DGM001357 (User Manual VenaCure 1470 Pro – WW) REVISION HISTORY

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angiodynamics

VenaCure 1470 Pro

1470 nm Diode Laser System

User Manual

DGM001357.02

CE
0123

Rev. date 21/09/2018

Dear Customer,

Thank you for choosing an **AngioDynamics Laser** product.

 In order to attain the best results with **VenaCure 1470 Pro 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

AngioDynamics 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 AngioDynamics further assumes no liability for patient treatment or outcome or for physician's negligence, breach of duty of care, or malpractice.

In no way does this or any of AngioDynamics' policies, procedures, training materials, guidelines, or instructions create an obligation for AngioDynamics to perform any services. Products and services may be purchased from AngioDynamics.

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

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1 GENERAL INFORMATION

1.1 Introduction

The *VenaCure 1470 Pro* is a diode laser device emitting at **1470 nm**, with 15 W maximum output power.

VenaCure 1470 Pro is manufactured following the 93/42/CEE Annex II directive and it is identified as follows:

Model	**VENACURE 1470 PRO**
Category of the device	Laser for medical use
Class	II (US); II b (CE)

1.2 Purpose of the manual

This manual contains essential information necessary for the installation, operation and maintenance of *VenaCure 1470 Pro*. The manual is intended to be used as a guide. These instructions were written specifically for staff who are fully trained in laser and conventional surgery.

This manual shall not be used as an alternative to surgical preparation. In addition, this manual does not provide specific technical information regarding operation of *VenaCure 1470 Pro*. For any information regarding technical assistance, please contact your local distributor.

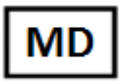
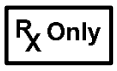
1.3 Manufacturer

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

Distributed by:
AngioDynamics, Inc
603 Queensbury Ave.
Queensbury, NY 12804

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

1.4 Symbols and Abbreviations used in this manual

Symbol	Description
	Read the enclosed documentation
CE 0123	CE label
	Symbol of applied part type CF According to standard 60601-1 3rd 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
	Manufacturer
	Serial Number
	Medical Device Symbol
	Federal law restricts this device to sale by, or on the order of, a physician/surgeon
NOHD	Nominal Ocular Hazard Distance
NOHZ	Nominal Ocular Hazard Zone
MPE	Maximum Permissible Exposure
µm	Units, micrometer
s	Units, Second
mrad	Units, milliradiant
W	Units, Watt
J	Units, Joule
J/cm^2	Units, Joule per square centimeter
cm	Units, centimeter
OD	Optical Density
D	Continuous laser according to EN207
L	Glasses protection degree

kV	Units, kilovolt
A/m	Units, Ampere per meter
Vrms	Effective supply voltage
KHz	Units, Kilo Hertz
GHz	Units, Giga Hertz
WEEE	Waste Electrical and Electronic Equipment
CW	Continuous laser pulses
Vac	Volt alternating current
A	Units, Ampere
T	Slow blow fuse
I	Electrical Protection Class
nm	Units, nanometer
mm	Units, millimeter
EO	Sterilization Method
Ø	Diameter
SMA	Laser Fiber connector type
mW	Units, milliwatt
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 OFF configuration of the key switch
	A label that indicates the ON configuration of the key switch

2 SAFETY INSTRUCTIONS

2.1 General Safety Information

- For a safe use of the device it is necessary to know all the safety rules according to the international standards.
- This manual contains important information about the safe use of the device.
- All the persons operating with this equipment have to know the operation instructions and the safety instructions specified in this manual.
- Only authorized individuals with appropriate laser training and knowledge should operate the laser system.
- The laser device has to be closed. Only authorized personnel can open the external covering panels.
- Only authorized personnel providing technical service can have access to the internal components of the system.
- This User Manual should be available in the working area of the laser device.
- All the warning labels have to be continually in good condition.

2.2 Training of the staff

The use of the laser device must be restricted only to medical staff with experience in the specialties suitable for Indication for Use (Chapter 6). They can decide, according to their experience, what is the right use of the device depending on the type of application.
It is recommended that all the external staff, in contact with the device, is informed about all the safety rules and standards.

2.3 Working area

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

 **Warning:** *This device is not intended to be used in MR environment.*

 **Warning:** *RESTRICTED ACCESS TO THE WORKING AREA.*

The external personnel/visitors must also:

- **Be guided by internal personnel**
- **Always wear the protective goggles if inside the working area when the laser is armed**
- **Be instructed by internal personnel about laser, electrical and other risks related to the laser operation within the working area (laser radiation, electric shock etc.)**

The entrance is absolutely FORBIDDEN IF there is no operator inside the working area.

2.4 Eye and skin exposure

The laser beam emitted by this Laser Device can cause vision loss. The laser operates at different wavelengths, visible and invisible. Any energy transmitted by this Laser Device that enters the eye will be focused directly to the retina. Direct absorption of laser energy by retina can result in temporary clouded vision, retinal lesion, long-term scotoma and long-term photophobia.
A danger exists in any case of:

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

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

Use protective goggles for the desired wavelength with the specifications according to the UNI EN 207:

D 1470 LB1 for 1470 nm

Always check the goggles condition.

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

2.5 MPE and NOHD

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

- The **MPE** level represents the maximum level to which an eye, or skin, can be exposed without consequential injury, immediately or after a long time. The MPE is related to radiation wavelength, pulse duration or exposure time, the tissue at risk and, for visible and near infrared radiation in the 400-1400nm 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.

Results of MPE, NOHD and OD calculations are reported in the table available into Section 10.2.
Please, refer to previous Section 2.5 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.*

 **Warning:** *All operators should become familiar with all the requirements for safe use of the medical laser systems as described in CAN/CSA- Z386-14 (Safe use of lasers in health care).*

Where applicable, doors may be equipped with a special interlocking system and must be made of a material that does not transmit laser light (darkened glass, plastic, curtains, etc.) and windows must be darkened by using appropriate laser non-transmissive systems.

The skin can resist the higher values of laser energy but also the skin can be burned by a laser beam. If there is a need, the special protection clothing should be used.

If somebody is hurt from the laser beam:

- Turn off the laser device
- Immediately ask for a physician's assistance
- Inform the responsible person in charge of laser maintenance and safety

2.6 Potential fire hazard

The laser radiation of this device is able to melt, burn or vaporize almost all the 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 shallow, 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 working area.

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

- Do not use any flammable substance, such as alcohol or acetone, in the preparation of the skin for treatment. Use soap and water if necessary.
- Anesthetics administered either by inhalation or topically must be approved as non-flammable.
- Use particular care in the use of oxygen.
- Avoid using combustible material, such as gauze and drapes, in the treatment area. When they are required, these materials must be made fire-retardant by keeping them moist with water. Clothing should be kept away from the treatment area.
- Never use in presence of flammable anesthetic gases or oxidant gases like oxygen or N_2O.
- 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 any solvents or glues or flammable solutions used to clean or disinfect.
- **Attention:** endogenous gases can catch fire or explode.

2.7 Emission of plume

There is considerable concern about the biological plume (vapour/smoke) 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.

2.8 Interference with other devices

This Laser Device does not include any type of direct connection with other external or internal device.

This Laser Device can be disturbed by the interference of external electromagnetic fields generated by other electrical devices in the closest proximity of the laser device.

Warning: *Mobile phones and similar electrical devices must be switched off when the laser device is working.*

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

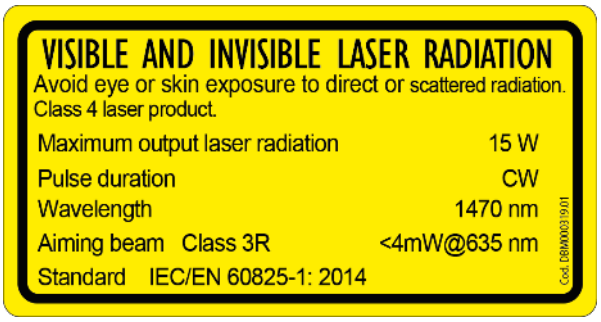
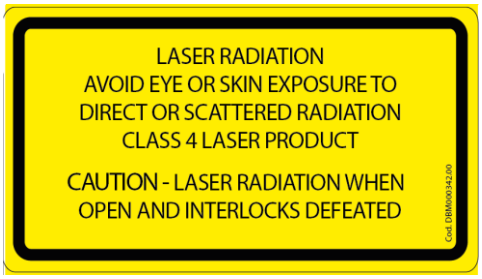
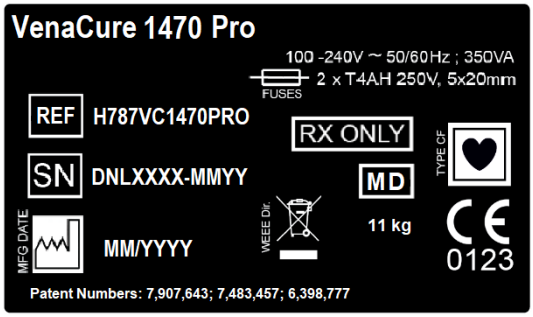
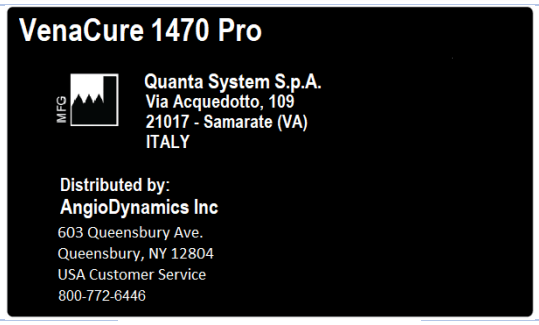
2.9 Emission of toxic gas or vapor

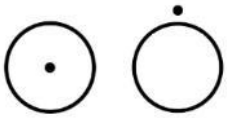
The laser radiation emitted by this laser device can melt, burn or vaporize all type of materials.
The use of this LASER device is limited to the applications specified in this manual.

2.10 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.

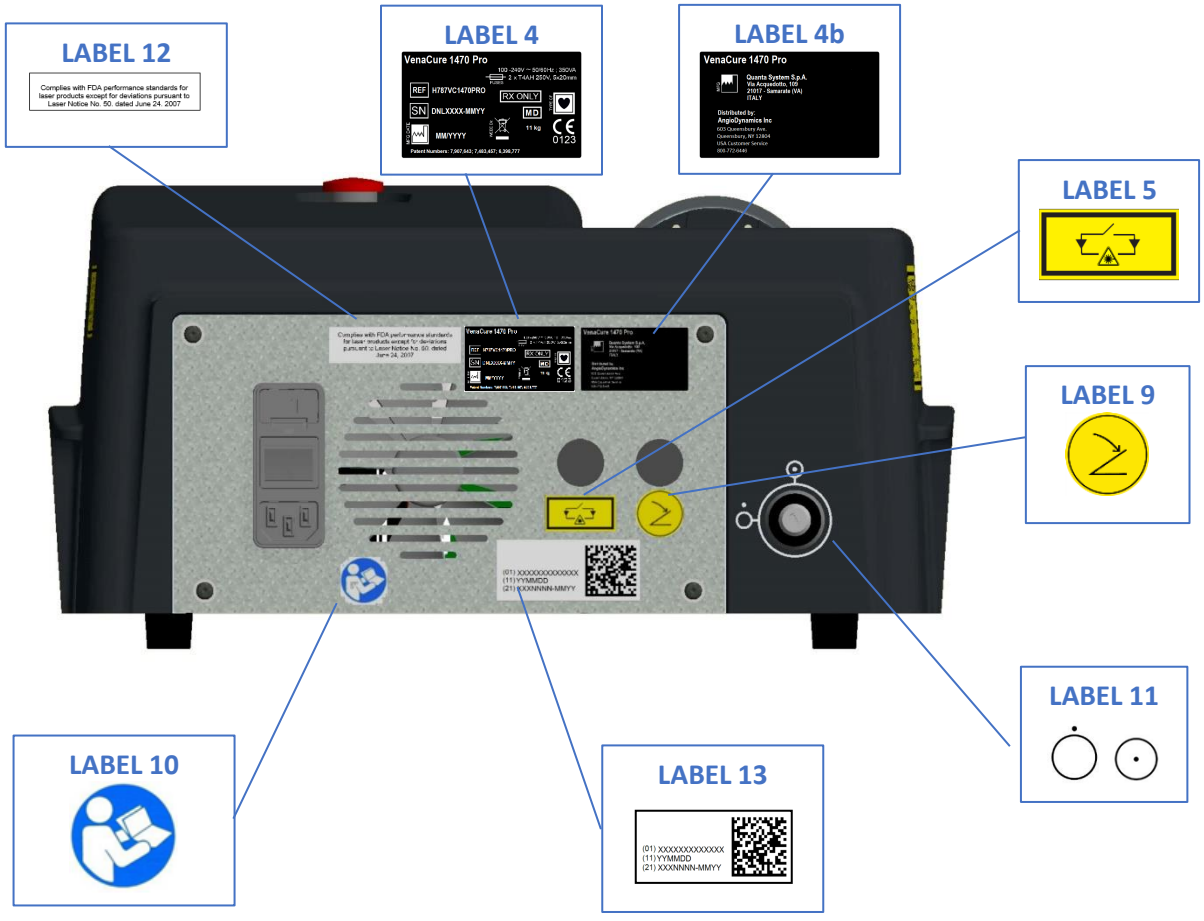
2.11 Labels

	**Label 1** Laser data label
	**Label 2** Warning label – hazard symbol according to IEC 60825-1
	**Label 3** Warning label – hazard symbol according to IEC 60825-1
	**Label 4** Rating label
	**Label 4b** Rating label (Manufacturer and Distributer addresses)
	**Label 5** Remote interlock connector label
	**Label 6** Type CF applied part

	**Label 7** Laser aperture label
	**Label 8** Emergency laser off label according to IEC 60601-2-22
	**Label 9** Footswitch connector symbol
	**Label 10** Read instructions for use symbol
	**Label 11** Key switch ON/OFF
Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007	**Label 12** FDA compliance label
(01) XXXXXXXXXXXXX (11) YYMMDD (21) XXXNNNN-MMYY	**Label 13** UDI label

2.11.1 *Device front view*

2.11.2 *Device rear view*



2.11.3 *Device side and top views*

3 WORKING AREA REQUIREMENTS and INSTALLATION

3.1 Responsibility of the customer

Before first installation the site has to be prepared.
The working area must be big enough for the laser device, with a line power socket as required (please see General Specifications, Chapter 10, Paragraph 10.1).
The working area should be marked with laser warning signs in order to avoid random entering in the area.
All the windows, mirrors, metal and other reflective objects should be covered in order to avoid the laser beam deflections.
All the staff members should know how to shut down the laser system in case of an emergency.
Take care that the keys of the laser system are in a secure place when the device is not used.

3.2 Requirements for the electrical connection

The Device has to be connected to a power socket in compliance with the local electrical safety regulations. Following the Standard IEC 60884-1 the device can be supplied with a cable with different plugs suitable with the electrical standard requirements of the country where the laser system is going to be installed.

WARNING: *To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.*
The Device shall be installed and used in compliance with the national or local requirements in place in your country.

3.3 Temperature and Humidity

The Device requires a dry, low-dust area with adequate ventilation. Air conditioning is suggested, but not essential. This Laser Device has to operate in ambient condition according to the suggested parameters in the following table:

Temperature	Max. Humidity
10° C – 30° C	85 %

3.4 Space requirements

The suggested minimum room size is 3X3 meters. Allow 50 cm of clearance on both sides of the device permitting the air vents are not being obstructed.

The Laser Device can be easily moved from room to room. Make sure that space and electrical socket requirements are available everywhere it has to work.

3.5 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 after transportation of the laser device.

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

The first procedure step typically takes several hours, during this time the access to the installation site is forbidden. The case is normally shipped to the distributor.

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

- Open the packaging and put the laser device in a proper site for a general check
- Execute the following operations for the general check:
    - Check the labels of the device
    - Connect the remote door interlock and the footswitch
    - Connect the laser device to the power supply and turn the system on
    - Connect the laser fiber and wait the system recognizes it
    - Change the status of the laser system to Ready and then to Standby
    - Check the system and verify if alert messages are displayed
    - Turn the system off
    - Disconnect the Laser System from the mains by unplugging the power cable
    - Remove the laser fiber, the footswitch, the interlock and the key

Note: *The Manufacturer advises wrapping the device with a large amount of protective plastics*.

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

- Install the device in the room indicated by the customer in the following way:
    - Connect the device to the power supply
    - Connect the interlock connector and the footswitch
    - Check the laser device
    - Train to the end user on the following items:
        - Proper fiber attachment
        - Operation of the device

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

3.5.1 *Remote Door Interlock Connection*

According to IEC 60825-1 all laser devices must be equipped with a remote block connector, connected to the room access door, which prevents laser emission when the door is opened. An appropriate micro-switch shall be wired to the remote door interlock cable and mounted on the doorframe so that a contact closure is activated when the entrance door to the treatment area is closed. Before operation, please check if the remote door interlock cable leading to the door-mounting micro-switch is connected to the rear panel of the laser unit. As shown in the picture, a lamp should be mounted at the entrance of the operating room, on the door frame. The lamp should light when the laser is turned on and the entrance door to the working area is closed.

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

Interlock male movable connector
(inner view)

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

3.5.2 *Footswitch Connection*

The footswitch cable must be firmly connected to the footswitch socket on the rear panel of the laser unit.

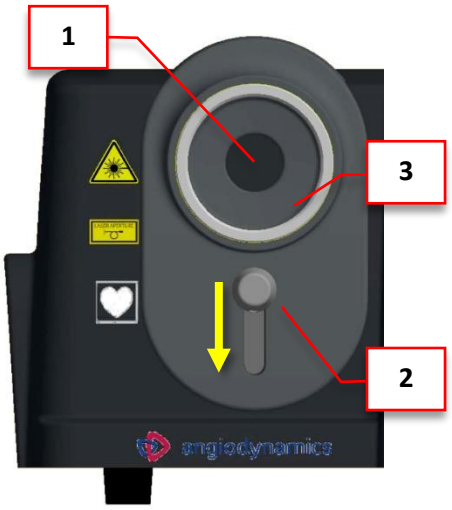
Warning: *Do not wrap the footswitch with any plastic (or other material) film or cover bag, unless authorized by the manufacturer. The unauthorized use of wrapping bags/films may block the pedal in pressed position and cause unwanted laser emission.*

3.5.3 *Optical Fiber connection*

The fiber is connected to the device through the fiber port on the front panel (**1**).

VenaCure 1470 Pro laser is capable of working with the AngioDynamics range of *VenaCure EVLT procedure kits*. The RFID system fitted as standard allows it to identify that the correct VenaCure EVLT fiber is connected.

In order to connect the fiber to the device, pull the sliding knob (**2**) down, opening the external protection shutter and accessing the fiber connector.
The device accepts only AngioDynamics fibers with SMA905 connector and RFID Recognizer System (with proprietary internal code).



1	Fiber connection
2	External shutter's sliding knob
3	RFID antenna

Insert the optical fiber connector into the laser aperture and turn the gripper clockwise until secured in place (light finger tight only).

Furthermore, this ring enables the automatic detection of fiber (present/absent) and its status (Valid/Invalid/Expired).

Warning: *If optical fiber is hardly bent or improperly secured, it can lead to damage the fiber and/or harm to the patient or user!*

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

4 DEVICE DESCRIPTION

This section of the manual gives a general description of the device.

4.1 Introduction

The *VenaCure 1470 Pro* is a diode laser system emitting at 1470 nm wavelength, with maximum output power 15 W. Only the use of optical fibers manufactured by AngioDynamics (provided with RFID tag with proprietary internal code) is allowed with the *VenaCure 1470 Pro* laser system.
Any other use is forbidden.

The front panel of the device includes the touch screen display, the optical fiber connector (SMA 905) with the RFID antenna, the external protection shutter and the sliding knob.
On the rear panel the footswitch connector, the key switch, the remote interlock and the main switch are located. The emergency stop button is on the upper part of the device.

4.1.1 *Front view*

1. Touchscreen display
2. Laser fiber connector
3. RFID antenna
4. Sliding knob
5. Emergency red button

4.1.2 *Rear view*

6. Key switch
7. Footswitch connector
8. Remote interlock connector
9. Fan
10. Main switch and line cable connector

4.2 Electrical controls

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

Main switch

The main switch feeds the device. There are two switch positions: **I** and **0**.
To switch the device on, turn the switch to **I**. To switch the device off, turn the switch to **0**.

Key switch

The key switch turns on/off the device. There are two positions on the switch:  and  .
To switch the device ON, insert the key and turn it clockwise -  . To switch OFF the device, turn the key counter clockwise -  .

Emergency stop red button

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

4.3 Optical fiber check

This Laser Device includes a low power red aiming beam to identify the target during operation. It is also useful to check the integrity of the optical fiber.
Connect the fiber to the optical fiber connector and check the output red spot shape. If it is well rounded, then the fiber is good and works properly.
If the spot of the aiming beam is absent, misshaped, or its intensity is reduced, then the fiber could be damaged.
In any case of malfunction, replace the optical fiber and contact technical service for further instructions.

 **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.*

 ***Warning:*** *For proper use, refer to the Instruction for Use for VenaCure EVLT procedure kits.*

5 OPERATING INSTRUCTIONS

The accessible elements of the Laser Device are:

- Mains switch
- Key switch
- Touch screen display
- Emergency stop button
- Optical fiber connector with external protection shutter
- Footswitch

5.1 Startup procedure

Assuming that the set up / installation procedure has been completed:

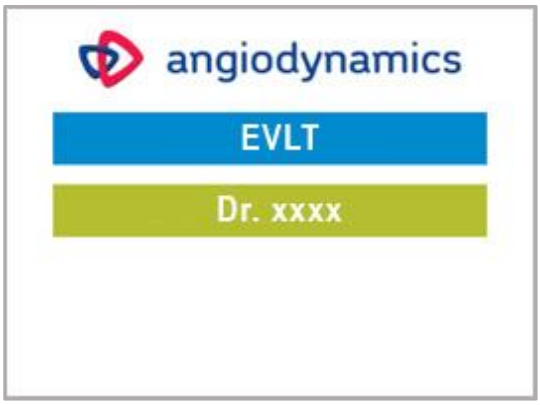
- Make sure that the red emergency stop button is released.
- Switch to **I** the main switch on the rear panel.
- Turn the key (clockwise) in order to start up the system.

When the system switches on, the device beeps three times displaying the loading screen:

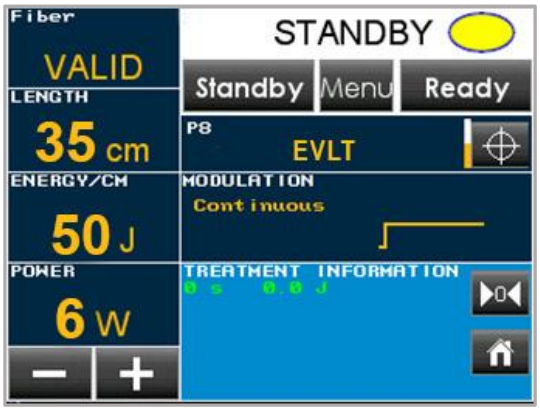
After a few seconds, the Welcome screen is displayed:

Press anywhere on the screen to continue.

The **Home screen** appears: select the preset program if previously saved by the user to continue:

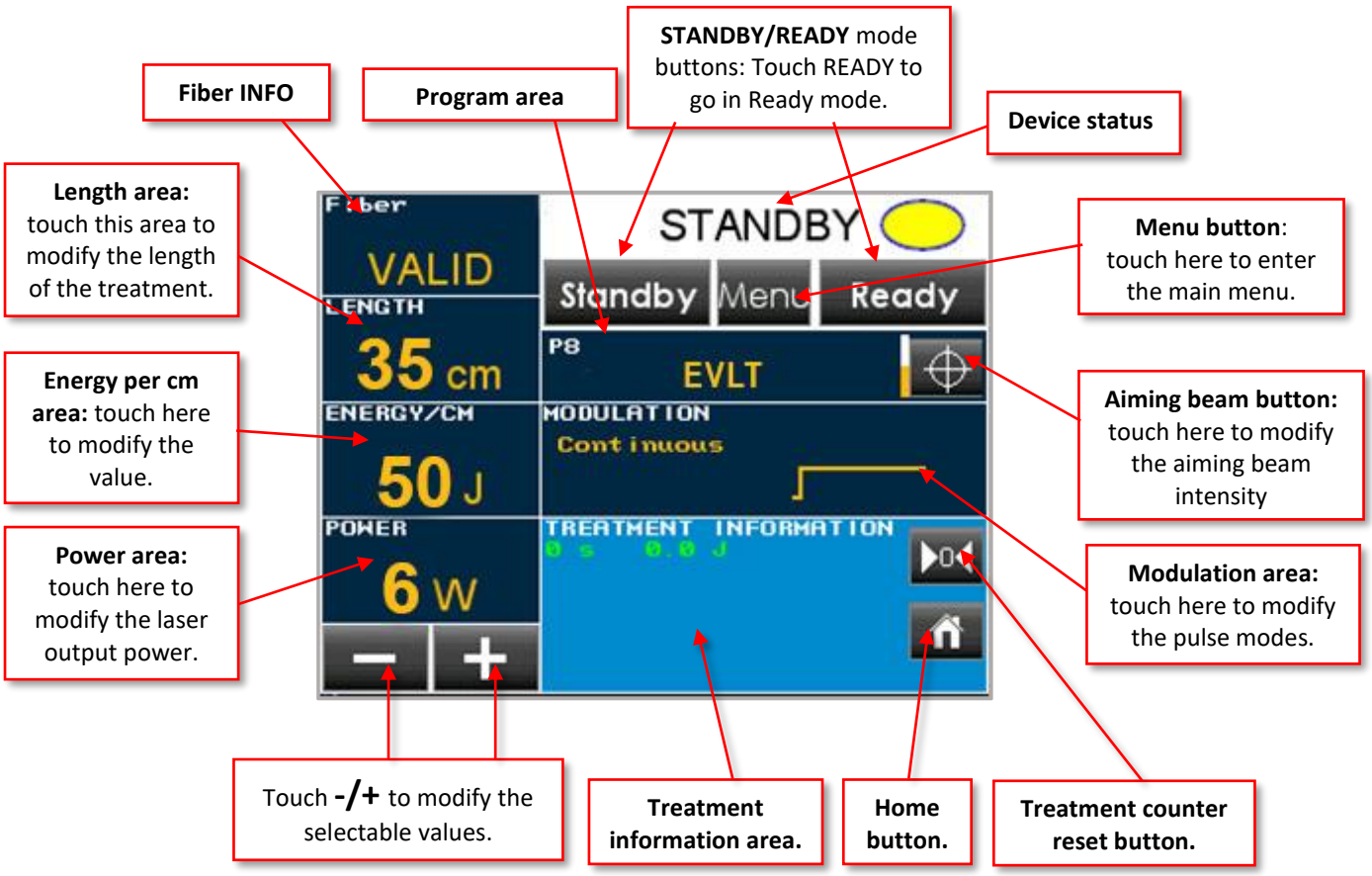


By pressing twice, the **Main screen** appears:



5.2 Main Screen

In this section details, Main Screen functions are described. Refer to the figure below.

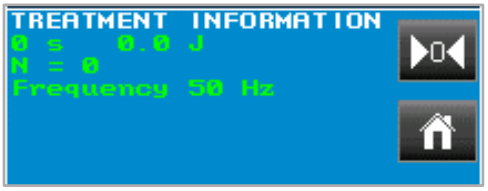


By selecting an area, its color turns yellow with blue values and allows to set the desired values with -/+ buttons.

Warning: *When selecting a pre-set program it is a Physician responsibility to check and verify the eligibility of the laser output parameters to the treatment of interest and, in case, to adjust them before proceeding.*

- **Fiber INFO:** displays the status of the fiber connected "Valid", "Invalid", "Expired"; refer to Section 5.2.1 for more details.
- **Length area:** displays the length of the vein to be treated. By clicking on it, the user can change the value using the -/+ buttons from 1 to 250 cm.
- **Energy per cm area:** displays the value of the laser energy released per cm of vein treated; by clicking on it, the user can modify the energy emitted from 1 to 100 J/cm by the -/+ buttons.
- **Power area:** by clicking on it, the user can modify the output power from 0.5W to 15W by the -/+ buttons.
- **Home button:** by clicking on it, the user can return to the Home Menu, requires confirming.
- **Treatment counter reset button:** by clicking on it, the user can reset the treatment counters.
- **Modulation area:** by clicking on, the user can choose the modulation modes among: *Continuous*, *Single Pulse*, *Continuous Pulsed*, editable Ton and Toff (for pulsed mode). Refer to Section 5.2.2.

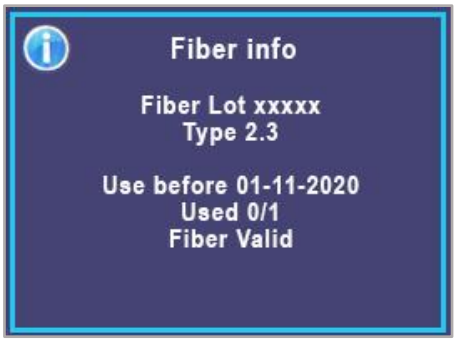
- **Pilot button:** by clicking on it you can choose between 10 intensity levels for the aiming beam, in continuous mode or in pulsed mode.
- **Program area:** it shows the selected program, if pressed, it redirects the user to the Home Screen requiring to confirm.
- **Menu button:** by clicking on it, the user can enter in the Main Menu (Section 5.3).
- **Ready button:** by clicking on it, the user can switch to the Ready status: at the first access to the Ready status, the system requires confirmation reminding the user to wear proper protective goggles.
- **Laser status:** this area displays the status of the device: "Standby", "Wait…", "Ready", "Lasing".
- **Treatment Information area:** depending on the type of modulation, the Treatment Information area may display different output parameters:
  - Total lasing time (s)
  - Total emitted Energy (J),
  - Total number of shoots (N) – *for pulsed modes only*
  - Frequency (Hz) – *for pulsed modes only*



NOTE: The setting operation can be performed in the STANDBY mode only.

5.2.1 *Fiber INFO area*

By touching on the Fiber INFO area, the following popup screen appears, displaying the information of the connected fiber:



- Lot number
- Type
- Expiration date (DD-MM-YYYY)
- Number of uses
- Status

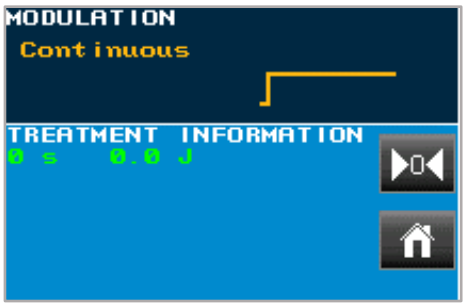
The RFID system accepts only *AngioDynamics fibers* with proprietary internal code. If an invalid, or expired fiber is connected, the system does not enter in READY mode.

Maximum energy/fiber session
The maximum value of deliverable energy per fibers is 10,000 J.
Once this value is reached, the fiber will be considered expired and the system will require the user to connect another fiber.

5.2.2 *Modulation modes*

The LASER device can operate in the following modes:

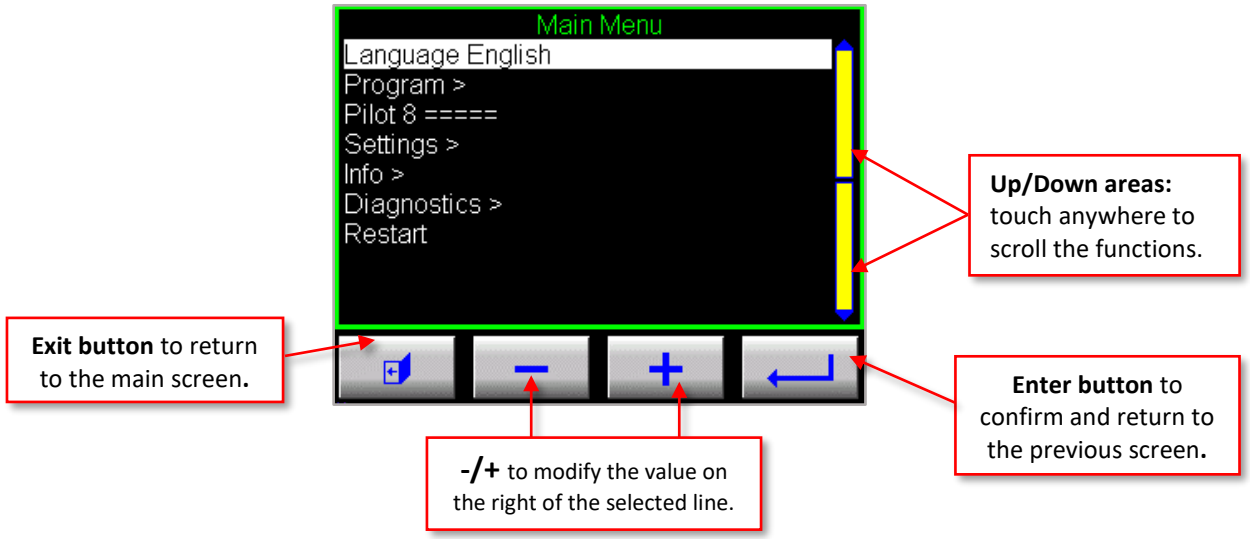
- **CONTINUOUS** mode
  Laser emission begins by pressing READY and then the footswitch. The laser emits a CW beam. A counter displays the total Energy (J) emitted during the treatment.



- **SINGLE PULSE** mode
  A single pulse is emitted by pressing READY and then the footswitch. Set pulse duration (Ton) to the desired value. A counter displays the total Energy (J) emitted and the total number of shoots.

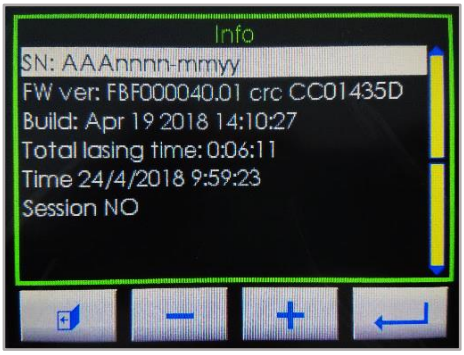
- **CONTINUOUS PULSED** mode
  In this mode, the *pulse duration* Ton and the *pause duration* Toff must be set.
  By pressing READY and then the footswitch, laser pulses emission begins, until the footswitch is released (as in the Continuous mode).
  A counter displays the total Energy (J) emitted, the total number of shoots and the emission Frequency (Hz).

5.3 Main menu

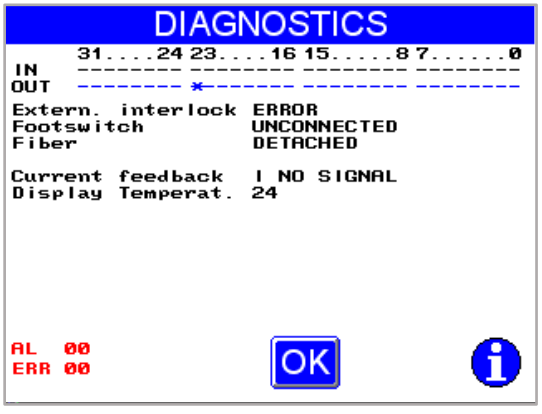


The Main Menu functions are:

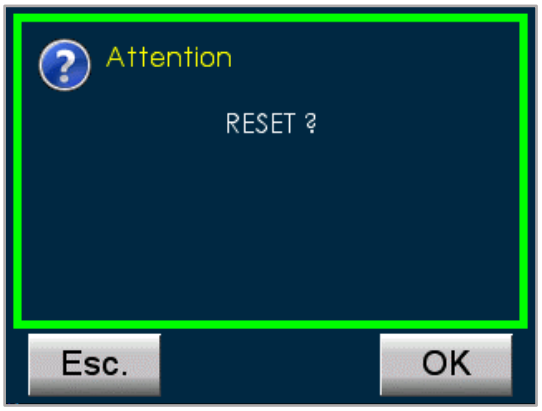
- **Language:** the current language is displayed (English is the default language)
- **Program**: this function opens the Program menu (Section 5.4)
- **Pilot level**: 1 to 10 levels of light intensity, in continuous (==), or pulsed (##) mode
- **Settings**: this function opens the Settings menu (Section 5.5)
- **Info**: in the INFO screen the following information are shown:
  - the device serial number
  - the FW version and its build data
  - the total lasing time
  - the date
  - Session information: it may display "NO", or "Started"; in this case, with an indication of the "session duration" an of the "total emitted energy" (in kJ).



- **Diagnostics**: this function open the Input/Output information, useful for diagnostic purpose:



- **Restart:** this function restart the laser device, the following confirmation popup screen appears:



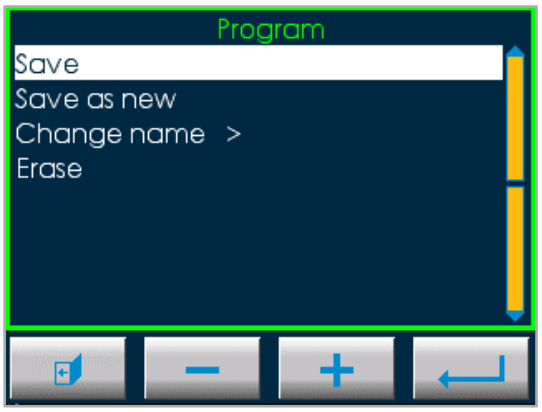
Press ESC to return to the previous screen, or OK to confirm restarting of the device.

5.4 Program Menu

The EVLT program is the preprogrammed default. The file name and settings can not be changed or erased in the saved default program. The settings for this program are:

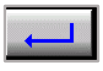
Length: 35 cm
Energy: 50 J/cm
Power: 6 watts

This function allows to manage the user personal programs.



5.4.1 *Save*

By selecting this function, it is possible to save certain parameters modifications which have been performed in the Main Screen.

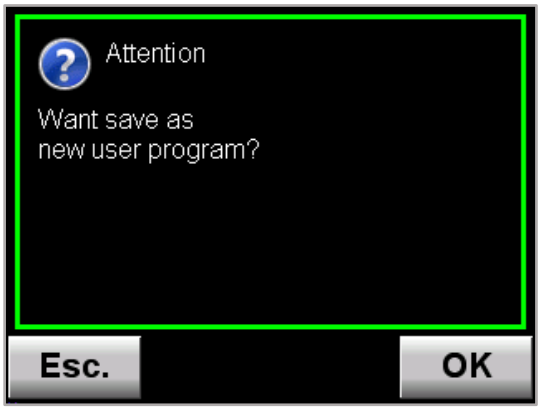
Click on the ENTER button to confirm 

5.4.2 *Save as new*

This function allows to save a new program with a new name and customized parameters as follows:

- Select a standard program;

- In the Main Screen, modify the standard parameters to desired parameters;
- Use this function



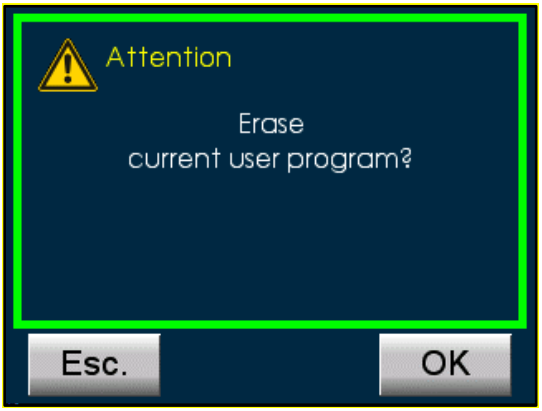
Press OK to confirm, or ESC to exit this menu without saving changes.
If the user presses OK, a Keypad appears for entering the New Program Name: enter the new name and press OK to confirm and return to the Programs Menu:

5.4.3 *Change name*

This function allows to rename a previous saved program using the keypad.

5.4.4 *Erase program*

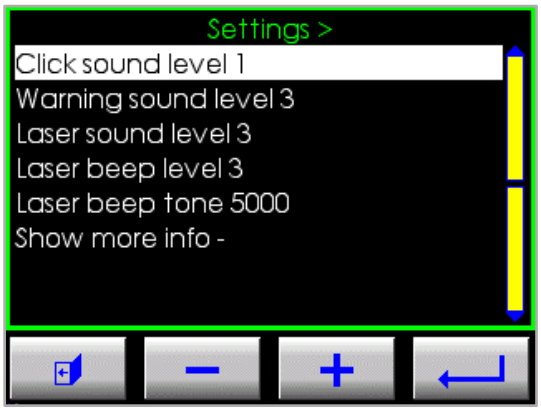
By selecting this function, it is possible to erase a previously saved program. The following popup screen appears:



Press OK to confirm, or ESC to exit the menu.

NOTE: the default *EVLT* program cannot be erased or changed.

5.5 Settings menu



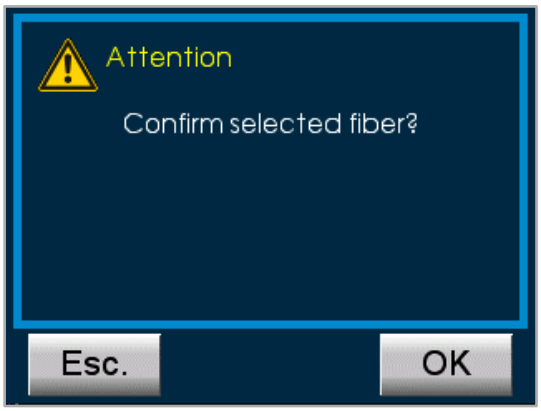
In the Settings menu you can modify:

- Click sound level
- Warning sound level
- Laser sound level
- Laser beep level
- Laser beep Tone
- Show more info *(option active in Service Mode only).*

5.6 Laser Emission procedure

After the parameters are set, enter Ready mode: the system is ready to emit laser radiation.

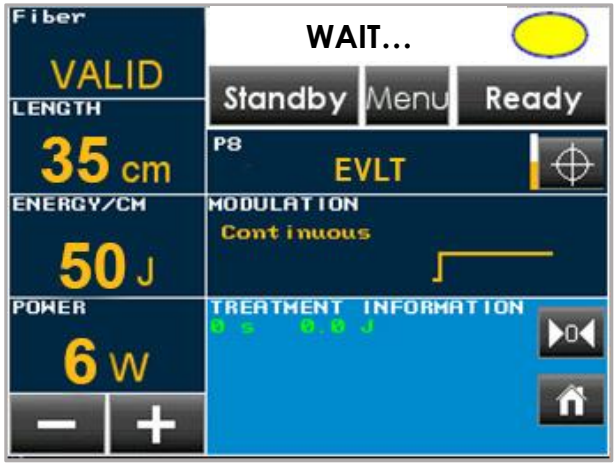
The first time you switch from Standby to Ready status, the following Warning appears:



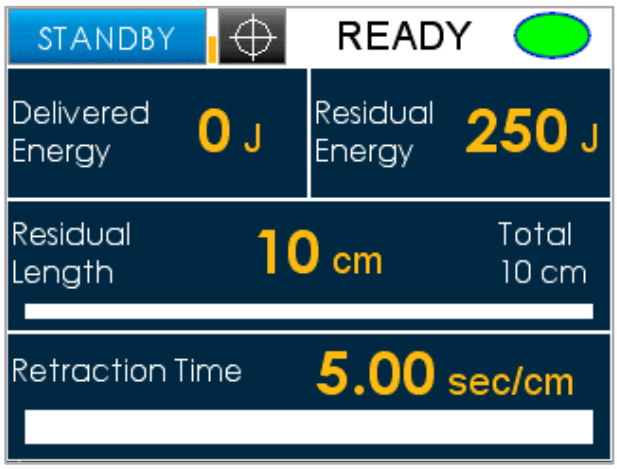
Press OK to confirm, or ESC to exit and return in Standby mode.

Every time you switch from Standby to Ready status, the following Warning appears:

Press OK to confirm you are wearing your protection goggles.
The following screen appears, displaying the "WAIT…" wording in the status area:



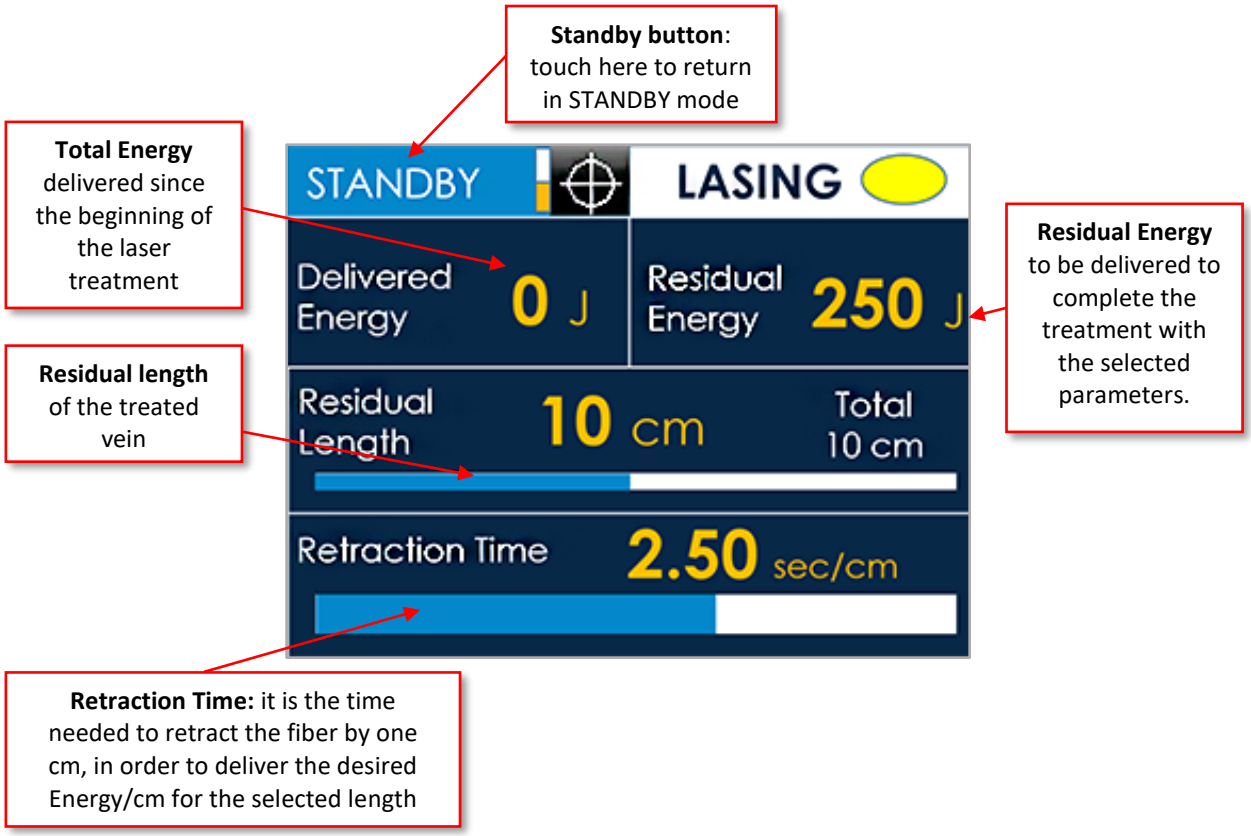
After a few seconds the system enter in READY status: in this status the user can enable laser emission by pressing the footswitch:



<u>For detailed operating procedure refer to the AngioDynamics fibers instruction for use.</u>

During emission, the following screen appears, displaying the "LASING" wording in the status area. The LASING screen allows the user to monitor the following parameters during the operating procedure:

- Total delivered energy (J)
- Residual energy (J) = *Energy/cm x Residual length*
- Residual length (cm) of the vein
- Suggested retraction speed (sec/cm)



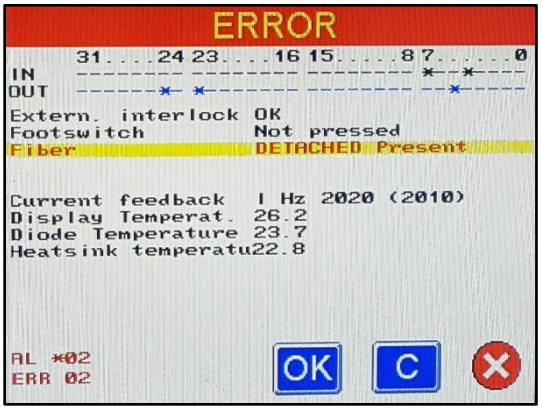
ANNOTATION: The **Retraction Time** is the time (in seconds) needed to treat 1 cm of vein and depends on the set parameters. It is automatically calculated by the device which beeps (every 2.5 sec in the example above) helping the Physician during operation.

If, for any reason, it is necessary to continue the operation for a length greater than the settled one (10 cm in the example above), the laser device does not interrupt the procedure, but inform the user of the exceeding laser treatment by turning the **Residual Length** and the **Residual Energy** to negative values.

5.7 Alarms

When an error occurs, a popup warning window appears (see the example below):

By entering in **Main menu → Diagnostics**, it is possible to see the error details. In the event of an Error, the Error message is displayed in red in the Diagnostics screen:



➔ In the event of laser system stop, transfer this information to the AngioDynamics Service.

The following alarms are possible:

Alarm type	Alarm message
Remote interlock alarm	EXTERNAL INTERLOCK OPEN
Footswitch alarms	PEDAL DETACHED
	PEDAL PRESSED IN STANDBY
	PEDAL FAULT
Diode temperature alarm	LASER OVER TEMPERATURE
Optical fiber alarm	FIBER DETACHED
Current feedback alarms	Current LOW, code: x
	Current HIGH, code: x
	NO SIGNAL
Laser power alarm	POWER HIGH
Fiber RFID messages/alarms	NOT CONNECTED
	NOT DETECTED
	CORRUPTED
	CHECKING
	CHECKING TIMEOUT
	STERILITY DATE EXPIRED
	USES NUMBER EXPIRED / EXPIRED
	NOT VALID / NOT IDENTIFIED
	FIBER USE TERMINATED. Energy exceeded 10 kJ
	FIBER USE TERMINATED. Fiber was disconnected

Refer also to the Troubleshooting Chapter 8.

5.8 Shut down procedure and protection against authorized use

To switch the device off:

- Turn the key anticlockwise to ⏻
- Switch OFF the main switch on the rear panel.

Disconnect the laser system from the main by unplugging the power cable.

When the laser device is not in use, it must be protected from any unauthorized use: ***in order to avoid improper use of the device, the key shall be removed when the device is not being used.***

6 CLINICAL APPLICATION

6.1 Training requirements

The User Manual supported by clinical application guidelines makes the laser therapy closer to the laser user. The laser users should be familiar with the Laser Physics and detailed Clinical Protocols. In this user manual, only a summary regarding the application treatments will be presented. Apart from the clinical protocols, it is important to provide the patients with clinical judgment from the side of a physician, that way giving possibility to verify the suggested protocols according to the case of individual patient.

6.2 Indications for use

The *VenaCure 1470 Pro* laser is intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb.

6.3 Contraindications

- Patients with thrombus in the vein segment to be treated
- Patients with an aneurismal section in the vein segment to be treated
- Patients with peripheral arterial disease as determined by Ankle-Brachial index <0.9

6.4 Side effects and complications

The complications of the laser therapy are similar as with any other surgical procedure. Some of these complications could be serious.

The potential for complications exists, including:

- Vessel Perforation
- Thrombosis
- Pulmonary Embolism
- Phlebitis
- Hematoma
- Infection
- Skin Pigmentation Alteration
- Neovascularization
- Paresthesia due to thermal damage of adjacent sensory nerves
- Anesthetic Tumescence
- Non-Target Irradiation
- Hemorrhage
- Necrosis
- DEHP Exposure
- Skin Burns and Pain

(This is not an exhaustive list.)

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

6.5 Suggested parameters

Specific parameters are not recommended, but are left to operator preference and best medical judgment.

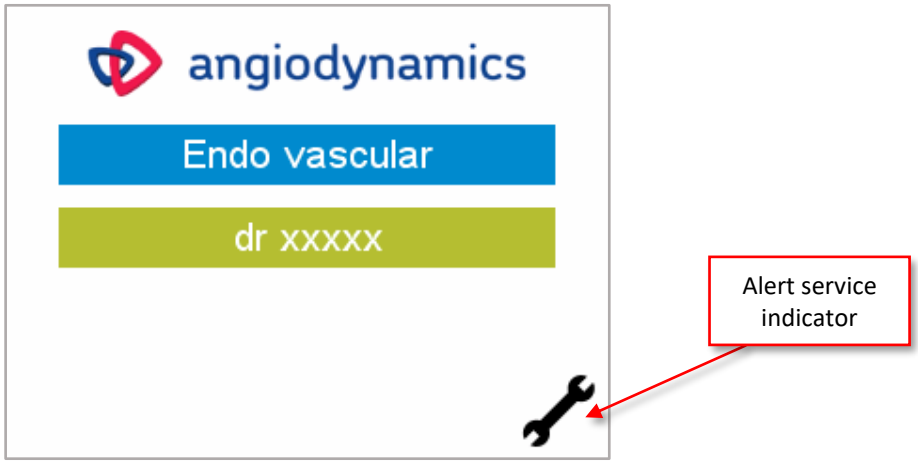
7 CALIBRATION and MAINTENANCE

7.1 Calibration and Maintenance

With a careful use and normal working conditions, we recommend an annual system Calibration and Preventative Maintenance service by a Manufacturer Authorized Service Group. The intense use, presence of dust, and not-careful operation may require more frequent maintenance.

7.2 Service Indicator

After the *VenaCure 1470 Pro* laser is activated with the key switch and the welcome screen is bypassed, the program screen may display an indicator to inform the user that the system requires service.



The *VenaCure 1470 Pro* laser should have an initial calibration check three years after the date of manufacture with subsequent annual calibration checks. If this check is due, a "wrench" symbol will be displayed on the program screen. This symbol will be removed after the calibration is completed.

This symbol is for information only and does NOT prevent the *VenaCure 1470 Pro* laser from being used. Please contact your AngioDynamics representative for further details.

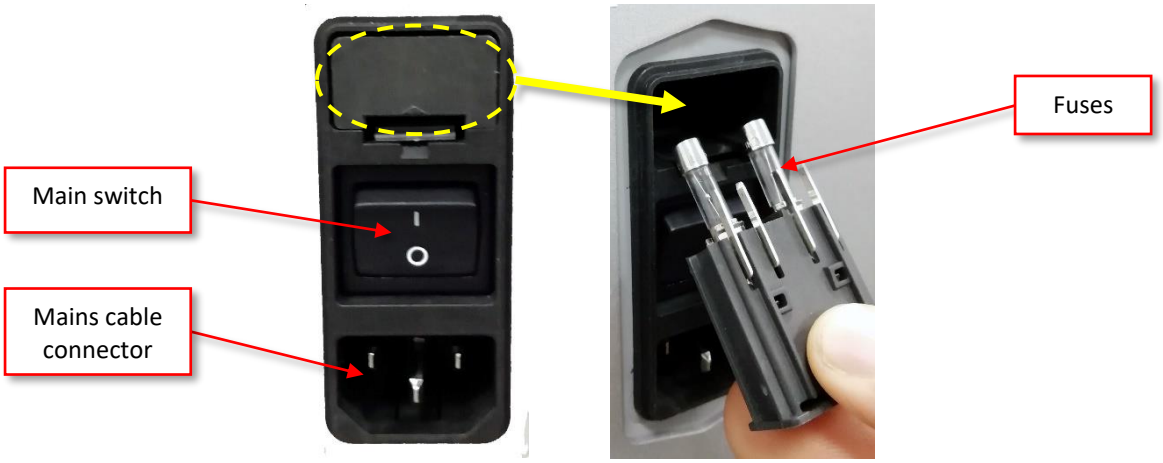
7.3 Type and nominal value of the fuses

The fuses utilized for the main power connector have the following specifications:

- F1: 250V T4AH
- F2: 250V T4AH

Fuse replacement:

- In order to check, or replace the fuses, remove the small black tray at the power socket on the rear panel of the device, as shown in the figures below:



- After replacing the fuses, close the cover.

Warning: *This operation shall be performed with the device switched off and disconnected from the mains.*

7.4 Device cleaning

Clean the visible surfaces with a damp cloth, taking care not to let the water enter the device. Do not use alcohol or disinfectant solutions, because they are highly flammable. While cleaning, be careful not to let the cleaning solution leak in the fiber connection port. Use the supplied caps to close the fiber connection port after each use. Do not use any alcohol solution to clean the display.

7.5 Optical fiber maintenance

Only the use of AngioDynamics Fibers is allowed with the *VenaCure 1470 Pro* Laser System.

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.*

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!*

Carefully read and follow the Instruction for Use *"AngioDynamics Fiber Procedure Kit"*

7.6 Check the Power cable

Laser device has a power cable 2 m long. Power cable can be subject to deterioration over time and therefore it is necessary to check periodically the status of the power cable.

7.7 Safety labeling check

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

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

8 TROUBLESHOOTING

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

Alarm type/Trouble	Alarm message	Issue related	Possible solution
The system doesn't switch on	----------	• Power not connected • Main power switch off • Emergency stop button pressed • Broken main fuse	• Check power cord connected • Check main power switch • Check the stop button • Replace the fuse
Low output power	----------	• Damaged optical fiber	• Inspect the fiber • Replace the fiber • Call service
No output power	----------	• The laser isn't in ready mode • Footswitch broken	• Select mode selection • Call service
Power supply faulty and acoustic alarm	----------	• Power supply broken • CPU supply not working	• Switch power off immediately and call service
Remote interlock alarm	EXTERNAL INTERLOCK OPEN	Interlock not connected when pressing the REDY button	• Connect the interlock
Footswitch alarms	PEDAL DETACHED	Footswitch not connected when pressing the READY button	• Connect the footswitch; • Substitute the footswitch; • Call Service
	PEDAL PRESSED IN STANDBY	Footswitch pressed in STANDBY mode	• Release the footswitch
	PEDAL FAULT	Footswitch status not correct	• Disconnect and reconnect the footswitch; • Substitute the footswitch; • Call Service
Diode temperature alarm	LASER OVER TEMPERATURE	The diode laser temperature exceeds a warning threshold	• Check the fan area is not obstructed: leave enough empty space behind the device; • Wait few minutes the temperature falls below the warning level; • If the error persists, call Service
Optical fiber alarm	FIBER DETACHED	The fiber is not connected when pressing the READY button	• Connect the fiber

Alarm type/Trouble	Alarm message	Issue related	Possible solution
Current feedback alarms	Current LOW, code: x	The diode laser current is not in the acceptance range	• Call Service
	Current HIGH, code: x		
	NO SIGNAL		
Laser power alarm	POWER HIGH	The laser power measured by the internal photodiode exceeds by 20% the set power	• Restart the device; • If the error persists, call Service
Fiber RFID messages/alarms	NOT CONNECTED	The fiber RFID chip cannot be read or is not present	• Properly connect the fiber; • Replace the fiber
	NOT DETECTED		
	CORRUPTED		
	CHECKING	Reading data from RFID tag	• Wait
	CHECKING TIMEOUT	Cannot communicate with the RFID reader	• Replace the fiber; • Call Service
	STERILITY DATE EXPIRED	The shelf life of the connected fiber has expired	• Replace the fiber
	USES NUMBER EXPIRED / EXPIRED	The connected fiber has already been used and cannot be used again	• Replace the fiber
	NOT VALID / NOT IDENTIFIED	The connected fiber is not an AngioDynamics fiber	• Replace the fiber with an AngioDynamics fiber
	FIBER USE TERMINATED. Energy exceeded 10 kJ	The total energy emitted by the fiber exceeds the threshold limit of 10 kJ. The system is forced in STANDBY mode.	• Replace the fiber
	FIBER USE TERMINATED. Fiber was disconnected	The fiber has been already used and was disconnected for a time greater than 5 minutes. The fiber cannot be used anymore.	• Replace the fiber

9 CUSTOMER SERVICE

9.1 Contact Information

Please contact AngioDynamics to report any malfunctions, manufacturing defects or non-conformities of your device, or for calibration and preventative maintenance.

US Customer Service 800-772-6446

Go to Angiodynamics.com and “About US” for International Customer Service contact information.

9.2 Manufacturer Warranty and Responsibility

The Manufacturer disclaims any responsibility for any misuse of the system.

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

Correct use consists of:

- Following the instructions described in this manual
- Following a proper maintenance program of the system
- Complying with international safety standards

The device is warranted against any defect in material and workmanship for a period of (3) full years from its delivery.
Repairs needed in case of natural disasters, accidents, electrical circuit failures, negligence, improper use or misuse of the device, or repairs or servicing carried out by persons not authorized by the Manufacturer are not covered by warranty.

Repairs and service performed by Manufacturer Authorized Service Groups will be performed in their depot repair centers.

This warranty is void for any of the following reasons:

- Use of the device is not in accordance with the procedures and instructions contained in this user manual.
- Incorrect installation and maintenance.
- Use of a damaged or improperly installed device or use with a damaged safety system.
- Noncompliance with the user manual instructions regarding: transportation, storage, installation, and maintenance.
- Any alteration or modification of the device.
- Incorrect repairs.
- Accidents caused by external elements.
- The goggles for operator and patients are not used while operating the device, while the device is in any mode, including the STANDBY mode.

In no case the customer can be entitled to claim compensation for any damage resulting from the machine being out of operation.

Please contact Customer Service as stated above for warranty information.

9.3 Repairs and modifications of the device

- Only authorized service personnel can perform repairs and maintenance
- It is recommended to follow an annual calibration and preventative maintenance program
- It is recommended to replace all the damaged components
- Use only manufacturer approved replacement parts
- Any unauthorized changes or alterations are not permitted

Please keep on hand the Serial Number of your device.

10 TECHNICAL SPECIFICATIONS

10.1 General Specifications

Model name	VenaCure 1470 Pro
Product category	Laser for medical use
Classification according Medical Device Directive 93/42/EEC	Class IIb
Laser Classification according to IEC / EN 60825-1:2014	Class 4
Aiming beam classification according IEC / EN 60825-1:2014	Class 3R
Mains	100-240 Vac; 50/60Hz; 350VA
Type of protection against electric shock	Class I
Degree of liquid ingress protection	IP 20 (Not protected)
Degree of electric shock protection	Type CF
Mode of operation	Continuous
Dimensions	196 mm(H) x 378mm(W) x 379 mm(D)
Weight	11 kg
Operating temperature	10° - 30° C
Storage/transport temperature	Min. + 5° C / max. 40° C
Humidity	30% - 85% non-condensing
Pressure	from 800 hPa to 1060 hPa
Cooling system	Air cooled
Max noise (dB)	60 dB
Fuse	2 x T4AH 250V
Useful life	5 years after product is delivered.

10.2 Laser characteristics

Laser type	Diode laser
Wavelength	1470 nm ± 20nm
Maximum Power	15W
Operating mode	CW, pulsed
Pulse duration	Up to 10000 ms
Pulse pause	Up to 2500 ms
Repetition Rate	Up to 2000 Hz
Beam divergence	220 mrad
Beam transmission	Optical Fiber
Aiming Beam	635 nm, <4mW, class 3R
MPE (W/m^2)	1000
NOHD (m)	0,31
OD	1
Exposure Time (s)	100
Goggles	LB1

11 ACCESSORIES and DETACHABLE PARTS

11.1 Accessories

- User Manual
- Laser warning sign (quantity =2)
- Test fiber
- Protective goggles (quantity =3)

11.2 Detachable parts

- IEC power cable
- Footswitch
- Remote Interlock bypass connector
- 2 x Key

Appendix A: EMC Tables

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

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

<table>
<tr><td colspan="3">IEC 60601-1-2 Table 201
Guidance and manufacturer’s declaration – electromagnetic emission</td></tr>
<tr><td colspan="3">The equipment is intended for use in the electromagnetic environment specified below. The customer or the end user 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>The device 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">The device is not suitable for installation in all buildings including domestic and those directly connected to the public supply network in low voltage, but only in buildings like the hospital with dedicated supply system.</td></tr>
<tr><td>Harmonic emission
IEC 61000-3-2</td><td>Compliant</td></tr>
<tr><td>Voltage fluctuation/flicker emission
IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

IEC 60601-1-2 Table 202 Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the end user should assure that it is used in such an environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	Compliant	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for input power ports ±1 kV for I/O ports	Compliant N/A	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	Input power ports: 0.5 and 1.0 kV (line to line) 0.5, 1.0 and 2.0 kV (line to earth) Signal I/O: 2 kV (line to earth)	Compliant N/A	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Dips: 0% Ut for 0,5 and 1 cycle 70% Ut for 25 cycles (50 Hz) 70% Ut for 30 cycles (60 Hz) Interruption: 0% Ut for 250 cycles (50 Hz) 0% Ut for 300 cycles (60 Hz)	Compliant	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an Uninterruptible Power Supply or Battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Compliant	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

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

<table>
<tr><td colspan="4">IEC 60601-1-2 Table 204
Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The equipment is intended for use in the electromagnetic environment specified below. The customer or the end user 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>3 Vrms
150KHz to 80MHz

10 V/m
80 MHz to 2,7 GHz</td><td>Compliant</td><td>Portable and mobile RF communication equipment should be used no closer to any part of the device, 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 the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device

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 the device

The equipment is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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.