

SECTION TWO DESCRIPTION

INTRODUCTION

The *Constellation®* Vision System is a multi microprocessor-controlled ophthalmic surgical instrument with associated memory and input/output (I/O) circuitry. The system communicates with the user via its Front Panel display, with voice confirmations, and with tones. An automatic self-test is initiated each time the system power is turned on.

This test performs a variety of functions including the following:

- Tests the Central Processing Unit (CPU)
- Tests the RAM and ROM memory, and the I/O circuits
- Initializes the system

When the system successfully completes the self-test, it automatically goes into the Setup mode. If the system fails the self-test, an error message is displayed.

This section of the manual is broken into two major parts. The first part describes the console and its accessories. All the parts of the system are described, including the front panel, rear panel, IV pole, connectors, fluidic interface, footswitch, remote control, and VideOverlay system.

The second part of this section describes the operator interface. This is where the display screens for system setup, surgery, programming, and dialogs are shown.

FRONT PANEL

Fluidics Module

The fluidics module is located in the center of the front panel. The module allows fast and easy insertion of the cassette that contains all the fluidics connections required for surgery.

Front Display Panel and Touch Screen

The 17-inch front display panel tilts and extends forward to allow easy positioning during setup and surgery. The front display is the user's main source of system control, allowing fingertip command of system functions through the enhanced graphical user interface.

A data card slot is located just beneath the LCD display. A data card (SD Memory Card) can be inserted into this slot when the user wants to back up or restore system settings.

Pneumatic and Electrical Connectors

The *Constellation*® Vision System console contains two vertical columns of connectors, located on the left side of the cassette, for surgical probes and handpieces. The right column is for pneumatic probes, and the left column is for electrical handpieces.

LED Rings - The rings surrounding each front panel connector automatically illuminate in a particular color to guide the user in making the proper connection to the system as follows:

- Blue - When a surgical tool selection is made in a Setup screen, the LED ring around the related connector illuminates in a blue color
- Green - When the surgical tool is connected correctly, the system changes the LED ring to green. Once lit, the LED ring remains on until another tool/port is selected or the system transitions to the surgery screen(s).
- Amber - If the surgical tool is connected incorrectly, the LED ring illuminates in an amber color until the condition is corrected.

WARNING!

Connect only Alcon supplied consumables to console/cassette connectors. Do not connect consumables to patient intravenous connections.

Footswitch Storage Hook

This footswitch storage hook is located at the bottom of the front panel. When the footswitch is not in use or the system is being moved, use this hook to store and protect the footswitch.

Instrument Tray (optional)

Provides a movable instrument tray within the sterile field. There is a curved metal rod on either side of the tray arm that allows for creation of a sterile pouch when used with sterile tray arm cover. The tray is capable of accommodating a variety of positions in the operating room environment: right, left, front and rear of the surgeon as well as the front of the bed. The tray is height adjustable.

WARNINGS!

The maximum allowable load on the instrument tray is 20 lb (9 kg). If the load exceeds this limit, the tray arm will automatically lower itself in order to avoid tipping the system over. Additionally, if the instrument tray is positioned over a patient, a mayo stand should be placed beneath it to avoid a potential collapse of the tray arm onto the patient.

Place the instrument tray in the stored position (see Figure 2-1) prior to transportation to avoid a situation that could cause the system to tip.

IV Pole with Bottle Hanger (optional)

A bottle of *BSS*® or *BSS Plus*® irrigating fluid is hung from the hook on top of this pole. The IV pole is used to raise and lower the bottle height, causing irrigation pressure to increase or decrease.

WARNING!

Do not use *Legacy*® IV pole extender with *Constellation*® Vision System IV pole.

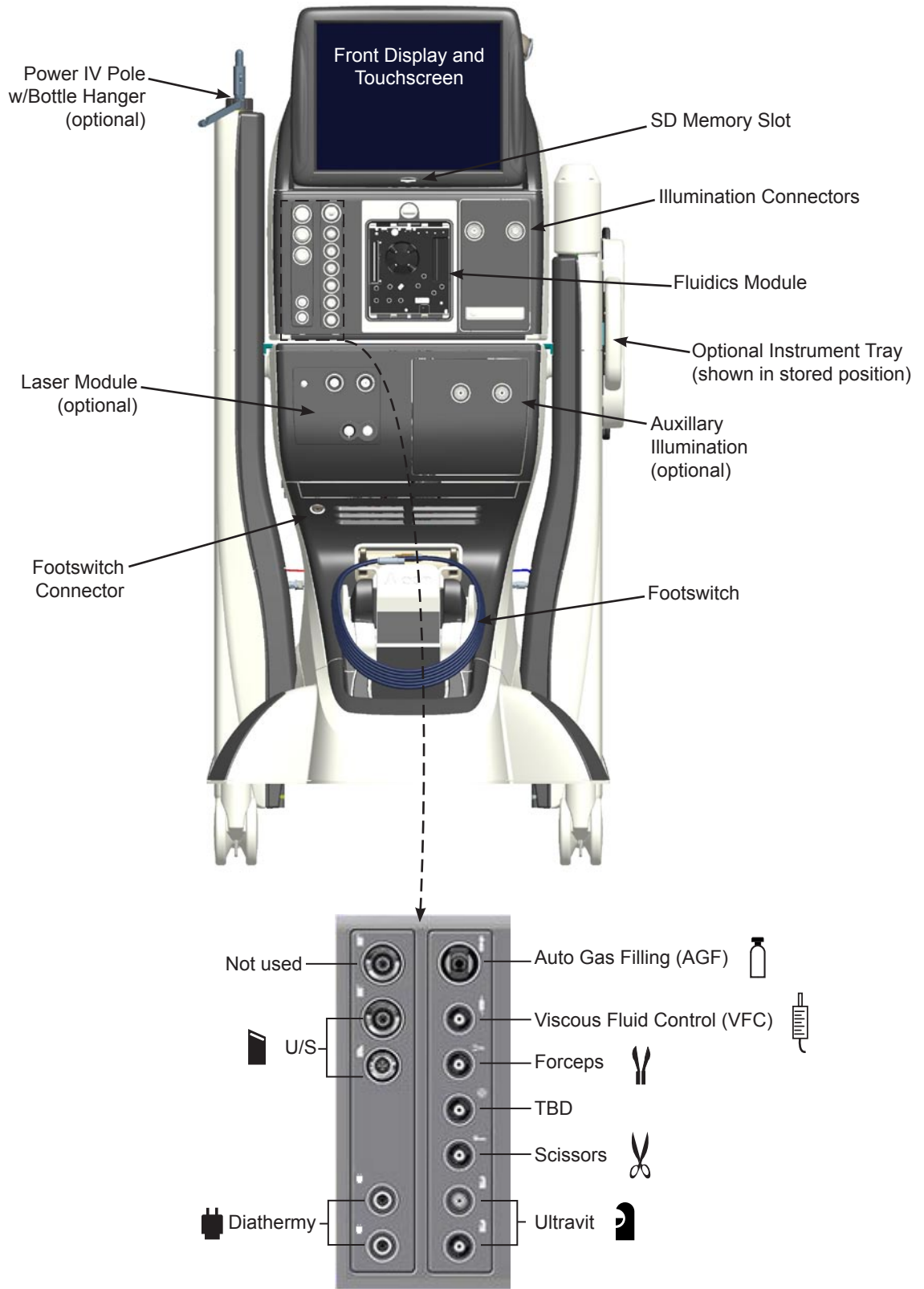


Figure 2-1 The Constellation® Vision System Console Output Connectors

Caster Wheels

Four large caster wheels support the *Constellation®* Vision System. The wheels rotate 360° for ease of system mobility, and have a locking lever to secure the system in place. The wheels should always be locked (handle up) when the unit is in use, and unlocked when being moved.

Illumination

Primary illumination is provided by two independently controlled ports located just below the display. The light output at these ports is based on xenon arc lamp technology that generates high brightness white light. Each port will allow the use of 20, 23, and 25 GA ACMI Terminated fiber probes. For 20 GA probes, the port provides a minimum of 50 lumens at 100% setting (0-200 hours), and for 25 GA probes, the port provides a minimum of 15 lumens at 100% setting (0-200 hours).

Auxillary illumination is available as an optional feature that provides for two additional channels of high brightness white light.

Laser (optional)

The optional laser module is used for retinal and macular photocoagulation; iridotomy and anterior segment procedures; trans-scleral cyclophotocoagulation; laser trabeculoplasty, trans-scleral retinal photocoagulation, and other diode laser treatments.

Footswitch Connector

The footswitch connector is located on the front panel and is used to connect the *Constellation®* Vision System footswitch to the console. (In monolith configuration, the footswitch connection is made in the front of the base.)

Handles

Handles are located on the sides and back of the instrument, and should always be used to move the unit. For greater safety and control, the unit should be pulled, not pushed.

CAUTION

The system must be moved carefully, otherwise the system could tip over and become damaged. Do not push or pull the unit by the display, the tray, or the IV pole. Handles located at the rear and sides of the unit are provided for moving the instrument. The unit should be pulled and not pushed, especially over elevator and door thresholds.

REAR PANEL**Barcode Reader**

The barcode reader allows the user to quickly scan any pak or related consumable at any time during the case to input critical information about the pak into the system. The information enables the system to direct the operating room staff to any special requirements of the device, offer in-depth videos, and automatically prime the device once connected (if required).

When the operator scans a barcode through the reader and the system recognizes the barcode as one that is preconfigured in the system, it produces an audible beep and adds the associated consumable to the current surgical case. If the barcode is not recognized by the system then an advisory message is displayed.

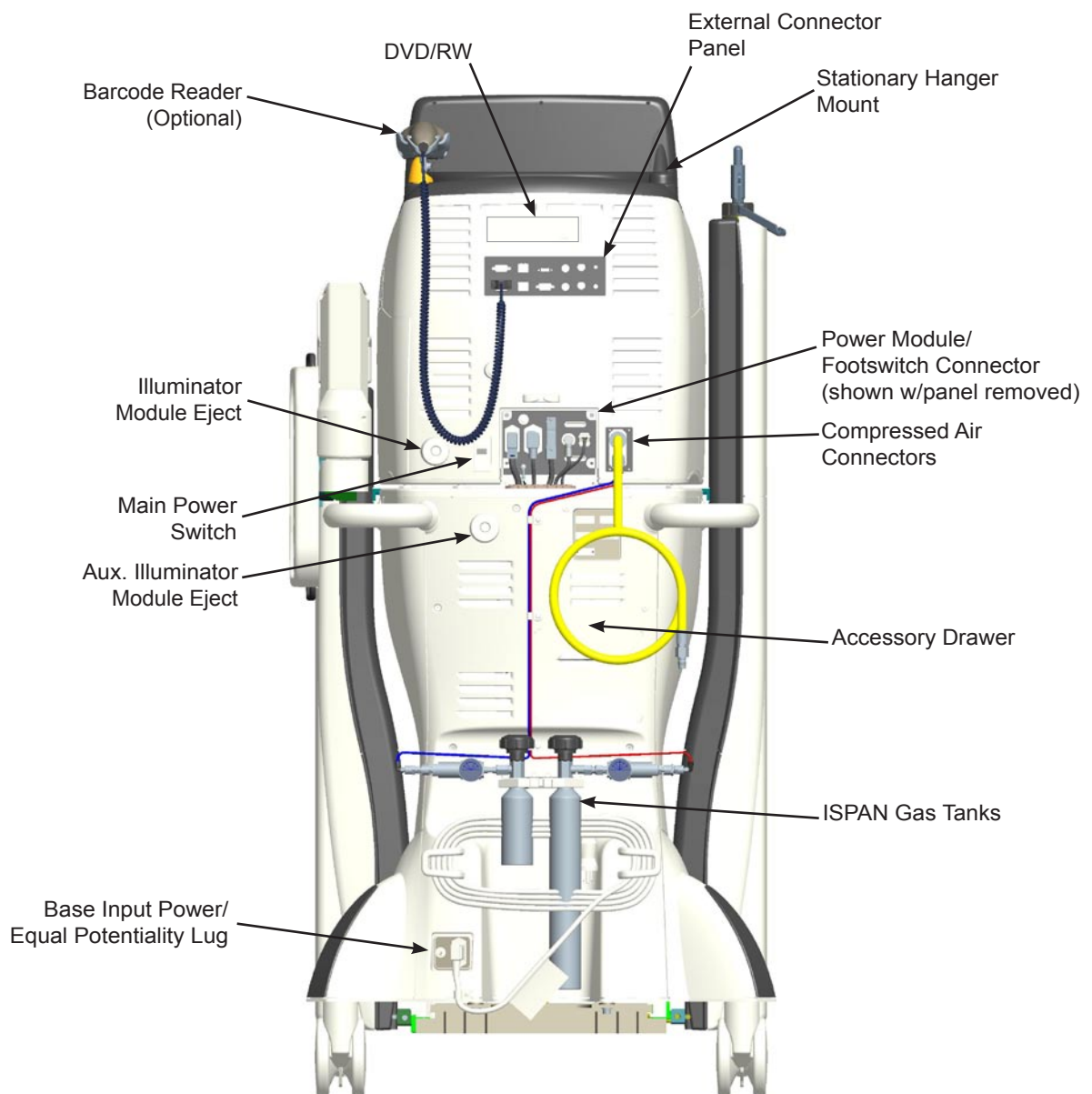


Figure 2-2 The Constellation® Vision System Rear Panel

The operator can verify the bar code has been properly entered into the system by tapping the Consumables button to bring up the Consumables list window. In addition, all surgical tools associated with consumable (e.g., pack) will be pre-selected by the system.

DVD/RW

The DVD player/recorder allows the recording of the surgery process onto a DVD through an external device for reference or teaching purposes.

Laser Connection

The rear panel connections for the optional laser provide connections for the Laser Footswitch, Remote Interlock, External Ready Indicator, and two Dr. Filter ports.

Power Module

The power module is located on the lower rear panel shown in Figure 2-2 and contains an AC power connector.

- AC Power Connector - Power cord from AC power outlet connects here. A hospital grade power cord must be used.
- Main Power Switch - Connects AC power to power supply.

Equipotential Ground Connector

For Service personnel use.

External Connectors

This module, located in the middle of the rear panel, contains various connectors and outlets used for electrical interconnections.

- USB Connector - Not used.
- Serial Connector - Used for VideOverlay.
- Barcode scanner connection
- Video in s-video
- Video out s-video
- Video in component
- Video out component
- VGA out
- Service Ethernet (not used)
- Tethered Laser
- Audio input

CAUTION

The USB connector () and service ethernet connector located on the rear panel are for use by Alcon trained personnel only. Failure to comply will void warranty.

Accessory Drawer

One drawer allows the storage of miscellaneous accessories.

FOOTSWITCH

Functional operations of the *Constellation*® Vision System console are controlled by the footswitch shown in Figure 2-3. The footswitch consists of a treadle, left and right horizontal/vertical switches, left and right heel switches, and a tension adjustment knob. An advisory popup window is displayed if the footswitch is not connected.

Generally, the treadle is used to provide control of a parameter, such as vacuum, with the treadle's angle of depression proportional to the parameter output. In some modes of operation, the treadle is used to provide on/off control of a function, with any depression resulting in a fixed output of its parameter.

The footswitch treadle is used in a mode-dependent fashion during system operation. In U/S mode for example, when the treadle is depressed its range of travel is divided into ranges 0, 1, 2 and 3. Each range, except range 1, is separated from the previous range by a detent. Detent firmness levels are programmable in the *Doctor Settings menu* which is discussed later in this section of the manual (see *Settings*). The footswitch icon located in the upper left corner of the screen displays the current treadle position.

Right and left switches are used to enable and disable system functions. The switches are nudged sideways (horizontal) for some functions, and pressed down (vertical) for others.

The tension adjustment knob, located on the front of the footswitch, is used to adjust the pressure needed to depress the treadle.

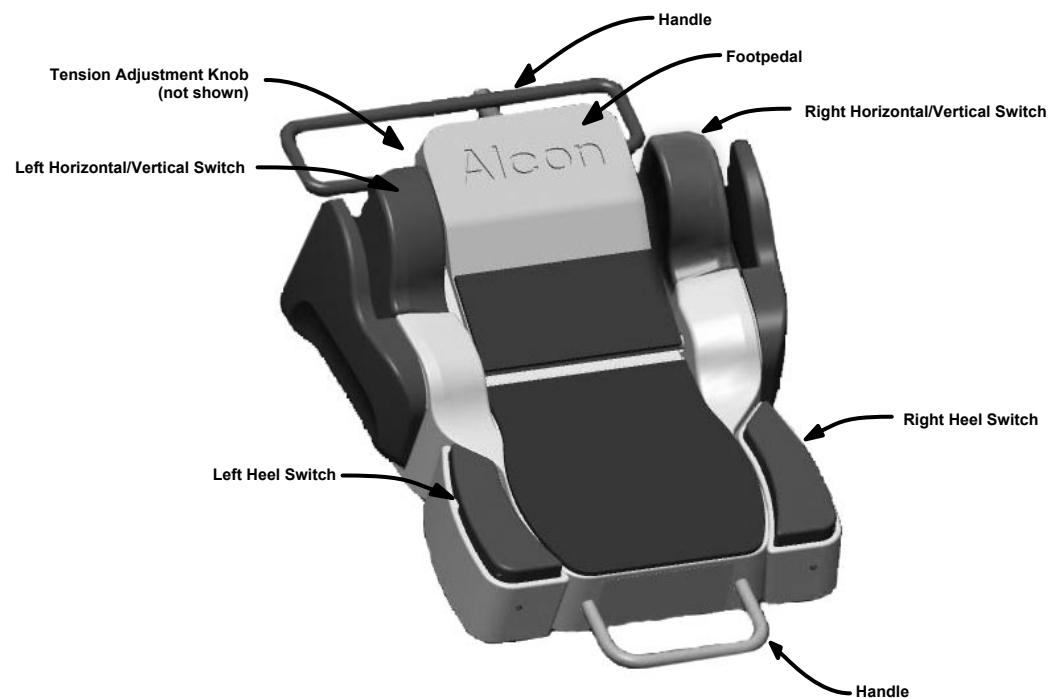


Figure 2-3 The *Constellation*® Vision System Footswitch

REMOTE CONTROL

The Remote Control is a wireless, handheld, battery operated device that uses infrared light to communicate with the *Constellation*® Vision System console. Each of the different keys on the Remote Control unit has its own unique key code that is transmitted to the *Constellation*® Vision System console when the key is pressed. The transmitted key codes are translated into commands that control the *Constellation*® Vision System console.

Figure 2-4 shows the Remote Control and the keys provided. When a Remote Control Transmitter key is pressed, the *Constellation*® Vision System console determines whether or not the key press was valid and generates an appropriate valid or invalid key tone.



Figure 2-4 The *Constellation*® Vision System Remote Control

The Remote Control is divided into three sections from top to bottom. The three sections of the display screen are 1) the top section is for Global Selection and adjustments of global values, 2) the main (middle) window is for surgery screen navigation and parameter settings, and 3) the bottom section is for selecting steps and enabling/disabling selected controls. Some items on the *Constellation*® Vision System console display screens are not accessible with this Remote Control unit.



Global Control Up/Down Keys

The Global Control up/down keys on the remote control function as they do on the Host Display touchscreen. Each individual press of the up arrow key increments the setting on the selected global control in the Globals panel on the touchscreen. Each individual press of the down arrow key decrements the setting on the selected global control. To move rapidly up or down, the key is pressed and held until the desired setting is reached. The Global Control keys are only valid in the Setup and Surgery screens, and are not valid when any pop up dialog is displayed.



Global Controls Navigation Key

The function of the Global Controls Navigation key is to navigate to any control on the Globals panel and be able to select a specific control (refer to Figure 2-6 to see the Globals panel). Pressing this button the first time selects the Infusion Control which is the first control on the Globals panel. The selected control will be highlighted with a golden outline. Each successive press of the Global Controls Navigation key causes the next available control on the Globals panel to be selected. An exception to this rule occurs if the Infusion Control is selected. In this case the IOP Compensation button on the control is selected to adjust IOP settings.



Surgery Screen Navigation Key

The Surgical Screen Navigation key is a four way switch that enables a remote control user to move up, down, left and right on the surgery screen and to select the controls and/or panels on the screen. Once a control is selected, the user can press the Parameter Value Adjustment keys to increase/decrease the control parameters. When the ON/Off button is highlighted with a gold border, pressing the Enter key alternately toggles the control ON and OFF.

The Navigation Key button is valid when the Surgery screen is being shown, but is invalid when a dialog is displayed.



Parameter Value Adjustment Up/Down Keys

The Parameter Value Adjustment Up/Down keys are used to adjust settings (parameters) in a Surgery Control Panel that has adjustment arrows (i.e., pressure, vacuum, cut rate). Surgery control panels are selected via the Navigation Key and a blue border indicates that the panel is selected.



Previous Step/Next Step Keys

The Previous Step/Next Step keys are used to move left and right through the surgery steps at the bottom of the Surgery screen (see Figure 2-29). In the Surgery screens, when a step is selected by using the Previous Step/Next Step key on the remote, the system selects the next step to the left or to the right. If it is a valid step, it will be selected immediately without having to press any other keys. Continuing to press the keys causes the system to move through the steps and wrap around to the beginning step. It is not possible to access the submodes from the Remote Control Unit.

The Previous Step/Next Step keys can also be used in an information dialog to select a button (e.g., OK, Cancel, Save, etc.).



Enter Key

The Enter key is used to enable/disable a selected control. For example, if the vacuum control is selected and the Enter key is pressed, the vacuum control is disabled and the ON/OFF button is grayed out.

Remote Control Batteries

When the batteries in the remote control are low, the status message “Remote Battery Low” will appear in a popup dialog the first time a key is pressed after the system is turned on. The message will disappear after new batteries are installed and a remote control key is pressed. A battery holder inside the remote holds three (3) AAA (LR3) batteries.

To replace batteries:

1. Loosen two captive screws on the rear cover with a standard slotted screwdriver and remove cover.
2. Replace old batteries and replace cover (correct battery positions are identified inside each battery slot). When closing the cover it is important that the rubber buttons slide into the slots in other half of the remote without binding (see Figure 2-5).
3. To check correct installation of batteries, press a backlight button on the side of the remote and verify that the remote control buttons illuminate, then turn off after a few seconds. If illuminated buttons don't turn off, rubber buttons are not properly inserted into slots, so you must repeat the procedure.
4. Dispose of batteries following local governing ordinances and recycling plans.

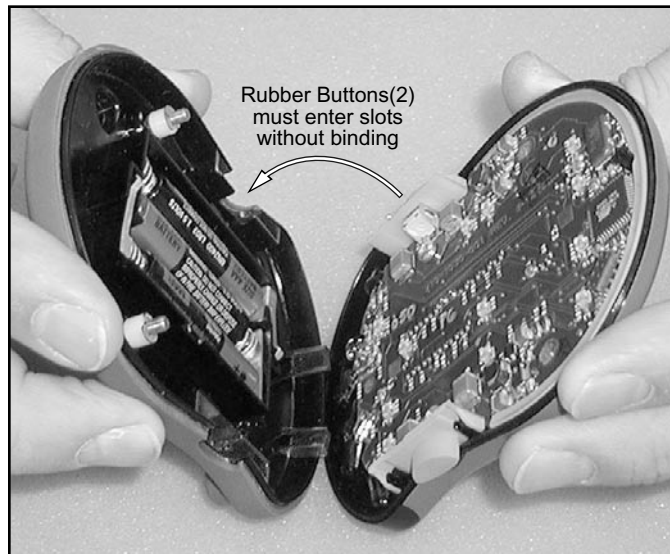


Figure 2-5 Remote Control Battery Replacement

Select Remote Control Channel

The remote control can be configured to operate on one of four channels. This feature allows four remote controls to independently control four *Constellation®* Vision Systems operating in the same room or area. Remote controls are factory preset to channel A. For proper remote operation, the *Constellation®* Vision System must be set to the same channel as the remote.

The Option/System Settings/Remote Control window allows the selection of four remote receive codes: A, B, C, & D. This selection must correspond to the channel selection on the remote control. Set the remote channel as instructed below.

To select a remote channel on the *Constellation®* Vision System:

1. Press the **Options** button to open the Options popup screen.
2. Press the **System** key to bring up the System Settings screen.
3. Press the **Remote Control** tab to display the Remote Control Settings screen (see Figure 2-6).
4. Hold the remote control in front of the *Constellation®* Vision System display screen and simultaneously press its **parameter value adjustment up/down** keys (labeled 1 & 2 on the screen). Simultaneously release the buttons.
5. On the remote control, press the **navigation** key corresponding to the new channel as label in the Remote Control Settings screen.
6. Press the **Enter** key on the remote, then press **Save** on the screen.

No additional steps are needed once the remote channel is set, and only one remote channel is stored per unit.

NOTE: If necessary to distinguish between remote controls, identify the remote controls and the units with unique labels.

CAUTION

Do not sterilize the remote control as it will damage the unit.



Figure 2-6 Remote Control Channel Selection Screen

FRONT PANEL DISPLAYS AND TOUCHSCREEN

The *Constellation®* Vision System front display panel and touch screen has a flat, non-glare surface, and is mounted above the console. Control buttons are located within the active touch screen area. There are three basic types of pushbuttons on the display screen: up/down arrow buttons, sliders, and momentary buttons. The user can press and hold the up/down arrow buttons until the desired adjustment is complete, or press the momentary buttons with a single push-and-release to activate a function.

The *Constellation®* Vision System emits an audible tone to indicate button activation. Activation of a valid touchscreen button or remote control button results in a valid key tone; an invalid button results in an invalid key tone, and, in some circumstances, its icon symbol is ghosted to indicate an invalid function.

There are four types of display screens: the Setup screen, Surgery screens, End Case, and Dialogs.

- The Setup screen is used to prepare for surgery; i.e., connecting instruments, priming the fluidic management system and testing the handpiece.
- Surgery screens contain surgical settings for each of the current surgical procedures. Settings can be adjusted by pressing the touch screen buttons for the associated controls.
- The End Case screen provides the user with a summary of the case and a tabbed interface area for display of the various metrics associated with the case.
- Dialogs are displayed as a result of selecting an option from the Options drop list (i.e., System Settings, Doctor Settings, etc.) or pressing the Footswitch button. Dialogs enable the user to view and modify system settings, doctor settings, and some surgical settings. There are also dialogs displayed to advise or warn the user of a situation, or to indicate progress on a function in the Setup screen.

Startup Screen

Upon power-up of the system, an introductory screen is displayed as shown in Figure 2-7 while the system completes initialization and self-test diagnostics. All user inputs are locked out while this screen is displayed. If initialization is successful, the main screen is displayed as shown in Figure 2-8.

Main Screen



Figure 2-7 The Startup Screen

The main screen is divided into three areas: Menu Bar, Globals, and the System State area as shown in Figure 2-8. The Menu Bar provides selections that are available in any system state. The Globals area provides control of functions that are available in all surgical modes and for any system state. The System State area provides specific information on one of the following available states : Setup, Surgery, or End Case. These states are selected by pressing the associated tab in the menu bar. Figure 2-8 shows the Setup state.



Figure 2-8 The Main Screen

Menu Bar

Figure 2-9 below shows the Menu Bar section of the screen. This portion of the screen is always available regardless of the System State. The menu bar allows the user to change various high-level functions as well as certain system options.

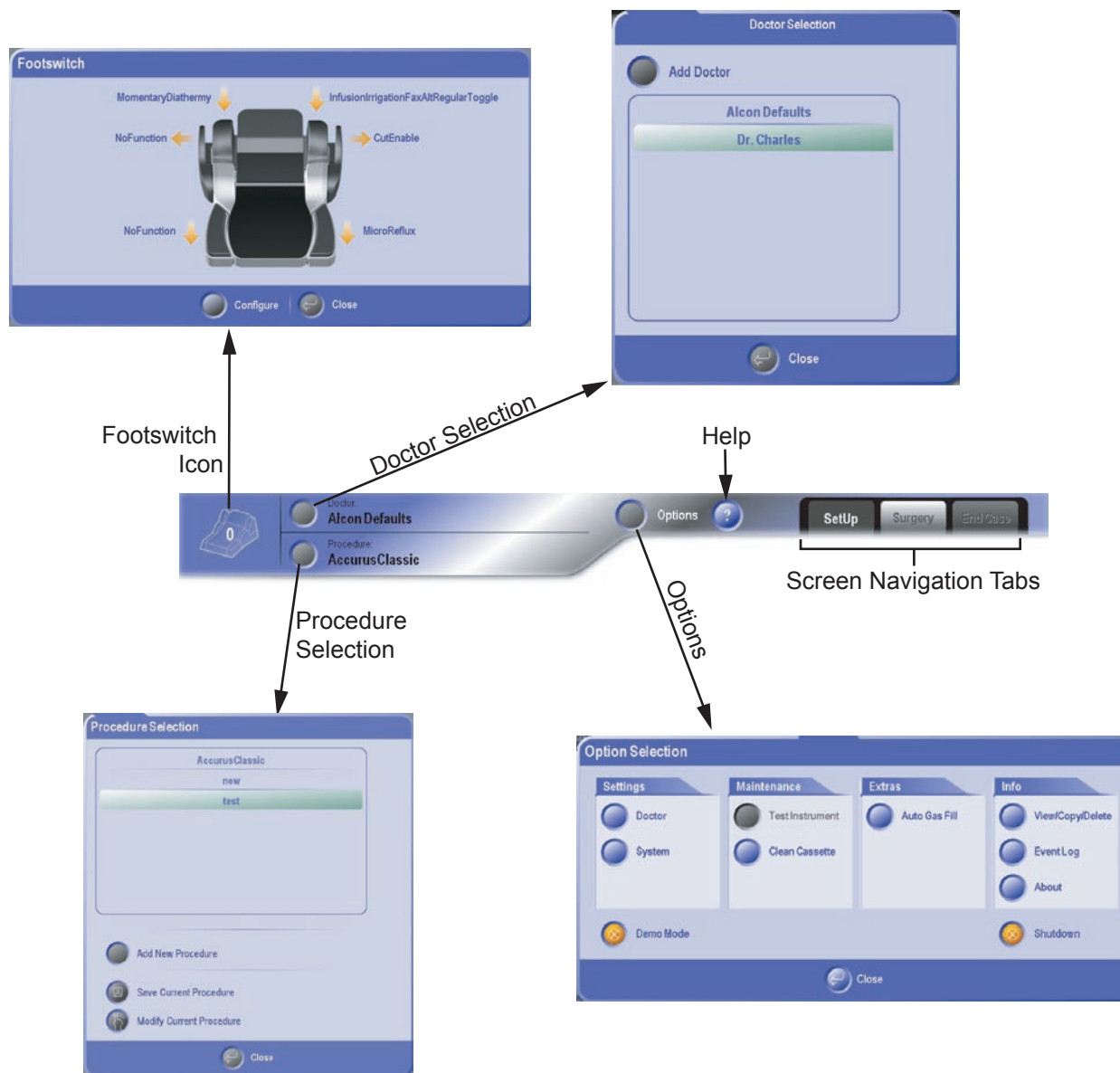


Figure 2-9 The Main Screen Menu Bar

Menu Bar: Footswitch Icon

The Footswitch icon provides feedback relating to the current state of the main console footswitch as follows:

- The icon displays the current position of the treadle indicated by the number shown on the icon.
- When a button on the footswitch is pressed, the icon shows which button and, when applicable, which way it was pressed.

Selecting the Footswitch icon displays the Footswitch popup shown in Figure 2-9. This popup shows the footswitch with labels indicating the current mapping for each button. Pressing the Configure button closes the dialog box and displays the Doctor Settings screen with the Footswitch tab selected. In this screen the footswitch can be configured as desired. Refer to *Doctor Settings\Footswitch* later in this section for detail information on configuring the footswitch.

Menu Bar: Doctor Selection

Pressing the Doctor Selection button displays a popup with the names of all available doctors. Selecting one of the entries will change the currently selected doctor and also update the current procedure and – if in surgery – the current step.

New doctors can be added to the list by pressing the “Add Doctor” button. When this entry is selected, a keyboard is displayed allowing the user to enter a new doctor. The new doctor is automatically selected if the name is valid (the name cannot be more than 40 characters or a duplicate name). If the name is identical to a doctor already in the system, an advisory is displayed.

Menu Bar: Procedure Selection

The Procedure Selection popup (see Figure 2-9) contains the names, sorted alphabetically, of all available procedures for the current doctor with the currently selected procedure highlighted. To select another procedure, simply press the desired procedure. The procedure will become highlighted and the popup will close. The Close button can be used to exit the dialog without changing the procedure.

Pressing the "Add New Procedure" button starts the process of adding a new procedure to the list of available procedures for the currently selected doctor. Refer to the following section entitled "Adding a New Procedure" for detailed instructions on adding a new procedure and an description of the screens used to setup the procedure.

ADDING A NEW PROCEDURE...

To add a new procedure to the list of procedures available to the current doctor, follow the steps below:

1. Press the "Add New Procedure" button in the Procedure Selection Popup.
A keyboard is displayed allowing the user to name the new procedure.
2. Using the keyboard, enter the name of the new procedure then press "Save".
The keyboard popup closes and the Modify procedure screen is displayed as shown in Figure 2-9a.

The Modify procedure screen is used to create custom surgical procedures. The dialog presents a scrollable list of available surgical steps the user can add to the procedure being created or modified. **Note: Procedures can also be modified in Surgical mode by pressing the Modify button.** In addition to adding steps, the user can also remove, rename, and move steps within the current procedure. The steps can be manipulated using the buttons in the Modify or by Drag-and-Drop functionality, i.e., press and drag the step icon to the new location.

In general, customization of a procedure is performed by selecting a step from the list of available source steps in the Procedure Manager and inserting the step into a list of destination steps in the upper panel named "In Procedure". Only the current procedure can be modified. The available steps in the Procedure Manager can be filtered as desired using the selections in the "Filter by:" drop down menus.

Creating Or Editing Procedures

As shown in Figure 2-9a, the name of the current procedure and surgeon are shown at the top of the screen. This is followed by the steps comprising the current procedure. Below the current procedure steps is the Procedure Manager which contains a complete library of steps that can be added to the current procedure.



Figure 2-9a Procedure Modify Screen

The items on the Modify screen are defined and operate as follows:

In Procedure: xxx - Shows the name of the procedure containing the selected available Step.

Left button - Moves the selected step one position to the left.

Rename button - Opens the keyboard popup to enable renaming of the currently selected step.

Right button - Moves the selected step one position to the right.

Add to Favorites button - Adds the selected step to the Favorite Steps panel.

Add button - Adds the selected step to the list of steps in the current "In Procedure" steps list.

Delete button - Deletes the selected step from the list.

Procedure Manger Panel - This panel contains the list of steps available for insertion into the In Procedure list. Pressing the arrows on the scroll bar scrolls through the complete list. Also included in this panel are the following filters:

- *Doctor Step Filter* - Restricts the available steps to those belonging to the specified doctor's procedures.

- *Procedure Step Filter* - Restricts the available steps to those belonging to the specified Procedure.
- *Mode Step Filter* - Restricts the available steps to those belonging to the specified Mode.
- *Favorites* - Clicking this button restricts the available steps to those that have been added to the current doctor's Favorites list.

Trash icon - Allows for removal of the selected step from the In Procedure steps list or Favorites List by dragging the step onto the icon.

Save button - Closes the dialog and saves all changes to the current procedure.

Note: The changes are saved in temporary memory only. To save changes after the system has shut down, the procedure must be saved from the Quick Save popup. If no steps are in the procedure an error message is displayed saying, "At least one step must be added to the procedure".

Cancel button - Closes the dialog and discards all changes made to the current procedure.

EDITING THE CURRENT PROCEDURE:

1. To filter the available steps listed in the Procedure manager, set the Doctor, Procedure, and Mode filters so that only the desired steps are shown. The system default is to show all available steps.
2. To add a step to the current procedure, select a step from the Procedure Manager steps list and then press the Add button. When pressed, the selected step is inserted into the In Procedure panel at the position immediately following the currently selected procedure step. Alternatively, the same action can be performed by selecting and dragging the step into the In Procedure panel. To ensure step name uniqueness, if the name of the added step matches the name of an existing step in the procedure, the step name is modified by appending a numeric suffix (e.g. Vitrectomy2).
3. To move a procedure step to the left or right, select the step and drag it to the left or right.
4. To remove a step from the procedure, select the step from the procedure then press the Remove button. If all steps are removed from the procedure, the Remove and Add to Favorite buttons are disabled.

EDITING THE FAVORITE STEPS LIST:

1. To add a step from the procedure to the list of Favorite steps, select the step from the procedure then press the Add to Favorites button. Upon being pressed, the procedure step will be added to the end of the Favorites list.
If a step is added which has the same name as an existing Favorite Step, a prompt is displayed stating: "Overwrite existing favorite step with the same name?" If the user replies Yes, the existing Favorite Step is overwritten. If the user replies No, the keyboard is displayed allowing a new step name to be entered.
2. To delete a Favorite step from the Favorite Steps list, select the Favorite Step and then press the Delete button.

Menu Bar: Options

Button Pressing the Options button on the Menu Bar displays the Options Selection popup shown in Figure 2-9. Each of the four tabs contains various options that may be adjusted here.

SETTINGS: Doctor Settings; System Settings

MAINTENANCE: Test Instrument; Clean Cassette

EXTRAS: Auto Gas Fill; Video Recorder

INFO: View/Copy/Delete; Event Log; About

Menu Bar: Options - DOCTOR SETTINGS

Selecting "Doctor Settings" from the Options menu displays the screen shown in Figure 2-10. It allows the user to specify doctor specific configurations in the following areas as indicated by the tabs at the top of the popup window:

- Surgical Preferences
- Footswitch Programming of buttons and treadle
- Laser settings including laser footswitch programming
- Volume levels for all sounds

The Save, Cancel, and Revert to Defaults buttons apply to all pages.

- **Close Button** - Saves the configurable items on the current settings tab into persistent memory and also applies the settings to the current surgery screen (if applicable).
- **Cancel Button** - Exits the dialog without saving or applying any settings.
- **Revert To Defaults Button** - Resets all the configurable items on the current settings tab to default values.

Menu Bar: Options - DOCTOR SETTINGS - GENERAL

The General Preferences tab contains the following items:

- Language - Drop down list that allows the user to select the language for labels and annunciations. The drop list contains an entry for English and for each language pack installed on the machine.
- Heel Double Click - This selection determines whether or not heel double click functionality is available. Choices: Enabled or Disabled.
- PIN - This section allows the user to add a Personal Identification Number (PIN) the must entered before accessing that doctor's settings.
 - *Add Button* - Pressing the Add button displays a numeric keypad that enables the user to enter a PIN. Not present for Alcon Defaults.
 - *Modify Button* - Allows the user to change an existing PIN for a doctor. Not present for Dr. Alcon Defaults.
 - *Delete Button* - Allows the user to delete an existing PIN for a doctor. Not present for Dr. Alcon Defaults.
- Extraction Display Mode - Allows the user to determine which controls and functionality are present in the extraction panel.
- Ultrasound Display Mode - Allows the user to determine which controls and functionality are present in the ultrasound panel.
- Vitrectomy Display Mode - Allows the user to determine which controls and functionality are present for Vitrectomy Bimanual Mode.



Figure 2-10 The Doctor Settings Popup - General Tab

Menu Bar: Options - DOCTOR SETTINGS - SURGICAL

The Surgery tab contains three sub-tabs that are related to surgery: Infusion/Irrigation, Reflux, and General

Menu Bar: Options - DOCTOR SETTINGS - SURGICAL - INF/IRR

The infusion/irrigation (INF/IRR) surgery sub-tab (shown in Figure 2-10a) allows the user to change certain preferences related to infusion and irrigation during surgery.

- Gravity Mode - Currently disabled.
- IOP Compensation - Determines whether IOP Compensation should be used (when possible).
- Infusion Flow Limit - Allows the user determine whether or not infusion flow limiting functionality should be used.
- Elevated Infusion Alarm Set point - Allows the user specify which infusion value should be regarded as elevated. When the current infusion setting equals or exceeds the specified value, the elevated infusion timer is started. **NOTE: the timer is applicable to both liquid and air infusion.**
- Infusion Units - Allows the user specify the units (mmHg or cmH2O) used for the Infusion Global control.
- Irrigation Units - Allows the user specify the units (mmHg or cmH2O) used for the Irrigation Global control.



Figure 2-10a The Doctor Settings Popup - Surgery/Inf/Irr Tab

Menu Bar: Options - DOCTOR SETTINGS - SURGICAL - REFLUX

This surgery sub-tab (shown in Figure 2-10b) allows the user change certain preferences related to reflux during surgery.

- Posterior Reflux Mode - Allows the user to choose which reflux mode, Proportional or Micro, should be used in posterior steps.
- Anterior Reflux Mode - Allows the user to choose which reflux mode, Continuous or Micro, should be used in anterior steps.
- Continuous Reflux Set point - Allows the user choose the set point for continuous reflux. Range: 0 – 120.
- Proportional Reflux Set point - Allows the user choose the set point for proportional reflux. Range: 0 – 120.
- Micro Reflux Set point - Allows the user choose the set point for micro reflux. Range: 10, 25, 50, 75, 100.



Figure 2-10b The Doctor Settings Popup - Surgery/Reflux Tab

Menu Bar: Options - DOCTOR SETTINGS - SURGICAL - GENERAL

This is Surgery sub-tab (shown in Figure 2-10c) allows the user to change the following preferences related to surgery.

- Diathermy Control Type - Allows the user to determine the type of diathermy, Fixed or Proportional, to be used.
- Illumination Units Selection - Allows the user to determine the units, Lumens or Percent, used for the Illumination Global controls.

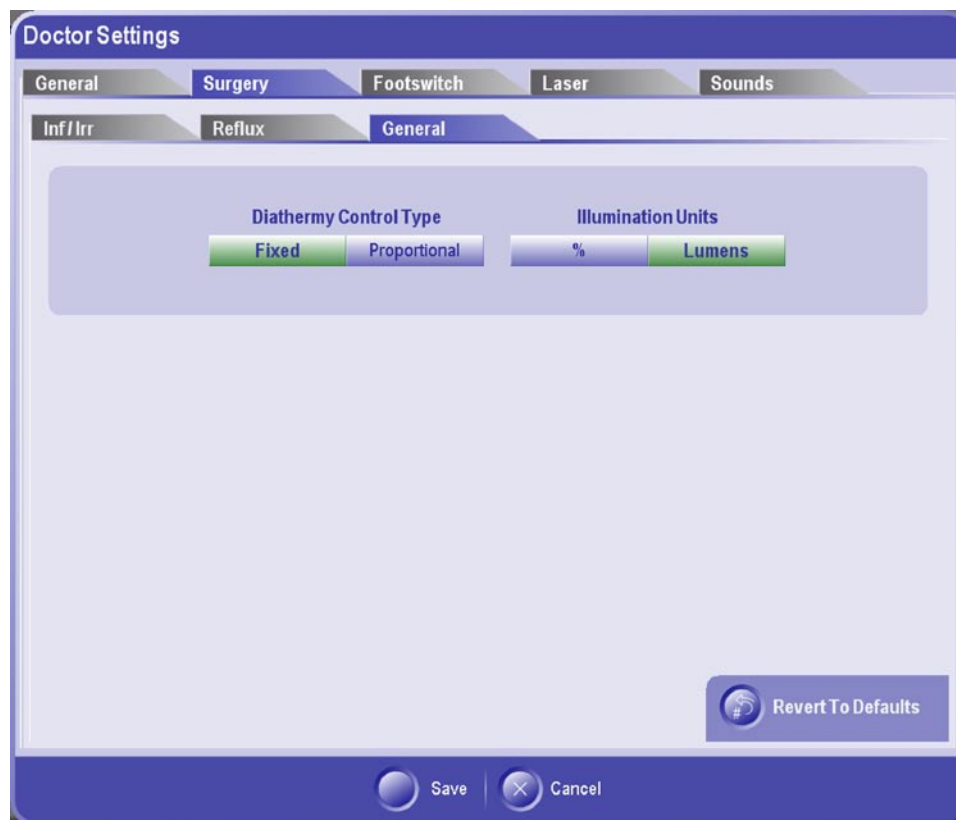


Figure 2-10c The Doctor Settings Popup - Surgery/General Tab

Menu Bar: Options - DOCTOR SETTINGS - FOOTSWITCH

Selecting the Footswitch Settings tab from the Doctor Settings screen allows the user to specify functions for each surgical footswitch button and configure the treadle detents and transitions (see Figures 2-11 through 2-13).



Figure 2-11 Doctor Settings - Footswitch Buttons Screen

Menu Bar: Options - DOCTOR SETTINGS - FOOTSWITCH BUTTONS

The Footswitch Buttons screen allows the user change the function of each footswitch button associated with the currently connected footswitch. Each button is labeled with a dropdown menu that lists the all possible selections for that button in the current mode. Below the footswitch is a horizontal list of modes for the currently selected domain; Anterior or Posterior.

EXAMPLE: Changing the button configuration.

In the Footswitch Buttons Screen, follow the steps below to change the button assignments.

1. Select the domain: Anterior or Posterior.
2. Select the mode.
3. If applicable, select the submode.
4. Select the label next to the button to be changed. The Footswitch Action Selection popup shown in Figure 2-12 appears with the available selections.

5. Select the desired action from the list shown on the popup. To show additional actions, use the scrollbar to the right of the list.
6. Select whether to apply the change to the current mode/submode or to all modes in the current domain. Selecting cancel will close the popup without changing the button action.



Figure 2-12 Footswitch Action Selection Popup

Menu Bar: Options - DOCTOR SETTINGS - FOOTSWITCH TREADLE

The Footswitch Treadle screen shown in Figure 2-13 enables the user to program the treadle vibration, detent firmness, and spans. Depending on the current surgical mode and sub-mode, the treadle has either 2 or 3 positions and the user can program the treadle travel of each position.

- 2-Position Footswitch Transition Position - Sets the transition position (in % of treadle travel). Valid range: 20% - 80%
- 3-Position Footswitch Transitions
 - Point 1 - Sets the transition position (in % of treadle travel) for transition point 1. Valid range: 15% - 31%
 - Point 2 - Sets the transition position (in % of treadle travel) for transition point 2. Valid range: 50% - 100%
- Vibration Enable/Disabled - Allows the user to enable/disable treadle vibration (for both treadle up and treadle down).
- Vibration Frequency - Adjusts the vibration frequency of the treadle when it goes through detents.
- Treadle Firmness - Adjust the firmness of the treadle in a range from 0 to 100%.



Figure 2-13 Doctor Settings - Footswitch Treadle Screen

Menu Bar: Options - DOCTOR SETTINGS - SOUND SETTINGS

Selecting the Sound tab displays the screen shown in Figure 2-14. This screen enables the operator to set a volume for all continuous tones as well as voice confirmations for each doctor. In addition to volume level, the operator can also enable/disable a sound, except for the following, which can never be completely turned off:

- Diathermy
- Errors
- Invalid Key

Each sound can be changed individually or all at once by enabling the Master Override button.



Figure 2-14 Doctor Settings - Sound Screen

Menu Bar: Options - DOCTOR SETTINGS - LASER

The settings available in the Laser settings screen are for setting the Revert to Standby Timeout and Footswitch configuration (see Figure 2-15).

Revert to Standby Timeout

This setting determines the time period, in minutes, after which the system will revert to the Standby mode of operation due to inactivity. Inactivity is defined as no footswitch activation during the time period. The setting can be adjusted to 2, 5 or 10 minutes.

Footswitch Configuration

The Side Switch settings allow the user to enable the side switches to control laser power and transition the system between Ready and Standby.

Power Control Only

This selection allows the side switches to increment (left switch) or decrement (right switch) the treatment laser power.

Power & Ready <-> Standby

When this selection is enabled, the user can transition from Standby to Ready by pressing the right side switch longer than 1.5 seconds until a tone sounds. Similarly, pressing the left side switch longer than 1.5 seconds (until a tone sounds) will transition the system from Ready back to Standby. Pressing the side switches for intervals shorter than 1.5 seconds will increase or decrease treatment laser power.

Standard

This setting disables the side switches entirely so the footswitch can only be used for firing the laser. Power control and switching from Standby to Ready mode can only be done from the front panel of the system.



Figure 2-15 Doctor Settings - Laser Screen

Figure 2-16 Deleted

Menu Bar: Options - SYSTEM SETTINGS

Selecting "System" from the Options menu displays the screen shown in Figure 2-17. This popup screen allows the user to configure settings that are part of the system's normal operation. Once saved by pressing the Close button, the settings become the default when the system is powered up.

SYSTEM SETTINGS - SETTINGS

The settings screen allows adjustments to the following system parameters:

- Screen Brightness - Sets the relative brightness of the touch screen. The allowable range is 1 – 9 with 7 as the default.
- Language - Allows the user set the language used for system purposes such as end case reports.
- WiFi Status - Allows the user determine whether or not WiFi functionality will be available.
- Patient Eye Level Offset - Allows the user set the difference in height between the cassette and the patient's eye level. Range: 0 – 100.
- Patient Eye Level Offset Units - Allows the user determine the units (inches or cm) associated with Patient Eye Level Offset values.
- Auto Gas Fill Purge Cycles - Allows the user determine the number of purge cycles (0-3) when performing an AGF.



Figure 2-17 System Settings - Settings Screen

Menu Bar: Options - SYSTEM SETTINGS - CONNECTION

The Connection screen shown in Figure 2-18 allows the operator to specify connection information for the instrument to communicate with the Alcon Enterprise Server for eConnectivity activities.

- Time of Day - Allows selection of time slots in .5 hour increments to schedule connection activities.
- Recurring Frequency - Indicates at what frequency a connection will be made:
 - Daily - Every day at the specified time.
 - Weekly - Once a week at the specified time on the specified day of week.
 - Monthly - Once a month on the specified day of month and time of day.**Note:** Selecting a day greater than 28 will prevent a connection from occurring in all months.
- Network Connection:
 - Enabled - Indicates the connection is active and available for use.
 - Disabled - Connection is not active or not available for use.

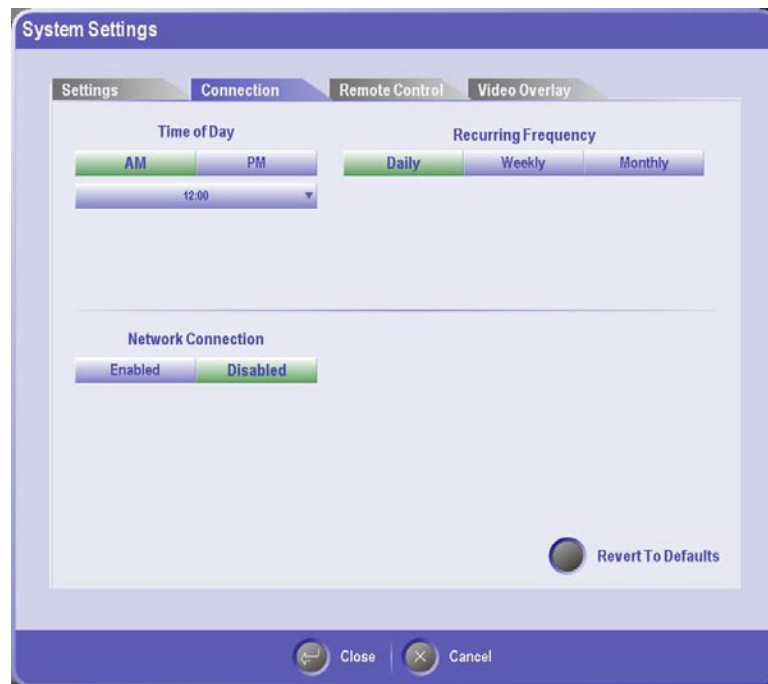


Figure 2-18 System Settings - Connection Screen

Menu Bar: Options - SYSTEM SETTINGS - REMOTE CONTROL

For information regarding the Remote Control Settings (see Figure 2-6), refer to the Remote Control description found earlier in this section.

Menu Bar: Options - SYSTEM SETTINGS - VIDEO OVERLAY

The VideoOverlay setting screen shown in Figure 2-19 provides the settings to enable and setup the VideoOverlay system with the *Constellation®* Vision System.

- Video Overlay - Allows the user determine whether or not Video Overlay is available. Choices: Enabled or Disabled.
- Video Broadcast - Allows the user determine the video format (NTSC or PAL).
- Video Connection - Allows the user set the type of cable (S-Video or Composite) used to connect to the video recording equipment.
- Label Opacity - Allows the user determine the opacity of the video overlay output (range: 0 – 100).



Figure 2-19 System Settings - VideoOverlay Screen

Video Recorder - There are no controls for configuring a Video Recorder other than footswitch mapping that allows the user to start recording and to pause recording when the footswitch is pressed and also a Video Camera icon that appears in the upper left hand corner of the Main *Constellation®* screen when the recorder is recording.

The Video Recorder is a separate user supplied piece of equipment. There are two video recorders that have been officially approved for use with *Constellation®* Vision System. The approved recorders are:

- Sony Medical Grade DVD Recorder P/N DVO-1000MD
Sony Electronics Inc. - Medical Systems Division
1 Sony Drive, Park Ridge, NJ 07656-8003
- Vitec DVD Recorder P/N VMS-3200
Vitec Multimedia Products
2914 Seagull Drive
Duluth, GA 30096

Menu Bar: Options - MAINTENANCE

Maintenance options selectable from the Options popup (see Figure 2-9) include Test Instrument and Clean Cassette.

Test Instrument - This button is reserved for additional functionality.

Clean Cassette - The Clean Cassette feature allows the operator to pump the aspirated fluids from the cassette into the drainbag without having to go through to End Case. Pressing the Clean Cassette button causes the process begin without further user interaction. Once the cleaning process has begun, a popup appears providing feedback on the progress of the cleaning.

Note: This popup also comes up automatically when the user transitions from the Surgery screen area to End Case.

Menu Bar: Options - EXTRAS

Extras options selectable from the Options popup (see Figure 2-9) include Auto Gas Fill and Video Recorder.

Auto Gas Fill - The Auto Gas Fill popup shown in Figure 2-20 steps the operator through the process of filling syringes with the specified gas (either C3F8 or SF6). In Surgery Mode, the operator can optionally use the Auto Gas Fill button within the surgery header to launch this popup. Either technique will launch the same popup with the same functionality and interactions.



Figure 2-20
Auto Gas Fill Popup

WARNING!

Be sure to connect gas bottles to the proper connectors. Bottle valves, tubing, and connectors are color coded as follows: C3F8 = Red, SF6 = Blue.

1. **Make Canister Selection: C3F8/SF6** - Connect gas bottle(s) to system through the mechanical regulator valve located at the back of the console.
2. **Press Start To Begin Filling** - Press the “Start” button to start filling the syringe with the selected gas type. The button is initially disabled and is only enabled during the time period between a gas selection and the commencement of a fill operation.
3. **Purge Cycles Requested: (XX)** - The number of purge cycles can be set by the user ranging from 0 to 5 cycles. The purge cycle is designed to remove any impurities within the system prior to initial use. Press the Stop button to stop filling the syringe in the middle of a fill cycle. The button is initially disabled and is only enabled during a fill operation. The status bar graphically illustrates the progress of the fill operation.

Menu Bar: Options - INFO

Info options selectable from the Options popup (see Figure 2-9) include View/Copy/Delete, Event Log, and About (system information).

View/Copy/Delete - The View/Copy/Delete screen shown in Figure 2-21 is where the user can perform data management related tasks including:

- Copy data from a source memory device to a destination memory device. This is essential to backup data or to move settings to another system.
- Rename selected data items including doctor names, procedure names, and surgical end case names.
- Delete selected data items including procedures, doctor settings, and surgical end cases.
- View selected data items including procedures, doctor settings, and surgical end cases.
- Print selected data items including procedures, doctor settings, and surgical cases.

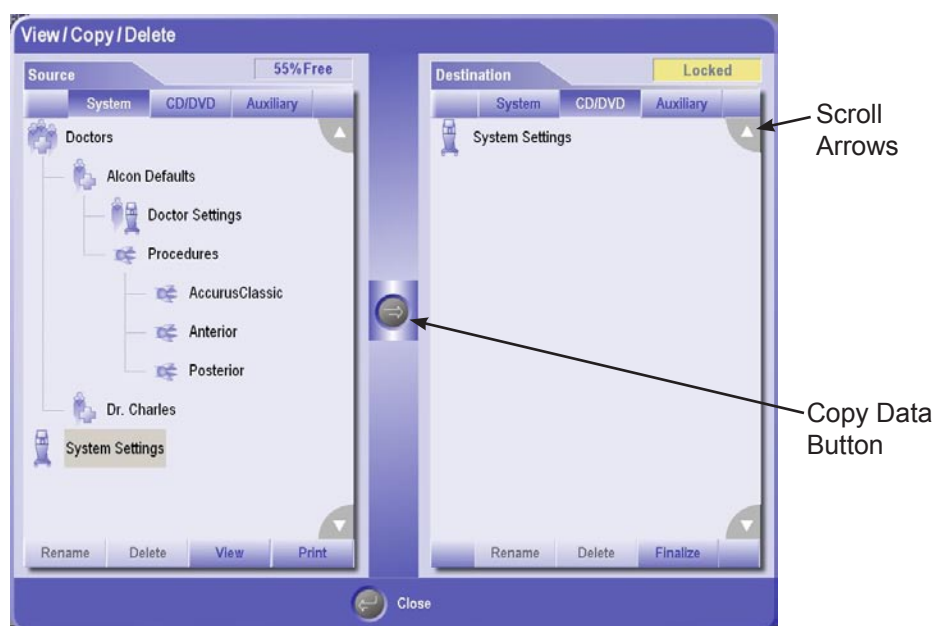


Figure 2-21 View/Copy/Delete Screen

The Source tab of this screen shows information about the media used as the source of a data management or copy operation. The Destination section shows the information for the media used as the targeted location to move data to. Each section shows the media options available to manage data. To select a media option, simply press the selection and the display will show the current contents in a hierarchical structure. The media options are:

- System – refers to the local *Constellation®* Vision System file.
- DVD/CD – Removable media.
- Auxiliary – Removable USB Media card.

If DVD/CD or Auxiliary are selected and no disk or USB media inserted into the system, a popup will appear indicating that no media has been detected and prompting the user to insert a valid media.

At the top of each section, the status of the selected media is displayed.

- xx% Free - Percent of total space available for storage. In Figure 2-21, the display indicates that 35% of the system data storage media is available for additional data.
- Locked – Indicates that a read-only CD/DVD is inserted into the system.

The Data Structure Tree displayed after media selection allows the user to rename, delete, view, or print the selected item. If any of these operations can be performed on the item, the associated button, located at the bottom of the screen, will have a dark background color. There are items such as "Alcon Defaults" that cannot be renamed or deleted.

If an item has additional items below it in the structure, selecting it will expand the structure and selecting again will collapse the structure. If the structure tree expands beyond the screen limits, scroll arrows are available in each corner to scroll to hidden parts of the structure.

To Rename an item:

1. Press the item to select it then press the Rename button. Only doctor names, procedure names, and surgical end case data items can be renamed. Items that cannot be renamed include the Alcon Defaults and the currently selected doctor.
2. When the Keyboard popup appears, press the Backspace key to delete the current name then type in the new name.
3. Press Close to save the name and return to the previous screen. Pressing Cancel will close the keyboard popup without saving the changes.

To Delete an item:

1. Press the item to select it then press the Delete button. Some items cannot be deleted such as the Alcon Defaults or the currently selected doctor.
2. When the confirmation popup appears, press Yes confirm or No to cancel the delete action.

Menu Bar: Options - INFO - VIEWING AND PRINTING DATA

Procedures, Doctor Settings, and Surgical end case data items can be viewed and printed. To view the data associated with one of these items, select the item then press the View button. A detailed view of the item is displayed such as the sample shown in Figure 2-22. The Page arrow buttons are used to navigate to the previous page and next page. Pressing the close button will close the View screen and return to the previous screen.

To print a detailed report of an item, select the item then press the Print button. A popup will be displayed indicating that the report is being sent to the printer connected to the system. Printouts of data are identical to the layout of a reports displayed using the View button.

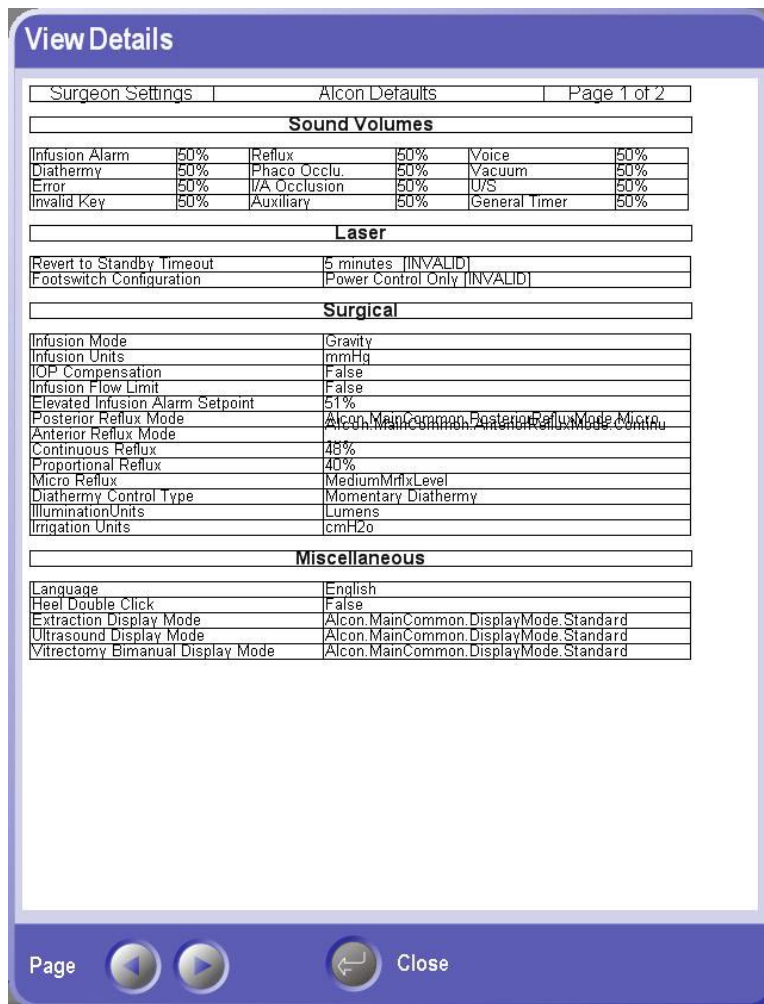


Figure 2-22 Sample View of a Doctor Settings Report

Menu Bar: Options - INFO - COPYING DATA

Copying data between the source device and destination device is performed by first selecting a source data item and then pressing the Copy Data button. When pressed, the source data item is copied to the destination device at the same location defined by the source data item (i.e. the hierarchy is preserved). To write the data to a DVD/CD, the Finalize button must be pressed. If the selected destination device is not the DVD/CD, then the Finalize button is disabled.

If an attempt is made to copy a file that already exists on the destination device, a popup will be displayed indicating the file already exists and three options are available as follows:

- Overwrite - replaces the destination file with the new source file.
- Copy - selecting Copy opens the keyboard popup so the user can rename the file. The old file is not overwritten in this case.
- Cancel - Stops the Copy process with no changes.

Menu Bar: Options - INFO - Event Log

The Event log displays error, advisory, and information messages for the current case (see Figure 2-23). If the user needs to see a message that was previously displayed for the current case, it can be found in the Event Log. Errors, Advisories, and Information messages will be displayed by selecting the respective buttons.

To view the Event Log:

1. Press Options from the Menu bar.
2. Under the Info tab press "Event Log." The default view is displayed show a list of all errors, advisories, and information messages. Pressing the associated button will hide that type of message on the list. If the list goes beyond the viewable area, a scroll bar is provided to move through the list.
3. To view the details of a specific message, select the message on the list, then press View Details. A pop appears with a description of the message and the date and time it occurred.
4. Press Close to go back to the previous screen.

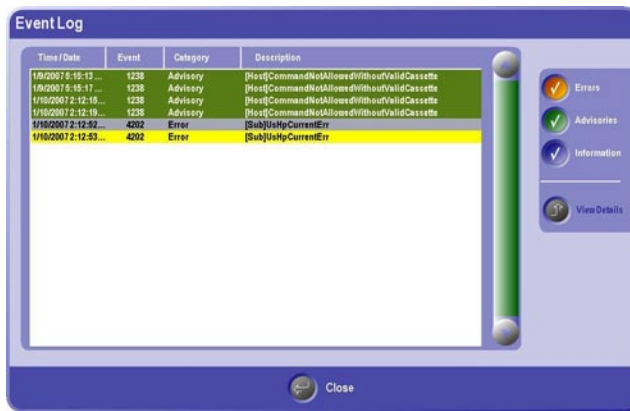


Figure 2-23 Event Log

Menu Bar: Options - INFO - About Constellation

The About Constellation popup (shown in Figure 2-24) displays the following information for the Host and all sub modules:

- Software Revision
- Slot ID
- Hardware Revision
- Logicware Revision
- Patent listings

All Languages installed in the system are also listed here.

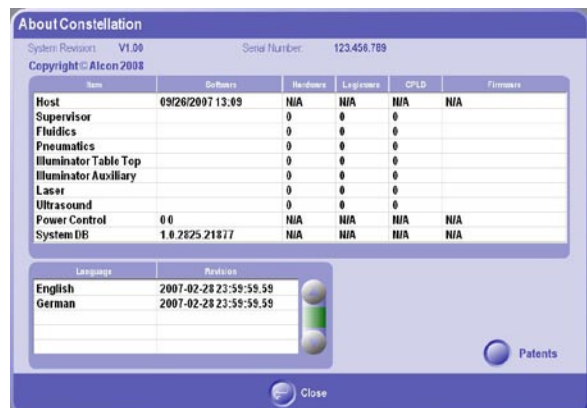


Figure 2-24 About Constellation

Menu Bar - Screen Navigation

The *Constellation®* Vision System system operates in one of three “System States”:

- Setup – Contains the screens for setting up the system in preparation for surgery.
- Surgery – Contains the screens for controlling and viewing surgical functions (vacuum, ultrasound, etc.)
- End Case – Contains the screens for completing and reporting a case.

Navigation between the System States is associated with certain rules stated in the following table:

From	To	Rules
Setup	Surgery	None
Surgery	End Case	Going from Surgery to End Case will “close” the case. This includes saving case related information. To avoid accidentally closing a case, the user is asked to confirm the transition.
End Case	Setup	None
Surgery	Setup	The intended use of the system is to always end each case by going to End Case. However, the user is not forced to go through End Case to start a new case. In order for the system to know when a case ends without going through End Case, a pop-up is displayed when navigating from Surgery to Setup. This popup asks the user whether he wants to start a new case (or just go back to Setup for the current case).
End Case	Surgery	Not possible
Setup	End Case	Not Possible

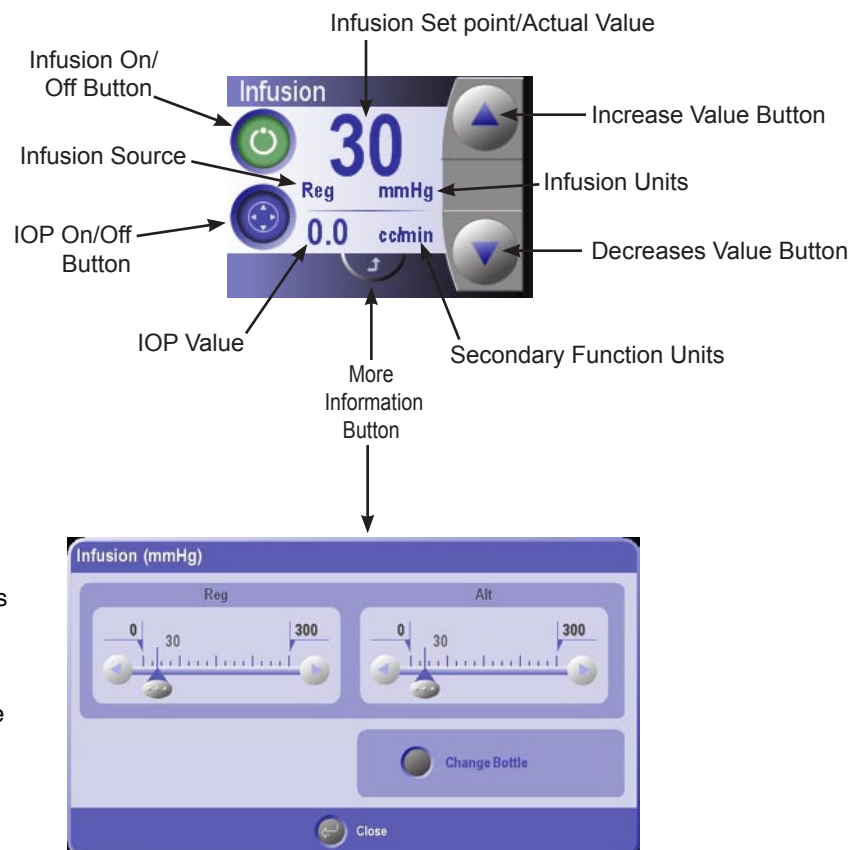
GLOBAL CONTROLS

The Globals area of the screen allows the user to control certain functions that are available in any of the system states (Setup, Surgery and End Case). Global functions can typically be turned on or off independently of other surgical functions (vacuum, U/S power, etc.), although in some cases global functions are required to be on in order to perform surgery. When a global function is on, the On/Off button is green and the background becomes lighter in color.

Infusion Global Control

The Infusion global control (see Figure 2-25) is a dual function that controls both infusion and IOP Compensation. Currently, infusion is the only dual control used on the system. The infusion global control allows the user to:

- Turn infusion On/Off
- Adjust infusion setpoints
- Enable IOP Compensation mode (secondary function buttons)
- Display an advanced configuration screen that allows the infusion values to be changed in more detail. Pressing the Advanced Setup button on the global control displays the Advanced Infusion Setup screen.



NOTE: Advanced Setup Popups have built-in timers that allow them to fade away after a few seconds of inactivity. In addition, pressing anywhere outside the popup causes it to disappear.

Figure 2-25 Infusion Global Control and Advanced Setup Popup

The More Information popup for Infusion allows the user to quickly set values for its two different set points:

- Regular infusion - Infusion value the system will go to upon entering infusion mode.
- Alternate infusion - Infusion value the system will go to when the footswitch button is pressed that is assigned the "InfusionFaxAltRegularToggle" action.

Additionally, the popup contains a change bottle button that will open the Fluid Container Setup popup discussed later in this section.

Fluid/Air Exchange (F/AX) Global Control

The F/AX global control turns F/AX on/off, adjusts setpoints and brings up advanced settings. The More Information popup is design to enable the user to quickly set values for its two setpoints:

- Regular F/AX - F/AX value the system will go to upon entering F/AX mode.
- Alternate F/AX - F/AX value the system will go to when the footswitch button is pressed that is assigned the "InfusionFaxAltRegularToggle" action.

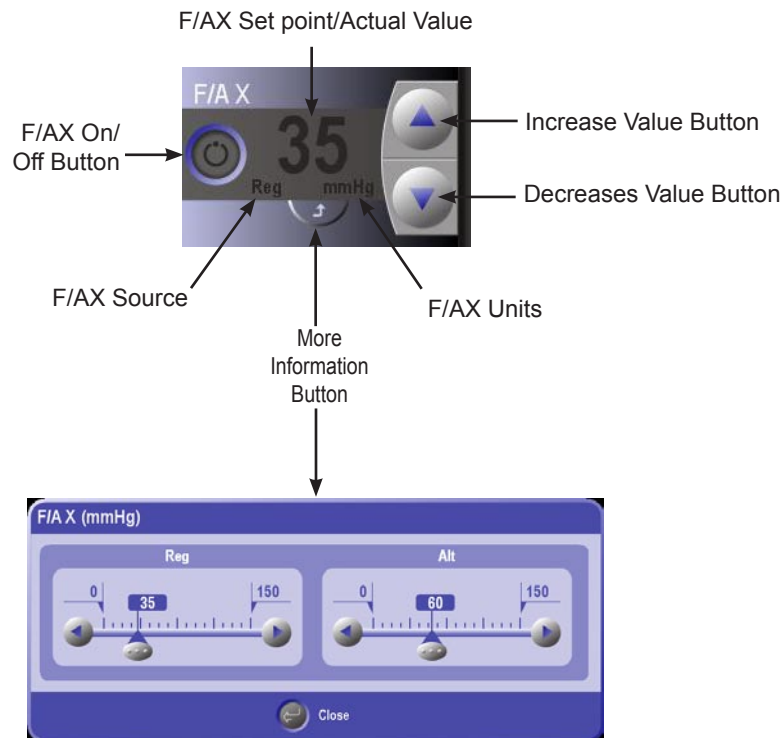


Figure 2-26 F/AX Global Control and Advanced Setup Popup

Irrigation Global Control

The Irrigation global control turns Irrigation On/Off, adjusts setpoints and brings up advanced settings. The advanced setup popup for Infusion allows the user to quickly set values for its two different set points:

- Regular Irrigation - Irrigation value the system will go to upon entering Irrigation mode.
- Alternate Irrigation - Irrigation value the system will go to when the footswitch button is pressed that is assigned the "InfusionFaxAltRegularToggle" action.

Additionally, the popup contains a change bottle button that will open the Fluid Container Setup popup discussed later in this section.

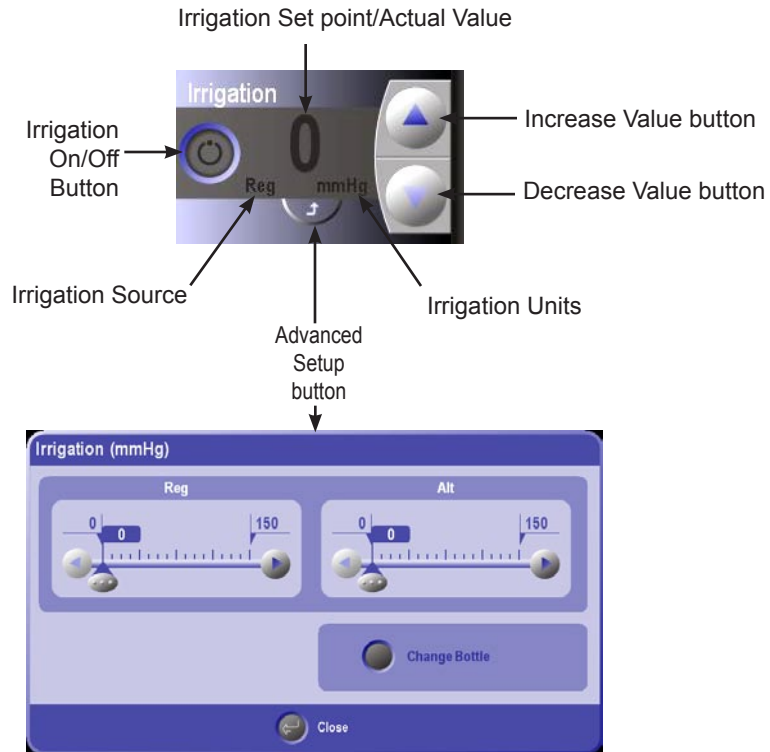


Figure 2-27 Irrigation Global Control and Advanced Setup Popup

Diathermy Global Control

Diathermy Global control turns diathermy on/off, enables fixed or proportional mode, adjusts setpoints, and displays an advanced configuration screen that allows diathermy values to be changed in more detail. Selecting Fixed diathermy provides a fixed percentage of diathermy power when the footswitch treadle is pressed. Proportional diathermy increases the diathermy power in proportion to the distance the footswitch treadle is depressed.

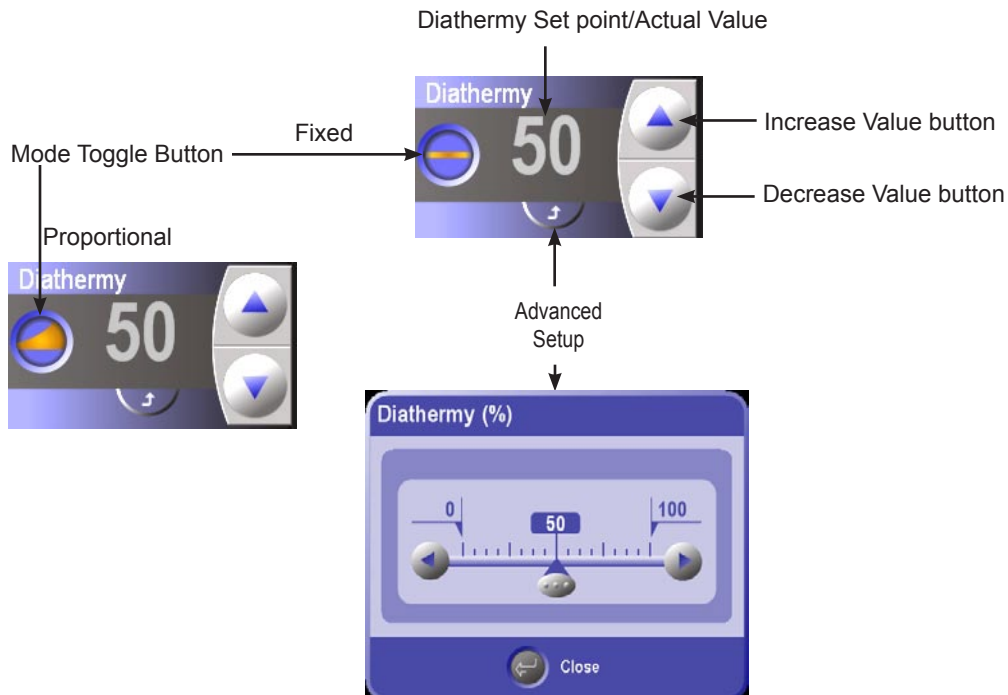


Figure 2-28 Diathermy Global Control and Advanced Setup Popup

Illuminator Global Control

The Illuminator globals control turns up to four illuminators on/off, adjusts setpoints and opens the advanced settings popup. The bulb usage indicator ring light that surrounds the On/Off button, shows how long the illuminator bulb has been in use. This indicator ring has three indication colors:

- Green: 0 to 200 hours
- Yellow: 201 to 400 hours
- Orange: 401 to 800 hours

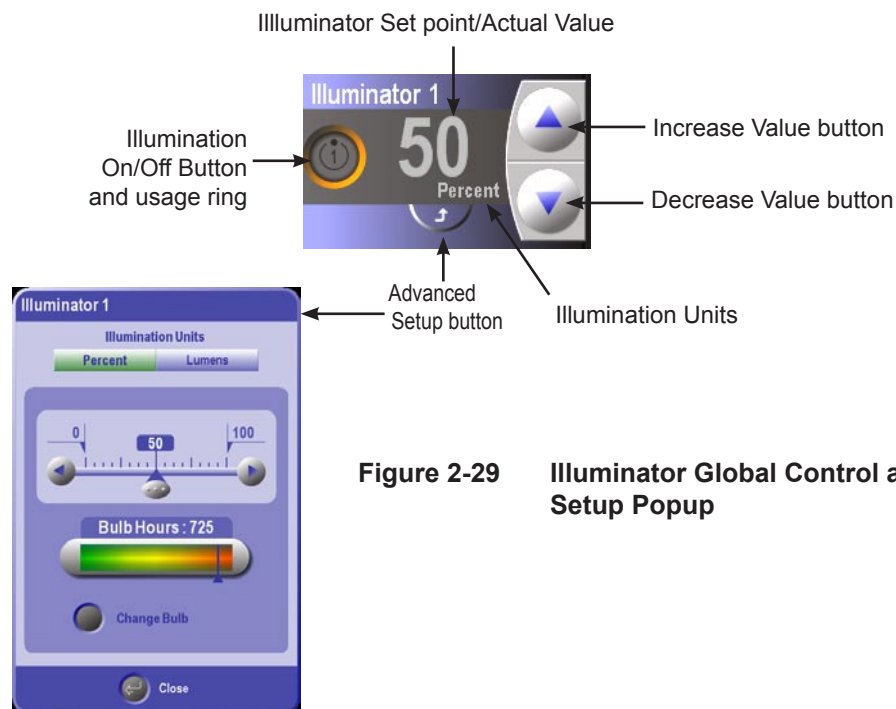


Figure 2-29 Illuminator Global Control and Advanced Setup Popup

The advanced setup popup for the Illuminators allows the user to set values for the setpoints, select unit type, and confirm bulb changes. The system automatically sets the lumen upper limit for each probe by reading the RFID tag for the probe. The surgeon has the ability to override this automatic upper limit for luminous flux, but if he does so, a pop-up will appear that will alert him to the consequences of doing so (i.e. reduction in exposure time to give the equivalent aphakic energy exposure)

Pressing the Change Bulb button displays a popup asking the user to confirm a bulb change. If four illuminators are available, the Advanced Setup screen allows for the setup of all four illuminators in one screen.

WARNING!

To minimize hazardous light exposure, operate light source at lowest intensity setting consistent with adequate visibility of the surgical area. **NOTE:** Light output from a new lamp may greatly exceed the output from the old lamp. Adjust output to lower settings after installing a new lamp.

CAUTION

Avoid prolonged operation of any fiber optic illuminator probe in air at output settings higher than 10 Lumens. This may result in tip deformation of plastic fiber optic illuminator probes. Avoid placing illuminated fiber optic illuminator probes in contact with materials such as sterile drapes.

SYSTEM STATE AREA


The System State area provides specific information on one of the following available states : Setup, Surgery, or End Case. These states are selected by pressing the associated tab in the menu bar.

Setup

System setup can be accomplished using the six setup panels shown in Figure 2-30, the Detailed Setup screens, or a combination of both. The Detailed Setup screens are explained later in this section and include much more detailed information than the Setup panels. In both the Setup panels and Detailed Setup screens the user can perform the following actions:

- View available surgical tools and consumables options.
- Connect the surgical tools and options essential for the upcoming operation.
- Prime/Test the surgical tools before commencing surgery.

Basic Setup

The basic setup uses the six setup panels shown in Figure 2-30. These panels are always displayed in the system state area during setup. Experienced *Constellation®* Vision System users will normally use these panels to quickly setup the system. If desired, the detailed setup screens can be displayed by pressing the Setup button in the Menu Bar or pressing the expand button  on any of the six panels.

Note: Using the barcode scanner to scan a pak automatically sets up these panels for the accessories in that pak.

The six panels displayed on the Setup Screen are:

- Fluidics
- Accessories
- Probe
- Illuminators
- Handpiece
- Lasers



Figure 2-30 The Setup Screen

Basic Setup: The Fluidics Setup Panel

The Fluidics Setup panel allows the user to view and update setup information relating to the cassette, fluid container, and associated surgical tools. Figure 2-31 shows the panel first without a cassette inserted then with a cassette inserted and primed.

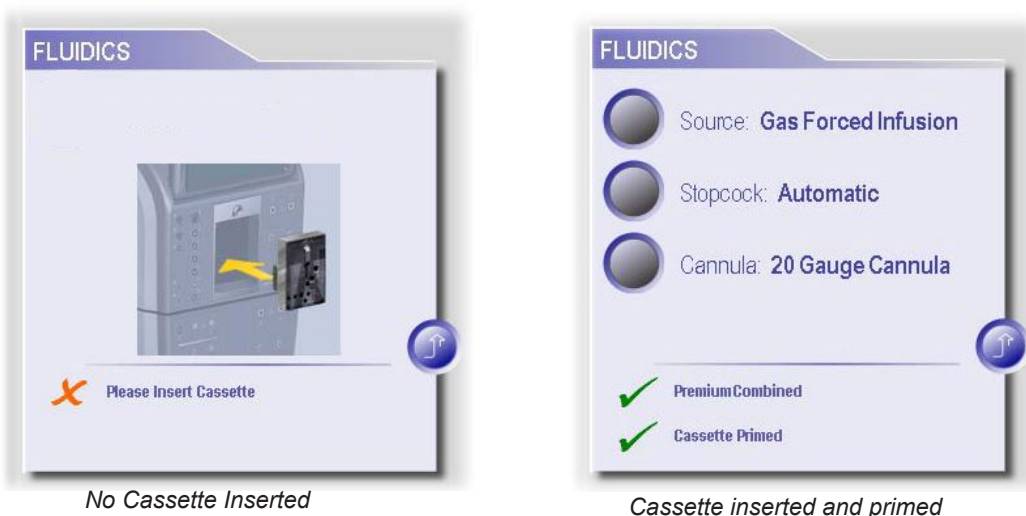


Figure 2-31 The Fluidics Popup Screen(s)

Pressing the option buttons on these panels displays the following selections:

Source Button (Infusion/Irrigation):


- Gas Forced Infusion
- Power Pole
- Gravity

Tubing Set Button:

- Automatic Stopcock – User does not have to operate the stopcock when switching between air and fluid.
- Manual Stopcock – User has to turn the switch on the tubing set to alternate between air and fluid flow.

Infusion Cannula Button:

- 20 guage cannula
- 23 guage cannula
- 25 guage cannula

Pressing the expand button  opens the detailed setup popup that is covered later in this section.

Basic Setup: The Probe Setup Panel

This panel shows setup information related to the handpiece and vitreous probe selections. Figure 2-32 shows the Probe Setup Panel:

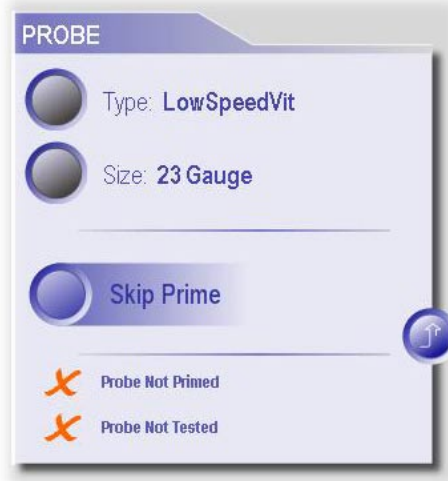


Figure 2-32 The Probe Setup Panel

Type Button - Pressing this button displays the options for vitreous probe selection. The following probe types are selectable from the drop list:

- UltraVit
- Low Speed Vit

The panel shows the vitreous probe the user has chosen and/or plugged in. When the system detects that a probe has been connected, the probe type is automatically selected and the “connected” icon  appears next to the selection list.

Type Button - Pressing this button displays the gauge size options. When the system detects connection of a probe and probe gauge size, the user will not be able to select another probe from the touchscreen (the selection list is locked). The following probe gauge sizes are selectable from the drop list:

- 20 Gauge
- 23 Gauge
- 25 Gauge

Skip Prime Option Button - Selecting this option tells the system to skip priming the selected vitreous probe. This button is a toggle switch that displays a checkmark in the center of the button when active. When the checkmark is present, the system will not prime nor tune the vitreous probe in the next Prime/Tune request.

Expand Button  - Pressing the expand button opens the detailed setup popup that is covered later in this section.

Probe status is displayed at the bottom of the setup panel and indicates whether the probe has been primed and tested. A "✓" indicates that the priming and/or testing has been completed, while an "X" indicates they have not.

Basic Setup: The Handpiece Setup Panel

This panel shows setup information related to handpiece selections. Figure 2-33 shows the Handpiece Setup Panel and the Detailed Handpiece Setup Popup screen.

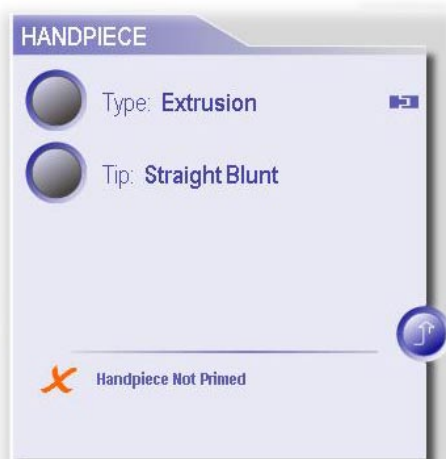



Figure 2-33 The Handpiece Setup Panel


Type Button - Pressing the Type button on the panel displays the list of handpieces that may be used with the system. When the system detects that the user has plugged in the handpiece, the handpiece name is automatically selected and the “connected” icon  appears next to the selection list.

The following handpiece types are selectable from the drop list:

- Extrusion
- Extrusion SoftTip
- Fragmentation*
- Irrigation/Aspiration
- Phaco*
- None

Handpieces that are marked with an asterisk (*) are automatically detected by the system. When the system detects connection of a handpiece, the user will not be able to select another handpiece from the touchscreen (the user list is locked).

Tip Button - Pressing the Tip button displays the tips that the operator can choose for the currently selected/inserted handpiece. The tip selection button is hidden if the currently selected handpiece is “None”

Expand Button  - Pressing the expand button opens the detailed setup popup that is covered later in this section.

Handpiece status is displayed at the bottom of the setup panel and indicates whether the probe has been primed and/or tuned. A "✓" indicates that priming and/or tuning has been completed, while an "X" indicates the it has not.

Basic Setup: The Accessories Setup Panel

Figure 2-34 shows the Accessories Setup Panel. On the panel, pressing a button next to an accessory will display a popup with specific selections for that accessory.

The following accessories selections are available:


- Scissors Handpiece
- Forceps Handpiece
- VFC (Viscous Fluid Control)
- AGF (Auto Gas Fill)
- Diathermy



Figure 2-34 The Accessory Setup Panel


Scissors - Pressing the button next to Scissors shows the following scissors options:


- Proportional
- Multicut
- Undefined - no scissors has been selected or scissors has been detected but is not a known type.

When the system detects that the user has plugged in the Scissors handpiece, the scissors type is automatically selected and the connected icon  appears next to the selection list. In addition, when the user selects an item from this list, the system illuminates the LED on the scissors port on the front panel.


Forceps - Pressing the Forceps button displays the forceps options that are available:

- Normally Open
- Normally Closed

When the system detects that the user has plugged in the Forceps handpiece, the forceps type is automatically selected and the connected icon  appears next to the selection list. In addition, when the operator presses this drop list, the system illuminates the LED on the forceps port on the front panel.

VFC (Viscous Fluid Control) - Pressing this button illuminates the ring on the VFC port on the front panel. When the system detects connection of the VFC tubing set, the connected icon  appears next to VFC.

AGF (Auto Gas Filling) Syringe - Pressing this button illuminates the ring on the AGF port on the front panel.

Diathermy Handpiece - Pressing this button illuminates the ring on the Diathermy port on the front panel. When the system detects that a diathermy handpiece has been plugged in, the connected icon  appears.

Expand Button  - Pressing the expand button opens the detailed setup popup that is covered later in this section.

Illuminators Setup Panel

This panel shows setup information related to illuminator selections. Figure 2-35 shows the Illuminators Setup Panel and the Detailed Illuminators Setup Popup screen.

Illuminator Ports 1 through 4 - Pressing any one of the four illuminators ports allows the user to select between a straight or wide angled illuminator probe. In addition, when the operator presses this drop list, the system illuminates the ring on the associated illuminator port on the front panel. When the system detects connection of an illuminator probe on a port, the “connected” icon will appear next to that port on the selection list. The operator will not be able to select another probe type from the touchscreen for that port.


Expand Button  - Pressing the expand button opens the detailed setup popup that is covered later in this section.




Figure 2-35
The Illuminator Setup Panel

Basic Setup: Lasers Setup Panel

The Laser Setup panel shown in Figure 2-36 displays setup information related to laser probes.

Laser Port 1 and 2 Probe Selection - Pressing the Laser Port 1 or 2 button displays a list of selectable probe types.

- Endo
- Aspirating Endo

When one of the buttons is pressed, the system also illuminates the ring on the associated laser port on the front panel. When the system detects the connection of a laser probe on a port, the connected icon  appears next to the selection list, and the user will not be able to select another probe from the touchscreen for this port.

Expand Button  - Pressing the expand button opens the detailed setup popup that is covered later in the advanced setup section.

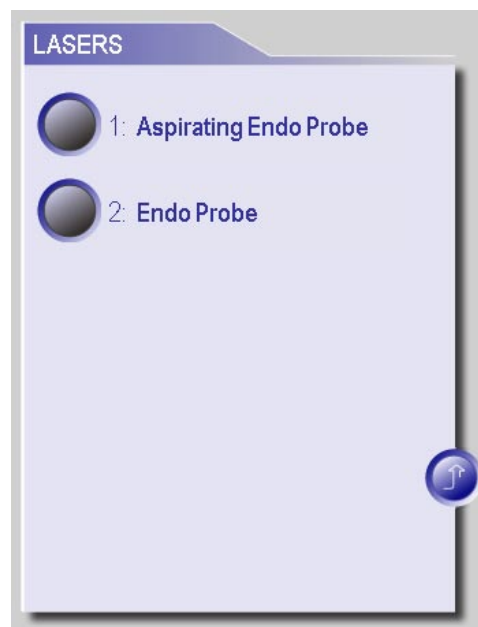



Figure 2-36 The Laser Setup Panel

Detailed Setup

The Detailed Setup screens are displayed by pressing the Setup button in the Menu Bar or pressing the expand button  on any of the six setup panels discussed previously. Figure 2-37 shows the Fluidics Detailed Setup screen. On the left side of the screen are seven selection controls that, when pressed, display the detailed information related to that control.

The seven selections on the Detailed Setup screen are:

- Fluidics
- Probe
- Handpiece
- Accessories
- Illuminators
- Lasers
- Priming Tray

Pressing a selection presents a graphical display of the step required to successfully setup that selection. The Help button at the bottom of the setup screen allows the user to access a video demonstration of the setup process (see Video Help at the end of the Detailed Setup section).

Connection Help - Pressing a highlighted area on the *Constellation*® system shown below the selection area displays a detailed view of the connections for each the following areas on the front panel: electrical/pneumatic, cassette, illuminators, and lasers.

Start Prime Button - The Start Prime button at the bottom of the screen enables the user to initiate the priming process from this screen.

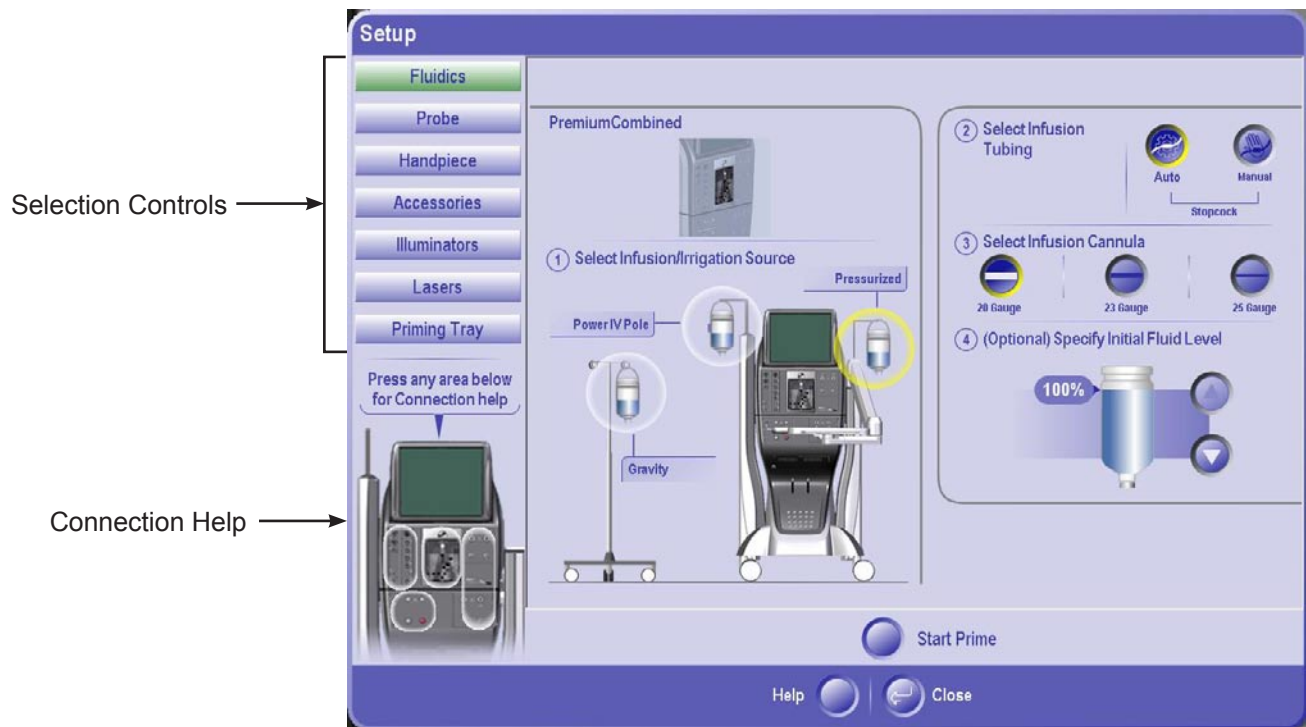


Figure 2-37 The Detailed Fluidic Setup Panel

Detailed Setup: Fluidics

The Fluidics setup panel shown in Figure 2-37 displays the steps required to properly setup the fluidics system after a cassette has been inserted. If a cassette has not been inserted, this screen will direct the user to insert the cassette. Once inserted, the type of cassette is displayed at the top of the panel.

1. **Select Operating Mode** - The options available here are dependent upon the type of cassette inserted into the system. A Premium Combined cassette is inserted in Figure 2-38 and therefore all options are available. If an anterior or posterior only cassette is inserted, the user can only select the associated mode.
2. **Select Infusion/Irrigation Source** - A selection from the Power IV Pole, Gravity or Pressurized options is made here by pressing the bottle associated with the source to be used. The desired source is highlighted in yellow when selected.
3. **Select Infusion Tubing** - Allows the user to select between Auto and Manual Stopcock tubing sets.
4. **Select Infusion Cannula** - Allows the user to select one of the following infusion cannula: 20, 23, or 25 gauge.
5. **(Optional) Specify Initial Fluid Level** - Allows the user to set the starting level of the fluid in the container using the increment and decrement arrow buttons. This enables the system to accurately track the fluid level (in terms of percentage) as the operation progresses and alerts the operator when fluid level is low.