SECTION ONE - GENERAL INFORMATION

GENERAL DESCRIPTION OF THE *CENTURION*™ VISION SYSTEM

1.1.1

The *Centurion*™ Vision System is an ophthalmic surgical instrument designed to provide for cataract lens extraction using the *Centurion*™ *OZil*™ handpiece, *Centurion*™ *Active Sentry*™ handpiece, and the *Infiniti*™ *OZil*™ handpiece.

The *Centurion*™ Vision System is intended for use in small incision cataract lens extraction and IOL injection surgical procedures. This system allows the surgeon to emulsify and aspirate the lens in the eye, while replacing aspirated fluid and lens material with balanced salt solution. This process maintains a stable (inflated) eye chamber volume. Using system controls, the surgeon regulates the amount of energy applied to the handpiece tip, the rate of aspiration, vacuum, and the flow of *BSS*™ irrigating solution. The system includes a footswitch to enable the surgeon to control flow of fluidics, aspiration rate, phaco power, vitrectomy cut rate, IOL injection rate, and coagulation power.

Figure 1-1 The *Centurion*™ Vision System

Key Features of the *Centurion*™ Vision System

- Customized cataract lens removal options:
  - High performance *Centurion*™ *Active Sentry*™ handpiece with precise point of action fluidics control.
  - High performance *Centurion*™ *OZil*™ handpiece with ultrasonic torsional oscillations which can be used exclusively, combined, or alternated with traditional phaco.
  - High performance *Infiniti*™ *OZil*™ handpiece with ultrasonic torsional oscillations which can be used exclusively, combined, or alternated with traditional phaco.
- Advanced fluidics with quick, smooth control of aspiration and vacuum.
- Advanced *Active Fluidics*™ technology with quick, smooth control of irrigation flow, controlled via the front panel, footswitch, or remote control.
- Automated IV pole for traditional gravity fluidics, controlled via the front panel, footswitch, or remote control.
- Programmable IOP target setting.
- Fully programmable, multi-microprocessor control.
- Modularized fluidic connections with disposable Fluidic Management System (FMS).
- Emulation of venturi-like fluidic performance.
- Power assisted IOL insertion by way of lightweight, autoclavable *AutoSert*™ handpiece.
- Ability to drive a high performance *Centurion*™ UltraVit™ vitrectomy guillotine cutter.
- Bipolar coagulation capability.
- Several traditional modalities of ultrasonic power control including continuous, pulsed, and burst application of ultrasonic power, as well as duty cycle management.
- Wireless linear footswitch control of ultrasonic power in phaco steps (sophisticated control loop offers low-end control).
- Wireless linear footswitch control of aspiration flow rate in I/A, vit, and lens removal steps.
- Wireless linear footswitch control of vacuum in I/A, vit, and lens removal steps.
- Wireless linear footswitch control of IOL insertion.

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- On-demand continuous irrigation.
- Programmable, pressurized reflux via the footswitch.
- Ability to set IOP, vacuum levels, and aspiration flow rates to desired levels in phaco, I/A, and vit steps.
- Ability to switch between surgical steps using touch screen, remote control, or footswitch.
- Emission of variable tones for confirmation of system operational status.

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- Voice confirmation during surgical step or mode changes.
- Articulating flat screen: active matrix color LCD with touch screen.
- High-tech graphical user interface.
- Multi-channel IR remote control.

The *Centurion*™ Vision System, including accessories approved by Alcon, constitutes a complete surgical system and is intended exclusively for use by licensed ophthalmic surgeons and their surgical teams. These surgical teams are experienced at conducting phacoemulsification procedures in a properly maintained surgical environment (qualified personnel, availability of backup equipment) and are familiar with the operation of the equipment used as outlined in operator's manuals and directions for use (setup/checkout procedures to be completed before the surgical procedure; processing of reusable devices; maintenance; etc.).

Table 1-3 SPECIFICATIONS

This table is a quick reference point to identify basic system specifications, system requirements, and performance figures.

Product Requirements	Performance Requirements
Console Dimensions: Height: 165 cm (65 in) Width: 51 cm (20 in) Depth: 61 cm (24 in)	**Phacoemulsification:** **(CENTURION™ *OZil*™ handpiece, INFINITI™ *OZil*™ handpiece, CENTURION™ *Active Sentry*™ handpiece)**
Console Weight: Unpackaged: 104 kg (229 lb) Packaged: 142 kg (314 lb)	Submodes: Continuous, Burst, Pulse 1.1.3 (1)(2) a, b, c Longitudinal Tip Stroke @ 100 %: .0084 ± .0018 cm (.0033 ± .007 in) 1.1.2 (1) Resonant Frequency: 43.5 kHz ± 3.0 kHz Tip Velocity: 11.5 m/s ± 2.3 m/s (451 in/sec ± 90.2 in/sec)
Safe Working Load: 24.1 kg (53 lb)	Torsional Tip Stroke @ 100 %: .0069 ± .0023 cm (.0027 ± .0009 in) 1.1.2 (2) Resonant Frequency: 32.0 kHz ± 2.0 kHz 1.1.3 (2)c Pulse Rate Range: 1 - 250 pps 1.1.3 (1)(2) b On Time: 0 - 100 % Burst On Time: 2 - 500 ms 1.1.3 (1)c (2)d Burst Off Time: 2500 - 0 ms
Environmental Limitations – Operating: Altitude: 3,000 m (9,842 ft) Temperature: 10 °C to 35 °C (50 °F to 95 °F) Relative Humidity: 10 % to 95 % without condensation	**Anterior Vitrectomy:** Submodes: Anterior Vit, Epi Removal, I/A Cut, Peripheral Irid, Visco-Asp *Centurion*™ UltraVit™ Probe: 1 to 4,000 cpm 1.1.5 (1)
Environmental Limitations – Non-Operating: Altitude: 5600 m (18,300 ft) Temperature: -40 °C to 70 °C (-40 °F to 158 °F) Relative Humidity: 10 % to 95 % without condensation	**Diathermy (Coagulation):** 10 W max, 75 Ω load 76 Vpp @ 1.5 MHz ± 5 %, 75 Ω load 1.1.4 (2) Waveshape: Sinusoidal
Shock, Bump & Drop: The system conforms to EN ISO 15004-1 requirements for vibration, bump, and shock.	**Vacuum @ Sea Level:** Phacoemulsification: 0 - 650 mmHg (0 - 867 hPa) max 1.1.5 (1)2 Vitrectomy: 0 - 650 mmHg (0 - 867 hPa) max Irrigation / Aspiration: 0 - 650 mmHg (0 - 867 hPa) max
Caster Wheels: Unpackaged instrument must withstand two impacts under conditions: - 7.6 cm (3 in) free fall onto all four casters - 7.6 cm (3 in) tilt drop onto each caster (raise one caster 7.6 cm (3 in) above the floor, then allow device to fall back to normal position)	**Power IV Pole:** Height Range: 20 to 110 cm
Console Stability: Meet IEC 60601-1 placed on incline of 10 ° from horizontal	**IOP Controlled Infusion:** Range: 20 - 110 mmHg (27 - 150 cmH_2O) (27 - 147 hPa) 1.1.5 (3) Accuracy: ± 15 mmHg (20 hPa) Usable Fluid Volume: ≥ 350 cc (350 mL) Aspiration Flow Rate: 0 - 60 cc / min (0 - 60 mL/min) 1.1.5 (2)2
Maximum Weights: Console: 128.7 kg (283.7 lb)	**Voice Confirmation:** Range: 0 to 65 dB
Degree of Protection by Enclosure: Meets IP10 (console), IPX1 (IR remote control), IPX6 (footswitch) as specified in IEC 60529 and IEC 60601-2-2, clause 201.11.6.5 (footswitch)	**Tone Volumes @ 1 meter** Faults: 65 dB, short tone Diathermy: 50 to 65 dB, continuous tone Phaco/Vacuum level: 50 to 65 dB continuous tone Phaco Occlusion: 50 to 65 dB double chime
IR Remote Control: Method: Infrared Channels: 6 Batteries: (2x) AA	**Proportional and Continuous* Reflux @ Sea Level** 1.1.10 (2) Pressure Range: 20 to 140 mmHg (27 - 187 hPa) Pressure Accuracy: ± 10 % of setpoint + 5 mmHg (7 hPa) *Total available Reflux volume: 5 cc (5 mL) replenishable via Aspiration
***Centurion*™ Footswitch:** Dimension: 9.3 cm (3.74 in) tall x 23.5 cm (9.25 in) wide x 38.4 cm (15.1 in) deep Weight: 4.1 kg (9.0 lb) Environmental: Footswitch construction is water tight in compliance with IEC 60601-1 and IEC 60601-2-2 Electrical: Footswitch is configured for wireless transfer Channels: 16	***INTREPID*™ *AutoSert*™ IOL Injector:** Max Speed: 4.4 mm / s
AC Electrical Requirements: 1.1.11 Input Voltage: 100 - 240 VAC 50 / 60 Hz Maximum Input Current: 10 A	**Maximum Loads:** IV Pole: 2.0 kg (4.4 lb) Tray: 9.1 kg (20 lb) Rotating Work Surface: 4.5 kg (10 lb) Footswitch Hanger: 7.0 kg (15.4 lb) Accessories Drawer: 1.5 kg (3.3 lb)
Protection against Electrical Shock: Class I	
Classification of All Applied Parts: Type BF	
Data Card: USB data stick: 8 Gb min.	

Table 1-4 ABBREVIATIONS USED WITH THE *CENTURION*™ VISION SYSTEM

Abbrev.	Description	Abbrev.	Description	Abbrev.	Description
ABS	Aspiration Bypass System	HP	Handpiece	U/S	Ultrasound
AFR	Aspiration Flow Rate	I/A	Irrigation/Aspiration	USB	Universal Serial Bus
Asp	Aspiration	IOL	Intraocular Lens	V	Volt
BF	Body Floating	IOP	Intraocular Pressure	Vac	Vacuum
BSS	Balanced Salt Solution	IR	Infra Red	Vit	Vitrectomy
cc/min	Cubic centimeters per minute	Irr	Irrigation	IEC	International Electrotechnical Commission
Coag	Coagulation	IVO	*Infiniti*™ Video Overlay	IPN_1N_2	International Protection Code N_1 - solid objects (0 to 6, or X - not required to be specified) N_2 - ingress of water (0 to 8, or X - not required to be specified)
CPM	Cuts Per Minute	kg	Kilogram		
DFU	Directions For Use	lb	Pound		
ESD	Electro Static Discharge	LCD	Liquid Crystal Diode		
FMS	Fluidic Management System	mmHg	Millimeters of Mercury		
FTSW	Footswitch	PEL	Patient Eye Level		
HF	High Frequency	PPS	Pulses Per Second		

DESCRIPTION OF CONSOLE

Fluidics Module

The fluidics module is located in the center of the front panel. The module allows fast and easy insertion of the Fluidic Management System (FMS), and because the module contains all the connections required, surgery can be started with minimal delay.

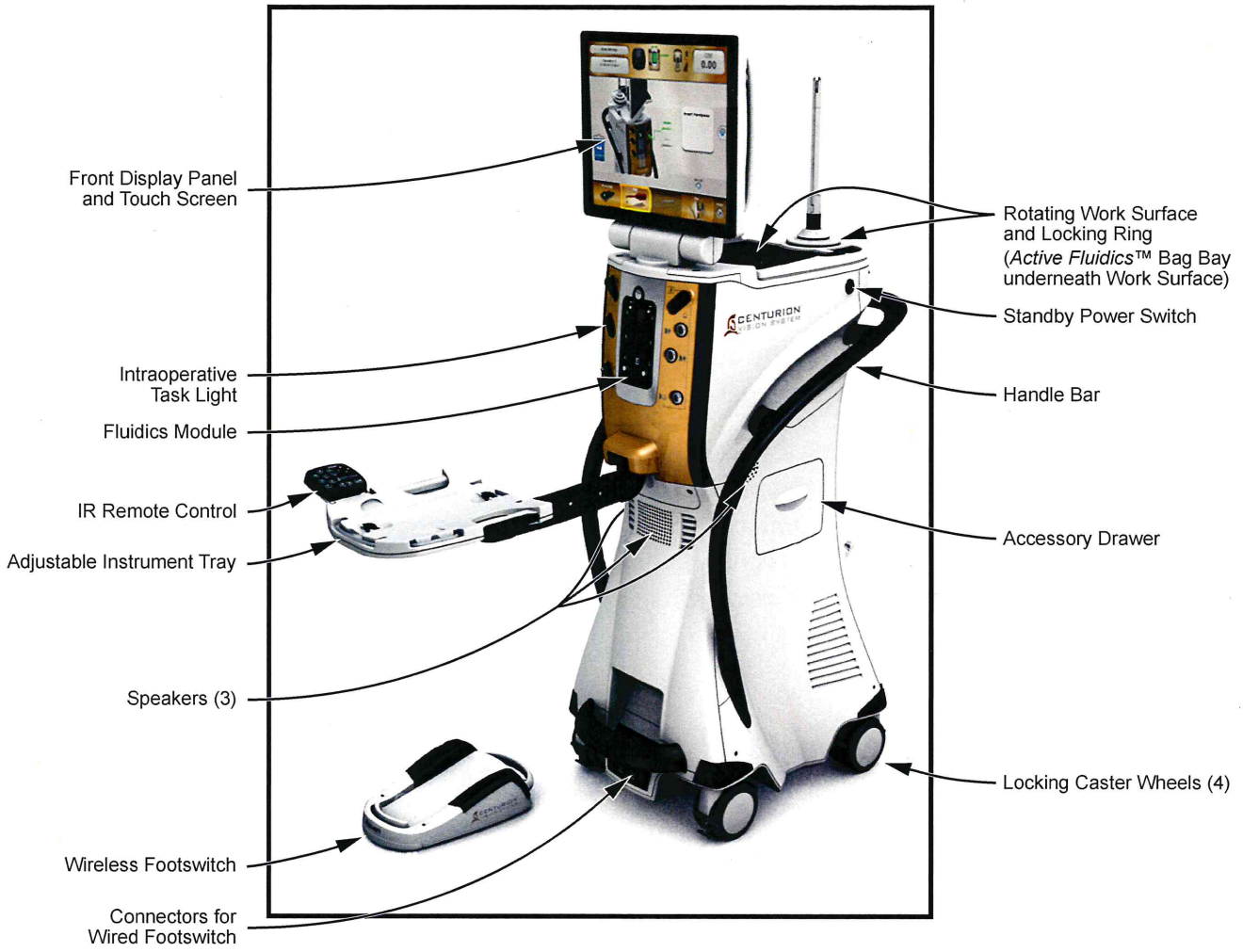


Figure 2-1 The Console
The console contains all the controls, connectors, and communication devices required by the surgeon to perform cataract lens extraction surgery.

1.1.2 (2)

Front Display Panel and Touch Screen

The front display panel tilts and rotates, allowing easy maneuverability during setup and surgery. For storage and transport, the front panel folds down. The front display is the user's main source of system control, allowing fingertip command of system functions.

NOTE: If the *Centurion*™ console is stored in a humid area that is warmer than the use area, allow the system to acclimate to the use area for at least one hour before initializing to avoid condensation on the inside of the display. This will cause the display to appear foggy. If this condition exists, it will take approximately one hour for the condensation to dissipate.

FLUIDICS ADMINISTRATION

1.1.9(1)
1.1.9(2)

The *Centurion*™ Vision system supports two types of fluidics administration to deliver and control fluidics fluid pressure: **Gravity Fluidics** is used for fluid administration using the power IV pole, and ***Active Fluidics***™ technology is an automated system that administers fluid from a bag of irrigating fluid within its bag bay (see *Figure 2-3*).

Power IV Pole and Hanger for Gravity Fluidics

For gravity fluidics a bottle or bag of irrigating fluid is hung from a hanger on top of the IV pole. Raising and lowering the pole increases and decreases the irrigation pressure delivered to the tip of the handpiece. The hanger can be installed in 45° increments by releasing the chrome nut at the bottom of the IV pole, lifting the pole up, and setting it back down at the desired angle.

Bag Bay for *Active Fluidics*™ Technology

For *Active Fluidics*™ technology a bag of irrigating fluid is compressed between two plates within the *Active Fluidics*™ bag bay, located under the rotating work surface on the top of the console. The pressure created by compressing the bag of irrigating fluid is monitored to provide an accurate pressure source, allowing control of intraocular pressure (IOP).

This precise pressure control creates the opportunity to tailor IOP performance based on surgical preference. There are two functions related to *Active Fluidics*™ technology which allow the surgeon to tailor IOP performance: Irrigation Factor and IOP Ramp. These functions are described later in this section of the manual (Fluidics Controls).

WARNING!

Use of irrigating fluid bags other than those approved by Alcon for use in the Active Fluidics™ system can result in patient injury or system damage.

DESCRIPTION OF FOOTSWITCH

The *Centurion*™ Vision System utilizes the *Centurion*™ footswitch (wireless or wired), or can be used with the *Laureate*™, *Constellation*™, *Infiniti*™, or Global wired footswitches (the *Constellation*™ and *Infiniti*™ footswitches require a special cable to connect to the *Centurion*™ system). The *Centurion*™ footswitch can be used wirelessly or can be wired to the console, while the other footswitches must be wired. When the footswitch is operated wirelessly, it retains the same functionality as it does when it is wired to the system.

The footswitch icon button on the display screen is a graphical representation of the footswitch connected. When connected, the current footpedal position (0, 1, 2, or 3) is displayed in the center of the icon, and a triangular arrow appears next to the icon each time a switch is activated. If a footswitch is not connected, a graphical representation of the footswitch is shown in the status bar and no footpedal position is displayed.

Several functions within the system's operating modes are controlled by the surgeon using the footswitch's footpedal and on/off toe switches (horizontal and vertical). The footpedal enables the surgeon to control irrigation flow, aspiration rate, phaco handpiece power, vitrectomy cutting, coagulation power, and IOL injection. The switches are used to turn functions on/off, to adjust function settings, and to progress through surgical steps.

The footswitch's footpedal and switch adjustments are programmable and are available by pressing the Footswitch icon button at the top of the display screen, or by selecting Custom/Doctor Settings/Footswitch (see *Figure 2-7*).

PRECAUTION: A power reset switch is located under the *Centurion*™ footswitch. In the case that a reset is required, simply press a cotton swab into the small hole in the bottom to depress the switch and turn power back on (see *Figure 2-9*). Re-pairing of the footswitch will restore the previously-programmed footswitch settings.

CAUTION

Never pick up or move the footswitch by the cable. Dropping or kicking the footswitch can cause irreparable damage.

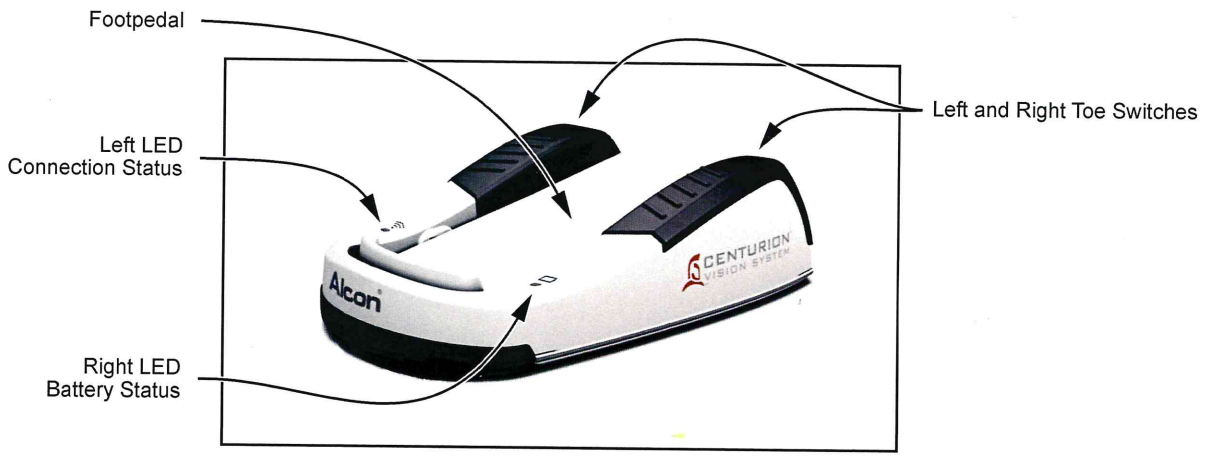


Figure 2-5 The *Centurion*™ Footswitch

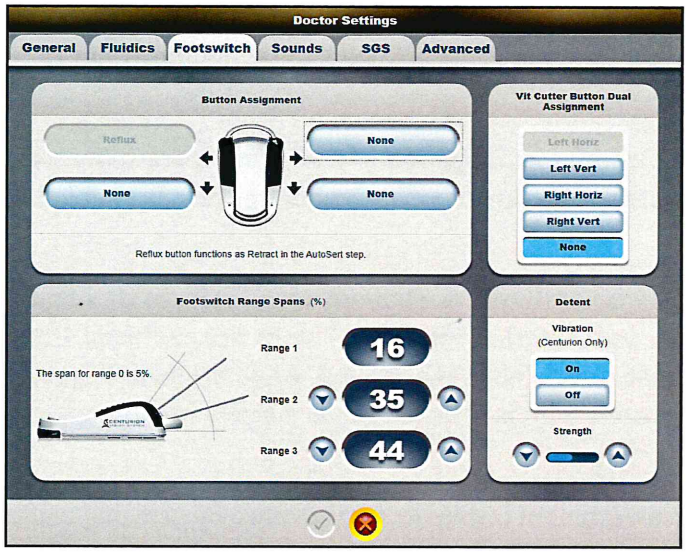


Figure 2-7 **Doctor Settings Dialog Screen - Footswitch Tab**

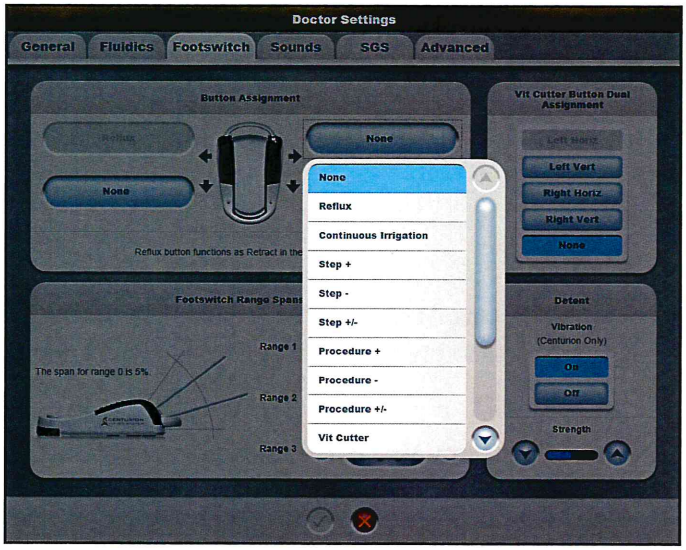


Figure 2-8 **Doctor Settings Dialog Screen - Button Assignment Selections**
Pressing one of the Button Assignment buttons brings up a drop-down menu of functions that can be activated with the surgeon's toe. Several selections are hidden below the selections shown here; the slide bar on the right is used to expose the other selections.

Toe Switch Button Assignment Selections

- None - This selection is made to eliminate functionality from the toe switch.
- Reflux
  The Reflux switch has dual functionality. In most modes of operation the switch function is Reflux, while within the *AutoSert*™ injector step the switch function is to Retract the plunger. At least one toe switch must be dedicated to the Reflux function.

  Reflux: The default reflux pressure is equal to the current bottle height IOP pressure. The reflux pressure can be increased using the Reflux Offset control in the *Custom/ Doctor Settings/Fluidics* menu. In all cases, reflux is not available when the footpedal is depressed, and is not available in a Coagulation step.

Retract: In the *AutoSert*™ injector step this switch moves the plunger in a reverse direction. Control of this function is not allowed while the footpedal is depressed.

- Continuous Irrigation
  Delegating Continuous Irrigation to a switch on the footswitch allows the user to turn Continuous Irrigation on and off, whether or not it is enabled for the selected doctor.

- Step +, Step –
  A switch may be assigned as step advance (Step +) or step back (Step –). The Setup, Coagulation, and Anterior Vitrectomy steps are excluded from this stepping sequence. If step advance or step back is assigned, when the switch is pressed, the next or previous step to the current step is selected in the surgery menu.

- Step +/–
  This switch assignment is used to step advance by pressing and releasing the switch, or to step back by pressing and holding the switch. This switch will not enter the Coagulation or Anterior Vitrectomy steps, but if pressed in a Coagulation or Anterior Vitrectomy step, the system returns to the last-used step.

- Procedure +, Procedure –
  A switch may be assigned to advance to the next procedure (Procedure +) or go back to the preceding procedure (Procedure –). If procedure advance or procedure back is assigned, when the switch is pressed, the next or preceding procedure to the current procedure is selected.

- Procedure +/–
  This switch assignment is used to advance to the next procedure by pressing and releasing the switch, or go back to the preceding procedure by pressing and holding the switch.

- Vit Cutter
  When in Anterior Vitrectomy mode of operation, a selected footpedal button can be assigned the function of enabling and disabling the vitrectomy cutter function.

- Toggle SGS
  When using the *Verion*™ Digital Marker Microscope (DMM) the doctor can turn the SGS display on and off by pressing this programmed toe switch, allowing the doctor to use the *Centurion*™ system with and without a verion video display in his view or on the DMM screen.

- Toggle Video Overlay
  When using a Video Overlay system with the *Centurion*™ system, the doctor can turn the Video Overlay display on and off by pressing this programmed toe switch.

- Irrigation Pressure +, Irrigation Pressure -
  When using gravity fluidics, a toe switch can be selected to move the IV pole up and down to increase or decrease the irrigation pressure. These toe switch assignments are not functional when *Active Fluidics*™ technology is in use.

- Irrigation Pressure +/-
  When using gravity fluidics, this switch assignment is used to increase irrigation pressure by pressing and releasing the switch, and to reduce irrigation pressure by pressing and holding the switch. This toe switch assignment is not functional when *Active Fluidics*™ technology is in use.

Footswitch Status LEDs

Two LEDs, one on the left and one on the right of the footpedal heel, illuminate to indicate footswitch status. The following table shows the LED display patterns with respect to the footswitch's operation state.

Table 2-2 Footswitch Status LEDs

Left LED Indicating Connection Status with *Centurion*™ System	
Color and Behavior	**Description**
Solid Blue	Connected (wired or wireless)
Off	When footswitch is in wireless mode and not engaged*, or in wireless mode and does not hear beacons from console, or in shipping state
Right LED Indicating Battery Status	
Color and Behavior	**Description**
Solid Green	Battery level > 40 % of usable range
Solid Yellow	Battery level ≤ 40 % of usable range
Blinking Green	Battery level > 40 % while charging
Blinking Yellow	Battery level ≤ 40 % while charging
Off	When footswitch is in wireless mode and not engaged*, or in shipping state

* LEDs remain on/blinking for a few seconds after disengagement of the footswitch; i.e., not pressing on the footpedal or any of the footswitch buttons.

Charging Footswitch Battery

- The footswitch is capable of operating on battery power (when fully charged) for 10 complete surgical days.
- The battery is capable of being charged by the *Centurion*™ system in less than 5 hours when charged through the wired connection.
- The battery is capable of being charged by the *Centurion*™ system in less than 10 hours when charged through the wireless charger.
- Footswitch battery charging (for more details see *Table 2-3* & *Table 2-4*):
  - In wired configuration will only charge if *Centurion*™ system is ON.
  - In wireless configuration will charge wirelessly as long as AC is connected or *Centurion*™ system batteries are charged.

Table 2-3 Footswitch Battery Charging Conditions

	Cabled Charging of FS Battery	Wireless Charging of FS Battery
AC Available, *Centurion*™ system ON	Yes	Yes
AC Available, *Centurion*™ system Standby	No	Yes
AC not available, *Centurion*™ system ON	Yes	Yes
AC not available, *Centurion*™ system Off	No	Yes (if system batteries are charged)

DESCRIPTION OF IR REMOTE CONTROL

1.1.7(3)

The IR remote control for the *Centurion*™ system can be used in one of two ways. It can be cradled in the curved metal rods that extend from the instrument tray, and operated under the sterile tray support cover supplied in the disposable pack; this offers the Scrub Nurse or Sterile Assistant access to the controls from the sterile field. Alternatively, the Circulating Nurse can operate the remote control outside the sterile field. Programmability and custom user setup features are functions which are not accessible from the remote control.

CAUTION

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

Remote Control Keys and Buttons

The remote control allows the user to quickly navigate procedure steps and make simple parameter value adjustments (see *Figure 2-11*). The following describes the remote control keys and buttons with the function of each, and explanations of when they are valid. When a remote control key or button is pressed, a valid or invalid key tone is generated as appropriate.

- Parameter Selection Button (▲, ▼, ◀, ▶)
  The keys on the remote control Parameter Selection button are pressed to select parameters for adjustment, and to select Coag and Vit steps. The current selection on the display screen is indicated with a yellow border. With this button the user can move up, down, left, and right to select the desired parameter. This button is valid when the footpedal and/or a footswitch button is up or depressed, but is invalid when a dialog is displayed.

- Snap Keys (**A, B, C, D, E, F**)
  Pressing remote control Snap Keys A through F causes the system to snap focus to various parameter sections on the surgery screen, reducing the number of keystrokes to invoke control of the desired section. When a parameter section is selected using the remote control, the affected setting appears with a yellow border (see *Figure 2-12*), allowing its values to be adjusted using other remote control keys.

Snap Key	Parameter Selected
A	Top Status Section
B	Phaco Parameter Section
C	Task Light/Menu Section
D	Fluidics Parameter Section
E	Fluidics Qualifiers Section
F	Coag/Vit Section

Pressing the *Remote Control* button icon in the upper Status Panel displays the remote control's six snap navigation buttons (A, B, C, D, E, and F) as an overlay on the current screen (white letters in center of black buttons, see *Figure 2-42*).

Centurion™ UltraVit™ Probe

The *Centurion™* system supports the 23 gauge *Centurion™ UltraVit™* vitrectomy probe (see *Figure 2-23*). The probe is a sterile, single-use, vitreous cutter which provides for aspiration and cutting. An irrigating cannula is provided in each pack to allow for bimanual irrigation.

The 23 gauge *Centurion™ UltraVit™* probe supports higher cut rates by utilizing an additional pneumatic actuation line.

Each probe is completely preassembled and requires no lubrication or cleaning prior to surgery. These guillotine vitreous cutters are intended for single use only.

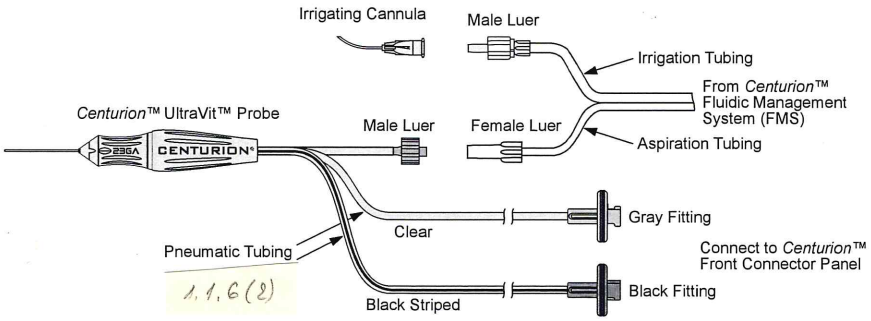


Figure 2-23 **VITRECTOMY PROBES**
The 23 gauge *Centurion™ UltraVit™* probe operates at up to 5000 cpm (5000 cpm available with market approval) and utilizes two pneumatic lines. The probe is packaged with an irrigating cannula. 1.1.6 (1) (2)

VITRECTOMY PROBE WARNINGS!

- **Do not test or operate vitrectomy probes unless tip of probe is immersed in sterile irrigating solution or distilled water or is in surgical use. Irreparable damage to the probe and tip can result if run dry.**
- **Connect pneumatic tubing connectors from vitrectomy probe to console prior to initiating prime of probe. Initiating prime of the vitrectomy probe, or running the vitrectomy system, with one or both pneumatic connectors disconnected may cause the flow of non-sterile air over the sterile field for a brief moment.**
- **After filling and testing, and before surgical use, verify that the probe is properly actuating and aspirating. This may require lowering cut rate to achieve good visualization. The port should always remain in open position in footpedal position 1. If cutting port is partially closed while in position 1, replace the probe. Prior to entry into the eye, and with tip of probe in sterile irrigating solution, the surgeon should step on the footpedal for visual verification that the probe is cutting:**
  - **If the cutter is observed to not fully close, or does not move when the probe is actuated, replace the probe.**
  - **If cutting port is partially closed while idle, replace the probe.**
  - **If air bubbles are observed in the aspiration line or exiting the probe tip during priming, replace the probe.**
  - **If a reduction of cutting capability or vacuum is observed during the surgical procedure, stop immediately and replace the probe.**

These settings are toggled only if they are "On" or "Auto" in the Fluidics settings tab. If the settings are "Off" or "Manual," they are not toggled when the AS button is pressed. When the AS icon is toggled to "Off" or "Manual," it is grayed-out and the PEL button shows the current Patient Eye Level setting.

PEL (cm)

The PEL (cm) button is pressed to manually set the Patient Eye Level to any level between 10 cm and -40 cm above or below the FMS fluid pressure sensor. The PEL lights on the left and right ridges of the console's front panel must match the patient's eye level (see the *Centurion*™ FMS Pack Setup Procedure in Section Three of this manual for details). The numeric level selected is displayed on the button.

If the *Active Sentry*™ handpiece is being used, and the system is in a phaco surgery mode, the PEL button can display "Auto." This means the PEL value is not required when PEL Control is set to Auto rather than Manual in the Custom/Doctor Settings/*Active Sentry*™ tab. Auto PEL is only active for the *Active Sentry*™ handpiece and must be manually established for other handpieces.

1.1.5(1)3

Vacuum Rise

At the onset of an occlusion, it may be desired to slow down the activity at the ultrasound tip. The Vacuum Rise feature slows the aspiration pump rate, decreasing the rate at which vacuum level rises when the ultrasound tip begins occluding. The setting values range from 0 (unadjusted rise time) to -1 to -2 (slowest rise time).

IOP Ramp (s) (used with Active Fluidics™ technology)

IOP Ramp control applies whenever Active Fluidics™ technology is used. The IOP Ramp feature is intended to soften the pressure change impact on the anterior chamber upon irrigation initiation or between changes in IOP target setpoints while in footswitch position 1. It allows adjustment of the time it takes to ramp up from the initial pressure to the target IOP pressure. The establishment of the initial pressure is controlled by the IOP FP0 Ramp Control setting. (Custom / Doctors Settings / Fluidics tab). When the IOP Ramp button is depressed, an adjustment pop-up dialog is displayed which allows adjustment of the transition time from 0 seconds (Fast) to 3.0 seconds. The Anterior Vitrectomy IOP ramp setting is independent from phaco and I/A steps.

Irr Factor (x) (used with *Active Fluidics*™ technology)

When *Active Fluidics*™ technology is used, the Irrigation Factor (Irr Factor) function is available, and works in conjunction with the Estimated Leakage Comp feature (Custom/ Doctor Settings/Fluidics). This feature attempts to compensate for the pressure losses along the irrigation path by adding a factor which is based on the estimated irrigation fluid flow. The scale factor ranges from Off (0) to 2; the larger the value the more compensation is employed. This scale factor is empirically adjusted to compensate for numerous factors including: tip, sleeve, wound architecture, wound size, and surgical technique.

Vacuum Control

The operator can adjust the vacuum limit using the front display panel or the remote control. The adjustable vacuum limit range is 0 to 700+ mmHg (0 to 933+ hPa), where 700+ mmHg (933+ hPa) is limited by atmospheric pressure.

- Fixed Vacuum Control - Fixed vacuum control provides a fixed vacuum limit when aspirating in footpedal position 2.
- Linear Vacuum Control - Linear vacuum control provides linear control of vacuum in footpedal position 2. The actual vacuum limit is proportional to the footpedal position, and tracks with footswitch penetration within the footpedal position.

Aspiration Control

The operator can adjust the aspiration limit using the front display panel or the remote control. The adjustable aspiration limit range is 0 to 60 cc/min (0 to 60 mL/min).

- Fixed Aspiration Control - Fixed aspiration control provides a fixed aspiration flow rate through footpedal position 2.
- Linear Aspiration Control - Linear aspiration control provides linear control of aspiration flow rate in footpedal position 2. Aspiration flow rate is controlled linearly based on settings and by footpedal penetration in position 2

Using Fill Step for Irrigation/Aspiration

The Fill step can be added at any location in the procedure using the Custom/Procedure Builder menu. It is recommended to add the Fill step before the first I/A step to facilitate removal of air from the I/A handpiece prior to use. Adding the Fill step after the last I/A step helps clean the I/A tip and handpiece.

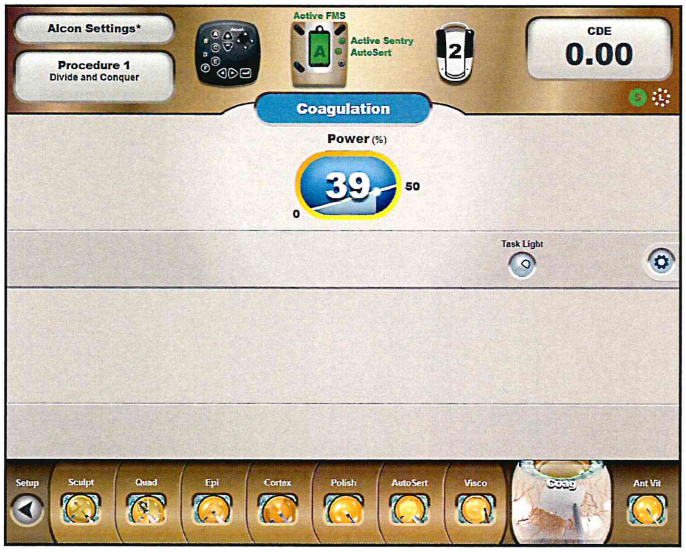
When transitioned into the Fill step, irrigation and reflux will be enabled simultaneously for up to 10 seconds. If Irrigation Fill is enabled in the Custom/System Settings/General menu, this step will be Irrigation Fill, and irrigation will be enabled without reflux.

Coagulation Mode of Operation

The Coagulation mode provides approximately 1.5 MHz frequency bipolar coagulation to drive a brush or forceps in footpedal position 2. The percentage of maximum available coagulation power can be set from 0% to 100% by pressing the Power display button to bring up the adjustment dialog window. In the window select either fixed or linear footpedal control, then press the up or down arrows to increase or decrease the power limit (s).

Coagulation begins upon entering footpedal position 2, and an audible tone is initialized. As in all other steps, coagulation settings are retained in memory so that when re-entering the Coagulation step, the previous settings are displayed.

- Fixed Coagulation Control -Fixed control provides bipolar coagulation at the preset limit when the footpedal enters position 2.
- Linear Coagulation Control - Coagulation Power begins at its lower setting when entering footpedal position 2, and it reaches its maximum setting when the footpedal is fully depressed.



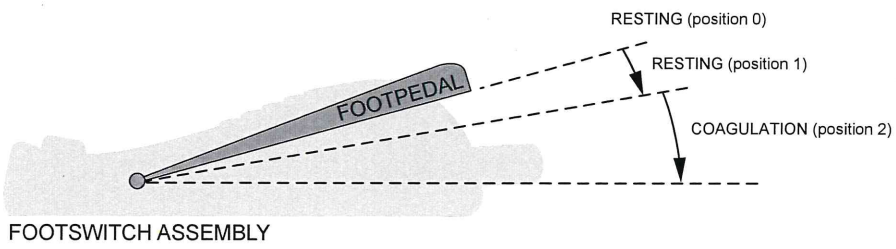


Figure 2-92 The Coagulation Screen