS), duty cycle (DC), burst duration (BD), and pulse interval (PI), waveform type, waveform depth, waveform duration and Foot Control preview. You can adjust any of these settings.

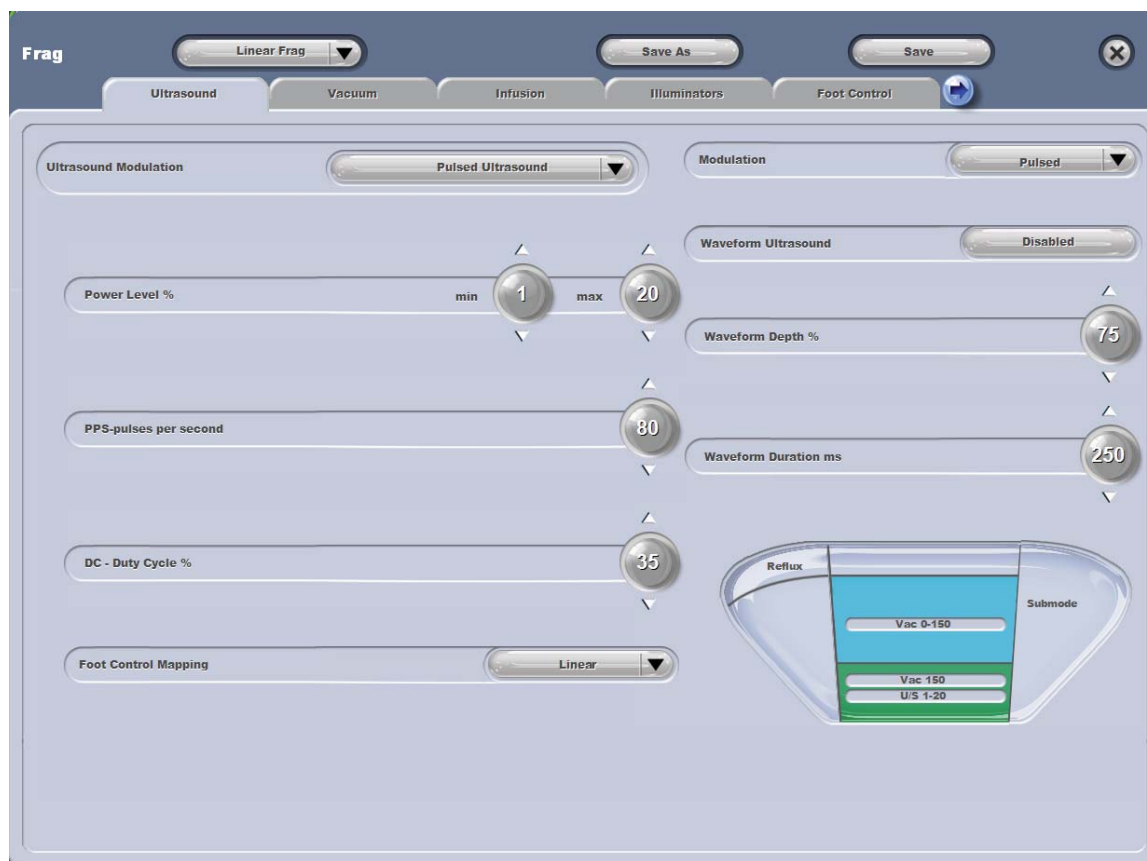


Figure 2.24. Fragmentation More Settings Screen Tab.

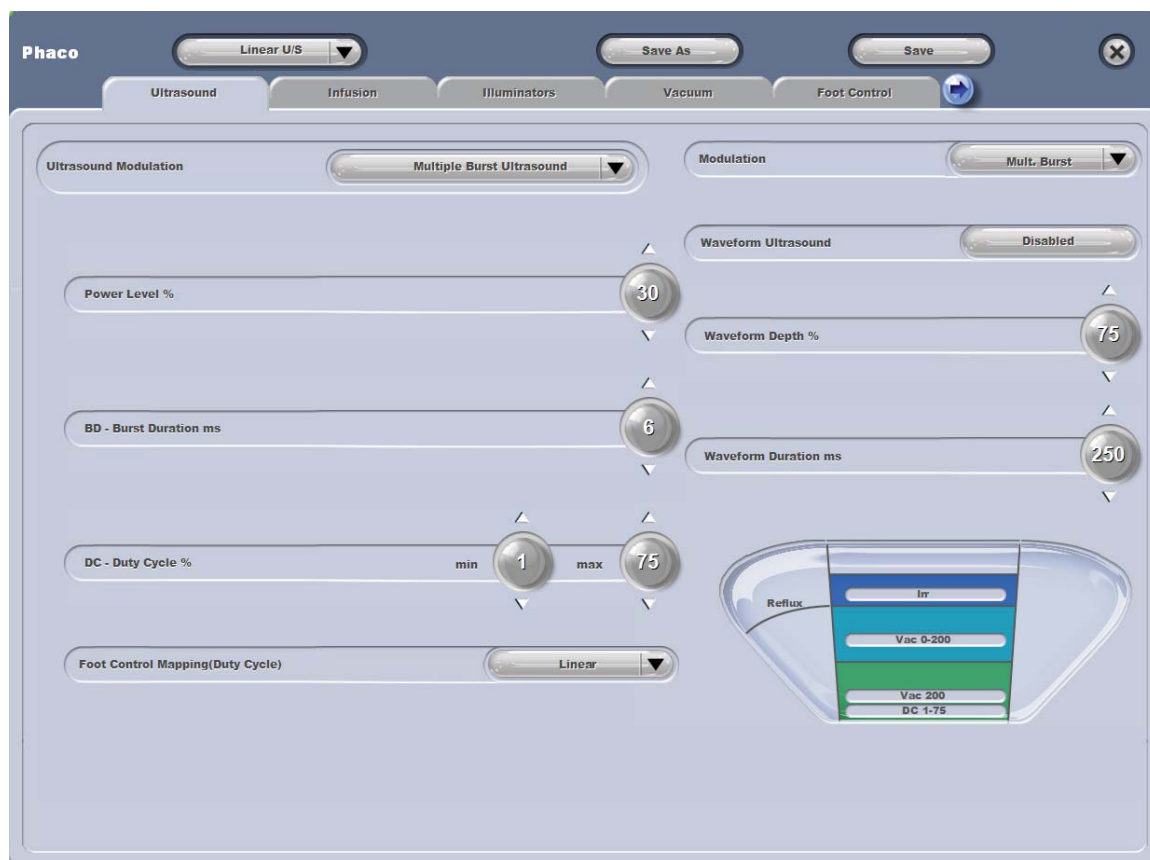


Figure 2.25. Phaco More Settings Screen Tab.

Coagulation More Settings Screen Tab

The Coagulation More Settings Screen tab shows the current minimum and maximum power levels, and the Foot Control mapping mode. You can adjust either power level setting.

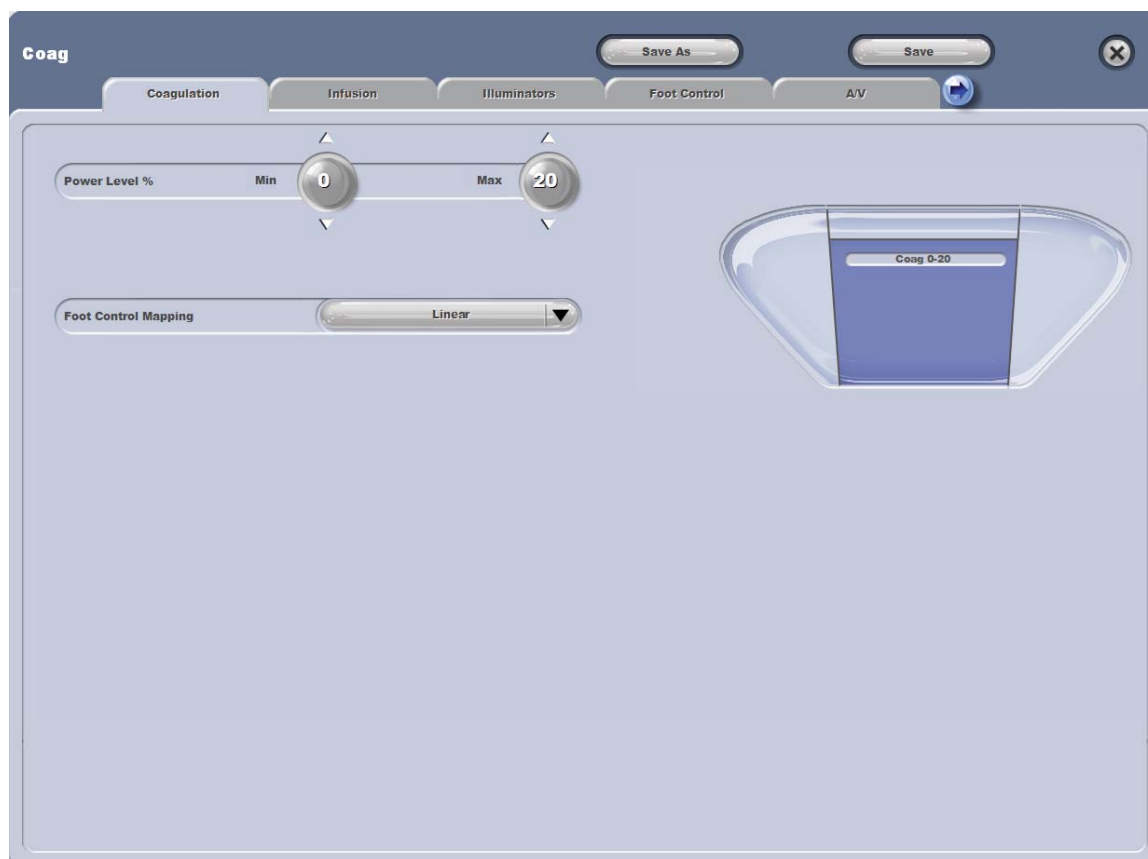


Figure 2.26. Coagulation More Settings Screen tab.

Cut More Settings Screen Tab

The Cut More Settings Screen tab shows the current settings for the minimum and maximum CPM (cuts per minute). You can adjust either setting. The current Foot Control preview is also shown. For submodes with fixed cutting, only one cut rate will be displayed. For Anterior Procedures, Foot Control mapping is not adjustable from this popup.

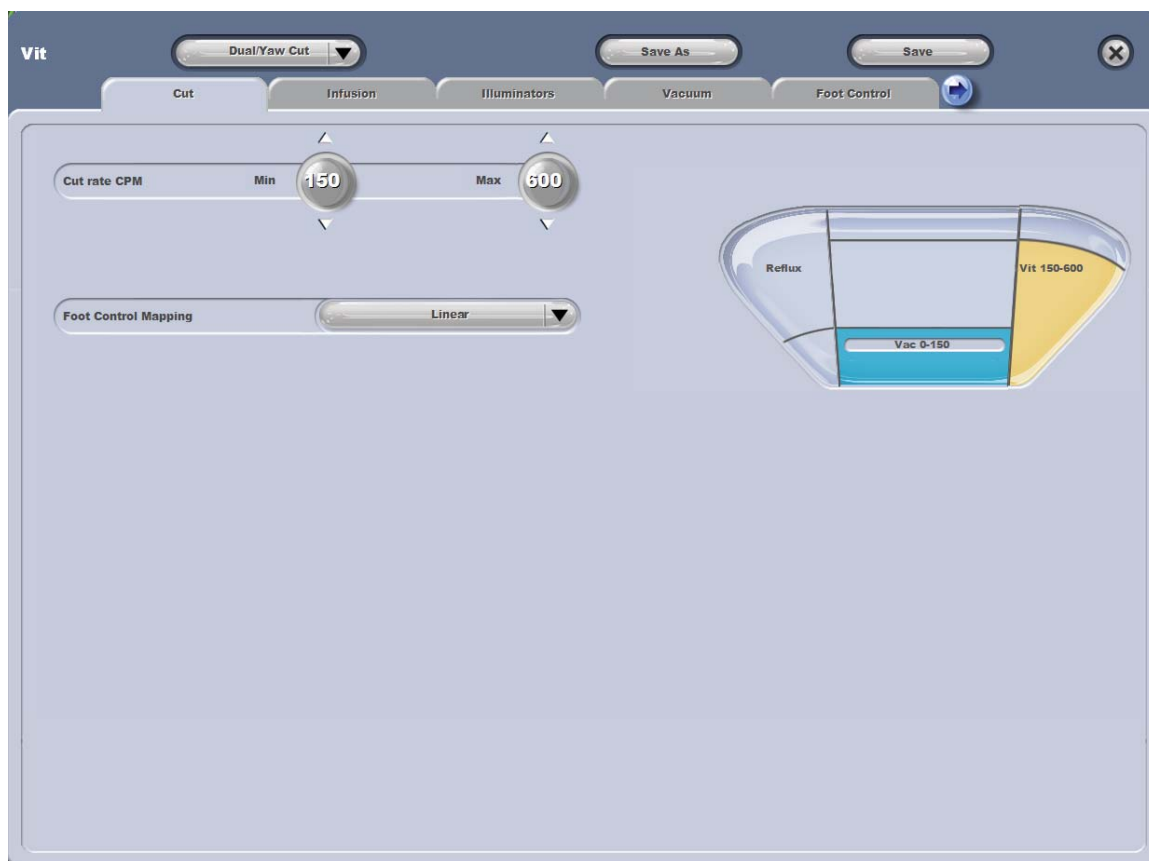



Figure 2.27. Cut More Settings Screen Tab.

Footpedal More Settings Screen Tab

The **Footpedal More** Settings Screen tab has three buttons that allow you to view and edit Settings, Regions, and the Status of the Foot Control. These functions are described in detail in the Foot Control section (see page 1-40).

The **Settings Button** shows the current status of the Foot Control switches, right or left foot operation, Dual Linear Control, Mode Change Control, Next U/S (Ultrasound) Modulation on Yaw, Reflux Type, and Fixed Coag Power. Selecting  next to any of these options will open a list of additional selectable options.

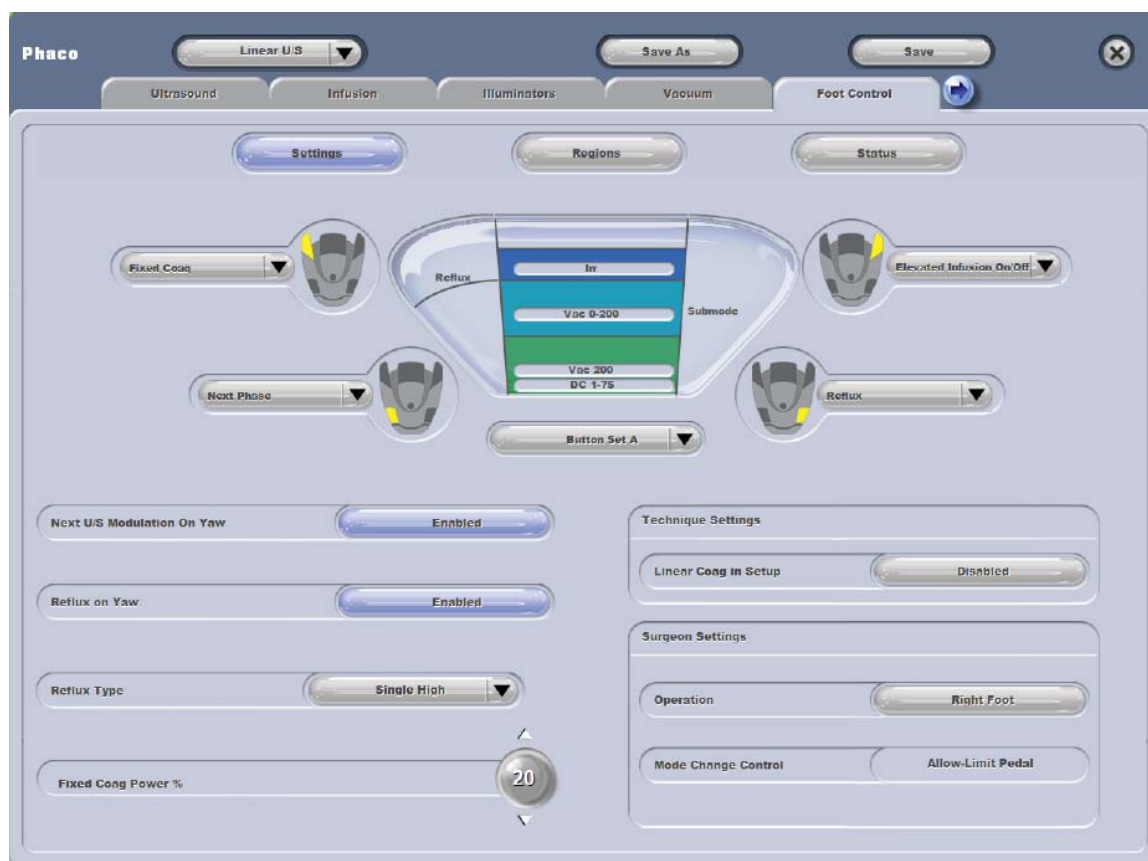


Figure 2.28. Footpedal More Settings Screen Tab.

Select Default Button Grouping in the middle of the screen (at arrow) provides a selection of default button groupings for toe/heel Foot Control buttons. The default button groupings are shown in the table below.

Foot Control Switches default configuration	Upper Left	Lower Left	Upper Right	Lower Right
A	Fixed Coagulation	Next Phase	Elevated Infusion On/Off	Reflux
B	Irrigation On/Off (anterior) or Fixed Coagulation (posterior/combined)	Confirm Settings	Increment bottle height (anterior) or Increment Infusion Pressure (Posterior and Combined)	Decrement bottle height (anterior) or Decrement Infusion Pressure (Posterior and Combined)
C	Fixed Coagulation	Irrigation On/Off	None	None
D	Fixed Coagulation	None	Irrigation On/Off	None

When the foot control button is programmed to change infusion pressure, pressing on the button will change infusion settings until it is released.

2 User Interface

The **Regions** button shows the current settings for the footpedal pitch regions and detent options. You can modify the starting depression position for each region.

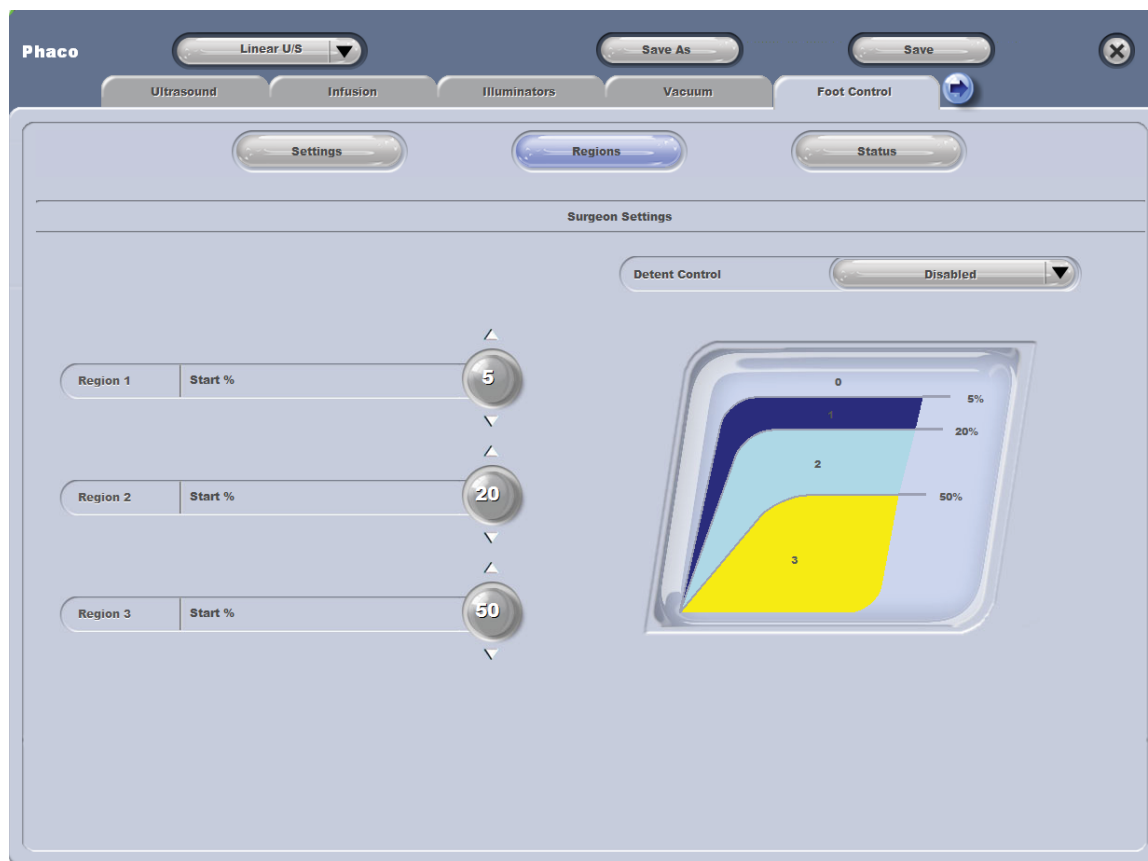


Figure 2.29. Footpedal More Settings Screen tab (Regions button).

The **Status button** shows the current status of several footpedal options, including communication status, battery status, and signal strength.

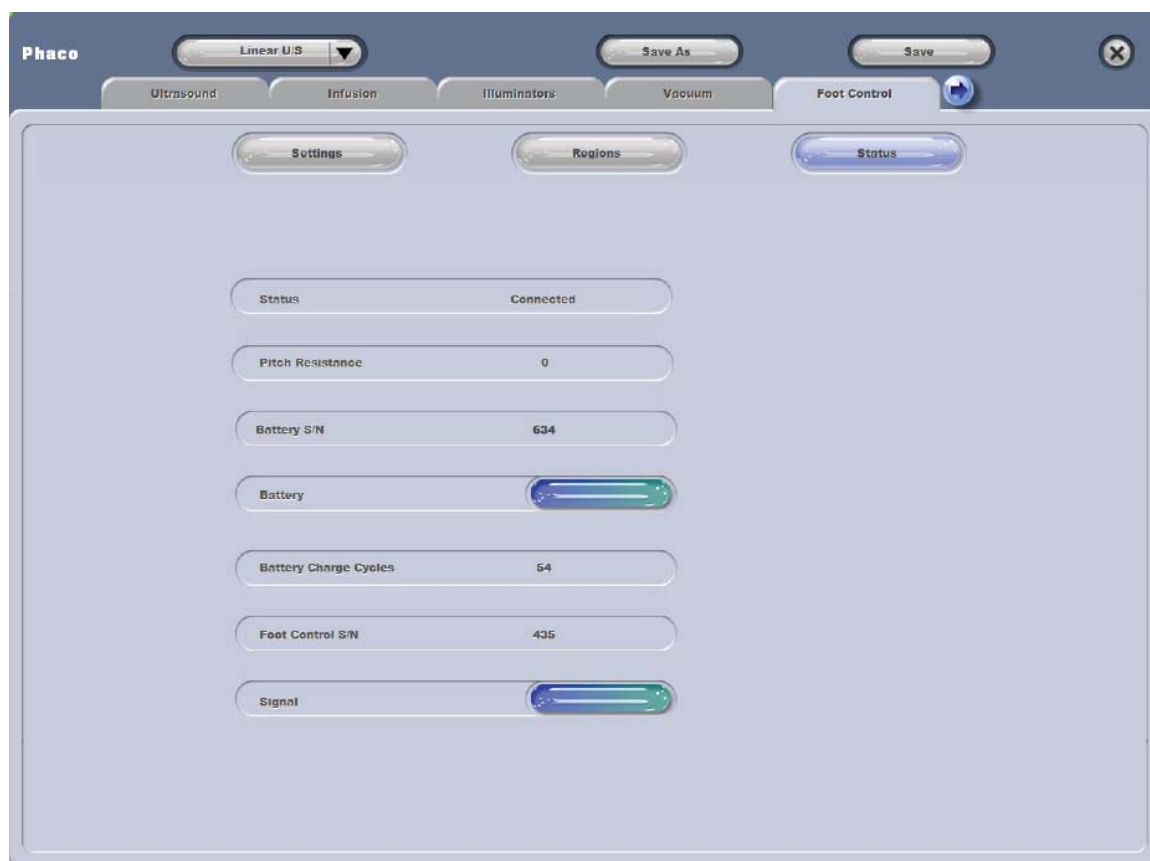


Figure 2.30. Footpedal More Settings Screen tab (Status button).

A/V More Settings Screen Tab

The A/V More Settings Screen tab has three buttons that allow you to change many aspects of the audio and visual displays. Each button allows you to change the settings and configuration for aspects of the display.

The **Audio** button allows you to control the master volume for the system, as well as the specific tone and volume used for each of the following events: Irrigation, Vacuum, Occlusion, Ultrasound, Coagulation, Vitrectomy, and Alert. 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.

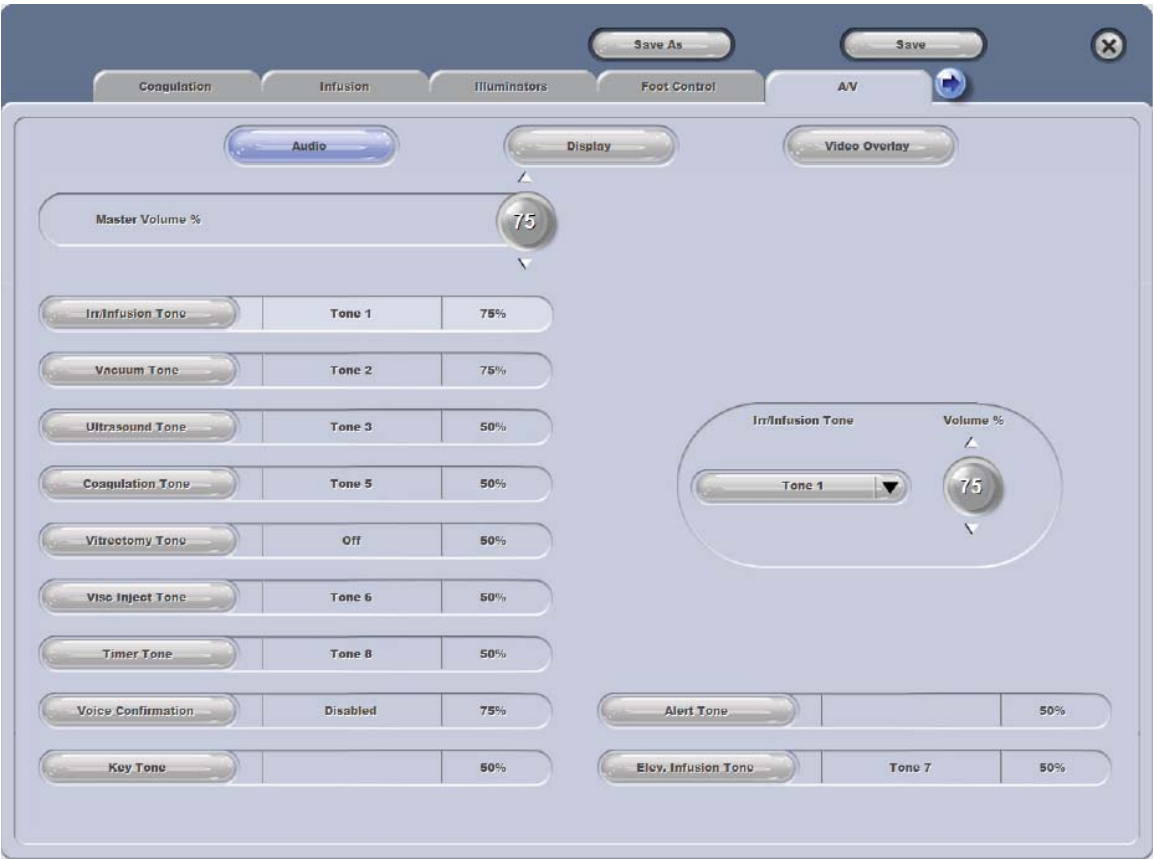


Figure 2.31. A/V More Settings Screen tab, Audio button.

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 available for selection.

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

The **Display button** control allows you to adjust the screen brightness, change the display format level, and select the system language, as shown below.



Figure 2.32. A/V More Settings Screen tab, Display button.

2 User Interface

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

You can also set whether or not the system will combine Video Overlay Format information, such as U/S Averages, settings, and case 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 cycle through the three values. Similarly, settings are normally displayed on four lines, and case information on two lines, but if the combine option is set to **Yes** each will appear on one line that will cycle through the values.

Finally, you can set the video overlay overscan in one degree increments from 0% to 5%. Setting the overscan to 0% would maximize the display area of the display monitor.

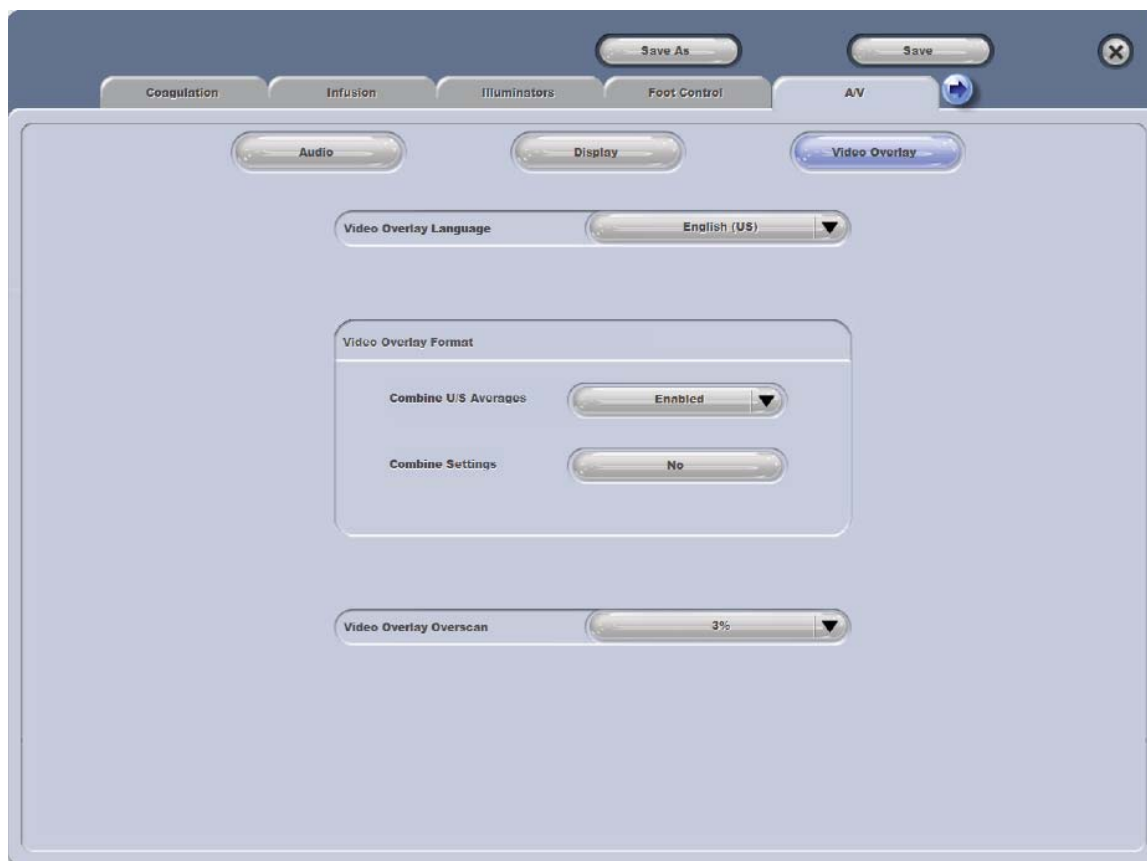


Figure 2.33. A/V More Settings Screen tab, Video Overlay button.

Viscous Fluid Control More Settings Screen Tab

The Viscous Fluid Control Settings Screen tab allows control of parameters for both injection and extraction. The appearance of this screen will differ slightly depending on the current submode. Injections will show minimum and maximum psi, and extractions will show minimum and maximum mmHg. The Foot Control preview will only appear when the fluid exchange is linearly controlled.

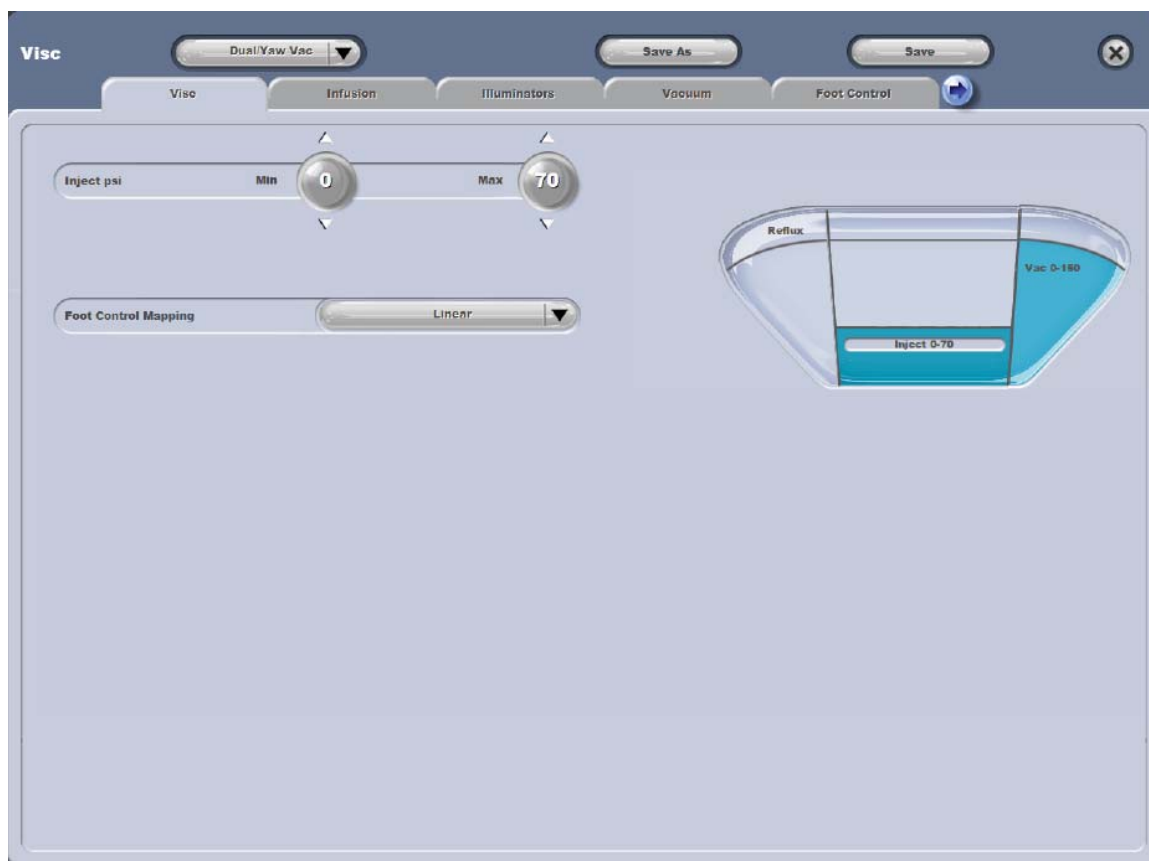


Figure 2.34. Viscous Fluid Control More Settings Screen tab.

Infusion More Settings Screen Tab

The Infusion More Settings Screen tab allows control of parameters related to infusion, the IV pole, and pressurized air output port selection.

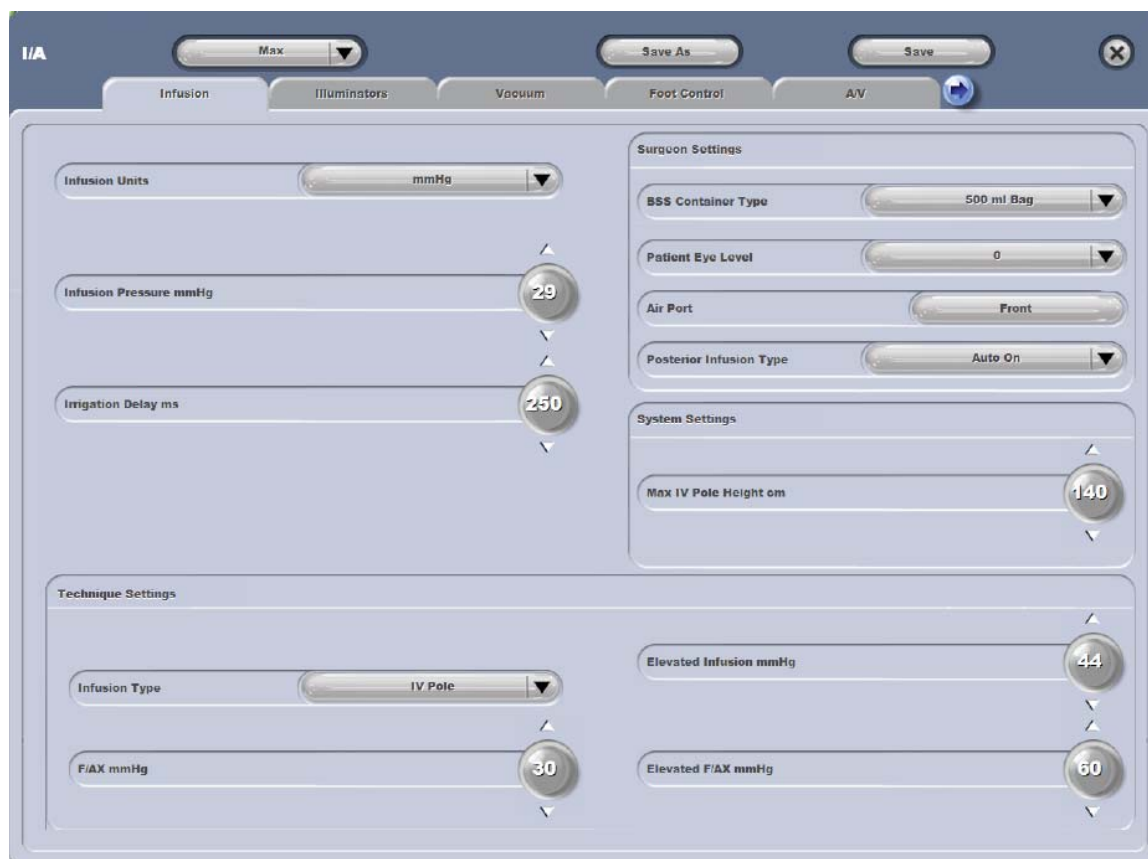


Figure 2.35. Infusion More Settings Screen tab.

Illuminator More Settings Screen Tab

The Illuminator More Settings Screen tab allows you to control the settings for the fiber optic illuminator, including range and filter usage.

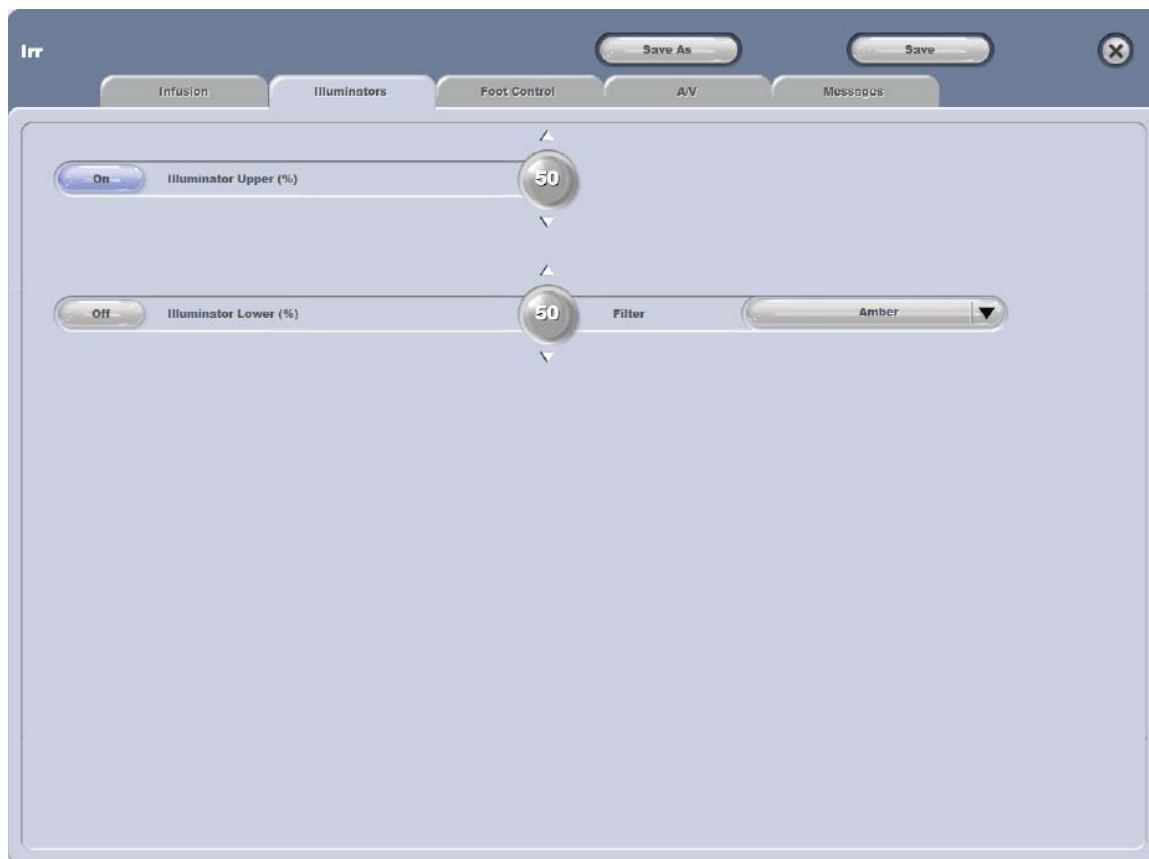


Figure 2.36. Illuminator More Settings Screen tab.

2.3. Posterior and Combined Domain Surgical Screen Layouts



Note:

Following the successful completion of Prime and Tune, the system will transition to the Surgical Screen with a dark background for posterior surgical modes. Selecting Advance to Surgery from the Setup Screen would produce the same result. For Anterior modes, the background will remain light grey.



Note:

Voice confirmation (if enabled) responds to Foot Control and remote operation and on-screen buttons.

Clock Menu



Figure 2.37. Clock Menu.

The round **Clock Menu** in the middle of the screen can display up to 12 phases—eight normal phases and four exceptions. The exceptions appear on the left side of the clock menu, against a darker background. These are user-defined to be any mode type (Irrigation only, Ultrasound, Irrigation/Aspiration, Vitrectomy, Coagulation or Viscous Fluid Control (VFC)). The **Setup** and **End** are the system function keys in the clock menu to move from surgical display screen to Setup and End Screens.

The global functions of bottle height, Fluid/Air Exchange, air forced infusion, illumination and fixed coagulation do not appear in the clock menu. Sample screens with clock menus are shown in Figure 2.38 and Figure 2.39.

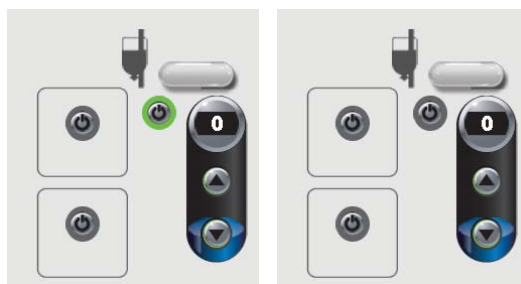


Figure 2.38. Vitrectomy Surgical Screen in Posterior Domain.



Note: When the case option is disabled in programming, the surgical screen status bar will not show the case selection button.

When using Air Forced Infusion in the posterior and combined domains; the air pump can be turned On/Off in the Surgical or Setup screen. When the air pump is off, aspiration will be disabled.



Air Pump On/Off button. On state (left) has green light.

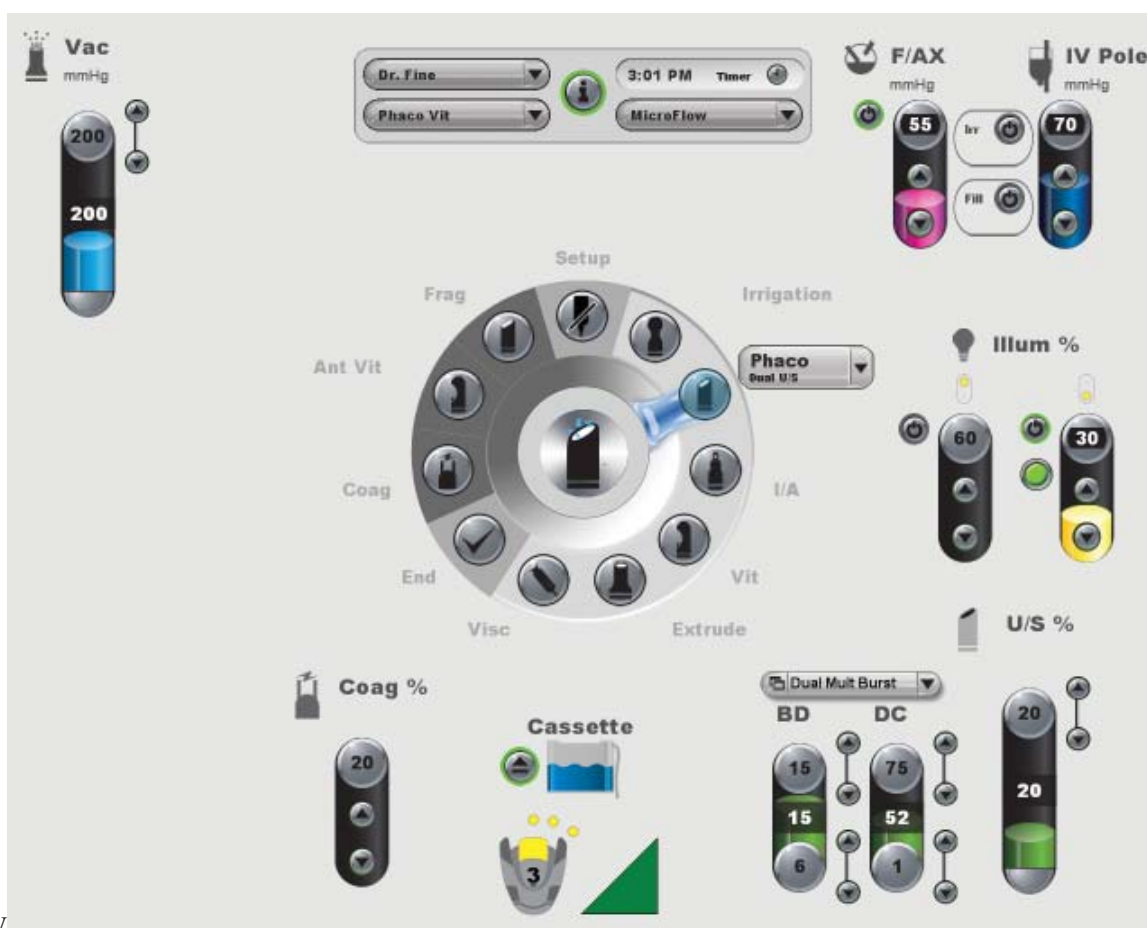


Figure 2.39. Phaco Surgical Screen in Combined Domain.

If you have the optional MMC system installed, the center of the **Clock Menu** will show the video from the microscope camera, when video is available. You can touch the video itself to switch between small and large video display formats.

Note the small on/off buttons (🔌) next to some functions on the Surgical Screens. When the ring around the button is green, the function is on. When the ring is grey, the function is off. Note that Fluid/Air Exchange and air forced infusion (AFI) are toggled - when one function is on, the other is off.

See Chapter 3 for details on customizing your system.

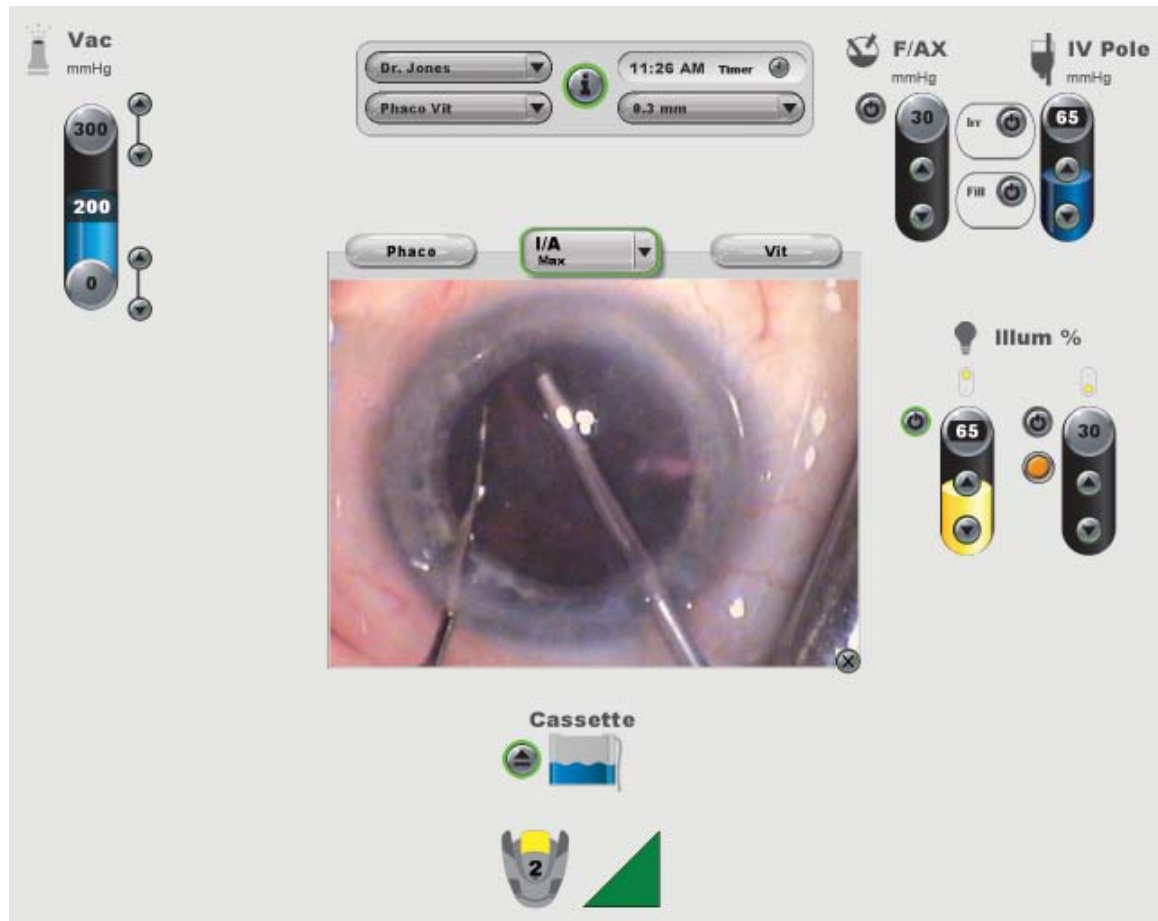


Figure 2.40. Large Video Combined Surgery Screen.

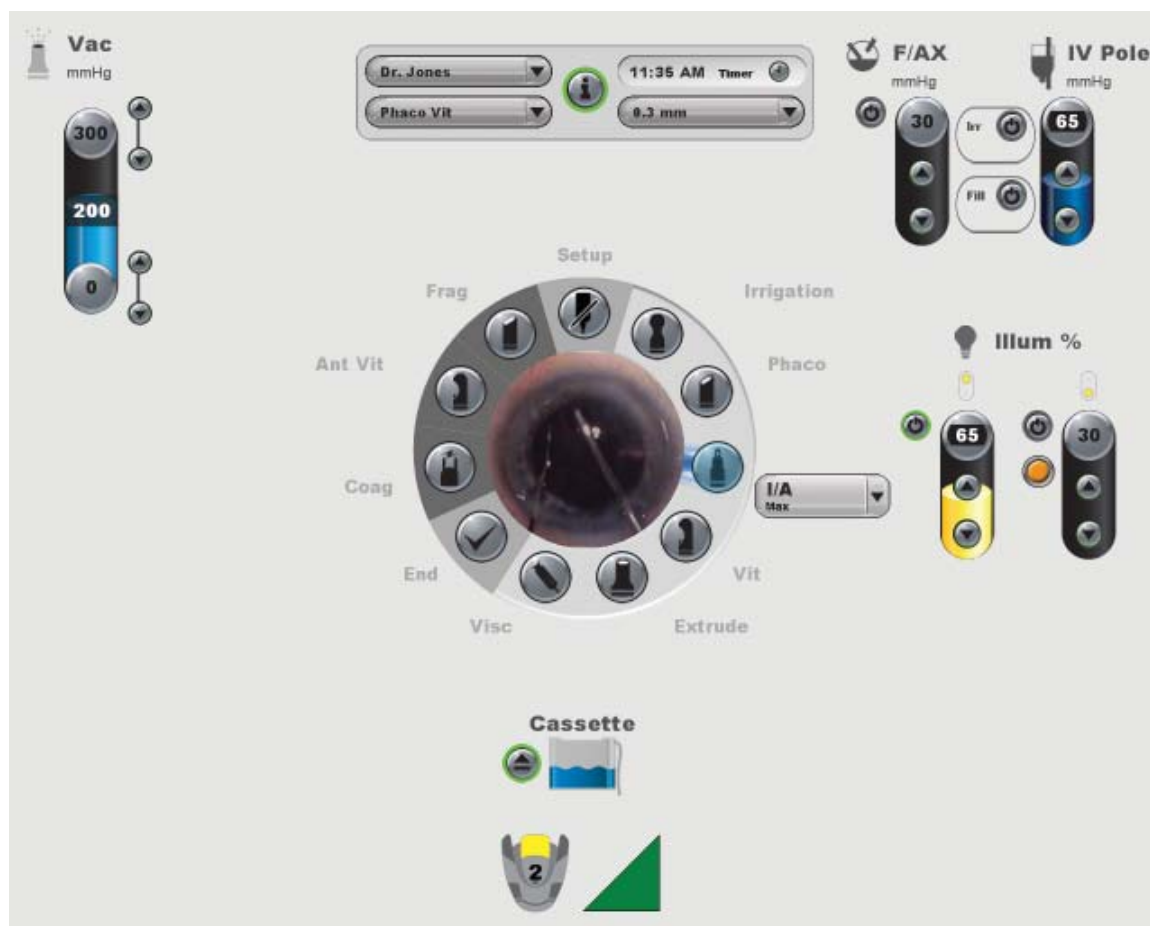


Figure 2.41. Small Video Combined Surgery Screen.

IV Pole

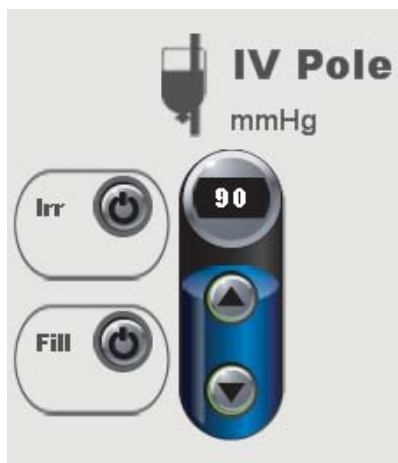


Figure 2.42. IV Pole Control display.

The upper right corner of the screen displays the current setting for the IV Pole (displayed numerically at the top of the test tube). 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. If the irrigation control is turned off in anterior mode, the function will still be managed by the Foot Control—when the footpedal enters Region 1, irrigation will commence.

Selecting the fill button opens the pinch valves in the fluidics system for 20 seconds. This function is useful for filling surgical beakers without using BSS. A green ring around the button shows indicates that the fill system is currently on. You can select the fill button to toggle to the off state.

The automatic “Fill” function is user programmable with a fill time range from 20s to 120s. To program the fill time, perform the following steps

- Select the More Screen
- Select the “Infusion” tab
- Change the fill time, “Fill (sec)” to the desired value
- Select “Save” to save changes.

Air Pressure


When using Air Forced Infusion, the air pump will turn ON after the cassette vacuum check is completed. The upper right corner of the screen displays the actual air pressure. The actual air pressure may not reach the maximum setting if the air tubing is not connected to the air output connector. The air pump can only be turned off using the  More Settings Screen.

When the infusion type is Air Forced Infusion, the infusion pressure unit of measurement display can be toggled between cmH₂O and mmHg. Pressing the display unit button will change the displayed unit of measure.



Ultrasound, Coagulation or Viscous Fluid Control (VFC)

The lower right corner displays either the Ultrasound or VFC status, depending on which mode is currently selected from the clock menu. The current setting is shown on the top of the test tube, with a green background for ultrasound, and an aqua background for VFC. The actual value is displayed in the middle of the test tube.

When ultrasound is active, an option list control appears in the lower right corner, and selecting the small  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) spin controls appear if the display option button is selected.

Footpedal and Coagulation

The current footpedal status is displayed in the bottom center of the screen. The current pitch region (1, 2, or 3) is shown, and the circles around the top indicate yaw position. See the chart on page 1-59 for details on Foot Control setup.

If one of the Foot Control Buttons has been programmed to control coagulation, a Coagulation control will appear just to the left of the Foot Control display, showing the current maximum power setting for the coagulation function.

When Linear Coagulation Mode is selected from the clock menu, the same area of the screen will display linear coagulation settings.

2.4. Customizing Your System Settings

The **Stellaris® PC** Vision Enhancement System has a programming interface, through which you can program the system for your own preferred operating configuration and instrument parameters. For details on how to program your system, see Chapter 3.

2.5. Anterior Domain Basic Interface Controls

Spin Button

Pressing one of the arrows will increase (up) or decrease (down) a value to set a system parameter. The current setting is displayed inside the spin buttons. Pressing the displayed number will take you to the numeric keypad (see page 2-3) so you can enter an exact number only if the surgical function is not currently in use.



Figure 2.43. Sample Spin Button.

Push Bar

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

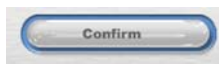


Figure 2.44. Sample Push Bar.

Option List

The Option List allows you to select an option. A small + next to a setting indicates that additional choices are available, and selecting the currently displayed option will bring up a list. Only one option can be selected at a given time. Selecting one option automatically deselects others.



Figure 2.45. Sample Drop Down Option List.

Test Tube Display and Control

This type of control allows you to set the limits of a system parameter. The actual value is displayed above the tube, and the allowable minimum and maximum values are shown beside the tube. The current setting may be changed by selecting and dragging the slider ring. The slider ring may not be positioned below the current setting minimum value. The minimum value may be changed with the surgical function More Settings Screen.

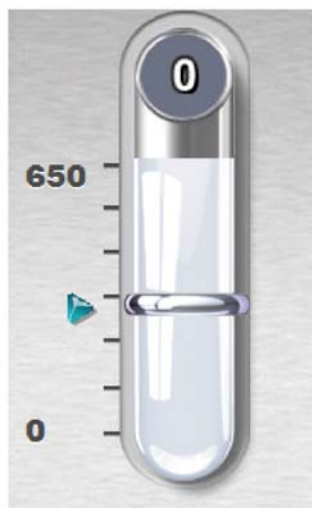


Figure 2.46. Sample Test Tube Display.

Progress Bar

This graphic shows the progress of execution of a command.



Figure 2.47. Sample Progress Bar.

Numeric Keypad

Selecting a number on a spin control button 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 select **Enter** to make the change. When a surgical function is active, the keypad for settings associated with that function will be removed or disabled.

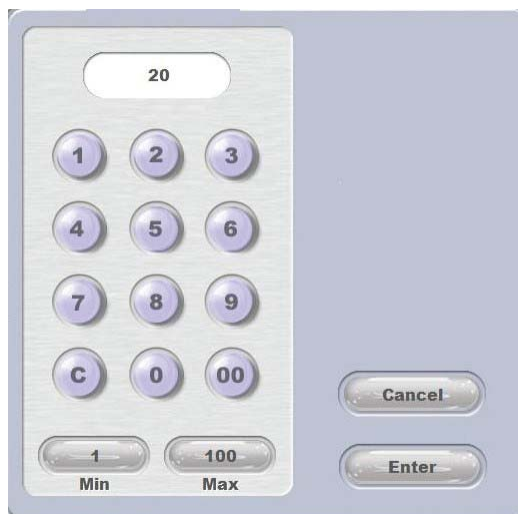


Figure 2.48. Numeric Keypad.

Keyboard

Sometimes you will need to enter alphabetical or numeric data into the *Stellaris® PC* 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.



Figure 2.49. Keyboard.

Character Lengths

When naming functions, there is a limit to the number of characters that can be used. That limit is the lesser of the number of characters in the table below, or the number of characters displayable in the corresponding area on the screen.

Function	Maximum Characters
Mode	8
Technique	20
Submode	20
Pathology	20
Surgeon	30

Display Format

Selecting this button, shown below, steps that section of the display through multiple levels of complexity. It appears on both the **Status Bar Window** and the **Ultrasound Submode List**.



Figure 2.50. Display Format Selection Button.

Pop-Up Message Window

This type of window appears to display error and warning messages. You should take the appropriate action before the system will continue. Nothing else can be done on the screen while a pop-up window is on the screen. The surgeon may be able to continue with the procedure once the error has been rectified.



Figure 2.51. Sample Message Window.

For each message displayed, suggested actions to resolve the condition are displayed. If more than one suggested action is available, pressing the **Next** button will cycle through all possible suggested actions. Selecting **Close** will close this window.

2.6. Anterior Domain Surgical More Settings Screens



More Settings Screens allow easy access to all system parameters.

In the anterior domain, pressing the More Settings Screen button will cause a tabbed window (More Settings Screen) to appear, through which system settings and parameters can be changed.



Figure 2.52. More Settings Screen Button.

Anterior Domain Mode	Tabs on More Settings Screen	
Setup with Linear Coagulation	Coag, Infusion, Foot Control, A/V, Messages	Figure 2.53.
Setup without Linear Coagulation	Infusion, Foot Control, A/V, Messages	Figure 2.54.
Anterior Vitrectomy	Cut, Vacuum, Infusion, Foot Control, A/V, Messages	Figure 2.55.
Phaco	U/S, Vacuum, Infusion, Foot Control, A/V, Messages	Figure 2.56.
I/A	Vacuum, Infusion, Foot Control, A/V, Messages	Figure 2.57.
Irrigation	Infusion, Foot Control, A/V, Messages	Figure 2.58.
Linear Coagulation	Coag, Infusion, Foot Control, A/V, Messages	Figure 2.59.

Each More Settings Screen has a dropdown submenu selection window , as well as **Save**, **Save As** and **Cancel** () buttons. Selecting **Save As** allows you to save the new parameters to a particular surgeon, technique, gauge, and fragmentation needle file.

If a setting has been changed in a More Screen, the text will be blue (instead of black) to highlight the modification. Once the change is saved, the text will turn black.



Figure 2.53. Setup with Linear Coagulation More Settings Screen. Coagulation tab.

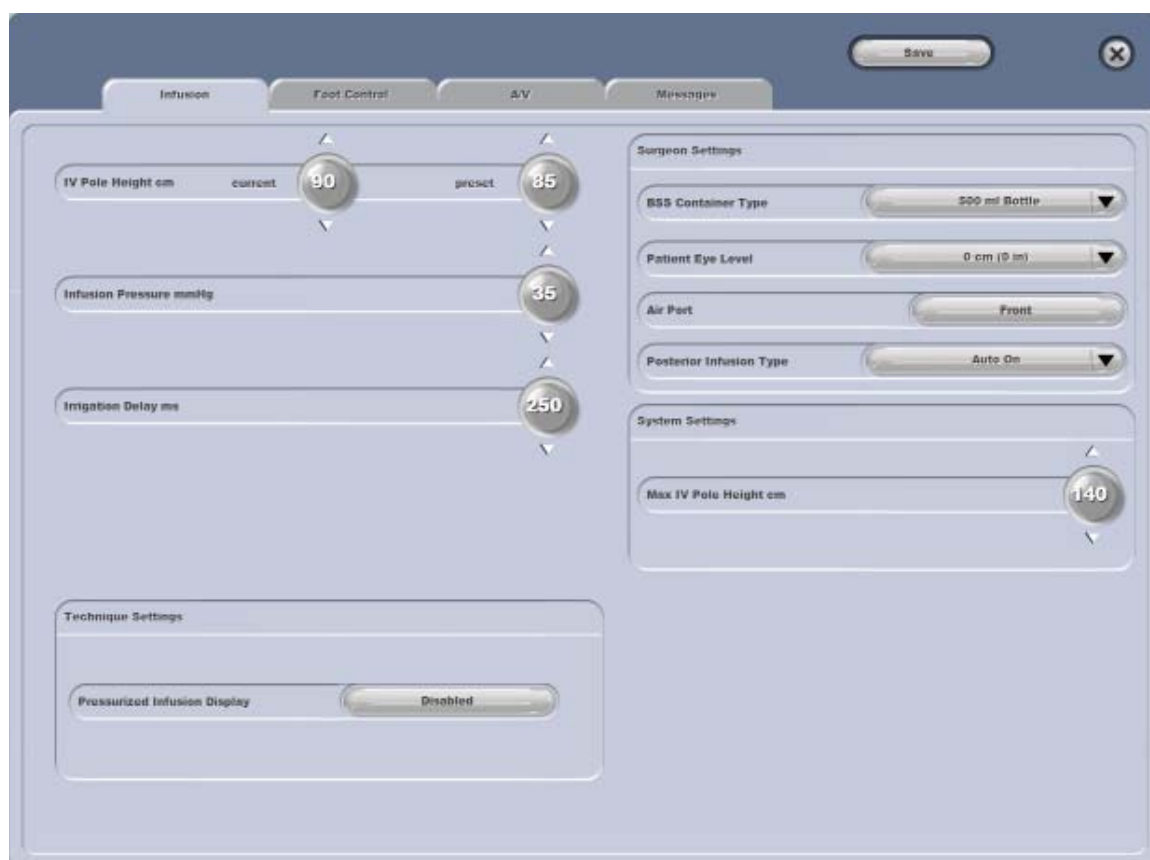


Figure 2.54. Setup without Linear Coagulation More Settings Screen. Infusion tab.

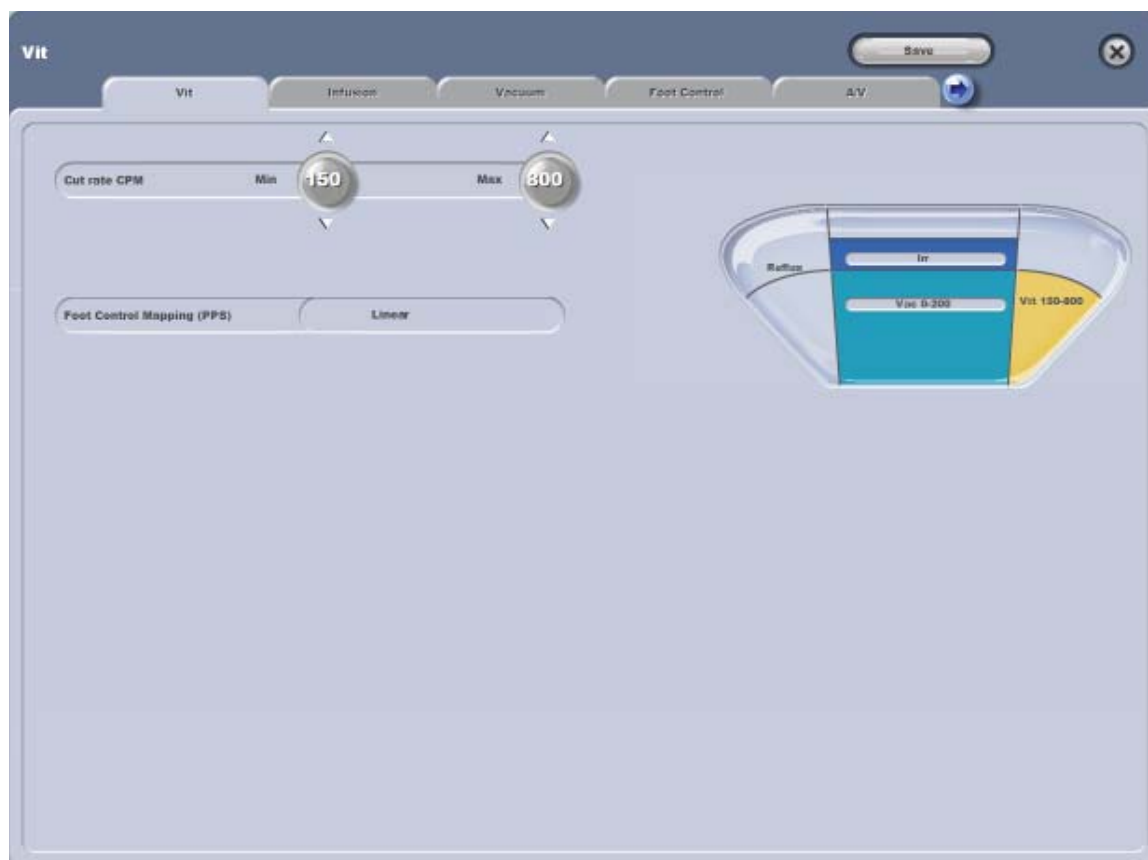


Figure 2.55. Anterior Vitrectomy More Settings Screen. Cut tab.

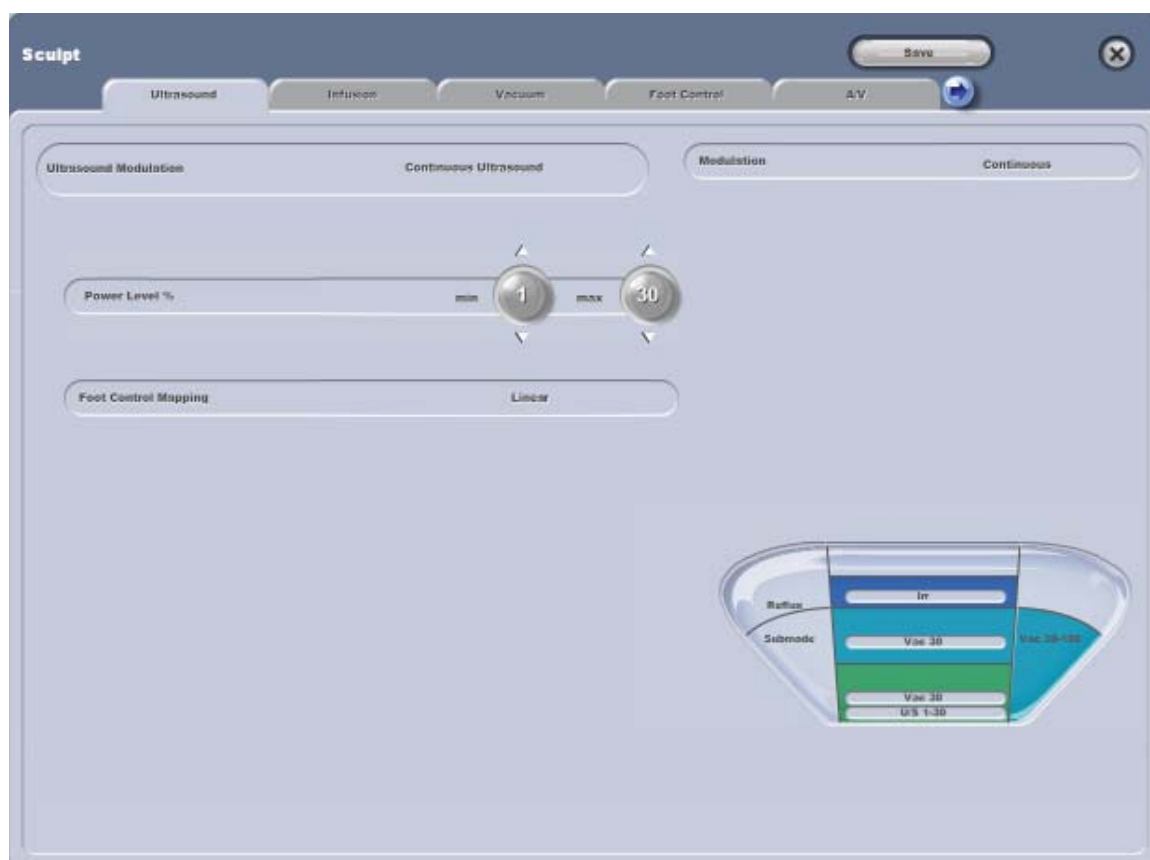


Figure 2.56. Phaco More Settings Screen. Ultrasound tab.

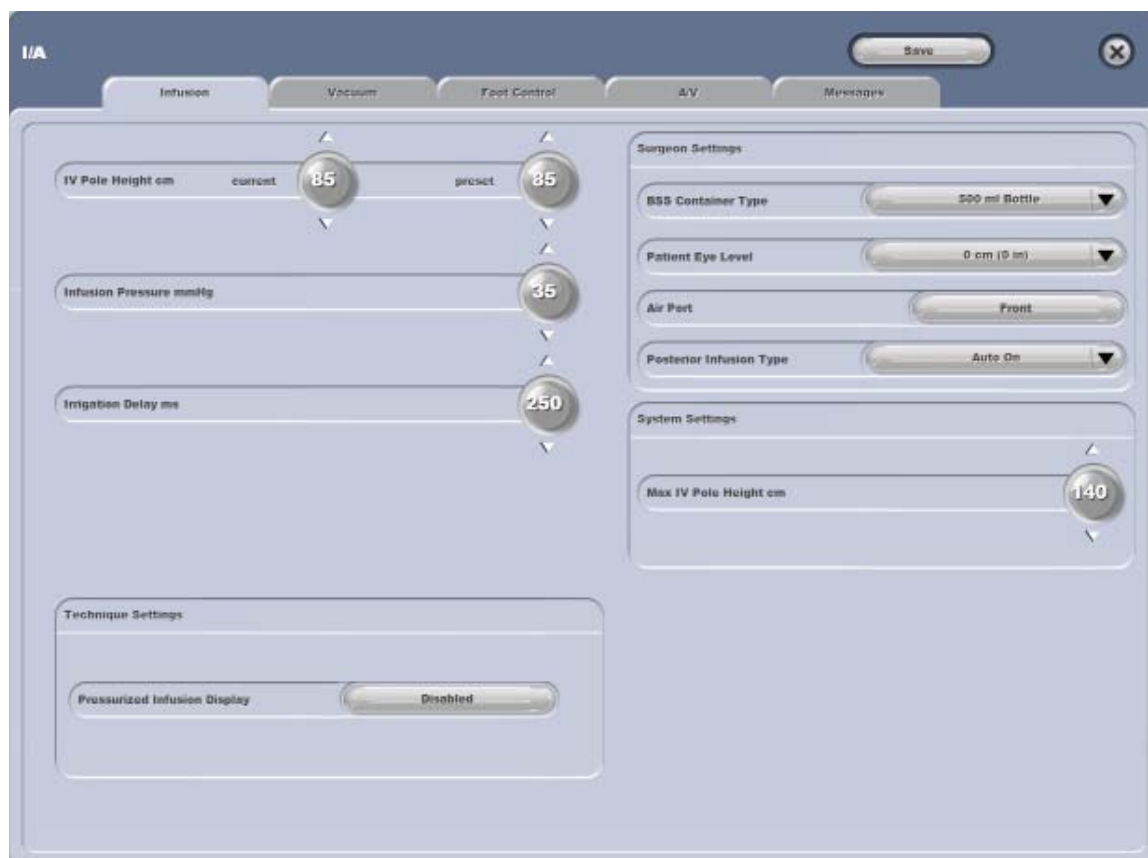


Figure 2.57. I/A More Settings Screen. Infusion tab.

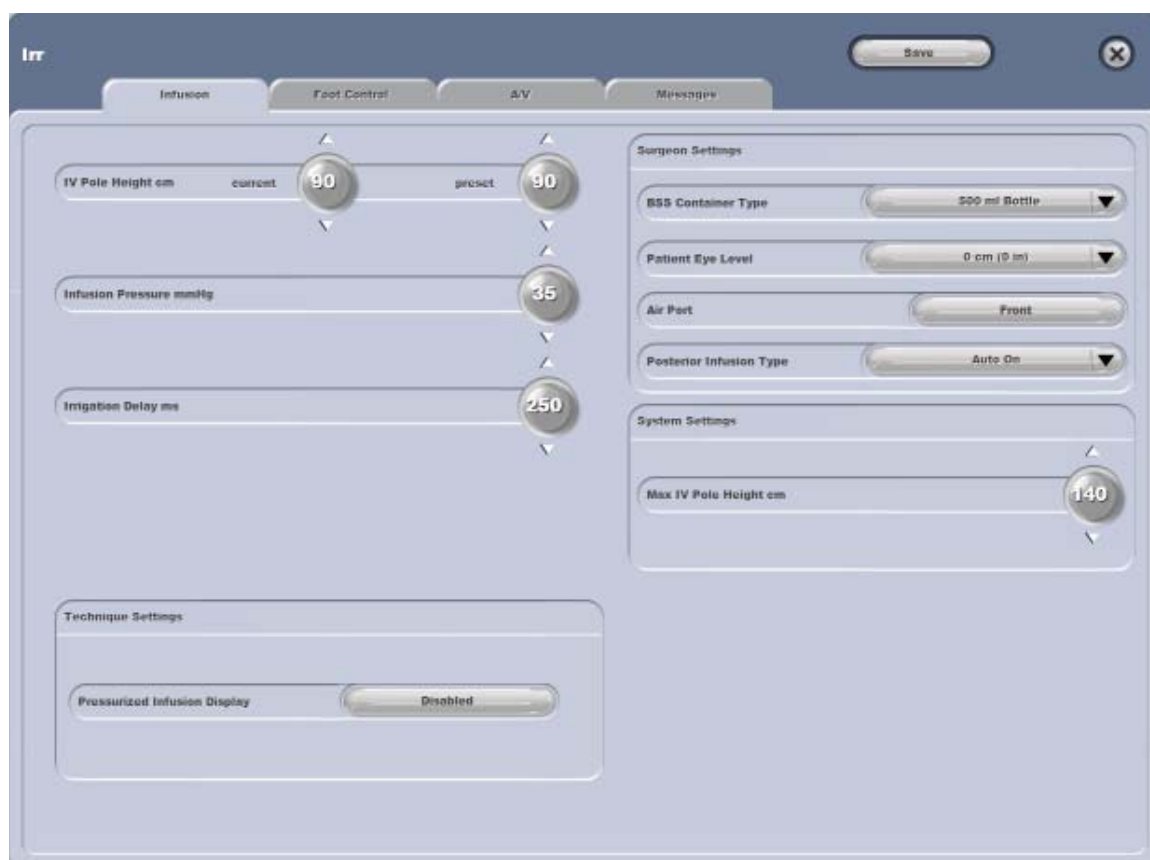


Figure 2.58. Irrigation More Settings Screen. Infusion tab.

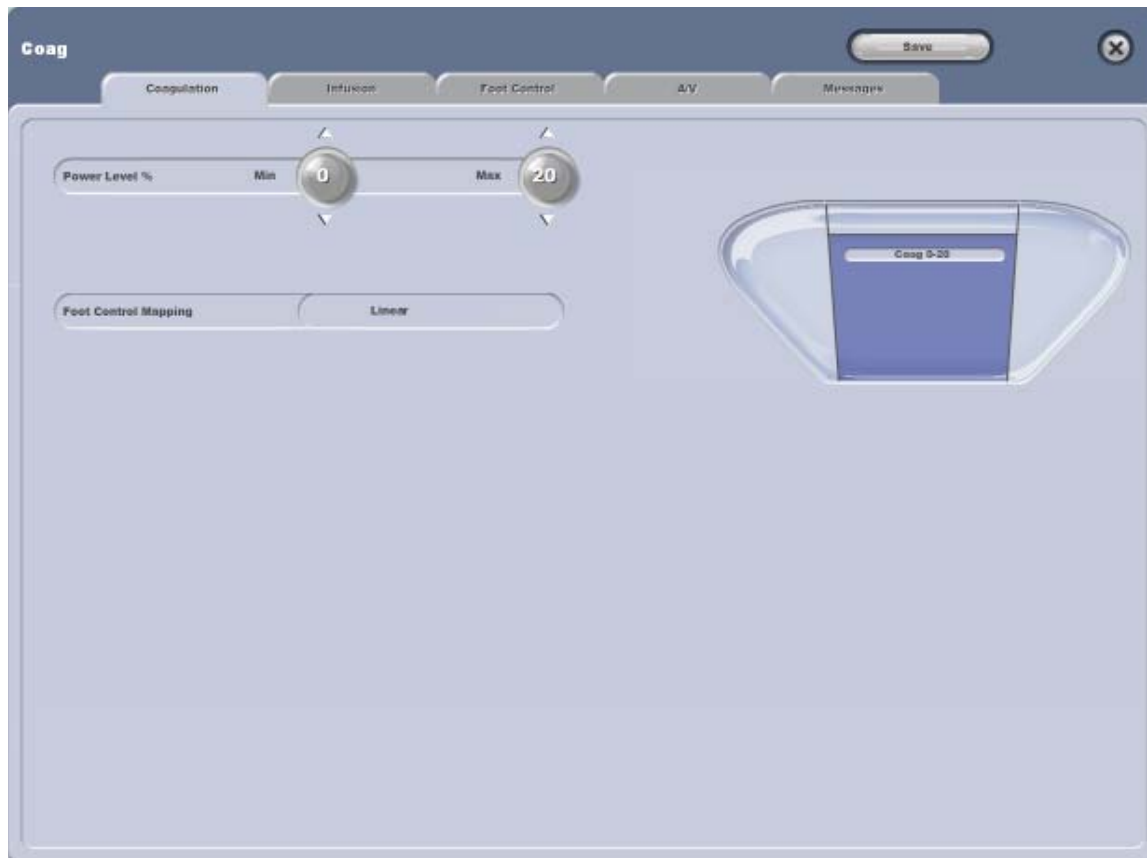


Figure 2.59. Linear Coagulation More Settings Screen. Coagulation tab.

The **Aspiration Tab** shows the current mode, vacuum settings, vacuum response setting, venting method, and Foot Control preview.

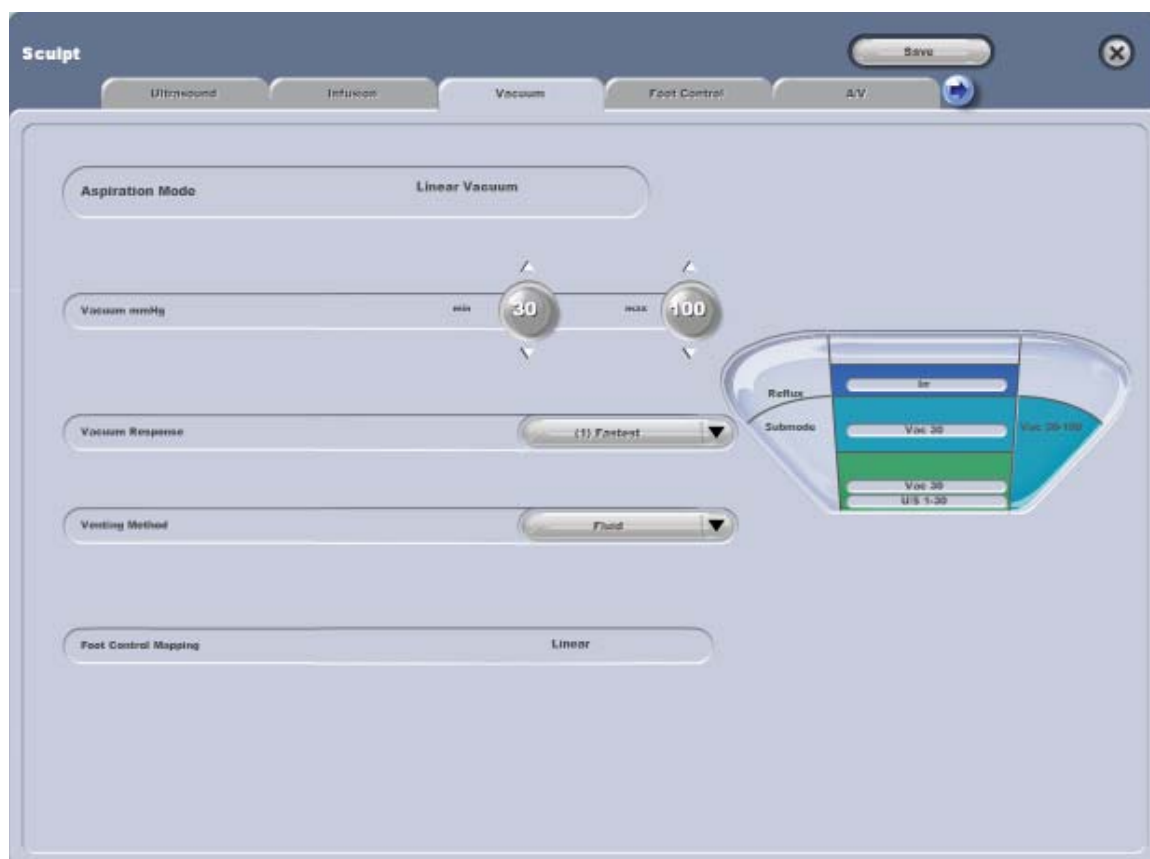


Figure 2.60. More Settings Screen, Aspiration Tab.

2 User Interface

The **Infusion Tab** shows the current Infusion mode, IV Pole Height (actual, preset and maximum), BSS Container Type, Patient Eye Level, Irrigation Delay and Pressurized Infusion (enabled/disabled, pressure settings and pump on/off status).

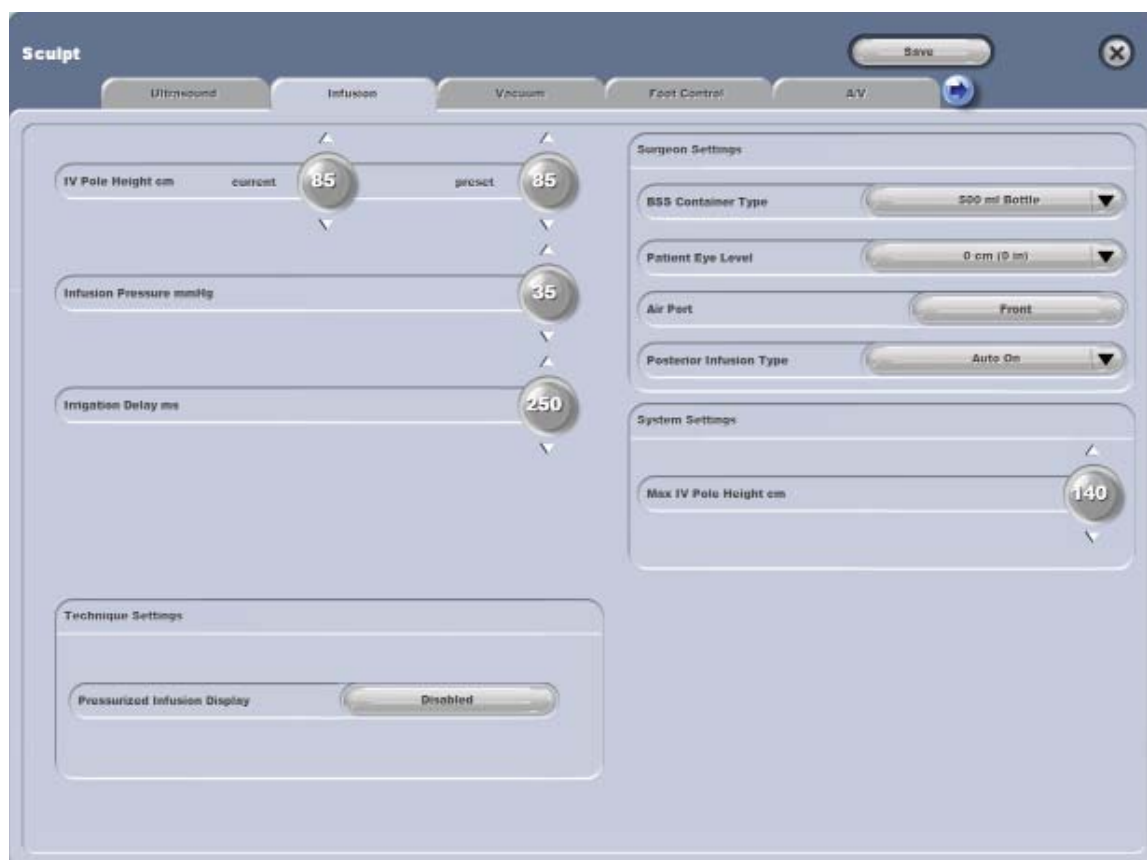


Figure 2.61. More Settings Screen, Infusion Tab.

The actual IV Pole height is the current distance between the aspiration port and the mid-point of the BSS 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 in the room and set at the time of system installation.

A zero level bottle hanger (BL4363) allows the BSS drip chamber to be level with the aspiration port.

Ultrasound More Settings

The Ultrasound More Settings Screen shows the current modulation status and power level. Depending on which type of ultrasound and programming level you are currently using, you may also see number of pulses per second (PPS), duty cycle (DC), burst duration (BD), and pulse interval (PI), waveform type, waveform depth and waveform duration may also be shown. All of these settings are adjusted through these screens.

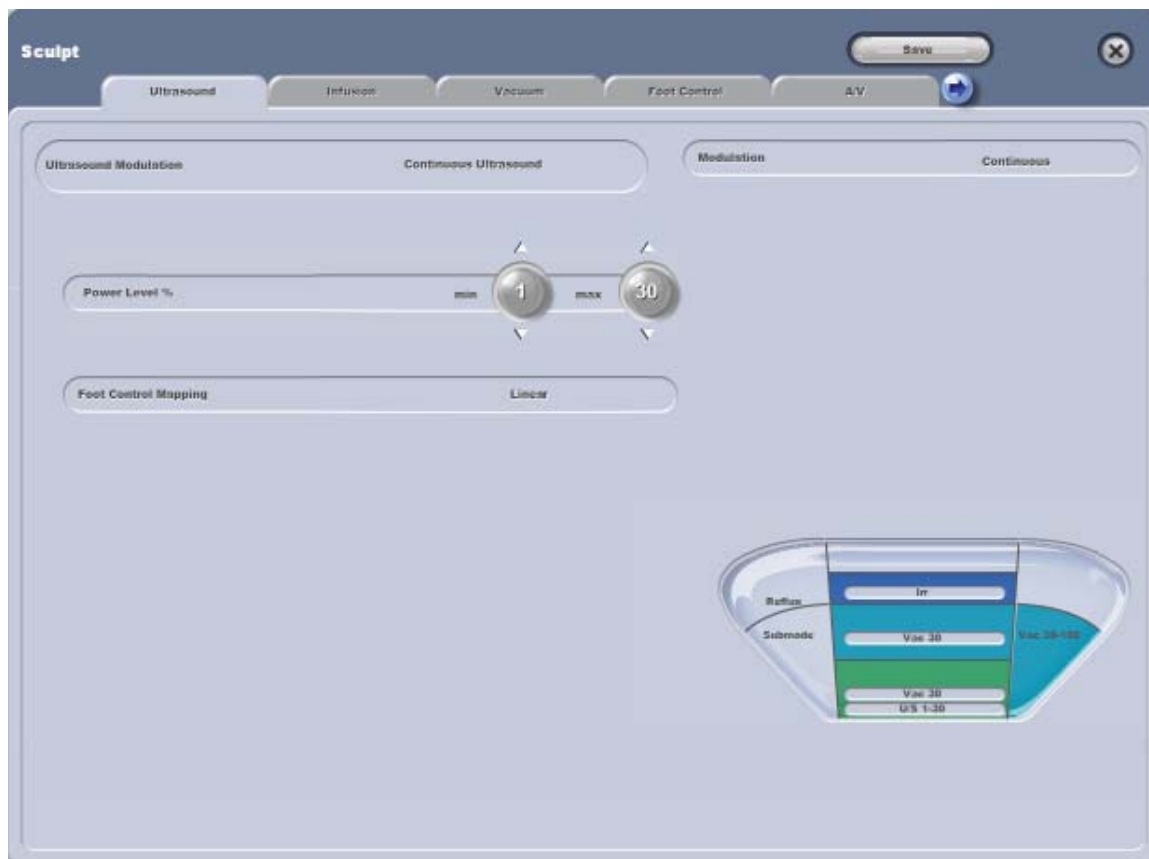


Figure 2.62. Ultrasound More Settings Screen, Continuous Ultrasound.

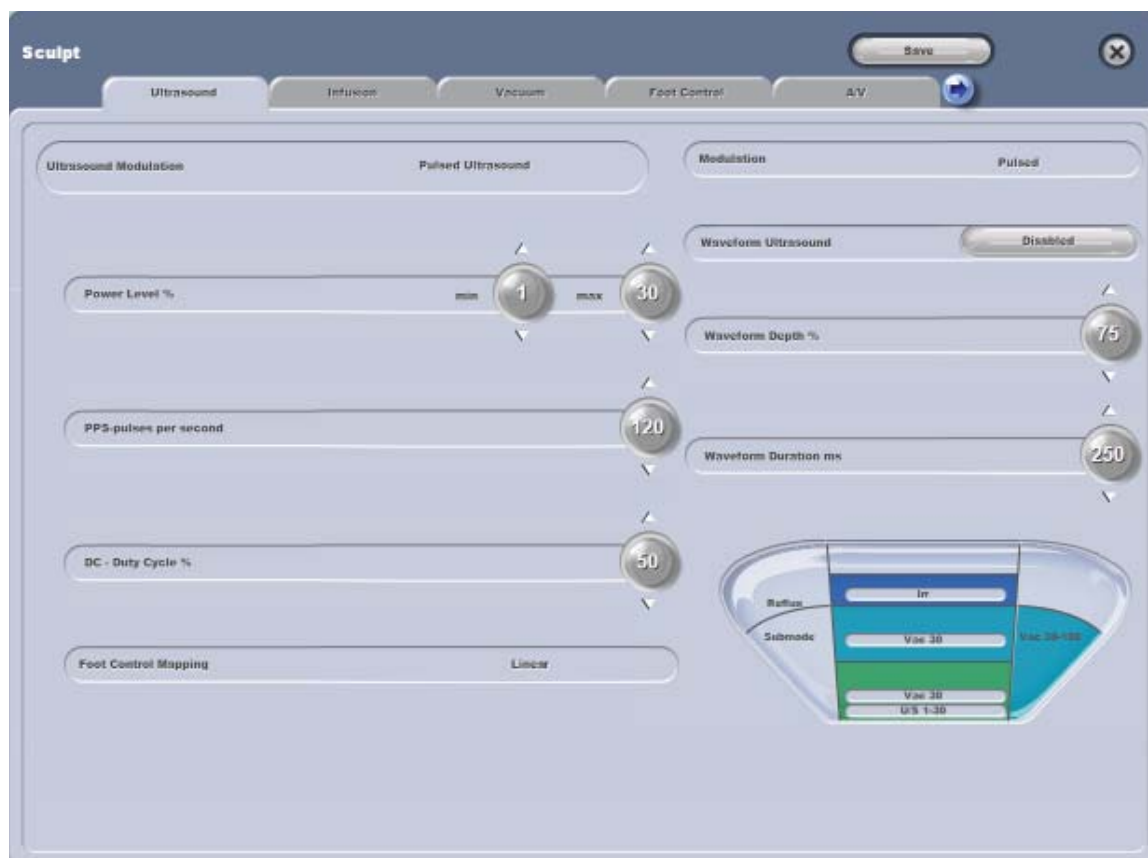


Figure 2.63. Ultrasound More Settings Screens, Pulsed Ultrasound.

Coagulation More Settings

The Coagulation More Settings Screen shows the current minimum and maximum power levels, and the Foot Control preview. You can adjust either power level setting.

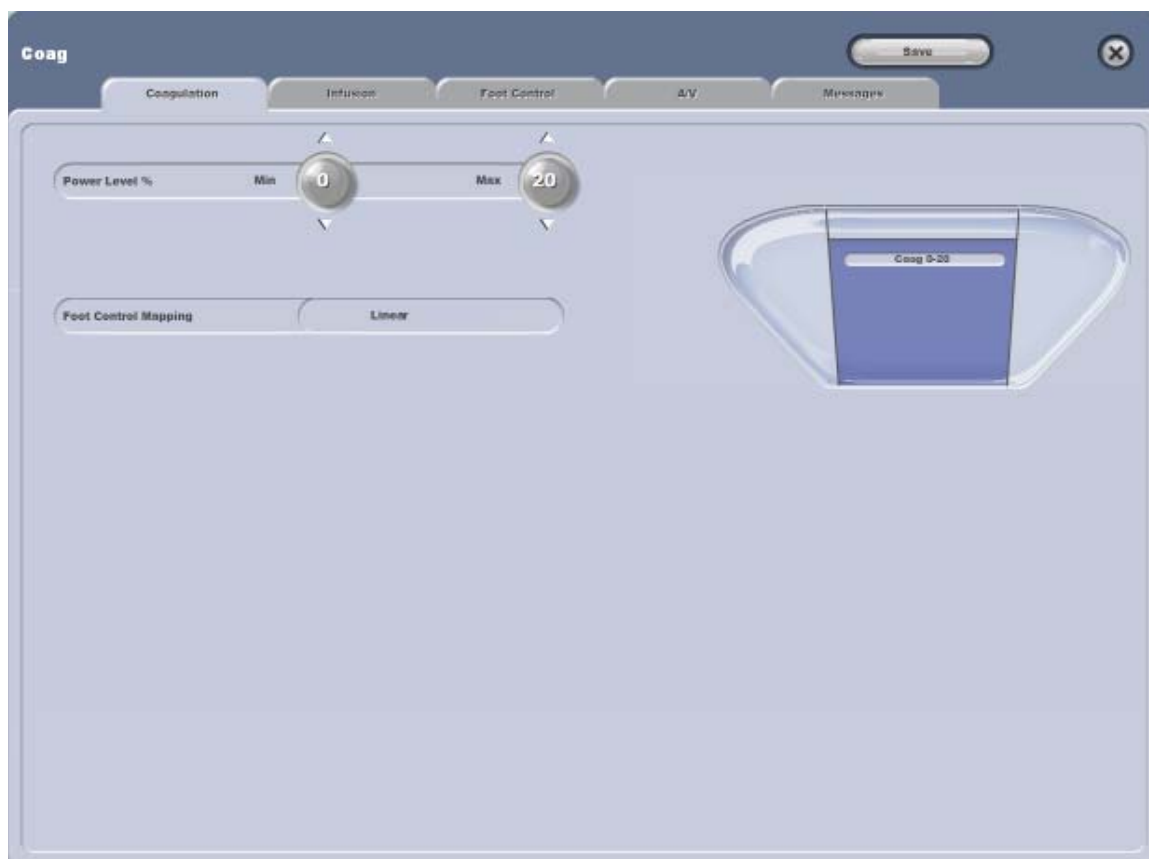


Figure 2.64. Coagulation More Settings Screen.

Vitrectomy More Settings

The Vitrectomy More Settings Screen shows the current settings for the minimum and maximum CPM (cuts per minute).

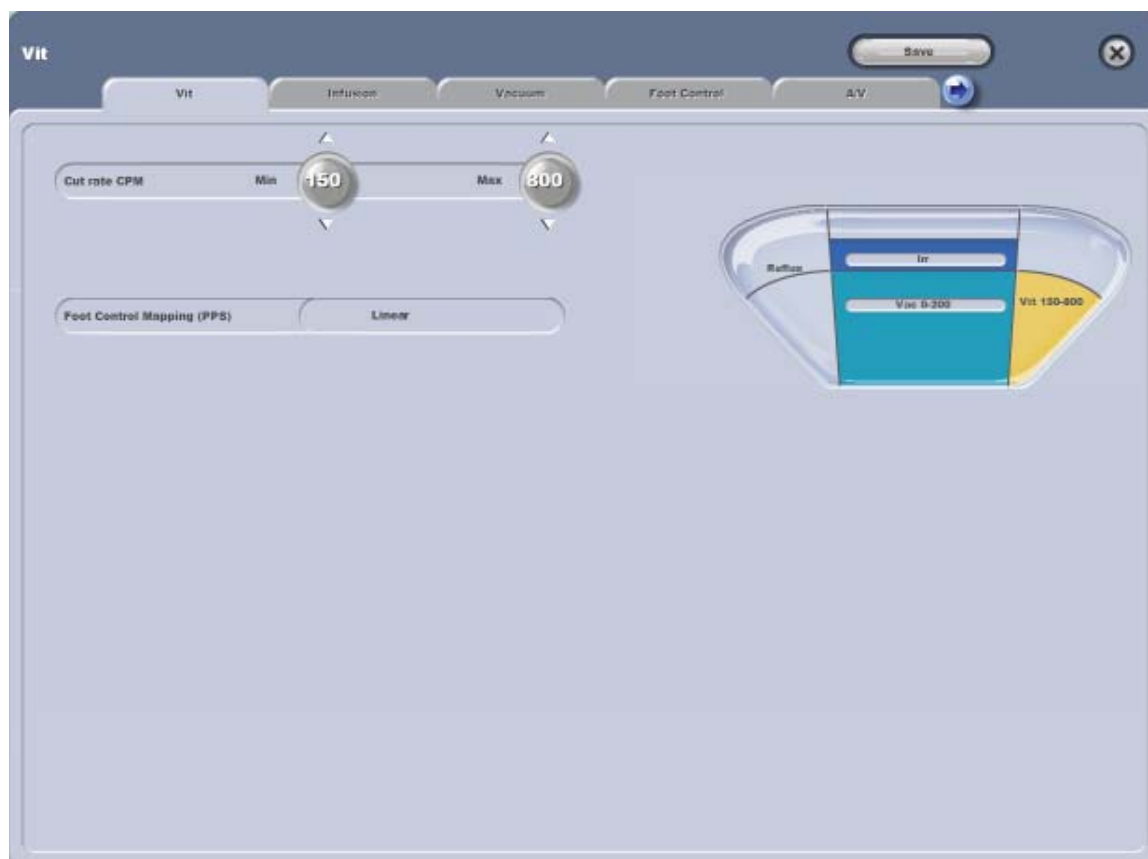


Figure 2.65. Vitrectomy More Settings Screen.

You can adjust either setting. The current Foot Control preview is shown for reference.

Foot Control More Settings

The Footpedal More Settings Screen has three tabs that allow you to view and edit Settings, Regions, and the Status of the Foot Control. These functions are described in detail in the Foot Control section (see page 1-40).

The **Settings Tab** shows the current status of the Foot Control buttons, right or left foot operation, Dual Linear Control, Mode Change Control, Next U/S (Ultrasound) Modulation on Yaw, Reflux Type, and Fixed Coag Power. Editable functions are highlighted with a blue or gray background and marked with a +.

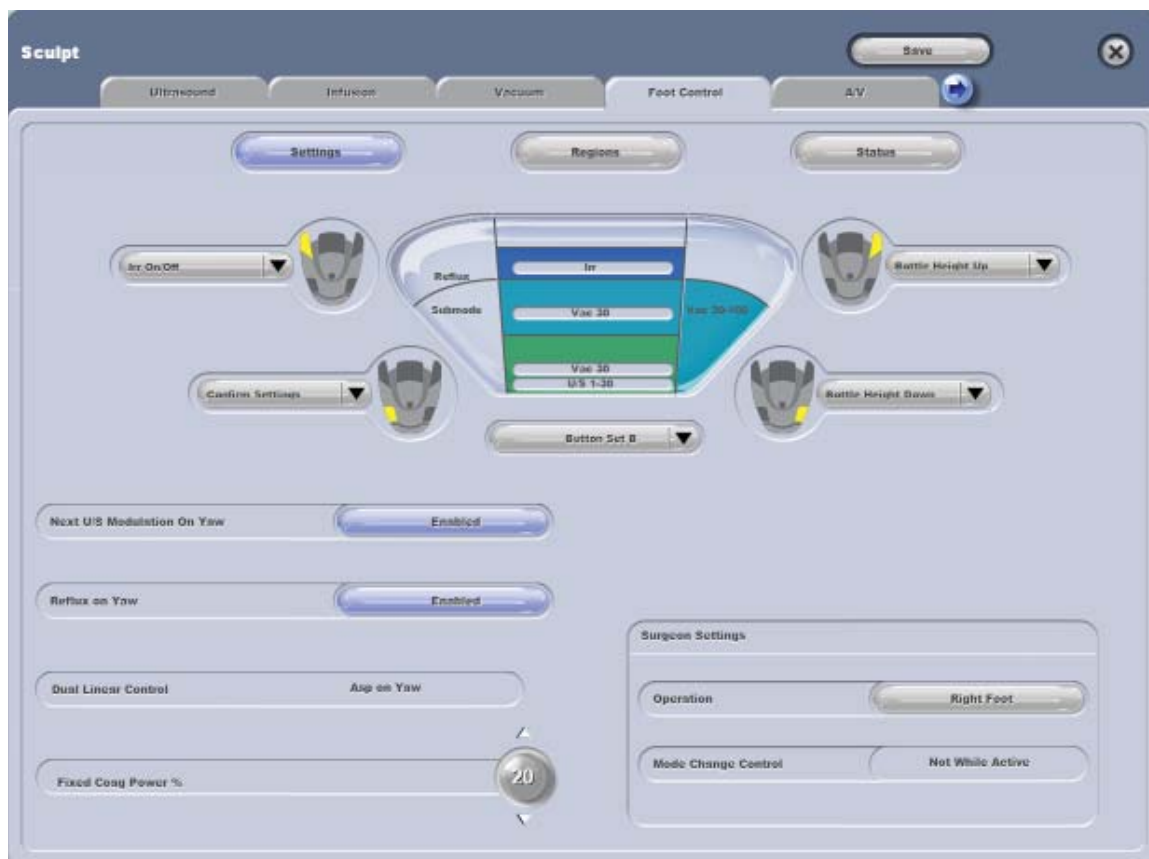


Figure 2.66. Foot Control More Settings Screen.

2 User Interface

The **Regions Tab** shows the current settings for the footpedal pitch regions and detent options. You can modify the starting depression position for each region.



Figure 2.67. Foot Control More Settings Screen, Regions tab.

The **Status Tab** shows the current status of several footpedal options, including communication status, battery status, and signal strength.



Figure 2.68. Foot Control More Settings Screen, Status Tab.

A/V More Settings Screen

The A/V More Settings Screen allows you to change many aspects of the audio and video display. Each tab allows you to change the settings and configuration for aspects of the display.

The **Audio Tab** controls the master volume for the system, as well as the specific tone and volume used for each of the following events: Irrigation, Vacuum, Occlusion, Ultrasound, Coagulation, Vitrectomy, and Alert. 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.

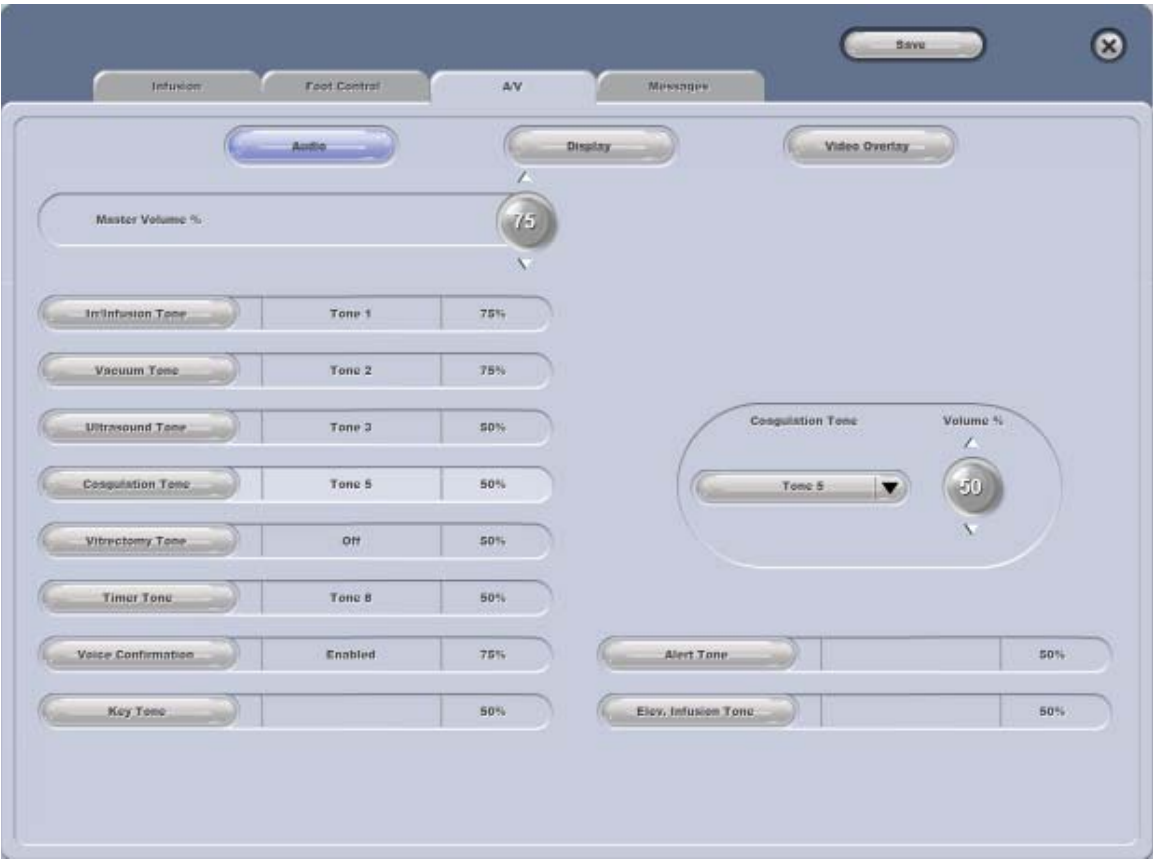


Figure 2.69. A/V More Settings Screen, Audio Tab.

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 screen brightness, change the display format level, select the system language, and view the programming level.



Figure 2.70. A/V More Settings Screen, Screen Display Tab.

2 User Interface

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

You can also set whether or not the system will combine Video Overlay Format information, such as U/S Averages, settings, and case 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, and case information on two lines, but if the combine option is set to **Yes** each 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%.

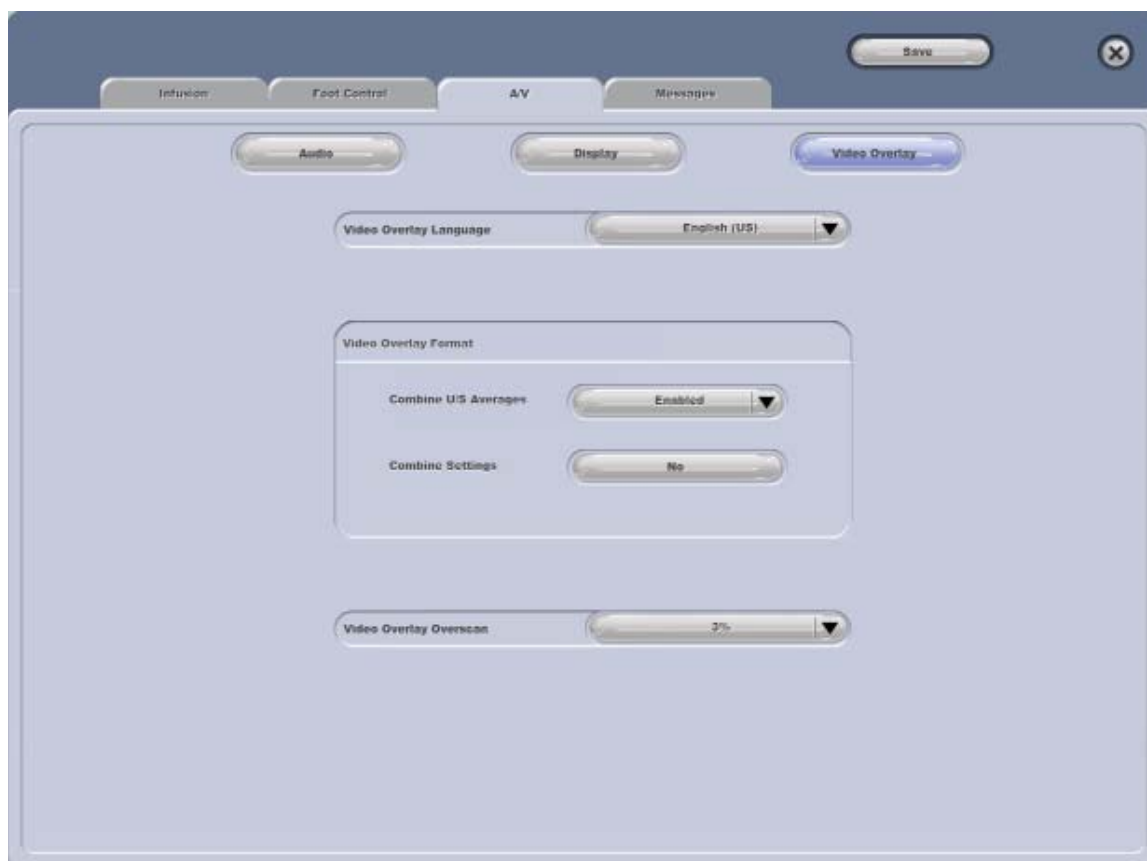


Figure 2.71. A/V More Settings Screen, Video Overlay Tab.

Case More Settings Screen

The Case More Settings Screen shows the case number, total number of rooms in which the *Stellaris® PC* Vision Enhancement System will be used, the room number in which the system currently resides, as well as the technique, needle, grade and pathology for the current case. Select the parameter to be changed, and then select the new setting from the option list. When you have made all the desired changes, select **Close** and the change will take effect.

You can select **Save Settings** to have the new settings overwrite the current surgeon's preferences, and be stored in the main preferences file.



Figure 2.72. Case More Settings Screen.



Note:

Selecting **Save Settings** here will save all changes made through any aspect of the user interface. You can select **Reset Averages** to clear the average values and elapsed times for the surgical functions for this case.

2.7. Anterior Domain Surgical Screen Layout



Note: Voice confirmation (if enabled) responds to Foot Control and remote operation and on-screen buttons.

The Main Surgical Screen can appear in one of two formats. The default format is set as a surgeon preference. To switch between levels, click the **A/V More Button** (located at the top of the screen), select the **Screen Display Tab**, then select the desired **Display Format Level**.

Level 1 Display

At Level 1, only the basic controls are displayed.



Figure 2.73. Surgical Screen, display level 1.

**Note:**

More Settings Screens for the *Fluidics, Ultrasound, Coagulation, and Vitrectomy* functions are only available at Display format 2.

Clock Menu

The round **Clock Menu** in the middle of the screen can display up to 12 phases—eight normal phases and four exceptions. The exceptions appear on the left side of the clock menu, against a darker background. These are user-defined to be any mode type (Irrigation only, Ultrasound, Irrigation/Aspiration, Pneumatic Vit or Coagulation). The **Setup** and **End** are the system function keys in the clock menu to change from surgical display screen to Setup and End Screens.

If you have the optional MMC system installed, the center of the **Clock Menu** will show the video from the microscope camera, when video is available. You can select the video itself to switch between small and large video display formats.

See Chapter 3 for details on customizing your system.

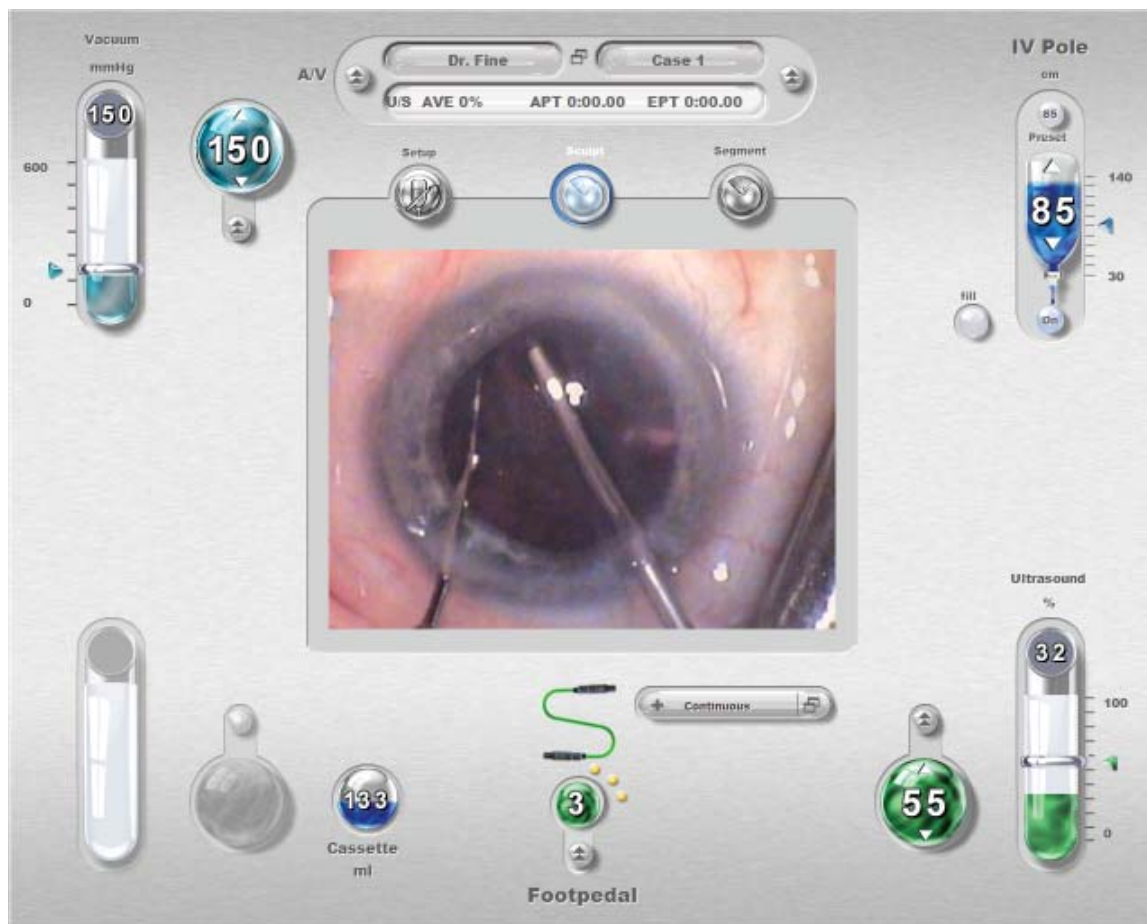


Figure 2.74. Large Video Anterior Surgery Screen.



Figure 2.75. Small Video Anterior Surgery Screen.

IV Pole



Figure 2.76. IV Pole Control Display.

The upper right corner of the screen also displays the current setting for the IV Pole (on the bottle), as well as the preset value (above the bottle). 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 Preset value is a pre-programmed value to which you can jump quickly, simply by selecting it on the screen. Different surgical modes may have different preset values. You can change the preset value for the current session by opening the More Settings Screen (see Figure 2.61) and selecting the **Infusion Tab**.

The On/Off button controls the continuous irrigation function, by opening or closing the irrigation pinch valve in the fluidics system. If the irrigation control is turned off, the function will still be managed by the Foot Control—when the footpedal enters Region 1, irrigation will commence.



Figure 2.77. Setup Screen showing I/V Pole Control and Fill Control.

Selecting the fill button opens the pinch valves in the fluidics system for a fixed period of time. This function is useful for filling surgical beakers without overflow. A green ring around the button indicates that it is currently on. You can select it to toggle to the other state.

Air Pressure

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, Coagulation or Vitrectomy

The lower right corner displays either the Ultrasound, Coagulation or Vitrectomy status, depending on which mode is currently selected from the clock menu. The current setting is shown in the large spin control, with a green background for ultrasound, yellow background for vitrectomy, and purple background for coagulation. The actual value is displayed in a small grey circle below the spin control.

When ultrasound is active, an option list control appears in the lower right corner, and selecting the small + allows you to select from a list of preprogrammed ultrasound submodes. If you select pulsed ultrasound, the pulse per second (PPS) and duty cycle (DC) spin controls appear if the display option button is selected.

Vacuum


The upper left section of the screen shows the maximum vacuum or vacuum limit setting in a spin control button, with the current actual value shown below it.

Footpedal and Coagulation

The current footpedal status is displayed in the middle of the bottom of the screen. The current pitch region (1, 2, or 3) is shown. The **Footpedal More Button** brings up a More Settings Screen that allows you to change settings on the footpedal. See page 2-61 for details on changing these settings.

If one of the Foot Control **Buttons** has been programmed to control coagulation, a small Coagulation spin control will appear just to the left of the Foot Control display, showing the current maximum power setting for the coagulation function.

Case Window

At the top of the screen, a status bar display shows the name of the surgeon currently working, as well as the current case number. Selecting the **Display Format Button** () repeatedly shows progressively more detail.

Level 2 Display

At Level 2, more detailed information is added to each display about the current value of each system. In addition to the spin control buttons that are present in the Level 1 display, the Level 2 display adds a test tube display and control (see page 2-2). The current value of the function is displayed at the top of the tube, and a slider ring on the tube can be used to change the setting.



Figure 2.78. Main Surgical Screen display, level 2.

2.8. Customizing Your System Settings

The *Stellaris® PC* Vision Enhancement System has a programming interface, through which you can program the system for your own preferred operating configuration and instrument parameters. The programming screens are organized as shown in the following figure.

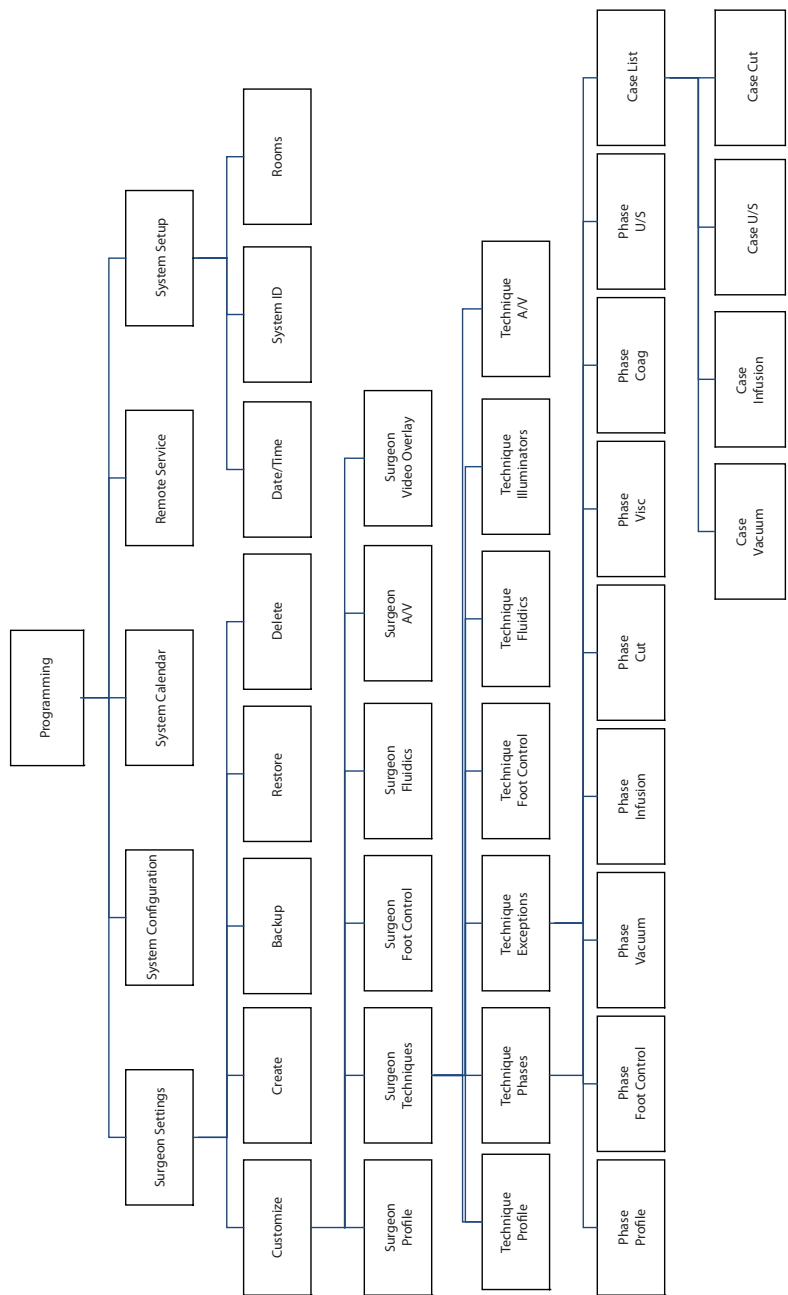


Figure 2.79. Programming Screen layout.

Customizing Your System

This chapter explains how to customize your *Stellaris® PC* 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® PC* Vision Enhancement System can program the system for their own preferred operating configuration and instrument parameters. Several default surgeon preference files are pre-loaded on the system, and you may copy and modify any of them using the Programming interface. You can create, modify and backup surgeon setting preference files, as well as modify system parameters.

To program system parameters, select **Programming** from the main clock menu on any setup screen.

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

- Manage Surgeon Settings
- System Setup
- System Configuration
- System Calendar
- *TruLink®* Customer Support Network (optional function)

3 Customizing Your System

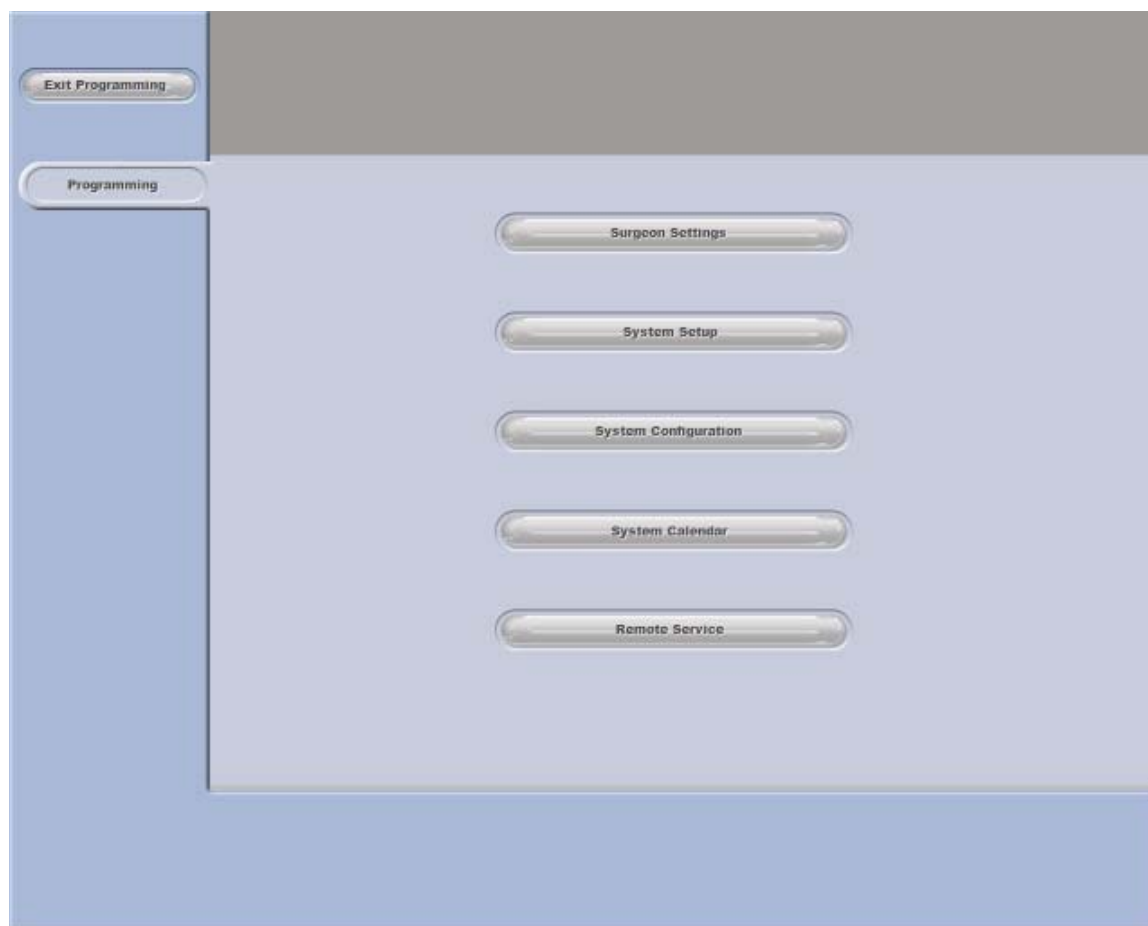


Figure 3.1. Main Programming Screen

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 Select Surgeon Screen or the Setup Surgical Screen. In either case, the *Stellaris® PC* 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, and **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, backup files, restore files from a backup, or delete surgeon preference files.

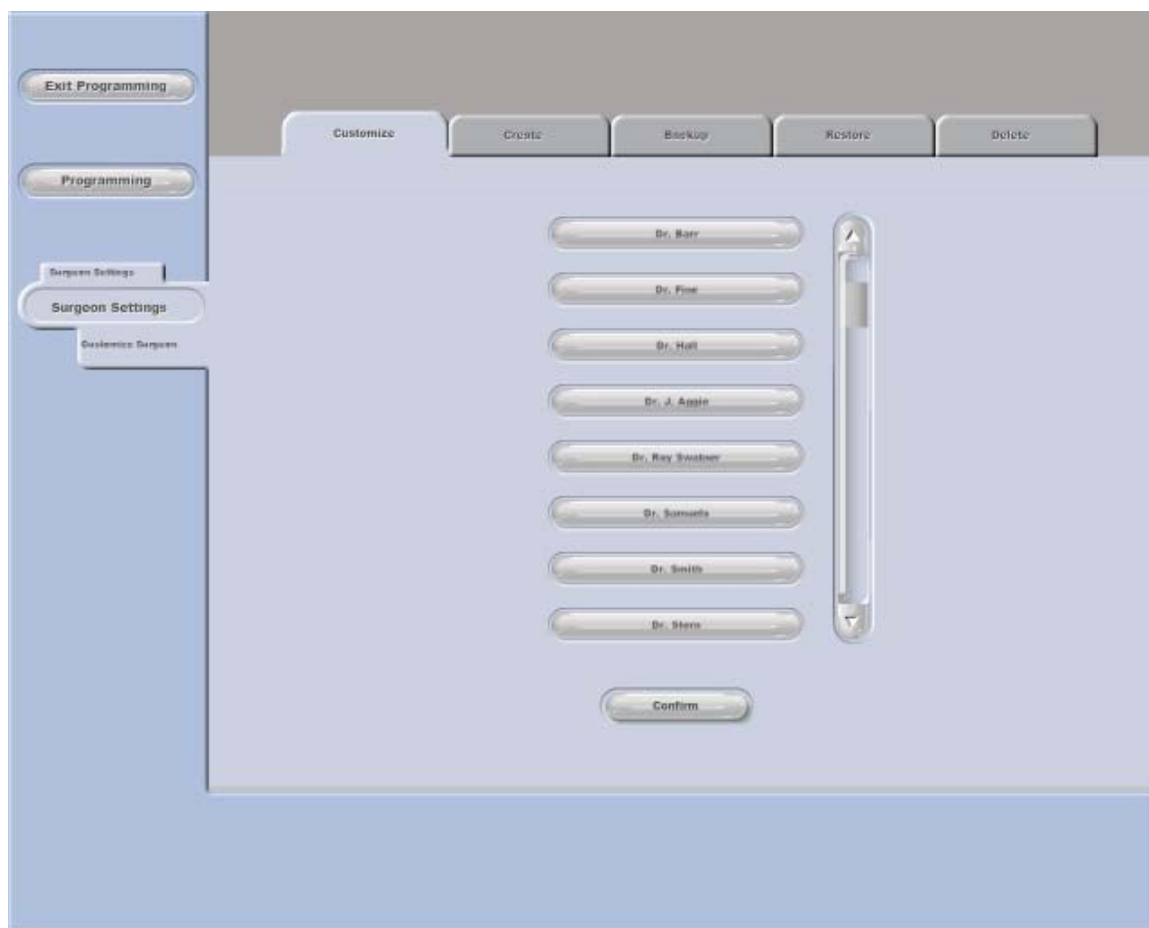


Figure 3.2. Surgeon Settings Screen.

Customize a Settings File

To change the settings for a currently existing preference file, select the **Customize Tab** on the Main Programming Screen. A list of all surgeon preference files currently loaded on your *Stellaris® PC 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 seven tabs across the top (see page 3-6). These tabs are **Profile**, **Technique**, **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.

3 Customizing Your System

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 on page 3-27 for details on which options can be customized at which level.

Customize Profile

To change the surgeon's name associated with a settings file, or change the default language, select the **Profile Tab** on the Surgeon Level Programming Screen. Select the surgeon's name, and use the keyboard interface that appears to modify the name of that file. Select Screen Voice Confirmation drop down menu, and a list of all available languages will appear, and you can select the one you prefer. You can also enable or disable use of the remote control.

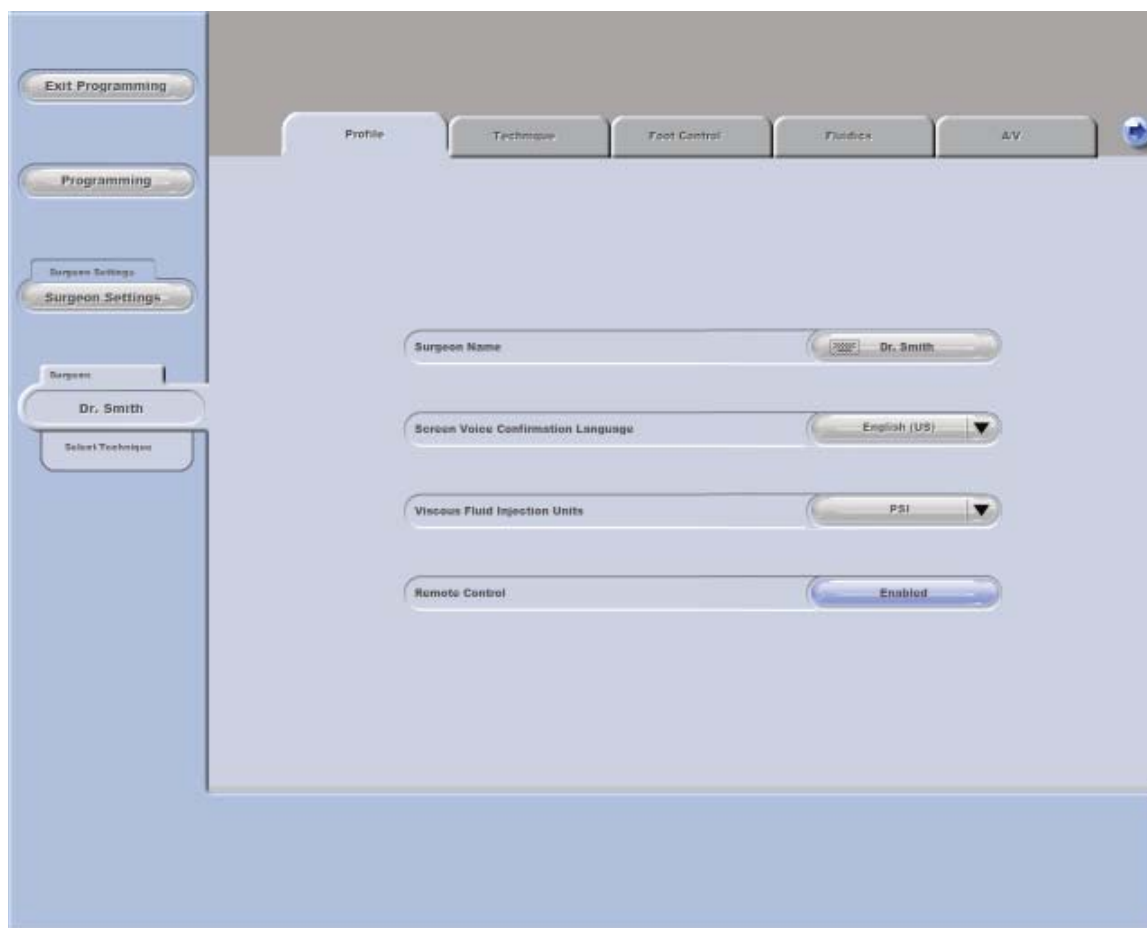


Figure 3.3. Profile Tab on Surgeon Programming Screen.

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.

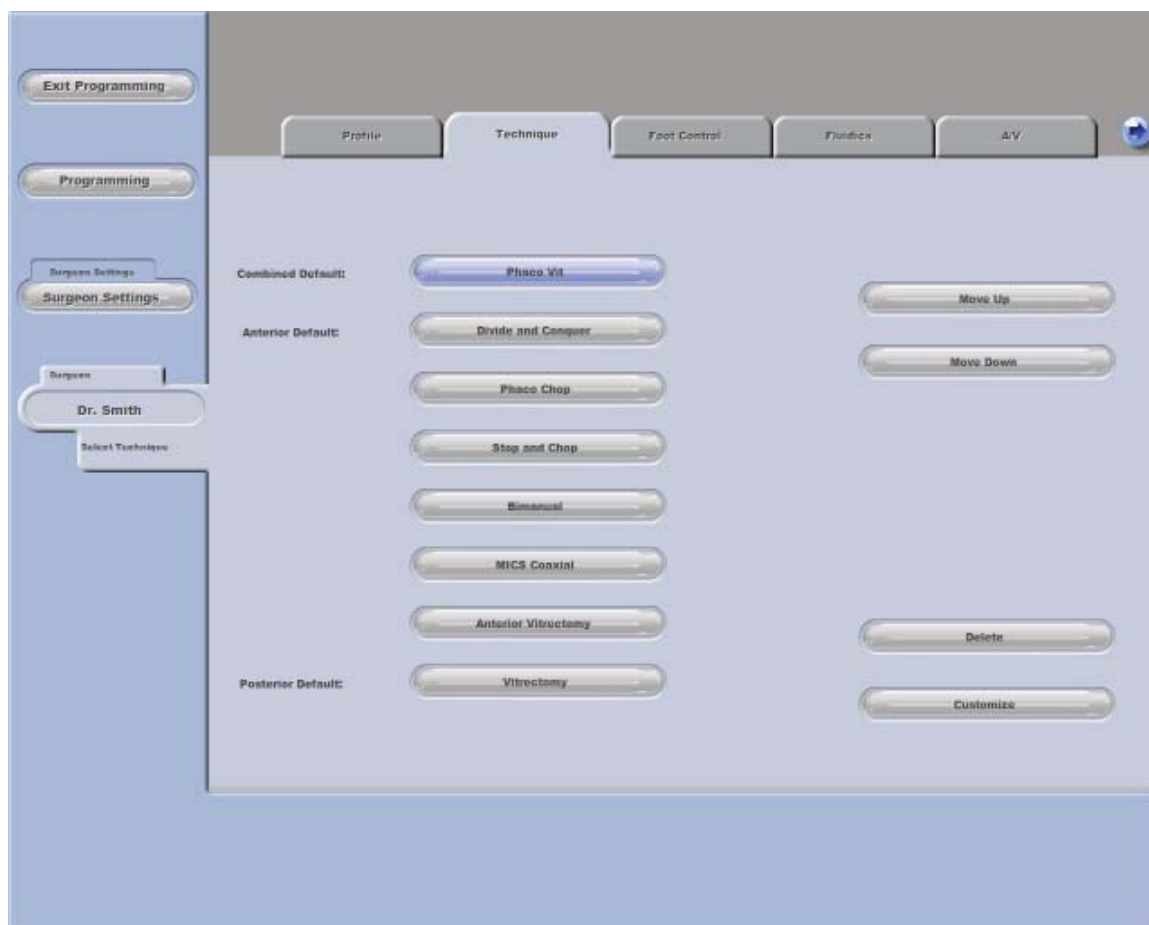


Figure 3.4. Techniques Tab on Surgeon Level Programming Screen.

Surgeon Level 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**, **Foot Control**, **Fluidics**, **A/V** and **Illuminators**. Various parameters may be adjusted through these tabs, as described below.



Figure 3.5. Customize Technique Screen.

- **Profile Tab**—Technique Name, Patient Pathology
- **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 8 exceptions. Exceptions can be added, deleted, or re-ordered. They may also be customized, as described below.
- **Foot Control Tab**—Foot Control Button (4 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**—Vacuum response (1 Fastest to 5 Slowest), venting method (fluid, air), F/AX (mmHg), air port (front, back), Infusion Type (IV Pole, pressurized), Infusion Units (cm H₂O, mmHg), Infusion Pressure, elevated infusion, elevated F/AX.
- **Illuminators Tab**—Upper lamp on/off and percent on, lower lamp on/off, percent on, and filter (none, amber, green, yellow)

For posterior techniques, the Irrigation Delay setting will not be displayed.

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, Pressurized Infusion pressure setting, and Pressurized Infusion Display setting are displayed.

- **A/V Tab**—Display Format (1 or 2), Status Bar Format (1, 2, 3), Remote Control (Enable/Disable)

For posterior techniques, the A/V tab is not available.

For combined techniques, status bar format and preview are available.

For anterior techniques, display format, display format preview, and status bar format are available.

Customizing Phases and Exceptions

Both Phases and Exceptions can be reordered and customized. Select a phase or exception from the list on the appropriate tab, and the **Customize** button will appear.



Note:

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

3 Customizing Your System

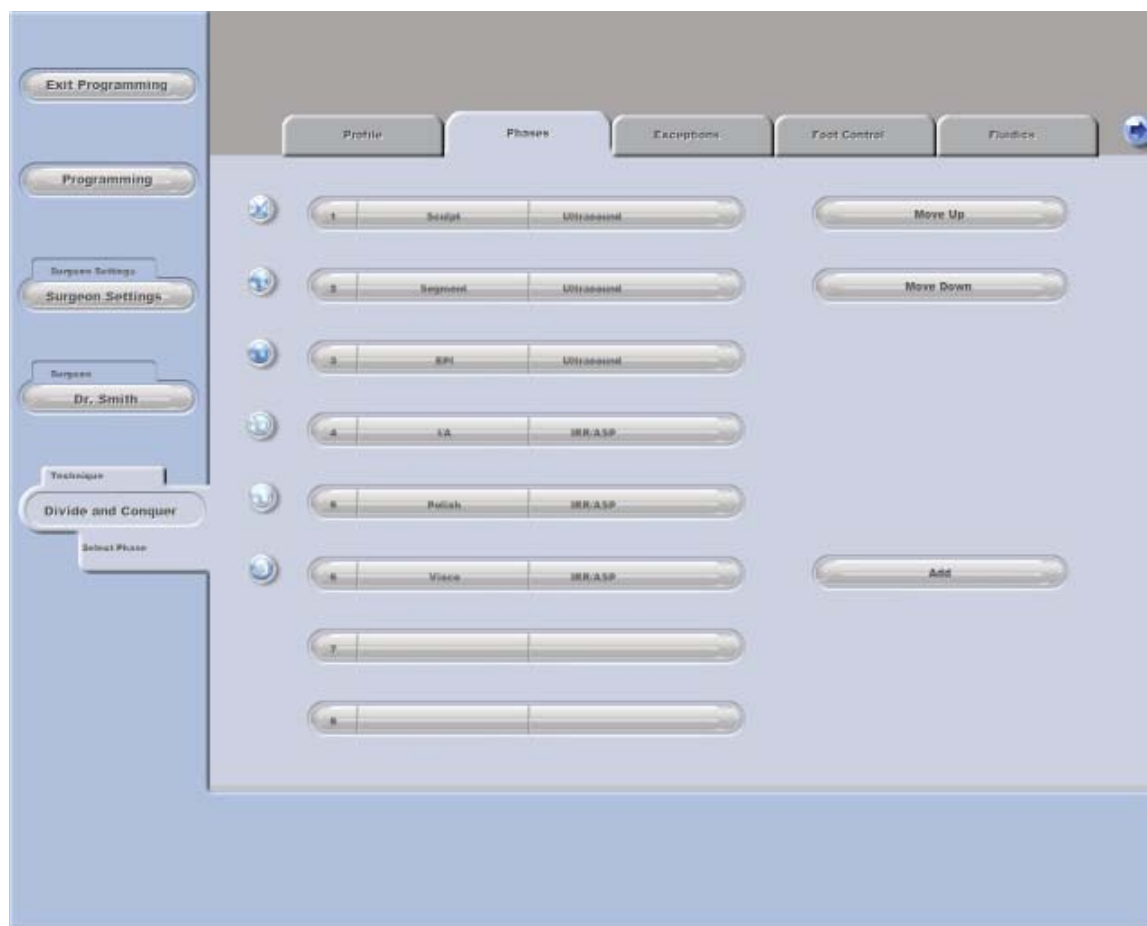


Figure 3.6. Customize Phase Screen.

Select **Customize**, and more options specific to that function will appear, and can be modified. These can include Profile, 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, Foot Control, Vacuum, Infusion, Cut
Phaco Frag	Profile, Foot Control, Vacuum, Infusion, U/S Settings, U/S Waveform
I/A	Profile, Foot Control, Vacuum, Infusion
Irrigation	Profile, Foot Control, Infusion
Viscous Fluid Control	Profile, Foot Control, Visc

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

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

The **Mode Change Control** allows you to set the *Stellaris® PC* Vision Enhancement System response when the footpedal is activated and you change surgical modes. Options are Allow Limit Pedal, Allow Range Pedal, Allow No Limiting, and Not While Active.

The **Detent Control** determines what feedback the *Stellaris® PC* Vision Enhancement System will give when changing footpedal regions. This can be disabled, Enabled for regions 1, 2 and 3 or Enabled for regions 2 and 3 only.

The **Region Spin Control Buttons** controls at what percent depression at which each region begins.

In combined configuration systems, a button is displayed that allows selection of Posterior Modes or Anterior Modes. When Posterior Modes is selected, the footpedal region 1 and 2 start positions are adjustable. The posterior mode start positions are used in the posterior domain and the posterior modes of the combined domain.

3 Customizing Your System

When Anterior Modes is selected, the footpedal 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.

In posterior-only configuration systems, the Posterior Modes / Anterior Modes button will not be displayed, and only the footpedal region 1 and 2 start positions will be adjustable.

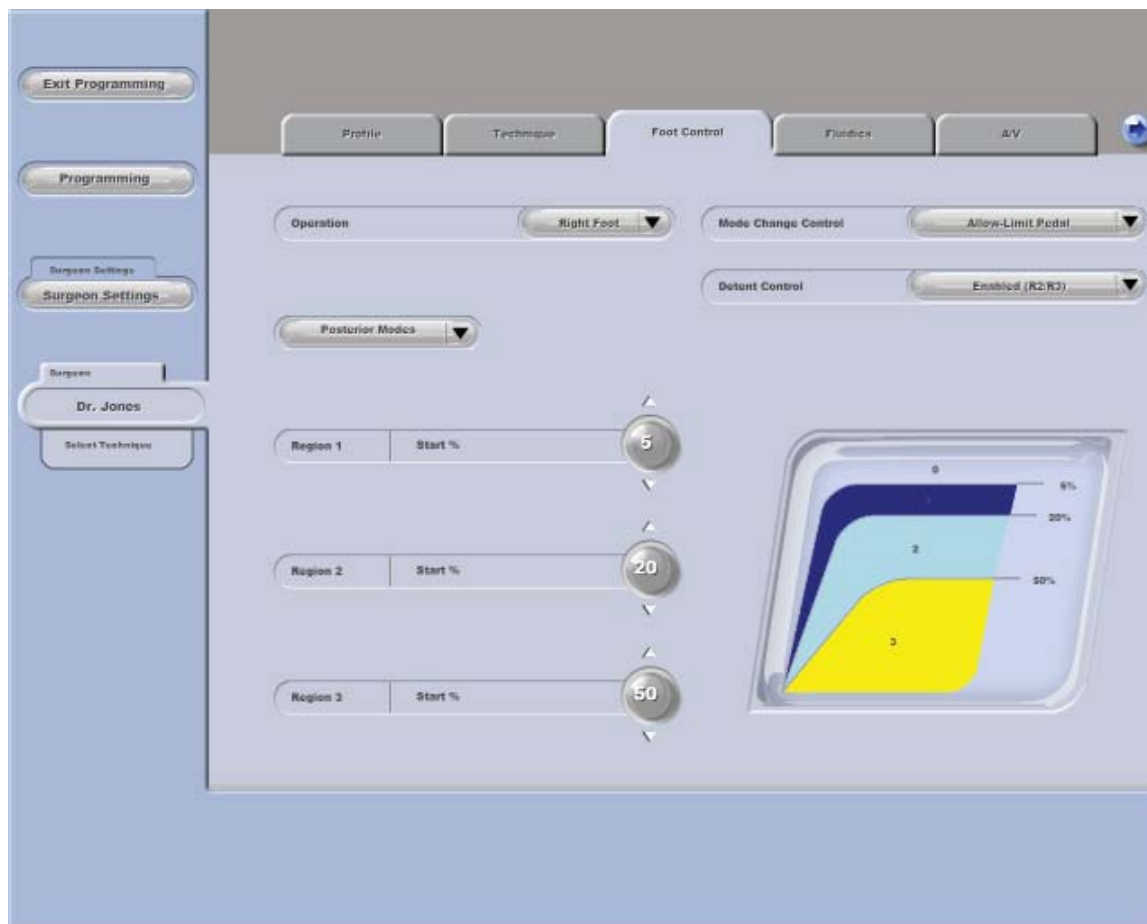


Figure 3.7. Customize Foot Control Screen.

Customize Fluidics

To set the parameters for Fluidics functions, select the **Fluidics Tab** from the **Surgeon Level Programming Screen**. You can set the **BSS Bottle Type**, **Patient Eye Level** (relative to the aspiration port on the fluidics system), **Ultrasound Needle Type**, **I/A Tip Type**, **Vit Tip Type** and **Frag needle**, by selecting the from the drop down menu that appears for each variable.

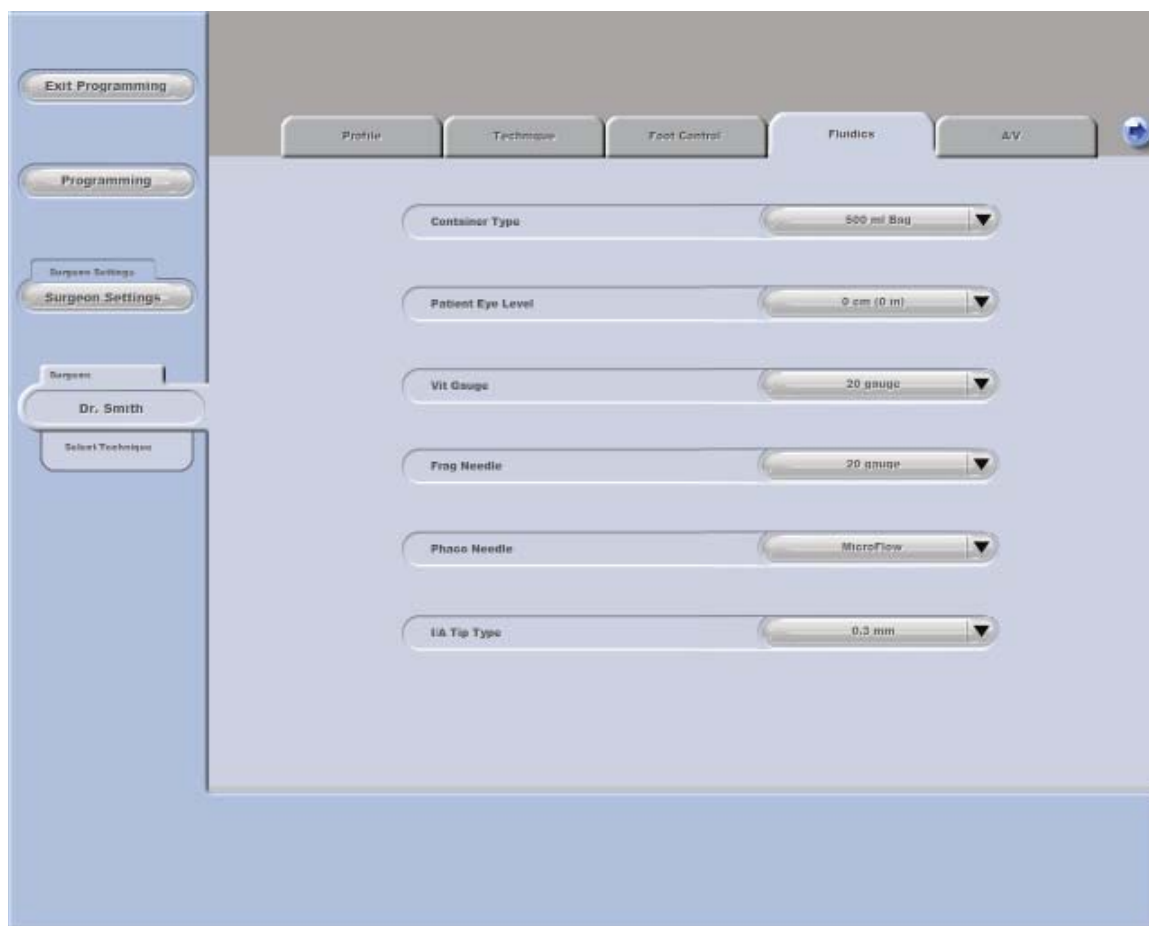


Figure 3.8. Customize Fluidics Screen.

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 spin controls 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 spin control button to increase or decrease the volume.



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

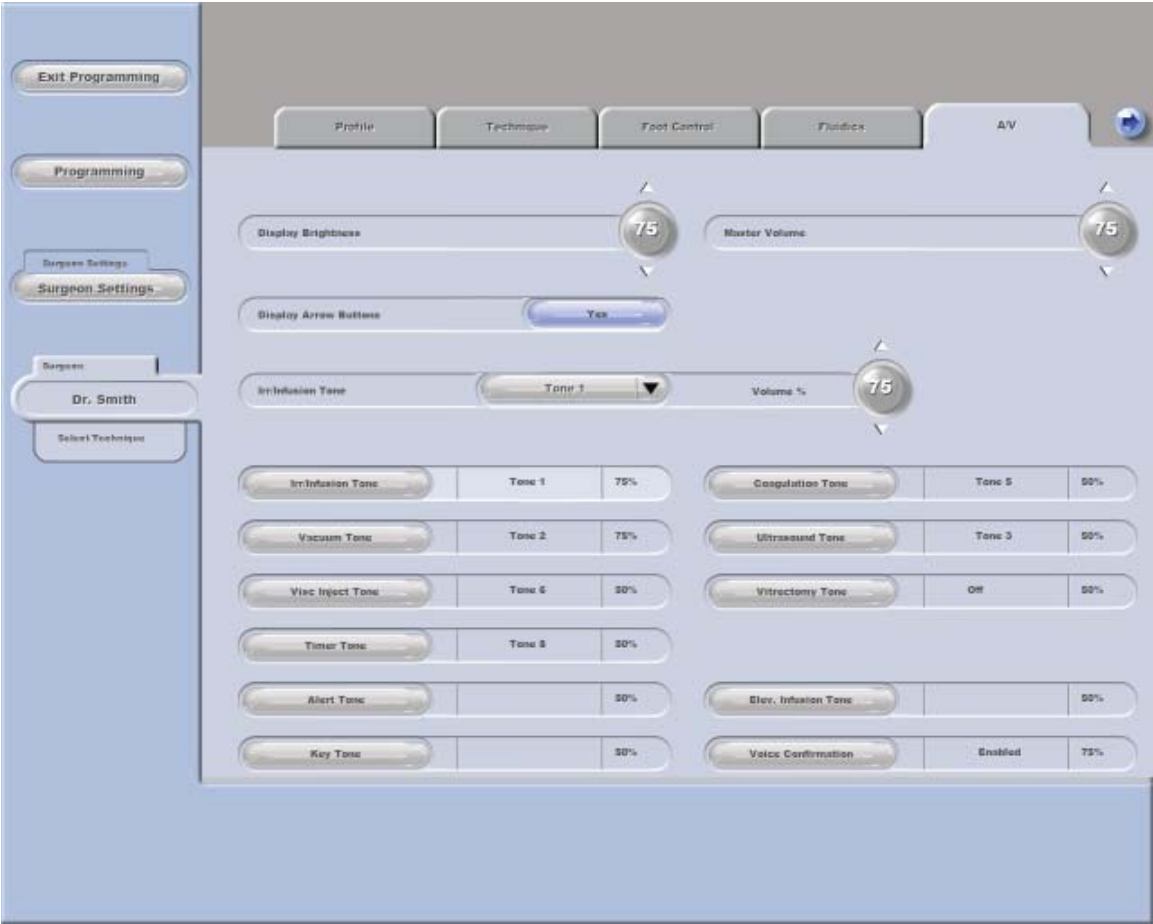


Figure 3.9. Customize Audio/Visual Settings Screen.

Customize Video Overlay

To set the parameters for the MMC 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, and case 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, and case information on two lines, but if the combine option is set to **Yes** each 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%.

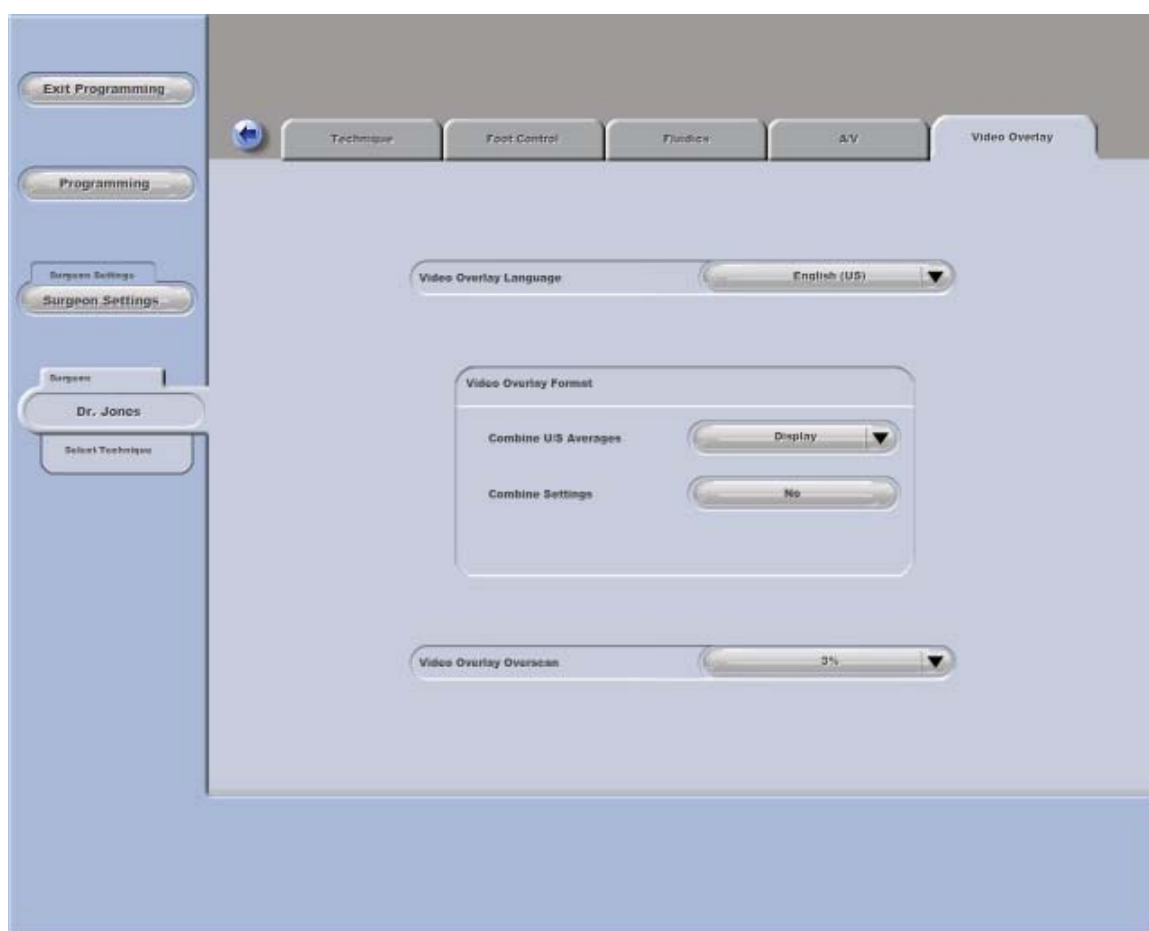


Figure 3.10. Customize Video Overlay Screen.

3.3. Manage Surgeon Files

Create a New Settings File

To create a new surgeon preference file, select the **Create Tab** from the **Manage 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.

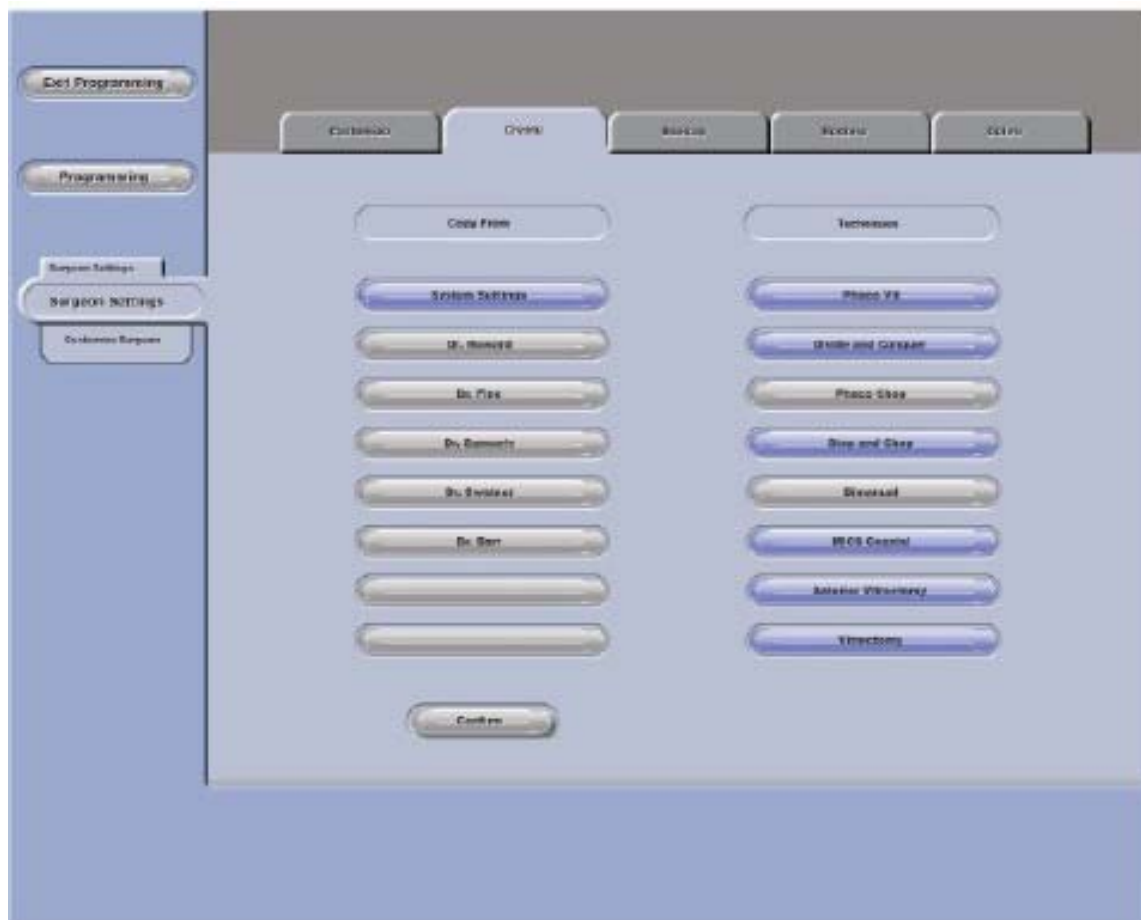


Figure 3.11. Create New Settings File Screen.

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**, **Foot Control**, and **Fluidics**) will appear across the top of the screen. These can be used to further customize the preference file (see page 3-6).

Backup a Settings File

To backup an existing surgeon preference file to a USB memory device, select the **Backup Tab** from the **Manage Settings Screen**, 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 USB device after this screen is selected.



Note: Memory devices complying with either USB 1.1 or USB 2.0 standards are supported by the **Stellaris® PC Vision Enhancement System**. Operations with other USB devices are **NOT** supported.

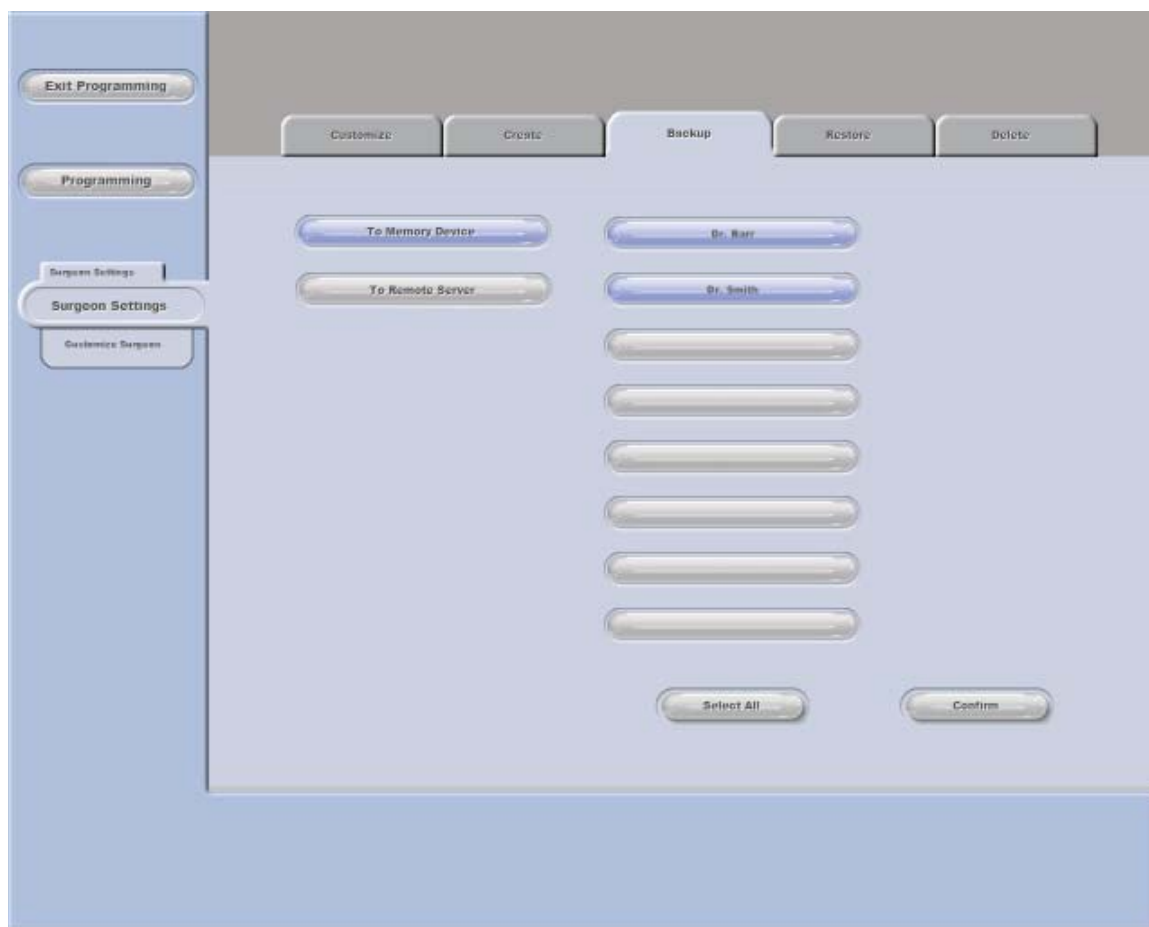


Figure 3.12. Backup Settings File Screen.

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**.



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.

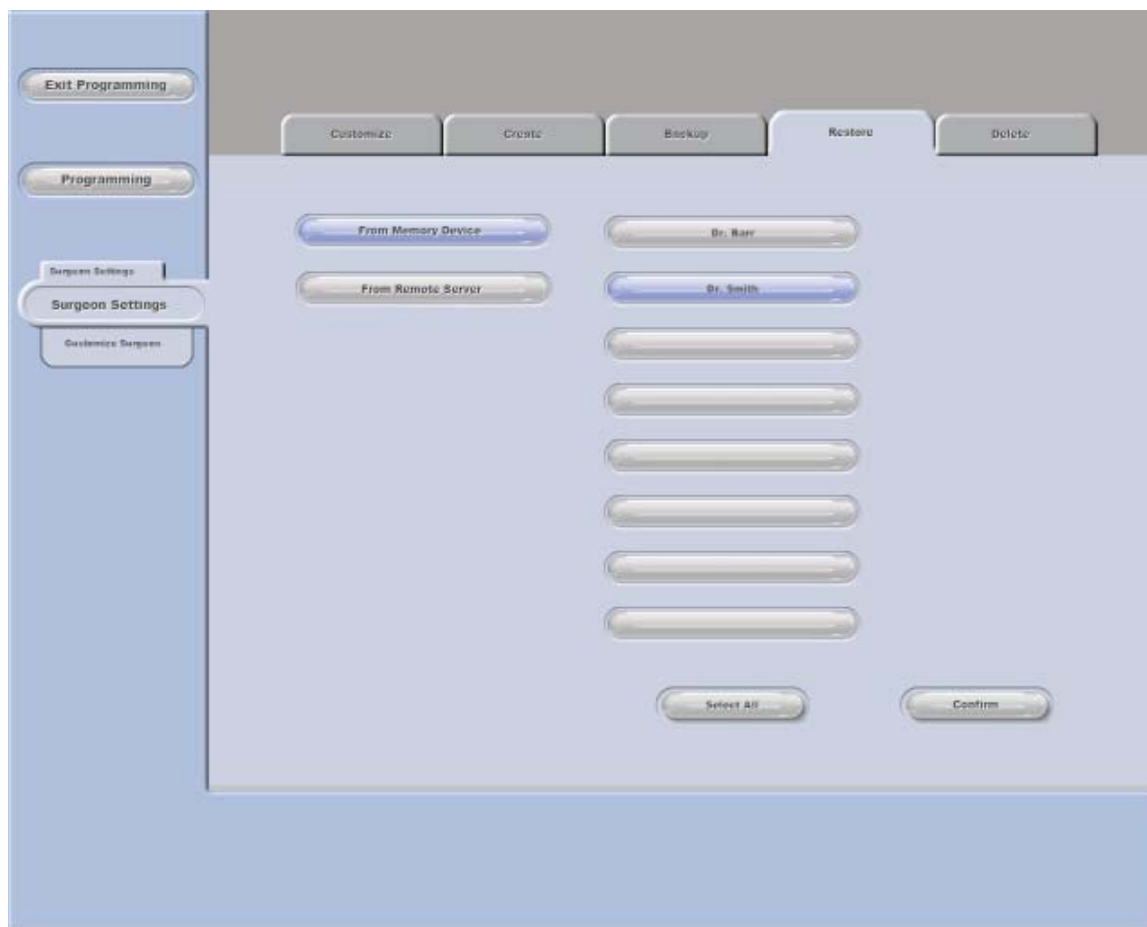


Figure 3.13. Restore Settings File Screen.

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**.

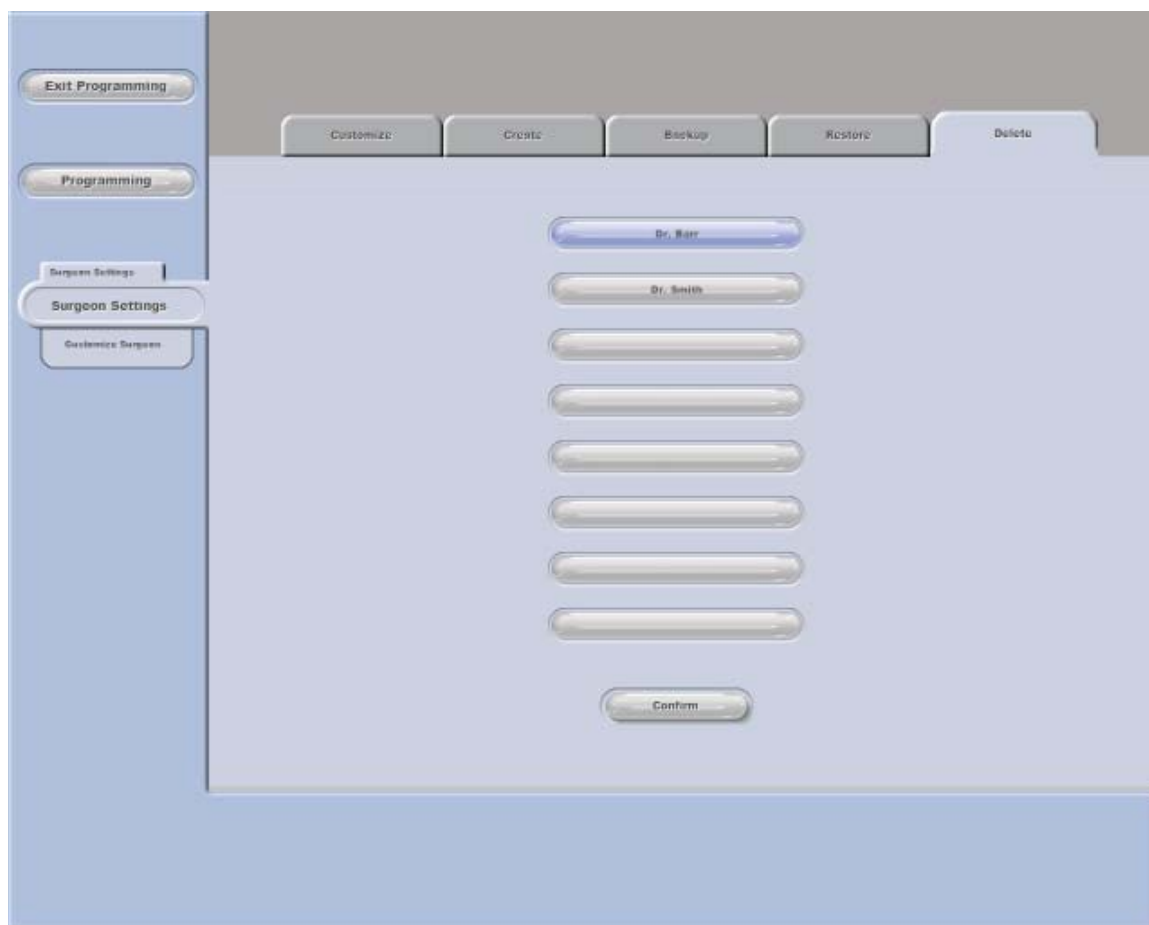


Figure 3.14. Delete Settings File Screen.

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** 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.

The screenshot shows the 'Set System Date/Time Screen'. On the left is a blue sidebar with three buttons: 'Exit Programming', 'Programming', and 'System Setup'. The main area has a header with three tabs: 'Date/Time', 'System ID', and 'Rooms'. The 'Date/Time' tab is selected. Below the tabs are several settings: 'System Default Language' set to 'English (US)', 'Month' set to 'Sep', 'Day' set to '29', 'Year' set to '2008', 'Format' set to '12 Hour', 'Hours' set to '3 PM', and 'Minutes' set to '27'. To the right of these settings is a digital clock display showing '03:27:41 PM'. At the bottom right is a 'Confirm' button.

Figure 3.15. Set System Date/Time Screen.

System ID

To monitor or change the identifying names of your *Stellaris*® PC 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*® PC Vision Enhancement System. You can view the system catalog number as well as its installation number, but these are not editable.

The screenshot shows the 'System ID' screen. On the left is a blue sidebar with three buttons: 'Exit Programming', 'Programming', and 'System Setup'. The 'System Setup' button is highlighted. The main area has a header with three tabs: 'Date/Time', 'System ID', and 'Rooms'. The 'System ID' tab is selected. Below the tabs are five input fields: 'System Catalog Number', 'System Serial Number', 'System Installation Number', 'Account Name', and 'System Name'. The first three fields are read-only, while the last two have text input boxes and a 'Change' button.

Figure 3.16. System ID Screen.

Rooms

To assign names to the operating rooms in which your *Stellaris® PC* Vision Enhancement System is used, select any room button, the keyboard will appear, and 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 spin control 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).

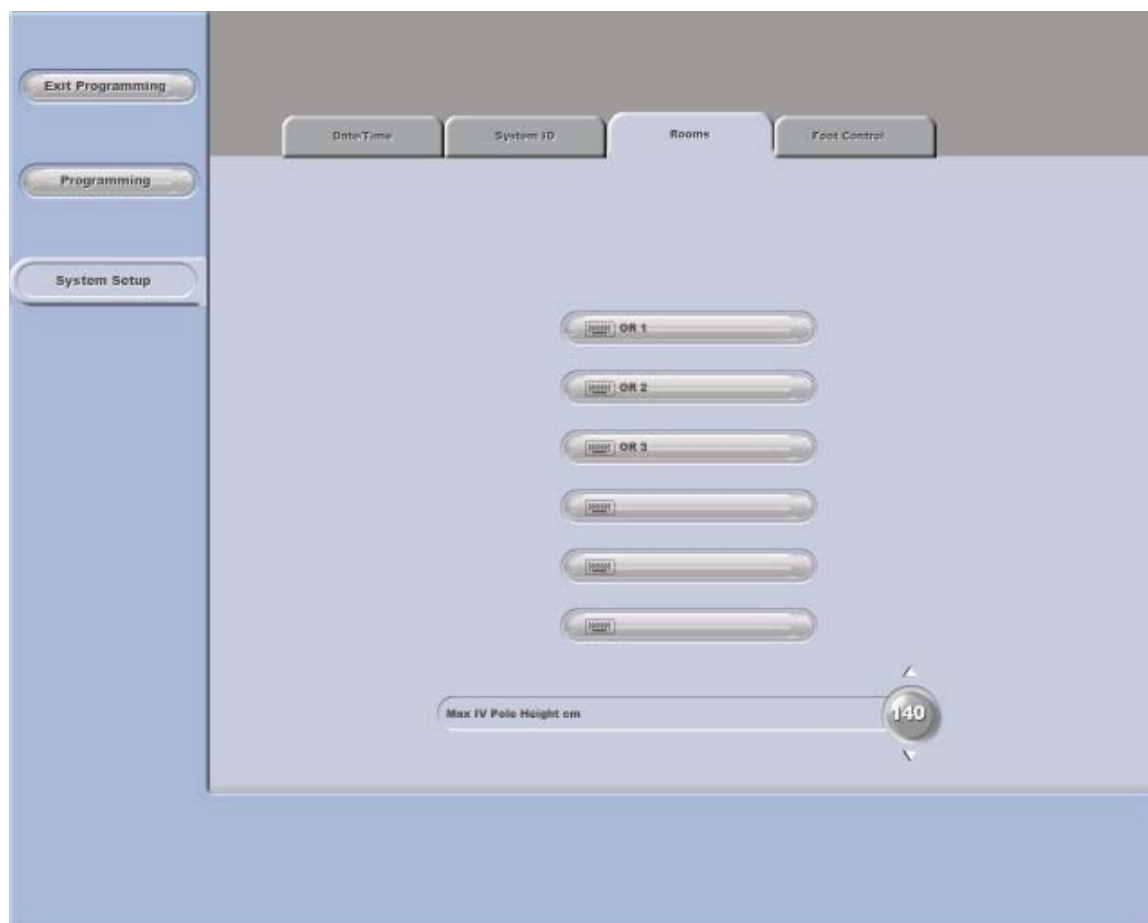


Figure 3.17. Room Assignment Screen.

Foot Control

To change the way you *Stellaris*® PC Vision Enhancement System connects to the Foot Control, select the **Foot Control Tab** at the top of the **System Setup Screen**. Select **Enabled** or **Disabled** to configure the connection mode.

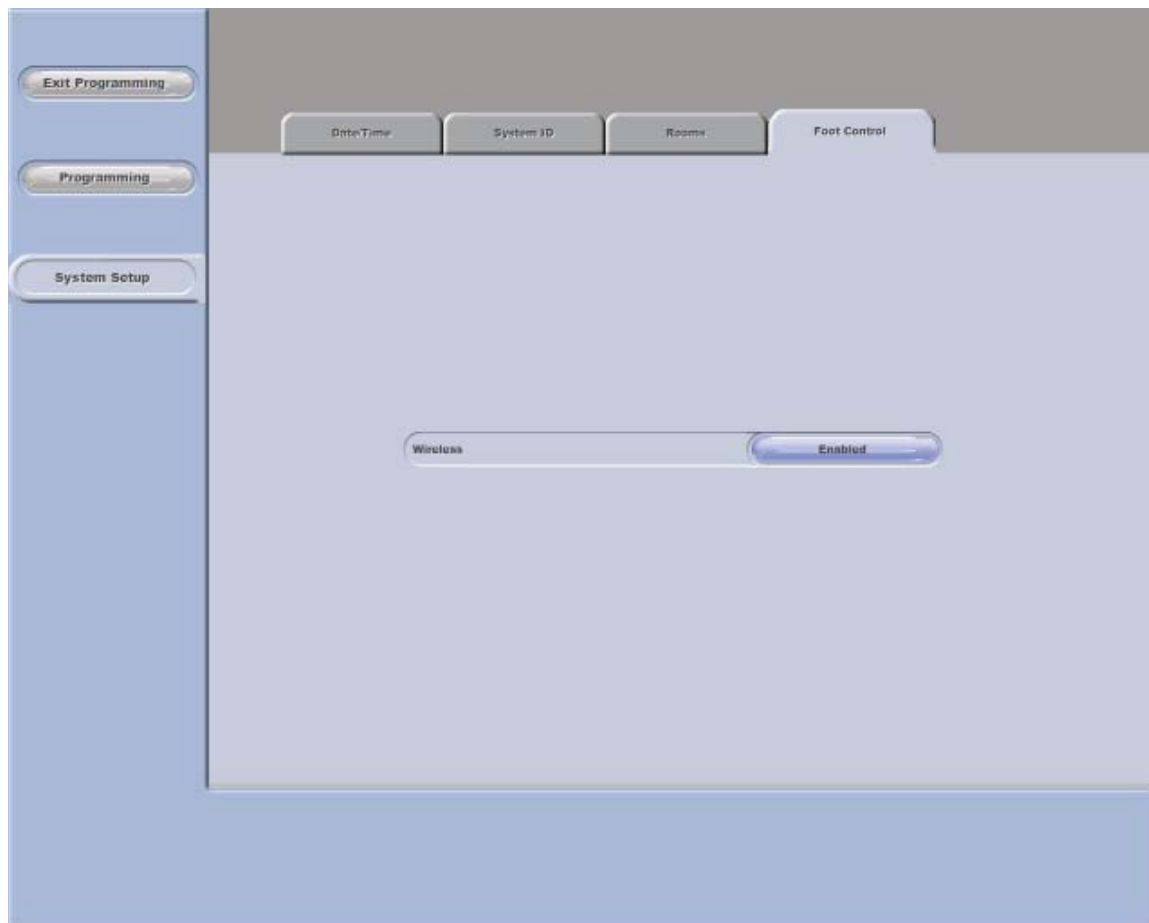


Figure 3.18. Foot Control Connectivity Screen.

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**.

Exit Programming

Programming

System Configuration

Software Options

Surgical Functions	Anterior Only
Fluidics Module	VFM
Electric Vitrectomy	Enabled
Multimedia Center	Enabled
TruLink Remote Access	Enabled

Run Option

Install/Uninstall

Module Configuration

Module Configuration	Serial Number	Software Version	Hardware Version
User Interface Computer		1.5	1.0
Remote Control Receiver			
Multimedia Center			
Foot Control Receiver			
Foot Controller			
Vacuum Fluidics Module			
Advanced Flow Module			
Ultrasound Module			
IV Pole Controller			
Compressor Module			
Power Supply Module			

Figure 3.19. 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 four user-editable columns.

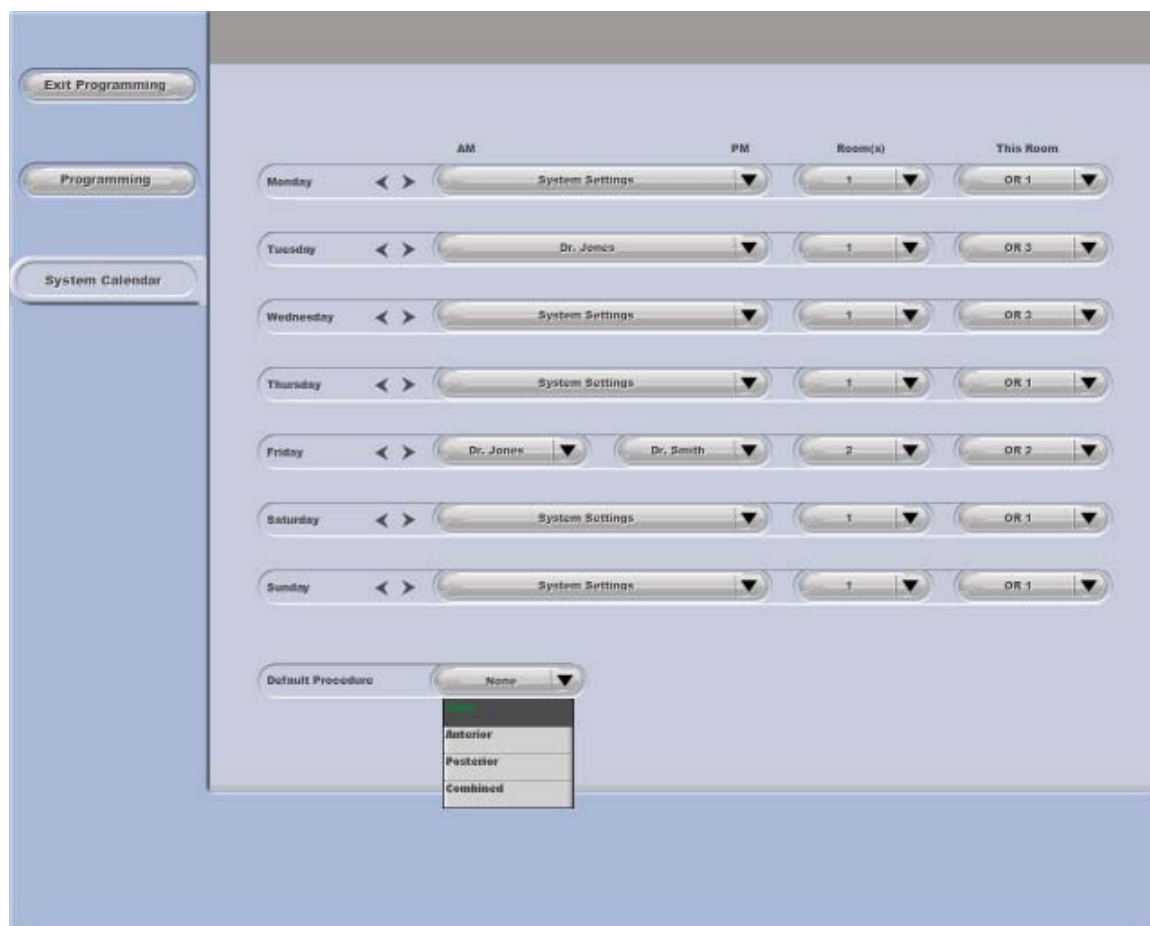


Figure 3.20. System Calendar Screen.

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 **>** **<** or **<** **>** 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*® PC 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*® PC 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 pull-down menu at the bottom of the screen allows you to select the default mode for the system.

The Default Procedure setting, Rooms column, and This Room column are not displayed in posterior only configuration systems.

3.7. TruLink® Customer Support Network



WARNING: *You must contact your local Bausch + Lomb sales and support office before activating the TruLink® Customer Support Network function. See Technical Assistance on page 7-1 for the sales and support office that serves your location.*



WARNING: *Do not conduct surgery or any patient procedures while TruLink® Customer Support Network is activated. Serious patient injury may occur.*

This feature allows Bausch + Lomb technicians to remotely access your system, to diagnose problems and provide updates.

To manage the secure point-to-point connection between your system and Bausch + Lomb, select **Remote Service** from the **Main Programming Screen**, and a new screen will appear through which you can monitor and initiate remote service on your system.



Figure 3.21. TruLink® Customer Support Network.

Ensure that the Ethernet cable is connected to the **Stellaris® PC** Vision Enhancement System, and to the designated hospital network port. Confirm that the system is not being used for surgery and select **Initiate TruLink Connection**.



Note:

If you have the optional MMC system, the Ethernet cable should be connected to the MMC, then the MMC connected to the designated network hospital Ethernet port.

3 Customizing Your System

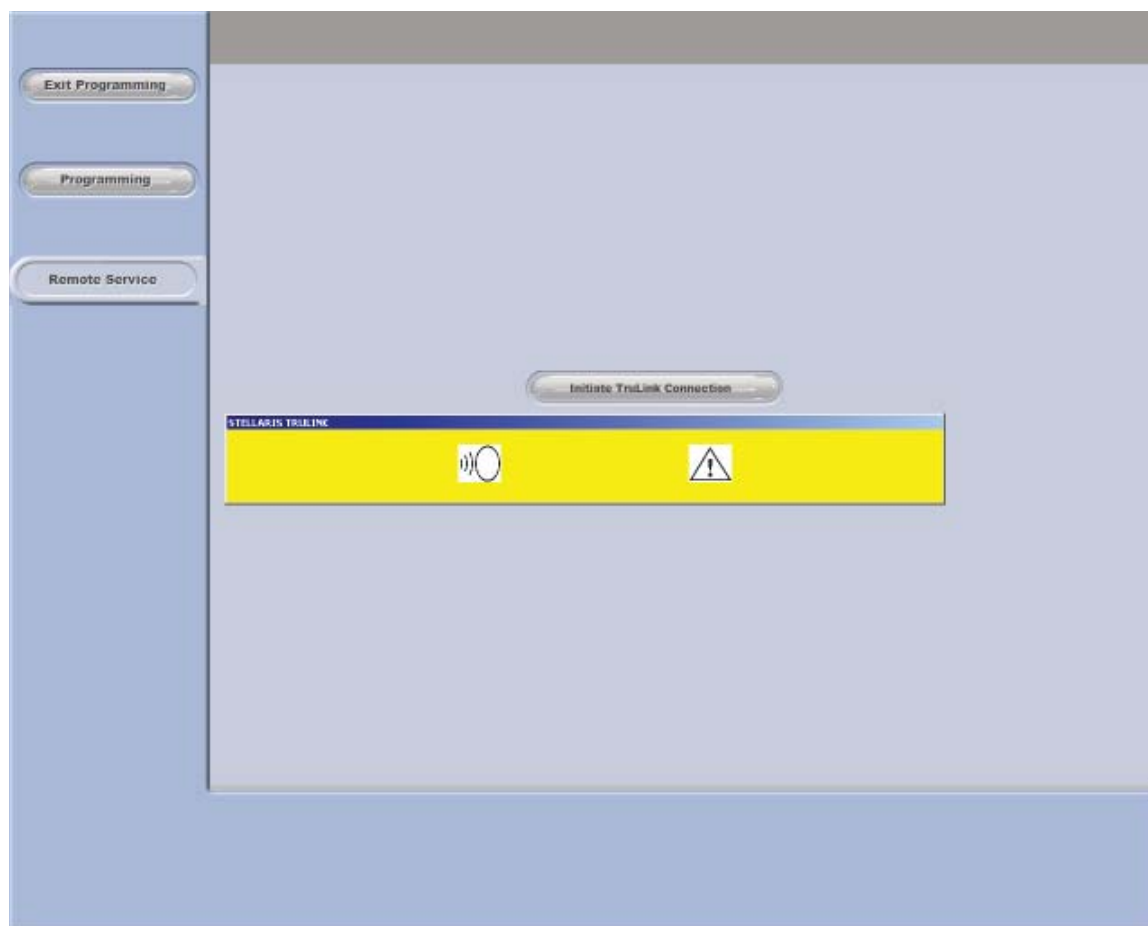


Figure 3.22. TruLink® Customer Support Network Activated Screen.

The system will then be controlled by the remote technician.

When the remote technician is finished, your **Stellaris® PC** Vision Enhancement System will be shut down. You may then restart the system.



Note: *Off-the-shelf Ethernet cables may be used with the **Stellaris® PC** Vision Enhancement System to establish or restore connections.*

3.8. Customization Levels

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

Audio/Visual Customization Level

Parameter	Options, Ranges, Step Sizes	
Surgeon name	Typewriter data entry (30 characters max)	Surgeon
Screen / voice language*	English (US), English (UK), Czech, Danish, German, Greek, Spanish, Estonian, Finnish, French, Hungarian, Italian, Dutch, Polish, Portuguese, Romanian, Slovak, Swedish, Simplified Chinese, Japanese, Korean, Russian	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	Irr/Infusion - No tone, Tone 1 - Tone 10, 0% to 100%, by 5% Vacuum - No tone, Tone 1 - Tone 10, 0% to 100%, by 5% U/S, No tone, Tone 1 - Tone 10, 0% to 100%, by 5% Vit, No tone, Tone 1 - Tone 10, 0% to 100%, by 5% Visc and Timer: No tone, Tone 1 to Tone 10, 0% to 100% by 5% Key Tone - 0% to 100% by 5% Coag - Tone 1 to Tone 10, 20% to 100% by 5% Alert and Elev. Infusion - 20% to 100% by 5%	Surgeon
Voice confirmation	Enabled / Disabled Volume: 0% to 100%, by 5%	Surgeon
Video overlay language*	English (US), English (UK), Czech, Danish, German, Greek, Spanish, Estonian, Finnish, French, Hungarian, Italian, Dutch, Polish, Portuguese, Romanian, Slovak, Swedish, Simplified Chinese, Japanese, Korean, Russian	Surgeon
Video overlay display format	Combine U/S Averages: Display, Combined Display, No Display Combine settings lines - No, Yes	Surgeon
Video overlay overscan allowance	0% to 5%, by 1%	Surgeon
Technique Name	Typewriter Data Entry (20 characters max)	Technique
Surgical Mode Display Format	Format 1, Format 2 (Anterior Domain Only)	Technique
Status Bar Display Format	Anterior: Formats 1, 2, and 3 Combined: Formats 1 and 2 only Posterior: Format 1 only (not user programmable)	Technique

* when available

Case Customization Levels

Parameter	Options/Ranges/Step Sizes	
Customize Settings by Case	Disabled, Enabled	Phase
Customize Fluidics Settings by Needle/Tip	Disabled, Enabled	Phase
Customize Fluidics Settings by Cataract Grade	Disabled, Enabled	Phase
Customize Fluidics Settings by Pathology	Disabled, Enabled	Phase
Customize Ultrasound Settings by Needle/Tip	Disabled, Enabled	Technique
Customize Ultrasound Settings by Cataract Grade	Disabled, Enabled	Technique
Customize Ultrasound Settings by Pathology	Disabled, Enabled	Technique
Pathology Name	Typewriter data entry (20 characters max)	Technique
Phase Name	Typewriter data entry (8 characters max)	Phase
Mode Type	Ultrasound, Irrigation/Aspiration, Irrigation, Coagulation, Vitrectomy	Phase
Mode Icon	All icons for the given mode type	Phase
Ultrasound Submode Name	Typewriter data entry (20 characters max)	Phase

Foot Control

Parameter	Options/Ranges/Sizes	
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
Group toe/ heel switches	Left side: Group / Ungroup Right side: Group / Ungroup	Technique
Linear Coagulation in Setup Mode	Disabled, Enabled	Technique
Reflux	Continuous, Single High, Single Low	Technique, Phase
Next Ultrasound Modulation on Yaw	Disabled, Enabled Note that for single linear footpedal modes, the outward yaw motion would be used for next ultrasound modulation, and for dual linear footpedal 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 Foot Control buttons is programmed to activate fixed coagulation.	Technique, Phase
Dual Linear Control	Mode Level: (If Enabled at Technique Level) U/S Modes: Disabled, Asp on Yaw, Asp on Pitch, Dual Linear U/S I/A Modes: Disabled Vit Modes: Disabled, Asp on Pitch, Asp on Yaw, Dual Irr Mode / Coag Modes: Disabled (not displayed)	Phase

Foot Control Switches

The Foot Control switches can be customized at the Technique and Phase levels.

Anterior Domain	<ul style="list-style-type: none">• unassigned• previous phase• next phase• next U/S modulation submode• previous 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
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Posterior and Combined Domains	<ul style="list-style-type: none"> • unassigned next phase • previous phase • next U/S modulation submode • confirm settings • infusion on/off • elevated 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 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 • decrease viscous fluid pressure • 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
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Fluidics

Parameter	Options/Ranges/Step Sizes	
Max bottle height	140 cm	System
BSS Container Type	500 ml Bottle, 500 ml Bag, 250 ml Bottle	Surgeon
Patient Eye Level	-15 cm to +15 cm	Surgeon
Default Ultrasound Tip Type	Standard, MicroFlow+, MicroFlow, Thin Tip, Coaxial MICS, Stable Flow 20 Gauge, Stable Flow 19 Gauge	Surgeon
Default I/A Tip Type	0.3 mm, 0.5 mm	Surgeon
Default Vitrectomy Tip Type	20, 23 and 25 Gauge	Surgeon
IV Pole bottle height	30 to 140 cm, by 5 cm	Technique, Phase/ Case
Irrigation Delay	100 to 3000 ms, steps of 50 milliseconds. 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
Aspiration type: -Anterior Domain: Types available depend on aspiration types enabled at the technique level, the dual linear control options and the mode handpiece type selected) -Posterior and Combined Domain: Types available depend on the sub-mode selection.	<ul style="list-style-type: none"> • Fixed vacuum • Fixed vacuum, with aspiration control feature • Linear vacuum • Linear vacuum, with aspiration control feature 	Phase/Case
Fixed vacuum level or linear vacuum maximum level	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 600 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case
Linear vacuum minimum level	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 600 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case
Region 2 minimum vacuum, for aspiration control feature	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 600 mmHg by 10 mmHg	Phase/Case
Foot control mapping (for linear control)	Linear, Front Loaded, Back Loaded	Phase/Case

Parameter	Options/Ranges/Step Sizes	
Pitch function for dual linear flow aspiration modes	Vacuum limit, Flow	Phase/Case
Foot control mapping (for yaw function linear control in dual linear aspiration flow modes)	Linear, Front Loaded, Back Loaded	Phase/Case
Pressurized infusion displayed (Anterior Domain Only)	Enabled/Disabled	Technique
Pressurized infusion Pump	On/Off	Technique
Pressurized infusion Pressure	0 mmHg to 20 mmHg, by 2 mmHg 20 mmHg to 150 mmHg, by 5 mmHg (tab)	Technique, Phase/ Case
Infusion Units (Posterior and Combined Domains)	mmHg and cmH ₂ O	Surgeon
Posterior Infusion Type	Manual, Auto On, Auto On/Off	Surgeon

Ultrasound

Parameter	Options/Ranges/Step Sizes	
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	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
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

3 Customizing Your System

Parameter	Options/Ranges/Step Sizes	
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 msec and a maximum off time of 1500 msec	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 msec and a maximum off time of 1500 msec	Phase/Case
Foot control mapping (for linear control) - front loaded, linear, back loaded	Linear, Front Loaded, Back Loaded	Phase/Case
Waveform Type	Ramped (not programmable)	Phase/Case
Waveform duration	250 ms to 1000 ms by 50 ms (resolution of 50 ms even with calculator)	Phase/Case
Waveform Depth	25% to 100% by 5%	Phase/Case
Pulsed mode linear pulse rate minimum	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
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
Foot control mapping (for second ultrasound linear control)	Linear, Front Loaded, Back Loaded, Reverse Linear, Reverse Front Loaded, Reverse Back Loaded	Phase/Case

Vitrectomy

Parameter	Options/Ranges/Step Sizes	
Fixed cut rate or linear cut rate maximum rate	Pneumatic: 30 cpm to 5000 cpm 30 cpm to 100 cpm by 10 cpm 100 cpm to 1000 cpm by 50 cpm 1000 cpm to 5000 cpm, in steps of 100 cpm	Phase/Case
Linear cut rate minimum rate	Pneumatic: 30 cpm to 5000 cpm 30 cpm to 100 cpm by 10 cpm 100 cpm to 1000 cpm by 50 cpm 1000 cpm to 5000 cpm, in steps of 100 cpm	Phase/Case
Foot control mapping	Linear, Front Loaded, Back Loaded, Reverse Linear, Reverse Front Loaded, Reverse Back Loaded	Phase/Case

Coagulation

Parameter	Options/Ranges/Step Sizes	
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
Foot control mapping	Linear, Front Loaded, Back Loaded	Phase

Detailed Reference

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



WARNING: *Do not use in the presence of flammable anaesthetics, disinfectants, aerosol sprays, or in an oxygen rich atmosphere.*



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® PC 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® PC** Vision Enhancement System, the irrigation line from an inverted bottle of balanced salt solution (BSS) is integrated into the tubing manifold at the top part of the vacuum cassette. The delivery pressure of the BSS 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 Footpedal (for Anterior modes or Posterior modes with infusion type Auto On/ ON).

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 and reprime before aspiration will be re-enabled. In Posterior/Combined domains, surgery can be resumed without re-priming if the cassette is ejected from the surgical screen.



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, such as do not bend, cut or engrave, as they could break or malfunction.*



Note: *Stellaris® PC 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

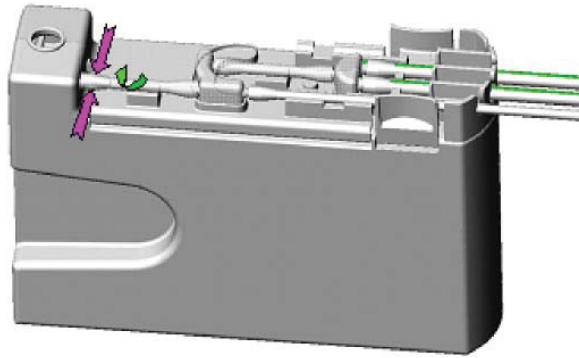


WARNING: *Improper reassembly of tubing manifold to the cassette may result in inadequate system performance.*

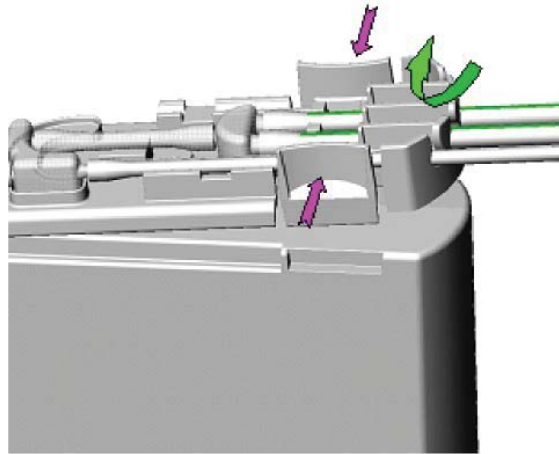
The **Stellaris® PC** Vision Enhancement System's cassette can be emptied during operation by using following instructions:

1. Stop the 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.
4. Remove the cassette from the system.

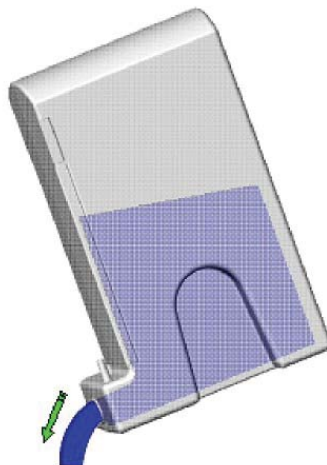
5. Detach the aspiration tubing that connects to the cassette. Hold aspiration tubing very close to the connector to facilitate removal (pink arrows).



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

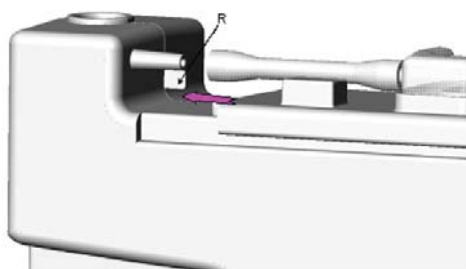


7. Drain the fluid out of the cassette.

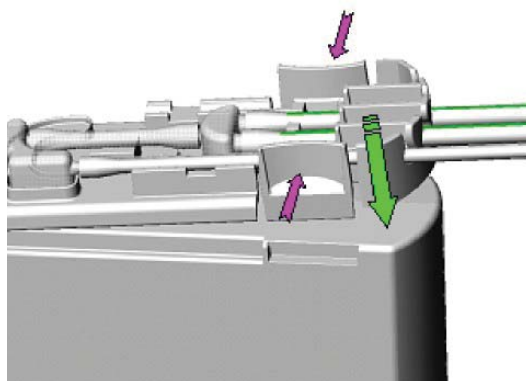


4 Detailed Reference

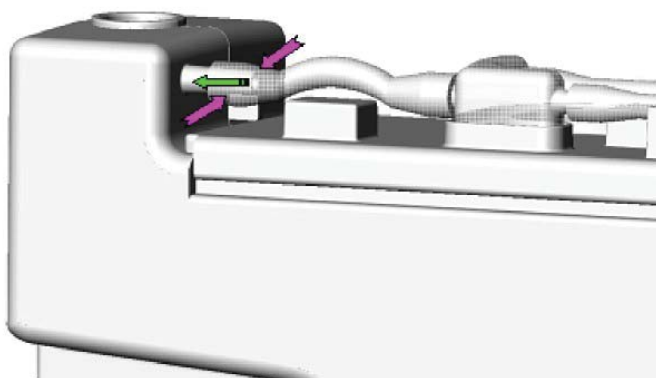
8. Assemble tubing manifold by first sliding the front end under the cassette retainer (R).



9. Press the manifold to latch manifold to the cassette.



10. Connect aspiration tubing to the cassette connector.



11. Insert cassette to the system.
12. Release irrigation clamp. (The clamp near the bottle and the clamp at the 2-way stopcock).
13. Resume surgery once system pass vacuum check and surgical screen is displayed.



Note: *No re-priming is needed.*

4.2. Posterior Functions

Posterior Vitrectomy Function

The *Stellaris® PC* 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 is then cut and aspirated into a disposable collection container through the attached tubing.

Vitrectomy Cutter Modes

The *Stellaris® PC* Vision Enhancement System provides four vitrectomy cutter modes as described below. The cut rate may be adjusted from 30 to 5000 cpm, with increments as shown in the table below, or to any specific value using the keypad.

Range	Step Size
30 to 100 cpm	10 cpm
100 to 1000 cpm	50 cpm
1000 to 5000 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).

Fixed Cut

Fixed cut is a single region pitch control mode, and vitreous cutting is activated the moment footpedal is depressed. The cut rate is fixed. Vacuum is proportional to footpedal depression. Each successive outward yaw movement of the footpedal 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.

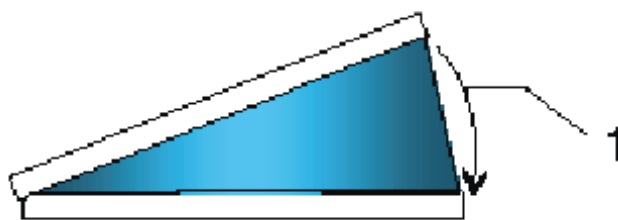


Figure 4.1. Single region pitch control, Fixed cut, linear vacuum.

Dual Linear Cut: Dual/Yaw Cut

Dual Linear cut uses two region pitch and yaw control. Pressing the footpedal downward into Region 1 is necessary to activate cutting with outward yaw. Outward yaw while in Region 1 activates cutting without

4 Detailed Reference

vacuum. Linear control of the cut rate is a function of footpedal yaw displacement. Further depressing the footpedal downward to Region 2 activates linear vacuum.

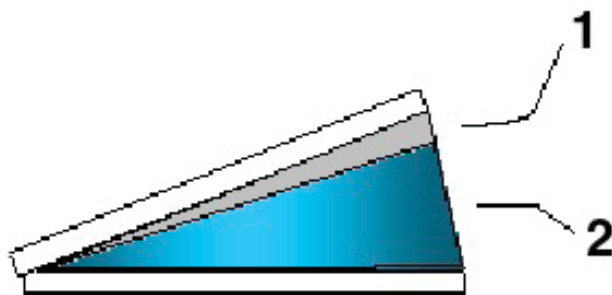


Figure 4.2. Diagram showing two region pitch control programmed for Dual Linear Cut.

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 footpedal 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.

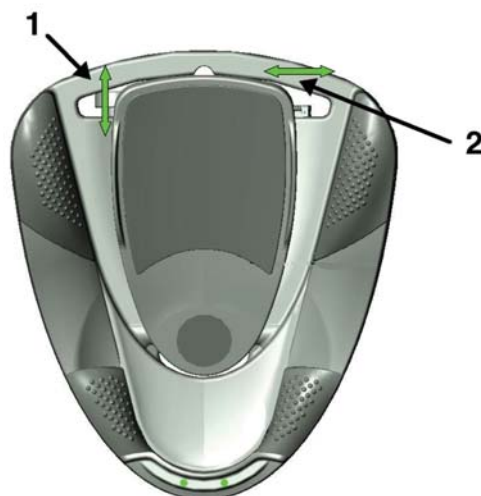


Figure 4.3. Foot control pop view to illustrate Dual/Yaw Cut vitrectomy programmed for Right Foot.

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 a yaw control mode. Pressing the footpedal 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 footpedal yaw displacement. Further depressing footpedal downward into Region 2 activates the linear cut rate.

The actual cut rate and vacuum level is displayed on the screen. When the footpedal 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 footpedal 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 footpedal 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 footpedal pitch controls linear Vacuum. Single cut will be activated when the footpedal move to 95%. Release the footpedal back to at least 75% in order to have the subsequent single cut.

For all vitrectomy modes, reflux (if enabled) is by inward yaw movement of the footpedal. The foot control side button can also be programmed to activate reflux function.



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

Posterior Vitrectomy Setup and Use



Note: Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.



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® PC Vision Enhancement System aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.

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 Foot Control or other system messages.
3. Acknowledge and close all messages.
4. To operate the Foot Control wirelessly, press any button on the Foot Control and wait until the right 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 1.7.)

4 Detailed Reference

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 left hand and the thumb placed in the thumb notch. (Circulating Nurse)
 - b. Tear open the Tyvek® seal 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 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)

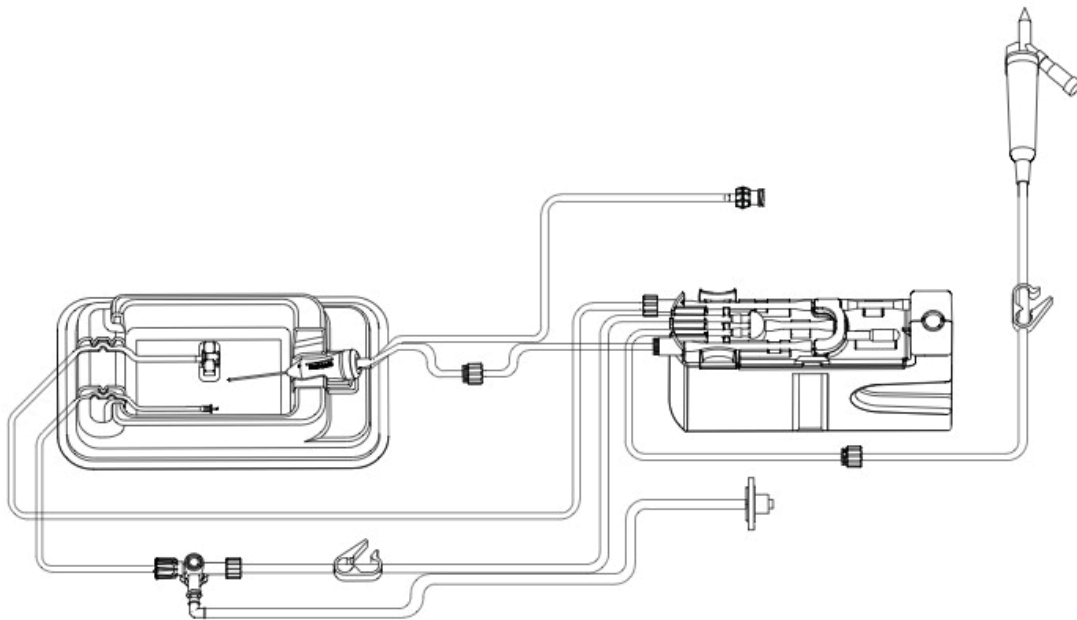


Figure 4.4. Pre-connected Tubing set arrangement to facilitate setup.

- 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 BSS bottle on the automated I/V 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.

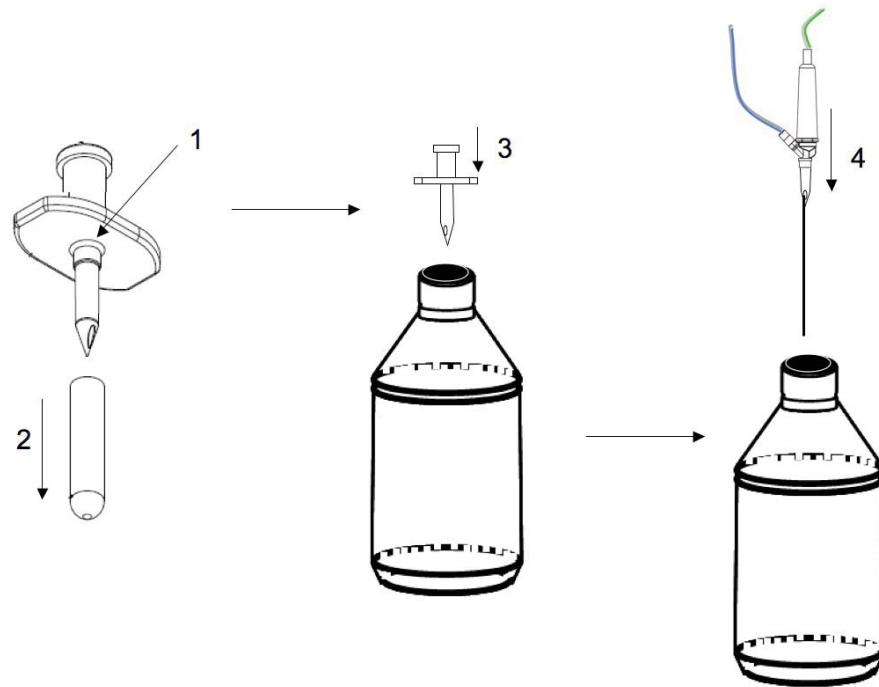


Figure 4.5. AFI Setup instructions

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)

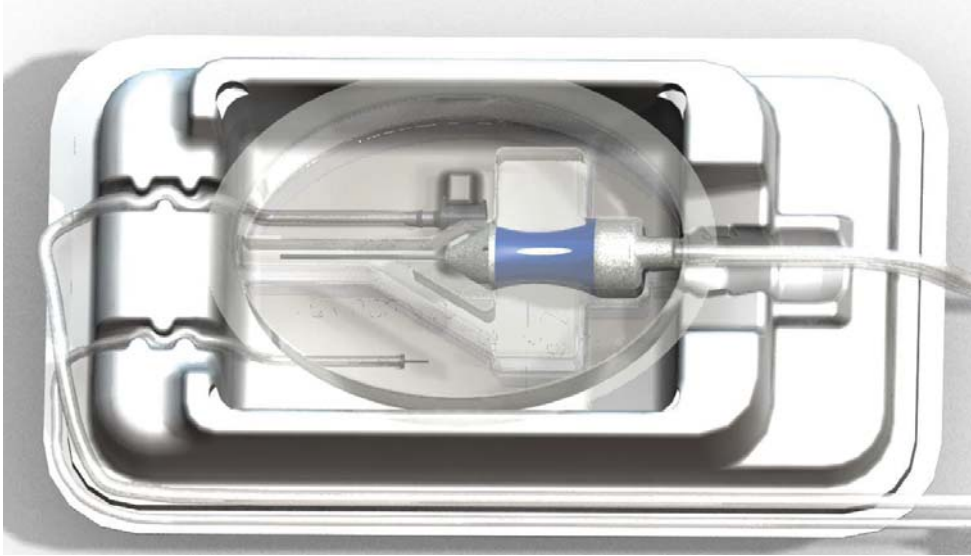


Figure 4.6. Priming cup with infusion cannula, left aspiration and vitrectomy cutter attached.

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 and they are: “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 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.

- 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 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 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 foot control pedal is in region 1 or beyond.



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 and infusion line and the cannula. Irrigation will be shut off and some BSS 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 if of the air bubbles. To turn irrigation off, use the tubing clamp or toggle **Irrigation Off** from the screen.*



Note: *Make sure to remove vitrectomy cutter by pulling it away from the priming cup, without allowing the cutter needle to touch the priming tray.*

Illumination Function (Posterior/Combined Domain)



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® PC** Vision Enhancement System. 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 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.


4 Detailed Reference

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 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 Foot Control:

1. Using the foot control tab of the More Settings Screen .
2. Programming the technique level foot control settings.
3. Overriding the technique level settings on the phase level foot control settings screen in programming also.

Illumination Setup and Use

1. Connect the fiber optic illuminator to the desired port (see Figure 1.22). Push the connector into the port until the groove on the connector is aligned with the front surface of the port receptacle. See Figure 4.7. (Scrub nurse or Circulating nurse)

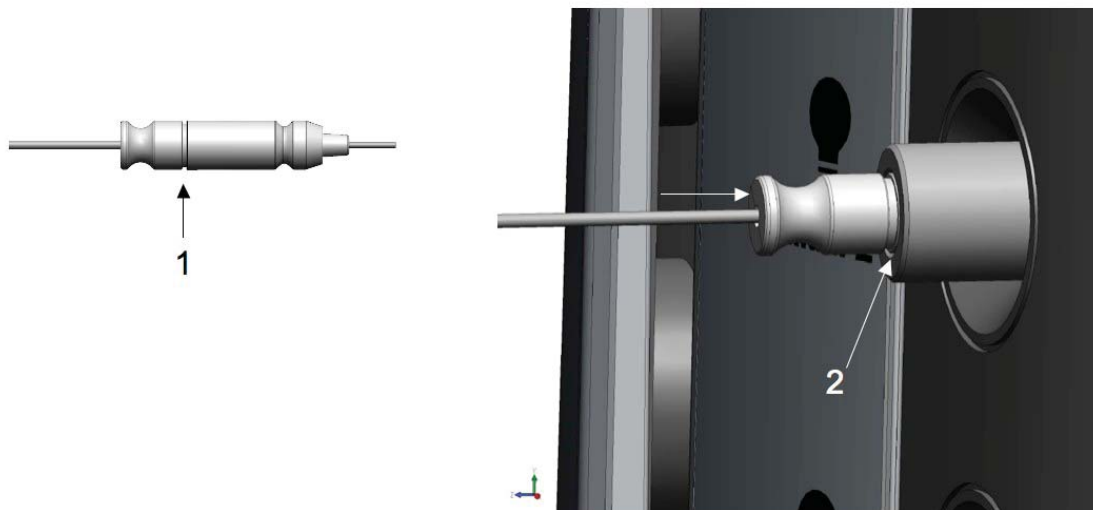


Figure 4.7. Connecting fiber optic connector to the illumination port

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 4.8. 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.



Note: *Lamp may take several minutes to complete the warm up, but can be used once a required intensity has been reached.*



Note: *Never turn the illumination on and off rapidly.*

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 3 optional filters that can be used.

You can change the current filter using the touch screen display and 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 Settings screen.

4 Detailed Reference

By default, the filter is set to None. To change this, edit your surgeon preferences file (see page 3-9).

The output level should be set in accordance to the guidance shown in the detail section on page 1-61.

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® PC** Vision Enhancement System 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



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® PC Vision Enhancement System 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 clockwise. The dot should be on the right, and the door should then lift off.

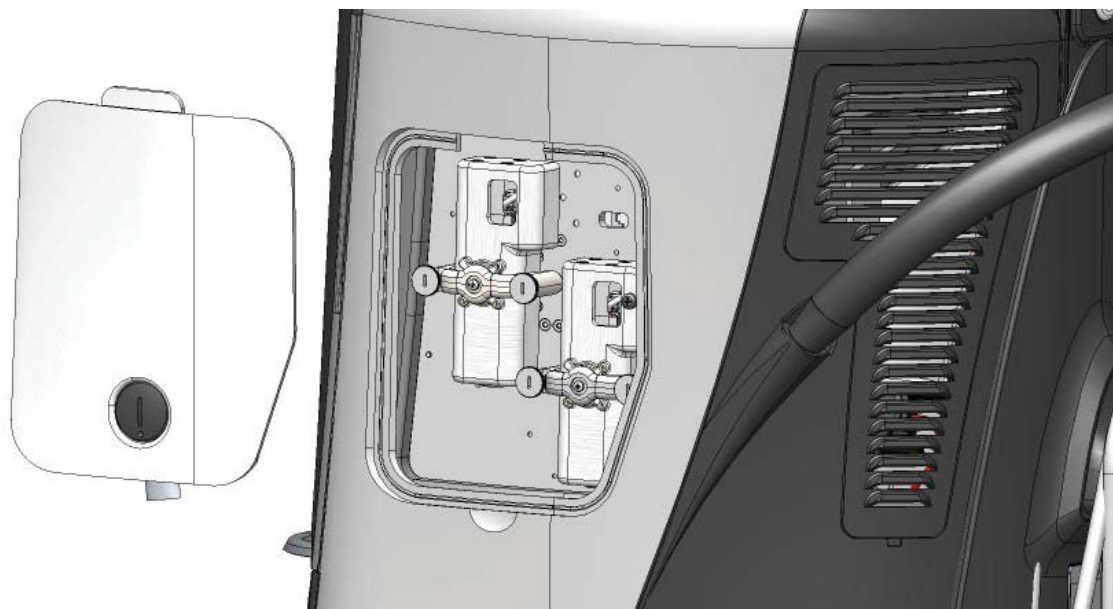


Figure 4.9. System side with lamp access door open.

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 counter-clockwise.

4 Detailed Reference

5. Carefully pull the lamp housing from the unit and dispose of according to applicable regulations.



Note: *A spent lamp that contains mercury must be recycled by an approved recycling collection facility, in accordance with applicable domestic and international environmental laws and directives.*

6. If the bulb is shattered and glass fragments are found, contact B&L service to remove them to prevent damage to the unit.

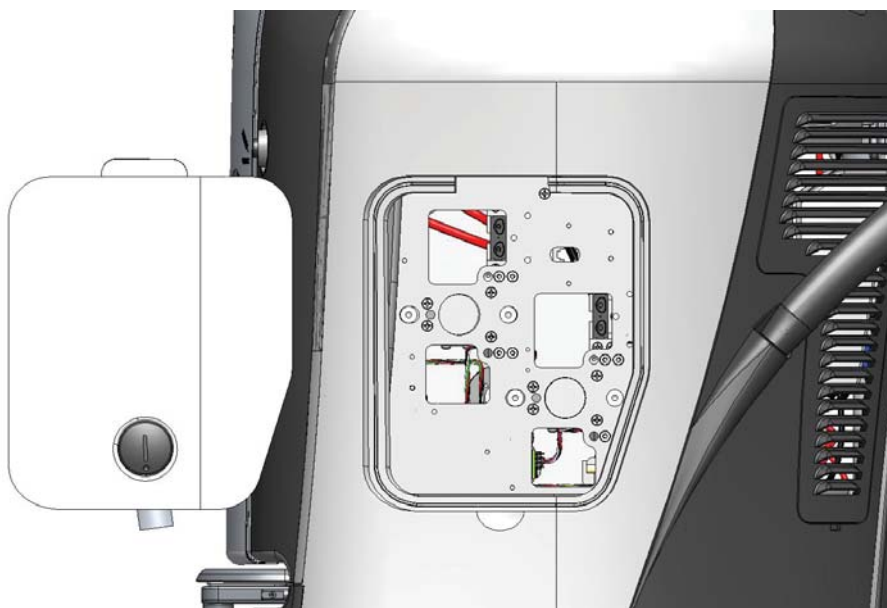


Figure 4.10. Side of the unit with lamps removed, with lamp location and orientation shown.

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 BEING CAREFUL NOT TO TOUCH ANY PART OF THE GLASS BULB OR CIRCUIT BOARD.

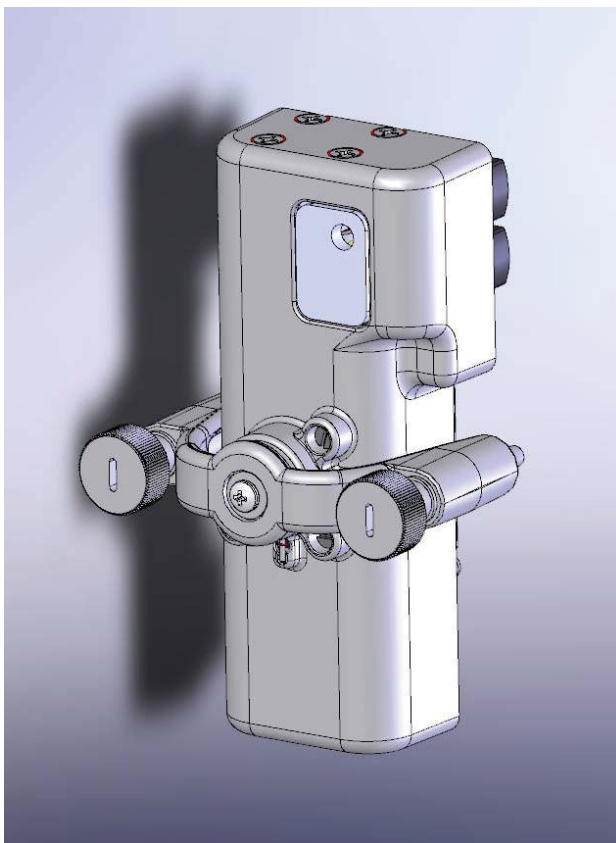


Figure 4.11. Lamp Housing Exterior.

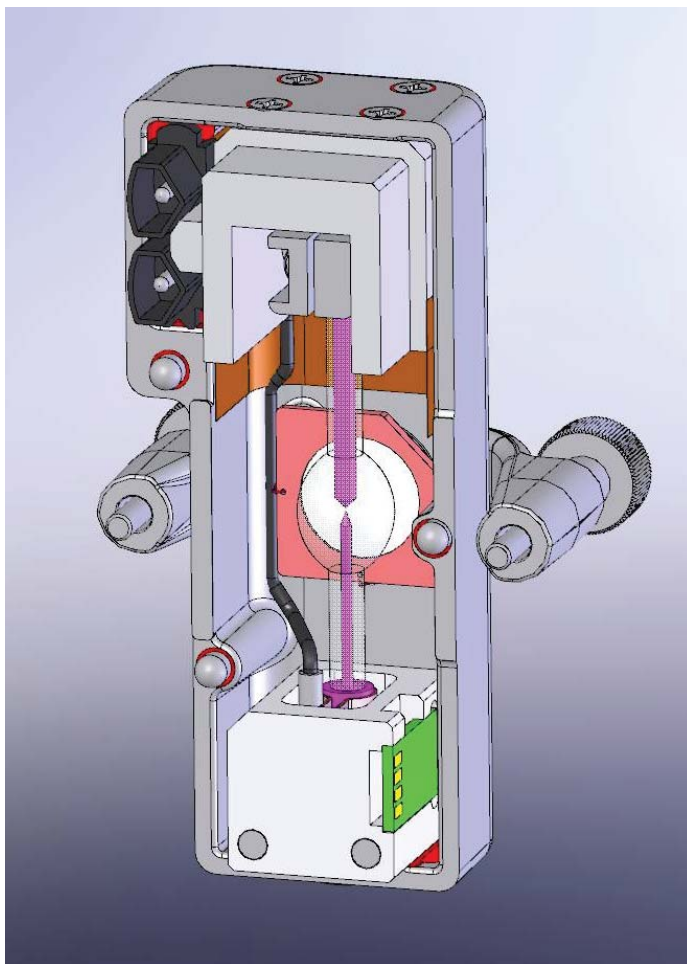


Figure 4.12. Lamp Housing Interior.

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. Replace the door before applying power to the System. 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) (Posterior Only)

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 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 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® PC** Vision Enhancement System 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. Setup the system for posterior vitrectomy (see page 4-7) or combined surgery (see page 4-50).
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 4.13. 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 4.14 (top). (Scrub nurse)

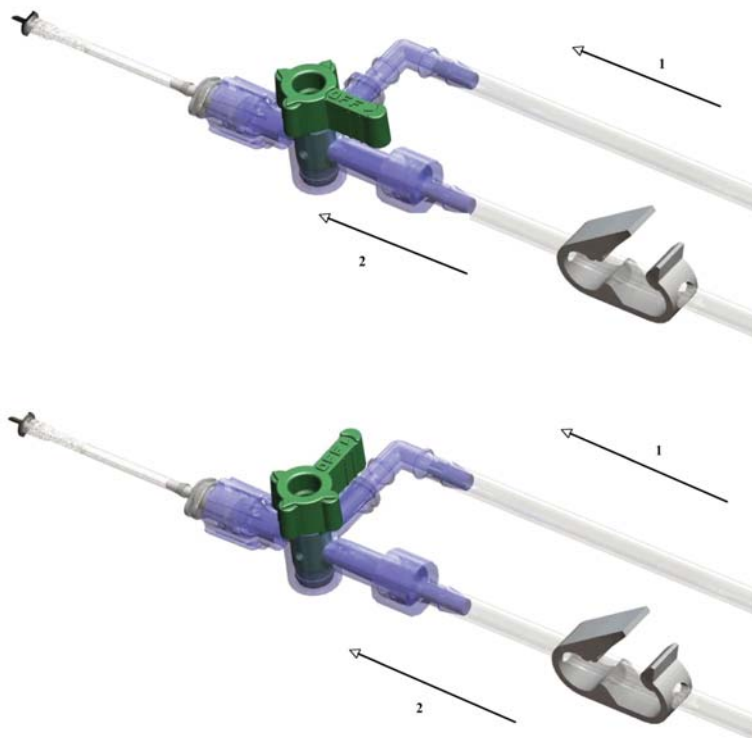


Figure 4.14. The 2-way stopcock control of Fluid/Air Exchange.

Top: On - Air flows into 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 is enabled by the **Elev Inf** On/Off button on the display (see Figure 4.15), or the foot control switch if it is programmed to control Elevated Infusion. Adjusting the air pressure above 60 mmHg will also enabled elevated infusion. The tamponade pressure is displayed in the surgical screen and may be adjusted by selecting the numeric pressure display or using the touchscreen 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 voice confirmation will sound and an elapsed time counter will be displayed in the surgical screen.

A voice confirmation for tamponade duration will be provided at one minute intervals. A bell will be sounded at 30 second intervals. When **Elev Inf** is disabled or the Fluid/Air Exchange level is reduced below the tamponade level, a voice confirmation will sound and the timer will be cleared from the screen.

When **Elev Inf** is toggled off, the Fluid/Air Exchange function status and pressure will return to the value it had prior to turning **Elev Inf** on, and the timer will be cleared from the screen.



Figure 4.15. Surgical screen displays Elevated Infusion control (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 is enabled by the **Elev Inf** On/Off button on the display, or the foot control switch if it is programmed to control the Elevated Infusion. Adjusting IV Pole above 81 cm 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 touchscreen Up/Down arrows. Fluid Tamponade would also be enabled whenever the Fluid/Air Exchange pressure level is raised or the I/V pole is adjusted above the programmed tamponade level.

When the function is enabled, a voice confirmation will sound and an elapsed time counter will be displayed in the surgical screen.

A voice confirmation for tamponade duration will be provided at one minute intervals. A bell will be sounded at 30 second intervals. When **Elev Inf** is disabled or the Fluid/Air Exchange level is reduced below the tamponade level, a voice confirmation will sound and the timer will be cleared from the screen.

When **Elev Inf** is toggled off, the air pressure and I/V pole will be set to the value it had prior to turning **Elev Inf** on, and the timer will be cleared from the screen.

To program the Elevated infusion pressure for Air Tamponade and Fluid Tamponade; go to the Technique programming level Fluidics tab to set desire pressure (see page 3-5). By default, the pressure is set at 80 mmHg and 100 cm.

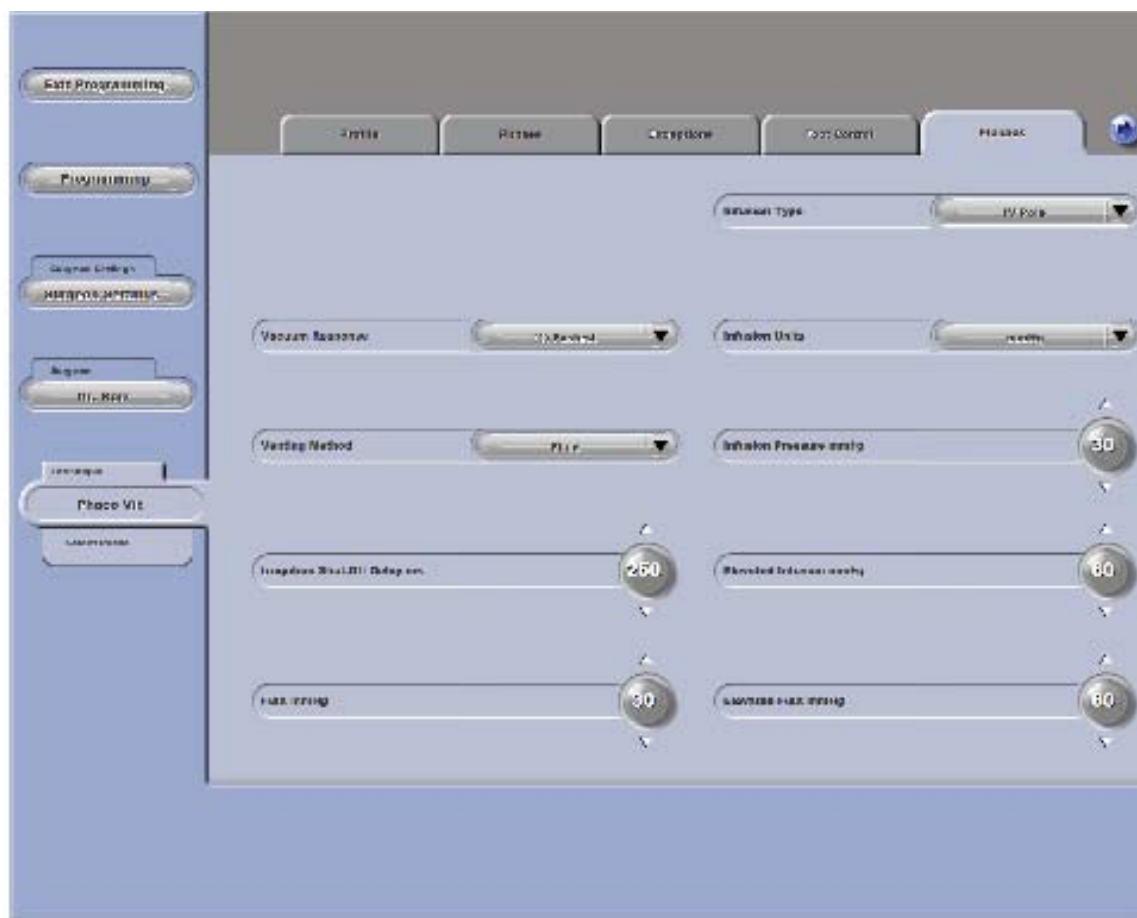


Figure 4.16. Technique programming level Fluidics screen with Air and Fluid Tamponade settings.

Viscous Fluid Control (VFC) (Posterior Only)



WARNING: *The Viscous Fluid Control is not intended for aspiration of balanced salt solution.*



WARNING: *Subretinal cannulas are not intended for aspiration of viscous fluid or balanced salt solution.*

The *Stellaris® PC* Vision Enhancement System's Viscous Fluid Control 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.

4 Detailed Reference

Silicone Oil: When used in the injection mode, the system can inject up to 5 cc of 1000 to 5000 centistoke silicone oil @ 24° C in less than 6.25 minutes.

Viscous Fluid Control Setup and Use

Injection

1. Open a CX5720 disposable pack and place contents on a sterile surface.
2. Connect the locking air connector on the tubing set to the *Stellaris® PC* system (Top right connector, Figure 1.22.)
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. (Refer to Figure 4.17).



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 ga. 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.

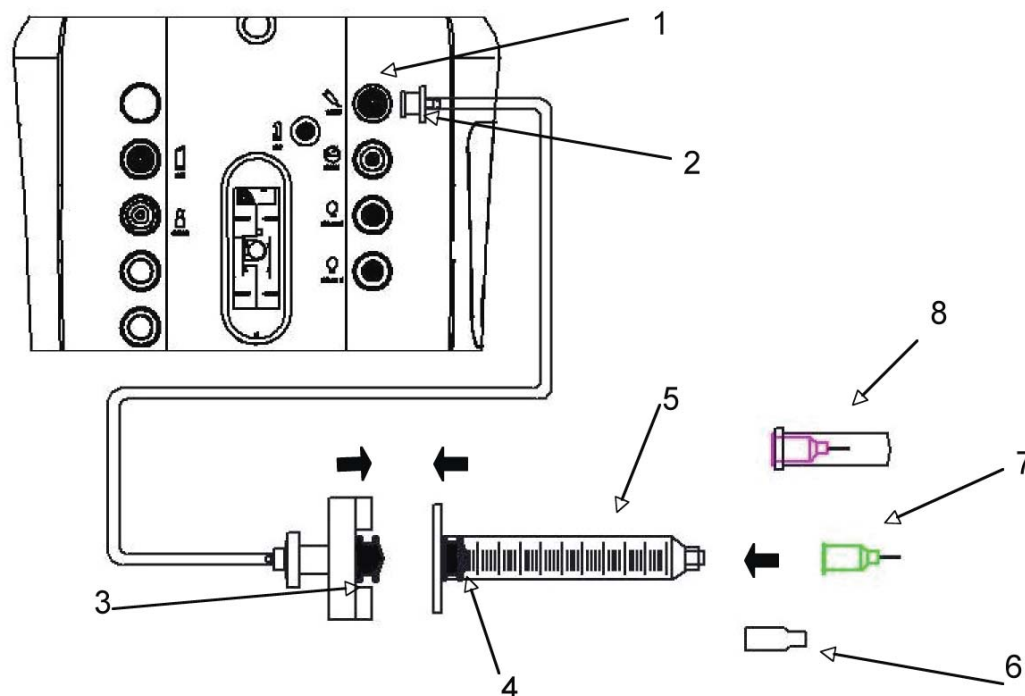


Figure 4.17. Viscous Fluid Injection Setup.

1. Viscous Fluid Port. 2. Air Tubing Connector. 3. Coupler. 4. Piston. 5. Syringe with Silicone Oil.
6. Syringe Cap. 7. 19g Injection Cannula (for injection). 8. 19g Extraction Cannula.

Viscous Fluid Injection Operation Modes

Fixed Fluid Injection

The footpedal is used to control the injection with a pre-programmed fixed pressure. The pressure level is set using the spin buttons on the touch screen.

Linear Fluid Injection

Control of linear fluid injection is via the footpedal. The injection pressure increases proportional to footpedal 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 footpedal. Linear aspiration through the left aspiration line is actuated by an outward yaw movement of the center footpedal. The minimum and maximum pressure levels are set using the touch screen.

Extraction

1. Open a CX5710 disposable pack and place contents on a sterile surface.
2. Connect the locking air connector on the tubing set to the *Stellaris® PC* system (Top right connector, Figure 1.22.)

4 Detailed Reference

3. Remove the syringe cap (item 6 of Figure 4.20). (Must be done 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 4.18 and Figure 4.19.)



WARNING: *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 4.20.)
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 Extract** from the Surgical Screen clock menu to perform the VFC extraction procedure.

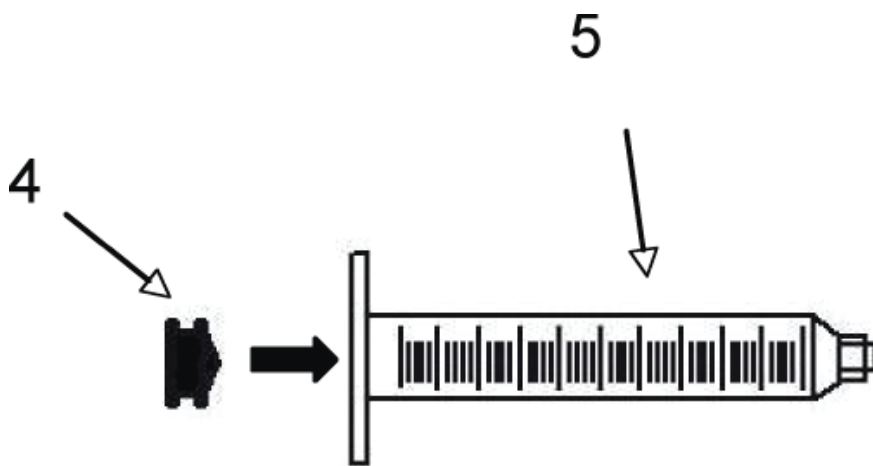


Figure 4.18. Viscous Fluid Extraction Setup.
Inserting Piston (4) into the empty syringe (5).

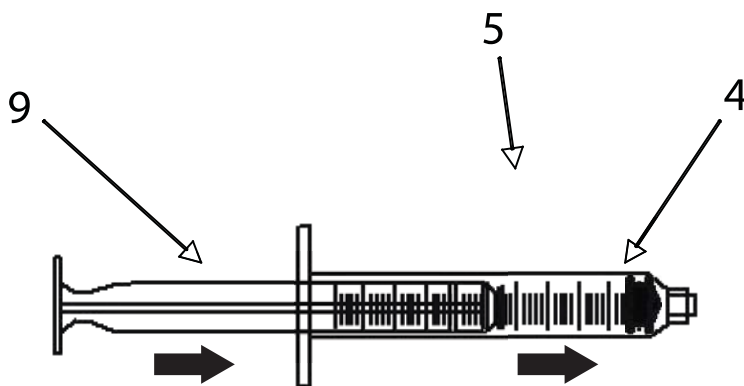


Figure 4.19. Viscous Fluid Extraction Setup.
Use plunger (9) to push piston (4) to the end of the empty syringe (5).

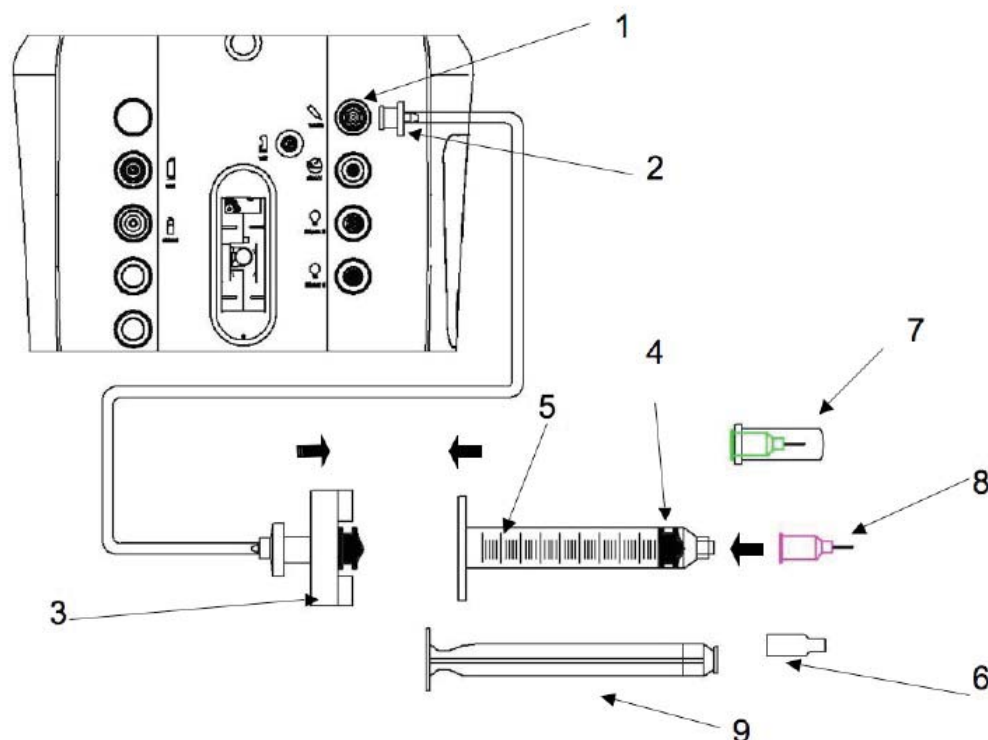


Figure 4.20. Viscous Fluid Extraction Setup.

1. Viscous Fluid Port. 2. Air Tubing Connector. 3. Coupler. 4. Piston. 5. Empty Syringe. 6. Syringe Cap.
7. 19g Teflon Cannula. 8. 19g Extraction Cannula. 9. Plunger.

Viscous Fluid Extraction Operation Modes

Fixed Extract

Extraction is activated when the footpedal is depressed. Aspiration pressure is fixed and pre-programmed through the touch screen user interface.

Linear Extract

Extraction is controlled via the center footpedal. The extraction vacuum increases proportional to footpedal travel from the minimum programmed setting to the maximum programmed setting. The minimum and maximum vacuum are set using the touch screen.

Fragmentation (Posterior Only)

The *Stellaris® PC* Vision Enhancement System Fragmentation function provides ultrasound emulsification and vacuum for lens removal from the posterior segment of the eye.



Note:

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

4 Detailed Reference

from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

Fragmentation modes

The **Stellaris® PC** Vision Enhancement System provides two Fragmentation modes with adjustable ultrasound power and vacuum control. Refer to the table on page 3-33 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 of this chapter.

Linear Frag

Linear Frag submode provides linear vacuum in footpedal region 1 and fixed maximum vacuum and linear ultrasound in foot pedal region 2. The outward yaw in any footpedal region controls ultrasound On/Off.

Dual/Yaw US Frag

This submode provides linear vacuum control on footpedal pitch, and linear ultrasound on outward yaw in footpedal region 1.

Fragmentation Setup and Use:



Note:

*Prior to setting up Fragmentation, the **Stellaris® PC** Vision Enhancement System has to be setup for Posterior Vitrectomy or Combined surgery.*



Note:

Specific instructions for cleaning and sterilization included with a handpiece or accessory take precedence over these instructions.



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.*

1. Setup the system for posterior vitrectomy (page 4-7) or combined surgery (page 4-50).
2. Ensure the screen is displaying the Prime/Tune Setup screen.
3. Connect the handpiece electrical connector to the connector on the machine. (Scrub nurse or Circulating nurse)
4. Thread and firmly secure the single use fragmentation needle onto the fragmentation handpiece using a needle wrench. (Scrub nurse)



Note:

Pack number BL5275 would be appropriate for use.

5. Connect the clear aspiration line to the fragmentation handpiece. (Scrub nurse)

6. Hold the handpiece with tip submerged into BSS solution. (Scrub nurse)
7. Select **Prime/Test U/S** to initiate the auto priming and tune ultrasound sequence. Hold the handpiece until prime/tune completes and the system transition 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)

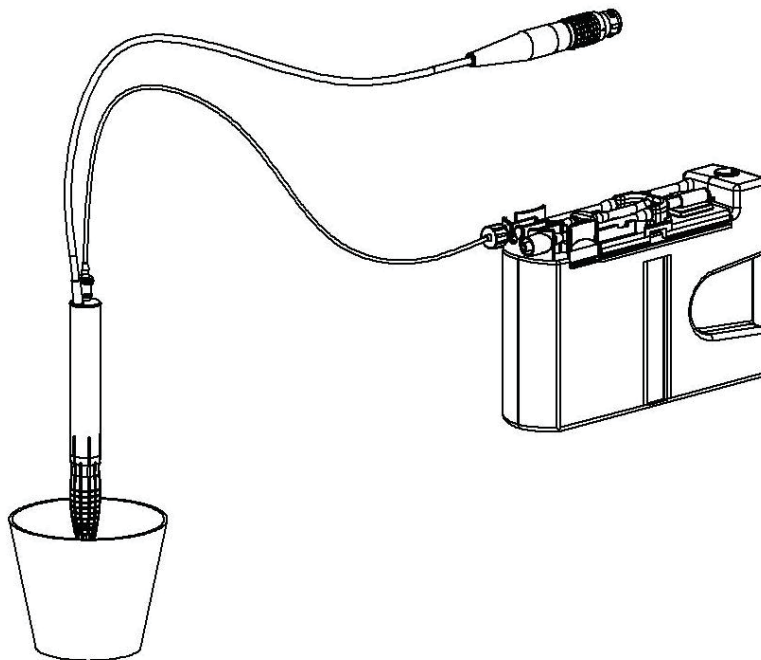


Figure 4.21. Hold frag handpiece with tip submerged into water during priming and tuning.

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 footpedal is pressed and closed when the footpedal is released.

An Irrigation-only mode is available, in which the footpedal 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 Function (I/A)



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 600 mmHg in 1 mmHg increments depending upon the mode of operation. Aspiration limits are set via the touch screen, the remote control, or the Foot Control buttons (if programmed).

In I/A mode, irrigation is activated in Region 1 of footpedal travel, and both irrigation and aspiration are activated in Region 2 of footpedal 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 footpedal 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 Footpedal 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® PC** 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 footpedal 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 combined cassette only.

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 Fluidics More Screen (see page 2-55). The Advanced Vacuum System has five levels of vacuum response setting, with one being fastest response and five being slowest response.

Foot Control of Irrigation/Aspiration

As the footpedal is initially pressed, the irrigation control valve will open to allow irrigation into the eye.

Once irrigation has been initiated and the footpedal has been depressed approximately five degrees (or as programmed), a momentary increase in footpedal resistance will be noted signifying the transition from Region 1 to Region 2 and the start of aspiration. Aspiration increases proportional to footpedal 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® PC Vision Enhancement System's aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.*



WARNING: *Assure 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 Foot Control and wait until the right light turns solid green, indicating wireless communication has been established.

4 Detailed Reference

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 BSS bottle and hang it at the desired bottle 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® PC** 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 insure all air has been removed.*

I/A Use

1. Select the I/A mode on the clock menu.
2. Use the spin control buttons 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 2-74), 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 Case More Screen (see page 2-67) 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 1% to 100% using the up/down spin buttons, Foot Control buttons, or remote, and 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 occur 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 burst using a fixed power or in fixed burst using a linear control of power. The burst duration can range from 2 to 600 msec.

When single burst mode is selected, a burst of ultrasound energy is emitted when the 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.

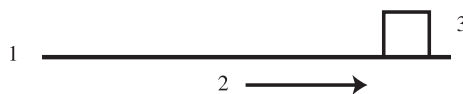


Figure 4.22. Burst Mode Ultrasound.

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.

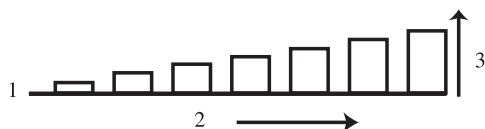


Figure 4.23. Fixed Pulse Ultrasound.

1. Fixed Pulse. 2. Pedal Position. 3. Power.

The ultrasound power is controlled by the linear control position of the footpedal.

When multiple burst mode is selected, a sequence of bursts of ultrasound energy are emitted. The time interval between bursts is controlled by the linear control position of the footpedal. When the pedal reaches full travel in the linear control, the ultrasound energy is limited by the **Max Duty Cycle** setting.

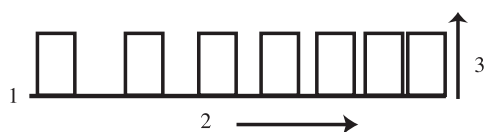


Figure 4.24. Multiple Burst Mode Ultrasound.

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. Foot Control activation of the submode sequence may be enabled or disabled. Submodes can be toggled with the Foot Control heel switch or by footpedal outward yaw motion in Region 2 or 3, depending on how the system has been programmed.

The options to change submodes with the 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 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 footpedal between zero and the maximum limit set on the console.

Ultrasound power may be adjusted from 0% to 100% in 5% increments using the up/down spin buttons, Foot Control buttons, or remote, and 1% increments using the keypad. The ultrasound output will be activated at the minimum programmed power level as the footpedal moves into the active ultrasound region, and will increase to the maximum programmed output as a function of linear footpedal travel.

Single Linear Ultrasound Mode with Fixed Aspiration

Once irrigation has been initiated and the footpedal has been depressed approximately five degrees (or as programmed), an increase in footpedal 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 footpedal travel. Another momentary increase in footpedal 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 footpedal travel in Region 3. The next ultrasound submode may be selected (if enabled) by moving the footpedal in the outward yaw direction.

Single Linear Ultrasound Mode with Linear Aspiration

Once irrigation has been initiated and the footpedal has been depressed approximately five degrees (or as programmed), an increase in footpedal 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 footpedal 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 footpedal travel. Another momentary increase in footpedal 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 footpedal travel in Region 3. Pulsed ultrasound may be toggled on/off by moving the footpedal 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 4-36).

Dual Linear Ultrasound Mode with Aspiration in Yaw (Fixed Minimum Vacuum in Region 2)

Once irrigation has been initiated and the footpedal has been depressed approximately five degrees (or as programmed), an increase in footpedal 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 footpedal travel. The screen will display the actual amount of aspiration.

Ultrasound power is activated in Region 3 of footpedal travel. Another momentary increase in footpedal 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 footpedal 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 footpedal has been depressed approximately five degrees (or as programmed), an increase in footpedal 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 footpedal travel in Region 2. Linear aspiration to the maximum setting will be controlled by outward yaw footpedal travel. The screen will display the actual amount of aspiration.

Ultrasound power is activated in Region 3 of footpedal travel. Another momentary increase in footpedal 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 footpedal 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 footpedal travel. As the footpedal travels through Region 1, the irrigation pinch valve will open to apply irrigation to the eye.

Aspiration is activated by Region 2 of footpedal travel. A momentary increase in footpedal 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 footpedal 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 one provides irrigation, position two 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, such as do not bend, cut or engrave, 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® PC 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 the handpiece or accessory take precedence over these instructions.*



Note: *The ultrasound handpiece, needle, and irrigation sleeve must be sterilized before performing these steps.*

1. Turn Power on.
2. Press any button on the Foot Control and wait until the right light turns solid green indicating wireless communication has been established.
3. Select Surgeon's Name and select **Confirm**.

4 Detailed Reference

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 BSS bottle and hang it at the desired bottle 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® PC** 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. 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)

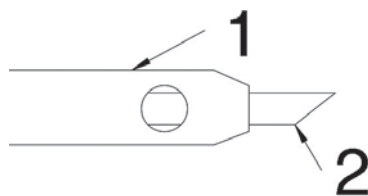


Figure 4.25. Irrigation Sleeve.

1. Irrigation Sleeve. 2. Needle.

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 2-39 for details on the irrigation flow button (activate the Fill button with turn flows on for 20 seconds).
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



CAUTION: *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.*



Note: *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 insure all air has been removed.*

You have connected the external components of your **Stellaris® PC** 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 spin control buttons to set the desired aspiration level, and the ultrasound maximum power. Set the desired number of PPS for pulsed ultrasound.



Note: *Assure 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 cancelled when tuning has been completed or cancelled. Re-tune if either the handpiece or ultrasound needle is changed.*

3. Press the footpedal to begin ultrasound operation. Aspiration and ultrasound power will be applied as the footpedal enters their pre-programmed regions (as described in Chapter 3).
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.*

Anterior Vitrectomy Function

The *Stellaris® PC* 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 to 5000 cuts per minute.

Dual Linear Cut

Pneumatic cutter: The control may be adjusted to provide a linear cutting speed from 30 to 5000 cuts per minute. The footpedal yaw is used to achieve dual linear function.

The cut rate may be adjusted from 30 to 5000 cpm, with increments as shown in the table below, or to any specific value using the keypad.

Range	Step Size
30 to 100 cpm	10 cpm
100 to 1000 cpm	50 cpm
1000 to 5000 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® PC 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 the handpiece or accessory take precedence over these instructions.*

1. Turn Power on.
2. Press any button on the 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 BSS bottle and hang it at the desired bottle 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® PC 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® PC** 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 administration line.
9. Ensure the irrigation clamp is opened and the tip is immersed in irrigation solution, then select **Cutter 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 spin control buttons to set the desired vacuum level and cut rate.
3. For Fixed cut vitrectomy, yaw the footpedal outward to toggle the cutter on and off, and depress the footpedal for aspiration. An audio tone will signify cutter operation (if enabled). Fixed cut rate is activated in footpedal Region 2.
4. For Linear cut vitrectomy, activate the cutter by outward yaw travel of the footpedal in Region 2.
5. For Reflux (if enabled), rotate the footpedal 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® PC** 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.

Foot Control of Anterior Vitrectomy Mode

As the footpedal is initially pressed, the irrigation control valve will open to allow irrigation into the eye.

Once irrigation has been initiated and the footpedal has been depressed approximately five degrees (or as programmed), a momentary increase in footpedal resistance will be noted signifying the transition from Region 1 to Region 2 and the start of aspiration. Aspiration increases proportional to footpedal 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 footpedal displacement once it is within Region 2. The actual cut rate is displayed on the screen. When the footpedal 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 by inward yaw movement of the footpedal.

By default, the vitrectomy cutter is On.

Pressurized Infusion Function



WARNING: *This system is to be used in either air pressured infusion mode or IV Pole mode but never both together as high intraocular pressures may result.*



Note: *Specific instruction for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.*



Note: *Once pressurized infusion pump is turned ON, it will continue to operate even when the function is removed from the screen display.*



Note: *When using air pressured infusion, hang the bottle so that the drip chamber is close to patient eye level.*

The Pressurized Infusion function infuses a preset air pressure to pressurize the BSS bottle. The pressure generated would force BSS 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.

Pressurized Infusion is an optional function of the *Stellaris® PC* Vision Enhancement System. The function could be built into the system according to the customer order or the function could be added into existing field systems with an upgrade

Enable Pressurized Infusion Function

If system is installed with Pressurized Infusion software, the function could be enabled from surgeon file programming or surgical More Screen.

To enable Pressurized Infusion Function from surgical More Screen:

1. Ensure surgical screen Format 2 is displayed.
2. Select fluidic More Screen button (A double arrow up button below the vacuum preset display.)
3. Select Infusion Tab of the pop up screen.
4. Select Infusion Pressurize Display to **Enabled**. See diagram below.

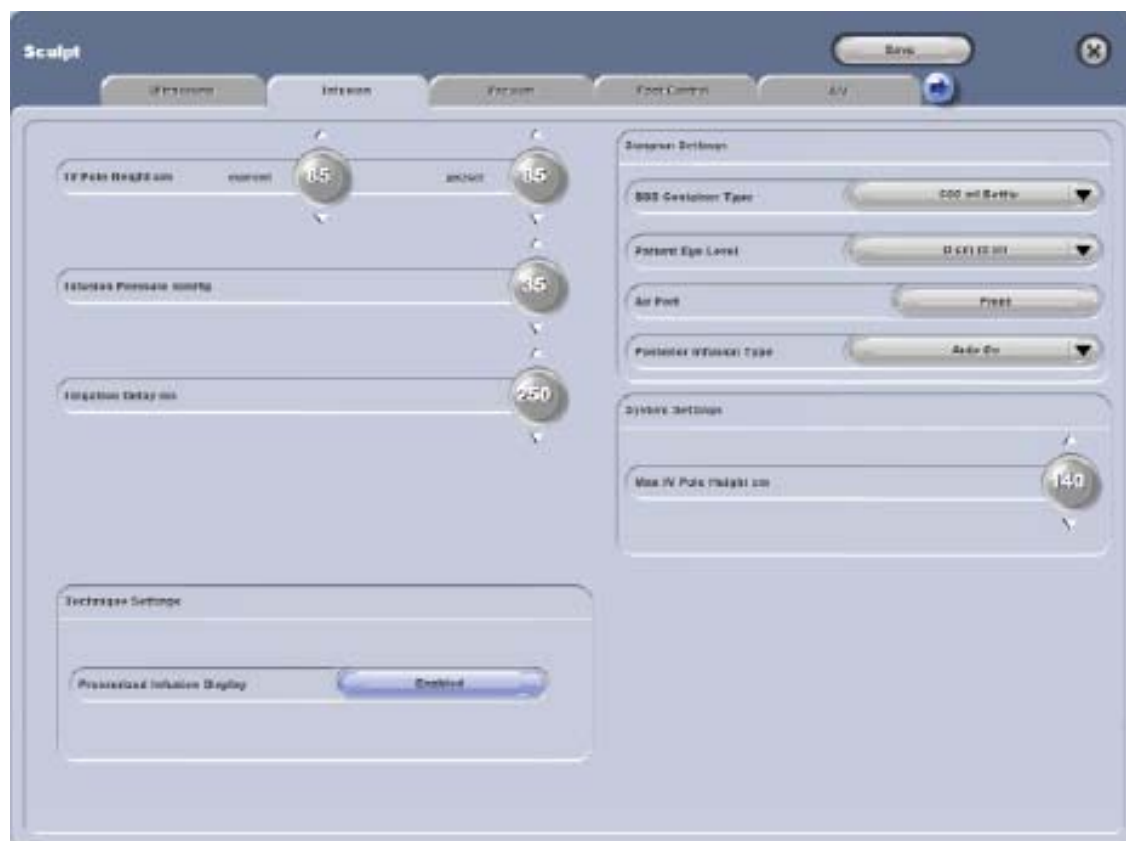


Figure 4.26. More Settings Screen, Infusion Tab (Anterior).



Figure 4.27. More Settings Screen, Infusion Tab (Combined).

5. Selecting Infusion Pump to **On** will automatically activate the air pump whenever the surgeon file is selected for surgery. (For Combined Domain Only)
6. Pressurized Infusion settings and function could be saved with Case More Settings Screen.

Pressurized Infusion Setup

1. Remove the filter cap (A) from the bottle spike venting port that comes with the system disposable pack in Figure 4.28.
2. Connect the Air Tubing Line male connector to the bottle spike venting port (A) in Figure 4.28.
3. Connect the Air Tubing Line filter to the microsurgical system air source (B) in Figure 4.28.
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 **Off** button below the setting display. Selecting the same button will turn off the pump.

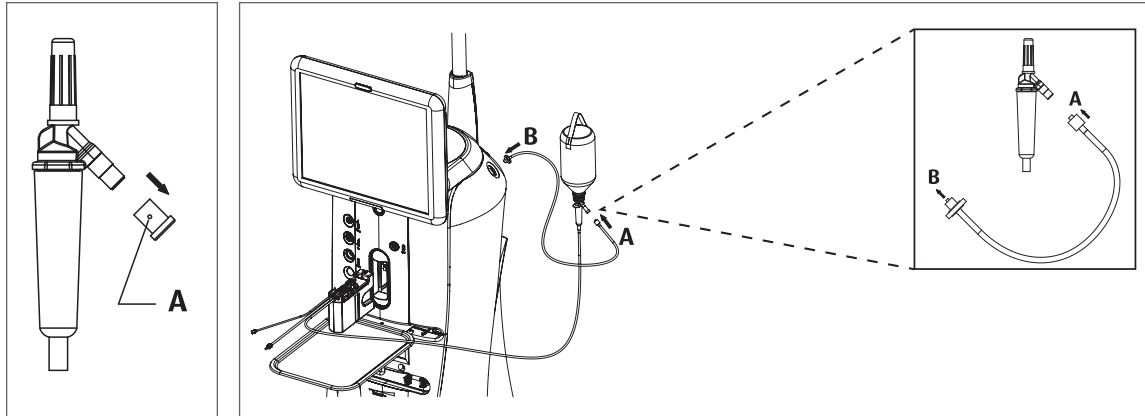


Figure 4.28. Pressurized Infusion Setup.

The Pressurized Infusion air pump could be programmed to default pump status to **On**. If programmed to default **On**, the pump will turn on automatically when the surgeon technique file is selected.

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 designated by Bausch + Lomb for use with this system.*



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.*



Note: *The output power selected should be as low as possible for the intended purpose..*



Note: For explanation of Dual Linear Foot Control see page 1-4.

Bipolar coagulation is accomplished with the **Stellaris® PC** 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 spin button control. Fixed coagulation may be actuated by any 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 spin button control. Linear Coagulation is selected from the clock menu on the Main Surgical Screen. Linear coagulation is actuated by depressing the footpedal, if it has been programmed to provide linear control as a function of angular footpedal displacement.

Fixed Coagulation Setup and Use



WARNING: Assure 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.

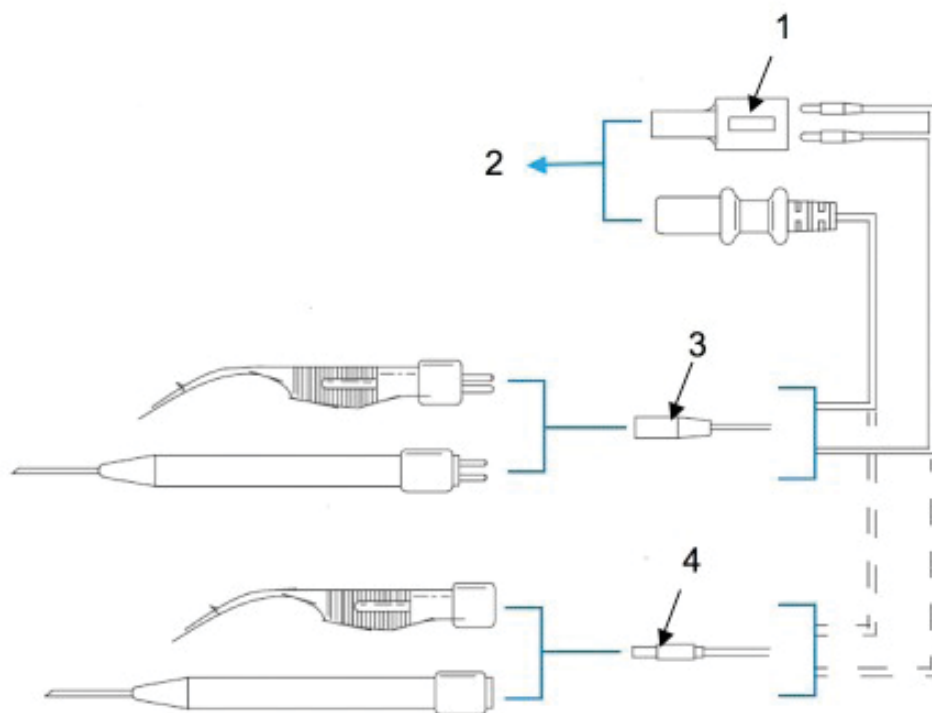


Figure 4.29. Fixed Coagulation Handpiece setup.

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 spin buttons to adjust the percentage of coagulation power desired.
4. The fixed coagulation function is activated by pressing the programmed 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: *Assure 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 IEC 60601-2-2, position 1 will not start until approximately 35% of pedal travel is attained in the linear coagulation mode.

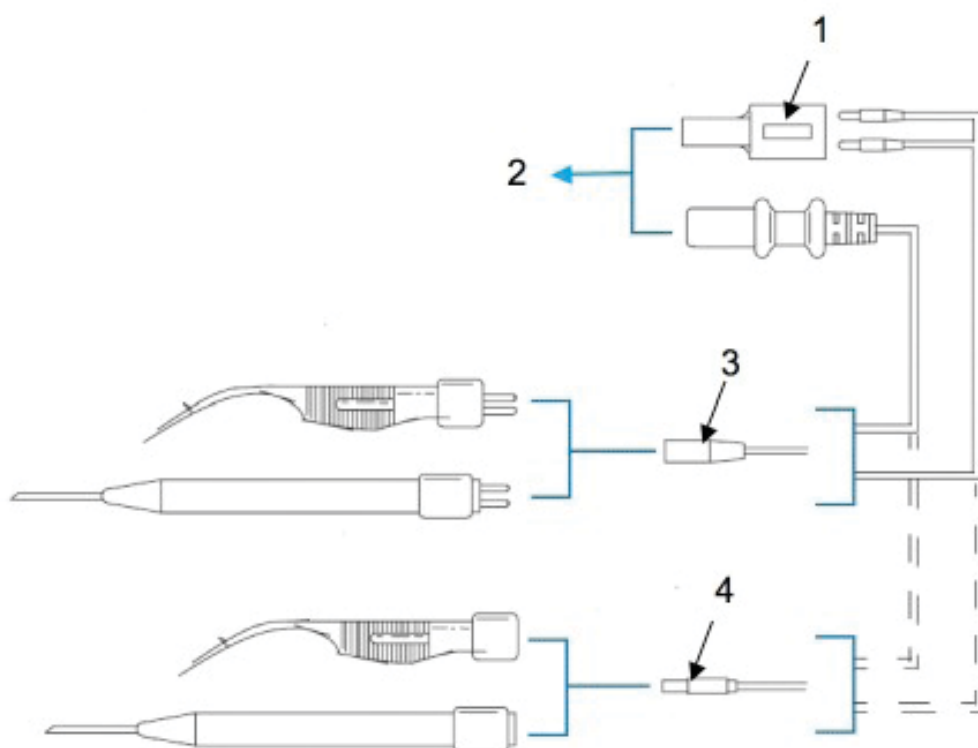


Figure 4.30. Linear Coagulation Handpiece Setup.

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 adaptor may be necessary.
2. Connect the bipolar cable to the coagulation electrical connector, if required.
3. Select Coag from the clock menu.

4 Detailed Reference

4. Use the spin buttons to adjust the **Max Coagulation** power desired.
5. The linear coagulation function is actuated by the footpedal, 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® PC** Vision Enhancement System supports combined procedures to allow user perform both posterior and anterior segment surgeries with the dedicated software interface and packs. Select Posterior/Anterior Domain in the Select Procedure start up 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



Note: Specific instructions for cleaning and sterilization included with any handpiece or accessory take precedence over these instructions.



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® PC 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 Foot Control or other system messages.
3. Acknowledge and close all messages.
4. To operate the Foot Control wirelessly, press any button on the Foot Control and wait until the right 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 1.7).
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 left hand and the thumb placed in the thumb notch. (Circulating Nurse)
 - b. Tear open the Tyvek® seal 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 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)

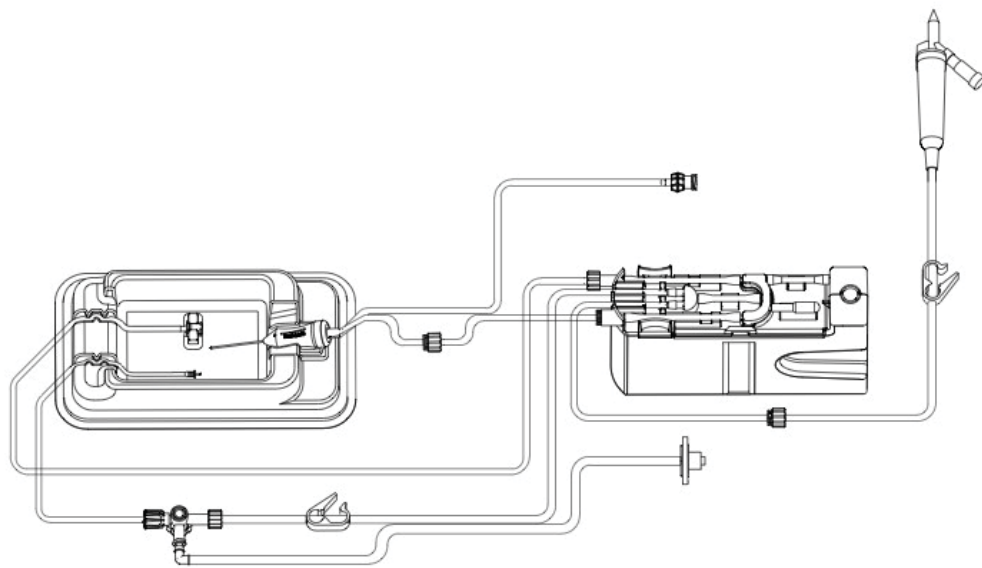


Figure 4.31. Pre-connected tubing set.

- 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. 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 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)

4 Detailed Reference

- 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 BSS bottle on the automated I/V 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.
- 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)

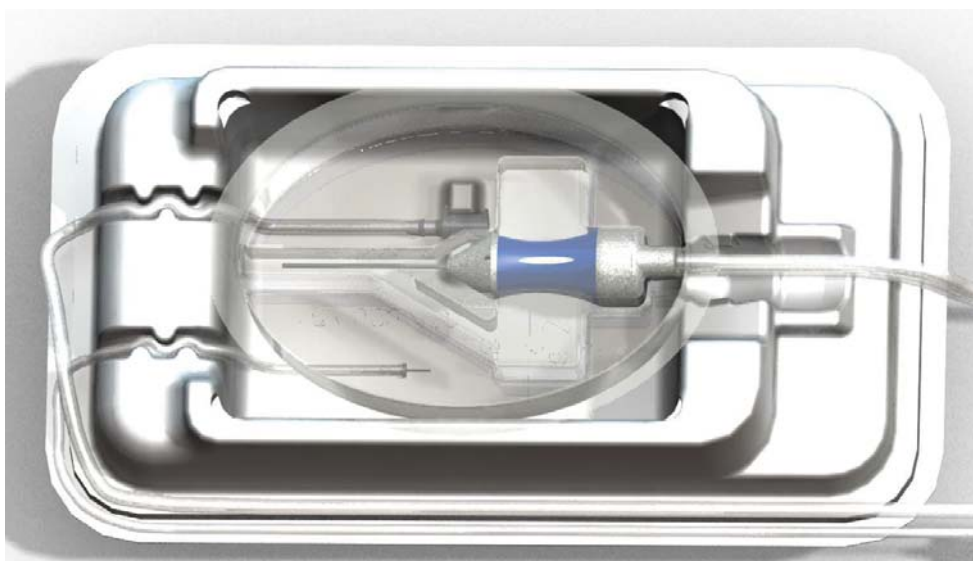


Figure 4.32. Priming cup with infusion cannula, left aspiration and vitrectomy cutter attached.

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. The following steps are to setup the anterior functions:

10. Remove the second aspiration line from the priming cup and connect to the phaco handpiece.
11. 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.

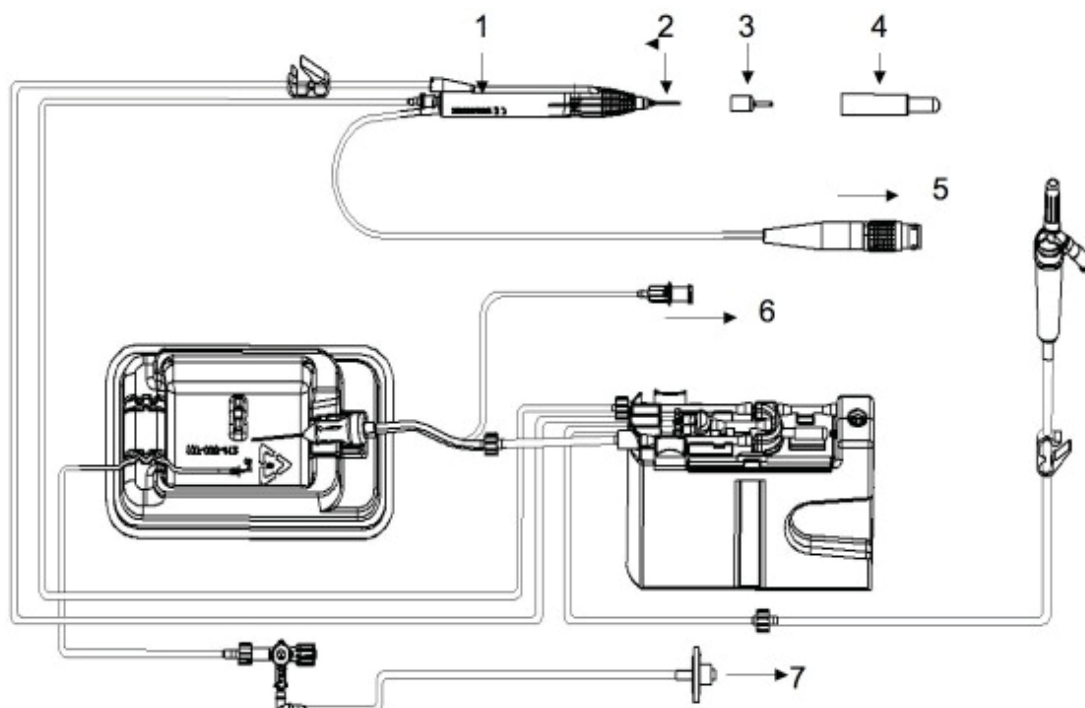


Figure 4.33. Connecting tubing to the phaco handpiece.

1. Phaco Handpiece. 2. Phaco Needle. 3. Infusion sleeve. 4. Test Chamber. 5. Connect to U/S connector.
6. Connect to Vit actuation port. 7. Connect to air pressure port.

12. Plug the handpiece connector to the machine (Second connector from the top).
13. Thread and firmly secure the ultrasound needle onto the ultrasound handpiece using a needle wrench.
14. 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)
15. Toggle the **Irrigation Off** button to turn flow on, and allow the flow to fill the irrigation tubing up to the handpieces. See page 2-39 for details on the irrigation flow button (activate the Fill button with turn flow on for 20 seconds).
16. Fill the test chamber with irrigating solution, then slide over the tip of the handpiece.
17. Select Prime and Tune. A vacuum test is part of the priming cycle.

After successful priming and tuning, the Main Surgical Screen will appear.

Cleaning and Sterilization Requirements

This chapter provides instructions for cleaning the **Stellaris® PC** Vision Enhancement System, and for cleaning and sterilization of the reusable accessories.



Note: *Specific instructions for cleaning and sterilization included with any handpiece or accessory take precedence over these instructions.*



Note: *Preventative scheduled maintenance is recommended once a year to insure that the **Stellaris® PC** 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.*



CAUTION: *Allow 20 minutes after sterilization for the handpiece and cord to cool before using them again. The handpiece connector must be completely dry before it is connected to equipment.*

5.1. Routine Cleaning



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® PC** 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® PC** Vision Enhancement System, Foot Control and remote control with a soft cloth moistened with cleaning solution on a weekly basis, while the **Stellaris® PC** 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.

5 Cleaning and Sterilization Requirements

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.

1. Window.

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. Bipolar Coagulation Accessories



WARNING: *The coagulation accessories should not be sterilized using a cold soaking solution.*



WARNING: *All bipolar accessories must be rated for an operating voltage of at least 120V.*



CAUTION: *Allow 20 minutes after sterilization for the handpiece and cord to cool before using them again. The handpiece connector must be completely dry before it is connected to equipment.*



Note: No neutral electrode is required for use of the bipolar function.

The bipolar coagulation forceps, eraser, and reusable cord should be inspected before each use for signs of misalignment, pitting, contamination (blood, tissue, etc.), or other damage. Blood, saline, tissue, and other contamination on the tips may be removed by gently scraping with a scalpel blade. If the forceps are dropped and seriously misaligned, or if deep pits or scores appear on the tips after long use, the forceps may be returned to Bausch + Lomb for repair, refinishing, or repotting of the insulating base. With the exception of flash methods, the items may be wrapped in a surgical towel, CSR wrap, or equivalent.

Wipe the forceps using a soft cloth moistened with a mild soap water solution. Avoid excessive quantities of solution around the electrical connector. Remove all traces of the solution with a cloth dampened with clean water. The surfaces should then be dried with a lint-free cloth.

The forceps and reusable cables may be sterilized as follows:

- **Standard Gravity Steam Sterilization:** Wrapped for 30 minutes at 121° C/104.8 kPa [1.048 bar] (250° F/15.2 psi).
- **Flash Sterilization:** Unwrapped but covered for 10 minutes at 132° C/186.8 kPa [1.868 bar] (270° F/27.1 psi).
- **High Vacuum (Pre-vacuum) Sterilization:** Wrapped for 3 minutes at 134° C/206.8 kPa [2.068 bar] (274° F/30.0 psi).

Refer to ANSI/AAMI ST79-2006, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*, and/or your institution's policies regarding restrictions on the use of flash sterilization.

5.3. Irrigation and Irrigation/Aspiration Handpieces



CAUTION: Use only warm (30° C to 40° C or 85° F to 105° F) distilled or deionized water to flush the handpiece.

The handpiece must be cleaned and autoclaved before it is placed into service the first time, before initial use each day, and between each use in accordance with the following instructions.

Handpiece Cleaning Instructions

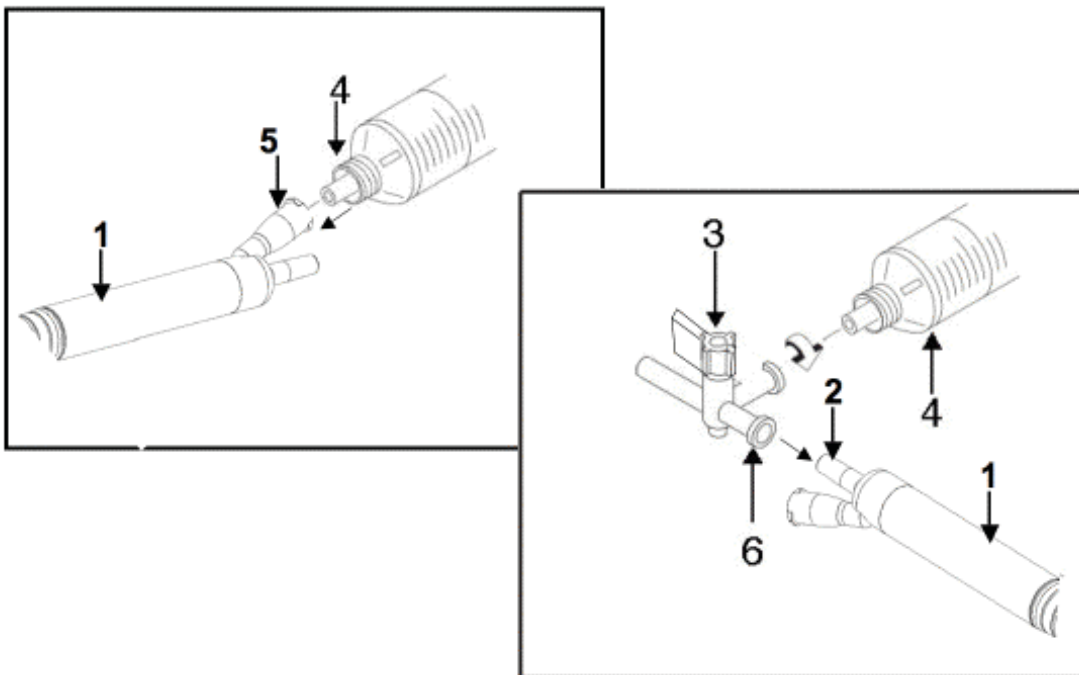


Figure 5.2. Irrigation and Aspiration Handpiece Flushing Setups.

1. I/A Handpiece. 2. Aspiration Fitting. 3. 3-Way Stopcock.
4. Syringe. 5. Irrigation Fitting. 6. Female Luer.

- A. Disconnect the tubing and remove the irrigation sleeve.
- B. Place the end of the syringe into a beaker of warm (30° C to 40° C or 85° F to 105° F) distilled or deionized water, and fill the syringe to the 50 cc (ml) mark.
- C. Connect the end of the syringe to the irrigation fitting of the handpiece (see Figure 5.2).
- D. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **Do not draw flushing fluid back through the handpiece.** Disconnect the syringe.
- E. Repeat Steps B through D at least three times.
- F. Fill the syringe with air, reattach to handpiece, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.
- G. Repeat Step F at least three times.
- H. Refill the syringe to the 50 cc (ml) mark with warm (30° C to 40° C or 85° F to 105° F) distilled or deionized water.
- I. Connect the syringe to the center stopcock fitting.
- J. Rotate the stopcock lever to allow fluid flow to the female luer fitting.
- K. Connect the stopcock female luer fitting to the handpiece aspiration fitting.

- L. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **Do not draw flushing fluid back through the handpiece.** Disconnect the syringe.
- M. Repeat Steps H through L at least three times.
- N. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.
- O. Repeat Step N at least three times.



CAUTION: Use only warm (30° C to 40° C or 85° F to 105° F) distilled or deionized water to flush the handpiece.

Irrigation and I/A Handpiece Sterilization



WARNING: Do not cold sterilize the instrument. The sterilizing solution may not be flushed out prior to surgery and could be flushed into the eye, resulting in serious eye injury.



CAUTION: Allow 20 minutes after sterilization for the handpiece and cord to cool before using them again. The handpiece connector must be completely dry before it is connected to equipment.



Note: To maintain flexibility and prevent cable damage, wind the cord only loosely if needed, and do not store it coiled with a less than 6" diameter.

The handpiece and any reusable accessories must be autoclaved before any item is used. With the exception of flash sterilization, the items may be wrapped in a surgical towel, CSR wrap, or equivalent. The minimum requirements for sterilization are:

- **Standard Gravity Steam Sterilization:** Wrapped for 30 minutes at 121° C/104.8 kPa [1.048 bar] (250° F/15.2 psi).
- **Flash Sterilization:** Unwrapped but covered for 10 minutes at 132° C/186.8 kPa [1.868 bar] (270° F/27.1 psi).
- **High Vacuum (Pre-vacuum) Sterilization:** Wrapped for 3 minutes at 134° C/206.8 kPa [2.068 bar] (274° F/30.0 psi).

Refer to ANSI/AAMI ST79-2006, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*, and/or your institution's policies regarding restrictions on the use of flash sterilization.

5.4. Ultrasound Handpiece and Accessories

The ultrasound handpiece, reusable accessories, and cord should be inspected before each use for signs of contamination, or other damage. If the handpiece, its cord, or any reusable accessory show signs of damage or cracked insulation, it should not be used. The handpiece must be flushed clean and autoclaved before being placed into service the first time, before initial use each day, and after each use in accordance with the following instructions:



Note: Use compressed, filtered medical grade air (medical grade nitrogen) to blow out the handpiece lumens. The pressure should not exceed 29 psi (200 kPa, 2 bar).



Note: Remove the rubber plugs from the tip of the handpiece and lumen port(s) at the end of the handpiece before autoclaving and placing into service for the first time.



Note: To maintain flexibility and prevent cable damage, wind the cord only loosely if needed, and do not store it coiled with a less than 6" diameter.

Handpiece Cleaning Instructions

Bausch + Lomb recommends the use of the **Universal Maintenance Kit CX7120** in the following instructions. The irrigation sleeve, needle, and tubing must be removed from the handpiece before beginning.

- A. Remove the silicone irrigation sleeve and the needle. Remove any tubing from the rear of the handpiece. See Figure 5.3 and Figure 5.4. Rinse the exterior of the handpiece by holding it under cold running tap water for fifteen seconds, rotating the handpiece to expose all surfaces to the flowing water.
- B. Wipe the handpiece using a soft cloth moistened with a mild soap and water solution. Avoid excessive quantities of solution around the electrical connector. Remove all traces of the solution with a cloth dampened with clean water. The surfaces should then be dried with a lint-free cloth.



Note: For users in the United Kingdom, please refer to page 5-11 for special cleaning and sterilization instructions before proceeding.



Figure 5.3. Ultrasound Handpiece and Needle.

1. Needle Sleeve. 2. Needle. 3. Irrigation Port. 4. Aspiration Port. 5. Power Cord.

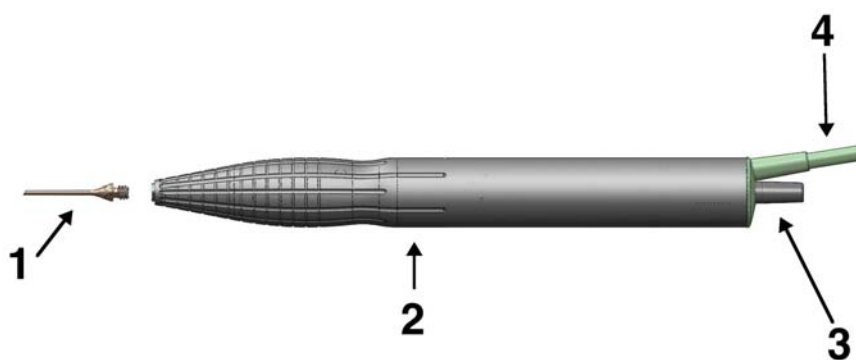


Figure 5.4. Fragmentation Needle and Handpiece.

1. Needle. 2. Frag handpiece. 3. Aspiration port. 4. Power cord.



CAUTION: Use only warm (30° C to 40° C or 85° F to 105° F) distilled or deionized water to flush the handpiece.



Note: You may use filtered compressed medical grade air (medical grade nitrogen) to blow out the tubing. The pressure should not exceed 29 psi (200 kPa, 2 bar).

C. Flush the irrigation lumen as follows (see Figure 5.5 below):

1. Place the end of the syringe into a container of warm (30° C to 40° C or 85° F to 105° F) distilled or deionized water, and fill the syringe to the 50 cc (ml) mark.
2. Connect the end of the syringe to the infusion line on the ultrasound handpiece.

5 Cleaning and Sterilization Requirements

3. Push on the syringe plunger to force fluid through the handpiece into another container for proper disposal. **Do not draw flushing fluid back through the handpiece.** Disconnect the syringe.
4. Repeat Steps 1 through 3 at least three times.
5. Fill the syringe with air, reattach to infusion line, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.
6. Repeat Step 5 at least three times.

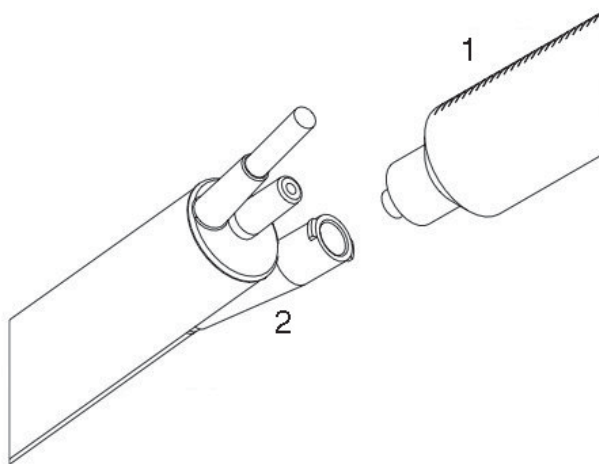


Figure 5.5. Flushing Ultrasound Handpiece.

1. Syringe. 2. Handpiece.

- D. Flush the aspiration lumen as follows (see Figure 5.6 and Figure 5.7 below):
1. From the rear of the handpiece, insert aspiration brush (provided in the **Universal Maintenance Kit CX7120**) into the aspiration fitting.
 2. Push the brush bristles through the handpiece aspiration lumen, then pull the brush back out. Thoroughly clean the brush after each use and sterilize at the end of each day according to the maintenance kit instructions.
 3. Refill the syringe to the 50 cc (ml) mark with warm (30° C to 40° C or 85° F to 105° F) distilled or deionized water.
 4. Connect the syringe to the center stopcock fitting.
 5. Rotate the stopcock lever to allow fluid flow to the female luer fitting.
 6. Connect the stopcock female luer fitting to the handpiece aspiration fitting.
 7. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **Do not draw flushing fluid back through the handpiece.** Disconnect the syringe.
 8. Repeat Steps 3 through 7 at least three times.
 9. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.

10. Repeat Step 9 at least three times.

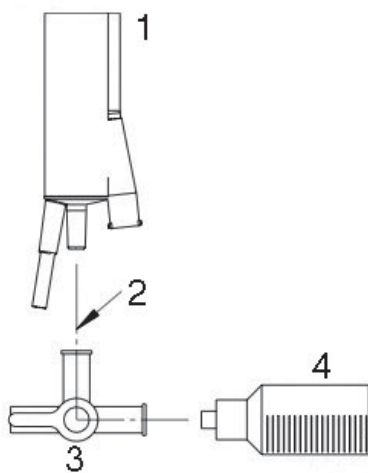


Figure 5.6. Flushing Aspiration Lumen (Ultrasound Handpiece).

1. Handpiece. 2. Fluid Pathway. 3. Stopcock. 4. Syringe.

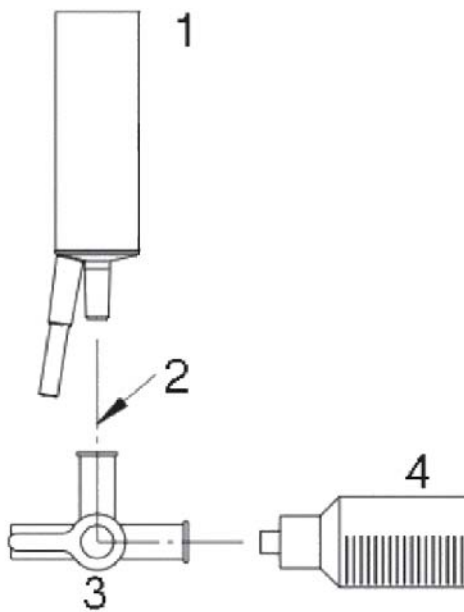


Figure 5.7. Flushing Aspiration Lumen (Fragmentation Handpiece).

1. Fragmentation Handpiece. 2. Fluid Pathway. 3. Stopcock. 4. Syringe.

Needle Cleaning Instructions (for reusable ultrasound needle only)

- A. Use a handpiece that was cleaned but not sterilized. Attach the needle and a irrigation sleeve to the handpiece. See page 5-6.
- B. Clean the needle in the same manner that the handpiece was cleaned in Steps C and D above.
- C. Remove the irrigation sleeve and needle from the handpiece.

Ultrasound Handpiece and Accessories Sterilization



WARNING: *Before each use, the handpiece and power cord should be inspected for damage (nicks, crimps, dents, exposed wires, and so on). If the handpiece is damaged, it should be immediately removed from service. Use of damaged handpiece may result in serious permanent patient injury.*



WARNING: *Do not cold sterilize the instrument. The sterilizing solution may not be flushed out prior to surgery and could be flushed into the eye, resulting in serious eye injury.*



CAUTION: *Allow 20 minutes after sterilization for the handpiece and cord to cool before using them again. The handpiece connector must be completely dry before it is connected it to equipment.*



Note: *To maintain flexibility and prevent cable damage, wind the cord only loosely if needed, and do not store it coiled with a less than 6" diameter.*

The handpiece, needle and irrigation sleeve must be sterilized before use. With the exception of flash sterilization, the items may be wrapped in a surgical towel, CSR wrap, or equivalent.

Except for users in the United Kingdom, the minimum requirements for sterilization are:

- **Standard Gravity Steam Sterilization:** Wrapped for 30 minutes at 121° C/104.8 kPa [1.048 bar] (250° F/15.2 psi).
- **Flash Sterilization:** Unwrapped but covered for 10 minutes at 132° C/186.8 kPa [1.868 bar] (270° F/27.1 psi).
- **High Vacuum (Pre-vacuum) Sterilization:** Wrapped for 3 minutes at 134° C/206.8 kPa [2.068 bar] (274° F/30.0 psi).



Note: For users in the United Kingdom, please refer to page 5-11 for special cleaning and sterilization instructions before proceeding.

Refer to ANSI/AAMI ST79-2006, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*, and/or your institution's policies regarding restrictions on the use of flash sterilization.

5.5. Special Instructions for United Kingdom Users

Flush aspiration lumen (phaco) as follows:

- Place the end of the syringe into a beaker of warm (30° C to 40° C) distilled or deionized water, and fill the syringe to the 50 cc (ml) mark.
- Connect the syringe to the center stopcock fitting.
- Rotate the stopcock lever to allow flow to the female luer fitting.
- Connect the stopcock female luer fitting to the handpiece aspiration fitting.
- Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **Do not draw flushing fluid back through the handpiece.** Disconnect the syringe.
- Repeat Steps A through E at least three times.
- Prepare a neutral pH detergent solution using warm distilled or deionized water, per the detergent manufacturer's labeling instructions.
- Immerse aspiration brush (part of CX7120 *Universal Maintenance Kit*) into the detergent solution sufficiently to cover all of the brush bristles.
- From the rear of the handpiece, insert the aspiration brush into the aspiration fitting.
- Push the brush bristles through the handpiece aspiration lumen several times. Care must be taken not to create an aerosol effect by pushing the bristles past the end of the handpiece. Then pull the brush back out. Thoroughly clean the brush after each use and sterilize at the end of each day according to CX7120 *Universal Maintenance Kit* instructions.

5 Cleaning and Sterilization Requirements

- K. Rinse both ends of the handpiece aspiration lumen. Holding the handpiece downward at a 45° angle, and rinse the aspiration fitting with warm (30° C to 40° C) distilled or deionized water. Repeat this process for the front of the handpiece.
- L. Wipe each end of the handpiece with clean gauze to remove any deposited protein material.
- M. Refill the syringe with 50 cc (ml) of warm distilled or deionized water.
- N. Connect the end of the syringe to the center stopcock fitting.
- O. Rotate the stopcock lever to allow fluid flow to the female luer fitting.
- P. Connect the stopcock female luer fitting to the handpiece aspiration fitting.
- Q. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **Do not draw flushing fluid back through the handpiece.** Disconnect the syringe.
- R. Repeat Steps M through Q at least four times.
- S. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.
- T. Repeat Step S at least three times.
- U. Sterilize the handpiece as follows:
 - **High Vacuum (Pre-vacuum) Sterilization:** Wrapped for a minimum of 3 minutes at 134° C/206.8 kPa [2.068 bar] (274° F / 30.0 psi).

Refer to your institution's policies regarding restrictions on the use of sterilization.

Automated Cleaning

1. Inspect the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece to ensure that it is free of any gross soiling or debris. If gross soiling or debris is evident, manual pre-cleaning with a neutral pH detergent with a disposable cloth or paper wipe while wearing appropriate personal protective equipment may be necessary. It is recommended that the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece be reprocessed as soon as is reasonably practical following use.
2. Connect the lumens of the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece to the lumen connectors or adaptors of the washer to allow detergent and rinse water to circulate freely through the lumens of the handpiece.
3. Ensure that the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece is placed within the washer such that all surfaces of the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece components are accessible to the detergent and rinse water during cleaning and the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece does not move about excessively during cleaning.
4. Process the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece according to the conditions listed below. Cleaning times and conditions may be adjusted based on the degree of soiling present on the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece. The conditions indicated below were validated using a neutral pH detergent (Getinge Neutrawash) and a severe organic soil challenge (BS 2745: Part 3: 1993). The use of a neutral pH detergent solution is recommended to avoid damage to the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece components.

Phase	Time	Temperature
Pre-Wash	3 minutes	30° C (86° F)
Wash 1 ¹	10 minutes	40° C (104° F)
Wash 2 ¹	10 minutes	30° C (86° F)
Rinse	3 minutes	30° C (86° F)
Heated Final Rinse	50 minutes at 80° C (176° F) or 10 minutes at 90° C (194° F) ²	
Drying	By observation—Do not exceed 110° C (230° F) ³	

1. Neutral pH detergent. Adjust concentration according to the detergent manufacturer's directions regarding water quality and the extent of instrument soiling.

2. Minimum exposure conditions for thermal disinfection using purified water.

3. As cleaning frequently involves mixed instrument loads, the efficacy of drying will vary based on the equipment employed and the nature and volume of the load being processed. Therefore, the drying parameters selected must be determined by observation.

5. Following processing carefully inspect the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece for cleanliness, any evidence of damage, and proper operation. If residual soiling is apparent, reprocess the **Stellaris® PC** Vision Enhancement System's Ultrasound handpiece as indicated above.

5.6. Cleaning the MMC



CAUTION: *To preserve the chassis finish, avoid the use of abrasive cleaners. If possible, clean spots before they dry.*



WARNING: *Disconnect AC power before cleaning the chassis.*

The following cleaning solutions are recommended to clean the MMC.

- Isopropyl alcohol (70%)
- Mild soap and water

Wipe the area to be cleaned using a soft cloth moistened with cleaning solution. Avoid excessive quantities of cleaning solution around the open vents on the MMC outer chassis. Remove all traces of the cleaning solution with a cloth dampened with clean water. The surfaces should then be dried with a lint-free cloth.

A periodic visual inspection of the system components should be performed to inspect for damaged cables or connectors.

Store the MMC in a dry and clean area and avoid extreme temperatures.

There are no requirements for periodic calibration or adjustments.

Troubleshooting

This chapter contains procedures for identifying and resolving problems that may occur with your *Stellaris® PC* Vision Enhancement System.

6.1. User Troubleshooting

- 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

If you flip the main power switch and no power is sent to the system (i.e., the stand-by power switch does not light up, there is no faint fan noise from the lower rear of the system, etc.) you may have 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® PC** Vision Enhancement System has 2 user-replaceable fuses. If an over-current condition should occur which opens these fuses, they should be replaced with fuses of the same value 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 stand-by 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® PC** 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

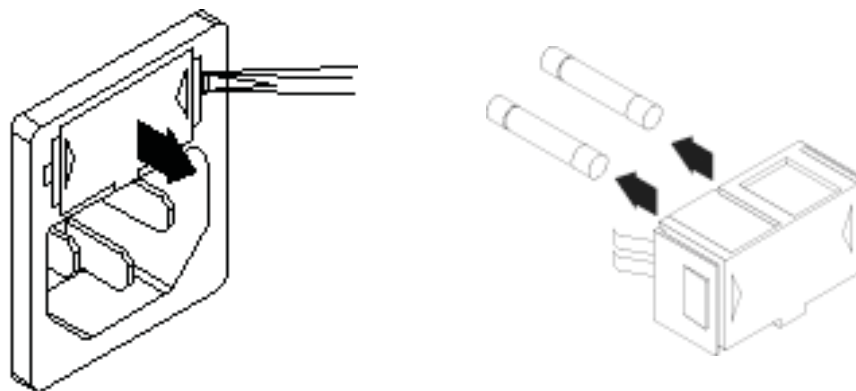


Figure 6.1. Fuse Holder Location.

6.3. Informational and Warning Messages

All messages displayed by the user interface are uniform in their appearance. However, the dialog box will have a red border as a warning 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 message displayed. The pop-up window will provide the user with a choice of options for proceeding. Nothing else may be done while a pop-up window is displayed.

Messages and suggested corrective actions are shown in the following tables.

Message Prefix	Trouble Area
BPS	Power Supply Module
CPX	Compressor Module
EIV	IV Pole Module
LM	Light Module
MMC	MultiMedia Center Module
RCR	Remote Control Receiver Module
UIC	User Interface Computer Module
USM	Ultrasound Module
VFM	Vacuum Fluidics Module
WFC	Foot Control Module
WFR	Foot Control Receiver Module

Power Supply Module Messages

ID	Type	Text Message	Suggested Action(s)
BPS02	Warning	The power supply was not detected in the system.	SG01 Call your product service representative.
BPS03	Warning	The power supply software version is not compatible with this software version. Surgical mode is not available.	SG02 Call your product service representative. A compatible software version must be downloaded.
BPS04	Warning	The power supply has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
BPS05	Warning	The power supply has reset. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
BPS08	Warning	The power module is at an over temperature condition. System shutdown is imminent.	SG67 Confirm that the bottom and lower rear areas of the system are not blocked from free air flow. SG04 Call your product service representative if this problem persists.

Compressor Module Messages

ID	Type	Text Message	Suggested Action(s)
CPX01	Warning	The compressor module was not detected in the system. Surgical mode is not available.	SG01 Call your product service representative.
CPX02	Warning	The compressor module software version is not compatible with this software version. Surgical mode is not available.	SG02 Call your product service representative. A compatible software version must be downloaded.
CPX03	Warning	The compressor module has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
CPX04	Warning	The compressor module has reset. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
CPX05	Warning	The air pressure output is lower than commanded.	SG44 Check that the air line tubing is connected tightly to the system. SG45 Check that there are no leaks in the air line and that the air line tubing is connected tightly to the other pack components. SG04 Call your product service representative if this problem persists.

ID	Type	Text Message	Suggested Action(s)
CPX06	Warning	The air pressure output is higher than commanded.	SG46 Check the air or fluid infusion pressure to be suitable for use in surgery. SG04 Call your product service representative if this problem persists.
CPX08	Warning	The internal air pressure system cannot reach the full pressure expected.	SG25 Confirm correct infusion and aspiration function. SG31 Confirm correct vitrectomy function. SG04 Call your product service representative if this problem persists.
CPX09	Warning	The internal vitrectomy air pressure is low.	SG31 Confirm correct vitrectomy function. SG04 Call your product service representative if this problem persists.
CPX10	Warning	Viscous fluid injection pressure is low.	SG91 Confirm correct viscous fluid injection function. SG04 Call your product service representative if this problem persists.
CPX11	Warning	Viscous fluid injection pressure is high.	SG91 Confirm correct viscous fluid injection function. SG04 Call your product service representative if this problem persists.
CPX12	Warning	Viscous fluid extraction vacuum is low.	SG92 Confirm correct viscous fluid extraction function. SG04 Call your product service representative if this problem persists.
CPX13	Warning	Viscous fluid extraction vacuum is high.	SG92 Confirm correct viscous fluid extraction function. SG04 Call your product service representative if this problem persists.
CPX14	Warning	Source pressure is low.	SG90 Increase input pressure to 72.5 to 100 psi. (5.0 bar - 6.9 bar)
CPX15	Warning	The internal air pressure supply to the vacuum fluidics module is low. The irrigation and aspiration pinch valves may not be functioning properly.	SG25 Confirm correct infusion and aspiration function. SG04 Call your product service representative if this problem persists.
CPX19	Warning	The vitrectomy cutter input pressure is high. The vitrectomy cutter is not available.	SG04 Call your product service representative if this problem persists.
CPX20	Warning	The internal air pressure supply to the vacuum fluidics module is high. The irrigation and aspiration pinch valves may not be functioning properly.	SG25 Confirm correct infusion and aspiration function. SG04 Call your product service representative if this problem persists.

6 Troubleshooting

ID	Type	Text Message	Suggested Action(s)
CPX22	Warning	The internal air pressure is higher than expected.	Ensure system input pressure is 72.5 to 100 psi. (5.0 bar - 6.9 bar). SG25 Confirm correct infusion and aspiration function. SG31 Confirm correct vitrectomy function. SG04 Call your product service representative if this problem persists.
CPX23	Info	Source pressure is high.	SG102 Decrease input pressure to 85 psi.

IV Pole Module Messages

ID	Type	Text Message	Suggested Action(s)
EIV01	Warning	The IV pole controller was not detected in the system. The motorized IV pole function is not available.	SG01 Call your product service representative.
EIV02	Warning	The IV pole controller software version is not compatible with this software version. The motorized IV Pole function is not available.	SG02 Call your product service representative. A compatible software version must be downloaded.
EIV03	Warning	The IV Pole controller has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
EIV04	Warning	The IV pole controller has reset. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
EIV05	Warning	The IV pole position cannot be determined.	SG62 Please command the IV pole to the minimum bottle height position. SG04 Call your product service representative if this problem persists.
EIV07	Warning	The IV pole is not detecting the home position switch or the IV pole motor may have failed.	SG62 Please command the IV pole to the minimum bottle height position. SG04 Call your product service representative if this problem persists.
EIV08	Warning	The IV pole panel button sensors have failed or the buttons have been activated continuously since being powered on.	SG64 Ensure that the IV pole back panel buttons are not activated. SG65 Confirm proper operation of the IV pole back panel buttons. SG04 Call your product service representative if this problem persists.

Light Module Messages

ID	Type	Text Message	Suggested Action(s)
LM01	Warning	The light module was not detected in the system. Illumination and viscous fluid control are not available.	SG01 Call your product service representative.
LM02	Warning	The light module software version is not compatible with this software version. Illumination and viscous fluid control are not available.	SG02 Call your product service representative. A compatible software version must be downloaded.
LM03	Warning	The light module has failed to respond to a settings command. The module settings have been re-sent to the module.	SG93 Confirm correct illuminator and viscous fluid control function. SG04 Call your product service representative if this problem persists.
LM04	Warning	The light module has reset. The module settings have been re-sent to the module.	SG93 Confirm correct illuminator and viscous fluid control function. SG04 Call your product service representative if this problem persists.
LM05	Warning	The upper illuminator bulb is near end of life.	SG94 Replace the upper illuminator bulb.
LM06	Warning	The lower illuminator bulb is near end of life.	SG95 Replace the lower illuminator bulb.
LM07	Warning	The illuminator temperature is too high. The illuminators have been turned off.	SG04 Call your product service representative if this problem persists.
LM08	Warning	The illuminator temperature is too low.	SG97 Wait for the system to reach room temperature, then try again. SG04 Call your product service representative if this problem persists.
LM09	Warning	The upper illuminator bulb has failed.	SG94 Replace the upper illuminator bulb.
LM10	Warning	The lower illuminator bulb has failed.	SG95 Replace the lower illuminator bulb.
LM11	Warning	The illuminator filter control has failed.	SG04 Call your product service representative if this problem persists.
LM12	Warning	The upper illuminator brightness control has failed.	SG04 Call your product service representative if this problem persists.
LM13	Warning	The lower illuminator brightness control has failed.	SG04 Call your product service representative if this problem persists.
LM14	Warning	The illuminator bulb type is not valid.	SG96 Replace illuminator bulb with a valid type.
LM16	Warning	The upper illuminator fan has failed. Illuminator use may be limited if overheating occurs.	SG04 Call your product service representative if this problem persists.
LM17	Warning	The lower illuminator fan has failed. Illuminator use may be limited if overheating occurs.	SG04 Call your product service representative if this problem persists.

6 Troubleshooting

ID	Type	Text Message	Suggested Action(s)
LM18	Warning	The upper illuminator has a bulb ballast error and cannot be used. It will be turned off in 30 seconds.	SG01 Call your product service representative.
LM19	Warning	The lower illuminator has a bulb ballast error and cannot be used. It will be turned off in 30 seconds.	SG01 Call your product service representative.
LM20	Warning	The upper illuminator bulb voltage is high.	SG94 Replace the upper illuminator bulb.
LM21	Warning	The lower illuminator bulb voltage is high.	SG95 Replace the lower illuminator bulb.
LM23	Warning	The illuminator ballast fan has failed. The illuminators will be turned off in 30 seconds.	SG04 Call your product service representative if this problem persists.
LM24	Warning	The upper illuminator bulb is at end of life. Lamp will be disabled if turned off.	SG94 Replace the upper illuminator bulb.
LM25	Warning	The lower illuminator bulb is at end of life. Lamp will be disabled if turned off.	SG95 Replace the lower illuminator bulb.
LM26	Warning	The illuminator temperature is too high. The illuminators may be turned off within 2.5 minutes.	SG04 Call your product service representative if this problem persists.
LM27	Info	<p>Note that the level of light output being requested should be used with awareness of exposure time and proximity to the retina.</p> <p>Limiting exposure to less than a guidelines value of 10 J/cm² helps maintain retinal tissue. At the requested setting, this does level may be exceeded in less than 30 minutes with the Bausch + Lomb focal light probe positioned 15 mm from the retina.</p>	<p>The time to reach the exposure guidelines will vary with:</p> <p>1) Filter selection - Value reached within 30 minutes with the following settings:</p> <ul style="list-style-type: none"> a) White - 60% b) Green - 68% c) Yellow - 88% d) Amber - 100% <p>2) Distance from the retina</p> <p>3) Light dispersing probes</p>

ID	Type	Text Message	Suggested Action(s)
LM28	Info	<p>Note that the level of light output being requested should be used with awareness of exposure time and proximity to the retina.</p> <p>Limiting exposure to less than a guidelines value of 10 J/cm² helps maintain retinal tissue. At the requested setting, this does level may be exceeded in less than 30 minutes with the Bausch + Lomb focal light probe positioned 15 mm from the retina.</p>	<p>The time to reach the exposure guidelines will vary with:</p> <p>1) Filter selection - Value reached within 30 minutes with the following settings:</p> <p>a) White - 60%</p> <p>b) Green - 68%</p> <p>c) Yellow - 88%</p> <p>d) Amber - 100%</p> <p>2) Distance from the retina</p> <p>3) Light dispersing probes</p>

MultiMedia Center (MMC) Module Messages

ID	Type	Text Message	Suggested Action(s)
MMC01	Info	The multimedia center was not detected.	<p>SG73 Please ensure that the multimedia center is plugged in and powered on.</p> <p>SG74 Check that the multimedia center data cable is plugged in to both the system and the multimedia center.</p>
MMC02	Info	The multimedia center software version is not compatible with this software version. The video overlay function is not available.	SG02 Call your product service representative. A compatible software version must be downloaded.
MMC03	Info	The multimedia center has failed to respond to a settings command. The settings have been re-sent.	SG04 Call your product service representative if this problem persists.

Remote Control Receiver Module Messages

ID	Type	Text Message	Suggested Action(s)
RCR01	Warning	The remote control receiver was not detected in the system. Remote control and display backlight control functions are not available.	SG01 Call your product service representative.
RCR02	Warning	The remote control receiver software version is not compatible with this software version. Remote Control is not available.	SG02 Call your product service representative. A compatible software version must be downloaded.

6 Troubleshooting

ID	Type	Text Message	Suggested Action(s)
RCR03	Warning	The remote control receiver has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
RCR04	Warning	The remote control receiver has reset. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
RCR05	Warning	Possible interference with remote control receivers. Remote control function may not be available.	SG70 Turn off or dim room lights. Certain types of room lighting may cause this type of interference. SG71 Check remote functions with 'A/V' pop-up display. SG04 Call your product service representative if this problem persists.
RCR06	Warning	The remote control battery level is low. Remote control function may not be available shortly.	SG72 Replace the remote control battery at your earliest convenience. SG71 Check remote functions with 'A/V' pop-up display. SG04 Call your product service representative if this problem persists.

User Interface Computer (UIC) Module Messages

ID	Type	Text Message	Suggested Action(s)
UIC01	Info	IV pole height range is X to Y cm.	SG88 Go to Infusion More screen or programming function to reset max IV Pole Height.
UIC03	Info	Phase/Mode change not allowed while surgical functions are in use.	SG77 Change Phase/Mode while surgical functions are not in use.
UIC04	Warning	Initialization of surgical system failed. Surgical mode not available.	SG78 Power down the system and then restart the system. SG04 Call your product service representative if this problem persists.
UIC05	Warning	The system database is corrupt. Surgical mode is not available.	SG01 The system database is corrupt. The system will shutdown upon confirmation of error.
UIC06	Info	Cassette type does not match procedure type. Do you want to enter the matching procedure type?	SG84 Press Yes for a {0} cassette or press No to eject the cassette.
UIC07	Info	Cassette type does not match procedure type.	SG85 Please insert a posterior cassette.

ID	Type	Text Message	Suggested Action(s)
UIC08	Info	Incorrect ultrasound handpiece connected.	SG86 Please plug in a {Phaco, Frag} handpiece, or try another ultrasound handpiece. SG04 Call your product service representative if this problem persists.
UIC09	Info	Vitrectomy cutter testing is in progress.	SG87 Priming/Tuning/Vitrectomy cutter testing is in progress.
UIC13	Info	Surgeon File Is Not Usable due to loss of database integrity. Try a system default setting file.	SG04 Call your product service representative if this problem persists.
UIC14	Info	The IV pole and AFI are both engaged. Please confirm that the AFI bottle is at patient eye level.	

Ultrasound Module Messages

ID	Type	Text Message	Suggested Action(s)
USM01	Warning	The ultrasound module was not detected in the system. Ultrasound and coagulation are not available.	SG01 Call your product service representative.
USM02	Warning	The ultrasound module software version is not compatible with this software version. Ultrasound and coagulation are not available.	SG02 Call your product service representative. A compatible software version must be downloaded
USM03	Warning	The ultrasound module has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
USM04	Warning	The ultrasound module has reset. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
USM05	Info	The ultrasound handpiece is not connected or detected.	SG48 Please plug in the {Phaco, Frag, ultrasound} handpiece. The ultrasound connector light is flashing. SG49 If the handpiece is not detected, unplug the handpiece and try another ultrasound handpiece. SG04 Call your product service representative if this problem persists.
USM06	Info	The ultrasound handpiece has not been tuned.	SG50 Select 'Setup', then select 'Prime / Tune' or 'Tune Only'.

6 Troubleshooting

ID	Type	Text Message	Suggested Action(s)
USM08	Info	The ultrasound handpiece has failed the tuning process.	SG52 Ensure ultrasound needle is properly tightened. Select 'Prime / Tune' or 'Tune Only' again to repeat the handpiece tuning process. SG53 Unplug the handpiece and try another ultrasound handpiece. SG04 Call your product service representative if this problem persists.
USM09	Info	The ultrasound handpiece may have failed or may be failing.	SG54 Confirm proper ultrasound handpiece operation in a test chamber. SG53 Unplug the handpiece and try another ultrasound handpiece. SG04 Call your product service representative if this problem persists.
USM10	Warning	Coagulation circuit may have failed, potential coagulation output over-voltage condition.	SG55 Confirm proper operation of the coagulation handpiece in a beaker of BSS; activate the function and ensure the error message does appear again. If similar message appears, stop using the function and call B&L service support. SG56 Unplug the handpiece and try another bipolar coagulation cord. SG04 Call your product service representative if this problem persists.
USM11	Warning	Coagulation circuit may have failed, potential uncommanded or incorrect coagulation output.	SG55 Confirm proper operation of the coagulation handpiece in a beaker of BSS; activate the function and ensure the error message does appear again. If similar message appears, stop using the function and call B&L service support. SG56 Unplug the handpiece and try another bipolar coagulation cord. SG04 Call your product service representative if this problem persists.
USM15	Info	Unable to read ultrasound handpiece data. Attempt to tune the handpiece to confirm proper operation.	SG53 Unplug the handpiece and try another ultrasound handpiece. SG04 Call your product service representative if this problem persists.

Vacuum Fluidics Module Messages

ID	Type	Text Message	Suggested Action(s)
VFM01	Warning	The vacuum fluidics module was not detected in the system. Surgical mode with the vacuum fluidics module is not available.	SG01 Call your product service representative.
VFM02	Warning	The vacuum fluidics module software version is not compatible with this software version. Surgical mode is not available.	SG02 Call your product service representative. A compatible software version must be downloaded.
VFM03	Warning	The vacuum fluidics module has failed to respond to a settings command. The module settings have been re-sent to the module.	SG03 Confirm correct infusion, aspiration, and vitrectomy function. SG04 Call your product service representative if this problem persists.
VFM04	Warning	The vacuum fluidics module has reset. The module settings have been re-sent to the module.	SG03 Confirm correct infusion, aspiration, and vitrectomy function. SG04 Call your product service representative if this problem persists.
VFM05	Warning	The vacuum fluidics module does not have valid factory calibration data. Surgical mode is not available.	SG05 Call your product service representative to replace the vacuum fluidics modules. SG06 Call your product service representative to replace or calibrate the vacuum fluidics module.
VFM07	Info	The vacuum fluidics module cassette vacuum check is in progress.	SG13 Please wait for the vacuum fluidics module cassette vacuum check to complete.
VFM08	Info	The cassette vacuum check has failed.	SG11 Re-insert the cassette for the cassette vacuum check. SG15 Replace the cassette. SG04 Call your product service representative if this problem persists.
VFM09	Info	System priming has not been completed.	SG20 Select 'Setup', and select 'Prime' to complete the system priming.
VFM10	Info	System priming is in progress.	SG21 Please wait for the system priming to complete.
VFM11	Info	System priming has failed.	SG22 Check irrigation and aspiration tubing connections for leaks. Check that the test chamber is forming a tight seal around the handpiece. Try priming the system again. SG23 Eject the cassette, load a new pack, and try priming the system again. SG04 Call your product service representative if this problem persists.

6 Troubleshooting

ID	Type	Text Message	Suggested Action(s)
VFM13	Info	The cassette has just become nearly full.	SG26 Arrange the soonest convenient time to empty the cassette. To empty cassette and reprime: 1. Clamp irrigation line. 2. Select the Setup icon 3. Eject the cassette. 4. Empty the cassette. 5. Re-insert the cassette. 6. Open irrigation clamp. 7. Select Prime to prime cassette. 8. After priming, select Advance to Surgery to resume surgery. Refer to operator's manual for detailed instructions to detach tubing manifold from the cassette. SG27 Call your product service representative if the cassette is not nearly full and this message persists.
VFM14	Warning	The cassette is full.	SG28 Empty the cassette. To empty cassette and reprime: 1. Clamp infusion line. 2. Select the 'Setup' icon 3. Eject the cassette. 4. Empty the cassette. 5. Re-insert the cassette. 6. Open irrigation clamp. 7. Select Prime to prime cassette. 8. After priming, select Advance to Surgery to resume surgery. Refer to operator's manual for detailed instructions to detach tubing manifold from the cassette. SG29 Call your product service representative if the cassette is not full and this problem persists.
VFM15	Warning	The vitrectomy cutter output pressure is low. Vitrectomy cutter may not be cutting.	SG30 Check that the vitrectomy cutter tubing is connected tightly to the system. SG31 Confirm correct vitrectomy function. SG04 Call your product service representative if this problem persists.
VFM17	Info	Please insert the cassette.	
VFM18	Info	Unrecognized cassette.	SG83 Please re-insert the cassette or try a different cassette. SG04 Call your product service representative if this problem persists.
VFM19	Warning	A Vacuum Fault has occurred.	SG04 Call your product service representative if this problem persists.

Foot Control Module Message

ID	Type	Text Message	Suggested Action(s)
WFC01	Info	The Foot Control battery has exceeded 300 charge cycles. The Foot Control battery may not provide power for the entire day.	SG32 If the battery does not provide power for the full day, replace the battery. SG33 Use the wired cable connection to the system. SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system.
WFC02	Warning	The Foot Control does not have valid factory calibration data. Surgical mode is not available.	SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system. SG35 Call your product service representative to have the Foot Control calibrated.
WFC03	Info	The Foot Control is programmed for right footed operation, but is set up for left footed operation.	SG36 Change the Foot Control home position switch selection. SG37 Confirm that the correct surgeon settings are loaded. If incorrect, select 'Setup', then select 'Select Surgeon' to select the correct surgeon settings.
WFC04	Info	The Foot Control is programmed for left footed operation, but is set up for right footed operation.	SG36 Change the Foot Control home position switch selection. SG37 Confirm that the correct surgeon settings are loaded. If incorrect, select 'Setup', then select 'Select Surgeon' to select the correct surgeon settings.
WFC05	Warning	The Foot Control center pedal or switch sensors have failed or the Foot Control has been activated continuously since being powered on.	SG38 Reposition the Foot Control and ensure that the center pedal and buttons are not activated. SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system. SG04 Call your product service representative if this problem persists.
WFC08	Info	System not detecting the Foot Control.	SG40 Initiate wireless Foot Control connectivity by pressing one of the Foot Control buttons momentarily, the left LED will light up. SG33 Use the wired cable connection to the system. SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system.

6 Troubleshooting

ID	Type	Text Message	Suggested Action(s)
WFC09	Warning	The Foot Control software version is not compatible with this software version. Surgical mode is not available.	SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system. SG02 Call your product service representative. A compatible software version must be downloaded.
WFC10	Info	Foot Control detected on wired cable connection.	SG41 Please wait while the Foot Control configuration completes.
WFC11	Info	Foot Control configuration on wired cable connection has completed successfully.	SG42 You may disconnect the Foot Control cable and operate the Foot Control wirelessly.
WFC12	Info	Foot Control configuration on the wired cable connection has failed.	SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system. SG04 Call your product service representative if this problem persists.
WFC13	Warning	The Foot Control battery charge level is low.	SG33 Use the wired cable connection to the system.
WFC14	Warning	The Foot Control battery is nearly discharged.	SG43 Disconnect the Foot Control cable, reconnect the cable and try again. SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system.
WFC16	Warning	The Foot Control spring has failed; the Foot Control center pedal has been disabled.	SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system. SG04 Call your product service representative if this problem persists.
WFC17	Warning	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.	SG82 Immediately replace the battery to ensure foot control functionality. SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system.
WFC18	Info	System not detecting the Foot Control.	SG33 Use the wired cable connection to the system. SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system.
WFC19	Warning	The system has lost communications with the Foot Control, wireless disabled.	SG100 Connect the Foot Control cable to continue case. SG101 See Operators Manual for re-enabling wireless communication.

ID	Type	Text Message	Suggested Action(s)
WFC20	Warning	The system has lost communications with the Foot Control.	SG99 Check the cable connection. SG34 Replace the Foot Control with another Foot Control using the wired cable connection to the system. SG04 Call your product service representative if this problem persists.

Foot Control Receiver Module Messages

ID	Type	Text Message	Suggested Action(s)
WFR01	Warning	The Foot Control receiver was not detected in the system. Surgical mode is not available.	SG01 Call your product service representative.
WFR02	Warning	The Foot Control receiver software version is not compatible with this software version. Surgical mode is not available.	SG02 Call your product service representative. A compatible software version must be downloaded.
WFR03	Warning	The Foot Control receiver has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.
WFR04	Warning	The Foot Control receiver has reset. The module settings have been re-sent to the module.	SG04 Call your product service representative if this problem persists.

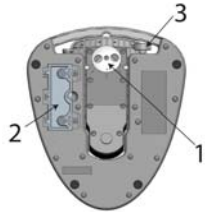
Internal Application Messages

The system requires restarting due to an internal error, please perform the following:

1. Select **Close** to initiate system shutdown.
2. If system does not shutdown after 30 seconds, power off the system by pressing and holding the power button at 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	Foot Control lost Pitch control of Region 2, 3 and Yaw. Pitch could only control Irrigation On/Off. The four side buttons function normally.	<p>The Foot Pedal Offset switch not properly engaged. System not detecting if foot pedal is offset to Left, Right or Center.</p>  <p>1. Pitch Tension Adjustment. 2. Battery Door. 3. Offset Adjustment.</p>	Check Offset switch at the back of the foot pedal, ensure switch is fully engaged to the Left, Right or Center.
2	Foot Control does not automatically transition to wireless operation after disconnecting the Foot Control backup cable.	The Foot Control does not automatically transition to wireless operation every time the backup cable is disconnected.	Following the disconnection of backup cable, initiate wireless Foot Control connectivity by pressing one of the 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.	<p>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.</p> <p>This may also occur if the cassette is inserted too fast and released before the capture mechanism captures the cassette at the optimum position.</p>	<p>Eject cassette and reinsert.</p> <p>To ensure cassette is properly positioned in the system, firmly insert the cassette until it snaps in place.</p>

	Symptom	Potential Cause	Corrective Action
4	No or low infusion with Pressurized Infusion function.	<p>System displays actual pressure correctly and air is coming out of the air output connector.</p> <p>If problem persists with the all of the above corrective actions, stop using Pressurized Infusion and call service.</p>	<p>1. Air tubing or irrigation tubing may be kinked. Check air tubing and irrigation tubing for kink or pinch.</p> <p>2. The air tubing pathway may be obstructed. Ensure new air tubing is used. Otherwise, replace with new tubing.</p> <p>3. Preset pressure may be set too low. Increase air pressure setting to desired level.</p>
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 unplug from the wall.	<p>1. Stop surgery and remove handpiece from the eye.</p> <p>2. Close irrigation clamp to stop fluid flow into the cassette/cartridge and handpiece.</p> <p>3. Replace test chamber to the handpiece that is connected to the tubing.</p> <p>4. Reboot system, prime and tune handpiece when power supply resumes (ensure to open irrigation clamp before starting to re-prime and tune system).</p>
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.

6.4. Troubleshooting the MMC

When a problem appears with the MMC, the first step in troubleshooting is to remove the MMC components from the video setup, and then assure that the rest of the system is operating correctly.

Symptom	Action Required
Video display not centered on screen or edge off screen	Check video monitor for overscan or underscan adjustments.
No camera video	Is camera powered on? Turn the MMC off. If video is displayed, the input and output cables to the MMC are reversed. Check for video when camera is plugged directly into monitor. Is video input selection correct on VCR and Monitor? Is camera plugged into VIDEO IN or S-VIDEO IN?
No overlay logo displayed	Is MMC powered up (power indicator on)? Are power cord(s) connected correctly? Check video connections: IN/OUT, S-Video/Video.
No settings displayed	Is the <i>Stellaris</i> ® PC Vision Enhancement System in a surgical mode? Is the data cable connected correctly?
Overlaid displays not visible	Check monitor adjustments. Is monitor set to correct format: NTSC or PAL?
Intermittent or flickering video	Check all video cables and connections. Is monitor set to correct format: NTSC or PAL?
Rolling video	Is camera powered on? Video format may not be supported. Is monitor set to correct format: NTSC or PAL?
No streaming video on console	Ethernet cable connected? Camera turned on? Check video connections. Cycle power on MMC. Cycle power on system and power up MMC.
System modules reset momentarily	When the problem occurs, the system will automatically turn on the irrigation valve to provide continuous irrigation. System main functions such as aspiration and ultrasound will cease to operate. To resume system operation, perform the following: A. Go to Setup Screen. B. Replace test chamber on the ultrasound handpiece. C. Select Prime and Tune . D. Following successful prime and tune, the system will go to surgical mode to resume operation.

Symptom	Action Required
GUI hung up and system ceased operation	<p>When the problem occurs, the system will automatically turn ON the irrigation valve to provide continuous irrigation. System and MMC need to be restarted to resume operation.</p> <p>To restart system, perform the following:</p> <ul style="list-style-type: none"> A. Power down system by pressing and holding the standby power switch in front of the system. B. Wait until the system powers down completely. C. Power down MMC by pressing and holding the power switch until the light turns brighter (if not already powered down). D. Restart MMC by pressing the power switch. E. Restart system by pressing the standby power switch once. F. Repeat system set up sequence, Prime and Tune system to resume operation.

6.5. System Configurations, Modules, Accessories and Packs

Use of non-approved accessories, packs or parts may affect system performance. The unauthorized modification or alteration of the equipment, or the use of non-approved accessories, packs or 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.

For additional information, please contact a Bausch + Lomb sales representative or your local sales office.

The system configurations, modules, accessories and packs provided on the following pages are to be used with the **Stellaris® PC** Vision Enhancement System. Although not provided in the list; the ultrasound needles, I/A handpiece, I/A tips, and bipolar accessories for the *Millennium* Microsurgical System and Stellaris® are compatible and could be used with the **Stellaris® PC** Vision Enhancement System.

Available Accessories and Packs

The packs listed below can be used with the **Stellaris® PC** Vision Enhancement System. A complete list of accessories, including approved needles and sleeves and packs is available from your sales representative upon request.

Stellaris® PC System and Module List

System	BL1333	Stellaris® PC Posterior System
System	BL1433	Stellaris® PC Combined System
Module	BL2111	Remote Control Anterior Module
Module	BL2213	Vacuum Fluidic Module (Stellaris® PC)
Module	BL2270	Posterior module
Module	BL2282	Compressor C module - (Stellaris® PC)
Module	BL2300	Multimedia Center Module
Module	BL2330	Ultrasound Module
Module	BL2340	I/V Pole Module
Module	BL2341	I/V Pole Interface Module
Module	BL2342	I/V Pole Interface Module II
Module	BL2351	Power Supply module II
Module	BL2362	Computer Unit Module (Stellaris® PC)
Module	BL2391	Foot control receiver Module (FCIB)
Module	BL2390	Foot control Module

Anterior Accessories and Packs

Accessory	BL3151	Anterior Sys User Manual, CD
Accessory	BL3160	I/A Handle for Stellaris I/A Handpiece System
Accessory	BL3161	I/A 0.4 Tip Curved—Silicone Sleeve—20 Gauge Aspirating Cannula
Accessory	BL3162	I/A 0.4 Tip Straight—Silicone Sleeve—20 Gauge Aspirating Cannula
Accessory	BL3163	I/A 0.4 Tip Angled 45 Deg—Silicone Sleeve—20 Gauge Aspirating Cannula
Accessory	BL3164	I/A 0.4 Tip Straight—Metal Outer Cannula—17.5 Gauge
Accessory	BL3165	I/A 0.4 Tip Curve—Metal Outer Cannula—17.5 Gauge
Accessory	BL3166	I/A 0.4 Tip Angled 45 Deg—Metal Outer Cannula—17.5 Gauge
Accessory	BL3170	Ultrasound Phaco Handpiece
Accessory	BL3379	Stellaris Ultrasound Handpiece Tray
Accessory	DP9731	I/A 0.3 Tip Straight, Silicone Sleeve
Accessory	DP9733	I/A 0.3 Tip Angled 45 Deg, Silicone Sleeve
Accessory	DP9739	Softip I/A 0.3 Straight, Silicone Sleeve—20 Gauge Aspiration Cannula
Accessory	DP9740	Softip I/A 0.3 Curve, Silicone Sleeve—20 Gauge Aspiration Cannula
Accessory	DP9741	Softip I/A 0.3 Angled 45 Deg, Silicone Sleeve—20 Gauge Aspiration Cannula
Accessory	DP9742	Softip Threaded Tip Adapter
Pack	BL5110	Premium Vacuum Phaco Pack
Pack	BL5111	Basic Vacuum Phaco Pack
Pack	BL5112	Optimized Stability Vacuum Pack

Pack	BL5113	StableChamber™ Phaco Pack with MICST™
Pack	BL5113A	StableChamber™ Phaco Pack with MICST™
Pack	BL5114	Premium Vacuum Phaco Pack with MICST™ needle
Pack	BL5114A	Premium Vacuum Phaco Pack with MICST™ needle
Software	BL6310	TruLink® Remote Service Software
Software	BL6340	Multimedia Center Software
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	Foot Control Battery
Miscellaneous	BL4391	Foot Control Wall Charger (without adapter)
Miscellaneous	BL4392US	Foot Control Charger Adapter, United States
Miscellaneous	BL4392EUR	Foot Control Charger Adapter, Europe
Miscellaneous	BL4392UK	Foot Control Charger Adapter, United Kingdom
Miscellaneous	BL4392JPN	Foot Control Charger Adapter, Japan
Miscellaneous	BL4392AUS	Foot Control Charger Adapter, Australia
Miscellaneous	BL4392ROW	Foot Control Charger Adapter, Rest of World
Miscellaneous	BL4393	Foot Control Charging Cradle
Miscellaneous	BL4394	Foot Control Backup Cable
Miscellaneous	CX7120	Universal Maintenance Kit
Miscellaneous	CX9400	Millennium/Stellaris Reusable Bipolar Cord with 2 Pin Connector
Miscellaneous	CX9404	Millennium/Stellaris Reusable Bipolar Cord with Banana Connector
Miscellaneous	CX9430	Millennium/Stellaris Reusable Bipolar Cord with Lemo Connector
Miscellaneous	D8200	Straight Bipolar Forceps 0.5 mm Tip Lemo Connector
Miscellaneous	D8201	Bipolar Eraser, 31 Shaft with 45 Degree Beveled Lemo Connector
Miscellaneous	E7918	Bipolar Pencil 18g Str 10/box
Miscellaneous	S2050 B	Bipolar Cord with Banana Connector (Disposable)
Miscellaneous	S2050 10A	Bipolar Forceps Ang McPherson—Banana Connector
Miscellaneous	S2050 10S	Bipolar Forceps McPherson Straight—Banana Connector

Posterior Accessories and Packs

Category	SKU	Description
Accessory	BL3270	Fragmentation Handpiece
Accessory	BL3251	<i>Stellaris® PC</i> User Manual CD
Accessory	BL3253EN	<i>Stellaris® PC</i> User Manual Print Binder, English
Accessory	BL3253DE	<i>Stellaris® PC</i> User Manual Print Binder, German
Accessory	BL3253ES	<i>Stellaris® PC</i> User Manual Print Binder, Spanish
Accessory	BL3253FR	<i>Stellaris® PC</i> User Manual Print Binder, French
Accessory	BL3253IT	<i>Stellaris® PC</i> User Manual Print Binder, Italian
Accessory	BL3253NL	<i>Stellaris® PC</i> User Manual Print Binder, Dutch
Accessory	BL3253PT	<i>Stellaris® PC</i> User Manual Print Binder, Portuguese
Accessory	BL3253SV	<i>Stellaris® PC</i> User Manual Print Binder, Swedish
Accessory	BL3253NO	<i>Stellaris® PC</i> User Manual Print Binder, Norwegian
Accessory	BL3320	Xenon Lamp Assembly
Accessory	BL3321	Xenon-Mercury lamp assembly
Pack	BL5220	20 Ga. Posterior Procedural Pack
Pack	BL5223	23 Ga. Posterior Procedural Pack
Pack	BL5225	25 Ga. Posterior Procedural Pack
Pack	BL5275	20 Ga. Fragmentation Needle 15 deg single use.
Pack	BL5320	20 Ga. Combined Procedural Pack
Pack	BL5323	23 Ga. Combined Procedural Pack
Pack	BL5325	25 Ga. Combined Procedural Pack
Pack	BL5420	20 Ga. Posterior Procedural Pack with AFI
Pack	BL5423	23 Ga. Posterior Procedural Pack with AFI
Pack	BL5425	25 Ga. Posterior Procedural Pack with AFI
Pack	BL5520	20 Ga. Combined Procedural Pack with AFI
Pack	BL5523	23 Ga. Combined Procedural Pack with AFI
Pack	BL5525	25 Ga. Combined Procedural Pack with AFI
Pack	BL5612	20 Ga High Speed Anterior Vitrectomy Cutter
Pack	BL5620	20 Ga High Speed Pneumatic Vitrectomy Cutter
Pack	BL5623	23 Ga High Speed Pneumatic Vitrectomy Cutter
Pack	BL5625	25 Ga High Speed Pneumatic Vitrectomy Cutter
Pack	CX5720	20 Ga Viscous Fluid Injection Pack
Pack	CX5710	20 Ga Viscous Fluid Extraction Pack
Pack	BL5220W	20 Ga. Posterior Vitrectomy Pack with Wide Field Illuminator
Pack	BL5223W	TSV 23 Ga. Posterior Vitrectomy Pack with Wide Field Illuminator
Pack	BL5225W	TSV 25 Ga. Posterior Vitrectomy Pack with Wide Field Illuminator
Pack	BL5320W	20 Ga. Combined Vitrectomy Pack with Wide Field Illuminator
Pack	BL5323W	TSV 23 Ga. Combined Vitrectomy Pack with Wide Field Illuminator

Category	SKU	Description
Pack	BL5325W	TSV 25 Ga. Combined Vitrectomy Pack with Wide Field Illuminator
Pack	BL5420W	20 Ga. Posterior Vitrectomy Pack with AFI and Wide Field Illuminator
Pack	BL5423W	TSV 23 Ga. Posterior Vitrectomy Pack with AFI and Wide Field Illuminator
Pack	BL5425W	TSV 25 Ga. Posterior Vitrectomy Pack with AFI and Wide Field Illuminator
Pack	BL5520W	20 Ga. Combined Vitrectomy Pack with AFI and Wide Field Illuminator
Pack	BL5523W	TSV 23 Ga. Combined Vitrectomy Pack with AFI and Wide Field Illuminator
Pack	BL5525W	TSV 25 Ga. Combined Vitrectomy Pack with AFI and Wide Field Illuminator
Pack	BL5720	20 Ga Standard Focal Light Pipe
Pack	BL5723	23 Ga Standard Focal Light Pipe
Pack	BL5725	25 Ga Standard Focal Light Pipe
Pack	BL5820	20 Ga Wide Field Light Pipe
Pack	BL5823	23 Ga Wide Field Light Pipe
Pack	BL5825	25 Ga Wide Field Light Pipe
Software	BL6230	Software Upgrade from <i>Stellaris® PC</i> Posterior to Combined system
Miscellaneous	BL4360	Adapter, Alternate Mayo Tray
Miscellaneous	BL4363	<i>Stellaris® PC</i> Zero Level Bottle Hanger
Miscellaneous	E7930	23 Ga Bipolar Coagulation Probe, Single use Lemo
Miscellaneous	E7931	23 Ga Bipolar Coagulation Probe, Single use 2-pin
Miscellaneous	BL5280	Dual Infusion Kit

Service and Warranty

This chapter contains instruction on how to contact Bausch + Lomb to obtain service on your **Stellaris® PC** Vision Enhancement System, as well as warranty and environmental information.



Note: *Preventive scheduled maintenance is recommended once a year to insure that the **Stellaris® PC** 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 and lamps, 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® PC** Vision Enhancement System is available from Global Product Support as follows:

Bausch & Lomb Incorporated
3365 Tree Court Industrial Blvd.
St. Louis, Missouri 63122 U.S.A.
Attention: Global Product Support Department

http://www.bausch.com/en_US/ecp/age/surg_prod_support.aspx

- For product support **within the U.S.A.** call the 24-hour telephone line 1-800-338-2020 or fax 636-226-3070.
- For product support from **outside the U.S.A.** 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 7-2).

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® PC** Vision Enhancement System, located on the label on the back panel
- Date of purchase

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- 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® PC** 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® PC** 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

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.

Av. Juan B. Justo 2781 (1414)

Capital Federal, Argentina

*Tel: 54-11-4856-4694

*Fax: 54-11-4857-1318

Australia

Bausch & Lomb Australia Pty, Ltd. & Surgical

Level 4, 113 Wicks Rd.
North Ryde, NSW 1670
Australia

*Tel: 61-2-9887-1444

*Fax: 61-2-9888-9642

Austria

Bausch & Lomb GmbH
Horlgasse 12 Mezzanin TOP 5
1090 Wien, Österreich
Tel: 49-6221-823184

Belgium

Bausch & Lomb

Uitbreidingstraat 46
2600 Antwerpen Belgium

*Tel: 32-3-280-82-40

*Fax: 32-3-280-82-59

Bermuda

Bausch & Lomb Ireland/Bermuda HQ 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
04571-000- Sao Paulo - Brazil
Tel: 55-11-3238-2900
Fax: 55-11-5506-5528

Canada

Bausch & Lomb Canada

520 Applewood Crescent
Vaughan, Ontario L4K 4B4
Canada

Tel: 905-695-7695

Fax: 905-695-7656

*Tel: 800-567-2696

*Fax: 905-578-0103

Customer service 1-800-387-3284

China

Bausch & Lomb Surgical

Room 906-909, Tower 1
No. 218, Tianmu Road (W)
Shanghai 200070
P.R. China

Tel: 86-21-6317-7143

Fax: 86-21-6354-7780

France

Bausch & Lomb France SAS

416 rue Samuel Morse
Le Millenaire
CS79005
34967 Montpellier Cedex 2
France

Tel: 33-4-67-12-30-30

Fax: 33-4-67-12-30-31 (General)

*Tel: 33-4-67-12-30-68

*Fax: 33-4-67-12-30-66

Bausch & Lomb France SAS (DistOps Office)

Tel: 33-4-37-48-83-83 Reception

Fax: 33-4-37-48-83-84 Reception

Germany

Bausch & Lomb GmbH

Im Schumachergewann 4
69123 Heidelberg
Germany

Tel.: +49 6221 / 823184

Fax.: +49 6221 / 823149

Hotline (within Germany) 0800 2233331

Greece

Bausch & Lomb Greece

73 Apostolopou Street
Chalandri, 15231
Athens, Greece
Tel: 30-210-674-8170
Fax: 30-210-674-8234
*Tel: 33-4-37-48-83-83
*Fax: 33-4-37-48-83-84

Hong Kong

Bausch & Lomb Asia

15/F One Kowloon
Wang Yuen Street, Kowloon Bay
Kowloon, Hong Kong
*Tel: 85-2-2-213-3333
*Fax: 85-2-2567-8170

India

Bausch & Lomb Eyecare (India) Private Ltd.

2nd Floor, Tower A
Building no. 8
DLF Phase-II
DLF Cyber City
Gurgaon-122002
Haryana India
*Tel: 91-124-4152-100
*Fax: 91-124-4152-236

Indonesia

Bausch & Lomb (Indonesia)

c/o address in Singapore, see Singapore

Italy

Bausch & Lomb-IOM S.p.a.

Via Pasubio 34
20050 Macherio
Milan Italy
Tel: 39-039-20731
Fax: 39-039-2010081
*Tel: 39-039-207-3744
*Tel: 39-039-207-3308
*Fax: 800-17-3931

Japan

Bausch & Lomb Japan Ltd.

Tower B, Omori Bellport
6-26-2, Minami-Oi, Shinagawa-ku
Tokyo 1400-0013, Japan
*Tel: 81-3-5763-3700
*Fax: 81-3-5763-4003

Korea

Bausch & Lomb Surgical

11F Cannon B/D
168-12, Samsung-dong, Kang-namgu
Seoul, Korea
Tel: 822-558-2988
Fax: 822-642-1586

Malaysia

Bausch & Lomb Malaysia Sdn Bhd

3rd Floor, Bangunan THK, Lot 2A
Jalan 243/51A, 46100 Petaling Jaya
Selangor Darul Ehsan, Malaysia
*Tel: 60-3-7680-8828
*Fax: 60-3-7680-8871

Mexico

Bausch & Lomb Mexico S.A.de C.V.

Av. Santa Fe # 505, Piso 6
Colonia Cruz Manca, Santa Fe
Delegacion Cuajimalpa
Mexico D.F.
C.P. 05349
Tel: 52-55-30-67-4600
Fax: 52-55-30-67-4658
*Tel: 52-55-3067-4611

Netherlands

Bausch & Lomb B.V.
Koolhovenlaan 110
1119 NH Schiphol-Rijk
The Netherlands
Tel: 31-20-65-54-500
Fax: 31-20-65-37-871
*Tel: 31-20-65-54-555
*Fax: 31-20-65-37-873

New Zealand

Bausch & Lomb NZ Ltd.
2A Fisher Crescent
Mt. Wellington
Auckland, New Zealand
*Tel: 64-9-259-2762
*Fax: 64-9-259-4067

Philippines

c/o address in Singapore, see Singapore

Portugal

Bausch & Lomb S.A. (Sucursal Portugal)
Avenida do Forte N°3
Edificio Suecia IV Piso O Esq.
2795-504 Carnaxide
Lisbon, Portugal
*Tel: 351-214-24-1510
*Fax: 351-214-24-1519

Singapore

Bausch & Lomb (S) Pte. Ltd.
Bausch & Lomb (S) Pte Ltd
151 Lorong Chuan #04-03A
New Tech Park, Lobby C
Singapore 556741
*Tel: (65) 6834 9112
*Fax: (65) 6286 0448

South Africa

Bausch & Lomb South Africa Pty. Ltd.

P.O. Box 5435, Rivonia

2128, South Africa

Street address:

Bausch & Lomb House

19 Autumn Street

Rivonia, Sandton

South Africa

Tel: 27-11-259-2600

*Tel: 27-82-820-5845

*Fax: 27-11-259-2650

Spain

Bausch & Lomb S.A.

Avda. Valdelaparra 4

28108 Alcobendas (Madrid) Spain

Tel: 34-91-657-6300

Fax: 34-91-661-4266

*Tel: 34-902-381-010

*Fax: 34-902-250-310

Sweden

(Denmark, Finland, Norway and Sweden)

Bausch & Lomb Nordic AB

Söder Mälarstrand, 45

P.O. Box 15070

S-104 65 Stockholm, Sweden

Tel: 46-8-616-9500

Fax: 46-8-669-8623

*Tel: 46-8-616-9585

*Fax: 46-8-658-2541

Switzerland

Bausch & Lomb Swiss AG

Dammstrasse 19

6301 Zug, Swiss

Tel: 0848-228726

Taiwan

Bausch & Lomb Taiwan Ltd.

11th Floor, No. 102, Section 4
Civil Boulevard
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Taiwan, Republic of China
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Europe, Middle East & African Division
European Headquarters

Vietnam

c/o address is Singapore, see Singapore

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 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® PC Vision Enhancement System Warranty

Bausch & Lomb Incorporated warrants, for the benefit of the purchaser only, that the **Stellaris® PC** 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, in 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® PC** 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® PC** Vision Enhancement System has been altered, neglected, abused or misused, (e) the **Stellaris® PC** 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® PC** 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® PC* Vision Enhancement System.

BAUSCH + LOMB EXCLUDES AND DISCLAIMS ALL OTHER WARRANTIES OR REPRESENTATIONS RELATING TO THE *Stellaris® PC* 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® PC* 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® PC* Vision Enhancement System OR THIS WARRANTY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE OF THE *Stellaris® PC* 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 6 (six) 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.

Post-Warranty Information:

When warranty coverage expires, Bausch + Lomb is pleased to provide Service Agreements that provide the assurance customers are seeking in managing equipment performance and budgeted service expense. Contact your local Bausch + Lomb sales representative for additional details and current 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 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, safety of operation of any handpiece repaired or serviced by anyone other than the Bausch + Lomb service organization.

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.

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° to 40° Celsius (50° to 104° Fahrenheit) Ambient Storage/Transport Temperature: -20° to 60° Celsius (-4° to 140° Fahrenheit)
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
Shock/Vibration	Passes ISTA 3A and 3H
Air Input	Filtered medical grade air or medical grade nitrogen, at 72.5 (5 bar or 50 kPa) to 100 psig Max (6.9 bar or 690 kPa) and a flow rate of 2.25 SCFM (63.7 SLPM).

MMC (Optional) Specifications

Parameter	Specifications
Electrical Input	Detachable international power cord Universal Input (100-240 VAC, 50/60 Hz) 75 VA rating Fuse: Type GDC T1.0 A, 250V
Composite Video Cable	RCA, male/male, 6 feet
S-Video Cable	S-Video, male/male, 6 feet
FireWire Cable	IEEE-1394 6P/4P 30 ANG, 6 feet
Ethernet Cable	RJ-45, 350 MHz, 50 feet

Physical Specifications

Parameter	Specifications
Stellaris® PC 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 pounds (114 kg) Recommended Tray Capacity: 12 lbs (5.4 kg)

Standards Compliance

The **Stellaris® PC** Vision Enhancement System is designed to meet the requirements of IEC 60601-1:2005 3rd edition and all appropriate amendments, collateral standards, particular standards and country differences.

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

The **Stellaris® PC** Vision Enhancement System is a piece of medical equipment. As such, it requires special precautions regarding electromagnetic compatibility (EMC). It should be installed and put into service according to the EMC information provided in the tables below.

Portable and mobile RF communications equipment can potentially affect all electronic medical equipment, including the **Stellaris® PC** Vision Enhancement System. Guidance on maintaining appropriate separation between communications equipment and the **Stellaris® PC** Vision Enhancement System is provided in the tables below.

A complete line of accessories for the **Stellaris® PC** Vision Enhancement System and other surgical instruments is available from Bausch & Lomb. Contact your Bausch & Lomb sales representative or login to Storzeye.com and visit the online store for detailed information. 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.

As with all medical electronic equipment, the **Stellaris® PC** Vision Enhancement System should not be used adjacent to other equipment. If adjacent use is necessary, the **Stellaris® PC** Vision Enhancement System should be observed to verify normal operation in the configuration in which it will be used.

**Note:**

*The **Stellaris® PC** 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® PC** 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.

Table of Cables


Cable	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 Foot Control Backup Cable	144"
BL3270 Frag Handpiece	84"
S2050B Autoclavable Bipolar Cord	144"
CX9400 Bipolar Cord	144"
CX9430 Bipolar Cord with Lemo	144"
CX9404 Bipolar Cord	144"

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Cable	Length
BL4394 Foot Control Power Cable	144"

Guidance and Manufacturer's declaration – electromagnetic emissions		
The <i>Stellaris® PC</i> Vision Enhancement System is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 2	The <i>Stellaris® PC</i> Vision Enhancement System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The <i>Stellaris® PC</i> Vision Enhancement System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic Emissions IEC61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 611000-3-3	Complies	

Guidance and Manufacturer's declaration – electromagnetic immunity			
The Stellaris® PC Vision Enhancement System is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.			
Emissions test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% U_T (95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	5% U_T (95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Stellaris® PC Vision Enhancement System requires continued operation during power mains interruptions, it is recommended that the Stellaris® PC Vision Enhancement System be powered from an uninterruptible power supply or battery.
Note: U_T is the a.c. mains voltage prior to the application of the test level.			
Power frequency (50/60 hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's declaration – electromagnetic immunity			
The Stellaris® PC Vision Enhancement System is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Stellaris® PC Vision Enhancement System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	<p>Recommended Separation distance $d = \sqrt[1,2]{P}$ (Conducted) $d = \sqrt[1,2]{P}$ 80 Mhz to 800 MHz (Radiated) $d = \sqrt[2,3]{P}$ 800 Mhz to 2,5 GHz (Radiated) Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Note: At 80 MHz and 800 MHz, the higher frequency range applies.			
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Stellaris® PC Vision Enhancement System is used exceeds the applicable RF compliance level above, the Stellaris® PC Vision Enhancement System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Stellaris® PC Vision Enhancement System.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the *Stellaris® PC* Vision Enhancement System

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter – metres (m)		
	150 kHz to 80 MHz $d = \sqrt[1,2]{P}$	80 MHz to 800 MHz $d = \sqrt[1,2]{P}$	800 MHz to 2,5 GHz $d = \sqrt[1,2]{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Foot Control Specifications

Parameter	Specification
General	<p>External components and housing are corrosion resistant</p> <p>Watertight housing</p> <p>Wireless control (10 m standard range)</p> <p>Corded, low voltage connection to system</p> <p>Non-skid base</p> <p>4 gray-colored function switches</p> <p>Wall Charger</p> <p>3.6v battery (lithium)</p> <p>Battery charging cradle</p>
Physical	<p>12.22 cm, 4.8125 in.(H)</p> <p>27.6 cm, 10.875 in. (W)</p> <p>32.4 cm, 12.75 in. (L)</p> <p>Weight 2.7 kg, 6 lbs.</p>
Center pedal: Pitch	Linear on/off
Center pedal: Yaw	<p>Left On/Off (simulated)</p> <p>Right On/Off (simulated)</p> <p>Left Linear</p> <p>Right Linear</p>
Function switches	<p>Increase/decrease</p> <p>On/Off</p> <p>Function</p>
Center pedal: Pitch	<p>Motion: Pitch (up/down)</p> <p>Automatic return to up position</p> <p>Detent: (2) programmable as to position, may be enabled or disabled</p> <p>Control: Provides primary linear function or on/off</p>
Center Pedal: Yaw	<p>Motion: Yaw (Left/Right)</p> <p>Automatic return to center</p> <p>Detent: (1) center detent,</p> <p>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</p>
Function switches	<p>Motion: Momentary Push-button</p> <p>Control: Provides programmable increment/decrement or on/off control of assigned function</p>

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
	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	Future Use
Parameter increment/decrement	Future Use

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, 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		Linear Mode, Fixed Mode
Operating Parameters	Linear Mode	Output Range: 7.5 Watts 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 footpedal
	Fixed Control	Output Range: 7.5 Watts 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 footpedal

8 Specifications

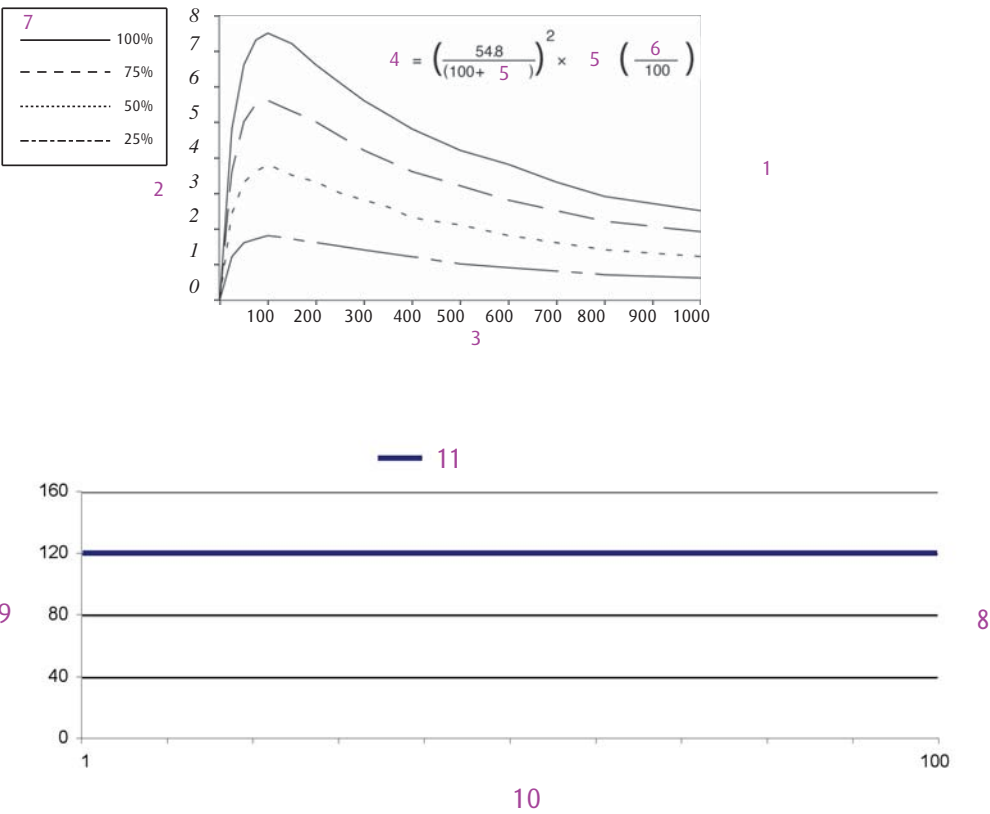


Figure 8.1.

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	Programming Levels 1,2,3: Continuous ultrasound Pulsed ultrasound Fixed pulse ultrasound Single burst ultrasound Multiple burst ultrasound Programming Level 3 only: 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 Wave for Ultrasound: Disabled/Enabled (throughout) Control: Linear power control via the footpedal Nominal phaco handpiece tip stroke at 100% power setting with DP8230 Microflow needle is 130 um at 28.5 kHz. This results in a nominal peak tip velocity of 11.6 m/sec.
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 Rise Time: 1 or 2
Single Burst Ultrasound Mode	Maximum Power: 35 Watts @ approx. 900 ohms Frequency: 28.5 kHz nominal Range: 80 to 600 msec. 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 to 600 msec Interval: 2 to 600 msec Control: Linear power control via the footpedal. Burst duration and interval as selected
Multiple Burst Ultrasound Mode	Maximum Power: 35 Watts @ approx. 900 ohms Frequency: 28.5 kHz nominal Range: 2 to 600 msec. 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 600 mmHg Phaco: 10 mmHg to 600 mmHg Vitrectomy: 0 mmHg to 600 mmHg Extrude: 0 mmHg to 600 mmHg Vacuum Control: 1 mmHg increments
Irrigation		Gravity feed from I/V bottle with pinch valve On/Off control via footpedal
Reflux	Control	Gravity feed from I/V bottle Modes: Continuous, Pulsed Activated via the Foot Control
Vitrectomy	Linear Cut Rate Mode Operating Parameters	Range: 30 to 5000 cuts per minute in 1 cut per minute increments Control: Linear control of cut rate via the footpedal
	Fixed Cut Rate Mode Operating Parameters	Range: 30 to 5000 cuts per minute in 1 cut per minute increments Cut rate is derated no more than 20% above 3000 feet (915 meters) altitude Control: On/Off control of cut via the footpedal
<p>The system will provide a minimum of 600 mmHg up to 3,000 feet (915 m) above sea level. A derating of 25 mmHg per 1000 ft. will be used for operation above 3,000 ft.</p> <p>The vacuum rise time, with an empty cassette, shall not increase more than 25% above 1.6 seconds per 1000 feet (305 m) of altitude up to 3000 feet (915 m).</p>		

Viscous Fluid Control Specifications

Parameter	Specification
Injection Mode	Pressure: 70 psi (482.6 kPa, 4.8 bar)
Extraction Mode	Vacuum: Between 5 to 600 mmHg in 10 mmHg increments

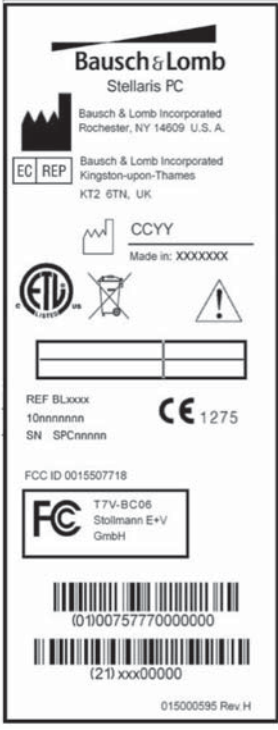
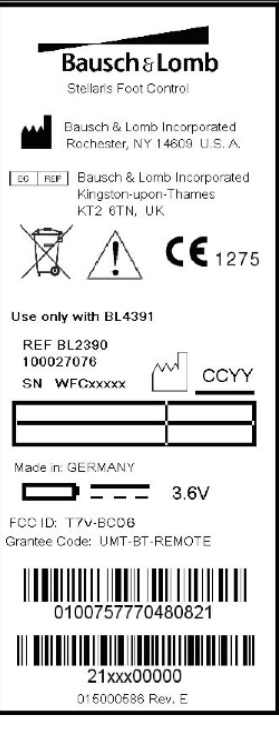
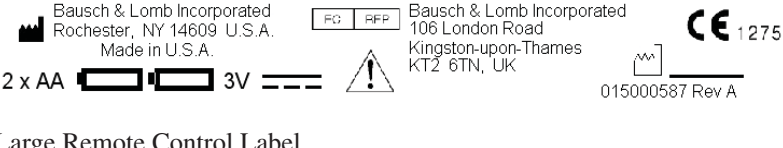

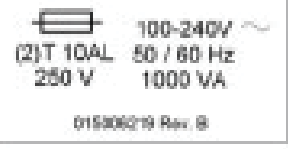

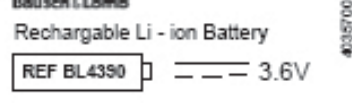
Fluid Air Exchange, Pressurized Infusion and Air Forced Infusion specifications

Parameter	Specification
Output	0.1 micron hydrophobic filtered air
Pressure	150 mmHg 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 20g 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)

8.3. System Labels

 <p>Bausch & Lomb Stellaris PC</p> <p>Bausch & Lomb Incorporated Rochester, NY 14609 U.S.A.</p> <p>EC REP Bausch & Lomb Incorporated Kingston-upon-Thames KT2 6TN, UK</p> <p>CCYY Made in: XXXXXXXX</p> <p>ETL</p> <p>REF BLxxxx 10nnnnnn SN SPCnnnnn</p> <p>CE 1275</p> <p>FCC ID 0015507718</p> <p>FC T7V-BC06 Stollmann E+V GmbH</p> <p>0100757770000000 (21) xxx00000</p> <p>015000595 Rev H</p>	 <p>Bausch & Lomb Stellaris Foot Control</p> <p>Bausch & Lomb Incorporated Rochester, NY 14609 U.S.A.</p> <p>EC REP Bausch & Lomb Incorporated Kingston-upon-Thames KT2 6TN, UK</p> <p>CE 1275</p> <p>Use only with BL4391</p> <p>REF BL2390 100027076 SN WFCxxxxx</p> <p>CCYY</p> <p>Made in: GERMANY</p> <p>3.6V</p> <p>FCC ID: T7V-BC06 Grantee Code: UMT-BT-REMOTE</p> <p>0100757770480821 21xxx00000</p> <p>015000586 Rev E</p>
Main System Label	Foot Control Label
 <p>Bausch & Lomb Incorporated Rochester, NY 14609 U.S.A. Made in U.S.A.</p> <p>EC REP Bausch & Lomb Incorporated 106 London Road Kingston-upon-Thames KT2 6TN, UK</p> <p>CE 1275</p> <p>2 x AA 3V</p> <p>015000587 Rev A</p>	
Large Remote Control Label	
 <p>REF: BL2111 SN REMxxxx 101028117</p> <p>010075777048xxxx 21 REMxxxx</p>	 <p>100-240V ~ (2)T 10AL 50 / 60 Hz 250 V 1000 VA</p> <p>015000676 Rev B</p>
Small Remote Control Label	System Power and Fuse Label
 <p>Bausch & Lomb (Rechargeable Li-Ion Battery)</p> <p>Bausch & Lomb Incorporated Rochester, NY 14609 USA</p> <p>EC REP Bausch & Lomb Incorporated Kingston-upon-Thames KT2 6TN UK</p> <p>REF BL4390 100027051 SN: SSSSS</p> <p>3.6V</p> <p>2250 mAh</p>	 <p>Bausch & Lomb Rechargeable Li - ion Battery</p> <p>REF BL4390 3.6V</p>
Foot Control Battery Label	Foot Control Battery Compartment Label



Xenon Lamp Label



Xenon-Mercury Lamp Label

Glossary

AFI

Air Forced Infusion. Refers to the use of pressurized air to create necessary pressure for infusion of fluid into the eye. The *Stellaris® PC* 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 foot control. Ultrasound power is fixed.

Case

Settings relating to instrument gauge, needle type, cataract hardness or pathology.

Detent

Tactile feedback in *Stellaris® PC* Vision Enhancement System foot control to alert user when foot pedal is moved from one region to another.

Domain

System functionality and set up that provides a group of functions related to either anterior, posterior or combined surgery.

Dual Linear

Foot control feature that controls various surgical function 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® PC* Vision Enhancement System, elevated infusion is defined as pressure above 60 mmHg for air infusion or above 81 cm H₂O for fluid infusion.

9 Glossary

End Case

Describes the conclusion of surgery. A touch screen button in the *Stellaris® PC* Vision Enhancement System graphical user interface would conclude a surgery and transition system to the End of Case screen.

Extrude

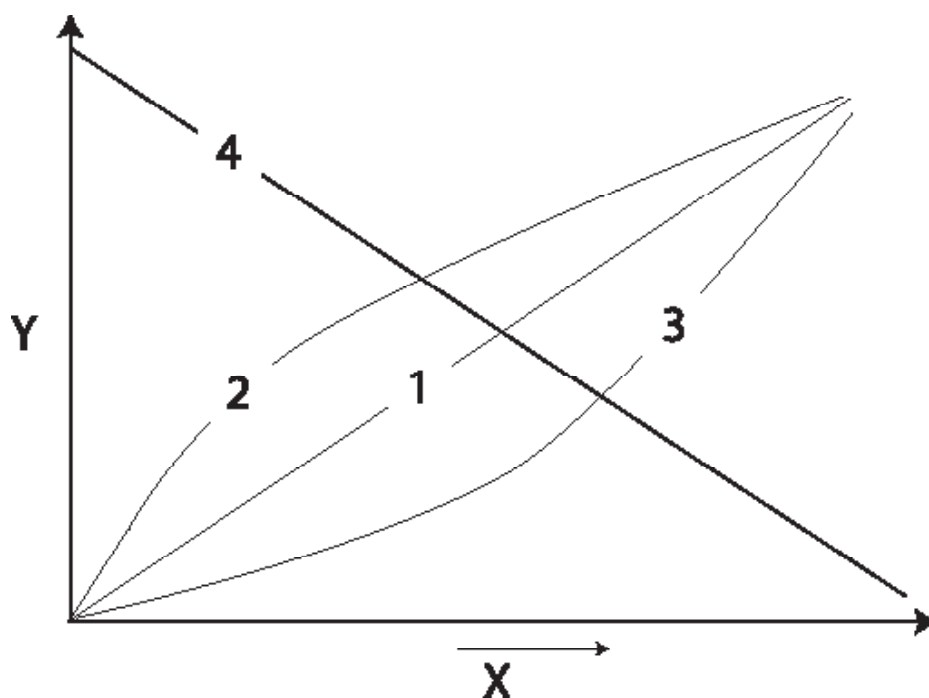
A surgical mode that aspirates fluid out of the eye. Selecting the Extrude mode activates vacuum from the left aspiration line to be used during the procedure.

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. 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*® *PC* 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.

MMC

Multi Media Center. MMC provides two video display functions. The first is video overlay where real time system settings are displayed simultaneously on the surgical screen and/or projected on external monitors or video recording devices. The second function of the MMC is to provide streaming video from the microscope camera to the system display screen.

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*® *PC* 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 Settings Screens

Secondary menu-driven graphical user interface screens that allow the user to adjust surgical settings. The More Settings Screens are hidden during normal operation and can be accessed from the main screens when needed.

9 Glossary

Patient Eye Level

The vertical distance from patient eye level to the aspiration ports of the *Stellaris® PC* Vision Enhancement System system. *Stellaris® PC* 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 *Stellaris® PC* 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 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. *Stellaris® PC* 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 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*® *PC* Vision Enhancement System system hierarchy. Typical Surgeon level settings are language, 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. *Stellaris*® *PC* 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.

TruLink®

Bausch & Lomb technology that provides the capability to interact with *Stellaris*® *PC* Vision Enhancement System installations remotely for diagnostic purposes.

Vacuum Response

Speed with which system generates commanded vacuum level. *Stellaris*® *PC* 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.

Volume

System audio feedback output level.

Waveform

Ultrasound modulation where power delivery is software controlled to simulate a sinusoidal wave pattern.

9 Glossary

Xenon lamp

A type of lamp used in the *Stellaris*® *PC* 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 *Stellaris*® *PC* 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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