Records processed under FOIA Request # 2015-10223; Released by CDRH on 03-15-2016

JUN 2 5 2014
K140336

510(k) Summary for the Quantel Medical

Family of OPTIMIS FUSION Ophthalmic Laser Systems, (OPTIMIS FUSION SLT/YAG, OPTIMIS FUSION YAG, OPTIMIS FUSION SLT) and Delivery Device (Slit lamp adaptor) and Accessories

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter: Quantel Medical
11 Rue du Bois Joli – CS 40015
63808 Cournon D'Auvergne Cedex
FRANCE
33-473 745 745
33-473 745 700 (Fax)

Contact Person: Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Telephone: 978-207-1245
Fax: 978-824-2541

Summary Preparation Date: June 13, 2014

2. Names

Device Trade Name: Family of OPTMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories
OPTIMIS FUSION SLT/YAG
OPTIMIS FUSION YAG
OPTIMIS FUSION SLT

Common Name: Ophthalmic Laser

Classification Names: Laser Instrument, Surgical, Powered and Laser, Ophthalmic
Product Code: HQF (21 CFR 886.4390)
Panel: Ophthalmology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. Predicate Device

- Lumenis Family of Selecta Ophthalmic laser Systems, Delivery Device and Accessories : (K081704)
- Carl Zeiss Meditec VISULAS YAG III (K042139)
- Quantel Medical Solutis (K130933)

4. Device Description

The QUANTEL MEDICAL OPTIMIS FUSION is an ophthalmic surgical laser designed for performing photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser including discission of the posterior capsule of the eye (posterior capsulotomy), discission of the pupillary membranes (pupillary membranectomy), and iridotomy/iridectomy; and selective laser Trabeculoplasty.

The Family of OPTIMIS FUSION Ophthalmic Lasers, Delivery Device and Accessories consists of the following models:

1) OPTIMIS FUSION YAG – a Nd: YAG Laser providing-switched laser pulses at a wavelength of 1064 nm for use in photodisruption of ocular tissue (posterior capsulotomy, pupillary membranectomy, iridotomy/iridectomy). The 1064 treatment beam delivers 4 ns, 0.3 -10mJ adjustable and selectable single, double or triple pulse of energy. It is conditioned trough beam shaping optics to generate a photodisruption micro pulse of plasma at a precision adjustable location relative to the visual focal plane (located at slit lamp center of rotation) and along the slit lamp objective lens axis. A twin aiming beam is also focused by the slit lamp objective to a converging 10 μm spot located at the focal point of the lens. The focal point of photodisruption is adjustable 150μm in the posterior direction and -150μm in the anterior direction by the physician relative to this convergence of the twin aiming beams.

2) OPTIMIS FUSION SLT - a Nd: YAG Laser providing Q-switched frequency doubled pulses at a wavelength of 532 nm for use in Selective Laser Trabeculoplasty. The treatment beams delivers a 4 nsec, 0.3-2mJ adjustable single pulse of energy. The aiming and treatment beams are coaxial with each other and focussed by the slit lamp objective to a 400μm spot at the focal point of the lens.

3) OPTIMIS FUSION YAG/SLT - a Nd: YAG Laser providing Q-switched laser pulses at a wavelength of 1064 nanometers for use in photodisruption or Q-switched frequency doubled pulses at a wavelength of 532 nm for use in Selective Laser Trabeculoplasty, depending upon the mode selected. The OPTIMIS FUSION YAG/SLT contains two aiming beam modules that produce a single beam for the 532nm mode and a dual beam for the 1064nm mode, respectively.

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For each OPTIMIS FUSION model, the physician controls delivery of laser energy from the OPTIMIS FUSION control display unit and activates the treatment laser beam with a footswitch or joystick pushbutton. In addition, a laser slit lamp adaptor may be coupled to each of the above OPTIMIS FUSION models and connected to a currently cleared QUANTEL MEDICAL 532nm photocoagulator (VITRA (K04236), SUPRA (K07776), VITRA MULTISPOT (K122251)) to allow to the physician to use the *Slit Lamp Adaptor* to deliver 532 nm continuous wave laser energy for retinal photocoagulation.

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

When the photodisruptor mode is selected, the treatment wavelength is 1064nm. A twin-aiming beam targets the area of tissue disruption. The energy contained within a single short pulse is concentrated by focusing to a very small spot size so that plasma formation occurs at the focal point. This creates an acoustic wave which disrupts nearby tissue.

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

5. Indications for Use

- OPTIMIS FUSION YAG: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy.

- OPTIMIS FUSION SLT: Selective Laser Trabeculoplasty

- OPTIMIS FUSION YAG/SLT: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy; and Selective Laser Trabeculoplasty

6. Substantial Equivalence

The indications for use statement for the OPTIMIS FUSION FAMILY is exactly the same as the indications for use statement for the Lumenis Family of

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SELECTA Ophthalmic Laser Systems, Delivery Device and accessories (predicate device). Each of the families contains multiple configurations of the laser system with different indications for use statements. Both families include an SLT model, a YAG model and a model which combines the SLT and YAG. The indications for use statements for each version of the product are identical between the families. Additionally, the YAG model of the Optimis Fusion Family is also being compared to the Carl Zeiss Meditec VISULAS YAG III cleared in K042139. Both systems are cleared for performing posterior capsulotomy and peripheral iridotomy procedures while the Optimis Fusion YAG is also indicated for pupillary membranectomy. The SLT model of the Optimis Fusion Family is also being compared to the Quantel Medical Solutis cleared in K130933. Both systems are cleared for Selective Laser Trabeculoplasty (SLT).

The OPTIMIS FUSION FAMILY and the predicate devices have the same technological characteristics. The OPTIMUS FUSION FAMILY and the Lumenis SELECTA family each include multiple models within the family. Both the OPTIMUS FUSION FAMILY and the Lumenis SELECTA family include an SLT model, a YAG model and a model that combines the SLT and YAG lasers in one unit. The VISULAS YAG III only includes a YAG model and therefore, will only be compared to the YAG model of the Optimis Fusion. The Quantel Medical Solutis has only a SLT model and therefore, will only be compared to the SLT model of the Optimis Fusion.

The Optimis Fusion SLT is a Q-Switched frequency doubled Nd: YAG laser with a wavelength of 532 nm as are the Selecta SLT model and Solutis. The Optimis Fusion SLT, the Selecta SLT model and Solutis all operate in single pulse modes. The energy range for both devices is 0.3-2.0 mJ and the Solutis is 0.2-2.0 mJ. The spot size in air is 400 microns with a focus angle of < 3 degrees for all systems. The maximum energy density at minimum exposure is 1.6 J/cm^2 for all three systems. The repetition rate for all three systems is 2.0 Hz, the pulse duration is 4 ns for the Optimis Fusion SLT and Solutis and is 3 ns for the Selecta SLT. The maximum average power is 4 mW for all three systems. The differences between the three systems are considered extremely minor in significance and don't affect the safety or efficacy of the devices.

The OPTIMIS FUSION YAG is a Q-Switched Nd: YAG laser with a wavelength of 1064 nm as is the Selecta 1064 model and the VISULAS YAG III. All of the devices are pulsed with single spot modes and all modes operate in user selectable bursts of 1, 2 or 3 pulses. The energy range for all devices is 0.3-10.0 mJ. The spot size in air is 10 microns with a focus angle of 16 degrees for all three systems.

The OPTIMIS FUSION YAG/SLT includes the features and specification of both the OPTIMIS FUSION SLT system and the OPTIMIS FUSION YAG system. combined in one device. The specifications of each individual system remain

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unchanged when they are combined into one unit. This is exactly the same as the Lumenis Selecta Duet which combines the Selecta SLT and Selecta 1064 features.

All of the systems use a 635 nm red diode for aiming. All of the systems use a slit lamp as the delivery system for the laser energy. The Optimis Fusion models use the CSO SL980 slit lamp previously cleared by FDA in K992836.

Therefore, the OPTIMIS FUSION FAMILY is substantially equivalent to the predicate devices.

7. Performance Data

Laboratory testing was conducted to validate and verify that the Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories met all design specifications and was substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2014

Quantel Medical
c/o Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K140336
Trade/Device Name: Optimis Fusion: SLT, YAG and YAG/SLT
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Codes: HQF
Dated: May 16, 2014
Received: May 19, 2014

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known): K140336

Device Name: **Family of OPTIMIS FUSION Ophthalmic Laser Systems, (FUSION SLT/YAG, FUSION YAG, FUSION SLT) and Delivery Device (Slit lamp adaptor) and Accessories**

Indications for Use:

- OPTIMIS FUSION YAG: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy.

- OPTIMIS FUSION SLT: Selective laser Trabeculoplasty

- OPTIMIS FUSION YAG/SLT: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy ; and Selective laser Trabeculoplasty

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles Chiang -S
2014.06.24 11:25:03 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA CDRH DMC
FEB 10 2014
Received

February 6, 2014

Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center (W066-G609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K140336

Re: Quantel Medical OPTIMIS FUSION Family
Traditional Premarket Notification 510(k)

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act ("FDC Act"), Quantel Medical ("Quantel" or the "company") is submitting the attached traditional premarket notification ("510(k) notification") for the OPTIMIS FUSION Family.

The QUANTEL MEDICAL OPTIMIS FUSION FAMILY is a family of ophthalmic surgical lasers designed for performing photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser including discission of the posterior capsule of the eye (posterior capsulotomy), discission of the pupillary membranes (pupillary membranectomy), and iridotomy/iridectomy; and selective laser trabeculoplasty. Three versions of the product are included in the family: Optimis Fusion YAG, Optimis Fusion SLT and Optimis Fusion YAG/SLT.

The OPTIMIS FUSION FAMILY Lasers are Class II devices, classified as laser instruments, surgical, powered with product code GEX under 21 CFR 878.4810, and laser, ophthalmic with product code HQF under 21 CFR 886.4390. As explained in more detail in the attached 510(k) notification, the OPTIMIS FUSION FAMILY is substantially equivalent to the Lumenis Selecta Family of Ophthalmic Laser Systems (K081704) (the "predicate device") that FDA has already cleared.

Quantel Medical is located at:
11 rue Bois Joli
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FRANCE

The contact person for this submission is:
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
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Email: Maureen@oconnellregulatory.com

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In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Quantel has submitted the required application fee of (b)(4) [redacted] electronically. A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

There have been no prior regulatory submissions for the OPTIMIS FUSION FAMILY.

This 510(k) is provided in duplicate with one paper and one electronic copy. The electronic copy is an exact duplicate of the paper copy. Please contact Maureen O'Connell at (978) 207-1245 or maureen@oconnellregulatory.com or Patrick Quero at +33-4-73-745-732 or quero@quantel-medical.fr with any questions regarding this submission.

Sincerely,

Patrick Quero
Quality Director & Regulatory Affairs

Cc: Maureen O'Connell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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February 6, 2014

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10903 New Hampshire Avenue
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Re: Quantel Medical OPTIMIS FUSION Family
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The QUANTEL MEDICAL OPTIMIS FUSION FAMILY is a family of ophthalmic surgical lasers designed for performing photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser including discission of the posterior capsule of the eye (posterior capsulotomy), discission of the pupillary membranes (pupillary membranectomy), and iridotomy/iridectomy; and selective laser trabeculoplasty. Three versions of the product are included in the family: Optimis Fusion YAG, Optimis Fusion SLT and Optimis Fusion YAG/SLT.

The OPTIMIS FUSION FAMILY Lasers are Class II devices, classified as laser instruments, surgical, powered with product code GEX under 21 CFR 878.4810, and laser, ophthalmic with product code HQF under 21 CFR 886.4390. As explained in more detail in the attached 510(k) notification, the OPTIMIS FUSION FAMILY is substantially equivalent to the Lumenis Selecta Family of Ophthalmic Laser Systems (K081704) (the "predicate device") that FDA has already cleared.

Quantel Medical is located at:
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The contact person for this submission is:
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Sincerely,

Patrick Quero
Quality Director & Regulatory Affairs

Cc: Maureen O'Connell

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Quantel Medical

OPTIMIS FUSION FAMILY

Traditional Premarket Notification 510(k)

Quantel Medical
11 rue Bois Joli
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63808 Cournon d'Auvergne - Cedex
FRANCE

CONFIDENTIAL
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.2 IEC 60825-1 Test Report
6.1 ISO 14971 FDA Form 3654
6.2 ISO 14971 Device Hazard Analysis
7 Draft User's Manual
8 Software Requirements Specification
9 Architecture Design Chart
10 Software Design Specification
11 Software Development Environment
12 Software Configuration Management Plan
13 Maintenance Plan
14 Traceability Analysis
15 Software Verification and Validation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The following information is provided as required by 21 C.F.R. 807.87 (2003) for Quantel Medical's OPTIMIS FUSION FAMILY 510(k) premarket notification.

I. NAME OF DEVICE

Trade Name:	OPTIMIS FUSION Family of Ophthalmic Laser Systems, Delivery Device and Accessories consisting of: OPTIMIS FUSION SLT/YAG Ophthalmic Laser System OPTIMIS FUSION YAG Ophthalmic Laser System OPTIMIS FUSION SLT Ophthalmic Laser System
Common Names:	Ophthalmic Laser System
Classification Name:	Laser Instruments, Surgical, Powered and Laser, Ophthalmic

II. ESTABLISHMENT REGISTRATION NUMBER

Manufacturer: 9680671

III. DEVICE CLASSIFICATION/FDA REVIEWING BRANCH

The General Surgery Branch has classified Laser Instruments, Surgical, Powered as Class II devices pursuant to 21 C.F.R. §878.4810. The Ophthalmic Branch has classified Lasers, Ophthalmic as Class II devices pursuant to 21 C.F.R. §886.4390.

IV. PERFORMANCE STANDARDS

We have reviewed the requirements of Sections 513 and 514 of the Act and are not aware of any requirements of either section applicable to this device. No performance standards or special controls have been developed under Section 514 of the FDC Act for Laser Instruments, Surgical, Powered or Lasers, Ophthalmic. No special controls apply.

Consistent with FDA's guidance document entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000), Quantel has included this statement that the OPTIMIS FUSION FAMILY complies with the following recognized consensus standards demonstrating compliance with these standards:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1, Medical Electrical Equipment-Part 1: General Requirements for Safety, 2005

IEC 60601-1-2, Medical Electrical Equipment-Part 1: General Requirements for Safety 2; Collateral Standard: Electromagnetic Compatibility-Requirements and Tests; 2007

IEC 60601-1-4, Medical Electrical Equipment-Part 1: General Requirements for Safety; 4. Collateral Standard: Programmable Electrical Medical Systems; 2000

IEC 60825-1, Safety of laser products - Part 1: Equipment classification and requirements; 2007

ISO 14971, Medical Devices-Application of Risk Management to Medical Devices; 2012

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; 2007

The completed FDA Forms 3654 and the complete test reports can be found in the following Appendices:

Standard	FDA Form 3654	Test Report
IEC 60601-1	Appendix 1.1	Appendix 1.2
IEC 60601-1-2	Appendix 2.1	Appendix 2.2
IEC 60601-1-4	Appendix 3.1	Appendix 3.2
IEC 60601-2-22	Appendix 4.1	Appendix 4.2
IEC 60825-1	Appendix 5.1	Appendix 5.2
ISO 14971	Appendix 6.1	Appendix 6.2

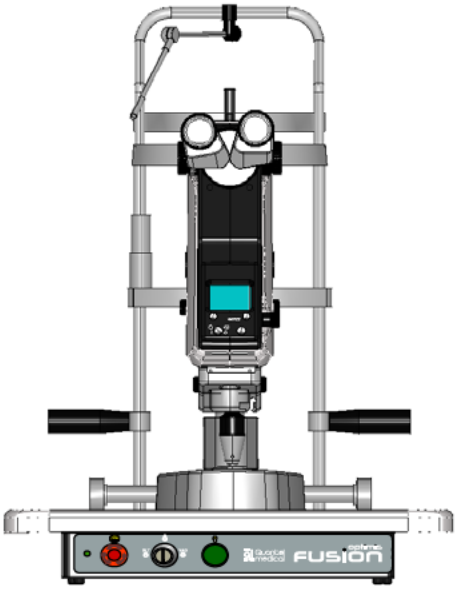
The device also complies with European Medical Directive 93/42/EEC + Amendment 2007/47/EEC and the US Federal Performance Standards 21 CFR 1002.10 Requirements (21 CFR 1040.10 and 21CFR 1040.11 for Class IV Laser Products with permissible deviations defined in Laser Notice 50, dated July 26, 2001), Part 1010.2 and 1010.3,Part 820 – Quality System Regulation, and have passed ISO 9001 and 13485 System Certification.

V. PROPOSED LABELING

A copy of the draft User's Manual can be found in **Appendix 7**. Information regarding system labels is provided in the Chapter II of the User's Manual and is reproduced below.

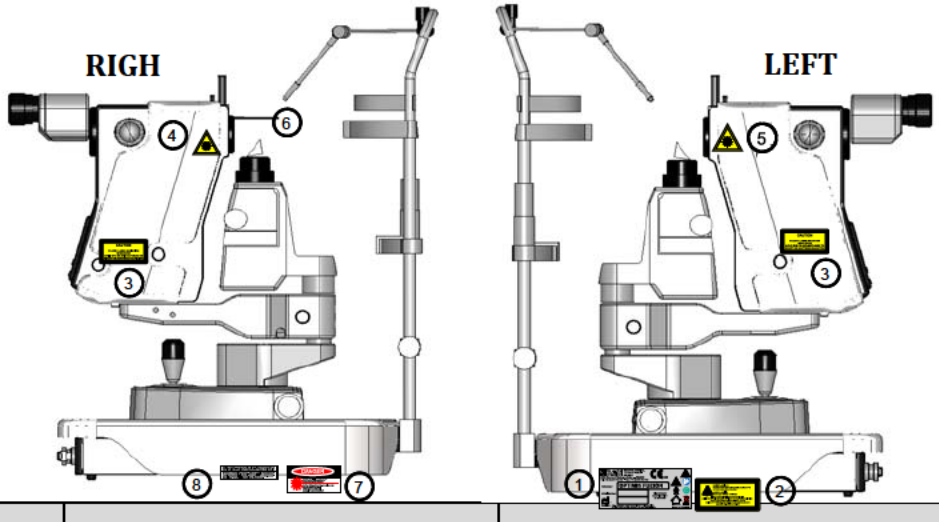
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

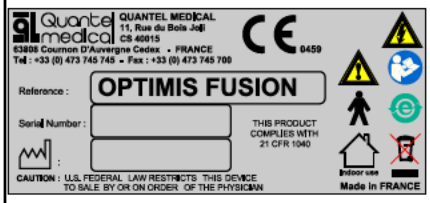
1.1 FRONT VIEW



Réf.	Label	
	FRONT label: Situated on the front panel of the laser console.	
		"OFF" for a part of equipment. **IEC 60417 - 5265**
		Stand-by or preparatory state for a part of equipment. **IEC 60417 - 5266**
		EMERGENCY STOP label: Situated next to the red emergency stop button.
		LAMP GENERATOR BOOST label: Situated next to the green push button button.

1.2 RIGHT / LEFT VIEWS



Réf.	Label	Description	
1		**IDENTIFICATION LABEL:** Contains the following information:	
		Protection against electrical shocks: the applied parts are classified as '**B Type**". The accessible conductive parts are connected to ground. **IEC 60417-5840**	
		IEC protection class: **"Class I"** - Main insulation. Accessible conductive parts are connected to ground.	
		IP 20: Protection from solid substances (Diameter > 12,5mm).	
		Refer to the instruction manual/ booklet. **ISO 7010-M002**	
		For indoor use only. **IEC 60417-5957**	
		Electrical/electronic equipment in accordance with the Directive 2012/19/UE (WEEE) Do not dispose with domestic household wastes. **EN 50419**	
		GENERAL WARNING SIGN: **ISO 7010-W001 General**	
		This sign specifies the manufacturing date indication. **ISO 7000-2497**	
		HIGH VOLTAGE WARNING: High voltage on the connector indicated by this warning sign	
		RoHs SIGN: Restriction of Hazardous Substances.	

Réf.	Label	Description
2	LASER CLASS IV / 4 Nd:YAG Laser: 1064nm 30mJ Max. (3 pulses x 4ns) Nd:YAG Laser: 532nm 2mJ Max LASER CLASS II / 2 Diode Laser: 635nm, <1mW Max VISIBLE AND / OR INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT per IEC 60825-1:2007 + AC1:2008 Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50, dated June 24, 2007	**LASER RADIATIONS WARNING LABEL:** With treatment and aiming beam wavelengths and powers specifications.
3	**CAUTION** **CLASS 4 LASER RADIATION WHEN OPEN** **AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION**	**INTERNAL RADIATION LABEL:** Indicates existing laser radiations inside the apparatus.
4		**RIGHT LASER OUTPUT LABEL:** Laser radiations warning label: located next to the laser radiation output
5		**LEFT LASER OUTPUT LABEL:** Laser radiations warning label: located next to the laser radiation output
6	**LASER APERTURE**	**LASER OUTPUT:** Indicates that a laser beam is emitted from this output
7	DANGER LASER RADIATION WHEN OPEN Avoid eye or skin exposure to direct or scattered radiation Nd:Yag 1064nm 30mJ Max. (3 pulses 4 ns) Nd:Yag 532nm 2mJ Max. Diode 635 nm 1 mW Max. CLASS IV LASER PRODUCT	**LASER RADIATIONS WARNING LABEL FOR US:** With treatment and aiming beam wavelengths and powers specifications.
8	CAUTION : FEDERAL US LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR AN OPTOMETRIST LICENCED BY THE LAW OF THE STATE IN WHICH HE PRACTISES TO USE OR ORDER THE USE OF THIS DEVICE DANGER : EXPLOSION HAZARD. DO NOT USE IN PRESENCE OF FLAMMABLE ANESTETICS OR IN OXYGEN-RICH ATMOSPHERE. CAUTION : ELECTRIC SHOCK HAZARD. DO NOT OPEN. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.	**FEDERAL US LAW LABEL**

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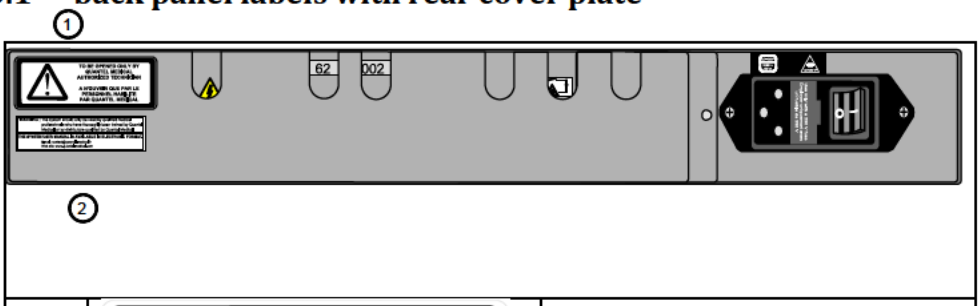
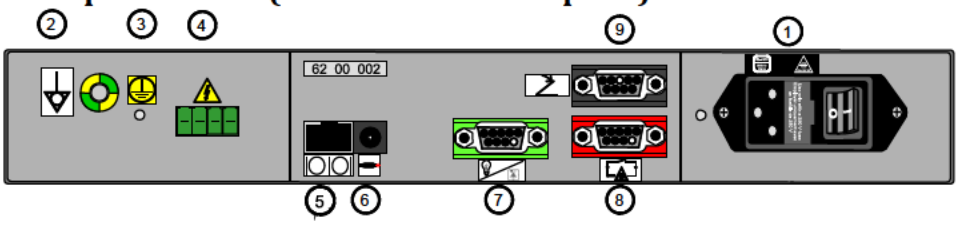
1.3 BACK PANEL VIEWS

1.3.1 back panel labels with rear cover plate



1	TO BE OPENED ONLY BY QUANTEL MEDICAL AUTHORIZED TECHNICIAN A N'OUVRIR QUE PAR LE PERSONNEL HABILITE PAR QUANTEL MEDICAL	**SERVICING LABEL :** Indicates that only authorized technician can open the unit.
2	**WARNING :** The system should only be used by qualified medical professionals who have thoroughly been trained by Quantel Medical or by distributors qualified by Quantel Medical. **THE SYSTEM USER MANUAL IS AVAILABLE IN ELECTRONIC FORMAT.** E-mail: contact@quantel-medical.fr Web site: www.quantel-medical.com	This label specifies that the User Manual is available in electronic format: **COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices**

1.3.2 back panel labels (without rear cover plate)



Réf.	Label	Description
1		**FUSES AND VOLTAGES LABEL:** With power supply specifications Voltages Fuses Frequency Powers
2		**EQUIPOTENTIALITY CONNECTOR LABEL:** Indicates the equipotentiality point connection.

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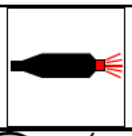
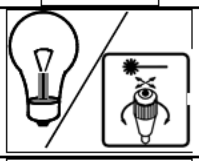
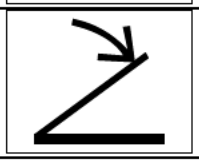
3		**GROUND LABEL:** Indicates the ground connection
4		**HIGH VOLTAGE WARNING LABEL:** Situated next to the connector on which a high voltage could be present
5		**COMMUNICATION PORT LABEL:** Indicates the communication port between laser console and laser head.
6		**FIXATION LED LABEL:** Indicates the power supply connector of the fixation LED.
7		**LAMP / JOYSTICK PORT LABEL:** Indicates the generator lamp supplying and joystick control port.
8		**DOORSWITCH CONNECTOR LABEL:** Indicates connector of the doorswitch.
9		**FOOTSWITCH CONNECTOR LABEL:** Indicates the connector of the footswitch.

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VI. DEVICE DESCRIPTION

Introduction

The Family of OPTIMIS FUSION Ophthalmic Lasers, Delivery Device and Accessories consists of the following models:

1) OPTIMIS FUSION YAG – a Nd: YAG Laser providing-switched laser pulses at a wavelength of 1064 nm for use in photodisruption of ocular tissue (posterior capsulotomy, pupillary membranectomy, iridotomy/iridectomy). The 1064 nm treatment beam delivers 4 ns, 0.3 -10mJ adjustable and selectable single, double or triple pulse of energy. It is conditioned through beam shaping optics to generate a photodisruption micro pulse of plasma at a precision adjustable location relative to the visual focal plane (located at slit lamp center of rotation) and along the slit lamp objective lens axis. A twin aiming beam is also focused by the slit lamp objective to a converging 10 µm spot located at the focal point of the lens. The focal point of photodisruption is adjustable 150µm in the posterior direction and -150µm in the anterior direction by the physician relative to this convergence of the twin aiming beams.

2) OPTIMIS FUSION SLT - a Nd: YAG Laser providing Q-switched frequency doubled pulses at a wavelength of 532 nm for use in Selective Laser Trabeculoplasty. The treatment beam delivers a 4 nsec, 0.3, 2mJ adjustable single pulse of energy. The aiming and treatment beams are coaxial with each other and focussed by the slit lamp objective to a 400µm spot at the focal point of the lens.

3) OPTIMIS FUSION YAG/SLT - a Nd: YAG Laser providing Q-switched laser pulses at a wavelength of 1064 nm for use in photodisruption or Q-switched frequency doubled pulses at a wavelength of 532 nm for use in Selective Laser Trabeculoplasty, depending upon the mode selected. The OPTIMIS FUSION YAG/SLT contains two aiming beam modules that produce a single beam for the 532nm mode and a dual beam for the 1064nm mode, respectively.

For each OPTIMIS FUSION model, the physician controls delivery of laser energy from the OPTIMIS FUSION control display unit and activates the treatment laser beam with a footswitch or joystick pushbutton. In addition, a laser slit lamp adaptor, may be coupled to each of the above OPTIMIS FUSION models and connected to a currently cleared QUANTEL MEDICAL 532 nm photocoagulator (VITRA (K04236), SUPRA (K07776), VITRAMULTISPOT (K122251)) to allow to the physician to use the *slit lamp adaptor* to deliver 532 nm continuous wave laser energy for retinal photocoagulation. All photodisruptor and SLT laser functions are disabled. The slit lamp adaptor is used for treatments specifically for the compatible lasers retinal photocoagulator.

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

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When the photodisruptor mode is selected, the treatment wavelength is 1064 nm. A twin-aiming beam targets the area of tissue disruption. The energy contained within a single short pulse is concentrated by focusing to a very small spot size so that plasma formation occurs at the focal point. This creates an acoustic wave which disrupts nearby tissue.

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

Figure 1 provides the Block Diagram for the OPTIMUS FUSION. Figure 2 shows the layout of the laser head of the OPTIMUS FUSION. Figures 3 and 4 show the front and rear, respectively, of the system.

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O 'TIMIS FUSION Diagrams and Photos

(b)(4)

[redacted]

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(b)(4) Diagram

[redacted]

Figure 3 Front View

Figure 4 Rear View

Specifications

GENERAL SPECIFICATIONS

	YAG Mode	SLT Mode
Laser Energy source	Q-Switched, Nd: YAG	Q-Switched, frequency doubled Nd: YAG
Pulse Setting	1,2 or 3 pulses per burst, selectable	Single pulse only
Laser energy Intensity	Selected by Physician	Selected by Physician
Power requirements: Current	2A	2A
Power requirements: Voltage	100 to 240 Vac	100 to 240 Vac
Computer control	Yes	Yes
Can user change computer program?	No	No

LASER OUTPUT

Output Wavelength	1064 nm	532 nm
Energy Settings	0.3 – 10 mJ	0.3 – 2.0 mJ
Repetition Rate (Max)	2.0 Hz	2.5 Hz
Pulse Duration	4 nanoseconds	4 nanoseconds
Spot Size	10 microns	400 microns
Focus angle	16 degrees	< 3 degrees
Laser Safety Class	4 / IV	4/IV
Cooling Method	Air convection	Air convection
Aiming Beam:	Dual diode, variable intensity	Coaxial with treatment beam
Aiming Beam: Type	Red diode	Red diode
Aiming Beam: Wavelength	635 nm	635 nm
Aiming laser power	< 1mW	< 1mW
Laser Safety Class	2/II	2/II
Safety measures	Conform to standard 60601-2-22 and 60825-1	Conform to standard 60601-2-22 and 60825-1
Accessories	NA	Standard footswitch provided as a standard system component

DELIVERY SYSTEM

Slit lamp ADAPTOR	Adaptor to suit the following slit lamp: • CSO SL 980

The Nd: YAG treatment beam is derived from a solid-state laser module that produces short (approximately 4 ns), individual pulses of focused infrared light with a wavelength of 1064 nm.

The output of the laser module is passed through several optical modules to allow the beam leaving the objective lens of the slit lamp microscope to be focused to a high energy spot with a diameter of eight microns.

The Nd: YAG treatment beam operates by photodisruption. The energy of the pulses produced by the laser is adjustable and the energy density at the focal point is sufficient to create a small ionization site (plasma) in the vitreous cavity. The plasma produces an acoustic wave that radiates from the focal point and ruptures or disrupts adjacent tissue. This is known as the 'photodisruptive effect'.

Once formed, the plasma absorbs and scatters further incident light. This shields the underlying structures from damage. The beam divergence after the focal point protects the retina from damage that could otherwise occur by the absorption of concentrated Nd:YAG treatment energy.

The laser pulses are accurately positioned by means of a 'twin dot' aiming laser and an integrated slit lamp microscope. The treatment and aiming laser systems exit the microscope along its Nd:YAG optical axis and focus at the slit lamp center of rotation.

The Selective Laser Trabeculoplasty treatment laser provides a low energy, short pulse of laser light that produces a thermal effect in pigmented cells in the trabecular meshwork of the eye.

Collateral thermal and coagulative damage does not occur because the pulse duration is less than the time it takes for melanin in the pigmented cells to convert the absorbed electromagnetic radiant energy into heat energy (this is the thermal relaxation time). Even in the treatment area, non-pigmented cells and structures are unaffected.

In SLT treatment mode, the OPTIMIS FUSION emits single visible light pulses of 4ns in duration with a 400µm spot size and pulse energies ranging from 0.3 to 2mJ. The mechanism of action of OPTIMIS FUSION is the selective targeting of pigmented trabecular meshwork cells, when operated within a defined energy range.

The short duration of the laser pulses minimizes the amount of heat dissipated from pigmented cells and absorbed by surrounding non-pigmented tissues. When the OPTIMIS FUSION SLT mode is operated from a defined energy range, the fluency of the energy levels may result in photo acoustic and/or photomechanical damage to adjacent non-melanized cells or the trabecular support architecture.

A Latina gonioscopy lens without magnifying optics is used to visualize the angle during treatment. Pulse delivery is controlled by means of a joystick or footswitch.

The optimum energy level for treatment is defined as the maximum energy that can be delivered without causing photo disruption/optical breakdown of the trabecular meshwork. The optimum energy level will vary from patient to patient because the threshold for thermal energy, evidenced by bubble formation, is determined primarily by the level of pigmentation in cells of the trabecular meshwork.

To determine the optimum energy level for treatment, the user should set the initial laser energy at 0.6mJ and increase the energy in 0.1mJ increments until bubble formation is observed. The energy at which bubble formation occurs is known as the "threshold energy". After the threshold energy has been identified, decrease the laser energy level by 0.1mJ. This lower energy level is known as the "treatment energy"

Treatment should continue at the treatment energy until 50 (±10) single, non-overlapping laser spots have been created along 180 degrees of either the nasal or temporal segment of the trabecular meshwork.

The following figures show several views of the laser head, power supply and optional accessories (Stand column, footswitch, Slit Lamp adaptor).

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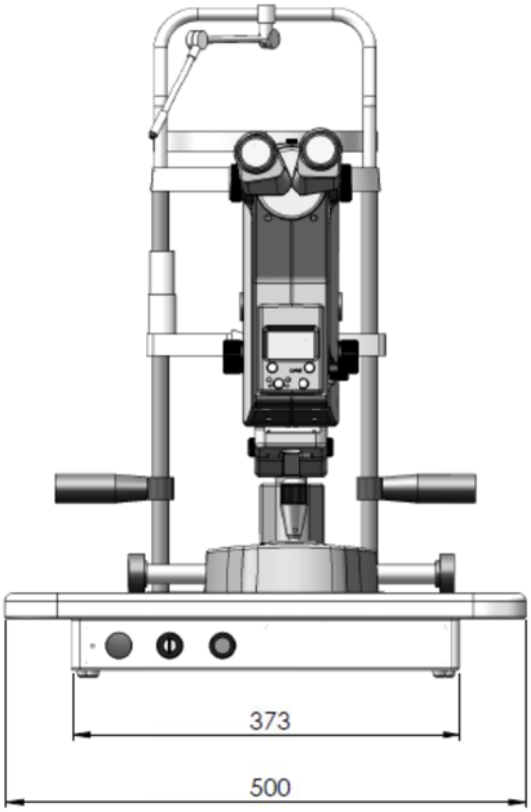

Figure 5 Front View

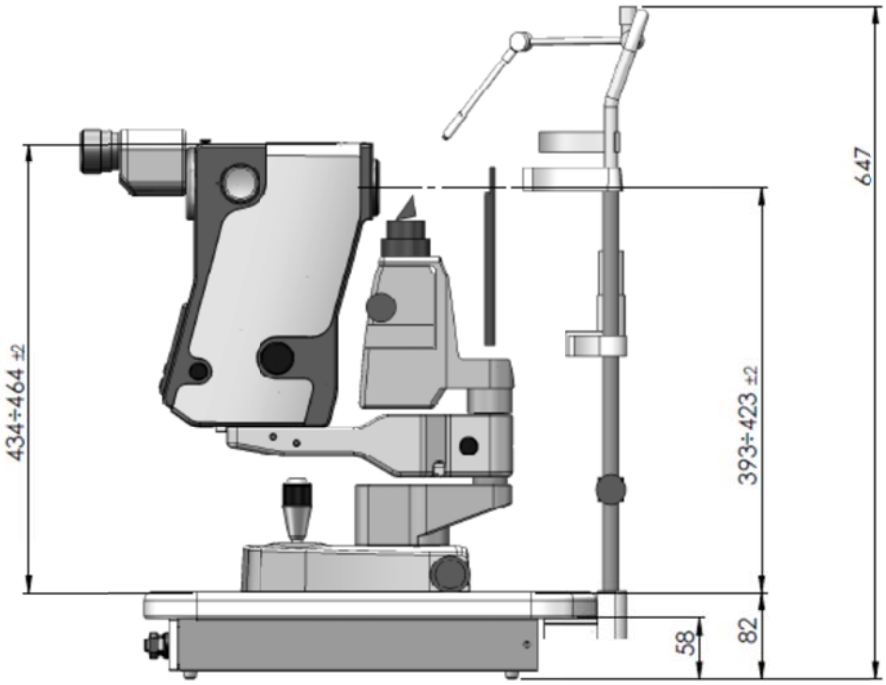

Figure 6 Left Side Laser Head

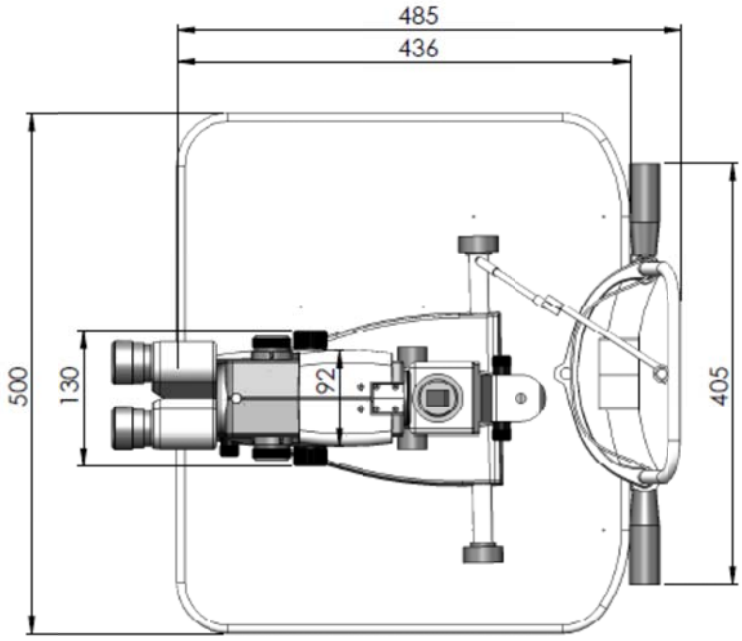

Figure 7 Bottom Laser Head

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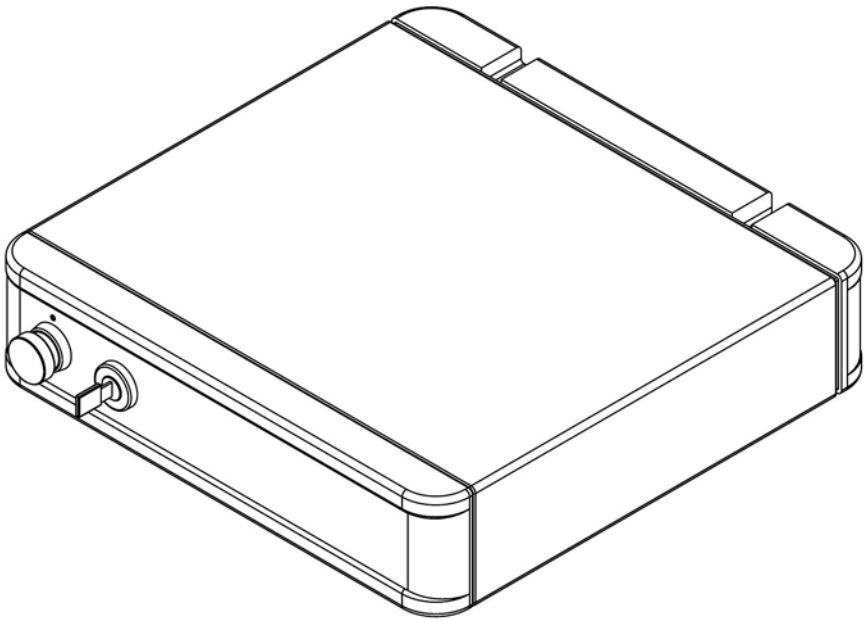

Figure 8 3D Power Supply

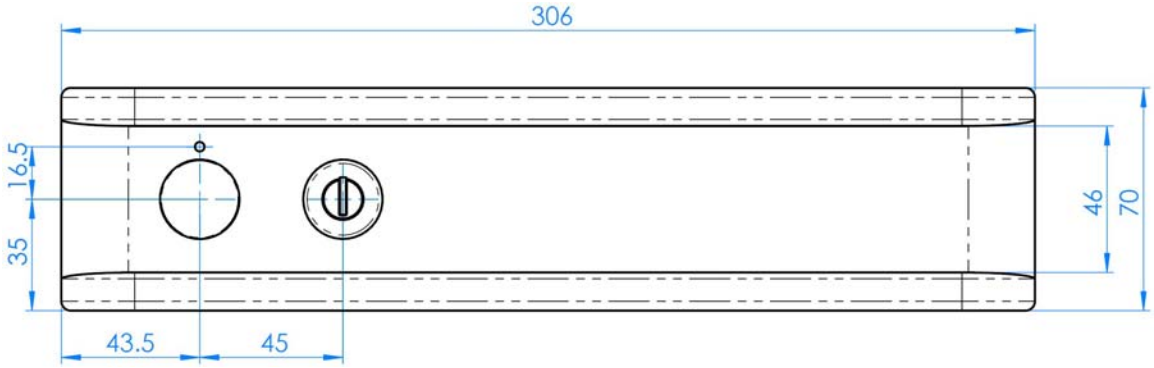

Figure 9 Power Supply Front

UPPER SIDE POWER SUPPLY

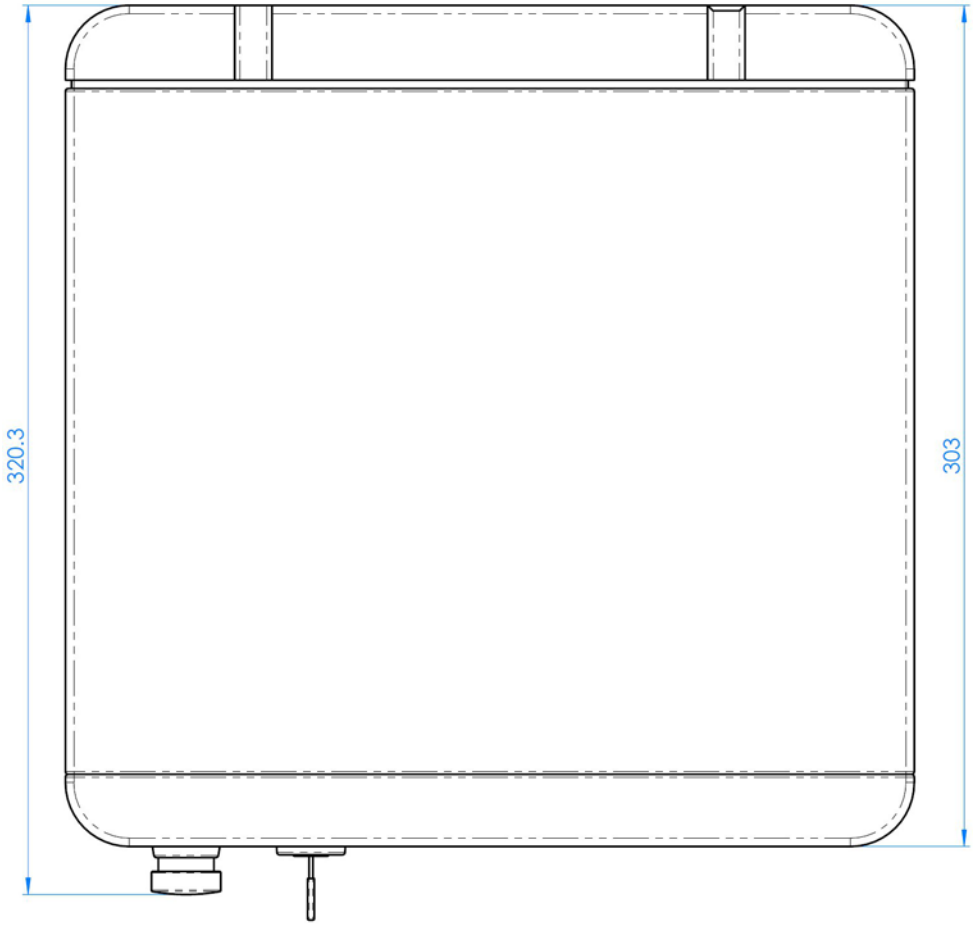

Figure 10 Power Supply (from above)

Figure 11 Power Supply (Left Side)

Figure 12 Footswitch (Optional)

Figure 13 Stand Column (Optional)

PARAMETER	DETAILS
Stand Column dimensions :	
Table height:	Max: 38 in (960 mm) Min: 28 in (708 mm)
Table width:	Standard stand: 24 in (605 mm) Wheelchair accessible stand: 31 in (790 mm)
Table depth:	17 in (435 mm)

Figure 14 Slit Lamp Adaptor (Optional)

VII. SUBSTANTIAL EQUIVALENCE

Quantel Medical believes that the OPTIMIS FUSION FAMILY described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to legally marketed predicate devices that are Class II medical devices. The following is a tabular presentation of the OPTIMIS FUSION compared with the predicate devices.

Predicate Comparison Table

GENERAL SPECIFICATIONS COMPARISON TABLE

Manufacturer	**QUANTEL MEDICAL**			**LUMENIS**		
Model	Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories			Family of SELECTA Ophthalmic Laser Systems, Delivery Device and Accessories		
510 (K) Number				K081704		
Intended Use	Treatment of ocular pathology			Treatment of ocular pathology		
Device Name	Optimis Fusion SLT	Optimis Fusion YAG	Optimis Fusion YAG/SLT	Selecta SLT	Selecta 1064	Selecta Duet
Indications for Use	Selective Laser Trabeculoplasty (SLT)	Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy.	Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy and Selective Laser Trabeculoplasty (SLT)	Selective Laser Trabeculoplasty (SLT)	Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discussion of the posterior capsule (posterior capsulotomy), and discussion of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy.	Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discussion of the posterior capsule (posterior capsulotomy), and discussion of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy, Selective Laser Trabeculoplasty (SLT)
Laser energy Intensity	Selected by Physician			Selected by Physician		

Treatment Lasers

Manufacturer	**QUANTEL MEDICAL**			**LUMENIS**		
Model	Family of OPTIMIS FUSION Ophthalmic laser Systems, Delivery device and Accessories			Family of SELECTA Ophthalmic laser Systems, Delivery device and Accessories		
510 (K) Number				K081704		
	Optimis Fusion SLT	Optimis Fusion YAG	Optimis Fusion YAG/SLT	Selecta SLT	Selecta 1064	Selecta Duet
Laser Energy source	Q-Switched, frequency doubled Nd: YAG	Q-Switched, Nd: YAG	Q-Switched, frequency doubled Nd: YAG and Q-Switched, Nd: YAG	Q-Switched, frequency doubled Nd: YAG	Q-Switched, Nd: YAG	Q-Switched, frequency doubled Nd: YAG and Q-Switched, Nd: YAG
Laser Wavelength	532 nm	1064 nm	532 nm and 1064 nm	532 nm	1064 nm	532 nm and 1064 nm
Pulse setting	Single pulse only	1,2 and 3 pulses per burst, selectable	SLT mode: single pulse only YAG mode: 1,2 and 3 pulses per burst, selectable	Single pulse only	1,2 and 3 pulses per burst, selectable	SLT mode: single pulse only YAG mode: 1,2 and 3 pulses per burst, selectable
Energy Settings	0.3 – 2.0 mJ	0.3 – 10 mJ	SLT mode: 0.3-2.0 mJ YAG mode: 0.3-10 mJ	0.3 – 2.0 mJ	0.3 – 10 mJ	SLT mode: 0.3-2.0 mJ YAG mode: 0.3-10 mJ
Repetition Rate (Max)	2.5 Hz	2.0Hz	SLT mode: 2.5 Hz YAG mode: 2.0 Hz	2.0 Hz	2.0 Hz	2.0 Hz
Pulse Duration	4 nanoseconds	4 nanoseconds	4 nanoseconds	3 nanoseconds	3 nanoseconds	3 nanoseconds
Spot Size in air	400 microns	10 microns	SLT mode: 400 microns YAG mode: 10 microns	400 microns	10 microns	SLT mode: 400 microns YAG mode: 10 microns
Offset (in air)	---	ANT -150;0;POST +150 microns	YAG mode: ANT -150;0;POST +150 microns	---	100-350 microns, continuously variable	YAG mode: 100-350 microns, continuously variable
Focus angle	< 3 degrees	16 degrees	SLT mode: < 3 degrees YAG mode: 16 degrees	< 3 degrees	16 degrees	SLT mode: < 3 degrees YAG mode: 16 degrees
Laser Safety Class	4/IV	4/IV	4/IV	4/IV	4/IV	4/IV

Aiming Lasers

Aiming Beam laser type	Red diode	Red diode	Red diode	Red diode	Red diode	Red diode
Aiming Wavelength	635 nm	635 nm	635 nm	635 nm	635 nm	635 nm
Aiming laser power	< 1mW	< 1mW	< 1mW	< 1mW	< 1mW	< 1mW
Aiming Beam :	Coaxial with treatment beam	Dual diode	SLT mode: coaxial with treatment beam YAG mode: dual diode	Coaxial with treatment beam	Dual diode	SLT mode: coaxial with treatment beam YAG mode: dual diode
Laser safety class	2/II	2/II	2/II	2/II	2/II	2/II

Electrical and Mechanical Characteristics of Devices

Manufacturer	**QUANTEL MEDICAL**	**LUMENIS**
Model	Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories	Family of SELECTA Ophthalmic Laser Systems, Delivery Device and Accessories
510 (K) Number		K081704
Mains Electrical Supply voltage	100 to 240 Vac	---
Supply Frequency	50/60Hz	50/60Hz
Weight	24.5 kg	25lbs
Min/Max height (top of chinrest)	H x W x D = 647 mm x 540 mm x 485 mm	5.4¨x7¨x11.4¨
Operating Temperature Range	+15°C to +35°C; RH 90%	+15°C to +32°C; RH 90%@ 32°C
Transport & Storage Temperature Range	- 20°C to +70°C; - RH 10 to 85%	- 10°C to +55°C; - RH up to 90%@55°C
Cooling (console)	Air convection	Air cooled

Slit Lamp Delivery Systems Characteristics

Manufacturer	**CSO**	**LUMENIS**
Type	Galilean converging binocular	Galilean stereoscopic microscope with converging optics
510 (K) Number	Previously cleared in K992836	K081704
Objectives lens	1.1x	1.25 x
Eyepiece lens	12.5 x	12.5 x, dioptre adjustable in range ± 5D
Total magnification	10 x 16x 25x	16 x (12.5 x eyepiece)
Magnification changer	3 position, removable	3 position, removable
Interpupillary distance adjustment	48.5 - 80 mm	2.16 to 3.5 in (55-88 mm)
Working distance	3.14 in (80 mm)	2.16 in (55mm)
Focal length	3.7 in (94 mm)	3.6 in (92 mm)
Chin rest	Adjustable, vertical travel 2.5 in (70 mm)	Adjustable, vertical travel 2 in (50 mm)
Slit lamp source		
Slit width	0 to 14 mm	0 to ½ (0 to 12 mm)
Illumination view field	0.2mm, 5.5mm, 9mm, 14mm, continuously variable	0.5 mm, 5 mm, 8 mm, 12 mm, continuously variable
Slit rotation	180 degrees	180 degrees
Illumination angle	180 degrees at horizontal plane (90 degrees for right/left)	180 degrees at horizontal plane (90 degrees for right/left)
Filters	cobalt-blue,	Green, cobalt-blue, neutral density (ND) (28% attenuation)
Bulb	LED bulb, 6V, 20W pre-centered bulb	Halogen lamp, 12V, 30W pre-centered bulb
Cross slide table		
Vertical adjustment of binocular arm	1.2 in (30 mm), by rotation of joystick	1 in (26 mm), by rotation of joystick
Fine horizontal movement	± 7mm	By tilting joystick lever, fine movement of 11 mm

Coarse horizontal movement	By moving the slit lamp base, coarse movement of 4.52 in (115 mm) longitudinal and 4.3 in (110 mm) lateral travel.	By moving the slit lamp base, coarse movement of 4 in (103 mm) longitudinal and 4 in (103 mm) lateral travel.

Accessories

Manufacturer	**QUANTEL MEDICAL**	**LUMENIS**
Model	Family of OPTIMIS FUSION Ophthalmic laser Systems, Delivery device and Accessories	Family of SELECTA Ophthalmic laser Systems, Delivery device and Accessories
510 (K) Number	---	K081704
Standard Accessories	---	Footswitch
Optional Accessories	Footswitch, Slit lamp Adaptor, Stand Column	LaserLink S,Beam splitter, 35mm Camera adapter, video camera adapter, co-observation tube, Latina lens

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Substantial Equivalence Discussion for the OPTIMIS FUSION FAMILY per the 510(k) Substantial Equivalence Decision-Making Process Flowchart

1. **Does the new device have the same Indication Statement?**

Yes, the indications for use statement for the OPTIMIS FUSION FAMILY is exactly the same as the indications for use statement for the Lumenis Family of SELECTA Ophthalmic Laser Systems, Delivery Device and accessories (predicate device). Each of the families contains multiple configurations of the laser system with different indications for use statements. Both families include an SLT model, a YAG model and a model which combines the SLT and YAG. The indications for use statements for each version of the product are identical between the families.

Additionally, all of the devices are prescription devices which are intended to be used by trained medical personnel. Therefore, the OPTIMIS FUSION FAMILY has the same intended use as the identified predicate device and may be found to be substantially equivalent to the predicate device.

2. **Does the new device have the same technological characteristics?**

Yes, the OPTIMIS FUSION FAMILY and the predicate device have the same technological characteristics. Each of the families includes multiple models within the family. Both the OPTIMUS FUSION FAMILY and the Lumenis SELECTA family include an SLT model, a YAG model and a model that combines the SLT and YAG lasers in one unit.

SLT Mode
The Optimis Fusion SLT is a Q-Switched frequency doubled Nd: YAG laser with a wavelength of 532 nm as is the Selecta SLT model. Both the Optimis Fusion SLT and the Selecta SLT models operate in single pulse modes. The energy range for both devices is 0.3-2.0 mJ. The spot size in air is 400 microns with a focus angle of < 3 degrees for both systems. The repetition rate for the Optimis Fusion SLT is 2.5 Hz while it is 2.0 Hz for the Selecta SLT and the pulse duration is 4 ns for the Optimis Fusion SLT and 3 ns for the Selecta SLT. The two differences between the two systems are considered very minor in significance and don't affect the safety or efficacy of the devices. There are other FDA cleared devices for SLT that have the same repetition rate and pulse duration as the Optimis Fusion SLT system including the Carl Zeiss Meditec Visulas YAG III cleared in K042139.

YAG Mode
The Optimis Fusion YAG is a Q-Switched Nd: YAG laser with a wavelength of 1064 nm as is the Selecta 1064 model. Both the Optimis Fusion YAG and the Selecta 1064 models operate in user selectable bursts of 1, 2 or 3 pulses. The energy range for both devices is 0.3-10.0 mJ. The spot size in air is 10 microns with a focus angle of 16 degrees for both systems. The repetition rate for the Optimis Fusion YAG is 2.0 Hz as it is for the Selecta

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1064. The pulse duration is 4 ns for the Optimis Fusion YAG and 3 ns for the Selecta 1064. This difference between the two systems are considered very minor in significance and don't affect the safety or efficacy of the devices. There are other FDA cleared devices for the same indications for use that have the pulse duration as the Optimis Fusion YAG system including the Carl Zeiss Meditec Visulas YAG III cleared in K042139.

SLT/YAG modes
The Optimis Fusion YAG/SLT includes the features and specification of both the Optimis Fusion SLT system and the Optimis Fusion YAG system combined in one device. The specifications of each individual system remain unchanged when they are combined into one unit. This is exactly the same at the Lumenis Selecta Duet which combines the Selecta SLT and Selecta 1064 features. Therefore, the similarities and differences outlined above for the SLT and YAG models apply to the Optimis Fusion YAG/SLT device.

All of the systems use a 635 nm red diode for aiming. All of the systems use a slit lamp as the delivery system for the laser energy. The Optimis Fusion models use the CSO SL980 slit lamp previously cleared by FDA in K992836.

3. Are the descriptive characteristics precise enough to ensure equivalence?

Yes, the descriptive characteristics available on both the OPTIMIS FUSION FAMILY and the predicate device are precise enough to ensure equivalence. Therefore, the OPTIMIS FUSION FAMILY is substantially equivalent to the predicate device.

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VIII. SOFTWARE INFORMATION

Quantel Medical has followed the FDA "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" dated May 11, 2005.

Table 1 Major Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.
1. Does the Software Device qualify as Blood Establishment Computer Software? NO
2. Is the Software Device intended to be used in combination with a drug or biologic? NO
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern? NO
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:
a. Does the Software Device control a life supporting or life sustaining function? NO
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? NO
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? YES
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? NO
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary? NO

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Table 2 Moderate Level of Concern

Question	Answer
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	NO
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	YES
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	NO

Therefore, the Level of Concern for the software is Major.

As a result of the Major Level of Concern, the documentation provided in this submission includes the following:

Software Requirements Specification	**Appendix 8**
Device Hazard Analysis	**Appendix 6.2**
Architecture Design Chart	**Appendix 9**
Software Design Specification	**Appendix 10**
Software Development Environment	**Appendix 11**
Software Configuration Management Plan	**Appendix 12**
Maintenance Plan	**Appendix 13**
Traceability Analysis	**Appendix 14**
Software Verification and Validation	**Appendix 15**
Revision Level History	**Appendix 16**
Unresolved Anomalies	**Appendix 17**

IX. BIOCOMPATIBILITY INFORMATION

The OPTIMIS FUSION FAMILY does not come into contact with the patient during the treatment, therefore, biocompatibility information is not provided.

X. STERILIZATION / CLEANING / DISINFECTION / SHELF LIFE

The OPTIMIS FUSION FAMILY is not supplied sterile and does not require sterilization before use. Cleaning is described in the User's Manual which is provided in **Appendix 7**.

The outside of the OPTIMIS FUSION FAMILY should be cleaned as needed with a cloth dampened with a non-caustic cleaning solution such as soap and water, isopropyl alcohol

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or a hospital grade disinfectant. The optics should be cleaned as needed using lint free optical tissues, cotton swabs and ethanol or methanol.

XI. PERFORMANCE TESTING-BENCH

Appendix 18 provides a summary of the functional control activities for the OPTIMIS FUSION FAMILY. The testing validated that the power output, position at focal point, and dimensions of treatment conform to functional requirements.

XII. PERFORMANCE TESTING-CLINICAL

No clinical data is required or provided for this 510(k).

XIII. FINANCIAL DISCLOSURES

There is no clinical data submitted in this 510(k) so a financial disclosure is not required.

XIV. 510(K) SUMMARY

Appendix 19 of this submission contains the Company's 510(k) Summary.

XV. CONFIDENTIALITY

Some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

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XVI. SUBMITTER'S NAME AND ADDRESS

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11 rue Bois Joli
CS 4015
63808 Cournon d'Auvergne - Cedex
FRANCE

XVII. CONTACT PERSON AND TELEPHONE/FACSIMILE NUMBERS

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Phone: (978) 207-1245
Facsimile: (978) 824-2541

XVIII. MEDICAL DEVICE USER FEE

The Company has electronically remitted the Medical Device User Fee of (b)(4) [redacted] concurrent with this submission. A copy of the Medical Device User Fee Cover Page is provided in **Appendix 20.**

XIX. INDICATIONS FOR USE STATEMENT

The company's Indications for Use Statement for OPTIMIS FUSION Family is provided in **Appendix 21**.

XX. TRUTH AND ACCURACY STATEMENT

The company's signed Truth and Accuracy statement is included in **Appendix 22.**

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Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-77	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatt ng convent on for the t t e s: [SDO] [numer c dent f er] [t t e of standard] [date of pub cat on]

[2] Author ty [21 U S C 360d] www fda gov/cdrh/stdsprog htm

[3] http://www accessdata fda gov/scr pts/cdrh/cfdocs/cfStandards/search cfm

[4] The summary report shou d nc ude: any adaptat ons used to adapt to the dev ce under rev ew (for examp e a ternat ve test methods); cho ces made when opt ons or a se ect on of methods are descr bed; dev at ons from the standard; requ rements not app cab e to the dev ce; and the name address of the test aboratory or cert f cat on body nvo ved n conformance assessment to th s standard The summary report nc udes nformat on on a standards ut zed dur ng the deve opment of the dev ce

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[6] The on ne search of CDRH Gu dance Documents can be found at www fda gov/cdrh/gu dance htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY, 1988; A 1 1991-11, A2 1995

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
19.4	Continuous Leakage Currents and Patients Auxiliary Currents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Exclusion of test

DESCRIPTION
The tests after humidity preconditioning treatment were not yet performed. A test proving the conformity to this section will be performed before marketing the device in the USA

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
20.4	Dielectric strength after humidity preconditioning treatment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Exclusion of one test

DESCRIPTION
he tests after humidity preconditioning treatment were not yet performed. A test proving the conformity to this section will be performed before marketing the device in the USA

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2, (Edition 3, 2007), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests. (General)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-53	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatt ng convent on for the t t e s: [SDO] [numer c dent f er] [t t e of standard] [date of pub cat on]

[2] Author ty [21 U S C 360d] www fda gov/cdrh/stdsprog htm

[3] http://www accessdata fda gov/scr pts/cdrh/cfdocs/cfStandards/search cfm

[4] The summary report shou d nc ude: any adaptat ons used to adapt to the dev ce under rev ew (for examp e a ternat ve test methods); cho ces made when opt ons or a se ect on of methods are descr bed; dev at ons from the standard; requ rements not app cab e to the cert f cat on body nvo ved n conformance assessment to th s standard The summary report nc udes nformat on on a standards ut zed dur ng the deve opment of the dev ce

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
NON APPLICABLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-4:2000 Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1. (General)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-41	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Author ty [21 U S C 360d] www fda gov/cdrh/stdsprog htm

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EXTENT OF STANDARD CONFORMANCE
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STANDARD TITLE
NON APPLICABLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

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❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-22 (2007), Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment - Edition 2.0. (Radiology)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 12-208	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
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Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
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SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

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APPENDIX 2

FUSION YAG_SLT – USER MANUAL

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60825-1 Ed.2.0 (2007), safety of laser products - Part 1:Equipment classification, and requirements

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 12-168	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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JUSTIFICATION		

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STANDARD TITLE [1]

ISO:2007/(R)2010 (Corrected 4 October 2007), Medical devices - Application of risk management to medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-70	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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Introduction
I Regulatory & safety information
II Technical information
III Using the laser system
IV Maintenance
V Clinical information

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User Manual

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December 2013

YAG and SLT Laser

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Fax : +33 (0) 473 745 700
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FRANCE Tel. : +33 (0) 473 745 745
Fax : +33 (0) 473 745 700
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Software version 1.00
International version
(Ref: XL_FUSION_ME_AN)
December 10th, 2013

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1 USER MANUAL DESCRIPTION

The OPTIMIS FUSION user manual is organized into the following chapters:

Introduction
I Regulatory & safety information
II Technical information
III Using the laser system
IV Maintenance
V Clinical information

2 USER MANUAL TERMS AND SAFETY SYMBOLS

WARNING

Potential hazards which, if not avoided, could result in serious injury or death

CAUTION

Potential hazards which, if not avoided, could result in minor or moderate injury and/or product damage

NOTE

Significant additional information or explanation

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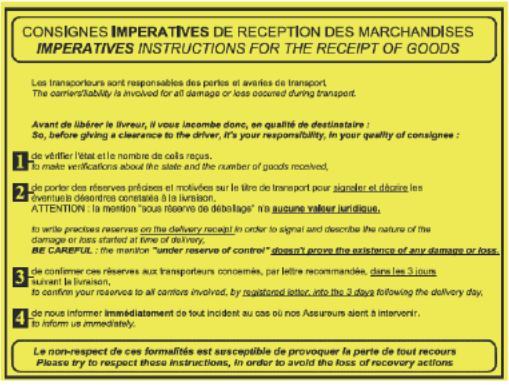
3 UNPACKING THE INSTRUMENT

3.1 TRANSPORTATION INFORMATION

To minimize transportation risks, this instrument has been packed with special care. However, before unpacking the laser, check the packaging for any sign of damage or improper handling.

① Handling label

② Delivery label



CONSIGNES **IMPERATIVES** DE RECEPTION DES MARCHANDISES
***IMPERATIVES** INSTRUCTIONS FOR THE RECEIPT OF GOODS*

Les transporteurs sont responsables des pertes et avaries de transport.
The carriers'liability is involved for all damage or loss occured during transport.

Avant de libérer le livreur, il vous incombe donc, en qualité de destinataire :
So, before giving a clearance to the driver, it's your responsibility, in your quality of consignee :

1. de vérifier l'état et le nombre de colis reçus.
To make verifications about the state and the number of goods received,

2. de porter des réserves précises et motivées sur le titre de transport pour signaler et décrire les éventuels désordres constatés à la livraison.
ATTENTION : la mention "sous réserve de déballage" n'a **aucune valeur juridique.**
to write precises reservas on the delivery receipt in order to signal and describe the nature of the damage or loss started at time of delivery.
BE CAREFUL** : the mention **"under reserve of control"** **doesn't prove the existence of any damage or loss.

3. de confirmer ces réserves aux transporteurs concernés, par lettre recommandée, dans les 3 jours suivant la livraison.
to confirm your reserves to all carriers involved, by registered letter, into the 3 days following the delivery day.

4. de nous informer **immédiatement** de tout incident au cas où nos Assureurs aient à intervenir.
to inform us immediately.

Le non-respect de ces formalités est susceptible de provoquer la perte de tout recours
Please try to respect these instructions, in order to avoid the loss of recovery actions

NOTE

In case of any problem, immediately contact the shipping company. Do only open the box in the presence of a company representative. Draw up a list of all damaged parts and ask for it to be signed by the company representative.

CAUTION

If the instrument is at a temperature below **15°C** (59°F), switching on the instrument may cause serious damages. Unpack the instrument and leave it at normal temperature for at least half a day to ensure that the internal components warm up gradually.

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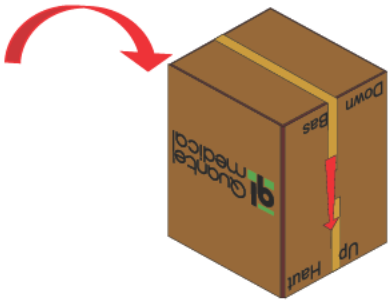
3.2 UNPACKING THE INSTRUMENT

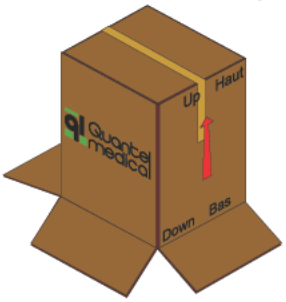
1/ Normal position :

2/ Turn upside down :

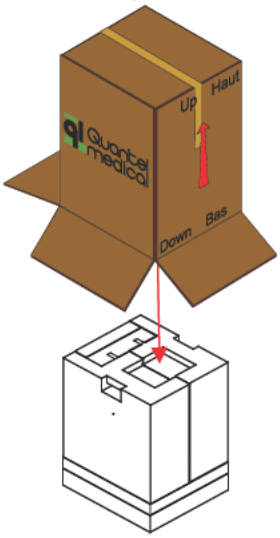


3/ Open the box :

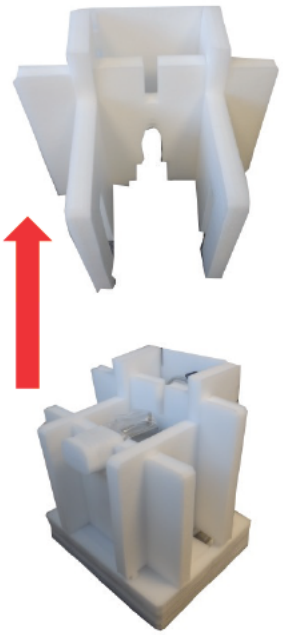
4 / Turn it back to the normal position :



5 / Pull up the box :



6 / Pull up the main foam with caution :



7 / Turn the binocular with caution to remove it from main frame :

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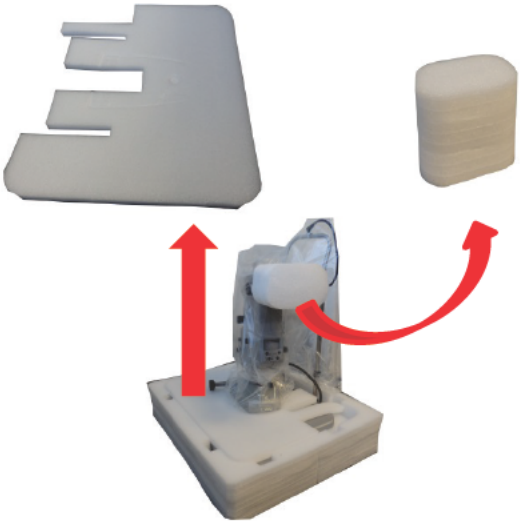
8 / Remove the flat foam located on the table and binocular foam :



9 / Remove the OPTIMIS FUSION from the bottom foam :

To mount the laser, refer to the:
OPTIMIS FUSION User Manual: II – Technical information
Section 4.2: Mounting the laser

NOTE

To repack the OPTIMIS FUSION laser: use the above procedure in reverse order.

CAUTION

The chinrest must be placed on “high” position.

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3.3 PACKING LIST

3.3.1 BASIC CONFIGURATION

Before beginning the installation, check the contents of the package against the following list:

Basic configuration	Codes
LASER OPTIMIS FUSION Nd:YAG	*XLFUSION*
Power cord	
Keys (2)	
Remote	
User Manual	*XL_FUSION_ME_AN*
Gear cover (2)	
Focusing bar	

3.3.2 ACCESSORIES

Please contact QUANTEL MEDICAL to ask for any of the following accessories:

Accessories	Codes
For ancillary personnel	
Laser safety goggles OD 5 for 532nm	*XL 532 PROT*
Laser safety goggle OD 6 for 1064nm	*XL 1064 PROT*
Slit Lamp Adaptor	
Retractable 532nm adaptor	*XL 532 CSO4ST*
Base	
Base 220V	*XL LAF PIED*
Base 110V	*XL LAF PIED110*
Footswitch	
Footswitch	*XLAAAPEDALE5*

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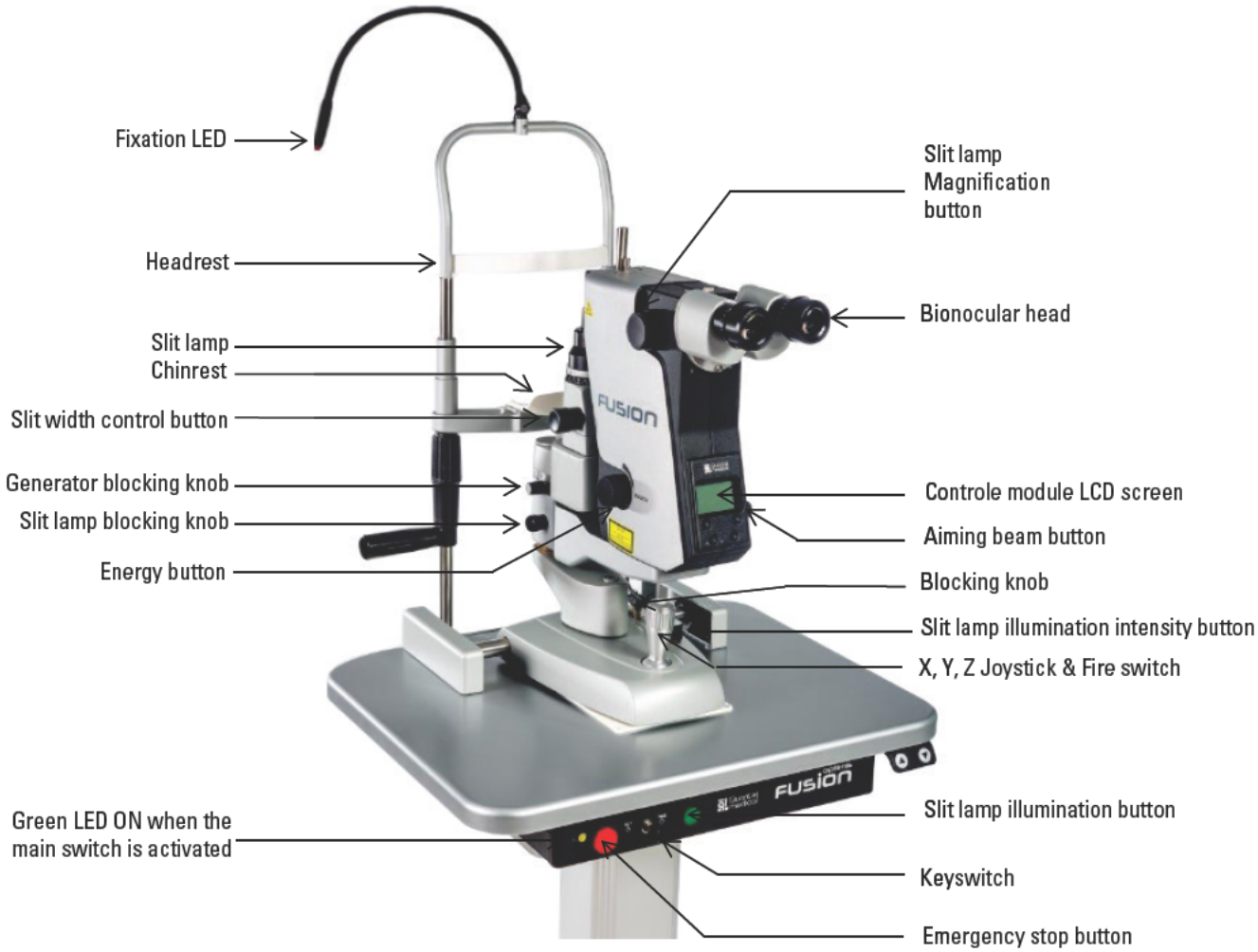
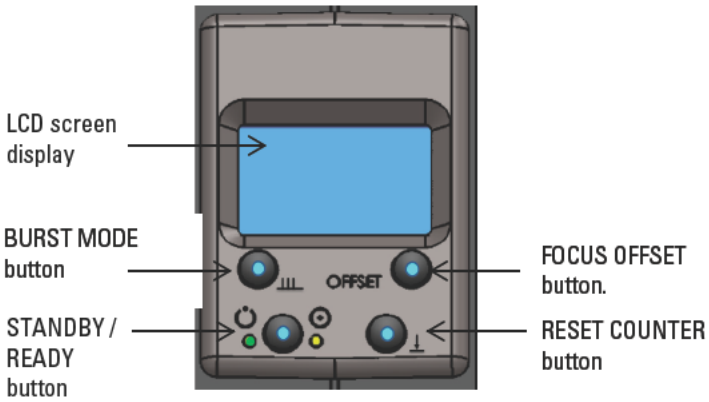
4 OPTIMIS FUSION LASER DESCRIPTION

4.1 GENERAL DESCRIPTION



4.2 CONTROL MODULE LCD SCREEN



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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL
I – REGULATORY AND SAFETY INFORMATION

Quantel medical

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DECEMBER 2013

2013 CE 0459

Directive 93/42/EEC

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1 INTENDED USE AND CONTRAINDICATIONS

The **OPTIMIS FUSION** is intented for:

- **FUSION YAG**: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy.
- **FUSION SLT**: Selective laser Trabeculoplasty
- **FUSION YAG/SLT**: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy; and Selective laser Trabeculoplasty.

2 CLASSIFICATIONS

The system is intended for continuous operation and has the following classifications:

Protective class	I (Main insulation)
Type	**B** (Protection against electrical shocks through the limiting of leakage current and the provision of a protective earth connection)
Protection degree	**IP20** (Protection from solid substances: Ø>12,5mm)
Operation	**Continuous** with short-time loading

3 SAFETY INFORMATION AND PRECAUTIONS

If any incident occurs, QUANTEL MEDICAL shall not be liable if the following safety information and precautions are not followed.

3.1 GENERAL WARNINGS AND SAFETY INFORMATION

WARNING: This user manual is designed to acquaint the user with the normal operation and maintenance of the OPTIMIS FUSION ophthalmologic laser. The manual scope is limited to the operation, maintenance and controls of the system. It is not intended to be a guide to laser eye treatment. Laser safety begins with the understanding that the purpose of this device is to perform controlled destruction of living tissues. Misuse of this system could result in patient, physician or attendees injuries. QUANTEL MEDICAL consequently strongly recommends the user to read and understand this entire manual before using the product, especially this section concerning safety.

WARNING: The American National Standards for the Safe Use of Laser in Health Care Facilities (**ANSI Z 136.3-1996 and ANSI Z 136.1-1993**) provide guidance to safely use lasers and laser systems in the diagnostic and therapeutic areas. Those two standards are related to eye and skin hazards and recommend the use of protective eye wear, clothing, barriers and screens.

WARNING: Any use of controls or performance adjustments for procedures other than those specified herein may result in hazardous radiation and/or electrical exposure.

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WARNING: This user manual is intended to solely be used by trained ophthalmologists for diagnosis and treatment of ocular pathology.

CAUTION: QUANTEL MEDICAL cannot be held responsible for any damage or injury that results from a failure to follow or incorrect use the instructions contained in this manual.

WARNING: This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

WARNING: To comply with medical electrical equipment safety standard requirements, the laser power plug must be connected on to a wall grounded single phase power socket on its own. The use of an adaptor (for multiple connections) or a power bar is prohibited.

WARNING: Do not connect the laser power plug (3 pin adaptor) on an ungrounded power socket (2-pin).

WARNING: Before cleaning the unit, unplug the power cord from the wall mains plug.
Please refer to the:
OPTIMIS FUSION user manual: IV – Maintenance
Section 2: Care and maintenance of the OPTIMIS FUSION laser system

WARNING: The instrument calibration must be performed every year by a technician authorized by QUANTEL MEDICAL.

WARNING: In case the laser efficacy is altered and the laser system needs servicing: you must contact QUANTEL MEDICAL Service Department or your local distributor.

WARNING: Unit servicing must only be performed by QUANTEL MEDICAL technicians or otherwise technicians authorized by QUANTEL MEDICAL (local distributors).

WARNING: Transport the OPTIMIS FUSION equipment only under the conditions described in the:
OPTIMIS FUSION user manual: II – Technical information
Section 4.3: Moving the OPTIMIS FUSION equipment

CAUTION: To preserve the appearance of the device, do not use abrasive cleaning products, or solvents. If possible, clean off stains immediately

CAUTION: The device's guarantee will be void if the equipment is opened (even partially), modified or repaired in any way by persons who have not been authorized to do so by QUANTEL MEDICAL.

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3.2 IMPORTANT RECOMMENDATIONS

WARNING: To prevent injury to personnel or damage to the instrument, all operators must fully versed in the instructions and procedures detailed herein and in the ANSI Standard Z136.3.

1. **Never** directly look into a laser light source and avoid exposure to reflected or scattered laser light. This device is classified as **Class 4** laser product: direct, reflected or scattered light from this laser may cause injury.

2. The treatment beam emitted from this instrument has the potential to ignite anesthetics or flammable materials or explosives. Do not use this system in proximity to these materials.

3. Safety goggles or masks are required for **anyone** who is present during a treatment session, except for the physician and the patient. During some procedures it may be advisable to shield untreated eyes (Please refer to Section 3.5.1: Safety eyewear).

4. **Never** leave the system on when it is unattended or within the reach of unauthorized persons. Before leaving the vicinity, turn off the system and keep the key with you.

5. When the laser is on, always keep the system in "STANDBY" mode unless it is used to perform treatment.

6. Contact lens wearers should use anti-reflection lenses treated for **532nm** and **1064nm** wavelengths. Contact lenses, particularly those with plano surfaces, can generate dangerous reflections.

7. **Never** open the laser enclosure as hazardous levels of visible and invisible optical radiations are present inside. Refer any servicing problem to qualified personnel authorized by QUANTEL MEDICAL.

8. Observe all **DANGER**, **WARNING** or **CAUTION** labels placed on the device:
   An overview of the location and contents of these labels can be found in the:
   OPTIMIS FUSION User manual: II - Technical information
   Section 1: Labels

9. Circuitry is provided for the connection of a remote interlock. When attached to the laser door room or other actuator, the interlock will prevent the laser from firing if someone enters in the room while the system is in use. Installation instructions are provided in:
   OPTIMIS FUSION User Manual: II - Technical information
   Section 4.5: Door switch & External red lamp installation

10. Regular maintenance, which can be performed by the user, is described in:
    OPTIMIS FUSION User Manual: IV – Maintenance
    Performing regular maintenance, which includes checking the power calibration, will help ensuring trouble-free operation.

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3.3 SAFETY FEATURES

FEATURE	DESCRIPTION
Lockable key switch	The lasers can only be turned on with the correct key that corresponds to the laser key switch. The key cannot be removed while the laser is operating, so the laser cannot function without the key in place.
Emergency Laser Stop switch	During normal operation the red push button (mushroom shaped) is in the "out" position (not down). When pressed in, it immediately switches off all power and eliminates any risk of laser irradiation. The button must be released by turning clockwise to the ON position to restart the system and return to "STANDBY" status.
Laser Selection Button	Once the Emergency Laser Stop switch is in the ON position, the main switch located behind the unit is switched on, and the interlock is closed (where applicable): the treatment mode can be selected by turning the keyswitch to the YAG or SLT position. Once the keyswitch is turned on the YAG or SLT position: the OPTIMIS FUSION laser system interface displays (after a start up automatic procedure) the welcome screen that corresponds to the selected mode (YAG or SLT).
Laser READY / STANDBY indicator	Once the treatment mode has been selected by turning the keyswitch to the YAG or SLT position: the system performs an autotests sequence and an initialisation procedure. Once completed, : the YAG or SLT treatment screen is displayed with the laser in STANDBY mode by default (GREEN LED is turned ON). The READY mode can now be selected by pressing the READY/STANDBY button (located on the LCD control module). Pressing on the READY/STANDBY button allows the user to switch the laser from STANDBY to READY. The green LED (STANDBY) turns off and the yellow LED (READY) switches ON. The system must thus be manually switched to READY status before the treatment laser can fire.
Safety remote interlock	**This is a user-installed feature that is highly recommended.** The doorswitch is a magnetically or mechanically triggered switch which closes the electrical circuit when the door is closed (the laser can fire) or which opens the electrical circuit when the door opens (to prevent the laser from firing). The user should provide the doorswitch. The unit is supplied with a bypass plug which allows the user to short-circuit the doorswitch security and thus use the laser without this security..
Safety shutter	Each laser and optical system module is equipped with a spring loaded safety shutter that keeps the treatment laser optical path blocked unless the system is manually switched to READY status: in this case, the safety shutter opens up ans stays open to allows the laser to fire.
Energy deviation warning	The system warns the operator if delivered energy deviates more than ±20% from the set value.
Protective housings	Protective housings on the laser and optical system, as well as the control and display systems, prevent the operator from being inadvertently exposed to laser emission or high voltage shock. The protective housings cannot be removed without tools and must only be opened by QUANTEL MEDICAL personnel or QUANTEL MEDICAL authorized personnel (local distributors)..
Location of controls	All the operator controls are located so that there is no risk to the operator of inadvertent laser exposure.
Ocular filters	The operator viewing port on the laser and optical system module contains a safety filter to limit the exposure level to the operator's eyes to below class 1 limits. Any standard slit lamp viewing accessory can be used with the OPTIMIS FUSION slit lamp without hazard.
FDA and IEC compliance labels	Locations and illustrations of the safety compliance labels are contained in the: OPTIMIS FUSION User Manual: II - Technical information Section 1: Labels
Electrical leakage protection	A medical grade power supply is built into the power supply console. This ensures that the complete instrument including the slit lamp power supply meets the requirements of IEC 601-1 for earth leakage protection.

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3.4 ADDITIONAL SAFETY FEATURES

FEATURE	DESCRIPTION
Memory test	When the OPTIMIS FUSION is first switched on, the system automatically checks the microprocessor memory. If a malfunction is detected an error code is displayed and the laser cannot be switched into READY status. Refer to: OPTIMIS FUSION User Manual: IV - Maintenance Section 10: Appendix – Error codes
Laser power-up test	After the memory test the system automatically performs a self-test program where it confirms the safe and correct operation of the modules. During this procedure the microprocessor fires a serie of test shots with the shutter closed. If this test routine is satisfied, the control module LCD screen displays the normal chosen treatment screen (YAG or SLT). The energy of the last test shot is displayed. If a malfunction is detected, an error code is displayed and the laser cannot fire. Refer to: OPTIMIS FUSION User Manual: IV - Maintenance Section 10: Appendix – Error codes
Treatment mode	At the end of the self-test routine and initialization process the control module automatically displays the selected treatment screen (YAG or SLT).
STANDBY status	At the end of the self-test routine and initialization process the control module automatically enters STANDBY status. In this state the aiming beam is activated and all the controls function allowing the user to adjust treatment parameters can be selected, however the treatment laser is disabled and the laser fire switch will not function. STANDBY status eliminates the risk of accidental treatment beam activation during patient set up. To enable the treatment laser to function, it is necessary to select READY so that the laser can fire. Note: There is a delay of two seconds after READY is selected before the laser can be fired.
Shutter monitor	A dual sensor shutter monitor checks the correct opening and closing of the shutter. In the event of a shutter malfunction, the laser fire switch is disabled and an error code is displayed in the LCD screen on the control module. Refer to: OPTIMIS FUSION User Manual: IV - Maintenance Section 10: Appendix – Error codes
Automatic test fire	Every time an energy setting is changed, either the energy selection or the number of pulses, an automatic test fire occurs. During this test fire, the shutter remains closed so there is no risk of exposing the patient or operator to laser radiation. After a test fire, the resultant energy is shown in the LCD screen on the control module.
Reset after power failure	When power is restored after a power failure, the system will restart and will be in STANDBY status.
Fault conditions	If the system detects a fault during operation, an error code is displayed on the control module LCD. Warnings may be cleared by the operator, while errors result in automatic system shut down. Refer to: OPTIMIS FUSION User Manual: IV - Maintenance Section 10: Appendix – Error codes

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3.5 LASER SAFETY AND NOHD

3.5.1 SAFETY EYEWEAR

Safety glasses or filters must protect the eyes from the emitted wavelength (spectral response) and should therefore have a high optical density at the emitted wavelength:

- ✓ Safety goggles or masks are required for anyone present at a treatment session.
- ✓ All terminals (including slit lamp accessories such as camera adaptors and co-observation tubes) must be equipped with filters that guarantee eye protection to the operator. Protection at an appropriate Optical Density (OD) must also be provided for the eye that is not directly viewing through the accessory.

WARNING: Appropriate safety glasses should be available before accessing the treatment room. Any treatment room window or opening should be protected.

WARNING: QUANTEL MEDICAL recommends the use of safety interlocks and warning lamps adapted to the treatment area.

WARNING: Any reflective instrument should be avoided. All room surfaces should be matt finished to prevent any potential laser light reflection.

WARNING: Avoid staring into the aiming beam unless under controlled conditions. However, damage to the retina from the aiming beam is most improbable.

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3.5.2 SAFETY EYEWEAR

3.5.2.1 OPTIMIS FUSION WITH 1064NM LASER SELECTION

The safety eyewear requirement is based on the Maximum Permissible Exposure (**MPE**), the Nominal Ocular Hazard Distance (**NOHD**) and the Optical Density (**OD**).

For additional information, please refer to the standard: **ANSI Z136.1-1993, ANSI Z136.3-1996**, or European Standard **EN 60825: 1992,** Appendix A.

The following formula has been used to calculate the NOHD for the worst case scenario for the 1064nm laser part of the OPTIMIS FUSION unit.

$$DNRO = \frac{\sqrt{Pf \,.\, (4 \,.\, Po \,/\, (3{,}14 \,.\, E_{EMP}))} - Ø}{\alpha}$$

Where:

Ø: beam waist diameter;

z: distance between the laser system and the beam waist;

a: full angle beam divergence;

Po: maximum laser power available;

Pf: profile correction factor;

E_{MPE}: Maximum Permissible Exposure, in power density units (power per unit area).

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

Parameters:

Ø	=	0.01 mm	
Po	=	$2.5\ 10^6$ W	**EMPE = 6.678 10^5 W/m²**
Pf	=	1	**NOHD = 7.82 m**
a	=	0.279 rad	

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

$$OD = -\,LOG\,(E_{MPE} \,/\, Fluence) = 3.16$$

Where Fluence = 1162.82 J/m² (taking into account the pupil diameter of 7 mm)

WARNING: For a maximum of security, the safety eyewear must have a protection class of:

L4 @ 1064nm (EN 207 Standard).

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3.5.2.2 OPTIMIS FUSION WITH 532NM LASER SELECTION

The safety eyewear requirement is based on the Maximum Permissible Exposure (**MPE**), the Nominal Ocular Hazard Distance (**NOHD**) and the Optical Density (**OD**).

For additional information, please refer to the standard: **ANSI Z136.1-1993, ANSI Z136.3-1996**, or European Standard **EN 60825: 1992,** Appendix A.

The following formula has been used to calculate the NOHD for the worst case scenario for the 532nm laser part of the OPTIMIS FUSION unit.

$$DNRO = \frac{\sqrt{Pf \,.\, (4 \,.\, Po \,/\, (3{,}14 \,.\, E_{EMP}))} - Ø}{\alpha}$$

Where: **Ø**: beam waist diameter;

z: distance between the laser system and the beam waist;

a: full angle beam divergence;

Po: maximum laser power available;

Pf: profile correction factor;

E_{MPE}: Maximum Permissible Exposure, in power density units (power per unit area).

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

Parameters:

Ø	=	0.4 mm	
Po	=	$5\ 10^5$ W	**EMPE = 1.56 10^6 W/m²**
Pf	=	1	**NOHD = 193 m**
a	=	0.0104 rad	

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

$$OD = -\,LOG\,(E_{MPE} \,/\, Fluence) = \mathbf{4.92}$$

Where Fluence = 1299.88 J/m² (taking into account the pupil diameter of 7 mm)

WARNING: For a maximum of security, the safety eyewear must have a protection class of:

L5 @ 532nm (EN 207 Standard).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.6 PRECAUTION TO TAKE CONCERNING WASTES AND ELIMINATION OF DEVICE AND ACCESSORIES

Product category: This product complies with the WEEE Directive (2012/19/UE) marking requirements. The FUSION is an electrical / electronic product and must not be discarded with domestic household waste

Do not dispose with domestic household wastes!

With reference to the equipment types in the WEEE Directive annex I,
this product is classed as category 8 among the "Medical devices (with the exception of all implanted and infected products)".
To dispose completely of the device and its accessories,
contact QUANTEL MEDICAL.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CONFIDENTIAL Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL

II – Technical information

Quantel medical

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DECEMBER 2013

2013 CE 0459

Directive 93/42/EEC

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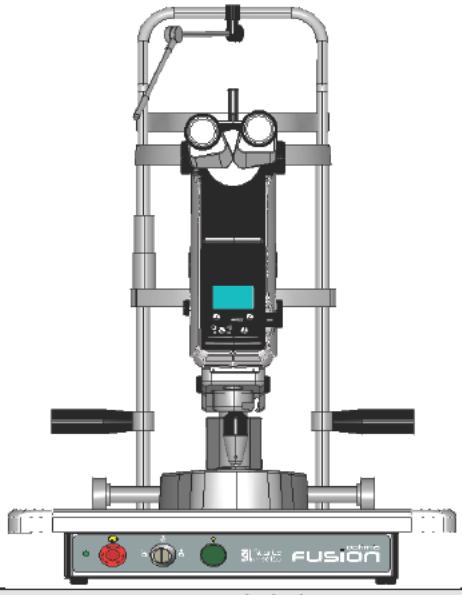
1 LABELS

1.1 FRONT VIEW



Réf.	Label	
	FRONT label: Situated on the front panel of the laser console.	
		"OFF" for a part of equipment. IEC 60417 - 5265
		Stand-by or preparatory state for a part of equipment. IEC 60417 - 5266
		EMERGENCY STOP label: Situated next to the red emergency stop button.
		LAMP GENERATOR BOOST label: Situated next to the green push button button.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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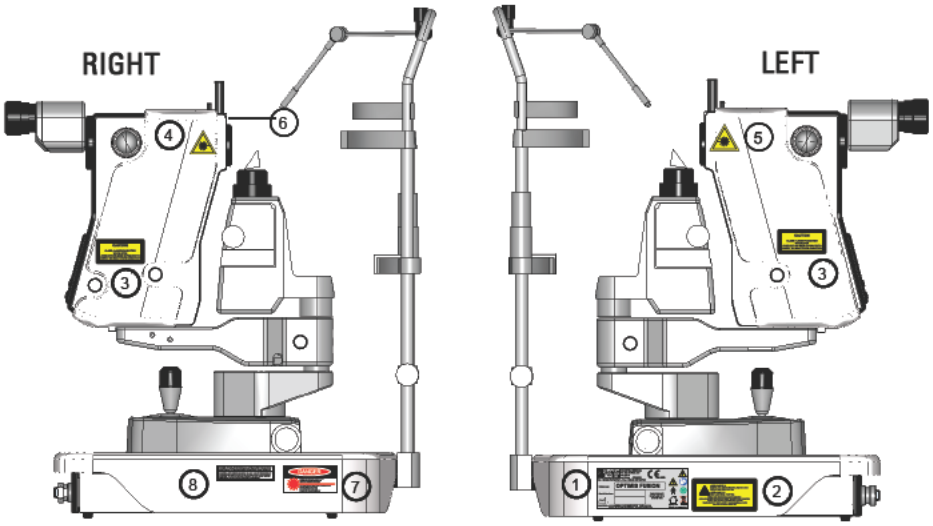
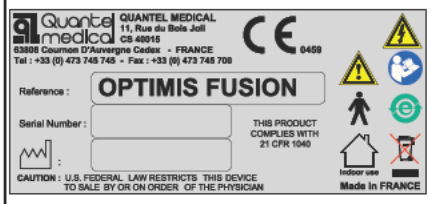
1.2 RIGHT / LEFT VIEWS



Réf.	Label	Description	
1		IDENTIFICATION LABEL: Contains the following information:	
			Protection against electrical shocks: the applied parts are classified as 'B Type". The accessible conductive parts are connected to ground. IEC 60417-5840
			IEC protection class: "Class I" - Main insulation. Accessible conductive parts are connected to ground.
			IP 20: Protection from solid substances (Diameter > 12,5mm).
			Refer to the instruction manual/ booklet. ISO 7010-M002
			For indoor use only. IEC 60417-5957
			Electrical/electronic equipment in accordance with the Directive 2012/19/UE (WEEE) Do not dispose with domestic household wastes. EN 50419
			GENERAL WARNING SIGN: ISO 7010-W001 General
			This sign specifies the manufacturing date indication. ISO 7000-2497
			HIGH VOLTAGE WARNING: High voltage on the connector indicated by this warning sign
			RoHs SIGN: Restriction of Hazardous Substances.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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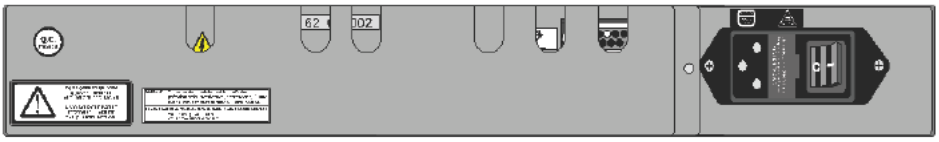
Réf.	Label	Description
2	LASER CLASS IV / 4 Nd:YAG Laser: 1064nm 30mJ Max. (3 pulses x 4ns) Nd:YAG Laser: 532nm 2mJ Max LASER CLASS II / 2 Diode Laser: 635nm, <1mW Max VISIBLE AND / OR INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT per IEC 60825-1:2007 + AC1:2008 Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50, dated June 24, 2007	LASER RADIATIONS WARNING LABEL: With treatment and aiming beam wavelengths and powers specifications.
3	CAUTION CLASS 4 LASER RADIATION WHEN OPEN AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION	INTERNAL RADIATION LABEL: Indicates existing laser radiations inside the apparatus.
4		RIGHT LASER OUTPUT LABEL: Laser radiations warning label: located next to the laser radiation output
5		LEFT LASER OUTPUT LABEL: Laser radiations warning label: located next to the laser radiation output
6	LASER APERTURE	LASER OUTPUT: Indicates that a laser beam is emitted from this output
7	DANGER LASER RADIATION WHEN OPEN Avoid eye or skin exposure to direct or scattered radiation Nd:Yag 1064nm 30mJ Max. (3 pulses 4 ns) Nd:Yag 532nm 2mJ Max. Diode 635 nm 1 mW Max. CLASS IV LASER PRODUCT	LASER RADIATIONS WARNING LABEL FOR US: With treatment and aiming beam wavelengths and powers specifications.
8	CAUTION : FEDERAL US LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR AN OPTOMETRIST LICENCED BY THE LAW OF THE STATE IN WHICH HE PRACTISES TO USE OR ORDER THE USE OF THIS DEVICE DANGER : EXPLOSION HAZARD. DO NOT USE IN PRESENCE OF FLAMMABLE ANESTETICS OR IN OXYGEN-RICH ATMOSPHERE. CAUTION : ELECTRIC SHOCK HAZARD. DO NOT OPEN. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.	FEDERAL US LAW LABEL

1.3 BACK PANEL VIEWS

1.3.1 BACK PANEL LABELS WITH REAR COVER PLATE



1 2

1	TO BE OPENED ONLY BY QUANTEL MEDICAL AUTHORIZED TECHNICIAN A N'OUVRIR QUE PAR LE PERSONNEL HABILITE PAR QUANTEL MEDICAL	SERVICING LABEL : Indicates that only authorized technician can open the unit.
2	WARNING : The system should only be used by qualified medical professionals who have thoroughly been trained by Quantel Medical or by distributors qualified by Quantel Medical. THE SYSTEM USER MANUAL IS AVAILABLE IN ELECTRONIC FORMAT. E-mail: contact@quantel-medical.fr Web site: www.quantel-medical.com	This label specifies that the User Manual is available in electronic format: COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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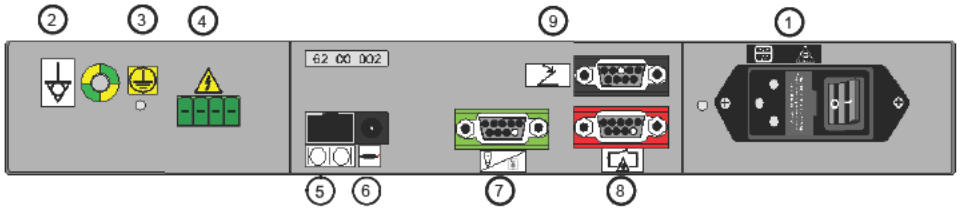
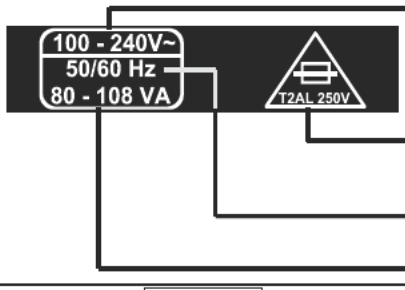
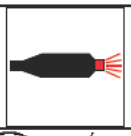
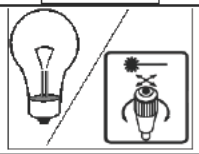
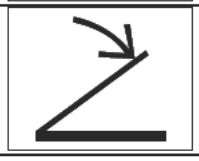
1.3.2 BACK PANEL LABELS (WITHOUT REAR COVER PLATE)



Réf.	Label	Description
1		**FUSES AND VOLTAGES LABEL:** With power supply specifications
2		**EQUIPOTENTIALITY CONNECTOR LABEL:** Indicates the equipotentiality point connection used to connect interfaces which require a common earth.
3		**GROUND LABEL:** Indicates the ground connection
4		**HIGH VOLTAGE WARNING LABEL:** Situated next to the connector on which a high voltage could be present
5		**COMMUNICATION PORT LABEL:** Indicates the communication port between laser console and laser head.
6		**FIXATION LED LABEL:** Indicates the power supply connector of the fixation LED.
7		**LAMP / JOYSTICK PORT LABEL:** Indicates the generator lamp supplying and joystick control port.
8		**DOORSWITCH CONNECTOR LABEL:** Indicates connector of the doorswitch.
9		**FOOTSWITCH CONNECTOR LABEL:** Indicates the connector of the footswitch.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 TECHNICAL SPECIFICATIONS

2.1 SYSTEM SPECIFICATIONS

PARAMETER	DETAILS
Table dimensions :	
Table height :	Max: 38 in (960 mm) Min: 28 in (708 mm)
Table width :	Standard stand: 24 in (605 mm) Wheelchair accessible stand: 31 in (790 mm)
Table depth :	17 in (435 mm)
Top of chin rest :	Max: 57 in (1440 mm) Min: 47 in (1190 mm)
Weight	133 lb (60kg) unpacked 180 lb (84 kg) packed
Laser control system	Microprocessor and programmable logic arrays
Cooling	Air convection

2.2 CLASSIFICATION

Protective class	I (Device connected to ground)
Type	B (Protection against electrical shocks)
Protection degree	IP20 (Protection from solid substances: Ø>12,5mm)
Operation	Continuous with short-time loading
Applied part	Chinrest

2.3 YAG TREATMENT LASER SPECIFICATIONS

PARAMETER	DETAILS
Laser class	Class IV (4)
Laser source	Q-Switched Nd: YAG photodisruptor laser
Wavelength	1064 nanometers (nm)
Energy settings	0.3 mJ to at least 10 mJ continuously variable
Maximum energy	30 mJ at triple pulse setting
Pulse duration	4 nanoseconds +4/-0 ns
Pulse setting	1, 2 or 3 pulses per shot ; pulse separation of 20 microseconds ± 20%
Repeat mode (max)	2.0 Hz single pulse
Treatment spot size	10 microns in air ($1/e^2$) 8 microns FWHM
Beam divergence	16 degrees +0°/ -2° full cone angle
Laser safety filters	Total filtering OD 5@ 1064 nm
Nominal Ocular Hazard Distance (NOHD)	25.6 Feets (7.8 meters)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2.4 SLT TREATMENT LASER SPECIFICATIONS

PARAMETER	DETAILS
Laser class	Class IV (4)
Laser source	Q-Switched frequency doubled Nd : YAG laser
Wavelength	532 nanometers (nm)
Energy settings	0.3 mJ to at 2 mJ continuously variable
Pulse duration	4 nanoseconds +4/-0 ns
Pulse setting	1 pulse per shot
Maximum repetition rate (manual)	2.5 Hz ± 20%
Treatment spot size	400 microns ± 10%
Beam divergence	< 3 degrees
Laser safety filters	Total filtering OD 5@ 532 nm
Nominal Ocular Hazard Distance (NOHD)	633 Feets (193 meters)

2.5 AIMING LASERS SPECIFICATIONS

PARAMETER	DETAILS
Type	Semi conductor laser diode
Wavelength	635 ±10 nanometers (nm)
Laser class	Class II (2)
Operation	CW (continuous wave)
Power	< 1 mW, continuously variable

2.6 SLIT LAMP DELIVERY SYSTEM

PARAMETER	DETAILS
Type	Galilean stereoscopic microscope with converging optics
Objective lens	1,25 x
Eyepiece lens	12.5 x, dioptre adjustable in range ± 5 D
Total magnification	16 x (12.5 x eyepiece)
Magnification changer	3 positions
Interpupillary distance adjustment	1.9 to 3.1 in (48,5 - 80 mm)
Working distance	3.1 in (80 mm)
Focal length	3.7 in (94 mm)
Chin rest	Adjustable, vertical travel 3.7 in (70 mm)

PARAMETER	DETAILS
Slit lamp source	
Slit width	0 to ½ in (0 to 14 mm)
Illumination view field	0.2 mm, 5.5 mm, 9 mm, 14 mm, continuously variable
Slit rotation	180 degrees
Illumination angle	180 degrees at horizontal plane (90 degrees for right/left)
Filters	Cobalt-blue,
Bulb	LED, 6 V, 20 W pre-centered bulb
Cross slide table	
Vertical adjustment of binocular arm	1.2 in (30 mm), by rotation of joystick
Fine horizontal movement	By tilting joystick lever, fine movement of 7 mm.
Coarse horizontal movement	By moving the slit lamp base, coarse movement of 4.5 in (115 mm) longitudinal and 4.3 in (110 mm) lateral travel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2.7 POWER SUPPLIES

2.7.1 LASER POWER SUPPLY

PARAMETERS	DETAILS
Supply voltage	100–120 VAC or 220–240 VAC
Supply Frequency	50/60 Hz
Supply power	80VA@100V-108VA@240V
Main fuses	2 A, 250 V
Internal fuses	Internal fuses are not user-accessible. Contact your QUANTEL MEDICAL Distributor if these fuses need replacing
Schok protection	Class 1, type B (IEC 601-1 6.8.1) *Type B equipment provides protection against electric shock by limiting the leakage current and by the provision of a protective earth connection.*

2.7.2 STAND COLUMN (OPTION) POWER SUPPLY

PARAMETERS	DETAILS
Supply voltage	110 VAC or 230 VAC
Supply Frequency	50/60 Hz
Supply power	400VA@110V - 800VA@230V
Main fuses	6.3 A, 250 V
Schok protection	Class 1, type B (IEC 601-1 6.8.1) *Type B equipment provides protection against electric shock by limiting the leakage current and by the provision of a protective earth connection.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2.8 STANDARDS COMPLIANCE

The OPTIMIS FUSION laser complies with the following regulatory and technical standards:

Standards	Descriptions
21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser Notice No.50, dated July 26, 2001.	Performance standard for light-emitting products.
IEC 60 601-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.
IEC 60 601-1-1	Medical electrical equipment - Part 1: General requirements for safety - 1: Collateral standard: safety requirements for medical electrical systems.
IEC 60 601-1-2	Medical electrical equipment - Part 1-2:General requirements for safety - Collateral standard: electromagnetic compatibility - requirements and tests.
IEC 60 601-1-4	Medical electrical equipment - Part 1: General requirements for safety 4. Collateral standard: programmable electrical medical systems.
IEC 60 601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: usability.
IEC 60 601-2-22	Medical electrical equipment - Part 2-22: particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60 529	Degrees of protection provided by enclosure (IP code).
IEC 60 825-1	Safety of laser products - Part 1: equipment classification and requirements.
IEC 62 304	Medical device software - Software life-cycle processes (IEC 62A/474/CDV).
ISO 14 971	Medical devices - Application of risk management to medical devices (ISO/DIS 14971).
93/42/EEC	European Medical Device directive.
IEC 62 366	Medical devices - Application of usability engineering to medical devices

WARNING: All other devices used in conjunction with the OPTIMIS FUSION using power supplies other than those provided for it must be conformed to the IEC standard 60 601-1 (electric compatibility).

WARNING: All other devices used in the same room as the OPTIMIS FUSION must be conformed to the IEC standard 60 601-1-2 (electromagnetic compatibility).

2.9 ENVIRONMENTAL CONDITIONS

The temperature of the room where the device is operated must be within the following range:

10°C (50°F) < **T°** < **35°C** (95°F)

The relative humidity without condensation must not exceed:

90%

The laser storage and shipping temperature must be within the following range:

-20°C (-4°F) < **T°** < **70°C** (158°F)

Maximum operating altitude: 2000m (about 6560 ft).

NOTE: This device is latex free.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 OPTIMIS FUSION EMC DATA AND GUIDELINES

WARNING: Medical electrical equipment needs special precautions regarding EMC. The following EMC guidelines must be observed during installation and commissioning of the OPTIMIS FUSION.

WARNING: Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The OPTIMIS FUSION is intended for use in the electromagnetic environment specified below. The operator of the OPTIMIS FUSION has to make sure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - Guidance**
RF emission acc. to EN 55011	Group 1	The OPTIMIS FUSION uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to impair nearby electronic equipment.
RF emissions acc. to EN 55011	Class B	The OPTIMIS FUSION is suitable in all establishments including those in living areas and those directly connected to the public low voltage power supply network that also supplies buildings used for living.
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions acc. to IEC 61000-3-3	Complies	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 404

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Guidance and manufacturer declaration – electromagnetic immunity			
The OPTIMIS FUSION is intended for use in the electromagnetic environment specified below. The operator of the OPTIMIS FUSION has to ensure that it is used in such an environment.			
CEI 60601 test level	CEI 60601 test level	CEI 60601 test level	Electromagnetic environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the OPTIMIS FUSION, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF disturbances according to IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	10 V	$d = 0{,}35\sqrt{P}$
Radiated RF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	$d = 1{,}2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ for 800 MHz to 2,5 GHz
			Where *P* is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

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

[a] Field strength from fixed transmitters, such as base stations for radio (Cellular / cordless) 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 device OPTIMIS FUSION is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorientation or relocating the OPTIMIS FUSION. In case unusual performance is witnessed, additional measures may be required such as change of orientation or location of the OPTIMIS FUSION.

[b] Field strength should be less than 10 V/m in the range between 150 kHz and 80 MHz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Recommended separation distances between portable and mobile RF communications equipment and the OPTIMIS FUSION

The OPTIMIS FUSION is intended for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The OPTIMIS FUSION user can help prevent electromagnetic interference by maintaining a minimal distance between portable and mobile RF communications equipment (transmitters) and the OPTIMIS FUSION as recommended below, according to the maximum output power of the communications equipment.

Maximum transmitter power output (W)	Separation distance according to the transmitter's frequency (m)		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5GHz $d = 2{,}3\sqrt{P}$
0,01	0,035	0.12	0.23
0,1	0.11	0.38	0.73
1	0.35	1.2	2.3
10	1.1	3.8	7.3
100	3.5	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: Between 80 MHz and 800 MHz, separation distance for the highest 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 406

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Guidance and manufacturer declaration – electromagnetic immunity			
The OPTIMIS FUSION is intended for use in the electromagnetic environment specified below. The operator of the OPTIMIS FUSION has to ensure that it is used in such an environment.			
Immunity Test	CEI 60601 test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients/ burst acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment.
Surge acc. to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment.
Voltage dips, short-term interruptions and voltage variations on power supply input lines acc. to 61000-4-11	<5% during 0,5 period 40% during 5 periods 70% during 25 periods <5% during 5 s	<5% during 0,5 period 40% during 5 periods 70% during 25 periods <5% during 5 s	The quality of the supply voltage should correspond to one characteristic for a typical commercial or hospital environment. If the user of the OPTIMIS FUSION requires a continuous function of the appliance also during interruptions of the power supply, it is recommended to supply the OPTIMIS FUSION out of an uninterruptible power supply or a battery
Power frequency (50/60Hz) magnetic fields acc. to IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic for commercial or hospital environments

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4 INSTALLATION

WARNING: No modification of this equipment is allowed.

4.1 INSTALLATION REQUIREMENTS

4.1.1 OPERATING ROOM

The apparatus should be positioned in such way that the laser beam emerging from the terminal (Slit lamp for example) can under no circumstances be directed toward an opening (door, window) or any kind of light reflecting materials. The instrument must be installed in a dust free room with no wall-to-wall carpet or rug. When not operating, the system should be covered to protect the optical lens from dust.

4.1.2 ELECTRICAL REQUITEMENTS

The OPTIMIS FUSION is equipped with a standard power plug at the end of its line cord. The user is responsible for the installation of an adequate power outlet prior to the laser system installation.

Only connect the laser system to a grounded single phase power socket:

- ✓ Voltage: 100 to 240 Vac.
- ✓ Frequency: 50 / 60 Hz.
- ✓ Minimum current: 2 A.

WARNING: Protection earth impedance: Ensure that the socket is properly earthed.

WARNING: Do not connect the laser power plug (3 pin adaptor) on an ungrounded power socket (2-pin).

WARNING: Never connect the laser to a multiple-plug outlet or power strip.

WARNING: Use two different power outlets:

- ✓ One for the OPTIMIS FUSION laser.
- ✓ Another one for the table.

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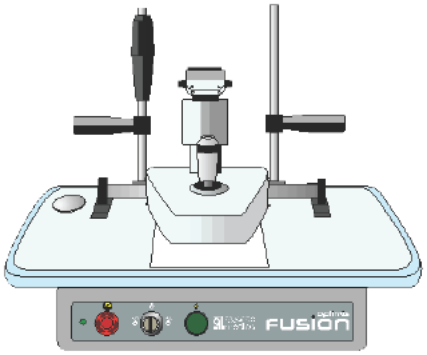
4.2 ASSEMBLING THE LASER

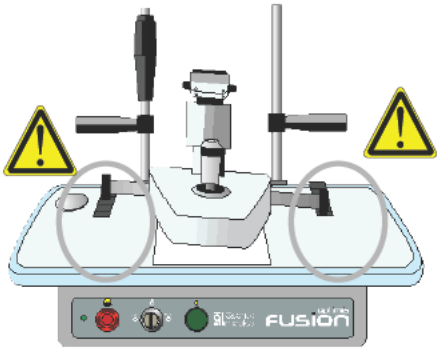
4.2.1 SLIT LAMP POSITIONING

Good position :

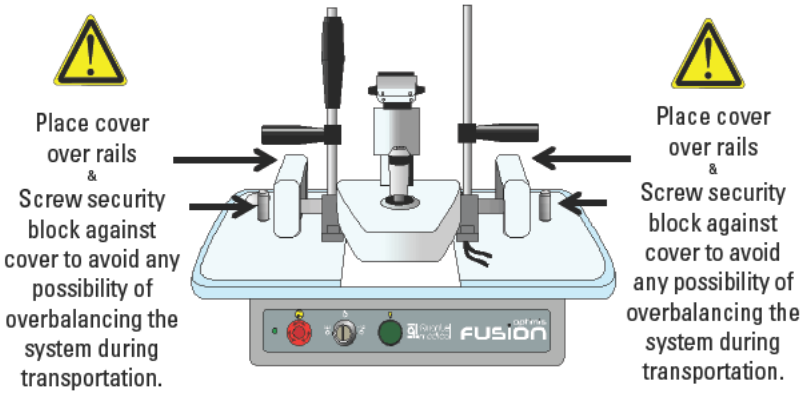


Place the slit lamp on the table.
Position the gears correctly on the rack of the table.

Bad position :



In case the wheels positioning is not identical on one side compared to the other: no displacement is possible.



Place both wheels covers by slipping them under the rails guides of the mobile table.

WARNING: In case the covers are not correctly mounted: the laser assembly may be unstable!

4.2.2 LASER MOUNTING ON THE STAND COLUMN (OPTION)

Stand column labeling

Place the assembly laser on the table.
Refer to the installation notice of the stand column for the assembly.

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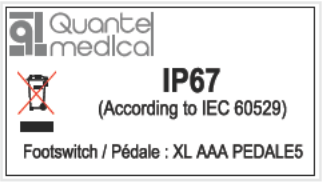
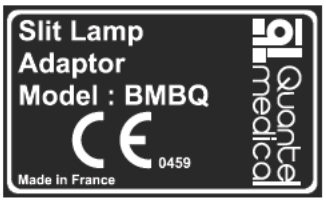
4.2.3 FOOTSWITCH (OPTION)

Footswitch labeling



4.2.4 SLIT LAMP ADAPTOR (OPTION)



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4.3 MOVING THE OPTIMIS FUSION EQUIPEMENT

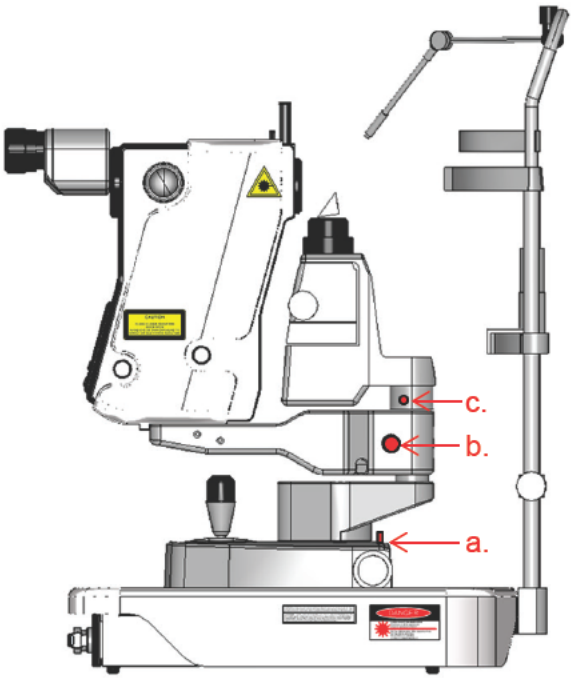
In case there is a need to move the equipement (from a room to an other one for example), follow the procedure below:

1. Select or check the unit is in "**STANDBY**" mode; then, switch off the laser with the key switch; and finally switch off the laser with the main switch.
   Refer to:
   OPTIMIS FUSION user manual: III – Using the laser system
   Section 6: Shutting down the laser system
2. Unplug the power supply cable from the wall socket; Unplug the footswitch cable (when available);
3. Block all laser moving parts as follows:

   a. Turn the button (marked as a.) clockwise to block the main laser assembly from moving left / right / front / back;

   b. Turn the button (marked as b.) clockwise to block the binocular laser head from moving left / right;

   c. Turn the button (marked as c.) clockwise to block the slit lamp movement;



4. Make sure the gear covers are correctly positioned as explained:
   Section 4.2.1: Slit lamp positioning

5. Then, the laser can be moved with caution taking care of the inclination.

NOTE: The mechanical stability is in accordance with the IEC 60601-1 (3rd ed.):
The equipment does not overbalanced when inclined by 10°;

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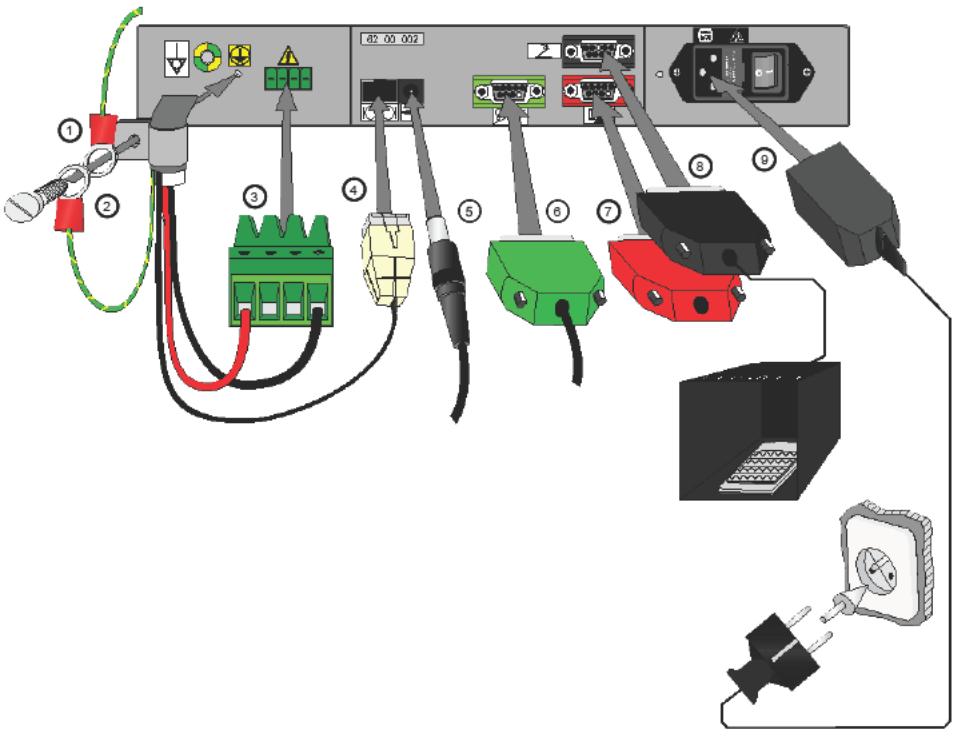
4.4 ASSEMBLING THE LASER

4.4.1 SLIT LAMP / CONSOLE CONNECTIONS

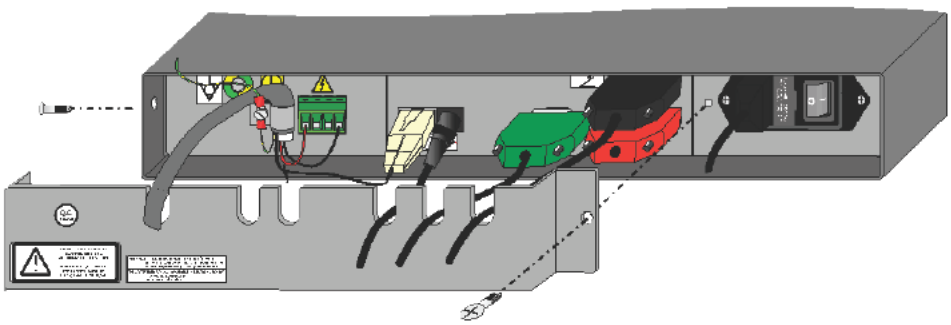
Connect the following cables and remote:

- Chin rest ground cable ①;
- Ground cable ②;
- High voltage cable ③;
- RJ45 cable ④;
- Fixation LED cable ⑤;
- Joystick / lamp cable ⑥;
- Remote ⑦;
- Footswitch cable ⑧;
- Power supply cable ⑨.



CAUTION: The ground cable of the chinrest must be fixed on the chinrest ground connector of the console with a screw.

4.4.2 REAR COVER POSITIONING



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4.5 DOOR SWITCH AND EXERNAL RED LAMP INSTALLATION

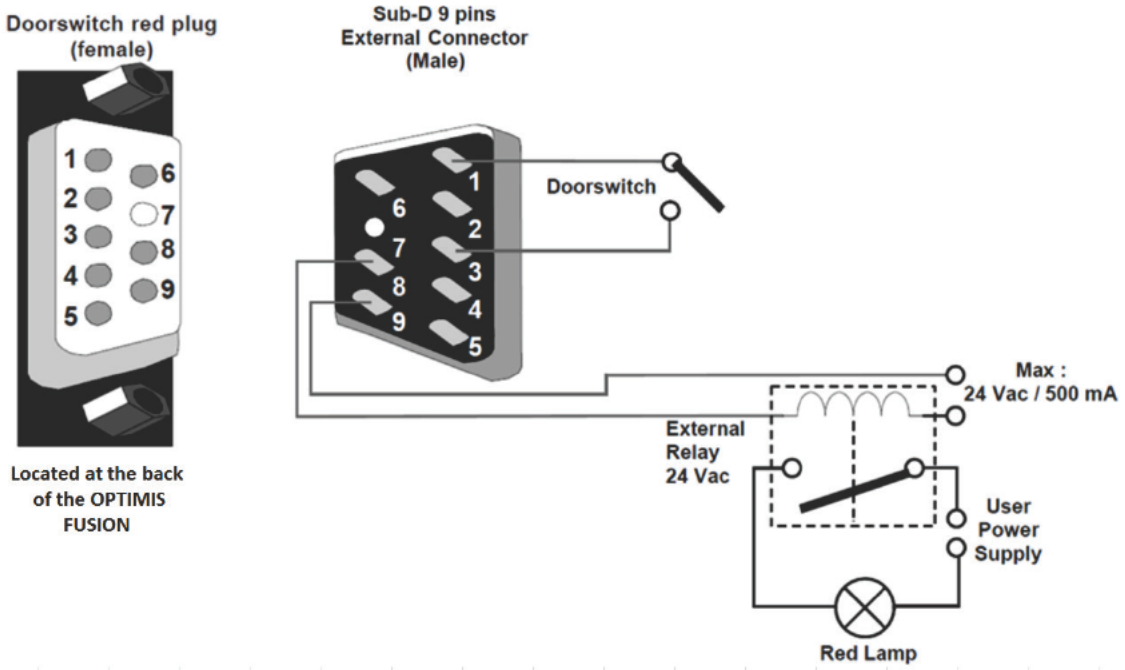
4.5.1 DOOR SWITCH

The user has to provide the door switch. The door switch may either be magnetically or mechanically triggered: it will close the electrical circuit when the door is closed and open the circuit when the door is opened. The switch (and its wiring) should be chosen to be supplied with: 24 Vac and 500 mA.

WARNING
The transformer used to deliver the 24 Vac from the 110 or 220 Vac must be TBTS (Very Low Safety Voltage); in compliance with the EN 61 558-2-6 standard.

This door switch must terminate by a SUB - D 9-pin male standard connector, commonly used for serial port computer connections. One of the contact wire must be connected to pin 1 and the other one to pin 3. Polarity is not important.

NOTE
In case this door switch option is not used, a red remote that shorts pins 1 and 3 and allows the device to go to "ready" mode can be connected instead.



Doorswitch installation figure.

To connect the doorswitch to the laser system: simply remove the red remote from the Vitra rear panel and replace it with the door switch circuit connector. Make sure it is firmly connected in order to avoid any unexpected system safety-interlock.

4.5.2 RED LAMP

The red lamp command is controlled via an external relay (as shown in Section 4.5.1: Door switch / "Doorswitch installation figure"). Connect the red lamp external relay to the same SUB - D 9-pin male standard connector: one of the contact wire must be connected to pin 8 and the other one to pin 9. Contact between Pin 8 and 9 is established when the laser is operational (it is controlled by an other relay, this one, internal to the laser system).
The external relay coil must be supplied with a maximum of 24Vac / 500mA. The user has to provide the red lamp power supply circuit.

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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL

III – USING the LASER SYSTEM

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DECEMBER 2013

2013 CE 0459

Directive 93/42/EEC

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1 SAFETY CHECKS BEFORE OPERATING THE LASER SYSTEM

Carry out the following checks before using the OPTIMIS FUSION laser system:

WARNINGS

- Make sure that all persons attending the laser treatment session (except for the user and patient) wear adequate laser safety glasses. Refer to the OPTIMIS FUSION user manual:
  OPTIMIS FUSION User Manual: I - Regulatory & safety information
  Section 3.5: Laser safety & NOHD
- Check that the laser emergency stop button is in the released position as explained in
  Section 3.1.1: Emergency stop button)
- Check that the safety interlock, when installed, is connected and the interlock switch is closed.

2 PREPARING THE OPTIMIS FUSION FOR TREATMENT

WARNINGS

Before treatment, check:

- The eyepieces are well adjusted to compensate for variance in individual user's vision (vision should be clear at focal plane).
- The aiming beam spot is clear and well defined with the illuminated slit at focal distance.
  If this not the case, call QUANTEL MEDICAL Service Department or your local distributor.
- The laser system should be used on test targets before using it on patients.
- Ensure the chinrest and head rest are thoroughly cleaned before positioning the patient behind the slit lamp table.

  Seat the patient behind the slit lamp table: ask him/her to place his/her chin on the chinrest and his/her forehead firmly against the headrest. Adjust the height of the chairs and slit lamp table (dedicated switch) to enable both ophthalmologist and patient to be at ease for the examination.

3 STARTING UP THE SYSTEM

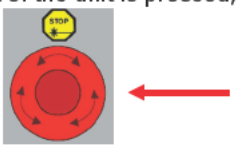
3.1 POWER CONTROL KEYS

The OPTIMIS FUSION laser unit has 3 power supply control keys that can successively be turned on to activate the system:

- Emergency stop button on the front panel (3.1.1.)
- Main switch on the back panel (3.1.2.)
- Key switch on the front panel (3.1.3)

3.1.1 EMERGENCY STOP BUTTON

When the emergency red STOP button at the front of the unit is pressed, all laser functions stop instantly:



Emergency stop button

The following procedure should be followed to restart the laser system after an "emergency" stop:

1) Press and turn the emergency button clockwise to release it.
2) Turn the key switch to the "OFF" position.
3) Restart the system as usual by turning the key to the "ON" position.

CAUTION

This emergency switch should **ONLY** be used in case of an emergency.

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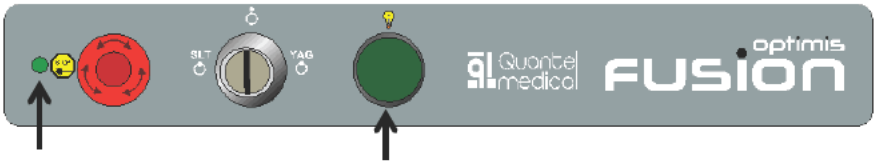
3.1.2 MAIN SWITCH

The main switch allows the user to supply power to the OPTIMIS FUSION system when it is turned on ("I" position):

The green power supply LED on the front panel lights on and the slit lamp can be turned on pressing on the green push button:



Green power supply LED

Slit lamp illumination button

NOTE

As long as the keyswitch is not turned on to the YAG, or SLT position: the OPTIMIS FUSION laser system can be used as a simple observation slit lamp microscope. Indeed, the slit lamp illumination and fixation leds are operating. The illumination generator can then be rotated to the proper angle to provide the desired effect and better visualization.

3.1.3 KEYSWITCH

The keyswitch allows the user to start the laser in YAG or SLT mode or stop the laser:

: ON position	When turning the key to the left ("ON" position for SLT): the laser starts, the system boots up and the LCD screen lights up to display the startup screen for laser treatment in SLT mode. When turning the key to the right ("ON" position for YAG): the laser starts, the system boots up and the LCD screen lights up to display the startup screen for laser treatment in YAG mode.
: OFF position	When turning the key to the "OFF" position: the laser stops. The screen shuts down.

NOTE

The key cannot be removed when the key is on the "ON" position.

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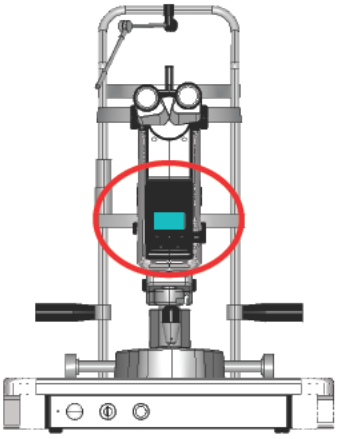
3.2 OPTIMIS FUSION LASER INTERFACE

The OPTIMIS FUSION Central Processing Unit controls the interface between the user and the laser system via the following information :

- Slit lamp inputs /outputs:
  Power switch; Emergency stop, Key switch, Aiming beam power knob, Energy selection knob, Joystick, Optional footswitch, Remote connector for door switch, Laser detection connector (for OPTIMIS FUSION combination to an other delivery system accessory) and buzzer.
- Control module inputs / outputs:
  The OPTIMIS FUSION laser control module is integrated inside the laser main frame, underneath the eyepieces:



It includes:

- A Liquid Control Display (LCD) screen, used to display in real time, the current state of the laser;
- Keypad with buttons to select parameters for treatment such as Burst mode, Focus offset, Reset counter and Laser status (STANDBY / READY). To warn the operator of a new setting: an audible sound is emitted each time a button is pressed.

WARNING

In case of a problem with a critical component: an error message is displayed on the LCD screen: either by a warning message or an error code. To ensure safety: the laser automatically goes back to STANDBY mode. For more information about error codes and management: refer to the OPTIMIS FUSION User Manual:

OPTIMIS FUSION User Manual: IV – Maintenance
Section 10: Appendix – Error codes

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3.3 OPTIMIS FUSION START UP AUTOMATIC PROCEDURE

Once the keywitch is turned on to the YAG or SLT position: the corresponding OPTIMIS FUSION welcome screen with software version and functioning mode (YAG or SLT) information is displayed on the laser interface screen.

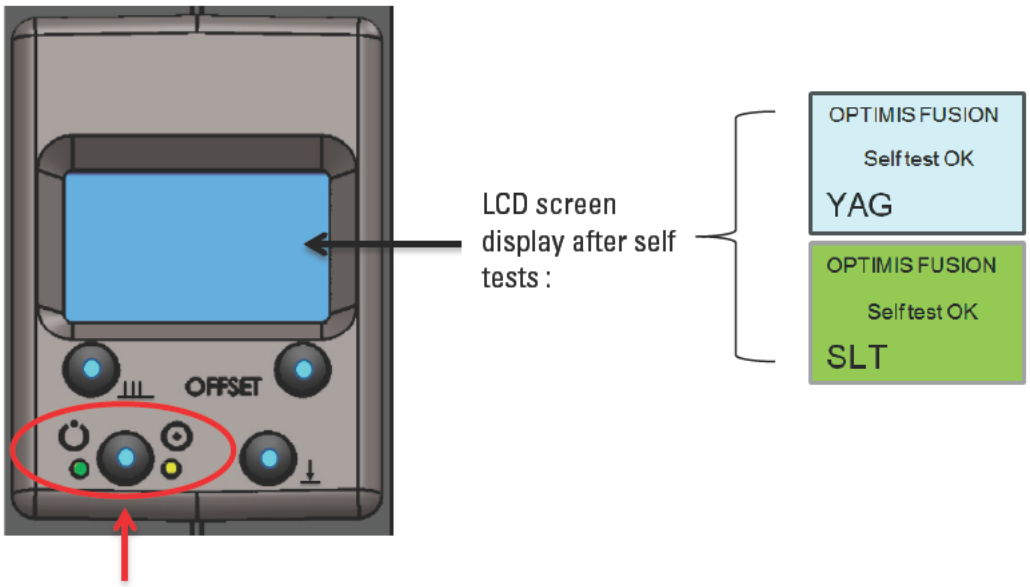
NOTE

In YAG mode, the screen color background is blue, whereas in SLT mode, it is green as shown below:

YAG Wecome screen

SLT Welcome screen

Then, the system performs a sequence of selftests and an initialization procedure. When this is finished: the YAG or SLT treatement screen is displayed with the STANDBY green led turned on by default:



STANDBY status: the STANDBY green led is turned on by default.

The slit lamp is activated and the red laser aiming beam(s) of the selected YAG or SLT laser system is turned on.

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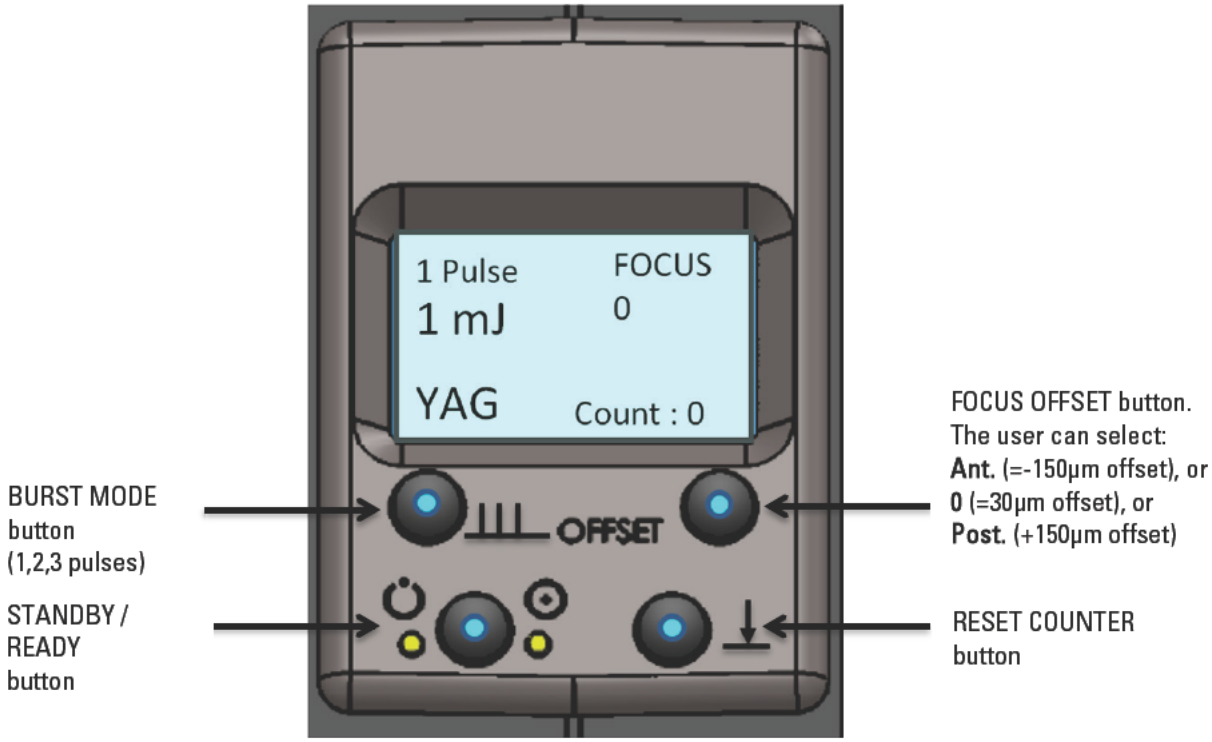
4 USING THE OPTIMIS FUSION YAG LASER FEATURES

Turn the key to the "YAG" position and wait until the self-test and initialization procedure is finished to finally display the OPTIMIS FUSION YAG treatment screen on the control module LCD screen (blue color).

4.1 AVAILABLE SETTINGS ON THE LCD CONTROL MODULE WITH YAG MODE



YAG treatement screen

In YAG mode: all four buttons (illuminated in blue) are active and can be adjusted.

NOTE
By default :

- The energy is adjusted to 1mJ
- The focus is set to 0 (=30µm offset)
- Burst mode is set to 1 pulse
- Counter count is rest to 0

4.1.1 NUMBER OF PULSES SELECTION (BURST MODE BUTTON)

Press the BURST MODE button on the control module LCD screen as many times as required to increase the number of pulses from one pulse to two pulses and then 3 pulses.

NOTE
Pressing one more time on the BURST MODE button allows the user to return to one pulse per burst.

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4.1.2 FOCUS OFFSET SELECTION (FOCUS OFFEST BUTTON)

Press the FOCUS OFFSET button on the control module LCD screen as many times as required to set the focus offset to "**0**" (=30µm offset), then to "**Post.**" (+150µm offset), then to "**Ant.**" (=-150µm offset).

WARNING

When the offset "**Ant.**" (=-150µm offset) is selected: the background LCD screen is changing color and 3 long beeps can be heard to warn the user that the focus is in the anterior chamber.

NOTE

Pressing one more time on the FOCUS OFFSET button allows the user to return to "**0**" (=30µm offset).

4.1.3 RESET COUNTER BUTTON

The OPTIMIS FUSION software displays on the control module LCD screen how many shots have been performed since the laser counter reset.
To reset the counter to zero: press on the RESET COUNTER button.

4.1.4 STANDBY / READY STATUS BUTTON

Press on the STANDBY / READY button to switch the laser from STANDBY to READY mode. The green LED switches OFF and the yellow LED switches ON:

Press the "**Stand-by / Ready**" state selection button

Laser state	LED State
STANDBY mode (Default Mode)	
READY Mode	

In READY mode, the OPTIMIS FUSION laser is ready to shoot.

NOTE

- If the user presses the STANDBY/READY button again: the OPTIMIS FUSION laser goes back to STANDBY mode.
- The OPTIMIS FUSION laser goes back to STANDBY mode after 3 minutes of inactivity (a long beep is emitted). When this happens: the YAG mode parameters return to their default value (Energy=1mJ, Focus offset=0 and Single pulse)

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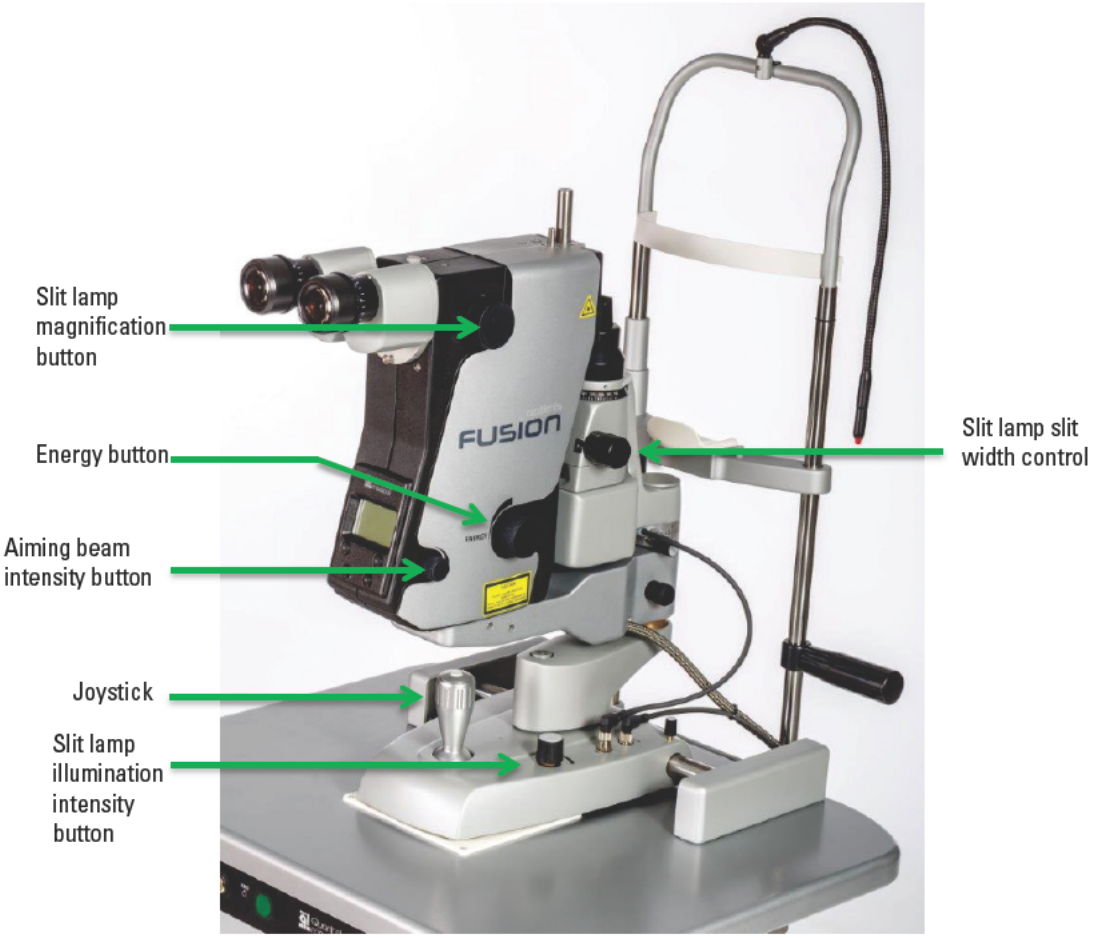
4.2 SLIT LAMP SETTINGS



4.2.1 ENERGY SELECTION BUTTON

Use the Energy knob on each side of the laser head to increase or decrease the energy.

NOTE

A different beep sound is emitted when the user increases the energy, compared as to when it is decreased.

- In single pulse burst mode: the energy can be adjusted from 0.3mJ to 10mJ:

Energy button	Energy range / mJ	By steps of (Incrementation) / mJ
Aiming beam button	From 0,3 to 3	0,1
	From 3 to 5	0,2
	From 5 to 10	0,5

In double pulses burst mode: the energy can be adjusted from 0.6mJ to 18mJ maximum.
In triple pulses burst mode: the energy can be adjusted from 0.9mJ to 25,5mJ maximum.

As a consequence, the OPTIMIS FUSION laser automatically performs a test fire and the energy value is displayed on the control module LCD screen. The displayed energy value is the cumulative energy for all pulses within a burst.

WARNING

- It is advised to adjust the energy as low as possible for treatment.

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4.2.2 AIMING BEAM BUTTON

The laser use low power visible red laser beams for aiming purposes. The diode laser lightbeam splits in two aiming beams focusing in one at focal plane. It is possible to adjust the aiming beam intensity by turning the aiming beam intensity button left to lower the intensity; or right to increase it.

WARNINGS

- The aiming beams focus is found at the distance where the two red spots merge into a single spot. The OPTIMIS FUSION software will display an error message and will prevent the system firing if one or both of the aiming beam(s) has (have) deviated from the initial position (unfocused aiming beam).
- Use the lowest practicable aiming beam intensity for treatment to protect the patient from possible retinal damage.

NOTE

The aiming beam is suppressed during shooting and for 0.1 second after each pulse for better examination of the burn.

4.2.3 JOYSTICK BUTTON OR OPTIONAL FOOTSWITCH

Each time the joystick button or the optional footswitch is pressed, with the laser satus is in READY mode, the laser fires:

- A beep sound is emitted
- The counter is increased by the number of emitted pulses
- The delivered energy is displayed

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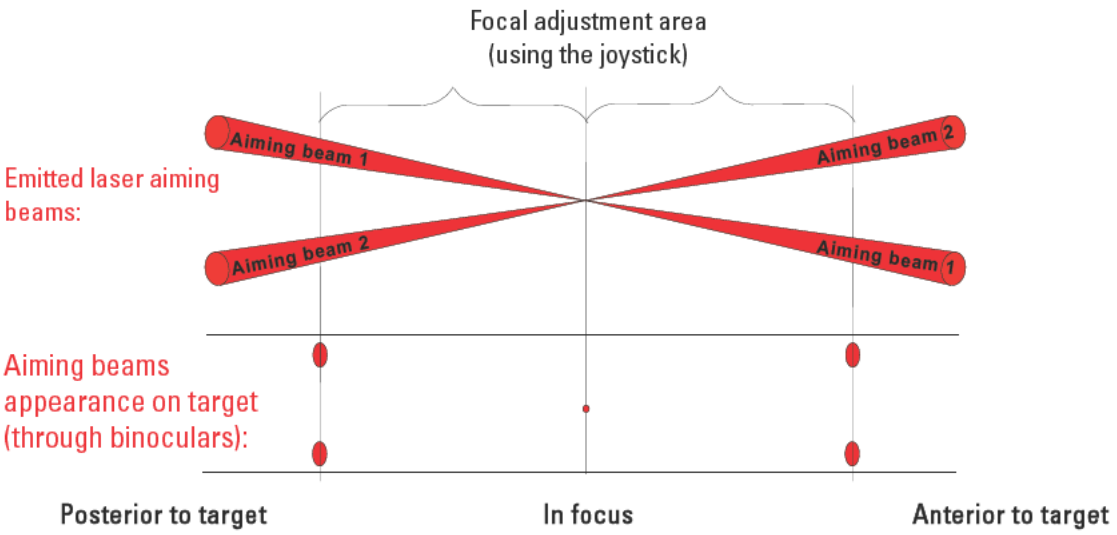
4.3 OPTIMIS FUSION YAG LASER TREATMENT PROCEDURE

1. Pre-conditions:
- The laser system has to be turned on as explained:
  Section 3.1: Power control keys
- The key switch should be turned on the "YAG" position until the "YAG" treatment screen is displayed (blue background).
- The patient is correctly positioned.

2. Use the minimum slit lamp illumination intensity that still provides good visualization. Rotate the slit lamp generator to a position where the illumination allows the best eye depth perception.

3. Adjust the aiming beam intensity to the minimum setting but where it still provides a good spot contrast on the target background as explained:
   Section 4.2.2: Aiming beam button

4. Move the microscope towards the target until the target can be clearly seen (at focal distance). Fine tune the focus with care using the joystick in order to bring the two red aiming beam dots into coincidence:



5. Set the energy as explained:
   Section 4.2.1: Energy selection button
   In general and for safety purposes, the energy for treatment should be set as low as possible, unless experience dictates otherwise.

6. Set the number of pulses and focus offset as explained:
   Section 4.1.1: Number of pulses selection (BURST MODE button)
   Section 4.1.2: Focus offset selection (FOCUS OFFSET button)
   A posterior focus offset greater than **"0"** (=30µm / min offset position) will reduce the risk of pitting the implanted lens. As the treatment laser energy is increased: it is recommended to select an even higher offset. Indeed, for higher energy settings, the plasma elongates anteriorly along the laser beam axis, which is increasing the risk of pitting the implanted lens;

7. Before firing the laser, make sure:
- The laser parameters are correctly selected and laser is accurately targeted on eye tissue to be treated.
- Press the STANDBY/READY button to put the laser in "READY" mode as explained:
  Section 4.1.4: STANDBY / READY STATUS button
  The orange "READY" led turns ON (whereas the green "STANDBY" led switches OFF): the laser is ready to fire.

8. Before starting the treatment procedure: press the RESET COUNTER button as explained:
   Section 4.1.3: RESET COUNTER button

9. Press on the laser fire button: using the joystick button or the optional footswitch if connected.
   Every time the laser fires: a beep can be heard.

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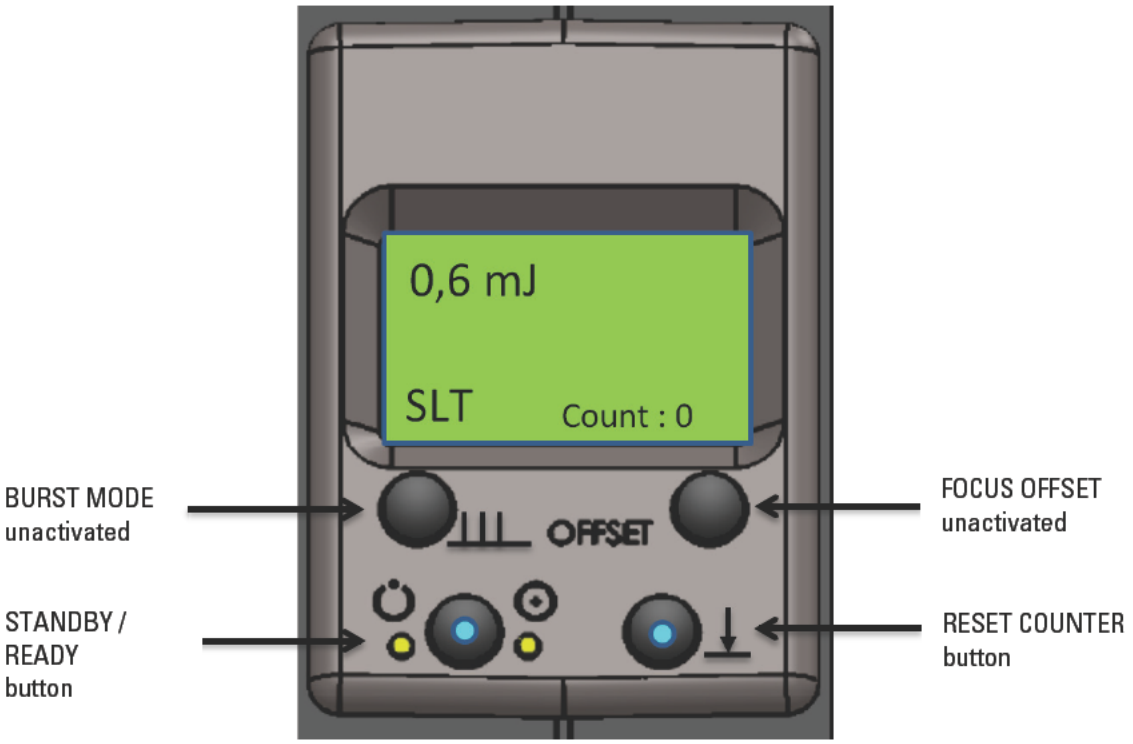
WARNING
The laser system should be used on test targets before using it on patients.

NOTE
Nd:YAG contact lens may be recommended for some treatments for eye stabilization and to minimize the risk of impact on non targetted sites such as cornea and IOL. Since contact lenses alter the energy density at the treatement site: the energy setting should be re-adjusted;

5 USING THE OPTIMIS FUSION SLT LASER FEATURES

Turn the key to the "SLT" position and wait until the self-test and initialization procedure is finished to finally display the OPTIMIS FUSION SLT treatment screen on the control module LCD screen (green color).

5.1 AVAILABLE SETTINGS ON THE CONTROL MODULE WITH SLT MODE



SLT treatement screen

In SLT mode: only two buttons (illuminated in blue) are active and can be adjusted: STANDBY/READY button and RESET COUNTER button. The other two buttons are unactivated.

NOTE
By default :
- The energy is adjusted to 0,6mJ
- Counter count is rest to 0

The **RESET COUNTER button** and **STANDBY/READY button** functions are explained:
- Section 4.1.3: RESET COUNTER button
- Section 4.1.4: STANDBY / READY STATUS button

NOTE
- The OPTIMIS FUSION laser goes back to STANDBY mode after 3 minutes of inactivity (a long beep is emitted). When this happens: the SLT mode Energy parameter returns to its default value (Energy=0,6mJ)

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5.2 SLIT LAMP SETTINGS

5.2.1 ENERGY SELECTION BUTTON

Use the Energy knob on each side of the laser head to increase or decrease the energy as explained:
Section 4.2.1: ENERGY SELECTION BUTTON

The energy can be adjusted from 0.3mJ to 2mJ by steps of (increment) 0,1mJ:

As a consequence, the OPTIMIS FUSION laser automatically performs a test fire and the energy value is displayed on the control module LCD screen.

5.2.2 AIMING BEAM BUTTON

Use the AIMING BEAM knob to increase or decrease the energy as explained:
Section 4.2.2: AIMING BEAM BUTTON

The laser uses a visible red diode laser beam for aiming purposes. This low power diode laser light beam is parfocal with the slit lamp and coaxial to the SLT treatment laser beam.

WARNINGS
Use the lowest practicable aiming beam intensity for treatment to protect the patient from possible retinal damage.

NOTE
The aiming beam is suppressed during shooting and for 0.1 second after each pulse for better examination of the burn.

5.2.3 JOYSTICK BUTTON OR OPTIONAL FOOTSWITCH

Each time the joystick button or the optional footswitch is pressed, with the laser satus is in READY mode, the laser fires:

- A beep sound is emitted
- The counter is increased by the number of emitted pulses
- The delivered energy is displayed

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5.3 OPTIMIS FUSION SLT LASER TREATMENT PROCEDURE

1. Pre-conditions:
- The laser system should be turned on as explained:
  Section 3.1: Power control keys
- The key switch should be turned on the "SLT" position until the "SLT" treatment screen is displayed (green background).
- The patient is correctly positioned.

2. Use the minimum slit lamp illumination intensity that still provides good visualization. Rotate the slit lamp generator to a position where the illumination allows the best eye depth perception.

3. Adjust the aiming beam intensity to the minimum setting but where it still provides a good spot contrast on the target background as explained:
   Section 5.2.2: Aiming beam button

4. Move the microscope towards the target until the target can be clearly seen (at focal distance).

5. Set the energy to the required value for treatment as explained:
   Section 5.2.1: Energy selection button

6. Before firing the laser, make sure:
- The laser parameters are correctly selected and laser is accurately targeted on eye tissue to be treated.
- Press the STANDBY/READY button to put the laser in "READY" mode as explained:
  Section 5.1: Available settings on the control module with SLT mode
  The green "READY" led turns ON (whereas the orange "STANDBY" led switches OFF).

7. Before starting the treatment procedure: press the RESET COUNTER button as explained:
   Section 5.1: Available settings on the control module with SLT mode
8. Press on the laser fire button: using the joystick button or the optional footswitch if connected.
   The OPTIMIS FUSION SLT laser delivers a single pulse at each footswitch depression. The orange "READY" status LED turns OFF (and green "STANDBY" LED turns ON) for a short time period while the laser recharges. When the orange "READY" LED turns back ON: the laser is ready to fire again.

WARNING
The laser system should be used on test targets before using it on patients.

NOTE
A standard gonioscopy lens with magnifying optics is used to visualize the angle during treatment.

6 SHUTTING DOWN THE LASER SYSTEM

At the end of the treatment:
- Select or check the unit is in **"STANDBY"** mode.
- Switch off the laser with the key switch and remove the key to prevent unauthorized use of the system (Section 3.1.3: Key switch).
- Switch off the laser with the main switch (Section 3.1.2: Main switch).

NOTE
At the end of the day, place a dust cover on all devices (laser, adaptors and slit lamp).

WARNING
The red emergency stop button (on the front panel) must only be used in case of an emergency situation.

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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL
IV – MAINTENANCE

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1 PREVENTIVE MAINTENANCE

Contact your QUANTEL MEDICAL or your local distributor at least every six months to carry out a preventive maintenance visit to confirm the correct function of your system.

At each six-monthly visit QUANTEL MEDICAL or your local distributor will clean the optics, check the safety filter coatings, and check general performance, alignment and calibration of the system.

At least once a year QUANTEL MEDICAL or your local distributor will fully re-calibrate the system and check ground resistance and earth leakage current (in accordance with IEC 60601-1).

2 CARE AND MAINTENANCE OF THE OPTIMIS FUSION LASER SYSTEM

2.1 CLEANING AND DISINFECTION FOR PATIENT AREAS

The use of the OPTIMIS FUSION involves only brief skin contact with the patient, but attention should be given to the possibility of cross-contamination between patients via the patient contact areas of the system. These are the chin rest, headrest and steadying handles.

2.1.1 RESPONSIBILITIES FOR CLEANING AND DISINFECTION

The health care facility where the instrument is to be used is responsible for:

1) Determining the level of cleaning and disinfection of patient contact areas required between patients.
2) Appropriate education and training for staff required to carry out cleaning and disinfection.
3) Ensuring that routine cleaning and disinfection methods used in the facility are compatible with the instrument.
4) Routine cleaning of the entire system.

2.1.2 CLEANING AND DISIFECTION OF PATIENT AREAS

Although cleaning and disinfection procedures and standards within different health care facilities may vary considerably, the following points are provided as general guidelines:

1) Thorough cleaning of all patient contact areas is recommended for each procedure.
2) Disposable chinrest papers can also be attached to the chinrest area and changed between patients.
3) Manual cleaning can be carried out by wiping all contact areas using a suitable liquid cleaning agent which is non-corrosive, non-toxic and low in residue.

2.1.3 CLEANING THE GONIOSCOPY CONTACT LENSES

The contact lenses for use with the OPTIMIS FUSION have a special low-reflectivity coating bonded to the lens, and they must therefore be handled carefully.
As soon as a lens is removed from the patient's eye, thoroughly rinse it in cold or warm water to remove salts, mucous and gonioprism solution. Wash in warm water with a few drops of clear dishwashing liquid, then rinse with cool water and blot dry. Dry completely before storing in the case.
To effectively disinfect the lens, soak in a solution of sodium hypochlorite 1,2° chl. for a recommended exposure time of 30 minutes. Rinse thoroughly with cool water and blot dry. Dry completely before storing in the case.

To sterilize, use ethylene oxide gas with aeration not to exceed 125°F (52°C), following the sterilizer manufacturer's recommendation. Remove the lens from the case before sterilizing.

CAUTION:
Do not boil or autoclave a lens. Do not use alcohol, hydrogen peroxide or acetone on a lens, as this will damage it and render it unusable.

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2.2 MAINTENANCE OF THE OPTIMIS FUSION LASER SYSTEM

The QUANTEL MEDICAL OPTIMIS FUSION laser system has been designed to provide trouble-free operation with a minimum of down time. As a result very little user maintenance is required.

There are four routine maintenance tasks that are explained in the next sections:

- External cleaning of the OPTIMIS FUSION system — see Section 2.2.1
- Cleaning the optics — see Section 2.2.2
- Checking YAG aiming beam accuracy — see Section 2.2.3
- Checking SLT aiming beam accuracy — see Section 2.2.4

2.2.1 EXTERNAL CLEANING OF THE OPTIMIS FUSION SYSTEM

WARNING
Ensure that the power is switched off and disconnect AC power before cleaning external surfaces.
All surfaces should be thoroughly dried after cleaning.

Keep the laser system external surfaces clean at any time. Only use a damp cloth and mild detergents for cleaning. Do not use abrasive cleaners such as solvent or alcohol. Make sure the laser system (& slit lamp) is covered with a dust cover when not in use.

2.2.2 CLEANING THE OPTICS

WARNING
Ensure that the power is switched off and disconnect AC power before cleaning the optics.

The laser head objective lens and the oculars must be kept free of dust, fingerprints and other contamination or performance will be compromised. Periodically inspect and clean these optics.

Required equipment:

- Lint free optical tissues (available from a photographic store)
- Cotton swabs
- Pure or AR grade ethanol or methanol

Method:

1) Remove dust from the optics with an appropriate lens brush.
2) Moisten the optical tissue or Q-tip in the solvent and gently wipe it across the optical surfaces in linear strokes. Use a very light pressure to avoid misaligning the mirrors. Do not wipe the mirrors more than one or two times because excess wiping will only redistribute the dirt over the optical surface and cause scratches.
3) Use one tissue or one Q-tip per wipe, then discard and use a fresh one for the next wipe.

CAUTION
In case any scratching is visible do not use the laser system and call QUANTEL MEDICAL or your local distributor.

CAUTION
Never use dry swabs or tissues to clean an optical surface, as this may damage the surface.

In case of any problem when cleaning the optics, contact QUANTEL MEDICAL or your local distributor.

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2.2.3 CHECKING YAG AIMING BEAM ACCURACY

WARNING
Wearing appropriate safety glasses is required for all persons present when the laser is in use.
Ensure there is no refelective surfce behind the target.

The aiming and treatment beam (1064nm) coincidence should be checked on a regular basis: the following procedure should be carried out at least every three months or as considered necessary by the user.

Required material:
Photographic paper (Kodak linagraph direct printer)
Alignment target / focusing bar

Checking procedure:

1. Attach a piece of photographic paper on the alignment target / focusing bar *(See Figure 1)*

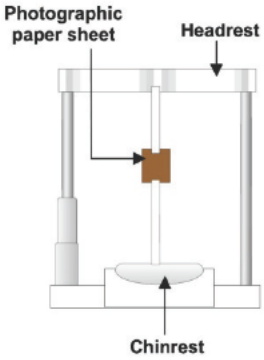

Figure 1: Piece of photographic paper in position

2. Switch ON the main switch located at the back of the OPTIMIS FUSION unit. The slit lamp is automatically turned "ON" and illuminates the target paper.
3. Turn the keyswitch to the YAG position and wait for the OPTIMIS FUSION treatment screen to be displayed (the laser is in STANDBY status by default).
4. Swing the illumination tower on the side so that it does not obstruct the aiming beams.
5. Adjust the eyepieces to accommodate the user's eyes.
6. View the target through the binocular (with the magnification changer set to x16).
7. Adjust the slit lamp position so that the aiming beams converge to form one spot on the paper attached to the target. The aiming spot should be centered in the field of view and in the center of the illumination aperture. Lock the slit lamp in this position *(See Figure 2)*

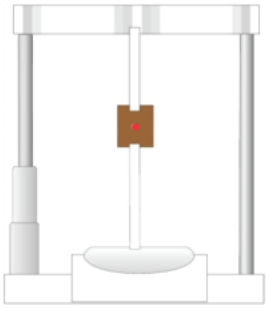

Figure 2: Aiming beams in focus

WARNING
If the aiming beam is not centered: do not use the système and contact QUANTEL MEDICAL Service Department or your local distributor.

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8. Adjust:
   - Burst mode to 1 pulse
   - Focus offset to 0 (30µm offset)
   - Low energy
9. Press the STANDBY/READY button on the control module to select READY status and fire the laser on the target paper.
10. Inspect the burn mark through the binoculars to check that the aiming beam spot coincides with the burn mark *(See Figure 3)*

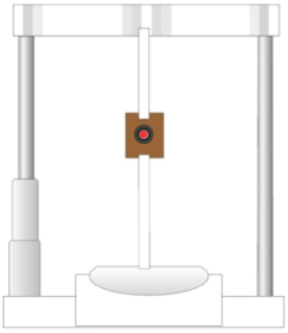

Figure 3: Burn mark after firing the treatment laser

NOTE

Depending of the photographic type of paper used for the checkup: the burn mark might not clearly be distinguished with minimum power in use. In this case, power may have to be increased step by step until coincidence can clearly be checked.

WARNING

In case the aiming beam/treatment beams do not coincide: do not use the system on patients. Contact QUANTEL MEDICAL Service Department or your local distributor.

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2.2.4 CHECKING SLT AIMING BEAM ACCURACY

WARNING
Wearing appropriate safety glasses is required for all persons present when the laser is in use.
Ensure there is no refelective surfce behind the target.

The aiming and treatment beam (532nm) coincidence should be checked on a regular basis: the following procedure should be carried out at least every three months or as considered necessary by the user.

Required material:
Photographic paper (Kodak linagraph direct printer)
Alignment target / focusing bar

Checking procedure:

1. Attach a piece of photographic paper on the alignment target / focusing bar *(See Figure 1 in the above section 2.2.3)*
2. Switch ON the main switch located at the back of the OPTIMIS FUSION unit. The slit lamp is automatically turned "ON" and illuminates the target paper.
3. Turn the keyswitch to the SLT position and wait for the OPTIMIS FUSION treatment screen to be displayed (the laser is in STANDBY status by default).
4. Adjust the eyepieces to accommodate the user's eyes.
5. View the target through the binocular (with the magnification changer set to x16).
6. Adjust the slit lamp position so that the aiming beam forms only one clear, well defined spot on the paper attached to the target (focal distance) and lock the slit lamp in this position. The aiming spot should be centered in the field of view and in the center of the illumination aperture. Lock the slit lamp in this position *(See Figure 2 in the above section 2.2.3)*

WARNING
If the aiming beam is not centered: do not use the système and contact QUANTEL MEDICAL Service Department or your local distributor.

7. Adjust:
   - Low energy
8. Press the STANDBY/READY button on the control module to select READY status and fire the laser on the target paper.
9. Inspect the burn mark through the binoculars to check that the aiming beam spot coincides with the burn mark *(See Figure 3 in the above section 2.2.3)*

NOTE
Depending of the photographic type of paper used for the checkup: the burn mark might not clearly be distinguished with minimum power in use. In this case, power may have to be increased step by step until coincidence can clearly be checked.

WARNING
In case the aiming beam/treatment beams do not coincide: do not use the system on patients. Contact QUANTEL MEDICAL Service Department or your local distributor.

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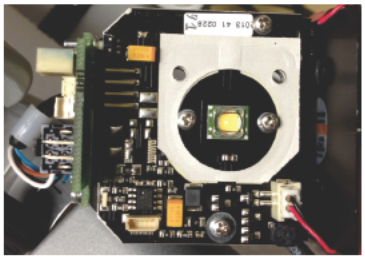
2.3 SLIT LAMP ILLUMINATION LED REPLACEMENT

The slit lamp illumination LED module is accessible by removing two screws located under the illumination tower:



In case the slit lamp illumination LED fails: call QUANTEL MEDICAL Service Department or your local distributor to replace it.

2.4 FUSES REPLACEMENT

AVERTISSEMENT
When replacing a fuse and before removing it from its housing: turn the power off and disconnect the power cord from the wall outlet.

The IEC mains power sockets on the base of the stand column and on the laser console contain a dual fuse holder. To check fuses, remove the power cable from the IEC socket and pull out the fuse holder slide.

If a fuse blows, replace it with an other one that has the exact same specifications.

Fuse specifications:	- Laser console:	T2AL 250V
	- Stand column:	T6.3AL 250V

NOTE:
The internal power supply is protected against overload, so fuses should rarely need replacement. A blown fuse is likely to indicate an internal fault.

3 ERROR CODES

The system microprocessor monitors all important system components. If an irregularity is found during operation the control module is disabled and displays an error code. In this condition the footswitch and joystick laser fire switch are disabled and the unit defaults to the STANDBY status.
If this occurs, turn the unit off, wait a few seconds and turn the unit back on. If the self-test does not find any errors on the second start up, the condition was temporary and the unit can be used. If an error code continues to be displayed, refer to section 10: Appendix for the list of error codes.

Then, consult QUANTEL MEDICAL Service Department or your local distributor.

NOTE:
The system will not accept operator commands until the fault is rectified.

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4 TROUBLESHOOTING

In case of any problem during installation or operation of the system, the following troubleshooting guide may be of assistance:

Table 4–1: Troubleshooting table

Fault	Probable cause	Action required
The system does not start up when the main switch located on the back panel of the unit is turned ON (the green power supply LED located on the front panel does not turn ON)	No mains power.	Check that the local supply is functioning and switched on. Check with another appliance to be certain.
	Power lead not connected.	Check the power lead is correclty connected to the local supply / the mains supply socket.
	Blown fuse.	Check that the fuses are not blown. Disconnect the power cord from the local power supply before removing the fuses.
The LCD screen does not start up (no display) when the main switch located on the back panel of the unit is turned ON. However, the green power supply LED located on the front panel is turned ON.	Emergency Laser Stop switch in OFF position.	Check that the Emergency Laser Stop switch is in the ON position. To be certain, rotate the switch a quarter of a turn clockwise to release it.
	Keyswitch is in the OFF position.	Turn the keyswitch to the SLT or YAG position.
YAG: Warning Remote SLT: Warning Remote	Safety interlock activated.	- Close theater door, or - Check that the "red" remote (removable bypass connector) is connected at the back of the unit. This remote allows to shortcut pin 1 and 3 when the door switch option is not used.
No user controls on the module.	Faulty control module buttons.	Call QUANTEL MEDICAL Service Departement or your local distributor.
YAG: Warning Footswitch SLT: Warning Footswitch	The Footswitch (optional) is pressed whereas the laser is in STANDBY status.	Select READY status before using the Footswitch (optional).
YAG: Warning Joystck SLT: Warning Joystick	The Joystick is pressed whereas the laser is in STANDBY status.	Select READY status before using the Joystick.
YAG: Move Light Tower	Treatment beam path obstructed by the illumination tower.	Rotate the illumination tower out of the treatment beam path.
Low aiming beam intensity.	The aiming beam intensity is not properly adjusted to match the examination conditions.	Adjust the aiming beam intensity.
Low aiming beam intensity when set at maximum intensity.	The optics on slit lamp may be dirty.	Clean the slit lamp external optic, or call QUANTEL MEDICAL Service Departement or your local distributor if the problem continues.

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No slit lamp illumination.	Error : E12	Slit lamp error: check that the green remote (joystick / lamp cable) is properly connected at the back of the unit. Call QUANTEL MEDICAL Service Departement or your local distributor if the problem continues.
	No power.	Check power is ON.
	Slit closed.	Open slit.
	Fuse blown.	Replace fuse.
	LED lamp faulty	In case the LED connector is not properly connected: the green LED (surrounded in red above) turns to red. Make sure both POWER IN and LED cables are properly connected. Call QUANTEL MEDICAL Service Departement or your local distributor is problem continues..
Microscope vision is not clear at focus.	Eyepieces incorrectly fitted into binoculars.	Insert eyepieces fully into binoculars.
	LED lamp faulty.	Call QUANTEL MEDICAL Service Departement or your local distributor to replace LED lamp.
Illumination is blurred.	LED lamp faulty.	Call QUANTEL MEDICAL Service Departement or your local distributor to replace LED lamp.
	Illumination tower prism is dirty.	Clean prism;

5 VERIFICATION AND CALIBRATION PROCEDURE

The calibration must be checked at least annually. This is normally carried out as part of a service visit.

NOTE:
Due to the complexity of the instrument, calibration procedures must only be carried out by a trained and properly qualified QUANTEL MEDICAL trained personal.

NOTE:
Any meter used to calibrate the laser energy must be traceable to N.I.S.T (US National Institute of Standards and Technology) or an equivalent standard in another country.

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6 TRANSPORTATION

CAUTION:
The system should be handled with care to preserve its accuracy and to ensure a trouble-free operation. QUANTEL MEDICAL cannot be held responsible for any damage that could result from mishandling the equipement during use, storage or transportation.

6.1 MOVING THE EQUIPEMENT

The OPTIMIS FUSION is a tough and durable instrument, but it contains complex optical and mechanical systems that may be damaged if the unit is mishandled or subjected to excessive shock or vibration. Ensure that the temperature requirement for storage and transportation is respected. If the OPTIMIS FUSION needs to be moved: put the instrument back in its original packaging to protect it from any possible transportation shock damage.

6.2 DECONTAMINATION OF RETURNED EQUIPEMENT

To comply with United States postal and transportation law, equipment shipped to QUANTEL MEDICAL' US offices for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for use as a "Hospital Disinfectant".

7 PRODUCT LIFETIME

The OPTIMIS FUSION has a design life of at least seven years from the manufacturing date. The system is of modular construction so that correct operation can be maintained via parts replacement. If the system needs to be discarded, it can be done as described in the next section.

8 PRODUCT DISPOSAL

The OPTIMIS FUSION contains no toxic or radioactive elements that would adversely affect a dismantler or the area of disposal. However, the product is largely non- biodegradable and recycling of the base materials is recommended. Contact local authorities to determine the correct method for disposal.

The following list indicates the composition of the major elements of the OPTIMIS FUSION to assist recycling.

Table 8–1: Component materials

Base materials	Component parts
Steel	Power supply console chassis Laser module body Slit lamp cross-slide and bearings Chassis top plate Chin rest posts and pillars
Copper	Wiring
Aluminum	Laser head casting Optics module bodies Slit lamp knobs and components
Wood	Table
Plastic	Slit lamp base body Chin rest and headband Joystick skid plate Insulation in wiring, terminals, transformers, electrical components and front panel
Glass	Optics within laser and optics bench Optics within slit lamp

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9 WARRANTY INFORMATION

For specific and detailed warranty information for this instrument, please refer to general terms and conditions and / or distribution contract.

10 APPENDIX – ERROR CODES

Table A–1: Error codes

Display	Error code	Meaning
Error : E1	E01	High voltage problem.
Error : E2	E02	Shutter detector error .
Error : E3	E03	Energy P>+20%
Error : E4	E04	Energy P<-50%
Error : E5	E05	YAG/SLT detection error
Error : E6	E06	Energy control YAG position detector error
Error : E7	E07	Energy control SLT position detector error
Error : E8	E08	Energymeter heating
Error : E9	E09	SHG1 error
Error : E10	E10	SHG2 error
Error : E11	E11	Aiming beam focusing error
Error : E12	E12	Slit lamp error
Error : E13	E13	Laser detection
Error : E14	E14	Not calibrated

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Table A–2: Warning messages

Display	Warning	Meaning
SLT <20% YAG <20%	-<20%	Energy -20%<P<-50%
SLT Warning Joystick YAG Warning Joystick	Joystick	The Joystick is pressed whereas the laser is in STANDBY status.
YAG Move Light Tower	Move Light Tower	Slit lamp interlock : The illumination tower is in front of the aiming beam.
YAG Warning Remote SLT Warning Remote	Warning Remote	Safety interlock activated.
SLT Warning Footswitch YAG Warning Footswitch	Footswitch (optional)	The Footswitch (optional) is pressed whereas the laser is in STANDBY satus.

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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL
V - CLINICAL INFORMATION

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DECEMBER 2013

2013 CE 0459

Directive 93/42/EEC

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The following sections refer to treatment procedures. They are intended as a guide only and are not intended to be a complete and thorough procedure. They are not meant to replace the judgment of a trained ophthalmic surgeon.

WARNING: QUANTEL MEDICAL accepts no responsibility for negligent medical practices or for any event that results from the improper use of this equipment.

1 YAG TREATMENT LASER — THEORY OF CLINICAL USE

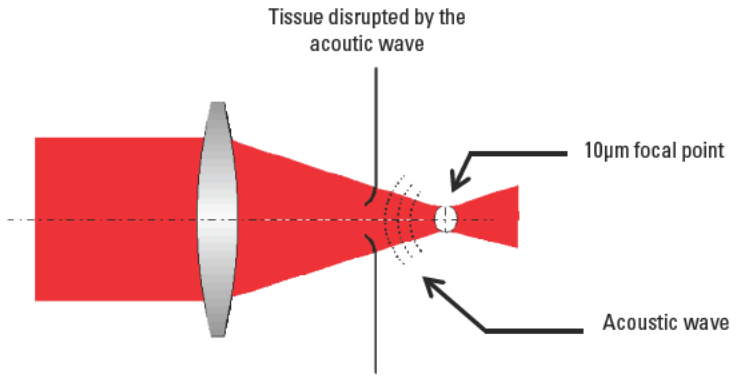
The **OPTIMIS FUSION mode** YAG treatment laser is intended to be used for dissection of the posterior capsule of the eye (posterior capsulotomy), dissection of the pupillary membrane of the eye (posterior membranectomy), as well as other surgical procedures such as iridotomy (opening a hole in the iris).

Like all Nd:YAG ophthalmic laser surgery, there are risks involved and use of the laser may be contraindicated for patients with certain pre-existing ocular pathologies. Objective assessment of candidate patients for this procedure must be done in light of the risks.

1.1 YAG (YTTRIUM ALUMINIUM GARNET) LASER SYSTEM THEORY

This ophthalmic YAG laser system is capable of producing short, individual pulses of focused infrared light with a wavelength of 1064nm. These pulses may be accurately positioned on the posterior capsule with the aid of a slit lamp microscope and a "twin dot" aiming system. The energy contained within a single short pulse is concentrated by focusing on a very small spot size (10 microns) so that a small ionization site (plasma) formation occurs at the focal point. This creates an acoustic wave that radiates from the focal point and disrupts nearby tissues. This is known as the "photo disruptive effect".

Once formed, the plasma absorbs and scatters further incident light. This shields the underlying structures from damage. Further, the beam divergence after the focal point protects the retina from damage that could otherwise occur by the absorption of concentrated Nd:YAG treatment energy.



Plasma formation

As the treatment energy is increased, the size of the plasma formed also increases, thus causing a larger, stronger acoustic wave. When energy is increased, it is necessary to focus the treatment beam further from (posterior to) the membrane to be penetrated. This is particularly important to:

1. Avoid the possibility of the plasma entering the IOL and causing chipping or cracking of the IOL;
2. Allow the accompanying shock wave to grow to its most effective size.

The reverse applies when smaller amounts of energy are used, when the focus should be brought closer to the membrane.

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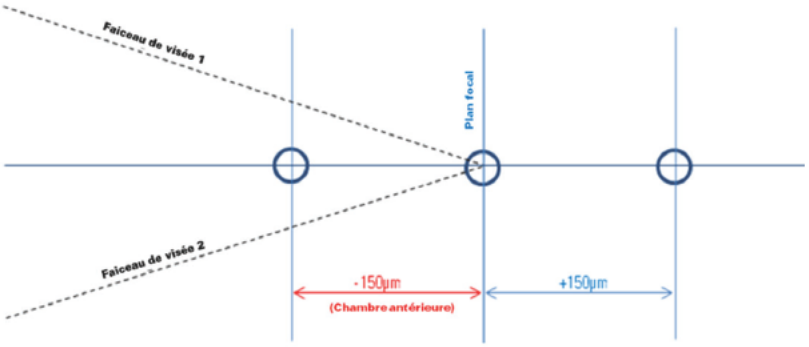
Some authors suggest that the lowest effective energy be used to perform photo disruptive procedures as a means of minimizing unwanted side effects such as retinal detachment.

The **OPTIMIS FUSION** laser system has a specific motorized offset control that allows the user to set the offset using the FOCUS OFFSET button on the control module LCD screen to:

- **"Post."**
  The therapy beam is focused posteriorly to the aiming beam focus. This setting should only be used in applications for which the area to be treated is posterior to the tissue to be protected.
- **"Ant."**
  The therapy beam is focused anteriorly to the aiming beam focus. This setting should only be used in applications for which the area to be treated is anterior to the tissue to be protected.
- **"0"**
  The therapy beam and aiming beam are focused in the same plane (parfocal). This setting should only be used in applications for which there is no tissue that needs to be protected either directly anterior or posterior to the treatment region.



Focus offset selection

1.2 GENERAL DESCRIPTION OF TREATMENTS

In summary, the laser is aimed at the membrane or tissue of the patient's eye using the aiming beams. The energy is set to the lowest possible effective level, then the laser is fired.
If the capsule is tough or scarred, higher energy levels may be required, but the energy is increased in small increments and the minimum number of shots required to obtain an adequate opening is used.
Once an opening has been established, it is enlarged as required until it is of adequate size.

1.3 TISSUE EFFECTS

The **OPTIMIS FUSION mode YAG** has a cutting or disrupting effect with the capability to damage any tissue or structure on which the beam is focused.
Unlike other lasers commonly used in ophthalmology (such as argon, krypton and ruby laser coagulators), it does not rely on thermal effects.

WARNING: The laser is designed to damage tissues. Make sure it is focused only on tissues that are to be operated on. Do not focus it on or near iris blood vessels because the shock wave may produce bleeding and induce astigmatism. The beam should never enter the eye at greater than 30 degrees from the visual axis.

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1.4 INDICATIONS AND CONTRAINDICATIONS FOR USE — POSTERIOR CAPSULOTOMY

The YAG laser is indicated for disruption of the posterior capsule of the eye (posterior capsulotomy).

CONTRAINDICATIONS

The following may represent contraindications for posterior capsulotomy:

Pre-existing ocular pathologies including:

- corneal edema that interferes with visualization of the capsule
- diffuse haze of the aqueous humor
- extensive corneal dystrophy
- chronically elevated intraocular pressure (IOP), especially when uncontrollable under medication
- eyes with no potential visual function
- subjects with glass posterior chamber intraocular lenses (IOL), except those subjects whose medical condition precludes invasive surgery

WARNING: Variations in IOL material and geometry may affect YAG procedural parameters and clinical success. Consult the IOL implant packaging and/or the IOL manufacturer for special considerations.

WARNINGS

Poor candidates for posterior capsulotomy

As in any surgical procedure, there are risks involved in Nd:YAG laser posterior capsulotomy. Candidate patients for this procedure must be assessed objectively in light of the risks discussed below. Certain patients may not improve and, further, may be at increased potential risk of postoperative complications. This includes patients with:

- active ocular disease
- nystagmus or other neurological conditions that make ocular fixation impossible
- slight or moderate haze of the aqueous humor or cornea
- inability to cooperate in positioning and immobilization
- 20/30 or better preoperative vision and no other serious vision disability, such as glare or poor reading vision, associated with the posterior capsule condition

(Several clinical studies have shown that 2-7% of these subjects experience a decrease in postoperative vision.)

Intraocular pressure rise

Significantly increased IOP has been reported in a substantial number of laser- treated patients, particularly those presenting with preoperative glaucoma or preoperative IOP of greater than 20 mm Hg. Physicians should carefully monitor all subjects for IOP rise in the 2-5 hours after treatment with the laser.

Patients who exhibit a pressure rise generally return to pretreatment levels within 24 hours but should be followed throughout this period. Persistent IOP elevation occurs in some patients. Clinical estimates are that 2-3% of patients may be treated for secondary glaucoma.

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

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Damage to intraocular lens

Pitting or marking of IOLs occurs in Nd:YAG laser posterior capsulotomy with several clinical studies reporting a 25% or greater incidence. The potential to IOL damage is a function of lens type, proximity to the posterior capsule, the level of laser energy used and physician familiarity.

Posterior chamber lenses, particularly those close to the posterior capsule, have the greatest potential for damage. This potential can be minimized by care in focusing behind the lens in pseudophakic subjects, optimizing the view of the posterior capsule with the use of a contact lens and avoiding repetitive shots to the same spot.

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

Inadvertent patient movement

Mis-aiming of the device or movement of the patient may result in damage to non- target ocular tissue or the area surrounding the target tissue. If the patient cannot fixate, use of a contact lens or retrobulbar anesthesia injection is recommended.

Bleeding

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

Pupillary block

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

Rupture of the anterior hyaloid face

A proportion of subjects (about 25% in clinical studies) may experience rupture of the anterior hyaloid face. This potential is greater for aphakic subjects (no IOL present). Such patients are at increased risk of anterior vitreous movement from the normal plane. In the event of vitreous movement to the cornea, an increased incidence of corneal edema may result.

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

Retinal damage

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

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Patients at risk

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

- extracapsular cataract patients without a patent iridectomy are at an increased risk of pupillary block
- patients with preoperative glaucoma, prior filtering surgery or preoperative IOP of greater than 20 mm Hg are at a significantly higher risk of postoperative IOP rise to levels of clinical concern
- patients with IOLs, particularly posterior chamber lenses close to the posterior capsule, are at risk of IOL pitting or cracking
- the greater the total amount of energy employed to effect capsule opening, the greater the risk of damage to the IOL
- patients with pre-existing ocular conditions have a greater chance of experiencing postoperative complications

PRECAUTIONS

Targeting

Focus the unit in accordance with the description provided in:
OPTIMIS FUSION User Manual: III – Using the laser system
Since in dual beam diode systems such as **OPTIMIS FUSION**, the Nd:YAG beam cross-section extends beyond the diode beams, there is an increased probability of Nd:YAG beam impingement of the iris. Therefore, the operator should not fire the therapeutic shot without assurance that the two diode spots have become coincident on the target tissue (that is, neither of the diode beams is blocked or obstructed by other tissues of the eye in the beam pathway). Care should be exercised when working at the iris margin or at a wide angle to the patient's visual axis.

Energy use

The lowest possible energy level should be used, beginning with 1-2 mJ and increasing the energy as required.
The burst-mode button can be adjusted to effect capsule dissection.
If the capsule is tough or scarred, higher energy shots may be required. It is recommended that the increase be in 1-2 mJ steps. The clinical experience indicates that the mean power level used is 2.7 mJ, and 97% of the subjects were treated at less than 5 mJ.
The minimum number of shots required to obtain an adequate opening should be used. The mean is 40 shots, although greater than 100 shots may be required for membranous tissue

WARNING: The risk of IOL damage increases with increasing energy level and number of shots used.

Once an opening has been established, it is enlarged as required until the capsulotomy is adequate.
In the presence of edematous, clouded, scarred or irregular astigmatic corneas, the laser beam may defocus, necessitating higher energy settings to obtain optical breakdown Medical judgment must be used to determine whether the corneal condition in such circumstances contraindicates laser posterior capsulotomy.

Patient focus

A thin fluid layer on the cornea is desirable. The patient is asked to blink regularly to avoid corneal drying.
Topical steroids should be used for any significant postoperative inflammation.

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Adverse effects

Adverse effects include:

- IOP rise to 50 mm Hg or greater, regardless of duration
  (Hospitalization may be required for the institution of IOP-reducing therapy. Pain and nausea may accompany such a significant IOP rise.)
- IOP rise to 30 mm Hg or greater persisting for one week or more
- secondary glaucoma
- hyphema
- pits on IOL, if present
- inflammatory reactions, such as iritis, vitritis or uveitis
- retinal complications, such as cystoid macular edema and retinal detachment
- pupillary block
- anterior hyaloid face rupture
- vitreous movement with corneal touch
- corneal edema
- iris damage

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1.5 INDICATIONS AND CONTRAINDICATIONS FOR USE — IRIDOTOMY

OPTIMIS FUSION mode YAG is indicated for performing an iridotomy (hole in the iris).

CONTRAINDICATIONS

The following may represent contraindications for iridotomy. Pre-existing ocular pathologies including:

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

WARNINGS

Risks

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

- significant transient elevation of IOP
- damage to the lens
- transient bleeding from the iridotomy margin, and hyphema
- localized corneal damage
- anterior chamber reaction (including flare, cells and debris)
- closure of the iridotomy with time
- inability to control glaucoma adequately (despite a successful iridotomy), necessitating chronic medical therapy or further invasive intraocular surgery

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

- persistent elevation of the IOP
- rupture of the anterior hyaloid face and anterior displacement of the vitreous in an aphakic eye
- damage to the retina or choroid

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

Poor candidates for Nd:YAG laser iridotomy

Patients with any of the following conditions may not be suitable candidates for Nd:YAG laser iridotomy because of the risks of bleeding, or inability to create an iridotomy or iridotomy closure:

- slight or moderate haze of the cornea or aqueous humor
- chronic uveitis
- pupillary block associated with neovascular glaucoma or with any condition causing engorged iris blood vessels
- tendency to bleed (as with hemophilia or patients receiving anticoagulant therapy)
- inability to cooperate in the procedure
- nystagmus
- blepharospasm

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Intraocular pressure rise

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

The decision to use additional medical treatment in the event of a rise of IOP should be based on the status of the individual patient. Most elevations resolve without intervention within 24 hours of Nd:YAG laser surgery. The treating physician should take into consideration the pre-existing condition of the optic nerve and other ocular structures when deciding whether to treat the eyes with IOP-lowering medication.

Damage to the lens

Clinically visible evidence of lens damage has not been reported to date following Nd:YAG laser iridotomies in humans, but Nd:YAG laser-induced damage to the crystalline lens has been noted in animal studies and in human histologic studies. The risk of lens damage during Nd:YAG laser iridotomy will increase if:

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

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

- ensure good patient fixation.
- use an appropriate contact lens.
- select an iris treatment site as far in the periphery as is practical.

As with all iridotomies, the site should be located under the upper lid whenever possible.

- focus the aiming beam upon the surface of the treatment site.
- use the minimum number of pulses per burst.
- use the lowest possible amount of energy per pulse.
- avoid treatment through a site that is already totally or partially patent.

Inadvertent patient movement

Inadvertent or uncontrolled eye movement by the patient may result in hitting tissues adjacent to the target. If a patient cannot fixate with the untreated eye to assure stabilization of the treated eye, use of anterior segment treatment contact lens and/or retrobulbar anesthesia injection is recommended.

Bleeding

Mild, localized bleeding occurs in 20% to 50% of eyes undergoing Nd:YAG laser iridotomy. Mild hyphema is rare (less than 2%) and severe hyphema is very uncommon (less than one in 200). Unlike an argon laser, a Nd:YAG laser creates minimal heat at the treatment site and therefore does not cauterize vessels. Eyes with engorged iris blood vessels (active uveitic or neovascular angle closure glaucoma) are at an increased risk of bleeding. Patients who are otherwise at risk of bleeding (as with hemophilia or those receiving anticoagulant therapy) are also at an increased risk of bleeding and hyphema. In otherwise normal patients with pupillary block glaucoma, bleeding usually stops spontaneously and can be controlled by digital pressure upon the contact lens. All eyes should be observed with a biomicroscope for bleeding. If bleeding occurs, additional

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

Corneal damage

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

Retinal damage

Although no retinal damage after Nd:YAG iridotomy has been noted to date, it is theoretically possible.

Closure of the iridotomy with time

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

Failure to control glaucoma

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

- the eye may have developed peripheral anterior synechiae (PAS)
- the angle may be open but the eye may have residual open angle glaucoma
- a combination of the above

Patients should be monitored for persistent glaucoma.

Patients at risk

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

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

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PRECAUTIONS

Targeting

Focus the unit in accordance with the description provided in *Chapter III*.
Unlike other lasers commonly used in ophthalmology (argon, krypton, and dye lasers) which rely on thermal effects, the Nd:YAG laser is a cutting or disrupting instrument with capability of damaging any tissue or structure on which the beam is focused. Therefore, the Nd:YAG laser should only be focused on target tissues and caution should be used to avoid exposure of all adjacent tissues and structures.

Energy use

Minimal effective energy and minimal pulses per burst should be used to reduce risk of damage to non-target areas. In animal studies, use of higher total energy, larger numbers of pulses, and more pulses per burst have been associated with an increased risk of damage to the lens. Lens damage has not been reported clinically in human eyes that have undergone Nd:YAG iridotomy.

ADVERSE EFFECTS

The following sight-threatening adverse effects and complications have been observed in patients who have undergone Nd:YAG iridotomy:

- transient elevated IOP
- hyphema
- Other problems reported following Nd:YAG laser iridotomy are:
- corneal injury (including damage to the endothelium, stroma or epithelium)
- anterior chamber reaction (including flare, cells and debris)

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2 SLT TREATMENT LASER — THEORY OF CLINICAL USE

The SLT treatment laser provides a low energy, short pulse of laser light that produces a thermal effect in pigmented cells in the trabecular meshwork of the eye.
Collateral thermal and coagulative damage does not occur because the pulse duration is less than the time it takes for melanin in the pigmented cells to convert the absorbed electromagnetic radiant energy into heat energy (this is the thermal relaxation time or TRT). Even in the treatment area non-pigmented cells and structures are unaffected.
The clinical effect of the 532 nm wavelength is similar to the effect of argon 514 nm wavelength but the SLT treatment beam offers an alternative treatment for glaucoma (and other conditions requiring a reduction in intraocular pressure) that avoids the photocoagulation and collateral thermal damage in surrounding tissues that can occur in argon laser treatments.

2.1 INDICATIONS AND CONTRAINDICATIONS FOR USE

INDICATIONS

The **OPTIMIS FUSION mode SLT** is indicated for use in selective Trabeculoplasty.

CONTRAINDICATIONS

The following conditions contraindicate the use of the **OPTIMIS FUSION mode SLT**:

- neovascular glaucoma
- angle closure glaucoma
- Congenital glaucoma
- Active uveitic glaucoma
- Any disease that does not allow visualization of the trabecular meshwork

PRECAUTIONS

The following precautions are suggested when using the **OPTIMIS FUSION mode SLT**:

- Use the minimum treatment energy necessary to perform the treatment, to reduce the risk of damage to non-targeted tissues — exercise particular caution when using pulse energies exceeding 1.4 mJ.
- Exercise caution in treating if blood vessels are present in the angle
- Avoid treating blood vessels in the vicinity of the trabecular meshwork due to the risk of hemorrhage
- Exercise caution when treating patients with pre-existing anterior chamber inflammation, including uveitis, since the procedure itself may induce a mild anterior chamber inflammatory response
- Perform ocular surgery only when the structures to be treated can be clearly visualized and the single aiming beam is on the treatment site

COMPLICATIONS AND ADVERSE EVENTS

In some clinical studies*, patients who received selective laser trabeculoplasty treatment experienced some complications and adverse events that were considered to be related to the treatment. These included :

- mild transient anterior chamber inflammation in many patients,
- intraocular pressure increase of ≥ 10 mm Hg,
- conjunctivis
- and eye pain.

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A number of other complications occurred at an incidence of <1%. These included:

- blurred vision,
- iritis,
- corneal edema,
- corneal lesion, and
- headache.

Although not considered treatment-related, another potential complication of laser trabeculoplasty is the formation of peripheral anterior synechiae.

* ***Clinical studies references:***

1. **Inflammation assessment after selective laser trabeculoplasty (SLT) treatment.**
   Ayala M, Landau Högbeck I, Chen E.

   Source
   Glaucoma department, St Eriks Eye Hospital, Karolinska Institutet, Stockholm, Sweden.

   Acta Ophthalmol. 2011 Jun;89(4):e306-9. doi: 10.1111/j.1755-3768.2010.02029.x. Epub 2011 Mar 22.

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   LATINA MA, SIBAYAN SA, SHIN DH, NOECKER RJ, MARCELLINO G.

   Source
   WELLMAN LABORATORIES OF PHOTOMEDICINE, MASSACHUSETTS GENERAL HOSPITAL, HARVARD MEDICAL SCHOOL, BOSTON, USA.

   OPHTHALMOLOGY. 1998 NOV;105(11):2082-8; DISCUSSION 2089-90.

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2.2 CLINICAL PARAMETERS

In SLT treatment **mode** the OPTIMIS FUSION emits single visible light pulses 4 ns in duration with a 400 µm spot size and pulse energies ranging from 0.3 to 2 mJ. The mechanism of action of the OPTIMIS FUSION **mode** SLT is the selective targeting of pigmented trabecular meshwork cells, when operated within a defined energy range.

The short duration of the laser pulses minimizes the amount of heat dissipated from pigmented cells and absorbed by surrounding non-pigmented tissues. When the OPTIMIS FUSION **mode** SLT is operated within a defined energy range, the fluency of the resulting laser pulses is below the level where optical breakdown occurs. However, higher energy levels may result in photoacoustic and/or photomechanical damage to adjacent non-melanized cells or the trabecular support architecture.

A Latina gonioscopy lens without magnifying optics is used to visualize the angle during treatment. A coupling medium (i.e. Hydroxypropyl methylcellulose ophthalmic) is required when using the Latina gonioscopy lens to properly visualize the angle anatomy.

The optimum energy level for treatment is defined as the maximum energy that can be delivered without causing photodisruption/optical breakdown of the trabecular meshwork. The optimum energy level will vary from patient to patient because the threshold for thermal energy, evidenced by bubble formation, is determined primarily by the level of pigmentation in cells of the trabecular meshwork.

To determine the optimum energy level for treatment, set the initial laser energy at 0.6 mJ.
Increase the energy in single, stepwise 0.1 mJ increments until bubble formation is observed.
The energy at which bubble formation occurs is known as the 'threshold energy'. After the threshold energy has been identified, decrease the laser energy level by 0.1 mJ. This lower energy level is known as the 'treatment energy'.

Treatment should continue at the treatment energy until 50 (±10) single, non-overlapping laser spots have been created along 180 degrees of either the nasal or temporal segment of the trabecular meshwork.

WARNING: After the laser treatment, prednisolone acetate 1% drops should immediately be administered to the treated eye and continued four times daily for four to seven days

WARNING: Exercise particular caution when using pulse energies exceeding 1,4mJ.

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Revision History

Revision Number	Revision Date	Summary of Changes	Author
1.0	September 4th, 2013	Initial release	(b)(6) [redacted]

Reference Documents

Please see the following documents for more information:

Document Name	Version	Author
ISO/IEC 12207: Systems and *software engineering - Software life cycle processes*	2008	ISO
ISO/IEC 14764– *Software Engineering – Software Life Cycle Processes - Maintenance*	2006	ISO
IEEE Std 14764 - *Software Engineering – Software Life Cycle Processes - Maintenance*	2006	IEEE

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Document History

Paper copies are valid only on the day they are printed. Contact the author if you are in any doubt about the accuracy of this document.

Revision History

Revision Number	Revision Date	Summary of Changes	Author
(b)(4)	September 4th, 2013	(b)(4)	(b)(6)

Reference Documents

Please see the following documents for more information:

Document Name	Version	Author
ISO/IEC 12207: Systems and *software engineering - Software life cycle processes*	2008	ISO
ISO/IEC 14764– *Software Engineering – Software Life Cycle Processes - Maintenance*	2006	ISO
IEEE Std 14764 - *Software Engineering – Software Life Cycle Processes - Maintenance*	2006	IEEE

Distribution List

This document has been distributed to:

Name	Position	Company	Action
(b)(6)	Software Developper		
	Security Officer		
P.QUERO	QA&RA Director		

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ATTACHMENT # 10

Design Control Document

Quantel Medical – OPTIMIS FUSION

Title: Hardware/Software Security Verification (HSV) Rev (b)(4)

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[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISION LEVEL HISTORY

Item	Date	Hardware	
0	7/10/13	(b)(4) [redacted]	(b)(4) [redacted]
	12/20/13		
1	1/6/14		

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Unresolved Anomalies

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Unresolved Anomalies

CERTIFICATION

The software test procedures provided in the 510(k) notification are as follows:

(b) [redacted]

This information is correct and tests have been conducted following these procedures. At this date, we certify that there are no bugs or defects unresolved that could have been identified during our tests or recorded to us by our customers.

In case of software revision, all the procedures described will be used to retest and revalidate the new software version.

Patrick QUERO

Quality & Regulatory Affairs Director

Date: January 20th, 2014

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T - LABELING VERIFICATION *(Vérification de l'étiquetage)*

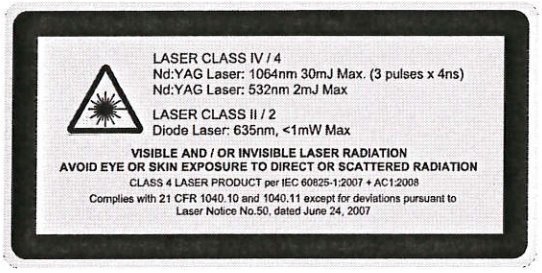
Tick the case corresponding to the good laser configuration.

Cocher la case correspondante à la bonne configuration laser.

FUSION

Refer to the label guide of the device to verify the correct location and content of the labels sticked on the OPTIMIS FUSION.

Se référer au guide des étiquettes de l'appareil pour vérifier le bon emplacement et le contenu des étiquettes collées sur l'OPTIMIS FUSION.

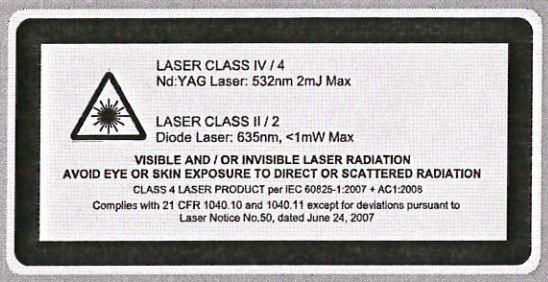


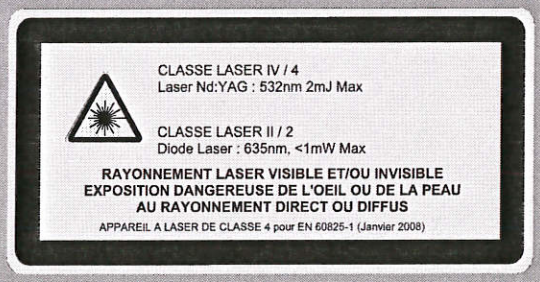
CONFORMITY ~~YES~~ NO **T**

FUSION SLT

Refer to the label guide of the device to verify the correct location and content of the labels sticked on the OPTIMIS FUSION SLT.

Se référer au guide des étiquettes de l'appareil pour vérifier le bon emplacement et le contenu des étiquettes collées sur l'OPTIMIS FUSION SLT.



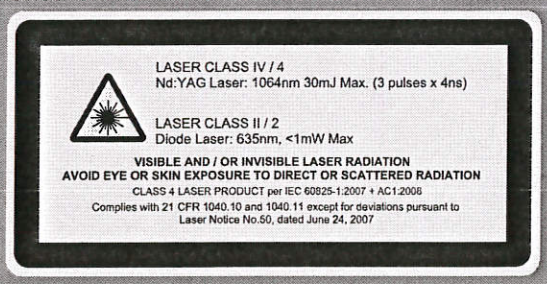


CONFORMITY YES NO **T**

FUSION YAG

Refer to the label guide of the device to verify the correct location and content of the labels sticked on the OPTIMIS FUSION YAG.

Se référer au guide des étiquettes de l'appareil pour vérifier le bon emplacement et le contenu des étiquettes collées sur l'OPTIMIS FUSION YAG.



CONFORMITY YES NO **T**

U - AESTHETIC VERIFICATIONS *(Contrôle d'aspect)*

CONFORMITY ~~YES~~ NO **U**

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510(k) Summary for the Quantel Medical

Family of OPTIMIS FUSION Ophthalmic Laser Systems, (OPTIMIS FUSION SLT/YAG, OPTIMIS FUSION YAG, OPTIMIS FUSION SLT) and Delivery Device (Slit lamp adaptor) and Accessories

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:

Quantel Medical
11 Rue du Bois Joli – CS 40015
63808 Cournon D'Auvergne Cedex
FRANCE
33-473 745 745
33-473 745 700 (Fax)

Contact Person:

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Telephone: 978-207-1245
Fax: 978-824-2541

Summary Preparation Date: February 6, 2014

2. Names

Device Trade Name: Family of OPTMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories
OPTIMIS FUSION SLT/YAG
OPTIMIS FUSION YAG
OPTIMIS FUSION SLT

Common Name: Ophthalmic Laser

Classification Names: Laser Instrument, Surgical, Powered and Laser, Ophthalmic
Product Code: GEX (21 CFR 878.4810) and HQF (21 CFR 886.4390)
Panel: General & Plastic Surgery and Ophthalmology

3. Predicate Device

- Lumenis Family of Selecta Ophthalmic laser Systems, Delivery Device and Accessories : (K081704)

4. Device Description

The QUANTEL MEDICAL OPTIMIS FUSION is an ophthalmic surgical laser designed for performing photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser including discission of the posterior capsule of the eye (posterior capsulotomy), discission of the pupillary membranes (pupillary membranectomy), and iridotomy/iridectomy ; and selective laser Trabeculoplasty.

The Family of OPTIMIS FUSION Ophthalmic Lasers, Delivery Device and Accessories consists of the following models:

1) OPTIMIS FUSION YAG – a Nd: YAG Laser providing-switched laser pulses at a wavelength of 1064 nm for use in photodisruption of ocular tissue (posterior capsulotomy, pupillary membranectomy, iridotomy/iridectomy). The 1064 treatment beam delivers 4 ns, 0.3 -10mJ adjustable and selectable single, double or triple pulse of energy. It is conditioned trough beam shaping optics to generate a photodisruption micro pulse of plasma at a precision adjustable location relative to the visual focal plane (located at slit lamp center of rotation) and along the slit lamp objective lens axis. A twin aiming beam is also focused by the slit lamp objective to a converging 10 µm spot located at the focal point of the lens. The focal point of photodisruption is adjustable 150µm in the posterior direction and -150µm in the anterior direction by the physician relative to this convergence of the twin aiming beams.

2) OPTIMIS FUSION SLT - a Nd: YAG Laser providing Q-switched frequency doubled pulses at a wavelength of 532 nm for use in Selective Laser Trabeculoplasty. The treatment beams delivers a 4 nsec, 0.3, 2mJ adjustable single pulse of energy. The aiming and treatment beams are coaxial with each other and focussed by the slit lamp objective to a 400µm spot at the focal point of the lens.

3) OPTIMIS FUSION YAG/SLT - a Nd: YAG Laser providing Q-switched laser pulses at a wavelength of 1064 nanometers for use in photodisruption or Q-switched frequency doubled pulses at a wavelength of 532 nm for use in Selective Laser Trabeculoplasty, depending upon the mode selected. The OPTIMIS FUSION YAG/SLT contains two aiming beam modules that produce a single beam for the 532nm mode and a dual beam for the 1064nm mode, respectively.

For each OPTIMIS FUSION model, the physician controls delivery of laser energy from the OPTIMIS FUSION control display unit and activates the treatment laser beam with a footswitch or joystick pushbutton. In addition, a laser slit lamp adaptor may be coupled to each of the above OPTIMIS FUSION models and connected to a currently cleared QUANTEL MEDICAL 532nm photocoagulator (VITRA (K04236), SUPRA (K07776), VITRAMULTISPOT (K122251)) to allow to the physician to use the *Slit Lamp Adaptor* to deliver 532 nm continuous wave laser energy for retinal photocoagulation.

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

When the photodisruptor mode is selected, the treatment wavelength is 1064nm. A twin-aiming beam targets the area of tissue disruption. The energy contained within a single short pulse is concentrated by focusing to a very small spot size so that plasma formation occurs at the focal point. This creates an acoustic wave which disrupts nearby tissue.

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

5. Indications for Use

- OPTIMIS FUSION YAG: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy.

- OPTIMIS FUSION SLT: Selective Laser Trabeculoplasty

- OPTIMIS FUSION YAG/SLT: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy; and Selective Laser Trabeculoplasty

6. Substantial Equivalence

The indications for use statement for the OPTIMIS FUSION FAMILY is exactly the same as the indications for use statement for the Lumenis Family of SELECTA

Ophthalmic Laser Systems, Delivery Device and accessories (predicate device). Each of the families contains multiple configurations of the laser system with different indications for use statements. Both families include an SLT model, a YAG model and a model which combines the SLT and YAG. The indications for use statements for each version of the product are identical between the families.

The OPTIMIS FUSION FAMILY and the predicate device have the same technological characteristics. Each of the families includes multiple models within the family. Both the OPTIMUS FUSION FAMILY and the Lumenis SELECTA family include an SLT model, a YAG model and a model that combines the SLT and YAG lasers in one unit.

The specifications of the SLT and YAG modes are almost identical between the OPTIMUS FUSION FAMILY and the SELECTA FAMILY. The OPTIMIS FUSION SLT is a Q-Switched frequency doubled Nd: YAG laser with a wavelength of 532 nm as is the Selecta SLT model. Both the Optimis Fusion SLT and the Selecta SLT models operate in single pulse modes. The energy range for both devices is 0.3-2.0 mJ. The spot size in air is 400 microns with a focus angle of < 3 degrees for both systems.

The OPTIMIS FUSION YAG is a Q-Switched Nd: YAG laser with a wavelength of 1064 nm as is the Selecta 1064 model. Both the Optimis Fusion YAG and the Selecta 1064 models operate in user selectable bursts of 1, 2 or 3 pulses. The energy range for both devices is 0.3-10.0 mJ. The spot size in air is 10 microns with a focus angle of 16 degrees for both systems. The repetition rate for the Optimis Fusion YAG is 2.0 Hz as it is for the Selecta 1064.

The OPTIMIS FUSION YAG/SLT includes the features and specification of both the OPTIMIS FUSION SLT system and the OPTIMIS FUSION YAG system combined in one device. The specifications of each individual system remain unchanged when they are combined into one unit. This is exactly the same as the Lumenis Selecta Duet which combines the Selecta SLT and Selecta 1064 features.

All of the systems use a 635 nm red diode for aiming. All of the systems use a slit lamp as the delivery system for the laser energy. The Optimis Fusion models use the CSO SL980 slit lamp previously cleared by FDA in K992836.

Therefore, the OPTIMIS FUSION FAMILY is substantially equivalent to the predicate device.

7. Performance Data

Laboratory testing was conducted to validate and verify that the Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories met all design specifications and was substantially equivalent to the predicate devices.

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Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

QUANTEL MEDICAL
CS 40015
Cournon d'Auvergne
FRANCE
63808
FR

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
QUERO Patrick

2.1 E-MAIL ADDRESS
quero@quantel.fr

2.2 TELEPHONE NUMBER (include Area code)
33 473 745 745

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted] 24-Jan-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees
Pay.gov Tracking ID: (b)(4) [redacted]
Agency Tracking ID: [redacted]
Transaction Date and Time: 01/24/2014 09:16 EST

Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: QUANTEL MEDICAL	**Card Type:** (b)(4) [redacted]	**Payment Amount:** (b)(4) [redacted]
Billing Address: 11 Rue du Bois Joli	**Card Number:** [redacted]	**Transaction Date and Time:** 01/24/2014 09:16 EST
Billing Address 2:		
City: COURNON D'AUVERGNE		
State / Province:		
Zip / Postal Code: 63808		
Country: FRA		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known): _____

Device Name: **Family of OPTIMIS FUSION Ophthalmic Laser Systems, (OPTIMIS FUSION SLT/YAG, OPTIMIS FUSION YAG, OPTIMIS FUSION SLT) and Delivery Device (Slit lamp adaptor) and Accessories**

Indications for Use:

- OPTIMIS FUSION YAG: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy.

- OPTIMIS FUSION SLT: Selective laser Trabeculoplasty

- OPTIMIS FUSION YAG/SLT: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy; and Selective laser Trabeculoplasty

Prescription Use X___ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

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Premarket Notification
Truthful and Accurate Statement
(As required by 21 CFR 807.87(k))

I certify that, in my capacity as Quality Assurance Manager & Regulatory Affairs of QUANTEL MEDICAL, I believe to the best of my knowledge, that all data and information submitted in this Premarket notification are truthful and accurate and that no material fact has been omitted.

Signature

Patrick QUERO

January 20th, 2014

Date

Family of FUSION Ophthalmic Laser Systems, (FUSION SLT/YAG, FUSION YAG, FUSION SLT) and Delivery Device (Slit lamp adaptor) and Accessories

510(k) Pre-market Notification Title

510(k) Pre-market Notification Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1-CD Records processed under FOIA Request # 2015-10223; Released by CDRH on 03-15-2016

K140336/S1

May 16, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-002
Attn: Charles Chiang

FDA CDRH DMC
MAY 19 2014
Received

RE: Supplement 1 to K140336

Dear Mr. Chiang:

The following information and additional documents are provided in response your telephone hold memorandum dated April 4, 2014. Each question is followed by Quantel Medical's response.

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

23

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2015-10223; Released by CDRH on 03-15-2016

(b)(4) Deficiencies

[redacted]

This 510(k) Supplement is provided in duplicate with one paper and one electronic copy. The electronic copy is an exact duplicate of the paper copy. Please contact me at (978) 207-1245 or maureen@oconnellregulatory.com with any questions regarding this submission.

Sincerely,

Maureen O'Connell
Regulatory Consultant
O'Connell Regulatory Consultants, Inc.

Cc: Patrick Quero

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Maureen O'Connell
Regulatory Consultant
O'Connell Regulatory Consultants, Inc.

Cc: Patrick Quero

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-10223; Released by CDRH on 03-15-2016

Select a chapter:

Introduction
I Regulatory & safety information
II Technical information
III Using the laser system
IV Maintenance
V Clinical information

optimis FUSION™

Cataract and Glaucoma Laser Platform

MAY 2014

DRAFT

YAG and SLT Laser

QUANTEL MEDICAL
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FRANCE
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Fax : +33 (0) 473 745 700
E-mail : contact@quantel-medical.fr
Web site: www.quantel-medical.com

2013 CE 0459

Directive 93/42/EEC

Quantel medical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Any question regarding the installation or the use of the OPTIMIS FUSION system should be directed to the QUANTEL MEDICAL Service Department or to a local distributor:

International

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11, rue du bois joli - CS 40015
63808 Cournon d'Auvergne Cedex
FRANCE

Tel. : +33 (0) 473 745 745
Fax : +33 (0) 473 745 700
E-mail : contact@quantel-medical.fr
Web site: www.quantel-medical.com

U.S.A.

QUANTEL USA MEDICAL UNIT
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BOZEMAN MT 59715
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E-mail : info@quantelmedical.com
Web site www.quantel-medical.com

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OPTIMIS FUSION User Manual
Software version 1.00
International version
(Ref: XL_FUSION_ME_AN)
May 14th, 2014

2013 CE 0459
Directive 93/42/EEC

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Nd:YAG Ophthalmic Laser System

USER MANUAL
INTRODUCTION

Quantel medical

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14/05/14

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1 USER MANUAL DESCRIPTION

The OPTIMIS FUSION user manual is organized into the following chapters:

Introduction
I Regulatory & safety information
II Technical information
III Using the laser system
IV Maintenance
V Clinical information

2 USER MANUAL TERMS AND SAFETY SYMBOLS

WARNING

Potential hazards which, if not avoided, could result in serious injury or death

CAUTION

Potential hazards which, if not avoided, could result in minor or moderate injury and/or product damage

NOTE

Significant additional information or explanation

DRAFT

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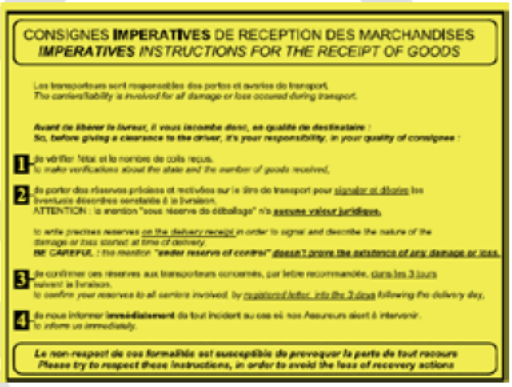
3 UNPACKING THE INSTRUMENT

3.1 TRANSPORTATION INFORMATION

To minimize transportation risks, this instrument has been packed with special care. However, before unpacking the laser, check the packaging for any sign of damage or improper handling.

① Handling label

② Delivery label



CONSIGNES **IMPERATIVES** DE RECEPTION DES MARCHANDISES
***IMPERATIVES** INSTRUCTIONS FOR THE RECEIPT OF GOODS*

Les transporteurs sont responsables des pertes et avaries de transport.
The carrier/liability is involved for all damage or loss occured during transport.

Avant de libérer le livreur, il vous incombe donc, en qualité de destinataire :
So, before giving a clearance to the driver, it's your responsibility, in your quality of consignee :

1 - de vérifier l'état et le nombre de colis reçus.
to make verifications about the state and the number of goods received,

2 - de porter des réserves précises et motivées sur le titre de transport pour signaler et décrire les éventuels désordres constatés à la livraison.
ATTENTION : la mention "sous réserve de déballage" n'a **aucune valeur juridique.**

to write precises reserves on the delivery receipt in order to signal and describe the nature of the damage or loss started at time of delivery.
BE CAREFUL** : this mention **"under reserve of control"** **doesn't prove the existence of any damage or loss.

3 - de confirmer ces réserves aux transporteurs concernés, par lettre recommandée, dans les 3 jours suivant la livraison.
to confirm your reserves to all carriers involved, by registered letter, into the 3 days following the delivery day,

4 - de nous informer **immédiatement** de tout incident au cas où nos Assureurs seraient à intervenir.
to inform us immediately.

Le non-respect de ces formalités est susceptible de provoquer la perte de tout recours
Please try to respect these instructions, in order to avoid the loss of recovery actions

NOTE

In case of any problem, immediately contact the shipping company. Do only open the box in the presence of a company representative. Draw up a list of all damaged parts and ask for it to be signed by the company representative.

CAUTION

If the instrument is at a temperature below **15°C** (59°F), switching on the instrument may cause serious damages. Unpack the instrument and leave it at normal temperature for at least half a day to ensure that the internal components warm up gradually.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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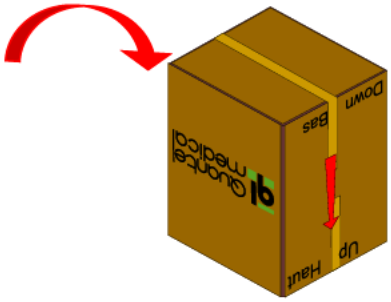
3.2 UNPACKING THE INSTRUMENT

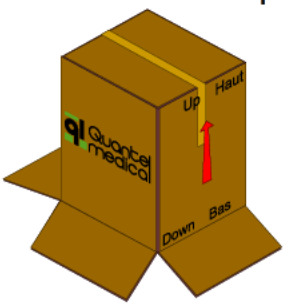
1/ Normal position :

2/ Turn upside down :

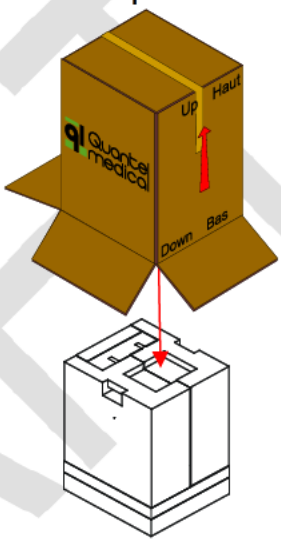


3/ Open the box :

4 / Turn it back to the normal position:



5 / Pull up the box :



6 / Pull up the main foam with caution:

7 / Turn the binocular with caution to remove it from main frame : :

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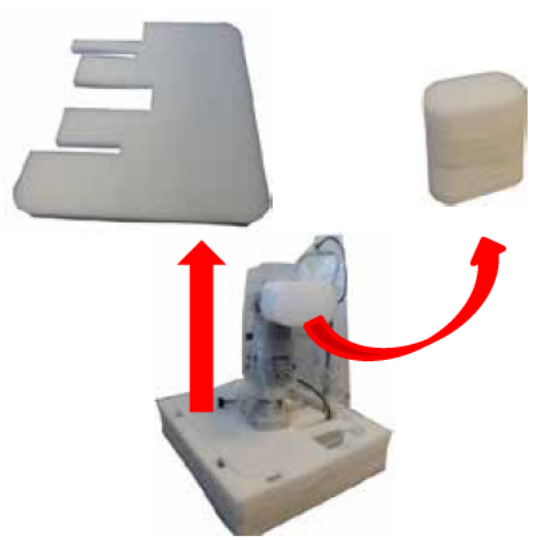
8 / Remove the flat foam located on the table and binocular foam :



9 / Remove the OPTIMIS FUSION from the bottom foam::

To mount the laser, refer to:
FUSION User Manual: II – Technical information
Section 4.2: Mounting the laser

NOTE

To repack the OPTIMIS FUSION laser: use the above procedure in reverse order.

CAUTION

The chinrest must be placed on "high" position.

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3.3 PACKING LIST

3.3.1 BASIC CONFIGURATION

Before beginning the installation, check the contents of the package against the following list:

Basic configuration	Codes
OPTIMIS FUSION Nd:YAG LASER slit lamp with its slit generator:	
Console with chinrest	
Power cord	*XLFUSION*
Keys (2)	
Remote	
User Manual	*XL FUS ME AN*
Gear cover	
Focusing bar	
Laser safety goggles OD 5 for 532nm	*XL 532 PROT*
Laser safety goggle OD 6 for 1064nm	*XL 1064 PROT*

3.3.2 ACCESSORIES

Please contact Quantel Medical to ask for any of the following accessories:

Accessories	Codes
For ancillary personnel	
Laser safety goggles OD 5 for 532nm	*XL 532 PROT*
Laser safety goggle OD 6 for 1064nm	*XL 1064 PROT*
Slit Lamp Adaptor : FusionLink	
~~Retractable 532nm adaptor~~	~~*XL 532 CSO4ST*~~
Fusion Link adaptor	*XL FUS 1*
Base	
Base 220V	*XL LAF PIED*
Base 110V	*XL LAF PIED110*
Metallic Plate	*XL LAF PLATEAU*
Footswitch	
Footswitch	*XLAAAPEDALE5*

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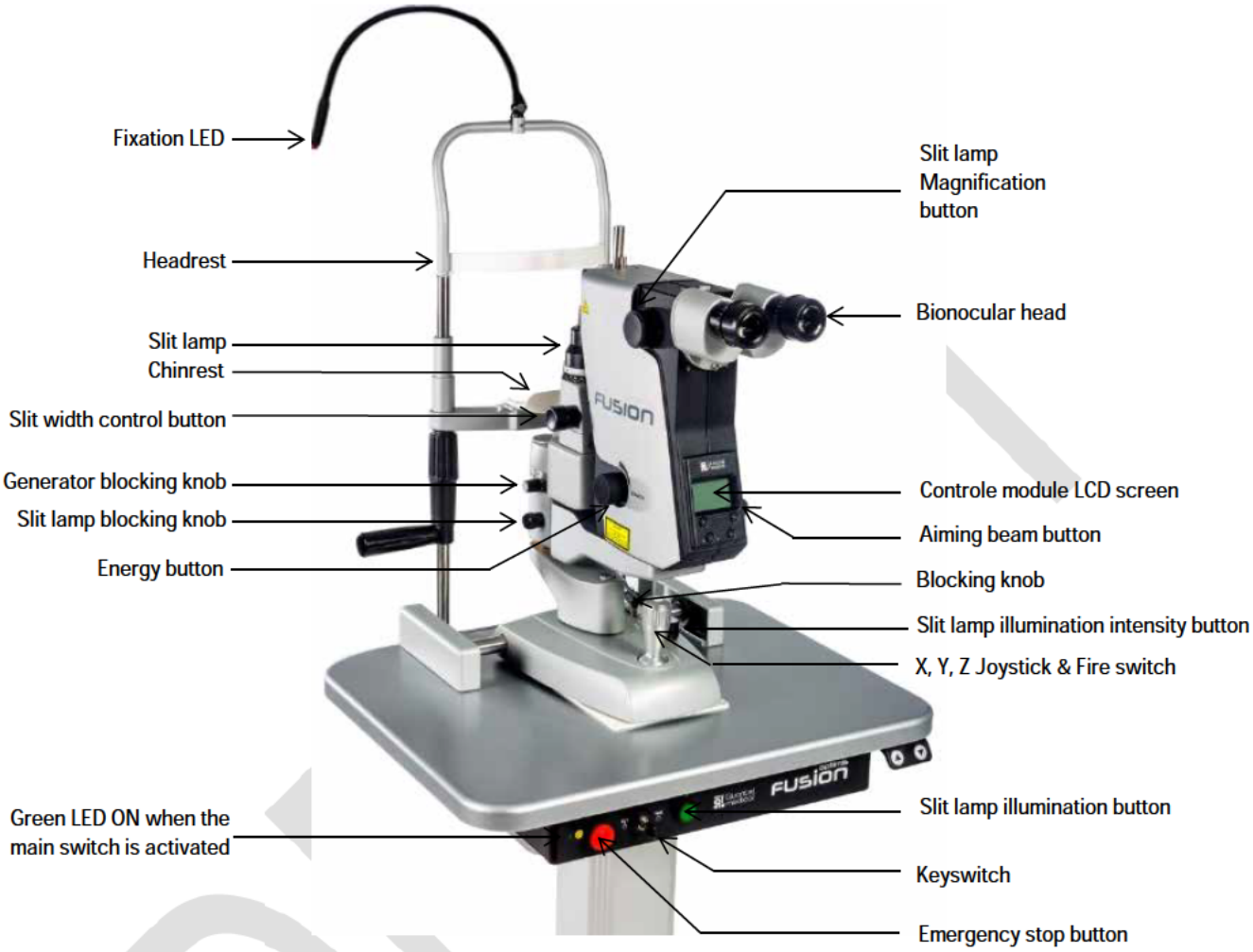
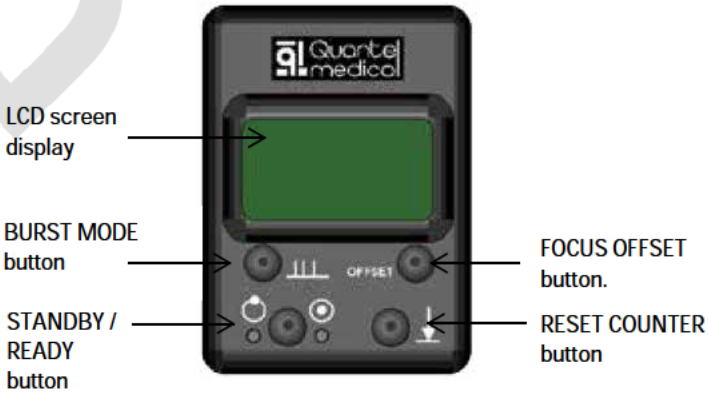
4 OPTIMIS FUSION LASER DESCRIPTION

4.1 GENERAL DESCRIPTION



4.2 CONTROL MODULE LCD SCREEN



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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL
I – REGULATORY AND SAFETY INFORMATION

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1 INTENDED USE AND CONTRAINDICATIONS

The **OPTIMIS FUSION** is intented for:

- **FUSION YAG**: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy /~~iridectomy~~.
- **FUSION SLT**: Selective laser Trabeculoplasty
- **FUSION YAG/SLT**: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / ~~iridectomy~~; and Selective laser Trabeculoplasty.

2 CLASSIFICATIONS

The system is intended for continuous operation and has the following classifications:

Protective class	I (Main insulation)
Type	B (Protection against electrical shocks through the limiting of leakage current and the provision of a protective earth connection)
Protection degree	IP20 (Protection from solid substances: Ø>12,5mm)
Operation	**Continuous** with short-time loading

3 SAFETY INFORMATION AND PRECAUTIONS

If any incident occurs, QUANTEL MEDICAL shall not be liable if the following safety information and precautions are not followed.

3.1 GENERAL WARNINGS AND SAFETY INFORMATION

WARNING: This user manual is designed to acquaint the user with the normal operation and maintenance of the OPTIMIS FUSION ophthalmologic laser. The manual scope is limited to the operation, maintenance and controls of the system. It is not intended to be a guide to laser eye treatment. Laser safety begins with the understanding that the purpose of this device is to perform controlled destruction of living tissues. Misuse of this system could result in patient, physician or attendees injuries. QUANTEL MEDICAL consequently strongly recommends the user to read and understand this entire manual before using the product, especially this section concerning safety.

WARNING: The American National Standards for the Safe Use of Laser in Health Care Facilities (**ANSI Z 136.3-1996 and ANSI Z 136.1-1993**) provide guidance to safely use lasers and laser systems in the diagnostic and therapeutic areas. Those two standards are related to eye and skin hazards and recommend the use of protective eye wear, clothing, barriers and screens.

WARNING: Any use of controls or performance adjustments for procedures other than those specified herein may result in hazardous radiation and/or electrical exposure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CAUTION: USA Federal Law restricts this device to sale by, or on the order of, a physician.

WARNING: This user manual is intended to solely be used by trained ophthalmologists for diagnosis and treatment of ocular pathology.

CAUTION: QUANTEL MEDICAL cannot be held responsible for any damage or injury that results from a failure to follow or incorrect use the instructions contained in this manual.

WARNING: This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

WARNING: To comply with medical electrical equipment safety standard requirements, the laser power plug must be connected on to a wall grounded single phase power socket on its own. The use of an adaptor (for multiple connections) or a power bar is prohibited.

WARNING: Do not connect the laser power plug (3 pin adaptor) on an ungrounded power socket (2-pin).

WARNING: Before cleaning the unit, unplug the power cord from the wall mains plug.
Please refer to the:
OPTIMIS FUSION user manual: IV – Maintenance
Section 2: Care and maintenance of the OPTIMIS FUSION laser system

WARNING: The instrument calibration must be performed every year by a technician authorized by QUANTEL MEDICAL.

WARNING: In case the laser efficacy is altered and the laser system needs servicing: you must contact QUANTEL MEDICAL Service Department or your local distributor.

WARNING: Unit servicing must only be performed by QUANTEL MEDICAL technicians or otherwise technicians authorized by QUANTEL MEDICAL (local distributors).

WARNING: Transport the OPTIMIS FUSION equipment only under the conditions described in the:
OPTIMIS FUSION user manual: II – Technical information
Section 4.3: Moving the OPTIMIS FUSION equipment

CAUTION: To preserve the appearance of the device, do not use abrasive cleaning products, or solvents. If possible, clean off stains immediately

CAUTION: The device's guarantee will be void if the equipment is opened (even partially), modified or repaired in any way by persons who have not been authorized to do so by QUANTEL MEDICAL.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 25

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3.2 IMPORTANT RECOMMENDATIONS

WARNING: To prevent injury to personnel or damage to the instrument, all operators must fully versed in the instructions and procedures detailed herein and in the ANSI Standard Z136.3.

1. **Never** directly look into a laser light source and avoid exposure to reflected or scattered laser light. This device is classified as **Class IIIb (3B)** laser product: direct, reflected or scattered light from this laser may cause injury.

2. The treatment beam emitted from this instrument has the potential to ignite anesthetics or flammable materials or explosives. Do not use this system in proximity to these materials.

3. Safety goggles or masks are required for **anyone** who is present during a treatment session, except for the physician and the patient. During some procedures it may be advisable to shield untreated eyes (Please refer to Section 3.5.1: Safety eyewear).

4. **Never** leave the system on when it is unattended or within the reach of unauthorized persons. Before leaving the vicinity, turn off the system and keep the key with you.

5. When the laser is on, always keep the system in "STANDBY" mode unless it is used to perform treatment.

6. ~~Contact lens wearers should use anti-reflection lenses treated for 532nm and 1064nm wavelengths. Contact lenses, particularly those with plano surfaces, can generate dangerous reflections.~~ Contact lenses should be removed prior to treatment.

7. **Never** open the laser enclosure as hazardous levels of visible and invisible optical radiations are present inside. Refer any servicing problem to qualified personnel authorized by QUANTEL MEDICAL.

8. Observe all **DANGER**, **WARNING** or **CAUTION** labels placed on the device:
   An overview of the location and contents of these labels can be found in the:
   OPTIMIS FUSION User manual: II - Technical information
   Section 1: Labels

9. Circuitry is provided for the connection of a remote interlock. When attached to the laser door room or other actuator, the interlock will prevent the laser from firing if someone enters in the room while the system is in use. Installation instructions are provided in:
   OPTIMIS FUSION User Manual: II - Technical information
   Section 4.5: Door switch & External red lamp installation

10. Regular maintenance, which can be performed by the user, is described in:
    OPTIMIS FUSION User Manual: IV – Maintenance
    Performing regular maintenance, which includes checking the power calibration, will help ensuring trouble-free operation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.3 SAFETY FEATURES

FEATURE	DESCRIPTION
Lockable key switch	The lasers can only be turned on with the correct key that corresponds to the laser key switch. The key cannot be removed while the laser is operating, so the laser cannot function without the key in place.
Emergency Laser Stop switch	During normal operation the red push button (mushroom shaped) is in the "out" position (not down). When pressed in, it immediately switches off all power and eliminates any risk of laser irradiation. The button must be released by turning clockwise to the ON position to restart the system and return to "STANDBY" status.
Laser Selection Button	Once the Emergency Laser Stop switch is in the ON position, the main switch located behind the unit is switched on, and the interlock is closed (where applicable): the treatment mode can be selected by turning the keyswitch to the YAG or SLT position. Once the keyswitch is turned on the YAG or SLT position: the OPTIMIS FUSION laser system interface displays (after a start up automatic procedure) the welcome screen that corresponds to the selected mode (YAG or SLT).
Laser READY / STANDBY indicator	Once the treatment mode has been selected by turning the keyswitch to the YAG or SLT position: the system performs an autotests sequence and an initialisation procedure. Once completed, : the YAG or SLT treatment screen is displayed with the laser in STANDBY mode by default (GREEN LED is turned ON). The READY mode can now be selected by pressing the READY/STANDBY button (located on the LCD control module). Pressing on the READY/STANDBY button allows the user to switch the laser from STANDBY to READY. The green LED (STANDBY) turns off and the yellow LED (READY) switches ON. The system must thus be manually switched to READY status before the treatment laser can fire.
Safety remote interlock	**This is a user-installed feature that is highly recommended.** The doorswitch is a magnetically or mechanically triggered switch which closes the electrical circuit when the door is closed (the laser can fire) or which opens the electrical circuit when the door opens (to prevent the laser from firing). The user should provide the doorswitch. The unit is supplied with a bypass plug which allows the user to short-circuit the doorswitch security and thus use the laser without this security..
Safety shutter	Each laser and optical system module is equipped with a spring loaded safety shutter that keeps the treatment laser optical path blocked unless the system is manually switched to READY status: in this case, the safety shutter opens up ans stays open to allows the laser to fire.
Energy deviation warning	The system warns the operator if delivered energy deviates more than ±20% from the set value.
Protective housings	Protective housings on the laser and optical system, as well as the control and display systems, prevent the operator from being inadvertently exposed to laser emission or high voltage shock. The protective housings cannot be removed without tools and must only be opened by QUANTEL MEDICAL personnel or QUANTEL MEDICAL authorized personnel (local distributors)..
Location of controls	All the operator controls are located so that there is no risk to the operator of inadvertent laser exposure.
Ocular filters	The operator viewing port on the laser and optical system module contains a safety filter to limit the exposure level to the operator's eyes to below class 1 limits. Any standard slit lamp viewing accessory can be used with the OPTIMIS FUSION slit lamp without hazard.
FDA and IEC compliance labels	Locations and illustrations of the safety compliance labels are contained in the: OPTIMIS FUSION User Manual: II - Technical information Section 1: Labels
Electrical leakage protection	A medical grade power supply is built into the power supply console. This ensures that the complete instrument including the slit lamp power supply meets the requirements of IEC 601-1 for earth leakage protection.

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3.4 ADDITIONAL SAFETY FEATURES

FEATURE	DESCRIPTION
Memory test	When the OPTIMIS FUSION is first switched on, the system automatically checks the microprocessor memory. If a malfunction is detected an error code is displayed and the laser cannot be switched into READY status. Refer to: OPTIMIS FUSION User Manual: IV - Maintenance Section 10: Appendix – Error codes
Laser power-up test	After the memory test the system automatically performs a self-test program where it confirms the safe and correct operation of the modules. During this procedure the microprocessor fires a serie of test shots with the shutter closed. If this test routine is satisfied, the control module LCD screen displays the normal chosen treatment screen (YAG or SLT). The energy of the last test shot is displayed. If a malfunction is detected, an error code is displayed and the laser cannot fire. Refer to: OPTIMIS FUSION User Manual: IV - Maintenance Section 10: Appendix – Error codes
Treatment mode	At the end of the self-test routine and initialization process the control module automatically displays the selected treatment screen (YAG or SLT).
STANDBY status	At the end of the self-test routine and initialization process the control module automatically enters STANDBY status. In this state the aiming beam is activated and all the controls function allowing the user to adjust treatment parameters can be selected, however the treatment laser is disabled and the laser fire switch will not function. STANDBY status eliminates the risk of accidental treatment beam activation during patient set up. To enable the treatment laser to function, it is necessary to select READY so that the laser can fire. Note: There is a delay of two seconds after READY is selected before the laser can be fired.
Shutter monitor	A dual sensor shutter monitor checks the correct opening and closing of the shutter. In the event of a shutter malfunction, the laser fire switch is disabled and an error code is displayed in the LCD screen on the control module. Refer to: OPTIMIS FUSION User Manual: IV - Maintenance Section 10: Appendix – Error codes
Automatic test fire	Every time an energy setting is changed, either the energy selection or the number of pulses, an automatic test fire occurs. During this test fire, the shutter remains closed so there is no risk of exposing the patient or operator to laser radiation. After a test fire, the resultant energy is shown in the LCD screen on the control module.
Reset after power failure	When power is restored after a power failure, the system will restart and will be in STANDBY status.
Fault conditions	If the system detects a fault during operation, an error code is displayed on the control module LCD. Warnings may be cleared by the operator, while errors result in automatic system shut down. Refer to: OPTIMIS FUSION User Manual: IV - Maintenance Section 10: Appendix – Error codes

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3.5 LASER SAFETY AND NOHD

3.5.1 ~~SAFETY EYEWEAR~~ YAG LASER EMISSION WARNING (1064 nm)

~~Safety glasses or filters must protect the eyes from the emitted wavelength (spectral response) and should therefore have a high optical density at the emitted wavelength:~~

~~✓ Safety goggles or masks are required for anyone present at a treatment session.~~

~~✓ All terminals (including slit lamp accessories such as camera adaptors and co-observation tubes) must be equipped with filters that guarantee eye protection to the operator. Protection at an appropriate Optical Density (OD) must also be provided for the eye that is not directly viewing through the accessory.~~

WARNING: **Class IIIb (3B) laser product: avoid direct exposure to beam.**

Viewing through all slit lamp optical accessories including camera adaptors and co- observation tubes is safe for the viewing eye because the built-in filter provides protection. Protection at an OD of at least 4 @ 1064 nm must be provided for the eye that is not directly viewing through the accessory.

All other persons attending the procedure (except the patient being treated) must wear safety glasses, goggles or masks designed to prevent transmission of 1064 nm wavelength laser light (optical density (OD) 4 @ 1064 nm).

Safety glasses or safety filters providing protection from other wavelengths may not offer any protection from 1064 nm wavelength and should not be used. For users who must comply with EN207, the safety eyewear must have a protection class of L4.

WARNING: Appropriate safety glasses should be available before accessing the treatment room. Any treatment room window or opening should be protected.

WARNING: QUANTEL MEDICAL recommends the use of safety interlocks and warning lamps adapted to the treatment area.

WARNING: Any reflective instrument should be avoided. All room surfaces should be matt finished to prevent any potential laser light reflection.

WARNING: Avoid staring into the aiming beam unless under controlled conditions. However, damage to the retina from the aiming beam is most improbable.

The safety eyewear requirement is based on the Maximum Permissible Exposure (**MPE**), the Nominal Ocular Hazard Distance (**NOHD**) and the Optical Density (**OD**).

For additional information, please refer to the standard: **ANSI Z136.1-1993, ANSI Z136.3-1996**, or European Standard **EN 60825: 1992**, Appendix A.

The following formula has been used to calculate the NOHD for the worst case scenario for the 1064nm laser part of the OPTIMIS FUSION unit.

$$DNRO = \frac{\sqrt{Pf \cdot (4 \cdot Po / (3{,}14 \cdot E_{EMP}))} - Ø}{\cdot}$$

Where:
- **Ø:** beam waist diameter;
- **z:** distance between the laser system and the beam waist;
- **a:** full angle beam divergence;
- **Po:** maximum laser power available;
- **Pf:** profile correction factor;
- E_{MPE}: Maximum Permissible Exposure, in power density units (power per unit area).
- **NOHD:** Nominal Ocular Hazard Distance (measured from laser aperture) the distance required to reduce the power density to the MPE.

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Parameters:

Ø	=	0.01 mm	
Po	=	2.5 10^6 W	EMPE = 6.678 10^5 W/m²
Pf	=	1	NOHD = 7.82 m
a	=	0.279 rad	

Safety Eyewear:

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

$$OD = - LOG (E_{MPE} / Fluence) = 3.16$$

Where Fluence = 1162.82 J/m² (taking into account the pupil diameter of 7 mm)

WARNING: For a maximum of security, the safety eyewear must have a protection class of:

L4 @ 1064nm (EN 207 Standard).

3.5.2 ~~SAFETY EYEWEAR~~ SLT LASER EMISSION WARNING (532 nm)

~~3.5.2.1 OPTIMIS FUSION WITH 1064NM LASER SELECTION~~

~~3.5.2.2 OPTIMIS FUSION WITH 1064NM LASER SELECTION~~

WARNING: **Class IIIb (3B) laser product: avoid direct exposure to beam.**

The operator is protected from hazard while in the normal operating position because the instrument is fitted with protective infrared absorption filters. All other persons attending the procedure (except the patient being treated) must wear safety glasses, goggles or masks designed to prevent transmission of 532 nm wavelength laser light (optical density (OD) 5 @ 532 nm).

Viewing through all slit lamp optical accessories including camera adaptors and co- observation tubes is safe for the viewing eye because the built-in filter provides protection. Protection at an OD of at least 5 @ 532 nm must be provided for the eye that is not directly viewing through the accessory.

Safety glasses or safety filters providing protection from other wavelengths may not offer any protection from 532nm wavelength and should not be used. For users who must comply with EN207, the safety eyewear must have a protection class of L5.

WARNING: Appropriate safety glasses should be available before accessing the treatment room. Any treatment room window or opening should be protected.

WARNING: QUANTEL MEDICAL recommends the use of safety interlocks and warning lamps adapted to the treatment area.

WARNING: Any reflective instrument should be avoided. All room surfaces should be matt finished to prevent any potential laser light reflection.

WARNING: Avoid staring into the aiming beam unless under controlled conditions. However, damage to the retina from the aiming beam is most improbable.

The safety eyewear requirement is based on the Maximum Permissible Exposure (**MPE**), the Nominal Ocular Hazard Distance (**NOHD**) and the Optical Density (**OD**).

For additional information, please refer to the standard: **ANSI Z136.1-1993, ANSI Z136.3-1996**, or European Standard **EN 60825: 1992,** Appendix A.

The following formula has been used to calculate the NOHD for the worst case scenario for the 532nm laser part of the OPTIMIS FUSION unit.

$$DNRO = \frac{\sqrt{Pf \cdot (4 \cdot Po / (3{,}14 \cdot E_{EMP}))} - Ø}{\cdot}$$

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Where: **Ø:** beam waist diameter;
z: distance between the laser system and the beam waist;
a: full angle beam divergence;
Po: maximum laser power available;
Pf: profile correction factor;
E_{MPE}: Maximum Permissible Exposure, in power density units (power per unit area).
NOHD: Nominal Ocular Hazard Distance (measured from laser aperture) the distance required to reduce the power density to the MPE.

Parameters:				
	Ø	=	0.4 mm	
	Po	=	$5\ 10^5$ W	**EMPE = 1.56 10^6 W/m²**
	Pf	=	1	**NOHD = 193 m**
	a	=	0.0104 rad	

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

$$OD = -\ LOG\ (E_{MPE} / Fluence) = 4.92$$

Where Fluence = 1299.88 J/m² (taking into account the pupil diameter of 7 mm)

WARNING: For a maximum of security, the safety eyewear must have a protection class of:
L5 @ 532nm (EN 207 Standard).

3.6 PRECAUTION TO TAKE CONCERNING WASTES AND ELIMINATION OF DEVICE AND ACCESSORIES

Product category: This product complies with the WEEE Directive (2012/19/UE) marking requirements. The FUSION is an electrical / electronic product and must not be discarded with domestic household waste

Do not dispose with domestic household wastes!

With reference to the equipment types in the WEEE Directive annex I,
this product is classed as category 8 among the "Medical devices (with the exception of all implanted and infected products)".
To dispose completely of the device and its accessories,
contact QUANTEL MEDICAL.

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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL

II – Technical information

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MAY 2014

2013 CE 0459

Directive 93/42/EEC

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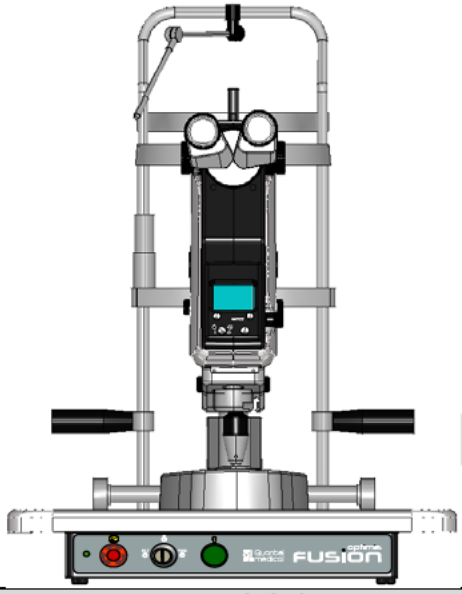
1 LABELS

1.1 FRONT VIEW



Réf.	Label	
	FRONT label: Situated on the front panel of the laser console.	
		"OFF" for a part of equipment. **IEC 60417 - 5265**
		Stand-by or preparatory state for a part of equipment. **IEC 60417 - 5266**
		EMERGENCY STOP label: Situated next to the red emergency stop button.
		LAMP GENERATOR BOOST label: Situated next to the green push button button.

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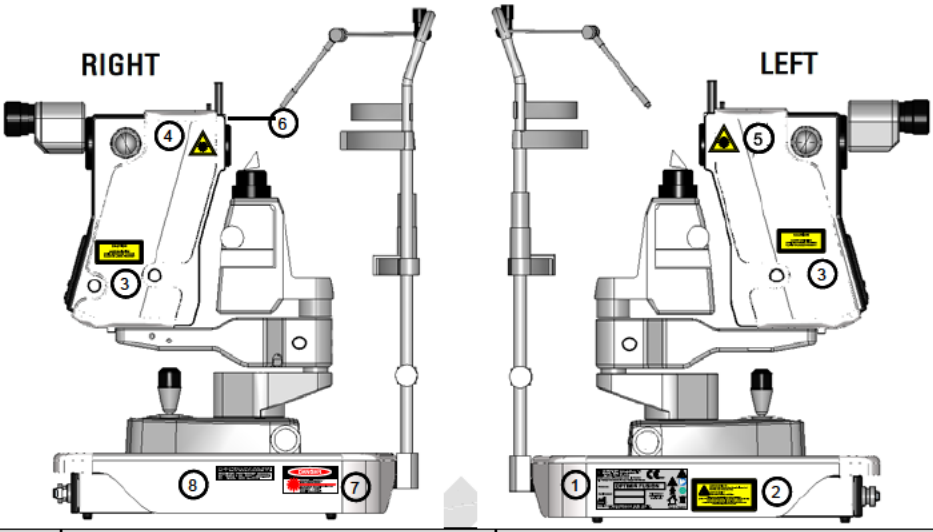
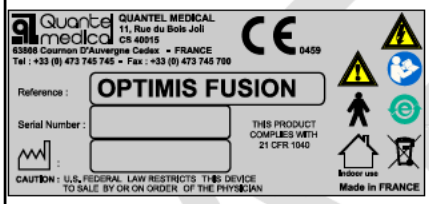
1.2 RIGHT / LEFT VIEWS



Réf.	Label	Description
1		**IDENTIFICATION LABEL:** Contains the following information:
		Protection against electrical shocks: the applied parts are classified as '**B Type**'. The accessible conductive parts are connected to ground. **IEC 60417-5840**
		IEC protection class: "**Class I**" - Main insulation. Accessible conductive parts are connected to ground.
		IP 20: Protection from solid substances (Diameter > 12,5mm).
		Refer to the instruction manual/ booklet. **ISO 7010-M002**
		For indoor use only. **IEC 60417-5957**
		Electrical/electronic equipment in accordance with the Directive 2012/19/UE (WEEE) Do not dispose with domestic household wastes. **EN 50419**
		GENERAL WARNING SIGN: ISO 7010-W001 General
		This sign specifies the manufacturing date indication. **ISO 7000-2497**
		HIGH VOLTAGE WARNING: High voltage on the connector indicated by this warning sign
		RoHs SIGN: Restriction of Hazardous Substances.

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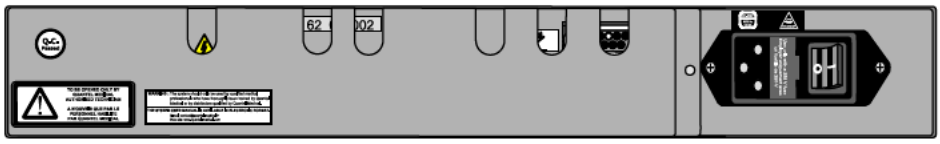
Réf.	Label	Description
2	LASER CLASS 4b / 3B Nd:YAG Laser: 1064nm 30mJ Max. (3 pulses x 4ns) Nd:YAG Laser: 532nm 2mJ Max LASER CLASS 1 / 2 Diode Laser: 635nm, <1mW Max VISIBLE AND / OR INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT per IEC 60825-1:2007 + AC1:2008 Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50, dated June 24, 2007	**LASER RADIATIONS WARNING LABEL:** With treatment and aiming beam wavelengths and powers specifications.
3	CAUTION LASER RADIATION AVOID EXPOSURE TO BEAM CLASS 3B LASER PRODUCT	**INTERNAL RADIATION LABEL:** Indicates existing laser radiations inside the apparatus.
4		**RIGHT LASER OUTPUT LABEL:** Laser radiations warning label: located next to the laser radiation output
5		**LEFT LASER OUTPUT LABEL:** Laser radiations warning label: located next to the laser radiation output
6	LASER APERTURE	**LASER OUTPUT:** Indicates that a laser beam is emitted from this output
7	DANGER LASER RADIATION WHEN OPEN Avoid eye or skin exposure to direct or scattered radiation Nd:Yag 1064 nm 30 mJ Max. (3 pulses 4 ns) Nd:Yag 532 nm 2 mJ Max. Diode 635 nm 1 mW Max. CLASS 4b LASER PRODUCT	**LASER RADIATIONS WARNING LABEL FOR US:** With treatment and aiming beam wavelengths and powers specifications.
8	CAUTION : FEDERAL US LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR AN OPTOMETRIST LICENCED BY THE LAW OF THE STATE IN WHICH HE PRACTISES TO USE OR ORDER THE USE OF THIS DEVICE DANGER : EXPLOSION HAZARD. DO NOT USE IN PRESENCE OF FLAMMABLE ANESTETICS OR IN OXYGEN-RICH ATMOSPHERE. CAUTION : ELECTRIC SHOCK HAZARD. DO NOT OPEN. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.	**FEDERAL US LAW LABEL**

1.3 BACK PANEL VIEWS

1.3.1 BACK PANEL LABELS WITH REAR COVER PLATE



1	TO BE OPENED ONLY BY QUANTEL MEDICAL AUTHORIZED TECHNICIAN A N'OUVRIR QUE PAR LE PERSONNEL HABILITE PAR QUANTEL MEDICAL	**SERVICING LABEL :** Indicates that only authorized technician can open the unit.
2	WARNING : The system should only be used by qualified medical professionals who have thoroughly been trained by Quantel Medical or by distributors qualified by Quantel Medical. THE SYSTEM USER MANUAL IS AVAILABLE IN ELECTRONIC FORMAT. E-mail: contact@quantel-medical.fr Web site: www.quantel-medical.com	This label specifies that the User Manual is available in electronic format: **COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices**

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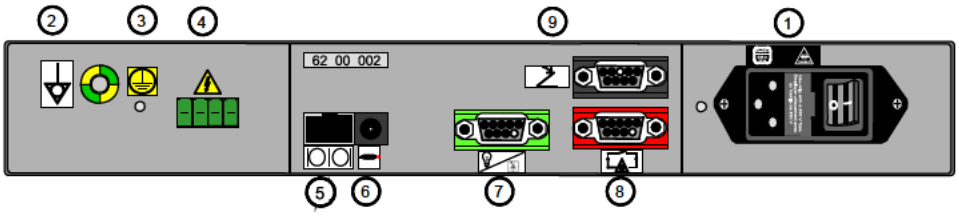
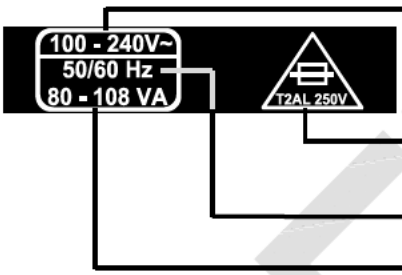
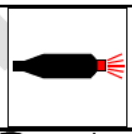
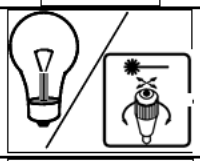
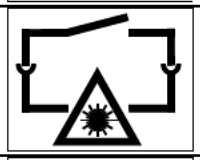
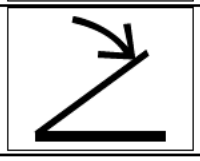
1.3.2 BACK PANEL LABELS (WITHOUT REAR COVER PLATE)



Réf.	Label	Description
1		**FUSES AND VOLTAGES LABEL:** With power supply specifications
2		**EQUIPOTENTIALITY CONNECTOR LABEL:** Indicates the equipotentiality point connection used to connect interfaces which require a common earth.
3		**GROUND LABEL:** Indicates the ground connection
4		**HIGH VOLTAGE WARNING LABEL:** Situated next to the connector on which a high voltage could be present
5		**COMMUNICATION PORT LABEL:** Indicates the communication port between laser console and laser head.
6		**FIXATION LED LABEL:** Indicates the power supply connector of the fixation LED.
7		**LAMP / JOYSTICK PORT LABEL:** Indicates the generator lamp supplying and joystick control port.
8		**DOORSWITCH CONNECTOR LABEL:** Indicates connector of the doorswitch.
9		**FOOTSWITCH CONNECTOR LABEL:** Indicates the connector of the footswitch.

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2 TECHNICAL SPECIFICATIONS

2.1 SYSTEM SPECIFICATIONS

PARAMETER	DETAILS
Table dimensions :	
Table height :	Max: 38 in (960 mm) Min: 28 in (708 mm)
Table width :	Standard stand: 24 in (605 mm) Wheelchair accessible stand: 31 in (790 mm)
Table depth :	17 in (435 mm)
Top of chin rest :	Max: 57 in (1440 mm) Min: 47 in (1190 mm)
Weight	133 lb (60kg) unpacked 180 lb (84 kg) packed
Laser control system	Microprocessor and programmable logic arrays
Cooling	Air convection

2.2 CLASSIFICATION

Protective class	**I** (Device connected to ground)
Type	**B** (Protection against electrical shocks)
Protection degree	**IP20** (Protection from solid substances: Ø>12,5mm)
Operation	**Continuous** with short-time loading
Applied part	**Chinrest**

2.3 YAG TREATMENT LASER SPECIFICATIONS

PARAMETER	DETAILS
Laser class	Class **IIIb (3B)**
Laser source	Q-Switched Nd: YAG photodisruptor laser
Wavelength	1064 nanometers (nm)
Energy settings	0.3 mJ to at least 10 mJ continuously variable
Maximum energy	30 mJ at triple pulse setting
Pulse duration	4 nanoseconds +4/-0 ns
Pulse setting	1, 2 or 3 pulses per shot ; pulse separation of 20 microseconds ± 20%
Repeat mode (max)	2.0 Hz single pulse
Treatment spot size	10 microns (84% energy in diameter) 8 microns FWHM
Beam divergence	16 degrees +0°/ -2° full cone angle
Laser safety filters	Total filtering OD 5@ 1064 nm
Nominal Ocular Hazard Distance (NOHD)	25.6 Feets (7.8 meters)

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2.4 SLT TREATMENT LASER SPECIFICATIONS

PARAMETER	DETAILS
Laser class	Class IIIb (3B)
Laser source	Q-Switched frequency doubled Nd : YAG laser
Wavelength	532 nanometers (nm)
Energy settings	0.3 mJ to at 2 mJ continuously variable
Pulse duration	4 nanoseconds +4/-0 ns
Pulse setting	1 pulse per shot
Maximum repetition rate (manual)	2.5 Hz ± 20%
Treatment spot size	400 microns ± 10% (84% included energy)
Beam divergence	< 3 degrees (84% included energy)
Laser safety filters	Total filtering OD 5@ 532 nm
Nominal Ocular Hazard Distance (NOHD)	633 Feets (193 meters)

2.5 AIMING LASERS SPECIFICATIONS

PARAMETER	DETAILS
Type	Semi conductor laser diode
Wavelength	635 ±10 nanometers (nm)
Laser class	Class II (2)
Operation	CW (continuous wave)
Power	< 1 mW, continuously variable

2.6 SLIT LAMP DELIVERY SYSTEM

PARAMETER	DETAILS
Type	Galilean stereoscopic microscope with converging optics
Objective lens	1,25 x
Eyepiece lens	12.5 x, dioptre adjustable in range ± 5 D
Total magnification	16 x (12.5 x eyepiece)
Magnification changer	3 positions, removable
Interpupillary distance adjustment	1.9 to 3.1 in (48,5 - 80 mm)
Working distance	3.1 in (80 mm)
Focal length	3.7 in (94 mm)
Chin rest	Adjustable, vertical travel 3.7 in (70 mm)

PARAMETER	DETAILS
Slit lamp source	
Slit width	0 to ½ in (0 to 14 mm)
Illumination view field	0.2 mm, 5.5 mm, 9 mm, 14 mm, continuously variable
Slit rotation	180 degrees
Illumination angle	180 degrees at horizontal plane (90 degrees for right/left)
Filters	Cobalt-blue,
Bulb	LED, 6 V, 20 W pre-centered bulb
Cross slide table	
Vertical adjustment of binocular arm	1.2 in (30 mm), by rotation of joystick
Fine horizontal movement	By tilting joystick lever, fine movement of 7 mm.
Coarse horizontal movement	By moving the slit lamp base, coarse movement of 4.5 in (115 mm) longitudinal and 4.3 in (110 mm) lateral travel.

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2.7 POWER SUPPLIES

2.7.1 LASER POWER SUPPLY

PARAMETERS	DETAILS
Supply voltage	100–120 VAC or 220–240 VAC
Supply Frequency	50/60 Hz
Supply power	80VA@100V-108VA@240V
Main fuses	2 A, 250 V
Internal fuses	Internal fuses are not user-accessible. Contact your Quantel Medical Distributor if these fuses need replacing
Schok protection	Class 1, type B (IEC 601-1 6.8.1) *Type B equipment provides protection against electric shock by limiting the leakage current and by the provision of a protective earth connection.*

2.7.2 STAND COLUMN (OPTION) POWER SUPPLY

PARAMETERS	DETAILS
Supply voltage	110 VAC or 230 VAC
Supply Frequency	50/60 Hz
Supply power	400VA@110V - 800VA@230V
Main fuses	6.3 A, 250 V
Schok protection	Class 1, type B (IEC 601-1 6.8.1) *Type B equipment provides protection against electric shock by limiting the leakage current and by the provision of a protective earth connection.*

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2.8 STANDARDS COMPLIANCE

The OPTIMIS FUSION laser complies with the following regulatory and technical standards:

Standards	Descriptions
21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser Notice No.50, dated July 26, 2001.	Performance standard for light-emitting products.
IEC 60 601-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.
IEC 60 601-1-1	Medical electrical equipment - Part 1: General requirements for safety - 1: Collateral standard: safety requirements for medical electrical systems.
IEC 60 601-1-2	Medical electrical equipment - Part 1-2:General requirements for safety - Collateral standard: electromagnetic compatibility - requirements and tests.
IEC 60 601-1-4	Medical electrical equipment - Part 1: General requirements for safety 4. Collateral standard: programmable electrical medical systems.
IEC 60 601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: usability.
IEC 60 601-2-22	Medical electrical equipment - Part 2-22: particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60 529	Degrees of protection provided by enclosure (IP code).
IEC 60 825-1	Safety of laser products - Part 1: equipment classification and requirements.
IEC 62 304	Medical device software - Software life-cycle processes (IEC 62A/474/CDV).
ISO 14 971	Medical devices - Application of risk management to medical devices (ISO/DIS 14971).
93/42/EEC	European Medical Device directive.
IEC 62 366	Medical devices - Application of usability engineering to medical devices

WARNING: **All other devices used in conjunction with the OPTIMIS FUSION using power supplies other than those provided for it must be conformed to the IEC standard 60 601-1 (electric compatibility).**

WARNING: **All other devices used in the same room as the OPTIMIS FUSION must be conformed to the IEC standard 60 601-1-2 (electromagnetic compatibility).**

2.9 ENVIRONMENTAL CONDITIONS

The temperature of the room where the device is operated must be within the following range:

10°C (50°F) < **T°** < **35°C** (95°F)

The relative humidity without condensation must not exceed:

90%

The laser storage and shipping temperature must be within the following range:

-20°C (-4°F) < **T°** < **70°C** (158°F)

Maximum operating altitude: 3000m (about 9842 ft).

NOTE: This device is latex free.

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3 OPTIMIS FUSION EMC DATA AND GUIDELINES

WARNING: Medical electrical equipment needs special precautions regarding EMC. The following EMC guidelines must be observed during installation and commissioning of the OPTIMIS FUSION.

WARNING: Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The OPTIMIS FUSION is intended for use in the electromagnetic environment specified below. The operator of the OPTIMIS FUSION has to make sure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - Guidance
RF emission acc. to EN 55011	Group 1	The OPTIMIS FUSION uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to impair nearby electronic equipment.
RF emissions acc. to EN 55011	Class B	The OPTIMIS FUSION is suitable in all establishments including those in living areas and those directly connected to the public low voltage power supply network that also supplies buildings used for living.
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions acc. to IEC 61000-3-3	Complies	

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Guidance and manufacturer declaration – electromagnetic immunity			
The OPTIMIS FUSION is intended for use in the electromagnetic environment specified below. The operator of the OPTIMIS FUSION has to ensure that it is used in such an environment.			
CEI 60601 test level	CEI 60601 test level	CEI 60601 test level	Electromagnetic environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the OPTIMIS FUSION, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF disturbances according to IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	10 V	$d = 0{,}35\sqrt{P}$
Radiated RF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	$d = 1{,}2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ for 800 MHz to 2,5 GHz
			Where *P* is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. NOTE 2: This guidance may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strength from fixed transmitters, such as base stations for radio (Cellular / cordless) 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 device OPTIMIS FUSION is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorientation or relocating the OPTIMIS FUSION. In case unusual performance is witnessed, additional measures may be required such as change of orientation or location of the OPTIMIS FUSION. [b] Field strength should be less than 10 V/m in the range between 150 kHz and 80 MHz			

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Recommended separation distances between portable and mobile RF communications equipment and the OPTIMIS FUSION			
The OPTIMIS FUSION is intended for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The OPTIMIS FUSION user can help prevent electromagnetic interference by maintaining a minimal distance between portable and mobile RF communications equipment (transmitters) and the OPTIMIS FUSION as recommended below, according to the maximum output power of the communications equipment.			
Maximum transmitter power output (W)	Separation distance according to the transmitter's frequency (m)		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5GHz $d = 2{,}3\sqrt{P}$
0,01	0,035	0.12	0.23
0,1	0.11	0.38	0.73
1	0.35	1.2	2.3
10	1.1	3.8	7.3
100	3.5	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: Between 80 MHz and 800 MHz, separation distance for the highest 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.			

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Guidance and manufacturer declaration – electromagnetic immunity			
The OPTIMIS FUSION is intended for use in the electromagnetic environment specified below. The operator of the OPTIMIS FUSION has to ensure that it is used in such an environment.			
Immunity Test	CEI 60601 test level	Compliance level	Electromagnetic environment - Guidance
Immunity Test	CEI 60601 test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients/ burst acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment.
Surge acc. to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment.
Voltage dips, short-term interruptions and voltage variations on power supply input lines acc. to 61000-4-11	<5% during 0,5 period 40% during 5 periods 70% during 25 periods <5% during 5 s	<5% during 0,5 period 40% during 5 periods 70% during 25 periods <5% during 5 s	The quality of the supply voltage should correspond to one characteristic for a typical commercial or hospital environment. If the user of the OPTIMIS FUSION requires a continuous function of the appliance also during interruptions of the power supply, it is recommended to supply the OPTIMIS FUSION out of an uninterruptible power supply or a battery
Power frequency (50/60Hz) magnetic fields acc. to IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic for commercial or hospital environments

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4 INSTALLATION

WARNING: No modification of this equipment is allowed.

4.1 INSTALLATION REQUIREMENTS

4.1.1 OPERATING ROOM

The apparatus should be positioned in such way that the laser beam emerging from the terminal (Slit lamp for example) can under no circumstances be directed toward an opening (door, window) or any kind of light reflecting materials. The instrument must be installed in a dust free room with no wall-to-wall carpet or rug. When not operating, the system should be covered to protect the optical lens from dust.

4.1.2 ELECTRICAL REQUITEMENTS

The OPTIMIS FUSION is equipped with a standard power plug at the end of its line cord. The user is responsible for the installation of an adequate power outlet prior to the laser system installation.

Only connect the laser system to a grounded single phase power socket:

- ✓ Voltage: 100 to 240 Vac.
- ✓ Frequency: 50 / 60 Hz.
- ✓ Minimum current: 2 A.

WARNING: Protection earth impedance: Ensure that the socket is properly earthed.

WARNING: Do not connect the laser power plug (3 pin adaptor) on an ungrounded power socket (2-pin).

WARNING: Never connect the laser to a multiple-plug outlet or power strip.

WARNING: Use two different power outlets:

- ✓ One for the OPTIMIS FUSION laser.
- ✓ Another one for the table.

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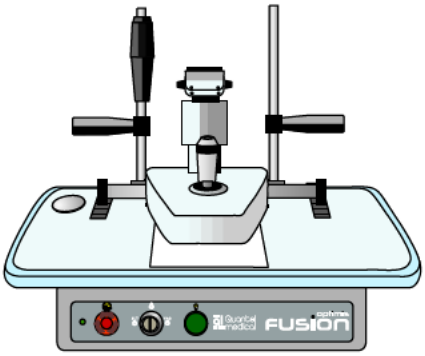
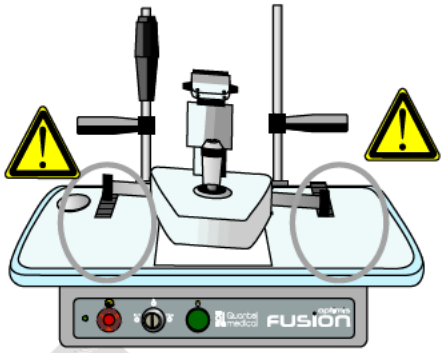
4.2 MOUNTING THE LASER

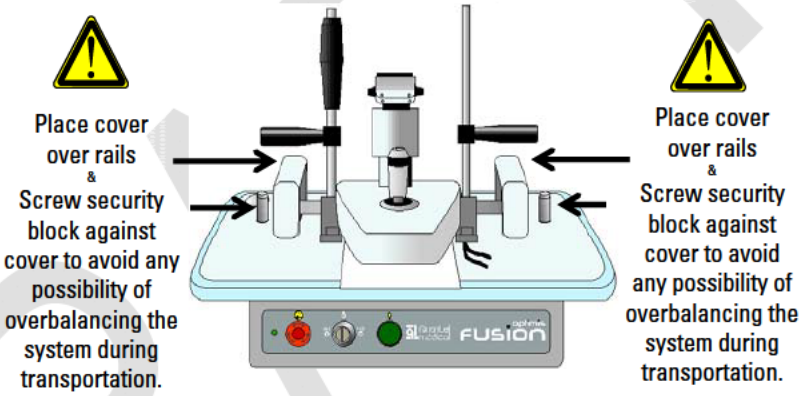
4.2.1 SLIT LAMP POSITIONING



Place the slit lamp on the table.
Position the gears correctly on the rack of the table to avoid malfunction of the cross-slide table.



Place both gear covers sliding it under the rail guides of the cross slide table.



Make certain that bottom sides (viewed from operator) of the cross-slide table are parallel to the side-lines of white plate. In the opposite case, the table cannot move.

WARNING: In case the covers are not correctly mounted: the laser assembly may be unstable!

4.2.2 LASER MOUNTING ON THE STAND COLUMN (OPTION)

Stand column labeling

Place the assembly laser on the table.
Refer to the installation notice of the stand column for the mounting.

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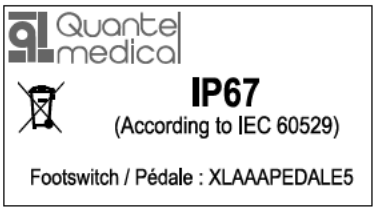
4.2.3 FOOTSWITCH (OPTION)

Footswitch labeling



4.2.4 FUSION LINK (OPTION)

Fusion Link labeling

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4.3 MOVING THE OPTIMIS FUSION EQUIPEMENT

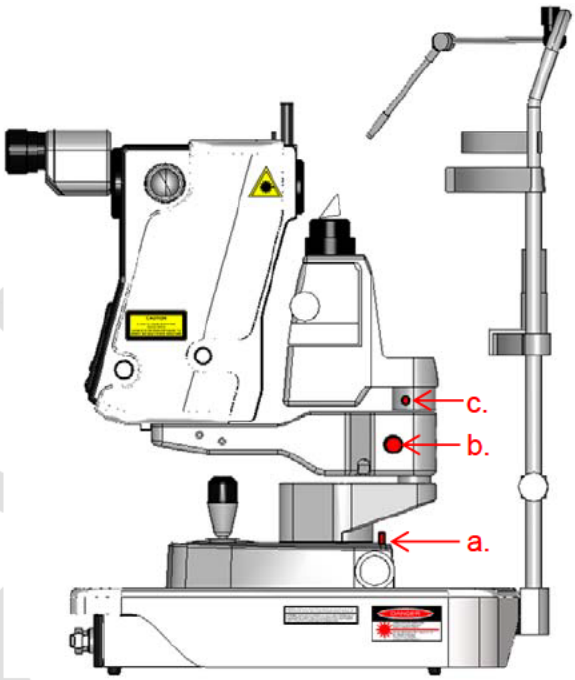
In case there is a need to move the equipement (from a room to an other one for example), follow the procedure below:

1. Select or check the unit is in **"STANDBY"** mode; then, switch off the laser with the key switch; and finally switch off the laser with the main switch.
   Refer to:
   Chapter III – Using the laser system / Section 6: Shutting down the laser system
2. Unplug the power supply cable from the wall socket; Unplug the footswitch cable (when available);
3. Block all laser moving parts as follows:

   a. Turn the button (marked as a.) clockwise to block the main laser assembly from moving left / right / front / back;

   b. Turn the button (marked as b.) clockwise to block the binocular laser head from moving left / right;

   c. Turn the button (marked as c.) clockwise to block the slit lamp movement;



4. Make sure the gear covers are correctly positioned as explained:
   Section 4.2.1: Slit lamp positioning

5. Then, the laser can be moved with caution taking care of the inclination.

NOTE: The mechanical stability is in accordance with the IEC 60601-1 (3rd ed.):
The equipment does not overbalanced when inclined by 10°;

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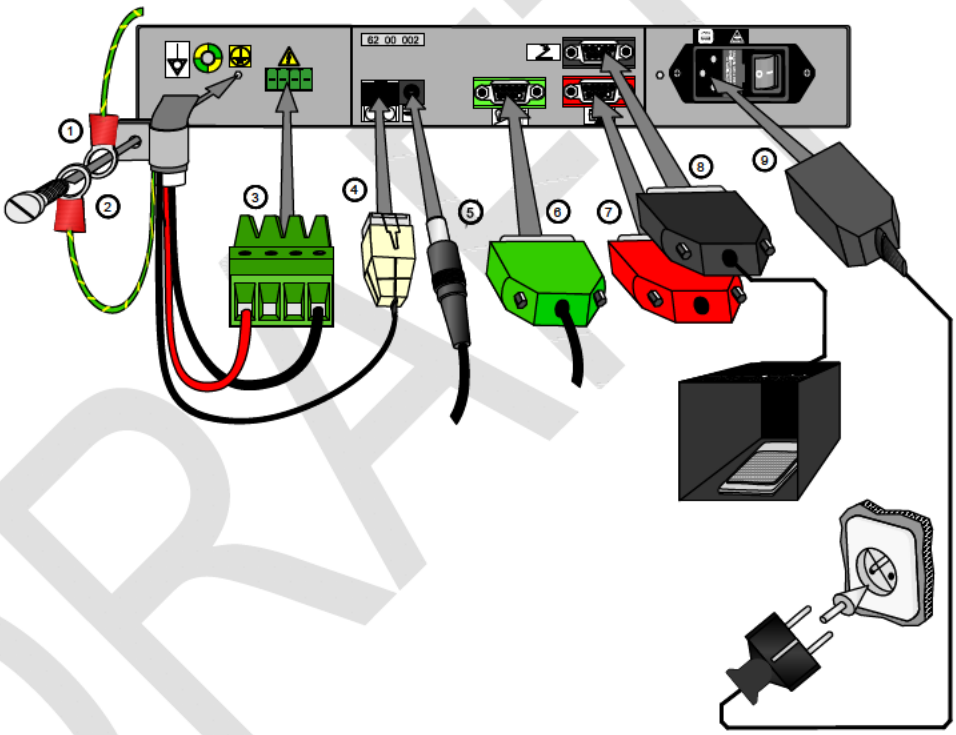
4.4 MOUNTING THE LASER

4.4.1 SLIT LAMP / CONSOLE CONNECTIONS

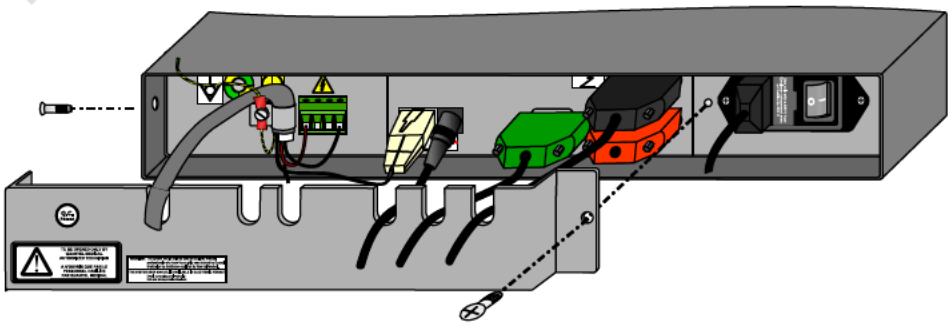
Connect the following cables and remote:

- Chin rest ground cable ①;
- Ground cable ②;
- High voltage cable ③;
- RJ45 cable ④;
- Fixation LED cable ⑤;
- Joystick / lamp cable ⑥;
- Remote ⑦;
- Footswitch cable ⑧;
- Power supply cable ⑨.



CAUTION: **The ground cable of the chinrest must be fixed on the chinrest ground connector of the console with a screw.**

4.4.2 REAR COVER POSITIONING



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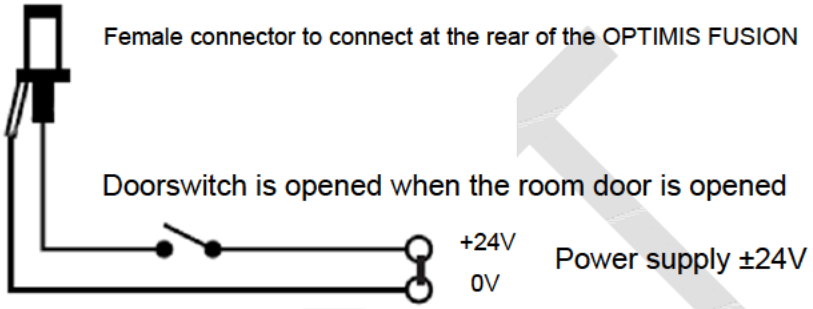
4.5 DOOR SWITCH AND EXERNAL RED LAMP INSTALLATION

The user has to provide the door switch. The door switch may either be magnetically or mechanically triggered: it will close the electrical circuit when the door is closed and open the circuit when the door is opened. The switch (and its wiring) should be chosen to be supplied with: 24 Vac and 500 mA.

If this option is not used, there is no remote connector.



CAUTION: **The connector must be correctly wired because you risk destroying electronic board in OPTIMIS FUSION, if you commutate cables.**

NOTE: **When the door is opened, the laser is turned off, no error message is displayed and the screen is turned off.**

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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL

III – USING the LASER SYSTEM

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2013 CE 0459

Directive 93/42/EEC

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1 SAFETY CHECKS BEFORE OPERATING THE LASER SYSTEM

Carry out the following checks before using the OPTIMIS FUSION laser system:

WARNINGS

- Make sure that all persons attending the laser treatment session (except for the user and patient) wear adequate laser safety glasses. Refer to the OPTIMIS FUSION user manual:
  Chapter I - Regulatory & safety information / Section 3.5: Laser safety & NOHD
- Check that the laser emergency stop button is in the released position as explained in Section 3.1.1: Emergency stop button)
- Check that the safety interlock, when installed, is connected and the interlock switch is closed.

2 PREPARING THE OPTIMIS FUSION FOR TREATMENT

WARNINGS

Before treatment, check:

- The eyepieces are well adjusted to compensate for variance in individual user's vision (vision should be clear at focal plane).
- The aiming beam spot (adjusted to 200µm) is clear and well defined with the illuminated slit at focal distance. If this not the case, call Quantel Medical Service Department or your local distributor.
- The laser system should be used on test targets before using it on patients.
- Ensure the chinrest and head rest are thoroughly cleaned before positioning the patient behind the slit lamp table.

  Seat the patient behind the slit lamp table: ask him/her to place his/her chin on the chinrest and his/her forehead firmly against the headrest. Adjust the height of the chairs and slit lamp table (dedicated switch) to enable both ophthalmologist and patient to be at ease for the examination.

3 STARTING UP THE SYSTEM

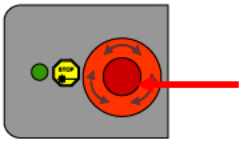
3.1 POWER CONTROL KEYS

The OPTIMIS FUSION laser unit has 3 power supply control keys that can successively be turned on to activate the system:

- Emergency stop button on the front panel (3.1.1.)
- Main switch on the back panel (3.1.2.)
- Key switch on the front panel (3.1.3)

3.1.1 EMERGENCY STOP BUTTON

When the emergency red STOP button at the front of the unit is pressed, all laser functions stop instantly:



The following procedure should be followed to restart the laser system after an "emergency" stop:

1) Press and turn the emergency button clockwise to release it.
2) Turn the key switch to the "OFF" position.
3) Restart the system as usual by turning the key to the "ON" position.

CAUTION

This emergency switch should **ONLY** be used in case of an emergency.

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3.1.2 MAIN SWITCH

The main switch allows the user to supply power to the OPTIMIS FUSION system when it is turned on ("I" position):

The green power supply LED on the front panel lights on and the slit lamp can be turned on pressing on the green push button:

NOTE

As long as the keyswitch is not turned on to the YAG, or SLT position: the OPTIMIS FUSION laser system can be used as a simple observation slit lamp microscope. Indeed, the slit lamp illumination and fixation leds are operating. The illumination generator can then be rotated to the proper angle to provide the desired effect and better visualization.

3.1.3 KEYSWITCH

The keyswitch allows the user to start the laser in YAG or SLT mode or stop the laser:

: ON position	When turning the key to the left ("ON" position for SLT): the laser starts, the system boots up and the LCD screen lights up to display the startup screen for laser treatment in SLT mode. When turning the key to the right ("ON" position for YAG): the laser starts, the system boots up and the LCD screen lights up to display the startup screen for laser treatment in YAG mode.
: OFF position	When turning the key to the "OFF" position: the laser stops. The screen shuts down.

NOTE

The key cannot be removed when the key is on the "ON" position.

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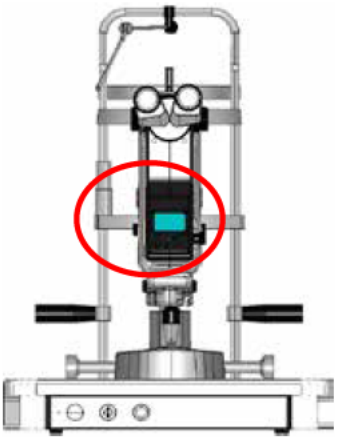
3.2 OPTIMIS FUSION LASER INTERFACE

The OPTIMIS FUSION Central Processing Unit controls the interface between the user and the laser system via the following information :

- Slit lamp inputs /outputs:
  Power switch; Emergency stop, Key switch, Aiming beam power knob, Energy selection knob, Joystick, Optional footswitch, Remote connector for door switch, Laser detection connector (for OPTIMIS FUSION combination to an other delivery system accessory) and buzzer.
- Control module inputs / outputs:
  The OPTIMIS FUSION laser control module is integrated inside the laser main frame, underneath the eyepieces:



It includes:

- A Liquid Control Display (LCD) screen, used to display in real time, the current state of the laser;
- Keypad with buttons to select parameters for treatment such as Burst mode, Focus offset, Reset counter and Laser status (STANDBY / READY). To warn the operator of a new setting: an audible sound is emitted each time a button is pressed.

WARNING

In case of a problem with a critical component: an error message is displayed on the LCD screen: either by a warning message or an error code. To ensure safety: the laser automatically goes back to STANDBY mode (closed shutter).

For more information about error codes and management: refer to the OPTIMIS FUSION User Manual: Section IV – Maintenance

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3.3 OPTIMIS FUSION START UP AUTOMATIC PROCEDURE

Once the keywitch is turned on to the YAG or SLT position: the corresponding OPTIMIS FUSION welcome screen with software version and functioning mode (YAG or SLT) information is displayed on the laser interface screen.

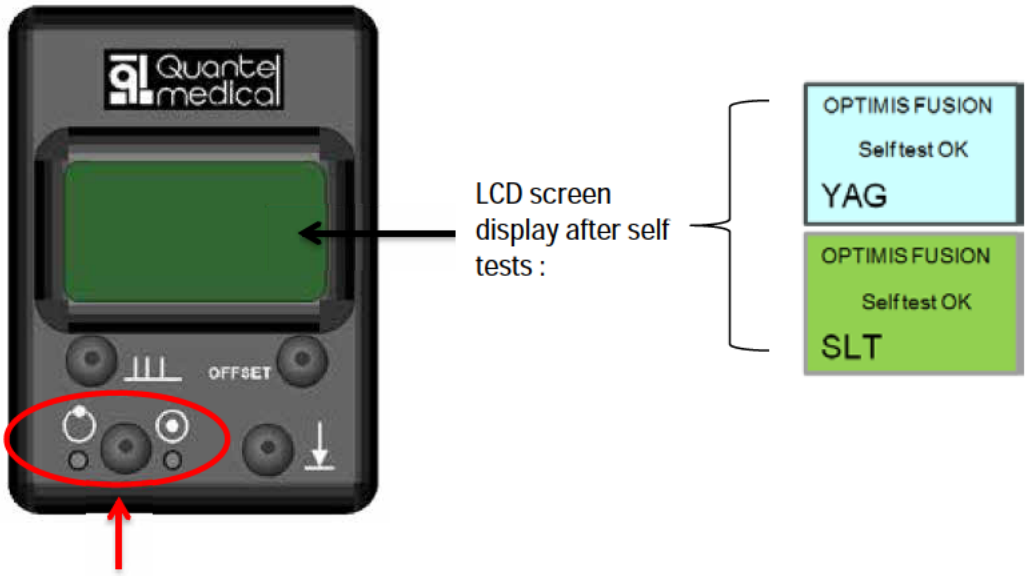
NOTE

In YAG mode, the screen color background is blue, whereas in SLT mode, it is green as shown below:

YAG Wecome screen

SLT Welcome screen

Then, the system performs a sequence of selftests and an initialization procedure. When this is finished: the YAG or SLT treatement screen is displayed with the STANDBY green led turned on by default:



STANDBY status: the STANDBY green led is turned on by default.

The slit lamp is activated and the red laser aiming beam(s) of the selected YAG or SLT laser system is turned on.

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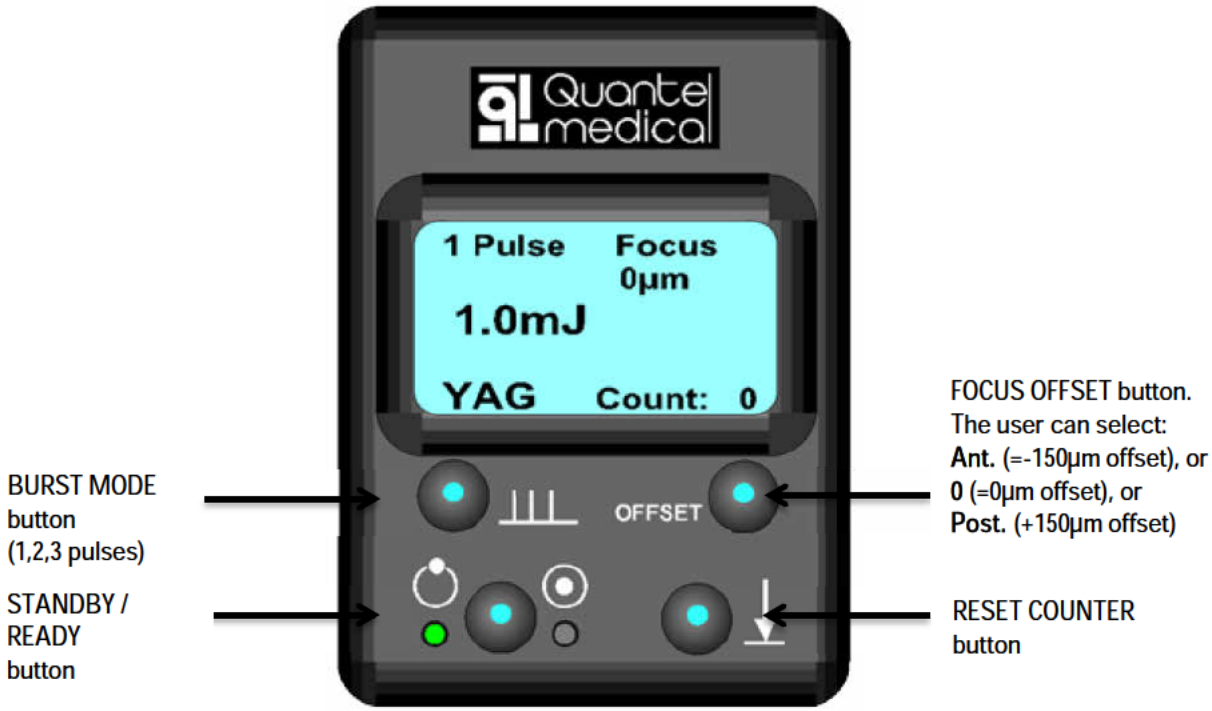
4 USING THE OPTIMIS FUSION YAG LASER FEATURES

Turn the key to the "YAG" position and wait until the self-test and initialization procedure is finished to finally display the OPTIMIS FUSION YAG treatment screen on the control module LCD screen (blue color).

4.1 AVAILABLE SETTINGS ON THE LCD CONTROL MODULE WITH YAG MODE



YAG treatement screen

In YAG mode: all four buttons (illuminated in blue) are active and can be adjusted.

NOTE
By default :

- The energy is adjusted to 1mJ
- The focus is set to 0 (=0µm offset)
- Burst mode is set to 1 pulse
- Counter count is rest to 0

4.1.1 NUMBER OF PULSES SELECTION (BURST MODE BUTTON)

Press the BURST MODE button on the control module LCD screen as many times as required to increase the number of pulses from one pulse to two pulses and then 3 pulses.

NOTE
Pressing one more time on the BURST MODE button allows the user to return to one pulse per burst.

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4.1.2 FOCUS OFFSET SELECTION (FOCUS OFFEST BUTTON)

Press the FOCUS OFFSET button on the control module LCD screen as many times as required to set the focus offset to "**0**" (=0µm offset), then to "**Post.**" (+150µm offset), then to "**Ant.**" (=-150µm offset).

WARNING

When the offset "**Ant.**" (=-150µm offset) is selected: the background LCD screen is changing color and 3 long beeps can be heard to warn the user that the focus is in the anterior chamber.

NOTE

Pressing one more time on the FOCUS OFFSET button allows the user to return to "**0**" (=0µm offset).

4.1.3 RESET COUNTER BUTTON

The OPTIMIS FUSION software displays on the control module LCD screen how many shots have been performed since the laser counter reset.
To reset the counter to zero: press on the RESET COUNTER button.

4.1.4 STANDBY / READY STATUS BUTTON

Press on the STANDBY / READY button to switch the laser from STANDBY to READY mode. The LED changes color (from green to yellow):

Press the "**Stand-by / Ready**" state selection button

Laser state	LED State
STANDBY mode (Default Mode)	
READY Mode	

In READY mode, the OPTIMIS FUSION laser is ready to shoot.

NOTE

- If the user presses the STANDBY/READY button again: the OPTIMIS FUSION laser goes back to STANDBY mode.
- The OPTIMIS FUSION laser goes back to STANDBY mode after 3 minutes of inactivity (a long beep is emitted). When this happens: the YAG mode parameters return to their default value (Energy=1mJ, Focus offset=0µm and Single pulse)

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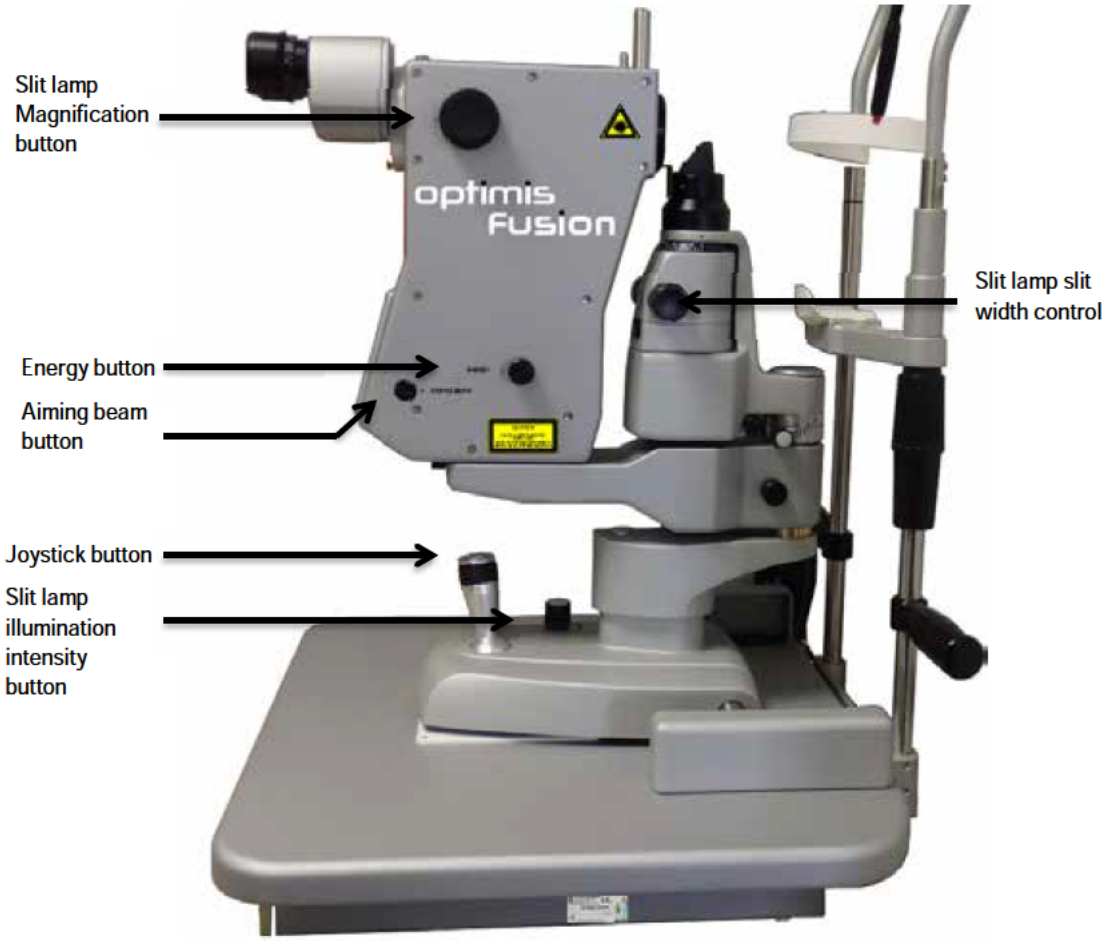
4.2 SLIT LAMP SETTINGS



4.2.1 ENERGY SELECTION BUTTON

Use the Energy knob on each side of the laser head to increase or decrease the energy.

NOTE

A different beep sound is emitted when the user increases the energy, compared as to when it is decreased.

- In single pulse burst mode: the energy can be adjusted from 0.3mJ to 10mJ:

Energy range / mJ	By steps of (Incrementation) / mJ
From 0,3 to 3	0,1
From 3 to 5	0,2
From 5 to 10	0,5

In double pulses burst mode: the energy can be adjusted from 0.6mJ to 18mJ maximum.
In triple pulses burst mode: the energy can be adjusted from 0.9mJ to 25,5mJ maximum.

As a consequence, the OPTIMIS FUSION laser automatically performs a test fire and the energy value is displayed on the control module LCD screen. The displayed energy value is the cumulative energy for all pulses within a burst.

WARNING

- It is advised to adjust the energy as low as possible for treatment.

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4.2.2 AIMING BEAM BUTTON

The laser uses visible red diode laser beams for aiming purposes. The low power diode laser lightbeam splits in two aiming beams focusing in one at focal plane.
Turn the aiming beam button to adjust the aiming beam intensity (turn left to lower the intensity; turn right to increase it).

WARNINGS

- The aiming beams focus is found at the distance where the two red spots merge into a single spot. The OPTIMIS FUSION software will display an error message and will prevent the system firing if one or both of the aiming beam(s) has (have) deviated from the initial position (unfocused aiming beam).
- Use the lowest practicable aiming beam intensity for treatment to protect the patient from possible retinal damage.

NOTE

The aiming beam is suppressed during shooting and for 0.1 second after each pulse for better examination of the burn.

4.2.3 JOYSTICK BUTTON OR OPTIONAL FOOTSWITCH

Each time the joystick button or the optional footswitch is pressed, with the laser satus is in READY mode, the laser fires:

- A beep sound is emitted
- The counter is increased by the number of emitted pulses
- The delivered energy is displayed

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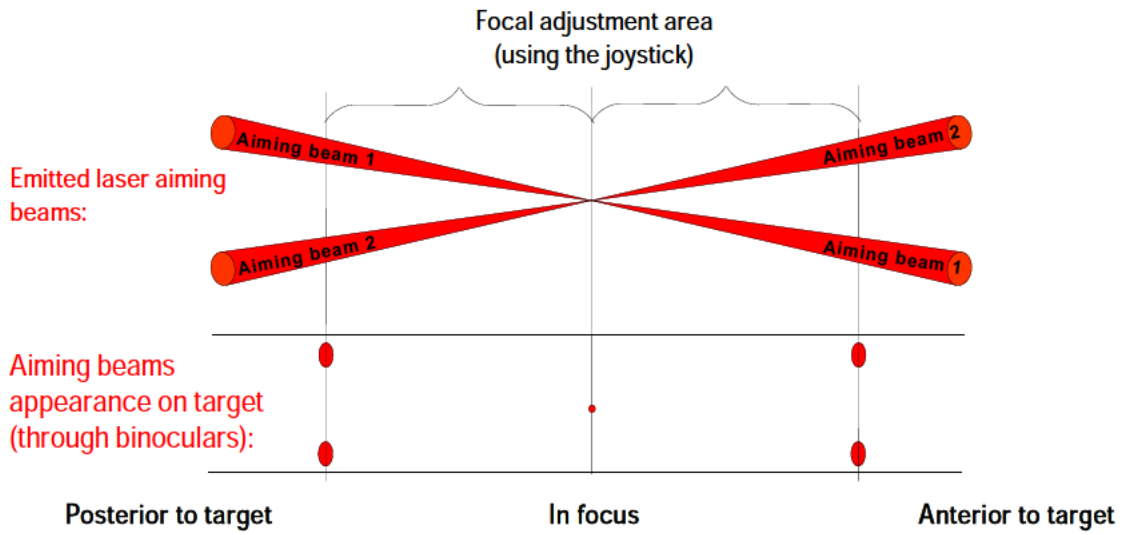
4.3 OPTIMIS FUSION YAG LASER TREATMENT PROCEDURE

1. Pre-conditions:
- The laser system has to be turned on as explained:
  Section 3.1: Power control keys
- The key switch should be turned on the "YAG" position until the "YAG" treatment screen is displayed (blue background).
- The patient is correctly positioned.

2. Use the minimum slit lamp illumination intensity that still provides good visualization. Rotate the slit lamp generator to a position where the illumination allows the best eye depth perception.

3. Adjust the aiming beam intensity to the minimum setting but where it still provides a good spot contrast on the target background as explained:
   Section 4.2.2: Aiming beam button

4. Move the microscope towards the target until the target can be clearly seen (at focal distance). Fine tune the focus with care using the joystick in order to bring the two red aiming beam dots into coincidence:



5. Set the energy as explained:
   Section 4.2.1: Energy selection button
   In general and for safety purposes, the energy for treatment should be set as low as possible, unless experience dictates otherwise.

6. Set the number of pulses and focus offset as explained:
   Section 4.1.1: Number of pulses selection (BURST MODE button)
   Section 4.1.2: Focus offset selection (FOCUS OFFSET button)
   A posterior focus offset greater than "0" (=0µm / min offset position) will reduce the risk of pitting the implanted lens. As the treatment laser energy is increased: it is recommended to select an even higher offset. Indeed, for higher energy settings, the plasma elongates anteriorly along the laser beam axis, which is increasing the risk of pitting the implanted lens;

7. Before firing the laser, make sure:
- The laser parameters are correctly selected and laser is accurately targeted on eye tissue to be treated.
- Press the STANDBY/READY button to put the laser in "READY" mode as explained:
  Section 4.1.4: STANDBY / READY STATUS button
  The orange "READY" led turns ON (whereas the green "STANDBY" led switches OFF).

8. Before starting the treatment procedure: press the RESET COUNTER button as explained:
   Section 4.1.3: RESET COUNTER button

9. Press on the laser fire button: using the joystick button or the optional footswitch if connected.
   Every time the laser fires: a beep can be heard.

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WARNING

The laser system should be used on test targets before using it on patients.

NOTE

Nd:YAG contact lens may be recommended for some treatments for eye stabilization and to minimize the risk of impact on non targetted sites such as cornea and IOL. Since contact lenses alter the energy density at the treatement site: the energy setting should be re-adjusted;

5 USING THE OPTIMIS FUSION SLT LASER FEATURES

Turn the key to the "SLT" position and wait until the self-test and initialization procedure is finished to finally display the OPTIMIS FUSION SLT treatment screen on the control module LCD screen (green color).

5.1 AVAILABLE SETTINGS ON THE CONTROL MODULE WITH SLT MODE

SLT treatement screen

In SLT mode: only two buttons (illuminated in blue) are active and can be adjusted: STANDBY/READY button and RESET COUNTER button. The other two buttons are unactivated.

NOTE

By default :

- The energy is adjusted to 0,6mJ
- Counter count is rest to 0

The **RESET COUNTER button** and **STANDBY/READY button** functions are explained:

- Section 4.1.3: RESET COUNTER button
- Section 4.1.4: STANDBY / READY STATUS button

NOTE

- The OPTIMIS FUSION laser goes back to STANDBY mode after 3 minutes of inactivity (a long beep is emitted). When this happens: the SLT mode Energy parameter returns to its default value (Energy=0,6mJ)

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5.2 SLIT LAMP SETTINGS

5.2.1 ENERGY SELECTION BUTTON

Use the Energy knob on each side of the laser head to increase or decrease the energy as explained:
Section 4.2.1: ENERGY SELECTION BUTTON

The energy can be adjusted from 0.3mJ to 2mJ by steps of (increment) 0,1mJ:

As a consequence, the OPTIMIS FUSION laser automatically performs a test fire and the energy value is displayed on the control module LCD screen.

5.2.2 AIMING BEAM BUTTON

Use the AIMING BEAM knob to increase or decrease the energy as explained:
Section 4.2.2: AIMING BEAM BUTTON

The laser uses a visible red diode laser beam for aiming purposes. This low power diode laser light beam is parfocal with the slit lamp and coaxial to the SLT treatment laser beam.

WARNINGS
Use the lowest practicable aiming beam intensity for treatment to protect the patient from possible retinal damage.

NOTE
The aiming beam is suppressed during shooting and for 0.1 second after each pulse for better examination of the burn.

5.2.3 JOYSTICK BUTTON OR OPTIONAL FOOTSWITCH

Each time the joystick button or the optional footswitch is pressed, with the laser satus is in READY mode, the laser fires:

- A beep sound is emitted
- The counter is increased by the number of emitted pulses
- The delivered energy is displayed

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5.3 OPTIMIS FUSION SLT LASER TREATMENT PROCEDURE

1. Pre-conditions:
- The laser system should be turned on as explained:
  Section 3.1: Power control keys
- The key switch should be turned on the "SLT" position until the "SLT" treatment screen is displayed (green background).
- The patient is correctly positioned.

2. Use the minimum slit lamp illumination intensity that still provides good visualization. Rotate the slit lamp generator to a position where the illumination allows the best eye depth perception.

3. Adjust the aiming beam intensity to the minimum setting but where it still provides a good spot contrast on the target background as explained:
   Section 5.2.2: Aiming beam button

4. Move the microscope towards the target until the target can be clearly seen (at focal distance).

5. Set the energy to the required value for treatment as explained:
   Section 5.2.1: Energy selection button

6. Before firing the laser, make sure:
- The laser parameters are correctly selected and laser is accurately targeted on eye tissue to be treated.
- Press the STANDBY/READY button to put the laser in "READY" mode as explained:
  Section 5.1: Available settings on the control module with SLT mode
  The green "READY" led turns ON (whereas the orange "STANDBY" led switches OFF).

7. Before starting the treatment procedure: press the RESET COUNTER button as explained:
   Section 5.1: Available settings on the control module with SLT mode
8. Press on the laser fire button: using the joystick button or the optional footswitch if connected.
   The OPTIMIS FUSION SLT laser delivers a single pulse at each footswitch depression. Every time the laser fires: the safety shutter operation can be heard. The orange "READY" status LED turns OFF (and green "STANDBY" LED turns ON) for a short time period while the laser recharges. When the orange "READY" LED turns back ON: the laser is ready to fire again.

WARNING
The laser system should be used on test targets before using it on patients.

NOTE
A standard gonioscopy lens with magnifying optics is used to visualize the angle during treatment.

6 SHUTTING DOWN THE LASER SYSTEM

At the end of the treatment:
- Select or check the unit is in "STANDBY" mode.
- Switch off the laser with the key switch and remove the key to prevent unauthorized use of the system (Section 3.1.3: Key switch).
- Switch off the laser with the main switch (Section 3.1.2: Main switch).

NOTE
At the end of the day, place a dust cover on all devices (laser, adaptors and slit lamp).

WARNING
The red emergency stop button (on the front panel) must only be used in case of an emergency situation.

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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL
IV – MAINTENANCE

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1 PREVENTIVE MAINTENANCE

Contact your QUANTEL MEDICAL or your local distributor at least every six months to carry out a preventive maintenance visit to confirm the correct function of your system.

At each six-monthly visit QUANTEL MEDICAL or your local distributor will clean the optics, check the safety filter coatings, and check general performance, alignment and calibration of the system.

At least once a year QUANTEL MEDICAL or your local distributor will fully re-calibrate the system and check ground resistance and earth leakage current (in accordance with IEC 60601-1).

2 CARE AND MAINTENANCE OF THE OPTIMIS FUSION LASER SYSTEM

2.1 CLEANING AND DISINFECTION FOR PATIENT AREAS

The use of the **OPTIMIS FUSION** involves only brief skin contact with the patient, but attention should be given to the possibility of cross-contamination between patients via the patient contact areas of the system. These are the chin rest, headrest and steadying handles.

2.1.1 RESPONSIBILITIES FOR CLEANING AND DISINFECTION

The health care facility where the instrument is to be used is responsible for:

1) Determining the level of cleaning and disinfection of patient contact areas required between patients.
2) Appropriate education and training for staff required to carry out cleaning and disinfection.
3) Ensuring that routine cleaning and disinfection methods used in the facility are compatible with the instrument.
4) Routine cleaning of the entire system.

2.1.2 CLEANING AND DISIFECTION OF PATIENT AREAS

Although cleaning and disinfection procedures and standards within different health care facilities may vary considerably, the following points are provided as general guidelines:

1) Thorough cleaning of all patient contact areas is recommended for each procedure.
2) Disposable chinrest papers can also be attached to the chinrest area and changed between patients.
3) Manual cleaning can be carried out by wiping all contact areas using a suitable liquid cleaning agent which is non-corrosive, non-toxic and low in residue.

2.1.3 CLEANING THE GONIOSCOPY CONTACT LENSES

The contact lenses for use with the **OPTIMIS FUSION** have a special low-reflectivity coating bonded to the lens, and they must therefore be handled carefully.
As soon as a lens is removed from the patient's eye, thoroughly rinse it in cold or warm water to remove salts, mucous and gonioprism solution. Wash in warm water with a few drops of clear dishwashing liquid, then rinse with cool water and blot dry. Dry completely before storing in the case.
To effectively disinfect the lens, soak in a solution of sodium hypochlorite 1,2° chl. for a recommended exposure time of 30 minutes. Rinse thoroughly with cool water and blot dry. Dry completely before storing in the case.

To sterilize, use ethylene oxide gas with aeration not to exceed 125°F (52°C), following the sterilizer manufacturer's recommendation. Remove the lens from the case before sterilizing.

CAUTION:
Do not boil or autoclave a lens. Do not use alcohol, hydrogen peroxide or acetone on a lens, as this will damage it and render it unusable.

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2.2 MAINTENANCE OF THE OPTIMIS FUSION LASER SYSTEM

The QUANTEL MEDICAL OPTIMIS FUSION laser system has been designed to provide trouble-free operation with a minimum of down time. As a result very little user maintenance is required.

There are four routine maintenance tasks that are explained in the next sections:

- External cleaning of the OPTIMIS FUSION system — see Section 2.2.1
- Cleaning the optics — see Section 2.2.2
- Checking YAG aiming beam accuracy — see Section 2.2.3
- Checking SLT aiming beam accuracy — see Section 2.2.4

2.2.1 EXTERNAL CLEANING OF THE OPTIMIS FUSION SYSTEM

WARNING
Ensure that the power is switched off and disconnect AC power before cleaning external surfaces.
All surfaces should be thoroughly dried after cleaning.

Keep the laser system external surfaces clean at any time. Only use a damp cloth and mild detergents for cleaning. Do not use abrasive cleaners such as solvent or alcohol. Make sure the laser system (& slit lamp) is covered with a dust cover when not in use.

2.2.2 CLEANING THE OPTICS

WARNING
Ensure that the power is switched off and disconnect AC power before cleaning the optics.

The laser head objective lens and the oculars must be kept free of dust, fingerprints and other contamination or performance will be compromised. Periodically inspect and clean these optics.

Required equipment:

- Lint free optical tissues (available from a photographic store)
- Cotton swabs
- Pure or AR grade ethanol or methanol

Method:

1) Remove dust from the optics with an appropriate lens brush.
2) Moisten the optical tissue or Q-tip in the solvent and gently wipe it across the optical surfaces in linear strokes. Use a very light pressure to avoid misaligning the mirrors. Do not wipe the mirrors more than one or two times because excess wiping will only redistribute the dirt over the optical surface and cause scratches.
3) Use one tissue or one Q-tip per wipe, then discard and use a fresh one for the next wipe.

CAUTION
In case any scratching is visible do not use the laser system and call QUANTEL MEDICAL or your local distributor.

CAUTION
Never use dry swabs or tissues to clean an optical surface, as this may damage the surface.

In case of any problem when cleaning the optics, contact QUANTEL MEDICAL or your local distributor.

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2.2.3 CHECKING YAG AIMING BEAM ACCURACY

WARNING
Wearing appropriate safety glasses is required for all persons present when the laser is in use.
Ensure there is no refelective surfce behind the target.

The aiming and treatment beam (1064nm) coincidence should be checked on a regular basis: the following procedure should be carried out at least every three months or as considered necessary by the user.

Required material:
Photographic paper (Kodak linagraph direct printer)
Alignment target / focusing bar

Checking procedure:

1. Attach a piece of photographic paper on the alignment target / focusing bar *(See Figure 1)*

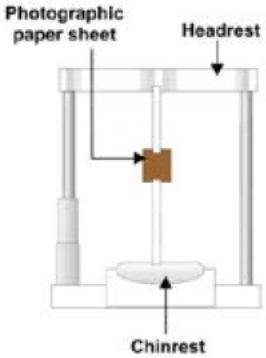

Figure 1: Piece of photographic paper in position

2. Switch ON the main switch located at the back of the OPTIMIS FUSION unit. The slit lamp is automatically turned "ON" and illuminates the target paper.
3. Turn the keyswitch to the YAG position and wait for the OPTIMIS FUSION treatment screen to be displayed (the laser is in STANDBY status by default).
4. Swing the illumination tower on the side so that it does not obstruct the aiming beams.
5. Adjust the eyepieces to accommodate the user's eyes.
6. View the target through the binocular (with the magnification changer set to x16).
7. Adjust the slit lamp position so that the aiming beams converge to form one spot on the paper attached to the target. The aiming spot should be centered in the field of view and in the center of the illumination aperture. Lock the slit lamp in this position *(See Figure 2)*

Figure 2: Aiming beams in focus

WARNING
If the aiming beam is not centered: do not use the système and contact QUANTEL MEDICAL Service Department or your local distributor.

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8. Adjust:
   - Burst mode to 1 pulse
   - Focus offset to 0 (30µm offset)
   - Low energy
9. Press the STANDBY/READY button on the control module to select READY status and fire the laser on the target paper.
10. Inspect the burn mark through the binoculars to check that the aiming beam spot coincides with the burn mark *(See Figure 3)*

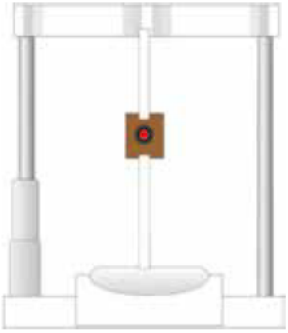

Figure 3: Burn mark after firing the treatment laser

NOTE

Depending of the photographic type of paper used for the checkup: the burn mark might not clearly be distinguished with minimum power in use. In this case, power may have to be increased step by step until coincidence can clearly be checked.

WARNING

In case the aiming beam/treatment beams do not coincide: do not use the system on patients. Contact QUANTEL MEDICAL Service Department or your local distributor.

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2.2.4 CHECKING SLT AIMING BEAM ACCURACY

WARNING

Wearing appropriate safety glasses is required for all persons present when the laser is in use.
Ensure there is no refelective surfce behind the target.

The aiming and treatment beam (532nm) coincidence should be checked on a regular basis: the following procedure should be carried out at least every three months or as considered necessary by the user.

Required material:

Photographic paper (Kodak linagraph direct printer)
Alignment target / focusing bar

Checking procedure:

1. Attach a piece of photographic paper on the alignment target / focusing bar *(See Figure 1 in the above section 2.2.3)*
2. Switch ON the main switch located at the back of the OPTIMIS FUSION unit. The slit lamp is automatically turned "ON" and illuminates the target paper.
3. Turn the keyswitch to the SLT position and wait for the OPTIMIS FUSION treatment screen to be displayed (the laser is in STANDBY status by default).
4. Adjust the eyepieces to accommodate the user's eyes.
5. View the target through the binocular (with the magnification changer set to x16).
6. Adjust the slit lamp position so that the aiming beam forms only one clear, well defined spot on the paper attached to the target (focal distance) and lock the slit lamp in this position. The aiming spot should be centered in the field of view and in the center of the illumination aperture. Lock the slit lamp in this position *(See Figure 2 in the above section 2.2.3)*

WARNING

If the aiming beam is not centered: do not use the système and contact QUANTEL MEDICAL Service Department or your local distributor.

7. Adjust:
   - Low energy
8. Press the STANDBY/READY button on the control module to select READY status and fire the laser on the target paper.
9. Inspect the burn mark through the binoculars to check that the aiming beam spot coincides with the burn mark *(See Figure 3 in the above section 2.2.3)*

NOTE

Depending of the photographic type of paper used for the checkup: the burn mark might not clearly be distinguished with minimum power in use. In this case, power may have to be increased step by step until coincidence can clearly be checked.

WARNING

In case the aiming beam/treatment beams do not coincide: do not use the system on patients. Contact QUANTEL MEDICAL Service Department or your local distributor.

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2.3 SLIT LAMP ILLUMINATION LED REPLACEMENT

The slit lamp illumination LED module is accessible by removing two screws located under the illumination tower:

In case the slit lamp illumination LED fails: call QUANTEL MEDICAL Service Department or your local distributor to replace it.

2.4 FUSES REPLACEMENT

AVERTISSEMENT
When replacing a fuse and before removing it from its housing: turn the power off and disconnect the power cord from the wall outlet.

The IEC mains power sockets on the base of the stand column and on the laser console contain a dual fuse holder. To check fuses, remove the power cable from the IEC socket and pull out the fuse holder slide.

If a fuse blows, replace it with an other one that has the exact same specifications.

Fuse specifications:	- Laser console:	T2AL 250V
	- Stand column:	T6.3AL 250V

NOTE:
The internal power supply is protected against overload, so fuses should rarely need replacement. A blown fuse is likely to indicate an internal fault.

3 ERROR CODES

The system microprocessor monitors all important system components. If an irregularity is found during operation the control module is disabled and displays an error code. In this condition the footswitch and joystick laser fire switch are disabled and the unit defaults to the STANDBY status.
If this occurs, turn the unit off, wait a few seconds and turn the unit back on. If the self-test does not find any errors on the second start up, the condition was temporary and the unit can be used. If an error code continues to be displayed, refer to section 10: Appendix for the list of error codes.

Then, consult QUANTEL MEDICAL Service Department or your local distributor.

NOTE:
The system will not accept operator commands until the fault is rectified.

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4 TROUBLESHOOTING

In case of any problem during installation or operation of the system, the following troubleshooting guide may be of assistance:

Table 4–1: Troubleshooting table

Fault	Probable cause	Action required
The system does not start up when the main switch located on the back panel of the unit is turned ON (the green power supply LED located on the front panel does not turn ON)	No mains power.	Check that the local supply is functioning and switched on. Check with another appliance to be certain.
	Power lead not connected.	Check the power lead is correclty connected to the local supply / the mains supply socket.
	Blown fuse.	Check that the fuses are not blown. Disconnect the power cord from the local power supply before removing the fuses.
The LCD screen does not start up (no display) when the main switch located on the back panel of the unit is turned ON. However, the green power supply LED located on the front panel is turned ON.	Emergency Laser Stop switch in OFF position.	Check that the Emergency Laser Stop switch is in the ON position. To be certain, rotate the switch a quarter of a turn clockwise to release it.
	Keyswitch is in the OFF position.	Turn the keyswitch to the SLT or YAG position.
YAG: Warning Remote SLT: Warning Remote	Safety interlock activated.	- Close theater door, or - Check that the "red" remote (removable bypass connector) is connected at the back of the unit. This remote allows to shortcut pin 1 and 3 when the door switch option is not used.
No user controls on the module.	Faulty control module buttons.	Call QUANTEL MEDICAL Service Departement or your local distributor.
YAG: Warning Footswitch SLT: Warning Footswitch	The Footswitch (optional) is pressed whereas the laser is in STANDBY status.	Select READY status before using the Footswitch (optional).
YAG: Warning Joystick SLT: Warning Joystick	The Joystick is pressed whereas the laser is in STANDBY status.	Select READY status before using the Joystick.
YAG: Move Light Tower	Treatment beam path obstructed by the illumination tower.	Rotate the illumination tower out of the treatment beam path.
Low aiming beam intensity.	The aiming beam intensity is not properly adjusted to match the examination conditions.	Adjust the aiming beam intensity.
Low aiming beam intensity when set at maximum intensity.	The optics on slit lamp may be dirty.	Clean the slit lamp external optic, or call QUANTEL MEDICAL Service Departement or your local distributor if the problem continues.

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No slit lamp illumination.	Error : E12	Slit lamp error: check that the green remote (joystick / lamp cable) is properly connected at the back of the unit. Call QUANTEL MEDICAL Service Departement or your local distributor if the problem continues.
	No power.	Check power is ON.
	Slit closed.	Open slit.
	Fuse blown.	Replace fuse.
	LED lamp faulty	In case the LED connector is not properly connected: the green LED (surrounded in red above) turns to red. Make sure both POWER IN and LED cables are properly connected. Call QUANTEL MEDICAL Service Departement or your local distributor is problem continues..
Microscope vision is not clear at focus.	Eyepieces incorrectly fitted into binoculars.	Insert eyepieces fully into binoculars.
	LED lamp faulty.	Call QUANTEL MEDICAL Service Departement or your local distributor to replace LED lamp.
Illumination is blurred.	LED lamp faulty.	Call QUANTEL MEDICAL Service Departement or your local distributor to replace LED lamp.
	Illumination tower prism is dirty.	Clean prism;

5 VERIFICATION AND CALIBRATION PROCEDURE

The calibration must be checked at least annually. This is normally carried out as part of a service visit.

NOTE:
Due to the complexity of the instrument, calibration procedures must only be carried out by a trained and properly qualified QUANTEL MEDICAL trained personal.

NOTE:
Any meter used to calibrate the laser energy must be traceable to N.I.S.T (US National Institute of Standards and Technology) or an equivalent standard in another country.

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6 TRANSPORTATION

CAUTION:
The system should be handled with care to preserve its accuracy and to ensure a trouble-free operation. QUANTEL MEDICAL cannot be held responsible for any damage that could result from mishandling the equipement during use, storage or transportation.

6.1 MOVING THE EQUIPEMENT

The OPTIMIS FUSION is a tough and durable instrument, but it contains complex optical and mechanical systems that may be damaged if the unit is mishandled or subjected to excessive shock or vibration. Ensure that the temperature requirement for storage and transportation is respected. If the OPTIMIS FUSION needs to be moved: put the instrument back in its original packaging to protect it from any possible transportation shock damage.

6.2 DECONTAMINATION OF RETURNED EQUIPEMENT

To comply with United States postal and transportation law, equipment shipped to QUANTEL MEDICAL' US offices for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for use as a "Hospital Disinfectant".

7 PRODUCT LIFETIME

The OPTIMIS FUSION has a design life of at least seven years from the manufacturing date. The system is of modular construction so that correct operation can be maintained via parts replacement. If the system needs to be discarded, it can be done as described in the next section.

8 PRODUCT DISPOSAL

The OPTIMIS FUSION contains no toxic or radioactive elements that would adversely affect a dismantler or the area of disposal. However, the product is largely non- biodegradable and recycling of the base materials is recommended. Contact local authorities to determine the correct method for disposal.

The following list indicates the composition of the major elements of the OPTIMIS FUSION to assist recycling.

Table 8–1: Component materials

Base materials	Component parts
Steel	Power supply console chassis Laser module body Slit lamp cross-slide and bearings Chassis top plate Chin rest posts and pillars
Copper	Wiring
Aluminum	Laser head casting Optics module bodies Slit lamp knobs and components
Wood	Table
Plastic	Slit lamp base body Chin rest and headband Joystick skid plate Insulation in wiring, terminals, transformers, electrical components and front panel
Glass	Optics within laser and optics bench Optics within slit lamp

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9 WARRANTY INFORMATION

For specific and detailed warranty information for this instrument, please refer to general terms and conditions and / or distribution contract.

10 APPENDIX – ERROR CODES

Table A–1: Error codes

Display	Error code	Meaning
Error : E1	E01	High voltage problem.
Error : E2	E02	Shutter detector error .
Error : E3	E03	Energy P>+20%
Error : E4	E04	Energy P<-50%
Error : E5	E05	YAG/SLT detection error
Error : E6	E06	Energy control YAG position detector error
Error : E7	E07	Energy control SLT position detector error
Error : E8	E08	Energymeter heating
Error : E9	E09	SHG1 error
Error : E10	E10	SHG2 error
Error : E11	E11	Aiming beam focusing error
Error : E12	E12	Slit lamp error
Error : E13	E13	Laser detection
Error : E14	E14	Not calibrated

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Table A–2: Warning messages

Display	Warning	Meaning
SLT <20%	-<20%	Energy -20%<P<-50%
YAG <20%		
SLT Warning Joystick	Joystick	The Joystick is pressed whereas the laser is in STANDBY status.
YAG Warning Joystick		
YAG Move Light Tower	Move Light Tower	Slit lamp interlock : The illumination tower is in front of the aiming beam.
YAG Warning Remote	Warning Remote	Safety interlock activated.
SLT Warning Remote		
SLT Warning Footswitch	Footswitch (optional)	The Footswitch (optional) is pressed whereas the laser is in STANDBY satus.
YAG Warning Footswitch		

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optimis FUSION™

Nd:YAG Ophthalmic Laser System

USER MANUAL
V - CLINICAL INFORMATION

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The following sections refer to treatment procedures. They are intended as a guide only and are not intended to be a complete and thorough procedure. They are not meant to replace the judgment of a trained ophthalmic surgeon.

WARNING: **QUANTEL MEDICAL accepts no responsibility for negligent medical practices or for any event that results from the improper use of this equipment.**

1 YAG TREATMENT LASER — THEORY OF CLINICAL USE

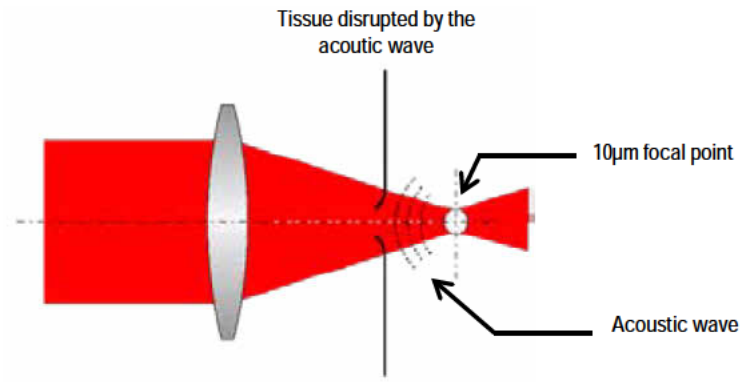
The **OPTIMIS FUSION mode** YAG treatment laser is intended to be used for dissection of the posterior capsule of the eye (posterior capsulotomy), dissection of the pupillary membrane of the eye (posterior membranectomy), as well as other surgical procedures such as iridotomy (opening a hole in the iris).

Like all Nd:YAG ophthalmic laser surgery, there are risks involved and use of the laser may be contraindicated for patients with certain pre-existing ocular pathologies. Objective assessment of candidate patients for this procedure must be done in light of the risks.

1.1 YAG (YTTRIUM ALUMINIUM GARNET) LASER SYSTEM THEORY

This ophthalmic YAG laser system is capable of producing short, individual pulses of focused infrared light with a wavelength of 1064nm. These pulses may be accurately positioned on the posterior capsule with the aid of a slit lamp microscope and a "twin dot" aiming system. The energy contained within a single short pulse is concentrated by focusing on a very small spot size (10 microns) so that a small ionization site (plasma) formation occurs at the focal point. This creates an acoustic wave that radiates from the focal point and disrupts nearby tissues. This is known as the "photo disruptive effect".

Once formed, the plasma absorbs and scatters further incident light. This shields the underlying structures from damage. Further, the beam divergence after the focal point protects the retina from damage that could otherwise occur by the absorption of concentrated Nd:YAG treatment energy.



Plasma formation

As the treatment energy is increased, the size of the plasma formed also increases, thus causing a larger, stronger acoustic wave. When energy is increased, it is necessary to focus the treatment beam further from (posterior to) the membrane to be penetrated. This is particularly important to:

1. Avoid the possibility of the plasma entering the IOL and causing chipping or cracking of the IOL;
2. Allow the accompanying shock wave to grow to its most effective size.

The reverse applies when smaller amounts of energy are used, when the focus should be brought closer to the membrane.

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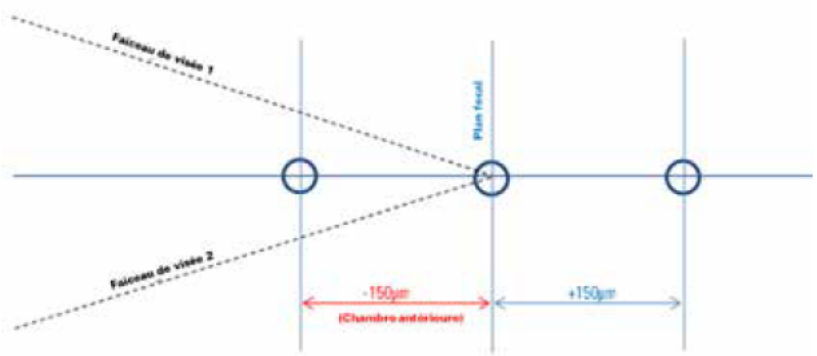
Some authors suggest that the lowest effective energy be used to perform photo disruptive procedures as a means of minimizing unwanted side effects such as retinal detachment.

The **OPTIMIS FUSION** laser system has a specific motorized offset control that allows the user to set the offset using the FOCUS OFFSET button on the control module LCD screen to:

- **"Post."**
  The therapy beam is focused posteriorly to the aiming beam focus. This setting should only be used in applications for which the area to be treated is posterior to the tissue to be protected.
- **"Ant."**
  The therapy beam is focused anteriorly to the aiming beam focus. This setting should only be used in applications for which the area to be treated is anterior to the tissue to be protected.
- **"0"**
  The therapy beam and aiming beam are focused in the same plane (parfocal). This setting should only be used in applications for which there is no tissue that needs to be protected either directly anterior or posterior to the treatment region.



Focus offset selection

1.2 GENERAL DESCRIPTION OF TREATMENTS

In summary, the laser is aimed at the membrane or tissue of the patient's eye using the aiming beams. The energy is set to the lowest possible effective level, then the laser is fired.
If the capsule is tough or scarred, higher energy levels may be required, but the energy is increased in small increments and the minimum number of shots required to obtain an adequate opening is used.
Once an opening has been established, it is enlarged as required until it is of adequate size.

1.3 TISSUE EFFECTS

The **OPTIMIS FUSION mode YAG** has a cutting or disrupting effect with the capability to damage any tissue or structure on which the beam is focused.
Unlike other lasers commonly used in ophthalmology (such as argon, krypton and ruby laser coagulators), it does not rely on thermal effects.

WARNING: The laser is designed to damage tissues. Make sure it is focused only on tissues that are to be operated on. Do not focus it on or near iris blood vessels because the shock wave may produce bleeding and induce astigmatism. The beam should never enter the eye at greater than 30 degrees from the visual axis.

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1.4 INDICATIONS AND CONTRAINDICATIONS FOR USE — POSTERIOR CAPSULOTOMY

The YAG laser is indicated for disruption of the posterior capsule of the eye (posterior capsulotomy).

CONTRAINDICATIONS

The following may represent contraindications for posterior capsulotomy:

Pre-existing ocular pathologies including:

- corneal edema that interferes with visualization of the capsule
- diffuse haze of the aqueous humor
- extensive corneal dystrophy
- chronically elevated intraocular pressure (IOP), especially when uncontrollable under medication
- eyes with no potential visual function
- subjects with glass posterior chamber intraocular lenses (IOL), except those subjects whose medical condition precludes invasive surgery

WARNING: Variations in IOL material and geometry may affect YAG procedural parameters and clinical success. Consult the IOL implant packaging and/or the IOL manufacturer for special considerations.

WARNINGS

Poor candidates for posterior capsulotomy

As in any surgical procedure, there are risks involved in Nd:YAG laser posterior capsulotomy. Candidate patients for this procedure must be assessed objectively in light of the risks discussed below. Certain patients may not improve and, further, may be at increased potential risk of postoperative complications. This includes patients with:

- active ocular disease
- nystagmus or other neurological conditions that make ocular fixation impossible
- slight or moderate haze of the aqueous humor or cornea
- inability to cooperate in positioning and immobilization
- 20/30 or better preoperative vision and no other serious vision disability, such as glare or poor reading vision, associated with the posterior capsule condition

(Several clinical studies have shown that 2-7% of these subjects experience a decrease in postoperative vision.)

Intraocular pressure rise

Significantly increased IOP has been reported in a substantial number of laser- treated patients, particularly those presenting with preoperative glaucoma or preoperative IOP of greater than 20 mm Hg. Physicians should carefully monitor all subjects for IOP rise in the 2-5 hours after treatment with the laser.

Patients who exhibit a pressure rise generally return to pretreatment levels within 24 hours but should be followed throughout this period. Persistent IOP elevation occurs in some patients. Clinical estimates are that 2-3% of patients may be treated for secondary glaucoma.

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

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Damage to intraocular lens

Pitting or marking of IOLs occurs in Nd:YAG laser posterior capsulotomy with several clinical studies reporting a 25% or greater incidence. The potential to IOL damage is a function of lens type, proximity to the posterior capsule, the level of laser energy used and physician familiarity.

Posterior chamber lenses, particularly those close to the posterior capsule, have the greatest potential for damage. This potential can be minimized by care in focusing behind the lens in pseudophakic subjects, optimizing the view of the posterior capsule with the use of a contact lens and avoiding repetitive shots to the same spot.

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

Inadvertent patient movement

Mis-aiming of the device or movement of the patient may result in damage to non- target ocular tissue or the area surrounding the target tissue. If the patient cannot fixate, use of a contact lens or retrobulbar anesthesia injection is recommended.

Bleeding

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

~~**Pupillary block**~~

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

Rupture of the anterior hyaloid face

A proportion of subjects (about 25% in clinical studies) may experience rupture of the anterior hyaloid face. This potential is greater for aphakic subjects (no IOL present). Such patients are at increased risk of anterior vitreous movement from the normal plane. In the event of vitreous movement to the cornea, an increased incidence of corneal edema may result.

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

Retinal damage

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

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

- extracapsular cataract patients without a patent iridectomy are at an increased risk of pupillary block
- patients with preoperative glaucoma, prior filtering surgery or preoperative IOP of greater than 20 mm Hg are at a significantly higher risk of postoperative IOP rise to levels of clinical concern
- patients with IOLs, particularly posterior chamber lenses close to the posterior capsule, are at risk of IOL pitting or cracking
- the greater the total amount of energy employed to effect capsule opening, the greater the risk of damage to the IOL
- patients with pre-existing ocular conditions have a greater chance of experiencing postoperative complications

PRECAUTIONS

Targeting
Focus the unit in accordance with the description provided in:
OPTIMIS FUSION User Manual: III – Using the laser system
Since in dual beam diode systems such as **OPTIMIS FUSION**, the Nd:YAG beam cross-section extends beyond the diode beams, there is an increased probability of Nd:YAG beam impingement of the iris. Therefore, the operator should not fire the therapeutic shot without assurance that the two diode spots have become coincident on the target tissue (that is, neither of the diode beams is blocked or obstructed by other tissues of the eye in the beam pathway). Care should be exercised when working at the iris margin or at a wide angle to the patient's visual axis.

Energy use
The lowest possible energy level should be used, beginning with 1-2 mJ and increasing the energy as required.
The burst-mode button can be adjusted to effect capsule dissection.
If the capsule is tough or scarred, higher energy shots may be required. It is recommended that the increase be in 1-2 mJ steps. The clinical experience indicates that the mean power level used is 2.7 mJ, and 97% of the subjects were treated at less than 5 mJ.
The minimum number of shots required to obtain an adequate opening should be used. The mean is 40 shots, although greater than 100 shots may be required for membranous tissue

WARNING: The risk of IOL damage increases with increasing energy level and number of shots used.

Once an opening has been established, it is enlarged as required until the capsulotomy is adequate.
In the presence of edematous, clouded, scarred or irregular astigmatic corneas, the laser beam may defocus, necessitating higher energy settings to obtain optical breakdown Medical judgment must be used to determine whether the corneal condition in such circumstances contraindicates laser posterior capsulotomy.

Patient focus
A thin fluid layer on the cornea is desirable. The patient is asked to blink regularly to avoid corneal drying.
Topical steroids should be used for any significant postoperative inflammation.

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Adverse effects

Adverse effects include:

- IOP rise to 50 mm Hg or greater, regardless of duration
  (Hospitalization may be required for the institution of IOP-reducing therapy. Pain and nausea may accompany such a significant IOP rise.)
- IOP rise to 30 mm Hg or greater persisting for one week or more
- secondary glaucoma
- hyphema
- pits on IOL, if present
- inflammatory reactions, such as iritis, vitritis or uveitis
- retinal complications, such as cystoid macular edema and retinal detachment
- pupillary block
- anterior hyaloid face rupture
- vitreous movement with corneal touch
- corneal edema
- iris damage

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1.5 INDICATIONS AND CONTRAINDICATIONS FOR USE — IRIDOTOMY

OPTIMIS FUSION mode YAG is indicated for performing an iridotomy (hole in the iris).

CONTRAINDICATIONS

The following may represent contraindications for iridotomy. Pre-existing ocular pathologies including:

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

WARNINGS

Risks

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

- significant transient elevation of IOP
- damage to the lens
- transient bleeding from the iridotomy margin, and hyphema
- localized corneal damage
- anterior chamber reaction (including flare, cells and debris)
- closure of the iridotomy with time
- inability to control glaucoma adequately (despite a successful iridotomy), necessitating chronic medical therapy or further invasive intraocular surgery

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

- persistent elevation of the IOP
- rupture of the anterior hyaloid face and anterior displacement of the vitreous in an aphakic eye
- damage to the retina or choroid

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

Poor candidates for Nd:YAG laser iridotomy

Patients with any of the following conditions may not be suitable candidates for Nd:YAG laser iridotomy because of the risks of bleeding, or inability to create an iridotomy or iridotomy closure:

- slight or moderate haze of the cornea or aqueous humor
- chronic uveitis
- pupillary block associated with neovascular glaucoma or with any condition causing engorged iris blood vessels
- tendency to bleed (as with hemophilia or patients receiving anticoagulant therapy)
- inability to cooperate in the procedure
- nystagmus
- blepharospasm

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Intraocular pressure rise

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

The decision to use additional medical treatment in the event of a rise of IOP should be based on the status of the individual patient. Most elevations resolve without intervention within 24 hours of Nd:YAG laser surgery. The treating physician should take into consideration the pre-existing condition of the optic nerve and other ocular structures when deciding whether to treat the eyes with IOP-lowering medication.

Damage to the lens

Clinically visible evidence of lens damage has not been reported to date following Nd:YAG laser iridotomies in humans, but Nd:YAG laser-induced damage to the crystalline lens has been noted in animal studies and in human histologic studies. The risk of lens damage during Nd:YAG laser iridotomy will increase if:

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

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

- ensure good patient fixation.
- use an appropriate contact lens.
- select an iris treatment site as far in the periphery as is practical.

As with all iridotomies, the site should be located under the upper lid whenever possible.

- focus the aiming beam upon the surface of the treatment site.
- use the minimum number of pulses per burst.
- use the lowest possible amount of energy per pulse.
- avoid treatment through a site that is already totally or partially patent.

Inadvertent patient movement

Inadvertent or uncontrolled eye movement by the patient may result in hitting tissues adjacent to the target. If a patient cannot fixate with the untreated eye to assure stabilization of the treated eye, use of anterior segment treatment contact lens and/or retrobulbar anesthesia injection is recommended.

Bleeding

Mild, localized bleeding occurs in 20% to 50% of eyes undergoing Nd:YAG laser iridotomy. Mild hyphema is rare (less than 2%) and severe hyphema is very uncommon (less than one in 200). Unlike an argon laser, a Nd:YAG laser creates minimal heat at the treatment site and therefore does not cauterize vessels. Eyes with engorged iris blood vessels (active uveitic or neovascular angle closure glaucoma) are at an increased risk of bleeding. Patients who are otherwise at risk of bleeding (as with hemophilia or those receiving anticoagulant therapy) are also at an increased risk of bleeding and hyphema. In otherwise normal patients with pupillary block glaucoma, bleeding usually stops spontaneously and can be controlled by digital pressure upon the contact lens. All eyes should be observed with a biomicroscope for bleeding. If bleeding occurs, additional

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

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

Retinal damage
Although no retinal damage after Nd:YAG iridotomy has been noted to date, it is theoretically possible.

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

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

- the eye may have developed peripheral anterior synechiae (PAS)
- the angle may be open but the eye may have residual open angle glaucoma
- a combination of the above

Patients should be monitored for persistent glaucoma.

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

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

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PRECAUTIONS

Targeting

Focus the unit in accordance with the description provided in *Chapter III*.
Unlike other lasers commonly used in ophthalmology (argon, krypton, and dye lasers) which rely on thermal effects, the Nd:YAG laser is a cutting or disrupting instrument with capability of damaging any tissue or structure on which the beam is focused. Therefore, the Nd:YAG laser should only be focused on target tissues and caution should be used to avoid exposure of all adjacent tissues and structures.

Energy use

Minimal effective energy and minimal pulses per burst should be used to reduce risk of damage to non-target areas. In animal studies, use of higher total energy, larger numbers of pulses, and more pulses per burst have been associated with an increased risk of damage to the lens. Lens damage has not been reported clinically in human eyes that have undergone Nd:YAG iridotomy.

ADVERSE EFFECTS

The following sight-threatening adverse effects and complications have been observed in patients who have undergone Nd:YAG iridotomy:

- transient elevated IOP
- hyphema
- Other problems reported following Nd:YAG laser iridotomy are:
- corneal injury (including damage to the endothelium, stroma or epithelium)
- anterior chamber reaction (including flare, cells and debris)

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2 SLT TREATMENT LASER — THEORY OF CLINICAL USE

The SLT treatment laser provides a low energy, short pulse of laser light that produces a thermal effect in pigmented cells in the trabecular meshwork of the eye.
Collateral thermal and coagulative damage does not occur because the pulse duration is less than the time it takes for melanin in the pigmented cells to convert the absorbed electromagnetic radiant energy into heat energy (this is the thermal relaxation time or TRT). ~~Even in the treatment area non-pigmented cells and structures are unaffected. The clinical effect of the 532 nm wavelength is similar to the effect of argon 514 nm wavelength but the SLT treatment beam offers an alternative treatment for glaucoma (and other conditions requiring a reduction in intraocular pressure) that avoids the photocoagulation and collateral thermal damage in surrounding tissues that can occur in argon laser treatments.~~
The amount of heat and potential for damage is minimized to non-pigmented cells and structures.

2.1 INDICATIONS AND CONTRAINDICATIONS FOR USE

INDICATIONS

The **OPTIMIS FUSION mode SLT** is indicated for use in selective Trabeculoplasty.

CONTRAINDICATIONS

The following conditions contraindicate the use of the **OPTIMIS FUSION mode SLT**:

- neovascular glaucoma
- angle closure glaucoma
- Congenital glaucoma
- Active uveitic glaucoma
- Any disease that does not allow visualization of the trabecular meshwork

PRECAUTIONS

The following precautions are suggested when using the **OPTIMIS FUSION mode SLT**:

- Use the minimum treatment energy necessary to perform the treatment, to reduce the risk of damage to non-targeted tissues — exercise particular caution when using pulse energies exceeding 1.4 mJ.
- Exercise caution in treating if blood vessels are present in the angle
- Avoid treating blood vessels in the vicinity of the trabecular meshwork due to the risk of hemorrhage
- Exercise caution when treating patients with pre-existing anterior chamber inflammation, including uveitis, since the procedure itself may induce a mild anterior chamber inflammatory response
- Perform ocular surgery only when the structures to be treated can be clearly visualized and the single aiming beam is on the treatment site

COMPLICATIONS AND ADVERSE EVENTS

In some clinical studies*, patients who received selective laser trabeculoplasty treatment experienced some complications and adverse events that were considered to be related to the treatment. These included :

- mild transient anterior chamber inflammation in many patients,
- intraocular pressure increase of ≥ 10 mm Hg,
- conjunctivis
- and eye pain.

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A number of other complications occurred at an incidence of <1%. These included:

- blurred vision,
- iritis,
- corneal edema,
- corneal lesion, and
- headache.
- Hyperopic shift
- Induced irregular astigmatism

Although not considered treatment-related, another potential complication of laser trabeculoplasty is the formation of peripheral anterior synechiae.

WARNING: The laser is designed to damage tissues. Make sure it is focused only on tissues that are to be operated on. Do not focus it on or near iris blood vessels because the shock wave may produce bleeding and induce astigmatism. The beam should never enter the eye at greater than 30 degrees from the visual axis.

* ***Clinical studies references:***

1. **Inflammation assessment after selective laser trabeculoplasty (SLT) treatment.**
   Ayala M, Landau Högbeck I, Chen E.

   Source
   Glaucoma department, St Eriks Eye Hospital, Karolinska Institutet, Stockholm, Sweden.

   Acta Ophthalmol. 2011 Jun;89(4):e306-9. doi: 10.1111/j.1755-3768.2010.02029.x. Epub 2011 Mar 22.

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2. **Q-SWITCHED 532-NM ND:YAG LASER TRABECULOPLASTY (SELECTIVE LASER TRABECULOPLASTY): A MULTICENTER, PILOT, CLINICAL STUDY.**
   LATINA MA, SIBAYAN SA, SHIN DH, NOECKER RJ, MARCELLINO G.

   Source
   WELLMAN LABORATORIES OF PHOTOMEDICINE, MASSACHUSETTS GENERAL HOSPITAL, HARVARD MEDICAL SCHOOL, BOSTON, USA.

   OPHTHALMOLOGY. 1998 NOV;105(11):2082-8; DISCUSSION 2089-90.

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2.2 CLINICAL PARAMETERS

In SLT treatment **mode** the **OPTIMIS FUSION** emits single visible light pulses 4 ns in duration with a 400 µm spot size and pulse energies ranging from 0.3 to 2 mJ. The mechanism of action of the **OPTIMIS FUSION mode SLT** is the selective targeting of pigmented trabecular meshwork cells, when operated within a defined energy range.

The short duration of the laser pulses minimizes the amount of heat dissipated from pigmented cells and absorbed by surrounding non-pigmented tissues. When the **OPTIMIS FUSION mode SLT** is operated within a defined energy range, the fluency of the resulting laser pulses is below the level where optical breakdown occurs. However, higher energy levels may result in photoacoustic and/or photomechanical damage to adjacent non-melanized cells or the trabecular support architecture.

A Latina gonioscopy lens without magnifying optics is used to visualize the angle during treatment. A coupling medium (i.e. Hydroxypropyl methylcellulose ophthalmic) is required when using the Latina gonioscopy lens to properly visualize the angle anatomy.

The optimum energy level for treatment is defined as the maximum energy that can be delivered without causing photodisruption/optical breakdown of the trabecular meshwork. The optimum energy level will vary from patient to patient because the threshold for thermal energy, evidenced by bubble formation, is determined primarily by the level of pigmentation in cells of the trabecular meshwork.

To determine the optimum energy level for treatment, set the initial laser energy at 0.6 mJ.
Increase the energy in single, stepwise 0.1 mJ increments until bubble formation is observed.
The energy at which bubble formation occurs is known as the 'threshold energy'. After the threshold energy has been identified, decrease the laser energy level by 0.1 mJ. This lower energy level is known as the 'treatment energy'.

Treatment should continue at the treatment energy until 50 (±10) single, non-overlapping laser spots have been created along 180 degrees of either the nasal or temporal segment of the trabecular meshwork.

WARNING: After the laser treatment, prednisolone acetate 1% drops should <u>immediately</u> be administered to the treated eye and continued four times daily for four to seven days

WARNING: Exercise particular caution when using pulse energies exceeding 1,4mJ.

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Indications for Use

510(k) Number (if known): _____

Device Name: **Family of OPTIMIS FUSION Ophthalmic Laser Systems, (FUSION SLT/YAG, FUSION YAG, FUSION SLT) and Delivery Device (Slit lamp adaptor) and Accessories**

Indications for Use:

- OPTIMIS FUSION YAG: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy.

- OPTIMIS FUSION SLT: Selective laser Trabeculoplasty

- OPTIMIS FUSION YAG/SLT: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy ; and Selective laser Trabeculoplasty

Prescription Use X___ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

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(b)(4) Diagram

(b)(4) Diagram

(b)(4) Diagram

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Specifications

GENERAL SPECIFICATIONS

	YAG Mode	SLT Mode
Laser Energy source	Q-Switched, Nd : YAG	Q-Switched, frequency doubled Nd : YAG
Laser Delivery Mode	1,2 or 3 pulses per shot, selectable	1 pulse per shot
Laser energy Intensity	Selected by Physician	Selected by Physician
Power requirements: Current	2A	2A
Power requirements: Voltage	100 to 240 Vac	100 to 240 Vac
Computer control	Yes	Yes
Can user change computer program?	No	No

LASER OUTPUT

Output Wavelength	1064 nm	532 nm
Energy Settings	0.3 – 10 mJ	0.3 – 2.0 mJ
Maximum Energy	10 mJ Single pulse 18 mJ Double pulse 30 mJ triple pulse	2 mJ (single pulse only)
Pulse Modes	Pulsed	Pulsed
Repetition Rate (Max)	2.0 Hz single pulse 1.5 Hz double pulse 1.5 Hz triple pulse	2.5 Hz
Pulse Duration	4 nanoseconds	4 nanoseconds
Spot Size	10 microns (84% energy in diameter) 8 microns FWHM	400 microns
Offset (in air)	Variable +150µm;0;-150µm	---
Focus angle	16 degrees	< 3 degrees
Laser Safety Class	IIIb (3B)	IIIb (3B)
Cooling Method	Air convection	Air convection
Aiming Beam:	Dual diode, variable intensity	Coaxial with treatment beam
Aiming Beam: Type	Red diode	Red diode
Aiming Beam: Wavelength	635±5 nm	635±5 nm
Aiming laser power	< 1mW	< 1mW
Laser Safety Class	2/II	2/II
Safety measures	Conform to standard 60601-2-22 and 60825-1	Conform to standard 60601-2-22 and 60825-1
Accessories	NA	Standard footswitch provided as a standard system component

DELIVERY SYSTEM

Slit lamp ADAPTOR (Fusion*Link*)	Adaptor to suit the following slit lamp: • CSO SL 980

(b)(4) Third Party Specification

(b)(4) Third Party Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Testing

Predicate Comparison Table for SLT Mode

GENERAL SPECIFICATIONS COMPARISON TABLE

Manufacturer	**QUANTEL MEDICAL**	**LUMENIS**
Model	Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories	Family of SELECTA Ophthalmic Laser Systems, Delivery Device and Accessories
510 (K) Number		K081704
Intended Use	Treatment of ocular pathology	Treatment of ocular pathology
Device Name	Optimis Fusion SLT	Selecta Duet
Indications for Use	Selective Laser Trabeculoplasty (SLT)	Selective Laser Trabeculoplasty (SLT)
Laser energy Intensity	Selected by Physician	Selected by Physician

Treatment Lasers

Manufacturer	**QUANTEL MEDICAL**	**LUMENIS**
Model	Family of OPTIMIS FUSION Ophthalmic laser Systems, Delivery device and Accessories	Family of SELECTA Ophthalmic laser Systems, Delivery device and Accessories
510 (K) Number	---	K081704
Device Name	Optimis Fusion SLT	Selecta Duet SLT
Laser Energy source	Q-Switched, frequency doubled Nd: YAG	Q-Switched, frequency doubled Nd: YAG
Laser Wavelength	532 nm	532 nm
Pumping system	Flash	Flash
Pulse Modes	Pulsed	Pulsed
Laser Delivery Mode	Single spot	Single spot
Pulse setting	1 pulse per shot	1 pulse per shot
Energy Settings	0.3 – 2.0 mJ	0.3 – 2.0 mJ
Multispot Spot Patterns (MSP)	**NA**	NA
Range of space between MSP	**NA**	NA
Energy Output (max)	2 mJ	2 mJ
Repetition Rate (Max)	2.5 Hz (single pulse only)	2.0 Hz (single pulse only)
Pulse Duration	4 nanoseconds	3 nanoseconds
Maximum Average Power (W)	5 mW single pulse	4 mW single pulse
Maximum Energy Density at Minimum Exposure (J/cm²)	1.6 J/cm² single pulse	1.6 J/cm² single pulse
Spot Size Diameter in air (µm)	400 microns	400 microns

Spot Placement	Spot centered on Guide beam at focal plan	Spot centered on Guide beam at focal plan
Spot Diameter at Retinal Plan	**NA**	NA
Rotation Angle	**NA**	NA
Focus angle	< 3 degrees	< 3 degrees
Laser Safety Class	IIIb (3B)	IIIb (3B)

Aiming Lasers

Aiming Beam laser type	Red diode	Red diode
Aiming Wavelength	635±5 nm	635±5 nm
Aiming laser power	< 1mW	< 1mW, continuously variable
Operation	CW (Continuous wave)	CW (Continuous wave)
Aiming Beam :	Coaxial with treatment beam	Coaxial with treatment beam
Laser safety class	2/II	2/II

Predicate Comparison Table for YAG Mode

GENERAL SPECIFICATIONS COMPARISON TABLE

Manufacturer	**QUANTEL MEDICAL**	**LUMENIS**	**Carl Zeiss Meditec**
Model	Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories	Family of SELECTA Ophthalmic Laser Systems, Delivery Device and Accessories	VISULAS YAG III
510 (K) Number		K081704	K042139
Intended Use	Treatment of ocular pathology	Treatment of ocular pathology	Treatment of ocular pathology
Device Name	Optimis Fusion YAG	Selecta Duet	Visulas YAG III
Indications for Use	Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discussion of the posterior capsule (posterior capsulotomy), and discussion of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy	Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discussion of the posterior capsule (posterior capsulotomy), and discussion of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy / iridectomy,	Posterior capsulotomy and peripheral iridotomy.
Laser energy Intensity	Selected by Physician	Selected by Physician	Selected by Physician

Treatment Lasers

Manufacturer	**QUANTEL MEDICAL**	**LUMENIS**	**Carl Zeiss Meditec**
Model	Family of OPTIMIS FUSION Ophthalmic laser Systems, Delivery device and Accessories	Family of SELECTA Ophthalmic laser Systems, Delivery device and Accessories	VISULAS YAG III
Device Name	Optimis Fusion YAG	Selecta Duet YAG	Visulas YAG III
Laser Energy source	Q-Switched, Nd: YAG	Q-Switched, Nd: YAG	Q-Switched, Nd: YAG
Laser Wavelength	1064 nm	1064 nm	1064 nm
Pumping system	Flash	Flash	Flash
Pulse Modes	Pulsed	Pulsed	Pulsed
Laser Delivery Mode	Single spot	Single spot	Single spot
Pulse settings	1,2 and 3 pulses per shot, selectable	1,2 and 3 pulses per shot, selectable	1,2 and 3 pulses per shot, selectable
Energy Settings	0.3 – 10 mJ	0.3 – 10 mJ	0.3 – 10 mJ
Multispot Spot Patterns (MSP)	**NA**	NA	NA
Range of space between MSP	**NA**	NA	NA
Energy Output (max)	10 mJ Single pulse 18 mJ Double pulse 30 mJ triple pulse	10 mJ Single pulse -- 45 mJ Triple pulse	10 mJ Single pulse 23 mJ Double pulse 35 mJ triple pulse
Repetition Rate (max)	2.0 Hz single pulse 1.5 Hz double pulse 1.5 Hz triple pulse	2.0 Hz single pulse 1.8 Hz double pulse 1.6 Hz triple pulse	2.5 Hz single pulse 1 Hz double pulse 0.5 Hz triple pulse
Pulse Duration	4 nanoseconds	4 nanoseconds	4 nanoseconds
Maximum Average Power (W)	20mW single pulse 27 mW double pulse 45 mW Triple pulse	20mW single pulse --- 72 mW Triple pulse	25 mW single pulse 23 mW double pulse 17,5 mW Triple pulse
Maximum Energy Density at Minimum Exposure (J/cm²)	1.27 10^4 J/cm² single pulse 2.29 10^4 J/cm² double pulse 3.82 10^4 J/cm² Triple pulse	1.05 10^4 J/cm² single pulse --- 4.73 10^4 J/cm² Triple pulse	1.27 10^4 J/cm² single pulse 2.92 10^4 J/cm² double pulse 4.45 10^4 J/cm² Triple pulse

Spot Size Diameter in air	10 microns (84% energy in diameter) 8 microns FWHM	11 microns (84% energy in diameter) 8 microns FWHM	10 microns (84% energy in diameter) ---
Spot Placement	Spot centered on Guide beam at focal plan	Spot centered on Guide beam at focal plan	Spot centered on Guide beam at focal plan
Spot Diameter at Retinal Plan	**NA**	NA	NA
Rotation Angle	**NA**	NA	NA
Offset (in air)	Variable +150µm;0;-150µm	100-350 microns, continuously variable	Variable +150µm;0;-150µm
Focus angle	16 degrees	16 degrees	16 degrees
Laser Safety Class	IIIb (3B)	IIIb (3B)	IV

Aiming Lasers

Aiming Beam laser type	Red diode	Red diode	Red diode
Aiming Wavelength	635±5 nm	635±5 nm	660 to 680 nm
Aiming laser power	< 1mW, continuously variable	< 1mW, continuously variable	5µW -150µW
Operation	CW (Continuous wave)	CW (Continuous wave)	CW (Continuous wave)
Aiming Beam :	Dual diode	Coaxial with treatment beam	4 point aiming beam
Laser safety class	2/II	2/II	2/II

Electrical and Mechanical Characteristics of Devices

Manufacturer	**QUANTEL MEDICAL**	**LUMENIS**	**Carl Zeiss Meditec**
Model	Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories	Family of SELECTA Ophthalmic Laser Systems, Delivery Device and Accessories	VISULAS YAG III
510 (K) Number		K081704	K042139
Mains Electrical Supply voltage	100 to 240 Vac	---	100 to 240 Vac
Supply Frequency	50/60Hz	50/60Hz	50/60Hz
Weight	24.5 kg	25lbs	11 kg
Min/Max height (top of chinrest)	H x W x D = 647 mm x 540 mm x 485 mm	5.4¨x7¨x11.4¨	H x W x D = 625mm x 300 mm x 450 mm
Operating Temperature Range	+15°C to +35°C; RH 90%	+15°C to +32°C; RH 90%@ 32°C	+10°C to +40°C; RH 90%
Transport & Storage Temperature Range	-20°C to +70°C; RH 10 to 85%	-10°C to +55°C; RH up to 90%@55°C	-25°C to +55°C; RH 0 to 90%
Cooling (console)	Air convection	Air cooled	Air cooled

Slit Lamp Delivery Systems Characteristics

Manufacturer	**CSO**	**LUMENIS**	**Carl Zeiss Meditec**
Type	Galilean converging binocular	Galilean stereoscopic microscope with converging optics	VISULAS YAG III
510 (K) Number	Previously cleared in K992836	K081704	K042139
Objectives lens	1.1x	1.25 x	--
Eyepiece lens	12.5 x	12.5 x, dioptre adjustable in range ± 5D	10x (12,5x optional)
Total magnification	10 x 16x 25x	16 x (12.5 x eyepiece)	5x,8x,12x,20x,32x
Magnification changer	3 position, removable	3 position, removable	5 position
Interpupillary distance adjustment	48.5 - 80 mm	2.16 to 3.5 in (55-88 mm)	55 – 78 mm

Working distance	3.14 in (80 mm)	2.16 in (55mm)	--
Focal length	3.7 in (94 mm)	3.6 in (92 mm)	140 mm
Chin rest	Adjustable, vertical travel 2.5 in (70 mm)	Adjustable, vertical travel 2 in (50 mm)	--
Slit lamp source			
Slit width	0 to 14 mm	0 to ½ (0 to 12 mm)	0 to 14 mm
Illumination view field	0.2mm, 5.5mm, 9mm, 14mm, continuously variable	0.5 mm, 5 mm, 8 mm, 12 mm, continuously variable	1,3,5,9,14 mm
Slit rotation	180 degrees	180 degrees	0°,±45°,90°
Illumination angle	180 degrees at horizontal plane (90 degrees for right/left)	180 degrees at horizontal plane (90 degrees for right/left)	--
Filters	cobalt-blue,	Green, cobalt-blue, neutral density (ND) (28% attenuation)	--
Bulb	LED bulb, 6V, 20W pre-centered bulb	Halogen lamp, 12V, 30W pre-centered bulb	Halogen lamp, 12V, 30W

Accessories

Manufacturer	**QUANTEL MEDICAL**	**LUMENIS**	**Carl Zeiss Meditec**
Model	Family of OPTIMIS FUSION Ophthalmic laser Systems, Delivery device and Accessories	Family of SELECTA Ophthalmic laser Systems, Delivery device and Accessories	VISULAS YAG III
510 (K) Number	---	K081704	K042139
Standard Accessories	---	Footswitch	---
Optional Accessories	Footswitch, Fusion Link Adaptor, Stand Column	LaserLink S,Beam splitter, 35mm Camera adapter, video camera adapter, co-observation tube, Latina lens	---

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4.10.2 YAG treatment laser specifications

Table 4–9: YAG treatment laser specifications

Parameter	Details
Type	Q-switched solid state Nd:YAG photodisruptor laser
Wavelength	1064 nanometers
Safety class	IIIb (3B)
Mode of operation	Fundamental, diffraction limited
Energy settings	0.3 mJ to at least 10 mJ continuously variable
Maximum energy	45 mJ at triple pulse setting
Pulse duration	4 nanoseconds +4/-0 ns
Pulse setting	1, 2 or 3 pulses per shot; pulse separation of 20 microseconds ± 20%
Repeat mode (max)	2.0 Hz single pulse 1.8 Hz double pulse 1.6 Hz triple pulse
Treatment spot size	11 microns (84% energy in diameter) 8 microns FWHM
Beam divergence	16 degrees +0° /-2° full cone angle
Laser safety filters	Total filtering OD 5 @ 1064 nm
Nominal Ocular Hazard Distance (NOHD)	18 feet (5.5 meters)

4.10.3 SLT treatment laser specifications

Table 4–10: SLT treatment laser specifications

Parameter	Details
Type	Q-switched frequency doubled Nd:YAG laser
Wavelength	532 nanometers
Safety class	IIIb (3B)
Mode of operation	Frequency doubled, diffraction limited
Energy settings	0.3 mJ to 2 mJ continuously variable
Pulse duration	3 nanoseconds +3/-0 ns
Pulse setting	1 pulse per shot; pulse separation of 20 microseconds ± 20%

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Parameter	Details
Maximum repetition rate (manual)	2.0 Hz (single pulse only) ± 20%
Treatment spot size	400 +0/-40 microns (84% included energy)
Beam divergence	<3 degrees (84% included energy)
NOHD	Approx 75 yards (69 meters)
Safety filters	Total filtering OD 5 @ 532

4.10.4 Aiming lasers

Table 4–11: Aiming lasers specifications

Parameter	Details
Type	Semi conductor laser diode.
Wavelength	635 ±5 nanometers
Safety class	II (2)
Operation	CW (continuous wave)
Power	< 1 mW, continuously variable

4.10.5 Slit lamp delivery system

Table 4–12: Slit lamp specifications

Parameter	Details
Type	Galilean stereoscopic microscope with converging optics
Objective lens	1.25 x
Eyepiece lens	12.5 x, dioptre adjustable in range ± 5 D
Total magnification	16 x (12.5 x eyepiece)
Magnification changer	3 position, removable
Interpupillary distance adjustment	2.16 to 3.5 in (55-88 mm)
Working distance	2.16 in (55 mm)
Focal length	3.6 in (92 mm)
Chin rest	Adjustable, vertical travel 2 in (50 mm)

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Parameter	Details
Slit lamp source	
Slit width	0 to ½ in (0 to 12 mm)
Illumination view field	0.5 mm, 5 mm, 8 mm, 12 mm, continuously variable
Slit rotation	180 degrees
Illuminating angle	180 degrees at horizontal plane (90 degrees for right/left)
Filters	Green, cobalt-blue, neutral density (ND) (28% attenuation)
Bulb	Halogen lamp, 12 V, 30 W pre-centered bulb
Fixation lamp	Green incandescent lamp
Cross slide table	
Vertical adjustment of binocular arm	1 in (26 mm), by rotation of joystick
Fine horizontal movement	By tilting joystick lever, fine movement of 11 mm.
Coarse horizontal movement	By moving the slit lamp base, coarse movement of 4 in (103 mm) longitudinal and 4 in (103 mm) lateral travel.

4.10.6 Power supplies

Parameter	Details
Supply voltage	100–120 V AC or 220–240 V AC
Supply frequency	50/60 Hz
Supply power	520 VA
Mains fuses	6.3 A, 250 V
Internal fuses	Internal fuses are not user-accessible. Contact your Lumenis Distributor if these fuses need replacing
Shock protection	Class 1, type B (IEC 601-1 6.8.1) TYPE B EQUIPMENT

Type B equipment provides protection against electric shock by limiting the leakage current and by the provision of a protective earth connection.

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VISULAS YAG III laser system

Laser class	IV (CFR 21, Part 1040, Sec. 1040.10) 4 (DIN EN 60825-1:2003)		
Wavelength of therapy beam	1064 nm		
Mode	Supergaussian		
Pulse length	typ. 4 ns		
Pulse mode	Energy (typical)	Max. pulse repetition rate	Burst frequency
1 (single pulse)	10 mJ	2.5 Hz (5 pulse / 2 s)	-
2 (double pulse)	23 mJ	1 Hz (1 pulse / s)	33 kHz
3 (triple pulse)	35 mJ	0.5 Hz (1 pulse / 2 s)	33 kHz
Energy attenuation	22 levels: 2, 4, 6, 8, 10, 12, 14, 16, 20, 24, 28, 32, 36, 40, 42, 48, 56, 60, 64, 70, 80 and 100 % transmission		
Beam diameter at the focus	10 µm in air (1 / e^2)		
Angle of exit aperture (divergence)	16° (round angle)		
Aiming beam	Wave length: 660 to 680 nm Power output: max. 150 µW 4-point aiming beam system for focusing		
NOHD	2 m		
Rated voltage	100 V to 240 V ± 10 %		
Rated frequency	50 to 60 Hz		
Rated current	Max 1.4 A to 0.7 A; transient: max. 2.8 A (< 1 s)		
Fuses	2x T 3.15 A / E, 5 x 20 mm in acc. with IEC 60127		
Electrical Protection Class	SK I		
Protection type	IP 20		
Instrument type	B (in acc. with IEC 60601-1)		
Earth conductor	The instrument should only be connected to properly earthed power outlets.		
Control unit dimensions	H x W x D = 135 mm x 210 mm x 330 mm		
Control unit weight	4 kg		

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Substantial Equivalence Discussion for the OPTIMIS FUSION FAMILY per the 510(k) Substantial Equivalence Decision-Making Process Flowchart

1. **Does the new device have the same Indication Statement?**

Yes, the indications for use statement for the Optimis Fusion Family is exactly the same as the indications for use statement for the Lumenis Family of SELECTA Ophthalmic Laser Systems, Delivery Device and accessories cleared in K081704. Each of the families contains multiple configurations of the laser system with different indications for use statements for each individual device. Both families include an SLT model, a YAG model and a model which combines the SLT and YAG. The indications for use statements for each version of the product are identical between the families. Additionally, the YAG model of the Optimis Fusion Family is also being compared to the Carl Zeiss Meditec VISULAS YAG III cleared in K042139. Both systems are cleared for performing posterior capsulotomy and peripheral iridotomy procedures while the Optimis Fusion YAG is also indicated for pupillary membranectomy.

All of the devices are prescription devices which are intended to be used by trained medical personnel. Therefore, the Optimis Fusion Family has the same intended use as the identified predicate devices and may be found to be substantially equivalent to the predicate devices.

2. **Does the new device have the same technological characteristics?**

Yes, the Optimis Fusion Family and the predicate devices have the same technological characteristics. The Optimis Fusion Family and the Lumenis SELECTA family include multiple models within the family. Both the Optimis Fusion Family and the Lumenis SELECTA family include an SLT model, a YAG model and a model that combines the SLT and YAG lasers in one unit. The VISULAS YAG III only includes a YAG model and therefore, will only be compared to the YAG model of the Optimis Fusion. All of the systems use a red aiming laser and both the Optimis Fusion YAG and Selecta Duet YAG use a 635 nm diode for aiming purposes. All of the systems are delivered by a slit lamp delivery system previously cleared in prior 510(k)s.

SLT Mode

The Optimis Fusion SLT is a Q-Switched frequency doubled Nd: YAG laser with a wavelength of 532 nm as is the Selecta SLT model. Both the Optimis Fusion SLT and the Selecta SLT models operate in single pulse modes. The energy range for both devices is 0.3-2.0 mJ. The spot size in air is 400 microns with a focus angle of < 3 degrees for both systems. The maximum energy density at minimum exposure is 1.6 J/cm^2 for the Optimis Fusion SLT and the Selecta Duet SLT. The repetition rate for the Optimis Fusion SLT is 2.5 Hz while it is 2.0 Hz for the Selecta SLT, the pulse duration is 4 ns for the Optimis Fusion SLT and 3 ns for the Selecta SLT, and the maximum average power is 5 mW for the Optimis Fusion and 4 mW for the Selecta SLT. The differences between the two systems are considered very minor in significance and don't affect the safety or efficacy

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of the devices.

YAG Mode
The Optimis Fusion YAG is a Q-Switched Nd: YAG laser with a wavelength of 1064 nm as are the Selecta Duet YAG model and the VISULAS YAG III. All of the devices are pulsed with single spot modes and all models operate in user selectable bursts of 1, 2 or 3 pulses. The energy range for all devices is 0.3-10.0 mJ. The maximum energy output in single pulse mode is 10 mJ for all three devices; is 18 mJ for the Optimis Fusion YAG and 23 mJ for the VISULAS YAG III in double pulse mode; and is 30 mJ for the Optimis Fusion YAG in triple pulse mode, which is lower than the 45 mJ for the Selecta Duet YAG and the 35 mJ for the VISULAS YAG III. Therefore, the energy output in all pulse modes is the same or less than the predicate devices.

The repetition rate for the single pulse mode in the Optimis Fusion YAG is 2.0 Hz as it is for the Selecta Duet YAG; is 1.5 Hz for the Optimis Fusion YAG in the double pulse mode which is between the 1.8 Hz rate for the Selecta Duet YAG and the 1.0 Hz rate for the VISULAS YAG III; and is 1.5 Hz for the triple pulse mode for the Optimis Fusion YAG which is between the 1.6 Hz for the Selecta Duet YAG and the 0.5 Hz for the VISULAS YAG III. The pulse duration is 4 ns for the Optimis Fusion YAG and both predicate devices.

The maximum average power of the Optimis Fusion YAG is 20 mW in single pulse mode which is the same as the Selecta Duet YAG; is 27 mW in the double pulse mode which is similar to the 23 mW in the VISULAS YAG III; and is 45 mW for the triple pulse mode for the Optimis Fusion YAG which is between the Selecta Duet YAG at 72 mW and the VISULAS III at 17.5 mW. The maximum energy density at the minimum exposure is 1.27 10^4 J/cm^2 in single pulse mode which is exactly the same as the VISULAS YAG III; 2.29 10^4 J/cm^2 in double pulse mode which is slightly lower than the VISULAS YAG III at 2.92 10^4 J/cm^2; and is 3.82 10^4 J/cm^2 in triple pulse mode which is slightly below both of the predicate devices. Therefore, the maximum energy density at the minimum exposure is the same or less than the predicate devices.

The spot size in air is 10 microns which is identical to the VISULAS YAG III. The spot placement is centered on the guide beam at the focal plane for all three systems. The focus angle is 16 degrees for all three systems. The offset in air is variable from 0 to 150 microns which is the same as the VISULAS YAG III.

This difference between the two systems are considered very minor in significance and don't affect the safety or efficacy of the devices.

SLT/YAG modes
The Optimis Fusion YAG/SLT includes the features and specification of both the Optimis Fusion SLT system and the Optimis Fusion YAG system combined in one device. The specifications of each individual system remain unchanged when they are combined into one unit. This is exactly the same at the Lumenis Selecta Duet which combines the Selecta SLT and Selecta YAG features. Therefore, the similarities and

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differences outlined above for the SLT and YAG models apply to the Optimis Fusion YAG/SLT device.

3. Are the descriptive characteristics precise enough to ensure equivalence?

Yes, the descriptive characteristics available on both the Optimis Fusion Family and the predicate devices are precise enough to ensure equivalence. Therefore, the Optimis Fusion Family is substantially equivalent to the predicate device.

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Patients at risk

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

⇒ extracapsular cataract patients without a patent iridectomy are at an increased risk of pupillary block

⇒ patients with preoperative glaucoma, prior filtering surgery or preoperative IOP of greater than 20 mm Hg are at a significantly higher risk of postoperative IOP rise to levels of clinical concern

⇒ patients with IOLs, particularly posterior chamber lenses close to the posterior capsule, are at risk of IOL pitting or cracking

⇒ the greater the total amount of energy employed to effect capsule opening, the greater the risk of damage to the IOL

⇒ patients with pre-existing ocular conditions have a greater chance of experiencing postoperative complications

An increase in IOL pitting is possible when silicon IOLs are used. We advise caution when using silicon IOLs and recommend using +250 offset position. If pitting persists, defocus the laser further posterior manually.

Precautions

Targeting

Focus the unit in accordance with the description provided in *Chapter 5*.

Since in dual beam diode systems such as **Selecta Duet**, the Nd:YAG beam cross-section extends beyond the diode beams, there is an increased probability of Nd:YAG beam impingement of the iris. Therefore, the operator should not fire the therapeutic shot without assurance that the two diode spots have become coincident on the target tissue (that is, neither of the diode beams is blocked or obstructed by other tissues of the eye in the beam pathway). Care should be exercised when working at the iris margin or at a wide angle to the patient's visual axis.

The diode aiming beam focus spot is longitudinally offset up to a maximum of 350 microns in front of the Nd:YAG beam. This offset is individually set for the laser using the posterior offset control.

*With the offset control set at MIN, **Selecta Duet** delivers a preset offset equal to 100 microns in air.*

Energy use

The lowest possible energy level should be used, beginning with 1-2 mJ and increasing the energy as required.

The burst-mode capability should not be used initially to effect capsule dissection. It should be used only when increasing levels of single shot energy have been attempted and are not successful in opening the capsule.

If the capsule is tough or scarred, higher energy shots may be required. It is recommended that the increase be in 1-2 mJ steps. The clinical experience indicates that the mean power level used is 2.7 mJ, and 97% of the subjects were treated at less than 5 mJ.

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-77	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatt ng convent on for the t t e s: [SDO] [numer c dent f er] [t t e of standard] [date of pub cat on]

[2] Author ty [21 U S C 360d] www fda gov/cdrh/stdsprog htm

[3] http://www accessdata fda gov/scr pts/cdrh/cfdocs/cfStandards/search cfm

[4] The summary report shou d nc ude: any adaptat ons used to adapt to the dev ce under rev ew (for examp e a ternat ve test methods); cho ces made when opt ons or a se ect on of methods are descr bed; dev at ons from the standard; requ rements not app cab e to the dev ce; and the name address of the test aboratory or cert f cat on body nvo ved n conformance assessment to th s standard The summary report nc udes nformat on on a standards ut zed dur ng the deve opment of the dev ce

[5] The supp ementa nformat on sheet (SIS) s add t ona nformat on wh ch s necessary before FDA recogn zes the standard Found at http:/www accessdata fda gov/scr pts/cdrh/cfdocs/cfStandards/search cfm

[6] The on ne search of CDRH Gu dance Documents can be found at www fda gov/cdrh/gu dance htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY, 1988; A 1 1991-11, A2 1995

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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