IntraLase™
FS Technology

iFS™ Advanced Femtosecond Laser System

Operator's Manual

CE 0413

J900050-001 Rev. A

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Revision History

Section Affected	Part Number	Rev.	Revision Date	Description
All	J900050	A	9-18-2008	Initial Release
Title Page, Section 13, 15 and 16.	J900050-001	A	10-8-2008	Update information relevant to Milpitas plant.

Table of Contents

Section 1 – Introduction

The iFS Advanced Femtosecond Laser System

The iFS 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 iFS Laser is a class IIb device in accordance with Rule 9 of the Medical Device Directive. The IntraLase FS Patient Interface (referred to as IntraLase Patient Interface or Patient Interface) is classified as a class IIa device in accordance with Rule 5 of the Medical Device Directive.

Indications for Use

The iFS 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 IEK 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 IEK and for the creation of a penetrating cut/incision for penetrating IEK

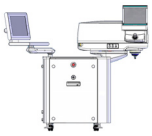
The iFS Laser delivery system is used in conjunction with a sterile disposable IntraLase Patient Interface, consisting of pre-sterilized suction ring assemblies and pre-sterilized applanation cones, intended for single-use.

The iFS 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 iFS Laser System.

Operator's Manual Overview

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

Notes, Cautions, Warnings



NOTE: 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.

CAUTION: Presents information that needs 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.

WARNING: Presents very important warning and safety information.

Section 2 – General Warnings

General Safety Precautions

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 iFS Laser should not be operated in the presence of flammable anesthetics, volatile substances, or oxygen flow lines.

In Canada, installation and operation of the iFS Laser must be in accordance with CAN/CSA-Z386: Safe use of lasers in healthcare facilities.

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

WARNING: Only certified accessories that conform to National and International standards (i.e., IEC 60950-1, IEC 60601-1 or similar) should be connected to the input/output ports on the iFS Laser.

WARNING: The operator should halt any procedure if either the Video Microscope or the User Monitor interface display fails.

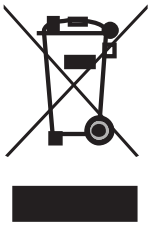
WARNING: If an articulating chair is used in conjunction with the iFS Laser system, take proper precautions to avoid any unintended movement of the chair toward the laser system. Refer to the specific operating instructions provided by the manufacturer of the articulating chair.

Combustion and Fire Precautions

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 iFS Laser.

Environmental and Chemical Safety

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



This symbol is located on AMO 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. 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 AMO for disposal.

Flap Contraindications

Lamellar resection for the creation of a corneal flap using the iFS Laser is contraindicated if any of the following conditions exist. Potential contraindications are not limited to those included in this list.

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

IEK Contraindications

Contraindications to use of the iFS Laser for the indications described for the IEK procedure include the following:

- 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
- Corneal thickness requirements that are beyond the range of the system

IEK Precautions

Use of the iFS Laser for IEK is not recommended for the following:

- Subjects with severe corneal thinning
- Subjects with pre-existing glaucoma
- Subjects with a history of steroid responsive rise in intraocular pressure
- Subjects with preoperative intraocular pressure greater than 21 mmHg in the operative eye
- Subjects with more than 1200 μm corneal thickness at the 9 mm peripheral zone
- Subjects with active intraocular inflammation
- Subjects with active ocular infection

Flap Complications

Possible complications resulting from LASIK surgery include the following. 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, AMO recommends that you include a description of the following sporadically reported visual symptoms, which may occur following LASIK flap creation with the iFS Laser.

Transient Light Sensitivity Syndrome

Transient Light Sensitivity Syndrome (TLSS) 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 iFS 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

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.

Section 3 – System Hazards and Safety Features

FDA Requirements

Surgical lasers must meet requirements established by the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). 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 iFS 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.

Eye Safety and Nominal Ocular Hazard Distance

The iFS 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. The maximum NOHD for a direct beam exposure from the iFS Laser is 42 cm at 150 kHz (see Appendix A 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.

Mechanical Motion Control

The iFS 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 AMO 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 safety hazard and should be performed only by trained AMO service representatives.

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

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).

iFS Safety Features

The iFS 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, a software system window appears and requests a user name and password. This security feature prevents unauthorized use of the 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 User Monitor screen. 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 User Monitor.

Protective Housing

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

Warning 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 Product 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 the footswitch being depressed), 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 iFS 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 interlock connection for using safety interlock switches on the surgical operating suite door(s) that automatically disables laser emission when the suite door(s) is opened.

All laser shutters are closed and a message on the User Monitor 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 AMO 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.

Applanation Limit Switches

Applanation limit switches monitor the position of the objective lens and alert the user to initial contact of the coupled applanation cone to the cornea (green applanation indicator illuminates), increased contact pressure within the acceptable range (yellow applanation indicator illuminates), and maximum contact pressure (red applanation indicator illuminates along with an audible beep). If the Beam Delivery Device moves down more than a pre-set distance beyond the maximum contact pressure limit indicated by the red applanation indicator, the system prevents further downward movement.

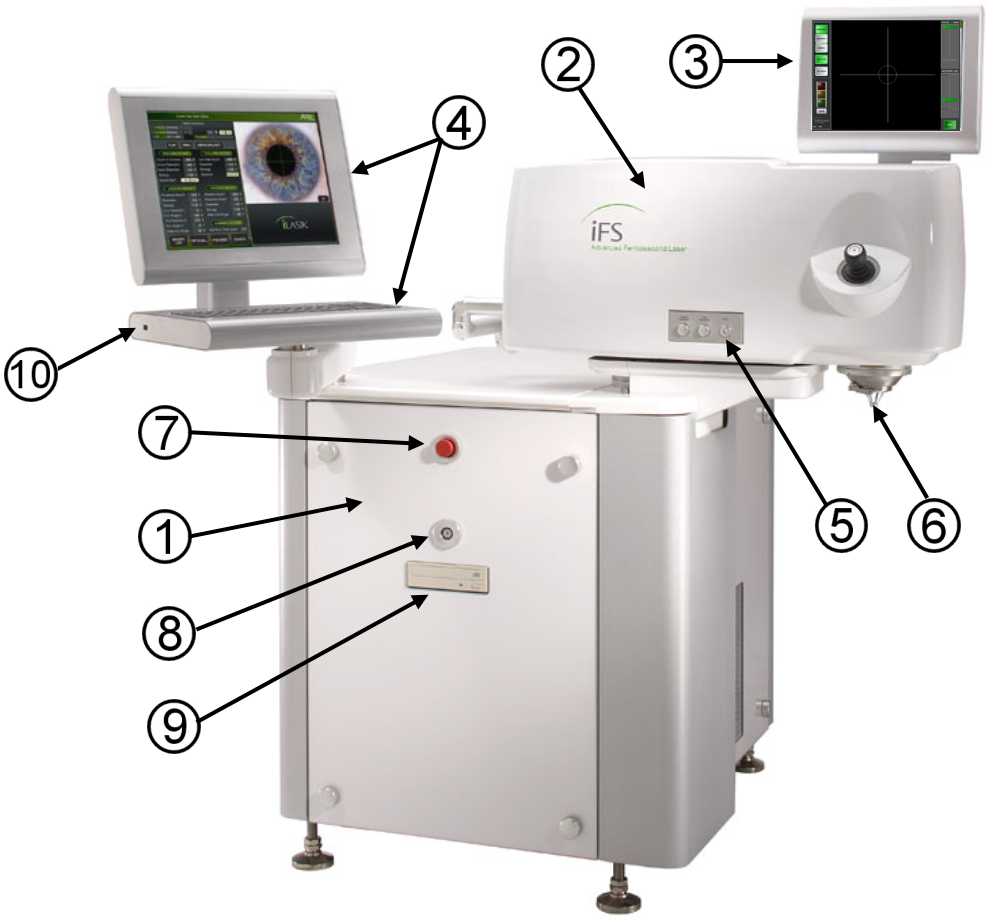
Emergency Shut-Down

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

Section 4 – System Description

The iFS Laser consists of the following principal hardware components:

1. Laser Console
2. Beam Delivery Device
3. Video Microscope
4. User Monitor and Keyboard
5. Control Panel
6. Loading Deck for Patient Interface
7. Emergency OFF Button
8. Key ON Switch
9. CD-ROM Drive
10. USB Port
11. Patient Interface and Footswitch (not shown)



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.

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 alert the user to initial contact of the coupled applanation cone to the cornea (green applanation indicator illuminates), increased contact pressure within the acceptable range (yellow applanation indicator illuminates), and maximum contact pressure (red applanation indicator illuminates along with an audible beep). If an attempt is made to move the Beam Delivery Device beyond the maximum pre-set downward contact pressure limit indicated by the red applanation indicator, the system prevents further downward movement.

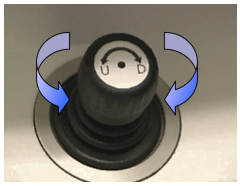
WARNING: When the green applanation indicator is activated during a docking procedure, sensors on the Beam Delivery Device monitor the continued downward travel distance of the gantry to a maximum preset distance to mitigate potentially hazardous applanation overpressure.

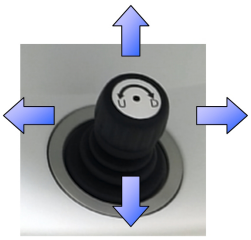
The Beam Delivery Device also features a Joystick, Loading Deck, and Control Panel. Each of these components is described in the sections that follow.

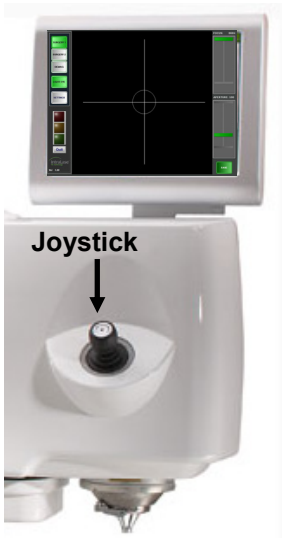
Joystick

The Joystick, located underneath the Video 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 clockwise to move down
- 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.

Loading Deck

The Loading Deck is a precision assembly located at the output of the Beam Delivery Device, coupling the Beam Delivery Device laser output to the disposable IntraLase Patient Interface applanation cone. The Loading Deck locking arm secures the applanation cone into position, preventing it from slipping out of place. Sensors detect that the applanation cone is properly positioned in the Loading Deck and that the lock is closed. A lock sensor continuously monitors and verifies that the Loading Deck is locked during a procedure.

The patient is not exposed to the laser beam until the beam exits the applanation cone. Manual controls allow the user to position the Beam Delivery Device pre- and post-operatively. During laser emission, the positioning controls are disabled.

Control Panel

The Control Panel, located on the side of the Beam Delivery Device, consists of two knobs to adjust LED light intensity, and one button to initiate HOME position for the Beam Delivery Device.

- The **Surgical Illumination knob** varies the illumination intensity from maximum to OFF for the LEDs mounted on the objective lens assembly used for viewing the surgical field.

- The **Cone Illumination knob** varies the illumination intensity from maximum to OFF for the LEDs mounted on the interior of the objective lens assembly used for viewing the applanation cone and the applanated cornea. The Cone Illumination must be ON in order to observe the laser pattern during surgery.

- 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 upward 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. The Home button is disabled whenever the green applanation indicator is illuminated, whenever the footswitch is depressed, or during laser emission. Home button travel can be halted at any time by lifting the objective slightly, allowing 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.

Video Microscope

The Video Microscope provides a view of the surgical field at all times. Software buttons on the video microscope screen allow the user to vary the viewing magnification and visual field size. A high-resolution video camera relays the magnified image of the surgical field to the video microscope. Viewing the field with the video microscope is required for the user-defined treatment offset function and is useful for general viewing of the surgical field.

Touch Screen Software Buttons

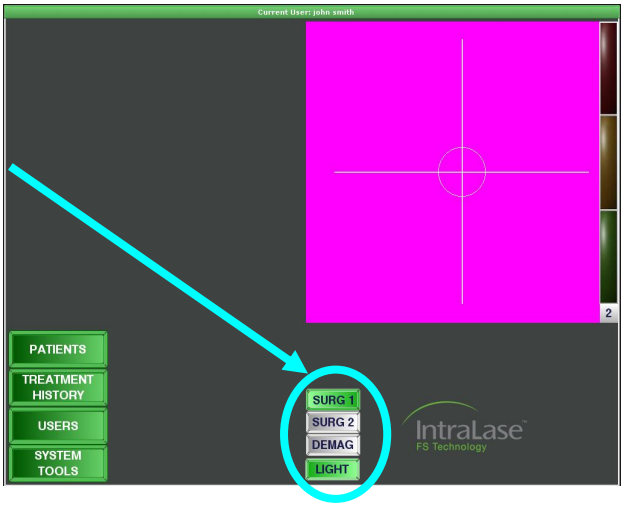
The Video Microscope features a touch-sensitive screen, allowing the user to conveniently select from the displayed software buttons. When a procedure is started, all touch screen functions are locked in their current settings (software buttons are grayed out) and cannot be changed until the procedure is completed or canceled.

Software Button	Function
Surgery 1	Selects a user-defined view (focal depth) of the surgical field
Surgery 2	Selects a user-defined view (focal depth) of the surgical field
Demag	Selects a user-defined view (focal depth) of the surgical field, typically set at a deeper focal depth than is selected for Surgery 1 or Surgery 2.
Light/Dark Eye	Selects a user-defined contrast ratio (gamma) used to optimize illumination of the surgical field for light and dark eyes.
Settings	Provides access to the Gamma, Focus and Aperture settings.
Save	Saves the selected Gamma, Focus and Aperture settings.
Done	Exits the Settings menu without saving changes and displays the Focus and Aperture sliders.

WARNING: The operator should halt any procedure if either the Video Microscope or the User Monitor interface display fails.

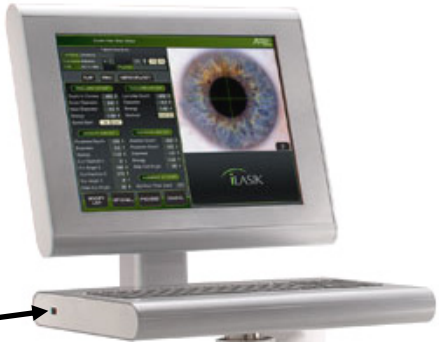
Software Button Options

The Video Microscope view control buttons (Surgery 1, Surgery 2, Demag, and Light/Dark Eye) can be moved from the Video Microscope to the User Monitor (circled in blue) using the System Tools menu. When the Video Microscope view control buttons are moved to the User Monitor screen, the Video Microscope will display only the currently selected microscope view.



User Monitor, Keyboard and USB Port

The User Monitor consists of a flat panel color display, keyboard, touch pad, and a USB port mounted on a swiveling platform located opposite the Video 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 User Monitor.



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. A USB port is provided on the left side of the keyboard for convenient backup of patient data. The USB port will accommodate most USB flash memory devices.

The User Monitor features a touch-sensitive screen, allowing the user to conveniently select the desired software functions using the displayed software buttons. The touch pad, located below the keyboard, may also be used as a pointing device to select software functions. When the footswitch is depressed, all software functions displayed on the User Monitor are locked in their current settings and cannot be changed until the footswitch is released.

Laser Console

The Laser Console houses the laser assembly, electronic circuits, and cooling system. The Emergency OFF button, Key ON Switch, and CD-ROM drive are located on the front panel of the laser console.

Emergency OFF Button

The Emergency OFF button (1) is an easily accessible, large, red button. When pressed, 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.

Key ON Switch

The Key ON switch (2) 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. When the key ON switch is in the ON position, the key cannot be removed. The key can only be removed with the key ON switch in the OFF position.

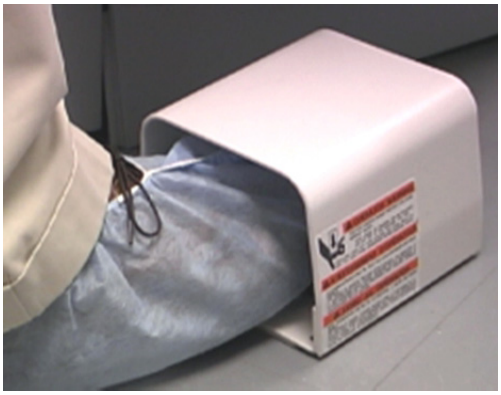
Normal shutdown of the system power is accomplished by selecting **Shutdown** in the **Options** menu and rotating the Key ON switch from "**I**" to "**O**".

CD-ROM Drive

A CD-ROM drive (3) is located in the middle of the iFS Laser Console front panel. Pushing the button on the lower left corner of the drive will alternately open and close the CD tray used for loading and unloading a CD. The CD-ROM drive is used for software updates, procedure updates, record backups, and service functions.

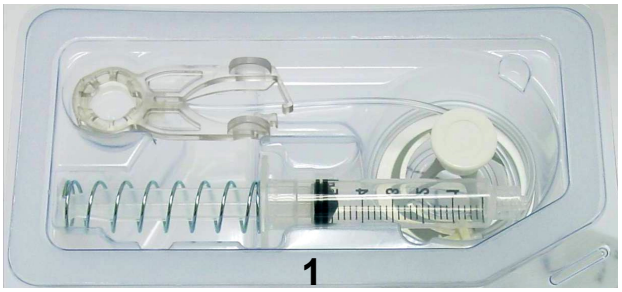
Footswitch

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. The iFS Laser will not emit a laser beam if the footswitch is not connected to the console. Releasing the footswitch will immediately stop laser treatment.

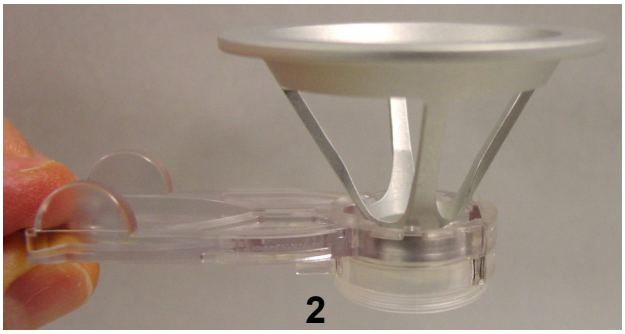


Patient Interface

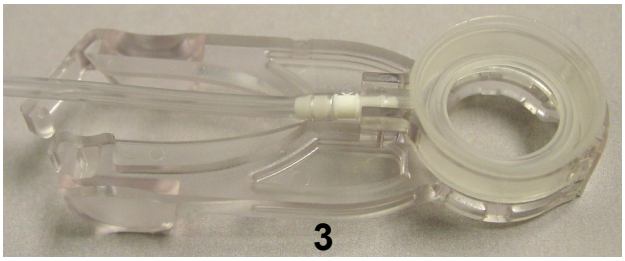
A pre-sterilized, single-use, IntraLase Patient Interface (1) mechanically couples the Beam Delivery Device to the patient cornea. The IntraLase Patient Interface is designed for exclusive use with the iFS and FS Lasers and indicated for corneal resection surgery. All components are sterile and intended for single use only. The IntraLase Patient Interface is also intended for use on one patient.


1

The IntraLase Patient Interface applanation cone (2) is a precision reference surface that mates to the Beam Delivery Device. Alignment of the iFS 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 cone contact surface.


2

The IntraLase Patient Interface suction ring assembly (3) consists of a limbal suction ring made of a biocompatible thermoplastic elastomer that is attached to a flexible "gripper" unit, and a syringe connected to the limbal suction ring with tubing. The limbal suction 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 locking levers holds the cylindrical aperture open until it is released.


3

The Beam Delivery Device is positioned using the Joystick to "dock" the applanation cone in the suction ring assembly. The gripper locking 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.

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 applanation indicator during applanation, and the red Emergency Off button main power shut-off located on the front panel of the laser console.

When the objective encounters resistance that activates the green applanation indicator (initial contact with the eye during applanation), the Z-Verifier registers the position of the gantry. The Z-Verifier then monitors the movement of the gantry. Continued downward movement within the acceptable range after initial contact activates the yellow applanation indicator. If an attempt is made to move the gantry beyond the maximum pre-set downward contact pressure limit indicated by the red applanation indicator, 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 applanation indicator. 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 Monitor.
4. Attempt to move the gantry up using the Joystick. If the gantry does not respond or response is not normal, call AMO Global Support.

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

The Z-Verifier monitors the gantry motion after eye contact is detected. If the green or yellow applanation indicator is activated and remains active before the IntraLase Patient Interface cone contacts the patient's eye, the Z-Verifier may prohibit the full range of downward gantry motion, making full applanation impossible. This may occur, for example, in the following situations:

- The applanation cone (IntraLase Patient Interface cone) inadvertently contacts the suction ring assembly. The surgeon must ensure that the green applanation indicator activates only as a result of eye contact. If full applanation is not achieved, the surgeon must elevate the gantry until the green applanation indicator is deactivated before re-applanating.
- 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 situation, the suction ring assembly can be held in the neutral position with your 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.

Section 5 – Patient Interface

Application of the IntraLase Patient Interface

Indications for Use

The IntraLase Patient Interface is designed for the exclusive use with the iFS and FS Lasers and indicated for corneal resection surgery. All components are sterile and intended for single use only. The 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 glass in the applanation cone becomes etched by the laser during the side-cut procedure and MUST NOT be re-used. Laser light will not effectively permeate an etched glass, 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 iFS Laser. A surgeon should have successfully completed one or more courses on the iFS Laser before attempting to create a corneal resection.
- 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.

Patient Interface Packaging

The IntraLase Patient Interface is intended for **SINGLE USE ONLY** and is supplied in a sterile pack. 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 of the Patient Interface

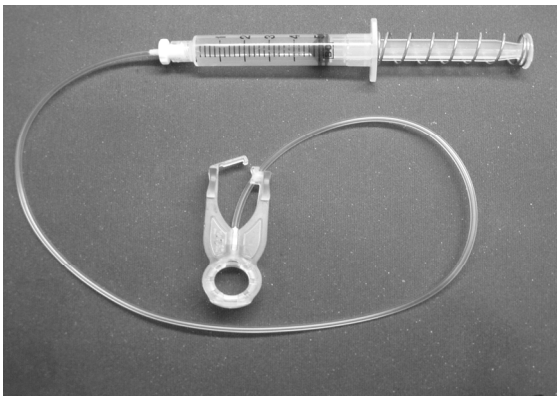
WARNING: To preserve sterility, open the disposable tray while wearing sterile, powder free, surgical gloves and complete the following steps.

Open the Package

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

Inspect the Patient Interface Contents

1. Remove the applanation cone, 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 AMO 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 surface facing downward.
3. Remove the protective cap from the applanation cone 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. Inspect the applanation glass through the Video Microscope for scratches and defects prior to use. Return damaged or questionable components to AMO for replacement.

Assemble the Suction Ring Assembly

The IntraLase Patient Interface suction ring assembly is used to fixate the eye and couple the eye to the applanation cone contact surface. 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 the suction ring assembly.
2. Using light pressure, squeeze the levers of the suction ring assembly to engage the locking 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. The patient interface assembly is now ready for use. Refer to **Section 10 – Patient Treatment** for the applanation procedure.

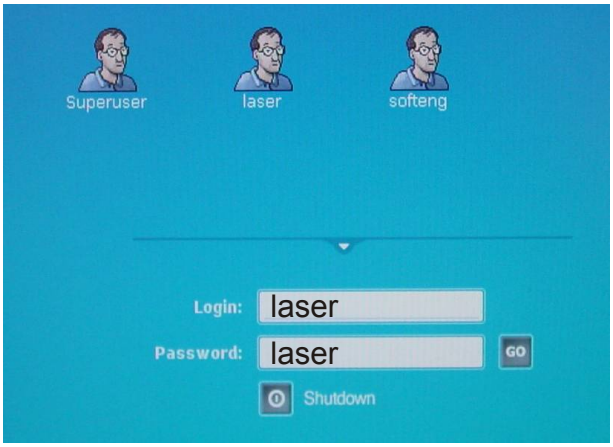
WARNING: If the clip fails to disengage, or if it prematurely disengages, do not attempt use. Return the IntraLase Patient Interface suction ring assembly to AMO for replacement.

Section 6 – Software Interface

Functional Overview

Computer control and software interface functions are performed using the Touch Pad pointing device and Keyboard in conjunction with the User Monitor touch-sensitive screen. The cursor displayed on the User Monitor is controlled using the touch pad. Software options may be selected by moving the cursor with the Touch Pad and clicking the left Touch Pad button or by using the touch-sensitive screen of the User Monitor. Alphanumeric data are entered using the Keyboard.

When power is switched ON for the iFS Laser, the QNX operating system Login screen is displayed. Type the word "**laser**" in the Login field. Type the word "**laser**" in the Password field (user names and passwords are case sensitive). Clicking on the laser-titled icon at the top of the screen will fill in the Login field with the word "laser". The *superuser* and *softeng* login icons are reserved for AMO personnel only. Click on **GO** to start the laser software.



After successful entry, the laser 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 principal software windows.

User Login Window and System Startup

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

- 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 Patients window before treatment.

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

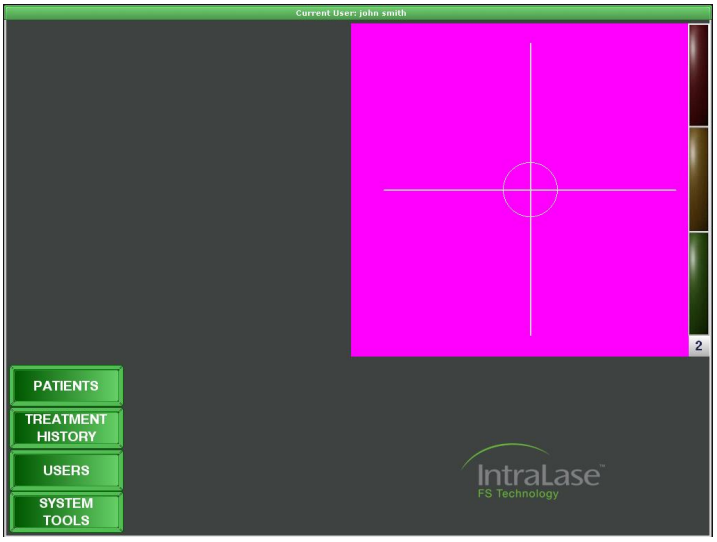
Procedure Window

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

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

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

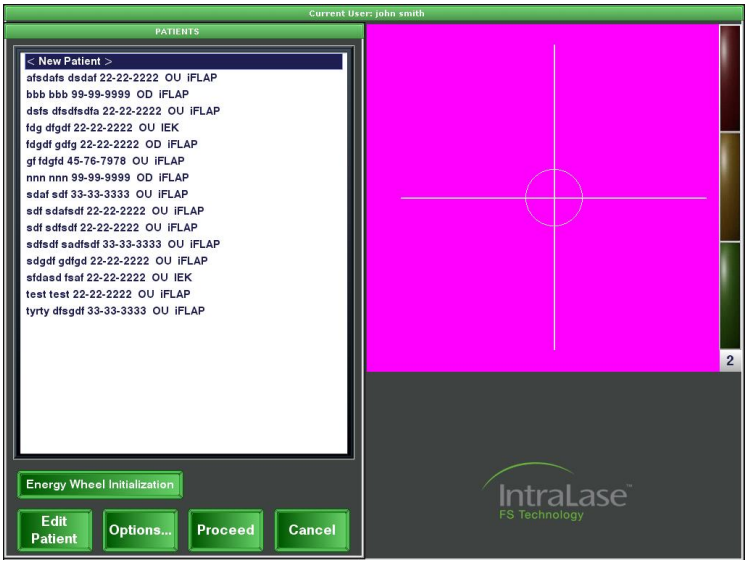
A live video of the surgical field is displayed in the **Procedure** window. Applanation indicators (green, yellow and red) are located along the right-hand side of the surgical field display.



Patients Window

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

- **<New Patient>** (double-click to activate) is used to add new patient records.
- **Energy Wheel Initialization** button is used to initiate energy wheel initialization. When **Quick Warm-up** is selected at login, energy wheel initialization must be performed from the **Patients** window before treatment.
- **Edit Patient** button is used to edit a patient's treatment parameters after selecting the patient from the Patients list.
- **Options** button is used to remove a patient record from the list, move a patient to the treated log, empty the patient list, print the patient list, and enable/disable Test Mode (see Test Procedure Mode for additional information).
- **Proceed** is used to treat the selected patient.
- **Cancel** is used to exit the Patients window.

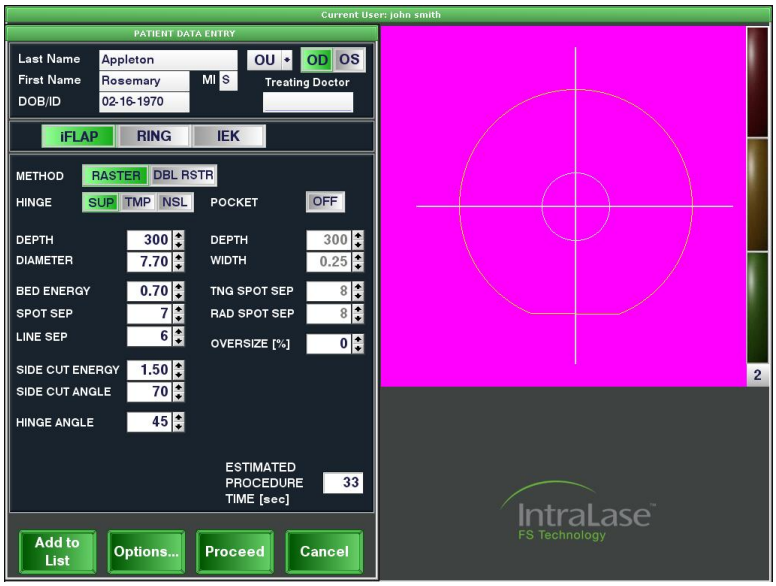


Patient Data Entry Window

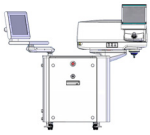
Two methods can be used to access the **Patient Data Entry** window from the **Patients** window: (1) Double-click on a patient name to edit existing patient data, or double-click on **<New Patient>** to create a new patient record; (2) Click on a patient name, and then click on the **Edit Patient** button to edit existing patient data, or click on **<New Patient>**, and then click on the **Edit Patient** button to create a new patient record.

- **Edit Patient** button is used to modify a patient's treatment parameters after selecting a patient from the patients list.
- **<New Patient>** is used to create a new patient record.

At the top of the window, the patient's last and first names, middle initial, date of birth/identification, treating doctor, patient type, and eye selection is displayed. The patient's last and first names and all eight numbers for DOB/ID fields must be filled in. Patient type (eye selection) indicates whether both eyes (OU) or only the left (OS) or right eye (OD) will be treated. OD/OS selection determines which eye's treatment parameters are currently displayed.



The section below the patient data displays the pattern type chosen (i.e., iFlap, Ring, or IEK) and the modifiable treatment parameters for the eye currently selected.



NOTE: Eye selection does not determine which eye will be treated first.

NOTE: To program an OU patient, the parameters for each eye must be explicitly modified.

- **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** provides access to the following options:

Preview Pattern (IEK only)	Provides a preview of the selected IEK pattern.
Save as User Default	Saves the currently entered parameters and will be displayed as the default parameters each time a new patient entry of that type (i.e., iFlap, Ring, or IEK) is created.
Print User Defaults	Prints the currently saved user defaults.
More Parameters (IEK only)	Displays additional parameter settings for IEK procedures (Ring Lamellar Cut, Full Lamellar Cut, Anterior Side Cut, and Posterior Side Cut).
Factory Defaults	Restores the factory defaults and overwrites the currently saved user defaults.
FAQs (IEK only)	Provides answers to frequently asked questions regarding IEK procedures.

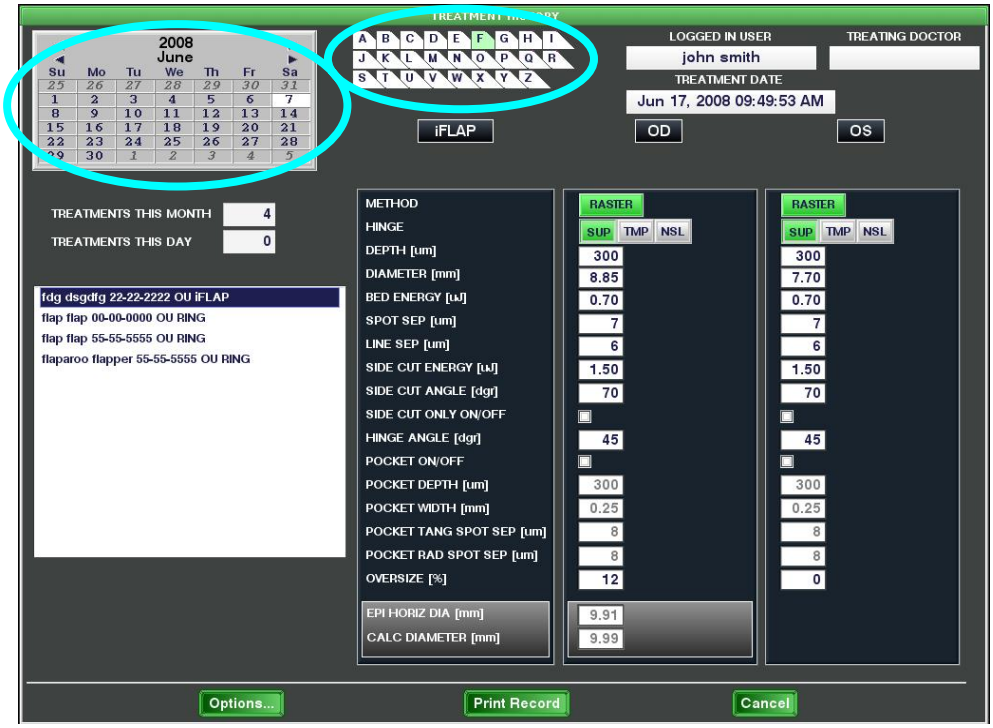
- **Accept Params** saves parameter changes.
- **Reset Params** restores the parameter values in effect for this patient when the Patient Data Entry window was opened.
- **Proceed** is displayed when all necessary patient information has been entered. Pressing the Proceed button will open the Patient Under Treatment window 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 the first letter of the patient's last name (using the keyboard displayed at the top of the screen) or treatment date (using the calendar displayed in the top-left corner of the screen).

- Click on a day from the calendar (circled in blue) to display all patients treated on the selected day (highlighted in white).
- Click on a letter from the keyboard (circled in blue) to display all patients ever treated with a last name starting with the selected letter (highlighted in light green).



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

- 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 AMO service representatives)

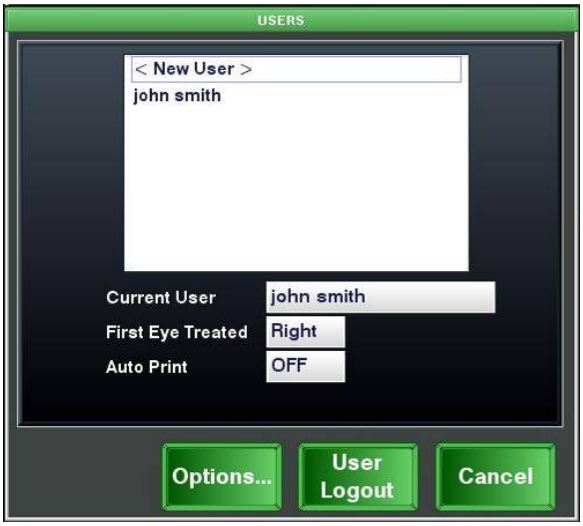
The **Print Record** button is displayed when a patient is selected.

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 AMO 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.



Create a New User

Double-click on **<New User>**. A window will appear requesting the following information:

- First name
- Last name
- Login name
- Password (entered twice)
- Passlevel (cannot be changed)
- First eye treated (OS or OD)
- Auto Print enable/disable (checkbox)
- Print Copies (1 to 5)

Edit a User

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

- Password (must be entered to save any changes)
- First eye treated
- Auto Print
- Print Copies

Delete 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

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

- Remove a user of the same or lesser Passlevel.
- 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 USB memory stick.
- View a registry of authorized users. The screen will display the Last Name, First Name, Login Name, Passlevel, Creator, and Date/Time of Creation. The **Options** button on this screen allows the user to print or backup the user registry to a USB memory stick.

User Logout

The **User Logout** 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.

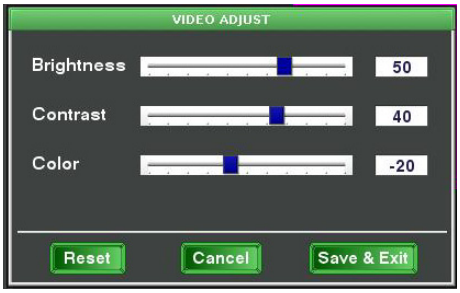
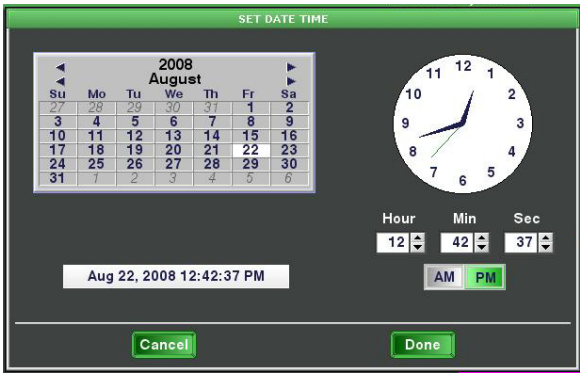
System Tools Window

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

Two system-checking routines and three user-defined settings 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. 
Microscope View Buttons on UI	Moves the Video Microscope surgical view software buttons between the User Monitor screen and the Video Microscope screen. 
Set Date/Time	Allows the user to view and/or modify the system date and time settings. 

System Status

This option opens the **System Status** window, displaying the operational status of system functions. A green light indicates an operational function, a yellow light indicates that maintenance is required, and a 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

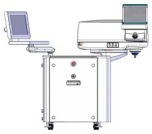
This option opens the **Laser Procedures** window, displaying the total number of procedures remaining for the User. See the Procedure Activation section in Setup for guidance on how to add Procedures.

About

This option opens the **About iFS** window, displaying the console model, serial number, current software version and current video microscope software version.

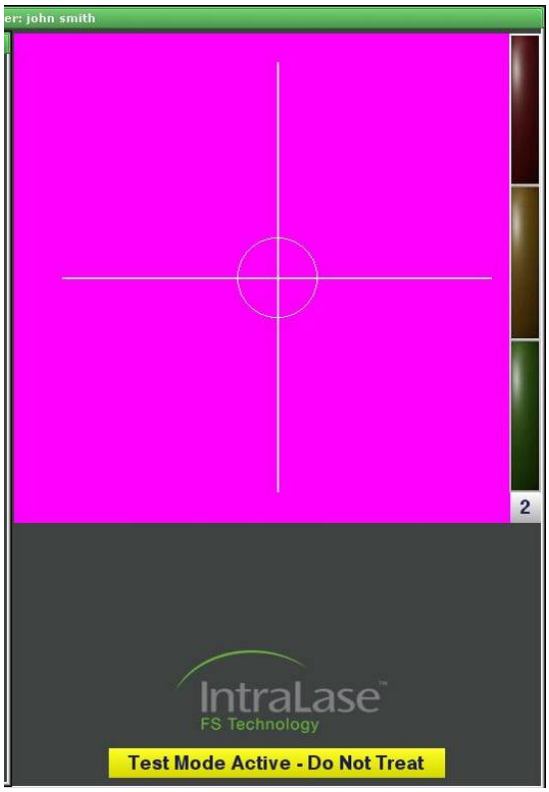
Shutdown

The Shutdown option shuts down the entire iFS Laser system. After selecting **Shutdown**, the user will be instructed to turn the key switch to the OFF position.



NOTE: See System Shutdown in Section 10 – Patient Treatment for details.

Test Procedure Mode



Test Procedure Mode provides the ability to exercise the laser mechanics and electronics without decrementing User Procedures. Test Procedure Mode does not allow laser emission to the focal plane; therefore, 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.

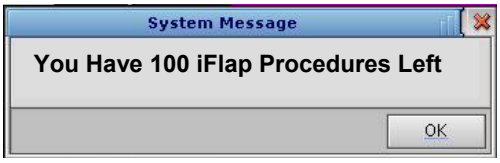
To turn on Test Procedure Mode: From the Patients window, click on **Options**, and then click on the **Test Mode Enable** toggle button**.** The toggle button text will change to **Test Mode Disable**. Clicking it again will disable the Test Procedure Mode.

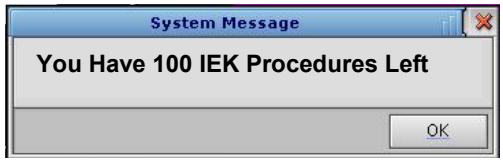
When Test Procedure Mode is active, patients cannot be added or removed and existing patients cannot be treated. A yellow banner with the text "Test Mode Active – Do Not Treat" will appear a the bottom of the screen. A test procedure is run by double-clicking on **<New Patient>** in the Patients window 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 7 – Procedure Activation

User Procedures

User Procedures (iFlap, Ring and IEK) are electronically activated in the iFS Laser. At the start of each treatment, the laser will decrement the selected procedure count by one. When the number of User Procedures remaining has dropped to 100 for any of the three types of procedures, and after every 10 additional procedures, a window will pop up to remind the user to contact AMO Global Support to activate additional procedures.





Two methods can be used 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.

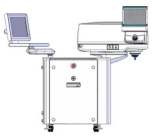
Once additional procedures are added, another window will pop up to notify the user of the amount of new Procedures that have been activated.

The following details IC and SAC procedure activation methods.

Internet Connectivity

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

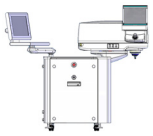
This feature requires a dedicated Internet connection to a static IP address, and requires the iFS Laser computer to be **ON**.



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 AMO Service Representatives to read and analyze critical system parameters, which can minimize the frequency and duration of down time.
Software Upgrades via Internet	Selected 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 Patient Interfaces (PIs) 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 iFS Laser, and the Internet connection is temporarily unavailable, contact AMO Global Support for assistance. An "emergency" Activation Code can be provided to ensure there are no treatment delays.

Secure Activation Code

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

Since there is no connection to the Internet, the other Internet connectivity features, including Automated Procedure Activation, are not included.

Follow these steps to order and activate procedures:

1. Place an order through the AMO 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 **Procedure** window, where two SAC entry boxes are provided (circled in blue).
4. After the SAC code is entered (twice for verification), click on 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.

Activation 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.

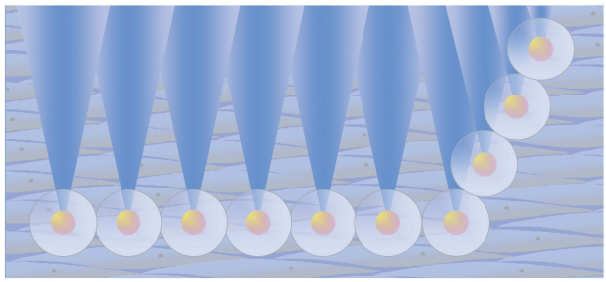
Secure Activation Code Log

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)
- Updated Total Procedure count.

Section 8 – Operational Geometry

Corneal Resection



The iFS Laser creates a resection plane using tightly focused femtosecond laser pulses to create individual micro-photodisruptions of tissue with micron-scale precision. 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 locking 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 Video Microscope visualization, the cornea is first contacted, and then applanated as the Beam Delivery Device is lowered further. After correct alignment and full corneal applanation are achieved, the locking clip on the suction ring assembly gripper levers is disengaged. The system software then prompts the user to center and initiate the treatment. Treatment is initiated by depressing the footswitch.

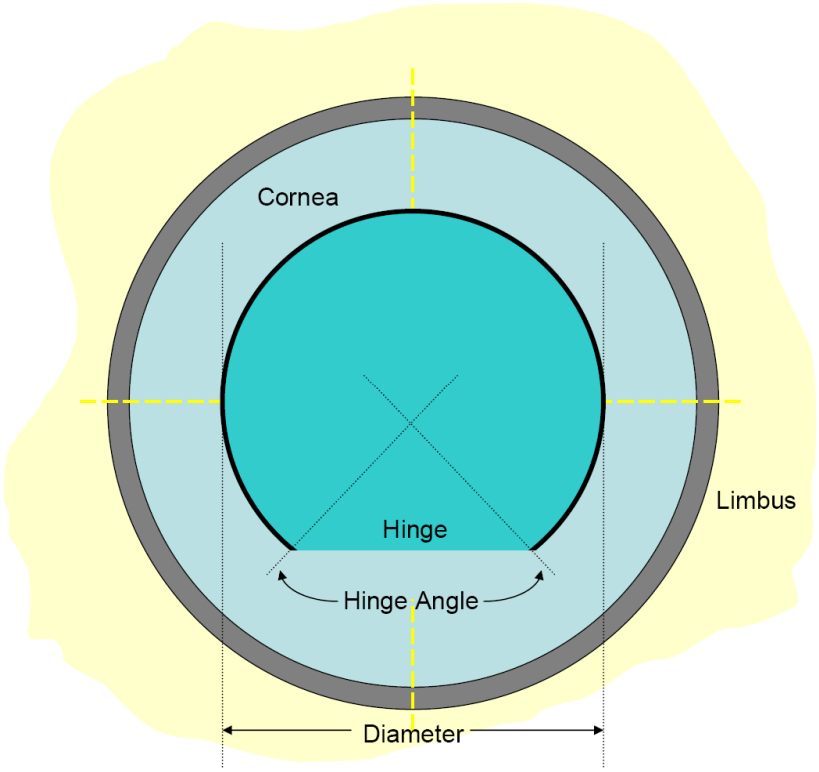
Pre-programmed patterns produce lamellar resections through a combination of user-determined and factory-set parameters. Procedures and parameters are selected using the software. Selection of a complete set of procedure parameters automatically initiates system safety checks and enables the iFS Laser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

Lamellar iFlap Procedure

Lamellar flaps are created using the iFS system software. All flaps are created as a two-part resection:

- A horizontal resection plane is created inside the cornea using a raster pattern at the user-selected flap depth
- a partial cylindrical arc cut is created, called a side cut, which is a vertical resection around the perimeter of the horizontal resection that extends from the horizontal resection plane to the corneal surface.

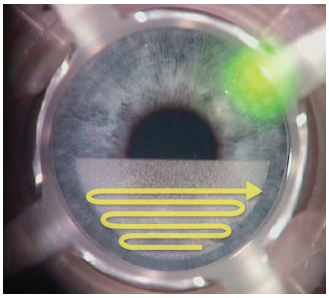
A section of the side cut is left untreated thereby leaving a flap hinge. Viewed in cross section, these two intersecting resections form a shallow disk-shaped resection. A schematic representation of a lamellar flap using software is shown in the figure below.



Schematic top view of a lamellar flap made with the iFS Laser.

Raster Scanning Patterns

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



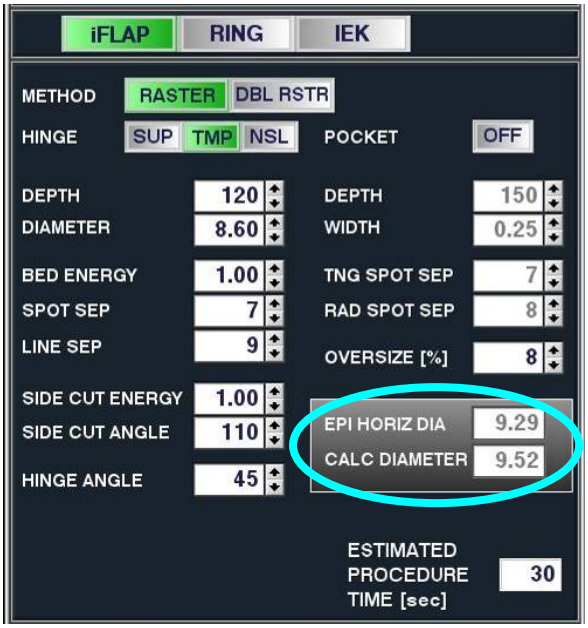
IntraLase Raster Pattern

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 or elliptical disk. After the completion of the planar-disk cut, a side cut is made beginning at the perimeter of the planar resection, extending to the anterior corneal surface.

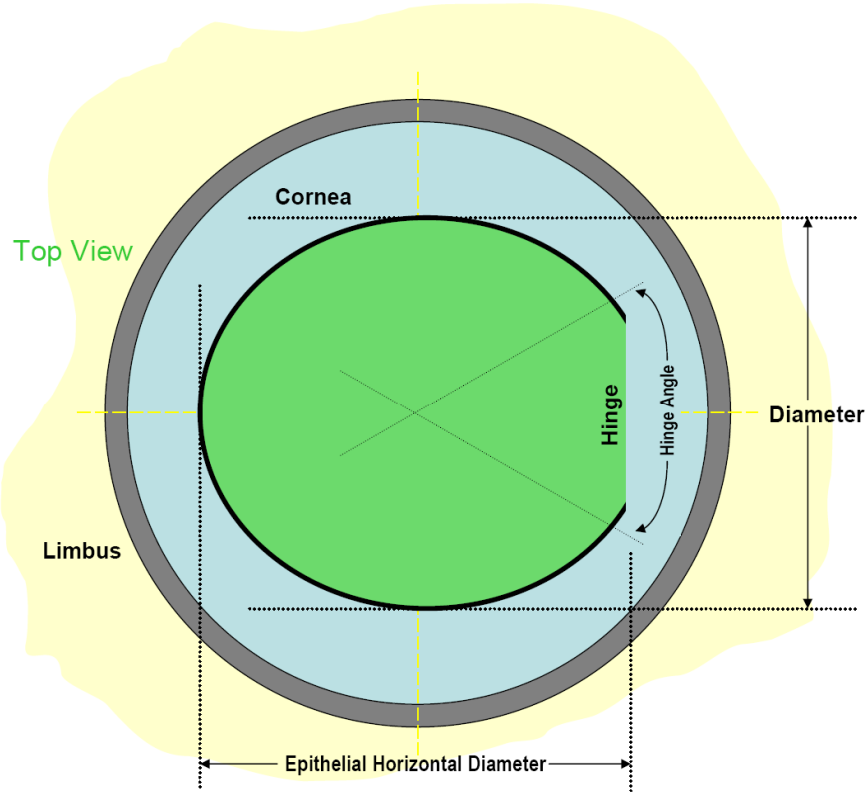
The software also allows the user to perform a double raster scanning pattern. When this option is selected, the laser is scanned across the horizontal resection plane twice in succession prior to the creation of the side cut. The programmable parameters of the second raster scan are the same as those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

iFlap Oversize Option

The iFS Laser provides the ability to set custom flap parameters that introduce ellipticity to the epithelial horizontal diameter for optimizing flap creation on eyes exhibiting significant corneal astigmatic features. The oversize option also allows for optimal hinge placement indicated by significant corneal astimagic conditions.



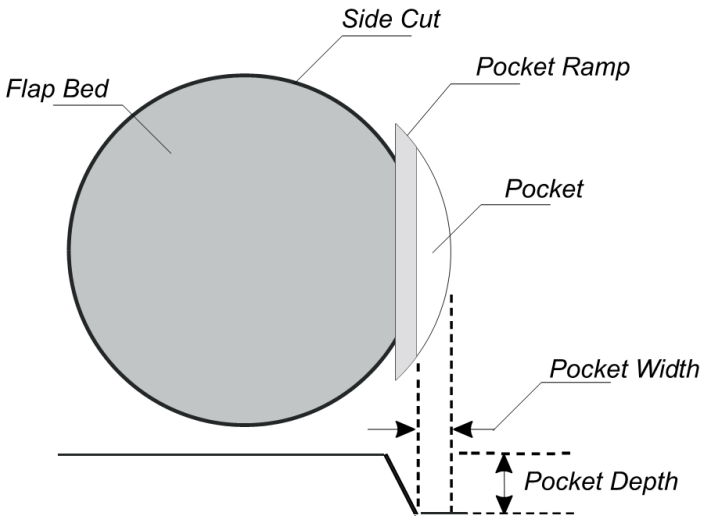
The maximum allowable diameter of a flap pattern is 9.50 mm. The preset system limits for epithelial horizontal diameter (9.50 mm), calculated diameter (10.00 mm), and posterior diameter (9.50 mm) cannot be exceeded. Modifying treatment parameters will affect these three diameter calculations. Treatment parameter settings that cause one or more of the diameter limits to be exceeded cannot be saved or used for a procedure.



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 below. 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.

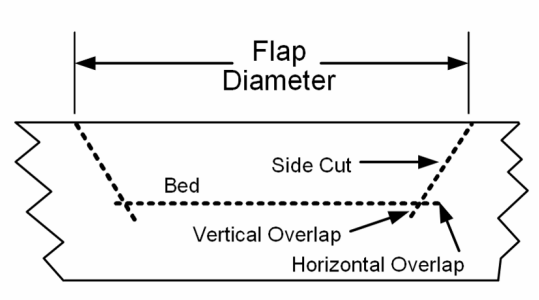


The width of the pocket ramp is dictated by the hinge angle: a smaller hinge angle results in a smaller ramp width and visa versa. When the pocket ramp is complete, the beam focus is reset to the edge of the hinge and a standard raster resection is started.

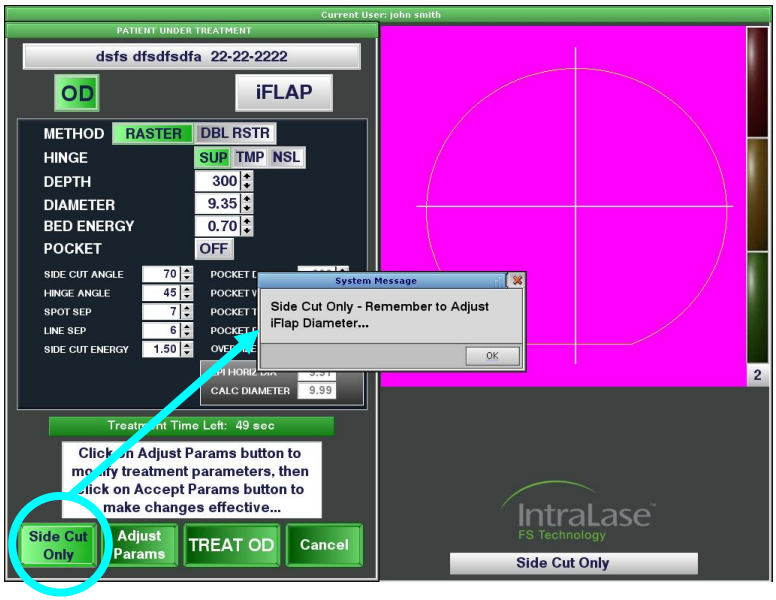
The pocket option is allowed only for flap resections using a raster pattern and must be targeted at a depth below the targeted depth of the flap pattern.

Side Cut Only Pattern

The 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, prior to selecting the **Treat** button or before **Pattern Centration** is performed.



The **Side Cut Only** button is displayed in the lower left hand corner of the **Patient Under Treatment** window. Select the button to perform the **Side Cut Only** procedure.



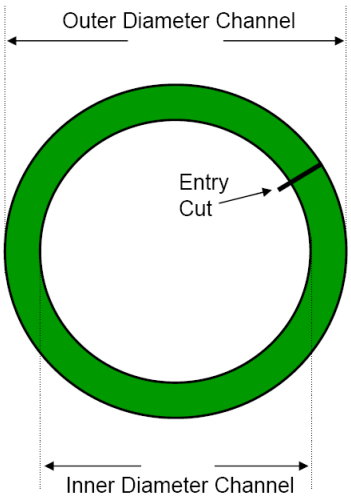
A message appears to inform the user that a **Side Cut Only** procedure will be performed and to remind the user to properly adjust the pattern diameter.

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.

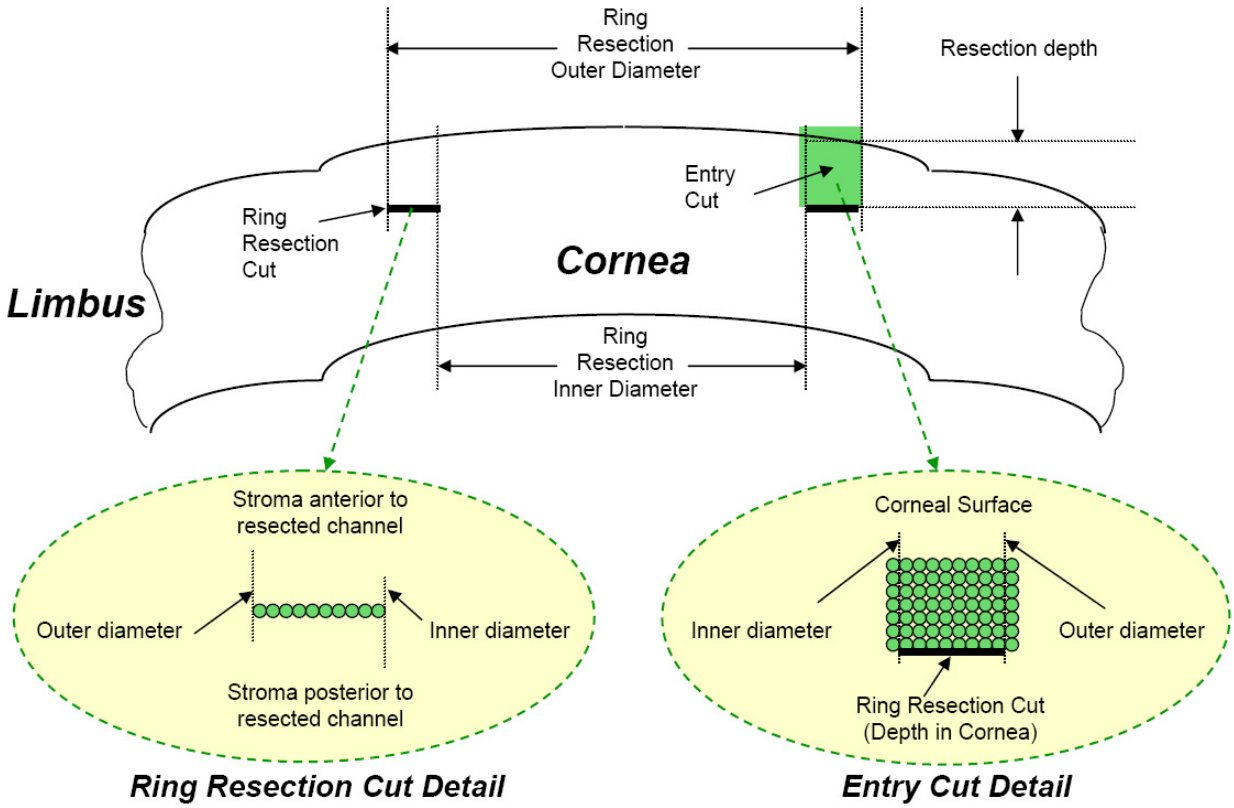
Optional Intrastromal Lamellar Ring Resection

Intrastromal channels (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 channel depth and progresses anteriorly to the corneal surface.



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

A schematic cross section of the channel resection is shown in the figure below. The viewing angle is such that the entry cut (green rectangle) is parallel to the plane of the figure.



IntraLase Enabled Keratoplasty (IEK)

WARNING: Use of this laser system allows laser surgical incisions to be created up to 1200 µm 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 IEK Application

The iFS 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 iFS Laser should only be operated by, or under the direct supervision of, a physician trained in the use of the iFS Laser.

The iFS Laser allows the physician to create a lamellar cut/resection of the cornea for lamellar keratoplasty and to create a penetrating cut/incision for penetrating keratoplasty. The IEK application allows the user to perform the following cut segments:

- Anterior Side Cut
- Posterior Side Cut
- Lamellar Cut (Full or Ring)

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.

The ability of the iFS Laser to safely and effectively perform corneal resection patterns beyond what is presented in this manual has not been fully characterized.

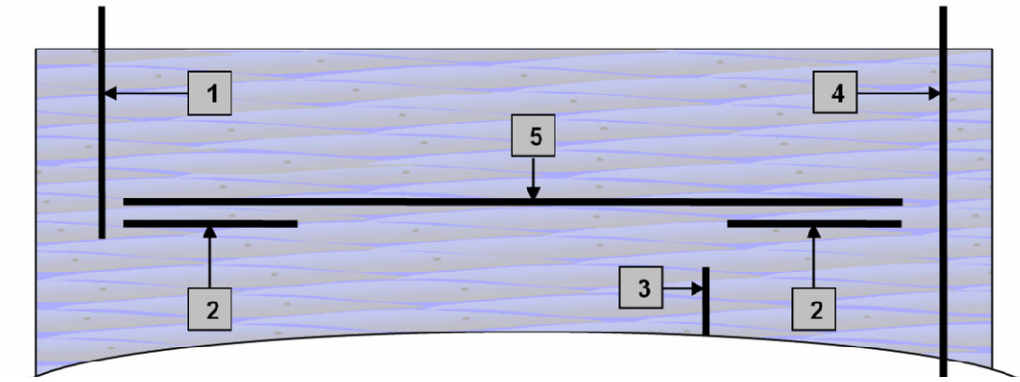


Diagram of Corneal Resections: (1) Anterior Side Cut, (2) Ring Lamellar Cut, (3) Posterior Side Cut, (4) Full Thickness Anterior Side Cut, and (5) Full Lamellar Cut.

Other Incision Patterns

Alignment Incisions and Anterior Side Cut openings using the **Cut Position** and **Cut Angle** buttons (one or two) are also available. The Alignment Incisions function creates 4, 8, 12, or 16 equally spaced, small incisions along the diameter of the Anterior Side Cut (within a 9.5 mm surgical field). The radial position of the incisions can be shifted in or out using the Radial Offset parameter. The Alignment Incision parameters can be adjusted, and the function can be toggled ON or OFF. Refer to **Section 9 – Patient Setup and Resection Parameters** for more detail.

Alignment Incisions

Anterior Side Cuts (two openings)

Energy and Spot Separation Settings

As with creating LASIK flaps, laser **Energy** and **Spot / Layer Separation** can be adjusted for optimized tissue resection. An AMO Clinical Development Specialist will provide you with an initial setting recommendation. As a rule, a higher **Energy** setting and a lower **Spot / Layer Separation** setting would result in easier tissue separation. For deeper cuts and cuts through corneas with some opacity, the **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 the **Energy** setting and/or increasing the **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 µm, the vertical overlap should be at least 40 µm.

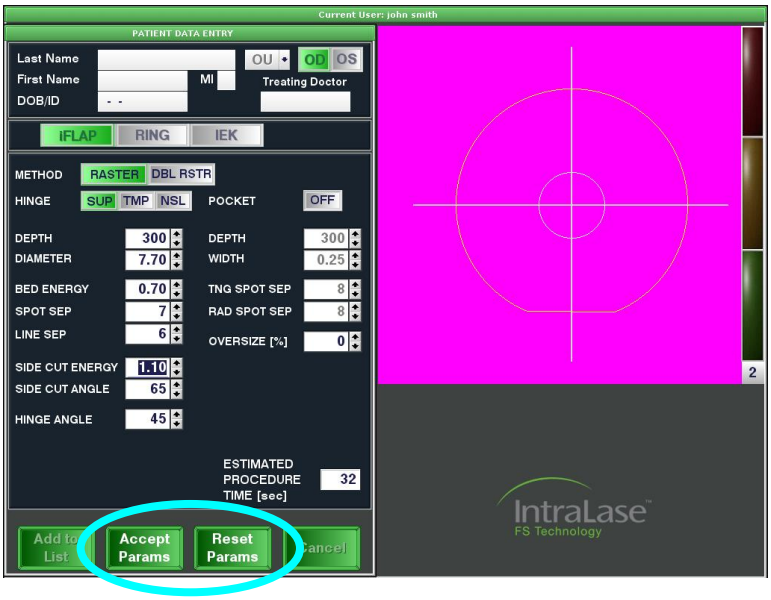
For example, if lamellar Depth is 400 µm, Posterior Depth of Anterior Side Cut should be set to 430 µm and Anterior Depth of Posterior Side Cut should be set to 370 µm. If the Inner Diameter of the Lamellar Cut is 6.9 mm, the intersecting Side Cut (either Anterior or Posterior) should be set to 7.0 mm.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

Section 9 – Patient Setup and Resection Parameters

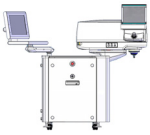
Patient Record Defaults

Individual defaults can be set up for each user. Once the defaults are set up, they are retained for the next login. 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 **iFLAP**. Enter the parameters specific for an iFLAP procedure.
4. Select **Accept Params** to save the changes.
5. Click on **Options**, and then select **Save as user default**.



6. Select **Yes** to "Are you sure you want to save new user defaults?"
7. Repeat Steps 3-7 above for the **RING** and **IEK** procedures.



NOTE: For IEK, select Options, More Parameters to access additional parameters.

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

At the top of the window, the patient's name, date of birth/ID, treating doctor, patient type, and eye selection is displayed. Entering data for this part of the screen is not required for setting user defaults.

The bottom of the window displays the modifiable treatment parameters. The relevant laser scanning parameters and ranges for iFlap, Ring and IEK resections are shown in the tables that follow.

iFlap Parameters

Parameter	Definition	Default	Range
Method	Method used to create the planar resection. The Double Raster pattern is an option that can be enabled by a Clinical Development Specialist. Note that Pocket is available only if the Raster pattern is selected.	Raster	Raster Double-Raster
Hinge Position	Location of the untreated portion of the side cut with respect to the current eye selection.*	SUP superior	SUP superior TMP temporal NSL nasal
Depth	Perpendicular distance from cornea anterior surface (flap anterior surface) to resection plane (flap posterior surface).	120 µm	90 - 400 µm
Diameter	Largest diameter of either flap anterior surface (if side cut angle is less than 90°) or posterior surface (if side cut angle is greater than 90°).**	9.0 mm	5.0 – 9.5 mm
Bed Energy	The pulse energy used to create the planar resection.	0.70 µJ	0.30 – 2.50 µJ
Spot Separations	**Spot Separation** The separation between adjacent spots along a common line or common circle.	7 µm	2 – 7 µm
	Line Separation The separation between adjacent lines of the raster pattern.	7 µm	2 – 9 µm
Side Cut Energy	The pulse energy used to create the side cut.	0.7 µJ	0.30 – 2.50 µJ
Side Cut Angle	Angle that the cylindrical side cut makes with the corneal surface (90° is perpendicular to the corneal anterior surface).	70°	30 - 150°
Hinge Angle	Angle that the uncut portion of the flap side cut arc makes related to the flap center.	45°	45 - 90°
Oversize	The percentage increase in length of the flap's major axis with respect to the flap's minor axis	0%	0 – 12%

* If a temporal or nasal hinge position is selected, the hinge is further away from the ablation center than for a circular flap. If a superior hinge position is selected, the distance from the ablation center to the hinge is no different than for a circular flap.

** If the percent oversize causes the diameter to exceed the surgical field, the system software will automatically reduce the diameter of the flap.

Pocket Parameters

Parameter	Definition	Default	Range
Pocket	Enables pocket with a raster pattern	ON	ON/OFF
Depth	Depth in cornea of the pocket. Must be greater than or equal to the iFlap Depth	180 µm	100 – 300 µm
Width	The greatest distance from the pocket ramp to the perimeter of the pocket	0.15 mm	0.10 – 0.50 mm
Tng Spot Separation	The separation between adjacent spots along a common line	4 µm	2 – 7 µm
Rad Spot Separation	The separation between adjacent lines of the raster pattern	4 µm	2 – 9 µm

Ring Parameters

Parameter	Definition	Default	Range
Depth in Cornea	Depth at which the Ring is made	500 µm	100 – 500 µm
Inner Diameter	Inner diameter of the Ring resection	6.8 mm	4.0 – 8.8 mm
Outer Diameter	Outer diameter of the Ring resection	7.6 mm	4.1 – 9.5 mm
Entry Cut Length	Length of entry cut for segments insertion	1.4 mm	1.0 – 1.5 mm
Entry Cut Thickness	Thickness of entry cut for segments insertion	1 µm	1 µm
Incision Axis	For Right Eye: 0° = nasal (180 for left eye) 90° = superior 180° = temporal (0 for left eye) 270° = inferior	90°	0 – 359°
Ring Energy	The pulse energy used to create the Ring	1.3 µJ	0.30 - 2.50 µJ
Entry Cut Energy	The pulse energy used for the entry cut	1.3 µJ	0.30 - 2.50 µJ

IEK Parameters

Ring Lamellar Cut Parameters

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

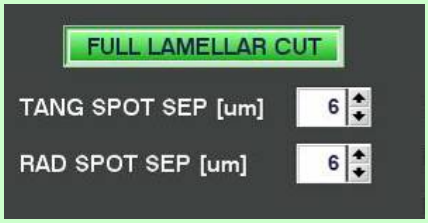
More IEK Parameters

Parameter	Definition	Default	Range
Ring Lamellar Cut (top button)	Enables or disables the lamellar cut function	ON	OFF/ON
Depth in Cornea	Perpendicular distance from the cornea anterior surface to the resection plane	400 µm	90 - 1200 µm
Outer Diameter	Outer diameter of the lamellar cut	9.1 mm	3 - 9.5 mm
Inner Diameter	Inner diameter of the lamellar cut	6.9 mm	3 - 9.5 mm
Energy (µJ)	Pulse energy used to create the planar cut	1 µJ less than posterior side cut energy	0.3 - 2.50 µJ
Spiral Start	Area at which the spiral pattern is initiated	OUT	IN/OUT
Tangential Spot Separation	Separation between adjacent spots along a common circle	4 µm	2 - 4 µm
Radial Spot Separation	Separation between adjacent circles with a common center	4 µm	2 - 4 µm

Full Lamellar Cut Parameters

The full lamellar cut is a planar cut parallel to the anterior corneal surface.

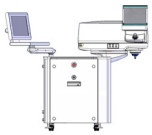
More IEK Parameters



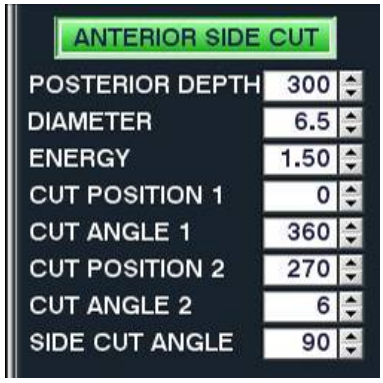
Parameter	Definition	Default	Range
Full Lamellar Cut (top button)	Enables or disables the full lamellar cut function	OFF	OFF/ON
Lamellar Depth	Perpendicular distance from the cornea anterior surface to the resection plane (replaces flap thickness)	380 µm	90 - 1200 µm
Diameter	Diameter of the lamellar cut	9 mm	7 - 9.5 mm
Energy (µJ)	The pulse energy used to create the planar cut	1.5 µJ	0.3 - 2.50 µJ
Method	The pattern of the Full Lamellar Cut	Raster	Raster Only
Tangential Spot Separation	Separation between adjacent spots along a common circle (not available for Full Lamellar Cut)	5 µm	2 – 6 µm
Radial Spot Separation	Separation between adjacent circles with a common center (not available for Full Lamellar Cut)	5 µm	2 – 6 µm

Anterior Side Cut Parameters

The anterior side cut is a cylindrical or arcuate cut from the stroma, anteriorly, proceeding 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, assuring 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 µm, this would create an Anterior Side Cut that ends 200 µm below the epithelial surface.



More IEK Parameters

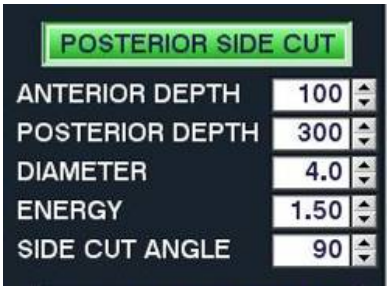
Parameter	Definition	Default	Range
Anterior Side Cut (top button)	Enables or disables the anterior side cut function	ON	OFF/ON
Posterior Depth	Start depth of the anterior side cut	430 µm	90 - 1200 µm
Diameter	Diameter of the anterior side cut (measured at the surface of the cornea)	7 mm	3 – 9.5 mm
Energy	The pulse energy used to create the anterior side cut	0.5 µJ less than max energy	0.3 - 2.50 µJ
Cut Position 1	Center point location of the cut (default 0°)	0°	0° - 359°
***Cut Angle 1**	Angled 'length' of the side cut (default 360°)	360°	0° - 360°
Cut Position 2	Center point location of the 2nd cut (default 180°)	180°	0° - 359°
***Cut Angle 2**	Angled 'length' of the 2nd side cut (default 0°)	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)	90°	30° - 150°

Parameter	Definition	Default	Range
Spot Separation	Distance between each laser pulse during the side cut procedure	3 µm	1 - 4 µm
Layer Separation	Distance between each side cut layer	3 µm	1 - 6 µm
Depth in Glass	End depth of the anterior side cut	50 µm	-200 - 100 µm

***** Zero is used to turn off the setting. Typical setting is 10° - 360°.

Posterior Side Cut Parameters

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

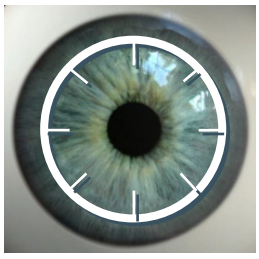


More IEK Parameters

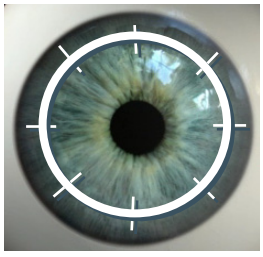
Parameter	Definition	Default	Range
Posterior Side Cut (top button)	Enables or disables the posterior side cut function	ON	OFF/ON
Anterior Depth	End depth of the posterior side cut	370 µm	90 - 1200 µm
Posterior Depth	Start depth of the posterior side cut	500 µm	90 - 1200 µm
Diameter	Diameter of the posterior side cut (measured at anterior depth)	9 mm	3 - 9.5 mm
Energy	The pulse energy used to create the posterior side cut	0.2 µJ lower than max energy	0.3 - 2.50 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)	90°	30° - 150°
Spot Separation	Distance between each laser pulse during the posterior side cut procedure	3 µm	1 - 4 µm
Layer Separation	Distance between each side cut layer	2 µm	1 - 6 µm

Alignment Incisions

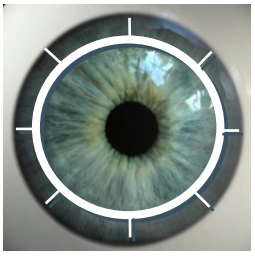
The alignment incision function creates 4, 8, 12, or 16 equally spaced, small incisions along the circumference of the Anterior Side Cut (within a 9.5 mm surgical field). The radial position can be shifted in or out using the **Radial Offset** parameter. The Alignment Incisions parameters can be adjusted, and the function can be toggled ON or OFF using the **Alignment Incisions** button in the **Patient Data Entry** window.



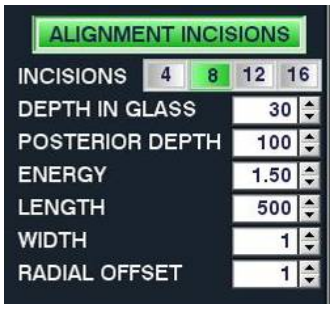
Alignment incisions shifted inwards (radial offset = -2)



Alignment incisions centered along diameter of ASC (radial offset = 0)



Alignment incisions shifted outwards (radial offset = +2)



Parameter	Definition	Default	Range
Alignment Incisions	Enables or disables the Alignment Incisions function	OFF	OFF/ON
Incisions	Number of alignment incisions	8	4, 8, 12, or 16
Energy	The pulse energy used to create the alignment incision	0.5 µJ less than lamellar energy	0.3 – 2.50 µJ
Depth in Glass	End depth of the alignment incision	20 µm	-99 – 100 µm
Posterior Depth	Start depth of the alignment incision	100 µm	0 – 100 µm
Length	Length of each alignment incision	800 µm	500 – 2000 µm
Width	The thickness of each alignment incision	10 µm	1 – 50 µm
Spot Separation	Distance between each laser pulse along a common line	2 µm	1 – 2 µm
Line Separation	Distance between adjacent lines along the alignment incision	1 µm	1 – 6 µm
Layer Separation	Distance between each layer along the alignment incision	3 µm	1 – 6 µm
Radial Offset	Distribution of the alignment incision in reference to the anterior side cut	0	* -2 to +2

* -2 = approximately 100% inside the Anterior Side Cut (ASC), -1 = approximately 75% inside the ASC, 0 = approximately 50% inside the ASC, 1 = approximately 25% inside the ASC, and 2 = approximately 0% inside the ASC.

Section 10 – Patient Treatment

Overview

Proper operation of the iFS 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 iFS Laser may produce poor or otherwise unacceptable resections, or may result in complications.

Laser Power Up

When power to the iFS Laser is switched on, the operating system access Login screen is displayed. Type the word "laser" (lowercase) as the login name, and then press Enter. Type the word "laser" (lowercase) again for the password, and then press Enter.

After successful entry, the 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 including three pop-up windows displaying the remaining number of iFlap, Ring and IEK procedures. Click on **OK** to continue.

Energy Wheel Initialization

Laser beam energy attenuation is achieved by positioning an energy wheel. The iFS 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 iFS Laser is being used.

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

Operative Precautions

The Nominal Ocular Hazard Distance (NOHD) for the iFS Laser is limited to 42 cm for the 150 kHz laser. The optical threshold for retinal damage is substantially higher than the intensity output of the iFS 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 iFS 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 iFS Laser.

WARNING: The operator should halt any procedure if either the Video Microscope or the User Monitor interface display fails.

WARNING: If an articulating chair is used in conjunction with the iFS Laser system, take proper precautions to avoid any unintended movement of the chair toward the laser system. Refer to the specific operating instructions provided by the manufacturer of the articulating chair.

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 iFS 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.

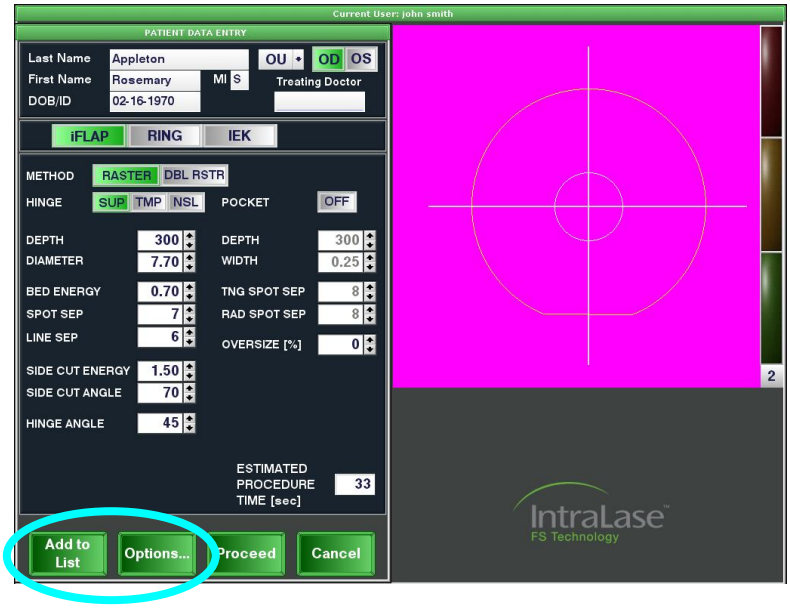
Patient Selection – Patient Data Entry Window

Adding a New Patient

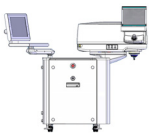
1. From the main window, click on the **Patients** button.
2. Double-click on **<new patient>** to open a new patient data entry window.
3. Enter the following information for each new patient. All data fields are required, except the patient's middle initial and the treating doctor's name, before the new patient can be added to the patient list.
   - Patient's last name
   - Patient's first name
   - Patient's middle initial (optional field)
   - Patient's date of birth/identification number (DOB/ID)
   - Patient type (OU, OD, OS)
   - Treating doctor's name (optional field)

Patient type (eye selection) indicates whether both eyes (OU) or only the left (OS) or right eye (OD) will be treated. OD/OS selection determines which eye's treatment parameters are currently displayed.

When OU (both eyes) is selected, the 'first eye treated' (OD or OS) will automatically correspond to the treating doctor's previously saved user preferences.



The middle portion of the window displays the pattern type chosen (i.e., iFlap, Ring, or IEK) and the associated modifiable treatment parameters for the currently selected eye.



NOTE: Eye selection does not determine which eye will be treated first.

NOTE: To program an OU patient, the parameters for each eye must be explicitly modified.

4. After all required data fields are populated and the desired surgical parameters are selected, click the **Add to List** button to save the patient information and add the patient to the patient list.
5. Click on **Proceed** to begin the treatment sequence, or click on Cancel to return to the Patients window.

Options provides access to the following options:

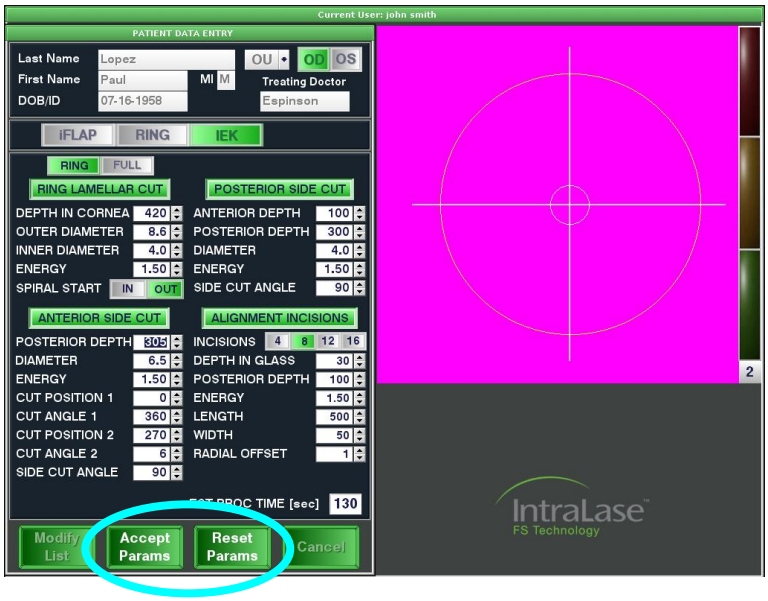
Preview Pattern (IEK only)	Provides a preview of the selected IEK pattern.
Save as User Default	The currently entered parameters will be saved and displayed by default each time a new patient entry is created.
Print User Defaults	Prints the currently saved user defaults.
More Parameters (IEK only)	Displays additional parameter settings for IEK procedures (Ring Lamellar Cut, Full Lamellar Cut, Anterior Side Cut, and Posterior Side Cut).
Factory Defaults	Restores the factory defaults and overwrites the currently saved user defaults.
FAQs (IEK only)	Provides answers to frequently asked questions regarding IEK procedures.

- **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. Clicking this button will initiate patient treatment with the currently entered patient parameters.
- **Cancel** returns to the **Patients** window.

WARNING: Check all treatment parameters for accuracy.

Editing an Existing Patient

1. From the main window, click on the **Patients** button.
2. Click on the desired patient name, and then click on the **Edit Patient** button. The **Patient Data Entry** window will be displayed.
3. Update the treatment parameters as needed, and then click on **Accept Params** to save the changes. To reset the treatment parameter values in effect for this patient when the Patent Data Entry window was opened, click on **Reset Params**.



4. After the desired surgical parameters are selected, click the **Modify List** button to save the patient information.
5. Click on **Proceed** to begin the treatment sequence, or click on **Cancel** to return to the **Patients** window.

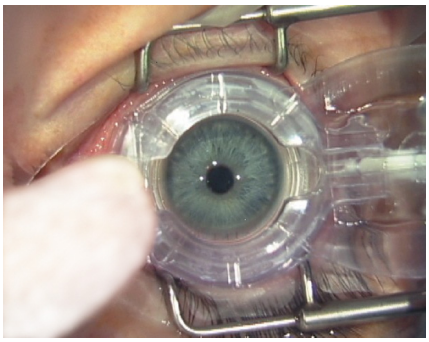
Applanation Procedure

Preparation of the IntraLase Patient Interface is described in **Section 5 – Patient Interface**. Verify the following before proceeding:

- The Applanation Cone is properly installed on the Loading Deck of the Beam Delivery Device.
- The Actuator Syringe tubing is properly connected to the Suction Ring Assembly.
- The Suction Ring Assembly locking clip properly engages/disengages.

Applying the Suction Ring Assembly

1. Fully depress and hold the syringe plunger, and then place the limbal suction ring onto the cornea, centering it over the pupil.
2. While applying a slight downward pressure on the suction ring, release the plunger and allow the suction ring to firmly affix to the eye. The suction ring will attach to the limbus using the low suction applied through the syringe.



Positioning the Applanation Cone into the Suction Ring Cylinder

1. With the eye fixated, center the Beam Delivery Device over the suction ring assembly opening using the X and Y joystick controls located below the Video Microscope. As the Beam Delivery Device is lowered into position, the applanation indicators (circled in blue) will illuminate on the Video Microscope and the User Monitor screen to indicate applanation status.

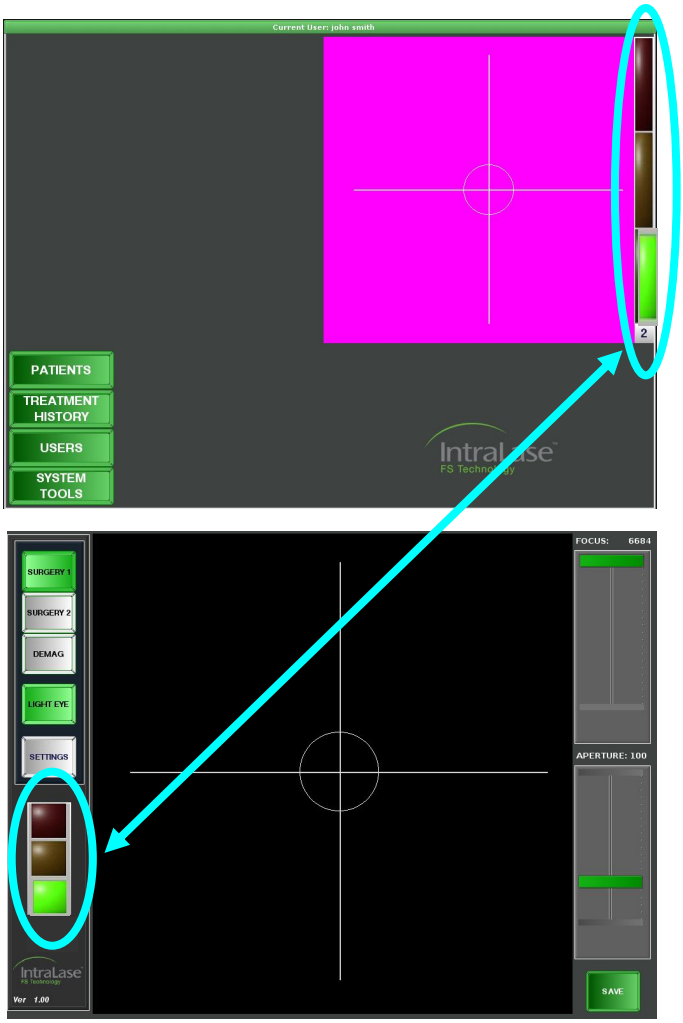
Indicator	Applanation Status
Green	Indicates initial contact of the applanation cone with the patient's cornea
Yellow	Indicates increased applanation pressure after initial contact
Red	Indicates maximum allowed applanation pressure

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 applanation cone contact surface and the cornea is made, the **green** applanation indicator will illuminate (see graphic at right). With increased applanation pressure, the **yellow** applanation indicator will illuminate.

3. When the cornea is fully applanated and the applanation cone is well centered in the suction ring assembly, gently squeeze the levers to disengage the locking clip. The suction ring assembly is then released to grip the applanation cone.

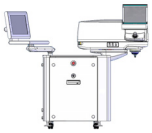
   The **red** applanation indicator will illuminate at a preset distance corresponding to the maximum allowed applanation pressure.



Adjusting Treatment Parameters – Patient Under Treatment Window

1. Click on the **Proceed** button to open the **Patient Under Treatment** window. The left side of the window displays the patient data and selected treatment parameters. The right side of the window displays the video image.

   Treatment parameters may be adjusted directly in this window by clicking on the **Adjust Params** button, modifying the values, and then pressing the **Accept Params** button to save the changes. The estimated laser treatment time is updated accordingly.



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

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

2. Press **Cancel** to return to the **Patient** window, or press the **Treat** button to initiate the next phase of treatment for the indicated eye.

iFLAP Oversize Considerations

The maximum allowable diameter of a flap pattern is 9.50 mm. The preset system limits for epithelial horizontal diameter (9.50 mm), calculated diameter (10.00 mm), and posterior diameter (9.50 mm) cannot be exceeded. Modifying treatment parameters will affect these three diameter calculations. Exceeding any one of these three system limits will generate the message, "*Diameter decreased to X.XX mm. Do you want to accept?*". Click on **Yes** to accept the new diameter (no other parameters will be affected), or click on **No** and then modify the desired parameters until the epithelial horizontal diameter, calculated diameter, and/or posterior diameter are within range. Treatment parameter settings that cause one or more of the diameter limits to be exceeded cannot be saved or used for a procedure. Consider the following when modifying treatment parameters:

The Calculated Diamter is the maximum width created on the horizontal axis of the ellipse. The following treatment parameters affect the calculated diameter:

- Diameter
- Depth
- Oversize percentage
- Horizontal overlap (not modifiable)
- Side cut angle
- Pocket width

The Epithelial Horizontal Diameter is the calculated diameter at the epithelial surface for the horizontal size of the ellipse based upon the desired diameter entered. The following treatment parameters affect the epithelial diameter:

- Diameter
- Oversize percentage

The Posterior Diameter is the diameter where the side cut intersects the bed. The following treatment parameters affect the posterior diameter (parameter not displayed):

- Diameter
- Depth
- Oversize percentage
- Side cut angle

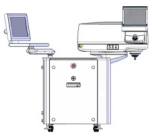
Automatic System Checks

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

Pattern Centration

The cross hairs live video image displayed on the screen is calibrated to correspond to the laser scan starting point. A keypad of arrows called the **Centration Tool** is located below the video image.

1. Use the touch pad on the keyboard or the touch-sensitive arrows on the **Centration Tool** (circled in blue), to change or adjust the pattern center.
2. Click the **OK** button on the **Centration Tool** to confirm pattern centration. After selecting **OK**, a dialog box asks the user to confirm the centration offset and treatment parameters.
3. Select **Yes** to enable the iFS Laser for the procedure, or select **No** to choose a new offset and/or to modify the treatment 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.

Procedure Initiation and Execution

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

WARNING: The operator should halt any procedure if either the Video Microscope or the User Monitor interface display fails.

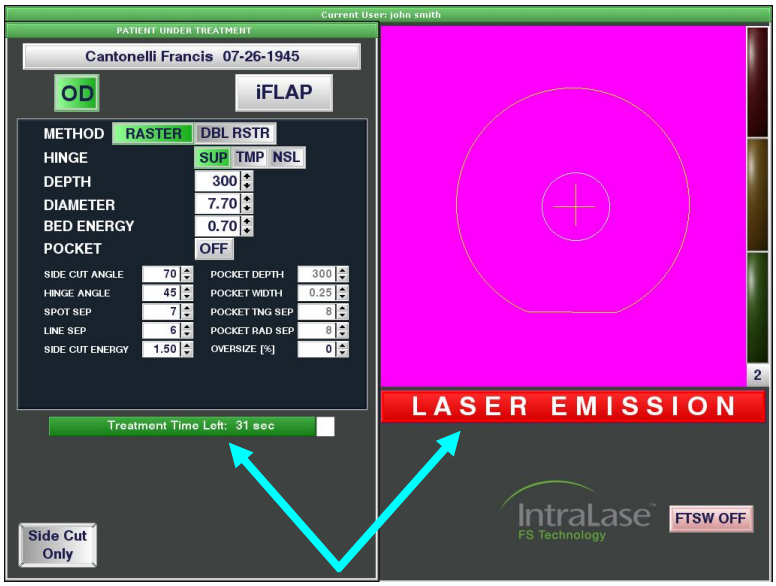
After completing the pattern centration, the iFS Laser will prompt the user when the system is ready to begin the resection procedure.

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

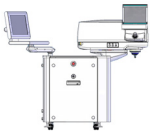
1. Press the footswitch to begin the procedure.

   Releasing the footswitch will immediately halt the procedure. Press the footswitch to resume the procedure.

   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 Video Microscope and on the User Monitor screen. As the laser is firing, a red **Laser Emission** bar appears under the live video image. The treatment progress bar will count down the remaining time until the procedure is complete.



2. When the **Procedure Complete** window appears, release the footswitch. The resection is complete.



NOTE: Do not release the footswitch until the Procedure Complete window appears.

Releasing Suction

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

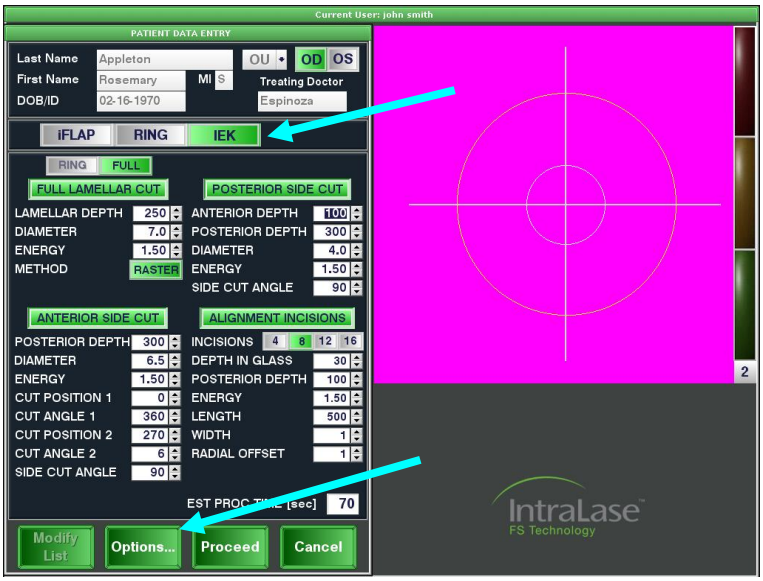
Using a new Patient Interface (applanation cone and suction ring assembly), repeat the instructions from the beginning of this section to perform the bilateral procedure. If the OU selection of the patient treatment parameters is chosen, the software will automatically display the Patient Under Treatment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

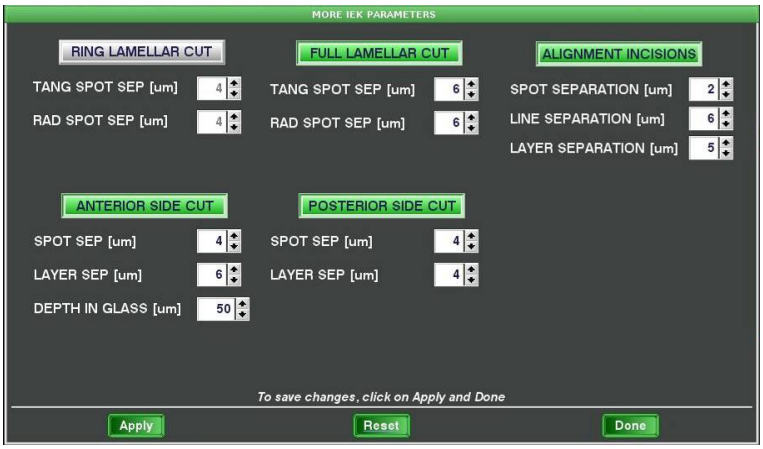
WARNING: The IntraLase Patient Interface is a single-use disposable, and when used, should be treated as medical waste. The IntraLase Patient Interface components may not be re-sterilized or stored for future use. Reuse or re-sterilization of the IntraLase Patient Interface may result in unsafe laser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

IEK Procedure

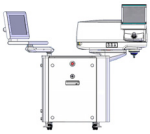
1. Measure the corneal thickness at the resection area using preferred techniques.
2. Select the IEK button (upper right button).
3. Enter patient first name, last name, and DOB/ID (8 digits must be entered before you can proceed). The Treating Doctor field can be left blank.
4. Select the Patient Type (OU, OD, OS). OD/OS selection determines which eye's treatment parameters are currently displayed.

   When OU (both eyes) is selected, the 'first eye treated' (OD or OS) will automatically correspond to the treating doctor's previously saved user preferences.





5. Program the desired parameters (refer to Section 9 – Patient Setup and Resection Parameters for parameter ranges and descriptions) to achieve the desired configuration.
6. Program the Posterior Depth of the Posterior Side Cut at least 50 µm deeper than Peripheral Corneal Thickness (PCT) for penetrating incisions.



NOTE: Cut segments can be turned OFF/ON or can be combined to create patterns for shaped IEK. Each segment has a set of associated parameters that can be set by the user.

NOTE: Eye selection does not determine which eye will be treated first.

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

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

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

7. Click on the **Proceed** button to proceed with the surgery. Refer to the Applanation Procedure described earlier in this section for docking instructions. 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 iFS laser optical system.

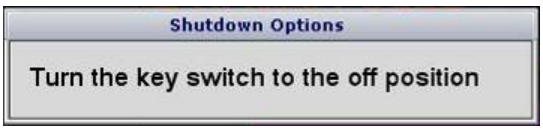
8. When the laser procedure is complete, fully depress and hold the syringe plunger to release the cornea from suction, and then simultaneously rotate the Joystick counter-clockwise to raise the Beam Delivery Device. This undocking procedure will simultaneously remove the Suction Ring Assembly and the 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.

System Shutdown

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

1. From the **Procedure** window, click on **System Tools**, and then select **Shutdown**.
2. When the message "**Turn the keyswitch to the OFF position**" appears, move the key ON Switch to the OFF position. The User Monitor and the Video Microscope will be powered down.



Section 11 – 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	150 kHz	
Laser pulse duration	600-800 fs (± 50 fs)	
Maximum laser pulse peak power	4.2 MW (± 0.8 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 32.5" (floor to applanation cone contact surface) Max 41.0" (floor to applanation cone contact surface)	
System weight	865 lbs	
Ambient operating temperature / humidity	19° C to 23° C (67° F to 73° F) / between 35% and 65% non-condensing	
Maximum pulse energy	2.5 µJ (± 0.5 µJ)	
Maximum laser beam output	400mW max (375 mW ± 25 mW)	
Input voltage and maximum current	**Line Condition**	**Maximum 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 12 – System Installation

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

LASER 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 AMO service representative will perform the following:

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

Shipping Contents

The iFS Laser system is shipped with the following components:

- Console (Chassis, Beam Delivery Device, Video Microscope, User Monitor and Keyboard)
- Footswitch
- System master keys
- Interlock connector
- UPS System

WARNING: The UPS (Uninterruptable Power Supply) is designed for exclusive use with the iFS Laser system. Do not connect any other electrical device to the UPS system.

System Requirements

The following conditions are required for proper installation and safe operation of the iFS Laser. All installation parameters should be measured and verified before beginning the installation.

Electrical

The iFS 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	7 A
100 VAC, 50 – 60 Hz	10 A
220-240 VAC, 50 – 60 Hz	4 A

Environmental

Ambient temperature in the room containing the iFS 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 13 – Service and Maintenance

Preventive Maintenance Requirements

To ensure continuous operation of the iFS Laser, preventive maintenance must be performed every three months by an AMO service representative.

Service Assistance and Replacement Parts

For service assistance and to order accessories or replacement parts, call the AMO Global Support Department at 1 (877) AMO-4-LIFE (266-4543) in the U.S. only, or contact your local AMO organization. To order online, go to www.amo-inc.com.

iFS Laser Cleaning Instructions

The outer surfaces of the iFS Laser should be kept clean and free of debris to maintain the system's overall cleanliness and appearance. Perform the system cleaning procedures only when the iFS Laser is powered off. Use only the recommended methods described in this section to clean the instrument.

Cleaning the Keyboard, User Monitor and Video Microscope Touch Screens

Use a lint-free cloth (i.e., microfiber cloth) to clean the User Monitor and Video Microscope touch screens. Never use facial tissue, paper towels, shop towels, or any other abrasive materials to clean the touch screen. Commercially available LCD screen cleaning solutions can be used if required, or a mix of one part distilled water and one part isopropyl alcohol may also be used. When using cleaning agents, the monitor should be switched off. Apply the cleaning solution to the cloth, and then gently wipe the screen using a light pressure. Do not spray the cleaning solution directly onto the screen. Disinfect the keyboard with isopropyl alcohol before the laser is powered on.

CAUTION: Never substitute isopropyl alcohol with any other alcohol (such as methanol), ammonia-based window cleaners, or acetone to clean the touch screen surface. Use of improper cleaning agents can permanently damage the screen material and/or the antiglare coating.

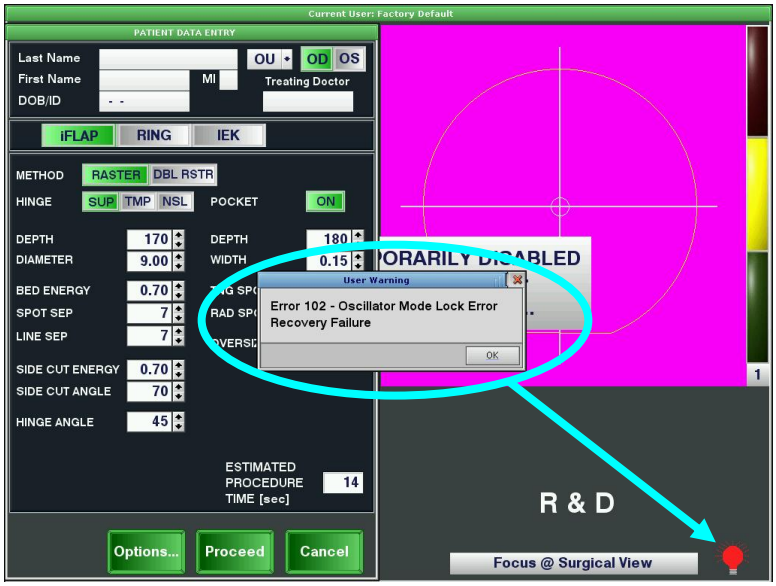
Cleaning the Outer Panels of the iFS Laser

Use only a soft, damp cloth to clean the outer panels of the iFS Laser. When needed, a small amount of a mild detergent can be used to clean the skin surface. Alcohols and ammonia-based cleaning solutions should not be used as they can damage the outer surface of the skins.

Section 14 – Troubleshooting

System Error Messages

If an error occurs, the system attempts to recover and solve the problem. A red light bulb will illuminate at the bottom right-hand area 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 continue flashing if the error condition is not resolved. Click on the red light while it is displayed to view the **System Status** window. The laser beam and other laser functions will remain disabled as long as the error condition exists.

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, and 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 AMO Global Support for further assistance.

If a re-settable error occurs and a procedure IS in progress, the procedure will stop, and an error message will appear. 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**. The system will start the procedure and display the results. If the results are not acceptable, an error message will be displayed and the red light will flash.

Troubleshooting by Symptom

The following table 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 AMO service representative be contacted for consultation.

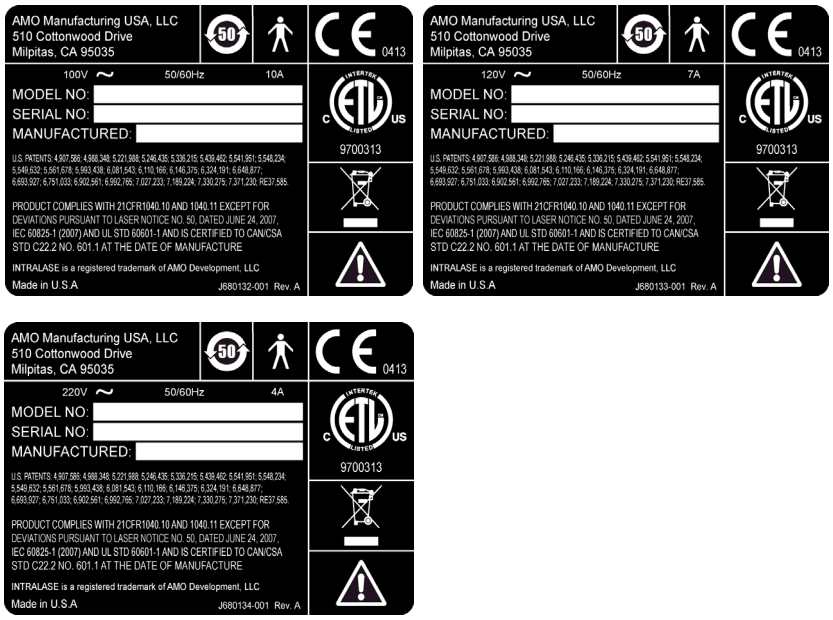
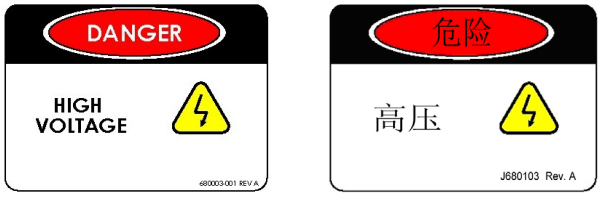
Symptom	Possible cause	Corrective action
Laser console will not energize upon power-on	Power cord disconnected	Connect cord
	Circuit breaker tripped	Reset breaker, check electrical service
	System electrical fault	Contact AMO representative
	Emergency OFF button is depressed	Reset Emergency OFF button 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 AMO 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 AMO 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 cone	Reposition Beam Delivery Device and re-applanate cornea.
	Patient movement	Immobilize patient

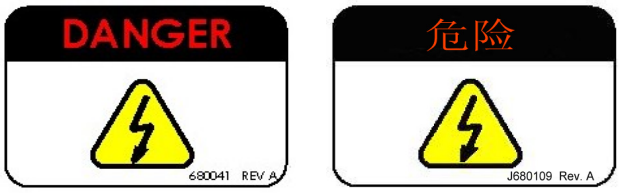
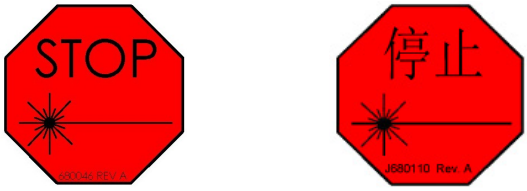
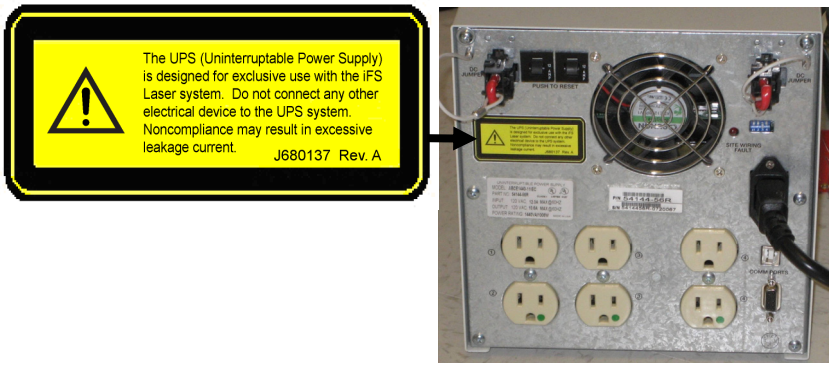
Symptom	Possible cause	Corrective action
Operating field not properly observable through video microscope	Applanation glass contaminated	Replace applanation cone
	Poor illumination	Adjust illumination control
Laser tissue effect not apparent during treatment	Applanation glass contaminated or damaged	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 AMO representative
	Laser output misaligned	Contact an AMO representative
	No laser light emitted	Contact an AMO representative
Flap thickness incorrect	Cornea not fully applanated	Fully applanate cornea
	Misaligned Beam Delivery Device	Contact an AMO 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 AMO representative
	Laser source misaligned	Contact an AMO representative
	Beam Delivery Device misaligned	Contact an AMO representative
Flap geometry incorrect	X-Y scanning unit failure	Contact an AMO representative
	Beam Delivery Device misaligned	Contact an AMO representative
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 AMO 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 AMO representative

Section 15 – Product Labels

Console Labels

Warning labels found on the iFS Laser denote specific hazards. Observe label warnings at all times. The iFS 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. The following pages contain drawings depicting label locations.

Label No.	Label	Label Name	Refer to Figure
1		Laser Aperture	2
2		Identification Label (3 options)	1
3		High Voltage	1 – 4, 6

Label No.	Label	Label Name	Refer to Figure
4		Protective Housing, Class 4	1 – 6
5		Laser Warning	2
6		High Voltage (Internal)	1, 3
7		Emergency Stop	2
8		Potential Equalization Connector	1
9		UPS Connection Warning	(refer to photo)

Label Locations

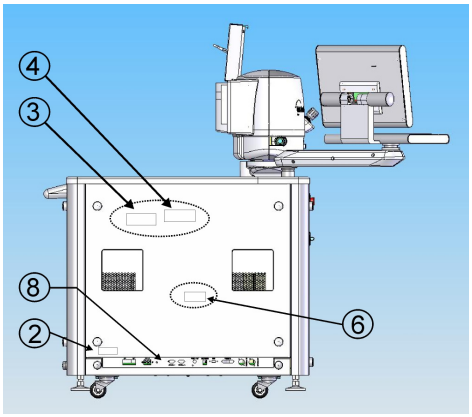


Figure 1: Label locations, left side view

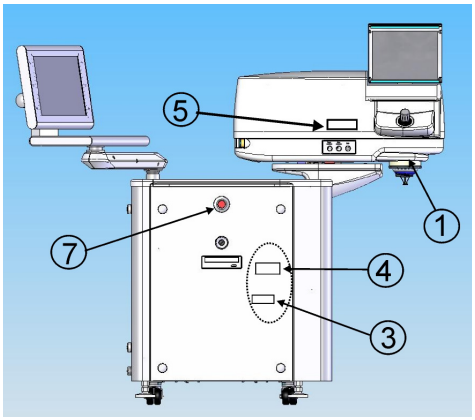


Figure 2: Label locations, front view

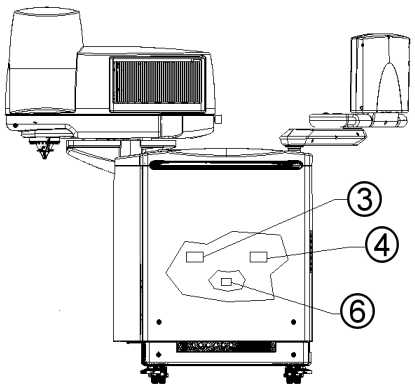


Figure 3: Label locations, back view

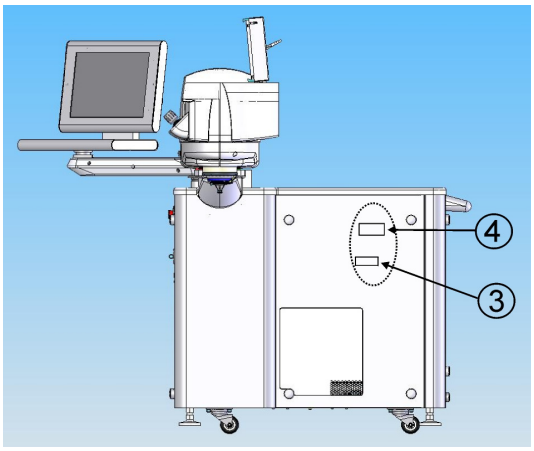


Figure 4: Label locations, right (patient) side view

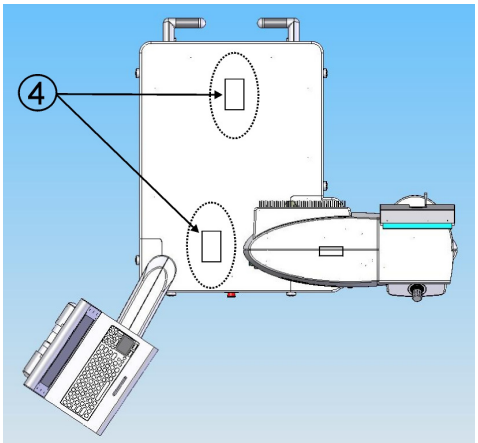


Figure 5: Label locations, top view (without covers)

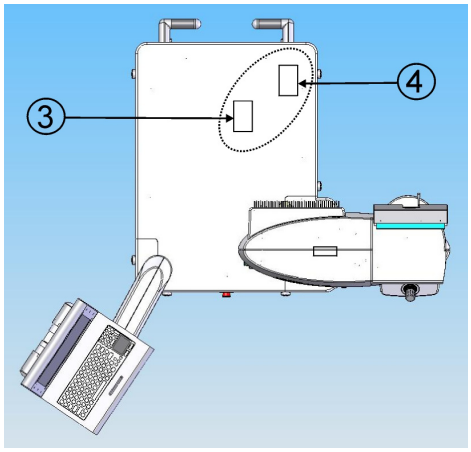
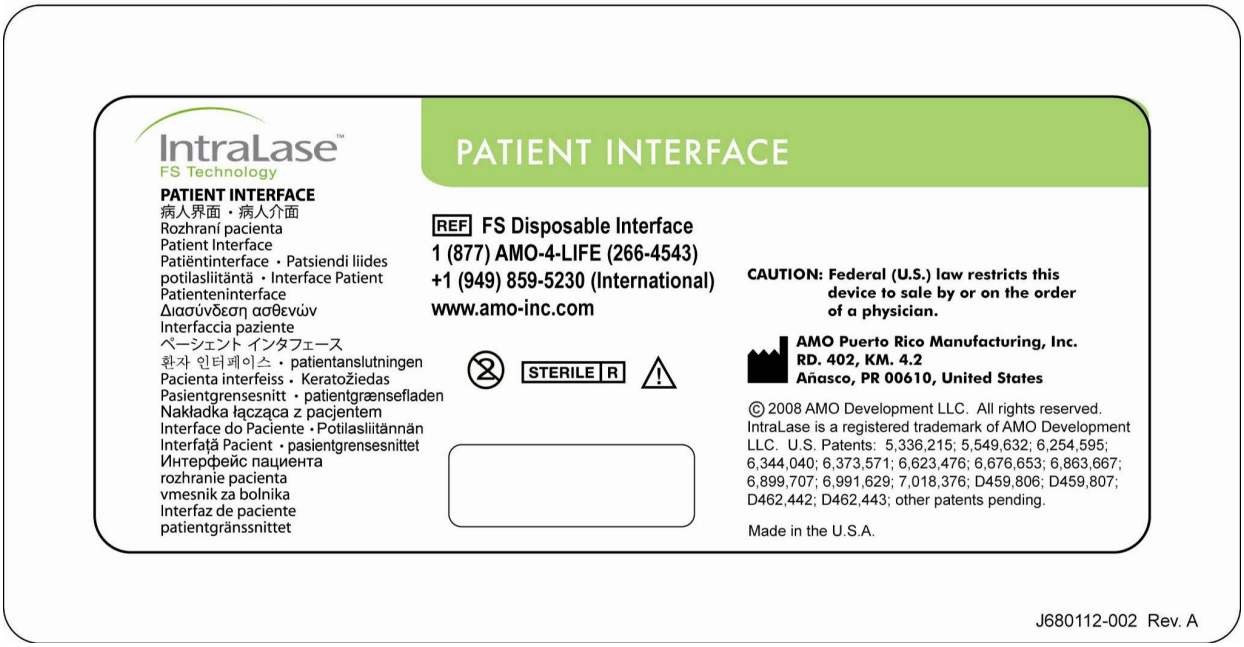


Figure 6: Label locations, top view

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 16 – Patient Interface Directions for Use

IntraLase Patient Interface™

CE 0086

Single-Use
Unilateral Procedure Pack

Contents are sterile if package is unopened and undamaged

REF 1 Procedure

STERILE R

Contents: Applanation Lens (2); Suction Ring Assembly (2); Syringe (2)

Indications: The IntraLase® Patient Interface is designed for exclusive use with the IntraLase® iFS and FS Lasers and indicated for corneal resection surgery. All components are sterile and intended for single use only. The unilateral procedure pack is intended for use on one eye.

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.

PRECAUTION

- 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 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 iFS and FS Lasers. A surgeon should have successfully completed one or more courses on the IntraLase iFS and / or the FS Lasers before attempting to create a corneal flap.
- Avoid damaging the IntraLase Patient Interface with rough instruments.
- Do not use Patient Interface if the package or any of the contents are dropped.
- Please refer to the IntraLase iFS and FS Laser Operator's Manuals for complete instructions for use of the laser and the disposable patient interface.

HOW SUPPLIED

The IntraLase Patient Interface is intended for SINGLE USE ONLY and is supplied in a sterile pack. The procedure packs are placed in a unit box with labels 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.

DIRECTIONS FOR USE

Preparation:

Step 1. Open Tray

To preserve sterility, open tray while wearing sterile, powderless surgical gloves and complete steps 1 through 6.

Position tray with IntraLase label facing up, grasp lower left corner and peel lid from left to right to remove. Discard label.

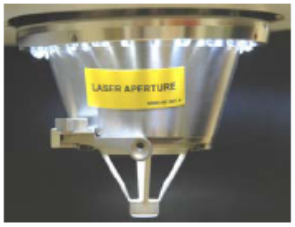
Step 2. Inspection

Remove applanation lens (cone), suction ring assembly, and syringe from tray. Place all parts onto sterile field. Inspect all parts for damage or disconnection. **Do not attempt to use any damaged product. Immediately return damaged product to AMO for replacement.**

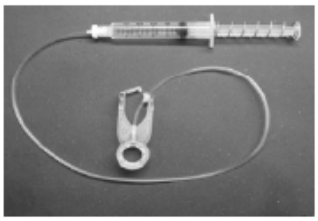
Application:

Step 3. Applanation Cone

Grasp applanation cone by the upper rim with the contact glass facing downwards. Remove the protective cap on the contact glass lens and slide the applanation cone into the loading deck guides located at the bottom of the lens aperture. To secure the applanation cone in place, move the locking arm into position. For iFS Lasers inspect the contact glass through the Video Microscope for scratches and defects prior to use. For FS Lasers inspect the contact glass through the Operating Microscope for scratches and defects prior to use. A questionable applanation cone should be returned to AMO for inspection.



Step 4. Suction Ring Assembly



The 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 actuating cylinder assembly. The suction ring attaches to the limbus by means of low suction applied with a syringe.

Suction Ring Assembly Preparation

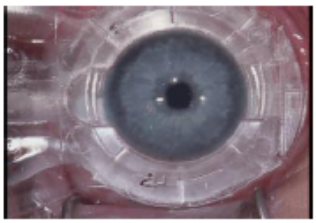
Connect and tighten the Luer-lock fitting of the syringe to the suction ring assembly. Using light pressure, squeeze the levers of the suction ring assembly and engage the clip onto the opposing lever handle. Test that the clip properly disengages the left lever handle by applying light pressure on the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

If the clip fails to disengage, or if it prematurely disengages, do not attempt use. Return the suction ring assembly to AMO for replacement.

Suction Ring Assembly Application

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

Step 5. Applanation Procedure



With the eye fixated, the laser's delivery system must then be properly centered over the suction ring assembly opening. This is accomplished by manipulation of the x and y joystick controls located on the laser's control panel. Slowly lower the delivery device using the z joystick control, gently guiding the applanation cone through the suction ring assembly. When the cornea is **FULLY** applanated gently squeeze the molded levers to disengage the clip. The suction ring assembly is then closed to grip the applanation cone. The laser treatment may now be initiated.

Step 6. Releasing the Cornea

When the "Procedure Complete" window appears on the screen, the resection is complete. **Depress and hold** the syringe plunger to release the cornea from suction. Rotate the z joystick on the control panel counter-clockwise to raise the delivery device and safely remove the patient from the surgical field. Release the cone assembly locking arm and remove the applanation cone, with suction ring assembly attached, by grasping the upper rim of the applanation cone and sliding it away from the objective lens assembly.

Important: IntraLase ® Patient Interface components may not be re-sterilized or stored for future use. Once the sterile seal on the package has been broken, unused components must be discarded.

SYMBOLOGY

The following symbols are used for the IntraLase Patient Interface and/or in the accompanying documentation.

SYMBOL	MEANING	SYMBOL	MEANING
	Caution, Read instructions prior to use	STERILE R	Sterilized by exposure to irradiation
	Each device is for one (1) use only		Expires and use by date
REF	Catalog Number	LOT	Lot Number

Manufactured by:
AMO Manufacturing USA, LLC
9701 Jeronimo Road
Irvine, California 92618
U.S.A.

European Representative:
MediTech Strategic Consultants B.V.
Maastrichterlaan 127
6291 EN Vaals
The Netherlands
Tel. 31.43.306.3320/Fax. 31.43.306.3338

For Customer Service, To Reorder
On-line: www.amo-inc.com
Call: 1 (877) AMO-4-LIFE (266-4543) / +1 (949) 859-5230 (International)

Section 17 – Appendix A

Instrument Abbreviations

BDD	Beam Delivery Device
VM	Video Microscope
PI	Patient Interface
iFlap	Custom flap parameters that introduce elliptically to the epithelial horizontal diameter of the flap resection

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.

Touch Pad
Touch-sensitive pointing device used to perform a similar function to a computer mouse.

Touch Screen
Touch-sensitive screen that allows the user to select options and change software settings by touching the software buttons displayed on the screen.

USB
Universal Serial Bus

Nominal Ocular Hazard Distance (NOHD)

The NOHD is defined according to American National Standards Institute Z136.1, "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 iFS 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 AMO service representatives should attempt to remove console covers or to service the iFS Laser.

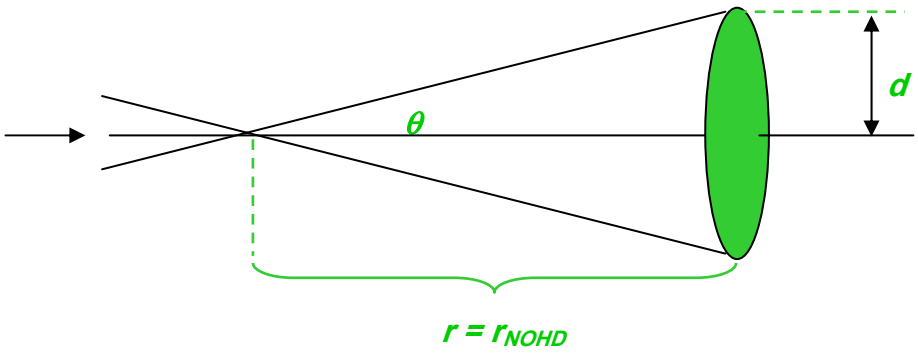
The steps required to calculate the NOHD according to Z136.1 (referred to hereafter as "the Standard") are described below. The Standard describes the calculation of *MPE* according to three rules and utilizes the prescribed *MPE* to compute the NOHD. The calculations presented here are prescribed for lasers operating at 150 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:

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

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



Geometry for calculation for possible ocular exposure

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 iFS Laser operating at:	E = 3.3 μJ and θ = 18°
The resulting NOHD using Rule 1 is:	r_{NOHD} = 7.1 cm

Rule 2: Average Power MPE for Thermal and Photochemical Hazards

According to Table 5a of the Standard, the average power, MPE_{AVG} 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 power of the laser is 375 mW ±25 mW (max 400 mW) for 150 kHz. The NOHD is computed by replacing the fluence with the *MPE* derived by the Rule and solving for *r*.

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

Using θ = 18°, the resulting NOHD using Rule 2 is:	r_{NOHD} = 15.0 cm

Rule 3: Multiple-pulse MPE for Thermal Hazards

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

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

where MPE_{SP} 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 number of pulses in an exposure is:	1.5×10^6
The resulting value for C_P is:	0.029
Using equation 6, the resulting *MPE / pulse* value is:	4.4×10^{-9} J/cm^2

The NOHD calculation for Rule 3 follows according to equation (3):	*E* = 2.5 μJ and θ = 18°
The resulting NOHD using Rule 3 is:	41.4 cm

Since Rule 3 provides the most conservative values of NOHD, the reported nominal optical hazard distance is 42 cm for the 150 kHz laser.

Declaration of Compliance

The following tables contain information for electromagnetic emissions and immunity.

Guidance and manufacturer's declaration – electromagnetic emissions		
The iFS System is intended for use in the electromagnetic environment specified below. The customer or the user of the iFS Laser should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The iFS 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 iFS 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 iFS Laser System is to be operated in conjunction with the applicable version of 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 iFS Laser System is intended for use in the electromagnetic environment specified below. The customer or the user of the iFS 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 80 MHz – 2.5 GHz 3 V/m	Range 80 MHz – 2.5 GHz 3 V/m	Electro-Magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Do not use cell phones, pagers, or radio frequency devices of any kind in the same room as the iFS 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 iFS Laser system is to be operated in conjunction with the applicable version of 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	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, Interruptions & Fluctuations IEC 61000-4-11	Dips >95% for 10 ms -60% for 1000 ms -30% for 500 ms Interruptions >95% for 5 sec Fluctuations Unom + 10% 15 min Unom – 10% 15 min	Dips >95% for 10 ms -60% for 1000 ms -30% for 500 ms 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 18 – Appendix B

Content of Toxic and Hazardous Substances or Elements

Component / Assembly	Toxic and Hazardous Substances or Elements					
	Cr6+	PBB	PBDE	Cd	Hg	Pb
Laser Oscillator	X	O	O	X	X	X
Stretcher/Compressor	X	O	O	X	X	O
Laser Amplifier	X	O	O	X	O	X
ECB Energy Control Board	X	X	X	X	O	X
Laser Diode Driver PCBA	X	X	X	X	O	X
Laser High Voltage PCBA	X	X	X	X	X	X
Laser Timer PCBAs	X	X	X	X	X	X
Galvanometer Interface PCBA	X	X	X	X	O	X
Power Supply Back Plane PCBA	X	X	X	X	X	X
Power Supply Control PCBA	X	X	X	X	X	X
System Power Supply	X	X	X	X	O	O
Heat Exchanger Assembly	X	X	X	X	X	X
System Computer Assembly	X	X	X	X	X	X
GSI Galvanometer Driver PCBA	X	X	X	X	X	X
Delivery System Electronics	X	X	X	X	X	X
Z Objective Assembly	X	X	X	X	X	X
Microscope Assembly	X	X	X	X	X	X
6X Beam Expander	X	O	O	O	O	O
Galvanometers	X	X	X	X	X	O
Shutter Two Assembly	X	X	X	X	X	X
User Interface Assembly (Monitor)	X	X	X	X	X	X
Chassis Frame and Shield	X	O	O	X	X	O
Gantry Assembly	X	O	O	X	O	X
Gantry Control PCBA	X	X	X	X	X	X
Isolation Transformer	X	O	O	X	X	X
Laser Control Back Plane PCBA	X	X	X	X	O	X
Video Splitter	X	X	X	X	X	X
Scanner Back Plane PCBA	X	X	X	X	X	X
Key Switch / Emergency Stop Button	X	X	X	X	X	X
Joystick Assembly	O	X	X	X	X	O
Foot Switch Assembly	O	O	O	O	O	O
Uninterruptable Power Supply (UPS)	X	X	X	X	X	X
Printer	X	X	X	O	O	X

O = Toxic or hazardous substance contained in all homogenous materials for this part is below SJ/T11363-2006 limit requirement.
X = Toxic or hazardous substance contained in all homogenous materials for this part is above SJ/T11363-2006 limit requirement.

Section 19 – Warranty Information

AMO warrants that the iFS Laser and IntraLase Patient Interface, docking interface devices and accessories (collectively, the "Equipment") and software will conform to the published product specifications of AMO and be free from material defects in materials and workmanship and will clinically perform to AMO 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 AMO warrants are equivalent to new components.

AMO will repair, or replace at no charge, any Equipment or Software found upon examination by AMO 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 AMO; (c) repair and maintenance necessitated by user-induced damage, neglect, misuse, or improper operation of the Equipment, Software or device; (d) modification of AMO Equipment, Software and devices without the express written authorization of AMO; (e) supplies, devices or electrical work external to the AMO Equipment; (f) use of docking interface devices and accessories other than those manufactured and distributed by AMO; (g) use of the docking interface devices and accessories that contravene the user instructions provided by AMO; (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 AMO service representatives; and (j) use of the Equipment and Software for uses for which they are not intended.

AMO 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 AMO Equipment, or unauthorized modification of AMO Equipment or Software. Warranty does not extend to any Equipment or Software not provided by AMO.

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, AMO DOES NOT WARRANT THAT THE OPERATION OF THE SOFTWARE SHALL BE UNINTERRUPTED OR ERROR FREE. IN NO EVENT WILL AMO 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 AMO HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.