ROCAMED

Hemera

200W Tm:YAG Laser System

User Manual

DGM001318.03

CE 0123

Rev date 24/07/2020

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.**

Notice

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

Disclaimer

ROCAMED provides this document in its commitment to help facilitate consistent, positive clinical outcomes, and to reduce patient risk and injury. These guidelines are not, however, intended to in any way replace or substitute a physician's duty of care, professional responsibility, or professional judgment, nor are they intended to provide any warranty, promise, guarantee, assumption of risk or duty, release, or indemnity. Physicians shall at all times maintain responsibility for patient treatment and outcomes, and ROCAMED further assumes no liability for patient treatment or outcome or for physician's negligence, breach of duty of care, or malpractice. In no way does this or any of ROCAMED's policies, procedures, training materials, guidelines, or instructions create an obligation for ROCAMED to perform any services. Products and services may be purchased from ROCAMED or Distributor Certified/Trained by ROCAMED.

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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**

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1 GENERAL INFORMATION

1.1 Introduction

The *HEMERA* Medical Device is a diode-pumped, solid-state, 200 W Tm:YAG laser, emitting at 2010 nm wavelength invisible radiation.

This manual contains important information regarding the safe use of the *HEMERA* medical device. It describes the instrument, use procedures, various inspections, routine maintenance and operator information for the use and care of the optical fibers used for laser radiation release to the patient.
Medical people using the *HEMERA* 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 further information regarding the installation, clinical applications or other problems 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 this medical device. It is intended to be used as a guide. Reported instructions were written specifically for staff who is fully trained in laser and conventional surgery.
This manual does not represent an alternative to surgical preparation. In addition, it does not provide specific technical information regarding operations of the medical device assistance. 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. For this reason, reading carefully through this manual before operating the laser for the first time represents a safety requirement 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 against the **risk of injury** from laser radiation (**Fig. 1**):  **Fig. 1: Symbol for Warning**

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 (Fig. 2).  **Fig. 2: Symbol for Caution**

1.4 Symbols and Abbreviations

Symbol	Description
	Read the enclosed documentation label
CE 0123	CE label
	Symbol of applied part type 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
	Device Part Number
	Medical Device symbol
	Fuses Symbol
	Manufacturer
NOHD	Nominal Ocular Hazard Distance
MPE	Maximum permissible exposure
µm	Units, micro meter
s	Units, Second
mrad	Units, milliradiant
W	Units, watt
J	Units, Joule
J/cm^2	Units, Joule for centimetre square
cm	Units, centimetre
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

1.5 Manufacturer

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

Manufactured by:

Quanta System S.p.A.
Via Acquedotto, 109
21017 Samarate (VA), ITALY
quanta@quantasystem.com
www.quantasystem.com

Distributed by:

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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 *HEMERA* Laser System.

Caution: *Products may be incorrectly combined! Injury of the patient and users or damage to the product are 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 device.*

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.
- Laser cover 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.*

2.2 Classification

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

2.3 System Safety Features

The *HEMERA* 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 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 the Ready (to fire) status when the READY button is pushed.
- A continuous audible tone is heard when the surgical beam is activated (i.e. foot pedal is pressed). This tone is different for the two pedals of the footswitch (yellow and blue).
- An Emergency Laser Stop switch is available to disable the system immediately, in case of emergency.

NOTE! *Do not attempt to remove any panel from the laser console. Any attempt to remove the panels, unless instructed by authorized personnel, can damage the laser and will void Manufacturer's warranty.*

2.4 Training of the Medical Staff

The use of this laser device is restricted to the specialist medical staff* only, who, 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 be adequately trained on laser safety standards.

**This device must only be used by adequately qualified and trained medical personnel with experience in the medical specialties listed in Section 6 of this operator's manual*

2.5 Working Area

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

IMPORTANT!
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 when no operator is inside 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 *HEMERA* can cause sight 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 the retina can result in temporary clouded vision, retina lesion, long-term scotoma and long-term photophobia.

A danger exists in any case of:

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

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

Use protective goggles with the following specifications according to the laser protection standard

2010 I LB3 for laser source Tm:YAG at 2010 nm

In addition, even if you wear goggles, never look directly at the laser beam.

 **Warning:** *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 goggles cover glasses are in good condition.*

To avoid any mix-up, laser goggles require adequate identification. Laser goggles with a higher degree (or level) of protection (such as LB3, LB4, ...), or goggles featuring a broadband filter of protection stage LB2 or higher also covering wavelengths around 2100 nm, could also be used.

The skin is generally able to withstand higher levels of laser radiation, but it can also be burned to a greater or lower degree depending on exposure duration and intensity. If necessary, wear suitable protective clothing.

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

Divergence Full angle (mrad)	Exposure time (s)	MPE (W/m^2)	NOHD (m)	OD
440	10	1000	1.13	3

From NOHD values we deduce that the laser system has to be used in an enclosed area that does not allow the direct, reflected or transmitted escape of 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 kept 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.
In accordance with safety Standards, the device is normally supplied with a cable with different plugs related to the different countries and models:

230 V, IEC309, 16 A, 50/60 Hz

 **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. The working temperature of the device should reside between 10°C and 30°C, whereas the humidity should not exceed 85%.

2.7.3 *Minimum space requirements*

The suggested minimum room size is 3×3 meters. Allow 50 cm of clearance on both sides of the device preventing air fan obstruction.
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 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 how brief, may raise the temperature of any material. This phenomenon is the basis of many useful medical and surgical applications; it is also the reason why these applications often require precautions against the risk of igniting combustible materials in and around the treatment area.

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

- Do not use any flammable substance, such as alcohol or acetone, in the preparation of the skin for treatment. Use soap and water if necessary.
- 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, allow the evaporation of solvents or glues or flammable solutions used to clean or disinfect.
- Attention: endogenous gases can catch fire or explode.
- Never use in presence of flammable anaesthetic gases or oxidant gases like oxygen or N2O.

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 Measures for the Electromagnetic Compatibility (EMC)

The device does not include any type of direct connection with other external devices.
The device could be disturbed by the interference with external electromagnetic fields generated by other electrical devices installed next to it.

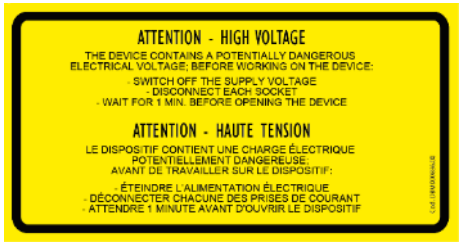
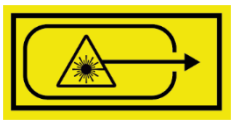
 **Warning:** *Turn off mobile phones and similar devices while operating the device.*

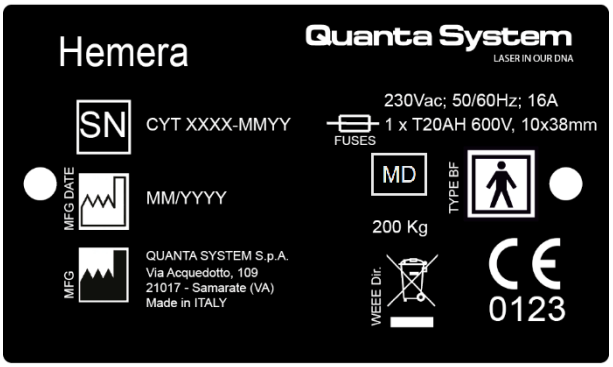
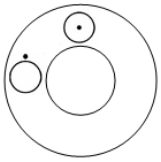
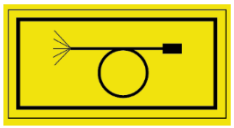
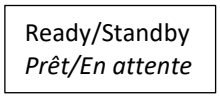
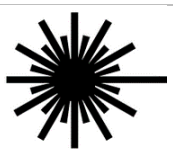
This device must be installed and used according to EMC information described in the tables reported in Appendix B.

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 the national standards regulating 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.

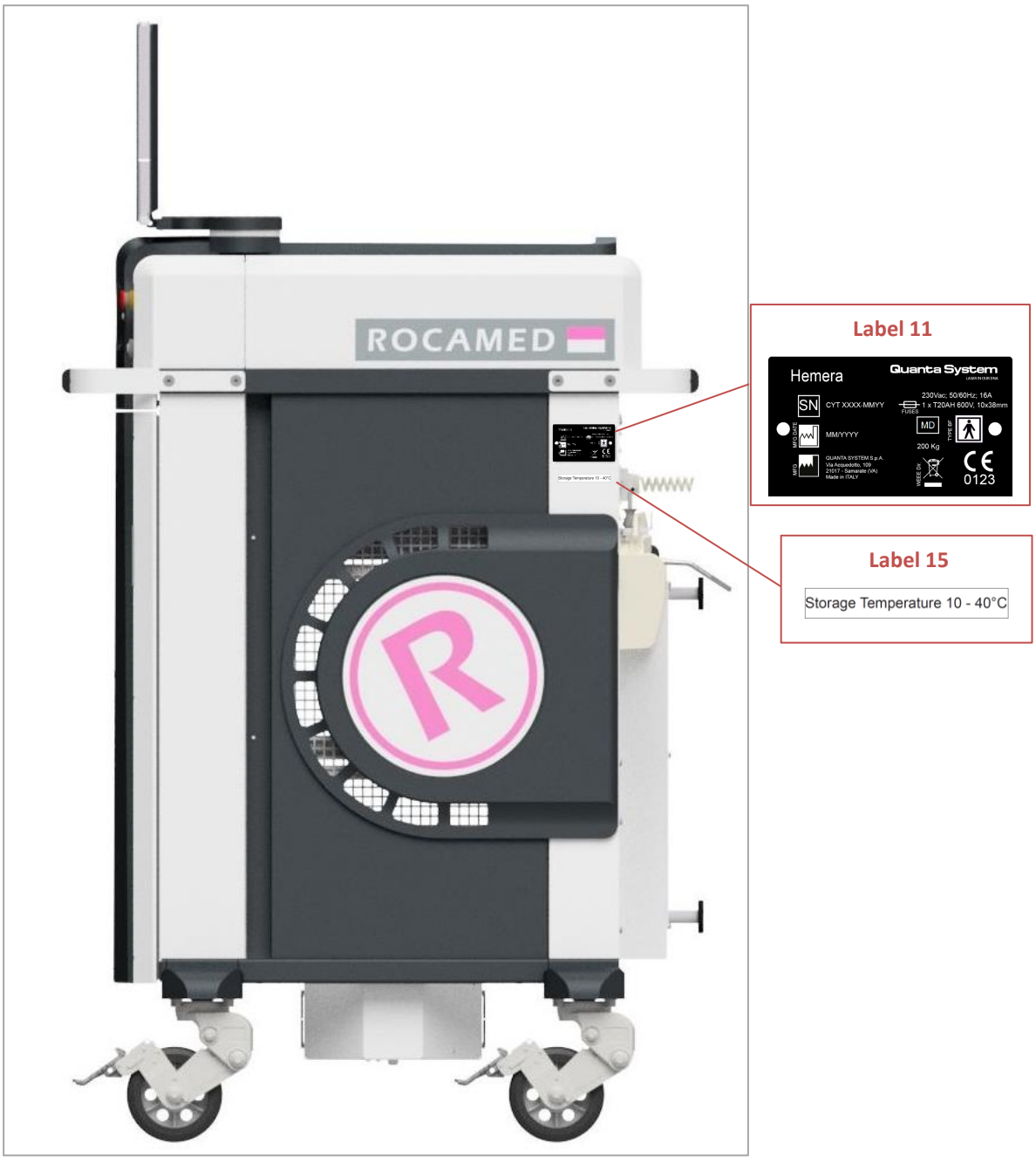
2.13 **Labelling Plan**

	**Label 1** Laser Characteristics
	**Label 2** Warning label of laser radiation
	**Label 3** High Voltage warning label
	**Label 4** Warning label – hazard symbol according to IEC 60825-1
	**Label 5** Laser aperture label
	**Label 6** Interlock connector label
	**Label 7** Footswitch connector label
	**Label 8** Emergency stop label (1)

	**Label 9** Emergency stop label (2) according to IEC 60601-2-22
	**Label 10** Read Instruction for Use label
	**Label 11** Rating label
	**Label 12** ON and OFF key switch logic interface
	**Label 13** Equipotential connector symbol
	**Label 14** Label of applied part type BF (according to IEC 60601-1)
	**Label 15** Storage Temperature
	**Label 16** Optical fiber applicator
	**Label 17** Footswitch “ready/standby” label
	**Label 18** Footswitch “emission” label
	**Label 19** UDI label (01) Product identifier (11) Manufacturing date (21) Serial number

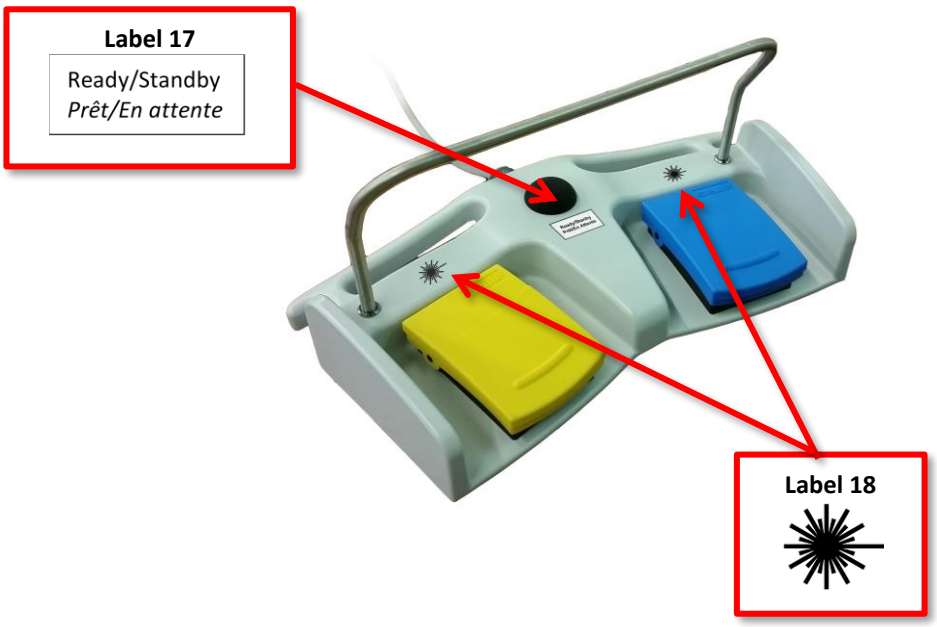
2.13.1 *Front view*

2.13.2 *Side view*



2.13.3 *Rear view*

2.13.4 *Footswitch*



3 DEVICE DESCRIPTION

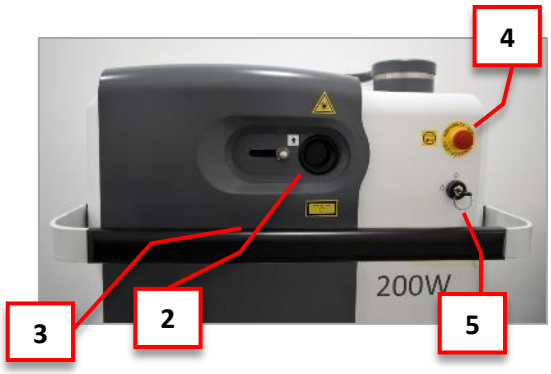
This Chapter provides a general description of the device and all its parts.
Optional accessories, such as optical fibers, are associated with the device (for a list of these optional accessories, refer to Chapter 11 "Accessories").

3.1 Introduction

The *HEMERA* laser system is a diode-pumped, solid state Tm:YAG laser. The laser system delivers invisible 2010 nm laser radiation.
Different fibers are available for different applications, with a core diameter ranging from 200 to 1000 µm. Each fiber has its own RFID tag that manages fiber recognition and keeps track of the number of fiber uses.
The laser system has an internal air-cooling system, ensuring safe operating temperatures with no permanently attached water tubes.

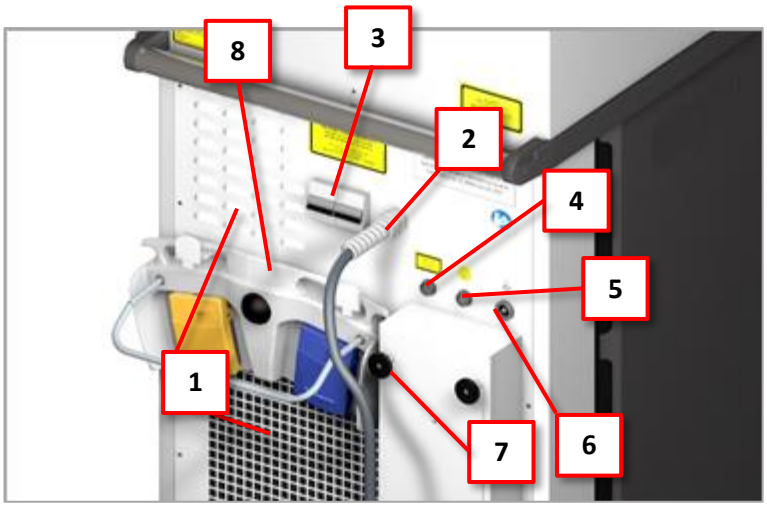
3.2 General Description of the Device

3.2.1 *Device front view*



1. Touchscreen Display (control panel)
2. Optical fiber connector (*WARNING: this is a laser aperture!*) and RFID antenna, protected by the External Protection Shutter
3. Sliding knob of the external **protection shutter**
4. Emergency red push button
5. Key switch
6. Front panel to access the hydraulic circuit loading connector and alarm internal display

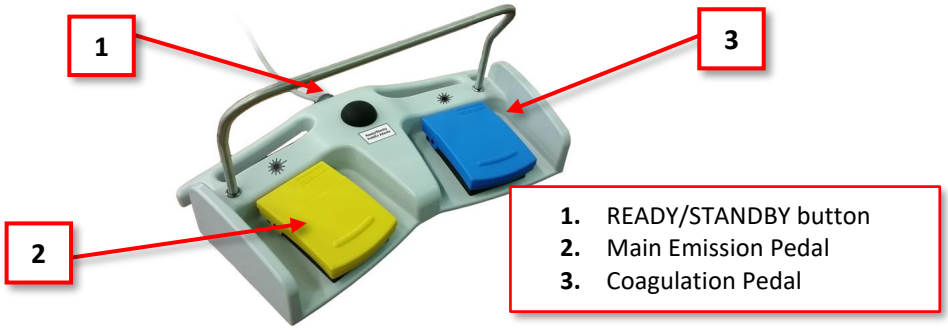
3.2.2 *Device rear view*



1. Air Exhaust
2. Power supply cord
3. Power/mains switch
4. Interlock connector
5. Footswitch connector
6. Equipotential connector
7. Cord storage
8. Footswitch (inside its dedicated housing)

3.2.3 *The double footswitch*

The double footswitch allows to change the system status (**1**), to activate standard laser emission (**2**) or to activate laser coagulation emission (**3**):



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.*

3.3 Electrical Controls

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 ON the device, insert the key and turn it clockwise - ⊙ configuration.

To switch OFF the device, 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.

3.4 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 re-sterilizable.
For more information about cleaning and sterilization of the fibers, refer to Chapter 7.

 **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).*

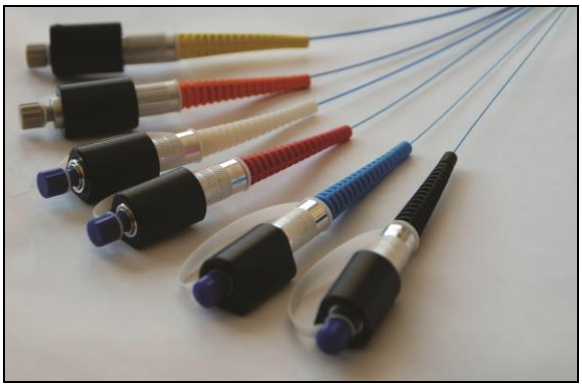
 **Warning:** *The metal sheath protects the user and the patient from the potential radiation emission in case of breakage of the fibers inside.*

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

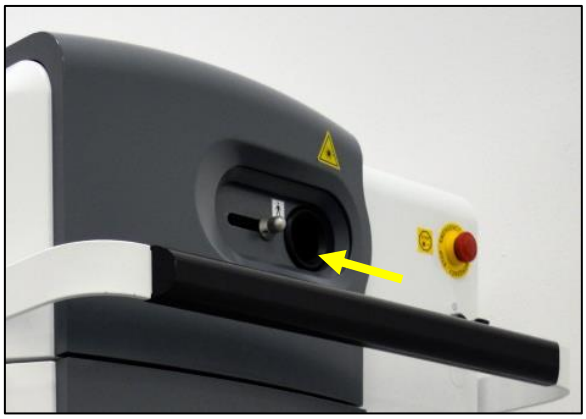
 **Caution:** *The use of fibers or accessories different from those supplied by the Manufacturer does not guarantee the achievement of security requirements.*

The fibers RFID tag

All the optical fibers are equipped with either a RFID tag which is directly fixed on fiber connector (black component around fiber extremity in the figure below).



The optical fiber has to be screwed into fiber port (yellow arrow in figure below), enabling automatic fiber recognition (through the coupling between RFID tag and antenna). Information on fiber type, diameter and number of uses…, are displayed on the screen.



Please refer to Section 4.6 for further details about fiber connection procedure.
HEMERA will work only when the fiber has been recognized and accepted though the RFID system, allowing *HEMERA* to enter the READY mode.

The ***policy* concerning optical fiber** usage is reported below:

- Each fiber has a specific number of sessions (written on the RFID tag);
- After all the sessions have expired, the fiber will not be considered anymore suitable for use.
- A session starts when the operator presses a footswitch pedal.
- A session ends as soon as the fiber has not been connected with the laser device for 20 minutes (disconnection event).
- Fiber information can be retrieved by pressing the dedicated display area (please refer to Section 5.2.6).

3.4.2 *Important prescriptions*

- Remove the *HEMERA* fiber optic from its sterile package by using an aseptic technique.
- Before starting the surgical procedure, the *HEMERA* fiber optic should be checked for damage.

- Connect the fiber hub into the fiber port on the laser system console. Keep the connecting end of the fiber clear of debris or liquids.
- Enter the READY mode to activate the aiming beam (**CAUTION:** *Do not press the footswitch while checking the aiming beam!*). Place the distal end of the fiber on a non-reflective sterile surface and move it slowly until the aiming beam can be visualized. If the aiming beam is not visible, the fiber may be defective and should not be used.
- Check for kinks or bright areas along the entire length of the *HEMERA* fiber. Do not use the fiber if it has been damaged.
- Once the *HEMERA* fiber has been checked, return the laser to the STANDBY mode.
- Position the *HEMERA* fiber optic at the targeted treatment site. The tip of the *HEMERA* fiber should be in clear view and protrude approximately 1 to 2 cm beyond the distal end of the endoscope.
- Set the laser in READY mode to enable the footswitch control.
- Laser software automatically compensates for fiber energy losses so that the power level shown on the system video display indicates the actual amount of power delivered to the tissue.
- Treatment times vary based on distance to tissue, power settings, and other factors.
- The efficiency of vaporization will decrease with increasing distance from the tissue and coagulation may result.
- Do not bend the fiber at sharp angles.
- Avoid contact of fiber tip with tissue. If the tip accumulates debris during the procedure, turn the laser to the STANDBY mode, remove the *HEMERA* fiber from the cystoscope, and carefully wipe the tip clean with a sterile gauze or towel. Begin at the end of the fiber and wipe along the fiber tip.
- Specific pulse duration depends on the tissue and is left to the surgeon's preference and best medical judgment.
- The lowest possible power settings required to achieve the desired tissue effect should be used for treatment.
- Higher power wattages may be necessary to achieve the desired tissue effects if fluid cooling is utilized.
- 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.

Warning: *Different energy densities induce different effects on 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.*

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

4 SYSTEM INSTALLATION

Device installation requires safety precautions, power requirements and environmental conditions to be followed within the working area.

Qualified technical personnel, authorized by the manufacturer, must perform the installation of the laser device. 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 without reading this manual. The warranty does not cover any damage occurred prior to installation.*

4.1 Transportation

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

4.2 Packaging

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

4.3 Inspection

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

- **Administrative check:**
  - Number of packages
  - Sizes and weights

- **Technical check:**
  - Packaging condition

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

4.4 Labeling Check

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

4.5 Installation Procedure

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

During installation, the device must be checked for proper operation and possible malfunctions after its transportation. Any observed problem must be corrected immediately.
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 packed materials are checked immediately upon their arrival, if possible, in the presence of the shipper's delivery employee, as follows:

- Open the packaging and put the laser device in a proper site for a general check.

- Execute the following operations for the general check:
  - ✓ Check the labels of the device
  - ✓ Remove the label "Caution no water inside"
  - ✓ Connect the remote door interlock
  - ✓ Connect the footswitch
  - ✓ Fill the system cooling circuit **with bidistilled or deionized water only**
  - ✓ Connect the laser device to the power supply
  - ✓ Connect the optical fiber
  - ✓ Check the laser device, its calibration and standard operation.

- After the general check:
  - ✓ Remove the optical fiber
  - ✓ Remove the footswitch
  - ✓ Remove the interlock
  - ✓ Remove the key

Note: *The Manufacturer 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. The Manufacturer is not responsible for any possible damage caused during this phase.*

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

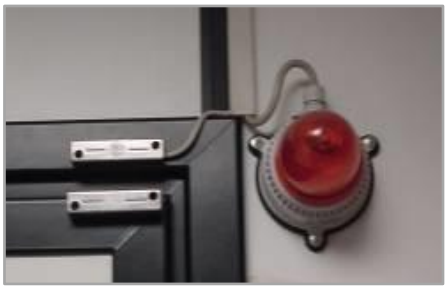
4.5.1 *Mains connection*

Once all the checks have been performed 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.

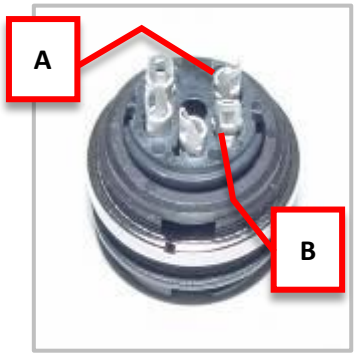
4.5.2 *Remote interlock connection*

According to IEC EN 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 open.



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 on the left). 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 device installation.

The interlock connector is wired on the laser side in the following way:

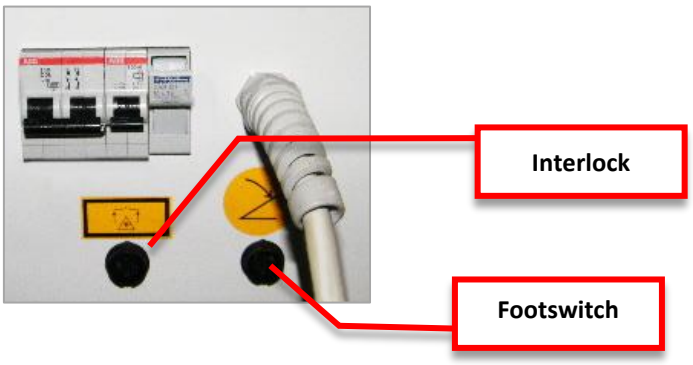


Pins A and B of the external micro switch have to be wired to the door cable

4.5.3 *Footswitch connection*

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

Insert the footswitch and interlock connectors in the proper position as shown in the figure below:



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 Optical Fiber Connection

The fiber is connected to the device through the fiber port on the front. The device accepts only *Rocamed* fibers with SMA905 connector and with the RFID element. The fiber connector has an additional ring that facilitates the clamping of the fiber to the connector on the device. Furthermore, this ring enables the automatic detection of fiber status (present or absent), its diameter and its type (disposable or reusable). If the fiber is not connected, the system will report an error message when the device is switched on.

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

Procedure:

The optical fiber must be connected through the Fiber Port on the front panel of the LASER. If the optical fiber is not connected to the laser a warning message is displayed on the screen. This prevents laser energy release if the footswitch is pressed when no fiber is connected.

Please refer to Section 5.5.1 for the description concerning fiber connection steps.

4.6.1 *Optical fiber check*

Please see Section 7.4.

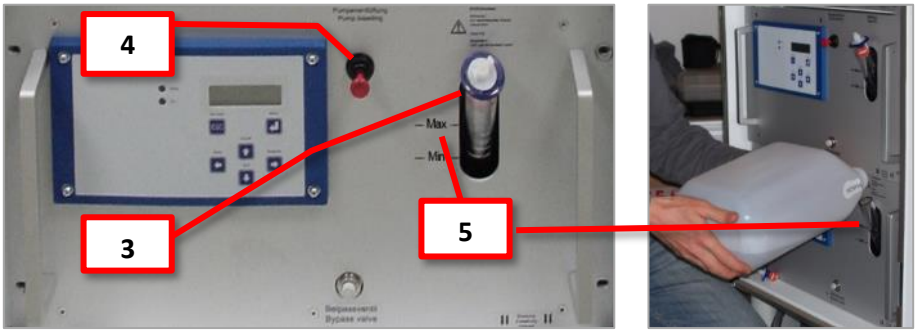
4.7 Hydraulic System Filling

Caution: *Use bidistilled or deionized water only.*

The following instruction sequence describes the correct procedure to fill the hydraulic circuit:

- ✓ Turn the circuit breaker off and unplug the laser
- ✓ Open the frontal panel **(1)** to access the two chiller modules **(2)**

- ✓ Remove the reservoir cap in the front of the chiller **(3)**
- ✓ Open the pump bleeding plug **(4)**
- ✓ Pour water into the filler reservoir until its level reaches MAX **(5)**
- ✓ Close the pump bleeding plug **(4)**



- ✓ Plug the device to power supply, turn the circuit breaker on and turn the laser key switch to the ⊙ configuration
- ✓ Refill the reservoir to maximum level if water level decreases
- ✓ Restart the system if flow alarm appears
- ✓ Close the cap **(3)** when the system works normally.

IMPORTANT!

Check periodically the water level using the graduated scale and refill as necessary following the above instructions.

Contact your local distributor Service engineer if you encounter any issue.

5 INSTRUCTION FOR USE

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

This chapter describes the use instructions of the *HEMERA* device. They include:

- Start-up procedure
- Operating instruction
- Description of possible Alarm messages
- Shutdown procedure and protection from unauthorized use

5.1 Start-up Procedure

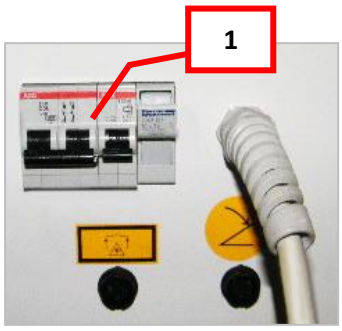
Before proceeding with the start-up procedure of the device, verify the correct connection of the following parts:

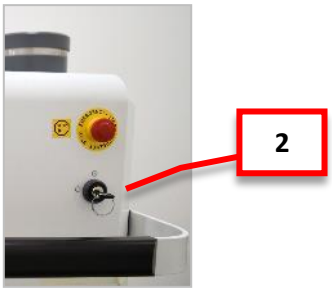
- Power supply cable
- Interlock connector
- Key switch
- Footswitch
- Optical fiber

Also make sure the emergency red button is not pushed.

To turn the device on:

- Switch the circuit breaker on **(1);**
- Insert the key into the key switch **(2)** and turn it clockwise, towards the ⊙ symbol. If the laser fails to start, check that the emergency red push button is not pressed. If this button is pushed, twist that to allow its release and turn the key to start the laser.





5.1.1 *The touchscreen PC panel – Start-up*

When the laser starts up, on the touchscreen panel this screen appears.

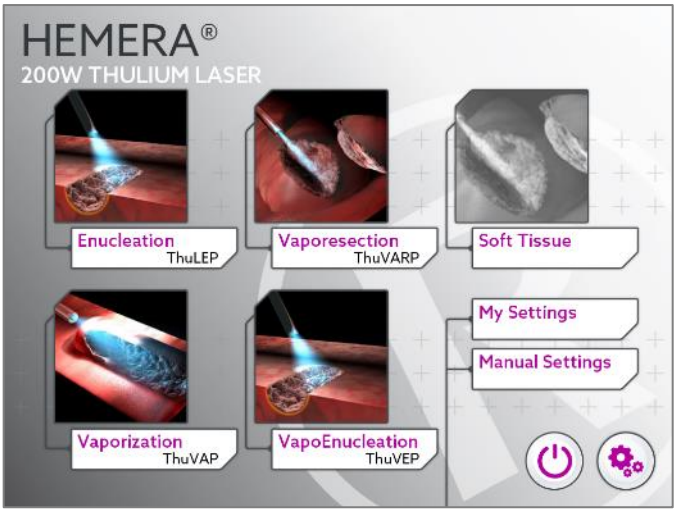
Once the laser has completed the check procedure, the Fast selection screen appears.

If the system displays an Alarm during the start-up operations, please call the Service responsible for maintenance.

5.2 Main Controls

5.2.1 *Fast selection screen*

Once the start-up is completed, the Fast Selection Screen appears:



In this screen the User can select the desired application by clicking on the related icon, access to previously saved personal applications (**My Settings** button), or enter the Main Menu in manual mode (**Manual Settings** button).

The preset application modes are listed below:
- **Enucleation (ThuLEP);**
- **Vaporesection (ThuVARP);**
- **Vaporisation (ThuVAP);**
- **Vapo-Enucleation (ThuVEP);**
- **Soft Tissue.**

Selecting one of the icons displayed, the system will show the Main Menu with suggested laser output parameters. These pre-set programs are intended as suggested settings, the surgeon has to consider changing the settings in order to have the desired effect over the target tissue.

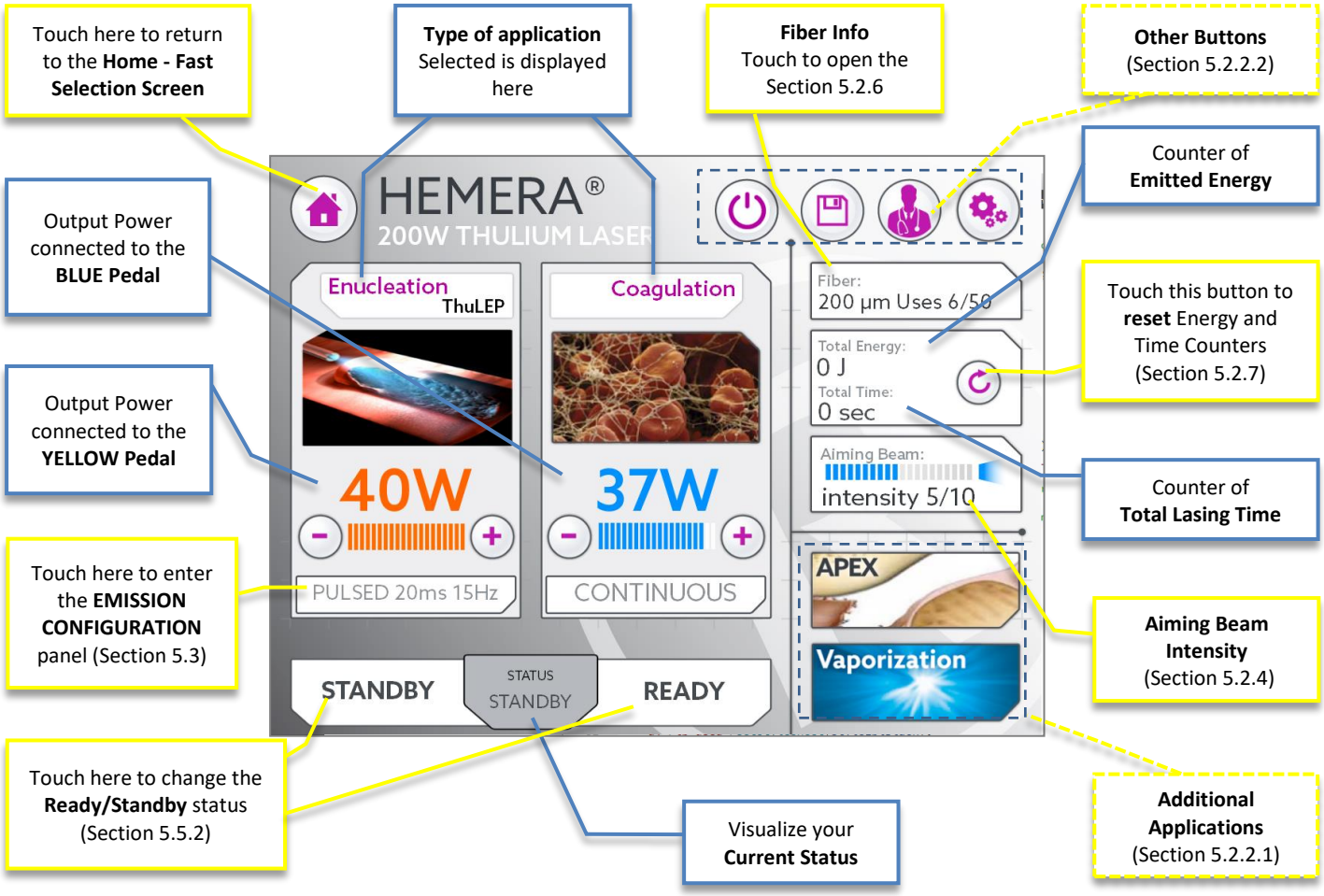
The two additional button in the bottom-right corner allows the user to **shut the device OFF** (see Section 5.6), or to access the **general device Settings** (Section 5.4)

5.2.2 *Main Screen*

The **Main User Screen** contains the laser controls and displays the technical elements for operating and monitoring the laser. It is essential that operators understand and use these controls properly.

The operating screen will contain the following information and active areas:

- Output power areas (connected to the double footswitch) with **+/-** regulating buttons
- Fiber Info
- Total energy and time counters
- Aiming Beam regulation area
- Laser System Status
- Standby and Ready button



Legend:

Display Areas

Active Buttons

5.2.2.1 *Additional Applications*

In the bottom-right corner of the screen two additional emission modes, connected with functioning of the BLUE pedal, are available: the **APEX** and **VAPORIZATION** modes.

APEX button ON:

It is a smart button used for application in apical or delicate areas that modifies the emission power to the preset limit.

When APEX is disabled, the emission returns to the values settled before the activation.

VAPORIZATION button ON:

It is a smart button used for application in which it is necessary to increase the emission power for a short time.

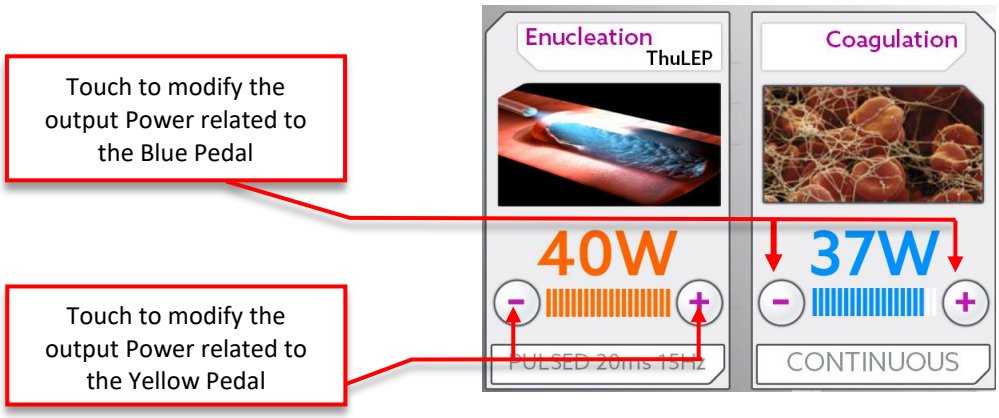
When VAPORIZATION is disabled, the emission returns to the values settled before the activation.

5.2.2.2 *Other Buttons on the Main Screen*

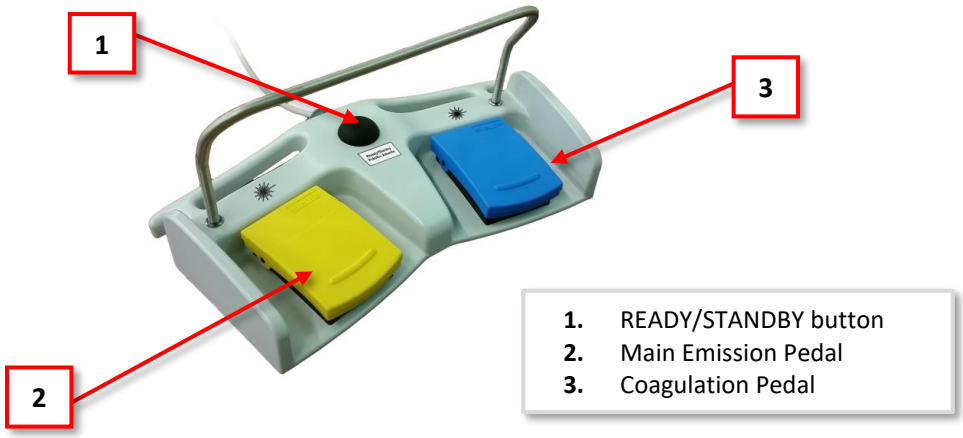
In the top-right corner of the Main Screen the following buttons are present:

Button	Description	Ref. to
	This button allows to **save the current User Settings**.	Section 5.3.3
	This button allows to enter the **My Settings** management area and select a User saved profile.	Section 5.3.4
	This button allows to enter the **Device Settings Menu**	Section 5.4
	This button allows to initiate the laser system **Shutdown**	Section 5.6

5.2.3 *Output power controls*



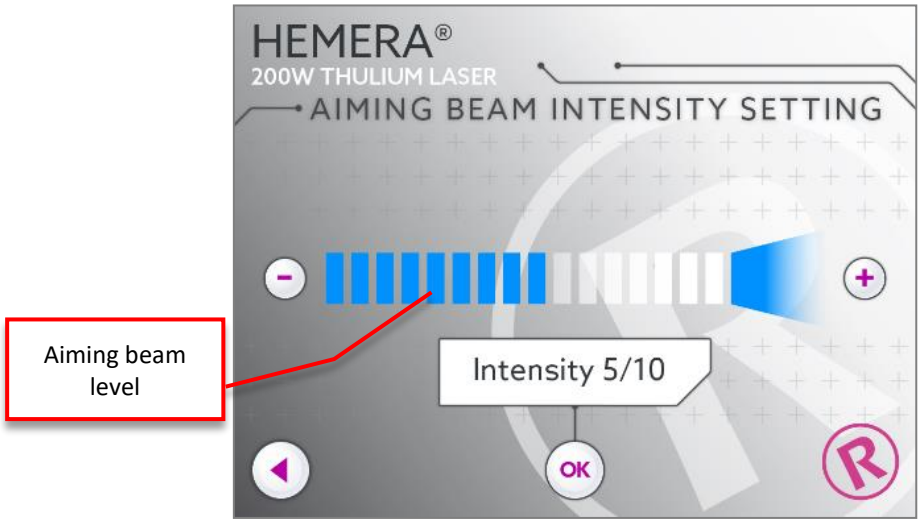
Touch the ⊕ / ⊖ button to increase/decrease the output energy related to the BLUE/YELLOW pedal.



- Press the black button (**1**), or touch the dedicated button on the main screen, to change the status from **Standby** to **Ready** and vice versa.
- The YELOOW Pedal (**2**) is dedicated to the main action over the Target Area *(Cutting/ Ablation/ Vaporization).* The user can set the output mode in Continuous Emission or in Pulsed Emission (Section 5.3).
- The BLUE Pedal (**3**) is dedicated to the *Coagulation Effect*. The emission mode, using this footswitch, is forced to Continuous.

5.2.4 *Aiming Beam*

Press the **Aiming Beam Button** on the Main Screen (see Section 5.2.2) to access the Aiming Beam Settings:



Touch the ⊕ / ⊖ button to increase/decrease 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 pilot laser (Green or Red) will be activated, maintaining the *HEMERA*

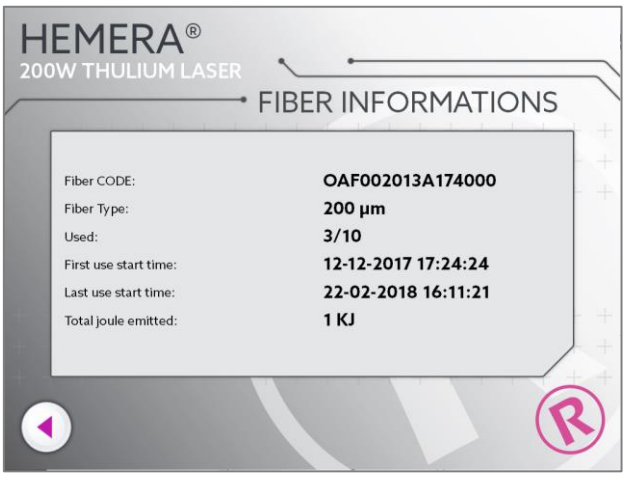
in Standby mode. This function gives the possibility to check connected fibers in a safe condition, evaluating the shape of the laser beam immediately out of the fiber tip.

5.2.5 *Buzzer*

The device emits an acoustic signal with a fixed duration when it runs in READY mode and the footswitch is pressed. Two different tones are associated to the Yellow and the Blue pedals. When operating the device with pulsed emission, the emitted signal varies according to the frequency of laser pulses (almost synchronously for low frequencies).

5.2.6 *Fiber INFO*

It is possible to open the **Fiber Info Panel** by touching the Fiber area in the Main Screen (Section 5.2.2).
The Fiber Info Panel will appear automatically when inserting a *Rocamed* fiber and its RFID tag is recognized (Section 5.5.1).



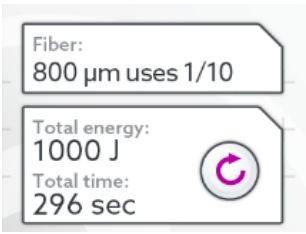
The Information, concerning the connected fiber, stored in the RFID tag, are:

- Fiber Serial Number
- Fiber Type
- Uses
- First use time (data)
- Last use time (data)
- Total emitted Energy (J)

Press  to return to the main Screen.

If an unauthorized fiber is connected, the *HEMERA* system will not recognize the fiber and will deny the change to the Ready status.
If an expired Optical Fiber (single-use / reusable) is connected to the laser system, an error message will appear.

5.2.7 *Reset energy counter and lasing time counter*

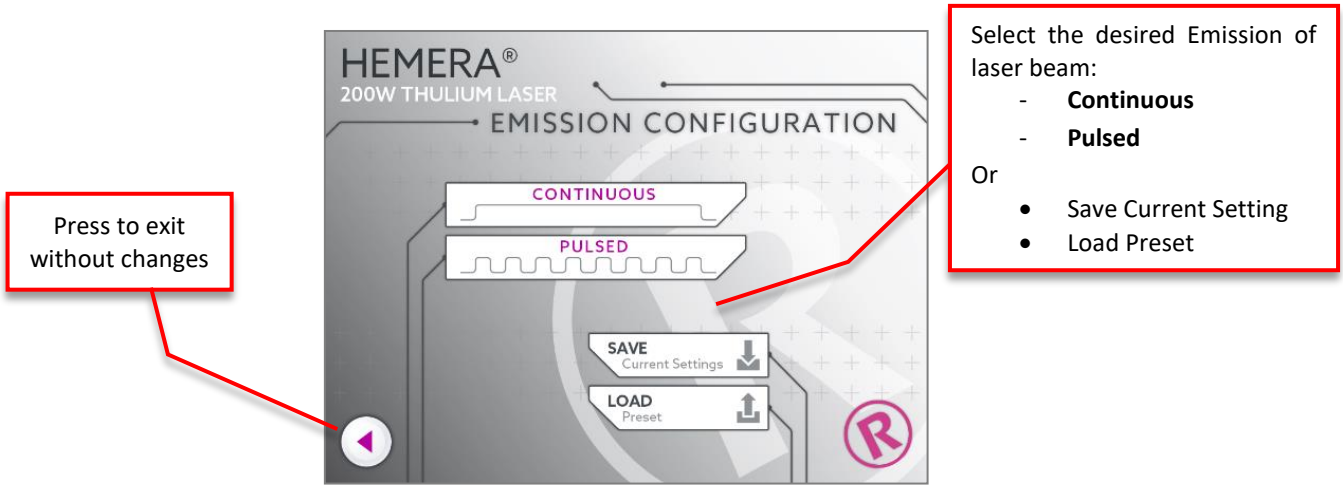


The values dealing with Emitted Joules and Lasing Time increase during radiation emission.

To reset the time/energy counters, press  .

5.3 Emission Control Panel

By pressing the CONTINUOUS/PULSED button in the Main Screen, the **Emission Configuration** panel shows up:



It is possible to select Continuous Emission, Pulsed Emission, Load a Preset or Save Current (emission) Setting (with a dedicated name)**.**

Press:

- **Continuous** to set a continuous emission and exit to the main screen
- **Pulsed** to enter the Pulsed Screen Selection
- **Save Current Setting** to enter the Save Setting Screen
- **Load Preset** to enter the Load Preset Screen

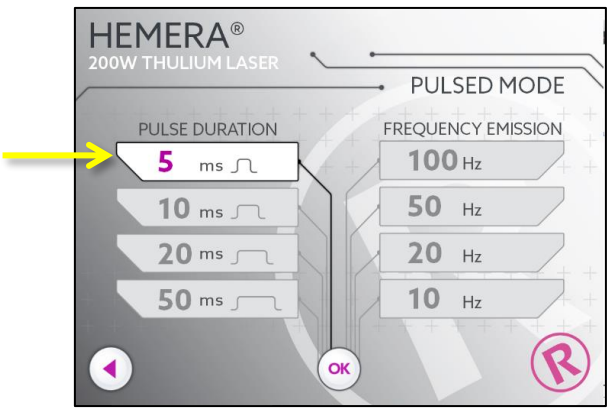
5.3.1 *Continuous emission*

Press “Continuous” in the Emission Configuration (see Section 5.3) to set a continuous (CW) laser emission.

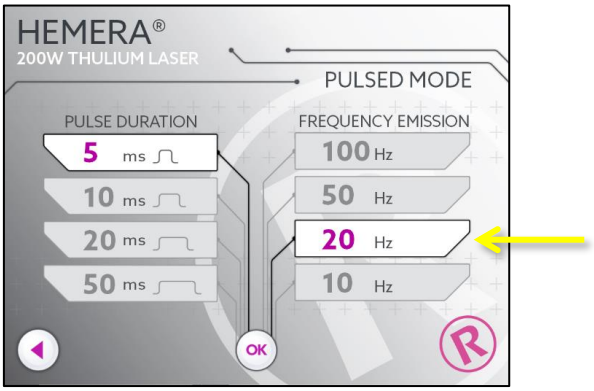
5.3.2 *Pulsed emission*

Press “Pulsed” in the Emission Configuration (see Section 5.3) to set a Pulsed laser emission. On the “Pulsed Mode” control panel the user can select the desired pulse duration and emission frequency, among the available ones.

- First select the **pulse duration**:



- Then select the **frequency**:



- Press OK to confirm the selected laser emission settings and return to the Main Screen.

Possible Pulse Options:

Pulse Duration	Pulse Emission Frequency			
5 ms	10 Hz	20 Hz	50 Hz	100 Hz
10 ms	10 Hz	20 Hz	50 Hz	58 Hz
20 ms	10 Hz	15 Hz	25 Hz	40 Hz
50 ms	10 Hz	15 Hz	-	-

5.3.3 *Save current setting*

The User can SAVE the current settings either by pressing the button on the *Main Screen* (Section 5.2.2), or by pressing the **SAVE Current Settings** button in the *Emission Configuration* panel (see Section 5.3).

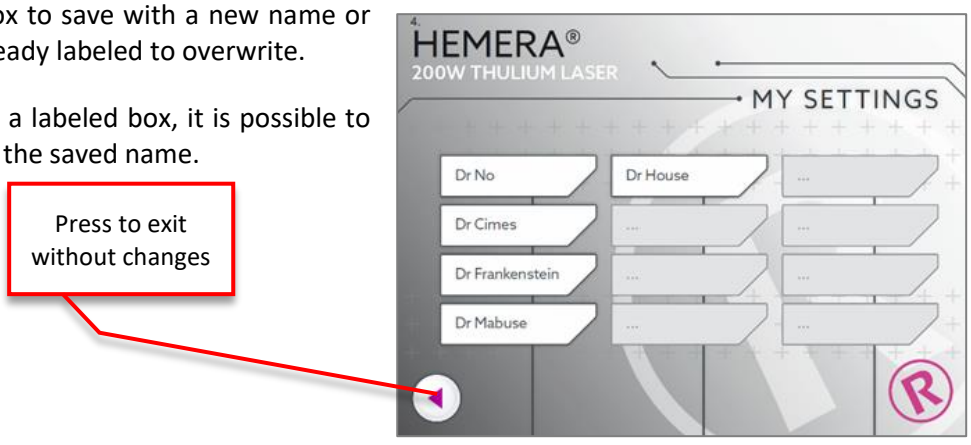
The system will save:

- The emission settings (Pulsed/Continuous) and output power related to the Yellow Pedal
- The output power related to the Blue Pedal

The Blue Pedal laser emission always runs in Continuous mode.

Select a free box to save with a new name or select a box already labeled to overwrite.

When selecting a labeled box, it is possible to keep or change the saved name.



5.3.4 *Load Preset*

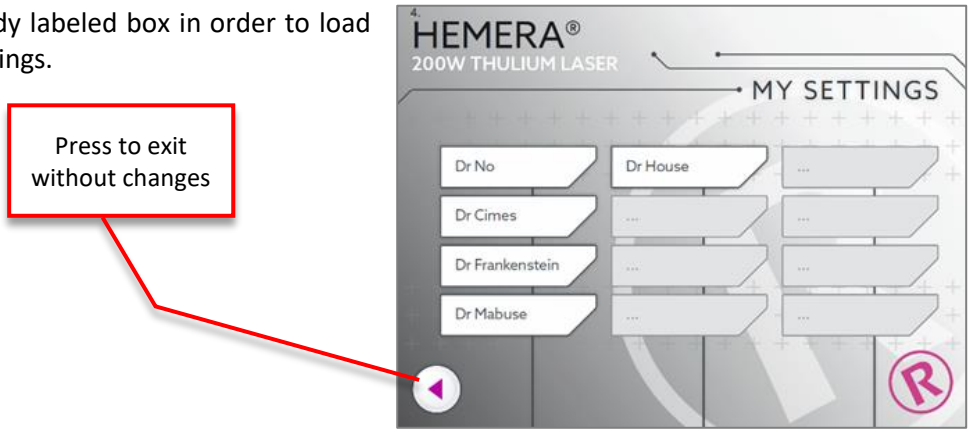
The User can LOAD a previously saved Preset either by pressing the button on the *Main Screen* (Section 5.2.2), or by pressing the **LOAD Preset** button in the *Emission Configuration* panel (see Section 5.3).

The system will load:

- The emission settings (Pulsed/Continuous) and output power related to the Yellow Pedal
- The output power related to the Blue Pedal

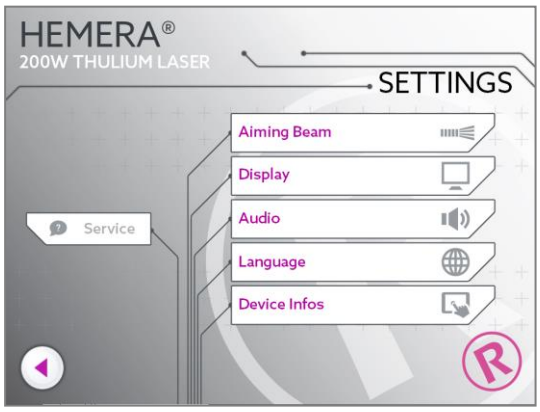
The Blue Pedal laser emission always runs in Continuous mode.

Select an already labeled box in order to load the related settings.



5.4 Settings Menu

Press the button (either in the HOME, or in the Main Screen) in order to enter the **Settings Control Panel:**



The available settings are:

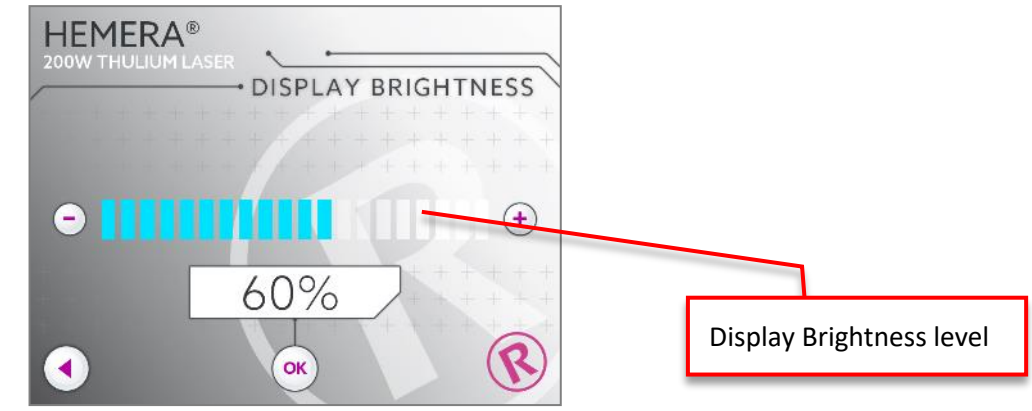
- **Aiming beam** (see Section 5.2.4)
- **Display**
- **Audio**
- **Language**
- **Device Info**

Other buttons are:

- **Service** (Password needed)
- to return to the Main Screen.

5.4.1 *Display brightness panel*

Press "**Brightness**" in the Settings Control Panel (Section 5.4) in order to enter the Display Brightness:



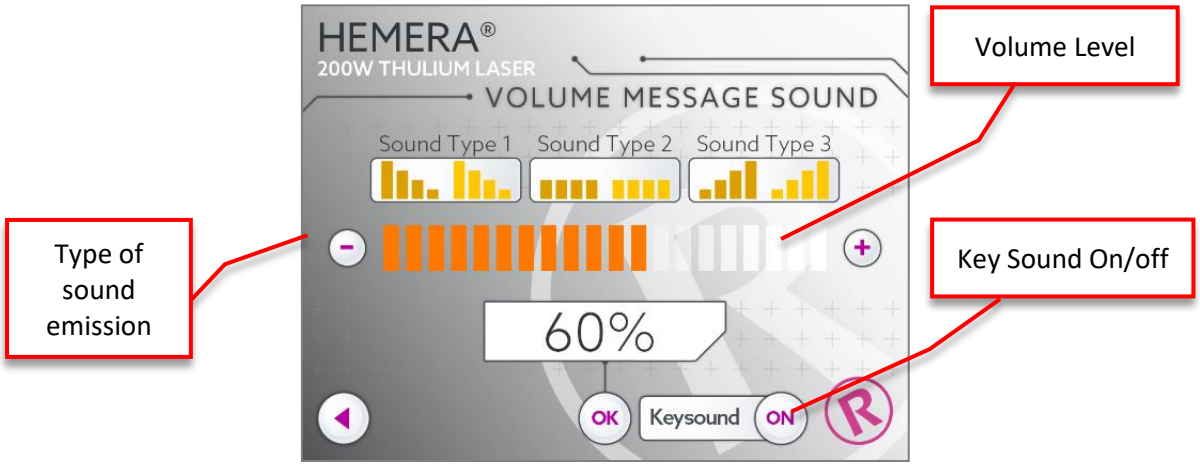
Touch the ⊕ / ⊖ button to increase/decrease the display Brightness.

Touch ◀ to return to the previous screen.

Touch "OK" to confirm the setting and return to the previous screen.

5.4.2 *Audio panel*

Press "**Sound**" in the Settings Control Panel (Section 5.4) in order to enter the Volume message sound:



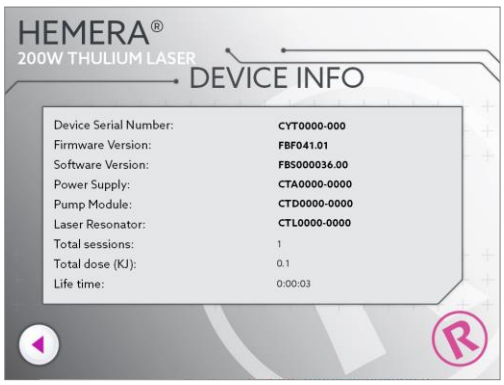
Touch the ⊕ / ⊖ button to increase/decrease the Volume.

Select *Sound Type 1* / *Sound Type 2* / *Sound Type 3* buttons to change the sound related to the emissions of the Yellow and Blue Pedals.

Once Sound Settings have been tuned to the desired condition, press OK to confirm and return to the Settings screen, or press ◀ to exit without saving changes

5.4.3 *Device info*

Press "**Device Info**" in the Settings Control Panel (Section 5.4) to enter the Device information:



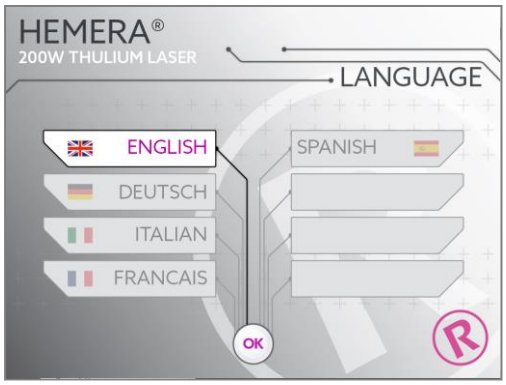
The Device Info Panel shows the following parameters:

- Device Serial Number
- Firmware Version
- Software version
- Power Supply
- Pump Module
- Laser Resonator
- Total Sessions
- Total Dose (KJ)
- Life Time

Press  to return to the Main Screen

5.4.4 *Language*

Press "**Language**" in the Settings Control Panel (Section 5.4) in order to enter the Language Control Panel:

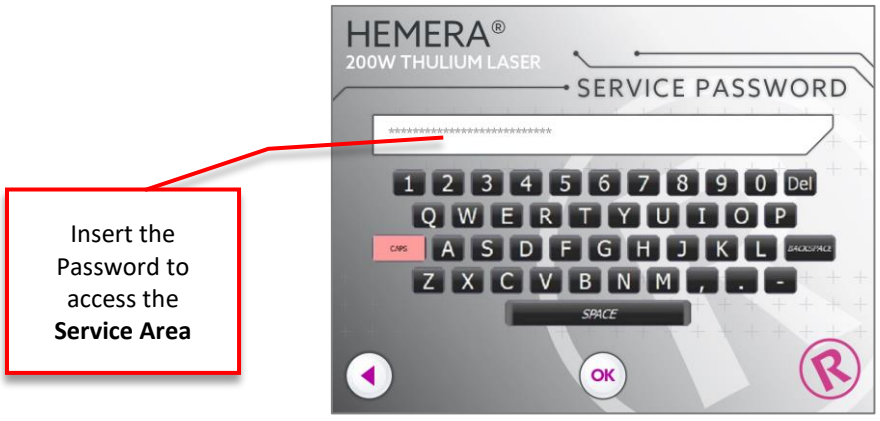


Select the desired language.

Press OK to confirm the selection.

5.4.5 *Service panel*

Press "**Service**" in the Settings Menu (Section 5.4) in order to enter the Service Access panel:



Access to the SERVICE Area is restricted to Service Personnel only, by typing the correct service password.

Press  to exit from the Service Panel.

5.5 Activation of Laser Emission

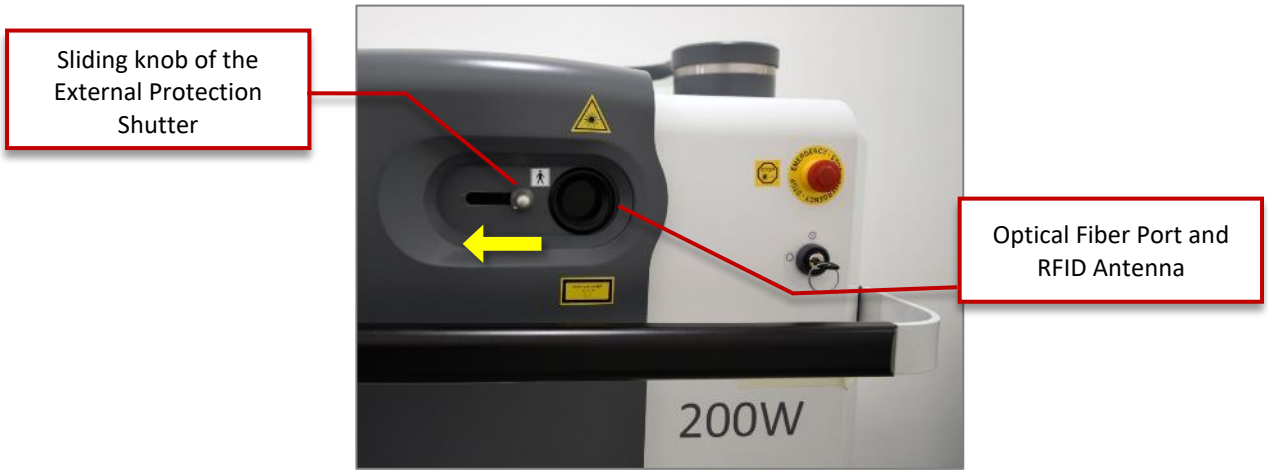
Once the user has chosen power and emission settings that are suitable for the surgery being undertaken (provided that they have been agreed by the surgeon), the laser operator can start laser emission as described in next sections.

5.5.1 *Insert the 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 which disables laser emission if the fiber is missing or not properly installed (see also Section 4.6).

In order to insert the optical fiber correctly, the user has to:

- Open the sterilization packaging containing the fiber.
- Remove the protective cap on top of the connector paying attention not to touch the connector extremity.
- Open the external protective shutter by moving the sliding knob to the left (see figure below).

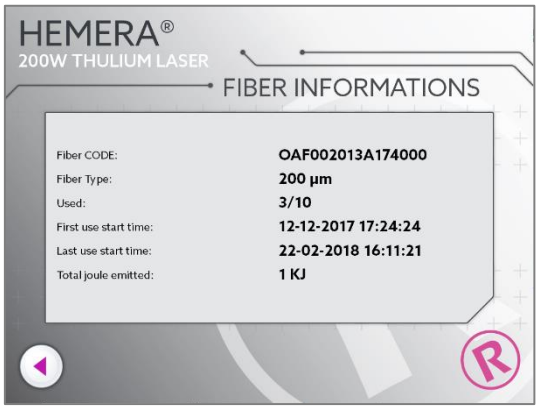


- Connect the Optical Fiber to the optical fiber port, rotating fiber connector clockwise until firmly fixed. The RFID will be automatically recognized by the system

Caution: *After the removal of protective cap, touching or dirtying the connector extremity could result in incorrect and partial radiation launch inside the fiber or fiber mechanical damage. These issues may result in low power emission, severe heating of the connector or fiber damage.*

The device accepts fibers with SMA905 connector and RFID Recognition System (only with ***Rocamed*** internal code). After the RFID tag has been accepted, the system automatically recognizes the diameter and type (single use/reusable) of the connected optical fiber. If the fiber is not connected or recognized by the device, an error message will appear when trying to change the status to Ready mode.

When the fiber is recognized, the Fiber Info Panel will appear (Section 5.2.6):

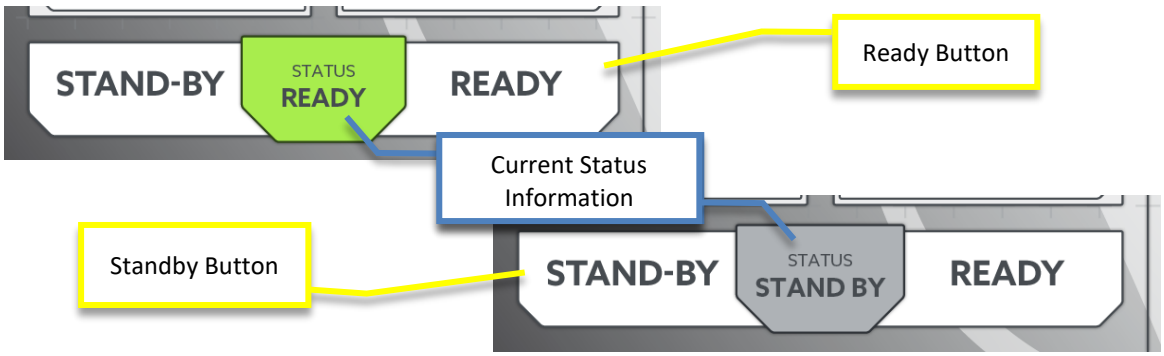


Press  to return to the main Screen.

If an unauthorized fiber is connected, the *HEMERA* system will not recognize the fiber and will deny the change to the Ready status. If an expired Optical Fiber (single-use / reusable) is connected to the laser system, an error message will appear.

5.5.2 *Ready / Standby*

Touch the READY or STAND-BY buttons to change the status of the laser System.



Current System STATUS is displayed between READY and STAND-BY buttons.

Once the System is switched on, the status is automatically set in STANDBY mode. In STANDBY mode, the laser is not firing and the system cannot emit any energy.

To enter the READY mode, press the Ready button on the display, or the dedicated button on the footswitch (see Section 5.2.3) and the status become green.

In the READY mode, the laser is ready to fire and emit energy when the footswitch is pressed.

5.5.3 *Ready mode*

When you change the system status for the first time from Standby to Ready, a “Warning Safety Screen” will appear:

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

Touch OK to exit the Warning Safety Panel.
If the fiber is not well connected or an invalid fiber is inserted, an error message will appear when touching the “Ready/Standby” buttons.

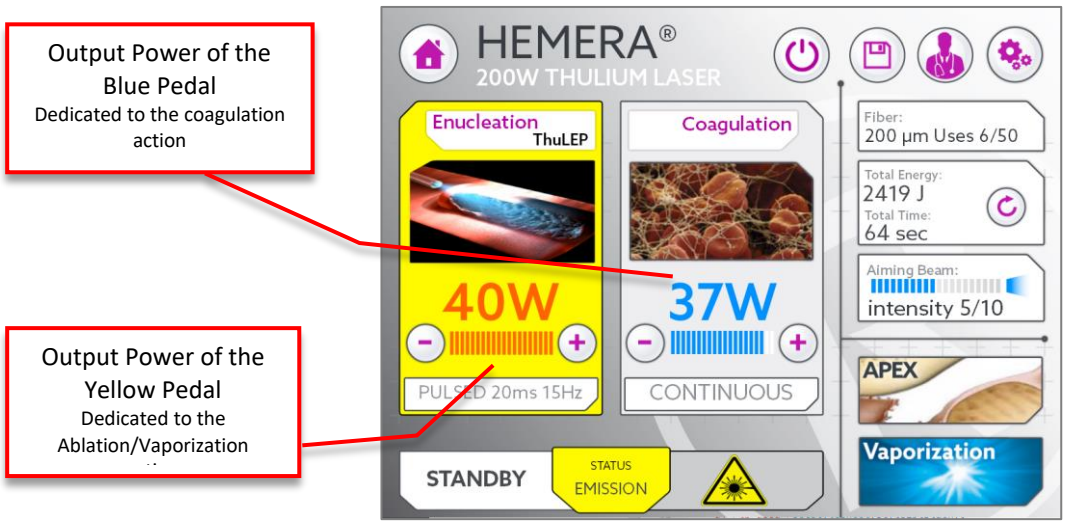
The internal photodiode starts monitoring the laser output energy.

Warning: *Laser emission can be started now by pressing the footswitch.*

Warning: *Before starting laser emission, be sure that the laser beam is pointing at the treatment area and the output power respects the desired setting.*

5.5.4 *Emission mode*

When pressing the footswitch in the Ready mode, the Laser System starts to emit the laser beam through the connected optical fiber. An audible tone is generated in the meanwhile (each footswitch pedal has a different tone). The emitted output power related to the Blue and Yellow Pedals (Section 5.2.3) are shown on the Main Screen (see picture below).

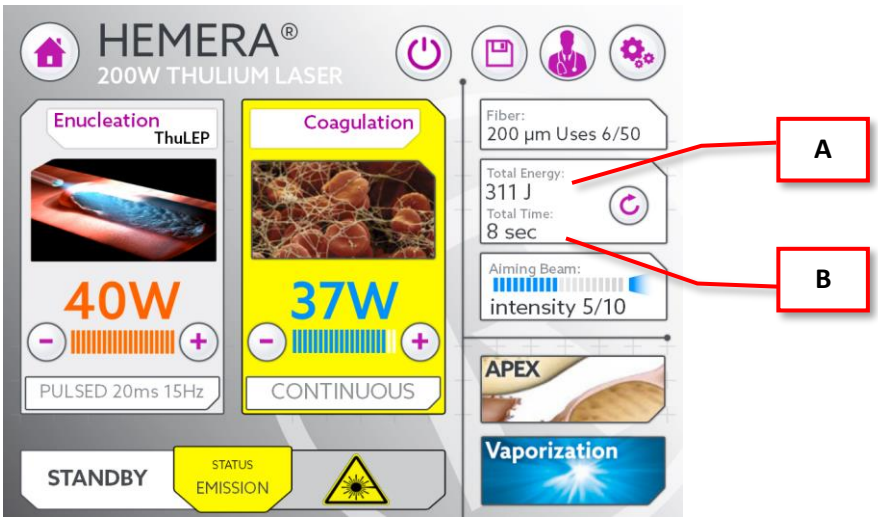


The Yellow Pedal is dedicated to the main action over the Target Area *(Cutting/ Ablation/ Vaporization).* The output can be set in Continuous Emission or in Pulsed Emission (Section 5.3).

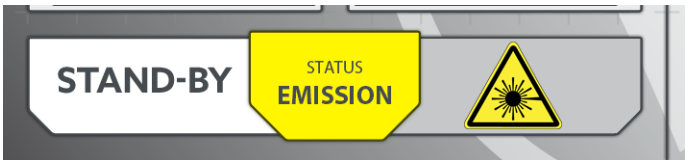
The Blue Pedal is dedicated to the Coagulation Effect. When running this emission mode, laser emission is forced to Continuous.

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.

During laser emission, values of **emitted Energy**, expressed in **Joules** (A), and **Lasing Time,** expressed in **seconds** (B), will be increased. To reset the time/energy counters, refer to Section 5.2.7.



During Laser emission, the Ready button will be inactive, displaying the Laser Warning Symbol instead and the Standby button remains:



During the treatment, the *Energy Warning* (HIGH or LOW Energy) appears as soon as output energy fluctuations exceed a 20% difference with respect to the selected output value. In case of Energy Warning the system does not stop, allowing in any case the continuation of the treatment.

At the end of the treatment, release the footswitch and enter the Standby mode by pressing the Standby button on the display, or the dedicated button on the double footswitch.
For starting a new session, press the Ready button on the display, or the dedicated button of the footswitch.

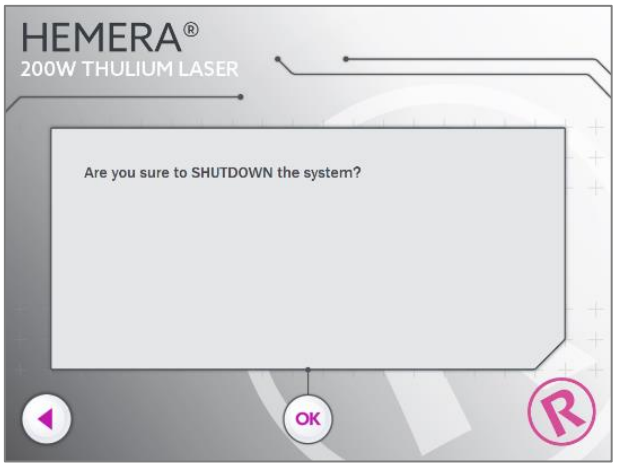
Note: *If the footswitch is kept released for a long time during the READY mode, the system will automatically enter the STANDBY mode.*

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).*

5.6 Shutdown Procedure

To shut down the laser device, press the button.
The window below will appear:



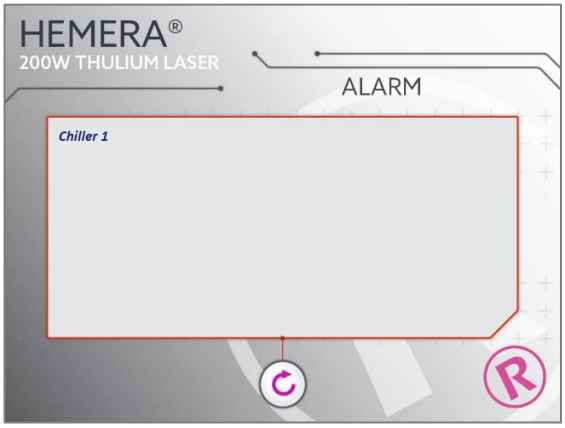
Press OK to confirm or to return to the Main Screen.

Wait the end of the shutdown procedure and then turn the key switch counter clockwise to the ○ configuration.

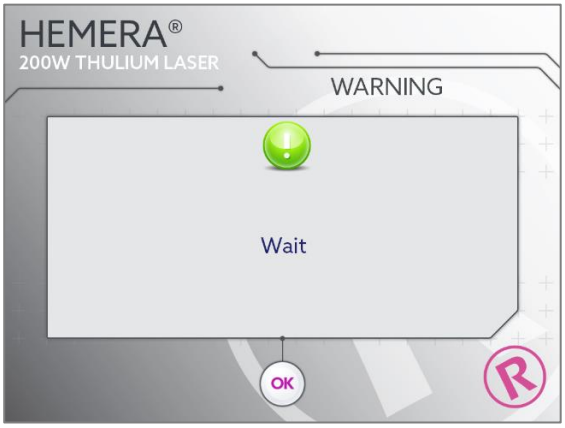
Caution: *Remove the key from its switch to avoid any use by unauthorized personnel.*

5.7 Error and Warning Description

While operating the laser device, different errors may be displayed.
A pop-up window will open in case of an error or warning:



Alarm



General Warning

Possible error messages are listed in the Table below, each of them reporting its possible causes and actions. Blocking errors need manual restart of the system (a “reset” button is provided in the error pop-up window).

Error Message	Type	Possible Cause	Actions
Shutter	Pop-up / Blocking	Application shutter is not in the required position. The shutter could be mechanically blocked or the motor could be faulty	• Call Service
Fiber	Pop-up / Blocking	The fiber presence sensor is faulty	• Call Service
Footswitch	Pop-up / Blocking	The footswitch has been disconnected for more than 1 minute or it is faulty	• Replace the footswitch • Call Service
Current check	Pop-up / Blocking	The diode current driver or the control chain is faulty	• Call Service
Chiller 1	Pop-up / Blocking	Chiller 1 (top) does not work correctly	• Check that there is enough water • Check that the temperature in the room is not exceeding the specifications or that the exhaust air is not recirculating (too close to a wall or to a corner)

Error Message	Type	Possible Cause	Actions
			• Call Service in case the issue is not among the ones above
Chiller 2	Pop-up / Blocking	Chiller 2 (bottom) does not work correctly	• Check that there is enough water • Check that the temperature in the room is not exceeding the specifications or that the exhaust air is not recirculating (too close to a wall or to a corner) • Call Service in case the issue is not among the ones above
Action not allowed in emission phase	Pop-up	The user tried to change a parameter that cannot be modified during the Emission mode	• Release the footswitch before modifying the parameter
Wait	Pop-up	The user tried to change a parameter when the system is in "WAIT" status	• Wait until the status turns to "READY" or to "STANDBY"
All Sessions Expired Replace the Fiber	Pop-up	The user tried to switch the system to the "READY" mode while using an optical fiber with no more sessions available	• Change the fiber with a new one
No fiber	Pop-up	No fiber was connected when the user tried to switch to "READY" status	• Connect an optical fiber to the laser
Fiber not Identified	Pop-up	The fiber was not correctly identified when the user tried to switch to "READY" status	• Check for correct RFID coupling and recognition
Footswitch Disabled	Pop-up	The user pressed the "READY/STANDBY" button on the footswitch out of the main control interface (for example in the settings menu)	• Go to the main user interface before using the "READY/STANDBY" button
Error in changing mode.	Pop-up	Internal error	• Restart the system, if the issue is not solved, call Service
Timeout communication	Pop-up	Communication error	• Restart the system, if the issue is not solved, call Service
Voltage Out Range	Warning	The wall socket does not supply the correct voltage (nominal voltage +/- 10%)	• Connect the system to a mains electrical circuit able to supply the correct voltage.
Warn footswitch	Warning	The yellow footswitch pre-alarm is active. The yellow pedal is disconnected or faulty. The user tried to go into the "READY" status with the yellow pedal pressed	• Release the footswitch before pressing the "go to READY" button • Check the footswitch connection

Error Message	Type	Possible Cause	Actions
Warn footswitch 2	Warning	The blue footswitch pre-alarm is active. The blue pedal is disconnected or faulty. The user tried to go into the "READY" status with the blue pedal pressed	• Release the footswitch before pressing the "go to READY" button • Check the footswitch connection
Power LOW	Warning	The internal powermeter measured a power 50% lower than the set value	• The user may decide to operate the system. • Call Service
Power -40%	Warning	The internal powermeter measured a power 40% lower than the set value	• The user may decide to operate the system. • Call Service
Power -30%	Warning	The internal powermeter measured a power 30% lower than the set value	• The user may decide to operate the system. • Call Service
Power -20%	Warning	The internal powermeter measured a power 20% lower than the set value	• The user may decide to operate the system. • Call Service
Power HIGH	Warning	The internal powermeter measured a power 50% greater than the set value	• The user may decide to operate the system. • Call Service
Power +30%	Warning	The internal powermeter measured a power 30% greater than the set value	• The user may decide to operate the system. • Call Service
Power +20%	Warning	The internal powermeter measured a power 20% greater than the set value	• The user may decide to operate the system. • Call Service
Curr.Out Range	Warning	The diode current is out of the range required to provide the set energy	• Call Service
Interlock Active	Warning	The door interlock is not correctly connected	• Connect the door interlock plug • Check the connection with the door sensor

6 CLINICAL APPLICATIONS

This Chapter provides information concerning the use of the *Hemera* Laser System in clinical applications. Information is divided according to its specialty and includes procedural recommendations, along with specific indications and contraindications. The information provided in this section is not intended to be all-inclusive and to replace surgeon's experience or training.
Hemera Laser System is designed as a multi-specialty system.

6.1 Intended Use

The *Hemera* and its accessories are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

CAUTION!

Hemera **Thulium lasers are 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.**

Please read Section 6.3.1 - Mechanism of Thulium Laser interaction with tissue.

The user can find the recommended parameters for each treatment based on the surgical procedure approach(es) it relates to. Four main procedure types can be defined:

(A1) *Treatment parameters and instructions for Endoscopic Procedures in large water-filled environment and carried out on large tissue portions*– see Section 6.2.2

(A2) *Treatment parameters and instructions for any other Endoscopic Procedures water-filled environment (dealing with small/narrow space and/or small tissue portion)* – see Section 6.2.2

(A3) *Treatment parameters and instructions for Endoscopic Procedures in non water-filled environment* – see Section 6.2.2

(B) *Treatment parameters and instructions for Open Surgery & Laparoscopic Procedures* – see Section 6.2.3

Urology:

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

- Urethral Strictures – (A2)
- Bladder Neck Incisions (BNI) – (A1&A2)
- Ablation and Resection of Bladder Tumors, Urethral and Ureteral Tumors – (A2)
- Ablation of Benign Prostatic Hypertrophy (BPH) – (A1)
- Transurethral Incision of the Prostate (TUIP) – (A1&A2)
- Laser Resection of the Prostate – (A1)
- Laser Enucleation of the Prostate – (A1)
- Laser Ablation of the Prostate – (A1)
- Condylomas– (A2) & (A3) & (B)
- Lesions of external genitalia – (B)

Note: *a power level greater than 150W is highly recommended in order to vaporize prostatic tissue during BPH treatment.*

Gastroenterology:

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

- Appendectomy – (A3) & (B)
- Polyps – (A3) & (B)
- Biopsy – (A3) & (B)
- Gall Bladder calculi - (A2) & (A3)
- Biliary/Bile duct calculi - (A2) & (A3)
- Ulcers - (A3) & (B)
- Gastric ulcers - (A3)
- Duodenal ulcers - (A3) & (B)
- Non-Bleeding Ulcers - (A3) & (B)
- Pancreatitis - (A3) & (B)
- Hemorrhoids - (B)
- Cholecystectomy - (A3) & (B)
- Benign and Malignant Neoplasm - (A3) & (B)
- Angiodysplasia - (A3)
- Colorectal cancer - (A3) & (B)
- Telangiectasias - (A3) & (B)
- Telangiectasias of the Osler-Weber-Rendu disease (OWRD) - (A3) & (B)
- Vascular Malformation - (A3) & (B)
- Gastritis - (A3) & (B)
- Esophagitis - (A3) & (B)
- Esophageal ulcers - (A3) & (B)
- Varices - (A3) & (B)
- Colitis - (A3) & (B)
- Mallory-Weiss tear - (A3) & (B)
- Gastric Erosions - (A3) & (B)

Gynecology:

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

- Intra-uterine treatment of submucous fibroids - (A2) & (A3)
- Benign endometrial polyps and uterine septum by incision, excision, ablation and vessel coagulation - (A2) & (A3) & (B)
- Soft tissue excision procedures such as excisional conization of the cervix - (A3)

ENT:

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

- Endonasal/sinus Surgery - (B)
- Partial turbinectomy - (B)
- Polypectomy - (B)
- Dacryocystorhinostomy – (A3) & (B)
- Frontal Sinusotomy - (B)
- Ethmoidectomy - (B)
- Maxillary antrostomy - (B)
- Functional endoscopic sinus surgery – (A3) & (B)
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal area - (B)
- Tonsillectomy - (B)
- Adenoidectomy - (B)

Dermatology and Plastic Surgery:

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

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

General Surgery:

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

- Cholecystectomy - (A3) & (B)
- Lysis of adhesion - (A3) & (B)
- Appendectomy - (A3) & (B)
- Biopsy - (A3) & (B)
- Skin incision - (B)
- Tissue dissection - (A2) & (A3) & (B)
- Excision of external tumors and lesions - (B)
- Complete or partial resection of internal organs, tumors and lesions - (A3) & (B)
- Mastectomy - (B)

- Hepatectomy - (A3) & (B)
- Pancreatectomy - (A3) & (B)
- Splenectomy - (A3) & (B)
- Thyroidectomy - (A3) & (B)
- Parathyroidectomy - (A3) & (B)
- Herniorrhaphy - (A3) & (B)
- Tonsillectomy - (B)
- Lymphadenectomy - (A3) & (B)
- Partial Nephrectomy - (B)
- Pilonidal Cystectomy - (A3) & (B)
- Resection of lipoma - (A3) & (B)
- Debridement of Decubitus Ulcer - (B)
- Hemorrhoids - (B)
- Debridement of Statis Ulcer - (A3) & (B)

Thoracic and Pulmonary:

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

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

Arthroscopy:

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) and ablation of soft and cartilaginous tissue in Minimally Invasive Spinal Surgery, including:

- Percutaneous Laser Disc Decompression/Discectomy – (A2) & (B)
- Foraminoplasty – (A2) & (A3) & (B)
- Ablation and coagulation of soft vascular and non-vascular tissue in minimally invasive spinal surgery - (A2) & (A3) & (B)

6.2 Treatment Parameters and Instructions

The Hemera laser system 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 *Hemera* is a Thulium Laser System emitting an invisible infrared beam at a 2010 nm 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 *Mechanism of Thulium laser interaction with tissue*

The mechanisms behind Thulium laser interaction with tissues at a microscopic level help explain the basis of the surgical technique.

Vaporization/Ablation of tissue water or *Coagulation* (denaturation) of tissue proteins occurs depending on the temperature reached locally in various parts of the targeted area:

- Ablation/Vaporization effects occur when tissue is heated to 100°C
- Coagulation effects occur when tissue is heated from 65° C to 99°C

The structure of soft tissue is basically composed of water, blood vessels and collagen matrix. The collagen matrix acts as the mechanical stabilizer of tissue.

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

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

Vessel Coagulation could be easily accomplished either by increasing the distance between fiber tip and tissue or by decreasing laser output power. Indeed, both techniques reduce the power density on the target tissue and cause tissue coagulation without tissue ablation/vaporization (as tissue temperature does not reach 100°C).

The manufacturer recommends that the surgeon consider tuning the laser power according to tissue response.

6.2.2 *Treatment parameters and instructions for endoscopic procedures **(A1-A2-A3)***

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 with water-filled large environments, as in BPH treatments, it is possible to use the maximum output power (200W). Power levels higher than 120W result in a Vaporization effect greater than the Ablation/Cutting effect.
It is possible to use the fiber in contact with the tissue

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.

When using the laser in water (as the surgical irrigation solution) within large cavities and targeting a large tissue volume (***A1***), as in bladder during BPH treatment, **it is recommended to start ablation or vaporization at 80W** and adjust the power according to the observed Ablation/Vaporization 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 to 40W.
Conversely, when using the laser in water within small cavities or narrow channels (as in ureter) and/or targeting a small tissue portions (***A2***), or when using the laser endoscopically, without any fluid in between of fiber tip and targeted tissue (***A3***), **it is recommended to start ablation or vaporization at 5-10W** in **continuous emission or pulsed mode** (pulse duration 5-20ms max 20Hz) and adjust the power according to the observed Ablation/Vaporization 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.

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

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.

Damage to Endoscope:
The Hemera system 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.

6.2.3 *Treatment parameters and instructions for open surgery & laparoscopic procedures (B)*

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:** *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 LASERING AT MAXIMUM POWER. Begin the procedure with a low power (5-10W) and increase the output power until the desired tissue vaporization/ablation/coagulation effect is achieved.
Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated.
When using the laser in open surgery or in laparoscopic **(B)** procedures (with the fiber output not submerged in water solution), it is recommended to start ablating or vaporizing with a 5-10W power, adjusting the power according to the observed ablation/vaporization effect.
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).

 **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 laser power to 5W.
If tissue adheres to the fiber tip, the tissue has to be removed from that.

The ablation in open surgery 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 (see Section 2.9).

6.3 Training

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

- Review of the following information.

- Published literature.
- General laser physics, biology and treatment techniques for each specific disease entity.
- Treatment techniques for other surgical modalities in several specialties.
- Familiarization with treatment parameters using all laser types, such as Argon, Ho:YAG, Tunable Dye, CO_2, KTP, Nd:YAG, Diode and Thulium.
- Attendance at medical meetings dealing with the use of the laser.
- Attendance at seminars and hands-on workshops on laser therapy in a specific specialty. Quanta System maintains a listing of instructional courses and mentorship sites in a broad range of medical specialties. Please contact your local distributor for more details about that.
- Mentorships should be made as frequently as possible with other surgeons who are performing laser therapy. These usually allow in-depth discussions about all aspects of laser treatment, along with the possibility of observing or participating in actual cases.

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

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

6.4 General Laser Warnings

The physician or surgeon should become fully acquainted with the unique surgical and therapeutic effects produced by the 2010 nm wavelength before using *Hemera* 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.

- The *Hemera* 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 *Hemera* 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 2010 nm laser energy.
- Careful assessment of the target and surrounding tissue should be made, and appropriate power and pulse duration should always be used.
- As with conventional endoscopic surgery, the possibility of complications and adverse events, such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis or infection may occur following treatment. In extreme cases, death may occur due to procedural complications 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.
- Aim and use the laser only on tissues that are fully visible.
- Extra caution should be used when lasing tissue close to known arteries, nerves and veins.
- Begin laser treatment at the lowest power, with short duration exposures until fully familiar with effects of the applied wavelength on the tissues.
- Flash fires may occur. Refer to Chapter 2 for more information. A bowl of water should be available in case a fire occurs.
- Quanta System S.p.A. has no clinical information or experience concerning the use of the *Hemera* 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 *Hemera* 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.
- The flammability of methane gas must be considered when treating in or near the perianal area.
- Alterations in surgical approach or technique may be required to accommodate laser use.
- The surgeon should schedule follow-up visits in the same manner as for any patient undergoing such surgery with other modalities.
- Surgeons should be thoroughly trained and proficient in all aspects of endoscopic surgery prior to using the laser through an endoscope. Depth perception through an endoscope is distorted. The surgeon must rely on both the visual and tactile feedback of the delivery system.
- Care must be taken to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.
- A smoke evacuator and in-line filter should be used to capture the smoke plume 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.

 **Warning:** *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.*

6.5 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.

6.6 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.

6.7 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.

6.8 Specific Precautions and Contraindications

Urology:

- 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).
- Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distention could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.
- Contraindicated for patients:
    - Diagnosed with acute or chronic prostatitis.
    - Diagnosed at the time of treatment with acute or chronic urinary tract infection.

- With confirmed or suspected malignancy of the prostate (digital rectal examination, elevated PSA or abnormal ultrasound of the prostate), unless they are not a candidate for radical prostatectomy or brachytherapy and present with bladder outlet obstruction.
- Whose general medical condition contraindicates surgical intervention.
- Where appropriate 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.

Gynecology:

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

General surgery:

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

Gastroenterology:

- Contraindicated for patients with previous multiple abdominal surgery.
- Contraindicated for patients with Intestinal obstruction.

Other medical specialties: no specific information - see Sections 6.5, 6.6, 6.7.

7 MAINTENANCE, CLEANING AND STERILIZATION

This Chapter provides information regarding the ordinary and preventative maintenance and care required for the laser system. Should you require any assistance concerning maintenance or technical intervention, please contact your distributor.

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 external panels should be cleaned periodically with a cloth dampened with a solution of warm water and mild detergent or a mild cleaning agent. Avoid spraying the cleaning detergent directly on the panels as this may result in damage to the finished surface, especially the touchscreen. Never pour water or any other liquid over the console. If any fluid may have leaked in the console, turn the laser off and call your local distributor to inspect the laser.

7.2 Laser Maintenance Schedule

The *HEMERA* Laser device is designed for maximum safety and performance. For optimum performance of this laser system, preventative maintenance needs to be carried out every six (6) months.
Please contact your local distributor service engineer for more information concerning preventative maintenance or to schedule an appointment.

7.3 Safety Labelling Check

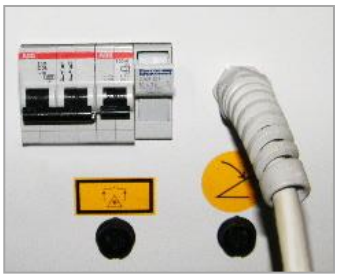
The user must to regularly verify the integrity and readability of the security labels placed on the device. If labels are damaged, they must be replaced immediately in accordance with the plan shown in paragraph 2.13 **Labelling plan**.

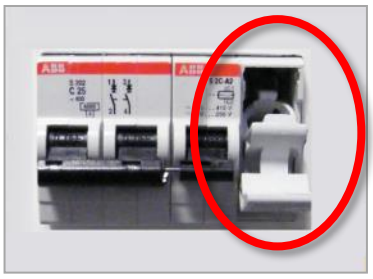
7.4 Coolant Refilling Instructions

The *HEMERA* laser system uses an air/water cooling system filled with distilled or de-ionized water. Over time, some evaporation can occur resulting in a “Water Low” system prompt. This condition is indicated by a red LED. Follow the prescriptions of Section 4.7 to refill the system if the low water level message is displayed.

7.5 Checking the Line Cable and Fuses

The fuse in the rear panel of the system has the following specification: **10x38mm, 20A, 600V**.
Before replacing a fuse, be sure that the plug is detached from mains!





The *HEMERA* device has a line cable mechanically fixed to it. The line cable can be subject to deterioration over time and therefore its status must be checked periodically. Only authorized service personnel can replace the line cable.

7.6 Optical Fiber Maintenance

Warning: *Be sure that the 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 sterilization, if applicable.

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.*

7.6.1 *Fiber management (application cycles)*

The number of application cycles of a laser fiber is mentioned on the label or in fiber instructions. The user himself should keep record of the number of fiber uses. This action prevents the user discovering all the sessions have expired (that fiber cannot be used) at very beginning of a treatment procedure only.

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

Caution: *A single-use 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.

7.6.2 *Check of the optical fiber before operation*

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 according to 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.

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

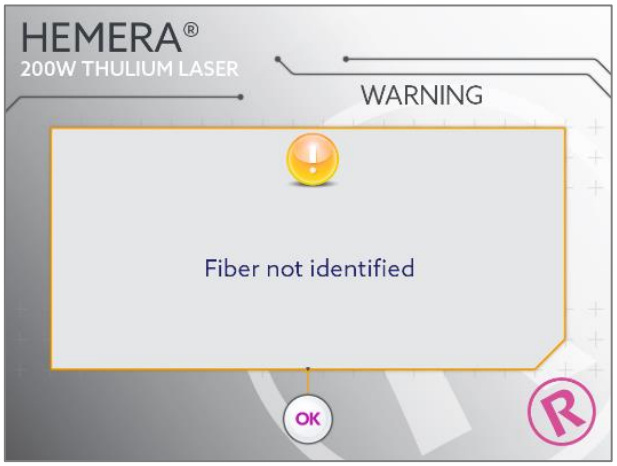
Warning: *Read carefully and follow optical fiber instruction manual*

8 TROUBLESHOOTING

The *HEMERA* laser system is provided with a self-check mechanism that alerts operating room staff in case of problems. A message will appear on the screen at the time of system malfunction. Depending on the severity of the problem, the system will either continue to work (Warning Messages) or require a solution before reactivating (Alarm Messages).

8.1 Warning Description

Different warnings and alarms may be displayed on the touchscreen.
All warnings set the system to a 'fail safe' condition. The system allows the continuation of all functions that are not dangerous for the user or for the system.



Example: Fiber not identified

The following table may assist you in identifying common problems. Please see also the description in Section **Errore. L'origine riferimento non è stata trovata.** "Alarm and warning description".

Problem	Possible cause	Solutions
The system does not switch on	Power cable not connected. Main electrical socket not on. Circuit Breaker not on. Broken Main Fuse	Connect mains cable. Turn on main socket. Check the circuit breaker, turn it on. Call Service.
Low output power	Damaged optical fiber	Inspect the Fiber. Replace the Fiber. Call Service.
No output power	The laser is not in Ready mode. Footswitch broken.	Select Ready mode. Call Service.
Alarm: footswitch not connected		Connect the footswitch.
Remote door interlock not connected		Connect the interlock.
Fiber: warning	Fiber not connected properly.	Re-connect the fiber, tighten it securely.
Chiller (1 or 2) Alarm	Chiller 1 or 2 not working. Low water level. Low flow.	Add water. Call Service.
Other Alarms SHUTTER FIBER CURRENT CHECK INTERLOCK 1 INTERLOCK 2		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 *HEMERA* 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 to Medical Device Directive 93/42/EEC	Class IIb
Laser Classification according to IEC / EN 60825-1:2014	Class 4
Aiming beam Classification according to IEC / EN 60825-1:2014	Class 3R
Mains	230VAC, single phase, 50/60Hz, 16A
Type of protection against electric shock	Class I
Degree of protection against the ingress of liquid	IP X0 (Not protected)
Degree of protection against electric shock	Type BF
Mode of operation	Continuous
Dimension	**w: 664 mm, d: 860 mm, h: 1249 mm *(display closed)***
Weight	200 kg
Operative temperature	10°- 30° C
Storage temperature	min 10° C / max 40° C
Transport temperature (without water)	min -5° C / max 70° C
Humidity	30% - 85%
Atmospheric Pressure	800-1060 hPa
Cooling system	Air cooled (closed water-air cooling circuit) Forced Air with Internal Chiller
Noise level	Less than 58 dBA
Fuse	1 x 10 x 38 mm, T20AH, 600V
Applied part	Optical fiber
Touchscreen display	12” colored touch panel
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.*

10.2 Laser Source Specifications

Laser type	Diode Pumped Solid State, Tm:YAG
Wavelength	2010 nm
Output power	5 to 200 W
Power adjustment	adjustable with 1, 2, 5 W increment steps
Operating mode	Continuous wave or pulsed[1]
Pulse duration	From 5 to 75 ms
Repetition rate	From 10 to 100 Hz, adjustable
Beam transmission	Optical fiber system Wide range of flexible silica frontal and side-firing fibers
Beam Divergence	440 [-40] – 540 [+40]mrad
Aiming Beam	Laser Diode, 532 nm or 650 nm (1-5 mW, class 3R, adjustable)
Actuating device	Two pedals: One for Vaporization/Ablation action; one for Coagulation One button: for Ready/Standby switching

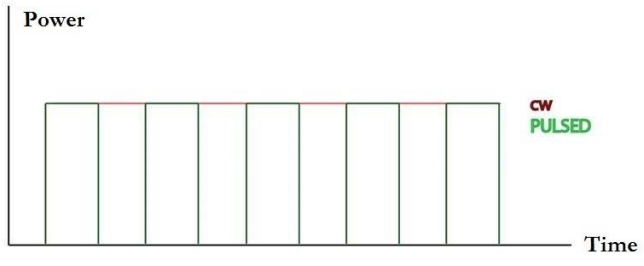
Note 1: During the lifetime of the device, energy laser values could diverge from the declared ones by a 20% maximum.
Note 2: the device is provided with an internal measuring system to control the actual emission of the laser. The device does not require calibration by the user.

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

IMPORTANT: *For shipment and storage below +5° C temperature, the cooling system must be emptied.*

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

[1] The term "Pulsed" refers to a modulation of the continuous wave, as displayed in the diagram below:



11 ACCESSORIES

Accessories	Description
Sterile single-use fibers **Sterile reusable fibers** ***(available according to customer requirements)***	Sterile single-use and reusable bare optical fibers with core diameter from 200 up to 1000 µm.
Connector	SMA905 free-standing
Fiber identification connector	Automatic Identification of fiber specifications and number of uses
Fiber stripper 1	Fiber stripper for 0.3 – 1.0 mm diameter
Fiber stripper 2	Fiber stripper for 0.1 - 0.4 mm diameter
Fiber cutter	Ceramic fiber cutter
Safety Goggles	Safety Goggles
Detachable parts	**Description**
Key switch	Key switch to switch the device ON/OFF
Footswitch	Double footswitch with ready/standby button
Interlock	Interlock connector to prevent laser emission when the door is open (IEC 60825-1)

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.

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 radiations 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.

Table 201 Guidance and manufacturer's declaration – electromagnetic emission		
The equipment **Medical device mod.** *HEMERA* is intended for use in the electromagnetic environment specified below. The customer or the end user of the **Medical device mod.** *HEMERA* should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment - guidance
RF emission – CISPR 11	Group 1	The **Medical device mod.** *HEMERA* 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 **Medical device mod.** *HEMERA* 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. The device is subject to conditional connection, the maximum permissible system impedance Z_{max} at the interface point of the user's supply is **0.472 Ω**
Harmonic emission IEC 61000-3-2	N/A	
Voltage fluctuation/flicker emission IEC 61000-3-11	Complies	

Table 202 Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment **Medical device mod.** *HEMERA* is intended for use in the electromagnetic environment specified below. The customer or the end user of the **Medical device mod.** *HEMERA* should assure that it is used in such an environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±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 input power supply ports	Compliant	Mains power quality should be that of a typical commercial or hospital environment

	±1 kV for I/O ports	N/A	
Surge IEC 61000-4-5	Input power ports: 0.5, 1.0 kV (line to line) 0.5, 1.0, 2.0 kV (line to earth) Signal I/O ports: 2.0 kV (line to earth)	Compliant N/A	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	Voltage dips: >95% Ut for 0.5 cycle > 95% Ut for 1 cycle 30% for 25 cycles (50 Hz) 30% for 30 cycles (60 Hz) Voltage interruptions: >95% for 250 cycles (50 Hz) >95% for 300 cycles (60 Hz)	Compliant	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Medical device mod.** *HEMERA* requires continued operation during power mains interruptions, it is recommended that the **Medical device mod.** *HEMERA* is 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 204 Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment **Medical device mod.** *HEMERA* is intended for use in the electromagnetic environment specified below. The customer or the end user of the **Medical device mod.** *HEMERA* should assure that it is used in such an environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
      Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	 3Vrms 150KHz to 80MHz 3V/m 80 MHz to 2,7 GHz	 3 Vrms 3 V/m	Portable and mobile RF communication equipment should be used no closer to any part of the **Medical device mod.** *HEMERA*, 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) d=1,167*sqrt (P) 80 MHz to 800 MHz d=2,333*sqrt(P) 800 MHz to 2,5 GHz

			Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in 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: 
Note 1: at 80 MHz and 800 MHz, the higher frequency range applies Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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

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

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

The equipment **Medical device mod.** *HEMERA* is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Medical device mod.** *HEMERA* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Medical device mod.** *HEMERA* 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 2,5 GHz d=2,33*sqrt (P) m
0,01	0,117	0,117	0,233
0,1	0,370	0,370	0,740
1	1,17	1,17	2,33
10	3,70	3,70	7,40
100	11,7	11,7	23,3

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

Note 1: at 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.

APPENDIX C: LOGBOOK

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