

**EC Declaration of Conformity to:
Medical Device Directive 93/42/EEC**

Legal Manufacturer:	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
Manufacturing Site(s):	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
EU Authorised Representative	Visiometrics, S.L., Vinyals, 131 08821 Terrassa, Spain
Device Description/Family:	Keeler Slit Lamps (See below Product Schedule)
EC Product Classification:	Class I, Annex IX, Rule 12
GMDN:	35148 – Ophthalmic slit lamp, examination A mains electricity (AC-powered), ophthalmic, binocular microscope designed to examine the interior anatomy of the eye (anterior and posterior surfaces) by viewing through the iris. It produces a narrow slit of powerful light which is projected into the eye, and resulting light reflections are detected obliquely with a travelling microscope to enable observation of the internal ocular surfaces. It is used to perform a variety of measurements [e.g., intraocular pressure (IOP) or tonometry, corneal thickness, anterior chamber depth] and to evaluate symptoms (e.g., eye itchiness, grittiness, pain, dry eyes, photophobia, and reduced visual acuity).

We herewith declare, as the sole manufacturer, that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices.

Applied Directives:	• Medical Device Directive (MDD) - 93/42/EC • Restriction of Hazardous Substance (RoHS)– 2011/65/EU • Waste Electrical and Electronic Equipment (WEEE) Directive – 2012/19/EU
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Keeler Ltd Clewer Hill Road Windsor Berkshire SL4 4AA Tel: +44 (0) 1753 857177 Email: info@keeler.co.uk
Fax: +44 1753 827145 (Customer Services) Fax: +44 (0) 1753 830247 (Manufacturing) **Website:** www.keeler.co.uk
Registered in England No.408759 Registered office: Clewer Hill Road Windsor Berkshire SL4 4AA VAT No. GB 349 0761 40

QM05 Reference 1 - DofC Template

Issue 6



Applied Standards:	• BS EN ISO 13485:2016 • BS EN ISO 14971:2012 • BS EN ISO 10993-1:2009 • IEC 60601-1:2005+ A1:2012 • IEC 60601-1-2:2014 • IEC 62133:2012 • IEC 62304:2008 • BS EN ISO 10939:2007 • BS EN 60601-1-6:2010 +A1:2015 • IEC 62366-1:2008 • BS EN ISO 15004-1:2009 • BS EN ISO 15004-2:2007 • BS EN ISO 15223-1:2016 • BS EN 1041:2008 + A1:2013 • BS EN ISO 14155:2011 • BS EN 50419:2006 • BS EN 62471:2008
Notified Body:	SGS Belgium NV SGS House, Noorderlaan – 87, Antwerp, 2030 Belgium +32 3 545 44 00 https://www.sgs.be/en/
CE Certificate Number:	Class I Self Certified
Date of Issuance of Original CE Certificate:	N/A

DofC Reference to Tech File: DofC 02

Rev: 15

Signed: 

Arminder Purewal

Date: 19 Jan 2021

Head of Regulatory Affairs
and Quality Assurance,
Keeler Ltd

**Product Schedule:
Keeler Slit Lamps**

Part Number	Device Description	Product Classification
3020-P-2000	SLH 5XC 6V TBL	I
3020-P-2000-001	SLH 5XC BULB - LARGE TABLE	I
3020-P-2001	SLH 5XC 12V Di REF	I
3020-P-2003	SLH 5XC 6V REF	I
3020-P-2003-001	SLH 5XC BULB REF STD - CHINA	I
3020-P-2004	SLH 5XC 12V Di TBL	I
3020-P-2005	SLH 5XC 12V Di TBL LEG	I
3020-P-2006	SLH 5XC LED REF	I
3020-P-2006-001	SLH 5XC LED REF STD - CHINA	I
3020-P-2007	SLH 5XC LED TBL	I
3020-P-2007-001	SLH 5XC LED - LARGE TABLE	I
3020-P-2009	SLH 5XC LED Di REF ST	I
3020-P-2010	SLH 5XC LED Di TBL	I
3020-P-2012	SLH 5XC 6V TBL USA	I
3020-P-2013	SLH 5XC LED TBL USA	I
3020-P-2014	SLH 5XC 12V Di TBL USA	I
3020-P-2015	SLH 5XC LED Di TBL USA	I
3020-P-2016	SLH 5XC 12V DiR REF	I
3020-P-2017	SLH 5XC 12V DiR TBL	I
3020-P-2018	SLH 5XC 12V DiR TBL USA	I
3020-P-2019	SLH 5XC LED DiR REF	I
3020-P-2020	SLH 5XC LED DiR TBL	I
3020-P-2021	SLH 5XC LED DiR TBL USA	I
3020-P-2081	SLH 5XC LED - PLATE SYSTEM	I
3020-P-2082	SLH 5XC LED Di - PLATE SYSTEM	I
3020-P-2083	SLH 5XC LED DiR - PLATE SYSTEM	I
3020-P-2089	SLH 3XC LED - REF	I
3020-P-2090	SLH 3XC LED - TABLE	I
3020-P-2091	SLH 3XC LED TABLE USA	I
3020-P-2092	SLH 3XC LED Di - REF	I
3020-P-2093	SLH 3XC LED Di - TABLE	I
3020-P-2094	SLH 3XC LED Di TABLE USA	I
3020-P-2095	SLH 3XC LED DiR - REF	I

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3020-P-2096	SLH 3XC LED DiR - TABLE	
3020-P-2097	SLH 3XC LED DiR TABLE USA	
3020-P-2098	SLH 3XP LED - REF	
3020-P-2099	SLH 3XP LED - TABLE	
3020-P-2101	SLH 3XP LED Di - REF	
3020-P-2102	SLH 3XP LED Di - TABLE	
3020-P-2104	SLH 3XP LED DiR - REF	
3020-P-2105	SLH 3XP LED DiR - TABLE	
3020-P-2112	SLH 5XP LED Di REF (WHITE)	
3020-P-2113	SLH 5XC LED REF (WHITE)	
3020-P-2114	SLH 5XC LED TABLE (WHITE)	
3020-P-2126	SLH 3XP LED REF WHITE	
3020-P-2127	SLH 5XP LED REF GREY	
3020-P-2128	SLH 5XP LED REF WHITE	
3020-P-2129	SLH 3XP LED DiR REF WHITE	
3020-P-2130	SLH 5XP LED DiR REF	
3020-P-2131	SLH 5XP LED DiR REF WHITE	
3020-P-2132	SLH 3XP LED Di REF WHITE	
3020-P-2133	SLH 5XP LED Di REF	
3020-P-2134	SLH 3XC 6V TBL	
3020-P-2135	SLH 5XC LED - PLATE SYSTEM - WHITE	
3020-P-2138	SLH 5XC LED Di PLATE SYSTEM (WHITE)	
3020-P-2139	SLH 3XC LED - PLATE SYSTEM	
3020-P-2140	SLH 3XC LED Di - PLATE SYSTEM	
3020-P-2141	SLH 3XC LED DiR - PLATE SYSTEM	
3020-P-2023	SLZ 3XP REF	
3020-P-2023-003	SLZ 3XP REF (WHITE)	
3020-P-2024	SLZ 3XP TBL	
3020-P-2025	SLZ 3XP TBL USA	
3020-P-2026	SLZ 3XP Di REF	
3020-P-2027	SLZ 3XP Di TBL	
3020-P-2028	SLZ 3XP Di TBL USA	
3020-P-2029	SLZ 3XP DiR REF	
3020-P-2030	SLZ 3XP DiR TBL	
3020-P-2031	SLZ 3XP DiR TBL USA	
3020-P-2032	SLZ 5XP REF	
3020-P-2033	SLZ 5XP TBL	
3020-P-2034	SLZ 5XP TBL USA	
3020-P-2035	SLZ 5XP Di REF	
3020-P-2036	SLZ 5XP Di TBL	

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3020-P-2037	SLZ 5XP Di TBL USA	
3020-P-2038	SLZ 5XP DiR REF	
3020-P-2039	SLZ 5XP DiR TBL	
3020-P-2040	SLZ 5XP DiR TBL USA	
3020-P-2041	SLZ 3XC REF	
3020-P-2042	SLZ 3XC TBL	
3020-P-2043	SLZ 3XC TBL USA	
3020-P-2044	SLZ 3XC Di REF	
3020-P-2045	SLZ 3XC Di TBL	
3020-P-2046	SLZ 3XC Di TBL USA	
3020-P-2047	SLZ 3XC DiR REF	
3020-P-2048	SLZ 3XC DiR TBL	
3020-P-2049	SLZ 3XC DiR TBL USA	
3020-P-2050	SLZ 5XC REF	
3020-P-2051	SLZ 5XC TBL	
3020-P-2052	SLZ 5XC TBL USA	
3020-P-2053	SLZ 5XC Di REF	
3020-P-2054	SLZ 5XC Di TBL	
3020-P-2055	SLZ 5XC Di TBL USA	
3020-P-2056	SLZ 5XC DiR REF	
3020-P-2057	SLZ 5XC DiR TBL	
3020-P-2058	SLZ 5XC DiR TBL USA	
3020-P-2059	SLH 5XC LED TBL VALON	
3020-P-2070	SLH 5XC LED REF OEM	
3020-P-2077	SLZ 3XC REF WHT	
3020-P-2078	SLZ 3XC TBL WHT	
3020-P-2079	SLZ 5XC REF WHT	
3020-P-2080	SLZ 5XC TBL WHT	
3020-P-2084	SLZ 5XC LED - PLATE SYSTEM	
3020-P-2085	SLZ 5XC LED Di - PLATE SYSTEM	
3020-P-2086	SLZ 5XC LED DiR - PLATE SYSTEM	
3020-P-2108	SLZ 5XC Di REF - WHITE	
3020-P-2109	SLZ 5XC Di TBL - WHITE	
3020-P-2110	SLZ 5XP Di REF - WHITE	
3020-P-2121	SLZ 5XP REF WHITE	
3020-P-2123	SLZ 5XP DiR REF WHITE	
3020-P-2124	SLZ 3XP Di REF WHITE	
3020-P-2125	SLZ 5XC LED PLT SYS - WHITE	
3020-P-2136	SLZ 5XC DiR REF (WHITE)	
3020-P-2137	SLZ 5XC DiR TABLE (WHITE)	

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3020-P-2142	SLZ 3XC LED - PLATE SYSTEM	I
3020-P-2143	SLZ 3XC LED DiR - PLATE SYSTEM	I
3020-P-2144	SLZ 3XC LED Di - PLATE SYSTEM	I
3020-P-2145	SL-B2 3XC SLIT LAMP	I
3020-P-2145-001	SL-B2 3XC SLIT LAMP	I
3020-P-2145-002	SL-B2 3XC SLIT LAMP	I
3020-P-2151	SLH 5XC LED DiR - PLATE SYSTEM - WHITE	I
3020-P-2155-002	SL-B3 3XC SLIT LAMP (GEN)	I
3020-P-2160	MODULIGHT SLIT LAMP	I

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Accessories	
Part Number	Device Description
1030-P-7160	BULB
1205-P-7012	KAPTURE SOFTWARE MEMORY STICK
1945-P-7000	REFRACTION STAND POWER ADAPTOR
2199-P-7136	LENS CLOTH
2207-P-1026	2x HALBERG TRIAL CLIPS IN CASE
3010-P-5026	SLIT LAMP CHARGING UNIT ASSEMBLY
3020-P-2022	DSL DIGITAL CAMERA KIT
3020-P-5005	DSL LED X-Y ASSEMBLY
3020-P-5006	DSL CHINREST ASSEMBLY
3020-P-5007	BASE ASSEMBLY (TABLE-TOP VARIANT ONLY)
3020-P-5031	DSL DIGITAL CAMERA ASSEMBLY
3020-P-5036	CHINREST ASSEMBLY
3020-P-5041	DSL TABLE ASSEMBLY - DIGITAL
3020-P-5042	REFRACTION STAND CHINREST ASSEMBLY
3020-P-5042-003	CHINREST ASSY - REF STAND - WHITE
3020-P-5058	DSL X-Y ASSEMBLY
3020-P-5062	DSL TABLE ASSY - USA REFRACTION STAND
3020-P-5063	DSL DIGITAL USA REFRACTION STAND ASSEMBLY
3020-P-5088	DSL LED DIGITAL X-Y ASSEMBLY
3020-P-5090	DSL LED DIGITAL TABLE ASSEMBLY 12V
3020-P-5091	DSL LED DIGITAL TABLE ASSEMBLY 12V US
3020-P-5120	VALON CHINREST ASSEMBLY
3020-P-5121	12V PSU & DRAWER KIT
3020-P-5131	DSL CAMERA ASSEMBLY - NO BRANDING
3020-P-5151	SL CHINREST ASSEMBLY - PLT SYS
3020-P-5179	SLH/SLZ LARGE TABLE TOP ASSEMBLY
3020-P-5191	SLH PLATE SYSTEM CHINREST ASSY
3020-P-5191-003	SLH PLATE SYSTEM CHINREST ASSY - WHITE
3020-P-5211	OCULUS/KEELER T/T ASSEMBLY - 12V
3020-P-5270	MARCO TABLE ASSEMBLY
3020-P-7000	MULTI VOLTAGE TABLE LEG ASSEMBLY
3020-P-7003	DSL REFRACTION ACCESSORIES KIT
3020-P-7004	DSL TABLE TOP ACCESSORIES KIT
3020-P-7007	MAINS CABLES – BRAZIL
3020-P-7008	MAINS CABLES - JAPAN
3020-P-7011	POWER SUPPLY TO SLIT LAMP BASE CABLE (TABLE-TOP VARIANT ONLY)

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3020-P-7012	DSL TABLE LEG TO PSU CABLE ASSEMBLY
3020-P-7013	DSL REFRACTION CABLE (XY - BULB)
3020-P-7014	REFRACTION STAND CABLE KIT
3020-P-7016	MAINS CABLES - NORTH AMERICA
3020-P-7017	REFRACTION STAND PSU & SKT KIT
3020-P-7020	LED REFRACTION STAND ACCESSORY KIT
3020-P-7020-003	SLH LED REF ACCESSORY KIT - WHITE
3020-P-7021	LED TABLE TOP ACCESSORY KIT
3020-P-7021-003	SLH LED TABLE ACCESSORY KIT (WHITE)
3020-P-7025	DSL DIGITAL REFRACTION STAND ACCESSORY KIT
3020-P-7026	DSL DIGITAL TABLE ACCESSORY KIT
3020-P-7032	SLIT LAMP USA REFR STAND KIT
3020-P-7033	DSL DIGITAL REFRACTION STAND POWER SOCKET KIT
3020-P-7051	DSL DIGITAL LED REFRACTION STAND ACCESSORY KIT
3020-P-7051-003	SLH LED Di REF ACCESSORY KIT - WHITE
3020-P-7052	TABLE ACCESSORY KIT DIGITAL
3020-P-7053	ILLUMINATION ASSEMBLY LED DIGITAL
3020-P-7055	Z-TYPE DSL REFRACTION STAND ACCESSORY KIT
3020-P-7055-003	Z-TYPE REFRACTION STAND ACCESSORY KIT
3020-P-7056	Z-TYPE DSL TABLE TOP ACCESSORY KIT
3020-P-7056-003	Z-TYPE TABLE TOP ACCESSORY KIT
3020-P-7057	Z-TYPE DSL DIGITAL REFRACTION STAND ACCESSORY KIT
3020-P-7057-003	SLZ Di REF STD ACCESSORY KIT - WHITE
3020-P-7058	Z-TYPE DSL DIGITAL TABLE TOP ACCESSORY KIT
3020-P-7058-003	SLZ Di TBL TOP ACCESSORY KIT - WHITE
3020-P-7059	DSL TABLE TOP ASSEMBLY (BLACK)
3020-P-7061	DIELECTRIC PROJECTION MIRROR KIT
3020-P-7065	OEM ACCESSORY KIT
3020-P-7070	VALON ACCESSORY KIT 1
3020-P-7081	SLH/SLZ MOUNTING PLATE SYSTEM
3020-P-7082	DSL/ZSL LARGE TABLE IN CARTON
3020-P-7084	QUANTEL DSL ACCESSORY KIT
3020-P-7086	SL CHINREST & MOUNTING PLATE SYSTEM
3020-P-7100	SLH CHINREST MOUNTING PLATE SYSTEM
3020-P-7105	EYEPIECE WITH RETICULE
3020-P-7115	LUMENIS SLIT LAMP CAMERA - WHITE
3020-P-7122	MARCO ACCESSORY KIT
3104-L-8201	CHIN REST PAPERS
EP39-70369	JOYSTICK RUBBER
EP39-80052	LONG PROJECTION MIRROR (STANDARD)

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EP39-80243	TEST BAR
EP39-80250	SMALL PROJECTION MIRROR
EP39-80273	DUST COVER

Certificate of Approval

This is to certify that the Management System of:

Keeler Ltd

Clewer Hill Road, Windsor, SL4 4AA, United Kingdom

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 1 November 2019

Expiry date: 31 October 2022

Certificate identity number: 10219036

Original approval(s):

ISO 13485 – 10 September 1995

Approval number(s): ISO 13485 – 0003723

The scope of this approval is applicable to:

Hardware and software design, development, manufacture, distribution and service of optometric and ophthalmic medical devices and general medical equipment. Design, Development and manufacture of halogen bulbs. Sales and distribution of own brand labelled medical devices.



001



The Keeler Slit Lamp

Exceeding performance expectations

Keeler
— A world without vision loss —

Keeler Slit Lamps

The Keeler Slit Lamp facilitates an examination of the anterior segment, or frontal structures and posterior segment, of the human eye, which includes the eyelid, sclera, conjunctiva, iris, natural crystalline lens and cornea.

The binocular Slit Lamp provides stereoscopic magnified view of the eye structures in detail, enabling anatomical diagnoses to be made for a variety of eye conditions.

Key features

- With over 100 years of industry experience, Keeler has become a household name among optometrists and ophthalmologists worldwide
- The wide range of diagnostic devices from Keeler are used by ophthalmology students and veteran doctors alike, often for the entire duration of their careers
- Extensive market presence, optics expertise, and the trusted Keeler brand drives Keeler to create innovative products that become essential additions to the everyday examination
- The H series tower illumination (KSL-H) and Z series lower illumination (KSL-Z) Slit Lamps from Keeler offer a quality build and great value Slit Lamps, backed by the Keeler optics heritage
- 3 or 5 step magnification (10x, 16x, 25x) or (6x, 10x, 16x, 25x, 40x)
- Our LED has been carefully selected for its performance, with a colour temperature of 3,800k, and a truly homogeneous light patch. Typically, a Keeler LED will provide 10,000 or more hours of life
- Filters - Clear, red free, neutral density, diffuser, blue filter permanently installed
- British built

Exceeding performance expectations



KSL-H

◀ Tower Illumination

Available in Traditional, Digital and Digital Ready and with a 3 or 5 step magnification.



World Class Keeler Optics

KSL-Z

Lower Illumination ▶

Available in Traditional, Digital and Digital Ready and with a 3 or 5 step magnification.



KSL Overview

World Class Keeler Optics

Keeler is renowned for market-leading optics and has been dedicated to optical design and manufacture for over 100 years. Experience has allowed Keeler to develop some of the best optics on the market, resulting in striking clarity and precision with the KSL optical performance.

Between our Traditional, Digital, and Digital Ready versions of our KSL-H and KSL-Z series Slit Lamps, along with our Keeler Approved accessories and add-ons, we can create the perfect solution to fit your clinical needs.

A Century of Reliability

We understand how important the Slit Lamp is to your practice. You rely on it to provide accurate diagnostic and examination results day in and day out, so failure is simply not an option.

With a Keeler Slit Lamp, you can rest assured that our exceptional attention to detail will ensure optimum performance and reliability time after time, and with our manufacturing on-site, our technical assistance and service teams are easily accessible for any support you require.

KSL-H Tower Illumination

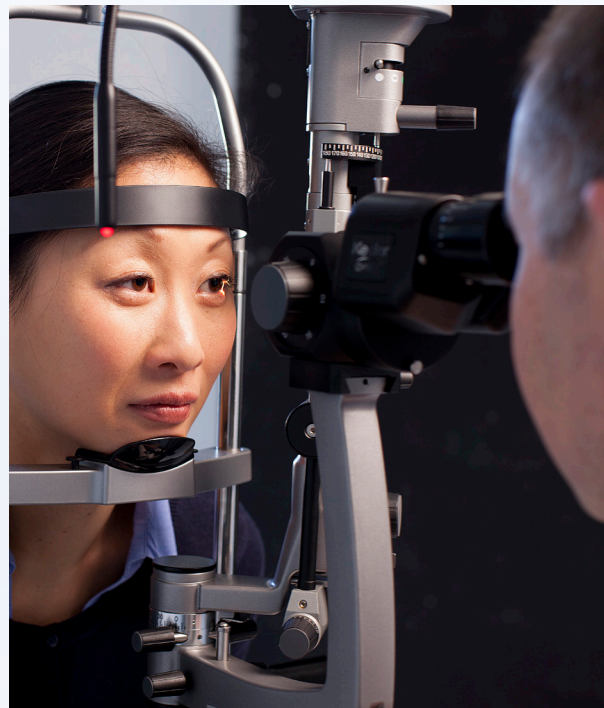
Traditional Slit Lamps

KSL-H3

Tower Illumination 3 step magnification (10x, 16x, 25x)

KSL-H5

Tower Illumination 5 step magnification (6x, 10x, 16x, 25x, 40x)



KSL-H Traditional Slit Lamp

Digital Slit Lamps

KSL-H3-D

Tower Illumination 3 step magnification

(10x, 16x, 25x)

Digital Slit Lamp 3 megapixel: 2056 x 1542 USB 3 camera

Kapture software

KSL-H5-D

Tower Illumination 5 step magnification (6x, 10x, 16x, 25x, 40x)

Digital Slit Lamp 3 megapixel: 2056 x 1542 USB 3 camera

Kapture software

Digital Ready Slit Lamps

KSL-H3-DR

Digital Ready Slit Lamp

Tower Illumination 3 step magnification (10x, 16x, 25x)

KSL-H5-DR

Digital Ready Slit Lamp

Tower Illumination 5 step magnification (6x, 10x, 16x, 25x, 40x)

Available add-ons: digital camera, Kapture software



KSL-H Digital Slit Lamp



KSL-H Digital Slit Lamp

Get more out of your Digital Slit Lamp

The KSL Digital and Digital Ready Slit Lamps come with many additional features outside the scope of the traditional Slit Lamp.

As well as benefiting from a selection of integrated cameras and beam splitters (optional for the Digital Ready version), additional features include a background illuminator, auxiliary diffuser, blue filter, and control buttons on the Slit Lamp base for the camera and review control.

Manage the camera exposure and Slit Lamp illumination from the base mounted buttons, and capture the perfect image using the joystick camera trigger for still images or videos, depending on the software package purchased.

External illumination can be controlled independently of the main illumination to ensure image contrast levels are optimised.

KSL-Z Lower Illumination

The Z series Keeler Slit Lamps share all the great qualities and features of the K series but with lower illumination.

Traditional Slit Lamps

KSL-Z3

Lower Illumination 3 step magnification (10x, 16x, 25x)

KSL-Z5

Lower Illumination 5 step magnification (6x, 10x, 16x, 25x, 40x)



KSL-Z Traditional Slit Lamp

Digital Slit Lamps

KSL-Z3-D

Lower Illumination 3 step magnification (10x, 16x, 25x)
Digital Slit Lamp 3 megapixel: 2056 x 1542 USB 3 camera
Kapture software

KSL-Z5-D

Lower Illumination 5 step magnification (6x, 10x, 16x, 25x, 40x)
Digital Slit Lamp 3 megapixel: 2056 x 1542 USB 3 camera
Kapture software



KSL-Z Digital Ready Slit Lamp with camera attachment



KSL-Z Digital Slit Lamp

Digital Ready Slit Lamps

KSL-Z3-DR

Digital Ready Slit Lamp
Lower Illumination 3 step magnification (10x, 16x, 25x)

KSL-Z5-DR

Digital Ready Slit Lamp
Lower Illumination 5 step magnification (6x, 10x, 16x, 25x, 40x)

Available add-ons: digital camera, Kapture software

KSL Software and Accessories

Innovative Software

Keeler has been working hard to find software options that will aid and improve diagnosis and image quality through different image capture programs. Efficiency and ease of use are crucial to keep up with high patient flow, therefore, Keeler has hand-picked software packages to allow users to get the most out of their Slit Lamp.



Kapture Software

Image Capture Software Options

Kapture Lite

A more comprehensive stand-alone system including still capture with live preview, video capture, patient database, image processing, crop, import, and export.

Kapture Digital

Upgrade from Lite to Digital to have network connectivity (essential if you require review station), measuring and multiple image printing and saving.

Kapture View

Allows patient data and images to be viewed over the network – this requires the Kapture station to be networked.

Kapture View Plus

Includes file import and measure – the Kapture station must be networked.



Accessories*

TTI Beam Splitter plus Canon SLR Camera

Get crystal clear images using this system combined with our very own Keeler optics.



20 Degree Adaptor

20° ocular adaptor which allows a user to use a different working position. The adaptor fits between the optical block and the oculars.



* Not sold by Keeler



DKAT Digital Tonometer

Keeler Applanation Tonometers (KAT)

Choose from the T Type (Traditional or Digital), R Type (Traditional or Digital), or Z Type (Digital).

THE T TYPE is removable and conveniently fits into a shaped guide plate that, in turn, fits in the test bar locating hole.

THE R TYPE is fitted to a mounting post, located on the optics block and can be swung in and out for use, as required.

THE Z TYPE is removable and mounted on the top of the drum of the KSL-Z Slit Lamp.



T Type KAT

R Type KAT

Z-KAT
Z Type Digital



Kapture Software

KSL-H Tower Illumination Specifications

KSL-H Optical System	
TYPE	Galilean converging binoculars @ 8° / Galilean 0° parallel
MAGNIFICATION	Rotating drum change x6, x10, x16, x25 and x40 / x10, x16 and x25
EYEPIECE	x12.5
FIELD OF VIEW	34, 22, 14, 8.5 and 5.5 mm / 22, 14 and 8.5mm
INTERPUPILLARY DISTANCE	8° converging eyepieces, 49 – 77mm 0° parallel eyepieces, 38 – 85mm
OBJECTIVE LENS FOCAL DISTANCE	107mm
OBJECTIVE LENS CONVERGENCE ANGLE	13°

Slit projection system and base

SLIT WIDTH	0-12mm continuously variable
SLIT LENGTH	12mm (1mm – 12mm continuously variable)
APERTURE DIAMETERS	0.2, 1mm square, 2, 3, 5, 9 and 12mm
FILTERS	Clear, red free, neutral density, diffuser, blue filter permanently installed
SLIT ANGLE	+/- 90° continuous
SLIT ROTATION	+/- 180° with reference scale
SLIT VERTICAL TILT	0°, 5°, 10°, 15° and 20°
BASE TRAVEL	25mm Z-axis, 107mm X-axis, 110mm Y-axis
HORIZONTAL FINE ADJUSTMENT	12mm
TABLE TOP DIMENSIONS	405 x 500mm
FIXATION LAMP	LED
LIGHT SOURCE	LED
LED OUTPUT POWER	160k Lux

Weight and dimensions packed (approx.)

SLIT LAMP COMPLETE	20.0Kg, 75 x 54 x 45cm W x D x H
--------------------	----------------------------------

Protection against Ingress IPxO

Class II ME Equipment

Insulation between mains parts and the functional earth provide at least two means of protection

Power supply

POWER SUPPLY UNIT	Switch mode, (110V – 240V input) 10% multi plug compliant to EN/IEC 60601-1 EN/IEC 61000-6-2, EN/IEC 61000-6-3
FUSE	T2.5AH, 250V
POWER SUPPLY OUTPUT	12V DC: 2.5 amps EN/IEC 60601 compliant
COMPLIES WITH	Electrical Safety (Medical) EN/IEC 60601-1
	Electromagnetic compatibility EN/IEC 60601-1-2
	Ophthalmic instruments - Fundamental requirements and test methods ISO 15004-1 Ophthalmic instruments - Optical radiation hazard ISO 15004-2

Environmental

TEMPERATURE	Operation +10°C to +35°C Storage -10°C to +55°C Transport -40°C to +50°C
HUMIDITY	Operation 30% to 90% Storage 10% to 95% Transport 10% to 95%
PRESSURE	Operation 800 hpa to 1060 hpa Storage 700 hpa to 1060 hpa Transport 500 hpa to 1060 hpa

Electrical Information (KSL-H and KSL-Z)

The Keeler Slit Lamp is a medical electrical instrument. The instrument requires special care concerning electromagnetic compatibility (EMC). It consists of 5 assemblies; Illumination Tower; Observation System; XYZ Translation Base; Chinrest Assembly and a Table Top with Power Supply and Accessory Drawer.

The light intensity is controlled by a variable rheostat located on the XYZ Translation Base. There are a number of selectable filters allowing the user to control the characteristics of the examination light.

Classification (KSL-H and KSL-Z)

The Keeler Slit Lamp is designed and built in conformity with EC Directive 93/42/EEC and the ISO 9000 and ISO 13485 series of quality standards. The ‘CE’ (European Community) mark attests that the Keeler Slit Lamp complies with the provisions of the EC Directive 93/42/EEC.

Classification: CE Regulation 93/42 EEC: Class I. FDA: Class II, EN/IEC Standard 60601-1: H-series - Safety Class II. Application part: Type B. Operation mode: continuous operation.

KSL-Z Lower Illumination Specifications

KSL-Z Optical System	
BINOCULARS TYPE	Galilean 8° converging I Galilean 0° parallel
MAGNIFICATION	Drum change x6, x10, x16, x25 and x40 / x10, x16 and x25
EYEPIECE	x12.5
FIELD OF VIEW	34, 22, 14, 8.5 and 5.5 mm / 22, 14 and 8.5mm
INTERPUPILLARY DISTANCE	8° converging eyepieces, 49 – 77mm 0° parallel eyepieces, 38 – 85mm
OBJECTIVE LENS FOCAL DISTANCE	107mm
OBJECTIVE LENS CONVERGENCE ANGLE	13°

Slit projection system and base

SLIT WIDTH	0 – 14mm continuously variable
SLIT LENGTH	14mm
APERTURE DIAMETERS	0.2, 1mm square, 2, 3, 5, 9, 14 and reserved
FILTERS	Clear, red free, neutral density, diffuser, blue filter permanently installed
SLIT ROTATION	360° continuous, detents at 0° and 180°
BASE TRAVEL	25mm Z-axis, 107mm X-axis, 110mm Y axis
HORIZONTAL FINE ADJUSTMENT	12mm
TABLE TOP DIMENSIONS	405 x 500mm
FIXATION LAMP	LED
LIGHT SOURCE	LED
LED OUTPUT POWER	280k Lux

Weight and dimensions packed (approx.)

SLIT LAMP COMPLETE	25Kg, 90 x 58 x 45cm W x D x H
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Protection against Ingress IPxO

Class II ME Equipment

Insulation between mains parts and the functional earth provide at least two means of protection

Power supply

POWER SUPPLY UNIT	Switch mode, (100V-240V input) 10% multi plug compliant to EN/IEC 60601-1 EN/IEC 61000-6-2, EN/IEC 61000-6-3
FUSE	T2.5AH, 250V
POWER SUPPLY OUTPUT	12V DC: 2.5 amps EN/IEC 60601 compliant
COMPLIES WITH	Electrical Safety (Medical) EN/IEC 60601-1
	Electromagnetic compatibility EN/IEC 60601-1-2
	Ophthalmic instruments - Fundamental requirements and test methods ISO 15004-1 Ophthalmic instruments - Optical radiation hazard ISO 15004-2

Environmental

TEMPERATURE	Operation +10°C to +35°C Storage -10°C to +55°C Transport -40°C to +50°C
HUMIDITY	Operation 30% to 90% Storage 10% to 95% Transport 10% to 95%
PRESSURE	Operation 800 hpa to 1060 hpa Storage 700 hpa to 1060 hpa Transport 500 hpa to 1060 hpa

KSL-H and KSL-Z

Fuse ratings and quantity (KSL-H and KSL-Z)

	2.5 amp anti-surge Fuse current 2.5A Voltage rating V AC 250V Breaking capacity 1500Amps Blow characteristic: Time Delay
--	--

Applied parts (KSL-H and KSL-Z)

	Chinrest Forehead rest Grab handles
--	---

Power supply (KSL-H and KSL-Z)

When the Slit Lamp is connected to the power supply together the constitute a Medical Electrical System as defined in EN/IEC 60601-1:2006. The power supply forms a part of ME equipment.

What's in the box?

KSL-H3 Traditional Slit Lamps 3 step magnification

3020-P-2089
KSL-H3 SILVER-GREY
WITH STAND

- KSL-H3 Traditional Slit Lamp
- Refraction Stand Chinrest Assembly
- Refraction Stand Accessory Kit
- Breath Shield

3020-P-2090
KSL-H3 SILVER-GREY
WITH TABLE TOP

- KSL-H3 Traditional Slit Lamp
- Table Top Assembly
- Chinrest Assembly
- Table Top Accessory Kit
- Breath Shield

3020-P-2139
KSL-H3 SILVER-GREY
PLATE MOUNT

- KSL-H3 Traditional Slit Lamp
- Refraction Stand Accessory Kit
- Mounting Plate Assembly
- Power Supply Assembly
- Analogue
- Plate System Chinrest Assembly
- Breath Shield

KSL-H3-D Digital Slit Lamp 3 step magnification

3020-P-2093
KSL-H3-D SILVER-GREY
WITH TABLE TOP

- KSL-H3-D Digital Slit Lamp
- Digital Camera Assembly
- Digital LED TT Accessory Kit
- Chinrest Assembly
- Digital Table Assembly
- Breath Shield

KSL-H3-DR Digital Ready 3 step magnification

3020-P-2095
KSL-H3-DR
SILVER-GREY
WITH STAND

- KSL-H3-DR Digital Ready Slit Lamp
- Digital LED Ref Accessory Kit
- Refraction Stand Chinrest Assembly
- Digital Ready IFU Supplement
- Breath Shield

KSL-H5 Traditional Slit Lamps 5 step magnification

3020-P-2006
KSL-H5 SILVER-GREY
WITH STAND

- KSL-H5 Traditional Slit Lamp
- Refraction Stand Chinrest Assembly
- Refraction Stand Accessory Kit
- Breath Shield

3020-P-2007
KSL-H5 SILVER-GREY
WITH TABLE TOP

- KSL-H5 Traditional Slit Lamp
- Table Top Assembly
- Chinrest Assembly
- Table Top Accessory Kit
- Breath Shield

3020-P-2081
KSL-H5 SILVER-GREY
PLATE MOUNT

- KSL-H5 Traditional Slit Lamp
- Refraction Stand Accessory Kit
- Mounting Plate Assembly
- Power Supply Assembly
- Analogue
- Plate System Chinrest Assembly
- Breath Shield

KSL-H Tower Illumination

KSL-H5-D Digital Slit Lamps 5 step magnification

3020-P-2009
KSL-H5-D SILVER-GREY
WITH STAND

- KSL-H5-D Digital Slit Lamp
- Digital Camera Assembly
- Digital LED Ref Accessory Kit
- Refraction Stand Chinrest Assembly
- Breath Shield

3020-P-2010
KSL-H5-D SILVER-GREY
WITH TABLE TOP

- KSL-H5-D Digital Slit Lamp
- Digital Camera Assembly
- Digital LED TT Accessory Kit
- Chinrest Assembly
- LED Digital Table Assembly
- Breath Shield

3020-P-2082
KSL-H5-D SILVER-GREY
PLATE MOUNT

- KSL-H5-D Digital Slit Lamp
- Digital Camera Assembly
- Digital LED Ref Accessory Kit
- Mounting Plate Assembly
- Power Supply Assembly
- Analogue
- Plate System Chinrest Assembly
- Breath Shield

3020-P-2112
KSL-H5-D WHITE
PARALLEL BINOCULAR
WITH STAND

- KSL-H5-D Digital Slit Lamp
- Digital Camera Assembly
- Chinrest Assembly Ref Stand
- Digital LED Ref Accessory Kit
- Breath Shield

KSL-H5-DR Digital Ready 5 step magnification

3020-P-2019
KSL-H5-DR
SILVER-GREY
WITH STAND

- KSL-H5-DR Digital Ready Slit Lamp
- Digital LED Ref Accessory Kit
- Refraction Stand Chinrest Assembly
- Digital Ready IFU Supplement
- Breath Shield

3020-P-2020
KSL-H5-DR
SILVER-GREY
WITH TABLE TOP

- KSL-H5-DR Digital Ready Slit Lamp
- Digital LED TT Accessory Kit
- Chinrest Assembly
- LED Digital Table Assembly
- Digital Ready IFU Supplement
- Breath Shield

3020-P-2083
KSL-H5-DR
SILVER-GREY
PLATE MOUNT

- KSL-H5-DR Digital Ready Slit Lamp
- Digital LED Ref Accessory Kit
- Digital Ready IFU Supplement
- Mounting Plate Assembly
- Power Supply Assembly
- Analogue
- Plate System Chinrest Assembly
- Breath Shield

What's in the box?

KSL-Z3 Traditional Slit Lamps 3 step magnification

3020-P-2023
KSL-Z3 SILVER-GREY
PARALLEL BINOCULAR
WITH STAND

- KSL-Z3 Traditional Slit Lamp
- Refraction Stand Chinrest Assembly
- Ref Stand Accessory Kit
- Breath Shield

3020-P-2041
KSL-Z3 SILVER-GREY
WITH STAND

- KSL-Z3 Traditional Slit Lamp
- Refraction Stand Chinrest Assembly
- Ref Stand Accessory Kit
- Breath Shield

3020-P-2042
KSL-Z3 SILVER-GREY
WITH TABLE TOP

- KSL-Z3 Traditional Slit Lamp
- Refraction Stand Chinrest Assembly
- Table top Assembly kit
- Table Top Assembly
- Breath Shield

3020-P-2142
KSL-Z3 SILVER-GREY
PLATE MOUNT

- KSL-Z3 Traditional Slit Lamp
- Ref Stand Accessory Kit
- Chinrest Assembly - Plate System
- Mounting Plate Assembly
- Power Supply Assembly Analogue
- Breath Shield

KSL-Z3-D Digital Slit Lamp 3 step magnification

3020-P-2045
KSL-Z3-D SILVER-GREY
WITH TABLE TOP

- KSL-Z3-D Digital Slit Lamp
- Refraction Stand Chinrest Assembly
- Table Top Assembly Kit
- Digital LED Table Assembly
- Digital Camera Assembly
- Breath Shield

KSL-Z5 Traditional Slit Lamps 5 step magnification

3020-P-2050
KSL-Z5 SILVER-GREY
WITH STAND

- KSL-Z5 Traditional Slit Lamp
- Refraction Stand Chinrest Assembly
- Ref Stand Accessory Kit
- Breath Shield

3020-P-2051
KSL-Z5 SILVER-GREY
WITH TABLE TOP

- KSL-Z5 Traditional Slit Lamp
- Refraction Stand Chinrest Assembly
- Table Top Assembly Kit
- Table Top Assembly
- Breath Shield

3020-P-2079
KSL-Z5 WHITE
WITH STAND

- KSL-Z5 Traditional Slit Lamp
- Chinrest Assembly-Ref Stand
- Refraction Std Accessory Kit
- Breath Shield

3020-P-2080
KSL-Z5 WHITE
WITH TABLE TOP

- KSL-Z5 Traditional Slit Lamp
- Table Top Assembly
- Chinrest Assembly - Ref Stand
- Table Top Accessory Kit
- Breath Shield

3020-P-2084
KSL-Z5 SILVER-GREY
PLATE MOUNT

- KSL-Z5 Traditional Slit Lamp
- Ref Stand Accessory Kit
- Chinrest Assembly - Plate System
- Mounting Plate Assembly
- Power Supply Assembly Analogue
- Breath Shield

3020-P-2121
KSL-Z5 WHITE
PARALLEL BINOCULAR
WITH STAND

- KSL-Z5 Traditional Slit Lamp
- Chinrest Assembly - Ref Stand
- Refraction Std Accessory Kit
- Breath Shield

KSL-Z5-D Digital Slit Lamps 5 step magnification

3020-P-2054
KSL-Z5-D SILVER-GREY
WITH TABLE TOP

- KSL-Z5-D Digital Slit Lamp
- Refraction Stand Chinrest Assembly
- Digital Table Top Assembly Kit
- Digital Table Assembly
- Digital Camera Assembly
- Breath Shield

3020-P-2085
KSL-Z5-D SILVER-GREY
PLATE MOUNT

- KSL-Z5-D Digital Slit Lamp
- Digital Ref Stand Assembly Kit
- Digital Camera Assembly
- Chinrest Assembly - Plate System
- Mounting Plate Assembly
- Power Supply Assembly Analogue
- Breath Shield

3020-P-2108
KSL-Z5-D WHITE
WITH STAND

- KSL-Z5-D Digital Slit Lamp
- Digital Camera Assembly
- Chinrest Assembly - Ref Stand
- Ref Std Accessory Kit
- Breath Shield

3020-P-2109
KSL-Z5-D WHITE WITH
TABLE TOP

- KSL-Z5-D Digital Slit Lamp
- LED Digital Table Assembly
- Digital Camera Assembly
- Chinrest Assembly-Ref Stand
- Table Top Accessory Kit
- Breath Shield

3020-P-2110
KSL-Z5-D WHITE
PARALLEL BINOCULAR
WITH STAND

- KSL-Z5-D Digital Slit Lamp
- Digital Camera Assembly
- Chinrest Assembly - Ref Stand
- Ref Std Accessory Kit
- Breath Shield

KSL-Z5-DR Digital Ready 5 step magnification

3020-P-2057
KSL-Z5-DR
SILVER-GREY
WITH TABLE TOP

- KSL-Z5-DR Digital Ready Slit Lamp
- Refraction Stand Chinrest Assembly
- Digital Table Top Assembly Kit
- Digital Table Assembly
- Breath Shield

3020-P-2086
KSL-Z5-DR
SILVER-GREY
PLATE MOUNT

- KSL-Z5-DR Digital Ready Slit Lamp
- Digital Ref Stand Assembly Kit
- Chinrest Assembly - Plate System
- Mounting Plate Assembly
- Power Supply Assembly Analogue
- Breath Shield

Part Numbers

Part Numbers			Slit Lamp Base Options			Illumination Type	Colour
Part Number	Magnification Unit Spec	Binocular Type	Table Top	Stand	Plate Mount		
TOWER ILLUMINATION TRADITIONAL SLIT LAMPS - KSL-H3 AND KSL-H5							
3020-P-2089	3 (KSL-H3)	Converging		●		LED	Silver-grey
3020-P-2090	3 (KSL-H3)	Converging	●			LED	Silver-grey
3020-P-2139	3 (KSL-H3)	Converging			●	LED	Silver-grey
3020-P-2006	5 (KSL-H5)	Converging		●		LED	Silver-grey
3020-P-2007	5 (KSL-H5)	Converging	●			LED	Silver-grey
3020-P-2081	5 (KSL-H5)	Converging			●	LED	Silver-grey
TOWER ILLUMINATION DIGITAL SLIT LAMPS - KSL-H3-D AND KSL-H5-D							
3020-P-2093	3 (KSL-H3-D)	Converging	●			LED	Silver-grey
3020-P-2009	5 (KSL-H5-D)	Converging		●		LED	Silver-grey
3020-P-2010	5 (KSL-H5-D)	Converging	●			LED	Silver-grey
3020-P-2082	5 (KSL-H5-D)	Converging			●	LED	Silver-grey
3020-P-2112	5 (KSL-H5-D)	Parallel		●		LED	White
TOWER ILLUMINATION DIGITAL READY SLIT LAMPS - KSL-H3-DR AND KSL-H5-DR							
3020-P-2095	3 (KSL-H3-DR)	Converging		●		LED	Silver-grey
3020-P-2019	5 (KSL-H5-DR)	Converging		●		LED	Silver-grey
3020-P-2020	5 (KSL-H5-DR)	Converging	●			LED	Silver-grey
3020-P-2083	5 (KSL-H5-DR)	Converging			●	LED	Silver-grey
LOWER ILLUMINATION TRADITIONAL SLIT LAMPS - KSL-Z3 AND KSL-Z5							
3020-P-2023	3 (KSL-Z3)	Parallel		●		LED	Silver-grey
3020-P-2041	3 (KSL-Z3)	Converging		●		LED	Silver-grey
3020-P-2042	3 (KSL-Z3)	Converging	●			LED	Silver-grey
3020-P-2142	3 (KSL-Z3)	Converging			●	LED	Silver-grey
3020-P-2050	5 (KSL-Z5)	Converging		●		LED	Silver-grey
3020-P-2051	5 (KSL-Z5)	Converging	●			LED	Silver-grey
3020-P-2079	5 (KSL-Z5)	Converging		●		LED	White
3020-P-2080	5 (KSL-Z5)	Converging	●			LED	White
3020-P-2084	5 (KSL-Z5)	Converging			●	LED	Silver-grey
3020-P-2121	5 (KSL-Z5)	Parallel		●		LED	White
LOWER ILLUMINATION DIGITAL SLIT LAMPS - KSL-Z3-D AND KSL-Z5-D							
3020-P-2045	3 (KSL-Z3-D)	Converging	●			LED	Silver-grey
3020-P-2054	5 (KSL-Z5-D)	Converging	●			LED	Silver-grey
3020-P-2085	5 (KSL-Z5-D)	Converging			●	LED	Silver-grey
3020-P-2108	5 (KSL-Z5-D)	Converging		●		LED	White
3020-P-2109	5 (KSL-Z5-D)	Converging	●			LED	White
3020-P-2110	5 (KSL-Z5-D)	Parallel		●		LED	White
LOWER ILLUMINATION DIGITAL READY SLIT LAMPS - KSL-Z5-DR							
3020-P-2057	5 (KSL-Z5-DR)	Converging	●			LED	Silver-grey
3020-P-2086	5 (KSL-Z5-DR)	Converging			●	LED	Silver-grey

More Keeler Instruments

With over 100 years of industry experience, Keeler has become a household name among optometrists and ophthalmologists worldwide.

View our full range at

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Keeler
— A world without vision loss —



A Halma company

Manufacturing address



Keeler Ltd. Clewer Hill Road Berkshire SL4 4AA UK

CE 1639

The management system of

Keeler Ltd

Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

**Keeler Cryomatic MKII Console & Pencils for use in ophthalmic surgery
Laser Indirect Ophthalmoscope (LIO)
for use in ophthalmic surgical procedures**

Tonometers to aid diagnosis and measurement of intraocular pressures:

Pulsair Intellipuff – Non-Contact Tonometer

TonoCare – Non-Contact Tonometer

Pulsair Desk Top Tonometer

Keeler Digital Applanation Tonometer (D-KAT)

Keeler Digital Applanation Tonometer (D-KAT), Z Type

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

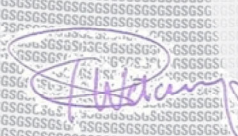
This certificate is valid from 28 February 2020 until 30 September 2022 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 10 September 1995

and first certified by SGS Belgium NV since 28 February 2020

Certification is based on reports numbered GB/PC 240569

Authorised by



SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

Page 1 of 1



Smart 532™ Platforms

Array™
LaserLink™

Pattern Scanning Laser Technology in CW and SmartPulse™

The Array™ LaserLink™ offers advanced pattern scanning capabilities compatible with all Lumenis laser systems and popular slit lamps, wavelength versatility, diverse adjustable patterns and a wide range of laser spot sizes.

Pattern scanning provides enhanced laser application uniformity, shortens treatment time, and offers more patient comfort.



Smart
SELECTA
Trio

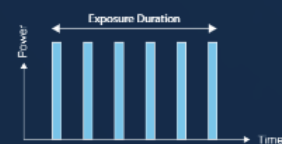
SLT + YAG + Smart532

The smart Selecta Trio offers the comprehensive solution to the ophthalmic practice, allowing glaucoma, cataract and retinal therapy in a single platform. The smart Selecta Trio combines the advantages of SLT, YAG and photocoagulation, all developed and brought to market by Lumenis.

The unit's integrated design, enhanced optics and advanced laser cavity make it a high performing laser product that offers maximal flexibility with minimal footprint.

Risks and warnings: Lumenis photocoagulators and delivery devices are intended solely for use by trained physicians. It is contraindicated for eyes with severe media opacities. Risks include increased macular edema and bleeding in areas of neovascularization. Refer to the operator manual for a complete list of intended use, contraindications and risks.

SmartPulse™ Mode



"Sub-threshold laser photocoagulation is a safe and effective complement to our armamentarium. It allows me to decrease the treatment burden on our patients while producing excellent and often long-term results."

"With our growing experience in targeted combination therapy for our patients, the Lumenis SmartPulse™ has been a vital addition to my practice"

Cassir K. Luo, MD

Delivery Devices

smartLIO™

Advanced Laser Indirect Ophthalmoscope*

The new Smart LIO™ is a wireless multi-color Laser Indirect Ophthalmoscope (LIO) that supports three wavelengths (green, yellow and red).

The LED illumination, provides brighter, whiter illumination, longer battery life and LED life expectancy of up to 10,000 hours.

*Pending US market clearance



LumeProbe™

Ophthalmic Endo-Ocular Probes

The LumeProbe™ product family was designed to deliver laser energy in the safest and most efficient manner, guaranteeing optimal clinical outcomes for all relevant vitreoretinal indications.

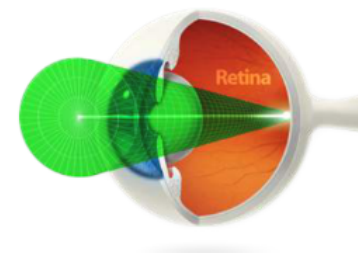
Gauger: 20, 23, 25.

Types: Straight, Curved and Aspirating (multifunctional)



Enhanced Patient Safety

SureSpot™ Patented Technology



✓ Safe and Low Power Density
on the Cornea and Lens

✓ Sharp Spot Beam Waist
on the Retina



Celebrating 50 years of innovation with the launch of the new retinal care photocoagulator



1970: Lumenis (previously Coherent) introduced the first argon laser photocoagulator in ophthalmology.

2016: Lumenis proudly launches the new retinal care portfolio, starring Smart 532™, the new green photocoagulator with SmartPulse™.

Smart532

The SmartPulse™ of Retinal Care

Smart 532™ is the newest photocoagulator by Lumenis, with SmartPulse™ sub-threshold technology.



What is SmartPulse™ Technology?

SmartPulse™ is a tissue-sparing solution for the treatment of retinal diseases, that allows sub-threshold retinal treatment.

Lumenis SmartPulse™ is integrated in the Smart 532™ system, to offer maximal efficacy with minimal collateral damage.

Smart532

The SmartPulse™ of Retinal Care

532nm Photocoagulator with SmartPulse™



 **Lumenis®**
Energy to Eye Care

Smart 532™ Specifications

Wavelength	532 nm Green
Weight	4 kg (8.82 lbs)
Dimensions	26.3 cm L x 29.5 cm W x 13.7 cm H (10.4 in x 11.6 in x 5.4 in)
Dual Port	FC and SMA connectors, Resistor type
Power Requirements	100-240 VAC, 50/60 Hz, Single phase
Cooling System	Air/TEC cooled
CW Pulse Duration	5 ms - 3,000 ms
CW Pulse Interval	10 ms - 1,500 ms or single pulse
SmartPulse™ Duration	0.05 ms - 0.5 ms
SmartPulse™ Interval	0.3 ms - 10 ms or single pulse
SmartPulse™ Duty Cycle	5% / 10% / 15%
Aiming Beam Laser	Diode laser, 635 nm nominal, intensity: 5 levels up to 1 mW
System Power Output	0 - 2,000 mW
Delivery Devices	Converging Optics Laser Link - Lumenis 1000 Lumenis 990 Lumenis 990 Zeiss 30SL Zeiss SL130 Zeiss 30SL Zeiss SL130 Heag Street 900BQ Lumenis Any-By LaserLink™ Smart Selecta Duet
Available Accessories	Physician eye safety filters for all listed slit lamps Single and Dual Endo Kits for Zeiss / Leica / Wild microscopes LIO (Kosiol® and Hono® models) Standard, Powerbase or Smart Footswitch

Manufactured by Lumenis Inc.
1610 South Mission Drive
Salt Lake City, UT 84144 USA
Tel: +801-655-2200
Fax: +801-655-2429

Lumenis (Germany) GmbH
Heinrich-Hertz-Str 3 D-83303
Dreieich/Dreieichhain
GERMANY
Tel: +49 (0) 8103 6339 0

AMERICAS
San Jose, CA, USA
Tel: +1 408 754 3000
+1 877 596 3647
Fax: +1 408 754 3699

EMEA
Dreieich/Dreieichhain,
Germany
Tel: +49 8103 6339 0
Fax: +49 8103 6339 300
Roma (RM), Italy
Tel: +39 06 60 75 220
Fax: +39 06 60 75 269
Hertfordshire, UK
Tel: +44 20 8736 4110
Fax: +44 20 8736 4119

JAPAN
Tokyo, Japan
Tel: +81 3 4421 6300
Fax: +81 3 4431 6301

ASIA / PACIFIC
Beijing, China
Tel: +86 10 5737 6677
Gurgaon, India
Tel: +91 124 422 07 95
Kowloon, Hong Kong
Tel: +852 217 426 00
Fax: +852 272 251 51



www.lumenis.com/Ophthalmology

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Yokneam Industrial Park
Hakidma Street 6, P.O.B. #240
Yokneam, 2069204
Israel**

for the scope

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Date 2021-01-08

Page 1 of 1

Product category	Class
Intense Pulsed Light (IPL) with accessories	IIb
Intense Pulsed Light (IPL), Nd:YAG, Erbium Laser with accessories	IIb
Diode Laser with accessories	IIb
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Holmium, Nd:YAG with accessories	IIb



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Head of Certification Body

Smart532TM

Solid-State 532-nm Green Laser Operator Manual



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Catalog Part Number: UM-1151440EN

May 2016

Revision C

Use of this Manual:

The Smart532 laser device is designed to meet international safety and performance standards. Personnel operating the device must have a thorough understanding of the proper operation of the device.

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

The information provided in this manual is not intended to replace physician training or professional training on the clinical use of the Smart532 laser device. Such training should include a review of published literature, seminars, workshops and appropriate preceptorships. Please contact your Lumenis representative for current information on available training.

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

Device and accessory specifications subject to change without notice.

For further information about Lumenis, visit the Lumenis Website: <http://www.Lumenis.com> or send email to information@Lumenis.com



Authorized Representative in the European Community:

Lumenis (Germany) GmbH
Heinrich-Hertz-Str. 3
Dreieich-Dreieichenhain D-63303
Germany
Tel: +49 (0) 6103-8335-0
Fax: +49 (0) 6103-8335-300



Manufactured by Lumenis Ltd.

Yokneam Industrial Park
6 Hakidma Street
P.O.B. 240
Yokneam 2069204, Israel
Tel: +972-4-959-9000
Fax: +972-4-959-9050
www.Lumenis.com



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In accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), any item which is marked with the crossed-out wheellie 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.

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Table of Contents

CHAPTER 1	Overview	Page
1.1.	Introduction.....	1-1
1.2.	Scope of This Manual	1-1
1.3.	Manual Conventions	1-2
1.4.	Physician Responsibility	1-3
1.5.	Maintenance.....	1-3
1.6.	Modification of the Device	1-3
1.7.	Resale Inspection	1-3
1.8.	Abbreviations and Acronyms	1-4

CHAPTER 2	Laser Safety and Regulatory	Page
2.1.	Introduction.....	2-1
2.2.	Training and Institutional Requirements.....	2-1
2.2.1.	Laser Safety Officer	2-2
2.2.2.	Laser Treatment/ Operating Area.....	2-3
2.3.	Laser Safety Eyewear	2-4
2.3.1.	Additional Ocular Protection.....	2-6
2.4.	Additional Safety Considerations	2-7
2.5.	Fire Hazards.....	2-8
2.6.	Electrical Hazards	2-8
2.6.1.	Grounding the System.....	2-9
2.7.	Operating Safety Cautions & Warnings.....	2-9
2.7.1.	Cautions.....	2-9
2.7.2.	Warnings	2-9
2.8.	System Safety Features	2-10
2.8.1.	Password Protection	2-10
2.8.2.	Self-Testing at Start Up.....	2-10
2.8.3.	Safety Shutter	2-10
2.8.4.	Door Interlock Connector.....	2-10
2.8.5.	Location of Controls.....	2-10
2.8.6.	Laser Emergency Stop Button.....	2-11
2.8.7.	Continuous Internal System Monitoring	2-11
2.8.7.1.	System Faults	2-11
2.8.7.2.	Internal Power Monitoring.....	2-11
2.8.7.3.	Temperature	2-11

2.9.	Laser Beam Emission Indicators	2-11
2.10.	Compliance with International Standards	2-12
2.11.	Warning, Certification and Identification Labels	2-14
2.12.	Symbol Descriptions.....	2-16

CHAPTER 3	System Description	Page
3.1.	Introduction.....	3-1
3.1.1.	Characteristics of the 532-nm Green Laser Beam.....	3-1
3.1.2.	Smart532 Laser System Components.....	3-2
3.1.2.1.	Laser Console.....	3-3
3.1.2.2.	Remote Interlock Connection Plug.....	3-3
3.1.2.3.	Footswitch.....	3-3
3.1.2.4.	Delivery Systems	3-3
3.1.3.	System Description – Front Panel	3-4
3.1.4.	Laser Emergency Stop Button.....	3-4
3.1.5.	System Description – Rear Panel	3-5
3.1.6.	Touch-Screen LCD Control Panel	3-6
3.1.7.	Optical Bench Assembly	3-6
3.1.8.	System Specifications.....	3-7
3.1.8.1.	Outputs.....	3-7
3.1.8.2.	Operation and Control.....	3-7
3.1.8.3.	Compatible Accessories.....	3-8
3.1.8.4.	Electrical Requirements	3-8
3.1.8.5.	Physical Specifications	3-8
3.1.8.6.	Environmental Specifications	3-8
3.1.8.7.	System Classifications	3-9

CHAPTER 4	System Installation and Initial Setup	Page
4.1.	Introduction.....	4-1
4.2.	Unpacking the System	4-1
4.3.	Facility Requirements	4-2
4.3.1.	Space and Positioning Requirements	4-2
4.3.2.	Electrical Requirements	4-2
4.3.3.	Environmental Requirements.....	4-3
4.4.	Installation and Setup.....	4-4
4.5.	Connection Instructions	4-6
4.5.1.	Connect the Footswitch.....	4-6
4.5.2.	Connect the Remote Interlock.....	4-7

4.5.3.	Connect the Main Power Cable.....	4-8
4.5.4.	Connect a Delivery System	4-9
4.5.5.	Eye Safety Filters	4-10
4.5.5.1.	Installing the Eye Safety Filter(s)	4-10
4.5.5.2.	Connecting an Automatic Eye Safety Filter to the Laser.....	4-10
4.5.5.3.	Connecting a Fixed Eye Safety Filter to the Laser.....	4-10
4.5.6.	Connecting an LIO Illumination Power Connector.....	4-12
4.5.7.	Connecting an Auxiliary Monitor	4-12
4.6.	Transporting and Storage.....	4-12

CHAPTER 5	Operating Instructions	Page
5.1.	Safety Considerations	5-1
5.2.	Starting the System	5-1
5.3.	Main Treatment Screen Elements.....	5-2
5.3.1.	Delivery System Selection	5-3
5.3.2.	Power Setting	5-3
5.3.3.	Exposure Time Setting	5-4
5.3.4.	Pulse Interval Selection.....	5-4
5.3.5.	Aiming Beam Intensity Adjustment.....	5-4
5.3.6.	SmartPulse Mode	5-5
5.3.7.	Pulse Counter	5-6
5.3.8.	Standby/Ready Mode Selection	5-6
5.3.9.	Preset Name.....	5-7
5.3.10.	Save a New Preset.....	5-7
5.3.11.	Edit, Delete or Select an Existing Preset.....	5-7
5.3.12.	Open Options Screen	5-8
5.3.12.1.	LIO Illumination Setting Screen	5-9
5.3.12.2.	Language Setting Screen.....	5-9
5.3.12.3.	Volume Setting Screen.....	5-10
5.3.12.4.	Backlight Setting Screen	5-11
5.3.12.5.	Eye Safety Filter (ESF) Mode Selection Screen	5-12
5.4.	Pre-Operative Instructions	5-13
5.4.1.	Aiming Beam Integrity Test.....	5-14
5.5.	Intra-Operative Instructions.....	5-15
5.6.	Post-Operative Instructions.....	5-15
5.7.	Extended Term Disconnection.....	5-15

CHAPTER 6	Maintenance and Troubleshooting	Page
6.1.	User Maintenance	6-1
6.1.1.	Annual Laser Maintenance.....	6-1
6.1.2.	Laser System Repair.....	6-1
6.1.3.	Clean the External Surfaces of the Laser Console	6-1
6.1.4.	Clean the LCD Panel.....	6-1
6.1.5.	Fuse Replacement.....	6-2
6.2.	Professional Maintenance	6-3
6.2.1.	Power Meter Calibration	6-3
6.2.2.	Internal Power Meter Test.....	6-3
6.3.	Warranty Information	6-4
6.4.	Decontamination of Returned Equipment.....	6-4
6.5.	Lumenis Customer Support	6-4
6.6.	Troubleshooting Guide	6-5

APPENDIX A	Clinical Guide	Page
A.1.	General Information.....	A-1
A.1.1.	Tissue effects	A-1
A.1.2.	General Warnings and Precautions	A-2
A.1.3.	Adverse Effects (AEs)	A-2
A.1.3.1.	Pain	A-2
A.1.3.2.	Infection	A-3
A.1.3.3.	Bleeding	A-3
A.1.3.4.	Visual Function	A-3
A.1.4.	Non-Contact and Free-Beam Devices.....	A-3
A.2.	Indications for Use	A-4
A.2.1.	Ophthalmology.....	A-4
A.2.2.	Ear, Nose and Throat (ENT)	A-4
A.2.3.	Dermatologic Applications	A-4
A.2.4.	Dentistry Applications.....	A-5
A.3.	Ophthalmic Photocoagulation.....	A-6
A.3.1.	Ophthalmology Indications for Use	A-6
A.3.2.	Contraindications in Ophthalmology	A-6
A.3.3.	Slit Lamp.....	A-6
A.3.4.	Laser Indirect Ophthalmoscope (LIO).....	A-6
A.3.5.	Endoprobe	A-7
A.3.6.	Ophthalmology Precautions.....	A-7
A.3.7.	Ophthalmology Warnings	A-8

A.4. Treatment Parameters in Ophthalmology	A-8
A.4.1. Parameters in continuous waveform (CW)	A-9
A.4.2. Parameters in SmartPulse.....	A-10
A.5. Posterior Segment Laser Procedures.....	A-11
A.5.1. Adverse Effects and Complications	A-11
A.5.2. Patient Warnings	A-12
A.5.3. Guidelines for Use	A-12
A.6. Anterior Segment Laser Procedures.....	A-13
A.6.1. Uses.....	A-13
A.6.2. Warnings	A-14
A.6.3. Adverse Effects	A-14
A.6.4. Guidelines for Use	A-15
A.6.4.1. Iridotomy.....	A-15
A.6.4.2. Trabeculoplasty	A-16
A.7. Ophthalmology Bibliography.....	A-16
A.8. Ear, Nose and Throat (ENT) Laser Applications	A-19
A.8.1. Indications.....	A-19
A.8.2. Contraindications	A-19
A.8.3. Uses.....	A-19
A.8.4. Warnings	A-20
A.8.5. Precautions.....	A-20
A.8.6. Guidelines for Use	A-20
A.9. Otolaryngology References.....	A-20
A.10. Delivery Devices and Accessories	A-22
A.10.1. Filters	A-22
A.10.2. Acculite Endoprobe.....	A-22
A.10.3. Fluence of laser energy delivered by endoprobe.....	A-23
A.10.4. Laser Indirect Ophthalmoscope (LIO)	A-26
A.10.5. Uses.....	A-26
A.10.6. Warnings	A-26
A.10.7. Guidelines for Use	A-26
A.10.8. Slit Lamps and LaserLinks for Slit Lamps	A-28
A.10.9. Description.....	A-28
A.10.10. Guidelines for use	A-28
A.11. Indirect Ophthalmoscope Bibliography	A-28

List of Illustrations

Figure 2-1: Laser Treatment Room Warning Sign	2-3
Figure 2-2: System Regulatory Labels.....	2-15
Figure 3-1: Smart532 Laser System Components	3-2
Figure 3-2: Smart532 Laser System – Front Panel	3-4
Figure 3-3: Smart532 Laser System – Rear Panel	3-5
Figure 3-4: Touch-Screen LCD Control Panel	3-6
Figure 4-1: Physical Dimensions	4-2
Figure 4-2: Smart532 Laser System – Front Panel	4-4
Figure 4-3: Smart532 Laser System – Rear Panel	4-5
Figure 4-4: Connecting the Footswitch.....	4-6
Figure 4-5: Remote Interlock Plug Connection	4-7
Figure 4-6: Connecting the Main Power Cable	4-8
Figure 4-7: Connecting a Delivery System (for illustration purposes only)	4-11
Figure 4-8: LIO Illumination and DVI Connections.....	4-12
Figure 5-1: Login Screen	5-1
Figure 5-2: Main Treatment Screen	5-2
Figure 5-3: SmartPulse Parameter Selection Pop-Up	5-5
Figure 5-4: Preset Screen	5-7
Figure 5-5: Options Screen	5-8
Figure 5-6: Option Screen: Adjust LIO Illumination.....	5-9
Figure 5-7: Option Screen: Language Setting.....	5-9
Figure 5-8: Option Screen: Volume Setting	5-10
Figure 5-9: Option Screen: Backlight Setting.....	5-11
Figure 6-1: Fuses Replacement.....	6-2
Figure 5-10: Option Screen: Eye Safety Filter (ESF) Selection	5-12
Figure A-1: Spot Size versus Distance of fiber tip from Tissue	A-24
Figure A-2: Irradiance versus Distance of Fiber Tip from Tissue	A-24

List of Tables

Table 6-1: Troubleshooting Guide: Error Messages with Corrective Actions..... 6-5

Table 6-2: Troubleshooting Guide: Error Messages Requiring Contact with Lumenis Service..... 6-7

Table 6-3: Undisplayed System Malfunctions Troubleshooting Guide..... 6-8

Table A-1: Typical Treatment Parameters for Ophthalmic Applications A-9

Table A-2: Several Examples of Repetitive Waveform Parameters A-10

Table A-3: Irradiance and Fluence at 1 W and 0.5 Sec and 1.0 Sec Delivered A-23

Table A-4: Spot Size and Irradiance at 1 W Delivered..... A-25

Chapter 1

Overview

1.1. Introduction

The Smart532-nm green laser system is indicated for ophthalmic applications; ear, nose and throat applications; dentistry and dermatologic applications. Complete and detailed lists of the system's clinical indications appear in Appendix A of this manual – **Clinical Guide**.

The Smart532 laser system is shipped directly from the factory to your site. A Lumenis-certified field engineer will initially uncrate, inspect, set up and install the laser to ensure that it is ready for use. In addition, Lumenis provides in-service training to ensure that your staff is experienced with the operation and safety considerations of the laser.

Thereafter, you or the staff at your facility will perform the daily maintenance routines associated with the laser and with any delivery systems and/or accessories used during surgery, including inspecting and cleaning the laser and delivery systems; sterilizing and connecting/disconnecting the accessories. These procedures are detailed in this manual or in the appropriate operator manuals of the delivery systems and accessories.

Most nursing staff prefer to inspect the laser and delivery systems daily, usually prior to scheduled cases and before patients are admitted and prepped. Doing so will ensure adequate time to troubleshoot a problem or seek professional service with the least disruption to patient care.

1.2. Scope of This Manual

This manual is intended to provide the surgeon, private practitioner and other personnel who operate or maintain the system with information regarding the operating principles, controls, safety precautions, installation and maintenance of the system. While this manual is intended to aid in the use and care of the equipment, it does not serve as a substitute for proper training in the clinical applications of medical laser devices.

This operator's manual incorporates the following chapters:

Chapter 1: Overview	Contains a general introduction to the system.
Chapter 2: Laser Safety and Regulatory	Contains explanations and directions concerning safety measures for operating the system. This chapter also includes regulatory information and requirements.

Chapter 3: System Description	Contains a detailed overview of the system and its various components, controls, displays and connections. Includes detailed specifications of all facets of the system.
Chapter 4: System Installation and initial setup	Lists electrical, space and environmental requirements for installation of the system and basic installation & setup instructions.
Chapter 5: Operating Instructions	Explains how to operate the system.
Chapter 6: Maintenance and Troubleshooting	• Provides a detailed review of how to maintain the system. • Lists the system's error messages that might occur during operation, their probable causes and what actions to take.
Appendix A: Clinical Guide	Offers information about staff training, indications and contraindications for use, recommended setup parameters and suggested professional reference literature.

1.3. *Manual Conventions*

Throughout this manual, notes, cautions and warnings are used to provide critical information needed before the device is used.

Examples:



Note

A **Note** is a statement that alerts the operator to particularly important information.



Caution

A **Caution** is a statement that alerts the operator to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, and damage to the device or other property. The caution statement includes the precaution that should be taken to avoid the hazard.

**Warning**

A **Warning** is a statement that alerts the operator to the possibility of injury, death, or serious adverse reactions associated with the use or misuse of the device.

1.4. Physician Responsibility

Federal (USA) law restricts prescription medical devices to sale by or on the order of a physician, or properly licensed practitioner.

The properly licensed practitioner will be responsible for the use and operation of the device and for all user 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.

1.5. Maintenance

The Smart532 laser system is a precision, technical medical device that requires routine service. All service must be performed by a Lumenis technician and all parts must be purchased from Lumenis. Failure to obtain service and parts through Lumenis voids all warranties, expressed and implied. Please call Lumenis or your local representative for details.

1.6. Modification of the Device

Unauthorized modification of the hardware, software or specifications of the Smart532 voids all warranties, expressed and implied. Lumenis takes no responsibility for the use or operation of such a device.

**Caution**

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

1.7. Resale Inspection

If any Lumenis device is resold by anyone other than an authorized sales representative, Lumenis offers a resale inspection by a Lumenis technician to assure that the device is working in accordance with manufacturer's specifications. Using the device after it has been resold and before it has been inspected is a misuse of the device, which may result in injuries and voids all warranties, express and implied.

Lumenis also offers service contracts and extended warranties for its devices. For more information about the services or about the costs of inspections or service calls, please call Lumenis or your local representative.

1.8. Abbreviations and Acronyms

µm	Microns
°C	Degrees Celsius
cm²	Centimeters squared
°F	Degrees Fahrenheit
ANSI	American National Standards Institute
CE	European Directives Compliance Marking
CFR	Code of Federal Regulations
cm	Centimeters
FCC	Federal Communications Commission (USA)
FDA	Food & Drug Administration (USA)
ESF	Eye Safety Filter
EU	European Union
GUI	Graphic User Interface
J/cm²	Joules per square centimeter
Kg	Kilogram(s)
Lbs.	Pounds
LCD	Liquid Crystal Display
LIO	Laser Indirect Ophthalmoscope
m	Meters
mm	Millimeters
ms	Milliseconds
mW	MilliWatts
NHZ	Nominal Hazard Zone
NOHD	Nominal Ocular Hazard Distance
nm	Nanometers
OD	Optical Density
PRP	Pan-Retinal Photocoagulation
RoHS	Restriction of Hazardous Substances Directive (RoHS) Compliance Marking
Sec	Seconds
UL	Underwriters Laboratories
USB	Universal Serial Bus
VAC	Volts, Alternating Current
VDC	Volts, Direct Current
W	Watts
WEEE	Waste Electrical and Electronic Equipment
W/cm²	Watts per square centimeter

Chapter 2

Laser Safety and Regulatory

2.1. Introduction

Operators must take precautions to prevent exposure of laser energy to the eyes and 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.

Patient safety should always be the clinician's first concern. This chapter of the manual includes the minimum information required to operate the system safely. In addition to the guidelines presented here, follow all applicable institutional procedures. Read this chapter completely before attempting a procedure with the Smart532 laser system.

This chapter includes:

- Basic institutional requirements, including responsibilities of the Laser Safety Officer.
- Detailed information concerning the safety eyewear required when using the Smart532 laser system and its associated delivery systems.
- Hazards associated with unsafe laser use.
- Safety features of the Smart532 laser system.
- Compliance with regulatory standards and regulatory labels adhered to the Smart532 laser system.

2.2. Training and Institutional Requirements



Caution

No one should use the Smart532, or any other medical laser, without specific training in both medical laser use and laser safety.

Both operator and safety training is available from Lumenis. Contact your Lumenis representative to inquire about seminars in your area.

2.2.1. *Laser Safety Officer*

Large institutions are following the prescriptions of ANSI 136.3 and EN 207 by setting up Laser Safety Committees and appointing Laser Safety Officers to manage laser use. Even the smallest office should have one person to act in the capacity of Laser Safety Officer.

ANSI Z136.3 and EN 207 require the Laser Safety Officer to fulfill the following responsibilities:

1. Classify, or verify classification of, lasers and laser systems.
2. Evaluate hazards of laser treatment areas.
3. Assure that the prescribed control measures are in effect and recommend or approve alternates when the primary ones are not feasible.
4. Approve operational procedures, including any procedural checklists.
5. Recommend or approve protective equipment, and assure that it is periodically inspected to ensure proper working order.
6. Approve wording on signs and equipment labels.
7. Approve installation and equipment prior to use, and modifications to existing equipment and facilities.
8. Assure adequate safety education and training is provided for all personnel.

The Laser Safety Officer may also assume other responsibilities, such as keeping laser use and maintenance logs. The Laser Safety Officer should become familiar with the periodic maintenance requirements in the **Maintenance** chapter of this manual.

For detailed information refer to Section 2.10. - **Compliance with International Standards.**

2.2.2. Laser Treatment/ Operating Area

According to ANSI Z136.3, the Laser Safety Officer is responsible for the area in which laser treatments are carried out. In meeting this requirement, the Laser Safety Officer should ensure that:

1. The surroundings are safe for both the patient and the operator.
2. The floor is uncluttered and clear access is maintained to the footswitch. Cables are secure and not crimped.
3. The operating area is occupied only by authorized personnel.
4. Appropriate warning signs are posted in the operating area and just outside of it. The Smart532 is a Class IV laser; the door warning sign for the Smart532 is shown in Figure 2-1.



Figure 2-1: Laser Treatment Room Warning Sign

2.3. Laser Safety Eyewear

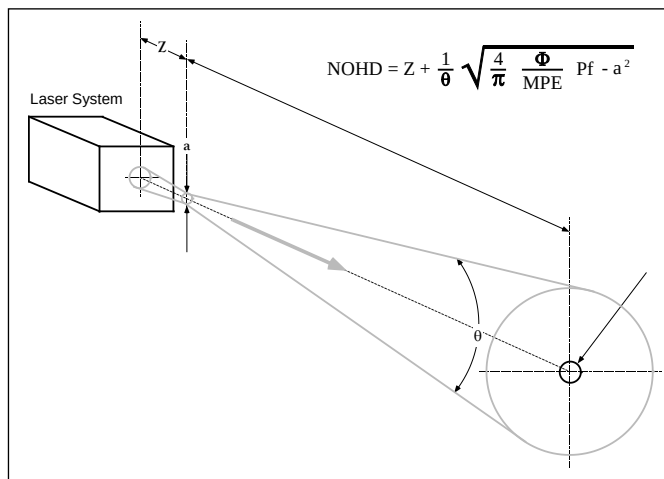
Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (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 Z136.1-2014, ANSI Z136.3-2011, or International Standard IEC 60825-1: 2014.

The following formula was used to calculate the *worst case* NOHD for Lumenis Smart532 lasers and compatible delivery systems:

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

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);
- 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:

	θ (rad)	Φ (W)	MPE (W/cm ²)	Pf	a (cm)	Z (cm)
LaserLink HS	0.020	2.5	0.00137	1	0.050	5.7
LaserLink Z	0.010	2.5	0.00137	1	0.100	9.8
LIO Keeler	0.024	2.5	0.00137	2	0.096	37
LIO Heine	0.022	2.5	0.00137	2	0.107	36
Endoprobe	0.140	2.5	0.00137	2	0.02	0
Lumenis 1000	0.010	2.5	0.00137	1	0.100	9.8
Insight	0.010	2.5	0.00137	1	0.100	9.8
Array LaserLink	0.010	2.5	0.00137	1	0.100	9.8

Which results in a worst case NOHD of:

	NOHD [m]
LaserLink HS	24.2
LaserLink Z	48.3
LIO Keeler	28.8
LIO Heine	31.3
Endoprobe	4.87
Lumenis 1000	48.3
Insight	48.3
Array LaserLink	48.3

Calculated OD value is OD=3.7 for all delivery types.

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:

LaserLink HS	OD 4+
LaserLink Z	OD 4+
LIO Keeler	OD 4+
LIO Heine	OD 4+
Endoprobe	OD 4+
Lumenis 1000	OD 4+
Insight	OD 4+
Array LaserLink	OD 4+

Laser safety eyewear must also be resistant to physical damage or photo-bleaching resulting from laser exposure as per ANSI Z136.1-2007, section 4.6.2 and Appendix C. For operators who must comply with EN 207, the safety eyewear must have a protection class of **LB6**.

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.

**Note**

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.

2.3.1. 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.
- 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.
- 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.
- 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.

2.4. Additional Safety Considerations



- When using a fiber optic delivery device, always inspect the fiber optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
 - Never deliver the treatment beam to the target tissue if the aiming beam is not visible; the fiber optic cable or the delivery device may be damaged. A damaged cable or device may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.
 - Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
 - Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, exposure duration, and power settings that are effective for the intended application should be used until familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
 - Laser beam integrity checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; contact your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to non-target tissues and possible injury.
 - To prevent accidental laser discharge, always place the laser in Standby mode before connecting the delivery system.
 - Never place hands or other objects in the path of the laser beam. Severe burns could occur.
 - Activate the laser only when the aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.
 - Only the person directing the aim of the laser beam should have access to the laser footswitch. Use caution pressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch pressed is the correct one to avoid accidental laser exposure.
 - Laser equipment not in use should be protected against unqualified use by ensuring that the access password is not accessible to unqualified personnel.
-

***In the US: Caution***

- Caution: Federal law restricts this device to sale by or on the order of a physician.
 - Do not use the device in environment with known sources of Electromagnetic Interference (EMI) such as; Magnetic Resonance Imaging (MRI), Computerized-axial Tomography (CT), Diathermy, Radio Frequency Identification (RFID) and electromagnetic security systems (e.g., metal detectors).
 - Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.
-

2.5. Fire Hazards

Personnel in operating rooms, private and out-patient clinics should be aware of the following safety considerations and potential fire hazards when using laser equipment:

- Laser energy can ignite most non-metallic materials.
- Use fire-retardant drapes and gowns.
- A UL or CE approved or equivalent fire extinguisher and water should be readily available.

***Warning***

- Do not use this device in an oxygen-rich environment and in the presence of flammables or explosives, such as volatile anesthetics, alcohol, volatile surgical preparation solutions, and similar substances. An explosion or fire could occur.
 - The area around the target site can be protected with wet towels or gauze sponges. If allowed to dry, these protective towels and sponges can increase the potential fire hazard.
-

2.6. *Electrical Hazards*

Because the Smart532 contains high-voltage components, there is a danger of severe shock if its covers are taken off by other than trained personnel.

To guarantee both operator and patient safety, operator service is limited to the items described in the **Maintenance** chapter of this manual. Other service must be performed only by Lumenis trained personnel.



Warning

- Never open the laser console protective covers. Opening the covers will expose personnel to high voltage components, the laser resonator and possible laser radiation. Only Lumenis-certified service technicians are qualified to service the system.
 - To avoid electrical shock, the area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cables are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis' recommendations and institutional standards.
-

2.6.1. Grounding the System

Proper grounding is essential for safe operation. The system is grounded through the grounding conductor in the power cable. To ensure grounding reliability, always plug the power cable into a properly wired hospital grade power receptacle.



Warning

Use the system only when it is properly grounded via the ground wire lead in the power cable supplied with the Smart532 system.

2.7. Operating Safety Cautions & Warnings

2.7.1. Cautions

Training – do not use the Smart532 laser system in clinical, office or surgical procedures unless you have been trained:

- In general laser safety, including operator and patient protection.
- By a qualified mentor in hands-on situations.
- On the Smart532 system.

Before Performing Procedures – read this manual before performing any patient procedures. The information in this manual should be used in conjunction with, not as a substitute for, formal training.

Power Settings – Lumenis suggests that you begin new or unfamiliar procedures at the lowest recommended power settings and gradually increase the setting until you see the desired effect.

Console Cleaning – when cleaning the console, use a dampened cloth. Avoid saturating the exterior panel areas and electrical input area.

Warranty Void – internal maintenance by unqualified service technicians may cause system damage. This damage is not covered under warranty.

2.7.2. Warnings

Class IV Laser – the Smart532 system contains a Class IV laser which produces a visible beam of high energy radiation. Improper use could result in serious personal injury. Observe all safety precautions for Class IV devices.

To Avoid Injury or Fire – observe all warning and other labels on the equipment. Failure to do so could result in injury or fire.

Inadvertent Lasing – when not actively lasing, set the system to **Standby** mode.

Laser Emission – in **Ready** mode laser energy will be emitted through the laser aperture when the footswitch is pressed.

2.8. System Safety Features

The Smart532 laser system is equipped with various built-in safety features to provide maximum protection for both clinician and patient. Before using the system for the first time, become familiar with these features and how they operate.

2.8.1. Password Protection

Entry to the system's surgical operating program is protected by a password (see Chapter 5). If the password is not keyed in, the operating system is not accessible and laser beam emission will not be available.

2.8.2. Self-Testing at Start Up

When the Smart532 is turned on, the system computer automatically executes system self-testing. Self-testing checks the following:

- Ability of the system to generate lasing power.
- Functionality of the electronic components.
- Safety monitoring circuits.

If the self-test is successfully completed, the system enters **Standby** mode. The test circuits continuously monitor the operation of the system during treatment.

2.8.3. Safety Shutter

The automatic safety shutter blocks the laser beam to prevent accidental lasing.

The safety shutter opens only when the laser is in **Ready** mode and the footswitch is pressed. 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.

2.8.4. Door Interlock Connector

The door interlock connector plug must be inserted into the proper receptacle on the system's rear panel in order for the laser to operate. It can be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.

2.8.5. Location of Controls

Operation and adjustment controls are all located on the system's front panel and touch-screen display so that the operator will enjoy the system's built-in ease-of-use design and ergonomic characteristics of the accessories.

- 2.8.6. *Laser Emergency Stop Button* This red knob is designed for emergency shut-down of laser energy emission. When pressed it immediately disables the laser.
- To disengage the emergency shut-off button, press it again.
- 2.8.7. *Continuous Internal System Monitoring* The system's computer continually monitors internal system status. The following are among the items monitored:
- 2.8.7.1. *System Faults* If a fault is detected an appropriate error message is displayed on the LCD monitor. If the error is non-recoverable lasing is disabled until the fault is corrected. If the error is recoverable, follow instructions on the screen. A complete discussion of system faults may be found in the **Trouble-shooting** chapter of this manual.
- 2.8.7.2. *Internal Power Monitoring* To prevent accidental delivery of excessive energy to tissue, laser energy is monitored continuously. An appropriate error message is displayed on the LCD monitor if a $\pm 20\%$ deviation in the laser output is detected, the system returns to **Standby** mode and issues an error message.
- 2.8.7.3. *Temperature* If the system begins to overheat, an appropriate error message will be displayed on the LCD monitor (refer to the **Troubleshooting** chapter of this manual).
- 2.9. *Laser Beam Emission Indicators* The system features two laser emission indicators: a blue LED-illuminated line located between the system display and buttons and a built-in speaker.
- The blue LED has three modes of operation
- **Low level continuous** - When the system is turned on, and in **Standby** mode.
 - **Medium level blinking** - When the system is in **Ready** mode.
 - **High level continuous** - During laser emission (footswitch pressed).
 - The speaker emits an audible indicator during laser emission.

2.10. Compliance with International Standards

Lumenis lasers and delivery systems comply with the current revision of 21 CFR Part 1040, Chapter I, Subchapter J (Performance Standards for Light-Emitting Products), as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).

CE-labeled devices comply with all appropriate performance standards as specified in Annex II of the European Medical Device Directive MDD 93/42/EEC.

The Smart532 laser system is classified as Class IV lasers by the Center for Devices and Radiological Health of the Food and Drug Administration and as Class 4 by the International Standard IEC 60825.

Refer to the current revisions of the American National Standard (ANSI) publications Z136.3, ANSI Z136.1 and EN 207 for recommendations on the safe use of lasers in health care facilities.

The current revisions of the American National Standards Institute specification ANSI Z136.3 & Z136.1 and EU standard EN 207 include very thorough discussions of laser safety and guidelines for medical laser use. These standards were developed in the earliest days of lasers and are routinely revised to keep up with growing technology. ANSI Z136.3 and EN 207 are written specifically for the use of lasers in medicine. While non-binding, the guidelines are excellent guides for an office or institution seeking to set up a formal safety program.

Lumenis strongly recommends that operators read these two ANSI and EN 207 standards before using a laser in clinical practice.

The Smart532 system is designed to comply with current revisions of the following international standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-2-22: Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.
- IEC 60825-1: Safety of Laser Products - Part 1: Equipment Classification and Requirements.
- IEC 60601-1-6: Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability.

- ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing in the Risk Management Process.
- RoHS: Restriction of Hazardous Substances
DIRECTIVE 2011/65/EU.
- REACH: Registration, Evaluation, Authorization and
Restriction of Chemicals.
- WEEE Waste Electrical and Electronic Equipment
Directive.

In compliance with these standards, the system is equipped with:

- Laser emission indicators
- Beam shutter
- Power display
- Laser emergency stop button
- Door interlock connector
- Proper labeling

In accordance with the regulations, a recommended routine inspection and maintenance schedule is provided in the **Maintenance** chapter of this manual.

2.11. Warning, Certification and Identification Labels

Figure 2-2 displays the labels affixed to the system:

1. **Identification and Certification** – the label contains the following information:
 - System's model name and part number.
 - Serial number and date of manufacture.
 - Manufacturing series number of the system.
 - The system's electrical requirements.
 - CSA compliance symbol.
 - CE marking.
 -  – Follow instructions for use.
 - **Rx Only – Caution:** Federal law restricts this device to sale by or on the order of a physician.
 - WEEE symbol – directs that the electrical/electronic product be disposed of in an environmentally safe way as the directive sets collection, recycling and recovery targets for all types of electrical goods.
 - Details of the manufacturer and of the authorized representative in the European Community.
2. **Laser Emission Danger** – the label contains the following information:
 - Warns against possible exposure to laser beam radiation and specifies the type and classification of laser beams present.
 - System's electrical requirements.
3. **Laser Aperture** – indicates laser beam exit port, located next to the fiber connection ports on the front and rear panels of the system.
4. **Type B/BF Equipment** – type BF relates only to the probe.
5. **Standard & Smart Footswitches IP Rating** – the watertight level of these footswitches conform to the **IP68** standard
6. **PowerEase Footswitch IP Rating** – the watertight level of this footswitch conforms to the **IP28** standard.
7. **Emergency Stop Switch** – pressing this switch immediately disables laser energy emission. Turn the switch 1/4 turn clockwise to reset it.
8. **Upper Window Port Labels** – displays the labels describing the connection ports in the upper window of the rear panel, including electrical specifications.
9. **Lower Window Port Labels** – displays the labels describing the connection ports in the lower window of the rear panel.

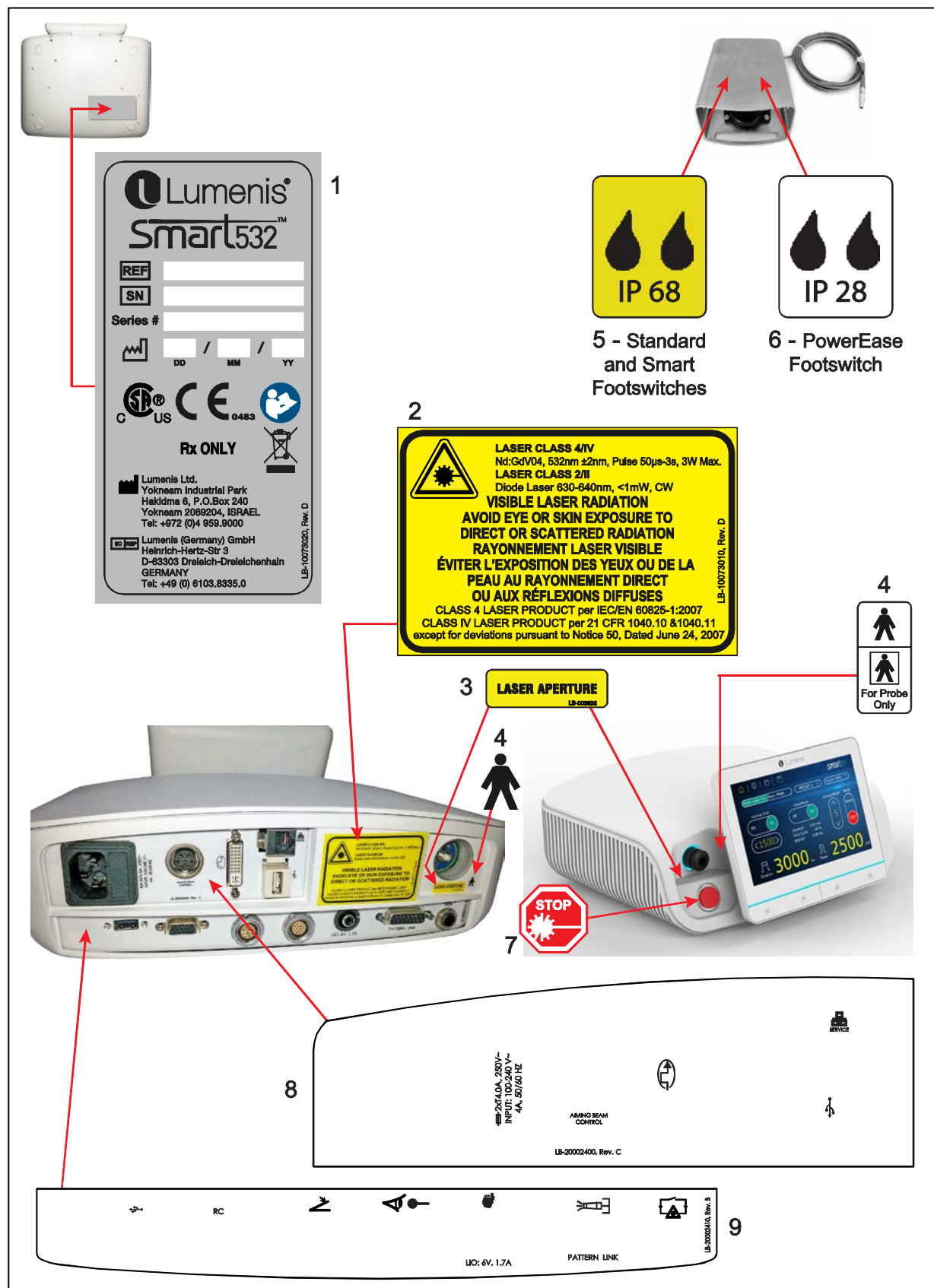
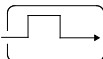
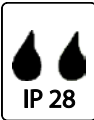


Figure 2-2: System Regulatory Labels

2.12. Symbol Descriptions

The following table provides a key to the symbols displayed on the Smart532 laser system:

<i>Symbol</i>	<i>Description</i>
	Danger: Laser Radiation
	Emergency Stop
	Type B Equipment
	Type BF Equipment
	Follow Instructions for Use
	CE Compliance
	CSA Compliance
	Serial Number
	Catalog Number
	Legal Manufacturer
	Date of Manufacture
	Waste of Electrical and Electronic Equipment (WEEE) Compliance
	Authorized Representative in the European Community

Symbol	Description
 2xT4.0A, 250V~ INPUT: 100-240 V~ 4A, 50/60 HZ	Electrical and Fuses Requirements
	Auxiliary Monitor Connection Port
	Service (Ethernet) Connection Port
	USB Connection Port
	Footswitch Connection Port
	Eye Safety Filter Connection Port
	LIO Connection Port
	Pattern Link Connection Port
	Remote Interlock Connection Port
	Water Ingress Protection Level – Standard & Smart Footswitches
	Water Ingress Protection Level – PowerEase Footswitch

2.13 EMC Guidance and Manufacturer's Declaration

2.13.1 Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Smart532 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart532 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Smart532 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 or B]	Class A
Harmonic emissions IEC 61000-3-2	[Class A, B, C, D, or Not applicable]	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	[Complies or Not applicable]	Complies
	[See 5.2.2.1 c) and Figure 1]	The Smart532 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

2.13.2 Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Smart532 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart532 should assure that it is used in such an environment.			
IMMUNITY Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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 IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Smart532 requires continued operation during power mains interruptions, it is recommended that the Smart532 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the AC mains voltage prior to application of the test level.			

2.13.2 Electromagnetic Immunity (continued)

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (continued)			
The Smart532 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart532 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Smart532, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
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 Smart532 is used exceeds the applicable RF compliance level above, the Smart532 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Smart532. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

2.13.3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Medical Equipment or Medical System

Recommended separation distances between portable and mobile RF communications equipment and the M22 with ResurFX			
The Smart532 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Smart532 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smart532 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}] \sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.334
10	3.689	3.689	7.378
100	11.667	11.667	23.334
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.			

Chapter 3

System Description

3.1. Introduction

The Smart532-nm green laser system is indicated for ophthalmic applications; ear, nose and throat applications; dentistry and dermatologic applications. Complete and detailed lists of the system's clinical indications appear in Appendix A of this manual – **Clinical Guide**.

Lumenis' complete line of delivery systems and accessories further extends the versatility of the Smart532 laser system.

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 Lumenis representative.



Warning

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

3.1.1. *Characteristics of the 532-nm Green Laser Beam*

The 532-nm wavelength falls in the green region of the electromagnetic spectrum. Visible or invisible laser energy can cause tissue damage; therefore, eye safety precautions must be taken by the physician, patient, and any observers in the room. A low-power, visible aiming beam that is coaxial with the treatment beam is used to target tissue.

Green light energy is readily absorbed by melanin, hemoglobin, and oxyhemoglobin in the eye, but avoids macular xanthophyll. These characteristics allow for effective laser photocoagulation of ocular tissue.

3.1.2. Smart532 Laser System Components

The Smart532 laser system is comprised of (see Figure 3-1):



1. A laser console with a touch-screen control panel.
2. All electrical cables necessary for proper connection.
3. Remote interlock connection plug.
4. A footswitch.
5. Safety eyewear.



Note

Delivery devices, including integrated slit lamps and slit lamp tables may be purchased separately.



Figure 3-1: Smart532 Laser System Components

- 3.1.2.1. Laser Console* The laser console houses the touch-screen control panel, laser emergency stop button, control electronics, laser source with associated optics and power supply. The laser console is the central unit to which the laser components and delivery devices are attached.
- 3.1.2.2. Remote Interlock Connection Plug* The remote interlock plug must be inserted into the external interlock connection port on the laser console's rear panel for the laser to operate. The plug may be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.
- 3.1.2.3. Footswitch* The footswitch activates the laser treatment beam when you press it while the laser is in **Ready** mode. Three different types of footswitch are available for the Smart532 system¹:
- **Standard Footswitch** – press the footswitch to emit laser energy.
 - **Smart Footswitch** – the **Smart** footswitch engages the automatic eye safety filter when you place your foot inside of the footswitch housing while the laser is in **Ready** mode.
 - **PowerEase Footswitch** – adjust the laser power by pressing the switches on the inside left (decrease power) and right (increase power) of the footswitch housing.
- 3.1.2.4. Delivery Systems* Delivery systems for a variety of applications may have been shipped with your Smart532 laser system laser. Refer to the operator manuals included with those delivery systems for specific descriptions and operating instructions.
- Compatible delivery systems include probes, fibers, laser indirect ophthalmoscopes (LIO), LaserLinks and slit lamps.

¹ Depending on the Lumenis purchase agreement.

3.1.3. System Description – Front Panel

The front panel of the Smart532 laser system is shown in Figure 3-2.



Figure 3-2: Smart532 Laser System – Front Panel

#	Description
1	Touch-screen control panel
2	Main on/off button
3	Power setting ▲ and ▼ buttons
4	Pulse duration setting ▲ and ▼ buttons
5	Fiber connection port (SMA-906)
6	Laser emergency stop button
7	Cooling grids

3.1.4. Laser Emergency Stop Button

In an emergency, press the laser emergency stop button on the front of the laser console to immediately turn off the laser.



Note

- When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all internal circuits, unplug the main power plug from the wall socket, or turn off the main electrical service (wall circuit breaker).
- The laser emergency stop button turns all power to the laser off, but does not turn off the CPU board or the control panel. When the button is pressed, a message will appear on the control panel, and the system will be in **Standby** mode. To clear the error, press the laser emergency stop button again to disengage it.

3.1.5. System Description – Rear Panel

The rear panel of the Smart532 laser system is shown in Figure 3-3:

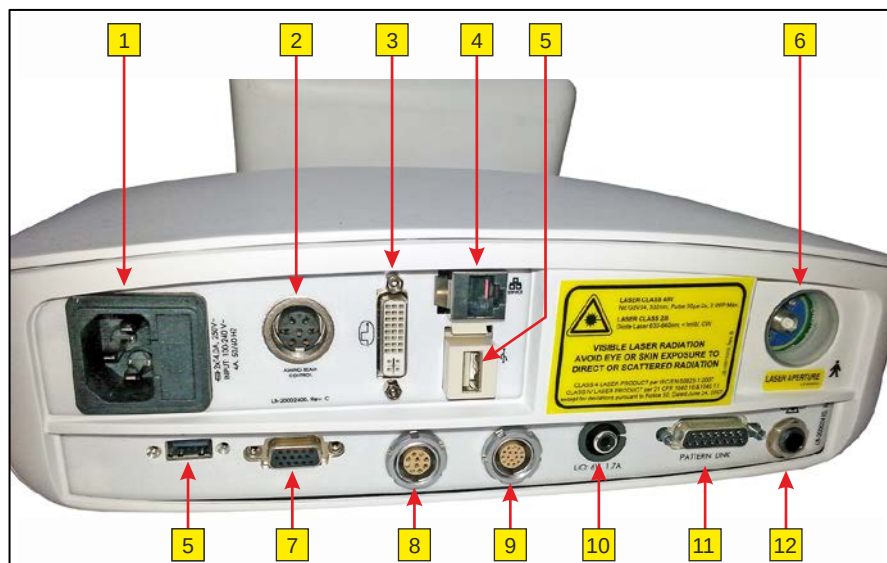


Figure 3-3: Smart532 Laser System – Rear Panel

#	Description
1	Power cable connection port and fuse housing
2	Array connection port to aiming beam
3	DVI connection port
4	Ethernet connection port
5	USB connection ports
6	Fiber connection port (FC)
7	Disabled
8	Footswitch connection port
9	Eye safety filter (ESF) connection port
10	LIO illumination connection port
11	Array data connection port
12	Remote interlock connection port



Note

The USB connection ports are normally utilized by Lumenis-authorized service engineers for servicing the system and for uploading periodical software upgrades.

3.1.6. Touch-Screen LCD Control Panel

The Smart532 system is controlled by pressing the buttons on the touch-screen. Figure 3-4 presents a sample control screen; all aspects of the operating system will be discussed in the **Operating Instructions** chapter later in this manual.

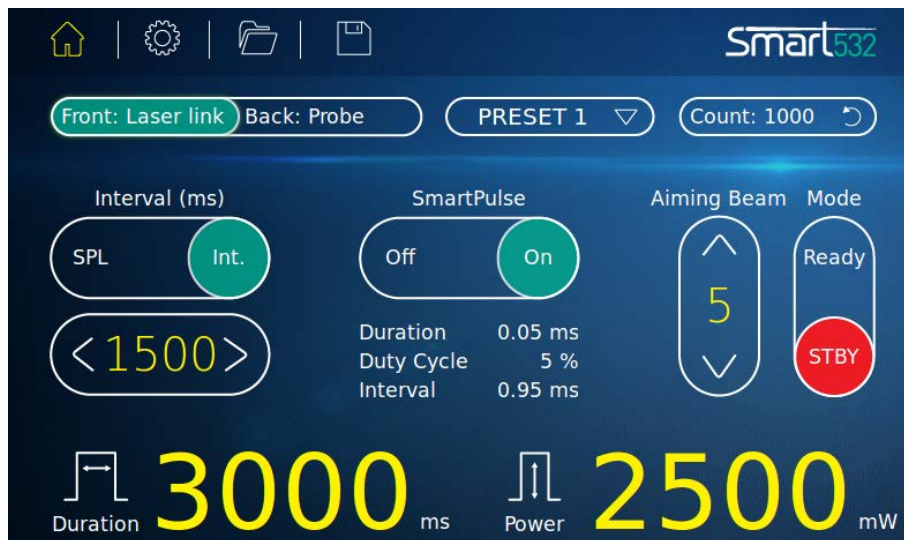


Figure 3-4: Touch-Screen LCD Control Panel

3.1.7. Optical Bench Assembly

The optical bench assembly is comprised of the optical resonator that generates the 532-nm green laser beam, the laser shutter assembly, the photodiodes, the aiming beam assembly and the beam combiner.

The aiming beam is a low-powered 635 nm diode laser with an adjustable intensity control.

The beam combiner combines the 532-nm green laser and the aiming beam coaxially, and guides them into the laser output aperture.

3.1.8. System Specifications

3.1.8.1. Outputs

Treatment Laser

- Type: Frequency-doubled Nd:gdVO₄, diode-pumped solid-state
- Wavelength: Green: 532 nm ±2 nm
- Nominal Laser Peak Power¹: 50 to 2,500 mW
- Exposure Duration: Single pulse²/Continuous Waveform: 5.0 to 3,000 ms
SmartPulse Waveform: 0.05 to 1.0 ms
- Exposure Interval: Continuous Waveform: 10 to 1,500 ms
SmartPulse Waveform: 0.5 to 10 ms

Aiming Laser

- Type: Red diode laser
- Wavelength: 635 nm ±5 nm
- Intensity: 7 settings from minimal to 1 mW max.
- Operational mode: Continuous

3.1.8.2. Operation and Control

Control

- Microprocessor based, touch screen, high resolution, multicolor GUI.
- Presets storing and display capability.

Laser Emission Control

- Footswitch

Laser Emission Indicators

- Blue LED
- Audible indicator

¹ At **Repeat** mode the peak power is limited by duty cycle limitation (refer to the Power Setting section).

² **Single Pulse** is a sub set of Continues one, with all the supporting work ranges, but where the interval is zero.

3.1.8.3. *Compatible Accessories*

- Lumenis Slit Lamps - 1000, 980, 990, SL130, 30SL
- Lumenis Array LaserLink (On-Axis or Off-Axis) 
- Lumenis Trio 
- LaserLink Z
- LaserLink HS 
- ESF for all LaserLinks Listed, green 532nm
- Single and Dual Endo Kits for Zeiss and Leica/Wild microscopes
- LIO (both Keeler and Heine models) 
- Standard, PowerEase or Smart Footswitch

3.1.8.4. *Electrical Requirements*

- 100-240 VAC, 4A, 50/60 Hz, single phase

3.1.8.5. *Physical Specifications*

Dimensions and Weight

- Height: 13.7 centimeters (5.4 inches)
- Width: 29.5 centimeters (11.6 inches)
- Depth: 26.3 centimeters (10.4 inches)
- Weight: 3.5 kilograms (7.75 pounds) 

3.1.8.6. *Environmental Specifications*

Ambient Temperature

- Operating: 10 to 30°C (50 to 86°F)
- Storage: (-20) to 55°C [(-4) to 131°F]

Relative Humidity

- Operating: 10 to 75% relative humidity, non-condensing.
- Shipping & Storage: 10 to 90% relative humidity, non-condensing.

Max. Altitude / Atmospheric Pressure

- Operating: 2,240 m (7,500 ft.) / 78 kPa
- Storage: 2,240 m (7,500 ft.) / 78 kPa

3.1.8.7. *System
Classifications*

Degree of Protection against Electric Shock for Applied Parts

- Type B Equipment

CDRH Classification

- Class IV

European MDD Laser Classification

- Class 4

Suitability for use in Presence of Flammable Mixture

- Not suitable

Protection against Ingress of Water

- IPX0 – water spillage protection for operation room
- IP68 – footswitch types: Standard footswitch & Smart footswitch
- IP28 – footswitch type: PowerEase footswitch

Chapter 4

System Installation and Initial Setup

4.1. Introduction

The Smart532 laser system has passed full quality assurance testing before shipment and should be operational upon delivery.

Your local Lumenis representative initially uncrates, inspects, sets up and installs the laser 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 laser.

Thereafter you, or the nursing staff at your facility, will perform the daily maintenance routines associated with the laser and delivery devices, including inspecting and cleaning the laser and delivery devices, connecting and disconnecting the delivery devices, and verifying the aiming beam. These procedures are detailed in this manual and in the delivery device operator manuals.



Note

In Canada this instrument must be installed and operated according to CAN/CSA-Z386-08: Laser Safety in Health Care Facilities.

4.2. Unpacking the System

The Smart532 system is shipped in a shockproof container. Contents may vary according to the purchase agreement with Lumenis, but the parts and accessories generally shipped in the container are:

- Smart532 system console
- Safety eyewear
- Footswitch
- Door interlock connector plug
- Laser danger sign(s)
- Power cable
- Operator's manual CD

To unpack the Smart532 system, carefully remove all components from the shipping container. Save all packaging materials in case repacking and shipping becomes necessary at a later date.



Note

Any damage to the packaging or to the system found prior to opening the packaging, or during unpacking and installation of the system, should be immediately reported to your Lumenis representative and to the insurance carrier.

4.3. Facility Requirements

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

4.3.1. 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 shown in Figure 4-1. 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.



Figure 4-1: Physical Dimensions

4.3.2. 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, 6A, 50/60 Hz, 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.

4.3.3. *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 between 10-30°C (50-86°F) and relative humidity of 10-75% non-condensing. When the system is used intensively it will emit heat. Therefore, it is recommended that the treatment room be air-conditioned.

4.4. Installation and Setup

The system has passed full quality assurance testing before shipment and should be operational upon delivery.

The front panel of the Smart532 laser system is shown in Figure 4-2.



Figure 4-2: Smart532 Laser System – Front Panel

#	Description
1	Touch-screen control panel
2	Main on/off button
3	Power setting ▲ and ▼ buttons
4	Pulse duration setting ▲ and ▼ buttons
5	Fiber connection port (SMA-906)
6	Laser emergency stop button
7	Cooling grids

The rear panel of the Smart532 laser system is shown in Figure 4-3:

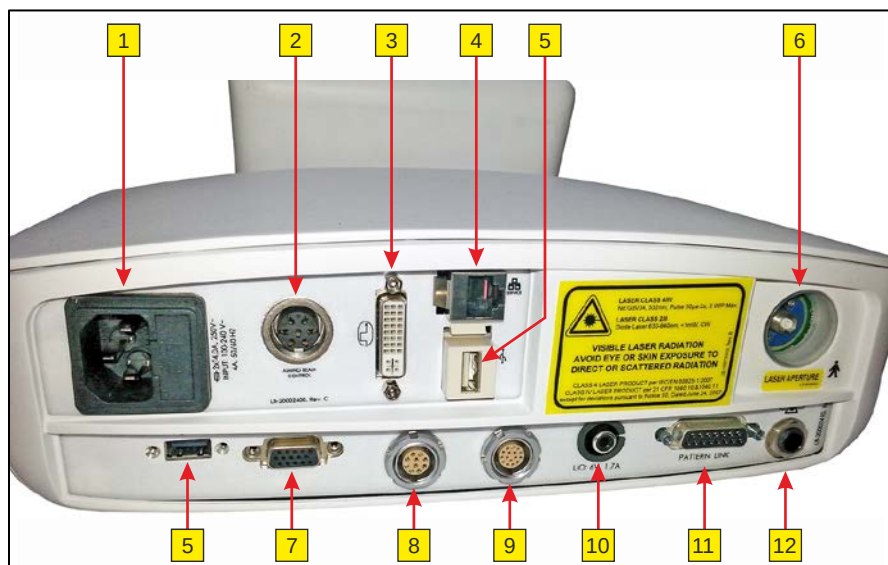


Figure 4-3: Smart532 Laser System – Rear Panel

#	Description
1	Power cable connection port and fuse housing
2	Array connection port to aiming beam
3	DVI connection port
4	Ethernet connection port
5	USB connection ports
6	Fiber connection port (FC)
7	Disabled
8	Footswitch connection port
9	Eye safety filter (ESF) connection port
10	LIO illumination connection port
11	Array data connection port
12	Remote interlock connection port

4.5. Connection Instructions

Before connecting the laser components, inspect the individual components, cables and electrical connections for dirt, debris or damage. Ensure that the electrical cables are not frayed or split. Inspect all delivery devices as instructed in the appropriate delivery device operator manual. Contact your Lumenis representative if any component appears damaged.



Caution

Do not touch any optical lens; finger oils may damage the delicate coatings.

4.5.1. Connect the Footswitch

Insert the footswitch plug into the footswitch connection port on the system's rear panel (see Figure 4-4). If the footswitch is not properly connected when the laser is turned on, an error message will display on the control panel until the footswitch is properly connected.



Figure 4-4: Connecting the Footswitch

4.5.2. Connect the Remote Interlock

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

Use of a remote interlock is optional; however, an interlock plug must be inserted into the remote interlock connection port (see Figure 4-5) whether or not you are using a remote interlock. The laser will be inoperative unless the plug is inserted into the receptacle. For your convenience, the Smart532 laser system is delivered from the factory with an interlock plug pre-installed.

A remote interlock is required for this system. When using a remote interlock, the laser automatically disables and returns to **Standby** mode if the treatment door is opened or the interlock plug is removed. An appropriate error message will appear on the control panel. To resume treatment, close the treatment room door or reinsert the interlock plug, and transition the system to **Ready**.



Figure 4-5: Remote Interlock Plug Connection

4.5.3. Connect the Main Power Cable

Insert the power cable plug into the Power cable connection port on the system's rear panel (see Figure 4-6).

Insert the other end of the power cable into the wall socket and ensure that the plug is secured.

The supplied hospital-grade power cable should be used with a hospital-grade wall outlet. The power cable shipped with the system will vary according to local electrical requirements.



Figure 4-6: Connecting the Main Power Cable

4.5.4. Connect a Delivery System



Warning

- To avoid possible damage to the laser, use only qualified, compatible Lumenis delivery systems. Using after-market devices may jeopardize safe operation or damage the laser and will void your Lumenis warranty or service contract.
- When using a fiber-optic delivery system always inspect the fiber-optic cable to ensure that it has not been kinked, punctured, fractured or otherwise damaged. The fiber-optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber-optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Carefully inspect any delivery system's sterile packaging to ensure that it has not been torn or punctured. If there is any damage to the sterile packaging, do not use the delivery system.

A variety of delivery systems¹ are compatible with the Smart532 laser system. To connect a delivery system, attach the device's laser connector to an available fiber connection port on the system's front or rear panel (see Figure 4-2 or Figure 4-3). Attach any additional connectors to the appropriate accessory connection port. Refer to the appropriate delivery system's operator manual for detailed connection and operating instructions.

When a delivery system is properly connected, the name of the device will be displayed on the control panel (see Chapter 5).

If the delivery system is not properly connected, an error message will be displayed on the control panel. Verify that the delivery system is properly connected to the appropriate connection ports before turning the laser system on. If the delivery system is not compatible with the Smart532 laser system, an error message will be displayed on the control panel.

¹ Optional purchase equipment

4.5.5. Eye Safety Filters

4.5.5.1. Installing the Eye Safety Filter(s)

When using a LaserLink, a Lumenis slit lamp or Acculite delivery system, you must install a compatible automatic or fixed eye safety filter onto the slit lamp or operating microscope. The eye safety filter protects the physician's eyes from exposure to laser energy while looking through the slit lamp or operating microscope.

If the eye safety filter is not properly connected to the Smart532 laser system, or if the eye safety filter is not compatible with the system, an error message will be displayed on the control panel.

Refer to the appropriate delivery system operator manual for detailed eye safety filter installation instructions.



Warning

During treatment the eye safety filter must be attached to the slit lamp or operating microscope. Failure to use an eye safety filter could result in ocular injury. In addition some slit lamps and microscopes require an auxiliary eye safety filter to protect persons observing the procedure through an observation tube. To determine if an auxiliary eye safety filter is required, review your slit lamp or microscope operator's manual or contact its manufacturer.

4.5.5.2. Connecting an Automatic Eye Safety Filter to the Laser

When using an automatic eye safety filter, you must connect the eye safety filter to the Smart532 laser system using the extension cable provided with your eye safety filter.

To connect the eye safety filter to the laser, connect the filter plug to the system as instructed in the appropriate delivery system operator's manual.

Insert the extension cable plug into the laser system's appropriate connection port.

4.5.5.3. Connecting a Fixed Eye Safety Filter to the Laser

If you are using a fixed eye safety filter, then you must insert an emulation plug² into the laser system's eye safety filter connection port.



Note

The LIO delivery system has an integrated eye safety filter. When using an LIO inserting an emulation plug is not necessary.

² Supplied with the Fixed ESF kit.



4.6. *Transporting and Storage*

Prepare the system for transport as follows:

1. Set the system to **Standby** mode and power it down by unplugging it from the wall outlet.
2. Disconnect the delivery system(s) from the laser system. If the delivery device is single-use dispose of it properly. Otherwise, inspect and clean the delivery system(s) as instructed in the appropriate operator's manual(s).
3. Disconnect the footswitch from the laser.
4. Disconnect the remote interlock or the remote interlock emulator.
5. Clean the exterior surfaces of the laser as instructed in the **Maintenance** chapter of this manual.

Caution

Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repacking instructions are required.

Chapter 5

Operating Instructions

5.1. *Safety Considerations*

Read Chapter 2 before attempting any procedures. Be aware of the hazards when using lasers and take appropriate protective measures. Some important reminders:

1. Restrict access to the laser operating area. Post the laser warning sign before beginning any procedure.
2. Make sure that the laser operating area is safe and secure. Any flammable materials should be moistened, or should be beyond contact of the laser beam. All assisting staff in the room should wear protective goggles or glasses.
3. Remember that the footswitch is enabled (allowed to operate the system) when the system is in **Ready** mode. The footswitch is disabled (not allowed to operate the system) when the system is in **Standby** mode. When not actively lasing, set the system to **Standby** mode.

5.2. *Starting the System*

1. Press the On/Off switch on top of the system's control panel; the system starts its initialization process, during which a splash screen is displayed on the LCD.
2. The **Login** screen will now appear (see Figure 5-1) and a self-test routine starts that tests the system; insert the password by pressing the 4-digit passpad (1 2 3 4) on the screen's virtual keypad. If you pressed a wrong button by mistake, press the button with the ← icon – this will clear the last character entered.
3. Press the **Enter** key; if a fault is detected, the system issues an appropriate error message (see Chapter 6). Once the system satisfactorily completes the self-test routine, it is ready for operation and displays the **Main Treatment** screen (see Figure 5-2).



Figure 5-1: Login Screen

5.3. Main Treatment Screen Elements

The elements of the **Main Treatment** screen are described in the following illustration and following table. Each of the elements is described in detail in the following sections.

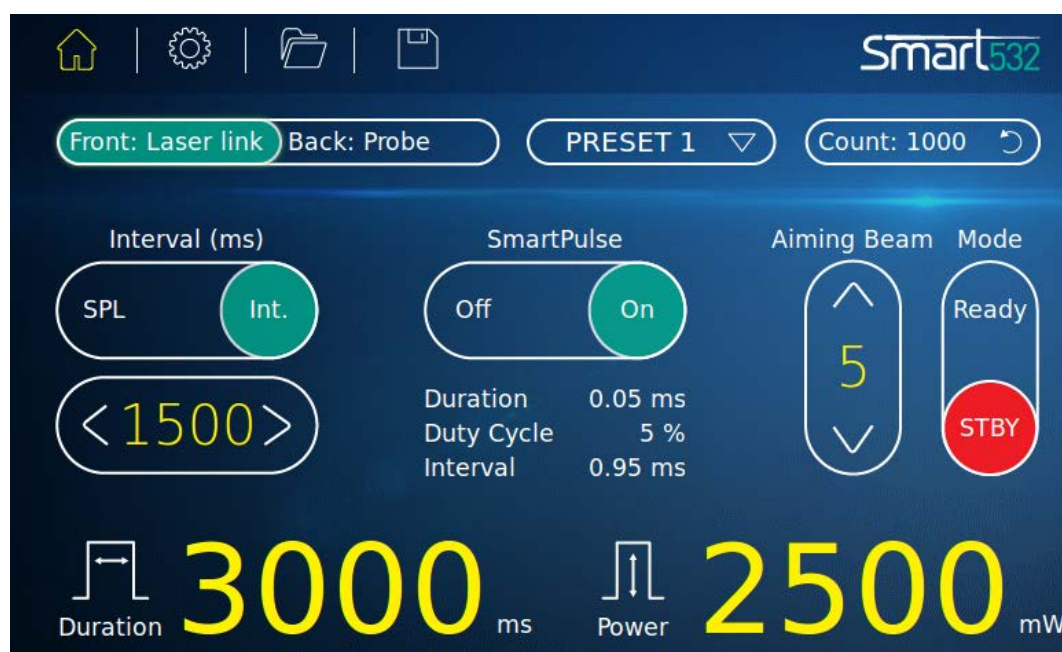


Figure 5-2: Main Treatment Screen

#	Description	See Section:
1	Delivery system selection buttons	5.3.1
2	Power setting display	5.3.2
3	Exposure time setting (pulse duration)	5.3.3
4	Pulse interval display	5.3.4
5	Aiming beam adjustment	5.3.5
6	SmartPulse ¹	5.3.6
7	Pulse counter	5.3.7
8	Standby/Ready mode selection	5.3.8
9	Selected preset name	5.3.9
10	Save new preset	5.3.10
11	Open Presets screen	5.3.10
12	Open Options screen	5.3.12
13	Return to Main Treatment screen	5.25.3

¹ Optional product configuration

**Caution**

Always verify that the desired treatment parameters are displayed on the control panel before initiating treatment. If there is no change in display values when you press the selectors on the control panel, or if the control panel appears otherwise erratic, do not use the laser system. Contact your Lumenis representative.

5.3.1. Delivery System Selection

Select one of two connected delivery systems by pressing the appropriate button on the screen; the highlighted delivery system and port (**Front** or **Back**) is the active one.



Front: Laser link Back: Probe

**Warning**

Always ensure that a compatible eye safety filter is properly connected for the selected delivery system. Failure to properly use an eye safety filter for those delivery systems that require them can result in serious eye injury. Refer to the appropriate delivery system operator manual for additional compatibility and safety information.

5.3.2. Power Setting



The available power level settings are from 50 mW up to 2,500 mW when:

- Between 50 to 100 mW the increments are 5 mW.
- Between 100 to 300 mW the increments are 10 mW.
- Between 300 to 500 mW the increments are 20 mW.
- Between 500 to 1,000 mW the increments are 50 mW.
- Between 1,000 to 2,500 mW the increments are 100 mW.

The available power settings are detailed in the Specifications section in Chapter 3 of this manual.

At a duty cycle of more than 50%, the average power will be limited to 1,250 mW and the peak power on the screen will change accordingly.

**Note**

If you are using the PowerEase footswitch, you can also adjust the laser power by pressing the switches on the inside left (decrease power) and right (increase power) of the footswitch housing.

**Warning**

Always inspect the optics and delivery system as described in this manual to ensure that the system is clean and undamaged. Never use a system that appears damaged or dirty. Doing so may dangerously reduce the delivered power and result in unintended, adverse tissue effects.

5.3.3. Exposure Time Setting

Set the exposure time (pulse duration) by pressing the ◀ or ▶ buttons on the left side under the LCD.



The available exposure time settings are detailed in the **Specifications** section in Chapter 3 of this manual.

5.3.4. Pulse Interval Selection

The pulse interval is the time between laser pulses. Single and repeat pulse modes are available. In single pulse mode, the laser delivers a single pulse each time you press the footswitch. In repeat pulse mode, the laser delivers repeated pulses at a specified interval until you release the footswitch.

The available interval time settings are detailed in the **Specifications** section in Chapter 3 of this manual.



Note

Not all interval settings are available at higher power and exposure time settings. If you attempt to select an interval that is unavailable at the existing power and exposure time settings, the laser changes to meet the duty cycle requirements for that power setting. You must reduce the power or exposure time setting to make available the desired interval. Conversely, if you select the minimum interval for the existing power and exposure time settings, and then you increase the power or exposure time setting, the interval automatically increases to the minimum setting for the new power and exposure time settings.

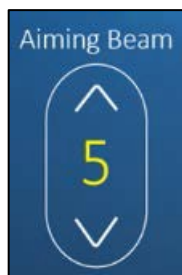


- Ensure that the **Int.** (Interval) button is selected.
- Set the pulse interval by pressing the ◀ or ▶ buttons on the LCD screen.
- If the Single Pulse option is selected (**SPL** button pressed), the Pulse Interval Selection function is disabled.

5.3.5. Aiming Beam Intensity Adjustment

Set the aiming beam intensity by pressing the ▲ or ▼ buttons on the selector icon.

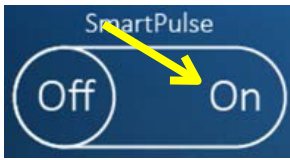
The available aiming beam intensity settings are detailed in the **Specifications** section in Chapter 4 of this manual.



During some procedures, the aiming beam may obstruct the view of the treatment site while lasing. The aiming beam can be either on or off while lasing. To turn the aiming beam off, press the ▼ selector to the lowest setting.

5.3.6. SmartPulse Mode

SmartPulse² mode allows the operator to apply greater fine-tuning to the system's operating parameters; proceed as follows:



- Press the **SmartPulse On** button; the **SmartPulse** parameter selection pop-up appears (see Figure 5-3).

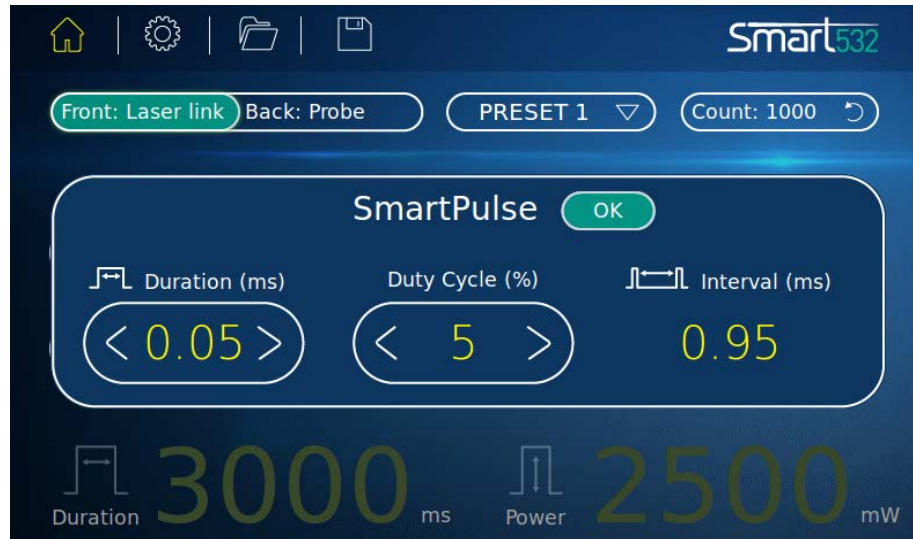
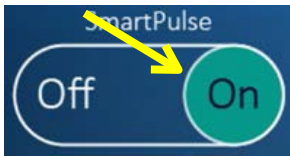


Figure 5-3: SmartPulse Parameter Selection Pop-Up

- Reconfigure the parameter levels of the **Duration** and/or **Duty Cycle** and/or **Interval** by pressing the < or > buttons in each of the parameters.
- Press the **OK** button; the pop-up will close and return to the **Main Treatment** screen. The **SmartPulse Off/On** button will be **On** and the selected parameters will be displayed on the screen.
- At any time during treatment the operator may press the **Pencil** button to display the **SmartPulse** parameter selection pop-up to further fine-tune the parameters.



² Optional product configuration

5.3.7. Pulse Counter



The pulse counter displays the total number of treatment pulses delivered since the reset button was last pressed. The range on the Smart532 laser system display is 0-10,000 pulses. It can be reset to zero by pressing the **Reset** button. The pulse count will reset to **0** (zero) when the laser system is powered down.

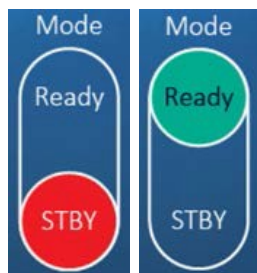
The count display will incrementally show the number of pulses delivered.

5.3.8. Standby/Ready Mode Selection



Warning

- Except during actual treatment, the system must always be in **Standby** mode. Maintaining the system in **Standby** mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before setting the laser to **Ready** mode.



When the Smart532 laser system is turned on and has finished warming up, it defaults to **Standby** mode. The aiming beam is present but the footswitch is disabled and the treatment laser cannot be activated.

Press the **Ready** button to transition the system from **Standby** to **Ready** mode; the **Ready** icon turns green. The system beeps to indicate the start of a two-second delay, after which the treatment beam can be activated by pressing the footswitch.

When the footswitch is pressed the eye safety filter will engage (if using an automatic eye safety filter) and the treatment beam will be activated. While the treatment beam is being delivered, an audible tone is emitted.



Note

- If the laser is not used for five minutes, the system automatically defaults to **Standby** mode.
- If the laser cannot be set to **Ready** mode, an error message displays on the control panel.

5.3.9. Preset Name



This area of the screen displays the name of the currently-selected preset. Press the ▼ button to open a drop-down menu of the last four presets that were used during a treatment.

5.3.10. Save a New Preset You may add your own proprietary treatment setting protocols as presets to the Smart532 laser system.



Adjust the treatment parameters on the touch-screen – power, exposure time, interval and other parameters – in the manner that you desire, and press the **Save** icon; a virtual keyboard will appear on the screen where you may assign a name to the new preset and save it to the system.

Press the **Done** button; a new screen will appear and on it all of the selected parameters will be displayed (see Figure 5-4).

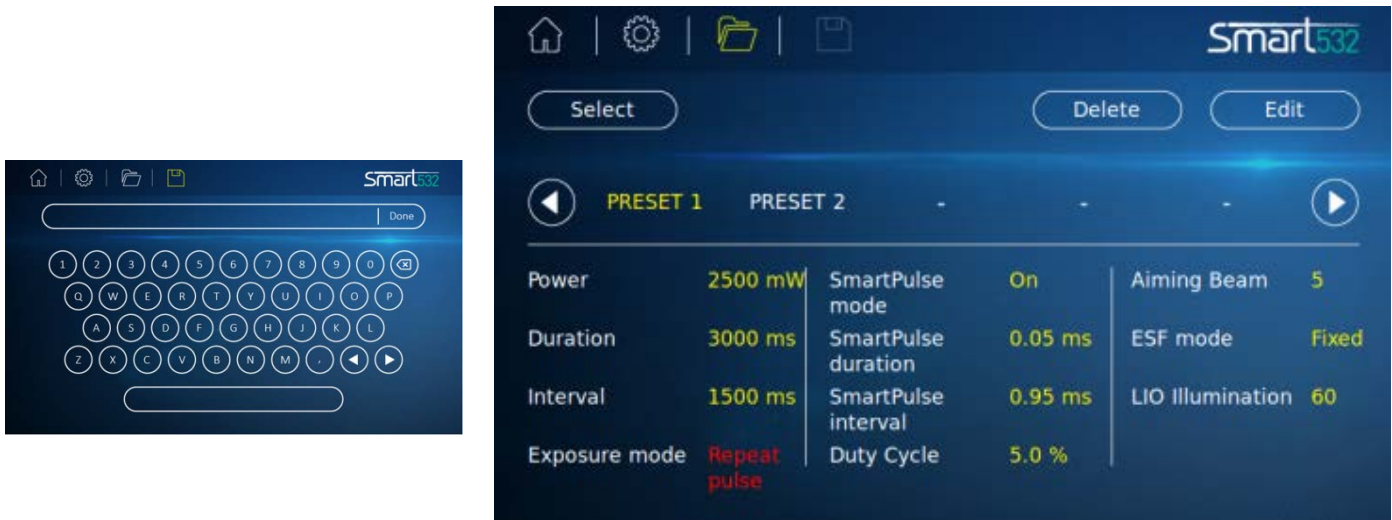


Figure 5-4: Preset Screen

5.3.11. Edit, Delete or Select an Existing Preset

Press the **Preset name** button and select the desired preset:

- Press the **Edit** button to readjust the names and/or the parameters of the preset.
- Press the **Delete** button to remove the selected preset from the system's memory.
- Press the **Done** button on the virtual keyboard to transition to the **Main Treatment** screen for treatment with the selected preset's parameters.

5.3.12. Open Options Screen

To configure the Smart532 system's software and hardware preferences, press the **Options** button on any screen; the **Options** screens will appear (see Figure 5-5).

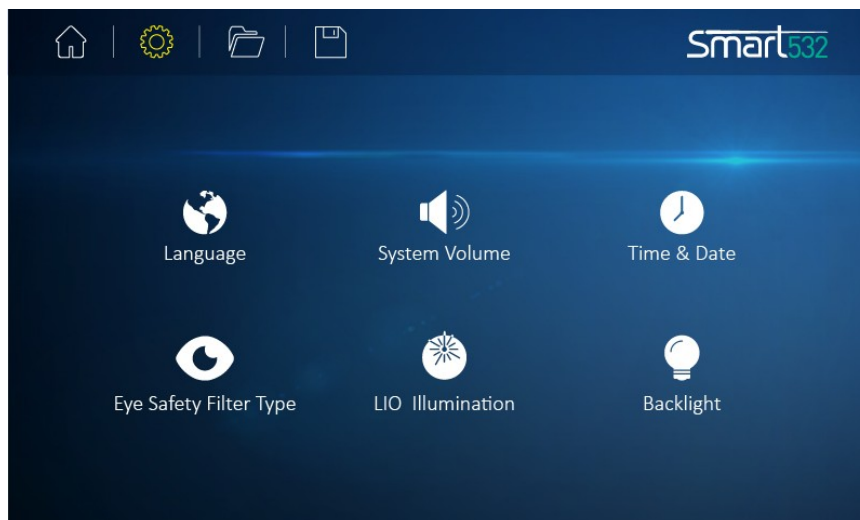


Figure 5-5: Options Screen

Pressing any of the **Options** icons in the screen will navigate the system to that particular Option screen. Pressing the ► or ◀ button at the top-left or top-right corner of the screen will navigate the system to the next or previous Option screen.



Press the **Home** button at any time to exit the **Options** screens and return to the **Home** screen.



Press the **Options** button at any time to exit the particular option screen and return to the **Options** screen (see Figure 5-5).

5.3.12.1. LIO Illumination Setting Screen

In this screen (see Figure 5-6) you may adjust the illumination level of the connected laser indirect ophthalmoscope (LIO) by pressing the ► or ◀ buttons.

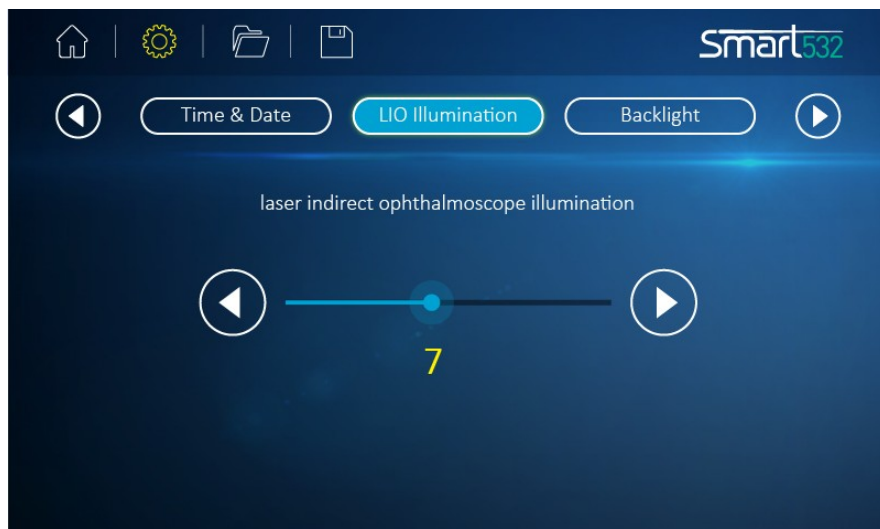


Figure 5-6: Option Screen: Adjust LIO Illumination

5.3.12.2. Time & Date Settings Screen

In this screen (see Figure 5-7) you may adjust the system's time and date settings by pressing the ▲ or ▼ buttons above or below each of the appropriate parameters.

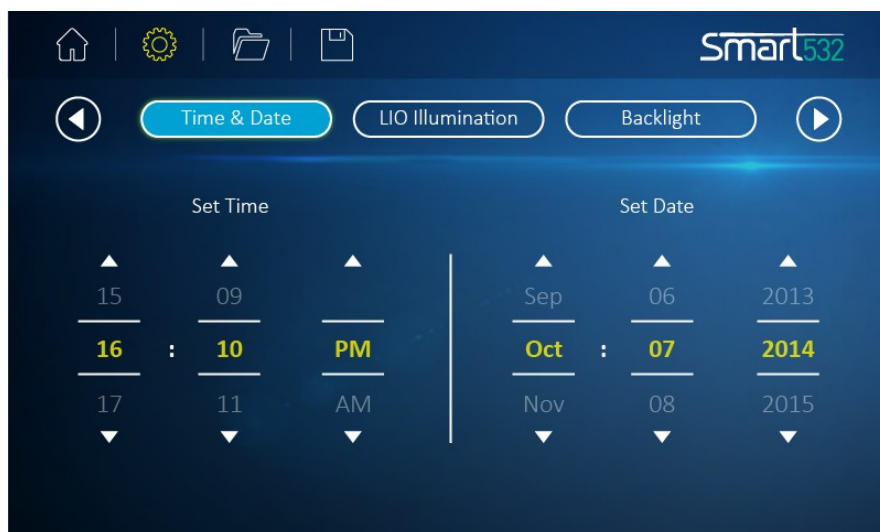


Figure 5-7: Option Screen: Time & date Settings

5.3.12.3. Language Setting Screen

In this screen (see Figure 5-8) you may select the user interface language by pressing the appropriate language icon on the screen. The available language selection is English, Italian, German, Japanese, Simplified Chinese, Russian, French, Spanish, Dutch and Portuguese.



Figure 5-8: Option Screen: Language Setting

5.3.12.4. Volume Setting Screen

In this screen (see Figure 5-9) you may adjust the volume of the system's feedback by pressing the ► or ◀ buttons.

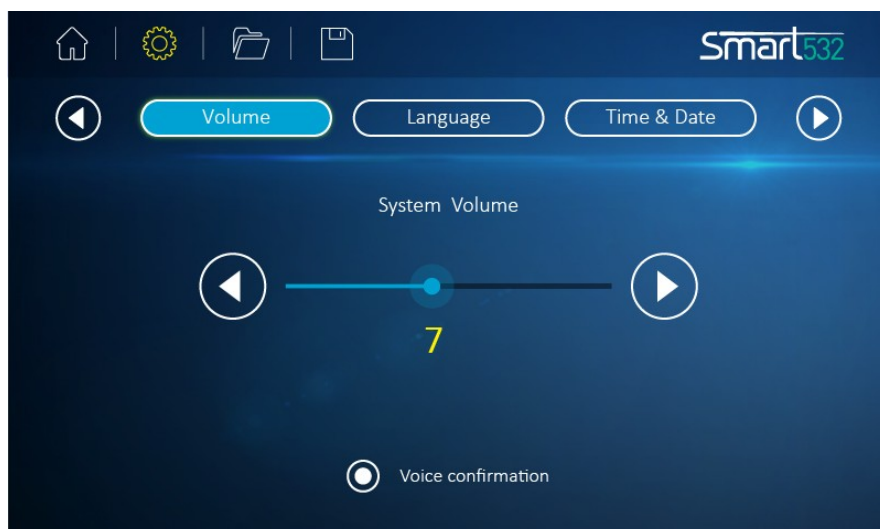


Figure 5-9: Option Screen: Volume Setting

5.3.12.5. Backlight Setting Screen

In this screen (see Figure 5-10) you may adjust the backlight illumination level of the user interface screen by pressing the ► or ◀ buttons. You can set the backlight separately for **Standby** and **Ready** system modes.



Figure 5-10: Option Screen: Backlight Setting

5.3.12.6. Eye Safety Filter (ESF) Mode Selection Screen

In this screen (see Figure 5-11) you may select the operational mode of the connected ESF by pressing the desired mode on the screen.

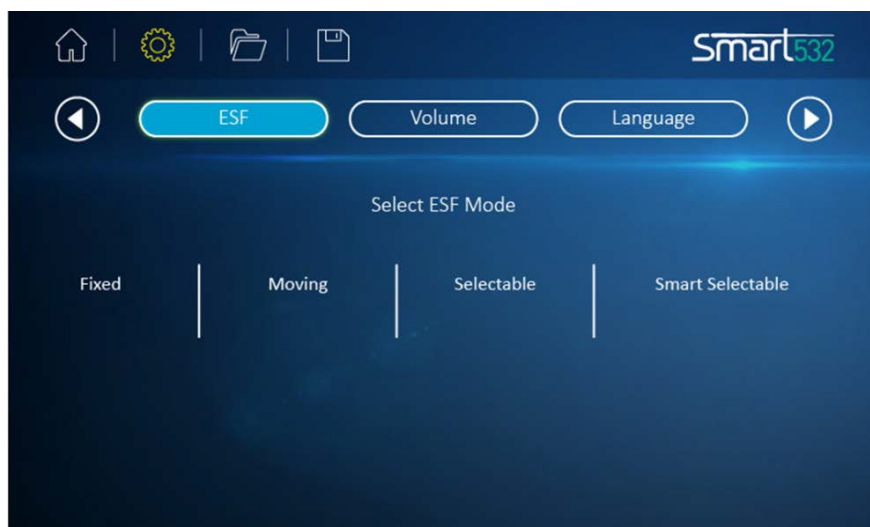


Figure 5-11: Option Screen: Eye Safety Filter (ESF) Selection

One or more of the following eye safety filter modes are available, depending upon the type of footswitch, delivery system(s), and eye safety filter(s) that you have connected to the laser:

- **Fixed:** the eye safety filter is always in position.
- **Moving:** the eye safety filter moves into position when you press the footswitch while the laser is in ready mode (available only with automatic eye safety filters).
- **Selectable:** the eye safety filter moves into position when you place the laser in Ready mode (available only with automatic eye safety filters).
- **Smart Selectable:** the eye safety filter moves into position when you place your foot inside the Smart footswitch housing while the laser is in Ready mode (available only with automatic eye safety filters and the Smart footswitch).



Note

If you are using a fixed eye safety filter, or if you are using a delivery system with an integrated fixed filter, such as the LIO, the eye safety filter mode is automatically set to **Fixed**; no other modes are available.

5.4. *Pre-Operative Instructions*

1. Verify that the laser system is properly connected as instructed in this manual.
2. Verify that the delivery system is properly connected as instructed in the delivery system operator manual. If using a remote interlock, verify that it is also properly connected.
3. Post the **Laser in Use** warning sign outside the treatment room door.
4. Plug the laser system's main power cable into the wall socket.
5. Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear. See Laser Safety Eyewear in Chapter 2 of this manual for detailed laser safety eyewear information.
6. Turn on the laser system.
7. Perform the aiming beam integrity check as instructed later in this chapter.



Warning

- Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
 - Do not use the delivery system if the aiming beam is set to high intensity and is weak or not visible; the fiber optic cable may be damaged. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
 - Before using the laser, always verify that the displays on the laser console are properly working.
-

5.4.1. Aiming Beam Integrity Test

**Warning**

- Refer to the appropriate delivery system manual for important, additional information on laser beam integrity specific to that device.
- When using a fiber delivery device always inspect the fiber to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the fiber with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the fiber. A damaged fiber may cause accidental laser exposure or injury to the treatment room personnel or patient and/or cause fire in the treatment room.

Before beginning treatment, verify the aiming beam integrity by performing the following:

1. Ensure that the delivery system is properly connected to the Smart532 laser as described in the **Connection Instructions** sections earlier in this chapter.
2. Turn on the Smart532 laser system.
3. Verify that there are no error messages displayed on the control panel. If a message is displayed, ensure that the connector is fastened properly to the fiber connection port. If **Incompatible Delivery Device Connected** is displayed, connect a compatible delivery system.
4. Set the aiming beam to the highest intensity.
5. Hold a non-reflective surface, such as a tongue depressor, in front of the probe fiber tip or at the delivery system's focal plane. A red spot (the aiming beam) should appear on the flat surface. If the aiming beam is weak, verify that the aiming beam is set to the highest intensity.

**Warning**

Do not use the delivery system if the aiming beam is set to the highest intensity and is still weak or not visible; the fiber may be damaged. A damaged fiber may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.

6. Set the desired laser treatment parameters.

5.5. Intra-Operative Instructions



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.

1. Set the treatment values, as instructed in this manual, and verify that the desired settings are displayed on the control panel.
2. Ensure that the aiming beam is visible and position it on the target tissue.
3. Set the laser system to **Ready** mode.
4. Press the footswitch to deliver the treatment beam to the tissue.
5. The laser emission icon will illuminate on the control panel, and the system will emit a beep for each pulse delivered.
6. If surgery must be interrupted, set the laser system to **Standby** mode to disable the footswitch.

5.6. Post-Operative Instructions

1. Set the laser system to **Standby** mode.
2. Turn off the laser system by unplugging it and coiling the power cable to prevent damaging it.
3. Unplug the footswitch and coil the cable to prevent damaging it.
4. If desired, disconnect the delivery system and store the laser and delivery system components, as instructed in this manual and in the delivery system operator manual. Refer to the delivery system operator manual for additional postoperative instructions specific to the delivery system.
5. Disconnect the remote interlock (if used).
6. Clean the exterior surfaces of the laser, as instructed in the **Maintenance** chapter of this manual.

Chapter 6

Maintenance and Troubleshooting

6.1. *User Maintenance*

6.1.1. *Annual Laser Maintenance*

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

6.1.2. *Laser System Repair*

All laser system repairs should be performed by a Lumenis-certified service engineer. For detailed information contact your Lumenis representative.

6.1.3. *Clean the External Surfaces of the Laser Console*

Use a cloth dampened with a hospital-grade disinfectant to wipe the external surfaces of the laser console. Dry with a clean cloth or allow to air dry.

6.1.4. *Clean the LCD Panel*

The LCD panel should be cleaned with a dedicated LCD cleaning liquid, available in most office supply stores.



Caution

Do not spray or pour cleaning agents directly on the laser console or LCD panel. You may damage the console, screen, and laser system electronics.

6.1.5. Fuse Replacement

1. Ensure that the system is turned off.
2. Unplug the main power cable from both the wall socket and the main power receptacle on the rear of the laser console.
3. Locate the fuse holder directly to the right of the main power receptacle.
4. Unlock and pull out the fuse holder by inserting a small, insulated flathead screwdriver into the slot on the fuse holder cover.
5. Replace the fuses as follows: two fuses rated 250V, 4A, Type T, Slo-Blo (5 x 20 mm)
6. Reinsert the fuse holder.



Note

Always replace both fuses.



Figure 6-1: Login Screen

6.2. *Professional Maintenance*

This section covers tests, calibrations and maintenance that require internal access to the Smart532 console and special skills.



Warning

These procedures demand specific knowledge, training and use of tools not available to repair personnel outside of Lumenis. Since performing these procedures may expose the user to potential electrical and laser energy hazards, Lumenis requires that these procedures only be performed by trained service personnel.

6.2.1. *Power Meter Calibration*

Regulatory agencies require that manufacturers of US FDA CDRH Class II and IV, and European IEC 60825 Class 2 and 4 medical lasers supply their customers with power calibration instructions.

Power meter check and calibration must be performed by an engineer or technician qualified to work with laser equipment. Questions regarding this procedure should be referred to your Lumenis representative.

Disclaimer warning:

Calibration is a service procedure to be performed only by Lumenis-certified service engineers. Adjustment by anyone other than a trained Lumenis service engineer voids any existing manufacturer's warranty on the instrument. 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.

6.2.2. *Internal Power Meter Test*

The Smart532 laser system incorporates an internal power meter which is used for display and control of lasing energy. The power meter test compares the internal power meter reading to the reading from an external power meter.



Note

Optical components must be clean before the power meter check is performed.



Warning

- All personnel in the immediate area must wear eye protection rated specifically for the 532 nm laser.
 - An out-of-calibration power meter will cause power delivery to tissue to be different than that displayed.
-

6.3. **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**.



Caution

Improper use or adjustment of this system may invalidate the service warranty agreement. Please contact your Lumenis representative before attempting to troubleshoot this system in any manner other than those specified in this manual.

6.4. **Decontamination of Returned Equipment**

In order to comply with postal and transportation laws, equipment shipped to the supplier's offices for return or repair must first be decontaminated. To communicate that the returned equipment has been properly decontaminated, a signed **Decontamination Certificate** (obtained from Customer Service) must be enclosed in the shipping package.

Failure to enclose the Decontamination Certificate will cause the supplier to assume the product is contaminated. The supplier will assess the customer with cleaning costs. Any decontamination inquiries should be directed to Customer Service.

6.5. **Lumenis Customer Support**

Lumenis Center	Address	Telephone/Fax
Lumenis Ltd.	Yokneam Industrial Park 6 Hakidma Street P.O.B. 240 Yokneam 2069204, Israel	Tel: + 972.4.959.9000 Fax: + 972.4.959.9050
Lumenis, Inc.	2033 Gateway Place, Suite 200 San Jose, CA 95110, USA	Tel: + 1.408.764.3000 Fax: + 1.408.764-3999
Lumenis (Germany) GmbH	Heinrich Hertz Str. 3 D-63303 Dreieich-Dreieichenhain Germany	Tel: + 49 (0) 6103.8335.0 Fax: + 49 (0) 6103.8335.300
Lumenis Co. Ltd., Japan	1-14-3 K-3 building 5F Oi Shinagawa-ku, Tokyo 140-0014 Japan	Tel: + 81.3.4431.8300 Fax: + 81.3.4431.8301
Lumenis Ltd. China	4th floor, South Tower, Kerry Centre, No.1 Guang Hua Road Beijing 100020, China	Tel: +86.10.5737.6677 Fax: +86.10.5737.6767

6.6. Troubleshooting Guide

Table 6-1 provides a list of error messages that may appear on the touch-screen control panel that include possible remedies that may be attended to by clinic staff. The operator has the option of correcting the problem, setting the system back to **Ready** mode and continuing with normal operation.

Table 6-2 provides a list of 'Fatal' error messages that may appear on the touch-screen control panel that will disable further use of the system. In the event of such a message, shut down the system, restart it and try to resume normal operation. If the situation persists, shut down the system and contact Lumenis Service. Report the error number and text to them and follow their advice.

Table 6-3 lists some possible system symptoms that indicate malfunctions that do not appear on the control panel. If the corrective action listed in the table does not solve the problem, contact Lumenis-authorized service personnel.

If any error situation cannot be resolved, or if an error message returns repeatedly, contact Lumenis Service.

The following troubleshooting tables do not attempt to list all possible system failures. Any fault not listed should be referred to authorized service personnel.

Table 6-1: Troubleshooting Guide: Error Messages with Corrective Actions

#	Error Message Text	Corrective Action
4	Internal Communication Error (C-S)	Restart system and try again; If error persists, shut down the system and contact Lumenis Service.
8, 11	System Warm-Up, Please Wait.	Wait until the system warms up sufficiently before attempting to operate.
14	Eye Safety Filter (1) Identification Error	Incompatible ESF connected. Connect compatible accessories.
15	Eye Safety Filter (2) Identification Error	Incompatible ESF connected. Connect compatible accessories.
16	Eye Safety Filter (1) Error	ESF failure; replace accessory and retry.
17	Eye Safety Filter (2) Error	ESF failure; replace accessory and retry.
18	Eye Safety Filter (1) is not connected	Check cable connection and retry.
19	Eye Safety Filter (2) is not connected	Check cable connection and retry.
21	Footswitch Disconnected	Check cable connection and retry.
22	Footswitch Pressed While Entering Ready Mode	Release the footswitch and press the Ready button again.
23	Footswitch Error	Footswitch failure; check cable connection and retry, replace or repair footswitch.

Table 6-1: Troubleshooting Guide: Error Messages with Corrective Actions (continued)

#	Error Message Text	Corrective Action
24	Footswitch Error	Smart footswitch failure; check cable connection and retry, replace or repair footswitch.
25	Footswitch Error	Power Ease footswitch failure; check cable connection and retry, replace or repair footswitch.
30	Power Converge Error (SubP)	System could not generate requested power. Restart system and try again; If error persists, shut down the system and contact Lumenis Service.
32.	Door Open (Interlock)	Close the interlocked door or connect the interlock plug. Access Ready mode and continue normal operation.
33	Emergency Button Pressed	Pull the laser emergency stop button out and restart the system.
34	On/Off Button Pressed	Release the button and resume normal operation.
35	Invalid Password	Enter the correct login password and resume normal operation.
39	Temperature Range Error (System)	The ambient temperature in the treatment room is outside of the system's specs. Adjust the room temperature and restart the system.
42	Front Port: Accessory Identification Error	Incompatible delivery device connected.
43	Rear Port: Accessory Identification Error	Incompatible delivery device connected.
44	No Delivery Device Connected	Connect a compatible delivery device and resume normal operation.
45	Two LIOs connected	Disconnect one of the LIOs and resume normal operation.
46	Two Laser Links connected	Disconnect one of the laser links and resume normal operation.
47	Two Probes connected	Disconnect one of the probes and resume normal operation.

Table 6-2: Troubleshooting Guide: Error Messages Requiring Contact with Lumenis Service

#	Error Message Text
1	Software Version Error
2	Internal Communication Error (G-C)
3	Internal Communication Error (C-F)
5	Aiming Beam Not Calibrated
6	Aiming Beam Error
7	Display Press-Buttons Error
9	Temperature Error (LBO)
10	Temperature Range Error (LBO)
12	Temperature Error (Diode)
13	Temperature Range Error (Diode)
20	Internal Clock Error
26	Shutter Error
27	Diode Error (Current)
28	Diode Error (Check)
29	Diode Error (Power)
31	Timing Error
36	Voltage Error (12V)
37	Voltage Error (3.3V)
38	Voltage Error (1.9V)
40	Port Selection Error
41	Power Calibration Error
48	Parameters Error
49	Diode Temperature Error
50	Diode Temperature Error
51	Diode (LBO) Temperature Error

Table 6-3: Undisplayed System Malfunctions Troubleshooting Guide

Symptom	Probable Cause	Corrective Action
System does not function when plugged in and turned on.	1. No AC power from wall outlet. 2. Tripped power circuit breaker (operating room power supply).	1. Check if AC power is available from wall outlet, and power cable is properly plugged into AC outlet. 2. Reset power circuit breaker.
System will not switch to Ready mode.	1. Footswitch or delivery system not connected properly. 2. Footswitch malfunction. 3. System malfunction.	1. Check external connections according to warning message. 2. Contact Lumenis Service. 3. Contact Lumenis Service.
Laser emission does not occur when footswitch is pressed.	1. System is not in Ready mode. 2. Damaged delivery system. 3. Footswitch malfunction. 4. System malfunction.	1. Set system to Ready mode. 2. Replace delivery system. 3. Contact Lumenis Service. 4. Contact Lumenis Service.
System not responding to touch-screen commands	Control panel's touch-screen is out of calibration.	Contact Lumenis Service.
Inadequate treatment beam or tissue effect.	The treatment or aiming beam is not properly aligned.	Contact Lumenis Service.
System does not turn on. Display does not illuminate.	1. The laser is not plugged in. 2. The building power (main electrical service) is turned off. 3. The electrical outlet is defective. 4. Blown surge-protection fuse(s).	1. Plug the power cord into the laser and into an appropriate outlet. 2. Turn on the building power. 3. Use another outlet or have the outlet professionally tested and, if appropriate, repaired 4. Replace fuses.

Appendix A

Clinical Guide

A.1. General Information



Warning

- The Indications for Use and Safety and Regulatory sections of this operator manual should be carefully read and comprehended in their entirety before attempting to use the laser system. Particular attention should be given to all cautions and warnings pertaining to the safe use of the laser.
- The use of a laser instrument for an application is at the physician's discretion except in cases where the indication has been contraindicated.

Successful clinical use of the laser depends upon the interaction of a number of variables. These variables include the type of tissue, the amount of tissue pigmentation, spot size, delivered power, pulse duration, and incidence angle of the laser beam onto the target tissue.

A.1.1. Tissue effects

Tissue effects are caused by the absorption of electromagnetic laser radiation and its conversion to heat. Diffusion of heat through the tissue depends on the thermal properties of the irradiated material. Pulse parameters such as duration, interval, frequency and power may be optimized for a desired tissue effect.

The irradiance (power density) required to elicit a specific tissue effect depends on a multitude of factors, such as, but not limited to:

- Reflection coefficient at air/water interface with target tissue.
- Density and type of pigmentation at target tissue
- Opacities of media preceding target tissue
- Wavelength of the laser beam
- Spot size of the laser beam at target tissue
- Time dependent parameters (e.g., pulse duration)
- Blood flow
- Other factors that may influence heat diffusion

Tissue effects include, in incremental order: expression of heat shock proteins¹, denaturation of proteins, photocoagulation, vaporization and ablation². For Smart532, the effect of interest is photocoagulation. Analysis of clinical and laboratory experience indicates that irradiance of ~100-500 W/cm², corresponding to heating the tissue by ~12-25°C above body temperature, is required for photocoagulation of tissues^{2,3}.

A.1.2. General Warnings and Precautions



Warning

- Lumenis and/or related entities assume no responsibility for parameters, techniques, methods or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, i.e. technique, proper power settings, intervals, durations, etc.
- Physicians should seek formal training from established courses on the use of the laser and its accessories. Any information given in this text is not intended to provide such instructions, and is not to be considered a substitute.



Caution

- The laser unit should be handled carefully. Maintenance and service should be performed only by Lumenis trained personnel.
- In using any delivery devices or accessories, attention must be paid to the specific instructions and precautions applicable to those devices. This manual and the appropriate delivery device operator manual should be carefully read and comprehended before use.

A.1.3. Adverse Effects (AEs)



Warning

Complications of laser therapy are the same as complications for any other surgical procedure. Some of these complications may be serious and could result in death or permanent blindness.

¹ C. Sramek, M. Mackanos, R. Spitler, L. Leung, H. Nomoto, C. Contag and D. Palanker, "Non-damaging retinal phototherapy: dynamic range of heat shock protein expression". *Invest. Ophthalmol. Vis. Sci.*, vol. 52, no. 3, pp. 1780-7, 2011.

² G. Kulkarni, "Laser-tissue interaction studies for medicine," *Bull Materials Sci*, vol. 11, pp. 239-44, 1988.

³ J. Krauss and C. Puliafito, "Lasers in ophthalmology," *Lasers Surg Med*, vol. 17, no. 2, pp. 102-59, 1995.

- A.1.3.1. Pain** Delivery of laser energy is occasionally associated with pain or discomfort. During the procedure, pain may be reduced by topical anesthesia or retrobulbar block. The extent and duration of pain following laser therapy are usually minimal.
- A.1.3.2. Infection** The possibility of infection must be considered and treated accordingly, especially when laser energy is delivered via endoprobes.
- A.1.3.3. Bleeding** The possibility of postoperative bleeding must be considered, and post-operative follow-up is advised. Laser irradiation may cause the regression newly formed vessels, thereby producing vitreous and subhyaloid hemorrhage. If laser application is applied close to the macula and with high power setting, there is a risk of disrupting the pigment epithelium and compromising the Bruch's membrane, thereby giving rise to foci of choroidal neovascularization which can bleed^{4,5}.
- A.1.3.4. Visual Function** In some cases, extensive photocoagulation may cause a reduction in visual acuity secondary to macular edema, a reduction in peripheral vision, a reduction in the power of accommodation, loss of color vision (especially in the blue spectrum), loss of contrast sensitivity, a scotoma or photophobia^{6,7,8}. Visual function may also be compromised by inadvertent delivery of laser energy to the fovea and parafoveal areas.
- A.1.4. Non-Contact and Free-Beam Devices** Tissue effect may be controlled by altering the distance between hand-held fiber-optic delivery devices and the target tissue.
- Once the treatment is completed, routine post-operative care is indicated according to the procedure done.



All recommendations for safe use of your laser system should be followed. Users should be aware of the recommended practices for the safe use of

⁴ A. Obana, B. Lorenz, A. Gassler and R. Birngruber, "The therapeutic range of chorioretinal photocoagulation with diode and argon lasers: an experimental comparison," *Lasers Light Ophthalmol.*, vol. 4, pp. 147-56, 2009.

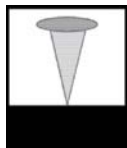
⁵ P. Romero-Aroca, J. Reyes-Torres, M. Baget-Bernaldiz and C. Blasco-Suñe, "Laser treatment for diabetic macular edema in the 21st century," *Curr. Diabetes Rev.*, vol. 10, no. 2, pp. 100-12, 2014.

⁶ H. McDonald and H. Schatz, "Visual loss following panretinal photocoagulation for proliferative diabetic retinopathy," *Ophthalmology*, vol. 92, pp. 388-93, 1985.

⁷ J. Evans, M. Michelessi and G. Virgili, "Laser photocoagulation for proliferative diabetic retinopathy," *Cochrane Database Syst. Rev.*, 2014doi:10.1002/14651858.CD011234.pub2.

⁸ F. P. A. Bandello, M. Del Borrello, N. Zemella and M. Isola, "'Light' versus 'classic' laser treatment for clinically significant diabetic macular oedema.," *Br J Ophthalmol*, vol. 89, no. 7, pp. 864-70, 2005.

lasers in health care facilities, as described in ANSI Z136.3⁹ and ANSI Z136.1¹⁰. Laser applications performed with non-contact devices are indicated throughout this manual by the icon shown on the left.



Laser applications using free-beam devices, such as slit lamps or laser indirect ophthalmoscopes, are indicated by the icon shown on the left.

A.2. Indications for Use

The Smart532 is intended for use in the treatment of ocular, otolaryngological, dermatologic and dentistry indications as listed below.

A.2.1. Ophthalmology

The indications for use in ophthalmology are:

- Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy
- Proliferative Diabetic Retinopathy (PDR)
- Retinal Tear
- Macular Edema or Proliferative Retinopathy associated with Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO).
- Choroidal Neovascularization (CNV) secondary to Age-related Macular Degeneration (AMD)
- Central Serous Chorioretinopathy (CSCR)
- Trabeculoplasty for Primary Open Angle Glaucoma (POAG)
- Iridotomy / Iridoplasty for Angle-Closure Glaucoma (CAG)

A.2.2. Ear, Nose and Throat (ENT)

The indications for use in ear, nose and throat are:

- Stapedectomy
- Stapedotomy
- Myringotomies
- Lysis of Adhesions
- Control of Bleeding
- Removal of Acoustic Neuromas
- Soft Tissue Adhesion in Micro/Macro Otologic procedures.

⁹ American National Standards Institute. "Safe Use of Lasers in Health Care Facilities" ANSI Standard Z-136.3. New York: ANSI, 1430 Broadway, 1996.

¹⁰ American National Standards Institute "Safe Use of Lasers" ANSI Standard Z-136.1. New York: ANSI, 1430 Broadway, 1993.

A.2.3. *Dermatologic Applications*

The indications for use in dermatology are:

- Pigmented lesion, including solar lentigines
- Vascular lesions, including cherry hemangiomas and angiokeratomas
- Extremities telangiectases, including facial and leg telangiectases
- Cutaneous lesions
- Flat warts
- Dermatitis
- Papulosa Nigra

A.2.4. *Dentistry Applications*

The indications for use in dentistry are

- Frenectomy
- Treatment of oral mucous cyst
- Treatment of benign vascular lesions:
 - Capillary hemangioma
 - Hemorrhagic hereditary telangiectasia
 - Capillary/cavernous hemangiomas
 - Lymphangioma
 - AV malformation of the tongue
 - Hemangio-lymphangiomas
- Photocoagulation of superficial vessels
- Vaporization of superficial blood or lymph containing vessels.
- Treatment of superficial tongue lesions
- Tissue management and hemostasis for crown and bridge impressions.
- Incision and drainage for abscess
- Gingivoplasty/Gingivectomy
 - Operative procedures
 - Crown and bridge, gingival reduction
 - Crown lengthening
- Hyperplasia (Drug, irritation, Epulis).
- Hemostasis during dental procedures
- Operculectomy (Operculotomy)
- Excisional biopsy
- Free Gingival Graft (Adjunct):
 - Hemostasis of donor site

- Hemostasis of graft site
- Vestibuloplasty
- Soften Gutta Percha
- Treatment of canker sores, herpetic lesions, and aphthous ulcers
- Laser-assisted bleaching/whitening

A.2.5 **Device energy delivery options**

Energy Delivery Option	Indication
SmartPulse	Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy, Proliferative Diabetic Retinopathy (PDR), Central Serous Chorioretinopathy (CSCR), Macular Edema or Proliferative Retinopathy associated with Branch Retinal Vein Occlusion (BRVO)
CW (Continuous Wave)	All Indications

A.3. ***Ophthalmic Photocoagulation***

The Smart532 system emits a laser beam with a wavelength of 532 nm (green). This type of energy can be used to treat several ocular conditions in both the anterior and posterior segments of the eye. It is particularly well suited for treating the eye because it is not absorbed in aqueous media and has minimal effect on transparent tissues and materials. Hence the laser energy can efficiently penetrate the cornea, aqueous humor, lens, and vitreous humor to target tissues of interest such as the retina in the posterior segment and the trabecular meshwork in the anterior segment.

Laser energy can be delivered by means of a slit lamp, a laser indirect ophthalmoscope or an endoprobe.

A.3.1. ***Ophthalmology Indications for Use***

See Section A.2.1.

A.3.1.1. ***Clinical conditions and associated treatment***

<u>Condition</u>	<u>Treatment</u>
Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy	Focal/Grid laser
Proliferative Diabetic Retinopathy (PDR)	Pan-retinal photocoagulation
Macular Edema or Proliferative Retinopathy associated with Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO).	Grid, sectoral or pan-retinal photocoagulation
Central Serous Chorioretinopathy (CSCR)	Focal/Grid laser
Choroidal Neovascularization (CNV) secondary	Focal/Grid laser

to Age-related Macular Degeneration (AMD)	
Retinal Tear	Barrage laser treatment
Primary Open Angle Glaucoma (POAG)	Trabeculoplasty
Angle-Closure Glaucoma (ACG)	Iridotomy/Iridoplasty

A.3.2. *Contraindications in Ophthalmology*

Laser treatment is contraindicated when an appropriate procedure cannot be performed safely. This could occur when tissue targets cannot be visualized properly. Corneal opacities, cataract formation and vitreous hemorrhage can all interfere with the physician's view of target tissues, possibly leading to inadvertent photocoagulation of tissues/structures adjacent to the tissue/structure of interest. Treatment should be delayed until the ocular media problem resolves or is treated. If it is not possible, an alternative form of therapy should be considered.

A.3.3. *Slit Lamp*

Laser energy is most commonly delivered to the eye by means of a slit lamp that has been specially adapted for use as a laser delivery system. In this case, the delivery system includes a lens system that focuses the laser energy and changes the size of the laser spot in the slit lamp observation plane. It may include a mechanism that manipulates the position of the laser beam without moving the slit lamp. The laser energy is delivered to the slit lamp by means of a flexible fiber optic.

For most procedures, a contact lens is used to direct the laser energy to the part of the eye being treated. The contact lens may have mirrors so that laser energy can reach peripheral areas of the retina or the irido-corneal angle (e.g., the trabecular meshwork). The contact lens is also instrumental in order to inhibit eye movements and to prevent eyelid closure, so that laser energy can be delivered effectively and safely.

A.3.4. *Laser Indirect Ophthalmoscope (LIO)*

In young children or in physically impaired, disabled or unconscious patients, the delivery of laser energy through a slit may not be possible. In these cases, examination is done in the supine position, using a laser indirect ophthalmoscope (LIO).

A.3.5. Endoprobe

Media opacities such as a non-transparent cornea, a dense cataract or a vitreal hemorrhage can obstruct the delivery of laser energy through a slit lamp or an LIO. A solution is to circumvent these media opacities by delivering the laser energy via an endoprobe (a disposable fiber optic). In addition, laser delivery via an endoprobe is often employed in the operation room, as an adjunct to vitreo-retinal surgery.

The endoprobe is inserted in the ocular globe via a scleral incision done at the pars plana level. The size of the laser burn can be controlled by changing the distance from the tip of the endoprobe to the target: the closer the tip probe is from the retina, the smaller and more fluent (i.e., higher energy density) is the spot of influence.

A.3.6. Ophthalmology Precautions

The following precautions should be taken when using laser energy in ophthalmic procedures:

- Excessive power density (power/area) may cause unwanted target tissue damage. Hence, caution must be exercised when reducing the spot size, as the spot size is inversely related to the power density: decreasing the spot diameter by $1/x$ multiplies the power density by x^2 . For example, halving the spot diameter quadruples the power density.
- Approximate power settings are usually found by titration using a continuous waveform at a peripheral location, starting from low values and gradually increasing the power, until the desired endpoint (such as blanching in posterior segment indications) is achieved. Once power settings P_{vis} are identified through titration with a continuous waveform, if the user desires to operate in SmartPulse Mode then the power typically used is P_{vis} multiplied by a factor of 1.2 to 2.0 (see Table A-2 for references)
- Increased pigment density can increase the absorption of laser energy, thereby increasing the thermal effect. Physicians should take account of this fact when intending to treat areas of increased pigmentation, either by reducing the power setting, or by treating areas with less pigmentation.
- Opacities in the ocular media may absorb the laser light and cause inadvertent and undesirable thermal damage to the tissues in which the opacities are located. Opacities in a patient's ocular media include makeup remnants in the corneal tear film, corneal lesions, pigment or blood on the surfaces of the crystalline lens, and cataract formation. Prior to laser therapy, debris should be removed from the patient's tear film.
- Direct treatment of vascular or vascularized structures can cause intraocular bleeding that can impair a patient's vision as well as the physician's ability to complete the laser procedure. Vascular/vascularized structures should be treated with caution, using treatment patterns and parameters appropriate for the specific indication and conditions.

A.3.7. Ophthalmology Warnings

- Only appropriate tissue targets should be subject to photocoagulation.
- Attention should be paid to avoid treating major retinal vessels, as vitreous hemorrhage and serious visual loss could occur.
- The optic nerve head should not be coagulated, as severe and permanent visual loss could occur.
- Inadvertent macular photocoagulation, especially close to the fovea (within 300-500µm), can cause severe and permanent visual loss.
- Excessively high power settings should not be used, as they can cause damage to tissues adjacent to the target of interest.

A.4. Treatment Parameters in Ophthalmology

Ophthalmic problems are successfully treated with laser photocoagulation. Treatment parameters such as power, duration of the pulse and spot size depend on a variety of factors including the type of tissue to be treated, the intensity of the lesion desired, and the individual pigmentation of tissue targets.

Smart532 comes with two types of waveforms: Continuous waveform (CW) and SmartPulse.

A.4.1. Parameters in continuous waveform (CW)

In CW, the stimulus is a single square pulse of duration 10-500 msec. The appropriate power is usually found by titration: the power is initially set to a low level and then increased gradually until the desired tissue effect is obtained. Table A-1 lists recommended clinical treatment parameters for intended medical conditions using CW pulse:

Table A-1: Recommended clinical treatment parameters in CW for intended medical conditions

Treatment (Mode)	Power (mW)	Required Tissue Reaction	Exposure duration (sec)	Spot size (μm)
Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy ¹¹	100-300	mild grey-white burn	0.05-0.5	50-200
Proliferative Diabetic Retinopathy (PDR) ^{12,13}	250-750	Whitening	0.02-0.1	100-500
Central Serous ChorioRetinopathy (CSCR) ¹⁴	150-400	Light grayish	0.02-0.2	50-200
Macular Edema or Proliferative Retinopathy associated with Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO) ¹²	175-410	Grey-white	0.02-0.2	100-400
Retinal Tear ¹⁵	175-575	Grey-white	0.01-0.4	200-400
Iridotomy for angle closure (Stretch) ¹⁶	500	Stroma at the iridotomy site becomes thin and tense	0.2	500
Iridotomy for angle closure (Penetration) ¹⁶	1000	Penetration, until a hole of 0.2 mm in the iris is formed	0.02-0.2	50
Trabeculoplasty for primary open angle glaucoma ¹⁷	400-600	Blanching	0.1	50
CNV ¹⁸	200	Mild whitish	0.2	150-250

¹¹ P. Romero-Aroca, J. Reyes-Torres, M. Baget-Bernaldiz and C. Blasco-Suñe, "Laser treatment for diabetic macular edema in the 21st century," *Curr. Diabetes Rev.*, vol. 10, no. 2, pp. 100-12, 2014.

¹² Y. Paulus and M. Blumenkranz, "Proliferative and nonproliferative diabetic retinopathy," *One Network*, 2013.

¹³ C. Sanghvi, R. McLauchlan, C. Delgado, L. Young, S. Charles, G. Marcellino and P. Stanga, "Initial experience with the Pascal photocoagulator: a pilot study of 75 procedures.," *Br J Ophthalmol*, vol. 92, no. 8, pp. 1061-4, 2008.

¹⁴ L. Ficker, G. Vafidis, A. While, P. Leaver, "Long-term follow-up of a prospective trial of argon laser photocoagulation in the treatment of central serous retinopathy," *Br J Ophthalmol*, vol. 72, pp. 829-34, 1988

¹⁵ M. Muqit, C. Sanghvi, R. McLauchlan, C. Delgado, L. B. Young, S. J. Charles, G. R. Marcellino and P. E. Stanga. "Study of clinical applications and safety for Pascal laser photocoagulation in retinal vascular disorders". *Acta Ophthalmologica* 90:155-161, 2012

¹⁶ R. Harrad, K. Stannard and J. Shilling, "Argon laser iridotomy," *Br J Ophthalmol*, vol. 69, no. 5, pp. 368-72, 1985.

¹⁷ E. Rosenfeld, G. Shemesh and S. Kurtz, "The efficacy of selective laser trabeculoplasty versus argon laser trabeculoplasty in pseudophakic glaucoma patients," *Clin Ophthalmol*, vol. 6, pp. 1935-40, 2012.

¹⁸ L.V. Angioletti, P.J. Colquhoun, A.D. Kulik, E.H. Malpica, "Indirect photocoagulation of subfoveal choroidal neovascularization in age-related macular degeneration", *Bull N Y Acad Med*, vol. 67(4), pp. 389-98, 1991

A.4.2. *Parameters in SmartPulse*

In SmartPulse, the stimulus is a train of brief pulses (see Table A-2). The characteristic use of SmartPulse is when a sub-visible tissue reaction is requested. In such a case, power is estimated by titration done at a peripheral retinal location: at this location, using a continuous waveform the power is gradually increased to P_{vis} , until a barely visible burn is obtained. In SmartPulse, the power typically used is P_{vis} multiplied by a factor of 1.2 to 2.0 (see Table A-2 for references).

Because the tissue reaction is sub-visible, physicians might not recognize if an area has been treated, leading to under-treatment (not treating an area) or over-treatment (treating over an area which was previously treated). Different strategies may be employed to address this issue.

For example, visible landmarks (e.g., light gray burns) obtained with continuous waveforms could delimit an area to be treated (for example, the corners of a square). The area within the delimited area could be then filled with sub-visible spots.

Another possibility is for the physician to draw a treatment plan before the actual treatment, clearly marking the fovea, the major arcades, the arterioles and an outline of the area to be treated. During treatment, treated areas could then be marked on the outlined areas in the treatment plan, thereby preventing the physician from treating the same areas twice, and indicating him which areas were not yet treated.

With gathering more experience using the system, physicians that treat in the sub-visible range will typically adopt their own strategies.

Table A-2 lists recommended clinical treatment parameters for intended medical conditions using SmartPulse:

Table A-2: Recommended clinical treatment parameters in SmartPulse for intended medical conditions

Indication	Power (mW)	References (links)	SmartPulse duration (ms)	SmartPulse interval (ms)	Exposure duration (sec)	Spot size (μm)
Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy ¹⁹	1.2 X test burn CW power	Lavinsky et al 2011	0.1	1.9	0.3	125
		Kwon et al 2014	0.2	1.8	0.02	100
		Laursen et al 2004	0.1	1.9	0.1	125
		Luttrull et al 2005	0.1	1.9	0.3	125
		Nakamura et al 2010	0.3	1.7	0.2	200
		Ohtman et al 2014	0.3	1.7	0.3	75-125
		Vujosevic et al 2010	0.1	1.9	0.2	100
		Range:	0.1-0.3	1.7-1.9	0.02-0.3	75-200
		Most commonly used value:	0.1	1.9	0.3	125
Proliferative Diabetic Retinopathy (PDR) ²⁰	2.0 X test burn CW power	Desmettre et al 2006	0.3	1.7	0.2	125
		Luttrull et al 2008	0.3	1.7	0.2	500
		Moorman & Hamilton 1999	0.1-0.3	1.7-1.9	0.1-0.3	200-500
		Range:	0.1-0.3	1.7-1.9	0.1-0.3	125-500
		Most commonly used value:	0.3	1.7	0.2	200
Central Serous Chorio Retinopathy (CSCR) ²¹	2.0 X test burn CW power	Koss et al 2012	0.3	1.7	0.2	125
		Breukink et al 2015	0.1	1.9	0.2	125
		Bandello et al 2003	0.2-0.3	1.8-1.9	0.2	200
		Range:	0.1-0.3	1.7-1.9	0.2	125-200
		Most commonly used value:	0.3	1.7	0.2	125
Macular Edema or Proliferative Retinopathy associated with Branch Retinal Vein Occlusion (BRVO) ²²	2.0 X test burn CW power	Inagaki et al 2014	0.3	1.7	0.3	200
		Ohkoshi et al 2010	0.3	1.7	0.2	125-200
		Moorman & Hamilton 1999	0.1-0.3	1.7-1.9	0.1-0.3	200-500
		Parodi et al 2006				
		Range:	0.1-0.3	1.7-1.9	0.1-0.3	125-500
		Most commonly used value:	0.3	1.7	0.3	200

¹⁹ D. Lavinsky, J.A. Cardillo, L.A.S. Meli, A. Dare, M.E. Farah, and R. Belfort Jr., "Randomized Clinical Trial Evaluating mETDRS versus Normal or High-Density Micropulse Photocoagulation for Diabetic Macular Edema", *IOVS*, vol. 52(7), pp. 4314-23, 2011

²⁰ T.J. Desmettre, S.R. Mordon, D.M. Buzawa, and M.A. Mainster "Micropulse and continuous wave diode retinal photocoagulation: visible and subvisible lesion parameters", *Br J Ophthalmol*, vol. 90, pp. 709-12, 2006

²¹ M.J. Koss, I. Berger, F.H. Koch, "Subthreshold diode laser micropulse photocoagulation versus intravitreal injections of bevacizumab in the treatment of central serous chorioretinopathy", *Eye*, Vol. 26, pp. 307-14, 2012

²² K. Inagaki, K. Ohkoshi, S. Ohde, G.A. Deshpande, N. Ebihara and A. Murakami, "Subthreshold Micropulse Photocoagulation for Persistent Macular Edema Secondary to Branch Retinal Vein Occlusion including Best-Corrected Visual Acuity Greater Than 20/40", *J Ophthalmol*, Epub 2014, Sep 4, 2014

A.5. Posterior Segment Laser Procedures



Note

- Users should be aware of general laser warnings, precautions, and adverse effects listed in **General Information** in this chapter.
- Refer to the Ophthalmology references in this chapter for literature regarding the use of the laser in retinal laser procedures.

A.5.1. Adverse Effects and Complications



Warning

- The most common complication is increased macular edema secondary to pan-retinal photocoagulation, usually with a concurrent decrease in visual acuity. Visual acuity loss is the result of redirection of the blood flow from the shunting vessels in the mid-periphery toward the macular region. In addition, blowout hemorrhages from areas of neovascularization, particularly on the optic nerve, have been observed. These may be caused by an increase in peripheral resistance secondary to photocoagulation, or by an inadvertent Valsalva maneuver by the patient.
- Only a contact lens specifically designed for use with laser energy should be used. Use of a standard diagnostic contact lens will result in a power loss due to reflection from the surface of the lens. The reflected energy may pose a hazard to both the patient and the physician.

Macular striae and increases in vitreoretinal traction are occasionally observed, particularly in advanced diabetic retinopathy. These areas, as well as zones along the vitreous base, should be observed closely so that pars plana vitrectomy can be used, if necessary, to alleviate excessive vitreoretinal traction caused by pan-retinal photocoagulation.

In rare cases, rapidly maturing cataract or lenticular opacities developed as a result of photocoagulation²³.

²³ Straub W. Complications after photocoagulation and cryotherapy. *Klin Monbl Augenheikd* 171:317-21, 1977.

A.5.2. Patient Warnings

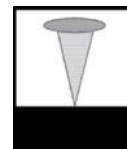


Warning

- Following photocoagulation, patients should be cautioned against any activity that could increase the venous pressure in head, neck, or eyes, such as straining, lifting, or holding their breath. Patients should be advised to sleep with the head of their bed elevated 15 to 20°.
- Patients should be cautioned against stifling a sneeze, as this may raise ocular blood pressure to a high level. Vigorous nose blowing should also be discouraged. Rubbing the eyes following photocoagulation may disrupt blood vessels inside the eyes. Sneezing and coughing should be controlled with cough syrup or other medications.
- Patients should be cautioned, however, against the use of medications such as nose drops, sprays, inhalators, or other medications that contain ephedrine or epinephrine, because these drugs tend to elevate systemic pressure.
- Immediately following treatment, patients should avoid altitudes over 2,400 m / 8,000 ft. (commercial aircraft cabins are pressurized below this altitude).

A.5.3. Guidelines for Use

- For retinal laser treatments, the pupil should be dilated.
- Topical anesthetic is normally adequate, but occasionally a retrobulbar block is needed.
- A contact lens specifically designed for use with laser energy is placed on the eye (note: a standard diagnostic contact lens will result in a power loss due to reflection from the surface of the lens. The reflected energy may pose a hazard both to the patient and the physician). Such a contact lens allows the physician to visualize and treat peripheral areas of the retina which otherwise cannot be reached.
- The power setting depends on a multitude of conditions, such as spot size, pulse duration, pigmentation and turbidity of the vitreous. The standard procedure is to find the approximate power by titration using a continuous waveform, done at a peripheral retinal location: titration is started with a low power that produces no visible reaction. The power is then gradually increased until a blanching (faint whitening) of the retinal spot occurs. Power setting for retinal procedures is usually 250-750 mW, though lower (down to 50 mW) or higher (up to 1,000 mW) are sometimes used. Once power settings P_{vis} are identified through titration using a continuous waveform, if the user desires to operate in SmartPulse Mode then the power typically used is P_{vis} multiplied by a factor of 1.2 to 2.0 (see Table A-2 for references)
- Tissue reaction depends also on pulse duration: longer pulse durations result in more thermal energy and more temperature increases. For



procedures performed on slit lamp or LIO, the pulse duration should be kept at 0.5 sec or less, to ensure that during treatment the patient does not move.

- Spot sizes are usually 200-1000 μm . In some cases, such as when treating close to the center of the macula, smaller spot sizes such as 50-100 μm should be used, so as to prevent inadvertent targeting of the fovea.
- For treatment of diabetic retinopathy in advanced (proliferative) stages, pan-retinal photocoagulation (PRP) is performed: The ischemic conditions characteristic of this condition are alleviated by confluent photocoagulation of 30-50% of the retina. Care should be taken to exclude the macula. Laser burns should be applied in a checker-board pattern, usually with spacing of 0.6-1.0 spot size between adjacent burns. This procedure requires ~1000-2000 burns. It may be split in two or more consecutive sessions.
-

A.6. Anterior Segment Laser Procedures



Note

- Users should be aware of general laser warnings, precautions, and adverse effects listed in **General Information** in this chapter.
- Refer to the Ophthalmology references in this chapter for literature regarding anterior chamber laser procedures.

A.6.1. Uses

Other uses of the laser in ophthalmology involve the anterior segment of the eye. The most common procedures are performed to reduce the intraocular pressure in angle closure glaucoma (with iridotomy) and in open angle glaucoma (with trabeculoplasty).

A.6.2. Warnings



Warning

- Following iridotomy or trabeculoplasty, intraocular pressure (IOP) should be closely monitored.
- Hemorrhage from the trabecular meshwork occasionally occurs and is manifested as an ooze of blood from Schlemm's canal to the site of laser impact. This can be easily stopped by increasing the pressure of the gonioscope to the cornea.
- Pupillary distortion may be encountered if the iris root or peripheral iris has been treated. This distortion may or may

not be permanent, depending on the severity of the accidental damage.

- Medical therapy should be continued following laser Trabeculoplasty²⁴.
 - Peripheral anterior synechiae may occur when the posterior portion of the trabecular meshwork or other structures posterior to the meshwork are treated. These are best avoided by meticulous delivery of a well-focused laser beam.
-

Transient corneal epithelial burns have reportedly resolved within 1 week without scarring. Endothelial burns are rarely encountered when careful focusing is employed.

A.6.3. Adverse Effects

A “snuff out” of the central visual acuity has been reported as a complication of an intraocular pressure spike. Patients with advanced field loss should be carefully treated and monitored. Progressive field loss following laser trabeculoplasty is possible, even in the presence of seemingly adequately controlled intraocular pressure²⁵.

Rarely, severe iritis may occur, related to either an unusual patient response or improper spot location.

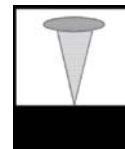
²⁴ J. Wise, "Errors in laser spot size in laser trabeculoplasty," *Ophthalmology*, vol. 91, no. 2, pp. 186-90, 1984.

²⁵ D. Spiegel, E. Wegscheider and O. Lund, "Argon laser trabeculoplasty: long-term follow-up of at least 5 years," *Ger J Ophthalmol*, vol. 1, no. 3-4, pp. 156-8, 1992.

A.6.4. Guidelines for Use

A.6.4.1. Iridotomy

Iridotomy is performed for treatment of angle- closure glaucoma. The photocoagulator can be used to thin a thick iris before perforation, where perforation can be done with Nd:YAG or with a green laser with a small spot size. The desired result is a perforation of approximately 150-200 μm (diameter) through the iris. The aqueous humor can then flow through this perforation, thereby relieving the intraocular pressure (IOP).



1. A rosette of 4-5 burns, approximately 500 μm in diameter, are made on the iris about 2/3 of the distance from pupillary border to the iris root. These burns are made with a typical power of 500 mW and a typical pulse duration of 0.2-0.5 sec. The purpose of these large burns is to soften the iris and to find a good site for the smaller, penetrating burn for finalizing the perforation
2. At the chosen site for final perforation, the iris is penetrated with either Nd:YAG laser or, if unavailable, with green laser (50 μm spot size, a power setting of 1200-1500 mW and a pulse duration of 0.2 -1.0 sec).

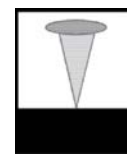


Warning

Glaucoma medications should be continued post-operatively. Occasionally, following iridotomy the intraocular pressure may briefly rise (a phenomenon termed IOP spike). In extreme cases the IOP spike the intraocular pressure to dangerous levels. For this reason, the patient should be closely monitored after the procedure, and glaucoma medications should be continued.

A.6.4.2. Trabeculoplasty

Trabeculoplasty is used to control open angle glaucoma. Laser burns are scattered around the trabecular meshwork. The mechanism of action is believed to be the scarring and shrinking of tissue at the laser burns, so that the trabecular meshwork between the laser burns is stretched. This mechanical stretching is thought to increase the outflow through the affected trabecular meshwork, thereby reducing the IOP.



1. Laser burns are placed at the border of the pigmented and the non-pigmented meshwork. Typical settings are a 50 µm spot size, a power setting of 300-1000 mW and a pulse duration of 0.1 sec. The immediate result of the laser burn should be a depigmentation of the trabecular meshwork and/or minimal bubble formation at the site of the laser burn.
2. Typically, 50 burns are homogenously spaced along 180° of the trabecular meshwork. Usually the inferior 180° are treated first, since this portion tends to be more pigmented and laser energy is hence better absorbed.
3. IOP should decrease within several weeks. Usually, this decrease is maintained for 1-2 years or more.

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A.8. Ear, Nose and Throat (ENT) Laser Applications



Note

Users should be aware of general laser warnings, precautions, and adverse effects listed in **General Information** in this chapter.

The laser is indicated in procedures where color-specific absorption, small spot size, and high power densities are required. The laser beam may be used to photocoagulate, vaporize, or cut tissue by utilizing the appropriate beam delivery accessory and varying spot size, output power, and pulse duration.

A.8.1. Indications

- The laser is indicated in procedures where color-specific absorption, small spot size, and high power densities are required. The laser beam may be used to photocoagulate, vaporize, or cut tissue by utilizing the appropriate beam delivery accessory and varying spot size, output power, and pulse duration.
- The laser has been shown to achieve satisfactory results in stapedotomy, stapedectomy, tympanoplasty with fascia graft²⁶, myringotomies²⁷, control of bleeding, lysis of adhesions, and soft tissue adhesion (“spot welding”)²⁸.

A.8.2. Contraindications

- One investigator reported that the laser was not indicated in the removal or vaporization of cortical bone or dense bone as found in obliterative otosclerosis²⁶.
- Uninflamed mastoid cases, such as endolymphatic sac surgery and cochlear implants do not benefit from the laser.

A.8.3. Uses

- The laser is indicated in both micro- and macro-otologic procedures.
- The selective absorption of the laser wavelength by color permits the surgeon to work on closely-approximated soft tissue which is colored red, but the laser is reflected and/or transmitted by adjacent non-red tissue.
- The laser may be used for procedures done in the hospital for in-patient or out-patient procedures. The use of the laser is not a

²⁶ L.H. Escudero L, A.O. Castro, M. Drumond, S.P. Portom D.G. Bozinis, A.F. Penna, and E. Gallego Lluesma, "Argon Laser in Human Tympanoplasty", *Arch Otolaryngol* 105(5):252-3, 1979

²⁷ J.R. DiBartolomeo, and M. Ellis, "The Argon Laser in Otology", *Laryngoscope* 90(11 Pt 1):1786-96, 1980

²⁸ T.M. McGee, "The Argon Laser in Surgery for Chronic Ear Disease and Otosclerosis", *Laryngoscope* 93(9):1177-82, 1983

contributing factor in deciding if a procedure is done on an in- or an out-patient basis.

A.8.4. Warnings



Warning

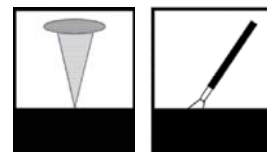
- The physician should be well acquainted with standard operating procedures and the use of the operating microscope. Formal instruction in these areas is available through established programs.
- Although hemostasis is to be expected from use of the laser, coagulation may prove difficult in highly vascular lesions and the use of means other than the laser may be needed.

A.8.5. Precautions

- Blood should not be allowed to contaminate or color the perilymph surface. A bloodless field will help prevent absorption of the laser energy by the clear perilymph²⁹.
- The usual precautions observed for general anesthesia for any purpose, and for otological procedures specifically, are to be followed.

A.8.6. Guidelines for Use

Formal instruction in operative procedures is the responsibility of the physician and should be obtained on a formal basis from recognized sources.



Caution

The operator should be aware of the irradiances required for specific tissue effects as are outlined throughout this manual, as well as detailed in the appropriate delivery system operator manual.

A.9. Otology References

- L.H. Escudero L, A.O. Castro, M. Drumond, S.P. Portom D.G. Bozinis, A.F. Penna, and E. Gallego Lluesma, "Argon Laser in Human Tympanoplasty", *Arch Otolaryngol* 105(5):252-3, 1979
- J.R. DiBartolomeo, and M. Ellis, "The Argon Laser in Otology", *Laryngoscope* 90(11 Pt 1):1786-96, 1980
- T.M. McGee, "The Argon Laser in Surgery for Chronic Ear Disease and Otosclerosis", *Laryngoscope* 93(9):1177-82, 1983

²⁹ J.R. DiBartolomeo, "The Argon and CO₂ Lasers in Otolaryngology: Which One and Why?", *Laryngoscope* 91(9 Pt 2 Supp 26): 1-16, 1981

- J.R. DiBartolomeo, “The Argon and CO₂ Lasers in Otolaryngology: Which One and Why?”, *Laryngoscope* 91(9 Pt 2 Supp 26): 1-16, 1981

A.10. Delivery Devices and Accessories

A.10.1. Filters

Lumenis offers fixed and moving physician’s filters for integrated slit lamps, indirect ophthalmoscope attachments, and microscopes. These filters shield the physician's or observer's eyes from laser light and allow a normal field of view when the laser is in the Ready mode. The filters contain high quality optical elements for high visibility and easily attach to operating room microscopes. For a list of available filters, contact your local Lumenis representative.

A.10.2. Acculite Endoprobe

Fiber-optic endoprobes, such as the Lumenis Acculite endoprobe, are useful for photocoagulation of the posterior segment, in procedures such as pan-retinal photocoagulation, barrage of retinal tears, and treatment of choroidal neovascularization secondary to age-related macular degeneration.

Spot sizes delivered through the Acculite endoprobes vary, depending on the distance of the Acculite endoprobe tip from the treatment site. Power requirements vary from 300-1000 mW, depending on the type of treatment and the desired tissue effect.

Endoprobes are supplied pre-packaged and sterile for one-time use only. Fibers are precision-cut and polished to rigid optical specifications to provide maximum energy delivery. An exterior jacket protects the fiber from damage. Fibers and probes attach to the fiber port on the front panel of the laser.

Fibers can be damaged or can injure a patient if not used carefully; therefore, the physician should make the following checks before activating the laser:

- Ensure that the fiber is fully inserted into the laser aperture. This will allow the best efficiency through the laser fiber.
- Care must be taken when handling the optical fiber not to bend or kink it excessively since this could fracture the fiber allowing laser light to emerge from the fracture site.
- Identify all tissues that lie in the potential path of the laser beam to avoid laser exposure to tissues other than those undergoing treatment.
- Carefully identify and protect all relevant anatomic structures from possible undesired exposure.
- Ensure that the probe tip does not come into direct contact with tissue when treating; if it does, the optical efficiency of the fiber will be compromised.
- Use a suction tip in the treatment area to evacuate the laser plume.

A.10.3. Fluence of laser energy delivered by endoprobe

Fluence is the measurement of energy delivered in relation to the area of the treatment beam or energy density. Irradiance is the measurement of power delivered in relation to the area of the treatment beam or power density. This measurement is helpful in determining the power setting to use for a particular treatment. Fluence and irradiance for various power and duration settings can be calculated using the following equations:

$$F = \frac{E}{A}$$

$$I = \frac{P}{A}$$

$$E = P \cdot T_s$$

$$A = \pi \left(\frac{d}{2} \right)^2 = 0.7854d^2$$

Where:

F = Fluence (J/cm²)

T_s = Pulse duration (sec)

I = Irradiance (W/cm²)

A = Spot area (cm²)

E = Energy (J)

d = Spot diameter (cm)

P = Power (W)

Table A-3 lists resulting spot sizes using approximate irradiance and fluence for a delivery power of 1 W, pulse durations of 0.5 s and 1.0 sec, and a fiber diameter of 300 or 600 μm.

Table A-3: Irradiance and Fluence at 1 W and 0.5 Sec and 1.0 Sec Delivered

Fiber Diameter (μm)	Spot Size (mm)	Spot Size Area (cm ²)	Irradiance (W/cm ²)	Fluence at 1 Sec (J/cm ²)	Fluence at 0.5 Sec (J/cm ²)
300	0.3	0.000707	1415	1415	707
	3.0	0.0707	14	14	7
600	0.6	0.00283	354	354	177
	3.0	0.0707	14	14	7

Figure A-1 shows the spot size as a function of distance from the fiber. Figure A-2 illustrates the relationship between irradiance and the distance from the fiber tip.

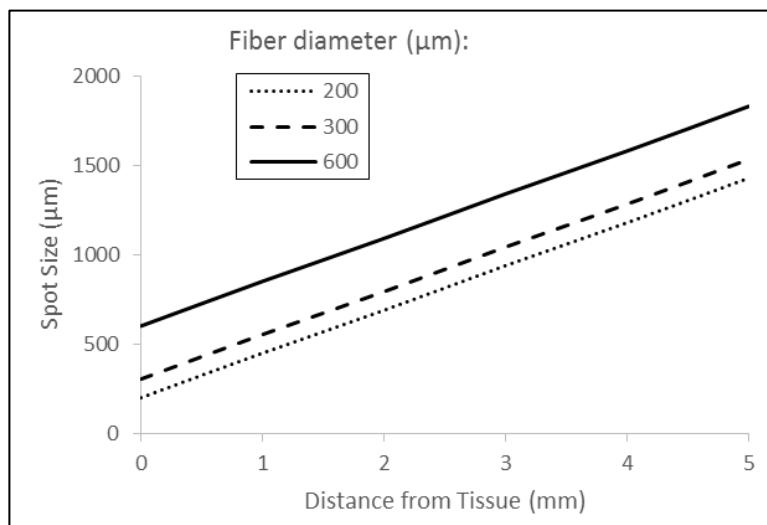


Figure A-1: Spot Size versus Distance of fiber tip from Tissue

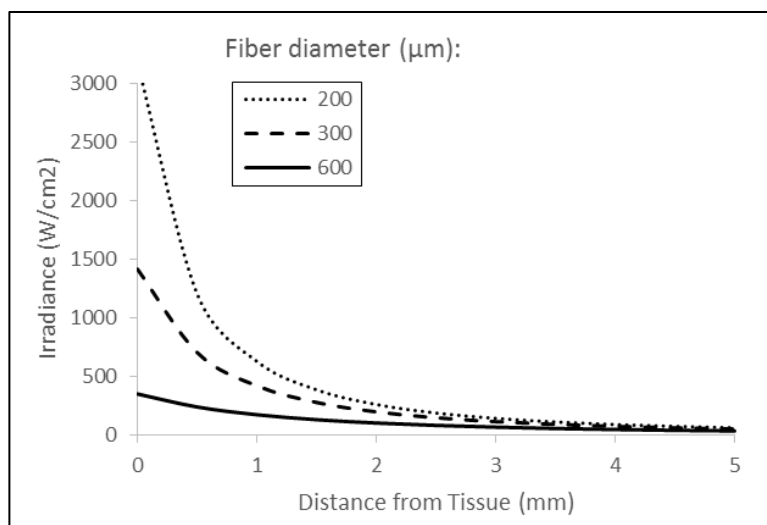


Figure A-2: Irradiance versus Distance of Fiber Tip from Tissue

Table A-4 lists the irradiance obtained at 1 W delivered power for 200, 300 and 600 μm diameter fiber optic accessories held from 0 to 5 mm from the tissue target. Taking into consideration the irradiance which is effective for each procedure, the user can determine the different laser power settings.

Table A-4: Spot Size and Irradiance at 1 W Delivered

Fiber Optic	Distance from tissue (mm)	Spot Size (mm)	Irradiance (W/cm^2)
200 μm	0	0.20	3183
	1	0.45	628
	2	0.69	267
	3	0.94	145
	4	1.18	91
	5	1.43	62
300 μm	0	0.30	1415
	1	0.55	421
	2	0.79	204
	3	1.04	118
	4	1.28	78
	5	1.53	54
600 μm	0	0.60	354
	1	0.85	176
	2	1.09	107
	3	1.34	71
	4	1.58	51
	5	1.83	38

A.10.4. Laser Indirect Ophthalmoscope (LIO)

**Note**

Users should be aware of the general laser warnings, precautions, and adverse effects out-lined in the **General Information** section in this chapter, as well as the warnings, precautions, and contraindications specific to ophthalmic procedures.

A.10.5. Uses

The LIO is used for treatment of retinal lesions in the peripheral fundus, anterior to the equator. Other uses include extending pan-retinal photocoagulation further anterior than can conveniently be reached with a conventional slit lamp laser photocoagulator, retinal photocoagulation in patients with media opacities where conventional photocoagulation with a slit lamp is difficult or impossible, and treatment of patients limited to the supine position.

A.10.6. Warnings

- Precautions pertaining to laser safety should be carefully observed: requiring the wear of laser safety goggles by all individuals present in the room, posting warning signs at all entrances to the area where the laser is being used, and using only nonflammable drapes and anesthetics.
- The LIO should be carefully inspected before each use to be sure that it is not damaged.

A.10.7. Guidelines for Use

- The LIO can be configured at the factory for use with a Lumenis argon laser, krypton laser, or diode-green (Smart532) laser. Only the filter material and electrical characteristics differ.
- The LIO consists of an indirect ophthalmoscope that has been modified with a fixed laser safety filter and a lens system to focus the laser beam.
- Like an unmodified indirect ophthalmoscope, the LIO is mounted on a headband. The LIO is connected to the laser by a fiber-optic which is plugged into the laser in the same way that any Lumenis fiber-optic is connected to the laser.
- The LIO is designed to conveniently deliver laser energy to the far periphery of the fundus. With the indirect ophthalmoscope, the doctor has a clearer view of the areas of the fundus which are anterior to the equator of the eye than can be obtained using a slit lamp.
- Another advantage is the ability to position the patient to take advantage of gas bubbles that are injected into the eye during pneumatic retinopexy to force the retina into the proper position (so that it is resting against the choroid). If the laser treatment can be performed when the retina is in this position, the retina can be attached using the laser and may be less likely to detach again. If the patient can be positioned so that the retina can be treated without the laser beam

having to pass through the gas bubble, it makes the laser treatment easier.

- A third potential advantage over conventional slit lamp delivery systems is the fact that the LIO does not employ a contact lens to direct the laser beam. Because there is no contact with the eye, it may be possible to treat eyes that are injured and cannot have any force exerted on them.
- The LIO can also be used with scleral depression in place of, or as an adjunct to cryotherapy. It has been theorized that the use of cryotherapy scatters cells from the retinal pigment epithelium, which may lead to proliferative vitreoretinopathy. There is no evidence that laser treatment scatters these cells, and so it may be an improved treatment modality for retinal reattachment procedures.
- The laser spot size can be changed by varying the distance between the LIO and the condensing lens, and by varying the distance from the condensing lens to the retina. Both of these distances are limited if a clear view of the fundus is to be obtained. However, the ability of the user's eyes to accommodate changing focal length can have an effect on the laser spot size if the user is not aware of this phenomenon while adjusting the image of the retina.
- Because this condensing lens is the last optical element that the laser beam passes through, the power and position of this lens will have an effect on the laser beam in terms of spot size and the focus of the image of the laser beam on the retina.
- For most eyes, the image of the retina formed by the hand-held lens is real, inverted, and located a few centimeters above the hand-held lens.

The magnification, **M**, of the two-lens system created by the hand-held lens and the eye is:

$$M = \frac{60 \text{ Diopter}}{\text{Power of hand - held lens}}$$

Where 60 diopter is the refractive power of a “standard” eye. The magnification of an indirect ophthalmoscope using a 20-diopter hand-held lens is 3X, and the magnification of the system when using a 30-diopter lens is 2X.

Because the laser beam is a converging beam, the size of the laser beam in the retinal image plane can be varied by moving the point of focus of the laser beam out of the laser beam's object plane (retinal image plane). Figure A-1 shows how altering working distance affects retinal spot size. Note that because the laser beam divergence angle of small spot sizes is greater than the laser beam divergence angle of large spot sizes, working distance has a greater effect on the small spot sizes.

A.10.8. Slit Lamps and LaserLinks for Slit Lamps



Note

Users should be aware of the general laser warnings, precautions, and adverse effects out-lined in the **General Information** section in this chapter, as well as the warnings, precautions, and contraindications specific to ophthalmic procedures.

A.10.9. Description

Several integrated slit lamp models are available from Lumenis, as are LaserLinks for adapting your existing diagnostic slit lamp to the Smart532. LaserLinks are available for Zeiss and Haag-Streit, as well as most third-party equivalent slit lamps.

The integrated slit lamp with laser delivery system is designed to project a focused laser beam into the focal plane of the microscope. The delivery system provides spot size zooming over a range of 50 - 1000 µm. It also incorporates an internal protective physician's filter.

A.10.10. Guidelines for use

Refer to the appropriate delivery system operator manual for specific instructions regarding the use of a slit lamp.

A.11. Indirect Ophthalmoscope Bibliography

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- Friberg T, Eller A. Pneumatic Repair of Primary and Secondary Retinal Detachments Using a Binocular Indirect Ophthalmoscope Laser Delivery System *Ophthalmology* 95:187-193, 1988.
- Campochario P, Gaskin H, Vinore S. Retinal cryopexy Stimulates Traction Retinal Detachments in the Presence of an Ocular Wound *Archives of Ophthalmology* 105:1567-1570, 1987.



EC Declaration of Conformity

Lumenis, Inc.
1870 S Milestone Dr
Salt Lake City, UT, 84104, USA

Does hereby declare under our sole responsibility that the **Photocoagulators Laser Systems and accessories**, which includes device catalog numbers referenced in the attached list, meets the provisions and essential requirements of the Council Directive 93/42/EEC concerning medical devices (MDD) as transposed in the national laws of the Member States.

Device Classification: **I/b, Rule: 9, Annex IX**

The regulatory route demonstrating the conformity is based on the criteria of Annex II of the MDD with the exemption of section 4, audited by TUV Nord, **Notified Body No: 0044**, located at TÜV NORD CERT GmbH, Langemarckstraße 20, D-45141 Essen, **Germany**, as an appointed Notified Body.

Certification Number: 44 232 117837 Expiration date: July 06, 2023
DOC Certificate Number- DOC-1012187

Initial manufacturing date of the systems:
Array LaserLink 2014
Smart532 2016
Vision One 2011

Authorized European
Representative:

Lumenis (Germany) GmbH
Heinrich-Hertz-Str. 3
Dreieich Dreieichenhain D-63303, Germany
Tel: +49 (0)6103-8335-0

Karen Smith, VP, Regulatory & Quality
Name & Title

01-Nov-20
Date

31-Oct-21
Declaration Validity Date





List of Products

Catalog Number	Product Name	Device Type	Class	Rule	UMDNS
GA-1005557	Smart532 Laser System	Laser, Ophthalmic, Nd:GdV04	IIb	9	16-947
GA-0006700	Array LaserLink	Laser Delivery system, Fiber Optic	IIb	9	17-807
GA-0006700CN	Array LaserLink	Laser Delivery system, Fiber Optic	IIb	9	17-807
GA-0007700CN	Array LaserLink, Off Axis, White	Laser Delivery system, Fiber Optic	IIb	9	17-807
RGA-0025050	Recondition Vision One System (532nm-Green)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808
GA-0025060	Vision One System (577nm-Yellow)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808
GA-0025070	Vision One System (659nm-Red)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808



GA-0025210CN	Vision One System, (532nm-Green, 577nm-Yellow, 659nm-Red)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808
GA-0025220CN	Vision One System, (532nm-Green, 577nm-Yellow)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808
GA-0025230CN	Vision One System, (577nm-Yellow, 659nm-Red)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808
GA-0025240CN	Vision One System, (532nm-Green, 659nm-Red)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808
GA-0025250CN	Vision One System, (532nm-Green)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808
GA-0025260CN	Vision One System, (577nm-Yellow)	Laser, Ophthalmic, Frequency-doubled Diode Pumped Nd:YAG	IIb	9	17-808



SmartLIO™
Advanced Laser Indirect Ophthalmoscope

Lumenis®
Energy to Eye Care

Illumination Filter Selection



White Light - Clear settings with no filter. Recommended for inspection of a specific pathology and when a brighter light is desired.



Green Filter - Red free filter. Used for examination of fine blood vessels and identification of microaneurysms.



Blue Filter - Cobalt blue filter for fluorescein angiography.



Diffuser - Extra wide beam of diffused light permits a more relaxed technique during more challenging fundus examinations.

Illumination Aperture Sizes



Large - Suitable for routine examinations through fully dilated pupils.



Intermediate - Designed to reduce reflections when entering a partially or poorly dilated pupil. Also ideal for closer inspection of particular fundal areas.



Small - Ideal for small, undilated pupils.

Smart LIO™ Specifications

LIO Headset

Binocular indirect ophthalmoscope	Modified Keeler
Headset dimensions (all dimensions adjustable)	Height: 22 cm (8.7 in) Width: 25 cm (9.8 in) Length: 38 cm (15 in)
Headset weight	800 g (1.75 lb)
Optical fiber length	5 m / 16.4 feet

Ophthalmoscope Technical Specifications

Illumination intensity	3500 Lux $\pm$ 500*
Illumination patch sizes	20/40/60 mm $\pm$ 10%*
Interpupillary adjustment	48 to 76 mm

Power Supply

Input mains power	100-240 VAC, 700 mA, 50-60 Hz
Power supply rating	12V: 2.5 A (PSU only)

Compatible Lumenis Lasers and Usable Wavelengths (with Appropriate Eye Safety Filters)

Spectra / Spectra DP	532 nm (green); 630–680 nm (aiming beam)
Smart532	532 nm (green); 635 nm (aiming beam)
Vision One	532 nm (green); 577 nm (yellow); 659 nm (red); 635 nm (aiming beam)

Working Distances

Approximately 28 cm (11 in)
Defined as the distance from the center of the LIO laser mirror to the image of the retina.

* Measurements taken at 440 mm from the front surface of the SmartLIO

Lumenis Inc.
1870 South Milestone Drive
Salt Lake City, UT 84104 USA
Tel: +801-656-2300
Fax: +801-656-2429

Lumenis (Germany) GmbH
Heinrich-Hertz-Str. 3 D-63303
Draisch-Draischonheim
GERMANY
Tel: +49 (0) 6103 8335 0

AMERICAS
San Jose, CA, USA
Tel: +1 408 764 3000
+1 877 586 3647
Fax: +1 408 764 3889

EMEA
Draisch-Draischonheim,
Germany
Tel: +49 6103 8335 0
Fax: +49 6103 8335 390
Rome (RM), Italy
Tel: +39 06 90 75 250
Fax: +39 06 90 75 269
Hertfordshire, UK
Tel: +44 20 8736 4110
Fax: +44 20 8736 4119

JAPAN
Tokyo, Japan
Tel: +81 3 4431 8300
Fax: +81 3 4431 8801

ASIA / PACIFIC
Beijing, China
Tel: +86 10 5737 6677
Gurgaon, India
Tel: +91 124 422 07 95
Kowloon, Hong Kong
Tel: +852 217 426 00
Fax: +852 217 251 51

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Lumenis®
Energy to Eye Care

Lumenis Smart LIO™

Advanced Laser Indirect Ophthalmoscope

Lumenis is proud to present the Smart LIO™, its newest high-end Laser Indirect Ophthalmoscope. Smart LIO™ offers a new standard of comfort and reliability:

Ergonomic

Lightweight and well balanced for maximal comfort.

Triple Wavelength Support

Superior optics supporting green, yellow and red wavelengths in one LIO.

Wireless

Unique patented wireless technology.

Patented Intelligent Optical System (IOS)

Ensures that as aperture size changes, the mirror and optics automatically adjust and converge.

Smart Illumination, Filters and Apertures

Illumination rheostat is located on the headband, providing easily accessible, fully controllable light. In addition, the Smart LIO™ has 4 different light filters and 3 aperture sizes (see back cover).

LED Illumination

Bright and white LED illumination provides improved retina visibility and allows for longer battery life.



The new Smart LIO™ is compatible with all Lumenis photocoagulators and multi-application platforms, allowing you to use one LIO for all your retinal care needs:

Smart532

The SmartPulse™ of Retinal Care

Smart532™: green photocoagulator with SmartPulse™ sub-threshold technology.



Vision One

Multi-color photocoagulator. Allows you to choose any desired combination of green (532nm), yellow (577nm) or red (659nm) wavelengths, for optimal clinical outcomes.

Smart SELECTA Trio

SLT + YAG + Smart532™. The comprehensive solution for ophthalmic practice, providing glaucoma, secondary cataract and retinal therapy within a single unified platform.

