Bausch & Lomb

Stellaris®

Vision Enhancement System

Operator's Manual

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℞ ONLY

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Indications for Use

The Bausch + Lomb ***Stellaris***® Vision Enhancement System is designed for use in anterior segment surgeries. It provides capabilities for phacoemulsification, irrigation/aspiration, bipolar coagulation, and vitrectomy 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***® 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***® Vision Enhancement System is covered by the following patents: 5,331,951; 5,370,602; 5,388,569; 5,406,503; 5,624,394; 5,795,328; 5,910,139; 5,964,746; 5,991,142; 6,045,527; 6,055,458; 6,077,272; 6,081,122; 6,083,195; 6,106,512; 6,203,516; 6,251,113; 7,168,930, 7,445,436 and 7,604,607; additional patents pending. Foreign and other patents may also apply.

Trademarks

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, and we don't want you to have to search to find 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***® 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 physician is ultimately responsible for determining the appropriate procedure for each patient.**

Note: *The user interface screens displayed in this manual copy may appear different than what is on your system depending on the 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.


Direct Current


Equipotential
Ground


Remote Control Reception Indicator
(Foot Control On/*TruLink*® Access)

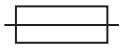

Dispose of Properly

Serial Number

Authorized Representative
in the European Community


Non Ionizing
Electromagnetic
Radiation

Frequency in Hertz


Fuse


Camera Recorder

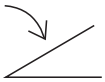

Ethernet

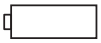

Monitor


Stellaris®
Vision Enhancement System.


USB


Alternating Current


Foot Control


Battery


Battery Condition Indicator


Manufacturer


Date of Manufacture


Caution: Consult
Accompanying Documents


Type BF Applied Part

Coagulation

Pneumatic Vitrectomy

Ultrasound

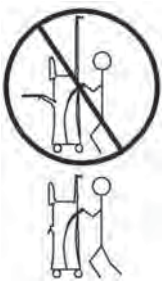
Ω Ohms
VA Volt Amps
A Amperes

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

No Latex

Member Green Dot Scheme

Do Not Use if Package is Damaged



System transport information, refer to page 1-12.

Caution: Consult Accompanying Documents

1. Getting Started

2. User Interface

3. Customizing Your System

4. Detailed Reference

5. Cleaning and Sterilization Requirements

6. Setup

7. Troubleshooting and Maintenance

8. Service and Warranty

9. Specifications

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.

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

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

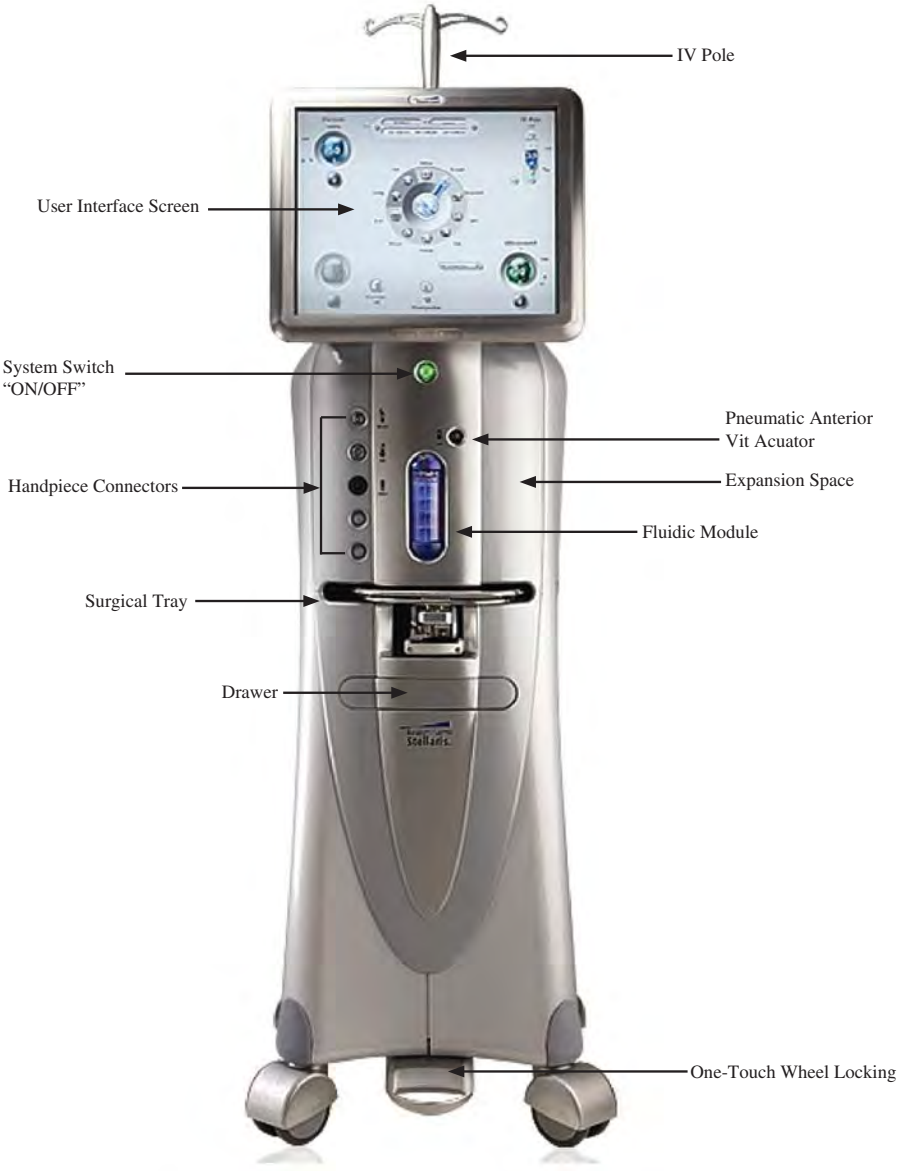
WARNING: ***Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade."***

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

1.1. System Description

The ***Stellaris***® Vision Enhancement System has a modular design which enables it to be 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, handpieces, and other accessories.

Note: *Do not use* ***StellarisPC*** Vision Enhancement System *posterior or combined packs on a Stellaris system.*



1.2. 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.***

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

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 and patient injury.***

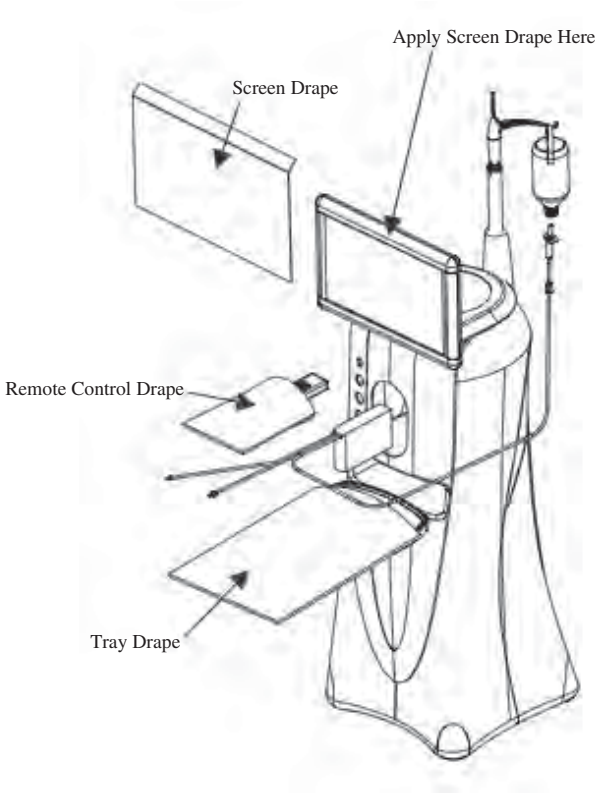
WARNING: ***When using gravity infusion, the ophthalmic irrigation source shall be at or above the patient's eye level to avoid patient injury.***

Before the first use of the ***Stellaris***® Vision Enhancement System, connect the Foot Control as described on page 6-3.

The following pages contain an overview for setup and use of your ***Stellaris***® 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.

Surgical Drape Setup

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



Turning System On

Plug the power supply cord into the wall.

If desired, connect the Ethernet cable to the port at the bottom of the ***Stellaris***® 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.

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

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

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

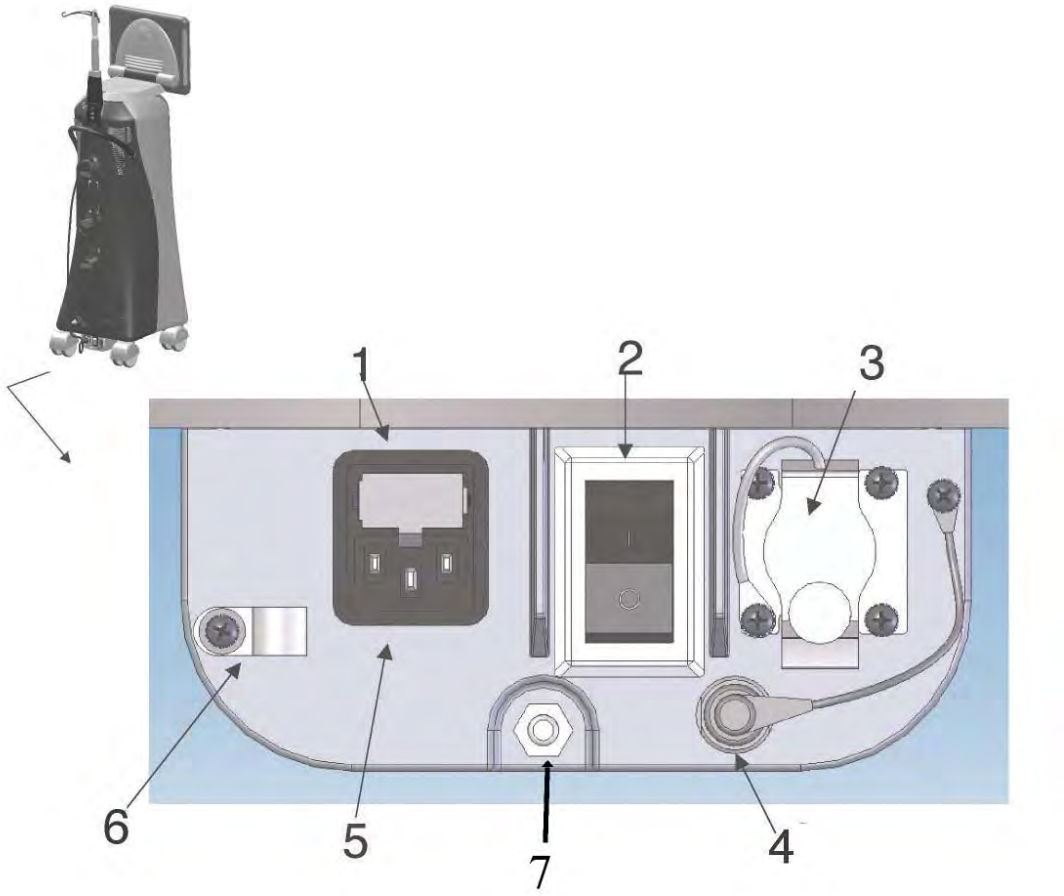


Figure 1.1. Lower Rear of System.

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.*

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***® Vision Enhancement System performs a self-check each time the power is turned on. The system automatically checks its configurations for any changes since the last time it was turned on.

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

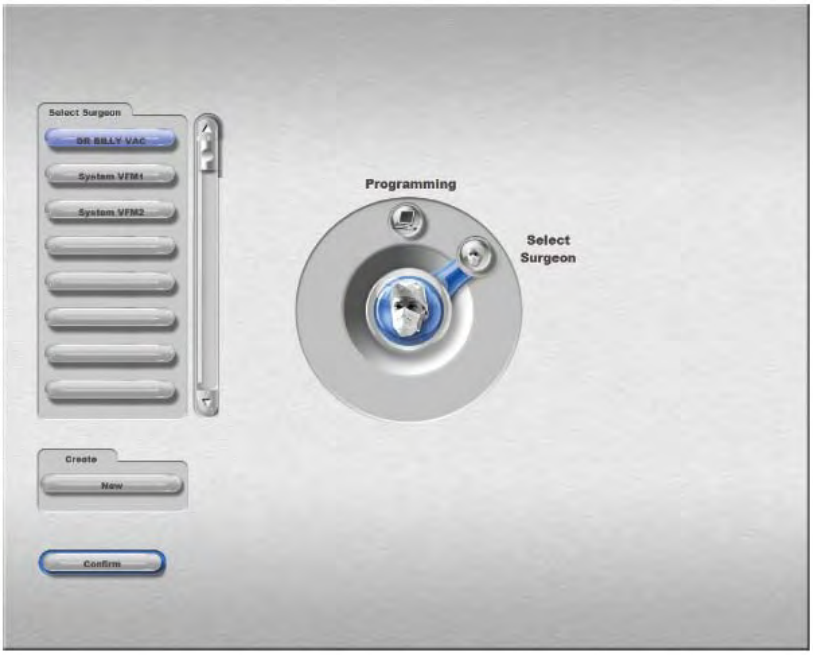
Only after the Foot Control has been synchronized to the specific ***Stellaris***® Vision Enhancement System (see page 6-3), may you use wireless communication.

Note: *The out-of-factory Wireless System Setup is "Disabled." Software upgrade will also reset the Wireless System Setup to "Disabled." See System Setup Instructions (Chapter 3) 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 **Select Surgeon** screen will appear.

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.*



Select Options

Touch the surgeon's name on the list that appears, and it will be highlighted. Then select **Confirm** to load the parameters for that surgeon and advance to the **Setup Screen**.

To setup a new surgeon instead of using an existing one, select **Create New** to setup a surgeon preference file for a new surgeon, using parameters from an existing surgeon.

Setup Screen

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

If desired, select **Select Room** 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** and choose the specific technique, needle, grade and pathology for the current procedure.

Advance to open pack step by selecting **Open Pack Insert Cassette** from the clock menu.

Uninterruptible Operation of Your System

Some Stellaris models may have a 60-second memory back-up battery. This battery is not considered a UPS (uninterruptible Power Supply) as it only sustains the software but is not sufficient to power surgical functions. If the user of the ***Stellaris***® Vision Enhancement System requires continued operation during power main interruptions, it is recommended that the ***Stellaris***® Vision Enhancement System be powered from an uninterruptible power supply.

All new Stellaris systems and Power modules manufactured after November 2009 will cease to have memory back-up battery function.

Note: *In the event the power source is interrupted causing the system to shut down, remove handpiece from the eye safely and pinch off irrigation clamp to stop fluid flowing into the cassette.*

To Start a New Procedure

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

The ***Stellaris***® 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.

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

1. **Setup Fluid Collection System**

   Open disposables pack and connect fluid collection system.

   - If using a vacuum system, 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 turn solid when the system captures the cassette.

     For surgical techniques that uses high vacuum settings please use vacuum-based packs containing the StableChamber® tubing to increase holdability (higher vacuum levels) while maintaining followability (controlled flow).

   - If using a flow system, insert the Fluidics Cartridge and select **Close Drawer**.

   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.

2. **Connect the accessories to the system for either an ultrasound or vitrectomy procedure.**

   The steps needed to setup for a surgical procedure are Spike Bottle, Connect Tubing, Plug-in Handpiece, Attach Needle, Attach Sleeve, and Fill Test Chamber, as detailed below.

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

a. Spike the Balanced Salt Solution bottle and hang it at the desired bottle height.

   Additional step if pressurized infusion is used: Connect the Air Tubing Line (D4600A) to the vent port at the bottle spike and the other end with air filter to the ***Stellaris®*** *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.*

b. Connect the irrigation and aspiration tubing to the appropriate (phaco or vitrectomy) handpiece, and plug the handpiece into the ***Stellaris®*** Vision Enhancement System. The connector will flash until the handpiece is connected, and then will remain solidly lit.

c. Attach the ultrasound handpiece needle.

d. Attach the irrigation sleeve.

e. Fill beaker and test chamber and attach the test chamber to the handpiece. The irrigation pinch valve shall be opened when this step is displayed.

For detailed instructions, select **Show Me Steps Ultrasound** or **Show Me Steps Vitrectomy** 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.***

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.***

When the fluidics collection device has been attached and all accessories, tubing and handpieces have been connected, the system will automatically advance to the **Prime and Tune** phase. This step will be highlighted on the clock menu.

- If you are performing an ultrasound procedure, select **Prime and Tune** from the menu on the left side of the screen.
- If you are performing a vitrectomy procedure, select **Prime** from the menu on the left side of the screen.

The selected action will begin, and the progress bar at the bottom of the screen will show when it is completed. If the system does not pass, the system status screen will suggest corrective action.

Once the system setup has completed successfully, the system 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 and phaco functions will be unavailable.*

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 **More Screens** (see page 2-6).

Your system is now ready for the surgical procedure.

For irrigation/aspiration procedures, select **I/A** and connect the I/A handpiece to the tube set, replacing the phaco handpiece.

Surgical Procedure Conclusion

Select **End** from the clock menu. You must confirm that you are ready to end the case and eject the fluid collection device, and you will be reminded to close the pinch valves.

Note: *Make sure to close the Irrigation Clamp on the Administration Tube Set before ending a procedure or overflow may occur.*

The system will then advance to the **End of Case** screen, lower the IV Pole, and eject the vacuum fluidics cassette or open the flow module drawer.

Remove the fluidics collection device.

Remove all disposables from the system. For assistance, 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** or press the button on the front of the system to completely power down the system.

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

If you have the *TruLink*® option enabled and have selected **Shut Down System** you will be asked to confirm the system shutdown. The system will then ask if you want to upload system data to the Enterprise Server. Ensure the Ethernet cable from the port at the bottom of the ***Stellaris***® Vision Enhancement System to the hospital network port is connected before attempting to upload data. The system will send diagnostic data (no patient data is transferred), then shut down when complete.

At the end of the surgical day, make sure to recharge the Foot Control, as described on page 2-27.

1.3. Moving Your System to Another Location

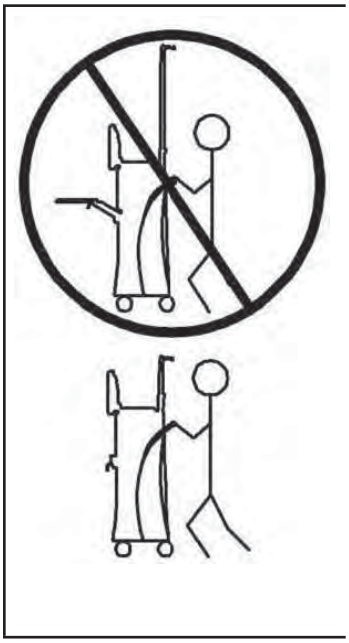
WARNING: ***Do not transport or move your system from room to room or up an inclination unless you have followed the steps below.***

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:

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



1. Power down normally by selecting “Shut Down” from the end of case screen or pressing and holding the front button for at least 8 seconds, ensuring the IV pole is fully retracted.
2. Remove any objects from mat on top of unit.
3. Store the tray all the way in the unit’s tray receptacle.
4. Fully close the front drawer.
5. Roll the power cord in its proper hooks at the rear end of the unit.
6. Place the Foot Control on its dedicated hook, at the rear end of unit.
7. Remove the bottles and tube sets from the unit’s pole hanger and store separately from the unit.
8. Make sure no objects such as air hose, electrical cord, video cables, etc... lie in the moving path.
9. Disengage the front brake lever.
10. Always maneuver the unit using the handle bar designed for this purpose.

Your system is now ready to be moved to a new location.

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

1.4. System Components

The ***Stellaris***® Vision Enhancement System has a modular design which enables it to be 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, handpieces, and other accessories.

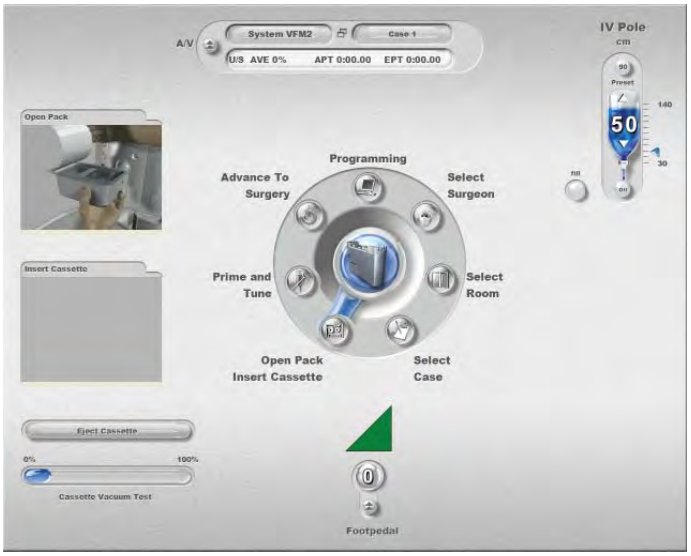
WARNING: ***Use only handpieces, cables, and accessories designated by Bausch + Lomb for use with this system.***

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.***

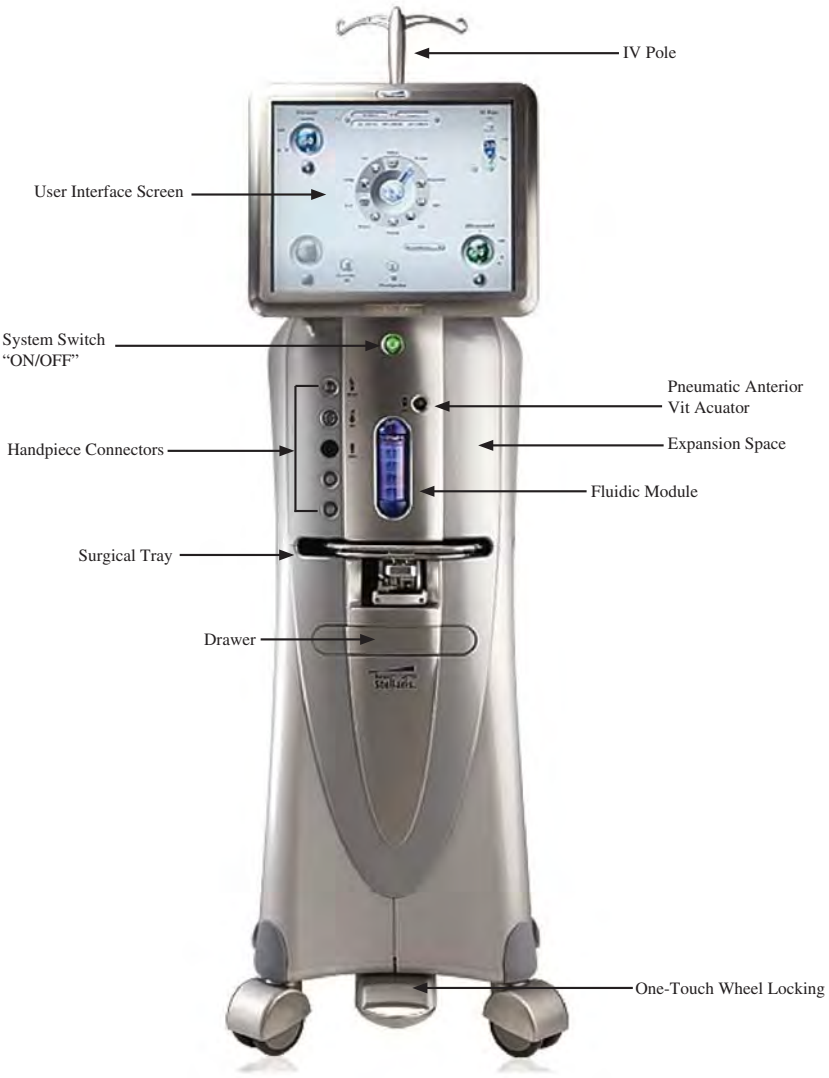
WARNING: ***Manufacturers of implantable defibrillators recommend that these devices be temporarily disabled when using bipolar cautery on patients with implants. The surgeon should determine if the patient has such a device and consult the manufacturer for appropriate actions.***

User Interface Screen

The User Interface Screen is the way the user communicates with the Vision Enhancement System. See page 2-1 for details. Technical specifications can be found in Chapter 9.

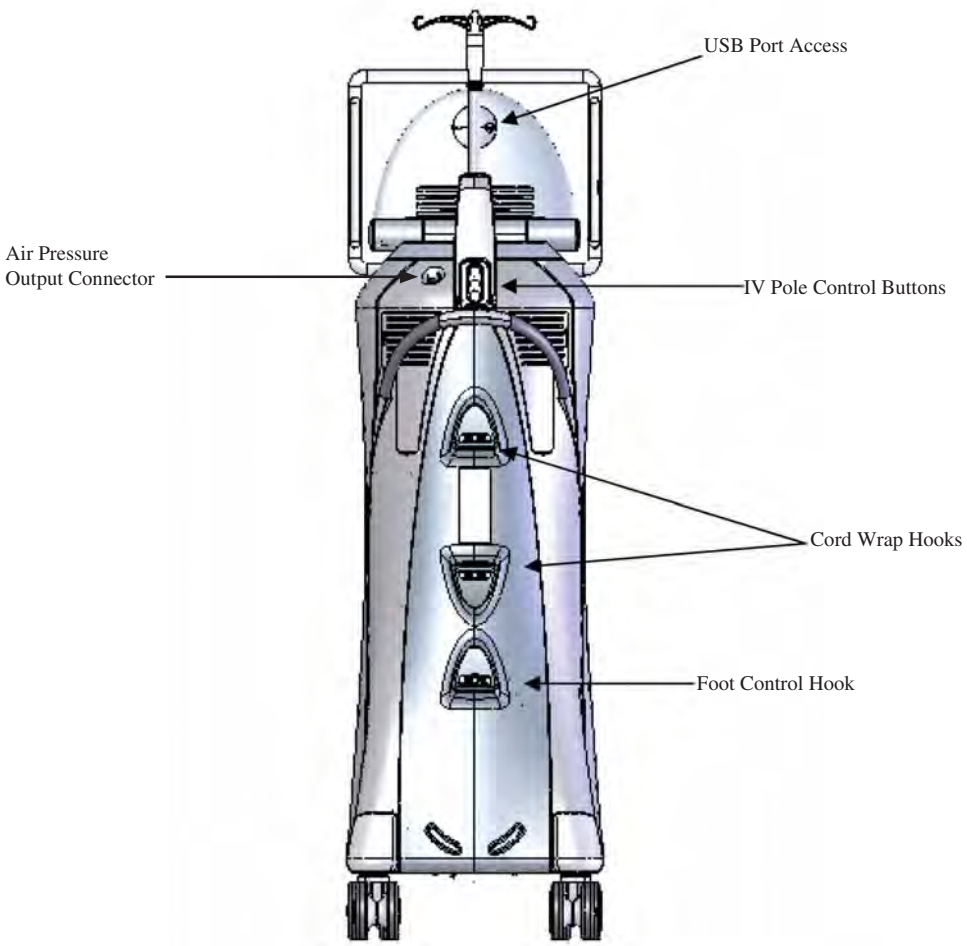


Stellaris® Vision Enhancement System Console



This is the main unit (see page 4-2), which contains the connections for all handpieces, tray, drawer, Ethernet connector and system housing. On the rear of the main unit, 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.

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



Ultrasound Module

This module contains five ports for connecting system accessories. The top three ports are active and the bottom two are reserved for future use.

Ultrasound Function (Phacoemulsification)

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 is for ultrasound handpieces. These support phacoemulsification procedures in continuous, pulsed, and burst modes.

Coagulation

The third port is for a coagulation handpiece which provides coagulation power in either Fixed or Linear modes. See page 4-27 for details of use and page 9-12 for technical specifications.

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. Specifications are in Chapter 9. See page 2-18 for detailed instructions for its use.

Fluidics Function

Each ***Stellaris***® Vision Enhancement System has one fluidics module, either an Advanced Flow or Advanced Vacuum system. Each fluidics module contains a port for a standard pneumatic vitrectomy cutter.

Advanced Flow Function

This function uses a peristaltic-based pump to provide flow from 1 ml/min to 60 ml/min, and vacuum levels from 0 to 650 mmHg. The corresponding pack has both irrigation and aspiration tubing and a 500 ml fluid collection bag which fits in a drawer on the front of the ***Stellaris***® Vision Enhancement System. Irrigation on/off control is provided by an internal pinch valve. Pneumatic vitrectomy supports both a Linear Cut Rate and a Fixed Cut Rate from 30 to 800 cpm. See page 4-12 for details and Chapter 9 for technical specifications.

Advanced Vacuum 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 irrigation and aspiration tubing. Pneumatic vitrectomy supports both a Linear Cut Rate and a Fixed Cut Rate from 30 to 800 cpm. See page 4-7 for details and Chapter 9 for technical specifications.

Air Compressor

The compressor module provides vacuum for aspiration in Advanced Vacuum systems, air pressure for pressurized infusion and air pressure to drive various pinch valves. See Chapter 9 for technical specifications.

Remote Control

The remote control allows control of various surgical functions from a distance. The receiver for the IR signal is at the bottom of the computer screen. See page 4-6 for details of operation and Chapter 9 for technical specifications.

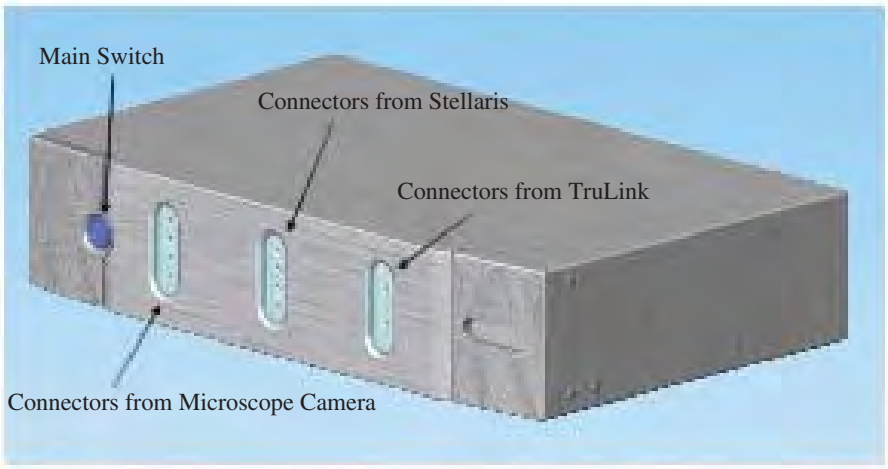
TruLink® Remote Access (optional)

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®*** 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®*** 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®*** Vision Enhancement System. Upon shutdown, from the “End of Surgery” screen, the system will prompt you if you would like to “Send data to TruLink”, if in agreement, please make sure that the Ethernet cable is connected to the designated port of location and follow instructions. After updating, the system will shut down automatically.

Multimedia Center (MMC) (optional)

The MMC is an optional accessory that 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.



Data is transferred between the MMC and the ***Stellaris***® 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 ***Stellaris***® Vision Enhancement System. Whenever the MMC is on and connected and the ***Stellaris***® Vision Enhancement System is in surgical mode, the 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® Remote Access can be activated by connecting the Ethernet port on the MMC to a designated Internet-enabled network connection and enabling the *Trulink* data download upon shutdown or Remote Access (if available in your area) function on the ***Stellaris***® Vision Enhancement System.

Note: *Off-the-shelf Ethernet cable may be used with the **Stellaris**® 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 Balanced Salt Solution bottle or other containers of fluid on top of the Multimedia Center.
- AC power source for the Multimedia Center must have a Ground Fault Interrupt.

User Interface

This chapter introduces you to the operating controls, displays and terminology used in the ***Stellaris***® Vision Enhancement System.

2.1. 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.

Push Bar

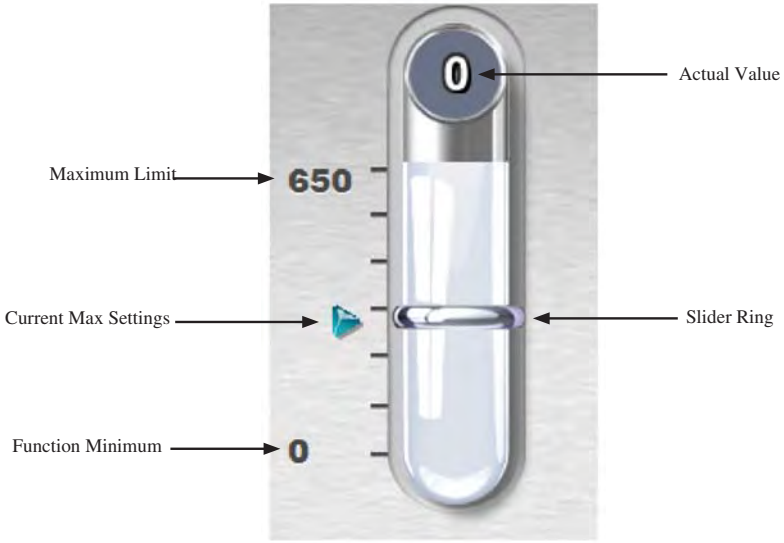
This is a single button control which displays a command, and initiates that action when you select it. No value is associated with this control and holding it down performs no additional function.

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.

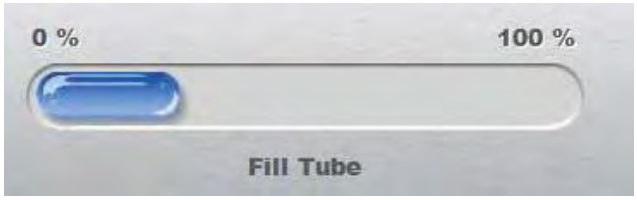
Test Tube Display and Control

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 Screen.**



Progress Bar

This graphic shows the progress of a procedure.



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.

Keyboard

Sometimes you will need to enter alphabetical or numeric data into the ***Stellaris®*** Vision Enhancement System. A keyboard similar to that shown below will appear, and you can touch the characters in order to enter them. Selecting the back arrow will delete the last character typed, and selecting **Clear** will delete all characters. Select **Enter** when you are done to save the entry and return to the previous screen or it will advance to next level of programming screen.

Character Lengths

There is a finite number of characters that can be used for certain functions. Refer to the table below:

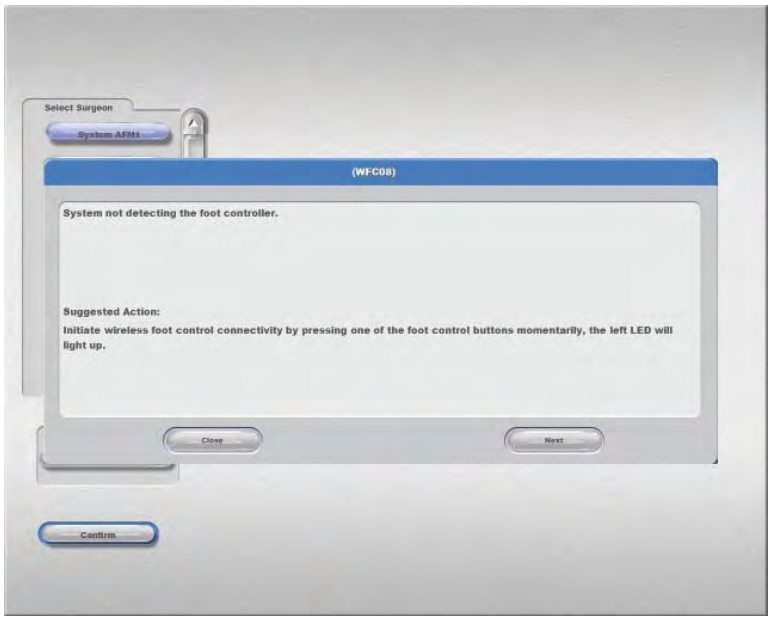
Function	Maximum Characters
Mode	8
Technique	20
Submode	20
Pathology	20
Surgeon	30

Display Format

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

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.*



* 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.

2.2. Surgical “More Screens”

More Screens allow easy access to all system parameters. The exact **More Screen** options available will depend on the current state of the system, current programming level, and other system settings. Select the **More Screen Button** (shown below) associated with an on screen surgical function to open the corresponding **More Screen**.

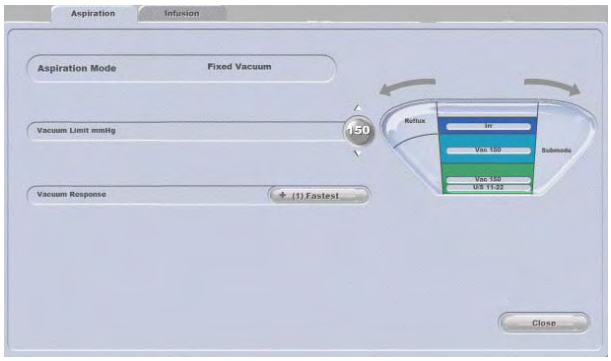
More Screens are available for the Fluidics (Aspiration and Infusion), Ultrasound, Coagulation, Vitrectomy, Footpedal, and Audio/Visual functions, and Case Selection options.

Note: ***More Screens*** *for the Fluidics, Ultrasound, Coagulation, and Vitrectomy functions are only available at Display Level 2.*

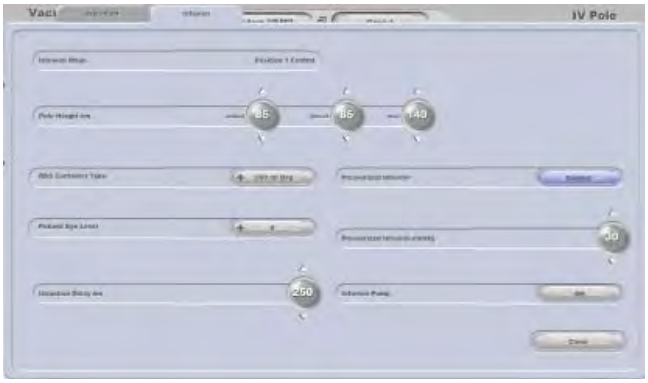
Fluidics (Flow and Vacuum) More Screen

The **Fluidics More Screen** has two tabs, one for Aspiration settings and one for Infusion settings. Select either tab at the top of the **Fluidics More Screen** to see options specific to the fluidics system installed on your system. The specific options available will depend on what accessories you have on your system, the current programming level, and other system settings.

The **Aspiration Tab** can show the current mode, vacuum settings, flow settings, vacuum response setting, venting method, and **Foot Control Mapping**.



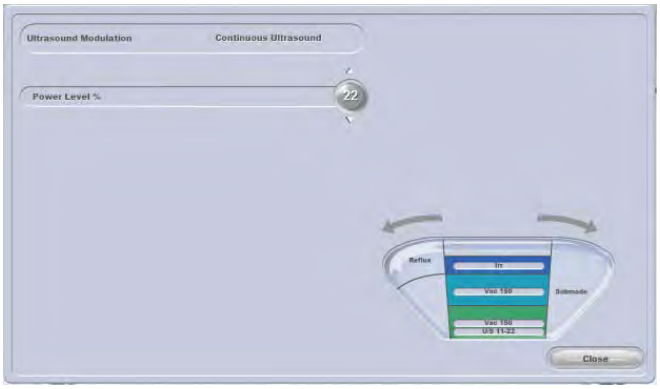
The **Infusion Tab** can show the current Infusion mode, IV Pole Height (actual, preset and maximum), Balanced Salt Solution Container Type, Patient Eye Level, Irrigation Delay and Pressurized Infusion (enabled/disabled, pressure settings, pump on/off status).

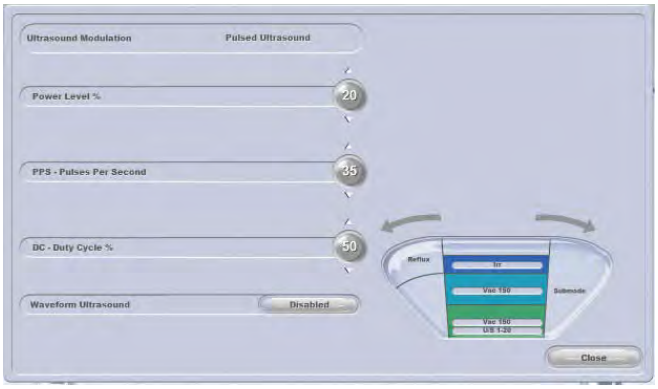


The actual IV Pole height is the current distance between the aspiration port and the mid-point of the viewing port of the Balanced Salt Solution drip chamber. The maximum IV Pole height is the highest setting the IV Pole will be allowed to reach, usually determined by the ceiling height and set at time of system installation. A zero level bottle hanger (BL4363) is an optional accessory that allows the Balanced Salt Solution drip chamber to be level with the aspiration port.

Ultrasound More Settings

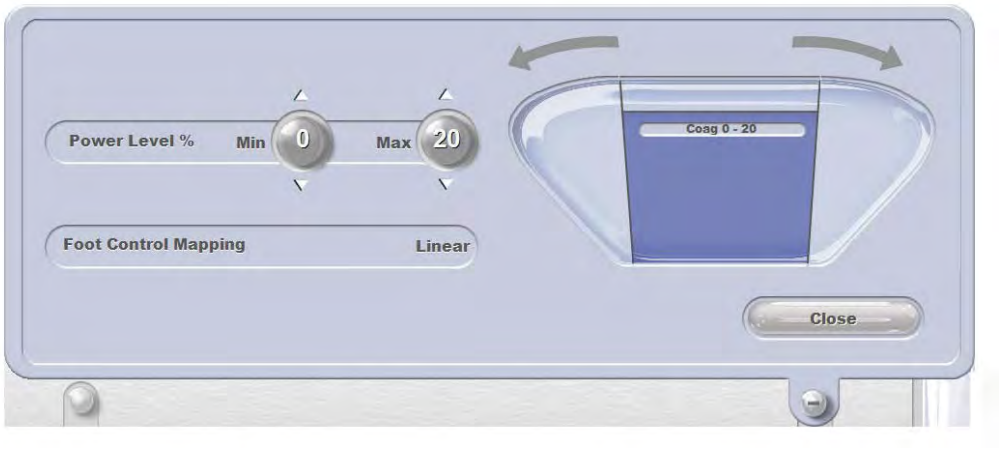
The **Ultrasound More Screen** shows the current modulation status and power level. Depending on which type of ultrasound and programming level you are currently using, you may also see number of pulses per second (PPS), duty cycle (DC), burst duration (BD), and pulse interval (PI), waveform type, waveform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





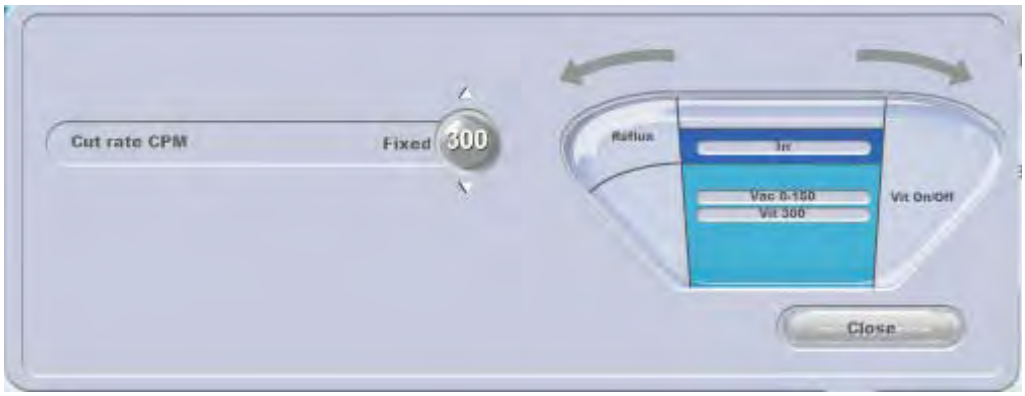
Coagulation More Settings

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



Vitrectomy More Settings

The **Vitrectomy More Screen** shows the current settings for the minimum and maximum CPM (cuts per minute). You can adjust either setting. The current **Foot Control Mapping** is also shown.

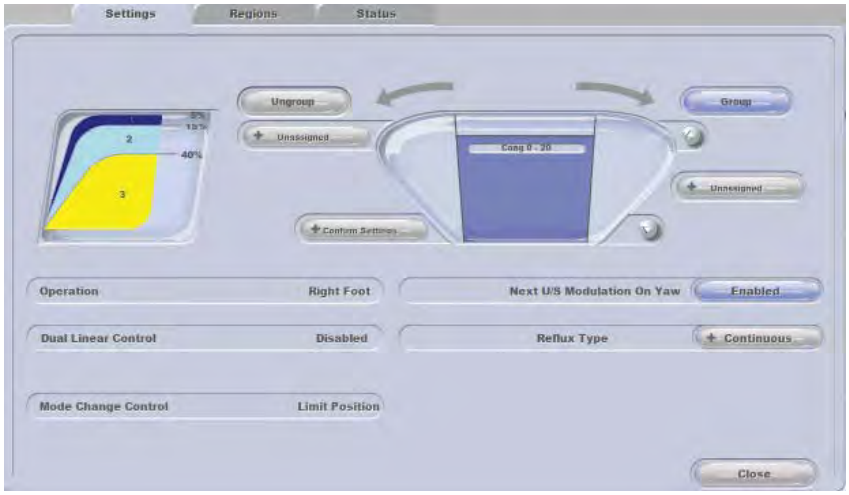


Note: *Foot Control mapping available on Programming Level 2 and 3 only.*

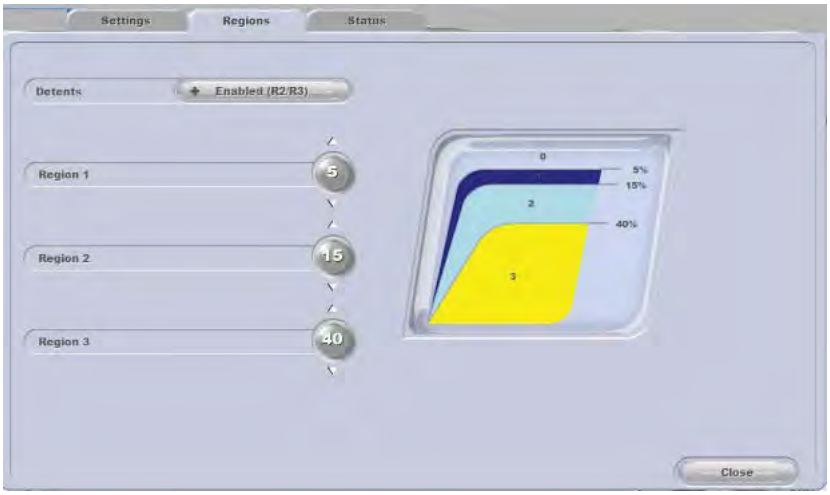
Footpedal More Settings

The **Footpedal More 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 2-18).

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 marked with "+".



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.

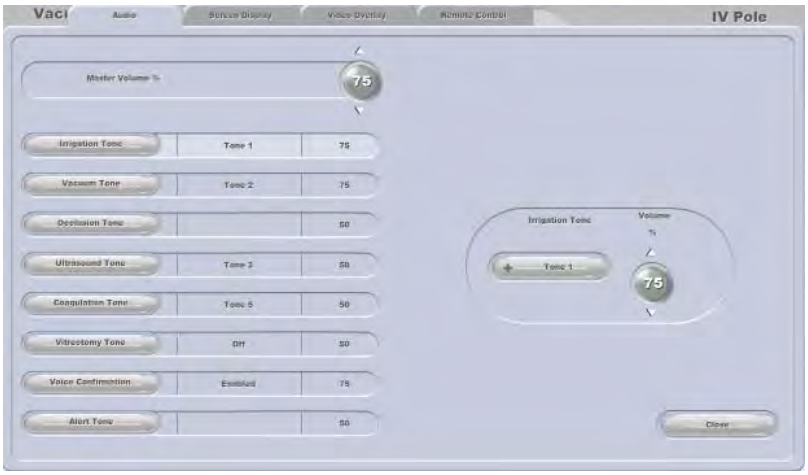


The **Status Tab** shows the current status of several footpedal options, including communication status, battery status, and signal strength.

A/V More Screen

The **A/V More 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.



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 **Screen Display Tab** control allows you to adjust the screen brightness, change the display format level, select the system language, and view the programming level.

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%.

The **Remote Control Tab** of the **A/V More Screen** allows you to enable or disable the remote control.

Case More Settings

The **Case More Screen** shows the case number, total number of rooms in which the ***Stellaris®*** 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.

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.*

2.3. 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.

Note: ***More Screens*** *for the Fluidics, Ultrasound, Coagulation, and Vitrectomy functions are only available at Display Level 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, Electric Vit, 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. You can select the edge of the video to display an animation showing the effect of the handpiece on the eye for the current surgical phase.

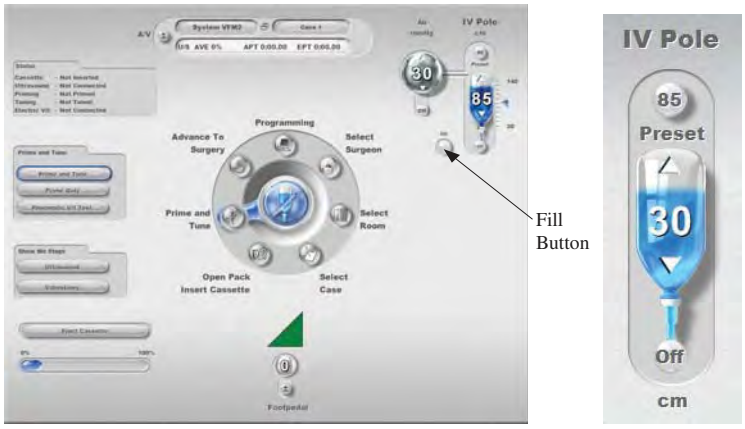
See Chapter 3 for details on customizing your system.

IV Pole

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 **Fluidics More Screen** (see page 2-7) 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.



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. The button shows the current state of the fill system (On or Off). You can select it to toggle to the other state.

Air Pressure

If 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.

Flow

The lower left corner of the screen shows the maximum flow setting, if enabled, with the current actual flow value below it. The volume of fluid in the collection device is also displayed here.

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, and the circles around the top indicate yaw position. The **Footpedal More Button** brings up a **More Screen** that allows you to change settings on the footpedal. See page 2-10 for details on changing these settings. See note on page 2-33.

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** (see page 2-4) 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.

2.4. Foot Control

The Foot Control is the main interface between the surgeon and the ***Stellaris***® 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 Cables** are 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.

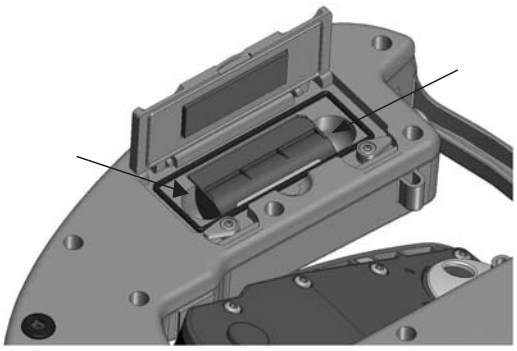
Placement of Foot Control During Storage

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

The battery needs to be charged overnight prior to initial wireless use, and if the system is idle for more than seven days, refer to the battery charging options section on page 2-27.

Foot Control Battery Installation Guide:

1. Place Foot Control upside down on a flat, dry surface.
2. Open 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 battery with two fingers holding on to the battery.
4. Before installing the replacement battery, check battery electrical contacts to ensure they are clean and free of contamination.
5. Install new battery.
6. Press the door toward the compartment and engage door latches to securely close battery door.



Battery compartment with recess (arrows) to facilitate battery replacement

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

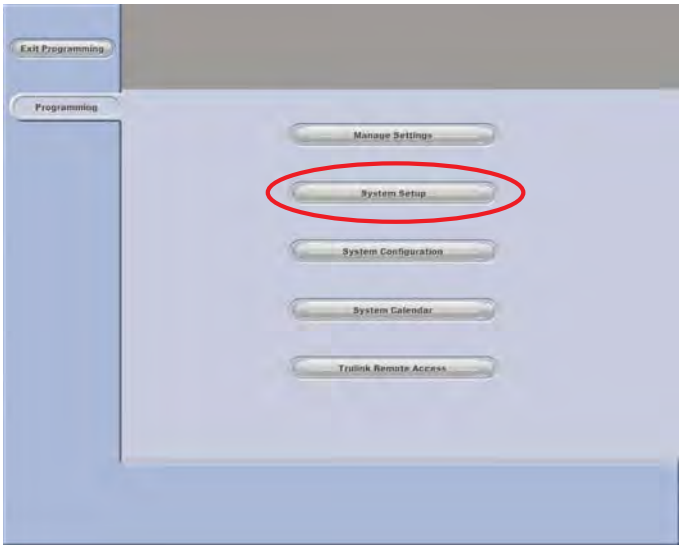
Note: *A battery must be installed in the Foot Control at all times, while operating either wired or wireless, to insure proper operation.*

LED Symbol for Battery on Foot Control

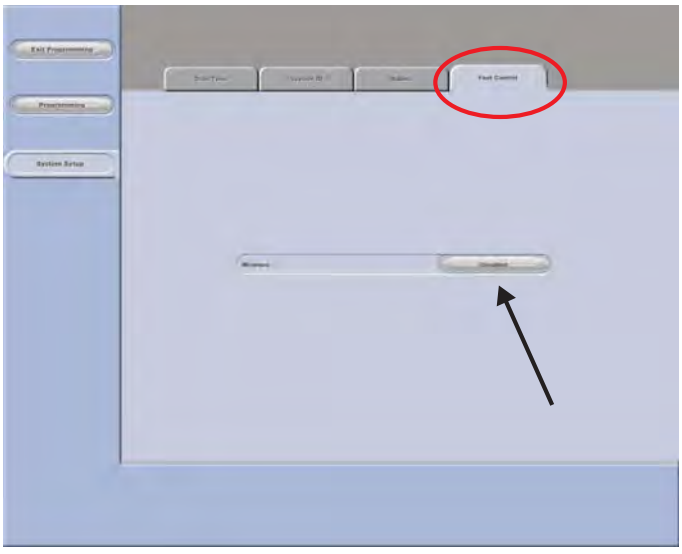
Note: *The out-of-factory Wireless System Setup is "Disabled." Software upgrade will also reset the Wireless System Setup to "Disabled."*

To setup wireless operation, follow steps below:

1. Select "Programming" from Setup or "Select Surgeon" screens.
2. Select "System Setup" from the Programming screen (screen image below).



3. Select "Foot Control" tab from the "System Setup" screen (screen image below).



4. Select Wireless "Enabled" or "Disabled" to configure Foot Control connection mode.

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: *System will disable wireless operation once it detects loss of wireless communication at setup and surgery screens. Once wireless connectivity is lost, the wireless opperation must be manually reconfigured using the system setup screens.*

Note: *The system will disable wireless operation when the battery is replaced or removed while system is in surgical or setup screens. To configure system to wireless operation, see section on Wireless Foot Control System Setup, page 2-20.*

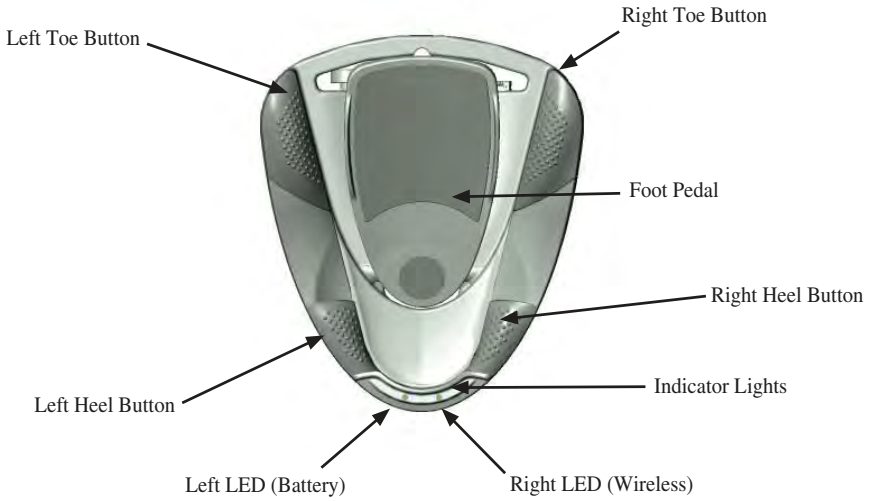
The first time a Foot Control is used, it must be connected via the back up cable to set the configuration. Once this is set, the Foot Control will only communicate wirelessly with that specific system. To begin wireless operation, make sure the ***Stellaris***® Vision Enhancement System is on, then press any **Foot Control Button** and wait up to ten seconds for communication to be established.

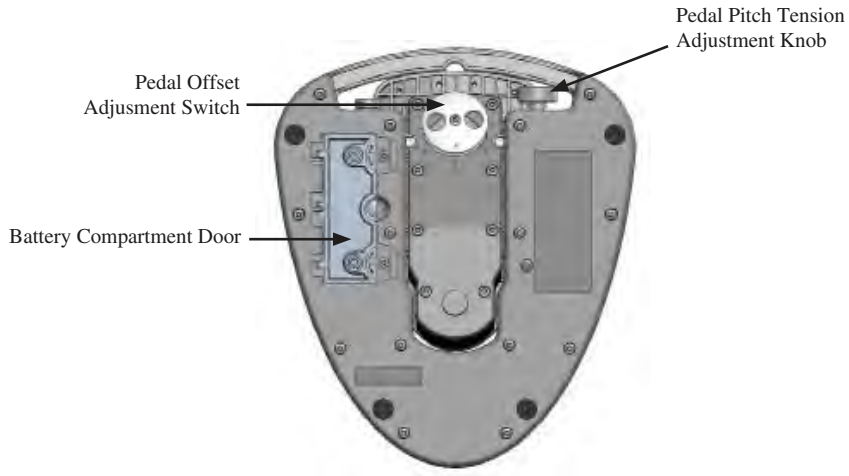
The ready light, identified by the symbol below, will turn solid green when the Foot Control is communicating wirelessly with the ***Stellaris***® Vision Enhancement System. During operation when system is not detecting Foot Control wireless connection; the system will disable wireless operation. This 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***® Vision Enhancement System.

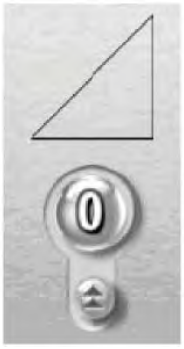
In some operating configurations the surgeon can change surgical phases using the Foot Control.

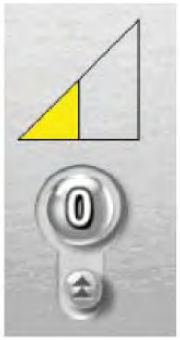




Foot Control Status and Wireless Signal Strength Meter Display

The status of Foot Control operation is represented by an 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 (Wireless disabled)	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
	Wireless	System detecting Low signal strength	No action required

Display Type	Foot Control Setup	Status	Action
	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 2-20.

Note: *The system will disable wireless operation when the battery is replaced or removed while system is in surgical or setup screens. To configure system to wireless operation, see section on Wireless Foot Control System Setup, page 2-20.*

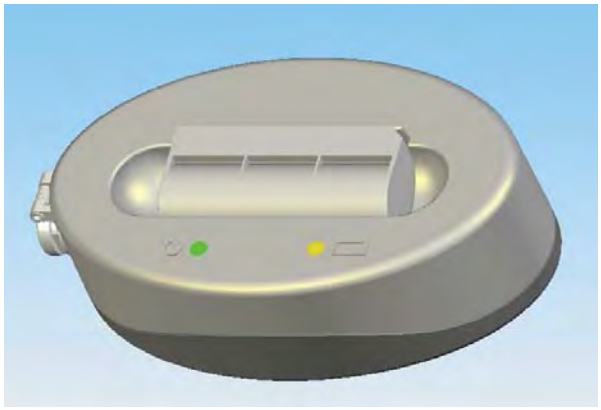
Note: *Irrigation will be turned ON and other functions will be disabled when the system does not detect Foot Control connectivity in surgical mode. Irrigation can be turned OFF from the touch screen.*

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 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.

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 shown below) while the other battery is being used.



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's 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®*** *Vision Enhancement System.*

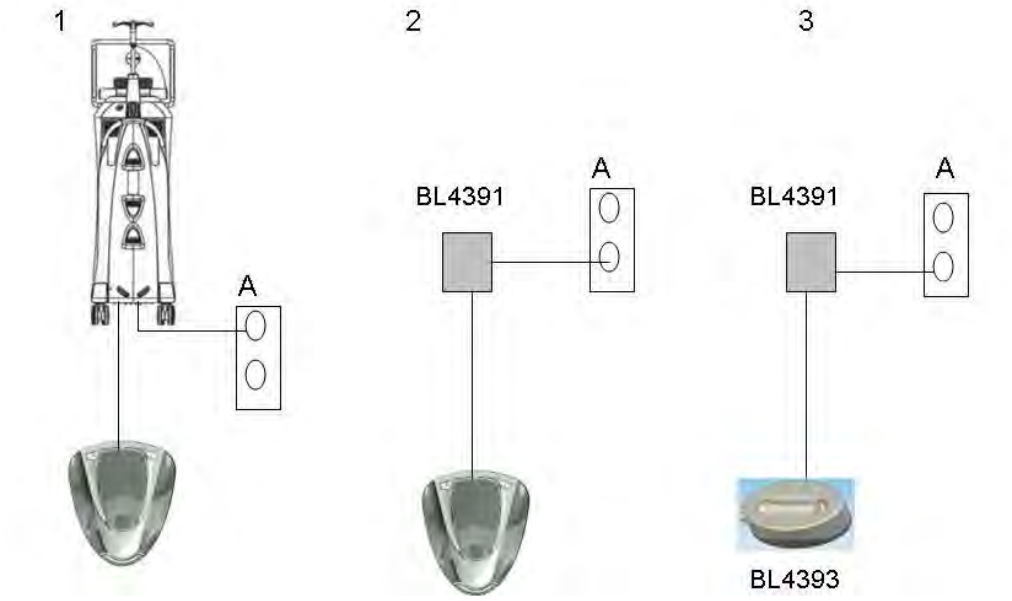
The **Foot Control Battery** should be charged whenever the system is not in use. Any one of three methods can be used to charge the battery.

- 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.
- 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.
- 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.

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 backup cable or wall charger to Foot Control, align red dot of the connectors to 12 o'clock position.*

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



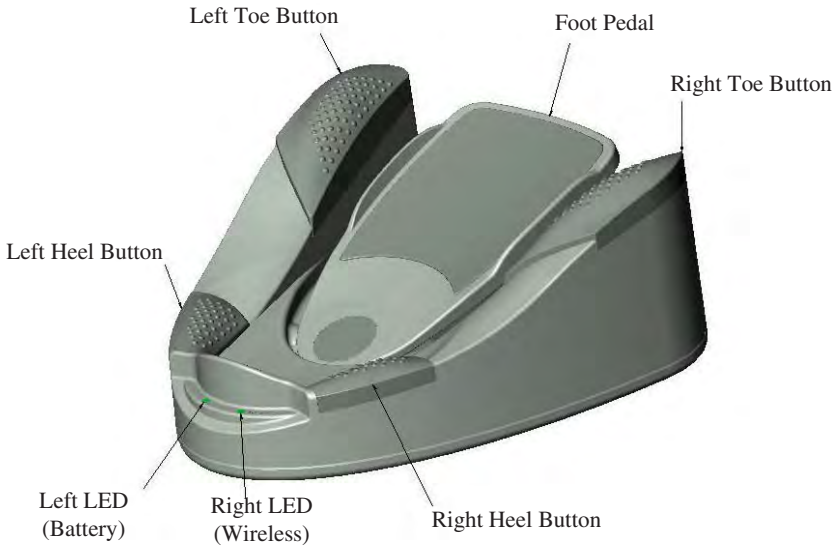
Note: *The battery charging cradle **MUST** be connected to the wall charger to charge the battery.*

The wireless communication is disabled when the backup cable is in place.

The ***Stellaris***® Vision Enhancement System will provide a warning message when the battery is nearing the end of its life. Call your customer service representative to get a replacement battery. See Chapter 8 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 2-33 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 2-34 shows the possible combinations of linear control.



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
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 **Footpedal More Screen** (see page 2-10).

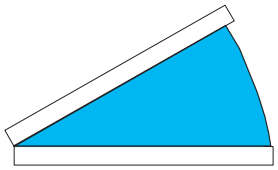
The **Footpedal More Screen** is used to convey the current footpedal configuration and status to the surgical team. It is displayed by selecting the **Footpedal More Button**, which is the below the Footpedal status icon on the bottom of the **Main Surgical Screen**.

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 2-33. When released, the footpedal will return to the home (up or center) position. The table on page 2-34 shows the possible combinations of control available. The programmable detents provide tactile feedback to the pitch movement when it moves between different regions.

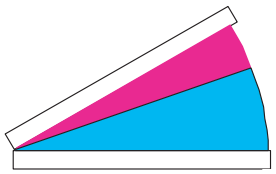
Single Region Pitch Control (one detent position)

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). An example of single region pitch control is the linear coagulation function.



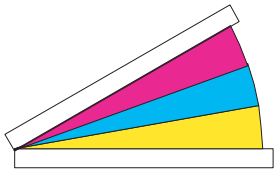
Two Region Pitch Control

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.



Three Region Pitch Control

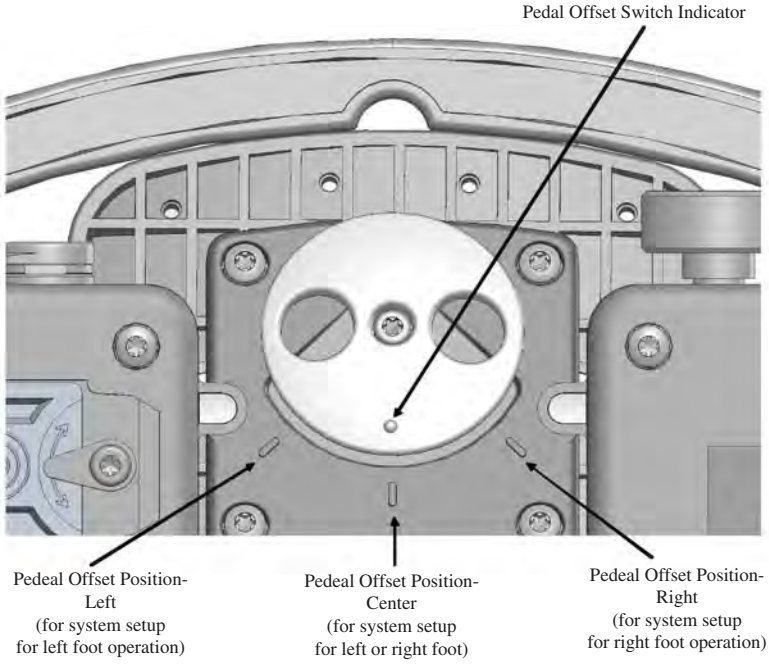
There are three programmable regions (three detent positions). When programmed for linear control, pitch movement is a function of relative footpedal displacement as shown below. An example is single linear ultrasound phases, where Region 1 is irrigation, Region 2 is fixed aspiration, and Region 3 is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



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 home position in the center giving approximately 10° of motion in both directions.
- **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. E.g.: If 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 diagram below.**



Single Linear Setup

In **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 for Anterior Modes

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, vacuum limit, or flow	
		R3	Fixed aspiration & linear ultrasound	
	Aspiration on yaw**	R1	Irrigation	
		R2	Minimum aspiration	Linear aspiration
		R3	Linear ultrasound	
	Aspiration on yaw & aspiration control feature on**	R1	Irrigation	
		R2	Aspiration R2 minimum to fixed vacuum, vacuum limit, or flow	To max. aspiration
		R3	Min. aspiration and linear ultrasound	
	Aspiration on Pitch**	R1	Irrigation	
		R2	Linear aspiration	Linear ultrasound
	Dual Linear Ultrasound***	R1	Irrigation	
		R2	Fixed Aspiration	
		R3	Linear U/S Function	Linear Ultrasound
Irrigation/ aspiration	Disabled	R1	Irrigation	
		R2	Linear aspiration	
	Dual Linear Flow***	R1	Irrigation	
		R2	Linear Vacuum or Flow	Linear Flow or Vacuum
Irrigation Only	Disabled	R1	Irrigation	

Phase Type	Dual Linear Control	Region	Pitch	Yaw Out
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
	Dual Linear Flow***	R1	Irrigation	
		R2	Linear Vacuum or Flow and Fixed Vitrectomy when on	Linear Flow or Vacuum
Coagulation	Disabled	R1	Linear Coagulation	

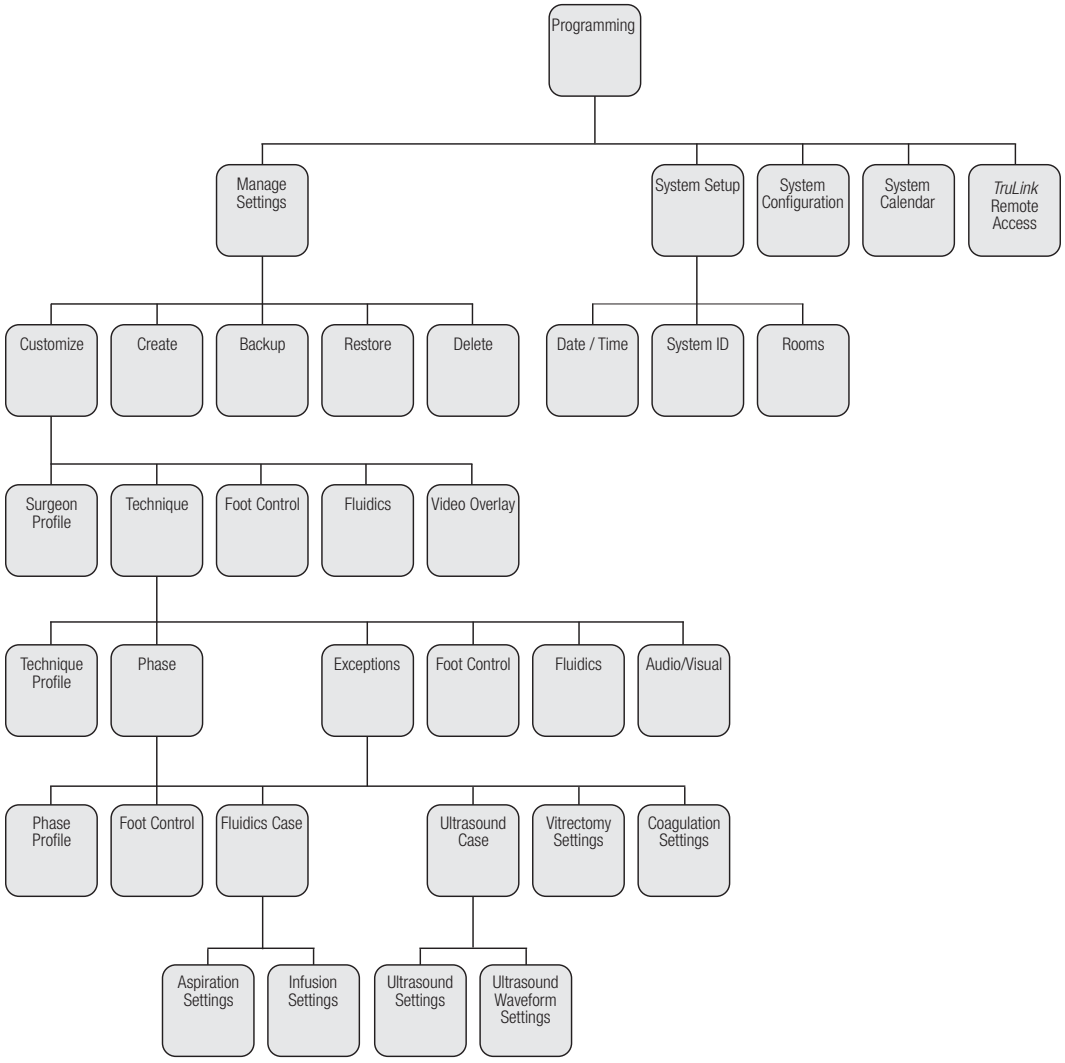
** Only available at Programming Level 2.
*** Only available at Programming Level 3.

Customizing Your System

This chapter explains how to customize your ***Stellaris®*** Vision Enhancement System to achieve maximum flexibility for your operating needs.

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

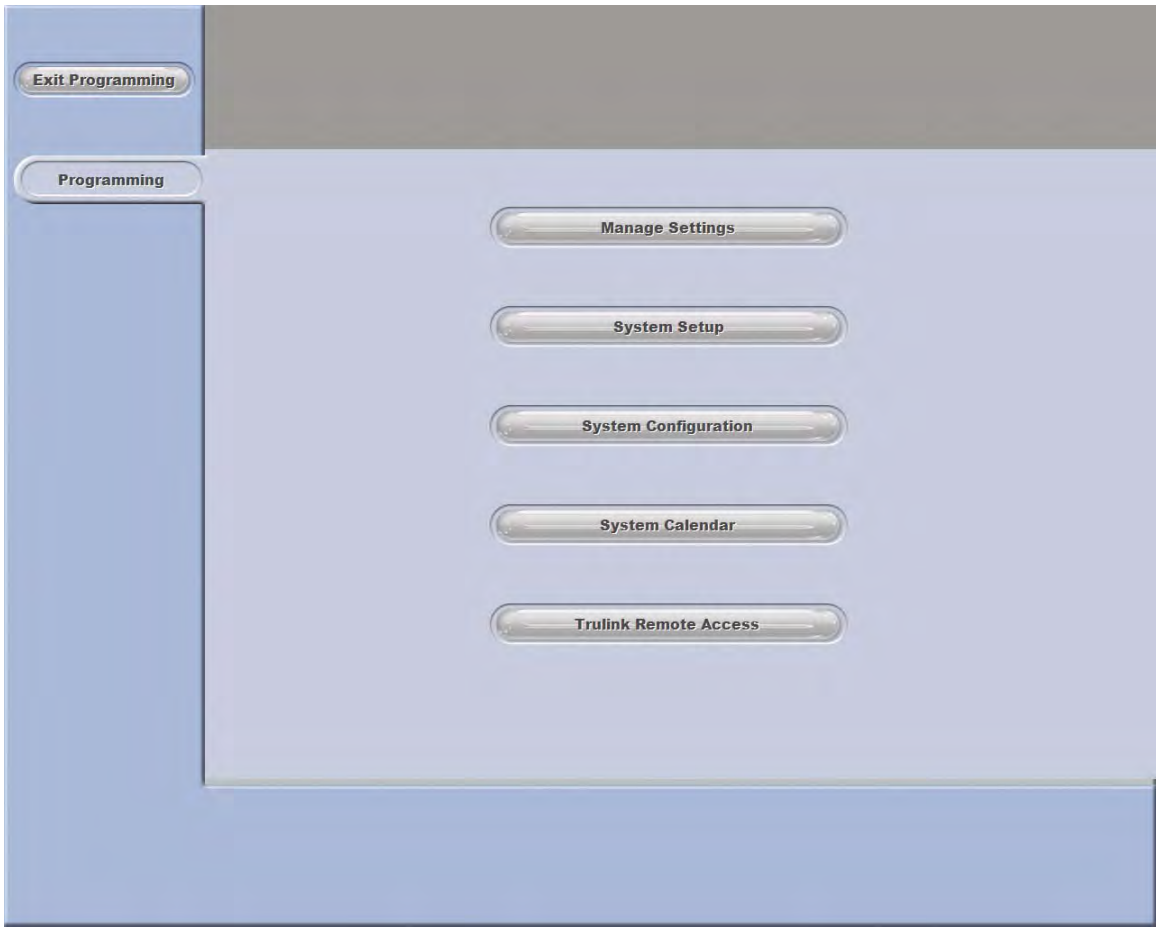
Each surgeon using the ***Stellaris®*** Vision Enhancement System can program the system for their own preferred operating configuration and instrument parameters. Several default surgeon preference files are pre-loaded on the system, and you may copy and modify any of them through the Programming interface. You can create, modify and backup surgeon setting preference files, as well as modify system parameters. The programming screens are organized as outlined in the diagrams below.



To program system parameters, select **Programming** from main clock menu on the **Select Surgeon Programming Level Screen** or the **Setup Surgical Screen**.

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

- Manage Settings
- System Setup
- System Configuration
- System Calendar
- *TruLink*® Remote Access (optional)

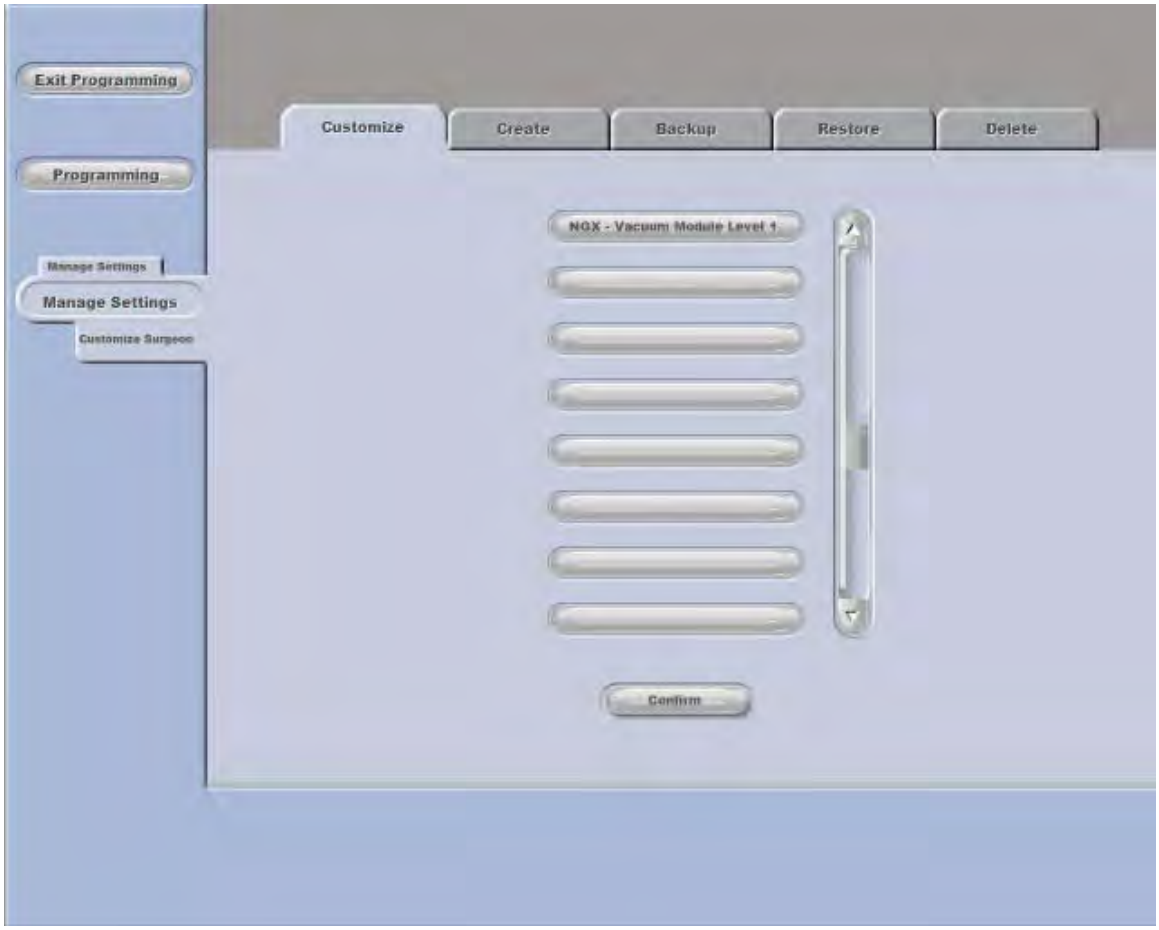


Each of these functions is described in more detail below.

At any time, you can select **Programming** to return to the **Main Programming Screen**, or **Exit Programming** to return to the **Select Surgeon Programming Level Screen** or the **Setup Surgical Screen**. In either case, the ***Stellaris***® 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

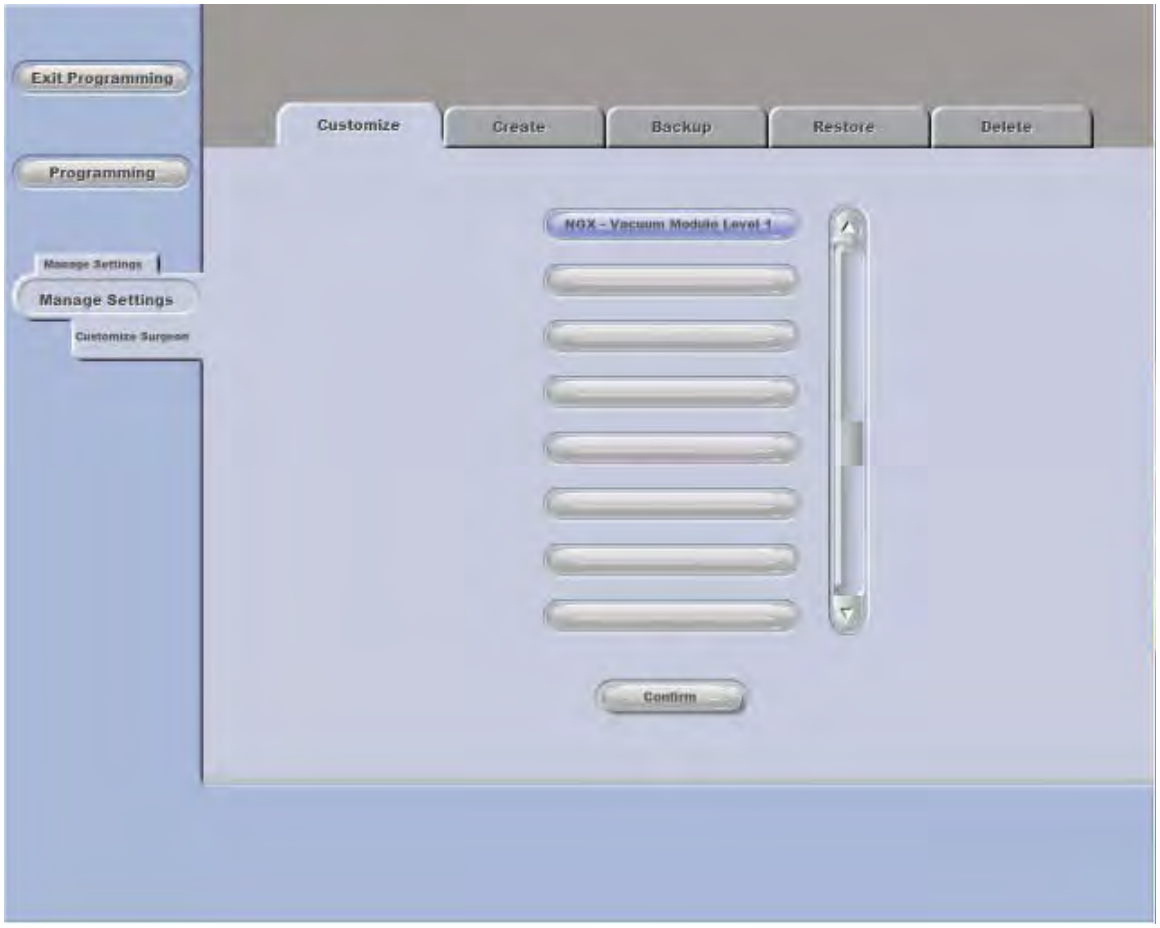
Select **Manage Settings** from the **Main Programming Screen**, and a new screen will appear through which you can customize an existing surgeon's file, create a new surgeon preference file by copying from an existing one, backup files, restore files from a backup, or delete surgeon preference files.



Customize a Settings File

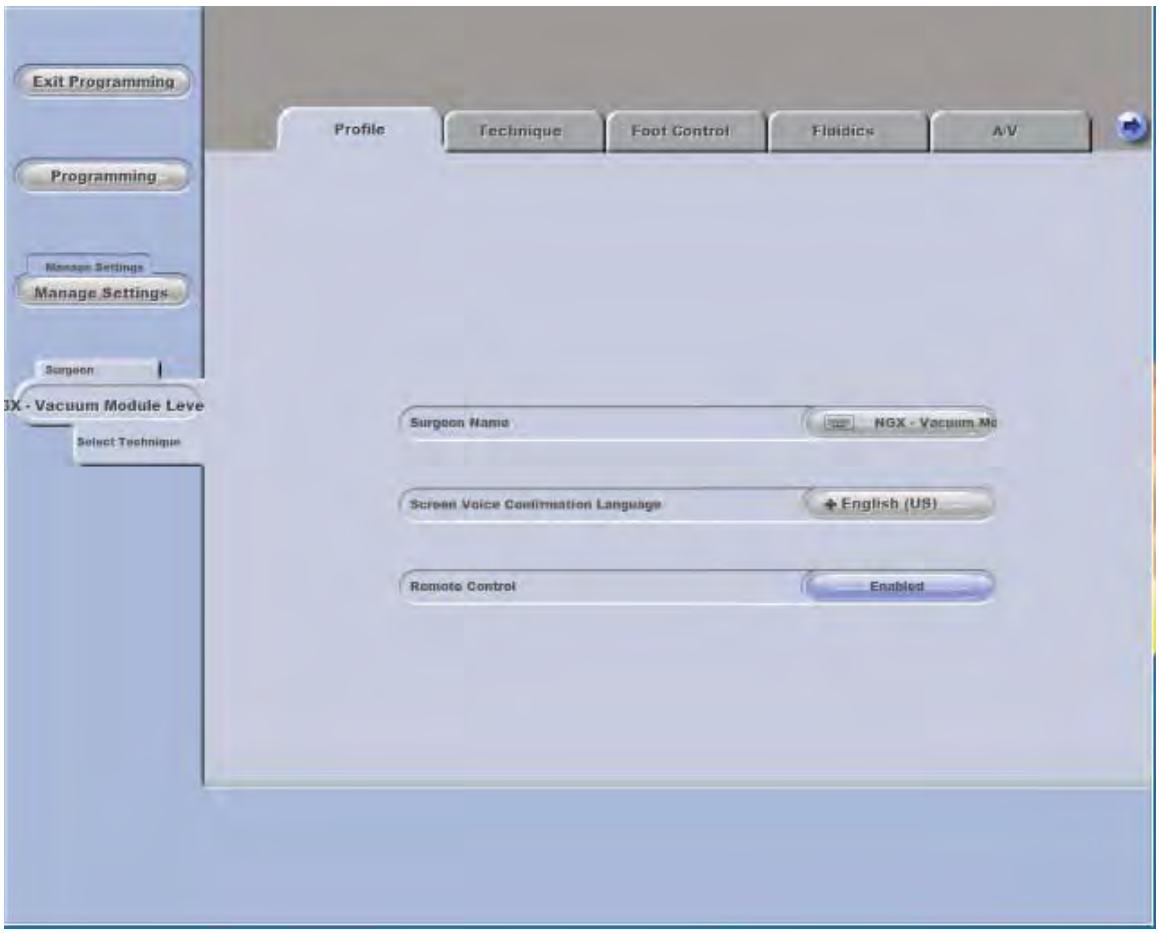
To change the settings for a currently existing preference file, select the **Customize Tab** on the **Main Programming Screen**. A list of all surgeon preference files currently loaded on your ***Stellaris***® Vision Enhancement System will appear. Select the name of the surgeon file to be modified, 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 3-5). These tabs are **Profile**, **Technique**, **Foot Control Settings**, **Foot Control Regions**, **Fluidics**, **A/V**, and **Video Overlay**. Each tab allows you to make global changes to system parameters, and is described in detail below.

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



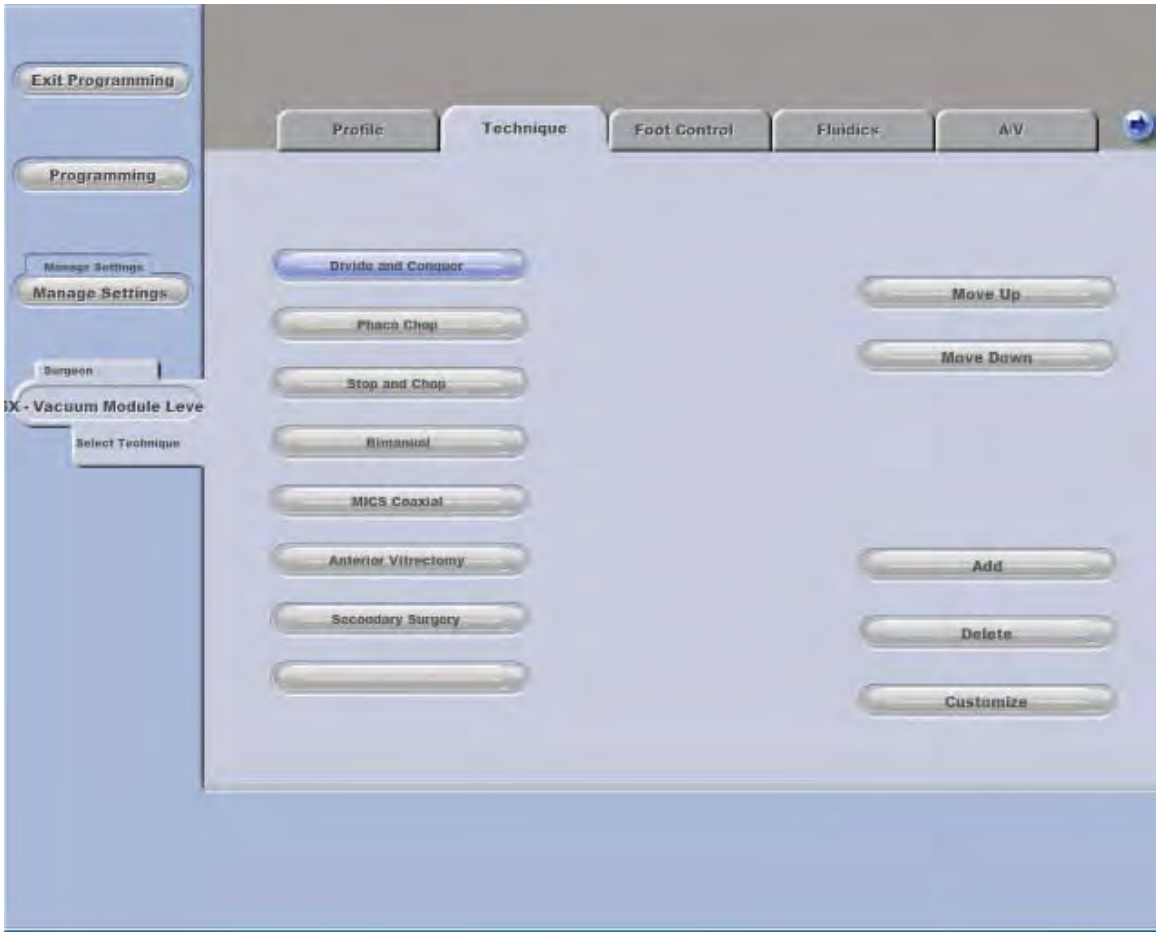
Customize Profile

To change the surgeon's name associated with a settings file, or change the default language, select the **Profile Tab** on the **Surgeon Programming Level Screen**. Select the surgeon's name, and use the keyboard interface that appears to modify the name of that file. Select the language, and a menu 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.



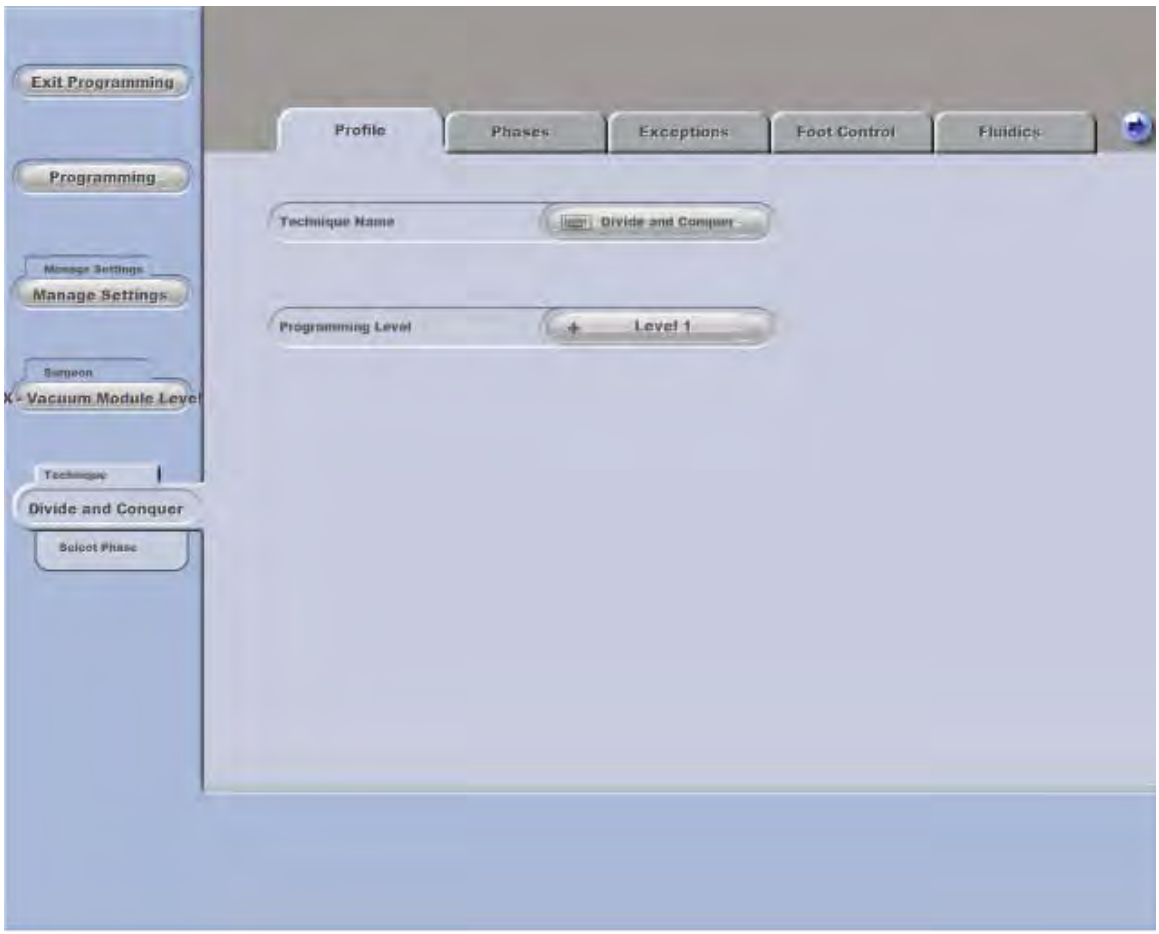
Customize Technique

To change the techniques available for a particular surgeon or modify their settings, select the **Technique Tab** on the **Surgeon Programming Level 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.



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 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** and **A/V**. Various parameters may be adjusted through various tabs, as described below.

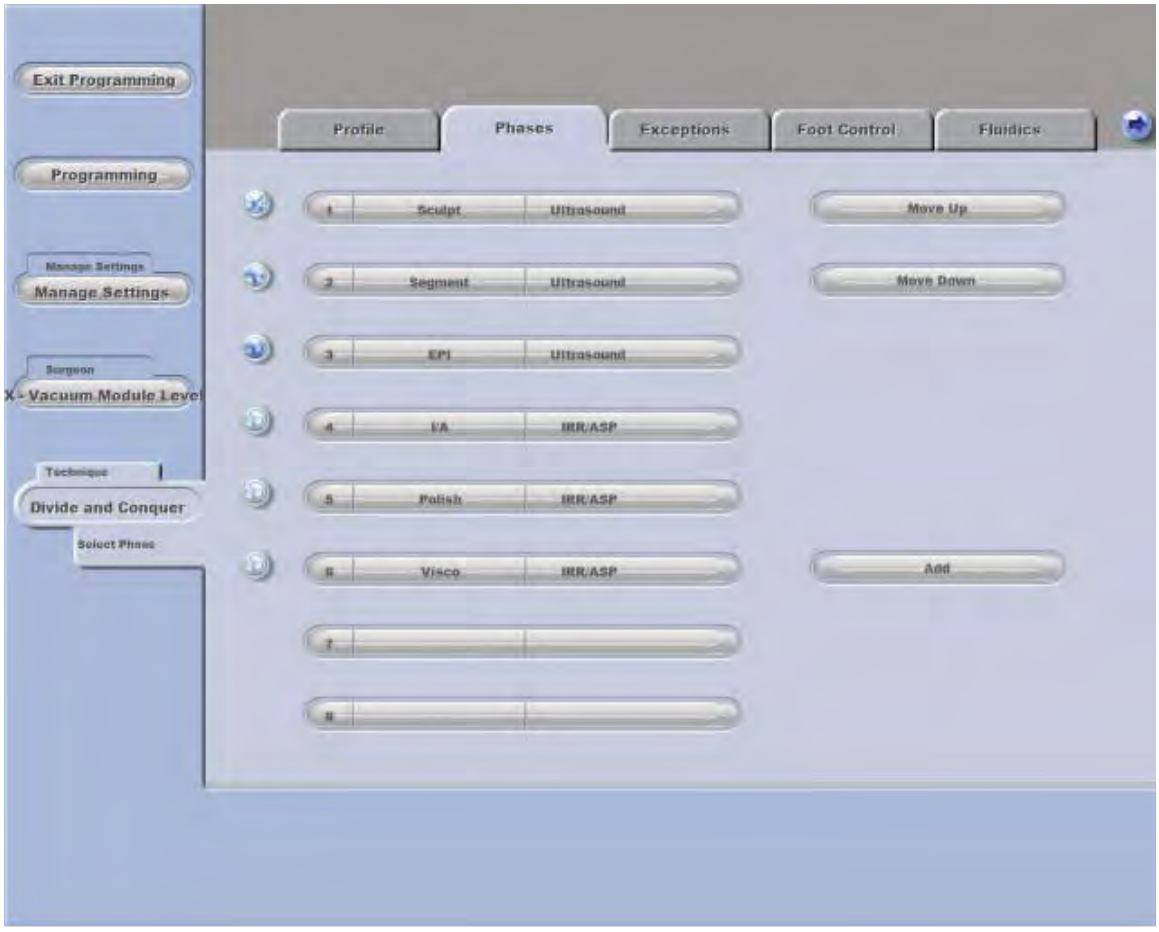


Note: *The programming level may be increased, to allow more control of feature details. However, once it has been increased it may not be decreased.*

- **Profile Tab**—Technique Name, Programming Level (1,2,3)
- **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 (ultrasound, irrigation/aspiration). Phases can be added, deleted, or re-ordered. They may also be customized, as described below.
- **Exceptions Tab**—Each technique may include up to four exceptions. Exceptions can be added, deleted, or re-ordered. They may also be customized, as described below.
- **Foot Control Tab**—Group or ungroup **Foot Control Buttons,** enable/disable next ultrasound modulation on yaw, reflux type (none or continuous).
- **Fluidics Tab**—Aspiration types (Vac; Vac Modes, Flow: Vac Modes, Flow: Flow Modes, Flow: All modes), IV Pole Height, Vacuum Response, Venting Method (Air or Fluid), Irrigation Shut-Off Delay (ms), Pressurized Infusion Function (enabled/disabled), Pressurized Infusion Pump (on/off) and Pressurized Infusion Settings (mmHg).
- **A/V Tab**—Display Format (1 or 2), Status Bar Format (1, 2, 3)

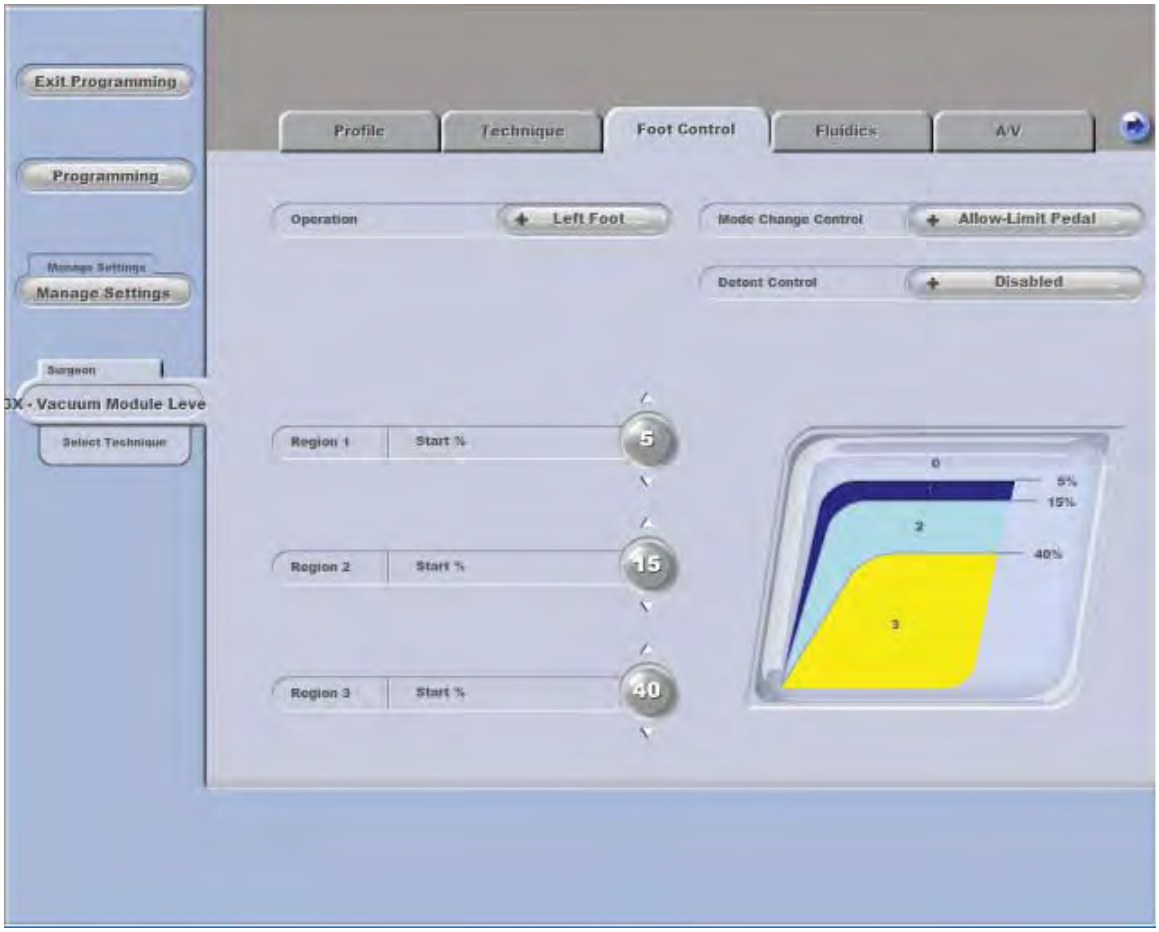
Customizing Phases and Exceptions

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. Select **Customize**, and more options specific to that function will appear, and can be modified. These can include Phase Information, **Foot Control** settings, Fluidics (Aspiration and Infusion), Ultrasound (Ultrasound and Wave Form), Vitrectomy, Coagulation settings. When you are done making changes, select **Exit Programming**. The system will ask you to confirm your changes before exiting.



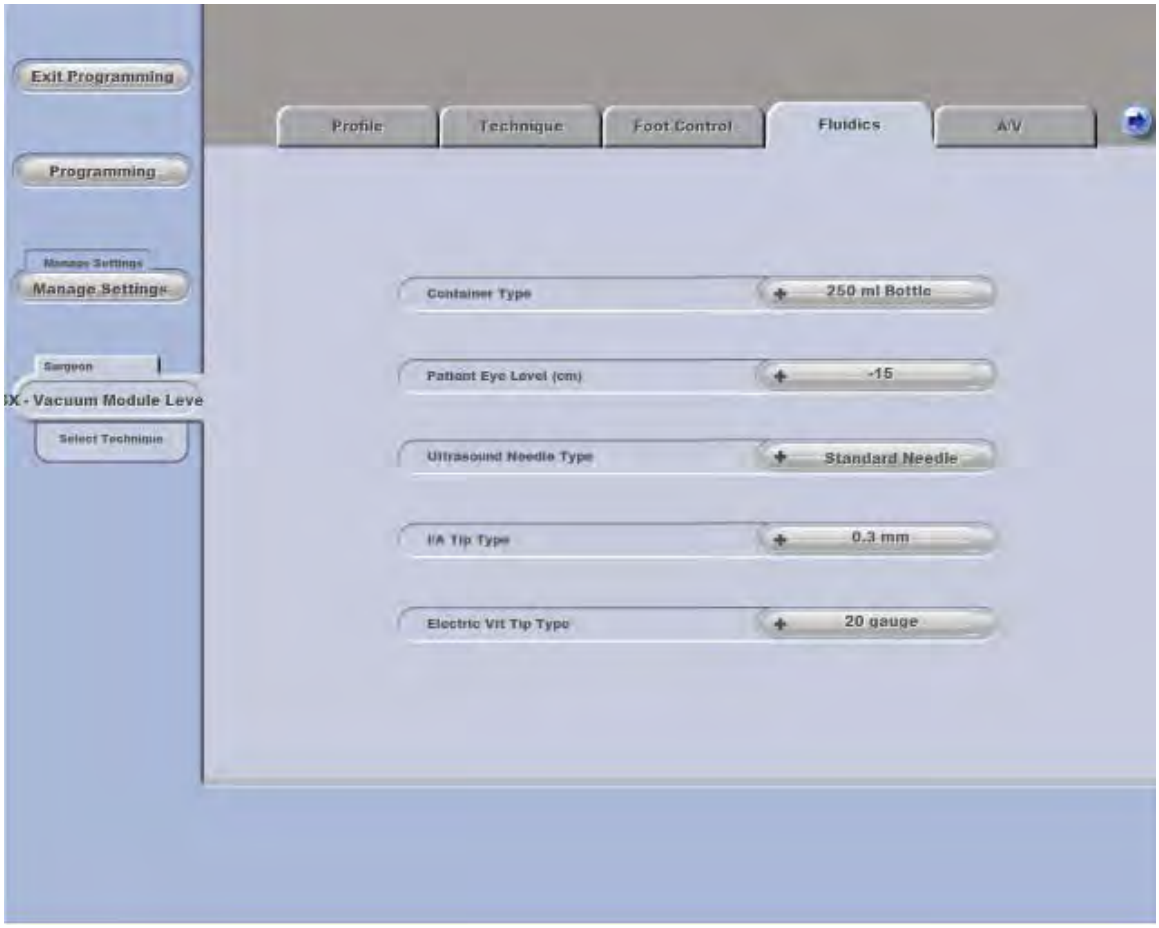
Customize Foot Control

To modify the techniques for the Foot Control, select the **Foot Control Tab** on the **Surgeon Programming Level Screen**. You can set the Foot Control to use right or left foot operation. The **Mode Change Control** allows you to set the ***Stellaris®*** Vision Enhancement System response when the footpedal is activated and you change surgical modes. The **Detent Control** determines what feedback the ***Stellaris®*** Vision Enhancement System will give when changing footpedal regions. Use the **Region Spin Control Buttons** to change the percent depression at which each region begins.



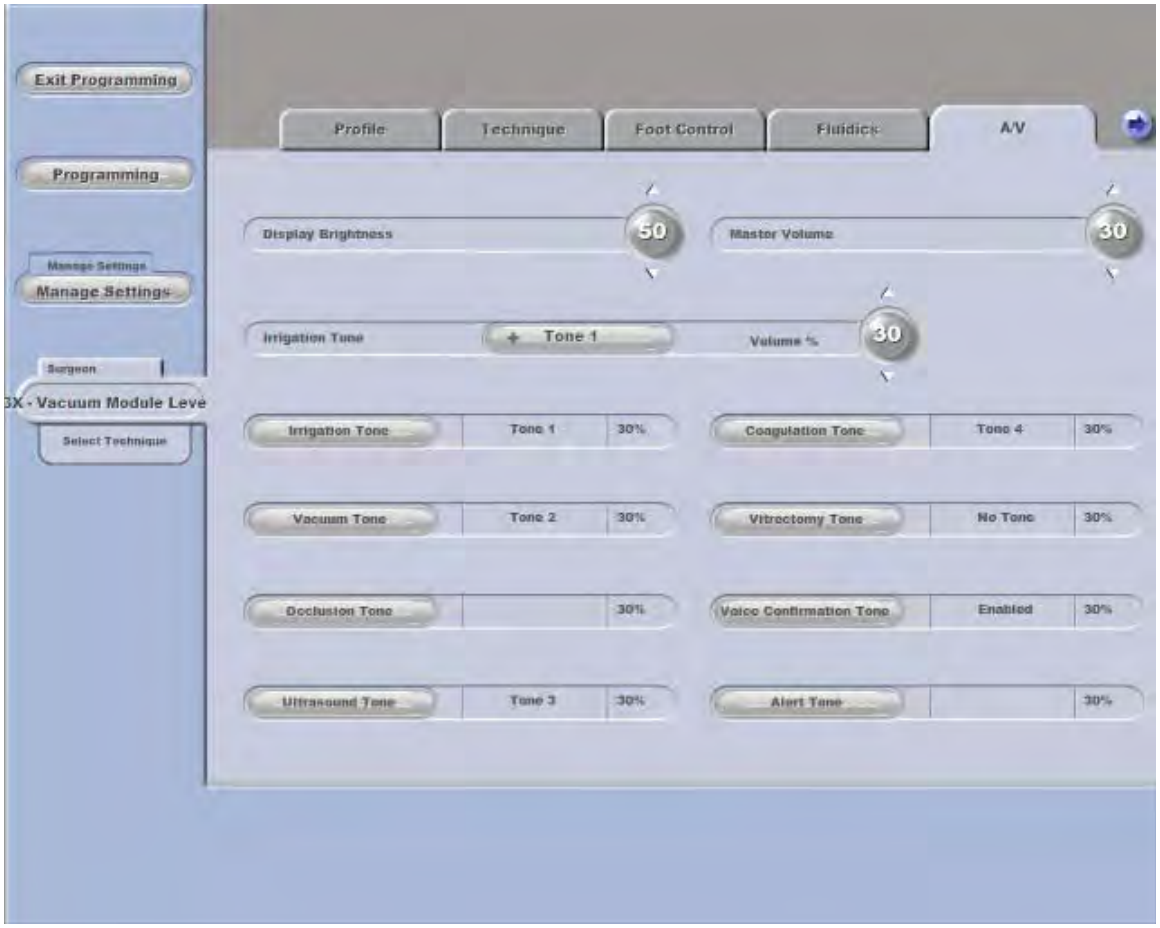
Customize Fluidics

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



Customize A/V (Audio/Visual)

To set the parameters for audio and visual functions, select the **A/V Tab** on the **Surgeon Programming Level 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 each 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.

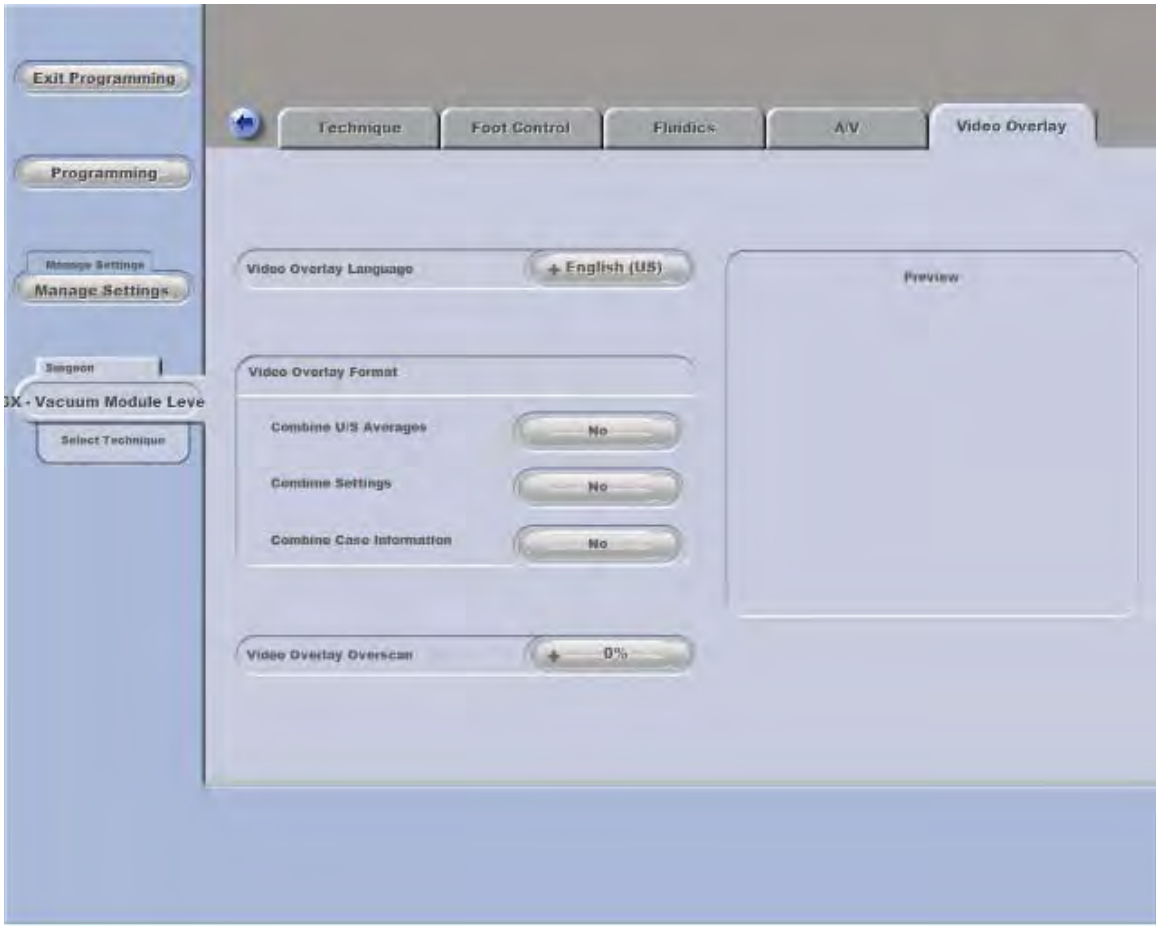


Customize Video Overlay

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

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.

You can select the language to be used on the Video Overlay. You can set the Video Overlay overscan rate from 0% to 5%.



Create a New Settings File

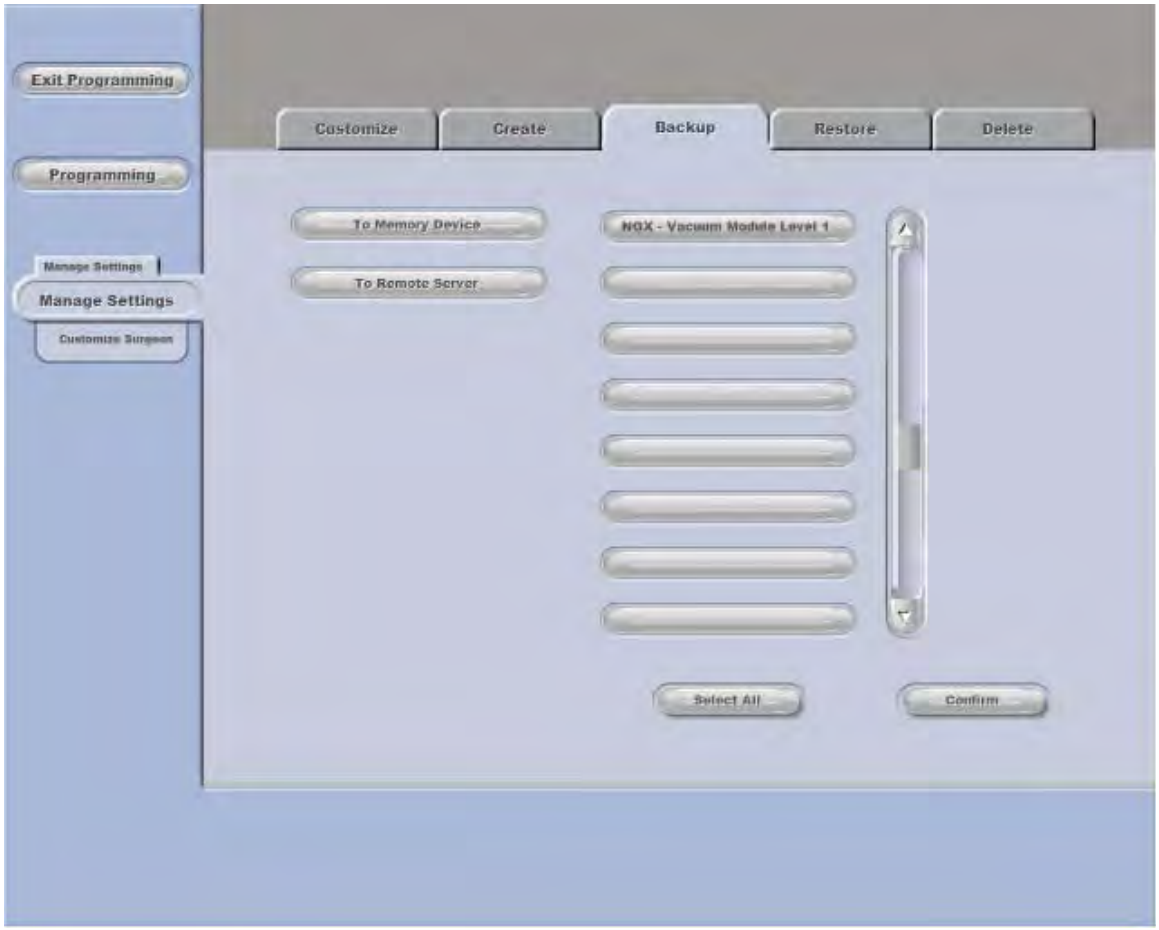
To create a new surgeon preference file, select the **Create Tab** from the **Manage Settings Screen**, then select the surgeon's file which has settings most like the file you are going to create. Once you have highlighted a preference file, the techniques in that file will be listed on the right side of the screen. Select techniques file by highlighting the tabs on the left-hand side of the Techniques list.

Once the desired techniques are highlighted, select **Confirm** and a keyboard will appear, through which you can enter the name for the new 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 3-5).

Backup a Settings File

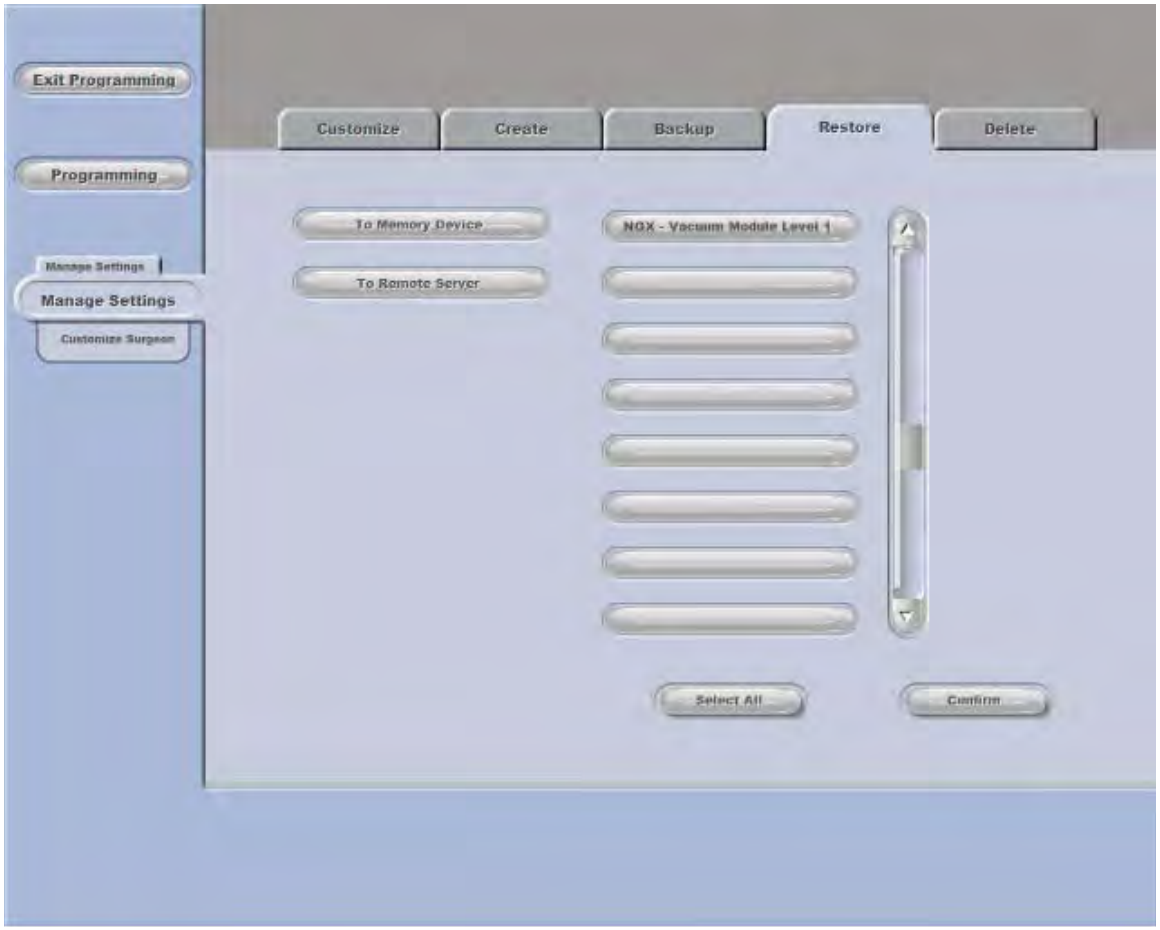
To backup an existing surgeon preference file to a USB memory device, select the **Backup Tab** from the **Manage Settings Screen**, insert the device into one of the two USB ports on the back of the display panel. Select the file or files to be backed up, the location to which they should be backed up, and select **Confirm** (You must select the screen first, then insert device. 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®*** *Vision Enhancement System. Operations with other USB devices are* ***NOT*** *supported.*



Restore a Settings File

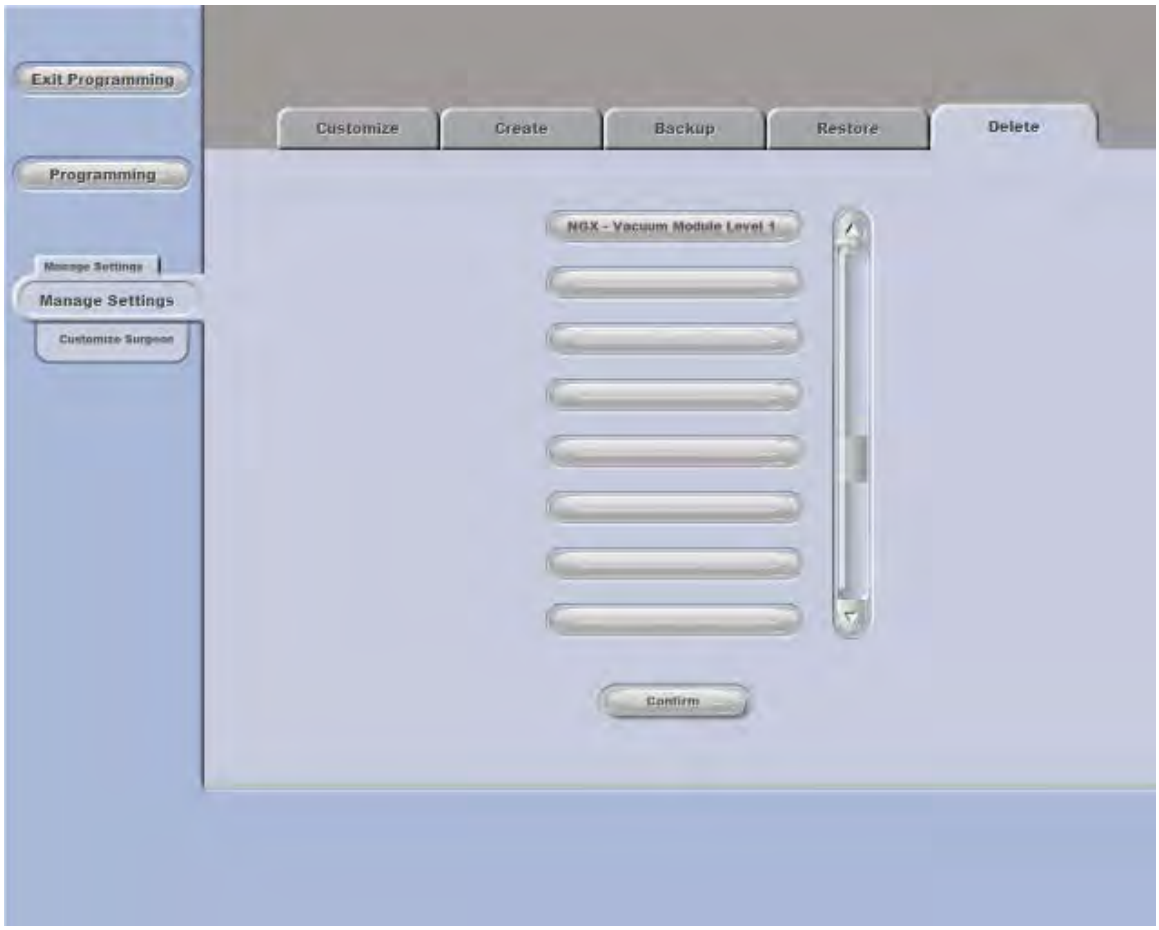
To restore an existing surgeon preference file from a USB memory device,* insert the device into one of the two USB ports on the back of the system console, behind the round sliding door. Make sure the **Restore Tab** is active at the top of the **Manage Settings Screen**, select the file or files to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



*Select the **Restore Tab** from the **Manage Settings Screen**.

Delete a Settings File

To delete an existing surgeon preference file, make sure the **Delete Tab** is active at the top of the **Manage Settings Screen**, select the file or files to be deleted, and select **Confirm**.

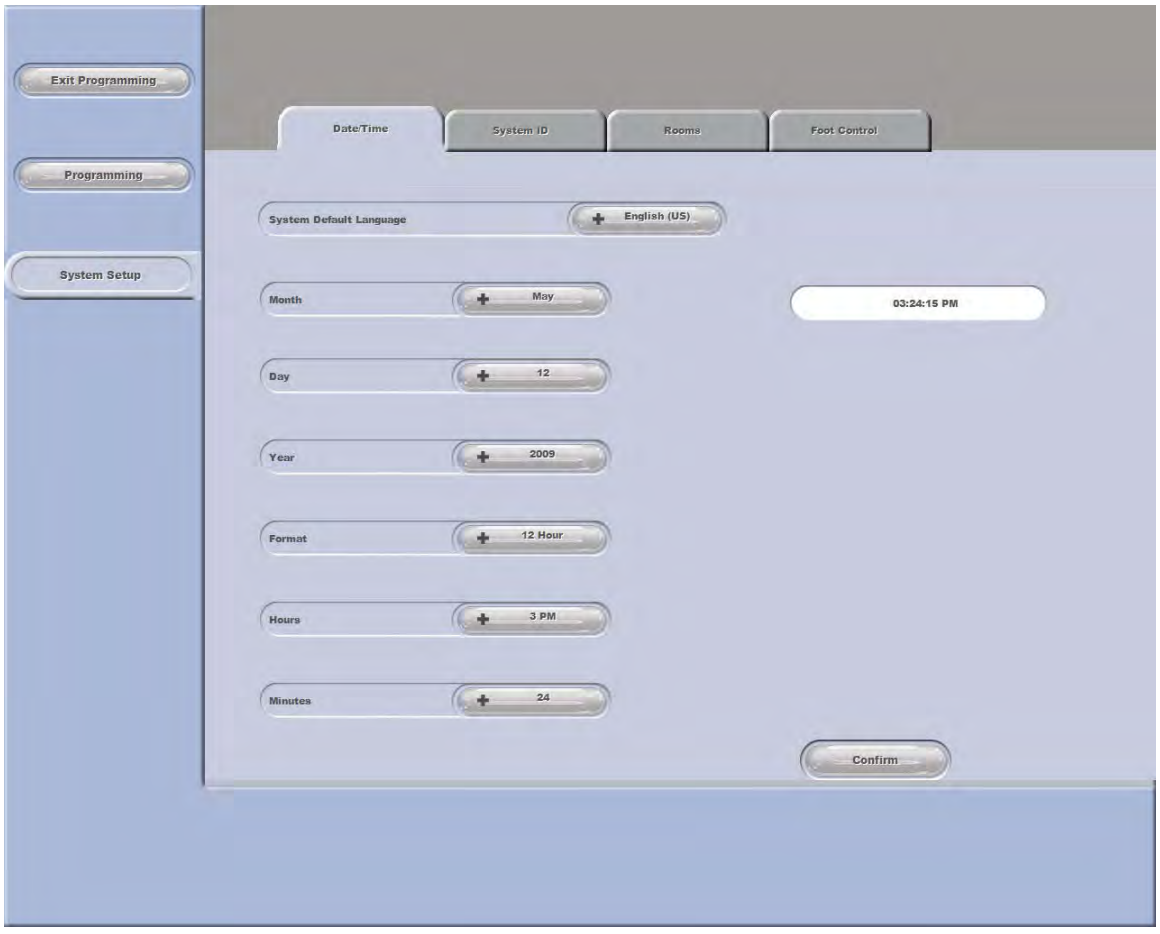


3.2. System Setup

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.

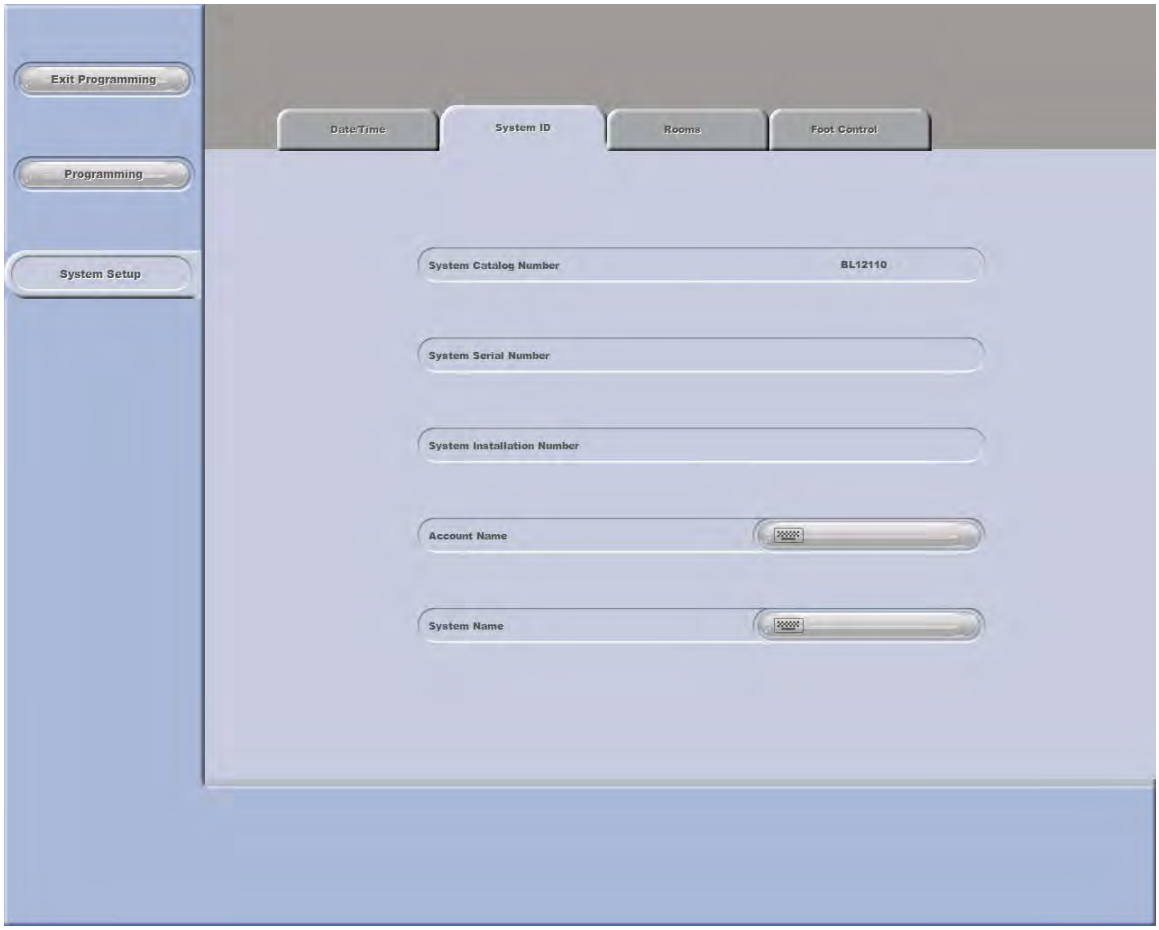
Set Date, Time and Language

To change the system language, current date, time and 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.



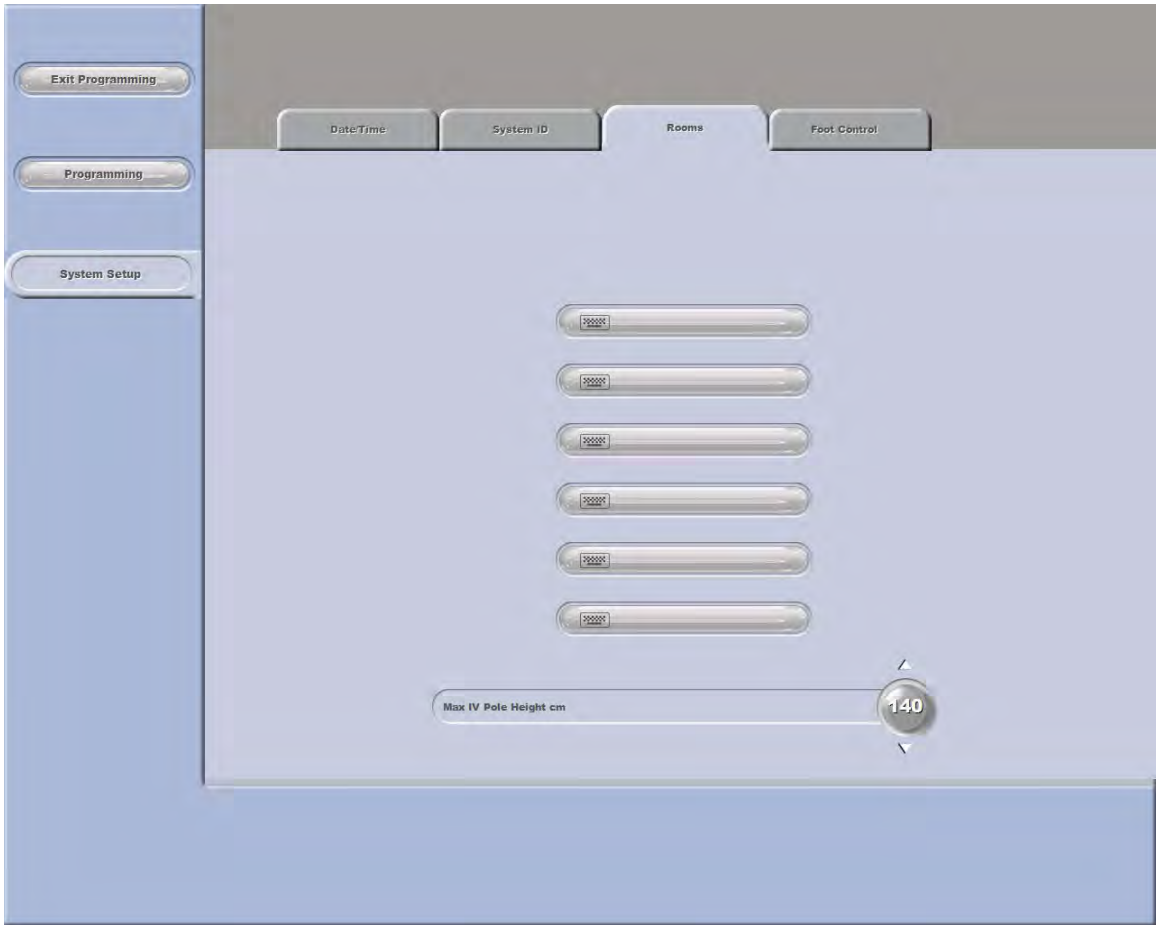
System ID

To monitor or change the identifying names of your ***Stellaris***® 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***® Vision Enhancement System. You can view the system catalog number as well as its installation number.



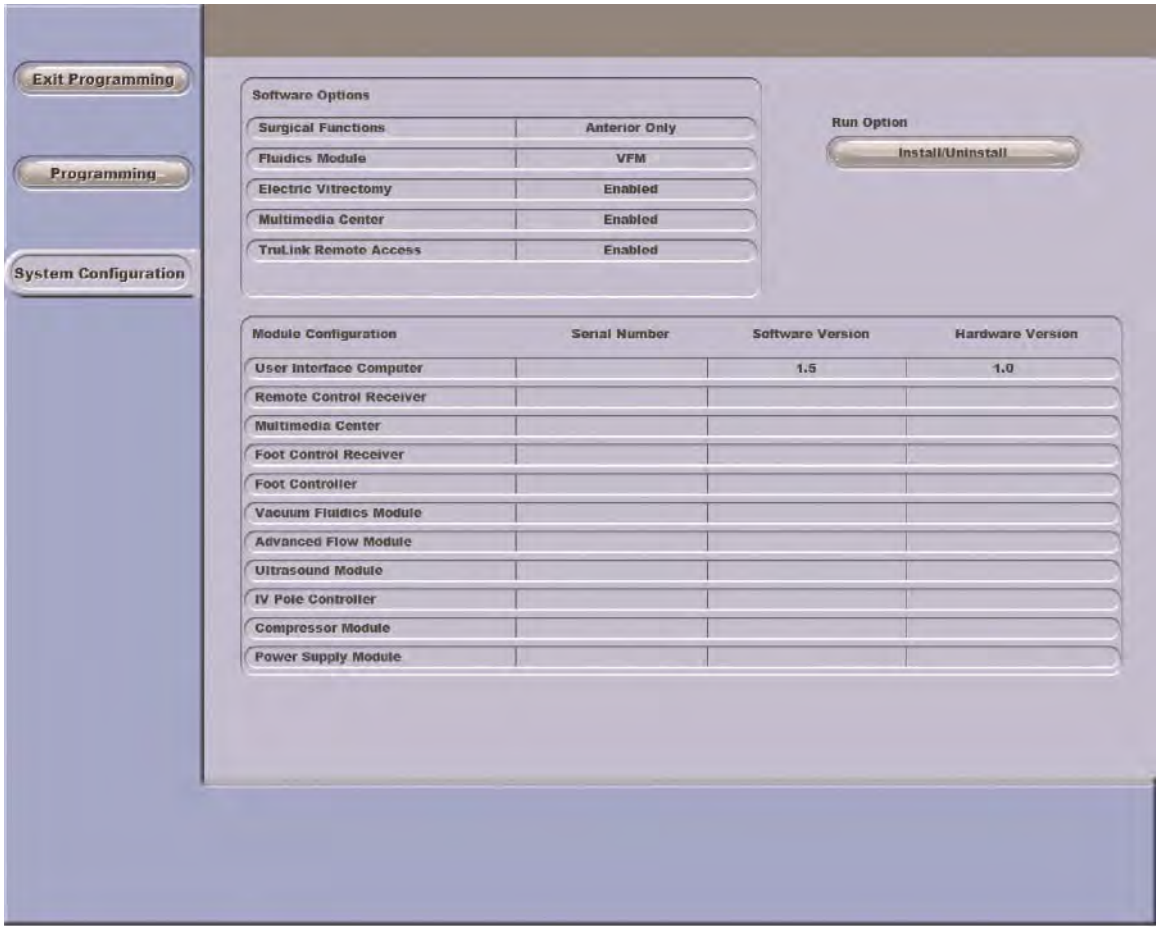
Rooms

To assign names to the operating rooms in which your ***Stellaris***® Vision Enhancement System is used, select the **Rooms Tab** at the top of the **System Setup Screen**. Select any room, 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).



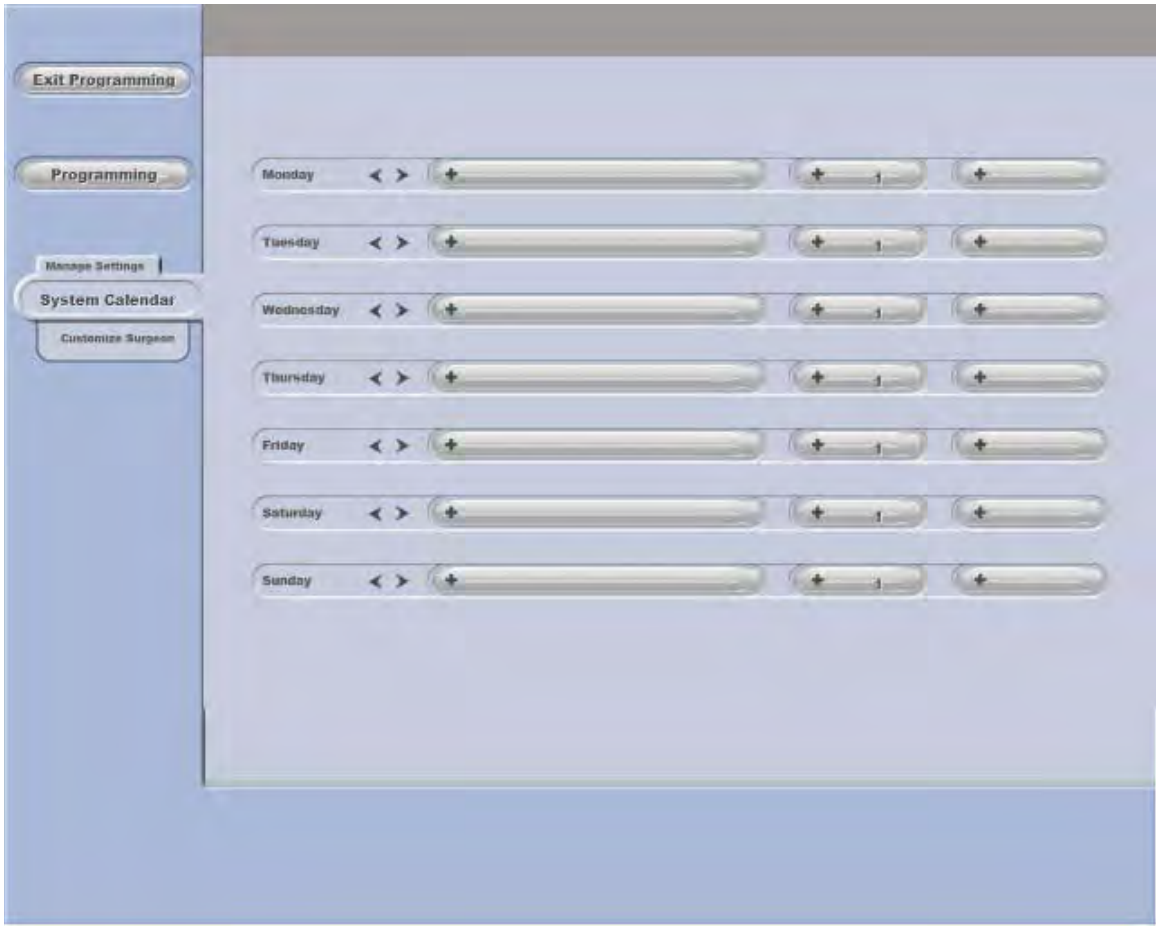
3.3. System Configuration

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



3.4. 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.



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 < > to toggle between full day or morning and afternoon settings.

The third column contains option lists with the names of all the surgeon preference files currently available. Select a file from the list, and that will be the default file when the ***Stellaris***® 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 selection which room number this ***Stellaris***® Vision Enhancement System is located. These settings determine how the case numbers will be incremented, to avoid duplicate case numbers for a single surgeon.

3.5. TruLink® Remote Access

WARNING: ***You must contact your local Bausch + Lomb sales and support office before activating the TruLink® Remote Access function. See "Technical Assistance" on page 8-2 for the sales and support office that serves your location.***

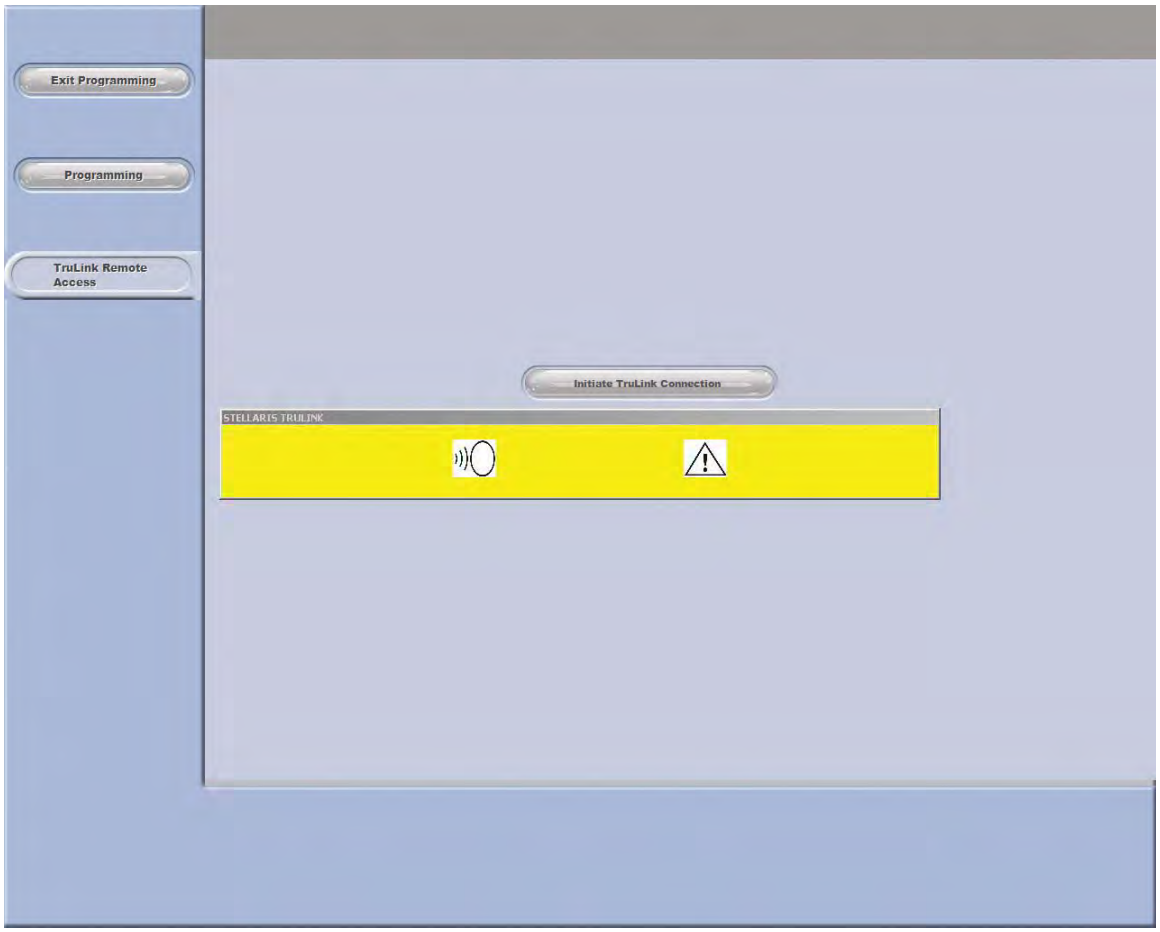
WARNING: ***Do not conduct surgery or any patient procedures while TruLink® Remote Access is activated. Serious patient injury may occur.***

This features 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 ***TruLink®*** **Remote Access** from the **Main Programming Screen**, and a new screen will appear through which you can monitor and initiate remote service on your system.

Select ***TruLink*® Remote Access**, and ensure that the Ethernet cable is connected to the ***Stellaris*®** Vision Enhancement System, and to the designated hospital network port.

Note: *If you have the optional MMC system, the Ethernet cable should be connected to the MMC, then the MMC connected to the hospital Ethernet port.*



Confirm that the system is not being used for surgery. The system will then be controlled by the remote technician.

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

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

3.6. 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	Surgeon
Display backlight brightness	20% to 100%, by 5%	Surgeon
System master audio volume	0% to 100%, by 5%	Surgeon
Tone selection and volume control	Irrigation, No tone, Tone 1 - Tone 10, 0% to 100%, by 5% 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% Bipolar, Tone 1 - Tone 10, 20% to 100%, by 5% Vit, No tone, Tone 1 - Tone 10, 0% to 100%, by 5% Occlusion, 0% to 100%, by 5% Error, 20% to 100%, by 5%	Surgeon
Voice confirmation	Enabled / Disabled Volume: 0% to 100%, by 5%	Surgeon
Video overlay language	English	Surgeon
Video overlay display format	Combine case information lines - No, Yes Combine ultrasound averages lines - No, Yes 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	Technique
Status Bar Display Format	Format 1, Format 2, Format 3	Technique

Case Customization Levels

Parameter	Options/Ranges/Step Sizes	
Programming Level	Level 1, Level 2, Level 3	Technique
Programming Level 2 Customize Settings by Case	Disabled, Enabled	Technique, Phase
Programming Level 2 Customize Fluidics Settings by Needle/ Tip	Disabled, Enabled	Technique
Programming Level 2 Customize Fluidics Settings by Cataract Grade	Disabled, Enabled	Technique
Programming Level 2 Customize Fluidics Settings by Pathology	Disabled, Enabled	Technique
Programming Level 2 Customize Ultrasound Settings by Needle/ Tip	Disabled, Enabled	Technique
Programming Level 2 Customize Ultrasound Settings by Cataract Grade	Disabled, Enabled	Technique
Programming Level 2 Customize Ultrasound Settings by Pathology	Disabled, Enabled	Technique
Programming Level 2 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, Pneumatic Vitrectomy, Electric 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%>R2 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
Dual Linear Enable	Programming Level 1: Disabled (not displayed, not programmable) Programming Level 2 / Level 3: Disabled, Enabled	Technique
Linear Coagulation in Setup Mode	Disabled, Enabled	Technique
Grouped switch assignment	Unassigned, Mode, U/S Submode, Vacuum, Flow, Bottle Height, U/S Power, U/S PPS/Duration, U/S DC/Interval, Coag Power, Vit Cut Rate	Technique, Phase
Ungrouped switch assignment	Unassigned, Next Phase, Previous Phase, Next U/S Submode, Confirm Settings, Irr On/Off, Continuous Reflux, Vit On/Off, Fixed Coag	Technique, Phase
Reflux	Vacuum Fluidics: None, Continuous AFS Fluidics: None, Single, Repeat, Continuous	Technique, Phase
Next Ultrasound Modulation on Yaw	Disabled, Enabled Note that for single linear foot pedal modes, the outward yaw motion would be used for next ultrasound modulation, and for dual linear foot pedal modes, the inward yaw motion would be used.	Technique, Phase
Fixed Coagulation Power Level	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5% Applicable if one of the 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, Programming Level 3 Dual Linear Flow (only for AFS fluidics if flow modes enabled) Vit Modes: Disabled, Asp on Pitch, Programming Level 3 Asp on Yaw, Programming Level 3 Dual Linear Flow (only for AFS fluidics if flow modes enabled) Irr Mode / Coag Modes: Disabled (not displayed)	Phase

Fluidics

Parameter	Options/Ranges/Step Sizes	
Max bottle height	30 to 140 cm, by 5 cm	System
Balanced Salt Solution Container Type	500 ml Bottle, 500 ml Bag, 250 ml Bottle	Surgeon
Patient Eye Level	-15 cm to +15 cm	Surgeon
Default Ultrasound Tip Type	Standard, MicroFlow+, MicroFlow, Thin Tip, Coaxial MICS, Stable Flow 20 Gauge, Stable Flow 19 Gauge	Surgeon
Default /A Tip Type	0.3 mm, 0.5 mm	Surgeon
Default Vitrectomy Tip Type	20 Gauge Pneumatic, 20 Gauge Electric, 25 Gauge Electric	Surgeon
Fluidics Types	VFM: Vac Modes AFM: Vac Modes, AFM: Flow Modes, AFM: All Modes	Technique
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
Programming Level 2 Vent Method	Fluid Venting, Air Venting	Technique, Phase/Case
Pressurized Infusion Displayed	Disabled/Enabled	Technique
Pressurized Infusion Pump	On/Off	Technique
Pressurized Infusion Pressure	0 mmHg to 20 mmHg, by 2 mmHg 20 mmHg to 100 mmHg, by 5 mmHg	Technique, Phase/Case

Parameter	Options/Ranges/Step Sizes	
Aspiration type Types available depend on aspiration types enabled at the technique level, the dual linear control option, and the mode handpiece type selected.	Fixed vacuum Fixed vacuum, with aspiration control feature Linear vacuum Programming Level 2 Linear vacuum, with aspiration control feature Fixed flow fixed vacuum Fixed flow fixed vacuum, with aspiration control feature controlling flow Fixed flow fixed vacuum, with aspiration control feature controlling vacuum Fixed flow linear vacuum Programming Level 2 Fixed flow linear vacuum, with aspiration control feature controlling flow Programming Level 2 Fixed flow linear vacuum, with aspiration control feature controlling vacuum Linear flow fixed vacuum Programming Level 2 Linear flow fixed vacuum, with aspiration control feature controlling flow Programming Level 2 Linear flow fixed vacuum, with aspiration control feature controlling vacuum Programming Level 3 Linear flow linear vacuum limit (available only in Irrigation / Aspiration and fixed Vitrectomy modes)	Phase/Case
Fixed vacuum level or linear vacuum maximum level, for vacuum modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 600 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case
Fixed flow level or linear flow maximum level, for flow modes	0 ml/min to 10 ml/min by 1 ml/min 10 ml/min to 30 ml/min by 2 ml/min 30 ml/min to 60 ml/min by 5 ml/min Minimum of 5 ml/min for U/S modes	Phase/Case
Fluidics - Fixed vacuum limit level or linear vacuum limit maximum level, for flow modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 650 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case
Programming Level 2 Linear vacuum minimum level, for vacuum modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 600 mmHg by 10 mmHg Minimum of 10 mmHg for U/S modes	Phase/Case
Programming Level 2 Region 2 minimum vacuum, for aspiration control feature vacuum modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 600 mmHg by 10 mmHg	Phase/Case

Parameter	Options/Ranges/Step Sizes	
Programming Level 2 Linear flow minimum level, for flow modes	0 ml/min to 10 ml/min by 1 ml/min 10 ml/min to 30 ml/min by 2 ml/min 30 ml/min to 60 ml/min by 5 ml/min Minimum of 5 ml/min for U/S modes	Phase/Case
Programming Level 2 Region 2 minimum flow, for aspiration control feature flow modes with control on flow	0 ml/min to 10 ml/min by 1 ml/min 10 ml/min to 30 ml/min by 2 ml/min 30 ml/min to 60 ml/min by 5 ml/min	Phase/Case
Programming Level 2 Linear vacuum limit minimum level, for flow modes	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 650 mmHg by 10 mmHg Minimum of 10 mmHg for U.S modes	Phase/Case
Programming Level 2 Region 2 minimum vacuum limit, for aspiration control feature flow modes with control on vacuum limit	0 mmHg to 20 mmHg by 1 mmHg 20 mmHg to 200 mmHg by 5 mmHg 200 mmHg to 650 mmHg by 10 mmHg	Phase/Case
Programming Level 2 Foot control mapping (for linear control)	Linear, Front Loaded, Back Loaded	Phase/Case
Programming Level 3 Pitch function for dual linear flow aspiration modes	Vacuum limit, Flow	Phase/Case
Programming Level 3 Foot control mapping (for yaw function linear control in dual linear aspiration flow modes)	Linear, Front Loaded, Back Loaded	Phase/Case

Ultrasound

Parameter	Options/Ranges/Step Sizes	
Ultrasound Modulation Type	Continuous Pulsed Single burst Fixed pulse Multiple burst Programming Level 3 Linear Power Linear Pulse Programming Level 3 Linear Power Linear Duty Cycle Programming Level 3 Dual Linear Multiple Burst Programming Level 3 Variable Power Multiple Burst Programming Level 3 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
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
Programming Level 2 Linear control power minimum level	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase/Case
Programming Level 2 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

Parameter	Options/Ranges/Step Sizes	
Programming Level 2 Foot control mapping (for linear control) - front loaded, linear, back loaded	Linear, Front Loaded, Back Loaded	Phase/Case
Programming Level 3 Waveform Type	Ramped (not programmable)	Phase/Case
Programming Level 3 Waveform duration	250 ms to 1000 ms by 50 ms (resolution of 50 ms even with calculator)	Phase/Case
Programming Level 3 Waveform Depth	25% to 100% by 5%	Phase/Case
Programming Level 3 Pulsed mode linear pulse rate minimum	1 PPS to 20 PPS by 1PPS 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
Programming Level 3 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
Programming Level 3 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
Programming Level 3 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 800 CPM by 30 CPM Electric: 600 CPM to 1500 CPM by 50 CPM	Phase
Programming 2 Linear cut rate minimum rate	Pneumatic: 30 CPM to 800 CPM by 30 CPM Electric: 600 CPM to 1500 CPM by 50 CPM	Phase
Programming 2 Foot control mapping	Linear, Front Loaded, Back Loaded, Reverse Linear, Reverse Front Loaded, Reverse Back Loaded	Phase

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
Programming Level 2 Power level minimum level	0% to 10% by 1% 10% to 30% by 2% 30% to 100% by 5%	Phase
Programming Level 2 Foot control mapping	Linear, Front Loaded, Back Loaded	Phase

Detailed Reference

This chapter provides a detailed reference for each system function and accessory, and surgical procedure setup and operation.

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

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

4.1. Computer Unit

Your ***Stellaris®*** Vision Enhancement System was designed to be easily upgradeable, to take advantage of future technology evolution. It includes a 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° forward and 15° back, and swiveled 90° right or left. The brightness of the display is controlled through the **A/V More Screen** (see page 2-11).

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.**

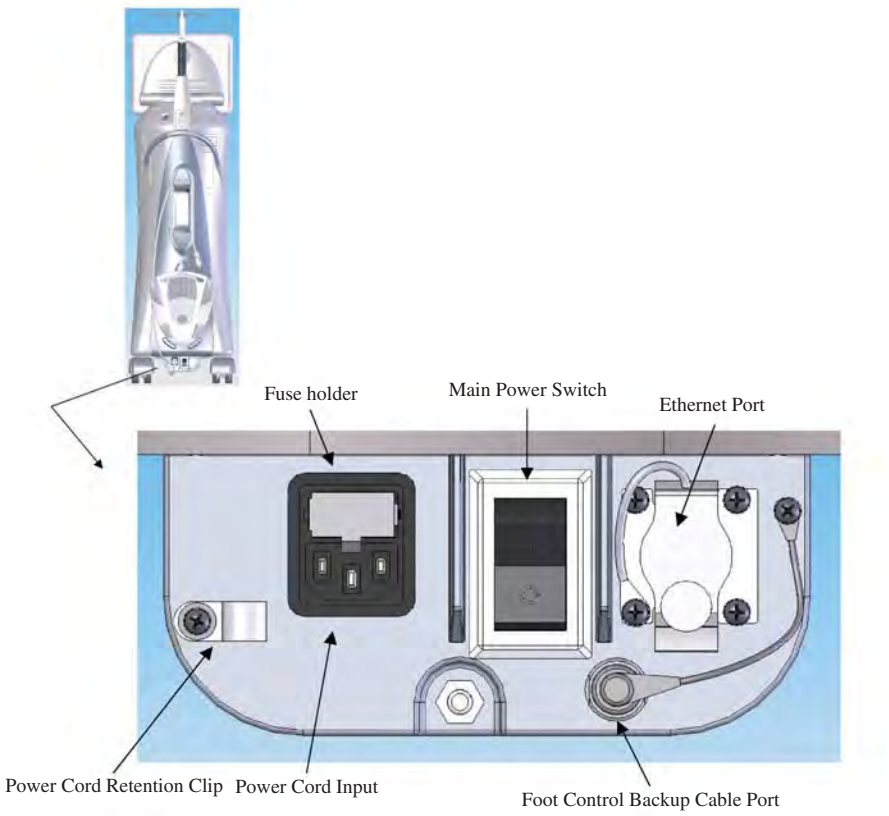
Two USB ports on the back of the display allow you to save, load and transfer your customized settings between systems.

4.2. System Console

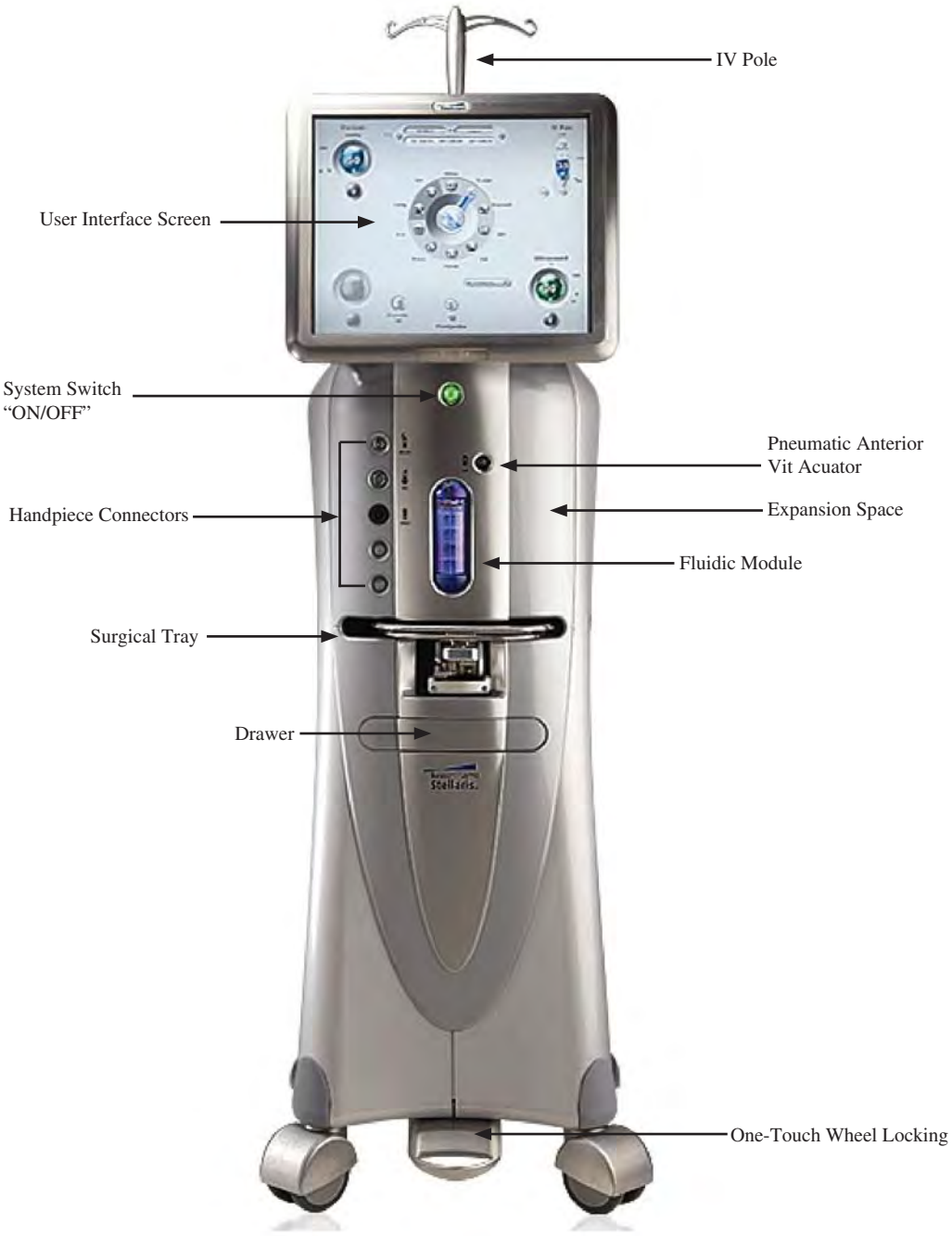
The ***Stellaris***® Vision Enhancement System modules are integrated into a protective console. The console includes a drawer for storing a remote control and the Foot Control backup cable, an integrated IV Pole, a handle, and a hook for storing the Foot Control.

Note: *Do not use the IV Pole for a handle.*

The system sits on four rotating casters. The front two wheels can be locked in place by pressing down on the wheel brake lever with your foot. Pulling up on the wheel brake releases the lock.



On the lower back of the system console are the ON/OFF power switch, power cord port, Ethernet port, and Foot Control cable port.


IV Pole
User Interface Screen
System Switch
"ON/OFF"
Pneumatic Anterior
Vit Acuator
Handpiece Connectors
Expansion Space
Fluidic Module
Surgical Tray
Drawer
One-Touch Wheel Locking

4.3. 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.***

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

The ***Stellaris***® 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 through any of several methods. It can be controlled through the touch screen, Foot Control (if programmed), remote control, 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 4-5), or use the buttons on the back of the system console.

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

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

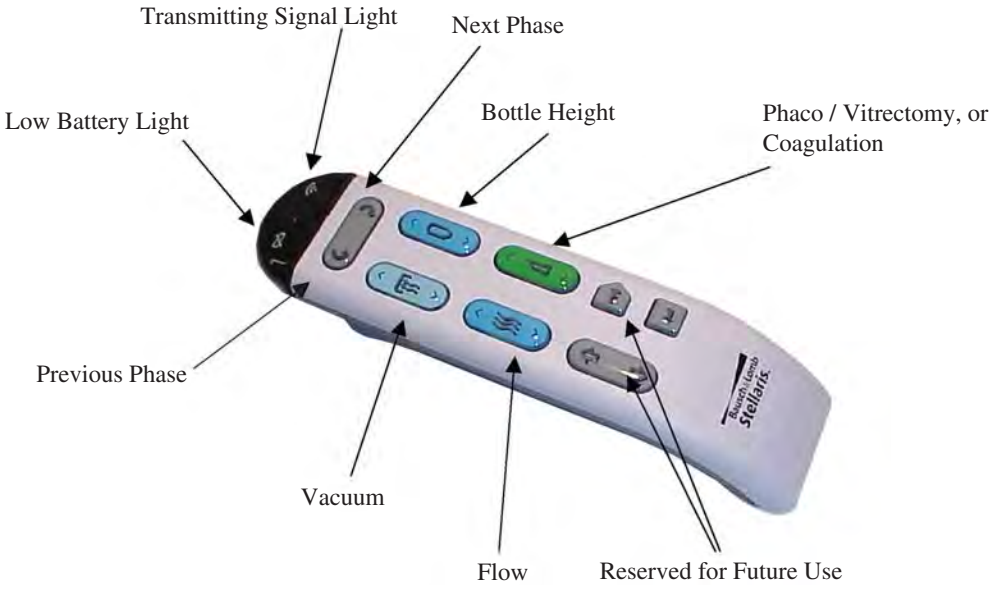
The maximum IV Pole height should be set when installing the ***Stellaris***® Vision Enhancement System in a particular medical facility. You can do this using the programming interface (see Chapter 3).

4.4. Remote Control

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 the 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 the figure below.

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.



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.*

4.5. Advanced Vacuum System Fluidics

Note: *Each **Stellaris®** Vision Enhancement System has either an Advanced Vacuum Fluidics or an Advanced Flow Fluidics function.*

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

With your ***Stellaris®*** Vision Enhancement System, the irrigation line from an inverted bottle of Balanced Salt Solution is integrated into the tubing manifold at the top of the vacuum cassette. The delivery pressure of the Balanced Salt Solution is adjusted by varying the height of the bottle in relation to the patient's eye. For pressurized infusion, pressure is determined by the pressure setting of the air pump (see page 4-31 for details). On/off control of irrigation is accomplished through the footpedal, or via the touch screen.

As the cassette fills up, the system will give a Cassette Nearing Full warning. When the fluid level reaches the maximum capacity, the system will give a Cassette Full warning. After this second warning, the aspiration function will be disabled. You must replace the fluidics cassette that is either empty or nearly empty and reprime before aspiration will be re-enabled.

Irrigation-Aspiration

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

Note: *Tubing must not be pulled 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 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 vacuum build up 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.

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, and is generated, in the Advanced Vacuum system, by irrigation pressure.

The ***Stellaris***® Vision Enhancement System's Advanced Vacuum system is designed for use with continuous reflux, but for any surgical mode reflux may be programmed to be either continuous or off (none). If enabled, the reflux feature is activated by inward movement of the footpedal in all aspiration modes.

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 much longer. The response can be changed through the programming interface (see Chapter 3) or the **Fluidics More Screen** (see page 2-7). The ***Stellaris***® Vision Enhancement System 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.

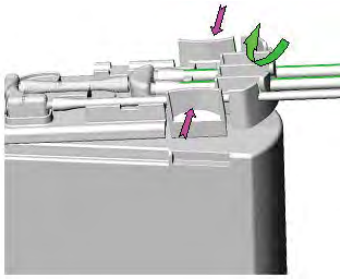
WARNING: ***Improper reassembly of tubing manifold to the cassette may result in inadequate system performance.***

Instructions To Empty Cassette

The ***Stellaris***® Vision Enhancement System's Advanced Vacuum Fluidics cassette can be emptied during operation with following instructions:

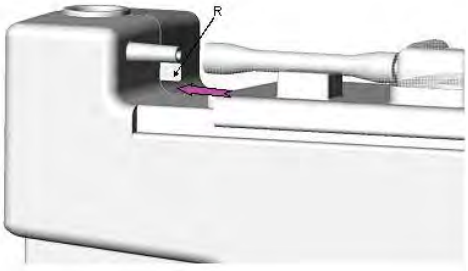
1. Stop operation and protects handpiece with test chamber.
2. Close irrigation clamp.
3. Select "Setup" from surgical screen to transition to Setup screen.
4. Select "Eject Cassette" from the setup screen.
5. Remove cassette from the system.
6. Detach the aspiration tubing that connects to the cassette. Hold aspiration tubing very close to the connector to facilitate removal (Pink arrows).

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

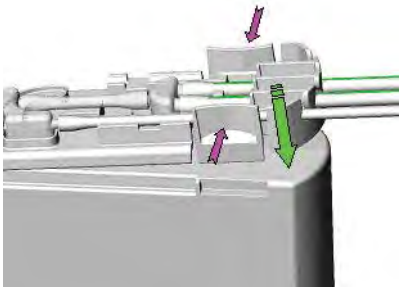


8. Drain fluid out of the cassette.

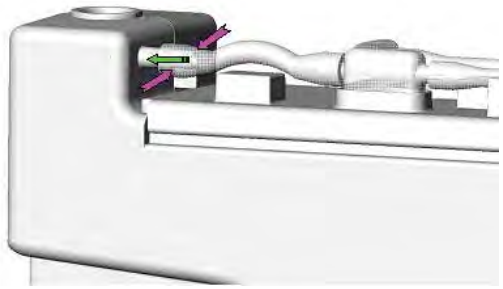
9. Assemble tubing manifold by first sliding the front end under the cassette retainer (R).



10. Press the manifold to engage manifold latch.



11. Connect aspiration tubing to the cassette connector.



12. Insert cassette to the system.
13. Release irrigation clamp.
14. Select “Prime Only” on the Setup screen to re-prime the cassette before use.

4.6. Advanced Flow 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 Vision Enhancement System aspiration port. Failure to follow this procedure may result in serious and permanent patient injury.***

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

The ***Stellaris***® Vision Enhancement System's Advanced Flow system consists of a retractable cartridge drawer, a vacuum transducer system, a drive motor, control solenoids and electronics.

The Advanced Flow System cartridge is manually loaded and sits tightly in the drawer slot. Select **Close Drawer** to engage the device.

Irrigation-Aspiration Mode

Irrigation

With your ***Stellaris***® Vision Enhancement System's Advanced Flow system, the irrigation line from an inverted bottle of Balanced Salt Solution is attached through the Advanced Flow System cartridge to the surgical handpiece. The delivery pressure of the irrigation solution is adjusted by varying the height of the bottle in relation to the patient's eye. On/off control of irrigation is accomplished through the Foot Control or touch screen. The inward yaw action of the Foot Control will always provide Continuous Reflux in the irrigation mode, overriding the global reflux option that applies in all other modes.

Irrigation/Aspiration

A single aspiration port, driven by the disposable Advanced Flow System cartridge, provides flow control of aspiration.

Flow Control: Aspiration in the flow mode of operation will provide flow rates from 1 ml/min. to 60 ml/min. in 1 ml/min. increments and vacuum limit control from 0 mmHg to 650 mmHg in 5 mmHg increments utilizing the up/down spin buttons. Aspiration limits are set via the touch screen and adjusted via the Foot Control or remote control.

There are two modes of flow control: Fixed Flow Linear Vacuum Limit and Linear Flow Fixed Vacuum Limit.

Capsule Polish

The capsule polish function is typically accomplished with a lower vacuum limit setting than standard settings. These settings may be customized to allow quick entry into a lower vacuum limit 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 higher vacuum limit level as explained in Chapter 3.

Venting

The ***Advanced 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 vacuum build up 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.

Reflux

Aspiration is applied via the Advanced Flow Pump and subsequently to the surgeon's handpiece via a tube set. Reflux applies a momentary pressure through the aspiration line to clear the aspiration port of lodged material. An additional reflux option is continuous reflux used to ease needle insertion through the incision. The reflux feature is applied with the inward rotation of the footpedal in all aspiration modes. Yaw inward the footpedal initiates the reflux cycle, releasing it completes the cycle. Subsequent reflux cycles may be applied with repeated footpedal operations. Single reflux is limited. Forward revolutions of the pump are required before reflux may be actuated.

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 much longer. The response can be changed through the programming interface (see Chapter 3) or the **Footpedal More Screen** (see page 2-10).

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. In Region 2, aspiration will be either fixed or proportional to footpedal travel, as programmed. The maximum level is set by the **Max Flow**, **Max Vacuum**, and **Vacuum Response Time** setting on the touch screen. The **Actual Flow** and **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

Refer to detailed instructions on page 4-14. The only difference when using the Advanced Flow system is that the fluid collection device is a bag instead of a cassette, and you must select **Close Drawer** on the **Setup Screen** after inserting the cartridge.

Vitrectomy Mode

Similar to the Vacuum Fluidic module, the ***Stellaris***® Vision Enhancement System Advanced Flow module offers a High Speed pneumatic vitrectomy cutter. The pneumatic vitrectomy cutter uses pressurized air generated from an internal pump to drive the pneumatically operated guillotine type vitrectomy cutter. The vacuum fluidic module provides aspiration to draw the vitreous material into the port and vitreous is then cut and aspirated into the disposable collection container through the attached tubing.

For detailed instructions for setup and use, see page 4-17.

4.7. 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 Vision Enhancement System 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: *Do not use* ***StellarisPC***® Vision Enhancement System *posterior or combined packs on a Stellaris system.*

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

a. Turn Power on.

b. Press any button on the Foot Control and wait until the right light turns solid green indicting wireless communication has been established.

c. Select **Surgeon's Name** and select **Confirm**.

d. Open disposables pack and insert fluid collection system:

- If using a vacuum system, 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 turn solid when the system captures the cassette.
- If using a flow system, insert the fluidics cartridge and select **Close Drawer**.

System will start cassette vacuum test or cartridge calibration automatically.

e. After vacuum test or cartridge calibration completes, the **Setup Screen** will display with **Prime and Tune** as the highlighted function.

f. Spike the BSS bottle and hang it at the desired bottle height.

Additional step if pressurized infusion is used:

Connect the Air Tubing Line (D4600A) to the vent port at the bottle spike and the other end with air filter to the Stellaris 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.

g. Connect tubing to the I/A handpiece. Select **Show Me Steps** for animated setup guide, if necessary.

h. Ensure the irrigation clamp is open and select irrigation **OFF** to turn the flow on and allow irrigation to fill the tubing up to the handpieces. See page 4-5 for details on the irrigation flow button (activating the Fill button will turn flow on for 20 seconds).

i. Fill the test chamber with irrigating solution, then slide over the tip of the handpiece.

j. Select **Prime Only**. A vacuum test is part of the priming cycle.

k. 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: *Hold the handpiece tip towards the ceiling while priming the irrigation line to insure all air has been removed.*

Use

a. Select the **I/A** mode on the clock menu.

b. Use the spin control buttons to set the desired aspiration vacuum.

c. Confirm that irrigation and aspiration are balanced by pinching the irrigation line and observing that the test chamber dimples.

d. The system is now ready for Irrigation/Aspiration.

Note: *See Chapter 5 for cleaning and sterilization requirements when surgery is completed.*

4.8. Vitrectomy Function

The ***Stellaris***® Vision Enhancement System supports both a pneumatic (standard) and a high-speed electric (optional) vitrectomy cutter. The pneumatic vitrectomy cutter uses pressurized air generated by an internal compressor 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.

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 800 cuts per minute in 30 cuts per minute increments utilizing the up/down spin buttons, or one cut per minute increments utilizing the numeric keypad.

Dual Linear Cut

- Pneumatic cutter: The control may be adjusted to provide a linear cutting speed from 30 to 800 cuts per minute in 30 cuts per minute increments utilizing the up/down spin buttons, or one cut per minute increments utilizing the numeric keypad.

WARNING: ***Never intentionally modify handpieces or tips, such as do not bend, cut or engrave, as they could break or malfunction.***

Planned 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® 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.*

a. Turn Power on.

b. Press any button on the Foot Control and wait until the ready light turns solid green, indicating wireless communication has been established.

c. Select **Surgeon's Name** and select **Confirm**.

d. Open disposables pack and insert fluid collection system:

- If using a vacuum system, 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 turn solid when the system captures the cassette.
- If using a flow system, insert the fluidics cartridge and select **Close Drawer.**

System will start cassette vacuum test or cartridge calibration automatically.

e. Spike the Balanced Salt Solution bottle and hang it at the desired bottle height.

Additional step if pressurized infusion is used:

Connect the Air Tubing Line (D4600A) to the vent port at the bottle spike and the other end with air filter to the Stellaris 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.

f. 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.

g. Open appropriate vitrectomy cutter pack. If you are using the pneumatic cutter, connect tubing and the actuation line to the pneumatic port on the ***Stellaris®*** Vision Enhancement System.

h. 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.

i. Ensure the irrigation clamp is opened and the tip is immersed in irrigation solution, then select **Cutter Test**.

j. After successful test, select **Advance to Surgery** and the **Main Surgical Screen** will appear.

Use

a. Select **Vit** from the clock menu. **The Show Me Steps** animated setup guide will appear.

b. Use the spin control buttons to set the desired vacuum level and cut rate.

c. 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.

d. For Linear cut vitrectomy, activate the cutter by outward yaw travel of the footpedal in Region 2.

e. For Reflux (if enabled), yaw the footpedal inward.

Unplanned Vitrectomy Setup

In the event anterior vitrectomy is needed during phaco surgery:

a. 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.

b. Open vitrectomy cutter pack. Connect aspiration tubing and the actuation line to the pneumatic port on the ***Stellaris***® Vision Enhancement System.

c. 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.

d. After a successful test, select **Advance to Surgery** and select the **Vit** phase from the clock menu.

Foot Control of Vitrectomy Mode

In the anterior mode, irrigation is supported by a single gravity fed irrigation system or Pressurized Infusion in which the irrigation tubing is routed through a pinch valve. 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.

At default, the vitrectomy cutter is set at On.

4.9. 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.

The ***Stellaris***® phaco handpiece is designed with SureLock®, a luer lock irrigation connector, to prevent tubing coming off during surgery and uses Attune™ energy management system, based on 6-crystal technology and advanced power modulation software (see programming section for details).

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 actual value are shown on the **Surgical Screen** display. The status bar (see page 2-14), visible at the top center of the surgical screen, may 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 2-13) 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 pulse per second (PPS) increments.

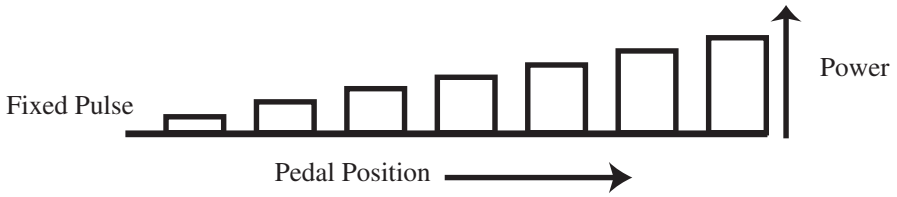
The pulse rate control does not adjust the ultrasound power. The control adjusts the number of cycles of ultrasound power that occur during a one second time interval. In **Pulsed Ultrasound Mode**, the phaco handpiece is energized for the portion of each time interval as programmed by the **Duty Cycle** setting.

Burst Mode Ultrasound

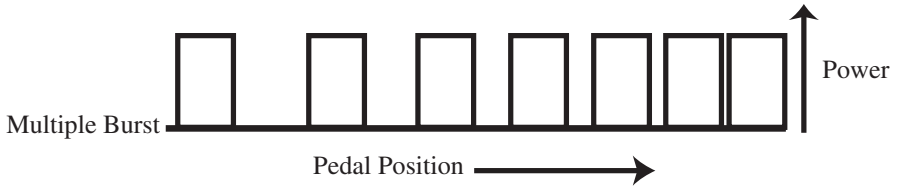
Burst mode ultrasound is an anterior only mode to provide minimal ultrasound energy. Ultrasound is applied in either single or multiple burst using a fixed power or in fixed burst using a linear control of power. The burst duration can range from 2 to 600 msec.

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.

When fixed pulse mode is selected, the pulse duration and interval may be selected with the screen settings. 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.



Ultrasound Submode

Up to three sets of ultrasound modulation settings may be stored with each ultrasound mode (see Description of Ultrasound Modes, page 4-22). 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 4-23).*

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

Note: *Do not use* ***StellarisPC*** Vision Enhancement System *posterior or combined packs on a Stellaris system.*

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.*

a. Turn Power on.

b. Press any button on the Foot Control and wait until the right light turns solid green indicting wireless communication has been established.

c. Select Surgeon's Name and select **Confirm**.

d. Open disposables pack and insert fluid collection system:

- If using a vacuum system, 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 turn solid when the system captures the cassette.
- If using a flow system, insert the fluidics cartridge and select **Close Drawer.**

System will start cassette vacuum test or cartridge calibration automatically.

e. After vacuum test or cartridge calibration completes, the **Setup Screen** will appear with **Prime and Tune** as the highlighted function.

f. Spike the Balanced Salt Solution bottle and hang it at the desired bottle height.

Additional step if pressurized infusion is used:

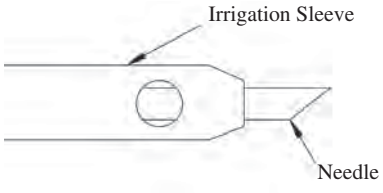
Connect the Air Tubing Line (D4600A) to the vent port at the bottle spike and the other end with air filter to the Stellaris air output connector. Switch on the air pump from the system setup screen, the control is at the upper right hand of the screen. The output connector will remain lit when it is at commanded pressure, and blink on and off when it is not at the commanded pressure.

g. Connect tubing to phaco handpiece. Select **Show Me Steps** for animated setup guide if necessary.

h. Plug handpiece connector to the machine (Second connector from the top).

i. Thread and firmly secure the ultrasound needle onto the ultrasound handpiece using a needle wrench.

j. 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)



k. Ensure the irrigation clamp is open and select irrigation **Off** to turn flow on, and allow the flow to fill the irrigation tubing up to the handpieces. See page 4-5 for details on the irrigation flow button (activate the Fill button with turn flow on for 20 seconds).

l. Fill the test chamber with irrigating solution, then slide over the tip of the handpiece.

m. Select **Prime and Tune**. A vacuum test is part of the priming cycle.

n. 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.

Phacoemulsification Operation

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 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 Vision Enhancement System. Now you are ready to set the operating parameters.

a. From the **Main Surgical Screen**, select the desired surgical mode from the clock menu.

b. 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 canceled when tuning has been completed or canceled. Re-tune if either the handpiece or ultrasound needle is changed.*

c. 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).

d. 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.*

4.10. Coagulation Function

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.***

CAUTION: ***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.***

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

Note: *When the device and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating high frequency current limiting devices are recommended.*

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

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

Note: *For explanation of Dual Linear Foot Control see page 2-29.*

Bipolar coagulation is accomplished with the ***Stellaris***® 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.

Coagulation modes available are:

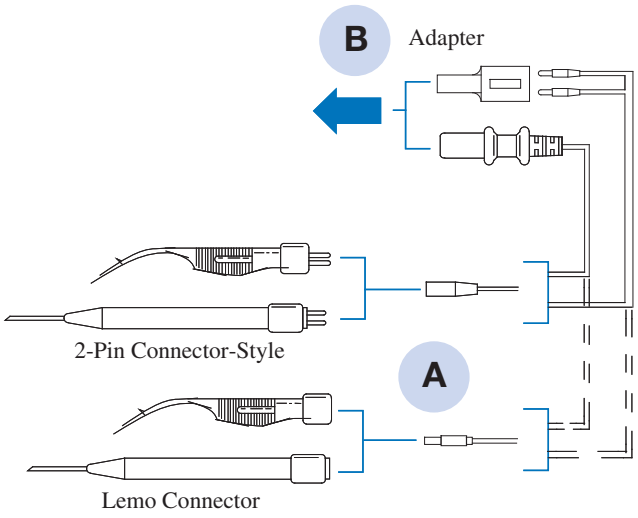
- **Fixed coagulation mode**—Provides an adjustable output between 0% and 100%. Power levels are set via spin button control. Fixed coagulation may be actuated by any Foot Control button, if programmed. Fixed coagulation remains activated as long as the button remains depressed.
- **Linear coagulation 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.*



a. Connect the desired bipolar forceps or pencil to its cable. You may need to use an adapter.

b. Connect the bipolar cable to the coagulation connector.

c. Use the spin buttons to adjust the percentage of coagulation power desired.

d. 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.

e. If programmed, a tone will signify bipolar coagulation operation.

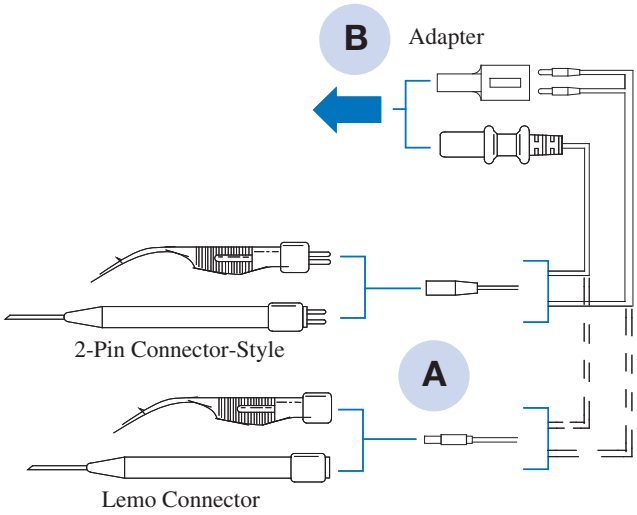
Linear Coagulation Setup and Use

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.*



a. Connect the desired bipolar forceps or pencil to its cable. The use of an adapter may be necessary.

b. Connect the bipolar cable to the coagulation electrical connector, if required.

c. Select **Coag** from the clock menu.

d. Use the spin buttons to adjust the **Max Coagulation** power desired.

e. 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.

f. A tone will signify bipolar coagulation operation if programmed.

4.11. DigiFlow™ Pressurized Infusion Function

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

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 pressurized infusion, hang the bottle so that the drip chamber is close to the patient eye level.*

The Pressurized Infusion function infuses a preset air pressure to pressurize the Balanced Salt Solution bottle. The pressure generated would force Balanced Salt Solution into the eye to maintain a preset intraocular pressure (IOP). The air pressure is generated by a compressor in the system and air is infused into the bottle through air tubing. The use of Pressurized Infusion function would replace the gravity infusion that depends on bottle height. The preset air pressure may be adjusted from the system screen display.

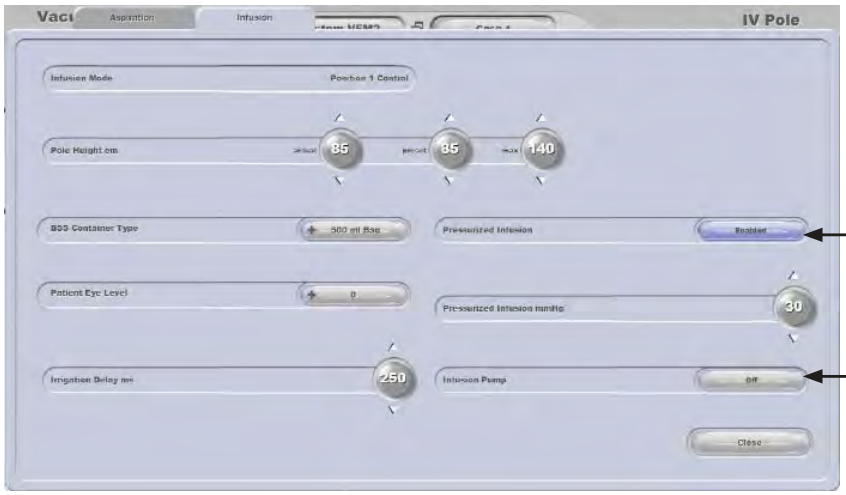
Pressurized Infusion is an optional function of Stellaris. The function could be built into the system according to the customer order or the function could be added into existing field systems with an upgrade. A zero level bottle hanger (BL4363) is an optional accessory that allows the Balanced Salt Solution drip chamber to be level with the aspiration port.

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 Pressurized Infusion to "Enabled." See diagram below.



Pressurized Infusion Enabled/Disabled

Infusion Pump On/Off

5. Selecting Infusion Pump to "On" will automatically activate the air pump whenever the surgeon file is selected for surgery.
6. Pressurized Infusion settings and function could be saved with **"Case" More 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 1.
2. Connect the Air Tubing Line male connector to the bottle spike venting port (A) in Figure 2.
3. Connect the Air Tubing Line filter to the microsurgical system air source (B) in Figure 2.
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 1

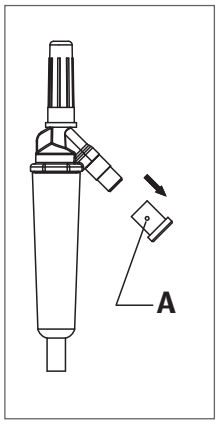
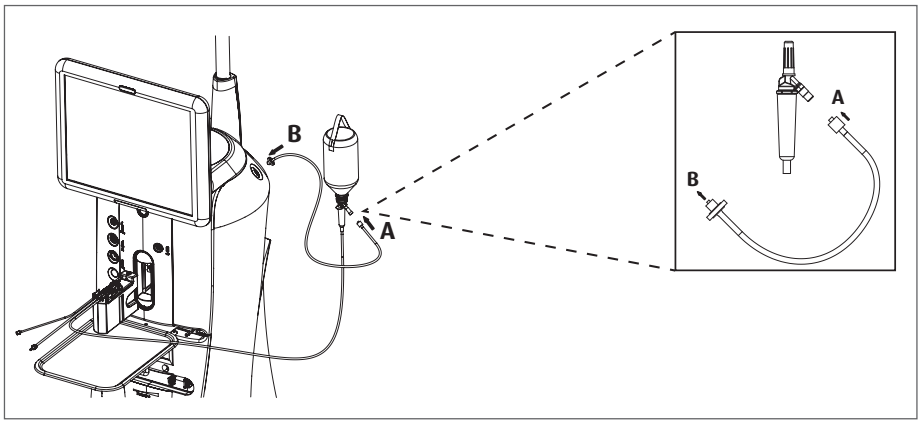


Figure 2



Note: *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.*

Cleaning and Sterilization Requirements

This chapter provides instructions for cleaning the ***Stellaris***® 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.*

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

If the system has an Advanced Vacuum Fluidics module, you should clean the fluid level detection lens every three months with a 4 x 4 in. gauze pad and isopropyl alcohol.

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: ***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.***

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

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.

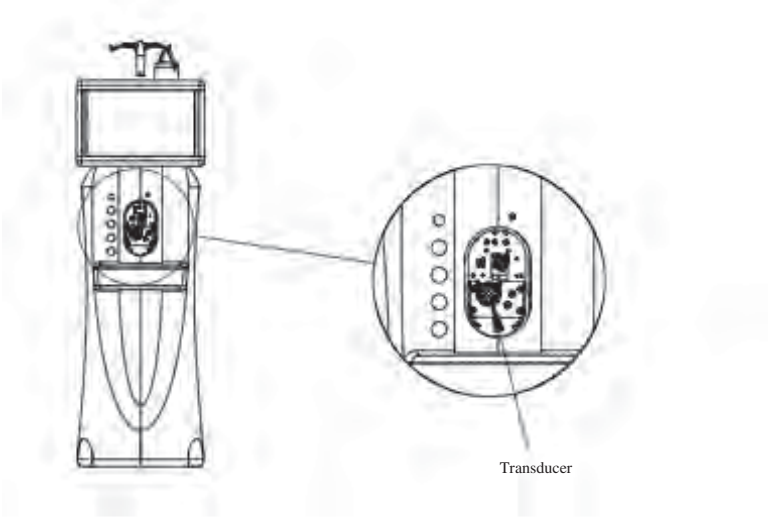
The forceps and reusable cables may be sterilized as follows:

- **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. Advanced Flow Fluidics Transducer

The transducer should be cleaned on a weekly basis. Refer to figure for the following instructions.



A. The ***Stellaris***® Vision Enhancement System must be in an Advanced Flow System operating mode.

B. Open the drawer by pressing the **Open Drawer** button.

C. Use an absorbent sponge (*SuperSorb™* sponge) moistened with isopropyl alcohol to remove contaminant or saline from the transducer surfaces shown.

D. Use a dry absorbent sponge to remove moisture from the transducer surfaces.

Note: *Transducer must be thoroughly dry before using this function.*

5.4. 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

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 50cc (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.

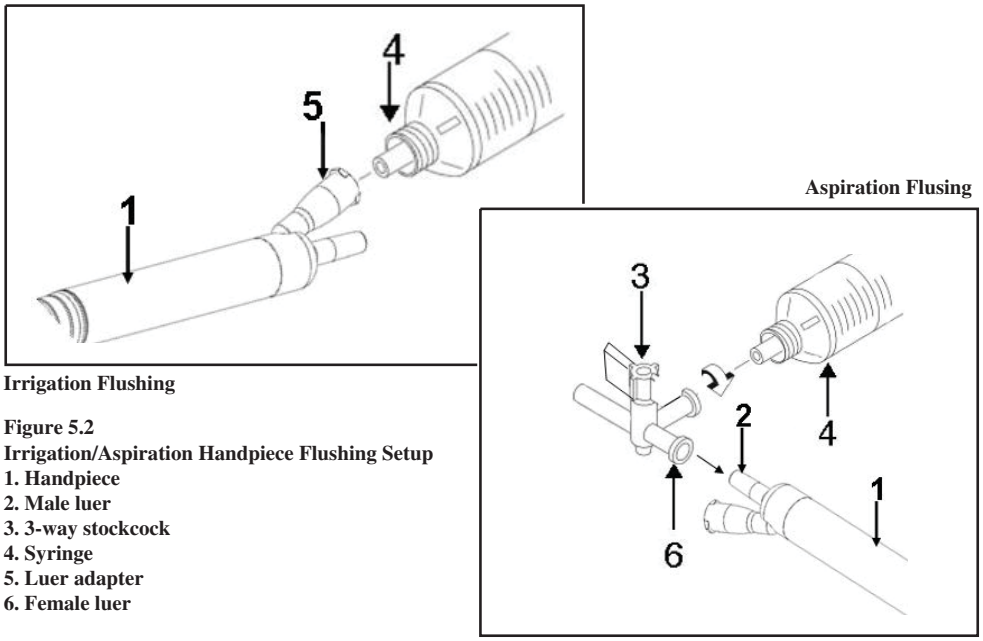


Figure 5.2
Irrigation/Aspiration Handpiece Flushing Setup
1. Handpiece
2. Male luer
3. 3-way stockcock
4. Syringe
5. Luer adapter
6. Female luer

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 50cc (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: ***After sterilization allow 20 minutes for the handpiece to cool before it is used.***

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.***

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.

5.5. Phacoemulsification 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 (200kPa, 2bar).*

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.*

Note: *Remove the rubber plugs from the tip of the handpiece (one plug) and lumen ports (two plugs) at the end of the handpiece before autoclaving and placing into service for the first time.*

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 below. 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 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.

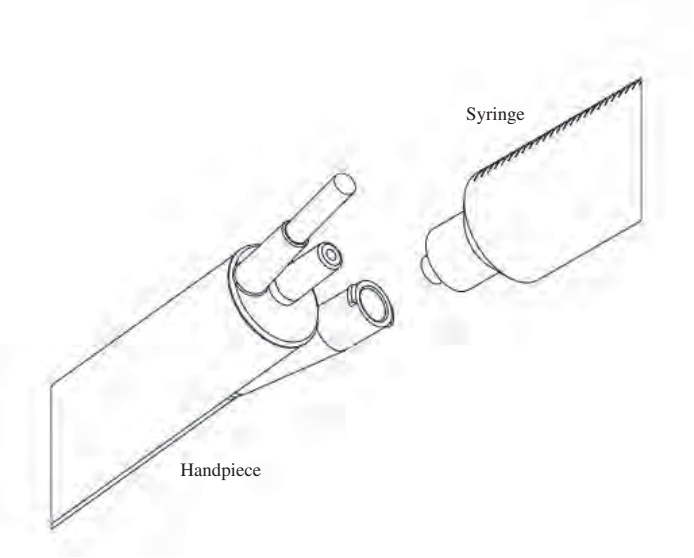
Note: *For users in the United Kingdom, please refer to page 5-12 for special cleaning and sterilization instructions before proceeding.*

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).*

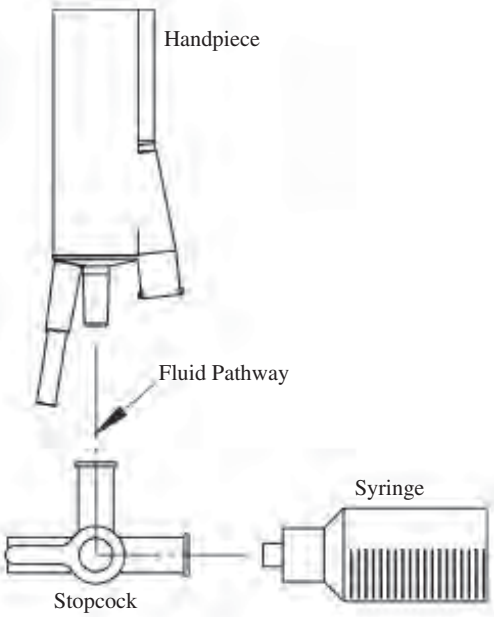
C. Flush the irrigation lumen as follows (see figure below):

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 50cc (ml) mark.
2. Connect the end of the syringe to the infusion line on the phaco handpiece.
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.



D. Flush the aspiration lumen as follows (see figure below):

1. From the rear of the handpiece, insert aspiration brush (provided in the ***CX7120 Universal Maintenance Kit***) into the aspiration fitting.
2. Push the brush bristles through the handpiece aspiration lumen, then pull the brush back out. 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 50cc (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.



Needle Cleaning Instructions (For reusable needle only)

A. Use a handpiece that was cleaned but not sterilized. Attach the needle and a irrigation sleeve to the handpiece. See page 5-5.

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.

Phacoemulsification 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.***

WARNING: ***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.***

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.

The minimum requirements for sterilization are:

Note: *For users in the United Kingdom, please refer to page 5-12 for special cleaning and sterilization instructions before proceeding.*

- **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.

5.6. Special Instructions for United Kingdom Users

Flush aspiration lumen (phaco) as follows (see figure on page 5-10):

A. 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 50cc (ml) mark.

B. Connect the syringe to the center stopcock fitting.

C. Rotate the stopcock lever to allow flow to the female luer fitting.

D. Connect the stopcock female luer fitting to the handpiece aspiration fitting.

E. 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.

F. Repeat Steps A through E at least three times.

G. Prepare a neutral pH detergent solution using warm distilled or deionized water, per the detergent manufacturer's labeling instructions.

H. Immerse aspiration brush (part of CX7120 ***Universal Maintenance Kit***) into the detergent solution sufficiently to cover all of the brush bristles.

I. From the rear of the handpiece, insert aspiration brush into the aspiration fitting.

J. 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.

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 50cc (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, 0° C./+3° C/206.8 kPa.

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

Automated Cleaning

1. Inspect the ***Stellaris®*** Vision Enhancement System's Phacoemulsification 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 or a disposable cloth or paper wipe while wearing appropriate personal protective equipment may be necessary. It is recommended that the ***Stellaris®*** Vision Enhancement System's Phacoemulsification Handpiece be reprocessed as soon as is reasonably practical following use.

2. Connect the lumens of the ***Stellaris***® Vision Enhancement System's Phacoemulsification Handpiece to the lumen connectors or adaptors of the washer to allow detergent and rinse water to circulate freely through the lumens of the ***Stellaris***® Vision Enhancement System's Phacoemulsification Handpiece.
3. Ensure that the ***Stellaris***® Vision Enhancement System's Phacoemulsification Handpiece is placed within the washer such that all surfaces of the ***Stellaris***® Vision Enhancement System's Phacoemulsification Handpiece components are accessible to the detergent and rinse water during cleaning and the ***Stellaris***® Vision Enhancement System's Phacoemulsification Handpiece does not move about excessively during cleaning.
4. Process the ***Stellaris***® Vision Enhancement System's Phacoemulsification Handpiece according to the conditions listed below. Cleaning times and conditions may be adjusted based on the degree of soiling present on the ***Stellaris***® Vision Enhancement System's Phacoemulsification 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***® Vision Enhancement System's Phacoemulsification 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***® Vision Enhancement System's Phacoemulsification Handpiece for cleanliness, any evidence of damage, and proper operation. If residual soiling is apparent, reprocess the ***Stellaris***® Vision Enhancement System's Phacoemulsification Handpiece as indicated above.

5.7. 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.

Setup

This chapter provides information for setting up your ***Stellaris***® Vision Enhancement System and making necessary connections.

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

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).***

6.1. Setup Instructions

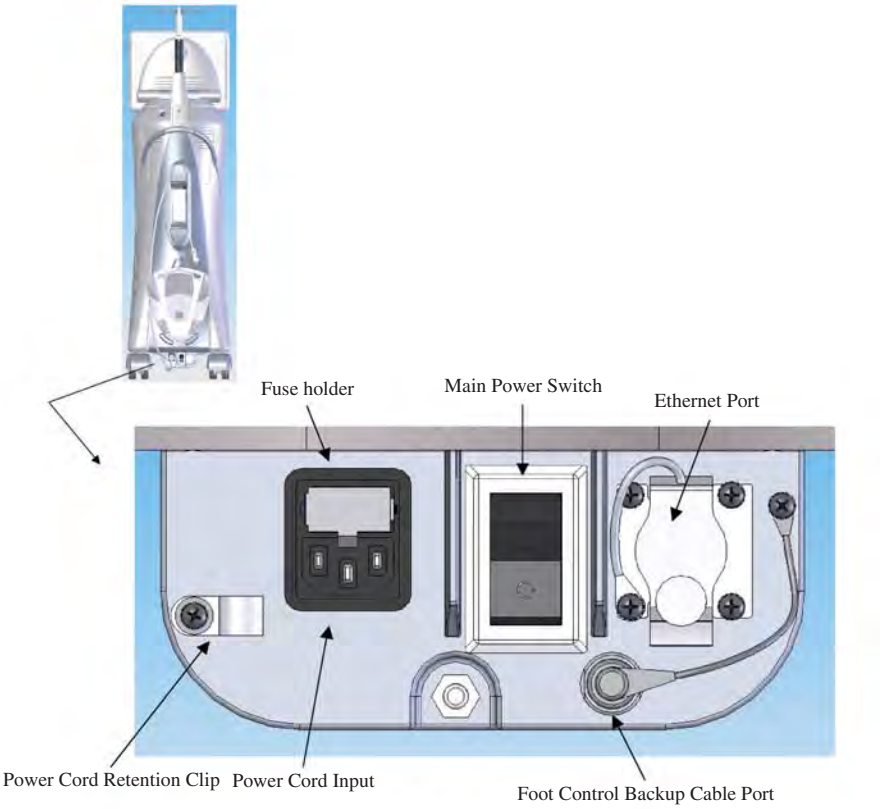
Before unpacking, inspect all packages for damage. Report any damage from shipping to the carrier. Before discarding packaging material, assure all parts are accounted for. Smaller parts may be attached to packing materials.

6.2. Connections and Setup

The ***Stellaris***® Vision Enhancement System is pre-configured at the factory to minimize setup and installation requirements. The following information explains the connections for the Foot Control, power cable and MMC (optional).

Power Cable

a. Connect the power cable at the bottom rear of the system.



Ethernet Cable

Connect the Ethernet cable from the back of the ***Stellaris***® 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.

Foot Control

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

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

Note: *The out-of-factory Wireless System Setup is "Disabled." Software upgrade will also reset the Wireless System Setup to "Disabled." To setup wireless operation, follow steps of "Wireless Foot Control Operations System Setup" a section provided in Chapter 2.*

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

To set up the ***Stellaris***® Vision Enhancement System:

a. Plug the power cord into the wall.

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

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

d. The battery in the Foot Control must charge at least overnight before it can be used wirelessly. To charge the battery, you can use one of three methods. See page 2-21. To use the system immediately, use the provided cable to connect the Foot Control directly to the ***Stellaris***® Vision Enhancement System.

e. If you purchased the MMC, see page 6-4 for setup details.

6.3. Multimedia Center (MMC) (optional accessory)

The Multimedia Center (MMC) is used to overlay the surgical parameters output from the ***Stellaris***® 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.

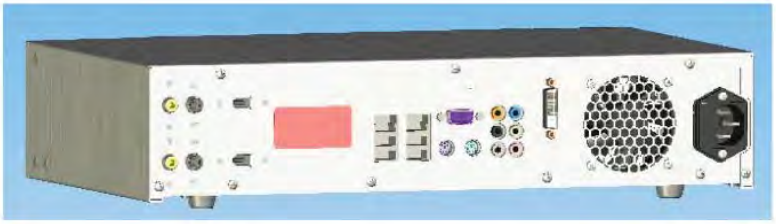
Installation

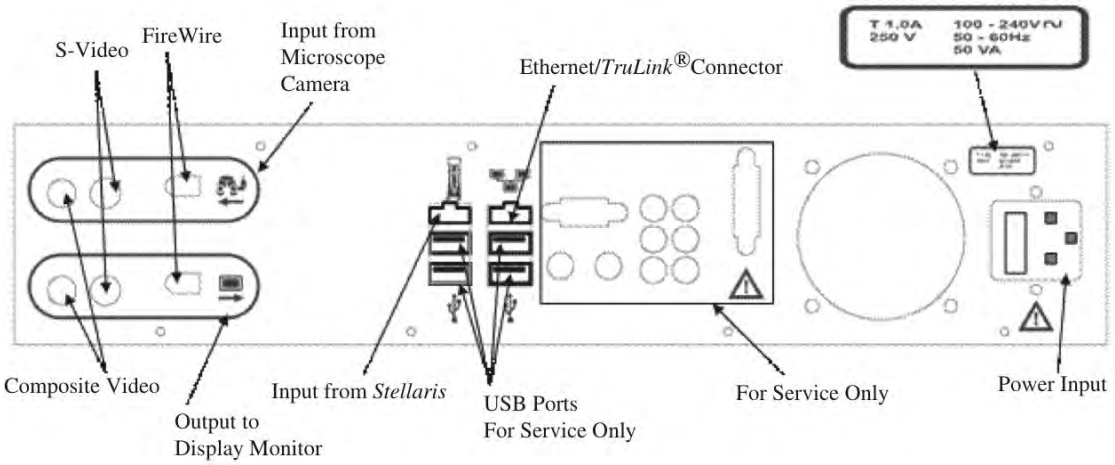
1. Assure all equipment is turned off before making any connections. Position the MMC (L) on a flat surface near the video monitor and/or recorder to be used.

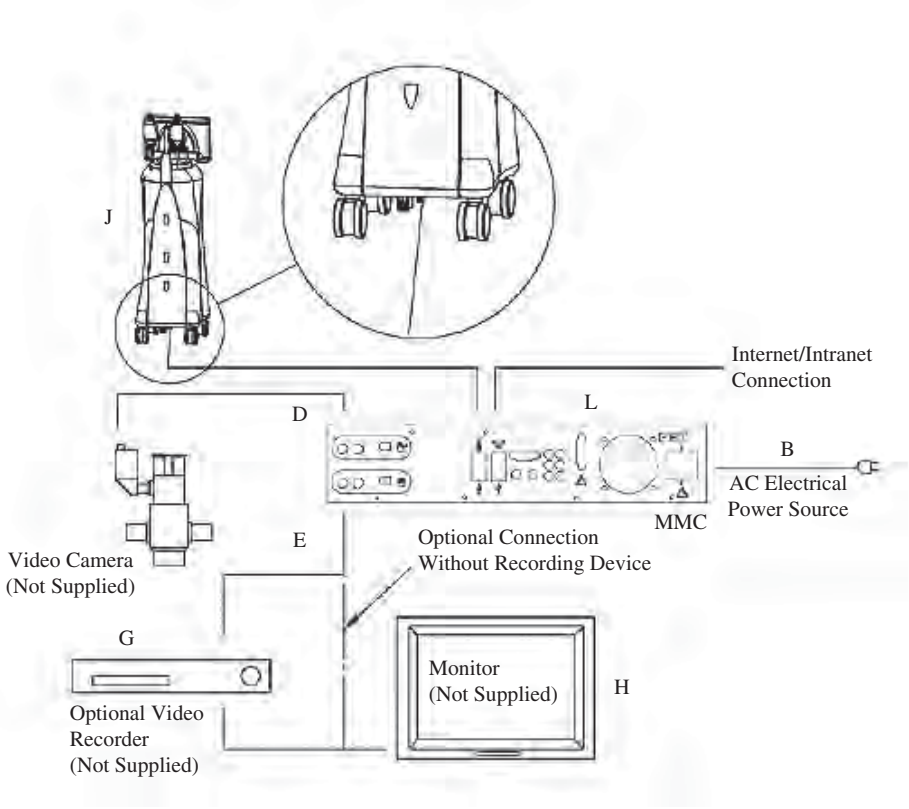
WARNING: ***The MMC is not to be placed inside the patient environment.***

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.***







2. 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.***

3. 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.*

4. 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.***

5. Attach the Ethernet cable on the back of the ***Stellaris***® 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***® icon.

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

6. Turn on the microscope camera and the video recorder and/or monitor.
7. Verify that the image captured by the surgical microscope camera is displayed on the video monitor. With the MMC powered off, the MMC is operating in a video bypass mode; thus the video input is directly connected to the video output.
8. Turn on the MMC by pressing the power on/off switch. The power indicator on the MMC front panel will change from a bright blue to a dimmer blue.

Note: *Allow the MMC to stabilize to room temperature before energizing.*

9. After approximately one minute, verify that the Bausch + Lomb logo appears in the lower right corner of the video image on the monitor.
10. Turn on the ***Stellaris***® Vision Enhancement System as directed in Chapter 1. The ***Stellaris***® Vision Enhancement System mode and settings information will not be displayed until a surgical mode is entered.
11. Verify that the ***Stellaris***® Vision Enhancement System's mode and setting information is overlaying the video image from the microscope camera on the video monitor.

Video Capture

The MMC has FireWire DCAM output capability, which can be used to send video to a personal computer for video capture. To take advantage of this capability, you must install software to support your video capture software. This software may be obtained by contacting Bausch + Lomb Global Product Support.

Note: *A six foot FireWire cable is provided with the MMC module.*

Troubleshooting and Maintenance

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

Note: *Preventative scheduled maintenance is recommended once a year to insure that the **Stellaris®** Vision Enhancement System meets it 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, 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. 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 Global Product Support (see Chapter 8).

7.2. 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, or 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®*** 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 9).

A blown fuse may be indicated by the following conditions:

- With the system off, using a known good outlet, 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***® Vision Enhancement System. The presence of the power cord will physically prevent the removal of the fuse drawer.

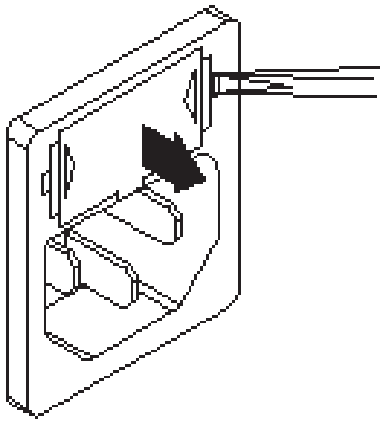
b. Using a flat-blade screwdriver, turn the fuse holder counter-clockwise, and pull outward. One style of fuse holder will come partially out and the fuse will drop out. On the other style, the fuse is retained by clips on the back.

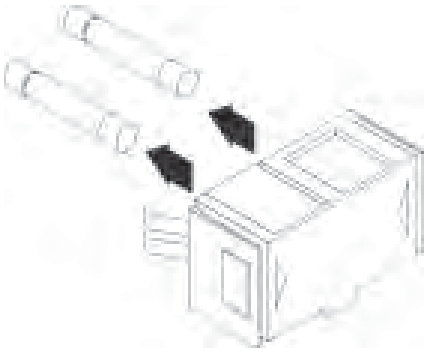
c. Reinstall the fuse holder, and lock it by turning clockwise.

d. Snap the fuse drawer back into place.

e. Replace the cord and the system should be ready to run again.

Fuse Holder Location





7.3. Informational and Warning Messages

All messages displayed by the user interface are uniform in their appearance. However, the box will have a red border if a safety related condition is present. When an event occurs, the system will sound a tone and display a pop-up window with the 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.

Prefix	Trouble Area
AFM	Flow Fluidics Module
BPS	Power Supply Module
CPX	Compressor Module
EIV	IV Pole 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

Flow Fluidics Module Messages

ID	Text Message	Suggested Action(s)
AFM01	The flow fluidics module was not detected in the system. Surgical mode with the flow fluidics module is not available.	SG01
AFM02	The flow fluidics module software version is not compatible with this software version. Surgical mode is not available.	SG02
AFM03	The flow fluidics module has failed to respond to a settings command. The module settings have been re-sent to the module.	SG03 SG04
AFM04	The flow fluidics module has reset. The module settings have been re-sent to the module.	SG03 SG04
AFM05	The flow fluidics module does not have valid factory calibration data. Surgical mode with the flow fluidics module is not available.	SG07 SG08
AFM06	The fluidics pump motor may have failed.	SG09 SG10
AFM07	The flow fluidics module cartridge vacuum sensor test has not been attempted.	SG12
AFM08	The flow fluidics module cartridge vacuum sensor test is in progress.	SG14
AFM09	The flow fluidics module cartridge vacuum sensor test has failed.	SG16 SG17 SG18 SG04
AFM10	The flow fluidics module vacuum sensor has failed.	SG19
AFM11	System priming has not been attempted.	SG20
AFM12	System priming is in progress.	SG21
AFM13	System priming has failed.	SG22 SG24 SG04
AFM14	The flow fluidics module vitrectomy cutter output pressure is low. Vitrectomy cutter may not be cutting.	SG30 SG31 SG04
AFM16	Please insert the flow fluidics cartridge.	SG80

Power Supply Module Messages

ID	Text Message	Suggested Action(s)
BPS01	The power module battery has exceeded the recommended number of charge cycles. Battery back-up of the system may not be available.	SG66
BPS02	The power supply was not detected in the system.	SG01
BPS03	The power supply software version is not compatible with this software version. Surgical mode is not available.	SG02
BPS04	The power supply has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04
BPS05	The power supply has reset. The module settings have been re-sent to the module.	SG04
BPS06	The power module back-up battery temperature is higher than expected.	SG67 SG04
BPS07	The power module temperature is higher than expected.	SG67 SG04
BPS08	The power module is at an over temperature condition. System shutdown is imminent.	SG67 SG04
BPS10	The power module battery is failing to charge properly. Battery back-up of the system may not be available.	SG69 SG66
BPS11	Main power input has been lost. System is running on back up battery power. Surgical functions are inhibited. System will shut down shortly if main power input is not restored.	SG81 SG04

Compressor Module Messages

ID	Text Message	Suggested Action(s)
CPX01	The compressor module was not detected in the system. Surgical mode is not available.	SG01
CPX02	The compressor module software version is not compatible with this software version. Surgical mode is not available.	SG02
CPX03	The compressor module has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04
CPX04	The compressor module has reset. The module settings have been re-sent to the module.	SG04
CPX05	The air pressure output is lower than commanded.	SG45 SG44 SG04
CPX06	The air pressure output is higher than commanded.	SG46 SG04
CPX07	The internal air pressure system cannot reach the full pressure expected.	SG31 SG25 SG04
CPX08	The internal vacuum pump has failed.	SG47 SG04

IV Pole Module Messages

ID	Text Message	Suggested Action(s)
EIV01	The IV Pole controller was not detected in the system. The motorized IV Pole function is not available.	SG01
EIV02	The IV Pole controller software version is not compatible with this software version IV Pole function is not available.	SG02
EIV03	The IV Pole controller has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04
EIV04	The IV Pole controller has reset. The module settings have been re-sent to the module.	SG04
EIV05	The IV Pole position cannot be determined.	SG62 SG04
EIV07	The IV Pole is not detecting the home position switch or the IV Pole motor may have failed.	SG62 SG04
EIV08	The IV Pole panel button sensors have failed or the buttons have been activated continuously since being powered on.	SG65 SG64 SG04

MultiMedia Center (MMC) Module Messages

ID	Text Message	Suggested Action(s)
MMC01	The multimedia center was not detected in the system.	SG74 SG73
MMC02	The multimedia center software version is not compatible with this software version. The video overlay function is not available.	SG02
MMC03	The multimedia center has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04

Remote Control Receiver Module Messages

ID	Text Message	Suggested Action(s)
RCR01	The remote control receiver was not detected in the system. Remote control and display backlight control functions are not available.	SG01
RCR02	The remote control receiver software version is not compatible with this software version. Remote Control is not available.	SG02
RCR03	The remote control receiver has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04
RCR04	The remote control receiver has reset. The module settings have been re-sent to the module.	SG04
RCR05	Possible interference with remote control receivers. Remote control function may not be available.	SG71 SG70 SG04
RCR06	The remote control battery level is low. Remote control function may not be available shortly.	SG72 SG71 SG04

User Interface Computer (UIC) Module Messages

ID	Text Message	Suggested Action(s)
UIC01	IV Pole height range is (0)-(1) cm. Note: (0) is IV Pole Min Value and (1) is IV Pole Max Value.	SG75
UIC02	IV Pole height range is (0)-(1) cm. Note: (0) is IV Pole Min Value and (1) is IV Pole Max Value.	SG76
UIC03	Phase/Mode change not allowed while surgical functions in use.	SG77
UIC04	Initialization of surgical system failed. Surgical mode not available.	SG78 SG04

Ultrasound Module Messages

ID	Text Message	Suggested Action(s)
USM01	The ultrasound module was not detected in the system. Ultrasound, coagulation, and electric vitrectomy functions not available.	SG01
USM02	The ultrasound module software version is not compatible with this software version. Ultrasound module functions not available.	SG02
USM03	The ultrasound module has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04
USM04	The ultrasound module has reset. The module settings have been re-sent to the module.	SG04
USM05	The ultrasound handpiece is not connected or detected.	SG48 SG49 SG04
USM06	The ultrasound handpiece has not been tuned.	SG50
USM07	The ultrasound handpiece tuning is in progress.	SG51
USM08	The ultrasound handpiece has failed the tuning process.	SG53 SG52 SG04
USM09	The ultrasound handpiece may have failed or may be failing.	SG54 SG53 SG04
USM10	Coagulation circuit may have failed, potential coagulation output overvoltage condition.	SG56 SG55 SG04
USM11	Coagulation circuit may have failed, potential uncommanded or incorrect coagulation output.	SG56 SG55 SG04
USM12	Incorrect ultrasound handpiece connected.	SG57 SG04
USM13	The electric vitrectomy handpiece is not plugged in to the system.	SG59 SG58 SG04
USM14	The electric vitrectomy handpiece may have failed.	SG61 SG60 SG04
USM15	Unable to read ultrasound handpiece data. Attempt to tune the handpiece to confirm proper operation.	SG53 SG04

Vacuum Fluidics Module Messages

ID	Text Message	Suggested Action(s)
VFM01	The vacuum fluidics module was not detected in the system. Surgical mode with the vacuum fluidics module is not available.	SG01
VFM02	The vacuum fluidics module software version is not compatible with this software version. Surgical mode is not available.	SG02
VFM03	The vacuum fluidics module has failed to respond to a settings command. The module settings have been re-sent to the module.	SG03 SG04
VFM04	The vacuum fluidics module has reset. The module settings have been re-sent to the module.	SG03 SG04
VFM05	The vacuum fluidics module does not have valid factory calibration data. Surgical mode with the vacuum fluidics module is not available.	SG05 SG06
VFM06	The vacuum fluidics module cassette vacuum check has not been attempted.	SG11
VFM07	The vacuum fluidics module cassette vacuum check is in progress.	SG13
VFM08	The vacuum fluidics module cassette vacuum check has failed.	SG11 SG15 SG04
VFM09	System priming has not been attempted.	SG20
VFM10	System priming is in progress.	SG21
VFM11	System priming has failed.	SG22 SG23 SG04
VFM13	The vacuum fluidics module cassette is nearly full.	SG26 SG27
VFM14	The vacuum fluidics cassette is full.	SG28 SG29
VFM15	The vacuum fluidics module vitrectomy cutter output pressure is low. Vitrectomy cutter may not be cutting.	SG30 SG31 SG04
VFM17	Insert the vacuum fluidics cassette.	SG79

Foot Control Module Messages

ID	Text Message	Suggested Action(s)
WFC01	The Foot Control battery has exceeded 300 charge cycles. The Foot Control battery may not provide power for the entire day.	SG32 SG33 SG34
WFC02	The Foot Control does not have valid factory calibration data. Surgical mode is not available.	SG34 SG35
WFC03	The Foot Control is programmed for right footed operation, but is set up for left footed operation.	SG36 SG37
WFC04	The Foot Control is programmed for left footed operation, but is set up for right footed operation.	SG36 SG37
WFC05	The Foot Control center pedal or button sensors have failed or the Foot Control has been activated continuously since being powered on.	SG38 SG34 SG04
WFC08	System not detecting the Foot Control.	SG40 SG33 SG34
WFC09	The Foot Control software version is not compatible with this software version. Surgical mode is not available.	SG34 SG02
WFC10	Foot Control detected on wired cable connection.	SG41
WFC11	Foot Control configuration on wired cable connection has completed successfully.	SG42
WFC12	Foot Control configuration on the wired cable connection has failed.	SG34 SG04
WFC13	The Foot Control battery charge level is low.	SG33
WFC14	The Foot Control battery is nearly discharged.	SG43 SG34
WFC15	The wireless Foot Control signal quality is poor.	SG43 SG34 SG33 SG04
WFC16	The Foot Control spring has failed; the Foot Control center pedal has been disabled.	SG34 SG04
WFC17	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 SG34
WFC18	System not detecting the Foot Control.	SG33 SG34
WFC19	The system has lost communication with the Foot Control, wireless disabled.	SG84 SG85

ID	Text Message	Suggested Action(s)
WFC20	The system has lost communication with the Foot Control.	SG83 SG34 SG04

Foot Control Receiver Module Messages

ID	Text Message	Suggested Action(s)
WFR01	The Foot Control receiver was not detected in the system. Surgical mode is not available.	SG01
WFR02	The Foot Control receiver software version is not compatible with this software version. Surgical mode is not available.	SG02
WFR03	The Foot Control receiver has failed to respond to a settings command. The module settings have been re-sent to the module.	SG04
WFR04	The Foot Control receiver has reset. The module settings have been re-sent to the module.	SG04

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.

Suggested Actions for Messages

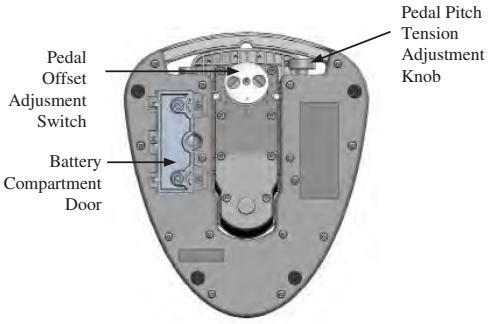
Suggestion Action ID	Suggested Action Text
SG01	Call your product service representative.
SG02	Call your product service representative. A compatible software version must be downloaded.
SG03	Confirm correct irrigation, aspiration, and vitrectomy function.
SG04	Call your product service representative if this problem persists.
SG05	Call your product service representative to replace the vacuum fluidics module.
SG06	Call your product service representative to replace or calibrate the vacuum fluidics module.
SG07	Call your product service representative to replace the flow fluidics module.
SG08	Call your product service representative to replace or calibrate the flow fluidics module.
SG09	Open the flow fluidics module drawer, re-insert the cartridge, and close the drawer again. Try to observe if the pump head moves as the drawer closes.
SG10	Call your product service representative to replace the flow fluidics module if this problem persists.
SG11	Select ‘Setup’, select ‘Eject Cassette’, and then re-insert the vacuum fluidics cassette for the cassette vacuum check.
SG12	Select ‘Setup’, select Open Drawer’, re-insert the flow fluidics cartridge, and select ‘Close Drawer’ for the cartridge vacuum sensor test.
SG13	Please wait for the vacuum fluidics module cassette vacuum check to complete.
SG14	Please wait for the flow fluidics module cartridge vacuum sensor check to complete.
SG15	Replace the vacuum fluidics cassette.
SG16	Select ‘Setup’, select Open Drawer’, re-insert the flow fluidics cartridge, and select ‘Close Drawer’ for the cartridge vacuum sensor test.
SG17	Make sure that the flow fluidics module and cartridge vacuum sensor surfaces are clean and dry.
SG18	Replace the flow fluidics cartridge.
SG19	Select ‘Setup’, select Open Drawer’, and make sure that the flow fluidics module and cartridge vacuum sensor surfaces are clean and dry. Select ‘Close Drawer’ to retry the cartridge vacuum sensor test.
SG20	Select ‘Setup’, and select ‘Prime and Tune’ or ‘Prime Only’ to complete the system priming.
SG21	Please wait for the system priming to complete.
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	Select ‘Eject Cassette’, load a new pack, and try priming the system again.
SG24	Select ‘Open Drawer’, load a new pack, and try priming the system again.
SG25	Confirm correct irrigation and aspiration function.

Suggestion Action ID	Suggested Action Text
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. Select 'Eject Cassette' button. 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 detail 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.
SG28	Empty the cassette. To empty cassette and reprime: 1. Clamp irrigation line. 2. Select the 'Setup' icon. 3. Select 'Eject Cassette' button. 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 detail instructions to detach tubing manifold from the cassette.
SG29	Call your product service representative if the cassette is not full and this problem persists.
SG30	Check that the vitrectomy cutter tubing is connected tightly to the system.
SG31	Confirm correct vitrectomy function.
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.
SG35	Call your product service representative to have the Foot Control calibrated.
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.
SG38	Reposition the Foot Control and ensure that the center pedal and buttons are not activated.
SG39	Position the Foot Control on a flat working surface.
SG40	Initiate wireless foot control connectivity by pressing one of the Foot Control buttons momentarily, the left LED will light up.
SG41	Please wait while the Foot Control configuration completes.
SG42	You may disconnect the Foot Control cable and operate the Foot Control wirelessly.
SG43	Disconnect the Foot Control cable, Reconnect the cable and try again.
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.
SG46	Turn the pressurized infusion pump off, wait for a few seconds, and then turn the pump back on.
SG47	Confirm correct operation of the aspiration function.
SG48	Please plug in the ultrasound handpiece. The ultrasound connector light is flashing.

Suggestion Action ID	Suggested Action Text
SG49	If the handpiece is not detected, unplug the handpiece and try another ultrasound handpiece.
SG50	Select ‘Setup’, then select ‘Prime and Tune’ or ‘Tune Only’.
SG51	Please wait for the ultrasound handpiece tuning to complete.
SG52	Ensure ultrasound needle is properly tightened. Select ‘Prime and Tune’ or ‘Tune Only’ again to repeat the handpiece tuning process.
SG53	Unplug the handpiece and try another ultrasound handpiece.
SG54	Confirm proper ultrasound handpiece operation in a test chamber.
SG55	Confirm proper operation of the coagulation handpiece in a beaker of Balanced Salt Solution.
SG56	Unplug the handpiece and try another bipolar coagulation cord.
SG57	If the handpiece is not detected, unplug the handpiece and try another ultrasound handpiece.
SG58	Please plug in the electric vitrectomy handpiece. The electric vitrectomy connector light is flashing.
SG59	If the handpiece is not detected, unplug the handpiece and try another electric vitrectomy handpiece.
SG60	Confirm proper operation of the electric vitrectomy handpiece in a beaker of Balanced Salt Solution.
SG61	Unplug the handpiece and try another electric vitrectomy handpiece.
SG62	Please command the IV Pole to the minimum bottle height position.
SG64	Ensure that the IV Pole back panel buttons are not activated.
SG65	Confirm proper operation of the IV Pole back panel buttons.
SG67	Confirm that the bottom and lower rear areas of the system are not blocked from free air flow.
SG68	Confirm proper system operation. System may not be available if needed functions cannot be verified.
SG69	Call your product service representative if this problem persists with multiple batteries.
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 on the ‘Remote Control’ tab
SG72	Replace the remote control battery at your earliest convenience.
SG73	Please ensure that the multimedia center is plugged in and powered on.
SG74	Check that the multimedia center data cable is plugged in to both the system and the multimedia center.
SG75	IV Pole valid range is (0)-(1) cm.
SG76	IV Pole valid range is (0)-(1) cm. Go to IV Pole more screen or programming function to reset ceiling limit.
SG77	Change Phase/Mode while surgical functions not in use.
SG78	Power down the system and then restart the system.

Suggestion Action ID	Suggested Action Text
SG79	Insert the vacuum fluidics cassette.
SG80	Insert the flow fluidics cartridge and press the Close Drawer button.
SG81	Check the main power input cord and ensure that the system is plugged in.
SG82	Immediately replace the battery to ensure Foot Control functionality.
SG83	Check the cable connection.
SG84	Connect the Foot Control cable to continue use.
SG85	See User Manual for re-enabling wireless communication.

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.	The Foot Pedal Offset switch not properly engaged. System not detecting if foot pedal is offset to Left, Right or Center.  	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.	The cassette was not fully inserted. This can occur if the cassette is inserted slowly and captured in a position that affects the performance of the fluid level sensor. This may also occur if the cassette is inserted too fast and released before the capture mechanism captures the cassette at the optimum position.	Eject cassette and reinsert. To ensure cassette is properly positioned in the system, firmly insert the cassette until it snaps in place.

	Symptom	Potential Cause	Corrective Action
4	No or low infusion with Pressurized Infusion function. System displays actual pressure correctly and air is coming out of the air output connector.	1. Air tubing or irrigation tubing may be kinked	Check air tubing and irrigation tubing for kink or pinch.
		2. The air tubing pathway may be obstructed	Ensure new air tubing is used. Otherwise, replace with new tubing.
		3. Preset pressure may be set too low	Increase air pressure setting to desired level
			If problem persists with the all of the above corrective actions, stop using Pressurized Infusion and call service.
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.	1. Stop surgery and remove handpiece from the eye. 2. Close irrigation clamp to stop fluid flow into the cassette/cartridge and handpiece. 3. Replace test chamber to the handpiece that is connected to the tubing. 4. Reboot system, prime and tune handpiece when power supply resumes (ensure to open irrigation clamp before starting to re-prime and tune system).
6	Remote Control not working with good or new batteries.	Remote firmware not responding to key inputs.	Reset the device by removing the batteries and waiting for at least one minute before re-installing the batteries.

7.4. 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 *Stellaris*® Vision Enhancement System in a surgical mode? Is the data cable connected correctly?
Overlayed 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.

Symptom	Action Required
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 phaco handpiece C. Select “Prime and Tune” D. Following successful prime and tune, the system will go to surgical mode to resume operation.
GUI hung up and system ceased operation	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. To restart system, perform the following: 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

7.5. System Configurations and Accessories

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.

Approved accessories will be appropriately labeled as Manufactured By, Manufactured For, or Distributed By Bausch & Lomb. For a complete list of approved accessories please consult your local Bausch + Lomb catalog or contact your local Bausch + Lomb representative.

Group	SKU	Description
System Configuration	BL11110	Anterior Deluxe Advanced Vacuum System
System Configuration	BL11120	Anterior Deluxe Advanced Flow System
Accessory	BL3170	Ultrasound Phaco Handpiece
Accessory	BL3379	*Stellaris*® Ultrasound Handpiece Tray
Software	BL6310	Remote Service Software
Software	BL6320	Pressurized Infusion Software
Software	BL6340	Multimedia Center Software
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	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	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	CX9400	Reusable Bipolar Cord with 2 Pin Connector
Miscellaneous	CX9430	Reusable Bipolar Cord with Lemo Connector
Miscellaneous	CX9404	Banana Plug Adapter, Reusable
Miscellaneous	D8200	Straight Bipolar Forceps 0.5mm Tip Lemo Connector
Miscellaneous	D8201	Bipolar Eraser, 31 Shaft with 45 Degree Bevelled 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

Service and Warranty

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

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

8.1. Service Information

Technical Assistance

Assistance for ***Stellaris***® Vision Enhancement System is available from Global Product Support either by phone or letter as follows:

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

- 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 8-4).

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***® Vision Enhancement System, located on the label on the back panel
- Date of purchase
- 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®*** 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®*** 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 and Lomb GmbH
Horlgasse 12 Mezzanin TOP 5
1090 Wien, Osterreich
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
Brunsbütteler Damm 165 - 173
13581 Berlin
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 Samseong-clong Gangnam-gu
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 Cresent
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.
151 Lorong Chuan # 04-03A
New Tech Park, Lobby C
Singapore 556741
*Tel: (65) 68349112
*Fax: (65) 62860448

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
Civill Boulevard
Taipei 10690
Taiwan, Republic of China
*Tel: 88-62-2776-0408
*Fax: 88-62-2776-6849

Thailand

Bausch & Lomb (Thailand) Limited
54 B.B. Building, 15th Floor, Room 1501
Sukhumvit 21 (Asoke) Road, Kwaeng Klong Toey Nua
Khet Wattana, Bangkok 10110
Thailand
*Tel: 66-2-259-6510
*Fax: 66-2-259-6511

Turkey

Bausch & Lomb Saglik ve Optik Urunleritic A.S.
Degirmen Yolu sok.
Sasmaz Plaza No: 4 Kat 12 Daire 24 Kozyatagi
Istanbul, Turkey
Tel: 90-216-373-3131 (switchboard)
Fax: 90-216-384-9489
*Tel: 33-4-37-488383
*Fax: 33-4-37-488384

United Kingdom

Bausch & Lomb U.K., Ltd.
106-114 London Road
Kingston-upon-Thames
Surrey KT2 6TN, England
Tel:44-20-8781-2900
Fax: 44-20-8781-2901
*Tel: 44-208-781-0000
*Fax: 44-208-781-0001
Europe, Middle East & African Division
European Headquarters

Vietnam

c/o address is Singapore, see Singapore

8.2. 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.

8.3. Warranty Information

Stellaris® Vision Enhancement System Warranty

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

BAUSCH + LOMB EXCLUDES AND DISCLAIMS ALL OTHER WARRANTIES OR REPRESENTATIONS RELATING TO THE *Stellaris*® 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*® 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*® Vision Enhancement System OR THIS WARRANTY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE OF THE *Stellaris*® 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 six (6) 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 then 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 special trade-in programs which offer reduced cost replacements with additional warranty coverage. Contact your Bausch + Lomb sales representative for additional details on current 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

9.1. 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.*

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 (5mm x 20mm) 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

MMC (Optional Accessory) 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® 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 pounds (5.4 kg)

Standards Compliance

The ***Stellaris***® 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***® 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***® Vision Enhancement System. Guidance on maintaining appropriate separation between communications equipment and the ***Stellaris***® Vision Enhancement System is provided in the tables below.

A complete line of accessories for the ***Stellaris***® 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***® Vision Enhancement System should not be used adjacent to other equipment. If adjacent use is necessary, the ***Stellaris***® Vision Enhancement System should be observed to verify normal operation in the configuration in which it will be used.

Note: *The **Stellaris**® 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**® 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 during the precheck or during surgery, 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 Phaco 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"

Guidance and Manufacturer's declaration – electromagnetic emissions		
The ***Stellaris***® 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.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 2	The ***Stellaris***® Vision Enhancement System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected
RF emissions CISPR 11	Class A	The ***Stellaris***® 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
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***® 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.			
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 IEC61000-4-4	+/- 2 kV for power supply lines +/- 1kV for input / output lines	+/- 2 kV for power supply lines +/- 1kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1kVdifferential mode +/-2 kV common mode	+/-1kV 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 61000-411	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***® Vision Enhancement System requires continued operation during power mains interruptions, it is recommended that the ***Stellaris***® 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
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance

Guidance and Manufacturer's declaration – electromagnetic immunity			
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***® Vision Enhancement System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation distance $d = {}_{1,2}\sqrt{P}$ (Conducted) $d = {}_{1,2}\sqrt{P}$ 80 Mhz to 800 MHz (Radiated) $d = {}_{2,3}\sqrt{P}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[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, and electromagnetic site survey should be considered. If the measured field strength in the location in which the ***Stellaris***® Vision Enhancement System is used exceeds the applicable RF compliance level above, the ***Stellaris***® 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***® Vision Enhancement System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

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

The ***Stellaris***® 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***® 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 $d = {}^{1,2}\sqrt{P}$	80 MHz to 800 MHz $d = {}^{1,2}\sqrt{P}$	800 MHz to 2.5 GHz $d = {}^{1,2}\sqrt{P}$
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 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Remote Control Unit Specifications

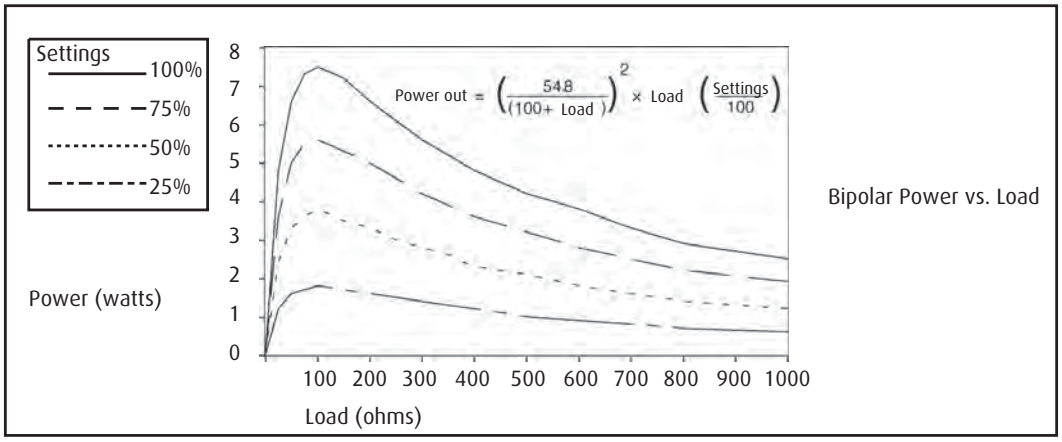
Parameter	Specification
General	Wireless pointing device providing line of sight operation using an IR transmitter
	Provides operation up to 15 feet from display console
	Powered from standard AA battery (batteries)
	Low battery indicator
	Transmit indicator
	Splash-proof
	Illuminated keys
Aspiration(ASP)	Vacuum Level Increase/Decrease Flow Rate 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

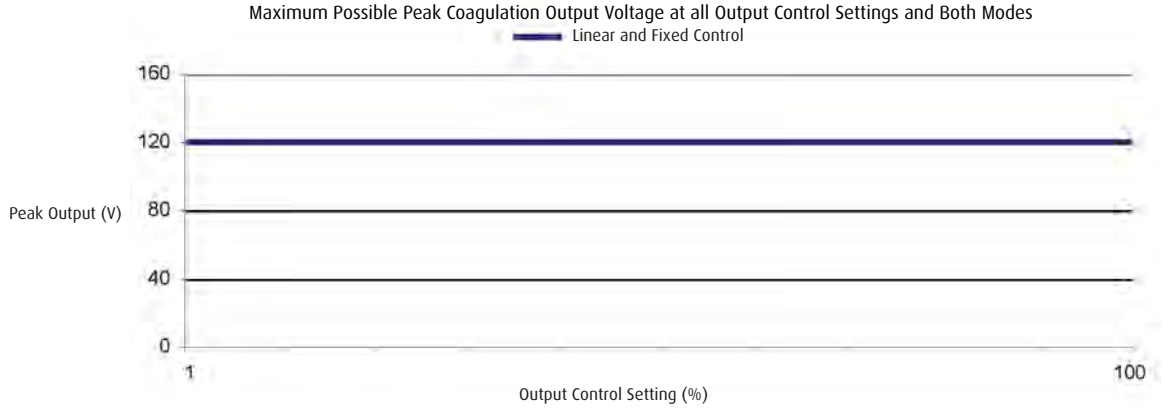
IV Pole Specification

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





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 Function Specifications

Operating 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 DP8130 Microflow needle is 130 µm 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 Duty Cycle: 50 to 99% in 1% increments Rise Time: 1 or 2 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

Vacuum Fluidics Function Specifications

Parameter		Specification
Aspiration	General	Provides Cassette Full, Near-Full and Continuous Fluid Level Sensing Programmable Rise time 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 Vacuum Control: 1 mmHg increments
Irrigation		Gravity feed from I/V bottle with pinch valve On/Off control via footpedal
Reflux	Control	Gravity feed or Pressurized Infusion from the Balanced Salt Solution bottle Modes: Continuous Activated via the Foot Control
Vitrectomy	Linear Cut Rate Mode Operating Parameters	Range: 30 to 800 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 800 cuts per minute in 1 cut per minute increments Control: On/Off control of cut via the footpedal
The compressor module will provide a minimum of 600 mmHg up to 3,000 feet above sea level. A derating of 19.4 mmHG per 1000 ft. will be used for operation above 3,000 ft.		

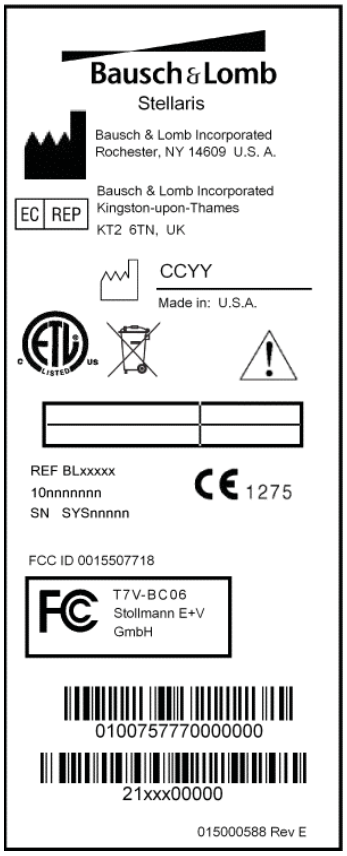
Advanced Flow Function Specifications

Parameter		Specification
Aspiration	General	Programmable vacuum response
	Modes of Operation	Flow Mode • Fixed flow fixed vacuum limit • Fixed flow linear vacuum limit • Linear flow fixed vacuum limit • Linear Flow Linear Vacuum Limit Vacuum Mode • Fixed vacuum • Linear vacuum
	Flow Mode Operating Parameters	Flow I/A Mode: 0 ml/min to 60 ml/min U/S Mode: 5 ml/min to 60 ml/min Vit Mode: 0 ml/min to 60 ml/min Vacuum Limit I/A mode: 0 mmHg to 650 mmHg U/S: 10 mmHg to 650 mmHg Vitrectomy: 0 mmHg to 650 mmHg Vacuum Control: 1 mmHg increments
	Vacuum Mode Operating Parameters	I/A: 0 - 600 mmHg U/S: 10 - 600 mmHg Vit: 0 - 600 mmHg
Irrigation		Gravity feed from I/V bottle with On/Off control provided in cassette
Reflux	Control	Activated via Foot Control
	Safety	Reflux volume depend on operation mode only
	Modes	Single, repeat or continuous
	Note: Active reflux volumes will be software controlled via reversal of Advanced Flow Pump	
Vitrectomy	Linear Cut Rate Mode Operating Parameters	Range: 30 to 800 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 800 cuts per minute in 1 cut per minute increments Control: On/Off control of cut via the footpedal

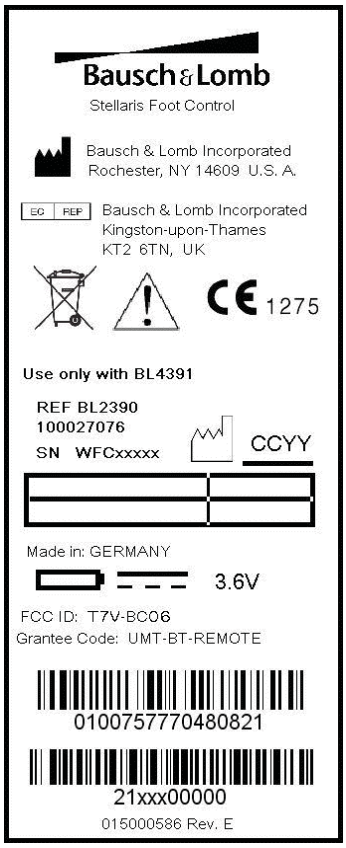
Pressurized Infusion Specifications

Parameter		Specification
Pressurized Infusion	Input	Atmospheric air with 0.1 micron hydrophobic filter
	Pressure	100mmHg maximum air pressure, flow rates up to 6.5 standard cubic feet per hour Range: 1-100mmHg Control: 1 mmHg increment

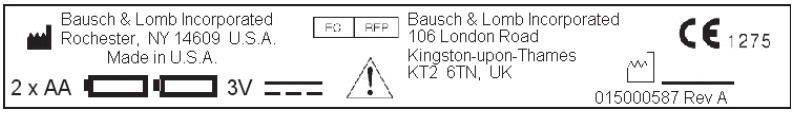
System Labels



Main System Label

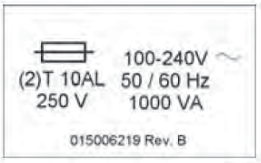


Foot Control Label



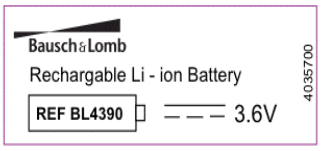
Large Remote Control Label

Small Remote Control Label



System Power and Fuse Label

Foot Control Battery Label



Foot Control Battery Compartment Label

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