Asclepion
Laser Technologies

MeDioStar

USER MANUAL

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.

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1 Intended Use

The MeDioStar is a pulsed diode laser (Class 4 laser product) that is used for the removal of undesired hair, the treatment of Acne inversa[1] and for the treatment of vascular lesions[1][2]. The melanin contained in hair respectively blood vessels strongly absorb the radiation of the wavelength emitted by this laser, whereas the absorption of the surrounding is very low. In this way, the radiation destroys hair follicle or pathologically changed blood vessels while protecting the normal 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.

[1] NOT FOR SALE IN USA

[2] with Vascular Upgrade only

Medical Device Directive

CE 1275

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

Device models:

Model	Model no.	Built-in laser modules
MeDioStar XT	1530	Diode modul 808nm
MeDioStar miXT 810	1531	Diode modul 75% 808nm and 25% 938nm
MeDioStar miXT 940	1532	Diode modul 75% 938nm and 25% 808nm

The basic unit is identical for all device models, the models only differ in the the type of built-in laser modules. The models can be identified by the Model Number specified on the type label on the rear panel of the device (see 10. Labels).

Laser type:	High-power laser diode array
Laser class:	4
Required laser safety goggles	**MeDioStar XT:** D (810 ± 15) nm L5
(acc. to EN 207: 2002)	**MeDioStar miXT 810:** D (810 ± 15) and (940 ± 15) nm L5
	MeDioStar miXT 940: D (810 ± 15) and (940 ± 15) nm L5
Wavelength:	**MeDioStar XT :** 808 nm
	MeDioStar miXT 810: 75% 808nm + 25% 938nm
	MeDioStar miXT 940: 75% 938nm + 25% 808nm
Pulse length:	Basic Mode: 170 ms double pulse with break
	Professional Mode: max. 500ms single/ double pulse
	Vascular Mode: max. 200 ms single pulse (NOT FOR SALE IN USA)
Pulse energy:	Max. 50 J
Spot size:	4, 6, 10, 12 AND 14 mm; Slit (0.28cm²)
Pulse frequency:	0.5 Hz, 1 Hz, 1.5 Hz, 2 Hz, 3 Hz and 4 Hz
Tolerance of output power:	Max. 20%
Laser beam mode:	Multimode
Laser beam size:	Max. 14 mm
Laser beam dive:rgence	Max. 350 mrad (full angle, 1/e²)
Nominal Ocular Hazard	
Distance (NOHD) with handpiece:	26 m

Aiming laser:	Diode
Wavelength:	635 nm
Power:	<1 mW; adjustable intensity
Laser class:	1
Spot size:	Max. 14 mm
Divergence:	Max. 350 nm (full angle, 1/e²)
Beam delivery:	Optical fiber with handpiece
Display:	LCD colour display
Operator guidance:	Touch screen, jog dial
Power requirements:	100/120/208/230/240 VAC, internally reversible, 50/60 Hz
Rated current:	Max.8A at 208/ 230/ 240V, max.12A at 100/ 120V
Skin cooling:	Integrated cooling by Peltier elements
Dimensions:	365 x 600 x 975 mm³ (W x D x H)
Weight:	90 kg
Environmental requirements:	Temperature: 15°C up to 28°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 Storage conditions:	Temperature: 0°C up to +70°C (32°F up to 158°F) Rel. humidity: 10 % ... 95 % (no condensation) Mechanical loads: as per Class 2M1 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).
Usage:	The device is designed for continuous operation.
Accessories:	See chapter 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. These safety checks are provided by the Asclepion Laser Technologies GmbH.

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).
  Every laser system supplied by the manufacturer comes with an additional laser warning sign. We recommend affixing this sign (see figure) at the entrance to the laser treatment room to warn the persons entering of the installed laser device.

Fig. 1: Laser warning sign at laser room entrance

- 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 at least a protection level that is specified in the technical data.

Laser-induced fire hazard

Do not install 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.

When the laser beam strikes the surface of an object, the surface will absorb the laser energy thus causing the surface temperature to rise, irrespective of whether it is skin, hair, clothes or any other flammable substance. The operators should take the following safety precautions to prevent laser-induced fire:

- Use non-flammable substances for anesthesia, for the preparation of soft tissue for treatment, and for the cleaning and disinfection of instruments.
- Be especially careful when using oxygen. Oxygen will increase both the severity and the extent of fire.
- Keep only a minimum of combustible materials in the treatment room. If treatment requires the use of combustible material, such as gauze, soak it in water first.
- Keep clothes away of the treatment area as far as possible.
- Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.
- Always keep a small fire extinguisher and water at hand in the treatment room.
- Avoid the use of flammable anesthetics or oxidizing gases, such as nitrous oxide (N_2O) and oxygen.
- When saturated with oxygen, some materials, such as cotton wool, may be ignited by the high temperatures produced in normal use of the laser equipment.
- Before using the laser, allow the solvents of adhesives and flammable solutions used for cleaning and disinfection to be evaporated. Also, take into consideration that endogenous gases may be ignited by laser light.

Electrical hazards

The laser uses line voltage and high voltage. Never open any protective covers if you are neither trained nor authorized to do so.

Never place any liquids onto the device as liquid entering the device might reduce the protection against hazardous electric voltages. If liquids got into the device, instantly switch the device off with the Laser STOP button and disconnect the power cable. Then, please contact Technical Service.

Radio frequency interference

The laser complies with the requirements of the EN 60601-1-2 standard. The system is not affected by electromagnetic noise generated by other devices that conform to the same standard. In addition, the system does not generate electromagnetic noise in compliance with EN 60601-1-2.

Medical devices are subject to particular precautions in respect to the electromagnetic compatibility (EMC). Please pay attention by installation and operation of the laser device to the special notes given in the accompanying documentation under "EMC Manufacturer's Declaration".

Portable and mobile HF – communication devices may effect medical electrical devices. Cellulars and similar devices have to be switched off before commissioning of the laser device.

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.

Additional information

Upon request, the manufacturer will provide circuit diagrams, component parts lists, descriptions, calibration instructions, or other information not yet contained in this user manual to assist appropriately qualified technical staff to repair those parts of the device that have been designated by the manufacturer as repairable. "Appropriately qualified technical staff" in this context means staff that attended a manufacturer's service training course on this device and that were authorized to repair it.

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
- Power cable
- Footswitch
- Beam delivery fibre and handpieces
- Warning lamp / door interlock connector
- Safety goggles acc. to chapter Technical Data (number according to order)
- Documents

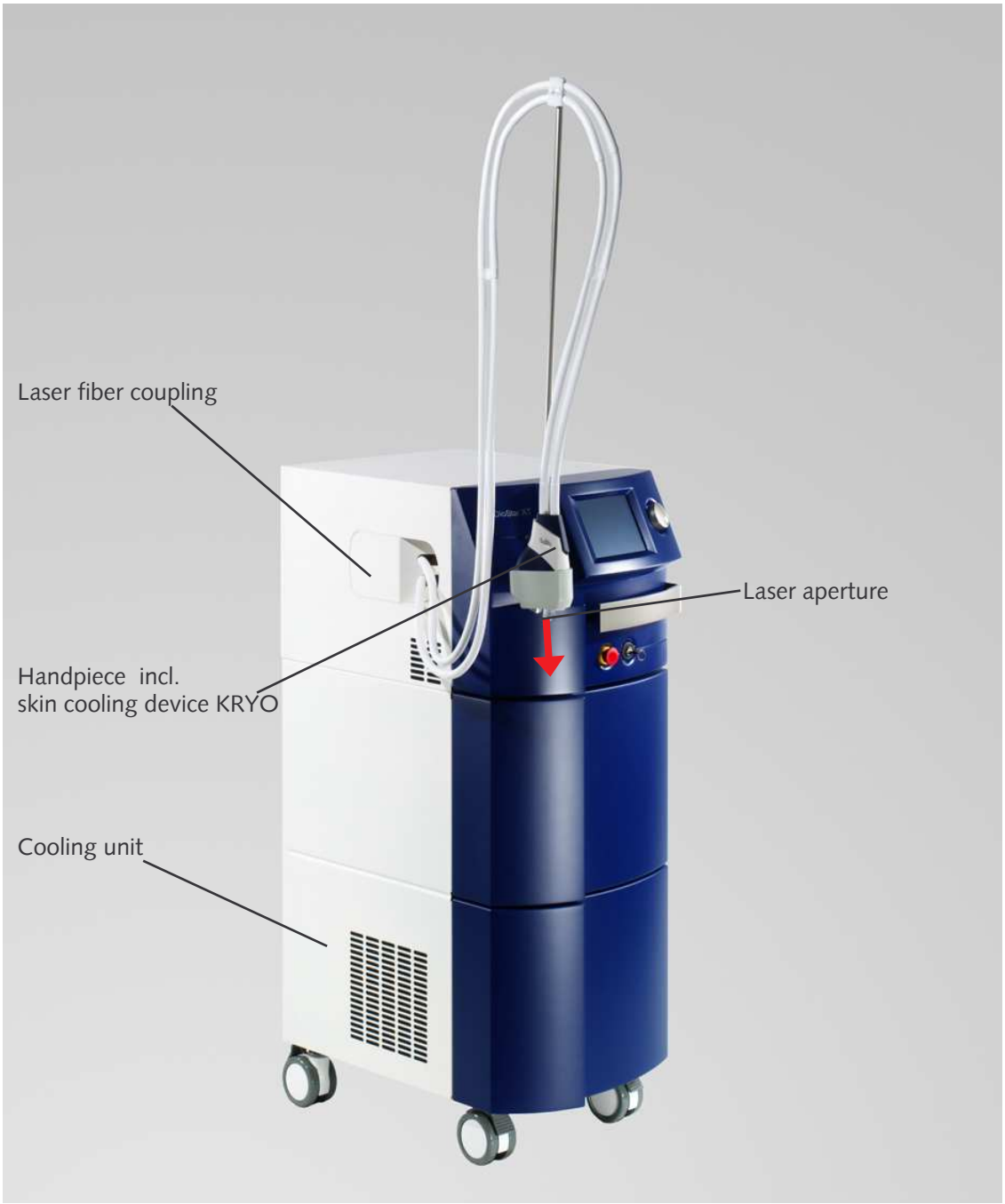


Fig. 2: Front view of MeDioStar

4.2. Installation

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

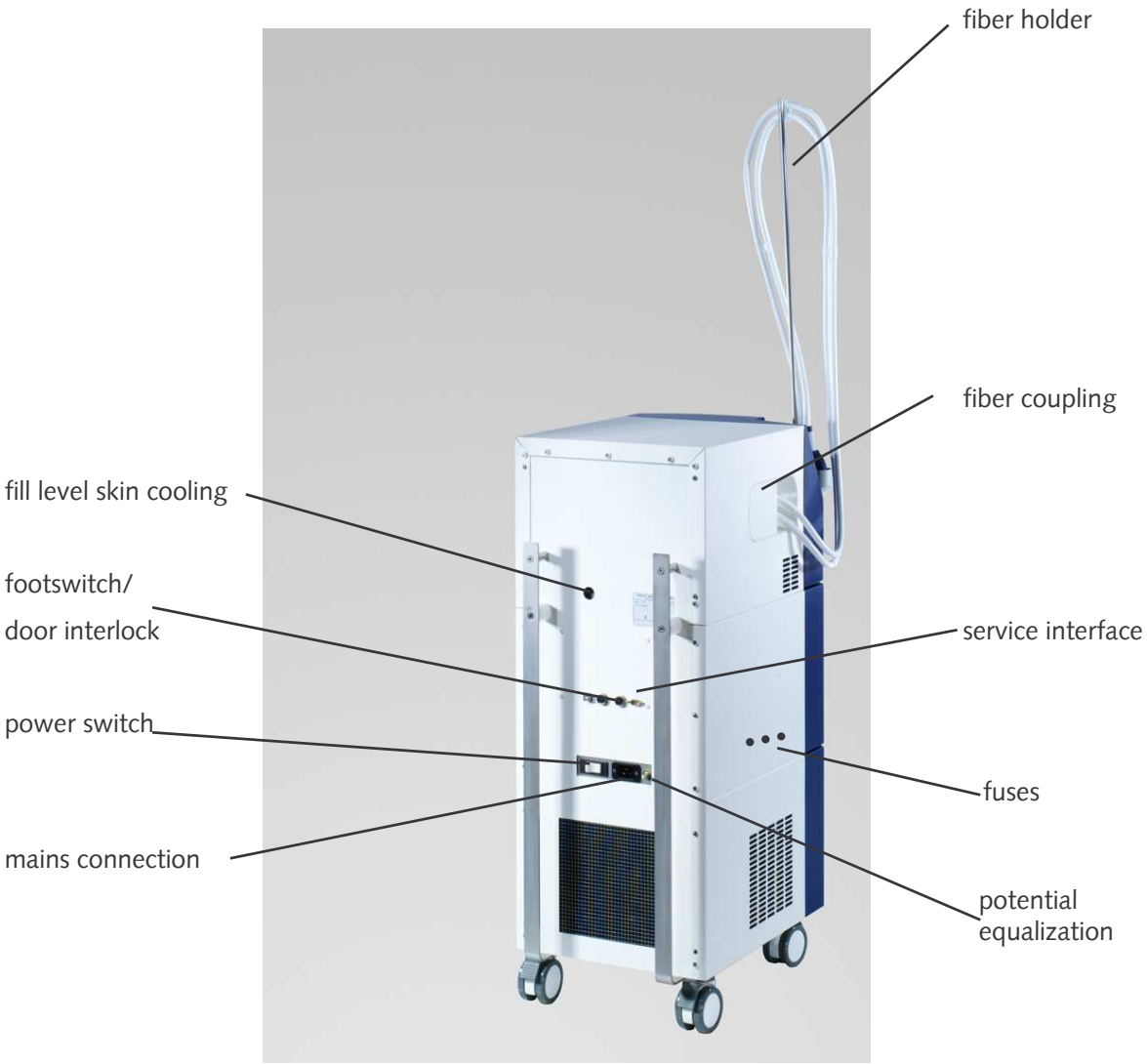


Fig. 3: Connections on the rare side of laser system

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 (see figure):

1. Mount the fiber holder in the front of the device
2. Mount the handpiece holder on the fiber holder
3. Connect the coolant interface as illustrated by means of the two quick-lock couplings.
4. Establish the electric connections between the socket as illustrated by using the cable from the handpiece.
5. Connect the laser fiber plug and fix the outer ring.
6. Mount the laser and cooling fiber inside of the top point of the fiber holder and place the handpiece in the holder
7. Close the Connection port by using the small white cover
8. Connect the footswitch and door interlock
9. Connect the power cable

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 (type C) fuse of 10 A for 208/230/240 VAC or 16 A for 100/120 VAC.

Confirm the local power outlet with the line voltage of the MeDioStar on the back side of the device!

The switched line voltage of the MeDioStar is available on the Certification / Identification label. Other Voltage's (see section 2) can be selected inside of the device. Please ask your local distributor for this option.

When choosing the internal voltage selector consider all technical data of local mains and the device (see section 2). Make sure that the internal voltage selector of the device is correctly set and the voltage option on the identification label is crossed.
This is only allowed persons employed with or authorized by Asclepion Laser Technologies GmbH.

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

If the switched voltage does not conform with you local mains all electronic components inside of the device could be damaged! In this case you will lose all warranty claims!

4.2.3. 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.

4.2.4. Connection of warning lamp and door interlock / Service

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.

When connecting a warning lamp and an external transformer the user is installing a device system, according to IEC 60601-1-1 and is potentially influencing the approved isolation system. Therefore only safety transformer with strengthened isolation with a minimal testing of 4 kV according to IEC/EN61558-2-6 must be used. Although it has to be granted, that the leakage current of the machine after connecting the transformer, fulfils the specification according to IEC-60601-1.

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.

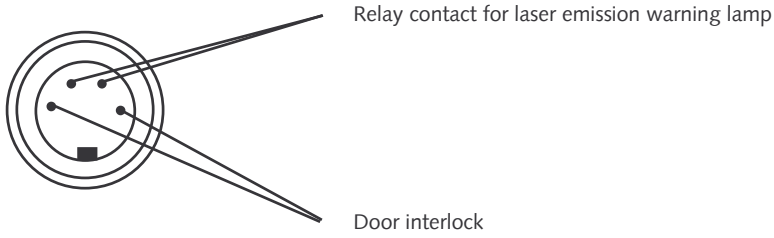


Fig. 4: Connectors for door interlock and laser warning lamp

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.

Service interface / I²C connector (USB)

Both connectors at the back of the device are used for service only by persons employed with or authorized by Asclepion Laser Technologies GmbH and must not at all be combined to any other device, otherwise irreparable damages are possible.

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)**

Non-observance of this instruction may destroy the device.

Make sure the following requirements have been met:

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

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. 5: 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.

The following treatment modes are available:

BASIC mode

PROFESSIONAL mode

VASCULAR mode (optional, not for sale in USA)

Switching between the available modes is by pressing the top key .

On completion of the start-up routine, the display shows the menu of the treatment mode used last.

On completion of the start-up routine, the display shows following the menu (Basic mode).

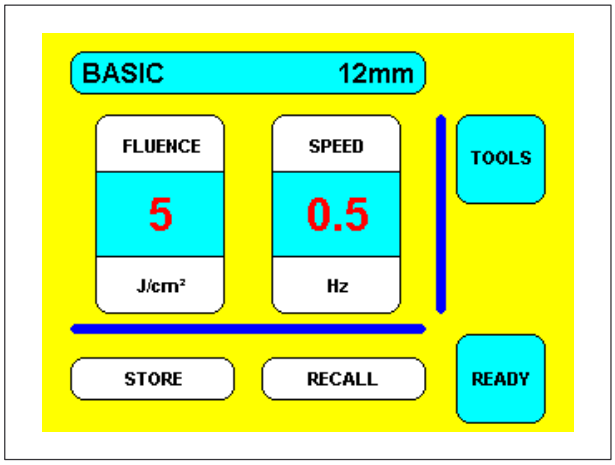


Fig. 6: Display BASIC (STANDBY)

Operation of the device via the touch screen and Jog Dial 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 parameters, which have to be changed (FLUENCE, SPEED or TIME) are activated for change by pressing the numerical field at the display. Then these values are changed by turning the jog dial. Afterwards the new numbers have to store by pressing the numerical field once more (or by pressing the jog dial), otherwise the old parameter is activated.

The energy density is the crucial parameter for laser treatment. It is displayed as **FLUENCE** in J/cm².

If the energy range is not sufficient to achieve the desired fluence value, replace the used beam tip by one having a smaller diameter. Tip 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.

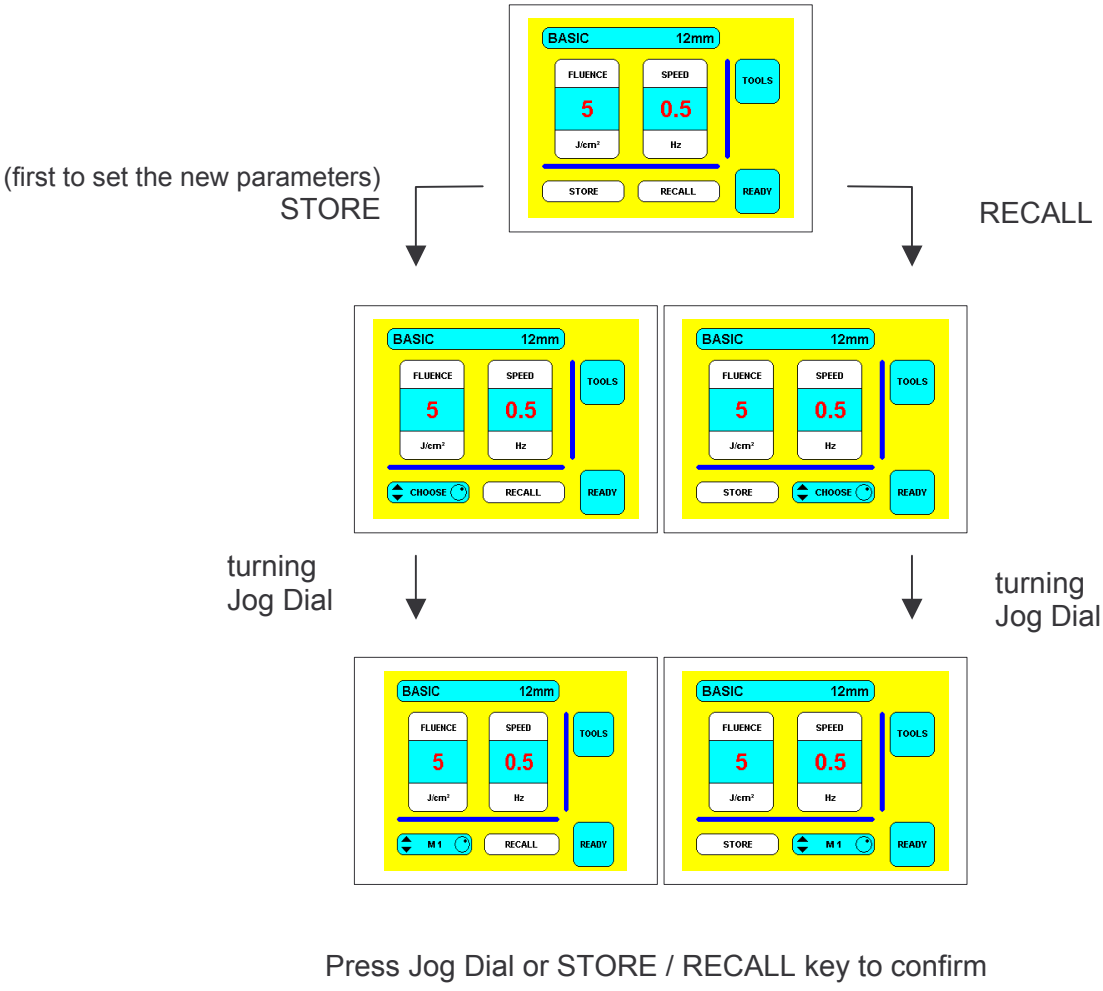
The pulse frequency is adjustable in the **SPEED** field. The following frequencies are selectable:
0.5 Hz, 1 Hz, 1.5 Hz, 2 Hz, 3 Hz and 4 Hz (dependent on adjusted fluence).

4.6.2. Adjustment of spot size

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

4.6.3. Memory Keys STORE/ RECALL

These 2 keys are memory keys for free program storage/ recall. For storage first the new parameters has to be adjusted at the display.
They provide the storage / recall of individual treatment parameters by shortly pressing the respective key, which shows then the Jog Dial sign. By turning of the Jog Dial you can choose your favorite memory field from M1 to M10, the display than shows the actual parameters of this special memory. By pressing the Jog Dial or the STORE- / RECALL- key you have to confirm the chosen parameter, otherwise the system will go back to the old settings.



Press Jog Dial or STORE / RECALL key to confirm

Fig. 7: Memory Keys

4.6.4. 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 180 sec. Therefore the software start a screen "Cool Down Handpiece" with a running bar. The screen will leave, if the cool tip has reached an temperature about +8°C. The nominal value of +4°C will be reached in the next 20 sec. The same for activating the device after 15 min of non using.

If the screen "Cool Down Handpiece" will not leave after 180 sec it seems to be a malfunction in the cooling device. Please contact in this case your local distributor.

It's 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. If the temperature comes to the upper limit, the screen "Cool Down Handpiece" will be shown. After leaving this screen, the treatment can be to 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 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 close contact of the skin with the cold metal probe. Therefore the cold Aluminium probe has to keep in close contact to the skin during treatment.

Fig. 8: Handpiece MeDioStar

4.6.5. Treatment

4.6.5.1. 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 at least a protection level that is specified in the chapter Technical Data

- 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 by pressing the footswitch.
- After the spot size and colour code of the active tip has briefly flashed on the display, the laser warning sign appears above the READY field (refer to Fig 8).
- 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 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.

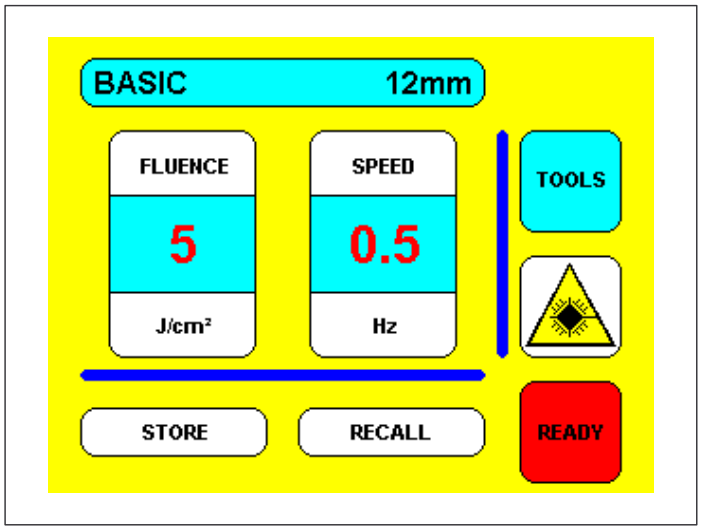


Fig. 9: Display BASIC (Laser READY)

4.6.5.2. Releasing the treatment beam

On release by 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 defects at the handpiece and excess treatment!

To release the surgical laser beam with the pre-selected parameters, press the foot switch.

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, or footswitch for more than five minutes, the MeDioStar will automatically switch some suppliers off.

4.6.5.3. 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'.

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 handpiece safely and check the beam exit face of the handpiece for contamination. **Contaminated beam exit faces must be cleaned immediately.**

4.6.6. Special functions (TOOLS)

Press the 'TOOLS'-key to activate the 'TOOLS'-menu (refer to Fig 9).

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:

pulse counter

- **reset current**
  Resets the current puls count on the display to zero.
- **current**
  Show the current puls counter.
- **total**
  Show the total puls counter.

display

- **brightness**
  Adjustment of the display brightness.
- **SW**
  Installed display software version.

special

- **pilot**
  Adjustment of the pilot brightness.
- **unlock mode – for service only**

ENERGY

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

RETURN

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

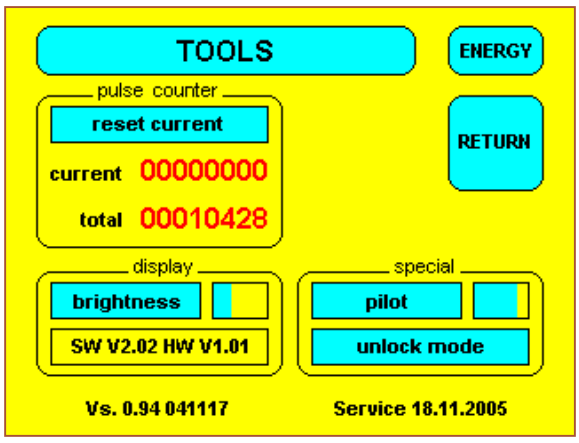


Fig. 10: Display (TOOLS)

4.6.7. Professional Mode

The PROFESSIONAL-mode allows to adjust the pulse length (TIME) individually. Par example it is possible to set the pulse length very long even at low fluences, this is recommendable for dark skin types.

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

In this mode, the screen looks as follows:

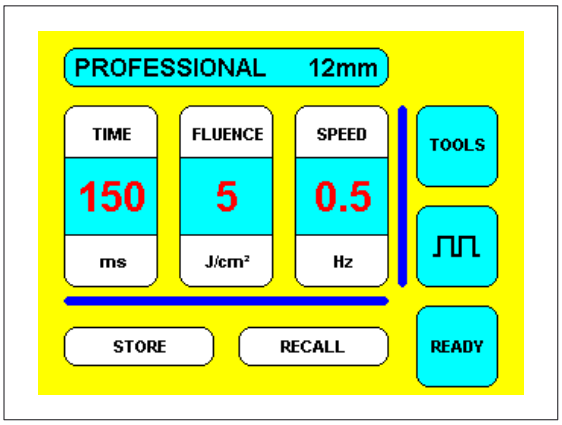


Fig. 11: Display PROFESSIONAL (In STANDBY)

Adjustment of treatment parameters

In contrast to the BASIC mode, in this mode you can additionally adjust the pulse duration of single/ double pulse within defined limits in the **TIME** field. The fluence is kept constant (within the defined limits).

The maximal frequency in PROFESSIONAL mode is 2Hz.

4.6.8. Vascular Mode (with Vascular Upgrade only)

In Vascular mode the pulse is applied as a single pulse with a max. pulse length about 200 ms. The maximum fluence is much more higher than in the other modes, it is max. 170J/cm².

Operation of the device is identical with that in PROFESSIONAL mode except for some parametric restrictions.

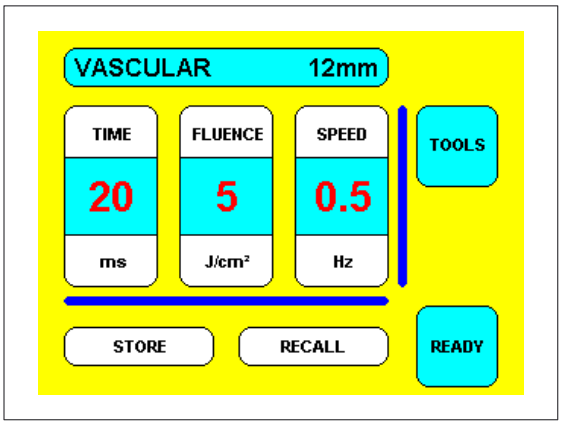


Fig. 12: Display VASCULAR (In STANDBY)

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 tipp 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.

Use only the original Asclepion Laser Technologies cleaning cloth to clean the glass components, other sheets may damage the optical coating.

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. We recommend to use NEVER 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.	
4241	Handpiece tip MeDioStar 14 mm
4240	Handpiece tip MeDioStar 12mm
4239	Handpiece tip MeDioStar 10 mm
4242	Handpiece tip MeDioStar 6 mm
4238	Handpiece tip MeDioStar 4 mm
4237	Handpiece tip MeDioStar Slit
1222	Protective eyewear MeDioStar XT
1231	Protective eyewear MeDioStar miXT and MeDioStar XT
2931	Upgrade MeDioStar Vascular

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.

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

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

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 tip 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.

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/ gain channel A/ B
- adjust/ check energy adjustment
- safe energy adjustment, restart system

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
Im Semmicht 1a
D-07751 JENA

Phone: +49 (0) 36 41/ 77 00 - 401
Fax: +49 (0) 36 41/ 77 00 – 402
e-mail: service@asclepion.com

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

Do not start up the device unless you have read this user manual.
Always keep the manual handy.

Portable and mobile HF – communication devices may effect medical electrical devices. Cellulars and similar devices have to be switched off before commissioning of the laser device.

Only specialists who are appropriately qualified and authorized by Asclepion Laser Technologies are allowed to open the laser device.

All persons present in the laser room during laser operation must wear laser protective eyewear appropriate for this type of laser and provided by the laser manufacturer.

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

Even if you wear laser protective eyewear, never look directly into the laser exit aperture of the articulated arm or the handpiece.

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 must you look into the distal end of the handpiece, as the laser may fire further pulses when you depress the footswitch.

Make sure to switch the laser device into STANDBY mode, before you start cleaning it. Never use any alcohol or isopropyl alcohol near the treatment area to avoid the risk of fire.

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 place any liquids onto the device as liquid entering the device might reduce the protection against hazardous electric voltages. If liquids got into the device, instantly switch the device off with the Laser STOP button and disconnect the power cable. Immediately contact Technical Service.

Never connect any other devices than released by Asclepion Laser Technologies to the connectors accessible on the back panel of the laser device. Never try to connect other devices to the terminals. This could affect the safety of the device and could lead to serious hazard for the patient and for the user. Additionally it could lead to a damage of the device.

11. Labels

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

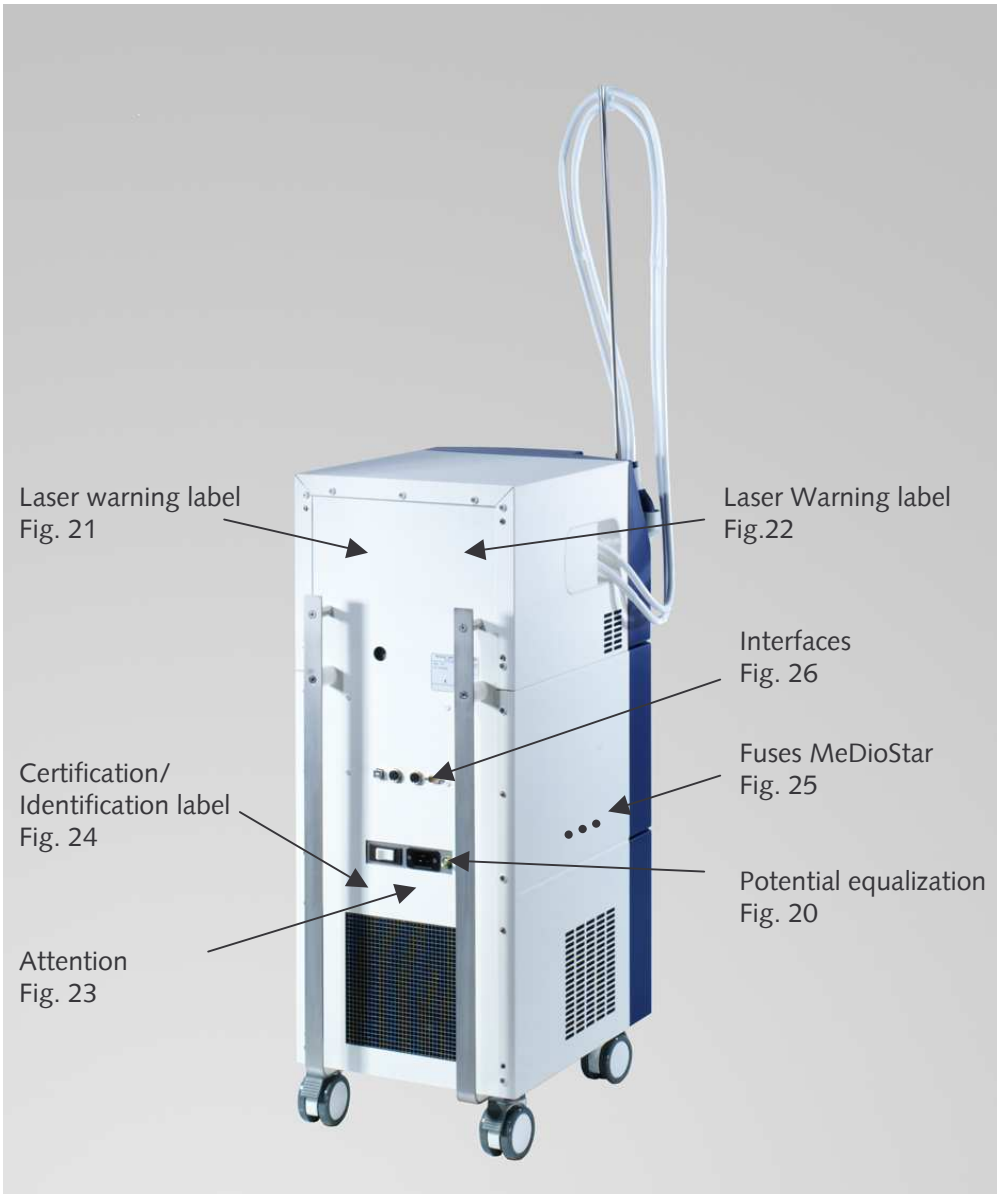


Fig. 12: Back view of MeDioStar

Laser Warning label
Fig. 15, 16, 17

Fig. 13: Front view of MeDioStar

Warning label for the U.S.:
Laser aperture
Fig.18

Fig. 14: View of MeDioStar handpiece

Fig. 15: Laser aperture warning label

Fig. 16: Fiber with handpiece warning label (not for US)

Fig. 17: Laser aperture warning label (US)

Fig. 18: Laser aperture warning label at handpiece (US)

Fig. 19: Potential equalization

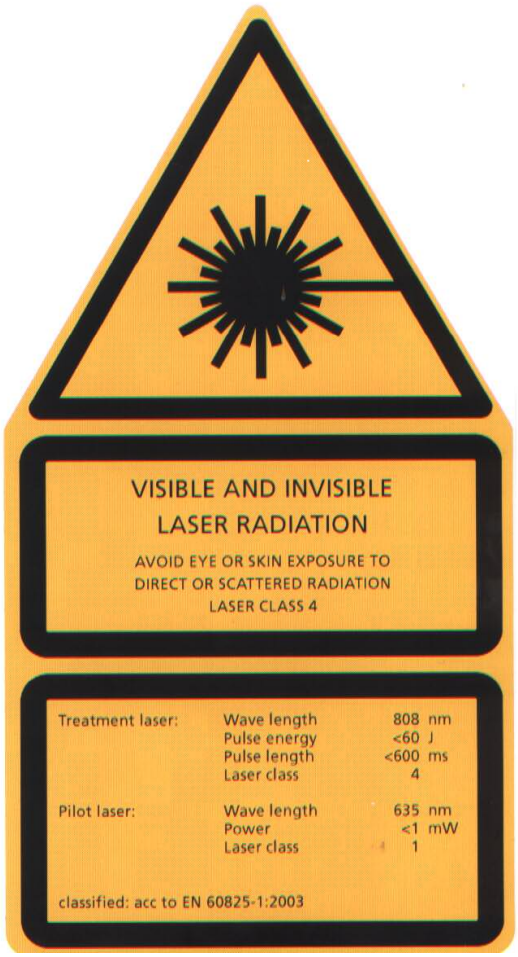
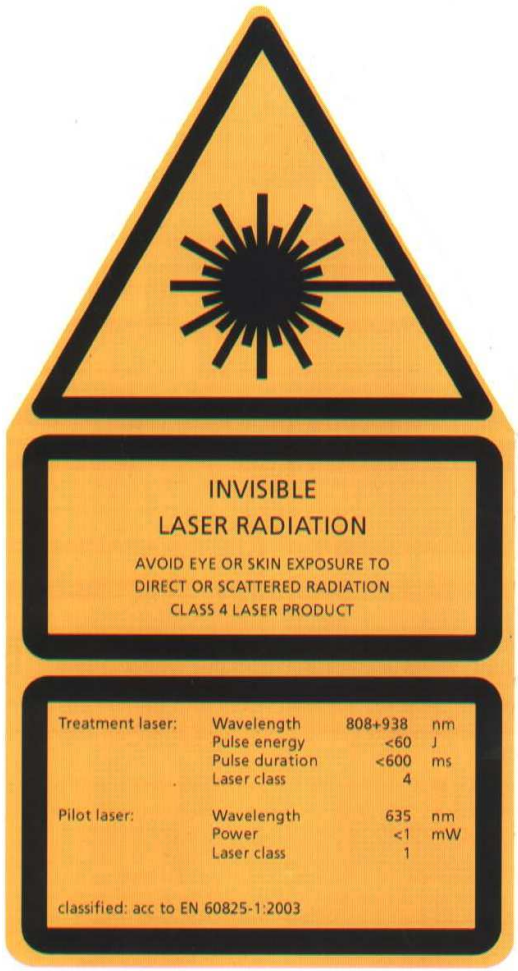


Fig. 20: Laser warning label MeDioStar XT



Laser warning label MeDioStar miXT

Fig. 21: Laser warning label MeDioStar XT

Laser warning label MeDioStar miXT

Fig. 22: Attention: Observe accompanying documentation

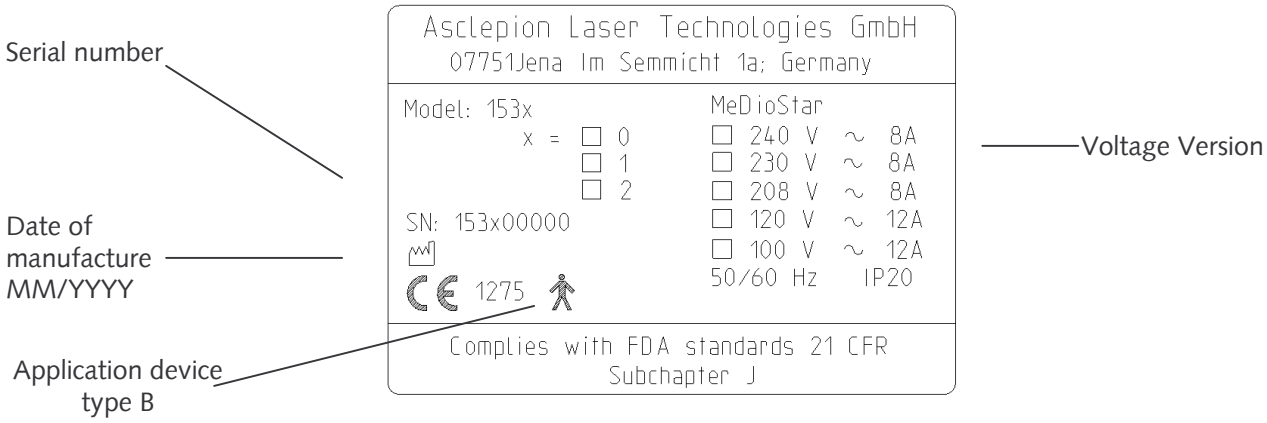


Fig. 23: Certification / Identification label MeDioStar

F 1 T6.3A	F 2 T2.5A	F 3 T 2A	F4 T 1A

Fig. 24: Fuses MeDioStar

Fig. 25: Interfaces

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

Frequency of safety checks

We recommend strongly to make at least one safety check by the year!

Wear parts of safety checks yearly

- Filter candle F10-25µm
- Desiccator cartridge 68000
- Deionisation cartridge

Wear parts of safety checks additional every 2 years

- Deionised water
- Transmission laser fiber

Please note, that there is no longer warranty in case of reclamation against Asclepion Laser Technologies GmbH, if there was no officially required safety check and calibration by using the original spare parts / consumables.

Accessible Fuses (Fuse 5x20mm; 250 V):

• F1	T 6,3 A	diode driver
• F2	T 2,5 A	compressor
• F3	T 2,0 A	pump
• F3	T 1,0 A	solenoid valve

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.

Annex: EMC Guidance and Manufacturer's Declaration

Caution

The usage of others than the following accessories, transducers and cables may result in an increased interference emission and/or decreased immunity of the equipment and/ or system.

Accessory/ Title	Item number	Lenght / Dimensions
Laser handpiece	**4235 00 000**	**< 3,0 m**
Foot switch with cable	**5501 99 021**	**< 3,0 m**
Power cord	**5507 04 013**	**< 3,0 m**

1. Electromagnetic Emissions

The Device is suitable for use in the specified electromagnetic environment. The customer and/or the user of the Device should assure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

2. Electromagnetic Immunity

The Device is suitable for use in the specified electromagnetic environment. The customer and/or the user of the Device should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power ± 1 kV for input/output lines	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV ± 2 kV	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T for 0,5 cycle (> 95 % dip) 40 % U_T for 5 cycles (60 % dip) 70 % U_T for 25 cycles (30 % dip) < 5 % U_T for 5 sec (> 95 % dip)	< 5 % 40 % 70 % < 5 %	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the Device requires continued operation during power mains interruptions, it is recommended that the Device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

The Device is suitable for use in the specified electromagnetic environment. The customer and/or the user of the Device should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = \frac{3,5}{V_1} \sqrt{P}$
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V	$d = \frac{3,5}{E_1} \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = \frac{7}{E_1} \sqrt{P}$ 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.[b] **Interference may occur in the vicinity of equipment marked with the following symbol:** 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Device is used exceeds the applicable RF compliance level above, the Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

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

3. Recommended Seperation Distances

Recommended Seperation Distances between Portable and Mobile RF Communications Equipment and the Device according to EN 60 601-1-2			
Frequency of Transmitter	**150 kHz to 80 MHz**	**150 kHz to 800 MHz**	**800 MHz to 2,5 GHz**
Equation	$d = [3,5 / V_1] \sqrt{P}$	$d = [3,5 / V_1] \sqrt{P}$	$d = [7 / E_1] \sqrt{P}$
Rated Maximum Output Power of Transmitter (Watts)	Seperation distance (metres)	Seperation distance (metres)	Seperation distance (metres)
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,70	11,70	23,30
For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.			
NOTE:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			