THE NEW SHAPE OF VISION®

INTRALASE® CORP

IntraLase FS™ Laser

Operator's Manual

CE 0086

900009-007 Rev. A

This manual contains information for the IntraLase FS and FS30 Lasers, running at 15, 30, or 60kHz. The information contained in this document is the confidential and proprietary property of IntraLase Corp. Any reproduction, dissemination, or distribution of this document in whole or in part is strictly prohibited without the prior written permission of IntraLase Corp.

Please note that while every effort has been made to ensure that the data provided in this document are accurate, the information, figures, illustrations, tables, specifications, and schematics contained herein are subject to change without notice.

For service assistance and to order accessories or replacement parts, call our Global Support Department at (877) 393-2020 (in the U.S. only), or (949) 859-5230. To order on the World Wide Web, go to www.intralase.com. Please direct all inquiries regarding this manual to IntraLase Corp., 9701 Jeronimo Road, Irvine, California 92618.

Manufacturer:
IntraLase Corp.
9701 Jeronimo Road
Irvine, California 92618
U.S.A.
Tel. 1 (877) 393-2020 (U.S.A. Only)
Tel. +1 (949) 859-5230 Option #1 (Outside the U.S.A.)

European Representative:
MediTech Strategic Consultants B.V.
Maastrichterlaan 127
6291 EN Vaals
Netherlands
Tel. 31 43 306 3320

Revision History

Section Affected	Part Number	Rev.	Release Date	Description
All	900009	A	04-27-04	Initial Release
All	900009-001	A	06-09-04	Initial Production Release
Software, Setup	900009-002	A	08-05-04	Parameter update
System Description, System Specification, Overview of Operation, Software, Setup, Procedure, Troubleshooting, Labels	900009-003	A	12-30-04	Internet connection
All	900009-004	A	06-06-05	Test Mode and 30kHz Upgrade
General Warnings, Setup, and Procedure	900009-005	A	10-03-05	Shutdown, IC, and SAC
Setup	900009-005	B	12-05-05	Flap Depth Range
System Hazards and Safety Features, System Specifications, Software, Setup, Labels, and Appendix	900009-006	A	02-23-06	60kHz Upgrade
All	900009-007	A	11-20-06	Update indications, WEEE directives, and complications. Add IEK application.

Table of Contents

Section 1 - Introduction 1-1
Indications for Use 1-1
Operator's Manual Overview 1-2
Notes, Cautions, Warnings 1-2
Section 2 – General Warnings 2-1
Section 3 – System Hazards and Safety Features 3-1
Unauthorized Use of the Laser 3-1
Electrical 3-1
Eye Safety and Nominal Ocular Hazard Distance 3-2
Patient Interface 3-2
Mechanical Motion 3-3
Combustion & Fire 3-3
Environmental & Chemical 3-3
Sterilization & Biological Contamination 3-3
Emergency OFF 3-3
Safety Features 3-4
Key ON Switch 3-4
Laser Enabling 3-4
Laser Emission Indicator 3-4
Protective Housing 3-4
Labels 3-4
Safety Shutter Monitor 3-5
Footswitch Control 3-5
Remote Interlock Connector 3-5
Emergency OFF Button 3-5
Section 4 - System Description 4-1
Laser Console 4-2
Beam Delivery Device 4-2
Z-Verifier 4-3
Operating Microscope 4-4
Eye Contact Indicator 4-4
Maximum Eye Pressure Indicator 4-5
Magnification Dial 4-5
Eyepiece Adjustment 4-5
Binocular Separation Adjustment 4-5
Binocular Tilt 4-5
Control Panel 4-6
Joystick 4-6
Surgical Illumination Knob 4-6

Cone Illumination Knob 4-6
Home Button 4-7
Loading Deck 4-7
Lens Assembly Lock 4-7
Display Panel and Keyboard 4-7
Footswitch 4-8
Floppy Disc and CD-ROM Drives 4-8
Patient Interface 4-8
System Power 4-9
Key ON Switch 4-9
Emergency OFF Button 4-9
Section 5 - System Specifications 5-1
Section 6 - Overview of Operation 6-1
Method of Resection 6-1
Corneal Resection with the IntraLase FS Laser 6-1
Lamellar Flap Procedure Using IntraLASIK® Software 6-2
Spiral and Raster Scanning Patterns 6-3
Pocket Option 6-3
Side Cut Only Pattern 6-4
Optional Intrastromal Lamellar Ring Resection 6-4
Section 7 - Software 7-1
User Login Window and System Startup 7-1
Procedure Window 7-2
Patients Window 7-3
Patient Data Entry Window 7-4
Treatment History Window 7-6
Users Window 7-7
Creating a New User 7-7
Editing a User 7-7
Deleting a User 7-7
Options 7-8
User Logout 7-8
System Tools Window 7-8
System Checks 7-8
System Status 7-9
Procedures 7-9
About 7-9
Shutdown 7-9
Test Procedure Mode 7-10
Section 8 - System Installation 8-1
Installation 8-1
Shipping Contents 8-1

System Requirements 8-2
Electrical 8-2
Environmental 8-2
Particulate 8-2
Vibration and Stability 8-2
Section 9 - Setup 9-1
Procedure Activation 9-1
Internet Connectivity (IC) 9-2
Secure Activation Code (SAC) 9-3
Secure Activation Code Log 9-3
Patient Record Default 9-4
Flap Parameters 9-5
Pocket parameters 9-6
Ring Parameters 9-7
Patient Selection 9-8
Lamellar Resection for Corneal Flaps 9-8
Flap Contraindications 9-8
Complications 9-9
Procedure and Parameters Selection 9-10
Section 10 - Procedure 10-1
Energy Wheel Initialization 10-1
Operative Precautions 10-1
Application of the IntraLase Patient Interface 10-2
Indications 10-2
Precautions 10-2
How Supplied 10-2
Preparation 10-3
Open the Tray 10-3
Inspect the Patient Interface Contents 10-3
Install the IntraLase Patient Interface Applanation Cone 10-4
Suction Ring Assembly Application 10-5
Applanation Procedure 10-6
Automatic System Checks 10-6
Pattern Centration 10-7
Procedure Initiation and Execution 10-8
Releasing Suction 10-9
Preparation for Bilateral Procedure 10-9
System Shutdown 10-10
Section 11 - IntraLase-Enabled Karatoplasty (IEK) 11-1
Intended Use (IEK Application) 11-1
Contraindications 11-2
Keratoplasty Application 11-3

Examples of Pattern Combinations 11-5
Other Incision Patterns 11-5
Examples of Non-Intersecting Pattern Combinations 11-6
Parameters 11-7
Lamellar Parameters 11-7
Anterior Side Cut Parameters 11-8
Posterior Side Cut Parameters 11-9
Alignment Incisions 11-10
Energy and Spot Separation Settings 11-11
Overlapping Resection Patterns (Intersecting) 11-11
Non-Intersecting Resection Patterns 11-11
Section 12 - Service and Maintenance 12-1
Section 13 - Troubleshooting 13-1
Error Messages 13-1
Re-Settable System Errors 13-1
Beam Steering Errors 13-1
Troubleshooting Guide 13-2
Section 14 - Labels 14-1
Console Labels 14-1
Label for the IntraLase Patient Interface Single-Use Disposables 14-4
Section 15 - Appendix 15-1
Abbreviations 15-1
Terms 15-1
Nominal Ocular Hazard Distance (NOHD) 15-2
Declaration of Compliance 15-5
Section 16 - Warranty Information 16-1

Section 1 - Introduction

The IntraLase FS Laser is a CDRH CFR 1040 class IIIb precision ophthalmic surgical laser indicated for use in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea.

United States Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. Further, United States Federal Law restricts the use of this device to practitioners who have been trained in the calibration and operation of this device, and who have experience in the surgical treatment and management of refractive errors.

In the European Union, the IntraLase FS Laser is a class IIb device in accordance with Rule 9 of the Medical Device Directive. The IntraLase Patient Interface is classified as a class IIa device in accordance with Rule 5 of the Medical Device Directive.

Indications for Use

The IntraLase FS Laser is a 21 CFR 1040 class IIIb ophthalmic surgical laser with the following indications for use:

- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments
- In lamellar keratoplasty and corneal harvesting
- In keratomileusis *in situ* for the correction of myopia
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and for the creation of a penetrating cut/incision for penetrating keratoplasty.

The IntraLase FS Laser delivery system is used in conjunction with a sterile disposable IntraLase Patient Interface, consisting of pre-sterilized suction ring assemblies and pre-sterilized applanation lenses, intended for single-use.

The IntraLase FS Laser should only be operated by, or under the direct supervision of a trained physician with certification in laser safety and in the use of the IntraLase FS Laser.

Operator's Manual Overview

This Operator's Manual provides background, safety information, and specific instructions for the use of the IntraLase FS Laser. A Table of Contents can be found at the beginning of this Manual. IntraLase recommends that the Operator's Manual be read by all personnel using the IntraLase FS Laser. Moreover, the Manual should be used in any training activity involving the IntraLase FS Laser. Abbreviations and terms used throughout the Manual are defined in text where they first appear. A glossary of terms is also found in the Appendix.

Notes, Cautions, Warnings

NOTES: Presents helpful notes or tips that make certain tasks easier and more efficient. Using these tips will save a lot of time and in some cases make sure that the task is performed adequately.

CAUTIONS: Information that need extra attention. These are steps or instructions that prevent damage to any of the system's components.

LASER WARNING: Signals possible exposure to laser beam.

WARNINGS: Very important warning and safety information.

Section 2 – General Warnings

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

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

In Canada, installation and operation of the IntraLase FS Laser must be in accordance with CAN/CSA-Z386-92: Laser safety in health care facilities.

WARNING: Do not use cell phones, pagers, or radio frequency devices of any kind in the same room as the IntraLase FS Laser.

This symbol is located on IntraLase systems and indicates that the equipment consists of electronic assemblies and other components that may be subject to Directives 2002/96/EC, 2003/108/EC, and 2002/95/EC of the European parliament, which advises that electrical and electronic devices must not be disposed of as normal domestic refuse. In order to prevent environmental risks or endangerments by non-professional disposal, the disposal of this product, including any accessories, must comply with valid practices as outlined in Directives 2002/96/EC, 2003/108/EC, and 2002/95/EC, and local regulations. All electronic components and systems should be returned to IntraLase Corp. for disposal.

Section 3 – System Hazards and Safety Features

Surgical lasers must meet requirements established by the Food and Drug Administration (FDA) Center for Devices and Radiological Health. To prevent accidental exposure of laser energy to the eye and skin from both direct and reflected laser beams, specific controls are required. In addition, precautions to be taken in the surgical area to prevent fire and electrical hazards are listed below.

Unauthorized Use of the Laser

When the instrument is not operating, the *master key* should be removed from the IntraLase FS Laser and kept in a secure location to prevent use by unauthorized personnel. Once the console is switched on, password protection is required to access any laser functions.

Electrical

WARNING: High voltage electrical circuits are accessible if the console panels are removed. Only trained IntraLase service representatives should attempt to open the console panels. Serious injury or death may occur as a result of exposure to electrical circuits in the unit interior.

The IntraLase FS Laser uses a variety of electrical service as shown below. The line voltage should be tested prior to laser installation and must be within specified limits for proper operation of the unit.

Line Condition	Peak Current
120 VAC, 60 Hz	7A
100 VAC, 50 – 60 Hz	10 A
220-240 VAC, 50 – 60 Hz	4 A

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

The area around the IntraLase FS Laser and the *footswitch* should be kept dry. The laser should not be operated if there is any leakage of water from the console. Contact an IntraLase service representative immediately.

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

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

Eye Safety and Nominal Ocular Hazard Distance

The IntraLase FS Laser generates a high peak power laser pulse specifically designed to produce micro-photodisruption in the tissues of the eye. However, the very small pulse energies and the strongly diverging beam together produce a minimal hazard to the user or patient. The Nominal Ocular Hazard Distance (NOHD) is defined as that distance from the laser aperture within which exposure to the eye may exceed the Maximum Permissible Exposure limit (MPE) as per ANSI standard Z136.1 – 2000. The maximum NOHD for a direct beam exposure from the IntraLase FS Laser is 54 cm when operating at 15 kHz, 58 cm when operating at 30 kHz, and 53 cm when operating at 60 kHz. (See the Appendix for details.) This means that only the patient's operative eye will be exposed to laser radiation exceeding the MPE. Protective eyewear for operating suite personnel is not required, but is recommended as a part of standard laser safety protocols.

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

Patient Interface

Centration of the Beam Delivery Device on the patient eye is accomplished by manipulation of the control *joystick*. The objective lens of the Beam Delivery Device is mechanically counter balanced and its motion is dampened to allow the contact glass to gently touch the eye. When eye contact is established, the contact glass gently applanates the eye as the Beam Delivery Device is moved downward. When the Beam Delivery Device reaches a pre-determined position, a limit switch disables further downward motion, preventing potential applanation overpressure.

WARNING: The Patient Interface disposables should not be reused or re-sterilized.

Mechanical Motion

The IntraLase FS Laser console is stable and non-mobile. No significant tipping or rolling hazard exists once the console is installed. If the console must be moved for any reason, contact an IntraLase service representative.

Movement of the Beam Delivery Device is under electrical power and caution must be used when it is actuated. Care should be taken to prevent trapping of clothing, limbs, fingers or other body parts when the Beam Delivery Device housing and the articulating arm are in motion.

Removing console covers constitutes a potential mechanical hazard and should be performed only by trained IntraLase service representatives.

Combustion & Fire

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

Environmental & Chemical

No hazardous gases or chemicals are used in the IntraLase FS Laser. The IntraLase FS Laser does not emit or purge any chemical gas or ozone.

Sterilization & Biological Contamination

The IntraLase Patient Interface is designed for patient contact and is pre-sterilized as a single-use disposable. Disposable assemblies should not be reused and should be stored unopened in their factory-sealed packaging.

WARNING: Used IntraLase Patient Interface assemblies should be treated as medical waste. Use and disposal of the IntraLase Patient Interface is detailed in the IntraLase Patient Interface Directions for Use (DFU).

Emergency OFF

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

Safety Features

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

Key ON Switch

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

Laser Enabling

When the *master key* is turned to the ON position, an **Operating System Login** window appears and requests a login name and password. Upon access, an IntraLASIK® Software system window appears and requests a user name and password. This security feature prevents unauthorized use of IntraLASIK® Software. Following successful login, laser operation is disabled for approximately twenty minutes while the microprocessor checks for basic fault conditions and the system stabilizes. After this period, the **Procedure** window will appear on the Display Panel. Laser emission is disabled until the user selects appropriate treatment parameters.

Laser Emission Indicator

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

Protective Housing

The IntraLase FS Laser has a protective housing that prevents unintentional access to laser radiation. This housing is to be opened only by a qualified IntraLase service representative.

Labels

Appropriate warning labels are mounted in appropriate locations on the laser system to indicate conditions under which the user could be subjected to laser radiation (See the Labels Section of this manual).

Safety Shutter Monitor

Dual safety shutters, closed unless the system is in the TREATMENT state, prevent any laser radiation from exiting the instrument. Shutter status is continuously monitored. Should a malfunction occur (i.e. a safety shutter opens in the absence of a *footswitch* press), all laser emissions are prevented and a message is displayed. Laser emission cannot be re-enabled until the fault condition has been cleared.

Footswitch Control

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

Remote Interlock Connector

The system is equipped with an outlet for the interlocking of room doors. All *laser shutters* are closed and a message on the Control Panel appears when the remote interlock is not connected properly or has been broken by some action such as the opening of an operating room door. An IntraLase service representative may be contacted for assistance in establishing a remote interlock.

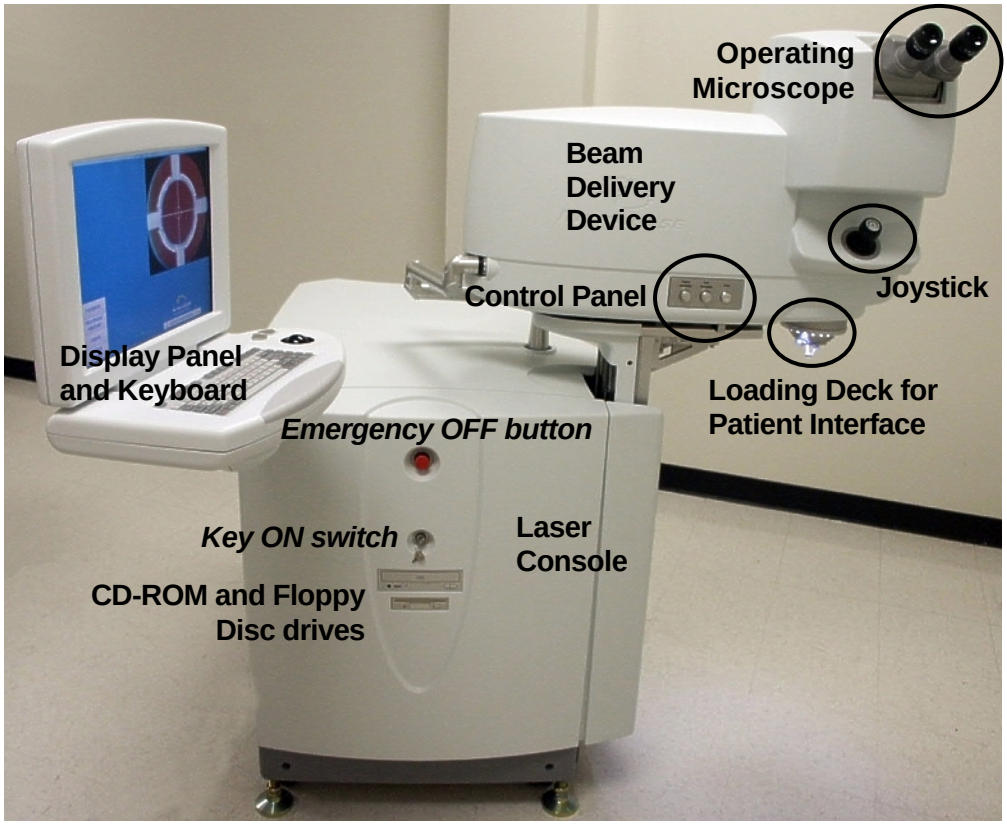
Emergency OFF Button

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

Section 4 - System Description

The IntraLase FS Laser consists of the following principal hardware components.

- Laser Console
- Beam Delivery Device
- Operating Microscope
- Control Panel
- Loading Deck for Patient Interface
- Display Panel and Keyboard
- Emergency OFF Button
- *Footswitch* (not shown below)
- Floppy Disc and CD-ROM drives
- Patient Interface (not shown below)



Laser Console

The IntraLase FS Laser Console houses the laser source, control and power supply electronics, cooling system, and computer. No external water or gas connections are required. The laser beam is completely shielded inside the console. The console is designed for use in medical settings and complies with United States and international standards for electromagnetic emissions in medical devices.

The *key ON switch* and *Emergency OFF button* are located on the front panel of the console where they are easily identified and accessed.

The console is enclosed in rugged panels that must not be removed except by IntraLase service representatives.

Beam Delivery Device

The Beam Delivery Device focuses and places the scanned laser beam in the cornea with high precision. The laser beam is relayed through an articulating beam coupler into two scanning units. Computer control of the scanning units and of a focusing lens allows 3D software control of the laser focus. Located at the distal end of the Beam Delivery Device is the Patient Interface Loading Deck, which couples the Beam Delivery Device laser output to the disposable IntraLase Patient Interface. The patient is not exposed to the laser beam until the beam exits the applanation lens. Manual controls allow the user to position the Beam Delivery Device pre- and post-operatively. During laser emission, the positioning controls are disabled.

Safety and reliability features of the Beam Delivery Device are the following:

- An *electronic beam position monitor* detects the laser beam position through the articulating arm and provides feedback information to an actively controlled steering mirror in the console. Beam positioning is checked during system startup and prior to each procedure.
- *Applanation limit switches* monitor the position of the objective lens and alerts the user to initial contact of the coupled applanation lens to the cornea (by illuminating a green Light Emitting Diode, LED) and maximum contact pressure (by illuminating a red LED and an audible beep). The illuminated LEDs are visible through the Operating Microscope and on the Display Panel.

WARNING: When the green light is obtained during a docking procedure, sensors on the BDD limit the downward travel distance of the gantry to further mitigate potentially hazardous applanation overpressure.

- If the Beam Delivery Device moves down more than a pre-set distance beyond the red light position, the system prevents further downward movement.

Z-Verifier

The Z-Verifier is a series of electronic circuits and software controls that provide backup safety features to ensure that the gantry will not move inadvertently in an unexpected direction. These controls are in addition to the current primary active safety features, the red light limit during applanation, and the red Emergency Off Button main power shut-off located on the front of the system chassis.

When the objective encounters resistance that activates the green eye contact LED (such as when the eye is applanated), the Z-Verifier registers the position of the gantry. The Z-Verifier then monitors the movement of the gantry. If the gantry moves down more than predetermined distance beyond the anticipated red light (over-travel) position, then the Z-Verifier prevents further downward movement of the gantry.

WARNING: To ensure the proper operation of the Z-Verifier safety features, use the joystick to applanate and to activate the green eye contact LED. Do not lift and place the objective on the eye in lieu of using the joystick.

If the Z-Verifier is activated as a result of a system failure, an error message will be displayed (Gantry Z–Axis 5V Failure) and gantry functions will be disabled.

To clear the error and enable gantry movement, the surgeon may click on the reset button that appears within the error dialog box. If the patient is fully applanated when an error occurs, lower the patient's head from beneath the cone BEFORE attempting to reset the error.

1. Before selecting "reset" on the user interface, attempt to move the gantry up using the joystick.
2. Move the patient from beneath the objective before attempting to reset.
3. Select "reset" on the user interface.
4. Attempt to move the gantry up using the joystick.
5. If the gantry does not respond or response is not normal, call IntraLase Global Support.

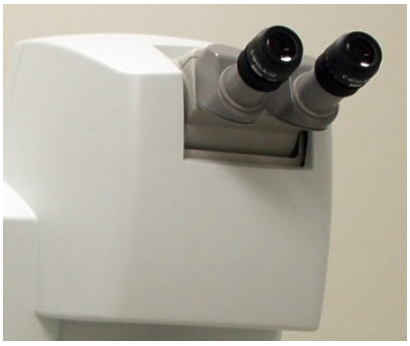
If the Z-Verifier continues to register a fault condition, the error message will reappear and gantry function may be disabled (procedure cannot begin). A procedure cannot begin if an error is present.

The Z-Verifier monitors the gantry motion after eye contact is detected. If the green eye contact LED is activated before the IntraLase Patient Interface cone contacts the patient and remains active, the Z-Verifier may prohibit the full range of downward gantry motion, making full applanation not possible. This may occur, for example in the following situations:

1. If the applanation lens (IntraLase Patient Interface cone) inadvertently contacts the suction ring assembly. The surgeon must ensure that the green eye contact LED activates only as a result of eye contact. If full applanation is not achieved, the surgeon must elevate the gantry until the green eye contact LED is deactivated before re-applanating.
2. This can also occur if the eye is lifted with the gripper prior to eye contact, or is pushed back (retropulsed) into the orbit, thereby using the additional travel allowed by the Z-Verifier. To avoid or remedy this, the suction ring assembly can be held in the neutral position with the free hand to avoid downward movement of the eye. Alternatively, the eye can be elevated in the orbit to its normal position by gently elevating the suction ring assembly after eye contact is made. This "walking up" maneuver will bring the cornea into full applanation.

Operating Microscope

The Operating Microscope provides a view of the surgical field at all times. A magnification dial on the side of the Operating Microscope allows the user to vary the viewing magnification and visual field size. A miniature video camera relays the magnified image of the surgical field to the Display Panel. Viewing the field with the Display Panel is required for the user-defined treatment offset function and is useful for general viewing of the surgical field.



NOTE: To perform the treatment offset function the magnification dial must be in Position 2. Before or after this function is performed, the user may use any magnification Position preference.

Eye Contact Indicator

As the objective lens or applanation lens coupled to the objective lens makes contact with the patient eye (or any other surface), a *green LED* is illuminated and is visible in the Operating Microscope and on the Display Panel. The motion of the Beam Delivery Device is slowed whenever the green LED is illuminated.

Maximum Eye Pressure Indicator

As the Beam Delivery Device is lowered further after initial contact with the patient eye (or any other surface), the applanation force increases while the counter-balanced objective lens continues to move upwards with respect to the Beam Delivery Device. At a preset position of the objective lens deflection corresponding to the maximum allowed eye pressure, a sensor is actuated and a *red LED*, which is visible in the Operating Microscope as well as on the video display, is illuminated. In addition, an *audible beep* will be activated as long as the maximum pressure sensor is actuated. Further downward movement of the Beam Delivery Device is disabled whenever the red LED is illuminated, but upward movement is still enabled. To disengage the audible beep the user must move the Beam Delivery Device upward to de-actuate the maximum pressure sensor.

Magnification Dial

A magnification selection dial is located to the right of the microscope. The IntraLase FS Laser Operating Microscope offers four magnification selections:

- 1 = 11 mm field of view
- 2 = 15 mm field of view
- 3 = 18 mm field of view
- D = focal position is approximately 1.5 to 2 inches below the plane of the applanation lens (bottom of the cone). This deeper focal position is intended to pre-operatively assist the user in placing the suction ring assembly as described below. Post-operatively this position allows the user to view the resection.

All magnified views can be seen on the video display.

Eyepiece Adjustment

The eyepiece cups can be individually rotated for fine correction for each viewing eye.

Binocular Separation Adjustment

The separation between the binocular viewing tubes can be adjusted by rotating the tubes towards or away from each other.

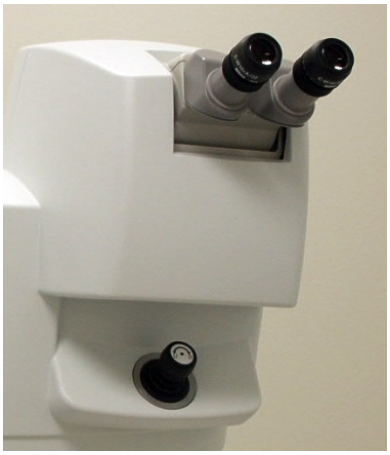
Binocular Tilt

The entire ocular portion of the binocular assembly can be tilted to adjust to the physician viewing height. Additionally, the viewing tubes may be rotated 180 degrees to further adjust for the physicians viewing height or preference.

Control Panel

The Beam Delivery Device houses an Operating Microscope that allows a magnified view of the surgical field. The Beam Delivery Device also features a *joystick*, a *surgical illumination* knob, a *cone illumination* knob, and a *HOME* button. Each of these functions is described in the sections below.

Joystick



The *joystick*, located underneath the microscope, controls the X-Y-Z positioning of the Beam Delivery Device. The following are the Beam Delivery Device movements controlled by the *joystick*:

- Tilt up to move away from the user
- Tilt down to move towards the user
- Tilt left to move left
- Tilt right to move right
- Turn counter-clockwise to move up

During laser emission, all *joystick* control functions are disabled. If the maximum eye pressure indicator is illuminated, the Beam Delivery Device cannot be lowered further.

Surgical Illumination Knob

Illumination from a ring of LEDs mounted on the objective lens produces a wide field of light intended for viewing the entire surgical field. The illumination field is concentrated onto a plane located about two inches below the applanation position. The Surgical Illumination knob varies the light intensity from maximum to OFF.

Cone Illumination Knob

Illumination of the applanation lens and the applanated cornea is provided by LEDs mounted on the interior of the objective lens assembly. The Cone Illumination knob varies the light intensity from maximum to OFF. The Cone illumination must be ON in order to observe the laser pattern during surgery.

Home Button

The *Home* button is used to quickly move the Beam Delivery Device from the surgical field following completion of a resection procedure by moving the Beam Delivery Device upwards at a pre-set distance. The movement can be repeated by pressing the *Home* button again to gain additional clearance. This feature can be used instead of the *joystick* for convenience and speed. The *Home* button is disabled whenever the *green contact LED* is illuminated, whenever the *footswitch* is depressed, or during laser emission. *Home* button travel can be halted at anytime by lifting the objective slightly. This allows the surgeon to terminate an unwanted HOME movement.

WARNING: The suction ring assembly must be disengaged from the patient's cornea before using the Home button.

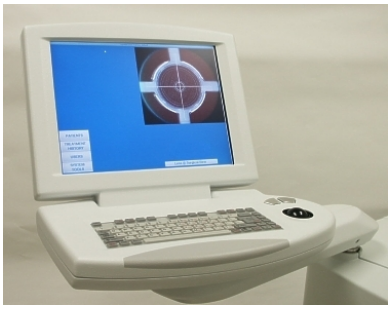
Loading Deck

The Loading Deck is a precision assembly located at the output of the Beam Delivery Device that accepts an IntraLase Patient Interface disposable applanation cone. It consists of a smooth flat surface with guiding rails. A Loading Deck-locking arm secures the applanation cone into position. Sensors detect that the applanation cone is properly positioned in the Loading Deck and that the lock is closed.

Lens Assembly Lock

The Lens Assembly lock holds the applanation cone in the Loading Deck and prevents it from slipping out of place. A *lock sensor* continuously monitors and verifies that the Loading Deck is locked during a procedure.

Display Panel and Keyboard



A flat panel color display, keyboard, and trackball-pointing device are mounted on a swiveling platform located opposite the Operating Microscope at a corner of the console. System status, patient logs, procedure data, user registry, procedure license information, and live video display of the microscope field of view can be viewed on the Display Panel.

Laser resection parameters are entered, controlled, and monitored from the Display Panel and Keyboard. The entire station swivels on a mounting post for optimal viewing and control access.

Footswitch

Actuation of the *footswitch* is required to initiate laser treatment. The *footswitch* is actuated by placing a foot inside the housing and pressing down on the spring-loaded pedal until it contacts the bottom of the *footswitch*.

The *footswitch* is housed in an industrial grade enclosure, with a rugged electrical cord attached at the rear panel of the Laser Console, near floor level. The IntraLase FS Laser will not emit a laser beam if the *footswitch* is not connected to the console.

Floppy Disc and CD-ROM Drives

A standard 3.5-inch PC floppy disc drive and a CD-ROM drive are located in the middle of the IntraLase FS Laser Console front cover. These drives are used for software updates, procedure updates, record backups, and service functions.

Patient Interface

A pre-sterilized, single-use, bilateral or unilateral IntraLase Patient Interface mechanically couples the Beam Delivery Device to the patient cornea. The IntraLase Patient Interface is designed for exclusive use with the IntraLase FS Laser and indicated for corneal resection surgery. All components are sterile and intended for single use only. The bilateral Patient Interface is also intended for use on one patient.

The IntraLase Patient Interface applanation cone base is a precision reference surface that mates to the Beam Delivery Device. Alignment of the IntraLase FS Laser is verified and adjusted upon installation such that the vertical position of the laser beam focus is precisely known with respect to the applanation contact glass surface.

The IntraLase Patient Interface suction ring assembly consists of a limbal suction ring attached to a flexible "gripper" unit, and a syringe connected to the limbal suction ring with tubing. The limbal ring is used to fixate the eye for the duration of the procedure by means of a low suction applied with a small syringe. The suction ring assembly is designed to accommodate the applanation cone in the central cylindrical aperture. A molded clip on the end of the gripper levers holds the cylindrical aperture open until it is released.

The Beam Delivery Device is positioned using the Control Panel *joystick* to "dock" the applanation cone in the suction ring assembly. The gripper levers are released when the cornea is fully applanated. The gripper firmly holds the applanation cone, coupling the patient's cornea and the Beam Delivery Device.

System Power

Key ON Switch

Located on the lower center of the Laser Console front panel, the *key ON switch* has two positions: "O" and **"I."** Rotating the key from "O" to **"I"** turns on the main power and initiates laser warm-up and self-checking routines. Normal shutdown of the system power is accomplished by selecting **Shutdown** in the **Options** menu and rotating the *key ON switch* from "I" to "O" when instructed.

Emergency OFF Button

Located on the upper front center of the Laser Console front panel, the *Emergency OFF button* is an easily accessible, large, red button. When pressed the system power is immediately shut off. The *Emergency OFF button* is reset by twisting the button clockwise until it pops up. Use of the *Emergency OFF button* should be limited to emergencies. Normal shutdown procedures should be followed during normal operation.

Section 5 - System Specifications

System Parameter	Specifications	
Laser type	Mode-locked, diode-pumped Nd:glass oscillator with a diode-pumped regenerative amplifier	
Mode	Fundamental (TEM_{00})	
Spot size	< 3 μm	
Beam divergence	≥ 0.31 sr (± 0.05 sr)	
Pulse repetition rate	15 kHz, 30 kHz, or 60 kHz	
Laser pulse duration	600-800 fs (± 50 fs)	
Maximum laser pulse peak power	15 kHz: 12 MW (± 2 MW) 30 kHz: 12 MW (± 2 MW) 60 kHz: 8.3 MW (± 1.4 MW)	
Central laser wavelength	1053 nm	
Remote interlock	Yes	
System footprint (min)	47"(W) x 49"(L) x 57"(H)	
Beam delivery device height	Min 33.5" (floor to applanation lens) Max 41.0" (floor to applanation lens)	
System weight	900 lbs	
Ambient operating temperature / humidity	19° C to 23° C (67° F to 73° F) / between 35% and 65% non-condensing	
Maximum pulse energy	15 kHz operation: 7.3 μJ (± 0.7 μJ) 30 kHz operation: 7.3 μJ (± 0.7 μJ) 60 kHz operation: 5.0 μJ (± 0.5 μJ)	
Maximum laser beam output	15 kHz operation: 110 mW (± 11 mW) 30 kHz operation: 220 mW (± 22 mW) 60 kHz operation: 300 mW (± 30 mW)	
Input voltage & maximum current	**Line Condition**	**Max current**
	120 VAC, 60 Hz	7 A peak
	100 VAC, 50–60 Hz	10 A peak
	220-240 VAC, 50–60 Hz	4 A peak

Section 6 - Overview of Operation

Method of Resection

Corneal Resection with the IntraLase FS Laser

The IntraLase FS Laser creates a resection plane using precise individual micro-photodisruptions of tissue created by tightly focused femtosecond laser pulses. Individual photodisruption locations are controlled by repeatedly moving the laser focus in the cornea at high speeds under software control. The surgical effect is produced by scanning tens of thousands of nearly overlapped individual pulses each second, resulting in incisions equivalent to those produced with mechanical blades.

The laser pulses are delivered through an IntraLase Patient Interface composed of a suction ring assembly and an applanation cone. The applanation cone holds an applanation glass that flattens the cornea and creates a reference surface for depth control, while the suction ring assembly fixes the eye with respect to the applanation cone and the Beam Delivery Device.

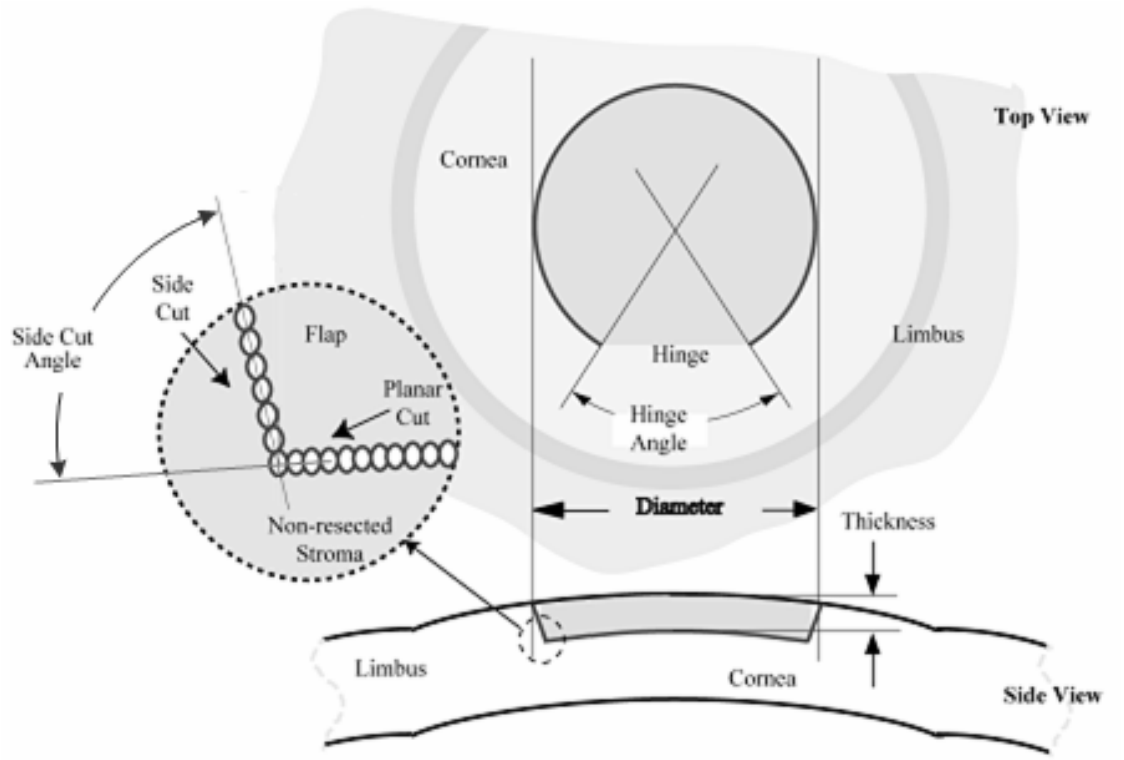
Prior to laser resection, the molded clip on the gripper levers of the suction ring assembly are engaged to hold the cylindrical aperture open. To hold the patient's eye, the suction ring assembly is applied onto the eye, over the pupil center. The Beam Delivery Device, with applanation cone installed, is then centered over the patient's eye by manipulation of the *joystick*. While the surgeon guides the applanation cone through the suction ring assembly under Operating Microscope visualization, the cornea is first contacted, and then applanated as the Beam Delivery Device is further lowered. After correct alignment and full corneal applanation are achieved, the molded clip on the suction ring assembly gripper levers is released. The IntraLASIK® Software will prompt the user to center and initiate the treatment. Treatment is initiated by depressing the *footswitch*.

Pre-programmed patterns produce lamellar resections through a combination of user-determined and factory-set parameters. Procedures and parameters are selected using the IntraLASIK® Software. Selection of a complete set of procedure parameters automatically initiates system safety checks and enables the IntraLase FS Laser for treatment.

Lamellar Flap Procedure Using IntraLASIK® Software

Lamellar flaps are created using the IntraLASIK® Software. All flaps are created in a two-part resection: first by a horizontal resection plane at the user selected flap depth and, second, by a partial cylindrical arc cut, called a side cut, that extends from the horizontal resection plane to the corneal surface. A section of the side cut is left untreated thereby leaving a flap hinge.

Viewed in cross section, these two intersecting resections form a shallow disk-shaped resection. A schematic representation of a lamellar flap using the IntraLASIK® Software is shown in the figure below.



Schematic top and cross section views of lamellar flap made with IntraLase FS Laser.

Spiral and Raster Scanning Patterns

The IntraLASIK® Software allows three user-selected scanning patterns for the creation of lamellar flaps. These scanning patterns, the spiral, raster and double raster patterns, affect the manner in which the flap bed resection is created.

With a spiral pattern, the resection starts from the center of the cornea and moves outward in a pattern of expanding concentric rings. After completion of the planar cut, a side cut is made, beginning at the planar resection perimeter and extending to the anterior corneal surface.

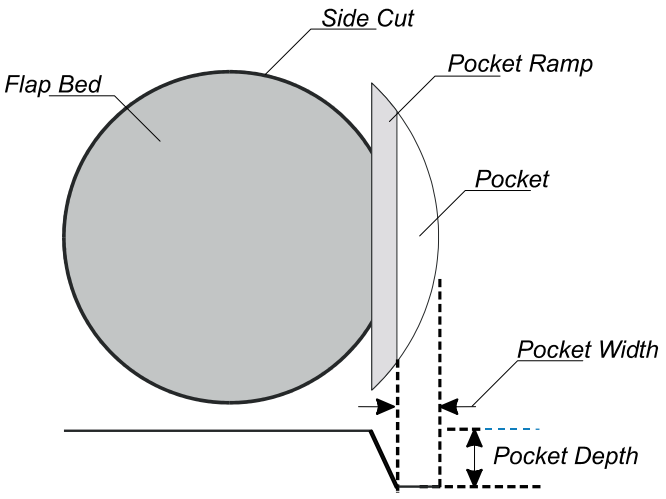
With a raster pattern, the resection begins at the hinge position on the flap periphery. The scan creates a linear chord across the resection field intersecting the flap perimeter. The scanned resection chords advance through the center of the pattern, filling out a circular disk. After the completion of the planar-disk cut, a side cut is made beginning at the perimeter of the planar resection and extending to the anterior corneal surface.

The IntraLASIK® Software also allows the user to perform a double raster scanning pattern. When this option is selected, the laser is scanned across the horizontal resection plane twice in succession prior to the creation of the side cut. The programmable parameters of the second raster scan are the same as those of the first pass. After the completion of the second pass, the side cut and hinge creation proceed normally.

Pocket Option

The pocket option is an auxiliary pattern that may be used with a raster pattern. The pocket option creates a small resection centered at the hinge position but outside the perimeter of the side cut.

A schematic of the pocket is shown in the figure on the right. When the pocket is enabled, the pattern begins by first making a pocket at a user-defined distance below the raster resection. The beam is scanned, starting at the hinge position, until the pocket reaches the circumference of the flap resection. A pocket ramp is then cut up to the level of the flap depth. The edge of the pocket ramp ends at the chord defined by the hinge.



The width of the pocket ramp is dictated by the hinge angle: a smaller hinge angle results in a smaller ramp width and visa versa. When the pocket ramp is complete, the beam focus is reset to the edge of the hinge and a standard raster resection is started.

The pocket option is allowed only for flap resections using a raster pattern and must be targeted at a depth below the targeted depth of the flap pattern.

Side Cut Only Pattern

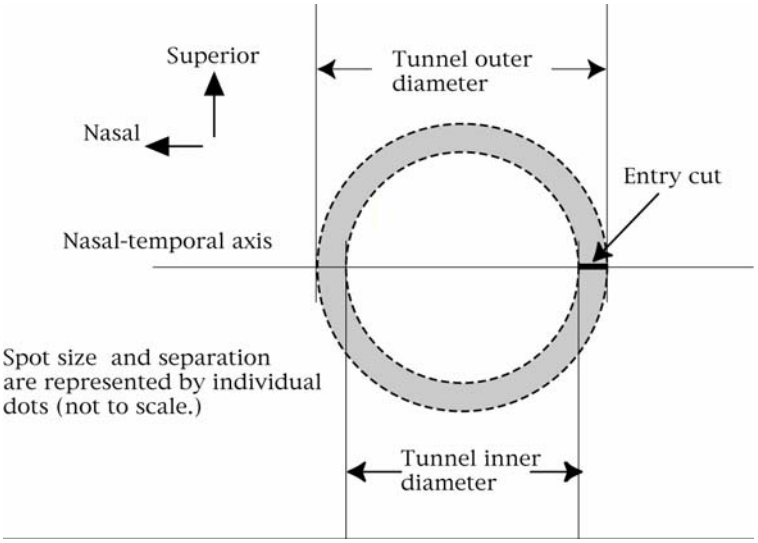
The IntraLASIK® Software allows the user to perform a side cut only pattern without first performing a horizontal planar cut; this capability may have utility in that the side cut can be performed independent of the planar horizontal cut. This feature is accessed in the **Patient Under Treatment** window, after the **Treat** button has been pressed and before **Pattern Centration** is performed. To bring up the **Side Cut Only** button do the following:

1. Select the **Adjust Params** button which is to the right of the centration tool.
2. Click the pointing device anywhere within the **Patient Under Treatment** window (left hand side of screen).
3. Press **CTRL**/**ALT**/**S.**

The **Side Cut Only** button will appear in the lower left hand corner. Select the button to perform the **Side Cut Only** procedure. A message appears to inform the user that a **Side Cut Only** procedure will be performed and to remind the user to properly adjust the pattern diameter. A thick yellow overlay will also appear in the video image display to indicate where the side cut will be performed. The user may also adjust the depth of the side cut, side cut angle, etc. in this window. The **Side Cut Only** procedure is started when the user presses the *footswitch*. Releasing the *footswitch* during the procedure will immediately halt treatment. Treatment can be resumed by pressing the *footswitch* again. When the side cut is completed a message is displayed and the *footswitch* may be released.

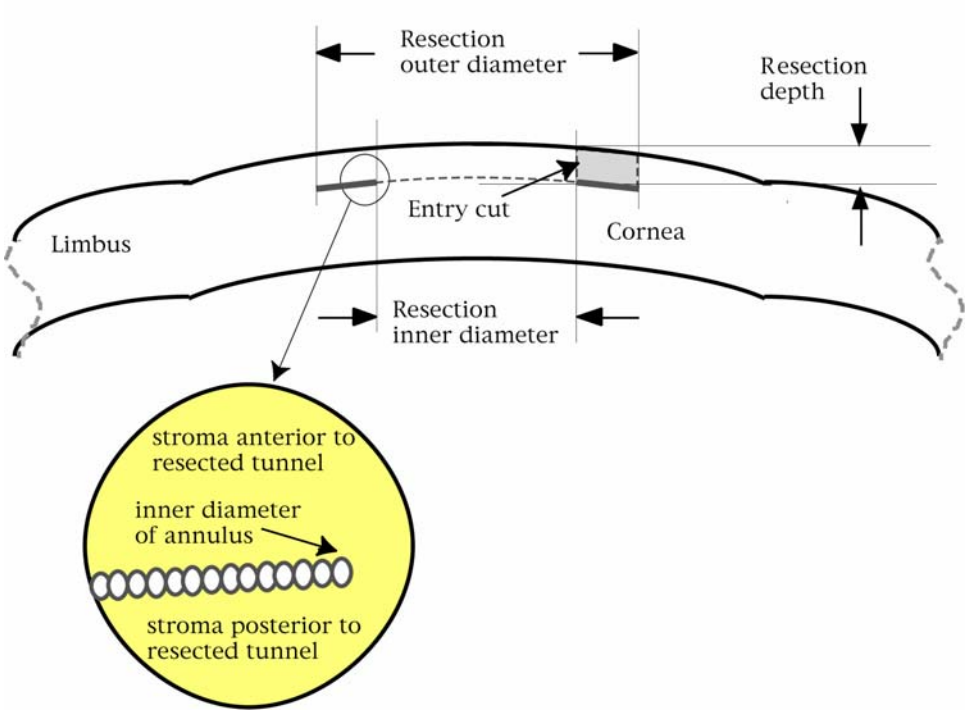
Optional Intrastromal Lamellar Ring Resection

Intrastromal tunnels (or rings) are an annular cut without a side cut at the desired depth. The annual cut is made at a predetermined inner radius from the corneal center and proceeds outward in a spiral fashion to a predetermined outer radius. This is followed by a small continuous entry cut along a radial direction that starts at the tunnel depth and progresses anteriorly to the corneal surface.



A schematic top view of an intrastromal tunnel resection is shown above. The entry cut, denoted as the bold solid line, is the only opening to the corneal surface.

The figure below shows a schematic cross section of the tunnel resection. The viewing angle is such that the entry cut (gray rectangle) is parallel to the plane of the figure.



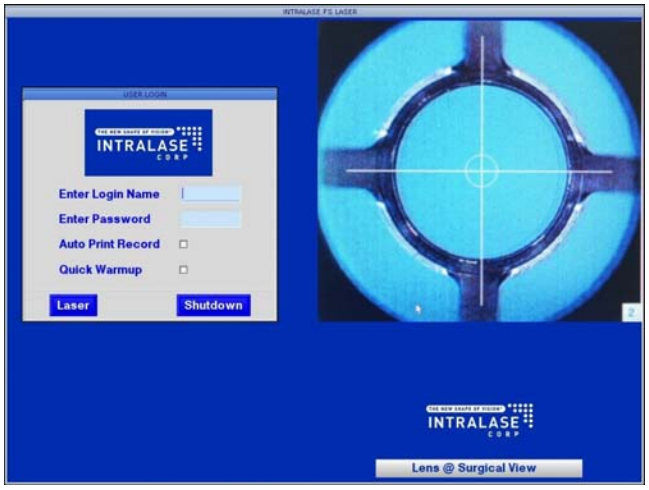
Section 7 - Software

Computer control and software interface functions are performed using the trackball pointing device and Keyboard in conjunction with the Display Monitor. A cursor on the display is controlled using the trackball. Software options may be selected by moving the cursor with the trackball and clicking the left trackball button. Alphanumeric data are entered using the Keyboard.

When power to the IntraLase FS Laser is switched on, the user encounters the operating system access Login. Enter the word "laser" as the login name. Enter the word "laser" again for the password.

After successful entry, the IntraLASIK® Software will start up and display the **User Login** window. Following successful user login, a warm-up, and self-check phase is initiated. At the conclusion of the warm-up phase, the **Procedure** window will be displayed. This section presents a general description of the principle windows presented by the IntraLASIK® Software.

User Login Window and System Startup



Login Name and **Password** are used to access the software.

Auto Print Record is used to print an operative report after each treatment.

Quick Warm-up shortens the warm-up phase of the system. This feature should only be used when system power was off for a brief period of time. When **Quick Warm-up** is selected, Energy Wheel Initialization must be performed from the **System Tools** | **System Checks** menu before treatment.

Laser will start and warm-up the system. The status of the system during the warm-up and self-test phase is indicated on the screen by a checklist and status bar.

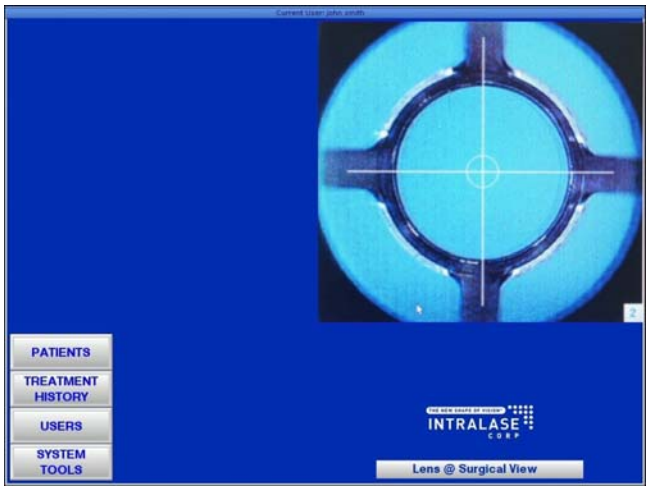
Shutdown is used to shut down the system entirely, if needed. The Shutdown dialog provides 3 options:

- End Photon Session: return to QNX Operating Software login window,
- Shutdown System,
- Shutdown and Reboot.

NOTE: See *System Shutdown* section of Procedure for notes regarding Shutdown.

Procedure Window

Following successful system warm-up and self-test, the **Procedure** window will be displayed.



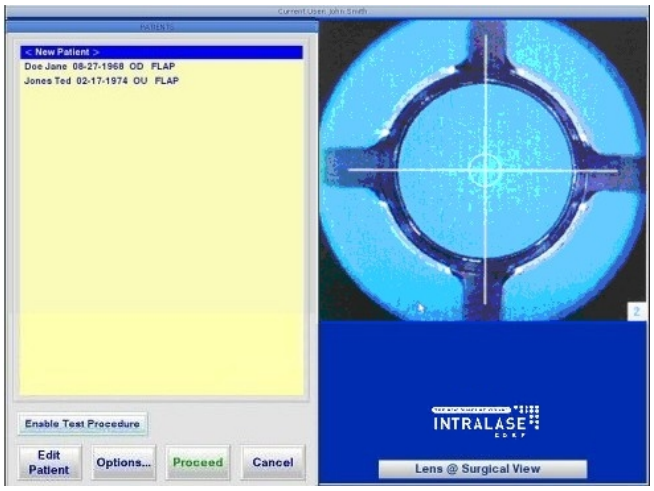
From this window, the user may select the following functions:

- Patient treatments,
- View treatment history,
- Manage users,
- Access system tools.

A live video of the surgical field is displayed in the **Procedure** window.

The current magnification of the Operating Microscope is displayed in the lower right corner of the surgical view.

Patients Window



From the **Procedure** window, click on the **Patients** button to open the **Patients** window. Patients records saved in memory will be displayed.

<New Patient> is used to add new patient records.

Enable Test Procedure/Disable Test Procedure toggle button is used to enable/disable the Test Procedure mode. Test Procedure mode provides a way to exercise the laser mechanics and electronics without decrementing User Procedures. Test Procedure mode does not allow laser emission to the focal plane and thus this mode cannot be used for patient treatment. See the end of this **Software** section for more information regarding Test Procedure mode.

Edit Patient button is used to edit a patient record after selecting the patient from the list.

Options button is used to remove a patient record from the list, empty the patient list, and print the patient list.

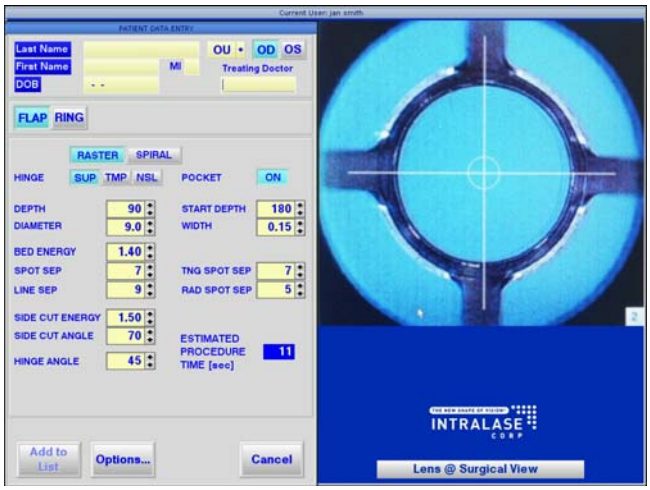
Proceed is used to treat the selected patient.

Cancel is used to exit the **Patients** window.

Patient Data Entry Window

To access the **Patient Data Entry** window, from the **Patients** window:

- double click on a patient name,
- select a patient and click the **Edit Patient** button,
- double click on **<New Patient>** to create a new patient record.



At the top of the window, the patient's first and last name, date of birth, treating doctor, patient type, and eye selection is displayed. The patient's first and last name and all 8 numbers for date of birth fields must be filled in. Patient type indicates whether both eyes (OU) or only the left or right eye will be treated. Eye selection determines which eye's treatment parameters are currently displayed.

NOTE: Eye selection is **not** an indicator of which eye will be treated first (this is determined by the **First Eye Treated** chosen when the User was created).

The bottom of the window displays the modifiable treatment parameters for the eye currently selected.

NOTE: Each eye's parameters must be explicitly modified for an OU patient.

Add to List saves the record for a new patient and blanks the fields in the Patient Data Entry window for addition of the next patient.

Modify List updates and saves the record for an existing patient.

Options gives access to the following:

Save as User Default	The currently entered parameters will be saved and displayed by default each time a new patient entry is created.
Print User Defaults	Prints the currently saved user defaults.
Backup User Defaults	Saves the user defaults onto a floppy disc.
Restore User Defaults	Restores the user defaults previously saved onto a floppy disc by the same user (independent user default files are stored in the software for each user). Restore User Defaults overwrites the currently saved user defaults.
Factory Defaults	Restores the factory defaults and overwrites the currently saved user defaults.

Accept Params saves parameter changes.

Reset Params restores the parameter values in effect for this patient when the Patient Data Entry window was opened.

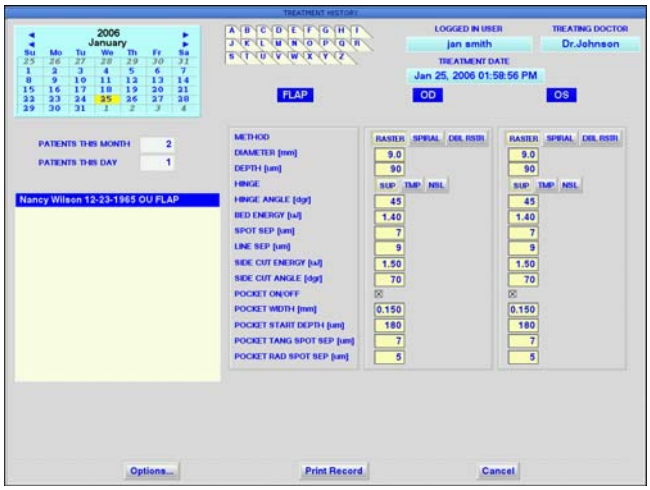
Proceed is displayed when all necessary patient information has been entered. Pressing this button will initiate patient treatment with the currently entered patient parameters.

Cancel to return to the **Patients** window.

WARNING: Check all treatment parameters for accuracy.

Treatment History Window

From the **Procedure** window, click on the **Treatment History** button to open the **Treatment History** window.



Patient records can be accessed using last name (graphic Keyboard) or treatment date (calendar).

- Click on a day to display all patients treated on the selected day (highlighted in yellow.)
- Click on a letter to display all patients ever treated with a last name starting with the selected letter (highlighted in aqua.)

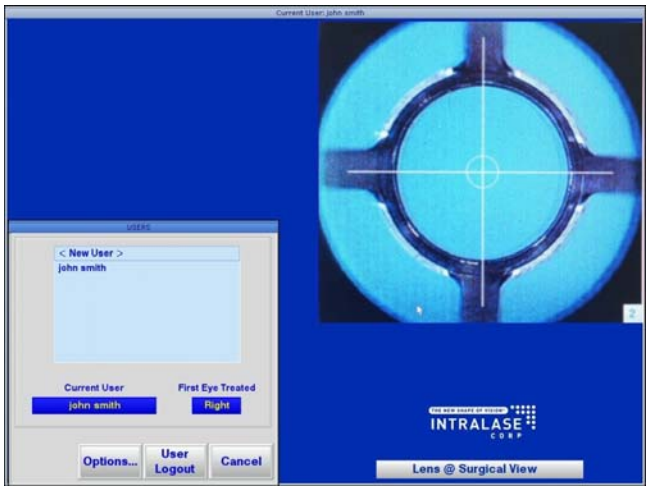
The **Options** button allows the user to:

- Print all patient records
- Print patient records by last name
- Print patient records by day
- Print patient records by month
- Backup user's patient records
- Restore user's patient records (available only to IntraLase service representatives)

The **Print Record** button is displayed when a patient is selected.

Users Window

From the **Procedure** window, click on the **Users** button to open the **Users** window.



The functions and privileges available to each user are assigned by a Pass Level. Pass Levels greater than 2 are reserved for IntraLase service representatives and are not described in this document.

A list of authorized users for the system is displayed at the top of the Users window.

Creating a New User

Double click **<New User>**. A window appears requesting the following information:

- First name
- Last name
- Login name
- Password (entered twice)
- Pass Level (cannot be changed)
- First eye treated (OS or OD)

Editing a User

Double click on the appropriate user from the list. The following parameters can be edited:

- Password
- First eye treated

Deleting a User

Select the user name to be deleted. Click on the **Options** button and select **Remove User**. Confirm the deletion. Once a user is deleted, a user with the same login name or with the same first and last names cannot be created.

Options

This button allows the user to:

- Remove a user of the same or lesser Pass Level.
- View the login history of the system. The screen will display the Login Name, Login Time, and Logout Time. The **Backup** button on this screen copies the login history to a floppy disc.
- View a registry of authorized users. The screen will display the Last Name, First Name, Login Name, Pass Level, Creator, and Date/Time of Creation. The **Options** button on this screen allows the user to print or copy the user registry to a floppy disc.

User Logout

This button allows the current user to logout of the system without shutting down the laser system. Afterward, the **User Login** window is displayed and another user may login.

System Tools Window

From the **Procedure** window, click on the **System Tools** button to access all non-procedure functions. The following options are available:

- System Checks
- System Status
- Procedures
- About
- Shut Down

System Checks

Three system-checking routines are accessible.

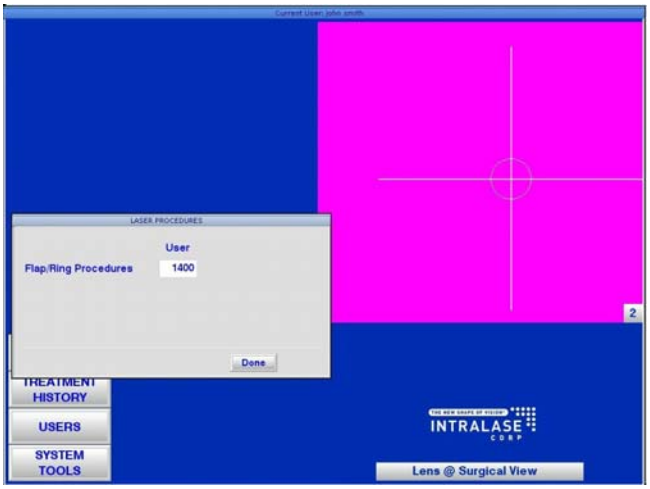
Beam Steering	Initiates a brief routine that checks and adjusts (if necessary) the alignment of the laser beam into the Beam Delivery Device.
Energy Wheel Initialization	Initializes the energy wheel.
Adjust Video	Adjusts the brightness, contrast, and color of the live video display.

System Status

This option opens the **System Status** window, displaying the operational status of system functions. Green light indicates an operational function, yellow light indicates that maintenance is required, while red light indicates an error condition. Press the **Error Log** button located at the bottom of the window to view all errors recorded by the system.

Procedures

This option opens the **Laser Procedures** window, displaying the total number of procedures remaining for the User. See the Procedure Activation section in Setup for guidance on how to add Procedures.



About

This option opens the **About INTRALASE FS** window, displaying the console model number, serial number, current software version and contact telephone number.

Shutdown

This option shuts down the entire IntraLase FS Laser system. After selecting **Shutdown**, a Shutdown dialog provides 3 options:

- End Photon Session: return to QNX Operating Software login window,
- Shutdown System,
- Shutdown and Reboot.

NOTE: See *System Shutdown* section of Procedure for notes regarding Shutdown.

Test Procedure Mode

Test Procedure mode provides a way to exercise the laser mechanics and electronics without decrementing User Procedures. Test Procedure mode does not allow laser emission to the focal plane and thus this mode cannot be used for patient treatment. Warnings are provided indicating that Test Procedure Mode is active and that patient treatment should not be attempted.

To turn on Test Procedure Mode click on the **Enable Test Procedure** toggle button**.** It will change to a **Disable Test Procedure** toggle button. Clicking it again will disable the Test Procedure Mode.

When this mode is active, patients cannot be added or removed and existing patients cannot be treated. A procedure is run by selecting **<New Patient>** in the Patients window and then either selecting the **Edit Patient** or **Proceed** buttons. Treatment parameters will be the defaults for the current user, but parameters may be modified. Treatment History is not provided for procedures run in Test Procedure Mode. When in Test Procedure mode, a Patient Interface cone must be present, docking is not necessary, and the centration feature is not provided. Test Procedure mode is automatically disabled when the Patients window is closed.

Section 8 - System Installation

WARNING: Only trained IntraLase service representatives should perform unpacking, installation, and servicing of the IntraLase FS Laser. Covers must not be removed by anyone other than IntraLase service representatives. Accidental contact with the high voltage electrical circuits in the interior of the IntraLase FS Laser console may result in serious injury or death.

WARNING: Ocular exposure to collimated beams contained in the console interior can produce retinal damage.

Installation

Instructions for site installation will be provided prior to shipment. At installation, an IntraLase service representative will:

- Inspect the entire system
- Verify proper operation of the IntraLase FS Laser
- Verify calibrations
- Explain the instrument operating controls and indicators
- Demonstrate the various safety features of the IntraLase FS Laser

Shipping Contents

The IntraLase FS Laser system is shipped with the following components:

- Console (Chassis, Beam Delivery Device, Operating Microscope, Display Panel and Keyboard)
- *Footswitch*
- System *master keys*
- *Interlock connector*
- UPS System

System Requirements

Electrical

The IntraLase FS Laser requires electrical service as listed in the table below. The line voltage should be tested upon installation to ensure proper operation and should not vary by more than ± 10 % from nominal.

Line Condition	Peak Current
120 VAC, 60 Hz	7A
100 VAC, 50 – 60 Hz	10 A
220-240 VAC, 50 – 60 Hz	4 A

Environmental

Ambient temperature in the room containing the IntraLase FS Laser should remain between 19° C and 23° C (67° F and 73° F) and remain stable 24 hours a day. Humidity should be between 35% and 65% non-condensing.

Particulate

No specific requirement for dust or particulates exists; however, the operating suite should be relatively free of dust and particulate contamination.

Vibration and Stability

No specific requirement for vibrational tolerance exists; however, the operating suite should be relatively stable and free of vibrations.

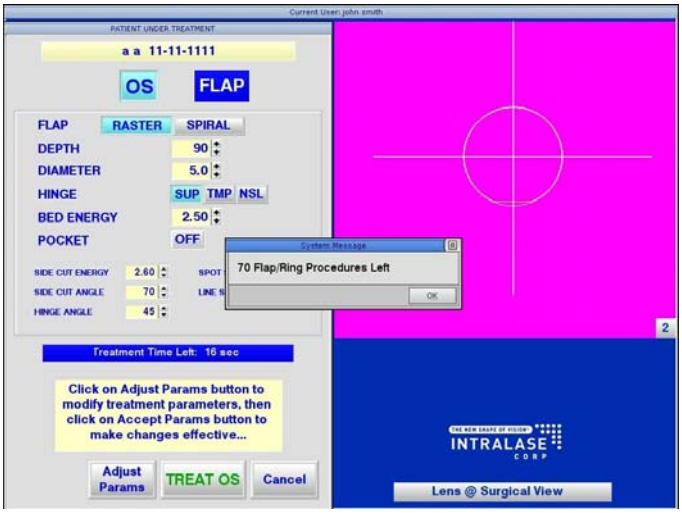
Section 9 - Setup

When power to the IntraLase FS Laser is switched on, the user encounters the operating system access Login. Type the word "laser" as the login name, and then press Enter. Type the word "laser" again for the password, and then press Enter.

After successful entry, the IntraLASIK® Software will start up and display the **User Login** window. Following successful user login, a warm-up, and self-check phase is initiated. At the conclusion of the warm-up phase, the **Procedure** window will be displayed.

Procedure Activation

User Procedures are electronically activated in the IntraLase FS Laser. At the start of each treatment, the laser will decrement the procedure count by one. When the number of User Procedures remaining has dropped to 100, and after every 10 additional procedures, a window will pop up to remind the User to contact IntraLase Global Support to activate additional procedures.



There are two methods to activate, or add procedures:

Internet Connectivity (IC)	Procedures are remotely activated through a secure internet connection.
Secure Activation Code (SAC)	Procedures are manually activated using a secure code.

Once additional procedures are added, another window will pop up to notify the User of the amount of new Procedures that have been activated.

The following details IC and SAC procedure activation methods.

Internet Connectivity (IC)

Each IntraLase FS Laser is provided with a fully automated, on-line method to remotely activate User Procedures with each order of IntraLase Patient Interfaces.

This feature requires a dedicated Internet connection to a static IP address, and requires the IntraLase FS Laser system computer to be **ON**.

NOTE: Patient treatment will not be interrupted by procedure updates or remote diagnostics. Internet connectivity is disabled during patient procedures for safety. Once the patient procedure is completed, internet connectivity will automatically reactivate and any pending procedure updates and/or remote diagnostics can occur.

Internet Connectivity offers other benefits in addition to remote, automated procedure activation:

Remote Laser Diagnostics	Internet Connectivity will allow the company to read and analyze critical system parameters, which can minimize the frequency and duration of down time.
Software Upgrades via Internet	Select software upgrades can be sent via the Internet, giving the user immediate access.
Automated Procedure Activation via Internet	Provides fully automated on-line capability to activate procedure as PIs (Patient Interfaces) are ordered. When orders are placed for PIs, Customer Support will automatically send the corresponding number of procedures via the Internet, giving the User a consistent balance of PI packs and electronic procedures.

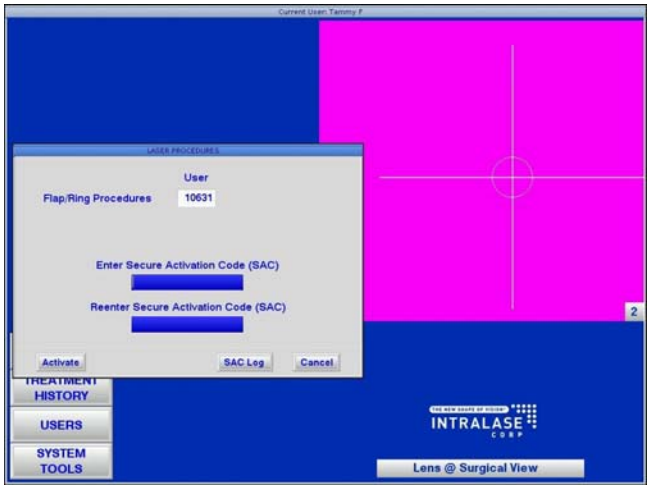
NOTE: If no User Procedures remain on the IntraLase FS Laser, and the Internet connection is temporarily unavailable, contact IntraLase Global Support for assistance. We can provide an "emergency" Activation Code to ensure there are no treatment delays.

Secure Activation Code (SAC)

Secure Activation Code (SAC) is similar to the Internet Connectivity (IC) feature, in that it keeps a consistent balance of PI packs and electronic procedures. Corresponding quantities of PI packs are shipped with each order of procedures.

Since there is no connection to the internet, the other IC features, including Automated Procedure Activation, are not included. Follow these steps to order and activate procedures:

1. Place an order through our Global Support Department.
2. Once the order is processed, a unique SAC (10-digit alpha numeric, upper/lower case sensitive code) will be provided.
3. Enter the SAC into the laser from the laser **Procedure** window, where two SAC entry boxes are provided.



4. After the code is entered (twice for verification), choose the **Activate** button at the bottom of the window. A message will appear displaying the number of procedures loaded onto your laser, which will correlate to the number of procedures you ordered. In addition, a corresponding quantity of Patient Interfaces will be shipped.
5. Codes must be entered in the same sequence they are issued, preferably the same day the procedures are ordered. This will avoid potential down-time caused by mismatched codes.

Secure Activation Code Log

There is also a SAC Log available for reference from the **Procedure** window. This log displays the following for the last ten valid SACs entered: Date and Time entered, User Name, SAC entered, New Procedures entered (quantity), and the updated Total Procedure count.

Patient Record Default

Individual defaults can be setup for each user. Once the defaults are setup, they are retained for the next power-up. Use the following sequence to set the defaults for the user currently logged in.

1. From the **Procedure** window, click on the **Patients** button to open the **Patients** window.
2. Double click on **<New Patient>**. The **Patient Data Entry** window will be displayed.
3. Select **FLAP**. Enter the parameters specific for a FLAP procedure.
4. Select Accept Params.
5. Click on Options. Select Save as user default.
6. Select **Yes** to "Are you sure you want to save new user defaults?"
7. Repeat steps 3-6 above for the **RING** procedure.
8. Select **Cancel** to return to the **Patients** window.

At the top of the window, the patient's name, date of birth, treating doctor, patient type, and eye selection is displayed. This part of the screen is not necessary for setting user defaults.

The bottom of the widow displays the modifiable treatment parameters. The relevant laser scanning parameters and ranges that define the size and shape of a flap resection are summarized in the table below.

Flap Parameters

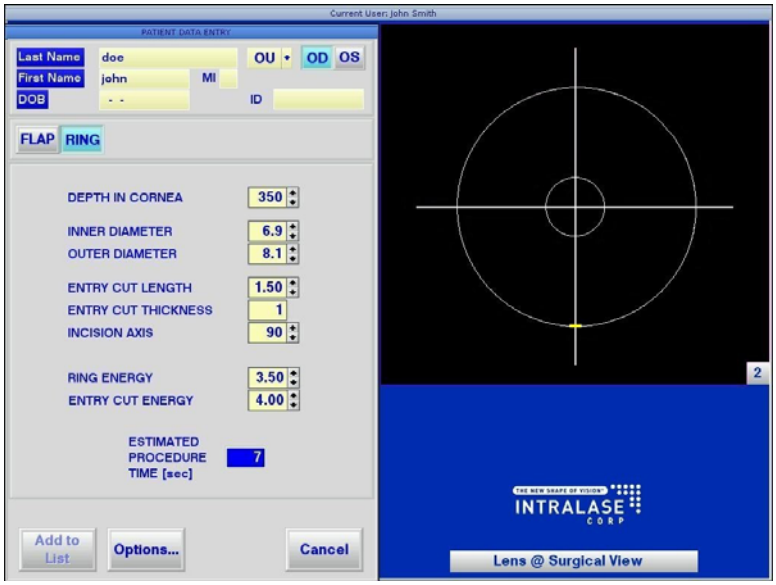
Parameter	Definition	Range	
Eye Selection	Eye for which the currently displayed parameters apply	OS left eye OD right eye	
Patient Type	Indicates which eye(s) will be treated.	OU both eyes OS left eye OD right eye	
Treating Doctor	Will report in the Treatment History Window.	10 char max	
Pattern	Method used to create the planar resection. The Double Raster pattern is an option which can be enabled by a Clinical Application Specialist. Note that Pocket is available only if the Raster pattern is selected.	Raster Spiral Double Rstr	
Hinge position	Location of the untreated portion of the side cut with respect to the current eye selection.	SUP superior TMP temporal NSL nasal	
Flap Depth	Perpendicular distance from cornea anterior surface (flap anterior surface) to resection plane (flap posterior surface).	90 - 400 μm	
Flap diameter	Anterior diameter of the flap bed	5.0 – 9.5 mm	
Bed energy	The pulse energy used to create the planar resection.	15 kHz	1 – 6 μJ
		30 kHz	0.5 - 4 μJ
		60 kHz	0.3 - 3 μJ
Spot Separations	**Spot Separation** The separation between adjacent spots along a common line or common circle.	**Spot**	
		15 or 30 kHz	6 - 14 μm
		60 kHz	4 - 10 μm
	Line Separation The separation between adjacent lines of the raster pattern or between adjacent circles with a common center of the spiral pattern.	**Line**	
		15 or 30 kHz	6 - 14 μm
		60 kHz	4 - 10 μm

Parameter	Definition	Range	
Side cut energy	The pulse energy used to create the side cut.	15 kHz	1 – 6 μJ
		30 kHz	0.5 - 4 μJ
		60 kHz	0.3 - 3 μJ
Side cut angle	Angle that the cylindrical side cut makes with the corneal surface (90° is perpendicular to the corneal anterior surface).	30 - 90°	
Hinge angle	Angle that the uncut portion of the flap side cut arc makes related to the flap center.	Raster: 45 - 90° Spiral: 0 - 350°	

Pocket parameters

Parameter	Definition	Range	
Pocket Enable	Enables pocket with a raster pattern.	ON/OFF	
Pocket Width	The greatest distance from the pocket ramp to the perimeter of the pocket.	0.100 – 0.500 mm	
Pocket Start Depth	Depth in cornea of the pocket. Must be greater than or equal to the Flap Thickness.	100 – 300 μm	
Pocket Tangential Spot Separation	The separation between adjacent spots along a common line.	15 or 30 kHz	4 – 14 μm
		60 kHz	2 - 10 μm
Pocket Radial Spot Separation	The separation between adjacent lines of the raster pattern.	15 or 30 kHz	4 - 14 μm
		60 kHz	2 - 10 μm

Ring Parameters



Parameter	Definition	Range
Depth in Cornea	Depth at which the Ring is made	100 – 400 μm
		IEK: 100 - 500 μm*
Inner Diameter	Inner diameter of the Ring resection	4.0 – 9.4 mm
Outer Diameter	Outer diameter of the Ring resection	4.1 – 9.5 mm
Entry Cut Length	Length of entry cut for segments insertion	0.8 – 1.5 mm
Incision Axis	For Right Eye: 0° = nasal (180 for left eye) 90° = superior 180° = temporal (0 for left eye) 270° = inferior	0 – 359°
Ring Energy	The pulse energy used to create the Ring.	.3 - 6 μJ
Entry Cut Energy	The pulse energy used for the entry cut.	.3 - 6 μJ

* *Available only with the IntraLase-Enabled Keratoplasty (IEK) option installed.*

Patient Selection

The physician should base patient selection criteria on professional experience, published literature, and educational courses.

The following guidelines should be considered by the physician in selecting patients for surgery with the IntraLase FS Laser:

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

Lamellar Resection for Corneal Flaps

Flap Contraindications

Lamellar resection for the creation of a corneal flap using the IntraLase FS Laser is contraindicated if any of the following conditions exist:

- Corneal lesions
- Corneal edema
- Hypotony
- Glaucoma
- Existing corneal implant
- Keratoconus

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

Complications

Possible complications resulting from Lasik surgery include (potential complications are not limited to those included in this list):

- Corneal edema
- Corneal pain
- Epithelial ingrowth
- Epithelial defect
- Infection
- Flap de-centration
- Incomplete flap creation
- Flap tearing or incomplete lift-off
- Free cap
- Photophobia
- Corneal inflammation, such as diffuse lamellar keratitis (DLK), corneal infiltrates, and iritis
- Thin or thick flaps
- Flap striae

In order to provide your patients with a more comprehensive Informed Consent Document, we recommend that you include a description of the following sporadically reported visual symptoms which may occur following LASIK flap creation with the IntraLase FS laser.

Transient Light Sensitivity Syndrome (TLSS)

Transient Light Sensitivity Syndrome is characterized by symptoms of mild to severe light sensitivity which manifests between two and six weeks postoperatively. Patients experience no decrease in uncorrected or best spectacle-corrected visual acuity. The incidence of this sensitivity is observed in approximately 1% of patients who undergo flap creation with the IntraLase FS laser. Patients respond to the use of hourly topical steroids such as Pred Forte, and most report improvement within one week of treatment.

Peripheral Light Spectrum (PLS)

Peripheral Light Spectrum (PLS) is a temporary phenomenon whereby patients report the perception of a spoke-like spectrum of light in the periphery of their vision. PLS has no clinical examination findings and no effect on visual acuity; however the potential diffractive effects may be bothersome to some patients. Reported in only 0.03% of cases, the onset of symptoms occurs during the immediate postoperative period, and typically resolves within three months but may be slightly persistent in rare cases. The visual impact of PLS is clinically inconsequential for the vast majority of patients.

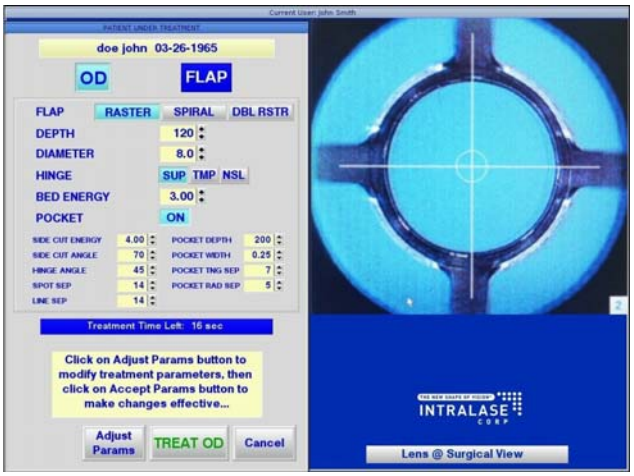
Procedure and Parameters Selection

The purpose of this section is to provide systematic instructions in the preparation of the IntraLase FS Laser as well as the patient for a lamellar resection.

To treat a patient, the user may perform any one of the following sequences:

1. From the **Patient Window**, select **<New Patient>,** press the **Edit Patient** button, enter the treatment parameters, and press the **Proceed** button.
2. From the **Patient Window**, select a Patient name, select the **Edit Patient** button, and then press the **Proceed** button.
3. From the **Patient Window**, select a Patient name and then press the **Proceed** button.

The **Proceed** button will not appear in the **Patient Data Entry Window** until the patient **Last Name**, **First Name,** and **DOB** have been entered.



Press the **Proceed** button to open the **Patient Under Treatment** window. The left side of the window displays the patient's name, date of birth, and a list of treatment parameters.

Treatment parameters may be adjusted directly in this window by pressing the **Adjust Params** button, modifying the values, then pressing the **Accept Params** button. The estimated laser treatment time is displayed in the blue box.

NOTE: If parameters must be adjusted for **OD and OS**, select **OD**, change and accept the new parameters, then repeat with **OS** selected.

The right side of the window displays the live video image and an indicator of whether the microscope lens is at the surgical view.

WARNING: Check all parameters for accuracy before proceeding to the next phase.

Press **Cancel** to return to the **Procedure** window. Press the **Treat** button to initiate the next phase of treatment.

Section 10 - Procedure

Proper operation of the IntraLase FS Laser should be verified prior to patient procedures by performing simple calibration checks. If any of these calibration checks indicate improper operation, treatment must not proceed.

WARNING: Patient procedures performed with an improperly operating IntraLase FS Laser may produce poor or otherwise unacceptable resections, or may result in complications.

Energy Wheel Initialization

Laser beam energy attenuation is achieved by positioning an energy wheel. The IntraLase FS Laser performs a laser energy wheel initialization procedure in order to check its operation. At the end of the procedure, the energy wheel is set to a pre-determined position and is ready for operation.

An Energy Wheel Initialization should be performed every two hours when the IntraLase FS Laser is being used.

1. From the **Procedure** window, click on the **System Tools** button.
2. Select **System Checks**, and then select **Energy Wheel Initialization**.
3. The system will start the procedure and display the results.
4. If the results are not acceptable, an error message will be displayed.

Operative Precautions

The Nominal Ocular Hazard Distance (NOHD) for the IntraLase FS Laser is limited to 54 cm and 58 cm for the 15 kHz and 30 kHz lasers, respectively. The optical threshold for retinal damage is substantially higher than the intensity output of the IntraLase FS Laser. Protective eyewear for operating suite personnel is not required, but is recommended as a part of standard laser safety protocols.

Improper use of the IntraLase FS Laser may result in patient corneal trauma, infection, complications or mechanical trauma to either patient or operating suite personnel.

All warnings, labeling and instructions must be observed.

WARNING: Do not use cell phones, pagers, or radio frequency devices of any kind in the same room as the IntraLase FS Laser.

Application of the IntraLase Patient Interface

Indications

The IntraLase Patient Interface is designed for the exclusive use with the IntraLase FS Laser and indicated for corneal resection surgery. All components are sterile and intended for single use only. The bilateral Patient Interface is intended for use on one patient. Read all instructions carefully prior to use.

Caution: Federal (US) law restricts this device to sale by, or on the order of, a physician.

WARNING: The applanation lens becomes etched by the laser during the side-cut procedure and MUST NOT be re-used. Laser light will not effectively permeate an etched lens, and the precision of the laser will be altered.

Precautions

- Do not use the IntraLase Patient Interface if the Use By Date is expired.
- Check the integrity of the sterile pack before use.
- Do not use this device if the packaging appears damaged or shows evidence of exposure to dampness.
- Do not transport the IntraLase Patient Interface to any location outside the office of delivery, if any of the factory packaging in which the Patient Interface arrived has been opened.
- The IntraLase Patient Interface must not be re-sterilized.
- A high level of surgical skill is required for the IntraLase FS Laser. A surgeon should have successfully completed one or more courses on the IntraLase FS Laser before attempting to create a corneal flap.
- Avoid damaging the IntraLase Patient Interface with rough instruments.
- Do not use the IntraLase Patient Interface if the package or any of the contents are dropped.

How Supplied

The IntraLase Patient Interface is intended for **SINGLE USE ONLY** and is supplied in a sterile pack and is non-pyrogenic. The Patient Interfaces are placed in a unit box with labeling and product information. The IntraLase Patient Interface has been sterilized by gamma radiation. Sterility is assured until the expiration date on the package label, if the pack seals are not punctured or damaged. The devices should be stored in a dry place at room temperature.

Preparation

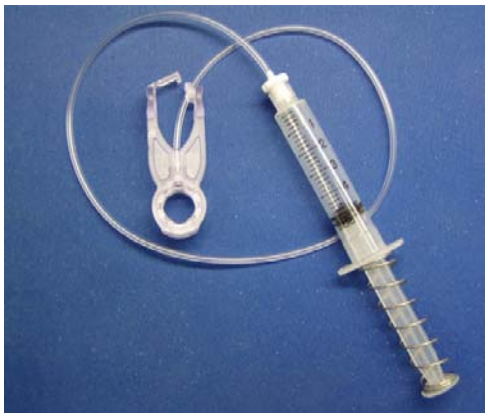
WARNING: To preserve sterility, open the disposable tray while wearing sterile, powder free surgical gloves and complete the following steps.

Open the Tray

1. Position the tray with the IntraLase Patient Interface label facing up, grasp lower left corner and remove the label by peeling from left to right.
2. Discard the label.

Inspect the Patient Interface Contents

1. Remove an applanation cone, a suction ring assembly, and syringe from the tray and place them onto a sterile field.
2. Inspect all parts for damage or disconnection.



WARNING: Do not attempt to use any damaged product. Return damaged components immediately to IntraLase Corp. for replacement.

Install the IntraLase Patient Interface Applanation Cone

1. Open the Loading Deck Locking Arm.
2. Grasp the applanation cone by the upper rim with the applanation contact glass facing downwards.
3. Remove the protective cap from the applanation glass and slide the base of the applanation cone into the Loading Deck guides located at the bottom of the lens aperture.
4. To secure the applanation cone in place, move the locking arm into position. Using high illumination, inspect the applanation glass through the Operating Microscope for scratches and defects prior to use. Return damaged or questionable components to IntraLase Corp. for replacement.

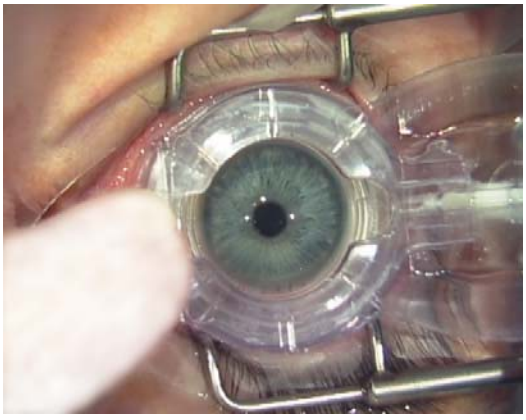
Suction Ring Assembly Application

The IntraLase Patient Interface suction ring assembly serves two functions: 1) fixating the eye and 2) coupling the eye to the contact glass. The suction ring assembly consists of a limbal suction ring mounted on the bottom of an actuation cylinder assembly. The suction ring attaches to the limbus by means of low suction applied through a syringe.

1. Connect and tighten the Luer-lock fitting of the syringe to a suction ring assembly.
2. Using light pressure, squeeze the levers of the suction ring assembly and engage the clip onto the opposing lever handle.
3. Test that the clip properly disengages the left lever handle by applying light pressure on the suction ring assembly. If the clip properly disengages, re-engage the clip.

WARNING: If the clip fails to disengage, or if it prematurely disengages, do not attempt use. Return the IntraLase Patient Interface suction ring assembly to IntraLase Corp. for replacement.

4. Fully depress and hold the syringe plunger and place the limbal suction ring onto the cornea, centering over the pupil.
5. While applying a slight downward pressure on the ring, release the plunger allowing the suction ring to firmly affix to the eye.



Applanation Procedure

1. With the eye fixated, the laser's delivery system must then be properly centered over the suction ring assembly opening. This is accomplished by using the X and Y *joystick* controls located on the laser's Control Panel.
2. Slowly lower the Beam Delivery Device by twisting the *joystick* clockwise, gently guiding the applanation cone through the suction ring cylinder. As contact between the contact glass and the cornea is made, an *illuminated green LED* will be visible in the Operating Microscope and the Display Panel.
3. When the cornea is **FULLY** applanated and the applanation lens is well centered in the suction ring assembly, gently squeeze the molded levers to disengage the clip. The suction ring assembly is then closed to grip the applanation cone. A *red LED* will be illuminated at a preset distance corresponding to the maximum allowed applanation.
4. To proceed to the next phase of the procedure, select the green **Treat** button.

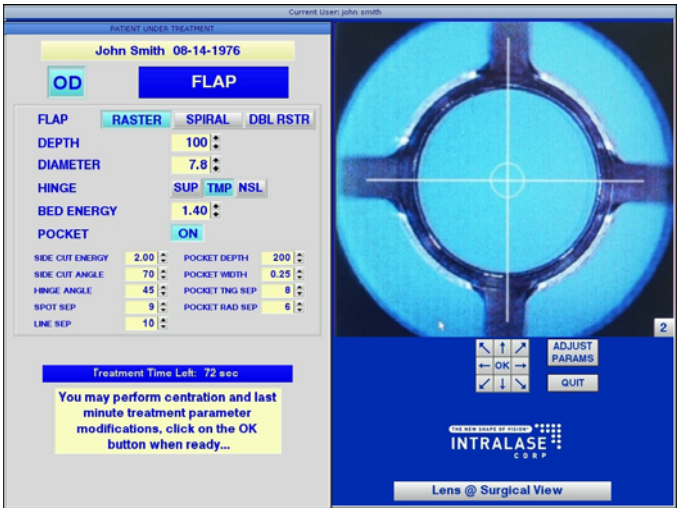
Automatic System Checks

After selecting the **Treat** button, the IntraLase FS Laser will automatically perform final checks of the system. When these checks are successfully completed, the system is ready for pattern centration.

Pattern Centration

NOTE: Before starting the Pattern Centration, make sure the magnification dial is set to the surgical view, **position 2**.

The cross hairs live video image displayed on the screen is calibrated to correspond to the laser scan starting point.



1. Patient parameters and the live video display can be modified one last time before proceeding. Select the **Adjust Params** button. Edit the appropriate parameters and proceed with the centration.

NOTE: The **Adjust Video** button appears in the lower, left corner, once **Adjust Params** is selected. **Adjust Video** adjusts the brightness, contrast, and color of the live video display

2. A keypad of arrows called the **Centration Tool** is located below the video image. Use the trackball on the video display or the arrows on the Centration Tool to select a different pattern center.
3. The pattern is committed by selecting the **OK** button on the **Centration Tool**. After pressing the **OK** button, a dialog box asks the user to confirm the centration offset and the parameters.

NOTE: If the selected pattern center is outside the central circle, a dialog box will alert the user to the largest diameter allowable at the selected offset, and ask the user to confirm the reduced diameter.

4. Select **Yes** to enable the IntraLase FS Laser for the procedure, or select **No** to choose a new offset or modify the parameters.

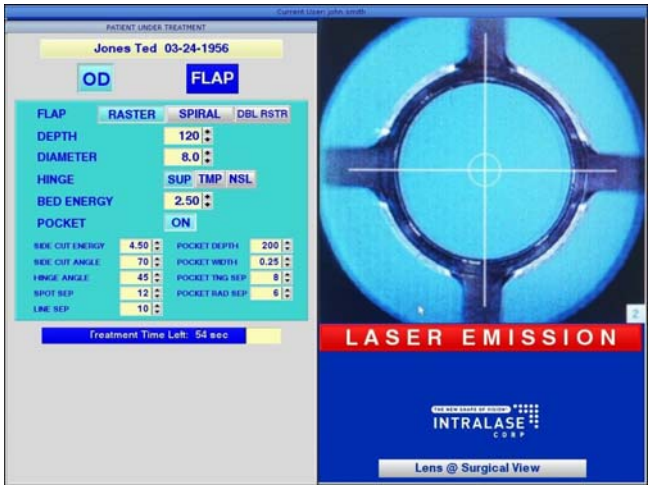
Procedure Initiation and Execution

WARNING: Do not use cell phones, pagers, or radio frequency devices of any kind in the same room as the IntraLase FS Laser.

1. After completing the pattern centration, the IntraLase FS Laser is ready to begin the resection procedure.

WARNING: Check all parameters for accuracy before proceeding to the next phase.

2. The system prompts the user that the system is ready to fire. The procedure is started by pressing the *footswitch*. Releasing the *footswitch* will immediately halt the procedure. Press the *footswitch* to resume the procedure.



3. The effect of the laser treatment on the cornea will be apparent at treatment initiation. The photo-disruptive action of the laser will be visible through the Operating Microscope and on the live video display. As the laser is firing, a red **Laser Emission** bar appears under the live video image. The blue time bar will count down the remaining time until the procedure is complete.

NOTE: <u>Do not</u> release the *footswitch* until the **Procedure Complete** window appears.

Releasing Suction

When the resection is complete, the **Procedure Complete** window appears.

1. **Depress and hold** the syringe plunger to release the cornea from the suction.
2. On the Control Panel, rotate the *joystick* counter-clockwise to raise the Beam Delivery Device and safely move the patient from the surgical field.
3. Release the Loading Deck Locking Arm and remove the IntraLase Patient Interface applanation cone, with the suction ring assembly attached, by grasping the upper rim of the applanation cone and sliding it away from the objective lens assembly.

WARNING: The used IntraLase Patient Interface applanation cone and suction ring assembly should be treated as medical waste and disposed according to local regulations.

Preparation for Bilateral Procedure

1. Using a new Patient Interface (applanation cone and suction ring assembly), repeat instructions from the beginning of this section to perform the bilateral procedure.
2. If the OU selection of the patient treatment parameters is chosen, the IntraLASIK® Software will automatically display the Patient Under Treatment window for the second eye.

WARNING: The IntraLase Patient Interface is a single-use disposable and, when used, should be treated as medical waste. The IntraLase Patient Interface components may not be re-sterilized or stored for future use. Reuse or re-sterilization of the IntraLase Patient Interface may result in unsafe laser operation or non-sterile conditions. Once the sterile seal on the package has been broken, unused components must be discarded.

System Shutdown

To ensure that the laser cooling system remains on, to maintain consistent temperature of your laser system and reduce potential down time, observe the following steps during System Shutdown.

1. From the **Procedure Screen**, click on **System Tools**, and then select **Shutdown**.
2. When the message "**Are You Sure You Want to Shut Down System?**" appears, select **Yes.**
3. When the **Shutdown Options** box appears, select **Shut Down System**.
4. Another window will open asking "**How would you like to shut down?**". Select **Shut Down System**, and then select **OK**.

NOTE: <u>Do not</u> select the **Shut Down and Reboot** option.

5. A pop-up window with the message "**Your system is in the process of shutting down. Please wait while all applications are terminated.**" appears.
6. Wait for 15 to 30 seconds for the message "**All applications have been terminated, it is now safe for you to turn off your computer.**" to appear.
7. Turn the front Keyswitch **OFF**. The cooling system will remain on.

Section 11 - IntraLase-Enabled Karatoplasty (IEK)

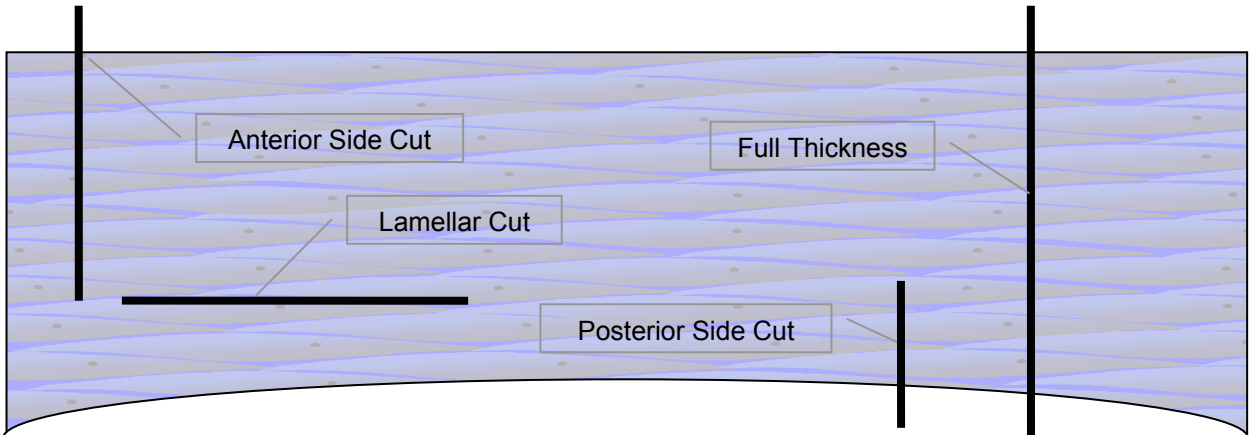
WARNING: Use of this laser system allows laser surgical incisions to be created up to 1200 um deep. Additionally, resection patterns can be freely adjusted to create various geometric shapes. It is advised that the user check all treatment parameters, and then verify the pattern outline in the graphical display, before proceeding to the next phase.

Intended Use (IEK Application)

The IntraLase FS Laser defines resection planes through tightly focused femtosecond laser pulses that photodisrupt tissue with micron-scale precision. Resection is achieved by contiguously placed micro-photodisruptions scanned at high repetition rates by a computer-controlled delivery system. The IntraLase FS Laser should only be operated by, or under the direct supervision of, a physician trained in the use of the IntraLase FS Laser.

Performance testing, including animal studies, has shown that this device can be used as a cutting tool for the indications listed. There is insufficient clinical data to support the use of this device for any surgical modifications of conventional lamellar keratoplasty and penetrating keratoplasty procedures.

CAUTION: IEK applications may be performed using 30 kHz or 60 kHz lasers only.



A schematic diagram of the various resections of the cornea.

Contraindications

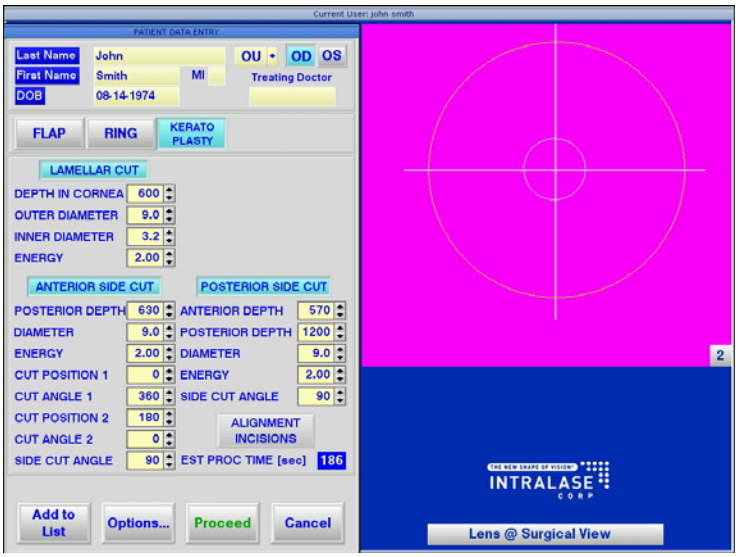
Contraindications to use of the IntraLase FS Laser for the indications described for the IEK procedure include:

- Any corneal opacity adequately dense to obscure visualization of the iris;
- Descemetocoele with impending corneal rupture;
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape; and
- Corneal thickness requirements that are beyond the range of the system.

WARNING: Do not use cell phones, pagers, or radio frequency devices of any kind in the same room as the IntraLase FS Laser.

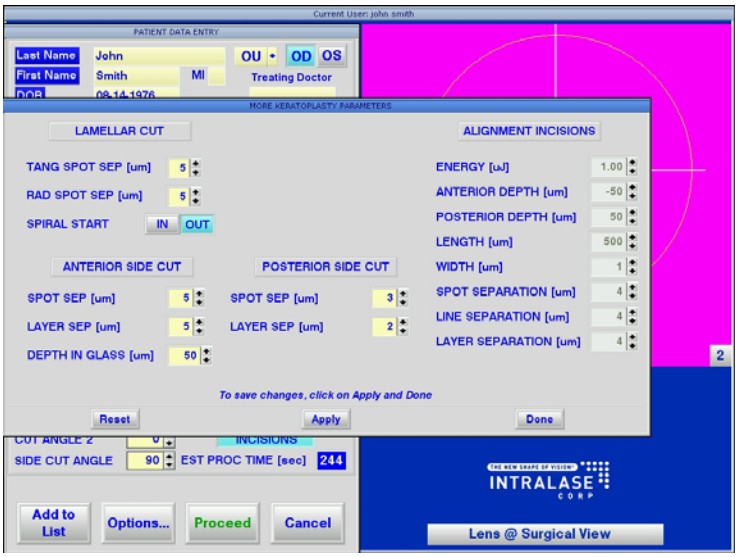
Keratoplasty Application

1. Select the Keratoplasty button (upper right button).



2. Enter patient first name, last name, and DOB (8-digit DOB must be entered before you can proceed). Treating Doctor can be left blank.

3. Select **Options** then select **More Parameters** to access additional parameters.



4. Measure the corneal thickness at the resection area using preferred techniques.

WARNING: Operation of this system, with the Keratoplasty Application, requires that the user provide a calibrated corneal thickness measurement device.

5. Program the Posterior Depth of the Posterior Side Cut at least 50 μm deeper than Peripheral Corneal Thickness (PCT).

WARNING: Setting the Posterior Depth too deep could result in injury to other intraocular structures.

6. Program the desired necessary parameters (see *Parameters* section for descriptions) to achieve the desired configuration. See *Overlapping* and *Non-Intersecting Resection Patterns* later in this section.

WARNING: Check all parameters for accuracy before proceeding to the next phase.

7. Select the **Proceed** button to proceed with the surgery.
8. Refer to section eight, *Guide to Procedures*, for docking procedure.
9. At the end of the surgery the Procedure window will be displayed.

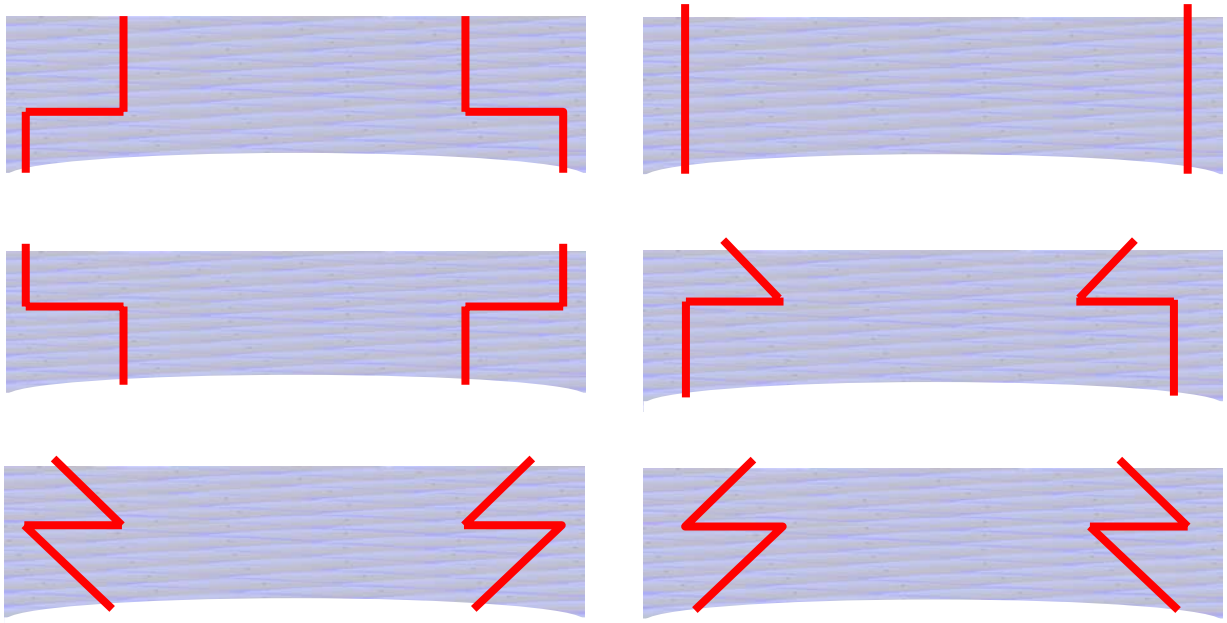
CAUTION: On completion of the donor tissue harvesting portion of the procedure, care must be taken to reduce the fluid pressure in the Artificial Anterior Chamber prior to removing applanation. This will aid in preventing fluid contamination of the FS laser optical system.

10. When the laser procedure is complete, fully depress and hold the syringe plunger to release the cornea from suction, and then simultaneously rotate the joystick counter-clockwise to raise the Beam Delivery Device. This undocking procedure will simultaneously remove the Suction Ring Assembly and the Applanation Cone, thus minimizing the exposure of the eye to elevated intraocular pressure.

WARNING: Caution must be taken to remove suction prior to removing applanation to avoid injury to intraocular structures.

Examples of Pattern Combinations

The following diagrams illustrate possible laser resection combinations.



Other Incision Patterns

Alignment Incisions and *Anterior Side Cut* openings (one or two) are also available. See the following *Parameters* section for more detail.

Alignment Incisions

Anterior Side Cuts (two openings)

Examples of Non-Intersecting Pattern Combinations

The following diagrams illustrate possible non-intersecting laser resection combinations. Non-intersecting cuts are used when the final cuts need to made manually, by the surgeon, during the procedure.

- 40-100 um gap
- Vertical gap requires sharp blade to complete the cut if > 40 um
- Horizontal overlap on inner diameter to ensure intersection

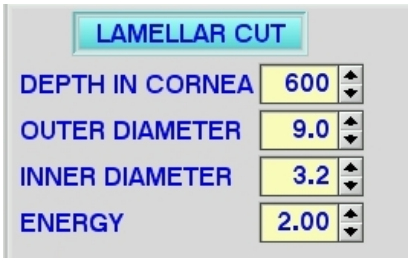
- 150-400 um gap
- Horizontal orientation allows blunt dissection
- Vertical overlap on posterior side cut to ensure intersection

- 100-400 um gap
- Vertical gap requires sharp blade and scissors to complete the cut
- Non-penetrating cut

Parameters

Lamellar Parameters

The lamellar cut is a planar cut (ring-shaped) parallel to the anterior corneal surface.



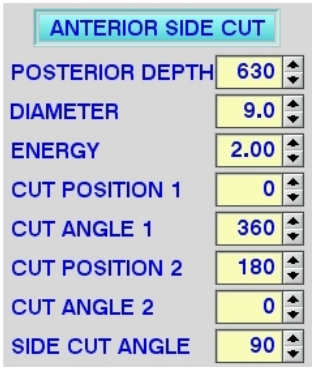
More Keratoplasty Parameters

Parameter	Definition	Range
Lamellar Cut (top button)	Enables or disables the lamellar cut function.	0 - OFF or 1 - ON
Depth in Cornea	Perpendicular distance from the cornea anterior surface to the resection plane (replaces flap thickness).	90 - 1200 µm
Outer Diameter	Outer diameter of the lamellar cut.	3 - 9.5 mm
Inner Diameter	Inner diameter of the lamellar cut.	3 - 9.5 mm
Energy (µJ)	The pulse energy used to create the planar cut.	0.3 - 9.99 µJ
Tangential Spot Separation	The separation between adjacent spots along a common circle.	4 - 10 µm
Radial Spot Separation	The separation between adjacent circles with a common center.	4 - 10 µm
Spiral Start	Area at which the spiral pattern is initiated.	0 - IN or 1 - OUT

Anterior Side Cut Parameters

The anterior side cut is a cylindrical or arcuate cut from the stroma, anteriorly, to the epithelial surface.

Note: A positive value in **Depth in Glass** creates an **Anterior Side Cut** from the programmed **Posterior Depth** into the contact glass. This is to assure that the **Anterior Side Cut** surfaces through the epithelium. However, if a non-surfacing **Anterior Side Cut** is desired, a negative value can be entered in **Depth in Glass**. For example, if Depth in Glass was programmed to -200 um, this would create an Anterior Side Cut that ends 200 um below the epithelial surface.



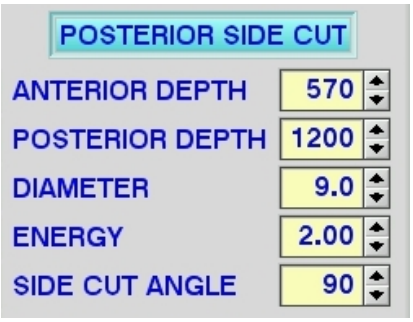
More Keratoplasty Parameters

Parameter	Definition	Range
Anterior Side Cut (top button)	Enables or disables the anterior side cut function.	0 - OFF or 1 - ON
Posterior Depth	Start depth of the anterior side cut.	90 - 1200 µm
Diameter	Diameter of the anterior side cut measured at the surface of the cornea.	3 - 9.5 mm
Energy	The pulse energy used to create the anterior side cut.	0.3 - 9.99 µJ
Cut Position 1	Center point location of the cut (default 0°).	0° - 359°
*Cut Angle 1	Angled 'length' of the side cut (default 360°).	0° - 360°
Cut Position 2	Center point location of the 2nd cut (default 180°).	0° - 359°
*Cut Angle 2	Angled 'length' of the 2nd side cut (default 0°).	0° - 180°
Side Cut Angle	Angle that the cylindrical side cut makes in respect to the corneal surface (90° is perpendicular to the corneal anterior surface).	30° - 150°
Spot Separation	Distance between each laser pulse during the side cut procedure.	1 - 6 µm
Layer Separation	Distance between each side cut layer.	1 - 6 µm
Depth in Glass	End depth of the anterior side cut.	-200 - 100 µm

***** It is recommended to avoid settings from 1 to 9 degrees**.**

Posterior Side Cut Parameters

The posterior side cut is a cylindrical cut from the endothelial surface, anteriorly, into the stroma.



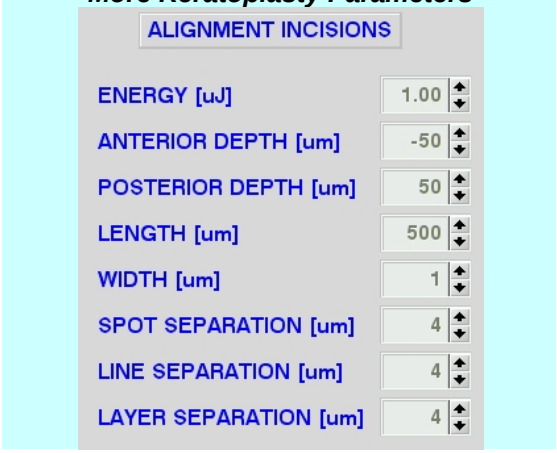
More Keratoplasty Parameters

Parameter	Definition	Range
Posterior Side Cut (top button)	Enables or disables the posterior side cut function.	0 - OFF or 1 - ON
Anterior Depth	End depth of the posterior side cut.	90 - 1200 µm
Posterior Depth	Start depth of the posterior side cut.	90 - 1200 µm
Diameter	Diameter of the posterior side cut (measured at anterior depth).	3 - 9.5 mm
Energy	The pulse energy used to create the posterior side cut.	0.3 - 9.99 µJ
Side Cut Angle	Angle that the cylindrical side cut makes in respect to the corneal surface (90° is perpendicular to the corneal anterior surface).	30° - 150°
Spot Separation	Distance between each laser pulse during the posterior side cut procedure.	1 - 6 µm
Layer Separation	Distance between each side cut layer.	1 - 6 µm

Alignment Incisions

The alignment incision function creates eight, equally spaced, small incisions radially centered along the circumference of the Anterior Side Cut (within a 9.5mm surgical field). The alignment incision parameters are all fixed settings. The function can be toggled ON or OFF using the top right button in the **More** window.

More Keratoplasty Parameters



Parameter	Definition	Settings	
Alignment Incision (top button)	Enables or disables the alignment incision function.	Default is OFF 1 - ON / 0 - OFF	
Energy	The pulse energy used to create the Alignment incisions.	1.00 µJ	All settings are fixed. Contact your IntraLase Clinical Applications representative for further information.
Anterior Depth	End depth of the alignment incision cut.	-50 µm	
Posterior Depth	Start depth of the alignment incision cut.	50 µm	
Length	The fixed length of each incision.	500 µm	
Width	The fixed width of each incision.	1 µm	
Spot Separation	Distance between each laser pulse during the alignment incision cut procedure.	4 µm	
Line Separation	The separation between adjacent lines.	4 µm	
Layer Separation	Distance between each alignment incision cut layer.	4 µm	

Energy and Spot Separation Settings

As with creating LASIK flaps, laser **Energy** and **Spot / Layer Separation** can be adjusted for optimized tissue resection. Our Clinical Applications Specialists will provide you with an initial setting recommendation. As a rule, higher **Energy** setting and lower **Spot / Layer Separation** setting would result in easier tissue separation. For deeper cuts and cuts through corneas with some opacity, **Energy** setting should be increased to compensate for transmission loss. **Spot Separation** can also be decreased for optimized resection.

In some occasions, it may be desirable to have more residual tissue adhesions, or, the cornea could be thin and clear (i.e. keratoconus). In this case, lowering **Energy** setting and/or increasing **Spot / Layer Separation** is needed.

Overlapping Resection Patterns (Intersecting)

To assure continuity of resection patterns, vertical and horizontal overlaps should be instituted. There should be at least 30 um vertical overlap and 0.1 mm horizontal overlap between each connecting pattern. For Lamellar Depth settings greater than 900 um, the vertical overlap should be at least 40 um.

For example, if lamellar Depth is 400 um, Posterior Depth of Anterior Side Cut should be set to 430 um and Anterior Depth of Posterior Side Cut should be set to 370 um. If the Inner Diameter of the Lamellar Cut is 6.9 mm, the intersecting Side Cut (either Anterior or Posterior) should be set to 7.0 mm. If the Outer Diameter of the Lamellar Cut is 8.1 mm, the intersecting Side Cut (either Anterior or Posterior) should be set to 8.0 mm.

Non-Intersecting Resection Patterns

If a non-intersecting resection is desired, make the necessary adjustments to the depth and diameter settings. For example, if a gap between an Anterior Side Cut and Lamellar Cut is required, the depth of the Anterior Side Cut should be shallower than the depth of the Lamellar Cut. There should be at least 30µm vertical gap between non-intersecting segments. For lamellar depth settings greater than 900µm, the vertical gap should be at least 40µm.

If a gap between a Posterior Side Cut and a Lamellar Cut is required, the outer diameter of the Lamellar Cut should be smaller than the diameter of the Posterior Side Cut.

Section 12 - Service and Maintenance

To ensure continuous operation of the IntraLase FS Laser, it is recommended that a preventive maintenance service be performed every three months by an IntraLase service representative.

For service assistance and to order accessories or replacement parts, call our Global Support Department at (877) 393-2020 (in the U.S. only), or (949) 859-5230. To order online, go to www.intralase.com.

Section 13 - Troubleshooting

Error Messages

If an error occurs, the system attempts to recover and solve the problem. A red light bulb will flash at the bottom right of the screen. The system will display the code and error message, and will prompt "**Recovery in Process**". Click **OK** to continue.

The red light will keep flashing if the error condition is not solved. Click on the red light while it is displayed and the **System Status** window will appear. The laser beam and other laser functions will stay disabled as long as the error condition remains.

Re-Settable System Errors

Some errors reported by the system may be reset by the user. Examples of re-settable errors are: Gantry, oscillator mode lock, interlock, energy, X, Y1, Y2, Z galvo position errors. If one of these errors occurs and a procedure IS NOT in progress: attempt to reset the error by clicking on the red **Reset** button in the **System Status** window. If the error persists, contact IntraLase Global Support for further assistance.

If a re-settable error occurs and a procedure IS in progress, the procedure stops, and an error message appears. When attempting to run the next procedure, the **Treat** button will not be enabled until the error is cleared.

Beam Steering Errors

Certain Beam Steering errors can be reset by performing a Beam Steering check.

1. From the **Procedure** window, click on the **System Tools** button.
2. Select **System Checks**, and then select **Beam Steering**.
3. The system will start the procedure and display the results.
4. If the results are not acceptable, an error message will be displayed and the red light will flash.

Troubleshooting Guide

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

Symptom	Possible cause	Corrective action
Laser console will not energize upon turn-on	Power cord disconnected	Connect cord
	Circuit breaker tripped	Reset breaker, check electrical service
	System electrical fault	Contact IntraLase representative
	Emergency OFF button is depressed	Reset *Emergency OFF* button switch
Laser console will not proceed to the treatment stage	*Footswitch* actuated	Release *footswitch*
	Incomplete patient info	Enter required info
	System fault	Check if error is recoverable, if not contact an IntraLase representative
Laser console will not begin treatment when enabled	*Footswitch* not connected or malfunctioning	Connect *footswitch*
	Footswitch not fully actuated	Completely actuate *footswitch*
Laser beam halts during treatment	*Door safety interlock* disabled laser	• Close suite doors • Check interlock connections
	Footswitch not fully actuated	Fully depress *footswitch* during procedure
	Fault condition	Contact an IntraLase representative
Fixation cannot be achieved or maintained	Suction not present	Reapply suction ring assembly
	Suction ring tubing failure	Replace suction ring assembly and/or syringe
	Improper applanation or improper coupling of suction ring assembly and applanation lens	Reposition Beam Delivery Device and re-applanate cornea.
	Patient movement	Immobilize patient

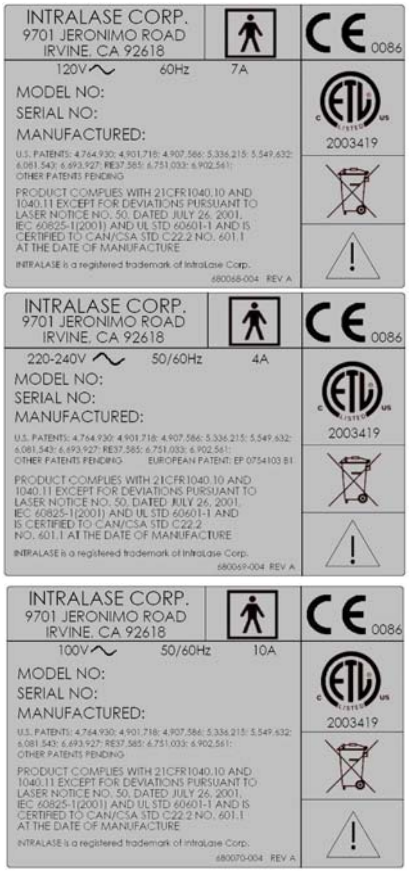
Symptom	Possible cause	Corrective action
Operating field not properly observable through a microscope	Demagnification lens in wrong position	Toggle demagnification lens switch
	Applanation lens contaminated	Replace applanation cone
	Poor illumination	Adjust illumination control
	Microscope optically misaligned	Verify position magnification knob
Laser tissue effect not apparent during treatment	Applanation lens contaminated or damaged	Replace applanation cone
	Corneal fixation vacuum lost	Reposition suction ring assembly and fixate. Reposition Beam Delivery Device and re-applanate cornea.
	Laser output blocked	Contact an IntraLase representative
	Laser output misaligned	Contact an IntraLase representative
	No laser light emitted	Contact an IntraLase representative
Flap thickness incorrect	Cornea not fully applanated	Fully applanate cornea
	Misaligned Beam Delivery Device	Contact an IntraLase representative
Flap resection incomplete	Corneal fixation vacuum lost	Allow one hour before retreatment. Reposition suction ring assembly and fixate. Reposition Beam Delivery Device and re-applanate the cornea.
	Laser output block	Contact an IntraLase representative
	Laser source misaligned	Contact an IntraLase representative
	Beam Delivery Device misaligned	Contact an IntraLase representative
Flap geometry incorrect	X-Y scanning unit failure	Contact an IntraLase representative
	Beam Delivery Device misaligned	Contact an IntraLase representative

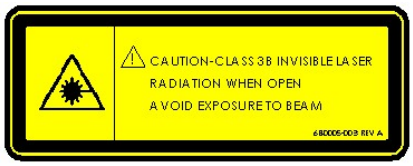
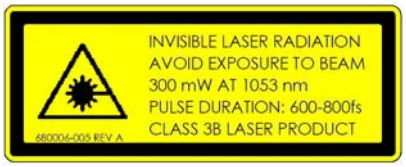
Symptom	Possible cause	Corrective action
Gantry Error	X, Y, or Z gantry motor error	If red light is ON and if the patient is applanated, remove the patient from under the Beam Delivery Device. Reset the error as described in "Re-Settable System Errors" above.
	Gantry error fails to reset	Contact an IntraLase representative
Unable to receive electronically activated procedures	Computer not ***ON***	Power up computer (turn laser system keyswitch to on position)
	Internet cable disconnected	Connect cable
	Non-operational Internet Connection	Contact an IntraLase representative

Section 14 - Labels

Console Labels

Warning labels found on the IntraLase FS Laser denote specific hazards. Observe label warnings at all times. The IntraLase FS Laser is labeled in accordance with requirements for all medical devices as well as with requirements for laser products. Below are representations of labels 1-9. On the next page are drawings depicting label locations.

Label No.	Label	Label Name	Refer to Figure
1		Laser Aperture	2
2		Identification Label (3 options)	1

Label No.	Label	Label Name	Refer to Figure
3		High Voltage	1 – 4, 6
4		Protective Housing, Class 4	5
5		Protective Housing, Class 3B	1 – 4, 6
6	15 kHz:  30 kHz:  60 kHz: 	Laser Warning	2
7		High Voltage (Internal)	1, 3
8		Emergency Stop	2
9		Potential Equalization Connector	1

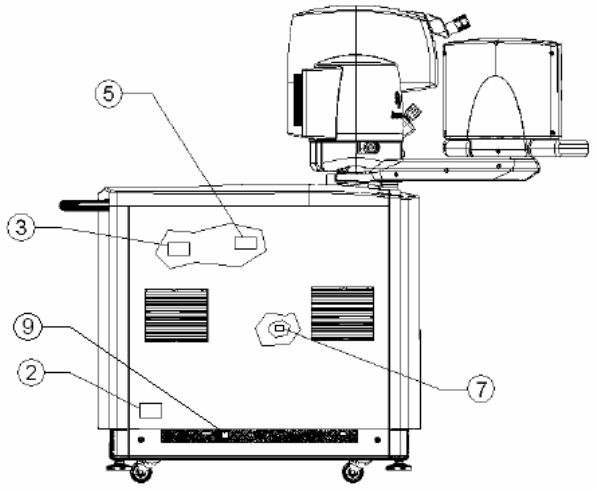


Figure 1: Label locations, left side view

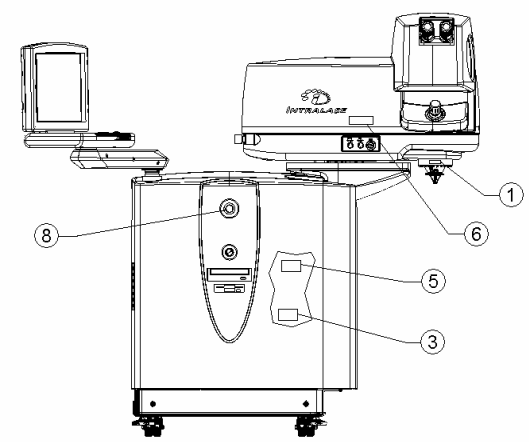


Figure 2: Label locations, front view

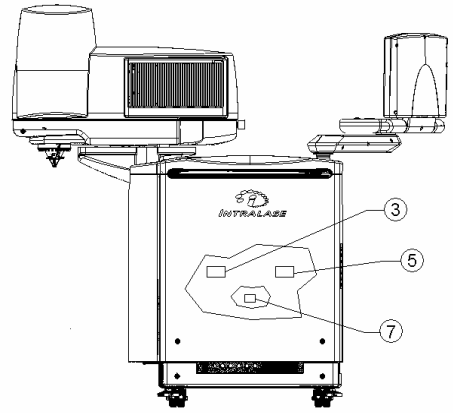


Figure 3: Label locations, back view

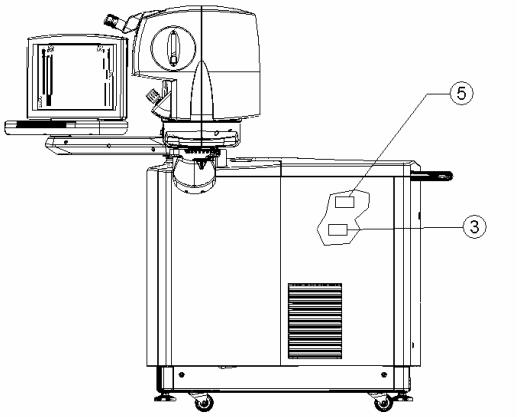


Figure 4: Label locations, right (patient) side view

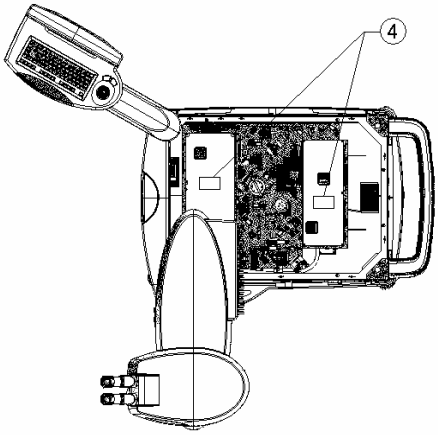


Figure 5: Label locations, top view (without covers)

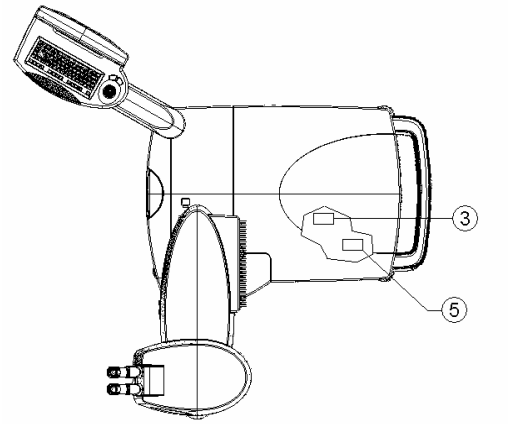
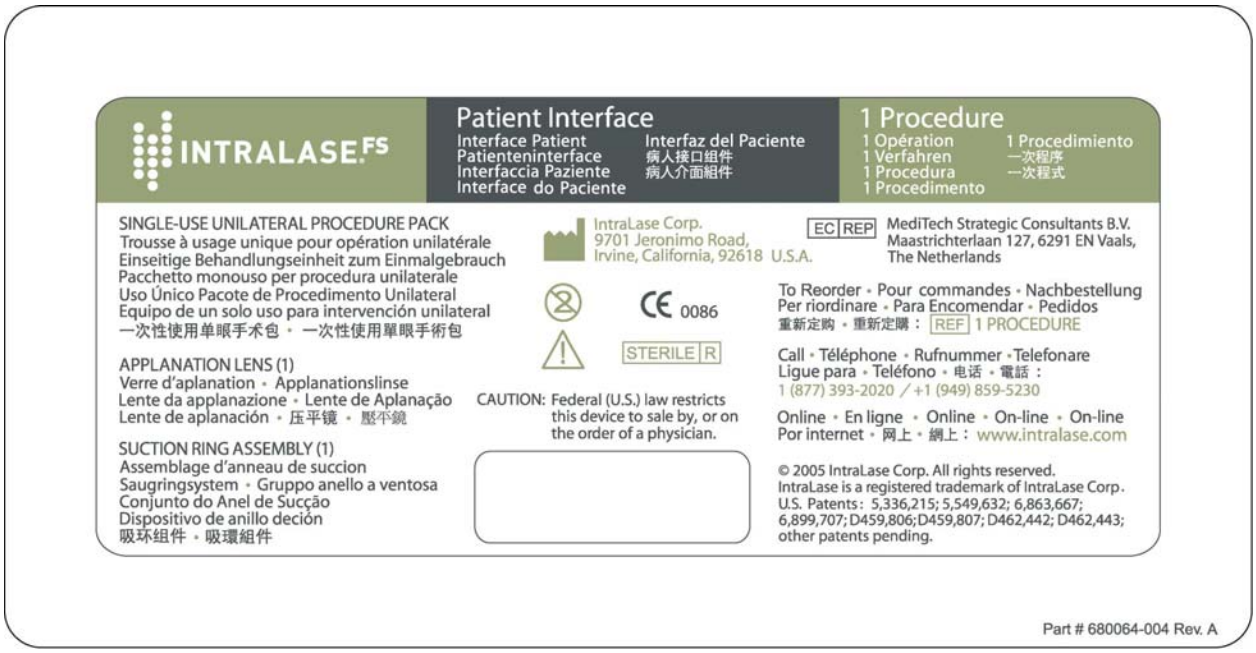


Figure 6: Label locations, top view (with covers)

Label for the IntraLase Patient Interface Single-Use Disposables

The IntraLase Patient Interface single-use disposable assemblies are shipped pre-sterilized in sealed packaging with the following label:



Directions for Use (DFU) are packaged with the IntraLase Patient Interface.

Section 15 - Appendix

Abbreviations

AL	Applanation Lens
BDD	Beam Delivery Device
OM	Operating Microscope
SRA	Suction Ring Assembly
PI	Patient Interface

General Abbreviations

ANSI	American National Standards Institute
CDRH	Center for Device and Radiological Health
DFU	Directions for Use
FDA	Food and Drug Administration (United States)
LED	Light Emitting Diode
NOHD	Nominal Ocular Hazard Distance
MPE	Maximum Permissible Exposure

Terms

Applanation

Flattening of cornea performed for the purpose of corneal resection.

Femtosecond

Measure of time; 1 fs = 10^{-15} seconds, or 0.000000000000001 seconds.

Laser Emission Warning

Indicates the release of potentially hazardous laser radiation.

Picosecond

Measure of time; 1 ps = 10^{-12} seconds, or 0.000000000001 seconds.

Trackball

Pointing device used with computer performing a similar function to a computer mouse.

Nominal Ocular Hazard Distance (NOHD)

The NOHD is defined according to American National Standards Institute Z136.1-2000, "American National Standard for Safe Use of Lasers." The NOHD is computed in terms of the Maximum Permissible Exposure (*MPE*) allowed onto the eye. The NOHD calculated using this standard for *the* IntraLase FS Laser is very short due to the small pulse energies and very large beam divergence used.

The practical consequence is that operators and support personnel are not at any optical radiation danger during normal and routine operation of the laser. Any service operation requiring the removal of any covers or shields on the console will require eyewear of OD ≥ 5 at a wavelength of 1054 nm. Only authorized IntraLase service representatives should attempt to remove console covers or to service the IntraLase FS Laser.

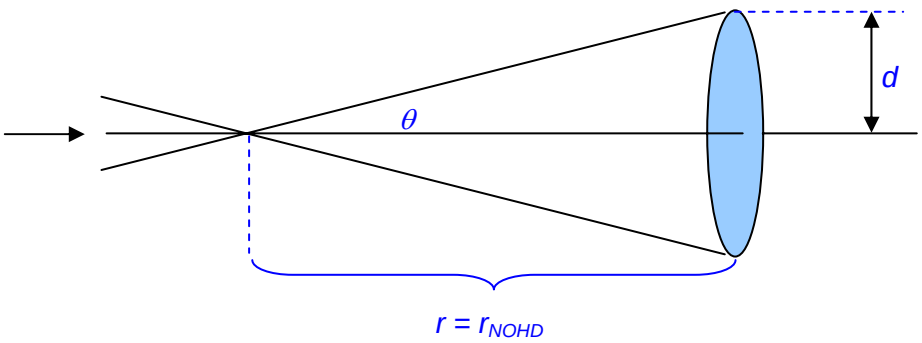
The steps required to calculate the NOHD according to Z136.1-2000 (referred to hereafter as "the Standard") are described below. The Standard describes the calculation of *MPE* according to three rules and utilizes the prescribed *MPE* to compute the NOHD. The calculations presented here are prescribed for lasers operating at 15, 30, and 60 kHz.

Rule 1: Single-pulse MPE

Table 5a of the Standard lists the single-pulse *MPE* for a laser of wavelength 1054 nm and a single pulse exposure of 600 fs as

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

From Table 5 of the Standard, *CC* = 1 so that *MPESP* = 1.5×10^{-7} J/cm^2. To compute the NOHD, consider the figure below.



Geometry for calculation for possible ocular

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

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

Here *E* is the maximum energy delivered by a single pulse. The NOHD is computed by replacing the fluence with the *MPE* derived by the Rule and solving for *r*.

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

For the IntraLase FS Laser operating at:	15 kHz	E = 7.3 μJ and θ = 18°
	30 kHz	E = 7.3 μJ and θ = 18°
	60 kHz	E = 5.0 μJ and θ = 18°
The resulting NOHD using Rule 1 is:	15 kHz	r_{NOHD} = 12.1 cm
	30 kHz	r_{NOHD} = 12.1 cm
	60 kHz	r_{NOHD} = 10.0 cm

Rule 2: Average Power MPE for Thermal and Photochemical Hazards

According to Table 5a of the Standard, the average power, *MPEAVG* for an exposure of 10 s is 5.0×10^{-3} W/cm^2. In order to compute the NOHD, consider Figure 18-1 and compute the irradiance as follows:

$$I = \frac{P_{AVG}}{\pi d^2} = \frac{P_{AVG}}{\pi r^2 \tan^2 \theta}. \quad (4)$$

The average maximum power of the laser is 110mW for 15 kHz, 220mW for 30 kHz, and 300mW for 60 kHz. The NOHD is computed by replacing the fluence with the *MPE* derived by the Rule and solving for *r*.

$$r_{NOHD} = \left[\frac{P_{AVG}}{\pi (MPE_{AVG}) \tan^2 \theta} \right]^{1/2}. \quad (5)$$

Using θ = 18°, the resulting NOHD using Rule 2 is:	15 kHz	8.1 cm
	30 kHz	11.5 cm
	60 kHz	13.5 cm

Rule 3: Multiple-pulse MPE for Thermal Hazards

Section 8.2.3 of the Standard defines the MPE for this rule as

$$MPE / pulse = MPE_{SP} \cdot C_P, \quad (6)$$

where *MPESP* is computed from (1) and $CP = n^{-1/4}$ and *n* is number of pulse in an exposure. The number of pulses in an exposure is taken to be the exposure time multiplied by the laser repetition rate. Since at infrared wavelengths a natural blink response is not expected, the exposure time *T* is taken to be 10 s.

Multiplying *T* by the repetition rates of the laser, the numbers of pulses in an exposure is:	15 kHz	1.5×10^5
	30 kHz	3.0×10^5
	60 kHz	6.0×10^5
The resulting values for C_P are:	15 kHz	0.051
	30 kHz	0.043
	60 kHz	0.036
Using equation 6, the resulting *MPE / pulse* values are:	15 kHz	7.62×10^{-9} J/cm^2
	30 kHz	6.45×10^{-9} J/cm^2
	60 kHz	5.40×10^{-9} J/cm^2

The NOHD calculation for Rule 3 follows according to equation (3):	15 kHz	E = 7.3 μJ and θ = 18°
	30 kHz	E = 7.3 μJ and θ = 18°
	60 kHz	E = 5.0 μJ and θ = 18°
The resulting NOHD using Rule 3 is:	15 kHz	53.7 cm
	30 kHz	58.4 cm
	60 kHz	52.8 cm

Since Rule 3 provides the most conservative values of NOHD, the reported nominal optical hazard distance is 54 cm for the 15 kHz laser, 58 cm for the 30 kHz laser, and 53 cm for the 60 kHz laser.

Declaration of Compliance

The following tables contain information for electromagnetic emissions and immunity.

Guidance and manufacturer's declaration – electromagnetic emissions		
The INTRALASE FS System is intended for use in the electromagnetic environment specified below. The customer or the user of the IntraLase FS Laser should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The IntraLase FS Laser 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.
Conducted emissions CISPR 11	Class A	The IntraLase FS Laser System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The IntraLase FS Laser system is to be operated in conjunction with the applicable version of the UPS: 100V, P/N 660020-xxx 120V, P/N 660018-xxx 220V, P/N 660021-xxx
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The IntraLase FS Laser System is intended for use in the electromagnetic environment specified below. The customer or the user of the IntraLase FS Laser System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV	±6 kV contact ±8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated EM Field IEC 61000-4-3	Range 80MHz – 2.5GHz 3V/m	Range 80MHz – 2.5GHz 3V/m	Electro-Magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Do not use cell phones, pagers, or radio frequency devices of any kind in the same room as the IntraLase FS Laser.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge Immunity IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment. The IntraLase FS Laser system is to be operated in conjunction with the applicable version of the UPS: 100V, P/N 660020-xxx 120V, P/N 660018-xxx 220V, P/N 660021-xxx
Conducted Disturbances IEC 61000-4-6	Range 0.15 – 80 MHz 3(Vrms)	Range 0.15 – 80 MHz 3(Vrms)	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field Immunity IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, Interruptions & Fluctuations IEC 61000-4-11	Dips >95% for 10ms -60% for 1000ms -30% for 500ms Interruptions >95% for 5 sec Fluctuations Unom + 10% 15 min Unom – 10% 15 min	Dips >95% for 10ms -60% for 1000ms -30% for 500ms Interruptions >95% for 5 sec Fluctuations Unom + 10% 15 min Unom – 10% 15 min	Mains power quality should be that of a typical commercial or hospital environment. It is required that the user powers the FS Laser System with the supplied Uninterruptible Power Supply (UPS).
NOTE: U_{nom} is the a.c. mains voltage prior to application of the test level			

Section 16 - Warranty Information

IntraLase Corp. warrants that the IntraLase FS Laser and IntraLase Patient Interface, docking interface devices and accessories (collectively, the "Equipment") and IntraLASIK® Software and other software (together, "Software") will conform to the published product specifications of IntraLase and be free from material defects in materials and workmanship and will clinically perform to IntraLase specifications during the time a contractually obligated warranty period is in place and during the time any continuous service and support agreement is in place and payment is current. The Equipment may contain refurbished components, which IntraLase warrants are equivalent to new components.

IntraLase will repair or replace at no charge, any Equipment or Software found upon examination by IntraLase, to be defective during the warranty period and thereafter where continuous service and support payments are current. This warranty is subject to the following exclusions, exceptions, and limitations: (a) expenses such as labor or other expenses due to delays or inability to render any service herein described; (b) correction of operator problems related to environmental conditions beyond the control of IntraLase; (c) repair and maintenance necessitated by user-induced damage, neglect, misuse, or improper operation of the Equipment, Software or device; (d) modification of IntraLase Equipment, Software and devices without the express written authorization of IntraLase; (e) supplies, devices or electrical work external to the IntraLase Equipment; (f) use of docking interface devices and accessories other than those manufactured and distributed by IntraLase; (g) use of the docking interface devices and accessories that contravene the user instructions provided by IntraLase; (h) unopened docking interface devices and accessories, which have a warranty period expiring on the unopened packaging sterilization expiration date; (i) moving of the Equipment, except by IntraLase service representatives; and (j) use of the Equipment and Software for uses for which they are not intended..

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

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