3 SYSTEM SETUP

Safety Precautions

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

Read the following Safety Precautions and Warnings carefully before you use the WHITESTAR SIGNATURE System in surgery.

1. The WHITESTAR SIGNATURE System comes equipped with 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.

2. Do not use extension cords with your system.
3. Do not overload your electrical receptacle (outlet).
4. 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.
5. 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.
6. Do not try to move the WHITESTAR SIGNATURE System cart on deep pile carpets or over objects on the floor such as cables and power cords.
7. Take care not to trip over power and footpedal cords.
8. Do not try to lift the WHITESTAR SIGNATURE System cart.
9. Do not place the instrument on uneven or sloped surfaces.
10. 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.
11. Do not operate the WHITESTAR SIGNATURE System in a condensing environment. Take care to protect the instrument from fluid sprays or fluid buildup.
12. To protect the patient from contaminated fluids or handpieces, use only:
    - sterile tubing packs
    - sterile irrigation fluid
    - sterile handpieces
13. Use caution when you extend, retract, or swivel the Mayo stand articulating arm. Stay clear of the hinged hardware.
14. Use caution when you use handpieces with sharp edges or pointed tips.

15. Always replace the tubing pack between cases.
16. Wrap the excess power cord neatly around the cord wrap on the back of the console.

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. 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 Diagnostics screen.

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 footpedal to Position 0

When power is restored:

- 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, IA, Vitrectomy, or Diathermy)

Connecting Handpieces

It is very important that the electrical connectors on the handpieces are completely dry before you connect the handpiece to the WHITESTAR SIGNATURE System receptacles. You can receive a “Handpiece Ground Fault Error” message if the connector is wet.

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 9, “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. Do not activate the tips in the 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 a test chamber filled with a balanced salt solution, in a container of balanced salt solution, or in the patient's eye.

Vitrectomy

Failure to properly attach the tubing to the appropriate 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.

Wireless Remote Control

This device complies with Ppart 15.19 of the FCC (Federal Communications Commission) Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
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 pPart 15.105 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.

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: The surgical nursing staff must monitor the fluid level in the balanced salt solution bottle. The result of a low bottle or an empty bottle affects the fluid balance and the intraocular pressure (IOP) while aspirating. The low or empty bottle can result in:

- The inadvertent chamber shallowing or collapse
- The Aspiration of tissue
- An ultrasonic wound heating commonly called wound burn (extreme case)

The surgical staff must monitor the fluid level at all times.

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 tubing pack, mayo stand drape, and monitor drape.

WARNING: Place monitoring electrodes or other types of equipment as far from those of the WHITESTAR SIGNATURE 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).

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 contains 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 ELETRODE 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 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 nonsterile 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.

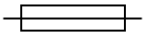
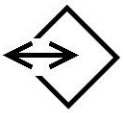
WARNING: Do not use non-AMO approved products with the WHITESTAR SIGNATURE System, as this can affect overall system performance. AMO cannot be responsible for system surgical performance if you use these products in surgery.

Symbol Definitions

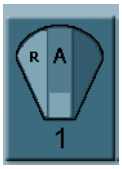
The following symbols appear on the WHITESTAR SIGNATURE System front and back panels and in the software:

Table 3.1 – Symbol Definitions

Symbol	Definition
	Symbol on the power switch indicates Power is On.

Symbol	Definition
	Symbol on the power switch indicates Power is Off.
	Indicates there is a possible danger to the user. In the manual, the symbol indicates information the user must read.
	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.
	Indicates fuse.
	Single phase alternating current.
	Indicates isolation of the patient applied part from earth ground.
	Indicates grounding of the patient applied part OR no involvement of direct electrical energy.
	Footpedal connection.
	Communications Port
	Programmable IV Pole
	Diathermy Receptacle

Symbol	Definition
	Phaco Handpiece Receptacle
	Vitrectomy Cutter Connection
	Potential Equalizer
	Indicates compliance with the Medical Device Directive.
	Indicates the authorized European Union representative.
	Separate Disposal/Collection Required
	Indicates manufacturer of the WHITESTAR SIGNATURE 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 Note: Use only AMO recommended USB stick drives.

Symbol	Definition
	Federal Communications Commission (FCC) The FCC regulates interstate and international communications by radio, television, wire, satellite, and cable under the FCC's jurisdiction.
	FUSION Mode button used to open the CASE settings screen.
	Single Linear Foot Pedal Icon. Shows the position of the footpedal when you press the footpedal. The number changes when the position of the footpedal changes.
	Advanced Control Pedal (Dual Linear) Icon. Shows the position of the footpedal when you press the footpedal. The number changes when the position of the footpedal changes. The letters indicate the location of Aspiration (A), Irrigation (I), Phaco (P), Reflux (R), Whitestar Increment/ Decrement (WS) and Switch (S).
	WHITESTAR Technology is On.
	WHITESTAR Technology is On and ICE Pulse Shaping is On.
	ELLIPS Technology is On.
	ELLIPS FX Technology is On.
	The Reload button cycles through the surgeon's programs.

System Disposal

WEEE

The electronic components of the WHITESTAR SIGNATURE 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 the following 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 nearest you.

Belgium Contact De Ceunynck Medical nv/sa Kontichsesteenweg 36 B-2630 AARTSELAAR Belgium	**Denmark** Distributor AMO Denmark ApS c/o Advanced Medical Optics Norden AB Kanalvagen 3A SE 19461 Upplands Vasby **Sweden**
Finland AMO Norden AB Vantaa/Finland Rajatorpantie 41 C, 3 krs FIN-01640 Vantaa Finland Phone: +358 9 8520 2192	**France** AMO France SAS Greenside 15, 750 Avenue de Roumanille 06410 Biot France Phone: +33 4 93 00 11 95

Germany AMO Germany GmbH Rudolf-Plank Strasse 31 D-76275 Ettlingen Germany Phone: +49 7243 729 444 (Hotline)	**Ireland** AMO Ireland Block B Liffey Valley Office Campus Quarryvale, Co. Dublin, Ireland
Italy AMO Italy Srl Via Pio Emmanuelli, n.1 00143 Rome Italy Phone: +39 06 51 29 61	**Netherlands** AMO Netherlands B.V. Kantoorgebouw La Residence Weverstede 25 3431 JS Nieuwegein The Netherlands Phone: +31 (0)30 600 8787
Norway Distributor Advanced Medical Optics Norway AS c/o Advanced Medical Optics Norden AB Kanalvagen 3A SE 194 61 Upplands Vasby Sweden	**Poland** Distributor Oko-Vita Polska sp.z o.o. ul Marywilska 34, 03-228 Warsaw, Poland
Portugal Advanced Medical Optics Spain S.L. sucursal em Portugal Praca Nuno Rodreguez dos Santos no 7, 1600-171 Lisboa Portugual	**Russia** Distributor Tradomed Ltd., Marksistskaya Str. 3, Bld 1, Moscow, 109147, Russia
Spain Advanced Medical Optics Spain, S.L. c/Dr. Zamenhof, n. 22, 4B 28027 Madrid Spain Phone: +34 9176 88 000	**Sweden** Advanced Medical Optics Norden AB Kanalvagen 3A SE 194 61 Upplands Vasby Sweden

Switzerland	**United Kingdom**
Distributor AMO Switzerland GmbH, Churerstrasse 160 B, CH-8808 Pfäffikon, Switzerland	AMO United Kingdom Ltd Jupiter House Mercury Park Wooburn Green High Wycombe Buckinghamshire HP10 0HH United Kingdom Phone: +44 1628 551600

RoHS (Restriction of Hazardous Substances)

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

Names and Content of Toxic and Hazardous Substances or Elements

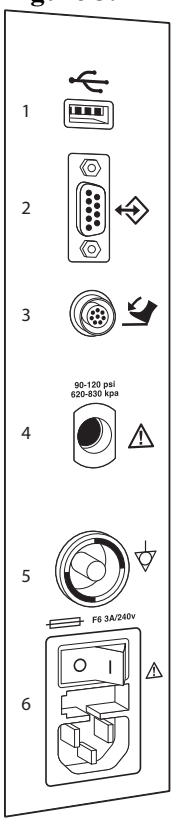
Parts Name	Toxic and Hazardous Substances or Elements					
	Pb	Hg	Cd	Cr6+	PBB	PBDE
Housing	x	o	o	x	o	o
Power Supply	x	o	o	x	x	x
Motherboard	x	o	o	o	x	x
Rear Panel Assembly Board	x	o	o	x	x	x
Pneumatics	x	o	o	x	o	o
LCD	x	x	o	o	x	x
Base Unit	x	o	o	o	x	x
Fluidics	x	o	o	x	o	o
o: Indicates that this toxic or hazardous substance contained in all the homogeneous materials for this part is below the limit requirement in SJ/ T11363-2006						
x: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006. (Enterprises may further provide in this box technical explanation for marking "X" based on their actual conditions.)						

Setup Sequence – Anterior Segment Surgery

The following is a general overview of the steps to take to prepare the WHITESTAR SIGNATURE System for surgery:

1. Connect the WHITESTAR SIGNATURE System power cord to the rear of system. Plug the power cord into a grounded power outlet.
2. Connect the footpedal to the rear panel receptacle.
3. Connect 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 Start Up Self Test, select the surgeon and program.
7. Install the tubing pack, attach the required accessories (phaco, vitrectomy, or diathermy handpieces) and set up the tubing.
8. Prime and tune the handpieces. (Refer to Chapter 4, Equipment Operation, Prime/Tune.)
9. Perform the final test of the fluidics and the handpiece integrity with the footpedal. (Refer to Chapter 4, Equipment Operation, Verify Irrigation/ Aspiration Balance.)

Figure 3.1 – Rear Panel Connections



1. USB Port
2. Communications Port
3. Foot Pedal Connector
4. Compressed Air
5. Potential Equalizer
6. Power Switch and Power Cord Connection

Phacoemulsification Ultrasonic Handpiece

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

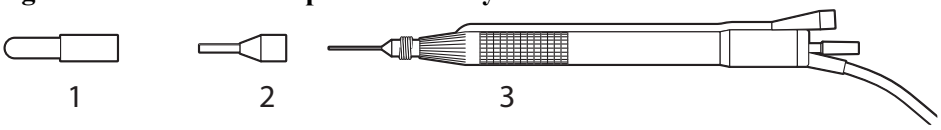
WARNING: Prior to using any invasive portions of the handpiece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. Use a backup handpiece for surgery if there are any questionable characteristics of the handpiece. Use of contaminated or damaged 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 tubing pack 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 infusion sleeves and the test chamber.

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

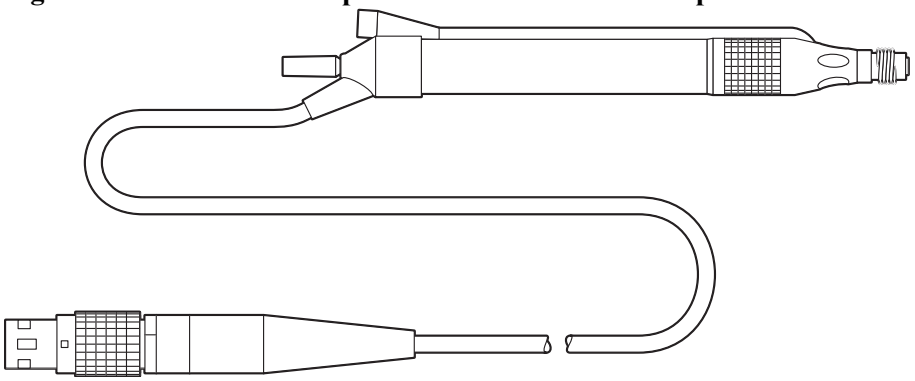
Figure 3.2 – Phaco Handpiece Assembly



1. Test Chamber
2. Infusion Sleeve
3. Handpiece with Tip

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

Figure 3.3 – ELLIPS Handpiece and ELLIPS FX Handpiece



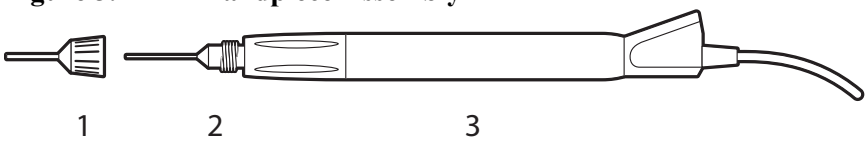
Note: You can use the ELLIPS handpiece or the ELLIPS FX handpiece with WHITESTAR Technology and ELLIPS Technology phaco settings.

Irrigation/Aspiration Handpiece

1. Assemble the SOLO Irrigation/Aspiration (IA) Handpiece by attaching the infusion sleeve.

   Note: Both the infusion sleeve and the test chamber are provided in the FUSION Tubing Pack. The LAMINAR Flow 20 ga. infusion sleeves can also be used and are available with the OPOS20L or any 20 ga. LAMINAR Phaco Tip.

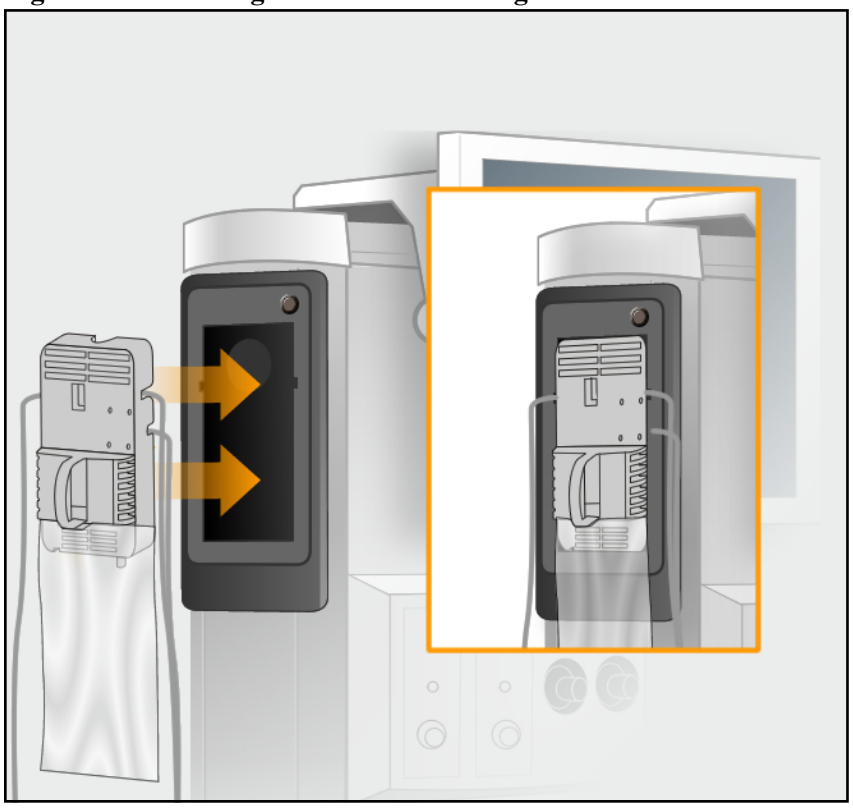
Figure 3.4 – IA Handpiece Assembly



1. Infusion Sleeve
2. SOLO Straight Tip
3. Handpiece
4. SOLO Curved Tip
5. SOLO 45o Silicone Sleeve Tip

2. Load the FUSION Tubing Pack
3. Open the tubing pack packaging.
4. Install the FUSION pack into the side receptacle, as shown below.
5. Make sure that the pack has a properly attached drainage bag.

Figure 3.5 – Loading the FUSION Tubing Pack



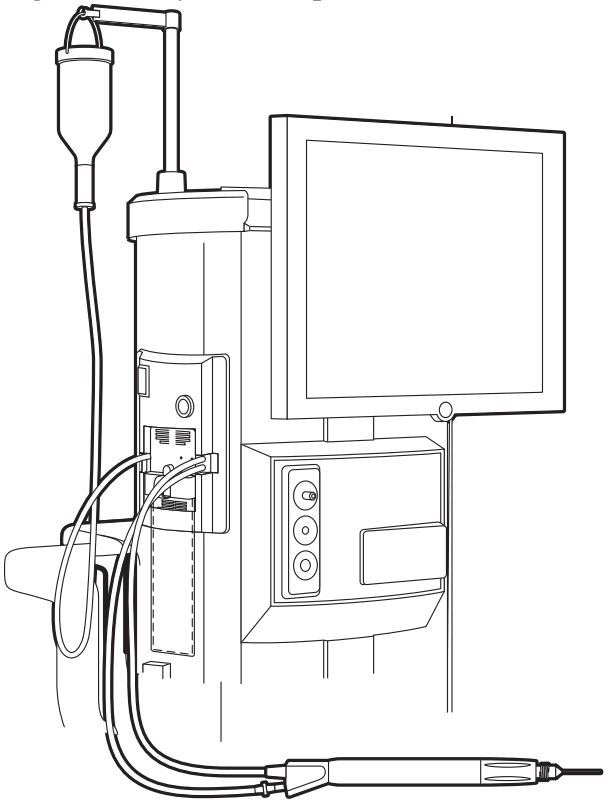
Note: Press the button above the pack to remove the pack.

Setup Completion

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.

1. Place a new bottle of balanced salt solution on the top of the system console.
2. Insert the drip chamber spike into the balanced salt solution bottle.
3. Hang the balanced salt solution bottle from the Programmable IV Pole and squeeze the drip chamber.
4. Fill the drip chamber with fluid to the half-full level. The Programmable IV Pole moves to the appropriate height automatically.
5. Raise or lower the pole if needed. Use the IV pole Up and Down arrows on upper right of the touch screen. You can also use the Up/Down switch on the console.

Figure 3.6 – System Setup



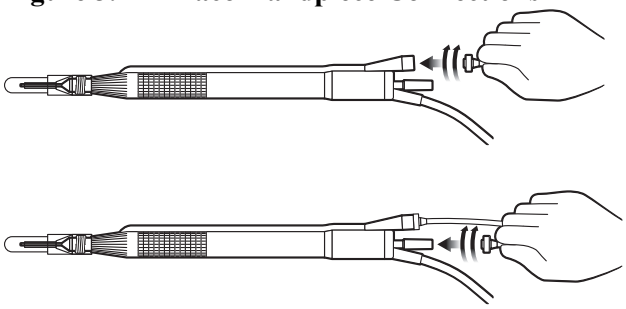
6. Connect the IA tubing to the desired handpiece.
7. Insert the male luer end of the irrigation tubing into the phaco handpiece.

8. 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 irrigation fluid
   - sterile handpieces

Figure 3.7 – Phaco Handpiece Connections



Diathermy

1. Connect the diathermy cord to the Diathermy Forceps or Pencil Probe.
2. Connect the diathermy cord to the diathermy receptacle on the front panel.

Figure 3.8 – Diathermy Forceps

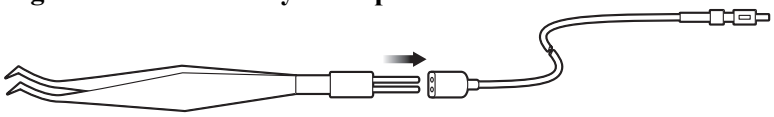
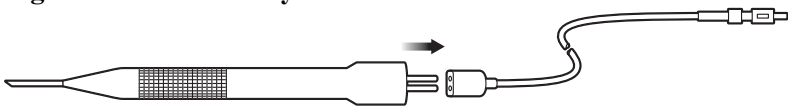


Figure 3.9 – Diathermy Pencil



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

Vitrectomy

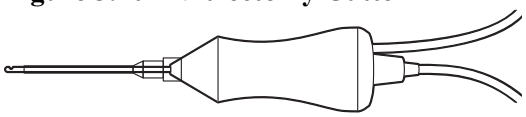
If you need to use vitrectomy during surgery:

1. Connect the AMO Vitrectomy Cutter as shown below. Vitrectomy requires the following components:

   - IA Tubing (from FUSION Tubing Pack)
   - Vitrectomy Cutter
   - Vitrectomy Infusion Sleeve, or a 23 Gauge Limbal Infusion Needle, if desired.

2. Use the instructions provided with the vitrectomy cutter to assemble the handpiece.

Figure 3.10 – Vitrectomy Cutter



3. Attach the connector end of the vitrectomy cord to the vitrectomy receptacle on the front panel.

Pre-Operative Sterilization

Prior to each surgical case, sterilize the WHITESTAR SIGNATURE System instruments identified in Chapter 9, “Care and Cleaning” Instrument Sterilization Procedures. The recommended sterilization techniques, times and temperatures are given in Chapter 9, “Care and Cleaning”. AMO recommends that you follow the sterilization guidelines to maximize the life of your WHITESTAR SIGNATURE System instruments.

Footpedal

The footpedal controls all of the WHITESTAR SIGNATURE System functions, therefore, it is essential that you understand the footpedal operation.

The System software automatically detects if a footpedal and what type of footpedal is connected during power up.

The footpedal settings and adjustments can be selected and preset for the footpedal in the Configuration screen. Instructions for the footpedal settings are given in Chapter 5, “Anterior Segment Surgery Operating Modes”. The footpedal housing incorporates a handle, making the footpedal easy to grip for repositioning and storage.

The Footpedal cable attaches to the footpedal connector on the rear of the console.

Note: You must NEVER handle the footpedal by the cable.

Figure 3.11 – Footpedal - Single Linear

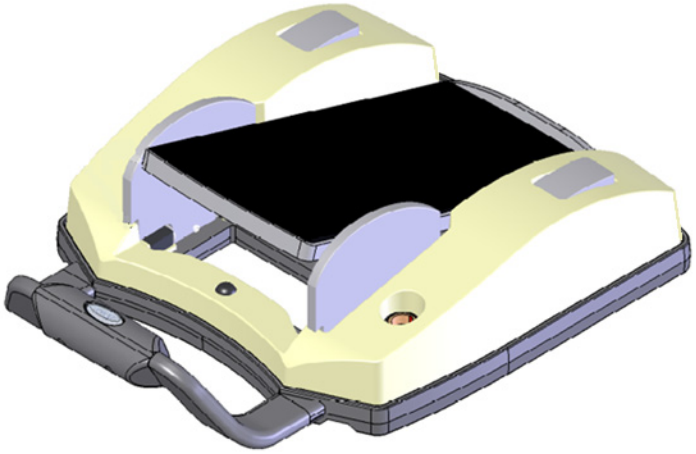
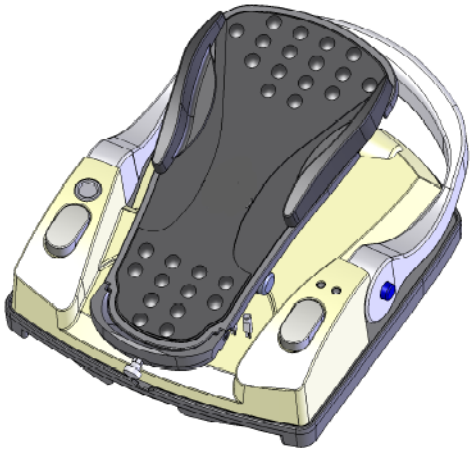


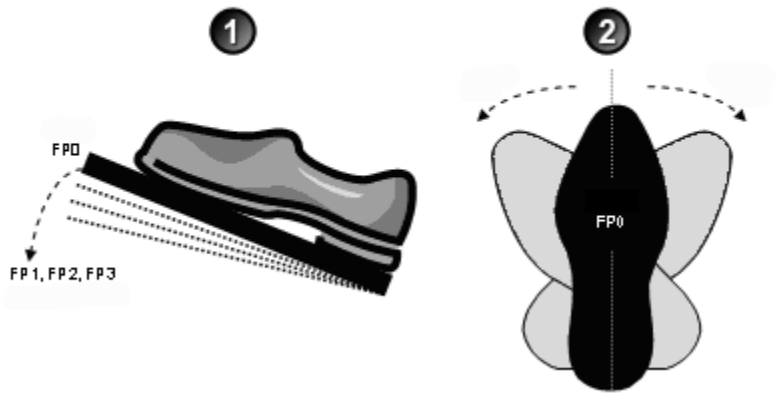
Figure 3.12 – Footpedal - Advanced Control Pedal (Dual Linear)



Footpedal Operation

The footpedal has three active “PITCH” ranges, which are referred to as Positions 1, 2 and 3. 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 3.13 – Footpedal "Pitch" and "Yaw" Positions



1. Pitch
Toe Down/Up
Configurable Ranges

2. Yaw
Toe Right/Left
Configurable Ranges

The footpedal position determines the function that is delivered by the handpiece, which depends on the mode selected on the touch screen. When the footpedal has been connected, place your foot on the pedal and press to the desired position. The footpedal settings and programming are addressed in Chapter 5, "Anterior Segment Surgery Operating Modes".

Reflux

Reflux is the controlled backflow of fluid through the aspiration port of the handpiece. Reflux is used to gently release or dislodge unwanted material from the handpiece tip. Reflux can also be used to "tent" the incision site to allow easier tip insertion. Reflux pressure depends on bottle head pressure (IV pole height and gravity) for the FUSION Fluidics pack (OPO70), and as such, is not intended to clear a clogged handpiece. However, reflux can be used to identify a blockage.

The reflux action can be programmed on any available footpedal switch. This causes fluid to be expelled from the aspiration line into or towards the eye.

The reflux is active until the footpedal switch is released.

The FUSION Fluidics 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.
- has no time restriction for Reflux as there is no pump reversal

The DP pack (OPO71):

- includes support for the vacuum tank used in the Venturi vacuum system
- does not support inter-connecting the irrigation line to the aspiration line. Therefore, only previously aspirated fluid is being refluxed.

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 switch on the side of the console can also be used to control the IV Pole. These controls are used to raise and lower the pole, and the height is indicated in the Programmable IV Pole screen. The Programmable IV Pole moves at a rate of approximately 6 cm (2 inches) per second.

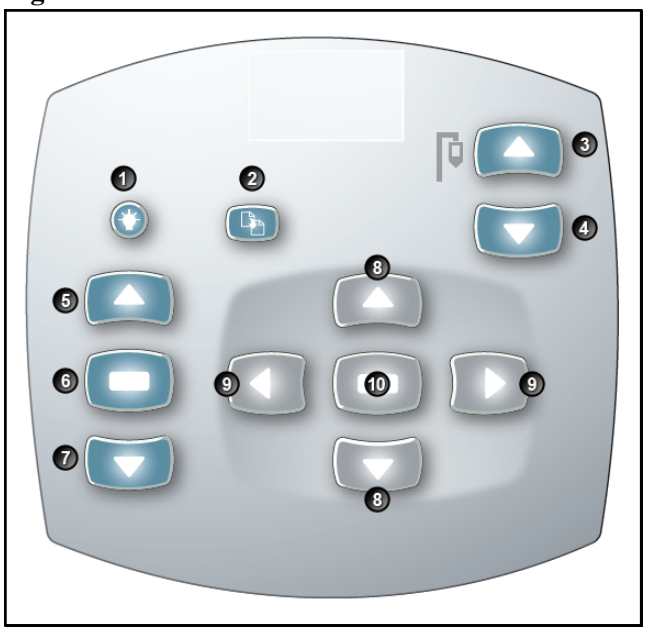
The Programmable IV Pole is adjustable from 0 to 104 centimeters, and can be set for either inches or centimeters. The height measurement is relative to the distance from the irrigation valve to the center of the drip chamber. The Programmable IV Pole height for each fluidic mode or submode (PHACO, IA, VIT) is saved in the WHITESTAR SIGNATURE System memory. A Maximum IV Pole height can be set on the Diagnostics screen.

When a surgery mode is selected, the Programmable Power 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 will not move above that height.

Wireless Remote Control

The wireless remote control keypad can be used to operate the WHITESTAR SIGNATURE System. All Modes, Programs, Diagnostics and End Case can be accessed and adjustments to the settings can be made with the remote control. The buttons on the remote keypad work the same as the controls on the WHITESTAR SIGNATURE System touch screen.

Figure 3.14 – Wireless Remote Control Module



1. Remote Backlight On
2. Reload
3. IV Pole Up
4. IV Pole Down
5. Mode Up
6. Mode Select
7. Mode Down
8. Navigation Up/Down
9. Navigation Left/Right
10. Select

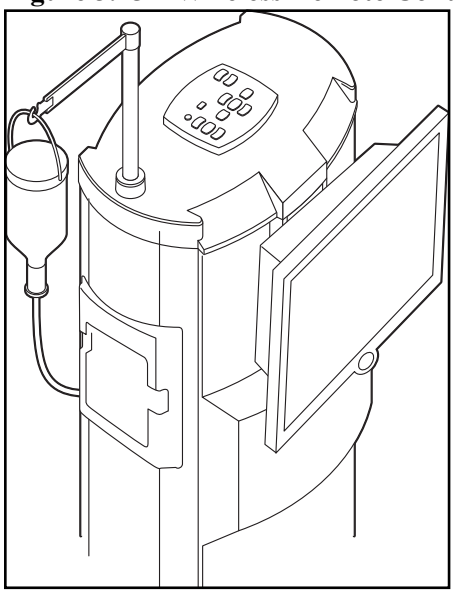
When not in use, store the Wireless Remote Control on the top of the system to charge the batteries.

After you turn the system On, press the Remote Control Backlight button to activate the Remote Control. When the system is Off the Remote Control is in a power save mode.

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 Backlight button.

WARNING: DO NOT try to replace the Wireless Remote Control batteries. Call your AMO Technical Service representative to replace the batteries.

Figure 3.15 – 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 connected to your WHITESTAR SIGNATURE System Communications port on the rear panel. (See Figure 3.1 Rear Panel Connections.)

Note: If you select Configuration during surgery, the Program Settings screen opens directly. The Configuration dialog box only shows when you are not in a case. If you need to access the System Configuration screens, you must select End Case, Next Case and then select the Configuration button.

1. To configure the Surgical Media Center, select:

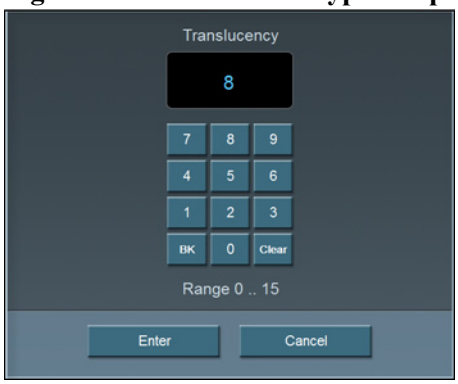
   - Configuration
   - System Configuration
   - SMC

Figure 3.16 – Surgical Media Center Pop-up Window

2. Use the Up and Down arrows to adjust the settings. Translucency is used to make the overlay (instrument settings) more or less opaque.

   Note: Press on the number in the control panel to open a numeric keypad and enter the required value. Press Enter on the Keypad pop-up window when you are finished.

Figure 3.17 – Numeric Keypad Pop-up Window



3. Select the Recording Mode. Off, On, or Automatic. If the Recording Mode is On, the recording continues between cases. Automatic stops recording between cases.

   Note: The Footpedal Switch can be set up to activate the SMC Record function.

4. Press Finished to close the pop-up window.

Shutdown Sequence – Anterior Segment Surgery

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. Place the footpedal in the storage area on the console.
8. Place the Wireless Remote Control on top of the console to charge.
9. Refer to Chapter 9, “Care and Cleaning”, Cleaning Procedures for additional information.