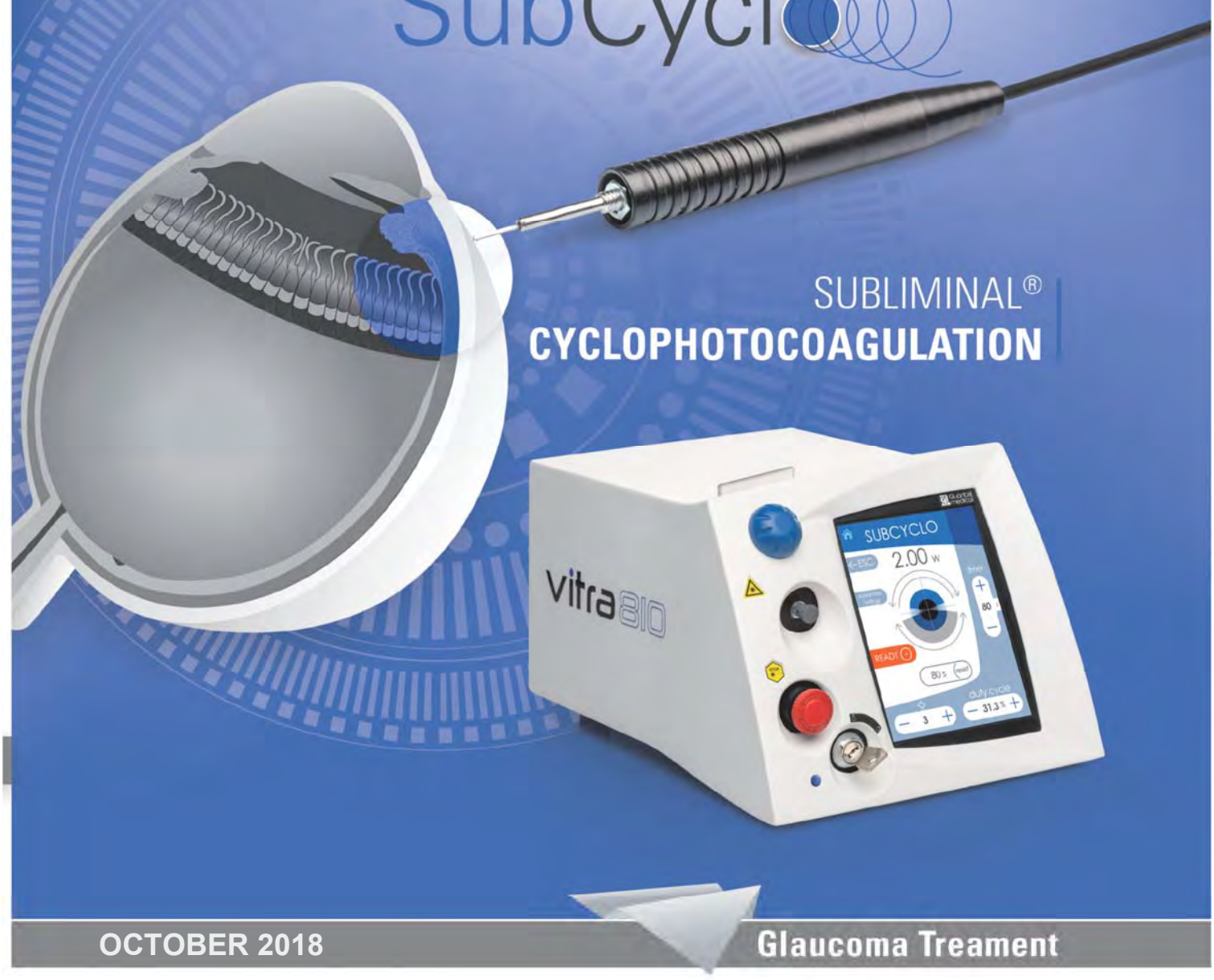
USER MANUAL

vitra 810™

SubCyclo®



SUBLIMINAL®

CYCLOPHOTOCOAGULATION

OCTOBER 2018

Glaucoma Treament

2018 CE 0459

Directive 93/42/EEC

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63808 Cournon d'Auvergne Cedex
FRANCE
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E-mail : contact@quantel-medical.fr
Web site: www.quantel-medical.com

Quantel medical

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

International

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

Tél.: +33 (0) 473 745 745
Fax: +33 (0) 473 745 700
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U.S.A.

QUANTEL MEDICAL USA
49 Willow Peak Drive
BOZEMAN MT 59718
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Quantel Medical
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User manual VITRA 810
Software version 1.0 and over
International version
(Ref : XL_VIT810_ME_AN)
October, 5th 2018

2018 CE 0459

Directive 93/42/EEC

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Rev.
05/10/2018

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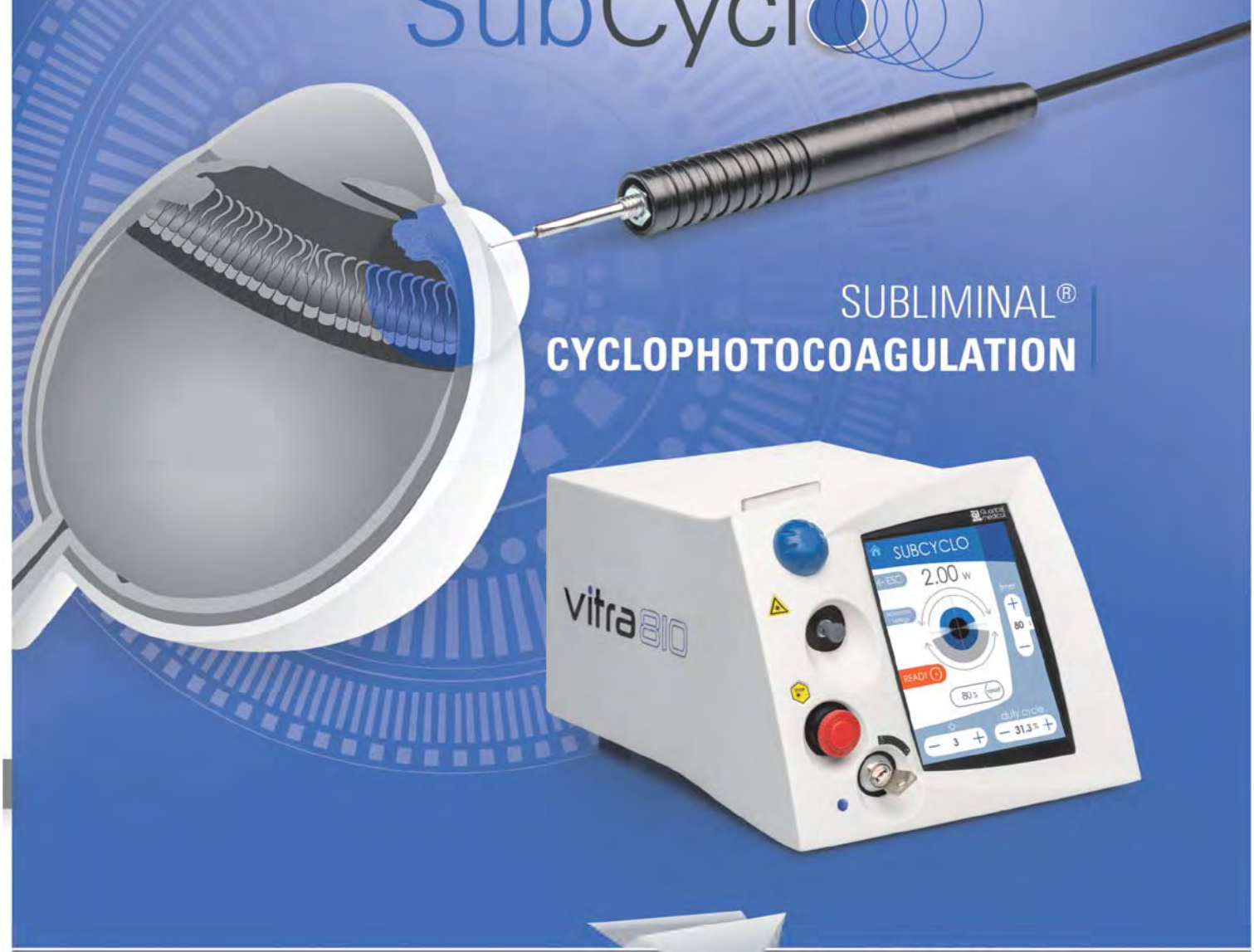
INTRODUCTION

SubCyclo®



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1. USER MANUAL DESCRIPTION

This user manual is organized into the following chapters:

- Introduction
- I – Regulatory information and safety
- II – Technical information
- III - Use
- IV - Maintenance
- V – Clinical information

This manual is provided with the device under electronic format (PDF) with the documentation package of the USB stick.
A player software (Sumatra) for this file format is also furnished on the USB stick.

WARNING: The system should only be used by qualified healthcare professionals trained by Quantel Medical or qualified Quantel Medical distributors.
THE SYSTEM USER MANUAL IS AVAILABLE IN ELECTRONIC FORMAT. E-mail: contact@quantel-medical.fr Web site: www.quantel-medical.com

The user is able to ask Quantel Medical for a paper version of this user manual.

2. TERMS AND SYMBOLS

This manual uses symbols and terms that draw the attention of the reader to additional security information.
Their signification is described below:

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

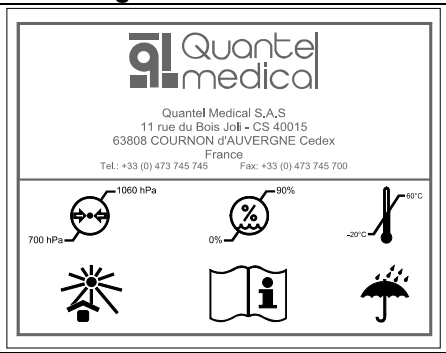
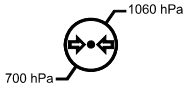
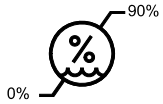
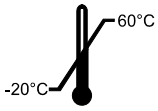
CAUTION: Potential hazards which, if not avoided, could result in minor or moderate injury and/or product damage.

NOTE: Significant additional information or explanation.

3. UNPACKING THE INSTRUMENT

3.1. TRANSPORTATION INFORMATION & LABELS

Before being shipped, the unit has been packed with special care in order to reduce the risk of damage during transportation. However, before unpacking the laser, it is imperative to check and identify any possible sign of package deterioration.

① Shipping label – Handle with care		② Environmental conditions eligible for transportation and storage.	
			
	Package positioning direction.		Pressure limit.
	Fragile. Handle with care.		Relative humidity limit.
	Keep dry.		Temperature limit.
	Fragile. Keep dry.		Keep away from sunlight.
			Consult the user manual.
			Keep dry.

③ **Goods receipt 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 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 : *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.

3.2. PACKING LIST

When receiving the shipment, check the contents of the package in the following list:

	- Laser VITRA 810	
	- Power cord (5 m)	
	- Red bypass connector doorswitch	
	- Blue bypass connector	
	- Keys (2)	
14.	GentleFootTM pedalas - GentleFoot™ footswitch	
	- Elbow rest	
	- User manual on electronic format (USB)	
	- Quick start guide	
15.	Apsauginiai akiniai , 2 vnt. - Protection goggles (2)	

NOTE: The device could be delivered with one or several accessories from the following table.

3.3. ACCESSORIES

To order the following elements,
contact QUANTEL MEDICAL or your local distributor.

Accessories for the laser VITRA 810	
FOR ANCILLARY PERSONNEL	
Laser safety goggles for 810 nm wavelength	
FOR CALIBRATION PURPOSE	
Laser power measurement system	
CARRYING CASE	
Carrying case	
SHOT FOOTSWITCH	
Wireless GentleFoot™ footswitch	
LASER PROBES	**sterile for single use**
20 gauges	
Straight laser probe (pack of 10)	
Curved laser probe (pack of 10)	
Sterile for single use STM Straight laser probe, caliber 20 (pack of 5)	
Sterile for single use STM curved laser probe, caliber 20 (pack of 5)	
23 gauges	
Straight laser probe (pack of 10)	
Flexible curved laser probe (pack of 10)	
Steerable laser probe (pack of 10)	
STM Straight laser probe (pack of 5)	
STM curved laser probe (pack of 5)	
25 gauges	
Straight laser probe (pack of 10)	
Flexible curved laser probe (pack of 10)	
Steerable laser probe (pack of 10)	
STM Straight laser probe (pack of 5)	
STM curved laser probe (pack of 5)	
CYCLOPHOTOCOAGULATION PROBES	**sterile for single use**
Cyclophotocoagulation probe (unit)	
Cyclophotocoagulation probe (pack of 5)	
Autoclavable footplate for Thermocyclo only	
RETINOPEXY PROBES	**sterile for single use**
Retinopexy probe (unit)	
Retinopexy probe (pack of 5)	

LASER ADAPTOR FOR INDIRECT OPHTHALMOSCOPE
KEELER VANTAGE type
810 nm adaptor for KEELER VANTAGE PLUS indirect ophthalmoscope fiber size: 100µ)
OPTION: KEELER VANTAGE PLUS Indirect Ophthalmoscope (lighting LED)
INDIRECT OPHTHALMOSCOPE WITH LASER ADAPTOR
HEINE type
Indirect ophthalmoscope HEINE OMEGA 500 with integrated adaptor 810 nm (fiber size: 100µm)

DOCTOR FILTER
WILD
Fixed doctor filter 810 nm for WILD microscope
Push-pull doctor filter 810 nm for WILD microscope
ZEISS
Fixed doctor filter 810 nm for ZEISS microscope
Push-pull doctor filter 810 nm for ZEISS microscope
LEICA/WILD
Quad doctor filter 810 nm for LEICA/WILD M844 microscope

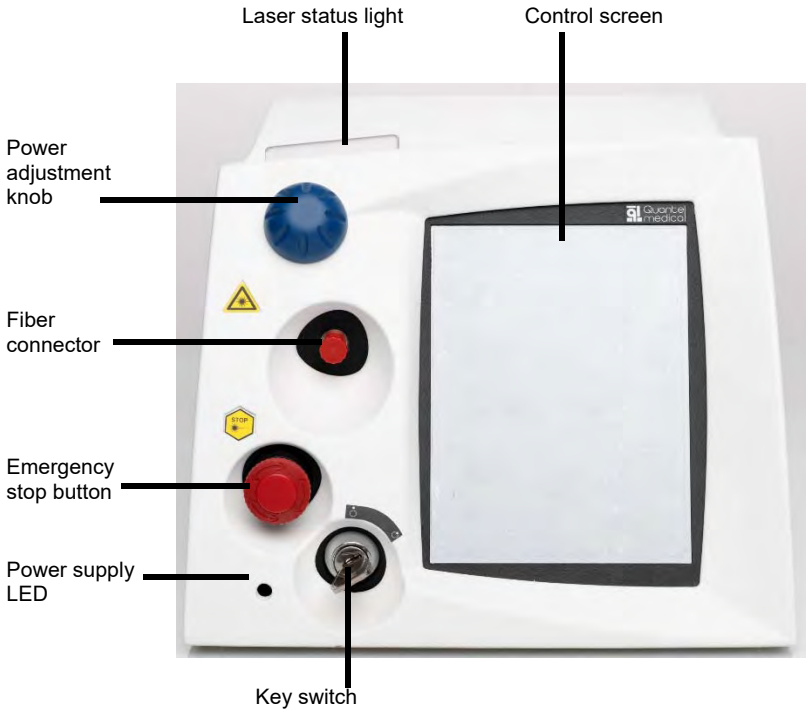
SLIT LAMP ADAPTOR
HAAG STREIT type
810 nm Single Spot Adaptor for Transpupillary Thermo Therapy (TTT)

OPERATING MICROSCOPE ADAPTOR
LEICA type
810 nm adaptor for LEICA microscope
ZEISS type
810 nm adaptor for ZEISS microscope
MOLLER WEDEL HIR 900 type (XL810MIZST + XLMIMWSUP)
810 nm adaptor for ZEISS microscope
Adaptor support for MOLLER WEDEL HIR 900 microscope

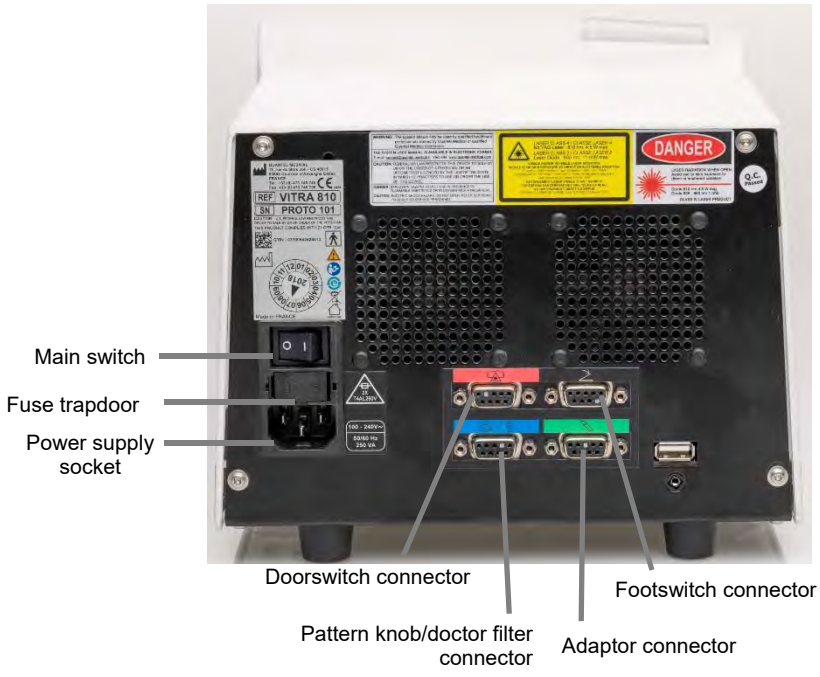
4. GENERAL DESCRIPTION

4.1. LASER

4.1.1. FRONT PANEL



4.1.2. REAR PANEL

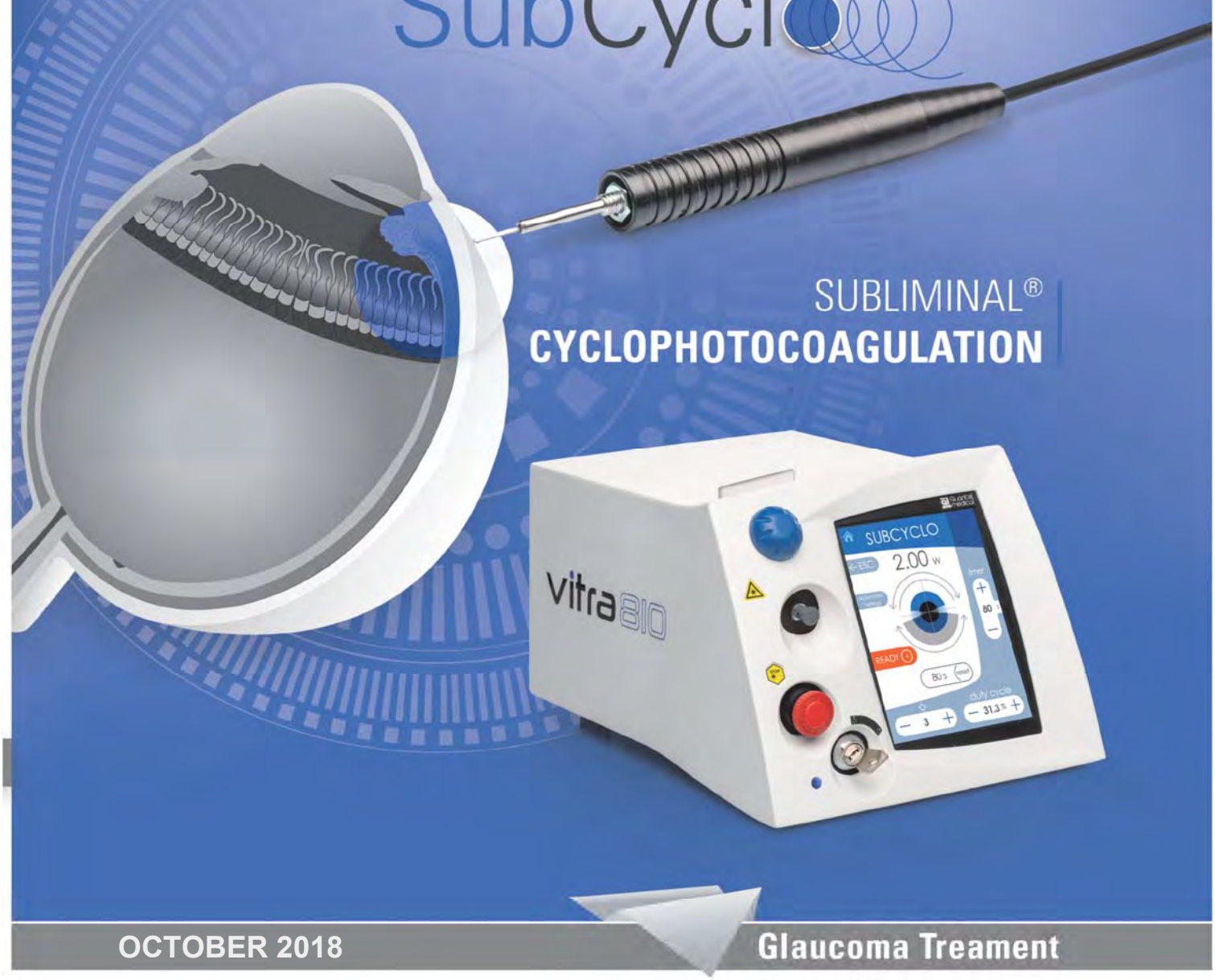


USER MANUAL

vitra 810™

I – REGULATORY INFORMATION AND SAFETY

SubCyclo®



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1. INTENDED USE AND CONTRAINDICATIONS

The VITRA 810 treatment laser provides a high energy to perform a wide variety of ophthalmic photocoagulation procedures where depth of penetration and lack of absorption in hemoglobin are primordial.

With **slit lamp terminal**:
This system is indicated for use in retinal photocoagulation for the treatment of ophthalmic conditions including:
- Proliferative Diabetic Retinopathy,
- Macular Degeneration,
- Retinal Detachment.

With **indirect ophthalmoscope**:
This system is indicated for use in peripheral photocoagulation only.

The laser's indirect ophthalmoscope is indicated to be used for:
- Any eye requiring laser treatment out to the ora serrata.
- Any eye with rubeosis iridis from central vein occlusion.
- Any eye undergoing pneumatic retinopexy retinal reattachment procedures.
- Any time laser energy must be delivered through any eye with focal lens opacity or with a small pupil.
- Laser treatment of the eye with the patient in the supine position.

With **laser probe**:
The laser probe has been designed to provide a means for intraocular photocoagulation as an adjunct to vitrectomy surgery.

Specific indications for use of the laser probe include:
- Treatment of complicated rhegmatogenous,
- Tractional retinal detachments,
- Proliferative vitreoretinopathy,
- Proliferative diabetic retinopathy,
- Various retinal vascular tumors.

With a **Cyclophotocoagulation probe** (for SubCyclo procedure):
The SubCyclo procedure is indicated for the treatment of:
- The primary glaucoma with opened angle
- Glaucoma with closed angle
- Refractory glaucoma.

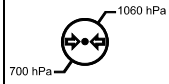
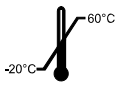
NOTE: The laser probe should only be used in conjunction with vitrectomy surgery, but should not be the sole indication for vitrectomy.

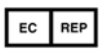
WARNING: **This user manual is intended to solely be used by trained ophthalmologists for diagnosis and treatment of ocular pathology.**

2. SYMBOLS

Symbols situated on the laser system, its packaging and accessories, are described in the following charts.

SYMBOL	PUBLICATION	DESCRIPTION
	IEC 60417 - 5007	ON POSITION (Power: mains connection)
	IEC 60417 - 5008	OFF POSITION (Power : mains disconnection)
	IEC 60417 - 5265	"OFF" Switching off for a part of the equipment.
	IEC 60417 - 5266	Stand-by or preparatory state for a part of the equipment.
	IEC 60417 - 5264	"ON" Switching on for a part of the equipment.
	IEC 60417 - 5016	Fuses
	IEC 60417 - 5032	Alternating current
	IEC 60417 - 5114	Footswitch
	IEC 60417 - 5152	Radiation of laser products
	IEC 60417 - 5333	BF type equipment *(Protection against electrical shocks)*
	ISO 7010-W001 General	GENERAL WARNING SIGN
	ISO 7000-3082 ISO 15223-1 :2017 n°5.1.1	"MANUFACTURER" of the device
	ISO 7000-2497 ISO 15223-1:2017 n° 5.1.3	"DATE OF MANUFACTURE" of the medical device
	ISO 7000-2493 ISO 15223-1:2017 n° 5.1.6	"CATALOGUE NUMBER" of the medical device
	ISO 7000-2498 ISO 15223-1:2017 n° 5.1.7	"SERIAL NUMBER" of the medical device
	ISO 7010-M002	"REFER TO INSTRUCTION MANUAL"
		RoHs sign: Restriction of the use of hazardous substances
	IEC 60417-5957	For indoor use only
	EN50419	Electrical and electronic equipment in accordance with Directive 2012/19/EU (WEEE) Do not dispose in domestic waste.

SYMBOL	PUBLICATION	DESCRIPTION
		Package positioning way
	ISO 7000-0621 ISO 15223-1:2017 n° 5.3.1	Fragile HANDLE WITH CARE.
	ISO 7000-0626 ISO 15223-1:2017 n° 5.3.4	“KEEP DRY”
	ISO 7000-2621 ISO 15223-1:2017 n° 5.3.9	Upper and lower limits of atmospheric pressure for transport and storage.
	ISO 7000-2620 ISO 15223-1:2017 n° 5.3.8	Upper and lower limits of relative humidity for transport and storage.
	ISO 7000-0632 ISO 15223-1:2017 n° 5.3.7	“TEMPERATURE LIMIT”
	ISO 7000-0624 ISO 15223-1:2017 n° 5.3.2	“KEEP AWAY FROM SUNLIGHT”
	ISO 7000-1641 ISO 15223-1:2017 n° 5.4.3	Consult operating instructions

SYMBOL	PUBLICATION	DESCRIPTION
	ISO 7000-1051 ISO 15223-1:2017 n° 5.4.2	“DO NOT RE-USE” Must be used only once and on only one patient as part of a single treatment.
	ISO 7000-2607 ISO 15223-1:2017 n° 5.1.4	“USE BY DATE”
	ISO 7000-2492 ISO 15223-1:2017 n° 5.1.5	“BATCH CODE”
	ISO 7000-2501 ISO 15223-1:2017 n° 5.2.3	“STRERILIZED USING ETHYLENE OXIDE”
	ISO 7000-0434A ISO 15223-1:2017 n° 5.4.4	“CAUTION” It is necessary to read use instruction for all important information linked to the security.
	ISO 15223-1:2017 n° 5.1.2	“AUTHORIZED REPRESENTATIVE IN THE EUROPEAN UNION”
	ISO 7000-2606 ISO 15223-1:2017 n° 5.2.7	“DOT NOT USE IF PACKAGE IS DAMAGED”
	USA Code of Federal Regulations 21 CER Part 801	“Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed ophthalmologist.”

3. CLASSIFICATIONS

The conception of the system is classified into the following way:

3.1 CLASSIFICATION OF THE DEVICE

European 93/42/EEC, Appendix IX	**IIb**
Laser Safety Classification US FDA	**Classe Laser II**
Product code US FDA	**HLI, MYC, HQF**

3.2 ELECTRICAL CLASSIFICATION OF THE DEVICE

Protective class	**I**	(MAIN INSULATION)
Type	**BF**	(Protection against electrical shocks)
Protection degree	**IP20**	(Protection from solid substances: Ø>12,5 mm)
Operation	**Continuous** with short time loading.	

3.3 ELECTRICAL CLASSIFICATION OF TERMINALS

Conception of terminals class them in the following way:

Terminal	**Type**
Laser probe	Protection against electrical shocks: Applied parties with **BF type**
Slit lamp adaptor	
Operating microscope adaptor	
Indirect ophthalmoscope adaptor	

3.4 CLASSIFICATION OFTHE TREATMENT BEAM

Laser classification US FDA CDRH	Class **IV**
European laser classification IEC 60825-1: 2007	Class **4** *Lasers are hazardous under both intrabeam and diffuse reflection viewing conditions. They may cause also skin injuries and are potential fire hazards.*
Type	**Laser diode**
Output power	**50 – 3000 milliWatts** (adaptor output)
Wavelength	**810 nm**

3.5 CLASSIFICATION OF THE AIMING BEAM

Laser classification US FDA CDRH	Class **II**
European laser classification IEC 60825-1: 2007	Class **2** *These sources are harmless for the eye because of the action reflex. This reaction to visible light ensures a sufficient protection in standard conditions of use, even if the user needs optical instruments to look at the beam.*
Type	**Laser diode**
Output power	**< 1 milliWatt** (Delivery system output)
Wavelength	**635 - 650 nm**

4. WARNINGS AND PRECAUTIONS

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

4.1. GENERAL WARNINGS AND SAFETY INFORMATION

WARNING: This user manual is designed to acquaint the user with the normal operation and maintenance of the laser system. 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 136.3-2011 and ANSI Z 136.1-2014**) provides 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.

WARNING: 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.

WARNING: 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: Do not use an electric cable extension.

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. Refer to the user manual:
Chapter 4 – Maintenance *Section 2.4 - Cleaning the 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: 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.

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

WARNING: The expected lifespan of the system laser is 7 years.

4.2. 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 IV (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:
Chapter I – Regulatory information & safety
Section 5 - Laser safety glasses and NOHD

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) **Always** keep the system in STANDBY mode When the laser is on, unless it is used to perform treatment.

6) Contact lens wearers should use anti-reflection lenses treated for **810 nm** wavelength. 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 user manual:
Chapter 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 the user manual:
Chapter II – Technical information
Section 5.5 - Doorswitch & warning red lamp

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

4.3. SAFETY FEATURES

CARACTERISTIC	DESCRIPTION
Key switch	The laser system can only be turned on with the 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	In normal position, the red push button is in the « UP » position (not pressed). Once pressed, all power is immediately cut off and the risk of laser radiation is thus eliminated. This button can be released by turning it clockwise to the ON position (while pressing on it) to the operating position to restart the system and return to the “STANDBY” status.
Treatment screen selection	To display the treatment screen, the user has to: ▪ Make sure that the emergency stop button is released (operating position); ▪ Switch on the laser system main switch (located under the unit table); ▪ Make sure that the door interlock system is closed (if applicable); ▪ Turn the laser system ignition key (located on the front of the system) to the “ON” position; ▪ Select the treatment screen: Glaucoma, Retina; And at this stage only, the user can access the treatment screen and thus activate the laser system by pressing on the “STANDY” / “READY” button.
“STANDBY”/ “READY” status	The “STANDBY” / “READY” laser status can be selected by pressing on the “STANDBY” / “READY” icon. Selecting the “STANDY” / “READY” icon while the laser is in “STANDBY” status, switches it to “READY” status. The “READY” status allows the user to shoot by pressing on the footswitch. Selecting the “STANDBY” / “READY” icon while the laser is in “READY” status, switches it to “STANDBY” status. In “STANDBY” status, the user cannot shoot, even when pressing on the footswitch. The laser must be manually switched to “READY” status to enable the laser treatment shot.
Door safety remote interlock	**The « door safety remote interlock » feature is highly recommended (to be installed by the user).** The « door switch » connector is available under the unit table; it is indicated by the label:  Connecting the door safety remote interlock prevents the laser from firing when the door is open. The unit is supplied with a bypass connector.

CARACTERISTIC	DESCRIPTION
Safety shutter	The laser optical module is equipped with a safety shutter that blocks the laser treatment optical path. To “unblock” it, it is necessary to: - select the laser treatment, - manually switch the system to “READY” status, and press on the footswitch.
Energy deviation warning	The system warns the operator if the delivered energy deviates more than ±20% from the set value.
Protective housing	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).
Controls location	All user controls are located so that there is no risk of accidental laser exposure.
FDA and CEI regulatory labels	The regulatory safety labels are positioned as indicated in the user manual: ***Chapter II – Technical information*** *Section 1 - Labels*
Electrical leakage protection	A medical grade power supply is built in the power supply console. This ensure that the whole instrument, including the slit lamp power supply meets the IEC 60601-1 related to the earth leakage protection.

5. LASER SAFETY EYEWEAR & NOHD

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: Safety glasses and filters providing protection to other emitted wavelength do not provide suitable protection to the device specific wavelength and should therefore absolutely not be used.

WARNING: Appropriate safety glasses should be available outside of the treatment room for anyone wanting to enter in this room. Any treatment room opening to the outside (windows) must be protected.

WARNING: QUANTEL MEDICAL recommends that the treatment area is equipped with a safety interlock and warning lamp.

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

WARNING: Even if it is most improbable to damage the retina with the aiming beam: it is recommended to avoid staring into the aiming beam unless under controlled conditions.

5.2. NOHD

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**,
- **ANSI Z136.3**, or
- **IEC 60825-1**, Appendix A.

The following formula has been used to calculate the NOHD for the worst case scenario for the SUPRA 810 unit among its compatible delivery systems.

The values specified here meet or exceed the laser safety eyewear requirements for the Indirect Ophthalmoscope Delivery System.

$$DNRO = \frac{a - \sqrt{Pf \cdot (4 \cdot Po / (3{,}142 \cdot E_{EMP}))}}{Ø}$$

Where:

a	= beam waist diameter;
z	= distance between the laser system and the beam waist;
Ø	= full angle beam divergence;
Po	= maximum laser power available;
Pf	= profile correction factor (Gaussian or uniform) ;
E_{MPE}	= Maximum Permissible Exposure, in power density units (power per unit area); $E_{MPE} = 18(t^{0.75})C_6$ where t = 0.25s is the maximum exposure time at maximum laser power
NOHD	= Nominal Ocular Hazard Distance (measured from laser aperture) the distance required to reduce the power density to the MPE

NOHD and MPE calculation are realized with a 50 µm optical fiber connected to the SUPRA 810.

Parameters:

a	=	$8\ 10^{-4}$ m	
Po	=	3 W	**EMPE = 25,46 W/m²**
Pf	=	1	**DNRO = 30,96 m**
Ø	=	0.0125 rad	
z	=	0,03 m	

Safety goggles:

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:

DO = - LOG (E_{MPE} / Power density) = **3,49**

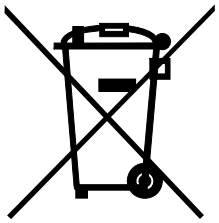
Where power density = 77 992,98 W/m²
(taking into account the pupil diameter: 7 mm)

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

L4 @ 810 nm (EN 207 standard).

6. ELIMINATION OF WASTES

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



Do not dispose with domestic household wastes!

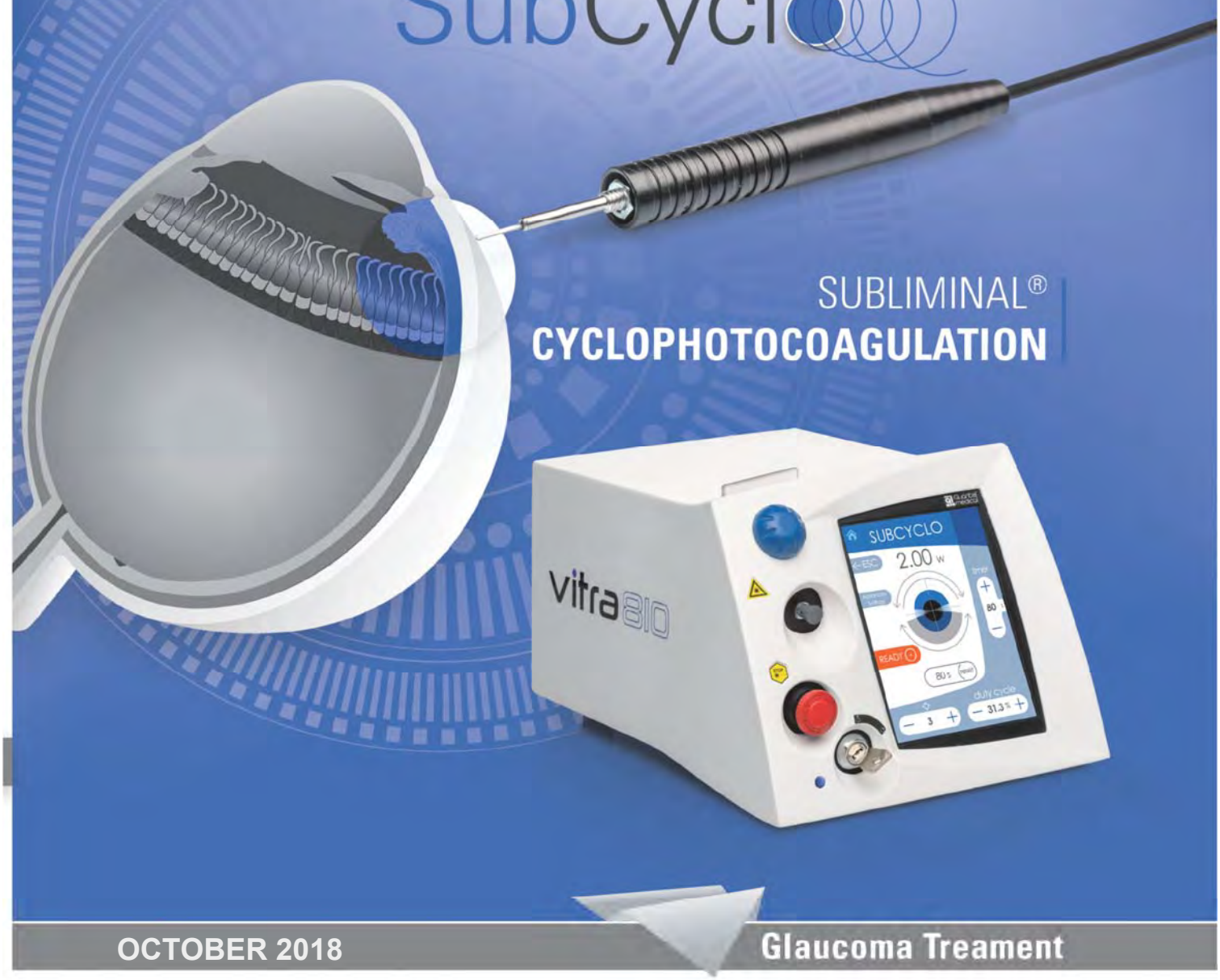
WEEE category:
This product is classed as category 8 among the "Medical devices (with the exception of all implanted and infected products)".
To dispose completely of the device and its accessories, contact **QUANTEL MEDICAL**.

USER MANUAL

vitra 810™

II – TECHNICAL INFORMATION

SubCyclo®



OCTOBER 2018

Glaucoma Treament

2018 CE 0459

Directive 93/42/EEC

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

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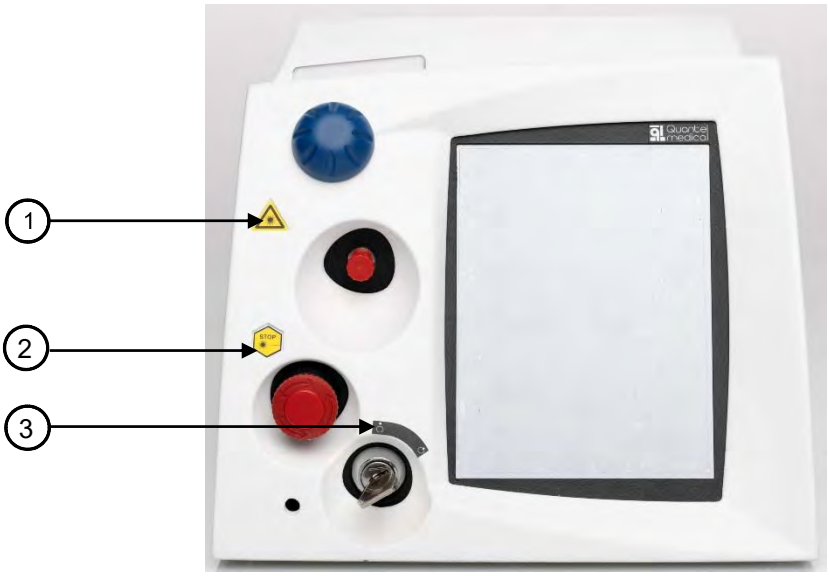
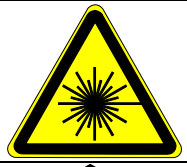
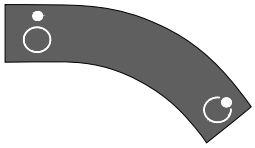
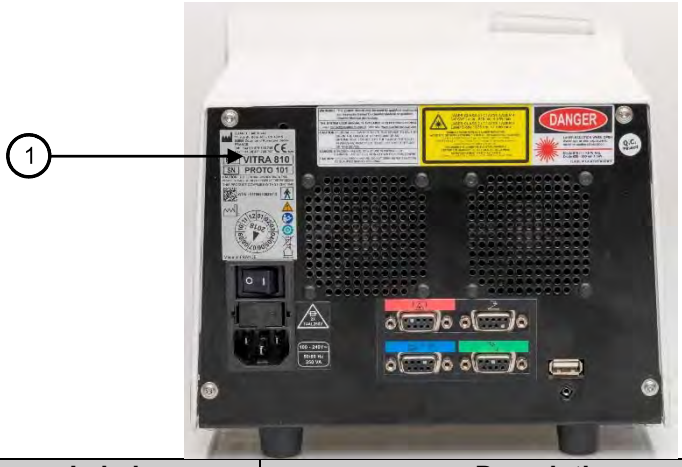
Rev.
05/10/2018

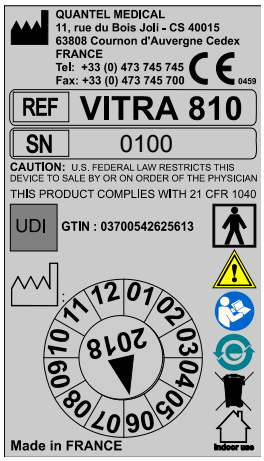
1. LABELS

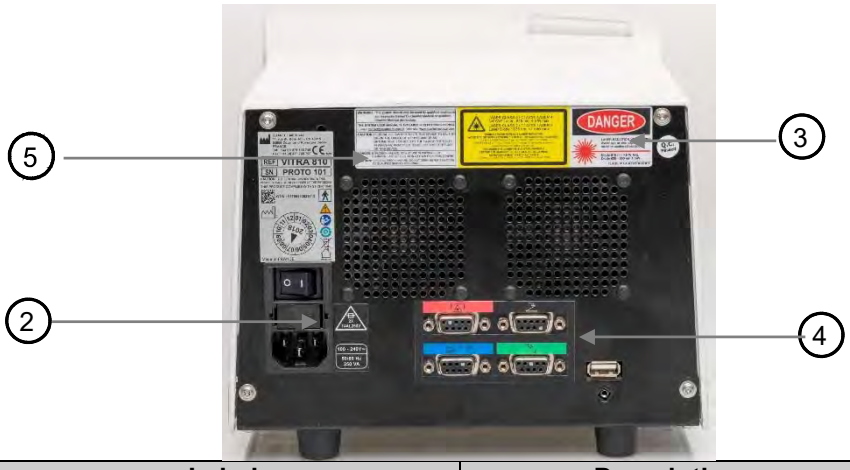
1.1. FRONT PANEL

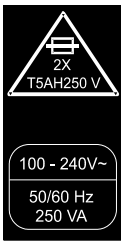
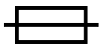
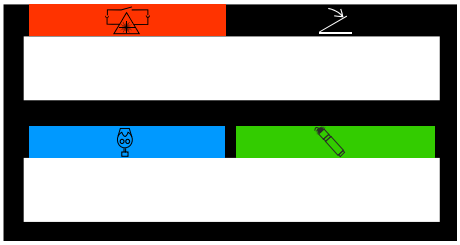
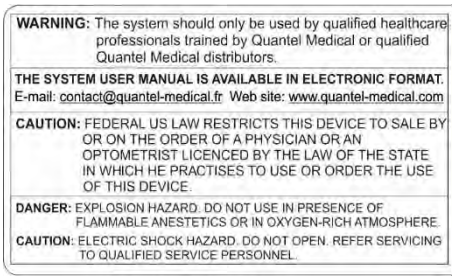


Ref.	Label	Description
1		**LASER APERTURE:** Located next to the laser aperture.
3		**EMERGENCY STOP**: Located next to the red emergency stop button.
2		**KEY POSITION:** Indicates the "OFF" and "ON" positions of the key.
		"OFF" for a part of equipment **IEC 60417 - 5265**
		Stand-by or preparatory state for a part of equipment **IEC 60417 - 5266**

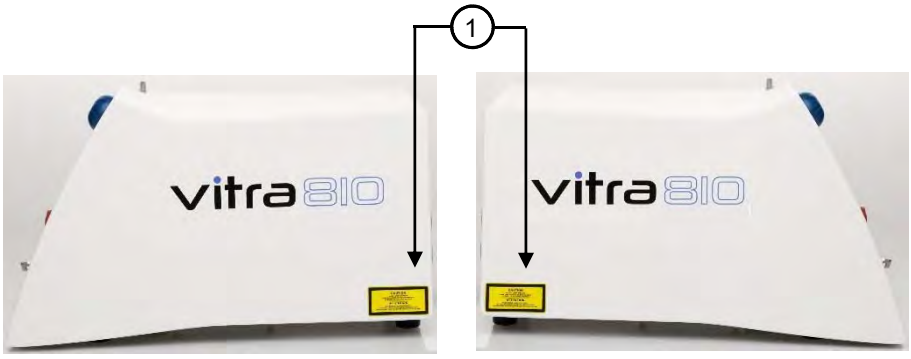


Ref.	Label	Description	
1	**IDENTIFICATION LABEL**  		**Manufacturer** of the device
		CE 0459	**CE marking** relating to medical devices (European directive 93/42/CEE)
		REF	Reference catalogue of medical equipment
		SN	Serial number of medical equipment
			« Class I » – Main insulation. Accessible conductive parts are connected to the ground.
			IP 20: Protection against solid bodies (Diameter > 12.5mm).
		UDI GTIN : 03700542625613	**Unique Device Identification (UDI)** - Flash code - GTIN n° of medical device
			Protection against electrical shocks: Applied parts are classified as **BF type**
			Manufacturing date of the medical device
			GENERAL WARNING
			Refer to the instruction manual/ booklet.
			RoHS : Restriction of the use of certain hazardous substances in electrical and electronic devices.
			Electrical/electronic equipment in accordance with the Directive 2012/19/UE (WEEE) Do not dispose with domestic household wastes.
			For indoor use only.



Ref.	Label	Description
2	**FUSES AND VOLTAGES**	
		Specification of voltages, currents, frequencies, power and fuses
		Fuse
		Alternative current
3	**INDICATIVE PLATE and WARNING**	
		DANGER RADIATIONS LASER Specification of laser beam (treatment and viewfinder): - Laser class, - Wavelength - Maximum power
4	**CONNECTEURS**	
		 Doorswitch
		 Footswitch
		 Doctor filter
		 Adaptor
5	 WARNING: The system should only be used by qualified healthcare professionals trained by Quantel Medical or qualified Quantel Medical distributors. THE SYSTEM USER MANUAL IS AVAILABLE IN ELECTRONIC FORMAT. E-mail: contact@quantel-medical.fr Web site: www.quantel-medical.com 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.	The system should only be used by professionals trained by Quantel medical or by distributors qualified by Quantel Medical.
		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).*
		US FEDERAL LAW RESTRICTION. The device could be sold only by a professional licensed by the state in which the device is used.
		Danger: explosion or electric shock risks.

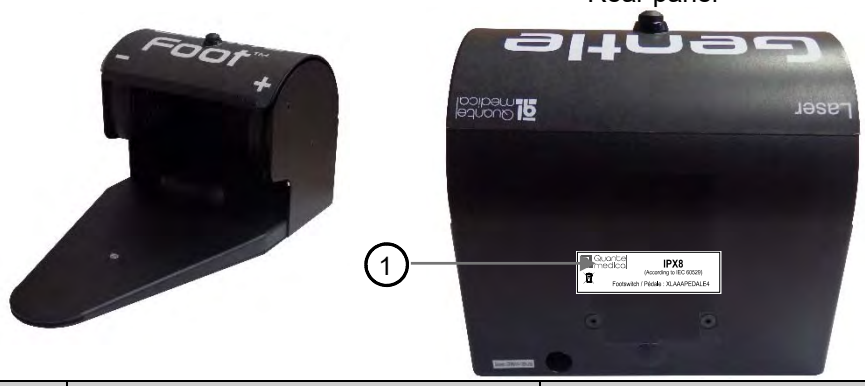
1.2. LATERAL PANELS



Ref.	Label	Description
1	CAUTION CLASS 4 LASER RADIATION WHEN OPEN AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION ATTENTION RAYONNEMENT LASER DE CLASSE 4 - EN CAS D'OUVERTURE EXPOSITION DANGEREUSE AU RAYONNEMENT DIRECT OU DIFUS DES YEUX OU DE LA PEAU	**INTERNAL RADIATIONS**: Laser radiation is present inside the apparatus.

1.3. FOOTSWITCH

Rear panel



Ref.	Label	Description	
1	Quantel medical IPX8 (According to IEC 60529) Footswitch / Pédale : XLAAAPEDALE4	Protection against intrusion of solid bodies or liquid :	
		IP	Protection degree
		X	Protection against intrusion of solid bodies: Not necessary
		8	Protection against intrusion of liquid: Submersible material under specified conditions (prolonged immersion) beyond 1 m.
			Electrical/electronic equipment in accordance with the Directive 2012/19/UE (WEEE). Do not dispose with domestic household wastes.

NOTE: A wireless GentleFoot™ footswitch is available in option.

2. TECHNICAL SPECIFICATIONS

2.1. TREATMENT LASER BEAM

PARAMETERS	DESCRIPTION		
Laser class	Class **4 (IV)** laser product		
Laser source	Laser diode		
Wavelength	810 nm (nanometers)		
Fiber output	1 output port		
Output power	50 – 3000 mW (milliWatts) (out of optical delivery)		
Exposure time Shot interval	**SINGLE REPEAT** 0,01 s to 60 s	**PAINTING** 0,05 s (shot max= 80 s)	**Subliminal** 0,1 ms to 1 ms (duty cycle: 5 % to 35 %)
Laser class	**REPEAT** 0,1 –0,2 – 0 ,3 –0,5 –0,7 – 1s		
	PAINTING MODE 0,02 s		
	Subliminal 0,3 ms to 19 ms (duty cycle: 5% to 35%)		
Laser source	Shot number delivered (from 0 to 9999)		

2.2. AIMING LASER BEAM

PARAMETERS	DESCRIPTION
Laser class	Class **2 (II)** laser product
Laser source	Laser diode
Wavelength	635 nm – 650 nm (nanometers)
Output power	< 1 mW (milliWatt) (out of optical delivery)

2.3. POWER SUPPLY

PARAMETERS	DESCRIPTION
Operating voltages	100 – 240 Vac
Operating frequencies	50/60 Hz
Power	250 VA
Fuse	4 A T5AH 250V P (IEC 60127-1 standard)
Protection	Class I

2.4. OTHER SPECIFICATIONS

PARAMETRES	DESCRIPTION	
Cooling	Thermoelectric solid-state cooler based on the Peltier effect + fan	
Dimensions Height Width Depth Weight	**Laser console** 18 cm 19,5 cm 30 cm 5,6 kg	**Footswitch** 16,5 cm 17,5 cm 34 cm 2,7 kg
Dimensions screen Height Width	13,5 cm 5,3 inch 10,1 cm 3,9 inch	

2.5. CONTROL INTERFACES

PARAMETERS	DESCRIPTION
Key switch	Power supply ON / OFF.
Front panel	Touch screen with illuminated push buttons.
Footswitch	Connected at the back of the unit.
Emergency stop	Cuts off power supply and all the laser functions.
Pattern selecting knob	Selects, resizes and rotates the treatment pattern.

11. Prisilietimu valdomas ekranas su šviečiančiais mygtukais.

2.6. AVAILABLE APPLICATIONS

Only connect delivery systems provided by Quantel medical.
The following Quantel Medical adaptors are available:

PRP adaptor for slit lamp
Adaptor for Keeler / Heine indirect ophthalmoscope
Adaptor for Leica / Zeiss operating microscope
T.T.T (Transpupillary Thermo Thérapy) adaptor
Cyclo photocoagulation / Thermocyclo sterile laser probe

WARNING:

Laser probes are sterile and disposable.
They are not designed to be re-used.
Do not dispose with domestic household wastes.
Chapter I – Regulatory information and safety
Section 6 – Elimination of wastes

2.7. ENVIRONMENTAL CONDITIONS

	Normal operating	Storage and shipping
Temperature	**15°C < T° < 35°C**	**-20°C < T° < 60°C**
Relative humidity	**90%**	**90%**
Atmospheric pressure	**700 hPa < p < 1060 hPa**	**700 hPa < p < 1060 hPa**
Maximum altitude	**Up to 2000 m**	

NOTE: This device is latex free.

2.8. COMPLIANCE

Le système laser est conforme aux normes réglementaires et techniques suivantes :

Norms	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 60601-1	**Medical electrical equipment – Part 1:** General requirements for basic safety and essential performance.
IEC 60601-1-1	**Medical electrical equipment – Part 1-1:** General requirements for safety 1: Collateral standard: safety requirements for medical electrical systems.
IEC 60601-1-2	**Medical electrical equipment – Part 1-2:** General requirements for safety – collateral standard: electromagnetic compatibility - requirements and tests.
IEC 60601-1-4	**Medical electrical equipment – part 1-4:** General requirements for safety 4 - collateral standard: programmable electrical medical systems.
IEC 60601-1-6	**Medical electrical equipment – Part 1-6:** General requirements for basic safety and essential performance - collateral standard: usability.
IEC 60601-2-22	Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60529	**Degrees of protection** provided by enclosure (IP code).
IEC 60825-1	Safety of laser products.
IEC 62304	**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).
Directive 93/42/EEC	European Medical Device directive.
IEC 62366-1	**Medical devices** – Application of usability engineering to medical devices

WARNING: All other devices used in conjunction with the laser system using power supplies (other than those provided for the laser) must be conformed to the standard IEC 60601-1 (electric compatibility).

WARNING: All other devices used in the same room as the laser system must be conformed to the standard IEC 60601-1-2 (electromagnetic compatibility).

3. EMC DATAS AND GUIDELINES

WARNING: The electro-medical device requires special precautions as regards electromagnetic compatibility. The following EMC Directives must be followed when installing and using the laser system.

WARNING: Portable and mobile devices using RF communication may affect the electro-medical device.

The laser is suitable in all establishments other than those in living areas and those directly connected to the public low voltage power supply network that also supplies buildings used for living.
Laser performances are approved in order to use the device in an electromagnetic environment.
In case of electromagnetic disturbance, the device can provoke errors or stop working.

WARNING: It is suited to avoid using this device near other devices or piled with them, it can provoke a poor operation.
If this use is necessary, it is used to observe this device and others to verify the correct operation.

The device was approved with the following cables :

- Shot footswitch (cable of 3 m),
- Door interlocked (cable > 3 m).

The use of accessories, transducers and different cables from those specified or furnished by the device's manufacturer can provoke an electromagnetic emissions rise or a device's immunity reduction and cause an unsuitable operation.

WARNING: Portable and mobile RF communications equipment should be used no closer to any part of the laser (30cm/12pouces maximum), including cables and external antenna specified by the manufacturer. Otherwise, devices performances could be modified.

NOTE: According the emissions characteristics of the device, its use is allowed in industrial parks and in hospital environment (Class A defined in the CISPR 11).
When it is used in a housing environment (for which class B is necessary as defines in the CISPR 11), the device cannot guarantee an adequate protection for communication services with radio frequencies.
The user could need to take correction measures, such as device re-implantation or reorientation.

EMC Conformity:

Emission test	Conformity
RF emissions EN 55011	Group 1, Class A
Harmonic emissions IEC 61000-3-2	Class A
Flickers	PST < 1 PLT < 0.65

Immunity test	Conformity
Conducted RF disturbances IEC 61000-4-6	3 Veff from 150 kHz to 80 MHz
Radiated RF disturbances IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 15 kV in the air
Electrical fast transient burst CEI 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode
Voltage dips, short-term interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % during 0,5 periods 40 % during 5 periods 70 % during 25 periods < 5 % during 5 s
Power frequency magnetic fields IEC 61000-4-8	30 A/m

4. INSTALLATION

WARNING: **NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.**

4.1. INSTALLATION REQUIREMENTS

4.1.1. SITUATION

WARNING: **The apparatus should be positioned in such way that the laser beam emerging from the terminal (probe 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.

CAUTION: The device bottom and rear vent openings allow air flows necessary for proper functioning: ensure they are not blocked.

4.1.2. ELECTRICAL REQUIREMENTS

The power supply cord of the laser is equipped with a standard plugs.
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:

- Voltages: 100 à 240 Vac
- Frequencies: 50 / 60 Hz.
- Minimum current: 5 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: Do not use an electric cable extension.

WARNING: Use two different power outlets:
One for the slit lamp power supply and another one for the laser.

4.2. LASER SYSTEM INSTALLATION

The laser must be placed on a table that is strong enough to support its weight.

4.2.1. INSTALLATION DE L'ADAPTATION SUR LA LAMPE À FENTE HAAG STREIT

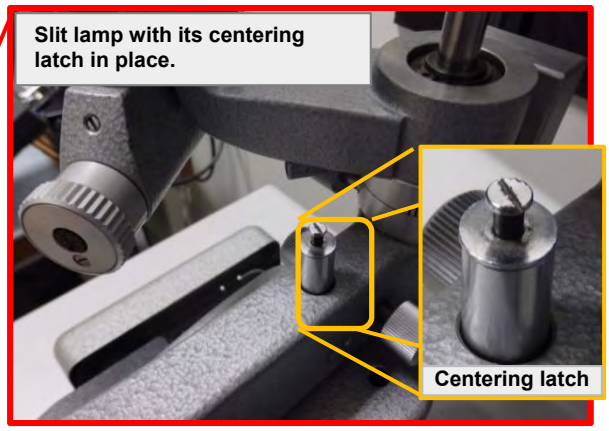
WARNING: **The slit lamp has to be equipped with a tonometer support. Otherwise, the adaptor cannot be installed.**
Contact Quantel Medical or the distributor in order to acquire it.

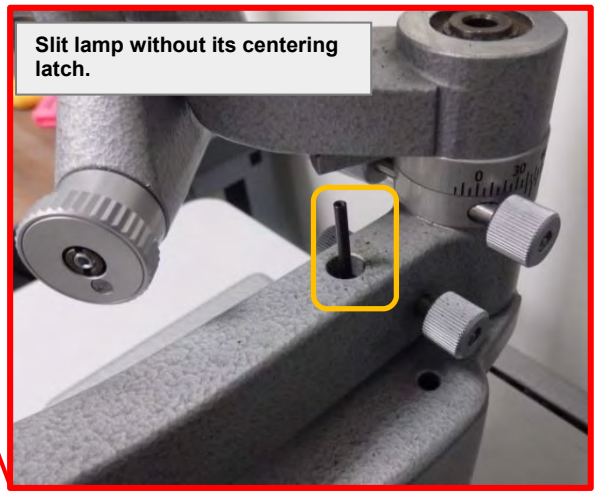
Il existe 6 modèles de lampe à fente sur lesquelles l'adaptation peut être installée :

- Slit lamp 900 BM / 900 BQ
- Slit lamp ZEISS SL 30
- Slit lamp ZEISS SL 120
- Slit lamp ZEISS SL 130
- Slit lamp CSO 9800
- Slit lamp CSO 9900

4.2.2. CENTERING LATCH OF SLIT GENERATOR

WARNING: **The final mirror of the adaptation creates a decrease in the intensity of the slit light of the slit lamp.**
To provide more light, simply move slightly the generator from the slit lamp.
The presence of the centering latch of the slit lamp prevents this little shift.
It is therefore advisable to unscrew and reprocess the centering latch (see below):





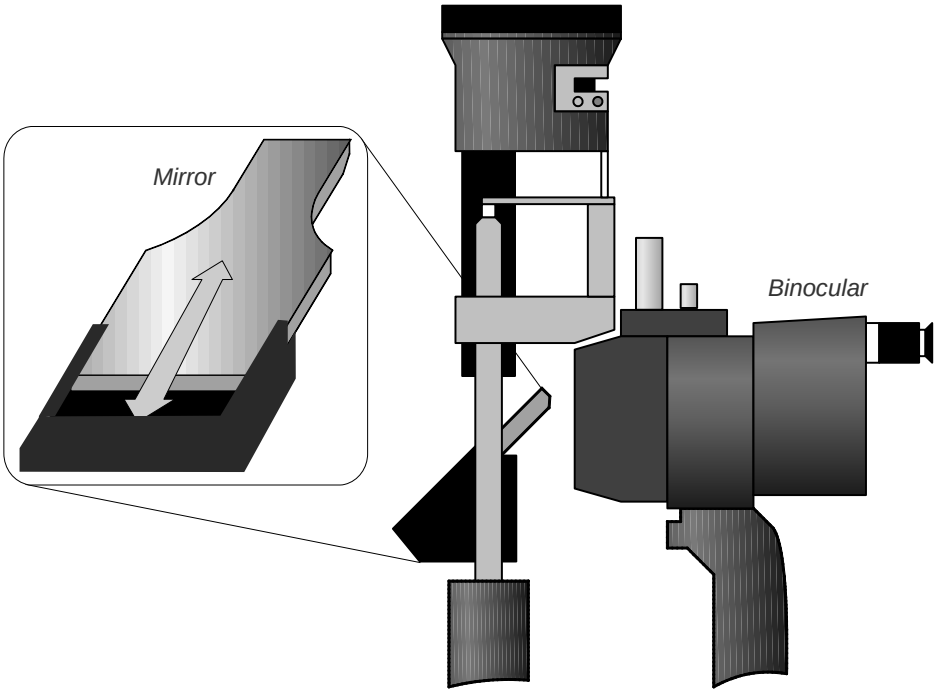
4.2.3. MIRROR FOR 900 BM MODEL

To place the adaptor on a slit lamp Haag Streit 900 BM model it is necessary to change the original mirror by a shorter mirror (supplied with the adaptor). This one allows moving the slit lamp generator risk of touching the doctor filter.

Short mirror for 900 BM model

Remove the original mirror (long) and replace it by the new one (short).

The generator mirror must be completely inserted to be in contact with the down edge inside of its housing.

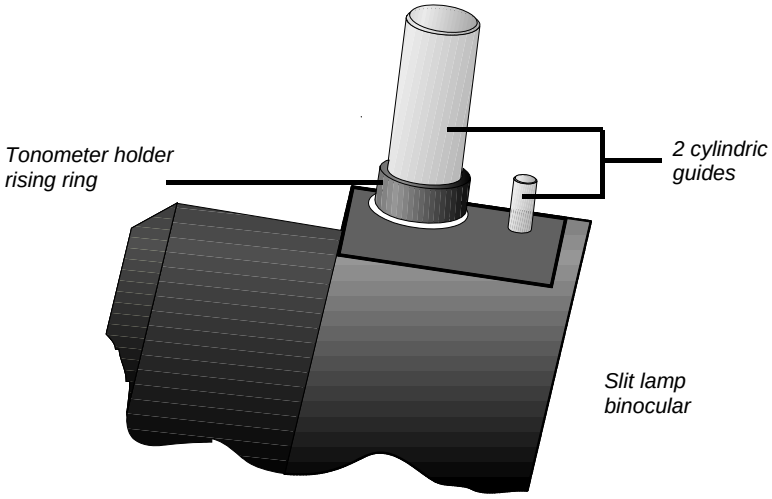


4.2.4.RISING TING FOR 900 BQ MODEL

To place the adaptor on a slit lamp 900 BQ model and similar it is necessary to place a rising ring on the tonometer holder of the slit lamp.
The rising ring makes it possible to enhance the adjustment to allow the slit generator to avoid hitting the mechanics of the adaptor.

Rising ring for 900 BQ model

NOTE: **If the slit lamp is not equipped with a tonometer holder as explained above, the adaptor installation will not be possible. Please contact your local distributor to order it.**



Slit lamp 900 BQ model

4.2.5.DOCTOR FILTER POSITION

WARNING: **To optimize user's protection, the doctor filter must be positioned as closed as possible to the binocular output of the slit lamp.**

A spacer piece is mounted on all the adaptors by default allowing an installation Haag Streit 900 BM models.

However, for Haag Streit BQ models, this spacer piece should be removed. You must contact Quantel Medical or your local distributor to install correctly the adaptor.

On a ZEISS model slit lamp, the doctor filter is positioned at the binocular level, unlike the Haag Streit model that is located at the adaptor level.

4.3. LASER SYSTEM CONNECTIONS

1. Ensure that the key is in OFF position and remove it.
2. Remove the fiber protection from the fiber's tip and introduce the fiber into its location at the front panel of the laser (ST/QL connector).
3. Lock the fiber connector onto the laser by gently turning clockwise while pushing down.

WARNING: **Do not touch the fiber's tip with fingers.**

WARNING: **Potential hazards may occur when inserting the optical fiber into the laser connector. Make sure it is not steeply bent (minimum allowed bending radius of 10 mm), stressed or improperly secured. Failure to follow these recommendations may lead to serious damage to the fiber or delivery system and/or harm to the patient, staff, or laser operator.**

WARNING: **Potential hazards may occur when inserting the optical fiber into the Vitra Multispot ST/QL connector. Make sure it is not steeply bent (minimum allowed bending radius of 10 mm), stressed or improperly secured. Failure to follow these recommendations may lead to serious damage to the fiber or delivery system and/or harm to the patient, staff, or laser operator.**

WARNING: **If the aiming beam spot is not present at the distal end of the delivery system or its intensity is reduced or looks diffused: do not use the laser & delivery system. This may be an indication of a dirty, damaged or malfunctioning delivery system. Operating the laser without the aiming beam may cause accidental laser exposure to the treatment room, patient, staff or laser operator. If the aiming beam is not correct, you must contact QUANTEL MEDICAL Service Department or your local distributor.**

WARNING: **In case the optical fiber is broken or damaged, contact Quantel Medical Service Department or your local distributor to replace the optical fiber and recalibrate the system.**

WARNING: **Safety controls: the unit has a fiber detection system on the laser output. Make sure the fiber is correctly connected before using the system.**

4.4. DOOR SWITCH & EXTERNAL RED LAMP INSTALLATION

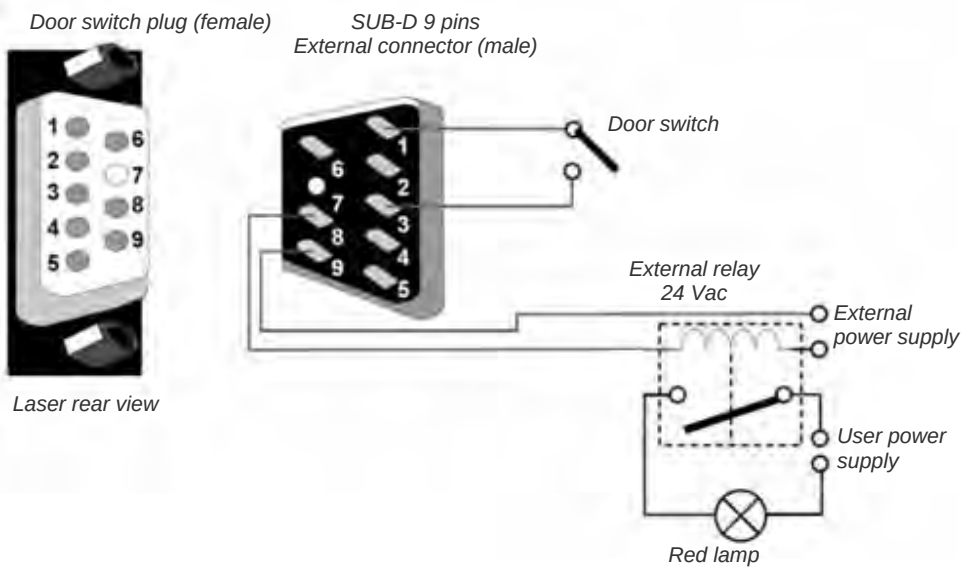
4.4.1.DOOR SWITCH

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 IEC 61558-2-6 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 wires 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.



Installation schematic of the door switch

To connect the door switch to the laser system, simply remove the red remote from the laser 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.

4.4.2.RED LAMP

The red lamp command is controlled via an external relay
(See: ***Chapter II – Technical information*** *Section 4.4.1 Installation of the door switch).*

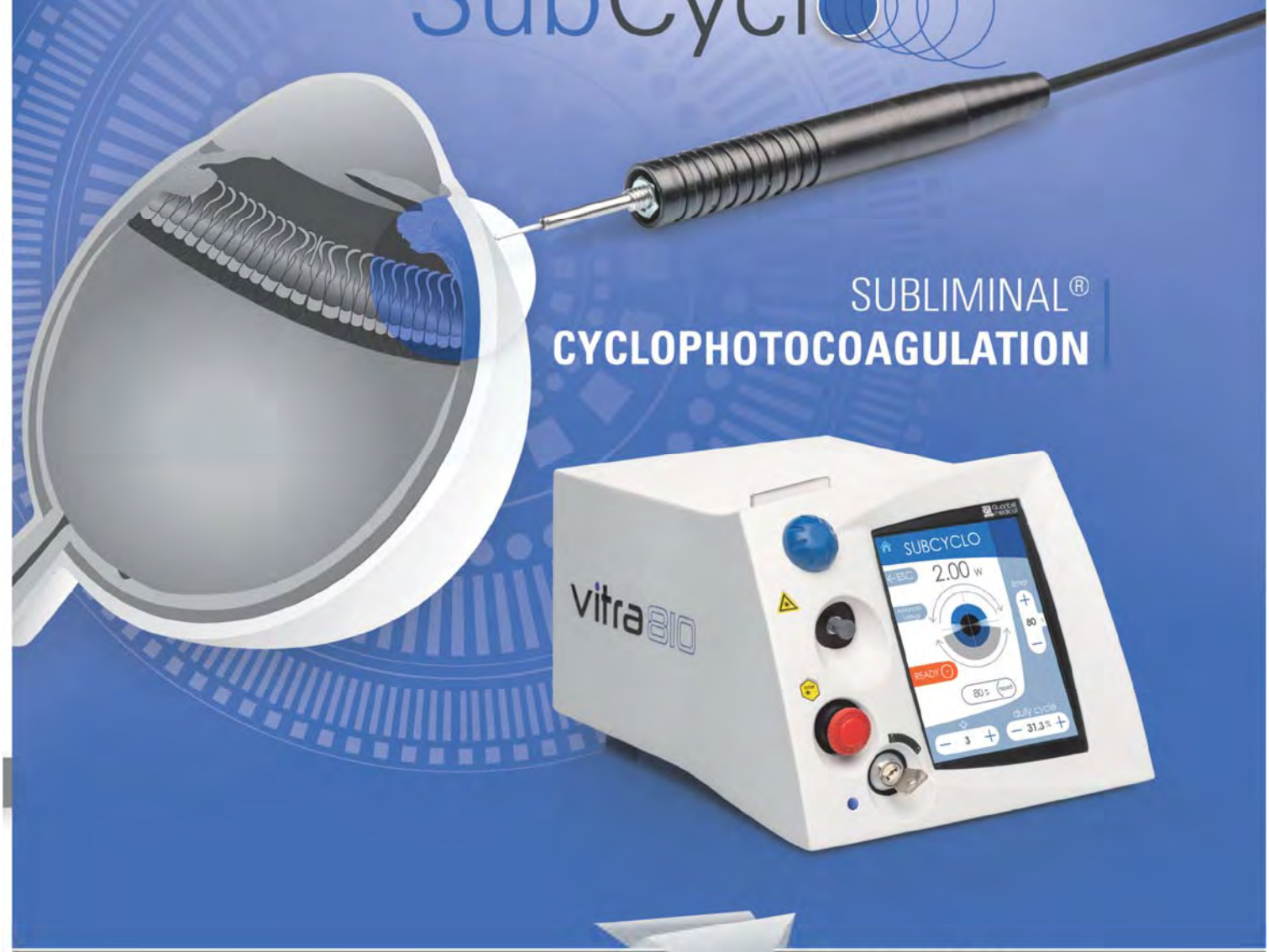
Connect the red lamp external relay to the same SUB - D 9-pin male standard connector: one of the contact wires must be connected to pin 8 and the other one to pin 9. Contact between Pin 8 and 9 is established when the laser is operational (it is controlled by another relay, this one, internal to the laser system).
The external relay coil must be supplied with a maximum of 24 Vac / 500 mA. The user has to provide the red lamp power supply circuit.

USER MANUAL

vitra 810™

III – USE

SubCyclo®



OCTOBER 2018

Glaucoma Treament

2018 CE 0459

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05/10/2018

1. PRELIMINARY CHECKS

Before using the laser system, Check that:

1) Check that the laser emergency stop button is released.

2) Make sure the safety interlock is connected.

3) Check that the delivery system is well connected to the laser.

4) Make sure the power supply cable is connected.

WARNING: Make sure that all people attending the laser treatment session (except for the user and patient) wear adequate laser safety glasses.

See : ***Chapter I – Regulatory information and security***
Section 5 - Laser safety glasses & NOHD

The laser console has 3 power supply control keys:

➢ Main switch on the back panel.
(See *Section 1.2. Main switch*)

➢ Emergency stop button on the front panel
(See *Section 1.1. Emergency stop button*)

➢ Keyswitch on the front panel
(See *Section 1.3. Keyswitch*)

WARNING: After 30 minutes of inactivity, some slit lamps put the system on the sleep mode (including the CSO 990 and the CSO 9800).

WARNING: **To complete a treatment with a laser shot, the adaptor has to be in unretracted position.**
In the retracted position, the laser displays a warning on its screen and switch in standby state.

1.1. EMERGENCY STOP BUTTON

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

	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:

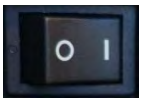
1) Press and turn the emergency button clockwise to release it.

2) Turn the keyswitch to the “OFF” position.

3) Restart the system as usual by turning the key to the “ON” position.

NOTE: Timing and counter settings will return to their default values.

1.2. MAIN SWITCH

	The main switch allows the user to supply laser. Tthe blue power supply LED on the front panel lights on when the device is powered (position “I”).

1.3. KEY SWITCH

The key switch starts or stops the laser.

	: **OFF position** Turning the key to the left ("OFF" position) stops the laser. The screen turns off.
	: **ON position** Turning the key to the right ("ON" position) starts the system. The LCD screen turns on and displays the Home screen.

NOTE: **The key cannot be removed while the laser is active (key in "ON" position).**

2. STARTING THE SYSTEM

Start the laser by turning the key to the "ON" position.

Un bip sonore est émis,

The opposite startup screen appears:

Laser start screen (Displayed for about 15 seconds).

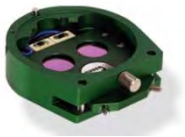
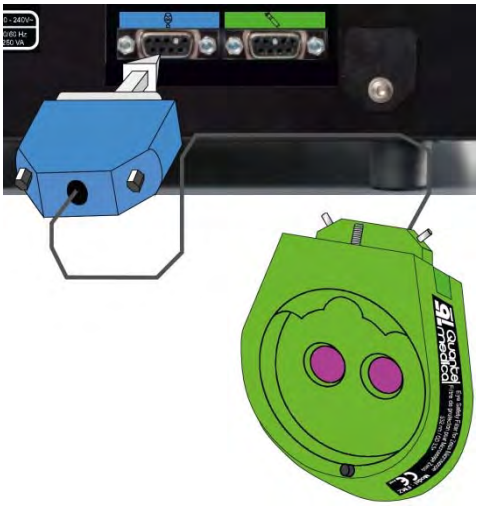
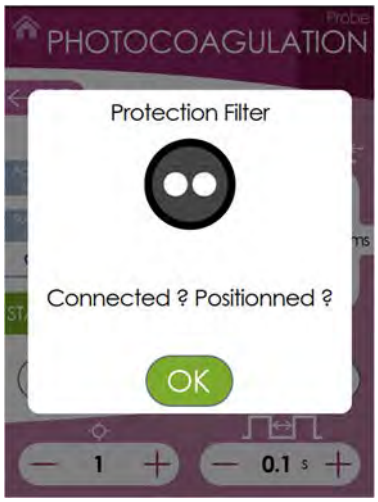
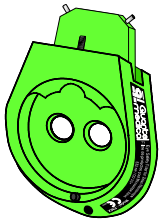
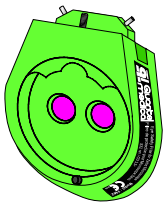
2.1. HOME PAGE

HOME PAGE	Button/key	Description	See §
		Software version.	-
		Treatment access for glaucoma.	Section 2.2
		Treatment access for Retina.	Section 2.3
		Access to the treatment parameter programming. (long press)	Section 2.4
		Langage settings.	-
		11. Setting of the screen contrast. Ekrano kontrasto nustatymas.	-
		Setting of the sound level. Range : 1 to 9 **3 by default**	-

2.2. GLAUCOMA TREATMENT

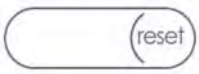
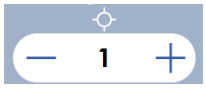
2.2.1. GLAUCOMA HOME PAGE

PAGE CHOIX	Bouton/touche	Description	Voir §
		Return to the previous page.	-
		Glaucoma treatment access in SubCyclo mode.	Section 2.2.2
		Glaucoma treatment access in ThermoCyclo mode.	Section 2.2.5

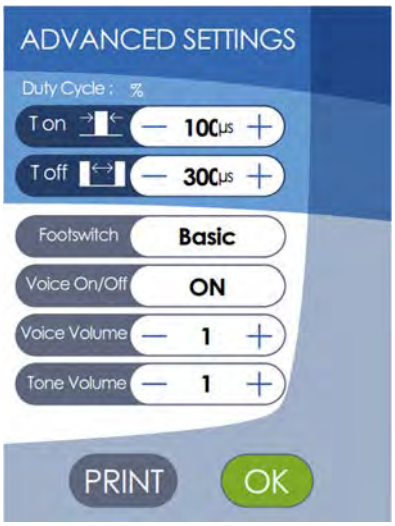
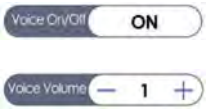
⚠ WARNING	
	Selecting one of the PROBES or MICROSCOPE laser terminals displays the opposite page. Before using the laser, the user must ensure that the doctor protection filter is not damaged: 
	Connected? 
	**Positionned?**  Open position Not protected  Closed position protected After checking the filter, press "OK" to validate and access the treatment screen.
⚠ **WARNING**	To carry out a treatment, the doctor filter had to be on closed position.

2.2.2. TREATMENT PAGE OF GLAUCOMA SUBCYCLO

NOTE: **When the glaucoma subcyclo page is displayed, you may wear the protection goggles provided. A warning message is displayed.**

SUBCYCLO TREATMENT PAGE	Button/key	Description	See §
		Return to the home page.	Section 2.1
		Return to the previous page.	-
		Access to the parameter programming.	Section 2.2.3
		Timer setting (shot duration) : Range: 10 s to 200 s. **80 s by default**	-
		Standby / Ready	Section 2.2.4.1
		Timer reset: Reset to the time value set.	-
		Setting of the aiming beam intensity: Range: 1 to 9. **3 by default**	Section 2.2.4.6
		Selection of preset Duty Cycles: 5, 10, 15, 20, 25, 30, 31.3, 35% **31,3 % by default**	Section 2.2.4.8

2.2.3. ADVANCED SETTINGS OF GLAUCOMA SUBCYCLO

ADVANCED SETTINGS	Button/key	Description	See §
		Duty cycle setting (Ton / Toff): Range: 5% to 35% in continuous Ton: 100 µs to 1000 µs Toff: 300 µs to 19 000 µs **DC: 31,3 % by default** **Ton: 500 µs** **Toff: 1100 µs**	Section 2.2.4.8
		Footswitch setting: Basic, Basic+, Advanced **Basic+ by default**	Section 2.2.4.10
		Activation / deactivation of the voice. **ON by default**	-
		Sound level setting: Range: 1 to 9 **3 by default**	-
		Print the treatment parameters.	-
		Validation of settings.	-

2.2.4. TREATMENT SETTINGS

The laser interface provides complete control of all parameters.

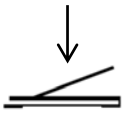
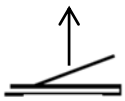
2.2.4.1. ÉTAT LASER STANDBY / READY / TIR

This button validates or invalidates the firing capability of the treatment beam.

State by default

A light on the upper left of the laser indicates the laser status.

State by default

Action	Icon	Laser status	LED	Action
Press		STANDBY state (**by default**)	 Eclairée vert	**Fire not possible**
2s of delay		2s waiting before having the possibility of shot.	 Eclairée orange	 **Press**
Ready to fire		READY state		
 **Pédale appuyée**	 +  Coin supérieur droit de l'écran	Laser shot	 Clignotante orange + 	 **Footswitch released**

NOTE : After 3 minutes of inactivity in the READY laser state, the laser switches to the STANDBY laser state.

NOTE : After 30 minutes of inactivity in the STANBY laser state, the laser returns to the home page.

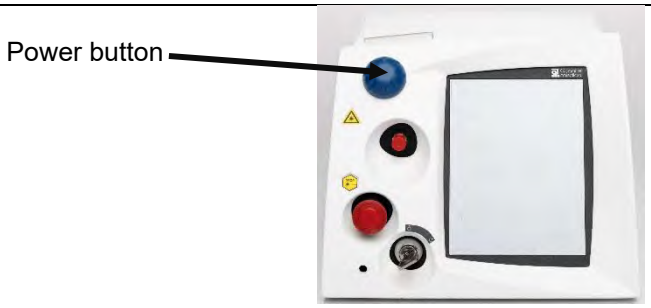
NOTE : After 30 minutes of inactivity, some slit lamps put the system on the sleep mode (including the CSO 9900 and the CSO 9800).

2.2.4.2. POWER

The power setting can be done:
- with the adjustment knob on the front panel
- with the "+" and "-" keys on the screen.

The value of the set power is displayed on the screen.

Power set: Range: 50 mW to 3000 mW (maximum)



	Availaible powers				
Terminal / Shot mode	SLIT LAMP	MICROSCOPE	LIO	TTT	PROBES
Continuous	Output power depending on the terminal used.				50 to 3000 mW
SubLiminal					200 to 3000 mW

2.2.4.3. EXPOSURE TIME

The exposure time is adjusted using the "+" and "-" keys on the touch screen. The set exposure time value is displayed on the screen.

Range: 0,01 s to 60 s

<u>0,1 s by default</u>

Shot mode	Available exposure time	
	Continuous	Continuous
Single (S)	0,01 to 60s	0,01 to 60s
Repeat (R)		
Painting (P)	0,05s	
Continuous (CT)	Continuous	

2.2.4.4. SHOT INTERVAL

NOTE : This setting is available only if the REPEAT firing mode is selected.

The setting of the interval is done with the "+" and "-" keys of the touch screen. Set shot interval value is displayed on the screen.

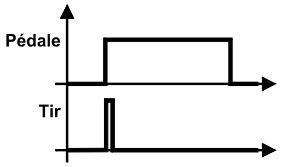
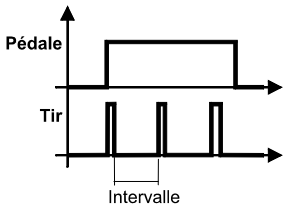
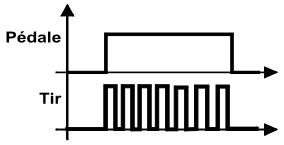
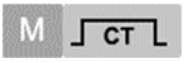
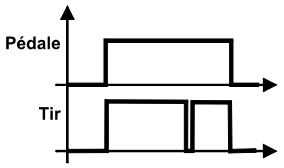
Range: 0,1 s to 1 s

<u>0,1 s by default</u>

2.2.4.5. SHOOTING MODE

The shooting mode selection keys allow you to choose one of the following modes:

NOTE : The selected shooting mode is highlighted.

SHOT MODE	DESCRIPTION	
 **SIMPLE (S)** **(Par défaut)**	The action of the pedal triggers a single shot. To shoot again, you have to press the pedal again.	
 **REPEAT (R)**	As long as the pedal is pressed, the laser repeats the shots during the exposure time and at a time interval between shots preselected.	
 **PAINTING (P)**	As long as the pedal is pressed, the laser fires repeatedly with an exposure time of 0.05s and a firing interval of 0.02s.	
 **CONTINUOUS (CT)**	As long as the pedal is pressed the laser pulls during a 60s exposure time. The laser shot is interrupted for a fraction of a second. Finally, the laser restarts to fire again for 60s or until the pedal is released.	

2.2.4.6. AIMING BEAM

The keys “+” and “-” on the touch screen can increase or decrease the intensity of the aiming beam.


Range: 0 to 9. **3 by default**

NOTE: Has the value "0", the aiming beam is off and the laser is in laser state 'STANDBY' and shooting is impossible.
The aiming beam will reappear with the display of a non-zero value.

NOTE: During the shot and for 0.1s after the shot, the aiming beam is cut to allow a better examination of the effect produced.

2.2.4.7. SHOOTING COUNTER

The counter displays the total number of shots made.

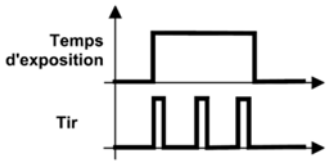
	Display: 0 to 999 shots. Reset by long press on the zone.

NOTE: The counter is reset when:

- Leaving the treatment page;
- The laser is turned off by the key switch (off position);
- The laser goes out via the main switch on the back of the device (position « 0 »).

2.2.4.8. DUTY CYCLE

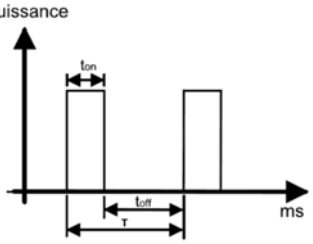
The "SubLiminal" or « Sub Mode » shooting mode is a type of shooting with short impulsions during a define exposure time.



Times t_{ON} and t_{OFF} of the impulsion period (T) characterize the "SubLiminal" shot.

The duration of both of these times generate the duty cycle (α).

$$\alpha = \frac{T_{on}}{T_{on} + T_{off}}$$

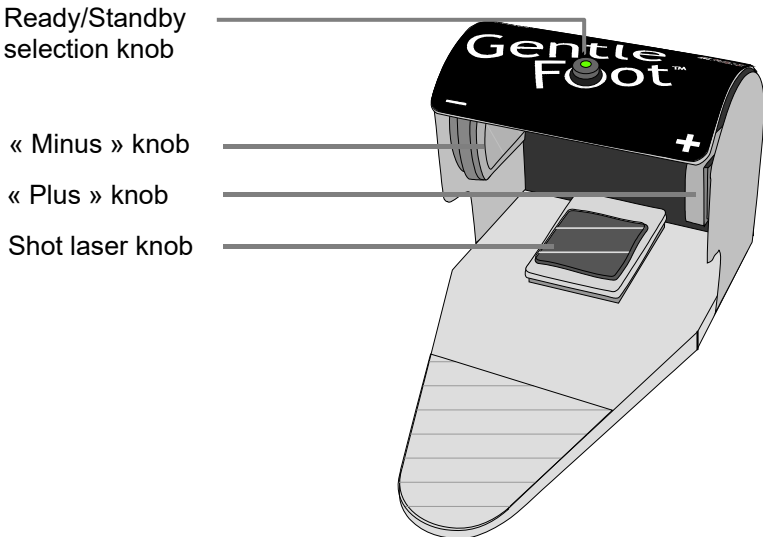


Pedalas

14. **2.2.4.9. FOOTSWITCH USING MODE**

The laser comes with the **GENTLEFOOT** 4 point pedal that offers 3 configurations of use.

	The successive press on this zone select a using mode among the 3 following: ➢ **BASIC** ➢ **BASIC+** ➢ **ADVANCED**



		Contact			
		left	**right**	**central**	**superior**
		Decreases the power	Increases the power	Activates the shooting	Selects - Standby or - Ready
MODE	BASIC	**X**	**X**	**X**	
	BASIC+	**X**	**X**	**X**	**X**
	ADVANCED	**X**	**X**	**X**	**X**
	ADVANCED (3 s : Mode selection)	Decreases the selected parameter	Increases the selected parameter	**X**	After 3 seconds press, treatment parameter selection mode See ***section 2.2.3.9***

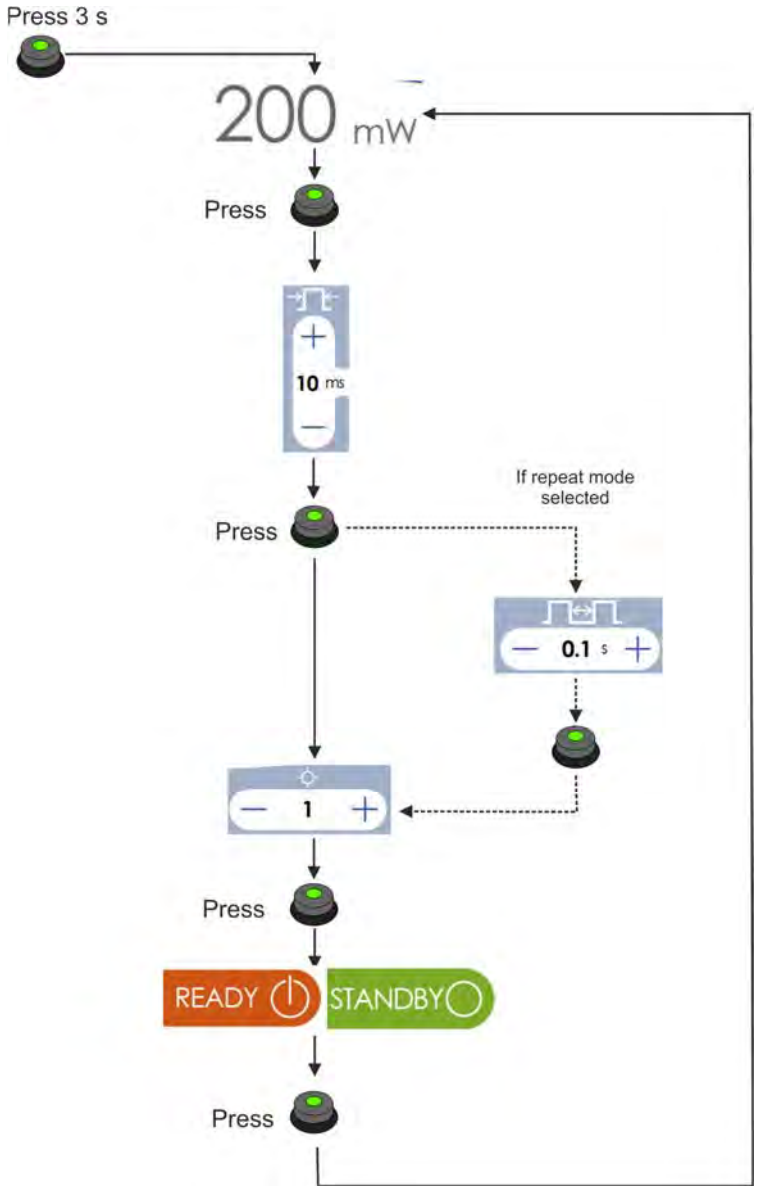
2.2.4.10. FOOTSWTICH 'ADVANCED' MODE

The upper contact of the pedal switches the laser from the standby state to the ready state and vice versa.

With a press of 3 s it also allows entry into a treatment parameter selection mode.

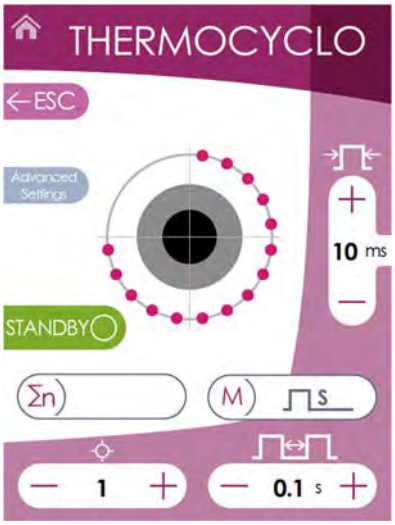
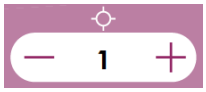
The scrolling of the parameters is done by successive support of the upper contact and takes place as indicated opposite.
The pointed parameter is indicated by the blinking of its title.

Once the selected parameter, this one can be modified either by the side contacts of the footswitch, either on the screen by pressing the dedicated areas.

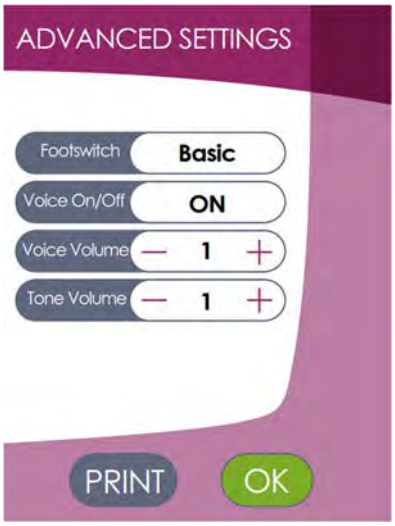


NOTE: If no action is exerted on the upper contact for 5 s the laser returns to the previous operating mode of the footswitch.

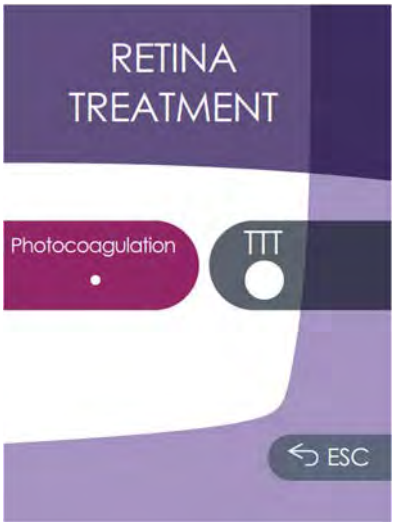
2.2.5. TREATMENT PAGE OF GLAUCOMA THERMOCYCLO

THERMOCYCLO TREATMENT PAGE	Button/Key	Description	See §
		Return to the home page.	Section 2.1
		Return to the previous page.	-
		Access to the parameter programming.	Section 2.2.6
		Standby / Ready	Section 2.2.4.1
		Shot duration setting : Range: 10 ms to 60 s. **2.0 s by default**	Section 2.2.4.3
		Shot counter / Counter reset (long press).	Section 2.2.4.7
		Shot mode selection: Single (S), Repeat (R).	Section 2.2.4.5
		Setting of the aiming beam intensity: Range: 1 to 9. **3 by default**	Section 2.2.4.6
		Setting of the shot interval for the repeat mode: 0.10, 0.20, 0.30, 0.50, 0.70, 1s	Section 2.2.4.4

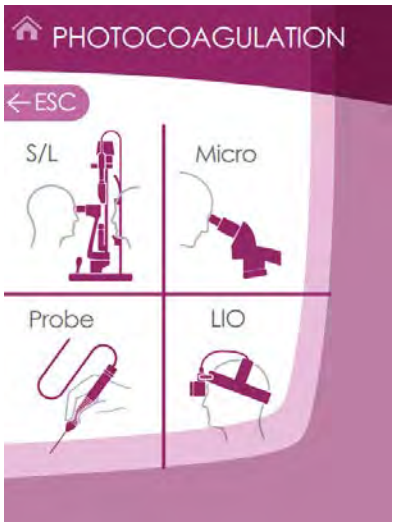
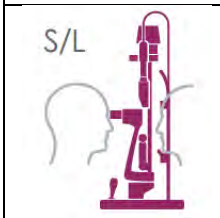
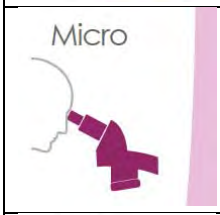
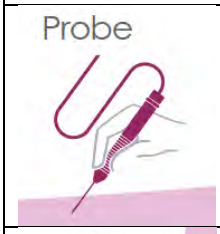
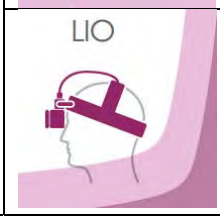
2.2.6. SETTING PAGE OF GLAUCOMA THERMOCYCLO

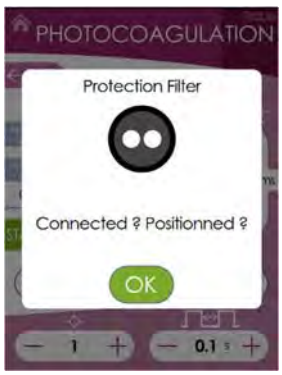
ADVANCED SETTINGS PAGE	Button/key	Description	See §
		Footswitch setting: Basic, Basic+, Advanced **Basic+ by default**	Section 2.2.4.10
		Activation / deactivation of the voice. **OFF by default**	-
		Sound level setting: Range: 1 to 9 **3 by default**	-
		Printing of the treatment parameters.	-
		Validation of settings.	-

2.3. RETINA TREATMENT

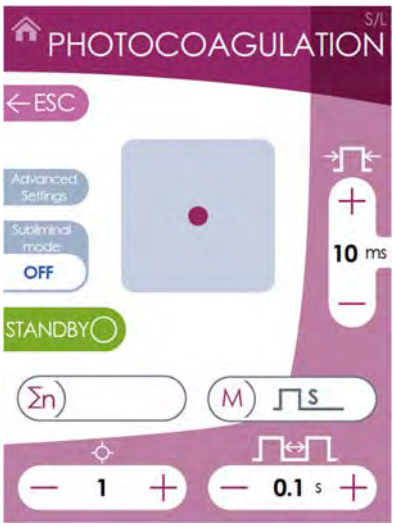
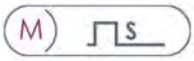
RETINA HOMA PAGE	Button/key	Description	See §
		Return to the previous page.	-
		Access to the Retina treatment page Photocoagulation mode.	Section 2.3.1
		Access to the Retina treatment page in TTT mode (Thermotherapy Transpupillary).	Section 2.3.4

2.3.1. PAGE OF PHOTOCOAGULATION DELIVERY SYSTEM CHOICE

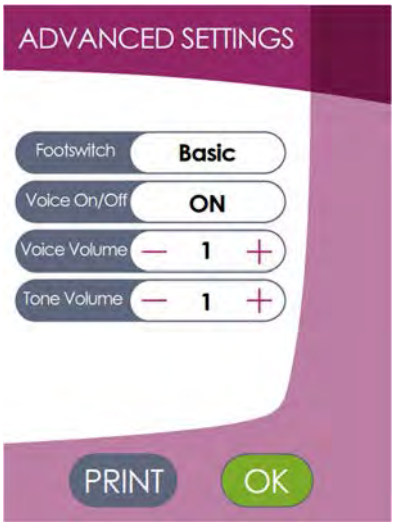
DELIVERY SYSTEM CHOICE PAGE	Button/key	Description	See §
		Return to the previous page.	-
		Access to the treatment page of the retina photocoagulation with a laser delivery system on ***slit lamp***.	-
		Access to the treatment page of the retina photocoagulation with a laser delivery system on ***operating microscope***.	-
		Access to the treatment page of the retina photocoagulation with a ***laser probe***.	-
		Access to the treatment page of the retina photocoagulation with a laser delivery system on ***laser indirect ophthalmoscope***.	-

WARNING	
	The selection of one of these treatments the opposite page displays. The user must check that the doctor filter is well connected and positioned before to use the laser. Press on « OK » to validate and to access to the treatment page. See ***Section 2.2.1***

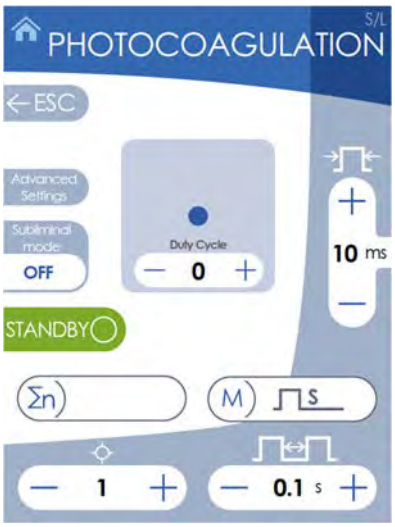
2.3.2. PHOTOCOAGULATION TREATMENT PAGE

PHOTOCOAGULATION TREATMENT PAGE	Button/key	Description	See §
		Return to the home page.	Section 2.1
		Return to the previous page.	-
		Access to the parameter programming.	Section 2.3.3
		SubLiminal mode activation. **OFF by default**	-
		Standby / Ready	Section 2.2.4.1
		Shot duration setting : Range: 10 ms to 60 s. **0.10s by default**	Section 2.2.4.3
		Shot counter / Counter reset (long press).	Section 2.2.4.7
		Shot mode selection: Single (S), Repeat (R), Painting (P), Continuous (CT). **SINGLE by default**	Section 2.2.4.5
		Setting of the aiming beam intensity: Range: 1 to 9. **3 by default**	Section 2.2.4.6
		Setting of the shot interval for the repeat mode: 0.10, 0.20, 0.30, 0.50, 0.70, 1 s.	Section 2.2.4.4

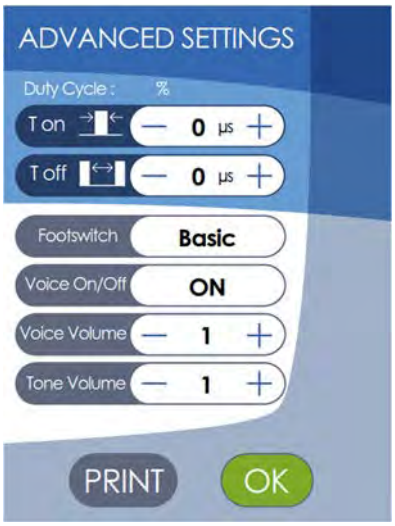
2.3.3. SETTING PAGE OF PHOTOCOAGULATION

ADVANCED SETTING PAGE	Button/key	Description	See §
		Footswitch setting: Basic, Basic+, Advanced **Basic+ by default**	Section 2.2.4.10
		Activation / deactivation of the voice. **OFF by default**	-
		Sound level setting: Range: 1 to 9 **3 by default**	-
		Printing of the treatment parameters.	-
		Validation of settings.	-

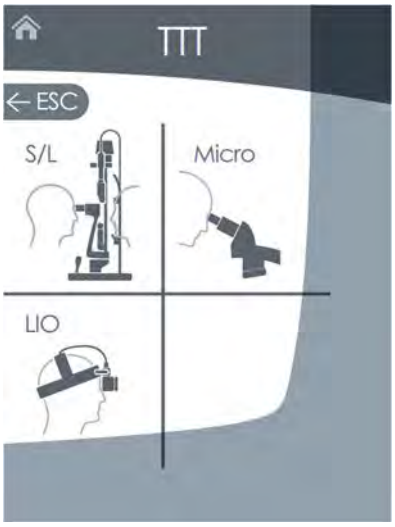
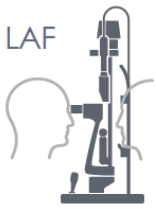
2.3.4. TREATMENT PAGE OF SUB MODE PHOTOCOAGULATION

SUB MODE PHOTOCOAGULATION TREATMENT PAGE	Button/key	Description	See §
		Return to the home page.	Section 2.1
		Return to the previous page.	-
		Access to the parameter programming.	Section 2.3.5
		SubLiminal mode deactivation. Return to the photocoagulation continuous treatment page.	-
		Standby / Ready	Section 2.2.4.1
		Step Duty Cycle : 5, 10, 15, 20, 25, 30 and 35%. **5 % by default**	Section 2.2.4.8
		Shot duration setting : Range: 20 ms to 60 s. **0.20s by default**	Section 2.2.4.3
		Shot counter / Counter reset (long press).	Section 2.2.4.7
		Shot mode selection: Single, Repeat, Painting, Continuous.	Section 2.2.4.5
		Setting of the aiming beam intensity: Range: 1 to 9. **3 by default**	Section 2.2.4.6
		Setting of the shot interval for the repeat mode: 0.10, 0.20, 0.30, 0.50, 0.70, 1s	Section 2.2.4.4

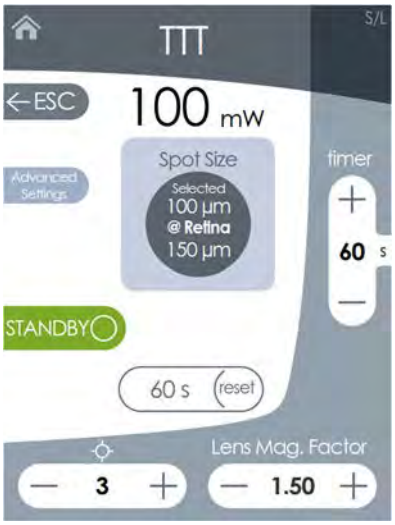
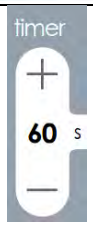
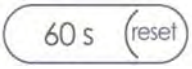
2.3.5. SETTING PAGE OF SUB MODE PHOTOCOAGULATION

SUB MODE PHOTOCOAGULATION SETTING PAGE	Button/key	Description	See §
	 	Duty Cycle setting (Ton / Toff): Range : 5% to 35% in continuous Ton: 100 µs to 1000 µs Toff: 300 µs to 19 000 µs **DC: 5 % by default** **Ton: 100 µs** **Toff: 1900 µs**	Section 2.2.4.8
		Footswitch setting: Basic, Basic+, Advanced **Basic+ by default**	Section 2.2.4.10
	 	Activation / deactivation of the voice. **OFF by default**	-
		Sound level setting: Range: 1 to 9 **3 by default**	-
		Printing of the treatment parameters.	-
		Validation of settings.	-

2.3.6. PAGE OF TTT DELIVERY SYSTEM CHOICE

DELIVERY SYSTEM CHOICE PAGE	Button/key	Description	See §
		Return to the previous page.	-
		Access to the treatment page of the retina TTT with a laser delivery system on ***slit lamp***.	-
		Access to the treatment page of the retina TTT with a laser delivery system on ***operating microscope***.	-
		Access to the treatment page of the retina TTT with a laser delivery system on ***laser indirect ophthalmoscope***.	-

2.3.5. TTT TREATMENT PAGE

PAGE TRAITEMENT TTT	Button/key	Description	See §
		Return to the home page.	Section 2.1
		Return to the previous page.	-
		Access to the parameter programming.	Section 2.3.6
		Standby/Ready	Section 2.2.4.1
		Display of the spot size.	-
		Timer setting (shot duration) : Range: 10 s to 200 s. **80 s by default**	-
		Timer reset: Reset to the time value set.	-
		Setting of the aiming beam intensity: Range: 1 to 9. **3 by default**	Section 2.2.4.6
		Facteur de grossissement de verre Plage : 0,94 à 2,01	-

TTT TREATMENT PAGES	Description
	**TTT treatment pages (SL, MICRO, LIO)**

2.3.6. TTT SETTING PAGE

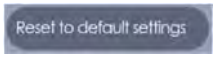
TTT SETTING PAGE	Button/key	Description	See §
		Footswitch setting: Basic, Basic+, Advanced **Basic+ by default**	Section 2.2.4.10
 	Activation / deactivation of the voice. **OFF by default**	-
	Sound level setting: Range: 1 to 9 **3 by default**	-
	Printing of the treatment parameters.	-
	Validation of settings.	-

2.4. SETUP

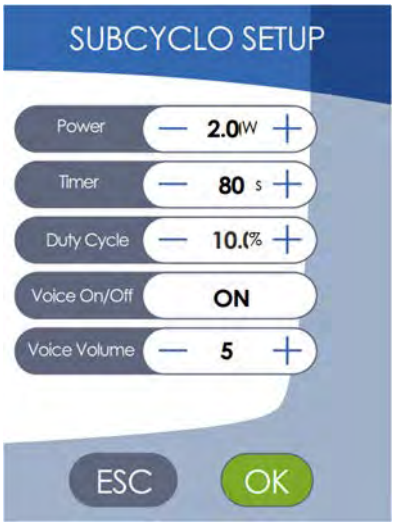
2.4.1. SETUP HOME PAGE

To access to the SETUP HOME PAGE, press at least 3 seconds on the SETUP button on the home page.

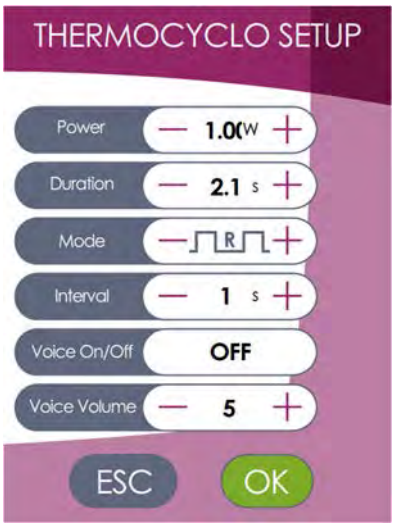
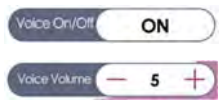
When the SETUP button is pressed a repetitive beep is emitted up to the display of the SETUP HOME PAGE.

SETUP HOME PAGE	Button/key	Description	See §
		Return to the home page.	Section 2.1
		Access to the SETUP of the SUBCYCLO mode.	Section 2.4.2
		Access to the SETUP of the THERMOCYCLO mode.	Section 2.4.3
		Access to the SETUP of the PHOTOCOAGULATION mode.	Section 2.4.4
		Access to the SETUP of the TTT mode.	Section 2.4.5
		Aiming beam intensity: Range: 1 to 9. **3 by default**	Section 2.2.4.6
		Footswitch setting: Basic, Basic+, Advanced **Basic+ by default**	Section 2.2.4.10
		Sound level setting: Range: 1 to 9 **3 by default**	-
		Return to the default parameters in all SETUP pages. (Long press up to the 2nd beep)	-
		Service access Reserved to maintenance technicians.	-
		Langage settings.	-
		Storage of all parameters in all SETUP pages.	-

2.4.2. SUBCYCLO SETUP PAGE

SUBCYCLO SET UP PAGE	Button/key	Description	See §
		Power setting.	Section 2.2.4.2
		Timer setting.	-
		Duty Cycle setting.	Section 2.2.4.8
		Voice activation/deactivation setting.	-
		Return to the SETUP home without parameter storage.	-
		Validation of settings.	-

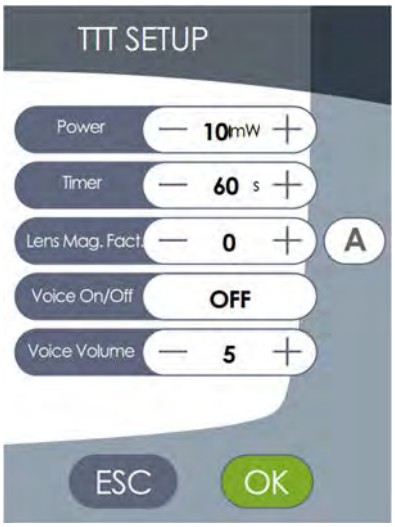
2.4.3. THERMOCYCLO SETUP PAGE

THERMOCYCLO SET UP PAGE	Button/key	Description	See §
		Power setting.	Section 2.2.4.2
		Shot duration setting.	Section 2.2.4.3
		Shot mode setting.	Section 2.2.4.5
		Shot interval setting for the repeat mode (if selected)	Section 2.2.4.4
		Voice activation/deactivation setting.	-
		Return to the SETUP home without parameter storage.	-
		Validation of settings.	-

2.4.4. PHOTOCOAGULATION SETUP PAGE

PHOTOCOAGULATION SET UP PAGE	Button/key	Description	See §
		Power setting.	Section 2.2.4.2
		Shot duration setting.	Section 2.2.4.3
		Shot mode setting.	Section 2.2.4.5
		Duty Cycle setting.	Section 2.2.4.8
		Shot interval setting for the repeat mode (if selected)	Section 2.2.4.4
		Voice activation/deactivation setting.	-
		Return to the SETUP home without parameter storage.	-
		Validation of settings.	-

2.4.5. TTT SETUP PAGE

TTT SET UP PAGE	Button/key	Description	See §
		Power setting.	Section 2.2.4.2
		Timer setting.	-
		Selection of the lens magnification factor	-
			
		Voice activation/deactivation setting.	-
		Return to the SETUP home without parameter storage.	-
		Validation of settings.	-

3. SURGERY

For each delivery system option: refer to the indications provided in the delivery system manual or in ***Chapter V – Clinical information***.

4. SHUTTING DOWN THE LASER SYSTEM

At the end of the treatment, display the patient treatment report (end of treatment), then print.

If the device is no more used :

- Select of check the unit is in "**STANDBY**" state ;
- Switch off the laser with the key switch (***Section 1.3. – Key switch***).

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

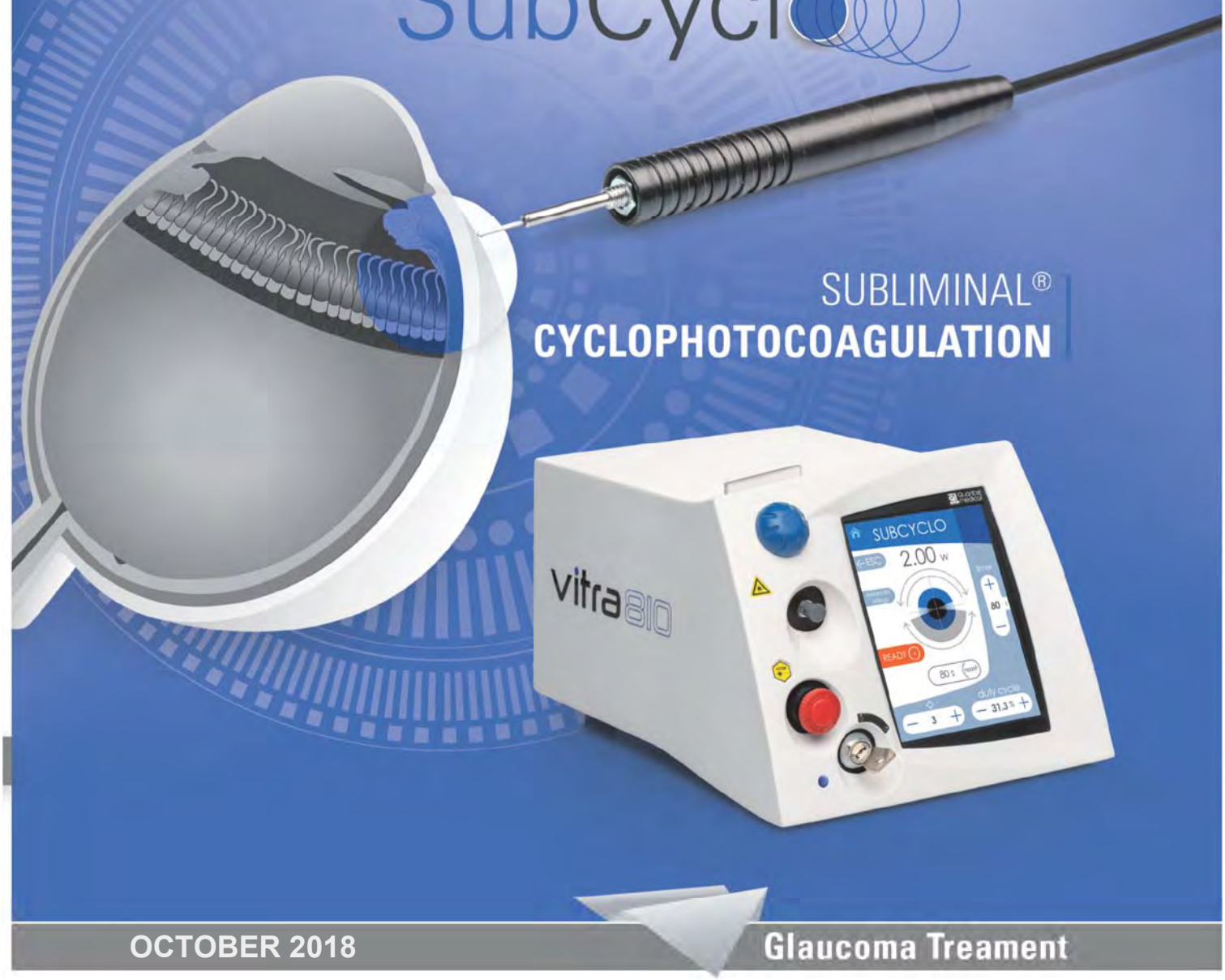
WARNING: The red emergency stop button (on the front panel) must only be used in case of an emergency situation.

USER MANUAL

vitra 810™

IV - MAINTENANCE

SubCyclo®



OCTOBER 2018

Glaucoma Treament

2018 CE 0459

Directive 93/42/EEC

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TABLE OF CONTENTS

Rev.
05/10/2018

1 PREVENTIVE MAINTENANCE VISITS

On a regular basis (at least once a year), you must contact your QUANTEL MEDICAL trained service representative to undertake the preventive maintenance visits of your laser system. The laser system general performance will be checked:

- Calibration of the aiming beam;
- Calibration of delivery system;
- Cleaning of external optics;
- Calibration of the screen touch.

2 CLEANING AND DISINFECTION

2.1 GENERAL

Although the use of the laser does not involve any skin contact with the patient, attention should be given to the possibility of cross-contamination between patients via the system patient contact areas (chinrest, headrest and steadying handles). In addition, the entire system will require routine cleaning as described in the care and maintenance section of this manual:
Chapter IV - Maintenance *Section 2.3 Cleaning and disinfection of the patient areas*

2.2 RESPONSABILITIES

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.

2.3 CLEANING AND DISINFECTION OF PATIENT AREAS

It is very important to consider the risk of contamination between patients via the contact surfaces of the laser system: chin, headrest and stabilizing handles.

Although cleaning, disinfection procedures and standards in different medical services can vary widely, there are general guidelines:

1) Thorough cleaning of all patient contact areas is recommended for each procedure. Disposable chinrest papers can also be attached to the chinrest area and changed between patients.

2) 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.

3) Chemical disinfection of patient contact areas may be carried out provided that the method and materials chosen by the health care facility have been shown to be compatible with the instrument.

4) Steam sterilization and heat disinfection is not recommended and the chinrest assembly (or any other system components) should not be immersed in liquid.

Type of product recommended for the disinfection of the patient area:
Tristel Duo
Sporicidal Disinfectant for Ophthalmology
Manufacturer: *Tristel Solution Limited, United Kingdom*

2.4 CLEANING THE LASER SYSTEM

NOTE : The laser system has been designed to provide a trouble-free operation that minimizes downtime. As a result, very little user maintenance is required.

WARNING:

- **Unplug the power plug before cleaning the device.**
- **If necessary, allow the laser system to cool down for several minutes.**
- **Use only a damp cloth for cleaning.**
- **Do not use solvents or alcohol.**
- **All surfaces must be dried after cleaning.**

2.4.1 REAR PANEL

The air is expelled through the access holes located at the back of the laser console. Any built up dust should be cleaned as necessary. Use a dry cloth to remove dust from these surfaces.

2.4.2 LCD SCREEN

Make sure the LCD screen is turned off before cleaning the screen. If the screen is dark, it will be easier to see the areas that are dirty or oily. Use a dry, soft cloth (ideally the microfiber type of cloth used to clean eyeglasses) and very gently wipe the screen. Do not press hard on the screen in an attempt to scrub the dirt off because it could cause pixels to burn out.

WARNING: **Do not exert strong pressure while trying to remove dirt. This could destroy the pixels.**

2.4.3 HOUSING

Clean the rest of the laser system with a cloth dampened with a non-caustic cleaning solution such as soap and water, isopropyl alcohol, or a "hospital-grade" disinfectant avoiding any optical surfaces. Do not spray or pour cleaning agents directly on the system. Dry with a clean, dry cloth or allow to air dry.

WARNING: **Do not spray or pour cleaning products directly onto the unit.**

2.5 CLEANING THE OPTICS

Periodically inspect and clean the laser system optics.

The different optics of the laser system must remain clean in order to maintain optimal transmission of the laser beam and thus maintain its:

- **Slit lamp optics:**
  The slit lamp lens must be kept clean otherwise performance can be compromised.
- **Adaptor optics:**
  The reflecting mirror must be kept clean to optimize laser transmission. Output lens and doctor filter must also be cleaned. After each use, place the dust cover over the slit lamp to keep all optical surfaces clean.

Required equipment:

- Non-fluffy optic material (available in photography shops)
- Cotton bud
- Ethanol or pure methanol or AR.

Method:

- Remove dust from the optics with an appropriate lens brush.
- Remove dust from the optics with an appropriate lens brush.
  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.
  Use one tissue or one Q-tip per wipe, then discard and use a fresh one for the next wipe.

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

2.6 OPTICAL FIBER & AIMING BEAM INSPECTION

Before beginning treatment procedure, check the aiming beam integrity: it is essential to the laser system safe operation.

WARNING: If the aiming beam is weak (blur / barely or not visible red spot): do not use the laser or delivery system: the optical fiber may be damaged. Operating the laser without the aiming beam may result in laser exposure to non-targeted tissue and possible injury. A damaged cable may cause accidental laser exposure to the treatment room personnel or patient, and/or set fire in the treatment room. Contact your local distributor or QUANTEL MEDICAL Service Department.

WARNING: When using an optical fiber delivery device, always inspect the optical fiber cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The optical fiber cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments.

2.7 ROUTINE CHECKS

2.7.1 ADJUSTING THE EYEPIECES

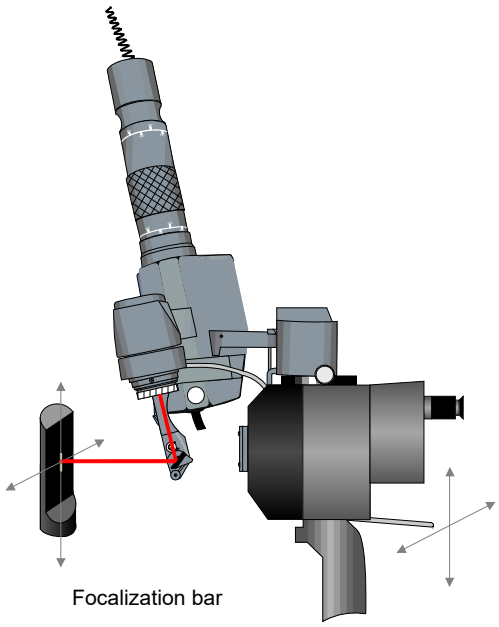
Pupillary distance and visual acuity vary from one person to another. It is important that the user adjusts the eyepieces to suit his/her sight:

Step 1 / Adjusting the pupillary distance
This distance may be adjusted manually by narrowing or widening the distance between the eyepieces.

Step 2 / Adjusting for visual acuity
Adjust the eyepieces as often as necessary to obtain the sharpest possible image.

2.7.2 CHECKING SPOT MOVEMENT LIMITS

Refer to the following instructions :



Horizontal and vertical movement of the micromanipulator.

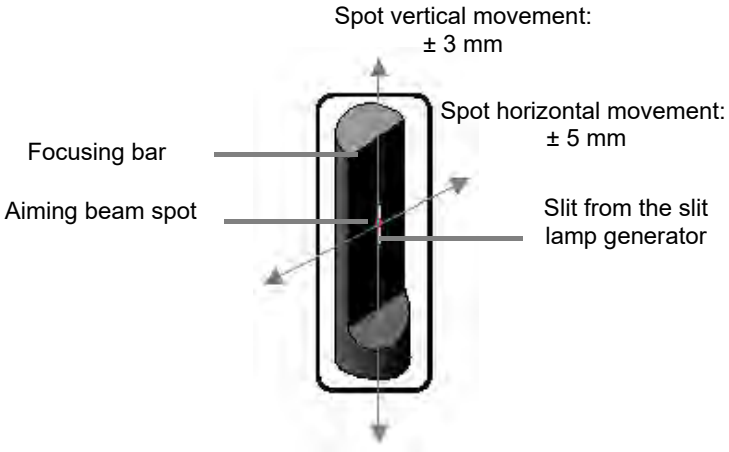
Preliminary conditions:

- Position the focusing bar on the slit lamp;
- Position the slit lamp generator at the center of the oculars;
- Switch on the slit lamp, position 8 (longest slit);
- Verify the fiber to laser connection;

Select a monospot treatment page.
The aiming beam is activated: project the aiming beam on the focusing bar.

NOTE : Do not select a multi-spot screen.

The red spot of the aiming beam and the slit of light must appear as clearly as possible on the focusing bar at the focal length of the slit lamp



Using the micromanipulator, check that the aiming beam spot can move likewise in both horizontal and vertical directions, up the lighted slit limits.

WARNING: If this is not the case, you must contact: your local distributor or QUANTEL MEDICAL Service Department

2.7.3 AIMING BEAM INTEGRITY

Before starting any laser treatment procedure, the integrity of the aiming beam must be checked:

WARNING: Do not use the laser system or the indirect ophthalmoscope terminal if the aiming beam is weak (blur / red dot barely visible or invisible): the optical fiber may be damaged. Using the laser without the aiming beam may result in non-targeted tissue being exposed to the laser beam and thus causing injury. Damaged fiber can cause accidental and dangerous laser exposure to the patient, personnel in the treatment room, and / or can cause a fire.
Contact your local distributor or QUANTEL MEDICAL customer service.

WARNING: Always inspect the fiber optic cable before use to make sure it is not bent, cracked, cracked, or damaged. It can be damaged, if a person walks on it, pulls it, leaves it in a bad position, wrongly or wraps it too strongly.

2.7.4 AIMING BEAM POSITION

The red aiming spot projected on the focusing bar must be positioned in the center of the luminous slot in position vertically and whatever the diameters of the laser spot.
If it is not the case, Contact your local distributor or QUANTEL MEDICAL customer service.

2.8 TOUCH SCREEN CALIBRATION

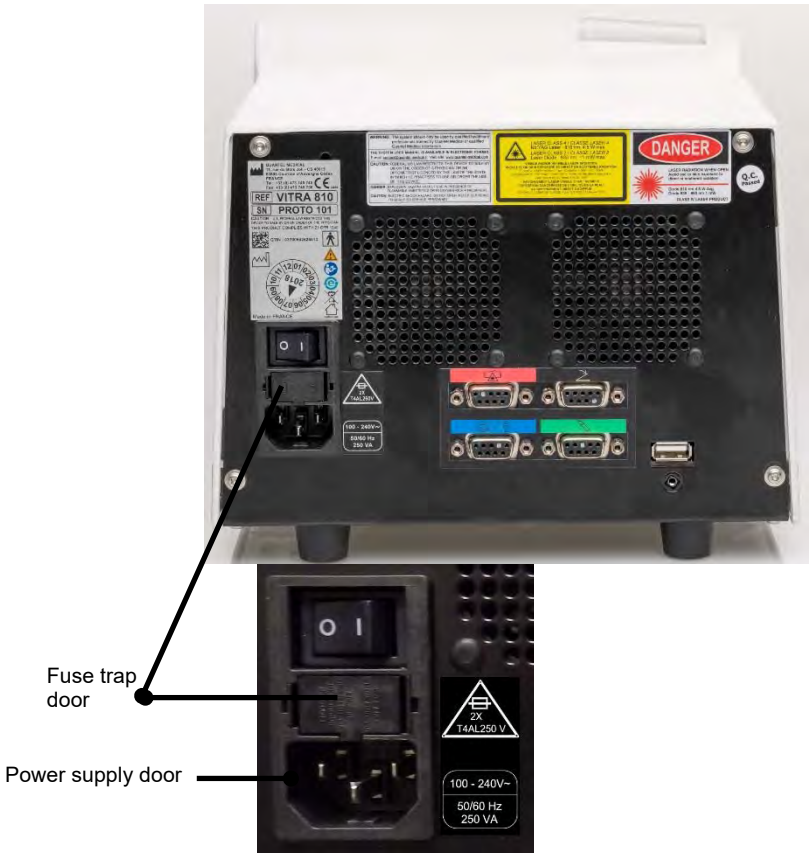
From the homepage, turn the power knob at the front of the unit clockwise until the following screen displays:

Press on grey crosshairs that display one after another (upper left, upper right, lower right, liwer left, and center of the screen).

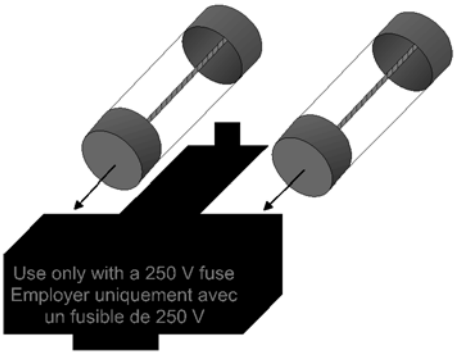
The laser system automatically turns off and turns on when the calibration is completed.

3 FUSES REPLACEMENT

WARNING: **Disconnect the power cord before any intervention on the instrument.**



Fuse trap door situated at the back panel of the device.

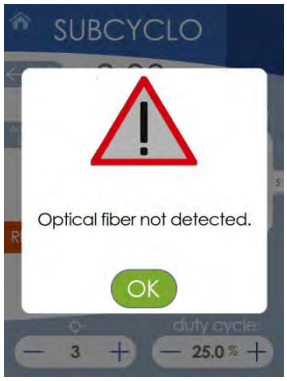


Specifications:
Manufacturer: LITTLEFUSE
Model: T5ALH250V P

The fuses must comply with standard IEC 60127-1

4 ERROR MESSAGES AND SYMBOLS

Error and warning messages are displayed in the middle of the screen:



4.1 ERROR MESSAGES

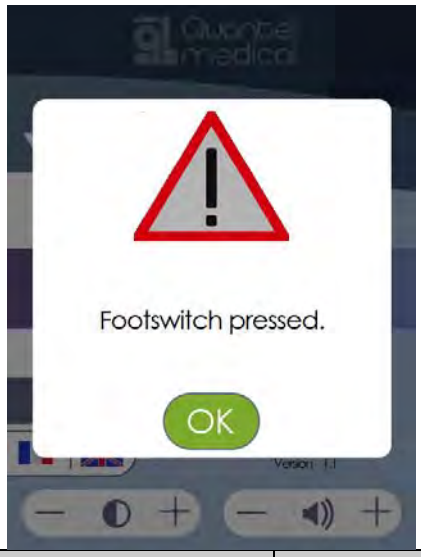
Error number	Message displayed	Action
1	Error, please restart the laser	Validate to Restart the laser.
2	Error, please restart the laser	
3	Error, please restart the laser	
4	Laser error	
5	Laser error	Contact the customer service.
6	Laser error	
7	Laser error	
8	Cavity not calibrated. Please contact support.	
9	Terminal not calibrated. Please contact support.	
10	Error, please restart the laser	Validate to Restart the laser.
11	Error, please restart the laser	
12	Error, please restart the laser	
13	Laser error	
14	Filter 1 error	Check the filter 1 connection (Blue connector at the laser back).
15	Filter 2 error	Check the filter 2 connection (Red connector at the laser back).
16	Footswitch not detected	Check the footswitch connection (Black connector at the laser back).

Error number	Message displayed	Action
17	Laser energy error, please contact support	Contact the customer service.
18	Laser energy error, please contact support	
19	Laser energy error, please contact support	
20	Laser energy error, please contact support	
21	Laser energy error, please contact support	
22	Laser energy error, please contact support	
23	Laser energy error, please contact support	
24	Laser energy error, please contact support	
25	Scanner error. Please turn OFF and ON the laser	Validate to Restart the laser.
26	Scanner error. Please turn OFF and ON the laser	
27	Scanner error. Please turn OFF and ON the laser	
28	Scanner error. Please turn OFF and ON the laser	Contact the customer service.
29	Laser error, please restart the laser	Validate to Restart the laser.
30	Laser error, please restart the laser	
31	Laser temperature error, 15°C < temperature < 35 °C	Check the external temperature. The device must be used at a temperature between 15 and 35°C
32	Cavity temperature error, please contact support	Contact the customer service.
33	Cavity temperature error, please contact support	
34	Cavity temperature error, please contact support	
35	Cavity temperature error, please contact support	
36	Cavity temperature error, please contact support	
37	Cavity temperature error, please contact support	
38	Optical fiber not detected	Check the optical fiber connection at the front panel.
39	Laser energy error, please contact support	Contact the customer service.
40	Laser energy error, please contact support	
41	Filter 2 error	Check the filter 2 connection (Red connector at the laser back).
42	Filter 2 error	Check the filter 2 connection (Red connector at the laser back).
43	Adaptation badly positionned	Check the adaptor position.

Error number	Message displayed	Action
44	Humidity error	Check the external humidity.
45	Error, please restart the laser	Contact the customer service.
46	Error, please restart the laser	
47	Remote interlock not connected	Check the doorswitch connection (red connector at the laser back).
48	Error, please restart the laser	Contact the customer service.
49	Error, please restart the laser	
50	Error, please restart the laser	
51	Error, please restart the laser	Contact the customer service.
52	Laser not detected, Please start it.	Validate to Restart the laser.
53	Temperature error. Contact customer service.	Contact the customer service.
54	Invalid configuration laser.	
55	Laser connection impossible, Restart application AND laser	Restart the laser. Contact the customer service.
56	Aiming beam intensity must be > 0	Set the aiming beam intensity > 0
57	Scanner filter not present	Contact the customer service.
58	Présence scanner modifiée. Le laser va redémarrer.	Validate to Restart the laser.
59	Spot size modified during shot ! Shot stopped.	Validate to Restart the laser.
60	Cavity or aiming red not calibrated. Contact customer service.	Contact the customer service.

4.2 WARNINGS

The warning messages are not errors but the laser shot is deactivated and switches to "Standby".



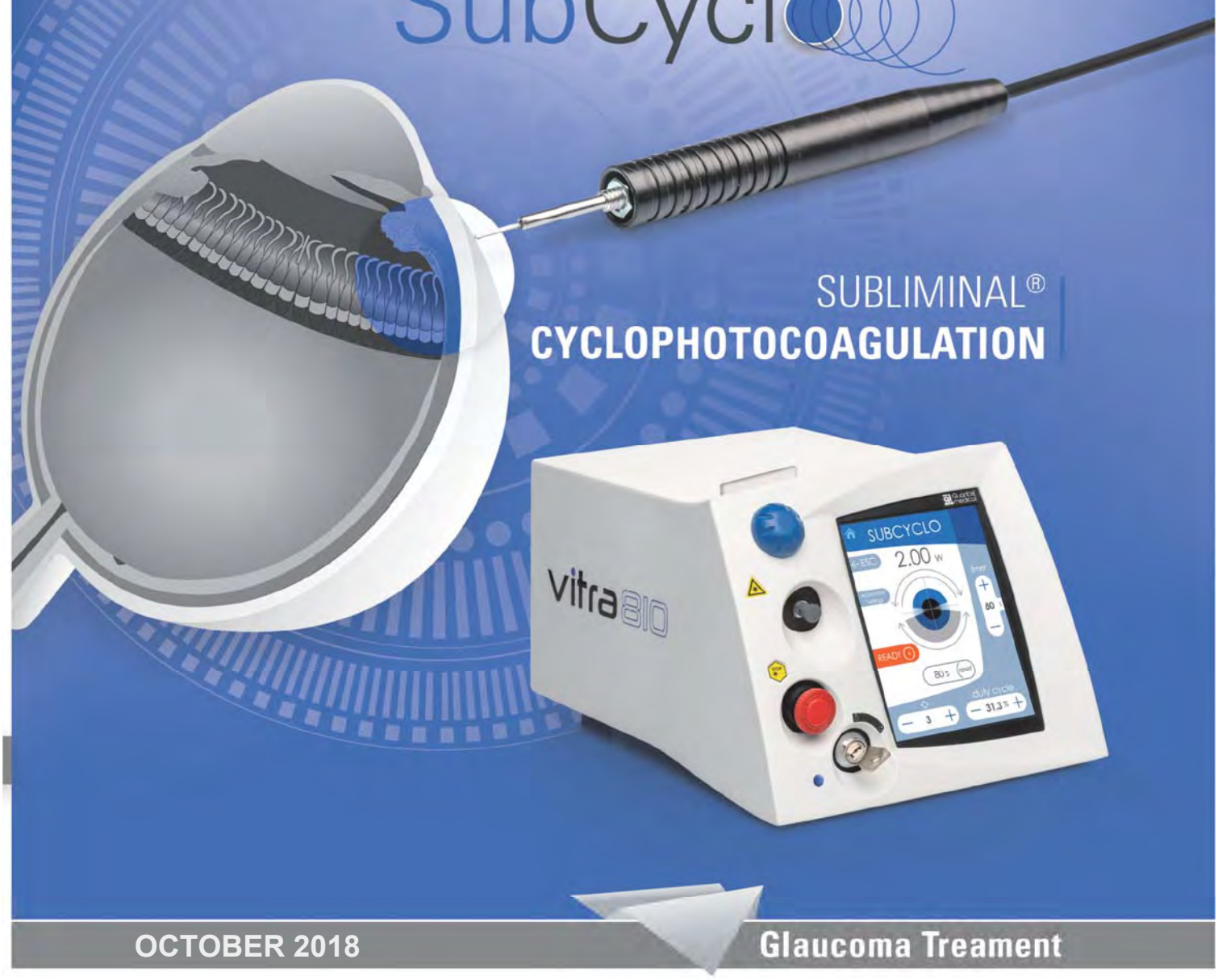
Error number	Message displayed	Action
0	Warning laser (filter 1)	Check the filter 1 connection (Blue connector at the laser back).
1	Warning laser (scanner lock)	Check the adaptor position.
2	Footswitch pressed	The pedal is pressed while the laser is in the standby state.
3	Remote interlock not connected.	Check the doorswitch connection (Red connector at the laser back).
4	Low energy. Please contact support.	Low energy. Contact the customer service.
6	The spot size must be > 100	Set the zoom at a value > 100 µm.
7	Please wait to the end of the printing	Wait the printing end.
8	The TTT adaptor is not connected Connect it or select another terminal.	Connect the terminal or select another terminall.

USER MANUAL

vitra 810™

V – CLINICAL INFORMATION

SubCyclo®



OCTOBER 2018

Glaucoma Treament

2018 CE 0459

Directive 93/42/EEC

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Quantel medical

TABLE OF CONTENTS

Rev. 05/10/2018

1. VITRA 810 WITH SLIT LAMP

1.1. INDICATIONS

The slit lamp adaptation has its own 100 microns optic fiber to connect directly the 810 nm output of the laser. This non-contact delivery system incorporates a optical system to provide an adjustment of the spot diameter from 100 µm to 100(µm.
The treatment beam will cause photocoagulation of the pigmented tissues within the eye through the burning action of the laser. This effect can be controlled by varying the parameters of beam power, spot size and exposure duration.

1.2. APPLICATIONS

This system is indicated for use in retinal photocoagulation for the treatment of ophthalmic conditions including: Proliferative Diabetic Retinopathy, Macular Degeneration and Retinal Detachment.

1.3. BIBLIOGRAPHY

Retinal photocoagulation and mechanisms of action.
Dr Mac Hugh and J. Marshall ; Moorfields Eye Hospital, London.

1.4. ROUTES

The laser treatment beam is directed through the cornea to the target tissue. Accessory contact lenses which consist of special mirrors and lenses may be used to aid in treatment of particular targets such as the fundus.

1.5. CONTRAINDICATIONS

Patients in following situations which prevent visualization of target tissue are contraindicated for laser treatment:
- Cloudy cornea or extreme haze of the aqueous humor of the anterior chamber.

1.6. ADVERSE EFFECTS

Adverse effects may occur as a result of laser treatment:
- Corneal burns and inflammation
- Transient elevations in intraocular pressure.

Excessive combinations of power and exposure can cause undesirable tissue vaporization and charring.
No evidence of non-thermal effects has been observed.

1.7. SETTINGS

The desired treatment parameters of power, exposure duration, and spot size are selected as required. If unsure which settings are required, select a medium spot size and a minimal power and exposure time. Increase power as necessary to result in the desired effect: An efficient shot exposure will typically cause a blanching of target tissue.

CAUTION: **The resulting effect can be delayed from the exposure the laser beam. Exposure time and spot size can also be modified.**

1.8. AIMING BEAM

The aiming beam, while low power, is still an intense light source and retinal exposure should be limited to that required for target acquisition. Proper aiming is aided by low aiming beam intensity (see the user manual of your photocoagulator).

1.9. PRECAUTION FOR PERSONNEL

Backscattered radiation is not dangerous when viewed through a protective filter. Eye protection designed for the wavelength (**810 nm**) and for the power density emitted must be worn by all auxiliary personnel present in the room.

For more information, refer to the user manual:
Chapter I – Regulatory information & safety
Section 5 - Safety glasses & NOHD

WARNING: **Federal (US) law states that only a physician may buy this device.**

WARNING: **Use of controls or adjustments, or performance of procedures other than those specified in the instruction manual, can result in hazardous radiation exposure.**

WARNING: **This device may only be used by a physician or at the request of a physician.**

2. VITRA 810 WITH OPERATING MICROSCOPE

2.1. INDICATIONS

The Zeiss operating microscope adaptor has been specially designed for physicians who are using this type of operating microscope in conjunction with a slit lamp. The only Zeiss model available comes with a slit lamp. The adaptor has its own optical fiber to connect it directly to the laser. The treatment beam will cause photocoagulation of pigmented tissues within the eye through the burning action of the laser (810 nm). This effect can be controlled by varying the parameters of beam power, exposure duration and spot sizes.

2.2. APPLICATIONS

This system can be used on recumbent patients.

2.3. ROUTES

The laser treatment beam is directed through the cornea to the target tissue. The laser is used in conjunction with a focusing lens. The focusing lens will determine the spot size on the retina.

2.4. CONTRAINDICATIONS

The following situations prevent visualization of target tissue and are contraindicated for laser treatment:

- Cloudy cornea
- Extreme haze of the aqueous humor of the anterior chamber.

2.5. PRECAUTION

The laser beam aiming is dependent upon the three-mirror lens, so the doctor operating the apparatus should take caution.

2.6. ADVERSE EFFECTS

The following adverse effects may occur as a result of laser treatment:

- Corneal burns and inflammation.
- Transient elevations in intraocular pressure.

Undesirable vaporization and charring of tissue due to excessive combinations of power and exposure.

2.7. SETTINGS

Select the desired treatment parameters of power, exposure duration, and spot size (from 1000 to 2000 microns) as required. If unsure of the required setting, select a low power, short duration, and large spot size. Then increase the power and duration or decrease the spot size as necessary. 0.1 second exposure and 150mW is a low starting combination. An efficient exposure will typically cause an immediate blanching of target tissue. Exposure duration can be adjusted to achieve the desired effect by using the touch screen as required.

2.8. AIMING BEAM

Even while low power, the aiming beam is an intense light source and retinal exposure should be limited to that which is required for target acquisition. Proper aiming is aided by low aiming beam intensity.

2.9. PRECAUTION FOR PERSONNEL

Backscattered radiation is not dangerous when viewed through a protective filter. Eye protection designed for the wavelength (**810 nm**) and for the power density emitted must be worn by all auxiliary personnel present in the room.

For more information, refer to the user manual:
Chapter I – Regulatory information & safety
Section 5 - Safety glasses & NOHD

WARNING: **A doctor's filter must be affixed onto the microscope for the both operating physician and assistant**

WARNING: **Federal (US) law states that only a physician may buy this device.**

WARNING: **Use of controls or adjustments, or performance of procedures other than those specified in the instruction manual, can result in hazardous radiation exposure.**

WARNING: **This device may only be used by a physician or at the request of a physician.**

3. VITRA 810 WITH LASER PROBE

Sterile probes (single use only)

3.1. INDICATIONS

The laser probe has been designed to provide a means for intraocular photocoagulation as an adjunct to vitrectomy surgery.

NOTE: A doctor protection filter has to be fixed on the microscope for the medical practitioner and the assistant.

3.2. CONTRAINDICATIONS

Use of the laser probe is contraindicated except when used in conjunction with vitrectomy.

3.3. APPLICATIONS

Specific indications for use of the laser probe include treatment of complicated rhegmatogenous and tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, and various retinal vascular tumors

NOTE : The laser probe should only be used in conjunction with vitrectomy surgery, but should not be the sole indication for vitrectomy.

3.4. EFFECTS

The instrument causes photocoagulation of the target tissue within the eye through the thermal action of the laser beam. This effect can be controlled by adjusting the beam power and exposure duration. The spot size of the treatment burn can be varied from 200 microns to 1000 microns by varying the distance between the probe tip and the target tissue.

3.5. PREPARATION

Put the laser in STANDBY mode. Only the red aiming beam is ON. To attach the probe, first remove the protective cap, which may be on the laser end of the laser probe.
Screw the fiber connector onto the receptacle **(finger tight)**. If the laser probe is not fully inserted and screwed into the receptacle, the terminals internal safety shutter will not open and allow the laser probe to operate. Check for the presence of the red aiming beam at the laser probe output by directing the tip of the probe's handpiece towards a diffused target such as a piece of paper. By pressing the. +. and "**-**" buttons, adjust the AIMING BEAM INTENSITY.

3.6. ROUTES

The laser probe is inserted into the vitreous cavity through the sclerostomy incision made for the vitrectomy instruments. No separate incision is necessary.

3.7. TREATMENT METHOD

A single treatment exposure should produce a blanching of the target tissue. To achieve the desired effect, exposure duration can be adjusted from 0.01 seconds to continuous. Power settings can be varied from 50 milliwatts up to the desired treatment levels. If unsure what settings are required, select a low power and short duration and increase each as necessary.

3.8. HAZARD

Even while low power, the aiming beam is an intense light source and retinal exposure (particularly in the macular region) should be limited to that which is required for target acquisition.

3.9. ADVERSE EFFECTS

Corneal burns, inflammation, choroidal detachment, and transient elevation of intraocular pressure can occur as a result of laser treatment. Unintentional retinal burns can occur if excessive beam power or duration is used.

3.10. PRECAUTION

Backscattered radiation is not dangerous when viewed through a protective filter. Eye protection designed for the wavelength (**810 nm**) and for the power density emitted must be worn by all auxiliary personnel present in the room.

For more information, refer to the user manual:
Chapter I – Regulatory information & safety
Section 5 - Safety glasses & NOHD

WARNING: **Contents are sterile unless package is opened or damaged. Sterilized with Ethylene Oxide Gas. Use once and discard. Use only with viewing optics that have been fitted with appropriate protective filters.**

WARNING: **The laser probe is a single-use, disposable component. It is shipped prepackage and sterilized from the factory. It must not be reused or re-sterilized.**

WARNING: **A doctor protection filter should be attached to the microscope for the practicing physician and for the assistant.**

WARNING: **Federal (US) law states that only a physician may buy this device.**

WARNING: **Use of controls or adjustments, or performance of procedures other than those specified in the instruction manual, can result in hazardous radiation exposure.**

WARNING: **This device may only be used by a physician or at the request of a physician.**

4. VITRA 810 WITH INDIRECT OPHTALMOSCOPE

4.1. INDICATIONS

The indirect ophthalmoscopes adaptations for the laser photocoagulator have been designed for physicians who are already currently using those types of ophthalmoscopes. The adaptations are easily removable. They have an integrated non-moving, eye safety filter for the treating physician. An adaptation has its own 50 micron optical fiber, which is directly connected to the laser. The burning action of the treatment beam will cause photocoagulation of pigmented tissues within the eye. This effect can be controlled by varying the beam power and the exposure duration.

4.2. USE

The laser's indirect ophthalmoscope is indicated to be used for:

1) Any eye requiring laser treatment out to the ora serrata.
2) Any eye with rubeosis iridis from central vein occlusion.
3) Any eye undergoing a pneumatic retinopexy retinal reattachment procedure.
4) Any time laser energy must be delivered through any eye with focal lens opacity or with a small pupil.
5) Laser treatment of the eye with the patient in the supine position.

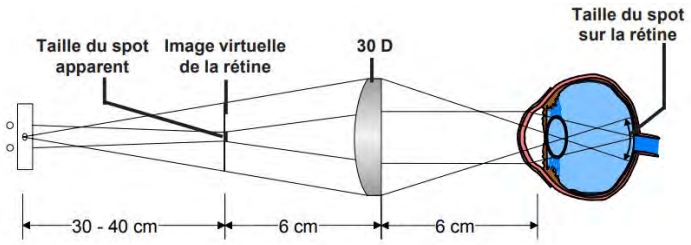
4.3. APPLICATIONS

This system has the same clinical indications as the Slit Lamp delivery system, but only when used for peripheral photocoagulation.

4.4. ROUTES

The laser treatment beam is directed through the cornea to the target tissue. As it is usual for the indirect ophthalmoscope, the laser is used in conjunction with an auxiliary lens. The power of this lens determines the enlargement of the fundus image; it will also determine the laser spot size on the retina. For an eye with an average focusing power of 60 Diopters:
Two examples:

- For a 20 diopter lens, the spot size will be 133 microns
- For a 30 diopter lens, the spot size will be 200 microns



4.5. PRECAUTION

Laser beam aiming is dependent upon the doctor's line of sight.

4.6. ADVERSE EFFECTS

These adverse effects may occur as a result of laser treatment:

- Corneal burns and inflammation
- Transient elevations in intraocular pressure.

Undesirable tissue vaporization and charring caused by excessive combinations of power and exposure. The combination of a 200 micron spot, 0.05 second exposure and 0.40 Watt has caused tissue vaporization in rabbits. Studies indicate that these hazards are no different from the adverse effects from continuous wave argon lasers used at these same settings. No evidence of non-thermal effects has been observed.

4.7. SETTINGS

The desired treatment parameters of power, exposure duration, and spot size are selected as required. If unsure which settings are required, select a low power, short duration, and large spot size. Increase power and duration or decrease spot size as necessary: 0.1 second exposure and 150 milliwatts is a low starting combination. An efficient shot exposure will typically cause a blanching of target tissue. Exposure duration can be adjusted from 0.01 second to continuous.

4.8. AIMING BEAM

Even, while at low power, the aiming beam is an intense light source; retinal exposure should be limited to that required for target acquisition. Proper aiming is aided by low beam intensity.

4.9. PRECAUTION FOR PERSONNEL

Backscattered radiation is not dangerous when viewed through a protective filter. Eye protection designed for the wavelength (**810 nm**) and for the power density emitted must be worn by all auxiliary personnel present in the room.

For more information, refer to the user manual:
Chapter I – Regulatory information & safety
Section 5 - Safety glasses & NOHD

WARNING: **Federal (US) law states that only a physician may buy this device.**

WARNING: **Use of controls or adjustments, or performance of procedures other than those specified in the instruction manual, can result in hazardous radiation exposure.**

WARNING: **This device may only be used by a physician or at the request of a physician.**

4.10. REFERENCES –INDIRECT OPHTALMOSCOPE

Friberg T.
Clinical Experience with a Binocular indirect.
Retina 7 : 28-31, 1987

Friberg T.
Principles of Photocoagulation using Binocular Indirect Ophthalmoscope Laser Delivery Systems.
International Ophtalmology Clinics 30(2) : 89-94, 1990.

Friberg T, Eller A.
Pneumatic repair of Primary and Secondary Retinal Detachments Using a Binocular
Indirect Ophthalmoscope Laser Delivery System.

5. VITRA 810 WITH SUBLIMINAL CYCLOPHOTOCOAGULATION PROCEDURE (SUBCYCLO)

CYCLOPHOTOCOAGULATION PROBE
Sterile probes (single use only) using for 810 nm.

5.1. INDICATIONS

The Cyclo-Photocoagulation probe is a probe designed for the SubLiminal cyclophotocoagulation (SubCyclo). The optic fiber has a 600 microns diameter.

5.2. CONTRAINDICATIONS

Cyclo-photocoagulation is contraindicated in cases the eye has inflammatory vascularization with a high elevation of pressure.
In these cases wait for the inflammation to decrease before performing cyclo-Photocoagulation.

5.3. APPLICATIONS

The SubCyclo procedure is indicated for the treatment of the primary glaucoma with opened angle, glaucoma with closed angle and refractory glaucoma.

5.4. EFFETCS

The SubLiminal laser beam stimulates the uveoscleral way and the cillary body.
This effect can be controlled by adjusting the parameters of beam power and exposure duration.

5.5. PATIENT PREPARATION

Local anesthesia is necessary: retrobulbar or peribulbar injection.
An eyelid spreader is used for the treated eye. The other must be protected from scattered radiation.

5.6. LASER ADJUSTMENT

The treatment method below describes treatment settings corresponding to no specific affection. The patients will have to undergo an individual examination to determine their operational needs in keeping with the indication, the treatment location and the patient characteristics. In case of doubt on the result respond it is necessary to start the treatment with preserving parameters of power and/or of exposure time and increase it very gradually.
According to the recommendations of experienced clinicians[1]:
Use the SubLiminal mode at 31,3 % of Duty Cycle (500 µs laser beam on, 1100 µs off).

1- *Tan A, Chockalingam M, Aquino M, Lim Z, See J, Chew P. Micropulse transscleral diode laser cyclophotocoagulation in the treatment of refractory glaucoma. Clin Exp Ophthalmol. 2010 Apr;38(3):266-72*
2- *Aquino MC, Barton K, Tan AM, SngC, Li X, Loon SC, Chew PT. Micropulse vs continuous wave transcleral diode cyclophotocoagulationin refractory glaucoma: a randomized exploratory study. Clinical And Experimental Ophthalmology, 43 (1) pp. 40-46.*

5.7. TREATMENT METHOD

Transillumination is recommended to confirm the position of the ciliary body.
Average position of the probe: at 3 mm of the limbus and directed perpendicular to the ocular sphere.

Treat the upper quadrant applying a decisive pressure.
Move the probe in continuous use through an arc of circle between the position 9:30 and the position 2:30.
Apply continuously the laser beam on 4 to 7 applications between the both positions aforementioned with duration of 50 seconds on the whole avoiding the shots at 3H and 9H in order to prevent damage on the cillary veins.

Treat the lower quadrant performing again the procedure during 50 s on the whole on the area in lie between the positions 3:30 and 8:30.
If the probe traps a portion of conjunctiva, stop laser treatment to release the conjunctiva blocked and positions again the probe at the same place and continue the treatment.

In case of trabeculectomy, tube, derivation or thinning area of the sclérotic, the area between the 2 positions 9h30-2h30 and 3h30-8h30 must be reduced according to avoid the affected area. It is recommended to apply 50 s of treatment on this reduced area.

A local treatment against a possible inflammation is necessary just after the cyclophotocoagulation.

5.8. HAZARD

During the treatment, keep the eyes humid to avoid the probe bulb sticking to the conjunctiva.
Do not treat:
- trabeculectomy sites of the sclerotic,
- thinning sites of the sclerotic,
- tubes and derivations directly.

A treatment power too high can occur burns of the ocular surface or a haemorhage of the cillary body.
The contamination of the optic fiber end by blood or burnt out tissues can occur burns of the ocular surface.

The application of an excessive energy can occur burns at the equator site of the eye.
The presence of a high prelimbic pigmentation of the conjunctiva can occur a local absorption and burns. Then it is recommended to avoid the area with high prelimbic pigmentation.

5.9. ADVERSE EFFECTS

Inflammation, choroid detachment, and transient elevation of intraocular pressure can occur as a result of laser treatment, if excessive beam power and/or duration is used.
It is advisable to control the Intra Ocular Pressure during the hours following the treatment.
The drug treatment against glaucoma must be maintained until the referring physician considers that the I.O.P. is satisfactory.

5.10. PRECAUTION

Backscattered radiation is not dangerous when viewed through a protective filter. Eye protection designed for the wavelength (**810 nm**) and for the power density emitted must be worn by all auxiliary personnel present in the room.

For more information, refer to the user manual:
Chapter I – Regulatory information & safety
Section 5 - Safety glasses & NOHD

WARNING: **Contents are sterile unless package is opened or damaged. Sterilized with Ethylene Oxide Gas. Use once and discard. Use only with viewing optics that have been fitted with appropriate protective filters.**

WARNING: **The laser probe is a single-use, disposable component. It is shipped prepackage and sterilized from the factory. It must not be reused or re-sterilized.**

WARNING: **A doctor protection filter should be attached to the microscope for the practicing physician and for the assistant.**

WARNING: **Federal (US) law states that only a physician may buy this device.**

WARNING: **Use of controls or adjustments, or performance of procedures other than those specified in the instruction manual, can result in hazardous radiation exposure.**

WARNING: **This device may only be used by a physician or at the request of a physician.**

6. VITRA 810 WITH THERMAL CYCLOPHOTOCOAGULATION PROCEDURE (THERMOCYCLO)

CYCLOPHOTOCOAGULATION PROBE
Sterile probes (single use only) using for 810 nm.

6.1. INDICATIONS

The Cyclo-Photocoagulation probe is a probe designed for the thermal cyclophotocoagulation (ThermoCyclo). The optic fiber has a 600 microns diameter.

6.2. CONTRAINDICATIONS

Cyclo-photocoagulation is contraindicated in cases the eye has inflammatory vascularization with a high elevation of pressure.
In these cases wait for the inflammation to decrease before performing cyclo-photocoagulation.

6.3. APPLICATIONS

The thermal Cyclo-Photocoagulation of ciliary body is reserved, for patients with chronic glaucoma and those do not respond to conventional treatments.
Other application: painful non-functional eye with glaucoma.

6.4. EFFECTS

The laser beam is focused by the bulb tip to 1.5 mm under the sclera.
The instrument causes photocoagulation of the ciliary processes within the eye through the thermal action of the laser beam. This effect can be controlled by adjusting the parameters of beam power and exposure duration.

6.5. PATIENT PREPARATION

Local anesthesia is necessary: retrobulbar or peribulbar injection.
An eyelid spreader is used for the treated eye. The other must be protected from scattered radiation.

6.6. LASER ADJUSTMENT

The power must be adjusted just below the tissue-disruption reaction: a "pop" or "snap" sound from within the eye.
It is necessary to determine at what energy (Power x Time) this disruption occurs; then to decrease the energy by 0,5 Joule.

In general, the pulse duration is: 2 seconds. The power will be adjusted for each patient.
If unsure what settings are required, select a low power (ex: 900 mW). The duration being fixed to 2 s, adjust the power by steps of 250 mW.

6.7. METHOD OF TREATMENT

Transillumination is recommended to confirm the position of the ciliary body.
Position of the probe: more than 1 mm behind the limbus and directed perpendicular to the iris plane (or parallel to the visual axis).
Perform 3 to 4 applications by quadrant, avoiding application at 3 and 9 O'clock so as not to hit the ciliary nerves.
During the treatment, keeps the eye humid to avoid the probe bulb sticking to the conjunctiva.
A local treatment against a possible inflammation is necessary just after the treatment.

6.8. HAZARDS

For phakic eyes, the probe must be placed at more than 1 mm behind the limbus to avoid the risk to damage the lens with the laser beam.
The probe must be directed parallel to the visual axis for each laser application.

6.9. ADVERSE EFFECTS

Inflammation, choroid detachment, and transient elevation of intraocular pressure can occur as a result of laser treatment, if excessive beam power and/or duration is used.
It is advisable to control the Intra Ocular Pressure during the hours following the treatment.
The drug treatment against glaucoma must be maintained until the referring physician considers that the I.O.P. is satisfactory.

6.10. PRECAUTIONS

Backscattered radiation is not dangerous when viewed through a protective filter.
Eye protection designed for the wavelength (**810 nm**) and for the power density emitted must be worn by all auxiliary personnel present in the room.

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7. VITRA 810 WITH TTT

7.1. APPLICATIONS

✓ T.T.T. adaptor has been designed to treat ocular tumors.
Spot size, exposure time and power depend on type and size of tumor.

✓ T.T.T. adaptor can be used to treat occult choroid neovascularization:
This is a 'new' treatment which experimental studies have shown functional increase of approximately 25% after treatment of occult subfoveale neovascularization.

7.2. PRINCIPLE

The transpupillary thermotherapy consists in an application of a light laser radiation intended to cause a slow increase of temperature of the choroid. The aim is to obtain a gradual fibrosis of the neovascular membrane and then to reduce the exudation that causes metamorphosis and the decreasing of visual acuity.

Exposure time: 60 seconds.
Magnification lens: 1, 08.

The spot sizes are corresponding to those indicated on the adaptor.

Spot size Indication (mm)	Power (mW)	Power density (W/cm^2)
1.20	160 à 320	12 à 24
2.00	255 à 509	8 à 15
3.00	400 à 800	5 à 10

As the absorption of the Infra-red light by the retina differs from one patient to another, an assessment and an adjustment of those parameters is required.
If uncertain of required parameters, select a low power and increase power as necessary in accordance with the clinical effect.

CAUTION: **The standard parameters should be reduced for:**

- Myopia,
- Hard retinal detachment,
- Pseudo-Phakic eye,
- Hemorrhage under retina,
- Highly pigmented lesions.

A constant control during the operation is very important to stop the treatment from the first signs of thermal damage. Moreover, you must warn your patients to inform you should they feel a stinging sensation during the operation and inform them of the experimental nature of this treatment. The short term danger of this treatment is to overexpose the tissue that may cause a photocoagulation of the posterior pole.

7.3. CONTRAINDICATIONS

Patients with opaque cornea or cloudy aqueous humor of anterior chamber preventing visualization of target tissue are contraindicated for laser treatment.

7.4. AIMING BEAM

The aiming beam, while low power, is still an intense light source and retinal exposure should be limited to a minimum.
Proper aiming is aided by low aiming beam intensity (see the user manual of your photocoagulator).

7.5. ADVERSE EFFECTS

Adverse effects may occur as a result of laser treatment:
- Corneal burns and inflammation.
- Temporary elevations in intraocular pressure.

Excessive combinations of power and exposure can cause retinal burns.

7.6. PRECAUTION FOR PERSONNEL

Backscattered radiation is not dangerous when viewed through a protective filter. Eye protection designed for the wavelength (**810 nm**) and for the power density emitted must be worn by all auxiliary personnel present in the room.

For more information, refer to the user manual:
Chapter I – Regulatory information & safety
Section 5 - Safety glasses & NOHD

WARNING: Federal (US) law states that only a physician may buy this device.

WARNING: Use of controls or adjustments, or performance of procedures other than those specified in the instruction manual, can result in hazardous radiation exposure.

WARNING: This device may only be used by a physician or at the request of a physician.