Lumenis, Inc.®
Digital Duet™

Ophthalmic Laser System
Operator Manual

Lumenis®
Energy to Healthcare

Manufactured by:
Lumenis, Inc.

Lumenis®

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EC REP

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Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)

In accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), any item which is marked with the crossed-out wheelie bin symbol must not be disposed of as unsorted municipal waste, but segregated from other waste types for eventual treatment and recovery at an approved recycling facility.

By returning waste electrical and electronic equipment via the correct segregated disposal channel, users can ensure the environmentally sound treatment and disposal of the waste equipment, thereby reducing the potential for any environmental or health risks that could arise as a result of incorrect disposal.

Lumenis provides web-based collection, recycling and reporting arrangements to the business end-user for equipment marked with the crossed-out wheelie bin.

Visit http://www.lumenis.com/Service-Support/Recycle to understand what arrangements Lumenis has made in each EU Member State.

Use of this manual:

The Digital Duet system is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of the proper operation of the system.

This manual has been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual and gaining a clear understanding of the operation of the system. If any part of this manual is not clear, contact your Lumenis representative for clarification.

This manual should always accompany the system, and its location must be known to all personnel operating the system. Additional copies of this manual areavailable from your Lumenis distributor.

System and accessory specifications subject to change without notice.

For further information about Lumenis, visit the Lumenis Website:
http://www.lumenis.com

Contents

1. Safety and Regulatory

1.1. Introduction

The Digital Duet ophthalmic laser systems are classified as Class IIIb lasers by the Center for Devices and Radiological Health of the Food andDrug Administration and as Class 3B by the International Standard
IEC 60825/ EN 60825-1.

Users must take precautions to prevent exposure of laser energy to the eyesand skin from either direct or diffusely reflected laser beams, except as a therapeutic application. Additional precautions must be taken to prevent fire, electrical injury, and explosion.

Lumenis does not make recommendations regarding the practice of medicine. Laser treatment parameters are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints.

The essential performance of the Lumenis Digital Duet is to deliver the treatment parameters, and specifically the energy value, as set by the user.

See the American National Standard (ANSI) publications ANSI Z136.1 and EN 207 for recommendations on the safe use of lasers in health care facilities.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.2. Laser Safety Eyewear

Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (OD) for each of the available laser emissions and the configuration of the treatment room (usually within the controlled area). For additional information, refer to ANSI Z136.1 or International Standard IEC 60825-1.

The following formula was used to calculate the *worst case* NOHD for the Lumenis Digital Duet laser and compatible delivery systems:

$$NOHD = Z + \frac{1}{\theta}\sqrt{\frac{4}{\pi}\,\frac{\Phi}{MPE}\,Pf - a^2}$$

where,

Z = the distance of the beam waist from the laser system;

a = the beam waist diameter ($1/e^2$ of axial irradiance for gaussian beam);

θ = minimum full angle beam divergence ($1/e^2$ of axial irradiance for gaussian beam);

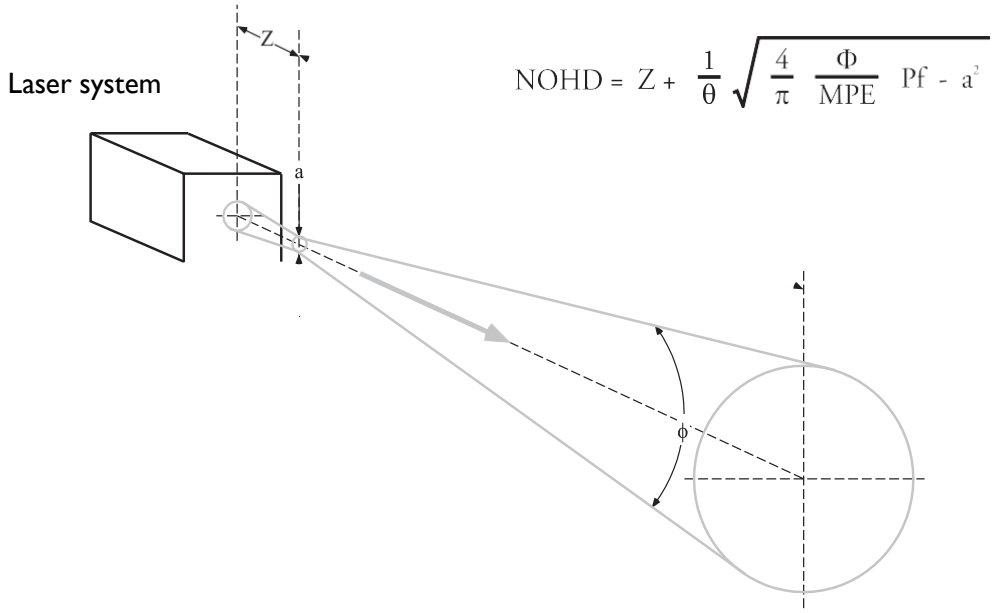
e $\approx$ 2.7182818285, the base of natural logarithms;

Φ = maximum energy of one laser pulse or maximum CW laser power;

Pf = the profile correction factor (1 for uniform profile or 2 for gaussian irradiance profile);

MPE = Maximum Permissible Exposure, in energy density units (energy per unit area), or power density units (power per unit area);

NOHD = the Nominal Ocular Hazard Distance (measured from laser aperture); the distance required to reduce the energy density or power density to the MPE.



Using this approach we derive the following values:

Laser System	θ	Φ	MPE	Pf	a	Z
Digital Duet 1064 nm laser	0.262	0.03 J	1.67 (10^{-6}) J/cm^2	2	0.0007 cm	9.3 cm
Digital Duet 532 nm laser	0.016	0.002 J	0.50 (10^{-6}) J/cm^2	2	0.004 cm	9.3 cm

which results in a *worst case* NOHD of:

Laser System	NOHD
Digital Duet 1064 nm laser	8.4 meters
Digital Duet 532 nm laser	63.0 meters

All personnel who are within the NOHD are considered to be within the controlled area and shall wear eye protection with a *minimum* optical density (OD) of:

Laser System	OD
Digital Duet	5.0

Laser safety eyewear must also be resistant to physical damage or photo-bleaching resulting from laser exposure as per ANSI Z136.1, section 4.6.2 and Appendix C. For users who must comply with EN 207, the safety eyewear must have a protection class of L5.
In addition to providing the required laser safety eyewear, take the following steps to secure the treatment room, or the controlled area:

1. To alert personnel before they enter the controlled area, place a warning sign on the outside of the treatment room door when the laser is in use.
2. Close the treatment room door during operation of the laser.
3. External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.

A blocking barrier, screen, or curtain capable of blocking or filtering the laser beam could be placed to create a controlled area inside a large treatment room. The barrier should be made of material that can withstand the power of the treatment beam for the maximum exposure time, relative to the configuration of the controlled area and the treatment parameters for the specific medical application.

1.3. Additional Ocular Protection

WARNING - Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.

WARNING - Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.

WARNING - Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.

WARNING - Never look directly into any optical lens, except for therapeutic purposes, nor any optical fiber, probe, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn OFF the laser before inspecting any delivery system or laser components.

1.4. Additional Safety Considerations

1 Electrical Hazards

WARNING - Never remove the laser protective covers. Removing the covers will expose the user to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians shall work inside the laser console.

WARNING - The area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.

2 Fire Hazard

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

3 Protecting Non-target Tissues

WARNING - Except during actual treatment, the system must always be in STANDBY mode. Keeping the system in STANDBY mode prevents accidental laser exposure if the footswitch or joystick laser activation pushbutton is inadvertently depressed.

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

WARNING - Only the person directing the laser beam should have access to the laser footswitch or joystick pushbutton. Use caution depressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch depressed is the correct one to avoid accidental laser exposure.

WARNING - To avoid accidental exposure to laser radiation, always move the patient out of the beam path before restarting the system.

WARNING - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

CAUTION - U.S. federal law restricts this device to sale by or on the order of a physician.

CAUTION - Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

1.5. Regulatory Compliance

Lumenis lasers systems comply with 21 CFR 1040.10 & 1040.11, except for deviations pursuant to Laser Notice 56, Dated May 8th, 2019, as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).
CE-labeled devices comply with all applicable standards as specified in the European Medical Device Regulation MDR 2017/745.

Additionally, the Digital Duet complies with the following standards:

- Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [AAMI ES60601-1, EN 60601-1]
- Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance [CSA C22.2#60601-1]
- Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability [IEC 60601-1-6, EN 60601-1-6]
- Medical Electrical Equipment – Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment [IEC 60601-2-22, EN 60601-2-22]
- Safety of Laser Products - Part 1: Equipment Classification And Requirements [IEC 60825-1, EN 60825-1]

In compliance with international standards for laser medical equipment, the system is equipped with the following safety features:

1 Key Lock Switch

To prevent unauthorized use, the laser can only be turned ON with the master key, the key can only be removed when the laser is turned OFF, and the laser only operates when the key is inserted into the keyswitch. When the keyswitch is turned to the start position, the laser power-up sequence is initiated.

2 Emergency-Off Switch

The laser has an emergency-off switch which immediately turns OFF the laser.

3 Laser Emission Indicator

Illumination of the laser emission indicator on the display panel provides a visible warning to the operator that after approximately 2 seconds laser radiation is accessible. The time delay is incorporated to allow appropriate action by the operator to avoid unintentional laser radiation exposure.

4 External Door Interlock

An external door interlock receptacle and plug are provided to disable the laser if the treatment room doors are opened. Refer to the Laser Safety

Eyewear section of this manual for additional information.

5 Manual Reset

If laser emission is externally interrupted during treatment by remote interlock activation, the laser will automatically go into STANDBY and the safety shutter will revert to a closed position. To resume treatment, manually reset the laser by placing the laser in READY mode. If laser emission is interrupted during treatment by main electrical power loss, the laser system will automatically turn OFF. To resume treatment after an electrical power loss, the system must be manually restarted by rotating the keyswitch to the start position. The laser will automatically go into STANDBY when electrical power is resumed. To resume treatment, manually reset the laser by placing the laser in READY mode.

6 Protective Housing

The laser has a protective housing that prevents unintended human access to laser radiation above Class I limits. The housing must only be opened by a Lumenis-certified technician.

7 Safety Interlocks

The protective housing is not designed to be removed by the user during operation or maintenance. Therefore, the laser does not have, and is not required to have, any safety interlocks within the meaning of US FDA 21 CFR, Section 1040 or International Standard IEC 60825-1. However, the protective housing cannot be easily opened without special tools.

8 Location of Controls

Operation and adjustment controls are located so that the user need not be exposed to laser radiation during laser operation or adjustment.

9 Eye Safety Filters

The slit lamp has specially designed eye safety filters which guard the operator from exposure to laser radiation. The protective filter ensures that all laser radiation returned to the operator's eyes is below the Class I limit.

10 Safety Shutter

The laser includes an electronic safety shutter that prevents unintentional laser emission. The safety shutter opens only when the user places the system in READY mode and presses the footswitch or joystick laser activation pushbutton. The safety shutter remains closed when the system is turned OFF, during self-test at system turn ON, when the system is placed in STANDBY mode, or when the safety monitor detects a fault.

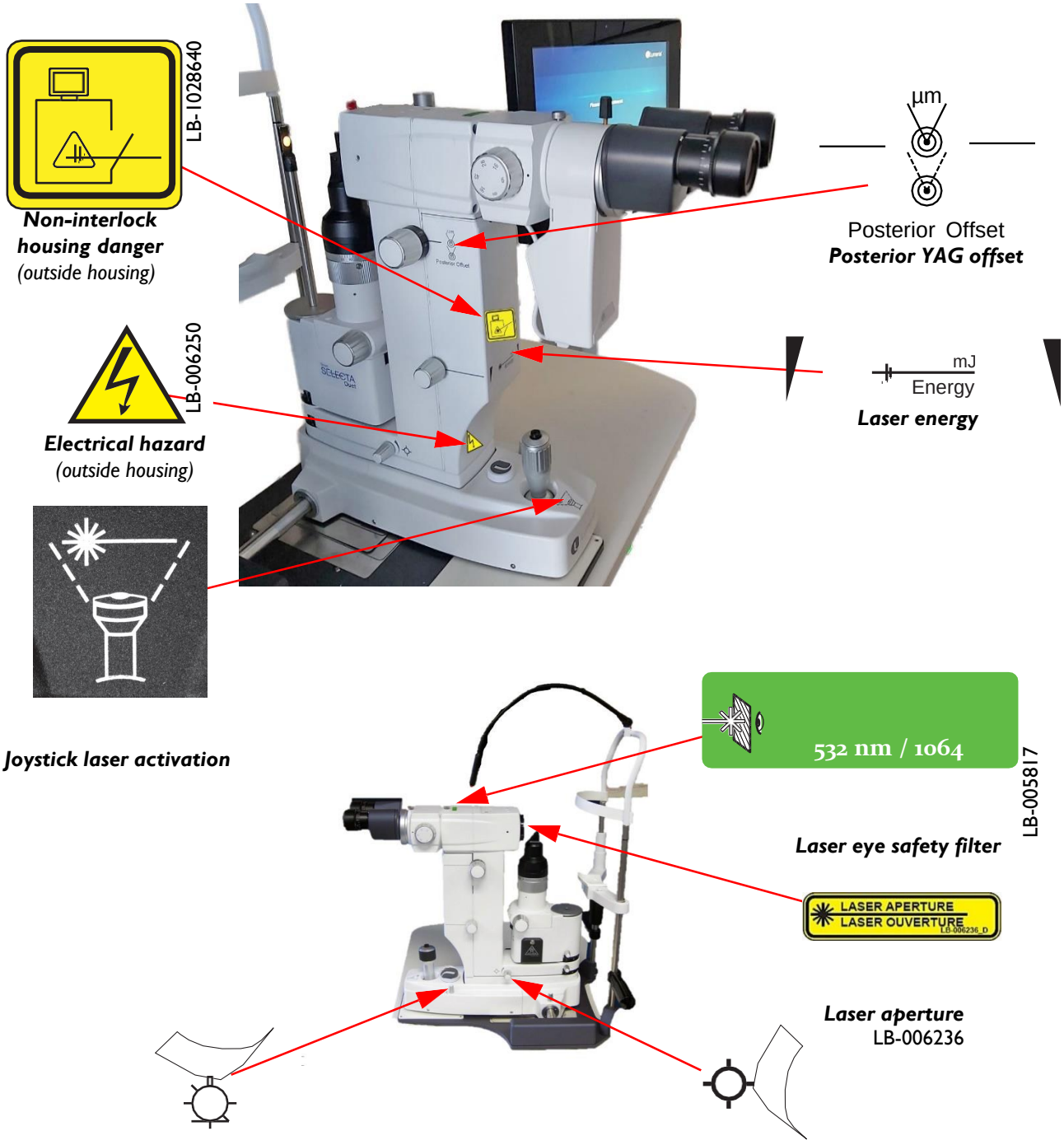
11 Electronic Fault Detection Circuitry

If the electronic system detects a fault condition, laser exposure cannot occur. The high voltage power supply is turned off, the high voltage capacitor is discharged, the safety shutter is closed, and the footswitch and joystick laser activation pushbutton is disabled.

Some fault conditions may be cleared by the operator. Refer to the Troubleshooting Guide in this manual for additional information.

1.6. Location of Regulatory and Other System Labels

As required by national and international regulatory agencies, appropriate warning labels have been mounted in specified locations.

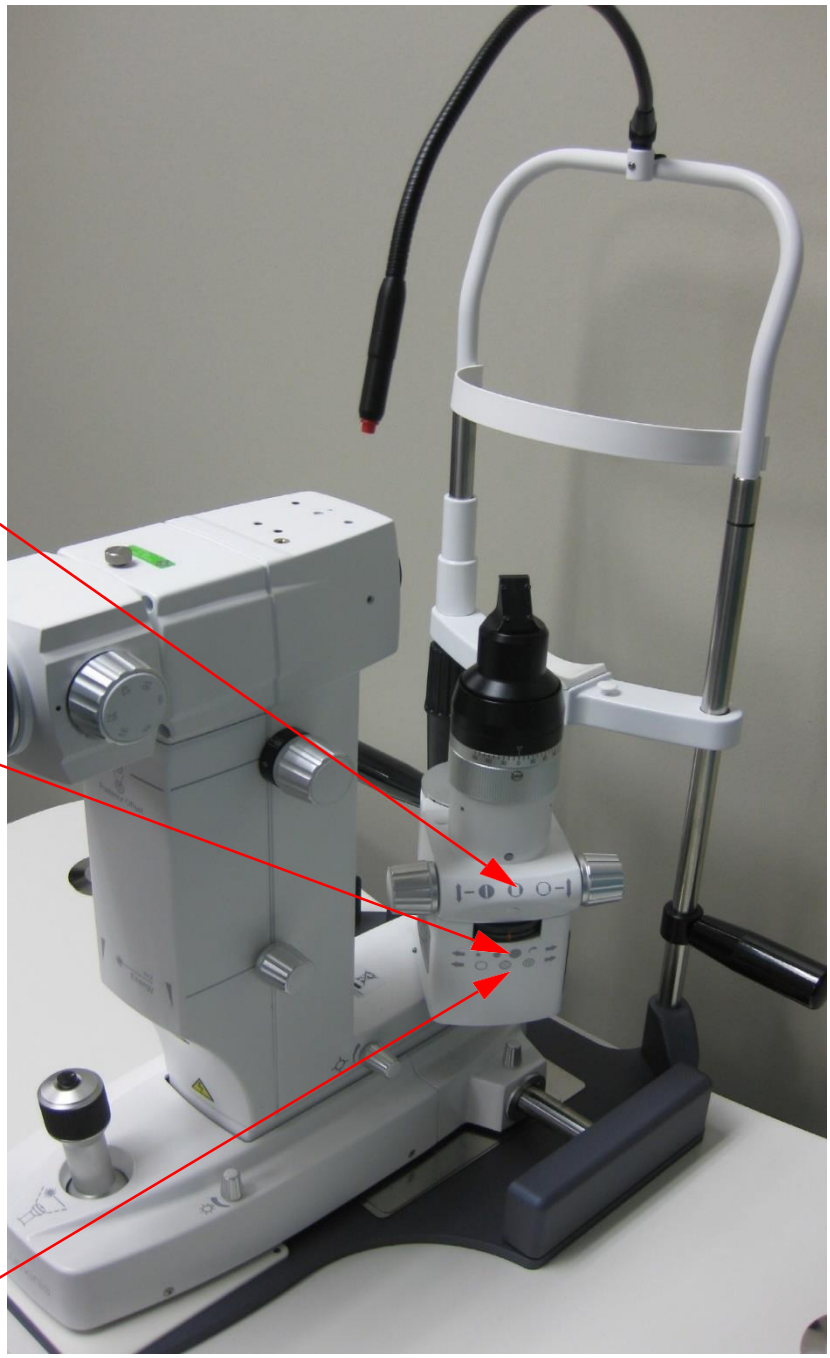


Location of Regulatory Compliance Labels

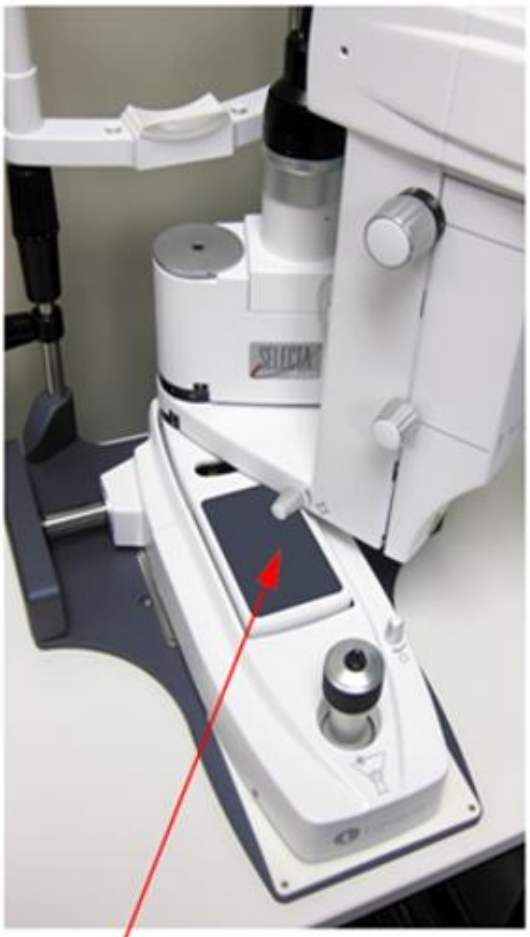
Slit lamp slit width selector wheel

Slit lamp illumination aperture selector wheel

Slit lamp color filter selector wheel



Location of Regulatory Compliance Labels—Illumination Tower



Manufacturing label containing the Unique Device Identifier (UDI) barcode
(label picture for reference only)

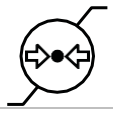
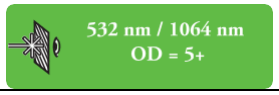
Location of Regulatory Compliance Labels—Illumination Tower

1.7. Explanation of the symbols used in the labels

As required by national and international regulatory agencies, appropriate warning labels and operation symbol labels have been mounted in the specified locations. The following pages display the warning, identificationand certification labels affixed to the system:

Symbol	Description
Lumenis® Energy to Healthcare	Lumenis, Inc., Energy to Healthcare
CE 0044	CE Compliance
MD	Medical Device
EC REP	Authorized Representative in the European Community
	Legal Manufacturer
	Date of Manufacture
REF	Catalogue Number
SN	Serial Number
SERIES	Series Number
#	Model Name
	Dangerous Voltage
	Warning– Laser Hazard
	Follow Instruction for Use
100-240 V~ 50/60 Hz 3.15A	Electrical Requirements
	Mains receptacle

Symbol	Description
	Fuse rating
	Caution
	Mass; Weight Maximum Working Weight
	Type B Applied Part
	Do not use if package is damaged and consult instructions for use
IPN_1N_2	Mechanical and Liquid Ingress Footswitch: IPx8
Includes FCC ID: XMR201903EG25G, RYK-WPEA251ACNIBT	FCC Identification (US)
Includes IC ID: 10224A-201903EG25G 6158A-EA251ACNIBT	IC Identification (Canada)
	Regulatory Compliance Mark (RCM) for Australian Communications Media Authority (ACMA) (Australia)
	Product Includes RF Transmitter
	Laser Class Label **WARNING!** **VISIBLE AND INVISIBLE LASER RADIATION** **AVOID EXPOSURE TO BEAM** **CLASS 3B LASER PRODUCT** Nd:YAG: 532 nm, 2 mJ Max / 3 ns pulse Nd:YAG: 1064 nm, 30 mJ Max / 3 ns pulse **VISIBLE LASER RADIATION; DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT DIODE LASER: 635 NM, <1 MW MAX, CW** CLASS 3B LASER PRODUCT per IEC 60825-1:2014 CLASS IIIb LASER PRODUCT per 21CFR 1040.10 & 1040.11 Complies with 21CFR 1040.10 & 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice No. 56, dated May 8, 2019.
	Emergency Laser Stop
	Laser Aperture

Symbol	Description
	External Interlock Receptacle
	Footswitch Connection
	Temperature Limitation
	Humidity Limitation
	Atmospheric Pressure Limitation
Rx ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician
	ETL Compliance
	Waste of Electrical and Electronic Equipment (WEEE) compliance
	RoHS Compliance (China)
	USB Connection
	Ethernet Connection
	Unique Device Identifier (UDI) Code
	Unique Device Identifier
	Laser Eye Safety Filter

2. Operation

2.1. Introduction

The Lumenis Digital Duet ophthalmic laser system is a fully integrated, high-performance diagnostic slit lamp and therapeutic laser delivery system. The Digital Duet laser is capable of delivering 1064 nm Nd:YAG and/or 532 nm SLT laser light. In addition, a Lumenis LaserLink S can be attached to provide 532 nm photocoagulation when connected to a Lumenis Smart532 laser system.

The Digital Duet/Trio opthalmic laser systems includes the following configurations:

- Digital Duet — a combined 1064 nm photodisruptor and 532 nm SLT laser.
- Digital Trio — a Digital Duet and a LaserLink S with a compatible Lumenis 532 nm photocoagulator.

The Digital Duet/Trio has all of the standard controls and functions of a diagnostic slit lamp and is intended for use in eye examination of the anterior segment, from the cornea epithelium to the posterior capsule.

In addition, the Digital Duet/Trio incorporates a digital camera which enables to view the treated area, on the system's touch-screen.

The Lumenis Digital Duet/Trio is also an ophthalmic surgical laser designed for performing:

- Photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and Iridotomy & Iridectomy.
- Photocoagulation
- Selective laser trabeculoplasty

The Digital Duet produces short, individual pulses of focused laser light with wavelengths of either 1064 nm or 532 nm, depending on the selected operational mode. Using a slit lamp microscope and aiming beam, the pulsed light is accurately targeted on a structure within the patient's eye.

When the photodisruptor mode is selected, the treatment wavelength is 1064nm. A twin-aiming beam targets the area of tissue disruption.

When the SLT mode is selected, the treatment wavelength is 532 nm. A coaxial aiming beam targets the trabecular meshwork via a contact lens dedicated for gonioscopy. The SLT treatment laser provides a low energy, short pulse of laser light that produces a thermal effect in pigmented cells in the trabecular meshwork.

If an optional LaserLink S delivery device is attached to the Digital Duet system and a Lumenis Smart532 photocoagulator, the Digital Duet becomes a Digital Trio configuration, and it works strictly as a standard

diagnostic slit lamp—all photodisruptor and SLT laser functions are disabled. The LaserLink S laser delivery adapter is used for treatments specifically cleared for the compatible laser photocoagulator.

The Digital Duet is shipped directly from the factory to your site. Your local Lumenis representative initially unpacks, inspects, sets up, and installs the Digital Duet to ensure that it is working properly. In addition, Lumenis provides in-service training to ensure that your surgical staff is experienced with the performance and safety considerations of the device.

CAUTION - Do not attempt to operate the laser system until a qualified Lumenis representative has installed and checked it for proper operation.

Thereafter, you, or the nursing staff at your facility, will perform the daily maintenance routines associated with this device, including inspecting and cleaning the components; focusing; and verifying the aiming beam. These procedures are detailed in this manual.

Lumenis lasers and delivery systems are precision medical instruments. They have undergone extensive testing and with proper handling are useful and reliable clinical instruments. If you have questions regarding your laser or delivery system, contact your local Lumenis representative.

WARNING - Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and operating personnel, the entire laser and your delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.

2.2. Facility Requirements

Before unpacking the system, ensure that the site meets the requirements described in the following sections.

2.2.1. Space and Positioning Requirements

Space should be allocated with adequate ventilation and free air flow. The working area for the system should be prepared according to the dimensions detailed in the Specifications section. In order to guarantee proper ventilation, always keep the sides of the system at least 0.5 m (20") from the wall or from other obstructions to air flow.

2.2.2. Electrical Requirements

The system is equipped with a universal power supply module. Accordingly, the system will require a separate line supply of:

- 100 -240 VAC, 50/60 Hz, 3.15 Amps, Single-Phase

Input power lines should be free of transients, voltage and current spikes, sags and surges. Consequently, the system power line should not be shared with other heavy variable loads such as elevators, air conditioning systems, large motors, etc.

It is strongly recommended that the system be connected to a separate power line with separate circuit breakers. Lumenis cannot guarantee adequate performance unless the system is connected to a dedicated circuit.

2.2.3. Environmental Requirements

Air Quality:

The system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of optical components.

Air-borne dust particles should be kept to a minimum. Dust particles absorb light and heat up. Hot particles located on the optical lenses can damage them. Metallic dust is destructive to electrical equipment.

Temperature:

To ensure that the system performs optimally, it is recommended to maintain ambient room temperature as detailed in the Specifications section. When the system is used intensively it will emit heat. Therefore, it is recommended that the treatment room be air-conditioned.

2.2.4. Physician Responsibility

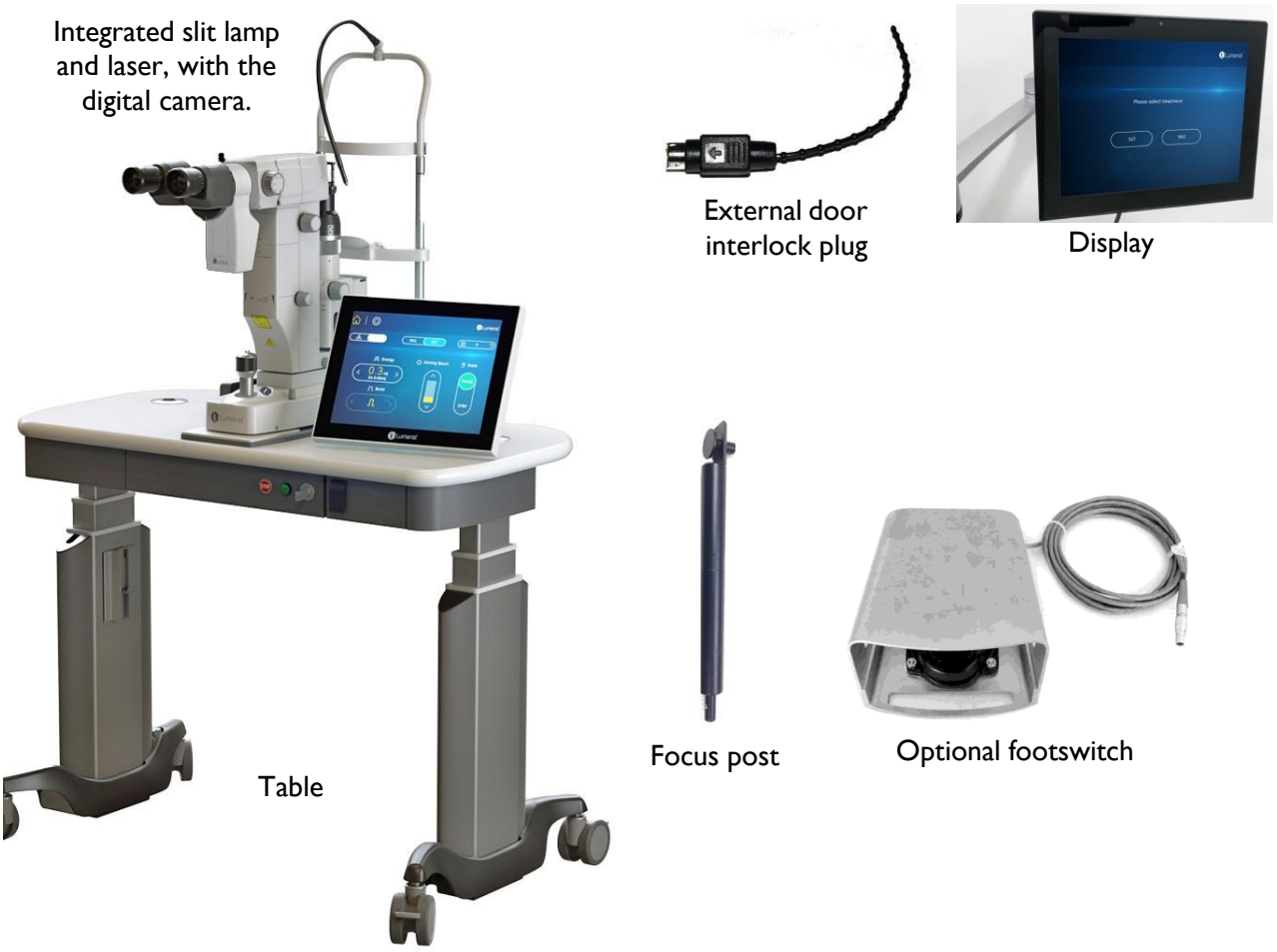
The licensed physician will be responsible for the use and operation of the system and for all operator qualifications. Lumenis makes no representations regarding federal, state or local laws or regulations that might apply to the use and operation of any medical device. The physician is responsible for contacting his or her local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

2.3. Digital Duet System Components

The Digital Duet is comprised of the following major components:

- A diagnostic slit lamp with parallel binocular optics and five-position magnification.
- An integrated Nd:YAG laser module that delivers 1064 nm and/or 532 nm wavelengths, depending on the operation mode of the laser.
- A display module with an integrated liquid crystal display (LCD) for operating the device.
- A fixed, internal laser eye safety filter.
- An electrically adjustable table with slit lamp power supply. The table is available in two sizes: a medium-sized, wheelchair-accessible table or a smaller, non wheelchair-accessible version that is specifically suited to small offices.
- An optional footswitch, door interlock plug, and all the necessary cables for proper connection and operation of the system.
- A focus post for verifying the alignment of the illumination and aiming beams at the focal plane.
- A digital camera for viewing the treated area, on the system display.

The system connections and controls are described in the following pages.



Digital Duet components

2.3.1. Laser Module

The integrated laser module houses the treatment and aiming beams, laser source, and associated optics, enabling an otherwise diagnostic slit lamp to be used as a therapeutic laser instrument.

2.3.2. Display Module

The display module is the control panel for the Digital Duet laser. The display allows you to select laser treatment settings, such as laser mode, energy, and aiming beam intensity. The display is placed above the table so that the operator can verify the laser treatment parameters without moving back from the slit lamp binoculars. The display can be adjusted to an angle and height of your preference.

2.3.3. Slit Lamp Table and Console

The slit lamp table and console incorporate the main power keyswitch, emergency off button, control electronics, and power supply. The integrated slit lamp is mounted on the slit lamp table. The table height is electronically adjustable. The table also includes the mains receptacle, a fused IEC socket for 100-120 or 220–240 VAC.

2.3.4. Footswitch and Joystick Pushbutton

The laser treatment beam can be activated either by a pushbutton on the slit lamp joystick or by an optional footswitch. The method of activation is user-selectable via the laser options screen. For safety reasons, when the user selects either footswitch or joystick, the system automatically disables the other.

2.3.5. Main Power Cable

The main power cable connects the laser to the main power source. The length of the cable shall not exceed 3 meters / 9.8 ft.

2.3.6. External Door Interlock Plug

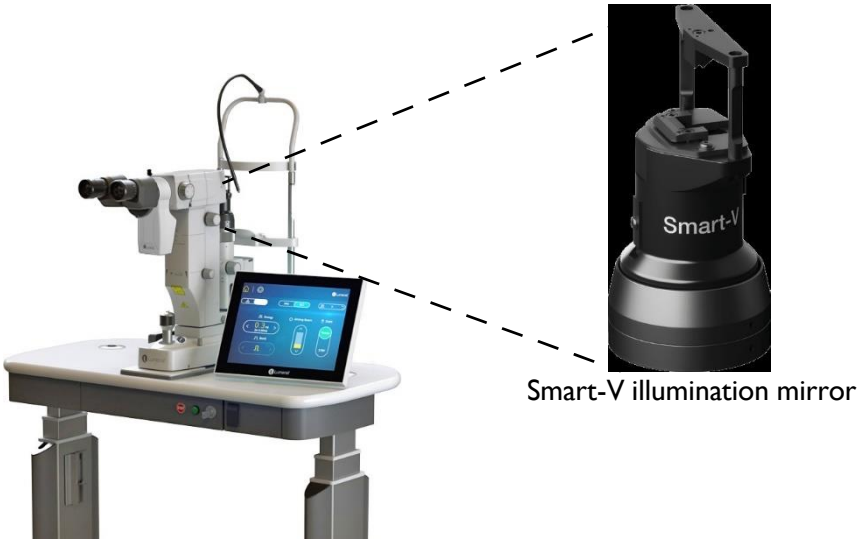
The external door interlock is a safety feature that disables the laser if someone opens the treatment room door or removes the interlock plug.

2.3.7. Digital Camera

The digital camera enables to view the treated area, on the system display.

2.3.8. Smart-V Illumination Mirror

The Smart-V enables laser treatment of the anterior and posterior parts of the eye with both on-axis and off-axis illumination.



2.4. Connection Instructions

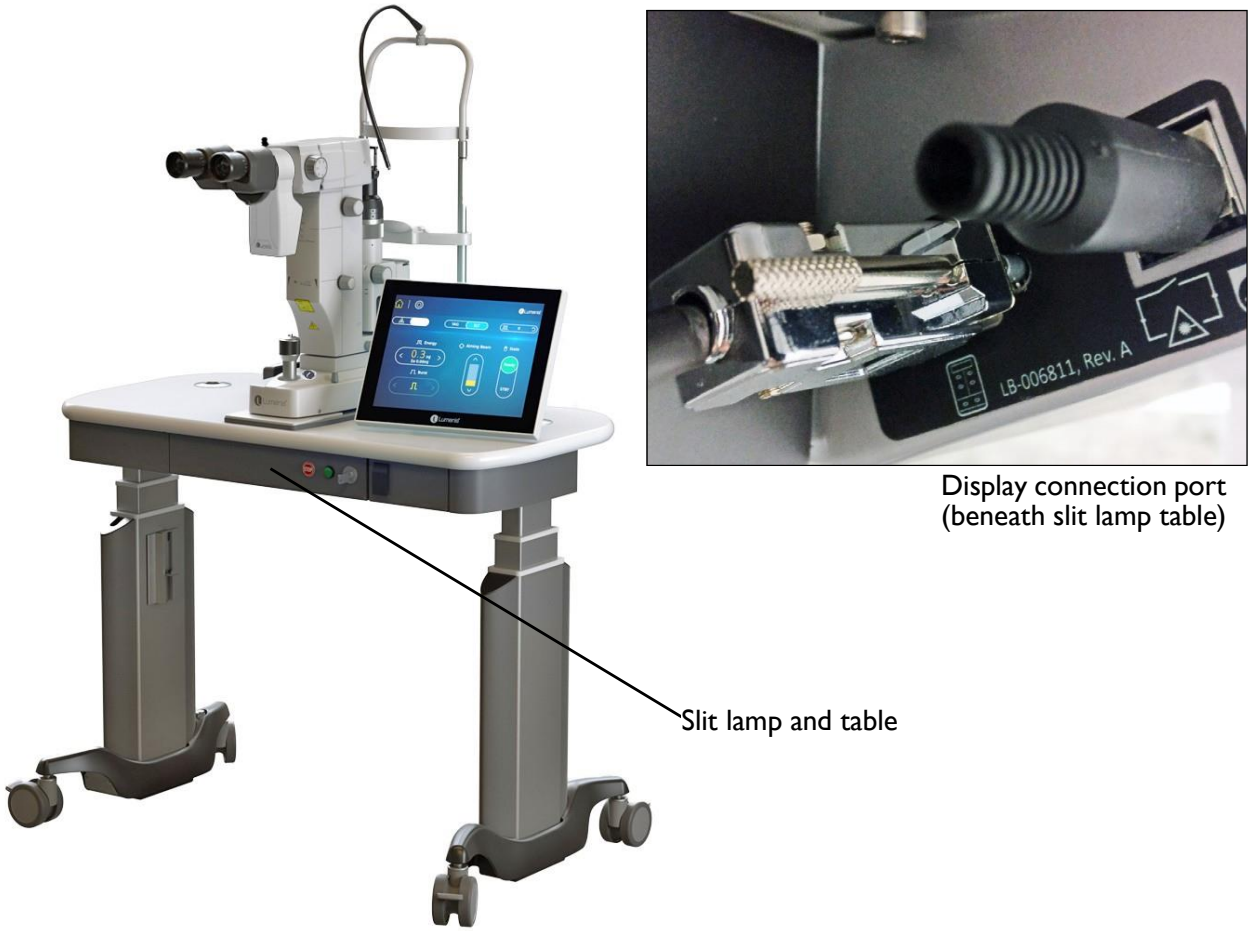
⚠ **CAUTION -** Do not use device if slit lamp seems unstable or inadequately secured.

2.4.1. Inspect the Digital Duet Components

Before connecting the Digital Duet components, inspect the individual components for dirt, debris, or damage. Check the electrical cables to ensure that they are not frayed or split.

2.4.2. Connect the Display

Plug the display cord into the display receptacle on the slit lamp console, as shown.



Connecting the display to the slit lamp console

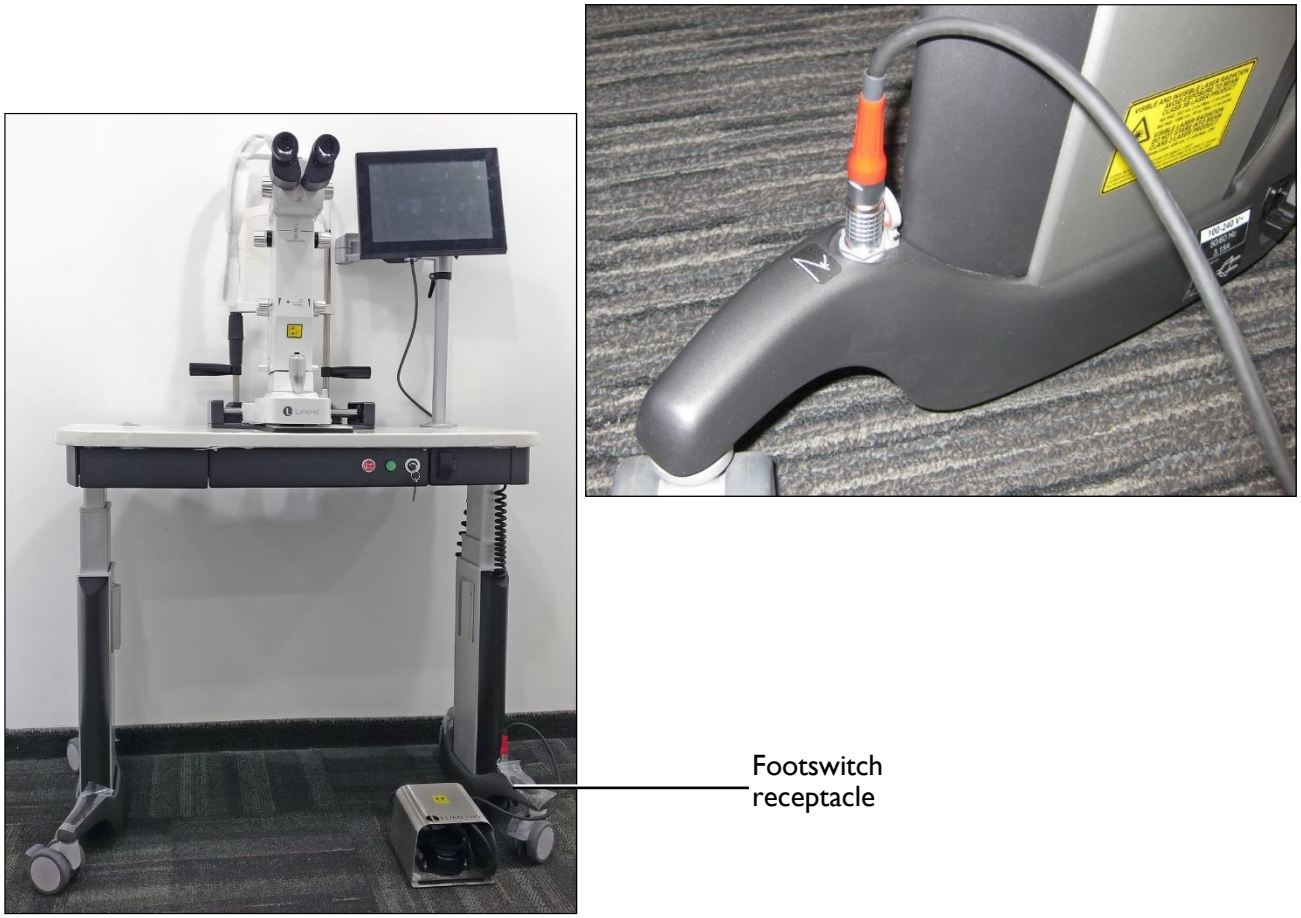
2.4.3. Connect the Footswitch (Optional)

The Digital Duet provides a choice of laser activation. By default, the laser is activated by the joystick laser pushbutton. However, many physicians prefer footswitch activation, and Lumenis provides a footswitch that may be used with the system. If the footswitch is used, plug the footswitch cable into the footswitch receptacle, as shown.

> If a footswitch is connected, the Footswitch laser activation mode must also be selected on the options screen of the laser's display, as described in the "Laser Basics—Display" section of this manual.

If the footswitch is selected on the **Treatment** screen, but is not properly connected when the laser is turned ON, (footswitch not connected) The display will show that the laser cannot be set to **READY** mode.

The length of the footswitch cable shall not exceed 3 meters / 9.8 ft.



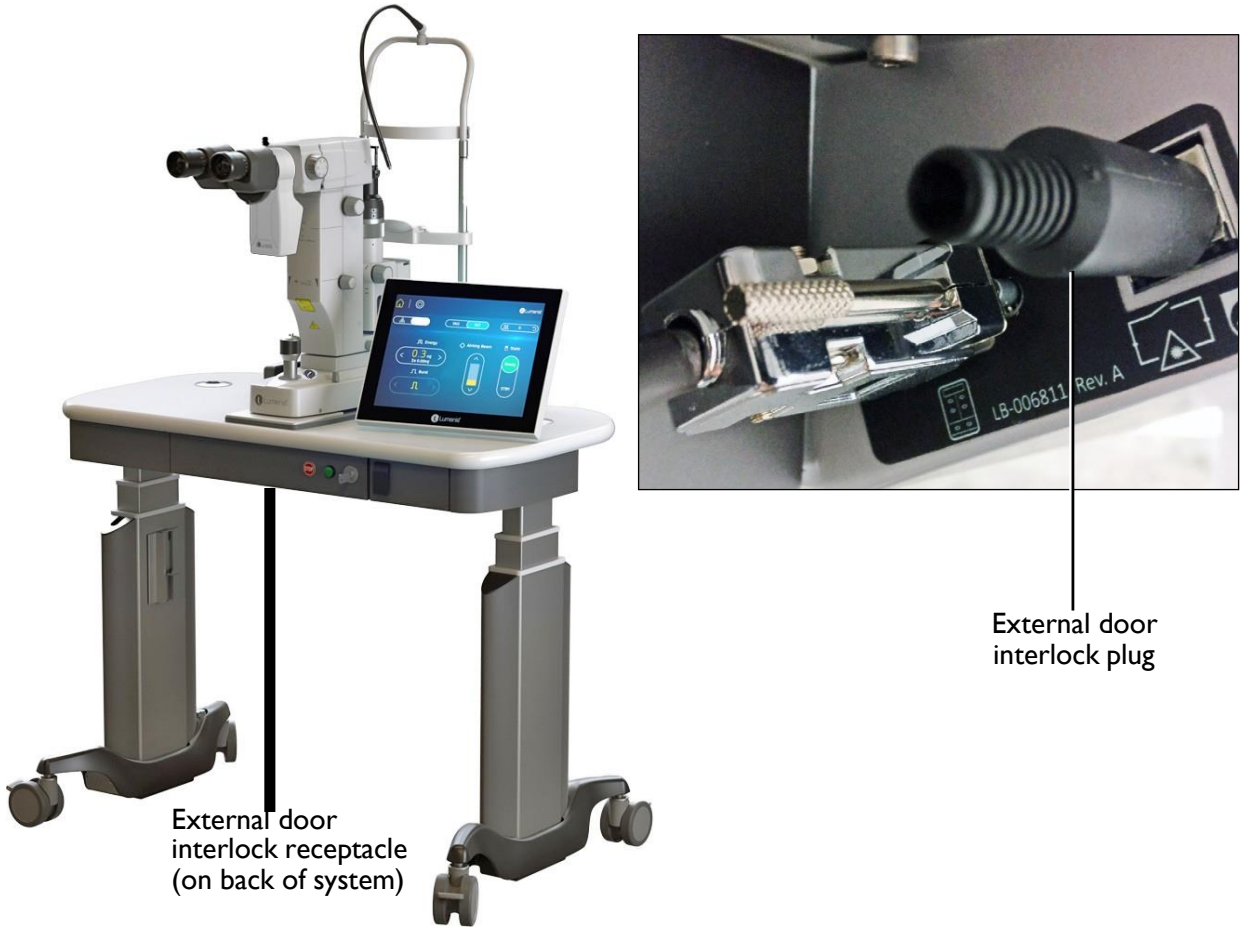
Connecting the footswitch

2.4.4. Connect the External Door Interlock Plug

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

Use of an external door interlock is optional; however, if you do not use a door interlock, you must insert the external door interlock plug into the (external interlock) receptacle, as shown.

If you use an external door interlock, the laser can only be placed in **READY** mode when the interlocked door is closed. If the interlocked door is subsequently opened, or the plug is removed, the laser is disabled and (external interlock not connected) illuminates on the display. To resume treatment, close the treatment room door or reinsert the interlock plug, and press the **READY** button on the display.



Connect the interlock plug

2.4.5. Plug In the Main Power Cable

1. Ensure that the system keyswitch is turned OFF.
2. Insert the main power plug into the main power receptacle, as shown.
3. Plug the other end into an electrical outlet.

Plugging in the main power cable

2.4.6. Attaching the LaserLink S Delivery Device

⚠ **CAUTION -** Before use, refer to the LaserLink S Operator Manual for detailed installation and operation instructions.

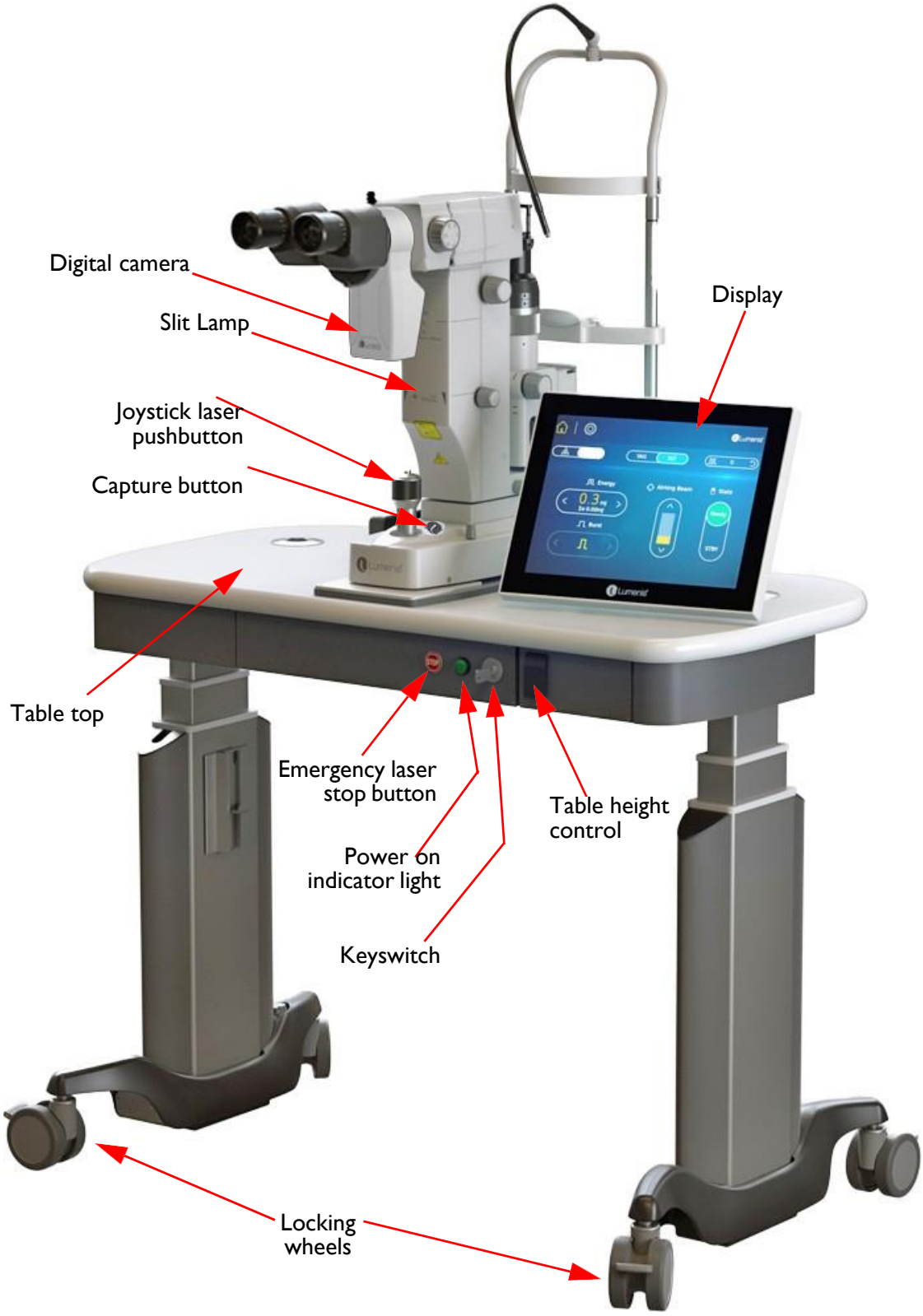
1. Position the illumination tower out of the way.
2. Place the LaserLink S on top of the Digital Duet Slit Lamp.
3. Secure the LaserLink S with the attached thumb screw.
4. Verify that the display shows the **Smart532** icon and does not allow the system to display YAG or SLT functions.
5. Replace the Digital Duet Slit Lamp's single illumination mirror with the dual illumination mirror. If the Smart-V illumination mirror is installed, no replacement is necessary.
6. Attach the LaserLink S fiber optic to the photocoagulator, as described in the LaserLink S operator manual.

2.5. System Basics

2.5.1. Main System Controls

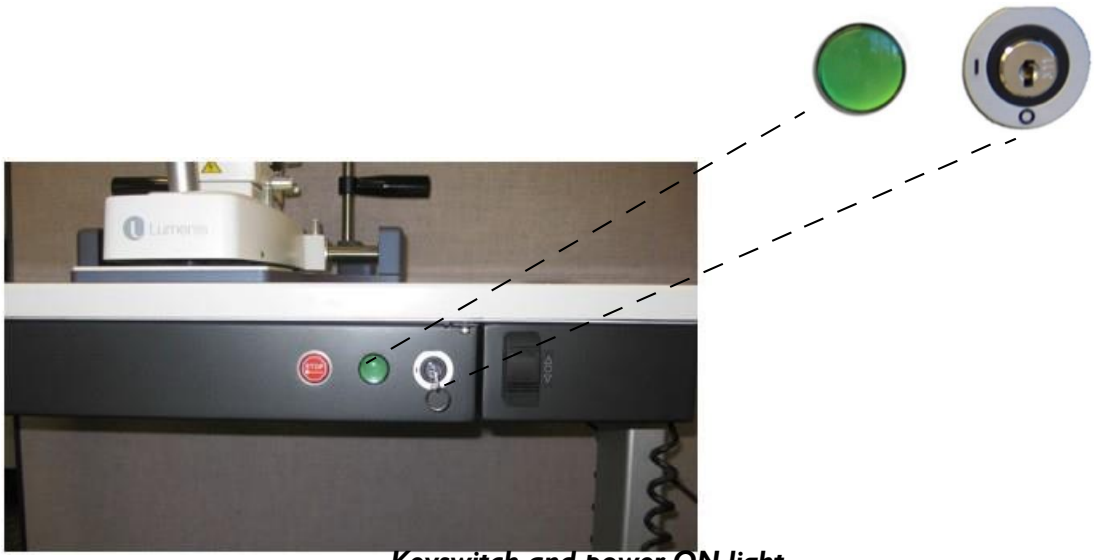
The integrated slit lamp is mounted on an electronically adjustable table. Located on the slit lamp table are the main system controls: the system keyswitch, the laser emergency off pushbutton, and the table height control button. Locking wheels enable the table to be easily and safely moved from one treatment room to another. The power supply provides power to the illumination tower and fixation light. The main power receptacle, fuse module, and the display, external door interlock, and footswitch receptacles are located on the table.

Laser settings are selected from the display. The laser activation mode is user-selectable: either a footswitch or joystick pushbutton may be used.


Digital camera
Slit Lamp
Joystick laser pushbutton
Capture button
Table top
Display
Emergency laser stop button
Power on indicator light
Keyswitch
Table height control
Locking wheels

2.5.2. Turning ON the System

Insert the key into the keyswitch and turn it to the **I** (ON) position.



Keyswitch and power ON light

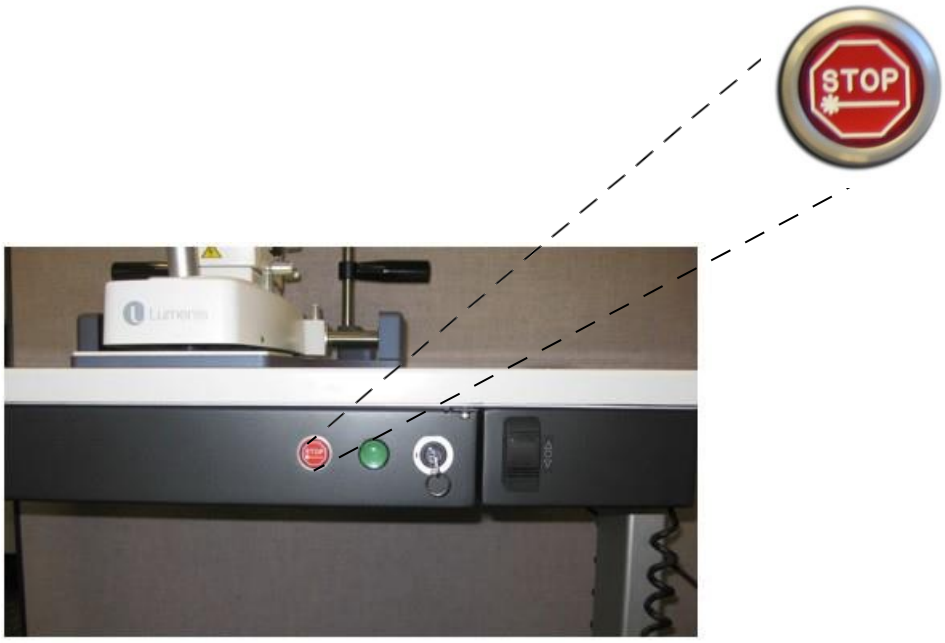
The power ON indicator lights up and the system initiates a self-test. During self-test, the initialization screen displays progress and status messages. Upon successful completion of the self-test, the system beeps, and the display changes to the laser mode screen. The STANDBY icon ON the display illuminates, and the laser is in STANDBY mode. The system will default to minimum settings.

2.5.3. Turning OFF the System

Under normal operating conditions, turn the keyswitch to the **O** (OFF) position.

2.5.4. Emergency-Off Switch

In an emergency, press the red emergency-off switch to immediately de-energize the system.



Emergency-off switch

2.5.5. System Beeps

The system emits unique beeps to distinguish certain types of events. For example, the system beeps when the STANDBY or READY laser status mode is changed, when the system is not ready to accept input, when the maximum or minimum treatment setting is reached, when the energy delivered was less than requested, or when an error has occurred.

2.5.6. Disconnecting the System

1. Turn the keyswitch to the **O** (OFF) position.

2. Remove the system power plug from the electrical outlet.

2.5.7. Moving the System

After disconnecting the system, move the slit lamp table and accessories to the desired site. Step ON the wheel brake to lock the wheel, as shown. To unlock the wheel, place your foot under the brake and lift the lever up.

Locking the wheels

2.6. Slit Lamp Basics

2.6.1. Slit Lamp Positioning and Joystick Control

The slit lamp is mounted to the table and allows for coarse positioning of the slit lamp. Loosen or tighten the instrument base locking screw, as shown in the following illustration, to move the slit lamp and to adjust the friction between the base and the table top. The slit lamp position can be locked by tightening the instrument base locking screw.

The joystick controls lateral, longitudinal, and vertical positioning of the slit lamp. Moving the joystick moves the instrument in the corresponding direction. Turning the joystick clockwise raises the slit lamp microscope; turning it counter-clockwise lowers it.

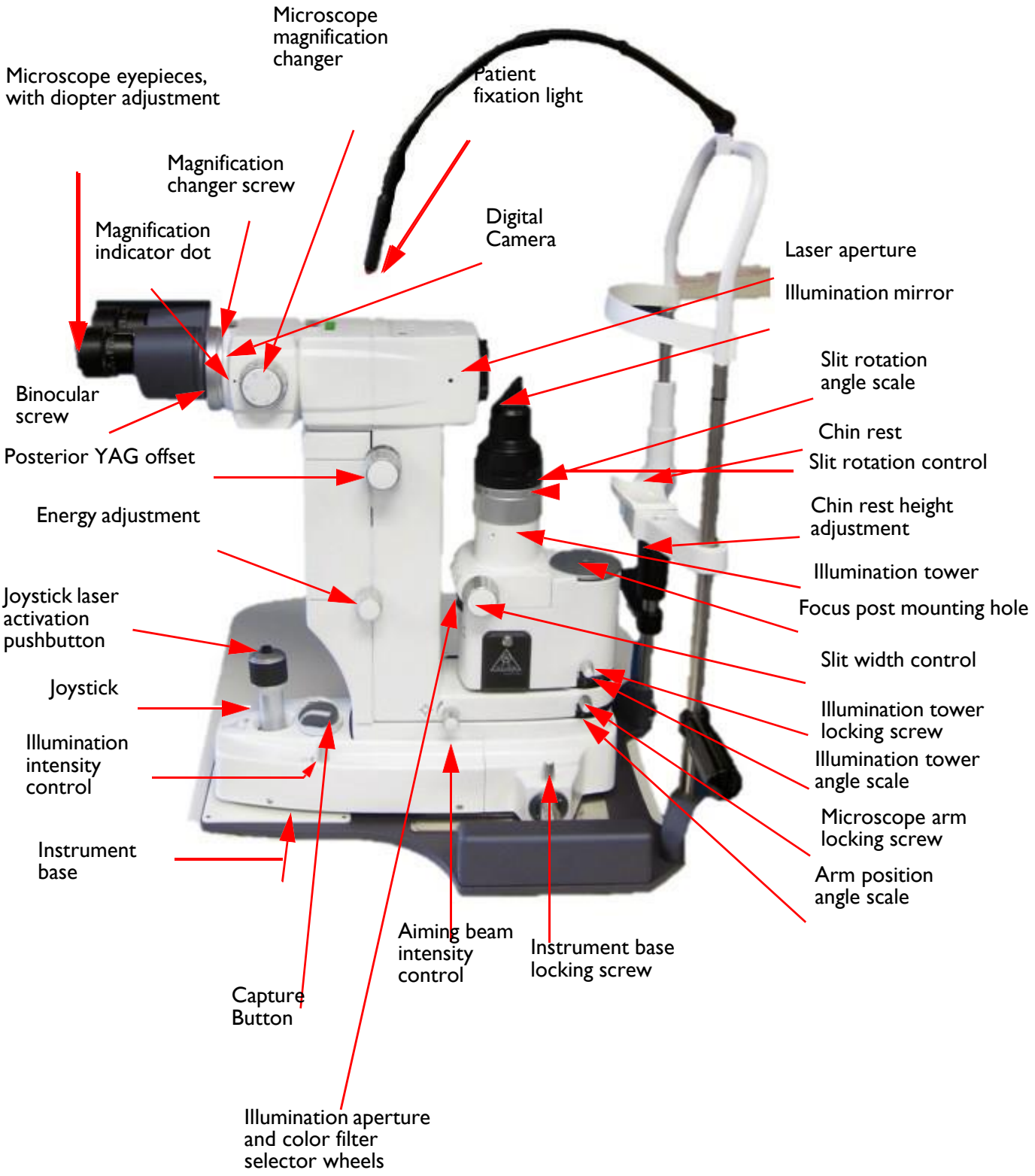
The positions of the laser aiming and treatment beams are fixed in the system. Therefore, moving the joystick to position the slit lamp, correspondingly adjusts the position of the laser aiming and treatment beams. The joystick also has a laser pushbutton which can be used to activate the laser treatment beam.

The laser may be activated by either a footswitch or by the joystick laser pushbutton. The method of laser activation is user selectable via the footswitch/joystick mode button on the display options screen. For safety, the laser enables only the selected mode, and automatically disables the other.

Forcing the joystick to move after the slit lamp base has been locked may damage the instrument.

2.6.2. Slit Lamp Controls

As shown in the following illustration and described in the following section, the Digital Duet slit lamp has all of the standard diagnostic slit lamp controls such as illumination intensity, illumination aperture, slit width adjustment and rotation, as well as the typical diagnostic slit lamp adjustments, such as diopter eyepiece adjustments, magnification, binocular focus, and interpupillary distance adjustment. In addition, as an integrated laser slit lamp, the Digital Duet also has controls that are specific to operation of the laser. The laser controls that are located on the slit lamp itself are: the joystick laser activation button, the energy adjustment knob, the posterior YAG offset control, and the aiming beam intensity control. All other laser functions are located on the display.



Slit lamp controls

2.6.3. Slit Lamp Controls

2.6.3.1 Eyepieces, diopter adjustment, and interpupillary distance

The Digital Duet slit lamp microscope eyepieces have a 12.5x magnification, with diopter adjustments on both eyepieces of ±5. One eyepiece has cross-hairs to aid focusing. The eyepiece positions can be manually adjusted to suit the operator's interpupillary distance. Eye cups can be pushed back if the operator wears spectacles.

2.6.3.2 Microscope Magnification Changer

The magnification changer is used to select the slit lamp viewing magnification. The magnification is adjusted using the large rotary control knob behind the binocular assembly.

2.6.3.3 Illumination Tower Rotation

The illumination tower incorporates the illumination mirror which directs the slit lamp illumination to the treatment area. The tower can be rotated approximately 90° either side of center. To rotate the tower, loosen the illumination tower locking screw and manually rotate the tower as desired. Tighten the tower locking screw to lock the tower into position. An angle scale, located below the illumination tower locking screw, indicates the rotation angle of the tower.

2.6.3.4 Slit Width Control

Slit width ( )is adjusted using a rotary control knob on each side of the illumination tower. Rotate the knob clockwise to widen the slit width, counter-clockwise to narrow the slit, as shown on the control icon.

2.6.3.5 Slit Rotation Control

The slit can be rotated up to 90° either side of vertical. The slit rotation control is a knurled section of the illumination tower. Rotate the control in the direction of the desired rotation. A slit rotation angle scale is located directly above the slit rotation control.

2.6.3.6 Illumination Aperture and Color Filter Selector Wheels

The illumination aperture ( ) and color filter ( ) selector wheels are located on the front of the illumination tower beneath the slit width control. The top wheel selects the illumination aperture. The bottom wheel selects the colored viewing filters. The filter selections are: green, cobalt blue, neutral density (ND at 28% attenuation), red and none.

2.6.3.7 Microscope Arm Rotation

The microscope arm can be rotated approximately 30° either side of center. To rotate the microscope arm, loosen the microscope arm locking screw and manually rotate the microscope arm to the desired position. An arm position angle scale, located directly beneath the microscope arm locking screw, indicates the rotation angle of the microscope arm.

2.6.3.8 Slit Lamp Illumination Intensity Control

A rotary control on the right hand side of the slit lamp base adjusts the slit lamp illumination intensity ( ). Rotate the control clockwise to increase intensity, counter-clockwise to decrease intensity, as shown on the control icon.

2.6.3.9 Chin Rest Height Adjustment

The patient chin rest may be adjusted up and down using the chin rest height adjustment knob, located on the chin rest assembly. Rotate the knob to adjust the chin rest up or down.

2.6.3.10 Capture Button

The Capture button enables capturing of images and recording videos, as retrieved by the digital camera. The button is active only after starting a patient session.

2.6.4. Laser Controls On the Slit Lamp

2.6.4.1 Laser Eye Safety Filter

The microscope contains an integrated, fixed eye safety filter that protects the operator's eyes from exposure to laser radiation.

2.6.4.2 Laser Aiming Beam Intensity Control

A rotary control on the right side of the slit lamp base adjusts the laser aiming beam intensity ( ). To increase the laser aiming beam intensity rotate the control clockwise, to decrease intensity rotate the control counter-clockwise, as shown on the control icon.

2.6.4.3 Energy Adjustment Control

Laser energy is adjusted using a rotary control (mJ) located on each side of the microscope column. As indicated on the icon next to the control, rotate the control clockwise to increase laser energy, counter-clockwise to decrease laser energy.

2.6.4.4 Posterior YAG Offset Control

The posterior YAG offset control () is located on each side of the microscope column. The YAG offset control adjusts the focal plane of the treatment laser energy posteriorly. 100 µm is the nominal setting, as indicated on the control knob. The posterior YAG offset is continuously adjustable from 0 to 350 µm posterior, with detents at 0, 100, 250, and 350 µm.

2.7. Laser Basics

2.7.1. Display Module

The laser's display activates when the display is connected and the system is turned ON. Use the on-screen buttons, icons, and textual tags to change and monitor laser system information.

WARNING - Do not use the device if the display is blank, unresponsive, or incorrect.

WARNING - Do not use the device if error messages are displayed; refer to maintenance section of this manual.

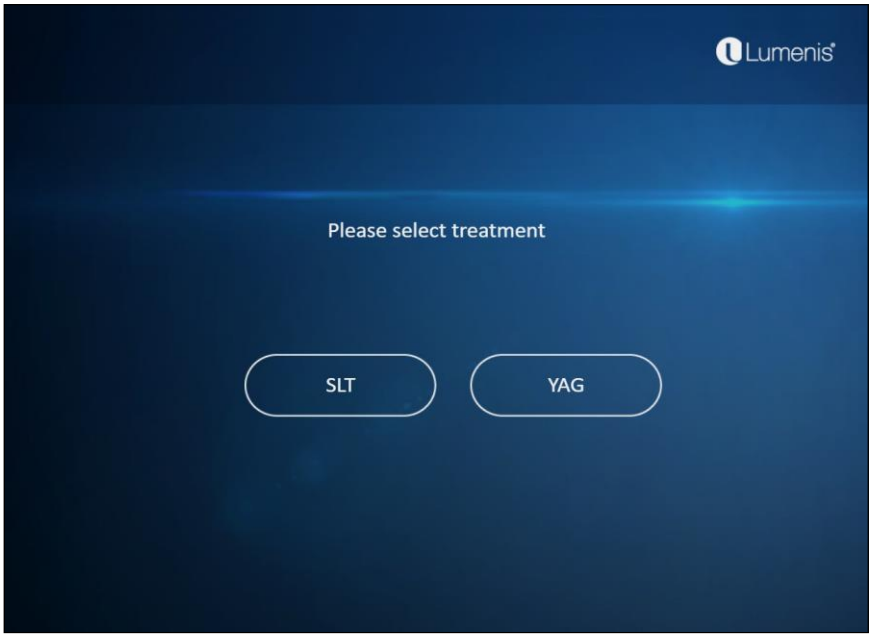
2.7.2. Startup Screen

Turning ON the system's keyswitch powers up the various modules of the system and the following splash screen appears on the LCD display:

Startup Screen

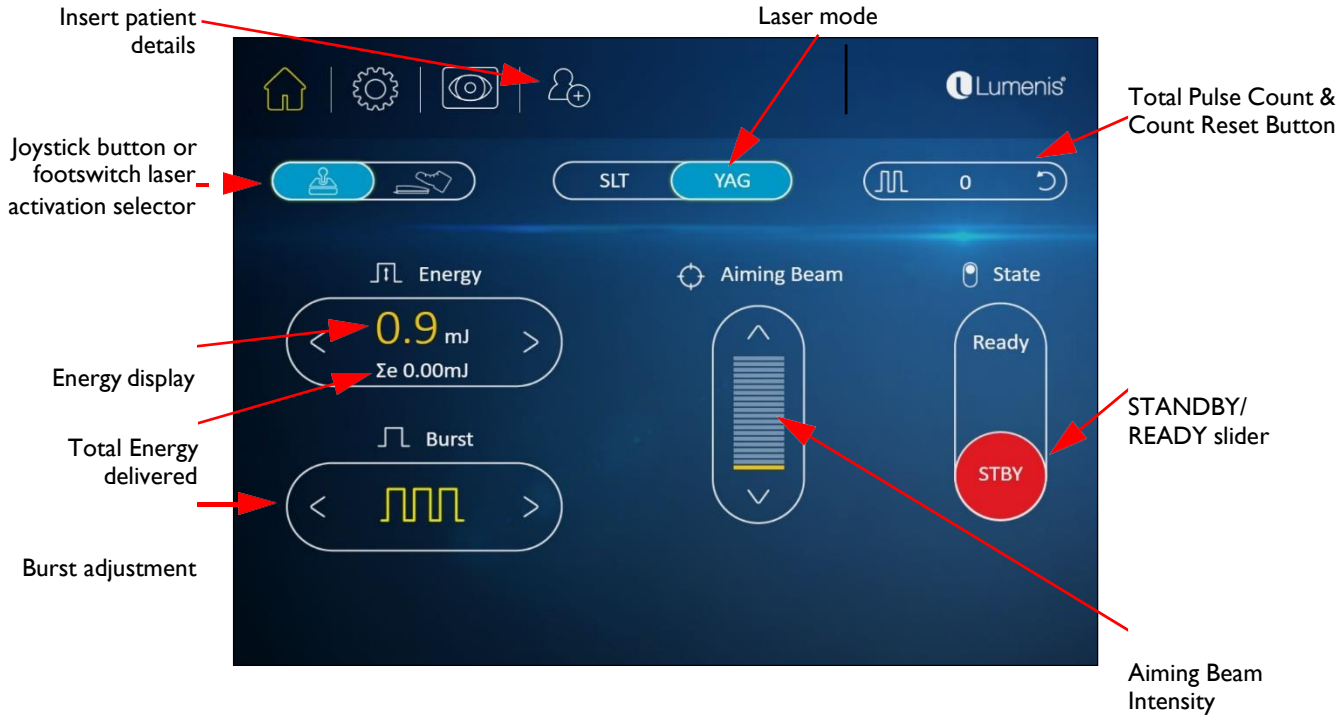
The startup screen also automatically displays on Digital Trio configurations whenever the LaserLink S is detached from the laser system.

When the startup screen displays, you must select the treatment mode: SLT or YAG. Always verify the treatment mode and energy settings before, during and after treatment.



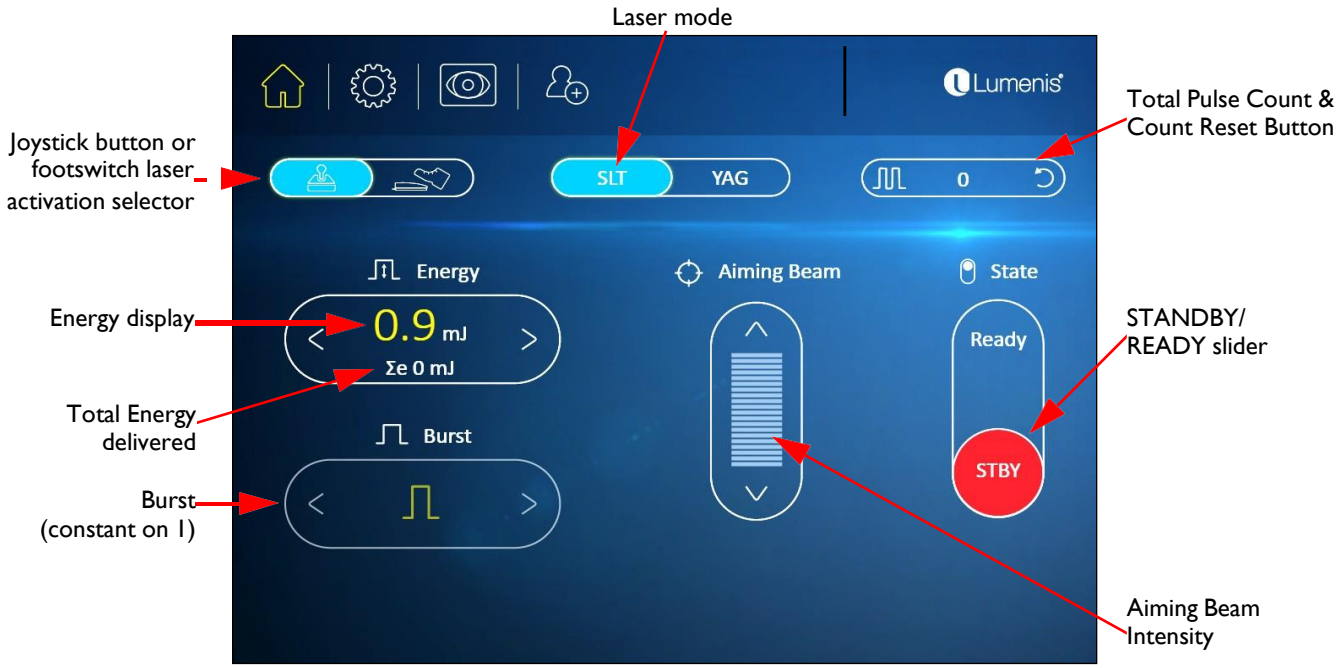
Startup Screen

2.7.3. Photodisruptor Mode



Display (Photodisruptor-1064 nm Screen Shown)

2.7.4. SLT Mode

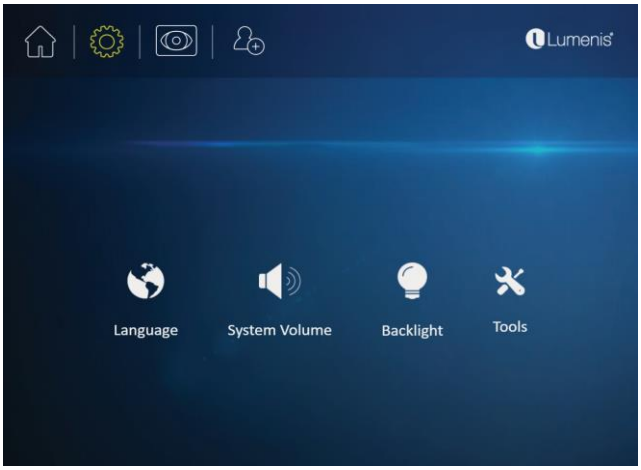


Display (SLT-532nm Screen Shown)

2.7.5. Smart532 Mode

Display

2.7.6. Options and Tools Screens



Access various Tools from the **Options Access** screen

Tools screen (sample)

Options Access and Tools Screens (for illustration purposes only)

2.7.7. STANDBY, READY, and Laser Emission Modes

Use the on-screen **STANDBY/READY** status button to select the laser mode: standby or ready. When the laser is turned on and has completed initialization, the laser defaults to **STANDBY** mode. **STANDBY** appears on the display.

In **STANDBY** mode, the joystick pushbutton or footswitch is disabled and the safety shutter is closed; no treatment beam is available. In **READY** mode, the joystick pushbutton or footswitch is enabled and the treatment beam is available.

To commence treatment, the clinician presses the **STANDBY/READY** status button, placing the laser in **READY** mode. There is a two-second transition between **STANDBY** and **READY** mode, during which a **Test Fire** indicator flashes on the display. When the system beeps and **READY** is highlighted on the display, it indicates that the laser is fully powered and that laser radiation (the treatment beam) is accessible via the user-selectable footswitch or joystick pushbutton. When the clinician depresses the footswitch or joystick pushbutton, **Lasing** appears on the display, indicating that the system is emitting laser energy to the treatment site.

> The Digital Duet provides a choice of laser activation. By default, the laser is activated by the laser pushbutton on the slit lamp joystick. However, many physicians prefer footswitch activation, and Lumenis provides a Digital Duet footswitch that may be used with the system. If a footswitch is connected, the Footswitch laser activation mode must also be selected on the options screen of the display, as described in the "Laser Basics—Display" section of this manual.

Selecting STANDBY or READY Mode (photodisruptor screen shown)

2.7.8. Laser Mode

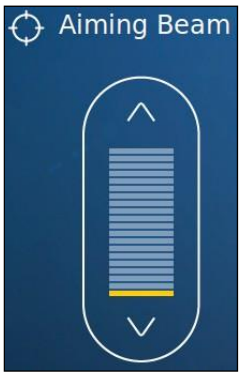
If you've purchased the Digital Duet, the laser mode selector lets you select either the **YAG** or **SLT** laser mode. The display screen will change to reflect all of the treatment settings available in the selected laser mode.

Smart532 mode is used in the Digital Trio configuration, which utilizes a LaserLink S delivery device and a Smart532 photocoagulator. This mode will appear when the LaserLink S delivery device is connected to the Digital Duet. In **Smart532** mode, the laser **STANDBY/READY**, aiming beam intensity, treatment settings, and treatment delivery are all controlled by the Smart532 laser.

Selecting the Laser Mode

2.7.9. Aiming Beam

The aiming beam intensity can be adjusted with the aiming beam intensity control knobs located on the slit lamp (shown on the "Slit Lamp Controls" illustration on page 40), or by using the display's aiming beam adjustment controls. To decrease the intensity, press the down (∨) button. To increase the intensity, press the up (∧) button.

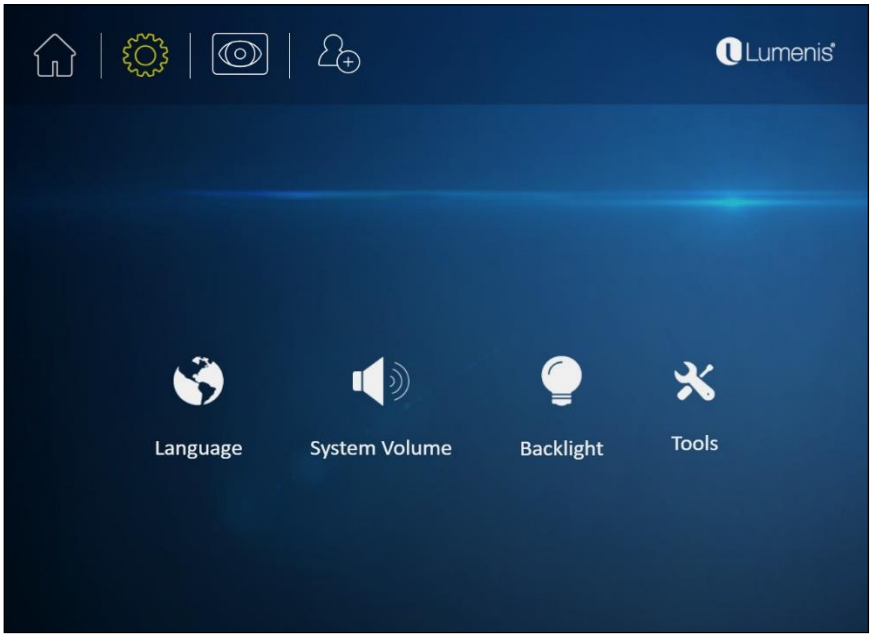


Adjusting the aiming beam intensity

2.7.10. System Display Options

2.7.10.1 Select the Options Screen

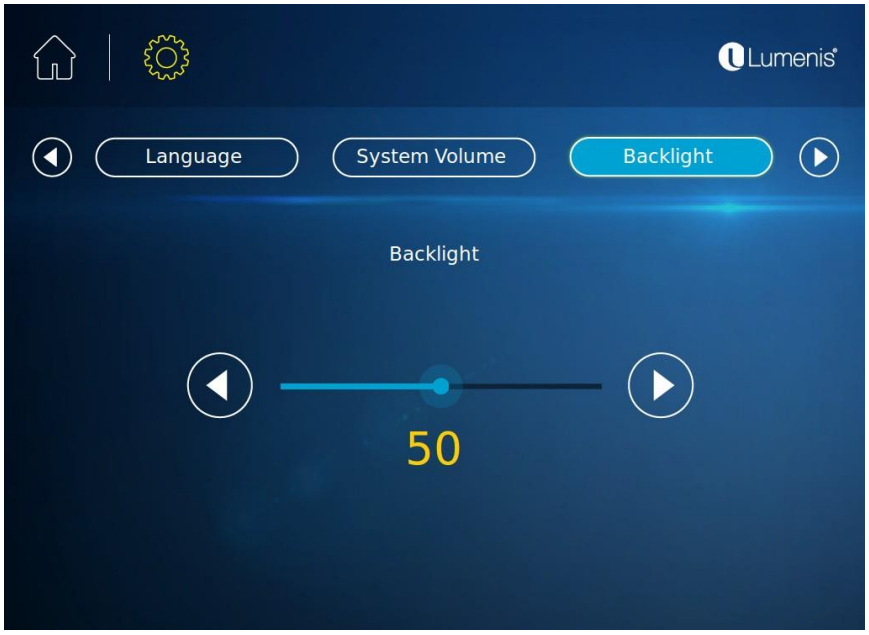
The Digital Duet options screen is where you can set system preferences such as the volume of system beeps, the interface language and backlight level. To enter the options screen, press the **Options** icon in the upper left area of the screen. To return to the laser treatment screens, press the **Home** icon.



Selecting the Options Screen

2.7.10.2 LCD Screen Backlight

The backlight brightness of the display's LCD screen can be adjusted to suit treatment room light conditions by using the **Backlight** slider. To decrease the brightness of the LCD screen, move the slider control (◀) to the left. To increase the brightness, move the slider control (▶) to the right.



Adjusting the Display Screen Backlight Brightness

2.7.10.3 Laser Activation Mode—joystick Or Footswitch

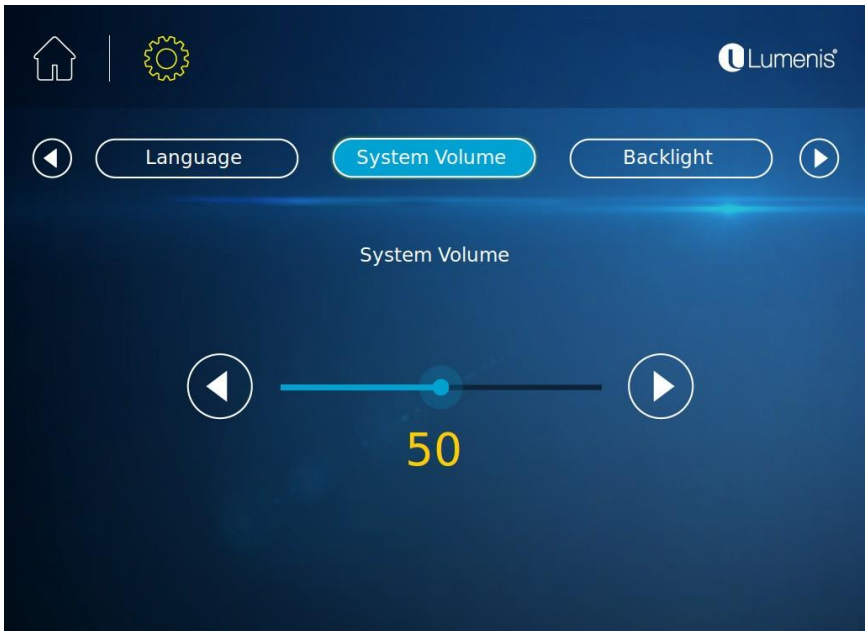
The Digital Duet provides a choice of laser activation. By default, the laser is activated by the laser pushbutton on the slit lamp joystick. However, the laser can be activated either by a pushbutton on the slit lamp joystick or by a footswitch. The currently active mode is highlighted on the **Treatment** screen, as shown below. To change the laser activation mode, press the Joystick/ Footswitch selector.

For safety, when the user selects either footswitch or joystick, the system automatically disables the other. If the footswitch is selected on the screen, but is not properly connected when the laser is turned ON, (footswitch not connected) appears on the display and the laser cannot be placed in **READY** mode.

Selecting joystick or footswitch laser activation

2.7.10.4 Volume

The preferred volume of the system beeps can be adjusted using the volume controls. The volume control is located on the display options screen. To lower the beep volume, move the slider control (◀) to the left. To increase the volume, move the slider control (▶) to the right.

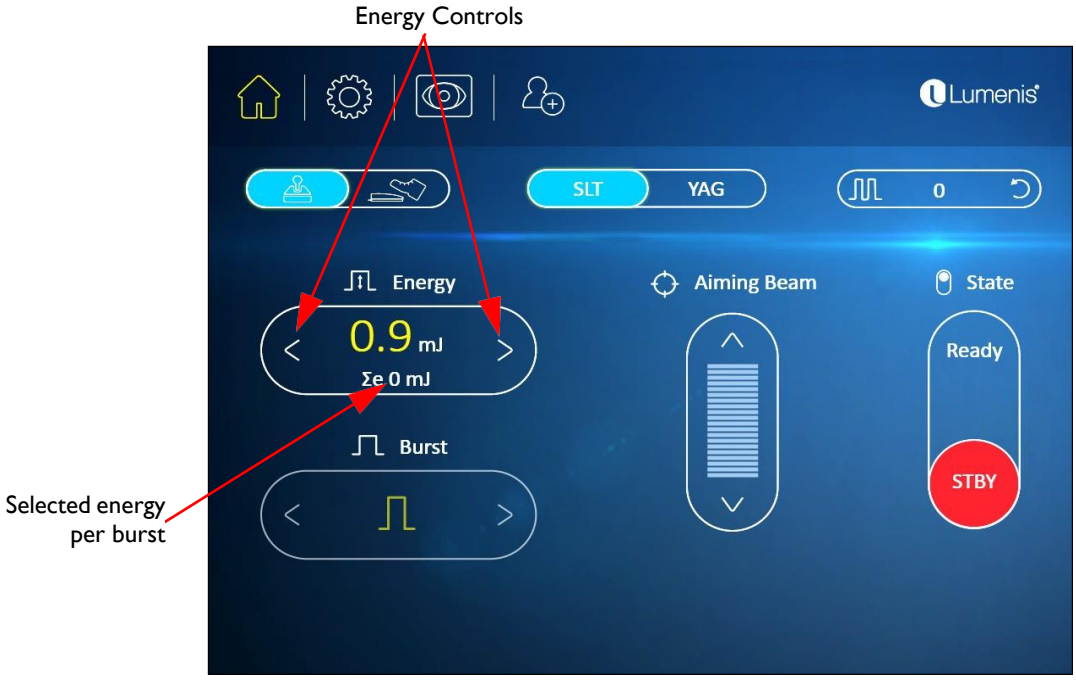


Adjusting the System Volume

2.7.11. Treatment Settings

2.7.11.1 Energy and Photodisruptor Laser Mode

Use the energy control to adjust the energy per pulse or energy per burst, depending on the laser mode. Press the **>** button to increase laser energy, and the **<** button to decrease energy. Laser energy is displayed in millijoules (mJ). Refer to the **Specifications** section on page 89 for available energy settings. The energy display shows the currently selected energy.



Selecting the Energy per Burst (SLT Mode Shown)

2.7.11.2 Total Energy and Pulse Count Displays (Photodisruptor and SLT Mode), and Burst Mode (Photodisruptor Mode)

The total energy (**mJ**) delivered since the **Count Reset** button was pressed is shown in the **Energy** display. Press **Count Reset** to reset both the **Energy** count and the total pulse count to **0** (zero).

There are three burst modes available in photodisruptor laser mode: single, double, and triple burst. For example, if triple burst is selected, when the treatment laser is activated, the selected energy will be delivered in a "pulse train" of three pulses. Refer to the **Specifications** section on page 89 for additional detailed information.

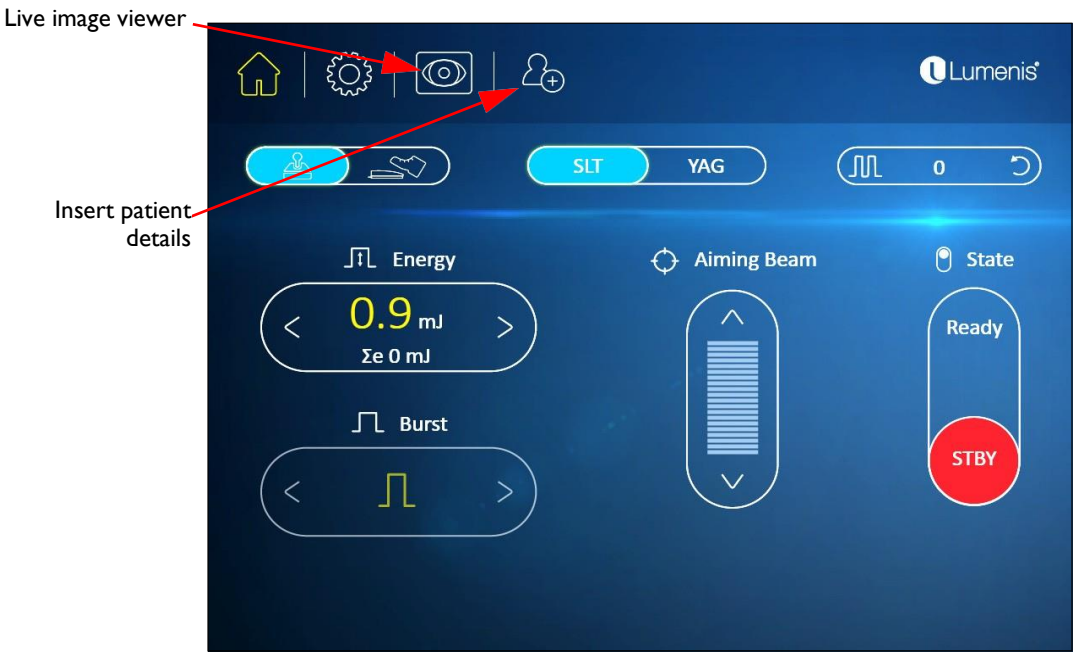
Set the burst mode using the burst mode selector. The currently selected burst mode is shown in the burst mode display.

Total energy count, total pulse count, and the count reset button

2.8. Using the Digital Camera

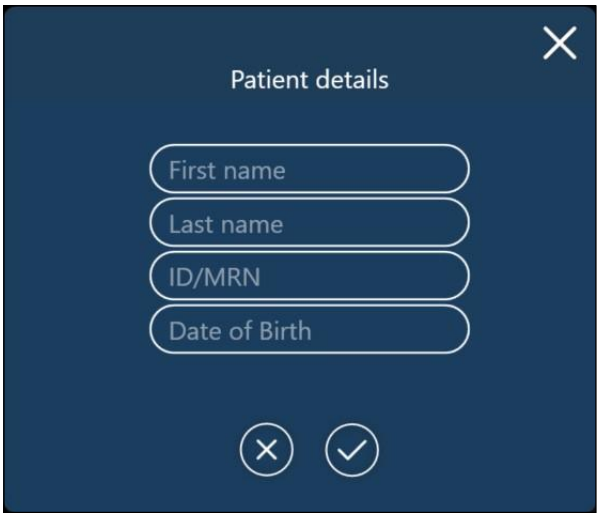
The digital camera enables to view the treated area, on the display of the system.

- In order to view the live image, press on the “eye” icon.



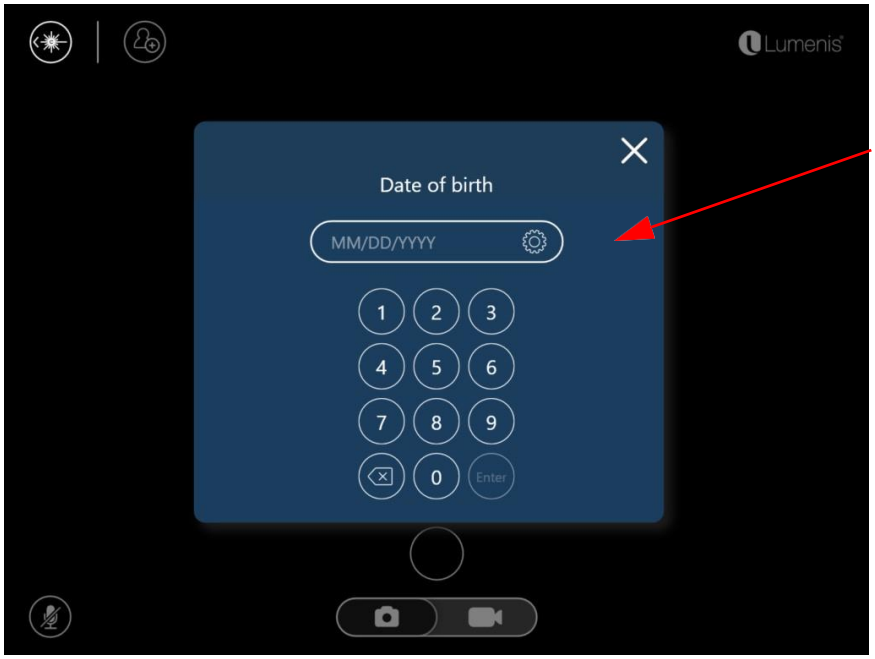
“Eye” icon; press to view the live image

- It is also possible to capture images and record videos using the Digital camera. In order to do so, you need to enter patient details. All fields must be entered, in order to proceed.



Fill in Patient Details

- Note that you can change the date format for the date of birth (DD/MM/YYYY or MM/DD/YYYY), by clicking on the cogwheel icon.



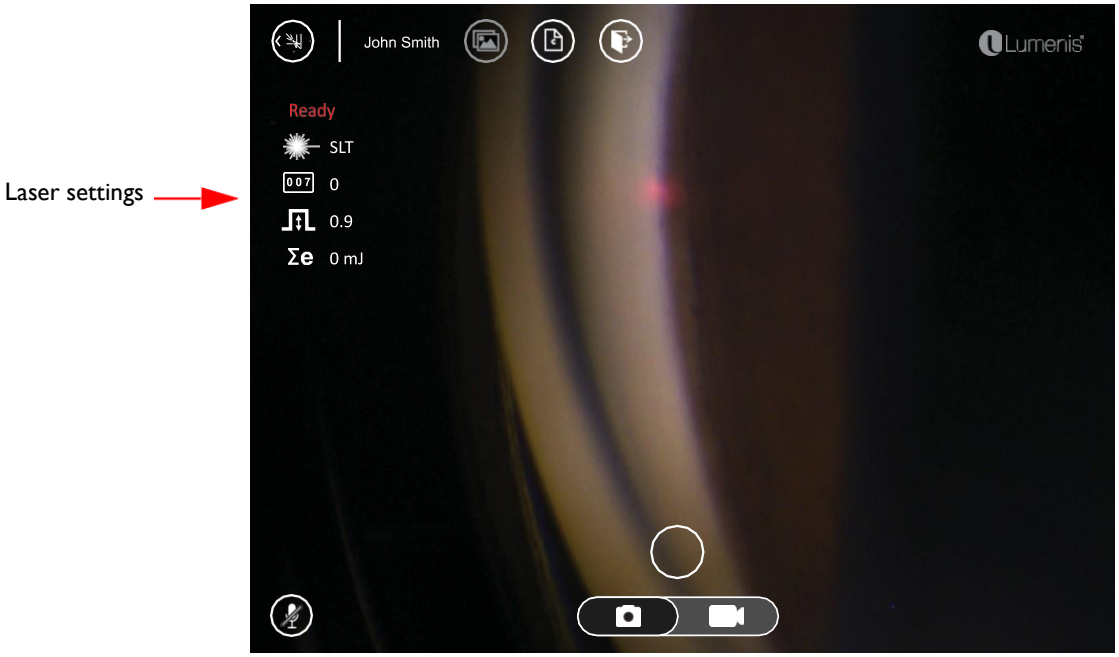
Change date formats (USA/EU)

- The date format you've selected will be saved for future uses.
- After filling the patient details, images can be captured and videos can be recorded.

Live Image

- Capturing an image can be done either by clicking on the button on the display, or by clicking on the Capture button on the slit lamp base. Note the image mode is selected.
- Recording a video can be done either by clicking on the button on the display, or by clicking on the Capture button on the slit lamp base. Stopping the video is done by clicking the same buttons. Note the video mode is selected before recording a video.
- A video recording can also include a sound. The microphone icon indicates if the microphone is muted or not. Clicking on the button will change the microphone status. The microphone is muted by default.
- The laser icon will take you back to the laser settings screen, where you can adjust the laser settings.
- Once the laser is in READY mode, the laser settings will also appear on the live image.

WARNING - Do not perform treatment while looking at the display.



Live Image in "READY" mode

- If the area of interest in the live image appears too dark, you can press and hold your finger for two seconds on the selected area; a yellow square will appear for a second, and then the image will be optimized in order to view the area of interest more clearly.

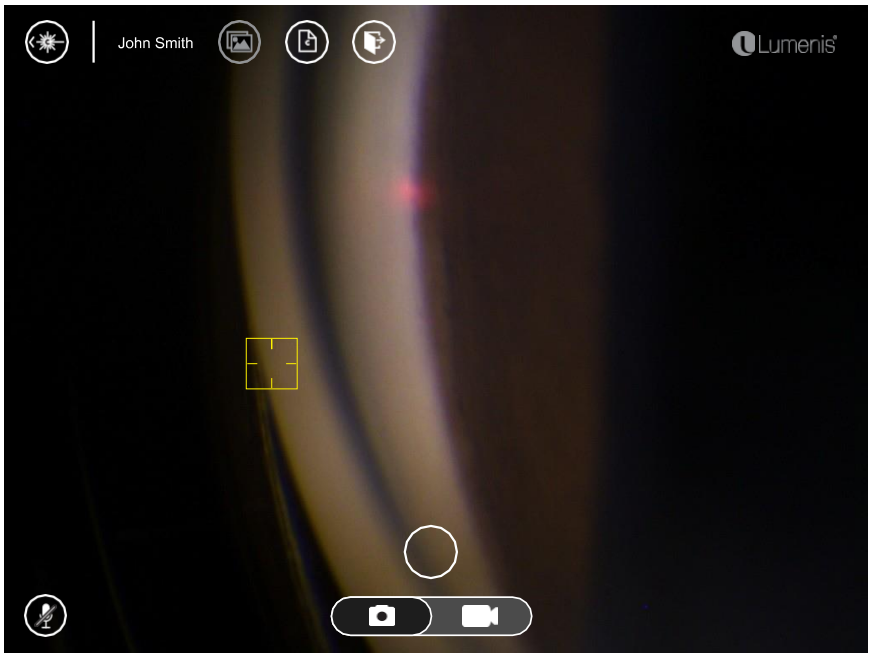
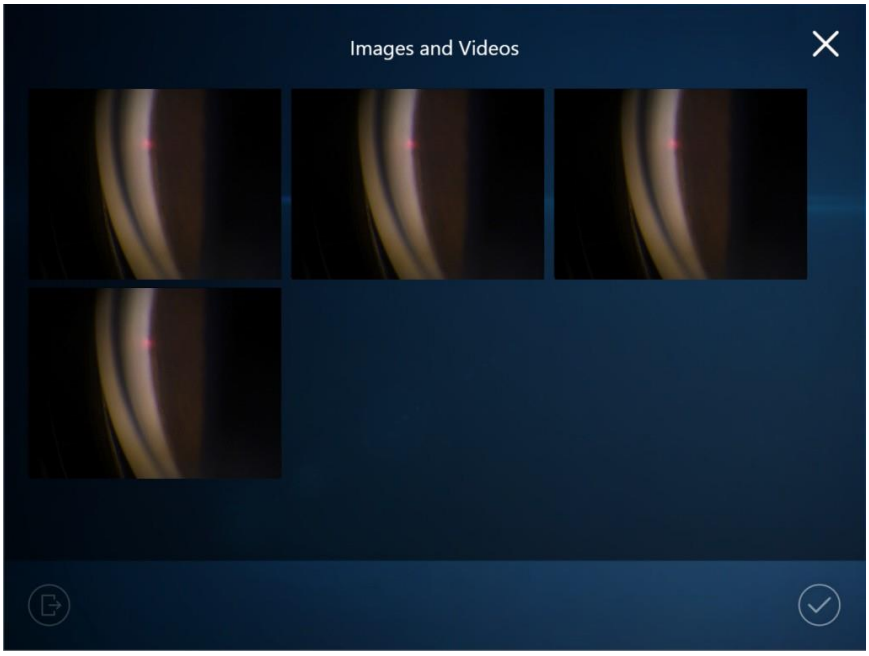


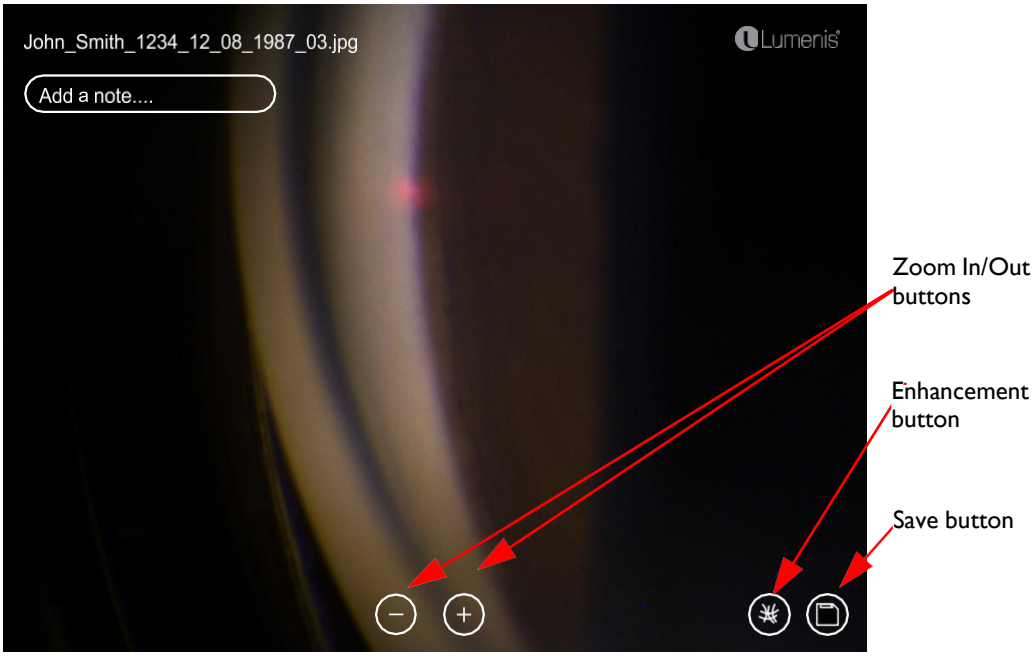
Image area brightness enhancer

- Pressing on the “Gallery” icon, will display all the images and videos which were taken to this point, for the specific patient.



View existing images or videos

- In order to view an image in full screen or playback a video, click on the thumbnail, and press on the **V** icon on the bottom right of the screen.
- In order to export images and\or videos externally, select the desired thumbnails, and click on Export icon (bottom left of screen).
- When viewing an image on the full screen you can zoom in and out, add notes to it, and\or apply an enhancement algorithm to it. After applying the changes, click on the **Save** icon in order to save the changes.



Make changes to an image

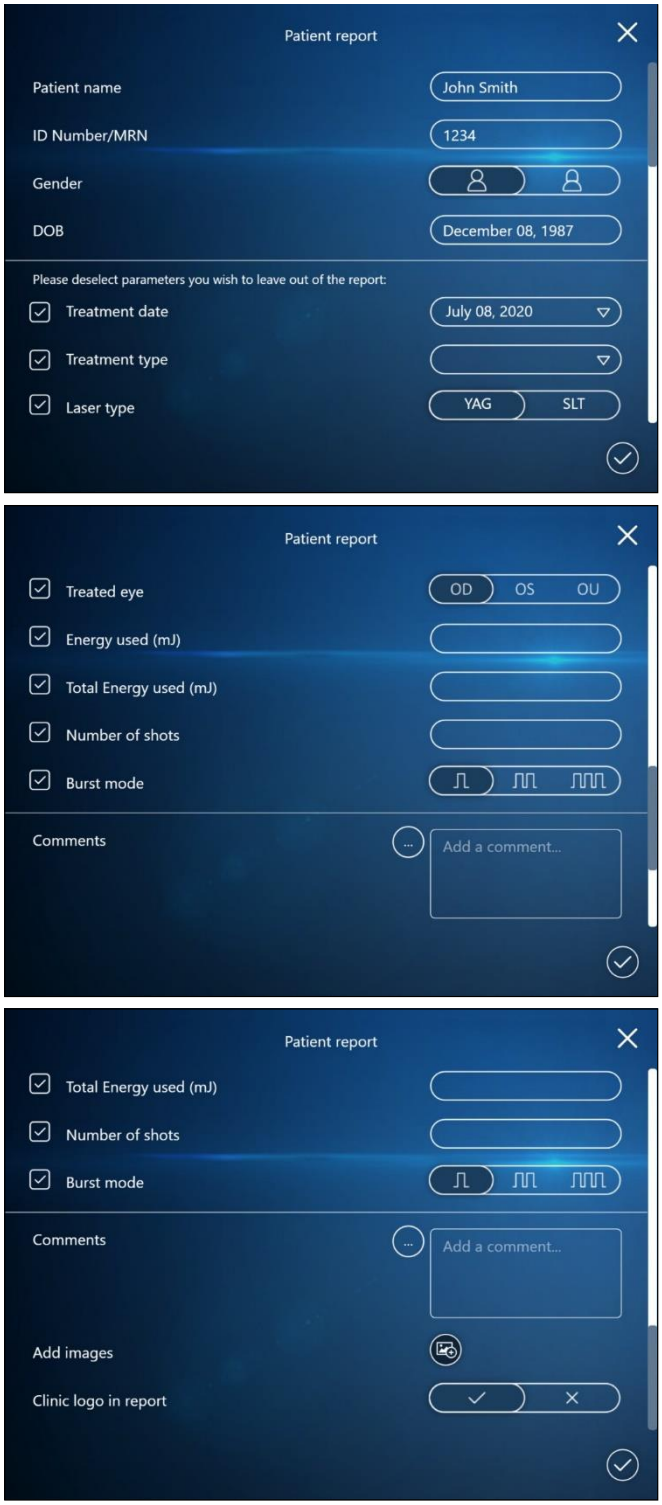
- Then select if you would like to export to a USB flash drive, or to the shared network folder (see section 2.11. for more information).
- You can also check the **Image Auto Export** option, if you prefer captured images to be exported automatically, avoiding the need to export them manually. Note that the **Auto Export** images feature applies only for images. It does not apply to videos and reports.

Export dialog box

- The USB flash drive must be connected to the display in order to select this Export method. It is recommended to use a USB 3.0 storage device, and to connect it to the USB 3.0 connection port in the display, in order for files transfer speed to be faster.
- Export to shared network folder is enabled, only if such folder was defined during the installation of the system, with the service technician (see section 2.11. for more information).

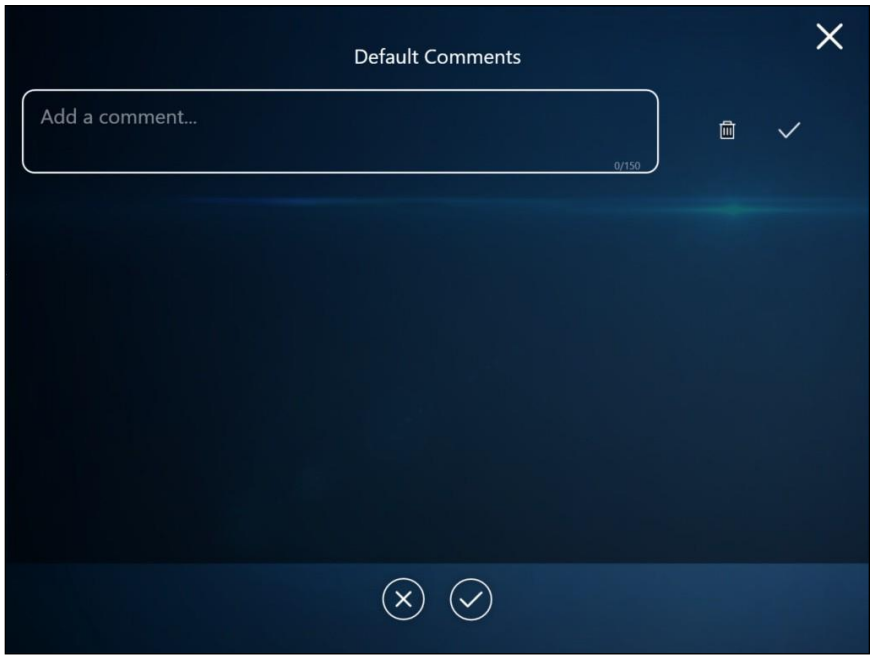
2.9. Treatment Report

It is possible to generate a treatment report after the treatment has ended. Clicking on the **Report** icon will open a treatment report dialog.



Patient Report Screens

- Some of the fields will be auto filled, according to data which was previously entered, or laser settings data which was obtained from the software. Other fields can be filled manually. The check-boxes on the left indicate which fields you would like to see in the final report.
- You can add to the report up to 4 images from the previously captured images. Clinic logo can appear on the report, in case it was predefined during the system installation, together with the service technician.
- Comments can be added to the report manually. By clicking on the "…" icon, It is also possible to add "default comments" which can be used in future generation of treatment reports.



Comment Dialog Screen

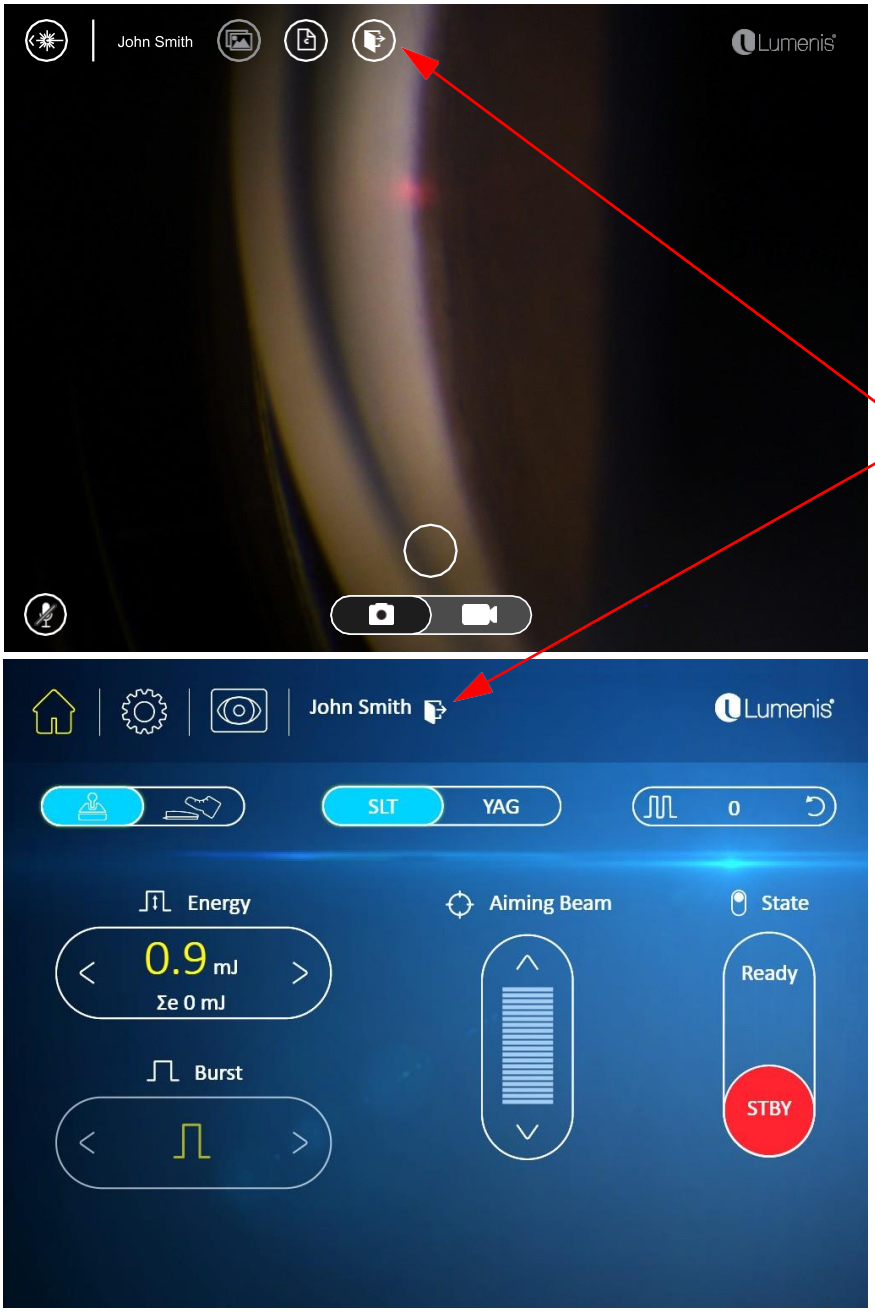
- Clicking on the “V” icon on the bottom right of the screen, will open the export dialog, asking you where you would like to export the report to a USB flash drive, or shared network folder.

Export Menu

- The USB flash drive must be connected to the display in order to select this Export method. It is recommended to use a USB 3.0 storage device, and to connect it to the USB 3.0 connection port in the display, in order for files transfer speed to be faster.
- Export to a shared network folder is enabled, only if such folder was defined during the installation of the system, with the service technician (see section 2.11. for more information).
- The report will be generated in PDF format and will be saved in the selected export location.

2.10. End Patient Session

- When switching between patients, you need to end the current patient session before starting a new one.
- In order to end a session, click on the **End Session** icon on the Live Image screen, or the **End Session** icon in the laser settings screen.



End Session Buttons

- Note that all images, videos and reports for the current patient will be deleted after ending a session. Pay attention to exporting all the required data prior to ending a session.
- Images, videos, and reports will also be deleted if the system is shut down before the files were exported.

2.11. Connecting to the Shared Network Folder and the EMR

The Digital Duet/Trio can connect to the local network at the customer site. Connection to the network enables transfer of images, videos and reports from the Digital Duet/Trio system to a predefined shared network folder, or to the local EMR.

The connection to the network can be either via a wired LAN connection, or via wifi.

Setting up the connection to the network and EMR is done during the system installation, by the service engineer together with the local IT support. This set up may involve providing IT permissions for the Digital Duet/Trio system, to access the local network.

The local IT network characteristics, configuration, technical specifications, must support work with Windows 10 operating system.

It is recommended that the local network be secured with Anti-Virus, firewall or other security measures.

Connecting to the EMR depends on the EMR compatibility to the Digital Duet/Trio files structure.

Connection of the Digital Duet/Trio to the local IT network, which also includes other equipment connected to it, could result in previously-unidentified risks to patients, operators or third parties. the customer IT representative should identify, analyze, evaluate, and control these risks. Changes to the IT network (such as changes in network configuration, connection of additional items, disconnection of items, update of equipment, or upgrade of equipment) could introduce new risks that require additional analysis.

2.12. Pre-Operative Setup of the Slit Lamp and Laser

WARNING - Do not use the device if the illumination is not present or cannot be made to appear after adjusting slit knobs.

WARNING - Use caution when adjusting the table up and down to prevent patient injury or discomfort.

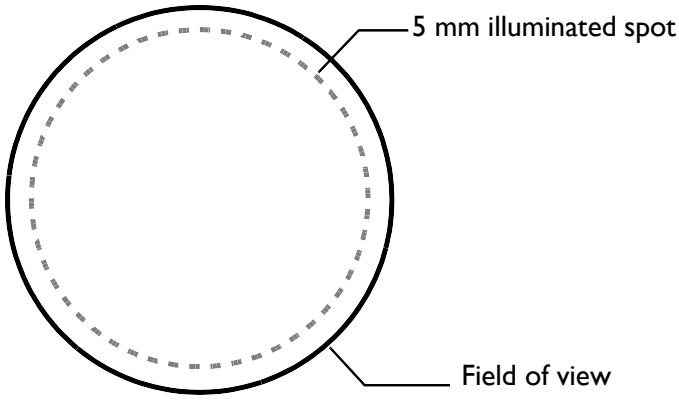
2.12.1. Focusing the Slit Lamp

To ensure that there is no focal shift between magnifications and to provide maximum working distance with the contact lenses:

1. Turn ON the system as instructed in "Turn ON the system" section of this manual.
2. Affix a paper target on the headrest so that it is visible through the slit lamp eyepieces. Do not use the slit lamp focus post as a target.
3. Use detail on the paper within the field of view as a focusing target, and adjust the aiming beam intensity to the lowest setting, until it is not visible.
4. Set the binocular eye piece diopter setting to 0 (zero).
5. Set the magnification to the highest setting, and focus the slit lamp on the target. Lock the slit lamp base.
6. Set the magnification to the lowest setting. Adjust the eyepieces, alternating from + to - to achieve the best focus on the target; complete the procedure for each eye.
7. Set the magnification to the highest setting. Unlock the slit lamp base, and focus the slit lamp on the target. Lock the slit lamp base.
8. Set the magnification to the lowest setting. Adjust the eyepieces, alternating from + to - to achieve the best focus on the target; complete the procedure for each eye.
9. Note the index number of the slit lamp eyepieces relative to the index marks as a future starting point for this procedure.
10. View the target through the eyepieces, and adjust the focus to obtain the smallest spot on the target.
11. Remove the paper target from the headrest.

2.12.2. Verify That the Slit Spot Is Centered

1. Verify that the laser system is in STANDBY mode.
2. Set the slit spot to 5 mm.
3. Set the microscope magnification to the maximum setting.
4. Visually verify that the slit spot is centered in the field of view. If the spot is not centered, contact your Lumenis service representative.



Verify that the slit spot is centered

Verify the Laser Aiming Beam Accuracy—Nd:YAG

WARNING - Verifying the aiming beam is extremely important for the safe operation of your laser equipment. Do not use the laser if the aiming beam is not visible or otherwise not functioning properly. Operating the laser without the aiming beam may result in laser exposure to non-target tissue and possible injury.

WARNING - Correct optical alignment is critical for accurate aiming of the equipment. This pre-operative procedure should be performed daily.

1 Tape a piece of laser alignment thermal-sensitive paper (Kentek Zap-It® or equivalent) onto the slit lamp headrest so that it is visible through the slit lamp eyepieces. Do not use the slit lamp focus post as a target.

WARNING - Ensure that there are no reflective surfaces behind the paper mounted on the forehead assembly.

Follow the original manufacturer's instructions regarding the proper use of thermal paper.

2 Turn ON the system as instructed in "Turn ON the system" section of this manual. Verify that the laser is in STANDBY mode.

3 Set the aiming beam to the highest intensity.

4 Look through the slit lamp eyepieces at the paper target. A red spot, the aiming beam, should appear on the paper target. If the aiming beam is weak, verify that the aiming beam is set to the highest intensity.

WARNING - Do not use the device if the aiming beam is set to the highest intensity and is still weak or not visible. Doing so may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.

5 Reduce the aiming beam to a comfortable intensity.

6 Adjust the eyepieces to the desired accommodations.

7 Adjust the slit width to full circle illumination and low intensity.

8 Swing the illumination tower to one side, if necessary, so that it does not obstruct the aiming beam. If the Smart-V illumination mirror is installed, this step is unnecessary.

9 Position the slit lamp so that the aiming beams converge to form one spot on the paper target.

WARNING - If the aiming beams cannot be made coincident, do not use the laser on patients. Doing so may cause inadvertent damage to non-target tissue and injury to the patient. Contact your local Lumenis representative.

10 Lock the slit lamp in this position.

11 Select minimum energy settings.

12 Select the READY mode.

13 Verify that the aiming beams are still converged into a single spot.

14 Depress the joystick pushbutton or the footswitch to activate the laser.

15 Inspect the burn mark through the binoculars. Verify that the burn mark on the target photographic paper is coincident with the aiming beam spot.

16 Repeat the test as necessary.

WARNING - If the laser burn mark and the aiming beams are not coincident, do not use the laser on patients as it may cause serious injury. Contact your local Lumenis representative.

2.12.3. Verify the Laser Aiming Beam Accuracy—SLT

WARNING - Verifying the aiming beam is extremely important for the safe operation of your laser equipment. Do not use the laser if the aiming beam is not visible. Ensure that it is a clear circular shape, with no part of the beam missing. Operating the laser without the aiming beam or with a poor aiming beam may result in laser exposure to non-target tissue and possible injury.

WARNING - Correct optical alignment is critical for accurate aiming of the equipment. This pre-operative procedure should be performed daily.

1 Swing the illumination tower to the center position.

2 Tape a piece of laser alignment thermal-sensitive paper (Kentek Zap-It® or equivalent) onto the slit lamp headrest so that it is visible through the slit lamp eyepieces. Do not use the slit lamp focus post as a target.

WARNING - Ensure that there are no reflective surfaces behind the paper mounted on the forehead assembly.

3 Turn ON the system as instructed in “Turn ON the system” section of this manual.

4 Verify that the laser is in STANDBY mode.

5 Turn ON the slit lamp illumination.

6 Look through the slit lamp eyepieces at the paper target.

7 Set the slit to vertical.

8 Focus each eyepiece until the target is seen clearly.

9 With the illumination set to the narrowest slit, swing the illumination tower from side to side and verify that the slit does not move on the target.

10 Open the slit and set the illumination to the smallest round aperture.

11 Set the magnification to the middle setting and view the target through the binoculars. The aiming beam should be centered in the field of view and in the center of the illumination aperture.

At high magnification settings, the spot may not appear exactly in the center of the field of view, but this will not affect the beam positioning accuracy.

WARNING - Ensure that there are no reflective surfaces behind the paper mounted on the forehead assembly.

12 Select SLT mode.

13 Select an energy of approximately 1 to 2 mJ.

14 Select the READY mode.

15 Depress the joystick pushbutton or the footswitch to activate the laser.

16 Inspect the burn mark through the binoculars. Verify that the burn mark on the target photographic paper is coincident with the aiming beam spot. A round, 400 µm burn spot should be visible if the microscope is properly focused on the target.

WARNING - If the laser burn mark and the aiming beams are not coincident, do not use the laser on patients as it may cause serious injury. Contact your local Lumenis representative.

17 Repeat the test as necessary.

2.13. Operation Instructions

2.13.1. Pre-Operative Instructions

1. Ensure that the Digital Duet system is properly connected, as described in the "Connection instructions" section of this manual.
2. Post the "Laser in Use" warning sign outside the treatment room door.
3. Verify that the pre-operative system set up, as described in this manual, was properly performed.
4. Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear, as described in the "Laser Safety Eyewear" section of this manual.
5. Turn ON the laser, as instructed in this manual.

2.13.2. Intra-Operative Instructions

1. As detailed in this manual, prepare the treatment room and verify that the laser is turned ON and in STANDBY mode.
2. Position the patient.
3. Turn ON the slit lamp illumination.
4. If used, place the contact lens in the patient's eye.
5. Adjust the slit lamp, if necessary. Verify a clear view of the target tissue.
6. Select the desired treatment parameters.

WARNING - Verify energy settings before, during, and after treatment.

WARNING - Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings until you are familiar with the instrument's capabilities. Use extreme caution until you thoroughly understand the biological interaction between the laser energy and tissue.

7. Place the laser in READY mode.
8. Depress the joystick laser pushbutton or footswitch to deliver the treatment beam to the target site.

Post-Operative Instructions

1. Place the laser in STANDBY mode.
2. Turn the system keyswitch to the **O** (OFF) position. Remove the key to prevent unauthorized use of the laser.
3. Clean the Digital Duet, as instructed in the Maintenance section starting on page 74.
4. Cover the Digital Duet with its dust cover to protect it and ensure that the optical components remain free of dust and other contaminants.

3. Maintenance

3.1. Troubleshooting Guide

If the instrument fails to operate properly, this troubleshooting guide will help you to locate and correct the malfunction. First, please check for the following items:

3.1.1. Electrical Power Source

Verify that the electrical disconnect switch, the circuit breaker, is turned on.

3.1.2. System Console Electrical

Verify that the system is on and properly connected to an electrical service outlet.

3.1.3. Delivery System Connection

Verify that the delivery system is properly connected.

3.1.4. External Door Interlock

If the external door interlock is used in conjunction with a remote switch, verify that the external door interlock plug is inserted in the external door interlock receptacle. Close the interlocked door.

Symptom	Probable Cause	Suggestion
System does not turn on, and the display will not illuminate	The system is not plugged in.	⇨ Place the electrical service disconnect switch in the OFF position, plug the laser power cord into the appropriate outlet, and turn the electrical service disconnect switch to the on position.
	The building power (main electrical service) is turned OFF.	⇨ Turn on the building power.
	The remote interlock has been activated.	⇨ Close the operating room door.
	The system is not turned on.	⇨ Verify that the system key is turned to the ❙ (on) position.
	The display is not properly connected.	⇨ Refer to the Operation section of this manual, and check the display connections.
	The emergency stop switch is depressed.	⇨ Ensure that the emergency stop switch is not depressed.
	System fuses are blown.	⇨ Check that the fuses are not blown. Disconnect the power cord before removing or changing the fuses. Refer to "Changing the Fuses" in the Maintenance section of this manual for additional information.
The display does not function.	The display is not properly connected.	⇨ Refer to "Connect the Display" in the Operation section of this manual, and verify that the remote is properly connected.
Inadequate or no aiming beam	The aiming beam is set to the lowest intensity.	⇨ Increase the aiming beam intensity, as described in "Laser Basics" in the Operation section of this manual.
	The system components are not properly connected.	⇨ Refer to the Operation section of this manual, and check the system connections.
	Slit lamp binocular eyepieces are not properly adjusted.	⇨ Refer to the Focusing the Slit Lamp section of this manual for additional information for properly adjusting the Slit lamp binocular eyepieces.

Symptom	Probable Cause	Suggestion
	Slit lamp optics are dirty.	⇨ Inspect and clean the slit lamp optics, as detailed in "User Maintenance" in this chapter.
No treatment beam is delivered when the footswitch or joystick pushbutton is pressed, or the beam is of poor quality	The laser is in STANDBY mode.	⇨ Place the laser in READY mode.
	The laser activation mode is not properly selected on the display options screen.	⇨ As detailed in the "Laser activation mode" section of this manual, verify that the correct laser activation mode is selected on the display options screen. For example, if you are using the footswitch to activate the treatment beam, ensure that the footswitch mode is selected.
	The laser components are not properly connected.	⇨ Refer to the Operation section of this manual, and check the laser system connections.
	The laser module optics are dirty or misaligned.	⇨ Contact your local Lumenis representative.
Inadequate laser power	The laser module optics are dirty or misaligned.	⇨ Contact your local Lumenis representative.
Cannot select the READY mode	The LaserLink S is attached and the Digital Duet system is in YAG or SLT laser mode.	⇨ Remove the LaserLink S.
	The slit lamp table is in motion.	⇨ Adjust the table to the desired height and position, and then select the READY mode.
	The incorrect illumination mirror is installed. Note: this is not applicable if the Smart-V illumination mirror is installed.	⇨ Install the single illumination mirror, as described in the LaserLink S operator manual.
No or inadequate slit lamp illumination	The illumination intensity control is not in the proper position.	⇨ Refer to the Operation section of this manual and adjust the illumination intensity control.
	The illumination bulb is burned out.	⇨ Contact Lumenis Customer Service.

Symptom	Probable Cause	Suggestion
	Slit adjustments are needed.	⇨ Refer to the Operation section of this manual for information on adjusting the slit width.
	Slit Lamp table power cord not plugged in.	⇨ Plug in power cable and ensure that the power switch is turned on.
	Fuse is blown.	⇨ Check that the fuses are not blown. Disconnect the power cord before removing or changing the fuses. Refer to "Changing the Fuses" in the Maintenance section of this manual for additional information.
Microscope does not focus	The eyepieces are incorrectly fitted into the binoculars.	⇨ Ensure that the eyepieces are fully inserted into the binoculars.
	The illumination bulb is faulty.	⇨ Contact Lumenis Customer Service.
Illumination is blurred	The illumination bulb is incorrectly fitted or faulty.	⇨ Contact Lumenis Customer Service.
"External room interlock" or "W104" displays on the display	The external room interlocked door has been opened or the external door interlock plug has been pulled out of the system.	⇨ Close the interlocked door, or connect the remote interlock plug, as described in the Operation section of this manual.
"Energy High >20%" or "I109" displays on the display	The detected energy level was more than 20% higher than the level selected.	⇨ Place the laser in READY mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative.
"Energy Low < 20%" or "I110" displays on the display	The detected energy level was at least 20% lower than the level selected.	⇨ Place the laser in READY mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative.
"Energy High > 50%" or "C101" displays on the display	The detected energy level was at least 50% higher than the level selected.	⇨ Place the laser in READY mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative.

Symptom	Probable Cause	Suggestion
"Energy Low < 50%" or "C102" displays on the display	The detected energy level was at least 50% lower than the level selected.	⇨ Place the laser in READY mode. If the condition continues, restart the laser. If the condition persists, contact your local Lumenis representative.
"Over Temperature" or "W106" displays on the display	The laser temperature is too high.	⇨ Place the laser in STANDBY mode. Allow the laser to cool down. Place the laser in READY mode to continue treatment. If the condition continues, contact your local Lumenis representative.
"Footswitch Not Present" or "W108" displays on the display	The footswitch is not properly connected to the laser.	⇨ Refer to the Operation section of this manual, and connect the footswitch as instructed. If the condition continues, restart the system, ensuring that the footswitch is not pressed during start up. If the condition persists, the footswitch may be defective; contact your local Lumenis representative.
	The footswitch is properly connected, but the footswitch laser activation mode is not selected on the display options screen.	⇨ Refer to the Options Screen in the Operation section of this manual for instructions on selecting the footswitch laser activation mode.
"No LaserLink" or "W110" displays on the display.	The LaserLink S delivery device is not properly connected.	⇨ Refer to the LaserLink connection instructions in the LaserLink S operation manual, and connect the LaserLink S as instructed.
If any other code displays that is not explained here...	The error condition is not user correct-able.	⇨ Contact your local Lumenis representative.

3.2. User Maintenance

3.2.1. Annual Laser Maintenance

Preventative maintenance, safety, power, and calibration checks should be performed annually by a Lumenis-certified service engineer to ensure proper laser performance.

3.2.2. Laser Repair

All laser repairs should be performed by a Lumenis-certified service engineer. For training and information, contact your local Lumenis service representative.

3.2.3. Inspecting the Laser System Components

Before and after each use, inspect the laser system components for evidence of dirt, debris, or damage.

3.2.4. Cleaning the Slit Lamp and Laser Module Optics

Before each use, inspect the slit lamp oculars and objective lens for dirt, debris, or damage. If necessary, clean the surfaces as follows:

1. Turn OFF the system power.
2. Wrap a piece of lens tissue (Kodak® or equivalent) around one end of a cotton-tipped applicator (Puritan® or equivalent non-glued tip applicator).
3. Place several drops of reagent or 100% ethanol or methanol on the tissue.

Do not use ethanol or methanol to clean the external surfaces of the console or slit lamp. Doing so may harm the surface.

4. Wipe the optic gently in one direction with lens tissue to remove all dust and debris. Do not wipe in more than one direction, as loose particles might be dragged across the surface and scratch the optical coating.

The optics have delicate coatings. When cleaning, wipe them gently, and avoid getting fingerprints on them. If an optic appears to be damaged, contact your local Lumenis representative.

Never use dry swabs or tissues to clean optics. They may damage the optical coatings or scratch the surface.

3.2.5. Cleaning the External Surfaces of the Laser Console and Slit Lamp

Clean the external surfaces of the laser console and slit lamp before every patient. Use a cloth dampened with a non-caustic cleaning solution, such as soap and water, 70% isopropyl alcohol, or a "hospital-grade" disinfectant, to wipe the external surfaces of the laser console and slit lamp. Dry with a clean cloth, or allow to air dry.

⚠ **CAUTION -** Do not spray or pour cleaning agents directly on the laser console. You may damage the console and laser system electronics.

3.2.6. Cleaning Areas of Patient Contact

The Digital Duet laser treatment involves only brief skin contact with the patient, but attention should be given to the possibility of cross-contamination between patients. The areas of skin contact include the slit lamp table, chin rest, headrest and handles.

3.2.6.1 Responsibilities of the Health Facility

Follow your institution's standard procedures and guidelines for cleaning areas of patient contact, such as:

- determining the level of cleaning required between patients.
- developing appropriate education and training for proper cleaning.
- ensuring that routine cleaning methods used in the facility are compatible with the device.
- scheduling and performing a routine cleaning regimen.

3.2.6.2 Guidelines for Cleaning Patient Contact Areas

The following is provided as a general guideline:

- thorough cleaning of all patient contact areas is recommended before every new patient.
- disposable chin rest papers can also be used (chin rest papers are supplied with the Digital Duet and can be ordered separately).
- the system may be cleaned by wiping all contact areas using a suitable, hospital-grade liquid cleaning agent that is non-corrosive, non-toxic and low in residue.

3.2.7. Clean the Gonioscopy Contact Lens

The Lumenis Digital Duet contact lenses have a special low-reflectivity coating bonded to the lens, and so must, therefore, be handled carefully. As soon as a lens is removed from a patient's eye, thoroughly rinse it in cold or warm water to remove salts, mucous and gonioprism solution. Wash in warm water with a few drops of clear dish-washing liquid, then rinse with cool water and blot dry. Dry completely before storing it in the case.

3.2.8. Water Utilities

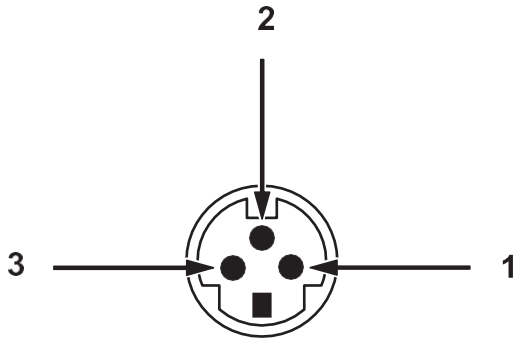
No water utilities are required for this laser. It has a self-contained cooling system.

3.3. External Door Interlock Pin Assignments

The external door interlock is a safety feature that disables the laser if the treatment room doors are opened or the interlock plug is removed while the laser is in READY mode.

The interlock can be set up with a remote switch, or an external switch can be wired to the interlock plug. Plug wiring shall only be performed by a qualified electrical professional. Total length of cable shall not exceed five meters
(16 feet).

Pin assignments are as follows:

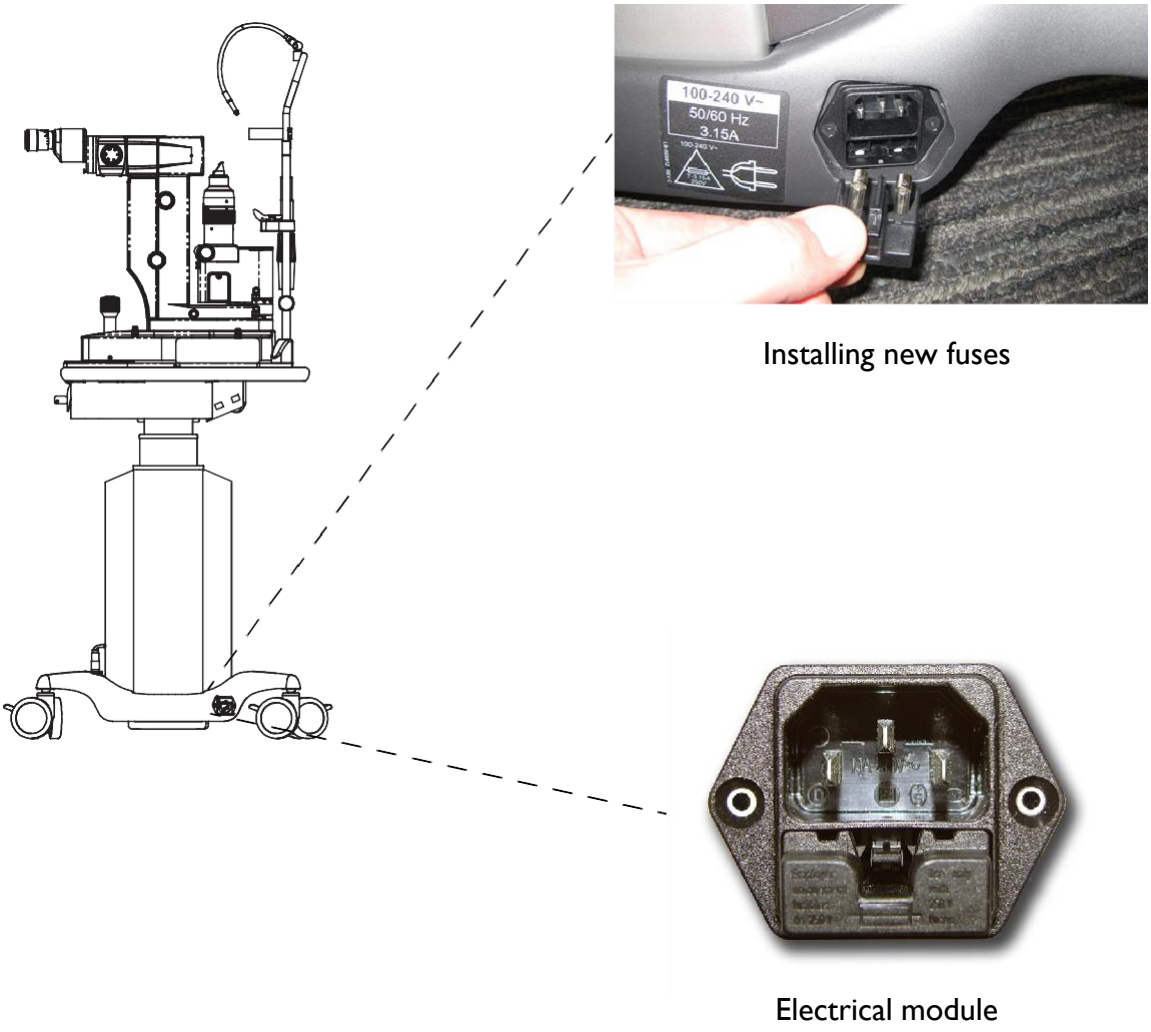


Pin	Signal Name	Signal Description
1	Remote Interlock	Connect to switch, normally open
2	Return	Connect to switch common
3	None	No connection

Remote door interlock pin assignments (mating face shown)

3.4. Changing the Fuses

1. Turn OFF the system.
2. Remove the power plug from the wall receptacle and unplug the cord from the system's main power receptacle.
3. Locate the electrical input module, which is adjacent to the main power receptacle.
4. Unlock the electrical input module cover by inserting a small flathead screwdriver into the slot. Gently push against the locking tab until the lock releases. Remove the fuse cover.



Changing the fuses

5 Replace the two 5 millimeter by 20 millimeter fuses with the appropriate replacement fuses as indicated below:

Voltage Configuration	Fuse Rating
100-240VAC	3.15A

Fuse Table

6 Place the cover back onto the module. Gently push against the cover until the locking tab latches.

3.5. Energy Calibration

Energy calibration should be performed annually by a Lumenis-certified service engineer to ensure proper laser performance. Calibration must be performed by an engineer or technician qualified to work on energized electronic laser equipment. Calibration questions should be referred to your local Lumenis representative.

3.5.1. Disclaimer Warning

Calibration is a service procedure to be done only by Lumenis-certified service engineers or customers who have taken and passed a Lumenis Service Certification Training course. Adjustment by anyone other than a trained Lumenis service engineer or a certified customer voids any existing manufacturer's warranty on the instrument. A service manual for the laser may be purchased from Lumenis. It is company policy not to distribute service tools outside of the Lumenis service organization. Possession of service instructions or tools does not authorize repair or modification of a Lumenis instrument by uncertified personnel.

3.5.2. Calibration Procedure

3.5.2.1 Equipment Required:

If you do not have all the required equipment, call Lumenis service.

- Laser energy meter.
- Laser detector.
- Serial interface cable.
- Lumenis serial adapter cable.
- Lumenis laser detector mounting plate.
- 3mm hex driver.

3.5.2.2 Calibration Procedure:

1 Open the control drawer by removing two 3mm socket screws from under the front of the tabletop.

WARNING - Danger, high voltage! Exposure to high voltage components may result in serious injury or death!

2 Connect the meter serial connector to the Lumenis adapter cable and then to the system control board JM22.

WARNING - Danger, high voltage! Exposure to high voltage components may result in serious injury or death!

3 Turn on the system in calibration mode.

4 Run “Auto Calibrate All”.

5 The system will automatically calibrate.

6 If the system displays any error messages during calibration call Lumenis service.

7 After calibration is completed, the display will show **Operation Complete**.

8 Turn OFF the device, close the drawer, and install the drawer screws.

3.6. Electromagnetic Compatibility

Like other electrical medical equipment, the Digital Duet requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the Digital Duet must be installed and operated according to the EMC information provided in this manual. See Appendix 1, EMC Guidance and Manufacturer's Declarations.

The Digital Duet has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

WARNING - This system is intended for the use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.

WARNING - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Lumenis Digital Duet system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING - Use of this equipment adjacent to- or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING - The Lumenis Digital Duet system requires special precautions regarding EMC and must be installed and put into service according to the specific instructions for maintaining basic safety and essential performance, with regard to electromagnetic disturbances for the expected service life of this system.

3.7. Specifications

The Digital Duet Ophthalmic laser system delivers both a 1064 nm and 532 nm treatment beam; therefore, the laser specifications outlined below for each wavelength are applicable to the Digital Duet model.

	Digital Duet 532 nm laser	Digital Duet 1064 nm laser
Laser Specifications		
Type	Frequency-doubled, Q-switched Nd:YAG	Q-switched Nd:YAG
Principal output—wavelength	532 nm wavelength	1064 nm wavelength
Operating mode	Frequency doubled, pulsed	Fundamental, pulsed
Pulse duration	3 nanoseconds	3 nanoseconds
Pulse mode	single pulse	single, double, or triple pulse
Energy	0.3 to 2 mJ	**Single pulse:** 0.3 to 10 mJ, continuously variable in 0.1 to 0.5 mJ increments; **Double pulse:** 0.6 to 20 mJ, continuously variable in 0.2 to 1.0 mJ increments; **Triple pulse:** 0.9 to 30 mJ, continuously variable in 0.3 to 1.5 mJ increments.
Maximum Rep Rate	3.0 Hz	3.0 Hz
Laser beam spot size	400 µm at visual focal plane	<11 µm, 8 µm full width half maximum, calculated
Cone angle	<3°	14° to 16°
Posterior Offset	N/A	100 µm nominal, continuously adjustable from 0 to 350 µm posterior, with detents at 0, 100, 250, and 350 µm.
CDRH classification	Class IIIb	Class IIIb
IEC 60825 classification	Class 3B	Class 3B
Aiming Beam Specifications		
Type	CW Diode laser	CW Diode laser
Power	300 µW maximum	150 µW maximum
Principal output	635 nm wavelength	635 nm wavelength
CDRH Classification	Class II	Class II
IEC 60825 classification	Class 2	Class 2

	Digital Duet 532 nm laser	Digital Duet 1064 nm laser
Laser Safety Eyewear		
	Laser safety glasses with an OD5 @532 nm. Refer to the Laser Safety Eyewear section of this manual for information.	Laser safety glasses with an OD5 @1064 nm. Refer to the Laser Safety Eyewear section of this manual for information.
Electrical Requirements		
	100 -240 VAC, 50/60 Hz, 3.15 Amps	100 -240 VAC, 50/60 Hz, 3.15 Amps
Cooling		
	Air-cooled	Air-cooled
Physical characteristics		
Table height	Wheelchair accessible, 945 mm max, 695 mm min, travel ~250 mm (37.8 in max, 27.4 in min, travel ~10.4 in)	
Table width	Small: 630 mm (24.8 in) Medium: 880 mm (34.5 in)	
Table depth	Small: 400 mm (15.7 in) Medium: 450 mm (17.8 in)	
Table wheel base	Small: 520 mm x 440 mm (20.4 in x 17.2 in) Medium: 460 mm x 830 mm (18.1 in x 32.7 in)	
Weight + safe working load	56 kg max	56 kg max
Environmental requirements (operating)		
Temperature range	15°C to 40°C (59°F to 104°F)	
Humidity	0 to 75% at 40°C, non-condensing	
Atmospheric pressure	64 kPa (Maximum)	
Environmental requirements (non-operating)		
Temperature range	-5 to 55°C (23 to 131°F)	
Relative humidity	0 to 90% at 55°C, non-condensing	
Atmospheric pressure	77 kPa to 106 kPa	
Vibration	Capable of surviving transport by normal commercial recognized air, sea, and land carriers	
Shock	Lumenis shock requirements, based on size and weight	

Accessories, delivery devices, and compatible lasers		
	0642-507-01 0642-509-01 GA-1005557	Basic footswitch PowerEase Footswitch Smart532 Laser

Slit Lamp	
Type	Galilean stereoscopic microscope with converging optics
Lamp	LED, 12V, 5W
Objective lens	1.25 x, anti-reflection coating (AR) for visible and laser wavelengths.
Eyepiece lens	12.5 x, diopter adjustable in range ±5 D.
Total magnification	42 x (12.5 x eyepiece)
Magnification changer	5 positions—6 x, 9 x, 16 x, 28 x, 42 x
Interpupillary distance adjustment	55 - 80 mm
Field of view	11.3 mm diameter at 16 x magnification.
Illumination tower working distance	60 mm from center of illumination prism optical axis to focal point.
Focal length	93 mm
Slit width	0.01 to 12 mm, continuously adjustable.
Slit rotation	-90° (horizontal) to 0° (vertical) to +90° (horizontal), continuously variable. Detent at 0° and stops at ±90°.
Illumination apertures	0.2, 5, 8.9, 13.3 mm and tear drop (variable 1.7 to 12.2 mm).
Illumination filters	Green, cobalt blue, Neutral Density (ND) 28% attenuation, red and none.
Fixation lamp	Green or red, 12V.
Chin rest	Adjustable, vertical travel 50 mm (2 in), with fixation lamp.
Digital camera	High Definition (HD) resolution

3.8. Warranty Information

For specific and detailed warranty information for this instrument, please refer to the first page of your purchase "Agreement" and the last page of the "Terms and Conditions of Sale."

3.9. Decontamination of Returned Equipment

To comply with United States postal and transportation law, equipment shipped to Lumenis US offices for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for use as a "Hospital Disinfectant." To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate (provided at the back of this manual) must be enclosed in the package, or Lumenis will assume that the product is contaminated and will assess the customer with cleaning costs.

Any decontamination inquiries should be directed to the Lumenis US service offices.

4. Clinical Guide

General Clinical Instructions

4.1. Introduction

Lasers in the Selecta family (Digital Duet/Digital Trio) operate in one of two operational modes,[1] selected in the GUI: an SLT mode for selective laser trabeculoplasty in Open-angle Glaucoma (OAG), and a YAG mode for posterior capsulotomy capsule in Posterior Capsule Opacification (PCO) and iridotomy (also known as Laser Peripheral Iridotomy or LPI) inAngle Closure Glaucoma (ACG) or Primary Angle Closure Suspect (PACS).

In SLT mode, the pulse duration is 3-4 nsec, the spot size is 400 nm, and the wavelength is 532 nm. In YAG mode, the pulse duration is the same, the spot size is 8 µm and the wavelength is 1064 nm. It is essential for the physician to make sure that the correct operational mode is selected, according to the desired procedure. Using an incorrect operational mode may result in serious ocular injuries.

4.2. Selective Laser Trabeculoplasty- Treatment Guidelines, Mechanism of Action, Complications and Precautions

4.2.1. Treatment Guidelines

In the Digital Duet/Digital Trio systems, selective laser trabeculoplasty is performed using the SLT mode only (wavelength: 532 nm, spot size: 400 µm).

Prior to treatment, a topical anesthetic is administered to the eye to be treated. A standard gonioscopy lens without magnifying optics is placed on the eye to be treated. The pigmented Trabecular Meshwork (TM) is brought into focus using the slit lamp. The aiming beam must be used to target the area to be treated, and therefore treatment must not start until the aiming beam is clearly seen.

Before treatment, make sure that the angle is adequately opened and that the TM is clearly visualized.

Treatment must be performed when the physician visualizes the TM via the binocular pieces only. When lasing the tissue must not be visualized with the external display.

Treatment consists of delivering non-overlapping YAG laser pulses over the pigmented TM layer. Some physicians prefer to cover 180 degrees only

1. Excluding the photocoagulator part in the Digital Trio and Digital Trio systems. Instructions for using the photocoagulator part (The Novus Spectra system or the Smart532 system) are described in the respective operator manuals of these systems.

(approximately 50 laser pulses), but others prefer covering the entire 360 degrees (approximately 100 laser pulses). While several studies found that a 180° treatment with the SLT can provide sufficient outflow of aqueous to lower the mean IOP, other studies suggested that a 360° treatment might be more effective, especially in lowering IOP fluctuations.[1] In case of a 180° and 360° treatment, approximately 50 and 100 adjacent non-overlapping laser pulses are required, respectively.

The optimal energy level for treatment is defined as the maximal energy that can be delivered without causing mechanical damage (which would be induced by optical breakdown). This optimal energy level varies from patient to patient because optical breakdown, as evidenced by bubble formation, is primarily determined by the level of pigmentation in cells of the TM.

To determine the optimal energy level for treatment, a titration procedure must precede the treatment: the laser energy should be set initially to a low fluence, for example 0.4 mJ. A single laser pulse should be delivered, using the footswitch or the trigger button on the slit lamp joystick, to either the six- o'clock or twelve-o'clock position of the TM. The energy level should be gradually increased in increments of 0.1 mJ until fine cavitation bubbles (commonly known as 'champagne bubbles') are observed. The energy level at which bubble formation starts to appear is the "threshold energy". After the threshold energy has been identified, the laser energy level should be decreased just below this threshold, by reducing the energy by 0.1 mJ; treatment should continue at this energy level until 50 (±10) single, non-overlapping laser spots have been confluently delivered along 180° of either the nasal or temporal segment of the TM.

4.2.2. Selective Laser Trabeculoplasty- Mechanism of Action

Selective laser trabeculoplasty is based on the principle of selective sub-threshold stimulation of pigmented cells within the trabecular meshwork (TM). The precise mechanism of action in not completely understood, but experimental studies demonstrated that sub-threshold stimulation of these cells triggers a range of biological mechanisms such as cytokine secretion, matrix metalloproteinase induction, increased cell division, re-population of burn sites and macrophage recruitment,[2] which together increase the aqueous outflow and reduce the IOP.

For selective laser trabeculoplasty, lasers in the Selecta family achieve their intended effect by emission of single, 532 nm, short-duration and low-fluence laser pulses. The 532 nm wavelength selectively targets melanin granules stored within pigmented cells of the TM. The short duration (3 nsec) of laser pulses minimizes the amount of heat dissipated from these

1. Prasad et al 2009 (*J. Glaucoma,* 18(2), 157-60); Shibata et al 2012 (*J. Glaucoma,* 21(1),17-21)
2. Kagan et al 2013 (*Clin Exp Ophth.* 42(7), 675-81)

melanin granules, thus minimizing collateral damage within the TM cells and in surrounding tissues. The low energy (below the energy required for optical breakdown) reduces the risk of photo-mechanical damage caused by acoustic waves, which normally accompany an optical breakdown.

4.2.3. Selective Laser Trabeculoplasty- Warnings

4.2.3.1 Contraindications

Selective laser trabeculoplasty is contraindicated in patients with neovascular glaucoma and angle closure glaucoma.

4.2.3.2 Risks

As with any surgical procedure, there are risks involved in Nd:YAG selective laser trabeculoplasty, including mild transient anterior chamber inflammation, transient IOP increase of more than 10mm Hg, conjunctivitis and eye pain.
A number of other complications occurred at incidences below 1%, including blurred vision, iritis, corneal edema, corneal lesion and headaches. Although not considered treatment-related, another potential complication of selective laser trabeculoplasty is the formation of peripheral anterior synechiae.

4.2.3.3 Precautions

The following precautions are suggested when using the Digital Duet/ Digital Trio for selective laser trabeculoplasty:

- To reduce the risk of damage to non-targeted tissues, the treatment energy should be the minimal energy necessary to perform the treatment. Caution should be exercised when using pulse energies exceeding 1.4 mJ.
- Blood vessels present in the angle should be avoided due to the risk of hemorrhage.
- Caution should be exercised when treating patients with pre-existing anterior chamber inflammation (e.g., uveitis and iritis), since the procedure itself may induce a mild, anterior chamber inflammatory response.
- Ocular surgery should be performed only when the structures to be treated, and the aiming beam, can be clearly visualized.
- Lasing should be performed only when the tissue of interest is visualized through the slit lamp binoculars.

4.3. Posterior Capsulotomy—Treatment Guidelines, Warnings, Risks and Complications

In the Digital Duet/Digital Trio systems, posterior capsulotomy is performed using the YAG mode only (wavelength: 1064 nm, spot size: 8 µm). Photo-disruption with these systems is intended for posterior capsulotomy and iridotomy (also termed Laser Peripheral Iridotomy, or LPI).

As in all surgery, there are risks involved and use of the laser may be contraindicated for patients with certain pre-existing ocular pathologies. Objective assessment of potential patients for these procedures must be performed in light of the risks.

For optimal treatment, the objective is to use a minimal number of laser pulses to achieve the desired tissue effect, depending on the procedure. The initial energy should be set to the lowest possible effective level, and gradually increased until the desired tissue effect is achieved. For posterior capsulotomy, the energy level required to create an opening depends on the toughness of the capsule: if the capsule is tough or scarred, higher energy levels may be required.

Unlike photocoagulators (such as argon, krypton, ruby, or frequency-doubled non-Q-switched Nd:YAG laser), which principally act on the chromophore of the target tissue and which primarily produce a thermal effect, the brief 1064 nm pulse of the Nd:YAG laser acts principally on water in tissue and produces a cutting or disrupting tissue effect. Therefore, this laser will damage any tissue or structure on which the beam is focused. Care should be taken to avoid inadvertent damage to non-target tissue.

WARNING - Care should be taken to focus the laser only on intended target tissue. In addition, the physician should be aware of non-target tissue that may be beyond or near the target treatment area. Do not focus the laser on or near iris blood vessels because shock waves generated by an optical breakdown may produce bleeding and induce astigmatism. The beam should never enter the eye at greater than 30° from the visual axis.

4.3.1. Treatment Guidelines

In the Digital Duet/Digital Trio systems, posterior capsulotomy is performed using the YAG mode only (wavelength: 1064 nm, spot size: 8 µm). Posterior capsulotomy is indicated for disruption of the posterior capsule and creating a clear visual pathway in case of posterior capsule opacification. Disruption is achieved by generating an optical breakdown. Acoustic waves generated by the optical breakdown are disrupting (tearing or perforating) the tissue of interest.

4.3.1.1 Targeting

In YAG mode, the aiming beam is dual: the two aiming beams coalesce at the focal point. In such dual aiming beams, it is important to keep in mind that the Nd:YAG beam extends beyond the focal point, albeit with reduced fluence as one moves away from the focal point. Hence, for example, when focusing the Nd:YAG beam on the posterior capsule, in pseudo-aphakic eyes the Nd:YAG beam might also affect the IOL and pit it. To prevent this, the focal point of the Nd:YAG beam should be slightly defocused posterior to the plane at which the two aiming beams coalesce. The Lumenis laser systems are equipped with a posterior offset button which can achieve this defocus (4 different offsets: 0, 100 µm, 250 µm and 350 µm). So for example, setting the posterior offset to 100 µm will cause the focal point of the Nd:YAG beam to be 100 µm behind the point where the two aiming beams converge. This option can be used to focus on the posterior capsule while generating the optical breakdown 100 µm posterior to the posterior capsule.

The operator should not activate the laser without verifying that the aiming and treatment beams are appropriately coincident and properly targeted. In addition, the treatment beam path must not be obstructed by other non-target tissues. Care should be taken when working at the iris margin or at a wide angle to the patient's visual axis.

4.3.1.2 Energy Settings

To reduce risk of damage to non-target tissues, the lowest possible energy level should be used, beginning with 1 mJ and increasing the energy as required. The burst-mode capability should not be used initially for capsule dissection. Burst mode should be used only when increasing levels of single-pulse energy have not been successful in opening the capsule. If the capsule is tough or scarred, higher energy pulses may be required. It is recommended that the increase be in 0.1 mJ increments. Clinical experience indicates that the mean power level used is 2.7 mJ, and 97% of the patients were treated at less than 5 mJ.

The minimum number of pulses required to obtain an adequate opening should be used. 5-10 pulses may be sufficient to create an adequate and optimal opening by an experienced laser surgeon, but more pulses may be required for tough or scarred capsules. The risk of IOL damage increases with the increasing energy level and number of pulses used. Once an opening has been established, it is enlarged as necessary, until the capsulotomy is adequate. Capsulotomy size is determined by the size of the pupil in ambient light conditions (about 4-5 mm).

4.3.1.3 Post-Operative Instructions

Topical steroids should be used for any significant post-operative inflammation. Cornea, iris, and IOL status should be evaluated after procedures in which high pulse energies were used. IOP spikes that may follow a Nd:YAG laser posterior capsulotomy should be closed monitored as well.

4.3.2. Warnings and Precautions

4.3.2.1 Contraindications

The following represent contraindications for posterior capsulotomy:

- Pre-existing ocular pathologies including:
  - Corneal edema that interferes with visualization of the capsule.
  - Diffused haze of the aqueous humor.
  - Extensive corneal dystrophy.
- Chronically elevated intraocular pressure (IOP), especially when uncontrollable under medication.
- Eyes with no potential visual function.
- Patients with glass posterior chamber intraocular lenses (IOL), except those patients whose medical condition precludes invasive surgery.
- Variations in IOL material and geometry may affect YAG procedural parameters and clinical success. Consult the IOL implant packaging and/or the IOL manufacturer for special considerations.

4.3.2.2 Risks

As with any surgical procedure, there are risks involved in Nd:YAG laser posterior capsulotomy. Major risks include:

- Significant transient elevation of intraocular pressure (IOP).
- Persistent elevation of IOP.
- Cystoid macular edema.
- Rupture of the anterior hyaloid face and anterior displacement of the vitreous.
- Retinal damage, including retinal detachment and macular holes.
- Iris bleeding.
- Uveitis

The potential impact of using of high energy per pulse, and high total energy, must be considered. As fluence increases, the anterior shift of the plane of optical breakdown from the focal point, and elongation of the breakdown region, become more significant. These effects may result in increased risk of injury to the corneal endothelium or the iris and, in pseudophakic patients, could result in pitting of the intraocular lens (IOL). Cornea, iris and IOL status should be evaluated prior to, and monitored closely during and after procedures in which high pulse-energies are used. In addition, the transient rise in IOP that may follow an Nd:YAG laser posterior capsulotomy should be monitored as well.

4.3.2.3 Patients at Special Risk

The following patients are at special risk when undergoing Nd:YAG posterior capsulotomy:

- Extra-capsular cataract extraction patients without a patent iridectomy are at an increased risk of pupillary block.
- Aphakic patients are at increased risk of immediate post-operative IOP elevation.
- Patients with pre-operative glaucoma, prior filtering surgery or pre-operative IOP of greater than 20 mm Hg, or other evidence of deranged aqueous dynamics or poor facility outflow, are at a significantly higher risk of post-operative IOP rise to levels of clinical concern.
- Patients with posterior chamber lenses close to the posterior capsule are at risk of IOL pitting or cracking.
- Patients with pre-existing ocular conditions have a greater chance of experiencing post-operative complications.
- In patients with difficulties in fixating the risk of inadvertent lasing at non-target tissues is increased.
- Patients with vascularization of any target membrane are at increased risk of bleeding.

4.3.2.4 Poor Candidates for Posterior Capsulotomy

Patients with any of the following conditions may not be suitable candidates for posterior capsulotomy or because the procedure may not improve visual acuity or visualization of the posterior segment, or may pose a special risk to the patient's eyesight:

- Active ocular disease.
- Nystagmus, blepharospasm, or other neurological conditions that make ocular fixation impossible.
- Slight or moderate haze of the aqueous humor or cornea.
- Inability to cooperate in positioning and immobilization.

- Poor vision (20/40 or worse) when the optical media (including the capsule) are clear.
- Visual acuity better than 20/30 with no glare or poor reading vision.[1]

4.3.2.5 Precautions

- **Inadvertent Patient Movement:** Mis-aiming the laser or movement of the patient may result in damage to non-target ocular tissue or the area surrounding the target tissue. If the patient cannot fixate, use of a contact lens or retrobulbar anesthesia injection is recommended.
- **Visualization of the posterior capsule during lasing:** Treatment must be performed when the physician visualizes the site of iridotomy via the binocular pieces only. This comment is relevant for the Digital Duet/Digital Trio systems- in those systems, when lasing the tissue must not be visualized with the external display.
- **Targeting:** Focus the slit lamp in accordance with the description provided in the Operation section of this manual. Unlike other lasers commonly used in ophthalmology (argon, krypton, dye lasers) which rely on thermal effects, the 1064 nm Nd:YAG laser is a cutting or disrupting instrument capable of damaging any tissue or structure on which the beam is focused. Therefore, the Nd:YAG laser should only be focused on target tissues and care should be used to avoid exposure of all adjacent tissues and structures.
- **Energy:** To reduce risk of damage to non-target tissues, the lowest possible energy level should be used (see **Treatment Guidelines**). In the presence of edematous, clouded, scarred or irregular astigmatic corneas, the laser beam may be less effective, necessitating higher energy settings to obtain optical breakdown. Medical judgment must be used to determine whether the corneal condition in such circumstances contraindicates laser posterior capsulotomy.

1. A patient with a visually significant PCO that warrants a YAG capsulotomy should have a visual acuity of 20/30 or worse with Snellen conditions, contrast sensitivity, or simulated glare testing, affecting activities of daily living, and no other possible cause for decreased vision found (Corcoran S. Coding and reimbursement: Continuing questions about YAG. *Ophthalmology Management.* December 2010).

4.3.3. Complications and Adverse Events

Below is a list of adverse events that may be related to Nd:YAG posterior capsulotomy:

- IOP rise to 50 mm Hg or greater, regardless of duration.[1]
- IOP rise to 30 mm Hg or greater persisting for one week or more.
- Inflammatory reactions (e.g., iritis, vitritis, uveitis).
- Retinal complications (e.g., retinal hemorrhage, retinal tears or holes, retinal detachment, and cystoid macular edema).
- Pupillary block.
- Anterior hyaloid face rupture.
- Intraocular lens damage (including pits, fractures or dislocations).
- Ocular bleeding.
- Secondary glaucoma.
- Hyphemia
- Anterior displacement of the vitreous.
- Vitreous movement with corneal touch.
- Corneal injury (including damage to the endothelium, stroma or epithelium).
- Anterior chamber injury (including loose cortex, or capsular fragments, flare, cells or debris).
- Vitreous chamber injury (including loose cortex or capsular fragments).
- Generalized endophthalmitis with vitreous involvement.
- Corneal edema.
- Neovascularization of the iris.
- Iris damage.
- Vitreous hemorrhage.

Following are more details about several of these adverse events:

4.3.3.1 Intraocular Pressure Rise

Significantly increased IOP has been reported in a substantial number of laser- treated patients, particularly those presenting with pre-operative glaucoma or pre-operative IOP of greater than 20 mm Hg, and those with

1. Hospitalization may be required for institution of IOP- reducing therapy. Pain/nausea may accompany such a significant IOP rise.

other evidence of deranged aqueous dynamics or poor outflow facility. Other risk factors for elevations of IOP include:

- Use of high amounts of energy during the procedure.
- Absence of an IOL.
- Use of cycloplegic drugs.

Physicians should carefully monitor all patients for IOP rise in the 2-5 hours after treatment with the laser. Patients who exhibit a pressure rise generally return to pre-treatment levels within 24 hours but should be carefully followed throughout this period. Persistent IOP elevation occurs in some patients.

Clinical estimates are that 2-3% of patients may be treated for secondary glaucoma.

Medical therapy should be instituted as circumstances and medical judgment dictate. Persistent administration of an oral hyperosmotic agent in the first several hours after treatment may be warranted.

4.3.3.2 Inflammatory Reactions

Anterior uveitis of moderate degree was observed in some cases. The incidence is less than 2%[1].

4.3.3.3 Retinal Complications

Retinal damage, such as retinal detachment, tears, holes, and cystoid macular edema, has been reported in several clinical studies. The incidence of such retinal problems remains low. Clinical estimates of these problems indicate an incidence of less than 2%.[2]

4.3.3.4 Pupillary Block

Extra-capsular cataract extraction (ECCE) patients who did not have a concurrent iridectomy are at increased risk of pupillary block. Although the incidence is low, the patients should be advised that if symptoms of pupillary block occur (such as pain), they should immediately contact the treating physician.

4.3.3.5 Anterior Hyaloid Face Rupture

A proportion of patients (about 25% in clinical studies) may experience rupture of the anterior hyaloid face. This potential is greater for aphakic

1. Chambless 1985 (Am. Intra-Ocular Implant Soc J, 11(1), 31-32).
2. A patient with a visually significant PCO that warrants a YAG capsulotomy should have a visual acuity of 20/30 or worse with Snellen conditions, contrast sensitivity, or simulated glare testing, affecting activities of daily living, and no other possible cause for decreased vision found (Corcoran S. Coding and reimbursement: Continuing questions about YAG. *Ophthalmology Management.* December 2010).

patients (no IOL present). Such patients are at increased risk of anterior vitreous movement from the normal plane. In the event of vitreous movement to the cornea, an increased incidence of corneal edema may result.

Focusing the laser is recommended, posterior to the target treatment plane (particularly in pseudophakic patients), then moved anteriorly as required. In aphakic patients, the alternative technique of focusing anterior to the target treatment plane and moving posteriorly can be used.

4.3.3.6 Intraocular Lens Damage

Pitting or marking of IOLs occurs in Nd:YAG laser posterior capsulotomy with several clinical studies reporting a 25% or greater incidence. The potential of IOL damage is a function of lens type, proximity to the posterior capsule, the level of laser energy used, and physician experience. Risk of damage increases if the patient has a posterior chamber IOL, if the posterior capsule lies close to the IOL, and as the total amount of energy employed to effect capsule opening increases.

Posterior chamber lenses, particularly those close to the posterior capsule, have the greatest potential for damage. This potential can be minimized by carefully focusing behind the lens in pseudophakic patients, by optimizing the view of the posterior capsule with the use of a contact lens, by avoiding repetitive pulses to the same area, and by using the lowest energy setting necessary to open or sever the membrane.

Numerous pits on the IOL may result in glare, which can affect the visual outcome. Physicians who experience problems with continued pitting should consider ending the treatment.

To minimize the risk of pitting the IOL, the aiming beam can be offset longitudinally up to 0.35 mm in front of the Nd:YAG beam. Physicians who experience continued focusing problems, which can lead to IOL pitting, should first check the ocular setting of each eyepiece on the slit lamp. If this does not correct the problem, contact your Lumenis service representative for assistance.

Use extreme caution in assessing patients with glass IOLs for Nd:YAG treatment. Instances of shattered glass IOLs have been reported. In such cases, explantation of the IOL may be necessary. If the Nd:YAG treatment is selected, it should be conducted on low energy and with extreme care.

An increase in IOL pitting is possible when silicon IOLs are used. We advise caution when using silicon IOLs and recommend using a 250 µm posterior offset. If pitting persists, manually position the lamp to increase the posterior offset.

4.3.3.7 Ocular Bleeding

Minimal bleeding may occur if the iris or vascular tissue is inadvertently lased. The bleeding generally stops spontaneously, but if it does not subside, this condition may require treatment or may interfere with, or be aggravated by continuation of the Nd:YAG procedure.

4.4. Iridotomy—Treatment Guidelines, Warnings and Complications

4.4.1. Treatment Guidelines

In the Digital Duet/Digital Trio systems, iridotomy is performed using the YAG mode only (wavelength: 1064 nm, spot size: 8 µm). Iridotomy is indicated for the perforation of the iris in case of angle closure glaucoma.

Optional pre-treatment of the iridotomy site with a green (532 nm) laser photocoagulator can be performed to reduce the risk of bleeding (recommended settings: spot size 400 µm, duration 0.2 sec, power 150-300 mW).

The recommended site of iridotomy is supra-nasal, such that the upper lid covers the hole and the potential for stray light is reduced. Ideally, the site of the iridotomy should be at about ¾ the distance between the pupillary margin and the iris periphery. To facilitate the creation of the hole and minimize the number of laser pulses required, the site of iridotomy should be selected where the stroma is thin (i.e., a crypt). The posterior offset should be set to **0**, and the beam should be within the iris stroma, rather than on the surface of the iris. To minimize the risk of bleeding, look for blood vessels and avoid lasing near them.

Minimal energy and a minimal number of pulses per burst should be used to reduce risk of damage to non-target areas. Burst mode is not preferred, since a hole in the iris may occur before completion of the burst, leading to damage to the anterior lens capsule. Usually several single pulses of 3-8 mJ are sufficient to create an opening, unless the iris is thickened. In a thin blue iris, a single pulse is sometimes sufficient. Pulse energy should not exceed 10 mJ, especially if the anterior chamber depth is shallow or nil.

Once a full thickness hole has been made, fluid will be observed coming out of the hole. The iridotomy should be enlarged horizontally (50-70 µm) to prevent re-occlusion. Enlargement can be done by targeting the edges of the hole with a few additional Nd:YAG laser pulses. Optionally, enlargement of the hole can be done with a photocoagulator.

If any bleeding occurs, pressure for 1-2 minutes with the contact lens is usually enough to stop the bleeding.

4.4.2. Warnings

4.4.2.1 Contraindications

The following represent contraindications for iridotomy:

- Eyes with opacities of the media such that the iris cannot be adequately visualized.
- Eyes without a pupillary block component to their glaucoma.
- Eyes with a glass IOL.

Variations in IOL material and geometry may affect YAG procedural parameters and clinical success.

Consult the IOL implant packaging and/or the IOL manufacturer for special considerations.

4.4.2.2 Risks

As with any surgical procedure, there are risks in Nd:YAG laser iridotomy, including:

- Significant transient elevation of IOP.
- Damage to the lens.
- Transient bleeding from the iridotomy margin and hyphemia.
- Localized corneal damage.
- Anterior chamber reaction (including flare, cells and debris).
- Closure of the iridotomy with time.
- Inability to control glaucoma adequately (despite a successful iridotomy), necessitating chronic medical therapy or further invasive intraocular surgery.
- Damage to the retina or choroid.

In addition, there are risks that have not been reported but which are theoretically possible in Nd:YAG laser iridotomy, including:

- Persistent elevation of the IOP.
- Rupture of the anterior hyaloid face and anterior displacement of the vitreous in an aphakic eye.

Accordingly, the physician should make an objective assessment of the potential benefits of Nd:YAG laser iridotomy in light of these risks.

4.4.2.3 Patients at Special Risk

The following categories of patients are at special risk when undergoing Nd:YAG laser iridotomy:

- Patients with chronic uveitis have an increased tendency towards both early and late iridotomy closure.
- Patients with vascularization of the iris or engorgement of iris vessels are at increased risk of bleeding.
- Patients with a bleeding tendency (as with hemophilia or those receiving anticoagulant therapy) are at increased risk of bleeding.

4.4.2.4 Poor Candidates for Nd:YAG Iridotomy

Patients with any of the following conditions may not be suitable candidates for Nd:YAG laser iridotomy due to risks of bleeding, excessive inflammation, or inability to create a successful iridotomy:

- Slight or moderate haze of the cornea or aqueous humor.
- Chronic uveitis.
- Pupillary block associated with neovascular glaucoma or with any condition causing engorged iris blood vessels.
- Tendency to bleed (as with hemophilia or patients receiving anticoagulant therapy).
- Inability to cooperate in the procedure.
- Nystagmus
- Blepharospasm

4.4.2.5 Precautions

- **Inadvertent Patient Movement:** Inadvertent or uncontrolled eye movement by the patient may result in striking tissues adjacent to the target. If a patient cannot fixate with the untreated eye to assure stabilization of the treated eye, retrobulbar anesthesia injection is recommended.
- **Visualization of the Iridotomy Site During Lasing:** Treatment must be done when the physician visualizes the site of iridotomy via the binocular pieces only.
- **Targeting:** Focus the slit lamp in accordance with the description provided in the Operation section of this manual. Unlike other lasers commonly used in ophthalmology (argon, krypton, dye lasers) which rely on thermal effects, the 1064 nm Nd:YAG laser is a cutting or disrupting instrument capable of damaging any tissue or structure on which the beam is focused. Therefore, the Nd:YAG laser should only be focused on target

tissues and care should be used to avoid exposure of all adjacent tissues and structures.

- **Energy:** Minimal effective energy and minimal pulses per burst should be used to reduce risk of damage to non-target areas. In animal studies, the use of higher total energy, larger numbers of pulses, and more pulses per burst have been associated with an increased risk of damage to the lens. Lens damage has been reported clinically in human eyes that have undergone Nd:YAG iridotomy.

4.4.3. Complications and Adverse Events

Below is a list of adverse events that are possibly related to Nd:YAG iridotomy:

- Transient elevated IOP.
- Hyphemia
- Corneal injury (including damage to the endothelium, stroma or epithelium).
- Anterior chamber reaction (including flare, cells and debris).
- Transient blurred vision immediate post-operative.
- Minor, transient, pupillary distortion.
- Corneal edema.
- Transient bleeding from the iridotomy margin.
- Closure of iridotomy over time.
- Damage to the crystalline lens (perforation or rupture).

Following are more details about several of these adverse events:

4.4.3.1 Intraocular Pressure Rise

Significant rise in IOP was observed following both argon (green) laser and Nd:YAG laser iridotomy in a substantial proportion of treated eyes. The risks of IOP elevation do not appear to differ between Nd:YAG laser and argon laser treatment. Patients should therefore be carefully monitored during the post-operative period. Clinical data suggest that if a pressure IOP rise develops, it is almost always detectable within the first two to three post-operative hours. No risk factors are known to be positively associated with this IOP rise after iridotomy. However, eyes with acute pupillary block glaucoma tend not to have this problem.

The decision to use additional medical treatment in the event of an IOP rise should be based on the status of the individual patient. Most IOP elevations resolve without intervention within 24 hours of Nd:YAG laser surgery. The treating physician should take into consideration the pre-existing condition

of the optic nerve and other ocular structures when deciding whether to treat the eyes with IOP-lowering medication.

4.4.3.2 Damage to the Crystalline Lens

Clinically visible evidence of crystalline lens damage has been reported following Nd:YAG laser iridotomies in humans, and has been noted in animal studies and in human histologic studies. The risk of lens damage during Nd:YAG laser iridotomy will increase if:

- Laser focusing is inaccurate.
- Laser energy is applied through an already patent iridotomy.
- Laser energy is applied through the pupil directly to the lens.
- Energy levels greater than 10 mJ are used.
- There is apposition of the peripheral iris to the lens as might occur with extensive posterior synechiae.

To reduce the risk of lens damage when an iridotomy is performed, the following actions are recommended:

- Ensure good patient fixation.
- Use an appropriate contact lens.
- Select an iris treatment site as far in the periphery as is practical (as with all iridotomies, the site should be located under the upper lid whenever possible).
- Focus the aiming beam on the surface of the treatment site.
- Use a minimum number of pulses per burst (i.e., it is advised to avoid using more than one pulse per burst).
- Use the lowest possible amount of energy per pulse.
- Avoid using the Nd:YAG laser on a site that is already totally or partially patent.

4.4.3.3 Bleeding

Mild, localized bleeding may occur in 20 to 50% of eyes undergoing Nd:YAG laser iridotomy. Mild hyphemia is rare (less than 2%) and severe hyphemia is very uncommon (less than one in 200). Unlike an argon laser, the Nd:YAG laser creates minimal heat at the treatment site and, therefore, does not cauterize vessels. Eyes with engorged iris blood vessels (active uveitic, neovascular, or angle closure glaucoma) are at an increased risk of bleeding. Patients who are otherwise at risk of bleeding (as with hemophilia or those receiving anticoagulant therapy) are also at an increased risk of bleeding and hyphema.

In otherwise normal patients with pupillary block glaucoma, bleeding usually stops spontaneously and can be controlled by digital pressure upon the contact lens. All eyes should be observed with a biomicroscope for

bleeding. If bleeding occurs, additional Nd:YAG laser treatment may aggravate it. Further, if bleeding does not stop spontaneously or after applying digital pressure, argon laser photocoagulation of the bleeding site may be necessary.

4.4.3.4 Corneal Damage

Localized corneal endothelial lesions were observed above the iridotomy site in 10-20% of eyes treated with the Nd:YAG laser. These opacities may interfere with visualization of the iridotomy. In most eyes these opacities clear within a few days, but occasionally there is a permanent, non-progressive, small- diameter opacity. The changes do not interfere with visual function. Careful laser focusing and the lower energy settings may decrease the likelihood of this problem.

4.4.3.5 Retinal Damage

Non-rhegmatogenous retinal detachment in nanophthalmic eyes and micro-perforations of the retina have been reported following Nd:YAG iridotomy.

4.4.3.6 Closure of the Iridotomy with Time

Closure of iridotomy has been reported in a small percentage of cases weeks or months after Nd:YAG laser treatments. This closure occurs most frequently in eyes with chronic uveitis. The closure rate for Nd:YAG laser iridotomies is much lower than for argon laser iridotomies. In a randomized study reported in the literature of bilateral primary chronic angle-closure glaucoma, each patient received treatment in one eye with an Nd:YAG laser and with an argon laser in the other eye. Within the first post-operative month, 9 of 50 argon laser-treated eyes experienced iridotomy closure, compared to none of the Nd:YAG laser-treated eyes.

4.4.4. Failure to Control Glaucoma

Successful iridotomies are not necessarily accompanied by long-term control of glaucoma, for several possible reasons:

- The eye may have developed Peripheral Anterior Synechiae (PAS).
- The angle may be open, but the eye may have residual open angle glaucoma.
- A combination of the above.

Patients should be monitored for persistent glaucoma.

5. EMC Appendix

5.1. EMC Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration Electromagnetic Emissions		
The Digital Duet ophthalmic laser family is intended for use in the electromagnetic environment specified below. The customer or the user of Digital Duet ophthalmic laser family should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The Digital Duet ophthalmic laser family 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.
RF emissions CISPR 11	Class A	The Digital Duet ophthalmic laser family is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning statement is heeded: **Warning:** This system is intended for use by health care professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
The Digital Duet ophthalmic laser family is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Duet ophthalmic laser family should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: Guidance**
Electrostatic Discharge (ESD) IEC61000-4-2	±8 kV contact ±15 kV air	Class A	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Class A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line(s) to line(s) ± 2kV line(s) to earth	Class A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC61000-4-11	0% U_T for 0.5 cycle 0% U_T for 1 cycle 70% U_T for 25 cycles 0% U_T for 250 cycles.	Class A Class A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Digital Duet ophthalmic laser family requires continued operation during power mains interruptions, it is recommended that the Digital Duet ophthalmic laser family be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	30 A/m	N/A	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity		
The Digital Duet ophthalmic laser family is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital Duet ophthalmic laser family should ensure that it is used in such an environment.		
Immunity Test	**IEC 60601 Level**	**Compliance Level**
IEC 61000-4-6 Conducted RF	6 V_{RMS} on 230 VAC mains and footswitch cables; 0.15 to 80 MHz, 80% AM 1 kHz.	[V] = 6 Vrms
IEC 61000-4-3 Radiated RF	3.0 V/m; 80 MHz to 2.7 GHz, 80% AM, 1 kHz	[E] = 3 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Digital Duet ophthalmic laser family system is used exceeds the applicable RF compliance level above, the Digital Duet ophthalmic laser family system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Digital Duet ophthalmic laser family unit. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

5.2. Decontamination Certificate

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

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

Individual/Institution	City, State, Country

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

The undersigned also agrees to reimburse Lumenis for any costs incurred in cleaning the enclosed equipment, in the event said item(s) is/are received by Lumenis in a contaminated condition.

Model	Model
Serial Number (if applicable)	Serial Number (if applicable)
Lumenis RMR Number	Lumenis RMR Number
Typed/Printed Name	Position/Title
Signature	Date