MeDioStar

USER MANUAL

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Copyright

Knowledge of this manual is required for the operation of the instrument. 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.

Content

1 Intended Use

The *MeDioStar* is a pulsed diode laser (Class 4 laser product) that is used for the removal of undesired hair. The melanin contained in hair relatively strongly absorbs the radiation of the wavelength emitted by this laser, whereas the skin surrounding the hair absorbs very little only. In this way, the radiation destroys hair while protecting the skin.

As a medical laser designed for this field of application the device features compactness, largely maintenance-free operation and long service life.

In designing the *MeDioStar*, a new powerful medical laser device, Asclepion Laser Technologies GmbH made use of its long-standing experience in the manufacture of medical lasers.

The *MeDioStar* is a reliable, compact laser device that features extreme simplicity of operation and that can be used in any private practice or clinic.

The device is easily relocated to the desired place of treatment.

The *MeDioStar* fully complies with the requirements of the Medical Product Law. It is designed to the generally accepted rules of technology and meets all relevant safety standards.

It must expressly be pointed out here, that the device may only be operated by persons who received introductory instructions on its use. This must be confirmed by signature in the medical device logbook. In addition, the user must have read this user manual and the application manual.
The initial introduction into the operation of the device will be given by persons employed with or trained by Asclepion Laser Technologies GmbH during the installation procedure.
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, among others, also by Asclepion Laser Technologies GmbH.
Non-observance of the instructions given may result in risks to the health of patients and operator as well as damage to the device! The manufacturer will not assume any liability for such damage.

Medical Device Directive

The *MeDioStar* meets the requirements of the EC Medical Device Directive 93/42/EEC and of their national equivalent in form of the German Medical Product Act (MPG)

Instrument class according to the MPG: II b

UMDNS-No.: 16-948

2 Technical Data

Laser type:	High-power laser diode array
Laser Class:	4
Wavelength:	810 nm
Pulse length:	max. 50 ms single pulse (max. 100ms double pulse)
Pulse energy:	MeDioStar HC: max. 50 J, MeDioStar C: max. 30 J
Spot size:	12 mm, 10 mm, 14 mm (MeDioStar C only: 8 mm)
Energy density:	MeDioStar HC: max. 64 J/cm^2 at 10 mm spot size
	MeDioStar C: max. 60 J/cm^2 at 8mm spot size
Pulse frequency:	0.5 Hz, 1 Hz, 1.5 Hz, 2 Hz, 3 Hz and 4 Hz
Aiming laser:	635 nm Diode, <1 mW; adjustable intensity
Beam delivery:	Optical fiber
Display:	LCD display, Touch Screen
Power requirements:	100/120/208/220/230/240VAC selectable, 50/60 Hz
Rated current:	max.8A at 208/220/230/240V,
	max.12A at 120V,max.15A at 100V
Skin cooling:	integrated
Dimensions:	365 x 600 x 975 mm³ (W x D x H)
Weight:	89 kg
Environmental requirements:	Temperature: 15°C ... 30°C, rel. humidity: ≤ 85%
Door contact supply:	5 V / 10 mA
Laser warning lamp:	Floating relay contact max. 24 V / 1,0 A
Transport and	Temperature: 0°C ... +70°C
Storage conditions:	Rel. humidity: 10 % ... 95 % (no condensation)
	Mechanical loads: as per Class 2M1 DIN IEC 721 Part 3-2
Enclosure Protection:	IP 20 (no protection against entry of water)
	Protection Class I (protection against electrical shocks)
	Device Type B
Medical Device Class	II b (EC Medical Device Directive 93/42/EEC).

Control	The safety devices of the laser are monitored and controlled via microprocessors.
Laser release	Optional by handpiece or footswitch
Operating mode	The device is designed for continuous operation.
Operation	User guidance is via touch screen in plain text. The following operating parameters are adjustable: frequency and energy density The following parameters and device states are additionally displayed: pulse energy, spot size, pulse count per session, total pulse count, readiness for laser operation and error messages in plain text in the event of troubles.
Accessories and **optional units**	see Section 6

3 Safety Notes

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

Risk of accidents or physical injury.

Risk of possible technical damage.

The *MeDioStar* complies with the EC Medical Device Directive (93/42/EEC).

Please observe any relevant national regulations !

The above directives bind the owner/operator, the authorized persons and users of Class IIb devices to take a number of precautions. In particular, such devices may be operated only in accordance with the generally accepted rules of technology and the relevant regulations on labour 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 exposure.
You are committed to keep a medical device logbook, which is enclosed to the folder for documents. Our service technician will assist you in filling it in as part of the start-up procedure.

Please make sure to have this device checked annually for technical safety. The results of these safety checks must be documented in the medical device logbook.

Do not install the Laser in explosion-risk areas.

The device may only be serviced, repaired or modified by persons employed with or authorized by Asclepion Laser Technologies GmbH.

The **regulations for the prevention of accidents by laser radiation IEC 60 825 –1 / EN 60 825-1 (or national requirements)** lay down general rules for the protection against hazardous laser exposure. In the context of medical application, they aim to protect operating personnel and patients during laser operation. The laser devices are classified in different classes depending on the potential risks involved. The *MeDioStar* is classified in Class 4.

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

To avert these risks, the owner/operator is obliged to comply among others with the following requirements:

- Prior to initial start-up, the intended use of the laser must be notified to the competent Professional Association and the labour-safety authority (see national requirements).
- A laser safety officer must be appointed in writing. The minimum responsibilities of the laser safety officer include:
  - ⇒ Supervision of the operation of the laser device
  - ⇒ Assistance to the owner/operator to ensure safe operation and implement the necessary precautions
  - ⇒ Co-operation with labour safety specialists in fulfilling their tasks, including information about important issues of the protection against laser radiation (see national requirements).
- While the laser is in use, the area in which the maximum permissible radiation level may be exceeded, the so-called "laser area", must be delimited and marked by a laser warning sign. Warning lamps at the entrances must indicate operation of the laser (see national requirements).
- The value of the **NOHD** (Nominal Ocular Hazard Distance) is so high, that the whole treatment room, where the laser is used, is defined as laser area.
- Personal eye protection: All persons present in the laser area must wear laser safety goggles. The safety goggles must provide a protection level of at least L 5 for (810 ± 15) nm (see EN 207, valid version).

Safety features of the device

Numerous precautions have been taken to provide a high level of active safety in combination with high operating convenience:

- Immediately on turning on the device, the microprocessor control performs a self-test.
- Following this test, a number of safety-related components are automatically tested.
- The device switches to Standby mode. The device will display an error message if the device failed to successfully pass this test.
- While the laser is in use, the microprocessor control is continuously being checked for proper function.
- Highest priority has been given to preventing any risk to the physician and the patient as a result of a component failure.
- The device is fitted with lockable castors. These castors must be locked again after any relocation of the device to secure it against any unwanted movement.

4 Start-up

Initial installation of the *MeDioStar* is always performed by an authorized representative of Asclepion Laser Technologies GmbH. Based on the instructions of this manual the representative will explain the responsible operator how to operate the laser device.

4.1 Check for completeness

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

- Basic unit consisting of three separable units:

  LASER UNIT

  POWER SUPPLY with drawer, three interface cables and skin cooling system for device version MeDioStar HC

  COOLING UNIT with castors

- Power cable
- Coolant interface with quick-lock couplings
- Snap-in rear cover
- Footswitch
- Beam delivery fibre and handpieces
- Warning lamp / door interlock connector
- Service hoses
- Safety goggles (number according to order)
- Documents

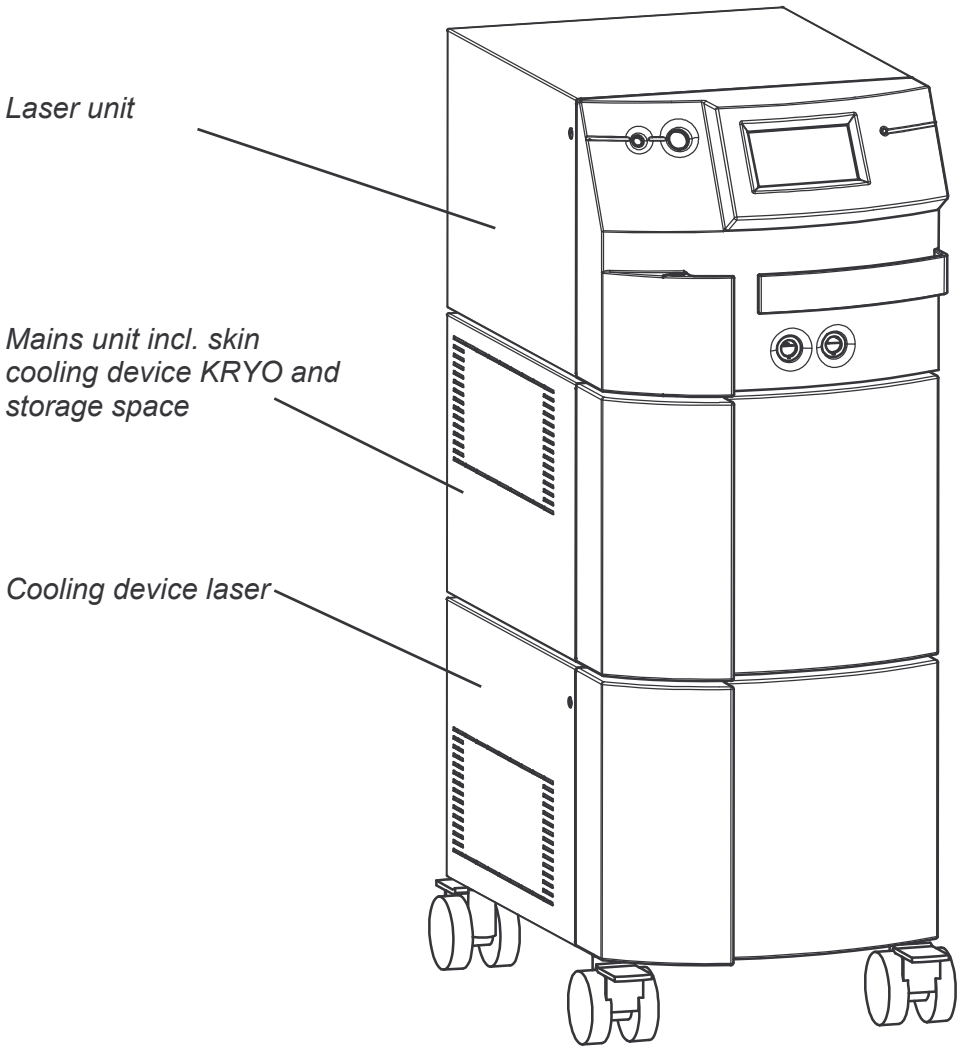


Fig. 1: MeDioStar

4.2 Installation

All major connectors are located at the rear panel of the device.

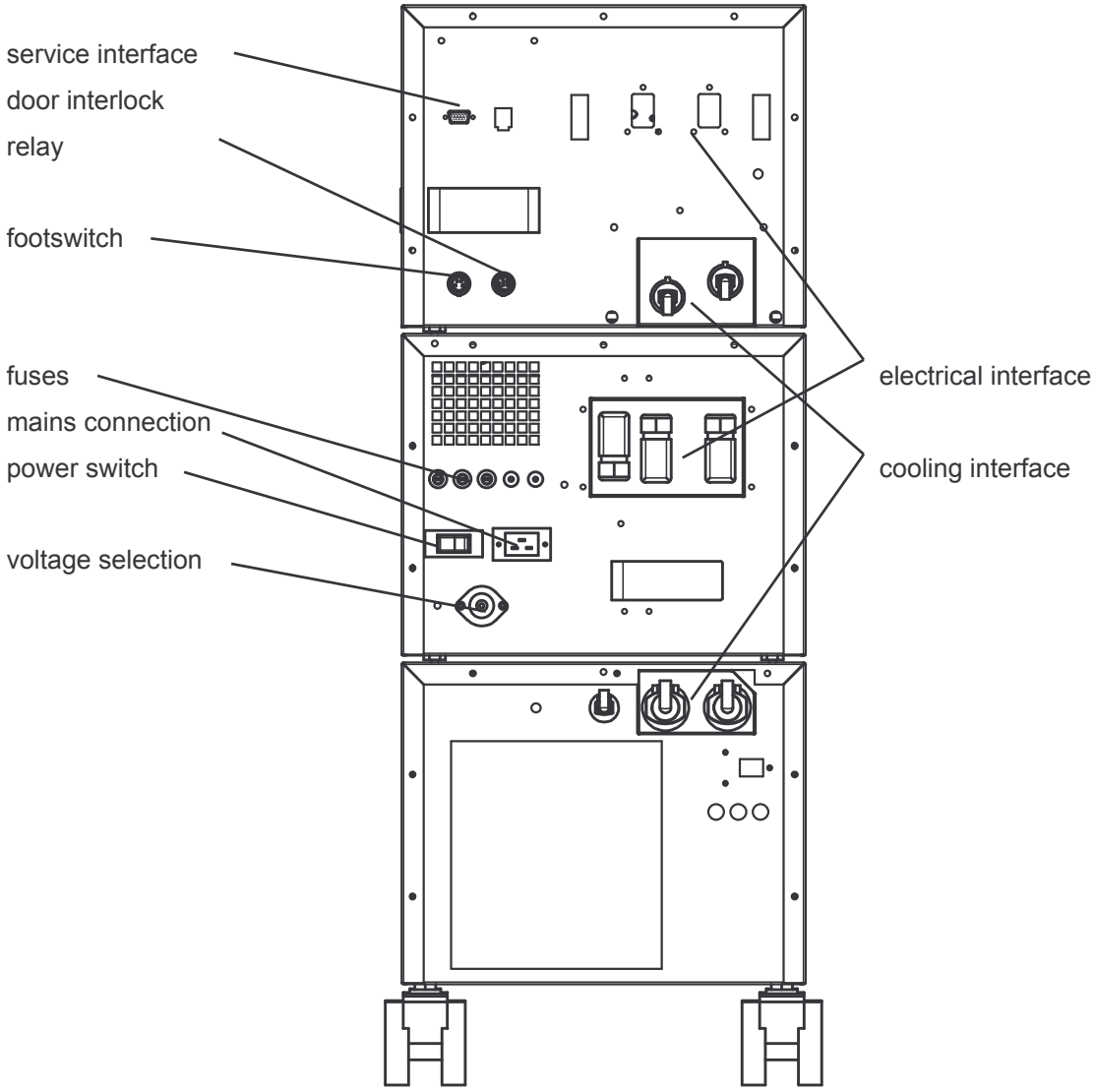


Fig. 2: connections on the rare side of laser system

4.2.1 Installation of basic device

Absolutely make sure to disconnect the power cable from the power outlet during installation!

Installation of the basic unit is very simple and should best be performed in the following order (refer to Fig. 2):

1. Set up the cooling unit at a freely accessible place. Lock its castors to avoid unwanted movement of the unit.
2. Put the power supply unit onto the cooling unit so that it snaps into the connecting elements provided. Then, secure the connection by screwing in the knurled screw.
3. Put the laser unit onto the power supply unit so that it snaps into the connecting elements provided. Then, secure the connection by screwing in the knurled screw.
4. Connect the coolant interface as illustrated by means of the four quick-lock couplings.
5. Establish the electric connections between the three units as illustrated by using the three firmly connected interface cables.
6. Connect the earthing contact by means of the flat connector. Attach the rear cover so that it snaps into the provided elements.
7. Make sure the setting of the voltage selector agrees with the available line voltage. If not, select the appropriate setting.
8. Connect the coolant and electrical interface of the skin-/applicator cooling system to the cooling device installed in the main unit above the drawer (see instructions of installation of the beam delivery system)
9. Connect the coolant interface of the laser applicator to the Y-distributor, located at the connection hose to the skin cooling system.
10. Connect the power cable to the power supply unit.

Now, the installation of the basic unit is concluded. Next, you can continue with the start-up procedure.

4.2.2 Connection to power outlet

Connect the laser device to a single-phase power outlet protected by a slow-blow fuse of 10 A for 208/220/230/240 VAC or 16 A for 100/120 VAC.

When choosing the power outlet consider all technical data of local mains and the device (see section 2). Make sure the voltage selector on the rear panel of the device is correctly set.

Please observe the requirements of IEC 64, respectivily national requirements in valid version.

Note on installation

Keep a free space of at least 15 cm to the wall to ensure the necessary efficiency of the cooling system. For service work, it should be possible to have a free space of 80 cm around the device.

4.2.3 Connection of warning lamp and door interlock

In addition to the prescribed warning signs, every entrance to the laser area (typically 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 (refer to Fig. 3). If you do not use these safety devices, make sure to plug the door-interlock plug provided into this connector.

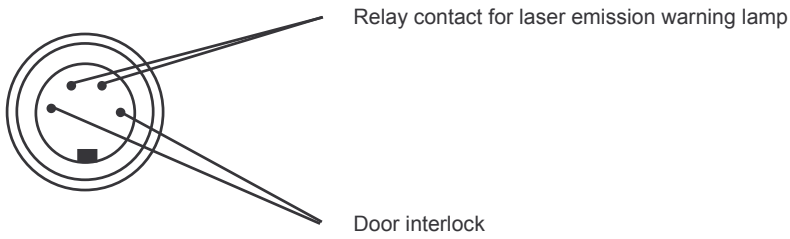


Fig. 3: Connectors for door interlock and laser warning lamp

If the two "door interlock 5VDC/10 mA" terminals are connected to an external contact, such as a door interlock, you can prevent laser radiation from being emitted when the door is being opened.

During laser operation, the surgical beam will instantly be switched off when the door is opened thus precluding any risk to the person entering.

This external circuit must not get in touch with a mains conductor and not be accommodated in a connector or any other connecting element carrying line voltage. To be able to operate the laser, this contact must be closed.

The door-interlock connector provided is therefore factory-fitted with a shorting bridge. For connection of a door-interlock circuit, remove this bridge and connect your door interlock to the same terminals. If you do not use a door-interlock circuit, make sure to keep the connector with shorting bridge connected.

The same connector provides connection to a floating normally open contact. This contact allows a circuit for a low-voltage warning lamp to be switched (max. 24V / 1A).

The contact closes when the laser is switched to ‘READY’-mode.

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.

4.3 Preparations for use

After every relocation of the device from a colder to a warmer environment with a temperature difference of more than 5°C (41°F), let the device in unpacked condition adjust to room temperature for the following periods :

min. 2 hours	**at a temperature difference of up to**	**10°C (50 °F)**
min. 4 hours	**at a temperature difference of up to**	**15°C (59°F)**
min. 10 hours	**at a temperature difference of more than**	**15°C (59 °F)**

Then, switch the device on without the fiber being connected and let it run for 30 minutes.

Non-observance of this instruction may destroy the device.

Make sure the following requirements have been met:

1. Voltage selector on rear panel of device has been set to the local line voltage.
2. Power plug of device has been connected to an appropriate power outlet. The main switch has been set to ON.
3. Optical fiber with handpiece have been connected.

The end of the fiber bundle (direction to the device) has to be checked for cleanness, each kind of dirty has to be removed (with moist, smoth pad, alcohol or isopropanol is also possible – than surface has to be polished dry) .
Each absorbent contamination generate a local overheating and might be lead damages at the device!

4. Footswitch has been connected (when requested).
5. Warning lamp has been installed at the entrance (when requested).
6. Safety door interlock has been connected (when requested).

4.4 Switching ON

Insert the safety key into the key switch and turn it clockwise as far as it will go.

The system will perform a self-test to check the essential and safety-relevant components of the device for proper function.

After some seconds, the basic menu will appear on the screen and guide you through further operation (refer to Fig. 5). It will take about 5 seconds for the self-test to finish. Only then the keys will be activated.

The device is in ‘STANDBY’-mode and displays all parameters adjustable.

4.5 Checking the beam delivery system

For checking the beam delivery system must be put on the enclosed safety goggles !

1. The beam delivery system consists of the optical fiber and the handpiece.
2. An aiming beam was integrated in the MeDioStar in order to check the beam delivery system. The aiming beam transmits the same optical path through the beam delivery system as the surgical beam. It is switched ON only in ‘STANDBY’-mode. If the aiming beam does not evenly illuminate the beam exit aperture of the handpiece, this may indicate that the beam delivery system is either damaged or misaligned.
3. The red aiming spot should be regarded with the installation of the device in order to be able to assess any later modifications.

If the aiming laser does not evenly illuminate the beam exit aperture of the handpiece or the optical fiber, do not activate the surgical beam to avoid local overheatings, overtreatments or damage to the device!

In this case the handpiece tip has to be replaced.

You can only assess the evenness of illumination in ‘STANDBY’-mode, as the aiming laser is on only in this mode!

This check can and must never be performed in ‘READY’-mode to prevent unintentional release of the surgical laser beam!

Make absolutely sure that the distal end of the handpiece keep cleaned. Each absorbent contamination generate a local overheating and might be lead to overtreatments and damages at the handpiece!

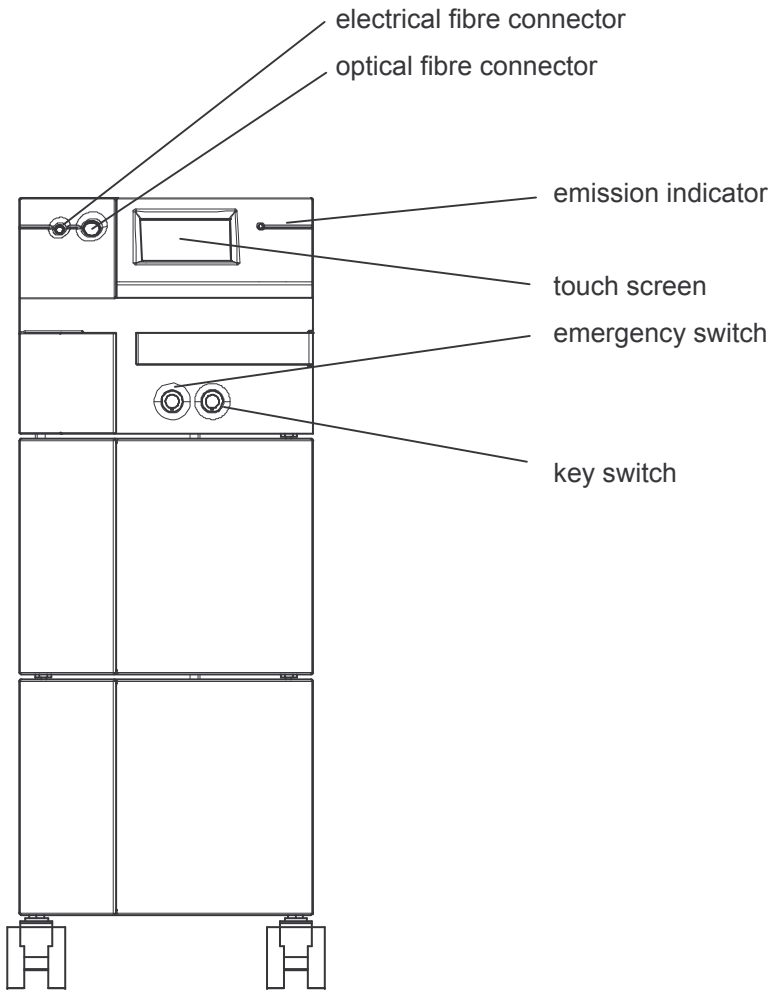


Fig. 4: Controls

4.6 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.

On completion of the start-up routine, the display shows following the menu.

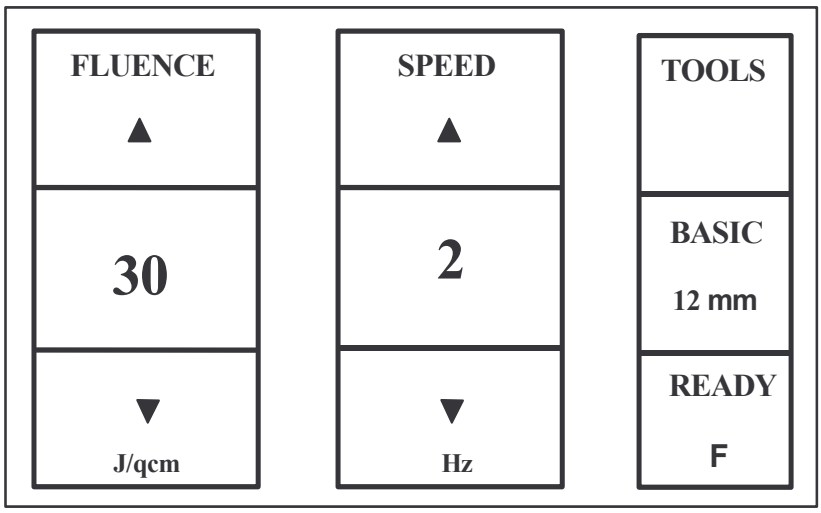


Fig. 5: Display (in STANDBY)

Operation of the device via the touch screen is very simple and self-explanatory.

The system will respond to every successful key pressure by a short beep.

4.6.1 Adjustment of treatment parameters

- The **energy density** is the crucial parameter for laser treatment. It is displayed as fluence in J/cm² and may be adjusted to the desired value by pressing the appropriate arrow keys in the **FLUENCE** field.

  If the energy range is not sufficient to achieve the desired fluence value, replace the used beam delivery system by one having a smaller diameter. Handpiece detection and recalculation of the new fluence value is automatic.

- If within the FLUENCE field a small triangle appears, the energy has slightly increased (arrowhead pointing upward) or decreased (arrowhead pointing downward) within the tolerance limits. These slight variations can be compensated for, if necessary, by slightly readjusting the fluence.

- The pulse frequency is adjustable by pressing the corresponding arrow fields in the **SPEED** field. The following frequencies are selectable:
  0.5 Hz, 1 Hz, 1.5 Hz, 2 Hz, 3 Hz and 4 Hz
  (depending on the adjusted FLUENCE, refer to the provided FLUENCE table)

4.6.2 Adjustment of spot size

On the *MeDioStar*, the laser spot size can be varied by changing the beam delivery system (handpiece). The system automatically detects any variation and considers it accordingly. The currently selected spot size is displayed.

4.6.3 Use of skin cooling device

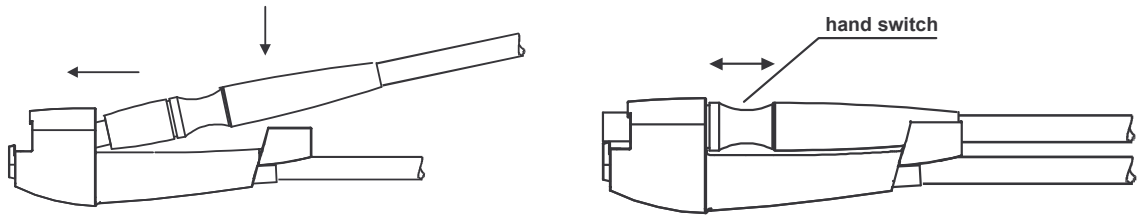
After switching on of the *MeDioStar* it is necessary to check, that the temperature of the cooling tip runs from room temperature to the setting +4°C within 70sec. The Same for activating the device after power save mode (‚continue').
As the cooling surface of the skin-cooling device is made of aluminium, sensitive persons may respond to its application with allergic skin reactions.

The console of the cooling system is in the middle of the device console. If the drawer is pulled out, one can see the actual temperature of the cool probe at the display from the cooling device. The temperature is set to +4°C and should be kept there. (Note: it is normal, that the temperature rises some degrees by moving the cold probe from one warm skin area to the next – what is necessary for the treatment.

The skin-cooling device employs the Peltier effect and serves for cooling the skin directly before the application of the next laser pulse.

Cooling is performed by direct contact of the skin with the cold aluminium.

The connection between laser handpiece and cooling unit is established by a simple snap-in action as illustrated below.



NOTE: First push the laser handpiece carefully to the stop of the cooling handpiece (to avoid damage af the laser tip) and than clip the laser handpiece together with the cooling handpiece.

4.6.4 Treatment

4.6.4.1 Making the laser operational

Prior to pushing the READY key, the attending physician must verify that all persons present in the laser room wear laser protective eyewear of protection level D 810 nm L5 (EN 207) or OD 5.

- When the **READY** key has been pressed, the laser is ready for operation. Radiation of the displayed parameters will be emitted by either pressing the handpiece onto the skin (letter **H** displayed in READY field) or by pressing the footswitch, if connected (letter **F** displayed in READY field). Selection of either hand switch or footswitch operation is via the **TOOLS** menu (HAND or FOOT).
- After the spot size has briefly flashed on the display, the laser warning sign appears above the READY field (refer to Fig 6).
- Whenever you change a parameter in READY mode, the device will automatically return to STANDBY mode. In this case, press the READY key again to reactivate the READY mode.
- Place the handpiece onto the desired treatment area.

Note that in READY mode a laser pulse will be fired when you accidentally release either the hand switch or the footswitch!

- While laser radiation is being emitted, the laser emission indicator beside the display is lighting. Additionally, an audible signal is being generated at the frequency adjusted for the treatment beam.

If you intend to interrupt the treatment for some time, press the READY key again to switch the laser to the safe STANDBY mode. In this mode, it is impossible to release emission unintentionally.

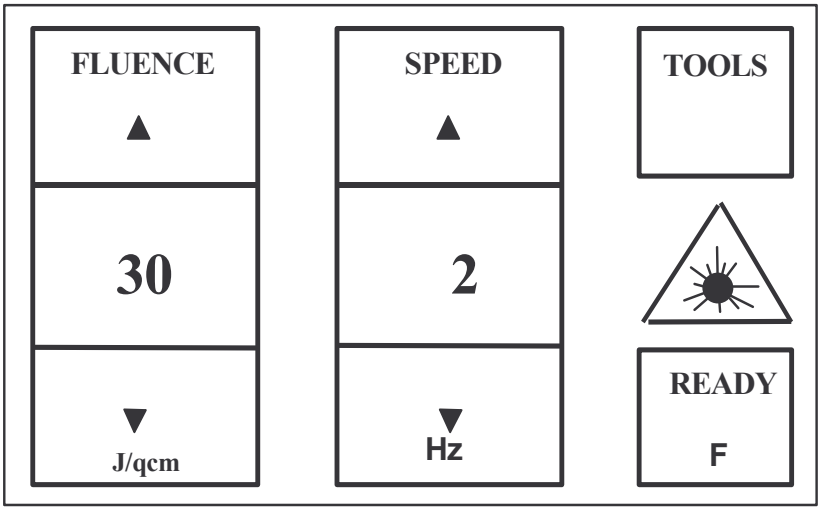


Fig. 6: Display (Laser READY)

4.6.4.2 Releasing the treatment beam

On release by either hand switch or footswitch, Class 4 laser radiation will be emitted from the end of 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 handpiece was placed directly onto the skin area to be treated.
The adjusted fluence has to be checked for correctness regularly. **Instantly press the EMERGENCY STOP pushbutton in the event of dangerous malfunction.**
Take care to keep the distal end of the handpiece clean! Any contamination absorbing laser light will cause local overheating and thus may lead to excess treatment and defects at the handpiece!

- To release the surgical laser beam with the pre-selected parameters, press the handpiece onto the skin (hand switch release) or, if preselected accordingly via the TOOLS menu, depress the footswitch (footswitch release).

In treatment breaks or on completion of a treatment session, press the READY key again to switch the laser to the STANDBY mode. In this mode, unintentional release of laser radiation is impossible.

If you do not press any key, hand switch or footswitch for more than six minutes, the *MeDioStar* will automatically switch to the energy saving mode. From this mode, you can easily reactivate the device by pressing the 'CONTINUE' key becoming visible then.

4.6.4.3 Logging of treatment parameters and finishing the laser session

- In the 'TOOLS'-menu that is accessible via the 'TOOLS'-key, the total number of emitted pulses and the pulses emitted after the last 'RESET'-action is displayed.
- Prior to the treatment of the next patient, you can reset the pulse count to zero by pressing the 'RESET' key (3 sec.).
- Shut down the laser by turning the key switch anti-clockwise. In doing this, the system automatically performs a 'RESET'.

Allow for an interval of at least 15 s between shutdown and restart of the *MeDioStar*.

After you have shut down the laser, absolutely make sure to remove the key and keep it in a safe place to prevent unauthorized use of the device.

- Switch off the instrument by power switch on the rear side.
- Suspend the optical fiber safely and check the beam exit face of the handpiece for contamination. **Contaminated beam exit faces must be cleaned immediately.**

4.6.5 Special functions (TOOLS)

Press the ‘TOOLS’-key to activate the ‘TOOLS’-menu.

In this menu, the total number of emitted pulses and the pulses emitted after the last ‘RESET’-action is displayed.

In addition, the ‘TOOLS’-menu provides keys for the following functions:

PILOT

Adjustment of aiming beam intensity by pressing the arrow keys.

HAND/FOOT

Changeover between laser release by handswitch (handswitch release) or foot switch (footswitch release) and vice versa.

E CHECK

On pressing this key, the basic menu additionally includes display of laser energy and spot size.

DRAIN OFF

This key serves for draining the coolant, if the device was prepared for this mode. By pressing the ‘CANCEL’-key, the system returns to the basic menu.

RESET

Resets the resetable pulse count on the display to zero.

M1 – M4

These four keys are memory keys for free program storage. They provide the recall of previously stored individual treatment parameters by shortly pressing the respective key, which then appears with a thick frame around. At the same time, the system returns to the basic menu.

By changing one of the parameters in the basic menu, the system automatically returns to the normal mode.

To store a desired parameter set, select the parameters in the basic menu and switch to the TOOLS menu. Then, press the desired memory key (M1 ... M4) for more than 2 seconds until an acoustic signal (**long** beep) is generated.

RETURN

Pressing this key stores the current settings of the TOOLS menu and returns to the basic menu.

5 Cleaning and disinfection

Handpiece

The distal optical surfaces of the handpiece are largely protected against contamination by the treatment technique recommended (refer to the Application Manual). Despite of this, you should check them also during treatment and clean them, if necessary, with a clean, lintless, moistened cloth. You may also use alcohol or isopropyl alcohol, if necessary.

Dirt on optical surfaces will burn in by laser radiation and lead to malfunction and overtreatments!

Make sure to switch the laser to 'STANDBY' before you start cleaning!
If you use alcohol or isopropyl alcohol, do not clean near the treatment area to avoid the risk of fire.

The holders of the glass components of the handpiece may easily be removed from the rest of the handpiece. Take care to make the handpieces complete again after cleaning. Only then you are allowed to reactivate the laser.

After every treatment, clean distal glass components moistly (in ultrasonic cleaning bath, if necessary) or with alcohol. Then carefully dry and disinfect them.

Cleaning of the interior parts of the rest of the handpiece is not necessary.

Optical fiber

All optical components and the end faces of the optical fiber must be handled with extreme care and protected from dust and contamination.

Prior to every removal of the beam delivery system, make sure to switch off the device!

General

Prior to cleaning, disconnect the laser device from mains by removing the power cable from the power outlet.

You may clean all accessible surfaces of device components, beam delivery system and handpieces with a soft, slightly moistened cloth. Never use a fully wet or even dripping cloth.
To remove sticking dirt, you may use a mild detergent or disinfectant.
Do not use any aggressive disinfectants or abrasives.

6 Accessories

Please note that the EC Medical Device Directive (93/42/EEC) binds you to use only such accessories that have been tested and approved and intended by Asclepion Laser Technologies GmbH for the use in combination with this laser.
We strongly advise against the use of accessories from other manufacturers. Even if an official testing authority has certified that a specific accessory unit can be used safely, Asclepion Laser Technologies GmbH will not assume any liability for its use.

Order No.	
4360/4365*	Handpiece set *MeDioStar* 12 mm with fibre
4361/4366*	Handpiece set *MeDioStar* 10 mm with fibre
4362/4367*	Handpiece set *MeDioStar* 14 mm with fibre
4384	Handpiece set *MeDioStar* 8 mm with fibre
4345	Handpiece tip *MeDioStar* 12 mm
4346	Handpiece tip *MeDioStar* 10 mm
4347	Handpiece tip *MeDioStar* 14 mm
4385	Handpiece tip *MeDioStar* 8 mm
1222	Protective eyewear *MeDioStar*
5501 99 021	Foot switch
2924	Extension Kit *MeDioStar* PRO
2925	Vascular upgrade option *MeDioStar* PRO-V (for *MeDioStar* HC only)

* The Part no. you are using is shown at the laser connector (first 4 digits).

7 Error Messages

- If the device does not respond to turning the key switch ON, make sure the following requirements are met:
    1. The ‘EMERGENCY STOP’-switch is unlocked. If not, turn the red knob of the push-button anti-clockwise.
    2. The main switch on the rear panel of the device is set to ON and the main fuses on the rear panel are not blown. To check the fine-wire fuses, turn off the device.
    3. As mentioned previously, you are guided in operating the laser and in fault finding by microprocessor controlled prompts displayed on the screen.

Errors are indicated by the system as follows:

- The display shows an error message with instructions in plain text. The touch screen is inoperative. Touching the screen will not generate a beep signal. The device will remain in this state until you switch it off. Then, wait at least for 5 s before you restart the device. If the error persists, call Technical Service.
- An acoustic signal from the skin cooling device in the middle console means, that the connection of the Skin-/applicator cooling system is not correct or there is a failure of the skin cooling device. If after reconnecting the error persists, call Technical Service.

You are strongly advised against any attempt to repair the device yourself!!! When you remove device covers, highly dangerous high voltage generated in the device is accessible and may be preserved even after the power cable was disconnected from the power outlet!!!

- In the case of safety-relevant faults, the device switches off within milliseconds. In this case, the display of error messages is impossible. If this should happen or any other fault appear that is not described in this manual, switch off the device by disconnecting it from power supply by unplugging the power plug from the power outlet.

  In this case, please contact our Technical Service.

8 Calibration Procedure

Tools

Energy meter display (Ophir NOVA)	Part No.:	660209022
Energy head (Ophir HE 1)	Part No.:	660209027

Service Mode

To perform the Calibration Procedure it is necessary to activate the service mode.

If you need assistance, please contact the Technical Service (details see next chapter).

Preparations for energy calibration:

Make the device ready for operation. Connect a 8mm, 10 mm, 12 mm or 14 mm fiber to the device. Fix the handpiece in front of the detector surface of the external energy-measuring head about 2 ... 3 mm away from the beam exit surface of the handpiece. On the energy meter, select a range of > 30 J.

Remove the cover of the laser unit and the lid of the energy-measuring unit located over the high-power laser diode array.

Prior to removing the cover of the laser unit, you must remove the white protective caps located at the top front corner of the right and left side panels and unscrew the fastening screws becoming now accessible. Then, remove the cover rearwards.

During energy calibration, laser pulses are being emitted. Make sure all persons present in the laser room wear appropriate laser safety goggles !

By pressing OK, the starting menu of the energy calibration mode appears. At the same time, the cooling system of the laser device is being switched on.

The menu for the energy calibration is exclusively accessible by pressing the

ENERGY ADJUST key at the bottom left. The key label changes to ADJUST OFFSET.

For calibration, always operate the device in single-shot mode.

Adjust Offset

The parameters of the menu are factory-adjusted and must not be changed.

This adjustment serves to balance the offset voltage of both channels of the energy-measuring amplifier in the energy-measuring unit. To balance the offset voltage, follow this procedure:

Press READY F key, then depress the footswitch to emit laser pulses (operation is below the laser threshold so that no laser radiation is generated unless the driving voltage was changed).

Turn potentiometer P5 of the energy measuring unit until the displayed value of Channel A reads A = 0.015 $\pm$ 0.01 V.

Then, turn Potentiometer P2 of the energy measuring unit until the displayed difference between the measuring channels reads D = $\leq$ 0.01 V. Finally, press the bottom left key. The key label changes to ADJUST ENERGY.

Adjust Energy

The parameters of the menu are factory-adjusted and must not be changed.

This mode serves to adjust laser energy by following the procedure described below:

Press READY F key, and then release a single laser pulse. Read the energy from the energy meter and vary the driving voltage by means of the UP / DOWN keys until the energy meter reads E = 24.0 $\pm$ 0.2 J (MeDioStarHC) / E = 15.0 $\pm$ 0.2 J (MeDioStarC)

Adjust Gain

The parameters of the menu are factory-adjusted and must not be changed.

This mode serves to adjust the gain of the two channels of the energy-measuring amplifier in the energy measuring unit . To perform the adjustment, follow this procedure:

Press READY F key, and then depress footswitch to **emit laser pulses**.

Turn potentiometer P6 of the energy measuring unit to adjust the displayed measured value of Channel A to A = 3.000 $\pm$ 0.01 V.

Then, turn potentiometer P3 of the energy measuring unit to adjust the displayed difference of the measuring channels to D = $\leq$ 0.01 V. Finally, press the bottom left key. The key label changes to ADJUST LIMIT 1.

9 Technical Service

Never open the device and attempt to repair the device yourself if the laser should 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 checks.

The energy delivered by the surgical laser must be checked at least annually by a service technician employed with or trained and authorized by Asclepion Laser Technologies GmbH.

If you need assistance by Technical Service, please contact:

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

Phone: +49 (0) 36 41/2 20-423
Fax: +49 (0) 36 41/2 20-374

Please note that the manufacturer, installer or importer will consider themselves responsible for the effects of servicing on safety, reliability and performance of the device only if the following requirements are met:

- Installation, extensions, readjustments, modifications or repairs have been performed by authorized persons.
- The electric installation of the room meets the requirements of relevant IEC regulations.
- The device is used in accordance with the instructions of this manual.

10 Warnings

The laser device may be opened only by instructed and authorized technicians.

When operating the laser make sure to wear the laser safety goggles appropriate for this type of laser that are provided by the manufacturer.

Other types of laser safety goggles possibly do not provide sufficient protection.

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), you must under no circumstances look into the distal end of the handpiece, as the laser may fire further pulses when you depress the footswitch.

Prior to use on patients, disinfect the removable glass parts of the handpiece.

Take care to keep the distal end of the handpiece clean! Any contamination absorbing laser light will cause local overheating and thus may lead to excess treatment and defects at the handpiece!

After switching on of the *MeDioStar* it is necessary to check, that the temperature of the cooling tip runs from room temperature to the setting +4°C within 70sec. The Same for activating the device after power save mode (‚continue').

11 Labels

Various warning and information labels are affixed to the laser device .

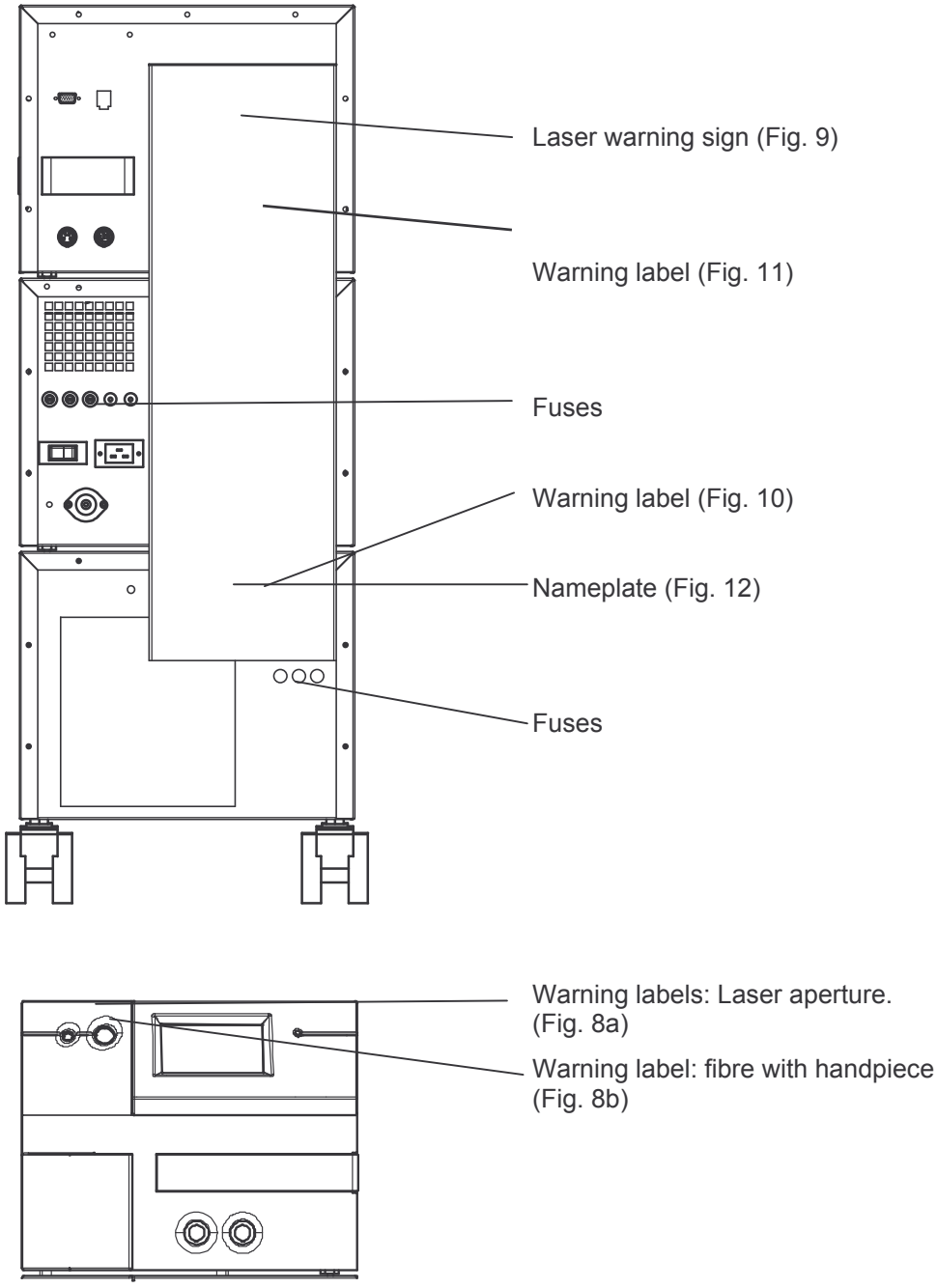


Fig. 7: View of MeDioStar

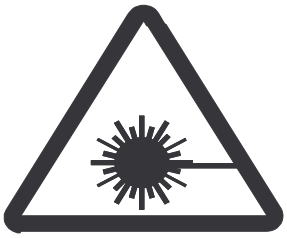


Fig. 8a: Laser aperture warning label

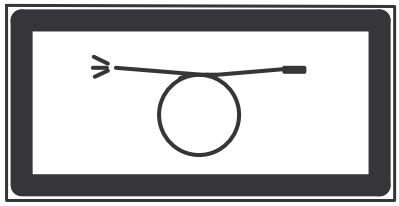
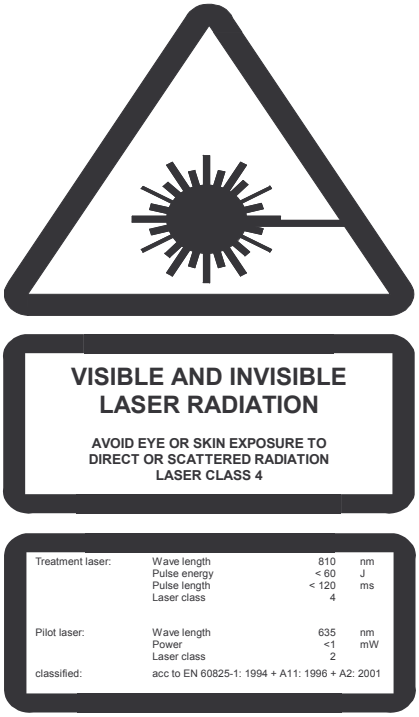


Fig. 8b: Fibre with handpiece warning label



German *Fig. 9: Laser warning label* *English*

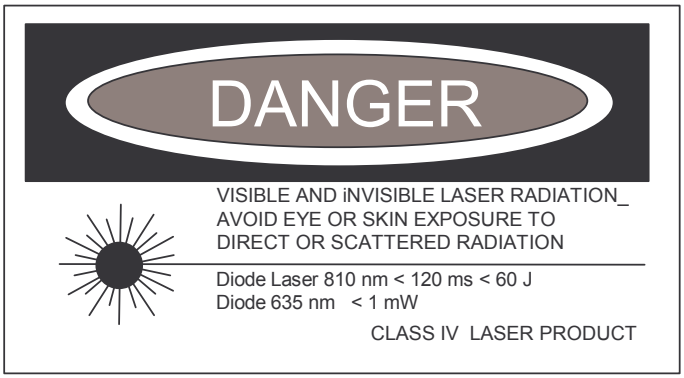


Fig. 10: Laser warning label

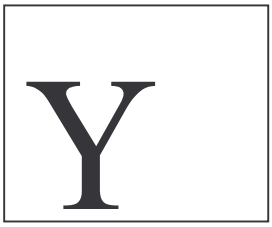
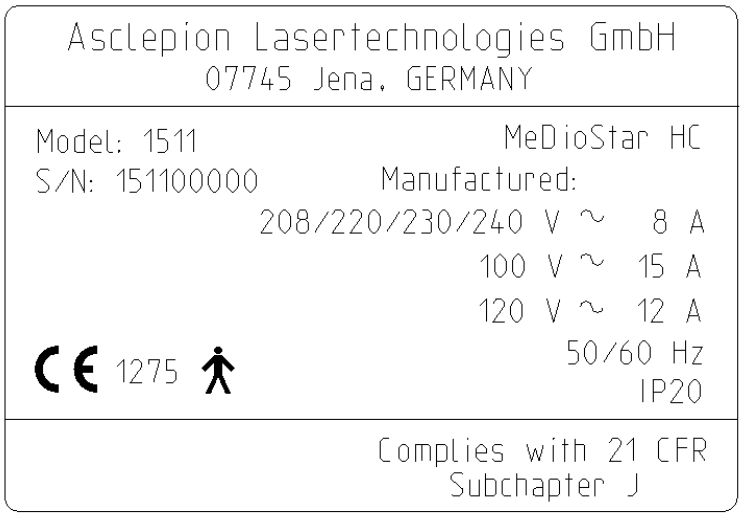


Fig.11: Attention: Observe accompanying documentation.



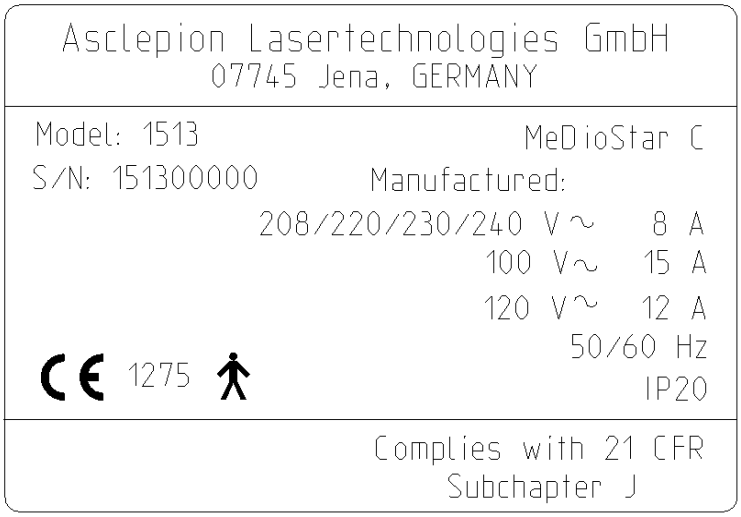


Fig. 12: Nameplate MeDioStar HC and *MeDioStar*C

Application device type B

Month and year of production: see ‘Manufactured’

12 Regular safety checks and calibration

Please note that the manufacturer recommends subjecting this device to regular safety checks and calibration of the device at annual intervals. The results of these safety checks must be documented in the medical device logbook.

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

The device may only be serviced, repaired or modified by persons employed with or authorized by Asclepion Laser Technologies GmbH.

Scope of safety checks

In compliance with the regulations laid down in national laws and EN 60 825 (or IEC 60 825) in the valid version the safety checks should at least include the following tests:

- Earth leakage test under normal operating conditions
- Visual inspection of laser device and accessories
- Functional test
- Check for leakage on the device
- Measurement of actual output energy at handpiece
- Calibration of the device
- Test of earthing conductor connection

13 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.