




# LENsX LASER SYSTEM OPERATOR'S MANUAL



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# LenSx Laser System Operator's Manual

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# 1 LenSx Laser System

## 1.1 Indications for Use

The LenSx Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

## 1.2 Summary Description

The LenSx Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision. The incision is achieved by contiguously placed micro-photodisruptions scanned by a computer-controlled delivery system. The LenSx Laser System should only be operated by a physician trained in its use.

The LenSx Laser delivery system employs one sterile disposable LenSx Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single-use, only. Refer to the Instruction for Use supplied with the LenSx Laser Patient Interface for preparation and application instructions for the patient interface.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

## 1.3 Contraindications

Contraindications for the anterior capsulotomy, phacofragmentation of the lens using the LenSx Laser include the following:

- Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetocle with impending corneal rupture
- Corneal opacity that would interfere with the laser beam
- Presence of blood or other material in the anterior chamber
- Hypotony, glaucoma, or the presence of a corneal implant
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy

- Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- A history of lens or zonular instability
- Any contraindications to cataract or keratoplasty surgery
- This device is not intended for use in pediatric surgery.

Contraindications for corneal incisions using the LenSx Laser include the following:

- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
- Corneal thickness requirements that are beyond the range of the system
- Corneal opacity that would interfere with the laser beam
- Hypotony, glaucoma, or the presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- This device is not intended for use in pediatric surgery.

Potential contraindications are not limited to those included in this list.

## 1.4 Complications

Possible complications resulting from anterior capsulotomy, phacofragmentation, or creation of a partial thickness or full-thickness cut or incision include:

- Capsulotomy, phacofragmentation, or cut or incision decentration
- Interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tear
- Corneal abrasion or defect
- Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse

In the case of an incomplete or interrupted capsulotomy, the procedure may be immediately repeated with a slightly larger diameter to complete the capsulotomy. In the case of an incomplete or interrupted fragmentation or partial thickness or full-thickness arc cut/incision, the procedure can be repeated at a slightly different position using the centration feature.

In the case of an incomplete or interrupted 360-degree keratoplasty incision, the procedure may be immediately repeated with a slightly larger diameter to the recipient and a resized corneal donor button. In the case of an interrupted procedure during donor tissue preparation, repeating the procedure at a larger diameter may not be recommended if the recipient cornea has been already prepared at a original diameter. In this case, a new donor cornea may be required.

Cataract removal should be performed after anterior capsulotomy with the LenSx Laser. In the initial clinical protocol using the LenSx, cataract removal was begun within 30 minutes after the laser procedure. In previous studies using the Nd:YAG laser to perform anterior capsulotomy, anterior chamber inflammation and elevated intraocular pressure were noted when cataract surgery was delayed from one hour to up to one day following laser treatment.<sup>1, 2</sup> The Nd:YAG laser requires 100 times more energy per pulse than femtosecond lasers to induce photodisruption.

Potential complications are not limited to those included in this list. These complications may be surgically or medically managed using currently accepted techniques for cataract or keratoplasty procedures.

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<sup>1</sup> Woodward PM. *Anterior Capsulotomy using a neodymium YAG laser.*  
Ann Ophthalmol: 16:534-9, 1984.

<sup>2</sup> Szweda E. Preoperative anterior capsulotomy using YAG laser in cataract extraction by the envelop method. Klin Oczna: 93: 334-6, 1991.



## 2 Warnings and Precautions

### 2.1 Warnings

The LenSx Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner. United States Federal Law restricts the use of this device to practitioners who have been trained in the operation of this device.

The performance of surgical procedures, operation of controls, or any other adjustments other than those specified herein may result in hazardous conditions for both patients and personnel.

While the risk of fire is extremely low, the LenSx Laser should not be operated in the presence of flammable anesthetics, volatile substances, or oxygen flow lines.

**WARNING:** Do not use cell phones or pagers of any kind in the same room as the LenSx Laser.

The LenSx Laser complies with 47 CFR 15 Federal Communication Commission Rules for radio frequency devices. Changes or modifications not expressly approved by Alcon LenSx Inc. can void the operator's authority to operate this radio frequency device.

Only trained LenSx representatives should perform unpacking, installation, and servicing of the LenSx Laser. Covers are not to be removed by anyone other than LenSx personnel. Accidental contact with the high voltage electrical circuits in the interior of the LenSx Laser console may result in serious injury or death. Ocular exposure to collimated beams contained in the console interior can produce retinal damage.

Surgical lasers must meet requirements established by the Food and Drug Administration (FDA) Center for Devices and Radiological Health and international standards and regulations for surgical lasers. Specific controls are required that prevent accidental exposure of laser energy to the eye and skin from both direct and reflected laser beams. In addition, precautions must be taken in the surgical area to prevent fire and electrical hazards. Improper use of the LenSx Laser may result in patient corneal trauma, infection, complications, or mechanical trauma to either patient or personnel. All warnings, labeling and instructions must be observed.

### 2.1.1 Unauthorized Use of the Laser

When not in use, the master key should be removed from the LenSx Laser and kept in a secure location to prevent use of the laser by unauthorized personnel. Once the console is switched ON, password protection is required to access any laser functions.

### 2.1.2 Electrical

High voltage electrical circuits are accessible if the console panels are removed. Only trained LenSx service representatives should attempt to open the console panels. Serious injury or death may occur while contacting electrical circuits in the unit interior. Tools are required to remove the console panels. Panels should not be removed by anyone other than LenSx service personnel. While the LenSx Laser requires 120VAC, 60Hz, 10A electrical service, the system is configurable for the following input voltages: 100VAC/12A, 120V/10A, 220-240V/7A, and 50/60Hz. The line voltage should be tested prior to laser installation and must be within specified limits for proper operation of the unit.

An interlock connection allows the use of safety interlock switches on the operating suite doors that automatically place the laser in STANDBY mode when the suite door(s) is opened.

The area around the LenSx Laser and the footswitch should be kept dry. The laser should not be operated if there is any leakage of water from the console. A LenSx service representative should be contacted immediately.

If the unit power cord is frayed or otherwise damaged, do not use unit until cord has been replaced.

A tripping hazard exists if the AC power cord is not protected from foot traffic. Care must be taken to avoid accidental unplugging of the LenSx Laser during treatment.

### 2.1.3 Eye Safety and Nominal Optical Hazard Distance

The NOHD is defined according to American National Standards Institute Z136.1-2007, "American National Standard for Safe Use of Lasers". The NOHD is computed in terms of the Maximum Permissible Exposure (MPE) allowed onto the eye. For the LenSx Laser the NOHD calculated using this standard is short due to the small pulse energies emitted by the laser. The most conservative NOHD for a direct beam exposure from the LenSx Laser is 106 cm (See Appendix 2). This means that only the patient operative eye will be exposed to laser radiation exceeding the MPE.

The practical consequence is that operators and support personnel are not at risk of optical radiation during normal and routine operation of the laser. Any service operation requiring the removal of any covers or shields on the console will require eyewear of OD  $\geq 5$  at a wavelength

of 1030 nm. Only authorized LenSx service representatives should attempt to remove console covers or to service the LenSx Laser.

Standard laser safety protocol requires that a warning sign be placed on the door of the room when the laser is in use, to warn personnel of laser usage in progress before they enter the controlled area. The door should be closed during the operation of the laser.

Removing the console covers increases the risk of eye injury. Only trained LenSx service representatives should remove the console covers or attempt servicing of the LenSx Laser.

An interlock connection allows the use of safety interlock switches on the operating suite door(s) that automatically disables laser emission when the surgical suite door(s) is opened.

The Patient Interface disposable cannot be reused or re-sterilized; the LenSx Laser will not be operable with a previously used Patient Interface.

## 2.1.4 Mechanical/Motion

The LenSx Laser console is stable and mobile within an operating room. No significant tipping or rolling hazard exists once the console is placed in the locked position for surgery. Only trained personnel should move the console. If the console must be moved for any reason, a LenSx service representative should be contacted.

When installed, a footbrake at the back of the unit prevents the console from rolling. The footbrake must be engaged during treatment.

Removing the console covers is a potential mechanical hazard. This operation should be performed only by trained LenSx service representatives.

After docking is complete, the user should not move the delivery system until patient is disengaged from the system.

## 2.1.5 Combustion/Fire

Although the possibility of combustion is remote, flammable anesthetics should not be used with the LenSx Laser. Oxygen lines and flammable materials should be kept clear of the immediate area surrounding the laser aperture.

## 2.1.6 Environmental/Chemical

No hazardous gases or chemicals are used in the LenSx Laser.

## 2.1.7 Sterilization/Biological Contamination

The LenSx Laser is used with the LenSx Laser Patient Interface. This sterile assembly cannot be reused and should be disposed of as medical waste.

## 2.1.8 Emergency Off

In the event of an emergency, the LenSx Laser should be immediately shut down by pressing the red emergency OFF button located at top center on the front panel.

If the LenSx Laser is shut down (by pressing the Emergency Off button or by a loss of power), the patient may be removed from under the delivery system by lowering the bed or by actuating the manual gantry lift located at the base of the delivery system gantry.

## 2.2 Precautions

### 2.2.1 General

The Patient Interface will increase intraocular pressure during the procedure. Care must be taken to minimize appplanation times. Incomplete appplanation may result in non-uniform or incomplete incisions.

### 2.2.2 Patient Selection

- Patients must be able to lie flat and motionless in a supine position.
- Patient must be able to understand and give an informed consent.
- Patients must be able to tolerate local or topical anesthesia. Patients with elevated IOP should use topical steroids only under close medical supervision.

### 2.2.3 Surgical Procedure

Full thickness cuts or incisions should be performed with instruments and supplies on standby to seal the eye in case of anterior chamber collapse or fluid leakage.

Surgical treatment should be halted if the OCT image is poor or disrupted.

During use, the user should not move, shake or bump the delivery system after docking is completed until patient is disengaged from the system.

### 2.2.4 Power Failure or Emergency Off

In the event of power failure or initiation of the Emergency Off button, remove the patient interface tube from the vacuum port to release the eye from suction. Grasp the delivery system objective and raise it 1 to 2 inches to safely remove the patient from the surgical field.

The Manual Gantry Lift, located at the base of the gantry, allows the user to lift the unpowered gantry if additional patient clearance is needed. Alternatively, the patient bed may be lowered to provide clearance.

## 2.3 Safety Features

The LenSx Laser complies with all performance standards specified by the Center for Devices and Radiological Health of the U.S. Food and Drug Administration and international standards for surgical lasers, and includes the following safety features:

### 2.3.1 Key Switch

The laser console can be turned ON only with the appropriate master key that controls the master switch. The key ON switch is located at the bottom center of the front panel of the laser console. When the master key is turned ON, power is available to the instrument. The master key cannot be removed when switched to the ON position, and the laser will operate only with the key in place.

### 2.3.2 Laser Enabling

When the key switch turns on the system power, a **Login** window appears. **Login** prevents unauthorized use. Following successful login, laser operation is disabled while the microprocessor checks for basic fault conditions and the system stabilizes. After this period, the **Procedure** window will appear on the Display Panel.

### 2.3.3 Laser Emission Indicator

Laser emission is indicated by a red LASER EMISSION indicator on the Display Panel.

### 2.3.4 Protective Housing and Safety Interlock

The LenSx Laser has a protective housing that prevents unintentional access to laser radiation. This housing should be opened only by a qualified LenSx representative.

### 2.3.5 Labels

Appropriate warning labels are mounted in specified locations on the laser system to indicate conditions under which the user could be subjected to laser radiation (See Section 10).

### 2.3.6 Safety Shutter Monitor

Dual safety shutters, closed unless the system is in the TREATMENT mode, prevent laser radiation from exiting the instrument. Shutter status is continuously monitored. Should a malfunction occur (i.e. a safety shutter opens in the absence of a footswitch press) the laser console is disabled and a message is displayed. The LenSx Laser cannot be re-enabled until the fault condition has been cleared.

### 2.3.7 Footswitch Control

The footswitch is housed in an industrial grade enclosure and cannot be activated unless the LenSx Laser has completed all steps in preparation for laser incision. Position switches in the housing are arranged such that the footswitch pedal position is redundantly monitored.

### 2.3.8 Remote Interlock Connector

The system is equipped with an outlet for the interlocking of room doors. A message on the system display appears when the remote interlock is not connected properly or has been broken by some action, such as the opening of an operating room door. LenSx representatives should be contacted for assistance in establishing a remote interlock.

### 2.3.9 Emergency OFF Switch

The emergency OFF switch is a red button located on the front panel of the console. When pressed, the emergency off switch shuts off the main system power. This control should be used only in the event of an emergency.

If the LenSx Laser is shut down (by pressing the Emergency Off button or by a loss of power), the patient may be removed from under the delivery system by lowering the bed or by actuating the manual gantry lift located at the base of the delivery system gantry.

To restart the system after the emergency off switch is actuated, twist the red emergency off button until it disengages; turn the key switch to the OFF position and return it to the ON position. The system will then reboot normally. Follow the System Startup instruction in section 4.6.1.

### 2.3.10 Laser Cooling System

The LenSx Laser uses an internal re-circulating cooling system whose fluid levels are checked during preventive maintenance. Coolant levels are automatically monitored by the system and if a low coolant error occurs, a message is displayed. An authorized LenSx service representative should be called if a coolant error occurs.

### 2.3.11 Manual Gantry Lift

The manual gantry lift allows the user to raise the gantry mechanism up using a manual screw. The manual lift knob is found at the base of the gantry a few inches above the floor. When the system is unpowered, the knob is free to turn.

### 2.3.12 Patient Interface RFID

Each LenSx Laser Patient Interface is instrumented with an RFID tag. The RFID tag authenticates the Patient Interface for use with the LenSx Laser and prevents reuse or use by unauthorized patient interfaces.

### 2.3.13 Console Footbrake

When the laser system is installed, a footbrake at the back of the unit prevents the console from rolling. The footbrake must be engaged during treatment.

## 2.4 Device Electrical Classification

- Protection against electric shock: Class I Equipment
- Protection against electric shock Patient Applied Part: Type BF
- Mode of Operation: Continuous Operation

## 3 System Description

### 3.1 Introduction

The LenSx Laser System uses focused femtosecond laser pulses to create incisions and separates tissue in the lens capsule, crystalline lens and cornea. Individual photodisruption locations are controlled by repeatedly repositioning the laser focus. The light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus. The surgical effect is produced by scanning thousands of individual pulses per second to produce a continuous incision or tissue separation. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision. The laser pulses are delivered through a sterile, disposable applanation lens and suction ring assembly that contacts the cornea and fixes the eye with respect to the delivery system.

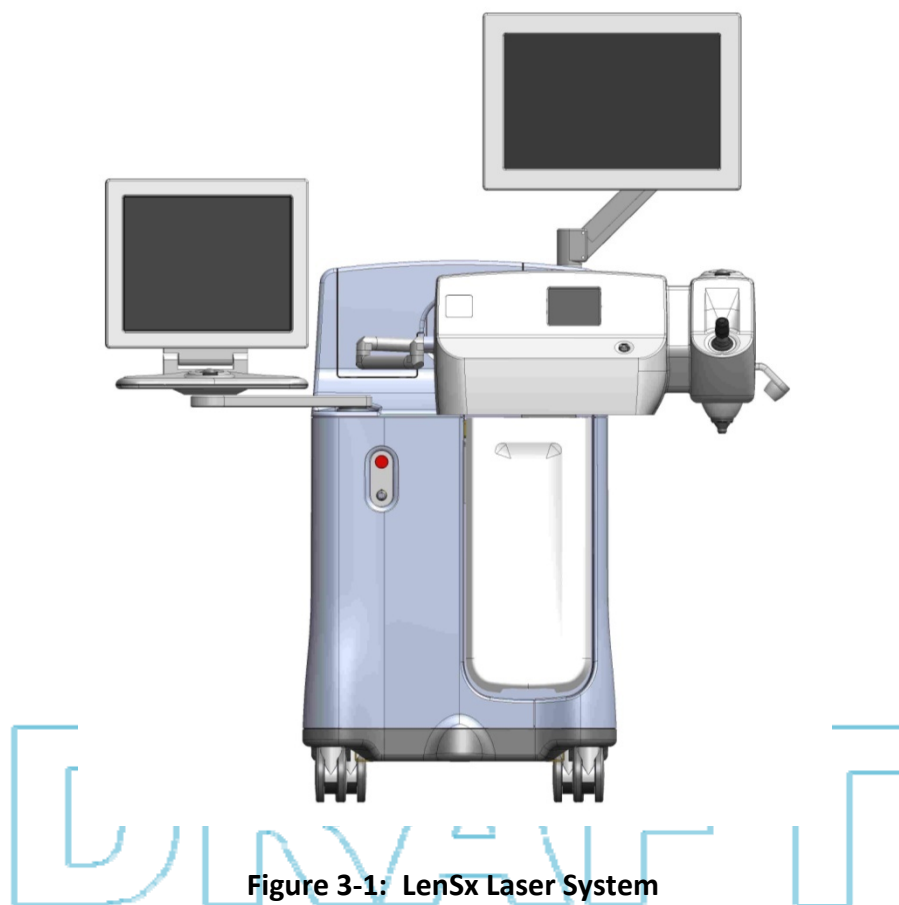
### 3.2 System Overview

The LenSx Laser is a CDRH CFR 1040 class 3B and a IEC 60825-1 class 3R laser system for ocular surgery consisting of the following components:

- a laser source to produce femtosecond laser pulses;
- an aiming device to localize specific targets in the eye;
- an optical delivery system to precisely deliver laser pulses to desired targets in the eye;
- computer controllers to perform clinical procedures;
- a disposable patient interface optically coupling the eye to the optical delivery system in order to prevent eye movement.

The LenSx Laser is a stand-alone unit requiring no external water or gas connections. The device console houses the laser source, power supplies, control electronics, cooling system, beam delivery device, optical coherence tomography (OCT) device, video microscope and computers. The console itself is designed for use in a medical setting meeting US and international standards (ETL) for electromagnetic emissions for medical devices. The laser beam and all collateral radiation are completely enclosed inside the console. The Key ON switch and Emergency Off button are located on the front panel of the console where they are easily identified and accessed. The LenSx Laser System is shown in Figure 3-1.





**Figure 3-1: LenSx Laser System**

An all-solid-state laser source produces a kHz pulse train of femtosecond pulses. The amplified pulse train is routed through a beam monitoring assembly comprised of energy monitors, an energy attenuator and the primary safety shutter. An optical articulated arm directs laser light to the delivery system where a second shutter controls the beam. Computer controlled scanning mirrors direct the light through a beam expander and through a focusing objective onto a spot at pre-determined depth within the eye. An optical coherence tomography (OCT) imaging device and a video camera microscope (VM) are used to localize specific targets and to view the patient's eye.

The LenSx Laser System uses a sterile disposable patient interface that attaches to the distal end of the focusing objective. The patient interface is lowered to the eye until it contacts the eye. Suction then holds the eye in position. Once parameters for the desired procedure are selected using the software interface, the procedure is initiated by pressing the footswitch. Although the system computer controls the laser operation during the incision and laser pulse positioning, the procedure may be stopped at any time by releasing the footswitch.

The following sections briefly describe the major components outlined in Figure 3-1.

### 3.2.1 Femtosecond Laser Engine

Consistent with well-established femtosecond laser principles, the laser engine uses a conventional amplified laser design in which pulses with sufficient bandwidth are generated by an oscillator, amplified to higher energies, and finally compressed in time to femtosecond pulse duration.

The oscillator produces femtosecond laser pulses of nanojoule energy. These pulses are temporally expanded by a pulse “stretcher” and are then directed into a diode-pumped regenerative amplifier where the pulse energy is increased as the pulse completes a number of round-trips within the amplifier cavity. When the pulse energy reaches microjoule energies, the pulse is switched out of the amplifier cavity. Amplified pulses are routed to a grating compressor to temporally compress the pulses back to the femtosecond range.

### 3.2.2 Energy Monitor

The beam of compressed pulses from the laser then enters the energy monitoring assembly. A computer controlled energy attenuator adjusts the beam energy to programmed levels and energy monitors verify the beam energy. A primary shutter, that is normally closed when not energized, controls the release of the beam from the energy monitor. Electronic hardware closes the shutters in the event that the energy monitors report an unexpected or out-of-tolerance pulse.

### 3.2.3 Delivery System

The delivery system focuses the beam of laser pulses onto a focus spot at a programmed location. Upon exiting the energy monitor, the beam enters an articulated arm that terminates at the delivery system. A second shutter at the delivery system controls the laser beam through the delivery system. The beam then enters a set of computer controlled scanning mirrors that scan the beam into a beam-expanding telescope. Each scanned position of the beam corresponds to an X, Y location in the focal plane of the focusing objective. The Z position of the focused laser spot is computer controlled by optical zoom lenses located in the beam expander. The entire delivery system is mounted on a motorized gantry attached to the system console to allow the user to position the delivery system.

The alignment of the beam through the delivery system is automatically verified before each procedure. Users can also request that an alignment check be performed using the **Beam Steering** selection in the **System Checks** menu.

### 3.2.4 Video Microscope

The delivery system includes a Surgical Display that provides a video microscope view of the surgical field at all times. Illumination of the field is controlled with an internal electronic controller and a touch screen interface mounted on the console. The video image provides the

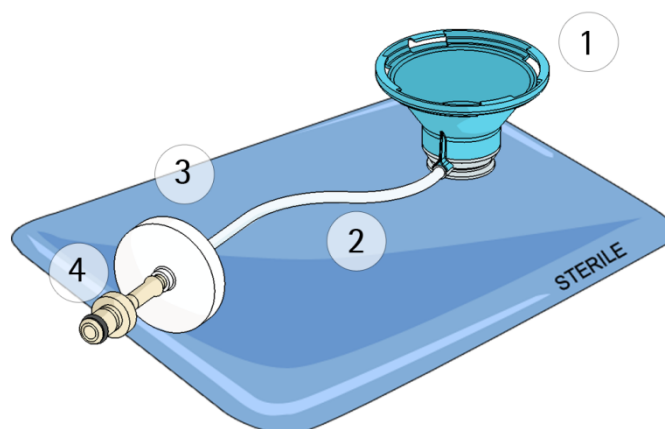
surgeon with surgical details such as the position of the pupil. The surgeon observes the video image to adjust and verify the position of the surgical patterns during programming and performance of the procedure.

### 3.2.5 Optical Coherence Tomography (OCT) Imaging Device

The Surgical Display also includes an optical coherence tomography (OCT) based imaging device that assists in localizing specific target locations. The OCT consists of a low power visible wavelength light source that is scanned throughout the transparent structures of the anterior chamber of the eye. Light scattered from ocular structures and surfaces within the eye is analyzed to produce cross sectional images of the eye's anterior segment. Various sectioned images may be produced, including a wide field line scan of the anterior chamber, magnified cross sections of the cornea at the points of planned incisions, and circle and line scans of the lens and capsule. The surgeon uses these OCT images to adjust and verify the position and orientation of the selected surgical patterns.

### 3.2.6 Patient Interface

The LenSx Laser uses a sterile, disposable Patient Interface (Figure 3-2). The Patient Interface is comprised of an applanation lens, suction ring and tubing. The suction ring and curved applanation lens are integrated into a single piece and mounted on the laser delivery system. The Patient Interface is mounted onto the distal end of the laser focusing objective and serves as a sterile barrier between the patient and the laser. Tubing is connected to a filter and to a vacuum port on the laser system. The Patient Interface also contains an integrated passive RFID identification device. The RFID identifier is sensed by a reader located inside the LenSx Laser System console. The lens is lowered onto the patient's eye until the cornea is applanated; suction is then activated.



**Figure 3-2: LenSx Laser Patient Interface – (1) Interface Cone and gripper; (2) tubing; (3) filter and RFID; (4) vacuum port.**

Using the gantry joystick and visualization via the video microscope, the curved applanation cone (that is attached to the laser delivery system) is lowered to make contact onto the eye. The applanation force indicator is in the yellow or green zone when adequate applanation force is achieved, allowing the surgeon to apply suction via touch screen activation of an internal pump to fixate the eye. Graphical overlay software tools (reference to a live video image of the eye on the graphical user interface) are used to adjust the centration of the programmed cutting pattern to the desired position.

When the procedure is completed, suction is released and the focusing objective is lifted, removing the applanation lens from the surface of the eye. The applanation lens and tubing are then disposed.

### 3.2.7 Surgeon Controls

The surgeon controls the LenSx Laser primarily by a console interface comprised of two display monitors (the Display Panel and Surgical Display), a keyboard, a touch pad and a trackball. Parameters for photodisruption pattern and system information are entered at the console interface. The system software allows the surgeon to select pattern parameters and to prepare the laser for treatment. Directly next to the console interface are the master key switch, which is used to start the system, and the emergency OFF switch.

Other important surgeon controls include an X, Y, & Z joystick that actuate the motorized gantry supporting the delivery system. The joystick is used to align the delivery system over the patient and to make contact with the patient eye. A small touch screen is used to control the utilities associated with the delivery system, including the illumination controls, docking controls and video microscope focusing controls.

A footswitch allows the surgeon to start and stop laser treatment. The surgeon initiates laser treatment by first navigating the software interface until the system is READY and starts the treatment by pressing the footswitch. The surgeon can interrupt the procedure at any time by releasing the footswitch. After interruption, the surgeon restarts the procedure by pressing and holding down the footswitch again. The laser will continue the treatment until the programmed pattern is complete.

### 3.2.8 System Electronics

The LenSx Laser console can be configured for 100V, 120V, 220-240V, 50/60Hz operation. AC to DC converters supply system electronics, laser diodes and thermoelectric coolers with low voltage DC current. The maximum power draw is less than 1.2 kW.

Electronic sensors monitor the position of the patient interface when mounted onto the delivery system. If the applanation lens is unlocked or out of position, hardware sends an error to the computer and prevents the procedure from starting. In addition, sensors authenticate the patient interface via the RFID tag on each patient interface.

A computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens. Hardware monitors the functioning of the computer and computer software. If an unsafe condition occurs, the safety shutters are immediately closed and the surgeon alerted. In addition, the surgeon monitors the procedure through the video microscope and can halt the procedure at any time by releasing the footswitch.

### 3.2.9 Console Chassis

The entire laser console is enclosed by a metal skin. These coverings cannot be removed without special tools. The laser radiation is not accessible outside the console chassis until the treatment beam exits the system at the patient interface. The console is designed for use in a surgical setting, it is easy to clean, and meets US and international standards for electromagnetic emissions from medical devices. The patient applied part is classified as floating "BF" device and is electrically isolated from the system electronics and mains input.

## 3.3 Procedure Overview

The LenSx Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

The LenSx Laser focuses a beam of low energy pulses of infrared light into the eye. Each pulse of energy creates photodisruption of a micro-volume of tissue at the focus of the beam. When scanned, the beam places individual photodisruption sites in a contiguous pattern to form continuous incisions. The spacing between photodisruption sites is programmed by the user. A typical incision consists of several tens of thousands micro-disruptions. By programming the size, shape and location of the scanning pattern, incisions are created.

An anterior capsulotomy incision consists of a cylindrical cut starting from below the surface of the anterior capsule and continuing through the capsule a few microns into the anterior chamber.

A lens phacofragmentation incision consists of two or more vertically oriented elliptical- shaped planes that intersect at the center of the lens. The maximum cutting depth should be at least

500  $\mu$ m above the posterior capsule. The cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule.

A partial thickness or full thickness cut for cataract surgery consists of an arc cut starting from the desired corneal thickness and continuing anteriorly towards the corneal epithelium. These cuts can consist of 1, 2 or 3 planes.

### 3.3.1 Pre-Operative Steps

The LenSx Laser uses a proprietary sterile disposable Patient Interface. The Patient Interface is comprised of an integrated applanation lens, suction ring, and tubing that connects to the suction port of the LenSx system. The patient interface is mounted onto the distal end of the system focusing objective and serves as a sterile barrier between the patient and the laser. Sensors in the LenSx console authenticate the patient interface. The surgeon uses the X, Y and Z joystick control to contact the operative eye. Following applanation, mild suction is applied via the tubing in order to stabilize the eye. **Refer to the Instruction for Use supplied with the LenSx Laser Patient Interface for preparation and application instructions for the Patient Interface.**

The surgeon observes applanation of the cornea using the video microscope, and then applies suction when the cornea is properly applanated.

The Surgical Display presents a live video microscope image of the surgical field. Graphics laid over the image are used to program the lateral position of the incision. When the lateral position is acceptable, OCT images appear on the right side of Surgical Display. The surgeon identifies the depth, position of the lens and corneal surfaces using the OCT images. Graphical tools allow the surgeon to program the incision depths on the OCT images.

Anterior capsulotomy patterns are programmed to cut from at least 100 microns below to 100 microns above the anterior capsule. Lens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule. Partial and full thickness corneal incisions are programmed as a percentage of corneal thickness at the position the cut is being made. When programming is complete, the system performs internal checks and notifies the surgeon when the system is ready to fire.

### 3.3.2 Anterior Capsulotomy

When the surgeon presses the footswitch, the main shutter is opened and the treatment begins. The treatment pattern begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached. When the

pattern is completed, the system automatically closes the main shutter and notifies the surgeon.

### 3.3.3 Phacofragmentation

When the surgeon presses the footswitch, the main shutter is opened and the treatment begins. The treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete, followed by successive x-shaped scans created a few microns apart. As each scan is completed, the lateral extent of the scans is adjusted to fill-in the elliptically shaped volume. The result is two or more vertically oriented, elliptically shaped planes that intersect at the lens center. The pattern is automatically completed when the programmed anterior depth is reached. When the pattern is completed, the system automatically closes the main shutter and notifies the surgeon.

### 3.3.4 Combined Treatments

Treatment patterns may be combined by selecting appropriate combinations of individual patterns. Not all combinations are allowed. The system software enables allowable combinations as the pattern selections are made. When the surgeon presses the footswitch, the main shutter is opened and the first treatment begins. After the first pattern is completed, the next pattern begins automatically. When the pattern is completed, the system automatically closes the main shutter and notifies the surgeon.

### 3.3.5 Post-Operative Steps

Following completion of the laser procedure, the suction to the Patient Interface is automatically released. The surgeon then uses the gantry joystick to lift the delivery system from the patient's eye. The Patient Interface is disposed of as medical waste.

## 4 Controls, Indicators and Displays

### 4.1 Display Panel & Keyboard

Computer control and software interface functions are performed using the touchpad and keyboard in conjunction with the display monitors. These are mounted on the console to the left of the delivery system. The entire station may be swiveled on its mounting post to optimize viewing and control access. Software functions may be selected by moving a display cursor with the touchpad and clicking the left button. Selecting a software function causes either a control function or a menu to appear. Alphanumeric data may be entered using the keyboard.

### 4.2 Surgical Display

The Surgical Display is mounted over the delivery system. It displays the video microscope and OCT images as well as the graphical overlays for pattern positioning. A trackball is used to control the input to the Surgical Display.

#### 4.2.1 Video Microscope

The video microscope image is shown on the Surgical Display. Overlay graphics of the surgical patterns and centration marks indicate the programmed position of the treatment. The position and size of graphical marks can be adjusted using the Surgical Display touchpad. The laser procedure is monitored live using the video microscope view.

#### 4.2.2 Optical Coherence Tomography (OCT) Device

The OCT images are shown on the Surgical Display. Graphics laid over the OCT image indicate the depths of incisions. The graphics can be vertically (axially) adjusted for position and depth using the Surgical Display touchpad. Although OCT images are not updated in real time, OCT images may be taken after the lens phacofragmentation to re-adjust capsulotomy or corneal incisions.



## 4.3 Delivery System Panel

The delivery system panel is located on the front of the delivery system, just below the video microscope. This panel contains the following controls:

### 4.3.1 Joystick

The delivery system is mounted on a motorized gantry that positions the delivery system. The joystick controls the gantry x-y-z positioning: twisting the stick varies the height while deflecting it controls the lateral positioning. The degree of twist or deflection controls the speed of the translations. The direction of lateral motion corresponds to the deflection direction. During a procedure, the joystick controls are disabled.

### 4.3.2 Delivery System Touch Screen

A small touch screen panel mounted directly on the delivery system is used to monitor and control some functions of the delivery system. The controls and indicators available on the touch screen include illumination levels, applanation force indicator, video microscope zoom and focus controls, and the fixation light on/off switch. Touching the screen allows the user to adjust or select the controls.

### 4.3.3 Applanation Indicator

The objective lens of the delivery system is spring-loaded to control the applanation force exerted by the objective. The delivery system is lowered until the Patient Interface makes contact with the patient's eye. When initial contact is made, the objective lens moves upward. Sensors in the delivery system detect the objective's position and applanation force. The applanation force is indicated on the Delivery System touch screen. As the objective is lowered, the indicated applanation force increases until, at a preset position, the maximum applanation force is achieved and further downward motion ceases. Only motion in the upward direction is enabled.

### 4.3.4 Illumination and Microscope Focus

Two illumination sources are available on the LenSx system: internal to the patient interface and external from the objective. External field and internal field Illumination levels are continuously varied using the delivery system touch screen. The camera focus for the video microscope can be changed using the Focus controls. Focusing of the microscope view is useful for visualization of the subject eye during Docking, Pattern Positioning and Laser treatment.

The Zoom and Illumination controls are located on the Delivery System touch screen. **Section 6 – Procedure Guide** describes the use of these controls.

### 4.3.5 Fixation Light

A fixation light is available to help a patient orient the eye during the Docking procedure. The switch for the fixation light is a button on the Delivery System touch screen.

## 4.4 System Power

### 4.4.1 Main Input Switch

After the LenSx System is connected to line power, electrical service to the console is switched on with the rocker switch located on the back panel of the console. When switched ON, power is switched to the transformers and to the laser chiller. The laser engine and computer systems are not turned ON.

### 4.4.2 Key Switch

Located on the front console panel, the key switch has two positions: “O” and “I”. Rotating the key from O to I turns on the main power to the system computers and initiates laser warm up and self-checking routines. Normal shutdown of the system power is accomplished by rotating the key on switch from I to O.

### 4.4.3 Emergency off switch

Located on the console front panel, the emergency off switch is an easily accessible, large red button. When pressed, the system power is immediately cut off. Use of the emergency off switch should be limited to emergencies and not for normal shut down of the system.

## 4.5 Footswitch

When the system is ready to commence a treatment, the surgeon starts the treatment by pressing the footswitch. The footswitch is actuated by placing a foot inside the housing and pressing the hinged, spring-loaded pedal until it contacts the bottom of the footswitch. The footswitch must be connected to the console while the system is switched ON.

## 4.6 Software Controls

### 4.6.1 System Startup

When power to the LenSx Laser is switched on, the user encounters the system access Login. Following successful user login, a warm-up and self-check phase is initiated. Status of the

system during the warm up and self-test phase is indicated on the screen. At the conclusion of the warm up phase, the system is ready for use.

## 4.6.2 Procedure Programming Window

Following successful login, system warm up and self- test, the Procedure window will be displayed. See **Section 6 – Procedure Guide** for programming instructions.

## 4.6.3 System Checks

All non-procedure system functions are accessed using the System Checks button. Selecting this button brings up a menu, including:

- The **Energy Calibration** option will cause the LenSx Laser to initiate a procedure that will verify the system's energy calibration.
- Selecting **Beam Steering** will cause the LenSx Laser to initiate a routine that checks and adjusts, if necessary, the alignment of the laser beam into the Beam Delivery System.

## 4.6.4 User Registration

**User Registration** allows for adding or removing users.

## 4.6.5 Shutdown

The system is shutdown by turning the key switch to the “O” position.

## 4.6.6 About

The **About** button produces a window displaying contact information, the system serial number and current software version number.

## 4.7 Accessories & Detachable Parts

The following accessories and detachable parts are used with the LenSx Lasers:

ACCESSORY / PART	LOCATION	INSPECTION / REPLACEMENT SCHEDULE
Footswitch	Rear Panel	Inspected at installation
Fuse: 3AG, Fast Acting, 250V, 15A (x2)	Rear Panel	Inspected at installation / replaced as needed
LenSx Patient Interface	Attaches to deliver system	Single use, disposable device. Dispose as medical waste.

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## 5 System Requirements

### 5.1 Electrical

The LenSx Laser is configurable for 100V/12A, 120V/10A, 220-240V/7A, 50/60Hz. The maximum power draw is less than or equal to 1.2 kW. The line voltage should be tested upon installation to ensure proper operation and should not vary by more than +/-10% from nominal.

The line and Neutral voltage is fused protected at the rear panel: 3AG, Fast Acting, 250V, 15A.

### 5.2 Environmental

Ambient temperature in the room containing the LenSx Laser should remain between 18°C and 24°C (65°F and 75°F). The ideal climate should be between 30% and 40% humidity.

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## 6 Procedure Guide

The LenSx Laser System allows the surgeon to program phacofragmentation, anterior capsulotomy, partial thickness and full thickness corneal incisions for cataract surgery, individually or combined in a single treatment session. The purpose of this section is to provide step-by-step instructions in the use of the LenSx Laser to program and execute a treatment session.

The LenSx Laser System allows the surgeon to tailor specific treatment patterns for each patient. After programming a treatment pattern and docking the system, the surgeon may adjust the treatment pattern position using information provided by the video microscope and OCT images. After confirming the treatment, the surgeon initiates and monitors the laser treatment.

### 6.1 Preparation and Treatment Planning

Prior to the actual treatment, the LenSx Laser System is turned on and used to specify and plan the surgical procedure using the system software and graphical user interface.

### 6.2 Start Up & Procedure Selection

Rotate the key on switch from the "O" position to the "I" position.

The LenSx Laser System software will be initiated and the Display Panel will display graphical user interface (GUI) information. User inputs to the GUI are made with the touchpad and keyboard peripheral devices. The first screen displayed is the Login screen (Figure 6-1). Select the "doctor" option, enter a valid password.



Figure 6-1: Log-in screen for the LenSx Laser System

In this first screen, options for saving or printing treatment parameters may also be selected. Saving or printing parameters may be useful as the initial choice of parameters can change during the pattern positioning steps taken after docking and under visualization with the video microscope and OCT imaging devices.

After system warm up and self-checks have been completed, the Biometrics window will appear on the Display Panel (Figure 6-2). A status indicator located on the right side of the biometrics window displays relevant system status.

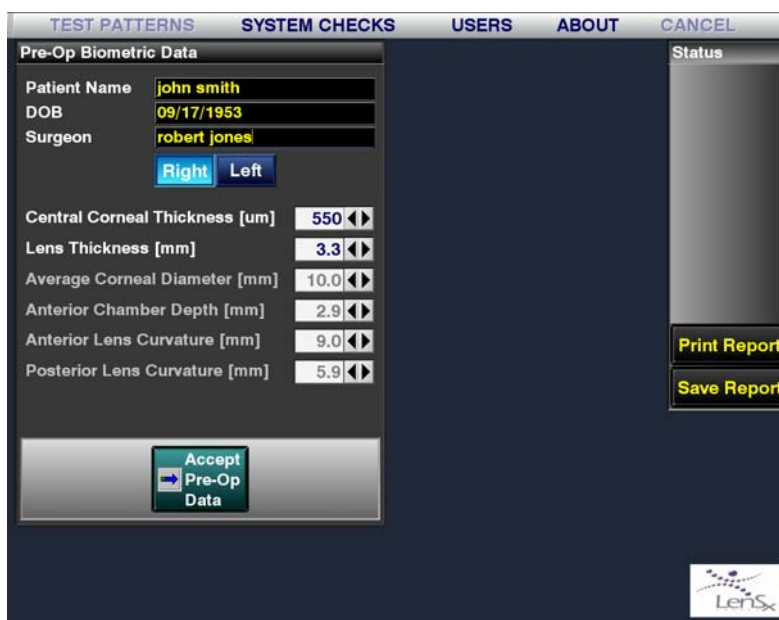


Figure 6-2: Patient biometric data screen

Within the Biometrics screen, patient biometric data collected during pre-surgical visits may be entered. Biometric data includes the lens thickness, and central corneal thickness. Other patient data includes patient and physician identification information.

The biometrics data may be used to define the positioning and orientation of the patterns if some or all of the OCT image guides are not used. For example, some lenses may have high-grade cataracts or opacities that prevent visualization of the posterior capsule. In the event of poor visualization of the posterior capsule, biometric data from A-scan ultrasound may be used to define the extent of the Lens pattern for phacofragmentation.

Once the biometric data has been entered and verified, press “Accept Pre-Op Data” to continue with treatment planning.

The Biometrics screen is now replaced with the Pattern Selection window shown in Figure 6-3. The Pattern Selection window displays the patient ID, controls for selecting and initiating programming of procedure types, an abbreviated view of the selected parameters for the various corneal incisions, the system status indicator box, and the Dock button.



**Figure 6-3: Pattern Selection screen.**

From the white pull-down menu, select a default or previously saved pattern.

Using the Select bar, the user may select a cutting pattern from the row of blue buttons. These selections determine the combination programmed treatments for a single session. When selected, the button is highlighted to indicate that selection.



Alternatively, previously saved patterns may be recalled using the Saved Pattern pull down menu located between the patient ID information and the Select bar.

Pressing the arrow button located at the lower right corner of the screen returns the display to the Biometrics screen.



**Figure 6-4: Pattern Selection screen appearance after a saved pattern file has been recalled. The cornea incisions loaded from the saved file are displayed in abbreviated form in the Quick View box at the top right side of the screen.**

After selecting a saved pattern, or selecting appropriate pattern elements from the Select bar, parameters may be specified for each pattern segment. Located directly below the Select bar is the Program bar. Each Program bar button corresponds to a Pattern button from the Select bar above. Selecting one of the Program bar buttons opens the parameter window for the corresponding pattern element. Note that selecting parameters from inside a particular Program bar selection window will not cause the Pattern to be enabled until the corresponding Select bar button has been pressed.

After a Pattern has been loaded or selected, the Cornea Incisions – Quick View field is populated with parameters for the various corneal incisions selected (upper right section of Figure 6-4).

Each Pattern has a number of parameters associated with the particular type of cut and tissue. For each Pattern selected, the parameters must be specified or verified prior to initiating the laser surgical procedure. In the following sections, the process of specifying or programming appropriate Patterns is outlined.

## 6.2.1 Programming the Lens Pattern

The Lens Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as either Chop or Cylinder patterns. The Chop Pattern is a series of vertical planes arranged radially in the lens, resembling the spokes of a wheel centered on the lens. The Cylinder Pattern a series of vertically oriented concentric cylinders centered on the lens.

When the Lens button has been pressed under the Program bar, the Lens Pattern parameter screen is displayed (Figure 6-5). User-settable parameters are displayed, with the present value for each parameter shown. Use the individual parameter buttons to increment or decrement each value. On the right side of the screen, columns of parameters may be specified for either the Chop or Cylinder patterns.

Figure 6-5: Lens Pattern parameter screen

Selectable parameters may be geometric or laser scanning parameters. Geometric parameters include the anterior capsule depth, the posterior capsule depth, and the lens diameter. Laser scanning parameters for the Lens screen include the separation of consecutive laser shots (spot separation) and the laser pulse energy. The parameters displayed depend on the particular pattern selected.

For the Lens Pattern only, OCT images of the post-laser treatment lens may be saved in order to evaluate the effect of the Lens Pattern on the positioning of subsequent patterns on the capsule and corneal patterns. If the Post-Lens OCT image is selected, the laser procedure will halt and provide an opportunity for the user to re-position the subsequent patterns before completing the procedure.

Select appropriate parameters. Press the Accept and Save buttons at the bottom of the Lens Pattern parameters. A dialog window for entering a file name to be saved is displayed. Previously saved parameters files may also be recalled and loaded by selecting the Param Files button. The system software returns the display to the Pattern Selection screen.

## 6.2.2 Programming the Capsulotomy Pattern

The Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens. The anterior capsulotomy is created by scanning a cylindrical shell extending from a position in the lens volume through the capsule and into the anterior chamber. The cylindrical scan pattern penetrates the capsule in a complete circular shape.

The Capsule Pattern parameter screen is used to select treatment parameters. These include the capsulotomy diameter, the estimated capsule posterior depth, the estimated capsule anterior depth, the capsule delta up distance, and the capsule delta down distance. As in the Lens Pattern, laser energy, spot and line separation distances may be specified.

The surgeon can elect to perform the capsulotomy cut either before or after the Lens Pattern is executed by selecting the Capsulotomy First button. The Capsule Pattern scan can also be selected to begin either at the posterior (bottom) or anterior (top) end of the scan pattern by toggling the Scan Start parameter.

After the information has been entered correctly, press the Accept and Save buttons displayed at the bottom of the Capsule Incision parameter screen. The system returns to the Select Patterns screen.

## 6.2.3 Programming the Primary Incision Pattern

The Primary Incision Pattern is used to create corneal incisions for penetrating keratoplasty or for cataract surgery.

The geometry of the Primary Incision Pattern is constructed from one, two or three angled planes arranged along a defined arc at the corneal periphery. The planes are connected to create a single opening. The Primary Incision Pattern may represent a completely penetrating cut or a partial thickness cut. Partial thickness cuts can be created and later opened manually by the surgeon.

Primary Incision Patterns begin at the programmed maximum posterior depth and progress anteriorly until the programmed anterior depth is reached. Depths are expressed as a percentage of the corneal thickness. Corneal thickness can be defined pre-operatively or by using the OCT image. (Figure 6-6)

The screenshot shows the 'Primary Incision' parameter screen. It has four main sections: 'SELECT CUTS', 'SINGLE PLANE', 'TWO PLANES', and 'THREE PLANES'. The 'TWO PLANES' section is currently selected. On the left, under 'SELECT CUTS', there is a list of parameters: Arc Diameter [mm], Arc Distance from Limbus [mm], Arc Position [dgr], Incision Width [mm], Central Cornea Thickness [um], Estimated Periph Cornea Thick [um], Energy [uJ], Spot Separation [um], Layer Separation [um], and Cut Overlap [um]. Each parameter has a corresponding value in the 'SINGLE PLANE' section. The 'TWO PLANES' section has three sub-sections: 'PLANE 1', 'PLANE 2', and 'PLANE 3'. Each plane has parameters for 'Ant Overlap [um]', '% Posterior Depth', and 'Side Cut Angle [dgr]'. The 'THREE PLANES' section is currently empty. At the bottom, there are buttons for 'Accept', 'Reset', 'Param Files', and 'Save'. A 'Param File' dropdown menu is set to 'all\_cuts'.

Parameter	Value
Arc Diameter [mm]	30.0
Arc Distance from Limbus [mm]	0.0
Arc Position [dgr]	180
Incision Width [mm]	3.7
Central Cornea Thickness [um]	550
Estimated Periph Cornea Thick [um]	800
Energy [uJ]	4.00
Spot Separation [um]	8
Layer Separation [um]	8
Cut Overlap [um]	1

Plane	Ant Overlap [um]	% Posterior Depth	Side Cut Angle [dgr]
PLANE 1	100	50	70
PLANE 2	65	10	1.0
PLANE 3	120	70	

Param File: all\_cuts

Buttons: Accept, Reset, Param Files, Save

Figure 6-6: Primary Incision Pattern parameter screen

The Primary Incision Pattern parameter screen allows the user to specify pattern geometry and laser scanning parameters. The basic shape is an arc cut at the periphery of the cornea. Users can select one, two or three plane incisions. The depth of each plane is set with the % Poster Depth parameter. The Side Cut Angle is angle that the plane makes with the corneal anterior surface. The planes may be overlapped to ensure complete cuts using the Ant Overlap parameter.

After the information has been entered correctly, press the Accept and Save buttons displayed at the bottom of the Primary Incision Pattern parameter screen. The system returns to the Select Procedures screen.

## 6.2.4 Programming the Secondary Incision Pattern

The Secondary Incision Pattern is used to create a corneal incision and is similar to the Primary Incision Pattern. Secondary Incision Patterns may be used to aid cataract surgery.

The Secondary Incision Pattern is a single angled plane located along an arc on the corneal periphery. The pattern is defined by the distance of the arc from the limbus, the radius of curvature of the arc, and the angular location of the arc. The Side Cut Angle defines the angle that the planar cut makes with respect to the cornea surface. The Secondary Incision Pattern is specified as a penetrating or a partial thickness keratoplasty cut by selecting the appropriate value for the % Posterior Depth parameter. The amount of overcut above the corneal anterior surface can be specified with the Anterior Overlap parameter.

After all parameters have been entered, press the Accept and Save buttons displayed at the bottom of the screen. The system returns to the Select Procedures screen.

## 6.2.5 Programming the Arcuate Incision Patterns

Arcuate corneal cuts can be made using the Arcuate Incision Pattern. Arcuate Incision Pattern cuts are made in the corneal periphery, and are arc-shaped partial thickness cuts. Arcuate Incision Pattern cuts start at a user-programmed posterior depth and progress in the anterior direction. The pattern depth chosen using the % Posterior Depth button and is expressed as a percentage of corneal thickness. Choosing the Diameter parameter determines the circle diameter wherein the arc cuts lie. Either one or two arcs may be selected using the Two Arcs/One Arc button near the bottom of the screen (see Figure 6-7). The depth of the arc cuts is specified with the % Posterior Depth parameter.

The Before Cornea Incisions button can be used to determine whether the pattern is executed before or after other corneal incision patterns.

After all parameters have been entered, press the Accept and Save buttons displayed at the bottom of the screen. The system returns to the Select Procedures screen.

**Arcuate Incision**

**SELECT CUTS**

Before Cornea Incisions

Parameter	Value
Diameter [mm]	7.5
Central Cornea Thickness [um]	550
Estimated Periph Cornea Thick [um]	625
% Posterior Depth	20
Anterior Overlap [um]	100
Energy [uJ]	4.00
Side Cut Angle [dgr]	90
Spot Separation [um]	8
Layer Separation [um]	8
Arc 1 Position [dgr]	90
Arc 2 Position [dgr]	270
Arc 1 Angle [dgr]	30
Arc 2 Angle [dgr]	30

**TWO ARCS**

Param File: all\_cuts

**Accept Reset Param Files Save**

Figure 6-7: Primary Incision Pattern parameter screen

## 6.2.6 Combining Patterns

Patterns may be combined in various ways to achieve a desired surgical procedure. Select appropriate pattern buttons in the Pattern Selection screen allows the surgeon to create the desired pattern combinations. However, not every combination of patterns is allowable. To view the allowed combinations in any pattern screen, select the Select Cuts button. A table of combinations is shown in a window (Figure 6-8 below). This window also shows the currently selected combination of patterns.

During laser treatment, the patterns will be executed in a sequence that generally proceeds from the most posterior cuts to the most anterior cuts. In some cases, the order of cuts may be specified within the pattern parameter screen.

**Valid Cut Combinations**

	Lens	Capsule	Cornea Primary	Cornea Secondary	Cornea Arcuate
NO	✓				
NO		✓			
NO	✓	✓			
NO		✓	✓	✓	
NO		✓	✓	✓	✓
NO		✓			✓
NO			✓	✓	
NO	✓	✓	✓	✓	
NO					✓
NO	✓	✓			✓
NO			✓	✓	✓
YES	✓	✓	✓	✓	✓

Done

Figure 6-8: Allowed pattern combinations.

### 6.2.7 Completing Pattern Selection

Once all the pattern selection and parameter programming has been completed, press the Save button located in the Corneal Incisions – Quick View box at the top of the Pattern Selection screen. To proceed to Docking, press the Dock button located at the far right side of the Select bar choices. The Treat screen will be then be displayed (Figure 6-9 below)

**Figure 6-9: Display Panel showing the Treat screen immediately after pressing the Dock button in the Pattern Select screen. The Treat screen indicates the system status in the box at the upper right and is used to initiate suction.**

## 6.3 Preparing the Patient Interface

When all pattern selections and parameter choices are complete, the system is ready to dock with the patient. After Docking has been successfully completed, the planned treatment patterns are oriented and adjusted with respect to the targeted ocular tissues in the Pattern Positioning process (Section 6.5)

The LenSx Laser System uses a proprietary disposable Patient Interface (PI). The sterile PI is comprised of an applanation lens, suction ring, and tubing (see Figure 3-2).

Open the packaging and place the PI onto a sterile field. Inspect the components of the PI for damage or disconnection. Grasp the contact lens mount of the PI. Place the contact lens mount on the delivery system laser aperture; twist the contact lens mount until it locks into place. Grasp the vacuum tube and insert it onto the vacuum port on the LenSx Laser System.

The PI also contains an integrated passive RFID identification device. The RFID identifier is sensed by a reader located inside the LenSx Laser System console. The Treat screen status indicator **PI** is displayed when the PI has been properly installed and the RFID transponder detects a valid identification code on the PI.



Once the PI has been properly installed on the LenSx Laser System, the patient should be prepared for Docking.

## 6.4 Docking

Place the patient in a supine position under the delivery system and Patient Interface. Apply a topical antiseptic to the eye prior to Docking.

Use the joystick to control the gantry and roughly align the Patient Interface to the eye.

While the patient's eye is located at distances greater than 1 centimeter from the PI, use the Zoom button on the Delivery System Touch screen to adjust the video microscope magnification.

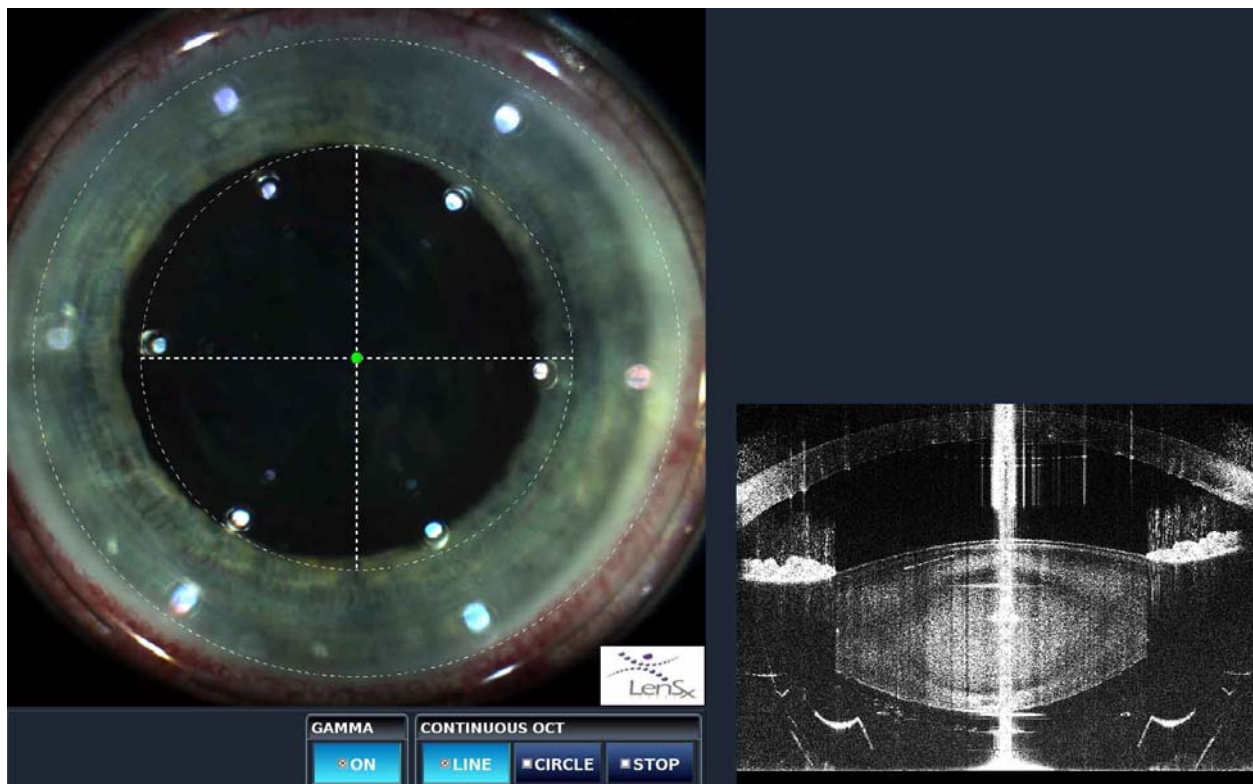
Touch the external illumination bar on the Delivery System Touch screen to set the desired level of Illumination. Touch the fixation light button to switch on the patient fixation light. Instruct the patient to maintain fixation on the light during the Docking process.

Use the joystick to center and lower the gantry until the Patient Interface contacts the eye. The Delivery System Touch screen monitors the applanation force continuously. The Treat screen will show the **CONTACT** status indicator when the force sensor integrated in the delivery system detects an initial applanation force. Graphical indicators show both the desired range of force and the measured force (see Figure 6-10 below). Use the joystick to adjust the applanation force to the desired range.

Switch off the microscope Zoom. The Surgical Display now shows only the internal view of the eye. Touch the internal illumination bar to set the desired level of illumination.



**Figure 6-10:** Left image shows the main Delivery System touch screen display. Set illumination levels by touching the wide vertical bars. Right image is displayed after selecting Video. Adjusting the camera focus zoom allows good visualization before the PI contacts the cornea. P1-P4 are focal position pre-sets. The applanation force indicator is on the right side of every screen. The applanation force is correct when the white ellipse is in the green range.



**Figure 6-11:** Surgical Display during Docking. The dashed lines represent centration guides and are used to position the delivery system and PI with respect to the patient eye.

Use the Surgical Display to verify that the PI is nominally centered on the cornea, slowly adjusting the joystick as necessary to center the PI on the cornea. Once the PI has been properly centered, press the PI SUCTION control button located at the lower left corner of the Treat screen. A low vacuum level applied to the PI gently fixates the eye to the contact lens. The joystick control is now inactive and the gantry cannot be moved until the suction is released. The Surgical Display screen then changes to show a live video image of the applanated eye and an indication that the OCT has been activated. The LenSx Laser System is now ready for positioning of the selected patterns.

## 6.5 Pattern Positioning

### 6.5.1 Overview

Once the delivery device and Patient Interface has been docked onto the patient's eye, the selected and programmed patterns may be re-positioned.

The Video Microscope and OCT are used to guide the positioning steps. The Surgical Display overlays the selected patterns onto the video microscope and the OCT images. The overlay patterns are shown as the outlines and centers of the patterns, along with graphical tools for manipulating and positioning the patterns.

The LenSx Laser System software assists the user in the positioning process. At each step, the user's next action is highlighted and appropriate buttons and views are enabled. Adjustments made by the operator with the aid of video microscope and OCT image guides are used to update the pattern positioning information stored by the LenSx Laser System.

The general order of pattern positioning and centration adjustments is as follows:

- Docking/PI Suction
- Limbus centration
- Primary and secondary incision pattern alignment
- Lens centration
- Capsulotomy and lens diameter adjustment
- Arcuate incision angle and diameter adjustment
- Capsule depth and cutting range adjustments
- Capsule/lens positioning alignment
- Cornea thickness measurements (primary, secondary and arcuate incisions)

Some pattern positioning steps may be omitted, depending on the patterns selected. The progression of pattern positioning steps is shown by changes in the status indicators located at the bottom of the Surgical Display. Highlighted action buttons indicate the required next steps for the user.

At any point in the pattern positioning process, selecting the action button with an arrow allows the user to return to the previous step or to exit the pattern positioning process.

### 6.5.2 Video Microscope, OCT Image Guides and Pattern Graphics

During pattern positioning, the Surgical Display shows a live video image of the eye on the top left side and OCT images on the top and bottom right side. On the bottom of the display, the status indicator and action buttons are displayed.

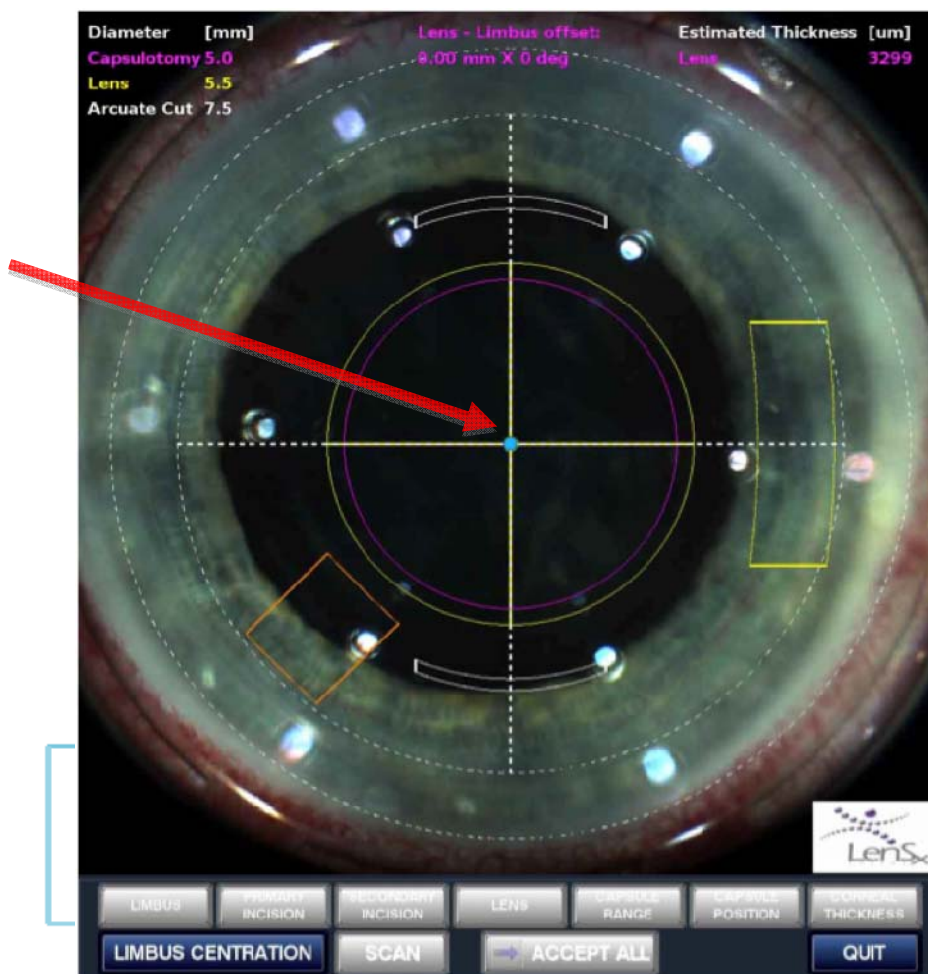
Graphical overlays on the Surgical Display and OCT images indicate the planned incision patterns and their relationship to the ocular tissues. Solid lines in the graphical overlays represent the outer boundaries of the patterns. Dashed lines represent centration or positional information relative to the video microscope and OCT images.

Control points are small solid circles that represent user-adjustable parameters. Point the cursor and click on a control point to make it active. Active control points can be moved by dragging the cursor to the desired location. A second click on the control point deactivates the control point. Active control points are a different color than inactive control points. Only one control point is active at any time.

### 6.5.3 Limbus Centration

After PI Suction has been initiated, limbus centration lines are overlaid on the Surgical Display. No OCT scans are used in this positioning step.

The limbus centration control points in the video microscope display are active. Place the cursor on the control point. Click and drag the control point to center the limbus centration lines on the limbus. Click again on the control point when centration is complete. The control point indicator changes appearance to indicate completion of this step. See Figure 6-12.



**Figure 6-12. Limbus centration.** Red arrow points to control point (blue dot) used to position the guides (white dashed lines) on the limbus. In this example, the Primary (heavy yellow), Secondary (orange), Arcuate (white), Capsule (pink) and Lens (light yellow) patterns have been selected.

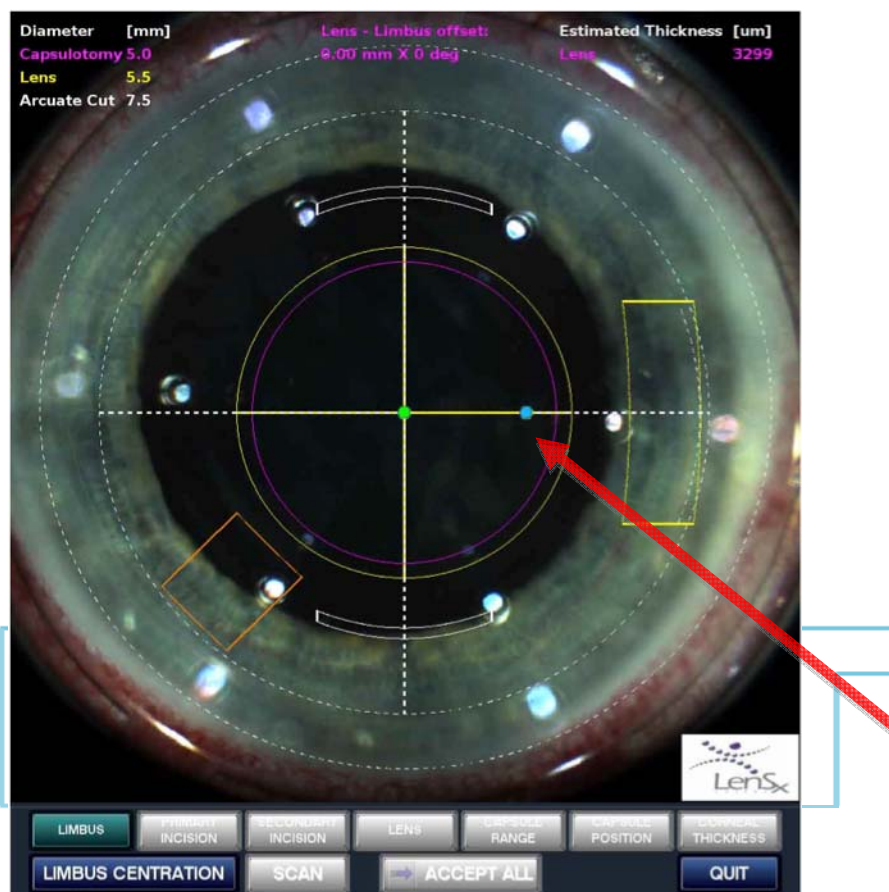
#### 6.5.4 Primary and Secondary Incision Alignment

If Primary or Secondary Incision Patterns are selected, the next step in pattern positioning is the radial location of these patterns. The pattern locations are displayed on the video microscope image on the Surgical Display. No OCT scans are used in this positioning step. A control point for the Primary Incision Pattern is active. Move the control point by clicking and dragging. The Secondary Incision Pattern is similarly positioned after the Primary Incision Pattern control point is deactivated with a second mouse click.

After completing the Primary and Secondary Incision Pattern positioning, an action button (either Scan or Limbus Centration) will cause the LenSx Laser System to verify that the adjusted pattern positions are consistent with other patterns and parameters. If the verification step



results in an error, a dialog box will alert the user to correct the pattern positioning before allowing the next step.



**Figure 6-13: Primary Incision Pattern positioning. Red arrow points to control point (blue dot) used to move the Primary Incision Pattern (heavy yellow shape at right) along the radial direction. Secondary Incision Pattern positioning proceeds in the same manner after the control point for the Primary Incision Pattern has been deactivated with a second click.**

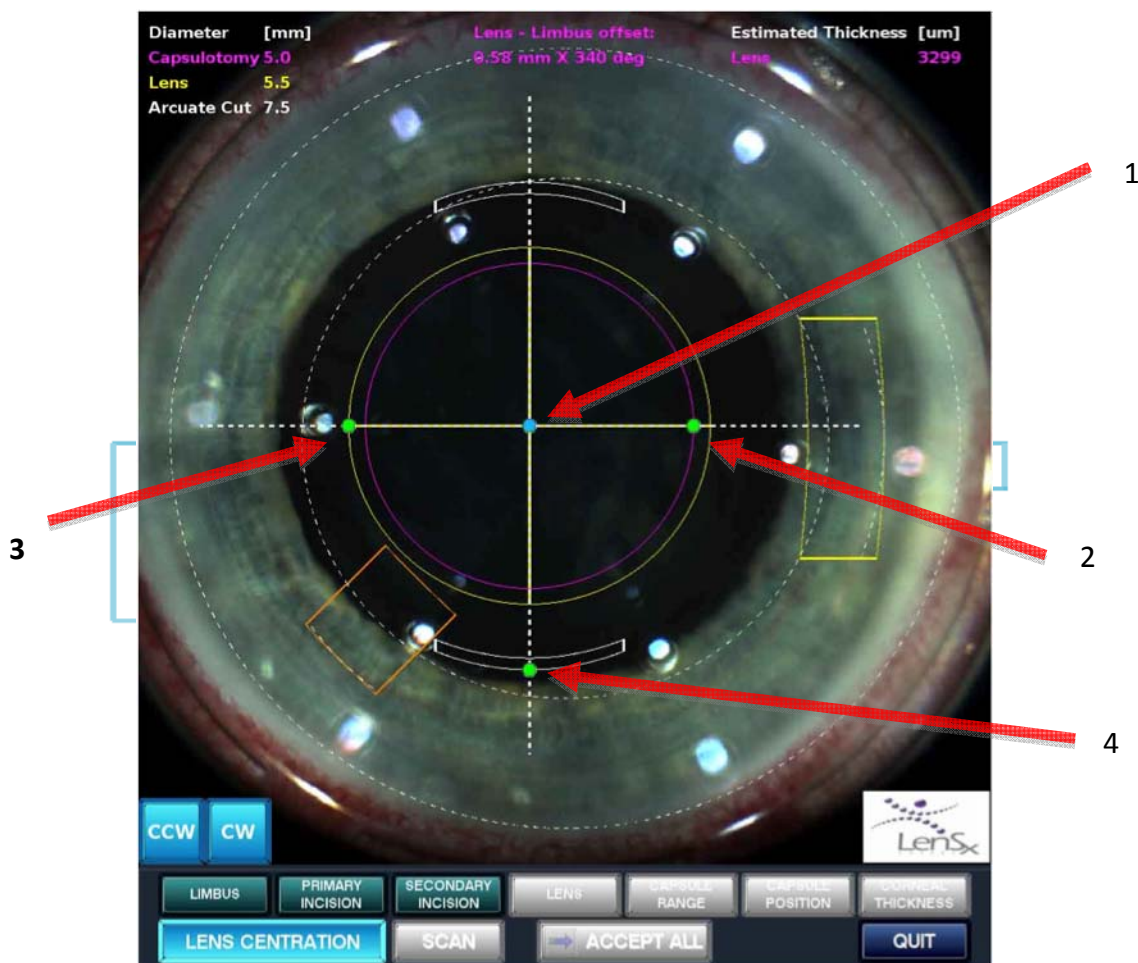
### 6.5.5 Lens Alignment

If lens or capsule patterns are selected, the Lens Centration action button will appear. If lens or capsule patterns are not selected, the lens alignment step will not be performed. Press the Lens Centration action button. Several control points may appear on the Video Microscope image, depending on the combination of patterns. No OCT scans are used in this positioning step.

The control points to be adjusted may include the Lens Pattern center, the Capsule Pattern diameter, the Lens Pattern diameter, and the Arcuate Incision Pattern diameter. Select and

activate each control point in turn, and adjust the Lens center and pattern diameters as appropriate. Users should verify that the Lens Pattern diameter falls within the 8mm diameter lens alignment dashed circle.

If necessary, the Arcuate Incision Pattern may be rotated in either direction up to a maximum of 20 degrees from the originally programmed value. Hold down the clockwise (CW) or counterclockwise (CCW) button to attain the desired rotation angle.

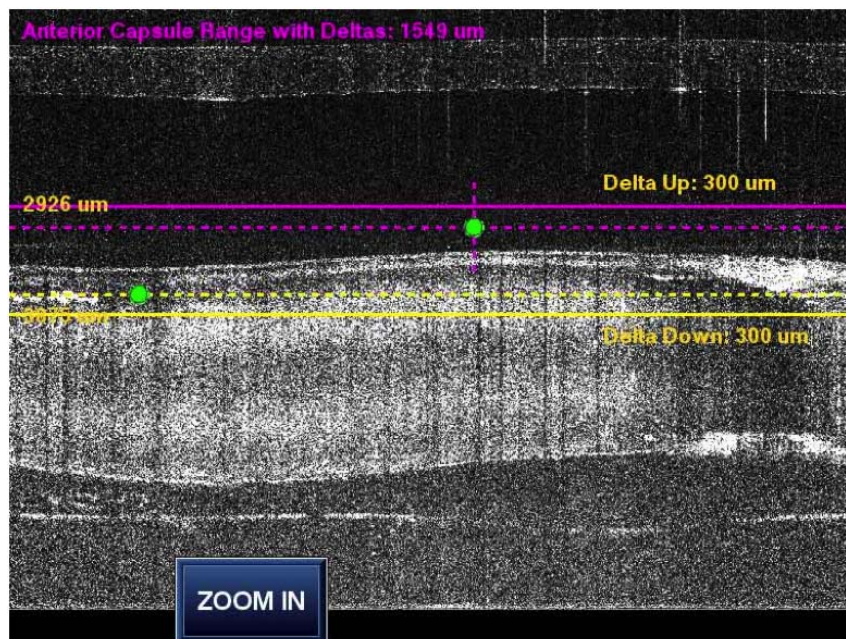


**Figure 6-14: Control points displayed in the Lens Pattern positioning step. Not all adjustments may be shown depending on the patterns selected. Arrow 1 = Lens Pattern centration, Arrow 2 = Capsule Pattern diameter, Arrow 3 = Lens Pattern diameter, Arrow 4 = Arcuate Incision Pattern diameter. When all positions have been adjusted, the Lens status bar changes indicating completion of this step.**

### 6.5.6 Capsule Depth Adjustment

After completing the Lens positioning steps, the next positioning adjustments are the ranges for capsule incisions (if Capsule Pattern has been selected). A circle scan OCT image of the lens and

capsule is displayed the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye.



**Figure 6-15: Rough adjustment of the Capsule pattern range. Control points can be moved up or down. The solid line represent previously programmed values for the Delta Up and Delta Down**

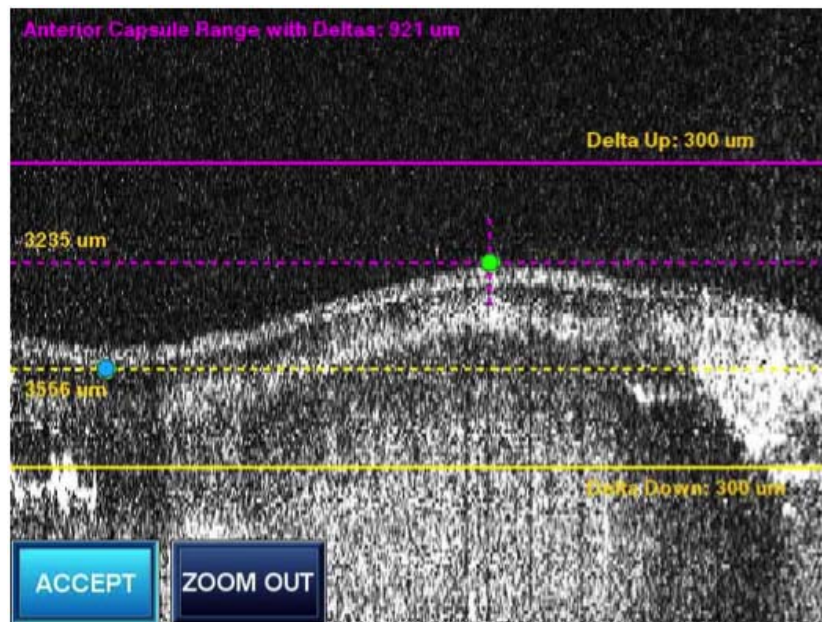
Two horizontal dashed lines are overlaid on the OCT image. Control points for the depth range adjustment and two other solid lines without control points are shown. The numeric values of the previously programmed up delta/down delta values are displayed.

The Anterior Depth control point can be moved vertically for depth. It can also be moved horizontally to indicate the angular position of the high point of the capsule. This Anterior Depth control point has short dashed line to indicate the ability to move it horizontally.

Move the Anterior Depth control point to the minimum depth of the capsule. Move the Posterior Depth control points to the maximum depth of the capsule. The solid Delta Up/Delta Down lines will move with the dashed horizontal lines associated with each control point. The Delta Up and Delta Down values themselves do not change. The positions of the maximum and minimum capsule positions determine the axis of tilt of the lens.

Press Zoom In when done. An enlarged image is shown and the control points allow for finer adjustment of the capsule depth range.

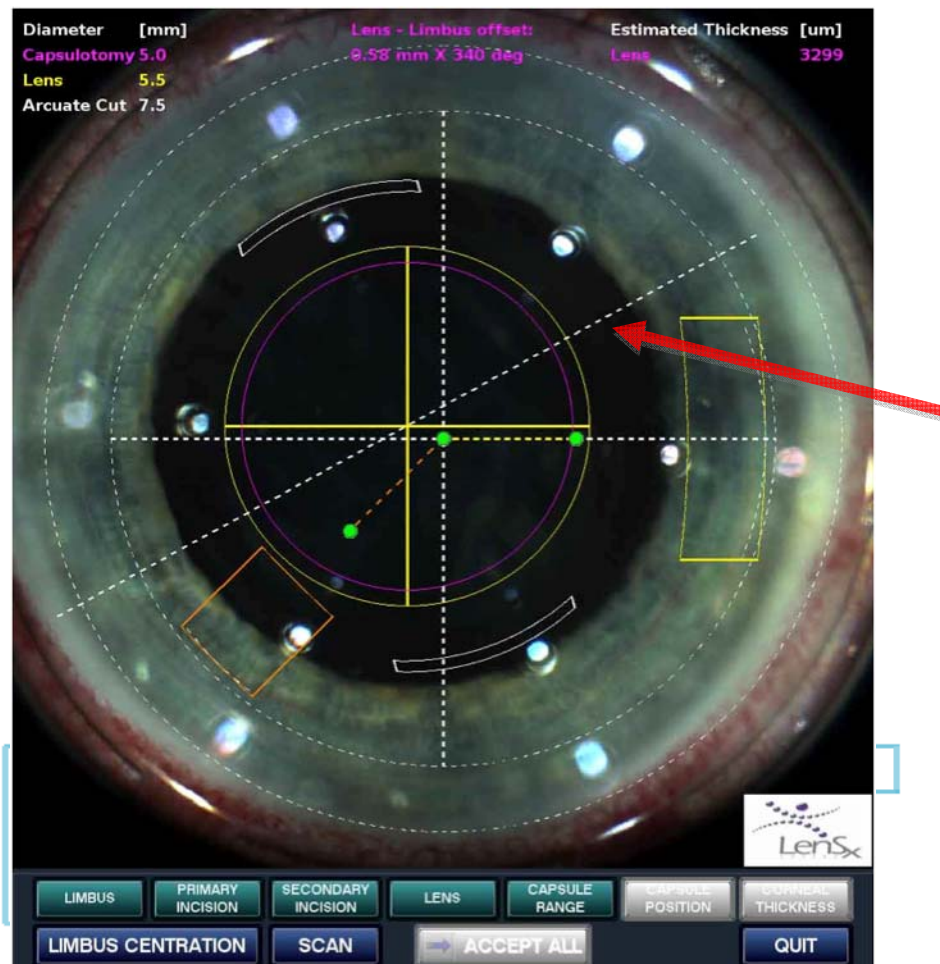




**Figure 6-16: Fine adjustment of the Capsule pattern range. The Anterior Depth and Posterior Depth control points are properly positioned. Pressing Accept stores the adjustments and enables the next Capsule range adjustment step.**

When the Capsule range adjustments are complete, press the Accept button. The LenSx Laser System software checks that the adjustments are valid for the patterns selected. If the adjustments check is successful, the video microscope image shows a dashed line indicating the tilt axis of the lens.

The Capsule Range status indicator changes to indicate completion, and the next pattern positioning step is enabled.



**Figure 6-17: Completion of Capsule Range adjustments. The phase angle associated with the capsule tilt is indicated by the dashed line (red arrow).**

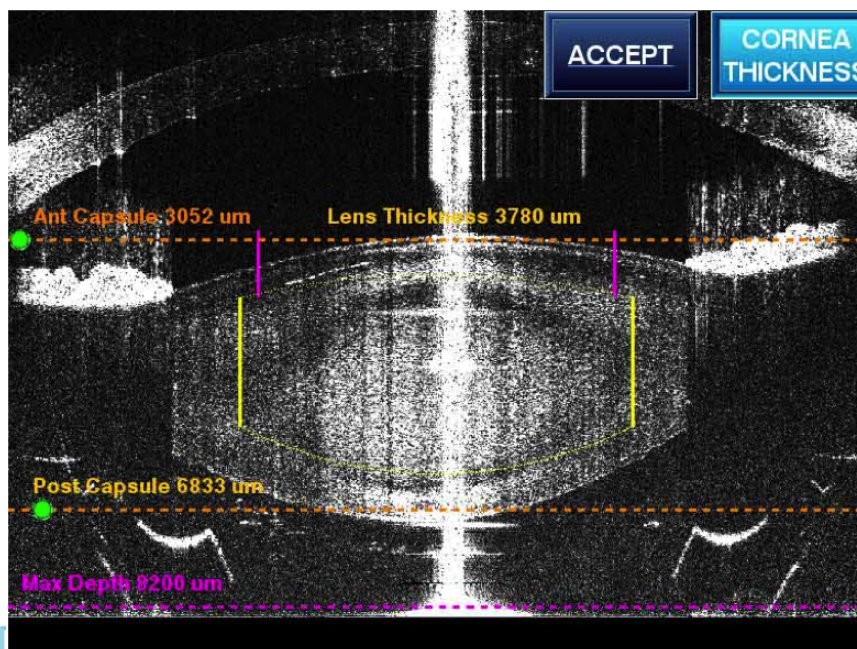
### 6.5.7 Lens Depth Adjustment

The Capsule position adjustment allows the user to adjust the position of the Lens patterns to match the surfaces and volume of the lens.

The adjustments are made for the depths corresponding to the posterior and anterior limits of the capsule and lens location. A line scan OCT image along the tilt angle previously defined is displayed with control points for the Anterior Capsule Depth, the Posterior Capsule Depth, and the maximum allowable depth. The control points can only be adjusted vertically.

If the Capsule pattern is enabled but the Lens Pattern is not, no control points will be available. For this combination of pattern selections, the Capsule positioning step is only used for displaying stored results.

The initial values for the control point depths correspond to pre-programmed values and values stored from previous pattern positioning steps.



**Figure 6-18: Adjustments for the Capsule Position step.** Anterior Capsule depth and Posterior Capsule depth control points are adjusted vertically. The maximum allowable depth is represented by a fixed dashed line (Max Depth). The OCT line scan is superimposed with the diameters of the Capsule Pattern (pink) and the volume outline of the Lens Pattern (yellow lines and curves).

Two solid (purple) vertical line segments are displayed representing the Capsulotomy Pattern. The capsulotomy diameter range is represented by the separation of the lines and the Capsule depth range is represented by the position and vertical height of the lines.

The Lens treatment volume is represented by an upper arc, a lower arc, and two vertical lines (all in yellow). The distance between the left and right vertical lines represents Lens diameter value stored in the Limbus Centration positioning step. The upper arc matches the Anterior Lens Curvature and the lower arc corresponds to Posterior Lens Curvature. Both curvature values are default values or user-supplied values taken from the Lens parameters screen. The difference between the Anterior Capsule Depth and the top of the upper arc is equal to the Lens Anterior Offset from the Lens parameters screen. The depth difference between the Posterior Capsule Depth and the bottom of the lower arc is equal to the Lens Posterior Offset from the Lens parameters screen.

Adjust the Anterior Capsule Depth control point to a position inside the anterior capsule apex. The Anterior Capsule Depth numeric value and the Lens Pattern treatment volume are updated

as the control point is changed.

Adjust the Posterior Capsule Depth to a position inside the posterior capsule apex. The Posterior Capsule Depth numeric value and the Lens Pattern treatment volume are updated as the control point is changed.

When the Capsule Position adjustments are complete, press the Accept button. The LenSx Laser System software checks that the adjustments are valid for the patterns selected. If the adjustments check is successful, the display shows the Video Microscope image. The Capsule Position status indicator changes appearance to indicate completion.

If corneal incision patterns have been selected, the final pattern positioning step of Corneal Thickness is enabled. If not, press the Accept All button to proceed with treatment.

### 6.5.8 Corneal Primary and Secondary Incisions Thickness Adjustment

If corneal incisions are selected, the last step in pattern positioning is adjusting the corneal thickness and corneal incision geometry parameters.

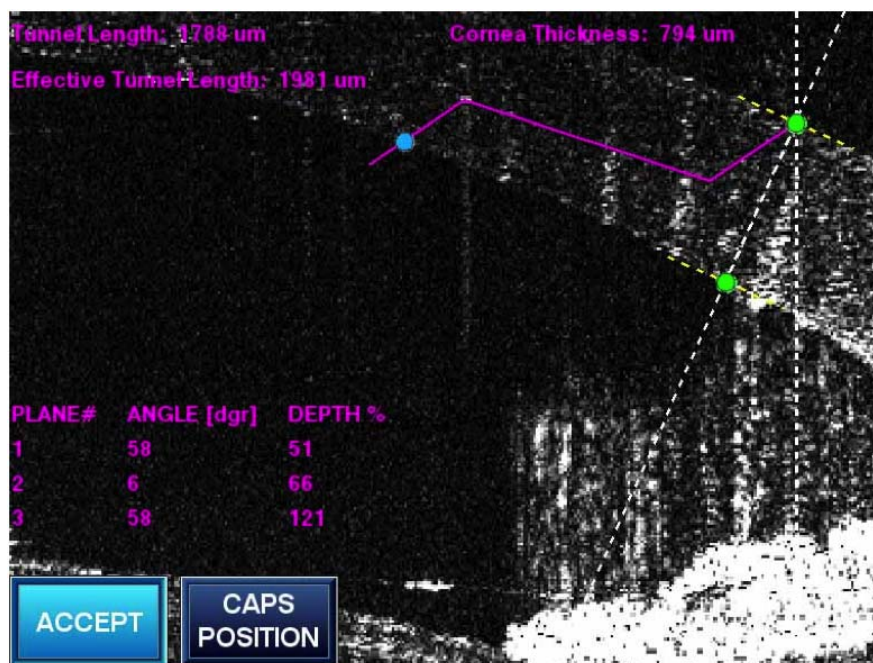
The Primary Incision Pattern geometry and the corneal thickness are adjusted first. Press the Scan button at the bottom of the Surgical Display to proceed. An OCT image of the corneal region of the Primary Incision Pattern is displayed. The OCT image appears at the bottom right corner of the Surgical Display.

An X-Z cross-section of the Primary Incision Pattern is depicted. This representation of the incision is referred to as the Tunnel. The Tunnel may be composed of 1, 2 or 3 separate line segments representing the planes specified in the Primary Incision Pattern parameter programming step.

Three control points that adjust the Epithelial, Endothelial and Tunnel End are also displayed. The Epithelial and Endothelial control points are used to set the positions of the anterior and posterior cornea. The Tunnel End control point is used to position the end of the tunnel.

The Epithelial control point can only be moved along the vertically dashed line. The Endothelial control point can be moved perpendicularly to the cornea along the normal dashed line. The Tunnel control point may be moved freely in the horizontal and vertical directions. Moving any of the three control points causes the graphical feature representing the Primary Incision Pattern to move as well.





**Figure 6-19: Completed adjustment of Primary Incision Pattern tunnel parameters. Pressing the Caps Position button allows the user to switch between Capsule Position adjustments and Corneal Thickness adjustments. Press the Accept button to save the parameters and proceed to the next step.**

The numeric values of the tunnel length (distance from Epithelial control point to Tunnel control point), effective tunnel length (sum of distances of each plane making up the tunnel), corneal thickness are displayed. The angles and the percent depth of cornea for each plane making up the Primary Incision Pattern are also displayed.

These numeric values are updated as the control points are moved.

The corneal thickness value as determined by setting the Epithelial and Endothelial control points is also used for the Secondary Incision Pattern.

As the Primary and Secondary Incision Patterns are positioned, the Capsule Position action button is displayed to allow easy switching between positioning modes.

Press the Accept button when the Primary and Secondary Incision Pattern positioning is complete. The LenSx Laser System software performs a validation check on the pattern parameters. An error message is displayed if the parameters are invalid. The parameters must be corrected before proceeding.

## 6.5.9 Arcuate Incision Thickness Adjustments

If an Arcuate Incision Pattern is selected, the Arcuate Thickness action button appears after pressing the Accept button. Selecting the Arcuate Thickness button initiates an OCT scan of the corneal region for the arcuate incision. The zoomed image of the Primary Arcuate Incision pattern is displayed on the top right portion of the Video Microscope display. If the Secondary Arcuate Incision pattern is enabled, the zoomed image of the Secondary Arcuate Incision area is displayed on the bottom right portion of the Surgical Display.

Epithelial and Endothelial control points, similar to those in the Primary and Secondary Incision Patterns above are displayed. The Epithelial control point can only be moved along the dashed vertical line in Figure XX below. The Endothelial control point is moved along the dashed line normal to the cornea. As the control points are moved, the numeric value of the distance between them, representing the corneal thickness, is displayed and updated.

Move the control points to produce the desired cut position and depth. Repeat for both the Primary and Secondary Arcuate Incision Patterns, if necessary. The corneal thickness value used is the smaller of the two adjusted thicknesses.

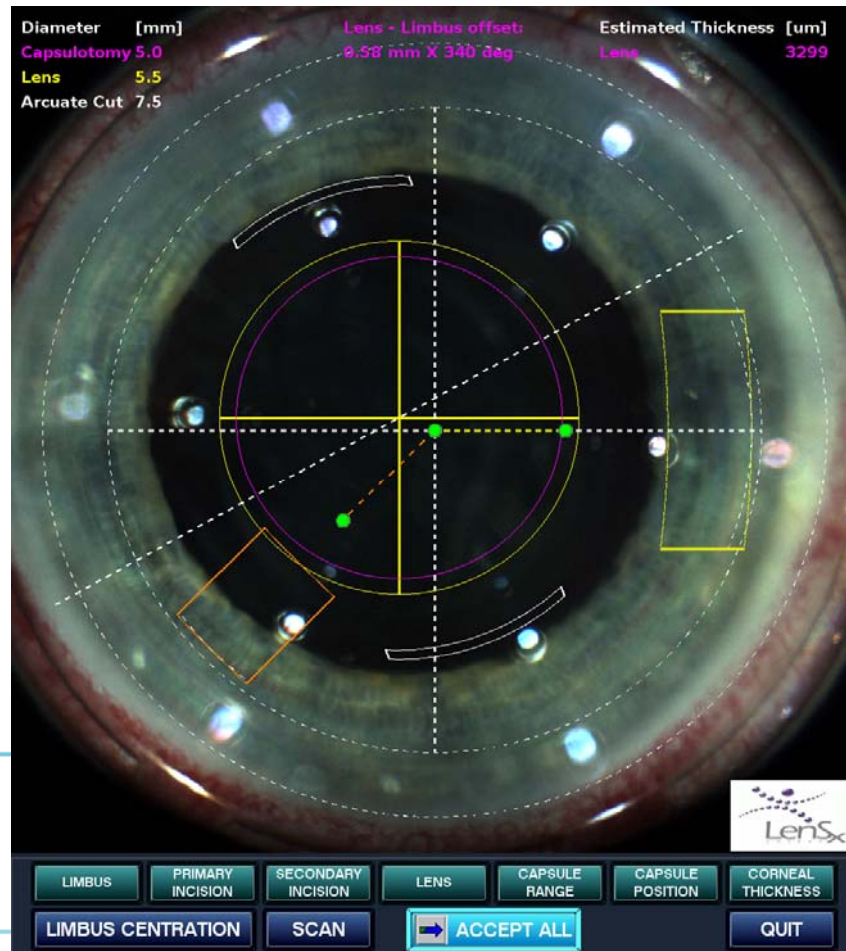
When the Arcuate Incision corneal thickness adjustments are complete, press the Accept button. The LenSx Laser System software performs a validation check on the pattern parameters. An error message is displayed if the parameters are invalid. The parameters must be corrected before proceeding.



**Figure 6-20: Line OCT guide and corneal thickness adjustments for Arcuate Incision Patterns.** Figure shows Primary Arcuate Incision and control points (not shown is the Secondary Arcuate Incision). The control points are adjusted to the desired position and thickness for the arcuate cuts. Previous View switches to the last displayed screen. Pressing the Accept button stores the adjusted values and returns the display to the Pattern Positioning Screen.

## 6.6 Confirmation

If all positioning steps have been completed, the Accept All action button is active (See figure 6-21 below). Press the Accept All button. A summary of altered pattern parameters will be shown on the Display Panel. Review the summary and select either Rerun OCT to repeat the sequence of positioning steps or select Apply to Patient to proceed to treatment.



**Figure 6-21:** Once the pattern positioning process has been successfully completed, press the Accept All button to begin the treatment.

## 6.7 Treatment

After the Accept All button has been selected, treatment is enabled. The Surgical Display shows a live microscope video image, a line OCT image of the anterior chamber, and a circle OCT image of the lens and capsule. Graphical outlines of the selected patterns are overlaid on each of these views. A message is displayed on the Display Panel indicating that the beam scanners have been moved to the starting position for treatment. The estimated laser treatment time in seconds is displayed. The Treat button is now enabled.





**Figure 6-22: Display Panel when system is ready for treatment. Treat button is enabled and the procedure time is indicated in the blue progress bar.**

Press the Treat button. The treatment dialog window is displayed in the middle of the Treatment screen. The OCT images are overlaid with progress indicator bars. Initially, these vertical indicators are unfilled.

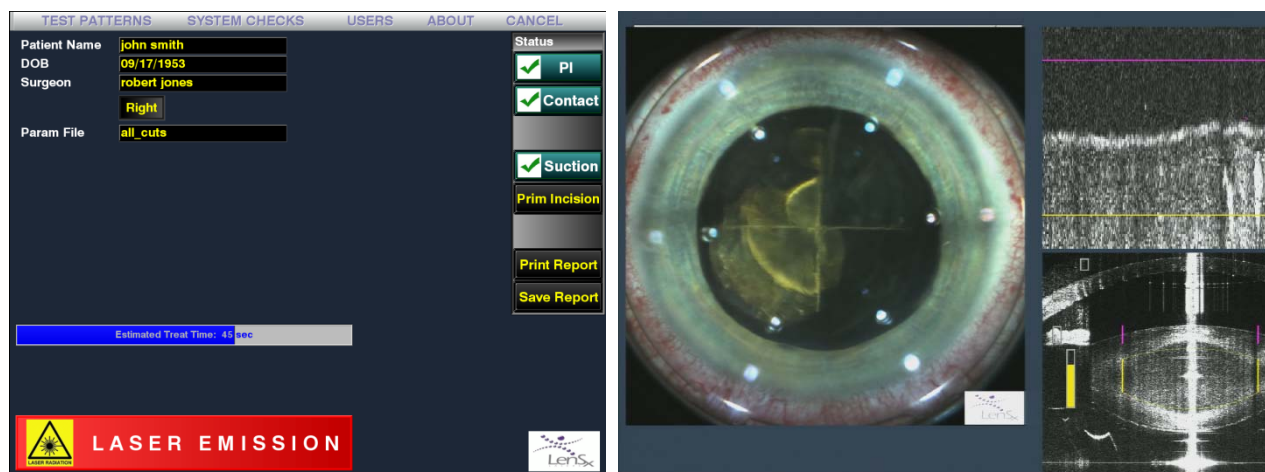
When ready to begin treatment, press and hold the footswitch. Releasing the footswitch during the procedure will immediately halt treatment. Treatment can be resumed by pressing the footswitch again. During laser treatment, a red laser emission message is shown on the Display Panel. Procedure progress may be monitored with the following indicators:

- vertical progress bars continuously track the progress of each incision
- a display of the pattern selections
- a display of the estimated remaining procedure time in seconds
- a live video camera image of surgical field

During treatment, monitor the surgical progress on the video monitor. If an incorrect pattern occurs, halt the procedure by releasing the footswitch. The procedure may then be continued. Alternatively, a traditional cataract surgical procedure may be performed.

In the event of power failure resulting in an interrupted procedure, remove the patient interface tube from the vacuum port to release the eye from suction. Grasp the delivery system objective and raise it 1 to 2 inches to safely remove the patient from the surgical field.

If at any time during the combination procedure the surgeon wishes to halt the procedure, the footswitch may be released.



**Figure 6-23: Display Panel and Surgical Display during treatment. The OCT images are overlaid with graphical indicators for the patterns and completion progress bars (lower right corner of right image).**

## 6.8 Procedure Completion

A message will be displayed indicating the completion of the procedure. The Surgical Display continues to show a live video image of the eye. The Display Panel returns to the biometrics screen.

Release the footswitch at this time. Completion of the procedure de-activates the footswitch and closes the main laser shutter. Vacuum is automatically halted and the eye is released from suction. Rotate the joystick on the control panel counter-clockwise to raise the delivery device and safely remove the patient from the surgical field. Unlock, remove and discard the Patient Interface.

Discard the Patient Interface as medical waste.

## 7 Calibration and Alignment

Calibration of the LenSx Laser should be performed by trained LenSx personnel. However, the following internal calibration procedures are available to the user.

### 7.1 Energy Calibration

The LenSx Laser performs a laser energy calibration during system startup. A user-requested calibration can be performed at any time by selecting **Energy Calibration** in the **System Checks** menu. No tools are required. Use of the console is disabled until the calibration has been completed.

### 7.2 Beam Steering

The LenSx Laser automatically performs a beam steering check prior to each procedure. This check ensures that the laser beam is optimally aligned into the delivery system. Users can also request that this check be performed using the **Beam Steering** selection in the **System Checks** menu.

DRAFT

## 8 Service and Maintenance

To ensure continuous operation of the LenSx Laser system, preventive maintenance service should be made every three months by an authorized LenSx service representative.

Only trained LenSx representatives should perform unpacking, installation, and servicing of the LenSx Laser. Covers are not to be removed by anyone other than LenSx personnel. Accidental contact with the high voltage electrical circuits in the interior of the LenSx Laser console may result in serious injury or death. Ocular exposure to collimated beams contained in the console interior can produce retinal damage.

The LenSx Laser uses a closed, internal re-circulating cooling system whose fluid levels are checked during preventive maintenance. Coolant levels are automatically monitored by the system and if a low coolant error occurs, a message is displayed. An authorized LenSx service representative should be called if a coolant error occurs.

The LenSx console is designed for use in a surgical setting. The outer surfaces of the console may be wiped down with a clean damp cloth if necessary. A mild disinfecting agent may be used. The console does not require further sterilization.

Accident fluid spills on the delivery system optics may be lightly wiped using an alcohol swab.

The LenSx Laser is designed for use with a LenSx Laser Patient Interface. The Patient Interface is the only component that contacts the patient. All used Patient Interfaces must be properly disposed as medical waste.

### 8.1 Transport and Storage

Contact LenSx representatives to move, transport or store the LenSx Laser. The transport and storage temperatures should not exceed operating temperature and humidity specifications.

## 9 Trouble Shooting

Below is a guide to some possible problems, with the symptoms, possible causes and corrective actions. If a particular condition is not listed here, it is advised that a LenSx authorized service representative be contacted for consultation.

**Table 9-A: LenSx Laser – Troubleshooting Guide**

Symptom	Possible cause	Corrective action
Laser console does not startup.	Fuse blown at system rear panel	Replace fuse located at the lower rear panel.
Laser console will not proceed to the treatment stage	Footswitch is actuated	Release footswitch
	Parameters not selected	Enter required fields
	System fault has occurred	Contact LenSx representative
	Door safety interlock has disabled laser console	Close operating suite doors, check interlock connections
Laser console will not treat when enabled	Footswitch not connected	Connect footswitch
	Footswitch not fully actuated	Completely actuate footswitch
Laser console will not energize upon start-up	Power cord disconnected	Connect cord
	Footswitch not connected	Connect footswitch
	Circuit breaker tripped	Reset breaker, check electrical service
	System electrical fault	Contact LenSx representative
Laser beam halts during treatment	Door safety interlock has disabled laser	Close operating suite doors, check interlock connections
	Footswitch not fully actuated	Maintain footswitch actuation during procedure
	Fault condition	Contact LenSx representative
Fixation cannot be achieved or maintained	Suction not present	Re-apply suction ring
	Suction tubing failure	Replace suction ring
	Improper applanation or improper coupling of the suction ring assembly or applanation lens	Re-position delivery system and re-applanate cornea.
	Patient movement	Immobilize patient

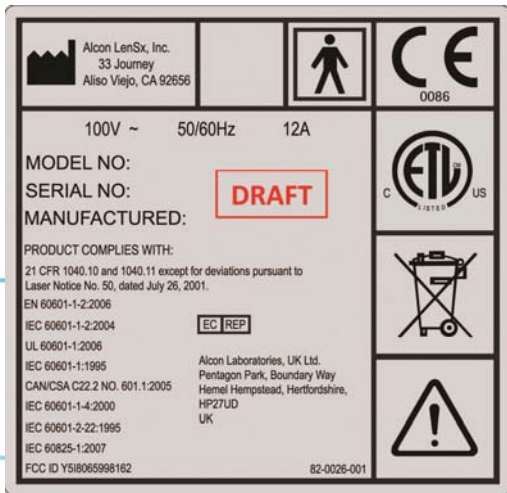
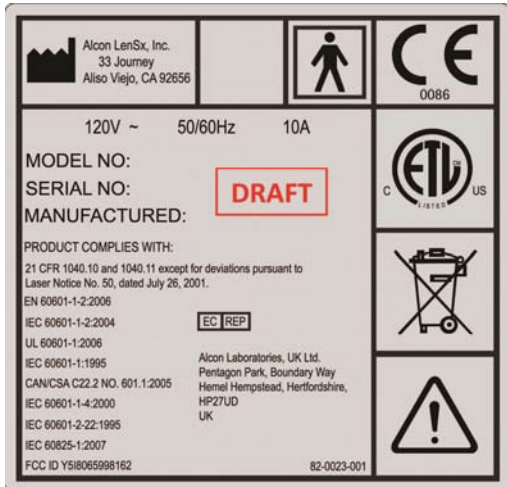
Symptom	Possible cause	Corrective action
Operating field not properly observable through microscope	Applanation lens contaminated	Replace disposable Patient Interface.
	Poor illumination or poor focus	Adjust illumination or focus controls.
	Microscope optically misaligned	Verify positioning of magnification knob.
Laser tissue effect not apparent during treatment	Applanation lens contaminated or damaged	Replace disposable Patient Interface.
	Applanation lost or vacuum integrity has been lost	Reposition suction ring and fixate. Reposition delivery system and re-applanate cornea.
	Laser output blocked	Contact LenSx service representative.
	Laser output misaligned	
	Laser optical malfunction	Contact LenSx service representative.
Procedure incomplete	Applanation lost or vacuum integrity has been lost resulting in an interrupted procedure	Reposition suction ring and fixate. Reposition delivery system and re-applanate cornea. Repeat phacofragmentation treatment at the same centered position and using same parameters as appropriate. Repeat capsulotomy treatment at the same center position and using slightly larger diameter.
	Laser output blocked	Inspect beam path. Allow 1 hour before retreatment.
	Laser source misaligned	Contact LenSx service representative. Retreat when LenSx Laser is repaired.
	Misaligned beam delivery device	
	Loss of line power	Release the eye from suction. Grasp the delivery system objective and raise it 1 to 2 inches to safely remove the patient from the surgical field.
Treatment geometry incorrect	x-y scanning unit failure	Contact LenSx service representative. Retreat when LenSx Laser is repaired.





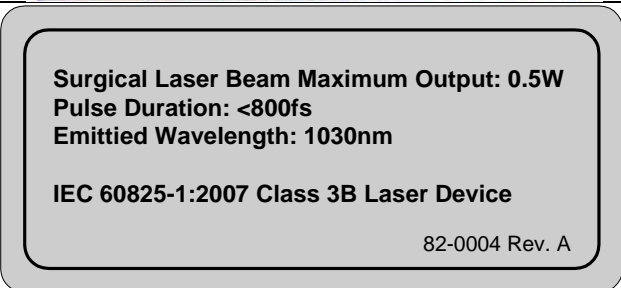
## 10 Labels

### 10.1 Console Labels

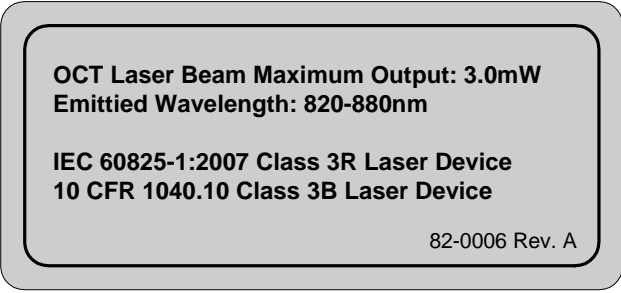



Warning labels are found on the LenSx Laser to denote specific hazards. Observe label warnings at all times. The LenSx Laser is labeled in accordance with requirements for all medical devices as well as with requirements for laser products.

**Table 10-A: Warning Labels used with the LenSx Laser**

Label	Label Name
	Identification Label (100 V)
	Identification Label (120 V)

Label	Label Name
	Identification Label (220-240 V)
	Laser Aperture
	Protective Housing, Class 4
	Protective Housing, Class 3B
	Laser Warning Surgical Beam



Label	Label Name
	OCT Beam Laser Warning
	High Voltage
	High Voltage (internal)
	Emergency Stop

## 11 System Specifications

<b><u>System Parameter</u></b>	<b><u>Specifications</u></b>
Laser type	Femtosecond Infrared laser
Mode	Fundamental (TEM <sub>00</sub> )
Cone angle	0.20 sr ( $\pm 0.05$ sr) half angle
Laser pulse width	600 - 800 fs ( $\pm 50$ fs)
Central laser wavelength	1030 nm ( $\pm 5$ nm)
Maximum pulse energy	15 $\mu$ J ( $\pm 1.5$ $\mu$ J)
OCT Device	Wavelength 820 – 880 nm ( $\pm 5$ nm) 3.0 mW ( $\pm 0.2$ mW) maximum power
Remote interlock	Included in system
Input voltage	Configurable 100V/12A, 120V/10A, 220-240V/7A, 50/60 Hz
Maximum Electrical Load	$\leq 1.2$ kW
External Fuse (x2)	3AG, Fast Acting, 250V, 15A
Console dimensions	Console footprint 24" (W) x 30" (L) x 48" (H) Beam delivery device 8"(W) x 23"(L) x 20"(H)
Beam delivery device height	Min 28.1 inches (floor to applanation lens) Max 41.7 inches (floor to applanation lens)
Console weight	1055 lbs
Ambient operating temperature	18 °C to 24 °C (65°F to 75°F)

## 12 Warranty Information

Alcon LenSx Inc. (Alcon LenSx) warrants that the LenSx Laser (the "Equipment") and software will conform to the published product specifications of Alcon LenSx and be free from material defects in materials and workmanship for the first year of continuous service. An Alcon LenSx service and support contract between Alcon LenSx or an Alcon affiliate and the end user must be maintained at all times.

Alcon LenSx will repair or replace at no charge any Equipment or software found upon examination by Alcon LenSx to be defective during the warranty period. This warranty is subject to the following exclusions, exceptions, and limitations: a) expenses such as labor or other expenses due to delays or inability to render any service; b) correction of operator problems related to environmental conditions beyond the control of Alcon LenSx; c) repair and maintenance necessitated by user-induced damage, neglect, misuse, or improper operation of the Equipment or software; d) modification or connection of other equipment to the Equipment or software without the express written authorization of Alcon LenSx, such authorization which may be withheld at Alcon LenSx's sole discretion; e) sublease or use of Equipment by anyone other than the end-user's qualified and trained personnel; f) use for any processes, procedures, experiments, or any other use for which the Equipment is not intended for use or approved for use by the Food and Drug Administration (FDA); g) supplies, devices, or electrical work external to the Alcon LenSx Equipment or software; and h) repairs due to the user's failure to perform any routine maintenance, which is the responsibility of the user.

Alcon LenSx is not responsible and will charge the user for repair, replacement, or maintenance caused by user-induced damage, neglect, misuse, improper operation, accident, fire, water, vandalism, unauthorized equipment attached to the Equipment, or unauthorized modification of Equipment or software. Warranty does not extend to any Equipment or software not provided by LenSx.

**THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER EXPRESS OR IMPLIED WARRANTIES, ARISING BY OPERATION OF LAW OR OTHERWISE, AND NO OTHER WARRANTIES EXIST, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY. FURTHERMORE, ALCON LENSX DOES NOT WARRANT THAT THE OPERATION OF THE SOFTWARE SHALL BE UNINTERRUPTED OR ERROR FREE. IN NO EVENT WILL ALCON LENSX BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, EXPENSES, LOST PROFITS, OR OTHER DAMAGES ARISING OUT OF THE USE OR INABILITY TO USE THE EQUIPMENT AND SOFTWARE, EVEN IF ALCON LENSX HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.**

## 13 Abbreviations and Terms



### 13.1 General Abbreviations

ANSI	American National Standards Institute
CDRH	Center for Device and Radiologic Health (FDA)
DFU	Directions for Use
FDA	Food and Drug Administration (United States)
LED	Light Emitting Diode
NOHD	Nominal Optical Hazard Zone

### 13.2 Terms

Applanation:	flattening of cornea
Femtosecond:	measure of time; 1 fs = $10^{-15}$ seconds, or 0.000000000000001 seconds
Picosecond:	measure of time; 1 ps = $10^{-12}$ seconds, or 0.000000000001 seconds

### 13.3 Symbols

	Manufacturer
	European Representative

## 14 Nominal Optical Hazard Distance (NOHD)

The NOHD is defined according to American National Standards Institute Z136.1-2000, "American National Standard for Safe Use of Lasers." The NOHD is computed in terms of the Maximum Permissible Exposure (MPE) allowed onto the eye. For the LenSx Laser the NOHD calculated using this standard is very short due to the small pulse energies emitted by the laser.

The practical consequence is that operators and support personnel are not endangered by optical radiation normal and routine operation of the laser. Any service operation requiring the removal of any covers or shields on the console will require eyewear of OD  $\geq 5$  at a wavelength of 1030 nm. Only authorized LenSx service representatives should attempt to remove console covers or to service the LenSx Laser.

The steps required to calculate the NOHD according to Z136.1-2000 (referred to hereafter as "the Standard") are described below. The Standard describes the calculation of MPE according to three rules and utilizes the prescribed MPE to compute the NOHD.

### Rule 1: Single-pulse MPE

Table 5a of the Standard lists the single-pulse MPE for a laser of wavelength 1030 nm and a single pulse exposure of 600 fs as

$$MPE_{sp} = 1.5C_c \times 10^{-7} \text{ J/cm}^2. \quad (1)$$

From Table 5 of the Standard,  $C_c = 1$  so that  $MPE_{sp} = 1.5 \times 10^{-7} \text{ J/cm}^2$ . To compute the NOHD, consider the figure below.

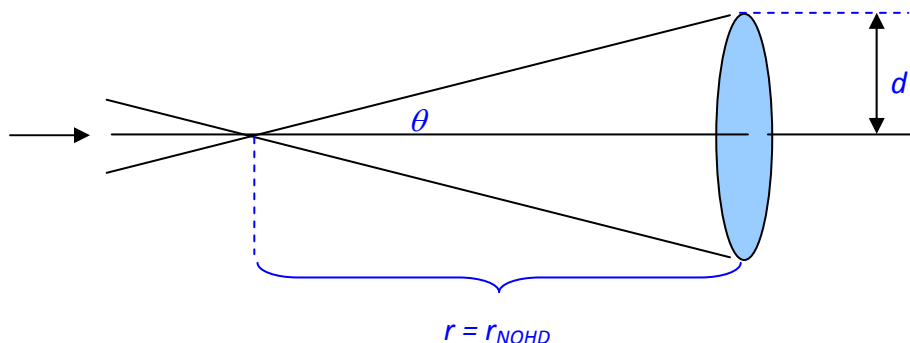


Figure 14-1: Geometry for calculation for possible ocular

This figure is similar to Figure B6 of the Standard. After the focal, light fills a cone of half-angle  $\theta$  and illuminates a plane at a distance  $r$ . The fluence,  $F$ , observed on the surface is

$$F = \frac{E}{\pi d^2}$$

$$= \frac{E}{\pi r^2 \tan^2 \theta} \quad (2)$$

Here  $E$  is the maximum energy delivered by a single pulse. The NOHD is computed by replacing the fluence with the  $MPE_{Sp}$  derived above and solving for  $r$ .

$$r_{NOHD} = \left[ \frac{E}{\pi(MPE_{Sp}) \tan^2 \theta} \right]^{1/2} \quad (3)$$

For the LenSx Laser, the maximum emitted energy is 15  $\mu$ J and  $\theta = 14.5^\circ$ . The resulting NOHD using Rule 1 is 21.8 cm.

## Rule 2: Average Power MPE for Thermal and Photochemical Hazards

According to Table 5a of the Standard, the average power,  $MPE$  for an exposure of 10 s is

$$MPE_{AVG} = C_c \times 10^{-3} \text{ W/cm}^2 \text{ where } C_c = 10^{2(\lambda - 0.700)} \quad (4)$$

Using  $\lambda = 1.030 \text{ mm}$ , the average power MPE is  $MPE_{AVG} = 4.57 \times 10^{-3} \text{ W/cm}^2$ . In order to compute the NOHD, consider the figure used in Rule 1 and compute the irradiance as follows:

$$I = \frac{P_{AVG}}{\pi d^2}$$

$$= \frac{P_{AVG}}{\pi r^2 \tan^2 \theta} \quad (5)$$

The NOHD is computed by replacing the irradiance with the  $MPE_{AVG}$  in (5) and solving for  $r$ .

$$r_{NOHD} = \left[ \frac{P_{AVG}}{\pi(MPE_{AVG}) \tan^2 \theta} \right]^{1/2} \quad (6)$$

For the LenSx Laser, the average maximum power of the laser is 500 mW at 33 kHz and  $\theta = 14.5^\circ$ . The resulting NOHD using Rule 2 is 22.8 cm.

## Rule 3: Multiple-pulse MPE for Thermal Hazards

Section 8.2.3 of the Standard defines the MPE for this rule as,  $MPE / \text{pulse} = MPE_{Sp} \cdot C_p$ , where  $MPE_{Sp}$  is computed from (1), and  $C_p = n^{-1/4}$  where  $n$  is number of pulses emitted during a 10 s exposure. During a 10 s exposure of the LenSx Laser:

$$\begin{aligned}n &= 3.3 \times 10^5; \\C_p &= 0.042; \\MPE_{MULT} &= 6.30 \times 10^{-9} \text{ J/cm}^2.\end{aligned}$$

The NOHD is computed by replacing  $MPE_{SP}$  in equation (3) with  $MPE_{MULT}$ . The resulting NOHD using Rule 3 is 106 cm.

Since Rule 3 provides the most conservative values of NOHD, the reported nominal optical hazard distance is 106 cm for the LenSx Laser.

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## 15 Declaration of Compliance

Guidance and manufacturer's declaration – electromagnetic emissions		
The LenSx Laser System is intended for use in the electromagnetic environment specified below. The customer or the user of the LenSx Laser should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11 IEC 60601-1-2	Class A	<p>The LenSx Laser System uses RF energy for its internal function and an RFID device for detection of a valid Patient Interface. The RFID is a low power single frequency device that complies with FCC and international standards for intentional transmitters. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.</p> <p>This device complies with 47 CFR 15 Federal Communications Commission Rules (FCC) for radio frequency devices. (1) The LenSx Laser does not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.</p> <p>Changes or modifications not expressly approved by Alcon LenSx Inc. can void the user's authority to operate this device.</p>
Conducted emissions CISPR 11 IEC 60601-1-2	Class A	<p>The LenSx Laser System is suitable for use in all establishments other than those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p>
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	



Guidance and manufacturer's declaration – electromagnetic immunity			
The LenSx Laser System is intended for use in the electromagnetic environment specified below. The customer or the user of the LenSx Laser System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 6$ kV contact $\pm 8$ kV	$\pm 6$ kV contact $\pm 8$ kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.  Operator Display Panel demonstrated susceptibility to ESD at 4 kV (and above) when applied to the metal arm and metal mount brackets at the rear of the monitor assembly. The susceptibility results in transient flicker of the display monitor. Performance and safety are not affected.
Radiated EM Field IEC 61000-4-3	Range 80 MHz – 2.5 GHz 3 V/m	Range 80 MHz – 2.5 GHz 3 V/m	Electro-Magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  Do not use cell phones, pagers, or radio frequency devices of any kind in the same room as the LenSx Laser.
Electrical fast transient / burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input / output lines	$\pm 2$ kV for power supply lines $\pm 1$ kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge Immunity IEC 61000-4-5	$\pm 1$ kV differential mode $\pm 2$ kV common mode	$\pm 1$ kV differential mode $\pm 2$ kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Disturbances IEC 61000-4-6	Range 0.15 – 80 MHz 3(V <sub>RMS</sub> )	Range 0.15 – 80 MHz 3(V <sub>RMS</sub> )	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field Immunity IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The LenSx Laser System is intended for use in the electromagnetic environment specified below. The customer or the user of the LenSx Laser System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, Interruptions & Fluctuations IEC 61000-4-11	Dips >95% for 10ms -60% for 1000ms -30% for 500ms Interruptions >95% for 5 sec Fluctuations $U_{NOM} + 10\%$ 15 min $U_{NOM} - 10\%$ 15 min	Dips >95% for 10ms -60% for 1000ms -30% for 500ms Interruptions >95% for 5 sec Fluctuations $U_{NOM} + 10\%$ 15 min $U_{NOM} - 10\%$ 15 min	Mains power quality should be that of a typical commercial or hospital environment.  It is a requirement that the user powers the Alcon LenSx Laser System with a UPS. The UPS must have enough back-up capacity for a minimum of 5 minutes at system full load. The rating for the UPS should be a minimum of 1400 Watts
NOTE: $U_{NOM}$ is the A.C. mains voltage prior to application of the test level			

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