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LEONARDO®

INSTRUCTION MANUAL

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LEONARDO®
INSTRUCTION MANUAL

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1. Safety provisions and regulations

The variants of the laser family LEONARDO® may only be operated by appropriately qualified and trained personnel in compliance with legislation and the safety regulations. This device may also only be implemented in a clinical setting by qualified and trained doctors.

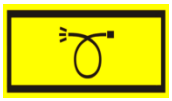
National legislation and safety regulations must be observed. In Germany, these are as follows:

- The German Medical Devices Operator Ordinance (MPBetreibV)
- The accident prevention regulation “Laser Radiation” (German Accident Prevention & Insurance Association safety prevention regulation no. 93)
- Electrical installations in hospitals and locations for medical use outside hospitals: DIN VDE 0107

The operator or a nominated laser safety officer is responsible for ensuring compliance with these regulations.

1.1 Warnings - Laser Safety

The LEONARDO® laser is a class 4 medical laser according to Directive EN 60825-1. Class 4 lasers can generate dangerous diffuse reflections. They can damage the eyes and skin, and represent a fire hazard. Class 4 lasers may also ignite flammable materials.

	**Warning:** Visible and Invisible Laser Radiation. Avoid eye or skin exposure to direct or scattered radiation! (Class 4 laser product)
	**Caution:** Laser aperture at distal end of the fiber!
	**Warning:** Direct eye exposure to the laser light leads to irreversible eye damage!

To avoid damage to the eye and retina, doctors, surgical personnel, patients and any other persons present in the room during treatment must wear appropriate protective eyewear (see section 5.2). The laser system is not suitable for ophthalmological applications.

	**Warning:** Protective eyewear must always be worn when using the laser! Eye protection must conform to Specification EN207 of the Directive 89/686/EEC as well as the Regulation 2016/425 with optical density in 980±30nm and/or 1064±30nm and/or 1470±30nm and/or 1940±30nm

Only use protective eyewear provided or approved by *CeramOptec*. Suitable protective eyewear can also be obtained from *CeramOptec*. *CeramOptec* recommends goggles which fulfill the requirements of the ANSI Z136.1 and CE / EN207 standards.

Safe distance – NOHD (Nominal Ocular Hazard Distance):

The safe distances for the following devices are from the laser outlet or from the emitting fiber:

LEONARDO® 1064: 1,76 m
LEONARDO® 1470: 0,34 m
LEONARDO® 1940: 0,28 m
LEONARDO® Dual 45: 2,60 m
LEONARDO® Dual 100: 4,30 m

Note that a greater distance must be maintained when using certain handpieces in derma mode (see section 4.3.7.5).

Caution: Do not look directly at the laser beam or a laser beam that is in use with optical devices or instruments. Doing so may result in permanent damage to the eyes or to the instruments.
Avoid placing reflective material, such as metal and glass, into the path of the beam.

Caution: Accidental irradiation to tissue not intended as the target tissue may result in laser burn.

	**Warning:** Do not use in the presence of flammable materials and endogenous gases!

1.2 Warnings - Electrical Safety

The LEONARDO® laser is a Electrical safety class I device according to directive EN60601-1.
Safety class I devices must only be connected to a supply mains with protective earth.

Warning: All variants of the laser family LEONARDO® may only be used with the accompanying footswitch and the specified application and light delivery systems, refer to section 1.6.

When operating the device, ensure that it is evenly balanced on a stable surface and that a distance of at least 25 cm is maintained between the ventilation fan and the walls. Position the device so that there are no cables or optical fibers suspended in the air between the wall socket, the device and the patient.

	**Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.

	**Warning:** Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the laser device, including cables specified by the manufacturer. Otherwise, degradation of the performance of the equipment could result.

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

To avoid risk of electric shock, do not open the housing. Service and maintenance may only be carried out by *CeramOptec* or by qualified personnel authorized by *CeramOptec*.
The equipment must be routinely inspected and maintained in accordance with the instructions provided in the maintenance section of this manual. A technical safety check must be performed on a yearly basis (see section 8.4).

Note: Ensure that the switch on the back of the unit is in the off position to prevent unauthorized use of laser devices.

Note: Note also the manufacturer's specifications regarding electromagnetic compatibility and the relevant requirements (see section 9.5).

1.3 Warnings – Enviromental Impact

Attention: All LEONARDO® laser generate a sound level of ca. 75 dB(A) for a few seconds during the start up phase and can generate similar sound level during the operation.

1.4 Warnings - Cleaning

Caution: Unplug the device before cleaning (see section 8.2).

Caution: Do not use this device in potentially explosive atmospheres. Avoid using flammable anesthetic gases or oxidizing gases such as nitrogen oxide or oxygen. Certain materials saturated with oxygen, such as cotton, may ignite even if the laser is used in accordance with the regulations. Allow sufficient time for flammable disinfectant solutions to evaporate before you use the laser. Note that endogenous gases may also ignite.

Caution: Use of non-approved equipment or procedures when the device is in operation may result in dangerous exposure to radiation.

Noncompliance with the safety and operating instructions provided in this manual will in all cases invalidate warranty and liability on the part of *CeramOptec*.

2. Product description

All variants of the laser family LEONARDO® are laser systems with functions and ergonomics specially developed for medical applications. A touchscreen is used to set treatment parameters, such as laser power. User-friendly menu navigation and microprocessor-supported control ensure reliable operation while allowing physicians to concentrate on the essential aspects of treatment. The fiber-coupled semiconductor laser diodes convert electrical energy to coherent laser radiation with the wavelength of 980±30nm and/or 1064±30nm and/or 1470±30nm and/or 1940nm±30nm (aiming beam 635nm +/-10nm and 532nm +/-10nm). A beam transporting system delivers this energy to affected surfaces and organs. All fields of application are listed in section 2.1; depending on the model, your LEONARDO® laser has a maximum laser output power of:

LEONARDO® 1064:	**20W @ 1064nm**
LEONARDO® 1470:	**15W @ 1470nm**
LEONARDO® 1940:	**10W @ 1940nm**
LEONARDO® Dual 45:	**30W @ 980nm + 15W @ 1470nm**
LEONARDO® Dual 45:	**30W @ 1064nm + 15W @ 1470nm**
LEONARDO® Dual 100:	**85W @ 980nm + 15W @ 1470nm**
LEONARDO® Dual 100:	**85W @ 1064nm + 15W @ 1470nm**

The LEONARDO® is available as devices with two wavelengths (980nm and 1470nm) or (1064nm and 1470nm) and as a single-wavelength device with 1064nm, 1470nm or 1940nm.
All LEONARDO® lasers can be operated in two basic modes, CONTINUOUS or PULSE MODE. Additional special treatment modes for specific treatment procedures or in combination with corresponding application fibers are available. Special treatment modes are available in combination with the corresponding application fibers for dermatology ("Derma mode") and phlebology ("ELVeS signal mode" and "ELVeS segment mode"). For safety reasons, the LEONARDO® laser is equipped with a system for automatic recognition of the used optical fibers. Application fibers from *CeramOptec* are coded for communicating with the laser device.
For delivery details, refer to section 5.1.

2.1 Intended purpose and indications

LEONARDO® is designed for delivering laser light to tissue in contact and non-contact surgical procedures, including endoscopic procedures.

The indications refer to the treatment of diseases, anomalies, functional disorders, intraoperative needs or specific - medically indicated - requirements.

The laser radiation through the respective fibers can penetrate either superficially or in a defined depth, depending on the surgeon's intended use.

The information above may be limited by the available parameter settings of the laser device and the fiber properties and is determined by the operator at his own discretion and responsibility.

LEONARDO® is suitable for the following fields of application:
incisions, excisions, vaporization, ablation, hemostasis or coagulation of soft tissue, carbonization, shrinkage, tightening, change of status and consistency; denaturation; micro-stimulation; direct and indirect increase or reduction of blood flow; mechanical manipulation; defined deformation; the reduction; resection; widening; hyperthermia; occlusion; (re-)opening of vessels, channels and passages; fraction; destruction; welding; joining; sealing; fusing; adhesion; sclerotherapy; constipation reconstruction; induction and stimulation of healing processes; denervation; liquefaction and in contact and non-contact processes of human organ parts and tissue.

An exemplary - not exhaustive, nor complete - list of indications and surgical procedures is given in the following medical, interdisciplinary disciplines:

- ENT: turbinectomy, septum, paracentesis, tonsillotomy, laryngeal cancer, hemangioma, adhesions, epistaxis, DCR, polyps, eustachian tube dysfunction
- Pulmonology/Thoracic surgery: coagulation and vaporization of endobronchial stenoses, metastasectomy, evaporation of tumors, resection of recurrent and metastatic tumors, tissue biopsy for histology, partial resection of pulmonary lobe, fistula sealing
- Gastroenterology: esophageal tumors
- Proctology: laserhemorrhoidoplasty, anal fistulas, sinus pilonidalis/ coccyx fistula, soft tissue tumors, polyps (polyposis coli and/or villous adenoma), anal stenoses, condylomata accuminata, fissures, mariscae, coccygeal fistulas)
- Phlebology : Endovenous ablation of surface veins (saphenous veins, magna and parva), tributaries, perforant veins, recurrences, venous leg ulcers)
- Dermatology and venereal diseases: Telangiectases, spider naevi, hemangioma, spider veins, vascular malformations, warts, lentigo
- Urology: Bladder tumors, Condylomata, Minimally invasive surgery, LITT, partial nephrectomy, prostate cancer
- Orthopedics: contained lumbar disc herniation, contained cervical disc herniation, discogenic spinal stenosis, discogenic pain syndrome, chronic facet and sacroiliac joint syndrome
- Neurosurgery (peripheral nervous system): contained lumbar disc herniation, contained cervical disc herniation, discogenic spinal stenosis, discogenic pain syndrome, chronic facet and sacroiliac joint syndrome
- Gynecology and Obstetrics: fibroids, polyps, cysts, condylomata, Minimally Invasive Surgery
- Plastic surgery: lipolysis, adstriction of the skin
- Dental application: periodontitis

Recommended lasers for indications

Indication/ Laser Model	ENT	Pulmonology/ Thoracic Surgery	Gastro-entrology	Proctology	Phlebology	Dermatology & venereal diseases	Urology	Orthopedics	Neurosurgery	Gynecology & Obstetrics	Plastic surgery	Dentistry
	turbinectomy, septum, paracentesis, tonsillotomy, laryngeal cancer, hemangioma, adhesions, epistaxis, DCR, polyps, eustachian tube dysfunction	coagulation and vaporization of endobronchial stenoses, metastasectomy, evaporation of tumors, resection of recurrent and metastatic tumors, tissue biopsy for histology, partial resection of pulmonary lobe, fistula sealing	esophageal tumors	laserhemorrhoidoplasty, anal fistulas, sinus pilonidalis/ coccyx fistula, soft tissue tumors, polyps (polyposis coli and/or villous adenoma), anal stenoses, condylomata accuminata, fissures, mariscae, coccygeal fistulas)	Endovenous ablation of surface veins (saphenous veins, magna and parva), tributaries, perforant veins, recurrences, venous leg ulcers)	Telangiectases, spider naevi, hemangioma, spider veins, vascular malformations, warts, lentigo	Bladder tumors, Condylomata, Minimally invasive surgery, LITT, partial nephrectomy, prostate cancer	contained lumbar disc herniation, contained cervical disc herniation, discogenic spinal stenosis, discogenic pain syndrome, chronic facet and sacroiliac joint syndrome	contained lumbar disc herniation, contained cervical disc herniation, discogenic spinal stenosis, discogenic pain syndrome, chronic facet and sacroiliac joint syndrome	fibroids, polyps, cysts, condylomata, Minimally Invasive Surgery	lipolysis, adstriction of the skin	periodontitis
LEONARDO® 1064 (20W@1064nm)	X	X	X	X	X	X	X	-	-	X	-	-
LEONARDO® 1470 (15W@1470nm)	X	X	X	X	X	X	X	X	X	X	X	X
LEONARDO® 1940 (10W@1940nm)	-	-	-	-	X	-	-	-	-	-	-	-
LEONARDO® Dual 45 (30W@980nm+15W@1470nm)	X	X	X	X	X	X	X	X	X	X	X	X
LEONARDO® Dual 45 (30W@1064nm+15W@1470nm)	X	X	X	X	X	X	X	-	-	X	-	-
LEONARDO® Dual 100 (85W@980nm+15W@1470nm)	X	X	X	X	X	X	X	X	X	X	X	X
LEONARDO® Dual 100 (85W@1064nm+15W@1470nm)	X	X	X	X	X	X	X	-	-	X	-	-

2.2 Contraindications

Contraindications for the Leonardo laser product group include:

- Allergy to local anesthetic
- Infection of the area to be treated
- Poor general health
- Laser treatments should not be conducted near implanted staples or stents due to the danger of overheating and/ or destruction
- Laser treatments should not be conducted for indications where there are potentially explosive atmospheres. Avoid using the laser in the presence of flammable anesthetic gases or oxidizing gases such as nitrogen oxide or oxygen.
- Laser treatments close to sensible areas (e.g. arteries, intestines) may cause perforations. Laser radiation should only continue for the required period needed for coagulation or vaporization.
- Additional contraindications may be determined by the individual physician at the time of treatment (e.g. pregnancy).

Consult the instructions for use for specific application fibers for contraindications related to specific applications.

The Leonardo laser is not approved for the treatment of the heart, central circulatory system, or central nervous system.

Intended user:	Qualified and trained physicians and surgeons.
Patient population:	The target population with regards to age, weight, and state of patient health are to be determined by the attending physician.

2.3 Side effects

Adverse events can result from the underlying procedure (e.g. endoscopy), concurrent illness or laser treatment application. Endoscopic therapy can lead to the following (non-thermal) complications: perforation, aspiration, induced haemorrhage, allergic reaction to medication, hypertension, arrhythmia, pain.

Results from conventional or endoscopic laser therapy can include, but not limited to, the following thermal complications:

acute:

- induced hemorrhage
- ulceration
- perforation
- edema
- pain
- fever
- leukocytosis

chronic:

- delay in healing
- perforation
- delayed hemorrhage
- pigment changes in skin layers
- scarring (possibly keloids)
- locally restricted pain of pressure

3. Description of the device

3.1 Controls and connections

[1] Screen
[2] Laser Stop - Button
[3] Laser output
[4] Laser warning light
[5] Standby - Button

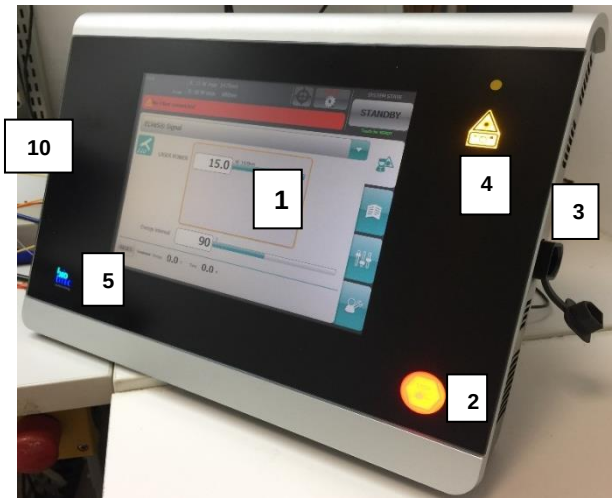


Figure 1: Front of the device

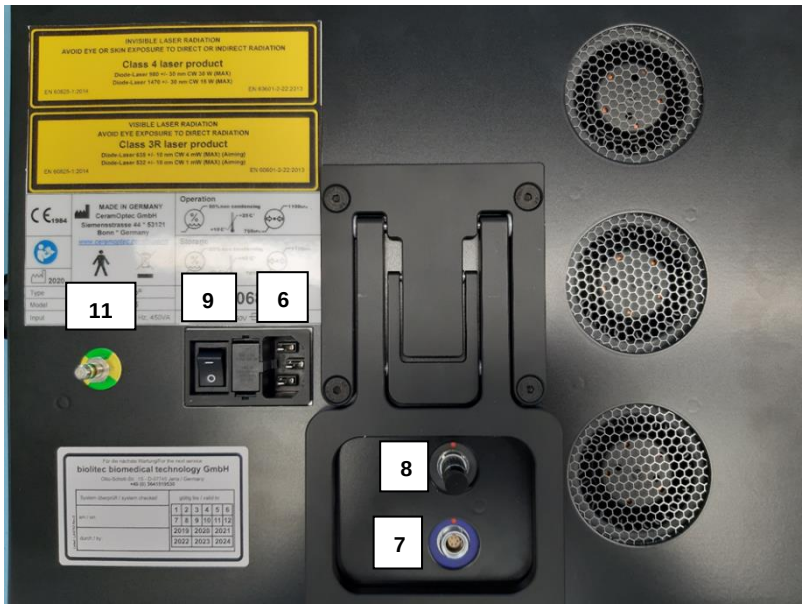


Figure 2: Rear of the device

[6] Power connection
[7] Footswitch port
[8] Door interlock port
[9] On-off switch
[10] Service Port
[11] Potential equalization plug

3.2 Description of controls, displays, connections

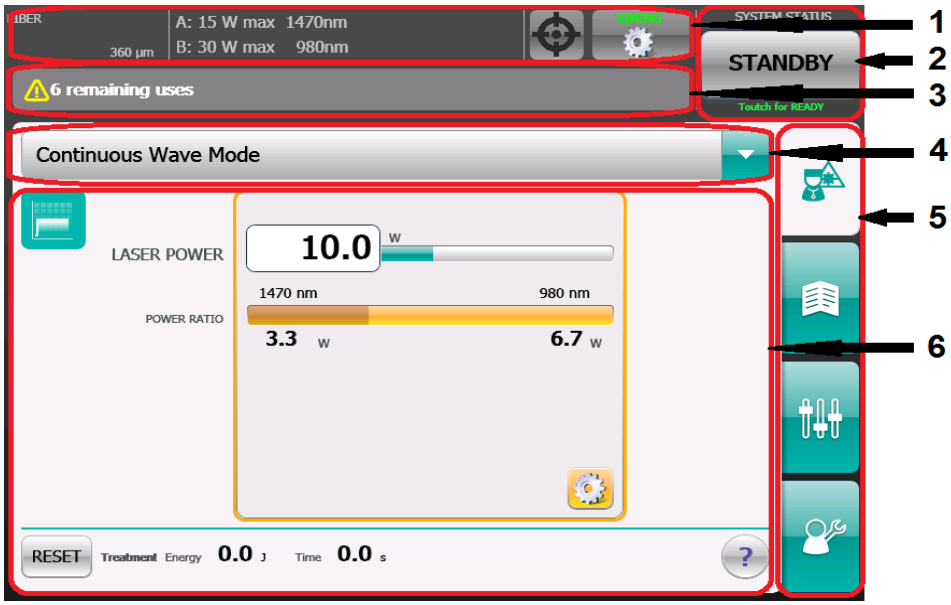
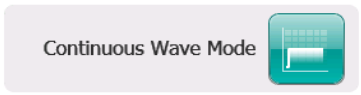
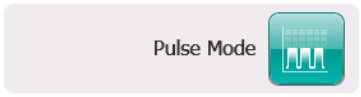
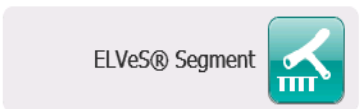
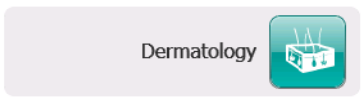
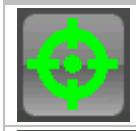
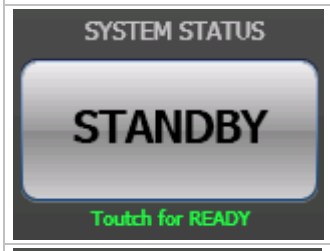
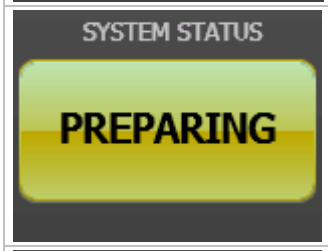
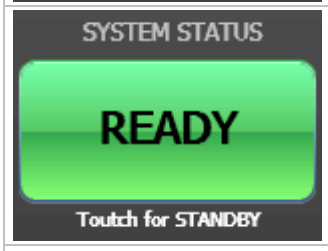


Figure 3: Subdivision of the operating interface

1. Info area
2. Laser status button
3. Status messages
4. Treatment mode options
5. Function options
6. Main area

Screen [1]	The display is subdivided into four main key fields and shows: - Status of the device (Enable/Standby) - Treatment mode (Continuous mode (Continuous Wave CW), Pulse mode and additional programs (optional)) - Treatment parameters (duration, energy, pulse parameter) - Power settings - Fiber information - Aiming beam settings Settings can be changed via the key fields and the cursor on the screen.
Key fields on the screen [1]	- Switch between enable and standby status - Change treatment mode (Continuous mode, Pulse mode and additional programs (optional)) - Select the parameter to be configured - Aiming beam (Off, On, CW mode or Pulse mode with intensity setting) - Save changed treatment modes - Select function

Key fields next to the screen	
Laser stop button [2]	Pressing the emergency stop button interrupts the power supply of the laser diodes and averts an emission of laser radiation. **Press the laser stop button in case of emergency only.**
Laser standby [5]	Pressing this button switches the laser to standby mode, from which it can be reactivated. To enter standby mode, the on-off switch on the rear of the device must be in the On position.
Selecting a function	
	**Treatment modes** Here you can select and set the treatment mode.
	**Info screen** Instructions for use and additional information about using lasers can be retrieved and read on screen.
	**Video area** Treatment videos provided by biolitec AG can be viewed here (coming soon).
	**Online shop for accessories** (coming soon).
	**User settings** Device version number, language version, aiming beam settings.
	**Feature settings** These settings are only to be used by the service staff of *CeramOptec* or other authorized personnel.

Selecting treatment modes	
	Continuous mode (Continuous Wave mode, CW)
	Pulse mode
	ELVeS® signal mode
	ELVeS® segment mode
	Derma mode (for LEONARDO® Dual only)
Header	
	**PILOT ON / OFF** The pilot beam can turned on or off and indicates if it's turned on. Furthermore the color of the pilot beam is displayed.
	**PILOT beam settings** Pilotbeam color, intensity and operatinn mode (CW/Pulse) can be adjusted
	**SYSTEM STATUS** In standby mode, the power connection is plugged in and the main switch is in the On position. The device does not emit any laser radiation in the standby mode even if the footswitch is pressed. Pressing this button switches the device from standby mode to ready mode.
	If the status is switched from standby to ready, the laser device prepares for use. Duration of the preparing phase is about 3 seconds.
	Indication that the laser is now ready. The laser device now emits laser radiation as soon as the footswitch is pressed. By pressing this button, the status switches from ready to standby.
Laser warning signal [4]	When laser radiation is emitted, the LED warning light comes on and a warning signal is sounded.

Side of the device	
Laser outlet [3]	Fiber coupling for connecting application fibers. If the fibers are not fully tightened or if they loosen/detach during treatment, the error message "No fiber connected" is displayed. If this error message occurs, the laser switches to standby and can no longer be activated. **Caution:** Only use approved application systems, fibers, and medical probes (see section 6.1). The use of non-approved systems may damage the unit and result in dangerous exposure to radiation. Noncompliance invalidates the warranty.
Application fibers	LEONARDO® is compatible with various application fibers. For the minimum fiber core diameters permitted and possible power restrictions, refer to the specifications for the different models in section 9.1. **The use of application fibers with a smaller fiber diameter or lower quality and the use of non-approved systems may damage the unit and result in dangerous exposure to laser radiation. Noncompliance invalidates the warranty.**
Rear of the device	
Power connection [6]	The laser may only be used in the standard power supply configuration. Proceed as described in section 4.1. Examine the cable for visible damage prior to connecting the plug to the power supply. If the cable is damaged, do not use the cable or replace it.
Footswitch [7]	The footswitch must be connected to the device using the plug connector at the rear of the device. Treatment starts when you press the footswitch. The laser emits radiation for the preselected time. Treatment can be interrupted at any time by releasing the footswitch. **The laser emits radiation only as long as the footswitch is pressed.** Laser emission continues once you press the footswitch again.
Door interlock [8]	A door interlock can be connected using the port on the rear of the device. The device can only be operated if the door interlock is closed or if the blanking plug supplied is connected to the port. To ensure a correct connection, refer to section 4.1.2 **Caution:** You must ensure that **no** voltage is connected to this port.
On-off switch [9]	For setting the laser system into operating state, press the switch on the rear of the device. If the switch is in the On position, it is possible to switch the laser to standby mode and back by pressing the standby button.
Service Port [10]	Using the service port is reserved for persons who are authorized by CeramOptec.
Potential equalization plug [11]	An additional potential equalization conductor can be connected using the potential equalization plug on the rear of the device. Contact CeramOptec if you would like to order this cable.

4. Operation

4.1 Preparing the laser unit

Check the device for any obvious signs of damage after unpacking the laser. Do not use the device if any damage is detected.

Before starting the laser, connect the footswitch cable to the footswitch port on the rear of the device [7]. The red markings on the plug and the socket must line up.

Then connect the cable of the door interlock or the interlock connector with the port on the rear of the device [8]. Connect the power cable [6]. Ensure that the connector is inserted completely into the optic port. The correct positioning of the connector is accompanied by an acoustic “click” as well as a tactile snapping of the connector into the end postion (Figure 2).

The noticeable recoiling of the connector is a sign that the connection was not successful. If the multiple connection efforts are unsuccessful, please contact a CeramOptec representative.

Warning: The device may only be connected to mains with a functioning protective conductor!

After that insert the application fiber approved by the manufacturer together with its plug (Figure 4) into the fiber coupling of the laser outlet [3] on the side of the device. When the fiber is connected correctly, the message "No fiber connected" disappears on the display.
The device is equipped with a system for automatic recognition of application fibers. If an application fiber has coding, information about the fiber is read from the coding once the fiber is connected to the device.

Figure 4: Application fiber connection

If the message "Not a valid biolitec® fiber" appears, this means that the device did not recognize the coding on the fiber or identified the fiber as unsuitable for the laser unit based on the data defined for the device. Only approved application fibers may be used with this device (see section 6). Please contact our service department if further information is required.

Caution: All operating steps after preparation of the laser unit may only be performed when all persons in the room are wearing appropriate laser safety goggles.
Use of the operating controls or configuration options of the LEONARDO® in a manner other than that described here in the instructions manual may result in radiation hazards.
Ensure that the treatment room is clearly identified and that only persons wearing the appropriate laser protective eyewear may enter the room during treatment. If this is not possible, you must install a door switch as per section 4.1.2 that switches off the laser output when the door is opened. Note that switching off the laser during treatment may result in unintended complications.

4.1.1 Footswitch

The footswitch is included in the delivery and is to be attached to the footswitch connector on the rear of the device. Connect the delivered footswitch cable with your footswitch before using. Please insert the 4 pin round connector of the foot switch cable to the 4-pin housing socket of the foot switch. Make sure that the mark tabs mesh. Last screw the union nut by hand. The permanent seat of the cable gland should be checked before each use of the laser device.

Note: Connect the footswitch cable with the footswitch before using.

Warning: Disconnect the footswitch cable from the footswitch during any kind of laser transportation. Transportation of a device with the cable connected will lead to device damage the warranty will be voided.

Warning: Do not touch the pins of the footswitch connector. Turn the device OFF before connecting or disconnecting the footswitch.

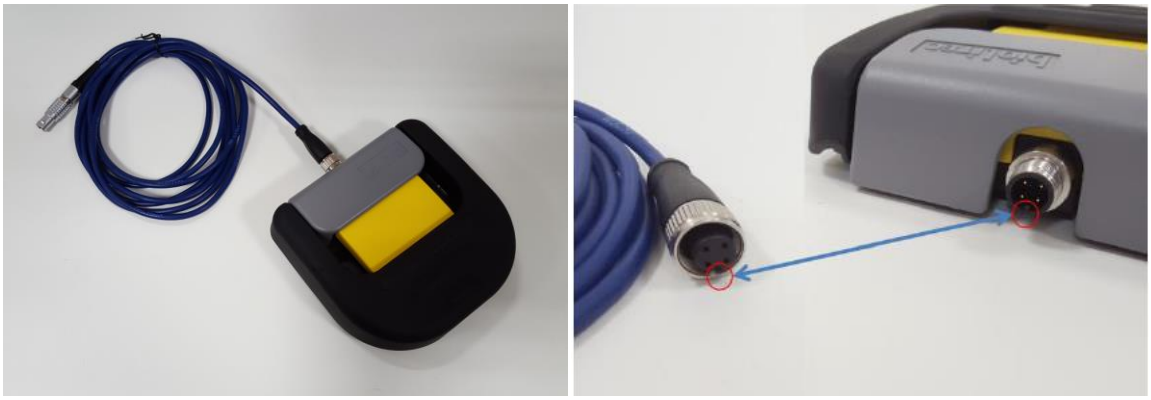


Figure 5: Foldable footswitch Steute

4.1.2 Door interlock connection scheme

Connect the door interlock as shown in figure 6. A door interlock cable can be requested free of charge from the manufacturer. For additional connections, see also section 4.1 (Preparing the laser unit).

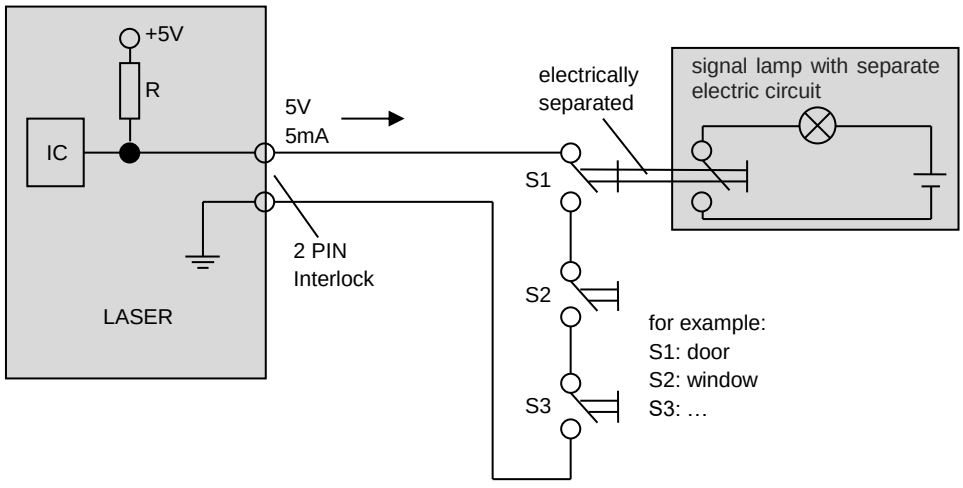


Figure 6: Door interlock connection scheme

Warning: Do not touch the pins of the door interlock connector. Turn the device OFF before connecting or disconnecting the door interlock connector.

Recommendation: It is recommended that all staff receive an explanation and training in ESD procedures. The ESD precautions procedure training shall include at least the safe connection and disconnection of the footswitch and door interlock connectors.

4.1.3 Fiber interlock

For safety reasons, a smart so called “Fiber Interlock” is integrated. The connection is recorded by a complex logic device by using two reflective interrupters. The beam can only pass from the optic to the application fiber when both reflective interrupters are enabled. The optic assembly is completely integrated into the LEONARDO® housing and no laser radiation will leak.

4.1.4 Potential equalization plug

An additional potential equalization conductor can be connected using the potential equalization plug on the rear of the device (chapter 3.1 [11]).

4.1.4.1 General information and advantages of equipotential bonding

The electrical voltage of a conductor or body to the ground is designated as "potential". The earth is electrically neutral and therefore has the potential of "zero". The unit of measure for potential is volts. A conductor or body has the potential "zero" (earth potential) when grounded. As a result of damage to the electrical insulation, electrical charge can be transmitted to metal parts that are within the circuit. This leads to the development of potentials between the metallic parts, which represents a danger to humans. If a human being contacts two different metal parts simultaneously, e.g. an electrical device and a water pipe, he acts as a conductor of existing potentials and electricity flows through his body. The flow of electrical current through the human body can be deadly. The potential equalization to the zero potential is a remedy for this. Therefore, the potential equalization as additional grounding must be considered (in addition to the normal grounding already included in the power lines) and improves the safety of medical devices and systems. Equipotential bonding has the added benefit of uniform voltage potential for all metal housings of medical devices and medical systems (e.g., Medical Lasers, EMG, ECG, Sono, etc.). Different voltage potentials on housings could lead to incorrect measurements during medical diagnosis, since the difference of the voltage potentials of the medical devices within a system would affect the voltage measurements (ECG, EMG, etc.) of the human body. Thus, the equipotential bonding for correct and valid measurements is vitally important.

4.1.4.2 Use and Instruction for equipotential bonding

All devices with additional equipotential conductors must be connected in a "star connection" to the equipotential bonding rail of the clinical room. First connect the potential equalization conductor to the earthing pin on the back of the laser device and than the mains plug with the mains voltage.

National legislation and safety regulations must be observed. In general these are as follows:

- The German Medical Devices Operator Ordinance (MPBetreibV)
- Medical electrical equipment – Part 1: General requirements for basic safety and essential performance EN60601-1
- Electrical installations in hospitals and locations for medical use outside hospitals: DIN VDE 0107

4.2 Laser STOP Options

Perform any of these actions to terminate laser emissions in the event of a real or perceived emergency:

1) Press the Laser STOP button.
2) Deactivate the footswitch by removing the foot.
3) Press the READY/STANDBY button to get into STANDBY mode.
4) Press the ON/OFF button for more than 2 seconds to shut down the device.

4.3 Working with the LEONARDO® laser system

4.3.1 Switching on the device

To switch on the device, use the switch on the rear of the device. The laser activates and enters standby mode. Now you can switch the device on and off by pressing the touch surface (biolitec® logo). During power-up the boot image and the first instructions appear on the start screen. After initialization, the login screen for entering the user code pops up. This user code must be entered everytime the device is switched on.

Attention: The LEONARDO® laser generates a sound level of ca. 75 dB(A) for a few seconds during the power-up phase and can generate similar sound level during the operation.

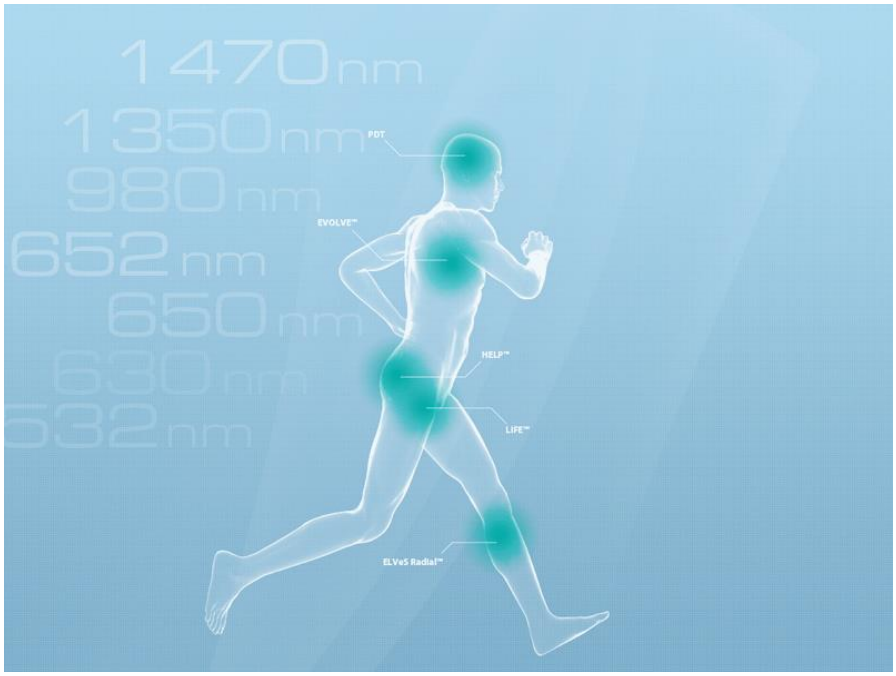


Figure 7: Start screen

4.3.2 Key control screen with password (PIN)

The LEONARDO® is secured by key control via password (standard PIN: 1234) against unauthorized usage for the protection of the patient, the laser operator and other persons present. The PIN is entered by using the numeric keypad. By pressing OK the code is being submitted and the device switches automatically into STANDBY mode. The code will be provided upon delivery of the laser and the related introduction by a service assistant or by personnel authorized by *CeramOptec*. For further information contact *CeramOptec* and refer to the software version in the left corner on top of the key control screen.

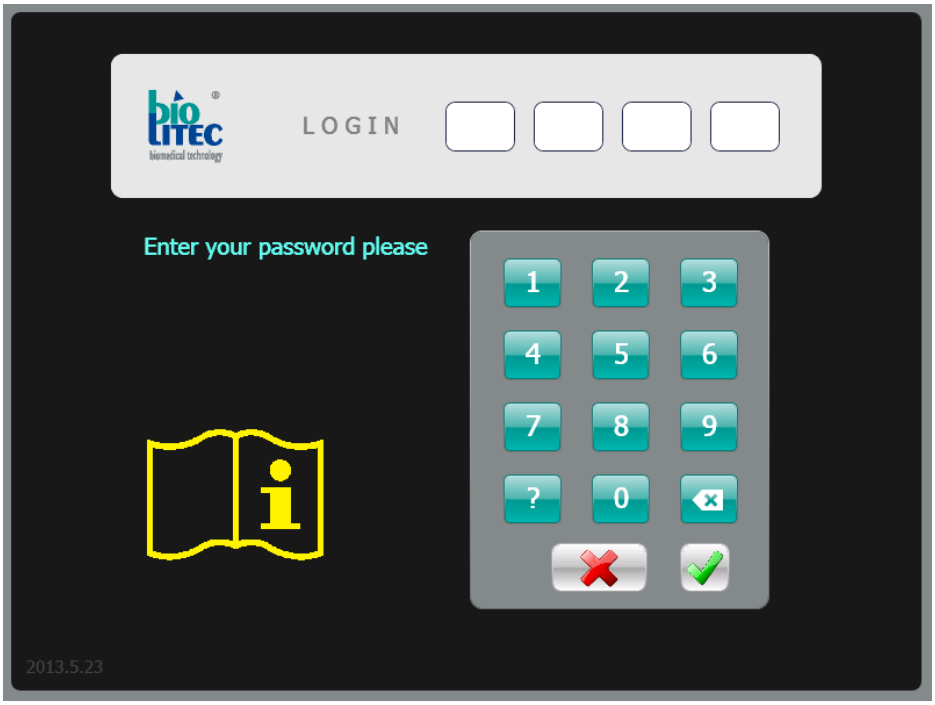


Figure 8: Login screen

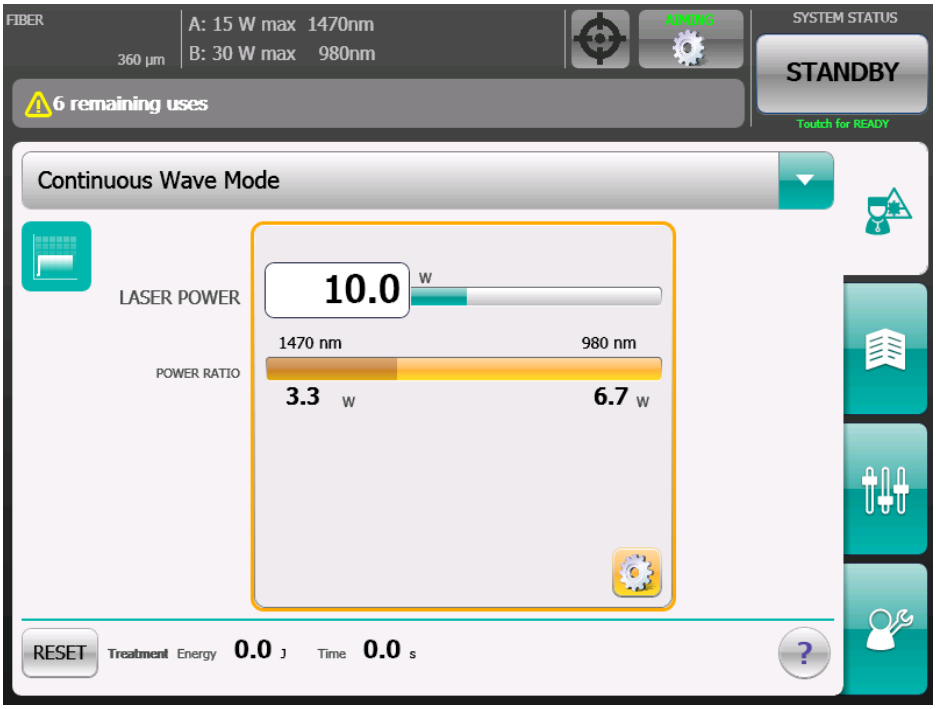


Figure 9: Display Screen for CW mode (dual-wavelength devices)

4.3.3 Setting language

The language the user would like can be selected by pressing the respective language button. This setting can be saved by tapping the save button on the control panel.

Figure 10: Menu item: language setting

4.3.4 Configuring the aiming beam

The aiming beam follows the same path as the therapeutic beam, so it also shows which area is receiving therapeutic radiation.

The device starts with the aiming beam switched off. You have to press the PILOT button  to switch on the aiming beam. The screen will then display whether the aiming beam is switched on and what color it is.
The color of the aiming beam can be selected using the PILOT box in the top bar.

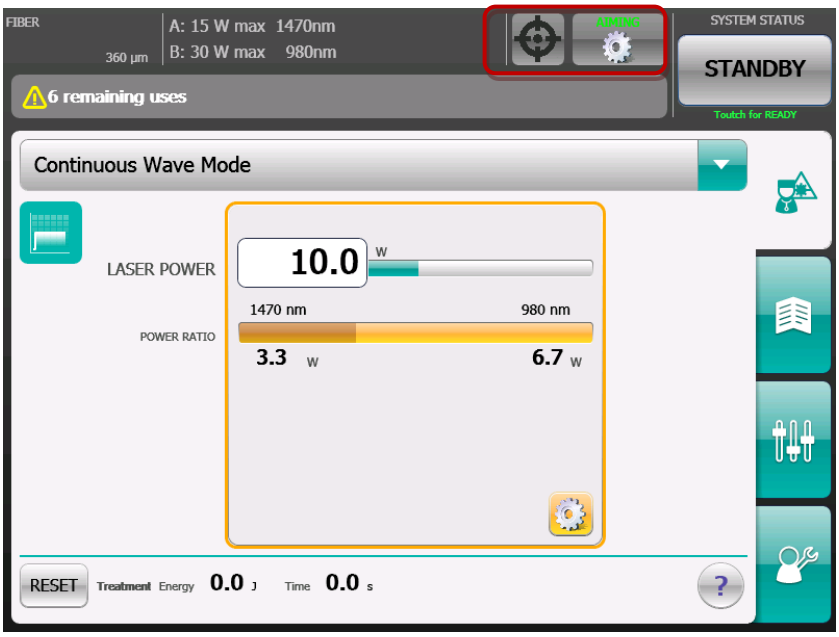


Figure 11: Menu item: setting the aiming beam

You can configure a number of different settings for the aiming beam (see illustration 15). There are options for a continuously active aiming beam and a flashing aiming beam, or it can be deactivated. Moreover, it is possible to interrupt the aiming beam as soon as the therapeutic beam is active. To change the intensity of the aiming beam, move the green bar or press the -/+ button. A numeric display also indicates the selected intensity. The operation panel can be used to set the aiming beam to green or red.

Figure 12: Aiming beam setting by using the PILOT box

4.3.5 Treatment

4.3.5.1 Configuring the laser output

You can configure the laser output in all treatment modes individually. The setting of the laser output for devices that emit a single wavelength can be configured by tapping the white operation panel during application (method 1). The laser output of devices that emit two wavelengths can be configured by method 1 (constant ratio between power of wavelength 1 and wavelength 2) or method 2 (laser powers for both wavelengths can be changed independently of each other).

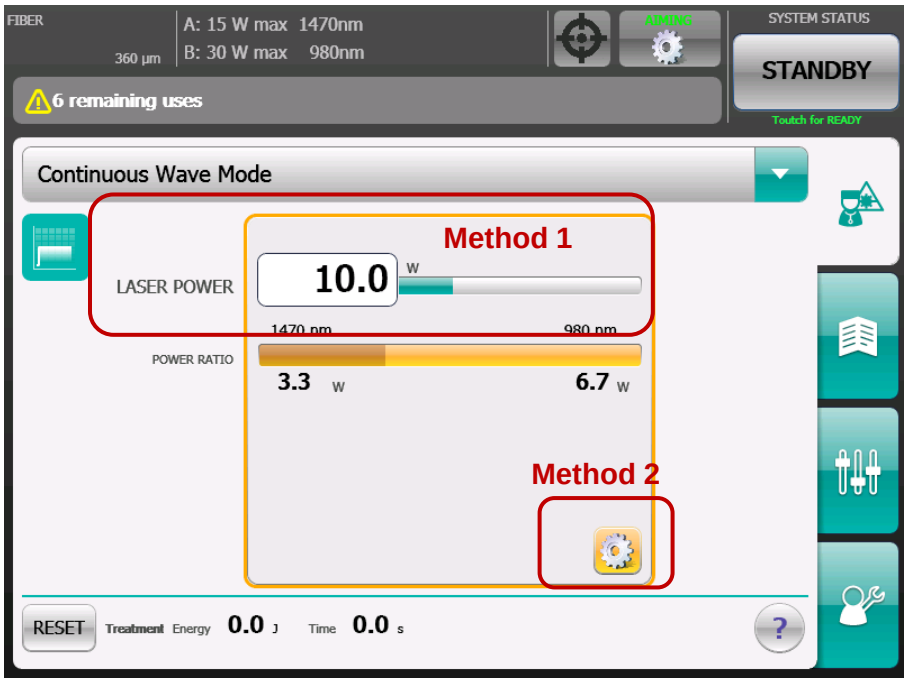


Figure 13: Setting the laser output for a dual-wavelength device

Figure 14: Setting the laser output for a single-wavelength device

Method 1: The setting of the laser output can be configured by tapping the white operation panel for laser power. To increase the power level currently set, move the bar to the right. To decrease the power level, move the bar to the left.

Alternatively, the and buttons can be used.

In devices that emit two wavelengths, laser output can be adjusted simultaneously for both wavelengths with a constant mixing ratio between the laser power output of the two wavelengths (Figure 15).

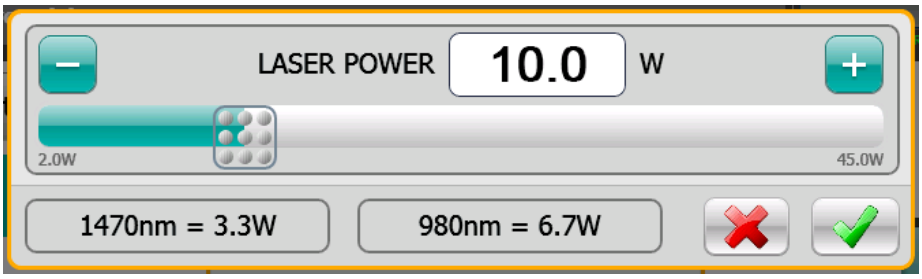


Figure 15: Setting the laser output for devices that emit one or two wavelengths

Method 2: In devices that emit two wavelengths, laser power output can be set separately for each wavelength by using the pencil field. If 2D Power Control™ is NOT enabled, a window with 4 scroll bars will pop up (Figure 16). In this window, the total output, the combined factor or the output for each wavelength can be set separately, either by moving the scroll bars or by pressing the or buttons.

Figure 16: Laser power setting for dual wavelength without 2D Power Control™

If 2D Power Control™ is enabled, two different therapy lasers can be set by using this function. The therapy laser at a wavelength of 1470nm is controlled on the horizontal axis and the therapy laser at a wavelength of 980nm or 1064nm is controlled on the vertical axis.

Figure 17: Method 2: Setting the laser power using 2D Power Control™

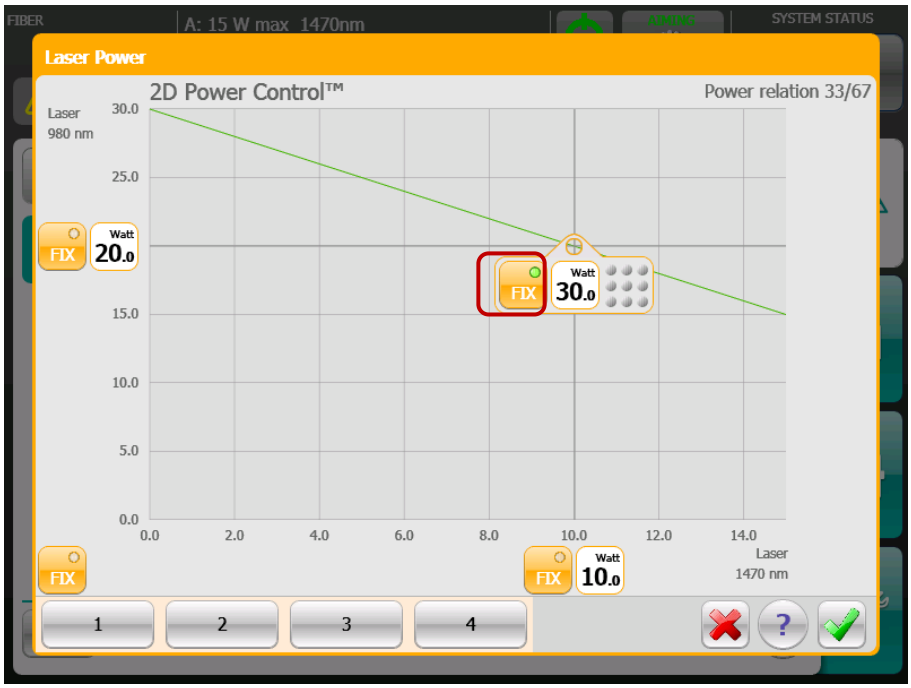


Figure 18: Setting output with constant total laser power output

By pressing the FIX field next to the guide surface, a green guide line pops up that helps you to adjust the mixing ratio between the two wavelengths while the total output is held constant.

Figure 19: Setting the output with constant relation between two wavelengths

By pressing the FIX field at the bottom left of the window, a green guideline pops up that helps you to adjust the total output of the laser.

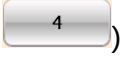
You can also fix the output of the laser for one wavelength on the respective axis while the output for the other wavelength remains adjustable.

Figure 20: Fixing the power for the wavelength 1470 nm on the horizontal

Figure 21: Fixing the power for the wavelength 980nm/1064nm on the vertical axis

2D Power Control™ also makes it possible for you to save four different power settings.

Figure 22: Saving four power settings

For power settings that have been saved, just press one of the four buttons in the lower part of the screen to retrieve the setting (e.g. 

).

To save a power setting, first make the selection using the control panel. Keeping one of the four save buttons for longer than 1 second stores the setting.
This opens another pop-up window for naming the button. The button needs to be pushed briefly so that a blank (_____) appears. Then you can use the screen keypad to enter and confirm any name you wish to give the setting.
Note: The previously selected power setting will appear below the button (the power for the 1470nm wavelength on the left and the power for the 980nm wavelength on the right).

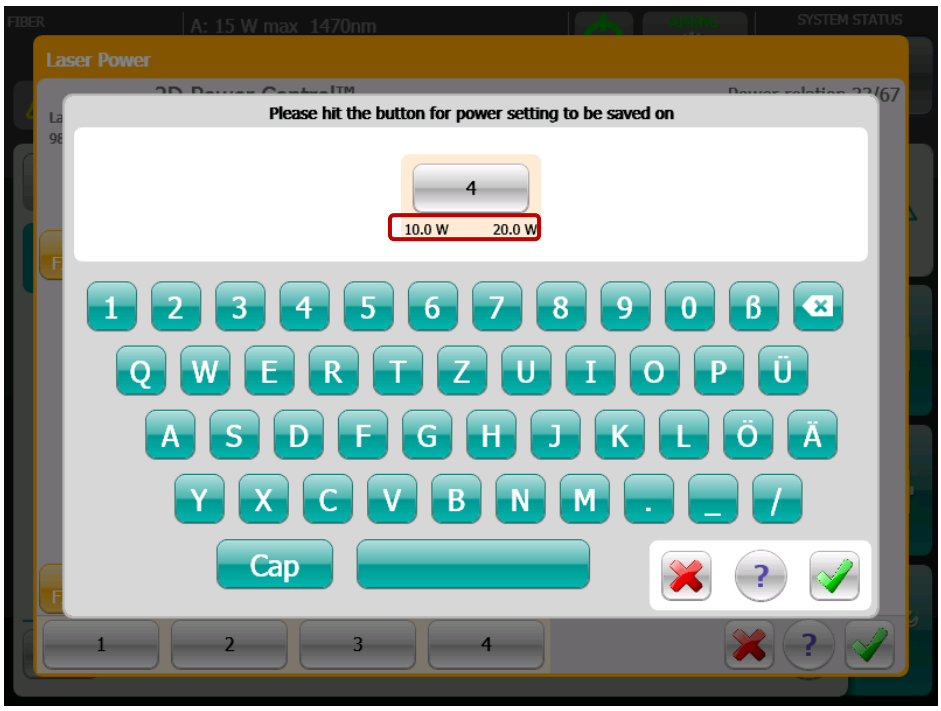


Figure 23: Pop-up window for saving the power setting

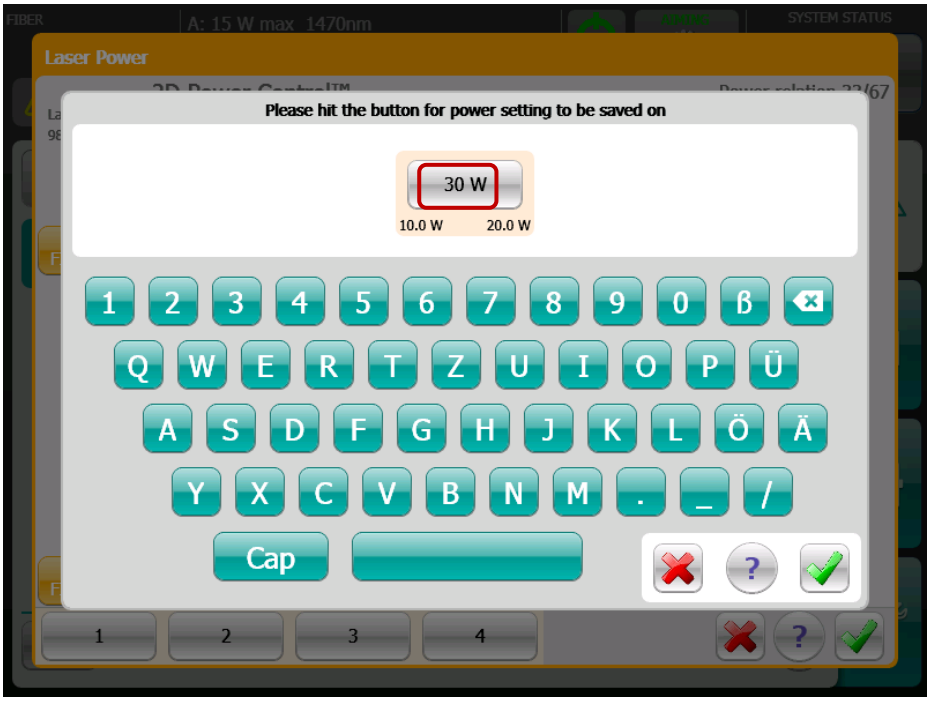


Figure 24: New name for the button

Tapping the button in the lower right of the screen saves the settings. Use the button to close the menu without saving any changes.

4.3.6 Select a treatment mode

Press the treatment mode field to select a treatment mode. All available modes will appear on the screen so that one can be selected.

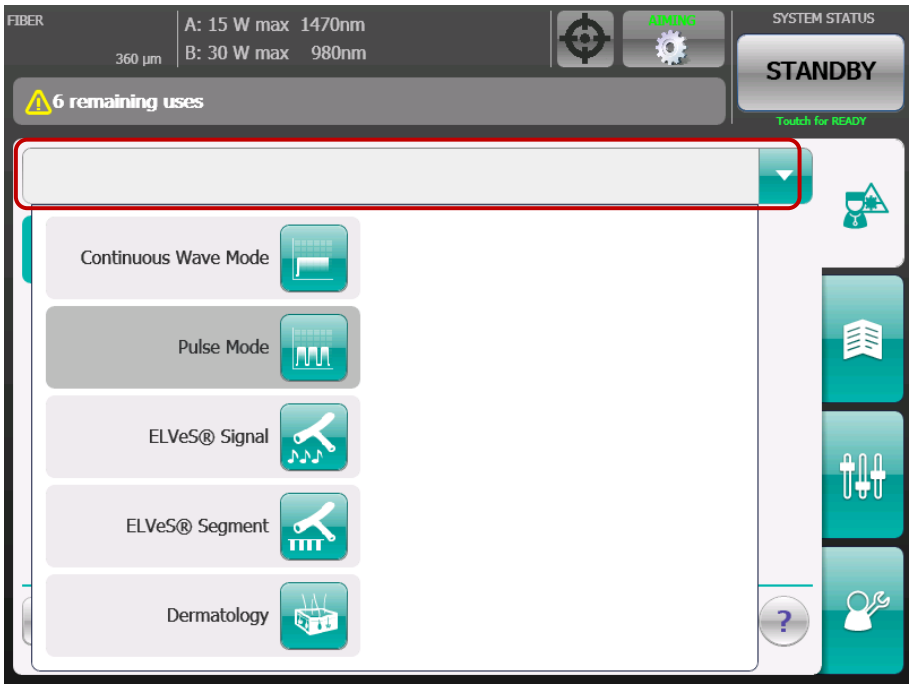


Figure 25: Selecting a treatment mode on the touchscreen

4.3.7 Description of the treatment modes

All LEONARDO® lasers can be operated in two basic modes, Continuous (Continuous Wave CW) or Pulse mode as well as in the conducted treatment modes ELVeS signal, ELVeS segment and Derma mode.

In CW mode, the laser continuously emits radiation at the selected power level as long as the footswitch is pressed.

In Pulse mode, the laser emits radiation at the selected power level with the specified number of pulses and pulse format (pulse duration/pulse pause) as long as the footswitch is pressed.

- Defined number of pulses → between 1 and max. 99 pulses (depending on configuration)
- A continuous series of pulses as long as the footswitch is pressed

This pulse procedure is repeated as long as the footswitch is pressed or until the defined number of pulses is reached. If the footswitch interrupts a pulse or a pulse pause, the entire pulse procedure is repeated when the footswitch is pressed again.

The ELVeS signal mode is derived from the continuous mode. The device indicates the energy applied from the fiber to the vein via auditory signals.

The ELVeS segment mode is derived from the continuous mode and has an additional visual support for the user during vein treatment.

The Derma mode for dermatology is derived from the pulse mode. Here, the laser sets the required laser output for the selected power density in relation to the selected handpiece.

4.3.7.1 Continuous mode CW

The laser starts in the last saved mode. The mode can be changed when the laser is in standby by pressing the treatment mode button on the screen. The laser shows CW mode here. In standby mode, you can change the settings of the laser. No radiation can be emitted in standby mode, even by pressing the footswitch.

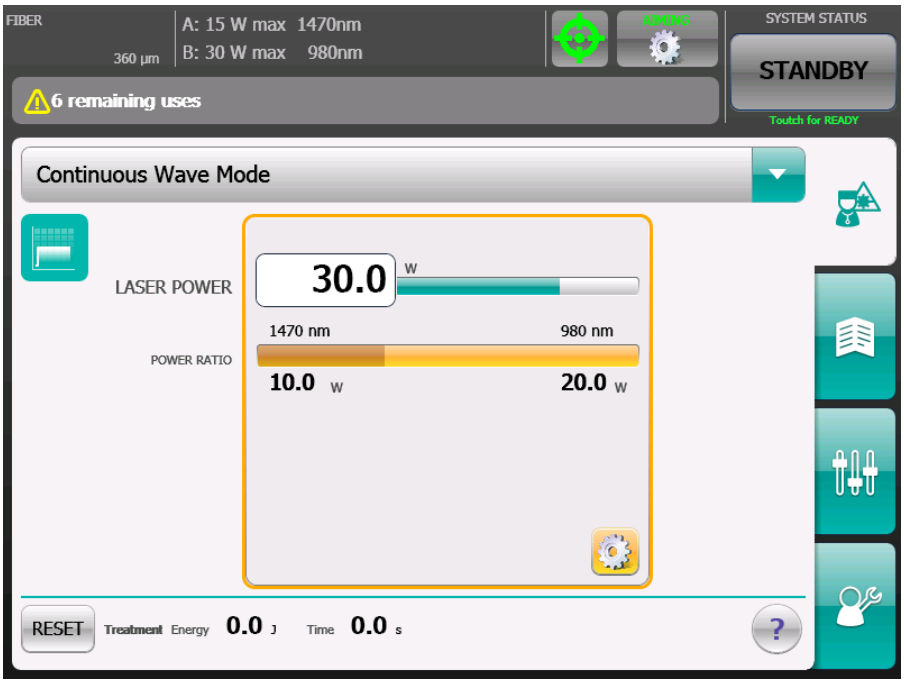


Figure 26: Screen display of CW mode in standby (DUAL wavelengths)

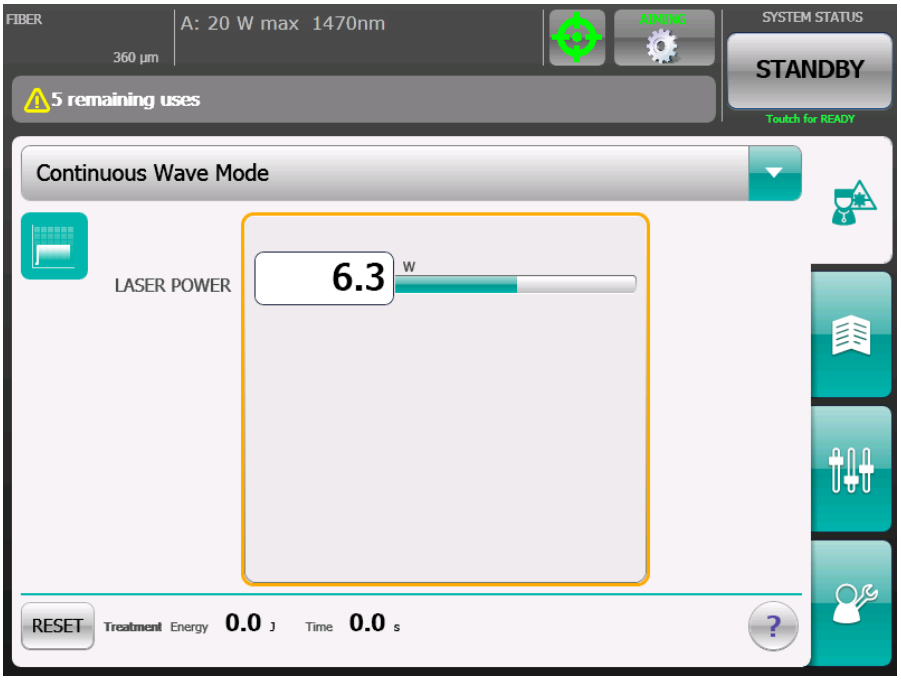


Figure 27: Screen display of Continuous mode CW (Single wavelength)

Laser power can be set in continuous mode as shown in Figure 26 and Figure 27. As soon as you have changed all settings (operating mode, power, aiming beam), you can enable the laser unit for laser emission by tapping the "Standby" button in the upper right corner of the screen and putting it into "Ready" mode.

When the "Standby" button is activated, the laser is put into the preparation phase for about 3 seconds. After that, the laser is ready for emission.

The laser is now active and the laser hazard area must be secured. The yellow LED next to the display flashes and the message "Press Footswitch to Fire Laser" appears in the screen footer.

When the unit is in "Ready" mode, pressing the footswitch causes the application fiber to emit laser light. The laser emits a continuous beep and the LED next to the screen remains lit during the entire laser emission.

When the unit is enabled in continuous mode, laser light is emitted using the connected application fiber as long as the footswitch is pressed. You can discontinue laser emission by simply releasing the footswitch. As long as the laser unit is in "Ready" mode, the laser can be activated repeatedly.

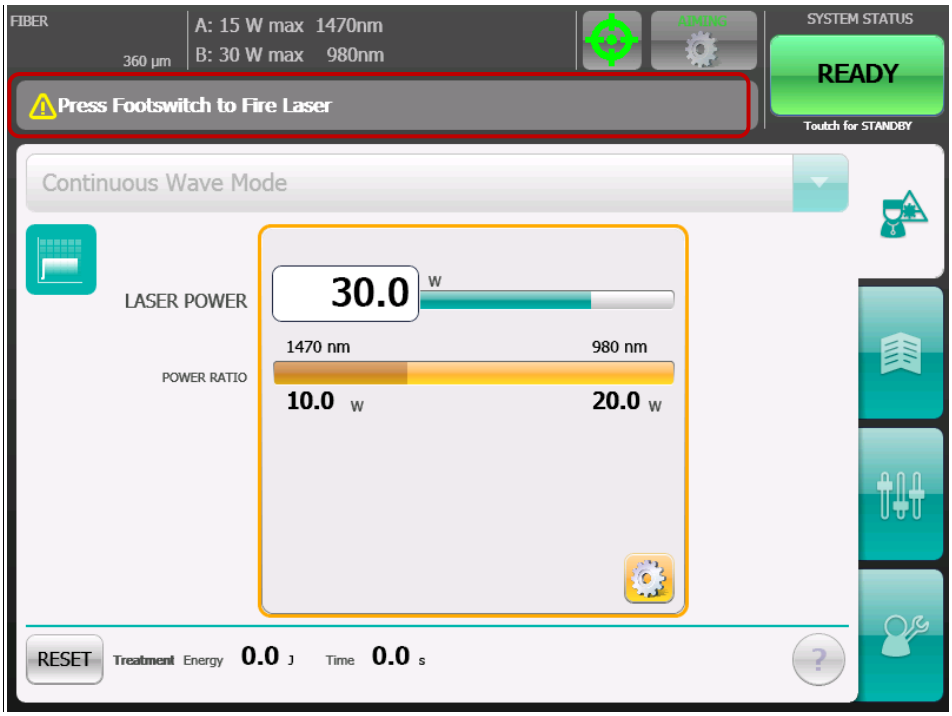


Figure 28: Display of laser ready for emission

During laser emission, the message "LASER FIRING" appears on the screen. The treatment time and the emitted treatment energy are simultaneously added up and displayed. The treatment time and treatment energy can be reset when the laser is enabled or when it is in standby mode.

You can use the "Ready" button in the upper right of the screen to switch to secure standby at any time. You should always switch to standby after a treatment is completed or when temporarily putting down the application fiber.

You can stop laser emission at any time by

- **releasing the footswitch**
- **pressing the "LASER STOP" button**
- **pressing the "Standby" button**

Laser emission can also be interrupted (usually unintentionally) by safety circuits. During normal use, these circuits should **not** be triggered intentionally to switch off laser emission:

- by opening the door in the case of a connected door interlock
- by disconnecting the application fibers

In these cases, laser emission stops immediately, the audible signal stops and the laser emission symbol is turned off. The laser unit switches to secure standby. Messages indicating the reason for shutdown appear on the screen.

Continuous mode:

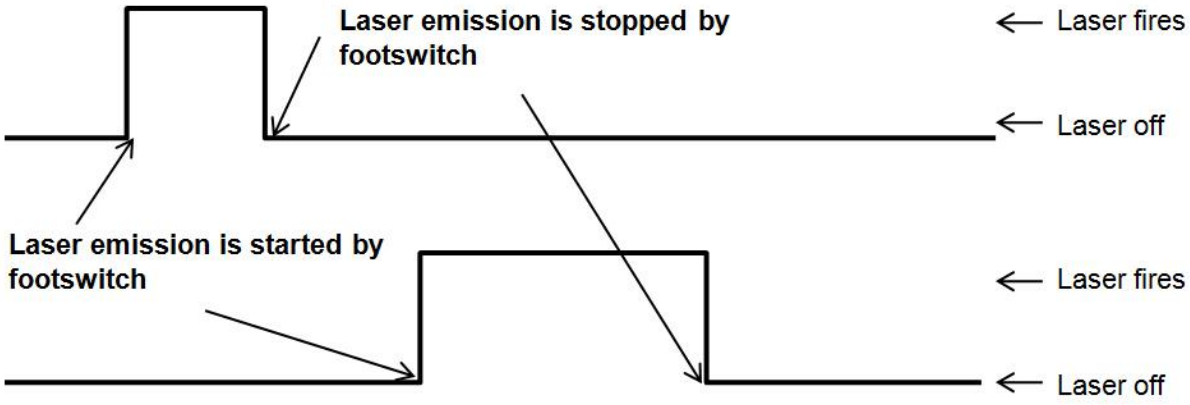


Figure 29: Examples for continuous mode

4.3.7.2 Pulse Mode

The laser starts in the last saved mode. The mode can be changed when the laser is in standby by pressing the treatment mode button on the screen. Now you can select the pulse mode.

Figure 30: Screen display of Pulse mode (DUAL wavelength)

Figure 31: Screen display of Pulse mode (Single wavelength)

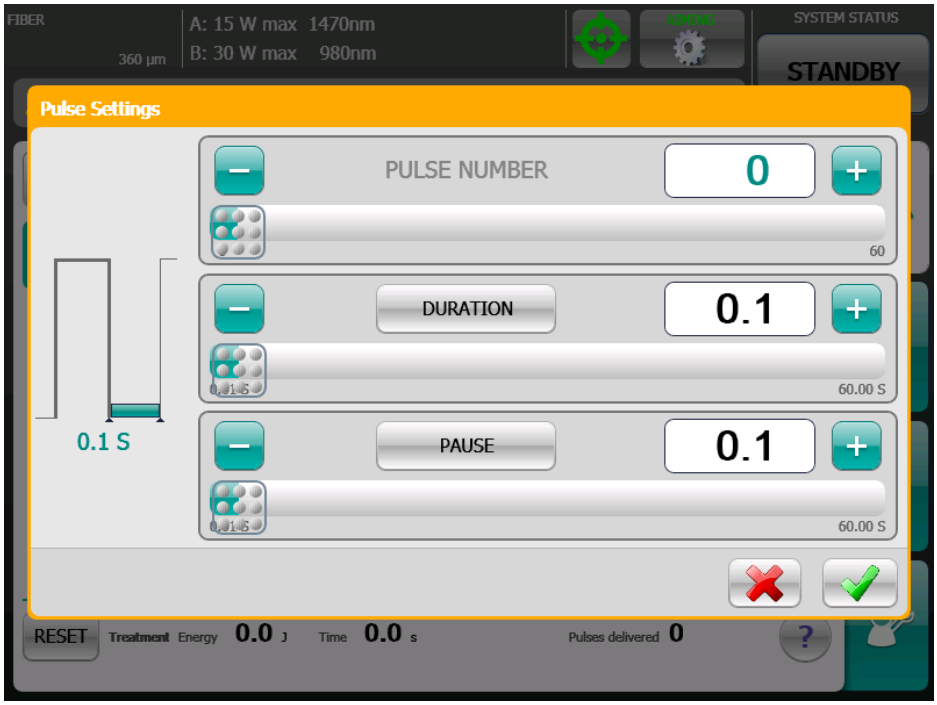


Figure 32: Screen display of Pulse mode, parameter settings

The settings for Pulse mode can be set on the display (as described on the following page). The intervals are displayed graphically on the left.

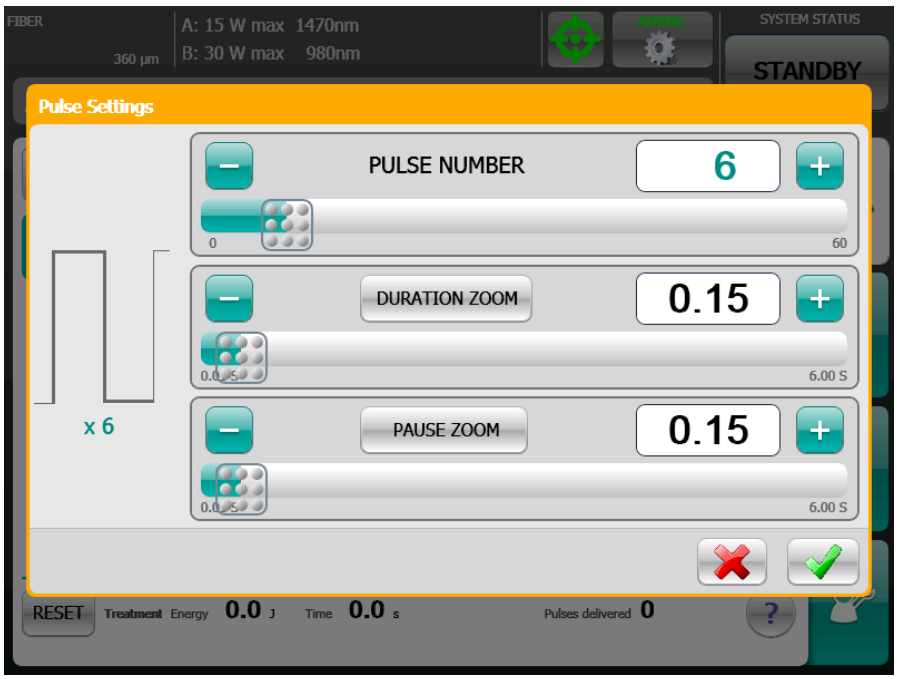


Figure 33: Pulse duration zoom settings

For fine adjustments of the pulse duration and the pulse pause, there is a zoom function for precisely adjusting single segments.

In pulse mode, you can set the following parameters by touching the appropriate bar on the screen:

Pulse *repetition* (Number of pulses)	Pulse *duration* (Pulse length max value configurable by service assistant)	Pulse *pause* (Interval between pulses max value configurable by service assistant)
1 – 99 pulses (depending on configuration)	0.01 – 60.0 s	0.01 – 60.0 s
Continuous series of pulses as long as the footswitch is pressed	0.01 – 60.0 s	0.01 – 60.0 s

To change the currently selected settings, touch the relevant field and move the green bar or press the and buttons.
To increase the set values (power, pulse duration, pulse pause, number of pulses), move the bar to the right or press the button. If the values are to be decreased, move the bar to the left or press the button.
Once you have set the desired pulse format, the setting can be saved via the OK field.
In PULSE MODE, the laser emits radiation at the selected power level with the specified number of pulses and pulse format (pulse duration, pulse pause) as long as the footswitch is pressed.

- Defined number of pulses → between 1 and max. 99 pulses can be selected
- A continuous series of pulses as long as the footswitch is pressed

This pulse procedure is repeated as long as the footswitch is pressed or until the defined number of pulses is reached. If the footswitch interrupts a pulse or a pulse pause, the entire pulse procedure is repeated when the footswitch is pressed again.

Single-pulse Mode:

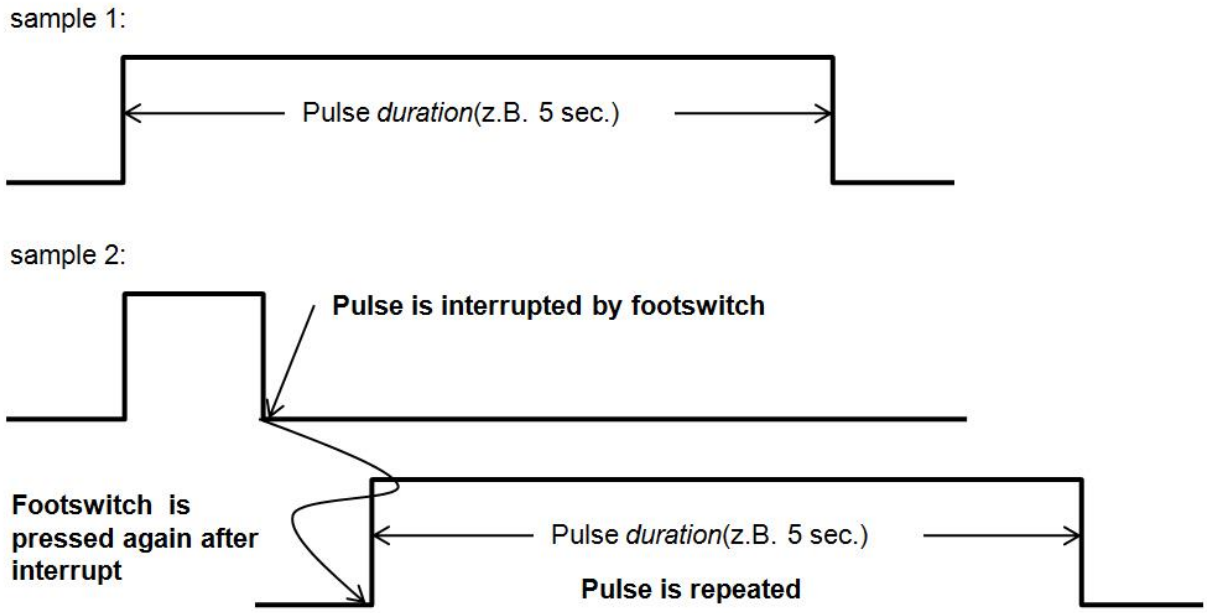


Figure 34: Single-pulse mode

Multi-pulse Mode (≥ 2 pulses):

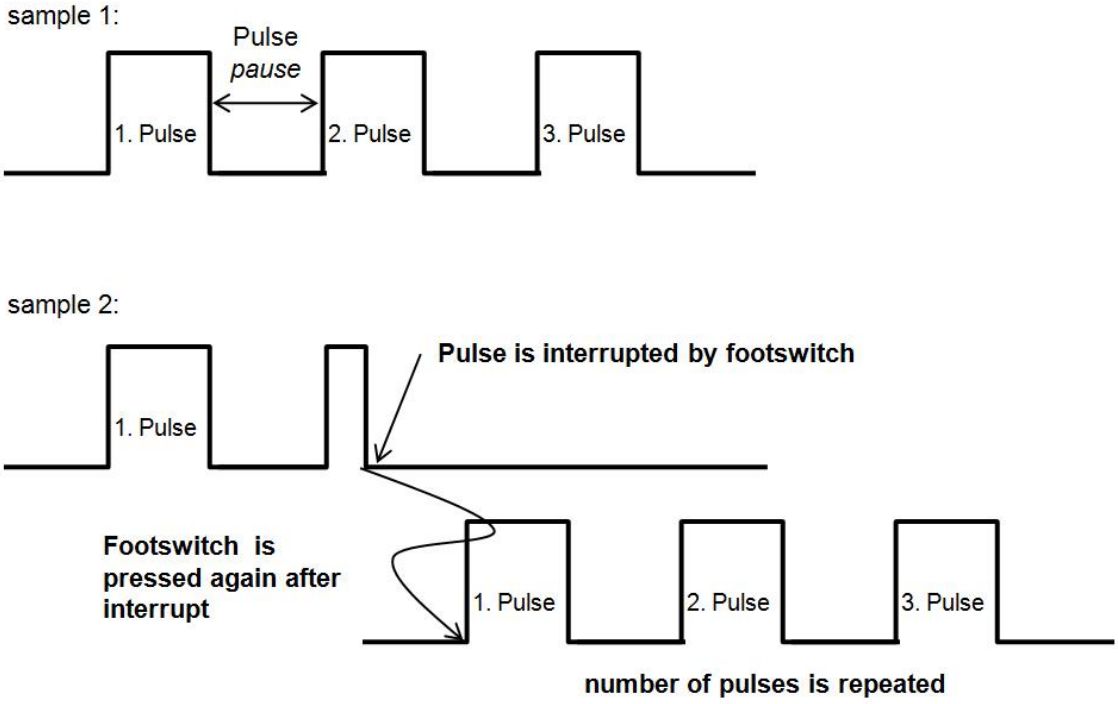


Figure 35: Multi Pulse mode

4.3.7.3 ELVeS® segment mode

ELVeS® segment mode is a continuous mode with additional acoustical and visual support for the user. To enable targeted treatment of individual vein sections, you configure the power settings for a specific vein length on the laser device. During treatment, a progress bar on the display indicates how much energy in joule per cm has been emitted by the laser in accordance with the settings for the selected vein segment.

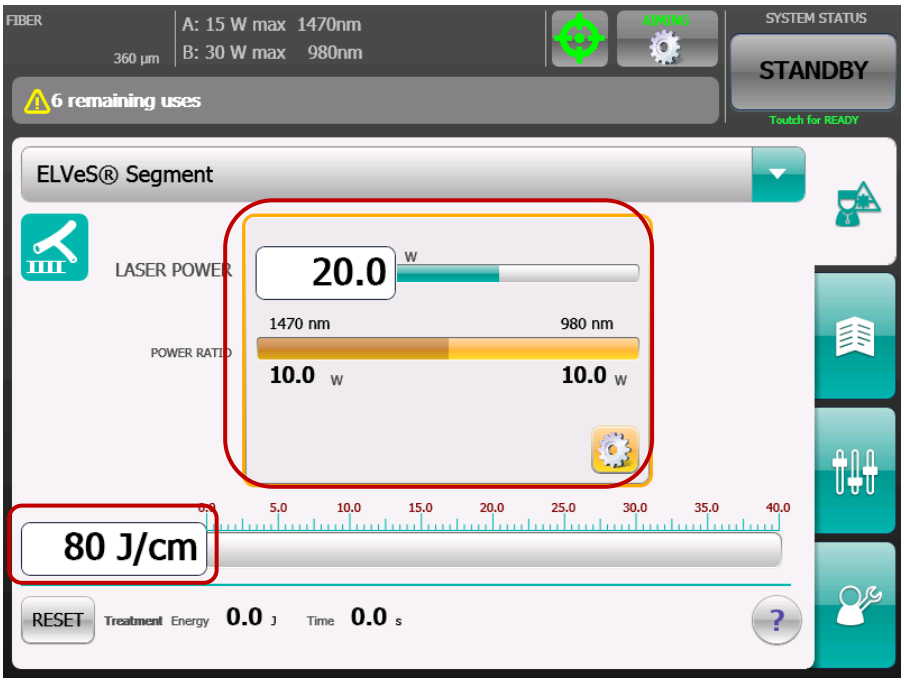


Figure 36: Screen display of ELVeS® segment mode for setting (DUAL wavelengths)

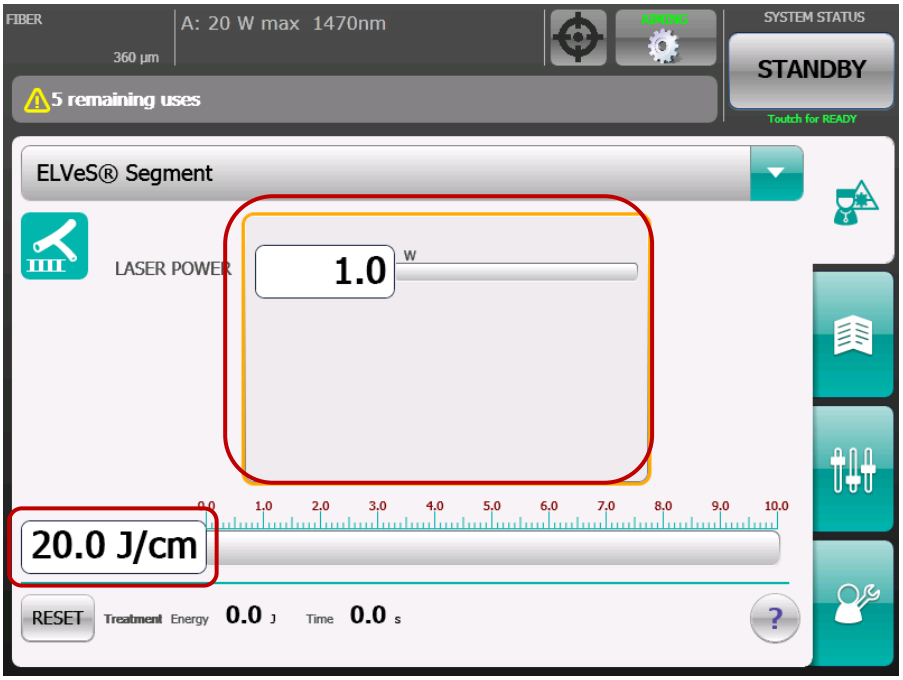


Figure 37: Screen display of ELVeS® segment mode for setting (Single wavelength)

In the upper screen section of the ELVeS® segment mode, the laser output can be defined. In the bottom section, pressing the white field opens a new window where the following parameters must be configured:

- **Vein length:** Select the length (in cm) of the vein segment that is to be treated (0 cm – 100 cm)
- **Energy/length:** Select how much energy (in joules) is to be emitted per cm

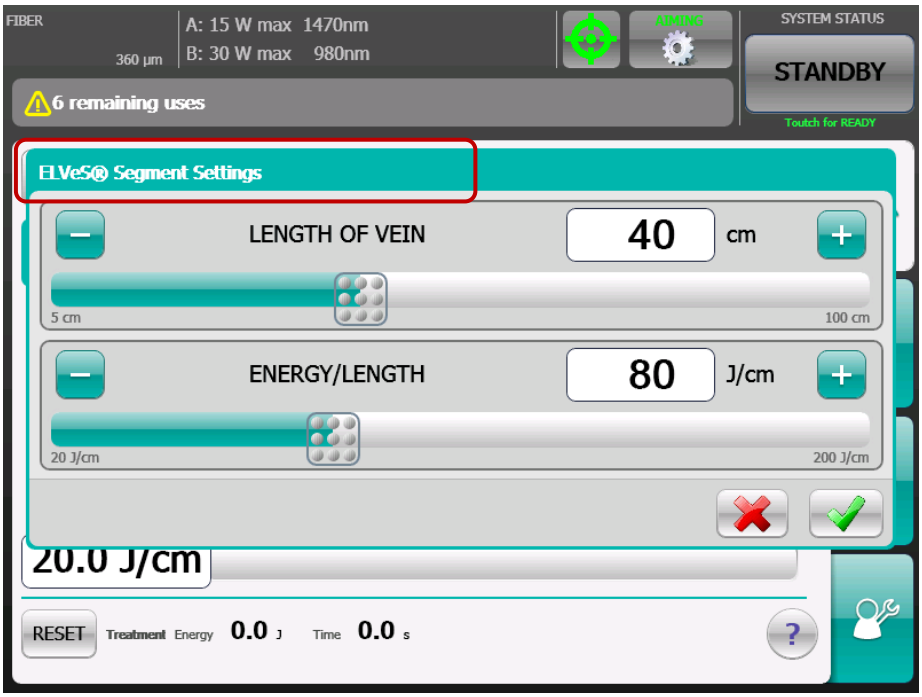


Figure 38: Setting the parameters in ELVeS® segment mode

To change the parameters, tap the  or  buttons or move the green bar. LEONARDO® then automatically calculates the length of the vein segment in proportion to the selected quantity of energy and displays it as a progress bar.

Once you have checked all parameters again, you can enable the laser unit for laser emission by tapping the "STANDBY" button in the upper right of the screen. When the "Ready" button is activated, the laser switches to the preparation stage. This is indicated by PREPARATION lighting up in the top right next to SYSTEM STATUS. The laser emits a continuous beep.

The laser is now active and the laser hazard area must be secured. The yellow LED next to the display flashes and the message "Press Footswitch to Fire Laser" appears in the screen header.

When the unit is enabled, pressing the footswitch causes the application fiber to emit laser light. The laser emits a continuous beep and the LED next to the screen remains lit during the entire laser emission.

When the unit is in "Ready" mode in the ELVeS® segment mode, laser light is emitted using the connected application fiber as long as the footswitch is pressed. You can discontinue laser emission by simply releasing the footswitch. As long as the laser unit is enabled, the laser can be activated repeatedly.

During laser emission, the message "LASER FIRING" appears on the screen. The treatment time and the emitted treatment energy are simultaneously added up and displayed on the progress bar.

Example: You want to emit treatment energy of 80 J per 1 cm of vein when treating a vein that is 50 cm long. You configure the vein length and the quantity of energy on the ELVeS® segment setting screen. Based on the selected energy per unit of length and the actually emitted treatment energy, the LEONARDO® automatically calculates the relevant vein segment length and indicates it on the progress bar.

Caution: Note that the actual energy per vein length emitted in this mode is still determined by the user. The laser unit only displays the target values as a guide to optimal and homogeneous energy

emission. This can be considered a theoretical (target) value and can be used for the purpose of comparing target and actual values.
The progress bar only provides a theoretical value indicating how much distance the user should have covered to maximize the homogeneity of the energy emitted within the vein. It never measures whether the fiber is moved or how far it is moved.
The user is personally responsible for comparing and reconciling the actual traction speed and distance covered by the laser within the vein with the parameters calculated by the device and indicated on the progress bar!

4.3.7.4 ELVeS® signal mode

ELVeS® signal mode is a continuous mode with additional visual and auditory support for the user.
In ELVeS® signal mode, you can configure an energy interval (of between 20 J and 200 J) in addition to the laser power. During treatment, a beep is sounded to indicate that the configured energy interval has been reached. This provides an auditory signal to the user indicating how much energy has already been emitted in the vein.

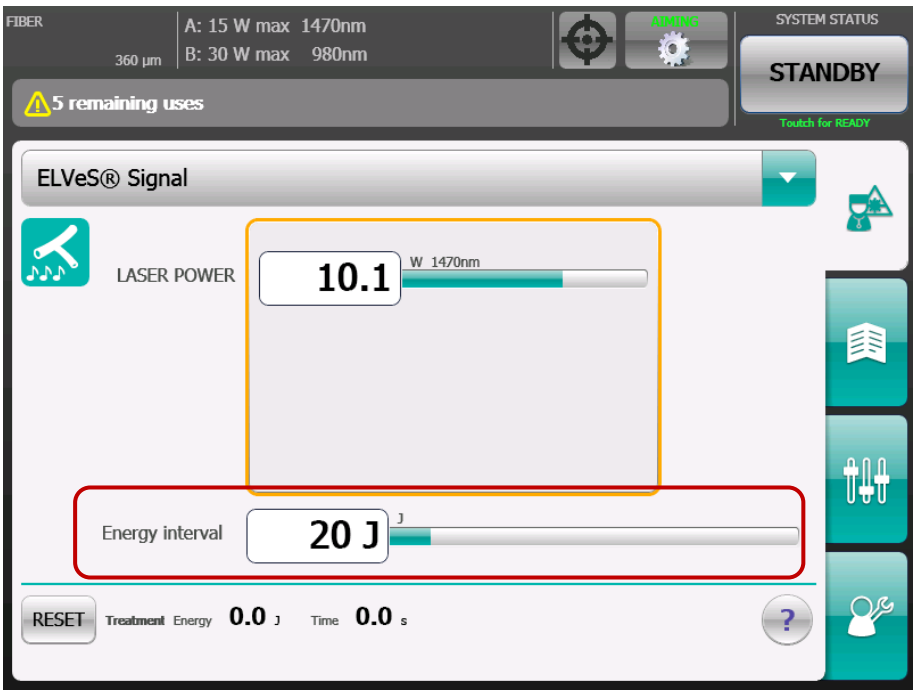


Figure 39: Setting the parameters in ELVeS® signal mode

The laser output can be configured in the top section of the screen by tapping the white operation panel.
Tapping the white field next to the energy interval opens another window where you can define the energy interval by moving the green bar or pressing the − or + button. When the OK button is pressed, the settings are accepted.

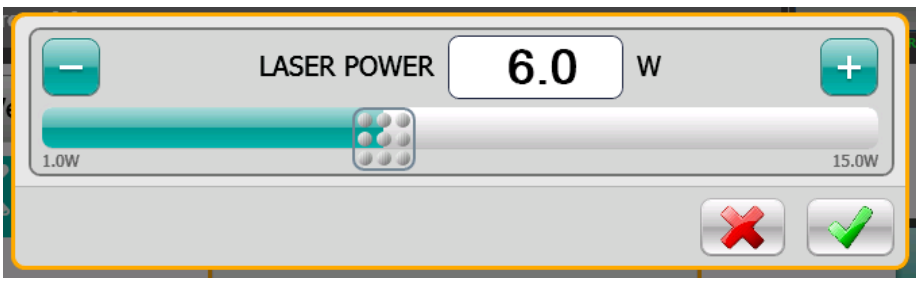


Figure 40: Setting laser power

Figure 41: Defining the energy interval

Example: You want to emit 140 J for each 1 cm of vein to be treated. You configure an energy interval of 140 J and also define the required laser power. During treatment, a beep sounds each time 140 J of treatment energy has been emitted. For example, you will hear a beep after 140 J, 280 J, 420 J, 560 J etc. If you have set power at, say, 10 W, the beep sounds every 14 seconds and you would have to have moved the laser 1 cm along the vein by the time each beep occurs in order to achieve the target energy density of 140 J/cm.

The total treatment energy emitted is calculated independently and displayed on the screen.

Once you have checked all parameters again, you can enable the laser unit for laser emission by tapping the "Ready" button in the upper right of the screen.

When the "Ready" button is activated, the laser switches to the preparation stage. This is indicated by PREPARATION lighting up in the top right next to SYSTEM STATUS. The laser emits a continuous beep.

The laser is now active and the laser hazard area must be secured. The yellow LED next to the display flashes and the message "Press Footswitch to Fire Laser" appears in the screen footer.

When the unit is enabled, pressing the footswitch causes the application fiber to emit laser light. The laser emits a continuous beep and the LED next to the screen remains lit during the entire laser emission.

When the unit is in "Ready" mode in the ELVeS® signal mode, laser light is emitted using the connected application fiber as long as the footswitch is pressed. You can discontinue laser emission by simply releasing the footswitch. As long as the laser unit is enabled, the laser can be activated repeatedly.

During laser emission, the message "LASER FIRING" appears on the screen. The treatment time and the emitted treatment energy are simultaneously added up and displayed on the progress bar.

Warning: Please note that the actual energy per vein length emitted in this mode is still determined by the user. The laser unit only displays the target values as a guide to optimal and homogeneous energy emission.

The user is responsible for comparing these values with the actual emitted energy and distance covered by the fiber within the vein!

Attention: In this mode, NO beep is heard during laser emission (in contrast to the other modes). An auditory signal is heard only when the energy interval is reached.

4.3.7.5 Derma mode (for LEONARDO® Dual 45, LEONARDO® Dual 100)

Derma mode is used in combination with handpieces for dermatological applications. Depending on the handpiece used (laser beam diameters on the skin may be 0.6 mm, 1.0 mm or 1.5 mm), the laser device automatically calculates part of the parameter configuration based on the energy density set (see Figure 43: Setting parameters for Derma mode).

Caution: Note that laser produced skin vaporisation / smoke could contain viable particles.

Caution: Note that the safe distance, i.e. the NOHD (Nominal Ocular Hazard Distance), depends on the handpiece selected. This distance is specified in the table below:

Table1: Overview of NOHD (Nominal Ocular Hazard Distance)

Handpiece for a beam diameter of	LEONARDO® Dual 45	LEONARDO® Dual100
	30W @ 980nm	85W @ 980nm
0.6mm	2.60 m	4.30 m
1.0mm	4.30 m	7.20 m
1.5mm	6.40 m	11.00 m

Select the energy density and the applied handpiece by tapping the respective pencil fields (gearwheel). All values can be selected by moving the green bar or pressing the − or + buttons.
If you then change the pulse duration or pulse pause, the laser automatically sets all additional parameters – in relation to the setted enery density and choosed handpiece (within the available range of values).

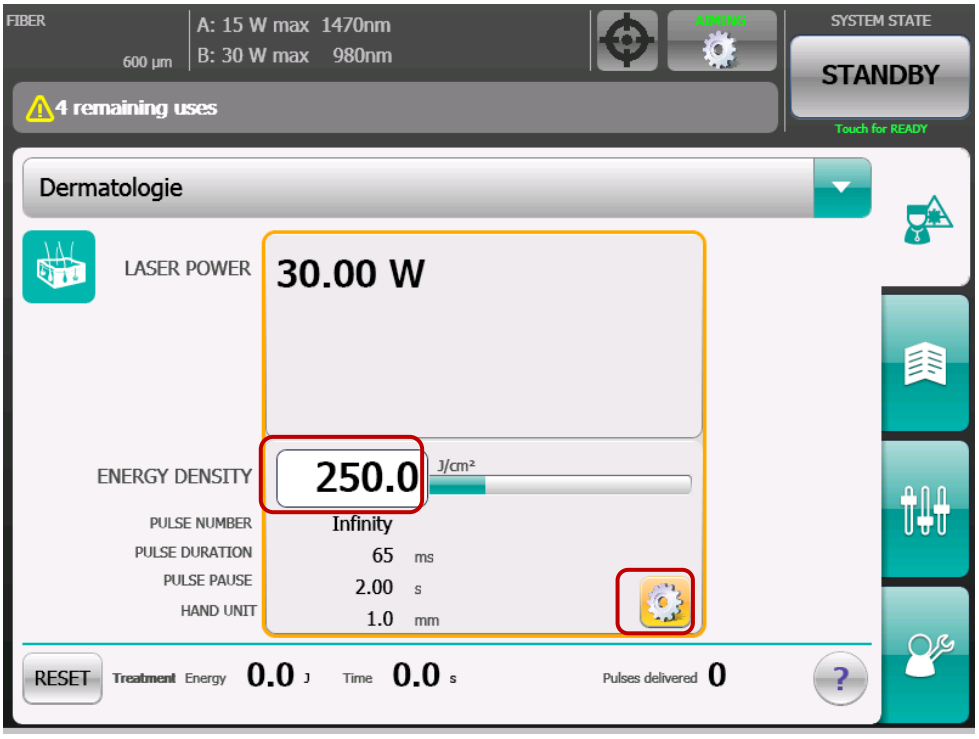


Figure 42: Screen display of Derma mode

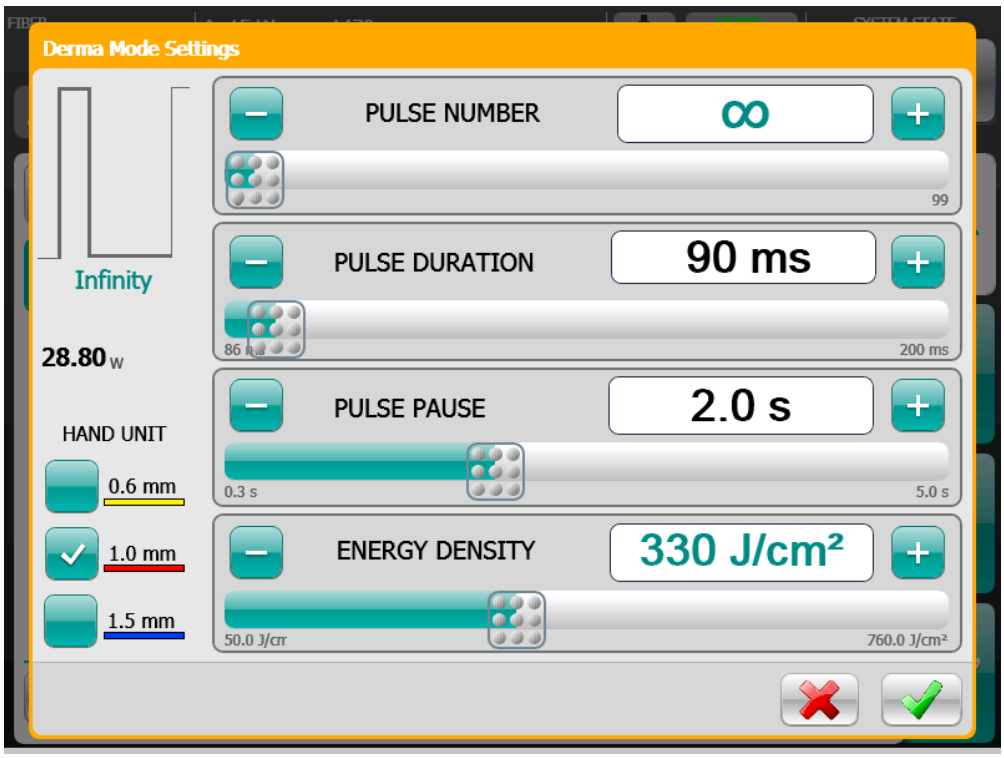


Figure 43: Setting parameters for Derma mode

4.3.8 Switching off the laser system

You can switch off the laser via the touch switch with the biolitec® logo in the front left. The last used mode is saved and is used the next time the system is started. Via the touch switch you can switch the laser on again and open the entry field for the user code.
With the switch on the rear of the device, you can cut off the power supply entirely.

4.4 Messages and possible causes

- In case the message "door interlock error" appears on the screen, the respective plug on the rear of the device is not in use. Please read the section on installation of the door interlock (see also section 4.1.2).
- In the case that no application fiber is connected to the laser output of the device, the message "No fiber connected" is displayed. In this case, connect an appropriate fiber.
- In the case that the message "Not a valid biolitec® fiber" appears on the screen, the intern, automatic fiber identification system has identified the connected application fiber as inappropriate (see section 0). Unconnect the fiber and then try reconnecting it. If the message appears again, even though it is an appropriate *CeramOptec* fiber, please contact our service department and use another application fiber in the meantime. In case the message appears for every application fiber, please also contact our service department.
- For the increased patient safety, our single-use products are shipped with a limited service life, which starts the first time the laser is switched to enable mode. After use, the device will automatically enter standby mode and a message will appear with information on the remaining service life. To continue the treatment, switch into enable mode. The device will inform you again about the exact remaining life of the fiber at a later time.

Table 2: Troubleshooting Table (Overview of Messages and possible causes)

Message/ Display	Possible causes	Suggested action
Black display	Power supply interrupted Plug not connected to the main power	Check the power connection. Check the fuse.
Black display	Laser is not switched on	Touch switch with the biolitec® logo.
Black display	Other reasons	Servicing required
Laser stop button	Laser stop button was pressed	Confirm by pressing OK.
Door interlock error	Door interlock not connected	Connect door interlock again, paying attention to the red markings.
Door interlock error	Error in door interlock system	Check and repair door interlock system, see section 4.1.2.
Door interlock error	Loose blanking plug	Connect blanking plug again, paying attention to the red markings.
Door interlock error	Faulty blanking plug	Replace blanking plug (obtain from service department).
Temperature out of tolerance	Temporary overheating	Check for blocked ventilation slots. Laser unit switches automatically to standby until the optimal operating temperature is restored.
No fiber connected	Fiber connection not complete	Reconnect and secure the application fiber.
No fiber connected	Fiber coupling faulty	Replace the application fiber.
Not a valid biolitec® fiber	The fiber was not recognized as approved.	Use an application fiber approved for this device (see also section 5).

		Contact the fiber supplier if necessary.
Can be used for less than xx min	The remaining time for this use is indicated. There will be at least one more use after the present use.	To proceed with treatment, switch back to Ready mode.
Fiber valid for less than xx min	The remaining time for using this fiber is indicated. It cannot be used again after this.	To proceed with treatment, switch back to Ready mode.
xx uses remaining	Indicates the number of uses remaining, excluding the current use.	
One use remaining	You have one use remaining, excluding the current use.	
Last use	Indicates that the current use is the last use remaining.	
Fiber expired	The fiber has expired.	Use a new application fiber.
Fiber: Software update recommended	The current version of the laser software is unable to interpret all of the data on the fiber. However, you can still continue using the fiber.	The laser requires a software update. Contact our service department.
Fiber: Software update required or Invalid fiber. Error Code 55.	The current version of the laser software is unable to interpret the data on the fiber and you must therefore stop using this fiber.	The laser requires a software update. Contact our service department. If possible, use an application fiber from an earlier delivery.
Footswitch not connected	No footswitch is attached to the device.	Please connect a suitable footswitch to the device.
Shunt Voltage Error	Relation between Laserdiode and Photodiode out of tolerance	Call service
Energy out of tolerance	Laserpower out of tolerance (+/- 20%)	Continue to monitor laser power and consult service
Device error	Internal Device Error	Call service

5. Accessories

5.1 Sales package for the laser includes

- Laser device
- Footswitch + Footswtich cable
- Power cable
- Door interlock
- Manual
- Laser warning triangle
- Carrying case
- 3 Laser safety goggles

If required, you can request an interlock cable for your door interlock free of charge from *CeramOptec*.

Order numbers for available replacement parts are listed in the table 3 below.

Note: Check that you have received all standard accessories listed here. Check the device and accessories for any obvious signs of damage, and do not use them should any be found.

	**Warning:** Use of accessories, transducers and cables other than those specifies or provided by the manufacturer or this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity or this equipment and result in improper operation.

Table 3: Accessories (all Leonardo models)

Accessories	CeramOptec Part Number	Name/Trademark	Model Type Reference	Manufacturer	Serial Number LOT/Batch	Date of manufacture	Affixed to:
Footswitch	SA1350	MKF 1PW-MED-SK12	1412301	Steute Schaltgeräte T: +49 (0)57 31 745-0	Serial number on label	On label	Accessories and their individual packaging
Footswitch cable	SA2423	Raymo	Escha plug 4pol – LEMO plug 6pin SZ0B	Raymo Electronics Technology Limited	n/a	n/a	Cable
Power cable	LA 0027 Europe LA 1271 India LA 1509 China LA 4264 UK LA 4265 Japan LA 4266 Italy LA 4425 Australia LA 4426 USA LA 1575 Brazil	HAWA Interpower Interpower Interpower Interpower Interpower Interpower Interpower Interpower	H05VV-F 86265010 86517040 86240070 86589010 86394000 86210280 70401020244 86286110	HAWA Hans Wagner GmbH T: +4992689700 Interpower T: +44 (0)1908 295 300	n/a	n/a	Cable
Door Interlock	SA2292	Raymo	SA2292	Raymo Electronics Technology Limited	n/a	n/a	On individual package

5.2 Laser safety eyewear

To avoid damage to the eye and retina, doctors, surgical personnel, patients and any other persons present in the room during treatment must wear appropriate protective eyewear.

Caution: Protective eyewear must always be worn when using the laser.

Eye protection must conform to specification ANSI Z136.1 (OD) and EN207 (DLB) of the directive 89/686/EEC as well as the Medical Device Regulation 2016/425 with optical density in 980±30nm and/or 1470±30nm and/or 1064±30nm or 1940±30nm.
Only use protective eyewear provided or approved by *CeramOptec*. Suitable protective eyewear can also be obtained from *CeramOptec*. *CeramOptec* recommends goggles which fulfill the requirements of the ANSI Z136.1 and CE / EN207 standards.

Table 4: Rated eyewear for all LEONARDO® models

Model	Wavelength 980nm	Wavelength 1064nm	Wavelength 1470nm	Wavelength 1940nm
LEONARDO® 1064		DBL4 (OD4)		
LEONARDO® 1470			DBL2 (OD3)	
LEONARDO® 1940				DBL2 (OD2)
LEONARDO® Dual 45 (980nm + 1470nm)	DBL4 (OD4)		DBL2 (OD3)	
LEONARDO® Dual 45 (1064nm + 1470nm)		DBL4 (OD4)	DBL2 (OD3)	
LEONARDO® Dual 100 (980nm + 1470nm)	DBL5 (OD5)		DBL2 (OD3)	
LEONARDO® Dual 100 (1064nm + 1470nm)		DBL5 (OD6)	DBL2 (OD3)	

6. Application systems, fibers and medical probes

Application fibers and medical probes named below (6.1) are considered as **applied parts.**

Attention: Only application systems, fibers and medical probes approved by *CeramOptec* may be used. Use of systems that have not been approved may damage the device and will invalidate the warranty.

6.1 Application fibers and medical probes

Only application fibers and medical probes with a minimal fiber core diameter, as indicated in the technical specifications (see section 9.1), may be used with your LEONARDO® model.

The following application fibers and medical probes are approved for use with Leonardo lasers:

- Bare Fiber, ID-Technology
- ELVES® Fiber, ID-Technology
- ELVeS® Radial®, ID-Technology
- FiLaC®, ID-Technology
- Gas-/Liquid Cooled Fiber, ID-Technology
- Varico Fiber, ID-Technology
- Side Fiber, ID-Technology
- Twister® Fiber, ID-Technology

For further information please refer to the instructions for each application fibers and medical probes.

6.2 Handling and use of application systems and medical probes

Caution: It is essential that you adhere to the clinical stipulations for handling sterile application systems, medical probes and handpieces. The valid regulations for the handling of sterile products must be observed. *CeramOptec* is not liable for accidents or damage to the device resulting from violations of these regulations.

To ensure the proper and safe use of medical laser systems, only qualified doctors who have received the appropriate training or instruction should use the application systems and medical probes.

Attention: Follow the instructions enclosed with the application fiber to ensure safe handling. Noncompliance with the manufacturer's handling recommendations may result in damage to the application fiber or medical probe and/or injury to the patient or user.

The application fiber or probe must only be cleaned and/or disinfected in accordance with the manufacturer's recommendations. Inappropriate use of cleaning or disinfectant products may result in (sometimes unnoticeable) damage to the fiber, which could cause injury to the patient or doctor.

Attention: Particular caution is required when handling application systems or medical probes. If these are knocked against a hard surface or bent excessively, they may be damaged and their functioning impaired. Fiber tips may be damaged by incorrect handling. Fibers suspected of being damaged may not be used.

- Check that the sterile packaging is undamaged.
  Laser probes delivered in opened or damaged packaging are not sterile and therefore should not be used.
- Remove the system from the packaging.
- Perform a visual inspection.
- Insert the probe into the laser device's aperture port and secure it fully. Otherwise, the safety contact of the fiber socket is not closed.
- Remove the protective covering at the distal end of the fiber. Visually inspect the laser tip for damage.
- Since the aiming beam follows the same path as the therapeutic beam through the application fiber, it can be used to check that the application fiber is undamaged. If the aiming beam does not appear at the distal end of the application fiber, if its intensity is weak or if it unexpectedly

appears to be diffuse, this may indicate a damaged or defective application fiber. Bright points glowing along the length of the laser are another possible indication of the same.

7. Safety

7.1 Safety elements

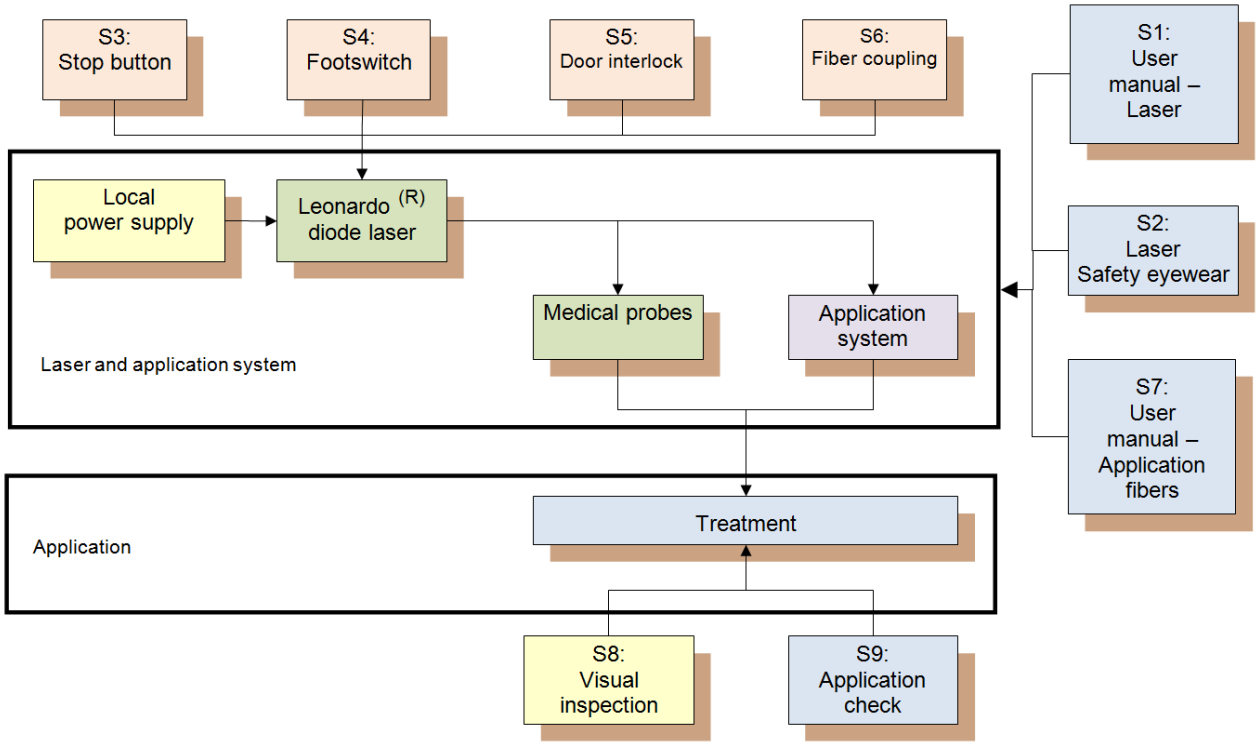


Figure 44: Safety elements

Attention: Safety elements S1 to S9 are part of the laser system. These must always be used to improve safety when using LEONARDO®. Therefore, check as thoroughly as possible that these are functioning correctly.

8. Maintenance and care

LEONARDO® is designed to be particularly low-maintenance and reliable.

<u>Attention:</u> LEONARDO® contains <u>no</u> parts that are serviceable by the user. Any attempt to repair, adjust, or modify the system (outside of the procedures outlined in this manual) by any person not authorized by *CeramOptec* is strictly FORBIDDEN and will invalidate the warranty.

The final decision will rest with *CeramOptec* in all cases.

To avoid risk of electric shock, do not open the housing. During the warranty period, servicing and maintenance may only be carried out by *CeramOptec* or by qualified personnel authorized by *CeramOptec*.

8.1 Routine maintenance

The following checks should be performed regularly, before each start:

- Check laser protective eyewear (correct type, intact).
- Check that all labels and markings can be read and are positioned correctly (see section 9).
- Check that the emergency off switch is working.
- Check that an interlock interruption puts the laser into standby mode.
- Check that the auditory signal is activated when the footswitch is pressed and that laser radiation is emitted.
- At the lowest possible power setting, check that the laser switches to standby when the connector of the application fiber is loosened.

8.2 Cleaning

<u>Attention:</u> The device must be turned off and the power line must be disconnected before cleaning!

Clean the housing with a damp cloth and a mild alcohol-based antiseptic detergent or mild cleaning agent. Chemical cleaning agents, abrasive cleaning agents, and rough cleaning cloths may damage the surface of the housing and therefore should not be used. Do not spray with water as it may penetrate the equipment.

<u>Attention:</u> Please follow national regulations for clinical hygiene.

8.3 Changing fuses

<u>Attention:</u> The device must be turned off and the power line must be disconnected before changing the fuses! The fuses are located on the rear of the device above the power plug.

Fuses that have blown must only be replaced with fuses of the same type (see the model-specific specifications in section 9.1.

Should a replacement fuse also blow, stop using the device and contact our service department.

8.4 Technical safety check

A technical safety check of the LEONARDO® laser system must be performed every year in accordance with statutory requirements, and the results documented in the relevant maintenance log. (see section 14.3).

For the purpose of this check, the laser must transported in the original packaging. The operator must also provide a statement guaranteeing that the device has been disinfected according to instruction provided in section 8.2. In case of transport damage, the device must be visually inspected for integrity before it is put into operation again.

9. Technical specifications and labeling

9.1 Model-specific specifications

ATTENTION: All tolerance levels +/-20 % including measurement uncertainty.

9.1.1 LEONARDO® 1064 (20W@1064nm)

Model	**20W @ 1064nm**
Power	20W ± 20% (max. 24W)
Wavelength	1064nm ± 30nm
Power supply / Power consumption	100 – 240VAC; 50/60 Hz / max. 450VA
Fuses	T4AL, 250V AC, 5x20mm
Fiber core diameter	≥ 360µm

9.1.2 LEONARDO® 1470 (15W@1470nm)

Model	**15W @ 1470nm**
Power	15W ± 20% (max. 18W)
Wavelength	1470nm ± 30nm
Power supply / Power consumption	100 – 240VAC; 50/60 Hz / max. 450VA
Fuses	T4AL, 250V AC, 5x20mm
Fiber core diameter	≥ 360µm

9.1.3 LEONARDO® 1940 (10W@1940nm)

Model	**10W @ 1940nm**
Power	10W ± 20% (max. 12W)
Wavelength	1940nm ± 30nm
Power supply / Power consumption	100 – 240VAC; 50/60 Hz / max. 450VA
Fuses	T4AL, 250V AC, 5x20mm
Fiber core diameter	≥ 360µm

9.1.4 LEONARDO® Dual45 (30W@980nm + 15W@1470nm)

Model	**30W @ 980nm + 15W @ 1470nm**
Power	30W ± 20% (max. 36W) + 15W ± 20% (max. 18W)
Wavelength	1470nm ± 30nm + 980nm ± 30nm
Power supply / Power consumption	100 – 240 VAC; 50/60 Hz / max. 450VA
Fuses	T4AL, 250V AC, 5x20mm
Fiber core diameter	≥ 360µm and 220µm with reduced Pmax. (optional)

9.1.5 LEONARDO® Dual45 (30W@1064nm + 15W@1470nm)

Model	**30W @ 1064nm + 15W @ 1470nm**
Power	30W ± 20% (max. 36W) + 15W ± 20% (max. 18W)
Wavelength	1064nm ± 30nm + 1470nm ± 30nm
Power supply / Power consumption	100 – 240 VAC; 50/60 Hz / max. 450VA
Fuses	T4AL, 250V AC, 5x20mm
Fiber core diameter	≥ 360µm and 220µm with reduced Pmax. (optional)

9.1.6 LEONARDO® Dual100 (85W@980nm + 15W@1470nm)

Model	**85W @ 980nm + 15W @ 1470nm**
Power	85W ± 20% (max. 102W) + 15W ± 20% (max. 18W)
Wavelength	980nm ± 30nm + 1470nm ± 30nm
Power supply / Power consumption	100 – 240 VAC; 50/60 Hz / max. 600VA
Fuses	T4AL, 250V AC, 5x20mm
Fiber core diameter	≥ 360µm and 220µm with reduced Pmax.

9.1.7 LEONARDO® Dual100 (85W@1064nm + 15W@1470nm)

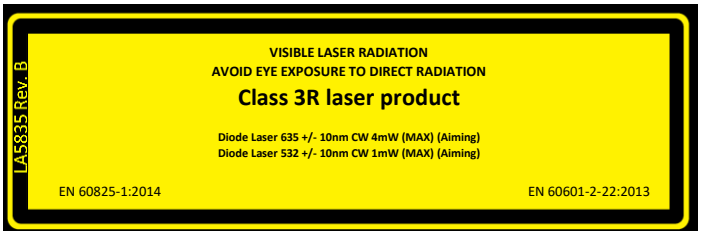
Model	**85W @ 1064nm + 15W @ 1470nm**
Power	85W ± 20% (max. 102W) + 15W ± 20% (max. 18W)
Wavelength	980nm ± 30nm + 1470nm ± 30nm
Power supply / Power consumption	100 – 240 VAC; 50/60 Hz / max. 600VA
Fuses	T4AL, 250V AC, 5x20mm
Fiber core diameter	≥ 360µm and 220µm with reduced Pmax.

9.2 General specifications for all LEONARDO® models

Numerical aperture	NA = 0.26
Fiber connector	Modified SC
Treatment mode	Continuous (CW) / Pulse
Pulse duration	Variable: 0.01 to 60.0 seconds
Power control	Integrated power control
Aiming beam; power	635nm ± 10nm; 4mW (max) and 532nm ± 10nm; 1mW (max)
Electrical protection class (EN60601-1)	Class I
Laser safety class (EN60825-1)	Class 4
Class of device directive 93/42/EEC	Class IIb
Cooling	Air cooling fan
Storage and transport conditions	Temperature: -10 to +40°C Rel. humidity: <80% RH non condensing Atmospheric pressure: 700 to 1100 hPa
Operating conditions	Temperature: +10 to +25°C Rel. humidity: < 50% RH non condensing Atmospheric pressure: 760 to 1100 hPa
Ingress Protection rating (EN60529)	IP20 (Protected from touch by fingers and objects greater than 12 millimeters. Not protected from liquids.)
Dimension housing (HxWxD)	275 mm x 370 mm x 85 mm
Weight	approx.8,5 kg
Weight of battery	Approx. 0.003 kg
Weight of packaging	Approx. 2 kg
Applied part	Type B
Mains isolation	Disconnection from mains is done by mains switch
Safety standards	EN 60601-1: 2006+A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 60601-1-9:2008+A1:2013 EN 60601-2-22:2013 EN 62304:2006+A1:2015 EN 62366: 2016 EN 60825-1:2008 EN 60825-1:2014
Footswitch Safety standards	EN60204-1 EN60947-5-1 VDE0660 Part200 IEC 947-5-1 IPX8 protection to EN 60529 (Protected against water submersion - The equipment is suitable for continual submersion in water under conditions which are identified by the manufacturer.)
Service	Annual

9.3 Safety labels and Type Labels

9.3.1 LEONARDO® 1064



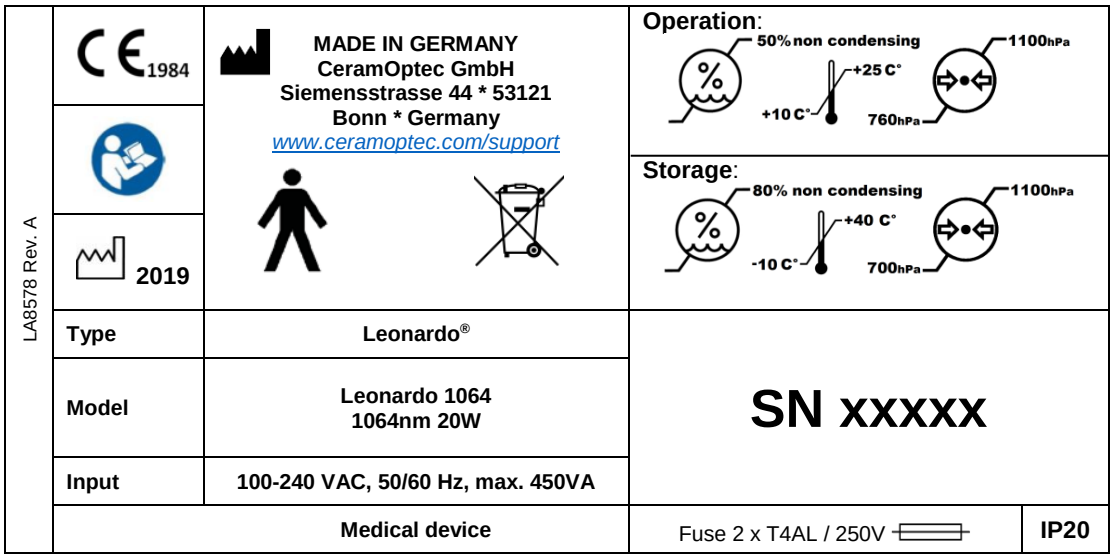
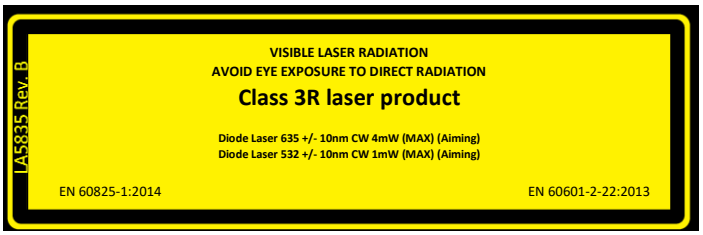


Figure 45: Label for devices LEONARDO® 1064 (20W@1064nm)

9.3.2 LEONARDO® 1470



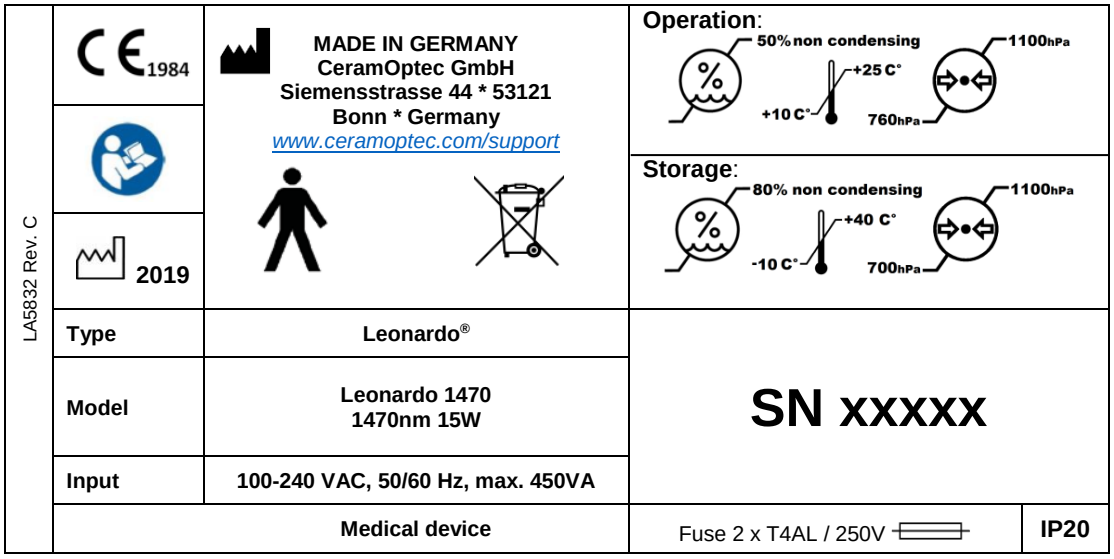
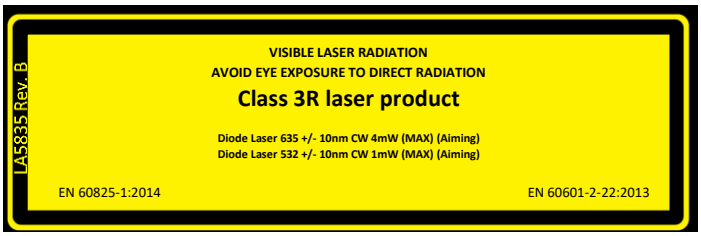


Figure 46: Label for devices LEONARDO® 1470 (15W@1470nm)

9.3.3 LEONARDO® 1940



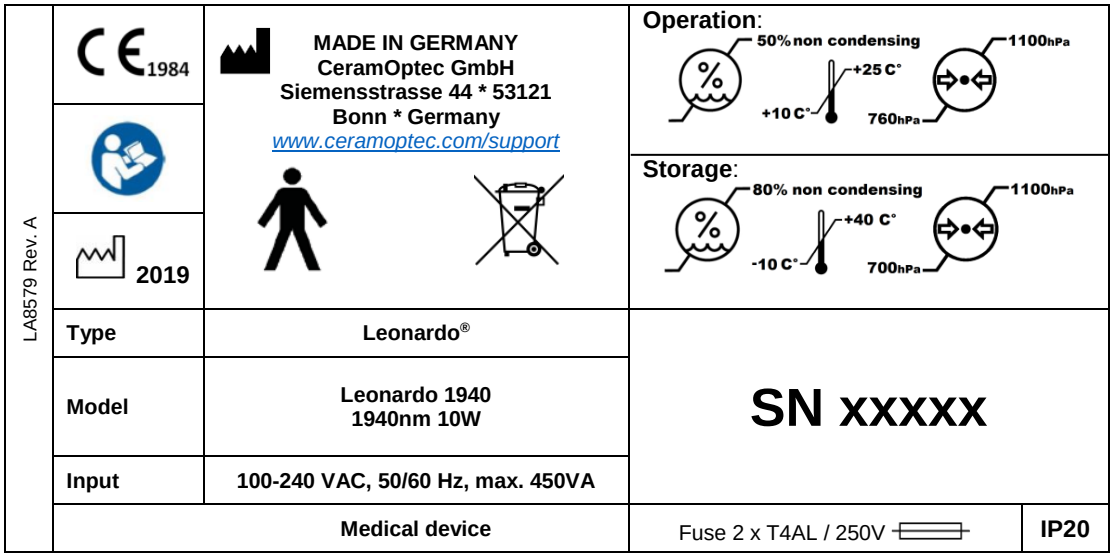
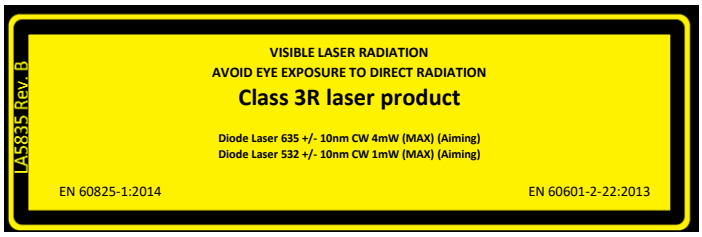


Figure 47: Label for devices LEONARDO® 1940 (10W@1940nm)

9.3.4 LEONARDO® DUAL 45 (30W@980nm + 15W@1470nm)



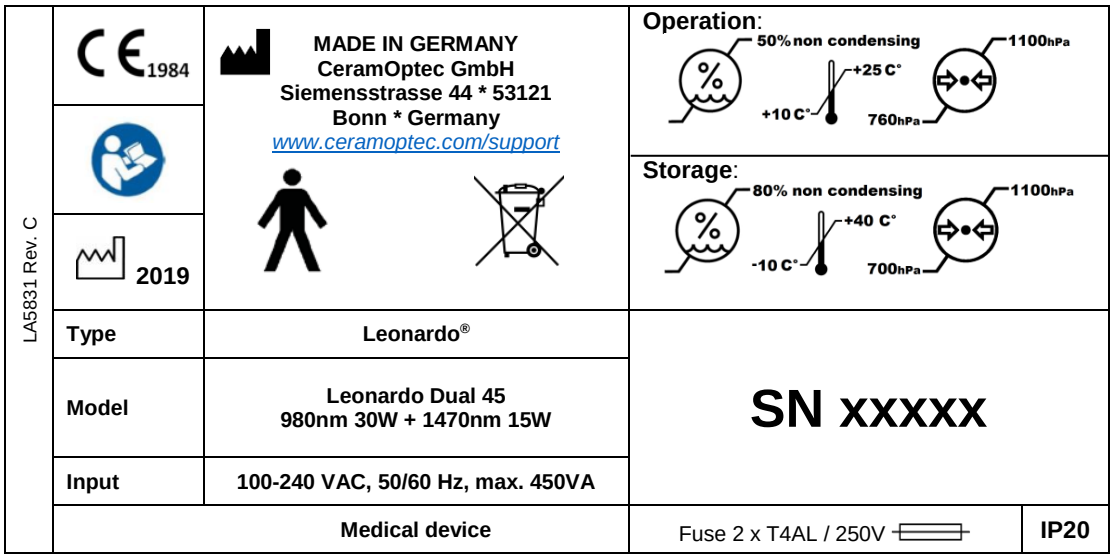
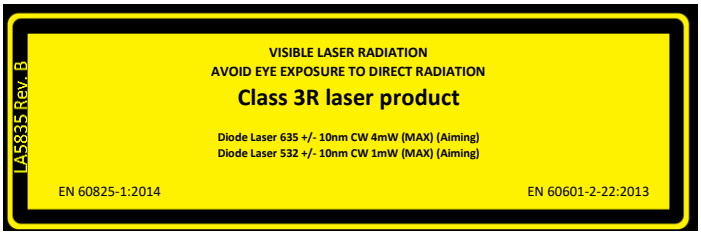


Figure 48: Label for devices LEONARDO® Dual45 (30W@980nm + 15W@1470nm)

9.3.5 LEONARDO® DUAL 45 (30W@1064nm + 15W@1470nm)



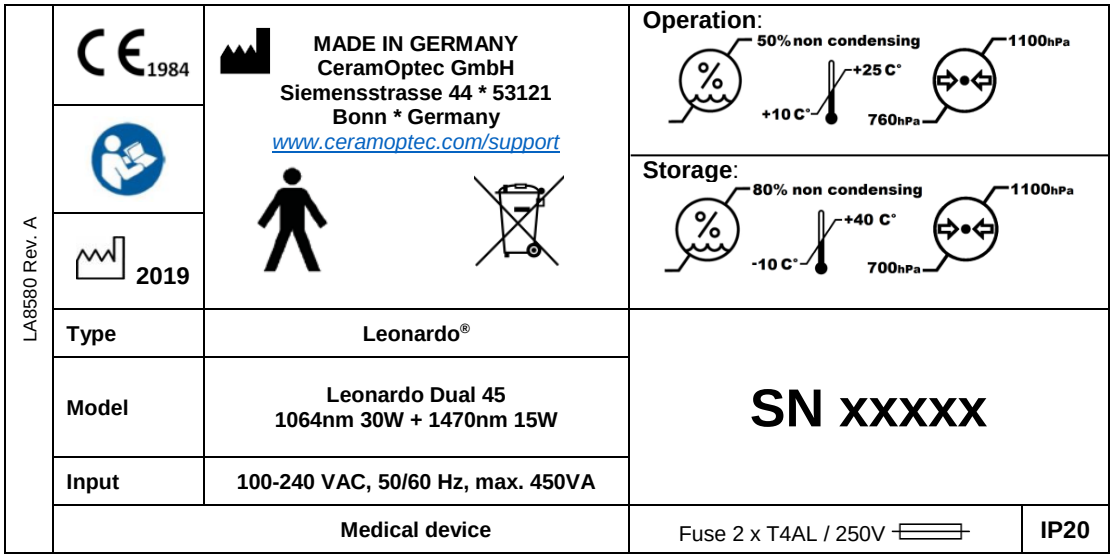
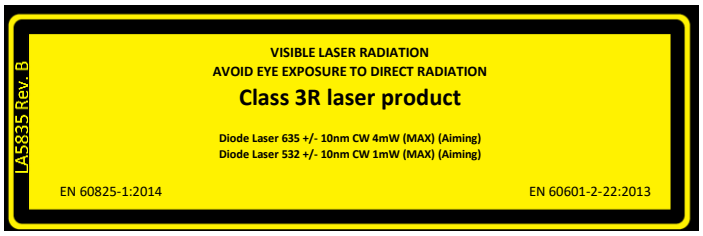


Figure 49: Label for devices LEONARDO® Dual45 (30W@1064nm + 15W@1470nm)

9.3.6 LEONARDO® DUAL 100 (85W@980nm + 15W@1470nm)



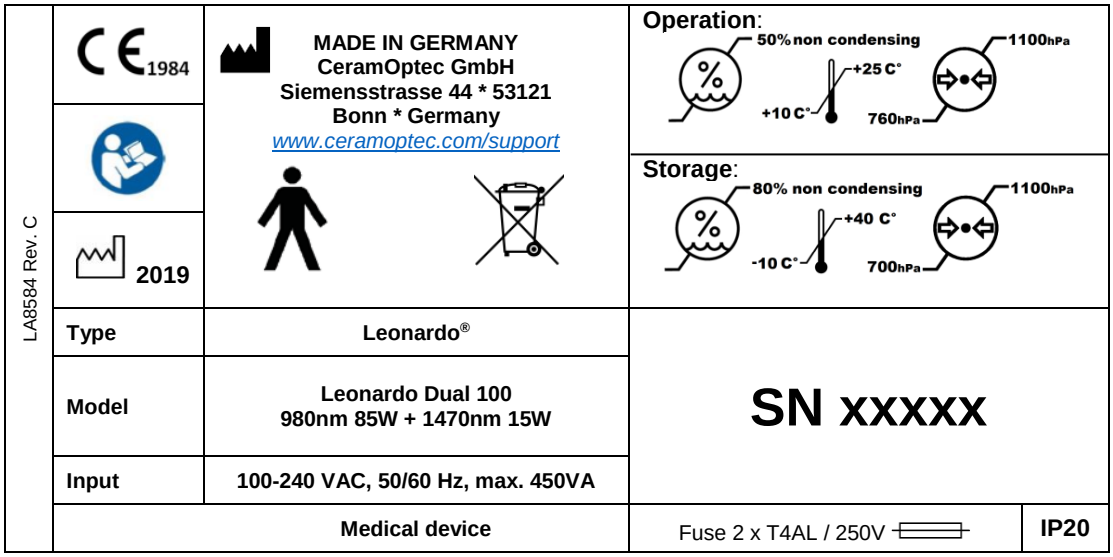
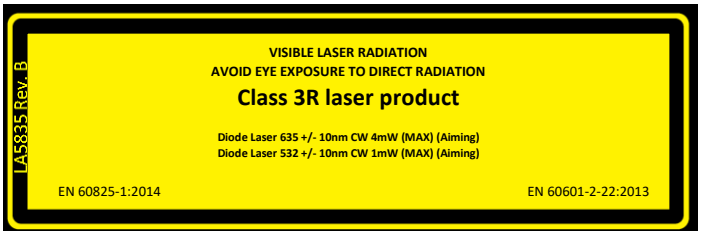


Figure 50: Label for devices LEONARDO® Dual 100 (85W@980nm + 15W@1470nm)

9.3.7 LEONARDO® DUAL 100 (85W@1064nm + 15W@1470nm)



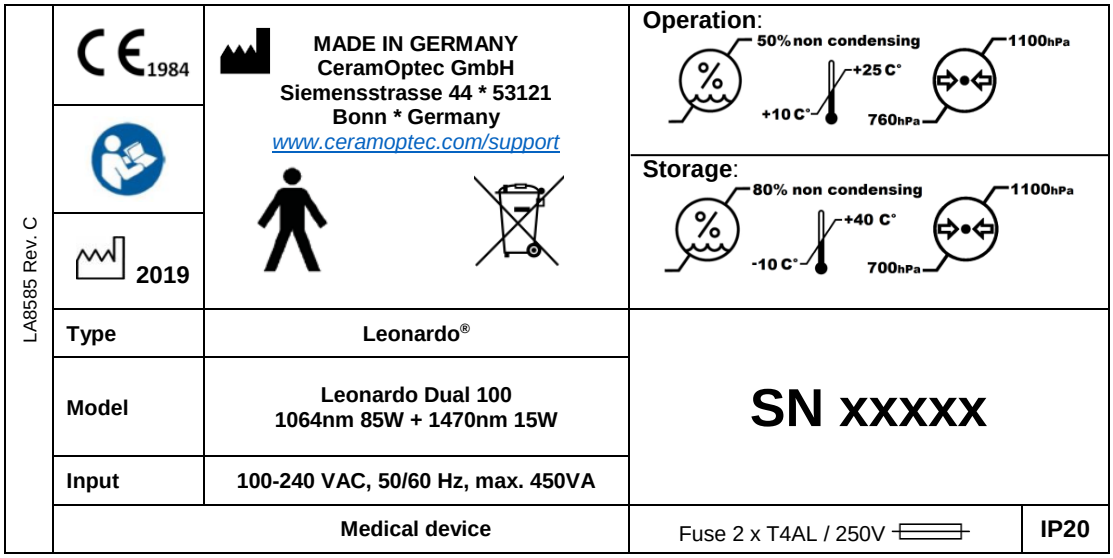
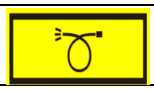


Figure 51: Label for devices LEONARDO® Dual 100 (85W@1064nm + 15W@1470nm)

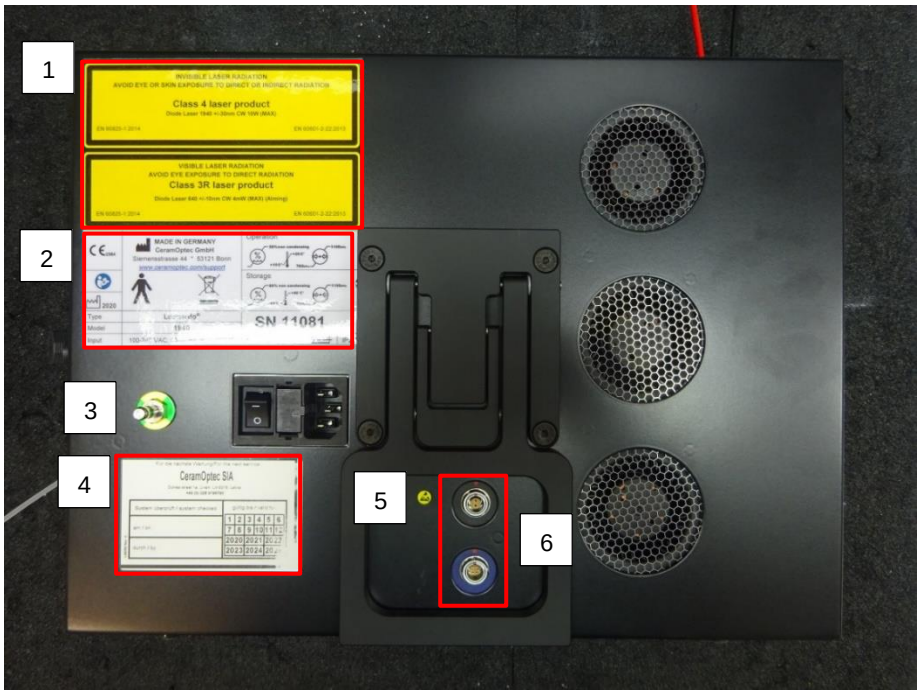
Warning: To avoid risk of electrical shock, this device must be connected to a power supply with protective conductor only.

9.4 Symbol key

Symbol	Description
	Laser warning sign
	Laser aperture at distal end of fiber
	General warning sign
	Laser stop button
	ESD warning symbol
	Refer to instruction manual "Follow instructions for use"
	Operating instructions
	Fuse
	Potential equalization plug
	Admissible temperature range
	Maximum admissible air humidity
	Atmospheric pressure limitation
	Type B applied part
	Up
	Fragile goods
	Keep away from water and dampness
	WEEE Symbol (Waste Electrical and Electronic Equipment Directive)
	Year of manufacture

	Manufacturer
CE XXXX	CE mark

9.5 Position of labels



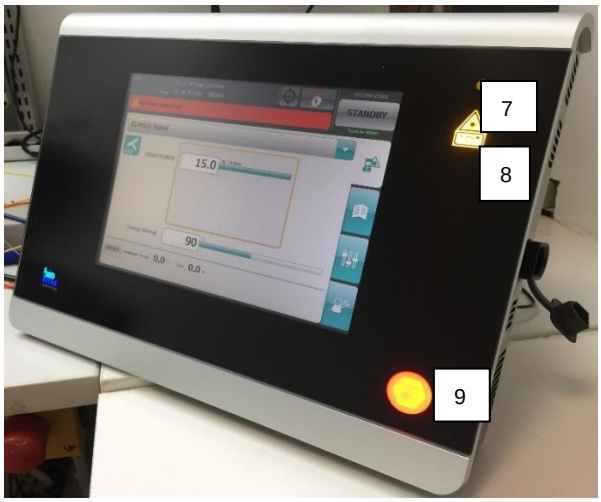


Figure 52: Position of labels

	Label	Position
1	Laser safety labels	On the left top corner of the back side of the device
2	Type label	Under the laser safety labels
3	PE Connector	On left side of the back side of the device, below the laser safety labels
4	Maintenance label	On the left bottom corner of the back side of the device
5	ESD	Left next to the foot switch and door interlock label
6	Footswitch and door interlock connector labels	On the footswitch and door interlock connector
7	Laser warning	Top, right on front of the device
8	Laser aperture at distal end of the fiber	Top, right on front of the device, below the laser warning
9	Laser stop button	Bottom, right on front of the device

9.6 Electromagnetic Compatibility

9.6.1 Electromagnetic Compatibility Requirements

WARNING:
Use of accessories other than those specified in this document may result in increased emission or decreased immunity of the LEONARDO.

WARNING:
The LEONARDO should not be used adjacent or stacked with other equipment and, if necessary, observe its operation to verify its normal operation during use. Refer to the Electromagnetic Immunity information in the following section of this document.

CAUTION:
The LEONARDO needs special precautions regarding Electromagnetic compatibility (EMC) and care should be taken in accordance to the EMC information provided in chapter 9.6 of this document.

CAUTION:
Use of portable and mobile RF communications equipment near the LEONARDO may affect its operation.

CAUTION:
Observe the following cautions when connecting LEONARDO with other equipment:

- Ensure that the connected equipment is in accordance with the EN60601-1 or EN safety standards.

Employ additional protective measures (e.g., additional protective earthing) as necessary.

CAUTION:
Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI), which could affect the performance of this device. Avoid operating the LEONARDO near cauterizers, diathermy equipment, FM 2-way radios, or cellular phones. Turn power off to radio, cellular and other like equipment near the LEONARDO.

9.6.2 Manufacturer’s Declaration Regarding Electromagnetic Compatibility

Please pay attention to the precautions of EMC (Electromagnetic Compatibility) of the LEONARDO. The LEONARDO must be installed and used according to the EMC information shown in this manual. The device can be affected by portable and mobile RF communication equipment.

Remove any devices that emit electromagnetic fields such as mobile phones from nearby the device. The LEONARDO has been tested and inspected to guarantee a proper performance.
Do not store or use the LEONARDO with other electric equipment.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration - Electromagnetic Emissions
EN 60601-1-2:2015, IEC 60601-1-2:2014</th></tr>
<tr><td colspan="3">The LEONARDO® laser device is intended for use in an electromagnetic environment as described below. The user of the device should ensure that the device is operated in such an environment.</td></tr>
<tr><th>Norms, measurements</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The device is suitable for use in all establishments, including domestic environments, directly connected to the public low-voltage power supply network that supplies residential buildings.</td></tr>
<tr><td>Harmonic emission
EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/
flicker emissions
EN 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and Manufacturer's Declaration - Electromagnetic Immunity EN 60601-1-2:2015, IEC 60601-1-2:2014			
The LEONARDO® laser device is intended for use in an electromagnetic environment as described below. The user of the device should ensure that the device is operated in such an environment.			
Norms, Measurements	**EN 60601 Test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) EN61000-4-2	Contact Discharge: ± 8 kV Contact Air Discharge: ± 2 kV Air ± 4 kV Air ± 8 kV Air ± 15 kV Air	 ± 8 kV ± 2 kV ± 4 kV ± 8 kV ± 15 kV	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material, the relative air humidity should be 30 % at least.
Electrical fast transient/bursts EN61000-4-4	± 2 kV for power lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	The quality of the supply voltage should conform to a typical business or clinic environment.
High energy pulses (surge) EN61000-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV ± 2 kV	The quality of the supply voltage should conform to a typical business or clinic environment.
Voltage dips, short interruptions and voltage variations in power supply input lines EN61000-4-11	0% UT 0.5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT 1 period 70% UT for 25 periodes / 50Hz for 30 periodes / 60Hz 0% UT for 250 periodes /50Hz for 300 periodes /60Hz	0% UT 0.5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT 1 period 70% UT for 25 periodes / 50Hz for 30 periodes / 60Hz 0% UT for 250 periodes /50Hz for 300 periodes /60Hz	The quality of the supply voltage should conform to a typical business or clinic 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.
Magnetic fields at the supply frequency 50Hz/60Hz EN61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Magnetic fields at the supply frequency should conform to the typical values as they occur in the business or clinic environment.
Conducted RF EN 61000-4-6	3 V_{eff} 0,15MHz–80 Mhz 6 V_{eff} 0,15MHz–80 Mhz (in ISM and amateur radio bands)	3 V_{eff} 0,15MHz–80 Mhz 6 V_{eff} 0,15MHz–80 Mhz (in ISM and amateur radio bands)	Portable and mobile RF communications equipment should be used in a no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distance: d=1.2 $\sqrt{P}$ 150kHz - 80MHz d=1.2 $\sqrt{P}$ 80MHz – 800MHz d=2.3 $\sqrt{P}$ 800MHz – 2.7GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d]
Radiated RF EN 61000-4-3	3 V/m 80MHz–2.7GHz 80% Am at 1kHz	3 V/m 80MHz–2.7GHz 80% Am at 1kHz	Interference may occour in the vicinity of equipment marked with the following symbol: 

NOTE 1: NOTE 2:	For 80 MHz and 800 MHz, the higher frequency range is applies. These guidelines may not apply in all stuations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) - The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.
b) - The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
c) - Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Rezūm Generator is used exceeds the applicable RF compliance level above, the Rezūm Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LEONARDO.
d) - Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distance between portable and mobile RF communication equipment and the LEONARDO® laser
EN 60601-1-2:2015, IEC 60601-1-2:2014

The device is intended for use in an electromagnetic environment with controlled RF disturbances. The user of the device can help to avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile telecommunication devices (transmitters) and the device - depending on the output power of the telecommunication devices as described below.

Nominal power of the transmitter P (W)	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.7 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum nominal power not mentioned above: To detect the recommended safety distance, use the equation in the corresponding column. P is the maximum nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

NOTE 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity EN 60601-1-2:2015, IEC 60601-1-2:2014						
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device, should assure that it is used in such an environment.						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Immunity Test Level (V/m)
	385	380-390	TETRA 400	Puls modulation[b] 18 Hz	1.8	27
	450	430-470	GMRS 460, FRS 460	FM[c] ±5 kHz deviation: 1 kHz sine	2	28
	710 745 780	704-787	LTE Band 13, 17	Pulse modulation[b]: 217 Hz	0.2	9
	810 870 930	800-960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b]: 18 Hz	2	28
	1720 1845 1970	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, UMTS, LTE Band 1, 3, 4, 25	Pulse modulation[b]: 217 Hz	2	28
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b]: 217 Hz	2	28
	5240 5240 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation[b]: 217 Hz	0.2	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: E= Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.						

9.6.3 Electromagnetic Compatibility Compliance

WARNING:
RF Interference - Known RF sources, such as cell phones, radio or TV stations, and two-way radios, may cause unexpected or adverse operation of the LEONARDO. Consult qualified personnel regarding system configuration.

WARNING:
The LEONARDO should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, test the LEONARDO to verify normal operation.

WARNING:
The LEONARDO needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be put into service according to the EMC information.

10. Product life time

The product life time of the Leonardo during operation at the customer is defined for five years. The maintenance period for serving of the laser is defined with one year. The maintenance activities are qualified to extend the life time.

11. Service policy

The manufacturer will provide, on request, schematic connection diagrams, lists of replacement parts, descriptions, configuration instructions and other information to be used by qualified technical personnel for first-line maintenance and repair of components of the LEONARDO® system that the manufacturer has deemed repairable.

When parts are deemed to be irreparable by the manufacturer or when special training and/or equipment are required to perform the repair or adjustments, the manufacturer reserves the right to withhold information on the grounds of safety.

If you wish to return the LEONARDO® laser to the manufacturer for servicing, it must be returned in its original packaging. You must also provide a statement guaranteeing that the device has been disinfected accordingly.

12. Environmental protection

CeramOptec has implemented and maintain a process to identify and document the relevant ENVIRONMENTAL ASPECTS of LEONARDO® lasers according EN60601-1-9 across all LIFE-CYCLE stages.

12.1 Packaging of Leonardo

The LEONARDO® laser comes in a reusable packaging (transport box, cardboard folding box and polystyrene inserts). This packaging can be stored during the entire product life cycle to save space and is thus at any time for the transport of the device available. If the packaging or parts of the packaging is damaged or on the end of device life time, it can be sent to the regulated recycling process. The weights of packaging are listed in chapter 9.2.

12.2 Instruction to minimize the environmental impact during normal use

There are no special precautions to be taken during the installation of the LEONARDO® laser to avoid additional risks to the environment or for reducing environmental effects.

The LEONARDO® laser contains no serviceable parts that need to be replaced and disposed during its expected service life.

During its product lifetime, the LEONARDO® laser consumes only electrical energy and converts it into laser light with high efficiency. The LEONARDO® laser produces not only laser light but also heat and electromagnetic radiation. Other types of emission do not occur. The LEONARDO® laser does not contain radioactive sources or induced radioactive materials.

The LEONARDO® laser contains lithium ion batteries.

12.3 Information for management of end useful life (EOL)

The LEONARDO® laser must be disposed of in compliance with the applicable regulations.

The bin symbol on the product or in the manual indicates that this product must not be disposed of with other waste. CeramOptec has built up a waste management system for electronic waste. This also includes free return of your LEONARDO® laser.

Arrangements for the return of all unusable equipment to CeramOptec for correct removal and environmentally friendly disposal should be discussed with the local distributor or dealer of the country in which the equipment was purchased.

12.3.1 Information to WASTE treatment facilities

The LEONARDO® laser contains one lithium ion battery in the display electronics. The battery must be removed before disposal of the Leonardo® device. The battery can be removed by unscrewing the device.

Otherwise, the LEONARDO® laser consists of an anodized aluminum housing, a copper heat sink and plastic parts, as well as electronic assemblies, which can be separated and disposed of according to current disposel guidelines.
The LEONARDO® laser does not contain any gasses or liquids that could be hazardous to disposal.

13. Warranty policy

CeramOptec provides a warranty of six months from the date of purchase on all LEONARDO® models, provided that no other warranty terms have been agreed in the contract of sale. Material defects detected during this period will be repaired by *CeramOptec*.

Attention: The warranty is invalidated in the cases listed below. The final decision will rest with *CeramOptec* in all cases:

- **Improper handling or misuse of the laser**
- **Use of components that do not belong to the laser**
- **Use of application systems that have not been approved**
- **Any of the following actions performed by persons not authorized by *CeramOptec*:**
    - **Installation**
    - **Servicing**
    - **Configuration or adjustment of the laser**

Notwithstanding any alternative terms of warranty that may have been specified in the contract of sale, the conditions of warranty specified here exclude and replace all other verbal warranties or warranties in writing that were explicitly agreed or tacitly implied.

The conditions of warranty specified here apply exclusively to defective devices. In no case will *CeramOptec* accept liability for accidental or indirect losses (including loss of profit), bodily injury, damages or costs directly or indirectly resulting from use of the LEONARDO® laser system.

13.1 Important conditions

The following conditions of warranty apply to your purchase of a LEONARDO® laser system (referred to below as “the laser”):

1. The only fiber optics that may be used in conjunction with the laser are fiber optics manufactured and sold by *CeramOptec* (“*CeramOptec* fiber optics”). The laser is specifically designed to work only with *CeramOptec* fiber optics. Attempts to use any other fiber product with the laser may result in suboptimal functioning of or damage to the laser.
   CeramOptec expressly excludes liability or responsibility for any loss or damage caused or suffered by you (“the purchaser”) arising from any attempt to use fiber optics other than original *CeramOptec* fiber optics in conjunction with the laser. The use of *CeramOptec* fiber optics with the laser should ensure effective functioning of the laser in accordance with the *CeramOptec* specifications. Any loss or damage arising from the use of fiber optics other than *CeramOptec* original fiber optics will be borne solely by the purchaser.
2. The laser incorporates proprietary *CeramOptec* software (“the software”). The software is essential for proper and effective functioning of the laser in accordance with the *CeramOptec* specifications. *CeramOptec* expressly reserves the right to replace, change, improve, modify and enhance the software (collectively referred to as “software upgrades”) at any time while the laser is in the possession of the purchaser or while the laser is in use by a person other than the purchaser. The purchaser and any other user of the laser undertake to grant *CeramOptec* continuous and unlimited access to the laser and the software for the purposes of monitoring the laser and its functional efficiency and for the purposes of installing software upgrades and monitoring the functioning and efficiency of the software. All software upgrades will be installed by *CeramOptec* free of charge to the purchaser, provided that the purchaser covers the cost of transporting the laser to *CeramOptec* for each software upgrade. The cost of returning the laser to the customer will be covered by *CeramOptec*. *CeramOptec* expressly excludes any liability or responsibility for failure of the laser to function properly and effectively in accordance with the *CeramOptec* specifications in cases where the purchaser or another user of the laser fails to send the laser to *CeramOptec* for all software updates of which *CeramOptec* provides notification.
3. If the laser does not function in accordance with the *CeramOptec* specifications, this is due to problems either with the laser hardware or with the software. The purchaser is requested to notify *CeramOptec* without delay should the laser fail to function in accordance with the

CeramOptec specifications in order to allow *CeramOptec* to eliminate the problem, to issue the purchaser with permission to return the material to *CeramOptec* for the purpose of running an appropriate diagnostic analysis and taking corrective action as needed. The scope of liability and responsibility that will be accepted by *CeramOptec* in cases where corrective action is required is specified in *CeramOptec*'s general terms and conditions of sale.

For more information, contact our service department or the manufacturer.

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14. Appendix

14.1 Device master data

DEVICE MASTER DATA LEONARDO®			
Model:	nm / W / µm	Operator:	
S/N:		Location:	
		Inventory no.:	

14.2 Training record

Person responsible Name / Signature:	
Date:	
Checked:	
Name of trained personnel / Signature:	

14.3 Technical safety check

Log entry no.:	*Person responsible / Date*	*Comments*	*Device status (Pass / Fail)*	*Signature*

1.	**Visual inspection**	**Passed**	**Failed**	**Assessment**
1.1	Labeling/warning labels (laser class, max. power, wavelength) (refer to the section on labeling)			
1.2	Information signs/warning signs correct and complete (refer to section 9 “Labeling”)			
1.3	User manual			
1.4	Equipment complete			
1.5	Connections			
1.6	External surfaces of device			
2.	**Functional capability check**			
2.1	Footswitch			
2.2	Beam guidance system: Coupling/decoupling/aiming beam			
2.3	Interlocks			
2.4	Display and operation			
3.	**Check of monitoring, safety, display and reporting systems**			
3.1	Laser safety eyewear			
3.2	Indicator lights			
3.3	Emergency stop button			
4.	**Electrical safety EN60601-1**			
4.1	Insulation resistance			Ω
4.2	Earth leakage current			**mA**
4.3	Protective ground wire resistance			Ω
5.	**Measurements for safety-critical output parameters**			

Attention: Always wear protective eyewear during this check.

Specifications for measuring equipment.

Detector: Thermopile detector head, fan cooled, 250W (for example: Gentec UP25N-250F-H12)
Minimum aperture 25mm (https://www.gentec-eo.com/products/power-detectors/UP25-H)
Calibrated to NIST standard
Reader : Gentec Maestro Monitor (https://www.gentec-eo.com/products/monitors/MAESTRO)

Test Fiber: CeramOptec Fiber jumper RFID Technology, programmed for multiple use.
REF Nr. LEONARDO® Bare Fiber 503200911

Laser calibration test:

Connect a new LEONARDO® Bare Fiber

to the output port of the laser. Place the distal end of the application system in the power meter adapter of your power measurement device. Enable and fire the laser, and record the value.

A1. CW-Test at Leonardo® 1064 / Leonardo® 1470 / Leonardo® 1940

Put the laser into **continuous mode.**
Fire the laser and use the power meter to check whether the output is within the tolerance limits:

Power selected [W] P@1470nm or P@1064nm	**Power Value [W] +/- 20%** Min / **Nominal /** Max	**Actual value**	**Passed**	**Failed**	**Comment**
2	1.6 - **2** - 2.4				
5	4 - **5** - 6				
10	8 - **10** - 12				
15	12 - **15** - 18				***Only for 1064 / 1470**
20	16 - **20** - 24				***Only for 1064**

A2. CW-Test at Leonardo® Dual 45 and Dual 100

Put the laser into **continuous mode.**

➔ Laser setting: 2/3 980nm + 1/3 1470nm, e.g. 45W = 30W@980nm + 15W@1470nm

OR

➔ Laser setting: 2/3 1064nm + 1/3 1470nm, e.g. 45W = 30W@1064nm + 15W@1470nm

Fire the laser and use the power meter to check whether the output is within the tolerance limits:

Power selected [W] P@980nm + P@1470nm or P@1064nm + P@1470nm	**Power Value [W] +/- 20%** Min / **Nominal /** Max	**Actual value**	**Passed**	**Failed**	**Comment**
4 + 2	4,8 - **6** - 7,2				
8 + 4	9,6 - **12** - 14,4				
16 + 8	19,2 - **24** - 28,8				
30 + 15	24 - **45** - 54				
40 + 15	44 - **55** - 66				***Only for Dual 100**
50 + 15	52 - **65** - 78				***Only for Dual 100**
60 + 15	60 **75** - 90				***Only for Dual 100**
70 + 15	68 - **85** - 102				***Only for Dual 100**
80 + 15	76 - **95** - 114				***Only for Dual 100**
85 + 15	80 - **100** - 120				***Only for Dual 100**

B1. Puls-Test at Leonardo® 1064 / Leonardo® 1470 / Leonardo® 1940

Put the laser into **pulse mode.**
- Pulse duration: 1 sec. / Pulse pause: 0.3 sec.
- No. of pulses: 3

Observe the pulse count and treatment energy [J] displayed.

Power selected [W] P@1470nm or P@1064nm	**Energy Value [J] +/- 20%** Min / **Nominal /** Max	**Actual value**	**Passed**	**Failed**	**Comment**
2	4,8 - **6** - 7,2				
5	12 - **15** - 18				
10	24 - **30** - 36				
15	36 - **45** - 54				***Only for 1064 / 1470**
20	48 - **60** - 72				***Only for 1064**

B2. Puls-Test at Leonardo® Dual 45 and Dual 100

Put the laser into **pulse mode.**

➔ Laser setting: 2/3 980nm + 1/3 1470nm, e.g. 45W = 30W@980nm + 15W@1470nm

OR

➔ Laser setting: 2/3 1064nm + 1/3 1470nm, e.g. 45W = 30W@1064nm + 15W@1470nm
- Pulse duration: 1 sec. / Pulse pause: 0.3 sec.
- No. of pulses: 3

Observe the pulse count and treatment energy [J] displayed from P (min) to P (max).

Power selected [W] P@980nm + P@1470nm or P@1064nm + P@1470nm	**Energy Value [J] +/- 20%** Min / **Nominal /** Max	**Actual value**	**Passed**	**Failed**	**Comment**
4 + 2	14,4 - **18** - 21,6				
8 + 4	28,8 - **36** - 43,2				
16 + 8	57,6 - **72** - 86,4				
30 + 15	108 - **135** - 162				
40 + 15	132 - **165** - 198				***Only for Dual 100**
50 + 15	156 - **195** - 234				***Only for Dual 100**
60 + 15	180 - **225** - 270				***Only for Dual 100**
70 + 15	204 - **255** - 306				***Only for Dual 100**
80 + 15	228 - **285** - 342				***Only for Dual 100**
85 + 15	240 - **300** - 360				***Only for Dual 100**