WHITESTAR SIGNATURE PRO

OPERATOR'S MANUAL

Abbott

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1 INTRODUCTION

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About this Manual

This manual includes information about the design of the **WHITESTAR SIGNATURE PRO** System for anterior segment (phacoemulsification) surgical procedures.

This manual includes information about optional system enhancements. Your Abbott Medical Optics Inc. (AMO) representative can confirm the availability of these features for your system configuration and availability in your area.

About Phacoemulsification

Over thirty years ago, Dr. Charles Kelman conceived and developed phacoemulsification (phaco), a method of cataract removal by use of ultrasonic emulsification with aspiration of the cataractous lens through a small incision. Phacoemulsification is advantageous for both patient and surgeon:

- Greater intraoperative control.
- The smaller incision requires fewer or no sutures, poses less risk of infection and induced astigmatism, and gives better long-term and short-term predictability of vision.
- Patients are able to resume normal activity much sooner and with fewer restrictions than with traditional cataract extraction surgeries.

AMO supports phacoemulsification with sophisticated instrumentation that optimizes the benefits of this surgical procedure.

Intended Use

The **WHITESTAR SIGNATURE PRO** System is a modular ophthalmic microsurgical system that facilitates anterior segment (cataract) surgery. The modular design allows the users to configure the system to meet their surgical requirements.

WHITESTAR SIGNATURE PRO System Description and Features

The **WHITESTAR SIGNATURE PRO** System is a multi-functional tool for use in anterior segment surgery procedures. The **WHITESTAR SIGNATURE PRO** System represents the latest generation of **AMO** phacoemulsification technology. Designed and manufactured into every **WHITESTAR SIGNATURE PRO** System are safety, ease-of-use, and reliability. The **WHITESTAR SIGNATURE PRO** System meets applicable United States and International safety requirements for this type of device.

The **WHITESTAR SIGNATURE PRO** System contains a number of features based on extensive research and clinical trials with highly trained and noted ophthalmologists with experience as phacoemulsification surgeons.

WHITESTAR Technology

The **WHITESTAR** Technology represents the many enhancements to the power modulation for the **WHITESTAR SIGNATURE PRO** System. The **WHITESTAR** Technology enhancement was the first to deliver finely modulated pulses of energy, interrupted by extremely brief cooling periods. This allows the system to achieve full ultrasound cutting efficiency and magnetic followability, while introducing less energy into the eye. Minimized ultrasonic time reduces the risk of thermal damage.

WHITESTAR ICE Technology

The **WHITESTAR ICE** Technology was the next advance in micropulse phacoemulsification technology. This technology combined modulated ultrasonic power (pulse shaping) with vacuum control through the use of the Chamber Stabilization Environment (CASE).

This pulse shaping technology modified the standard “square” wave pulse, by increasing the amplitude of the first millisecond of the on time “kick”. The technology then set the remaining part of the on time to the standard power setting. This process repeats for each on time pulse. This results in increased control and efficiency in phacoemulsification.

Occlusion Mode Phaco

The Occlusion mode phaco regulates the vacuum rise time following an occlusion of the phaco tip, without limiting the choice of aspiration rate through an unoccluded needle. To independently control the aspiration rate and the vacuum rise time, you can have a different aspiration rate when the needle occludes than when the needle is unoccluded.

The Occlusion mode phaco also regulates the ultrasound power modulation. You can program the power modulation of the phaco handpiece (continuous, pulse, burst) to automatically change when the phaco tip changes from an unoccluded condition to an occluded condition.

The **FUSION** mode allows the user to access the settings and variables for both CASE and Occlusion mode phaco. The CASE and Occlusion mode phaco can work together or independently.

FUSION Fluidics System

The system has both a flow-based peristaltic pump system and a vacuum-based Venturi pump system. The patented microprocessor-based system continuously monitors and controls intraocular conditions of the flow and vacuum in the eye.

Chamber Stabilization Environment (CASE)

CASE is an intelligent vacuum monitoring system that regulates the maximum allowable vacuum used following the occlusion of the phaco tip. When the phaco tip becomes occluded, the vacuum rises. Clearing of the occlusion while the vacuum is at a high-level can lead to a post occlusion surge. When CASE is on, the system monitors the actual vacuum levels. When the vacuum exceeds a specific threshold for a specified duration, the system automatically adjusts the maximum allowable vacuum setting to a lower predefined CASE maximum vacuum level. When the occlusion clears, the system automatically restores the settings to the original programmed maximum vacuum setting. This function makes it possible to have a different maximum vacuum setting when the needle occludes than when the needle is unoccluded.

Accessories

WHITESTAR Handpiece

The design of the phaco handpiece has a straight-through aspiration channel for more efficient removal of nuclear fragments, to minimize clogging and to facilitate cleaning. The handpiece is lightweight, slim, and well-balanced, making it comfortable to use and easy to control.

ELLIPS FX Handpiece

The **ELLIPS FX** phaco handpiece is available for use with the **WHITESTAR SIGNATURE PRO** System. The **ELLIPS FX** handpiece provides both longitudinal and transversal movement. You can use the handpiece with a straight tip or a curved tip.

Foot Pedal

The foot pedal controls the various operating modes of the instrument. You can program the foot pedal settings through the user interface. You can use either the Single Linear foot pedal, the Advanced Control Pedal or the Advanced Linear Pedal with the system.

The foot pedal design offers control through the use of increased linearity with the foot pedal movement. The design provides uniform pressure throughout the foot pedal movement, easing foot and leg fatigue. You can select the degrees of movement for each foot pedal position. You can save the settings for each surgeon/mode, pitch for the standard foot pedal and the Advanced Linear Pedal and pitch and yaw for the Advanced Control Pedal giving the pedal dual linear functionality. Programmable switches can activate reflux, giving an immediate response.

Wireless Remote Control

The surgery can be controlled from the wireless remote control keypad. You can access all surgical modes and adjust all surgical settings with the use of the wireless remote control. Back-lighting supports low light operating room conditions.

WHITESTAR SIGNATURE PRO System Console

Operating room teams contributed significantly to the successful design of the system console. The solid wheel base and locking wheels make the console stable and smooth rolling. An adjustable height Mayo tray accommodates the handpieces and tubing. The remote control is wireless and recharges when attached to the AC Charging Adapter. The foot pedal has an open bin area for storage.

WHITESTAR SIGNATURE PRO System Display (Graphic User Interface-GUI)

The system graphic screen display is easy to read and easy to operate. You can see at a glance the status of the system. The screen gives you visual indication of operating modes, settings, and system status. Messages cue you through the procedure, and error messages indicate improper connections, or selections. Help information is available when resolving error messages.

Prime/Tune

Before the start of each surgical case, the system requires that you run prime, tune or prime/tune. The prime mode incorporates the function of clearing the tubing of air, then fills the tubing and completes the fluid aspiration check and the vacuum check. The tune mode incorporates an ultrasonic power calibration check and safety check for the attached phaco handpiece. The prime/tune mode allows the system to prime and tune the handpiece at the same time.

Dual Pump

The system provides a fluid aspiration system that uses either a peristaltic (flow-based) pump or a Venturi (vacuum-based) pump system. The surgeon can use both the peristaltic pump and the Venturi pump in the phaco, irrigation/aspiration (I/A), and vitrectomy surgical modes.

Continuous Irrigation

Continuous Irrigation is immediately available by way of the touch screen. Surgeon control of continuous irrigation with the foot pedal is also available. You can use continuous irrigation to fill cups prior to prime/tune. You can use the cup fill feature in place of continuous irrigation when you fill a cup. The cup fill feature is only available from the prime/tune screen. (See “Prime/Tune” on page 3-11 for detailed information.)

Programmable Operating Parameters

The system is programmable through the screens on the touch screen monitor. You can select your desired settings for each portion of the anterior surgical procedure. The instrument program memory stores up to 50 surgeon names with a maximum of 20 different setups, plus the AMO default settings program and the Post Laser Cataract program. This allows different users to preset their preferences, or an individual user to select setups for different procedures, including a personalized initial operating mode.

MMP – Multiple Mode Programming

Multiple submodes are available within the system operating modes. The multiple submodes allows you to preset your settings for specific techniques such as phaco chop or viscoelastic removal.

Programmable IV Pole

The system has a programmable IV pole. You can set the programmable IV pole height parameters independently for each of the phaco modes plus settings for I/A, and vitrectomy. During surgery, the programmable IV pole height changes to the preprogrammed height when you switch modes.

The automated and programmable IV pole allows adjustment of the bottle height to provide gravity infusion through each procedural phase. The up and down arrows on the touch screen or the wireless remote control raises and lowers the bottled balanced salt solution, while maintaining the sterility of the operating field. A separate up and down switch allows IV pole adjustment from the side of the system. The foot pedal can also be programed to move the IV pole.

Note: The IV pole movement is calibrated in centimeters. When the IV pole height is set to inches, the height shown may not update immediately upon pressing the up arrow or down arrow.

WHITESTAR SIGNATURE PRO System Operating Modes

The design of the system provides all the operating modes and surgical capabilities that the anterior segment surgeon or the cataract surgeon requires. These capabilities include:

Phacoemulsification (Phaco)

You use the phacoemulsification mode to break up (emulsify) the nucleus of the lens. You then aspirate the nucleus of the lens from the eye through a small incision. The continuous autotuning circuitry maximizes the emulsification efficiency for each lens density, even varying densities within the same lens. The system displays phaco time in minutes and seconds. The convenient selection of linear or panel preset phaco power, in a variety of power delivery options (continuous, pulsed, burst), provides increased precision, and control.

The **WHITESTAR** Technology allows you to safely remove all lens types through small incisions with single-mode, single-instrument convenience.

The **WHITESTAR** Technology is a patented software program proven to change the characteristics of phacoemulsification using little or no ultrasound. The **WHITESTAR** Technology changes the thermal properties and improves control of the lens without reducing the cutting power or changing technique or efficiency.

Irrigation/Aspiration (I/A)

The irrigation and aspiration mode allows for controlled aspiration of cortical material from the eye, while maintaining intraocular stability, by replacing the aspirated material with a balanced salt solution. This mode gives you flexible control of each case with the independently adjustable vacuum level settings and flow rate settings. A peristaltic pump provides a predictable and stable aspiration rate. “Aspiration Rate” and “Vacuum” settings allows for complete control. Irrigation is gravity-fed.

Note: The vacuum units can be set to either mmHg or kPa. To set the vacuum units go to **Configuration**, **Set Vacuum Units**.

You can regulate the gravity-fed irrigation by adjusting the height of the balanced salt solution bottle (peristaltic). The Venturi pump can also be used to regulate irrigation.

Vitrectomy (VIT)

You use the Vitrectomy mode to remove vitreous from the eye during surgery. The system uses air pressure to drive the vitreous cutter. The wide range of user-controlled, programmable cut rates supports both anterior segment and posterior segment surgeries.

Diathermy (DIA)

Most surgeons use the diathermy mode to coagulate blood vessels during the procedure and by some surgeons to “coag” the conjunctiva at the end of the procedure. An isolated output frequency allows noncontact tissue coagulation, eliminating adhesion, and traction. Also, the depth of penetration of the energy field is less than that of lower frequency units, which minimizes tissue shrinkage or charring. The gentleness of the diathermy mode allows the surgeon to stop “bleeders” within the incision with only minimal scleral shrinkage.

CASE One Touch

The One Touch button simplifies the programming of the CASE function and allows you to easily define the basic CASE settings once. You can adjust the CASE function with the CASE One Touch settings on the surgical screens. When you use these controls, the CASE functionality changes to provide enhanced control or improved efficiency to suit any particular combination of cataract density, surgical technique or personal preferences. See “CASE One Touch” on page 5-27

Safety Precautions

Once you have set the system up and you have verified that all the functions are operating properly, you are almost ready to use your system.

Read the following safety precautions and warnings carefully before you use the system in surgery.

1. Do not use extension cords with your system.
2. Do not overload your electrical receptacle (outlet).
3. If there is damage to the cord or the plug, do not use the instrument. A damaged cable can cause an electric shock to the user or a fire hazard to the system. Call AMO customer service to order a new cord.
4. The instrument has ventilation openings at the rear of the console to allow ambient air intake and the release of heat generated during operation. Do not block the openings; as heat build-up can cause system failures which can result in a fire hazard.
5. Do not try to move the system cart on deep pile carpets or over objects on the floor such as cables and power cords.
6. Take care not to trip over power and foot pedal cords.
7. Do not try to lift the system console.
8. Do not place the instrument on uneven or sloped surfaces.
9. Only use disposables, accessories, or other surgical instruments designed for this system. For optimum performance of the system and safety, use only parts recommended by AMO.
10. Do not operate the system in a condensing environment. Take care to protect the instrument from fluid sprays or fluid buildup.
11. To protect the patient from contaminated fluids or handpieces, use only:
    - sterile tubing packs
    - sterile irrigation fluid
    - sterile handpieces
12. Wrap the excess power cord neatly around the cord wrap on the back of the console.
13. Use caution when you use handpieces with sharp edges or pointed tips.
14. Always replace the tubing pack and the balanced salt solution bottle between cases.

Changing Irrigation Flow

Use extreme caution when you lower or raise the balanced salt solution bottle to decrease fluid flow or increase fluid flow, and fluid pressure. If you lower the bottle too much it can cause the anterior chamber to collapse or to become too shallow; care should be taken to avoid abrasion of tissues during phacoemulsification. If you raise the bottle too high it can cause the anterior chamber to deepen. To make sure that the bottle height does not go too high, you can set the maximum bottle height on the Configuration screen. See “Setting the Maximum IV Pole Height” on page 6-2.

Note: Use a new bottle of balanced salt solution at the start of each case.

Phacoemulsification without Adequate Irrigation

Operating phacoemulsification without an adequate irrigation flow can result in an elevated temperature of the tip and subsequent damage to the eye tissue or could cause the chamber to collapse. Confirm that there is irrigation flow before you initiate phacoemulsification. A tight wound or the angle of the needle next to the wound can also constrict the irrigation flow. Pinching the coaxial irrigation sleeve assembly on the needle of the phaco handpiece causes the constriction.

Power Failure during Surgery

If there is a loss of power during a procedure, you need to:

- Withdraw the handpiece from the eye
- Release the foot pedal to position 0

When power is restored:

- Disconnect at least one of the luers from the handpiece before you insert the pack.
- Insert the pack.
- Connect the tubing to the handpiece.
- Select Prime/Tune to reprime the fluids and tune the phaco handpiece. Use Bypass to reduce the length of prime time.
- Select the mode that was in use when the system lost power (Phaco, I/A, Vitrectomy, or Diathermy)

Connecting Handpieces

It is very important that the electrical connectors on the handpieces are completely dry before you attach the handpiece to the system receptacles.

Handling the Phaco Handpiece

The phaco handpiece is a very delicate instrument and you must handle the handpiece with EXTREME care. If you drop the handpiece or the handpiece receives any other significant impact, the handpiece will not work properly. The ultrasonic titanium phaco tip must never touch any solid material while in use.

Always clear the handpiece of fluid immediately following surgery.

See cleaning instructions in Chapter 7, “Care and Cleaning”.

Handpieces can be extremely hot immediately after sterilization. Use care and caution when handling.

Phaco and Vitrectomy Operation

Do not activate the phaco handpiece and the vitrectomy cutter with the tips exposed to air, as this reduces the useful life of the handpiece and the cutter. When you introduce power to the phaco handpiece or the vitrectomy cutter, the tips must be in one of the following:

- a test chamber filled with balanced salt solution
- in a container of balanced salt solution
- in the patient's eye

Vitrectomy

Failure to properly attach the tubing to the vacuum source or pressure source can affect the vitrectomy cutter operation. Be sure to read the vitrectomy cutter package insert for the correct assembly procedures and connection procedures.

Diathermy

When you select the Diathermy mode, you hear an audible tone. Also, you will hear an audible tone when you apply diathermy power.

You must check the diathermy cable periodically for damage. If the cable shows signs of damage, replace the cable immediately with the same type of cable. Use of other types of cables can affect the diathermy performance.

During surgery, the diathermy output power must be as low as possible for the intended purpose. AMO recommends the 30% setting to start.

You must position the diathermy cable in such a way that the cable avoids contact with the patient or other leads. When you use diathermy, grounded or ungrounded metal parts must not come in contact with the patient.

For proper operation of the diathermy, replace the handpiece with the same type.

Programmable IV Pole

Do not exceed the maximum weight of two 500 ml balanced salt solution bottles on the IV pole bottle holder.

Foot Pedal

Never handle the foot pedal by its cable.

Do not place the foot pedal on a wet surface.

Regulatory Compliance Statements

Federal Communications Commission (FCC) Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by AMO can void the user's authority to operate the equipment. (FCC Part 15.21)

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Industry Canada (IC) Notice of Compliance

This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference; and

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

(1) l'appareil ne doit pas produire de brouillage;

(2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Warnings

WARNING: All personnel who might operate this equipment must read and understand the instructions in this manual before they use the system. Failure to do so might result in the improper operation of the system. Only a trained licensed physician can use this device.

WARNING: Do not modify the **WHITESTAR SIGNATURE PRO** System.

WARNING: The system comes equipped with a 3-prong power plug which you must plug into an outlet with a ground receptacle. If the plug does not fit the outlet, contact an electrician. DO NOT modify or remove the ground pin.

WARNING: When using peristaltic, make sure that the balanced salt solution bottle is at or above the eye level of the patient.

WARNING: The surgical staff must monitor the balanced salt solution bottle height and fluid level at all times. A low bottle or empty bottle affects the fluid balance and the intraocular pressure (IOP) while aspirating. Low bottle height or low or empty bottle fluid level can result in:

- Inadvertent chamber shallowing or collapse
- Aspiration or abrasion of the iris or other tissue
- An ultrasonic wound heating commonly called wound burn (extreme case)

WARNING: DO NOT attempt to use the system if the system fails to perform properly as stated in this manual.

WARNING: DO NOT use the system in the presence of any of the following as a fire can result:

- flammable anesthetics
- other flammable gases
- flammable fluids
- flammable objects
- oxidizing agents

WARNING: Make sure that the patient does not have a cardiac pacemaker as this unit might interfere with any cardiac pacemaker; therefore obtain qualified advice prior to such use.

WARNING: The patient must not come into contact with grounded metal parts or metal parts that have appreciable capacitance to ground. AMO recommends the use of an antistatic mat for this purpose.

WARNING: Use proper handling and disposal methods for biohazards when you dispose of the fluidics pack, Mayo tray drape, and monitor drape.

WARNING: Make sure that the fluidics pack drain bag does not over-fill. The maximum capacity of the bag is 750 cc.

WARNING: Use caution when you extend, retract, or swivel the Mayo tray articulating arm. Stay clear of the hinged hardware.

WARNING: Do not modify the pole height or manually force the pole height because this could cause incorrect indication of bottle height and patient injury.

WARNING: Place monitoring electrodes or other types of equipment as far from those of the **WHITESTAR SIGNATURE PRO** System as possible. AMO recommends high current limiting devices for the protection of such systems. Do not use needle monitoring electrodes.

WARNING: Keep the diathermy cord away from the patient and other handpieces or leads (for example, monitoring electrodes). Keep unused ACTIVE ELECTRODES away from the patient.

WARNING: The output power selected must be as low as possible for the intended purpose.

WARNING: This unit complies with all Electromagnetic Interference (EMI) standards and requirements. It is possible that interference provided by the operation of the HIGH FREQUENCY (HF) SURGICAL EQUIPMENT can adversely influence the operation of other electronic equipment.

WARNING: Do not have skin-to-skin contact on the patient. For example, between the arms and the torso. Insert dry gauze to avoid contact, as appropriate.

Note: The unit does not contain any neutral electrode.

Note: The diathermy output is bipolar.

Note: AMO recommends that you check the condition of all interconnecting and handpiece cables on a regular basis.

WARNING: Risk of burns and fire. Do not use the system near conductive materials such as metal bed parts, inner spring mattresses, or similar items. Replace electrode cables on evidence of deterioration.

WARNING: Hazardous electrical output. This equipment is for use only by qualified personnel.

WARNING: Disconnect the power before you service the equipment.

WARNING: Remove the power cord from the power outlet when the equipment is not in use.

WARNING: Do not obstruct the power outlet so you can readily remove the power cord.

WARNING: Not recommended for use in condensing environments. If exposed to a condensing environment, allow the system to equilibrate to typical operating room conditions prior to use.

WARNING: You do not need to use a NEUTRAL ELECTRODE with this HIGH FREQUENCY (HF) SURGICAL EQUIPMENT.

WARNING: Failure of the HIGH FREQUENCY (HF) SURGICAL EQUIPMENT could result in an unintended increase of output power.

WARNING: DO NOT try to replace the batteries for the Advanced Control Pedal. Call your AMO technical service representative to replace the batteries.

WARNING: DO NOT try to replace the wireless remote control batteries. Call your AMO technical service representative to replace the batteries.

WARNING: Sterility assurance is the responsibility of the user. You must sterilize all non-sterile accessories prior to use.

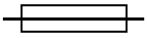
WARNING: Prior to using any invasive portions of the handpiece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. You must note any questionable characteristics; use a backup handpiece for surgery. Use of contaminated or damaged system accessories can cause patient injury.

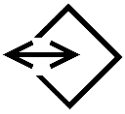
WARNING: Do not have the handpiece tip in the eye of the patient when you prime and tune the handpiece.

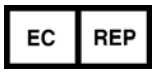
WARNING: Do not use non-AMO approved products with the **WHITESTAR SIGNATURE PRO** System, as this can affect overall system performance. AMO cannot be responsible for system surgical performance if you use these products in surgery.

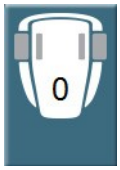
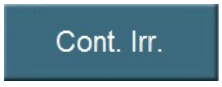
Symbol Definitions

The following symbols appear on the **WHITESTAR SIGNATURE PRO** System front and back panels and in the software:

Symbol	Definition
	Symbol on the power switch indicates power is on.
	Symbol on the power switch indicates power is off.
	Indicates WARNING; a potentially hazardous situation which, if not avoided, could result in serious injury.
	Indicates that there are important operating and maintenance instructions included in the operator's manual.
	Indicates that there are important operating and maintenance instructions included in the operator's manual.
	Indicates the presence of uninsulated high voltage inside the instrument. Risk of electric shock. Do not remove the instrument cover.
	Brazilian National Institute of Metrology, Standardization and Industrial Quality (INMETRO)
	Product Certification Body (OCP) - TÜV Rheinland do Brasil Ltda.
	Indicates fuse.
	Single phase alternating current.

Symbol	Definition
	Indicates isolation of the patient applied part from earth ground.
	Foot pedal connection.
	Communications port
	Programmable IV pole
	Diathermy receptacle
	Phaco handpiece receptacle
	Vitrectomy cutter receptacle
	Potential equalizer used to identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
IPX8	IPX8 is the International Protection code that indicates that the device is protected against the effects of continuous immersion in water.
IPX4	IPX4 is the International Protection code that indicates that the device is protected against splashing water sprayed at all angles.
IPX6	IPX6 is the International Protection code that indicates that the device is protected against powerful water jets.
CE 0413	Indicates compliance with the Medical Device Directive.

Symbol	Definition
	Indicates the authorized European Union representative.
	Separate disposal/collection required
	Indicates manufacturer of the **WHITESTAR SIGNATURE PRO** System.
	Date of manufacture of the **WHITESTAR SIGNATURE PRO** System.
	Environment friendly use period in years (RoHS)
	Indicates compliance with IEC 60601-1-2:2001, “Electromagnetic Compatibility Requirements and Tests for Medical Electrical Equipment.”
	ETL Listed Mark issued to those products that have met the requirements of product safety standards for the United States and Canada. (ETL formerly Edison Testing Laboratory)
	Universal Serial Bus (USB) port
	Federal Communications Commission (FCC) The FCC regulates interstate and international communications by radio, television, wire, satellite, and cable under the FCC’s jurisdiction.
	Mark on shipping crate indicating not to open the crate except by authorized personnel.

Symbol	Definition
	**FUSION** mode button used to open the CASE and the Occlusion mode settings screen.
	Single Linear Foot Pedal icon. Shows the current position of the foot pedal as you press the foot pedal. The number changes when the position of the foot pedal changes. When pressed, the Foot Pedal Configuration screen opens.
	Advanced Control Pedal (ACP) icon. Shows the current position of the foot pedal as you press the foot pedal. The number changes when the position of the foot pedal changes. The letters indicate the location of Aspiration (A), Irrigation (I), Phaco (P), Reflux (R), **WHITESTAR** increment/decrement (WS) and Switch (S). When pressed, the Foot Pedal Configuration screen opens
	Advanced Linear Pedal. Shows the current position of the foot pedal as you press the foot pedal and the activated foot switch. The number changes when the position of the foot pedal changes. When you press icon, the Foot Pedal Configuration screen opens.
	Battery icon on the Advanced Linear Pedal Test screen. Indicates the battery charge left in the battery.
	**WHITESTAR** Technology is on.
	**WHITESTAR** Technology is on and ICE pulse shaping is on.
	**ELLIPS FX** handpiece is attached.
	Reload - The reload button cycles through the surgeon's programs.
	Continuous Irrigation - Used to turn continuous irrigation on or off.
	Volume control - When pressed cycles through the volume settings.

Symbol	Definition
	Help - Only active when there is an error. Select this icon to show possible solutions to clear the error.
	Clear Error - Only active when there is an error. Select this icon after resolving the error. The icon removes the error from the display.
	Event Log - Select this button on the Configuration screen to view the Event Log.
	Touch Screen Calibration - Select this button on the Configuration screen to calibrate the touch screen on the system.
	Max IV Pole Height - Select this button on the Configuration screen to set the maximum height the IV pole can move.
	Wireless Setup - Select this button on the Configuration screen to pair the wireless remote control or the wireless foot pedals.
	View Software Versions - Select this button on the Configuration screen to view the version of the software installed on the system.
	IV Pole Test - Select this button on the Configuration screen to test the movement of the IV pole.
	Wireless Remote Test - Select this button on the Configuration screen to test the functionality of the remote control.
	System Self Test - Select this button on the Configuration screen to run a test of the system.
	Set Date/Time - Select this button on the Configuration screen to set the date and time.
	Language - Select this button on the Configuration screen to select the language used for the user interface.

Symbol	Definition
	Set Vacuum Units - Select this button on the Configuration screen to set the vacuum units to either mmHg or kPa.
	Surgical Media Center (SMC) - Select this button on the Configuration screen to format how the SMC starts to record surgery.
	Service Interval - Select this button on the Configuration screen to view when the next time maintenance is due on the system.
	Import/Export Database - Select this button on the Configuration screen to import or export a database to or from the system.
	Restore Database - Select this button on the Configuration screen to restore a database if the current database is corrupted.
	Backup All - Select this button on the Configuration screen to save data to a USB device.
	Restore All - Select this button on the Configuration screen to restore data from a USB device.
	Add Surgeon or Program - Select this icon to add a surgeon to the list of surgeons or a program to the list of programs.
	Delete Surgeon or Program - Select this icon to delete a surgeon from the list of surgeons or a program from the list of programs.
	Edit Surgeon - Select to edit the surgeon or program name.
	Foot Pedal Settings - Select to set up or edit the foot pedal settings.
	Sound Settings - Select to set the volume settings for the system.

Symbol	Definition
	Move Doctor Name Up - Select a surgeon name on the list of surgeons and use this icon to move the doctor's name up the list. This can be used to alphabetize the list of surgeons.
	Move Doctor Name Down - Select a surgeon name on the list of surgeons and use this icon to move the doctor's name down the list. This can be used to alphabetize the list of surgeons.
	Settings - Select to set the specific surgical program settings.
	More - Opens additional settings screens.
	Save - Used to save changes made to settings during surgery.
	Save As - Located on the Program Settings screen. Used to save the program with a new name.
	Restore Program - Located on the Program Settings screen. Used to change the settings back to the previous saved settings.
	Restore Submode - Located on the Program Settings screen. Used to change the submode settings to the previous saved settings.
	Lock Program - Select to lock the settings for the selected program. You cannot unlock a program once the program is locked.
	Copy Program - Select to copy an existing program and rename to a new program.
	Move Program Name Up - Select a program name on the list of programs and use this icon to move the program's name up the list. This can be used to alphabetize the list of programs for the active surgeon. The name at the top of the list becomes that surgeon's default program.
	Move Program Name Down - Select a program name on the list of programs and use this icon to move the program's name down the list. This can be used to alphabetize the list of programs for the active surgeon.

System Disposal

WEEE

The electronic components of the **WHITESTAR SIGNATURE PRO** System are subject to the European Union Directive 2002/96/EC on Waste Electrical and Electronic Equipment. This directive applies to all electronic equipment in the European Union only.

The disposal to municipal waste is prohibited for electronic equipment subject to this directive; this equipment must be treated or recycled. Each component that is subject to this regulation is marked on the component itself with this symbol:

In some cases where the component's size prohibits marking (such as handpieces) the marking can be found on the directions for use and the warranty. Treatment and/or recycling of the electronic equipment are provided at no cost to you. Please see the contact information below for disposition of unwanted AMO electronic equipment.

For disposal of your unit, contact your local AMO subsidiary or the AMO service center, http://www.abbottmedicaloptics.com/customer-service/overview.

RoHS (Restriction of Hazardous Substances)

For Chinese regulation: *Administrative Measure on the Control of Pollution Caused by Electronic Information Products*.

Names and Contents of Toxic/Hazardous Substances or Elements Contained in Products						
	Toxic/Hazardous Substances or Elements					
Assembly						
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr6+)	Polybrominated Biphenyl (PBB)	Polybrominated Diphenyl Ethers (PBDE)
Housing	X	O	O	O	O	O
Power Supply	X	O	O	O	O	O
Motherboard	X	O	O	O	O	O
Rear Panel Assembly	X	O	O	O	O	O
Pneumatics	X	O	O	O	O	O
Monitor	X	O	O	O	O	O
Base Unit	X	O	O	O	O	O
Fluidics	X	O	O	O	O	O
Remote Control	X	O	O	O	O	O
Single Linear Foot Pedal	X	O	O	O	O	O
Advanced Control Pedal (ACP)	X	O	O	O	O	O

Advanced Linear Pedal (ALP)	X	O	O	O	O	O

Format of this table is in compliance with SJ/T11364-2006

O: Indicates that this toxic/hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in GB/T26572.

X: Indicates that this toxic/hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in GB/T26572.

Restriction of Hazardous Substances in Electrical and Electronic Equipment (EU RoHS)

All homogeneous materials for the parts contained within the **WHITESTAR SIGNATURE PRO** System are below the limit requirement in Directive 2011/65/EU Annex II, or are addressed by an exemption noted in Annex III or IV.

Registration, Evaluation, Authorization and Restriction of Chemicals (EU REACh):

For information related to Article 33 of the EU REACh regulation (EC No. 1907/2006), please refer to Abbott Laboratories' (Abbott) Product Material Information System (http://pmis.abbott.com). If you have issues logging into the web site, contact Abbott at abbott.REACH@abbott.com.

2 SYSTEM COMPONENTS

Receipt and Inspection Instructions

WHITESTAR SIGNATURE PRO System Components

Receipt and Inspection Instructions

When you receive your **WHITESTAR SIGNATURE PRO** System inspect the exterior packaging for any signs of damage that might have occurred during shipping and record this damage on the shipping documents. If there are any signs of damage to the exterior packaging, have authorized personnel carefully unpack the **WHITESTAR SIGNATURE PRO** System and inspect the system for damage. If any damage to the package contents has occurred, you must immediately file a claim with the transporter. The transporters accept claims only from the recipient (you), not from the shipper (AMO).

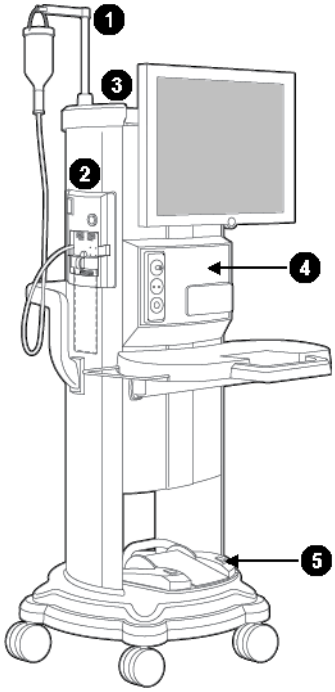
Your AMO representative will contact you to schedule both the installation and the in-service training when you receive your new **WHITESTAR SIGNATURE PRO** System. We suggest that you leave the **WHITESTAR SIGNATURE PRO** System in the original packaging. Store the package in a cool, dry environment until the AMO installation personnel arrive to assemble, install, and test your equipment. Extreme heat, cold or moisture can damage any electronic equipment.

WHITESTAR SIGNATURE PRO System Components

Your **WHITESTAR SIGNATURE PRO** System consists of all or some of the following components:

- **WHITESTAR SIGNATURE PRO** System console with a Mayo tray on an adjustable arm, detachable power cord, and a programmable IV pole
- **FUSION** pack (disposable)
- Foot pedal and foot pedal cable (Single Linear Pedal (SLP), Advanced Control Pedal (ACP), or Advanced Linear Pedal (ALP)) (With AC Charger for the ACP and the ALP)
- Wireless remote control module (With AC Charger)
- Surgical Media Center (optional)
- **WHITESTAR SIGNATURE PRO** System Operator’s Manual

Figure 2.1 – WHITESTAR SIGNATURE PRO System



1. Programmable IV Pole
2. **FUSION** Pack
3. Wireless remote control storage
4. **WHITESTAR SIGNATURE PRO** System console with Mayo tray
5. Foot pedal storage

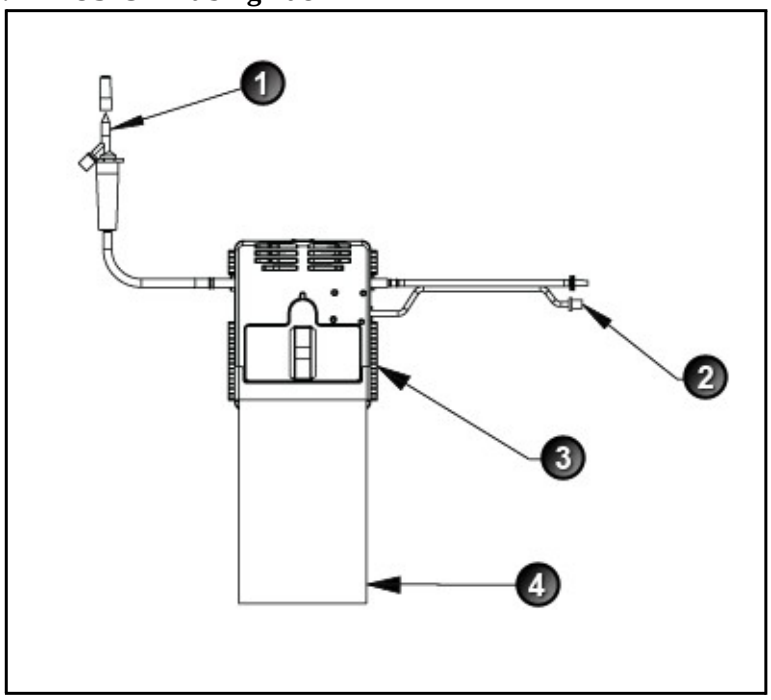
FUSION Packs

Each surgical procedure requires a disposable tubing pack for either the peristaltic pump or the Venturi pump. The **FUSION** Pack only works with the peristaltic pump used in anterior/cataract surgeries. The **FUSION** Dual Pump Pack works with both the peristaltic pump and the Venturi pump. With the **FUSION** Dual Pump Pack you can select either pump while you are in a surgical case.

The pack contains the following components:

- A pack with irrigation and aspiration tubing (administration set) with an attached, sealed drain bag
- Test chamber – to test and prime/tune the phaco handpiece
- Mayo tray drape – to cover the Mayo tray and arm
- Monitor drape – to cover the front of the touch screen

Figure 2.2 – FUSION Tubing Pack



1. To Irrigation Bottle
2. To Handpiece
3. Manifold
4. Drainage Bag

Use proper handling and disposal methods for biohazards when you dispose of the tubing pack, Mayo tray drape, and monitor drape.

The **FUSION** Pack (OPO70) allows an inter-connection of the irrigation line to the aspiration line, so that sterile balanced salt solution can enter the aspiration line and has no time restriction for reflux as there is no pump reversal.

The **FUSION** Dual Pump (DP) pack (OPO71) includes support for the vacuum tank used in the Venturi vacuum system but does not support inter-connecting the irrigation line to the aspiration line. Therefore, only previously aspirated fluid is being refluxed.

Foot Pedal

The foot pedal controls all of the system functions, therefore, it is essential that you understand the foot pedal operation.

The system software automatically detects if a foot pedal is present and what type of foot pedal is attached during start up.

The foot pedal settings and adjustments can be selected and preset for all of the foot pedals on the Foot Pedal Setup screen. Instructions for the foot pedal settings are given in “Foot Pedal Setup” on page 4-6. The foot pedal housing incorporates a handle, making the foot pedal easy to grip for repositioning and storage.

The foot pedal cable attaches to the foot pedal connector on the rear of the console. The Advanced Control Pedal and the Advanced Linear Pedal can also be set up with a wireless connection.

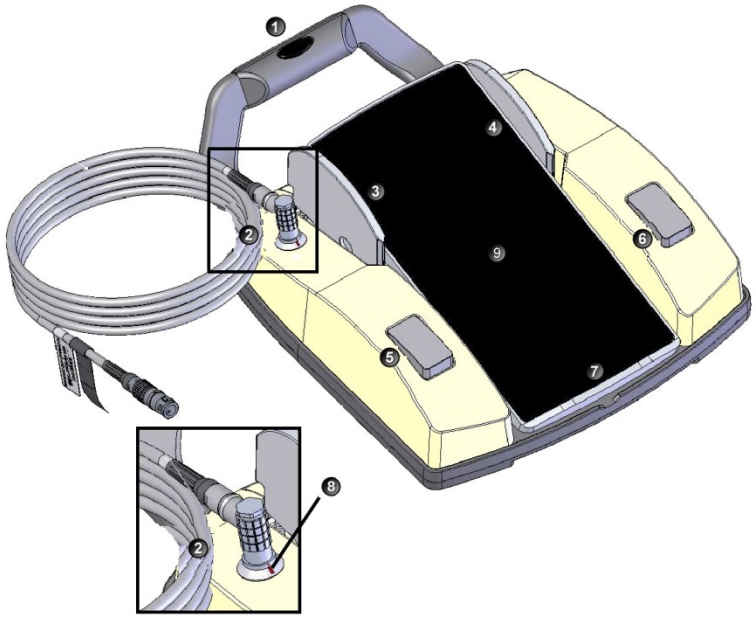
Four to six minutes after the system is shut down and power is turned off, both of the wireless foot pedals go into a power-save mode.

- To activate the Advanced Control Pedal after you start up the system, touch the wake-up button on the foot pedal.
- To wake-up the Advanced Linear Pedal after you start up the system, tap the pedal.

After two hours, when the system is on and the foot pedal switches and treadle are inactive, the foot pedal goes into a power-save mode:

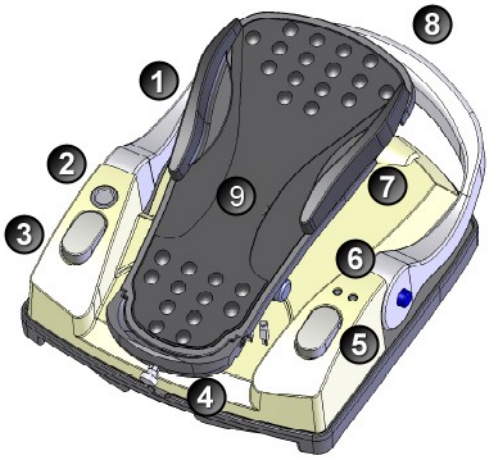
Note: You must NEVER handle the foot pedal by the cable.

Figure 2.3 – Single Linear Foot Pedal



1. Handle
2. Cable connector
3. Left toe switch
4. Right toe switch
5. Left heel switch
6. Right heel switch
7. Heel rest
8. Cable connector detail
9. Pedal

Figure 2.4 – Advanced Control Pedal



1. Left yaw
2. Wake-up button
3. Left heel switch
5. Right heel switch
5. Right heel switch
6. Lights
7. Right yaw
8. Handle
9. Pedal

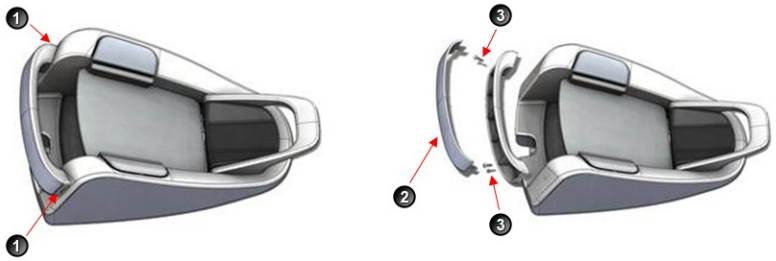
Figure 2.5 – Advanced Linear Pedal

1. Handle
2. Left and Right Top Switches
3. Left and Right Side Switches
4. Heel rest
5. Pedal

Removing the Handle from the Advanced Linear Pedal

1. To remove the handle, press the clips on either side of the handle.

Figure 2.6 – Foot Pedal Handle Diagram



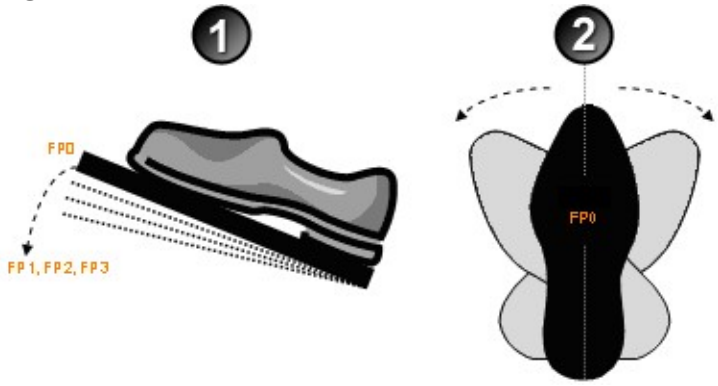
Removing the Foot Pedal Handle

2. Remove the cover of the handle.
3. Remove the screws and store the screws and handle in a safe place.
   Note: Do not lose the handle as it cannot be replaced.

Foot Pedal Operation

The foot pedal has three active “pitch” ranges, which are referred to as positions 1, 2 and 3 (FP1, FP2, FP3). Position 0 is the off position, and position 3 is the fully pressed position. The ranges are shown below. The Advanced Control Pedal has two Yaw switches.

Figure 2.7 – Advanced Control Pedal Pitch and Yaw Positions



1. Pitch
   Toe Down/Up
   Configurable Ranges

2. Yaw
   Toe Right/Left
   Configurable Ranges

Note: The foot pedal position determines the function that is delivered by the handpiece, which depends on the mode selected on the touch screen. When the foot pedal has been attached, place your foot on the pedal and press to the desired position. The foot pedal settings and programming are addressed in “Foot Pedal Setup” on page 4-6.

Programmable IV Pole

The programmable IV pole is controlled by the up and down arrows on the upper right of the touch screen, next to the bottle height indicator. The buttons on the remote control and the rocker switch on the side of the console can also be used to control the IV pole. The height is set on the **Programmable IV Pole** screen. The IV pole moves at a rate of approximately 7.62 cm per second.

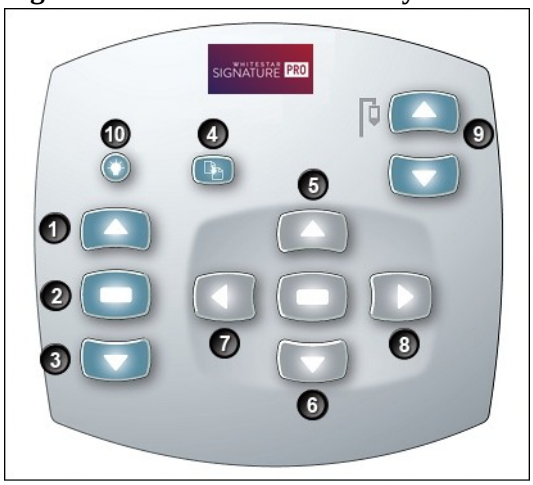
The IV pole is adjustable from 0 to 106 centimeters, and can be set for either inches or centimeters. The height measurement is relative to the distance from the irrigation valve to the center of the drip chamber. The IV pole height for each fluidic mode or submode (phaco, I/A, vitrectomy) is saved in the system memory. A maximum IV pole height can be set from the Configuration screen.

When a surgery mode is selected, the IV pole automatically moves to the preset height. To manually adjust the IV pole height, use the up and down arrows on the touch screen. Manual adjustments to the IV pole can also be made by pressing the rocker switch located on the side of the console. If a maximum height has been set, the IV pole does not move above that height.

Wireless Remote Control

The wireless remote control keypad can be used to move between the surgical modes and submodes. Adjustments to the surgical mode and submode settings can be made with the remote control. The buttons on the remote keypad work the same as the controls on the system touch screen.

Figure 2.8 – Remote Control Key Functions



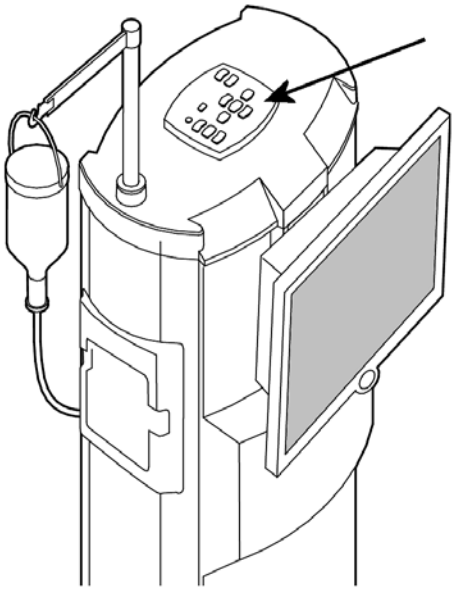
1. Previous Major Mode or Previous Submode
2. Mode Select
3. Next Major Mode or Next Submode
4. Reload
5. Up Arrow
6. Down Arrow
7. Backward/Left
8. Forward/Right
9. IV Pole Up/Down
10. Back Light Button

After you turn the system on, press the remote control back light button to activate the remote control.

Note: After four to six minutes of idle time, the remote control goes into a power-save mode. To turn the remote control on, press the back light button.

WARNING: DO NOT try to replace the wireless remote control batteries. Call your AMO technical service representative to replace the batteries.

Figure 2.9 – Wireless Remote Control Module Storage



Surgical Media Center (SMC) - Optional

The Surgical Media Center (SMC) is used to record the surgery and the instrument settings to be viewed at a later date and time. The surgery is displayed on a monitor with the instrument settings. The SMC hardware is attached to your system through the communications port on the rear panel.

3 SURGERY START UP

WHITESTAR SIGNATURE PRO System Setup

Front and Rear Panel Connections

IV Pole Setup

Handpiece Setup

Startup

Install the FUSION Pack

Cup Fill

Prime/Tune

Verify Irrigation/Aspiration Balance

Priming for Vitrectomy

Selecting and Changing Mode Parameters

System Check-out

Pre-operative Sterilization

System Shutdown

End Case

WHITESTAR SIGNATURE PRO System Setup

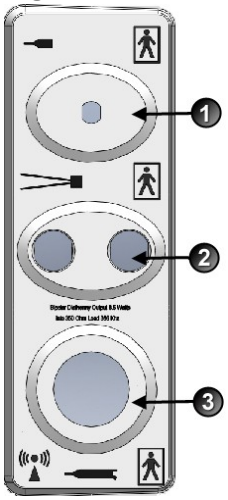
This is a general overview of the steps to take to prepare the **WHITESTAR SIGNATURE PRO** System for surgery:

1. Attach the power cord to the rear of system. Plug the power cord into a grounded power outlet.
2. Attach the foot pedal to the rear panel receptacle.
3. Attach the compressed air line to the compressed air receptacle (optional).
4. Turn the system on at the back of the console.
5. Press the on/off button on the touch screen monitor.
6. After completion of the self test, select the surgeon and program.
7. Install the tubing pack.
8. Assemble and attach the required accessories (phaco, vitrectomy, or diathermy handpieces) and set up the tubing.
9. Prime and tune the handpieces. (See “Prime/Tune” on page 3-11.)
10. Perform the final test of the fluidics and the handpiece integrity with the foot pedal. (Refer to “Verify Irrigation/Aspiration Balance” on page 3-14.)

Front and Rear Panel Connections

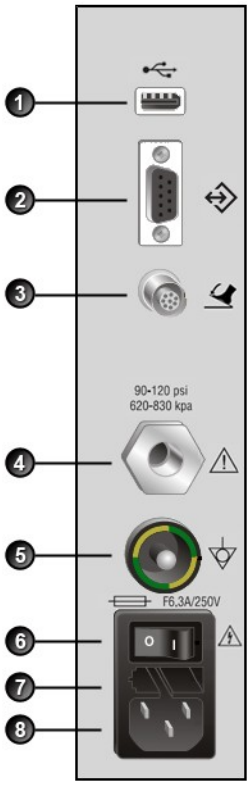
This section shows the front and rear panel connections.

Figure 3.1 – Front Panel Connections



1. Vitrectomy handpiece
2. Diathermy handpiece
3. Phaco handpiece

Figure 3.2 – Rear Panel Connections



1. USB port
2. Communication port
3. Foot pedal connector
4. Compressed air
5. Potential equalizer
6. Power switch
7. Fuse holder
8. Power cord connector

IV Pole Setup

IMPORTANT: Before you insert the spike into the bottle, shake the irrigation drip chamber at the end of the irrigation tubing to confirm that the irrigation valve moves. If the valve does not rattle, the valve cannot operate properly and irrigation cannot flow.

The IV pole moves to the appropriate height automatically based on the settings of the selected surgical mode. Follow these steps to set up the IV pole.

1. Insert the drip chamber spike into a new balanced salt solution bottle.
2. Hang the bottle of balanced salt solution on the IV pole.
3. Squeeze the drip chamber to fill the drip chamber with fluid to the half-full level.
4. Raise or lower the pole if needed. Use the IV pole up and down arrows on the upper right of the touch screen. You can also use the rocker switch on the console.
5. Attach the I/A tubing to the handpiece.

Note: To make sure that the bottle height does not change when you select I/A after Vitrectomy during surgery, check the box for **Bottle Height Hold** on the Vitrectomy Settings screen.

Handpiece Setup

This section presents information about setting up the handpieces.

- Phacoemulsification Handpiece Setup
- I/A Handpiece Setup
- Diathermy Handpiece Setup
- Vitrectomy Handpiece Setup

Phacoemulsification Handpiece Setup

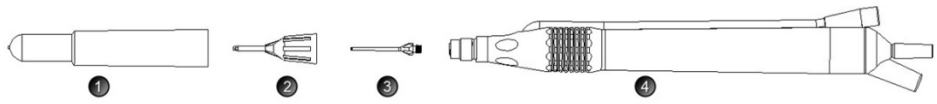
WARNING: Sterility assurance is the responsibility of the user. You must sterilize all non-sterile accessories prior to use.

WARNING: Prior to using any invasive portions of the handpiece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. Use a backup handpiece for surgery if there are any questionable characteristics of the handpiece. Use of contaminated or damaged system accessories can cause patient injury.

1. Use caution to prevent burns when handling the handpiece directly from sterilization.
2. Remove the tubing pack and accessories from the packaging and place them in the sterile area.
3. Assemble the phaco handpiece as shown below. You need the handpiece, titanium phaco tip, the appropriate tip wrench, one of the irrigation sleeves, and the test chamber.

CAUTION: NEVER ATTEMPT TO STRAIGHTEN A BENT NEEDLE. THIS MIGHT PRODUCE A BROKEN TIP WHEN YOU APPLY ULTRASOUND.

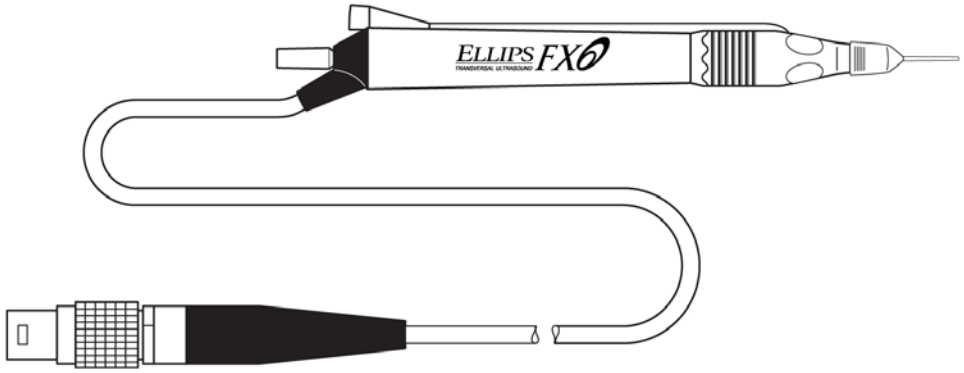
Figure 3.3 – Phaco Handpiece Assembly



1. Test Chamber
2. Irrigation Sleeve
3. Phaco Tip
4. Handpiece

4. Attach the connector end of the handpiece to the phaco receptacle on the front of the **WHITESTAR SIGNATURE PRO** System. Make sure there is no moisture on the connectors prior to attaching. Moisture prevents the handpiece from operating properly.

Figure 3.4 – ELLIPS FX Handpiece



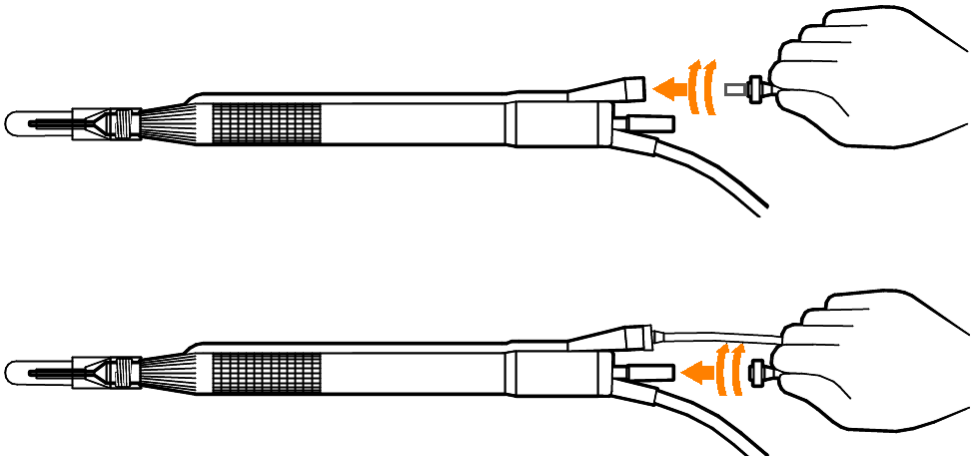
Note: You can use the **ELLIPS FX** handpiece with **WHITESTAR** Technology phaco settings.

5. Insert the male luer end of the irrigation tubing into the phaco handpiece.
6. Attach the female luer fitting end of the aspiration tubing to the phaco handpiece.

Note: To protect the patient from contamination, use only:

- sterile tubing sets
- sterile balanced salt solution
- sterile handpieces

Figure 3.5 – Phaco Handpiece Connections

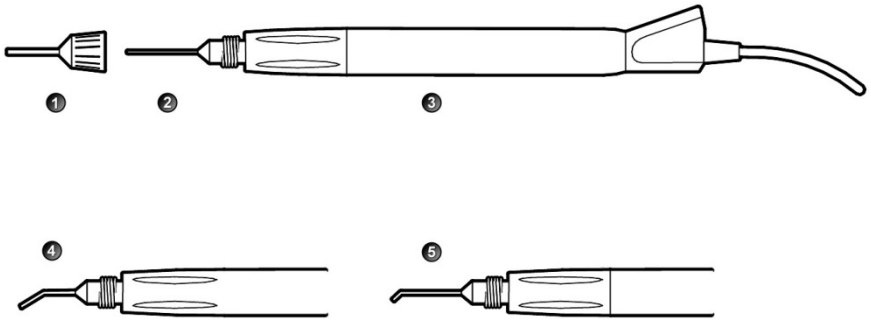


Irrigation/Aspiration Handpiece Setup

Assemble the SOLO Irrigation/Aspiration (I/A) handpiece by attaching the irrigation sleeve.

Note: The test chamber is provided in the **FUSION** Pack. The **LAMINAR** Flow 20 gauge irrigation sleeves can also be used and are available with the OPOS20L or any 20 gauge **LAMINAR** phaco tip.

Figure 3.6 – I/A Handpiece Assembly



1. Irrigation sleeve
2. Straight tip
3. Handpiece
4. Curved tip
5. 45° Tip

Diathermy Handpiece Setup

1. Attach the diathermy cord to the diathermy forceps or pencil.
2. Attach the diathermy cord to the diathermy receptacle on the front panel.

Figure 3.7 – Diathermy Forceps

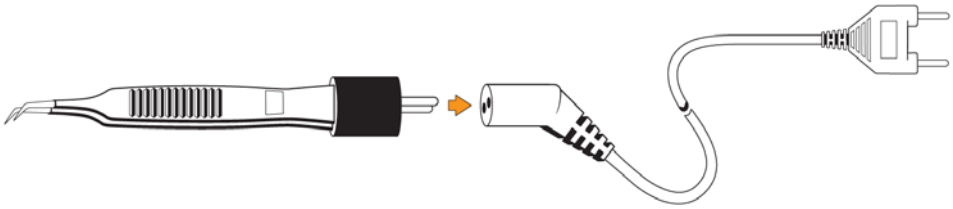
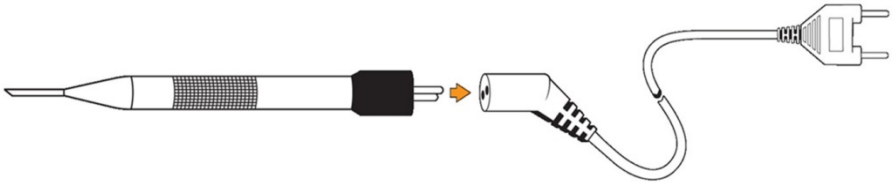


Figure 3.8 – Diathermy Pencil



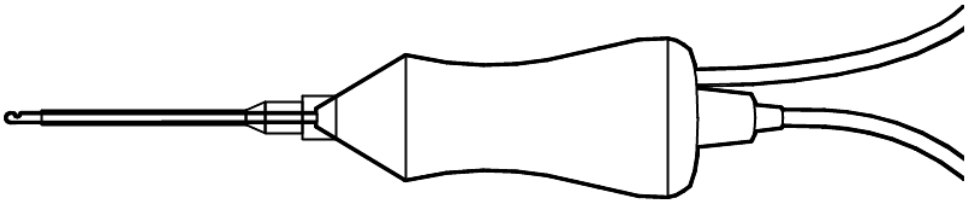
Note: Other diathermy accessories are regionally available. Contact your AMO representative.

Vitrectomy Cutter Setup

If you need to use vitrectomy during surgery:

1. Attach the vitrectomy cutter as shown below. Vitrectomy requires the following components:
   - I/A Tubing (from **FUSION** Pack)
   - Vitrectomy cutter
   - Vitrectomy irrigation sleeve, or a 23 Gauge Limbal Infusion Needle, if desired.
2. Use the instructions provided with the vitrectomy cutter to assemble the handpiece.

Figure 3.9 – Vitrectomy Cutter



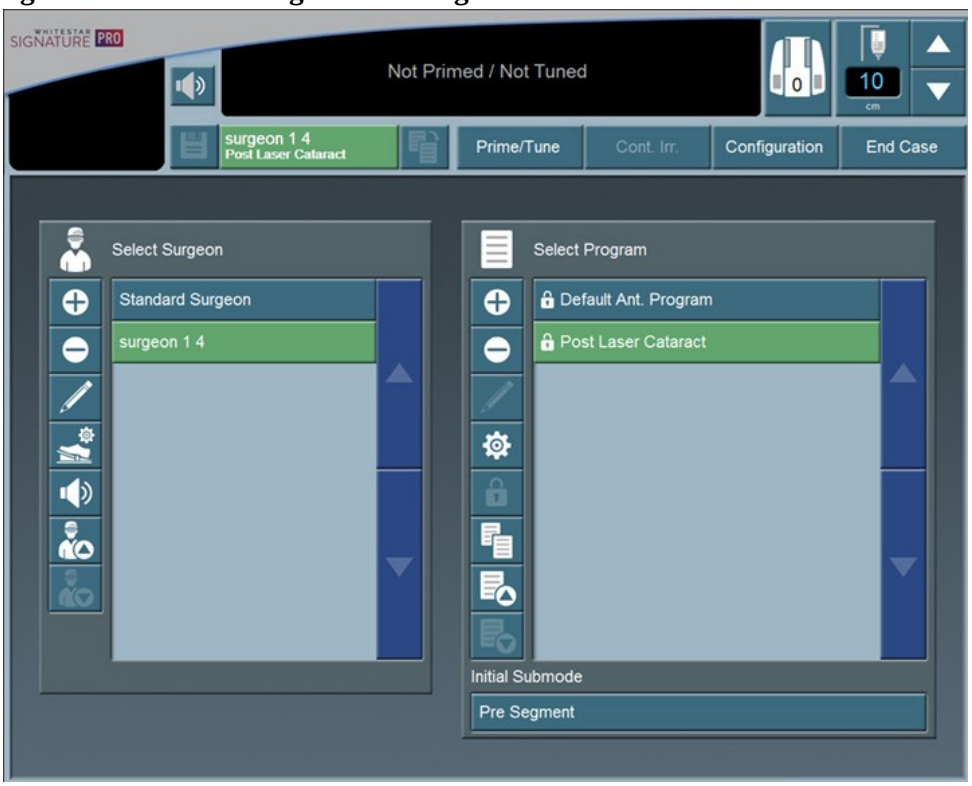
3. Attach the connector to the vitrectomy receptacle on the front panel.

Startup

After you have turned on the system, the system performs a series of self tests.

After start up, the screen shows the available surgeons and programs.

Figure 3.10 – Select Surgeon and Program Screen



From the main menu you can:

- Select a **Surgeon/Program** and begin surgery based on the values of that program
- Access the **Settings** screen, where you can edit programs and setup operating parameters
- Access the **Configuration** screen to set system parameters
- Access the **End Case** screen (See “End Case” on page 3-21.).

Install the FUSION Pack

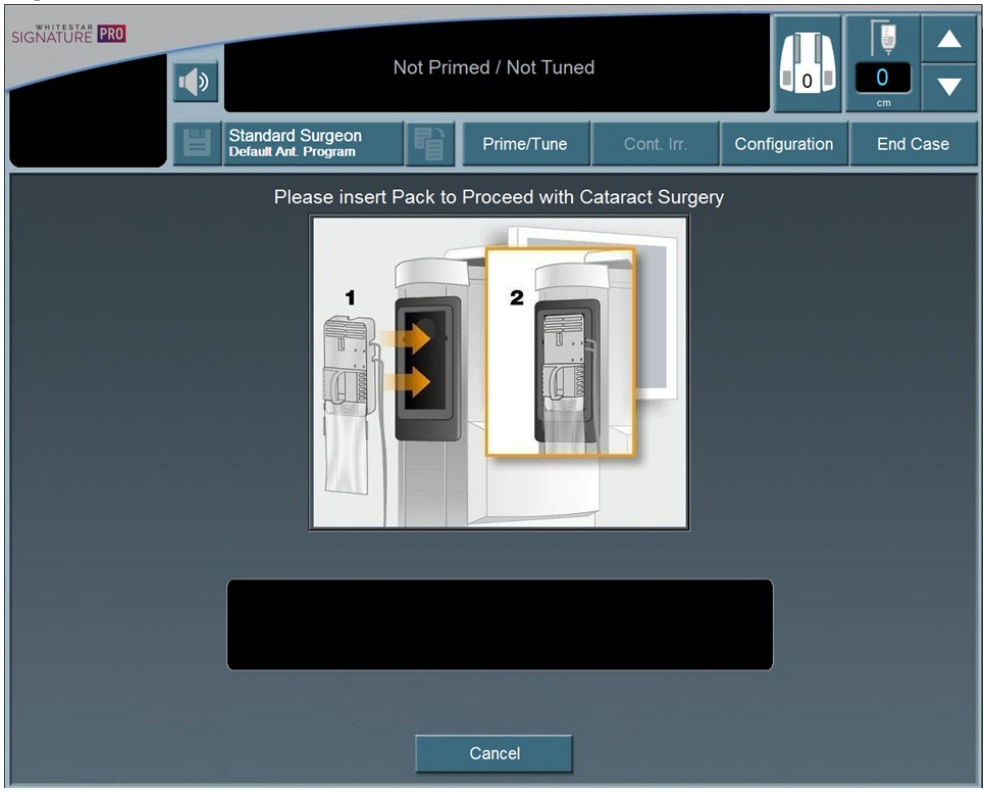
1. After you select a surgeon, you must select a program from the surgeon's available programs.

   Note: The program at the top of the list is the default program for that surgeon.

2. Select the **Prime/Tune** button.

   Note: If a pack is needed the Install Pack Screen is shown.

Figure 3.11 – Install Pack Screen



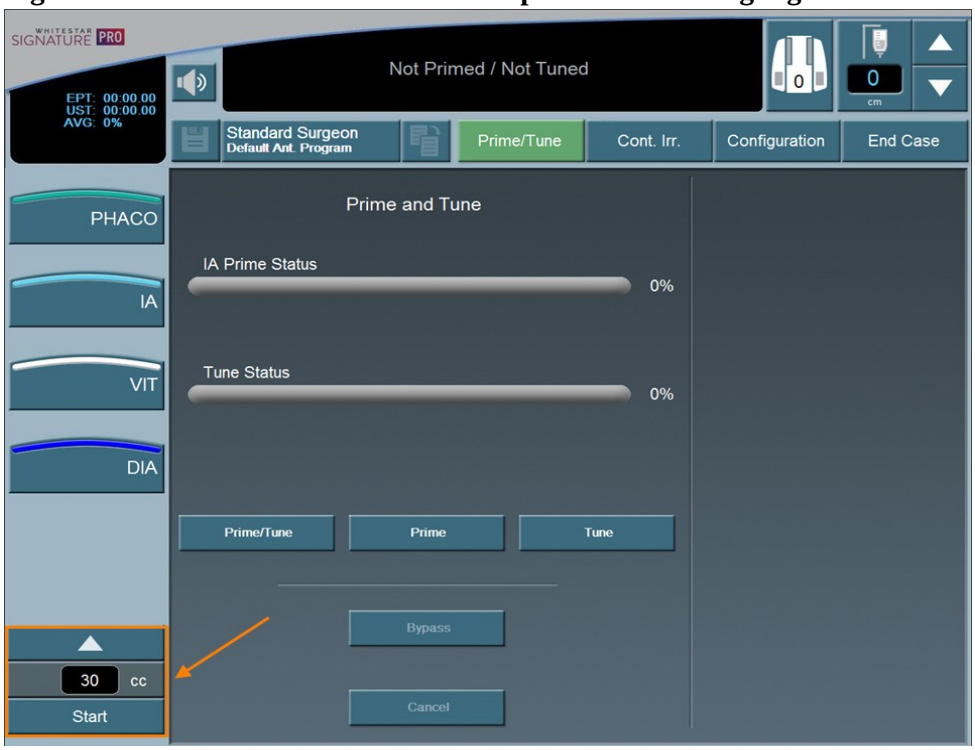
3. Install a pack as shown on the screen.

Cup Fill

To collect the balanced salt solution:

1. Use the test chamber, a medicine cup, or similar container.
2. Press the **Prime/Tune** button.

Figure 3.12 – Prime/Tune Screen with Cup Fill Controls Highlighted



3. Use the **up** arrow to cycle through the three available amounts of solution to be dispensed. You can choose from:
   - 30 cc
   - 60 cc
   - 90 cc

   Note: The fill rate and time is based on using the irrigation tubing with no handpiece attached and that there is fluid in the tubing. If you use an attached handpiece to fill the cup, the fluid amount dispensed is less during the time allowed.

   Note: Make sure that you have filled the tubing with fluid using the Continuous Irrigation feature. If the tubing does not have fluid, the amount dispensed during Cup Fill may not be the amount selected.

4. Press **Start** to turn on Cup Fill.
5. Use **Stop** to turn off Cup Fill. This stops the process before the system dispenses the requested amount of fluid.
6. Perform a phaco prime/tune. The **Prime/Tune** screen indicates the progress of the prime/tune process.

Prime/Tune

You must prime/tune:

- before each procedure
- anytime you reattach the phaco handpiece
- after you have inserted or replaced a tubing pack

WARNING: Do not have the handpiece tip in the eye of the patient when you prime and tune the handpiece.

The prime/tune process fills the I/A tubing with fluid, performs a vacuum check, and tests and characterizes the phaco handpiece.

You can select **Continuous Irrigation** to allow fluid to free flow from the bottle to collect fluid.

The design of I/A Prime allows for a procedure that does not require a phaco handpiece. The design of tune allows for a quick tune of the phaco handpiece with an I/A tubing set. You can use tune if you replace a phaco tip during a procedure.

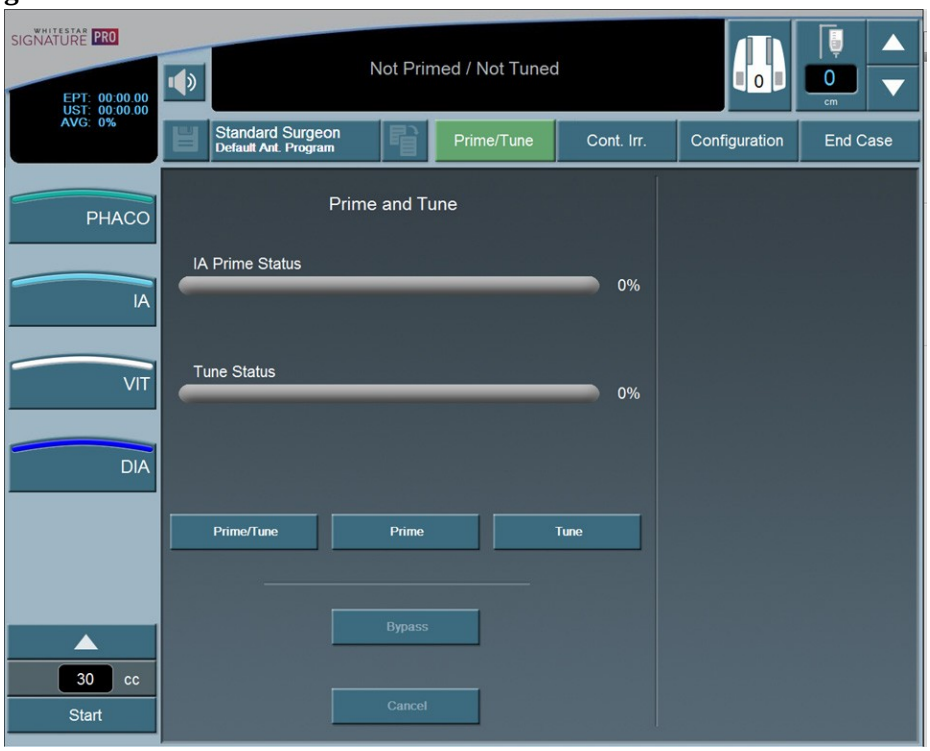
You can shorten the overall prime sequence by selecting **Bypass** prime. You also reduce the time to prime the system. You can use **Bypass** if you used **Continuous Irrigation** or primed the I/A tubing.

If you do not properly prime the I/A tubing, errors can occur.

To access the prime/tune routines, press the **Prime/Tune** button. The console shows the Prime/Tune screen with all the prime and tune options.

Note: Prime/Tune is a combination of tune followed by an I/A prime.

Figure 3.13 – Prime and Tune Screen



The system tracks the successful completion of the prime and tune cycles independently. If the system needs to be tuned again (new tip, failed tune), you only need to select and run the tune.

CAUTION: DO NOT ACTIVATE THE PHACO HANDPIECE AND VITRECTOMY CUTTER WITH THE TIP IN THE AIR. EXPOSURE OF THE TIP TO AIR DRASTICALLY REDUCES THE USEFUL LIFE OF THE HANDPIECE. IF YOU INTRODUCE POWER TO THE PHACO HANDPIECE OR VITRECTOMY CUTTER, THE TIP MUST BE IN A TEST CHAMBER FILLED WITH BALANCED SALT SOLUTION, IN A CONTAINER OF BALANCED SALT SOLUTION, OR IN THE PATIENT'S EYE.

Suggestions for Priming the Handpieces

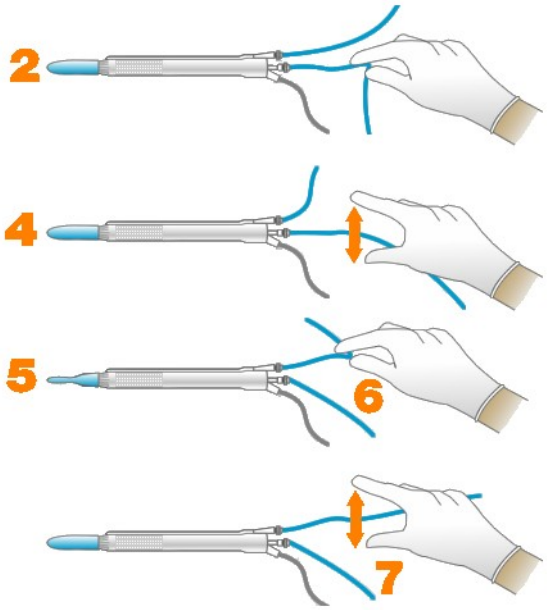
Do not lay the handpiece and the empty test chamber down and have the system fill the test chamber. When you lay down the handpiece, this allows air to collect in the test chamber and can produce an error. Point the tip of the handpiece up to reduce the amount of bubbles.

1. Use **Continuous Irrigation** to fill the tubing with fluid. Remember to hold the ends of the tubing over a container to catch any fluid.
2. Use the **Cup Fill** feature to fill the test chamber with fluid and to eliminate all air. Remember to remove the test chamber from the handpiece, if needed, before you start the cup fill process.
3. Place the test chamber over the handpiece tip and the sleeve hub.
4. Attach the tubing to the handpiece.
5. Press the **Prime/Tune** button, this starts the prime and tune sequences.
   - To perform a prime only, press the **Prime** button.
   - To perform a tune only, press the **Tune** button.
6. Make sure that low ceilings, light fixtures, or equipment do not block the movement of the IV pole.
7. Watch the fluid fill the drip chamber. The fluid moves toward the handpiece and fills the test chamber.
8. The display screen indicates the progress of the prime and tune process.
9. As the tubing lines fill, the system software performs functional checks. The checks include:
   - Monitoring for the presence of irrigation flow (bottle height)
   - Leaks (via vacuum rise checks)
10. When you attach the phaco handpiece and you select **Prime/Tune** or **Tune**, the system automatically includes a handpiece tuning test concurrently with the prime cycle.
    - At the end of the priming sequence, the system makes an audible sound to indicate that Prime process is complete.
    - At the end of the phaco tuning test, the system makes an audible alert sound to indicate that Tune process is complete.
11. To discontinue prime or tune during the process, select **Cancel**.
12. When prime and tune are complete, the system automatically proceeds to the preprogrammed submode or Phaco 1 operating mode. It is important that you verify the Irrigation and Aspiration balance prior to operating.

Verify Irrigation/ Aspiration Balance

We strongly recommend you verify that you balanced Irrigation/Aspiration properly for your settings used in surgery.

Figure 3.14 – Irrigation/Aspiration Balance Procedure



To verify irrigation/aspiration balance:

1. In Phaco 1 mode, hold the handpiece at the approximate patient eye level.

   Note: The numbers in the drawing Figure 3.14 correspond to the steps listed.

2. Occlude the aspiration line just below the handpiece, while you press and hold the foot pedal in position 2. Make sure the you attach the foot pedal. (See “Foot Pedal Setup” on page 4-6.)
3. The actual vacuum level should rise to the preset level.
4. Release the aspiration line and then watch the test chamber to make sure that the test chamber does not collapse. A slight shallowing of the test chamber is normal.
5. If the test chamber collapses, raise the IV bottle height or lower the vacuum setting.
6. Pinch the irrigation tubing at the handpiece and watch for the test chamber to collapse.
7. Release the irrigation line and the test chamber should fill.
8. Press **Reset** in the upper left corner of the screen to open the **Reset Timers** dialog box. Press **Yes** to reset the timers. You are now ready to begin surgery.

Priming for Vitrectomy

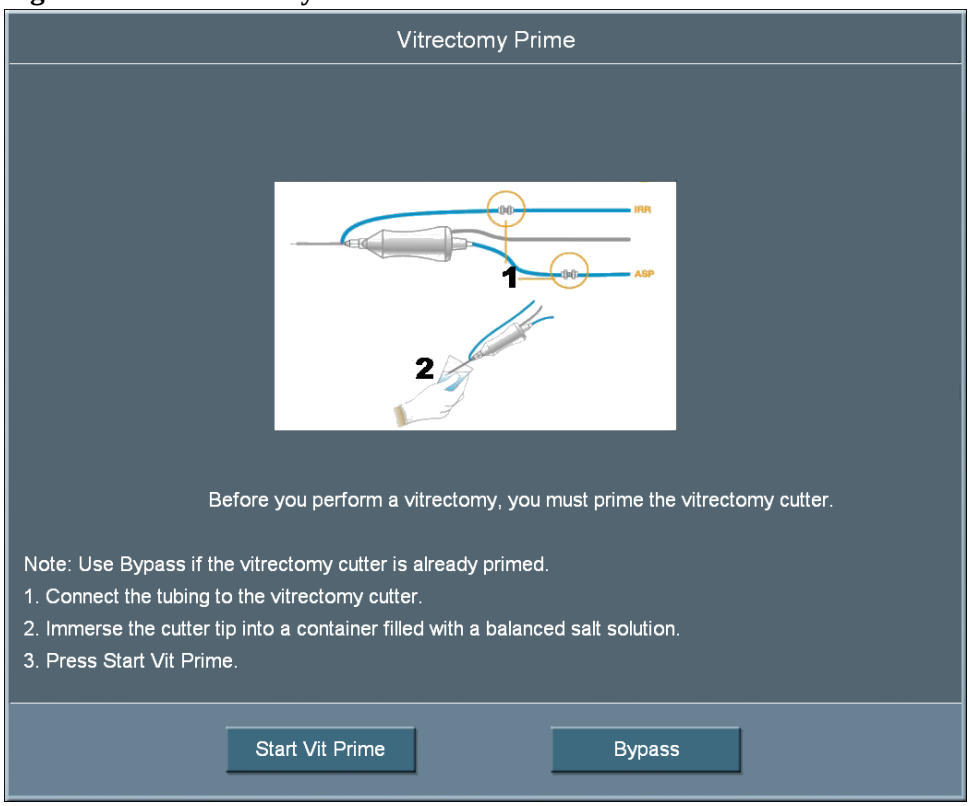
Before you perform vitrectomy, we recommend you prime the handpiece to reduce the chance of errors. Each time you select vitrectomy mode, a dialog box asks you to prime the vitrectomy handpiece. If you do not need to prime, press **Bypass**.

To prime the handpiece:

1. Attach the irrigation tubing and the aspiration tubing of the pack together.
2. Press **Prime** on the **Prime/Tune** screen.
3. Press the **VIT** button to access **VIT** mode.
4. Follow the instructions on the screen.
5. Press **Start Vit Prime**. The screen closes automatically after the system primes the handpiece.

Note: If you must perform vitrectomy in the middle of phaco surgery, perform steps 3 through 5.

Figure 3.15 – Vitrectomy Prime Procedure



Selecting and Changing Mode Parameters

The design of the system's graphical user interface (GUI) and touch screen is for ease-of-use, consistent look, and maximum informational display during all operating modes.

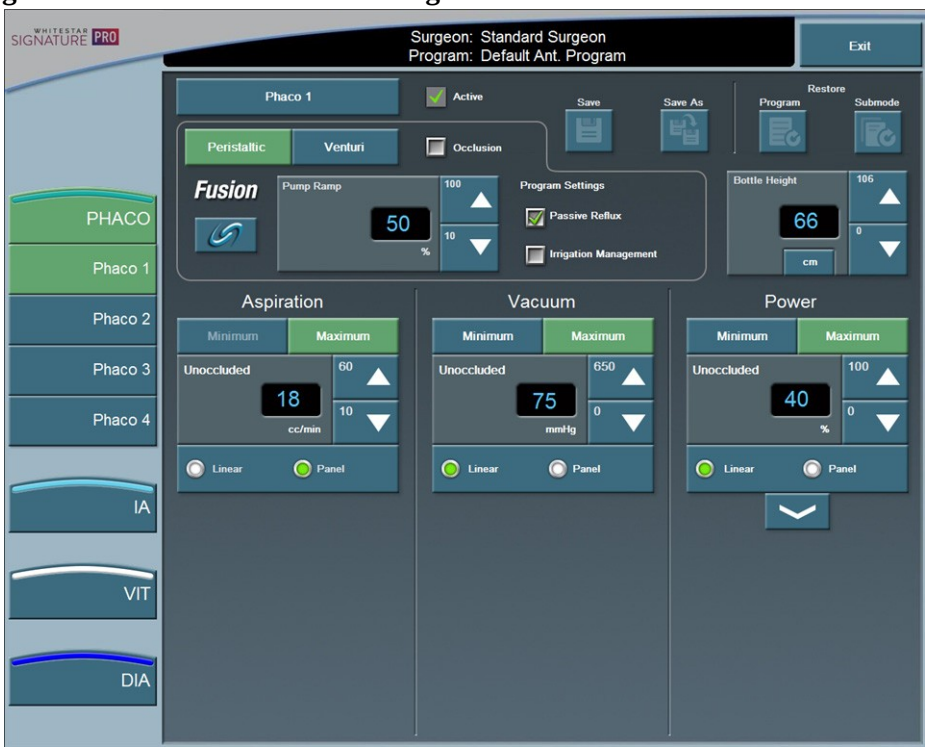
Your interface with the system requires only three basic steps, which apply to all the selections, settings and operations. Once you understand this basic organization, you can move quickly and easily through all the system functions and system operations.

Panels organize the text on the display screen. The top panel shows current status, configuration options, the bottle height, and the foot pedal icon. The left-side column lists the operating modes and submodes. The main panel that dominates the screen shows current operating levels for aspiration, vacuum and power.

Figure 3.16 – Phaco Mode Screen

- To switch operating modes or submodes, press a button in the left panel. The control panels in the main panel show the operating levels for that mode.
- To make basic changes to the settings, press the **up** and **down** arrows to increase or decrease a value.
- To change other control panel settings, such as **Panel** or **Linear** power and nonzero start, press the **Settings** button on that control panel. A **Settings** screen opens, and you can make your selections.

Figure 3.17 – Phaco Submode Settings Screen



System Check-out

The purpose of the check-out procedure is to verify that installation of the system is complete and the system is operating properly. You must perform the check-out procedure prior to the first case of the day, as outlined in the following steps. You test the I/A mode and handpiece, then the phaco mode and handpiece, so that the phaco handpiece (used first) is ready for surgery.

If any of the check-out steps fail, you must repeat the steps. If the instrument still does not work correctly, refer to Chapter 8, “Error Messages Troubleshooting and Diagnostics”.

Phacoemulsification

Follow these steps to check the system out for phacoemulsification.

1. Attach the tubing to the phaco handpiece.
2. Screw the phaco needle onto the handpiece, use your fingers to engage the screw thread, and then use the tip wrench to tighten the needle.
3. Screw the irrigation sleeve over the needle.
4. Place the test chamber over the irrigation sleeve.
5. Prime and Tune the system.
6. Select the phaco mode.
7. Press and hold the foot pedal in position 1.
8. Observe the irrigation flow.
9. Hold the handpiece approximately at the patient's eye level, and fill the test chamber with irrigation fluid.
10. Occlude the aspiration tubing just below the phaco handpiece.
11. Press and hold the foot pedal in position 2. The actual vacuum level should rise to the preset level.
12. Release the occlusion and watch the test chamber to make sure that the test chamber does not collapse. A dent or dimple in the test chamber is normal.
13. To test irrigation, pinch the irrigation tubing just below the phaco handpiece and watch for the test chamber to collapse. Release the irrigation tubing and the test chamber should fill.
14. Press **Reset** in the upper left corner of the screen to open the **Reset Timers** dialog box. Press **Yes** to reset the timers.
15. Phacoemulsification check-out is complete.

Irrigation and Aspiration

Follow these steps to check the system out for irrigation and aspiration.

1. Attach the tubing to the I/A handpiece.
2. Select I/A mode.
3. Hold the test chamber near the handpiece tip, press and hold the foot pedal in position 1
4. Observe the irrigation flow.

Diathermy

Follow these steps to check the system out for diathermy.

1. Attach the diathermy forceps to the cable and the cable to the front panel of the console.
2. Select the Diathermy mode.
3. Press the foot pedal. You should hear a tone when you press the foot pedal.

CAUTION: IF YOU DO NOT HEAR A TONE WHEN YOU PRESS THE FOOT PEDAL AND VOLUME ADJUSTMENT IS UNSUCCESSFUL, THE MODE IS NOT FUNCTIONING PROPERLY. REFER TO Chapter 8, “Error Messages Troubleshooting and Diagnostics”.

Vitrectomy

Follow these steps to check the system out for vitrectomy.

1. Attach the irrigation tubing and aspiration tubing of the pack together.
2. Press **Prime** on the Prime/Tune screen.
3. Press the **VIT** button to access the VIT mode.
4. Follow the instructions on the screen.
5. Press **Start Vit Prime**. The screen closes automatically after the handpiece primes.
6. Observe that:
   - irrigation fluid flows
   - the aspiration tubing is full and clear of air
   - the vitrectomy cutter motor activates (slight sense of motion of the handpiece)
   - the cutter blade operates
7. Vitrectomy check-out is complete.

Pre-operative Sterilization

Prior to each surgical case, sterilize the system instruments with the recommended sterilization techniques, times and temperatures given in Chapter 7, “Care and Cleaning”. AMO recommends that you follow the sterilization guidelines to maximize the life of your system instruments.

System Shutdown

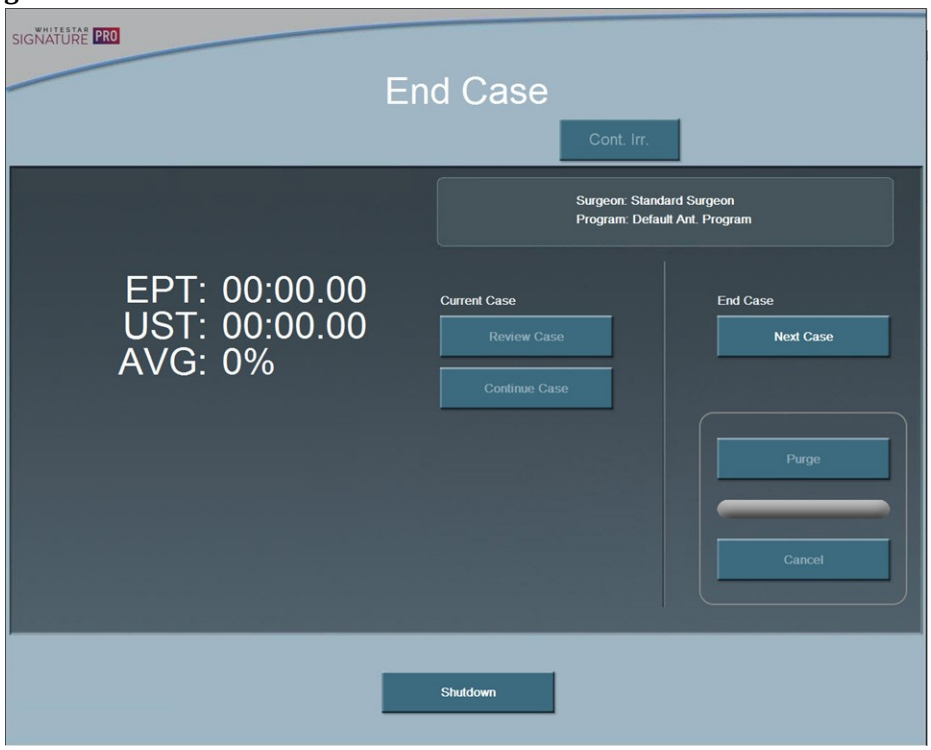
The following is a general overview of the steps to be taken to shut the system down after surgery:

1. Select **End Case**.
2. Select **Shutdown**. At the prompt, select **Yes**.
3. Wait for shutdown sequence to complete.
4. Turn the system off at the back of the console.
5. Remove the power cord from the power outlet.
6. Wrap the excess power cord neatly around the cord wrap on the back of the console.
7. Use the AC Charging Adapter to charge the ACP or ALP foot pedal.
8. Use the AC Charging Adapter to charge the remote control.
9. Refer to Chapter 7, “Care and Cleaning” for additional information.

End Case

End Case is available in the top panel from any programming or surgical mode. **End Case** allows you to terminate the programming session or surgical case.

Figure 3.18 – End Case Screen



Note: For ease of viewing, the EPT, EFX, UST, and DT times are in a large font size on the **End Case** screen. The EFX shows only when you attach an **ELLIPS FX** handpiece.

End Case

The timers on the upper left side of the screen indicate:

- Effective Phaco Time (EPT). Effective Phaco Time is ultrasound time as a weighted total that takes into account the amount of power being used:
  - at 100% power: 1 sec. U/S Time = 1 sec. EPT
  - at 50% power: 1 sec. U/S Time = 0.5 sec. EPT
  - Average phaco power (AVG) = EPT/UST
- Ultrasonic (U/S) time (UST) in foot pedal position 3
- **EFX** when you attach an **ELLIPS FX** handpiece
- DT - Diathermy Time

Next Case – Select **Next Case** to install a new pack.

Note: Use a new bottle of balanced salt solution at the start of each case.

Continue Case – Select **Continue Case** to return to the current case, after you selected **Review Case**.

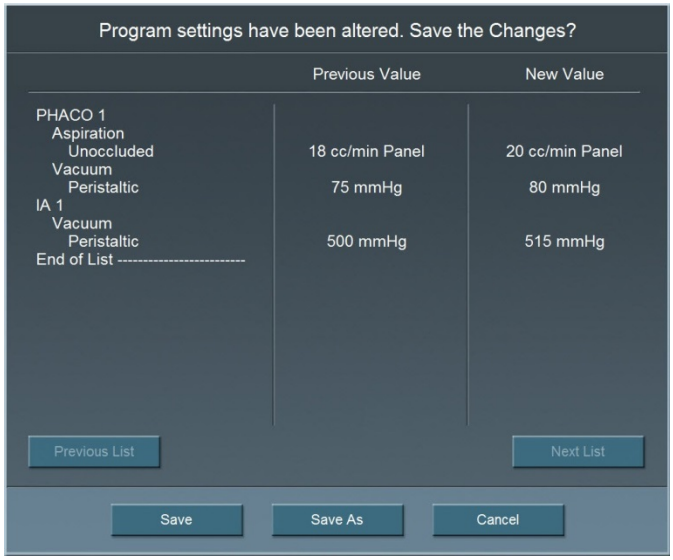
Purge – Select **Purge** to remove the fluid from the irrigation and aspiration tubing before you remove the pack.

Shutdown – Select the **Shutdown** button to turn the system off. At the prompt, press **Yes** to complete the process.

Next Case

If any changes were made to the settings, you are prompted to confirm and save the changes.

Figure 3.19 – Save Changes Confirmation Screen



Note: You can also select on the main surgical screen to save changes. When you save changes a confirmation screen is displayed to review the settings. If all of the settings are correct, select **Save** for the current program. Use **Save As** to save to a new program name.

Save - Saves any changes to the current program.

Save As – Saves the program changes (made to an existing program) to a new program name when you enter a program name.