ROCAMED

SIRIUS™

Thulium Fiber Laser

User Manual

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CE
0123

Rev. data 19/10/2021

Dear Customer,

Thank you for choosing a **ROCAMED** Medical Laser product.

In order to attain best results with **ROCAMED Laser Systems** and to avoid risks of dangerous faults, please **be sure that you carefully and completely read this user manual before starting any operation.**

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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 radiations**
- **Protect any operator by using personal protection means and environment protection barriers**
- **Please consult, in advance, the "Safety" chapter of this manual**

TABLE OF CONTENTS

1 GENERAL INFORMATION

1.1 Introduction

The *Sirius* is a Thulium fiber laser device emitting at a wavelength of 1940 nm, which is used by physicians as a tool in surgical procedures.

This manual contains important information regarding the safe use of the *Sirius* medical device. The manual describes the device, surgical procedures, various device 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.

Practitioner using the *Sirius* medical device must read this manual carefully. Professional information regarding specific surgical specialties can be found in Chapter 6, "Clinical Applications".

Like all surgical instruments, practice is necessary for a responsible and proper use. This manual should be read and understood thoroughly before the first use of the device!
For more information regarding the installation, clinical applications, or some issues you may encounter, please contact your distributor.

1.2 Purpose of the manual

This manual contains essential information necessary for the installation, operation and maintenance of the *Sirius* 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 is fully trained in laser and conventional surgery.

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 *Sirius* medical device. For any information regarding the technical assistance, please contact your distributor.

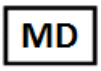
1.3 Safety instructions

The safety instructions in this manual are intended to prevent possible injuries, material damage and operational faults. Reading carefully through this manual before operating the laser for the first time is also considered a safe operation concerning this product.

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

WARNING 	**Risk of injury!** This instruction concerns the safety of patients, operators and other persons, who are in the room where the laser is being operated or maintained. In this manual the following symbol is used to warn the **risk of injury** from laser radiation.
CAUTION 	**Danger of operational fault**! Failure to follow this instruction can lead to damage of 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 of the laser system, which might result from it.

1.4 **Symbols and Abbreviations**

Symbol	Description
	Read the enclosed documentation label
	CE label
	Symbol of applied part type (i.e. optical fiber) BF According to standard 60601-1
	Symbol indicating that the device cannot be disposed of as municipal waste, but must be separated in accordance with the WEEE (Waste Electrical and Electronic Equipment)
	Manufacturing date
	Serial Number
	Medical Device Symbol
	Reference Number
	Manufacturer
NOHD	Nominal Ocular Hazard Distance
MPE	Maximum permissible exposure
µm	Units, micrometer
s	Units, Second
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 pulses
Vac	Volt AC
A	Units, Ampere
T	Slow blow fuse
I	Electrical Protection Class
nm	Units, Nanometre
mm	Units, millimetre
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

Pushing Prohibited

1.5 Manufacturer

This device is a Medical Laser classified as Class 4 according to IEC 60825-1.

Manufactured by

Quanta System S.p.A.
Via Acquedotto, 109
21017 - Samarate (VA)
ITALY

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98000 MONACO
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www.rocamed.eu

1.6 Combinations

We recommend to use fibers distributed by ***Rocamed*** in conjunction with the *Sirius* Laser System.

Caution**:** *Products may be incorrectly combined! Injury of the patient, user or damage to the product is possible. The different products may be only 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.*

2 LASER SAFETY

2.1 General Safety

- For the safe use of this device, it is necessary to be aware of all the safety standards.
- This manual contains important information about safe use of the device.
- All people working 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 console 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.

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

Warning: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2.2 Classification

This device is a Medical Laser classified as Class 4 according to IEC 60825-1.

2.3 System Safety Features

The *Sirius* 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 device is provided with 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 configuration.
- 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 fiber optic has been connected.
- Laser will go into Ready (to fire) status when the READY button is touched.
- A continuous audible tone is heard when the surgical beam is activated (i.e. foot pedal is pressed).
- An Emergency Laser Stop switch is available to disable the system immediately, in the case of an emergency situation.

2.4 Training of the medical staff

The use of the laser device is restricted only to the specialist medical staff*: these people, 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 Urology, Thoracic and Pulmonary, ENT, Neurosurgery, Gastroenterology, Gynecology, Lithotripsy and General Surgery.

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 60825-1.

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

The device shall be used in a position such that the mains switch and the other controls are easily accessible.

RULES OF ACCESS TO THE RESTRICTED WORKING AREA
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 (laser radiation, electric shock, etc.)

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

Warning: Equipment not suitable for use in the presence of flammable mixtures.
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.

2.6 Eye and skin exposure

The laser beam emitted by the *Sirius* can cause vision loss. The laser operates at different wavelengths, visible and invisible. Any energy transmitted by the laser system entering the eye will be focused directly on the retina. Direct absorption of laser energy by retina can result in temporary clouded vision, retinal 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 specifications shown in Chapter 10 according to the EN 207.

Always check goggles integrity and condition.
In addition, even if you wear goggles, never look directly at 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, make sure that the goggles are in a 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 L3, L4, ...) or goggles featuring a broadband filter of protection stage L2 or higher also covering wavelengths around 1940 nm could also be used.

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

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

2.6.1 *Nominal Ocular Hazard Distance*

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

- The **MPE** level represents the maximum level to which an eye, or skin, can be exposed without consequential injury, immediately or after a long time. The MPE is related to radiation wavelength, pulse duration or exposure time, the tissue at risk and, for visible and near infrared radiation in the 400-1400 nm range, to the size of the retinal image.
- The **NOHD** is the distance at which the beam irradiance or radiant exposure equals the appropriate corneal maximum permissible exposure.
- The **OD** of the protective goggles to be worn is defined as:

$$OD = \log_{10} (H_0/MPE)$$

Where H_0 is the expected unprotected eye exposure level.

Results of MPE, NOHD and OD calculations are reported in the table in section 10.2.

Please, refer to previous section 2.6 for further details concerning the protection level in googles.

Laser system has to be used in a closed area that does not allow the escape of direct, reflected or transmitted laser radiation.

 **Warning:** Openings inside installation area that are transparent to laser radiation must be properly darkened.

Doors equipped with a special interlocking system have to be made of a laser non-transparent material (glass, plastic, curtains ...) and windows have to be darkened by using appropriate laser non-transmissive systems.

2.7 **Environmental conditions**

 **Caution:** *The working area must be marked with the laser warning labels, 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.

2.7.1 *Electrical connection requirements*

The device must be connected to the electrical system in compliance with electrical safety regulations.
The device can be supplied with a cable with different plugs (Nema, Shuko etc.) suitable with the electrical standard requirements of the country where the laser system is going to be installed.

 **Warning**: To avoid any risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2.7.2 *Temperature and humidity*

Appropriate values of temperature and humidity are required for the proper device functioning. This Laser Device has to operate in ambient condition according to the parameters in the Technical Specification Chapter.

2.7.3 *Minimum space requirements*

To ensure proper device ventilation there must be at least 50 cm of free space on both sides.
The Laser device can be easily moved from room to room. Make sure that adequate space and appropriate electrical socket are available in the room. Place the device in such a way to have easy access when disconnecting it.

2.8 Fire hazard

The laser radiation of this LASER device is able to melt, burn or 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 the duration, 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.
- Anaesthetics administered either by inhalation or topically must be approved as non-flammable.
- Use particular care in the use of oxygen, do not use the laser device in oxygen rich environment, as it may lead to explosion.
- Avoid using combustible materials, such as gauze and drapes, in the treatment area. When required, these materials must be made fire-retardant by keeping them moist with water. Clothing should be kept away from the treatment area.
- Cotton wool and similar materials, when saturated with oxygen, can catch fire due to the high temperature emitted by laser.
- Before using the laser, let solvents, glues or flammable solutions evaporate if they are 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, bonesaws and lasers. Current medical literature recommends that a smoke evacuator and in-line filter can be used to capture this plume. The plume should be regarded as a source of active biological material and possibly carcinogenic.

 **Warning:** Laser plume may contain viable tissue particles.

2.10 **Emission of toxic gas or vapor**

The radiation of this LASER device is able to melt, burn or vaporize almost all materials. Vapors or emitted gases resulting from laser operation may be dangerous to both patient and medical personnel in the surgical area.
The use of this LASER device is limited to the applications specified in this manual.

2.11 **Safety features for the electromagnetic compatibility (EMC)**

The *Sirius* device does not include any type of direct connection with other external devices.

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

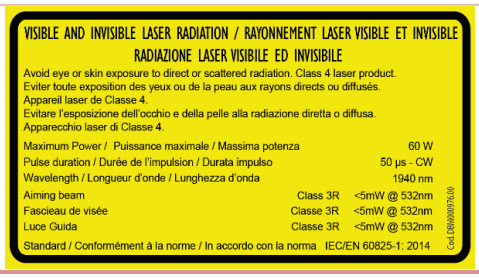
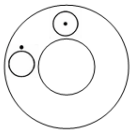
Warning: Turn off mobile phones and similar devices while operating the device.

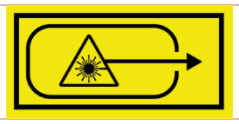
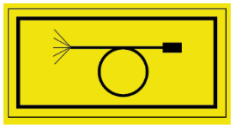
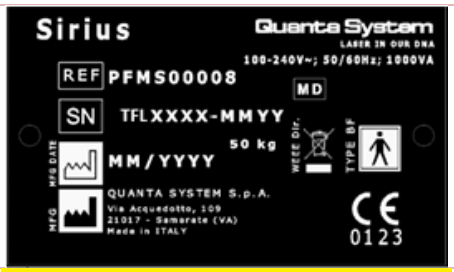
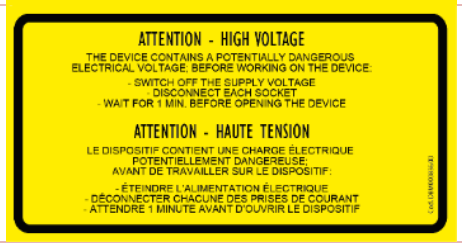
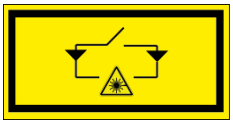
This *Sirius* device must be installed and used according to EMC information described in the tables reported in Appendix B.

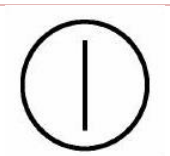
2.12 **Warning and instructions for the device disposal**

At the end of its lifetime, the device has to be handled 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, instead it has to be collected separately according to the WEEE Directive (Waste Electrical and Electronic Equipment).
The penalties for violating law requirements are severe.

2.13 **Labelling plan**

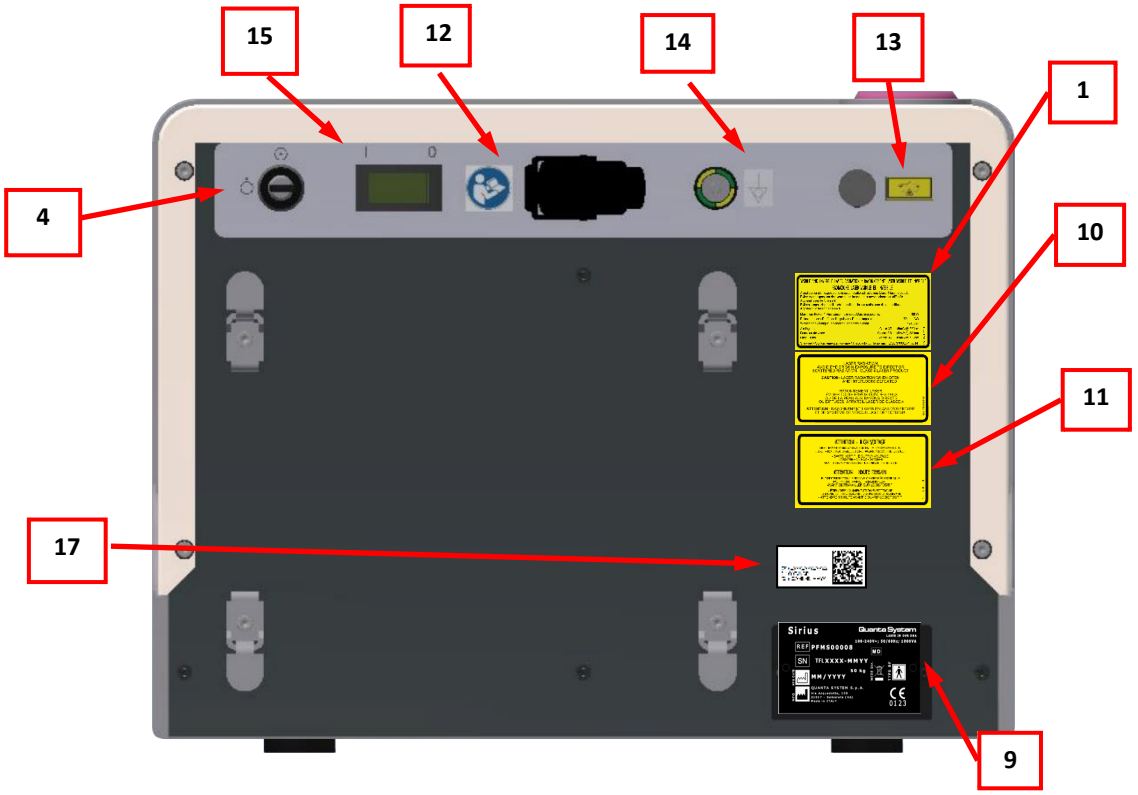
	**Label 1** Laser characteristics
	**Label 2** Footswitch connector label
	**Label 3** Emergency laser off label according to IEC 60601-2-22
	**Label 4** ON and OFF label

	**Label 5** Warning label of laser radiation
	**Label 6** Laser aperture label
	**Label 7** Optical fibre applicator label
	**Label 8** Applied part (i.e. optical fiber) type BF label
	**Label 9** Rating label
	**Label 10** High Voltage warning label
	**Label 11** Warning label – hazard label according to IEC 60825-1
	**Label 12** Read instructions for use label
	**Label 13** Remote interlock connector label
	**Label 14** Equipotential connector label

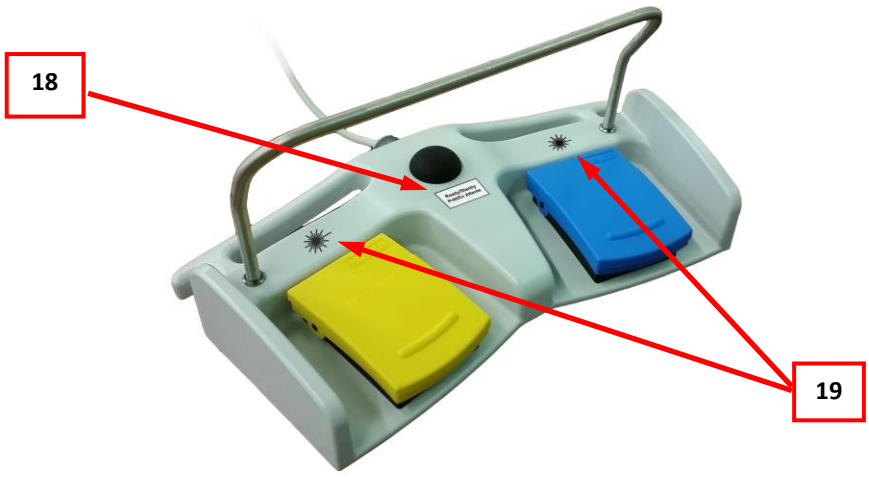
I 0	**Label 15** Circuit breaker ON(I)/OFF(0)
	**Label 16** Frontal button ON/OFF label
	**Label 17** UDI label
	**Label 18** Footswitch “emission” label
Ready/Standby *Prêt/En attente*	**Label 19** Footswitch “ready/standby” label

2.13.1 *Front view*

2.13.1 *Rear view*



2.13.1 *Footswitch*



3 DEVICE DESCRIPTION

This chapter provides a general description of the device and all its parts.

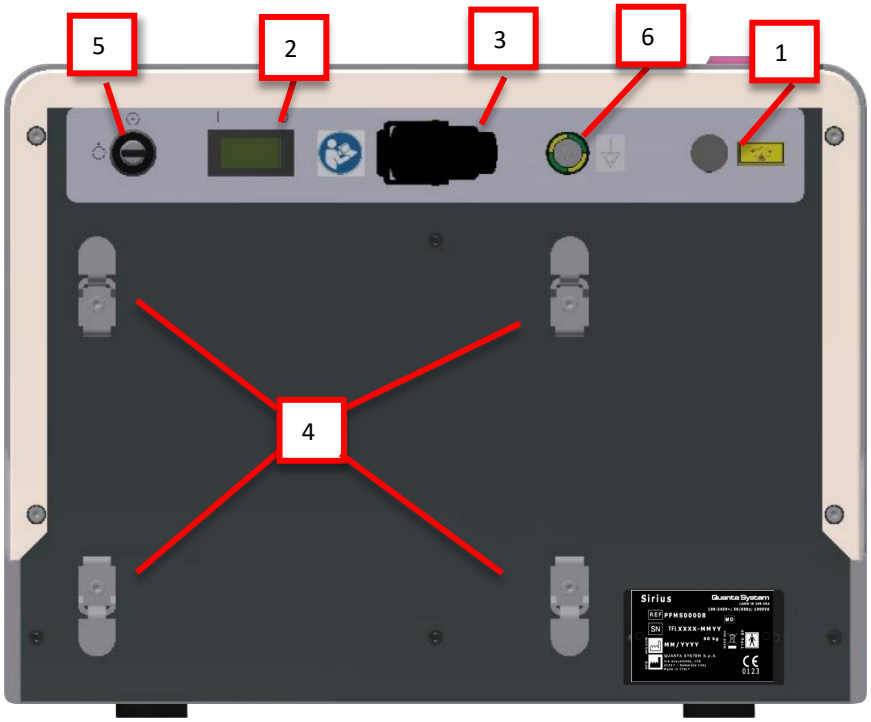
3.1 Introduction

Sirius Laser System is a Thulium fiber laser device. Its wavelength is 1940 nm, in the infrared portion of the EM spectrum. The maximum output power of the device is 60 W. For the release of laser radiation to the patient, the *Sirius* medical device uses a quartz optical fiber with a diameter up to 1000 µm (see Chapter 11 "Accessories") to be used for the surgical applications mentioned in Chapter 6, "Clinical Applications". In addition to the optical fiber launch system, this laser system has power and control electronics. For all technical information relating to the laser system and electrical system, contact the company QUANTA SYSTEM.
The laser can operate in a pulsed mode with maximum frequency of 2500 Hz. In this case, the release is by pulses that are repeated over time with an adjustable frequency (see Chapter 5 “Instructions for Use”).
Sirius is used in different clinical application (see Chapter 6 'Clinical Applications').

3.2 General description of the device

1 Touch screen Display (control panel)
2 Emergency red push button
3 Footswitch connector
4 Optical fiber connector *(WARNING: this is a laser aperture)*
5 RFID Antenna
6 Led indicator
7 External protection shutter
8 Frontal Button ON/OFF
9 Handle
10 USB port for Service *(only for Service personnel)*
11 Blast Shield access
12 Air exhaust

Warning: USB port is accessible to service personnel only.



1 Interlock connector
2 Power/mains switch
3 Power cable socket
4 Support for footswitch and power cord
5 Key switch
6 Equipotential connector

3.3 **Electrical control**

3.3.1 *Mains switch*

When the main switch is set in **I** configuration the device is power supplied.
In case you must disconnect the device from mains, turn the main switch to the **O** configuration and disconnect the power supply plug.

3.3.2 *Key switch*

The key switch turns on/off the device. There are two configurations on the switch: ⊙ and ○.
To switch the device ON, insert the key and turn it clockwise - ⊙ configuration. To switch the device OFF, turn the key counter clockwise - ○ configuration – and remove the key.

3.3.3 *Emergency red push button*

The emergency red push button is designed for emergencies or when the operator must immediately turn off the device. To switch the device off immediately, press this button. To reset the emergency red push button, turn the knob.

3.3.4 *Frontal Button ON/OFF*

By clicking on it, the user can turn on/off the device. A led ring around the button advises the user about the status of the device.

3.3.5 *Equipotential connector*

The device, in compliance with IEC 60601-1, is provided with an equipotential connector (item 16 in the image above) that can be connected to the equipotential line of the room where the device is used.

3.4 **Accessories**

Optional accessories are associated with the device (for a list of these optional accessories supplied with the device, refer to Chapter 11 "Accessories").

3.4.1 *Optical fiber*

The optical fiber is used to deliver laser energy to the patient. It is connected to the device through a special optical connector accessible from the frontal panel. The connector has a microswitch that disables laser emission if the fiber is missing or not installed properly.
The optical fiber is a quartz fiber that allows the transmission of laser radiation from the laser source to the patient. Depending on the surgical applications, the optical fiber may be sterile and disposable or sterile and resterilizable.
For more information about cleaning and sterilization of the fibers please refer to Chapter 7, “Maintenance, Cleaning and Sterilization”.

 ***Warning:*** *Any tampering of the optical fiber contact connector and the device may cause unwanted emission of laser radiation.*
Potential danger may occur in inserting, strongly folding, or not properly securing the optical fibers. Not following manufacturer recommendations may damage the fiber or the optical beam transmission system and/or cause injury to the patient or user.

 ***Warning:*** *Any tampering of the protection of the optical fiber may cause undesired emission of laser radiation.*
The fibers are reinforced externally near the SMA connector. Twisting, straining or inducing too exaggerated curves in the fiber could damage and/or break the optical fiber, resulting in internal radiation leakages out of the reinforcement structure or buffer layer (depending on the damaged area).

 ***Warning:*** *The metal sheath protects the user and the patient from the potential radiation emission in case of breakage of the fibers inside.*

 ***Warning:*** *Before performing any laser emission, make sure that the probe is properly inserted and pay attention to the pointing direction.*

 ***Caution:*** *The use of fibers or accessories different from those supplied by the Manufacturer does not guarantee the achievement of security requirements.*

4 SYSTEM INSTALLATION

4.1 Device installation

Device installation requires that safety precautions are followed, including power requirements and 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.


Caution: *Do not start using the laser device before reading this manual. The warranty does not cover any damage occurred prior to installation.*

4.2 Transportation

While transporting the laser, the fittings, fiber, power cord, the pedal and remote locking must be disconnected from it. Finally, the laser and the accessories should be stored in slots inside the packaging.


Caution: *In order to transport the laser device, it must be gripped on both sides using the proper grooves, by at least two people, and positioned on a trolley.*

4.3 Packaging

The laser system is normally shipped in a specific cardboard on wood pallet. Upon the container arrival, it will be a client responsibility to review the packaging, whereas its pre-positioning will be under the responsibility of the technician responsible for the installation near the working area.

4.4 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.

4.5 Labelling 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 with the labelling shown in the label plan (Section 2.13).

4.6 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 procedure step 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 are checked immediately upon their arrival, if possible, in the presence of the shipping agent's 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
    - Connect the remote door interlock
    - Connect the footswitch
    - Connect the laser device to the power supply
    - Turn on the system
    - Check the system and verify if alert messages are displayed
    - Connect the RFID fiber and wait that the Sirius system recognizes the type and the number of uses of connected fiber
    - Check the system and verify if alert messages are displayed
    - Change the status of the Sirius laser system in Ready
    - Check the system and verify if alert messages are displayed
    - Change the status of the Sirius laser system in Standby
    - Turn off the system

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

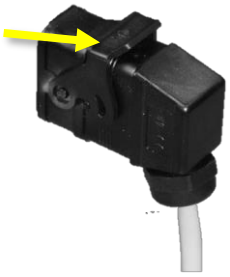
- Install the device in the room indicated by the customer in the following way:
    - Place the device so that the operator can have easy access to operate on the mains cable by connecting/disconnecting it when necessary
    - Connect the device to the power supply
    - Connect the interlock connector
    - Connect the footswitch
    - Check the laser device

- Perform further controls or additional tests.
- Perform a training to the end user on the following items:
    - Proper fiber attachment
    - Operation of the device

 **Caution:** *Do not start any action with the laser device before the official personnel have performed the installation procedure. The warranty does not cover any damage to the laser device before the installation.*

4.6.1 *Mains connection*

Once all the checks have been made and after placing the laser device in its final position in the working area, you can connect the device to the mains. Use the cable provided. Such cable can suffer wear over time. The operator or anyone involved in the ordinary maintenance of the device after the installation must take care of monitoring the maintenance status of the power cable.



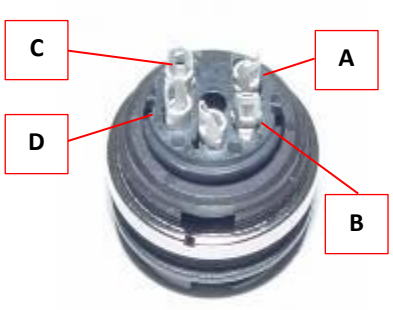
The device must be connected to the mains in compliance with electrical safety regulations.

Caution: *Before starting to use the device, be sure that the cable lock is fixed and the cable cannot be removed.*

4.6.2 *Remote interlock connection*

According to IEC 60825-1 all laser devices must be equipped with a remote block connector, connected to the room access door, which prevents laser emission when the door is opened.

A suitable switch shall be prepared by the client on the room access door where the device will be installed. In case of multiple access doors, each door should have its own switch, whose contacts have to be connected in series.
The remote interlock cable must be connected to a lamp mounted at the entrance of the working area (as shown in the picture). When the door is closed, the switch will enable laser emission with a dedicated electrical signal.
The connection, or the sequence of connections, has to be wired with a suitable cable to the interlock connector during the device installation.
The interlock connector is wired on the laser side in the following way:



Interlock male movable connector
(inner view)

The external door microswitch has to be connected to pins A and B.
Contacts C and D close the signal lamp circuit (max current 1A, 24Vdc).

4.6.3 *Footswitch connections*

The footswitch is used to start the laser emission and to switch from Ready to Standby status and vice versa.
To connect the footswitch, plug its connector into the dedicated device socket (on the frontal panel).

Warning: *Do not wrap the footswitch with any plastic (or other material) film or cover bag, unless authorized by the manufacturer. The unauthorized use of wrapping bags/films may block the pedal in pressed position and cause unwanted laser emission.*

4.6.4 *Optical fiber connection*

The fiber is connected to the device through the cable connector on the front.
The device accepts fiber with SMA905 connector and with RFID Recognition System (only with Quanta System internal code). The fiber connector has an additional ring which facilitates the clamping of the fiber to the connector on the device. Furthermore, this ring enables the automatic detection of fiber status (present / absent), its diameter and its type (single use / reusable). If the fiber is not connected to the device, an error message is displayed when the device is switched on.

N°	Component description
1	RFID Antenna
2	Optical fiber connection location
3	Led indicator
4	External protection shutter

Caution: *It is very important to tighten the fiber nut to the device by hand until it is firmly fixed. Improper connection may cause a low output power.*

4.6.5 *Optical fiber check*

Please see Section 7.5.

5 INSTRUCTIONS FOR USE

Warning: *Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.*

This section describes the use instructions of the *Sirius* device. They include:

- Start-up procedure
- Operating instructions
- Description of possible Error messages
- Shut down procedure and protection from unauthorized use

5.1 Start-up procedure

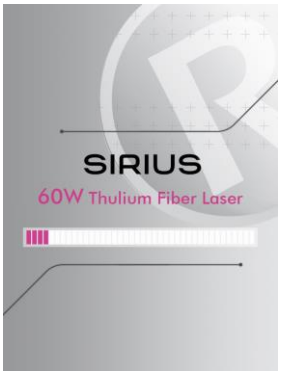
Before proceeding with the start-up procedure of the device, verify the proper connection of the following accessories:

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

Also, make sure that the emergency red button is not pushed.

To turn the device ON:

- Set the main switch to the **I** configuration on the rear panel. At the start-up, the LED bar on the front panel turns blue.
- Turn the key switch in the ⊙ configuration (clockwise) to turn on the system.
- Push the ON/OFF frontal button. If the laser fails to start, check that the emergency push button is not pressed. If the emergency push button is pressed, twist it to allow its release, turn the key and push the frontal ON/OFF button to start the laser.



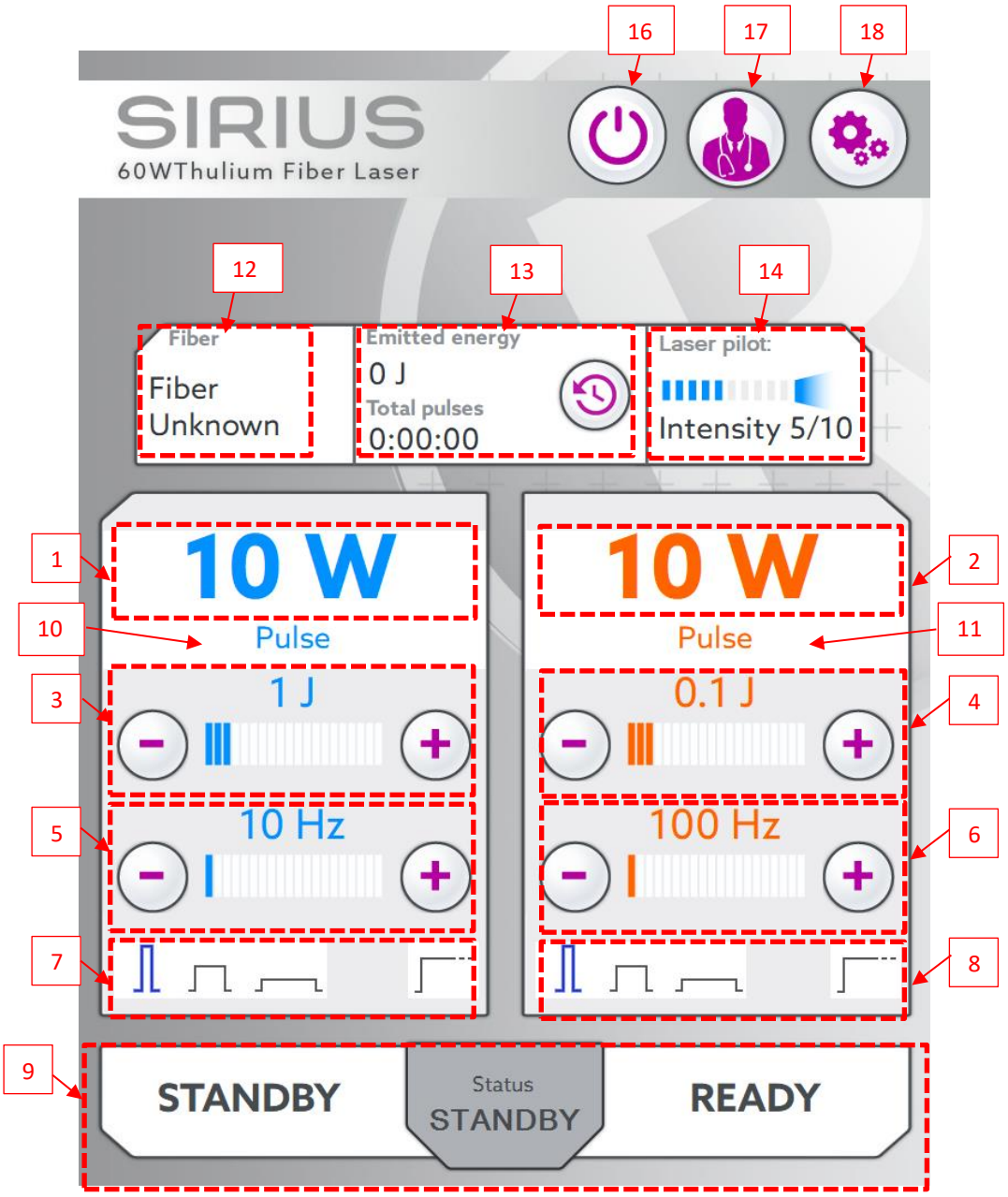
The **Loading screen** will appear.
Once the system has checked for the proper functioning and status of device elements, the **Main screen** will appear (see section 5.2.1 Main Screen).

Through the  , the **Settings screen** is reachable (see section 5.3 Settings).

5.2 Operating instructions

5.2.1 *Main Screen*

This section details the Main Display Screen. Refer to the figure below.



1	**Output power** for blue footswitch	10	Selected pulse duration for blue footswitch
2	**Output power** for orange footswitch	11	Selected pulse duration for orange footswitch
3	**Pulse energy** settings for blue footswitch	12	**Fiber info**
4	**Pulse energy** settings for orange footswitch	13	**Counters**
5	**Frequency** settings for blue footswitch	14	**Aiming beam** settings
6	**Frequency** settings for orange footswitch		
7	**Pulse mode** and **duration** settings for blue footswitch	16	**Shutdown**
8	**Pulse mode** and **duration** settings for orange footswitch	17	**Custom Presets / User profiles**
9	**Device status** settings	18	**Settings**

5.2.1.1 *System status*

Possible **System status** are:

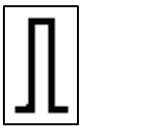
- STANDBY (see section 5.4.2): the laser cannot fire
- READY (see section 5.4.2): if the footswitch is pressed the laser will fire
- LASING (see section 5.4.4): the laser is firing
- ERROR (see section 5.5): the laser cannot fire
- OFF: during the shut-down procedure

Press the Ready or Standby button to switch between the device status.

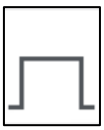
5.2.1.2 *Pulse mode and duration settings*

Press the desired pulse mode section to choose between Pulsed mode or Continuous mode (CW):

Pulsed mode:



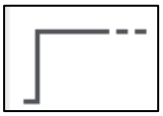
Short pulse



Medium pulse

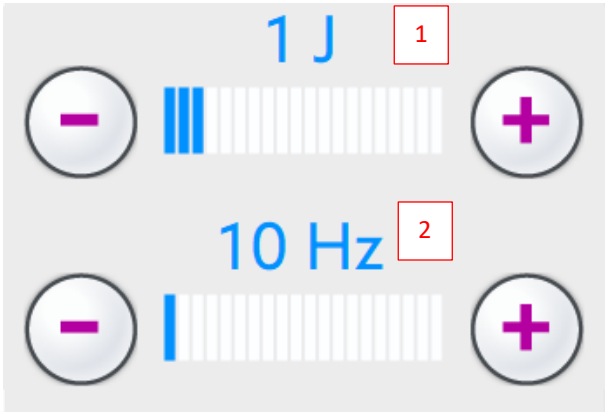
Long pulse

Continuous mode (CW):



The chosen mode will become highlighted and its description will appear under the output power indication.

5.2.1.3 *Energy and Frequency settings*

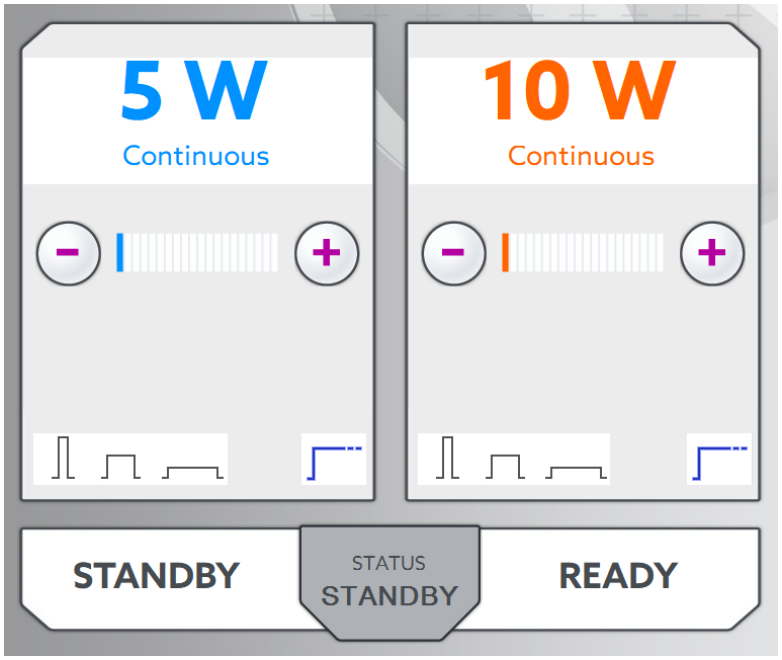


Press the **+ /-** buttons to increase or decrease the **pulse energy** (1) and the **frequency** (2).

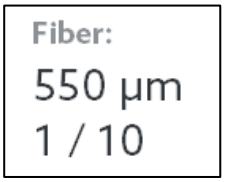
Energy (J) and **frequency** (Hz) adjustment does not require acceptance by pressing any confirmation button. In case of wrong adjustment, simply tune again the parameters according to the desired settings.

> When the user tries to increase the pulse energy over the maximum value available (with respect to the set frequency) the laser device will not allow additional energy increment, keeping both parameters unaffected.
>
> If the energy setting is too high for the selected frequency, the laser will automatically decrease the pulse energy value (output frequency is permitted to increase). The emitted sound, when firing, changes according to the selected frequency.

Note: in case of CW mode selected, the user can modify directly the output power.



5.2.1.4 *Fiber INFO*

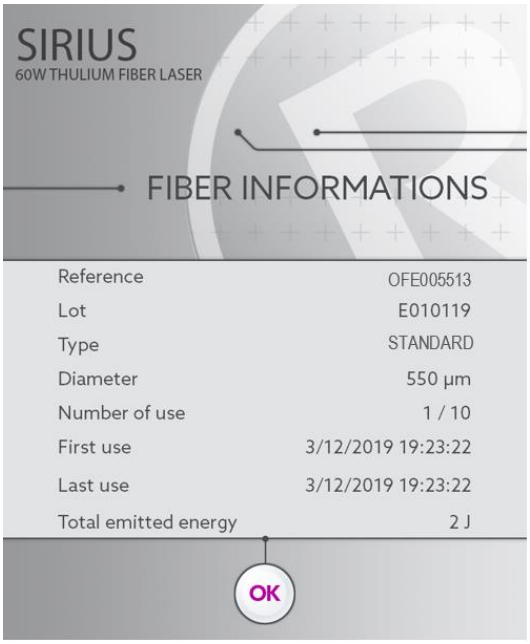


When a RFID Fiber is connected and the RFID system is active, the system automatically recognizes the type of the fiber and the number of the previous uses (see also Section 5.4.1), further showing the **Fiber Info Panel** on the display. The **Fiber Info Panel** appears also by pressing on the **Fiber Info area**.

Here you can find the following information:

- Fiber Code
- Fiber LOT
- Fiber Type
- Diameter
- Number of use
- Time of the first and the last use
- Total emitted energy

Press **OK** to return to the main Screen.



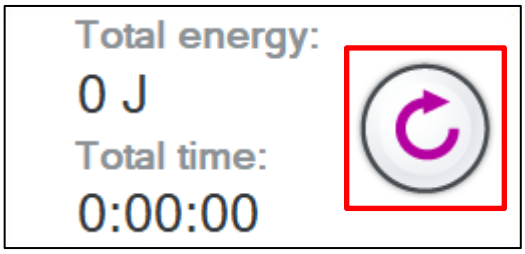
If an **unauthorized** fiber is connected to the RFID system, the fiber will not be recognized and an error message will appear.

If an **expired** optical fiber (disposable/reusable) is connected to the laser system, an error message will appear.

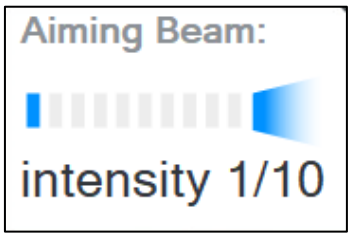
By touching the **Fiber Info area** with no fiber inserted, the user can approach the RFID connector to the laser port with the fiber still contained in its sterilization packaging. When doing so, the User can **identify the fiber without opening the fiber sterile envelope**. Follow the description detailed on the screen in order to perform this procedure.

5.2.1.5 *Counters*

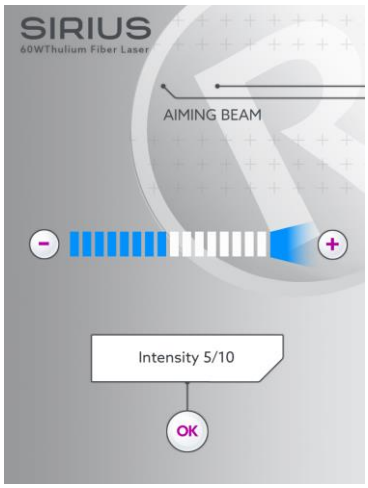
The emitted energy (Joules) and Lasing time counters are shown in the main screen and increase during radiation emission.
Press the highlighted button to reset the counters.



5.2.1.6 *Aiming beam*



The aiming beam is adjustable by software, by tapping on the related icon in the main interface. The current level of the aiming beam intensity is shown.

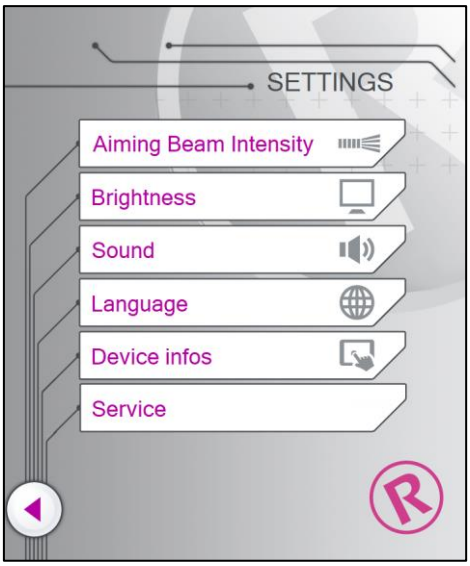


Touch the - / + buttons on the Aiming Beam settings screen (below) to decrease / increase the aiming beam intensity. Once the desired aiming beam intensity has been reached, press OK to confirm and return to the main screen.

NOTE: Pressing the Aiming beam Button on the Main Screen when the laser system is in Standby status, the green pilot laser will be activated, maintaining the laser system in Standby mode. This function gives the possibility to check connected fibers in a safe condition, evaluating the shape of the laser beam immediately out of the fiber tip.

5.3 **Settings**

When pressing the Settings button, the sub-menu panel will appear.

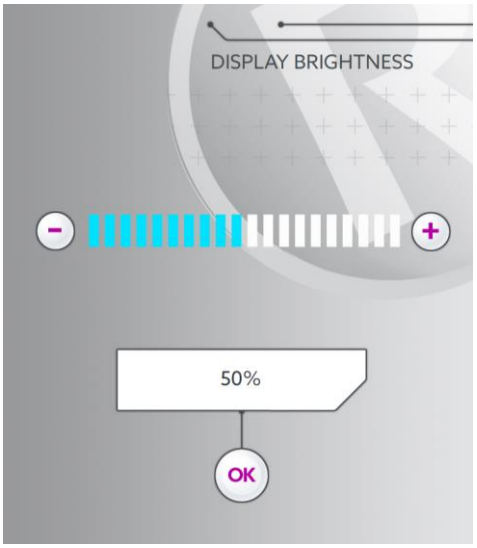


The available functions are the following:

- **Aiming beam intensity** (see section 5.2.1.6 Aiming beam)
- **Brightness**
- **Sound**
- **Language**
- **Device infos**
- **Service**

Press  to return to the Main Screen.

5.3.1 *Brightness*

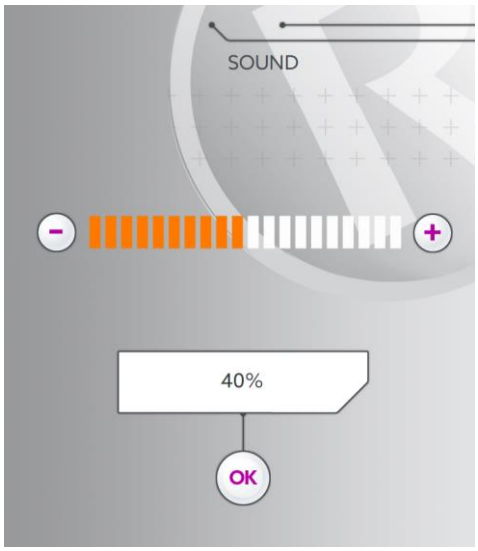


It is possible to tune the screen brightness.
Increase or decrease the sound volume using + / - buttons.
Press **OK** to give confirmation and return to the main interface.

Press  to return to the Main Screen.

Note: the percentage of the brightness, related to the max available, is shown on the screen.

5.3.2 *Sound*



The device emits an acoustic signal with a fixed duration when the device runs in READY mode and the footswitch is pressed. During the operation of the system, the emitted signal varies according to the frequency of laser pulses (almost synchronously for low frequencies).

By entering the Sounds Menu, it is possible to tune the sound level of the laser emission associated with the pressure of footswitch. Increase or decrease the sound volume using + / - buttons.
Press **OK** to give confirmation and return to the main interface.

Press  to return to the Main Screen.

Note: the percentage of the sound volume, related to the max available, is shown on the screen

5.3.3 *Language*

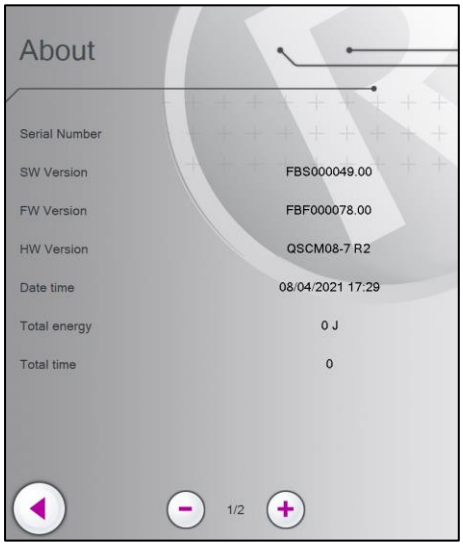
Select the desired language.

Press **OK** to confirm and return to the main interface.

Press  to return to the Main Screen.

5.3.3.1 *Device info*

The Device Infos Panel displays the following information:



- **Serial number**
- **Software Version (SW)**
- **Firmware Version (FW)**
- **Hardware Version (HW)**
- **Date time**
- **Total emission energy**
- **Total emission time**
- **Total emission pulses**

Move through the pages using + / - buttons.

Press  to return to the Main Screen.

5.3.3.2 *SERVICE (only for Technical Service)*

Use the keyboard to insert the Password and press OK to get access to the Service Area.

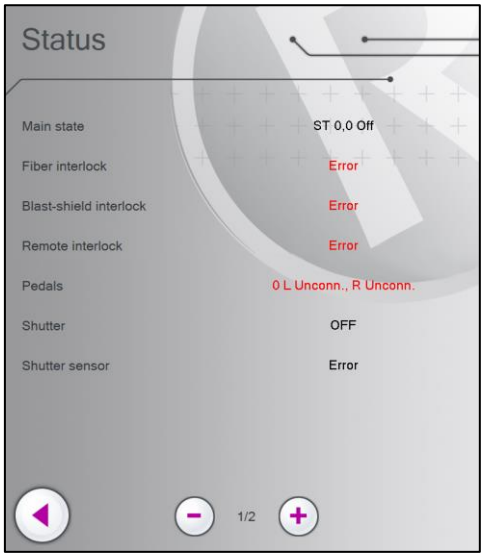
Press  to enter the Status Screen (see below).

Press  to return to the Main Screen.

5.3.3.3 *STATUS*

Without inserting the Service Password, it is possible to access the Diagnostics Panel by tapping on the “Diagnostics” button in the Service Screen.

On this screen, it is possible to check the device functioning parameters.



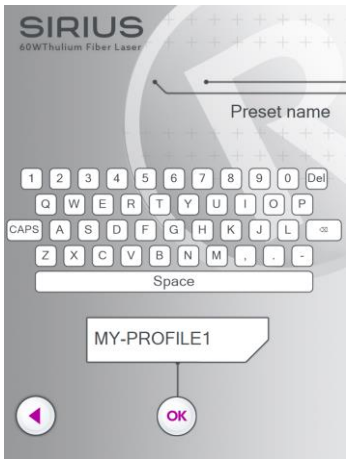
Move through the pages using + / - buttons.

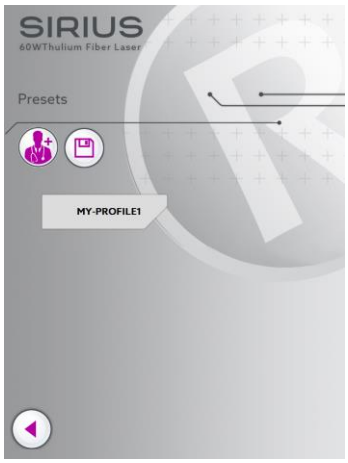
Press  to return to the Main Screen.

5.3.4 *Database*

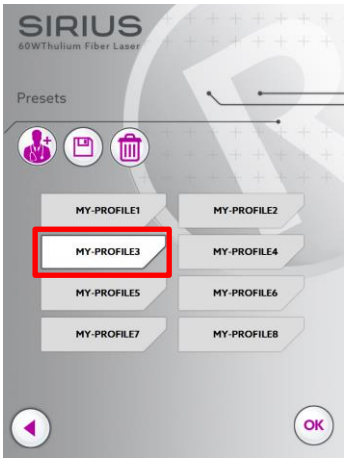
In the Database Menu, the user can:

- Press  to ADD a new preset;
- Press  to SAVE a desired set of treatment parameters (and overwrite a previous one);





- Select the preset (previously saved set of treatment parameters) and click  to LOAD a preset;
- Select the preset and click  to DELETE a preset. Press  to confirm the deletion.



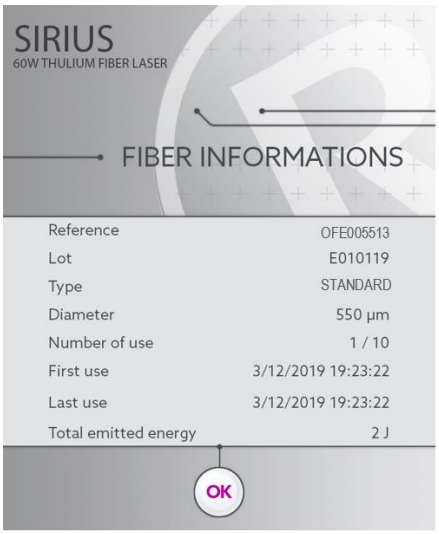
5.4 **Laser emission**

After setting the working parameters with suitable values, the user can start the laser emission as follows.

Laser Operation:

Press the Ready button in the lower part of the screen or push the dedicated button of the footswitch, changing the status from Standby to Ready.

5.4.1 *RFID fiber connection*



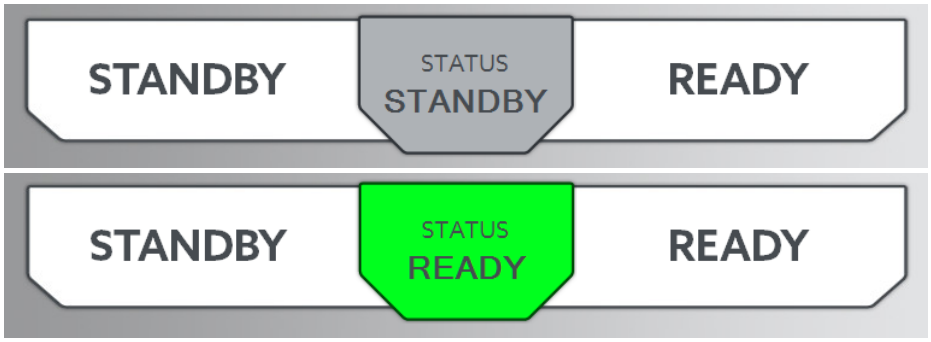
Open the external protective shutter by moving the sliding knob.
The system recognizes immediately its type and number of reuses, showing these information on a popup for a short time *(in the example picture, a disposable 200 µm fiber is ready to be employed for the 1th time)*.

Caution: *The optical fiber size visualized on the display must be the same of the used optical fiber. Before starting laser emission, please check that the optical fiber size matches the indications impressed on the fiber connector.*

5.4.2 *Ready / Standby*

When the user taps on the Ready/Standby area, the system will be set respectively in the Ready or Standby mode. In Standby mode the laser is not firing and the system cannot emit energy. In the Ready mode, the laser is firing and ready to emit energy.

The status area shows the current status of Laser System:



Along with the first change from Standby to Ready mode, the Warning Safety Screen will appear (see Section 5.5.3).

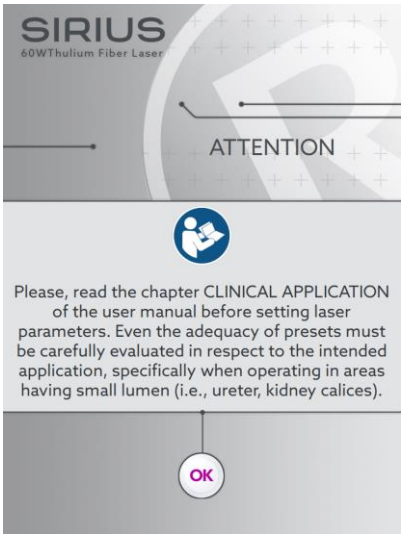
Warning: *Read carefully Chapter 2, LASER SAFETY, before operating the laser!*

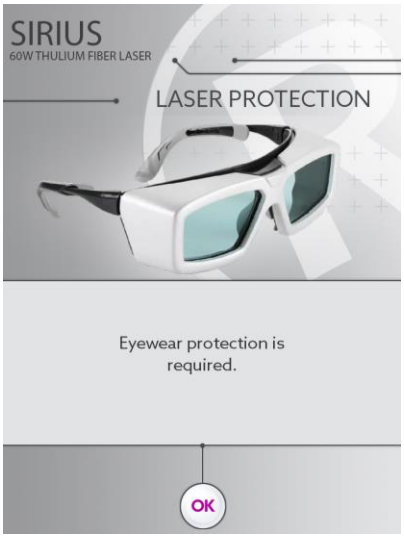
Warning: *All the personnel present in the laser working area must wear all the protective items.*

One can use the dedicated button on the footswitch element to change the system status from Standby to Ready or vice versa. The button on the footswitch, or the Ready/Standby display area can be used interchangeably.

5.4.3 *Ready mode*

When the user sets the device from Standby to Ready for the first time, the *Warning Safety Screen* will appear:

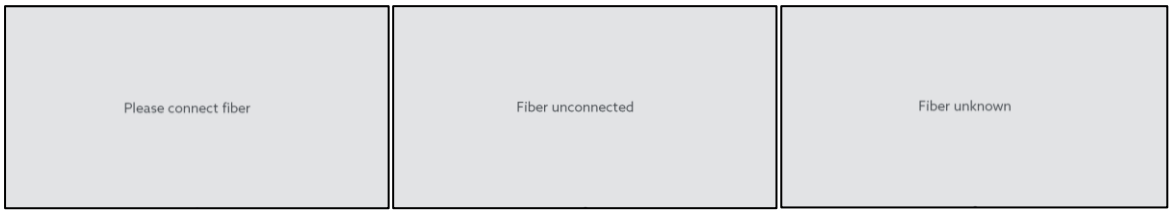




Touch 

to proceed, after the protection glasses worn.

When an Optical Fiber is connected, the type of the fiber is displayed on the screen before passing from Standby to Ready status. If the fiber is missing or an invalid fiber is inserted, an Error Message will appear when the user pushes the “Ready/Standby” button:



In READY mode, output energy and emission frequency can be still modified by the dedicate buttons.

The Touch Screen Control Panel contains the controls and displays for operating and monitoring the laser. It is essential that operators understand and use these controls properly.

5.4.4 *Emission*

In READY mode, the laser system starts to emit radiation as soon as the footswitch pedal is pressed: the laser beam is therefore delivered through the connected optical fiber. The values of radiation frequency and energy are shown on the display.
The operator must ensure that the set laser parameters are correct before actuating the footswitch.

Warning: *All the personnel present in the laser working area must wear all the protective items.*

During laser radiation emission, the device status turns into “*LASING*” and the Ready/Standby buttons will be inactive.

While delivering radiation, values of **emitted Energy**, in Joules, (**A**) and **Lasing Time** (**B**), will be increased. To reset the pulses/energy counters, refer to Section 5.2.1.5.

At the end of the treatment, release the footswitch and enter the Standby mode by pressing the Ready/Standby area on the display, or the dedicated button on the footswitch.

Note: *If footswitch pedal is kept released for a long time during the READY mode, the system will automatically enter the STANDBY mode.*

Warning: *While keeping the fiber tip inside of patient body, user should switch from Ready to Standby status when performing provisionally any procedure other than lasing.*

Warning: *Before removing the fiber from patient body, user MUST switch from Ready to Standby status (both when treatment is completed and when performing provisionally any procedure other than lasing).*

5.4.5 *Laser Parameters*

A wide range of combination of pulse energy (Joules, J) and frequency (Hertz, Hz) is available. The laser output power (Watt, W) for each possible combination is calculated (max 60 W) as follows:

$$\text{Power (W)} = \text{Energy (J)} \times \text{Frequency (Hz)}$$

The diameter, type and number of uses of the connected fibers are automatically detected. Optical fibers with diameter ≤ 200 µm may have limitations in the output power settings (energy / frequency) due to their technical features.

5.5 Error and warning description

Different errors may be displayed on the control panel. Every time an error occurs, a message appears at the top of the screen specifying the error type:

When an error occurs, the System behaviour is different depending on the issue level of severity:

ERROR Status: In the "ERROR" status power electronics are cut off through a suitable switch and the device starts running in a safe mode or gets restarted. This Error occurs every time the Control finds the System in a

status that is not-coherent with the command sent by the Microprocessor. This may occur also during the Start-Up procedure.

STANDBY Status: Some error/warnings force the system in "STANDBY" status, preventing to enter in Ready mode till the cause of the error has been solved

A complete list of all the possible errors types is provided below.

Error message	**Issue related** (see Chapter 8 – Troubleshooting)	**System behavior**
Connecting… **Cannot open Serial Port ComX**	Serial port communication fault	Message on screen
Capacitor voltage error	Capacitor voltage error	Force STANDBY status
Charger overload	Charger overload	Message on screen
Shutter not Closed ERROR	Shutter not closed	ERROR status
Shutter not Open ERROR	Shutter not open	ERROR status
Remote interlock open	The remote interlock contacts are open	Force STANDBY status
Pedal unconnected	Pedal not connected	Force STANDBY status
Pedal pressed in STANDBY	Pedal pressed in STANDBY	Message on screen
Blast Shield not present	Blast shield wrong installation	Force STANDBY status
Fiber not connected	Fiber not present/connected	Force STANDBY status
Fiber not identified	Fiber not identified by RFID	Force STANDBY status
Not identified and not selected	RFID warning	Force STANDBY status
Fiber code not valid	RFID warning	Force STANDBY status
Fiber expired	RFID warning	Force STANDBY status
High energy	Energy output warning	Message on screen (force STANDBY status if also "Energy sensor error" is present)
Low energy	Energy output warning	Message on screen (force STANDBY status if also "Energy sensor error" is present)
Very high energy	Energy output fault	Force STANDBY status
Very low energy	Energy output fault	Force STANDBY status
Energy sensor error	Energy output warning	Message on screen
Unwanted emission	Energy output fault	Force ERROR status
Laser source error	Laser source fault	Force ERROR status
Laser Internal Interlock Error	Laser source internal interlock fault	Force ERROR status
Critical Errors and Warnings appearing during start-up procedure		
Critical Error: FW_RAM	FW error	Message on screen - Fail safe status
Critical Error: FW_CRC32		
Critical Error: FW_FSCM		
Critical Error: FW Communication		
Critical Warning: FW watch dog	FW error	Message on screen - Fail safe status

5.6 Shutdown procedure and protection against unauthorized use

Once device operation is accomplished and the laser is in Standby mode, one can proceed with its shutdown procedure as follows:

- Disconnect the optical fiber from the device and cover the laser device output connector with its dedicated protection shutter
- Press the frontal ON/OFF button
- Turn the key switch to the ○ configuration and remove the key to prevent unauthorized uses
- Turn off the main switch on the rear panel and unplug the power cable
- Disconnect the remote interlock
- Disconnect the footswitch
- In order to disconnect the device from the mains it is necessary to detach the supply cable plug from the mains.
- Keep the device and its accessories in a dry and safe place

In order to avoid improper use of the device, keys shall be removed when the device is not being used.

5.7 Mains disconnection

In order to disconnect the device from the mains it is necessary to detach the supply cable plug from the mains.

6 CLINICAL APPLICATION

This section could help physicians in the use of the *Sirius* laser system. It adds or reinforces information presented in this User Manual about instructions for use, precautions and warnings necessary to reduce the risk of injury.
The following information must be considered as guidelines only, that do not replace the clinical knowledge of the surgeons. All operators must read the entire User Manual before reviewing this section and before operating the system.

6.1 Intended Use

Sirius laser is intended solely for use by surgeons and staff who have been appropriately trained and who are thoroughly familiar with the instructions and safety precautions provided in this manual. A review of the published literature is strongly encouraged and recommended.

The *Sirius* laser device 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 and lithotripsy of stones in use in medical specialties including: Urology, Thoracic and Pulmonary, ENT, Neurosurgery, Gastroenterology, Gynecology and General Surgery.

> ***Note***
> *The use of a laser instrument for an application is at the physician's discretion except in cases where the indication has been contraindicated.*
> *Physicians should frequently consult current literature and information provided in advanced workshops to keep abreast of the most effective and up-to-date practices.*

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

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and Resection of Bladder Tumors, Urethral and Ureteral Tumors
- Transurethral Incision of the Prostate (TUIP)
- Laser Resection of the Prostate
- Laser Enucleation of the Prostate
- Condylomas
- Lesions of external genitalia
- Urinary Lithotripsy

Thoracic and Pulmonary:
Open, laparoscopic and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue, including:

- Laryngeal lesions
- Airway obstructions including carcinoma
- Palliation of obstructing carcinoma of the tracheobronchial tree
- Lung Resection

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

- Sialolitiasis
- Endonasal/sinus Surgery
- Partial turbinectomy
- Polyps

- Dacryocystorhinostomy
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal area
- Tonsillectomy

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

- Removal / opening of membranes
- Excisions of benign tumors
- Ventriculocisternostomy
- Cystoventriculostomy

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

- Polyps
- Zenker Diverticulum
- Biliary/Bile duct calculi
- Gastric ulcers
- Duodenal ulcers
- Hemorrhoids
- Benign and Malignant Neoplasm
- Angiodysplasia
- Telangiectasias
- Telangiectasias of the Osler-Weber-Rendu disease (OWRD)
- Vascular Malformation
- Esophageal ulcers
- Mallory-Weiss tear
- Ablation of lesions potentially evolving in tumors.
- Ablation of vascular lesions with bleeding potential (e.g. GAVE)
- Hemostasis of bleeding lesions

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

- Intra-uterine treatment of submucous fibroids
- Benign endometrial polyps and uterine septum by incision, excision, ablation and vessel coagulation
- Soft tissue excision procedures
- Condylomas

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

- Lysis of adhesion
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resectomy of internal organs, tumors and lesions
- Tonsillectomy
- Partial Nephrectomy
- Pilonidal Cystectomy
- Hemorrhoids
- Zenker Diverticulum
- Incision, excision, resection, ablation, vaporization, couagulation and hemostasis of soft tissues

6.2 Treatment Parameters and Instructions

The *Sirius* 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 about laser use. No claim is made about the certainty of treating successfully any medical condition by laser.
All users and support staff must have thorough knowledge of its operation and its effects. Users should get acquainted with this manual and with the device in a non-clinical setting before using it for patient treatment 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 (Clinical Applications).
The *Sirius* is a Laser System emitting an invisible infrared beam at 1.9 µm wavelength. This laser beam is strongly absorbed by water (chromophore) which is ubiquitous in all tissues. Thus, the speed of cutting and vaporization action will remain relatively constant regardless of tissue vascularization.

6.2.1 *Treatment parameters and instructions for endoscopic procedures*

Before firing the laser, both aiming beam and fiber tip must be clearly visible through the endoscope. The aiming beam must be 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.

> **Caution:** *Fiber tip must protrude from endoscope when firing. Fiber or endoscope damage could result when operators do not comply with this provision.*

DO NOT START LASING AT MAXIMUM POWER. Begin the procedure with a low power and regulate the output power until the desired tissue vaporization/ablation/coagulation effect is achieved. Do not adjust laser power until the effect of the radiation on the tissue has been evaluated.
In endoscopic surgery within water-filled large environments (as in BPH procedure), it is possible to use the maximum output power (60W). It is possible to use the fiber in contact with the tissue.

If the fiber tip is submerged in water (e.g. endoscopic incision/ablation of soft tissues in urology treatments), it is possible to use the fiber in contact with the tissue. Conversely, if this condition does not apply, some tissue may remain attached to fiber tip upon ablation/cutting when in contact with the tissue. Thus, where/when possible, a near-contact (small distance) approach should be preferable in this case.

> **Warning:** *When the fiber is firing in contact with no liquid in between of fiber tip and target tissues or is deepened into that, the user should fire with extreme caution as the interaction between laser and tissue is not (or only partially) visible. Wrong evaluation of ongoing process may result in unwanted tissue damage or perforation.*

Ablation/Vaporization effect decreases when the distance between fiber tip and the tissue increases. On the contrary, Coagulation effect increases when the distance between fiber tip and tissue increases.

Depending on the environment where the surgical procedures is being carried out, different treatment recommendations apply:
o Water-surgery in large cavities: When using the laser in water (as the surgical irrigation solution) within large cavities (as in bladder during BPH treatment) **it is recommended to start ablation or cutting at 30W** and adjust the power according to the observed effect. 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 tip or by decreasing the laser power.

o Water-surgery in small cavities/channels: Conversely, when using the laser in water (as the surgical irrigation solution) within small cavities or narrow channels (as in ureter), **it is recommended to start ablation or vaporization at 5-10W** and adjust the power according to the observed effect. 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 tip or by decreasing the laser power.

o Other endoscopic procedures: When using the laser endoscopically, without any fluid in between of fiber tip and targeted tissue, **begin the procedure at a lower power (5-10W)** and increase the power until desired tissue effect is achieved. Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated. It is recommendable to use the fiber in non-contact with the tissue (distance from 1mm). If tissue adheres to the fiber tip, the fiber has to be extracted from the endoscope so that the tissue can be removed. For information and warnings regarding smoke formation, hemostasis and interaction with tissue, the same indications reported for laparoscopic procedures apply.

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. Similarly to any endoscopic prostate procedure involving tissue removal (including TURP, HoLEP, HoLAP or PVP), possibility of capsular perforation does exist. To minimize the risk of capsule perforation, it is important to recognize the end point of the procedure. The fiber has to be kept moving, without directing laser energy towards a fixed site for a prolonged time

When the treatment area is not filled with water, as the output power increases the smoke formation process increases. The treatments in endoscopic surgery could cause smoke formation and hinder dramatically field visibility (similarly to electro-ablative surgical tools), therefore the surgeon shall evaluate the use of a smoke evacuator system (if possible) or the use of water injection in the area of treatment to dissipate the smoke.

> **N.B.:** Maximum device power (60W) must be used with extreme caution and exclusively when the user is fully acquainted with the *Sirius* device and laser surgery within that specific field. Use of high power settings should be limited to treatment of large organs / tissue portions only (e.g. in prostate surgery and lung resection) and its use is under the responsibility of the operator based on his best medical knowledge.

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

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

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

6.2.1.1 *Clinical Parameters for Soft Tissue in Urology*

The thulium wavelength provides effective haemostasis without damaging surrounding or non-targeted tissues. Coagulation can be achieved by reducing the energy or power density over the vascularized tissue or by increasing the distance between fiber tip and point of bleeding.

The following table shows the suggested maximum power and recommended fibers for endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in urological applications:

Application	*Average Power (Watts)*	*Recommended Fiber Size*
Bladder Tumours	max 30	365 - 550 µm
Ureteral Tumours	max 15	272 - 365 µm
Incision of Strictures	max 30	272 - 550 µm
Benign Prostatic Hyperplasia	max 60	≥550 µm

Table 1 Urology-Recommended treatment clinical parameters

NOTE: *Laser settings are guidelines only; always start with low settings and increase them progressively to achieve the desired tissue effect.*

Benign Prostatic Hyperplasia
Note: Effect on tissue can be further tuned by the MasterPULSE when in pulsed mode: short pulse width generallty enhances mechanical dissection, whereas long pulse width generally results in gentler cutting of tissue.

Other Soft Tissues
Note: Effect on tissue can be further tuned by the MasterPULSE when in pulsed mode: short pulse width generally results in a more aggressive action, whereas long pulse width generally results in gentler ablation/cutting of tissue.

6.2.1.2 *Clinical Parameters for Urinary Lithotripsy*

Pre-clinical and clinical testing have demonstrated that urinary calculi can be safely and effectively fragmented from pulsed emission starting with power settings of 0.5 or 0.6 Joules and at a frequency of 5 or 6 Hertz.
The use of high-power output settings requires special attention, especially when the fiber tip is in close proximity to the ureteral walls in order to avoid ureter perforation. Similarly, for lithotripsy in other body areas, the use of high-power output settings requires special attention, especially when the fiber tip is in close proximity to tissues and structures that are particularly thin and fragile and/or must not be perforated/ablated as nerves, vessels and arteries functional membranes.

For effective fragmentation, the tip of the optical fiber should be directly in contact with the stone. Whenever possible, laser energy should be directed at the side of, or at weak points, in the stone.
The stone should be progressively reduced in size by slowly removing small fragments.
Continuous irrigation should be used to wash away stone fragments and to provide cooling of the treatment site.

DO NOT START LASERING AT MAXIMUM POWER. Begin the procedure with a low power (e.g. 5-10W in pulsed mode) and increase the output power until the desired effect is achieved.

Application	*Average Power (Watts)**	*Recommended Fiber Size*
Bladder Calculi	max 60	≥ 550 µm
Ureteral Calculi	max 15	272 – 365 µm
Renal Calculi	max 20	150 – 272 µm

**pulsed mode only*

Note: *Laser settings are guidelines only; always start with low settings and increase them progressively to achieve the desired tissue effect.*

Warning: T*he user must understand that the greater the increase of settings, the greater the additional energy released (along with fluid heating risk of injury risk).*

Use small pulse energy in order to minimize the size of fragments.
Consider using a shorter pulse duration in case of harder stones.
Use short pulse duration and high pulse energy in order to maximize the speed of fragmentation

Warning: In general, when performing endoscopic stone lithotripsy, it is recommended to start with a minimum power setup. High power setting (<20-30W) should be used with caution.

Further refer to "Treatment parameters and instructions for Endoscopic Procedures" section for additional information.

6.2.2 *Treatment parameters and instructions for open surgery & laparoscopic procedures*

Before firing the laser, the aiming beam and fiber tip must be clearly visible and directed towards the targeted tissue. Direct the aiming beam towards the tissue you intend to treat. Never fire the laser unless you can see the aiming beam on the targeted tissue. Use of a surgical handpiece is recommendable when manipulating the fiber.

Caution: *when firing, fiber tip must protrude from equipment operative channel (e.g. handpiece cannula). Damage to fiber or device operative channel could result when operators do not comply with this provision.*

DO NOT START LASERING AT MAXIMUM POWER. In open surgery or in laparoscopic procedures (with the fiber tip non-submerged in water solution) begin the procedure at a lower power (**5-10W**) and increase the power until desired tissue effect is achieved. Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated.
When using the laser in open surgery or in laparoscopic procedures with the fiber tip submerged in water solution, it may be reasonable to increase the output power (with respect to a similar endoscopic situation without irrigant presence) and adjust the power according to the observed effect. Indeed, part of the emitted energy will be absorbed by the liquid in between of fiber tip and targeted tissue.

In open surgery a maximum output power equal to 40W is recommendable.
It is recommendable to use the fiber in non-contact with the tissue (distance from 1mm).

N.B.: Maximum device power (60W) must be used with extreme caution and exclusively when the user is fully acquainted with the *Sirius* device and laser surgery within that specific field. Use of high power settings should be limited to treatment of large organs / tissue portions only (e.g. in lung resection) and its use is under the responsibility of the operator based on his best medical knowledge.

Warning: *When the fiber is firing in contact with the tissue or is deepened into that, the user should fire with extreme caution as the interaction between laser and tissue is not (or only partially) visible. Wrong evaluation of ongoing process may result in unwanted tissue damage or perforation.*

Ablation/Vaporization effect decreases when the distance between fiber tip and the tissue increases. On the contrary, Coagulation effect increases when the distance between fiber tip and tissue increases.

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 tip or by decreasing the laser power keeping the same distance from the tissue.

If tissue adheres to the fiber tip, the fiber has to be extracted from the endoscope so that the tissue can be removed.

The treatments in open surgery and laparoscopy could cause **smoke formation**, as in the similar surgical procedure with electro-ablative surgical tools, therefore the surgeon has to evaluate the use of a smoke evacuator system. As the output power increases, the smoke formation process increases.

6.3 General Laser Warnings

The physician or surgeon should become fully acquainted with the unique surgical and therapeutic effects produced by the 1.9 µm wavelength before using the Quanta System *Sirius* Laser in a clinical environment. These effects include coagulation, depth of penetration and cutting intensity.

Caution should be used with power (Watts) and lasing duration until the surgeon is completely familiar with the biological interactions of laser energy with various types of tissue. Unless otherwise stated in the specific application section, the surgeon should begin with the lowest power and use short duration exposures. The surgeon should observe carefully the induced surgical effect and adjust laser 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.

Warnings:

- The *Sirius* 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 about the certainty of treating successfully any medical condition by laser.
- BEFORE operating the laser system, surgeons and all staff operating this device should read carefully Chapter 2 of this manual.
- Surgeons using Quanta System *Sirius* Laser System must understand the laser's unique properties prior to using the device.
- Before turning the laser system on, operating room personnel and the conscious/sedated patient should wear protective eyewear suitable for 1.9 µm laser energy.
- Careful assessment of the target and surrounding tissue should be made, and appropriate power and pulse duration should always be used.
- Use extreme caution until the biological interaction between laser energy and tissue is thoroughly understood.
- 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 or concurrent illness. The risk of infection and scarring associated with any surgical procedure has to be taken into account as well. Therefore, appropriate pre- and postsurgical care should always be practiced.
- Tissue perforation may result if excessive laser energy is applied. This could occur through the use of excessive laser power or the application of a correct power for excessive periods, particularly in diseased tissue.
- Incorrect treatment settings can cause serious tissue damage; therefore, it is recommended that you use the lowest acceptable treatment settings until you get familiar with the instrument's capabilities
- Aim and use the laser only on tissues that are fully visible.
- The laser should be used only on tissues that are fully observable. Do not use the laser if the desired target is not visible.
- Extra caution should be used when lasing tissue close to known arteries, nerves and veins.

- Use of the laser on anatomical structures in proximity to known critical structures, such as large arteries, veins, nerves, bowel, ureter, bladder, etc., should be performed carefully to avoid inadvertent or unintended treatment of such structures.
- Begin laser treatment at the lowest power, with short duration exposures until fully familiar with effects of the applied wavelength on the tissues.
- Flash fire may occur. Refer to Chapter 2 for more information. A bowl of water should be available in case a fire occurs. Inhalation general anaesthetics must not be used if flammable. Oxygen levels in the direct surgical area must not exceed 50%. The risks of combustion, perforation, and laser-induced haemorrhage, any of which could cause death, must be fully explained to the patient.
- The flammability of methane gas must be considered when treating in or near the perianal area.
- Quanta System S.p.A. has no clinical information or experience concerning the use of the *Sirius* 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 *Sirius* 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 hemorrhage situations. The surgeon must be prepared to control hemorrhages with alternative non-laser techniques, such as ligature or cautery.
- 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 resulting 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 tissue texture and color are the best indicators of laser impact upon the targeted area. Specific pulse duration depends on the tissue and is left to 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 employed. Excessive power settings may cause damage to the Disposable Optical Fiber Delivery Devices.
- The use of mechanical pressure on the Disposable Optical Fiber Delivery Devices does not increase its cutting or vaporization effects but may induce bleeding, thermal damage and fiber destruction.
- For equal powers emitted from laser source, fibers with smaller diameter generate greater power densities (on the contrary fibers with bigger diameter generate lower power densities). Thus, the operator must regulate the output power (on laser device display) taking into account the fiber diameter.
- There is an increased risk of back-scatter (reflection) and forward scatter (penetration) when using the laser in non-contact mode.
- Different energy densities induce different effects upon tissues, therefore using fibers with different diameters with the same output power could have different outcomes on irradiated tissues. Employed laser power has to be tuned also according to fiber diameter.

6.4 General Laser Precautions

- 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 too large to be coagulated by 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 problem.
- Quanta System has no clinical information concerning the safety of laser treatment on pregnant or nursing women.
- Refer to the delivery system instruction guide for use instructions.

6.4.1 Urology precautions and warnings

- Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distension could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.
- Extra precautions should be taken when radiation therapy and laser therapy have to be carried out 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 fiber protrudes 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).
- Please further refer to the section "*Treatment parameters and instructions for Endoscopic Procedure*" for additional information regarding endoscopic surgery in urology field.

6.4.2 Precautions and warnings in other medical specialties

Thoracic and Pulmonary Surgery
It is suggested not to overcome a 40W output emission during lung resection (or at least to be extremely careful when doing so).

Lithotripsy

- The laser should be used with an optical fiber delivery system in direct view and in direct contact with the targeted ureteral stone. To minimize the potential migration up to the ureter, laser energy should be directed to the side of the stone, if possible, rather than the leading edge. Maintaining low energy levels and repetition rates will reduce the potential for possible stone migration.
- Be aware of edematous folds of epithelium that may lie between the optical fiber and the stone.
- Basketing may be used with larger stone fragments that are relatively hard or tend to escape to the ureter in a retrograde fashion.
- Baskets, guide wires, and other endoscopic accessories may be damaged by direct contact with the laser beam.
- The use of irrigation is recommended throughout the lithotripsy procedure to absorb any produced heat, to carry stone fragments out of the urinary system, and to enhance direct visualization. The rate of irrigation should be carefully adjusted to avoid flux of calculi into the kidney.

Other medical specialties:
Please refer to General Laser Warning and General Lasr Precautions for additional information

6.5 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 issues generally resolve without treatment.
- Laser ablated tissue may become necrotic or infected after treatment. In case of any concern about possible infection, 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. In case of any concern about possible sepsis, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. In order to diagnose perforations, patients must be followed carefully post-operatively with appropriate tests.

   **Warning:** *As with any conventional surgical operations, adverse reactions may occur following treatment. Use cautiously with patients who have had difficulty with previous laser procedures*.

Complications and risks are the same of the conventional laser surgery. These include, but are not limited to, the following:

Complications and non-thermal risks:

- Perforation;
- Aspiration;
- Induced hemorrhage;
- Allergic reaction to medication;
- Hypertension;
- Arrhythmia;
- Pain;
- Distension due to gases;
- Pneumothorax;
- Infection

Complications and thermal risks (acute)

- Induced hemorrhage;
- Ulceration;
- Perforation;
- Edema;
- Pain;
- Fever;
- Leukocytosis;
- Chills

Complications and thermal risks (critical)

- Healing delay;
- Perforation;
- Stenosis;
- Delayed hemorrhage;
- Sepsis;
- Embolism.

6.5.1 Complications for Urology

As with other endoscopic urologic procedures, there may be urine leakage following the laser procedure.

- The use of flexible endoscopes carries a risk of stricture formation; these rates may improve with further advances in ureteroscope design.
- Although rare, loss of a kidney may occur as a result of the procedure or because of the stone itself.
- Complications following endoscopic BPH management (and other endoscopic treatments for urinary soft tissues) may include UTI, AUR, urethra stricture, BNS, TUI and haematuria.
- Read General laser complications for a list of additional complications.

Complications for Ureterorenoscopy (URS):

- Minor complications are fever, macro haematuria and pain. In literature, the rate of significant complications (sepsis, ureter perforation or torn ureter) is repeated to be 3-11%.
- Urinary strictures as a long-term complication have become rare and are estimated to be 1-3%. Previous ureter perforations represent the key risk factor.

Complications for Percutaneous Kidney Surgery:

The following complications are more prone to occur:

- Fever, sepsis
- Bleedings requiring transfusion
- Absorption of irrigation fluid
- Perforation of the intestine
- Lesion of the pleura
- Sub-pelvic stenosis
- Loss of kidney
- Open revision

6.5.2 Complications in other medical specialties

Complications for ENT Surgery

- Swelling of the nasal membranes may cause nasal airway obstruction for up to one week. Patients should be followed after treatment to clean the nasal cavity from debris.
- Perforation of the orbit or intracranial cavity may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed after treatment with appropriate tests.
- The potential complications for transoral surgery apply when this surgical approach is chosen (e.g. hoarseness).

Read General laser complications for a list of additional complications.

Complications for Gynaecology

Read General laser complications for a list of additional complications.

Complications for Thoracic and Pulmonary Surgery

- As with the use of stapler, postoperative air leakages may occur

Read General laser complications for a list of additional complications.

Complications for General Surgery

Read General laser complications for a list of additional complications.

Complications for Lithotripsy

- The use of flexible endoscopes carries a risk of stricture formation; these rates may improve with further advances in ureteroscope design.
- For other complications related specifically to a certain medical specialty, further refer to the relevant section.

Read General laser complications for a list of additional complications

Complications for Gastroenterology Surgery

- Patients may experience gastrointestinal distension or pneumothorax during or after therapy.
- Swallowing may be worsened, rather than immediately improved, following esophageal procedures due to secondary tissue edema. This potential problem should be explained to the patient prior to the therapy.

Read General laser complications for a list of additional complications.

Other medical specialties

Read General laser complications earlier in this chapter for further information.

6.6 Contraindications for laser surgery

The use of the laser is contraindicated:

- In patients whose general medical condition contraindicates surgical intervention
- When appropriate anaesthesia is contraindicated by patient history or inability to receive anaesthesia.
- Where tissue (especially tumors) is calcified.
- For hemostasis of vessels with diameters over approximately two millimeters.
- Where laser therapy is not considered the treatment of choice.
- In patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- In patients unable to receive endoscopic treatment.
- In patient suffering from bleeding disorders and coagulopathy.

6.6.1 *Specific Precautions and Contraindications*

Urology:

The laser must not be used with patients with the following conditions:

- Inability to receive endoscopic treatment.
- Intolerance to anaesthesia.

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 anesthesia is contraindicated by patient history.
- Where tissue is calcified, especially tumors.
- Diagnosed with Prostate Cancer.
- Diagnosed with Acute Urinary Infection (UTI).
- Diagnosed with 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.

Contraindications for Uretero-renoscopy (URS):

- Acute proneness to bleeding, anticoagulation therapy
- Untreated infections of the urinary passages
- Difficult access to the stone in case of:
    - Narrow ureter
    - Adenoma of the prostate
    - Urinary diversion (conduit, neo bladder, pouch, urinary diversion through intestinal segments)
    - Implantation of new ureters
    - Ureteroceles
    - Ureteral / Urethral strictures

Contraindications for Percutaneous Nephrolithotomy (PCNL):

- Acute proneness to bleeding, anticoagulation therapy
- Untreated infections of the urinary passages
- Tumor in the access area
- Pregnancy
- Difficult access to the stone in case of:
    - Skeletal anomalies
    - Renal anomalies
    - Intestinal interposition
    - Pleural interposition

Read General contraindications for laser surgery earlier in this chapter for further information.

Gynecology:

- Current clinical data do not support a claim for indicating the use of the 1.9 µm 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

Read General contraindications for laser surgery earlier in this chapter for further information.

Gastroenterology:

The thulium wavelength should not be used in patients with any of the following conditions:

- Inappropriate candidates for endoscopic or laparoscopic treatment
- Contraindicated for patients with previous multiple abdominal surgery
- Intolerance to anaesthesia
- Contraindicated for patients with Intestinal obstruction

Read General contraindications for laser surgery earlier in this chapter for further information.

Thoracic Surgery:

- Contraindicated for patients with lung emphysema (risk of prolonged air leakages upon surgery)
- Contraindicated for patients with pulmonary hilar tumor close to large vessels.

Read General contraindications for laser surgery earlier in this chapter for further information.

ENT:

The thulium wavelength should not be used in patients with any of the following conditions:

- Inappropriate candidates for endoscopic treatment
- Endonasal malignant neoplasm
- The use of thulium laser is not recommended for stapedotomy/stapedectomy.

Read General contraindications for laser surgery earlier in this chapter for further information.

Lithotripsy:

- Contraindicated in case of inability to receive endoscopic treatment and intolerance to anaesthesia.
- Contraindicated in case of difficult access to the stone.
- The laser should be used with an optical fiber delivery system in direct view and in direct contact or close proximity with the target stone.
- Be aware of edematous folds of epithelium that may lie between the optical fiber and the stone.
- Baskets, guide wires, and other endoscopic accessories may be damaged by direct contact with the laser treatment beam.
- The use of irrigation is recommended throughout the lithotripsy procedure to absorb any produced heat, to carry stone fragments out of the urinary system, and to enhance direct visualization. The rate of irrigation should be carefully adjusted to avoid flux of calculi into the kidney.
- Unexpected tissue damage may occur due to excessive power application. Use of excessive power may result in inadvertent perforation or damage of tissue structures.

Read General contraindications for laser surgery earlier in this chapter for further information.

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 (e.g. spleen, liver)

Read General contraindications for laser surgery earlier in this chapter for further information.

Other medical specialties:

- No specific information, refer to General Contraindications and precautions.

7 MAINTENANCE, CLEANING AND STERILIZATION

This section contains mainly user information regarding the care and cleaning of the device. Should you require any assistance concerning maintenance or technical intervention, please contact Quanta System (or refer to the Service Manual to find more information).
The laser, cooling system and control electronics are enclosed in a tamper-resistant console.

 **Caution:** *The laser instrument does not contain any component that the user is authorized to modify or repair. Only service personnel authorized by the manufacturer can perform any modification of the device including the replacement of the power supply cable.*

7.1 Device cleaning

The Sirius laser device does not need special maintenance by the user. Switch off the device before starting the cleaning procedure. Clean the visible surfaces with a damp cloth, taking care not to let the water enter the device (in particular attention must be paid in not spilling any drop on monitor frame interstice and monitor itself). Do not use alcohol or disinfectant solutions, because they are highly flammable. While cleaning, be careful not to let the cleaning solution leak in the fiber connection port. Use the supplied caps to close the fiber connection port after each use. Do not use any alcohol solution to clean the display.

7.2 Laser Maintenance and technical check

The Sirius Laser device is designed for maximum safety and performance. Under normal operating conditions and when respecting a careful use, the manufacturer recommends a check-up of the device by a qualified technician every 12 months.
The intensive use, dust, or continuous movement of the laser in different places may require a more frequent monitoring.

7.3 Safety labelling check

The user must regularly verify the integrity and readability of the security labels placed on the device.
If labels are damaged, they must be replaced immediately in accordance with the plan described in paragraph 2.13, **Labelling plan**.

7.4 Check of the line cable

The Sirius device has a detachable line cable. The line cable can be subject to deterioration over time and therefore must be checked periodically its status.

 ***Warning:*** *Only the Manufacturer or trained and qualified personnel are permitted to substitute the line cable, in case of deterioration.*

7.5 Optical fiber maintenance

 ***Warning:*** *Be sure that fiber sterilization is not expired (expiration date is reported on fiber label).*

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

7.5.1 *Fiber management (application cycles)*

The number of application cycles of a laser fiber is mentioned on the label or in the instruction manual of the optical fiber. The RFID system keeps record of the number of uses (correlated with the required sterilization cycles) that the fiber undergoes.

Only the use of RFID Rocamed Fibers is allowed with the Sirius Laser System.

Caution: *A disposable laser fiber cannot be used a second time after the first use!*
A single-use laser fiber, even if new, in any case cannot be re-sterilized a second time!

After the use of a disposable laser fiber or at the end of the application cycles of a reprocessable laser fiber, change the old fiber with a new one.

7.5.2 *Check the optical fiber before operation*

Caution*: Before each use, check the shape of the aiming beam to verify the effective quality of the beam pattern. This check can be done by placing the fiber perpendicularly to a surface with the aiming beam activated.*

If the optical fiber connection is damaged, replace the optical fiber immediately. If optical fiber tip is dirty or damaged, renew it by following the instructions reported inside fiber user manual.
If you want to inspect the quality of the connected fiber in a safe way (Standby mode), you could activate the pilot laser without entering the Ready mode and evaluate its output profile. When performing this procedure, tap on the pilot laser area on the screen and tune that by selecting the desired intensity.

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

Caution: Read carefully and follow optical fiber instruction manual.

7.6 Blast shield replacement

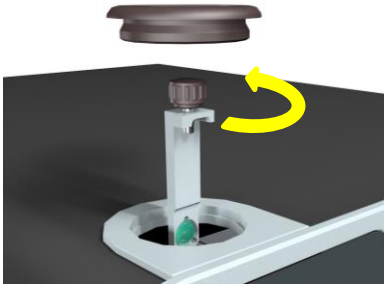
Any detection of efficiency decrease in laser emission or frequent failures of the connected optical fibers must be followed by an immediate check of the condition of the Blast Shield.

If the blast shield window has black spots, it must be replaced with a new one.

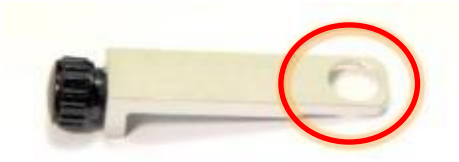
Warning: *This operation must be carried out with clean hands and extreme caution to avoid optical damage of the device*

The blast shield replacement must be performed in the following way:

1. Turn the device off, disconnecting the equipment from mains
2. Open the door knob
3. Remove the blast shield by unscrewing the knob



4. Check the protective glass for any visible damage
5. In case of damage, replace the whole blast shield paying attention not to touch the protective glass with hands



Example of new blast shield

Example of damaged blast shield

6. Reinsert the blast shield and firmly screw the knob
7. Close the protective door by screwing firmly the door knob
8. If you need assistance, please contact Service Department

8 TROUBLESHOOTING

Laser devices are designed to have the best performance and maximum safety. If the system does not work properly, the following diagnostic table may assist in identifying the cause.

Fault	Possible causes	Remedy
Turning the device key is not producing any detectable effect	• Plug not connected • Main switch not turned on • Emergency LASER STOP activated	• Check for main input • Deactivate Emergency LASER STOP switch
Energy error	Fluctuation of energy parameter during laser radiation	• Wait a few seconds for stabilization. • Call the service
Serial port communication fault	• This warning appears when the serial communication from PC to microprocessor fails	• Restart the system • Call service
Capacitor voltage error	• Power supply error or broken • Charger error or broken	• Call service
No correspondence between displayed energy and treatment effects and/or decrease of laser efficacy	•Fiber damaged • Blast shield mirror broken	• Change fiber/ Blast shield • Call service
Shutter not closed	• Incorrect shutter position	• Call service
Shutter not open	• Incorrect shutter position	• Call service
The remote interlock contacts are open	• The ext. Interlock is not connected or is poorly connected	• Control ext. Interlock connection
Pedal not connected	• Wrong pedal connections	• Check connections
Pedal pressed in STANDBY	• Pedal(s) should be pressed at the right moment	• Enter in Ready mode and press the footswitch
Blast shield wrong installation	• Wrong blast shield installation	• Check Blast shield • Call service
Fiber not present/connected	• Wrong fiber installation	• Check the fiber connection
Fiber not identified by RFID	• Wrong fiber installation • Wrong fiber type	• Check the fiber connection • Change fiber
RFID warning	• Wrong fiber type	• Change fiber
RFID warning	• Wrong fiber code	• Check or change fiber
RFID warning	• The fiber is expired	• Change fiber
Energy output fault	• The emission is too high or low	• Call service
Laser source error	• Laser source fault	• Restart the system • Call service
Critical Errors and Warnings appearing during start-up procedure		
FW error	• Message after new FW release installation • FW issues	• Shut down and restart • Call service
FW error	• FW issues	• Shut down and restart • Call service

Fault	Possible causes	Remedy
Turning the device key is not producing any detectable effect	• Plug not connected • Main switch not turned on • Emergency LASER STOP activated	• Check for main input • Deactivate Emergency LASER STOP switch
Energy error	• Fluctuation of energy parameter during laser radiation	• Wait a few seconds for stabilization. • Call the service
Serial port communication fault	• This warning appears when the serial communication from PC to microprocessor fails	• Restart the system • Call service
Capacitor voltage error	• Power supply error or broken • Charger error or broken	• Call service
No correspondence between displayed energy and treatment effects and/or decrease of laser efficacy	•Fiber damaged • Blast shield mirror broken	• Change fiber/ Blast shield • Call service
Shutter not closed	• Incorrect shutter position	• Call service
Shutter not open	• Incorrect shutter position	• Call service
The remote interlock contacts are open	• The ext. Interlock is not connected or is poorly connected	• Control ext. Interlock connection
Pedal not connected	• Wrong pedal connections	• Check connections
Pedal pressed in STANDBY	• Pedal(s) should be pressed at the right moment	• Enter in Ready mode and press the footswitch
Blast shield wrong installation	• Wrong blast shield installation	• Check Blast shield • Call service
Fiber not present/connected	• Wrong fiber installation	• Check the fiber connection
Fiber not identified by RFID	• Wrong fiber installation • Wrong fiber type	• Check the fiber connection • Change fiber
RFID warning	• Wrong fiber type	• Change fiber
RFID warning	• Wrong fiber code	• Check or change fiber
RFID warning	• The fiber is expired	• Change fiber
Energy output fault	• The emission is too high or low	• Call service
Laser source error	• Laser source fault	• Restart the system • Call service
Laser Internal Interlock Error	• Laser source internal interlock fault	• Restart the system • Call service
Critical Errors and Warnings appearing during start-up procedure		
FW error	• Message after new FW release installation • FW issues	• Shut down and restart • Call service
FW error	• FW issues	• Shut down and restart • Call service

*In case the device must be sent back to the company, fill the RMA request enclosed in **Appendix A** and send it to your local distributor.*

9 CUSTOMER SERVICE

9.1 Manufacturer Warranty and Responsibility

The Manufacturer will disclaim any responsibility for any misuse of the system.

The Manufacturer shall not be held responsible for any damage or failure deriving from incorrect use of the device.

Correct use consists in:

- following the instructions described in this manual
- following a proper maintenance program for the system.
- complying with national and international safety standards.

The *Sirius* system is warranted against any defect in material and workmanship for a period of one (1) full year from its delivery.

Repairs necessary as a result of natural disasters, accidents, electrical circuit failures, negligence, improper use or misuse of the appliance, or servicing or repairs carried out by persons not authorized by the Manufacturer, or by Rocamed S.A.M, are not covered by warranty.

Manufacturer staff must be allowed free access to the appliance.

Any repair that cannot be carried out on site will be effected in our labs.

- Warranty and responsibility of the Manufacturer will also expire for any of the following reasons:
- Use of the device not conforming to the procedures and instructions reported in the user manual.
- Incorrect installation and maintenance.
- Use of an out of order, not correctly installed or damaged safety system.
- Noncompliance with instructions of this manual concerning: transportation, storage, installation, and maintenance.
- Arbitrary alteration of the device.
- Incorrect repairs.
- Accidents caused by external element.

In no case the customer can be entitled to claim compensation for any damage resulting from the machine being out of operation.
On demand, the manufacturer will provide all technical information including electrical drawings, list of components and suggested applications protocols.
Please contact your distributor for Warranty information.

9.2 Repairs and Modifications of the Device

- Only authorized service personnel can execute repairs and maintenance.
- It is recommended to follow the standard maintenance program.
- It is strictly forbidden to unauthorized personnel to open the laser system and have access to any part or component of the device. The device contains dangerous parts and components that only trained and authorized personnel can access.

9.3 Service Department Contacts

Rocamed provides its customers with e-mail and telephone troubleshooting, in addition to customer trainings, repairs and maintenance.

Please contact Rocamed Customer Service through the contacts reported below. Please keep on hand the Serial Number of your device.

ROCAMED S.A.M.
Tel. +377 97 98 42 43
info@rocamed.eu
www.rocamed.eu

9.4 Reporting of serious incidents

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

10 TECHNICAL SPECIFICATIONS

10.1 General specifications

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	100-240 Vac; 50/60 Hz; 1000VA
Type of protection against electric shock	Class I
Degree of liquid ingress protection	IP 20 for the device IPX8 for the footswitch
Degree of electric shock protection	Type BF
Mode of operation	Continuous
Dimension	470mm (W) x 600mm (D) x 350mm (H)
Weight	50 kg
Operating temperature	15° - 30° C[1]
Storage/ Transport temperature	Min. + 5° C / max. 40° C
Atmospheric pressure	800-1060hPa
Operating humidity	30% - 85% non-condensing
Cooling system	Air cooling system
Max noise	< 70.0 dB
Fuse	breaking capacity *magneto-thermal* protection *switch*
Shelf life	10 years after production is discontinued *(With a proper ordinary and extraordinary maintenance, the device life is limited by the availability of spare parts, that are assured for 10 years after the manufacturing is discontinued)*

[1] *With a room temperature between 25°C and 30°C, continuous operation is granted with a maximum power up to 40 W.*

10.2 **Laser source specifications**

Laser type	TFL (Thulium Fiber Laser)
Wavelength	1940 nm ± 20 nm
Maximum power	60 W
Pulse Energy	0.02-6J
Operating mode	Pulsed / CW
Pulse duration	Up to 15 ms
Repetition rate	1-2500Hz
Beam divergence	440 [-40] mrad – 540 [+40] mrad
Beam transmission	Optical fiber system
Aiming Beam	Laser Diode, green 532nm (adjustable) < 5mW, class 3R
Exposure time	100 s
MPE	1000 W/m^2
NOHD	0.62 m
OD	2
Glasses specification	1940 D LB4

Note 1: During the lifetime of the device the laser energy values can diverge from the declared ones by a 20% maximum.
Note 2: The device is provided with internal measuring system to control the actual emission of the laser energy. The device does not require calibration by the user.

Warning: *Equipment not suitable for use in the presence of flammable mixtures.*

NOTE! To prevent damage during transport or shipment of products, we recommend using the original packaging material.

11 **ACCESSORIES**

Accessory	Description
Frontal optical fiber with RFID System (available according to customer requirements)	Sterile single-use and reusable bare optical fibers with core diameter from 150 up to 1000 µm.
Fiber stripper 1	Fiber stripper for 0,3-1 mm diameter
Fiber stripper 2	Fiber stripper for 0,1-0,4 mm diameter
Fiber cutter	Ceramic fiber cutter
Safety Goggles	Safety Goggles

12 Appendix A: RMA Request

SERVICE/ASSISTANCE REQUEST
RICHIESTA DI ASSISTENZA TECNICA
RMA NR:

FROM/DA:

TO/A: Rocamed S.A.M.
DATE/DATA:
DEVICE MODEL/MODELLO:
S/N:
MALFUNCTION DESCRIPTION / DESCRIZIONE DEL MALFUNZIONAMENTO:

DETAILED LIST OF THE SPARE PARTS/ DEVICE/ ACCESSORIES RETURNED TO Rocamed S.A.M. /
ELENCO DEI MATERIALI E ACCESSORI SPEDITI A Rocamed S.A.M.:

Please contact Rocamed S.A.M. to report the malfunctions, manufacturing defects and non-conformities of your device. If you need to send back goods or medical devices to Rocamed S.A.M. , send this document by fax and wait to ship the goods until the Service Department assigns a RMA number.

Contattate Rocamed S.A.M. con questo modulo per comunicare malfunzionamenti, difetti di produzione e non conformità del Vs. sistema. Se è necessario rispedire materiali o il dispositivo stesso a Rocamed S.A.M., inviate questo modulo via fax e aspettate a spedire le merci finché il Servizio di Assistenza non Vi ha assegnato un numero di RMA.

13 Appendix 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.

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.

IEC 60601-1-2 Table 201 **Guidance and manufacturer's declaration – electromagnetic emission**		
The equipment **SIRIUS** is intended for use in the electromagnetic environment specified below. The customer or the end user of the **SIRIUS** should assure that it is used in such an environment		
Emission test	**compliance**	**Electromagnetic environment - guidance**
RF emission – CISPR 11	Group 1	The **SIRIUS** 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 A	The **SIRIUS** is not suitable for installation in all buildings including domestic and those directly connected to the public supply network in low tension, but only in buildings like the hospital with dedicated supply system.
Harmonic emission IEC 61000-3-2	Compliant	
Voltage fluctuation/flicker emission IEC 61000-3-3	Compliant	

IEC 60601-1-2 Table 202 Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment **SIRIUS** is intended for use in the electromagnetic environment specified below. The customer or the end user of the **SIRIUS** should assure that it is used in such an environment			
Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 KV contact ±2, 4, 8, 15 KV air	Compliant	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	±2 KV for power supply lines ±1 KV for I/O lines	Compliant Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±0.5, 1 KV for power supply lines (line to line) ±0.5, 1, 2 KV for power supply lines (line to earth) ±2 KV for I/O lines	Compliant Compliant Not applicable	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	Dips: 0% Ut for 0,5 cycle 0% Ut for 1 cycle 70% Ut for 25 cycles (50 Hz) 70% Ut for 30 cycles (60 Hz) Interruptions: 0% Ut for 250 cycles (50 Hz) 0% Ut for 300 cycles (60 Hz)	Compliant	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **SIRIUS** requires continued operation during power mains interruptions, it is recommended that the **SIRIUS** be powered from an Uninterruptible Power Supply or Battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Compliant	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>
<tr><td colspan="4">IEC 60601-1-2 Table 204
Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The equipment SIRIUS is intended for use in the electromagnetic environment specified below. The customer or the end user of the SIRIUS should assure that it is used in such an environment</td></tr>
<tr><td>Immunity test</td><td>IEC 60601
Test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communication equipment should be used no closer to any part of the SIRIUS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance.
d=1,167*sqrt (P)</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3Vrms (150KHz to 80MHz)</td><td>Compliant</td><td>d=1,167*sqrt (P) 80 MHz to 800 MHz
d=2,333*sqrt(P) 800 MHz to 2,7 GHz

Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [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:</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>10 V/m
80 MHz to 2.7 GHz</td><td>Compliant</td><td></td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

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 assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **SIRIUS** is used exceeds the applicable RF compliance level above, the **SIRIUS** should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **SIRIUS**

b) Over the frequency range 80MHz to 2.7 GHz, field strength should be less than 10 V/m.

IEC 60601-1-2 Table 206
Recommended separation distances between portable and mobile RF communication equipment and the SIRIUS

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

	Separation distance according to frequency of transmitter		
Rated maximum output power of transmitter W	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 2,7 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.

EMC WARNING

The device is suitable for professional environment only, such as hospitals and surgery room.
When subject to Electromagnetic disturbance, the device assures, as essential performance, that laser emission accuracy is within 20% from the set value. By design the device cannot emit unwanted laser radiation due to a disturbance.
Warning: use of this equipment adjacent or stacked with other equipments should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipments should be observed to verify that they are operating normally.
Warning: portable RF communication equipments (including peripherals such as antenna cables and external antennas) other than RFID optical fibers should not be used closer than 30 cm to any part of the device, otherwise degradation of performance could result.

RFID SYSTEM INFORMATION

This laser device incorporates an RFID system that allows to read the information present in the RFID tag of our optical fibers and write on them.
Quanta optical fibers have a tag incorporated in their connector so that communication happens any time the fiber is connected to the laser device.
RFID communication has the following functions:

- Check if the fiber is compatible with the laser;
- set proper laser output limitations based on the fiber diameter;
- read the number of remaining possible uses, impairing the use of a fiber with no remaining uses available;
- Decrease of one the number of uses of a fiber, when it is used.

RFID specifications:
- Working frequency: 125kHz
- Operating mode: Continuous transceiver mode with passive RFID Tag (optical fiber)
- emission level: < 7dBµA/m
- operating distance: within 5cm.

14 **Appendix C: Logbook**

Diario / Logbook				
#	Data Date	# Colpi # Shots	Operazioni Eseguite Operations Done	Firma Signature
1			Collaudo Finale / Final Test	