DGM001033 REVISION HISTORY

File name	Description	Issued by	Approved by	Approving date
DGM001033 rev 00	Cyber Tm Family user manual	F. Fagnani	F. Dell'Antonio	Apr. 4th, 2013
DGM001033 rev 01	Cyber Tm Family user manual	F. Fagnani A. Raspa	F. Dell'Antonio	May 6th, 2013
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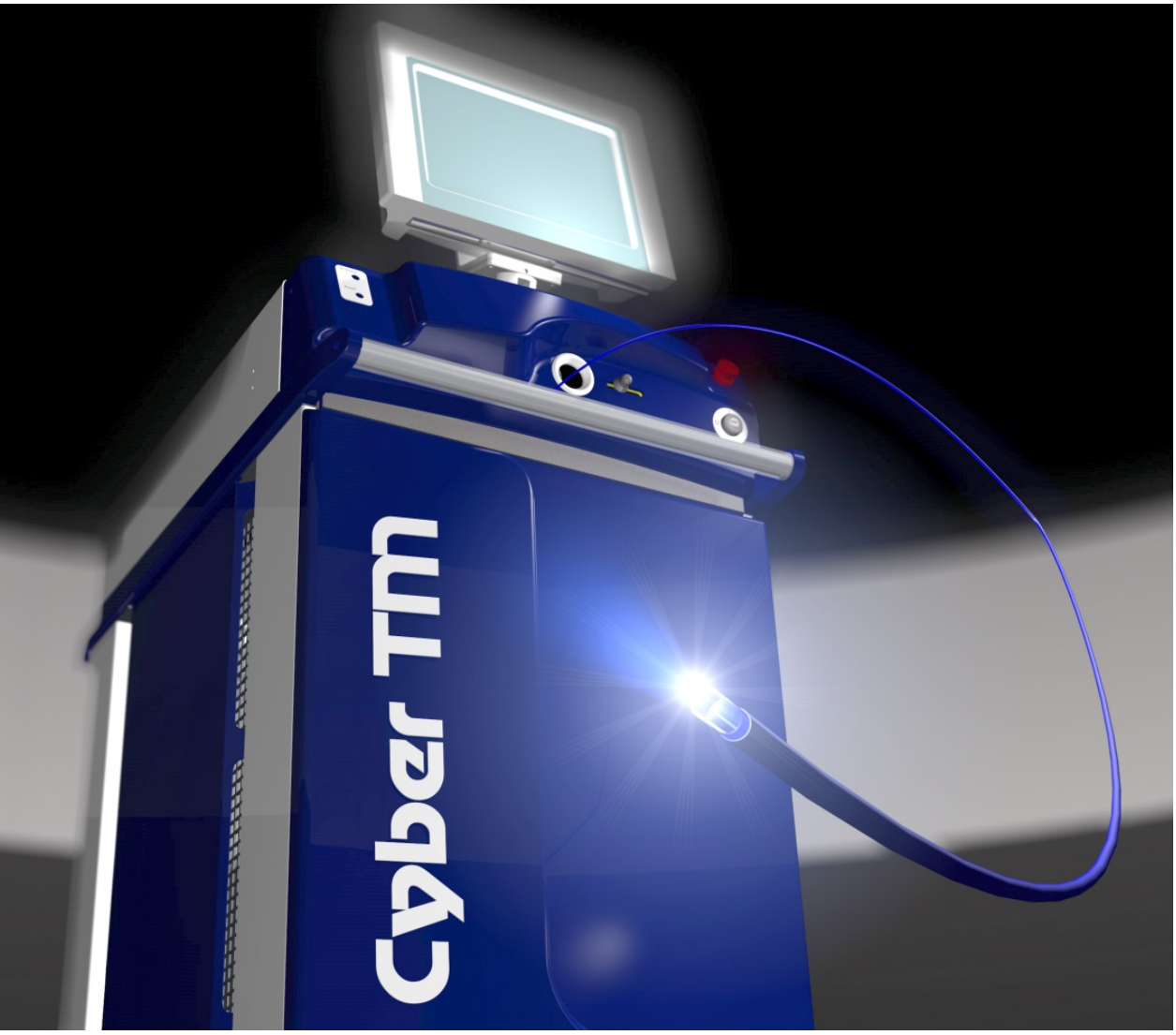
DGM001033 rev 04	Added cTUVus mark on labels of Cyber TM 180 & Cyber TM 200, added  symbol	F. Fagnani	F. Dell'Antonio	14/02/2014

USER MANUAL



Cyber Tm Family

Rx Only

Only for 230VAC Version

CE 0476

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For an optimal functioning of the equipment, and to ensure the maximum safety of operators and patients:

- **Verify that the treatment room temperature does not exceed 30 °C (86 F)**
- **Keep the equipment away from walls, especially where fans are positioned, ensuring the right ventilation**
- **Use protective goggles, ALWAYS**
- **Protect the patient from hazardous optical radiation**
- **Protect any operator, using personal protection means and environment protection barriers**
- **Please consult, in advance, the "Safety" session of this manual**

Caution: US Federal law restricts this device to safe by or on the order of a physician.

Notice

The information in this manual is subject to change without notice. **Disclaimer**

Quanta System SpA provides this document in its commitment to help facilitate consistent, positive clinical outcomes, and to reduce patient risk and injury. These guidelines are not, however, intended to in any way replace or substitute a physician's duty of care, professional responsibility, or professional judgment, nor are they intended to provide any warranty, promise, guarantee, assumption of risk or duty, release, or indemnity. Physicians shall at all times maintain responsibility for patient treatment and outcomes, and Quanta System SpA further assumes no liability for patient treatment or outcome or for physician's negligence, breach of duty of care, or malpractice.

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TABLE OF CONTENTS

1 GENERAL INFORMATION

1.1 *Introduction*

Medical Device Cyber Tm is a diode-pumped, solid state 2010nm laser wavelength.
This laser is the result of the long experience of QUANTA SYSTEM in the field of medical laser equipment
Cyber Tm family includes the following versions:

Version	maximum power	mains
Cyber Tm120	120W	230V Ac
Cyber Tm120	120W	208V Ac
Cyber Tm150	150W	230V Ac
Cyber Tm150	150W	208V Ac
Cyber Tm180	180W	230V Ac
Cyber Tm180	180W	208V Ac
Cyber Tm200	200W	230V Ac
Cyber Tm200	200W	208V Ac

This manual contains important information regarding the safe use of medical device Cyber Tm. The manual describes the instrument, use procedures, description of the various inspections, routine maintenance and operator information for the use and care of optical fibers used for the release of the laser radiation to the patient.

Medical people using the medical device Cyber Tm must read this manual carefully. Professional information regarding specific surgical specialties can be found in Chapter 6, "Clinical Applications".

Like all surgical instruments, for a responsible and proper use is necessary practice. **This manual should be read and understood thoroughly before first use!** For more information regarding the installation, clinical applications, or other problems you may encounter, please contact the company QUANTA SYSTEM.

1.2 *Purpose of the manual*

This manual contains essential information necessary for the installation, operation and maintenance of this medical device. The manual is intended to be used as a guide. This manual contains instructions for operation and maintenance. These instructions were written specifically for staff who are fully trained in laser and conventional surgery.

This manual contains information on the optional accessories supplied with the medical device, and their maintenance (Chapter 7, "Maintenance and cleaning").

This manual is not used as an alternative to surgical preparation. In addition, this manual does not provide specific technical information regarding operations of the medical device assistance. For any information regarding the technical assistance contact the company QUANTA SYSTEM.

1.3 *Safety instruction*

The safety instructions in this manual are intended to prevent possible injuries, material damage and operational faults. The fact that, before operating the laser for the first time, you should read through this manual carefully and keep it for future reference, is also considered to be part of the safe operation of this product.

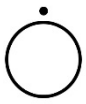
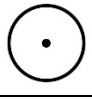
In this manual a distinction is made between the safety instructions used to warn of possible injury (**DANGER**) and instructions warning against operational faults (**WARNING**):

DANGER :	**Risk of injury!** This instruction concerns the safety of patients, operators and other persons, who are in the room, in which the laser is being operated or maintained. In this manual the following symbol is used to warn of the **risk of injury** from laser radiation (**Fig. 1**):  **Fig. 1: Symbol for Danger**
WARNING :	Danger of **operational fault**! Failure to follow this instruction can lead to damage to the laser system, the applicator or the laser fiber. In this manual the following symbol is used to indicate a possible **operational fault** and the damage to the laser system, which might result from it (Fig. 2).  **Fig. 2: Symbol for Warning**

 **Caution: US Federal law restricts this device to sale by or on the order of a physician/surgeon**

1.4 *Symbols and Abbreviations used in this manual*

Symbol	Description
	Read the enclosed documentation label
	CE label
	Symbol of type BF applied part according to standard 60601-1
	Attention: read instructions for use
	Symbol indicating that the device can not be disposed of as municipal waste, but must be separated in accordance with the WEEE (Waste Electrical and Electronic Equipment)
	Manufacturing date
	Manufacturer
	Serial Number
NOHD	Nominal Ocular Hazard Distance
NOHZ	Nominal Ocular Hazard Zone
MPE	Maximum permissible exposure
µm	Units, micro meter
s	Units, Second

Symbol	Description
mrad	Units, milliradiant
w	Units, watt
J	Units, Joule
J/cm^2	Units, Joule for centimeter square
cm	Units, centimeter
OD	Optical Density
D	Continuous laser according to EN207
L	Glasses protection degree
KV	Units, Kilovolt
A/m	Units, Ampere for metro
Vrms	Effective supply voltage
KHz	Units, Kilo Hertz
GHz	Units, Giga Hertz
WEEE	Waste Electrical and Electronic Equipment
CW	Continuous laser emission
Vac	Volt AC
A	Units, Ampere
T	Slow blow fuse
I	Electrical Protection Class
nm	Units, Nanometre
mm	Units, millimeter
EO	Sterilization Method
Ø	diameter
SMA	Optical Fiber connector type
mW	Units, milli Watt
T on	Pulse duration laser on
T off	Pulse duration laser off
Bar	Units, Pressure
°C	Units, Celsius degree
Kg	Units, Kilogram
%	Percentage
	A label that indicates the key switch off
	A label that indicates the key switch on

1.5 *Manufacturer*

QUANTA SYSTEM S.p.a.

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VAT: 10647810158

1.6 *Device specification*

This Laser Device has the following classification:

Type	
Product category	Surgical laser for medical use
Classification according Medical Device Directive 93/42/EEC	Class IIb
Laser Classification according IEC / EN 60825-1:2007	Class 4
Aiming beam classification according IEC / EN 60825-1:2007	Class 3R
Mains	208 Vac: 50/60 Hz; 18A 230 Vac; 50/60 Hz; 16A
Type of protection against electric shock	Class I
Degree of protection against the ingress of liquid	IP X0 (Not protected)
Degree of protection against electric shock	Type BF
Mode of operation	Continuous
Dimension	w: 550 mm, d: 750mm, h: 1100 mm
Weight	210 kg
Operative temperature	10°- 25° C
Storage temperature	Min 10° C / max. 40° C
Transport temperature (without water)	min -5° C / max 70° C
Humidity	30% - 85%
Cooling system	Forced Air with Internal Chiller
Laser characteristics	
Laser type	Diode Pumped Solid State, Tm:Yag
Wavelength	2010 nm
Maximum power	120 W (Cyber Tm120) 150 W (Cyber Tm150) 180 W (Cyber Tm180) 200 W (Cyber Tm200)
Operating mode	Cw or pulsed
Pulse duration	25-50-75 ms
Repetition rate	From 10 to 20 Hz
Beam transmission	Optical fiber system
Aiming Beam	Laser Diode, 532nm or 650nm (<5mW, class 3R)
Fuse	10x38mm, 20A; 600V
Note 1: During the lifetime oft he device the energy laser values can diverge from the declared one of maximum 5%. Note 2: the device has an internal measuring system to control the actual emission oft he laser. The device is not requiring calibration.	

WARNING!
Equipment not suitable for use in the presence of flammable mixtures.
Do not use the device in conjuction with oxygen-rich environment.

IMPORTANT!
For shipment and storage below +5°C, the cooling system must be emptied.
NOTE!
To prevent damage during transport or shipment of the products we recommend using the original packaging material.

1.7 *Combinations*

This laser system can only be used with Quanta System Optical Fibres.

CAUTION!
Products may be incorrectly combined!
Injury of the patient, user or others as well as damage to the product are possible.
The different products may only be applied jointly if the intended use and the relevant technical data, such as working length, diameter, peak voltage, etc. are suitable.
Follow the instruction manuals of the products used in combination with this product.

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2 LASER SAFETY

2.1 *General Safety*

- For safety use of this device, it is necessary to know all the safety standards.
- This manual contains important information about safety use of the device
- All people who work with this device must know the operation and safety instructions in this manual.
- Only trained personnel with appropriate safety guidelines can work with this device.
- The laser must be closed. Only authorized personnel can open the external cover.
- Only the service staff can work on the electrical section of the device.
- This User Guide should be available in the operation area of the laser device.
- All warning labels must always be in good condition.

2.2 *System Safety Features*

Cyber Tm laser system incorporates the following safety features:

- The laser will stop firing when the pressure is removed from the footswitch.
- An automatic circuit breaker shuts the system off in the event of an electrical overload.
- The laser provides an operating room door interlock connection, which must be set up by the hospital personnel.
- The key can only be removed when the key switch is in the OFF position.
- An on-board microprocessor continuously monitors the status of the system, and displays messages on the video screen along with appropriate operator prompts.
- Laser energy cannot be emitted from the system unless a fibre optic has been connected.
- Laser will go into ready when the READY button is touched.
- A fibre support pole elevates and positions the fibre in a safe and unobtrusive position.
- A continuous audible tone is heard when the surgical beam is activated (i.e. foot pedal is pressed).
- A 2-second delay occurs before laser energy is emitted after the laser is placed in READY status.
- An Emergency Laser Stop switch is available to disable the system immediately, in the case of an emergency situation.

NB: Do not attempt to remove any panel from the laser console. Any attempt to remove the panels, unless instructed by authorized Quanta System SpA personnel, can damage the laser and will void the manufacturer's warranty.

2.3 *Training of the medical staff*

The use of the laser device is restricted only to the specialist medical staff* that, depending on their experience and expertise, can make choices appropriate to achieve the desired therapeutic effects.
It is recommended that all operators and support personnel are adequately trained on laser safety standards.
**(This device must only be used by adequately qualified and trained medical personnel with experience in the*

medical specialties listed in section # 6 of this operator's manual)

2.4 *Nominal Ocular Hazard Distance*

Following the Standard IEC / EN 60825-1: 2007, the MPE (Maximum Permissible Exposure), NOHD (Nominal Ocular Hazard Distance) and OD (Optical Density) are calculated.

The formulas and the numerical coefficients are specified in sect. 3, chap. 13, tab. 6, fig. 1, 2, 5, 6, 7, 8 of EN 60825-1:2007 standard.

At first we calculate the MPE that is the Maximum Permissible Exposure. This is the level of radiation to which, under normal circumstances, persons may be exposed without suffering adverse effects. The MPE level represents the maximum level to which the eye or skin can be exposed without consequential injury immediately or after a long time and are related to the wavelength of the radiation, the pulse duration or exposure time, the tissue at risk and, for visible and near infrared radiation in the range 1800 nm to 2600 nm, the size of the retinal image.

Then, we evaluate the NOHD, Nominal Ocular Hazard Distance. It is the distance at which the beam irradiance or radiant exposure equals the appropriate corneal maximum permissible exposure.
NOHD is:

$$NOHD = \frac{\sqrt{\frac{4P_0}{\pi MPE}} - a}{\phi} \quad [m]$$

Where P0 is the peak power of the laser pulse, a is the output beam diameter and ϕ is the beam divergence.

Finally we calculate the OD Optical Density of the glosses to be worn. It is defined as OD=log10 (H0/MPE)

H0 is the expected unprotected eye exposure level. In this case this value has been calculated as the radiant exposure (W/m^2) averaged over a circular spot of 7 mm diameter according to the limiting aperture applicable to the eyes.

Peak Power P_0	Divergence Full angle (rad)	Maximum Permissible Exposure – EMP [W/m^2]	Nominal Ocular Hazard Distance – NOHD [m]	Optical Density – OD
120	0.44	1000	0.87	2
150	0.44	1000	0.98	2
180	0.44	1000	1.07	3
200	0.44	1000	1.13	3

From NOHD values we deduce that the laser system has to be used in an enclosed area that does not allow the escape of laser radiation direct, reflected or transmitted.
Openings inside installation area that are transparent to laser radiation must be properly darkened.
Doors equipped with a special interlocking system have to made by a laser non-transparent material (glass, plastic, curtains, …) and windows have to be darkened by using appropriate laser non-trasmittive systems

2.5 *Working Area*

This device is a laser of Class 4 and must be used in a specific working area defined and delimited following the international standards IEC / EN 60825-1: 2007.

IMPORTANT!
This device is certified to be used in the operating room.

RULES OF ACCESS TO THE RESTRICTED AREA OF WORK
External staff and visitors should also:

- Be guided by staff
- Always wear laser goggles in the working area when the laser is switched on
- Be briefed by staff on the laser, electrical hazards and other risks associated with the operation of the laser within the working area (the laser radiation, electric shock, etc.)

Admission is strictly prohibited if there is no operator in the working area.

2.6 *Environmental condition*

Working area

The working area must be marked with warning labels laser, so as to prevent accidental entry into the area. All windows, mirrors, metal and other reflective objects (clocks) should be covered, so as to avoid distortions of the laser beam. All staff in the working area should know how to turn off the laser system in case of emergency.
The use of mobile phones is prohibited in the working area while using the device, because it could interfere with its proper operation.
Be careful that the laser system key is in a safe place when not in use.

Electrical connection requirements

The device must be connected to the electrical system in compliance with electrical safety regulations.
In accordance with safety Standards, the device is normally supplied with a cable with different plug related to the different countries and models.

Temperature and humidity

Appropriate values of temperature and humidity are required for the proper functioning of the device. The working temperature of the device should be between 10°C and 25°C, while the humidity should not exceed 85%.

Minimum space requirements

To ensure proper device ventilation it must be stand with at least 50cm of free space on both sides. This laser device is easily moved from room to room. Check in every room there is the minimum space required and the electrical proper.

2.7 *Eye and skin exposure*

The laser beam emitted can cause sight loss. The laser operates at different wavelengths, visible and invisible. Any energy transmitted by the laser system that enters the eye will be focused directly on the retina. Direct absorption of laser energy by the retina can result in temporary clouded vision, retina lesion, long term scotoma and long term photophobia.

A danger exists in any case of:

- Direct laser radiation
- Reflected laser radiation
- Diffused laser radiation

WARNING!

All the personnel present in the laser working area must wear all the protective devices.
Use protective goggles with the following specifications according national standard:

2100 D LB3 for laser source Ho:YAG at 2100 nm

In addition, even if you wear goggles, never look directly into the laser beam.
IMPORTANT*!*
Within the range of the laser, every person must wear laser goggles.
Check the laser goggles for perfect condition before each use. The goggles must not be mechanically damaged in any way.

Before wearing goggles to make sure that the goggles cover glasses are in good condition.
The skin is generally able to withstand higher levels of laser radiation, but can also be burned to a greater or lesser degree depending on the duration and intensity of exposure. If necessary, wear suitable protective clothing.

To avoid any mix-up, the laser goggles require adequate identification.
Laser goggles with a higher degree (or level) of protection (such as LB3, LB4, ...) or goggles featuring a broad--band filter of protection stage LB3 or higher also covering wavelengths of 2010 nm can also be used.

If you suspect that you have received a laser damaged, now:

- Turn off the laser;
- Inform your supervisor and / or technical laser safety.

2.8 *Fire hazard*

The laser radiation of this LASER device is able to melt, to burn or to vaporize almost all materials. The use of this LASER device is limited to the applications specified in this manual.

Fire hazard can occur due to the nature of the laser treatment. The absorption of emitted laser energy, no matter how brief, may raise the temperature of any material. This phenomenon is the basis of many useful medical and surgical applications; it is also the reason why these applications often require precautions against the risk of igniting combustible materials in and around the treatment area.

When this LASER device is used, the following precautions should be taken:

- Do not use any flammable substance, such as alcohol or acetone, in the preparation of the skin for treatment. Use soap and water if necessary.
- Anesthetics administered either by inhalation or topically must be approved as non-flammable.
- Use particular care in the use of oxygen.
- Avoid using combustible material, such as gauze and drapes, in the treatment area. When they are required, these materials must be made fire-retardant by keeping them moist with water. Clothing should be kept away from the treatment area.
- Never use in presence of flammable anesthetic gases or oxidant gases like oxygen or N2O
- Cotton wool and similar materials, when saturated with oxygen can catch fire due to high temperature emitted by laser
- before using the laser let evaporate solvents or glues or flammable solutions used to clean or disinfect
- attention: endogenous gases can catch fire or explode

2.9 *Emission of plume*

Vapor/smoke plume
There is considerable concern about the biological plume created by electrocautery units, bone saws and lasers. Current medical literature recommends that a smoke evacuator and in-line filter be used to capture this plume. The plume should be regarded as a source of active biological material and a possible carcinogen.

CAUTION!
Laser plume may contain viable tissue particulates.

2.10 *Safety Measures for the electromagnetic compatibility (EMC)*

The device doesn't include any type of direct connection with other external devices.

The device can be disturbed by the interference with external electromagnetic fields generated by other electrical devices installed near to it.

Turn off mobile phones and similar devices while operating the device

This device must be installed and used according to EMC information described in the tables reported in Attachment B.

2.11 *Emission of toxic gas or vapor*

The laser radiation of this LASER device is able to melt, to burn or to vaporize almost all the materials. The use of this LASER device is limited to the applications specified in this manual.

2.12 *Warning and instructions for the device disposal*

At the end of the service life of the device, it has to be handle according to the National or Local regulations for the disposal of waste electrical and electronic equipment
The device is subject to national standards which regulates the disposal of waste such as electrical equipment. It is forbidden to dispose of the device as municipal waste but has to be collected separately according to the WEEE Directive (Waste Electrical and Electronic Equipment).
The penalties for violating the requirements of the law are severe.

2.13 *Labelling plan*

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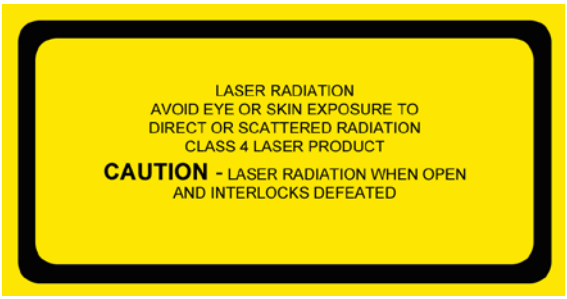
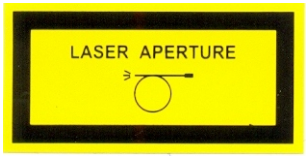
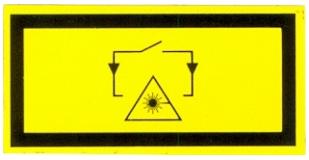
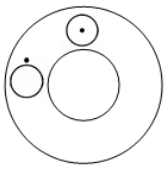
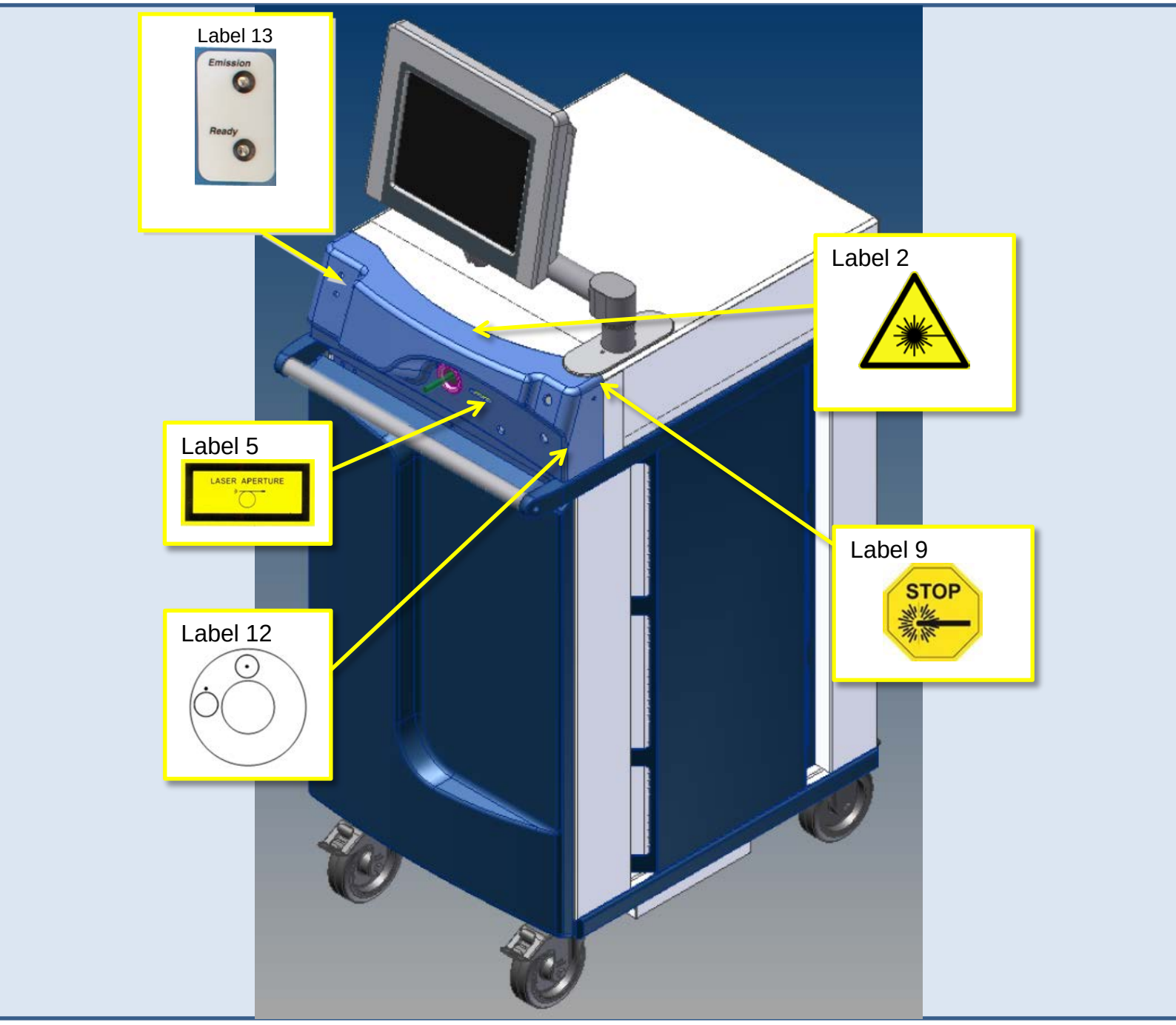
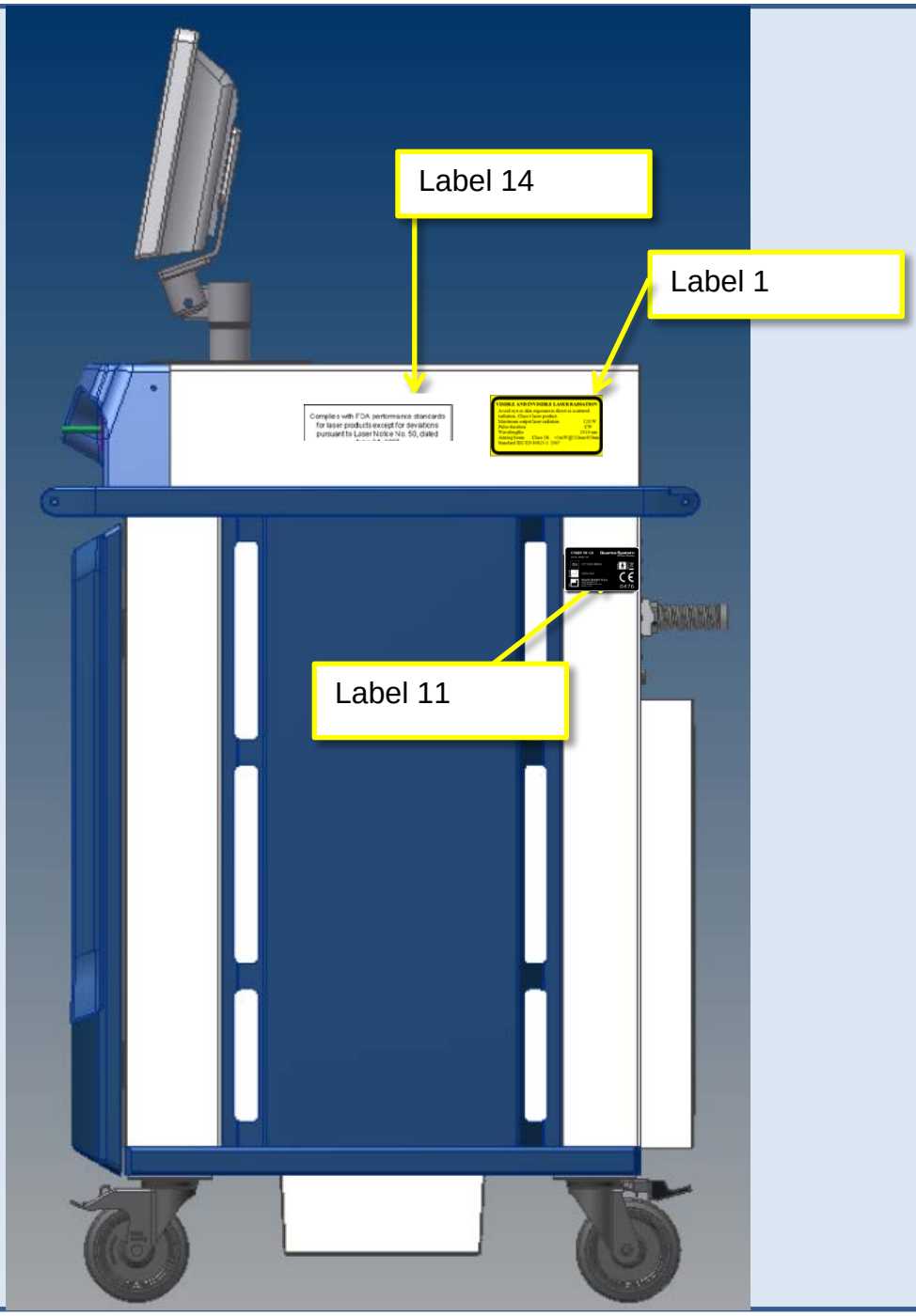
	Label 2
	Label 3
	Label 4
	Label 5
	Label 6
	Label 7

	Label 8
	Label 9
	Label 10
	Label 11 • XX = 120 for Cyber TM 120 (230V AC version) • XX = 150 for Cyber TM 150 (230V AC version) • XX = 180 for Cyber TM 180 • XX = 200 for Cyber TM 200
	Label 11 • XX = 120 for Cyber TM 120 (208V AC version) • XX = 150 for Cyber TM 150 (208V AC version) • XX = 180 for Cyber TM 180 (208V AC version) • XX = 200 for Cyber TM 200 (208V AC version)
	Label 12
	Label 13
Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007	Label 14

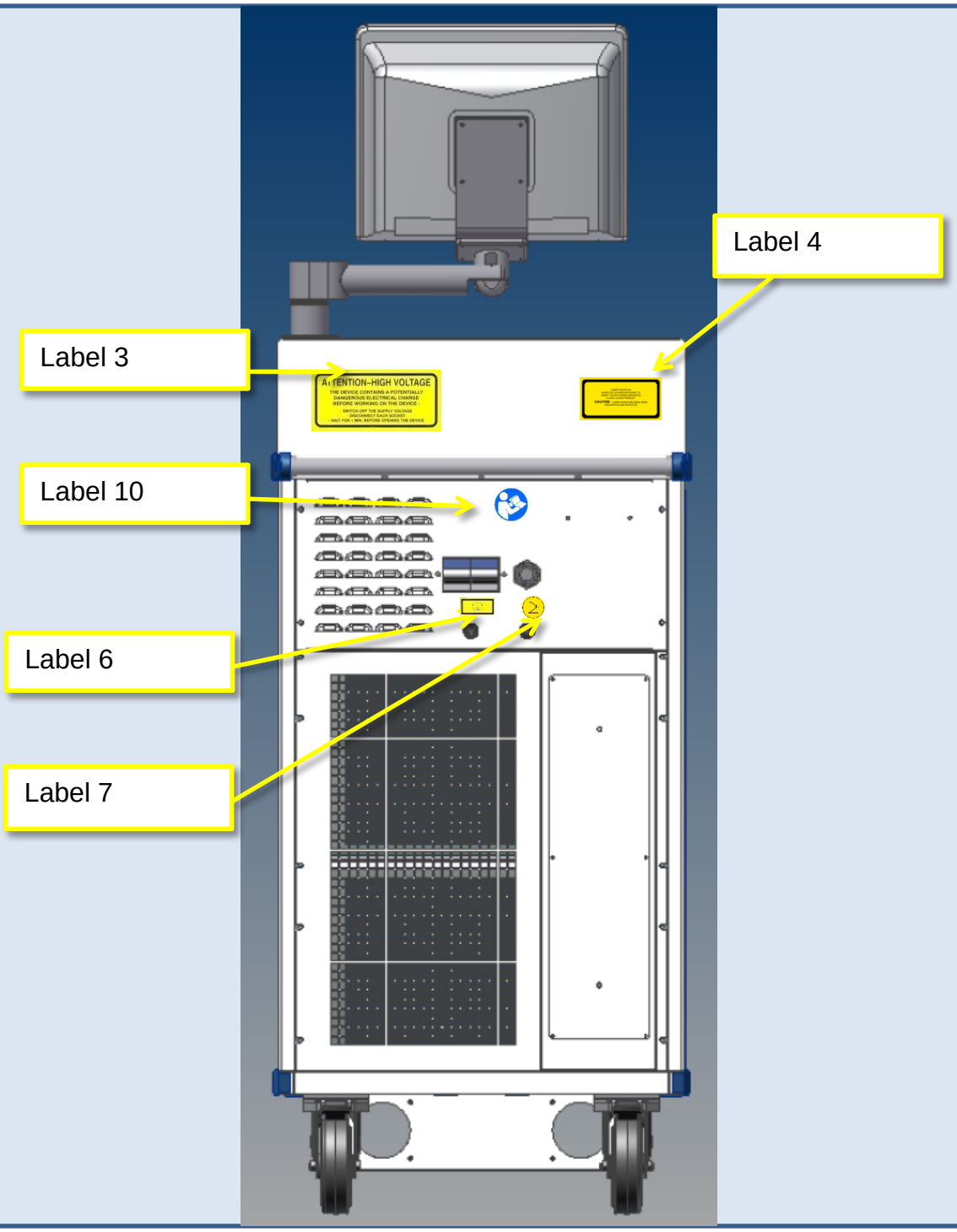
Front View


Label 13
Emission
Ready
Label 2
Label 5
LASER APERTURE
Label 9
STOP
Label 12

Lateral View



Rear View



3 DEVICE DESCRIPTION

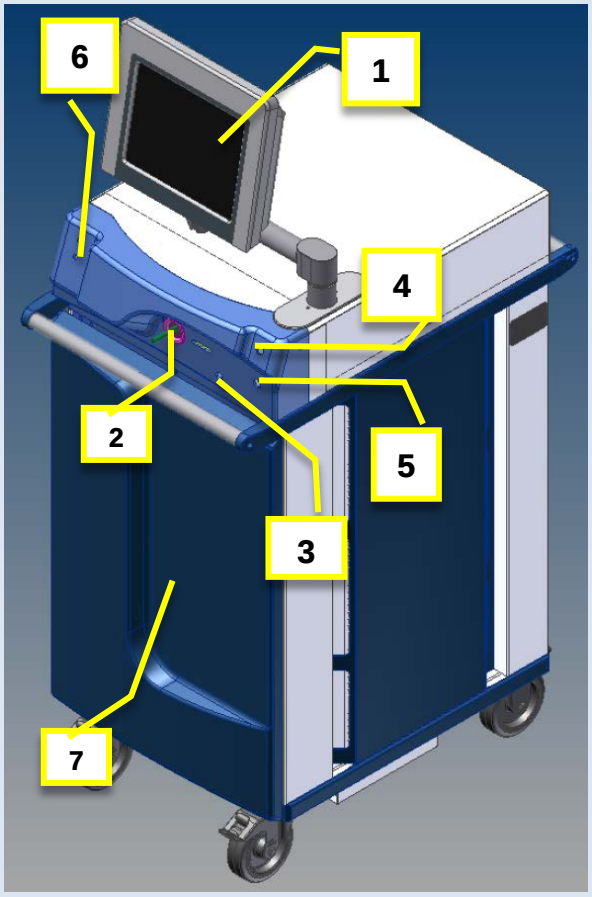
In this chapter a general description of the device and all its parts is given.
With the device are associated optional accessories, such as optical fiber (for a list of optional accessories supplied with the device, see Chapter 9 "Accessories").

3.1 *Introduction*

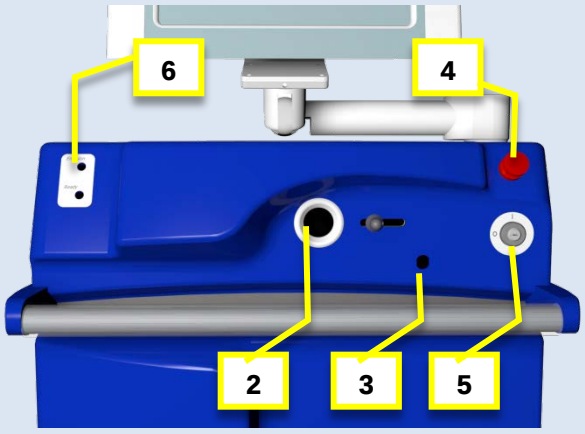
The Cyber Tm laser system is a diode-pumped, solid state 2010nm laser. The laser system delivers visible 2010nm laser radiation.
Different fibers are available for different applications: a side firing fibre with 600 µm core diameter and bare optical fibres with 200, 400, 600, 800 and 1000 µm core diameter. Each fibre has an its own code plug that manages the recognition and the expiration of the fibres themselves.
The laser system also consists of an air-cooled internal mechanism, ensuring safe operating temperatures with no external water connections. Laser energy emission and system status selection is activated through a touch screen feature located in the laser console.

3.2 *General description of the device*

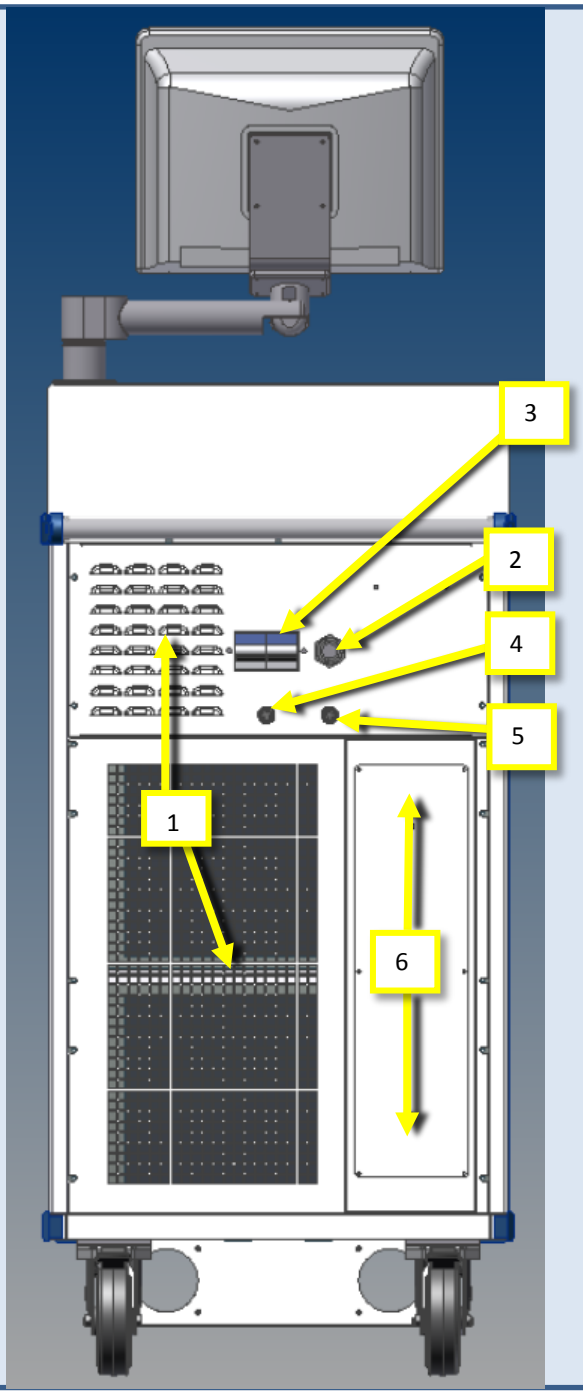
Device frontal view



1. Touch screen Display (control panel)
2. Optical fiber connector
   (WARNING: this is a laser aperture)
3. Code Plug connector
4. Emergency red push button
5. Key switch
6. Led Indicators
7. Frontal panel to access to de Hydraulic circuit loading connector and alarm internal display



Device Back view



1. Fans Area
2. Power supply cord
3. Power/mains switch
4. Interlock connector
5. Footswitch connector
6. Cord storage

3.3 *Cyber Tm Fibre Optic*

This laser system can only be used with Quanta System Optical Fibres from 200 µm to 1000 µm core diameter and side firing fibre with 600 µm core diameter.

The optical fiber is used for the application of the laser radiation to the patient. It is connected to the device through a special connector on the optical mechanism accessible from the frontal panel. The connector has a micro switch that stops the laser if the fiber is missing or not installed properly. Depending on the surgical applications, optical fiber used may be sterile and single-use or re-usable.

Read carefully optical fiber instructions for use and reprocessing (in case of reusable fibers).

Before use check the fiber as in cap 7.4

Any tampering between the optical fiber contact and the device may cause unwanted emission of laser radiation. Potential danger in inserting, folding strongly or not properly secure the optical fibers; if you do not follow the manufacturer recommendations may damage the fiber or the optical beam transmission system and / or cause injury to the patient or user.

The optical fiber consists of a quartz tube that allows the transmission of laser radiation from the laser source to the patient.

Any tampering of the protection of the optical fiber may cause undesired emission of laser radiation

The fibers are enhanced externally near the SMA connector. Twisting, straining, or too exaggerated curves can damage and / or break the optical fiber and the consequent internal irradiation of the metal sheath.

This sheath protects the user and the patient from the potential radiation danger cause of breakage of the fiber.
Before performing any laser emission, make sure that the probe is inserted, pay attention to the pointing direction.

The use of fibers or other connections than those not supplied by the manufacturer, not original, is not permitted.

Code plug

All the optical fibers are supplied with a code plug to be connected to the socket next to the optic fibre connector. The code plug is a plastic connector including a microchip. Once the code plug is connected the information of the fibre is displayed on the screen.
Cyber Tm can work only with the inserted code plug.
It allows Cyber Tm to enter the READY mode.
The control policy of the usage of the optical fiber is as follow:

- Side firing fibres are single use.
- Frontal fibres are available as single use or reusable (after sterilization process)
- Fibres that come pre sterilized will have an extra session.
- After all the sections are expired, the fibre will be considered non-able for use.

Session time control:

- Once the fibre and the codeplug is connected a **session** starts. The session will last **120 minutes** (**standard treatment time**).
- If the fibre is disconnected (or the system switched off) within the **standard treatment time** the session will NOT expire.
- After the session **standard treatment time** ends disconnection of the fibre WILL MAKE the session expire.
- If **the fibre is not** disconnected at the end of the **standard treatment time** the system will allow to work for few extra hours to finish the case.
- Once the session is expired we require to wait **30 min** (sterilization time) from the last connection before start a new session on the same codeplug (if the fiber is changed the system can be used immediately).

Total energy control:
The fibres will allow to deliver 800 kJ of energy per session. The limit is on the sum of the energy delivered in all the sessions.

For example a pre-sterilized fibre with 11 sessions, will expire after delivering 8800 kJ total.
After delivering the maximum energy the fibre will be considered dead.

3.4 *Important prescriptions*

- Remove the Cyber Tm fibre optic from its sterile package using aseptic technique.
- Before starting the surgical procedure, the Cyber Tm fibre optic should be checked for damage.
- Connect fibre hub into the fibre port on the laser system console. Keep the connecting end of the fibre clear of debris or liquids.

- Place the laser in READY mode to activate the aim beam. CAUTION: Do not press the footswitch while checking the aim beam. Place the distal end of the fibre on a non-reflective sterile surface and turn slightly until the aim beam can be visualized. If the aim beam is not seen, the fibre may be defective and should not be used.
- Check for kinks or bright areas along the entire length of the Cyber Tm fibre. Do not use the fibre if it has been damaged.
- Once the Cyber Tm fibre has been checked, return the laser to the STANDBY mode.
- Position the Cyber Tm fibre optic at the targeted treatment site. The tip of the Cyber Tm fibre should be in clear view and extended approximately 1 to 2 cm. beyond the distal end of the endoscope.
- Place the laser in READY mode to enable the footswitch control.
- Laser software automatically corrects for fibre losses such that the power level shown on the system video display indicates the actual amount of power delivered to tissue.
- Treatment times vary based on distance to tissue, power settings, and other factors.
- The efficiency of vaporization will decrease with increasing distance from the tissue and coagulation may result. Do not bend the fibre at sharp angles.
- Avoid contact of fibre tip with tissue. If, during the procedure the tip accumulates debris, turn the laser to the STANDBY mode, remove the Cyber Tm fibre from the cystoscope, and carefully wipe the tip clean with a sterile gauze or towel. Begin at the end of the fibre and wipe along the fibre tip.
- Specific pulse duration depends on the tissue and is left to the surgeon's preference and best medical judgment.
- The lowest possible power settings required to achieve the desired tissue effect should be used for treatment.
- Higher wattages of power may be necessary to achieve the desired tissue effects if fluid cooling is utilized.
- Due to the tip size of the Disposable Optical Fibre Delivery Devices, input power from the laser source must be reduced to achieve equivalent power densities obtained when using bare fibres of different diameters.

Do not re-sterilize and do not reuse single use fibers (e.g. side firing optical fiber) Reusable optical fibers shall be reprocessed according to the prescriptions available in their instructions for use.

4 System Installation

The device installation requires that safety precautions are followed, the power requirements and the environmental conditions in the working area.

The installation of the laser device must be performed by qualified technical personnel authorized by the manufacturer. This person should also carry out tests on the operation of the device after installation in the designated working area.

Warning:
Do not start using the laser device without reading this manual. The warranty does not cover damage that occurred prior to installation.

4.1 *Transportation*

The laser system has a weight of 210Kg. To transport the laser must disconnect fittings, fiber, power cord, plug the pedal and remote locking. Finally, the laser and the accessories should be stored in slots inside the packaging.

4.2 *Packaging*

The laser system is normally shipped in a specific carton on wood pallet. Upon the container arrival it will be a client reasonability to be reviewed and to do pre-positioned by the responsible technician for installation near the working area.

4.3 *Inspection*

It is important that the received material is inspected immediately upon arrival on the following terms:

- Administrative check:
  Number of packages
  Sizes and weights

- Technical check:
  Packaging condition

These checks must be made visually, with the greatest possible care and in the presence of the carrier.

4.4 *Labeling check*

Verifying the integrity and readability of the security labels placed on the device is responsibility of the user. If labels are damaged, they must be replaced immediately comply with the labeling shown in the label plan (Chapter 2.13).

4.5 *Installation procedure*

The installation procedure must be performed each time the device is installed for the first time or after being transported by means of cars, elevators, trucks, air cargo, etc.

During installation the device must be checked for proper operation and possible malfunctions after transportation of the laser device must be corrected.

The installation procedure includes also a training course from the distributor to the user concerning the use of the medical device.

The first turn on procedure typically takes several hours, during this time the access to the installation site is forbidden.

The case is normally shipped to the distributor.

It is extremely important that the packed materials be checked immediately upon their arrival, if possible, in the presence of the shipper's delivery employee, as follows:

- Open the packaging and put the laser device in a proper site for a general check.
- Execute the following operations for the general check:
  - Check the labels of the device
  - Remove the label "Caution no water inside"
  - Connect the remote door interlock
  - Connect the footswitch
  - Fill the system cooling liquid **with bi-distilled or deionized water only**
  - Connect the laser device to the power supply
  - Check the laser device, calibration and standard operation
- After the general check:
  - Remove the optical fiber
  - Remove the footswitch
  - Remove the interlock
  - Remove the key

Note: Quanta System advises wrapping the device with a large quantity of protective plastics.

Note: *The shipment of device to the final destination of the customer is under the responsibility of the distributor. Quanta System is not responsible for possible damage caused during this phase.*

WARNING:

Do not start any action with the laser device before the official personnel have performed the installation procedure. The warranty is not comprehensive of any damage to the laser device before the installation.

4.6 *Interlock and footswitch connection*

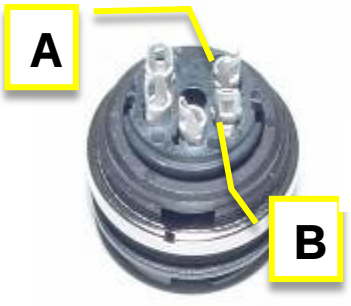
According to IEC EN 60825-1: 2007 all laser devices must be equipped with a remote block connector connected to the access door room to block the emission of the laser when it is open.

A suitable switch shall be prepared by the client on the access door room where the device will be installed : when the door is closed the switch will give consent through a closed contact; in the case of multiple access doors each have the its own switch, whose contacts are connected in series.

The remote interlock cable must be connected to a lamp mounted near the door. The lamp should light when the laser is activated and the door of the working area is closed. The lamp connected to the remote interlock cable is shown in the picture
The contact or the series of contacts will be led by a suitable cable near the laser, where the specific connector will be connected during installation. Internal pins (1 and 2) as shown in the picture below:

According to IEC/EN 60825-1:2007 all laser systems must be equipped with a remote interlock connector linked to the access door of the treatment room. It is necessary to avoid laser emission towards unprotected bystanders when door is open during use. A suitable switch have to be set up by the end user on access door of the treatment room the device will be installed. When the door is closed the switch will enable the laser emission with a dedicated electrical signal. In case of multiple access doors, each one has to have its dedicated switch, all of them sequentially connected.

The connection or the sequence of connection has to be wired with a suitable cable with to the interlock connector during product installation.
The interlock connector is wired on the laser side in the following way:

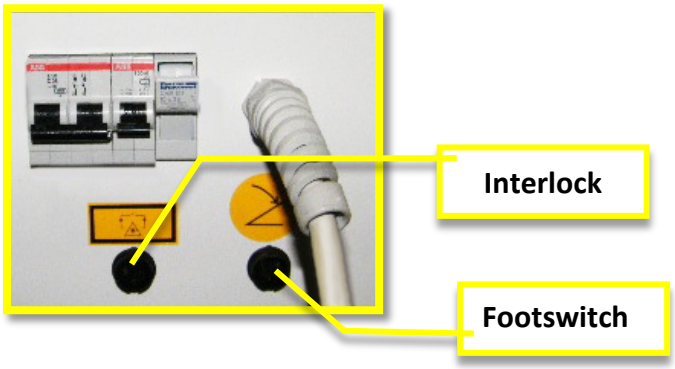


Pins A and B of the external micro switch have to be wired with the door cable

4.7 *Footswitch connection*

The footswitch is used to start the laser emission.
To connect it, put the footswitch connector to the device socket.

Insert the footswitch and interlock connectors in the proper connectors as shown in figure.



4.8 *Optical fiber connection*

The fiber is connected to the device through the cable connector on the front. The device accepts only Quanta System fibers with SMA905 connector and with the code plug element. The fiber connector has an additional ring which facilitates the clamping of the fiber to the connector on the device and enables automatic detection of the presence or absence of the fiber. If the fiber is not connected to the device is reporting an error when the device is switched on.

Warning:
It's very important to tighten to the device by hand the fiber nut until the end.

4.9 *Optical fiber check*

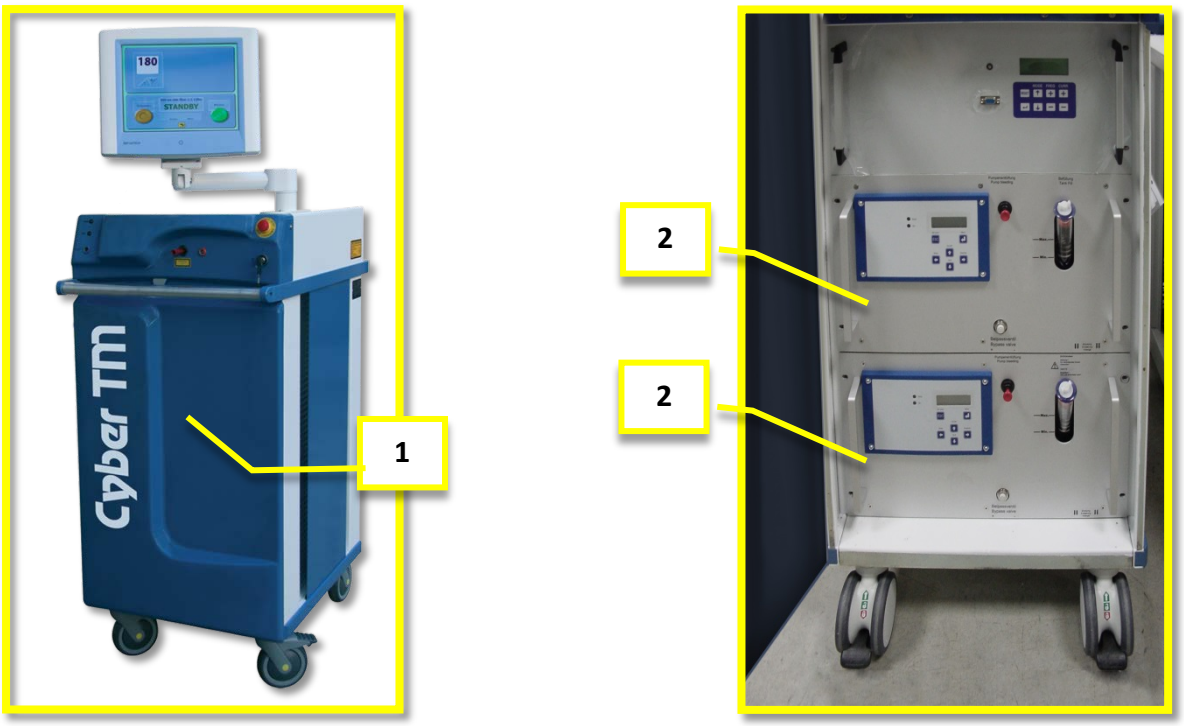
Please see Cap 7.4

4.10 *Hydraulic system filling*

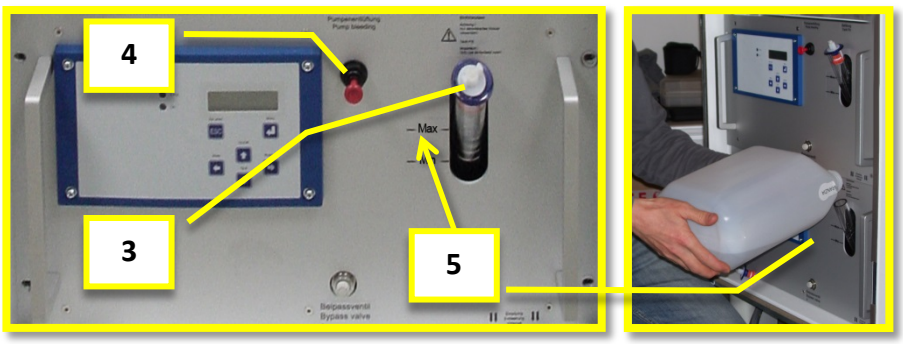
WARNING: Use only bi-distilled or deionized water.

The procedure for filling the hydraulic circuit is the following:

- Turn the circuit breaker off and unplug the laser
- Open the frontal panel (1) to access to the chiller elements (2)



- Remove the reservoir cap in the front of the Chiller (3).
- Open the pump bleeding plug (4)
- Pour water into the filler reservoir until its level is MAX (5).
- Close the pump bleeding plug (4)
- Plug system in, turn on circuit breaker, and turn the laser key switch to on.
- Re-Fill the reservoir to maximum level if the level decreases.
- Restart the system if flow alarm appears.
- Replace cap wen the system work normally.



Call Quanta System SpA or your local distributor service engineer if you have any issues.

5 INSTRUCTION FOR USE

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

This section describes the instructions for use of the device Cyber Tm. They include:

- Startup procedure
- Operating instruction
- Description of possible Alarm messages
- Shut down procedure and protection from unauthorized use

5.1 *Startup procedure*

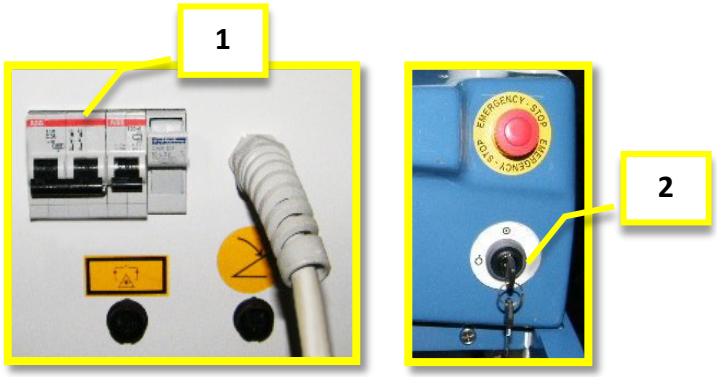
Before proceeding with the startup procedure of the device, verify the correct connection of the following accessories:

- Power supply cable
- Interlock connector
- Key switch
- Footswitch
- Optical fiber

Also make sure the emergency red button is not pushed.

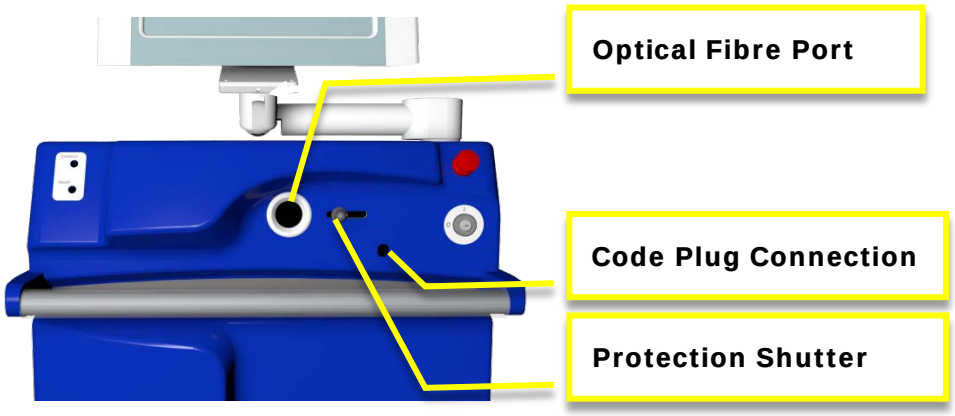
To turn on the device:

- Switch on the circuit breaker on the rear panel (1).
- Insert the key switch (2) and turn right, towards the ⊙ symbol marked on the key switch. If the laser fails to start check the emergency push button is not pressed. If the emergency push button is depressed twist to the right to release.
- Turn the key to start the laser



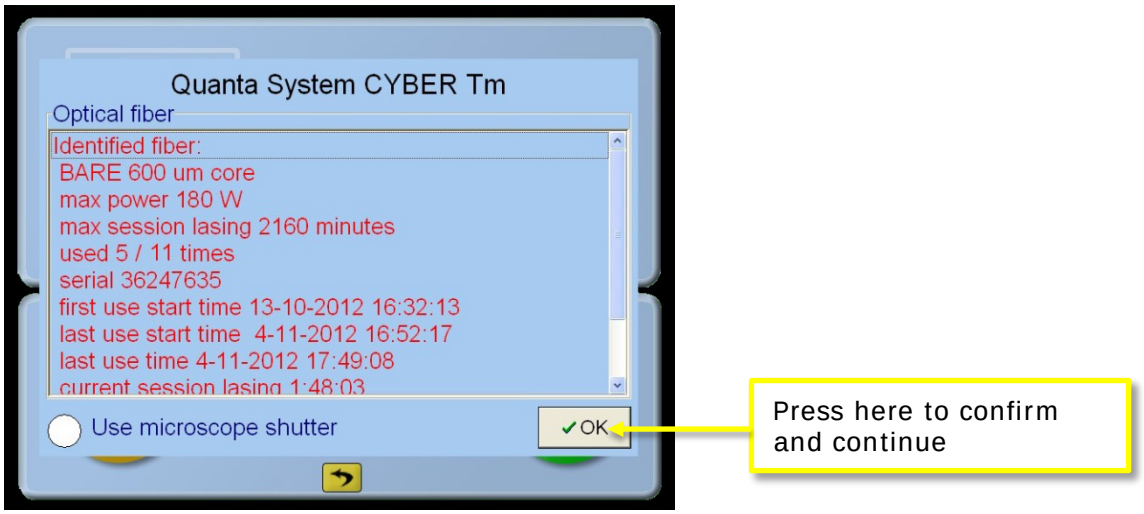
5.2 *Optical Fibre Connection*

The optical fibre must be connected through the Fibre Port on the front panel of the LASER. If the optical Fibre is not connected to the laser a warning is displayed on screen. This prevents laser energy being released if the footswitch is depressed when a fibre is not connected.



To connect the fibre, first open the protection shutter.

Then insert the fibre taking care not to touch the end of the connector with your fingers or splash with water. Now screw the fibre onto the internal connector by turning the fibre connector clockwise until finger tight.



The expansion nut of the optical fibre must be firmly tightened.

.

Once the fibre is connected also the code plug must be connected. If the code plug is not connected to the laser a warning is displayed on the screen the device will not enter the READY mode.
After some minutes in which both the fibre and the code plug are connected the system will increment the number of fibre re-use.

5.3 *The Touch Screen PC panel*

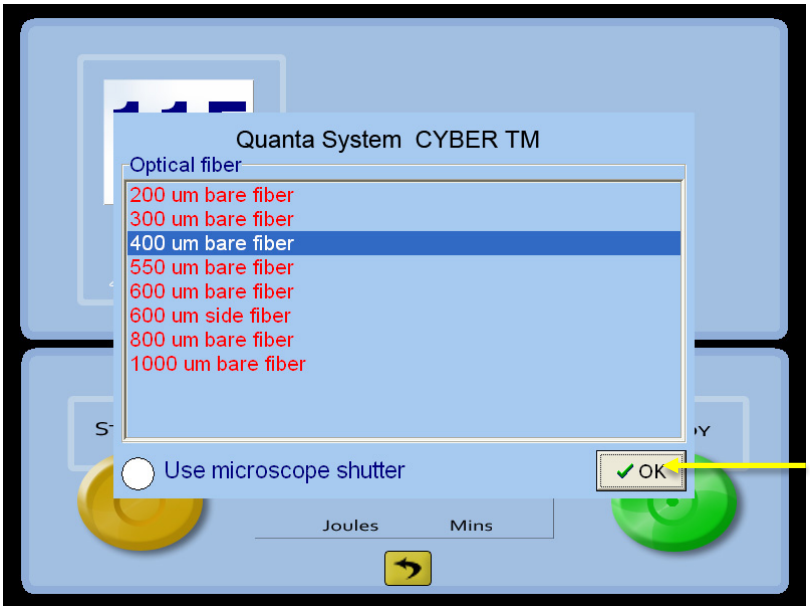
The laser starts up and checks safety and calibration. As the laser completes each check, information is displayed in the status field and warnings, if any, are displayed in the warnings field. See example below.

Sub Systems under test are displayed here

There are three different checks during Start Up:

- **STARTING 1**
- **STARTING 2**
- **Warm up**

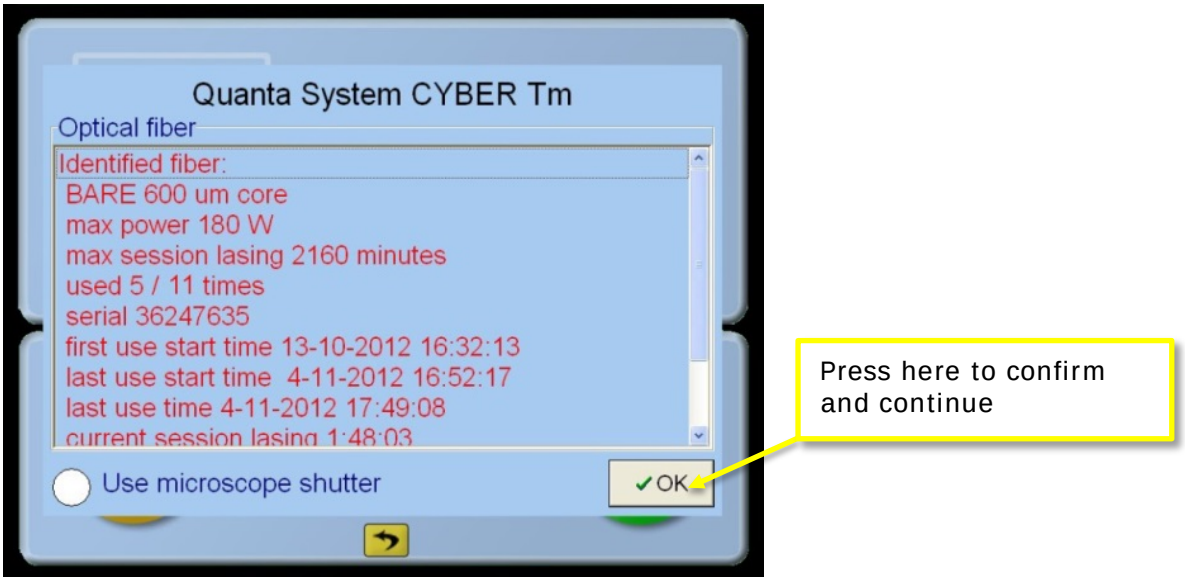
Once the start up is complete the main control screen appears:
If there is not fiber attached the fibres list window appears.
It can be closed pressing the "OK" button.



Press here to continue

The Main Screen of the Cyber Tm will appears after the Starting and Warm-up time.

When a code plug and the fiber are connected the following mask will appear:

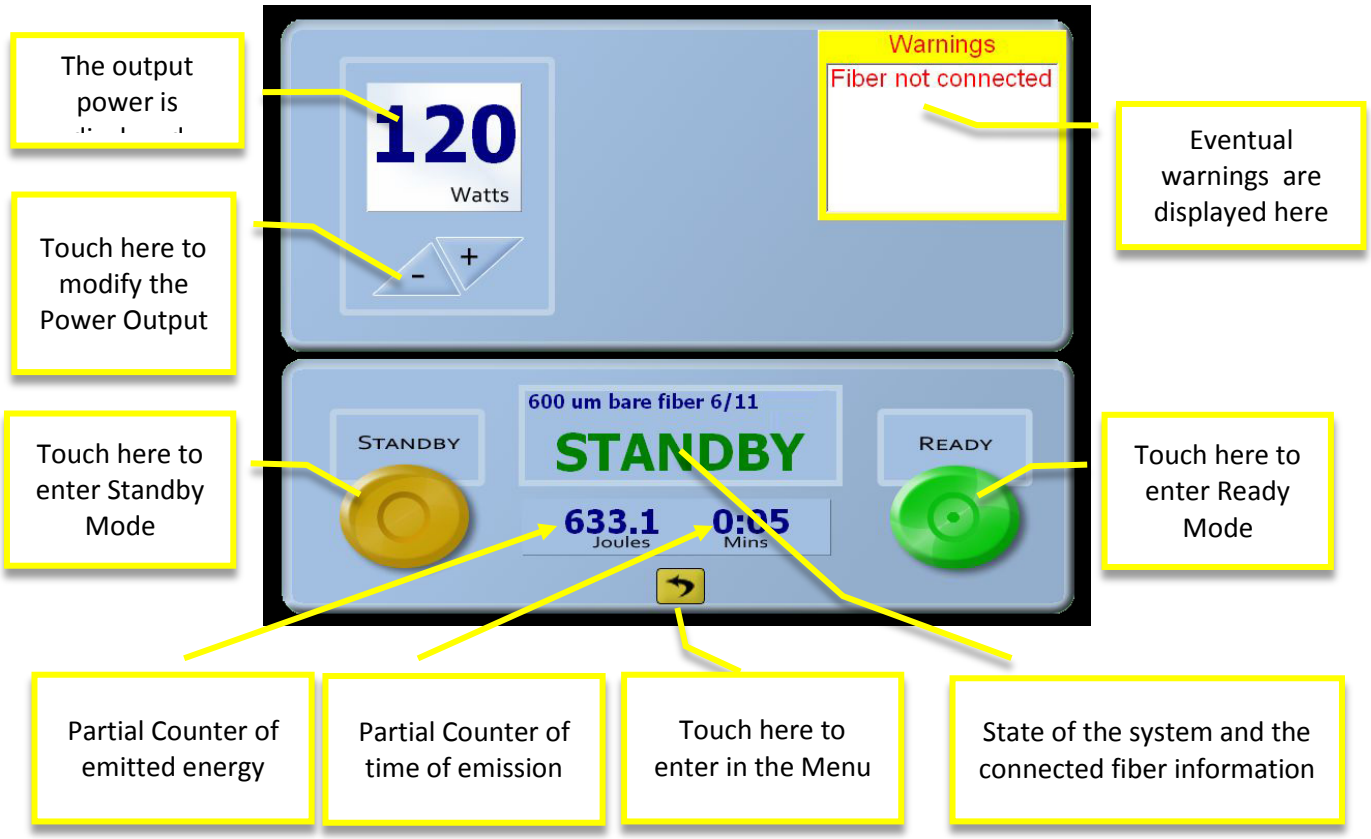


In this mask all the details related to the fibre are shown:

- type of fibre (side firing or bare) and core dimensions (200, 400 or 600 µm);
- max power (200W for 600and 400 µm core fibres, 40W for 200 µm core fibres);
- max session lasing time
- number of re-use;
- first use start time;
- last use start time;
- last use time;
- current session lasing time;
- total use time.

5.3.1 Main Screen

After the Starting and Warm-Up time the Main Screen will appears:



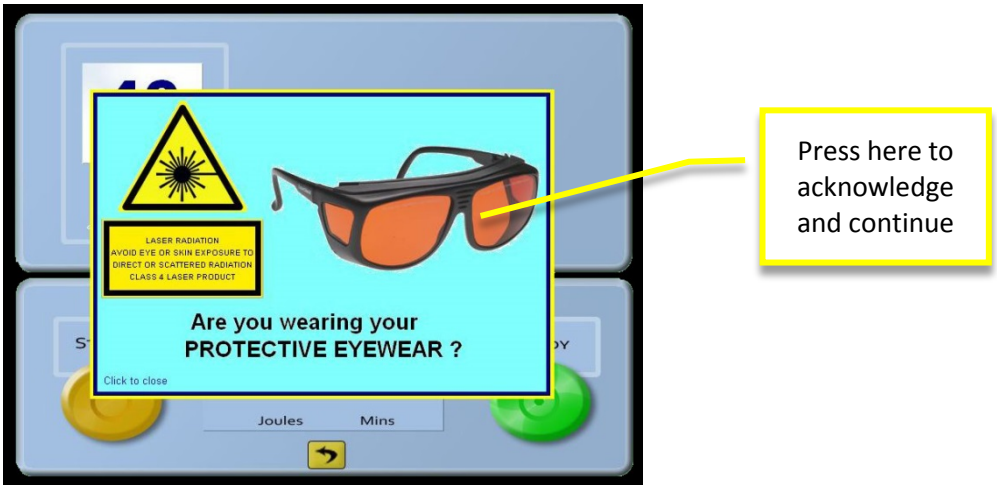
The possible states of the system are:

- **STANDBY**
- **READY**
- **Power Check**
- **EMITTING**
- **ALARM**

Ready and Standby

After choosing the power and emission setting that are suitable for the surgery being undertaken and the settings have been agreed by the surgeon. The laser operator can start the laser emission as follows:

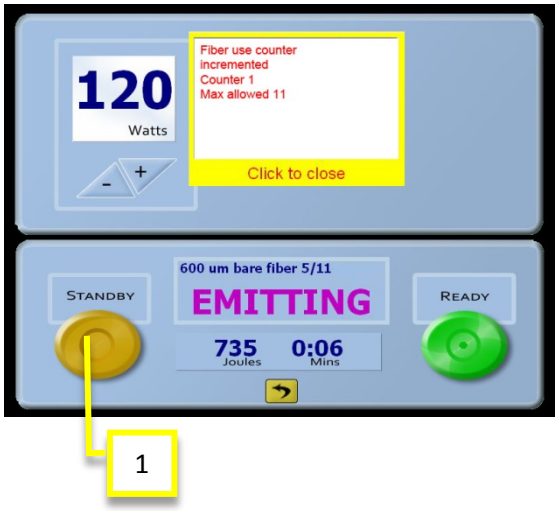
Press the Ready button to enter the READY MODE, the following screen will appear, asking you to confirm everyone is wearing suitable eyewear:



When the laser is in Standby Mode the Yellow light will flash. When the laser is in Ready Mode the Yellow light is on continuously.

When the footswitch is pressed and the laser is in Ready Mode, in addition to the Yellow light remaining on, the Green light is also on and the laser emits an audible

- Standby mode: green blinking
- Ready mode: green
- Emission mode: yellow blinking



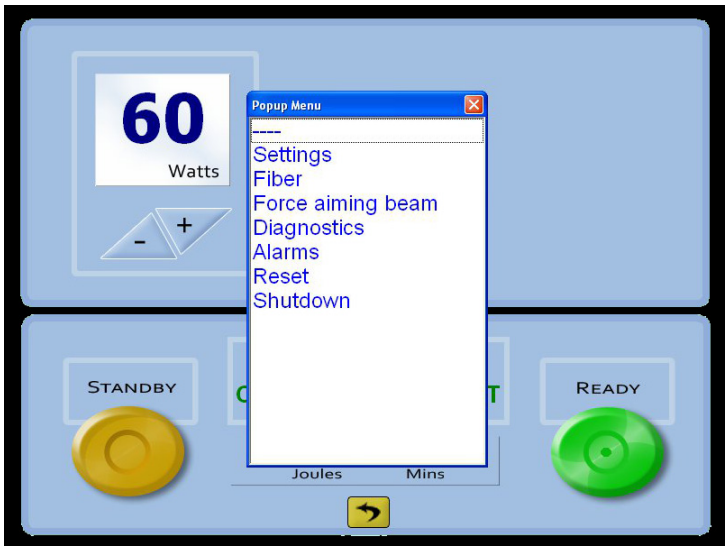
To return to the STANDBY mode press the STANDBY button (1).

When the system is in READY mode and the footswitch is pressed the following screen will appear:

The system increases the Fiber use counter.

5.3.2 MENU

When the Menu button is pressed the following screen is displayed:



In the pop-up Menu you can select the following options:

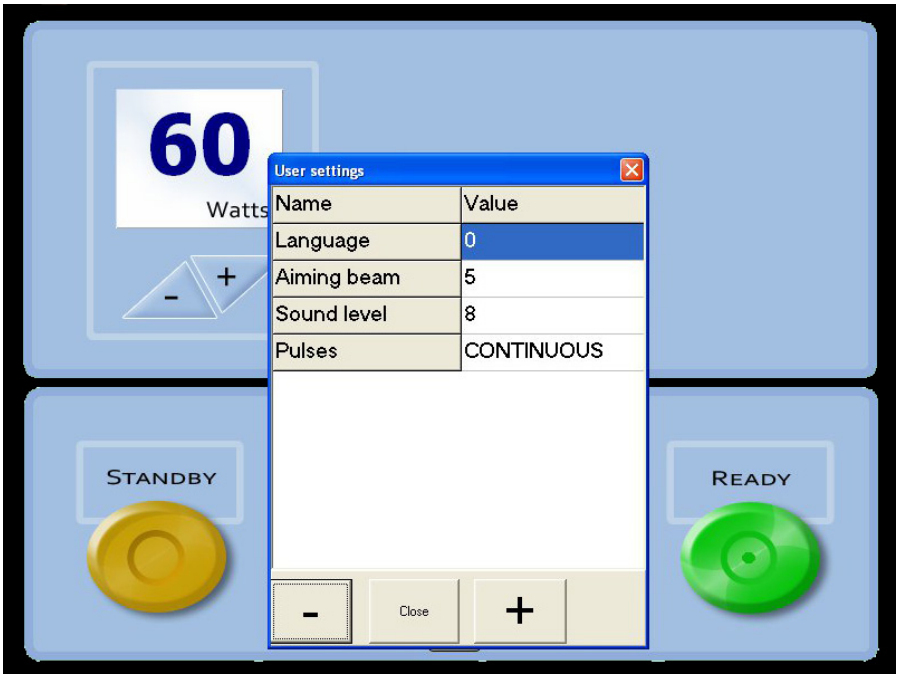
- **Setting Menu**
  Press here to access to Setting Menu
- **Fibre**
  Press here to see the Fiber Info
- **Force aiming beam**
  Press here to force the aiming beam emission also in the standby mode. Use this option to check the fiber integrity
- **Diagnostic**
  Press here to view the diagnostics windows (advanced user)
- **Alarms**
  Press here to view the alarms
- **Reset**
  Press here to restart the system
- **Shutdown**
  Press here to switch off the system

Protections against non-authorised use:

When the laser system is not in use and to protected against non-authorised use. The laser must be shut down and the laser key removed.

5.3.3 SETTINGS

When the Menu Setting is pressed the following screen is displayed:



In the pop-up Menu you can select the following options:

- **Language**
  Press here and then use the "-" and "+" buttons to change the Language
- **Aiming Beam**
  Press here and then use the "-" and "+" buttons to change the intensity of the aiming beam.
- **Sound Level**
  Press here and then use the "-" and "+" buttons to change the intensity of the sound
- **Diagnostic**
  Press here and then use the "-" and "+" buttons to change the intensity of the
- **Pulses**
  See Cap 5.3.4

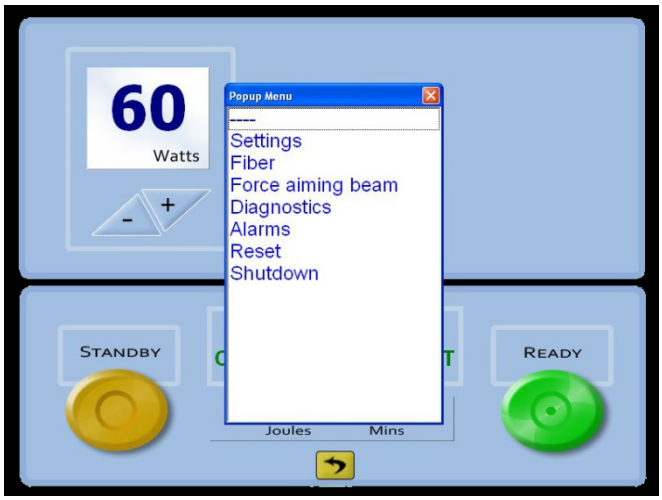
5.3.4 Pulsed modes

Cyber Tm implements, in addition to the standard CW mode, pulsed operation modes. In pulsed modes the current in the diodes is modulated to obtain flat top pulses.

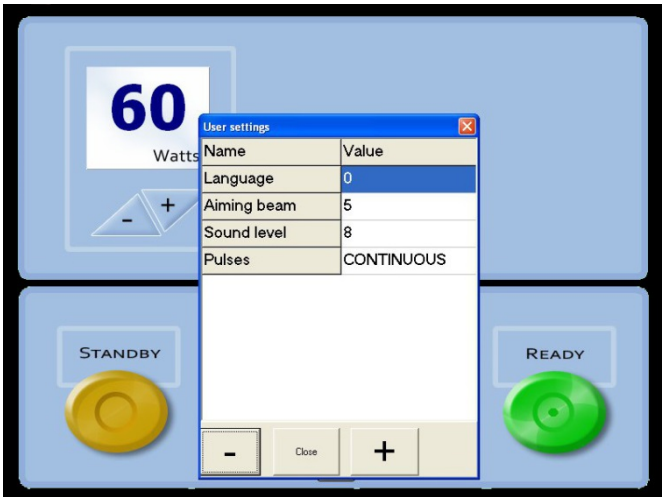
The user can select 6 pre-set pulse parameters:

Pulse mode	T_{on}	T_{off}	Repetition rate	Duty cycle	Max Average power
1	25 ms	25 ms	20 Hz	50%	75 W
2	50 ms	50 ms	10 Hz	50%	75 W
3	75 ms	25 ms	10 Hz	75%	112 W
4	25 ms	75 ms	10 Hz	25%	37 W
5	25 ms	50 ms	12.5 Hz	33%	50 W
6	50 ms	25 ms	12.5 Hz	66%	100 W

To activate one of the pulsed mode go to the MENU:

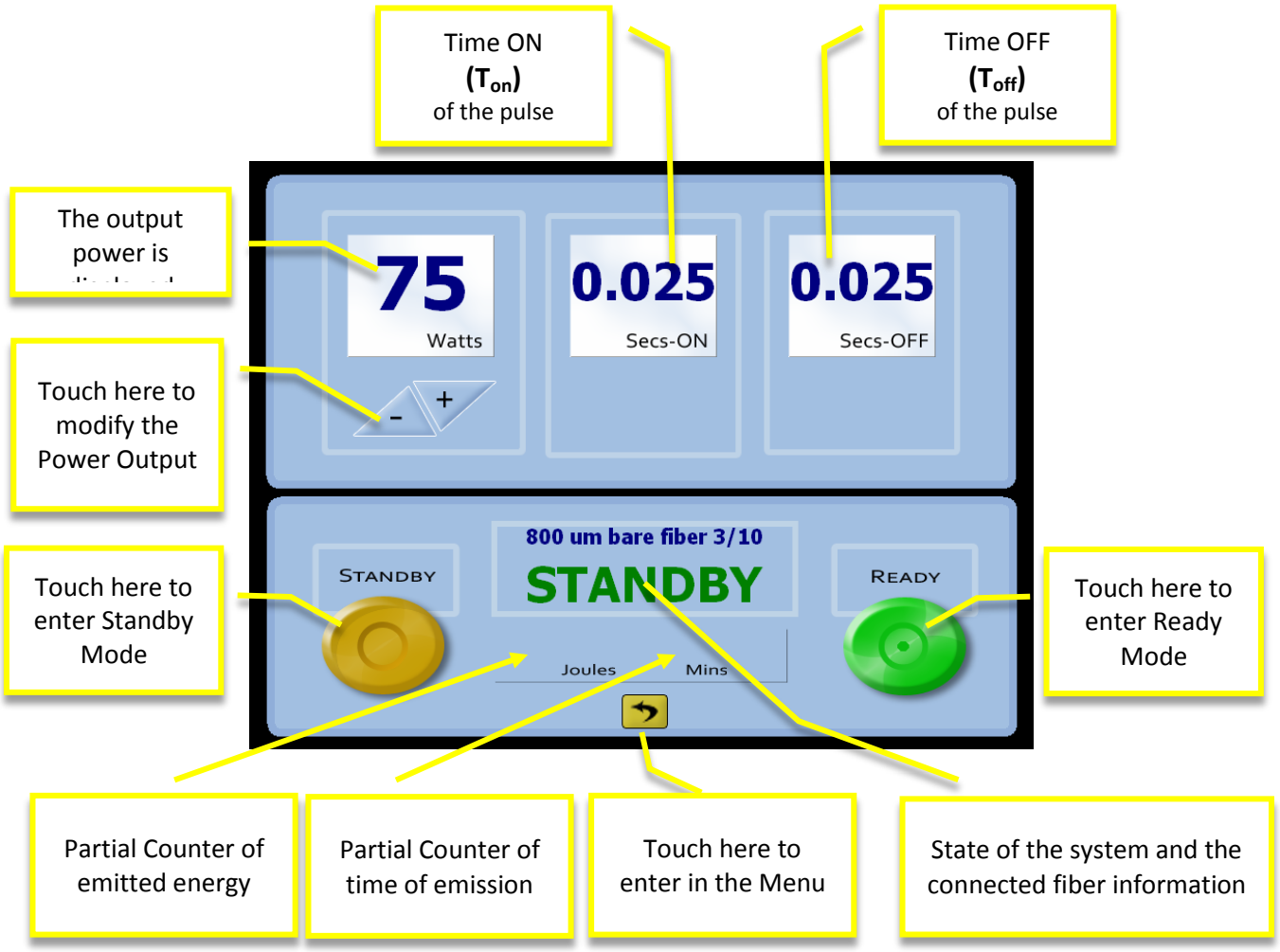


Select the “Settings” item to access the user settings:



Select the “Pulses” item and change the pulse mode with the “+” and “-“ buttons.

When the windows is closed a waiting message will appear to let the system safely switch between the modes.
The pulsed mode can be changed at any time when the system is in STANDBY status.
In pulsed mode the display will show the average power, the time on (T_{on}) and the time off (T_{off}) of the pulse train.



6 Physician Information

6.1 *Introduction*

This section provides information on the use of the Cyber Tm Laser System in clinical applications. Information is provided by specialty and includes procedural recommendations, along with specific indications and contraindications. The information provided in this section is not intended to be all-inclusive and is not intended to replace surgeon training or experience.

Surgeons and staff who have been appropriately trained and who are thoroughly familiar with the instructions and safety precautions provided in this manual should only use the laser system. A review of the published literature is strongly encouraged and recommended.

This manual is intended for operators of the Cyber Tm Laser System. The Cyber Tm Laser is available in several different configurations, therefore, not all specialties or procedures presented in this section may be applicable to your particular configuration. Quanta System Cyber Tm Laser System is designed as a multi-specialty system.

6.2 *Indications for Use*

The Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including:
Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

Please read Section *6.3.1 - Mechanism of Thulium Laser interaction with tissue.*
For each treatment is given the reference to the section(s) with the recommended parameters:
(A) *Sec. 6.3.2 Treatment parameters and instructions for Endoscopic Procedures.*
(B) *Sec. 6.3.3 Treatment parameters and instructions for Open Surgery & Laparoscopic Procedures.*

Urology:
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures – (A)
- Bladder Neck Incisions (BNI) – (A)
- Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors – (A)
- Ablation of Benign Prostatic Hypertrophy (BHP) – (A)
- Transurethral incision of the prostate (TUIP) – (A)
- Laser Resection of the Prostrate – (A)
- Laser Enucleation of the Prostate – (A)
- Laser Ablation of the Prostate – (A)
- Condylomas– (A) & (B)
- Lesions of external genitalia – (B)

Note: The Cyber Tm 180 and Cyber Tm 200 are only approved for the treatment of BPH when used at power levels greater than 150W.

Gastroenterology:

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy – (A) & (B)
- Polyps– (A) & (B)
- Biopsy– (A) & (B)
- Gall Bladder calculi - (A)
- Biliary/Bile duct calculi see -(A)
- Ulcers-(A) & (B)
- Gastric ulcers-(A)
- Duodenal ulcers-(A) & (B)
- Non Bleeding Ulcers-(A) & (B)
- Pancreatitas-(A) & (B)
- Hemorrhoids- (B)
- Cholecystectomy-(A) & (B)
- Benign and Malignant Neoplasm - (A) & (B)
- Angiodysplasia - (A)
- Colorectal cancer- (A) & (B)
- Telangiectasias - (A) & (B)
- Telangiectasias of the Osler-Weber-Renu disease - (A) & (B)
- Vascular Malformation -(A) & (B)
- Gastritis - (A) & (B)
- Esophagitis - (A) & (B)
- Esophageal ulcers - (A) & (B)
- Varices - (A) & (B)
- Colitis - (A) & (B)
- Mallory-Weiss tear - (A) & (B)
- Gastric Erosions - (A) & (B)

Gynecology:

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis):

- Intra-uterine treatment of submucous fibroids - (A)
- benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation - (A) & (B)
- Soft tissue excision procedures such as excisional conization of the cervix - (A)

ENT:

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

- Endonasal/sinus Surgery - (B)
- Partial turbinectomy - (B)
- Polypectomy - (B)
- Dacryocystorhinostomy – (A) & (B)
- Frontal Sinusotomy - (B)
- Ethmoidectomy - (B)
- Maxillary antrostomy - (B)
- Functional endoscopic sinus surgery – (A) & (B)
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal - (B)
- Tonsillectomy - (B)
- Adenoidectomy - (B)

Dermatology and Plastic Surgery:

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

- Basal Cell Carcinomas- (B)
- Lesion of skin and subcutaneous tissue- (B)
- Skin tags- (B)
- Plantar warts- Sec. 6.3.3

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy - (A) & (B)
- Lysis of adhesion - (A) & (B)
- Appendectomy - (A) & (B)
- Biopsy - (A) & (B)
- Skin incision - (B)
- Tissue dissection - (A) & (B)
- Excision of external tumors and lesions - (B)
- Complete or partial resection of internal organs, tumors and lesions - (A) & (B)
- Mastectomy - (B)
- Hepatectomy - (A) & (B)
- Pancreatectomy - (A) & (B)
- Splenectomy - (A) & (B)
- Thyroidectomy - (A) & (B)
- Parathyroidectomy - (A) & (B)
- Herniorrhaphy - (A) & (B)
- Tonsillectomy - (B)
- Lymphadenectomy - (A) & (B)
- Partial Nephrectomy - (B)
- Pilonidal Cystectomy - (A) & (B)
- Resection of lipoma - (A) & (B)
- Debridement of Decubitus Ulcer- (B)
- Hemorrhoids - (B)
- Debridement of Statis Ulcer - (A) & (B)

Thoracic and Pulmonary

Open and endloscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

- Laryngeal lesions - (B)
- Airway obstructions including carcinoma - (B)
- Polyps and granuloma - (B)
- Palliation of obstructing carcinoma of the tracheobroncial tree - (B)

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue):

- Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including
- Percutaneous Laser Disc Decompression/Discectomy – (A) & (B)
- Foraminoplasty - (A) & (B)
- Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery -(A) & (B)

6.3 *Treatment parameters and instructions*

Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories are surgical devices that should be used only by physicians or surgeons who have been trained in laser surgery through courses, mentorships, and under the guidance of other physicians or surgeons knowledgeable in laser use. No claim is made that the laser will cure any medical condition.
All users and support staff must have thorough knowledge of its operation and its effects. Users should familiarize themselves with this operator's manual and with this device in a non-clinical setting before using it for the treatment of patients in a clinical situation.
BEFORE operating the laser system, surgeons and all staff operating the laser should carefully read this User Manual. Please use major attention to the General Warning of Section 2 (Laser Safety) and Section 6 (Physician Information).
The Cyber TM is a thulium laser system that emits invisible infrared beam at a wavelength of 2010nm.
This laser beam (2010nm) is strongly absorbed by water (chromophore) which is ubiquitous in all tissues, the speed of cutting and vaporizing will remain relatively constant regardless of tissue vascularization.

The Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

6.3.1 Mechanism of Thulium Laser interaction with tissue.

The mechanisms behind Thulium laser interaction with tissues at a microscopic level help explain the basis of the surgical technique.
Vaporization/Ablation of tissue water or Coagulation (denaturation) of tissue protein occurs depending on the temperature reached locally in various parts of the targeted area.
Ablation/Vaporization effects occur when tissue is heated to 100°C.
Coagulation effects occur when tissue is heated from 65° to 99°C.
The structure of soft tissue is basically composed of water, blood vessels, and collagen matrix. The collagen matrix acts as the mechanical stabilizer of tissue.

1. The 2010nm (thulium laser) laser beam is absorbed strongly within the very superficial layer of tissue by virtue of the fact that blood vessels and water (chromophore) contained therein serve as primary absorbers.
2. Heat generated by absorption of the laser energy leads to formation of vapor (vapor bubbles in endoscopic procedures) inside the targeted tissue wherever the temperature of water reaches the boiling/vaporization point (Ablation/Vaporization effect).
3. Continued application of laser energy leads to continued boiling/vaporization of tissue water.
4. When vapor pressure exceeds the ultimate tensile strength of the matrix the structure of the targeted tissue disintegrates.
5. Continued exposure of the targeted area to laser energy leads to progressive Ablation/Vaporization of the newly exposed deeper layers of tissue, accompanied by release of more vapor and tissue fragments.

It is important to understand that the very process of ablation/vaporization carries away heat from the targeted tissue and, thus, prevents deep coagulation. Therefore, relatively little heat remains inside the tissue immediately after cessation of laser application.

If the purpose is the Coagulation of vessels the surgeons can be easily accomplished by increasing the working distance or by decreasing the laser power output as both techniques reduce the power density on the tissue and cause tissue coagulation without tissue ablation/vaporization (tissue is heated less than 100°C).

Quanta System recommends that the surgeon consider titrating the laser power according to the tissue response.

6.3.2 Treatment parameters and instructions for Endoscopic Procedures.

Before firing the laser, the laser aiming beam and fiber tip must be clearly visible through the endoscope and the aiming beam is directed towards the targeted tissue.
Illuminate the tissue you wish to treat with the aiming beam. Never fire the laser unless you can see the aiming beam on the targeted tissue.
DO NOT START LASING AT MAXIMUM POWER. Begin the procedure at a lower power (80W) and titrate the power upwards until desired tissue vaporization/ablation/coagulation effect is achieved.
Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated.
In endoscopic surgery it is possible to use the maximum power output (200W). Over 120W the vaporization effect is prevalent Vs Ablation/Cutting effect.
It is possible to use the fiber in contact with the tissue.
Increasing the distance between the fiber and the tissue, the Ablation/vaporization effect will be decreased.
Increasing the distance between the fiber and the tissue, the Coagulation effect will be increased.

Using the laser in water, as the surgical irrigation solution, it is recommended that you start ablation or vaporization at 80W and adjust the power according to the ablation/vaporization effect observed.
If bleedings are found coagulate the tissue surrounding the bleeders; the surgeon may choose to defocus the laser energy by increasing the distance between tissue and fiber or by decreasing the laser power to 40W.
If tissue adheres to the tip of the fiber it is important to remove the fiber from the endoscope and remove the tissue.

***Warning for BPH treatment**: Use caution when treating tissue at the bladder neck to avoid incidental injury to the bladder wall and/or ureteral orifices.*
As in any endoscopic prostate procedure that removes tissue, (including TURP, HoLEP, HoLAP, or PVP), the possibility of capsular perforation does exist.
To minimize the possibility of perforation of the surgical capsule, it is important to recognize the end point of the procedure. It is important to keep the fiber moving, and not direct the laser energy at a fixed site for an extended period of time.

Damage to Endoscope
The Cyber TM can cause significant damage to a endoscope. Damage will occur if the laser is activated while the laser fiber is aimed towards or if the laser is activated while the aiming beam directed towards the inside of the endoscope.

Damage to the endoscope's outer sheath may cause rough or sharp spots on the sheath which may be traumatic to tissue. Damage to the scope's inner sheath can create sharp points or ridges that may damage the fiber and result in premature fiber degradation or failure.

To avoid damage to the endoscope be sure the blue shell of the fiber is visible at all times.

6.3.3 Treatment parameters and instructions for Open Surgery & Laparoscopic Procedures.

Before firing the laser, the laser aiming beam and fiber tip must be clearly visible and directed towards the targeted tissue.
Illuminate the tissue you wish to treat with the aiming beam. Never fire the laser unless you can see the aiming beam on the targeted tissue. It is recommendable to use a surgical handpiece to manipulate the fiber.

DO NOT START LASING AT MAXIMUM POWER. Begin the procedure at a lower power (5-10W) and titrate the power upwards until desired tissue vaporization/ablation/coagulation effect is achieved.
Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated.
Using the laser in open surgery or in laparoscopic procedures (with the fiber output non submerged in water solution), it is recommended that you start ablation or vaporization at 5-10W and adjust the power according to the ablation/vaporization effect observed. In open surgery it is recommendable to use max 40W of laser power output.
It is recommendable to use the fiber in non-contact with the tissue (distance from 1mm).
Increasing the distance between the fiber and the tissue, the Ablation/vaporization effect will be decreased.
Increasing the distance between the fiber and the tissue, the Coagulation effect will be increased.
If bleedings are found coagulate the tissue surrounding the bleeders; the surgeon may choose to defocus the laser energy by increasing the distance between tissue and fiber or by decreasing the laser power to 5W.
If tissue adheres to the tip of the fiber it is important to remove it.

The ablation in open surgery could cause a formation of smoke, as in the similar surgical procedure with electro-ablative surgical tools, the surgeon have to evaluate the use of smoke evacuator system (see cap2.9).

6.4 *Training*

Standards of training for surgeons have been established by various Royal Colleges and University Hospitals. These standards include the following;

- Review of the following information.
- Published literature.
- General laser physics, biology and treatment techniques for each specific disease entity.
- Treatment techniques for other surgical modalities in several specialties.
- Familiarization with treatment parameters using all laser types, such as Argon, Ho:YAG, Tunable Dye, CO2, KTP/2010nm, Nd:YAG, Diode and Thulium.
- Attendance at medical meetings dealing with the use of the laser.
- Attendance at seminars and hands-on workshops on laser therapy in a specific specialty. Quanta System maintains a listing of instructional courses and mentorship sites in a broad range of medical specialties, contact your local distributor for more details.
- Mentorship's should be made as frequently as possible with other surgeons who are performing laser therapy. These usually allow in-depth discussions of all aspects of laser treatment, along with the possibility of observing or participating in actual cases.

Nursing education and training should include a review of the following information:

- Published literature.
- General laser physics, biology and treatment techniques for each specific disease entity.
- Treatment techniques for other surgical modalities in several specialties.
- Familiarization with treatment parameters using other laser types, such as Argon, Ho:YAG, Tunable Dye, CO2, KTP/2010nm, Nd:YAG, Diode and Thulium.
- Attendance at medical meetings dealing with the use of the laser; and
- Attendance at seminars and hands-on workshops on laser therapy in a specific specialty. Quanta System maintains a listing of instructional courses in a broad range of medical specialties contact your local distributor for more details.

6.5 *General Laser Warnings*

The physician or surgeon should become fully acquainted with the unique surgical and therapeutic effects produced with the 2010nm wavelength before using Quanta System Cyber Tm Laser clinically. These effects include coagulation, depth of penetration and cutting intensity.

Caution should be used with power (watts) and timing duration until the surgeon is completely familiar with the biological interactions of the laser energy on various types of tissue. Unless otherwise stated in the specific application section, the surgeon should begin at the lowest power and use short duration exposures. The surgeon should note the surgical effect and adjust the settings until the desired surgical effect is obtained.

The following warnings and precautions are applicable for each surgical specialty contained in this manual. For specific application warnings and precautions, see the section specific to a given surgical specialty.

- The Cyber Tm Laser System is a surgical device that should be used only by physicians or surgeons who have been trained in laser surgery through courses, mentorships, and under the guidance of other physicians or surgeons knowledgeable in laser use. No claim is made that the laser will cure any medical condition.
- BEFORE operating the laser system, surgeons and all staff operating the laser should carefully read Section 1, General Warnings and Caution, of this manual.
- Surgeons using Quanta System Cyber Tm Laser System must understand the laser's unique properties prior to using the device.
- Prior to turning the laser system on, operating room personnel and the conscious / sedated patient should be wearing protective eyewear suitable for 2010nm laser energy.
- Careful assessment of the target and surrounding tissue should be made, and appropriate power and pulse duration should always be used.
- As with conventional endoscopic surgery, the possibility of complications and adverse events, such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis, or infection may occur following treatment. In extreme cases, death may occur due to procedural complications, concurrent illness; there is a risk of infection and scarring associated with any surgical procedure. Therefore, appropriate pre- and postsurgical care should always be practiced.
- Tissue perforation can result if excessive laser energy is applied. This can occur through the use of excessive laser power or the application of power for excessive periods of time, particularly in diseased tissue.
- Aim and use the laser only on tissues that are in full view.
- Extra caution should be used when lasing tissue close to known arteries, nerves and veins.
- **Begin laser treatment at the lowest power, with short duration exposures until fully familiar with the tissue effects of the applicable wavelength**.
- Flash fires can occur. Refer to Section 1, *General Warnings and Caution,* for more information. A bowl of water should be available in case a fire occurs.
- Quanta System has no clinical information or experience concerning the use of the Cyber Tm Laser System on pregnant women or nursing mothers.
- Patients who experience discomfort during laser treatment may require analgesics.
- As with conventional non-laser surgical procedures, there is no guarantee that treatment with the Cyber Tm Laser System will entirely eliminate the disease. Repeated treatment or alternative therapies may subsequently be required.
- The laser may not be effective for coagulation in massive haemorrhage situations. The surgeon must be prepared to control haemorrhages with strident alternative non-laser techniques, such as ligature or

cautery.

- The flammability of methane gas must be considered when treating in or near the perianal area.
- Alterations in surgical approach or technique may be required to accommodate laser use.
- The surgeon should schedule follow-up visits in the same manner as for any patient undergoing such surgery with other modalities.
- Surgeons should be thoroughly trained and proficient in all aspects of endoscopic surgery prior to using the laser through an endoscope. Depth perception through an endoscope is distorted. The surgeon must rely on both the visual and tactile feedback of the delivery system.
- Care must be taken to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.
- A smoke evacuator and in-line filter should be used to capture the smoke plume that results from laser procedures. The plume should be regarded as a source of active biological material and a possible carcinogen.
- The recommended power settings are less important than the visual tissue effect. Changes in the tissue texture and colour are the best indicators of the laser's effect. Specific pulse duration depends on the tissue and is left to the surgeon's preference and best medical judgement.
- **The lowest possible power settings required to achieve the desired tissue effect should be used for treatment**.
- Higher wattages of power may be necessary to achieve the desired tissue effects if fluid cooling is utilised. Excessive power settings may cause damage to the Disposable Optical Fibre Delivery Devices.
- The use of mechanical pressure on the Disposable Optical Fibre Delivery Devices does not increase its cutting or vaporisation effects but may induce bleeding, thermal damage and fibre destruction.
- Due to the tip size of the Disposable Optical Fibre Delivery Devices, input power from the laser source must be reduced to achieve equivalent power densities obtained when using bare fibres of different diameters.

6.6 *General Laser Precautions*

Caution

- Use caution with patients who have had difficulty with previous endoscopic procedures.
- Electrocautery and/or suture (ligature) should be easily accessible in the event that a bleeding artery or vein is larger than possible to control with the laser.
- Use caution when treating patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- Discontinue laser treatment immediately if the patient develops any cardiopulmonary problems.
- Quanta System has no clinical information concerning the safety of laser treatment on pregnant or nursing women.
- Refer to the appropriate delivery system instruction guide for use instructions.

6.7 *General laser Complications*

- The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic surgery.
- Acute pain may occur immediately following laser therapy and may persist for as long as 48 hours.
- Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment.

- Laser ablated tissue may become necrotic or infected after treatment. If a question of infection exists, appropriate treatment should be carried out.

The following complications could be serious and could result in death:

- Patients may experience bleeding at the site of laser therapy. Post-treatment hematocrits are recommended to identify this potential complication.
- Sepsis can result from performing any surgical procedure. If a question of sepsis exists, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.

6.8 *Contraindications for Laser Surgery*

The use of the laser is contraindicated for patients:

- Whose general medical condition contraindicates surgical intervention;
- Where appropriate anaesthesia is contraindicated by patient history or inability to receive anaesthesia
- Where tissue (especially tumours) is calcified;
- For haemostasis of vessels over approximately two millimetres in diameter; and
- Where laser therapy is not considered the treatment of choice
- Patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- Inability to receive endoscopic treatment
- Bleeding disorders and coagulopathy

6.9 *Specific precautions and contraindications*

Urology

- Extra precautions should be taken when radiation therapy and laser therapy are to be used concurrently, including more stringent post-operative monitoring. Clinical studies have shown that patients who have undergone radiation therapy present a greater risk of perforation or tissue erosion.
- To avoid the potential risk of endoscope ignition or damage from the treatment beam or treatment beam backscatter, it is recommended that the fibre extend 4 to 6 mm beyond the distal port of the endoscope so it is fully in the visual field.
- Use of lower power levels and shorter exposure times are required in order to prevent thermal damage to underlying structures (e.g., to thin-walled structures such as the bladder).
- Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distention could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.
- Contraindicated for patients:
    - diagnosed with acute or chronic prostatitis.
    - diagnosed at the time of treatment with acute or chronic urinary tract infection.

- with confirmed or suspected malignancy of the prostate (digital rectal examination, elevated PSA, or abnormal ultrasound of the prostate), unless they are not a candidate for radical prostatectomy or brachytherapy and present with bladder outlet obstruction.
- Whose general medical condition contraindicates surgical intervention.
- Where appropriate anaesthesia is contraindicated by patient history.
- Where tissue is calcified, especially tumours.
- Prostate cancer.
- Acute urinary infection (UTI).
- Severe urethral stricture.

Other Considerations Requiring Physician's clinical judgement

- Patients with compromised renal function, i.e., serum creatinine level > 1.8 mg/dl or upper urinary tract obstructive diseases.
- Patients who still wish to have children.
- Patients with an ASA classification of physical status 5.
- Patients with a prostate gland >120g.

Gynecology

- Current clinical data does not support a claim for indicating the use of the 2010nm laser for treatment of menorrhagia or for use in female sterilization procedures.
- Laser surgical procedures may be contraindicated for women who are pregnant, or have suspected pregnancy, and for whom hysteroscopy or laparoscopy or open abdominal surgery would not be appropriate.
- These procedures may be contraindicated for women with other medical or surgical conditions that would contraindicate laparoscopic or hysteroscopic surgery (for those cases where such an approach would not be the method of choice).
- Contraindicated for patients with any of the following conditions:
  - Inability to receive laparoscopic treatment
  - Intolerance to anesthesia
  - Septic peritonitis
  - Intestinal obstruction
  - Septic shock
  - Resection or excision of large, highly vascularized organs

General surgery

- Contraindicated for patients with any of the following conditions
  - Septic peritonitis
  - Intestinal obstruction
  - Septic shock
  - Resection or excision of large, highly vascularized organs (spleen, liver)

Gastroenterology

- Contraindicated for patients with previous multiple abdominal surgery

- Contraindicated for patients with Intestinal obstruction

Other medical specialties: no specific information - see 6.4, 6.5, 6.6.

7 Maintenance

Introduction

This section provides information on the routine maintenance and care required for the laser systems.

The laser, cooling system, and control electronics are enclosed in a tamper-resistant console. The console does not contain any components that can be serviced by the user.

7.1 *Care of the Console*

Cleaning of the external panels

The external panels should be cleaned periodically with a cloth dampened with a weal solution of warm water and mild detergent or a mild cleaning agent.

Avoid spraying the cleaning detergent directly on the panels as this may result in damage to the finished surface, especially the touch screen.

Never pour water or any other liquid over the console. If it is thought that any fluid may have gone inside the console, turn the laser off and call your local distributor to inspect the laser.

Safety and Warning Labels

The external labels should be checked periodically for damage. It is up to the user to maintain the safety labels. If necessary any labels that have deteriorated must be replaced.

Coolant Refilling Instructions

The Cyber Tm laser system uses a vented internal cooling system that uses distilled or de-ionized water. Over time, some evaporation can occur resulting in a "Water Low" system prompt. This condition is indicated by a red LED. Follow the prescriptions of section 4.10 to refill the system if water low level message is displayed.

7.2 *Preventative Maintenance Schedule*

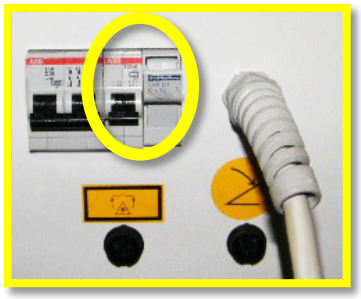
For optimum performance of the Cyber Tm laser system, preventative maintenance needs to be performed every three (3) months.
Please contact Quanta System SpA Customer Service or your local distributor service engineer for more information concerning preventative maintenance or to schedule an appointment.

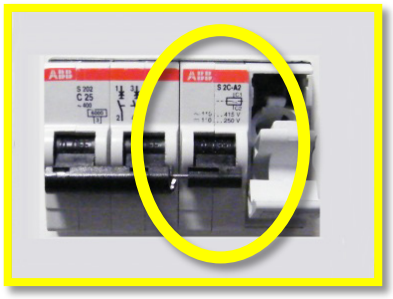
7.3 *Fuses*

The fuse in the rear panel of the system has the following specification:

10x38mm, 20A; 600V.

Before replacing a fuse be sure the plug is detached from mains!





7.4 *Optical fiber maintenance*

Be sure that the fiber sterilization is not expired (date of expiring on fibers label).

Please carefully read the instruction manual of fibres before use to assure a proper and safe use, maintenance and sterilization if applicable.

Before every use check the shape of the aiming beam to verify the effective quality of the beam pattern;
This check can be done placing the fiber perpendicularly on a surface with the aiming beam activated.

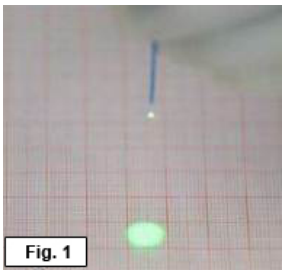


Fig. 1

Remember to wear laser goggles during this operation.

Fig. 1 shows a correct beam pattern. In this case it is possible to remove just the external outer plastic coating

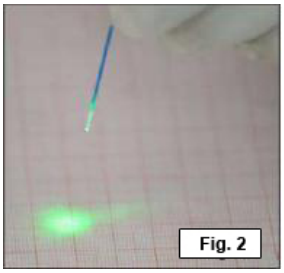


Fig. 2

Fig. 2 is giving an example of an incorrect laser beam pattern. In this case it is necessary to act as below indicated.

Remove the outer plastic coating.
Use a suitable fiber stripper to remove the outer plastic coating and the silicone layer of the laser fiber, if applicable, at a length of approximately 20 to 40 mm (Fig. 3).

Before stripping the fiber adjust the fiber stripper to the fiber diameter (A).

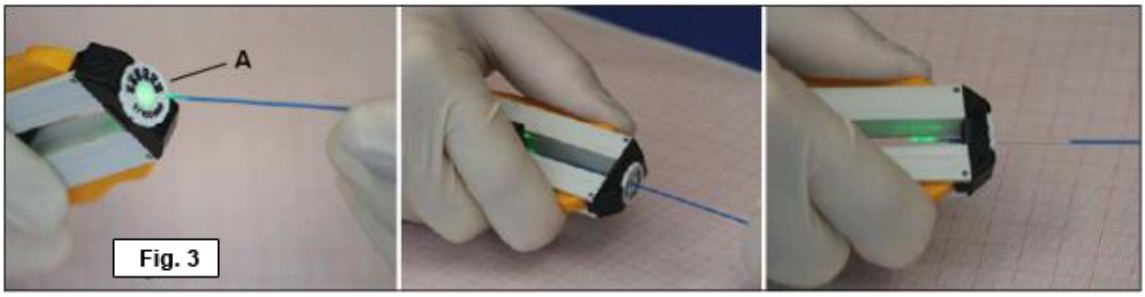


Fig. 3

- Prepare the fiber tip with a suitable scoring (slitting) tool approximately 5 mm away from the plastic coating.

    - Carefully score the light guide (Fig. 4) to create a predetermined breaking point, then break off the light guide at this point by bending it slightly while pulling forward (Fig. 5).

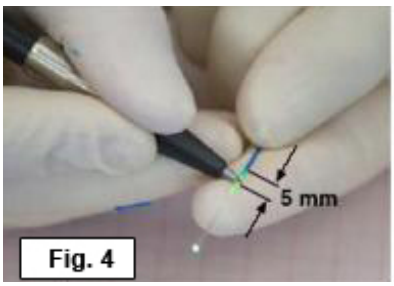


Fig. 4

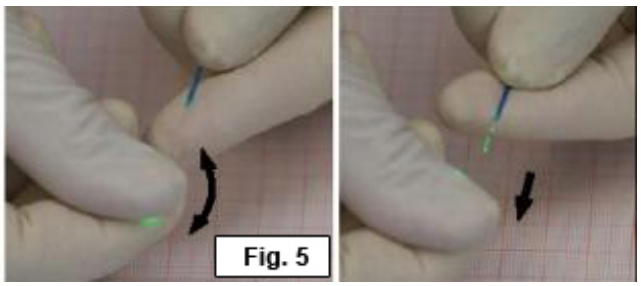


Fig. 5

- Check the beam pattern using the pilot beam (Fig. 1).
- In case of an uneven pattern repeat the preparation procedure.

Fiber management (application cycles):

The number of application cycles of a laser fiber is mentioned on the label or into the instructions of the fibers. Please keep record of the number of sterilization cycles the fiber undergoes.

Quanta System suggests the use of Quanta System fibres.

NOTE!
A disposable laser fiber cannot be used a second time after the first use!
After use of a disposable laser fiber or at the end of the application cycles of a re-processable laser fiber change the old fiber with a new fiber.

Check the optical fiber before operation

If the optical fiber connection is damaged, replace the optical fiber immediately.
If the end of the optical fiber is dirty or damaged, renew it following the instructions in the previous Section.

- After renewing, the optical fiber end will hardly have a circular shape;
- The renewing can have as a consequence an irregular end. This irregularity can be accepted only it is reasonably small. If the irregularity exceeds the acceptable level, repeat the optical fiber end renewing.

7.5 *Use, cleaning, disinfection, sterilization of optical fibers*

Carefully read and follow optical fibers instruction manual.

8 Troubleshooting

Introduction

Cyber Tm laser system's self-check mechanism will alert operating room staff if there is a problem. A message will appear on the screen at the time of system malfunction. Depending on the severity of the problem, the system will either continue to work (Warning Messages) or require a solution before reactivating (Alarm Messages).

8.1 *Warning Descriptions*

There are different warnings and alarms that will be displayed on the touch screen.

All warnings set the system to a 'fail safe' condition. The system allows all functions that are not dangerous for the user or for the system to continue.

Ex. Fiber not Connetted

The laser system indicates the following warnings

NO FIBRE	(if the optical Fibre is not connected)
INTERLOCK	(if the interlock is not connected)
POWER HIGH	(If the output energy is greater than + 30% the value selected)
POWER LOW	(If the output energy les than - 30% the value selected)
POWER ± 20%.	(if the power exceeds ±20% the set value)
POWER ± 30%.	(if the power exceeds ±30% the set value)

8.2 *Alarm Descriptions*

All the alarm alerts cause the laser system to stop. To restart the system it is necessary to resolve the cause of the alarm and RESET the lasers from the main Menu button.

Ex. Chiller 1 and Chiller 2

The laser system indicates the following alarms:

- **FOOTSWITCH.**
- **CHILLER. 1 or 2**
- **SHUTTER**
- **FIBRE**
- **CURRENT CHECK**
- **INTERLOCK 1 (internal)**
- **INTERLOCK**

These alarms may be cleared by restarting the laser. If the alarm(s) persists the operator should contact the service department of Quanta System SpA or the local distributor.

8.3 *Troubleshooting Guide*

The following table can help identify common problems.

Problem	**Possible cause**	**Solutions**
The system does not switch on	Power cable not connected. Main electrical socket not on. Circuit Breaker not on. Broken Main Fuse	Connect mains cable. Turn on main socket. Check the circuit breaker, turn on. Call service
Low output power	Damaged optical fibre	Inspect the Fibre Replace the Fibre Call service
No output power	The laser is not in ready mode. Footswitch broken	Select Ready mode. Call service
Alarm: footswitch not connected		Connect the footswitch
Remote door interlock not connected		Connect the interlock
Fibre: warning	Fibre not connected properly.	Re-connect the fibre, tighten securely.
Alarm chillers 1 or 2	Chiller 1 or 2 not working. Low water level. Low flow.	Call service. Add water. Call service.
Other Alarms SHUTTER FIBRE CURRENT CHECK INTERLOCK 1 INTERLOCK 2		 Call service. Call service. Call service. Call service. Call service. Call service. Call service. Call service. Call service.

8.4 *ACCESSORIES*

Accessory	Description
Sterile single-use fibers Sterile reusable fibers *(available according to customer requirements)*	Sterile single-use and reusable bare optical fiber with 200, 272, 365, 400, 550, 600, 800 & 1000 µm core diameter. Sterile single-use Lateral emitting optical fiber 600 µm core diameter.
Fiber stripper 1	Fiber stripper for diameter 0,3-1mm
Fiber stripper 2	Fiber stripper for diameter 0,1-0,4mm
Fiber cutter	Ceramic fiber cutter
Safety Goggles	Safety Goggles

8.5 *Warranty Policy*

The system is warranted against any defects in material and workmanship for a period of one (1) year from the date of delivery.

Any repairs that are necessary as a result of natural disasters, accidents, electrical system faults, negligence, improper use or misuse of the appliance, or servicing or repairs carried out by persons not authorised by Quanta System SpA are not covered by warranty.

Quanta System SpA staff or local distributor staff must be allowed free access to the device. Any repairs which cannot be carried out on site will be undertaken in our workshops.

Warranty and responsibility of the Manufacturer will also expire for any of these reasons:

- Use of the device not conforming to the procedures and instructions reported in the user manual.
- Incorrect installation and maintenance.
- Use of the faulty system, not correctly installed or damaged.
- Unfulfilling of the instruction of this manual concerning:
- Transportation
- Storage
- Installation
- Maintenance
- Arbitrary alteration of the device.
- Incorrect reparations.
- Accident caused by external element.

In no case is the customer entitled to claim compensation for any damage resulting from the system being out of operation.

On demand, the manufacturer will provide all technical information including electrical drawings, components list and suggested application protocols.

9 Annex A – RMA (Return Material Authorisation) Request

SERVICE/ASSISTANCE REQUEST

RMA NR:

FROM:

TO:

DATE:

DEVICE MODEL:

S/N:

MALFUNCTIONS DESCRIPTION

DETAILED LIST OF THE RETURNED SPARES/ DEVICE/ ACCESSORIES:

Please contact your local distributor with the model and serial number (S/N) and explain the malfunctions, manufacturing defects and non conformities of your device. If you need to send back the goods or medical devices complete this form and fax to the distributor. You will then be sent a RMA number and instructions for return of goods.

10 **Annex B – EMC TABLES**

CAUTION!
To guarantee the safety of the user, the patient and others, use only accessories and spare parts specified by the manufacturer of this product.
Other accessories or spare parts can cause the emission of increased electromagnetic radiation or reduced immunity against interference.

IMPORTANT!
Medical electrical devices are subject to special precautions with regard to electromagnetic compatibility (EMC) according to IEC 60601-1-2 (2007).
Make sure you observe the notes on EMC for installation and operation.
Medical electrical devices can be influenced by mobile HF communication devices (i.e. mobile phone).
If it is necessary to stack the devices or place them next to each other, and HF interference is observed, make sure you observe the intended use of the devices.

Table 201 Guidance and manufacturer's declaration – electromagnetic emission		
The equipment **Medical device mod. CYBER TM** is intended for use in the electromagnetic environment specified below. The customer or the end user of the **Medical device mod. CYBER TM** should assure that it is used in such an environment		
Emission test	compliance	Electromagnetic environment - guidance
RF emission – CISPR 11	Group 1	The **Medical device mod. CYBER TM** uses RF energy only for its internal function. Therefore its emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emission – CISPR 11	Class B	The **Medical device mod. CYBER TM** is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emission IEC 61000-3-2	complies	
Voltage fluctuation/flicker emission IEC 61000-3-3	complies	

Table 202 Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment **Medical device mod. CYBER TM** is intended for use in the electromagnetic environment specified below. The customer or the end user of the **Medical device mod. CYBER TM** should assure that it is used in such an environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 KV contact ±8 KV air	±6 KV contact ±8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst	±2 KV for power supply lines	±2 KV for power supply lines	Mains power quality should be that of a typical commercial or

IEC 61000-4-4	±1 KV for I/O lines	Not applicable	hospital environment
Surge IEC 61000-4-5	±1 KV differential mode ±2 KV common mode	±1 KV differential mode ±2 KV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut for 0,5 cycle 40% Ut for 5 cycles 70% Ut for 25 cycles <5% Ut for 5 sec	<5% Ut for 0,5 cycle 40% Ut for 5 cycles 70% Ut for 25 cycles <5% Ut for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Medical device mod. CYBER TM** requires continued operation during power mains interruptions, it is recommended that the **Medical device mod. CYBER TM** be powered from an Uninterruptible Power Supply or Battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note: Ut is the AC mains voltage prior to application of the test level

Table 204 Guidance and manufacturer's declaration – electromagnetic immunity

The equipment **Medical device mod. CYBER TM** is intended for use in the electromagnetic environment specified below. The customer or the end user of the **Medical device mod. CYBER TM** should assure that it is used in such an environment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the **Medical device mod. CYBER TM**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3Vrms 150KHz to 80MHz	3 V rms	**Recommended separation distance.** d=1,167*sqrt (P)
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2,5 GHz	3 V/m	d=1,167*sqrt (P) 80 MHz to 800 MHz d=2,333*sqrt(P) 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: at 80 MHz and 800 MHz, the higher frequency range applies Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Medical device mod. CYBER TM** is used exceeds the applicable RF compliance level above, the **Medical device mod. CYBER TM** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Medical device mod. CYBER TM**

b) Over the frequency range 150 KHz to 80 MHz, field strength should be less than 3 V/m.

Table 206 Recommended separation distances between portable and mobile RF communication equipment and the **Medical device mod. CYBER TM**

The equipment **Medical device mod. CYBER TM** is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Medical device mod. CYBER TM** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Medical device mod. CYBER TM** as recommended below, according to the maximum power of communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 KHz to 80 MHz d=1,17*sqrt (P) m	80 MHz to 800 MHz d=1,17*sqrt (P) m	800 MHz to 2,5 GHz d=2,33*sqrt (P) m
0,01	0,117	0,117	0,233
0,1	0,370	0,370	0,740
1	1,17	1,17	2,33
10	3,70	3,70	7,40
100	11,7	11,7	23,3

For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer
Note 1: at 80 MHz and 800 MHz, the higher frequency range applies
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11 Annex C – LOGBOOK

Logbook				
No	**Data Date**	**Faults / Errors / Alarms**	**Job Description**	**Firma Sign.**
1		**None**	**Final Test**	