Asclepion
Laser Technologies

TattooStar

Other brands:

RubyStar+
MelaStar

USER MANUAL

CE 0123

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Table of contents

1 Introduction

All versions of the device are referred to as TattooStar or device or equipment hereinafter.

1.1 General information

- This user manual contains the information required for the intended use of the device.
- It corresponds to the applicable national, European and international directives and laws on product liability of an integral component of the complete product.
- The most important objective is to protect persons against dangerous situations and the device against damages caused by improper use.

The information from this user manual is absolutely required to operate the devices. Therefore, please familiarize yourself with the contents and pay special attention to information concerning safe operation of the device.

WARNING

Incorrect use of this device can lead to severe health damage.

Unintended use of the device is understood as failure to observe the warnings, notes and information for this user manual, the improper use or maintenance and modification to the device!

1.2 Symbols in the user manual

The following symbols are used to draw your attention to residual risks, which could not be covered by appropriate safeguards, or to other possible dangers.

WARNING

This symbol indicates a potential danger to the life and health of persons.

Failure to follow these instructions can lead to severe health damage and life-threatening injuries.

CAUTION

This symbol indicates a potentially hazardous situation.

Failure to follow these instructions can lead to injuries.

The following symbols are used to give instructions on operating the device:

Important information

This symbol indicates important information about proper handling of the device. Failure to follow these instructions can lead to property damage, device malfunctions or interference in the surrounding area.

Tip

This symbol indicates application tips and particularly useful information. This information allows for optimal use of all functions on the device.

1.3 Changes and copyright

Subject to change based on further technical development.
For the latest information, contact customer service at Asclepion Laser Technologies GmbH or your Asclepion Laser Technologies distributor.

2 Intended use

This laser device is a Q-switched solid-state laser. With durations in the nanosecond range, Q-switched laser pulses are extremely short.

2.1 Intended application

The TattooStar is very well suitable for **the vaporization and ablation of soft tissue**, particularly for a selective damage of pigments in the epidermis and dermis and thus the gentle treatment of benign pigmented lesions and artificial lesions by means of selective photothermolysis.

More specific, detailed information about application can be found in the chapter *Application*.

2.2 Contraindications

CAUTION

Intensive laser light in the infrared range can cause damage to skin structures. The contraindications listed below stem from many years of clinical experience with laser devices for this intended use. They do not claim to be complete or to have unlimited validity.

The User is under obligation to notify his/her patient(s) of any risk involved in or resulting from actual therapy action, including pre-operative and post-operative care. He/she shall also provide all further information of relevance.

- Premalignant and malignant lesions, including nevus cell nevi/ melanocytic nevi (Before treating benign pigmented lesions neoplastic alterations have to be excluded by dermatoscopic, better histologic diagnosis; documentation strongly recommended!)
- Light sensitivity / Usage of preparations that increase sensitivity to light
  e.g. tetracycline, gold medication (to treat rheumatic arthritis)
- Tanned skin in the treatment area or treatment before planned UV exposition (e.g. beach vacation) - postpone treatment
- Infections, inflammation or open wounds in the treatment area including allergic reactions coming up during treatment (treatment to be discontinued)
- Microbiological infections, e.g. herpes (therapy or prophylaxis before treatment), pustular acne, impetigo
- Tendency to hypertrophic scarring or keloids (perform trial treatment in such cases)
- Conditions, that could cause the Koebner phenomenon (isomorphic response),
  e.g. psoriasis vulgaris, vitiligo, lichen ruber planus
- Usage of topical steroids longer than 1 month
- Children, pregnant and nursing women
- Patients with known unreasonable UV light exposure and/ or unrealistic expectation

2.3 Possible side effects

Please see chapters *Application/ Possible side effects*.

2.4 Requirements for the user

WARNING

Laser radiation from the device can lead to changes in tissue structures.

Treatment must only be carried out by a doctor or under the supervision of a doctor (simply referred to as the user in the following).

Furthermore, only users who demonstrate applicable technical knowledge based on their education, skills and practical experience may use active medical devices.

It must be expressly noted that only users who receive training for the device and have confirmed such training by signing the medical device book may use the device.

Corresponding courses on laser safety for medical applications are also offered by Asclepion Laser Technologies GmbH.

2.5 Classification of the medical device

CE 0123

This laser device meets the EU Medical Devices Directive 93/42/EEC.

Device class in accordance with Directive 93/42/EEC:	II b
UMDNS No.:	17-815

3 Safety

3.1 General safety information

This laser device complies with the requirements of the EU Medical Devices Directive (93/42/EEC) and the German Medical Product Act (MPG).

The device is a class IIb medical product in accordance with appendix IX of the directive (i.e. surgically invasive product intended to cause a biological effect; this is not to be confused with the laser class!).

As with any device, operation of this laser may lead to potential dangers, of which the user should be aware before using the device. These risks include optical, electrical and biological dangers and fire hazards.

Observe the national regulations for using a medical device.

Applicable law may require that device operators and users follow a specific series of safety precautions when using class IIb medical devices. Such devices may be operated only in accordance with the generally recognized rules of the technology and occupational safety and accident prevention regulations.
Furthermore, you may be required to maintain a medical device book. A corresponding copy is provided.

WARNING

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
Furthermore, there is also a risk of electrical and biological hazards as well as hazards caused by radio interference.

The instructions specified below must be observed:

- No modification of this equipment is allowed.
- The equipment and procedures for operation, configuration, maintenance, inspection and calibration specified in this user manual must be observed.
- Note that regular (annual) safety checks must be carried out for this device in order to ensure the safety of personnel and patients. Failure to regularly carry out the checks can lead to severe health damage.
  The results of the checks are to be documented in the medical device book.
- Note that, in order to ensure the safety of personnel and patients, service and repairs on or changes to this device may only be carried out by Asclepion Laser Technologies GmbH or by those authorized to do so.
  Service and repairs on or changes to the device carried out by non-authorized persons can lead to severe health damage.

WARNING

In the US or Canada this device should be installed and operated according to the US standard ANSI Z136.3 or the Canadian standard CAN/CSA-Z386: “Safe Use of Lasers in Health Care” in its current version.

3.2 Electric dangers

WARNING

The device is operated using line voltage.
To avoid the risk of electric shock, the following must be observed:

- This equipment must only be connected to a mains supply with protective earth.
- Never open the device if you are not trained or authorized to do so.
- Never set up the device such that disconnection from the power supply may be difficult.
- The device adheres to the specified limit values for leakage currents. Nevertheless, ensure that contact with the patient and device does not occur simultaneously when the device is switched on.
- The device is designed to prevent the ingress of liquids over the course of normal use. If, in exceptional cases, liquid enters into the device housing or handpiece, you must turn the power off and unplug the main power plug. Please contact our Technical Service.

3.3 Biological hazards

The device is developed and manufactured in a way that a safe use is ensured also with regard to compatibility of materials. The contact with materials of the device or with outgoing media (liquids, gases etc.) in normal use is not dangerous.

WARNING

The spacer (distance holder) of the handpiece comes into contact with the skin of the patient. There is the risk of transmitting microorganisms.
The handpiece used must be thoroughly cleaned and disinfected immediately after each application; if necessary the spacer can be sterilized.

3.4 Radio interference

The device fulfills the requirements of the IEC 60601-1-2 standard. The system is not affected by electromagnetic radiation from other devices that conform to the same standard. In addition, the system does not generate any electromagnetic radiation that exceeds the limit values of IEC 60601-1-2. The manufacturer's declaration about electromagnetic compatibility in accordance with IEC 60601-1-2 is included as an appendix to this user manual.

WARNING

Medical electrical equipment needs specific precautions regarding the electromagnetic compatibility (EMC). The instructions specified below must be observed:

- The equipment needs to be installed and put into service according to the EMC information provided in the Appendix.
- Portable and mobile RF communications equipment can affect medical electrical equipment. The same applies to other equipment that does not meet the standards listed above. This may result in unintended settings.
  Switch off cellular phones and similar devices before using the laser device!
- The use of accessories, handpieces and cables other than those specified, with the exception of handpieces and cables sold by the manufacturer of the device as replacement parts for internal components, may result in increased emissions or decreased immunity of the device. Only use accessories, handpieces and cables that are specified for use with this device by Asclepion Laser Technologies.

WARNING

- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories, handpieces or cables with other medical electrical devices that are not authorized by the manufacturer can lead to increased transmission or to reduced interference immunity of the device with the above mentioned effects.
  Only use accessories, handpieces and cables that are specified for use with the intended device by Asclepion Laser Technologies.
- The device emits small amounts of electromagnetic radiation that can potentially inFLUENCE devices that do not fulfill the standards listed above. This may result in unintended settings on those devices.

3.5 Laser

3.5.1 Optical danger due to laser radiation

The lasers are classified according to their potential for danger. The most dangerous laser class is class 4 (the least dangerous is class 1). This device is a class 4 laser.

The fundamental rules for handling laser devices are derived from the IEC 60825-1 international standard “Safety of laser products”, part 8 “Guidelines for the safe use of laser beams on humans”.
In addition, national regulations are intended to protect against dangerous laser radiation. For medical applications, these measures are intended to protect both the personnel and the patients.

Also observe the specific national regulations for your location.

WARNING

Caution – The use equipment and procedures for operation, maintenance, inspection or calibration other than those specified in this user manual can lead to hazardous irradiation by laser radiation.

The protective measures specified below must be strictly observed. In particular, everyone in the room where the laser is being used ("laser area") must wear suitable protective eyewear while the laser is active.

The following protective measures are a few essential requirements that must be supplemented further for the specific circumstances with the help of a laser safety officer.

1. A **laser safety officer** with expertise regarding laser applications in medicine must be commissioned in writing and carry out at least the following tasks:
   - Supporting the operator with respect to safe operation and necessary protective measures
   - Monitoring safe operation of the laser
   - Collaborating with specialists for workplace safety for fulfilling their duties, including training for important matters concerning protection from laser beams.

2. **Laser area**

   During operation, the area where the maximum permitted radiation level can be exceeded—called the "laser area"—must be cordoned off and marked by a laser warning sign. The laser area is the room in which the laser is being used. Use of the laser must be indicated by **warning lights** and the triangular yellow **laser warning sign** at all entrance points.

Figure 1: Laser warning sign (left: European, right: US style)

3. Personal eye protection

Everyone present in the laser room during a treatment session must wear laser safety glasses eye or shields for patients!
The laser safety glasses and eye shields for patients must comply with the specifications defined in the technical data section!

4. Additional safety precautions

- Cover up windows and other openings to the treatment room to prevent emission of laser radiation.
- Restrict access to the treatment room so that only people assisting with treatment and those trained to handle the laser device have access (besides the patient to be treated).
- Make sure that trained personnel assisting with treatment know how to switch off the laser in an emergency.
- Remove all metallic objects such as watches, rings, necklaces and similar objects from the working area and do not use any reflective tools or other reflective materials if at all possible.
  (Reflective objects could interrupt the laser beam and deflect it towards areas other than the intended treatment area. Many surfaces, even those that appear to be dull, can easily reflect the emission wavelength of the laser.)
- Only point the activated laser at the intended area to be treated.
- Never look directly into the outlet opening of the handpiece or the optical fiber, even if you are wearing laser safety glasses.
- Switch the laser into the STANDBY state when not in use (the laser cannot be activated accidentally while in the STANDBY state).
- Always remove the key from the key switch when the device is switched off and store the key in a secure place.

5. Responsibility

The user who triggers the laser emission is responsible for the safety of the laser. This user must ensure that all safety measures are being followed **before** activating the laser. Specifically, everyone present in the room—including the patient—must wear proper protective eyewear or eye protection for patient.

3.5.2 Laser-induced fire hazard

WARNING

A risk of fire and/or explosion exists when the laser output is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment

The device must, therefore, never be used in potentially explosive areas (in accordance with the AP and APG classification in accordance with IEC 60 601-1).

The following protective measures must be followed for this reason.

- Some materials, for example cotton wool when saturated with oxygen may be ignited by the high temperatures produced in normal use of the laser equipment.
  Keep clothing as far away from the treatment area as possible.
- The solvents of adhesives* and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
- Attention should also be drawn to the danger of ignition of endogenous gases.*
- Do not use any inflammable substances to cool the skin (such as inflammable cooling spray, but e.g. Cool-Packs) directly before or during treatment.
- If possible, do not use any inflammable substances for anesthesia if at all necessary.
- Avoid the use of oxidizing gases such as nitrogen oxide (N_2O) and oxygen. Be especially careful when using oxygen. Oxygen increases both the intensity and extent of fire.
- Keep combustible materials in the treatment room to a minimum. If treatment requires the use of combustible materials, moisten the materials.
- Only expose the surfaces of the body required for treatment to the laser emission.
- Always have a small amount of water READY in the treatment room and have a fire extinguisher for electric devices nearby.

*not applicable for treatments with TattooStar

4 Technical data

4.1 Device models

Designation*	Description
TattooStar, item no. 1640	Ruby laser (mains supply 230V)
RubyStar+, item no. 1642	Ruby laser (mains supply 230V)
MelaStar, item no. 1647	Ruby laser (mains supply 230V)
Standard handpiece for Ruby laser, item no. 4001	
MicroSpot handpiece for Ruby laser, item no. 4104	For fractional treatments

*The item no. of the device can be found at the type plate; no. of the handpiece is on the tube of the handpiece.

4.2 Specifications

Specification	TattooStar
Device model	Floor-based unit
Display	8.4" LCD display
User interface	Touchscreen with rotary/push button
Cooling	Internal cooling circuit, water to air heat exchange
Door interlock connector	12 V DC/max. 20 mA
Laser warning lamp	Isolated relay contact max. 24 V/1 A (normally open contact)
Permitted ambient conditions	Temperature: 20 °C to 30 °C Rel. air humidity: 20 - 80% (non-condensing) Altitude: max. 2000 m above sea level The device is not permitted for use inside an operating room.
Permitted transport and storage conditions	Upright standing position (do not lay it on its side!) Temperature: 5 - 50 °C Rel. air humidity: 10 - 90% (non-condensing) Air pressure: 700 – 1070 hPa
Dimensions	36 x 78 x 97 cm³ (W x D x H without articulated mirror arm)
Weight	approx. 95 kg
Power grid connection	230 V; 50/60 Hz, single-phase max. 2500 VA
Main fuse	16A overcurrent trip, medium time lag
Overvoltage category	II (IEC 60664-1)
Max. line voltage peaks Max. nominal line voltage	V MT peak = 2500 V peak V MN r.m.s. = 300V r.m.s.
Electrical protection class	I
Classification according to Directive 93/42/EEC	II b

Specification	TattooStar
Degree of protection of the application parts	B
IP protection class	IP 20
Accessories	See Chapter *Accessories*
Type of operation	Intermittent use (60min. use*, 20 min. interval)

* At high room temperatures and high average power, the device may switch to cooling mode for a short period of time during longer treatments to ensure cooling.

Laser specifications	Ruby laser	
Laser type	Ruby ($Cr:Al_2O_3$) solid state laser	
Wavelength	694 nm	
Laser class	4	
Required laser safety glasses (according to EN 207: 2009)	R 694nm L7	
Pulse length	Ca. 40 ns	
Pulse frequency	0.5 – 2 Hz or single pulse	
Pulse energy	Max. 1.2 J	
Spot sizes (handpieces)	Standard handpiece: MicroSpot handpiece:	2.5; 4 and 5.5, square 7.1 x 7.1 mm² (total, 14 x 14 spots) 300 µm (single spot)
Energy density (FLUENCE)	Standard handpiece: MicroSpot handpiece:	max. 20 J/cm² max. 8 J/cm²
Laser beam mode	Multimode	
Tolerance of the output energy	+/- 20%	
Laser beam diameter at the handpiece output	See spot sizes	
Beam divergence at the handpiece output (round angle, $1/e^2$)	Min. 1.2°	
Nominal distance for danger to the eyes (with handpiece)	35 m	

Pilot laser specifications	Pilot laser (all device versions)
Laser type	Diode laser
Wavelengths	635 – 670 nm
Laser class	1
Laser beam diameter	max. 1mm
Divergence	max. 4 mrad
Type of operation	Continuous

4.3 Technical description

4.3.1 Base unit

Even though the user of the laser doesn't come in contact with the internal parts of the device, it should be helpful to understand how the device performes.

Laser

The laser unit consists of the laser head, the optical resonator and the laser bench. In the laser head, the multispectral light of a pulsed flash lamp is imaged into the laser rod by means of an optical reflector. Through optical excitation of the laser rod, light is generated that is bundled in the optical resonator.
The optical resonator consists of mirrors that are arranged in parallel to each other with each being positioned at the end of the laser head. One mirror reflects 100% of the incident light, while the other one only reflects a portion of the beam and allows the remainder of the laser energy to pass as useable laser light.
The laser bench is the mechanical support for the laser head and resonator and accommodates further functional elements, such as the electrooptical q-switch for the reduction of the pulse length, the energy meter, the system for coupling in the aiming laser, and the mechanical beam shutter.
The treatment laser beam is coaxial with the aiming laser beam and directed into the articulated arm that delivers both beams to the handpiece.

Cooling

The cooling system cools the pump chamber to prevent it from being overheated. The generated heat is dissipated to the ambience via a water-air heat exchanger. A pump circulates the coolant through the laser head and the heat exchanger. In addition to this, integrated temperature and flow sensors provide safe operation. An external cooling-water connection is not necessary.
The coolant is not normal water!! The coolant is filled up by service technicians during yearly checks.

Power supply

The integrated power supply transforms the line voltage into rectified low voltage for the electrical supply of the device. At the same time, it generates the high-power pulses needed for the excitation of the flas hlamp.

Microcontroller

The device is equipped with a microcontroller that controls and monitors all functions of the system.

User interface

The device is operated via a touch screen in combination with a combined rotary/push button; display is in plain text on an LCD panel.

For details please see chapter *Operating the device*.

4.3.2 Beam delivery system

The beam delivery system is an opto-mechanical assembly that consists of the articulated mirror arm and the handpiece. It transmits the laser radiation to the treatment location.

Articulated mirror arm

The articulated mirror arm is permanently mounted to the device. It consists of seven mirrors that are installed at swiveling joints. The range of motion of the articulated mirror comprises a radius of about 100 cm. The transmission loss is compensated by an appropriate calibration of the internal energy meter.

Handpieces

There are standard handpieces for all versions of the device.
Additionally, there is an optional MicroSpot handpiece FRx. With this handpiece it is possible to treat fractionally by an array of very small spots.

The handpiece mounted to the distal end of the articulated arm. It has a purge gas connector to protect the optical system of the handpiece and an electrical connection to detect the spot size of the treatment beam. To adjust the spot size of the treatment spot the distance holder (spacer) of the handpiece can be changed (please see chapter *Start-up/ Installation/ Handpieces* and *Operating the device/ Change of the spot size of the standard handpiece and change of the handpiece*).

4.4 Safety equipment

The device is equipped with different safety units that have been provided to prevent incorrect operation and unintentional activation of the system. All persons who operate the laser or assist during the treatment should be familiar with these units.

Laser emergency STOP switch

The purpose of the red laser emergency STOP switch on the front of the device (see Figure below) is to immediately switch off the laser emission system in an emergency. It should only be used in emergency situations, i.e. when it is necessary to immediately interrupt laser emission.

To immediately switch off the system, press this switch. After resolving the emergency situation, the switch unlocks by turning to the left until it jumps out again.

Important information

Do not use the laser emergency STOP switch to switch the device on and off in its normal state.

Key switch

The system is activated with the key switch. Only authorized persons who have access to the key can start the system. The key switch can only switch on the system if the laser emergency STOP switch is not depressed.

WARNING

The laser device emits strong radiation in the infrared range. This radiation can lead to severe eye damage if the device is used improperly.

The device must not be switched on or used by unauthorized persons.
Always take out the key after you have switched off the device and only allow authorized personnel to store it.

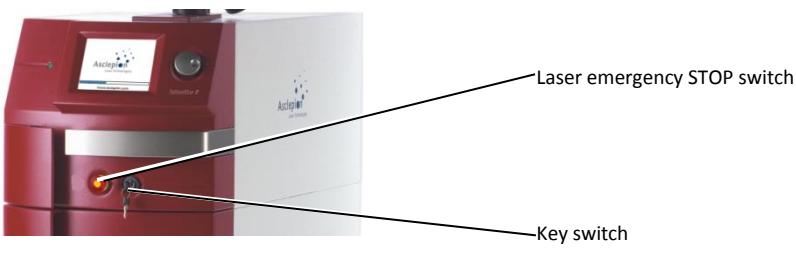


Figure 2: Safety equipment on the front side of the device

Power switch

The power switch separates the device from all poles of the supply voltage. When the device is not being used, the switch should be in the OFF (O) position.

Foot switch

The foot switch is equipped internally with two redundant switch elements to ensure safety. This does not affect how it is used. Additionally, accidental actuation of the switch is prevented by a protective flap.

The foot switch is an electric button that activates laser emission when pressed if the device is in the READY state.
Always set up the foot switch near the treatment area.

Operating state STANDBY

The STANDBY operating state prevents the laser from being unintentionally or accidentally activated. Laser emission is not possible if the system is in STANDBY. The operator can only activate emission after the READY button has been pressed.

The system goes into STANDBY in the following situations:

- After starting the system for the first time
- If the operator presses one of the buttons to select the laser parameters
- If the system has been in the READY state for a long period of time without the laser being initiated
- If the operator has pressed the STANDBY button while the system was in the READY mode.

Automatic shutoff

The device has an automatic shutoff. If a specific problem occurs, the system switches automatically to the following safe state:

The electronic laser lock is closed, the laser emission is immediately interrupted and the foot switch is deactivated. An error message appears on the display that identifies the specific error (see chapter *Error messages and trouble shouting*).

Remote interlock contact

The system is equipped with a remote interlock contact that can be connected at the entryways to the laser room. If the remote interlock contact is open (e.g. if the door is open), laser emission is automatically interrupted and the device goes into STANDBY.

Additional potential equalization

The additional potential equalization forms a basic protective measure in accordance with IEC 60601-1 in the areas of group 1 used for medical purposes (e.g. doctor's offices) and 2 (e.g. operating rooms; additional connections for the additional potential equalization are attached in the rooms for group 2).

This fulfills the purpose of equalizing potential differences between different devices in the patient's environment, to prevent the dropout of the ground wire of devices of protection class I (single-fault protection) and to ensure compliance of the required contact voltage with the housing of protection class I devices.

The potential equalization line can be connected to the potential equalization connection at the back of the device, to the corresponding connector of other devices and to the fixed installed system (of the room). The potential equalization does not replace the ground wire of the device.

Important information

Observe the requirements of IEC 60601-1 regarding ME systems.

Acoustic signal

Laser emission is displayed by an acoustic signal during emission.

Warning signs

The device has various warning labels (see chapter *Start-up/ Installation/ Labels on the device*). These labels must be clearly visible at all times and must be immediately replaced if damaged.
For more information about this, contact our technical customer service.

The manufacturer is only liable for safety, reliability and power of the device if:

1. The device is used in agreement with all instructions in this handbook (on safety measures and system application).
2. Installation, assembly, expansions, modifications, repair and maintenance work carried out by qualified and skilled persons.
3. The electrical system at the installation location that fulfills the requirements of IEC 60601-1 and of local regulations.

5 Start-up

5.1 Delivery

Important information

Please check with the transport company whether all of the components listed below that are necessary for safe operation of the device are available and are not damaged. Claims for incomplete and/or damaged deliveries are to be filed with the supplier immediately.
Asclepion Laser Technologies does not accept any liability unless another agreement has expressly been made.
Please keep the packaging to safely ship the device.

CAUTION

If you detect mechanical damage on the device or accessories, the device is not to be operated. Operating the device under these circumstances could result in injury.
Please contact the Service team of Asclepion Laser Technologies GmbH.

The basic equipment comprises the following device parts:

- Base unit with articulated mirror arm
- Mains cable
- Tube for air purge
- Cable for spot recognition
- Foot switch
- Standard handpiece, optional: MicroSpot FRx handpiece
- Warning lamp/door interlock connector
- Keys (x2 for key switch)
- Laser safety glass, blackout glass for patients
- User manual
- Laser warning sign

5.2 Installation

WARNING

The device is operated using line voltage and emits laser radiation. There is a risk of electric shock and injury to the eyes!

The installation and the mandatory functional test may not be performed by anyone other than our service technicians or other technicians trained and authorized by us.

5.2.1 Device design

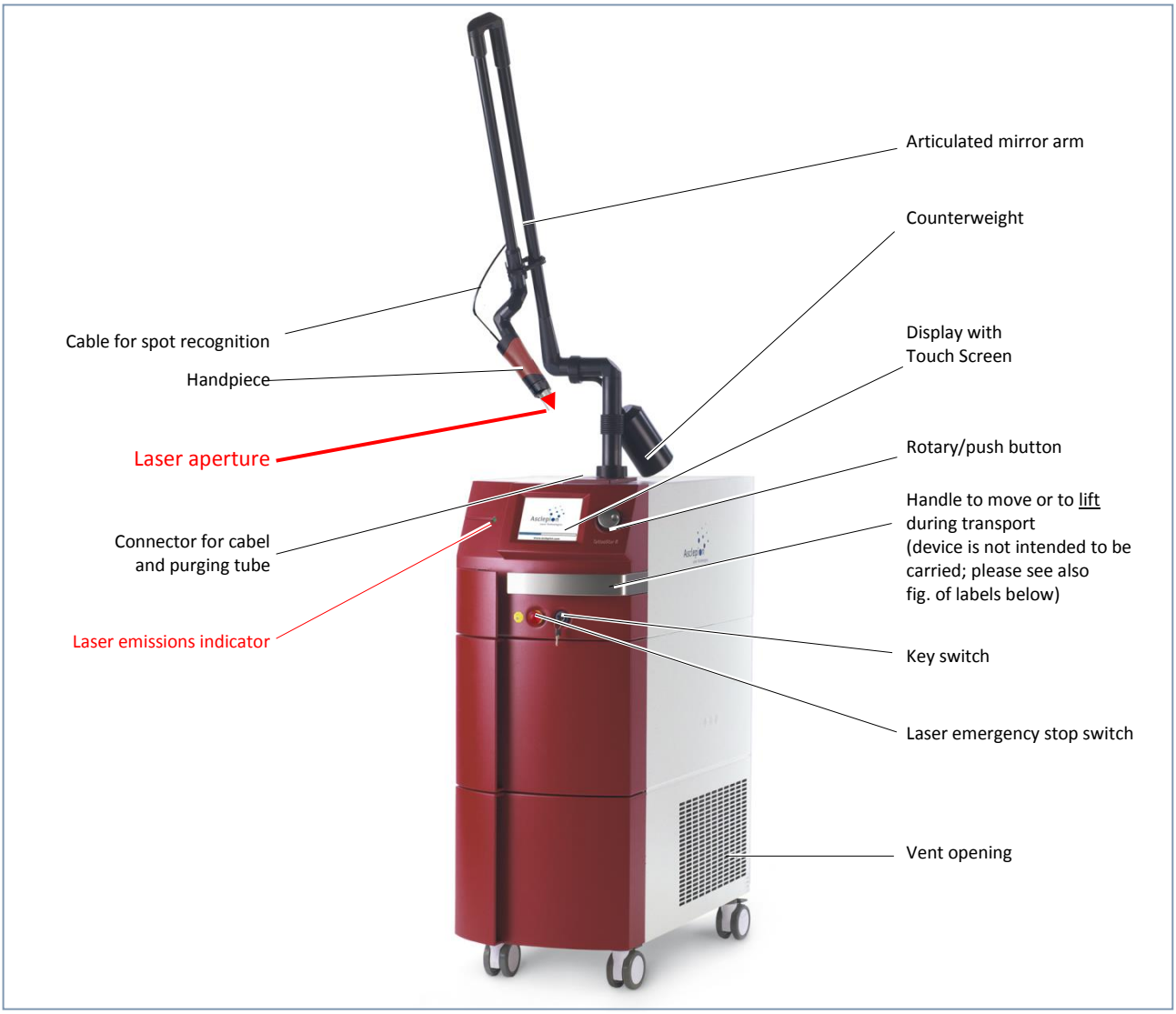


Figure 3: Front of the device

Figure 4: Back of the device

5.2.2 Labels on the device

WARNING

The laser device emits strong laser radiation. This radiation can lead to severe eye damage if the device is used improperly.
Therefore, there are warning and information labels on the appropriate places on the device. The entire personnel must know these labels and their meaning to ensure proper use of the device.
All labels must remain in their respective positions and in good condition. Replace damaged labels immediately to ensure proper use of the device.

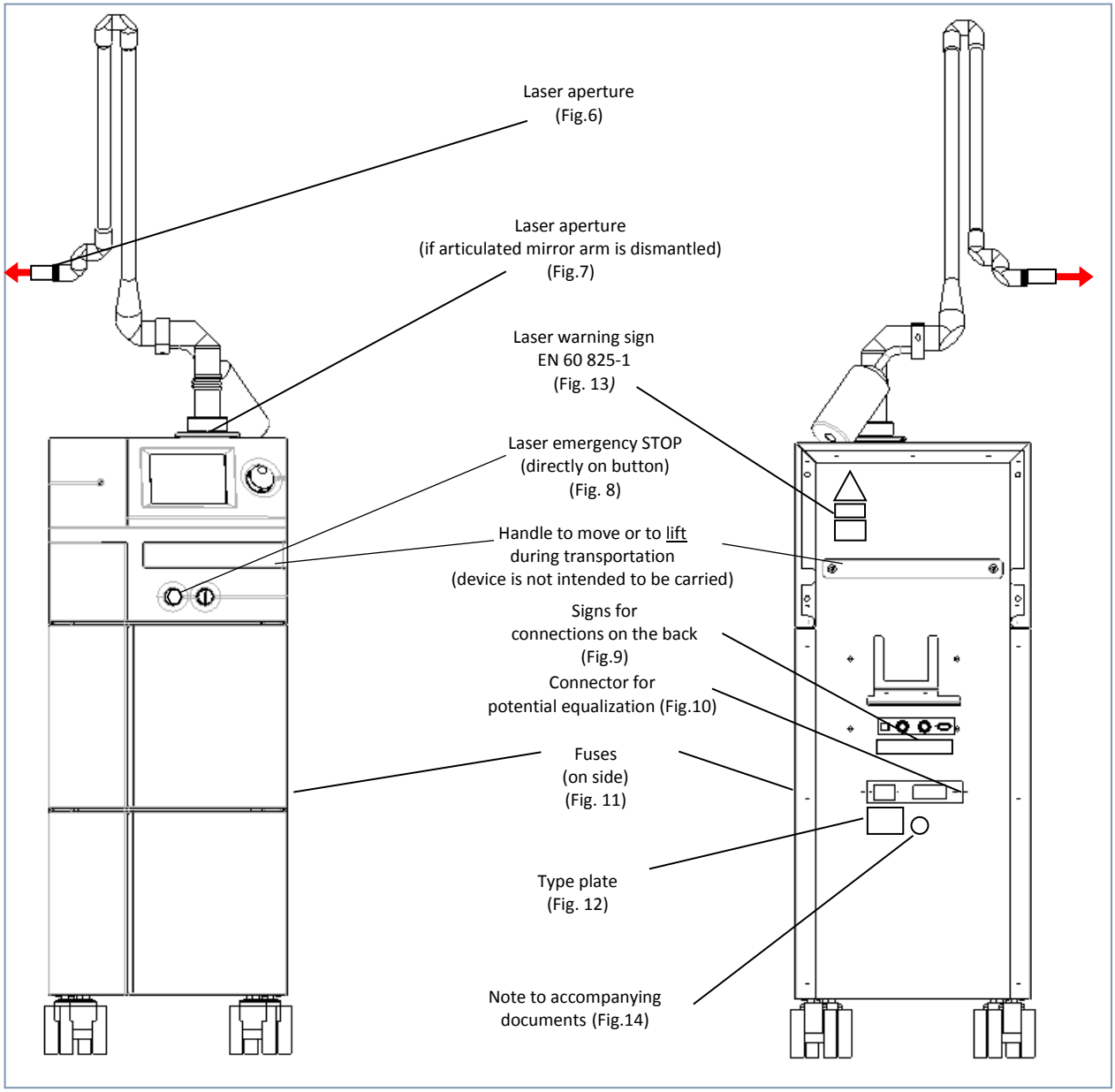
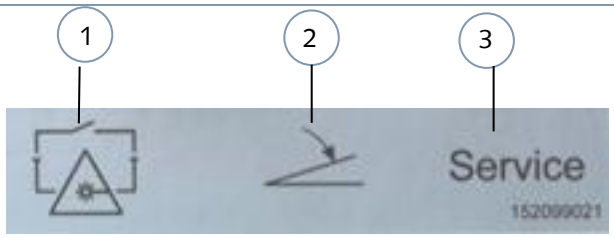
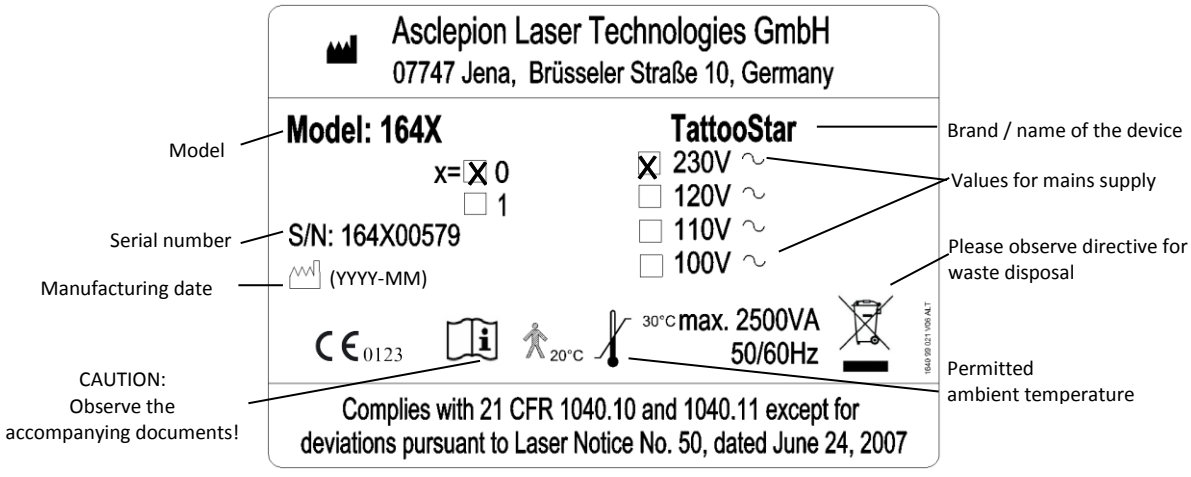


Figure 5: Labels on the TattooStar device

 Figure 6: Beam exit aperture	This label marks the place where the laser beam exits the transmission system.
 Figure 7: Beam exit aperture	This label marks the place where the laser beam enters the articulated mirror arm.
 Figure 8: Laser emergency STOP button	This sign marks the laser emergency STOP button for switching off the laser radiation in an emergency.
 Figure 9: Interface connections	Warning: No accessory parts other than those approved by Asclepion Laser Technologies are to be connected to these connections. "Service" is intended exclusively for use by authorized service personnel. 1 Connection for remote interlock contact 2 Connection for foot switch 3 Service interface
 Figure 10: Potential equalization connection	This contact is used for the additional connection of the device to a potential equalization system
F1 T2.0A | F2 T1.0A | F3 T0.063A Figure 11: Fuses	Labelling of device fuses with „T" for slow blow and nominal current value. (F1: pump for coolant; F2: pump for purging by air; F3: high voltage unit for Q-switch)



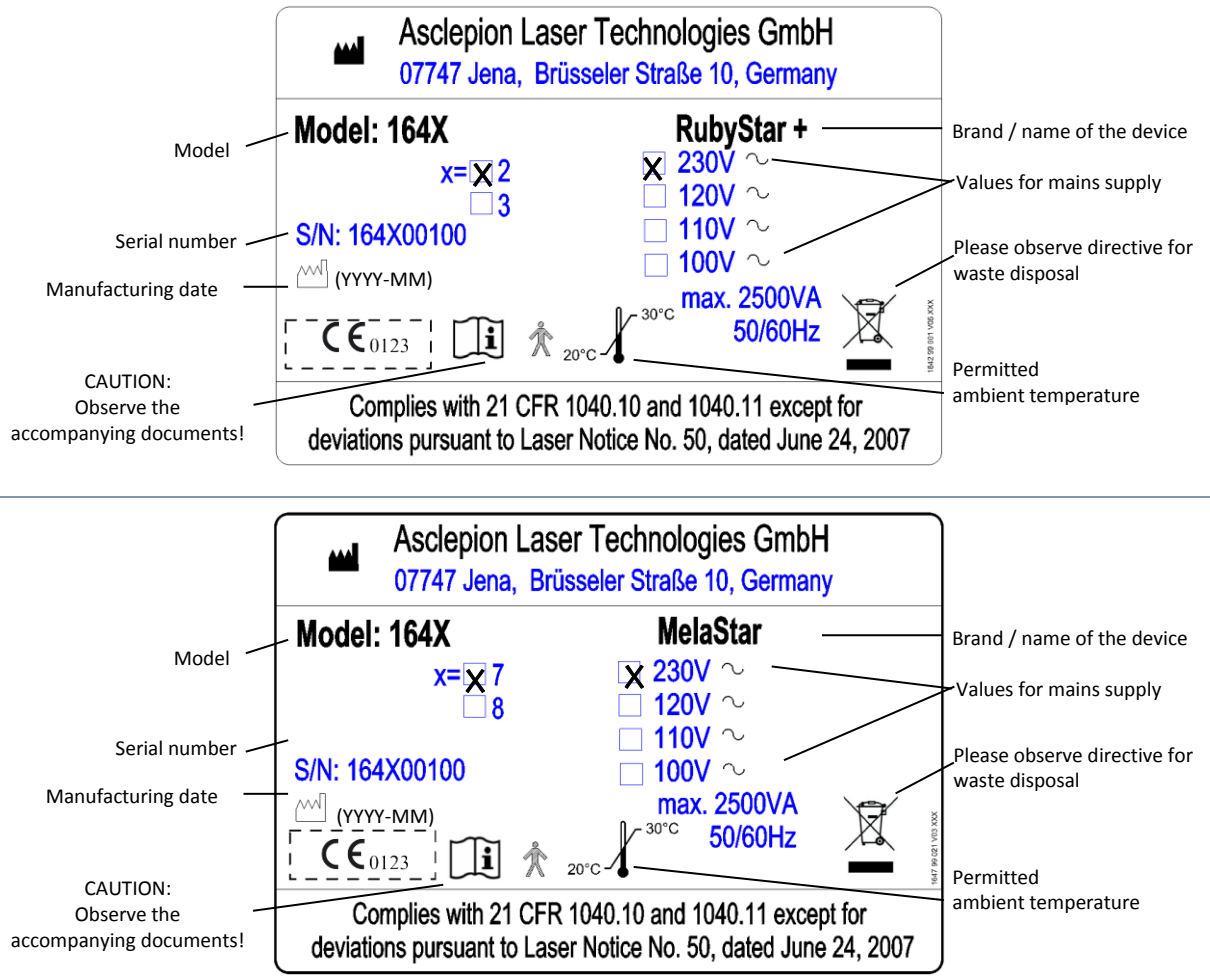
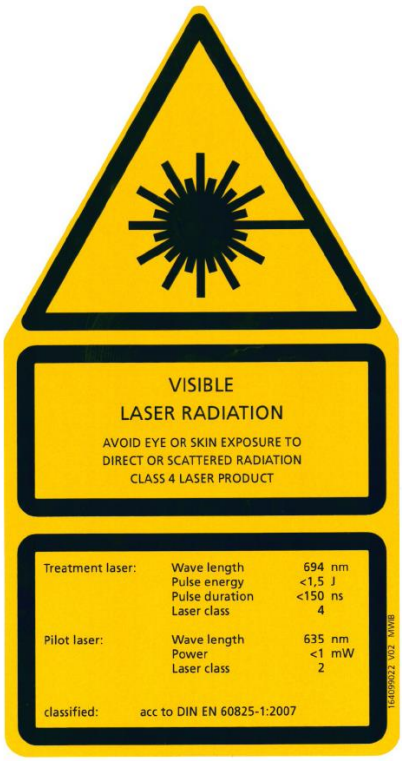


Figure 12: TattooStar type plate – Example for TattooStar (1640), RubyStar+ (1642), MelaStar (1647)

Type plates with type-specific data for the device, including the serial number and the manufacturing date.

 Figure 13: IEC 60 825-1 laser warning label	This label provides information on the dangers, maximum value of energy emission and classification of the laser source.
 Figure 14: CAUTION: Observe the accompanying documents!	This label informs the user that the device may not be used before the accompanying documents have been read.

5.2.3 General notes on installation

WARNING

The laser device emits strong radiation in the infrared range and is operated using line voltage. It needs specific precautions regarding the electromagnetic compatibility (EMC). It can lead to severe injuries to patients and users if the device is set up and installed improperly.

The equipment needs to be set up and installed in a way that all instructions given in the chapters *Safety, Technical data/ Specifications* and in appendix EMC are observed.

Important information

After installation and any relocation of the device from a cold to a warm environment with a temperature difference of more than 5 °C, allow the device to adjust to the room temperature in an unpacked condition before use. Allow it to adjust for at least:

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

Afterward, switch on the device without connecting a handpiece and allow the device to warm up for at least 30 minutes.

Make sure that the environment in which the device is to be installed and operated complies with the permitted ambient conditions stated in chapter *Techn. Data/ Specifications*.

Failure to observe this information can lead to destruction of the device.

To cool the device efficiently, maintain a minimum distance of 20 cm between the side and back panels of the device and the wall.

WARNING

The laser device emits strong laser radiation. This radiation can lead to severe eye damage if the device is used improperly.

Warning lamps that light up (or flash) while the laser is in use must be installed at all entrance points into the laser area (the room where the laser is being used). This warns people before they enter the room.

5.2.4 Connection for door contact

There is a socket on the rear side of the device that allows the device to be connected to a remote interlock contact (see figure below).

This requires the use of a circular connector that screws in place, type (x)V 40 in accordance with IEC 60130-9, such as the Lumberg WSV 40 (included).
(x): Depending on type, for example, WS for angled plugs, such as those provided

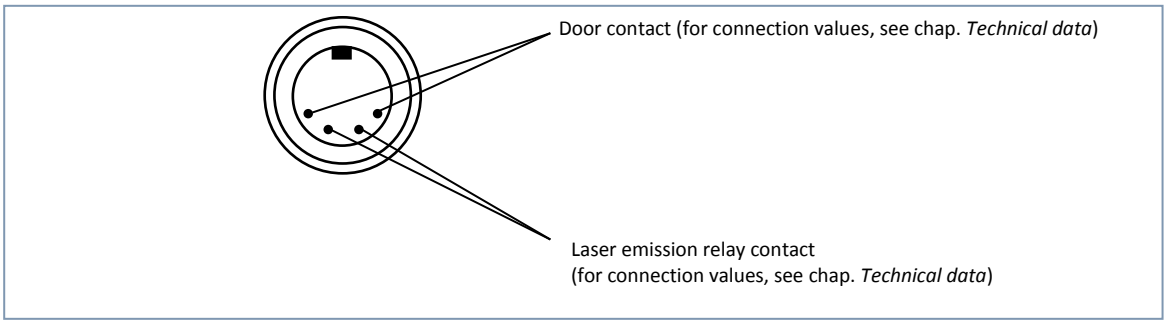


Figure 15: Connections for remote interlock contact and laser warning lamp

By connecting both *remote interlock contact* connections to an external door contact, you can prevent the laser radiation from being emitted if the door is opened.

This makes it possible to have the treatment beam of the laser switch off automatically if the entrance door to the laser area is opened, preventing hazards to the persons entering the room.

The included contact plug is equipped with a jumper at the factory. To connect a remote interlock contact, this jumper must be removed and your remote interlock contact must be connected to the same connectors. The external contact must be designed as a floating contact. If you do not want to use a remote interlock contact, the plug must be connected with the jumper provided at the factory.

Important information

The contact plug can only be connected if the device is switched off and disconnected from the power supply; otherwise the device could be damaged.

The contacts for the remote interlock and the foot switch must never be connected to the line voltage. Failure to observe this instruction could severely damage to the system. Only connect these connections as described in this section.

Tip

Please check that the laser cannot be switched to the READY state with this door open every day before starting treatment if you have connected a remote interlock contact to the entrance door. Please notify Technical Service in the event of a malfunction.

An external voltage source for a low-voltage warning lamp can be connected using two additional contacts of this plug connector. The switching relay inside the device is designed for the maximum voltage or maximum current as shown in the figure above. The safety requirements below must be followed when connecting an external warning lamp:

WARNING

Observe the following to prevent the risk of electric shock and associated severe health damage and the risk of fire in the transformer when operating the warning lamp using an external transformer:
A safety isolating transformer must be used in accordance with IEC 61558-2-6.

The internal relay is closed if the device is in the *READY* state.

The prescribed warning lamp can be switched on and off using a normal light switch when the laser is in use.

5.2.5 Foot switch

Now connect the foot switch to the foot switch socket on the rear side of the device (see figure *Connections on the rear side of the device*). The plug must be inserted as far as it will go and then secured by turning the coupler clockwise. The foot switch should be positioned in the immediate vicinity of the device.

5.2.6 Connection for spot recognition and purging air tube

The device is provided with an automatic detection system for the handpiece and thus for the spot size of the treatment beam. The information about the handpiece type connected is sent through an electrical cable to the control module of the device. This cable must always be connected. Otherwise, the system cannot detect the handpiece and will generate an error message.

In addition, the device is equipped with an internal pump, which produces a continuous airflow to prevent dust and particles from depositing on the optics during laser operations. A plastic tube, the purge tube, provides connection between the device and the handpiece.

Both connectors are mounted to the top of the device right next to the articulated arm and to the handpiece.

Important information

You should always make sure that both terminals of the purging air tube are firmly connected to the device and the handpiece, respectively. The device must not be operated with the tube disconnected, because this may cause damage to the handpiece optics.

5.2.7 Handpieces

The handpiece (with cable for spot-size recognition) is to be connected to the articulated arm. The plug of the cable for spot detection must be put into the corresponding socket of the cable, which is fixed at the articulated mirror arm by plastic holders. Please observe, that both red points of both connectors are at the same position. The tube, which must also be fixed at the articulated mirror arm, is put into the holes on the device (next to the articulated mirror arm) and on the handpiece (next to the cable). To change the handpiece and the spot size please see chapter *Operating the device/ Change of spot size of standard handpiece and change of handpiece*.

Important information

Make always sure that all connections are always properly engaged and the handpiece base body firmly screwed to the articulated mirror arm.

Configuration of the handpieces

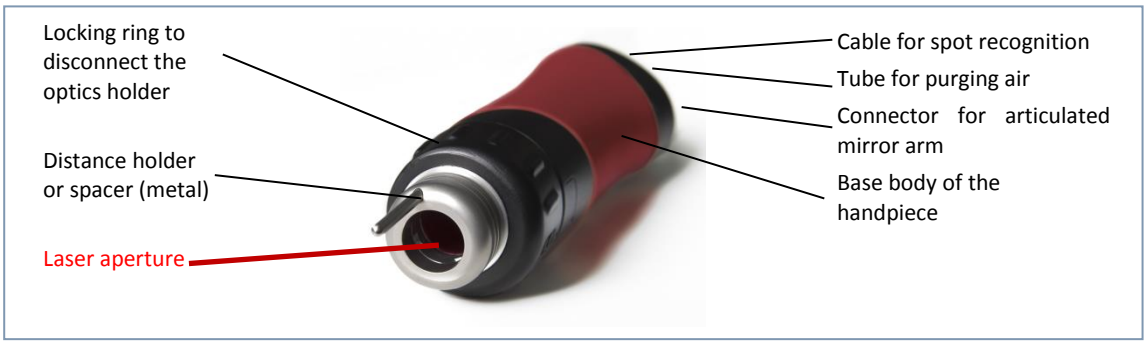


Figure 16: Standard handpiece

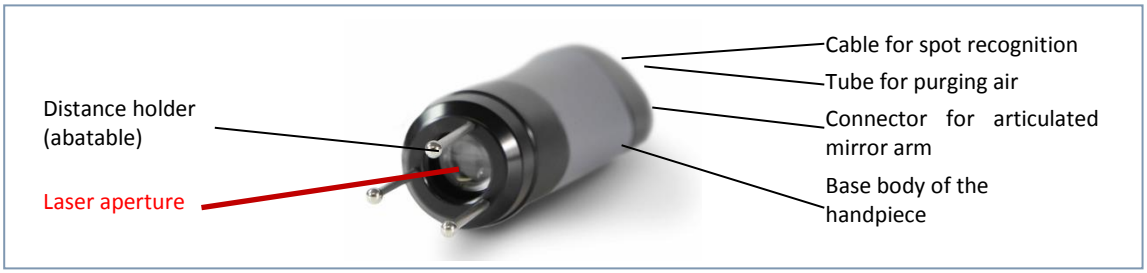


Figure 17: optional MicroSpot FRx handpiece for fractional treatments

5.2.8 Power grid connection

Important information

Observe all of the technical data for the local power supply and the device when selecting a power socket. First check that your power supply satisfies the previously mentioned connection requirements (supply voltage corresponding to type plate). Connecting the device to an unsuitable power supply can lead to damage to the device.

Please observe the requirements from regulations/standards in your country in their respective applicable versions.

Before connecting the device to the power grid, the shift paddle of the main switch must be on 0 (device de-energized). First plug the power cable into the power input on the rear side of the device before you connect the other side to the power socket. Operation of the laser requires that the device be connected to a single-phase power outlet protected by a **separate** fuse (delay-action fuse preferable).

5.2.9 Potential equalization line

The potential equalization line can be connected to the potential equalization connection at the back of the device, to the corresponding connector of other devices and to the fixed installed system. The potential equalization does not replace the ground wire of the device.

Important information

Please observe the requirements of the IEC 60601-1 regarding medical electric systems.

5.3 Switching on

Before switching on the device, make sure that the following requirements are fulfilled:

- The device is in proper condition (no damage).
- The voltage specified on the type plate is identical to the local supply voltage.
- The power plug of the device is connected to the correct power supply.
- The footswitch plug is properly connected and screwed to the footswitch socket on the rear side of the device.
- The plug for the remote interlock contact is properly connected and screwed to the rear side of the device.
- The handpiece is connected and clean and disinfected.
- Warning lamps are switched on at all entrance points.
- Secure the device against unintended moving by fixing the wheels. Otherwise there is the danger of injuries.
- Damaged parts must be exchanged immediately to avoid injuries.
  As long as a part of the device is damaged, it should under no circumstances be used.

Ensure that all safety measures have been met.

Then proceed as follows:

1. Switch the main switch on the rear side of the device to I (On).
2. Check whether the *Laser Emergency Stop* switch is deactivated (not pressed).
3. Then insert the key into the key switch and turn it clockwise as far as it will go.

6 Operating the device

WARNING

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
The equipment and procedures for operation, maintenance, inspection and calibration specified in this user manual must be observed.
The device is operated using line voltage. There is risk of electric shock!
The device adheres to the specified limit values for leakage currents. Nevertheless, ensure that contact with the patient and device does not occur simultaneously when the device is switched on.

6.1 General notes on operation

After switching on the start screen appears on the display while the device is automatically testing essential and safety-relevant parts.
Than the basic menu appears on the screen in STANDBY mode:

- the footswitch is disabled
- the pilot beam is disabled
- the spot size is displayed according to the spacer used
- the laser parameters used last are displayed

The READY state is activated by touching the STANDBY/ READY button
(see also chapter *Establishing the laser READY state and activating emission of the laser beam*).

STANDBY state:

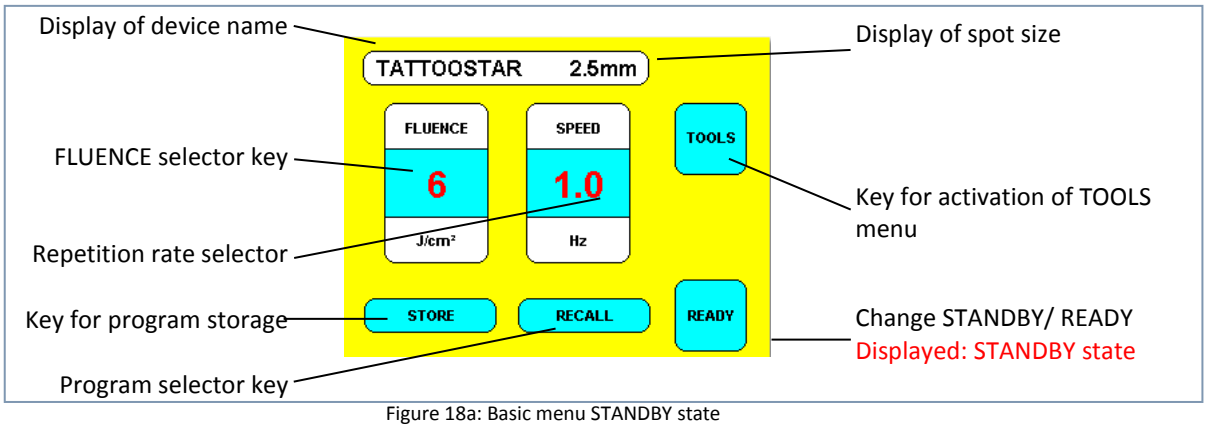


Figure 18a: Basic menu STANDBY state

READY state:

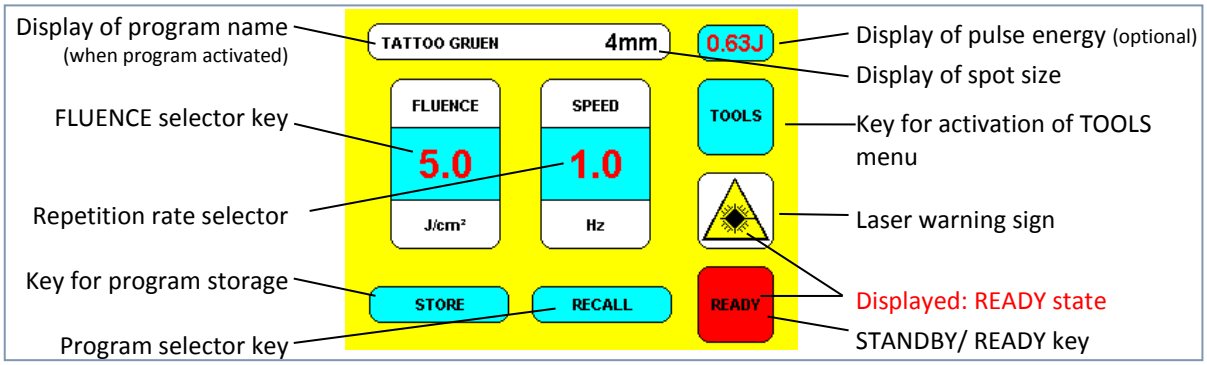


Figure 18b: Basic menu READY state

6.2 Setting the treatment parameters

The operation of the device with touch screen and combined rotary/push button (see Figure: *Front of the device*) is very simple and self-explanatory.

Successful key pressures are confirmed by the system by a short acoustic signal. This short acoustic signal can be disabled (see chapter *Operating the device/ Special function/ TOOLS*).

Laser parameters can be activated by touching the corresponding field on the touch screen. The enabled field is displayed with a red random.
The values of the activated parameter can be varied by turning the combined rotary/push button and accepted by either pushing the rotary/push button or pressing the parameter field on the touch screen.

The spot size of the connected optics holder, which is to be selected according to the structure to be treated, is automatically detected and displayed in millimeters in the screen header on the right. (For description of the change of the optics holder please see chapter *Operating the device/ Change of handpiece and spot size*.)

The adjustable FLUENCE (energy density), which is the crucial parameter for the treatment, is displayed in J/cm² in the FLUENCE field.

If the energy range is not sufficient to achieve the desired FLUENCE level for the selected spot size, an optics holder with a smaller spot size is to be used. The detection of the changed spot size and the new calculation of the FLUENCE value are performed automatically.

If within the FLUENCE field **a small triangle appears**, the energy has slightly increased (arrowhead pointing up) or decreased (arrowhead pointing down) within the tolerance limits. For details see chapter *Establishing the laser READY state and activating emission of the laser beam*.

The variable SPEED (pulse repetition rate), which determines the operating SPEED, is adjustable via the SPEED field: 0.5 Hz, 1 Hz, 1.5 Hz and 2 Hz (depending on the adjusted FLUENCE).

By pressing the READY key at the bottom right, the laser can be switched from STANDBY (footswitch not activated) to the READY mode (footswitch is activated, yellow laser warning appears).

6.3 Treatment database

The device lets you store 80 treatment records.

At the first start up of the system (after the installation), the database is completely empty. The manufacturer does not provide any predefined treatment protocols, as the treatment parameters must always be specifically selected to fit the treatment to be performed.

If you have found the correct parameters for the treatment, you can store them in the database as a treatment protocol. Thus, you can call them anew, if you have to treat either the same illness or kind of illness.

Please note: it is not possible to store parameters for the optional MicroSpot FRx handpiece.

6.3.1 Storing treatment parameters

Frequently used combinations of FLUENCE and SPEED values can be stored to the database under a definable program name.

In addition, the following values are stored automatically:

- program number,
- wavelength and
- spot size (used for the respective FLUENCE).

By pressing the STORE key, the database menu appears with the first free memory location being highlighted (see figure below).

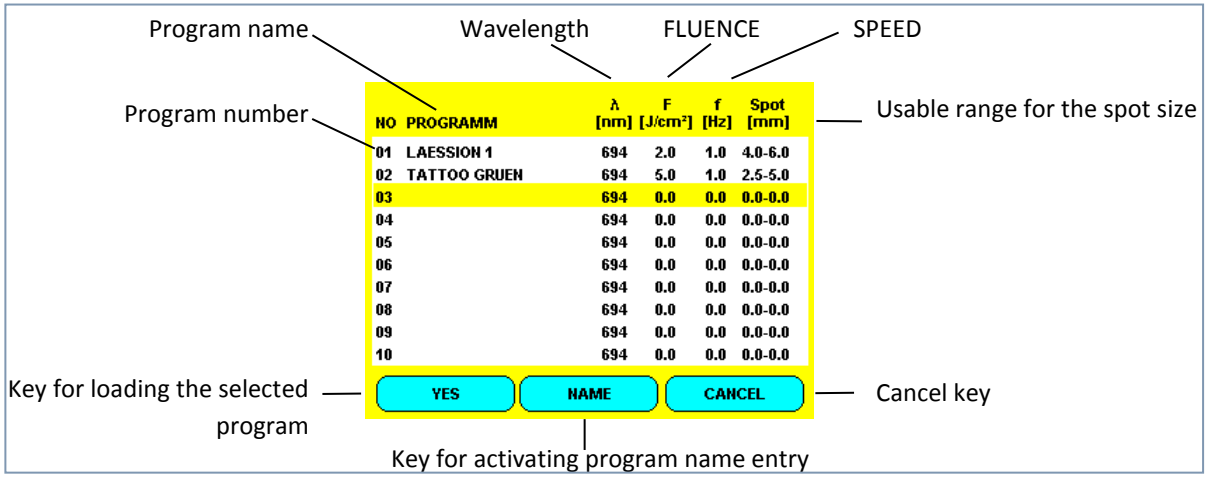


Figure 19: STORE screen

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

Key	Function	Notes
Rotary/push button	selecting another memory location	scrolling function
YES:	storing parameters to the selected memory location of the database and returning to the basic menu	automatically activates the NAME menu if a name has not yet been assigned
NAME:	activating the submenu for the entry of a program name	enters a new or edits an existing program name
CANCEL:	canceling	returns to the basic menu without saving any data

6.3.2 Editing the program name

To edit the program name, select the program name to be edited and press the NAME key in the STORE menu. This will bring up the keyboard display shown in the figure below:

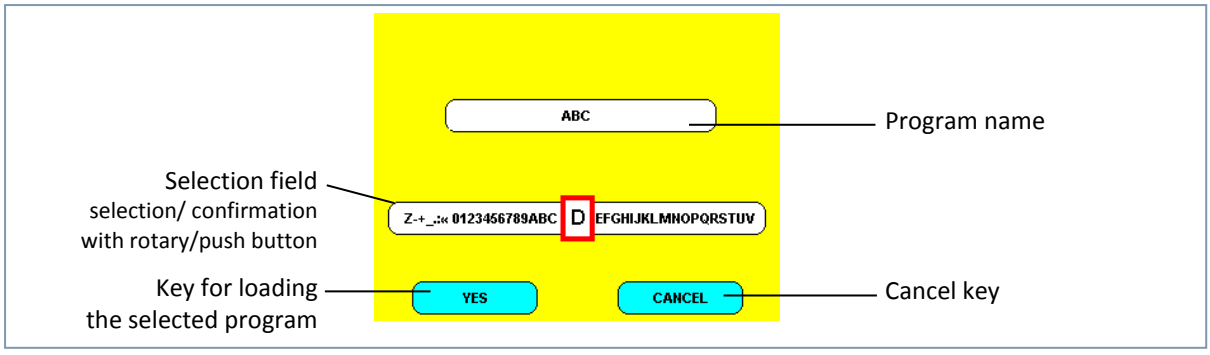


Figure 20: NAME menu

By turning and pushing the rotary/push button control, you can select and accept the desired characters. Names may have a length of maximally 12 characters.

An unintentionally entered character can be deleted by activating the sign «.

If the YES key is pressed, the name will be accepted and entered into the database. The name entry can be cancelled by activating the CANCEL key.

6.3.3 Activating a stored treatment

Stored parameters can be recalled by pressing the RECALL key (see figure below). In this list, the first program (Program No. 01) will be highlighted (see figure below). You can choose any other program by turning the rotary/push button.

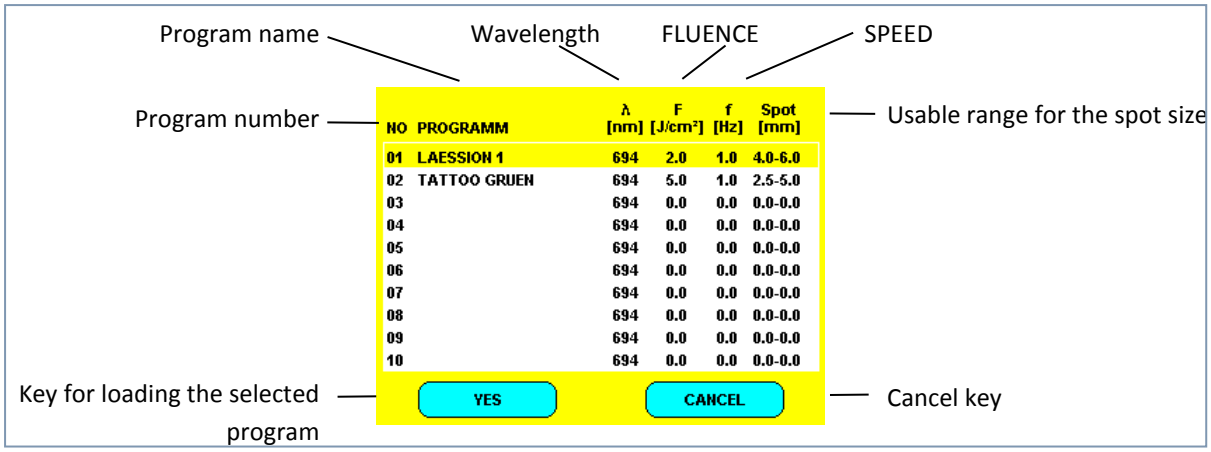


Figure 21: RECALL menu

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

KEY	Function	Notes
YES:	loading the selected program	loads the selected program and returning to the basic menu
CANCEL:	cancel	returns to the basic menu without loading new parameters

If, after a RECALL action, the selected FLUENCE cannot be adjusted with the currently used spot size, the system will prompt you to change the spacer.

6.3.4 Deleting a stored treatment

Stored treatments cannot be deleted but overwritten.

6.4 Special function/Tools

The TOOLS menu (see figure below) is activated by pressing the TOOLS key in the Basic menu.

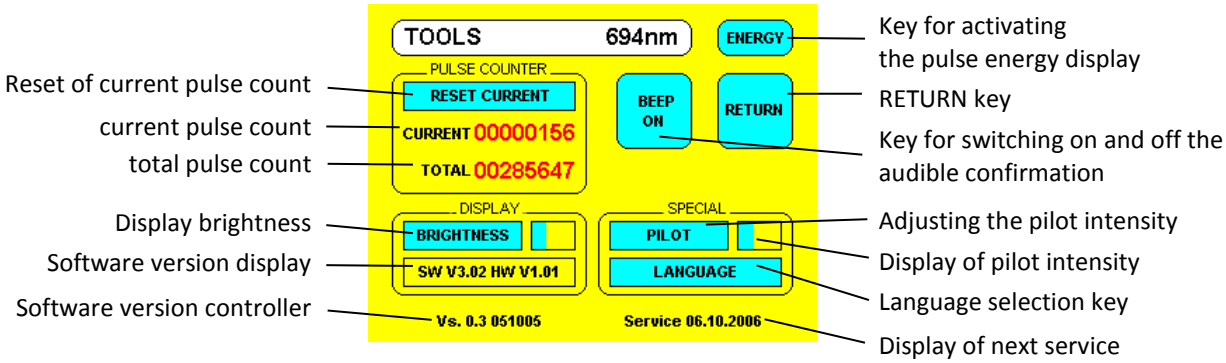


Fig. 22: TOOLS menu

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

KEY	Function	Notes
ENERGY:	activating/deactivating the display of energy in the Basic menu	display in Basic menu
RETURN:	returning to Basic menu	stores the changes made
BEEP ON/OFF	switches the acoustic confirmation of key pressures on and off	recommendation: activate the energy indication
RESET CURRENT (pulse counter)	manual resetting of the current pulse count (press the key **at least for 3 seconds**)	current pulse count will automatically be reset to zero when the device is switched off
CURRENT (pulse counter)	displaying the current pulse count	can be reset to zero
TOTAL (pulse counter)	displaying the total pulse count	cannot be reset to zero
BRIGHTNESS (display)	adjusting the brightness of the display	activation by pressing the key, adjustment by means of rotary/push button
PILOT (spezial)	adjusting the aiming beam brightness	activation by pressing the key, adjustment with rotary controls
LANGUAGE (spezial)	selecting the user interface language in the LANGUAGE menu	selection by scrolling with the rotary/push button; activation by pressing the YES key

6.5 Change of the spot size of the standard handpiece and change of the handpiece

The spot size of the standard handpiece can be changed by exchanging the optics holder, which includes the optics for the spot sizes. (Bayonet fitting; please see note in figure).

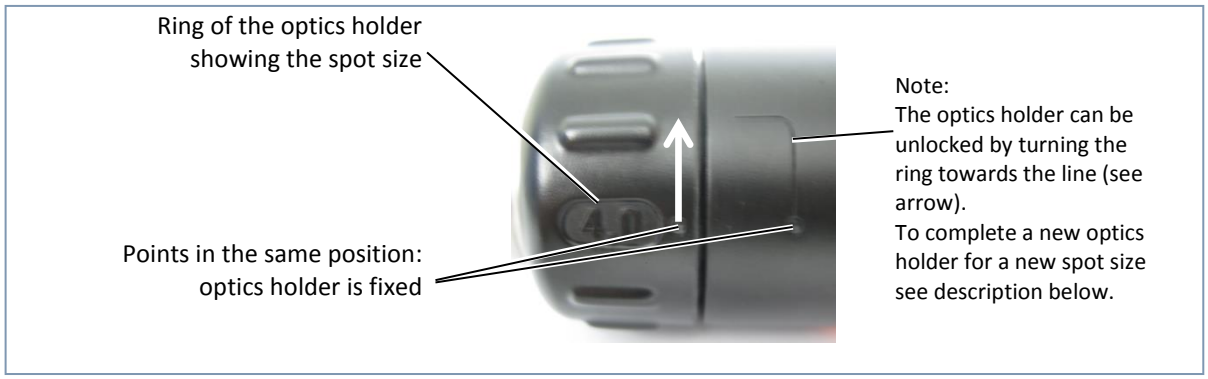


Figure 23: Markings on optics holder and basic body of the standard handpiece

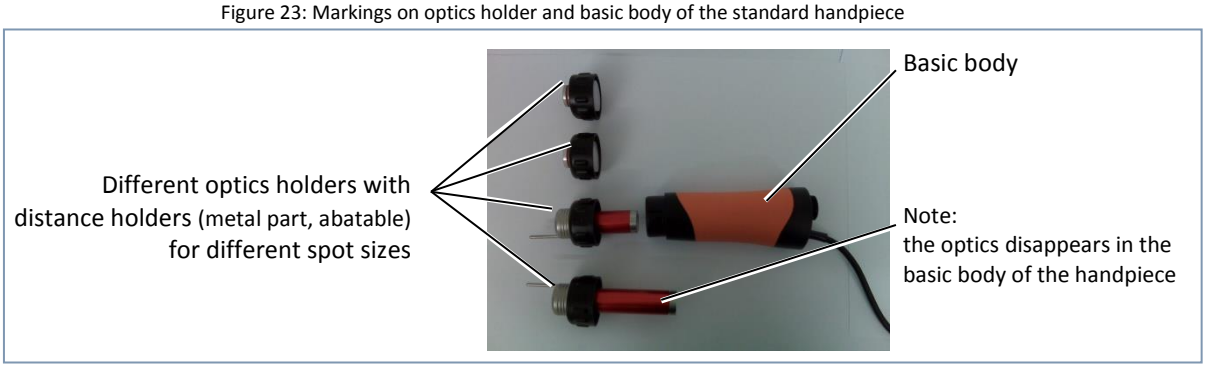


Figure 24: Standard handpiece with different optics holders separated

To adapt a new optics holder to the basic body of the standard handpiece, first the point on the ring must be positioned to the end of the line on the basic body.
Subsequently the optics, if protruding, must be slid into the basic body with slight pressure, but carefully. Than the ring of the optics holder is rotated in a way, that both points (ring – basic body) are at the same position and the optics holder is fixed.

For cleaning, disinfecting and sterilization the distance holder (spacer) can be removed from the plastic ring. Screwing is not necessary. Please see chapter *Cleaning, disinfection and sterilization of handpieces*.

The device must be switched off before the handpiece is changed. After, the purging tube is pulled out from the handpiece. Subsequently the plug of the cable is removed from the plug of the cable, which is fixed at the articulated mirror arm by plastic holders (not to be screwed). Then the handpiece can be screwed off the articulated mirror arm by the knurled ring.

The new handpiece is connected in reverse order. Please observe that both red points on both connectors of the cables are in the same position before connecting them (not to be screwed).

Important information

Please ensure that the optics holder is always fixed securely to the basic body of the handpiece as well as the basic body to the articulated mirror arm.

6.6 Establishing the laser READY state and activating emission of the laser beam

Also see chapter *Application*!

After switching on, the laser is in the STANDBY state.

Check again to make sure that

- The handpiece is connected correctly, clean, disinfected and the distance holder (metal part) sterilized if necessary (see chapter *Cleaning, disinfection and sterilization of handpieces*)
- All laser protection measures have been met
- Check the function of the door interlock if you have it installed: Open the door; it must **not** be possible to switch the laser to the READY state (an error message is displayed and must be acknowledged)

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

WARNING

Direct and scattered laser radiation can cause severe eye injuries.

Everyone in the room where the laser is being used must wear protective eyewear or patient blackout glasses suitable for this laser while the laser is active, as specified in chapter *Technical data*. Other forms of protective eyewear may not ensure sufficient protection!
The user must confirm this before pressing the READY button.

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

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

Pressing the READY/ STANDBY button lets you switch to the READY state. This causes the yellow laser warning sign to appear in the lower right of the display. First, a safety check of the hardware is carried out. This only takes a few seconds (see figure *READY state*).

Then the yellow laser warning sign appears on the bottom right on the display.

The airflow, which blows the ablated skin particles away (to minimize dirt on the optics of the handpiece) and the pilot laser are enabled.
Before activating the treatment beam, the beam delivery system has to be checked.

Check of the beam delivery system

The beam delivery system consist of the articulated mirror arm and the handpiece

Important information

As the aiming beam takes the same path through the laser beam delivery system as the working beam, it offers a good method for checking the integrity of the beam delivery system. If the aiming beam does not appear at the distal end of the beam delivery system, it's intensity is low or if it looks diffuse this may indicate that the beam delivery system is either damaged or misaligned.

Please proceed as follows:

- If the intensity is low, please check the setting in TOOLS
- Switch off the device
- Check once more, that the handpiece is correctly screwed to the articulated mirror arm. Loosen the screw.
  Please screw on again and make sure, that the handpiece is straight and not tilted. The knurled ring should easily be rotatable.
- Check once more, that the optics of the handpiece is clean and clean it if necessary (see chapter *Cleaning, disinfection and sterilization of handpieces*).
- If all is in best order and the pilot beam is not or hardly visible, the device must not be used any longer. In these cases, you should stop using the device and instantly contact the Technical Service.

Important information

If the spot of the aiming beam shows any imperfections at the distal end of the beam delivery system, you must not activate the treatment beam to avoid damage to the device.
Assess the spot of the aiming beam only by directing the handpiece to a white sheet of paper (spacer in contact). Never look directly into the beam (into the handpiece).

The therapy beam may only be activated after the successful check of the beam delivery system. Make sure that you do not press the footswitch unintentionally.

Pressing the foot switch releases the laser radiation from the laser tip of the handpiece with the set parameters. Releasing the foot switch immediately interrupts the laser emission.
The emission of the laser radiation is indicated audibly by a warning tone and visually by the flashing laser emission indicator on the device (see figure *Front of the device*).

WARNING

Laser radiation can cause severe eye injuries.
The device is equipped with a *Laser Emergency Stop* button that is easy to operate. This red button is on the front of the device. In an emergency, pressing this switch immediately deactivates the laser. This eliminates any danger to the operator and patient from the laser.

Once the emergency situation has been corrected, gently turn the *Laser Emergency Stop* button clockwise by hand until it is in its normal position to restore the proper device functionality.

CAUTION

If the symbols "△" or "▽" appear in the FLUENCE field while using the laser, this means the device has detected a deviation from the starting values that is more than 20% too high or too low.
An upward deviation can lead to unwanted side effects; a downward deviation makes the treatment less effective.
Reduce or increase the parameter accordingly and if this occurs frequently, please notify technical support.

Once treatment is finished, switch the laser to the secure STANDBY state by pressing the READY/STANDBY button. Also switch the laser to the STANDBY state if you temporarily interrupt treatment. Unintentional activation is not possible in this operating state.
After prolonged inactivity in the READY state, the device automatically switches to the STANDBY state.

The handpiece must be put into a safe position. For this purpose the distal end of the articulated mirror arm, to which the handpiece is screwed, is to be hooked into the plastic hook. It is mounted at the lower part of the articulated mirror arm.

6.7 Switching off the device

Exit the READY state and switch to the STANDBY state by pressing the STANDBY/ READY button.
The laser is switched off by turning the key switch counterclockwise as far as it will go. Only then should you switch off the power switch at the rear panel of the device *(*see Figure: *Rear side of the device*). Switching the device main switch to "0" (OFF) completely disconnects the device from the line voltage.

Immediately after the handpiece is to be cleaned and disinfected, if necessary the distance holder is to be sterilized (see chapter *Cleaning, disinfection and sterilization/ Handpiece*). It must be checked, that the handpiece is in order (see chapter *Regular maintenance, safety checks and calibration/ Routine maintenance*).

The device is also to be cleaned and disinfected (see chapter *Cleaning, disinfection and sterilization*). Subsequently it is checked, that the device is in order (see chapter *Regular maintenance, safety checks and calibration/ Routine maintenance*).

WARNING

Direct and scattered laser radiation can cause severe eye injuries.

Never leave the laser device unattended while it is switched on. Completely disconnect the device from the line voltage with the main device switch. After switching off the device, ensure that the key is removed and kept in a secure place to prevent unauthorized use of the device.

7 Application

7.1 General information

Specific information for application is provided in this application section. The instructions provided can never replace expert knowledge for the medical application of lasers, extensive studies of relevant literature, personal experience gained under supervision and critical assessment of the current situation.
However, these instructions serve as useful support for beginners and as a memory aid.
Therefore, we recommend studying current medical literature and contacting physicians in private practices using such equipment in order to familiarize yourself with the methods of laser treatment before you start to treat patients yourself.
We would be happy to assist you in mediating contact with other users. Your responsible sales Representative would be happy to provide detailed information.

User requirements

Please observe the chapter *Intended use/ Requirements for the user.*

Users must have sufficient knowledge of safe and efficient operation of this product before operating the device described in this User manual. Training is carried out by employees or authorized persons from Asclepion Laser Technologies GmbH based on the User manual and is documented in the medical device log book. The user must be trained on the following points:

- Instruction on operation and the intended use of the device with practical exercises
- Operating and functional principle of the device and the energies applied
- Settings for all control parts
- Indications for device use
- Contraindications and side effects
- Warnings in all operating states
- Carrying out functional tests

Additional training requirements differ by country. It is the responsibly of the operator to ensure that training corresponds to the requirements of all applicable regional laws and provisions.

WARNING

Laser radiation from the device can lead to thermal changes in tissue structures.
Make sure you have understood the principles of laser-tissue interaction as summarized below, the correlations between the individual application parameters, the application techniques as well as the basics of laser safety.
If you are even the slightest bit unsure of any aspect, consult one or more colleagues with practical experience and/or the application specialists from your distributor authorized by Asclepion Laser Technologies GmbH before you start performing laser treatment.

CAUTION

The application of laser radiation on skin can cause damage to tissue structures. This may be intentional or unintentional depending on the indication.
The user is responsible for correctly determining the indication, the treatment zone and the treatment parameters. The user is also responsible for the correct positioning of the handpiece.
Before and during treatment, the set parameters must be checked on the display.

CAUTION

During and after treatment, the effect of the laser beam can cause side effects in the treatment area. These side effects are individually very distinctive.

Therefore, a test treatment must always be carried out in a small area as described below. This is intended to minimize side effects while keeping treatment effective.

It is important to consider that the side effects can be more severe when treating larger areas than when treating a small test area.

Note: do not use frozen ice packs for skin cooling to avoid side effects caused by frostbite!

In addition, the test treatment gives patients a better impression of the treatment and allows them to make a better decision before consenting to treatment.

Tip

As part of the informed consent discussion, patients must be informed of all risks resulting from the actual treatment and from pre- and post-operative care. The discussion must also explain the operating mechanism behind laser treatment, alternative methods, the time required, the treatment prospects and information about patient behaviour after laser treatment.
A log of this discussion and a signed declaration of consent should be retained. Before and after photos are also recommended.

WARNING

The distance holder of the handpiece comes into contact with the patient when treating the skin. There is the risk of transmitting microorganisms.
The handpiece must be disinfected before each treatment and must be cleaned and disinfected after each treatment, if necessary the distance holder sterilized, according to the procedure described in Chapter *Cleaning and disinfecting*.

CAUTION

Any absorbent dirt on the optics of the handpiece generates localized overheating, which can lead to increased side effects and defects on the handpiece!
Make sure that the laser tip of the handpiece is clean and remains clean during treatment!

WARNING

For treatments with the laser the use of hearing protectors for all persons in the room is strongly recommended. There is the risk of hearing damage in particular in longer treatments.

7.2 Interaction between laser beam and tissue

The goal, specifically for dermatological and aesthetic treatments, is to eliminate lesions that require therapy or are bothersome without any side effects. The **selective photothermolysis** method, which was introduced by Anderson and Parrish in 1983 with this goal in mind, ensures effective damage to the target whilst protecting the surrounding skin.

With this in mind, the following issues must be observed for successful treatment:

Absorption of the laser beam - wavelength

- The absorption of the laser beam in the target (e.g. melanin in pigmented lesions, artificially introduced dyes, dirt particles) must be higher than in the surrounding skin, which primarily contains of water.
- However, with dark skin types and tanned skin the epidermis also contains melanin which, of course, likewise will absorb the energy of the laser beam. Therefore, tanned persons must not be treated (undesired side effect: pigment changes).
  Dark skin should be treated with care and pigment changes are also to be expected, of which the patient should be informed.
- The higher the absorption (i.e. the darker the pigment) is, the less FLUENCE is needed to reach the effect as gentle as possible.
- Multiple treatments sessions are needed for a number of indications. With every treatment a part of the pigment is removed and therefore the absorption becomes lower. That's why normally the treatments are started with low FLUENCE and in subsequent treatment sessions higher FLUENCE is necessary.

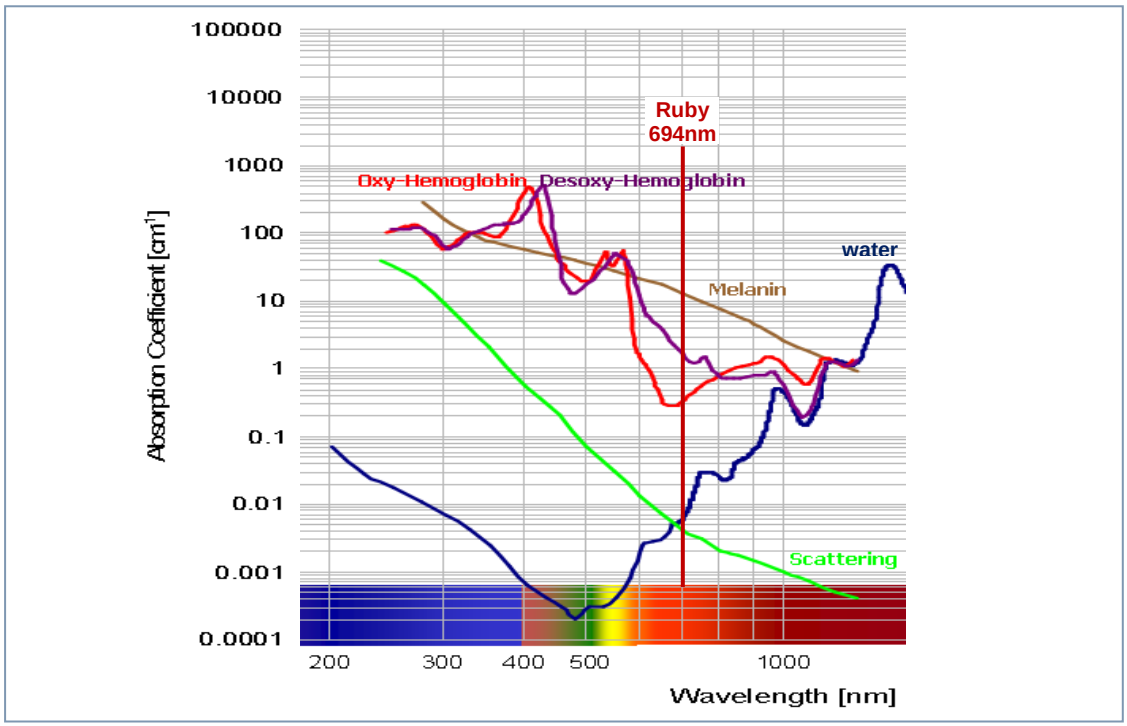


Figure 25: Absorption coefficients in relation to the wavelength of the laser beam

Overview of possible indications:

	694nm (Ruby laser)
Technology	Ruby
Benign pigmented lesions	yes
Tattoos and Permanent Make-up	black, green dark colours
Dirt	yes
Melasma/ Chloasma*	yes with MicroSpot FRx only

* Sun protection must be used all time (not only before and after treatment), otherwise recurrences have to be treated once more.

FLUENCE (energy density)

The crucial parameter in treatment with a pulsed laser device is the FLUENCE (corresponds to intensity). It can be set directly on the display.

The higher the FLUENCE the more effective is the treatment – but more side effects are possible, too. That's why test treatments must be performed first and when 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 maximally possible FLUENCE can be reached with the smaller spot sizes (due to technical reasons).

Spot size

The spot must be large enough so that the target located in the skin (e.g. pigment, dirt particles) is reached with sufficient energy density (FLUENCE). This is assured with this device.

The larger the spot, the deeper is the penetration of laser light with the same FLUENCE.

The spot size can be adapted to the needs by changing the optics holder of the standard handpiece.

Typically the spot size of 4mm is used.

Pulse duration

The pulse duration should be not significantly longer than the thermal relaxation time of the target to avoid unnecessary heating of the surrounding. The thermal relaxation time is the time in which the target emits 50% of the heat into the environment.

The relaxation time of natural and artificial pigments is very short (pigments are very small). For gentle removal of the pigment by fragmentation of melanin or artificial particles a laser is to be used, which emits Q-switched pulses in the nanosecond range, as the TattooStar.

Due to the extremely short pulse there is a micro-explosion at the target, which leads to a shock wave and disrupts the particles (**photo disruption**). At the same time the water of the tissue is vaporized. This can be seen as whitening of the epidermis (also called blanching). The water vapor disappears from the white "blisters" in about 20 minutes.

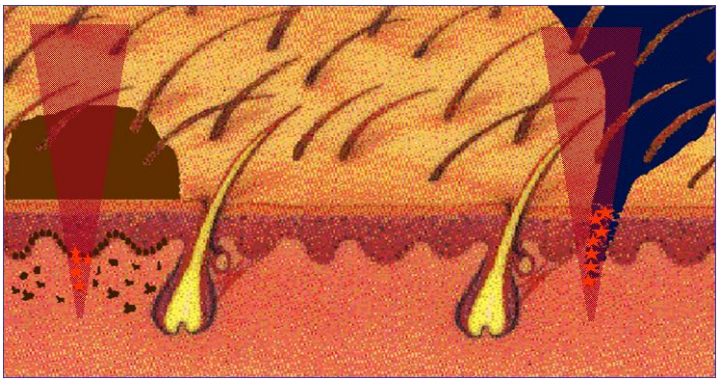


Figure 26: Interaction between very short pulses and pigments in the skin

Cooling the epidermis

Cooling of the skin after treatment is always recommended to avoid unwanted side effects. In particular it is important after treatment of larger areas and darker skin due to melanin absorption. During treatment of larger areas the sub-areas, which are already finished, should be cooled already.

Please take care, that the cold packs and the like are not frozen!

Fractional treatments with the MicroSpot FRx handpiece of the Ruby laser (optional)

The standard handpiece emits the energy homogeneously via the given spot size. Contrary to that, the MicroSpot handpiece applies with one pulse a series of very small micrometer spots simultaneously (by means of a special optics) as a square grid.

The advantage of this technique, which is called fractional treatment, is that it is extremely gentle and has very low side effects. Due to the amount of untreated skin (ca. 70%) between the micro-spots the wound healing is much better.

On the other side, with this technique multiple treatment sessions are necessary to reach a good result. Moreover, only superficial lesions can be treated, because the penetration depth is limited to the epidermis due to the very small spots.

7.3 Classification of skin types

Skin type		
I ("Irish" skin type)	Pale white skin, blond or red hair, freckles, blue or green eyes	Always burns, never tans
II (frequent in Central Europe)	Fair skin, blond hair, freckles, blue or green eyes	Usually burns, tans minimally
III	Light brown or brown hair, brown eyes	Sometimes mild burn, tans uniformly
IV (Mediterranean type)	Light brown skin, dark or black hair, brown eyes	Rarely burns, tans quickly
V (Some Indians, South Americans)	Dark skin, black hair, dark eyes	Rarely burns, tans very quickly
VI (some Africans, Indians)	Very dark or black skin, black hair, black eyes	Never burns, tans very quickly

7.4 Removal of benign pigmented lesions

Q-switched lasers as TattooStar are very well suited for the removal of natural pigment (melanin). Basically, however, only benign skin lesions can be treated with a laser!!

Examples for indications, that respond well:

- Lentigino benigna (simplex/ juvenilis, senilis/solaris)
- Ephelides

Examples for indications, that may respond – result individually different,
(condition may improve, remain unchanged or even worsen)

- Nevus Ota/ Ito
- Melasma/ Chloasma (fractional treatment with MicroSpot handpiece only!)

7.4.1 Effective mechanism of pigment removal

The dark red light of the Ruby laser (694 nm) is very strongly absorbed by the natural skin pigment melanin. This leads to the fragmentation of melanin because of the extremely short pulses emitted by Q-switched lasers. Afterswards, the skin reacts with an inflammation. Part of the fragmented particles will then be taken away by the lymphatic system, while the other part will be cast off by the following incrustation.

On the other hand, these wavelengths are only absorbed to a very low degree by tissue water and blood. Therefore, these wavelengths are well suitable for the removal of benign pigmented lesions.

7.4.2 Treatment notes

For contraindications please see chapter *Intended Use*.

WARNING

The removal of pigmented lesions of the skin holds a risk of not identifying and/ or incompletely removing malignant or pre-malignant conditions. This can cause serious and even life threatening health damages.

Before performing a laser therapy of pigmented skin lesions, you should verify by dermatoscope or better by histology, beyond any doubt, that you are dealing with a benign lesion. Make absolutely sure that no malignant melanoma or any pre-malignant stage is involved! The corresponding documentation is strongly recommended.

CAUTION

Patients with Fitzpatrick skin types I to III may well be treated with 694 nm.

But the darker the skin, the higher will be the risk of pigment changes. As a rule, these will persist during a few weeks or some months. With dark skin, however, in some cases they may persist permanently! Make sure to inform your patients accordingly.

Fractional treatments with the MicroSpot FRx handpiece

Due to the fact, that side effects are very low, this handpiece is very well suitable for larger treatment areas in the face. For indications with superficial melanin, such as ephelides and lentigo benigna, one can treat complete areas of the face. Besides a slight redness there are no more side effects. Patients can resume normal social activities immediately.
After treatments with the standard handpiece there would be many or larger crusts for some days.

Melasma/ Chloasma can only be treated with the gentle MicroSpot FRx handpiece. Abstention from UV light is absolutely necessary to prevent recurrences.

7.4.3 Preparation for treatment

Before a laser treatment, it is important to identify correctly possible factors, which could influence the effect of the treatment. For that reason a precise anamnesis and diagnosis is of crucial importance.

The area to be treated must be clean. Hair, deodorant or other cosmetic products must be completely removed!

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

Anesthesia is normally not required since laser treatments of small lesions using the TattooStar involves relatively little pain.
For sensitive or extensive treatment areas, a topical anesthetic such as EMLA is recommended, because it also reduces the subsequent swelling.

In addition, effective skin cooling before and after the treatment decreases pain sensitivity (e.g. Cool Packs or cold air; in case of larger areas also during treatment).

7.4.4 Test treatment

CAUTION

The laser radiation of this device can cause preventable unwanted modification of the tissue, when used with wrong application parameters. Moreover the success of the treatment varies individually for some indications and even a darker re-pigmentation is possible!

To be able to assess the success of a therapy, you should perform an initial trial treatment in case of multiple lesions or larger areas on a representative area with low starting parameters before you proceed with the treatment of extended skin areas.

Please consider, that there are normally more side effects, if the treated area is larger.

It is advisable to perform a test treatment within the scope of patient information. It allows to assess the skin reaction of the patient; besides it gives the patient a better idea of the treatment procedure.

The test treatment including the required pre-operative and post-operative treatments should be performed by using the same procedure as for the actual laser treatment, but a few pulses are emitted only.

WARNING

Laser radiation can cause in particular severe eye injuries.

Before starting laser treatment, all personnel in the room must put on the laser safety glasses including eye protection for the patient in compliance with the information in chapter *Technical data*!

If the treatment area is right next to the eyes, the eyes of the patient must be protected by special eye shields, which can be sterilized. They must be used with local anesthesia (drops) and are placed directly on the eyeball.

The procedure starts with low FLUENCE, which is increased until the typical noise of photodisruption can be heard and the whitening can be seen. That disappears after ca. 10 – 20 minutes. The lowest FLUENCE achieving this effect is the parameter to be used further.

The less pigment is in the skin, the higher the FLUENCE needed for the whitening effect.
If the highest FLUENCE with large spots is not efficient, a smaller spot must be used by changing the optics holder. The new spot size is automatically recognized by the device and a higher FLUENCE can be set.

Usually the spot size of 4mm is applied, because one can perform most of the treatments without changing the spot size (optics holder).

If the MicroSpot handpiece is used, the clinical endpoint is a slight redness or lightening. One to two grids are sufficient.

7.4.5 Laser treatment

CAUTION

It is in principle conceivable, that hearing impairments are caused by the typical noise of photodisruption during longer and often performed treatments. So far there are no reports known.

Nevertheless it is recommended to use hearing protection in these cases to be on the safe side.

For the laser treatment, adjust the FLUENCE found in the test treatment. Apply laser pulses to the area to be treated without any overlaps and gaps. The handpiece of the TattooStar is equipped with a microlens array that ensures an ideally homogeneous spot of square shape. This provides very homogeneous treatments without any 'hot spots' (increased power) and without leaving any gaps between the spots.

For darker skin types (type III and darker) you should not treat much area beyond the edge of the pigmentation. The spot size used is to be adjusted accordingly to avoid pigment changes in the area surrounding the treatment zone. With small lesions, of course, possibly a single spot will do.
It is also possible to cover the surrounding of a small lesion by a white, soft pencil (e.g. eyeliner pencil). The white coating reflects the laser light and the subjacent skin will not be treated.

The treatment should be performed as fast as reasonably possible to reduce the pain and urticarial alterations to a minimum if larger areas are treated (see also chapter *Possible side effects*).

When sensitive skin is to be treated, a careful procedure is advisable. So, for instance, you should not remove all lentigines from the back of the hand in the same session, if their number is great. This would be found very unpleasant by patients because of the following incrustation. Better would be the use of the MicroSpot handpiece.

If the MicroSpot handpiece is used, the treatment procedure is similar. The grids are applied without any overlaps and gaps. Always complete aesthetic areas should be treated to avoid visible lines between redness and untreated skin after treatments. If the cheeks are treated the grids should be applied around the jawbone.
Experienced users can also perform two passes successively for treatment of lentigo benigna to reduce the number of necessary sessions.

7.4.6 Post-treatment

The treated area should be continuously cooled after treatment, e.g. with Cool Packs (not frozen!) for about 20 minutes.

Possible epidermal irritations are to be covered with antibiotic ointments; they will heal within two weeks without leaving any scars normally.

CAUTION

Radiation on the treated area from the sun and tanning beds after treatment causes increased side effects, particularly alterations in pigment.
Therefore, this type of exposure must be avoided for a period of 6 – 8 weeks or sunscreen of SPF 50 must be worn.
Traumatizing the laser-treated area must also be avoided for 2-3 days. Crusts must not be manipulated.

7.4.7 Possible side effects

The intensity of all adverse reactions will be the higher the more pigments are embedded in the skin (including skin type), the larger the treatment area, the higher the fluence used and the more sensitive the skin is.

- During treatment the patients feel a prickling sensation, which becomes uncomfortable with larger areas to be treated. Reduction of pain by skin cooling, if necessary local anesthesia.
- Immediate reaction: whitening/ blanching (clinical endpoint)
  Immediately after treatment, for larger areas also during treatment, formation of local erythema and edema (for 1 – 2 days), subsequent exudation.
  The discrete crusts arising after 1 to 2 days fall off by itself within a few days and must not be manipulated or macerated by patients (no sauna or swimming pool).
- Urticarial reaction are caused by neuropeptides and can be inhibited by working fast, local anesthesia and capsaicin (nonsteroidal anti-inflammatory drugs have no effect)*.
  * Citation of Dr. med. A. Schwinn, dermatologist and laser expert, Memmingen, Germany
- Blisters are also possible (risk of superinfections and scars), but should be avoided by lower FLUENCE values (test treatment!).
- It is not in each case possible to avoid purpura up o pinpoint bleeding or hematomas.
  (less frequently with Ruby).
- Transient pigment changes and textural changes are possible (UV protection, patients tanned in the treatment area must not be treated!).
- With recommended treatment procedure and compliance of the patient scars are rare.
- If an allergic reaction occurs during treatment, stop treatment (see *Contraindications*).

If the MicroSpot handpiece is applied, the side effects are significantly less, normally a slight redness only.

7.4.8 Follow-up treatment

The number of treatment sessions needed for a good result depends on the depth of pigments in the skin and ranges from a single treatment only with most of the lentigines to numerous sessions to achieve complete brightening of some nevi Ota.

For some lesions a complete lightening is not always possible and should not be promised.

The interval between the treatment sessions should be at least six weeks. If after several treatments stagnation is to be observed in the brightening, a longer break of at least 3 months should be taken.

If the MicroSpot handpiece is applied, about 3 – 5 sessions are necessary for lentigines, whereas about 8 sessions are needed for treatment of Melasma (with shorter intervals).

7.5 Removal of tattoos and other kinds of dyschromia

The following artificial pigments can be treated:

- traumatic tattoos, e.g. debris, soot, carbon particles
  (bad results for harder matter as iron particles or pebbles)
- drug - induced dyschromia (inconsistent results)
- amateur tattoos
- professional tattoos / permanent make up

In recent years, many millions of people – especially young ones – had themselves tattooed. Later, tattoos often become annoying. Then, the wish to have the tattoo removed is the logical consequence. Only Q-switched lasers can do this without leaving any scars.

7.5.1 Effective mechanism in removal of tattoos and other kinds of dyschromia

Like the natural pigment melanin, color and dirt particles, which absorb the laser light much stronger than the surrounding skin, are destroyed by the high power density of the very short Q-switched pulses and subsequently phagocyted.
The darker the tattoo, the higher is the absorption and thus the effect, but also the side effects.

7.5.2 Treatment notes

For contraindications please see chapter *Intended use/ Contraindications*.

WARNING

The removal of pigments of the skin holds a risk of not identifying and/ or incompletely removing malignant or pre-malignant conditions. This can cause serious and even life threatening health damages.
Before performing this laser therapy, you should verify that no pigmented nevus is in the tattooed area. If there is a pigmented nevus, make absolutely sure that no malignant melanoma or any pre-malignant stage is involved by dermatoscope or better by histology! If any question about malignancy arises, it must be excised!
The corresponding documentation is strongly recommended.

Dark tattoos (black, dark blue, brown) and dirt particles can be removed very well by using the ruby laser.

Green tattoos can be treated with the red ruby laser (694 nm).

Because of their low absorption, bright tattoos (yellow, white, 'skin colored') can be removed only with difficulties or not at all.

Melanin absorbs the laser light too, of course, so that pigment changes are to be expected.

CAUTION

Tanned patients should postpone laser treatment! In most cases pigment changes are very likely, which are usually transient.

The success of treatment, however, depends on various factors.

- Amateur tattoos require fewer treatments (on average 5 – 10) than professional tattoos (more than 10, sometimes up to 20), where usually many more color pigments were introduced into the skin. Multi-colored tattoos are difficult to treat.
- The depth and the amount of ink particles play a role.
- Tattoos near the trunk show a faster reaction compared to the removal of very distal tattoos on the fingers, which takes longer.

- Old tattoos respond better normally.
- The chemical composition of the ink of professional tattoos or permanent make-up is very different. The reaction of the inks to laser treatment cannot be foreseen for each individual case. See chapter *Side effects* below.
- A test treatment is absolutely necessary (see below)!
- Moreover it is extremely difficult to remove tattoos, which were already tattooed several times (subjacent tattoo). We strongly advise against treatment of these tattoos!
- For professional tattoos which were very densely engraved, it is quite possible, that the tattooing procedure already caused scars. These scars cannot be seen due to the color, but they can be felt. After removal of the ink, the scar becomes visible!
  Caused by the scarred tissue the number of sessions needed may be higher and the result poorer.

The patients must be informed accordingly, so that they can decide for or against the treatment with regard to success rate and side effects (written consent!).

7.5.3 Preparation for treatment

Before a laser treatment, it is important to identify correctly possible factors, which could influence the effect and side effects of the treatment. For that reason a precise anamnesis is of crucial importance.

Pre-test before test treatment of the face (permanent make-up), which could be possible:

A test treatment in the face even with a few spots is very unwanted, if a color change happens – even if the patient is well informed. Alternatively there could be the following possibility:
If the patient can provide the **identical** ink, which was tattooed (not a similar e.g. red; the chemical composition is crucial and can be different even if it looks the same!), one can put the ink on a white paper and fix it with a transparent tape. Afterwards one can – as described below – fire some pulses onto the ink. Then one can see, if the color is changing or not.
It is even better, when the **identical** ink is tattooed on a small, inconspicuous place (e.g. axilla). Then it can be tested as described below and it is possible to assess the skin reaction additionally.

The area to be treated must be clean. Hair, deodorant or other cosmetic products must be completely removed!

Photos should be taken to document the success of the treatment, also for test treatment..

Anesthesia is normally not required since laser treatments of small lesions involve relatively little pain.
For sensitive or extensive treatment areas, a topical anesthetic such as EMLA is recommended, because it also reduces the subsequent swelling.

In addition, effective skin cooling before and after the treatment decreases pain sensitivity, e.g. with Cool Packs (not frozen!) or cold air (in case of larger areas also during treatment).

7.5.4 Test Treatment

VORSICHT

The laser radiation of this device can cause preventable unwanted modification of the tissue, when used with wrong application parameters. Moreover the reaction of the tattooed ink to the laser treatment cannot be foreseen for the individual case!
To be able to assess the success of a therapy, you should absolutely perform a trial treatment on a representative area with low starting parameters before you proceed with the treatment of extended skin areas.
In case of different colors, each color must be tested!
Particular care should be used in the case of:

- Dirt tattoos resulting from explosive device injuries
  (Danger of explosion, brush out and flush with physiological solution before treatment! Please use face protection)
- Dirt tattoos in connection with grazes
  (even dirt particles may explode! Please use face protection)
- Professional tattoos, so-called 'bio' tattoos, permanent make-up
  (color change may occur!)
- Allergic reaction to the piercing of a tattoo (allergic reaction during removal)

Please consider, that there are normally more side effects, if the treated area is larger.

It is advisable to perform a test treatment within the scope of patient information. It allows to assess the success and the side effects in a small area before the real treatment is started.
Besides the skin reaction of the patient can be seen and it gives the patient a better idea of the treatment procedure.

The test treatment including the required pre-operative and post-operative treatments should be performed by using the same procedure as for the actual laser treatment, but a few pulses are emitted only.

WARNING

Laser radiation can cause in particular severe eye injuries.

Before starting laser treatment, all personnel in the room must put on the laser safety glasses including eye protection for the patient in compliance with the information in chapter *Technical data*!

If the treatment area is right next to the eyes, the eyes of the patient must be protected by special eye shields, which can be sterilized. They must be used with local anesthesia (drops) and are placed directly on the eyeball.

The procedure starts with low FLUENCE, which is increased until the typical noise of photodisruption can be heard and the whitening can be seen. That disappears after ca. 10 – 20 minutes. The lowest FLUENCE achieving this effect is the parameter to be used further.

The more ink is in the skin the lower the starting FLUENCE to be set.

If the highest FLUENCE with large spots is not efficient, a smaller spot must be used by changing the optics holder. The new spot size is automatically recognized by the device and a higher FLUENCE can be set.

Usually the spot size of 4mm is applied, because one can perform most of the treatments without changing the spot size (optics holder).

7.5.5 Laser treatment

CAUTION

It is in principle conceivable, that hearing impairments are caused by the typical noise of photodisruption during longer and often performed treatments. So far there are no reports known.

Nevertheless it is recommended to use hearing protection in these cases to be on the safe side.

For the laser treatment, adjust the FLUENCE found in the test treatment. Apply laser pulses to the area to be treated without any overlaps and gaps.

The handpiece of the TattooStar is equipped with a microlens array that ensures an ideally homogeneous spot of square shape. This provides very homogeneous treatments without any 'hot spots' (increased power) and without leaving any gaps between the spots.

For darker skin types (type III and darker) you should not treat much area beyond the edge of the tattoo or dyschromia. The spot size used is to be adjusted accordingly to avoid pigment changes in the area surrounding the treatment zone.
It is also possible to cover the surrounding of a small lesion by a white, soft pencil (e.g. eyeliner pencil). The white coating reflects the laser light and the subjacent skin will not be treated.

The treatment should be performed as fast as reasonably possible to reduce the pain and urticarial alterations to a minimum if larger areas are treated (see also chapter *Possible side effects*).

If sensitive skin is to be treated, a careful procedure is advisable.

After gathering enough experience with laser treatments of tattoos, it is possible to apply the new R20 method* to reduce the number of sessions needed (by about 25%).
With this method the tattoo is treated a second time after 20 minutes (disappearance of the blanching).

*Kossida et al: Optimal tattoo removal in a single laser session based on the method of repeated exposures; J Am Acad Dermatol 2012, 66 (2): 271-277

It improves the result, more ink is removed, but the side effects are stronger. The authors of the method treated up to 4 times subsequently. But the improvement becomes less whereas the side effects are stronger**. That's why it is advised against treating more than two times in the same session.

**Drosner et al: Mehrfachbehandlung von Tätowierungen – bessere Aufhellung bei größerem Nebenwirkungsrisiko? Aktuelle Dermatologie 2013, 39:283-287

7.5.6 Post-treatment

The treated area should be continuously cooled after treatment, e.g. with Cool Packs (not frozen!) for about 20 minutes.
Possible epidermal irritations are to be covered with antibiotic ointments; they will heal within two weeks without leaving any scars normally.

CAUTION

Radiation on the treated area from the sun and tanning beds after treatment causes increased side effects, particularly alterations in pigment.
Therefore, this type of exposure must be avoided for a period of 6 – 8 weeks or sunscreen of SPF 50 must be worn.
Traumatizing the laser-treated area must also be avoided for 2-3 days. Crusts must not be manipulated.

7.5.7 Possible side effects

All side effects and notes stated for treatment of benign pigmented lesions are also valid for removal of artificial pigments.
Additionally the following side effects are possible when treating professional tattoos and permanent make-up:

- Permanent pigment changes are stated up to 4% (for professional tattoos)
- Following the recommended procedure and with compliance of the patient scars are seldom.
- Color changing
  Sometimes the changed color cannot be removed! (approach see above)
- Residual “shadow” may remain, because a complete removal of the ink is not possible.
- Local allergic dermal reactions to tattoo inks and photoallergic reactions
  (Stop treatment, see chapter *Intended use/ Contraindications*. It cannot be excluded that the allergen pigments spread around the body. This could lead in worse case to an anaphylactic reaction).
- In vitro chemical analysis has shown, that two widely used red azo dyes can lead to potentially toxic and carcinogenic cleavage products, such as nitroanilin. The results of the chemical analysis show, that the tattoo colorants already contain such compounds before laser irradiation. It is not clear yet, whether this is also the case in vivo and the extent to which this issue may be clinically relevant*.
  * Vasold et al.: Tattoo Pigments are Cleaved by Laser Light-The Chemical Analysis In Vitro Provide Evidence for Hazardous Compounds; Photochemistry and Photobiology; Volume 80, Issue 2, page 185–190.
- Koebner phenomenon (e.g. with psoriasis, Lichen ruber planus, vitiligo) was stated.
  See *Contraindications*.
- Formation of large bulla is very rare

7.5.8 Follow-up treatment

The interval between sessions should be at least 6 weeks. If after several treatments stagnation is to be observed in the brightening, a longer break of at least 3 months should be taken.

8 Accessories

WARNING

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

Accessories and application parts other than those specified in this user manual may not be used with this device.
All removable accessories and cables are approved for this device only and may be used only together with this device.

We strongly advise against the use of accessories or other parts made by other manufacturers. Even if an official testing authority has certified that a specific accessory unit is technically safe, Asclepion Laser Technologies GmbH cannot assume any liability for these products.

A current list can be procured at any time at Asclepion Laser Technologies GmbH.

9 Cleaning and disinfection

9.1 Procedure for cleaning and disinfection of the device

WARNING

The device is operated using line voltage. There is risk of electric shock!

Before cleaning and disinfecting, disconnect the device from the line voltage by unplugging the power cable from the power socket.

The user may only clean the outside surfaces of the device. Only slightly moistened, soft wipes, such as Kodan®- or Bacillol® wipes, may be used for cleaning and disinfecting. Cleaning or disinfecting using wet cloths or spraying products such as disinfectants is prohibited.

The device must be cleaned and disinfected at least daily after the last use of the device. The device should be covered with a clean cloth when it is not being used every day.

Procedure:

- Switch off the device by the key switch and power switch. Disconnect the device from the line voltage by unplugging the power cable from the power socket.
- Put on single use gloves.
- All accessible outside surfaces are cleaned using a slightly moistened, soft wipe. Doing this, the connections at the rear side of the device are left out.
- Use Kodan® or Bacillol® wipes to remove stubborn dirt. Abrasive agents must not be used!
- After, all accessible outside surfaces are carefully disinfected using Kodan® or Bacillol® wipes. Observe the instructions for disinfection given by the manufacturers.
  Doing this, the connections at the rear side of the device are left out.
  Aggressive disinfectants must not be used!

9.2 Procedure for cleaning and disinfecting the handpieces and for sterilization of the distance holder

WARNING

The distance holder of the handpiece comes into contact with the skin of the patient. There is the risk of transmitting microorganisms.
Before the first use and immediately after each use the handpiece must be thoroughly cleaned and disinfected by hand and if necessary the distance holder must be sterilized. Before use on the patient the handpiece must be clean and disinfected.

Automatic cleaning or disinfection is only possible for the distance holder; for the other parts of the handpiece it is prohibited.
If cleaning is required during a treatment, the device must be switched to the STANDBY state before cleaning starts! In this case, do not use any flammable substances, such as alcohol or isopropyl alcohol, near the treatment area, since there is a risk of fire if the laser is activated afterwards!

For the reprocessing procedure of the handpieces there is separate, detailed instruction, which is delivered with the handpieces and is to be observed absolutely.

CAUTION

Dirt deposits on the optical surfaces burn in due to the laser radiation and can cause damages of the optics and side effects!
Make sure that accessible optical surfaces are not damaged and remain clean after cleaning and during treatment.
The following notes for the procedure must be observed.

Important information

Cleaning the handpieces with wet cloths or under running water, or spraying with products, such as disinfectants, is prohibited. Cleaning in this way can damage the internal optics and electronics. Only damp cloths may be used, such as Kodan® or Bacillol® wipes. (Parts are damaged by strongly acidic or basic solutions!). The only exception is the distance holder.

The distance holder can be sterilized. All other parts of the handpiece cannot be sterilized.

Frequent cleaning has little effect on the handpieces. Colors can become faded or changed, but this does not affect the use.
The end of the product's service life is normally determined by wear and damage.

The handpieces must be protected from contamination if they are not used for prolonged periods.

The manufacturer has validated that the instructions listed above and the instructions for reprocessing delivered with the handpieces, are **SUITABLE** for reusing the application parts.

WARNING

The distance holder of the handpiece comes into contact with the patient when treating the skin. There is the risk of transmitting microorganisms.

The reprocessing of the handpieces must only be performed with means and devices, which are approved and performed professionally by trained and authorized personnel.

The person performing the reprocessing work is responsible for ensuring that the reprocessing process actually carried out with the equipment, materials and personnel used in the reprocessing facility achieve the desired results.

This usually requires normal validations and routine monitoring of the process. The person performing the reprocessing work should also carefully evaluate each deviation from the provided instructions for effectiveness and adverse consequences.

The manufacturer does not accept any liability for any direct or consequentional damages if the reprocessing was improperly.

10 Error messages and troubleshooting

WARNING

The device is operated using line voltage and emits laser radiation. There is a risk of electric shock and injury to the eyes!

The troubleshooting procedures specified below must be followed at all times. Any deviation from the specified methods and, of course, any opening of the devices is prohibited.

Important information

Improper use or maintenance of the laser system can invalidate the Asclepion Laser Technologies GmbH warranty.

For any questions not answered in this manual, contact your customer service representative (see chapter *Customer service*).

If the device does not respond after turning the key switch, check that:

1. The device is connected to the power supply
2. The main power switch on the rear side of the device is switched on (position “I” (on)). Switch off the device and after 5 minutes once more on.
3. The *Laser Emergency STOP* button is disengaged. If it is engaged, disengage it by turning the red button to the left until the lock is released and the button pops out.
4. The fuses of the room are in order.

As previously mentioned, the user interface on the display will help you with error analysis.

The TattooStar has an integrated fault management system that permanently monitors fault conditions that may be hazardous to the patient, the operator or the device. Every detected fault will be displayed in a system fault menu (see figure below).

Figure 27: Error message screen (example)

As soon as a fault condition is detected, the system will automatically switch to the safe mode: The shutter is closed, the laser is switched off and the footswitch is disabled. The device will remain in this condition until you switch it off. If after having restarted the device the fault persists, take down the displayed error message (error text and/or 4-digit error code) and contact the Technical Service.

For safety-relevant errors, the device shuts off within milliseconds. A note on the display is not possible in such cases. If this is the case or an error occurs that is not described in this user manual, disconnect the device by unplugging the power plug from the power supply at the power outlet and contact the Technical Service.

Before contacting the Technical Service of Asclepion Laser Technologies, **please make a note of the name and number of the error**.

11 Customer service

WARNING

The device is operated using line voltage and emits infrared radiation. There is a risk of electric shock and injury to the eyes!

You must never open the device and/ or attempt to carry out repair work yourself.

The device does not contain any parts inside the device or handpiece that can be maintained by the operator.

Service work may not be performed by anyone other than our service technicians or other technicians trained and authorized by us. This also applies for the mandatory annual safety checks.

WARNING

During treatment, the handpieces are in contakt with the uninjured skin of the patient. There is the danger of microorganisms being transferred.

If it is necessary to survey or to repair handpieces or the basic device in the medical centre or at the manufacturer, of course they have to be cleaned and disinfected before!

If you need help from customer service, use the address or telephone number below: When you contact your Asclepion Laser Technologies GmbH customer service representative, always have the model and serial number READY. The numbers are located on the type plate on the back side of the laser device.

Asclepion Laser Technologies GmbH
Brüsseler Str. 10
D - 07747 JENA
Germany
www.asclepion.com

Customer service:

Phone: +49 (0) 3641 / 7700 - 401
Fax.: +49 (0) 3641 / 7700 - 402
E-mail: **service@asclepion.com**

Note that manufacturers, installers or importers are only responsible for the effects on the safety, reliability and performance of the device if:

- Assembly, expansions, readjustments, changes or repairs are carried out by personnel authorized by them.
- The electric installation of the room in question corresponds to the requirements of of the standard IEC 64 that is currently in force.
- The device is used in compliance with the user manual.

12 Regular maintenance, safety checks and calibration

The device does not contain any internal parts that can be maintained by the operator.

WARNING

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure and there is a risk of electric shock.
Any deviation from the specified methods and, of course, any opening of devices.

Before maintenance, disconnect the device from the line voltage by unplugging the power cable from the power socket.

Service work may not be performed by anyone other than our service technicians or other technicians trained and authorized by us. This also applies for the mandatory annual safety checks including calibration. That applies to the mandatory annual safety checks including calibration, too.
In addition, the persons carrying out must have the necessary work equipment (e.g. laser measuring devices suitable for this laser). The service work has to be carried out correctly and comprehensible with regard to nature and extent and to be documented.

The work for maintenance and repair, which requires switching on of the device have to be carried out in the laser area. All precaution measures described in chapter *Safety/ Laser* must be observed.

Malfunctioning or damaged parts have to be exchanged immediatly. Only spare parts supplied by Asclepion Laser Technologies may be used. The safety cannot be guaranteed for the use of other parts, even if they have a certificate.

Any modification of the device is strictly prohibited.

CAUTION

If the output power of the laser is too high, this can cause increased side effects!
The power emitted from the therapy laser must be checked at least **every year** by an Asclepion Laser Technologies GmbH customer service technician or a trained customer service technician of the dealer as part of safety checks. A calibration is carried out if necessary. The results of the checks are to be documented in the medical device book.

If a calibration was done, the following (test) treatments must be carried out especially carefully. It is possible, that the real FLUENCE is a bit higher than before (to the factory setting), even for the same setting. The service technician should inform whether there was a deviation after adjustment. The same applies after refurbishing of handpieces.

Important information

Asclepion Laser Technologies grants a one-year warranty for the device. The warranty can be extended if you fill out a short-term registration on our website.

The carefully performed cleaning and repair as described in the chapter *Cleaning and disinfection* and in this chapter, ensures a long lifespan of your device.

The maximum number of pulses can be limited depending on the handpiece version.

Improper handling during operation, maintenance, safety checks or calibration may void the warranty. For any questions not answered in this manual, contact your customer service representative (see chapter *Customer service*).
Annual inspection of the device is required for granting the extended warranty.

Wear parts are not covered by the warranty. A current list of wear parts can be requested from the customer service department.

12.1 Routine maintenance

The routine maintenance described below must be carried out by hospital or clinic personnel:

Inspection of the outside of the device

Make sure that all cable connections as well as the purging tube are undamaged and plugged in securely.
Frequency: Weekly
Inspection by: Hospital or clinic personnel

Inspection of the cooling system

Make sure that all of the cooling system's ventilation grilles are free.
Frequency: Weekly
Inspection by: Hospital or clinic personnel

Inspection of the handpiece

Check whether the handpiece including optics is clean and undamaged (optics holder, basic body, cable and plugs undamaged, tube undamaged and fixed to the handpiece.
Frequency: Before each use
Inspection by: User of the device

The following maintenance must be performed at least once a year and it makes sense to do it before the annual safety check by the technician:

Wear parts to be exchanged:

- Filter insert F 100 µm
- Deionized water

Accessible fuses (fine fuses 5 x 20 mm; 250 V):

- F1 T 2,0 A water pump
- F2 T 1,0 A air pump
- F3 T 0,063 A high voltage unit for Q-switch

12.2 Regular safety checks

SCOPE OF THE ANNUAL SAFETY CHECKS

At least the checks listed below have to be performed according to the legal requirements in their currently valid version as well as to the international standard for Medical Electrical Equipment – recurrent test and test after repair of medical electrical equipment (IEC 62353).

The tests should be run in the specified order:

- Visual inspection of laser device and accessories
- check of coolant level and check for leaks in the cooling system

Important information

The coolant used for the *TattooStar* is distilled water (deionized and chemically pure according to VDE 0510). Do not use any liquids other than those supplied and recommended by the manufacturer. The use of unsuitable liquids may permanently damage the laser.

- Measurement of protective earth resistance
- Measurement of leakage currents
- Measurement of insulation resistance
- Functional test

Additionally to be performed:

- Measurement of the actual output power of the laser at the handpiece;
  adjustment of laser power, if necessary

Tip

Contact your distributor or Asclepion Laser Technologies GmbH directly for detailed specifications on the scope and implementation of the visual inspection.

Additional information

On request, the manufacturer can provide circuit diagrams, bills of material, descriptions, calibration instructions or other information not contained in the user manual to support appropriately skilled technical personnel with repairing parts of the device that have been deemed reparable by the manufacturer. "Appropriately skilled technical personnel" in this context is defined as personnel that have completed service training at the manufacturer's facilities and have been authorized to repair this device.

12.3 Preparation for relocation of the device within the facility

Before relocation of the device:

- Switch off the device by key switch and power switch (on rear side).
- Disconnect the mains plug from the socket.
- Fix the handpiece in the hook at the articulated mirror arm.
- Fix the footswitch on it‘s holder at the rear side of the device.
- If installed, disconnect the door interlock from it’s connectors.
- Unlock the wheels of the device.

Important information

When you move the device into another room, proceed carefully. Please make sure, that the device and in particular the articulated mirror arm doesn’t push to the door or other furnishings!

In case the device shall be moved to another facility, please contact the customer service.

Proceed in the new room in reverse order.

13 Disposal

The expected life time of the device is 7 years.
The life spam is determined on the basis of considerations concerning the aging of the type or class of product as well as of technical considerations concerning critical parts or components.

Disposal:
The device must be disposed of in accordance with the directive 2012/19/EU of the European Council for Waste Electrical and Electronic Equipment [WEEE].

WARNUNG

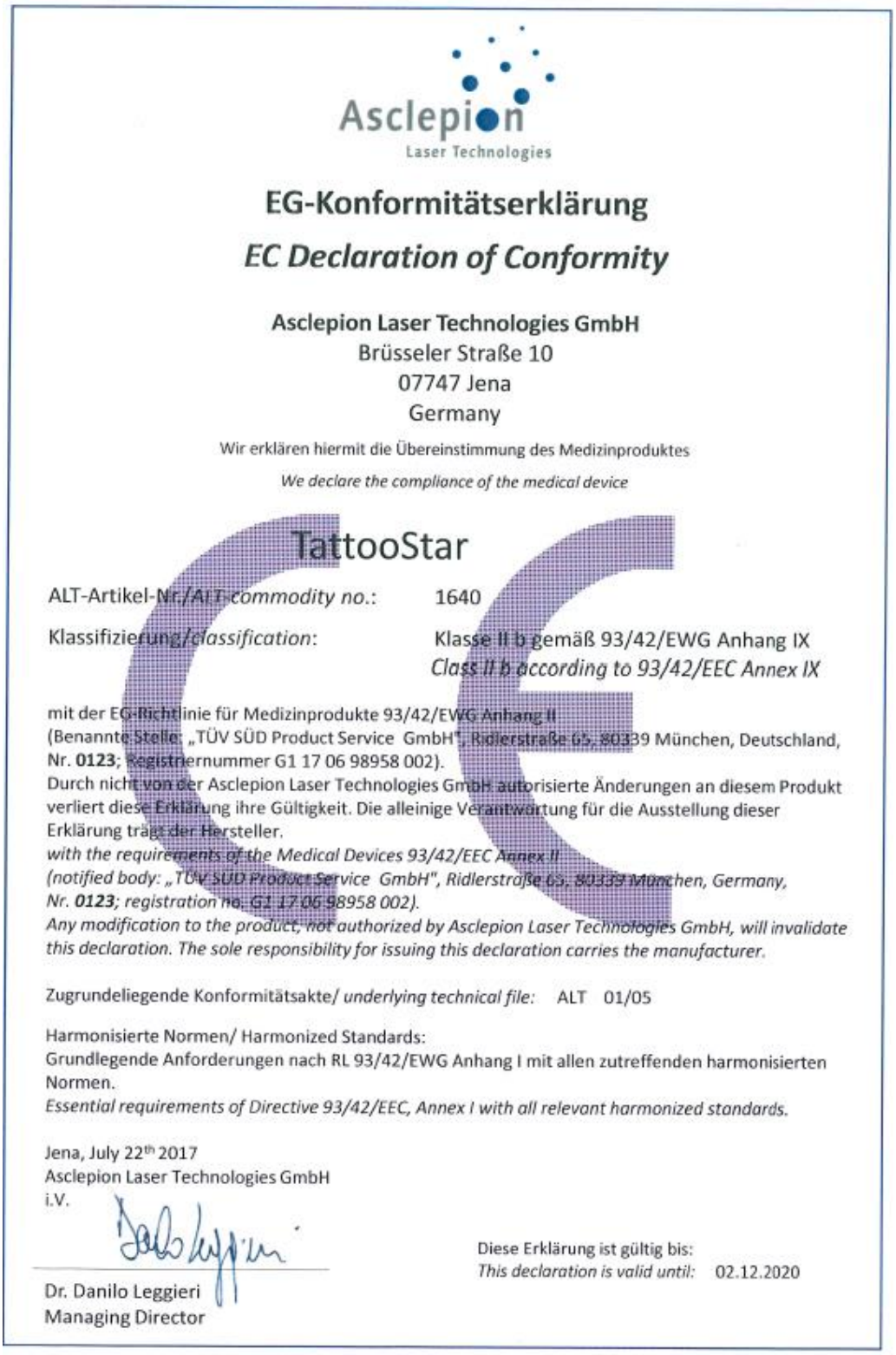
During treatment the handpieces are in contact to the skin of the patient. There is the danger of microorganisms being transferred.

Before disposal according to the acts stated above, the handpieces must be cleaned and disinfected!

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

14 EC declaration of conformity – copy

The declarations of conformity are issued for a limited time. Please consult our Technical Customer Service if you need the actual version.



Asclepion
Laser Technologies

EG-Konformitätserklärung

EC Declaration of Conformity

Asclepion Laser Technologies GmbH
Brüsseler Straße 10
07747 Jena
Germany

Wir erklären hiermit die Übereinstimmung des Medizinprodukte
We declare the compliance of the medical device

TattooStar

ALT-Artikel-Nr./*ALT commodity no.*: 1640

Klassifizierung/*classification*: Klasse II b gemäß 93/42/EWG Anhang IX
Class II b according to 93/42/EEC Annex IX

mit der EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II
(Benannte Stelle: „TÜV SÜD Product Service GmbH", Ridlerstraße 65, 80339 München, Deutschland, Nr. **0123**; Registriernummer G1 17 06 98958 002).
Durch nicht von der Asclepion Laser Technologies GmbH autorisierte Änderungen an diesem Produkt verliert diese Erklärung ihre Gültigkeit. Die alleinige Verantwortung für die Ausstellung dieser Erklärung trägt der Hersteller.
with the requirements of the Medical Devices 93/42/EEC Annex II
*(notified body: „TÜV SÜD Product Service GmbH", Ridlerstraße 65, 80339 München, Germany, Nr. **0123**; registration no. G1 17 06 98958 002).*
Any modification to the product, not authorized by Asclepion Laser Technologies GmbH, will invalidate this declaration. The sole responsibility for issuing this declaration carries the manufacturer.

Zugrundeliegende Konformitätsakte/ *underlying technical file:* ALT 01/05

Harmonisierte Normen/ Harmonized Standards:
Grundlegende Anforderungen nach RL 93/42/EWG Anhang I mit allen zutreffenden harmonisierten Normen.
Essential requirements of Directive 93/42/EEC, Annex I with all relevant harmonized standards.

Jena, July 22th 2017
Asclepion Laser Technologies GmbH
i.V.

Dr. Danilo Leggieri
Managing Director

Diese Erklärung ist gültig bis:
This declaration is valid until: 02.12.2020

Asclepion
Laser Technologies

EG-Konformitätserklärung

EC Declaration of Conformity

Asclepion Laser Technologies GmbH
Brüsseler Straße 10
07747 Jena
Germany

Wir erklären hiermit die Übereinstimmung des Medizinproduktes

We declare the compliance of the medical device

RubyStar+

ALT-Artikel-Nr./*ALT commodity no.*: 1642

Klassifizierung/*classification*: Klasse II b gemäß 93/42/EWG Anhang IX
Class II b according to 93/42/EEC Annex IX

mit der EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II
(Benannte Stelle: „TÜV SÜD Product Service GmbH", Ridlerstraße 65, 80339 München, Deutschland, Nr. **0123**; Registriernummer G1 17 06 98958 002).
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with the requirements of the Medical Devices 93/42/EEC Annex II
*(notified body: „TÜV SÜD Product Service GmbH", Ridlerstraße 65, 80339 München, Germany, Nr. **0123**; registration no. G1 17 06 98958 002).*
Any modification to the product, not authorized by Asclepion Laser Technologies GmbH, will invalidate this declaration. The sole responsibility for issuing this declaration carries the manufacturer.

Zugrundeliegende Konformitätsakte/ *underlying technical file:* ALT 01/05

Harmonisierte Normen/ Harmonized Standards:
Grundlegende Anforderungen nach RL 93/42/EWG Anhang I mit allen zutreffenden harmonisierten Normen.
Essential requirements of Directive 93/42/EEC, Annex I with all relevant harmonized standards.

Jena, July 22th 2017
Asclepion Laser Technologies GmbH
i.V.

Dr. Danilo Leggieri
Managing Director

Diese Erklärung ist gültig bis:
This declaration is valid until: 02.12.2020

Asclepion
Laser Technologies

EG-Konformitätserklärung

EC Declaration of Conformity

Asclepion Laser Technologies GmbH
Brüsseler Straße 10
07747 Jena
Germany

Wir erklären hiermit die Übereinstimmung des Medizinproduktes

We declare the compliance of the medical device

MelaStar

ALT-Artikel-Nr./*ALT-commodity no.*: 1647

Klassifizierung/*classification*: Klasse II b gemäß 93/42/EWG Anhang IX
Class II b according to 93/42/EEC Annex IX

mit der EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II
(Benannte Stelle: „TÜV SÜD Product Service GmbH", Ridlerstraße 65, 80339 München, Deutschland, Nr. **0123**; Registriernummer G1 17 06 98958 002).
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with the requirements of the Medical Devices 93/42/EEC Annex II
*(notified body: „TÜV SÜD Product Service GmbH", Ridlerstraße 65, 80339 München, Germany, Nr. **0123**; registration no. G1 17 06 98958 002).*
Any modification to the product, not authorized by Asclepion Laser Technologies GmbH, will invalidate this declaration. The sole responsibility for issuing this declaration carries the manufacturer.

Zugrundeliegende Konformitätsakte/ *underlying technical file:* ALT 01/05

Harmonisierte Normen/ Harmonized Standards:
Grundlegende Anforderungen nach RL 93/42/EWG Anhang I mit allen zutreffenden harmonisierten Normen.
Essential requirements of Directive 93/42/EEC, Annex I with all relevant harmonized standards.

Jena, July 22th 2017
Asclepion Laser Technologies GmbH
i.V.

Dr. Danilo Leggieri
Managing Director

Diese Erklärung ist gültig bis:
This declaration is valid until: 02.12.2020

15 A Attachment: EMC declaration

Important information

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the device as replacement parts for internal components, may result in increased emissions or decreased immunity of the device.

Device model	Description
TattooStar, item no. 1640	Ruby laser (mains supply 230V)
RubyStar+, item no. 1642	Ruby laser (mains supply 230V)
MelaStar, item no. 1647	Ruby laser (mains supply 230V)
Standard handpiece for Ruby laser, item no. 4001	
MicroSpot handpiece for Ruby laser, item no. 4104	For fractional treatments

Accessory/ designation	Model number	Length/ dimensions
Cable of the laser handpiece	1640 01 041	< 3.0 m
Footswitch with cable	6608 06 008	< 3.0 m
Line cord (3 - pole)	5507 04 013	< 3.0 m

Important information

The use of the accessory, transducer or cable with other medical electrical equipment than the TattooStar specified may result in increased emissions or decreased immunity of the equipment/ system.

Important information

The equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Important information

For the device the following essential performance features of EMC are determined:

- no independent leaving of the preset operating mode
- no independent switch of standby to ready and conversely
- no independent change of the preselected output energy
- no independent (unintentional) release of output power

A.1. Electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below.
The customer or the user of the TattooStar should assure that it is used in such an environment.

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

A.2. Electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below.
The customer or the user of the TattooStar should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 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 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2kV ± 1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1kV ± 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	< 5 % 40% 70% < 5 %	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TattooStar requires continued operation during power mains interruptions, it is recommended that the TattooStar be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the TattooStar should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the TattooStar, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$ 800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] 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: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

A.3 Recommended separation distances

Recommended separation distances between
portable and mobile RF communications equipment and the TattooStar

The TattooStar is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [TattooStar as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHZ** $d = 2{,}3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	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 recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			