Federal law (U.S.A.) restricts this device to sale by or on order of a physician.
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The term "cOS" is defined as "cataract operating system" and is followed by a numeric version number (e.g., cOS 3.90).

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Product of USA

For service assistance, please contact the OPTIMEDICA Service Department at +1-800-511-0911.

To order replacement parts, please contact Customer Service at +1-877-266-4543.
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Indications for Use, Contraindications, Warnings & Precautions
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Indications for Use

The OPTIMEDICA CATALYS Precision Laser System 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.

Contraindications

The CATALYS System is contraindicated in patients with corneal ring and/or inlay implant(s).

The CATALYS System is contraindicated in patients with severe corneal opacities, corneal abnormalities, significant corneal edema or diminished aqueous clarity that obscures OCT imaging of the anterior lens capsule.

The CATALYS System is contraindicated for pediatric use (i.e., patients younger than 22 years of age).

Descemetocele with impending corneal rupture.

Any contraindications to cataract surgery.

Warnings

- Every day, prior to use, a trained operator must verify that the CATALYS System is aligned.
- Never open the laser console protective covers or attempt internal repairs or adjustments not specifically detailed in this operator manual. Opening the covers will expose you to high voltage components, the laser resonator and possible laser radiation.
- Installation, maintenance and repair should be performed only by OPTIMEDICA-certified personnel per the manufacturer’s recommendation and institutional standards.
- Routinely inspect the system components for obvious signs of damage. Do not operate the laser if any of the components are damaged or if the cords are faulty or frayed.
- Do not use in the presence of flammables or explosives such as volatile anesthetics, alcohol, certain surgical preparation solutions, or other such substances. An explosion and/or fire could occur. Refer to the “Fire Hazards” section of this manual for detailed warnings.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- Do not use caustic cleaners or strong detergents when cleaning the CATALYS System.
- If the system becomes unresponsive at any time, press the emergency laser stop button and turn the key to the (OFF) position.
- Do not use the system if the touchscreen and/or the control panel is either unresponsive or blank. If restarting the system does not resolve the problem, please contact the Service Department at +1-800-511-0911.
- The (laser emission) indicator is displayed on the touchscreen control panel at all times the laser is energized to warn the user that the system is capable of emitting laser energy.
- Precautions, such as wearing appropriate laser safety eyewear, should be taken if required.
• Prior to INTEGRAL GUIDANCE imaging and laser treatment, the suction ring must be completely filled with sterile buffered saline solution, such as Alcon BSS (Alcon P/N 351/55005-1) or equivalent. Use the video image to verify that no air bubbles are entrapped within the sterile buffered saline solution after the suction ring is captured. The video image should provide a sharp and clear image of the patient’s eye.

• Continuously monitor the video image immediately before and throughout each laser treatment. Continuously verify that the suction ring remains completely filled with sterile buffered saline solution. If any air bubbles and/or a meniscus appear on the video image before treatment do not initiate laser treatment. If air bubbles and/or a meniscus appear during treatment, then terminate the laser treatment by immediately releasing the laser footswitch.

• Continuously verify that the eye has not moved with respect to its initial presentation at the time of fluid confirmation. If the eye moves during INTEGRAL GUIDANCE, then press “Rescan Eye”. If the eye moves during laser treatment, then terminate the laser treatment by immediately releasing the laser footswitch.

• Before initiating laser treatment, inspect the images created from the OCT data, surface fits, and overlaid pattern in both axial and sagittal views, and review the treatment parameters on the Final Review Screen for accuracy.

• Safety margins for all incisions are preserved only if Custom Fit Adjustments to ocular surface(s) are applied in accordance with the instructions for use. Purposeful misuse of the Custom Fit Adjustment to ocular surfaces can result in patient injury and complication(s), and therefore must be avoided.

• If a laser capsulotomy is interrupted, the system will not allow you to reinitiate the capsulotomy, as precise co-registration with the initial capsulotomy cannot be assured. Instead, use standard continuous curvilinear capsulorrhexis (CCC) surgical technique to complete the treatment.

• If at any point during laser delivery the patient becomes undocked (e.g. due to Vacuum Loss), the treatment will be interrupted and cannot be continued. Do not resume treatment afterwards. Revert to traditional cataract surgery.

• If the treatment is interrupted by a “Critical Error”, the system will go to a safe state and be disabled. Do not resume treatment afterwards. Revert to traditional cataract surgery.

• Never look directly into the laser aperture or scattered laser light from reflective surfaces when the treatment beam is activated. Severe eye damage could occur.

• Standard continuous curvilinear capsulorrhexis (CCC) surgical technique must be used for surgical removal of the capsulotomy disc. The capsulotomy may have residual uncut areas that should be completed by advancing the capsule through the incompletely cut area in a circumferential fashion, rather than pulling it radially. The use of improper capsulotomy disc removal technique may potentially cause or contribute to anterior capsule tear and/or a noncircular, irregularly shaped capsulotomy.

• Verify that the suction ring is correctly connected to the disposable lens component of the LIQUID OPTICS Interface during the initial patient docking procedure.
Precautions

- Federal law (USA) restricts this device to sale by or on order of a physician.
- The system should be used only by qualified physicians who have extensive knowledge of the use of this device and have been trained by OPTIMEDICA-certified personnel.
- Use of controls or adjustments or performance of procedures other than those specified herein (System Misuse) may result in hazardous radiation exposure.
- Users should be aware of general laser warnings, precautions and adverse effects. Read this operator manual thoroughly and be familiar with its contents prior to using this equipment.
- The key should not be turned to the start position for more than two seconds. If the key is held at the start position for more than two seconds, the system will return to the BIOS screen and shutdown, which will then require service by OPTIMEDICA personnel. If the control panel remains blank for an extended period of time during system start-up, press the Power button on the front of the control panel to turn on the control panel. If the control panel remains blank, turn off the system with the key, wait at least one minute, and then restart the system. If the screen is still blank, turn off the system and contact OPTIMEDICA Service.
- When not in use, laser equipment should be protected against unqualified use by removing the key from the key switch.
- When the CATALYS System is interconnected with other medical electrical equipment, leakage currents may be additive. Ensure all systems are installed according to the requirements of IEC 60601-1.
- Treatment may be discontinued at any time by pressing the ABORT TREATMENT button (before laser emission), STOP button (during INTEGRAL GUIDANCE scan) or PAUSE TREATMENT button (during laser emission) on the GUI or the emergency laser stop button on the system front panel.
- If the system displays a “Clearable Error” message, press the OK button to clear the error and continue the treatment. Alternatively, when in doubt, always choose the safest approach and shutdown the system and abort the treatment.
- The CATALYS System has not been adequately evaluated in patients with a cataract greater than Grade 4 (via LOCS III); therefore, no conclusions regarding either safety or effectiveness are presently available.
- Cataract surgery may be more difficult in patients with an axial length less than 22 mm or greater than 26 mm, and/or an anterior chamber depth less than 2.5 mm, due to anatomical restrictions.
- Use caution when treating patients who may be taking medications such as alpha blockers (e.g., Flomax®, tamsulosin HCL [Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany]) as these medications may be related to Intraoperative Floppy Iris Syndrome (IFIS); this condition may include poor preoperative pupil dilation, iris billowing and prolapse, and progressive intraoperative miosis. These conditions may require modification of surgical technique such as the utilization of iris hooks, iris dilator rings, or viscoelastic substances.
• Adequate iris dilation medication protocol should be used to ensure iris dilation of at least 1.0mm larger than the intended capsulotomy diameter.

• Surgical removal of the cataract more than 30 minutes after laser anterior capsulotomy and laser lens fragmentation has not been clinically evaluated. The clinical effects of delaying surgical removal more than 30 minutes after laser anterior capsulotomy and laser lens fragmentation are unknown.

• After removal of the capsulotomy disc, if any capsulotomy thread remnant (less than 50μm nominal thickness) is seen, do not remove it. Removal of a capsulotomy thread remnant could potentially cause or contribute to an anterior capsule tear and/or a non-circular, irregularly-shaped capsulotomy.

• The LIQUID OPTICS Interface is intended for single patient use only.

• Do not use the LIQUID OPTICS Interface after the expiration date on the package.

• Inspect all packaging for the LIQUID OPTICS Interface prior to use. Do not use if the sterile barrier has been breached, if the package is damaged in any way, or if the device has been dropped.

• Do not attempt to capture the disposable lens if the fluid catchment reservoir is full. After suction has been established, periodically verify and do not allow the maximum volume of fluid to fill beyond where the tubing enters the fluid catchment reservoir. If the fluid catchment reservoir does become full, replace the entire LIQUID OPTICS Interface before continuing.

• The touchscreen control panel must be kept dry at all times.

• Use blunt dissection to separate the edges of corneal incisions. Avoid using sharp instruments for manipulating the corneal incision, to preserve the original incision geometry, and to prevent unintended dissection.

• Full-thickness corneal 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.

• Patients who will undergo full-thickness corneal incisions with the CATALYS System should be given the same standard surgical preparation as used for patients undergoing cataract surgery for the removal of the crystalline lens.

• During intraocular surgery on patients who have undergone full-thickness corneal incisions with the CATALYS System, care should be taken if an eyelid speculum is used, in order to limit pressure from the speculum onto the open eye.

• Patients who will be transported between the creation of a full-thickness corneal incision and the completion of the intraocular surgery should have their eye covered with a sterile rigid eye shield, in order to avoid inadvertent eye injury during transport.

• Patients must be able to lie flat and motionless in a supine position.

• Patients must be able to tolerate local or topical anesthesia.

• When an incision is paused either by the system or by the user, wait at least one second prior to resuming the incision to avoid a critical alarm that will cause the system to shut down.
• If a corneal incision is interrupted and resumed, there may be a significant gap in the resulting incision. In order to minimize the risk of incomplete incisions users should avoid unnecessary interruptions of an ongoing treatment.

• In the event a corneal incision is interrupted and resumed do not attempt to force the incision open if it is not blunt dissectible. If the corneal incision is not blunt dissectible, use a bladed instrument to create a separate corneal incision to continue with the procedure.

• Do not connect anything other than a USB flash drive to the CATALYS System USB ports.

• Connection of the CATALYS System to a customer network that includes other networked equipment could result in previously unidentified risks. During system installation, OPTIMEDICA-trained personnel will review the installation site network with the installation site IT administrator to identify, analyze, evaluate and control these risks. Subsequent changes to the installation site network could introduce new risks due to:
  – Changes to the network configuration
  – Connection of additional devices to the network
  – Disconnection of devices from the network
  – Update and/or upgrade of equipment connected to the network

The HSA installed on the CATALYS System is designed to mitigate these risks to an acceptable level. If system performance or speed degrades when connected to a network, disconnect the CATALYS System from the network and contact OPTIMEDICA Service for assistance.

Adverse Effects

Complications associated with the CATALYS System include mild Petechiae and subconjunctival hemorrhage due to vacuum pressure of the LIQUID OPTICS Interface suction ring.

Potential complications and adverse events generally associated with the performance of capsulotomy and lens fragmentation, or creation of a partial-thickness or full-thickness cut or incision of the cornea, include:

Acute corneal clouding, age-related macular degeneration, amaurosis, anterior and/or posterior capsule tear/rupture, astigmatism, capsulorrhexis notch during phacoemulsification, capsulotomy/lens fragmentation or cut/incision decentration, cells in anterior chamber, choroidal effusion, choroidal hemorrhage, conjunctival hyperemia/injection/erythema/chemosis, conjunctivitis (allergic/viral), corneal abrasion/deep epithelization/epithelial defect, corneal edema, cystoid macula edema, Descemet’s detachment, decentered or dislocated intraocular lens implant, diplopia, dropped or retained lens, dry eye/superficial punctate keratitis, edema, elevated intraocular pressure, endothelial decompensation, floaters, glaucoma, halo, inflammation, incomplete capsulotomy, intraoperative floppy iris syndrome, iris atrophy/extrusion, light flashes, meibomitis, ocular discomfort (e.g., pain, irritation, scratchiness, itching, foreign body sensation), ocular trauma, petechiae, photophobia, pigment changes/pigment in corneal endothelium/foveal region, pingueculitis, posterior capsule opacification, posterior capsule rupture, posterior vitreous detachment, posteriorly dislocated lens material, pupillary contraction, red blood cells in the anterior chamber (not hyphema), residual cortex, retained lens fragments, retinal detachment, retinal hemorrhage, scar in Descemet’s
membrane, shallowing or collapsing of the anterior chamber, scoring of the posterior corneal surface, snailtrack on endothelium, steroid rebound effect, striae in Descemet’s, subconjunctival hemorrhage, thermal injury to adjacent eye tissues, toxic anterior shock syndrome, vitreous in the anterior chamber, vitreous band, vitreous loss, wound dehiscence, wound or incision leak, zonular dehiscence.
User Training and Certification

All users are required to participate in training provided by OPTIMEDICA personnel prior to treating patients with the CATALYS Precision Laser System. Training will be tailored for the surgeon(s) and support staff and will consist of lectures and hands-on experience with the equipment. Users may be trained and certified for two different roles: surgeon and system operator. In addition, OPTIMEDICA technical and clinical support personnel will observe and assist each user according to designated role during treatment of 10 patients, or as required for each user to achieve competence.

The training presentation will include a general review of this manual, with emphasis on those topics of particular individual relevance for the different user roles. The curriculum will cover:

- Plan (template driven treatment planning);
- Engage the LIQUID OPTICS Interface (docking and vacuum controls);
- Visualize/Customize (INTEGRAL GUIDANCE 3-D OCT imaging, automated surface detection and laser exclusion zones); and
- Treat (parameter choices and patterns for all treatments).

The curriculum and hands-on training are divided according to user roles. Overall the curriculum addresses the following:

1. System Overview
   a. Laser safety
   b. Specifications and operation
   c. Emergency system shutdown
   d. System error codes and their mitigation
   e. Daily system alignment verification and warm-up requirements
   f. System maintenance
2. Workflow Considerations
3. Use of the Graphical User Interface
   a. Treatment planning
   b. Treatment
4. Use of the LIQUID OPTICS Interface
   a. Packaging and handling of the LIQUID OPTICS Interface
   b. Docking with the LIQUID OPTICS Interface: Vacuum, Capture and Lock
5. Use of INTEGRAL GUIDANCE
   a. Acquisition of the INTEGRAL GUIDANCE data
   b. Surface detection and adjustments
   c. Laser treatment exclusion zones
6. Review of the clinical trial results – text and iPad presentation
7. Indications for use, contraindications, warnings and precautions
The hands-on training includes but is not limited to:

a. Treatment planning
b. Patient chair controls
c. Installing the LIQUID OPTICS Interface
d. Patient, head and eye positioning
e. Use of CATALYS System controls including the Graphical User Interface
f. Docking with the LIQUID OPTICS Interface with an artificial eye and head
g. The INTEGRAL GUIDANCE process and custom adjustments
h. Treatment application

Upon the recommendation of the OPTIMEDICA-certified Clinical Application Specialist, each user will be certified as competent according to the defined user roles, in the operation and use of the CATALYS System, ancillary equipment, as well as being well-informed about indications for use, contraindications, warnings, precautions and laser safety. Users who successfully complete the certification will receive a signed certificate from OPTIMEDICA personnel.

**Target Patient Profile**

- Male or Female; Age >= 22 years; Anthropometric characteristics fall within 2<sup>nd</sup> and 98<sup>th</sup> percentile in all target markets
- Weight: Patient chair limits patient weight to maximum of 181 kg (399lb)
- Health
  - ASA category 1: approx. 5% of patient population
  - ASA category 2: approx. 54% of patient population
  - ASA category 3: approx. 40% of patient population
  - ASA category 4: approx. 1% of patient population
- Nationality: Multiple
- Mobility: Ambulatory, ability to successfully transfer to patient bed, with help if necessary

**Target Operator Profile**

- Male or Female; Age >= 18 years; Anthropometric characteristics fall within 5<sup>th</sup> and 95<sup>th</sup> percentile in all target markets

**Physician**

- Education: Board certified ophthalmologist
- Knowledge and experience
  - Experienced in performing cataract surgery
  - Fully trained in the use of the device
- Permissible impairments
  - Vision: Mildly impaired but corrected to 20/30
  - Hearing: Mildly impaired but corrected to 85% of normal hearing
– Mobility: No impairment that can limit use of system controls and application of suction ring.

**Nurse**

- Education: registered nurse (RN)
- Knowledge and experience:
  - Experienced in assisting in ophthalmologic procedures
  - Fully trained to support the physician during the treatment

- Permissible impairments
  - Vision: Mildly impaired but corrected to 20/30
  - Hearing: Mildly impaired but corrected to 85% of normal hearing
  - Mobility: No impairment, must be able to assist with positioning of the patient
  - Hand-eye coordination: No impairment

**Technician/operator**

- Education: BS in applicable field
- Knowledge and experience
  - Fully trained to operate the system and support the physician during the treatment

- Permissible impairments
  - Vision: Mildly impaired but corrected to 20/30
  - Hearing: Mildly impaired but corrected to 85% of normal hearing
  - Mobility: No impairment, must be able to assist the positioning of the patient
  - Hand-eye coordination: No impairment
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System Overview
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Introduction

The OPTIMEDICA CATALYS Precision Laser System is an integrated scanning laser system that is used by cataract surgeons to create a precise anterior capsulotomy and/or subsequent fragmentation (phacofragmentation) of the crystalline lens, with or without single plane and multi-plane arc cuts/incisions in the cornea. Treatment is accomplished through the use of ultrafast (τ ≈ 10^{-13}s, or hundreds of femtoseconds [FS]) infrared laser pulses. The onboard Optical Coherence Tomography (OCT) subsystem provides a three-dimensional image of the anterior segment of the eye and guides laser treatment. A common optical scanning system is used for both the OCT and the FS laser to provide inherent co-registration of the two optical subsystems.

Each FS laser pulse creates a highly localized plasma and subsequent cavitation event that disrupts only microns of tissue per pulse. The treatment consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying FS laser pulses, guided by the OCT data.

Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.

The system has been designed to be used by a single operator. The Graphical User Interface (GUI) allows for pretreatment planning without interfering with the patient chair. The CATALYS System may be used for in-patient or out-patient treatments performed in a hospital or in an Ambulatory Surgery Center (ASC).

CATALYS System Components

The CATALYS Precision Laser System consists of the following components:

- Touchscreen control panel—Graphical User Interface (GUI)
- Docking keypad
- LIQUID OPTICS Interface
- LIQUID OPTICS Interface circular label reader
- Patient chair with headrest and joystick control
- Emergency laser stop button
- Key switch
- Vacuum and laser footswitches
- Door interlock connector
- Treatment laser
- Optical Coherence Tomography, video, monitoring, and control subsystems
CAUTION

If the control panel is blank, do not use the system. If the screen remains blank for more than 30 seconds, turn off the system with the key, wait at least one minute, and then restart the system. If the screen is still blank, turn off the system and contact OPTIMEDICA Service.
**Docking Keypad**

The docking keypad is located on the system front panel, directly above the patient. It contains the controls for capturing and releasing the suction ring, including the patient vacuum, Capture, and patient lock on/off buttons. Press buttons firmly when selecting on or off.

**Docking Keypad**

![Docking Keypad Diagram]

**LIQUID OPTICS Interface**

The patient-contact component of the CATALYS System, named the LIQUID OPTICS Interface, is a sterile, single patient use disposable element that functions to center and fixate the patient’s eye relative to the system.

The LIQUID OPTICS Interface is an aqueous contact patient interface that applies suction via an annular ring affixed to the patient’s sclera and a replaceable proximal lens that mounts to the system. The volume enclosed by the annular suction ring and its housing and the proximal lens is designed to be filled with an immersion fluid of sterile buffered saline solution.
**LIQUID OPTICS Interface Circular Label Reader**

The LIQUID OPTICS Interface circular label reader reads data from the circular label on the LIQUID OPTICS Interface packaging and transfers it to the CATALYS System software for identification and tracking purposes. The circular label must be held flat against the label reader on the left side of the system. Once the label has been read by the system, one treatment will be enabled on the CATALYS System. Laser treatment cannot be initiated until a new circular label has been scanned.

**Patient Chair with Headrest and Joystick**

**NOTE**

*Please see Appendix A – Instructions and Labels for the Original Patient Chair Configuration for the original description of the Patient Chair (prior to May 2013).*

The CATALYS System includes a custom patient chair that can be adjusted and orientated in three axes (x, y and z) by using a precision movement joystick control. The patient chair incorporates a headrest and restraint system that stabilizes the patient’s head for the duration of the treatment.

*Patient Chair in Reclined Position*

The chair allows for tilt articulation of the patient’s legs, torso, and head using manual adjustments. The chair accommodates three positions:

- **Patient load position**—chair rotated out from under system with patient chair back in upright position and patient footrest in lowered position.
- **Suction ring vacuum position**—chair rotated out from under system with patient chair back in reclined position and patient footrest in raised position.
- **Patient treat position**—chair rotated under system with patient chair back in reclined position and patient footrest in raised position.
NOTE
If the system becomes disabled for any reason during treatment, lower the patient’s head using the headrest vertical adjustment knob. This enables removal of the LIQUID OPTICS Interface and allows the patient chair to be rotated out from under the system.

⚠️ CAUTION
Do not stand on the patient chair, patient chair footrest or patient chair headrest. The patient chair is designed to support seated and reclined patients only.

Joystick Control
The joystick is a proportional controller—moving the joystick a small amount causes the chair to move slowly; moving the joystick a large amount causes the chair to move faster; holding the joystick at its maximum travel limit provides the maximum chair speed. The available chair speed is reduced as the suction ring enters the capture zone.

The joystick controls the chair position in three axes:
- Moving the joystick left or right causes the chair to move laterally (in the x axis);
- Moving the joystick fore or aft causes the chair to move superiorly or inferiorly (in the y axis);
- Rotating the joystick clockwise causes the chair to move upward (in the z axis); and
- Rotating the joystick counter-clockwise causes the chair to move downward (in the z axis).

Joystick Control from Surgeon’s Perspective

- Rotate joystick clockwise to raise chair; rotate joystick counter-clockwise to lower chair
- Moves chair laterally along x axis
- Moves chair orthogonally along y axis
- Moves chair laterally along x axis
- Moves chair orthogonally along y axis
NOTE
Once the suction ring is captured to the system, the patient chair joystick is disabled.

Patient Headrest
The headrest neck support adjustment knob enables adjustment of the patient neck support to provide patient comfort and to reduce patient head movement. Rotate the knob clockwise to raise the patient neck support; rotate the knob counter-clockwise to lower the patient neck support.

The headrest vertical adjustment knob enables adjustment of the patient head position to provide patient comfort and to accommodate variation in patient head size. Rotate the knob clockwise to lower the patient’s head; rotate the knob counter-clockwise to raise the patient’s head.

NOTE
Refer to the “Positioning the Patient“ section of this manual for detailed instructions on properly adjusting the patient headrest.

Emergency Laser Stop Button
The system is equipped with a latching emergency laser stop button. Pushing the emergency laser stop button stops emission of all laser output by closing the safety shutter, releases the patient vacuum, and disables the patient chair. Rotate the emergency laser stop button to disengage it. The emergency laser stop button is located on the system front panel, next to the key switch.

Key Switch
The system is equipped with a three-position key switch that enables the laser and its controls. In the Standby position, the key can be removed and the system is inactive. The Ready position enables power to the rest of the system. The switch is “momentary” when in the Start position. The key is not removable when switched to either the Ready or Start position. The laser is inoperable whenever the key is removed from the switch.

Emergency Laser Stop Button and Key Switch
Vacuum and Laser Footswitches

NOTE
Please see Appendix A – Instructions and Labels for the Original Patient Chair Configuration for the original description of the Vacuum Footswitch (prior to May 2013).

The system is equipped with two footswitch assemblies: a vacuum footswitch and a laser footswitch. The vacuum footswitch is a dual footswitch assembly containing two footswitches. The left footswitch is a “Vacuum OFF” footswitch that disables the vacuum that attaches the LIQUID OPTICS Interface suction ring to the patient’s eye. The left footswitch can also be used to clear vacuum errors displayed on the GUI. The right footswitch is a “Vacuum ON” footswitch that enables the vacuum that attaches the LIQUID OPTICS Interface suction ring to the patient’s eye. The laser footswitch is a shrouded footswitch that activates the laser treatment beam when depressed while the system is in READY mode.

**Vacuum Footswitch**

**Laser Footswitch**

Door Interlock Connector

The external door interlock is a safety feature that disables laser and OCT emission if the treatment room doors are opened or the interlock connector is removed.

Use of an external door interlock is optional; however, the door interlock connector must be inserted into the door interlock receptacle on the rear of the system whether or not the external door interlock feature is used. The laser remains inoperative until the interlock connector is inserted into the interlock receptacle.

NOTE
The services of a qualified electrical professional must be used to install the external door interlock switch. The total length of the cable must not exceed 5 m (16 ft).
Treatment Laser
The CATALYS System is classified as a CDRH Class 4 stand-alone laser device, because of intentional laser exposure to the patient's eye.\(^1\) The treatment laser is a diode-pumped solid-state configuration with a 1030 (±5) nm center wavelength incorporating femtosecond (FS) laser technology. The benefit of the FS laser is that the laser spot can be focused very tightly to deliver a pulse of light that is approximately 10\(^{13}\) seconds in duration, which delivers microjoule levels of energy to disrupt tissue (thereby using substantially lower energy levels than those required if ultrasound energy were used for lens fragmentation). With the addition of precision scanners under computer control, patterns may be pre-planned and exactly positioned for precise capsulotomy, lens fragmentation, and corneal cuts/incisions.

Optical Coherence Tomography
The CATALYS System uses an Optical Coherence Tomography (OCT) subsystem to create a three-dimensional model of the anterior portion of the eye to guide the laser treatment. The OCT system employs an 820–930nm spectral domain OCT to create three-dimensional images of anterior ocular structures. The system provides for identification of the anterior/posterior surfaces of both the cornea and the lens (“INTEGRAL GUIDANCE processing”). The system’s INTEGRAL GUIDANCE also detects the lens capsule, iris border, and limbus border, providing targeted centration for the capsulotomy. Similarly, the detection of the iris and limbus border also provides for targeted centration of corneal cuts/incisions. Centration of the capsulotomy and corneal cuts/incisions may also be adjusted at the discretion of the surgeon through the Graphical User Interface (GUI).

For lens fragmentation, the INTEGRAL GUIDANCE software algorithm analyzes the backscattered light from the OCT system to identify the posterior lens surface and presents that information graphically for the operating physician’s consideration. Streaming X- and Y-axis cross-sectional OCT images are displayed with computer modeling of potential laser cut patterns overlaid for verification by the operating physician. In the event that the INTEGRAL GUIDANCE processing cannot detect the posterior lens surface and the patient’s lens thickness is not known, the system can default to a conservative lens thickness value of 2.5mm.

Importantly, the system-integrated INTEGRAL GUIDANCE processing ensures that adequate safety margins with respect to iris, lens capsule, and cornea are maintained regardless of eye morphology, orientation, or tilt, thus assuring safe delivery of the treatment laser pulses.

\(^1\) Classification according to U.S. Code of Federal Regulations, Title 21, Part 1040.10 (Performance Standards for Laser Products).
Video Subsystem

The video imaging subsystem utilizes a monochrome megapixel video camera and collinear 735 nm light emitting diode (LED) illumination to provide constant, live imaging of the patient’s eye through the objective lens. The video subsystem offers 40 µm lateral resolution and a 17 mm diameter field of view. The display of clearly focused images is obtained only when immersion fluid fills the suction ring, offering a clear indication of its presence. The images from the video subsystem are presented to the physician during the suction ring capture procedure for centering and verification of immersion fluid use. The video images are also used for assessing the location of the capsulotomy pattern with respect to the patient’s iris and limbus.

Monitoring and Control Systems

The CATALYS System consists of three integrated optical subsystems, each controlled and monitored by dedicated electronics. A Windows-based computer controls and monitors the Graphical User Interface (GUI) and provides convenient storage and retrieval of system data files. The GUI is incorporated on a single surface acoustic wave flat panel touchscreen located to the right of the physician. The GUI is used to display magnified video of the patient’s eye from the on-board video camera, to enter treatment parameters, to display the results of INTEGRAL GUIDANCE with treatment pattern locations overlaid upon it, and to initiate the treatment. The GUI also provides suction ring capture input, including physician placement of the capsulotomy.

WARNINGs

The (laser emission) indicator is displayed on the touchscreen control panel at all times the laser is energized to warn the user that the system is capable of emitting laser energy.

If the control panel is blank, do not use the system. If the screen remains blank for more than 30 seconds, turn off the system with the key, wait at least one minute, and then restart the system. If the screen is still blank, turn off the system and contact OPTIMEDICA Service.

The system is controlled by a dedicated field programmable gate array (FPGA) and is accessed via the host computer. The host computer passes information between the user (via the GUI) and the FPGA control system. The Windows Operating System (OS) within the host computer is not used for any critical system operation nor is it used for safety monitoring, other than to regularly query (“watchdog”) the FPGA and vice-versa. Critical system operations and safety monitoring are executed using dedicated deterministic parallelized circuitry on the FPGA.
Bench Testing

Bench testing of the CATALYS System was conducted to demonstrate the OCT sub-system’s ability to measure depth, surface profiles and iris diameters with accuracy and precision. Various test article substrates of known dimensions were measured multiple times by the system’s OCT sub-system. All OCT-measured values met the test protocol acceptance criteria of ±40µm for all thicknesses and diameters, and ± 1% for all surface radii. This testing verifies that the OCT subsystem of the CATALYS System can measure depth, surface profiles and diameters accurately and precisely.

Bench testing of the CATALYS System was also conducted to demonstrate the system’s ability to deliver a variety of laser patterns intended for capsulotomy or phacofragmentation with corresponding accuracy and precision. In this test, all laser parameters, such as spot spacing, depth spacing and pulse energy, were bracketed to assess the full capability of the system. Additionally, the system’s entire suite of capsulotomy and phacofragmentation patterns was similarly bracketed to test the full spectrum of physician-selectable pattern variations. Multiple samples for a given test pattern were created in a test substrate that was subsequently cross-sectioned and measured using a NIST-traceable reticule, under magnified digital image analysis. All measured values met the test protocol acceptance criteria of ±100µm relative to the intended cut dimensions. The spectrum of pattern testing validated the system capability to cut a variety of capsulotomy and phacofragmentation patterns within specified limits for accuracy and precision.

Bench testing of the CATALYS System was conducted to demonstrate the System’s ability to deliver a variety of laser patterns intended for corneal incisions with corresponding accuracy and precision. In this test, the System’s entire suite of corneal incision patterns was bracketed to test the full spectrum of physician-selectable pattern variations. Multiple samples for a given test pattern were created in a test substrate that was subsequently cross-sectioned and measured using a NIST-traceable reticule, under magnified digital image analysis. All measured values met the test protocol acceptance criteria of ±75µm relative to the intended cut dimensions. The spectrum of pattern testing validated the system capability to cut a variety of single plane and multi-plane arc cuts/incisions patterns within specified limits for accuracy and precision.

Animal and Cadaver Testing

Animal testing was performed to demonstrate retinal and corneal safety. The irradiance levels on the corneal endothelium and retina ranged between 16x-64x greater than the levels allowed in clinical use. Histology samples were collected and analyzed for possible damage retrospectively. The results showed that no damage occurred. Additional animal testing was also conducted to establish the strength of the lens post-capsulotomy. The results demonstrate that the CATALYS System-created capsulotomies are stronger than the capsulorrhexis created by standard continuous curvilinear capsulorrhexis (CCC) surgical technique.

Animal testing was also performed to demonstrate corneal safety. In this test, laser-created corneal incisions and standard manual surgical incisions histology was compared. The laser parameters selected for this performance testing represent a worst case type evaluation, using the minimum horizontal and vertical spot spacing coupled with maximum pulse energy. All
laser-created corneal incisions met the histological acceptance criteria when compared to manual surgical incisions histology.

Cadaver eye testing was also conducted to demonstrate qualitatively the intended laser incisions can effectively cut a variety of tissue types. In this test, laser parameters, such as horizontal and vertical spot spacing, and laser pulse energy were bracketed to assess the full capability of the system. All laser-created corneal incisions met the qualitative acceptance criteria.

**Clinical Summary**

The OPTIMEDICA CATALYS Precision Laser System was clinically evaluated in a prospective, randomized non-inferiority trial in which one eye was randomly assigned to receive treatment with the CATALYS System, including capsulotomy and laser phacofragmentation, followed by standard ultrasound phacoemulsification as necessary. The subject’s contralateral eye, serving as the study Control eye, was assigned treatment with the current “gold standard” surgical technique of continuous curvilinear capsulorrhexis (CCC) and standard ultrasound phacoemulsification. CATALYS System treatment times for the combined capsulotomy and laser phacofragmentation were found to be less than one minute in all subjects. Total procedure time (defined as the total time the subject was under suction and docked to the System) averaged just over 5 minutes with a maximum of 14 minutes.

Capsulotomy efficacy was determined by evaluating the accuracy of the laser capsulotomy compared to CCC surgical Control. The following table shows the difference between the intended and the actual diameter of the capsulotomy (all subjects treated with the CATALYS System) versus capsulorrhexis (Control).

<table>
<thead>
<tr>
<th>Difference from Intended Diameter</th>
<th>CATALYS System</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (µm)</td>
<td>29</td>
<td>339</td>
</tr>
<tr>
<td>Standard Deviation (µm)</td>
<td>26</td>
<td>248</td>
</tr>
<tr>
<td>Minimum (µm)</td>
<td>1</td>
<td>23</td>
</tr>
<tr>
<td>Maximum (µm)</td>
<td>132</td>
<td>1013</td>
</tr>
</tbody>
</table>

Laser phacofragmentation efficacy was determined by comparison of the CATALYS System (all subjects) and surgical Control cohorts’ Cumulative Dissipated Energy (CDE) values reported at the conclusion of the cataract surgery. The CDE value represents the total ultrasound energy delivered during the phacoemulsification and are detailed in the table below.

**Cumulative Dissipated Energy (CDE) Values**

<table>
<thead>
<tr>
<th>Cumulative Dissipated Energy (CDE)</th>
<th>CATALYS System</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>10.39</td>
<td>18.54</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>6.61</td>
<td>12.07</td>
</tr>
<tr>
<td>Minimum</td>
<td>0.91</td>
<td>5.23</td>
</tr>
<tr>
<td>Maximum</td>
<td>27.65</td>
<td>47.86</td>
</tr>
</tbody>
</table>
Safety of the CATALYS System was evaluated by tallying all subject complications and adverse events and comparing these findings to those of the surgical Control cohort. Non-device-related complications and adverse events were found to be comparable between the two cohorts. Device-related complications ascribed to the CATALYS System were limited to petechiae (72% of eyes) and subconjunctival hemorrhage (5% of eyes). All device-related complications were determined to be mild and transitory in nature, as all resolved in less than 30 days without the need for additional medical intervention.
## System Specifications

<table>
<thead>
<tr>
<th><strong>Treatment Laser</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td>Diode pumped solid-state, mode-locked</td>
</tr>
<tr>
<td><strong>Center wavelength</strong></td>
<td>1030 (±5nm)</td>
</tr>
<tr>
<td><strong>Pulse energy</strong></td>
<td>1 - 10µJ</td>
</tr>
<tr>
<td><strong>Pulse duration</strong></td>
<td>&lt;600fs</td>
</tr>
<tr>
<td><strong>Pulse rep. rate</strong></td>
<td>120kHz ±5%, with integer down sampling when modulated on</td>
</tr>
<tr>
<td><strong>CDRH laser class (21 CFR 1040)</strong></td>
<td>Class 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Optical</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numerical aperture</strong></td>
<td>≥ 0.125 (e^-2)</td>
</tr>
<tr>
<td><strong>Scan field, lateral, max</strong></td>
<td>≥14mm diameter, telecentric</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Video Imaging</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td>Monochrome CCD</td>
</tr>
<tr>
<td><strong>Frame rate</strong></td>
<td>&gt;24 frames per second</td>
</tr>
<tr>
<td><strong>Field of view</strong></td>
<td>17mm ±0/-1mm DIA</td>
</tr>
<tr>
<td><strong>Illumination</strong></td>
<td>735nm ±10 nm LED array, variable brightness</td>
</tr>
<tr>
<td><strong>Optical resolution</strong></td>
<td>&lt;40µm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>OCT</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td>Spectral domain</td>
</tr>
<tr>
<td><strong>Center wavelength</strong></td>
<td>820 – 930nm, CW</td>
</tr>
<tr>
<td><strong>Resolution, lateral</strong></td>
<td>15µm or better at focus</td>
</tr>
<tr>
<td><strong>Resolution, axial</strong></td>
<td>30µm or better</td>
</tr>
<tr>
<td><strong>CDRH class (21 CFR 1040)</strong></td>
<td>Class 3R</td>
</tr>
<tr>
<td><strong>ANSI Z136.1</strong></td>
<td>Class 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Patient Interface – Aqueous Contact (LIQUID OPTICS Interface)</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contact element</strong></td>
<td>Sterile buffered saline solution, such as Alcon BSS (Alcon P/N 351/55005-1) or equivalent (not supplied).</td>
</tr>
<tr>
<td><strong>Inner diameter</strong></td>
<td>14.5mm (LIQUID OPTICS Interface) 12.0mm (LIQUID OPTICS Interface-12)</td>
</tr>
<tr>
<td><strong>Fixation method</strong></td>
<td>Annular vacuum flange onto sclera</td>
</tr>
<tr>
<td><strong>Suction ring seal material</strong></td>
<td>Medical grade silicone elastomer</td>
</tr>
<tr>
<td><strong>Vacuum pressure</strong></td>
<td>300 – 700mmHg (gauge)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Environmental Requirements (Operating)</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum altitude</strong></td>
<td>7,000 ft (2,134m)</td>
</tr>
<tr>
<td><strong>Temperature range</strong></td>
<td>59 – 89.6°F (15 – 32°C)</td>
</tr>
<tr>
<td><strong>Maximum humidity</strong></td>
<td>Up to 80% @ 89.6°F (32°C) non-condensing</td>
</tr>
<tr>
<td><strong>Operating Environment</strong></td>
<td>Temperature controlled environment with temperature controlled to within ±3.6°F (±2°C)</td>
</tr>
<tr>
<td>Environmental Requirements (Non-operating)</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Maximum altitude</td>
<td>Standard commercial shipping altitude</td>
</tr>
<tr>
<td>Temperature range</td>
<td>14 – 131°F (-10 – 55°C)</td>
</tr>
<tr>
<td>Maximum humidity</td>
<td>Up to 80% @ 131°F (55°C) non-condensing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>1.15m ±.025m</td>
</tr>
<tr>
<td>Length</td>
<td>1.64m ±.025m</td>
</tr>
<tr>
<td>Width</td>
<td>0.87m ±.025m</td>
</tr>
<tr>
<td>Weight</td>
<td>340kg (750lbs)</td>
</tr>
<tr>
<td>Optical NOHD</td>
<td>0m</td>
</tr>
<tr>
<td>Laser Safety Eyewear</td>
<td>Not required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IO</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Display</td>
<td>GUI: touch-screen, flat panel</td>
</tr>
<tr>
<td>Power cable length</td>
<td>≥8.2 ft (2.5m), detachable</td>
</tr>
</tbody>
</table>

*OPTIMEDICA reserves the right to make changes to the device(s) herein. Device(s), therefore, may not agree in detail with the published design or specifications. All specifications are subject to change without notice. Contact OPTIMEDICA or your local OPTIMEDICA representative for information on changes and new products.
System Installation and Setup

Overview

The CATALYS System is intended for use by trained Ophthalmologists for the treatment of cataracts. The system is designed for installation and use inside a sterile operating room or in a non-sterile pre-op area within an ambulatory surgery center (ASC) or a hospital. System installation and testing will be performed by OPTIMEDICA-certified personnel.

The CATALYS System is equipped with a detachable 3-wire AC power cord. When selecting the location for system installation, a correctly grounded power connection is required for safe system operation. Therefore, it is mandatory that the AC wall power outlet is correctly grounded and is rated for the electrical load of the system. Turn off the system circuit breakers and remove the system electrical power cord to isolate the system from mains power source. Follow local electrical codes to ensure proper grounding of the AC wall power outlet. An appropriate location for the CATALYS System must be selected such that it can accommodate the system size and allow for easy access by the patient, physician, nurse and/or assistant and OPTIMEDICA Service Personnel. The rear of the system must remain clear after installation to provide access to the system power cord, circuit breakers and remote interlock connections.

Proper system operation requires the selection of a well-ventilated space in an office or surgery room with a temperature controlled environment. The system will function at ambient temperatures between 15°C (59°F) and 32°C (89.6°F) with controlled relative humidity between 0% and 80% non-condensing. The Heating Ventilation and Air Conditioning (HVAC) system used to control the temperature in the installation environment must be able to control the temperature within ±2°C (±3.6°F) of the temperature set-point for the system to operate correctly. If the temperature of the installation environment changes by more than ±2°C (±3.6°F) during a 45 minute period, the system will shut down. If the temperature of the installation environment goes below 15°C or above 32°C at any time, the system will shut down. The system should be positioned such that the treatment beam is aimed away from any windows or doors. A laser safety sign must be posted at the entrance to the treatment room.

Do not block cooling airflow or cooling vents on the laser system. Allow at least 5 cm (2 in) of clear space around the laser system to provide adequate system cooling airflow. Use care when routing system cables to prevent a tripping hazard. If cords or cables must cross a floor where there is traffic, use of a floor cord/cable cover is recommended.

⚠️ WARNINGS

The detachable AC power cord is the main disconnect of the equipment from mains AC power. The detachable AC power cord must be disconnected from the system to ensure the system is completely isolated from mains AC power. Make sure adequate space is available during system installation to allow access to the AC power cord, the system circuit breakers, the remote interlock connector, and other rear panel connections.

Do not replace AC power cord. The CATALYS System is approved for use with the AC Power Cord supplied with the system. If a replacement AC Power Cord is required, contact OPTIMEDICA Service to obtain the correct replacement part for your system.
Connecting the System Components
Before starting up the system, connect the CATALYS System components as follows:

1. Insert the corresponding end of the power cable into the CATALYS System main power receptacle.

2. Insert the door interlock connector, laser footswitch cable, and vacuum footswitch cable into the respective receptacles. These are locking and keyed connectors. Align the red dot on the connector with the red dot on the receptacle, and insert the connector until it snaps in place.

3. Insert the opposite end of the system power cable into an appropriate wall power outlet.

4. If desired, connect to an NCast Telepresenter, connect to a network, and set up network printing and remote connectivity, as described on the following pages.

System Rear Panel Connections
Connecting to an NCast Telepresenter Video Recording System (optional)
The CATALYS System is equipped with a video output port that will provide streaming video of
treatments performed by the system for:

- Display on an external monitor for viewing by family members and training
- Recording on an external video recording device, such as the NCast Telepresenter or
equivalent, for archival purposes

If desired, connect the CATALYS System to an NCast Telepresenter video recording system, or
equivalent user-supplied video recording equipment, as follows:

1. Connect the video cable to the cable receptacle on the rear of the system console.
2. Set up the video recording system per the manufacturer’s instructions.

NOTES
When connecting an external video recording device to your CATALYS System, use only the video
cable that was supplied with your CATALYS System. The video cable supplied with your CATALYS
System is designed to work with your CATALYS System and matches the connector located on
the system rear panel. The video cable must be a minimum of six feet long.

Do not place the NCast Telepresenter system or equivalent user-supplied video recording
equipment on or near the CATALYS System when in use.

Connecting to a Network (optional)
The CATALYS System is equipped with an RJ45 network connection on the system rear panel.
Connecting the CATALYS System to a network allows for:

- Network printing of treatment reports
- Remote system access by OPTIMEDICA Service Personnel to view system performance
  logs and perform system diagnostics

OPTIMEDICA shall make available detailed instructions for implementing the optional network
connection, upon written request by any appointed Medical-IT Risk Manager. Please direct all
requests to 1-800-511-0911.
CAUTION

Connection of the CATALYS System to a customer network that includes other networked equipment could result in previously unidentified risks. During system installation, OPTIMEDICA-trained personnel will review the installation site network with the installation site IT administrator to identify, analyze, evaluate and control these risks. Subsequent changes to the installation site network could introduce new risks due to:

- Changes to the network configuration
- Connection of additional devices to the network
- Disconnection of devices from the network
- Update and/or upgrade of equipment connected to the network

The internal Hardware Security Appliance (HSA) installed on the CATALYS System is designed to mitigate these risks to an acceptable level. Access to the HSA is limited to OPTIMEDICA-trained personnel only. The HSA is not user-accessible. The HSA blocks attack attempts from any source outside the CATALYS System.

NOTES

Network communication is only available between the system and OPTIMEDICA. Network communication must be initiated and approved by a trained system user and confirmed by OPTIMEDICA Service Personnel before the remote connection can be enabled.

If system performance or speed degrades when connected to a network, disconnect the CATALYS System from the network and contact OPTIMEDICA Service for assistance.

Firewall Configuration

All inbound ports are blocked by default, not allowing any form of outside traffic to establish inbound communication with the CATALYS System.

WAN Configuration

The CATALYS System is capable of receiving an IP address from the customer LAN via a DHCP request. The CATALYS System will be configured by OPTIMEDICA-trained personnel to a static IP address, in the place of DHCP, if required by the site IT contact.

Network Ports

The CATALYS System is equipped with a single RJ45 Ethernet connection in the system rear panel. The Ethernet port conforms to the minimum requirements of:

- Ethernet standard 802.3u - 100BASE-TX, 100BASE-T4, 100BASE-FX
- Fast Ethernet at 100 Mbps (12.5 Mbps) w/auto-negotiation

The Ethernet port to which the CATALYS System is connected at the installation site must conform to these same standards and have active access to the internet via port 80 or 443.
Network Cabling
Ethernet cables connected to the CATALYS System must be Category 6 and meet all the requirements defined in the IEEE 802.3 standards. Ethernet cables must follow the straight through design. Cables cannot use the crossover design. Maximum cable length must not exceed 100 m (330 ft). There is no specified minimum length per the IEEE standard.

Setting Up Network Printing and Remote Connectivity (optional)
If desired, you can print treatment reports to a networked printer and/or establish remote connectivity with OPTIMEDICA Service Personnel. The CATALYS System must be configured to print to the networked printer by OPTIMEDICA-trained personnel during system installation. If the desired printer is changed or a new printer is added to your network, contact OPTIMEDICA Service to have the networked printer configured for use with your CATALYS System. To set up network printing and remote connectivity:

1. Connect an Ethernet cable to the RJ45 Network receptacle on the rear of the system console.
2. Connect the other end of the Ethernet cable to your local network port.
3. When logged in with administrative privileges, press the ENABLE NETWORK button on the Settings Screen.

The network connection is automatically disabled during treatment. To disable the network connection, press the DISABLE NETWORK button on the Settings Screen.

NOTE
Refer to the “Printing the Treatment Report(s)” section of this manual for detailed instructions on printing the treatment report to a network printer.

Moving the System
The CATALYS System is a delicate medical instrument and is not designed for the user to move or relocate the system after installation. If the system needs to be moved or relocated within the installation facility, contact OPTIMEDICA. Moving the system must be performed by trained OPTIMEDICA personnel.

Trained OPTIMEDICA Service Personnel will de-install the system and take the precautions necessary to ensure a successful move. Once the system has been positioned into its new location, trained OPTIMEDICA personnel will re-install and test the system to ensure it is operating within specification.
System Basics

Starting Up the System

1. Verify that the system components are properly connected and that the main power cable is connected to an appropriate wall power outlet, as described on the previous page.

2. Ensure that the system main power circuit breakers are in the ON position.

3. Insert the key into the key switch. Turn the key clockwise to the (START) position and immediately release. It may take up to 2 minutes for the computer screen to appear active.

⚠️ CAUTION

Do not hold the key in the start position for more than two seconds. If the key is held in the start position for more than two seconds, the system will return to the BIOS screen and shutdown. In the event of a system shutdown, you must contact the OPTIMEDICA Service Department at +1-800-511-0911. Re-starting the system will require a 45-minute warm-up period.

A system self-test and start-up routine begins, and the following screen displays on the system control panel:

Start-up Screen

When the system self-test and start-up is complete, the Login Screen displays.

⚠️ CAUTION

If the control panel remains blank for an extended period of time during system start-up, press the Power button on the front of the control panel to turn on the control panel. If the control panel remains blank, turn off the system with the key, wait at least one minute, and then restart the system. If the screen is still blank, turn off the system and contact OPTIMEDICA Service.
Logging Into the System

Enter your user name and password on the Login Screen, and then press the LOGIN button to log into the CATALYS System. If you cannot remember your username or password, press the CAN’T ACCESS ACCOUNT? button to submit a request to your CATALYS System administrator.

NOTE

During system installation at your facility, one system administrator will be set up to manage system users. Contact your CATALYS System administrator to set up additional user accounts.

Login Screen

The first time you log into the system, you are prompted to enter a new password. Enter and re-enter your new password, then press the ENTER key on the on-screen keyboard or the APPLY CHANGES button in the Enter New Password window to proceed to the Home Screen.

“Enter New Password” Window
Enabling the System

The CATALYS System has two operating states:

- Control panel enabled; system and laser disabled
- Control panel, system, and laser enabled

Only the control panel is enabled at system start-up. You can add new treatment plans and edit previously added treatment plans with only the control panel enabled. However, you cannot perform laser treatment until the system and laser are also enabled.

Prior to laser treatment, enable the system by pressing the ENABLE SYSTEM button on the Home Screen. The Enabling System window displays.

The system runs a system-wide self-test and safety check, and you are prompted to move the Disposable Lens carriage up and down through its full range of travel. Save the red protective lens cover that is provided with each CATALYS System.

Next, the system checks for the presence of the disposable lens. If a lens is present, you are prompted to remove the lens before continuing.

At the completion of the system-enabling sequence, press the OK button to close the Enabling System window.

One of the following laser status icons displays at the top of each screen to alert you to the laser status:

- **Asleep**: Laser is disabled/asleep; no laser energy is available
- **Waking**: Laser is powering up; no laser energy is available
- **Standby**: Laser power-up is complete, but treatment energy is not available
- **Ready**: Laser is ready to treat; footswitch is enabled (displays on Final Review Screen and Treatment Paused Screen only)
- **Treat**: Laser energy is being delivered (displays on Treatment Progress Screen only)
Verifying System Alignment

Every day, prior to use, a trained operator must verify that the CATALYS System is aligned. To verify that the system is in alignment, a simulated capsulotomy and fragmentation is performed on a plastic test hemisphere that serves as the simulated lens. Please order by calling Customer Service at +1-877-266-4543.

⚠️ CAUTIONS

Use only OPTIMEDICA part number SA-08044 for verifying system alignment. Previous versions of the plastic hemispheres are obsolete and should not be used.

System alignment verification must be performed by a trained operator on a daily basis prior to use, per the following instructions.

NOTE

Refer to the “Intraoperative Instructions” section of this manual for detailed instructions on the docking and undocking procedures described in the following steps.

To verify the system alignment:

1. From the Home Screen or Administrator Home Screen, press the VERIFY ALIGNMENT button to go to the Verify Alignment Screen.

2. As instructed on the screen, prepare the LIQUID OPTICS Interface and a new plastic test hemisphere for docking. Ensure that the suction ring handle is facing left and that the patient chair is latched in one of the three positions.

3. Press the CONFIRM button to continue to the Verify Alignment Docking Screen.

4. As instructed in the Disposable Lens panel, install the disposable lens.
5. When the system detects that the disposable lens has been properly installed, the Vacuum panel opens. As instructed in the Vacuum panel, place and center the suction ring of the LIQUID OPTICS Interface on the plastic test hemisphere, apply patient vacuum, then add sterile buffered saline solution to the suction ring.

6. When the system detects that the suction ring has been placed and the patient vacuum applied, either the Latch panel or the Capture panel opens, depending on whether or not you have latched the patient chair into position. If you have not already done so, latch the patient chair.
7. When the patient chair is latched, the Capture panel opens. As instructed in the Capture panel, raise the suction ring until the indicator arrow on the right is within the Capture Zone, as shown in the following figure.

8. When the indicator arrow is within the Capture Zone, press the CAPTURE button on the docking keypad to capture the suction ring in the disposable lens.

9. When the system detects that the suction ring has been captured, the Lock panel opens. As instructed in the Lock panel, adjust the position of the suction ring until all three indicators (i.e., the vertical green bar on the left, circular green area over the video, and vertical green bar on the right) are within their respective Lock Zones, as shown in the following figure.
10. When the three indicators are within their respective Lock Zones, press the LOCK button on the docking keypad.

11. When the system detects that the lock has been secured, the Verify Fluid panel opens. As instructed in the Verify Fluid panel, verify that the LIQUID OPTICS Interface is completely filled with fluid and that no air bubbles are present.

12. After verifying the fluid, press the FLUID CONFIRMED button to go to the Verify Scan Screen and initiate INTEGRAL GUIDANCE.
13. When INTEGRAL GUIDANCE is complete, verify that the overlay matches the suction ring alignment marks. If the alignment marks are contained within the overlay, press the YES button to go to the following screen.

**NOTE**

*If the alignment marks are not contained within the overlay, press the NO button to proceed to the Verify Alignment Results Screen. Refer to step 18 below.*

14. After verifying that the overlay matches the suction ring alignment marks, press and hold the laser footswitch to initiate laser treatment. Continue pressing the footswitch until the progress bar on the Treating Screen reaches 100%.
NOTE
If you lift the footswitch before the progress bar shows 100%, the following error displays. Press the OK button, and then press and hold the footswitch to resume laser treatment.

15. When laser treatment is complete, the Verify Treatment Screen displays. You can position the Treatment Scroll Slider to view various images that were captured during the laser treatment. Position the slider near the left side, and, using the suppress overlay button to hide and reveal the overlay images, verify that the fragmentation pattern is completely contained within the blue fragmentation overlay. If the fragmentation pattern is completely contained within the fragmentation overlay, press the YES button.
NOTE
If the fragmentation pattern does not match the fragmentation overlay, press the NO button to proceed to the Verify Alignment Results Screen. Refer to step 18 below.

16. Position the slider to the first image that has bubbles of any size over approximately 50% of the capsulotomy circumference. Press the OK button.

Image with Correct Amount of Bubbles

Image with Too Many Bubbles

Image with Too Few Bubbles
17. If system alignment is acceptable, “Verify Alignment Successful” displays on the Verify Alignment Results Screen.

18. If system alignment is unacceptable, “Verify Alignment Failed” displays on the Verify Alignment Results Screen. Contact OPTIMEDICA Service for assistance.

19. As instructed on the Verify Alignment Results Screen:
a. Release vacuum and capture using the docking keypad.

b. Remove the disposable lens.

c. Press the RETURN TO HOME button to return to the Home Screen.

Disabling the System

At the end of the treatment day, or if the system will not be used for at least 45-60 minutes between patients, disable the system by pressing the DISABLE SYSTEM button on the Home Screen. The Confirm Disable System window displays. Press the OK button to disable the system.

NOTE
To use the system after disabling it, the system will need to be enabled and will require a 45-minute warm-up period.

Confirm Disable System Window

After pressing the OK button, the Disabling System window displays. At the completion of the system-disabling sequence, press the OK button to close the Disabling System window.

Disabling System Window

Shutting Down the System

Except during an emergency, you must shut down the system from the Login Screen. To access the Login Screen from the Home Screen, press the LOGOUT button in the upper right corner of the screen.
Location of LOGOUT Button on the Home Screen

To access the Login Screen from a Treatment Planning Screen, press the HOME button in the upper right corner of the screen to go to the Home Screen, and then press the LOGOUT button on the Home Screen.

Location of HOME Button on the Treatment Planning Screen

From the Login Screen, press the SHUTDOWN button. The Confirm Shutdown window displays in the center of the screen. Press the OK button, and wait for the system to shut down.
Turn the key switch to the (OFF) position and remove the key to prevent unauthorized use of the system.

**NOTE**
*If the power cable is still connected to the electrical source, some internal circuits remain energized. To de-energize all internal circuits, switch the main system circuit breakers to the O (OFF) position and unplug the power cable from the wall.*

**Emergency Shut-down**

If the CATALYS System becomes unresponsive during system operation, press the emergency laser stop button. Pressing the emergency laser stop button rapidly disables all laser emission, disabled the patient chair, and disables the LIQUID OPTICS Interface vacuum system, thereby ensuring that the system and laser are in a safe state and that no laser emission is possible.

Press the LOGOUT button on the Home Screen and the SHUTDOWN button on the Login Screen to completely shut down the system. Turn the key switch to the (OFF) position before restarting the system.

To restart the CATALYS System after an emergency shut-down, rotate the emergency laser stop button to disengage it, and then start the system using the key switch.

**WARNING**
*If the system becomes unresponsive at any time, press the emergency laser stop button and turn the key to the (OFF) position.*

**NOTE**
*The emergency laser stop button is a latching switch that will remain depressed until the button is rotated to disengage it.*
Software Navigation
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Overview

The CATALYS System features six types of control screens:

- **Administrative Screens**—allow the system administrator to manage system users and adjust system settings; allow users to log into, log out of, and shut down the system and to search, view, and print treatment reports
- **Planning Screens**—allow users to add and edit treatment templates, to add, edit, and initiate treatment plans, to enable/disable the system, and to enable/disable the laser
- **Surgical Timeout Screen**—allows users to verify patient details and treatment parameters before proceeding to the Docking Screen
- **Docking Screen**—guides users through the process of positioning the suction ring, applying vacuum, and capturing the suction ring
- **Treatment Screens**—allow users to perform 3-D INTEGRAL GUIDANCE imaging, to verify and customize parameters prior to laser treatment, and to initiate and monitor laser treatment
- **Undocking Screen**—guides users through the process of releasing the patient, removing the LIQUID OPTICS Interface, and reviewing the treatment report

Control Screen Conventions

The following buttons and icons display at the top of most screens:

<table>
<thead>
<tr>
<th>Button/Icon</th>
<th>Description/Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>🟢</td>
<td>Help button—press to view on-screen Operator Manual</td>
</tr>
<tr>
<td>🏡</td>
<td>Return to Home Screen button—press to return to Home Screen</td>
</tr>
<tr>
<td>🟢</td>
<td>Treatment activation status icon—shows current treatment activation status (black = not activated; green = activated; red = LIQUID OPTICS Interface already consumed)</td>
</tr>
</tbody>
</table>

In addition, the laser status icon displays at the top of most screens. Refer to the “Enabling the System” section for a description of the laser status icons.
**Quick Navigation Bar**

All planning and most treatment screens have a Quick Navigation Bar at the bottom of the screen that allows you to easily navigate between screens. Refer to the following table for a description of the icons in the Quick Navigation Bar.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Press to go to…</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Icon" /></td>
<td>Plan a Treatment Screen</td>
</tr>
<tr>
<td><img src="image2.png" alt="Icon" /></td>
<td>Capsulotomy (Basic) or Details Screen</td>
</tr>
<tr>
<td><img src="image3.png" alt="Icon" /></td>
<td>Lens Fragmentation (Basic) or Details Screen</td>
</tr>
<tr>
<td><img src="image4.png" alt="Icon" /></td>
<td>Arcuate Incisions (Basic) or Details Screen</td>
</tr>
<tr>
<td><img src="image5.png" alt="Icon" /></td>
<td>Cataract Incisions (Basic) or Details Screen</td>
</tr>
<tr>
<td><img src="image6.png" alt="Icon" /></td>
<td>Treatment Summary or Final Review Screen</td>
</tr>
</tbody>
</table>

**Informational Icons**

In addition to the icons in the Quick Navigation Bar, there are two icons that provide treatment-related information. Refer to the following table for a description of the informational icons.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image7.png" alt="Icon" /></td>
<td>The orientation icon represents the orientation of the selected eye. When using cyclorotation compensation, the icon rotates to display axis markings for your reference. The colored ring provides a visual indication of the forces exerted on the disposable lens. The ring is green when the forces exerted on the disposable lens are within an acceptable range to lock the suction ring/disposable lens assembly to the system. The ring is yellow when the forces exerted on the disposable lens rise to a level of concern. The ring is orange when the forces exerted on the disposable lens rise to a level that will stop an OCT scan or a laser treatment. The ring is red when the forces exerted on the disposable lens rise to an unacceptable level.</td>
</tr>
</tbody>
</table>

**NOTES**

*If the ring is orange or red during INTEGRAL GUIDANCE, you must press the RESCAN EYE button to proceed.*

*If the ring is red during the docking process, the system will undock the patient after 3 seconds. If the ring is red during laser treatment, the system will undock the patient after 1 second.*
Administrative Screens

Home Screen

There are two different Home Screens: one for the CATALYS System operator and another for general users. In this manual, the Home Screen for the CATALYS System administrator is referred to as the “Administrator Home Screen” and the Home Screen for general users is referred to simply as the “Home Screen”.

The CATALYS System administrator has access to several features that are not accessible to other users. When the administrator logs into the system using the administrator username and password, the Administrator Home Screen displays. From the Administrator Home Screen, the administrator can:

- Go to the Users Screen, All Treatments & Reports Screen, Surgeon Templates Overview Screen, and Settings Screen
- Verify system alignment
- Add new treatment plans and edit previously added treatment plans
- Initiate a treatment plan
- Enable/disable the system and laser
- Return to the Login Screen
- Open the Software Info window

NOTE
Refer to the “Planning Screens” section in this manual for detailed information on creating and editing treatment plans.

Administrator Home Screen
After logging into the CATALYS System as a general user, the Home Screen displays. From the Home Screen, you can:

- Add new treatment plans and edit previously added treatment plans
- Initiate a treatment plan
- Enable/disable the system and laser
- Go to the Login Info Screen, All Treatments & Reports Screen, and Surgeon Templates Overview Screen
- Verify system alignment
- Return to the Login Screen
- Open the Software Info window

Home Screen
If you select a patient on the Home Page, the Treatments list will expand to show all treatment plans that have identical First Name, Last Name, ID, and Date of Birth. From this page, you can create a new treatment plan for this patient, as shown in the following figure.

**NOTES**
During treatment planning, you can return to the Home Screen at any time by pressing the HOME button in the upper right corner of the treatment planning screens.

Refer to the “Planning Screens” section in this manual for detailed information on creating and editing treatment plans.
**Users Screen**

From the Administrator Home Screen, press the USERS button to go to the Users Screen. From the Users Screen, the administrator can:

- Add user accounts
- Assign user permission levels
  - Admin—user has administrator privileges, as described in this section
  - General—user can plan and start treatments and perform system calibration and self-test
  - Disabled—user has no permissions
- Reset user passwords
- View requests for user accounts submitted from the Login Screen
- Sort users by name, requests, or permissions

![Users Screen](image)
All Treatments & Reports Screen

From the Home Screen or Administrator Home Screen, press the ALL TREATMENTS & REPORTS button to go to the All Treatments & Reports Screen. From the All Treatments & Reports Screen, you can:

- View a list of patients for whom there are incomplete, complete and/or aborted treatments
- View a list of treatments for each patient
- Search treatments by patient name, ID, date of birth, treatment date, and/or treatment status (i.e., pending, treated, aborted, disabled)
- Enable or disable incomplete treatments
- Go to the Treatment Results Screen for the selected treatment
- Print treatment reports to the network printer
- Save treatment reports as PDF files
- View the total number of treatments performed

NOTES

The number of reports that will print or be saved to PDF is displayed on the right side of the PRINT ALL and SAVE ALL TO PDF buttons. If no search parameters are entered, then “all” refers to the total number of pending, treated, aborted or disabled treatments created by all users. If search parameters are entered (e.g., Status: Pending), then “all” refers to the number of treatments that fit the search parameters. To print a single treatment report, select the desired treatment, then press the PRINT SELECTED or SAVE SELECTED TO PDF button.

Refer to “Printing the Treatment Report(s)” and “Saving the Treatment Report(s)” in the following section for additional instructions.
Treatment Results Screen

From the All Treatments & Reports Screen, select the desired patient to view a list of treatments for that patient. Select the desired treatment from the list, and then press the SHOW TREATMENT RESULTS button to go to the Treatment Results Screen for that treatment. From the Treatment Results Screen, you can:

- View treatment results
- Scroll through the treatment report
- Save the treatment report as a PDF file
- Print the treatment report to a network printer
- Return to the All Treatments & Reports Screen
Printing the Treatment Report(s)

To print the treatment report(s) to a network printer:

1. Ensure that the network is enabled, as described in the “Setting Up Network Printing and Remote Connectivity (optional)” section of this manual.

2. From the All Treatments & Reports Screen, press the PRINT ALL or PRINT SELECTED button, or from the Treatment Results Screen, press the PRINT button.

3. Select the report type (Video Images, Cross Section Images, and/or Text), and press the OK button.

4. Select the target printer, and press the PRINT button.
NOTE
If the target printer does not display on the screen, press the REFRESH button.

5. After printing, press the OK button to return to the All Treatments & Reports or Treatment Results Screen.

Saving the Treatment Report(s)

To save the treatment report to a USB flash drive:

1. From the All Treatments & Reports Screen, press the SAVE ALL TO PDF or SAVE SELECTED TO PDF button, or from the Treatment Results Screen, press the SAVE TO PDF button.

2. As instructed on the screen, insert a USB storage device into one of the two USB ports on the system front panel.
CAUTION

*Do not connect anything other than a USB flash drive to the CATALYS System USB ports.*

3. Enter a file name in the window, and press the SAVE button.

![Image 1](image1.png)

4. Verify that the target USB storage device displays on the screen, and press the SAVE button.

![Image 2](image2.png)

**NOTE**

*If the target USB storage device does not display on the screen, press the REFRESH button. If more than one storage device is connected to the system, then press the icon for the target device.*

5. After the file has been successfully saved, press the OK button to return to the All Treatments & Reports or Treatment Results Screen.

![Image 3](image3.png)
Sample Report

On the following pages is a sample report with graphics.
Patent: Doe, John  
ID: 12345  
Surgeon: Robert Wise  

Date of Birth: 07/15/1945  
Eye Treated: Left  
Treatment Date: 10/01/2016  

Axial  

Sagittal  

Axial  

Sagittal  

NOTES: ____________________________________________  Page 3 of 8
### Patient Information

- **Central Corneal Thickness**: 508 μm
- **Aqueous Depth**: 2.7 mm
- **Anterior Chamber Depth**: 3.3 mm
- **Lens Meridian Position**: 5.1 mm

### Treatment Times

- **Vacuum Time (mm:ss)**: 2:54
- **Total Laser Time**: 21.0 s
- **Surgical Timeout (hh:mm)**: 01:07 PM
- **Treatment Complete (hh:mm)**: 01:10 PM

### Capsulotomy

- **Template Name**: Custom
- **Incision Depth**: 600 μm
- **Pattern**: Circular
- **Horizontal Spot Spacing**: 6 μm
- **Diameter**: 6.0 mm
- **Vertical Spot Spacing**: 10 μm
- **Center Method**: Pupil
- **Pulse Energy**: 4.6 μJ
- **Laser Time Capsulotomy**: 20 s
- **Incision Status, Capsulotomy**: Treated

### Lens Fragmentation

- **Template Name**: Custom
- **Segmentation Repetitions**: 3
- **Segmentation and Softening**: Quadrants
- **Horizontal Spot Spacing**: 10 μm
- **Softened**: Vertically
- **Vertical Spot Spacing**: 40 μm
- **Diameter Type**: Maximized
- **Anterior Pulse Energy**: 8.0 μJ
- **Limited Diameter**: NA
- **Anterior Pulse Energy**: 10.0 μJ
- **Seg-Soft Spacing**: 200 μm
- **Anterior Capsule Safety Margin**: 500 μm
- **Grid Spacing**: 350 μm
- **Posterior Capsule Safety Margin**: 500 μm
- **Laser Time, Lens Frag**: 15.0 s
- **Incision Status, Lens Frag**: Treated

### Arcuate Incisions

- **Template Name**: Custom
- **Type**: Symmetric
- **Center Method**: Pupil
- **Horizontal Spot Spacing**: 6 μm
- **Penetration Type**: Anterior
- **Vertical Spot Spacing**: 10 μm
- **Depth Unit**: Percent
- **Pulse Energy**: 60 μJ
- **Uncut Anterior**: NA
- **Anterior Line Density**: 10
- **Uncut Posterior**: 20 %
- **Anterior Line Distance**: 30 %
- **Side Cut Angle**: 90 deg
- **Central Line Density**: 4
- **Laser Time, Arcuate**: 20 s
- **Total Energy, Arcuate**: 20 J
- **Axis 1**: 45 deg
- **Axis 2**: 225 deg
- **Optical Zone 1**: 9.0 mm
- **Optical Zone 2**: 9.0 mm
- **Length 1**: 20 deg
- **Length 2**: 20 deg
- **Cornea Thickness 1**: 500 μm
- **Cornea Thickness 2**: 500 μm
- **Total Energy 1**: 1.0 J
- **Laser Time 1**: 1.0 s
- **Incision Status 1**: Treated

### Notes

- The CATALYS Precision Laser System Operator Manual is part of the medical documentation for surgical procedures.
- It includes detailed specifications for the treatment, including the patient's information, treatment times, and parameters for incision and fragmentation.
- The manual provides a comprehensive guide for operators to ensure accurate and safe surgical procedures.

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### Cataract Incisions (Primary)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Template Name:</td>
<td>Custom</td>
</tr>
<tr>
<td>Primary(1):</td>
<td>1</td>
</tr>
<tr>
<td>Cyclorotation Compensation:</td>
<td>Off</td>
</tr>
<tr>
<td>Uncut Region:</td>
<td>Central</td>
</tr>
<tr>
<td>Depth Unit:</td>
<td>Percent</td>
</tr>
<tr>
<td>Uncut Anterior/Posterior:</td>
<td>NA</td>
</tr>
<tr>
<td>Anterior Plane Depth:</td>
<td>26 μm</td>
</tr>
<tr>
<td>Posterior Plane Depth:</td>
<td>70%</td>
</tr>
<tr>
<td>Anterior Side Cut Angle:</td>
<td>45°</td>
</tr>
<tr>
<td>Laser Time, All Primary:</td>
<td>1.0 s</td>
</tr>
<tr>
<td>Total Energy, All Primary:</td>
<td>1.0 J</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axis 1:</td>
<td>0°</td>
</tr>
<tr>
<td>Limbus Offset 1:</td>
<td>0.6 mm</td>
</tr>
<tr>
<td>Auto Limbus Offset 1:</td>
<td>Off</td>
</tr>
<tr>
<td>Width 1:</td>
<td>25 mm</td>
</tr>
<tr>
<td>Length 1:</td>
<td>1.5 mm</td>
</tr>
<tr>
<td>Cornea Thickness 1:</td>
<td>600 μm</td>
</tr>
<tr>
<td>Total Energy 1:</td>
<td>1.0 J</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision Status 1:</td>
<td>Treated</td>
</tr>
</tbody>
</table>

### Cataract Incisions (Sideport)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Template Name:</td>
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</tr>
<tr>
<td>Sideport(1):</td>
<td>1</td>
</tr>
<tr>
<td>Cyclorotation Compensation:</td>
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<td>Uncut Region:</td>
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<tr>
<td>Depth Unit:</td>
<td>Percent</td>
</tr>
<tr>
<td>Uncut Anterior/Posterior:</td>
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<tr>
<td>Anterior Plane Depth:</td>
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</tr>
<tr>
<td>Posterior Plane Depth:</td>
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</tr>
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<td>Anterior Side Cut Angle:</td>
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</tr>
<tr>
<td>Laser Time, All Sideport:</td>
<td>1.0 s</td>
</tr>
<tr>
<td>Total Energy, All Sideport:</td>
<td>1.0 J</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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<td>Width 1:</td>
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<tr>
<td>Length 1:</td>
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</tr>
<tr>
<td>Cornea Thickness 1:</td>
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</tr>
<tr>
<td>Laser Time 1:</td>
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</tr>
<tr>
<td>Incision Status 1:</td>
<td>Treated</td>
</tr>
</tbody>
</table>

NOTES:
Surgeon Templates Overview Screen

From the Home Screen or Administrator Home Screen, press the SURGEON TEMPLATES button to go to the Surgeon Templates Overview Screen. From the Surgeon Templates Overview Screen for administrators, you can:

- Add new surgeon template sets and edit previously added surgeon template sets
- Enable or disable surgeon template sets
- Copy surgeon template sets

Surgeon Templates Overview Screen for Administrators

Add Surgeon Template Set

Enable Template Set

Disable Template Set

Copy Template Set

Edit Template Set

Return to Previous Screen
From the Surgeon Templates Overview Screen for general users, you can edit previously created surgeon template sets.

**Surgeon Templates Overview Screen for General Users**

- **Edit Surgeon Template Set**
- **Return to Previous Screen**
**Surgeon Template Screens**

From the Surgeon Templates Overview Screen for administrators, select a surgeon name and press the EDIT button to go to the Surgeon Template Screens for that surgeon. From the Surgeon Templates Overview Screen for general users, select a surgeon name to go to the Surgeon Template Screens for that surgeon. From the Surgeon Template Screens, you can:

- Add a new template and edit previously added templates
- Set default parameters
- Set overlay settings for this surgeon
- Set general preferences for this surgeon

**NOTE**

Refer to the “Planning Screens” section in this manual for detailed information on creating and editing surgeon templates and setting default parameters.
Surgeon Template Screen for Arcuate and Cataract Incisions

- Add an Arcuate Incisions Template
- Set Default Arcuate Incisions Parameters
- Add a Cataract Incisions Template
- Set Default Cataract Incisions Parameters
- Set Overlay Settings
- Set General Preferences
- Go to Surgeon Template Screen for Capsulotomy and Lens Fragmentation
- Return to Previous Screen
**Overlay Drag Settings Screen**

From the Overlay Drag Settings screens, you can:

- Adjust the overlay effect during visualization, customization, and laser treatment
- Select whether to automatically turn on the overlay effect
- Hide incisions during capsulotomy
- Adjust the touchscreen drag sensitivity
Adjusting the Overlay Effect

Overlay images display on all treatment screens to provide a visual representation of the selected treatment parameters. The default setting is for solid overlay images to display on all treatment screens. However, you can adjust the overlay effect from the Settings Screen so that the overlay images blink fast, blink slow, fade fast, fade slow, or are hidden.

To select the overlay effect on the Surface Mapping Review, Incision Review, Incision Adjustment, and Final Review Screens, select the desired setting from the Visualize & Customize Overlay Effect drop-down menu. To select the overlay effect on the Treatment Progress Screen, select the desired setting from the Laser Treatment Overlay Effect drop-down menu.

If Automatically Turn On Overlay Effect is set to “Yes”, then the selected overlay effect automatically displays on the treatment screens. To turn off the overlay effect and revert to the default (i.e., solid) overlay images, press the button at the bottom of the treatment screen.

If Automatically Turn On Overlay Effect is set to “No”, then the default (i.e., solid) overlay images display on the treatment screens, and you must press the button to turn on the selected overlay effect.

NOTE
You can manually hide the overlay images by pressing and holding the button.

Sample Treatment Screen with Solid Overlay Images

Press once to toggle overlay effect on/off or press and hold to hide overlay images
**General Preferences Screen**

From the General Preferences screen, you can:

- Automatically hide the patient name on treatment screens
  
  **NOTE**
  
  *You can toggle the patient name on/off by pressing the area to the right of the icon at the top of all treatment screens.*

- Adjust the x,y direction in which the joystick moves the patient chair

- Automatically display INTEGRAL GUIDANCE dimensions on Surface Mapping Review Screen

  **NOTE**

  You can toggle the INTEGRAL GUIDANCE dimensions on/off by pressing the button at the bottom left of the Surface Mapping Review Screen.

![General Preferences Screen](image)
**Settings Screen**

From the Administrator Home Screen, press the SETTINGS button to go to the Settings Screen. From the Settings Screen, the administrator can:

- Enable and disable the network connection
- Select the displayed time zone, date, and time
- Select the user language and country for software localization
- Enable and disable graphic reports

---

1 For Catalys System software version cOS 3.90, English and English-speaking counties are the only localization settings available. Future software versions will enable other languages and countries.
**Software Info Window**

Press the CATALYS button in the upper left corner of the Home Screen or the Login Screen to open the Software Info window. The company address and phone number, as well as the software part number and revision level, display in the window. Press OK to close the window.

*Software Info Window on Home Screen*
**Help Screen**

The Operator Manual can be accessed from any screen by pressing the button, which is located at the top of the screen. The operator manual is not accessible during treatment or when treatment has been paused.

To scroll up and down on the current page, press the and buttons. To go back a page, press the BACK button. To go forward a page, press the NEXT button. Press the X in the upper right corner to close the Help Screen and return to the previous screen.
Planning Screens

There are three main types of planning screens, all of which appear essentially the same but perform different functions:

- Default Details Screen—allows you to set custom default parameters
- Treatment Template Screen—allows you to add templates with preset parameters, which can be recalled from the Treatment Planning Screens
- Treatment Planning Screen—allows you to add an individual treatment plan for a given patient

The unique features of the three types of planning screens are described in the following sections. Refer to the “Treatment Planning Screens” section for a detailed explanation of the parameters on each screen.

For corneal incisions, detailed default settings are separated into laser default details, such as pulse energy, and geometric default details, such as side cut angle and other parameters related to incision architecture.

Planning Screen Conventions

When you touch a parameter field on a planning screen, an input keypad displays on the screen. The range of allowable settings is shown at the top of the keypad. If you select a value that is outside of this range, you receive an “out of range” error, as shown in the following figure.

“Out of Range” Error and Input Keypad on the Planning Screen
If you select a value other than the default value for any parameter, an asterisk displays to the left of the value and a “return-to-default” button displays to the right, as shown in the following figure. Press the “return-to-default” button to revert to the default value displayed on the button. The default value may be derived from the system defaults, the Default Details, or the Treatment Template, as appropriate.
The following diagram shows the relationship between data in the System Defaults, Default Details, Treatment Templates, and Treatment Plans.

- **System Defaults**
  - All basic and details parameters are user-adjustable
  - Copy at time of adding a surgeon

- **Surgeon Default Details**
  - Editable on "edit templates" page
  - Copy (details only) at time of template creation

- **Treatment Template**
  - All basic and details parameters are user-adjustable
  - Copy (details only) at time of template creation
  - Copy details and clear basic parameters if "default" template is selected

- **Treatment Plan**
  - All basic and details parameters are user-adjustable
  - Copy basic and details parameters if template is selected
**Default Details Screens**

From the Surgeon Template Screen for the selected surgeon, press the DEFAULT DETAILS button for the desired treatment. The corresponding Default Details Screen displays. Enter the desired default parameters and then press the BACK button to return to the Surgeon Template Screen.

If you select a value other than the System Default value for any parameter on a Default Details Screen, an asterisk displays to the left of the value and a “return-to-default” button displays to the right. The value of the “return-to-default” button will be populated with the System Default. The values entered in the Default Details Screens carry over to the Treatment Template and potentially to the Treatment Planning Screens (see the following sections).

The following table summarizes user-adjustable basic and details parameters.

<table>
<thead>
<tr>
<th></th>
<th>LENS</th>
<th>CAPSULOTOMY</th>
<th>FRAGMENTATION</th>
<th>ARCUATE</th>
<th>PRIMARY</th>
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<td></td>
</tr>
</tbody>
</table>

† For Cataract Incisions, both primary and sideport incisions are shown on a single basic screen. For left and right, each value must be filled in for each user-adjustable parameter.

‡ For Cataract Incisions, both primary and sideport incisions are shown on a single basic screen.
Capsulotomy Default Details Screen

Lens Fragmentation Default Details Screen
Arcuate Incisions Default Details Screen

Cataract Incisions Primary Geometric Default Details Screen
Cataract Incisions Sideport(s) Geometric Default Details Screen

Cataract Incisions Primary Laser Default Details Screen
Cataract Incisions Sideport(s) Laser Default Details Screen
**Treatment Template Screens**

From the Surgeon Template Screen for the selected surgeon, press the + (add a new template) tab for the desired treatment. The corresponding Treatment Template Screen displays. The template name that is entered in the NAME field on this screen will display in a drop-down list on the Treatment Planning Screen for the selected treatment.

Press the COPY button to create a copy of the template, the X button to delete the template, the DETAILS button to go to the Treatment Template Details Screen, or the BACK button to return to the Surgeon Template Screen.

If you select a value other than the Default Details default value for any parameter on a Treatment Template, an asterisk displays to the left of the value and a “return-to-default” button displays to the right. The value of the “return-to-default” button will be populated with the Default Details value.

Note that the Cataract Treatment Template requires the specification of individual templates for both the left and the right eye. This is to accommodate surgeons who routinely choose different incision geometries depending on the operative eye.

**Capsulotomy (Basic) Template Screen**
Capsulotomy Template Details Screen

Lens Fragmentation (Basic) Template Screen
Lens Fragmentation Template Details Screen

Arcuate Incisions (Basic) Template Screen
Arcuate Incisions Template Details Screen

Cataract Incisions (Basic) Template Screen

Note that either “Left” or “Right” can be selected (circled).
Cataract Incisions Primary Geometric Template Details Screen

Cataract Incisions Sideport(s) Geometric Template Details Screen
Cataract Incisions Primary Laser Template Details Screen

Cataract Incisions Sideport(s) Laser Template Details Screen
**Treatment Planning Screens**

**Plan a Treatment Screen**

- To plan a treatment for a new patient, press the 🔄 tab on the Home Screen.
- To add a new plan for an existing patient, select the patient from the Home Screen or All Treatments & Reports Screen. The patient name will expand to list all plans associated with this patient. Press the 🔄 next to the patient’s date of birth to add a new plan that is pre-populated with the First Name, Last Name, ID, and Date of Birth of this patient.

In either case, the system will transition to the “Plan a Treatment Screen”.

**Treatment Planning Options on the Home Screen**

**NOTE**

*Treatment settings may be selected prior to seating the patient. However, the physician should verify all treatment parameters displayed on the screen prior to proceeding with treatment.*
Plan a Treatment Screen

The following information must be entered on the Plan a Treatment Screen before proceeding with treatment planning:

- Surgeon Name
- Patient First and Last Name
- Patient ID (recommended)
- Patient Date of Birth
- Treatment Eye (Left or Right)
- Selected Incision(s)

After entering the required information, press the NEXT button to proceed to the treatment parameter selection screens.

In each of the treatment planning pages the following rules apply:

- You will not be able to proceed to plan the next selected incision until the current incision is properly planned (e.g., if the capsulotomy is not completely planned, you will not be able to proceed to plan the lens fragmentation).
- For a given incision, if you have selected the “Default Template”, and you select a value other than the Default Details default value for any details parameter, an asterisk displays to the left of the value and a “return-to-default” button displays to the right. The value of the “return-to-default” button will be populated with the Default Details value.
- For a given incision, if you have selected a Treatment Template, and you select a value other than the Treatment Template value for any details parameter, an asterisk displays to the left of the value and a “return-to-default” button displays to the right. The value of the “return-to-default” button will be populated with the Treatment Template value.
Capsulotomy (Basic) Screen

The Capsulotomy (Basic) Screen can be accessed in any of the following ways:

- Press the NEXT button on the Plan a Treatment Screen.
- Press the BASIC button on the Capsulotomy Details Screen.
- Press the BACK button on the (Basic) Screen for the next treatment in the sequence.
- Select the Quick Navigation Bar Capsulotomy Icon on the Plan a Treatment Screen; the Lens Fragmentation, Arcuate Incisions, or Cataract Incisions (Basic) Screen; or the Treatment Summary Screen.

From the Capsulotomy (Basic) Screen, you can select the following parameters:

- Template Name
- Pattern—Circular is the only pattern option
- Diameter—capsulotomy circular opening diameter
- Center Method
  - “Pupil” uses the identified pupil to center the capsulotomy.
  - “Pupil Maximized” uses the identified pupil to center the capsulotomy and to maximize the capsulotomy diameter. The initial value you enter for “Diameter” will be adjusted once the diameter of the pupil has been identified. Pupil Maximized may be useful in cases of small non-dilating pupils.
  - “Limbus” uses the identified limbus to center the capsulotomy.
  - “Scanned Capsule” uses the INTEGRAL GUIDANCE data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the capsulotomy.
— “Custom” allows you to drag the touchscreen image to the desired location within the safety zone when in the treatment screens. Dragging is only available during treatment.

Once you have chosen valid settings, the selected diameter displays in the center of the eye model, as shown in the preceding figure. Press the DETAILS button to proceed to the Capsulotomy Details Screen, the BACK button to return to the Plan a Treatment Screen, or the NEXT button to proceed to the (Basic) Screen for the next treatment in the sequence.

NOTES
If you selected only the capsulotomy treatment on the Plan a Treatment Screen, pressing the NEXT button on the Capsulotomy (Basic) Screen will take you directly to the Treatment Plan Summary Screen.

If you press the HOME button on the Capsulotomy (Basic) Screen, the current treatment parameters will be saved.

Capsulotomy Details Screen
To access the Capsulotomy Details Screen, press the DETAILS button on the Capsulotomy (Basic) Screen or the Quick Navigation Bar Capsulotomy Icon on the Lens Fragmentation, Arcuate Incisions, or Cataract Incisions Primary or Sideport(s) Details Screen.
From the Capsulotomy Details Screen, you can select the following parameters:

- Incision Depth—axial extent of capsulotomy cylinder pattern, centered around the detected lens anterior surface
- Horizontal Spot Spacing—lateral spot-to-spot spacing
- Vertical Spot Spacing—axial spot-to-spot spacing
- Pulse Energy—energy delivered per pulse

Once you have chosen valid settings, the incision depth is displayed in the lower eye model, as shown in the preceding figure. Press the BASIC button to return to the Capsulotomy (Basic) Screen, the BACK button to return to the Plan a Treatment Screen, or the NEXT button to proceed to the (Basic) Screen for the next treatment in the sequence.

NOTES

All settings have a defined range and built-in error checking. Therefore, settings must be selected or entered within these bounds as defined in the “User-adjustable Capsulotomy Parameters” table in the “Selecting Treatment Parameters” section of this manual.

If you selected only the capsulotomy treatment on the Plan a Treatment Screen, pressing the NEXT button on the Capsulotomy Details Screen will take you directly to the Treatment Plan Summary Screen.

If you press the HOME button on the Capsulotomy Details Screen, the current treatment parameters will be saved.
Lens Fragmentation (Basic) Screen

The Lens Fragmentation (Basic) Screen can be accessed in any of the following ways:

- Press the NEXT button on the Capsulotomy (Basic) or Details Screen (if you selected the capsulotomy treatment) or on the Plan a Treatment Screen (if you did not select the capsulotomy treatment).
- Press the BASIC button on the Lens Fragmentation Details Screen.
- Select Quick Navigation Bar Lens Fragmentation Icon on the Plan a Treatment Screen; the Capsulotomy, Arcuate Incisions, or Cataract Incisions (Basic) Screen; or the Treatment Summary Screen.

From the Lens Fragmentation (Basic) Screen, you can select the following parameters:

- Template Name
- Segmentation—lens fragmentation pattern, with or without softening
  - Lens softening adds grid patterns to the spaces between the lens segments defined in the pattern type selection.

Once you have chosen valid settings, the selected fragmentation pattern displays in the center of the eye model, as shown in the preceding figure. Press the DETAILS button to proceed to the Lens Fragmentation Details Screen, the BACK button to return to the Capsulotomy (Basic) Screen, or the NEXT button to proceed to the Treatment Plan Summary Screen or the (Basic) Screen for the next treatment in the sequence.

NOTES

If you selected only the lens fragmentation treatment on the Plan a Treatment Screen, pressing the BACK button on the Lens Fragmentation (Basic) Screen will take you back to the Plan a Treatment Screen.
If you press the HOME button on the Lens Fragmentation (Basic) Screen, the current treatment parameters will be saved.

**Lens Fragmentation Details Screen**

To access the Lens Fragmentation Details Screen, press the DETAILS button on the Lens Fragmentation (Basic) Screen or the Quick Navigation Bar Lens Fragmentation icon on the Capsulotomy, Arcuate Incisions, or Cataract Incisions Primary or Sideport(s) Details Screen.

From the Lens Fragmentation Details Screen, you can select the following parameters:

- **Seg-Soft Spacing**—distance between segmentation lines and initial softening grid pattern lines
- **Grid Spacing**—distance between successive softening grid pattern lines
- **Diameter (Maximized or Limited)**—diameter for maximum allowed lens fragmentation pattern; if maximized is selected, diameter is given by the detected iris; if limited is selected, size will be given by the smaller of either the detected iris or the limited diameter specified
- **Segmentation Repetitions**—number of times the treatment of the selected segmentation lines is repeated in the lens fragmentation pattern as the treatment laser passes over the segmentation portion of the pattern
- **Horizontal Spot Spacing**—lateral spot-to-spot spacing
- **Vertical Spot Spacing**—axial spot-to-spot spacing
- **Anterior/Posterior Pulse Energy**—system varies pulse energy between these values (if they are different) as the pattern is delivered, moving from posterior to anterior
- **Anterior/Posterior Capsule Safety Margin**—safety distances between lens fragmentation incisions and anterior/posterior capsule surfaces
Once you have chosen valid settings, the anterior and posterior safety zones are displayed in the lower eye model, as shown in the preceding figure. The laser will not treat within the defined volume of a safety zone. Press the BASIC button to return to the Lens Fragmentation (Basic) Screen, the BACK button to return to the (Basic) Screen for the previous treatment in the sequence, or the NEXT button to proceed to the (Basic) Screen for the next treatment in the sequence.

NOTES
If you selected only the lens fragmentation treatment on the Plan a Treatment Screen, pressing the BACK button on the Lens Fragmentation Details Screen will take you back to the Plan a Treatment Screen.

If you press the HOME button on the Lens Fragmentation Details Screen, the current treatment parameters will be saved.

Arcuate Incisions (Basic) Screen
The Arcuate Incisions (Basic) Screen can be accessed in any of the following ways:

- Press the NEXT button on the Lens Fragmentation (Basic) or Details Screen (if you selected the lens fragmentation procedure), on the Capsulotomy (Basic) or Details screen (if you selected the capsulotomy procedure but did not select the lens fragmentation procedure), or on the Plan a Treatment Screen (if you did not select the capsulotomy or lens fragmentation procedure).
- Press the (BASIC) button on the Arcuate Incisions Details Screen.
- Select the Quick Navigation Bar Arcuate Incisions Icon on the Plan a Treatment Screen; the Capsulotomy, Lens Fragmentation, or Cataract Incisions (Basic) Screen; or the Treatment Summary Screen.
The arcuate incision parameters are defined in the “User-adjustable Parameters for Arcuate Incisions” table in the “Selecting Treatment Parameters” section. From the Arcuate Incisions (Basic) Screen, you can select the following parameters:

- **Template Name**
- **Type**
  - Single—single provides one incision
  - Symmetric—symmetric has two incisions that share the same optical zone and length and have an axis 180 degrees apart
  - Asymmetric—asymmetric has two incisions that can have independent axes, optical zones and lengths
- **Axis**—angular position around which the incision is centered
- **Optical Zone**—twice the radius from the lateral center of the eye (as determined with the user-selected centering method) to the cornea anterior penetrating point of the arcuate incision. In the case of intrastromal arcuate incisions, the optical zone is twice the radius from the center of the eye to the point where the incision would intersect the cornea anterior if the incision were extended. In the case of symmetric incisions, the optical zone is the diameter of separation through the user-selected center.
- **Length**—length of the incision(s)
- **Center Method**
  - “Pupil” uses the identified pupil to center the incision.
  - “Limbus” uses the identified limbus to center the incision.
  - “Scanned Capsule” uses the INTEGRAL GUIDANCE data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the arcuate incisions.
“Custom” allows you to drag the touchscreen image to the desired location within the safety zone when in the treatment screens. Dragging is only available during treatment.

Once you have chosen valid settings, the selected arcuate incisions pattern displays in the center of the eye model, as shown in the preceding figure. Press the DETAILS button to proceed to the Arcuate Incisions Details Screen, the BACK button to return to the (Basic) Screen for the previous procedure in the sequence, or the NEXT button to proceed to the (Basic) Screen for the next procedure in the sequence.

NOTES
If you selected only the arcuate incisions procedure on the Plan a Treatment Screen, pressing the BACK button on the Arcuate Incisions (Basic) Screen will take you back to the Plan a Treatment Screen.

If you press the HOME button on the Arcuate Incisions (Basic) Screen, the current treatment parameters will be saved.

Arcuate Incisions Details Screen
To access the Arcuate Incisions Details Screen, press the DETAILS button on the Arcuate Incisions (Basic) Screen or the Quick Navigation Bar Arcuate Incisions Icon on the Capsulotomy, Lens Fragmentation, or Cataract Incisions Primary or Sideport(s) Details Screen.

From the Arcuate Incisions Details Screen, you can select the following parameters:

- Penetration Type (Anterior Penetrating or Intrastromal)—Anterior Penetrating has uncut region in posterior cornea; Intrastromal has uncut regions in anterior and posterior cornea
- Depth Unit (Percent or Microns)—uncut tissue depth at a given location in the cornea
- Uncut Anterior/Posterior Percentage or Microns
• Side Cut Angle—angle at which incision is made with respect to the anterior cornea at location of incision
• Horizontal Spot Spacing—lateral spot-to-spot spacing
• Vertical Spot Spacing—axial spot-to-spot spacing
• Pulse Energy—energy delivered per pulse
• Anterior/Central Line Density—spacing between successive lines of the incision. For arcuate incisions, the line density can be independently defined for the anterior and central regions of the incision. Refer to page 169 for a graphic representation of line density.
• Anterior Line Distance—region as a percentage of corneal thickness that line density is applied to the respective cut segment; used to adjust the spot spacing from the anterior portion of the incision to the central portion of the incision. For example, if the anterior plane depth is 40% of the corneal thickness and the anterior line distance is 30%, then the anterior-most 30% of the corneal thickness will be at the anterior line density and the remaining 10% depth will be at central line density.

Once you have chosen valid settings, the side cut angle and uncut region(s) are displayed in the lower eye model, as shown in the preceding figure. Press the BASIC button to return to the Arcuate Incisions (Basic) Screen, the BACK button to return to the (Basic) Screen for the previous procedure in the sequence, or the NEXT button to proceed to the (Basic) Screen for the next procedure in the sequence.

NOTES
If you selected only the arcuate incisions procedure on the Plan a Treatment Screen, pressing the BACK button on the Arcuate Incisions Details Screen will take you back to the Plan a Treatment Screen.

If you press the HOME button on the Arcuate Incisions Details Screen, the current treatment parameters will be saved.

Cataract Incisions (Basic) Screen
The Cataract Incisions (Basic) Screen can be accessed in any of the following ways:

Press the NEXT button on the Arcuate Incisions (Basic) or Details Screen (if you selected the arcuate incisions procedure), on the Lens Fragmentation (Basic) or Details Screen (if you selected the lens fragmentation procedure but did not select the arcuate incisions procedure), on the Capsulotomy (Basic) or Details screen (if you selected the capsulotomy procedure but did not select the lens fragmentation or arcuate incisions procedure), or on the Plan a Treatment Screen (if you did not select the capsulotomy, lens fragmentation, or arcuate incisions procedure).
Cataract Incisions (Basic) Screen

From the Cataract Incisions (Basic) Screen, you can select the following parameters:

- Template Name
- Number of Primary Incisions (1 or 2)
- Number of Sideport Incisions (0 to 5)
- Axis of Primary/Sideport Incision(s)
- Limbus Offset of Primary/Sideport Incision(s)
- Automatic Offset for Primary/Sideport Incision(s)—incision(s) automatically offset from limbus based on the OCT-detected clear cornea boundary
- Width of Primary/Sideport Incision(s)—width of the cut from an en face view
- Length of Primary/Sideport Incision(s)—length of the cut from an en face view
- Cyclorotation Compensation (Off or On)

Once you have chosen valid settings, the selected cataract incision pattern displays in the center of the eye model. Press the DETAILS button to proceed to the Cataract Incisions Primary Geometric Details Screen, the BACK button to return to the (Basic) Screen for the previous procedure in the sequence, or the NEXT button to proceed to the Treatment Plan Summary Screen.

NOTES

If you selected only the cataract incisions procedure on the Plan a Treatment Screen, pressing the BACK button on the Cataract Incisions (Basic) Screen will take you back to the Plan a Treatment Screen.

If you press the HOME button on the Cataract Incisions (Basic) Screen, the current treatment parameters will be saved.
Cataract Incisions Primary Geometric Details Screen

To access the Cataract Incisions Primary Geometric Details Screens, press the DETAILS button on the Cataract Incisions (Basic) Screen or the Quick Navigation Bar Cataract Incisions Icon on the Capsulotomy, Lens Fragmentation, or Arcuate Incisions Details Screen.

Cataract Incisions Primary Geometric Details Screen

From the Cataract Incisions Primary Geometric Details Screen, you can select the following parameters:

- Uncut Region (Anterior, Central, Posterior, or None)
- Depth Unit (Percent or Microns)
- Uncut Anterior/Posterior Percentage or Microns
- Uncut Central Length
- Anterior/Posterior Plane Depth
- Anterior/Posterior Side Cut Angle

Once you have chosen valid settings, the anterior and posterior side cut angles and uncut region are displayed in the lower eye model, as shown in the preceding figure. Press the button to go to the Cataract Incisions Sideport(s) Geometric Details Screen, the BASIC button to return to the Cataract Incisions (Basic) Screen, the BACK button to return to the (Basic) Screen for the previous procedure in the sequence, or the NEXT button to proceed to the Treatment Plan Summary Screen.
Cataract Incisions Sideport(s) Geometric Details Screen

To access the Cataract Incisions Sideport(s) Geometric Details Screens, press the ➔ button on the Cataract Incisions Primary Geometric Details Screen or the ➔ button on the Cataract Incisions Primary Laser Details Screen.

From the Cataract Incisions Sideport(s) Geometric Details Screen, you can select the following parameters:

- Uncut Region (Anterior, Central, Posterior, or None)
- Depth Unit (Percent or Microns)
- Uncut Anterior/Posterior Percentage or Microns
- Uncut Central Length
- Anterior/Posterior Plane Depth
- Anterior/Posterior Side Cut Angle

Once you have chosen valid settings, the anterior and posterior side cut angles and uncut region are displayed in the lower eye model, as shown in the preceding figure. Press the ➔ button to go to Cataract Incisions Primary Laser Details Screen, the ➔ button to go to the Cataract Incisions Primary Geometric Details Screen, the BASIC button to return to the Cataract Incisions (Basic) Screen, the BACK button to return to the (Basic) Screen for the previous procedure in the sequence, or the NEXT button to proceed to the Treatment Plan Summary Screen.
Cataract Incisions Primary Laser Details Screen

To access the Cataract Incisions Primary Laser Details Screens, press the button on the Cataract Incisions Sideport(s) Geometric Details Screen or the button on the Cataract Incisions Sideport(s) Laser Details Screen.

From the Cataract Incisions Primary Laser Details Screen, you can select the following parameters:

- **Anterior/Central/Posterior Line Density**— spacing between successive lines of the incision. For cataract incisions, the line density can be independently defined for the anterior, central, and posterior regions of the incision. Refer to page 169 for a graphic representation of line density.

- **Anterior/Posterior Line Distance**—region as a percentage of corneal thickness that line density is applied to the respective cut segment; used to adjust the spot spacing from the anterior/posterior portion of the incision to the central portion of the incision. For example, if the anterior plane depth is 40% of the corneal thickness and the anterior line distance is 30%, then the anterior-most 30% of the corneal thickness will be at the anterior line density and the remaining 10% depth will be at central line density.

- **Horizontal Spot Spacing**—lateral spot-to-spot spacing

- **Vertical Spot Spacing**—axial spot-to-spot spacing

- **Pulse Energy**—energy delivered per pulse

Press the button to go to Cataract Incisions Sideport(s) Laser Details Screen, the button to go to the Cataract Incisions Sideport(s) Geometric Details Screen, the BASIC button to return to the Cataract Incisions (Basic) Screen, the BACK button to return to the (Basic) Screen for the previous procedure in the sequence, or the NEXT button to proceed to the Treatment Plan Summary Screen.
Cataract Incisions Sideport(s) Laser Details Screen

To access the Cataract Incisions Sideport(s) Laser Details Screens, press the button on the Cataract Incisions Primary Laser Details Screen.

From the Cataract Incisions Sideport(s) Laser Details Screen, you can select the following parameters:

- **Anterior/Central/Posterior Line Density**—spacing between successive lines of the incision. For cataract incisions, the line density can be independently defined for the anterior, central, and posterior regions of the incision. Refer to page 169 for a graphic representation of line density.

- **Anterior/Posterior Line Distance**—region as a percentage of corneal thickness that line density is applied to the respective cut segment; used to adjust the spot spacing from the anterior/posterior portion of the incision to the central portion of the incision. For example, if the anterior plane depth is 40% of the corneal thickness and the anterior line distance is 30%, then the anterior-most 30% of the corneal thickness will be at the anterior line density and the remaining 10% depth will be at central line density.

- **Horizontal Spot Spacing**—lateral spot-to-spot spacing

- **Vertical Spot Spacing**—axial spot-to-spot spacing

- **Pulse Energy**—energy delivered per pulse

Press the button to go to the Cataract Incisions Primary Laser Details Screen, the BASIC button to return to the Cataract Incisions (Basic) Screen, the BACK button to return to the (Basic) Screen for the previous procedure in the sequence, or the NEXT button to proceed to the Treatment Plan Summary Screen.
NOTES
If you selected only the cataract incisions procedure on the Plan a Treatment Screen, pressing the BACK button on any of the Cataract Incisions Details Screens will take you back to the Plan a Treatment Screen.

If you press the HOME button on any of the Cataract Incisions Details Screens, the current treatment parameters will be saved.

Treatment Plan Summary Screen
After you have selected the desired treatment parameters, press the NEXT button on the (Basic) or Details Screen for the last treatment in the sequence or press the Quick Navigation Bar Treatment Summary Icon on the Patient Info, Capsulotomy, Lens Fragmentation, Arcuate Incisions or Cataract Incisions Screen to proceed to the Treatment Plan Summary Screen. The Treatment Plan Summary Screen provides an overview of the current treatment plan, including a graphical representation of the selected treatment parameters.

After verifying the treatment plan summary, press the HOME button to return to the Home Screen. To make changes to the treatment plan, press the BACK button to return to the (Basic) Screen for the last treatment in the sequence, or press the Quick Navigation Bar icon for the desired treatment to return to the (Basic) Screen for that treatment.
Surgical Timeout Screen

After selecting a treatment plan from the Home Screen and pressing the SURGICAL TIMEOUT button on the Treatment Summary Screen, the Surgical Timeout Screen displays. Verify that the patient details and treatment parameters are correct, and then press the APPROVE button to proceed to the Docking Screen. If any information on the Surgical Timeout Screen is incorrect, press the Home button to return to the Home Screen or the BACK TO PLANNING button to edit the Treatment Plan.

**NOTE**

You must scan the circular label on the LIQUID OPTICS Interface packaging before proceeding to the Docking Screen. If a circular label has not been scanned, “Scan to Activate” displays at the top of the screen and the APPROVE button is disabled, as shown in the following figure. Please refer to the section entitled “Scanning the Treatment Activation Label” for additional information.
Docking Screen

After verifying the information on the Surgical Timeout Screen, scanning the circular label on the LIQUID OPTICS Interface packaging, and pressing the APPROVE button, the Docking Screen guides you through the patient docking procedure.

The Docking Screen displays live video on the left side of the screen and prompts for each step of the docking process with instructions on the right side of the screen. Also on the left side of the screen, overlaid on top of the video, are three indicators that are used to aid in the docking process. The arrow and green zone on the right side of the video indicate the vertical position of the patient chair and when it is in the correct range for certain steps of the docking process. The line centered on top of the video and the different colored zones, which change depending on the current step of the docking process, indicate the lateral forces being exerted on the disposable lens. The arrow on the left of the video and the different colored zones, which change depending on the current step of the docking process, indicate the vertical forces being exerted on the disposable lens.

Docking Aid Indicators on Sample Docking Screen
Disposable Lens Panel

**TIP**

Before seating the patient, ensure that the two arrows under the headrest neck support adjustment knob are aligned, as described in the “Positioning the Patient” section of this manual. If necessary, use the headrest vertical adjustment knob to adjust the vertical position of the headrest until the arrows are aligned.

**TIP**

If marking the sclera is part of your routine clinical practice pre-operatively, do so with the patient sitting upright before reclining the patient. Subsequently align the suction ring marks with the scleral marks during docking.

When the initial Docking Screen displays, the Disposable Lens panel is open. As instructed in the panel, install a new disposable lens on the system if you have not already done so. If the system detects that the disposable lens has not been replaced from a previous treatment, you will be prompted to remove the old disposable lens and install a new disposable lens.

**NOTE**

Refer to the “Installing the Disposable Lens” section of this manual for detailed instructions on installing the lens on the system.

Docking Screen with Disposable Lens Panel Open
**Vacuum Panel**

After the system verifies installation of the disposable lens, the Vacuum panel opens. As instructed in the panel, place and center the suction ring of the LIQUID OPTICS Interface on the patient’s eye, and then apply patient vacuum. An audio sound will play repeatedly while the system is attempting to apply vacuum and a success or failure sound will alert the user if the application of vacuum has succeeded or failed.

**NOTE**

Refer to the “Attaching the Suction Ring” section of this manual for detailed instructions on placing the suction ring and applying patient vacuum.

When the system detects that the suction ring has been placed and patient vacuum applied, a check mark displays in the Vacuum panel along with an audible “ding”, and the Latch panel opens. As instructed in the Vacuum panel, add sterile buffered saline solution to the suction ring.
Latch Panel

After the system verifies application of the suction ring of the LIQUID OPTICS Interface and patient vacuum, the Latch panel opens. As instructed in the panel, latch the patient chair in the treatment position using the chair’s foot-activated chair latching lever located at the chair base.

Docking Screen with Latch Panel Open
Capture Panel

After the system detects that the patient chair is latched in position, the Capture panel opens. As instructed in the panel, use the joystick to raise the chair until the indicator arrow on the right is within the Capture Zone. This indicator arrow corresponds to the position of the chair and must be within the green Capture Zone in order to enable the CAPTURE button.

The following are sample screens, which show the suction ring outside and inside of the Capture Zone.

Docking Screen with Capture Panel Open—Suction Ring Outside Capture Zone

The patient is centered, but the suction ring of the LIQUID OPTICS Interface is not in contact with the disposable lens. The green bar represents the Capture Zone, and the arrow indicates the patient’s position with respect to the Capture Zone. In this example, the patient chair needs to be lowered until the suction ring is in the Capture Zone and the disposable lens is engaged.
Docking Screen with Capture Panel Open—Suction Ring Inside Capture Zone

The green bar represents the Capture Zone. The white arrow (at left) will turn green to indicate the suction ring’s position within the Capture Zone.

When the indicator arrow on the right side of the video is within the Capture Zone, press the CAPTURE button to capture the suction ring in the disposable lens. When the system detects that the suction ring has been captured, a check mark displays in the Capture panel, and the Lock panel opens. An audio sound will play repeatedly while the system is attempting to capture the suction ring and a success or failure sound will alert the user if the capture has succeeded or failed.

**NOTE**

Refer to the “Capturing the Suction Ring” section of this manual for detailed instructions on positioning and capturing the suction ring, as well as adjusting the patient chair.
**Lock Panel**

After the system verifies suction ring capture, the Lock panel opens. As instructed in the panel, use the joystick to adjust the patient chair until all three indicators are within their respective Lock Zones (i.e. the vertical green bar on the left, circular green area over the video, and vertical green bar on the right). When all three indicators are within their respective Lock Zones, press the Lock button.

**NOTE**

Alternatively, you can activate Guided Docking by pressing and holding the Lock button. The system will adjust the patient chair until all three indicators are within their respective Lock Zones. After the lock engages, release the Lock button. To stop the chair at any point, release the Lock button.

When the system detects that the lock has been secured, a check mark displays in the Lock panel, and the lateral and vertical force indicators will minimize to the upper left corner of the video for the rest of the treatment process.

The following sample screens show the suction ring/disposable lens assembly outside and inside of the Lock Zones.

*Docking Screen with Lock Panel Open— Suction Ring/Disposable Lens Assembly Outside Lock Zone*

When the green ring appears in the center of the eye image, the suction ring is captured. The green areas on the three different indicators represent the Lock Zones. The line in the center indicates the lateral force on the disposable lens. Move the chair in the opposite direction of the ball at the end of the line (or in the direction of the ball, if the chair direction has been reversed on the Settings Screen), to reduce the force on the disposable lens, thereby moving the ball into the Lock Zone. The arrow at the right indicates the vertical position of the suction ring/disposable lens assembly. Move the chair up/down to center the suction ring/disposable lens assembly in the lock zone. The arrow at the left indicates the vertical force on the suction ring/disposable lens assembly, which will also be affected by moving the chair up/down.
Docking Screen with Lock Panel Open—
Suction Ring/Disposable Lens Assembly Inside Lock Zone

Adjust chair position to minimize forces until indicator arrows are within lock zones.
**Verify Fluid Panel**

After the system verifies that the lock is secure, the Verify Fluid panel opens. As instructed in the panel, check the video image of the patient’s eye to ensure that the suction ring is completely filled with sterile buffered saline solution and that no air bubbles are present. The video image should appear sharp and clear.

![Docking Screen with Verify Fluid Panel Open](image)

After verifying that the video image of the patient’s eye is sharp and clear, press the **FLUID CONFIRMED** button to initiate INTEGRAL GUIDANCE. A check mark will appear next to the Verify Fluid panel after pressing the **FLUID CONFIRMED** button. The force indicators will also change from only showing a red band, to showing yellow, orange and red bands, indicating different severity levels of forces being exerted by the patient on the disposable lens.

When the disposable lens, vacuum, capture and lock steps have all been completed, the lateral and vertical force indicators (indicator to the left of the video and on top of the video) will minimize to the upper left corner of the video for the remainder of the treatment.
**WARNING**
Continuously monitor the video image immediately before and throughout each laser treatment. Continuously verify that the suction ring remains completely filled with sterile buffered saline solution. If any air bubbles and/or a meniscus appear on the video image before treatment, do not initiate laser treatment. If air bubbles and/or a meniscus appear during treatment, then terminate the laser treatment by immediately releasing the laser footswitch.

**NOTE**
Small air bubbles are normal during the creation of the capsulotomy, towards the end of the lens fragmentation, anterior penetrating arcuate incisions, and at the beginning and end of cataract incisions.

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**WARNING**
Continuously verify that the eye has not moved with respect to its initial presentation at the time of fluid confirmation. If the eye moves during INTEGRAL GUIDANCE, then press “Rescan Eye”. If the eye moves during laser treatment, then terminate the laser treatment by immediately releasing the laser footswitch.

**NOTE**
Refer to the “Capturing the Suction Ring” section of this manual for detailed instructions on filling the suction ring with sterile buffered saline solution.

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**TIP**
If your finger is wet from the docking procedure, wipe it dry before using the touchscreen. Drops of fluid on the touchscreen may act like a finger touch. If there is fluid on the touchscreen, carefully wipe the touchscreen dry. Depending on the location of the fluid, wiping the touchscreen may cause the screen to change. Verify that the correct screen displays before proceeding.
Treatment Screens

The treatment screens allow you to perform 3-D INTEGRAL GUIDANCE imaging, to verify and customize surface fits and treatment parameters prior to laser treatment, and to initiate and monitor laser treatment. There are five main types of treatment screens:

- Surface Mapping Review Screen—allows you to verify and customize surface fits
- Incision Review Screens—allow you to review and verify treatment parameters
- Incision Adjustment Screens—allow you to adjust treatment parameters
- Final Review Screen—allows you to review and approve treatment parameters prior to laser treatment
- Treatment Progress Screen—allows you to monitor laser treatment

NOTE
Refer to the “Treatment Planning Screens” section of this manual for a detailed description of the parameter selections available on the treatment screens.

Surface Mapping Review Screen

After capturing and locking the suction ring; verifying that the video image of the eye is sharp and clear; and pressing the FLUID CONFIRMED button on the final Docking Screen, the Surface Mapping Review Screen displays, and INTEGRAL GUIDANCE begins automatically. The initial Surface Mapping Review Screen displays axial and sagittal cross-section images of the corneal surfaces. To display images of all surfaces, press the NEXT button or the icon.

WARNING
Safety margins for all incisions are preserved only if Custom Fit Adjustments to ocular surface(s) are applied in accordance with the instructions for use. Purposeful misuse of the Custom Fit Adjustment to ocular surfaces can result in patient injury and complication(s), and therefore must be avoided.

From the Surface Mapping Review Screen, you can use the automatically detected ocular surfaces or custom fit the identified surfaces of the:

- Cornea Anterior/Posterior
- Lens Anterior/Posterior
- Pupil/Iris
- Limbus
Surface Mapping Review Screen (Corneal Surfaces View)

Surface Mapping Review Screen (All Surfaces View)
Customizing Surface Fits

To custom fit a particular ocular surface, press the colored icon for that ocular surface, and then press the icon. After verifying and/or customizing all surface fits, press the DONE button to return to the main Surface Mapping Review Screen.

NOTE
An asterisk displays next to the icons for the ocular surfaces with custom fits.

Cornea Anterior/Posterior and Lens Anterior/Posterior

When custom fitting the Cornea Anterior, Cornea Posterior, Lens Anterior, or Lens Posterior surfaces, Slider Icons will appear for custom fitting the surface. The middle slider on each image will move all three sliders on that particular image. When moving the slider, the highlighted surface will disappear to allow accurate positioning of each slider over the image.

Start the custom fit by moving the middle sliders to the ocular surface for both axial and sagittal images. Next, move the two side sliders to the surface for both images. When all six sliders are on the ocular surface, custom fit for the particular surface is complete. The process can be repeated if the fit is not satisfactory. To revert to the automatically detected ocular surface, press the icon.

NOTES
You have the option of selecting a 2.5 mm diagnostic lens thickness for the Lens Posterior surface.

It is normal during the custom fit procedure for unusual fitting overlay to occur due to varying slider positions.

Pupil/Iris and Limbus

When custom fitting the Pupil and Limbus surfaces, use the image of the eye (shown from the anterior) on the left side of the screen. Press inside the marked area, and move the selected area to an area of your choice. To increase or decrease the size of the circle, touch on or outside the circle, and slide your finger away from or toward the center of the circle. To custom fit the Iris plane, use the Slider Icons in the sagittal and axial cross-section images.

Custom Cyclorotation Compensation

Cyclorotation compensation adjustments are available for all corneal incisions, with the same cyclorotation compensation angle applied to all corneal incisions in a given treatment plan (unless cyclorotation compensation has been turned off for cataract incisions).

The cyclorotation compensation adjustment can be selected as either suction ring position-based or it can be adjusted by the user:

• For suction ring-based cyclorotation compensation, the rotation angle of the patient suction ring is detected and used as the cyclorotation compensation angle.
• If the custom cyclorotation compensation method is selected, the cyclorotation compensation angle may be adjusted within the range of ±75°.
Surface Mapping Review Screen with Cornea Anterior Custom Fitting Selected

Surface Mapping Review Screen with Cornea Posterior Custom Fitting Selected
Surface Mapping Review Screen with Lens Anterior Custom Fitting Selected

Surface Mapping Review Screen with Lens Posterior Custom Fitting Selected
Surface Mapping Review Screen with Pupil/Iris Custom Fitting Selected

[Image of Surface Mapping Review Screen with Pupil/Iris Custom Fitting Selected]

Surface Mapping Review Screen with Limbus Custom Fitting Selected

[Image of Surface Mapping Review Screen with Limbus Custom Fitting Selected]
QUICK TIP: VERIFYING AND CUSTOMIZING SURFACE FITS
If you determine the pupil fit does not match the underlying image, then press the RESCAN EYE button and confirm the new pupil fit. If you still determine that the fit does not match the underlying image, adjust the pupil fit size and centration as described in the “Customizing Surface Fits” section. Once the pupil fit is properly adjusted, confirm the surface fits and, after the surgical timeout, start treatment.

QUICK TIP: VERIFYING AND CUSTOMIZING SURFACE FITS
Take your time when confirming the surface fits! This is not the time to speed up the treatment. Always confirm pupil first then axial and sagittal views (cornea anterior/posterior, lens anterior/posterior, and side-to-side, making sure that the safety zones do not overlap iris). Consider saying the following out loud as you walk through this confirmation process: “Anterior/posterior; anterior, posterior, side-to-side”.

QUICK TIP: VERIFYING AND CUSTOMIZING SURFACE FITS
Always remember that if you are adjusting surface fits with the sliders, always fit the center sliders first on both views then the side sliders to the surface.
INTEGRAL GUIDANCE Dimensions

You can toggle the INTEGRAL GUIDANCE dimensions on/off by pressing the button at the bottom left of the Surface Mapping Review Screen. The INTEGRAL GUIDANCE dimensions display the distance between the color-coded surface maps. As the surface maps are moved, either by INTEGRAL GUIDANCE or the user, the numeric value of the distance between the surface maps is displayed and updated.

Location of INTEGRAL GUIDANCE Dimensions

The following measurements are taken along a vector orthogonal to the tilt of the lens:

- CCT (central cornea thickness)—distance between anterior and posterior cornea
- AD (aqueous depth)—distance between posterior cornea and anterior lens
- ACD (anterior chamber depth)—distance between anterior cornea and anterior lens
- LMP (lens meridian position)—distance from anterior cornea to lens equator (i.e., intersection of lens anterior and lens posterior surface maps)
- LT (lens thickness)—distance from lens anterior to lens posterior
- PD (pupil diameter)—pupil diameter including minor and major axis
- WTW (white to white)—limbus diameter including minor and major axis
**Incision Review Screens**

After verifying surface fits, press the APPROVE button on the Surface Mapping Review Screen (all surfaces view) to go to the Incision Review Screens. From the Incision Review Screens, you can:

- Review and verify treatment parameters
- View streaming updates of section scans
- Suppress individual incisions
- Navigate to the Incision Adjustment Screens to adjust treatment parameters

To navigate to the Incision Review Screen for a particular incision, you can press the respective icon in the Quick Navigation Bar, press the greyed out incision in the eye image on the left side of the screen, or press the ** and ** buttons. After an incision has been reviewed, a green checkmark displays next to the icon in the Quick Navigation Bar. If an incision is suppressed, a red “X” displays next to the icon. After all incisions have been reviewed, an APPROVE button displays on the final Incision Review Screen. Press the APPROVE button to go to the Final Review Screen.

**Capsulotomy Incision Review Screen**

![Capsulotomy Incision Review Screen]

- Suppress Incision
- Quick Navigation Bar
- Go to Next Incision in Sequence
- Go to Incision Adjustment Screen
- Return to Surface Mapping Review Screen
- Press Greyed Out Incision to Review
- Go to Last Incision in Sequence
Lens Fragmentation Incision Review Screen

Arcuate Incisions Review Screen
Cataract Incisions Review Screen
**Incision Adjustment Screens**

To adjust treatment parameters for a particular incision, press the EDIT button on the Incision Review Screen to go to the Incision Adjustment Screens for that incision. After making the desired adjustments, press the DONE button to return to the Incision Review Screen. You can also navigate between Incision Adjustment Screens for the various incisions by pressing the icons in the Quick Navigation Bar.

**Adjust Capsulotomy Screens**

To adjust the capsulotomy parameters after performing INTEGRAL GUIDANCE, press the EDIT button on the Capsulotomy Incision Review Screen to go to the Adjust Capsulotomy (Basic) Screen.

**Adjust Capsulotomy (Basic) Screen**

Capsulotomy diameter can be adjusted by changing the value in the Diameter field or by pressing and dragging the capsulotomy video overlay. Dragging the overlay away from the center increases the diameter, and dragging the overlay toward the center decreases the diameter. The red area in the following figure represents the capsulotomy iris safety zone; the capsulotomy must stay within this boundary.

**NOTE**

*If you drag the capsulotomy outside of the capsulotomy iris safety zone, the system will not allow treatment. The Diameter value will update automatically to reflect the overlay size.*
Adjust the desired parameters on the Adjust Capsulotomy (Basic) Screen, and then press the DETAILS button to proceed to the Adjust Capsulotomy Details Screen; press the Quick Navigation Bar icon for a different incision to go the Incision Adjustment Screens for that incision; or press the DONE button to return to the Capsulotomy Incision Review Screen.

Adjust Capsulotomy Details Screen

Adjust the desired parameters on the Adjust Capsulotomy Details Screen, and then press the BASIC button to return to the Adjust Capsulotomy (Basic) Screen; press the Quick Navigation Bar icon for a different incision to go the Incision Adjustment Screens for that incision; or press the DONE button to return to the Capsulotomy Incision Review Screen.
Adjust Lens Fragmentation Screens

To adjust the lens fragmentation parameters after performing INTEGRAL GUIDANCE, press the EDIT button on the Lens Fragmentation Incision Review Screen to go to the Adjust Lens Fragmentation (Basic) Screen.

**Adjust Lens Fragmentation (Basic) Screen**

Adjust the desired parameters on the Adjust Lens Fragmentation (Basic) Screen, and then press the DETAILS button to proceed to the Adjust Lens Fragmentation Details Screen; press the Quick Navigation Bar icon for a different incision to go the Incision Adjustment Screens for that incision; or press the DONE button to return to the Lens Fragmentation Incision Review Screen.

**Adjust Lens Fragmentation Details Screen**
Adjust the desired parameters on the Adjust Lens Fragmentation Details Screen, and then press the BASIC button to return to the Adjust Lens Fragmentation (Basic) Screen; press the Quick Navigation Bar icon for a different incision to go the Incision Adjustment Screens for that incision; or press the DONE button to return to the Lens Fragmentation Incision Review Screen.

Adjust Arcuate Incisions Screens

To adjust the arcuate incisions parameters after performing INTEGRAL GUIDANCE, press the EDIT button on the Arcuate Incisions Review Screen to go to the Adjust Arcuate Incisions (Basic) Screen.

Adjust Arcuate Incisions (Basic) Screen

Adjust the desired parameters on the Adjust Arcuate Incisions (Basic) Screen, and then press the DETAILS button to proceed to the Adjust Arcuate Incisions Details Screen; press the Quick Navigation Bar icon for a different incision to go the Incision Adjustment Screens for that incision; or press the DONE button to return to the Arcuate Incisions Review Screen.
Adjust the desired parameters on the Adjust Arcuate Incisions Details Screen, and then press the BASIC button to return to the Adjust Arcuate Incisions (Basic) Screen; press the Quick Navigation Bar icon for a different incision to go the Incision Adjustment Screens for that incision; or press the DONE button to return to the Arcuate Incisions Review Screen.
Adjust Cataract Incisions Screens

To adjust the cataract incisions parameters after performing INTEGRAL GUIDANCE, press the EDIT button on the Cataract Incisions Review Screen to go to the Adjust Cataract Incisions (Basic) Screen.

NOTE
The ▪ icons in the Quick Navigation Bar represent the primary incisions, and the □ icons represent the sideport incisions. The number of icons displayed depends on the number of primary and sideport incisions selected on the Cataract Incisions (Basic) Screen. You may press any ▪ or □ icon to proceed to the Adjust Cataract Incisions (Basic) Screen for that particular incision. The image displayed in orange in the eye model on the left of the Adjust Cataract Incisions (Basic) Screen depends on which icon is selected. In the following example, the primary incision icon is selected, and the image displayed in orange in the eye model represents the primary incision.

Adjust the desired parameters on the Adjust Cataract Incisions (Basic) Screen, and then press the DETAILS button to proceed to the Cataract Incisions Adjust Primary Geometric Details Screen; press the Quick Navigation Bar icon for a different incision to go the Incision Adjustment Screens for that incision; or press the DONE button to return to the Cataract Incisions Review Screen.
Cataract Incisions Adjust Primary Geometric Details Screen

Adjust the desired parameters on the Cataract Incisions Adjust Primary Geometric Details Screen, and then press the button to go to the Cataract Incisions Adjust Sideport(s) Geometric Details Screen; press the BASIC button to return to the Adjust Cataract Incisions (Basic) Screen; or press the DONE button to return to the Cataract Incisions Review Screen.

Cataract Incisions Adjust Sideport(s) Geometric Details Screen

Adjust the desired parameters on the Cataract Incisions Adjust Sideport(s) Geometric Details Screen, and then press the button to go to the Cataract Incisions Adjust Primary Laser Details Screen; press the button to go to the Cataract Incisions Adjust Primary Geometric Details Screen; press the BASIC button to return to the Adjust Cataract Incisions (Basic) Screen; or press the DONE button to return to the Cataract Incisions Review Screen.
Cataract Incisions Adjust Primary Laser Details Screen

Adjust the desired parameters on the Cataract Incisions Adjust Primary Laser Details Screen, and then press the button to go to the Cataract Incisions Adjust Sideport(s) Laser Details Screen; press the button to go to the Cataract Incisions Adjust Sideport(s) Geometric Details Screen; press the BASIC button to return to the Adjust Cataract Incisions (Basic) Screen; or press the DONE button to return to the Cataract Incisions Review Screen.

Cataract Incisions Adjust Sideport(s) Laser Details Screen

Adjust the desired parameters on the Cataract Incisions Adjust Sideport(s) Laser Details Screen, and then press the button to go to the Cataract Incisions Adjust Primary Laser Details Screen; press the BASIC button to return to the Adjust Cataract Incisions (Basic) Screen; or press the DONE button to return to the Cataract Incisions Review Screen.
**Final Review Screen**

After making the desired adjustments on the Incision Adjustment Screens and verifying the graphical representation of all incisions on the Incision Review Screens, press the APPROVE button at the bottom of the Incision Review Screen to proceed to the Final Review Screen. The Final Review Screen allows you to perform a final review of treatment parameters before initiating laser treatment. If desired, press the BACK button to return to the Incision Review Screens. Otherwise, press the laser footswitch to initiate laser treatment.

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**WARNING**

Continuously monitor the video image immediately before and throughout each laser treatment. Continuously verify that the suction ring remains completely filled with sterile buffered saline solution. If any air bubbles and/or a meniscus appear on the video image before treatment, do not initiate laser treatment. If air bubbles and/or a meniscus appear during treatment, then terminate the laser treatment by immediately releasing the laser footswitch.

**NOTE**

Small air bubbles are normal during the creation of the capsulotomy, towards the end of the lens fragmentation, anterior penetrating arcuate incisions, and at the beginning and end of cataract incisions.
WARNING

Continuously verify that the eye has not moved with respect to its initial presentation at the time of fluid confirmation. If the eye moves during INTEGRAL GUIDANCE, then press “Rescan Eye”. If the eye moves during laser treatment, then terminate the laser treatment by immediately releasing the laser footswitch.
Treatment Progress Screen

After initiating laser treatment, the Treatment Progress Screen displays. Separate progress bars track the percentage treatment and time elapsed for the overall treatment, as well as the capsulotomy, lens fragmentation, arcuate incisions, and/or cataract incisions treatments. Adjacent to each progress bar is a count-down timer that displays the remaining treatment time.

When laser treatment is complete, the system automatically proceeds to the Undocking Screen.

NOTES
Laser treatment can be paused at any time by pressing the PAUSE TREATMENT button on the control panel or by releasing the laser footswitch. When laser treatment is paused, a “Clearable Error” message displays, and you must press the OK button to acknowledge and clear the error. To resume laser treatment, release the laser footswitch and then press it again.

Refer to the “Instructions for Interrupted Treatments” section for guidance on how to proceed when treatment is interrupted.
Undocking Screen

When laser treatment is complete, the system automatically proceeds to the Undocking Screen, which guides you through the patient release procedure, as well as the procedure for removing the suction ring and disposable lens from the system.

Vacuum Panel

When the initial Undocking Screen displays, the Vacuum panel is open. As instructed in the panel, release the patient vacuum and lower the patient chair.

**NOTE**
Refer to the “Releasing the Patient” section of this manual for detailed instructions.
**Latch Panel**

After the system verifies that the patient vacuum has been released and the patient chair lowered, the Latch panel opens. As instructed in the panel, unlatch the patient chair using the chair’s foot-activated chair latching lever located at the chair base.

![Undocking Screen with Latch Panel Open](image)
**Capture Panel**

After the system detects that the patient chair has been unlatched, the Capture panel opens. As instructed in the panel, remove and dispose of the suction ring.

**NOTE**

Refer to the “Removing the Suction Ring and Disposable Lens” section of this manual for detailed instructions.

Undocking Screen with Capture Panel Open
Disposable Lens Panel

After the system detects that the suction ring has been released, the Disposable Lens panel opens. As instructed in the panel, remove and dispose of the disposable lens.

Undocking Screen with Disposable Lens Panel Open
Treatment Results Screen

From the Undocking Screen, press the GO TO REPORT button to access the Treatment Results Screen.

![Treatment Results Screen]

If treatment was successfully completed, a check mark displays next to the icon(s) for the completed treatments(s). Refer to the “Instructions for Interrupted Treatments” section for guidance on how to proceed when treatment is incomplete.

⚠️ WARNINGS

If a laser capsulotomy is interrupted, the system will not allow you to reinitiate the capsulotomy, as precise co-registration with the initial capsulotomy cannot be assured. Instead, use standard continuous curvilinear capsulorrhexis (CCC) surgical technique to complete the treatment.

If the treatment is interrupted by a “Critical Error”, the system will automatically disable itself. Do not resume treatment afterwards. Revert to traditional cataract surgery.
CATALYS System Procedure
Preoperative Instructions

Preparing the Patient for Surgery
Prior to laser treatment, prepare the patient using the appropriate dilation medication protocol.

⚠️ CAUTION

*Adequate iris dilation medication protocol should be used to ensure iris dilation of at least 1.0mm larger than the intended capsulotomy diameter.*

Selecting Treatment Parameters
Prior to seating the patient, add a treatment plan, as described in the “Treatment Planning Screens” section. Refer to the following information for guidelines on selecting treatment parameters.

Capsulotomy Parameters
Capsulotomy parameters, including cut dimensions, laser settings and applicable safety margins, are illustrated in the following figures and summarized in the following tables.
Relationships of Key Anatomical Diameters

Concentric, geometric relationship of the pupil (bottom left) and limbus (bottom right) shown in blue shading; capsulotomy diameter (top left) shown by dotted line within orange shading; lens fragmentation diameter (top, right) shown in orange shading.

Corneal and Iris Safety Margins

Cross-sectional view highlighting geometric relationships of lens (shown in red) and respective safety margins for iris and cornea.
### User-adjustable Capsulotomy Parameters

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default</th>
<th>Range</th>
<th>Step Size</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pattern</td>
<td>Circle</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Depth</td>
<td>600</td>
<td>200-1000</td>
<td>200</td>
<td>µm</td>
</tr>
<tr>
<td>Diameter</td>
<td>N/A</td>
<td>2.0-8.0</td>
<td>0.1</td>
<td>mm</td>
</tr>
<tr>
<td>Horizontal Spot Spacing</td>
<td>5</td>
<td>3-7</td>
<td>1</td>
<td>µm</td>
</tr>
<tr>
<td>Vertical Spot Spacing</td>
<td>10</td>
<td>5-20</td>
<td>5</td>
<td>µm</td>
</tr>
<tr>
<td>Laser Pulse Energy</td>
<td>4</td>
<td>3-10</td>
<td>0.5</td>
<td>µJ</td>
</tr>
</tbody>
</table>

### Capsulotomy Parameters and Safety Margins

<table>
<thead>
<tr>
<th>Safety Margins</th>
<th>Feature</th>
<th>Value</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iris</td>
<td>500</td>
<td>µm</td>
<td></td>
</tr>
<tr>
<td>Corneal</td>
<td>500</td>
<td>µm</td>
<td></td>
</tr>
</tbody>
</table>
Lens Fragmentation Parameters

Lens Fragmentation parameters, including cut dimensions for lens segmentation and softening, laser settings, and applicable safety margins, are illustrated in the following figures and summarized in the following tables.

<table>
<thead>
<tr>
<th>Patterns</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Quadrants" /></td>
<td>Lens Segmentation: Quadrants (2 intersecting lines)</td>
</tr>
<tr>
<td><img src="image2.png" alt="Sextants" /></td>
<td>Lens Segmentation: Sextants (3 intersecting lines)</td>
</tr>
<tr>
<td><img src="image3.png" alt="Octants" /></td>
<td>Lens Segmentation: Octants (4 intersecting lines)</td>
</tr>
<tr>
<td><img src="image4.png" alt="Quadrants" /></td>
<td>Lens Softening: Quadrants</td>
</tr>
<tr>
<td><img src="image5.png" alt="Sextants" /></td>
<td>Lens Softening: Sextants</td>
</tr>
<tr>
<td><img src="image6.png" alt="Octants" /></td>
<td>Lens Softening: Octants</td>
</tr>
<tr>
<td><img src="image7.png" alt="Complete" /></td>
<td>Quadrants Complete</td>
</tr>
</tbody>
</table>
**Lens Fragmentation Patterns**

**SEG/SOFT** denotes distance between segmentation and softening. Incremental spacing is available for each parameter, as shown.
Iris Safety Margins for Lens Fragmentation – Axial and Sagittal Views

* Iris Safety Margin: axial (top) and sagittal (bottom) cross-sectional views depict the slope of the 500µm iris safety margin (shown in red) within the crystalline lens during lens fragmentation.

Safety Margins for Lens Fragmentation

- Anterior lens radius
- Iris safety margin 500µm
- Anterior safety margin*: 200–1000µm
- Central lens thickness
- Posterior lens radius
- Posterior safety margin*: User-adjustable from 500–1000 µm

* Safety margins follow lens surface contours

Cross-sectional view highlighting geometric relationships of lens radius (shown in red), lens fragmentation pattern (shown in orange) and respective safety margins for the iris and anterior and posterior lens radii.
### User-adjustable Lens Fragmentation Parameters

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default</th>
<th>Range</th>
<th>Step Size</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>*</td>
<td>3.0-10.0</td>
<td>0.5</td>
<td>mm</td>
</tr>
<tr>
<td>Horizontal Spot Spacing</td>
<td>10</td>
<td>5-10</td>
<td>2.5</td>
<td>µm</td>
</tr>
<tr>
<td>Vertical Spot Spacing</td>
<td>40</td>
<td>10-40</td>
<td>10</td>
<td>µm</td>
</tr>
<tr>
<td>Pulse Energy, Anterior**</td>
<td>8</td>
<td>4-10</td>
<td>0.5</td>
<td>µJ</td>
</tr>
<tr>
<td>Pulse Energy, Posterior**</td>
<td>10</td>
<td>4-10</td>
<td>0.5</td>
<td>µJ</td>
</tr>
<tr>
<td>Seg-Soft Spacing</td>
<td>200</td>
<td>100-1500</td>
<td>100</td>
<td>µm</td>
</tr>
<tr>
<td>Grid Spacing</td>
<td>350</td>
<td>100-2000</td>
<td>100</td>
<td>µm</td>
</tr>
</tbody>
</table>

* Default diameter is defined by available pupil diameter – 2*safety margin.
** Pulse energy to vary stepwise (linear) from posterior to anterior, if different.

### Lens Fragmentation Parameters and Safety Margins

<table>
<thead>
<tr>
<th>Safety Margins</th>
<th>Feature</th>
<th>Default</th>
<th>Range</th>
<th>Step Size</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iris</td>
<td>500</td>
<td>N/A</td>
<td>N/A</td>
<td>µm</td>
<td></td>
</tr>
<tr>
<td>Anterior ***</td>
<td>500</td>
<td>200-1000</td>
<td>100</td>
<td>µm</td>
<td></td>
</tr>
<tr>
<td>Posterior ***</td>
<td>500</td>
<td>500-1000</td>
<td>100</td>
<td>µm</td>
<td></td>
</tr>
</tbody>
</table>

*** Safety margins follow lens surface contours.
Arcuate and Cataract Incision Parameters

Arcuate Incision Characteristics

*Frontal view of arcuate incisions. Optical zone is user-adjustable. For asymmetric arcuate incisions, the optical zone is independently adjustable for each incision. Arc length is also user-adjustable.*
**Arcuate Incision Characteristics**

(a) Cross-section view of anterior penetrating incision

(b) Cross-section view of intrastromal incision

Side cut angle, uncut posterior and uncut anterior are user-adjustable. Cornea thickness is measured at the projected intersection of the incision with the cornea anterior/posterior measured at 90° to anterior/posterior corneal surface regardless of what side cut angle is chosen.
Primary and Sideport Cataract Incision Characteristics

Limbus offset, incision width and incision length are user-adjustable. Side cut angle and plane depth are also user-adjustable. Incision length is defined in the frontal view as the distance between the projected incision intersection with the cornea anterior and the cornea posterior.
Cross-sectional Diagrams of Primary and Sideport Cataract Incisions
Uncut Anterior and Posterior Regions

(a) Cross-section view of uncut anterior region

(b) Cross-section view of uncut posterior region

The side cut angle is user-adjustable, and the uncut posterior and anterior regions are user-adjustable. Cornea thickness is measured at the projected intersection location of the incision with the cornea anterior/posterior measured at 90° to the anterior/posterior cornea surface, regardless of what side cut angle is chosen.
Cross-sectional Diagrams of Primary and Sideport Cataract Incisions
Uncut Central Region and Uncut Region None

(a) Cross-section view of central uncut region

(b) Cross-section view of uncut region none

Uncut central (panel a, top) and “uncut region none” (panel b, bottom) shown in cross-section. Side cut angle is user-adjustable and can be independently adjusted for the anterior and posterior sections of the incision. Uncut central length is user-adjustable.
Line Density Characteristics

Line density is the spacing between successive lines of an arcuate, primary cataract, or sideport cataract incision. For arcuate incisions, line density can be independently adjusted for the anterior and central regions of the incision. For primary cataract and sideport cataract incisions, line density can be independently adjusted for the anterior, central, and posterior regions of the incision.

Z-Axis Iris Safety Margin for All Corneal Incisions

\[
z\text{-axis safety margin (µm)} = \sqrt{\frac{\text{Pulse Energy}}{10}} \cdot 700
\]

Lens Safety Margin for All Corneal Incisions

Lens anterior safety margin (500 µm)
### User-adjustable Parameters for Arcuate Incisions

<table>
<thead>
<tr>
<th>Feature, Unit of Measure</th>
<th>Default*</th>
<th>Range</th>
<th>Increment</th>
<th>Step Size</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision Type</td>
<td>N/A</td>
<td>Single, Symmetric, Asymmetric</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Centering Method</td>
<td>N/A</td>
<td>Pupil, Limbus, Scanned Capsule, Custom</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Penetration Type</td>
<td>Anterior</td>
<td>Anterior or Intrastromal</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Depth Units</td>
<td>Percentage</td>
<td>Percentage or Absolute</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Axis†</td>
<td>N/A</td>
<td>0-360</td>
<td>1</td>
<td>5</td>
<td>°</td>
</tr>
<tr>
<td>Optical Zone†</td>
<td>N/A</td>
<td>2-11</td>
<td>0.1</td>
<td>0.1</td>
<td>mm</td>
</tr>
<tr>
<td>Arc Length†</td>
<td>N/A</td>
<td>10-120</td>
<td>1</td>
<td>5</td>
<td>°</td>
</tr>
<tr>
<td>Penetration Type</td>
<td>Anterior</td>
<td>20%, 100 µm</td>
<td>20-50% (100-250 µm)</td>
<td>1% (1 µm)</td>
<td>2% (10 µm)</td>
</tr>
<tr>
<td>Surface</td>
<td>Posterior</td>
<td>20%, 100 µm</td>
<td>20-50% (100-250 µm)</td>
<td>1% (1 µm)</td>
<td>2% (10 µm)</td>
</tr>
<tr>
<td>Side Cut Angle</td>
<td>90</td>
<td>30-150</td>
<td>1</td>
<td>5</td>
<td>°</td>
</tr>
<tr>
<td>Line Density†</td>
<td>Anterior</td>
<td>10</td>
<td>1-10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Central</td>
<td>4</td>
<td>1-10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Line Distance†‡Anterior</td>
<td>30% (150 µm)</td>
<td>0-80% (0-400 µm)</td>
<td>1% (1 µm)</td>
<td>5% (25 µm)</td>
<td>% (µm)</td>
</tr>
<tr>
<td>Spot Spacing</td>
<td>Horizontal</td>
<td>5</td>
<td>3-50</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Vertical</td>
<td>10</td>
<td>5-50</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Pulse Energy</td>
<td>5</td>
<td>3-10</td>
<td>0.1</td>
<td>0.5</td>
<td>µJ</td>
</tr>
</tbody>
</table>

* Parameters do not have default values; the user must select each parameter.
† Independently adjustable parameters for asymmetric incisions.
‡ Not applicable for anterior penetrating.
‡‡ Note that the central line distance is not user-adjustable (it is the difference between the sum of anterior and posterior line distances).
### User-adjustable Parameters for Primary and Sideport Cataract Incisions

<table>
<thead>
<tr>
<th>Feature, Unit of Measure</th>
<th>Default*</th>
<th>Range</th>
<th>Increment</th>
<th>Step Size</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Primary Incisions, n</td>
<td>N/A</td>
<td>1-2</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Number of Sideport Incisions, n</td>
<td>N/A</td>
<td>0-5</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Axis</td>
<td>N/A</td>
<td>0-360</td>
<td>1</td>
<td>5</td>
<td>°</td>
</tr>
<tr>
<td>Limbus Offset</td>
<td>N/A</td>
<td>0.0-5.0</td>
<td>0.1</td>
<td>0.1</td>
<td>mm</td>
</tr>
<tr>
<td>Width</td>
<td>N/A</td>
<td>0.2-6.5</td>
<td>0.1</td>
<td>0.1</td>
<td>mm</td>
</tr>
<tr>
<td>Length</td>
<td>N/A</td>
<td>0.5-3.0</td>
<td>0.1</td>
<td>0.1</td>
<td>mm</td>
</tr>
<tr>
<td>Uncut Region</td>
<td>Central</td>
<td>Anterior, Central, Posterior, None</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Uncut Length</td>
<td></td>
<td>Anterior 20% (100 µm) Posterior 20% (100 µm)</td>
<td>20-50% (100-250 µm) 20-50% (100-250 µm)</td>
<td>1% (1 µm) 1% (1 µm)</td>
<td>5% (25 µm) 5% (25 µm)</td>
</tr>
<tr>
<td>Uncut Central Length</td>
<td>25</td>
<td>25-1000</td>
<td>1</td>
<td>25</td>
<td>µm</td>
</tr>
<tr>
<td>Plane Depth</td>
<td></td>
<td>Anterior 30% (150 µm) Posterior 70% (350 µm)</td>
<td>25-75% (125-375 µm) 25-75% (125-375 µm)</td>
<td>1% (1 µm) 1% (1 µm)</td>
<td>5% (25 µm) 5% (25 µm)</td>
</tr>
<tr>
<td>Side Cut Angle</td>
<td></td>
<td>Anterior 90 Posterior 45</td>
<td>30-150 30-150</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Line Density</td>
<td></td>
<td>Anterior 10 Central 1 Posterior 4</td>
<td>1-10 1-10 1-10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Line Distance†</td>
<td></td>
<td>Anterior 30% (150 µm) Posterior 30% (150 µm)</td>
<td>0-75% (0-375 µm) 0-75% (0-375 µm)</td>
<td>1% (1 µm) 1% (1 µm)</td>
<td>5% (25 µm) 5% (25 µm)</td>
</tr>
<tr>
<td>Spot Spacing</td>
<td></td>
<td>Horizontal 5 Vertical 10</td>
<td>3-50 5-50</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Pulse Energy</td>
<td></td>
<td>5</td>
<td>3-10</td>
<td>0.1</td>
<td>0.5</td>
</tr>
</tbody>
</table>

* If the uncut central length is longer than the length parameter, then the uncut central length will be set as equal to the length parameter.

† Note that the central line distance is not user-adjustable (it is the difference between the sum of anterior and posterior line distances).
Intraoperative Instructions

Installing the LIQUID OPTICS Interface Components

Prior to seating the patient, install the LIQUID OPTICS Interface components (i.e., disposable lens, fluid catchment, and vacuum hoses) on the system.

⚠️ CAUTION

Inspect all LIQUID OPTICS Interface packaging prior to use. Do not use if the packaging is damaged or if the device has been dropped, and do not use after the expiration date on the packaging. Keep LIQUID OPTICS Interface disposable package sealed and unopened until immediately prior to use.

⚠️ WARNING

The OPTIMEDICA CATALYS System is designed to work with the OPTIMEDICA LIQUID OPTICS Interface. The OPTIMEDICA LIQUID OPTICS Interface is the only patient interface approved for use with the CATALYS System. Do not use any other patient interface device with the CATALYS System. Do not modify or alter the LIQUID OPTICS Interface used with the CATALYS System.

Location of LIQUID OPTICS Interface Component Installation

[Diagram showing the location of LIQUID OPTICS Interface Circular Label Reader]
Scanning the Treatment Activation Label

Before pressing the APPROVE button on the Surgical Timeout Screen, scan the circular treatment activation label by touching the label against the LIQUID OPTICS Interface circular label reader on the patient side of the system. The circular label should contact and be held against the label reader until an audible “ding” is heard. “Activated - Scan Successful” displays momentarily at the top of the screen, and the Treatment Activation icon changes from 🍃 to 🌿.

Location of the treatment activation circular label on the LIQUID OPTICS Interface tray

Displays for the status of treatment activation
Installing the Disposable Lens

1. Open the LIQUID OPTICS Interface packaging by peeling back the Tyvek® package lid.

2. Remove the disposable lens from the Tyvek package.

3. While looking at the underside of the disposable lens carriage, bring the disposable lens up to the disposable lens carriage.

4. With *gentle* upward pressure, twist the disposable lens in the direction of the patient chair until the disposable lens tabs line up into the disposable lens carriage. The disposable lens should seat flush in the groove.
5. At this point turn the disposable lens in the opposite direction, or towards the touchscreen, or away from the patient chair until you feel a stop, and at the same time gently pull the disposable lens towards the floor.

6. Continue past the first stop by turning the disposable lens all the way towards the touchscreen, until the disposable lens locks into place.

7. Remove the protective cap from the disposable lens (save the protective cap for use after the treatment, when the disposable lens is removed).

NOTE
Verify that the disposable lens is correctly installed and securely attached to the system before proceeding.

Installing the Fluid Catchment and Vacuum Hoses
1. Remove the suction ring from the package and snap the bottom of the suction ring holder into the two tabs located on top of the fluid catchment. Remove the fluid catchment and vacuum hoses from the packaging.

Snap Suction Ring Holder onto Fluid Catchment

Two tabs on the top of Fluid Catchment accept the bottom of the Suction Ring holder (snap in place)
2. Install the fluid catchment into the holder onto the system. Press it into the holder until the catch lever snaps into position, securing the fluid catchment to the system.

   Install Fluid Catchment into Holder on System

3. Connect the LIQUID OPTICS Interface vacuum hoses to the (Patient Vacuum) and (Capture) ports on the system. The hoses have luer-style connectors that are easily installed by inserting the connectors into the ports and twisting to lock into place. The connectors are keyed to allow only the proper connection.

   Connect LIQUID OPTICS Interface Vacuum Hoses to System

NOTE
If the vacuum system malfunctions or becomes inoperative, disconnect the LIQUID OPTICS Interface vacuum hoses from the system to release vacuum from the LIQUID OPTICS Interface. This allows the LIQUID OPTICS Interface to be easily removed from the patient.
Positioning the Patient

QUICK TIP: PATIENT POSITIONING
Communicate with the patient throughout patient positioning to make certain the patient remains comfortable. Discomfort can make the patient tense and can increase the risk of a subsequent suction ring loss.

1. If you have not already done so, select the treatment parameters as described in the “Preoperative Instructions” section.

2. Before seating the patient, align the two arrows under the headrest neck support adjustment knob. If necessary, adjust the vertical position of the headrest until the arrows are aligned by using the vertical adjustment knob.

Correct Arrow Alignment

Incorrect Arrow Alignment

NOTE
The picture on the left shows the minimum allowable height of the headrest prior to beginning a treatment. The headrest must not be adjusted lower than this position unless the system becomes disabled for any reason during treatment and the headrest must be lowered to remove the patient from the docked position.

3. Ensure that the patient chair is in the upright position, and seat the patient in the patient chair. While the patient is upright, mark the eye as needed for corneal incisions, then recline the chair.

NOTE
Refer to the “CATALYS System Components” section for a detailed description of the patient chair, including instructions for chair adjustment.

QUICK TIP: PATIENT POSITIONING
Position the patient to achieve the most eye exposure for the suction ring. This means that the forehead and chin should be leveled to where the suction ring will not be tilted during docking. Also tilt the head slightly to the left when working on the right eye and tilt the head slightly right when working on the left eye.
4. Position the patient’s head in the center of the headrest to maximize eye exposure and to ensure that the top of the suction ring is parallel to the floor when vacuum is achieved. The proper head position is most often obtained by leveling the patient’s forehead and chin and turning the head away from the eye that is being operated on, as shown in the following images.

![Image of patient head placement](image)

QUICK TIP: PATIENT POSITIONING

*Use wedges and the attached head strap to secure and stabilize patient’s head and prevent movements.*

5. When the patient’s head is in the proper position, stabilize the head with the attached strap and, if necessary, a piece of surgical tape. Use the soft grey wedges for additional stability. The adjustment knobs on the chair can also be used to assist in aligning the patient.

**NOTE**

*Emphasize to the patient the importance of maintaining this head position.*

**CAUTION**

*Ensure that the patient is clear of the laser and the disposable lens before rotating the patient chair under the laser.*

6. Rotate the patient chair under the laser to pre-align the laser height.

QUICK TIP: PATIENT POSITIONING

*Pre-align the patient’s treatment eye with the disposable lens on the system to minimize patient chair movement required during docking and, therefore, less time in docking.*

QUICK TIP: PATIENT POSITIONING

*When pre-aligning, do not raise the patient too close to the disposable lens, because the suction ring or the patient’s nose may hit the disposable lens during docking. This can cause more suction ring movement that can increase the risk for a suction loss. Allow extra space when treating a right eye.*
7. Use the joystick to move the chair/patient up until the disposable lens is approximately 2 inches above the eye. This will allow the suction ring to glide under the disposable lens and yet decrease the amount of time under suction by minimizing the amount of upward movement necessary during the docking process. When pre-aligning for a right eye treatment, ensure clearance for the user’s hand while rotating the patient chair under the laser.

**QUICK TIP: PATIENT POSITIONING**

Allow for extra vertical space in chair height when treating a patient’s right eye to allow for clearance of your hand and the suction ring when the patient is rotated under the system.

**Attaching the Suction Ring**

**QUICK TIP: ATTACHING THE SUCTION RING**

Frequently communicate with the patient to ease them through the docking process.

After verifying the information on the Surgical Timeout Screen and pressing the APPROVE button, the Docking Screen guides you through the procedure for attaching the suction ring to the patient’s eye and capturing the suction ring.

**NOTE**

Verify that the disposable lens and vacuum hoses are properly connected to the system before performing the patient docking procedure. Refer to the “Installing the Disposable Lens” and “Installing the Fluid Catchment and Vacuum Hoses” sections for detailed instructions.

1. Center the suction ring with respect to the limbus and place it onto the eye. There should be approximately 1-2 mm of exposed sclera between the suction ring and the limbus, depending upon the size of the cornea.

**QUICK TIP: ATTACHING THE SUCTION RING**

Some physicians prefer to use a speculum. If a speculum is not used, however, the suction ring seal must be tucked under the eyelids. Tuck the suction ring seal under the upper eyelid first and then pull down on the lower eyelid and seat the suction ring on the eye.
Tegaderm or tape can be used to keep the eyelashes out of the operating field. Do not overlap the Tegaderm or tape, as this may restrict the amount of obtainable exposure.

QUICK TIP: ATTACHING THE SUCTION RING

When placing the suction ring, position your hands where you will want them for the next few steps. For maximum stability, support your elbow on the arm of the surgeon chair or on your leg, and position your hands on top of the tubing, with the handle pointing temporally 0 +/- 75 degrees for the left eye and 180 +/- 75 degrees for the right eye. This allows you to place your entire hand against the patient’s cheek, with your thumb resting on their forehead. The tips of your pointer finger and thumb should be slightly higher than the rim of the suction ring to provide tactile feedback in the coming steps. If the patient’s head is positioned properly and the patient is looking towards the ceiling, the top of the suction ring should be level with the floor.

2. After positioning the suction ring seal around the limbus, press down firmly to create a seal.

QUICK TIP: ATTACHING THE SUCTION RING

If the conjunctiva is too loose, pressing down on the conjunctiva with a speculum may stretch the conjunctiva and allow for a stronger seal.

3. While pressing down on the suction ring, activate the vacuum by depressing the (patient vacuum) footswitch or by pressing the (patient vacuum) button on the docking keypad (located on the system front panel directly above the patient). When vacuum is achieved, the system makes an audible “ding”, and a check mark displays in the Vacuum panel on the touchscreen.

CAUTION

Maintaining the suction ring level and stable is very important during the rest of the docking steps. Do not move the position of your hand, unless your hand feels unstable or the suction ring is no longer level.

QUICK TIP: ATTACHING THE SUCTION RING

When obtaining vacuum, center the suction ring with respect to the limbus and the alignment marks on the inside of the suction ring to the predetermined marks on the sclera. This will facilitate capture and compensate for cyclorotation.
4. Unlatch the patient chair, but do not move the hand holding the suction ring. Maintain a slight downward pressure on the suction ring.

5. Fill the suction ring with sterile buffered saline solution, such as Alcon BSS (Alcon P/N 351/55005-1) or equivalent. Consider filling the suction ring past the radial spacers until fluid leaks from the overflow ports to ensure that there is adequate fluid for later stages of the docking procedure.

⚠️ QUICK TIP: ATTACHING THE SUCTION RING

*It is advisable to remove or cover any patient hearing aids prior to adding the sterile buffered saline solution.*

**NOTE**

*Fill the suction ring slowly, making sure that there are no bubbles in the fluid. Also, observe the tubing and the fluid catchment to detect any leaks in the vacuum.*

6. Rotate the patient chair under the laser, taking care not to spill any fluid and maintaining slight downward pressure on the suction ring with your hand.

7. Latch the chair using the foot-activated chair latching lever located at the chair base.
QUICK TIP: LATCHING THE PATIENT CHAIR

Be gentle when latching the patient chair in place. Any sudden jerking of the chair can cause a suction loss. Look at the arrows on the base of the chair and confirm alignment before gently latching foot lever.

Capturing the Suction Ring

After attaching the suction ring to the patient’s eye, capture the suction ring as follows:

1. While maintaining the suction ring as level as possible, use the joystick to navigate the chair/patient up to the disposable lens. As the suction ring gets closer to the disposable lens, use the video image on the touchscreen as a guide.

2. Navigate the suction ring and chair/patient with the joystick, and center the suction ring within the red ring on the video image, as shown in the following figure.
3. As the suction ring and disposable lens get closer to each other, use your thumb and pointer finger as a tactile guide to verify that the suction ring and disposable lens are aligned.

Use both fingers to verify suction ring and disposable lens alignment.

4. When the suction ring and disposable lens are properly mated, release your hand from the suction ring.

**QUICK TIP: CAPTURING THE SUCTION RING**

*If you do not release the suction ring at this point, your finger may interfere or prevent capturing the suction ring in the disposable lens.*

5. Using the joystick, raise the chair until the suction ring (represented by white/green arrow on screen) is in the Capture Zone, as shown in the figure on the right.
QUICK TIP: CAPTURING THE SUCTION RING

When capturing the suction ring to the disposable lens, remember to let go of the suction ring once the disposable lens is immersed in fluid. Make sure that there are no bubbles present in the video image. If there are bubbles, then lower the patient chair until the disposable lens is no longer immersed, and wait for all bubbles to pop. Raise the patient chair again to immerse the disposable lens in the fluid of the suction ring. Remember to raise the patient chair and watch the video image indicators – when the arrow appears at the top of the green bar on the right side of the video image. Center by making sure that there is no sclera outside of red ring and no grey suction ring seal inside; remember, you are moving the eye, not the red ring.

QUICK TIP: CAPTURING THE SUCTION RING

If possible, move the arrow to the top of the capture zone. This may help you align the suction ring for the lock zone.

6. Using the joystick, move the edge of the suction ring to the outer edge of the red ring, as shown in the figure on the right. The red ring should be centered within the suction ring.

QUICK TIP: CAPTURING THE SUCTION RING

Do not center the pupil or limbus on the red ring. If the suction ring was not placed perfectly concentric with the pupil or limbus, the red ring will also not be concentric. This is OK. The red ring is a guide for the suction ring edge.

7. When the video image indicates that the suction ring is in the Capture Zone and you have verified that the suction ring is centered on the red ring and the force indicator minimized, press the (Capture) I (on) button on the docking keypad (located on the system front panel directly above the patient) to capture the suction ring.
NOTE
Verify that there are no bubbles in the video image that may degrade the optical clarity. If there are bubbles, release capture, lower the patient, and then proceed to recapture the suction ring in the disposable lens. You may also add sterile buffered saline solution.

NOTE
Place your finger on the “capture on” button but do not look at your finger. Keep your eyes on the video image of the eye. Always verify on the touchscreen that the suction ring has snapped into place as the suction ring is captured to the disposable lens, and that any and all movements have ceased.

Locking the Suction Ring/Disposable Lens Assembly to the Laser
1. Using the joystick, adjust the patient chair so that the suction ring/disposable lens assembly is in the Lock Zone and the lateral and vertical forces are within the green zones, as shown in the following figure.

**QUICK TIP: LOCKING THE SUCTION RING**
Monitor the Lateral Force Sensor and make proper adjustments with the joystick to minimize lateral forces.
When all three arrows in the video image are in the green zones, press the \( \text{(Lock) \ (on)} \) button on the docking keypad (located on the system front panel directly above the patient) to stabilize the suction ring/disposable lens assembly with the laser.

**QUICK TIP: LOCKING THE SUCTION RING**

Alternatively, you can activate Guided Docking by pressing and holding the Lock button. The system will adjust the patient chair until all three indicators are within their respective Lock Zones. After the lock engages, release the Lock button. To stop the chair at any point, release the Lock button.

![Lock ON Button](image)

**WARNING**

Verify that the suction ring is correctly connected to the disposable lens component of the LIQUID OPTICS Interface during the initial patient docking procedure.

3. To confirm that the suction ring and disposable lens are secured with respect to the laser, gently grab the handle of the suction ring and attempt to move it slightly. If the suction ring does not move, proceed to verify fluid. If the suction ring does move, wiggle it until it establishes a secure vacuum connection and locks into place, and then reconfirm eye stability by gently grabbing and moving the handle of the suction ring again.

**QUICK TIP: LOCKING THE SUCTION RING**

Always verify on the video image that the suction ring has snapped into place and that any and all movements have ceased.

4. Verify the fluid, and confirm that there are no bubbles in the video image, as shown in the following figure. Also verify that there is no fluid in the fluid catchment and tubing (slight amount is ok).
NOTES

Remove the fluid catchment from the holder and rock slightly to confirm the fluid level as needed.

Prior to enabling INTEGRAL GUIDANCE imaging and laser treatment, the system software verifies that the suction ring is properly positioned, captured, and locked and that there is fluid in the suction ring. If the suction ring is not well-seated, or if fluid is not present, the following error appears:

“Host No Treat 07-099 Suction ring incorrectly docked or missing fluid, verify suction ring positioning and fluid, then re-scan”.

The laser is prevented from firing until the error has been corrected.

QUICK TIP: LOCKING THE SUCTION RING

Monitor the level of fluid in the fluid catchment, especially if suction has been lost.
Starting and Verifying INTEGRAL GUIDANCE

⚠️ WARNING

Prior to INTEGRAL GUIDANCE imaging and laser treatment, the suction ring must be completely filled with sterile buffered saline solution, such as Alcon BSS (Alcon P/N 351/55005-1) or equivalent. Use the video image to verify that no air bubbles are entrapped within the sterile buffered saline solution after the suction ring is captured. The video image should provide a sharp and clear image of the patient’s eye.

퀵팁: INTEGRAL GUIDANCE

Always verify that fluid is present and that there are no air bubbles before pressing the FLUID CONFIRMED button.

퀵팁: INTEGRAL GUIDANCE

Monitor the Lateral Force Sensor and use the video to monitor the eye for movement. If movement occurs, rescan.

퀵팁: INTEGRAL GUIDANCE

Instruct the patient to be very still while the system is scanning the eye.

1. Press the FLUID CONFIRMED button on the final Docking Screen to start INTEGRAL GUIDANCE.
2. After INTEGRAL GUIDANCE is complete, view the INTEGRAL GUIDANCE data on the Surface Mapping Review Screen, and inspect the surface fits and overlaid incision patterns to ensure accuracy.

3. If the surface overlays are not properly superimposed on the desired anatomical features in the video and OCT, consider pressing the RESCAN EYE button. After a rescan, custom fit the identified surfaces, if desired (see “Customizing Surface Fits” section for instructions).

4. If the overlays are still not acceptable, release the patient (see “Releasing the Patient” section for instructions), re-capture the suction ring, and repeat INTEGRAL GUIDANCE.

5. When satisfied with the INTEGRAL GUIDANCE treatment customization, press the APPROVE button on the Surface Mapping Review Screen (all surfaces view) to go to the Incision Review Screens.
QUICK TIP: INTEGRAL GUIDANCE

Monitor the Lateral Force Sensor and use the video to monitor the eye for movement. If movement occurs, rescan.

QUICK TIP: INTEGRAL GUIDANCE

A common message for modifications required is: “Host NoTreat 07-016 Capsulotomy Intersects Iris, verify surface fits and adjust parameters”. Clear the message by clicking OK on the message and then navigate to the Capsulotomy Incision Review Screen to confirm that the pupil fit matches the underlying video image. When troubleshooting to address required modifications to the treatment, follow the order of INTEGRAL GUIDANCE with:

1) Rescan
2) Confirm surface fits
3) Confirm safety zones
4) Confirm incision parameters

QUICK TIP: INTEGRAL GUIDANCE

If you confirm that the pupil fit matches the underlying image on the Capsulotomy Incision Review Screen, then consider maximizing the capsulotomy diameter by selecting “Pupil Maximized” as the Center Method. Proceed to confirm your surface fits and each of the incisions. After performing a final review of treatment parameters on the Final Review Screen, start treatment.

QUICK TIP: INTEGRAL GUIDANCE

If you determine the pupil fit does not match the underlying image, then rescan and confirm the new pupil fit. If you still determine that the fit does not match the underlying image, adjust the pupil fit size and centration on the Surface Mapping Review Screen. Once the pupil fit is properly adjusted, confirm surface fits and, after performing a final review of treatment parameters on the Final Review Screen, start treatment.

QUICK TIP: INTEGRAL GUIDANCE

Take your time when confirming the surface fits! This is not the time to speed up the treatment. Always confirm pupil first then axial and sagittal views (cornea anterior/posterior, lens anterior/posterior, and side-to-side, making sure that the safety zones do not overlap iris). Consider saying the following out loud: “Anterior/posterior; anterior, posterior, side-to-side” as you walk through this confirmation process verbally.
QUICK TIP: INTEGRAL GUIDANCE

Always remember that if you are adjusting surface fits with the sliders, always fit the center sliders first on both views then the side sliders to the surface.

6. Review the treatment parameters on the Incision Review Screens, and verify that the graphical representation of all incisions is accurate and represents the selected treatment plan. If desired, press the EDIT button to go to the Incision Adjustment Screens to adjust treatment parameters. Otherwise, press the APPROVE button to proceed to the Final Review Screen.

7. Review the treatment parameters on the Final Review Screen. If desired, press the BACK button to return to the Incision Review Screen(s). Otherwise, start laser treatment, as described in the following section.
Performing Laser Treatment

⚠️ WARNING

Before initiating laser treatment, inspect the images created from the OCT data, surface fits, and overlaid pattern in both axial and sagittal views, and review the treatment parameters on the Final Review Screen for accuracy.

📝 QUICK TIP: TREATMENT

Watch the video image during the treatment. Confirm that large bubbles turn into small bubbles during the capsulotomy, to demonstrate breakthrough of the anterior capsule. You can toggle the overlay images on and off during the treatment in order to see the bubbles better.

After verifying the treatment parameters on the Final Review Screen, press the laser footswitch to initiate laser treatment. The Treatment Progress Screen displays.

When laser treatment is complete, the system automatically proceeds to the Undocking Screen.
NOTES
During the creation of cataract incisions, you should see bubbles start at the posterior portion of the incision and move anteriorly through the cornea to the sterile buffered saline solution in the suction ring. If creating posterior penetrating incisions in the cornea, watch for bubbles in the aqueous humor that rise to the apex of the anterior chamber. Then monitor bubbles through the cornea. Small bubbles appear as the laser penetrates the anterior cornea with overcut into the sterile buffered saline solution.

During the creation of arcuate incisions, you should not see bubbles in the aqueous humor. If bubbles are seen penetrating the posterior cornea, abort the treatment, and release the patient.

Laser treatment can be paused at any time by pressing the PAUSE TREATMENT button on the control panel or by releasing the laser footswitch. When laser treatment is paused, a “Clearable Error” message displays, and you must press the OK button to acknowledge and clear the error. To resume laser treatment, release the laser footswitch and then press it again.

Refer to the “Instructions for Interrupted Treatments” section for guidance on how to proceed when treatment is interrupted.

QUICK TIP: TREATMENT
Press firmly on foot pedal and do not lift especially during the capsulotomy. If there is any interruption during the capsulotomy, you may not restart the capsulotomy but may continue to lens fragmentation, arcuate incisions, and then to the cataract incisions, if planned. If there is any pause during the fragmentation, arcuate, or cataract incisions, you can resume the treatment. If you have a suction loss during laser treatment, you may not continue with treatment.

QUICK TIP: TREATMENT
Monitor the Lateral Force Sensor and patient’s movements.

QUICK TIP: TREATMENT
Once finished with the procedure, remember to press Vacuum off and be ready to catch the fluid once the suction ring separates from eye.

WARNING
Standard continuous curvilinear capsulorrhexis (CCC) surgical technique must be used for surgical removal of the capsulotomy disc. The capsulotomy may have residual uncut areas that should be completed by advancing the capsule through the incompletely cut area in a circumferential fashion, rather than pulling it radially. The use of improper capsulotomy disc removal technique may potentially cause or contribute to anterior capsule tear and/or a noncircular, irregularly shaped capsulotomy.
Instructions for Interrupted Treatments

The instructions for interrupted treatments differ depending on when the interruption occurred and what caused it.

Treatments Interrupted Prior to Initiating Laser Delivery

A treatment that is interrupted prior to initiating laser delivery (e.g., due to loss of vacuum or by pressing the ABORT TREATMENT button on a Docking screen) may be reinitiated by re-capturing the suction ring and resuming the treatment.

Treatments Interrupted During Laser Delivery

An incision other than capsulotomy that is interrupted during laser delivery for any of the following reasons can and may be re-initiated, since precise co-registration is not required and safety margins are preserved:

- the PAUSE TREATMENT button on the Treatment Progress Screen is pressed
- the laser footswitch is released
- the door interlock is activated
- the vertical or lateral force is in the orange zone
- abrupt changes in vacuum levels are detected
- abrupt changes in the forces on the eye are detected
- the software detects a change in the video image that could indicate a loss of fluid in the suction ring

Note

In the preceding cases, a “Clearable Error” message displays, and you must press the OK button to acknowledge and clear the error. To resume laser treatment, release the laser footswitch and then press it again.

When an incision is paused either by the system or by the user, wait at least one second prior to resuming the incision to avoid a critical alarm that will cause the system to shut down.

If a corneal incision is interrupted and resumed, there may be a significant gap in the resulting incision. In order to minimize the risk of incomplete incisions users should avoid unnecessary interruptions of an ongoing treatment.

In the event a corneal incision is interrupted and resumed do not attempt to force the incision open if it is not blunt dissectible. If the corneal incision is not blunt dissectible, use a bladed instrument to create a separate corneal incision to continue with the procedure.

An incision that is interrupted during laser delivery due to loss of vacuum cannot be reinitiated.

A capsulotomy treatment that is interrupted during laser delivery for any reason cannot be reinitiated.

WARNINGS
If a laser capsulotomy is interrupted, the system will not allow you to reinitiate the capsulotomy, as precise co-registration with the initial capsulotomy cannot be assured. Instead, use standard continuous curvilinear capsulorrhexis (CCC) surgical technique to complete the treatment.

If at any point during laser delivery the patient becomes undocked (e.g. due to Vacuum Loss), the treatment will be interrupted and cannot be continued. Do not resume treatment afterwards. Revert to traditional cataract surgery. If the treatment is interrupted by a “Critical Error”, the system will automatically disable itself. Do not resume treatment afterwards. Revert to traditional cataract surgery.

Postoperative Instructions

When laser treatment is complete, the system automatically proceeds to the Undocking Screen. The Undocking Screen guides you through the patient release procedure, as well as the procedure for removing the suction ring and disposable lens from the system.

Releasing the Patient

As instructed in the Vacuum and Latch panels of the Undocking Screen:

1. Release patient vacuum by pressing the (patient vacuum) (off) button on the docking keypad (located on the system front panel directly above the patient) or by pressing and holding the (patient vacuum) (off) footswitch for one (1) second. The one second requirement is to prevent accidental vacuum release if the footswitch is accidentally bumped.

2. Since the buffered saline solution within the suction ring will be free to seep out, be ready to capture it with a gauze or clean tissue.
Be ready to capture sterile buffered saline solution with gauze once the suction ring separates from eye.

3. Use the joystick on the patient chair to lower the chair.
4. Unlatch the patient chair and rotate it out from under the system.
5. Prepare the patient to be moved into position for surgery.

Removing the Suction Ring and Disposable Lens

As instructed in the Capture and Disposable Lens panels of the Undocking Screen:

1. Press the (Capture) button on the docking keypad (located on the system front panel directly above the patient) to release the suction ring.

2. Remove the suction ring and the disposable lens from the system, and dispose in compliance with local regulations and applicable municipal codes.
Safety and Regulatory
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General Safety and Regulatory Information

The CATALYS Precision Laser System is a Class II ophthalmic surgical laser system as defined by regulation number 21 CFR 886.4390.

OPTIMEDICA laser systems are precision medical instruments. The systems have undergone extensive testing. With proper handling, they are useful and reliable clinical instruments. To protect operating personnel and patients, this manual should be read thoroughly and understood before operation.

OPTIMEDICA lasers are classified as Class 4 lasers by the National Center for Devices and Radiological Health. Class 4 represents the highest power lasers; for this reason, you must take precautions to prevent exposure of laser energy to the eye and skin from either direct or diffusely reflected laser beams, except as an intentional application. In addition, precautions must be taken in the surgical environment to prevent the hazards of fire and electrical injury.

OPTIMEDICA does not recommend specific clinical practices. The following precautions are extensive but may not be complete. Laser users are advised to supplement this information with technological advances in surgical products and techniques as they become available to the medical laser user community through medical literature. See also the American National Standard (ANSI®) publications ANSI Z136.3-2005 “American National Standard for the Safe Use of Lasers in Health Care Facilities” and ANSI Z136.1-2007 “American National Standard for the Safe Use of Lasers”, as well as the International Organization for Standardization (ISO) publication ISO 15004-2:2007 Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light Hazard Protection and other national standards as may be applicable for the country in which the system is used.

Calculations regarding the use of lasers have defined a safe range of operating parameters, per ISO 15004-2:2007.

The LIQUID OPTICS Interface is a Type B Patient Applied Part per IEC 60601-1.

The LIQUID OPTICS Interface is not made with natural rubber latex.

The CATALYS System is Class 1 (Electrical Protection) medical electrical equipment.
Ocular Protection

![WARNING]

Never look directly into the laser aperture or scattered laser light from reflective surfaces when the treatment beam is activated. Severe eye damage could occur.

Laser Safety Eyewear

There are two conditions of system operation that need to be considered when defining the requirements for use of Laser Safety Eyewear: normal system operation and system alignment verification.

Normal System Operation

During normal operation of the CATALYS Precision Laser System, there is no user-accessible exposure to the Class 4 and Class 3 beams except for the intentional exposure of the patient for therapeutic purposes. The patient is in contact with the laser aperture of the system by means of the LIQUID OPTICS Interface. The interface keeps the laser beam confined to the patient and prevents accidental exposure to the treatment room personnel. The CATALYS System also imposes multiple sensor and safety checks to insure that no laser energy is emitted unless there is a patient in contact with the laser aperture by means of the LIQUID OPTICS Interface.

For the OPTIMEDICA CATALYS Precision Laser System during normal system operation, the NOHD is 0 (zero) m. Laser safety eyewear is not required for any personnel during normal system operation.

System Alignment Verification

During performance of the daily system alignment verification, as described in the “System Basics” section of this manual, the trained operator does not need to wear laser safety eyewear, because the treatment beam is directed into the opaque backing of the clear plastic hemisphere.

![CAUTION]

Use only OPTIMEDICA part number SA-08044 for verifying system alignment. Previous versions of the plastic hemispheres are obsolete and should not be used.
Definitions from ANSI Z136.1-2007

**Controlled area (laser):** An area where the occupancy and activity of those within is subject to control and supervision for the purpose of protection from laser radiation hazards.

**Embedded laser:** An enclosed laser that has a higher classification than the laser system in which it is incorporated, where the system's lower classification is appropriate due to the engineering features limiting accessible emission.

**Maintenance:** Performance of those adjustments or procedures (specified in the user information provided by the manufacturer and considered preventative, to maintain optimal performance of the laser system), which are to be carried out by the user to ensure the intended performance of the product. It does not include *operation* or *service* as defined in this section.

**Maximum Permissible Exposure (MPE):** The level of laser radiation to which an unprotected person may be exposed without adverse biological changes in the eye or skin.

**Nominal Hazard Zone (NHZ):** The space within which the level of direct, reflected, or scattered radiation may exceed the applicable MPE. Exposure levels beyond the boundary of the NHZ are below the appropriate MPE.

**Nominal Ocular Hazard Distance (NOHD):** The distance along the axis of the unobstructed beam from a laser, fiber end, or connector to the human eye beyond which the irradiance or radiant exposure is not expected to exceed the applicable MPE.

**Operation:** The performance of the laser or laser system over the full range of its intended functions (normal operation). It does not include *maintenance* or *service* as defined in this section.

**Service:** The performance of procedures, typically defined as repair, to bring the laser or laser system or laser product back to full and normal operation status. It does not include *operation* or *maintenance* as defined in this section. The following steps should be taken to secure the controlled area:

1. Treatment should be conducted in a dedicated, enclosed room.
2. A warning sign should be placed on the outside of the treatment room door when the laser is in use. The sign is intended to alert personnel before they enter the controlled area.
3. The treatment room door should be kept closed during treatment, system alignment verification, and any servicing activity.
4. Windows in the treatment room are to be covered or blocked whenever the system is operated with the system covers or shields removed.
Electrical Hazards

⚠️ WARNINGS

Installation, maintenance and repair should be performed only by OPTIMEDICA-certified personnel per the manufacturer’s recommendation and institutional standards.

Never open the laser console protective covers or attempt internal repairs or adjustments not specifically detailed in this operator manual. Opening the covers will expose you to high voltage components, the laser resonator and possible laser radiation.

Do not operate the laser if any of the components are damaged or if the cords are faulty or frayed.

Fire Hazards

⚠️ WARNINGS

Do not use in the presence of flammables or explosives such as volatile anesthetics, alcohol, certain surgical preparation solutions, or other such substances. An explosion and/or fire could occur.

The treatment beam can ignite most nonmetallic materials. Use fire retardant drapes and gowns. The area around the treatment site can be protected with towels or gauze sponges moistened with sterile buffered saline solution. If allowed to dry, protective towels and sponges can increase the potential fire hazard. A UL-approved fire extinguisher should be readily available.

Per IEC 60601-2-22, the use of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided. Some materials (e.g., cotton wool) when saturated with oxygen may be ignited by the high temperatures produced in normal use of the CATALYS System. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the system is used. Attention should also be drawn to the danger of ignition of endogenous gases.

Protecting Non-target Tissues

⚠️ WARNING

Never place hands or other objects in the path of the laser beam. Severe burns could occur.

⚠️ CAUTION

During treatment, only a certified operator should have access to the touchscreen control panel.
Regulatory Compliance Safety Features

The CATALYS System has been designed to comply with 21 CFR subchapter J as administrated by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA). The following compliance safety features are included:

Key Lock Switch

The system can be activated only with the proper key to operate the master key switch. The key cannot be removed in the (on) position, and the system will operate only with the key in place. When treatments are complete, always remove and secure the key to prevent unauthorized use of the system.

Laser Emission Indicator

The (laser emission) indicator is displayed on the touchscreen control panel at all times the laser is energized to warn the user that the system is capable of emitting laser energy.

Door Interlock

A door interlock may be used in conjunction with a remote switch to disable laser and OCT emission in case of certain external events (e.g., the opening of a treatment room door). A remote switch or interlock can be wired to the door interlock plug and connected to the system interlock receptacle on the system rear panel. If a remote switch is used, the system can deliver laser energy only when the remote switch is closed. Breaking the connection by opening the switch (door) or removing the plug disables laser and OCT emission, and the system displays a clearable “Door Interlock” error message on the control panel.

Emergency Stop

The system has an emergency laser stop button that, when pressed, rapidly disables all laser emission, disables the patient chair, and disables the LIQUID OPTICS Interface vacuum system.

Protective Housing

The CATALYS System has a protective housing that prevents unintended human access to laser radiation. This housing is to be opened only by trained OPTIMEDICA personnel.

Safety Interlocks

The protective housing is not designed to be removed by anyone other than an OPTIMEDICA-certified technician. Therefore, the system does not have, and is not required to have, any safety interlock within the meaning of US FDA 21 CFR, Section 1040, or European EN 60825-1. However, the protective housing cannot be opened without use of special tools.

Safety Shutter

The CATALYS System includes a safety shutter, which prevents any laser radiation from exiting the system. The safety shutter is activated when the system is off, during the self-test at turn-on, in STANDBY mode, or when the safety monitor detects a fault.
Location of Controls
Controls are located on the touchscreen control panels. They are conveniently situated for easy access.

System Reset
If treatment is interrupted by a critical error, the system will go to a safe state and be disabled. Do not resume treatment afterwards. Revert to traditional cataract surgery to complete the interrupted treatment.

Electrical Fault Detection Circuitry
If the electronic system detects a fault condition, laser exposure cannot occur. The safety shutter is closed, and the laser is disabled. Some fault conditions are user-clearable. Refer to the “System Error Codes, Faults and Messages” section of this manual for additional information.

Location and Definition of Regulatory and Other System Labels
As required by certain regulatory bodies, appropriate warning labels have been mounted in specified locations on the instrument to indicate conditions under which you could be subjected to laser radiation.
## System Labels

<table>
<thead>
<tr>
<th>Laser Aperture Label (located next to laser aperture)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser beam may exit this area.</td>
</tr>
<tr>
<td><img src="image" alt="Laser Aperture Label" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>System Information Label (located on rear panel), includes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Part Number</td>
</tr>
<tr>
<td>Serial Number</td>
</tr>
<tr>
<td>Manufacture Date</td>
</tr>
<tr>
<td>Follow Operating instructions</td>
</tr>
<tr>
<td>Attention, refer to accompanying documentation</td>
</tr>
<tr>
<td>Type B Equipment</td>
</tr>
<tr>
<td>WEEE Symbol</td>
</tr>
<tr>
<td><img src="image" alt="System Information Label" /></td>
</tr>
</tbody>
</table>

Label image for reference only

<table>
<thead>
<tr>
<th>Federal Communication Commission (FCC) identification label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifies FCC-regulated device installed in CATALYS System</td>
</tr>
<tr>
<td><img src="image" alt="FCC Label" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OPTIMEDICA Patents Identification Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patents: <a href="http://www.jv-patents.com">www.jv-patents.com</a></td>
</tr>
<tr>
<td><img src="image" alt="Patents Label" /></td>
</tr>
</tbody>
</table>
FDA Laser Danger Label (located on rear panel)
Laser emission warning, wavelength, power and laser class

Danger Label (located on internal laser safety enclosure cover when system is equipped with on-board alignment laser)
Laser emission warning, wavelength, power and laser class
<table>
<thead>
<tr>
<th>Label Description</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invisible Laser Radiation Caution Label (located on rear panel), includes:</td>
<td>Laser Emission Warning</td>
</tr>
<tr>
<td>Emergency Stop Label (located next to emergency laser stop button on front panel)</td>
<td></td>
</tr>
<tr>
<td>ON Label (located next to key switch on front panel)</td>
<td></td>
</tr>
<tr>
<td>OFF Label (located next to key switch on front panel)</td>
<td></td>
</tr>
<tr>
<td>Momentary Start Label (located next to key switch on front panel)</td>
<td></td>
</tr>
<tr>
<td>ON</td>
<td></td>
</tr>
<tr>
<td>Label</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
</tr>
<tr>
<td>O</td>
<td>OFF</td>
</tr>
<tr>
<td>0</td>
<td>Patient Vacuum Footswitch Label</td>
</tr>
<tr>
<td><img src="image" alt="Laser Footswitch Label" /></td>
<td>Laser Footswitch Label</td>
</tr>
<tr>
<td><img src="image" alt="Remote Interlock Label" /></td>
<td>Remote Interlock Label (located next to interlock port on system rear panel)</td>
</tr>
<tr>
<td><img src="image" alt="Dual Resettable Circuit Breaker Label" /></td>
<td>Dual Resettable Circuit Breaker Label (located next to main power circuit breakers on system rear panel)</td>
</tr>
<tr>
<td><img src="image" alt="Ground Label" /></td>
<td>Ground Label (located near system ground)</td>
</tr>
<tr>
<td><img src="image" alt="Patient Vacuum Label" /></td>
<td>Patient Vacuum Label (located on docking keypad)</td>
</tr>
<tr>
<td>VACUUM</td>
<td></td>
</tr>
<tr>
<td>Label Description</td>
<td>Location</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>System/Capture Label</td>
<td>Located on docking keypad</td>
</tr>
<tr>
<td>Patient Lock Label</td>
<td>Located on docking keypad</td>
</tr>
<tr>
<td>Patient Chair Joystick Label</td>
<td>Located on patient headrest at base of joystick</td>
</tr>
<tr>
<td>Laser Emission Indicator</td>
<td>Located on touchscreen control panel</td>
</tr>
<tr>
<td>Laser Emission Indicator Label</td>
<td>Located on docking keypad</td>
</tr>
<tr>
<td>Network Connection Label</td>
<td>Located on system rear panel</td>
</tr>
<tr>
<td>Video Output Label</td>
<td>Located on system rear panel</td>
</tr>
<tr>
<td>USB Connection Port Label</td>
<td>Located on system front panel</td>
</tr>
</tbody>
</table>
NOTE

The LIQUID OPTICS Interface is not made with natural rubber latex.
NOTE

The LIQUID OPTICS Interface is not made with natural rubber latex.
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Maintenance
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System Cleaning
The CATALYS System should be cleaned daily after use. Acceptable cleaning methods include wiping down the system with a clean cloth and rubbing alcohol.

⚠️ WARNING
*Do not use caustic cleaners or strong detergents when cleaning the CATALYS System.*

System Maintenance
The CATALYS System is a delicate medical instrument and requires regular maintenance to provide optimum performance. OPTIMEDICA recommends annual system maintenance for the CATALYS System. System maintenance must be completed by trained OPTIMEDICA Service Personnel. There are no user service adjustments on the CATALYS System. Contact OPTIMEDICA Service for system service and repair.

Electromagnetic Compatibility
Like other electrical medical devices, the CATALYS System requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the CATALYS System must be installed and operated according to the EMC information provided in this manual. Consult the tables on the following pages for guidance in placing the CATALYS System.

⚠️ WARNINGS
*Do not use cables or accessories other than those provided with the CATALYS System, as this may result in the increased electromagnetic emissions or decreased immunity to such emissions.*

*If the CATALYS System is used adjacent to other equipment, observe and verify normal operation of the CATALYS System in the configuration in which it will be used prior to use.*

⚠️ CAUTION
*Portable and mobile RF communications equipment may affect normal functioning of the CATALYS System.*

NOTE
*The CATALYS System has been designed and tested to comply with IEC 60601-1-2 Ed. 3.0 b: 2007 requirements for EMC with other devices.*
## Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The CATALYS System is intended for use in the electromagnetic environment specified below. The customer or the user of the CATALYS System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The CATALYS System uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>The CATALYS System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: <strong>Warning:</strong> This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the CATALYS System or shielding the location.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations/flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The CATALYS System is intended for use in the electromagnetic environment specified below. The customer or the user of the CATALYS System should ensure that it is used in such an environment.

**NOTE:** Ut is the a.c. mains voltage prior to application of the test level.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD) IEC 61000-4-2</td>
<td>±6kV contact ±8kV air</td>
<td>±2,4,6kV contact ±2,4,8kV air</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/ burst IEC 61000-4-4</td>
<td>±2kV for power supply lines ±1kV for input/output lines</td>
<td>±2kV line to ground ±1kV line to line</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1kV Differential mode ±2kV common mode</td>
<td>±0.5, 1kV differential mode ±0.5, 1, 2kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5% Ut (&gt;95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles &lt;5% Ut (&gt;95% dip in Ut) for 5 sec.</td>
<td>&lt;5% Ut (&gt;95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles &lt;5% Ut (&gt;95% dip in Ut) for 5 sec.</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the CATALYS System requires continued operation during power mains interruptions, it is recommended that the CATALYS System be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>N/A</td>
<td>Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
### Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The CATALYS System is intended for use in the electromagnetic environment specified below. The customer or the user of the CATALYS System should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the CATALYS System, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>Recommended Separation Distance</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td></td>
<td></td>
<td>d = 1.17 / P</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 1.17 / P 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 2.33 / P 800 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>
|               | | | Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
|               | | | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a), should be less than the compliance level in each frequency range(b). |
|               | | | Interference may occur in the vicinity of equipment marked with the following symbol: |![signal_strength]|

**NOTE 1:** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CATALYS System is used exceeds the applicable RF compliance level above, the CATALYS System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CATALYS System.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
System Error Codes, Faults and Messages

If the system encounters an error, an error code and/or message displays on the screen. There are four types of errors: critical, clearable, no treat, and warning.

Error Types

Critical Errors

Critical errors cannot be corrected. When a critical error occurs, the system goes to a safe state and is disabled, and the error screen gives instructions on how to proceed. There are three types of critical errors: Critical Error – Chair Active, Critical Error – Chair Inactive, and Critical Error – Shutdown.

When a Critical Error – Chair Active occurs, you have three options:

- Lower the chair to release the patient
- Press the LOGOUT button to log out of the system and go to the Login Screen
- Press the HOME button to go to the Home Screen

The chair remains active, but it can only be lowered to remove the patient from under the system; all other chair motions are disabled. If you do not take one of the preceding actions, the system automatically logs you out after 300 seconds.

NOTE

The chair can only be lowered while the error screen is displayed. If you press the HOME or LOGOUT button before lowering the chair, the chair is completely disabled. You must then release the patient by using the headrest height adjustment knob to lower the headrest.

Sample Critical Error – Chair Active
When a Critical Error – Chair Inactive occurs, you have two options:

- Press the LOGOUT button to log out of the system and go to the Login Screen
- Press the HOME button to go to the Home Screen

The chair is completely disabled, and you must release the patient by using the headrest height adjustment knob to lower the headrest. If you do not take one of the preceding actions, the system automatically logs you out after 30 seconds and returns to the Login Screen.

**Sample Critical Error – Chair Inactive**

When a Critical Error – Shutdown occurs, the only option is to press the SHUTDOWN button to shut down the system. The error screen continues to display until you press the SHUTDOWN button. If the error is due to a problem with the touchscreen, the system will have to be shut down by turning the key to the start position and holding it in that position for 10 seconds.

**Sample Critical Error – Shutdown**
Clearable Errors
Clearable errors are user-correctable and will not cause the system to shut down. Follow the on-screen prompts to correct and clear the error and proceed with treatment.

Sample Clearable Error

No Treat Errors
No Treat errors identify problems with the treatment parameters or INTEGRAL GUIDANCE and must be corrected (“Modifications Required”) before proceeding. To correct a No Treat error, first review the treatment parameters and make adjustments, as necessary. Next, re-initiate INTEGRAL GUIDANCE.

Sample No Treat Error
Sample No Treat Error List

Warning Errors
Warning errors notify the operator about the system’s performance. No action is required.

Warning Error—No Action Required
Error Code Table
The software error code table (presented in Appendix C) consists of system error codes, faults, and messages. Column headings are defined as follows:

- Error Type—categorizes each type of error
- Error Number—numeric error code for reference
- Error Message—description/explanation of each error code

“Host No Treat” errors do not indicate that something is wrong with the system. When necessary, the algorithms of INTEGRAL GUIDANCE will prompt the user to modify or confirm the surface fits and treatment plans. The system is performing as intended. Modifications-required messages are provided to guide the user through the treatment and to prompt the user to take the recommended action to confirm and correct the settings. However, if the system displays any of “Critical Error” codes during normal operation, contact OPTIMEDICA Service to correct and resolve the problem.

Calibration Disclaimer
Calibration of the CATALYS System is a service procedure to be performed only by OPTIMEDICA-certified personnel or customers who have taken and passed an OPTIMEDICA Service Certification Training course on the CATALYS System. Adjustment by anyone other than OPTIMEDICA-certified personnel or certified customers voids any existing manufacturer’s warranty on the instrument and can result in serious personal injury.

Warranty
PLEASE REFER TO OPTIMEDICA’S TERMS AND CONDITIONS FOR IMPORTANT LIMITATIONS REGARDING WARRANTY AND LIMITATION OF LIABILITY OR CONTACT OPTIMEDICA’S CUSTOMER SERVICE AT +1-877-266-4543.

Company Information
For assistance, contact Customer Service at +1-877-266-4543.

Decontamination of Returned Equipment
To comply with United States postal and transportation law, equipment shipped to OPTIMEDICA Corp. for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for sale as a Hospital Disinfectant. To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate (provided in this section) must be enclosed in the package.
**Decontamination Certification**

Under the provisions of Postal Law, Title 18, United States Code, Section 1716, and Department of Transportation regulations contained in CFR 49, Part 173.386 and 173.387, “etioologic agents, diagnostic specimens and biological products...are nonmailable...”

The undersigned therefore certifies that the OPTIMEDICA equipment being returned herein by

______________________________  ________________________________
Individual / Institution          City, State/Province, Country

has undergone decontamination with a commercially available germicide cleared for use as a Hospital Disinfectant and is clean and free from biohazards, including – but not limited – human or animal blood, tissue, or tissue fluids, or components thereof.

The undersigned also agrees to reimburse OPTIMEDICA for any costs incurred in decontaminating the enclosed equipment, in the event said item is received by OPTIMEDICA in a contaminated condition.

Model:  CATALYS Precision Laser System

Name (Printed):  

Signature:  

Date (MM/DD/YY):  

Appendices
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Appendix A – Instructions and Labels for the Original Patient Chair Configuration

Patient Chair with Headrest and Joystick

The CATALYS System includes a custom patient chair that can be adjusted and orientated in three axes (x, y and z) by using a precision movement joystick control. The patient chair incorporates a headrest and restraint system that stabilizes the patient’s head for the duration of the treatment.

Patient Chair in Reclined Position

The chair allows for tilt articulation of the patient’s legs, torso, and head using manual adjustments. The chair accommodates three positions:

- Patient load position—chair rotated out from under system with patient chair back in upright position and patient footrest in lowered position.
- Suction ring capture position—chair rotated out from under system with patient chair back in reclined position and patient footrest in raised position.
- Patient treat position—chair rotated under system with patient chair back in reclined position and patient footrest in raised position.

NOTES

The patient chair emits an audible tone when it is unlocked to allow motion.

If the system becomes disabled for any reason during treatment, lower the patient’s head using the headrest vertical adjustment knob. This enables removal of the LIQUID OPTICS Interface and allows the patient chair to be rotated out from under the system.

CAUTION

Do not stand on the patient chair, patient chair footrest or patient chair headrest. The patient chair is designed to support seated and reclined patients only.
Joystick Control

The patient chair is equipped with a “chair enable” feature to protect against unintended chair motion. The patient chair joystick can be enabled in either of two ways:

- The patient chair joystick incorporates a “chair enable” button located on the top of the joystick. You must continuously press the “chair enable” button to enable joystick control of the chair position.

![Patient Chair Joystick Mounted in Patient Chair Headrest](image1)

- The system has a dual function footswitch. The left footswitch is a “chair enable” footswitch and must be continuously depressed to enable joystick control of the chair position.

![System Dual Function Footswitch](image2)
The joystick is a proportional controller—moving the joystick a small amount causes the chair to move slowly; moving the joystick a large amount causes the chair to move faster; holding the joystick at its maximum travel limit provides the maximum chair speed. The available chair speed is reduced as the suction ring enters the capture zone.

The joystick controls the chair position in three axes:

- Moving the joystick left or right causes the chair to move laterally (in the x axis);
- Moving the joystick fore or aft causes the chair to move superiorly or inferiorly (in the y axis);
- Rotating the joystick clockwise causes the chair to move upward (in the z axis); and
- Rotating the joystick counter-clockwise causes the chair to move downward (in the z axis).

**Joystick Control from Surgeon’s Perspective**

*NOTE*

*Once the suction ring is captured to the system, the patient chair joystick is disabled.*
Appendix B – LIQUID OPTICS Interface 12 Quick Reference Guide

This guide is intended to be a simple reference tool for treating a patient using the LIQUID OPTICS Interface 12.

Plan

When planning to treat a patient using LIQUID OPTICS Interface 12, keep in mind that the clear aperture of the suction ring will measure 12 mm in diameter before placement on the patient’s eye, and then will reduce to 11.5 mm in diameter once applied to the patient’s eye. INTEGRAL GUIDANCE software prevents cataract incisions from being placed too close to the LIQUID OPTICS Interface 12 suction ring. In the event that a planned incision is placed too close to the LIQUID OPTICS Interface 12 suction ring, a clearable error would appear on the graphical user interface (GUI) screen, with a “modifications required” message displayed. If a planned incision is placed too close to the suction ring, the incision will either need to be moved or suppressed, in order to complete the CATALYS System treatment.

CAUTION

Confirm that the LIQUID OPTICS Interface 12 package has a red background on the label of the sterile packaging, as opposed to the LIQUID OPTICS Interface, which has a black background on the label of the package.

CAUTION

LIQUID OPTICS Interface 12 Package Label

LIQUID OPTICS Interface Package Label

Engage

To use the LIQUID OPTICS Interface 12, please proceed as follows:

1. **Alignment Mark Placement:** Consider placing marks used to compensate for cyclorotation on the limbus, or possibly more central for better visualization when applying the suction ring and aligning the fiducial marks inside of the LIQUID OPTICS Interface 12. Be careful not to place marks where a CATALYS System created incision is planned, as this may prevent the incision from being created properly.

2. **Docking:** When docking the LIQUID OPTICS Interface 12 to the patient’s eye, avoid pressing down too firmly, as excessive pressure can possibly cause the patient discomfort. After vacuum has been achieved and the CATALYS System gives an audible and visual
confirmation of suction, gently release some of the downward pressure applied onto the LIQUID OPTICS Interface 12 and check for any hissing noise coming from the suction ring. Audible hissing may be a sign of an inadequate vacuum seal of the suction ring onto the patient’s eye, and an inadequate vacuum seal can result in a suction loss, later.

3. Confirm the patient chair has been unlatched before adding sterile buffered saline solution to the LIQUID OPTICS Interface 12.

4. **Capture:** When raising the LIQUID OPTICS Interface 12 into the Capture zone, use the reflective surface of the central alignment ring and the inner edge of the red ring, displayed on the en face video image, to help center and capture the LIQUID OPTICS Interface 12. (Notice, more of the suction ring will be visible on the en face video image than with the LIQUID OPTICS Interface.)

5. **Visualize and Customize/Treat:** Throughout INTEGRAL GUIDANCE and treatment, continue to monitor the en face video image and the force sensors for any potential patient movement or suction loss.

---

*When reviewing the Axial and Sagittal OCT images in INTEGRAL GUIDANCE, notice that more of the LIQUID OPTICS Interface 12 is visible to the left and right of the cornea than would be visible if a portion of the vacuum port is visible on the en face video image. A flow of saline solution is*
a standard LIQUID OPTICS were used.
into the vacuum port may be noticed if there is an inadequate seal on the patient’s eye.

Appendix C – Software Error Code Table

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Error Number</th>
<th>Error Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning</td>
<td>01-001</td>
<td>Vacuum timed out, press vacuum on to retry</td>
</tr>
<tr>
<td>Warning</td>
<td>01-002</td>
<td>Disposable lens not in capture zone, vacuum on ignored</td>
</tr>
<tr>
<td>Warning</td>
<td>01-003</td>
<td>Engaging capture, vacuum on ignored</td>
</tr>
<tr>
<td>Warning</td>
<td>01-004</td>
<td>Releasing vacuum, vacuum on ignored</td>
</tr>
<tr>
<td>Warning</td>
<td>01-005</td>
<td>Capture timed out, press capture on to retry</td>
</tr>
<tr>
<td>Warning</td>
<td>01-006</td>
<td>Disposable lens not present, capture on ignored</td>
</tr>
<tr>
<td>Warning</td>
<td>01-007</td>
<td>Disposable lens not in capture zone, capture on ignored</td>
</tr>
<tr>
<td>Warning</td>
<td>01-008</td>
<td>Vacuum engaging, capture on ignored</td>
</tr>
<tr>
<td>Warning</td>
<td>01-009</td>
<td>Capture releasing, capture on ignored</td>
</tr>
<tr>
<td>Warning</td>
<td>01-010</td>
<td>Disposable lens not in lock zone, lock on ignored</td>
</tr>
<tr>
<td>Warning</td>
<td>01-011</td>
<td>Vertical force exceeds lock limit</td>
</tr>
<tr>
<td>Warning</td>
<td>01-012</td>
<td>Lateral force exceeds lock limit</td>
</tr>
<tr>
<td>Warning</td>
<td>01-013</td>
<td>Unlock in progress, lock on ignored</td>
</tr>
<tr>
<td>Warning</td>
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<td>Vertical force on Liquid Optics Interface exceeds treatment limit, reduce force before proceeding</td>
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<tr>
<td>Clearable Stop 02-003</td>
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<td>Possible fluid/suction loss, check for patient movement</td>
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<tr>
<td>Clearable Stop 02-007</td>
<td>Video frame rate too low for treatment, verify Liquid Optics Interface is correctly docked and patient is not moving before proceeding</td>
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<tr>
<td>Clearable Machine 03-001</td>
<td>Capture line pressure low, inspect Liquid Optics Interface and fluid catchment before attempting to dock</td>
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<tr>
<td>Clearable Machine 03-002</td>
<td>Capture lost, inspect Liquid Optics Interface and fluid catchment before attempting to re-dock</td>
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<tr>
<td>Clearable Machine 03-003</td>
<td>Disposable lens detection failure, ensure disposable lens is correctly installed before proceeding</td>
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<td>Clearable Machine 03-004</td>
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<tr>
<td>Clearable Machine 03-005</td>
<td>Lock not fully engaged, ensure vertical position indicator is centered in Lock Zone when re-docking</td>
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<td>Clearable Both 04-001</td>
<td>Vacuum line pressure low, inspect Liquid Optics Interface and fluid catchment before attempting to dock</td>
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<td>Clearable Both 04-002</td>
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<td>Clearable Both 04-003</td>
<td>Vertical force on Liquid Optics Interface exceeds docked limit, patient automatically undocked</td>
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<td>Clearable Both 04-004</td>
<td>Lateral force on Liquid Optics Interface exceeds docked limit, patient automatically undocked</td>
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<td>Clearable Both 04-005</td>
<td>Chair sync error, ensure chair is locked in 19° or 0° position before proceeding</td>
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<td>Clearable Both 04-010</td>
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<td>Clearable Both 04-011</td>
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<td>Clearable Both 04-012</td>
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<td>Clearable Both 04-013</td>
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<td>Capsulotomy parameter error, contact OptiMedica Service</td>
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<td>Automatic iris fit error, verify surface fits, consider re-scan</td>
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<td>Capsulotomy z out of range, re-scan and verify surface fits</td>
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<td>Lens incision centering error, re-scan and verify surface fits</td>
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<td>Lens Fragmentation parameter error, Contact OptiMedica Service</td>
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<td>Iris intersects limbus, verify surface fits, consider re-scan</td>
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<td>Iris intersects suction ring, verify surface fits, consider re-scan</td>
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<td>Suction ring detection error, verify suction ring fluid and position, then re-scan</td>
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<td>Blocked trajectory error, contact OptiMedica Service</td>
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<td>Iris scan error re-scan and verify surface fits</td>
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<td>Limbus scan error re-scan and verify surface fits</td>
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<td>OCT out of range, contact OptiMedica Service</td>
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<td>Zed error during scan, re-scan and verify surface fits</td>
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<td>Disposable lens moved during scan verify disposable lens correctly installed, re-scan</td>
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<td>Laser pulse energy not achievable, reduce largest treatment pulse energy</td>
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<td>Left/right eye detection error, verify suction ring position and fluid, re-scan</td>
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<td>Suction ring incorrectly docked or missing fluid, verify suction ring positioning and fluid, then re-scan</td>
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<td>Incorrect eye detected, verify position of suction ring and verify fluid in suction ring, then re-scan</td>
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<td>Cataract incision limbus offset too large, verify surface fits and adjust parameters</td>
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<td>Cataract incision computation error verify surface fits, adjust parameters, and consider re-scan</td>
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<td>Cataract incision plane depth/uncut depth cannot be achieved, adjust parameters</td>
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<td>Cataract incision does not intersect cornea, verify surface fits and adjust parameters, consider re-scan</td>
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<td>Cataract incision does not intersect cornea, verify surface fits and adjust sidecut angle</td>
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<td>Cataract incision plane outside of cornea, verify surface fits and adjust parameters</td>
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<td>Cataract incision intersects iris or lens anterior, verify surface fits, adjust parameters</td>
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<td>Cataract incision intersects suction ring, adjust parameters</td>
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<td>Cataract incision located outside of limbus, verify surface fits and adjust parameters</td>
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<td>Arcuate incision optical zone too large, verify surface fits and adjust parameters</td>
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<td>Arcuate incision projection does not intersect cornea posterior, verify surface fits and adjust sidecut angle</td>
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<td>Cataract incision pattern too large, verify surface fits and adjust parameters</td>
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<td>Arcuate incision pattern too large, verify surface fits and adjust parameters</td>
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<td>Cornea mapping error, re-scan and verify surface fits</td>
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<td>Cornea mapping OCT error, re-scan and verify surface fits</td>
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<td>Host data error, contact OptiMedica Service</td>
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<td>08-032</td>
<td>Intake temperature below limits, check room ambient temp</td>
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<td>08-033</td>
<td>Intake temperature above limits, check room ambient temp</td>
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<td>08-034</td>
<td>Device temperature above limit, contact OptiMedica Service</td>
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<td>08-035</td>
<td>Ambient temperature variation exceeds limits, check room temp</td>
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<td>Host data error, contact OptiMedica Service</td>
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<td>Treatment FIFO error, contact OptiMedica Service</td>
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<td>Config file checksum error, contact OptiMedica Service</td>
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<td>Host process ended</td>
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