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## INTRODUCTION

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Symbol Definitions

- About this Manual** This manual includes information about the design of the **COMPACT INTUITIV** 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 in your area.
- About Phacoemulsification** Over forty years ago, Doctor Charles Kelman conceived and developed phacoemulsification, a method of cataract removal by use of ultrasonic emulsification with aspiration of the cataract lens through a small incision. Phacoemulsification is advantageous for both patient and surgeon for the following reasons:
- 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.
- Indications for Use** The **COMPACT INTUITIV** System is an AC-powered device with a fragmenting needle for cataract surgery to disrupt a cataract with ultrasound and extract the cataract.
- COMPACT INTUITIV System** The **COMPACT INTUITIV** System is a modular ophthalmic micro surgical system that facilitates anterior segment (cataract) surgery. The modular design allows the users to configure the system to meet their surgical requirements.
- The **COMPACT INTUITIV** 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 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 or eliminated ultrasonic time reduces the risk of thermal damage.
- Pulse Shaping**
- Pulse Shaping delivers finely modulated, shaped pulses of energy, interrupted by extremely brief cooling periods. You can adjust the percentage of Low and High “kick” and the power of the “kick”. Pulse Shaping allows the **COMPACT INTUITIV** System to achieve full ultrasound cutting efficiency and excellent followability while putting less energy into the eye.

### **Occlusion Mode Phaco**

You can use the Occlusion Mode Phaco to regulate the vacuum rise time that follows the occlusion of the phaco tip, without limiting the choice of aspiration rate through an unoccluded needle. In order to independently control the aspiration rate and the vacuum rise time, it is possible to have a different aspiration rate for an occluded needle and an unoccluded needle.

You can use Occlusion Mode Phaco to regulate ultrasound power modulation. You can program the power modulation of the phaco handpiece (continuous, pulse, burst, etc.) to automatically change when the phaco tip changes from an unoccluded condition to an occluded condition.

### **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.

### **CASE One Touch**

The CASE 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 CASE One Touch, the CASE functionality changes to provide enhanced control or improved efficiency for any combination of cataract density, surgical technique or personal preferences.

## **Advanced Fluidics System**

One of the most advanced features of the **COMPACT INTUITIV** System is the fluidics system that allows for intraoperative intraocular control. An integral part of the advanced fluidics is resident in the proprietary technology of the Single-Use packs. The closed and isolated fluidics system provides the maximum safety and minimum biohazard risk.

## **Accessories**

### **Phacoemulsification Ultrasonic 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 **COMPACT INTUITIV** 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 operating modes (Diathermy, I/A, Phaco, and Vitrectomy) are controlled by the foot pedal. You can save the degree of travel for each foot pedal position for each surgeon/procedure.

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 foot pedal pitch settings for each surgeon. Programmable switches can activate reflux, which gives an immediate response. The system does not support the Sovereign Compact closed-toe foot pedal.

### **Wireless Remote Control**

You can access the surgical modes and adjust the surgical settings with the use of the wireless remote control keypad. The back light supports low light operating room conditions.

This Class [A] digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

### **COMPACT INTUITIV System Cart**

The cart's solid wheel base and two locking wheels make the cart stable and smooth rolling. An open design minimizes weight. A Mayo tray with a baling ring accommodates either an instrument tray that can be put in an autoclave or a solid tray. The Mayo tray provides easy access for the remote control under the sterile cover. The open bin and the foot pedal platform are available for storage.

### **IV Pole**

The automated IV pole allows adjustment of the bottle height through each procedural phase. Use the up and down arrows on the screen or the remote control to raise and lower the balanced salt solution bottle; this maintains the sterility of the operating field. A separate up/down switch allows access at the rear of the system. You can remove the pole from the cart for transport.

### **COMPACT INTUITIV System Console**

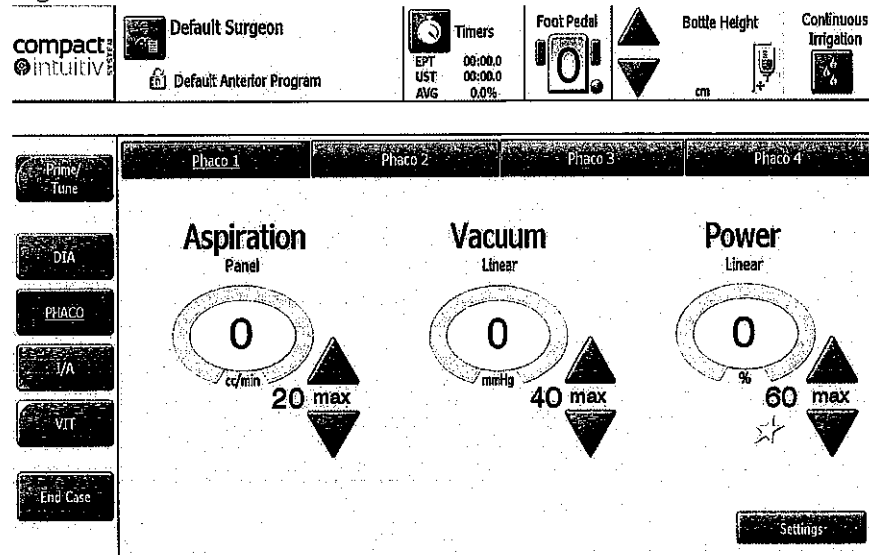
The **COMPACT INTUITIV** System screen is easy to read and easy to operate. You can see at a glance the exact status of the machine. The LCD display gives you visual indication of modes, settings, and system status. Event messages indicate improper connections. You can access all handpiece connections from the front for easy setup.

The design of the graphical user interface (GUI) gives you visual indication of the status for the control systems at all times. When you select a mode (DIA, PHACO, IA, or VIT), you see current settings on the screen. As you make adjustments to the settings, the screen shows the changes.

Each surgical mode and submode has its own distinct screen:

- Diathermy
- Phaco
- Irrigation/Aspiration
- Vitrectomy

**Figure 1.1 – Phaco Screen**



Additionally, there are screens or sub-screens for:

- Prime/Tune
- End Case
- Program Settings
- Surgeon Settings
- System Setup

### Prime/Tune

Before the start of each surgical case, the system requires that you run prime or prime/tune. The prime mode incorporates the function of clearing the tubing of air. The prime mode 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 then tune the handpiece.

### **Continuous Irrigation**

Continuous Irrigation is immediately available by way of the touch screen. Surgeon control of continuous irrigation with the foot pedal is an available setting for the foot pedal. 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 6-2. for detailed information.)

### **Programmable Operating Parameters**

The **COMPACT INTUITIV** System is programmable through the GUI. The surgeon may preselect their desired settings for each portion of the surgical procedure. The instrument program memory can store 30 surgeon names, plus the AMO Default Surgeon settings. Each surgeon can setup 8 unique programs, plus the AMO Default settings program. This allows different users to preset their preferences, or an individual user to preselect setups for different procedures.

### **Multiple Mode Programming (MMP)**

Multiple submode memories are available within the **COMPACT INTUITIV** System operating modes. The MMP allows users to preset their parameters for specific techniques such as phaco chop or viscoelastic removal.

## **COMPACT INTUITIV 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:

### **Diathermy (DIA)**

Most surgeons use diathermy to coagulate blood vessels during the procedure and some surgeons use diathermy to close the conjunctiva at the end of the procedure. An isolated output frequency allows non-contact tissue coagulation, eliminating adhesion and traction. Also, the depth of penetration of the energy field is less than that of higher frequency units, minimizing tissue shrinkage or charring. The gentleness of the diathermy mode allows the surgeon to stop bleeding within the incision with only minimal scleral shrinkage. The surgeon can stop bleeding from a 10-0 suture tract without melting the suture.

### **Phacoemulsification (Phaco)**

The surgeon uses the Phacoemulsification mode to break up (emulsify) the nucleus of the lens. The surgeon then aspirates the nucleus of the lens from the eye through a small incision. The continuous auto-tuning 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. Convenient selection of linear or panel-preset phaco power, in a variety of power delivery options (pulsed, burst, etc.), gives the surgeon increased precision and control.

### **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 the irrigation solution. A peristaltic pump provides a predictable and stable aspiration rate. You can achieve complete control with “Aspiration” and “Vacuum”.

**Note:** The vacuum units are available in either mmHg or kPa. To set the vacuum units go to System Setup and select Vacuum Units.

Irrigation is gravity-fed. You can regulate the gravity-fed irrigation pressure by adjusting the height of the irrigation solution bottle. This mode gives you flexible control of each case with the independently adjustable vacuum level settings and flow rate settings. The adjustable volume tone indicates the vacuum level.

### **Vitrectomy (VIT)**

You use Vitrectomy mode to remove vitreous from the anterior chamber of the eye during:

- a secondary IOL (intraocular lens) implant procedure
- following vitreous loss associated with trauma
- vitreous loss during primary cataract surgery

If there is vitreous loss during cataract surgery, the vitrectomy capability can be ready and available in seconds.

### **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 machine.
2. Do not overload your AC electrical 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. Do not block the openings; as heat build-up can cause system failures which can result in a fire hazard. The instrument has ventilation openings at the rear of the console to allow ambient air intake and the release of heat generated during operation.
5. Do not block the air fans on the bottom of the console; as heat build-up can cause system failures which can result in a fire hazard.
6. Do not try to roll the system cart on carpets or over objects on the floor such as cables and power cords.
7. Take care not to trip over the power cords and the foot pedal cords.
8. Do not place the instrument on uneven or sloped surfaces.
9. Only use disposables, accessories, or other surgical instruments designed for this system. Use only parts recommended by AMO to achieve the optimum performance and the safety of the system.

10. Do not operate the system in a condensing environment. Take care to protect the instrument from fluid sprays or fluid buildup.
11. Do not exceed maximum weight of 25 pounds (11.25 Kg) on the Programmable IV Pole bottle holder.
12. Do not use more than one IV pole extender with the IV pole.
13. If there is no IV pole attached to the system, hang the irrigation fluid container at least 77 cm from the patient's eye.
14. To protect the patient from contaminated fluids or handpieces, use only:
  - sterile tubing sets
  - sterile irrigation fluid
  - sterile handpieces
15. Use caution when handling handpieces with sharp edges or pointed tips.
16. Wrap the excess power cord neatly around the cord wrap on the back of the IV pole or cart.
17. Always replace the Single-Use Pack and irrigation solution bottle between surgical cases.

### **Changing Irrigation**

Use extreme caution when you lower or raise the irrigation 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; take care to avoid abrasion of tissues during phacoemulsification. If you raise the bottle too high it can cause the anterior chamber to deepen.

Note: Use a new bottle of irrigation 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 of 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; and
- Release the foot pedal 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 prior to connecting them to the system receptacles. You may receive a "Phaco Handpiece 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 might 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 and Vitrectomy handpieces with the tips in air, as this reduces the useful life of the handpiece and the cutter. When introducing power to the Phaco or Vitrectomy handpieces, the tips should be in one of the following:

- a test chamber filled with irrigating solution,
- a container of irrigating solution, or
- the patient's eye.

**Vitrectomy**

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

**Diathermy**

When you select the Diathermy mode, you hear a tone or a voice. Also, you 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 should be as low as possible for the intended purpose. AMO recommends 30% setting to start.

The patient should not come into contact with ungrounded metal parts when using diathermy.

Position the diathermy cable in such a way that the cable avoids contact with the patient or other leads.

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

**Power IV Pole**

Do not exceed maximum weight of 25 pounds (11.25 Kg) on the IV pole bottle holder.

**Foot Pedal**

Never handle the foot pedal by its power cord.

Do not place the foot pedal on a wet surface.

**Wireless Remote Control Battery Management System**

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

- This device may not cause harmful interference.
- 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 complies with the limits for a Class A digital device, pursuant to Part 15.105 of the FCC Rules. These limits provide reasonable protection against harmful interference when the equipment is operating 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 has to correct the interference at his own expense.

**Warnings**

**WARNING:** All personnel should read and understand the instructions in this manual before they use the system. Failure to do so may result in the improper operation of the system. Only a trained and licensed physician is to use this device.



**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:** The surgical staff must monitor the irrigation solution bottle height and the 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 eye tissue
- An ultrasonic wound heating commonly called wound burn (extreme case)



**WARNING:** DO NOT attempt to use the system if it 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 Single-Use Pack, Mayo stand cover, and monitor cover.



**WARNING:** Follow good operating room procedures to prevent injury or contamination.



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



**WARNING:** Make sure that you unlock the wheels before you move the cart. Make sure that the wheels move freely when moving the cart.



**WARNING:** Place monitoring electrodes or other types of equipment as far from those of the **COMPACT INTUITIV** 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 should 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 near conductive materials such as metal bed parts, inner spring mattresses, and the like. Renew 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 environment. If exposed to condensing environment, allow 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:** Sterility assurance is the responsibility of the user. You must sterilize all non-sterile accessories prior to use.









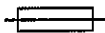

**WARNING:** Prior to using any invasive portions of the handpiece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. You must note any questionable characteristics; use a backup handpiece for surgery. Use of contaminated or damaged system accessories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



















**WARNING:** Do not use non-AMO approved products with the **COMPACT INTUITIV** 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 **COMPACT INTUITIV** System:











Symbol	Definition
	This symbol on the power switch indicates Power is ON.
	This 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 manufacturer of the <b>COMPACT INTUITIV</b> System.
	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.

Symbol	Definition
	Patient applied part is isolated from earth ground.
	Patient applied part is grounded OR no direct electrical energy is involved.
	Foot Pedal connection.
	Communications Port
	Ethernet Port
	IV Pole Connection
	Pack Eject
	Diathermy Forceps Receptacle
	Phaco Handpiece Receptacle
	Vitrectomy Cutter Receptacle
	Potential equalizer used to identify the terminals which, when you connect them together, bring the various parts of the equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
<b>IPX8</b>	IPX8 is the International Protection code that indicates that the device is protected against the effects of continuous immersion in water.

Symbol	Definition
<b>IPX4</b>	IPX4 is the International Protection code that indicates that the device is protected against splashing water sprayed at all angles.
<b>IPX6</b>	IPX6 is the International Protection code that indicates that the device is protected against powerful water jets.
<b>CE</b> 0413	Indicates compliance with the Medical Device Directive
<b>EC REP</b>	Indicates the authorized European Union representative.
	Indicates compliance with EN IEC 60601-1-2:2007, "Electromagnetic Compatibility Requirements and Tests for Medical Electrical Equipment."
	Indicates product listed with Intertek Testing Services
	Universal Serial Bus (USB) port Note: Use only AMO recommended USB devices (flash drives). External hard drives are not supported on the <b>COMPACT INTUITIV</b> System.
<b>FCC</b>	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 container indicating not to open the container except by authorized personnel.
	Do not reuse



Symbol	Definition
	Do not re-sterilize.
	Symbol for sterile medical devices processed using Ethylene Oxide (EtO).
	Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.
	Standard Foot 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 the icon, the Foot Pedal Configuration screen opens.
	Four Button Foot 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.
	Timers. When pressed shows an enlarged version of the timer and allows the resetting of the timers to zero.
	<b>WHITESTAR</b> technology is on.
	<b>WHITESTAR</b> technology is on and pulse shaping is on.
	<b>ELLIPS FX</b> handpiece is connected.
	Continuous Irrigation. Used to turn continuous irrigation on or off.
	Used to save changes made to settings.

Symbol	Definition
	Save As. Creates a new program with the current settings.
	Restore Program after to any modifications. Must be done before you save any changes.
	Restore Submode after to any modifications. Must be done before you save any changes.
	Keyboard, when pressed the virtual keyboard shows on the screen.
	Exit Settings without saving any changes.
	Indicates the selected surgeon. When selected goes to the Surgeons and Programs screen.
	The program is locked. You cannot save any changes or delete the program.
	Brightness indicators. The top icon increases the brightness of the screen. The bottom icon decreases the brightness of the screen.
	Volume indicators. The greater the number on the setup screen, the louder the volume.
	IV Pole