

## LEONARDO®

### INSTRUCTION MANUAL



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# LEONARDO®

## INSTRUCTION MANUAL

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## 1 Safety provisions and regulations

The LEONARDO® laser system 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.

The LEONARDO® laser is a class 4 medical laser according to Directive EN 60825-1:2003. 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.

### **Caution: Direct eye exposure to the laser light leads to irreversible eye damage!**

The laser system is not suitable for ophthalmological applications.

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.

Only use protective eyewear provided or approved by *CeramOptec*. Suitable protective eyewear can also be obtained from *CeramOptec* (see also the recommendations in section 5.2).

### **Safe distance – NOHD (Nominal Ocular Hazard Distance):**

The safe distances for the following devices are:

<b>LEONARDO® Dual45:</b>	<b>410 cm</b>
<b>LEONARDO® 1470 :</b>	<b>63 cm</b>

from the laser outlet or from the emitting fiber.

Note that a greater distance must be maintained when using certain handpieces in derma mode (see section 4.6.5).

**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.

**Attention:** The LEONARDO® laser may only be used with the accompanying footswitch and the specified application and light delivery systems.

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.

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 two year basis (see section 8.4).

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 bodily 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*.

**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 9.4).

## 2 Product description

LEONARDO® is a laser system 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 / 1470 nm +/-30 nm (aiming beam 635 nm +/-10 nm and 532 nm +/-10 nm). Depending on the model, your LEONARDO® laser has a maximum laser output power of 15 W (1470 nm) or 30 W (980 nm).

LEONARDO® is available as a device with two wavelengths (980 nm and 1470 nm) or as a single-wavelength device with 1470 nm.

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, depending on the configuration of the unit. 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 optical fibers used. Application fibers from *CeramOptec* have coding for communicating with the laser device.

For delivery details, refer to section 5.1.

### 2.1 Intended use and indications

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

LEONARDO® is suitable for the following fields of application: incisions, excisions, vaporization, ablation, hemostasis or coagulation of soft tissue in the following areas:

- ENT (turbinectomy, LAUPP, septum, paracentesis, tonsillotomy, laryngeal cancer, hemangioma, adhesions, epistaxis, DCR)
- Pulmonology (coagulation and vaporization of endobronchial tumors)

- Colorectal surgery (laserhemorrhoidoplasty), anal fistulas (FiLaC), 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)
- Dermatology (DUAL 45): Telangiectases, spider naevi, hemangioma, spider veins, vascular malformations, warts, lentigo

Intended user: Hospitals, Ops and set up physicians.

Patient population: Ages, weight and state of health: The attending physician decides here.

### 2.1.1 Recommended lasers for indications

Indication	ENT / Otorhinolaryngology										Pulmonology		Colorectal surgery										Endovenous ablation of surface veins				Dermatology
	turbinectomy	LAUPP	septum	paracentesis	tonsillotomy	laryngeal cancer	hemangioma	adhesions	epistaxis	DCR	coagulation & vaporization of endobronchial stenoses	coagulation & vaporization of endobronchial tumors	(laserhemorrhoidoplasty)	anal fistulas (FiLaC)	soft tissue tumors	polyps (polyposis coli and/or villous adenoma)	anal stenoses	condylomata accuminata	fissures	mariscae	coccygeal fistulas	saphenous veins (magna and parva)	tributaries	perforant veins	recurrences	venous leg ulcers	Telangiectases, spider naevi, hemangioma, spider veins, vascular malformations, warts, lentigo
Laser model																											
LEONARDO® 1470	X	X	X	X	X	X	X	X	X	-	X	Xx	X	X		X	X	X	X	X	X	X	X	X	X	X	-
LEONARDO® Dual 45	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X



## **2.2 Contraindications**

No contraindications are currently known for the LEONARDO<sup>®</sup> laser when used as intended.

## **2.3 Side effects**

Burning of the target tissue may occur if the intensity of the laser is set too high. Swelling, bleeding or fever may occur as a result of improper use of the laser.

### 3 Description of the device

#### 3.1 Controls and connections

- [1] Screen
- [2] Emergency stop button
- [3] Laser outlet
- [4] Laser warning light
- [5] Standby button



Figure 1: Front of the device

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



Figure 2: Rear of the device

**Note:** Detailed descriptions of labeling are provided in section 0.

3.2 Description of controls, displays, connections

3.2.1 Controls

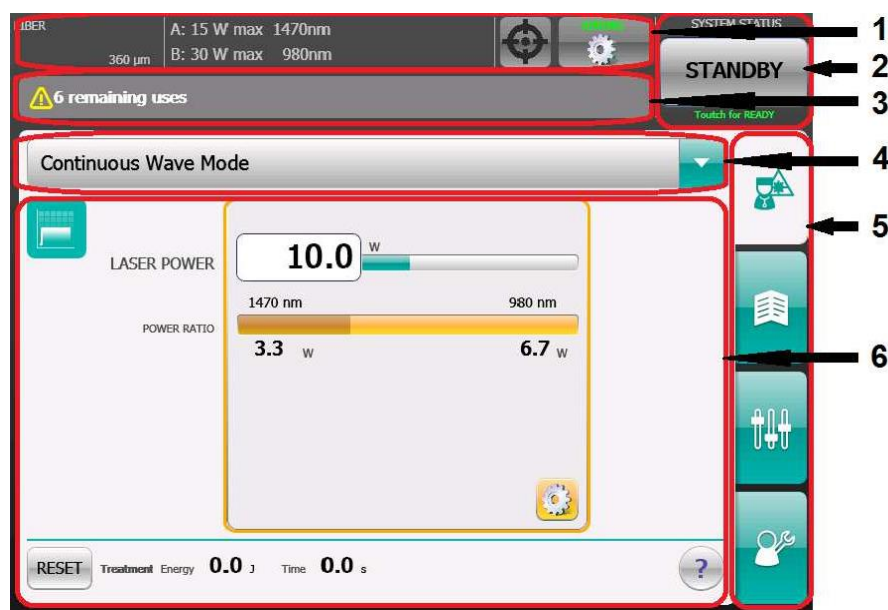













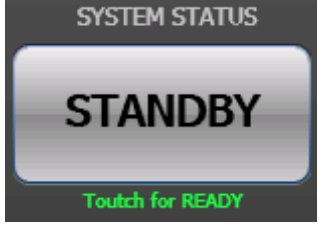
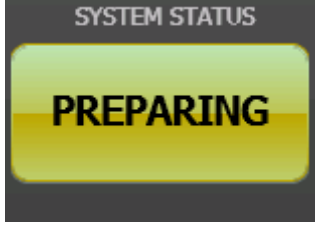



Figure 3: Subdivision of the operating interface

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

Screen [1]	<p>The display is subdivided into four main key fields and shows:</p> <ul style="list-style-type: none"><li>- Status of the device (Enable/Standby)</li><li>- Treatment mode (Continuous mode (Continuous Wave CW), Pulse mode and additional programs (optional))</li><li>- Treatment parameters (duration, energy, pulse parameter)</li><li>- Power settings</li><li>- Fiber information</li><li>- Aiming beam settings</li></ul> <p>Settings can be changed via the key fields and the cursor on the screen.</p>
Key fields on the screen [1]	<ul style="list-style-type: none"><li>- Switch between enable and standby status</li><li>- Change treatment mode (Continuous mode, Pulse mode and additional programs (optional))</li><li>- Select the parameter to be configured</li><li>- Aiming beam (Off, On, CW mode or Pulse mode with intensity setting)</li><li>- Save changed treatment modes</li><li>- Select function</li></ul>

Key fields next to the screen	
<b>Emergency stop button [2]</b>	Pressing the emergency stop button interrupts the power supply of the laser diodes and averts an emission of laser radiation. <b>Only press the laser stop button in case of emergency.</b>
<b>Laser standby [5]</b>	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	
	<b>Treatment modes</b> Here you can select and set the treatment mode.
	<b>Info screen</b> Instructions for use and additional information about using lasers can be retrieved and read on screen.
	<b>Video area</b> Treatment videos provided by biolitec biomedical technology GmbH can be viewed here (coming soon).
	<b>Online shop for accessories</b> (coming soon).
	<b>User settings</b> Device version number, language version, aiming beam settings.
	<b>Feature settings</b> These settings are only to be used by the service staff of <i>CeramOptec</i> or other authorized personnel.

Selecting treatment modes	
 Continuous Wave Mode	Continuous mode (Continuous Wave mode, CW)
 Pulse Mode	Pulse mode
 ELVeS® Signal	ELVeS® signal mode
 ELVeS® Segment	ELVeS® segment mode
 Dermatology	Derma mode (for LEONARDO® Dual 45 only)
Header	
	<b>PILOT ON / OFF</b> The pilot beam can be turned on or off and indicates if it's turned on. Furthermore, the color of the pilot beam is displayed.
	<b>PILOT beam settings</b> Pilotbeam color, intensity and operation mode (CW/Pulse) can be adjusted
	<b>SYSTEM STATUS</b> 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.
<b>Laser warning signal [4]</b>	When laser radiation is emitted, the LED warning light comes on and a warning signal is sounded.

Side of the device	
<b>Laser outlet [3]</b>	<p>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.</p> <p><b>Caution:</b> Only use approved application systems, fibers, and medical probes (see section 6). The use of non-approved systems may damage the unit and result in dangerous exposure to radiation. Noncompliance invalidates the warranty.</p>
<b>Application fibers</b>	<p>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.</p> <p><b>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.</b></p>
Rear of the device	
<b>Power connection [6]</b>	<p>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.</p>
<b>Footswitch [7]</b>	<p>The footswitch must be connected to the device using the plug connector at the rear of the device.</p> <p>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.</p> <p><b>The laser emits radiation only as long as the footswitch is pressed.</b></p> <p>Laser emission continues once you press the footswitch again.</p>
<b>Door interlock [8]</b>	<p>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.</p> <p><b>Caution:</b> You must ensure that <b>no</b> voltage is connected to this port.</p>
<b>On-off switch [9]</b>	<p>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 (see page 10 and 12 [5]).</p>
<b>Service Port [10]</b>	<p>Using the service port is reserved for persons who are authorized by CeramOptec.</p>

## 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]. You must use a power cable with Earth Ground (included in delivery) and a power outlet with an approved earth ground.

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



Figure 5: Foldable footswitch

The footswitch is included in the delivery and is to be attached to the footswitch connector on the rear of the device.

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

### 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).

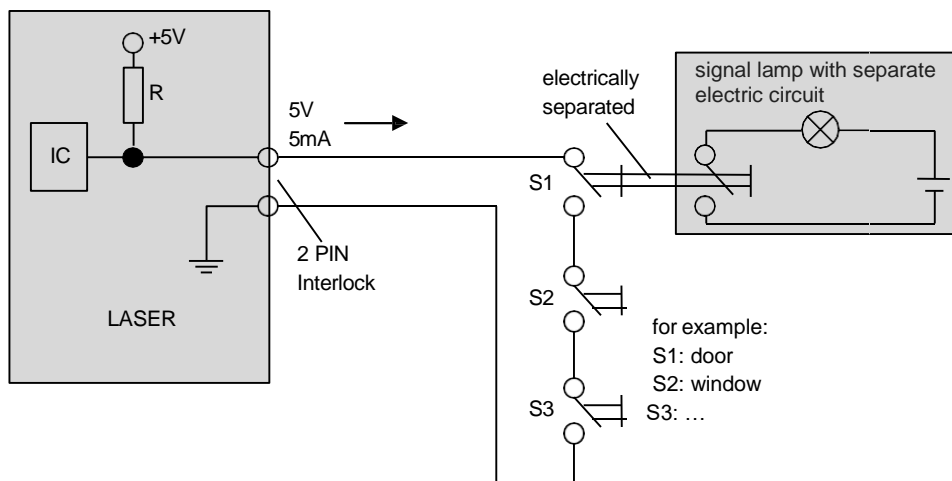


Figure 6: Door interlock connection scheme

**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.



## 4.2 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.



Figure 7: Start screen 1

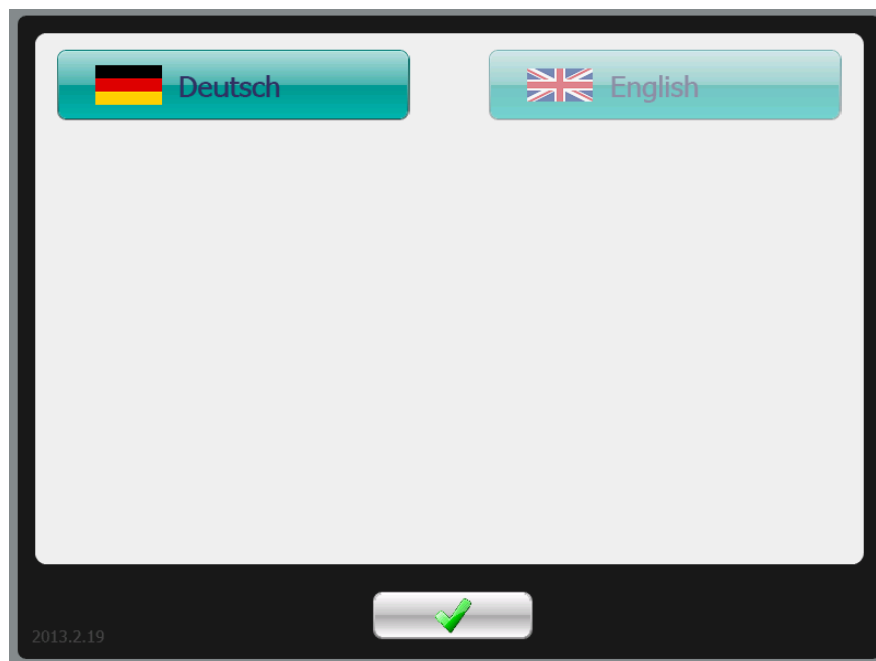


Figure 8: Start screen 2 (Selecting the language the first time the device is switched on)

The language used by the user interface needs to be entered the first time the device is switched on. This setting is requested just once, and only if the device does not have a saved preset language.

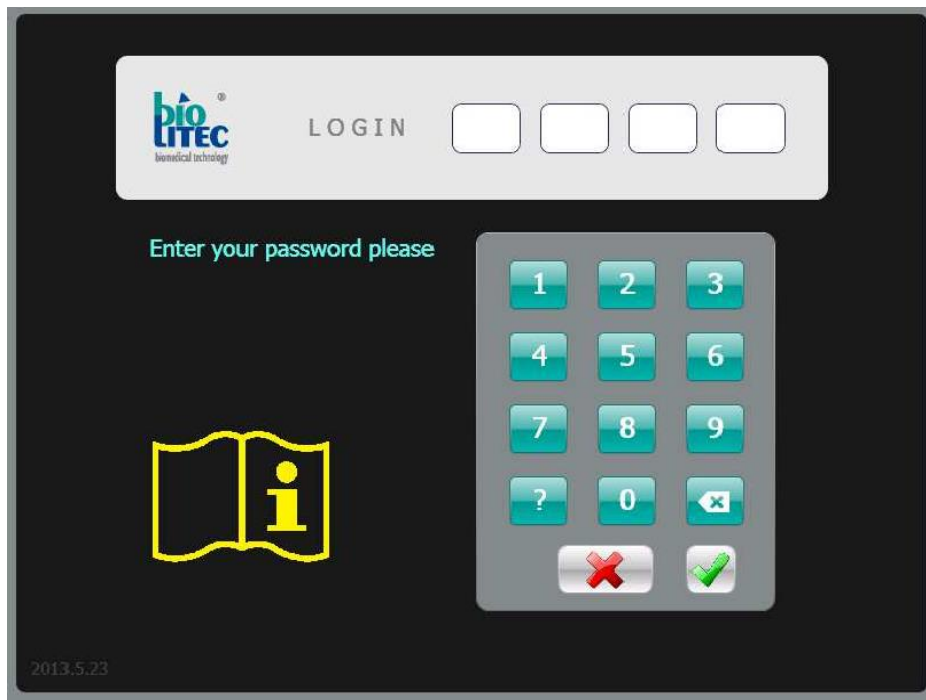


Figure 9: Login screen. The device activates after entering the number code

The access code is entered using the numeric keypad. By pressing OK the code is being submitted and the device switches to 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.

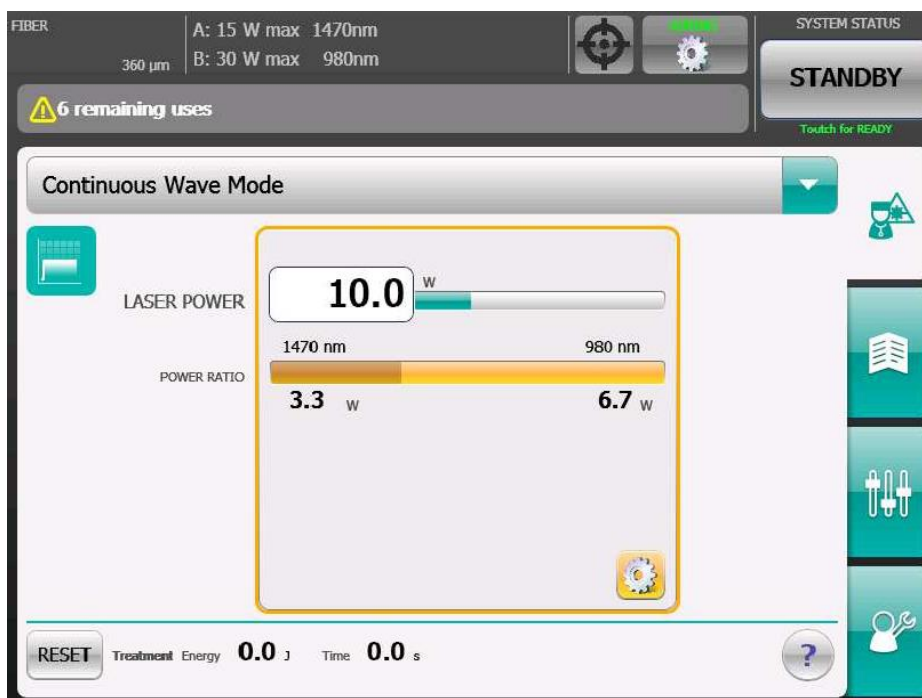


Figure 10: An example of the monitor display when CW mode was the last active mode (for dual-wavelength devices)

The monitor will display the following for single-wavelength devices:

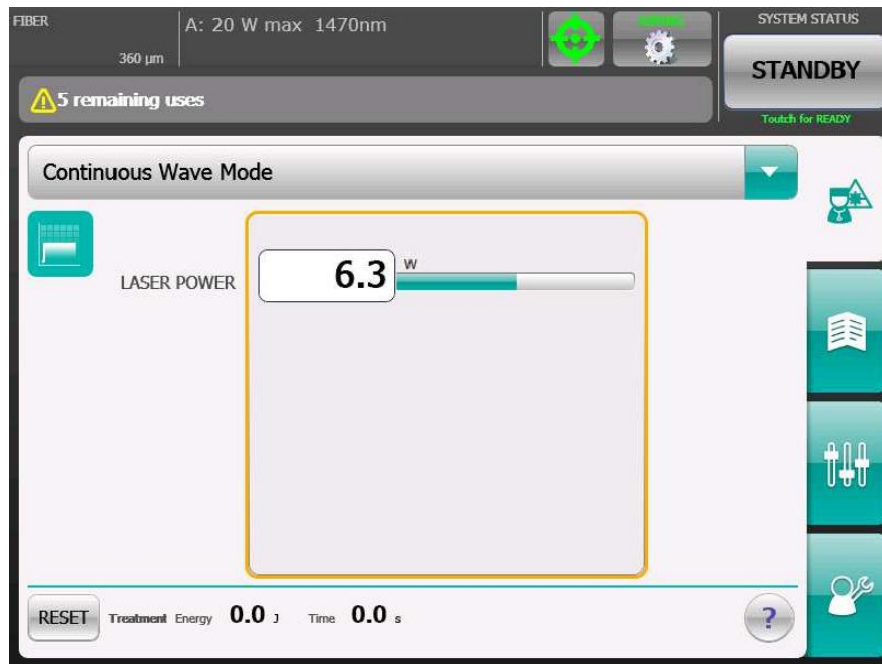


Figure 11: An example of the monitor display when CW mode was the last active mode (for single-wavelength devices)

## 4.3 Settings and parameters for all treatments

### 4.3.1 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.

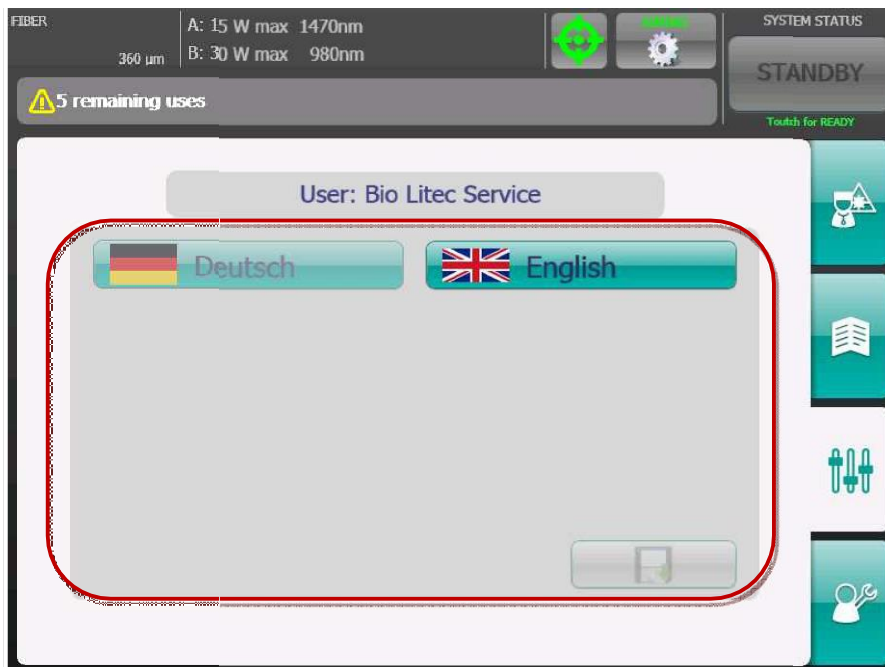



Figure 12: Menu item: language setting

### 4.3.2 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.

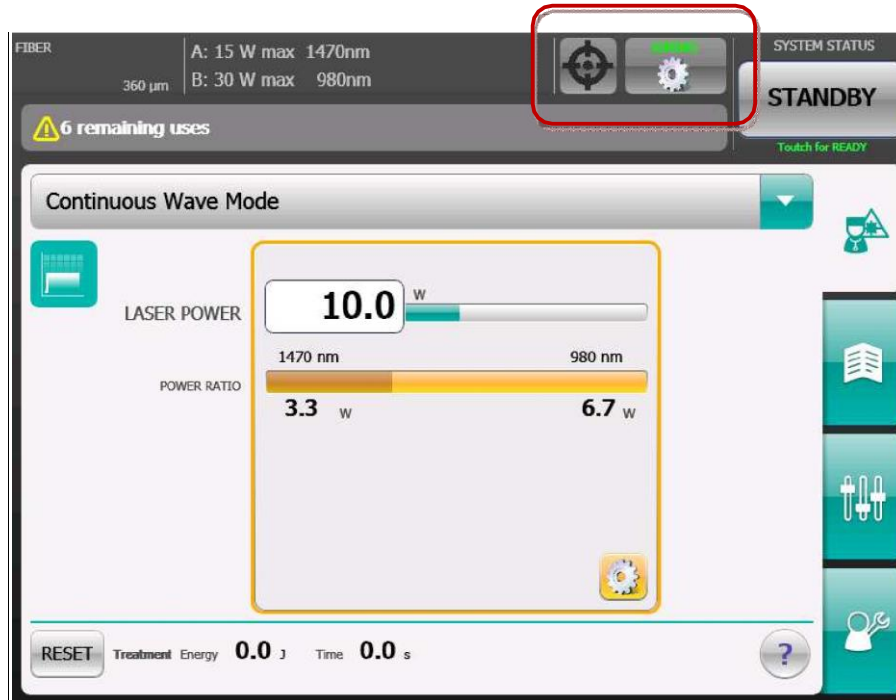


Figure 13: Menu item: setting the aiming beam

You can configure a number of different settings for the aiming beam (see illustration 14). 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 intensity selected. The operation panel can be used to set the aiming beam to green or red.



Figure 14: Setting the aiming beam in any application mode by using the PILOT box

### 4.3.3 Help system

Help is available for every treatment mode in the form of brief instruction guides. This information can be accessed by clicking the question mark icon on the screen.

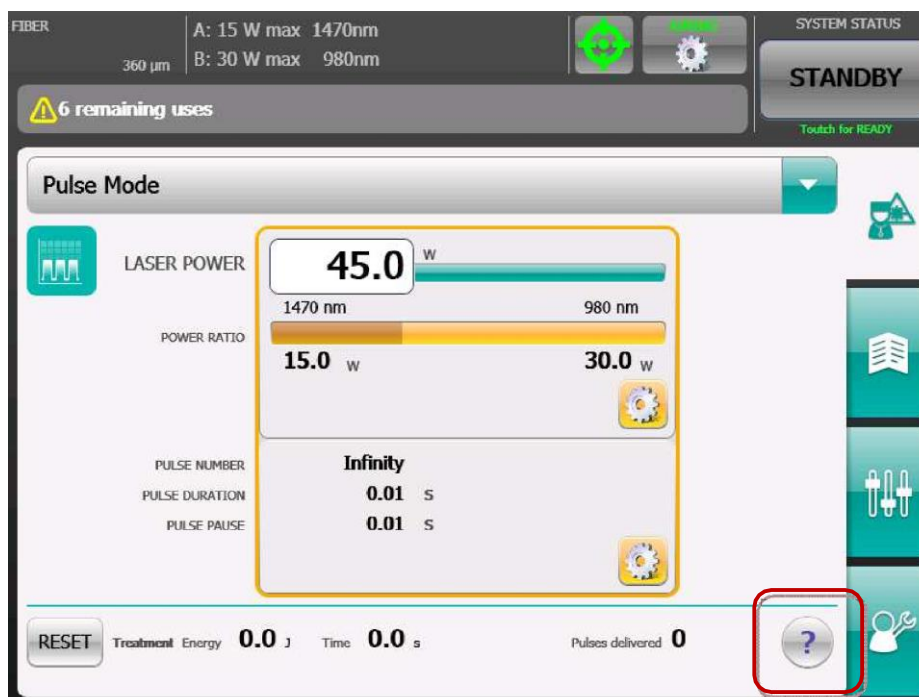


Figure 15: Controls for Help

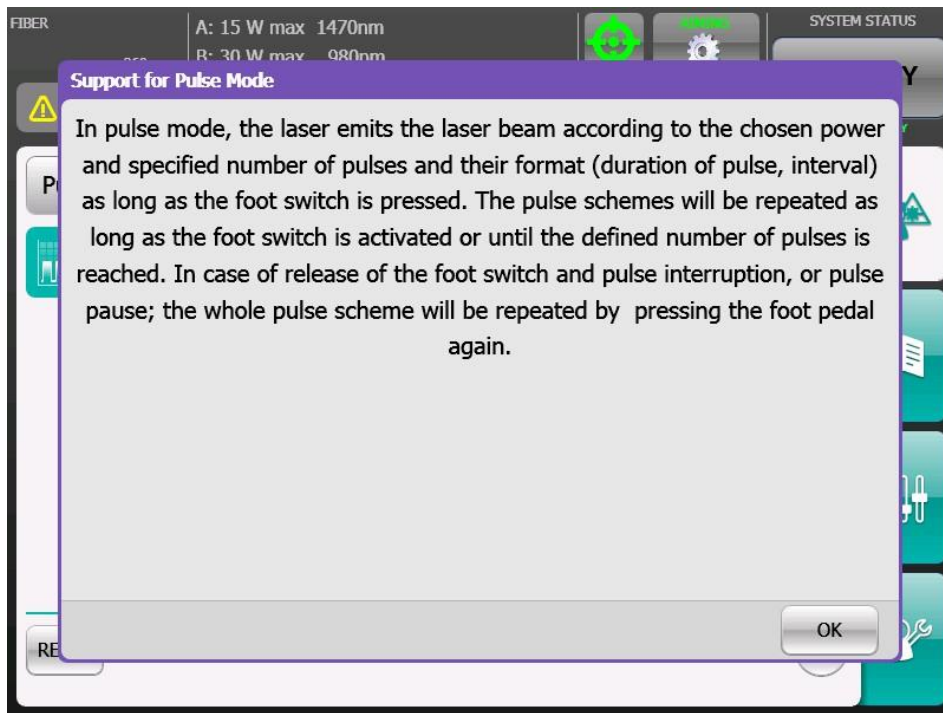


Figure 16: Help for Pulse mode

The help windows are marked by the violet frame and are intended to deliver quick information to the user that can be helpful while using the application.

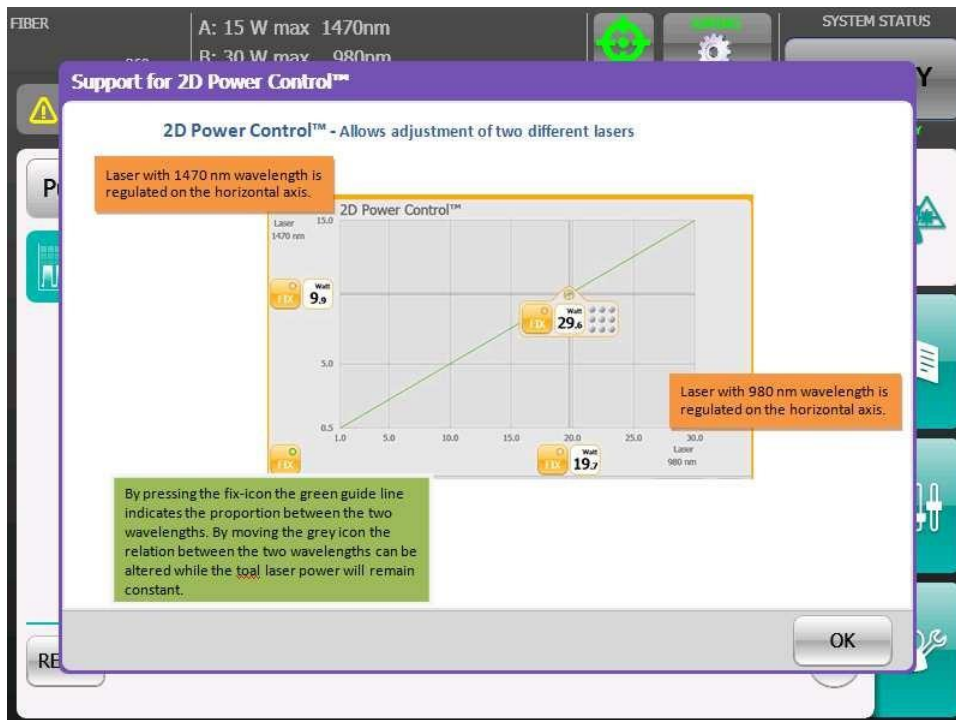


Figure 17: Help for 2D Power Control™ (not available in single-wavelength devices)

In case the brief instruction guide is not sufficient, by clicking the question mark you can find the respective section in the user manual that is saved in the device. It can be found via the info screen as well. A hard copy user manual is included in the delivery and should therefore also be available.



## 4.4 Extras

### 4.4.1 Info screen

The instructions for use and further information about the treatment modes and laser therapies can be viewed by pressing the corresponding button.

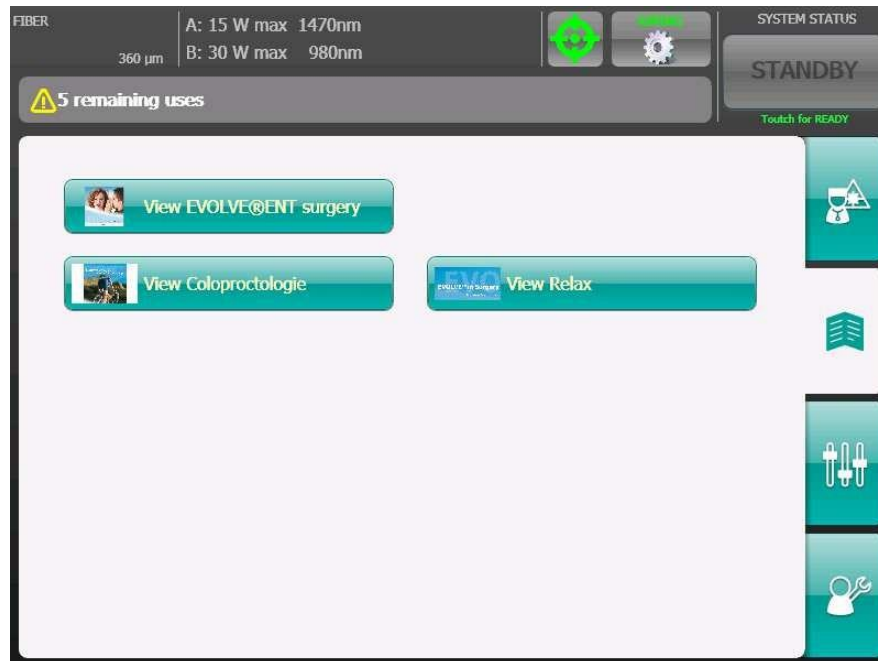


Figure 18: Information screen

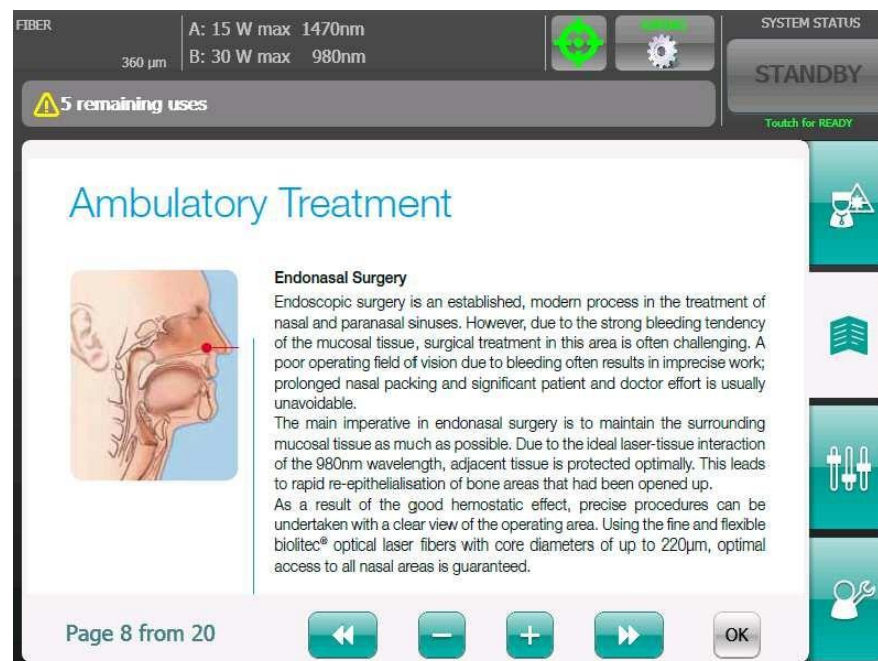


Figure 19: Navigating document display

By clicking the -/+ button you can scroll to the previous/next pages.

By pressing << you can directly jump to the first page of the document, by >> to the last one.

#### 4.4.2 User administration

This device has functionality for administrating more than one user. This allows each individual user to work with his or her laser settings after logging in. User administration can be accessed by entering and confirming the ADMIN password (53121) via the login screen.

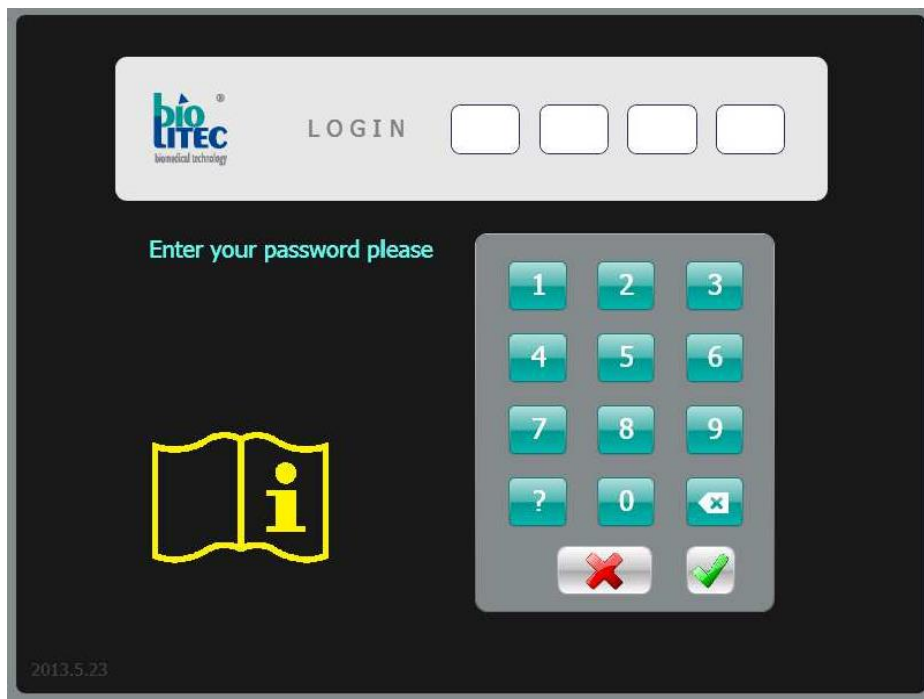




Figure 20: Login screen

It is possible to add, edit and remove users. These options appear in the pop-up window that appears after the ADMIN password has been confirmed.

Pressing the  and  buttons in the lower right of the screen closes user administration.

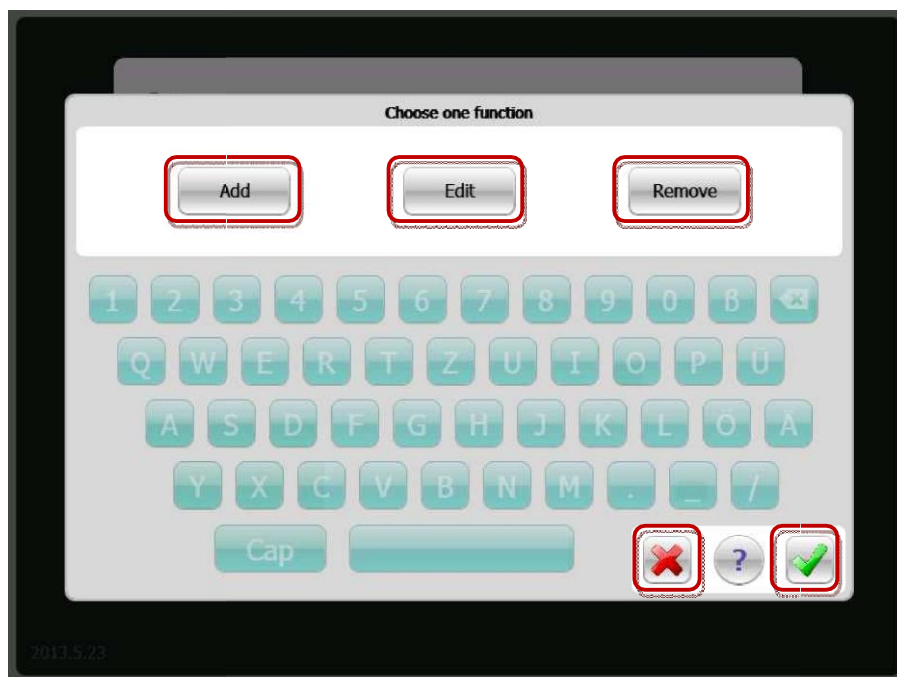




Figure 21: User administration option menu

To create a new user, press the “Add” button. This opens the fields for defining the new user:



- **User name**
- **Comment**
- **Setting number:** Laser settings can be defined here. Different users can have the same setting number – this allows them to use the same saved laser settings. If one user changes these laser settings, the change will then affect all users who have the same setting number.
- If one user would like to keep his or her laser settings independent of all other users, that user needs to be given a unique setting number that is not shared with any other users.
- **Password**
- **Repeat password**

When entering the parameters “Setting number”, “Password” and “Repeat password”, no letters may be used, so the letter keys on the touchscreen keyboard will appear in gray to show that they have been deactivated.

To save a new user, press the “disk” button  in the upper right of the screen. The  button in the upper right can be used to close the “Add” option without saving. After it is pressed, the option menu opens.

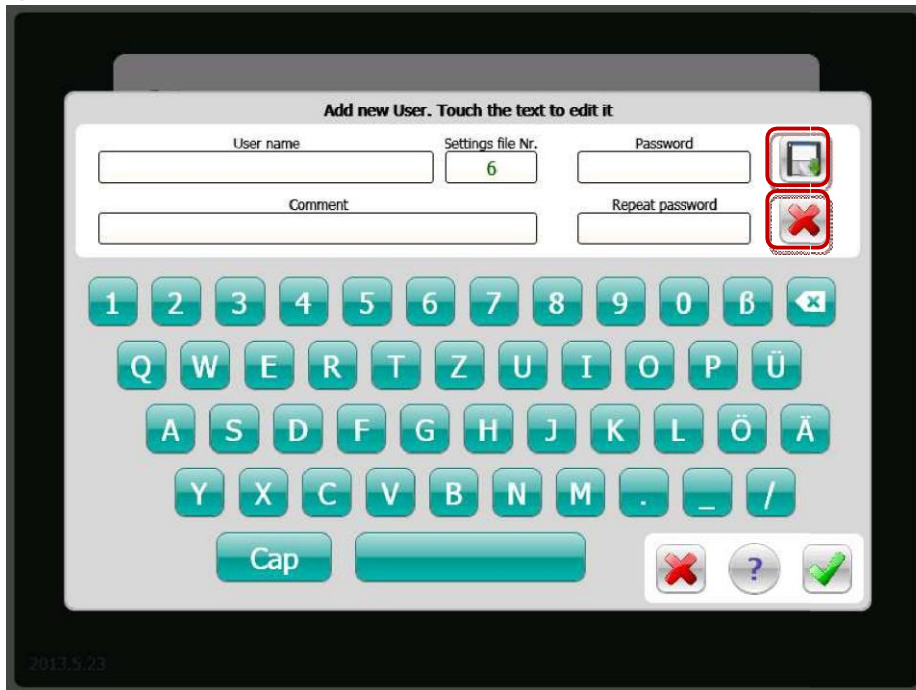




Figure 22: Add user

Choosing “Edit” from the option menu opens fields for making changes to existing user accounts. The user account you want to edit must be selected from the drop-down list in the upper left of the screen. Then the parameters “Comment” and “Password” (together with password confirmation) can be changed for the user you have selected.

When entering the parameters “Password” and “Repeat password”, no letters may be used, so the letter keys on the touchscreen keyboard will appear in gray to show that they have been deactivated.

To save changes to the user account, press the “disk” button  in the upper right of the screen. The  button in the upper right can be used to close the “Edit” option without saving. After it is pressed, the option menu opens.

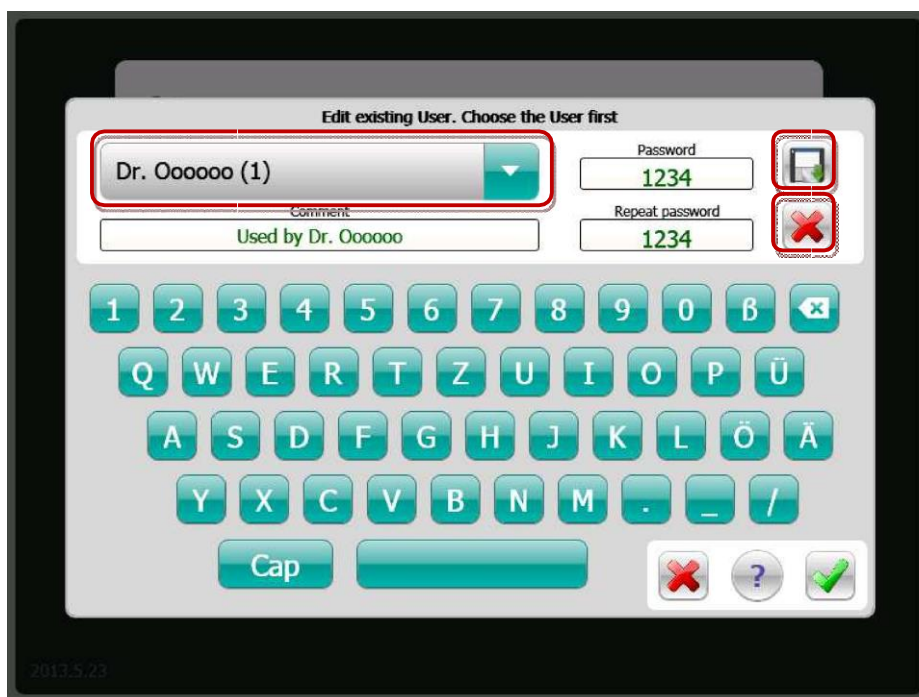




Figure 23: Edit user

To delete a user account, select “Remove” from the option menu. The user account you want to delete must be selected from the drop-down list in the upper left of the screen.

To remove the selected user account, press the “disk” button  in the upper right of the screen. The  button in the upper right can be used to close the “Remove” option without saving. After it is pressed, the option menu opens.

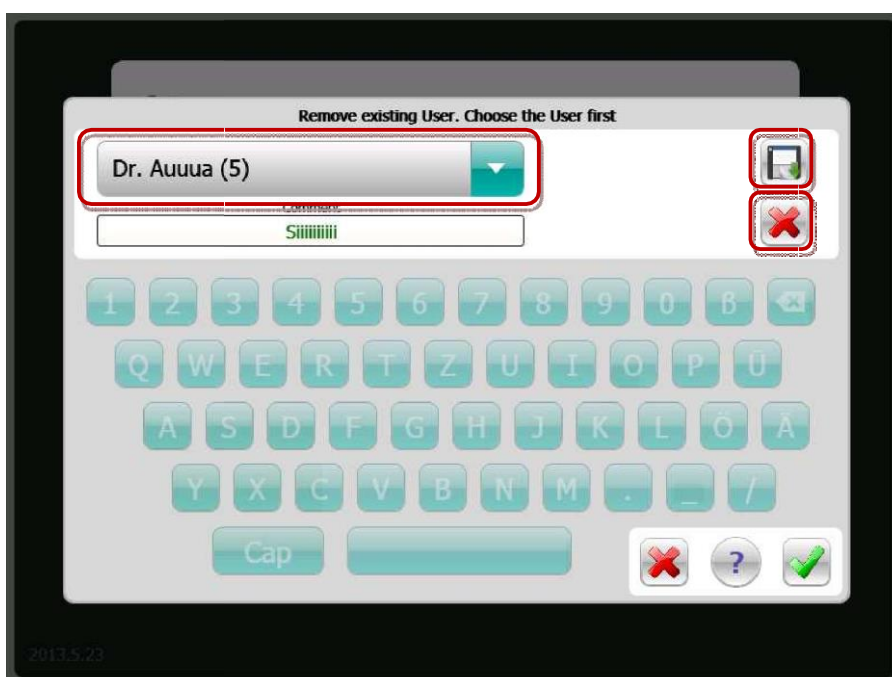


Figure 24: Remove user

#### **4.4.3 4.4.3 Video display**

Video display is still in the process of being prepared and will be installed on the device once it is ready.

#### **4.4.4 Online shop**

The online shop is still in the process of being prepared and will be installed on the device once it is ready.

## 4.5 Treatment

### 4.5.1 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).

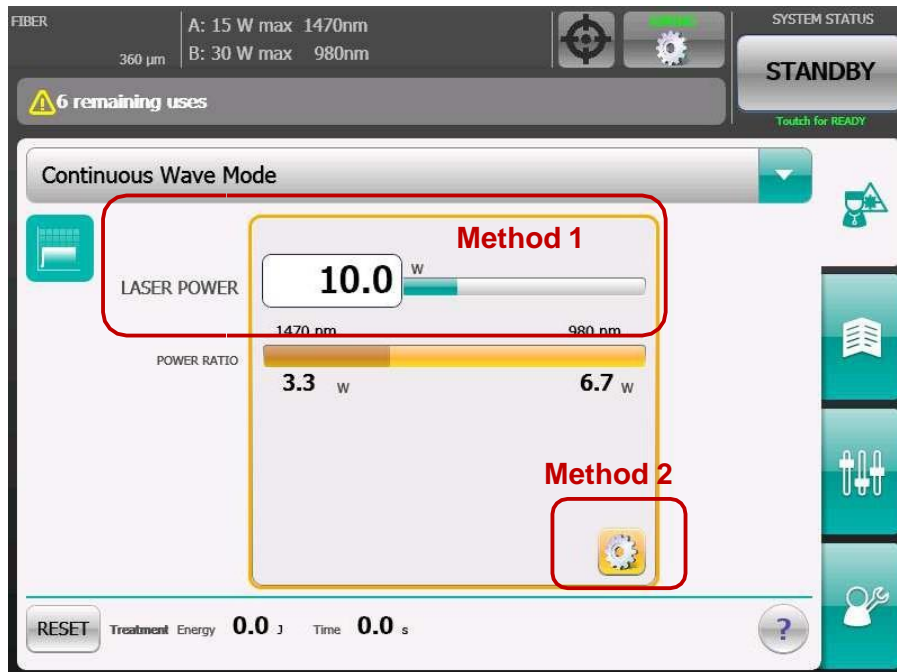


Figure 25: Setting the laser output for a dual-wavelength device

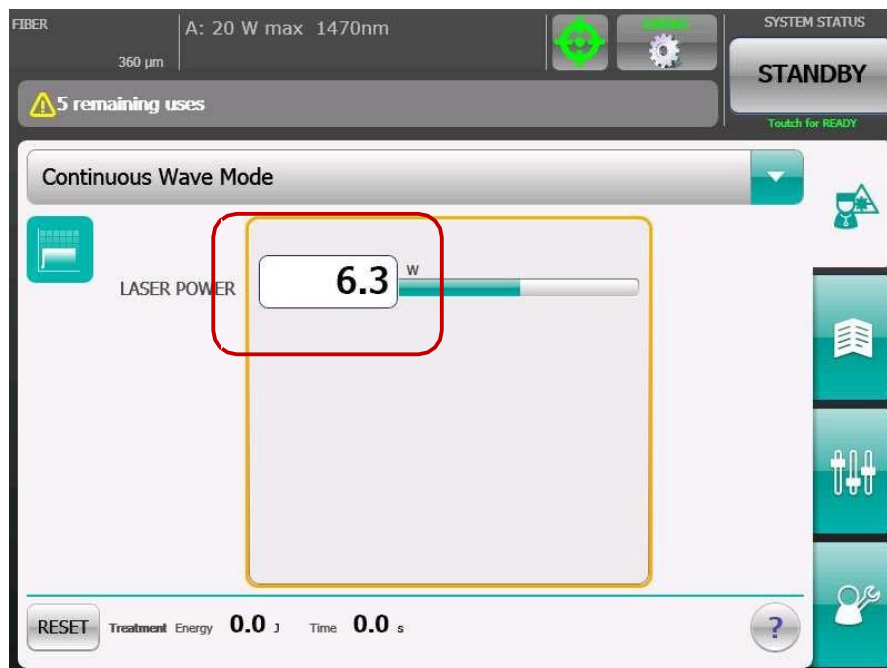


Figure 26: Setting the laser output for a single-wavelength device

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 27).

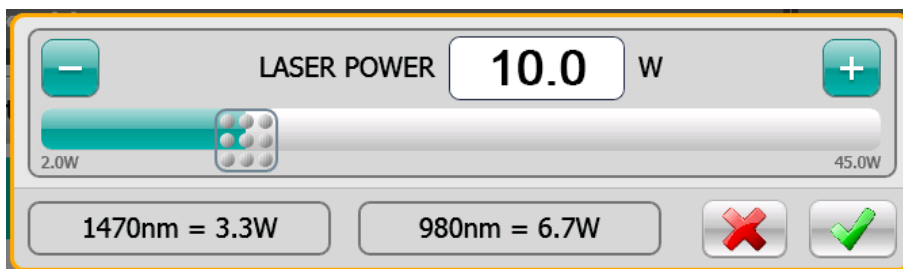




Figure 27: Setting the laser output for devices that emit one or two wavelengths

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 29). 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.

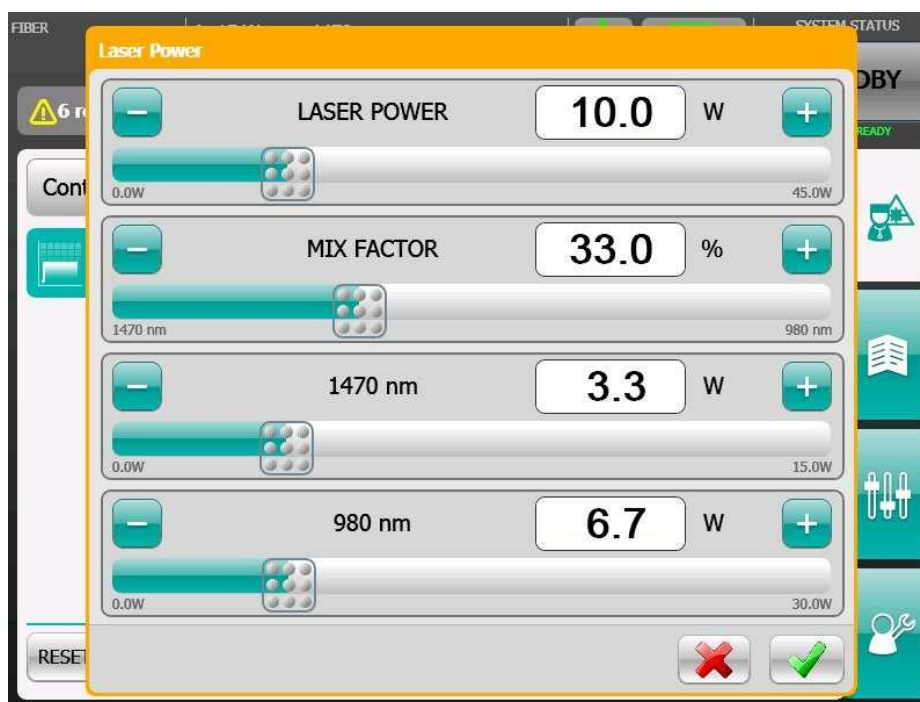


Figure 28: Laser power setting for dual wavelength without 2D Power Control™

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



**Figure 29: Method 2: Setting the laser power using 2D Power Control™**



**Figure 30: 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 31: 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 32: Fixing the power for the wavelength 1470 nm on the horizontal**






**Figure 33: Fixing the power for the wavelength 980 nm on the vertical axis**

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



**Figure 34: 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 1470 nm wavelength on the left and the power for the 980 nm wavelength on the right).



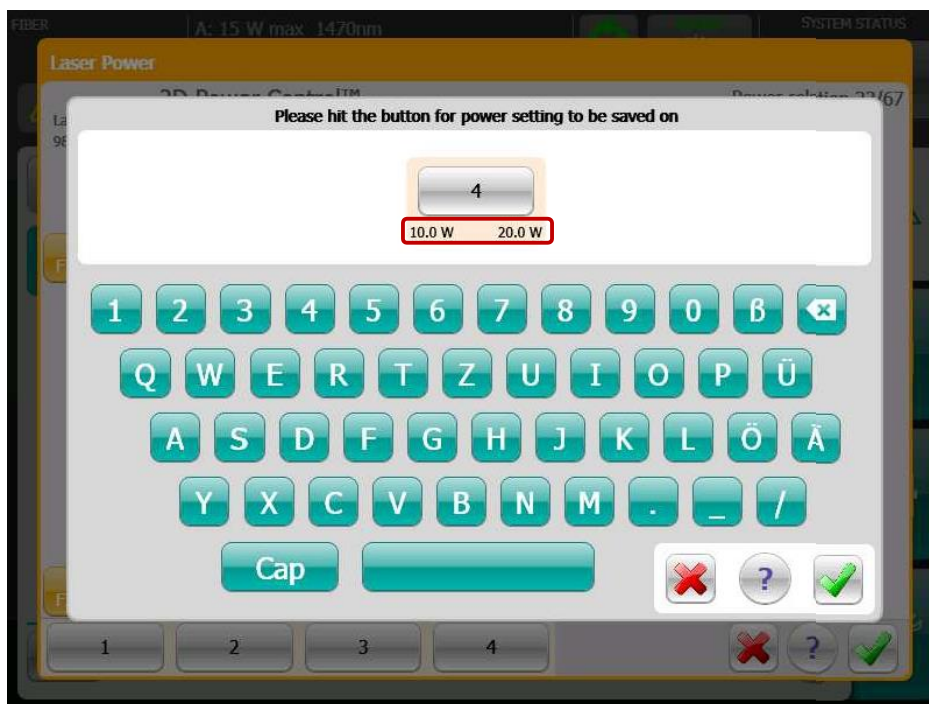


Figure 35: Pop-up window for saving the power setting

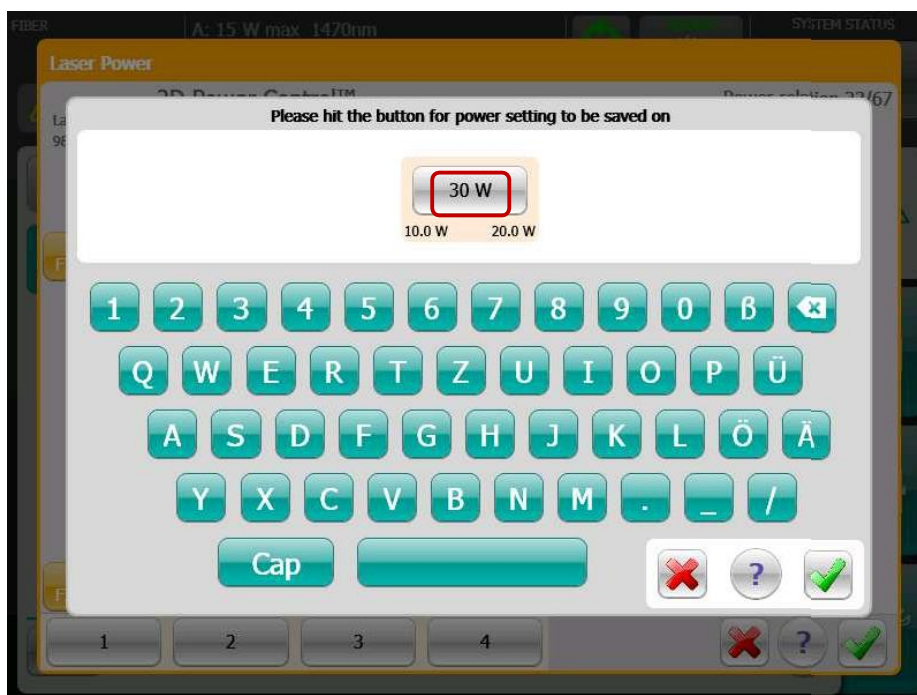


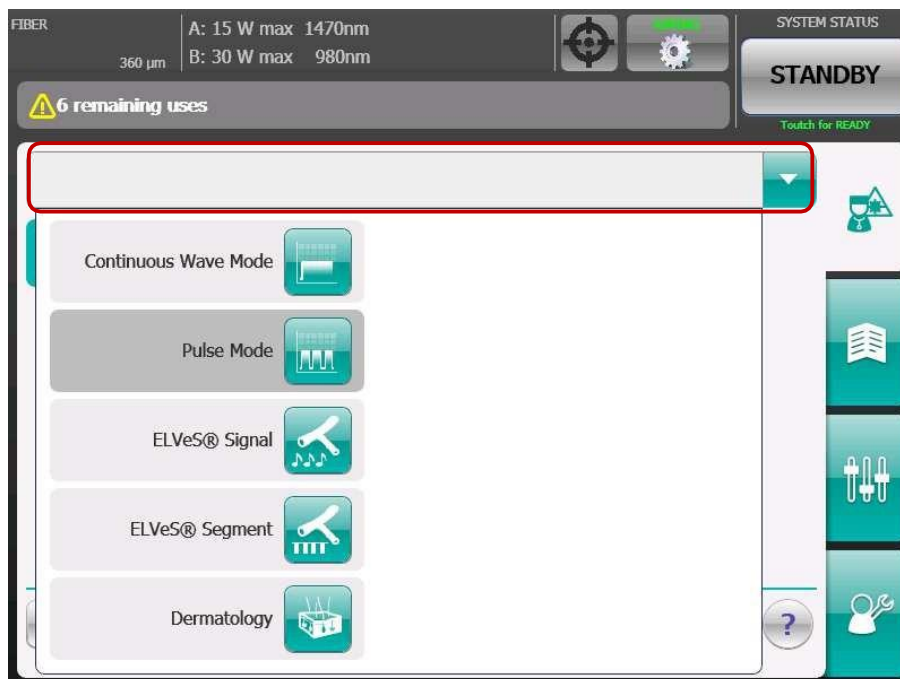


Figure 36: New name for the button

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

#### 4.5.2 Selecting 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 37: Selecting a treatment mode on the touchscreen**

## 4.6 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 pulling speed of the fiber from the vein via auditory signals. This speed is calculated from a combination of output and energy per signal that have been selected by the user.

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.

### 4.6.1 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 38: Screen display of Continuous mode CW in standby

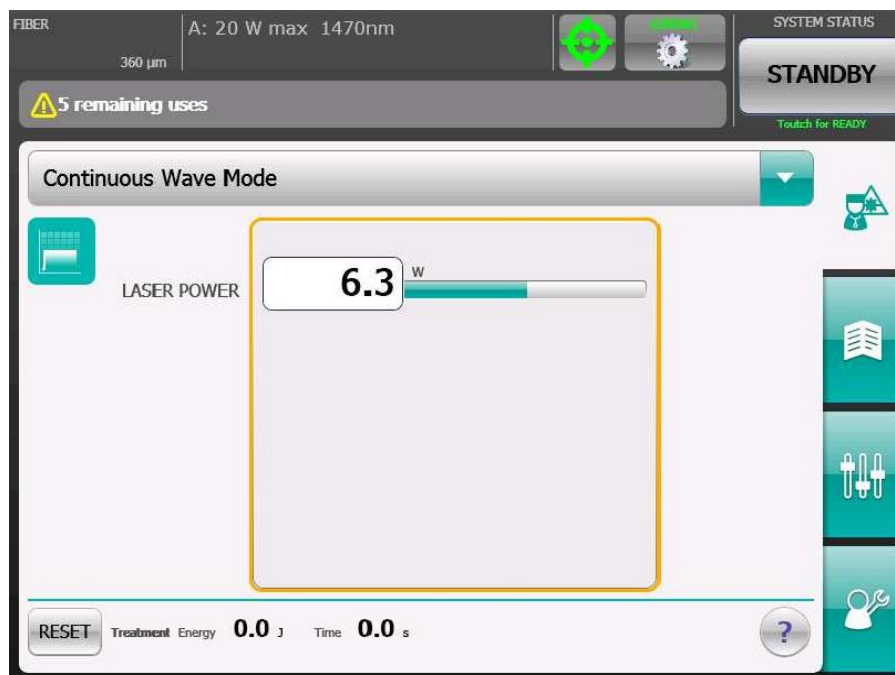


Figure 39: Screen display of Continuous mode CW (for devices that emit one wavelength)

Laser power can be set in continuous mode as shown in figures 26 - 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.

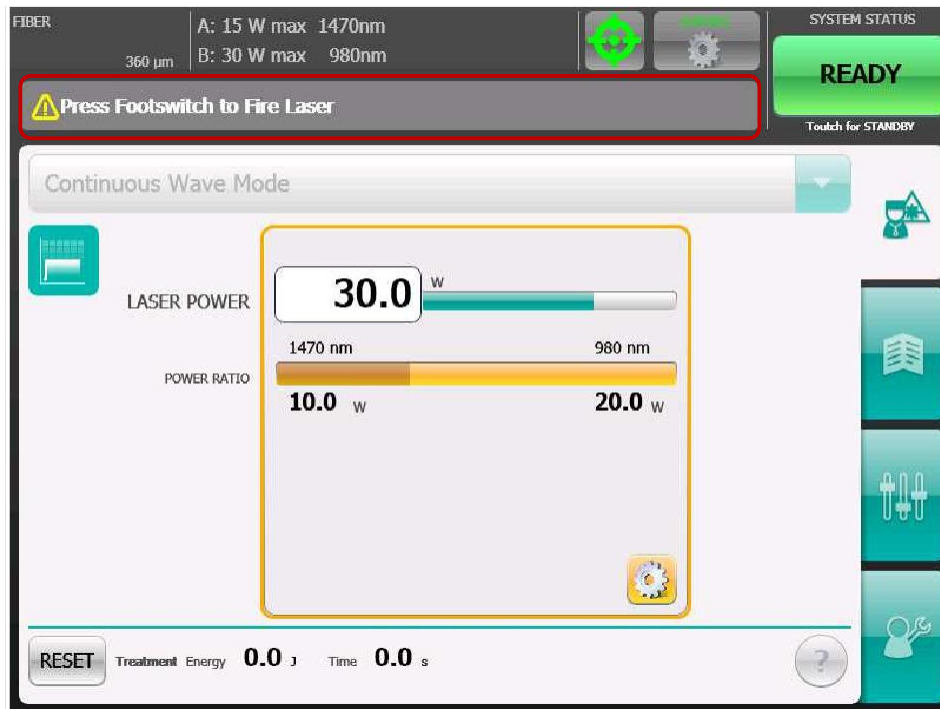


Figure 40: Display of laser ready for emission

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 end laser emission at any time by**

- releasing the footswitch
- pressing the "STOP LASER" 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:

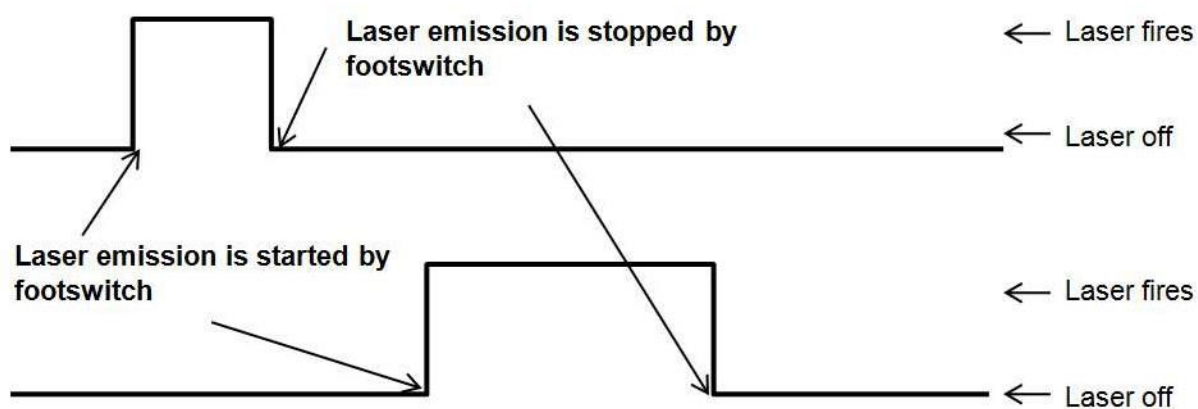


Figure 41: Examples for continuous mode

### 4.6.2 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.

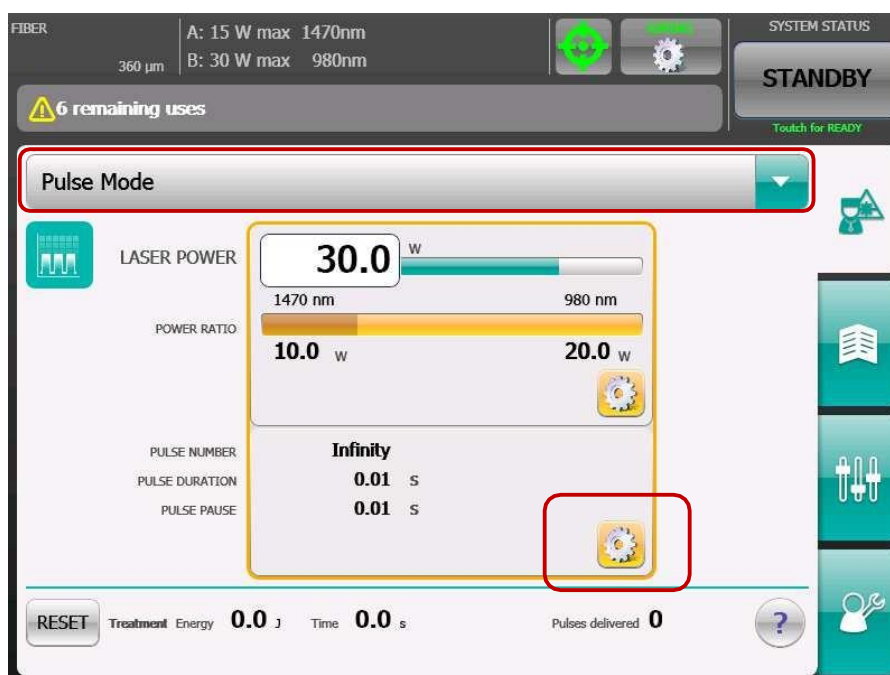




Figure 43: Screen display of Pulse mode (for devices that emit one wavelength)

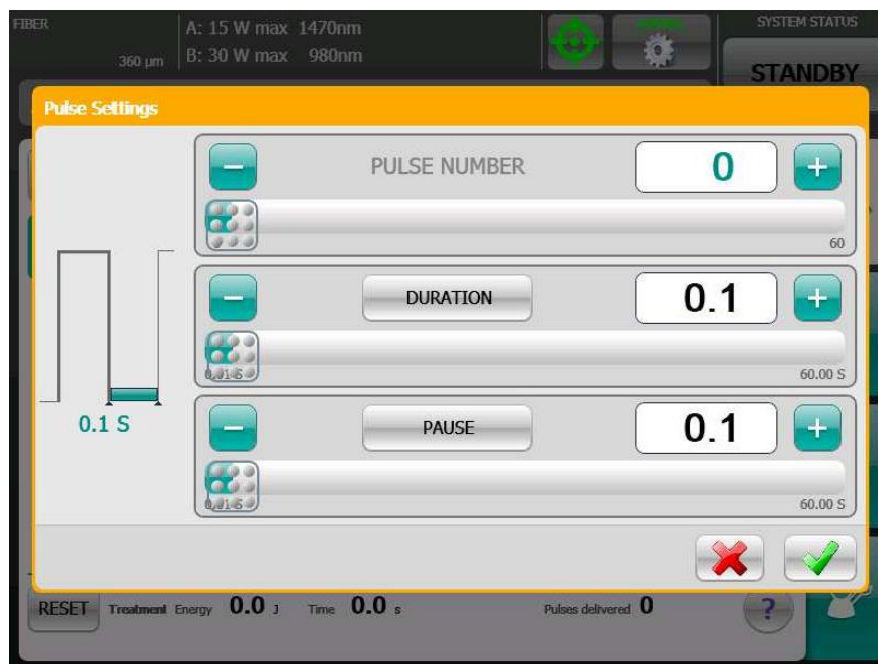


Figure 44: Screen display of Pulse mode, parameter settings

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.



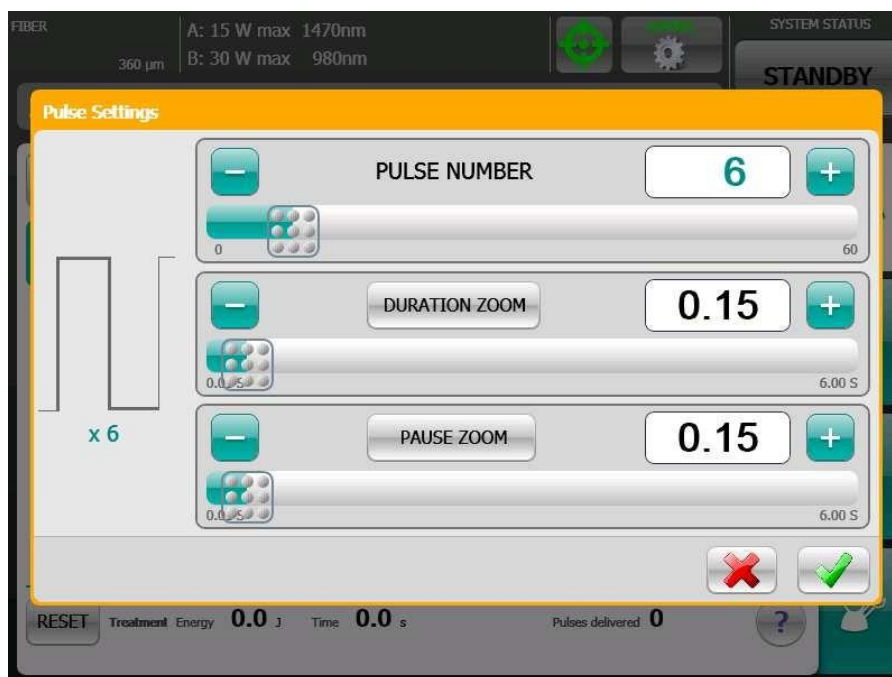






Figure 45: Pulse duration zoom settings

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 <i>repetition</i> (Number of pulses)	Pulse <i>duration</i> (Pulse length max value configurable by service assistant)	Pulse <i>pause</i> (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.

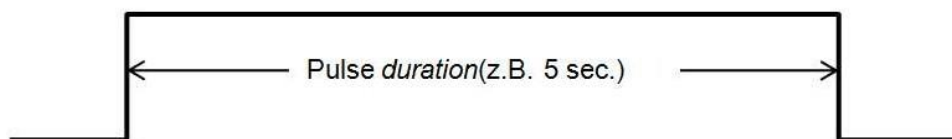
In PULSE MODE, the laser emits radiation at the selected power level with the specified number of pulses and pulse format (pulse duration, pulse pause) as long as the footswitch is pressed.

- Defined number of pulses → between 1 and max. 60 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:

sample 1:



sample 2:

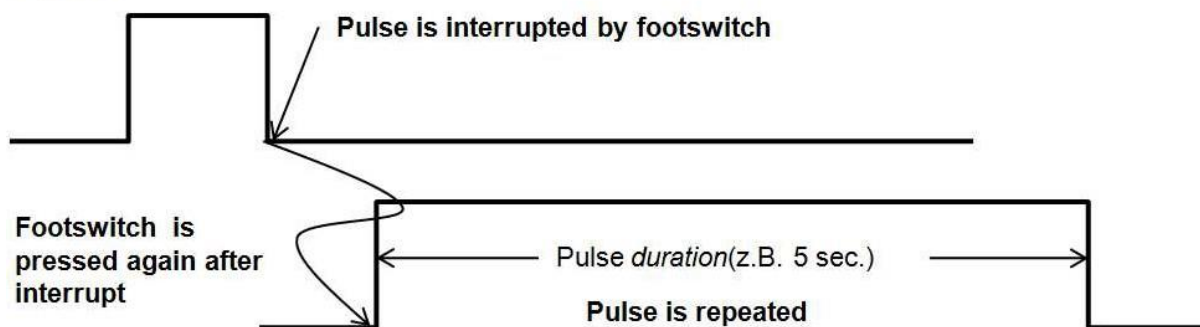
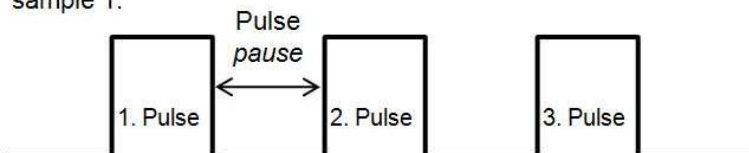


Figure 46: Single-pulse mode

## Multi-pulse Mode ( $\geq 2$ pulses):

sample 1:



sample 2:

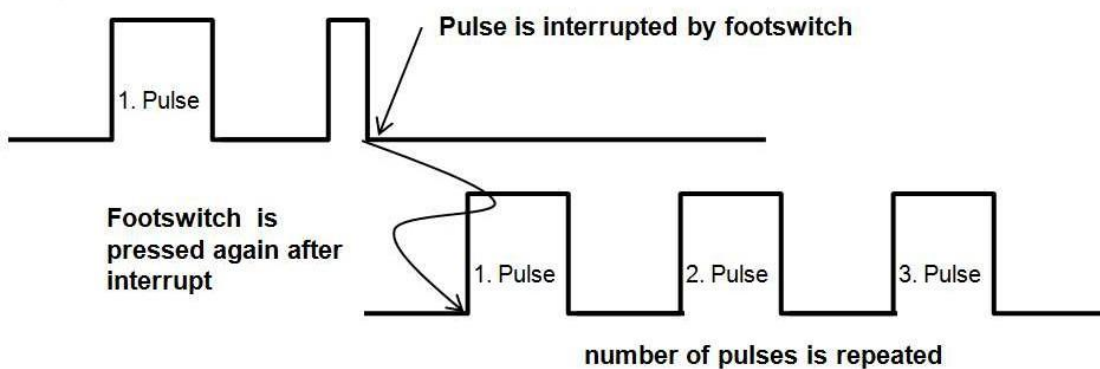


Figure 47: Multi Pulse mode



### 4.6.3 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.

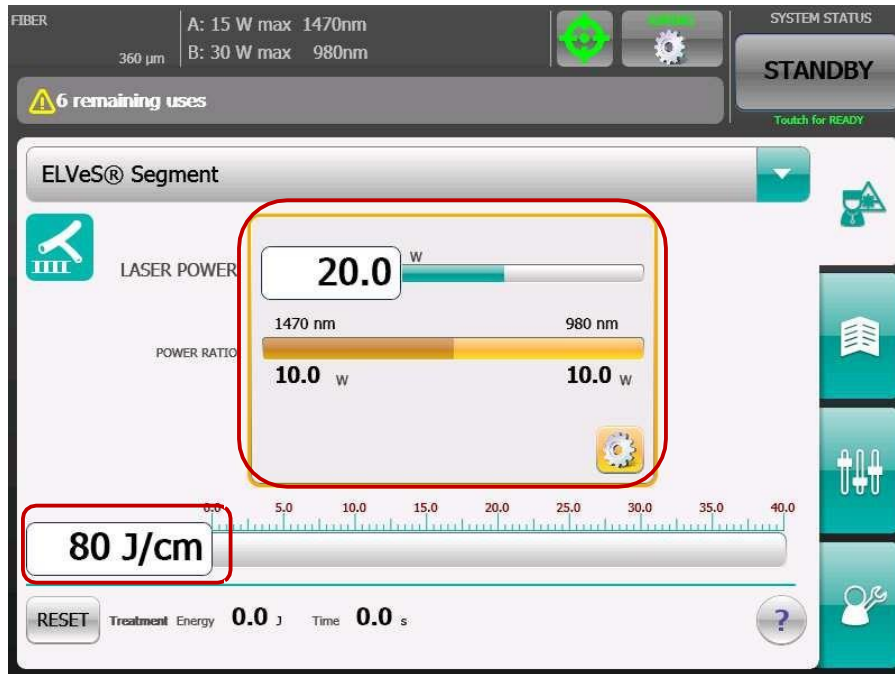


Figure 48: Start screen of ELVeS® segment mode for setting

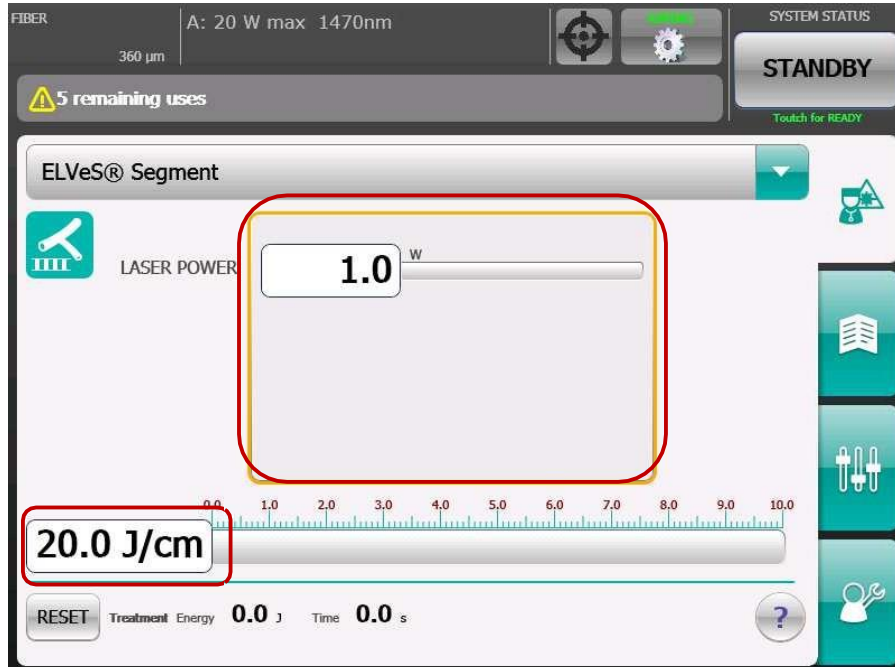


Figure 49: Start screen of ELVeS® segment mode for setting parameters (for devices that emit one wavelength)

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

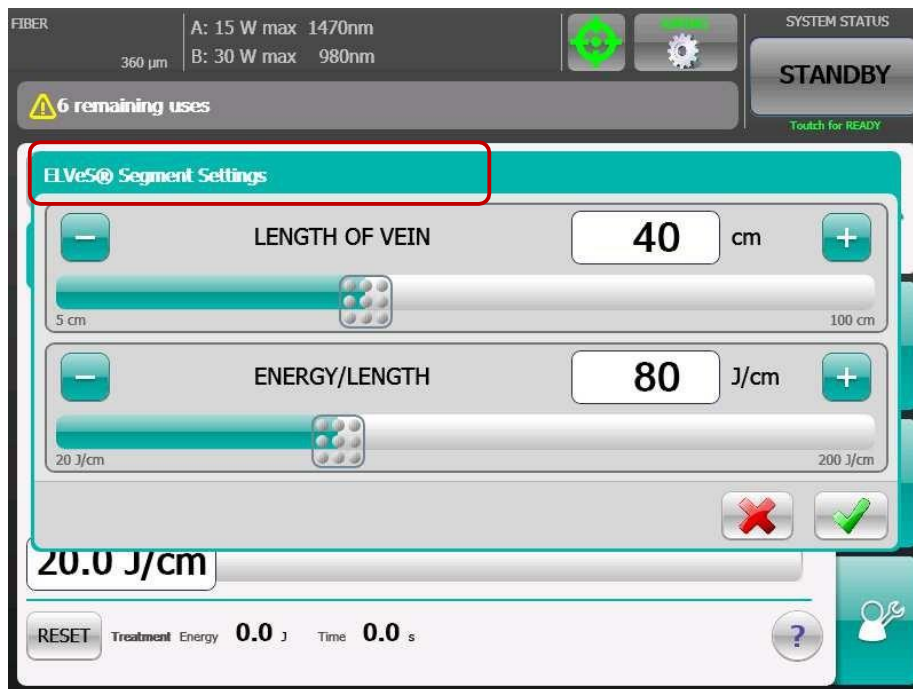




Figure 50: Setting the parameters in ELVeS® segment mode

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 "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 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!

#### 4.6.4 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.

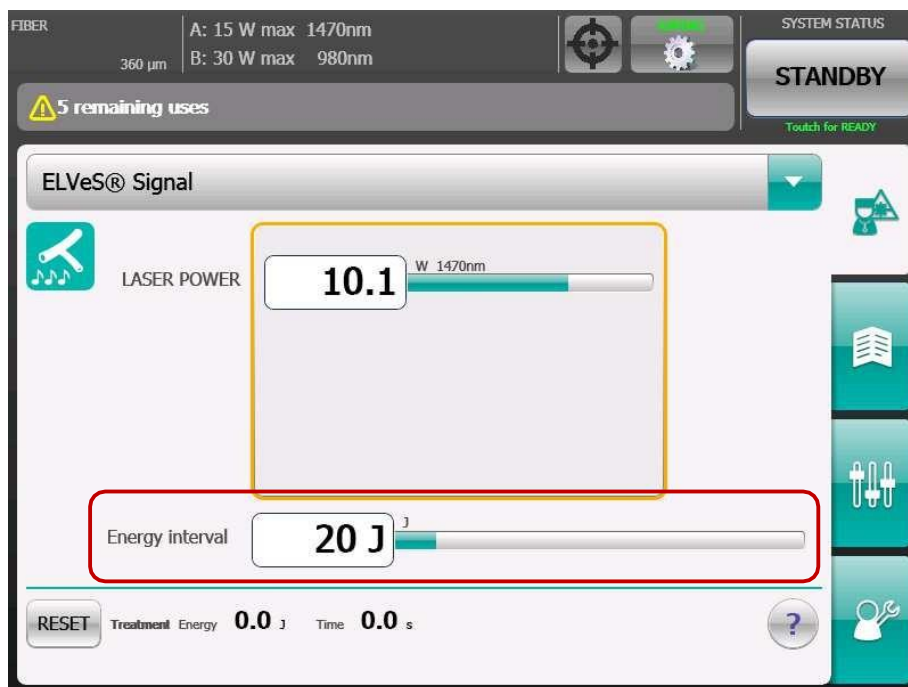




Figure 51: Setting the parameters in ELVeS® signal mode

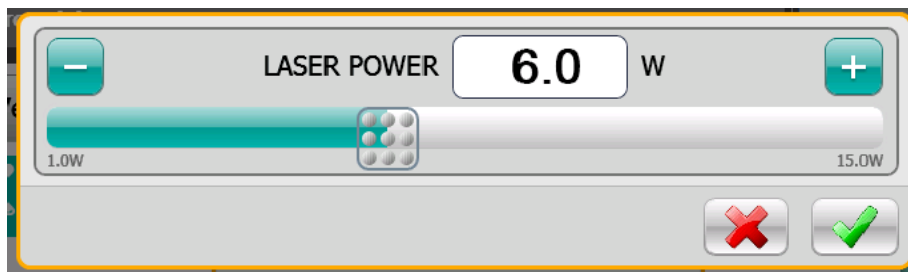


**Figure 52: Setting the parameters in ELVeS® signal mode (for devices that emit one wavelength)**

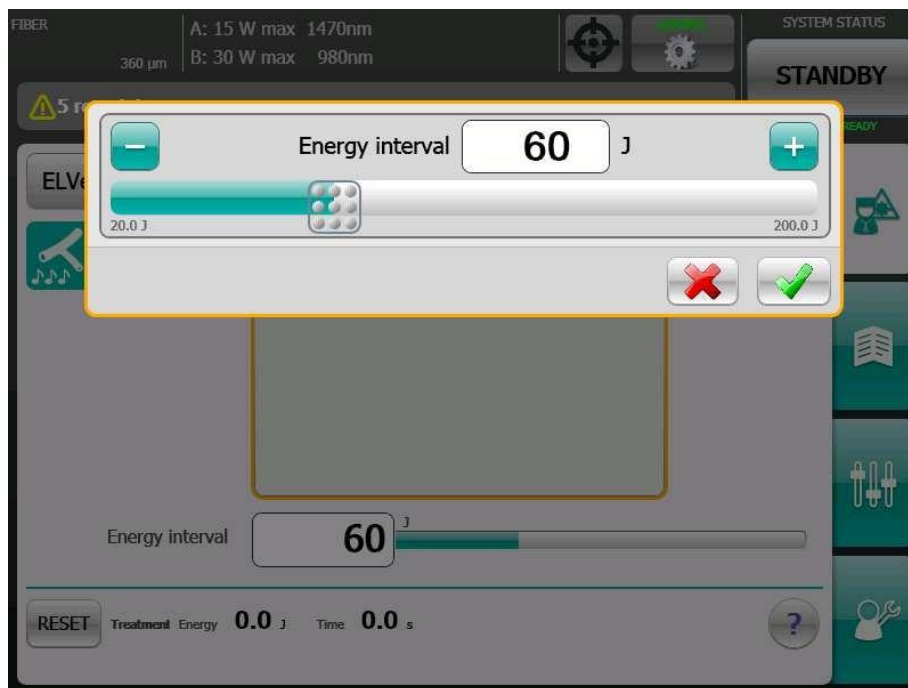
The laser output can be configured in the top section of the screen by tapping the white operation panel.

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 53: Setting laser power**



**Figure 54: 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.



#### 4.6.5 Derma mode (for LEONARDO® Dual 45 only)

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 mm or 1.5 mm), the laser device automatically calculates part of the parameter configuration based on the energy density set (see Figure 56: 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:

Handpiece for a beam diameter of	LEONARDO® Dual 45
	980nm/30W
0.6mm	4.1m
1.0mm	6.8m
1.5mm	11m

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).

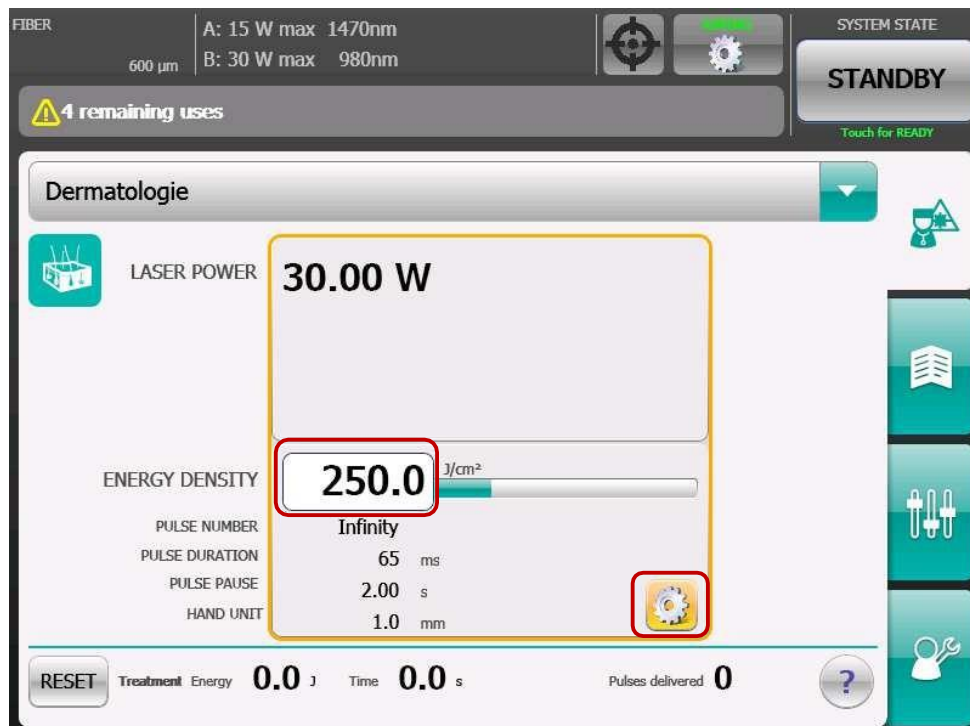


Figure 55: Screen display of Derma mode, dual laser setting



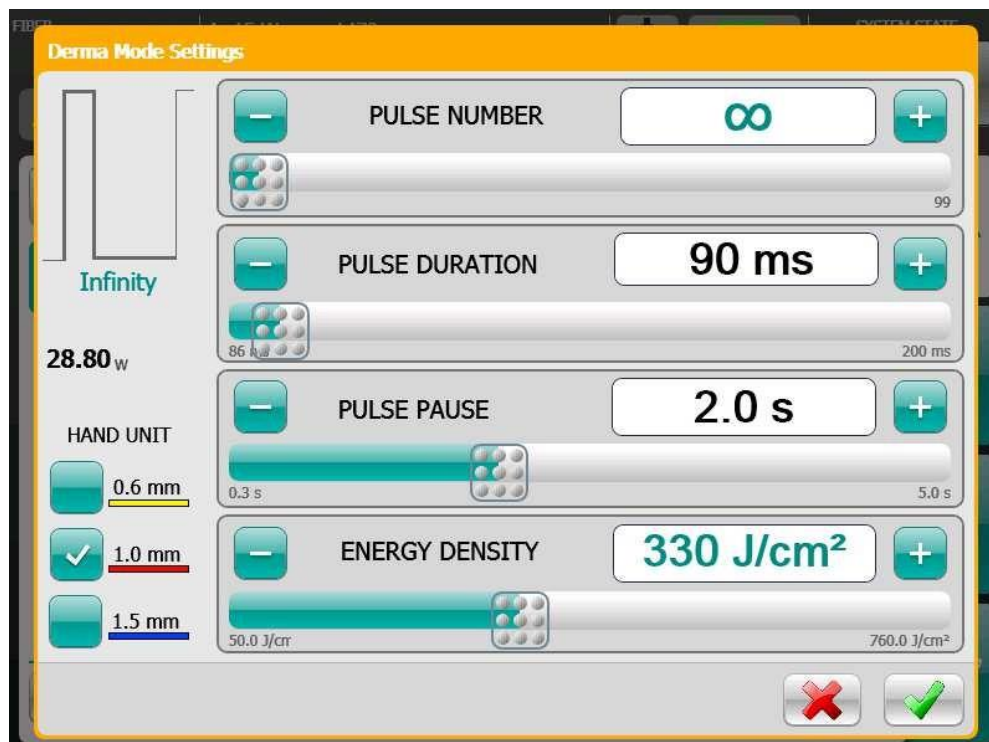


Figure 56: Setting parameters for Derma mode

#### 4.7 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.

## 4.8 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.

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
Emergency off switch pressed	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
- 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.

Footswitch	SA 2271
Power cable	LA 0027 Europe
	LA 1271 India
	LA 1509 China
	LA 4264 Great Britain
	LA 4265 Japan
	LA 4266 Italy
	LA 4425 Australia
	LA 4426 North America
	LA 4498 Canada
Door interlock	SA 2292

**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.

### 5.2 Laser safety eyewear



Figure 57: Laser safety eyewear

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

Goggles must have sufficient optical density for a laser beam wavelength of 980 +/- 30 nm or 1470 +/- 30nm. *CeramOptec* recommends goggles with the following lenses, which fulfill the requirements of the ANSI Z136.1 and CE / EN 207 standards. These goggles are manufactured by the company Sperian Eye (GPT-Glendale).

Model	Lens number (Honeywell)	Alternative lens number (Honeywell)	EN207:2002	EN207: 2010
LEONARDO® DUAL 45 980nm /30W 1470nm /15W	#xx-21096	-	950-1010 DL4 1430-1510 DL2	950-1010 DLB 6 1430-510 DLB 4
LEONARDO® 1470 1470nm/15W	#xx-2219	#xx-21096	1430-1510 DL2	1430-510 DLB 4

## 6 Application systems, fibers and medical probes

**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.

### 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

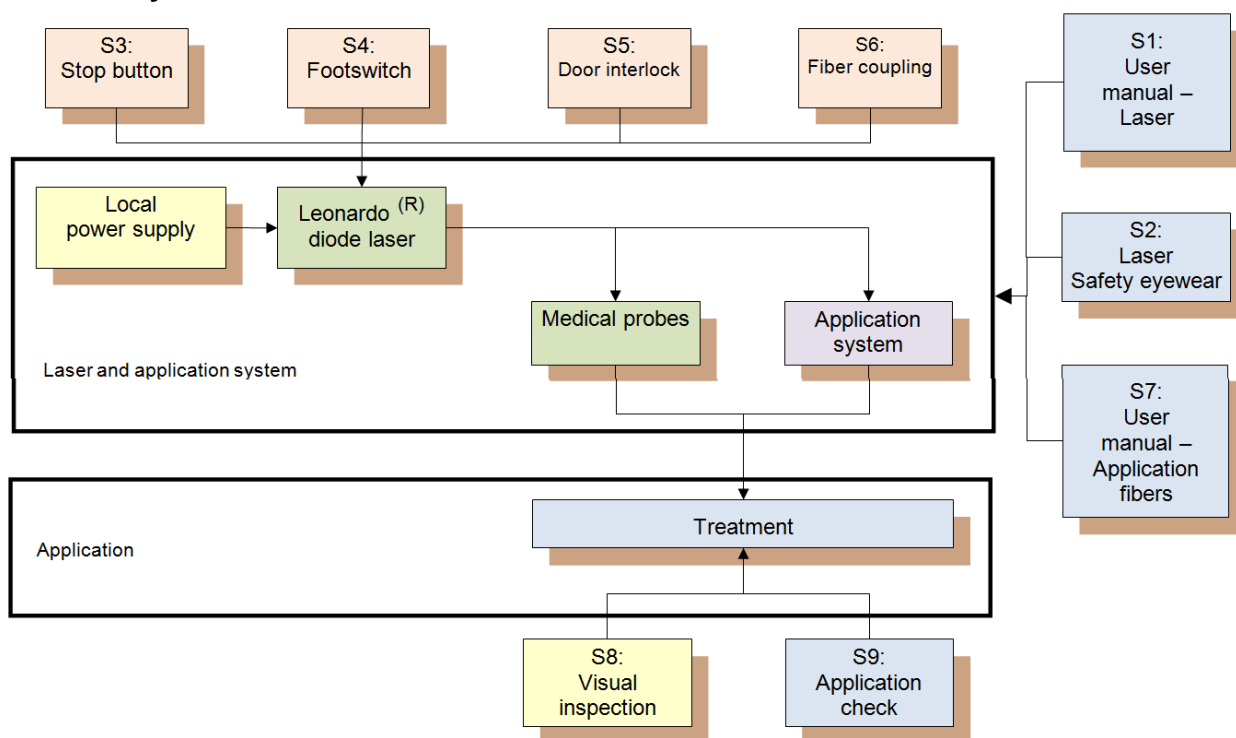


Figure 58: Safety elements

**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.

**Attention:** LEONARDO® contains no 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:

- Check laser protective eyewear (correct type, intact).
- Check that all labels and markings can be read and are positioned correctly (see section 0).
- 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

**Attention:** Unplug the device 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.

**Attention:** Please follow national regulations for clinical hygiene.

### 8.3 Changing fuses

**Attention:** Unplug the device 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 on a two year intervals in accordance with statutory requirements, and the results documented in the relevant maintenance log. To perform the technical safety check, proceed as described in section 13.3.

During the warranty period, the technical safety check must be performed by *CeramOptec* or by persons authorized by *CeramOptec*. Otherwise, any warranty or liability claims will be invalidated.

## 9 Technical specifications and labeling

### 9.1 Model-specific specifications

#### 9.1.1 LEONARDO® DUAL 45

<b>Model</b>	<b>1470 nm / 15 W + 980 nm / 30 W</b>
Power	15W ± 20% + 30W ± 20%
Wavelength	1470 nm ± 30 nm + 980 nm ± 30 nm
Power supply / Power consumption	100 – 240 VAC; 50-60 Hz / 450VA
Fuses	T4AL, 250V AC, 5x20 mm
Minimal fiber diameter	360µm

#### 9.1.2 LEONARDO® 1470

<b>Model</b>	<b>1470 nm / 15 W</b>
Power	15 W ± 20%
Wavelength	1470 nm ± 30 nm
Power supply / Power consumption	100 – 240VAC; 50-60 Hz / 450VA
Fuses	T4AL, 250V AC, 5x20 mm
Minimal fiber diameter	360µm

#### 9.1.3

## 9.2 General specifications for all LEONARDO® models

Numerical aperture	NA = 0.25 (or higher)
Fiber connector	Modified SC
Treatment mode	Continuous (CW) / Pulse
Pulse duration	Variable: 0.01 to 60.0 seconds
Working frequency (Hz)	0.01 - 1000
Display LCD Touch Screen	10 inch
Power control	Integrated power control
Aiming beam; power	635 ± 10 nm; 4 mW (max) 532 ± 10 nm; 1 mW (max)
Laser class according to 60825-1	4
Class of device according to 60601-1	I
Cooling	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
Dimensions (housing)	275 mm x 370 mm x 85 mm (HxWxD)
Weight	Approx. 8.5 kg
Applied part	Applied part: Type B
Mains isolation	Disconnection from mains is done by mains switch



## 9.3 Labeling

### 9.3.1 Certification and power rating label

Model: Model name as in section 9.1

Input: Electrical connection as specified for each model in section 9.1

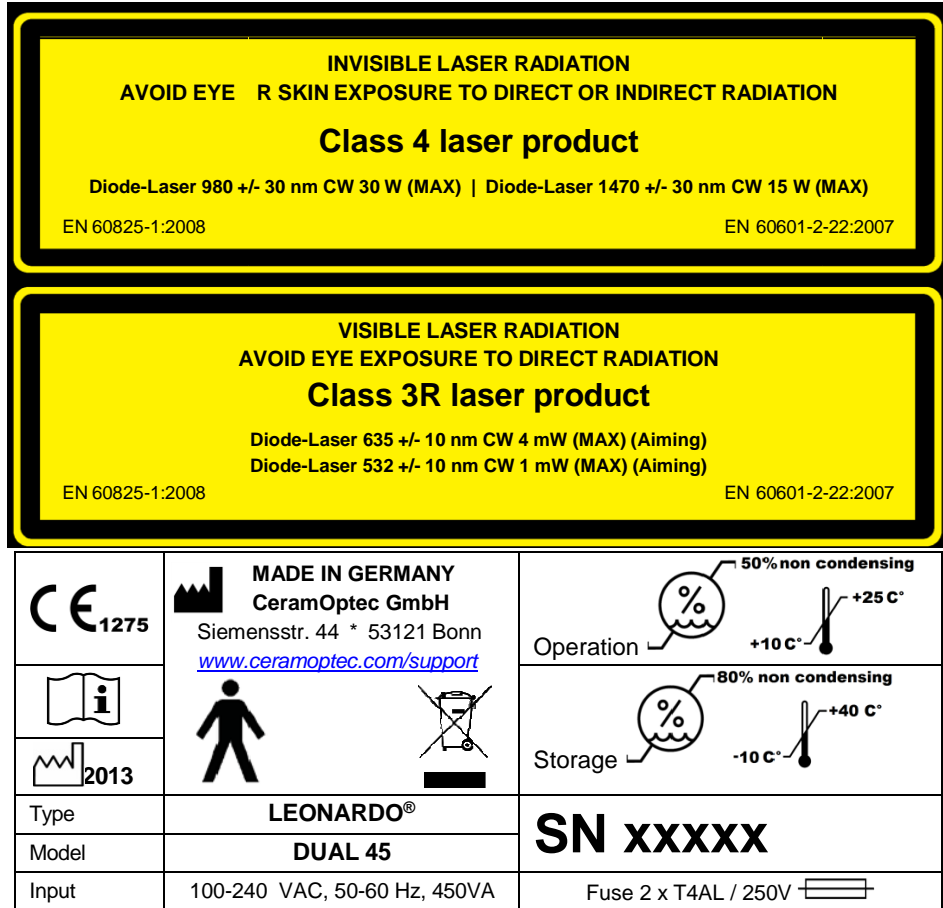


Figure 59: Label for devices that emit laser power of two wavelengths

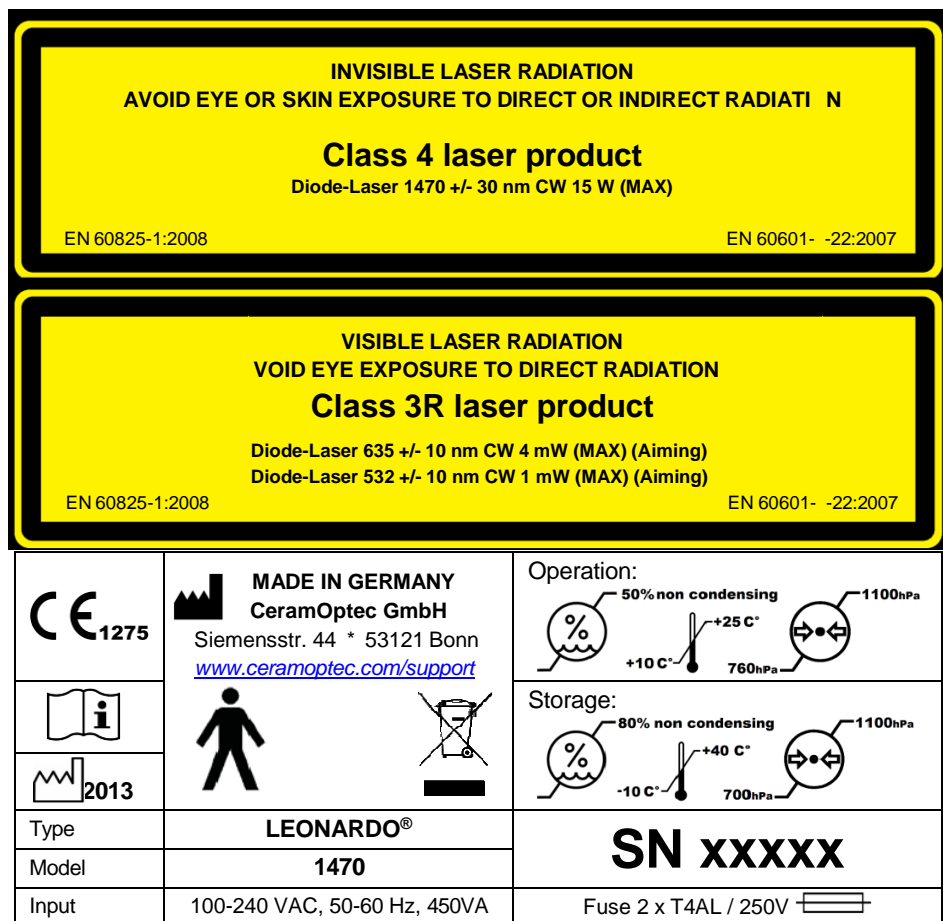


Figure 60: Label for devices that emit laser power of 15W at wavelength of 1470 nm

➤ Danger and laser warning

Diode laser xxx +/- 30 nm CW yy W (MAX)

Diode laser 635 +/- 10 nm CW 4 mW (MAX)

xxx, yy are the wavelength and power of the LEONARDO® model.

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



Figure 61: Laser warning sign



Figure 62: Laser emergency stop button



Figure 63: Laser aperture at distal end of fiber.



Figure 64: ESD warning symbol

### 9.3.2 Symbol key



Figure 65: Year of manufacture



Figure 66: Fuse



Figure 67: Manufacturer



Figure 68: Up



Figure 69: See user manual



Figure 70: Fragile goods



Figure 71: Admissible temperature range



Figure 72: Keep away from water and dampness



Figure 73: Maximum admissible air humidity



Figure 74: CE mark



Figure 75: Atmospheric pressure limitation



Figure 76: WEEE sign (see chapter 11)



Figure 77: Applied part type B

## 9.4 Manufacturer's Declaration Regarding Electromagnetic Compatibility


Table 201 as per EN 60601-1-2:2007, IEC 60601-1-2:2007

1	<b>Guidance and Manufacturer's Declaration - Electromagnetic Emissions</b>		
2	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.		
3	<b>Norms, measurements</b>	<b>Compliance</b>	<b>Electromagnetic Environment - Guidance</b>
4	RF emissions acc. to CISPR 11	Group 1	The device uses RF energy exclusively for its internal function. Thus the RF emission is very low and it is unlikely that nearby electronic devices would be disturbed.  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.
5	RF emissions acc. to CISPR 11	Class B	
6	Emission of overtones acc. to IEC 61000-3-2	Class A	
7	Emission of voltage fluctuation/flicker acc. to IEC 61000-3-3	Complies	

**Table 202 as per EN 60601-1-2:2007, IEC 60601-1-2:2007**

<b>Guidance and Manufacturer's Declaration - Electromagnetic Compatibility</b>			
<b>Norms, Measurements</b>	<b>IEC 60601 Test level</b>	<b>Compliance level</b>	<b>Electromagnetic Environment - Guidance</b>
EN 61000-4-2:2009 Electrostatic discharge (ESD)	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV  ± 8 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.
EN 61000-4-4: 2004 + A1: 2010 Fast transient electric disturbances / bursts	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV  ± 1 kV	The quality of the supply voltage should conform to a typical business or clinic environment.
EN 61000-4-5:2006 High energy pulses (surge)	± 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 drops, short interruptions and variations in supply voltage acc. to IEC 61000-4-11:2004	<5% UT (>95% break of UT for 0.5 period  40% UT (60% break of UT for 5 periods  70% UT (30% break of UT for 25 periods  <5% UT (>95% break of UT for 5 seconds	<5% UT (0 V)  40% UT (40V, 96 V)  70% UT (70V, 168 V)  <5% UT (0 V)	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.
EN 61000-4-8: 2010 Magnetic fields at the supply frequency	3 A/m 10 A/m	3 A/m 10 A/m	Magnetic fields at the supply frequency should conform to the typical values as they occur in the business or clinic environment.

**Table 204 as per DIN EN60601-1-2:2001+A1:2006, 6.8.3.201**

Norms, Measurements	IEC 60601- Test level	Compliance level	Electromagnetic Environment - Guidance
<p>EN 61000-4-6:2009 Conducted RF disturbances</p> <p>EN 61000-4-3: 2006 + A1:2008+A2:2010 Electromagnetic fields</p>	<p>3 V<sub>eff</sub> 150 KHz – 80 Mhz</p> <p>3 V/m 80 MHz – 2.5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used in a no less distances to the device including the cables than it is recommended by the equation for the frequency.</p> <p>Recommended safety distance:  <math>d=1.2 \sqrt{P}</math> for 150 kHz to 80 MHz  <math>d=1.2 \sqrt{P}</math> for 80 MHz to 800 MHz  <math>d=2.3 \sqrt{P}</math> for 800 MHz to 2.5 GHz                      whereby P is the nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer; d is the recommended safety distance in meters (m).                      The field strength of stationary transmitters should be lower than the accordance level for all frequencies according to testing on location.                      Disturbances are possible near devices with the following symbol:</p> 
<p>NOTE 1:</p> <p>NOTE 2:</p>	<p>For 80 MHz and 800 MHz, the higher frequency range is valid.                      These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.</p>		

- a. The field strength of stationary transmitters such as fixed parts of cellular phones and mobile radio sets, amateur radio stations, AM and FM radio and television cannot be determined exactly in theory. A study of the location may be considered to detect the electromagnetic environment in regard to stationary transmitters. If the measured field strength at the location where the device is being used exceeds the accordance level above, the device should be watched to verify proper functioning. If abnormal performance is observed, additional actions might be necessary such as a modified orientation or another location of the device.
- b. For the frequency range of 150 kHz to 80 MHz, the field strength should be lower than 3 V/m.

**Table 206 as per DIN EN60601-1-2:2001+A1:2006, 6.8.3.201**

<b>RECOMMENDED SAFETY DISTANCES BETWEEN PORTABLE AND MOBILE RF TELECOMMUNICATION DEVICES AND THE LEONARDO® LASER AS PER DIN EN 60601-1-2, 6.8.3.201, Table 206</b>			
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 2.5 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: For 80 MHz and 800 MHz, the higher frequency range is valid.

NOTE 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.

## 10 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.

## 11 Environmental protection

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 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.

### 12.1 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.

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

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## 13 Appendix

### 13.1 Device master data

DEVICE MASTER DATA LEONARDO®			
Model:	nm / W / $\mu\text{m}$	Operator:	
S/N:		Location:	
		Inventory no.:	

### 13.2 Training record

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

### 13.3 Technical safety check

[illegible]

<b>1.</b>	<b>Visual inspection</b>	<b>Passed</b>	<b>Failed</b>	<b>Assessment</b>
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 0 "Labeling")			
1.3	User manual			
1.4	Equipment complete			
1.5	Connections			
1.6	External surfaces of device			
<b>2.</b>	<b>Functional capability check</b>			
2.1	Footswitch			
2.2	Beam guidance system: Coupling/decoupling/aiming beam			
2.3	Interlocks			
2.4	Display and operation			
<b>3.</b>	<b>Check of monitoring, safety, display and reporting systems</b>			
3.1	Laser safety eyewear			
3.2	Indicator lights			
3.3	Emergency stop button			
<b>4.</b>	<b>Electrical safety EN60601-1</b>			
4.1	Insulation resistance			$\Omega$
4.2	Earth leakage current			<b>mA</b>
4.3	Protective ground wire resistance			$\Omega$

<b>5.</b>	<b>Measurements for safety-critical output parameters</b>
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**Attention: Always wear protective eyewear during this check.**

Laser calibration test:

Connect a new LEONARDO® Bare Fiber

**- Bare Fiber 400 µm, Flat Tip (BFF 403 DL)**

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. Test 1470 nm, Laser**

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

<b>Power selected up to max. output only [W]</b>	Power selected Value [W] +/- 20% Min / Nominal / Max	<b>Actual value</b>	<b>Passed</b>	<b>Failed</b>	<b>Comment</b>
2	1.6 - <b>2</b> - 2.4				
5	4 - <b>5</b> - 6				
10	8 - <b>10</b> - 12				
15	12 - <b>15</b> - 18				

**A2. Test 980 nm, Laser**

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

<b>Power selected up to max. output only [W]</b>	Power selected Value [W] +/- 20% Min / Nominal / Max	<b>Actual value</b>	<b>Passed</b>	<b>Failed</b>	<b>Comment</b>
5	4 - <b>5</b> - 6				
10	8 - <b>10</b> - 12				
15	12 - <b>15</b> - 18				
20	16 - <b>20</b> - 24				
30	24 - <b>30</b> - 36				

**B3. LEONARDO® 400 µm fiber**

Put the laser into **pulse mode**.

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

- Pulse duration: 1 sec. / Pulse pause: 0.3 sec.

- No. of pulses: 3

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

<b>Power selected up to max. output only [W]</b>	<b>Treatment energy Value [J] +/- 20% Min / Nominal / Max</b>	<b>Actual value</b>	<b>Passed</b>	<b>Failed</b>	<b>Comment</b>
5	12 - <b>15</b> - 18				
10	24 - <b>30</b> - 36				
15	36 - <b>45</b> - 54				
20	48 - <b>60</b> - 72				Only LEONARDO® DUAL 45
30	72 - <b>90</b> - 108				Only LEONARDO® DUAL 45
45	108 - <b>135</b> - 162				Only LEONARDO® DUAL 45