MeDioStar NeXT

USER MANUAL

Asclepion
Laser Technologies

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MeDioStar

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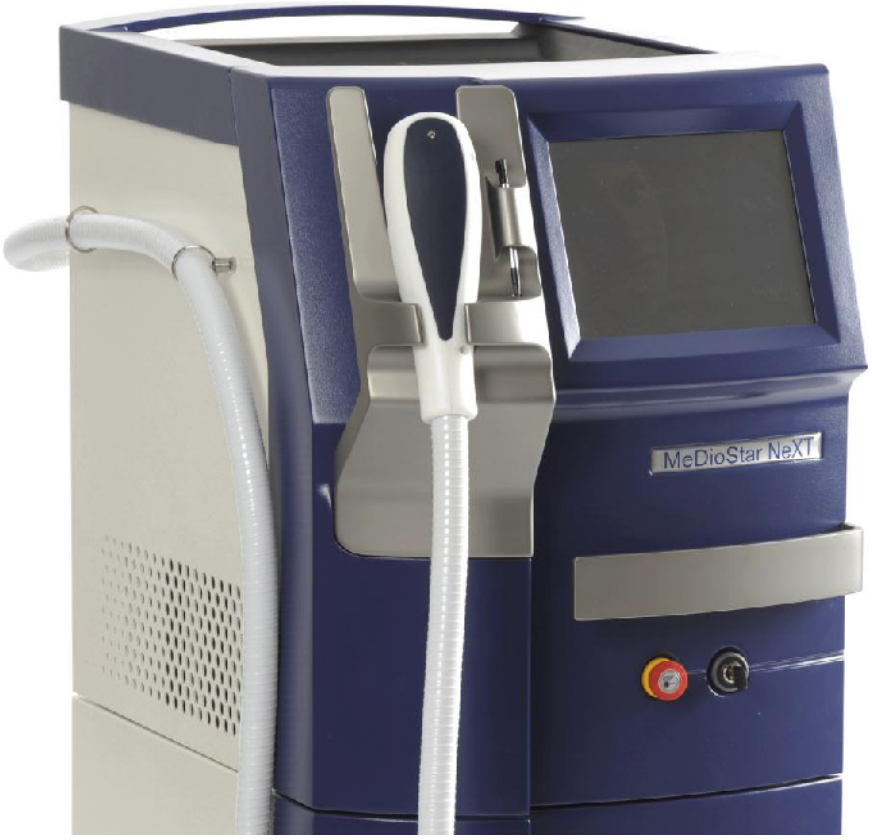

Contents

WARNING

The laser device MeDioStar emits high levels of emission in the infrared range that may cause serious damage to the eye if the device is used improperly. Moreover, further risks are possible.

Therefore, this User Manual must be studied carefully before using the device and all warnings and instructions are to be observed during its operation.

It is of particular importance that all persons in the room in which the laser is operated put on the appropriate eye protection during the active laser operation.

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1 Introduction

1.1 General information

- This User Manual contains the information required for the intended use of the device.
- It is an integral part of the complete product according to the applicable national, European and international directives and laws on product liability.
- The most important objective is to protect persons against risk situations and the device against damages caused by improper use.
- Regular maintenance according to the instructions given in this manual increases the precision and operability of the device during its entire service life.
- In case of malfunctions or errors that go beyond the scope of intervention of the User contact the Technical Service of Asclepion.

Knowledge of this User Manual is required for the operation of the devices. Therefore, please make yourself familiar with the contents and pay special attention to information concerning the safe operation of the device.

1.2 Symbols in the User Manual

In this manual, the following symbols are used to draw your attention to dangers or to give instructions on operating the device:

DANGER

This symbol indicates a direct danger for the life and health of persons.

Non-compliance with these instructions causes serious danger to health up to life-threatening injuries or even death.

WARNING

This symbol indicates a possible danger for the life and health of persons.

Non-compliance with these instructions can cause serious danger to health up to life-threatening injuries.

CAUTION

This symbol indicates a possible dangerous situation.

Non-compliance with these instructions can cause injuries.

Important information

This symbol indicates important information about the proper use of the device. Non-compliance with these instructions can cause damage to property or malfunctions of the device or in its surroundings.

Tip

This symbol indicates practical tips and particularly useful information that enables the User to use all the features of the device in an optimal manner.

1.3 Intended use

Recommended use

The MeDioStar NeXT is a pulsed diode laser (Class 4 laser product) that is used for the removal of unwanted hair, for the treatment of acne, for vascular treatments and for skin rejuvenation. Melanin and blood relatively strongly absorb the range of wavelengths of the radiation emitted by this laser, whereas the surrounding skin absorbs only a little bit of it. In this way, the radiation thermally destroys the target structure while protecting the surrounding skin.

Please refer to chapter 6 *Application* for detailed information about the use of this device.

WARNING

The incorrect using of this device can cause serious danger to health. Therefore, all warnings, instructions and informations of this User Manual are to be observed under all circumstances! The non-compliance is considered as unintended use of the device!

Any modification of this medical device is not allowed !

Contraindications

CAUTION

The intensive laser light in the infrared range can cause thermal damage of skin structures. The contraindications listed below are based on clinical experience in operating laser devices for said purposes of during about 15 years. They do not claim to completeness or unlimited validity.

- Light sensitivity
- Usage of preparations that increase sensitivity to light
- Cellulite therapies in the treatment area (wait a few weeks)
- Cancerous and pre-cancerous lesions in the treatment area
- Haired nevi in the treatment area
- Herpes simplex in the treatment area
- Keloids in the treatment area

WARNING

The intensive laser light in the infrared range can cause thermal damage to the eyes. Therefore it is NOT PERMITTED to laser the area of the eyes! Occasionally, eye inflammation and a reduction of the visual function were observed although the eyes were protected by eyeshields!

WARNING

The intensive laser light in the infrared range can cause thermal damage to skin structures. Therefore it is NOT PERMITTED to use laser treatment for pregnant women or children because clinical studies do not exist for these patients.

CAUTION

Patients with tanned skin – especially fresh tanned - develop more intensive side effects, particularly subsequent pigment changes. They should postpone the laser epilation!

Tattoos in the treatment area cause stronger side effects, too. Moreover, the color will be partly removed. Therefore, tattoos should not be treated.

Contraindications particularly for the treatment of spider leg veins

- Superficial varices with a diameter larger than 3 mm

- Branch and side branch varicose veins
- Ulcer
- Diabetes
- Vasculitis
- Stasis dermatitis
- Podedema
- Neuropathy of the legs
- Corticosteroids treatment in the last three months
- Thrombophlebitis

Restriction of use

WARNING

The laser emission of the device can cause thermal changes of tissue structures.

Treatment may not be performed by anyone other than a practicing physician or under the responsibility of a practicing physician (hereinafter referred to as user for simplification).

Active medical products may only be applied by Users who are adequately qualified to do so, based on their professional training background, expert knowledge and practical experience.

It is expressly pointed out that the use of the device is only permitted for Users that have been instructed to operate it and confirmed the training course by their signature in the Medical Device Logbook.

Among other institutions, Asclepion Laser Technologies GmbH also offers courses for laser expertise in medical applications.

Medical Device Directive / Medical Product Act

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

Device type acc. to RL 93/42/EEC: II b

UMDNS no.: 16-948 laser, therapeutic

1.4 Copyright

The specifications are subject to change due to further technical development. Contact the Technical Service of Asclepion Laser Technologies GmbH or your distributor of Asclepion Laser Technologies GmbH to get latest information.

2 Safety

2.1 General information

The MeDioStar NeXT complies with the requirements of the EC Medical Device Directive (93/42/EEC) and the German Medical Product Act (MPG).

The MeDioStar NeXT is a Class IIb medical device as per the directive in Annex IX (i.e. a surgical invasive product that is intended to develop a biological effect – that must not be confused with the laser class!).

Like each device, the MeDioStar NeXT may lead to potential risks when operated. The user should be aware of them before starting the system. Among these risks are optical, electrical and biological dangers as well as fire hazards.

Observe the national regulations applicable for the operation of a medical product.

According to the EC Medical Device Directive (93/42/EEC) the users in the European Union is obliged to keep a Medical Device Logbook. A corresponding sample is delivered with the device.

WARNING

The laser device emits high levels of radiation in the infrared range that may cause serious damage to the eye if the device is used improperly.

Absolutely observe the instructions given in this User Manual for equipment and procedures for operating, maintaining, checking or calibrating purposes.

WARNING

The laser radiation of the device can cause, whenever low, the risk of fire. Under no circumstances the device may be used in an explosive atmosphere (classified as AP and APG under IEC 601-1). Take care to preclude the existence of vapors from solvents or flammable liquids (these have been possibly used for cleaning or disinfection) in the room before you start working with the laser.

WARNING

Please note that this product is subject to scheduled technical safety tests that must be performed at **annual** intervals to ensure the safety for the staff and patients. If the tests are not performed regularly serious health problems can be caused.
The results of such safety tests are to be reported in the Medical Device Logbook.

WARNING

Work for service, repair or modification may not be performed by anyone other than Asclepion Laser Technologies GmbH personnel or other bodies duly authorized to handle such work to ensure the safety for the staff and patients.
If unauthorized persons carry out service works, repairs or modifications at the device serious health problems can be caused.

2.2 Electrical hazards

WARNING

The laser is operated with line voltage. There is the risk of an electrical shock! Do not open the device, if you are neither trained nor authorized to do so.

The device is only to be operated with reliably grounded and perfectly installed sockets with earthing contact.

WARNING

The laser is operated with line voltage. There is the risk of an electrical shock!

The device is designed to prevent the penetration of liquids during normal use. If liquid penetrates into the inner system space or the handpiece in exceptional cases, you must turn power off and pull the main power plug. Please contact our Technical Service.

2.3 Biological hazards

WARNING

The contact surface of the handpiece contacts the patient's skin during the treatment. There is the risk of microorganisms being transferred.
The selected handpiece must be deep cleaned and disinfected directly after each application!

2.4 Radio interference

The device complies with the requirements of the EN 60601-1-2 standard. The system is not affected by electromagnetic interference generated by other devices that conform to the same standard. Moreover, the system does not generate electromagnetic radiation beyond the limiting values indicated in EN 60601-1-2. The manufacturer's declaration about the electromagnetic compatibility according to EN 60601-1-2 is enclosed to this manual.

WARNING

Medical devices are subject to specific precaution measures concerning the electromagnetic compatibility (EMC). The device emits low levels of electromagnetic radiation that may have an effect on devices that do not comply with the standard. Unintended settings at these devices could be the result of such an effect.
Please observe the notes of the manufacturer's EMC declaration in the Appendix when installing and operating the device.

WARNING

The device may be influenced by devices that do not comply with the standard indicated above. The result may be unintended settings. Therefore, switch off cellular phones and similar equipment before putting the laser device into operation.

WARNING

The use of accessories and cables not authorized by the manufacturer may result in an increased interference emission or a decreased immunity of the device with the above mentioned consequences.
Use only accessories and cables that have been authorized by Asclepion Laser Technologies for this result.

WARNING

The device must not be stacked / arranged close to or in combination with other devices. If the device is operated close to or with other devices it must be checked if the device is working properly in this arrangement.

2.5 Laser

2.5.1 Optical hazards caused by laser emission

Lasers are classified in accordance with their potential for danger. The most dangerous class is class 4 (the less dangerous class 1).

WARNING

The device is a laser of class 4. That means that the direct and even scattered laser radiation can cause serious damage to the eye if the device is operated improperly.

The protection measures described in the following must be strictly observed.
It is of particular importance that all persons in the room in which the laser is operated put on the appropriate eye protection during the active laser operation.

For fundamental rules on the handling of laser devices you are referred to the international standard EN 60825. It is complemented by national regulations providing general protection from dangerous laser radiation. Their purpose is to protect operating personnel and patients during medical applications.

Please follow specific national regulations that may be valid for your location.

It is highly recommended to follow the rules specified below:

1. **A laser protection officer should be appointed in writing** who has at least the following responsibilities:
   - monitoring of laser operation,
   - supporting the user on issues of safe operation and necessary protective measures,
   - cooperating with expert personnel on occupational safety in fulfilling their tasks, including the information about important issues of laser radiation protection.

2. **Laser area**

   During operation, the area where the maximum permissible radiation level may be exceeded, i.e. the so-called laser area must be delimited and marked with a laser warning sign. The laser area is the room in which the laser is used. **Warning lights** and a triangularly shaped yellow **laser warning label** must be provided at all access points.

Figure 1: Laser warning label (European)

3. **The NOHD** (Nominal Ocular Hazard Distance) of this laser system is very great so that the entire laser session room is to be regarded the laser area.
4. **Personal eye protection**

WARNING

Laser radiation can cause serious damage to the eye.

Everyone present in the laser room during a treatment session must wear laser safety goggles, the patients an eyeshield!

The laser safety goggles and the eyeshield for patients must comply with the specifications defined in the technical data section!

5. **Further precautionary measures**
   - Cover up windows and other openings of the treatment room in order to prevent unwanted emission of laser radiation.
   - Restrict access to the treatment room to the patient to be treated and to those persons who will assist and are trained in the handling of this laser device.
   - Make sure that personnel trained and assisting in a therapy session know how to shut down the laser in the case of an emergency.
   - Remove all metal objects such as watches, rings, bracelets or similar belongings from the working range and refrain from the use of reflecting instruments or other comparable materials where possible.
     (Reflecting objects can interrupt the laser beam and guide it to another area than the intended one. Many surfaces, even the ones that seem to be mat, can strongly reflect the emission wavelength of the laser.)
   - Point the active laser only onto the area that is intended for treatment.
   - Refrain from looking directly into the outlet opening of the handpiece or that of the optical fiber, even if you wear laser safety goggles.
   - For phases of non-operation, you should switch to STANDBY mode (in the STANDBY mode accidental release of the laser is prevented).
   - Always remove the key from the key holder once power has been turned off and keep the key in a safe place.
6. **Responsibility**

   The user who releases the laser emission is responsible for the laser safety. He/she has to ensure that all preventive measures have been taken **before** activating the laser. It is of particular importance that all persons in the room, in which the laser is operated, including the patients, put on the appropriate laser safety goggles or eyeshield.

2.5.2 Laser-induced fire hazard

WARNING

Because of the laser radiation of the devices there is a risk of fire or explosion if the laser is used in the presence of flammable materials, solutions or gases or in an envirement which is enriched with oxygen.

The Users should take the following precautions in order to prevent fires caused by laser radiation:

- Please expose only the proposed body areas to laser emission
- Please use non flammable substances for the preparation of the treatment and for the cleaning and disinfection of the instruments directly before and during the treatment. If it is not possible to avoid usage of solvents such as alcohol or isopropyl alcohol directly before and during the treatment, the vapour should be removed by aeration before activation of the laser or at least wait for some time.
- Please use non-flammable substances for anesthesia, if at all.
- Avoid the use of oxidizing gases, e.g. nitrogen oxid (N_2O) and oxygen. Be especially careful when using oxygen. Oxygen increases both the intensity and the extent of fire.
- Please keep a minimum of flammable materials in the treatment room only. If it is necessary for the treatment to use flammable materials, please moisten these.
- Keep clothes as far as possible away from the treatment zone.
- Some materials, which are saturated with oxygen (e.g. cotton), could be inflamed at the high temperatures, which develop under the intended use of the laser.
- Have always a small fire extinguisher and water ready in the treatment room

3 Technical data

3.1 Device models

Designation	Description
MeDioStar (NeXT) (Part no. 1590)	High power diode laser (main unit)
MeDioStar Handpiece SDT (Part no. 4020)	Standard handpiece for hair removal
MeDioStar Handpiece HP (Part no. 4022)	High-power handpiece for hair removal
MeDioStar Handpiece VAS (Part no. 4021)	Handpiece for vascular treatments

The standard delivery includes the main unit with one freely selectable handpiece.
The handpieces differ in their spectral emission characteristics of the diode modules used and in the spot size.

3.2 Specifications

Specification	MeDioStar
Device model	Floor-based unit
Display	8.4“ LCD display
Operator guidance	Touchscreen
Cooling	Internal cooling cycle
Door interlock connector	5 V / 10 mA
Laser warning lamp	Potential-free relay contact max. 24 V / 1 A (make contact)
Permissible ambient conditions	Temperature: 15 °C to 30 °C rel. air humidity: max. 70 % (no condensation) height: max. 2000m above sea level
Permissible transport and storage conditions	Temperature: 0°C to +50°C rel. air humidity: 10 % to 95 % (no condensation)
Dimensions	365 x 560 x 465 mm (W x D x H) without handles and handpiece holder
Weight	ca. 35 kg
Power requirements	100 -240VAC, 50/60 Hz, max. 1500 VA
Main fuse	overcurrent release 16A, medium slow-blow
Overvoltage category	II (IEC 60664-1)
Max. peak of mains voltage Max. nominal mains voltage	V MT peak = 2500V peak V MN r.m.s. = 300V r.m.s.

Classification according to directive 93/42/EEC	II b
Accessories	see chapter **Fehler! Verweisquelle konnte nicht gefunden werden. Fehler! Verweisquelle konnte nicht gefunden werden.**
Operating mode	The device has been designed for continuous operation.

Specification	MeDioStar
Laser model	High-power diode laser array
Wavelength	800 - 950 nm (spectral distribution depends on the device model; see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**)
Laser class	4
Required laser safety goggles (acc. To DIN EN 207: 2009)	800 - 950 nm D LB5
Pulse duration	max. 400 ms (depending on the mode and handpiece)
Pulse energy	max. 60 J
Pulse frequency	max. 12 Hz (depending on the mode and handpiece)
Spot sizes (handpieces)	handpiece STD: 14x10 mm² handpiece HP: 8x6 mm² handpiece VAS: 4x3 mm²
Tolerance of output power	± 20 %
Laser beam mode	multimode
Laser beam diameter at the handpiece output	see spot sizes
Energy density	max. 44 J/cm² @ handpiece STD: 14x10 mm² max. 90 J/cm² @ handpiece HP: 8x6 mm² max. 210 J/cm² @ handpiece VAS: 4x3 mm²
Beam divergence at the handpiece output (round angle, $1/e^2$)	typ. 400 mrad @ handpiece STD typ. 700 mrad @ handpiece HP typ. 600 mrad @ handpiece VAS
Nominal ocular hazard distance (with handpiece)	35 m
Protection class of the part used	B

3.3 Technical description

Power supply unit

The integrated power supply units transform the line voltage in rectified low voltage for the electrical supply of the device.

Control

The output parameters and the safety systems of the device are monitored and controlled by a microcontrol system.

Operating modes

The device operates in both single pulse mode and continuous mode.

The device is designed for continuous operation in the specified ambient conditions.

If during this mode the temperature has increased to such a value that operations cannot be performed any longer, the device will automatically switch to a cooling mode till a normal operating temperature is reached

Operation

The device is operated via a touchscreen. The data are output by an LCD with plain-text user guidance. Depending on the operating mode different parameters – such as fluence, pulse duration, pulse rate and others – can be set as described in the Operation chapter.

In addition to the parameters selected, other data such as the laser mode (STANDBY or READY), the handpiece used and, if necessary, error plain-text messages are displayed.

The device contains a database where the user can store treatment reports with the parameters typically used for various types of treatment.

Cooling

The internal cooling system is required to prevent the component groups from being overheated. The lost heat is dissipated to the ambience via a water-air heat exchanger. A pump circulates the coolant through the component groups and the heat exchanger. In addition to this, integrated temperature and flow sensors provide safe operation.

The device cooling is ensured by the indoor air. External cooling water is not required

To maintain the cooling effect, the device should only be operated in the specified ambient conditions. The ambient air should be dustless. At the openings provided for cooling the device, a minimum distance should be kept to air-tight objects (e.g. the wall of the room). (See chapter *Installation*).

Laser

The MeDioStar laser is a pulsed high power diode laser (laser class 4).

The emitted wavelength is in the near infrared (NIR) of between 800 nm and 950 nm. The spectral distribution is optimized in dependence on the use of the different handpieces.
The laser beam emission is activated by pressing the foot switch.

Skin Cooling

Next to the laser tip is a metal probe at the handpiece, which is cooled by an integrated Peltier element. Together with the procedure described in chapter *Application* it is guaranteed that the epidermis is cold before the laser pulse impinges. The temperature of the probe is monitored.

3.4 Safety units

The device is equipped with several safety units that have been provided to avoid maloperation and the unintentional activation of the system. All the persons who operate the laser or assist during the treatment should make themselves familiar with these units.

Laser emergency STOP switch

The red Laser emergency STOP switch at the front of the device (see figure below) is for the purpose of switching off the system immediately in an emergency. It should only be activated in emergency situations, i.e. if the emission has to be interrupted immediately.

To turn off the system immediately press this button. To unlock this button after the elimination of the emergency, turn it to the left until it jumps out again.

Note

The Laser emergency STOP switch should not be used to turn the system on and off in its normal condition.

Key switch

The key switch is used to activate the system. Only authorized persons having access to the switch can start the system. The system can only be started via the key switch, if the Laser emergency STOP switch has not been pressed.

WARNING

The laser device emits strong radiation in the infrared range. This radiation can cause serious eye injuries if the device is not properly used.

The device must not be switched on or operated by unauthorized personnel.
Remove the key always after having switched off the system and ensure that it is kept by authorized persons only.

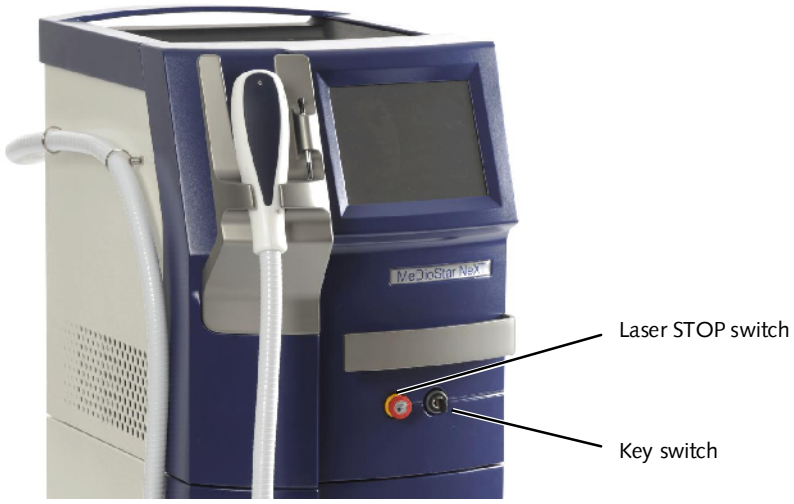


Figure 2: Safety units at the front panel of the device

Power switch

The power switch separates the device from the line voltage. If the device is not in use, the switch should be in the OUT (O) position.

Figure 3: Power switch at the rear panel of the device

Foot switch

The foot switch is an electric button that releases the laser emission if the laser is activated and if the device is in the READY mode. It is equipped with two redundant switching elements. Position the foot switch always close to the treatment area.

Figure 4: Foot switch

STANDBY mode

The STANDBY mode prevents the unintentional or inadvertent activation of the laser. If the device is in the STANDBY mode, laser emission cannot be activated. The user can only start the emission, if the READY button has been pressed.

The system switches to STANDBY in the following situations:

- after the first start of the device,
- if the User presses one of the buttons for selecting the laser parameters,
- if the system has been in the READY mode for a longer period of time without the laser released,
- if the User presses the STANDBY key when the system is in the READY mode.

Automatic shut-down

The device is equipped with an automatic shutdown system. If a specific problem arises, the system will automatically change into the following safe mode:

The laser beam shutter is closed, the laser discharge is interrupted and the footswitch is deactivated. The screen shows a fault message identifying the specific error (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**: **Fehler! Verweisquelle konnte nicht gefunden werden.**.).

Remote door interlock contact

The system is equipped with a remote interlock contact that may be connected to the entrances to the laser room. If the remote interlock contact is open (e.g. if the door is opened), the laser emission will be interrupted automatically and the device will change to the STANDBY mode.

Acoustic signal

The laser emission is indicated by an acoustic signal during the period of emission.

Warning labels

The device carries several warning labels (see chapter *Installation - Labels*). These labels must always be clearly readable and replaced immediately when damaged.
Contact the Technical Service immediately in such cases.

The manufacturer will only guarantee the safety, reliability and performance of the device, if:

1. the device has been used in accordance with the instructions given in this manual (on the safety measures and the use of the system),
2. the installation, assembly, extensions, changes, repair and maintenance works have been performed by persons being authorized and qualified for them, and
3. the electric system at the place of installation complies with the requirements placed by the EN/IEC and the local regulations.

4 Start up

4.1 Scope of delivery

Note

Check together with the haulier whether all components that are listed below and required for the safe operation of the device are present and not damaged. Incompleteness and/or damages in transit are to be claimed immediately at the supplier.

Asclepion Laser Technologies does not accept any liability unless another agreement has been made expressively.

Please, keep the packing for the future safe consignment of the device.

CAUTION

Refrain from start-up action of any kind if the device or its accessories are found to have suffered mechanical damage. There is risk of physical injury if this advice is disregarded. Contact the Technical Service of Asclepion Laser Technologies GmbH in such cases.

The basic equipment comprises the following device parts:

- basic device
- power cable
- foot switch
- handpiece
- warning lamp/door interlock connector
- keys (two for key switch)
- laser safety goggle, eye protection for patient
- user manual
- laser warning sign

4.2 Installation

4.2.1 Device design

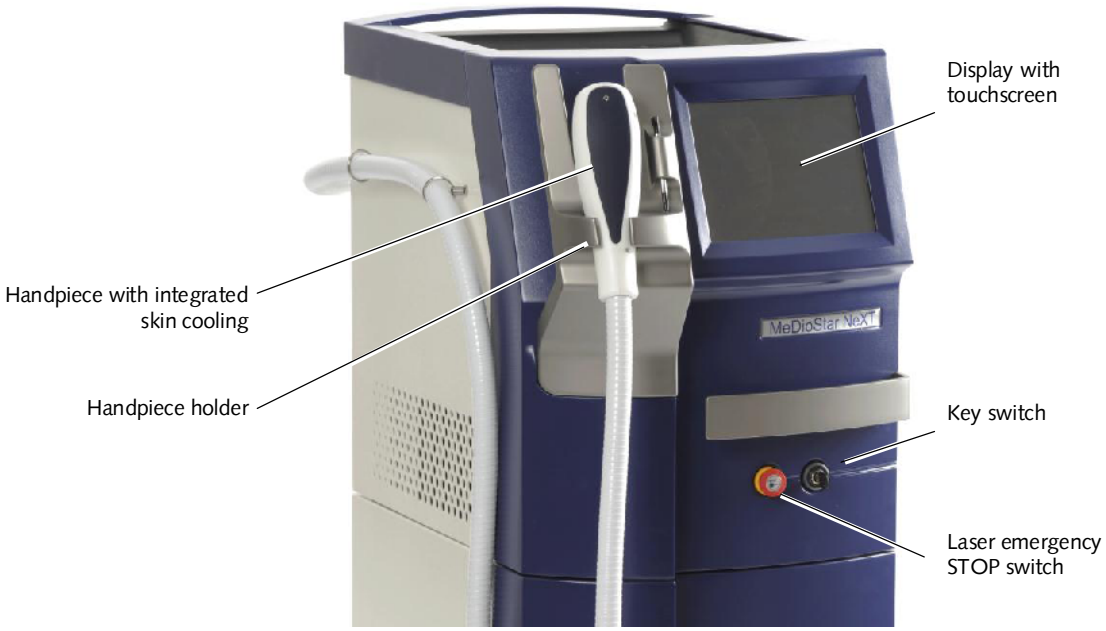


Figure 5: Connections at the front panel of the device

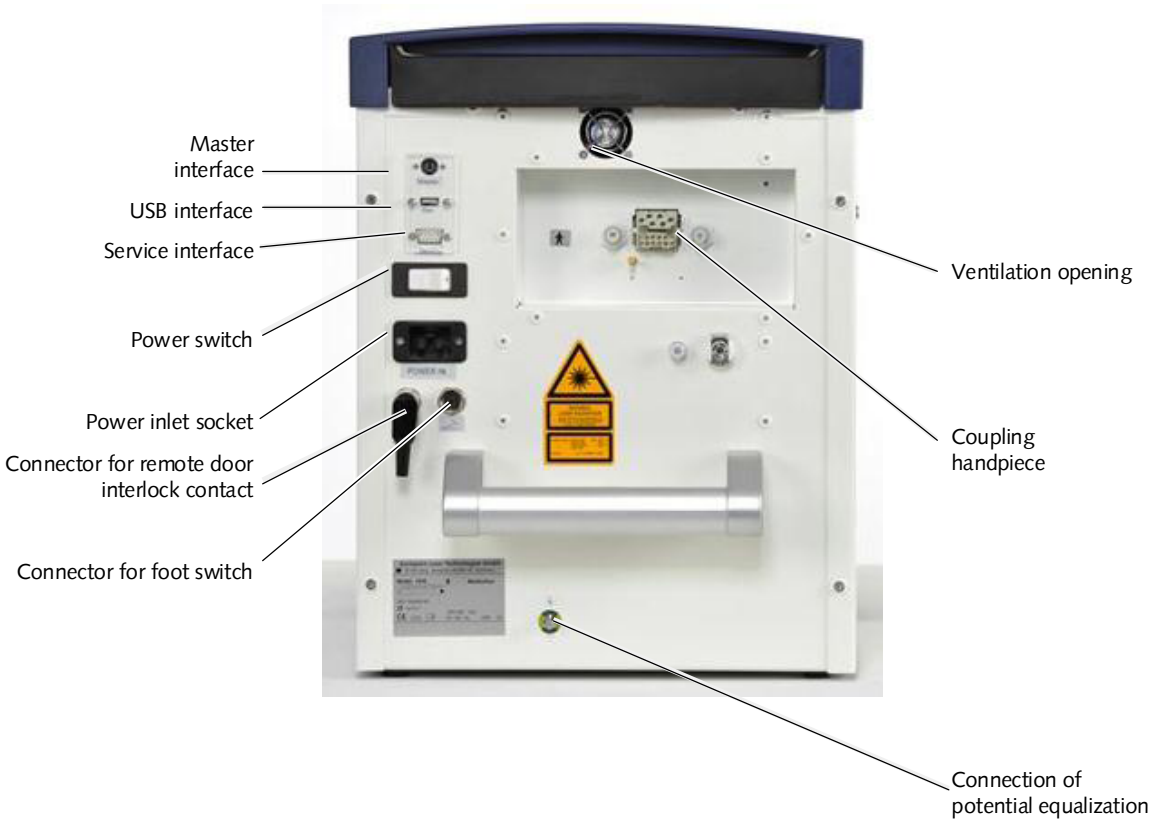


Figure 6: Connections at the rear panel of the device

4.2.2 Labels at the device

WARNING

The laser device emits high levels of radiation in the infrared range that may cause serious damage to the eye if the device is used improperly.

Therefore, warning and information labels are attached at appropriate points of the device. All the staff must know these labels and their meaning to ensure the proper use of the device.

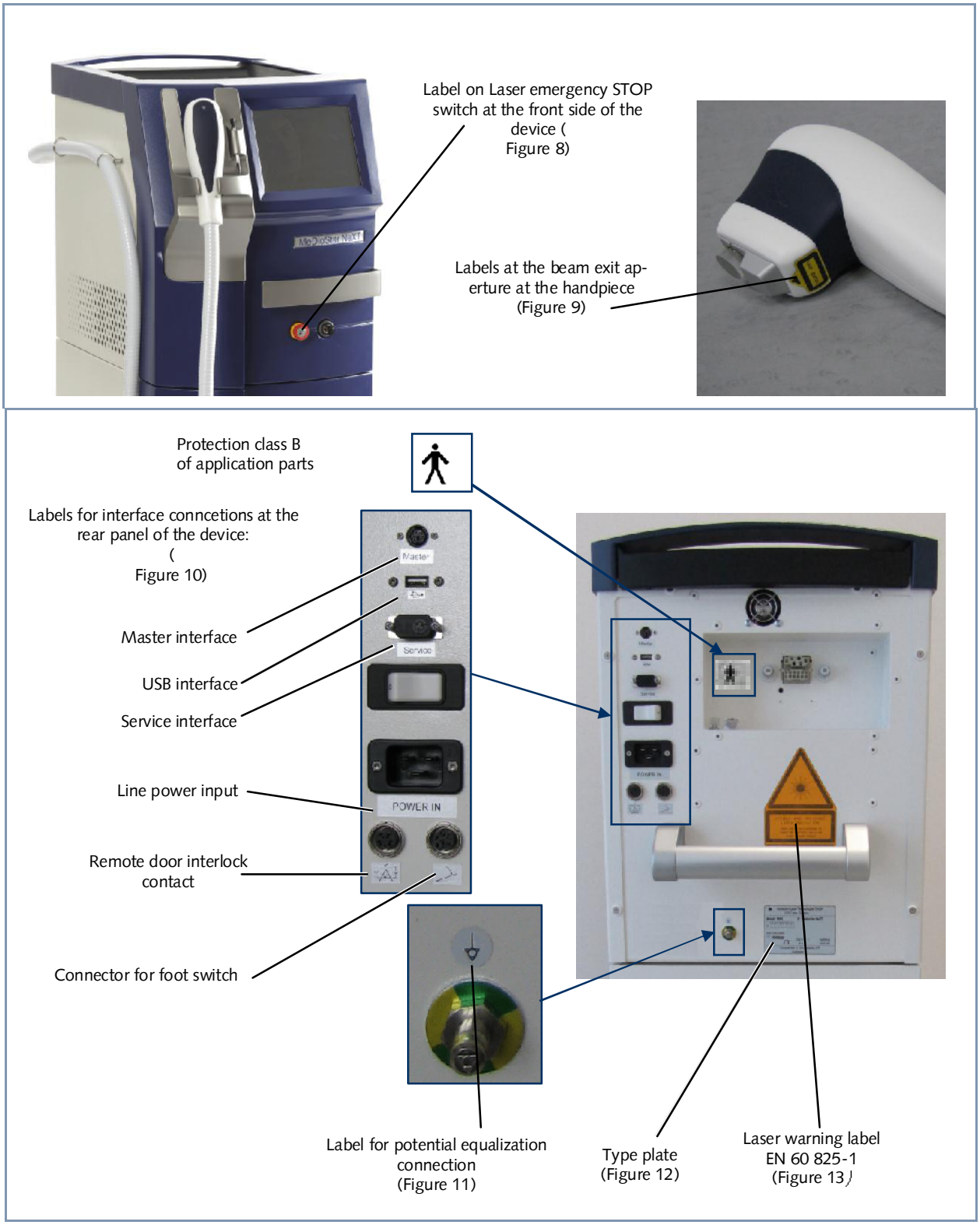


Figure 7: Labels at the MeDioStar device

Figure 8: Laser emergency STOP switch

This label indicates the Laser emergency STOP switch for switching off the laser radiation or emission of the modules promptly.

Figure 9: Beam exit aperture

This label indicates the exit point of the laser beam out of the transmission system.

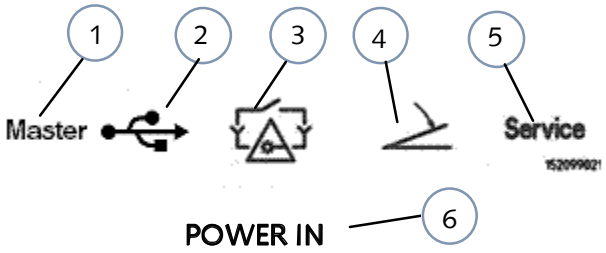


Figure 10: Interface connections

Warning: It is absolutely important that only the accessories released by Asclepion Laser Technologies are connected here. Master, Service and USB are exclusively designed for authorized personnel.

1. Master interface
2. USB interface
3. Remote interlock contact connector
4. Connector for foot switch
5. Service interface
6. Power inlet socket

Figure 11: Potential equalization connection

This contact is used to connect the device additionally to a potential equalization system.

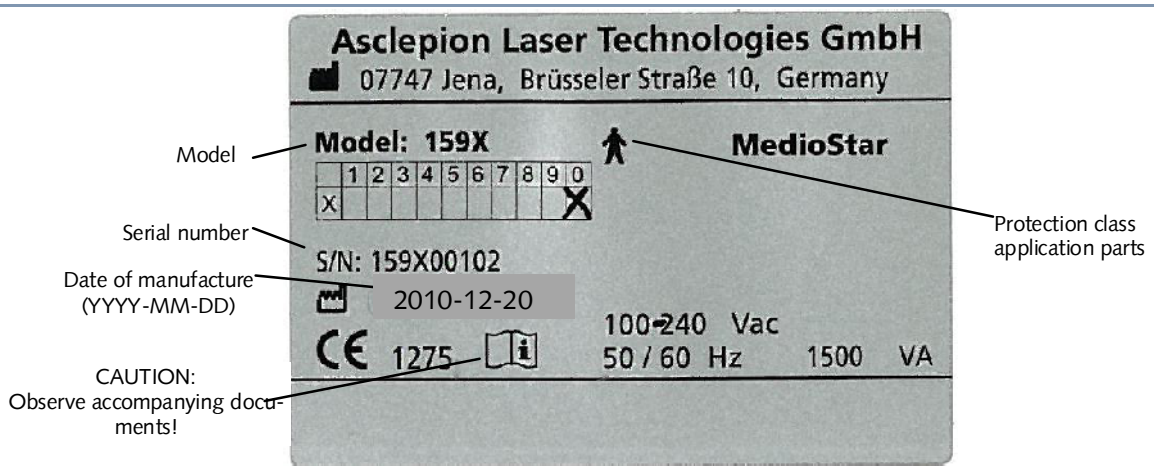


Figure 12: Type plate MeDioStar

Type plate indicating type-specific data of the device, such as serial number and date of manufacture.

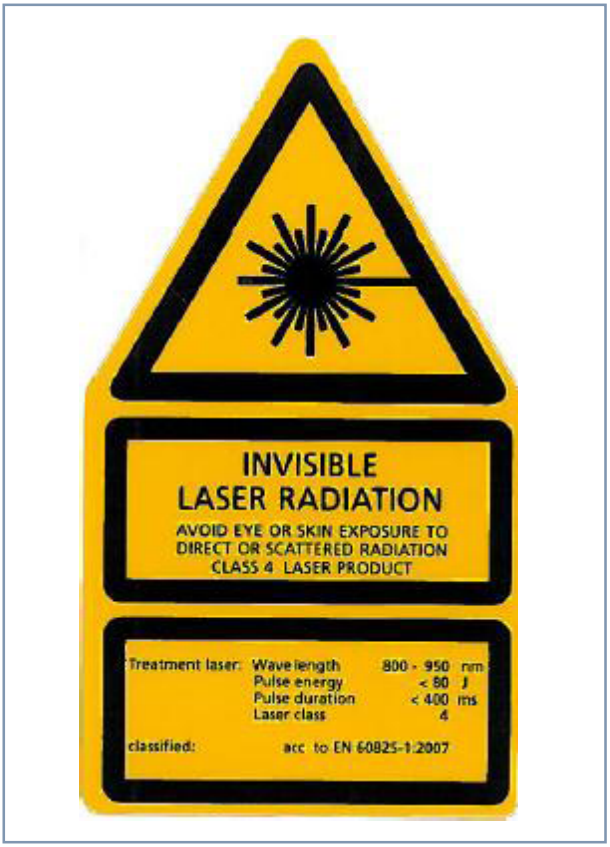


Figure 13: Laser warning label DIN EN 60 825-1

This label informs about the dangers, the maximum values of energy emission and the classification of the laser source.

WARNING

The laser device emits high levels of radiation in the infrared range that may cause serious damage to the eye if the device is used improperly.

Therefore, warning and information labels are attached at appropriate points of the device. All labels must be kept at their position and must be in good condition.

Replace defect labels immediately to ensure the appropriate use of the device.

4.2.3 General information about installation

Important information

After the installation and any relocation of the device from a cold to a warm environment with a temperature difference of more than 5°C, allow the device to adjust to the room temperature in unpacked condition before being used at least in the following way:

min. 2 hours at a temperature difference of up to 10°C
min. 4 hours at a temperature difference of up to 15°C
min. 8 hours at a temperature difference of more than 20°C.

Afterwards, switch the device on without a handpiece connected and allow the device to warm up for at least 30 minutes.
Take care that the installation and operating environment of the device meets the following conditions: temperature: 15 to 30°C, relative humidity: max. 70 % and height not more than 2000 m above sea level.
Non-observance of these instructions may result in the destruction of the device.

For an efficient cooling of the device, please keep a minimum distance of at least 20 cm between its lateral and rear sides to the wall.

CAUTION

Fix the wheels of the device to ensure that it cannot be moved unintentionally. Non-observance of this instruction may cause risks of injuries.

WARNING

The laser device emits high levels of radiation in the infrared range that may cause serious damage to the eye if the device is used improperly.

Every entrance to the laser area (usually the laser treatment room) must be equipped with warning lamps that are lighting (or flashing) as long as the laser emits radiation to warn persons against entering the room.

4.2.4 Door interlock connection

At the rear panel of the device, a connector is provided for the connection of a door interlock contact to the device (see Figure 14: *Connections for remote door interlock contact and laser warning lamp*).

As port a round plug hast o be used which can be screwed, type (x)V 40 according to IEC 60130-9, e.g. Lumberg WSV 40 (as delivered).
(x): dependent on type, e.g. WS for an angled plug as delivered.

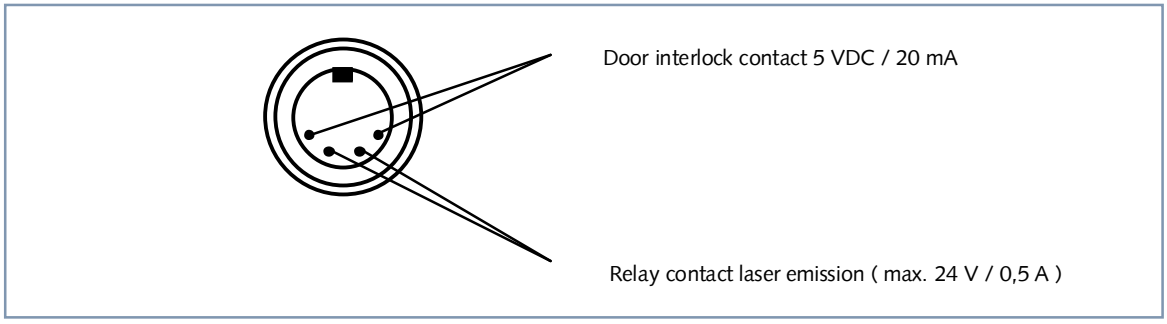


Figure 14: Connections for remote door interlock contact and laser warning lamp

By connecting the two connections *remote door interlock contact* and external door contact you can prevent laser radiation from being emitted when the door of the laser room is opened.

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

The contact connector delivered is factory-fitted with a jumper. To connect a door interlock contact, remove this jumper and connect your door interlock contact to the same terminals. The external contact must be potential-free and designed for at least 24 VDC and 0.5 A. If a door-interlock contact is not used, make sure to keep the plug with the factory-fitted jumper connected.

Important Information

The contact plug may only be connected with the device being turned off and disconnected from the power supply. Non-observance of this instruction can cause damages of the device.

The contacts for the remote interlock and the foot switch must never be connected with line power because otherwise the system will be seriously damaged. Connect these two connectors only in the way described in this section.

Tip

If you have connected the door interlock contact with the entrance door, please check every day before starting a treatment that the laser cannot be switched to the READY mode with this door being open. In case of malfunction please inform the Technical Service.

An external voltage source for a low-voltage warning lamp can be switched via two further contacts of this connector. The internally installed switching relay is designed for a maximum voltage of 24 VAC and a maximum current of 1 A. Absolutely observe the following safety requirements for the connection of an external warning lamp:

WARNING

To avoid the risk of an electric shock with consequential serious health problems as well as fire hazard of the transformer, if you use an external transformer to power the lamp, please note:
A safety transformer complying with IEC/EN61558-2-6 must be selected.

The internal relay of the device is closed, if the device is in the *READY* mode.

The prescribed laser warning lamp may, of course, also be turned on and off via a normal light switch if the laser is operated.

4.2.5 Foot switch

Now, connect the foot switch to the foot switch connector provided at the rear panel of the device (refer to *Figure 6:*). Make sure to insert the plug as deep as it will go. Then, lock it by turning the cap nut clockwise. The foot switch should be positioned right next to the device.

To be able to activate the foot switch later, the cover must be pressed first so that it opens. Thus, the real switch (black) can be accessed and can be activated by the foot to release the laser emission in the READY mode.

Figure 15: Foot switch

4.2.6 Handpiece with integrated skin cooling

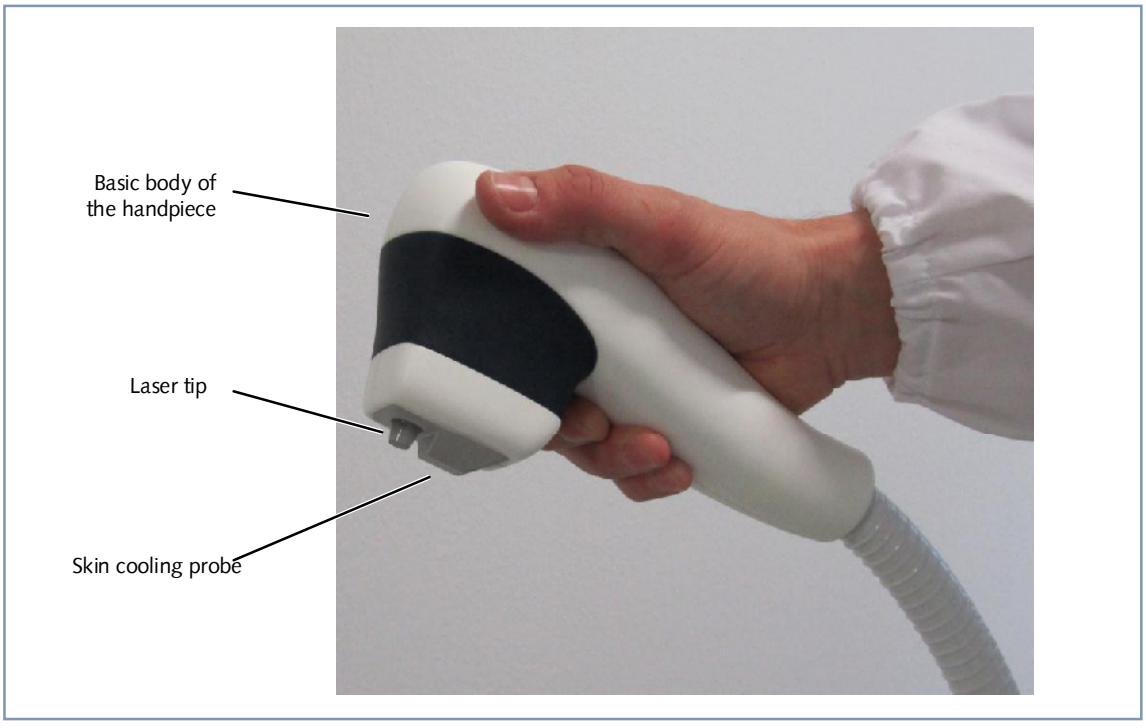


Figure 16: Handpiece MeDioStar with skin cooling

The laser spot size can be varied by changing the handpiece. The system automatically detects the new handpiece (optional) and considers it accordingly.

Figure 17: Handpieces MeDioStar with different spot sizes

4.2.7 Mains connection

Important Information

When selecting the power outlet, consider all technical data of your local network and the device. First, verify that the available line power corresponds with the specified power requirements (line power indicated on type plate). If the device is connected to an inappropriate power supply the device can be damaged.

Please observe the requirements stipulated in your national regulations/standards as amended.

Before the device is connected to the line power supply, the rocker switch of the main switch must be in position O (device without potential) First, plug the mains cable into the power inlet socket at the rear panel of the device before connecting the other end with the mains plug. The operation of the laser requires that the device is connected to a single-phase power outlet protected by a **separate** fuse rated for at least 1500 VA (circuit breaker type C).

4.3 Switching on

Verify that the following requirements have been met before switching on the device:

- The device is in perfect condition (no damages).
- The voltage specified on the type label agrees with the line voltage available at the place of installation.
- The power plug of the device has been plugged into an appropriate power outlet.
- The foot switch plug has been properly connected to the foot switch socket at the rear panel of the device and has been screwed down.
- The plug of the door contact is properly connected and screwed to its terminal at the rear panel of the device.

- Handpiece is connected.
- Warning lamps are switched on at every laser room entrance.

Make sure that all safety precautions have been taken.

Then, proceed as follows:

1. Switch the power switch at the rear panel of the device to I (O). (Figure 6*:*)
2. Verify that the Laser emergency STOP is deactivated (not pressed)
3. Then, put the safety key into the key switch and turn it clockwise as far as it will go.

While the device is automatically testing essential and safety-relevant parts, the start screen appears on the display. The main menu appears on the screen.

Figure 18: Start screen

5 Operation of the device

WARNING

The laser device emits high levels of radiation in the infrared range.

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

This may cause serious damage to the eye.

Absolutely observe the instructions included in this User Manual for equipment and procedures for operating, maintaining, checking or calibrating purposes.

5.1 General information on operation

The treatment parameters are to be set via the touch screen on the display at the front panel (refer to Figure 5:). The setting is very straightforward and self-explanatory.

- To select a function press the corresponding fields on the display. By pressing the +/- keys on the right side of the display you can browse through lists consisting of several pages (e.g. Indication lists).
- To select parameters press the corresponding parameter field of the activated function. Fields with a dark background (function fields) can be selected whereas fields with a light background (indication fields) are only used for giving information.
  By pressing the +/- keys on the right side of the display you can change the set diameters. If you keep the key pressed for a longer time, the parameters will run through automatically. The new parameters are loaded by pressing OK.
- Successful key pressure will be confirmed by a short beep signal.
- The device is activated by pressing the *STANDBY/READY* key. The active mode is shown in white. If the Device is switched to the *READY* mode, the yellow warning sign will be additionally shown on the display.

Overview on important functions of the device

Function/ parameter	Display	Remarks
Quick start		You access the Quick start menu. Here, the laser device can be started directly.
Patient database		Treatments with the relevant parameters can be retrieved and saved
Indications		All enabled indications are displayed and can be called.
Library		The library contains information on the individual treatment
Setup		General settings for the device can be made via the display.
Asclepion		Experience the advantages of the Asclepion Web Club.
Tools		Saved special functions for the laser can be called.
Save		Saving settings for your treatment
Start screen		Returning to the start screen
Setting keys		Scrolling through lists and changing settings
Back		Returning to the last screen without loading the changed settings
Cancel/ Delete		Exiting the current indication/patient/favorite Deleting
OK		Loading the changed setting
Ready/ Standby		The active mode is shown in white.

5.2 Setup

You can change the general settings of your display such as language and sound volume. Call the *Setup* menu by pressing the *Setup* key in the main menu. The Setup screen appears (see Figure 19: *Setup*).

Figure 19: Setup

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

Function/ parameter	Display	Remarks
Information	Device information	Indication of software version
Language	Display	Selection of different languages
Sound	Sound	Setting the sound volume
Release indication	Release new indication	New indications must be released
Import/export	Import - Export	Allows the export and import of the patient database, the indication list and the library to or from the USB stick

Tip

The use of the USB interface is allowed only in STANDBY and only for the export and import of data from or to a suitable USB stick, e.g. from Asclepion Laser Technologies.
A backup of the patient data should be performed at regular intervals by using a suitable USB stick to avoid data losses in case of a possible defect of the device!
The data can only be read on the device display.

5.3 Patient database

You want to get information about treatments you have already performed or you want to create new patients in your database. For this purpose, open the database by pressing the *Patient database* key in the main menu.

The *Patient database* screen appears (see figure below).

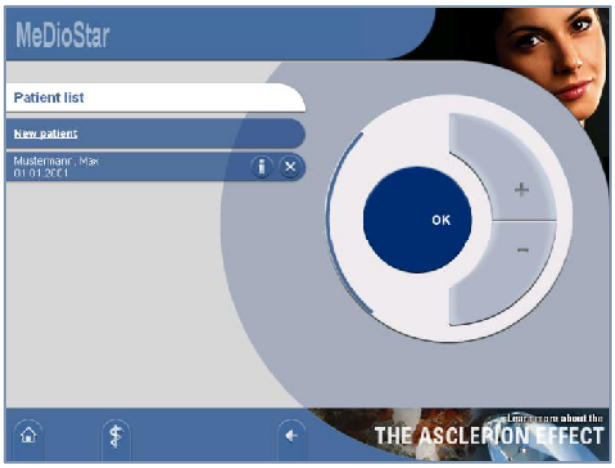


Figure 20: Patient database screen

Function/ parameter	Display	remarks
New patient	New patient	You have the option to include a new patient in your database. After pressing this button a keyboard is displayed that you can use for entering the new patient.
Information		Here, you can call a comment for a patient or enter other information for a patient (e.g. allergies, reactions to the treatment, etc.).

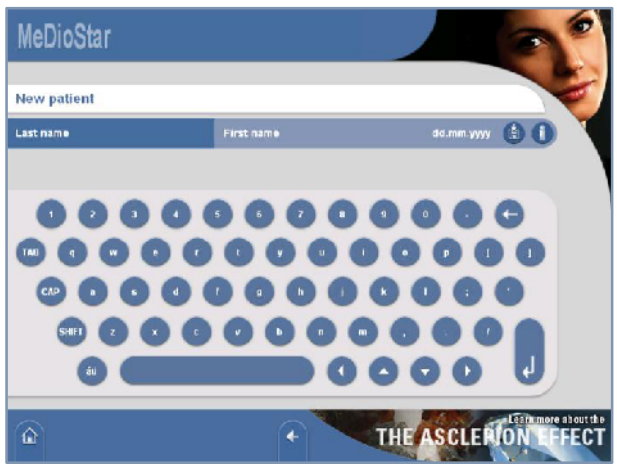


Figure 21: Screen for entering patient data

To write initial letters as caps, press the *Shift* key once, but do not keep it pressed. After one letter, the keyboard automatically returns to small letters again.

You can change the keyboard to caps by pressing the *Cap* key.

By activating the *Shift* or *Cap* key you can add special characters.

Use the äü key to add special characters of foreign languages. Also here, you can press the *Shift* or *Cap* key to write caps. To return to the original keyboard layout press the äü key again.

Tip

Make sure that the patient's date of birth is entered completely in **four digits and makes sense.** Otherwise, your entry will not be saved.

5.4 Library

The library contains information about the individual indications such as application, side effects and performance of the therapy. Moreover, you can display before and after photos as well as videos. To call the library, press the *Library* key in the main menu.

Figure 22: Library

You can call the following information:

Function/ parameter	Display	Remarks
Indications	Epilation BASIC	Select the indication for which you want to display information (here: Epilation BASIC)
Photos		Photos before and after the treatment (if existing)
Videos		Videos of treatments (if existing)
Application	Indications	Fields of application of the treatment
Contraindications	Contraindications	Contraindications
Preparation	Preparation	Note on preparing the treatment
Therapy	Therapy Procedure	Note on performing the treatment
Post-op care	Aftercare	Note on post-op care
Notes	Notes	General notes

Examples of available information:

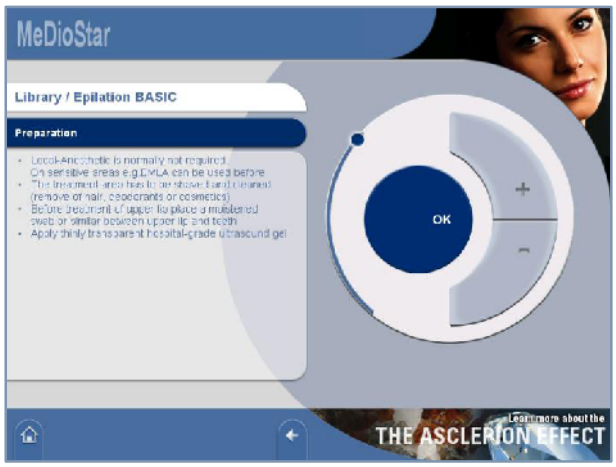


Figure 23: Therapy information

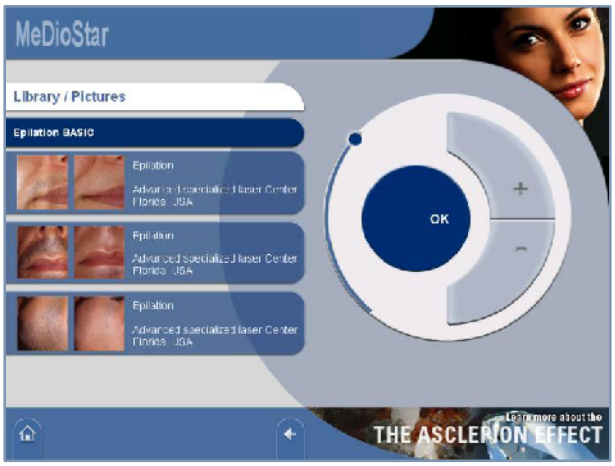


Figure 24: Library - photos

Figure 25: Library - videos

To enlarge the photos or to start the video please touch a photo or the video.

5.5 Asclepion Effect

The Asclepion Effect – a company philosophy that is useful both for you as the customer and for your patients.

Asclepion Effect offers you information on Asclepion Laser Technologies, the company strategy and marketing tools.

Are you already a member of our exclusive Web-Club? If you are not, you can inform about our offer here.

Figure 26: Asclepion Effect

5.6 Starting the treatment

Your device is designed for different applications.

To be able to start a treatment you have to change to the Treatment screen (see below example for starting with Indication list).

Figure 27: Treatment screen

The change to the Treatment screen via Indication list is only possible, if the correct handpiece has been connected. If no handpiece or the wrong one is connected, a corresponding message will be displayed.

You have several options to change from the main menu to the Treatment screen:

- Start via Quickstart 
  (User-selected parameters can be directly set on the display according to the selected mode – Basic, Professional, SmoothPulse, Burst or Vascular.)
- Start via Indication list 
  (According to the selected indication, appropriate parameters are already displayed for the **test treatment**. Depending on the reaction to the test treatment they are to be reduced or increased. See chapter 6 *Application*.)
- Start via Patient database 
  (This option is recommended for continuing a treatment.)

5.6.1 Start via Quickstart

To display the *Quickstart* screen, press the *Quickstart* key in the main menu. The system needs few seconds to open this window.

Via the Quickstart menu (*Figure 28*: Quickstart screen, example *Basic* mode) you can start your laser device.

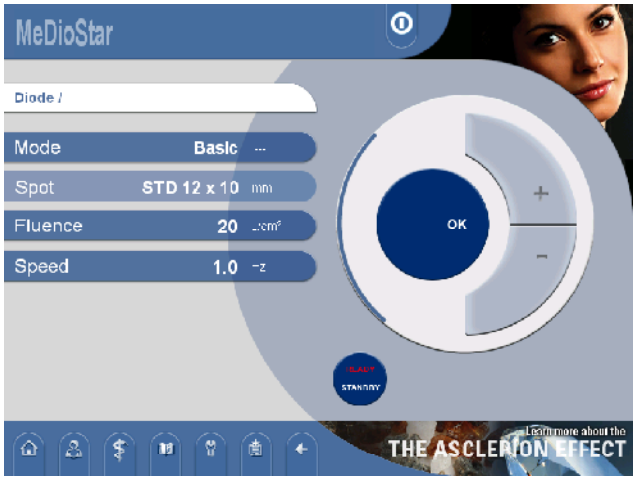


Figure 28: Quickstart screen

Refer to chapter **Fehler! Verweisquelle konnte nicht gefunden werden. Fehler! Verweisquelle konnte nicht gefunden werden.** for setting the parameters.

On the display in the Quickstart menu you can also select the different modes – Basic, Professional, Smooth Pulse, Burst and Vascular – apart from the parameters, if they are released for the connected handpiece. (See 6 *Application* for application instructions.)

5.6.2 Start via Indication list

Press the *Indication list* button in the main menu to open the screen with the list of indications (see Figure 29:).

All the indications that have been released for your device are indicated.

Figure 29: Indication list screen

Select your indication by pressing the corresponding field. The treatment screen of the indication will be opened. Refer to chapter **Fehler! Verweisquelle konnte nicht gefunden werden. Fehler! rweisquelle konnte nicht gefunden werden**. for setting the parameters.

5.6.3 Start via Patient database

You have a patient who has already been treated before and want to call the parameters saved for this treatment. For this purpose, open the patient database by pressing the *Patient database* key. The *Patient database* screen appears.

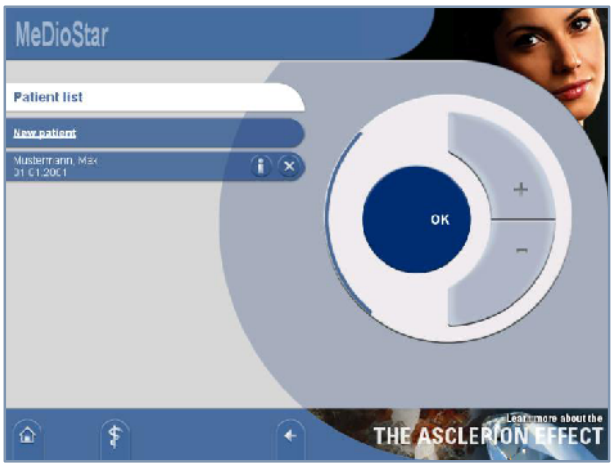


Figure 30: Patent database screen

Click the patient name and corresponding treatment to display the selected parameters promptly.

The patient is selected by pressing the program name on the left side. The +/- keys are used to 'turn' the screen. If confirming by OK, you open the *Treatment screen*. Refer to chapter **Fehler! Verweisquelle konnte nicht gefunden werden. Fehler! Verweisquelle konnte nicht gefunden werden.** for setting the parameters.

5.7 Setting and saving parameters

This section describes how to set the parameters for the individual treatment and how to save them. First, activate the Treatment screen.

Figure 31: Treatment screen

Select the parameter you want to change by pressing the field. The selected parameter will be visually marked (darker). Use the setting keys +/- to make changes.

Press *OK* for saving the changed settings.

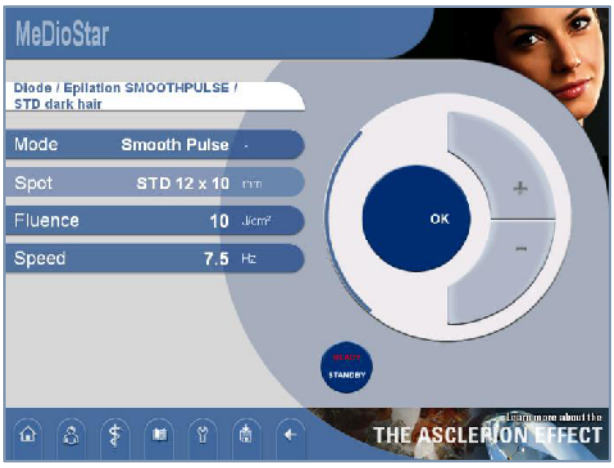


Figure 32: Standby of laser device screen

Now, you can save the changed settings by pressing the *Save* button. You have the option to save the settings for a patient or for an indication. For doing this, press the *Patient database* or the *Indications list* key.

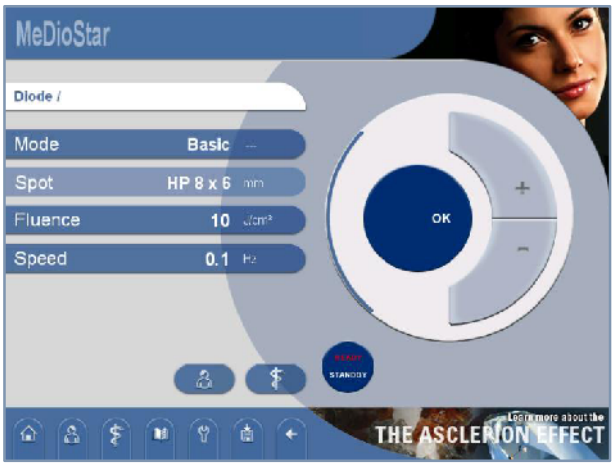


Figure 33: Saving parameters

Saving under patient database

If you want to save the parameters in the patient database you can choose between a new and an already registered patient. If you select a registered patient you can either create a new treatment or save the settings for an already recorded treatment. If you want to save the settings under an already recorded treatment, the old data will be overwritten.

To call the saved parameters open the patient database. *(Refer to chapter* 5.3 *Patient.)*

Saving under indication list

If you have decided to save the data in the indication list, you can choose either an already registered indication or a new favorite. If you want to save the settings for an already recorded indication, the old data will be overwritten.

To call the saved parameters open the indications list.

(See chapter 5.6.2 *Start via Indi.*)

5.8 Settings for your laser device

The parameters that can be set depend on the **mode**. The mode can only be changed if it is allowed for the handpiece which is attached (via Quick-Start) or for the selected indication (via Indication list).

Basic mode:

energy density (**Fluence**) and treatment speed (**Speed**)can be set

Note: In this mode, the shortest possible pulse duration (**Time**) for the set fluence will be used, always with double pulse.

Professional mode:

Fluence, **Speed**, **Time** as well as **Single** or **Double pulse** can be set

Note: For the double pulse Fluence and Time always refer to the sum of the two parts of the double pulse.

Vascular mode:

Fluence, **Speed** and **Time** can be set

Note: always single pulse

Smooth pulse mode:

Fluence and **Speed** can be set

Note: always single pulse, always shortest possible time for set fluence
low fluence, high frequency
contrary to the other modes, several passes are always required
(see Application Epilation)

Burst mode:

Fluence, **Speed**, **Time,** number of pulses (**Pulse**) and **Pause** between the pulses can be set

Note: the set Total fluence is distributed to the number of pulses
(several parts are applied to the same point)
Time refers to the pulse duration of one part-pulse
Pause is the time between the individual part-pulses (not the sum)

Tip

Please note that

- only the useful modes can be activated for a specific handpiece. That means that not all modes can be set for each handpiece.
- most of the parameters technically depend on each other. That means that, for example, the highest fluence is not simultaneously possible with the shortest pulse duration.

The spot size can be changed by changing the handpieces and is automatically recognized by the device and displayed.

In addition to the parameters selected, the device status [*STANDBY* or *READY*] and, if applicable, plain-text fault messages are displayed.

Furthermore, the pulse energy, the currently emitted pulse number and the total pulse number are indicated additionally (see chapter 5.8.2 *Special function/Tools*).

The laser is released by pressing the foot switch.

5.8.1 Parameters

Function/ parameter	Display	Remarks
Energy density	Fluence	Adjustment of fluence (total fluence in *Burst* mode)
Treatment speed	Speed	Adjustment of treatment speed (pulse frequency)
Spot size	Spot	Information about the spot size of the handpiece
Pulse duration	Time	Adjustment of the pulse duration *Professional*: for double pulse sum of the two pulse parts *Burst*: pulse duration of the part-pulses
Operating mode	Mode	Operating mode
Pulse	Pulse	*Professional*: switching between single pulse/double pulse *Burst*: number of pulses
Pulse-Pause	Pause	Only in *Burst* mode: adjustment of the pause between the part-pulses

5.8.2 Special function/Tools

Press the *Tools* key to open the *Tools* screen of the application).

Figure 34: Tools screen

Function/ parameter	Display	Remarks
Pulse counter	Actual	Current pulse counter
Pulse counter	Total	Total pulse counter
Pulse counter	Real	Real pulse counter (considers multiple pulses)
Temperature skin cooling	Skin Cooler	cold / medium / warm (recommendation: cold)
Cooling water pump	Pump OFF	Is switched on automatically after changing the handpiece
Energy indication	Display energy	Indication of the energy on the display

Important information

Before changing the handpiece the cooling water pump must always be switched off by pressing the *Pump off* key in the Tools menu. Thus, leakage of the cooling agent is prevented. When the handpiece has been changed the pump is switched on automatically.

5.8.3 Activating the laser ready mode and releasing the emission of the laser beam

See also chapter 6 *Application*!

After the activation of the Quick start key or of an indication from the indication list, the laser is in the *STANDBY* mode. Standby is highlighted in white on the *READY/STANDBY* key.

Verify again that

- the handpiece has been connected correctly,
- all laser safety precautions have been taken.
- the door interlock contact functions properly, if you have installed it: Open the door; it must **not** be possible to switch the laser to *READY* (an error message is displayed and must be confirmed).

Set the desired parameters according to the explanations given in the chapters before.

WARNING

The direct and scattered laser radiation can cause serious eye injuries.

During the active laser operation all persons present in the laser room have to wear protective eye goggles or patient eye shields appropriate for this laser as specified in chapter 3 *Techni*. Other types of laser protective eye-wear do possibly not provide the degree of protection needed!

Before pressing the READY key the attending user must check this.

In the *READY* mode you can also activate a laser pulse by pressing the foot switch unintentionally! Therefore, the laser device must be switched to *STANDBY* in the treatment pauses and at the end of the treatment.

The laser beam may only be released if the handpiece is precisely directed onto the skin area to be treated.

In case of dangerous malfunctions the Laser emergency STOP must be activated immediately.

By pressing the READY/STANDBY key you change to the *READY* mode; the yellow laser warning label appears on the bottom right of the display. First, the system performs a safety test of the hardware that takes about 2 sec (see Figure Hardware start).

Figure 35: READY mode of the Laser

Moreover the system checks, whether the temperature of the cooling probe of the handpiece is low enough. If the cooling temperature after the hardware start has not been reached yet, the Cooldown handpiece screen is displayed. Its progress bar reflects the cooling-down of the cooling probe. This screen will be faded out, if the cooling probe is cold.
(The same applies for activating the device after 15 minutes of inactivity.)

Figure 36: Cooldown handpiece

If the footswitch is pressed, the laser radiation is released from the laser tip of the handpiece. The release of the foot switch instantly stops the emission of laser radiation.

Emission of laser radiation is indicated acoustically by a warning beep and optically by the green blinking laser emission indicator on the display.

When you change any parameter in the *READY* mode, the device will automatically switch to *STANDBY*, i.e., you have to press the *STANDBY/READY* key once more to return to the *READY* mode.

During the treatment it is normal that the temperature of the cooling probe of the handpiece heats up a little bit, particularly for larger areas. If the upper limit of the cooling temperature is reached, the emission of the laser radiation will be interrupted and the cooldown handpiece screen will be faded in. The treatment can be continued as soon as the cooling tip is cold enough again.

The MeDioStar NeXT is equipped with a user-friendly Laser emergency STOP that is located at the front panel of the device (see Figure 5:). In an emergency, the laser is immediately deactivated by strongly pressing this key and thus any laser danger for the user and patient is removed.
If the emergency problem has been solved, restore the functionality of the device by slightly turning the Laser STOP switch manually anticlockwise to its normal position.

CAUTION

If during lasing the symbols ' △ ' or ' ▽ ', appear in the Fluence field, the device has detected a deviation of the output values higher or lower than 20 %.
Higher values can cause undesired side effects, whereas lower values can reduce the effect of the treatment.
If this deviation continues inform the Technical Service.

If you have finished the treatment, switch the laser to the safe *STANDBY* mode by pressing the *READY/STANDBY* key once more. If you intend to interrupt the treatment for some time, switch the laser to the *STANDBY* mode, too. In this mode, it is impossible to release laser emission unintentionally.
After a longer period of inactivity in the *READY* mode, the device automatically switches to the *STANDBY* mode.

5.8.4 Changing the handpiece

The handpiece shall be principally changed with the device being switched off. If this is not possible, the cooling pump must be deactivated imperatively before the handpiece is removed from the device. For doing this, press the Pump OFF key in the Tools menu (see 5.8.2 *Special function/Tools)* to switch off the pump and the LED at the handpiece extinguishes. Only now the handpiece plug can be separated from the device without any risk.

Important Information

Before changing the handpiece, the cooling water pump of the device must be switched off by pressing the Pump OFF key in the Tools menu. When the handpiece has been changed, the system switches on the pump automatically.

5.8.5 Switching off the device

Exit the *READY* mode and switch to *STANDBY* mode by pressing the *STANDBY / READY*-key.

To switch off the laser device, turn the key switch anticlockwise as far as it will go. Only then, you should switch off the power switch at the rear panel of the device (refer to Figure 3: *Connections at the rear panel of the* device). By switching the power switch to '0' the device is completely disconnected from the line voltage.

WARNING

The direct and scattered laser radiation can cause serious damage to the eye.

Never leave the device unattended while it is switched on. Shut down the device completely by switching the power switch.

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

6 Application

6.1 General instructions

This chapter contains detailed information on the operation and application of the laser device. Of course, the instructions given can never replace the expert knowledge for the medical application of lasers, the careful study of relevant literature, the personal experience gained under supervision and the critical assessment of the current situation.

But these instructions shall be a useful support for beginners and those not working regularly with the laser.

Therefore, we recommend you to study current medical literature and to contact physicians in private practices using such type of equipment in order to familiarize with the methods of laser treatment before you start to treat patients yourself.

We would like to assist you in getting contact with other users. The responsible partner of Asclepion Laser Technologies GmbH will readily inform you accordingly in detail.

Demands placed on the user

WARNING

The laser radiation of the device can cause thermal changes in the tissue structures.

Treatment may not be performed by anyone other than a practicing physician, or under the responsibility of a practicing physician (referred to as user for simplification hereafter).

Active medical products may only be applied by users who are adequately qualified to do so, based on their professional training background, expert knowledge and practical experience.

Make sure you have understood the principles of laser-tissue interaction, the correlation between the individual application parameters, the application techniques as well as the basics of laser safety.

If you have the slightest doubt, consult one or more colleagues with practical experience and/or application engineers of Asclepion Laser Technologies GmbH before you start a laser treatment.

Users who want to use this device must have been sufficiently informed about the safe and efficient operation of the laser equipment described in this manual before starting to operate it. Persons employed with or authorized by Asclepion Laser Technologies GmbH give instructions that are based on this manual. This is to be reported in the Medical Device Logbook. The Users must get instructions about the following aspects:

- operation and intended use of the device, practical exercises included,
- operating principle and functionality of the device as well as energies used,
- adjustments of all operating elements,
- indications for the use of the device,
- contraindications and side effects,
- warning labels in all operating modes,
- performance of functional tests.

Further training requirements vary in the different countries. The user takes responsibility for the compliance of the training with all requirements of the applicable regional laws and regulations.

6.2 General treatment information

CAUTION

The application of laser radiation on the skin can lead to thermal damages of tissue structures – intentionally according to the indication or unintentionally.
The physician is responsible for the precise determination of the indication, the treatment zone and the treatment parameters as well as for the correct positioning of the handpiece.
Also during the treatment the temperature of the cooling probe of the handpiece has to be checked by hand as well as the adjusted Fluence at the display.

CAUTION

Due to the effect of the laser beam side effects, such as inflammation and slight oedemas, may be observed in the treated area during the treatment. Blisters with subsequent incrustation and temporary pigmentary changes are seldom. Persistent pigmentary changes, scars and temporary urticarial changes are extremely seldom if the device has been operated as intended and there is the compliance of the patient.
The degree of these side effects varies from patient to patient; normally it is very low. Therefore, a test treatment must be performed in any case in a small area as described below to minimize the side effects and to optimize the effect of the treatment simultaneously.
It is important to bear in mind that the side effects can be stronger for the treatment of larger areas than for the treatment of a smaller test area.

Besides, the patients get a better impression of the treatment procedure and can better decide for or against a treatment before giving their consent.

Tip

In a pre-operation discussion, the patient should be informed about all risks that may be caused by the laser treatment and the pre- and post-operative care. Moreover, the patient should get all information about the mechanism of laser treatment, alternative procedures, the time required for the treatment, the prospects of successful treatment and about the behavior after the laser treatment.
You are advised to report this conversation and to make the patient sign a special consent form for this briefing. It is also recommended to take photos before and after the treatment.

WARNING

The contact surface of the handpiece contacts the patient's skin during the treatment. There is the risk of microorganisms being transferred.

The selected handpiece must be disinfected before each application and cleaned and disinfected after each application session as described in chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** *Cleaning and disinfection.*

CAUTION

Any absorbing contamination on the laser tip of the handpiece generates local overheat and can cause increased side effects and defects at the handpiece!
Make sure that the laser tip of the handpiece remains also clean during the treatment!

6.2.1 Interaction of laser beam and tissue

The goal especially for dermatological and aesthetic treatments is to remove the lesions to be treated or the unwanted lesions without any side effects. The **selective phototermolysis** method introduced by Anderson as a treatment concept in 1983 ensures an effective damage of the target and the simultaneous protection of the skin surrounding it.

Therefore, the following aspects are to be observed for a successful treatment:

Absorption of the laser beam – wave length

The absorption of the laser beam must be higher in the target (e.g. the melanin in the hair or the blood in the vessel) than the one in the surrounding skin mainly consisting of water. The higher the absorption in the target the greater the heat generated; the lower the absorption in the surrounding skin area, the lower the unwanted heating of the skin.

The wave length range of the MeDioStar device in the near infrared (IR) between 800nm and 950nm has a relatively high melanin and blood absorption. The wavelengths of the different handpieces are optimal adjusted within this range to the individually planned indication.

However, you have also to consider the absorption of melanin in the epidermis of dark skin that is generally not desired (apart from the treatment of benign pigmented lesions) and can produce side effects like stronger bad sensation, hyper- or hypo-pigmentation. Therefore, the Rubin and the Alexandrit lasers having wave lengths of 694nm and 755nm, respectively, are less suited for treating dark skin types due to their relatively high melanin absorption. The wave length range of the MeDioStar is considerably better suited.

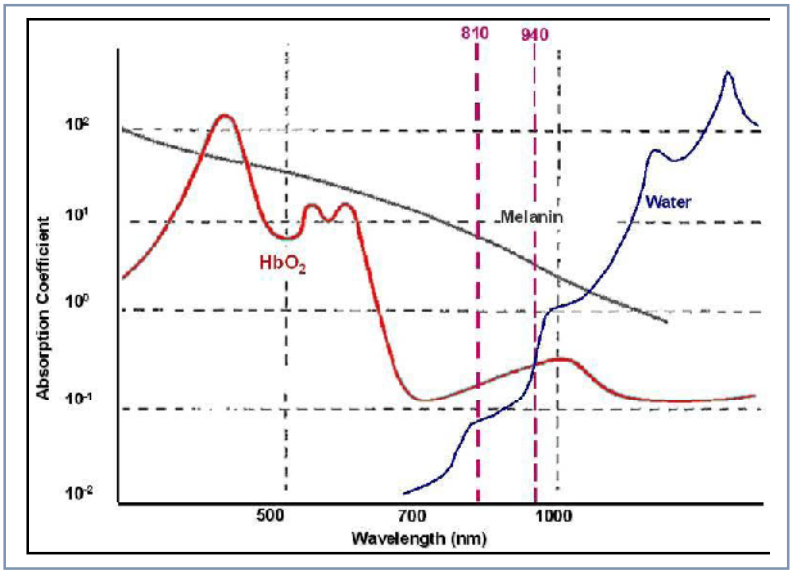


Figure 37: Absorption coefficients depending on the wavelength of the laser beam

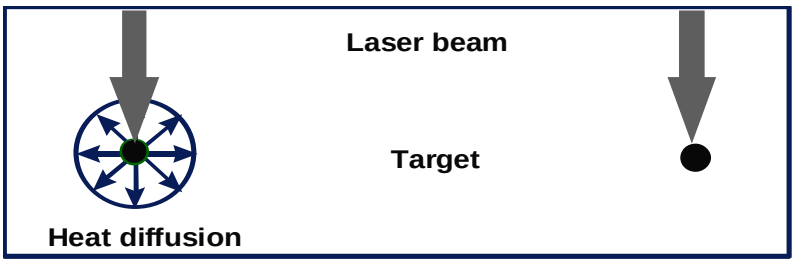
Spot size

The spot size must be so large that the target located some millimeters beneath the surface of the skin (e.g. a hair root or vessel) is reached with a sufficiently high energy density (FLUENCE). This requirement is met by the MeDioStar laser device.

It must be principally ensured that a larger spot heats a larger volume in the skin. Therefore, the required fluence is lower for larger spots.

Pulse duration

The pulse duration of the laser should be shorter or at least not significantly longer than the thermal relaxation time of the target (e.g. hair or blood vessel). The Thermal Relaxation Time is the time in which the target gives off 50% of the heat to the environment.
Thin structures (hair, vessels) give off the heat much more rapidly than thick structures. To achieve the desired temperature in thin targets it is necessary to deliver the required energy as quick as possible. If the pulse is too long, the heat loss into the surrounding skin must be compensated by a higher fluence, which causes by tendency more side effects.



Pulse duration longer than Thermal Relaxation Time

Pulse duration shorter than Thermal Relaxation Time

Figure 38: Thermal Relaxation Time and pulse duration of the laser beam

Target	Diameter	Therm. Relaxation time
Ectatic vessels	10 µm – 50 µm	50 µsec - 1 msec
	100 µm	5 msec
	300 µm	45 msec
	500 µm	125 msec
	1mm	(500 msec)
Hair bulge	ca. 300 µm	ca. 45 msec
Melanosomen	ca. 0.5 – 1 µm	ca. 0.05 µsec

Figure 39: Thermal relaxation time for different target diameters (examples)

However, for an effective treatment the required fluence and spot size are defined first. Only afterwards the shortest possible pulse is set for thin structures and light skin.

For dark skin it is important to consider that the melanin in the epidermis shall not be heated, i.e., a long pulse duration should be selected – no problem for thick structures.
A compromise must be made when treating thin hair/vessels of patients with dark skin. The pulse to be selected is longer than for light skin and thin target but shorter than for dark skin and thicker structures. This decision is acceptable because the development of heat of thin targets is considerably lower than of thick targets. Moreover, the MeDioStar ensures an effective cooling of the epidermis (see below).

The epidermis can be protected additionally by the pulse interruption (double pulse). In BASIC mode the double pulse is always emitted, in the PROFESSIONAL mode it can be activated on the display.

Cooling the epidermis

To avoid unwanted side-effects, the effective cooling of the epidermis is necessary (particularly important for dark skin types because of their melanin absorption).
The skin cooling system of the MeDioStar is integrated in the handpiece. The contact of the epidermis with the cold metal probe is extremely effective due to the high thermal conductivity (8 times better than a sapphire-based cooling mechanism). Moreover, the cooling temperature of the skin cooling system is automatically controlled at any point of time.

6.2.2 Classification of skin types

Skin type		
I ('Irish' skin type]	extremely fair skin, blond or red hair, freckles, blue or green eyes	always sunburn no tanning
II (frequent in Central Europe)	fair skin, blond hair, freckles blue or green eyes	mostly sunburn slight tanning
III	light brown or brown hair, brown eyes	sometimes sunburn good tanning
IV (Mediterranean type)	light brown skin, dark or black hair, brown eyes	seldom sunburn fast tanning
V (some Indians, South Americans)	dark skin, black hair, dark eyes	seldom sunburn very fast tanning
VI (some African, Indians)	very dark or black skin, black hair, black eyes	never sunburn, very fast tanning

Figure 40: Classification of skin types according to Fitzpatrick

6.2.3 Overview on zones sensitive to pain

Figure 41: Face zones sensitive to pain

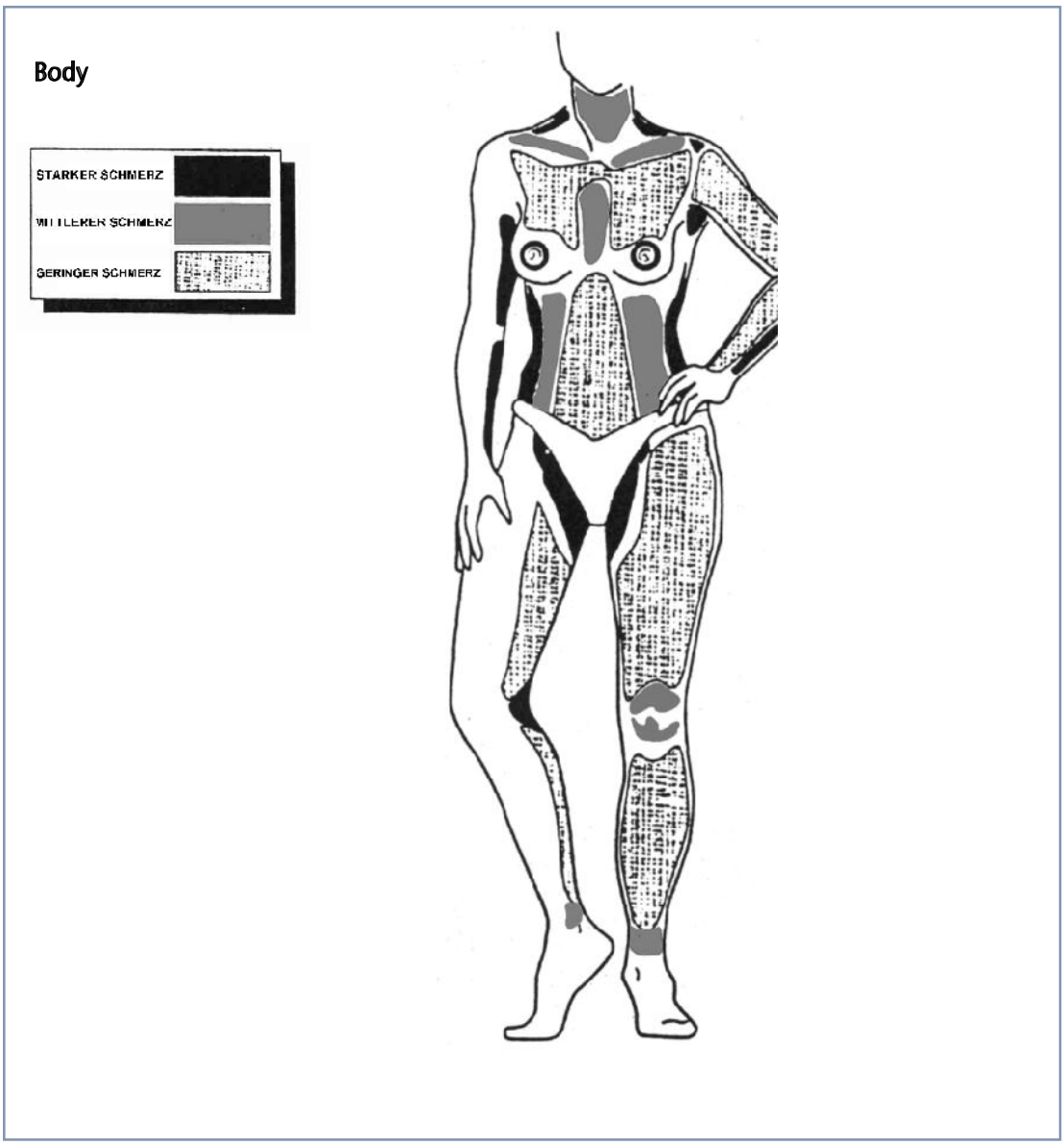


Figure 42: Body zone sensitive to pain

6.2.4 Application parameters

The **energy density (FLUENCE)** is the crucial parameter for the treatment with pulsed lasers like the MeDioStar. It is to set directly on the display. The higher the fluence the more efficient the treatment – but stronger side effects are possible. Therefore, test treatments are to be performed if the fluence is increased.

The mathematical relationships are as follows:

Energy density [Joule/cm²]	= energy [J] / spot-area [cm²](energy density = Fluence)
Power [Watt]	= energy [J] / pulse duration [sec]

The **spot size** used (depending on the handpiece) is automatically considered by the device.
As described above, smaller spots require a larger fluence.

The **pulse duration** can be set in the *Professional, Vascular* and *Burst* modes according to the explanation given above: shorter (with sufficient fluence) for thin hair and vessels as well as for lentigines and longer for protecting dark skin. Pauses between the pulse-parts (**double pulse, Burst**) are also a more gentle treatment for the melanin in the epidermis.

The *Basic* and *Professional* **modes** are intended to be used for epilation, *Professional* is also used for rejuvenation treatments (apart from lentigines). The *Vascular* mode is provided for vascular treatments and benign lentigines (with the small spot of the VAS handpiece). The *Burst* mode can be used for vascular treatments, too.
The *Smooth Pulse* mode can also be used for the epilation of larger areas, particularly for darker skin. Contrary to all the other treatments, in this mode the handpiece with the set pulse sequence (speed) and low fluence is moved rapidly over the area to be treated. However, several passes are required to be able to see a perifollicular erythema.

To ensure sufficient **cooling** of the epidermis, the handpiece is always drawn towards the cold metal probe in all treatments (apart from lentigines) so that the laser pulse always reaches the pre-cooled skin. The only exception is the treatment of lentigines because the melanin in the epidermis shall be destroyed.

The set **pulse sequence** (speed) in Hz (pulse per second) determines the treatment speed and does not influence the effect of the treatment. In sensitive areas a reduction can be less painful.

6.3 Typical indications – overview

- epilation
- vascular treatments
- acne incersa
- acne
- skin rejuvenation

The following sections contain treatment instructions for the individual indications.

6.4 Epilation

The removal of unwanted hair growth is undoubtedly one of the oldest cosmetic treatments performed by men. Over the past years, it has experienced greatly increased popularity. The methods range from regularly repeated shavings to a more lasting, though very painful wax epilation, to extremely time-consuming hair removal by means of electrolysis needles, which on the other hand can yield a rather lasting success.

Each of these methods, and, naturally, also laser epilation which is comparatively more pleasant, aims to remove hair with a maximum lasting effect.

6.4.1 The target: anatomy of hair

As everybody knows from one's own experience, lasting removal of hair cannot be achieved by simply plucking out unwanted hair. It will grow again. This means that the structures responsible for hair growth have to be destroyed, too.

Today researchers are virtually unanimous that the so called hair bulge with the germinative cells around it (matrix cells, melanin) and the papilla contribute to the hair growth. Therefore, they must be destroyed or at least impaired in their action for this reason.

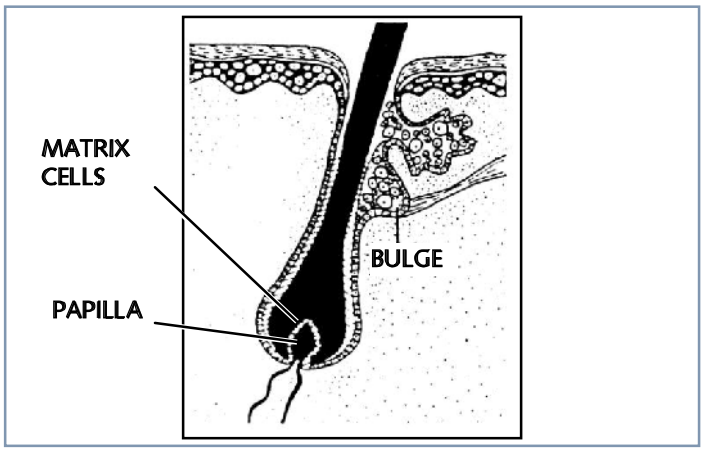


Figure 43: Anatomy of the hair follicle

Depending on the body part, the hair's roots may be located down to 5 mm beneath the skin surface. Therefore, the laser spot should be as large as possible to ensure a depth effectiveness of laser radiation.

A clinical study performed with the MeDioStar device showed that a spot size of 1.1 cm² is sufficient to treat hair on the legs effectively. A further enlargement of the spot did not achieve better results. The smaller spot size of 0.5 cm² led to a lower effectiveness of ca. 10%.

A point to bear in mind is that, for example at the upper lip, the hair root is not located very deep in the skin and therefore a smaller spot size can be absolutely effective and useful. The use of smaller spots is recommended particularly for finer hair because shorter pulses can be set with the smaller spot.

6.4.2 The phases of hair growth

In the embryonic state hair is already growing – but it is very fine up to infancy. This lanugo does not have a papilla yet, grows from the lower epidermis and successively migrates into the dermis.

Later on, terminal hair with papilla forms under the influence of hormones. From this point on, the human hair is subject to repeating growth cycles which may extend from some months to some years (depending on the body region).

The active growth phase is termed anagen, whereas telogen is the phase of little or no growth. To achieve efficient laser treatment, the transition phase to re-growth appears to be particularly suitable.

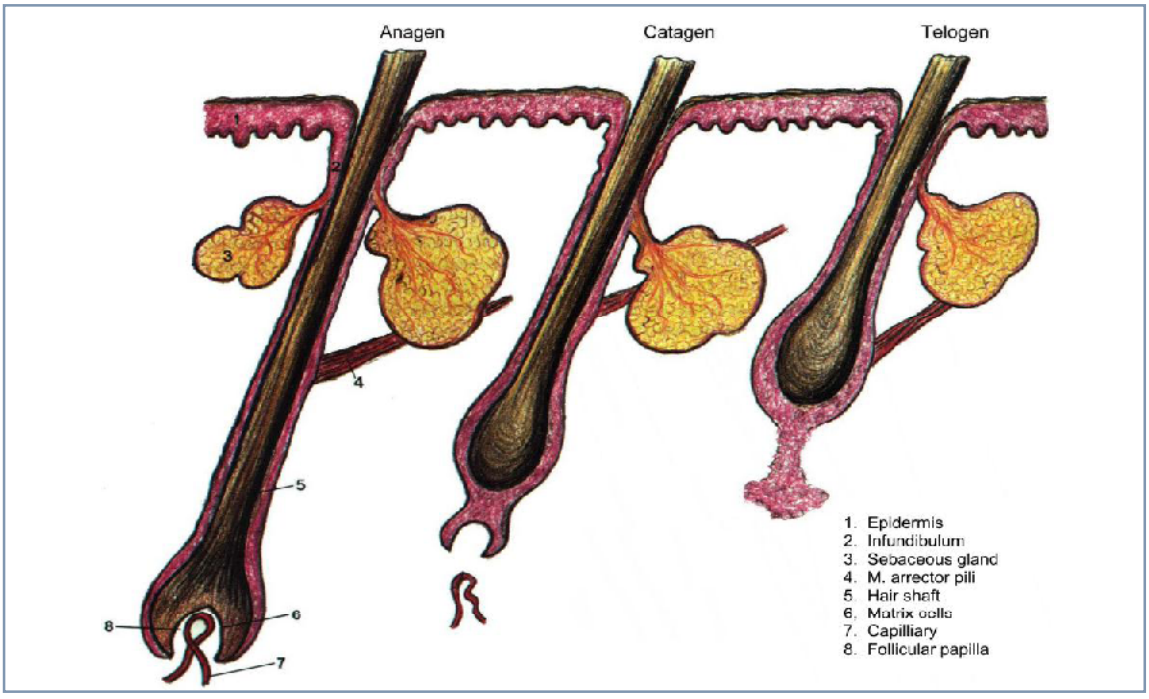


Figure 44: Hair growth cycle

In humans, the phases of different hair are not synchronized, i.e., different hair is in different phases. In a certain area only a specific percentage of hair reacts on the laser treatment. Therefore, a series of laser sessions is always necessary.

The shorter the telogen phase compared to the anagen phase the more rapid is the growth of the hair in a specific area. That's why it is necessary to shave the beard area more often than other parts of the body. Consequently, the interval between the subsequent laser treatments must be shorter, too.

	Depth of terminal anagen follicle	Telogen duration	Anagen duration	Follicle no. per cm²	Total follicle number	Growth per day
HEAD					1 Million	
Upper lip	1-2.5 mm	6 weeks	4 months	500		
Chin - beard	2-4 mm	10 weeks	1 year	500		0.38 mm
Cheeks	2-4 mm			880		0.32 mm
Eye brows	2-2.5 mm	3 months	4-8 weeks			0.16 mm
Ear		3 months	4-8 weeks			
Head hair	3-5 mm	3-4 months	2-6 years	350		0.35 mm
BODY						
Armpits	3.5-4.5 mm	3 months	4 months	65		0.3 mm
Legs	2.5-4 mm	5 months	4 months	60	370 000	0.21 mm
Pubic region	3.5-5 mm	3 months	4 months	70		
Arms		4 months	3 months	80	220 000	0.3 mm
Breast	3-4.5 mm			65		0.35 mm
Torso	2-4.5 mm			70	425 000	0.3 mm

Figure 45: Hair growth (extract from Richards-Meharg Table)

6.4.3 Selection of patients

Application of laser has been shown to achieve an extended delay in hair growth both in women and men.

Laser epilation of dark hair is particularly effective because dark hair has higher melanin content. Light hair typically requires higher energy densities that are tolerated because of the normally lighter skin. However, the success of treatment cannot be predicted in each particular case. Surprisingly good results have even been observed with fair hair. On the other hand, there are negative exceptions of particularly resistant dark hair.

Very fair hair, reddish hair (contain phaeomelanin) and grey hair react very poorly or not at all to a laser treatment. The same applies for very thin hair.

Before treating women with a very strong hair growth, the hormonal status should be controlled.

The hormonal status of transsexual men (man to woman) should also be controlled before starting a treatment.

A complete hair removal cannot be achieved, normally fine light hair cannot be removed. It is important to inform the patients about these facts!

Areas suited for epilation:

- upper lip beard
- Ladies' beard
- chin / upper neck
- thighs
- Bikini line
- lower legs
- upper arms
- lower arms
- breast
- back
- hands

6.4.4 Contraindications

CAUTION

The intensive laser light in the infrared range can cause thermal damage of skin structures. The contraindications listed below are based on clinical experience in operating laser devices for said purposes of during about 15 years. They do not claim to completeness or unlimited validity.

- Light sensitivity
- Taking of drugs that increase sensitivity to light
- Cellulite treatment in the area to be treated (wait some weeks after such a treatment)
- Cancerous and pre-cancerous lesions in the treatment area
- Hairy naevi in the treatment area
- Herpes simplex in the treatment area
- Keloids in the treatment area

WARNING

It is NOT permitted to laser in the area of the eyes! Occasionally eye inflammation and a reduction of the visual function were observed although the eyes were protected by an eyeshield!

WARNING

Pregnant women and children should NOT be treated because clinical studies do not exist for these patients.

CAUTION

Patients with tanned skin – especially fresh tanned - can develop more intensive side effects, particularly subsequent pigment changes. They should postpone the laser epilation!

Tattoos in the treatment area cause stronger side effects, too. Moreover, the color will be partly removed. Therefore, tattoos should not be treated.

A delay of 4-6 weeks is also recommended when other epilating procedures, such as waxing or plucking, have been used because the target chromophore, the 'target' is not available any longer and therefore the laser treatment does not have an effect.

6.4.5 Possible side effects

All side effects are less significant for light skin and light hair and become more intensive for darker, thicker and dense hair and for darker skin and, of course, in case of too high fluence for the individual case (test treatment!).
Therefore, the start values for test treatments are to be selected lower the darker the skin (and normally also the hair color).
During the treatment the patients have a pricking feeling connected with heat.

After the treatment a slight, perifollicular erythema can be seen. If the hair is dark and thick the formation of a perifollicular oedema is also possible. These effects are normal and last for a period of between few hours and 2 days.
If the device is used as intended and there is the compliance of the patient blisters, crusts as well as pigment changes seldom develop (light protection!) Normally, blisters and crust heal without any consequences within about one week. Pigment changes can be observed for some months.
Persistent pigment changes and scars are very seldom.

In rare cases dark hair can decolor and then it cannot be removed by the laser/light due to the missing absorption. It is also very seldom that a paradox hair growth, i.e. stimulation of hair growth at the border of the treated area, is observed.

6.4.6 Preparing laser epilation

As a compulsory pre-condition, the area to be treated must be absolutely shaved and cleaned. Remove also deodorants or other cosmetic products.
For applying the *SmoothPulse* mode (which is suitable for large areas only) an area of 10 x 10cm² has to be marked by a white pencil (e.g. Kajal)

Before treating the upper lip a moistened piece of gauze or the like should be placed between upper lip and teeth, in order to intercept the small part of the laser radiation, which can pass through the upper lip, and to avoid the heating-up of the teeth (can be possibly painful).

To document the treatment success photos should be taken.

Normally, anesthesia is not required because the laser epilation with the MeDioStar causes relatively little pain thanks to the precooling with the cold metal probe of the handpiece. For sensitive body areas or very extensive treatment areas, a topical anesthetic, for example EMLA, can be applied depending on the pain tolerance and the application technique (skin cooling!).

A **colorless** ultrasound gel optimizes the laser beam coupling into the skin to reduce the reflectance and scattering of the laser beam. Thus, a higher efficiency is reached.
The application technique used for the test treatment is also to be used for the later real treatment. A thin layer of clear ultrasonic gel is to be applied on the area to be treated. This also reduces the levels of emerging smoke/smell.

6.4.7 Test treatment

If the patient decides in favor of a laser epilation after getting the information from the physician, a test treatment should always be performed in the area that is to be treated later. The patients' individual skin reaction and pain sensitivity can vary.

The darker the patient's skin the lower the start fluence and the longer the pulse duration to be selected in *Professional* mode (including double pulse). The latter is not a problem for thicker hair. For thin hair the pulse must not be as long so that the efficiency of the treatment can be ensured. Due to the low absorption 'mass' the side effects are normally lower for thin hair.

The application technique used for the test treatment is also to be used for the later real treatment. For doing this, at least 4-6 test spots of the test FLUENCE in *Basic or Professional* mode are to set as a quadrate, because a single spot can cause fewer reactions (better cooling by the surrounding tissue). With *Smooth Pulse* mode an area of 10 x 10cm² is treated.

WARNING

Laser radiation can cause serious eye injuries.

Everyone present in the laser room during a treatment session must wear laser safety goggles according to the instructions given in chapter 3 *Technical Data*!

The set fluence as well as the temperature of the skin cooling probe must be controlled before and during the treatment!

The MeDioStar is switched to the *READY* mode with the desired FLUENCE.

At the start of the operation, the cold probe of the handpiece is shortly placed on the first point to be treated. Then, the handpiece is moved by the spot size so that the laser tip comes to the pre-cooled area. Afterwards, the laser emission is started by pressing the foot switch and the handpiece is further moved by the spot in the cycle of the set SPEED in direction to the skin cooling probe.
Practically, the handpiece should be kept in contact with the skin and should not always be put on anew. Due to the ultrasound gel the point can easily be seen at which the spot must be placed for the next line. A slight overlapping is necessary so that no hair line is left out because the cooling probe, which marks the track in the ultrasound gel, is a little bit larger than the active laser spot.
In the *SmoothPulse* mode – contrary to the procedure described above – an 'line' of 10cm is pre-cooled and than the handpiece is moved rapidly over an area of about 10 x 10 cm² in the cycle of the set speed. In doing so the handpiece has to be held in a way, that the laser spot moves over the pre-cooled line and the cold probe pre-cools the next line simultaneously. The handpiece can be moved than in a serpentine pattern back and foth. Several passes must be performed, whereas the direction is changed (e.g. from top-down to left-right).

Make sure that the cold probe of the skin cooling is kept in contact with the skin during the treatment to guarantee the pre-cooling of the epidermis. It is advantageous for epilation to apply a slight pressure by the handpiece onto the skin. Thus, the distance to the hair root is reduced and the effectiveness of the treatment is increased.

If the area is completely lasered, the device must be switched to the *STANDBY* mode.

Only if a skin reaction cannot be seen after 10 minutes the energy density (FLUENCE) can be increased gradually (test on a new area). In the *SmoothPulse* mode the number of passes must be increased step by step.

6.4.8 Treatment

Once the treatment area has been prepared, the area can be marked by using a white pencil (e.g. Kajal). This ensures that the treatment area will be lased evenly.

In the *SmoothPulse* mode areas of about 10 x 10 cm² are to be marked and then scanned systematically in several passes.

The FLUENCE that was well tolerated in the test treatment is to be set in the real operation. Then, the area is scanned as described above and the handpiece is always moved towards the skin cooling.

The simplest method to keep the tip also clean during the treatment is the use of a slightly moistened cloth after having lased one line. But if a crack can be heard when treating dark, dense hair, one hair rest is mostly on the tip. The tip must be cleaned immediately. If the laser treatment is continued nevertheless, the hair will burn in and can possibly not be removed by wiping it off.

If large areas need to be lased, the skin surface should preferably be treated in longitudinal direction (apart from the *SmoothPulse* mode) in order to keep effects of physical pain building up at a minimum level – particularly for dark, thick and dense hair (use EMLA if necessary).

Once the area is completed, the laser must be switched to STANDBY mode.

6.4.9 Post-op treatment

Immediately after completion of lasing, the skin should be cooled over an extended period, particularly for dark hair and dark skin. Continuous cooling can considerably reduce the side effects! This can easily be done with CoolPacks which the patient can apply as appropriate.

An anti-inflammatory ointment may be applied following sufficient cooling of the skin. In the event of overtreatment, a topical antibiotic is indicated and the monitoring of healing is absolutely necessary.

CAUTION

If the treated area is exposed to sun and solar radiation after the treatment, stronger side effects can develop, pigmentary changes in particular.
Therefore, such a radiation should be avoided for a period of 6 weeks or a sun protection cream with a protection factor not below 20 should be used at least.
The lased area should not be traumatized either for 2 to 3 days.

Exfoliation can be supported by using a lotion. Patients should be informed that up to two days after treatment the openings of hair follicles may secrete tissue liquid. Possibly resulting crusting should be removed by normal washing and application of skin lotions.

6.4.10 Follow-up treatment procedures

The decision about further treatment procedures should consider the patient's individual skin reaction and his/her personal interests, and the energy densities should be selected to be optimally suited for the given purpose.

The patients are to be informed that in some cases – particularly for thick hair – it takes two weeks that the hair is pushed out.

If the fluence of the last session was well tolerated, it can be increased gradually in the follow-up treatments. This increase is also recommended because the hair becomes less and less dense and thinner. Consequently, a higher fluence is required and normally well tolerated.

The number of required treatments depends on several factors:

- genetic diposition
- hormonal status
- the body region to be treated (different number of hair in the anagen phase, see *Extract from Richards-Mehharg table* p. 51)
- hair and skin type
- result desired by the patient (often, remaining fine hair are accepted)
- interval between the treatments.

To achieve a satisfactory result, four to seven treatment sessions may be necessary on average. Especially for the beard area and for people with very strong hair growth the number of sessions required is even higher.

The same goes for men with back or breast hair that grew only shortly ago. Then, it often seems that the laser treatment does not have any effect but with no treatment the hair growth would have been stronger. In this case it is helpful to ask the patient about the father's or uncle's hair growth at this age

The intervals between the sessions should not be too short (4-6 weeks; in case no hair regenerated the time interval can be longer) in order to allow as much hair as possible to change from the rest to the anagen phase.

In general, the interval for treating the beard area should be shorter (ca. 4 weeks) and for treating the other areas longer (ca. 6 weeks) as explained in chapter **Fehler! Verweisquelle konnte nicht gefunden werden. Fehler! Verweisquelle konnte nicht gefunden werden.**.
Normally, the interval is selected longer after several sessions because less hair is growing anew.

However, if a strong growth should have begun after the laser treatment, it is advisable to repeat the treatment in short time intervals because then very much hair is in the anagen phase and shows a good reaction to the treatment.

For patients with normal hair growth the achieved result can be stable for several years. For patients with genetically caused strong hair growth, typical for people of southern countries, it is to be expected that a follow-up treatment is necessary every year but with a low number of sessions.

6.5 Vascular treatment

A smaller spot adjusted to the vessels (optional handpiece) is used for the laser treatment of telangiectasias.

The laser treatment of superficial dilated vessels, particularly in the face but also in other locations, has been performed very successfully for more than 20 years – especially by using laser devices that emit light in the yellow and green ranges (argon, dye, KTP and copper bromide lasers).

These lasers are very well suited for the coagulation of very small vessels because their wavelength is absorbed very strongly by blood but very slightly by the water of the surrounding skin (see absorption curve). The selective photothermolysis method ensures an effective damage of the blood vessel and the simultaneous protection of the skin surrounding it. The penetration depth of this laser radiation is sufficient for very small vessels

Due to the deeper penetration of laser light, lasers having **wavelengths in the infrared range** – like the diode laser MeDioStar – are better suited for vessels with a larger diameter, for example for typical leg veins that are mostly larger and located deeper under the skin surface, and for hemangioma. The lower water absorption compared to the Nd:YAG laser (1064nm) is advantageous because normally fewer side effects develop.

Recent reports describe the successful treatment of port wine stains by using lasers in the near infrared range, which did not react well on the treatment with lasers in the green and yellow ranges before.
The relatively large spot diameter (that is possible due to the high power of the MeDioStar device) plays also an important role here: the penetration effectiveness of the laser radiation is the higher the larger the spot.

Leg vein telangiectasia are still a frequently asked cosmetic problem. The method of choice is sclerosing. The effectiveness of this therapy has been shown for decades. However, many patients prefer a laser treatment.

Generally, the success rate of the laser treatment of leg veins is lower than the one for treating, for example, teleangiectasias in the face because they are under hydrostatic pressure and vary considerably in their diameter and oxygen saturation. The success rate that can be achieved is about 70%.

The absorption of laser light in melanin in dark-skinned patients is less for the wavelength of the MeDioStar than for lasers operating in the green-yellow range (see absorption curve). To minimize undesired side effects it must nevertheless be considered during the treatment by a sufficient cooling of the skin surface.

Apart from the wavelength, the **energy density (FLUENCE)** and the exposure time of the laser radiation (pulse duration) are the crucial parameters for a successful treatment. The fluence must be selected so that on the one hand the vessel will be closed and on the other hand undesired side effects are not caused (therapeutic window).

The pulse duration should be similar or shorter than the **thermal relaxation time** of the vessel (this is the time the target needs to emit 50% of the heat produced by the absorption) to follow the treatment concept of selective photo-thermolysis mentioned above. If the pulse duration is too long, the skin surrounding the vessel will be heated up more, the effectiveness will be reduced and the risk of side effects will increase.

6.5.1 Selection of patients

Patients with skin type I to III who are not tanned in the area to be treated can be treated with the following restrictions.

The MeDioStar is best suited for treating dilated vessels having a diameter of about 0.5. to 2 mm. The treatment of hemangiomas is also possible.

Leg veins can be differentiated into red and blue ones. The red vessels are smaller, more superficial and exhibit higher oxygen saturation (dilatations of the arterial loop of the capillaries).

The blue ones are a dilatation of the venous capillaries with a lower flow speed. The larger vessels show a better reaction to the treatment than the smaller ones by means of this laser.

Before treating leg veins a varicosis, particularly of the lateral branch veins, is to be excluded, e.g. by Doppler sonography, or it is to be surgically treated or sclerosed.
Reticular varices should only be treated by laser if they occur solitarily or without connection to the depth.
Reticular varices should only be treated by laser if they are identified as solitary varices or if they do not go deeply.

6.5.2 Contraindications

General information

CAUTION

The intensive laser light in the infrared range can cause thermal damage of skin structures. The contraindications listed below are based on clinical experience of about 15 years in handling laser devices for said purposes. They do not claim to completeness or unlimited validity.

CAUTION

The higher fluence required for the treatment of dilated vessels and the stronger absorption due to the size of the vessel diameter can cause more intensive side effects (e.g. compared to hair removal).
Therefore, tanned areas or patients with skin type IV, V or VI must not be treated at all.

- Light sensitivity
- Taking of drugs that increase sensitivity to light
- Treatment of cellulites in the treatment area (wait a few weeks)
- Cancerous and pre-cancerous lesions in the treatment area
- Tendency to keloid formation
- Diseases that impair the normal skin healing process

WARNING

It is NOT permitted to laser the area of the eyes! Occasionally eye inflammation and a reduction of the visual function were observed although the eyes were protected by eyeshields!

WARNING

Pregnant women and children should NOT be treated because clinical studies do not exist for these patients.

CAUTION

Patients with tanned skin can have stronger side effects, subsequent pigmentary changes in particular.
They should postpone the treatment!

Contraindications for treatments of spider leg veins

- Superficial varices with a diameter larger than 3 mm
- Branch and side branch varicose veins
- Ulcer
- Diabetes
- Vasculitis
- Stasis dermatitis
- Podedema
- Neuropathy of the legs
- Corticosteroids treatment in the last three months (continuous treatment longer than two weeks)
- Thrombophlebitis

Useful information
Heavy smoking and/or overweight may adversely affect the efficacy of the treatment.

6.5.3 Possible side effects

The higher fluence required for the treatment of dilated vessels and the stronger absorption due to the size of the vessel diameter can cause more intensive side effects (e.g. compared to hair removal). Therefore, sufficient cooling of the skin as described in the following is absolutely necessary and more important than for hair removal treatments.

All side effects are less strong for patients with light skin and thinner vessels and become stronger the thicker the vessel and the darker the skin and, of course, if the fluence used is too high for the individual case (test treatment!).
Therefore, the start values for the test treatment of skin type III must be lower (darker skin types must not be treated).
During the treatment the patients have a pricking feeling connected with heat. It can even be a feeling of burning in case of thicker vessels.
After the treatment an erythema can be seen in the course of the vessels. If the vessels are thicker the formation of an oedema along the vessels is also possible. These effects are normal and last for a period of between few hours and 2 days. Blisters, incrustation and temporary pigmentary changes develop sometimes, but more often compared to epilation (light protection!).
Normally, blisters and incrustation heal without any negative consequences during about one week. Pigmentary changes can last for a period of up to some months.
Persistent pigmentary changes and scars are extremely seldom if the device has been operated as intended and if the treatment has been individually adjusted to the patient.

6.5.4 Preparing the laser treatment

As a compulsory pre-condition, the area to be treated must be cleaned. Remove also cosmetic products. The hair, if existing, must be carefully removed.

Photos of the initial situation should be taken to document the success of the treatment.

The treatment can cause pain, particularly for thicker vessels. However, anesthesia is normally not necessary if the area is sufficiently cooled before and after the treatment. The use of topical anesthetics, such as EMLA, does not reduce the sensation of pain.

A thin layer of a transparent, **colorless** ultrasound gel is to be applied onto the treatment area.

Cold cool packs (from the fridge, not frozen!) are to laid out.

6.5.5 Test treatment

If the patient decides in favor of a laser treatment after getting the information from the physician, a test treatment should be performed afterwards in any case.

Due the high number of different vessel diameters the practically optimum fluence can only be found empirically by treating test areas and must be defined anew for each area that has another vessel diameter (color/structure change).

CAUTION

The higher fluence required for the treatment of dilated vessels and the stronger absorption due to the size of the vessel diameter can cause more intensive side effects (e.g. compared to hair removal).
Therefore, a sufficient cooling before and after the treatment is very important to minimize the side effects!

After preparing the treatment area, the test area to be treated is pre-cooled during some seconds by using a cool pack (ca. 4-8°C). Afterwards the cooling probe of the handpiece is moved backwards and forwards in longitudinal direction over the vessel to be treated without an active laser.

The test fluence for skin type III must be set lower than for light skin, the pulse duration as short as possible for the set fluence for smaller vessels and longer for larger vessels and skin type III. The treatment speed principally used at the beginning is set to 0.5 Hz (SPEED). This setting allows to assess the situation after only one pulse because it is possible to deactivate the foot switch after one pulse.
Moreover, the lower the treatment speed the longer the pre-cooling time for the next area to be treated.

WARNING

Laser radiation can cause serious damage to the eye.

Everyone present in the laser room during a treatment session must wear laser safety goggles according to the instructions given in chapter 3 *Technical Data*!

The set fluence must be controlled before and during the treatment!

The MeDioStar is switched to the *READY* mode with the desired fluence.

Tip

Contrary to epilation treatments, pressure is NOT applied by the handpiece. .
It is recommended to keep a distance of about 1mm beween laser probe and skin. At the same time the cold probe of the skin cooling has to be in contact to the skin (please tilt the handpiece a little bit).

2-3 pulses are applied to the area to be tested; the laser tip is moved towards the skin cooling. Afterwards, the area treated is assessed.

If the vessel has faded (more typical for smaller vessels) or becomes darker (more typical for larger vessels) the fluence will be kept and spot by spot is placed along the vessel.

Immediately after the laser treatment, the cooling probe is used to post-cool the area for some seconds.

If a reaction cannot be observed, wait some minutes to see if an inflammation reaction develops. In this time it is also possible to test another vessel size in the same procedure.

The larger the vessel the lower the fluence required normally.

If even after waiting a reaction cannot be seen, the NEW (!) test area is again pre-cooled by using the cooling probe and then it is lasered in an overlapping manner or the same area twice before the fluence is increased, if required. The risk of side effects is less in case of overlapping than for a too high fluence!

It is important that the test areas are pre- and postcooled again and again by the cooling probe.

After the treatment the laser is to be switched to the *STANDBY* mode.

By performing a test treatment it is also possible to assess the risk of pigment changes, curing and the risk of subsequent scaring.

Moreover, the patient can get an impression about the way in which the lesion will be treated.

6.5.6 Treatment procedure

The handpiece with integrated skin cooling is placed onto the skin so that the area to be treated first (already precooled by using the cool packs) is again cooled by the metal probe. The handling is very easy, because the skin cooling system is adapted to the laser handpiece.

The first area to be treated is pre-cooled for some seconds by using, for example, cool packs. Then, the first vessel is pre-cooled by the cooling probe as described above.

The first area is lasered with the parameters defined during the test (possibly different for different vessels) and then the probe is used for post-cooling the treated vessel.
If one area has been completely treated, a cool pack is applied for post-cooling. Then, the next area is treated in the same way.

It must be ensured that the probe is always kept in contact to the skin (without applying pressure) and that the handpiece is always moved towards the cooling probe.

After the treatment the laser is to be switched to the *STANDBY* mode.

The total treated area is continuously cooled for at least 10 minutes.

Due to the consequent cooling this procedure leads to a reduced sensation of pain and to a reduction of the side effects.

6.5.7 Post-treatment

After cooling the skin sufficiently, apply an anti-inflammatory ointment that should not be removed before next day.

In case of over-treatment a topic antibiotic is indicated and it is absolutely necessary to control the curing process.

CAUTION

If the treated area is exposed to sun and solar radiation after the treatment, stronger side effects can develop, pigmentary changes in particular.
Therefore, such a radiation should be avoided for a period of 6 weeks or a sun protection cream with a protection factor not below 20 should be used at least.
The lased area should not be traumatized either for 2 to 3 days.

Moreover, the patients must do without extreme physical or vessel stress, such as jogging, sports in the fitness studio, Finish baths, hot baths, etc. for a short time.

6.5.8 Follow-up treatments

If the vessels have not directly faded press your finger along the vessel and see whether blood is flowing back or not to assess the results.

Depending on the result of the treatment, the individual skin reaction and the interests of the patient, a further treatment with higher energy density can be scheduled, if required.

The interval between the sessions should not be shorter than 12 weeks. It is reported that even after some months vessels disappear. Up to this time, some vessels can be darker than before (blood coagulation). The patients must be informed about these facts.

More than three treatments are not useful for leg veins. As mentioned a success rate of 70% can be reached.

6.6 Treatment of acne

Acne vulgaris is one of the most frequent diseases treated in dermatological practices. Mostly, the treatment takes a long time and is partly connected with considerable side-effects.
Most of the young patients concerned suffer much from it.

In most of the cases it is a disease of the pilosebaceous follicles that are mainly located in the face, on the back and on the chest. First, they generate non-inflammatory blackheads but in the later stages a number of inflammatory efflorescences such as papules, pustules and nodules can also be developed. Acne vulgaris or 'usual acne' is caused by an increased androgen influence in the puberty and fades away until the beginning of the third life decade at the latest.

The infrared radiation of the MeDioStar device penetrates – like necessary for hair removal – sufficiently deep into the skin to reach the pilosebaceous follicles.

The treatment as well as contraindications, side effects and treatment procedure are identical to epilation (see the corresponding chapters).

But unlike the epilation treatment, the acne treatment consists of 3-4 passes in direct succession and then it is the best to continuously cool the skin with a cooling mask. Due to the inflammation the treatment is painful.
3 to 5 treatments at one-week-intervals are required.

Acne inversa[1] is a disease of the skin appendage. It starts from the sebaceous glands and secondarily affects the apocrine perspiratory glands. Men and women are equally affected. This disease often starts during puberty but can also occur at any time later.

Predilection areas are especially axillas and the groin-pubic region, also spreading to the gluteal. The back and belly are less frequently affected and seldom the zones typical for acne like the face.

At the areas affected, first nodular, solitary foci of inflammation develop and in the course of the disease, they show recidivism and confluence to formations similar to carbuncles. Often, flat scar plates with a thickness of centimeters are caused. They have cutaneous/subcutaneous fistulas that can only be removed by an operation. The stress for the patient is not only caused by the inflammatory pains, the motoric restrictions by scar formation, but also by the repeated fetid infections.

The reasons for this disease may be a genetic disposition, its development in combination with other diseases (M. Dowling-Degos), keatinization defects of the follicular ducts, seborrhea, a special bacterial colonization by propioni bacteria and staph. Aureusin, smoking and adiposity are also responsible for the development of this disease.

According to the medical history, in some patients the development of the disease can be possibly explained by an intensive hormone fluctuation (temporary secondary amenorrhea due to a considerable loss in weight), but the disease does not stop at the end of this possible cause.

The therapeutic measures taken so far are the repeated antibiotic and antiseptic treatment, abscess splitting as well as scar excision and defect coverage by means of split-skin graft. The disadvantages of this procedure are the repeated development of recurrences, the repeated small- or large-area surgical procedures, pain, the required bandage changes, the work time losses due to sick notes as well as the psychological stress with possible subsequently limited social contacts.

An alternative therapy option is the laser treatment by using a diode laser such as the MeDioStar. The laser primary designed for epilation purposes penetrates deep under the skin surface and its effect is due to the absorption of light most of all by pigments or similar light-sensitive structures. The hair follicles are affected first. They are brought to involution due to the produced thermal damage after several treatment sessions. Porpyrhin-forming bacteria and fungi that are considered

[1] by courtesy of Dr. med. C. Passos Pereira, Dermatologe, Hürth-Hermühlheim
published in DERMAforum, September 2003

local causes of acne inversa are also destroyed in this procedure. After a normal epilation treatment, this effect becomes obvious by a reduced smell development of the axillas.

The treatment of the affected areas is performed at 810 nm with 30-40 J/cm2. First, it is a single treatment of the affected area. In the most favorable case, the treatment should be carried out in the primary pustule or abscess stage without scar formation.

20 patients were treated within the last three years. Their diseases showed very different development stages starting from the recessive abscess formation in the inguinal zone up to the extended finding with partly considerable complications (repeated operations, condition after sepsis with vertebral abscess formation).

All patients showed a positive reaction to the therapy. At best, new abscesses healed within few days without requiring further antibiotic therapeutic measures. In case of inflammation reactions that have already existed for a longer period of time (longer than 6 months) the inflammation could heal within 6 weeks. In case of extended scar abscess cavities, an antiseptic effect could be achieved but a healing of the cavity not; recessive symptoms are to be expected here.

Patients who have not had extensive scars yet or areas not scared yet showed a good recessive prophylaxis. In the longest period about three years, a complete freedom of recessive symptoms could be observed after an abscess separation performed under general anesthetic once a month before. As an additional finding the smell development was reduced.

Compared with earlier investigations it can be said that a further therapeutic option for treating acne inversa exists. It can be just used at the beginning of the development of the disease and go without an operation in favorable cases.

For advanced disease cases, a significant improvement of the finding and the general condition of the patients can be achieved. Here, primary radical operations with defect coverage are not required and instead of this only minimum operations are necessary so that the disease can be better tolerated by the patients.

6.7 Skin rejuvenation

Generally, the term skin rejuvenation is understood as an improvement of the skin structure (lifting, reduction of the pore size), clearance of pigmentations and reduction of small wrinkles so that the overall appearance is rejuvenated.

Also here, the treatment, contraindications, side effects and treatment procedure are similar to epilation procedures. (See the corresponding chapters.)

Three treatments at 4 weeks intervals are to be performed.

But unlike the epilation treatment, the treatment consists of 3 passes in direct succession and then it is the best to continuously cool the skin with a cooling mask.
3 treatments at one-month-intervals are required.

If, however, age spots shall be brightened(**diagnosis must be absolutely reliable** to exclude cancerous and precancerous lesions!) a small spot size at a distance of about 1 mm from the skin is to be used for the treatment. After the treatments the lentigines become darker first!
Make sure to inform your patients accordingly.
Lecture given by Sue McCoy, M.D. about Joint Laser Conference in Edinburgh, 2004
Translation from English:

Treatment of lengitines with a diode laser at 808nm

S. McCoy; Laser, Skin & Vein Clinic, North Adelaide, South Australia

Background

Lentigines are common benign epidermal skin lesions which occur predominantly on sun-exposed areas of individuals with fair (Fitzpatrick Types I-III) skin, increasing incidence with advancing age. Histologically, solar lentigines exhibit elongation of the epidermal rete ridges and an increase in the number of melanocytes and the amount of epidermal pigment.
Many different lasers have been used with a high degree of efficacy and low incidence of adverse effects including Q-switched Nd:YAG, ruby and aexandrite, frequency-doubled long-pulsed Nd:YAG, Erbium YAG, ultra-short pulsed CO_2 and others. This study evaluated treatment of lentigines with a long-pulsed 808 nm diode laser which is in common clinical use for the purpose of hair reduction.

Materials and method

Twelve healthy consenting female adults, age range 44 to 74 years, exhibiting numerous (at least 10) lentigines on the dorsum of the hands and/or the arms participated in this trial. A long pulsed 808 nm diode laser (MeDioStar, Carl Zeiss Meditec, Jena, Germany) was used only in the 'Pro 2' mode – single pulse without interval. Three patients were initially treated with a 12 mm spot. The remaining 9 patients were treated with a 6 mm spot which allowed higher fluence with a shorter pulse width. Treatment was carried out with a silicon spacer to hold the circular flat lens 1 mm from the skin surface (in contrast to the recommended method of treatment for hair reduction which is skin contact with clear gel coupling).
All patients were treated with energies commencing at 25 J/cm² and increasing in 5 J/cm² increments until darkening of the lentigine within 5 minutes of treatment was observed. The remainder of the lesions were treated at this fluence. One lentigo per patient located on the posterior arm was treated at a pre-selected fluence and was biopsied immediately after the treatment. A total of 12 biopsies were studied with 2 at each fluence from 25 an 50 J/cm². At follow-up 4 weeks later the estimated percentage disappearance of lentigines was recorded as 0-25%, 51-75% and 76-100%. Any adverse effects were noted.

Results

All patients showed 50% or greater reduction in lentigines at one month except one patient treated with a 12mm spot and 30 J who showed only 25-50%. There was poor correlation between clearance and fluence but strong correlation between clearance and color of the original lesions with darker lesions showing greater clearance. There was no scarring at one month but some lesions showed residual erythema at this short post-treatment interval. Histology consistently showed streaking of the nuclear chromatin of the pigmented basal keratinocytes, clefting of a thin upper rim of the papillary dermal collagen. The effects were more pronounced with the 6 mm than the 12 mm spot.

Summary

A diode laser emitting 25 to 50 50 J/cm² at 808 nm is capable of inducing limited and focal necrosis of solar lentigines in the forearm skin of Caucasian females with satisfactory clinical results. Treatment is rapid and well tolerated. Results are more dependent on the color of the lentigino than the fluence of the laser. Operator judgement and experience is therefore important in obtaining good results.

7 Accessories

WARNING

The use of accessories not tested and released by Asclepion Laser Technologies GmbH for the use with this laser device can cause severe damage to the eye or electrical shocks.

Only use accessories and cables provided by Asclepion Laser Technologies for this device.

Important information

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

The manufacturer offers the following accessories for this device:

Designation	Order number
Handpiece STD	840-2000-000
Handpiece VAS	840-2100-000
Handpiece HP	840-2200-000

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

8 Cleaning, disinfection and sterilization

8.1 General rules

Device

WARNING

The laser is operated with line voltage. There is the risk of an electrical shock!

Detach line power cable from the mains socket in order to break power supply to the system before you proceed with work for cleaning.

Only outer system surfaces may be cleaned by the user.

The accessible system components may be cleaned, using a soft, slightly moistened piece of cloth. A wet piece of cloth must not be used for this purpose.

To remove stubborn contamination, a **soft** cleaner solution or disinfectant may be applied. Refrain from the use of aggressive disinfectants or scouring agents.

Handpieces

WARNING

The contact surface of the handpiece contacts the patient's skin during the treatment. There is the risk of microorganisms being transferred.
Handpiece parts must be cleaned and disinfected immediately following use and before application on a patient.
If it should be necessary to clean the device during a treatment the device must be switched to the STANDBY mode before starting cleaning works! Do not use alcohol or isopropyl alcohol near the point of treatment because this causes risk of fire if the laser is activated afterwards!

CAUTION

Dirt settling on an optical surface may burn in when exposed to laser radiation and cause side effects such as reddening, possibly blistering, incrustation, seldom scars!
Ensure that all accessible optical surfaces are not damaged and clean after the cleaning process and remain clean during the treatment.
The procedure instructions given in the following sections are to be followed.

Important information

You are prohibited from cleaning a handpiece basic body under running water. This may destroy the internal optics and electronics.

The handpieces cannot be sterilized.

If the handpieces are not in use for a longer period they must be protected against contamination.

8.2 General advice for cleaning and disinfecting the handpieces

Important information

You are prohibited from cleaning a handpiece base body under running water. This may destroy the internal optics and electronics.

The handpieces cannot be sterilized.

Generally, neutral cleaning agents (e.g. Edisonite Super) are to be used!
(The parts are damaged by strongly alkaline solutions!)

Special care is required when cleaning and disinfecting long and narrow cannulas and blind holes, if existing.

Please observe the special recommendations of the following section, too.

Frequent cleaning and disinfection have low influence on the accessories. The color may become lighter or changes but this does not affect the use.
The end of the product service life is normally determined by wear, tear and damage caused by its use.

If the handpieces are not in use for a longer period they must be protected against contamination.

INSTRUCTIONS	
Workplace	The workplace must be clean and disinfected.
Preparations for cleaning	The cleaning of the accessories should be performed as soon as possible after their use. For this purpose they are to be removed from the device. Disassemble accessory units, if required, by following the instructions provided in the next chapter.
Cleaning: manual	Equipment: neutral cleaning agent (e.g. Edisonite Super); damp, lint-free cloth/swabs; soft brush; Q-tip; microfiber wipe delivered by Asclepion or similar lens cleaning tissues; alcohol or isopropyl alcohol 1. **Procedure for the body of the handpiece:** The accessible surfaces of the handpiece body are cleaned by using a soft, slightly damp cloth. The cloth must not be wet or even dripping. You can use neutral cleaning agent for stubborn dirt. When doing this make sure that possibly existing optical surfaces in the body interior are left out in this process! 2. **Procedure for optical surfaces:** The accessible optical surfaces must be absolutely clean and lint-free. Clean them only, if this is not the case. For doing this, first try to remove the dirt by blowing it away or by using a brush. If required, the surface is breathed on and then cleaned with a microfiber (as indicated above). The Q-tip and the microfiber wipe above the Q-tip can be used for areas that are difficult to access. Moisten the wipe with a little bit of alcohol and repeat the process for stubborn dirt.

INSTRUCTIONS	
Cleaning: manual	Make sure that these cleaning agents only get in contact with glass or metal surfaces of the handpiece. The optical surface must not get scratches and afterwards it must be lint-free and free of streaks.
Cleaning: automatic	not possible
Disinfection	The accessible outer surfaces are to be disinfected by means of a disinfection cloth (e.g. Kodan cloth). When doing this follow the manufacturer's instructions.
Sterilization	not possible, not required
Package for sterilized parts	not applicable
Storage and transport	The parts must be stored in a clean condition and protected against contamination. Ensure that the parameters of the correspondingly admissible ambient conditions indicated in chapter Technical Data are given.

The manufacturer has validated that the above instructions are **SUITED** for preparing the accessory parts for their reuse.

WARNING

The contact surface of the handpiece contacts the patient's skin during the treatment.
There is the risk of microorganisms being transferred.
The person who cares about cleaning has all the responsibility that the actually performed cleaning and disinfecting works by means of the equipment and materials and with the staff involved achieve the desired results.

To guarantee this, validations and routine monitoring of the procedures are normally required. The effect and adverse consequences of each deviation from the instructions given should also be evaluated.

8.3 Special recommendations for cleaning and disinfecting the handpieces

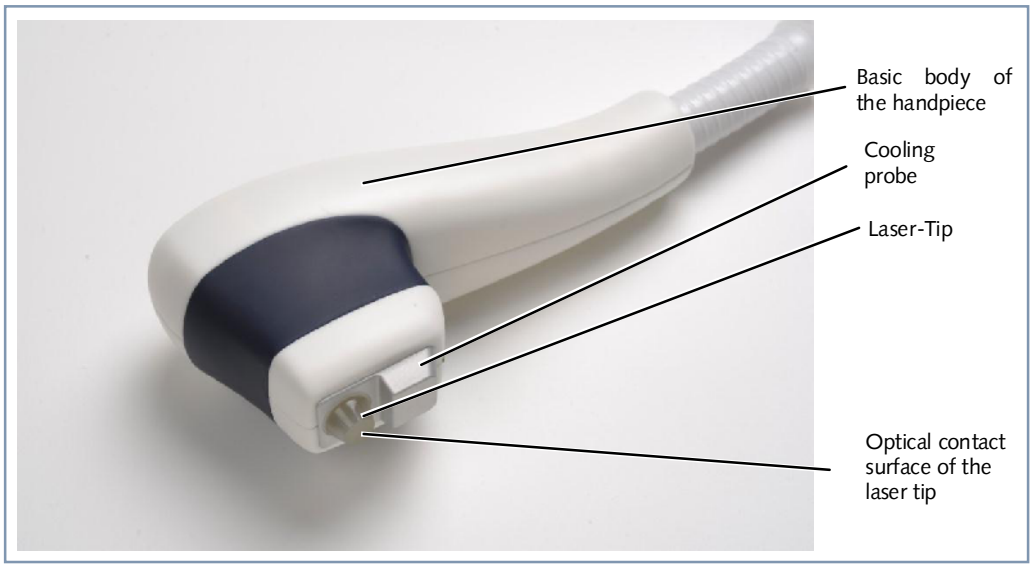


Figure 46: Handpiece laser

During the treatment:

The optical contact surfaces of the laser tip are largely protected against contamination to a great extent by applying the recommended technique. Nevertheless they are to be kept in clean condition during the treatment, too (particularly when treating thicker dark hair)!

CAUTION

Dirt settling on an optical surface may burn in when exposed to laser radiation and cause side effects such as reddening, possibly blistering, incrustation, seldom scars!
Ensure that the laser tip of the handpiece remains clean!

For this reason, the optical contact surface must be checked regularly and cleaned by using a clean, lint-free, damp cloth. You can, for example, rapidly wipe off the surface with a swab each time when a line has been lasered before starting to laser the next line. This method avoids that a possibly existing contamination burns in when the laser treatment is continued.

After the treatment:

The device must be switched off.
First, the outer surfaces of the handpiece are cleaned (see last section). If, for example, hair rests cannot be removed from the optical contact surface by means of a damp cloth, you can also use a swab moistened with alcohol or isopropanol for cleaning.

Afterwards, the outer surfaces of the handpiece are disinfected.

9 Fault messages and fault removal

9.1 General information

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

1. The device is connected to the line power supply.
2. The power switch at the rear panel of the device is switched on (position 'I', see Figure 6:).
3. The Laser emergency STOP switch is unlocked. If locked, please unlock by turning the red knob anticlockwise until the lock is released and the switch jumps out (see *Figure 5:*).

As mentioned before, you are assisted in fault finding by operator guidance via the display.

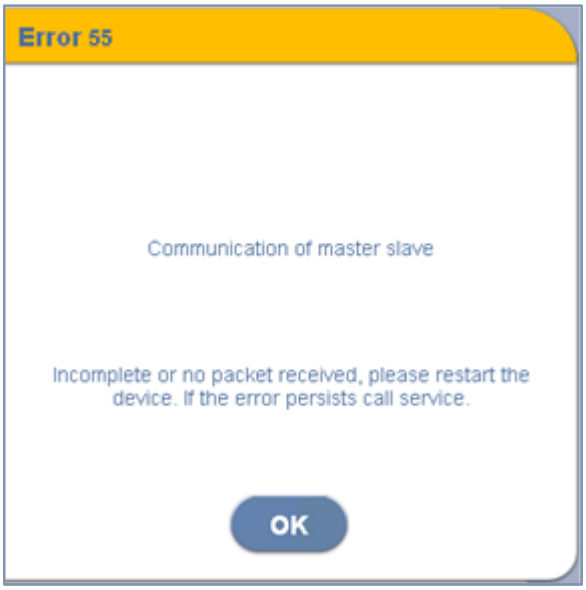


Figure 47: Fault messages screen (example)

For general faults, the display shows a fault message with instructions in plain text. Some faults can be removed by the user. For doing this, follow the instructions on the display.

WARNING

The laser is operated with line voltage. There is the risk of an electrical shock and damage to the eye!

You are strongly advised against trying to do repair works at the device yourself that go beyond the instructions given on the display!

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

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

Improper use or maintenance of the laser system may void the warranty granted by Asclepion Laser Technologies GmbH. Before starting any repair or if you have questions that have not been answered by this manual, contact your service partner (see chapter 10 **Fehler! Verweisquelle konnte nicht gefunden werden.**).

9.2 Fault messages and fault removal

The MeDioStar is provided with alarm systems. If they are released, the system will switch to the safe mode and stop the emission of laser radiation. Please try to remove the fault yourself by following the instructions given in the table below. If the error persists, contact Asclepion Laser Technologies GmbH or a service partner expressly authorized by Asclepion Laser Technologies GmbH.

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

Fault message	Explanation / Corrective action
Communication error (all 50 XXX errors)	The communication is interrupted. Start the device anew. Operation can be continued. Please contact the Technical Service if the error occurs again.
Temperature error (all 150 XXX errors)	The operating temperature is too low or too high. Check if the device is sufficiently ventilated. Start the device anew. Operation can be continued. Please contact the Technical Service if the error occurs again.
Foot switch (400 XXX errors)	Please release the foot switch. (do not activate the foot switch too early, wait until the display shows READY with yellow warning sign)
Door interlock (600 601 errors)	The door interlock contacts are open or the door interlock plug is not connected. If the door has been connected to the door interlock, door open. Connect the door interlock contacts correctly or activate the door interlock switch. If the door has been connected to the door interlock, close the door.
Handpiece error (all 110X errors)	Check the handpiece connection. Start the device anew. Please contact the Technical Service if the error occurs again.

Possible malfunctions

Malfunction	Explanation / corrective action
No power supply	Verify that the power cable has been connected to a power outlet. Is the power switch set to position 'I'? Verify that the Laser emergency Stop switch is released. Check the line fuses of the domestic power supply system.
Function keys of the display do not react (or only sporadically)	Faulty calibration of the touchscreen The calibration is to be performed by an authorized service engineer. Therefore, inform your vendor or directly the Technical Service of Asclepion Laser Technologies GmbH (see chapter 10 **Fehler! Verweisquelle konnte nicht gefunden werden.**).
No laser emission with the foot switch pressed	Verify that the connecting cable of the foot switch is properly connected. The device is in STANDBY. Press the READY key to switch to the READY mode.

10 Customer service

WARNING

The laser is operated with line voltage. There is the risk of an electrical shock and damage to the eye!

Never open the device and attempt to repair the device yourself if the laser does not work properly.

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

The laser does not contain any user-serviceable components. Only service engineers employed with or trained by Asclepion Laser Technologies GmbH are authorized to service the device. This also applies to the prescribed annual safety tests.

If you need assistance by the Technical Service, please contact us via the address or phone number given below. When contacting your service partner of Asclepion Laser Technologies GmbH, always keep the model and the serial number of the device at hand. These numbers are specified on the type plate located at the rear panel of the laser device.

Asclepion Laser Technologies GmbH
Service
Brüsseler Str. 10
D - 07747 JENA
Germany
Tel.: +49 (0) 3641 / 7700 - 401
Fax.:+49 (0) 3641 / 7700 - 402
E-mail: **service@asclepion.com**

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

- installation, extensions, readjustments, modifications or repairs have been performed by authorized persons,
- the electric installation conditions of the laser room meet the requirements of IEC 64, as amended, and
- the device has been used in accordance with the instructions given in this manual.

11 Regular maintenance, safety checks and calibration

The laser does not contain any user-serviceable components.

WARNING

The laser is operated with line voltage. There is the risk of an electrical shock and damage to the eye!

The operation, maintenance, test and calibration instructions given in this manually are to be followed.

Only service engineers employed with or trained by Asclepion Laser Technologies GmbH are authorized to service the device. This also applies to the prescribed annual safety tests, calibration included.

CAUTION

A too high output power of the laser can cause side effects such as reddening, possibly blistering, incrustation, seldom scars!
The output power of the therapeutic laser must be checked by a service technician of Asclepion Laser Technologies GmbH or a qualified service technician of the distributor within the technical safety check at least **once a year**, the device is to be calibrated, too if required. The results of the check are to be documented in the Medical Device Logbook.

11.1 Routine maintenance

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

General

Inspection of the outer surfaces of the device

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

Check of the cooling system

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

Check of the handpiece

Check if the handpiece is in perfect state.
Frequency: before each use
To be checked by: operator of the device

11.2 Regular safety check

SCOPE OF ANNUAL SAFETY CHECK

The safety check should be carried out in compliance with the relevant national legally regulations, as amended, and include at least the tests mentioned below. The tests should be run in the order specified:

- visual inspection of laser device and accessories
- measurement of protective ground wire resistance
- earth leakage test under normal conditions
- measurement of the actual output power of the laser modules at the handpiece; calibration of laser power, if necessary
- functional test.

Tip
To inform yourself about the extent and performance of the safety checks, please contact your distributor or directly Asclepion Laser Technologies GmbH.

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. In this context, "appropriately qualified technical staff" means staff that attended a manufacturer's service training course on this device and that was authorized to repair it.

12 Disposal

The device is to be disposed of according to regulation 2002/96/EC of the European Council for Waste Electric and Electronic Equipment [WEEE] or the specific national regulations on waste electric and electronic devices, as amended.

Please consult our Technical Service if you have any questions regarding disposal.

13 EC declaration of conformity

A Appendix: EMC manufacturer's declaration

Important information

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

Accessory / designation	Model number	Length / dimensions
Foot switch with cable	5501 99 021	< 3.0 m
Cold device supply line	5507 04 013	< 3.0 m

Important information

This device is subject to special terms of network connections. The maximally allowed impedance of the power grid is Z_{max} = 0.1753Ohm at the power supply point. If necessary, the local energy supplier is to be contacted to ensure that the device will be plugged in a supply which has an impedance lower or equal Z_{max}.

Important information

The MeDioStar must not be stacked or arranged directly next to or with other devices. If the MeDioStar is used close to other devices it must be monitored to control its proper operation.

A.1 Electromagnetic emissions

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

Emissions measurement	Compliance	Electromagnetic environment guidelines
High-frequent interference emission to CISPR 11	Group 1	The MeDioStar uses HF energy only for its internal function. Therefore, its emissions of HF interferences are very low and are not likely to cause any interference in nearby electronic equipment.
High-frequent interference emission according to CISPR 11	Class B	The MeDioStar is suitable for use in all establishments, including domestic establishments and those directly connected to the public power supply network that supplies buildings used for domestic purposes.
Emitted interference of harmonics according to IEC 61000-3-2	Class A	For harmonics: The MeDioStar is intended for use in all establishments, including domestic establishments and those directly connected to the public power supply network that also supplies buildings used for domestic purposes
Emitted interference of voltage fluctuations / flickers according to IEC 61000-3-3	Fulfilled 1*)	For flickers: During operation an influence of the supply network cannot be absolutely excluded. If necessary, it is to be ensured – after consultation with the energy supplier- that the max. admissible grid impedance Z_{max} = 0.1753 Ohm is not exceeded.

1*) acc. to IEC 61000-3-11:2000 with max. allowed impedance of the power grid of $Z_{max} = 0.1753$ Ohm.

A.2 Electromagnetic immunity

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

Immunity test	Test level acc. IEC 60601-1-2	Compliance level	Electromagnetic environment guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	+/- 6 kV contact charge +/- 8 kV air discharge	+/- 6kV +/- 8kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Fast transient electrical interferences/bursts acc. to IEC 61000-4-4	+/- 2 kV for power lines +/- 1 kV for input/output lines	+/- 2kV *	Mains power quality should be that of a typical commercial and/or hospital environment.
Surges acc. to IEC 61000-4-5	+/- 1 kV series-mode voltage +/- 2 kV common mode voltage	+/- 1kV +/- 2kV	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage fluctuations of power supply input lines acc. IEC 61000-4-11	< 5 % UT for ½ cycle (> 95 % interruption) 40 % UT for 5 cycles (60 % interruption) 70 % UT for 25 cycles (30 % interruption) < 5 % UT for 5 s (> 95 % interruption)	< 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, too, it is recommended to power the device by an uninterruptible power supply or a battery.
Magnetic field for the supply voltages (50/60Hz) acc. to IEC 61000-4-8	3 A/m	3 A/m	The magnetic field strength should be at levels typical for commercial and/or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level
* not tested, because line length shorter than 3m

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

Immunity test	Test level acc. IEC 60601-1-2	Compliance level	Electromagnetic environment guidelines
Conducted HF interferences acc. to IEC 61000-4-3	3 Veff 150 kHz to 80 MHz	3V	Portable and mobile radio equipment, including cables, should be used not closer to any part of the device than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distance: $d = [\frac{3,5}{3V}] \sqrt{P}$ $d = [\frac{3,5}{3}] \sqrt{P}$ for 80 MHz to 800 MHz $d = [\frac{7}{3}] \sqrt{P}$ for 800 MHz to 2,5 GHz where P is the nominal power of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[a] Field strength of fixed radio 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: 
Radiated HF interferences acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

[a] Field strengths of fixed transmitters, such as base stations for radio telephones (cellular/cordless) and land mobile radios, amateur radios, 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 levels given 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 from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

A.3 Recommended protection distances

Recommended protection distances between portable and mobile HF telecommunications equipment and the MeDioStar according to IEC 60 601-1-2.

Transmitter frequency Equation	150 kHz to 80 MHz $d = [\frac{3,5}{3}] \sqrt{P}$	150 kHz to 800 MHz $d = [\frac{3,5}{3}] \sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{3}] \sqrt{P}$
Rated output of the transmitter (Watt)	**Protection distance (meter)**	**Protection distance (meter)**	**Protection distance (meter)**
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 protection distance can be estimated by 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.			

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