ROCAMED

MH01

2100 nm Holmium
30W Laser System

User Manual

NOTE-MH01-EN rev05

CE
0123

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.
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ROCAMED

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

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

CONTENTS:

1 GENERAL INFORMATION

1.1 Introduction

Medical Device MH01 is a 30W Holmium Yag Laser with 2100nm wavelength which is used by physician as a tool in surgical procedure. The laser MH01 is the result of a long experience of ROCAMED in the field of medical laser equipment

This manual contains important information regarding the safe use of medical device MH01. The manual describes the instrument, surgical procedures, a description of the various inspections, routine maintenance and operator information for the use and care of optical fibers used for the release of the laser radiation to the patient.

Medical people using the medical device MH01 must read this manual carefully. Professional information regarding specific surgical specialties can be found in Chapter 6, "Clinical Applications".

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

1.2 Purpose of the manual

This manual contains essential information necessary for the installation, operation and maintenance of the medical device MH01. The manual is intended to be used as a guide. This manual contains instructions for operation and maintenance. These instructions were written specifically for staff who are fully trained in laser and conventional surgery.

This manual contains information on the optional accessories supplied with the medical device MH01, their cleaning and sterilization (Chapter 7, "Maintenance and cleaning").

This manual is not used as an alternative to surgical preparation. In addition, this manual does not provide specific technical information regarding operations of the medical device MH01 assistance. For any information regarding the technical assistance contact the company.

1.3 Safety instruction

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

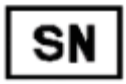
In this manual a distinction is made between the safety instructions used to warn of possible injury (**DANGER**) and instructions warning against operational faults (**WARNING**):

DANGER:	**Risk of injury!** This instruction concerns the safety of patients, operators and other persons, who are in the room, in which the laser is being operated or maintained. In this manual the following symbol is used to warn of the **risk of injury** from laser radiation (**Fig. 1**):  **Fig. 1: Symbol for Danger**

WARNING:	Danger of **operational fault**! Failure to follow this instruction can lead to damage to the laser system, the applicator or the laser fiber. In this manual the following symbol is used to indicate a possible **operational fault** and the damage to the laser system, which might result from it (Fig. 2).  **Fig. 2: Symbol for Warning**

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

1.4 Symbols and Abbreviations used in this manual

Symbol	Description
	Read the enclosed documentation label
	Symbol of applied part type BF According to standard 60601-1 2° ED
	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
	Manufacturer
NOHD	Nominal Ocular Hazard Distance
NOHZ	Nominal Ocular Hazard Zone
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
	Pushing Prohibited

1.5 Manufacturer

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

Distributed by:

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Manufactured by:

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

1.6 Combinations

We recommend to use ROCAMED fibres in conjunction with MH01 Laser System.

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

2 LASER SAFETY

2.1 General Safety

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

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

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.

2.2 Classification

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

2.3 Training of the medical staff

The use of the laser device is restricted only to the specialist medical staff*: that, depending on their experience and expertise, can make choices appropriate to achieve the desired therapeutic effects.
It is recommended that all operators and support personnel are adequately trained on laser safety standards.
**(*This device must only be used by adequately qualified and trained medical personnel with experience in Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy Pulmonary, Gynaecology, ENT, Dermatology, Plastic Surgery and General Surgery*)

2.4 Nominal Ocular Hazard Distance

Following the Standard IEC 60825-1, the MPE (Maximum Permissible Exposure), NOHD (Nominal Ocular Hazard Distance) and OD (Optical Density) are calculated.
The formulas and the numerical coefficients are specified in Section 3, Chapter 13, Table 6, Figures 1, 2, 5, 6, 7, 8 of IEC 60825-1 standard.

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

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

Where H_0 is the expected unprotected eye exposure level.

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

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

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

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

2.5 Working Area

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

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

RULES OF ACCESS TO THE RESTRICTED AREA OF WORK
External staff and visitors should also:
- Be guided by staff
- Always wear laser goggles in the working area when the laser is switched on
- Be briefed by staff on the laser, electrical hazards and other risks associated with the operation of the laser within the working area (the laser radiation, electric shock, etc.)

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

2.6 Eye and skin exposure

The laser beam emitted by MH01 can cause sight loss. The laser operates at different wavelengths, visible and invisible. Any energy transmitted by the laser system that enters the eye will be focused directly on the retina. Direct absorption of laser energy by the retina can result in temporary clouded vision, retina lesion, long term scotoma and long term photophobia.

A danger exists in any case of:
- Direct laser radiation
- Reflected laser radiation

Diffused laser radiation.

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

2100 I LB2 for laser source Ho:YAG at 2100 nm

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

IMPORTANT*!*
Within the range of the laser, every person must wear laser goggles.
Check the laser goggles for perfect condition before each use. The goggles must not be mechanically damaged in any way

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

To avoid any mix-up, the laser goggles require adequate identification.
Laser goggles with a higher degree (or level) of protection (such as L3, L4, ...) or goggles featuring a broad--band filter of protection stage L2 or higher also covering wavelengths of 2100 nm can also be used.

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

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

2.7 Fire hazard

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

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

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

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

WARNING!
Equipment not suitable for use in the presence of flammable mixtures.

2.8 Emission of plume

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

CAUTION!
Laser plume may contain viable tissue particulates.

2.9 Safety Measures for the electromagnetic compatibility (EMC)

The device MH01 doesn't include any type of direct connection with other external devices.

The device MH01 can be disturbed by the interference with external electromagnetic fields generated by other electrical devices installed near to it.

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

This device MH01 must be installed and used according to EMC information described in the tables reported in Attachment B.

2.10 Emission of toxic gas or vapour

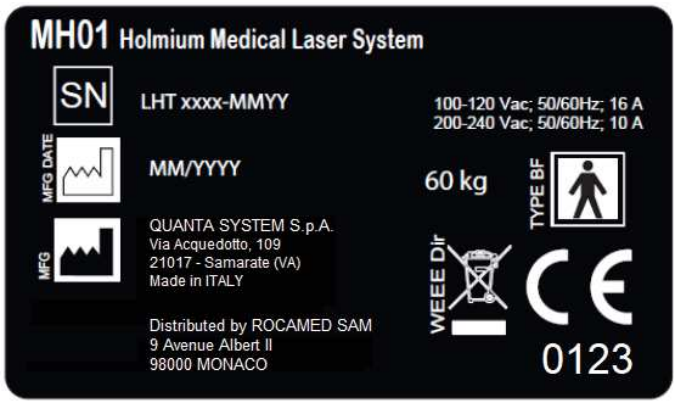
The laser radiation of this LASER device is able to melt, to burn or to vaporize almost all the materials. The use of this LASER device is limited to the applications specified in this manual.

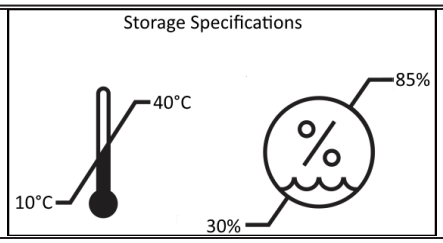
2.11 Warning and instructions for the device disposal

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

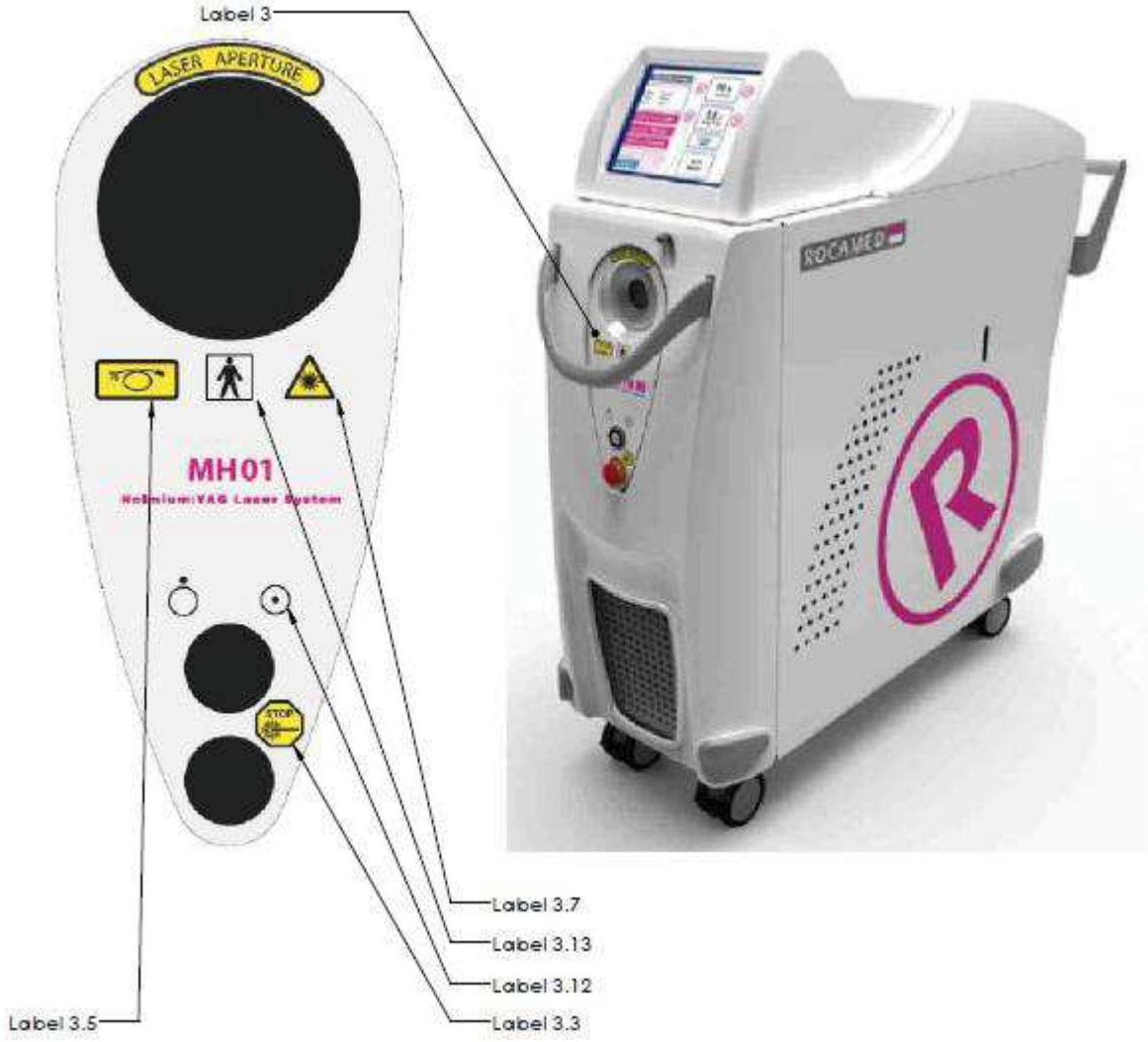
2.12 Labelling plan

	**Label 1** Laser characteristics
	**Label 2** Footswitch Connection
	**Label 3.3** Emergency Stop
	**Label 3.5** Laser Aperture
	**Label 3.7** Warning Label of Maser Radiation
	**Label 3.12** ON and OFF the key switch
	**Label 3.13** Applied Part BF

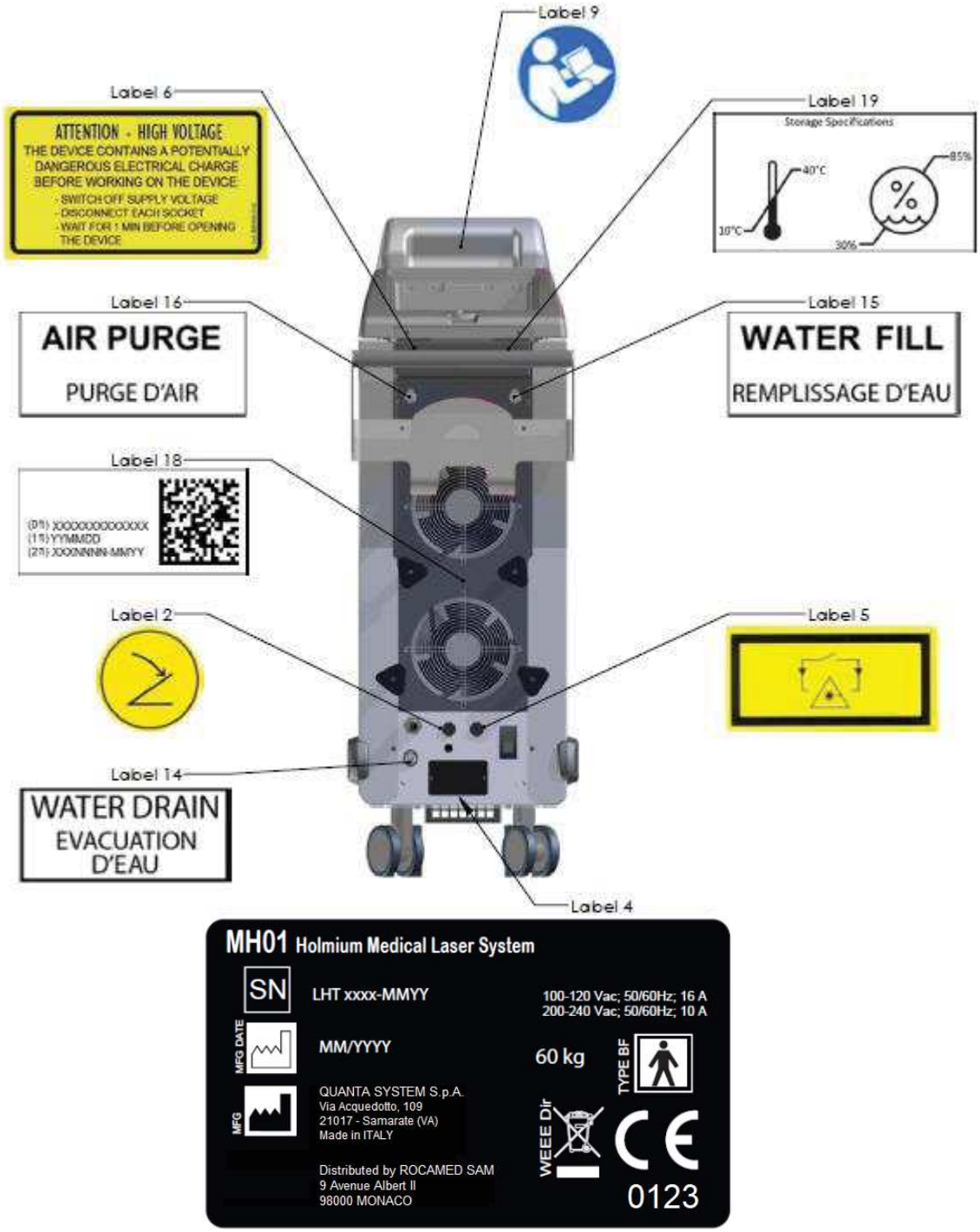
	**Label 4** Product Label
	**Label 5** Interlock connector
	**Label 6** Warning – High Voltage
	**Label 7** Caution – Laser Radiation
	**Label 8** Ground
	**Label 9** Read Instruction For Use
	**Label 10** Pushing Prohibited
	**Label 14** Water Drain Connector
	**Label 15** Water Fill Connector

AIR PURGE PURGE D'AIR	**Label 16** Air Purge Connector
(01) XXXXXXXXXXXXX (11) YYMMDD (21) XXXNNNN-MMYY	**Label 18** UDI label
	**Label 19** Storage Conditions

Frontal View



Rear View


Label 9
Label 6
ATTENTION - HIGH VOLTAGE
THE DEVICE CONTAINS A POTENTIALLY DANGEROUS ELECTRICAL CHARGE BEFORE WORKING ON THE DEVICE
- SWITCH OFF SUPPLY VOLTAGE
- DISCONNECT EACH SOCKET
- WAIT FOR 1 MIN BEFORE OPENING THE DEVICE
Label 19
Storage Specifications
40°C
10°C
85%
30%
Label 16
AIR PURGE
PURGE D'AIR
Label 15
WATER FILL
REMPLISSAGE D'EAU
Label 18
(01) XXXXXXXXXXXX
(11) YYMMDD
(21) XXXNNNN-MMYY
Label 2
Label 5
Label 14
WATER DRAIN
EVACUATION D'EAU
Label 4
MH01 Holmium Medical Laser System
SN
LHT xxxx-MMYY
100-120 Vac; 50/60Hz; 16 A
200-240 Vac; 50/60Hz; 10 A
MFG DATE
MM/YYYY
60 kg
TYPE BF
MFG
QUANTA SYSTEM S.p.A.
Via Acquedotto, 109
21017 - Samarate (VA)
Made in ITALY
WEEE Dir
Distributed by ROCAMED SAM
9 Avenue Albert II
98000 MONACO
0123

Lateral View

Left Side

Right Side

3 DEVICE DESCRIPTION

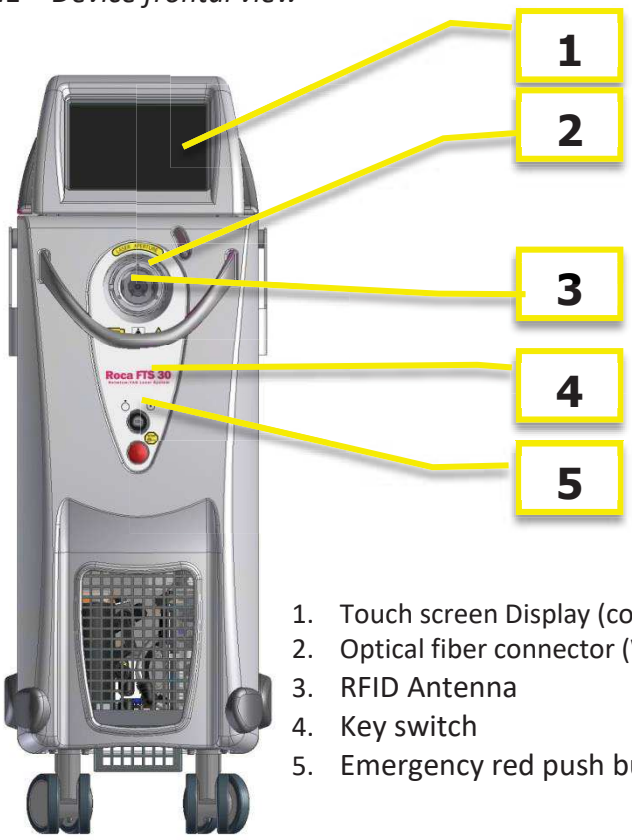
In this chapter is given a general description of the device and all its parts.

3.1 *Introduction*

Medical device MH01 has inside like laser source a flash pumped Ho:YAG laser. Its wavelength is 2100nm, then in the infrared part of the EM spectrum. The maximum power of the device is 30W. For the release of laser radiation to the patient the medical device MH01 uses a quartz optical fiber with a diameter up to 1000µm (see Chapter 11 "Accessories") to be used for surgical applications mentioned in Chapter 6, "Clinical Applications". The laser can operate in a pulsed mode with a max frequency of 25Hz. In the latter case, the release is by pulses that are repeated over time with an adjustable frequency[1] (see Chapter 5 "Operating Instructions").
Medical device MH01 is used in different clinical application (see Chapter 6 'Clinical Applications').

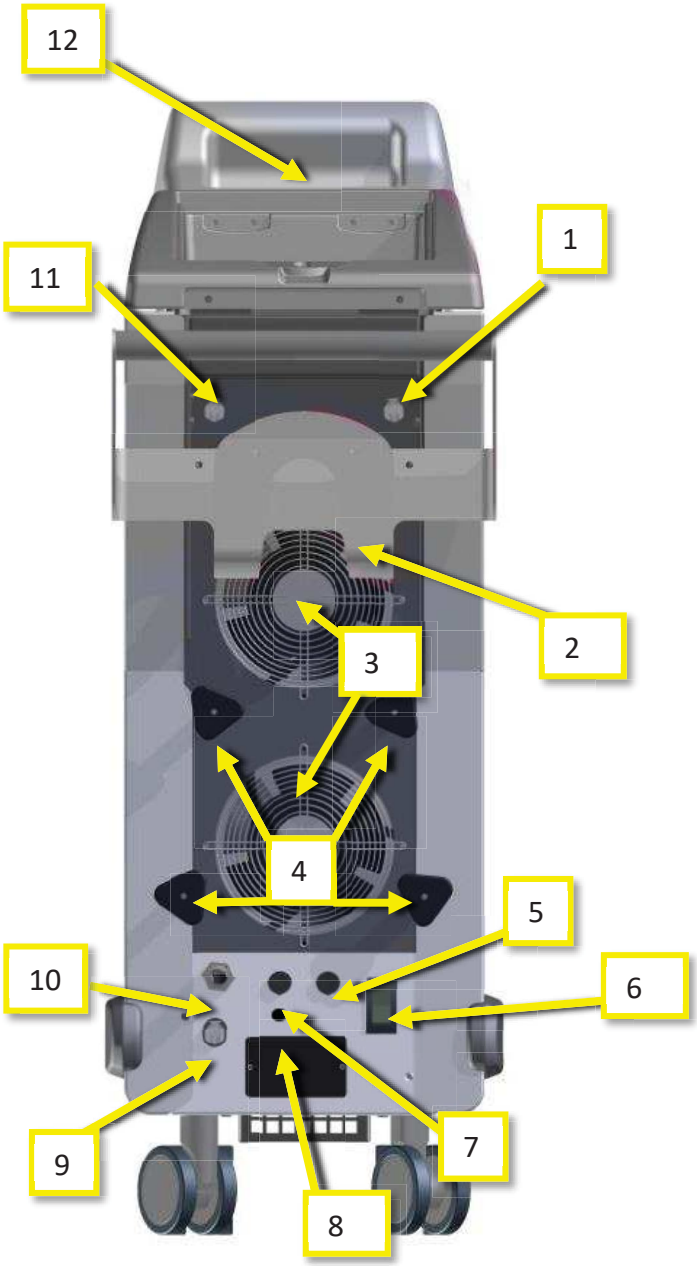
3.2 *General description of the device*

3.2.1 *Device frontal view*



1. Touch screen Display (control panel)
2. Optical fiber connector (WARNING: this is a laser aperture)
3. RFID Antenna
4. Key switch
5. Emergency red push button

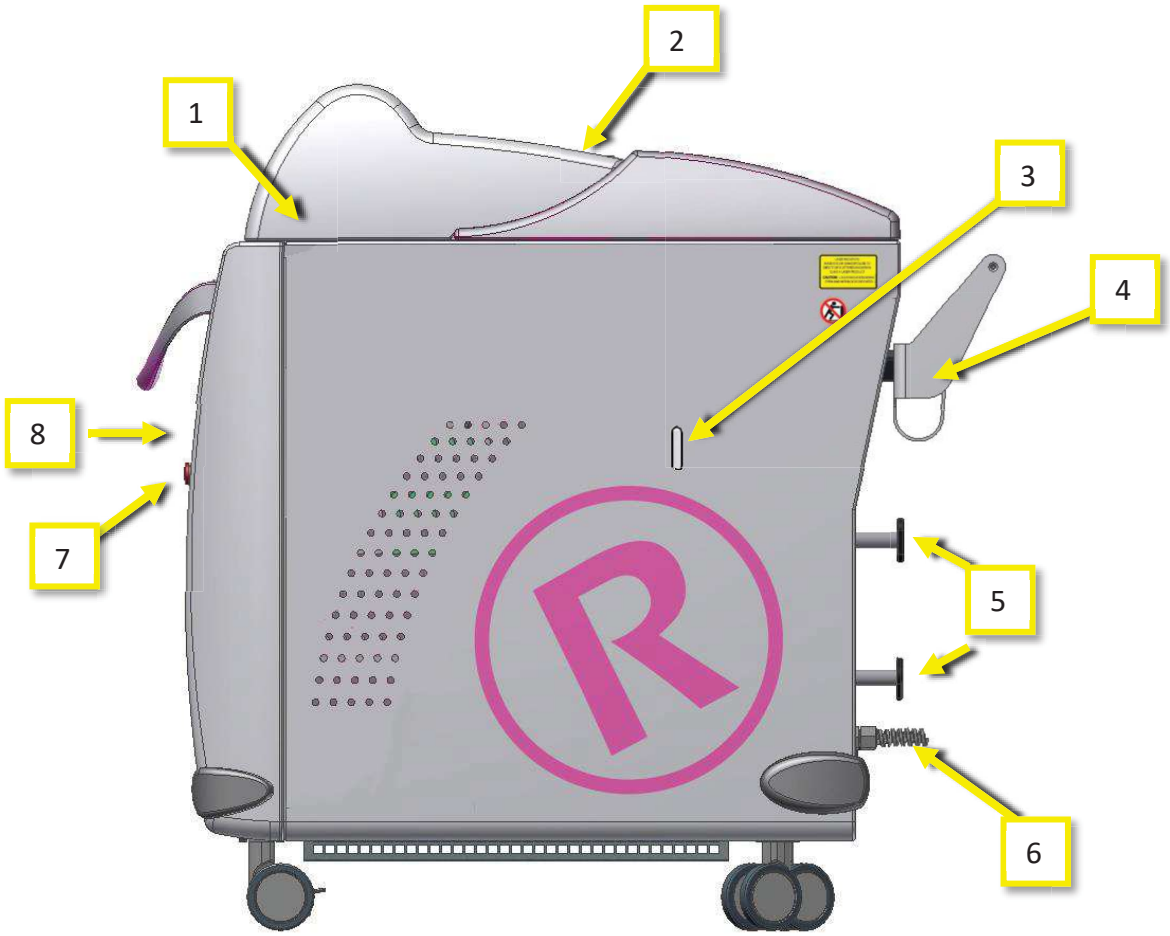
3.2.2 *Device Back view*



1. Hydraulic circuit loading connector
2. Fiber Box support
3. Fans Area
4. Cord storage
5. Interlock connector
6. Power/mains switch
7. Footswitch connector
8. ROCAMED ENDOFLO®II/ROCAFLOW Connection
9. Hydraulic circuit drain connector
10. Power supply cord
11. Bleeding
12. Blast Shield Access

3.2.3 *Device Lateral view*

1. Touch screen Display (control panel)
2. Blast Shield Access
3. Water Level
4. Fiber Box support
5. Cord storage
6. Power supply cord
7. Emergency red push button
8. Key switch



3.2.4 *Laser and electric system*

The laser system consists of the source (2100nm 30W Ho:YAG laser), the internal hydraulic circuit, the optical fiber launch system and the power and control electronics. For all technical information relating to the laser system and electrical system, contact the company ROCAMED

3.2.5 *Electrical control*

The electrical controls include a main switch and the key switch, the emergency red push button.

Main switch:
The main switch feeds the device. There are two positions on the switch: **I** and **O**.
To switch ON the device, make the switch to **I** position.
To switch OFF the device, make the switch to **O** position.

Key switch:

The key switch to turn on the device. There are two positions on the switch:  and  .

To switch ON the device, insert the key and turn to  position.

To switch OFF, turn the key on the  position and remove key.

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 off immediately, press the button.
To reset the emergency red push button turn the knob clockwise.

3.3 *Accessories*

With the device are associated optional accessories, such as optical fiber (for a list of optional accessories supplied with the device, see Chapter 11 "Accessories").

3.3.1 *Optical fiber*

The optical fiber is used for the application of the laser radiation to the patient. It is connected to the device through a special connector on the optical mechanism accessible from the frontal panel. The connector has a micro switch that stops the laser if the fiber is missing or not installed properly. Depending on the surgical applications, optical fiber used may be sterile and mono use or Sterilizable. For more information about cleaning and sterilization of the fibers refer to Chapter 7, "Maintenance and cleaning ".

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

DANGER:
Any tampering of the protection of the optical fiber may cause undesired emission of laser radiation.
The fibers are enhanced externally near the SMA connector. Twisting, straining, or too exaggerated curves can damage and / or break the optical fiber and the consequent internal irradiation of the metal sheath.

DANGER:
This sheath protects the user and the patient from the potential radiation danger cause of breakage of the fiber.

DANGER:
Before performing any laser emission, make sure that the probe is inserted, pay attention to the pointing direction

WARNING:
The use of fibers or other connections than those not supplied by the manufacturer, not original, does not guarantee the achievement of security requirements.

4 ENVIRONMENTAL CONDITIONS AND INSTALLATION

4.1 Environmental condition

4.1.1 Working area

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

4.1.2 Electrical connection requirements

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

- 115V, Nema L5-20P
- 230V, Shuko

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

4.1.3 Temperature and humidity

Appropriate values of temperature and humidity are required for the proper functioning of the device. The working temperature of the device should be between 10°C and 30°C, while the humidity should not exceed 85%.

4.1.4 Minimum space requirements

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

4.2 Device installation

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

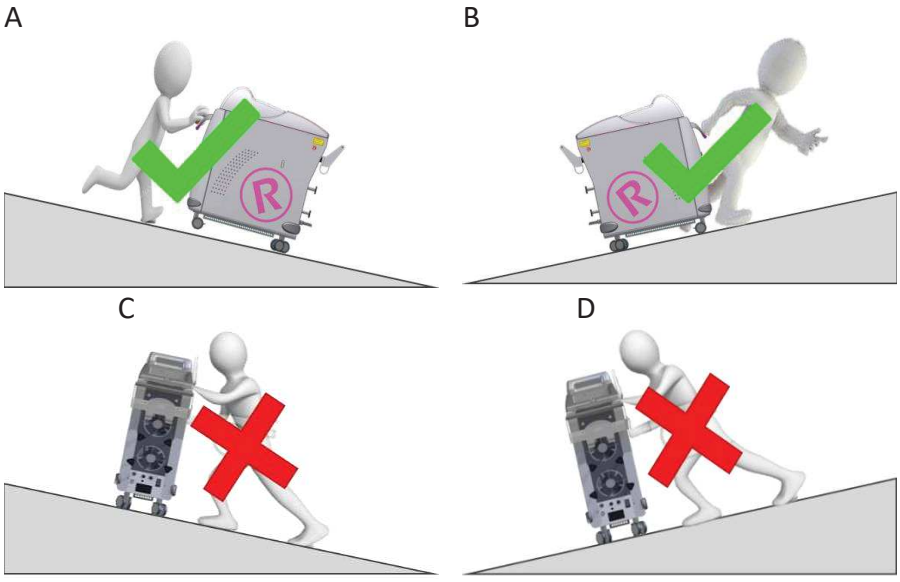
The installation of the laser device must be performed by qualified technical personnel authorized by the manufacturer. This person should also carry out tests on the operation of the device after installation in the designated working area.

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

4.2.1 Transportation

To transport the laser, disconnect fittings, fiber and power cord; unplug the pedal and remote locking. Finally, the laser and the accessories should be stored in slots inside the packaging.

Warning:
During device transportation from a room to another, the device shall be pulled using the handle placed on the front side of the device as shown in Figure A and B. Avoid pulling the device on sloping surfaces as shown in Figure C and D, the device could tip over.



4.2.2 Packaging

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

4.2.3 Inspection

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

- Administrative check:
  Number of packages
  Sizes and weights

- Technical check:
  Packaging condition

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

4.2.4 Labelling check

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

4.2.5 Installation procedure

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

During installation the device must be checked for proper operation and possible malfunctions after transportation of the laser device must be corrected.
The installation procedure includes also a training course from the distributor to the user concerning the use of the medical device.
The first turn on procedure typically takes several hours, during this time the access to the installation site is forbidden. The case is normally shipped to the distributor.
It is extremely important that the packed materials be checked immediately upon their arrival, if possible, in the presence of the shipper's delivery employee, as follows:

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

- Execute the following operations for the general check:
  - Check the labels of the device
  - Remove the label "Caution no water inside"
  - Connect the remote door interlock
  - Connect the footswitch
  - Fill the system cooling liquid **with bidistilled or deionized water only**
  - Connect the laser device to the power supply
  - Turn on the system
  - Check the system and verify if alert messages are displayed
  - Connect the RFID Fibers and wait that MH01 system recognizes type and the number of uses of employed fibers.

- Check the system and verify if alert messages are displayed
- Change the status of MH01 laser system in Ready
- Check the system and verify if alert messages are displayed
- Change the status of MH01 laser system in Standby
- Turn off the system

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

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

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

- Install the device in the room indicated by the customer in the following way:
  - Connect the device to the power supply
  - Connect the interlock connector
  - Connect the footswitch
  - Check the laser device

- Perform further controls or additional tests.

- Perform a training to the end user on the following items:
  - Proper fiber attachment
  - Operation of the device

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

4.2.6 Main device connection.

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

The device must be connected to the mains in compliance with electrical safety regulations. The laser system can be connected to a power socket that provides 100 120 VAC, 50-60 Hz, 16A or 200-240 VAC, 50-60 Hz, 10A.

WARNING:
During its use the device must be placed in a position such to keep the power/mains switch easily accessible.
The power/mains switch is the mean of disconnection from mains.

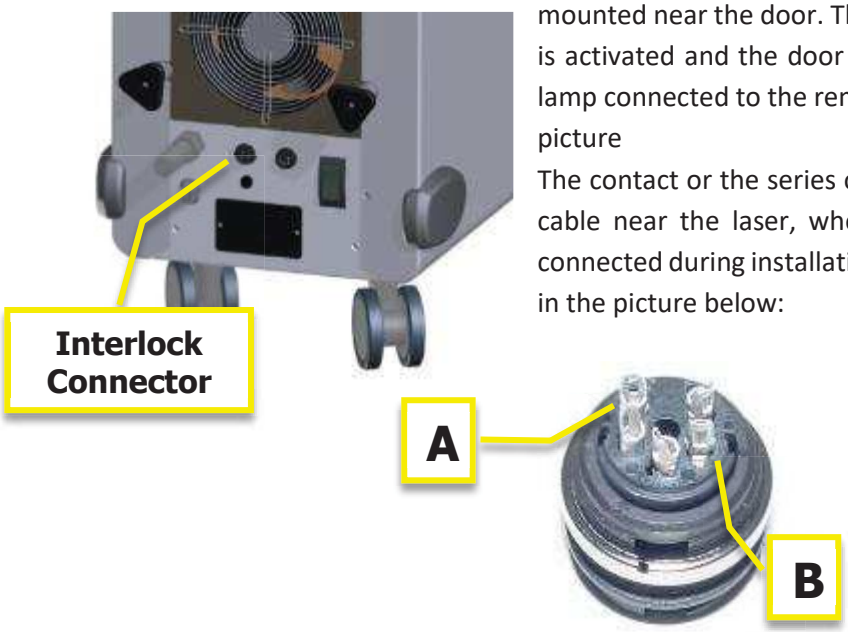
4.2.7 *Remote interlock connection*

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

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

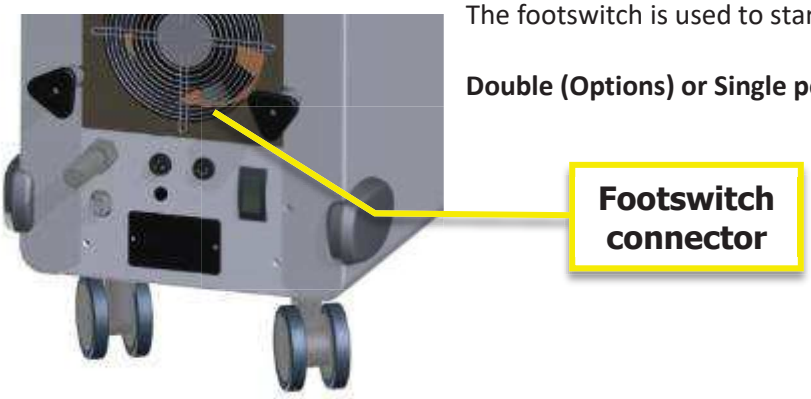
The remote interlock cable must be connected to a lamp mounted near the door. The lamp should light when the laser is activated and the door of the working area is closed. The lamp connected to the remote interlock cable is shown in the picture

The contact or the series of contacts will be led by a suitable cable near the laser, where the specific connector will be connected during installation. Internal pins (1 and 2) as shown in the picture below:



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

4.2.8 *Footswitch connections*

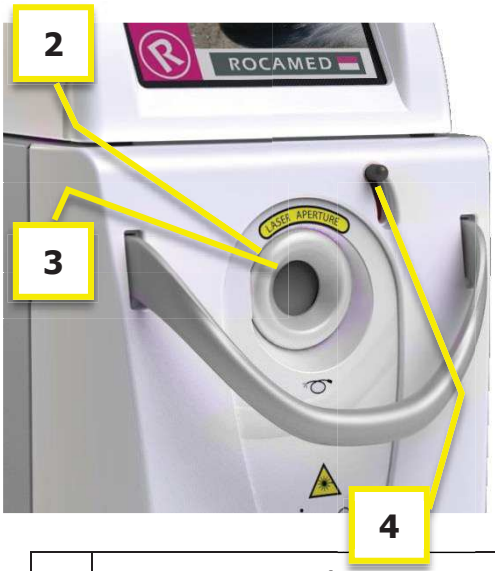


The footswitch is used to start the laser emission.

Double (Options) or Single pedal

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.*

4.2.9 *Optical fiber connection*



1	Components description
2	RFID Antenna
3	Optical fiber connection location
4	Stick of external shield

The fiber is connected to the device through the cable connector on the front.

Open by the dedicated stick the external shield of the fiber connector.

The device accepts fiber with SMA905 connector and with RIFD Recognizer System (only with ROCAMED internal code). The fiber connector has an additional ring which facilitates the clamping of the fiber to the connector on the device and enables automatic detection of the presence or absence of the fiber, diameter and type (single use / reusable) of the connected optical fiber. If the fiber is not connected to the device is reporting an error when the device is switched on.

Warning:
It's very important to tighten to the device by hand the fiber nut until the end.
Improper connection may cause a low output power.

4.2.10 *Optical fiber check*

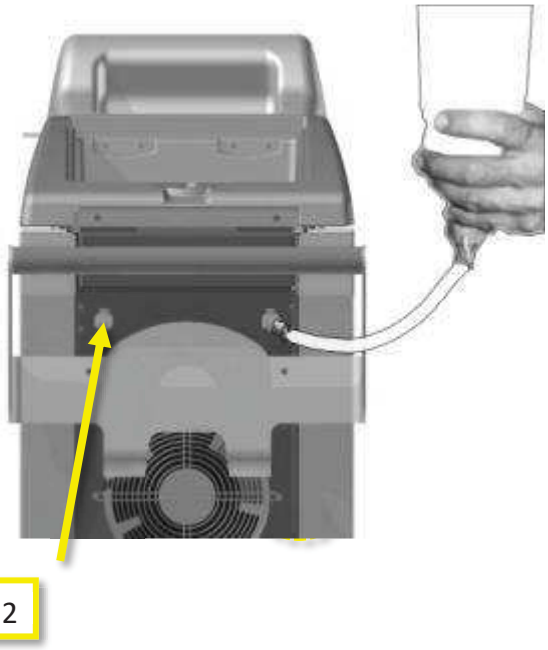
Please see Cap 7.6

4.2.11 *Hydraulic system filling*

WARNING:
Use only bidistilled or deionized water.

The procedure for filling the hydraulic circuit is the following:

- Turn ON the system
- Insert the blue tube supplied in the bleeding connector (2)
- Insert the suitable bottle with the previously filled bidistilled or deionized water to the quick hydraulic circuit loading connector (1)
- Check for the water level on the liquid bar on graduate scale (left side of the system - 1).
- Fill the water tank over the minimum (MIN) level.
- Do not exceed the maximum (MAX) level.
- Remove the bleeding tube after the filling



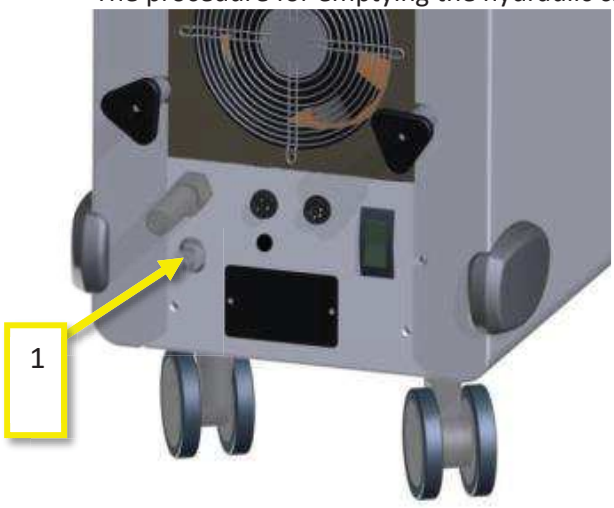
WARNING:
Do not activate the system with the bleeding tube connected.

- Turn the device on and check again the water level.
- Refill if necessary until reaching an optimal level.

IMPORTANT!
Check periodically the water level using the graduate scale and refill as necessary following the above instruction

4.2.12 Emptying the hydraulic circuit

The procedure for emptying the hydraulic circuit is the following:



Turn off the System

Insert the blue tube supplied in the water drain connector (1).
Place a container to collect the water released from the tube.
When the emptying is over remove the tube and push in red cap to close the Air Purge

5 INSTRUCTION FOR USE

This section describes the instructions for use of the device MH01. They include:

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

5.1 Start-up procedure

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

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

Also make sure the emergency red button is not pushed.

To turn on the device:

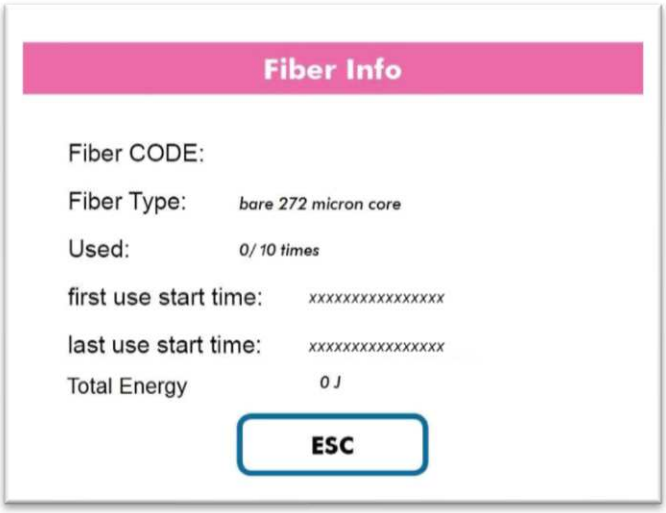
- Put to I position the main switch on the rear panel.
- Turn the key switch in position ⊙ (clockwise) to turn on the system.

The Loading screen appears:

After a few seconds the main screen will be displayed.

5.1.1 RFID Fiber connection

Connect the fiber. The system recognizes automatically type and uses of the fiber connected showing the information data on the display *(in the example first use of a reusable 272 µm fiber)*:



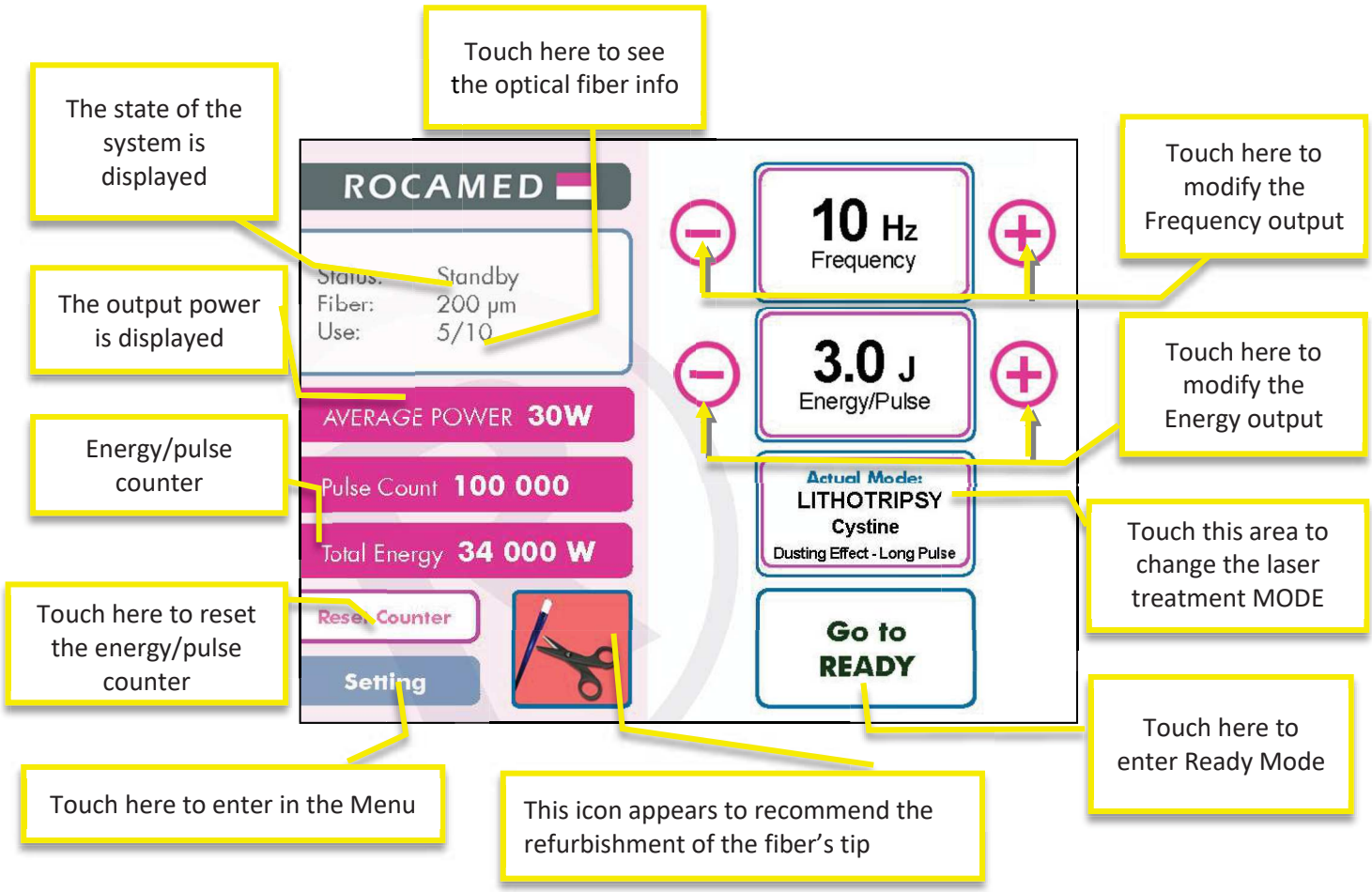
WARNING:
The optical fiber size visualized on the display must be the same of the used optical fiber size. Before starting the laser emission, please control that the optical fiber size coinciding with the indications impressed on the connector of the fiber.

After a few seconds, the main menu will be present the main screen.

5.2 Operating instruction

5.2.1 Main display screen

The section details the Main Display Screen functions. Refer to **Figure below.**

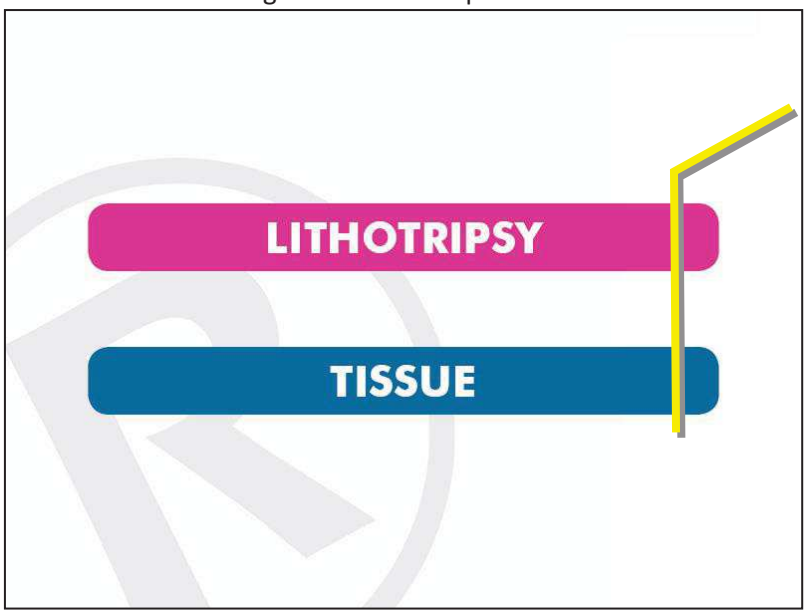


5.2.2 *Change Emission Mode*

When you insert a new optical fiber, MH01 will ask you to select the specific emission mode depending to the intended use of the laser system.
Press MODE Area to change the treatment mode.

Touch MODE Area
to enter the Emission Mode

The following screen shows up:

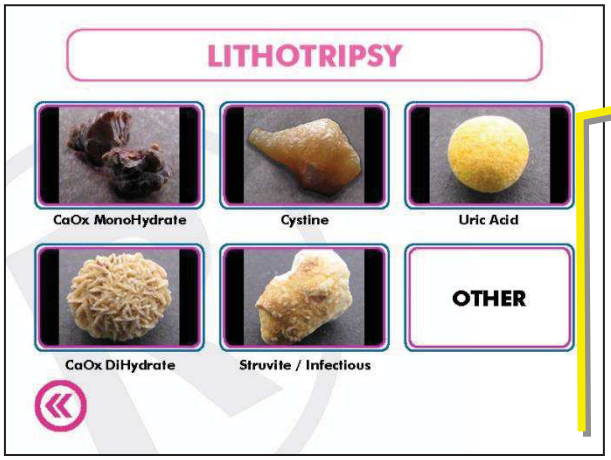


Select the desired
Treatment MODE:

- **Lithotripsy**
- **Tissue**

5.2.3 Lithotripsy Mode:

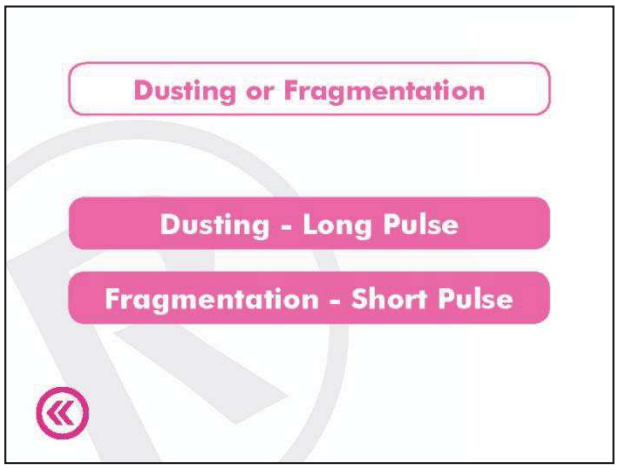
If you select "Lithotripsy" in the first mode emission selection (cap5.2.2) the following screen will appear:



Select the type of stone object of the treatment

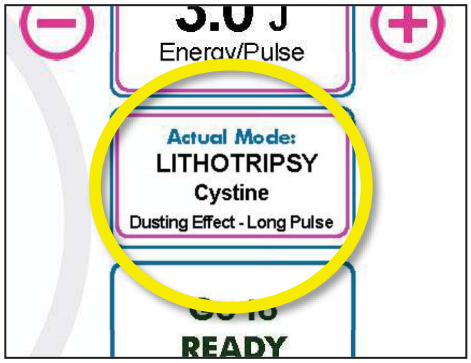
Select the Type of stone to treat:

- **CaOx MonoHydrate**
- **Cystine**
- **Uric Acid**
- **CaOx DiHydrate**
- **Struvite/Infectious**
- **Other**



After the selection of the chemical composition of the stone, it is possible to choice the desired lithotripsy effect: **Dusting** (Long Pulse)**, Fragmentation** (short Pulse)**.**

Use the Lithotripsy Dusting Effect Mode in order to minimize the size of fragments.
Use the Lithotripsy Fragmentation Mode in order to minimize the speed of lithotripsy but doing bigger size of fragments

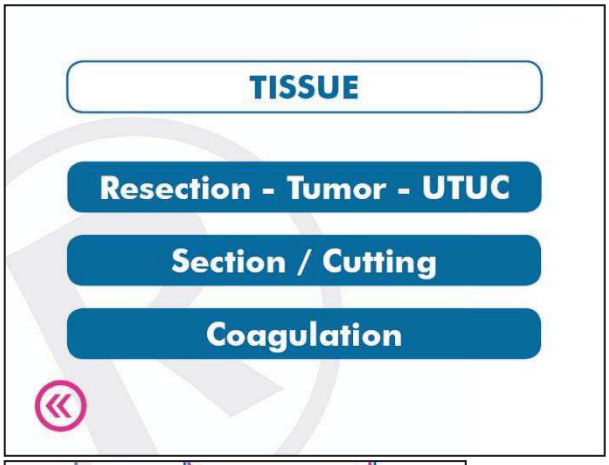


MH01 will suggest you a combination of energy pulse and frequency emission*, taking in consideration your selection and the connected fiber specifications.
The operator have to intend these pre-sets[1] just as suggestion and he can change the frequency and the energy before the use over the target stone.
The final output setting is under the responsibility to the operator.

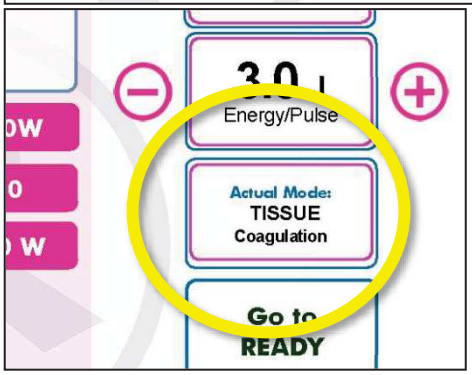
[1] *The pre-set combination are been suggested by Prof. Olivier Traxer*

5.2.4 *Tissue Mode:*

If you select “Tissue” in the first mode emission selection (cap5.2.2) the following screen will appear:



Select the type of laser action you need over the target tissue



MH01 will suggest you a combination of energy pulse and frequency emission, taking in consideration your selection and the connected fiber specifications.

The operator have to intend these pre-sets just as suggestion and he can change the frequency and the energy before the use over the target stone. The final output setting is under the responsibility to the operator

5.2.5 *Frequency*

The repetition rate is selected using frequency. Touching the **+** button increase the repetition rate displayed. Touching the **-** button decreases the repetition rate displayed.
If the energy set is too high for the frequency selected, the laser will automatically decrease the value of energy pulse. The sound emission of laser changes with the selected frequency.

5.2.6 *Energy*

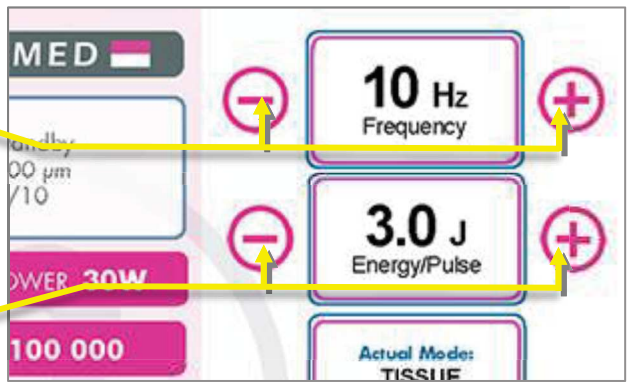
The treatment energy available is displayed. Touching the **+** button increase the energy displayed. Touching the **-** button decreases the energy displayed.

If the energy set is too high for the frequency selected, the laser will automatically decrease the value of energy pulse.

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

Touch here to modify the Frequency output

Touch here to modify the Energy output



5.2.7 *Fiber INFO*

When a RFID ROCAMED fiber is connected and the RFID system is active, the system recognizes the type of the fiber and any of the previous uses.
When the RFID System recognizes the fiber the Info Fiber Panel will appear.
If a non unauthorized fiber is connected the RFID system the fiber will not recognized.
If an expired Optical Fiber (disposable/reusable) is connected to the laser system, an error message will appear.
Pressing on the Fiber info area the Info Fiber Panel will appear

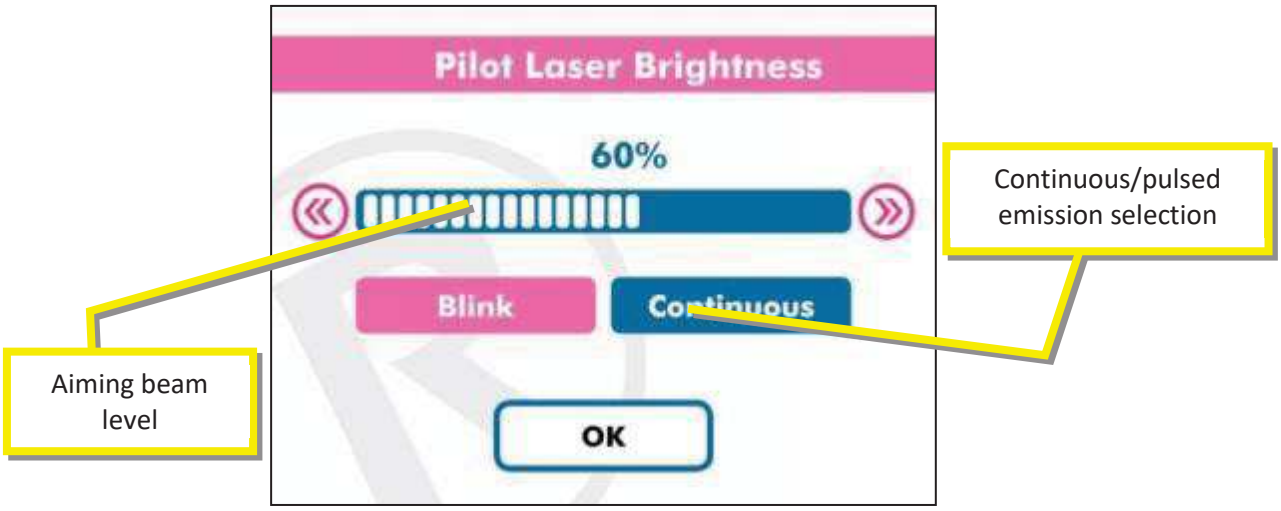
Here you can find the following information:

- **Code of the fiber**
- **Fiber Type**
- **Uses**
- **First use time (data)**
- **Last use time (data)**
- **Total Energy emitted (J)**

Press ESC to come back to the main Screen

5.2.8 *Pilot laser*

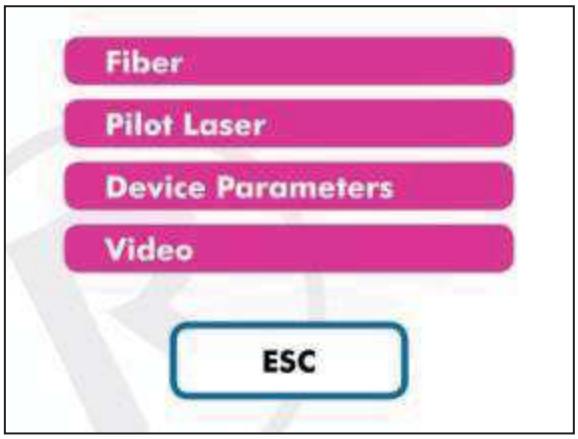
Aiming beam is adjustable by software, the minimal value is 1% and the maximal is 100%.
Also it is possible to select the aiming beam in pulsed mode or continuous mode.



Touching the » button increase the energy displayed. Touching the « button decreases the energy displayed. When the aiming beam emission corresponds to your desire, press OK to confirm and exit to the main screen.

5.3 MENU

When pressing on the Menu button *("Main Screen" 5.2.1),* the sub Menu panel will appear.



The available functions are the following:

- Fiber
- Pilot Laser Brightness
- Device Parameters
- User Manual

It is possible to access the "Fiber" information, "Pilot Laser Brightness", also by using the shortcut area from the Main Screen *("Main Screen" 5.2.1)*.

Press "Esc" to exit to the Main Screen.

5.3.1 *Fiber*

Please see chapter 5.2.5

5.3.2 *Pilot laser*

Please see chapter 5.2.6

5.3.3 *Device Parameters*

Please see chapter 5.4

5.3.4 *User Manual*

The electronic version of this User Manual is consultable directly from this area by the MH01 Software.

5.4 DEVICE PARAMETERS

By selecting the Device Parameters from the sub Menu (Menu Functions 5.3), the Device Parameters Panel will appear.

The available functions are the following:

- Service (Only for Technical Service)
- Display
- Audio
- Device Info
- Language

Press "Esc" to exit to the Main Screen.

5.4.1 Service (Only for Technical Service)

- Insert the Password and press OK to access to the Service Area.
- Press “Diagnostic” to access to the Diagnostic Screen (see below).
- Press ESC to come back to the Main Screen.

Diagnostic

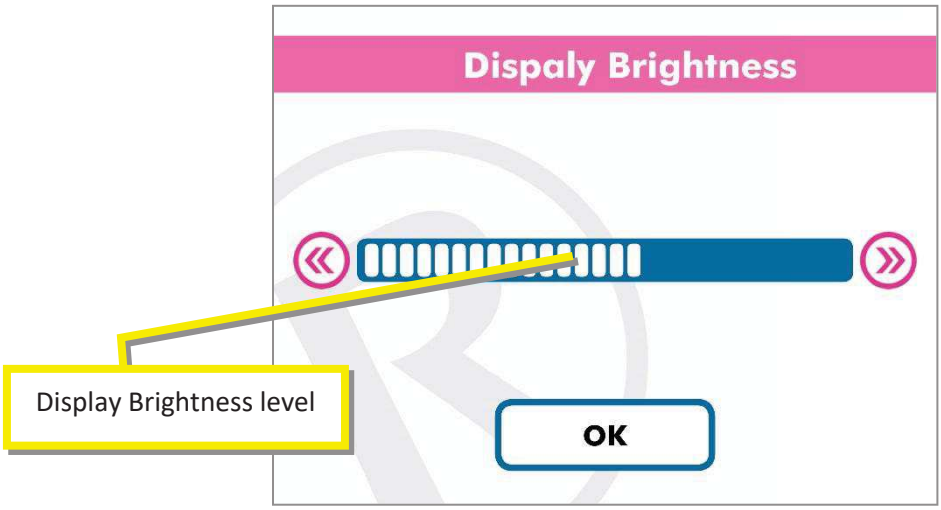
Without the Service Password it is possible to access the Diagnostic Panel by pressing on the “Diagnostic” button in the Service Screen.

Press “Esc” to exit to the Main Screen.

5.4.2 *Display*

Touching the » button increase the Brightness.

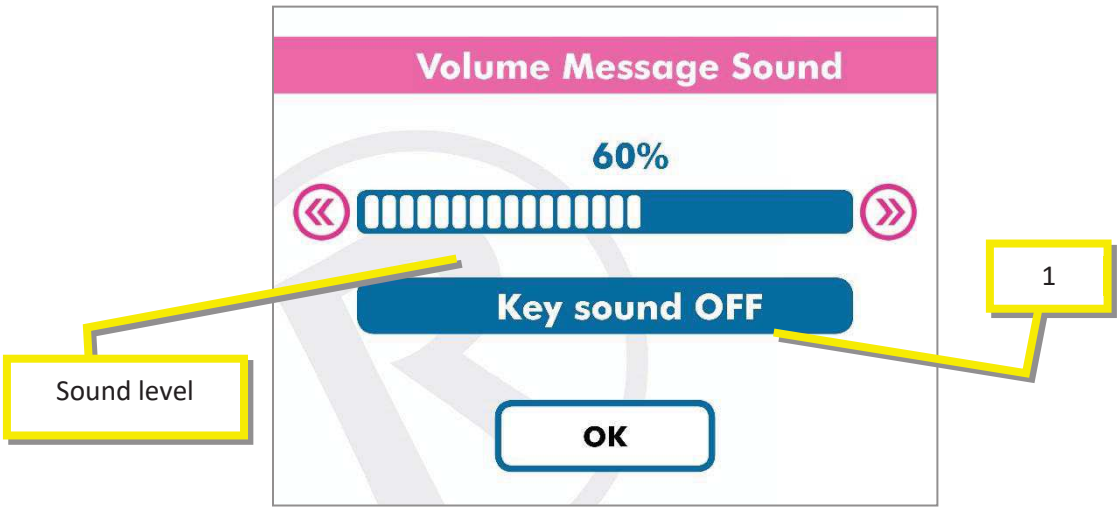
Touching the « button decreases the Brightness.



When the Display Brightness corresponds to your desire, press OK to confirm and exit to the main screen.

5.4.3 *Audio*

The Volume is adjustable by software, the minimal value is 1% and the maximal is 100%. Also it is possible to activate or deactivate the Key sounds by the Key Sound button (1) .



Touching the » button increase the energy displayed.

Touching the « button decreases the energy displayed.

When the Sound emission corresponds to your desire, press OK to confirm and exit to the main screen.

5.4.4 Device Info

The Device Info Panel shows the following parameters:

- Device Number
- Software Version (Fw)
- Software Version (Sn)
- Hardware Version (S)
- Flash Lamp Usage

Press “Esc” to exit to the Main Screen

5.4.5 Language

Select the desirable language.

Press ESC to exit to the main screen.

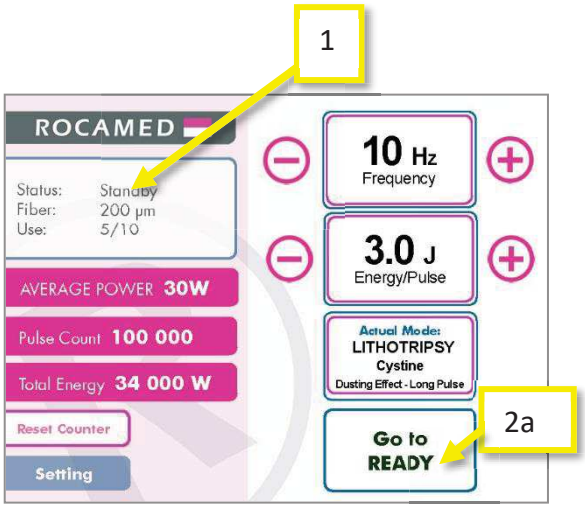
5.5 Laser emission

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

Laser Operation:
Press the ready/standby button area or push the dedicate pedal of the double footswitch (optional), changing the status from standby to ready.

5.5.1 *Ready / Standby*

The Ready / Standby function area places the system in the Ready or Standby Mode. In the Standby mode, the laser is not firing and the system cannot emit energy. In the Ready mode, the laser is firing and ready to emit energy.

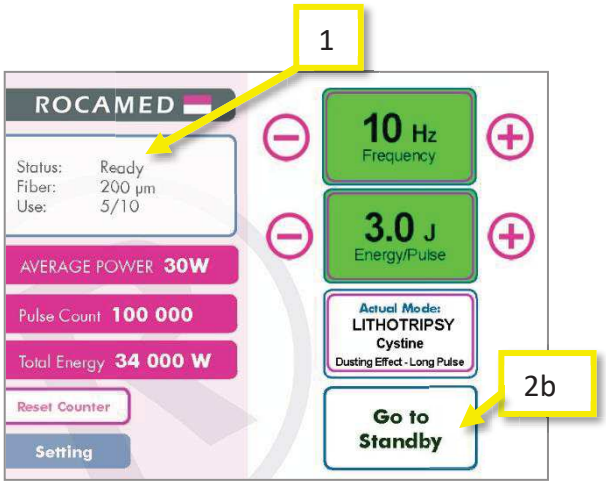


The Ready/Standby Area (1) show the actual state of the Laser System .

By touching the button Ready/Standby (2a) when in "**Standby**" the Laser will go to "**Ready**" mode.

By touching the button Ready/Standby (2b) when in "**Ready**" the Laser will go to "**Standby**" mode.

Along with the first change from Standby to Ready mode the Warning Safety Screen will appear.



IMPORTANT

Please read the Chapter:
2 - LASER SAFETY
before continuing using the laser!

If you use the double footswitch element you can use the dedicated button to change the system status from standby to ready or vice versa.
The footswitch (only with double footswitch – Optional) or the ready/standby display area can be used interchangeably for the same function.

WARNING!
All the personnel present in the laser working area must wear all the protective items

5.5.2 *Ready Mode*

When you change the system from standby to ready to the first time the Warning Safety Screen will appear:

Touch the display to exit from the "Warning Safety Screen".

When an Optical Fiber is connected and the RFID system is active, the system shows you the type of the fiber before passing from the Standby Status to the Ready Status. *(5.2.2 Fiber Information).*

If the fiber is missing or an invalid fiber is inserted, when touching the "Ready/Standby" button an Error Message will appear.

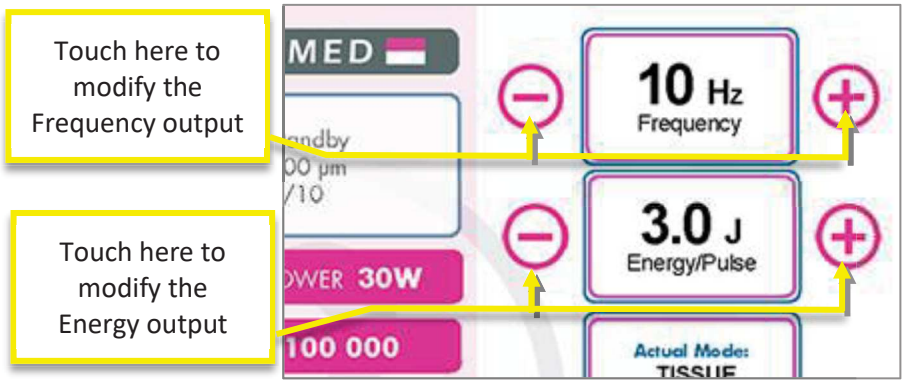
When you are in READY mode it is possible to change the energy output and the frequency of emission by the dedicate buttons.
The Touch Screen Control Panel contains the controls and displays for operating and monitoring the laser. It is essential that operators understand and use these controls properly

5.5.3 Mode of Emission

Please see cap. 5.2.2

5.5.4 Power output settings

The values for energy and frequency can be changed, within the permissible limits, using the dedicated buttons. The selected values are displayed.



Frequency
The repetition rate is selected using frequency.

Touching the **+** button increase the repetition rate displayed.

Touching the **-** button decreases the repetition rate displayed.

If the energy set is too high for the frequency selected, the laser will automatically decrease the value of energy pulse. The sound emission of laser changes with the selected frequency.

Energy
The treatment energy available is displayed.

Touching the **+** button increase the energy displayed.

Touching the **-** button decreases the energy displayed.

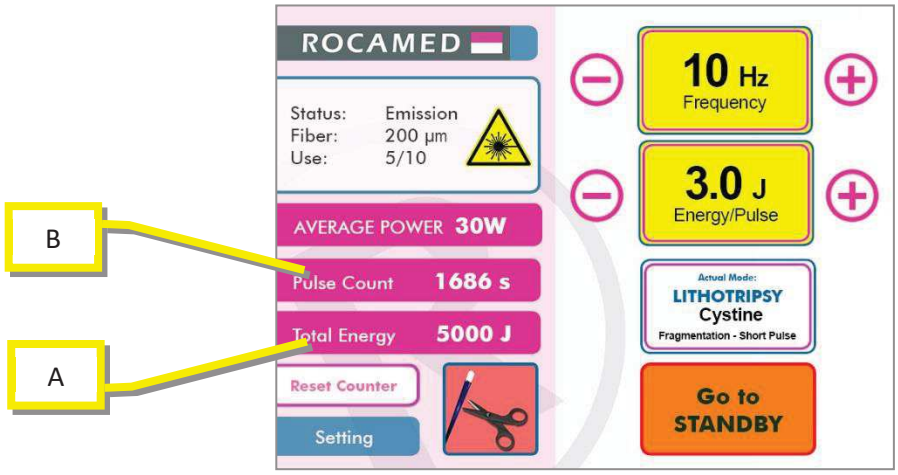
If the energy set is too high for the frequency selected, the laser will automatically decrease the value of energy pulse

5.5.5 Emission

While in "Ready" mode, by pressing the footswitch, the Laser System start to emit the laser beam through the connected optical fiber. The emitted values of frequency/energy are shown on the display.

WARNING!
All the personnel present in the laser working area must wear all the protective items

During the emission the display shows the EMISSION state:

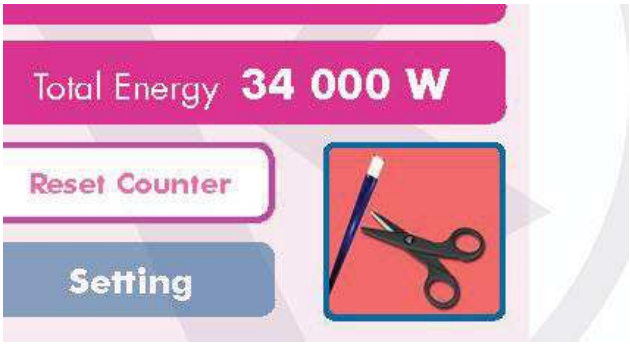


During the emission the values of Joules (A) emitted and Lasing Time (B) will be increased.

At the end of the treatment, release the footswitch and enter in the standby mode by pressing the Ready/Standby area on the display or the dedicated pedal of the double footswitch (optional).
For starting a new treatment press Ready/Standby area on the display or the dedicated pedal of the double footswitch (optional).

NOTE: If the footswitch is left unused for a long time in READY mode the laser device will enter automatically the STANDBY mode.

5.5.6 Alarm - fiber consumption



When this signal appears please move the system in standby and refurbish the tip of the fiber (cap 7.6).

The signal disappears automatically after few seconds or if the operator touch the screen.

5.5.7 Laser Parameters

The following tables give indication of maximum laser output for each possible combinations (Power=Energy*Frequency).

The size of the fiber has to be taken in consideration to detect power limits

For all fiber dimension*				**LITHOTRIPSY – Fragmentation**											
	200 mJ	**300 mJ**	**400 mJ**	**500 mJ**	**600 mJ**	**700 mJ**	**800 mJ**	**1 J**	**1.2 J**	**1.5 J**	**1.8 J**	**2 J**	**2.5 J**	**3 J**	**3.5 J**	**4J**
3 Hz				1,5 W	1,8 W	2,1 W	2,4 W	3 W	3,6 W	4,5 W	5,4 W	6 W	7,5 W	9 W	10,5 W	
5 Hz				2,5 W	3 W	3,5 W	4 W	5 W	6 W	7,5 W	9 W	10 W	12,5 W	15 W	17,5 W	20 W
8 Hz				4 W	4,8 W	5,6 W	6,4 W	8 W	9,6 W	12 W	14,4 W	16 W	20 W	24 W		
10 Hz				5 W	6 W	7 W	8 W	10 W	12 W	15 W	18 W	20 W	25 W	30 W		
12 Hz				6 W	7,2 W	8,4 W	9,6 W	12 W	14,4 W	18 W	21,6 W	24 W	30 W			
15 Hz				7,5 W	9 W	10,5 W	12 W	15 W	18 W	22,5 W						
20 Hz				10 W												
25 Hz	5 W	7,5 W	10 W													

For all fiber dimension*				**LITHOTRIPSY – Dusting**										
	200 mJ	**300 mJ**	**400 mJ**	**500 mJ**	**600 mJ**	**700 mJ**	**800 mJ**	**1 J**	**1.2 J**	**1.5 J**	**1.8 J**	**2 J**	**2.5 J**	**3 J**	**3.5 J**
3 Hz															
5 Hz				2,5 W	3 W	3,5 W	4 W	5 W	6 W	7,5 W	9 W	10 W	12,5 W	15 W	
8 Hz				4 W	4,8 W	5,6 W	6,4 W	8 W	9,6 W	12 W	14,4 W	16 W	20 W		
10 Hz				5 W	6 W	7 W	8 W	10 W	12 W	15 W	18 W	20 W	25 W		
12 Hz				6 W	7,2 W	8,4 W	9,6 W	12 W	14,4 W	18 W	21,6 W	24 W			
15 Hz				7,5 W	9 W	10,5 W	12 W	15 W	18 W	22,5 W					
20 Hz				10 W											
25 Hz															

For all fiber dimension*				Tissue – Resection/Cutting										
	200 mJ	300 mJ	400 mJ	500 mJ	600 mJ	700 mJ	800 mJ	1 J	1.2 J	1.5 J	1.8 J	2 J	2.5 J	3 J	3.5 J
3 Hz															
5 Hz															
8 Hz				4 W	4,8 W	5,6 W	6,4 W	8 W	9,6 W	12 W	14,4 W	16 W	20 W	24 W	
10 Hz				5 W	6 W	7 W	8 W	10 W	12 W	15 W	18 W	20 W	25 W	30 W	
12 Hz				6 W	7,2 W	8,4 W	9,6 W	12 W	14,4 W	18 W	21,6 W	24 W	30 W		
15 Hz				7,5 W	9 W	10,5 W	12 W	15 W	18 W	22,5 W					
20 Hz				10 W											
25 Hz															

For all fiber dimension*				Tissue - Coagulation										
	200 mJ	300 mJ	400 mJ	500 mJ	600 mJ	700 mJ	800 mJ	1 J	1.2 J	1.5 J	1.8 J	2 J	2.5 J	3 J	3.5 J
3 Hz															
5 Hz				2,5 W	3 W	3,5 W	4 W	5 W	6 W	7,5 W	9 W	10 W	12,5 W	15 W	
8 Hz				4 W	4,8 W	5,6 W	6,4 W	8 W	9,6 W	12 W	14,4 W	16 W	20 W		
10 Hz				5 W	6 W	7 W	8 W	10 W	12 W	15 W	18 W	20 W	25 W		
12 Hz				6 W	7,2 W	8,4 W	9,6 W	12 W	14,4 W	18 W	21,6 W	24 W			
15 Hz				7,5 W	9 W	10,5 W	12 W	15 W	18 W	22,5 W					
20 Hz				10 W											
25 Hz															

*** fibers with core diameter ≤ 272 µm could be limited (power output) depending to the technical specification of the connected device.**

5.6 Alarms and warning description

There are different alarms that can be displayed by the control panel. Every time that there is an alarm a yellow screen appears with an error message text that indicates the alarm type.
All the alarms cause the laser system stop: the power electronics are cut off through a suitable switch and the device is put in a safe mode or is restarted.
The possible types of alarm are the following (see picture below):

- **Remote Interlock alarm**: the remote connector near the footswitch is not connected or is connected in a wrong way. This alarm is displayed in the READY mode.
- **Footswitch (Pedal) alarm**: the footswitch connector is not connected or is connected in a wrong way. This alarm is displayed in the READY mode
- **Shutter alarm**: the shutter doesn't work well. Call Service
- **Fiber (Optical Interlock) alarm**: the optical fiber is not connected or it's connected in a wrong way. Try to unplug and plug again the fiber in the proper way.
- **Fiber expired:** you are searching to use the connected fiber beyond the expected uses.

- **Water flow alarm (H_2O pump)**: the cooling water flow is too low. Check the cooling water flows freely in the circuit. Check if tubes are truncated or twisted. If water level is low, fill the reservoir with distilled water only.
- **Water temp alarm (H_2O pump)**: the temperature of the cooling water is too high. Call service
- **Flash lamp (Simmer) alarm**: the flash lamp doesn't ignite. Call service.
- **Energy warning**: this warning appears every time there are energy fluctuations and it stops when the energy value is stable.

Buzzer
The device is equipped with an internal buzzer that emits an acoustic signal with a fixed duration. It is active in the following case:

- In READY mode when the footswitch is pressed;
- During the operation of the system the signal is emitted synchronously with the laser pulses.

5.7 Shutdown procedure and protection against unauthorized use

Once finished using the device and the laser is in standby mode, you can proceed with its shutdown as follows:

- Disconnect the optical fiber from the device and cover with the appropriate plug the laser device output
- Turn the key switch to position ○ and remove the key to prevent unauthorized use.
- Turn off the main switch on the rear panel and disconnect the power cable
- Disconnect the remote interlock
- Disconnect the footswitch
- Keep the device and accessories in a dry and safe place.

6 CLINICAL APPLICATION

This section is provided to aid professionals in the use of the MH01 laser system. It adds to or reinforces information presented in the operator's manual concerning instructions for use, precautions and warnings necessary to reduce the risk of injury. All operators must read the entire operator's manual before reviewing this section and before operating the system.

6.1 Intended use

The MH01 laser system and its fiber optic delivery system 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, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, ENT and General Surgery.

MH01 is a Class 4 laser emitting laser radiation at a wavelength of 2100 nm.
This particular wavelength is transmitted by a fiber optic wave guide (glass fiber) allowing efficient treatment in conjunction with the application related preselected parameters with at the same time minimum stress for the adjacent tissue

℞ Only

WARNING!
MH01 Holmium lasers are intended solely for use by physicians trained in the use of the Ho:YAG (2.1 µm) wavelength.
This device must only be used by adequately qualified and trained medical personnel with experience in Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, ENT and General Surgery.

NOTE!
Laser settings are guidelines only; always start with low settings and increase to achieve the desired tissue effect. Energy delivered endoscopically in a fluid medium.

The Ho:YAG (2.1 µm) wavelength is indicated for use in specific surgical applications as detailed in this chapter. Read and comprehend the following section, titled **General Warnings, Precautions, and Complications to Consider When Using the Holmium Wavelength**, before reading the sections that describe a particular surgical specialty.

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

6.2 General Warnings, Precautions, and Complications to consider when using the Holmium wavelength

The following warnings, precautions, and complications apply to all of the surgical specialties described in this chapter. For important information specific to a particular surgical specialty, such as **Urology**, read the corresponding section later in this chapter.

6.2.1 General Laser Warnings

Warning

a) Incorrect treatment settings can cause serious tissue damage; therefore, it is recommended that you use the lowest acceptable treatment settings until familiar with the instrument's capabilities.

b) Use extreme caution until the biological interaction between the laser energy and tissue is thoroughly understood.

c) As with conventional endoscopic surgery, the possibility of complications and adverse events, such as chills, fever, edema, haemorrhage, inflammation, tissue necrosis, or infection may occur following treatment. In extreme cases, death may occur due to procedural complications, concurrent illness.

d) Flash fire may occur. Flammable inhalation general anaesthetics must not be used. Oxygen levels in the direct surgical area must not exceed 50%. The risks of combustion, perforation, and laser-induced haemorrhage, any of which could cause death, must be fully explained to the patient.

e) The flammability of methane gas must be considered when treating in or near the perianal area.

f) There is a risk of infection and scarring associated with any surgical procedure. Therefore, appropriate pre- and postsurgical care should always be practiced.

g) The laser should be used only on tissues that are fully observable. Do not use the laser if the desired target is not visible.

h) Use of the laser on anatomical structures in proximity to known critical structures, such as large arteries, veins, bowel, ureter, bladder, etc., should be performed carefully to avoid inadvertent or unintended treatment of such structures.

i) There is an increased risk of back scatter (reflection) and forward scatter (penetration) when using the laser if the laser is in non-contact mode.

6.2.2 General Laser Precautions

Caution

- Use caution with patients who have had difficulty with previous endoscopic procedures.
- Blood vessels up to 1 millimetre in diameter can be effectively coagulated with the Ho:YAG wavelength
- Electrocautery and/or suture (ligature) should be easily accessible in the event that a bleeding artery or vein is larger than possible to control with the laser.
- Use caution when treating patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- Discontinue laser treatment immediately if the patient develops any cardiopulmonary problems.
- ROCAMED has no clinical information concerning the safety of laser treatment on pregnant or nursing women.
- Refer to the appropriate delivery system instruction guide for use instructions.

6.2.3 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 leucocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment.
- Laser ablated tissue may become necrotic or infected after treatment. If a question of infection exists, appropriate treatment should be carried out.

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

6.3 Urology Indications

The following applications are indicated for urology while using the Ho:YAG wavelength: open and endoscopic urological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including treatment of:
- Endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi
- Ablation and resection of Bladder Tumors, Ureteral Tumors and Ureteral Tumors;
- Condylomas;
- Lesions of external genitalia;
- Urethral strictures;
- Bladder neck incision.

6.3.1 *Urology Contraindications*

The Ho:YAG wavelength should not be used in patients with the following conditions:
- Inability to receive endoscopic treatment
- Intolerance to anaesthesia

6.3.2 *Urology Warnings*

Read **General Laser Warnings** (see Section 6.2.1) for a list of warnings.

6.3.3 *Urology Precautions*

Caution

Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distension could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.
Read **General Laser Precautions** (see Section 6.2.2) for a list of additional precautions.

6.3.4 *Urology Complications*

Read **General Laser Complications** (see Section 6.2.3) for a list of complications.

6.3.5 *Urology Clinical Parameters*

The Ho:YAG wavelength provides effective hemostasis without damaging surrounding or non-target tissues. Coagulation can be effected by reducing the energy or power density incident on vascularized tissue in two ways.

The following table shows the suggested pulse energy, repetition rate, and average power for endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in urological applications:

Urology – Recommended Treatment Clinical Parameters

Application	*Pulse Energy (Joules/Pulse)*	*Repetition Rate (Hertz)*	*Average Power (Watts)*	*Recommended Fiber Size*
Bladder Tumors	0.8 – 1.5	10 – 15	8 – 15	365-800 µm
Ureteral Tumors	0.5 – 1.2	10 – 15	5 – 15	272-550 µm
Incision of Strictures	0.8 – 3.5	8 – 15	8 – 20	365-800 µm

NOTE!
Laser settings are guidelines only; always start with low settings and increase to achieve the desired tissue effect. Energy delivered endoscopically in a fluid medium.

6.4 Urinary Lithotripsy Indications

The following applications are indicated for urinary Lithotripsy while using the Ho:YAG wavelength: Endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate and calcium oxalate dehydrate stones.

6.4.1 *Urinary Lithotripsy Contraindications*

The Ho:YAG wavelength must not be used in patients with the following conditions:

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

Contraindications for Uretero-renoscopy (URS):

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

Contraindications for Percutaneous Nephrolithotomy (PCNL):

- Acute proneness to bleeding, anticoagulation
- Untreated infections of the urinary passages
- Tumor in the access area
- Pregnancy

Difficult access to the stone in the case of:

- Skeletal anomalies
- Renal anomalies
- Intestinal interposition
- Pleural interposition

6.4.2 *Urinary Lithotripsy Warnings*

Warning

Unexpected tissue damage may occur due to excessive power application. Refer to **Urinary Lithotripsy Clinical Parameters** (see Section 6.4.5) for recommended initial power settings. Use of excessive power may result in inadvertent perforation of the ureter or damage to other urologic structures.

Read **General Laser Warnings** (see Section 6.2.1) for a list of additional warnings.

6.4.3 *Urinary Lithotripsy Precautions*

Caution

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

Read **General Laser Precautions** (see Section 6.2.2) for a list of additional precautions.

6.4.4 *Urinary Lithotripsy Complications*

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

- The use of flexible endoscopes carries an equivalent incidence of stricture formation; these rates may improve with further advances in ureteroscopic design.
- Although rare, loss of a kidney may occur as a result of the procedure or because of the stone itself.

Complications for Uretero renoscopy (URS):

Minor complications are fever, macro haematuria and pain. In literature, the rate of significant complications (sepsis, ureter perforation or torn ureter is 3-11%).

Urinary strictures as a long-term complication have become rare and are estimated to be 1 to 3%. Previous ureter perforations represent the key risk factor.

Complications for Percutaneous Nephrolithotomy (PCNL):

Typical are the following complications:

- Fever, sepsis
- Bleedings requiring transfusion
- Absorption of irrigation fluid
- Perforation of the intestine
- Lesion of the pleura

- Sub-pelvine stenosis
- Loss of kidney
- Open revision

Complications for Urology
Read “General laser complications 6.2.3.” for a list of additional complications.

6.4.5 *Urinary Lithotripsy Clinical Parameters*

Pre-clinical and clinical testing has demonstrated that urinary calculi can be safely and effectively fragmented starting from power settings of **0.5 or 0.6 Joules and at a frequency of 5 or 6 Hertz.** The use of high power output settings requires special attention, especially when the fiber tip is in close proximity to the ureteral walls in order to avoid the perforation of the ureter.

For effective fragmentation, the tip of the optical fiber should be directly in contact with the stone. Whenever possible, laser energy should be directed at the side of, or at weaknesses in the stone. The stone should be progressively reduced in size by slowly removing small fragments. Continuous irrigation should be used to wash away stone fragments and to provide cooling of the treatment site. The following table shows recommended pulse energy, repetition rate and average power for endoscopic fragmentation of urinary calculi. The use of higher power settings should be avoided, especially when the fiber tip is in close proximity to the ureteral wall, as perforation of the ureter may result.

Urinary Lithotripsy – Recommended Treatment Clinical Parameters[2]

Application	*Pulse Energy (Joules/Pulse)*	*Repetition Rate (Hertz)*	*Average Power (Watts)*	*Recommended Fiber Size*
Bladder Calculi	0.5 – 2	3 – 12	7 – 20	550 – 1000 µm
Ureteral Calculi	0.5 – 1	3 – 20	3 – 15	272 – 550 µm
Renal Calculi	0.5 – 1.2	5 – 12	3 – 15	200 – 272 µm
PCNL	0.8 – 2.5	3 - 12	7 – 25	365 – 1000 µm

Note
Laser settings are guidelines only; always start with low settings and increase to achieve the desired tissue effect. Energy delivered endoscopically in a fluid medium.
Use the Lithotripsy Dusting Effect Mode in order to minimize the size of fragments.

6.5 ENT – General Surgery – Gastroenterology – Arthroscopy

MH01 laser system and its fiber optic delivery system 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, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, ENT and General Surgery.

6.5.1 *Specific Contraindications*

Contraindications for ENT Surgery

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

- Inappropriate candidates for endoscopic treatment
- Endonasal malignant neoplasm

Contraindications for General surgery

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

- Inappropriate candidates for endoscopic or laparoscopic treatment
- Intolerance to anaesthesia
- Septic peritonitis
- Intestinal obstruction
- Septic shock
- Resection or excision of large, highly vascularized organs (spleen, liver)

Contraindications for Gastroenterology surgery

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

- Inappropriate candidates for endoscopic or laparoscopic treatment
- Intolerance to anaesthesia
- Intestinal obstruction

Contraindications for Arthroscopy

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

6.5.2 *Specific laser complications*

Complications for ENT Surgery

Swelling of the nasal membranes may cause nasal airway obstruction for up to one week. Patients should be followed post-treatment to clean debris from the nasal cavity.

- Perforation of the orbit or intracranial cavity may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-treatment with appropriate tests.
- Read “General laser complications” for a list of additional complications.

Complications for General surgery

Read “General laser complications” for a list of additional complications.

Complications for Gastroenterology surgery

- Patients may experience gastrointestinal distension or pneumothorax during or after therapy.
- Swallowing may be worsened, rather than immediately improved, following oesophageal procedures due to secondary tissue edema. This potential problem should be explained to the patient prior to therapy.
- Read “General laser complications” for a list of additional complications.

Complications for Arthroscopy

Read “General laser warnings”, “General laser precautions”, and “General laser complications” earlier in this chapter for further information.

7 MAINTENANCE, CLEANING AND STERILIZATION

This section is not a part of a service or technical assistance manual. It contains only the user information regarding the care and cleaning of the device, and the cleaning and sterilization information of optical fiber. For any issues not relating the maintenance contact ROCAMED

Warning:
Refer only to the Manufacturer or authorised distributors for service.
Only trained and qualified personnel are permitted to provide service for this LASER system. Service by non-authorized people will cause warranty to lapse

7.1 Device cleaning

The laser device MH01 doesn't need special maintenance by the user. Clean the visible surfaces with a damp cloth and a caustic solution such as foam. Do not use alcohol or disinfectant solution, because they are highly flammable. During cleaning be careful not to let the cleaning solution inside the fiber connection port. Use the supplied caps to close the fiber connection port after each use. Do not use any alcohol solution to clean the display.

7.2 Laser Maintenance and technical check

Laser device MH01 is designed for maximum safety and performance. With careful use and under normal operating conditions, the manufacturer recommends a review of the device by a qualified technician every 12 months.
The intensive use, dust, or continuous movement of the laser in different places may require a more frequent review.

Warning:
The laser device has to be closed. Only personnel authorized by the manufacturer can open the external covering panels.
Only personnel authorized by the manufacturer providing technical service can have access to the internal components of the system.
Only authorized service personnel can replace the replace the power supply cord

7.3 Safety labelling check

Verifying the integrity and readability of the security labels placed on the device by the user. I labels are damaged, they must be replaced immediately in accordance with the plan shown in paragraph labelled.

7.4 Water cooling system

If the level of the water is too low it is necessary to refill the water tank. It is recommended to check the water status at least every 6 months.

7.5 Check of the line cable

MH01 device has a line cable mechanically fixed to it. The cable has a length of 3m. The line cable can be subjected to deterioration over time and therefore, it is necessary to check periodically the status of the line cable.

7.6 Optical fiber maintenance

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

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

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 the instruction manual of the optical fiber. The RFID system keeps record of the number of uses (correlated with the required sterilization cycles) that the fiber undergoes.

Only the use of RFID ROCAMED Fibers is allowed with the LITHO Laser System.

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

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

7.6.2 Check the optical fiber before operation

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

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

Note: for more information please see Cap 4.2.11

7.7 Use, Cleaning, disinfection, sterilization of optical fibers

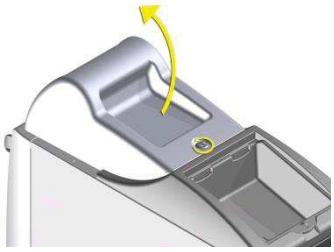
Carefully read and follow
Optical fibers instruction manual

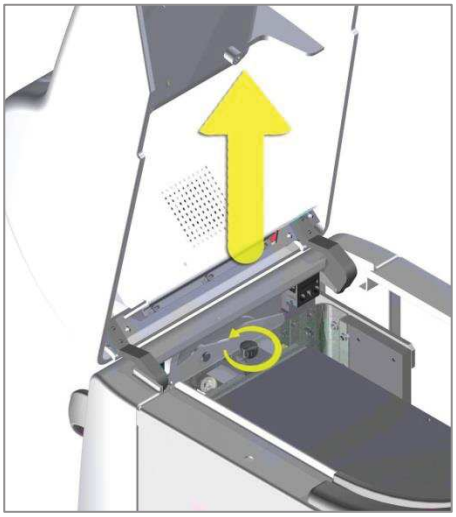
7.8 Blast shield replacement

WARNING:
This operation must be done with clean hands and extreme caution to avoid optical damage of the device.

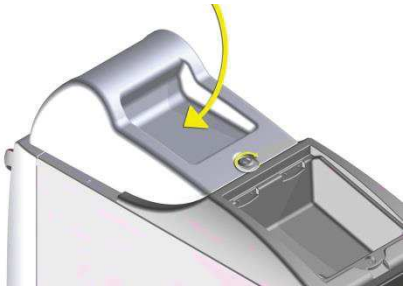
The blast shield replacement must be executed in the following way:

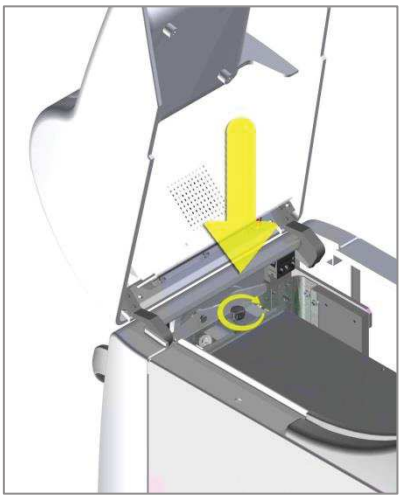
1. Turn the device off, disconnecting the equipment from mains
2. Open the Upper cover with the dedicated key to access to the blast shield area
3. Remove the blast shield unscrewing the knob





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





6. Close the protective door screwing well the doorknob.
7. In case of assistance, please contact Service Department

8 TROUBLESHOOTING

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

Trouble	Possible cause	Solution
Key switch does nothing	• Line power not connected • Main line breaker off • Emergency red push button pressed	• Check line cord breaker • Push the emergency red push button
Lamp error	• Simmering error • Lamp broken • Lamp old	• Call service
Flow error	• Not enough water • Water tube twisted	• Fill water reservoir • Check water tubing
Temperature error	• Room temperature too much high or air inlet/outlet not free	• Check cooling air circulation • Assure the correct distance of the rear panel from the wall
Shutter error	Incorrect shutter position	• Call service
Fiber error	Wrong installation of the fiber	• Check the proper connection of the fiber
Remote interlock error	The ext. interlock is not connected or is bad connected	• Control the ext. interlock connection
Footswitch error	The footswitch is not connected or is bad connected	• Control the footswitch connection
Energy warning	Fluctuations of the energy	• Wait some second until the energy is stabilized • If the energy always fluctuates, Call service
No correspondence between displayed energy and treatment effects	Damage of the fiber	• Change fiber • Call service

9 CUSTOMER SERVICE

9.1 Manufacturer warranty and responsibility

The Manufacturer will disclaim any responsibility about a misuse of the system.

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

A 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.

MH01 is warranted against any defects 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 system faults, negligence, improper use or misuse of the appliance, or servicing or repairs carried out by persons not authorized by Manufacturer are not covered by warranty.

Manufacturer staff must be allowed free access to the appliance.

Any repairs which cannot be carried out on site will be effected in our labs.

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

- Use of the device not conforming to the procedures and instructions reported in the user manual.
- Incorrect installation and maintenance.
- Use of the faulty safety system, not correctly installed or damaged.
- Unfulfilling of the instruction of this manual concerning: transportation, storage, installation, and maintenance.
- Arbitrary alteration of the device.
- Incorrect reparations.
- Accident 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, components list and suggested applications protocols.

9.2 Repair and modifications of the device

- Only authorized service personnel can execute repairing and maintenance.
- It is recommended to follows the standard maintenance program.
- It is recommended to replace all the damaged components.
- Use only original spare parts.
- Constructive modifications are not permitted.

9.3 Service department contacts

ROCAMED offers its customers resolve problems through e-mail and telephone contact, in addition to training courses for clients in ROCAMED, repairs and maintenance.

Please contact the Service Department of ROCAMED through the contacts listed below. Please keep to hand the serial number of your device.

Address:	9, avenue Albert II MC 98000 Monaco
E-mail:	info@rocamed.eu
Telephone:	+377 97 98 42 32

10 TECHNICAL SPECIFICATIONS

10.1 General specification

Product category	Surgical laser for medical use
Classification according to Medical Device Directive 93/42/EEC	Class IIb
Laser Classification according to Class 4 IEC 60825-1:2014	Class 4
Aiming Beam classification according to IEC 60825-1:2014	Class 3R
Electrical requirements	100-120 Vac; 50/60 Hz; 16A 200-240 Vac; 50/60 Hz; 10A
Degree of protection against the ingress of liquid (IEC529)	IP20
Type of protection against electric shock	Class I
Type of applied parts	BF
Dimensions	332 (W) X 967 (D) X 938 (H) mm
Weight	60kg
Operation temperature	10°C - 30°C
Storing temperature	5°C - 40° C
Relative Humidity	from 30% to 85% (no condensing)
Atmospheric Pressure	800-1060 hPa
Cooling system	Air cooled (closed water-air cooling circuit)

10.2 Laser source specification

Laser Type	Flashlamp Pumped Ho:YAG
Wavelength	2.1µm
Power to tissue	30 Watts
Energy/pulse	0.2÷4J
Application mode	Pulsed
Time function	Single pulse; Pulse sequence
Pulse Width	150 - 850µs
Repetition rate	3-25 Hz
Delivery Device	Wide range of flexible silica frontal fiber (sterile and reusable)
Aiming Beam	Diode laser, green, 532nm (<5mW, adjustable by software)

Results of MPE, NOHD and OD calculations are reported in the table below:

Wavelength	2100 nm
Divergence	440 mrad
Exposure time	100 s
MPE	1000 W/m^2
NOHD	0.44 m
OD	2

11 ACCESSORIES

Accessory	Description
Frontal optical fiber with RFID System *(available according to customer requirements)*	200µm, 272µm, 365µm, 550µm, 600µm, 800µm and 1000µm frontal optical fiber sterile and reusable
Fiber stripper 1	Fiber stripper for diameter 0,3-1mm
Fiber stripper 2	Fiber stripper for diameter 0,1-0,4mm
Fiber cutter	Ceramic fiber cutter
Safety Goggles	Safety Goggles

12 TABLES (EMC)

CAUTION!
To guarantee the safety of the user, the patient and others, use only accessories and spare parts specified by the manufacturer of this product.
Other accessories or spare parts can cause the emission of increased electromagnetic radiation or reduced immunity against interference.
IMPORTANT!
Medical electrical devices are subject to special precautions with regard to electromagnetic compatibility (EMC) according to IEC 60601-1-2.
Make sure you observe the notes on EMC for installation and operation.
Medical electrical devices can be influenced by mobile HF communication devices (i.e. mobile phone) and other devices that may be used in conjunction with them for treatment or diagnosis.
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>
<tr><td colspan="3">IEC 60601-1-2 Table 201
Guidance and manufacturer’s declaration – electromagnetic emission</td></tr>
<tr><td colspan="3">MH01 is intended for use in the electromagnetic environment specified below. The customer or the end user of the MH01 should assure that it is used in such an environment</td></tr>
<tr><td>Emission test</td><td>compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emission – CISPR 11</td><td>Group 1</td><td>MH01 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</td></tr>
<tr><td>RF emission – CISPR 11</td><td>Class A</td><td rowspan="3">MH01 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.</td></tr>
<tr><td>Harmonic emission
IEC 61000-3-2</td><td>not applicable</td></tr>
<tr><td>Voltage fluctuation/flicker emission
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

IEC 60601-1-2 Table 202 Guidance and manufacturer's declaration – electromagnetic immunity			
MH01 is intended for use in the electromagnetic environment specified below. The customer or the end user of **MH01** 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	2 to 8 kV contact 2 to15 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines	Complies	Mains power quality should be that of a typical hospital environment
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Complies	Mains power quality should be that of a typical hospital environment
Voltage Dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% Ut for 0,5 cycle Voltage interruption > 95% Ut, 5 "	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of **MH01** requires continued operation during power mains interruptions, it is recommended that **MH01** be powered from an Uninterruptible Power Supply or Battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	Not applicable	There aren't elements susceptible to magnetic fields	-

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

<table>
<tr><td colspan="4">IEC 60601-1-2 Table 204
Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">MH01 is intended for use in the electromagnetic environment specified below. The customer or the end user of MH01 should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601
Test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>10 Vrms
150KHz to 80MHz

10V/m
80 MHz to 2,5 GHz</td><td>Complies</td><td>Portable and mobile RF communication equipment should be used no closer to any part of MH01, 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 metres (m)
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">Note 1: at 80 MHz and 800 MHz, the higher frequency range applies
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which **MH01** is used exceeds the applicable RF compliance level above, **MH01** should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating **MH01**
b) Over the frequency range 150 KHz to 80 MHz, field strength should be less than 3 V/m.

IEC 60601-1-2 Table 206
Recommended separation distances between portable and mobile RF communication equipment and **MH01.**

MH01 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of **MH01** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and **MH01** as recommended below, according to the maximum power of communications equipment.

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

For transmitters rated at maximum output power not listed above, the recommended separation distance d in metres (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.