QuadroStar

USER'S MANUAL

1520 99 002 – 04 04

Copyright

Knowledge of this manual is required for the operation of the instrument. Would you therefore please make yourself familiar with the contents of this manual and pay special attention to hints concerning the safe operation of the instrument.

The specifications are subject to change; the manual is not covered by an update service.

1520 99 002 – 04 04

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1 Intended Use

The *QuadroStar* is optionally supplied with one or two laser modules, with only one laser being actively operated each. The laser modules used are either frequency-doubled disc lasers (LBO laser) or diode lasers. The diode laser is available with three different wavelengths. The availability of different wavelengths and the possibility to combine two laser modules result in a wealth of applications.

The LBO laser emits light at a wavelength of 532 nm, which is absorbed very well by hemoglobin. Thus, this laser is ideally suitable for dermatology, especially for the treatment of superficial vascular lesions, but also for the gentle vaporization of benign pigmented lesions and other skin irregularities.

The diode laser emits light in the near infrared at optionally 808, 938 or 978 nm. These wavelengths are absorbed by hemoglobin, melanin and water. However, because of the comparatively low absorption, they penetrate deeper into tissue. In dermatology, the diode laser can also be used for the treatment of vessels.

There are many applications of the diode laser in minor surgery. Tissue can be coagulated or vaporized depending on the energy or power density applied. Using the fiber-contact technique, tissue can also be cut. Besides, the diode laser is well suitable for the endovascular coagulation of dilated veins (varicose veins).

In dentistry, the diode laser is used for soft-tissue surgery by analogy to the described surgical applications or for tooth bleaching.

In providing this new, powerful medical device, Asclepion Laser Technologies GmbH rested on its many years of experience in the development and production of medical lasers and particularly its competence in the field of solid-state lasers and diode lasers.

The *QuadroStar* is a reliable, compact laser device that is extremely easy to use. The device fully complies with the requirements of the Medical Device Directive. It is largely maintenance-free and excels by a long service life.

The device is designed for use in both clinics and private practices. Because of its compact design and light weight, it can easily be transported.

The *QuadroStar* complies with the generally accepted rules of technology and the relevant safety regulations.

Intended Use

It must expressly be pointed out here, that only those persons are allowed to use the device who attended an introductory course on the use of the device as confirmed by their signature in the medical device logbook. In addition, the user must have read this user's manual and the application manual.

As part of the installation procedure, the installing technician employed with or trained by Asclepion Laser Technologies GmbH will give an initial introduction into the operation of the device.

Active medical devices may be used only by persons who can ensure proper handling because of their qualification and practical experience.

Specialist training courses are offered, for instance, also by Asclepion Laser Technologies GmbH.

Non-observance of the instructions given may result in risks to the health of patients and operators as well as damage to the device!
The manufacturer will not assume any liability for such damage.

Medical Device Directive / Medical Product Act

The *QuadroStar* complies with the EC Medical Device Directive 93/42/EEC and its national equivalent in form of the German Medical Product Act (MPA).

Device Type acc. to MPA: II b

UMDNS-No.: 16-948

2 Technical Data

2.1 General specifications

Beam guidance:	Flexible optical fiber
Display:	LCD display
Operator guidance:	Touchscreen
Cooling:	Internal air cooling, power-regulated
Door interlock connector:	Potential-free contact 5 VDC / max. 20 mA (TTL)
Laser warning lamp:	Potential-free relay contact Max. 24 V / 0.5 A (normally open contact)
Operating conditions:	Temperature: +15 °C ... +30 °C Rel. humidity: ≤ 85 % Atmospheric pressure: 700 ... 1060 hPa
Transport and storage conditions:	Temperature: -5°C … +55°C Rel. humidity: 10 % … 95 % (no condensation)
Dimensions (W x D x H):	41 x 39 x 21 cm
Weight:	Approx. 20 kg
Power requirements:	115 / 230 VAC 50/60 Hz Max. 600 VA
Classification acc. to MPA	II b
Protection Class:	I
Accessories	See *Section 7, page 35*.

2.2 Laser specifications

Laser type:	Diode-pumped, frequency-doubled solid-state laser (LBO)
Wavelength:	532 nm
Laser Class:	4 (requires laser-protective eyewear D 532 L4)
Laser power:	0.5 … 5 watts, distal
Operating modes:	cw, single pulse, burst and repeat pulse mode
Pulse duration:	5 ms ... 2.5 s, adjustable

Technical Data

Pulse repetition rate:	1 ... 120 Hz
Number of pulses in burst mode:	2 ... 50, infinite
Tolerance of output power:	Max. ± 20 %
Spot size:	Handpiece 0.5; 1.0 and 1.5 mm
Energy density:	0.5 … approx. 6,300 J/cm², adjustable depending on handpiece used
Beam divergence (half angle):	Max. 125 mrad (7.2°)
Laser type:	Diode laser
Wavelength:	808 nm 938 nm 978 nm
Laser Class:	4 (requires laser-protective eyewear D 808-978 L3)
Laser power:	1 … 25 watts, distal
Operating mode:	cw, single pulse, burst and repeat pulse mode
Pulse duration:	5 ms … 2.5 s, adjustable
Pulse repetition rate:	1 … 120 Hz
Tolerance of output power:	Max. ± 20 %
Spot size:	Handpiece 0.6; 1.0 and 1.5 mm Bare fiber 0.2; 0.3 and 0.6 mm
Energy density:	0.5 J/cm² … approx. 22,000 J/cm², adjustable depending on handpiece
Beam divergence (half angle):	Max. 390 mrad (21°) with handpiece Max. 370 mrad (22°) with bare fiber
Number of pulses in burst mode:	2 … 50, infinite
Laser type	Laser diode, aiming laser
Wavelength	635 nm
Laser Class	I
Laser power	<1 mW, adjustable in steps
Operating mode	cw or blinking (approx. 1 Hz)

2.3 Device models

Model	Model Number	built-in laser modules
QuadroStar 532/980	1520	LBO 532 and Diode 978
QuadroStar 532	1521	LBO 532
QuadroStar 532/940	1522	LBO 532 and Diode 938
QuadroStar 532/810	1523	LBO 532 nm and Diode 808
QuadroStar 980	1524	Diode 978
QuadroStar 940	1525	Diode 938
QuadroStar 810	1526	Diode 808

The basic unit is identical for all device models, the models only differ in the number and the type of built-in laser modules. On devices containing two built-in lasers, these cannot be operated simultaneously.

The models can be identified by the Model Number specified on the type label on the rear panel of the device.

Control

The output parameters and the safety equipment of the device are monitored and controlled by a computer system.

A calibration port automatically compensates both the aging of laser modules and the reduction in the transmission of the beam delivery system.

Operating mode

The device operates in both continuous (cw) and in pulsed mode (single pulse, pulse repetition, burst). It is designed for temporary use (less than 30 min continuous duty).

Operation

Operation is via a touchscreen with plain-text user guidance. The following operating parameters are adjustable: Wavelength or laser module, power or energy density, pulse duration and pulse pause or pulse rate.

In addition to the parameters selected, the following parameters and device states are displayed: Applied total energy, laser standby and, if necessary, plain-text error messages.

The system automatically detects the connected fiber type. When using a handpiece, the spot size is selectable via the touchscreen.

The laser is released by means of a footswitch.

3 Safety Notes

In this manual, the following symbols are used to refer you to dangers or notes on operation of the device:

Risk of accidents or physical injury.

Risk of technical damage.

The *QuadroStar* complies with the requirements of the German Medical Product Act (MPA) and thus those of the EC Medical Device Directive (93/42/EEC). Observe the German Medical Devices Operator Ordinance (MPBetreibV) or the relevant national legislation and regulations regarding the operation of laser devices.
The *QuadroStar* is a Class IIb device as per the above directive.

The MPA and the Medical Devices Operator Ordinance (MPBetreibV) bind the owner/operator, the authorized persons and users of Class IIb devices to take a number of safety precautions. In particular, such devices should be operated only in accordance with the generally accepted rules of technology and the relevant regulations on labor safety and the prevention of accidents.

In handling medical laser devices, observe the currently binding version of the relevant regulations on the prevention of accidents by laser radiation of the German Professional Associations. A copy of these regulations is provided with this manual. Furthermore, you are bound to keep a medical device logbook, which is also enclosed with this manual. Our service technician will assist you in filling it in as part of the startup procedure.

Please note that this device must be checked annually for technical safety. The results of these safety checks must be recorded in the medical device logbook.

Do not install the *QuadroStar* in explosion-risk areas.

Only persons employed with or authorized by Asclepion Laser Technologies GmbH are allowed to service, repair or modify the device.

Safety Notes

The Regulations for the Prevention of Accidents by Laser Radiation of the German Professional Associations (or any equivalent national regulations) lay down general rules for the protection against hazardous laser exposure. In the context of medical application, they aim to protect operating personnel during laser operation. The laser devices are classified in different classes depending on the potential risks involved. The *QuadroStar* is classified in Class 4.

This classification means that improper use of the device constitutes risks to the eyes by direct and scattered laser radiation. Besides, the laser radiation may cause fire and explosion hazards.

To avert these risks, the above regulations bind the owner/operator of the device, inter alia, to meet the following requirements:

- **Duty of notification:** Prior to initial start-up, the intended use of the laser must be notified to the competent Professional Association and the labor-safety authority
- A **Laser Safety Officer** must be appointed in writing.
  The duties of the laser safety officer should include at least the following:
    - Supervision of the operation of the laser device
    - Assistance to the owner/operator to ensure safe operation and implement the necessary safety precautions
    - Co-operation with labor-safety specialists in fulfilling their tasks, including the information about important issues of laser radiation protection.
- **Laser zone:** While the laser is in operation, the area in which the maximum permissible radiation level may be exceeded, the so-called "laser zone", must be delimited and marked by a laser warning sign. Warning lamps at the entrances must indicate the operation of the laser.
- The **NOHD** (Nominal Ocular Hazard Distance) of the laser device is so high that the entire room where the laser is operated is to be considered as laser zone.
- **Personal eye protection:** All persons present in the laser zone must wear laser protective eyewear. The laser protective eyewear must provide a protection level of at least D L4 for 532 nm and D L3 for 808 ... 978 nm (acc. to DIN EN 207 in the currently valid form).
- **Dangerous reflections:** The laser beam may be reflected by many metal surfaces and not only by those normally considered. Therefore, always take care to remove all metal objects, such as watches, earrings, etc. from the operational range of the laser.

- **Risk of fire:** Many non-metal materials may catch fire under normal operating conditions if exposed to laser radiation (e.g. plastic, paper, wood, cotton, etc.). Therefore, remove combustible objects from the operational range of the laser. Besides, the laser device must never be used in the presence of flammable anesthetics or disinfectants. Residues of these substances must have been fully evaporated before using the laser device.

The **Regulations for the Prevention of Accidents by Laser Radiation** lay down binding protection standards. Examples are given to illustrate how to achieve these standards.

The examples given cannot be regarded as final and complete because of the dramatic on-going technical progress especially in laser technology. Therefore, other equivalent precautions may also be suited and desired in the interest of the physician and the patient.

Safety features of the device

In the development of the *QuadroStar*, numerous precautions have been taken to ensure a high degree of active safety in combination with high operating convenience.

- Immediately after the device is switched on, the integral PC control performs a self-test of the device.
- Following this test, a number of safety-relevant components are tested automatically.
- If the device passed the test successfully, it will switch to the "Non-ready" mode ("Standby"). If the test was not successful, an error message will be displayed.
- While the laser is in operation, the PC control system is continuously checked for proper function.
- High priority has been given to preventing any risk to the physician and the patient caused by an individual component failure.
- The device carries various safety labels. These labels must always be clearly readable and replaced instantly when damaged.

4 Start-up

Initial installation of a new *QuadroStar* must always be performed by an authorized representative of Asclepion Laser Technologies GmbH, who will explain the responsible operator how to operate the device based on the instructions given in this manual.

4.1 Scope of delivery

Verify that all components required for safe operation of the laser device are present:

4.1.1 Basic device

- Basic laser device
- Power cable
- Footswitch
- Remote door interlock connector
- Two keys
- User's Manual
- Laser protective eyewear for physician (one each per laser module)
- Eye protection for the patient

4.1.2 Accessories

- Optical fiber with handpiece and three spacers for every laser module

4.1.3 Optional accessories

- Bare fiber Diode 810 ... 980 - 200 µm core diameter
- Bare fiber Diode 810 ... 980 - 300 µm core diameter
- Bare fiber Diode 810 ... 980 - 400 µm core diameter
- Bare fiber Diode 810 … 980 - 600 µm core diameter
- Bleaching handpiece
- Transport case

4.2 Installation

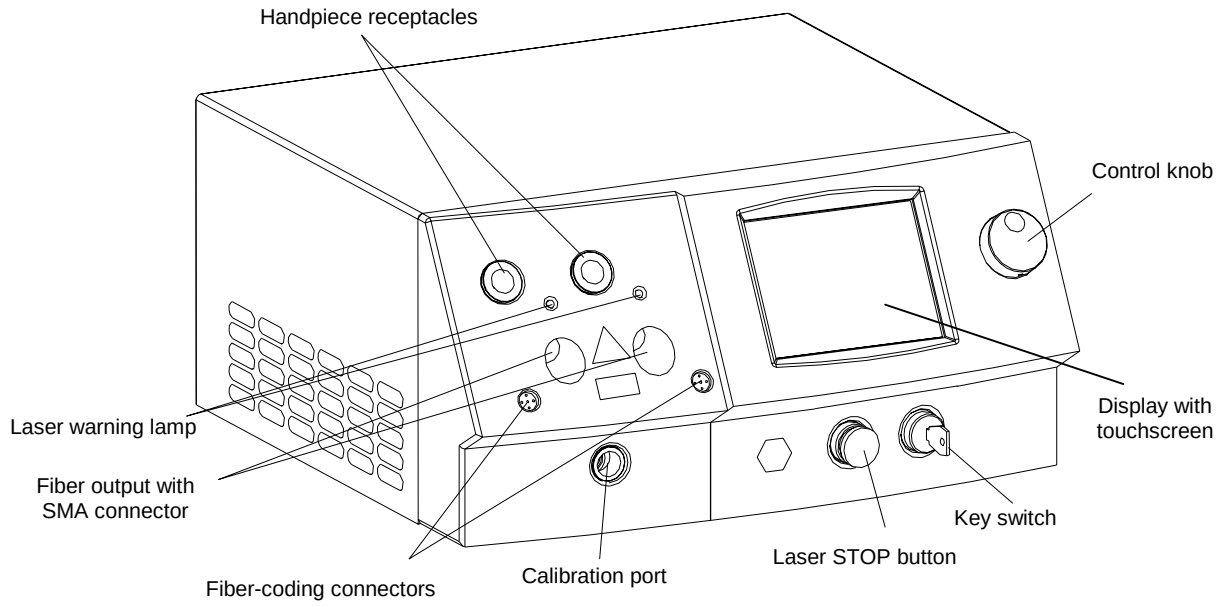


Figure 1: Front view

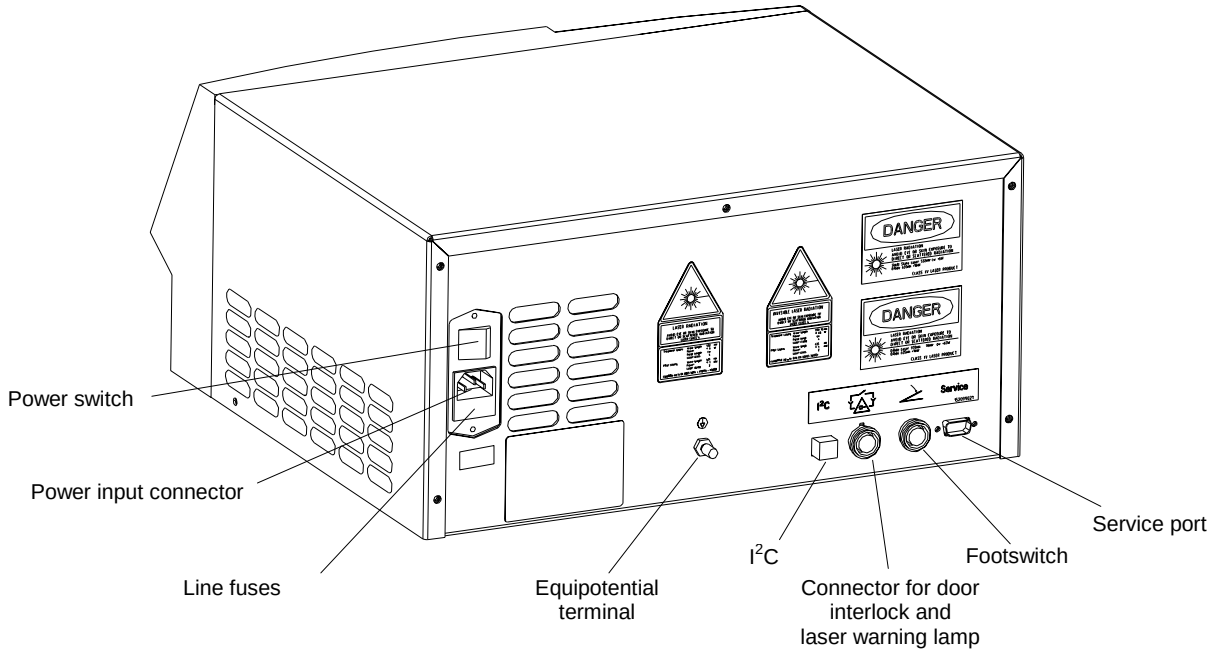


Figure 2: Connectors on rear panel of device

4.2.1 Installation note

Considering the cable connections and the optimum ventilation required for an efficient cooling of the device, keep a minimum distance of 20 cm between side and rear panels of the *QuadroStar* and the wall.

4.2.2 Connection of door interlock and warning lamp

In addition to the prescribed warning signs, every entrance to the laser area (usually the laser treatment room) must be equipped with warning lamps that are lighting (or flashing) as long as the laser emits radiation.

On the rear panel of the device, a connector is provided for the connection of a door interlock and a warning lamp (see illustration below).

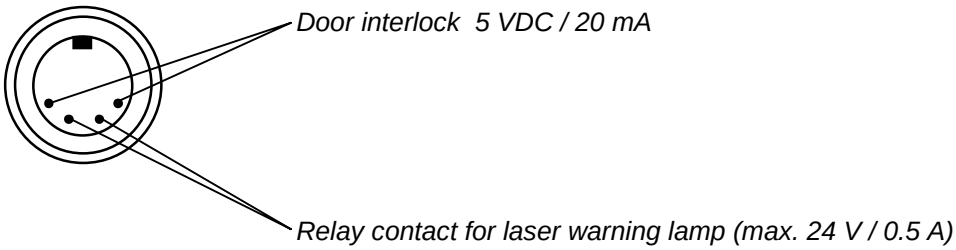


Figure 3: Connectors for door interlock and laser warning lamp

By connecting the two "door interlock 5 VDC / 20 mA" terminals to an external contact, such as a door interlock, you can prevent laser radiation from being emitted when the door of the laser room is opened.

This safety device serves to automatically shut off the surgical beam when the door is being opened thus precluding any risk to the person entering.

The laser can only be operated, when this contact is closed. Therefore, the door interlock connector is factory-fitted with a provided shorting bridge. To connect a door interlock circuit, remove this bridge and connect your door interlock circuit to the same terminals. If you do not use a door interlock circuit, make sure the shorting bridge is connected to the respective terminals.

The same connector provides connection to a potential-free normally open contact. This contact allows a circuit for a low-voltage warning lamp to be switched (max. 24V / 0.5 A). The contact closes when the laser is switched to READY mode.

If you intend to install a door interlock or the external laser warning lamp later, make sure to switch off the device before and disconnect the power cable from the power outlet.

The prescribed laser warning lamp may, of course, also be installed completely separately from the laser device and turned on and off via a normal light switch.

4.2.3 Connection to power outlet

Absolutely make sure that the power cable is disconnected from the power outlet when the device is installed!

When choosing the power outlet, consider all technical data of the local mains and the device (refer to *Section* 2.1*, page 5*). First, verify that the available line power agrees with the specified power requirements.

Please observe the requirements of DIN VDE 0100 or any national equivalent in the currently valid form.

The device is provided with a power cable. Before connecting the device to the power outlet, make sure the power switch is set to '0' (device being dead). First, plug the power cable into the power input connector on the rear panel of the device before connecting the other end of the cable to the power outlet.

If required, an earth wire can be connected between the equipotential terminal on the device and the earth-potential terminal of the electrical supply system.

Operation of the laser requires that the device be connected to a single-phase power outlet protected by a fuse rated for at least 600 VA (Type C, slow-blow).

4.2.4 Footswitch and applicator

Now, connect the footswitch to the footswitch connector provided at the rear panel of the device (refer to *Figure 2, page 12*). Make sure to insert the plug as far as it will go. Then, lock it by turning the cap nut clockwise.

Afterwards, plug the applicator (bare fiber or fiber with handpiece) as far as it will go into the SMA connector on the front panel of the device (refer to *Figure 1, page 12*) and

tighten the cap. Then, plug the fiber-coding plug into the corresponding connector below the fiber connector and lock it by turning the cap nut clockwise until it snaps in.

Make sure to use the correct fiber connector each for the selected laser module.

Consider that the transmission fiber may be damaged or show premature aging, if the fiber connector has not been screwed down correctly.

4.2.5 Service and I²C connector

These connectors located at the rear panel of the device are provided only for service purposes and should be used solely by service technicians employed with or authorized by Asclepion Laser Technologies GmbH.

Never connect any devices to the Service port and the I²C connector on the rear panel of the device.

4.3 Preparations for use

After installation and any relocation of the device from a cold to a warm environment with a temperature difference of more than 5°C, allow for the following periods of adjustment to the room temperature with the device unpacked before using the device (laser operation):

Min. 2 hours for temperature differences of up to 10°C,
Min. 4 hours for temperature differences of up to 15°C,
Min. 8 hours for temperature differences exceeding 20°C.

Afterwards, switch the device on without an applicator connected and let the device warm up for at least 30 minutes.

Take care that the installation and operating environment of the device meets the following conditions:
Temperature: 15 to 30°C
Relative humidity: max. 85%.

Non-observance may result in the destruction of the device.

Besides, verify that the following requirements have been met:

1. The line voltage specified on the label at the rear panel agrees with the line voltage available at the place of installation.
2. The power plug has been plugged into an appropriate power outlet.
3. The potential equalizing cable has been connected (if required).
4. The SMA connector of the applicator (bare fiber or fiber with handpiece) has been firmly connected to the SMA connector of the fiber output on the front panel of the device. The fiber-coding plug has been plugged into the corresponding connector.
5. The footswitch plug has been properly connected to the footswitch connector on the rear panel of the device and screwed down.
6. Warning lamps have been mounted at the laser room entrance and switched on (if necessary).

4.4 Switching on

Make sure that all safety precautions have been taken.

Then, follow this procedure:

- Switch the power switch on the rear panel of the device (see *Figure 2, page 12*) to I (ON).
- Verify that the Laser STOP button is deactivated (not pressed).
- Afterwards, insert the safety key in the key switch (see *Figure 1, page 12*) and turn it clockwise as far as it will go.

While the device automatically tests essential and safety-relevant modules, the starting screen appears on the display.

After a few seconds, one of the following menus will appear on the screen:
The menu for the selection of the laser wavelength (or the laser) appears (*Figure 4, page 17*) if your device is equipped with two laser modules. Otherwise, the basic menu in "Standby" mode appears (*Figure 6, page 19*).

5 Operation

The use of controls or adjustments or performance of procedures other than those specified in this manual may result in hazardous laser radiation exposure.

5.1 Adjustment of treatment parameters

The treatment parameters are to be adjusted via the touchscreen and the control knob at the right of the front panel (see *Figure 1, page 12*). Adjustment is very straightforward and self-explanatory.

Select the function by pressing the corresponding function key on the touchscreen:

- Simple ON/OFF function keys appear highlighted when activated.
- Function keys with several options are marked by a red frame after they were activated by tapping on them. To select the desired parameter, turn the control knob. To confirm and store the selected parameter, briefly depress the control knob or alternatively tap the activated function key on the touchscreen once more.

Keys of adjustable parameters are always highlighted in color. Keys that are not highlighted are deactivated. They only serve for information.

After the switch-on routine has been passed, always the following menu will appear on the display (only on devices with several laser modules):

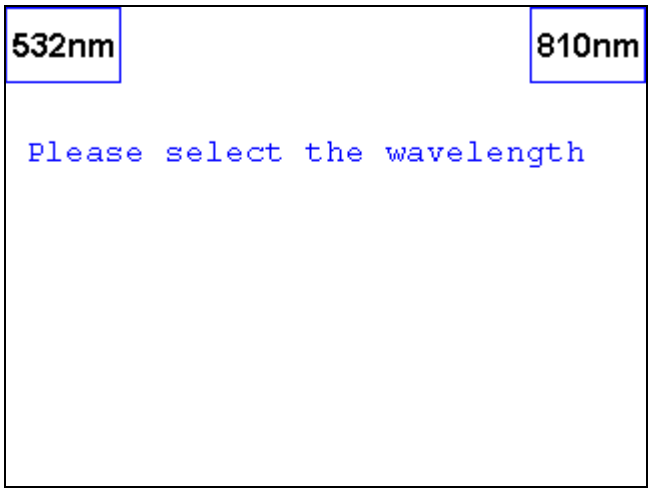


Figure 4: Menu for selection of laser module

Successful key pressure is confirmed by a short beep signal.

By tapping on the desired wavelength, the corresponding laser module is activated. Afterwards, the system prompts you to use the laser protective eyewear, laser applicator and fiber connector appropriate for the selected laser wavelength. Please confirm having done so by pressing the "Confirm" key (*Figure 5, page 18*).

The activated fiber connector is signaled by the laser warning LED directly above the SMA fiber connector (*Figure 1*).

Figure 5: System prompt to use correct protective eyewear, applicator and fiber connector

On devices with only one laser module, the menus of *Figure 4, page 17,* and *Figure 5, page 18* are inapplicable.

The device is in "Standby" mode then with the screen showing all adjustable parameters of the activated laser module (*Figure 6, page 19*).

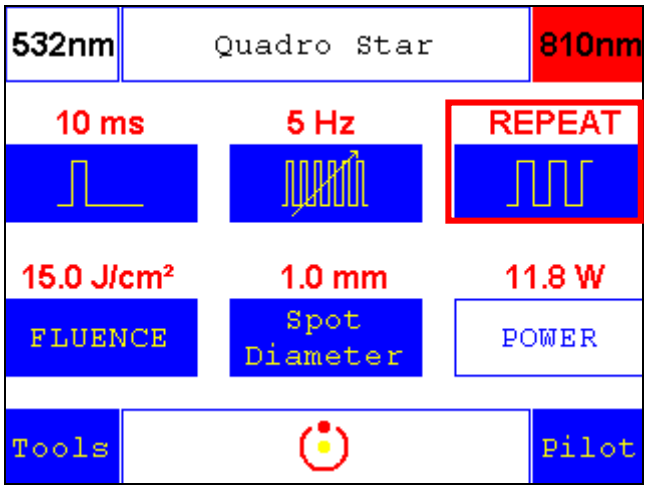
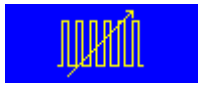
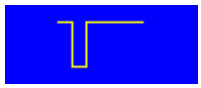
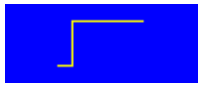
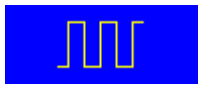


Figure 6: "Standby" menu: Repeat pulse mode with handpiece

The treatment parameters adjustable do not only depend on the laser module used, but also on the operating mode selected and the applicator used.

The following parameters are selectable (From top left to bottom right of the touchscreen):

Parameter	Symbol	Display	Restrictions
Wavelength		Wavelength in nm	Selectable only on devices with several laser modules, ON/OFF function
Pulse duration		Pulse duration in ms	Available only in the following operating modes: single pulse, repeat pulses and burst
Pulse repetition rate		Pulse repetition rate in Hz	Available only in repeat pulse mode
Pulse interval		Pulse pause in ms	Available only in burst mode
Operating mode			
Continuous		CW	
Single pulse		SINGLE	
Multiple pulses		BURST and number of pulses	
Repeat pulses		REPEAT	

Energy density	FLUENCE	Fluence in J/cm²	Available only in single pulse, repeat pulse and burst mode and when using an applicator with handpiece
Spot size	Spot Diameter	Spot diameter in mm	Available only when using a fiber applicator with handpiece
Laser power	POWER	Power in watts	Available only in cw mode or when using a bare fiber
Aiming beam laser	Pilot		In "Standby", intensity and operating mode (cw or blinking) are selectable, in "Ready", only the operating mode.

- **Wavelength** (only on devices with several laser modules)

  The wavelength is to be selected by pressing the wavelength key in the top left or top right corner of the screen (*Figure 6, page 19*). The key of the selected or activated wavelength appears highlighted in red. After every change of the wavelength, automatically the system prompt appears for confirming the use of the appropriate laser protective eyewear and the selection of the corresponding fiber output and fiber applicator (*Figure 5, page 18*).

- **Pulse duration**

  This parameter is selectable only if displayed on the screen.
  The pulse duration indicates the duration of emitted pulses while the footswitch is depressed.

- **Pulse interval**

  This parameter is selectable only if displayed on the screen.
  The pulse interval indicates the period between two successive laser pulses.

- **Pulse repetition rate**

  This parameter is selectable only if displayed on the screen.
  The pulse repetition rate indicates the number of laser pulses emitted per unit of time.

- **Continuous wave** operating mode (CW)

  This option indicates that the device can deliver the set power to the patient as long as the operator keeps the footswitch depressed. Emission of laser radiation is stopped when the footswitch is no longer pressed.

- **Single pulse** operating mode (SINGLE)

  In this operating mode, the device emits a single laser pulse of the selected power and pulse duration, when the operator presses the footswitch. At the end of the pulse, the laser is automatically switched off, even when the operator keeps the footswitch depressed. To deliver another pulse of the same power and duration, the footswitch must be pressed once more.

- **Repeat pulse** operating mode (REPEAT)

  In this operating mode, the device delivers a series of pulses of the selected power, duration and repetition rate when the footswitch is depressed. The time interval between two successive pulses results from the following equation:
  $T_{Interval}$ [ms] = 1000 / f [Hz] – T_{Pulse} [ms]
  The series of pulses is emitted without any interruption until the footswitch is released again.

- **Multiple pulse** operating mode (BURST)

  In this operating mode, the device delivers a defined number of pulses of the selected power, duration and interval when the footswitch is depressed. The pulse repetition rate results from the following equation:
  f [Hz] = 1000 / (T_{Pulse} [ms] + $T_{Interval}$ [ms])
  After the selected number of pulses has been emitted, the laser is automatically switched off even if the operator keeps the footswitch depressed. At any rate, the laser burst will be stopped immediately when the operator releases the footswitch even if the selected number of pulses has not been reached yet. To emit another burst of the same parameters, it is necessary to press the footswitch once more.

- **Energy density**

  This is the crucial parameter for the treatment. It is displayed as fluence in J/cm² and can be set to the desired value by activation of the FLUENCE parameter key. If the laser power is not sufficient to achieve the desired fluence value, you can reduce the spot diameter of the therapy laser by using another handpiece attachment. After the entry of the new spot diameter, the varied energy density is calculated automatically.

- **Spot diameter**

  This parameter indicates the spot size on the skin surface. With all types of bare fibers, this diameter corresponds to the core diameter of the bare fiber. The fiber core diameter is automatically detected when plugging in the fiber-coding plug. When handpieces are used, the spot diameter specified on the handpiece tip is achieved at the end of the spacer of the respective tip.

- **Laser power**

  This parameter indicates the laser power in watts emitted to the patient's skin.

- **Aiming beam laser (PILOT)**

  On activation of this key, you can adjust both the intensity (only in "Standby“ mode) and the operating mode (continuous or blinking) of the aiming beam laser.

5.2 Adjustment of spot size

Beside the used laser module, above all the beam diameter of the therapy laser depends on the applicator used.
As with **bare fibers** in general laser treatment is performed in contact mode, the spot size achieved with these fibers corresponds to the core diameter. The device automatically detects the fiber core diameter after the fiber plug was connected to the SMA connector and the fiber-coding plug plugged into the corresponding fiber coding connector.
When you use fibers with **handpiece**, the spot diameter will **not** be detected automatically. The effective beam diameter (spot size) is engraved on the handpiece tip and must be selected via the beam diameter parameter key. This is required for the correct calculation of the fluence values.

5.3 Adjustment of aiming beam intensity

In "Standby“ mode, the aiming beam intensity can be varied by activation of the Pilot key (*Figure 6, page 19*) and turning the control knob. The variations are directly visible at the aiming beam. However, the new setting will be stored only by a pressure of the control knob or the Pilot key. The intensity in continuous mode and a blinking mode are adjustable.

5.4 Special functions (TOOLS)

The "TOOLS" menu is activated by pressing the "Tools" key (*Figure 6, page* 19). On doing so, the Tools menu appears on the screen *(Figure 7, page 23*).

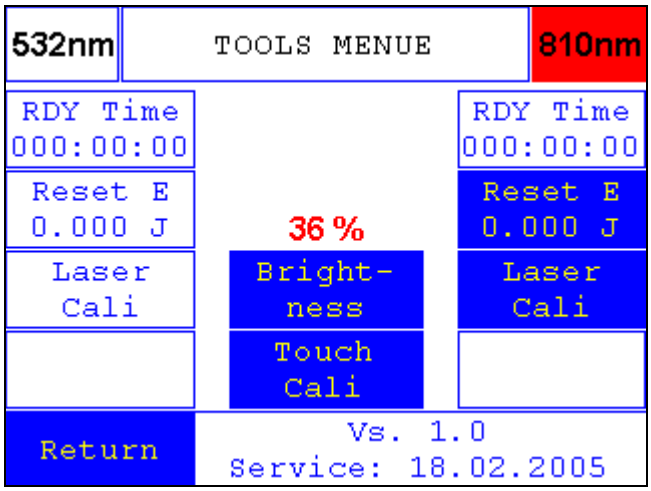


Figure 7: Tools menu

You can see, which of the laser modules is activated, by the red background color of the respective wavelength key. The corresponding displays of the total emission time, the applied total energy and the key for power calibration are arranged directly under the wavelength field. Active parameter fields are highlighted in blue.

You can execute the following functions by pressing the corresponding keys:

Key	Function	Remarks
RDY Time 000:00:00	Display of the accumulated total lasing time	Separate for every module. Display only Not resettable
Reset E 0.000 J	Resets the total energy applied to zero	To be done manually for every new patient. Performed automatically when you switch off the device.
Laser Cali	Initiates calibration of laser power	Refer to Section *5.4.1, page 24*
Bright-ness	Adjustment of display brightness	To be activated by pressing, variation by means of control knob and storage by pressing the key or the control knob
Touch Cali	Calibration of the touchscreen	See Section *5.4.2, page 24*
Return	Stores any variations of the settings and returns to the basic menu.	

5.4.1 Laser calibration

The device allows the periodic calibration of the laser parameters by the user. You are advised to calibrate the device at least once a month.

The periodic laser calibration does not take the place of the prescribed annual test of the laser power by service technician employed with or authorized and trained by Asclepion Laser Technologies GmbH (*Section 11, page 42*).

Periodic laser calibration must always be performed with the handpiece applicator. The use of any other applicator, such as bare fibers, may result in miscalibration. Therefore, their use is strictly forbidden for calibration.

If you intend to calibrate the laser, first select the laser module to be calibrated (laser wavelength) in "Standby" mode. After selection of the wavelength, activate the "Tools“ menu and press the "Laser Cali“ key allocated to the selected wavelength (*Figure 7, page 23*) and follow the prompts appearing on the display.

The calibration procedure may take up to five minutes. Please do not release the footswitch unless the laser switched to "Standby" mode by itself (laser warning sign disappears).

Then, you can save the new calibration data by pressing the "Save“ key or exit the calibration menu without saving the new data by pressing the "Exit" key.

A calibration procedure (also one interrupted by releasing the footswitch) can be repeated after three minutes at the earliest. During this time, the calibration key remains locked.

5.4.2 Calibration of the touchscreen

Recalibration of the touchscreen may become necessary when the touch-sensitive fields of the touchscreen (not visible) and the presentation of the keys on the screen do no longer coincide. This becomes apparent if the function key, if pressed, responds only sporadically or – in extreme cases – not at all.

The calibration is extremely easy. In the "Tools" menu, press the "Touch Cali" key (*Figure 7, page 23*) and follow the prompts displayed on the screen. For touching the adjusting cross hairs, use a pointed, but not scratching object (e.g. a toothpick, etc.). The more accurate you mark the cross hairs, the better the coincidence will be.

5.5 Activation of Ready mode and treatment

Prior to pushing the READY key, the attending physician should verify that all persons present in the laser room wear laser protective eyewear appropriate for the selected laser module as specified in *Section 2, page 5*. For the patient to be treated, the patient eyewear is provided.

Verify again that

- all laser safety precautions have been taken,
- the right applicator (SMA plug and fiber coding plug) has been firmly connected to the output of the selected laser module,
- the proper spot size of the handpiece has been set on the device,
- the aiming laser is visible at the treatment site and
- the handpiece or the end of the bare fiber has been placed onto the desired treatment area.

The aiming beam indicates the treatment area and the approximate spot size of the therapy beam.

As the aiming beam is transmitted through the same beam delivery system as the surgical beam (therapy beam), it provides a good means to check the intactness of the beam delivery system.

Key	Symbol	Display	Remarks
Standby/Ready		No	Visible only if the device is in "Standby“. By pressing this key, the device switches to the "Ready“ mode (laser is active).
Ready/Standby			Visible only if the device is in "Ready“ mode. By pressing this key, the device switches to the "Standby“ mode (laser not active).

After you pressed the **"Standby/Ready"** key, the laser switches to the "Ready“ mode and is then ready for operation. This means, that when you press the footswitch, laser radiation of the selected parameters is emitted at the end of the applicator.

On doing so, the "Standby/Ready“ symbol turns into the "Ready/Standby" symbol and the laser warning sign appears on the screen (*Figure 8, page 26*).

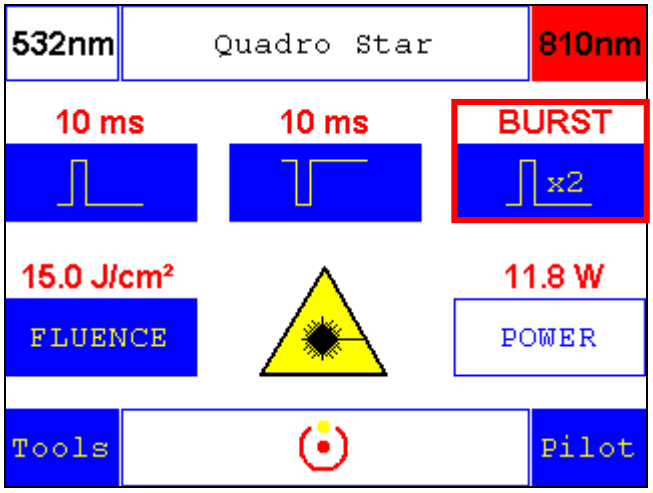


Figure 8: "Ready" menu in Burst operating mode with handpiece

When you change any parameter in "Ready" mode, the device will automatically switch to "Standby" again, which means that you have to press the "Standby/Ready“ key once more to return to the "Ready" mode.

Note that in READY mode a laser pulse will be fired when you inadvertently depress the footswitch!

The *QuadroStar* is equipped with an easy to operate **"Laser STOP" button**. It is located at the bottom front of the device (see *Figure 1*, *page 12*). In an emergency, the laser is instantly deactivated when you strongly push this button, thus eliminating any risk for operator and patient.

When the emergency was remedied, restore the functioning of the device by manually setting the Emergency Stop button in its normal position again by turning it slightly anticlockwise.

5.5.1 Releasing the treatment beam

The treatment beam is emitted with the selected operating parameters by pressing the footswitch. Releasing the footswitch instantly stops the emission of laser radiation.

On depression of the footswitch, Class 4 laser radiation will be emitted from the end of the fiber or the handpiece. Make sure to comply with all relevant regulations for the protection against unintentional laser radiation effects.

In particular, the attending physician is not allowed to release the laser unless the aiming beam spot was found to be perfect and the fiber end or the handpiece was directed directly onto the skin area to be treated.

Instantly press the Laser STOP button in the event of dangerous malfunction.

Emission of laser radiation is indicated acoustically by a warning sound and optically by the yellow blinking laser emission indicator located directly above the fiber output.

If during lasing the symbols "+ + +" or "- - -" appear below the fluence or power display, the device detected a positive or negative deviation of the output values of more than 20 %. In this case, recalibrate the laser as soon as possible (refer to *Section 5.4.1, page 24*).

If you intend to interrupt the treatment for some time or if you are finished with the treatment, switch the laser to the safe "Standby" mode by pressing the "Ready/Standby“ key once more. In this state, it is impossible to release laser emission unintentionally.

After a longer period of inactivity in "Ready" mode, the device will automatically switch to the "Standby“ mode.

5.5.2 Switching the device off

Exit the "Ready“ mode and switch to "Standby“ mode.

To switch off the laser device, turn the key switch anticlockwise as far as it will go. Only then, you should switch the power switch on the rear panel of the device to OFF (refer to *Figure 2, page 12*). By switching the power switch to "0“, the device is completely disconnected from line voltage.

Operation

Never leave the device unattended, while it is switched on. Switch the power switch to "0" to completely disconnect the device from line power supply.

After you have switched off the device, make sure you have removed the key from the key switch. Keep the key in a safe place to prevent unauthorized use of the device.

Safely put down the applicator and check its optics for any contamination. If it is contaminated, you should clean it immediately.

Never place any liquids on the device as liquids entering the device might reduce the protection against dangerous electric voltages. If liquids got into the device, instantly switch the device off by pressing the Laser STOP button and disconnecting the power cable. Immediately contact Technical Service.

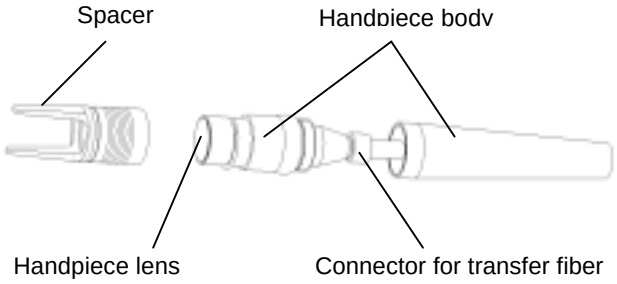
6 Cleaning, Disinfection and Sterilization

6.1 Advice for cleaning, disinfection and sterilization of accessories

Multiple use accessories

Handpieces and transfer fibers are designed for multiple use.
The spacers can be sterilized.
Parts that do not get into touch with patients, if used as intended, can be disinfected by wiping them with a disinfectant.

For that, follow the general advice given in Sections 6.2 and 6.3 of this manual.



Single use accessories

All optical fibers delivered in sterile condition are intended for single use only and must neither be reconditioned nor resterilized.

For that, please observe Section 6.3 of this manual.

6.2 General advice for cleaning, disinfection and sterilization

NOTE: Aluminum alloys can be made out by a colored layer on the metal components.

	Instruments containing aluminum are damaged by alkaline cleaning agents (pH > 7) and solutions. Cleaning elongated and narrow cannulas and blind holes requires particular attention. Please also observe the special instructions for use and cleaning provided with the accessory. The temperature should not exceed 150 °C.
Limitation of reconditioning:	The accessory is designed for 100 times reconditioning. A higher number of reconditioning cycles will affect the accessory.

Cleaning, Disinfection and Sterilization

INSTRUCTIONS:	
Workplace:	Remove dirt from surfaces using a disposable / paper towel.
Storage and transport:	No special requirements. It is advisable to recondition accessory items as soon as possible after their use.
Preparations for cleaning:	No special requirements. Disassemble accessory units by following the instructions for use/cleaning provided.
Manual cleaning:	Equipment: Neutral cleaning agent (e.g. Edisonite Super), brush, running water Procedure: 1. Rinse accessory to remove dirt from the surface (Temperature <30°C) 2. Apply cleaning agent to all surfaces using a brush. NOTE: For cleaning cannulas and blind holes, use a suitable brush to access all parts. Use an ultrasonic cleaning device, if necessary. 3. Hold the accessory under running water for three minutes. In doing so, make sure the water rinses through the cannulas. Blind holes must be filled with water and emptied repeatedly.
Automatic cleaning:	Equipment: Cleaning/disinfecting equipment, cleaning agent (e.g. Edisonite Super) 1. Load accessory parts in the equipment so that water can drain from cannulas and blind holes. 2. Set the standard cycle: Wash at least five minutes and rinse three minutes. 3. When taking the accessory parts out, inspect them visually for dirt. Particularly take care that blind holes and cannulas are clean. Repeat the cleaning cycle or clean the accessory manually, if necessary.
Disinfection:	In manual cleaning, spray disinfectant (e.g. Softasept N or Meliseptol) onto the accessory parts. Let the disinfectant take effect and wipe it off following the instructions of the manufacturer. In automatic cleaning procedures, generally use thermal disinfection (e.g. disinfection temperature: 93°C, time 10 min.)
Maintenance, control and testing:	No special requirements.
Packing:	A standard polyethylene / Tyvek bag can be used. The bag must be large enough for the accessory to allow closing without the seal being strained.

Sterilization:	Vacuum autoclave, at least five minutes at 134°C. 150°C must not be exceeded.
Storage:	No special requirements.

The manufacturer has validated that the instructions given above are SUITABLE for the preparation of the accessory parts for their reuse. The reconditioner is responsible that the actually performed reconditioning procedure yields the desired results with the equipment and material used and the personnel working in the reconditioning facility. For that, normally validation and routine supervision of the reconditioning procedures are necessary. Likewise, any departure from the provided instructions should be assessed carefully by the reconditioner for efficacy and negative consequences.

6.3 Special advice for handling, cleaning, disinfection and sterilization

Handpiece and spacers

As a rule, accessories should be cleaned and sterilized immediately after their use with the device switched off.

If immediate cleaning should be necessary, make sure to switch the device to "Standby" mode, before starting to clean the handpiece! Because of the risk of fire, do not use alcohol or isopropyl alcohol near the treatment area.

Dirt on optical surfaces burns in by exposure to laser radiation and results in malfunction and overtreatment!

To remove oil, grease, dirt, chemical compounds or other contaminating substances, use neither water nor soap.

The spacers detachable from the handpiece are to be sterilized before every use on the patient. If used without sterilization, there is the risk of contamination by viable particles.

Cleaning, Disinfection and Sterilization

For the reconditioning of handpieces and spacers, observe the general advice given in Section *6.1,* page *29*.

Clean handpiece lenses before use.

The spacer is to be inserted in the handpiece by pressing it in. To remove it from the handpiece, you need simply withdraw it.

If handpieces are not used for a longer period, the handpiece inserts must be protected from dust. To restore the original state, blow off dust deposits from the external or internal surfaces with air.

Please note that the spacers are to be used only in combination with the corresponding handpiece. You can easily identify the proper assignment of handpiece and spacer by means of the color code used.

Excessive heat-up of the handpiece in longer laser operation indicates contamination of the handpiece lens. In this case, instantly interrupt treatment ("Standby") and clean the lens.

Bare fibers

Bare fibers are intended for single usage. We do not assume any liability for damage caused by multiple use and improper handling.

Store the fibers at room temperature in the transport packaging and protect them from any damage.

Only if these requirements are met, the sterility of the fibers is ensured until the expiry date specified on the sterile packaging.

- Before opening the sterile packaging of the fiber, check it for intactness and correct labeling (fiber tape, sterility expiry date). Use only fibers taken from an intact packaging.
- After you have opened the sterile packaging, carefully take out the fiber and check it for any damage (fiber breaks).
- Carefully remove the protective cap of the SMA plug (grasp the metal plug, do not pull at the fiber; avoid contamination of the fiber end). You may only use fibers with clean fiber ends.

- Screw the SMA plug into its counterpart of the fiber coupling as far as it will go. Avoid torsional stress to the fiber.

In extreme cases, failure to screw down the fiber properly may result in damage to the coupling optics in the fiber connector.

- Defective coupling optics may cause destruction of the end face of the fiber in the SMA plug (even that of new fibers). This can be noticed by a strong loss in power despite the use of a new fiber.
- Assess the optical quality of the fiber after switch-on of the laser by examining the red spot of the aiming beam at the fiber end. A "frayed" edge indicates defects or contamination of one or both fiber ends.
- Dispose of used fibers as infectious material.

Beam delivery system

All optical components, especially all parts of the beam delivery system, must be treated with extreme care and protected from dust and contamination.

Laser fibers must not be bent too much. If possible, set up the device relative to the patient in such a way that the fiber is arranged straight. On no account, bend the fiber more than the specified minimum bending radius. As a rule of thumb, you can calculate the minimum bending radius by multiplying the fiber core diameter by 100, i.e. for a 600-µm fiber, the minimum bending radius is 6 cm. Observe also the instructions for use provided with the optical fibers.

Avoid directly touching optical surfaces.

Complete device

Before cleaning the device, disconnect the device from line power by unplugging the power cable from the power outlet.

Avoid the contact of water or other liquids with the device.

Cleaning, Disinfection and Sterilization

Users are allowed to clean the external surfaces of the device only.

You may clean all accessible components of the device with a soft, slightly moistened cloth. Take care that the cloth is neither wet nor even dripping wet.

To remove sticking dirt, you can use a mild detergent or disinfectant. Do not use aggressive disinfectants or abrasive cleaning agents.

7 Accessories

Please note that the Medical Product Law binds you to use only such accessories on the device that have been tested and approved and that are intended for this laser by Asclepion Laser Technologies GmbH.

On request, Asclepion Laser Technologies GmbH will readily send you an updated list of such accessories.

We strongly advise against the use of accessories from other manufacturers. Even if an official testing authority should have certified that a specific accessory unit could be used safely, Asclepion Laser Technologies GmbH cannot assume any liability for these products.

Designation	Part No.
Handpiece LBO 532	4201 00 000
Spacer LBO 532 – 500 µm	4204 00 000
Spacer LBO 532 – 1000 µm	4205 00 000
Spacer LBO 532 – 1500 µm	4206 00 000
Transfer fiber LBO 532	2801 00 0000
Handpiece set LBO 532 (Handpiece with 3 spacers and transfer fiber in case)	4210 00 000
Handpiece, Diode 810 ... 980	4202 00 000
Spacer, Diode 810 ... 980 – 600 µm	4207 00 000
Spacer, Diode 810 ... 980 – 1000 µm	4208 00 000
Spacer, Diode 810 ... 980 – 1500 µm	4209 00 000
Transfer fiber, Diode	2810 00 000
Handpiece set, Diode (Handpiece with 3 spacers, transfer fiber in case)	4211 00 000
Bare fiber, Diode 810 ... 980 – 200 µm	2882 00 000
Bare fiber, Diode 810 ... 980 – 300 µm	2883 00 000
Bare fiber, Diode 810 ... 980 – 400 µm	2885 00 000

Accessories

Designation	Part No.
Bare fiber, Diode 810 ... 980 – 600 µm	2884 00 000
Bleaching handpiece	4203 00 000
Physician's laser protective eyewear, LBO 532	1227 00 000
Physician's laser protective eyewear, Diode 810 - 980	1228 00 000
Eye protection for patient, 532 - 980	1229 00 000

8 Error Messages

If the device does not respond to turning the key switch to ON, make sure the following requirements are met:

1. The Emergency Stop button has been unlocked (by turning the red knob anticlockwise until the lock is released and the button jumps out; refer to *Figure 1,* page *12*).
2. The power switch on the rear panel of the device has been switched on:
   Position "1“, refer to *Figure 2,* page *12*)
3. The main fuses on the rear panel of the device (refer to *Figure 2,* page *12*) are not defective. To check the fine-wire fuses, switch the device off.

As mentioned previously, you are assisted in operating the laser and in fault finding by PC controlled operator guidance via the display.

The following types of error messages are possible:

- In the case of general faults, the display shows an error message with instructions in plain text. While error messages are displayed, the touchscreen is locked and inoperative. Also, touching the screen does not generate any acoustic response. The device will remain in this state until you switch it off. If – after restarting the device – the fault persists, call Technical Service.

You are strongly advised against any attempt to repair the device yourself! When you remove device covers, extremely dangerous high voltage becomes accessible that may still be applied even after the power cable was disconnected from the power outlet!

- In the case of safety-relevant faults, the device will shut down within milliseconds.
  In this case, the display of error messages is impossible. If this happens or any other fault appears that has not been described in this manual, disconnect the device from line power by unplugging the power plug from the power outlet.

9 Fault Removal

9.1 General information

This chapter provides information on possible causes of any malfunction of the *QuadroStar* system. Faults can be removed by the operating personnel except of those specially referred to as requiring repair by technicians employed with or authorized by Asclepion Laser Technologies GmbH.

Improper use or maintenance of the laser system may void the warranty granted by Asclepion Laser Technologies GmbH. Before starting any repair or if you have questions that have not been answered by this manual, contact your service representative (see *Section 10, page 41*).

9.2 Error messages and fault removal

The *QuadroStar* is equipped with alarm systems. If these are released, the system will switch in the safe state and stop the emission of laser radiation.

Before you contact the Service Department of Asclepion Laser Technologies GmbH, make a note of the error message and the error code displayed.

Error message	Explanation / Corrective action
Temperature too low **Code xxx**	- Temperature of laser module is too low Let the device run in "Standby" mode for a while, until it has reached the minimum operating temperature. Try to switch the device off and on again, if necessary. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Temperature too high **Code xxx**	Switch the device off and let it cool down. After some time, switch it on again. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Data Transfer **Code xxx**	- Internal fault in data exchange Switch the device off and on again. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.

Fault Removal

Error message	Explanation / Corrective action
Setup **Code xxx**	- Internal fault in data storage Switch the device off and then try to switch it on again. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Unknown applicator	- Fiber coding plug not plugged or defective Plug the fiber-coding plug in again or replace the applicator. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Fiber not connected	- SMA fiber plug not connected or not firmly locked in place Check the SMA fiber plug. The fiber plug must be plugged into the device-side SMA connector as far as it will go and the coupling nut tightened clockwise.
Door Interlock	- The door interlock contacts are open or the door interlock plug is not connected (*Figure 3,* page *13*). Connect the door interlock contacts correctly or activate the door interlock switch. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Power Supply **Code xxx**	- Fault in power supply Switch the device off and then try to switch it on again. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Footswitch **Code xxx**	- Footswitch depressed already when device is switched to the "Ready“ mode - Footswitch defective Release the footswitch and then switch to the "Ready“ mode. If the error persists, replace the footswitch or contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.

9.3 Possible malfunctions

Fault	Explanation / Corrective action
No power supply	- Verify that the power cable has been connected to a power outlet. - Is the power switch set to position "I"? - Verify that the Emergency Stop button is released. - Check both line input fuses by pulling out the fuse drawer (**Disconnect power plug before!** See *Figure 2, page 12*). - Check line fuses of domestic power supply system. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
The aiming beam does not appear at the fiber output of the handpiece	- Problems with aiming beam emission - Broken optical fiber - Problems with control electronics - Device in faulty condition Replace the fiber applicator or switch the device off and on again. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
No laser exposure of patient when footswitch is depressed	- Verify that the connecting cable of the footswitch is properly connected. - The device is in "Standby". Press "Ready" key to switch to "Ready" mode. If the error persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.

10 Service

Never open the device and attempt to repair the device yourself if the laser does not work properly.
The laser does not contain any user-serviceable components.
Only service technicians employed with or trained by Asclepion Laser Technologies GmbH are authorized to service the device.
This also applies to the prescribed annual safety tests.

If you need assistance by customer service, please get in touch with us via the address or phone number given below. When contacting your service representative of Asclepion Laser Technologies GmbH, always keep the model and the serial number of the device at hand. These numbers are specified on the type label located at the rear panel of the laser device (refer to *Figure 10,* page *46,* or *Figure 16,* page *48*).

Asclepion Laser Technologies GmbH
Service
Goeschwitzer Str. 51-52
D - 07745 JENA

Phone: +49 (0) 3641 220 – 423
Fax.: +49 (0) 3641 220 – 322
E-Mail: service@asclepion.com

Please note that the manufacturer, installer or importer will not consider themselves responsible for the effects of servicing on safety, reliability and performance of the device unless the following requirements are met:

- Installation, extensions, readjustments, modifications or repairs have been performed by authorized persons.
- The electric installation of the laser room meets the requirements of IEC 64 in the currently valid form.
- The device has been used in accordance with the instructions given in this manual.

11 Regular Safety Tests and Calibration

Please note that the device should be subjected to regular safety checks at annual intervals. The results of these safety checks must be recorded in the medical device logbook.

Do not set up this device in explosion-risk areas. Before using the laser device, allow for the evaporation of solvents and flammable solutions used for cleaning and disinfection.

Only persons employed with or authorized by Asclepion Laser Technologies GmbH are allowed to service, repair or modify the device.

The power delivered by the therapy lasers must be checked at least once a year by a service technician employed with or trained and authorized by Asclepion Laser Technologies GmbH.

The use of controls or adjustments of the equipment for operation, maintenance, testing and calibration or the performance of procedures other than those specified in this manual may result in hazardous laser radiation exposure.

The routine maintenance procedures described below can be performed by the personnel of the clinic or hospital:

VISUAL INSPECTION OF THE DEVICE

Check if all cables are intact and connected firmly.
Frequency: Weekly
To be checked by: Personnel of clinic or hospital

CHECK OF COOLING SYSTEM

Check if all ventilation grids of the cooling system are free.
Frequency: Weekly
To be checked by: Personnel of clinic or hospital

Regular Safety Tests and Calibration

CALIBRATION OF THE LASER

Perform the laser calibration according to *Section 5.4.1,* page *24*
Frequency: Monthly
To be checked by: Operator of the device

CHECKING THE FIBER HANDPIECE

Check if the fiber handpiece is in perfect state.
Frequency: Before every use
To be checked by: Operator of the device

PREPARATIONS FOR RELOCATION / TRANSPORT OF THE DEVICE

Before relocating the device:

- Disconnect the power plug.
- Disconnect the fiber / the handpiece.
- Disconnect the footswitch.
- Disconnect the door interlock plug.

If it is necessary to transport the device over longer distances by car or any other vehicle, it is best to store it in its original case.

SCOPE OF ANNUAL SAFETY TESTS (ST)

The safety tests should be carried out in compliance with the relevant national regulations in their presently valid form and include at least the tests mentioned below. The tests should be run in the order specified:

- Visual inspection of laser device and accessories
- Measurement of protective-conductor resistance
- Earth leakage test under normal conditions
- Measurement of the actual output powers of the laser modules at the handpiece; calibration of laser power, if necessary
- Functional test

Only authorized service technicians are allowed to calibrate the laser power.

12 Warnings

Do not start up the device unless you have read this User's Manual. Always keep the User's Manual in a handy location.

Before starting up the laser device, switch off cellular phones and similar equipment.

Only specialists appropriately qualified and authorized are allowed to open the laser device.

While the laser is in operation, the persons present must wear the laser-protective eyewear appropriate for this type of laser provided by the laser manufacturer.

Other types of laser protective eyewear possibly do not provide the degree of protection needed.

Never look directly into the distal end of the handpiece while the device is in "Ready" mode.

Even if, due to a fault in the device, the device fails to fire a laser pulse once or several times (skipped pulses), under no circumstances you must look into the distal end of the handpiece, as the laser may fire further pulses when you depress the footswitch.

Laser smoke might contain highly dangerous tissue particles.

Sterilize the used spacers, which are detachable from the handpiece, before every use on the patient.

Make sure the laser device has been switched to the NOT-READY state ("Standby" mode), before you can start cleaning it! Never use any alcohol or isopropyl alcohol near the treatment area to avoid the risk of fire.

Warnings

The use of controls or adjustments of the equipment for operation, maintenance, testing and calibration or the performance of procedures other than those specified in this manual may result in hazardous laser radiation exposure.

Never connect any devices to the Service and I²C connectors on the rear panel of the laser device.

Never place any liquids on the device as liquids entering the device might reduce the protection against dangerous electric voltages. If liquids got into the device, instantly switch the device off by pressing the Laser STOP button and disconnecting the power cable. Immediately contact Technical Service.

13 Labeling

Various warning and information labels are affixed to the front and the rear panel of the laser device.

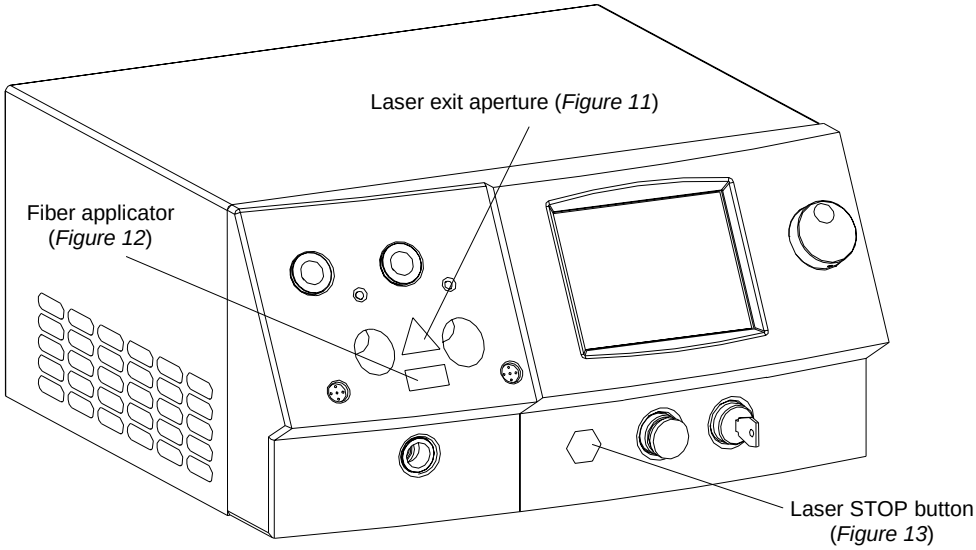


Figure 9: Labels on front panel

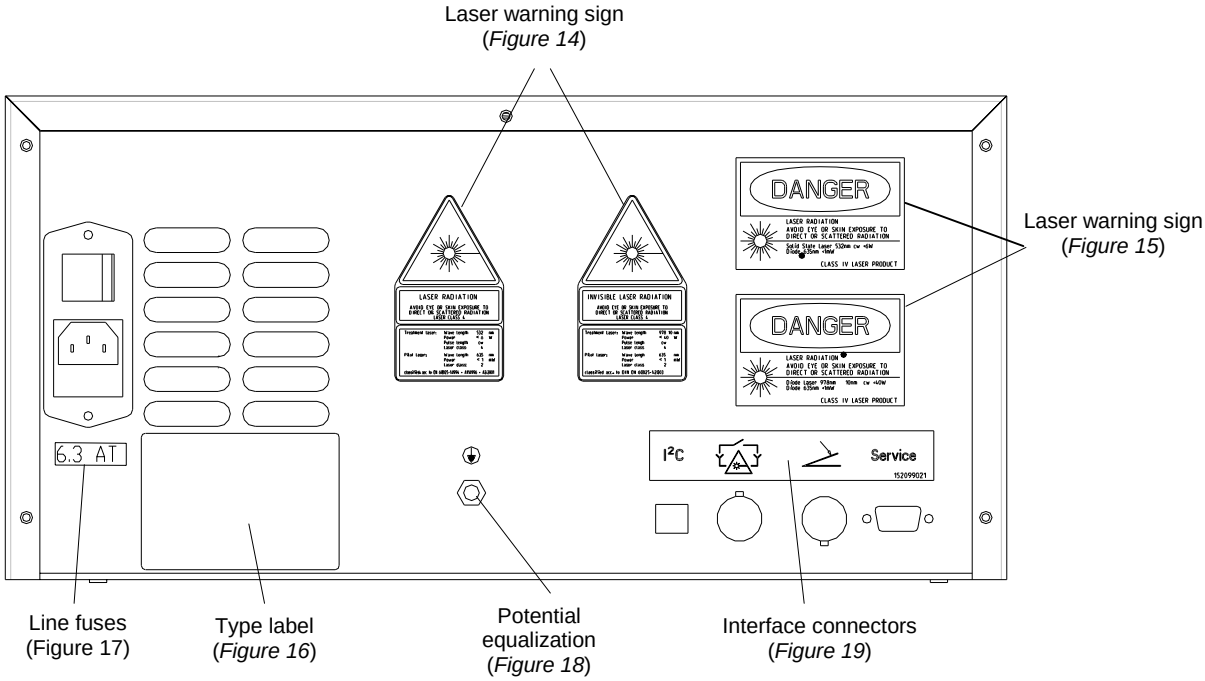


Figure 10: Labels on rear panel

Labeling

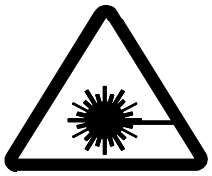


Figure 11: Laser exit aperture

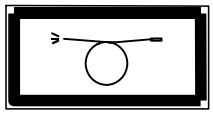


Figure 12: Optical fiber applicator

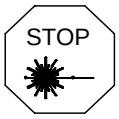


Figure 13: Laser STOP button

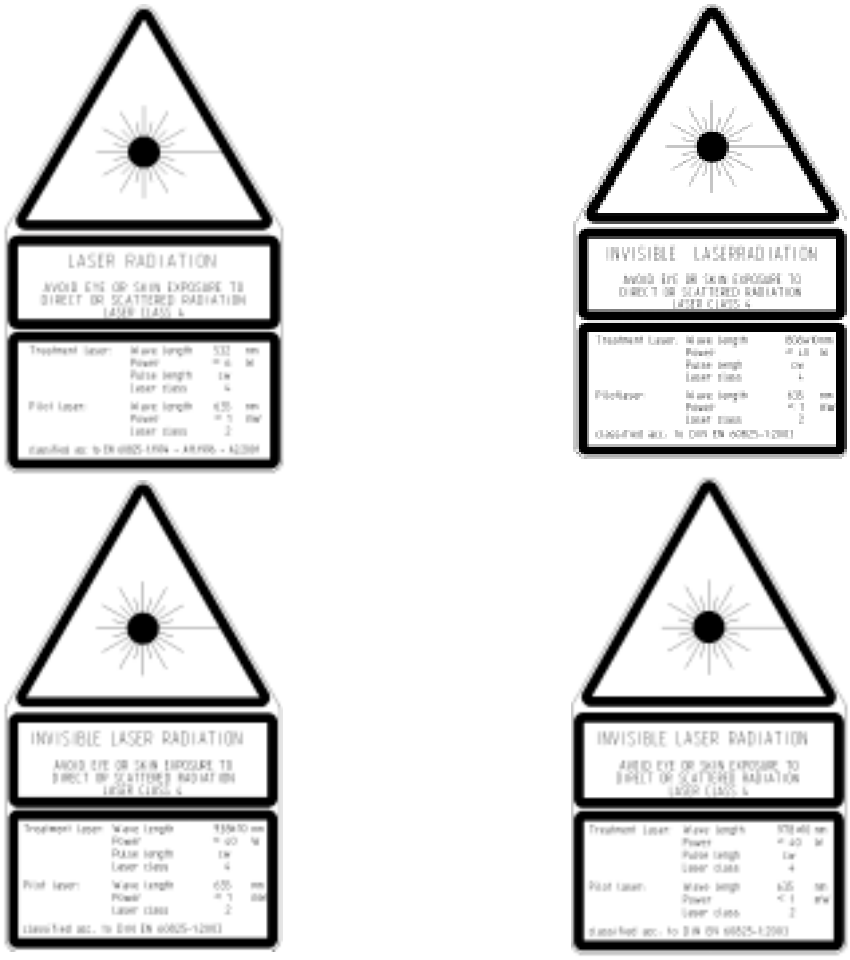


Figure 14: Laser warning sign EN 60825-1

Labeling

Figure 15: Laser warning sign 21 CFR

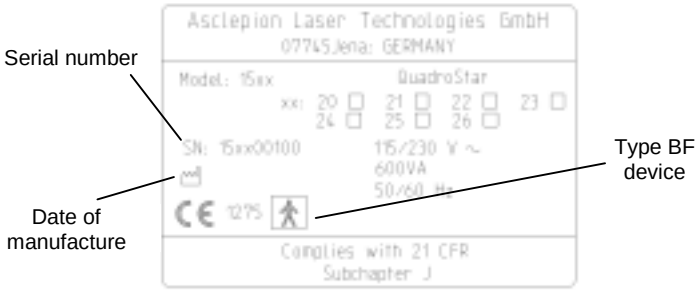


Figure 16. Type label

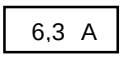


Figure 17. Line fuse

Figure 18. Potential equalization

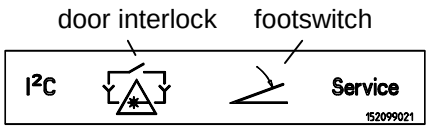


Figure 19: Interface connectors

14 Disposal

The device must be disposed of in compliance with the regulations on electronic waste. Please consult our Technical Service if you have any questions regarding disposal.