MultiStar

USER'S MANUAL

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Copyright

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

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

Risk of accidents or physical injury.

Risk of technical damage.

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

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1 Intended Use

The *MultiStar* system is a medical device for applications in general surgery.

The *MultiStar* system emits a wavelength of 10,600 nm that is highly absorbed by water. Since tissue is comprised mostly of water, this invisible wavelength is highly effective in the surgical treatment of soft tissues.

In providing this new, powerful medical device, Asclepion Laser Technologies GmbH rested on its many years of experience in the development and production of medical lasers.

The *MultiStar* is a reliable laser device that is easy to use. It is largely maintenance-free and excels by a long service life. The device is designed for use in both clinics and private practices.

The *MultiStar* complies with the generally accepted rules of technology and the relevant safety regulations. The device fully complies with the requirements of the EC Medical Device Directive 93/42/EEC.

The Manufacturer is not responsible for direct or side effects resulting from therapeutic or surgical use of the system, which is a direct responsibility of medical personnel.

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

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

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

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

Intended Use

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

Medical Device Directive / Medical Product Act

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

Device Type acc. to MPA: II b

UMDNS-No.: 17-771

2 Technical Data

The *MultiStar* system is equipped with a high power CO_2 laser source, emitting an infrared beam, and a low power diode laser source, emitting a visible red beam.

The diode laser beam is coaxial with the infrared beam and therefore used as aiming beam.

The two laser sources have the following specifications:

2.1 General specifications

Beam guidance:	Articulated arm
Display:	LCD display
Operator guidance:	Touchscreen
Cooling:	Enclosed, water to air
Door interlock connector:	Potential-free contact 5 VDC / max. 20 mA (TTL)
Laser warning lamp:	+24 V / 0.5 A
Operating conditions:	Temperature: 5°C ... +30 °C Rel. humidity: 20% …80% Atmospheric pressure: 700 ... 1060 hPa
Transport and storage conditions:	Temperature: 0°C … +50°C Rel. humidity: 10 % … 80 % (no condensation)
Use	Intermittent use: 90 min use, 30 min pause
Dimensions (W x D x H):	48 x 55 x 113 cm³ (with base)
Weight:	Approx. 48 kg (with articulated arm)
Power requirements:	110 - 115 / 220 - 230 VAC 50/60 Hz Max. 500 VA Fuses 2 x 6.3 AT (5 x 20) mm
Classification acc. to MPA	II b
Electrical protection class:	I
Device Type:	B
Accessories:	See Section 6

2.2 Laser specifications

2.2.1 CO_2 laser specifications

Laser type:	CO_2 gas laser
Wavelength:	10,600 µm
Laser Class:	4
Safety eyewear required	DI 10,600 L4
Operating modes:	Continuous, repeat pulse, super pulse
Laser power:	Continuous 2 … 30 watts distal Repeat pulse 0.5 … 25 watts distal Super pulse 0.5 … 12 watts distal
Exposure time:	Continuous (controlled by footswitch) Single exposure with exposure times of 0.1 … 0.9 s Repeat exposure with 0.4 s interval between single exposures with exposure times of 0.1 … 0.9 s
Tolerance of output power:	Max. ± 20 % (over 2h:30 min)
Laser beam mode:	Multimode
Laser beam diameter:	Typically 6.5 mm (1/e²)
Laser beam divergence:	Typically 5.4 mrad (full-angle 1/e^2)
Spot size of the handpiece:	Typical 300 µm at 100 mm focal length (Handpiece MF)
Divergence of the handpiece:	Typical 1.2° (full angle) at 100 mm focal length (Handpiece MF)
Nominal Ocular Hazard Distance (NOHD) with handpiece:	13 m

2.2.2 Aiming beam laser specifications

Laser type:	Laser diode
Wavelength:	635 – 670 nm
Laser Class:	2
Laser output power:	< 3 mW, adjustable in steps
Diameter of laser beam	< 1 mm
Divergence	< 4 mrad
Operating mode	cw

2.3 Technical description

Although laser operators have minimal contact with the interior portion of the laser unit, an understanding of how the system works may be helpful.

Laser Head

The *MultiStar* system head is a direct current (DC) excited, tube type, sealed laser medium (CO_2 gas) laser. When the operator steps on the footswitch, the laser emits either a continuous or a pulsed laser beam.

The optical resonator consists of aligned mirrors at each end of the resonator. One mirror is 100% reflective, while the other reflects only a portion of the beam thus allowing the remainder of the laser energy to pass as useable laser light. The treatment laser beam is combined with an aiming laser and directed to an articulated arm, which then delivers the two beams to the handpiece.

Coolant Circulation System

A coolant circulation system cools the laser tube to prevent overheating. A pump circulates coolant through laser head and heat exchanger. The coolant is circulating as long as the laser system is turned on.

High Voltage Power Supply

The High Voltage Power Supply transforms the line voltage into high voltage DC.

Microcontroller

The *MultiStar* system is provided with a microcontroller, which controls all functions of the system.

Operating mode

The device operates in Continuous Mode (CW), Pulsed Mode (PW) and in Superpulsed Mode. It is designed for intermittent use (90 min use, 30 min pause).

Technical Data

User interface

Operation is via a touchscreen with plain-text user guidance. The following operating parameters are adjustable: power, exposure mode, pulse duration, aiming beam intensity.

In addition to the parameters selected, the following parameters and device states are displayed: laser STANDBY, laser READY and, if necessary, plain-text error messages.

The system includes a database, to which the user can save treatment protocols with parameters he typically uses for different types of treatment.

The laser is released by means of a footswitch.

Laser Delivery System

The articulated arm is an optical assembly that delivers the laser radiation (see Figure 3). It is made up of seven mirrors placed on swivel joints. The field of motion of the articulated arm covers a radius of approximately 80 cm, the transfer efficiency of power is greater than 85%. The loss of 15% is compensated by suitable calibration of the internal power meter. The articulated arm is permanently mounted to the *MultiStar* system.

The detachable handpiece is mounted to the distal end of the articulated arm.

An internal pump produces an airflow in order to prevent dust and particles from depositing on the optics during laser operations.

The inlet connector is connected via a plastic transparent tube to an opposite output connector located on the top of the system.

Never disconnect the transparent tube.

Additional Information

Upon request, the Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information not already contained in the manual, to assist appropriately qualified technical personnel to repair those parts of the *MultiStar* system that are designated by the Manufacturer as repairable. “Appropriately qualified technical personnel” in this context refers to personnel who have attended a Manufacturer’s Service Training Course on the *MultiStar* system and who have been authorized to repair the laser.

2.4 Laser Safety Features

The *MultiStar* system offers several safety features to prevent misuse or unintentional activation of the system. All personnel who operate the laser or assist in the operation should be familiar with these safety features.

Power Switch

The power switch disconnects the device from line power. If the device is note used, the switch should be OFF (O).

Key Switch

The key switch controls the activation of the system. Only authorized personnel having access to the key can start the system. The key switch works to turn on the system only if the emergency switch has not been pushed in.

THE KEY MUST ALWAYS BE REMOVED WHEN THE SYSTEM IS TURNED OFF AND MUST BE KEPT ONLY BY AUTHORIZED PERSONNEL.

Laser STOP button

The Laser STOP button is a dedicated override switch for immediate emergency shut down of the laser system. Use it only under emergency circumstances, i.e. in case it is necessary for the operator to immediately stop laser emission.

To shut down the system, push in the button. To reset the switch, turn the button anticlockwise until it comes out again.

DO NOT USE THE EMERGENCY SWITCH TO TURN ON AND OFF THE SYSTEM UNDER NORMAL CIRCUMSTANCES.

Footswitch

The footswitch is an electrical switch. To connect it, plug the connector at the end of the footswitch cord into the socket located at the rear of the laser labeled ‘FOOTSWITCH’. Place the footswitch on the floor near the treatment area.

STANDBY Mode

The STANDBY mode prevents unintentional or accidental activation of the laser. When the system is in STANDBY mode, the CO_2 laser source is switched off. The operator cannot activate the laser beam until the READY key is pressed.

The system goes into STANDBY mode in the following cases:

?? after the system is initially started,

?? when the operator presses any of the laser parameter selection keys,

?? when the system has been in READY mode for several minutes without being activated,

?? when the operator presses the STANDBY key while the system is in READY mode.

Automatic Shutdown Feature

The *MultiStar* system includes an automatic shutdown feature. When specific problems occur, the system automatically switches to the following safety state: the shutter is closed, the CO_2 source is turned off and the footswitch is disabled. An error message is immediately displayed on the screen identifying the specific fault.
See Section *9,* “Troubleshooting”, for details about faults.

Remote Interlock

The system is also provided with a remote interlock that can be connected to the doors of the laser room. When the remote interlock is active, the laser automatically shuts down when anyone enters the treatment room.

Audible Tone

Laser emission is indicated by a pulsed tone, for the period of the emission.

Laser Warning Signs

The device carries various safety labels. These labels must always be clearly readable and replaced instantly when damaged.

The Manufacturer supplies a laser WARNING sign with each laser system. We recommend posting these signs (*Figure 1*) at the entrance to laser treatment room.

The Manufacturer is liable for the effects of servicing on safety, reliability and performance of the device only if:

?? the equipment is used according to all the instructions contained in this manual (concerning either safety precautions or use of the system),

?? installation, assembly, extensions, modifications, repairs and maintenance procedures have been performed by personnel having proper authorization and qualification,

?? the electrical system at the installation site of the device conforms to IEC and local regulations.

3 Safety Notes

As with any equipment, the operation of the *MultiStar* system involves potential hazards, which the user should be aware of before using it. These hazards include optical, electrical, biological and fire hazards.

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

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

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

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

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

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

3.1 Optical hazard by laser radiation

The *MultiStar* system emits an invisible beam of intense energy that can cause serious eye and skin injury by direct or indirect exposure to the beam. Please adhere to the following precautions to minimize optical damage to laser operators and assisting personnel:

?? All persons present in the room during treatment must wear protective eyewear.
The protective eyewear must comply with the European regulation EN 207 "Personal eye-protectors; Filters and eye-protectors against laser radiation" in the current version and possess the characteristics according to the technical specifications in chapter *2.2*.

?? Never look directly into the handpiece or articulated arm aperture even while wearing protective eyewear.

?? Mark treatment rooms clearly to avoid unexpected entry during treatment.
The label shown in *Figure 1* must be affixed to each entrance to these areas in order to warn the entering person of the presence of a laser source inside.

Figure 1: Door safety label

?? Restrict entry to the treatment room to only those who assist in treatment and are trained in the use of the equipment.

?? Cover windows and other openings in the treatment room to avoid the inadvertent escape of laser light.

?? Direct the activated laser only at the intended area of treatment.

?? Remove any metal object such as watches, rings, necklaces and similar items from the operating area and, if possible, do not use reflective instruments or materials.

?? Reflective objects could intercept the laser beam causing a deflection to an area other than the intended treatment area. Many surfaces that may seem matt can actually reflect the 10.6µm CO_2 laser emission wavelength.

?? Switch the laser into the STANDBY mode when the laser is not in use (when in STANDBY mode, the laser beam cannot be inadvertently activated).

?? Ensure that all trained personnel assisting in the treatment know how to shut down the laser in the case of an emergency.

?? Always remove the key from the key switch when the system is switched off and keep it in a safe place.

The Regulations for the Prevention of Accidents by Laser Radiation of the German Professional Associations (or any equivalent national regulations) lay down general rules for the protection against hazardous laser exposure. In the context of medical application, they aim to protect operating personnel during laser operation. The laser devices are classified in

different classes depending on the potential risks involved. The *MultiStar* is classified in Class 4.

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

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

?? **Duty of notification:** Prior to initial start-up, the intended use of the laser must be notified to the competent Professional Association and the labor-safety authority

?? A **Laser Safety Officer** must be appointed in writing.
The duties of the laser safety officer should include at least the following:

- Supervision of the operation of the laser device
- Assistance to the owner/operator to ensure safe operation and implement the necessary safety precautions
- Co-operation with labor-safety specialists in fulfilling their tasks, including the information about important issues of laser radiation protection.

?? **Laser zone:** While the laser is in operation, the area in which the maximum permissible radiation level may be exceeded, the so-called "laser zone", must be delimited and marked by a laser warning sign. Warning lamps at the entrances must indicate the operation of the laser.

?? The **NOHD** (Nominal Ocular Hazard Distance) of the laser device is so high that the entire room where the laser is operated is to be considered as laser zone.

?? **Personal eye protection:** All persons present in the laser zone must wear laser protective eyewear. The laser protective eyewear must provide a protection level of at least DI 10,600 L4 (acc. to DIN EN 207 in the currently valid form).

?? **Dangerous reflections:** The laser beam may be reflected by many metal surfaces and not only by those normally considered. Therefore, always take care to remove all metal objects, such as watches, earrings, etc. from the operational range of the laser.

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

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

3.2 Laser-induced fire hazard

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

When the laser beam contacts an exterior surface, the surface absorbs the laser energy, which raises the surface temperature, whether the surface is skin, hair, clothes, or any flammable substance. Operators should take the following precautions to prevent a laser-induced fire:

?? Use non-flammable substances for such uses as anesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.

?? Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of fire.

?? Keep a minimum of combustible materials in the treatment room. If treatment requires the use of combustible material, such as gauze, first soak it in water.

?? Keep all clothing as far as possible away from the treatment area.

?? Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.

?? Always keep a small fire extinguisher and water in the treatment room.

?? Avoid the use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen.

?? Some materials, such as cotton wool, may be ignited by the high temperatures produced in normal use of the laser equipment when saturated with oxygen.

?? 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 paid to the danger of ignition of endogenous gases.

3.3 Electrical hazard

The *MultiStar* system uses high voltages. Do not open the protective panels unless you are trained and authorized to do so.

3.4 Biological hazard

The laser smoke presents a possible biological hazard. Ablated particles from tissues exposed to radiation are present in the plume.

Laser plume may contain viable tissue particulates. Use of a laser smoke evacuator with filters is recommended.

3.5 Radio frequency interference

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

At the installation and initial operation special care must be taken regarding electromagnetic compatibility (EMC). See thereto the special notes in the accompanying documents under EMC guidance and manufacturer's declaration.

4 Start-up

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

4.1 Scope of delivery

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

Basic device

?? Basic laser device

?? Footswitch

?? Remote door interlock connector

?? Two keys

?? Power cord

?? Tube

Accessories

?? Articulated mirror arm

?? User's Manual

?? Laser protective eyewear for physician

?? Eye protection for the patient

?? 100 mm handpiece, straight

Optional accessories

?? Handpieces

?? Handpiece adapters

?? Micromanipulators

?? Laparoscope accessories

?? Microscope & colposcope adaptors

?? CO_2 Laser articulated arm thread adaptors

?? CO_2 Laser smoke evacuator

?? Miniscan Scanner

4.2 Storage and Transport Requirements

To maintain the laser system properly during storage and transport, make sure to meet the following requirements.

- Keep the ambient temperature between 0 and 50°C.
- Keep the laser system in a location where the humidity is between 10% and 80%, non-condensing.
- Minimize shock and vibration.
- Do not drop.
- Store the laser system in an atmosphere that is free of corrosive substances, such as salts or acids.
- Store the system in an atmosphere with a minimum of dust particles.

4.3 Environmental Requirements

Follow these environmental requirements to properly maintain the laser.

- Keep the air free of corrosive substances, such as salts and acids. These pollutants may damage electrical wiring and optical surfaces.
- Keep dust particles to a minimum. Dust particles may cause permanent damage to optical components.
- Keep humidity in the laser room between 20% and 80%, non-condensing.
- Keep the laser room temperature between 5°C and 30°C. Do not set up the laser unit near heating vents or other sources of temperature variation. Protect the laser from direct exposure to sunlight.

4.4 Installation

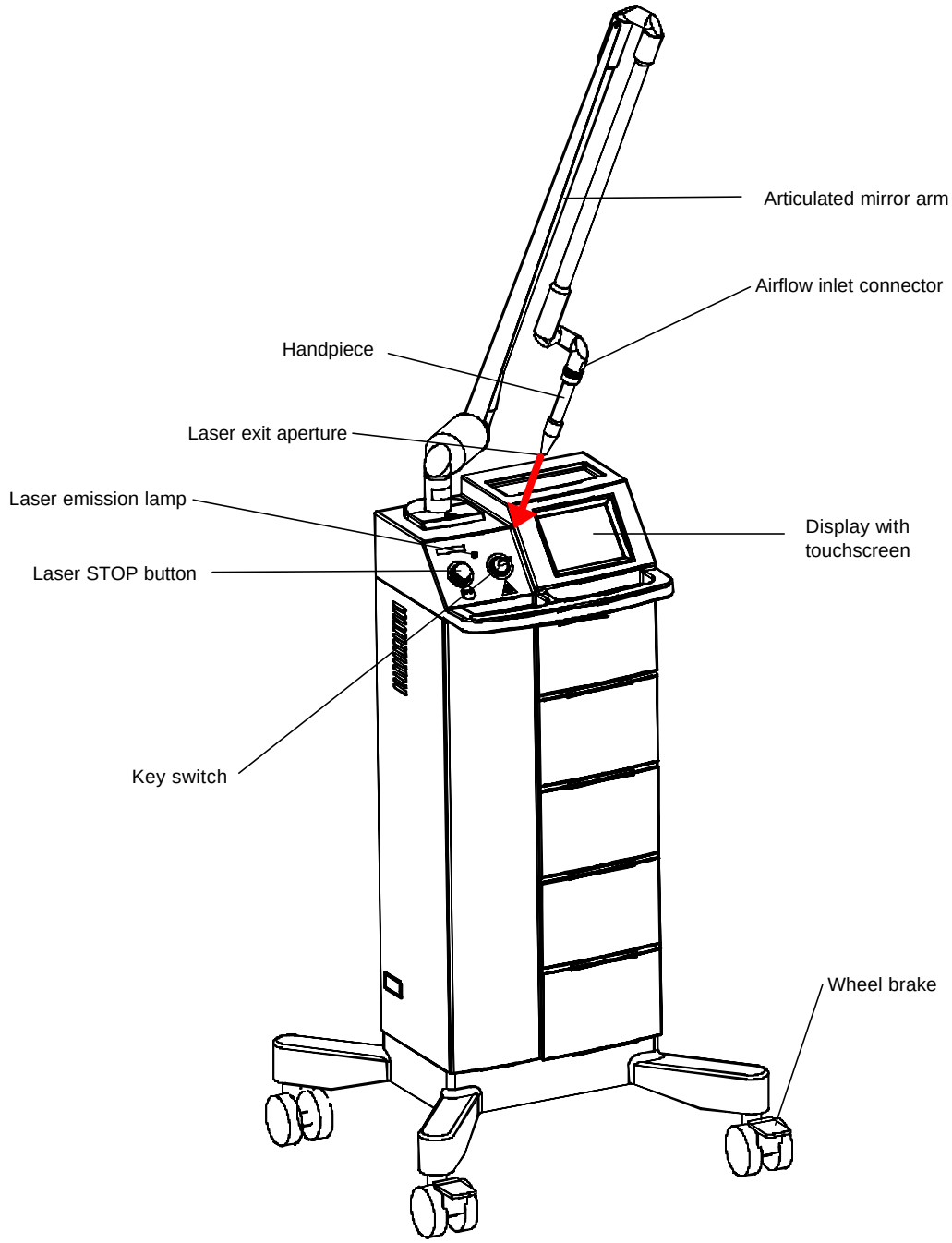

Figure 2: Front view

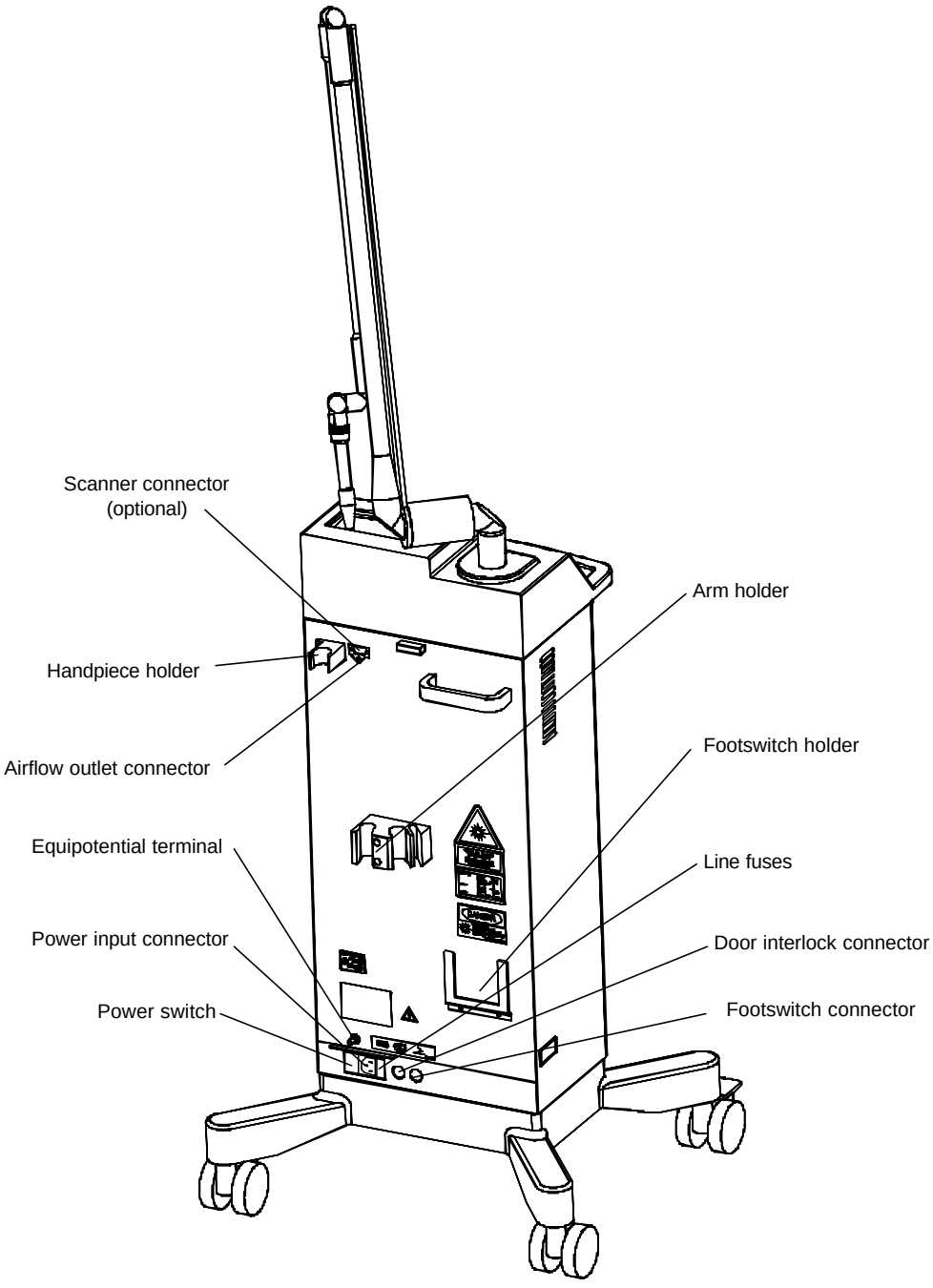

Figure 3: Connectors on rear panel of device

4.4.1 Installation note

Considering the footprint, the cable connections and optimum ventilation required for an efficient cooling of the device, keep a minimum distance of 10 cm between side and rear panels of the *MultiStar* and the wall.

4.4.2 Connection of door interlock

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

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

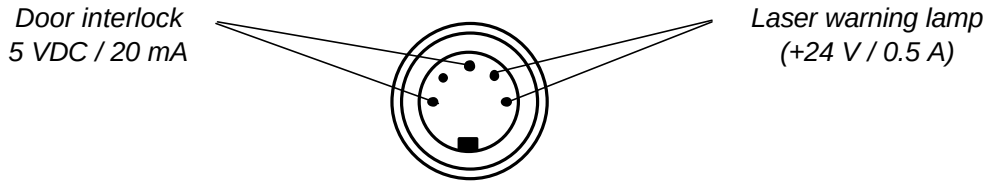

Figure 4: Connectors for door interlock and laser warning lamp

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

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

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

The same connector provides a voltage source open for a low-voltage laser warning lamp (max. 24 V / 0.5 A). The voltage is switched on during laser emission only.

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

The contacts of the "INTERLOCK" and "FOOTSWITCH" connectors must never be connected to line power, as this would seriously damage the system. Connect these terminals only as specified in this paragraph.

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

4.4.3 Air flow connection

The *MultiStar* system is equipped with an internal pump, which produces a continuous airflow to prevent dust and particles from depositing on the optics during laser operations.

The airflow outlet connector is located at the top of the rear panel of the device (see Figure 3). It is internally connected to the air pump.

A plastic tube, the purge tube, is provided to connect this outlet connector to the inlet connector located on the handpiece.

Always verify that the plastic purge tube is properly connected to both connectors.

4.4.4 Footswitch

Connect the footswitch to the footswitch connector located at the rear panel of the device (refer to *Figure 3*). Make sure to insert the plug as far as it will go. Then, lock it by turning the cap nut clockwise.

4.4.5 Handpiece

To change handpieces, disconnect the purge tube from the handpiece barrel. Unscrew the handpiece from the articulated arm. Screw on the new handpiece and connect the purge tube.
The handpiece adapter is easily changed by unscrewing the end part of the handpiece and screwing on the new adapter.

4.4.6 Connection to power outlet

The *MultiStar* system must be connected directly to a wall outlet. The system should be connected neither to an uninterruptible power supply (UPS) nor to and electronic phase advancer or to an isolation transformer.

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

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

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

The *MultiStar* system should not share a power line with other heavy power-load equipment such as air conditioners or elevators. Ideally, the laser unit should be powered from a separate power line with a separate circuit breaker.

The device is provided with a power cable. First, plug the power cable into the power input connector on the rear panel of the device before connecting the other end of the cable to the power outlet.

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

Operation of the laser requires that the device be connected to a single-phase power outlet protected by a fuse rated for at least 500 VA (Type C, slow-blow).

4.5 Preparations for use

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

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

After acclimatization, switch the device on without an applicator connected and let the device warm up for at least 30 minutes.
Take care that the installation and operating environment of the device meets the following conditions:
Temperature: 5 to 30°C
Relative humidity: max. 80%.
Non-observance may result in the destruction of the device.

Besides, verify that the following requirements have been met:

- The line voltage specified on the label at the rear panel agrees with the line voltage available at the place of installation.
- The power plug has been plugged into an appropriate and properly grounded power outlet.
- The potential equalizing cable has been connected (if required).
- The footswitch plug has been properly connected to the footswitch connector on the rear panel of the device and screwed down.
- Warning lamps have been mounted to the laser room entrance and switched on (if necessary).

4.6 Switching on

Make sure that all safety precautions have been taken.

Then, follow this procedure:

- Verify that the Laser STOP button is deactivated (not pressed).
- Afterwards, insert the safety key in the key switch (see *Figure 2*) and turn it clockwise as far as it will go.

While the device automatically tests essential and safety-relevant modules, the starting screen appears on the display (see *Figure 5*) with the message “System check”.

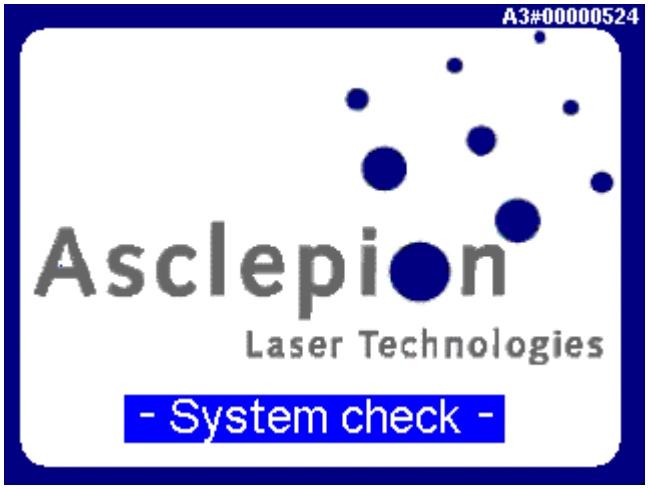

Figure 5: Screen at start up

After a few seconds, the BASIC menu (see *Figure 6*) will appear on the screen. The system automatically selects the following status:

- STANDBY mode
- Footswitch disabled
- Aiming source activated
- Exposure and emission parameters previously saved.

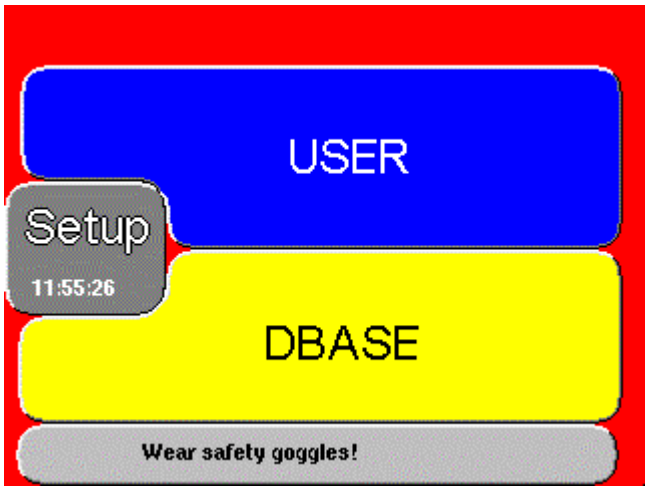

Figure 6: BASIC menu

From the BASIC menu, three menus are accessible:
– USER menu (*Figure 7*)
– SETUP menu (*Figure 20*)
– DBASE menu (*Figure 11*)
Enter the desired menu by touching the corresponding field.

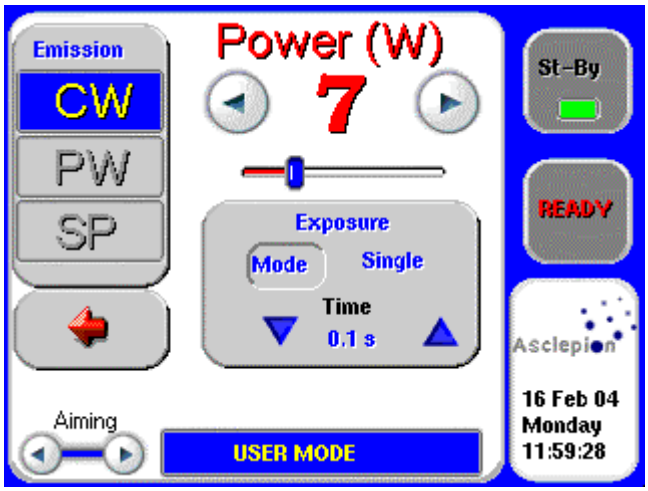

Figure 7: USER menu

In the USER menu, you can select the appropriate emission mode and parameters to be used for the treatment.
When you press the READY key, the green light near the control panel becomes red. This indicates that the system is calibrating the laser for the settings displayed.

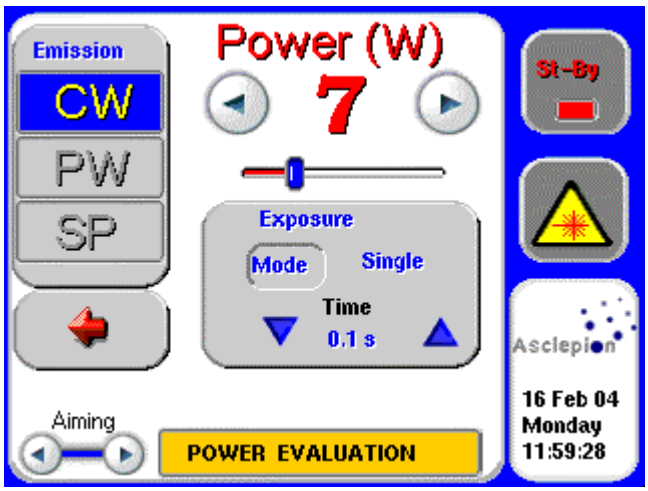

Figure 8: Power evaluation procedure

At the end of the power evaluation procedure, the red light remains lit. In addition, the READY key turns into the laser warning sign lighting yellow after a few seconds (see *Figure 8*).

The footswitch is enabled if both these indicators are permanently lighting.

The system is now ready for use. Step on the footswitch to start treatment.

5 Operation

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

5.1 USER menu

The USER menu *Figure 9* contains controls and displays for changing the system's operating parameters. A detailed description of each parameter is given below.

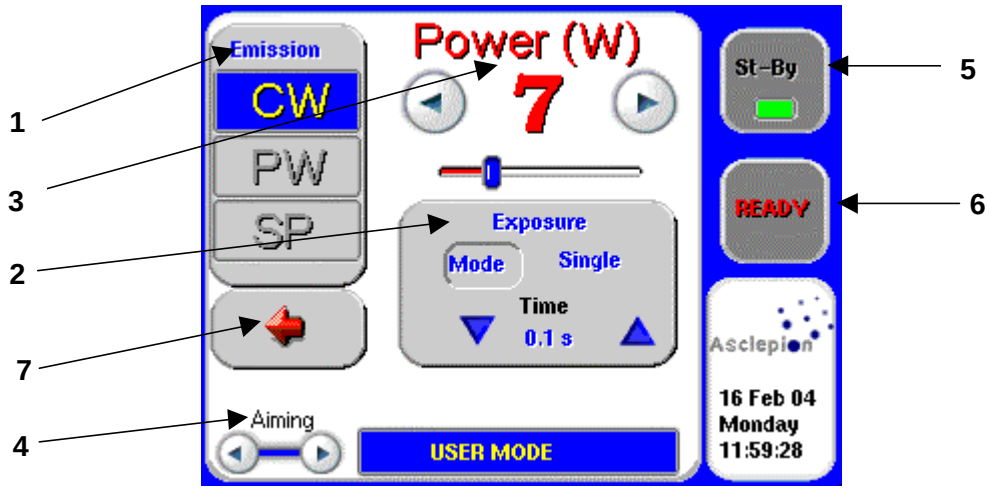

Figure 9: USER menu

5.1.1 Emission (1)

The CW key selects the **CONTINUOUS** (CW) laser emission mode with coagulation effect on tissue. In this mode, the CO_2 laser source emits radiation as long as it is switched on (and the footswitch is pressed). It provides a constant output power of a level to be selected by the operator according to the treatment to be performed.

The PW key selects the **PULSED** (PW) laser emission mode.

The system operates in pulsed mode using a fixed frequency. The power value will automatically be the last value set.

When you change the "Power" value, the system automatically changes the duty cycle: the higher the power, the higher is the duty cycle, and the effect on the patient is about the same as in "CW" mode (coagulation). The lower the power, the lower is the duty cycle, and the effect on the patient is about the same as in "SUPER PULSED" mode (vaporization).

With this mode, it is possible to cover the effects on the patient between “CW” and “SUPER PULSED” modes.

The SP key selects the **SUPER PULSED** (SP) laser emission mode.

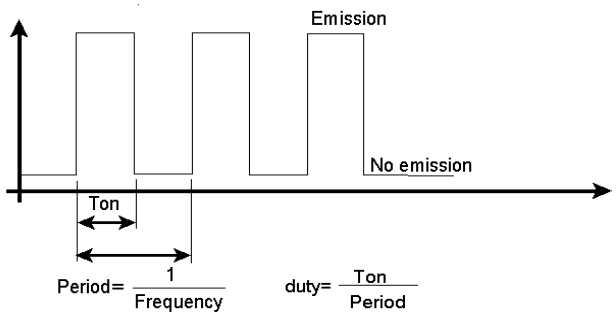

Figure 10: Emission mode SUPER PULSED

The superpulse mode permits high peak power with the best vaporization effects. If you select this mode while in “PULSED” mode, the power value will automatically be the last value set.

In SP mode, the system has a fixed laser pulse duration T_{ON} (see the example in *Figure 10*), while the output power is selectable – see the following *Section 5.1.3*.

Once the emission mode has been selected, the *MultiStar* system provides a constant output power, the level of which has to be selected by the operator according to the treatment to be performed.

See also Section *5.2,* “Power evaluation procedure”, for the description of the power calibration procedure performed by the system.

5.1.2 Exposure (2)

The *MultiStar* system allows controlling the exposure time during laser treatment via the CO_2 shutter.

The selected exposure mode is displayed on the screen (*Figure 9*) in the "Exposure" area. To change the exposure mode, touch the “Mode” button.

Three exposure modes can be selected:

- CONTINUOUS (Display: "Cont.")
- TIMED SINGLE EXPOSURE (Display: "Single")
- TIMED REPEATED EXPOSURE (Display: "Repeat")

Note that the exposure mode can be changed regardless of the emission mode selected.

In **continuous exposure mode**, the exposure time is fully controlled by the operator via the footswitch: as long as footswitch is kept pressed, the shutter is open, and thus laser radiation emitted.

When the **timed single exposure mode** has been enabled and the footswitch pressed, the *MultiStar* system opens the shutter and keeps it open only for the selected exposure time.

Once the selected exposure time has elapsed, the shutter is automatically closed regardless of whether the footswitch is still pressed.

If you want to start a new exposure, first release and then press the footswitch again.

The system displays the selected exposure time in the "Exposure" field (see Figure 9). Additionally, this field contains two keys to vary the exposure time between 0.1 s and 0.9 s (resolution: 0.1 s).

When the **timed repeated exposures mode** has been enabled and the footswitch pressed, the *MultiStar* system opens the shutter and keeps it open for the selected exposure time.

Once the selected exposure time has elapsed, the shutter is automatically closed. If the footswitch is still pressed, the system waits for 400 ms. After 400 ms the shutter is opened again and a new exposure performed. This sequence is continuously repeated as long as you keep the footswitch pressed.

The system displays the selected exposure time in the "Exposure" field (see Figure 9). Additionally, this field contains two keys to vary the exposure time between 0.1 s and 0.9 s (resolution: 0.1 s).
Note that the delay between two exposures is factory-set to 400 ms. The delay cannot be modified by the operator.

5.1.3 Power (3)

The POWER selector keys increase or decrease the power in the following ranges dependent on the emission mode selected:

Emission mode	Power range	Increments
CONTINUOUS (CW)	2 W … 30 W	1 W
PULSED (PW)	0.5 W … 25 W	1 W
SUPER PULSED (SP)	0.5 W … 12 W	1 W

The selected power is displayed between the power selector keys.

For the description of the power evaluation procedure performed by the system when the CO_2 source is switched on and each time the power level is changed, refer to Section 5.2, “Power evaluation procedure”.

5.1.4 Aiming (4)

The "Aiming" keys adjust the intensity of the aiming beam from OFF to 100% in intervals of 10%.

As the aiming beam passes through the same beam delivery system as the surgical beam, it provides a good method of checking the integrity of this system. If the aiming beam is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this may indicate a damaged or not properly aligned beam delivery system.

In these cases, you are advised to stop using the system and immediately call technical assistance.

5.1.5 St-By (STANDBY) key (5)

The STANDBY key allows you to switch off the CO_2 laser source.

5.1.6 READY status (6)

The READY key makes the system ready to operate – it switches on the CO_2 laser source and enables the footswitch.

If the device is not used for 10 minutes, the system automatically switches off the CO_2 laser source.

This automatic switch off allows extending the life of the internal system components.

5.1.7 Returning to the BASIC menu (7)

Press the Go Back key (7), *Figure 9*, to return to the BASIC menu.

This operation is possible only in STANDBY, otherwise the system will reply with an acoustic and visual signal indicating an action that is not permitted.

5.2 Power evaluation procedure

The *MultiStar* system is equipped with an internal power meter which allows to measure the real output power level of the CO_2 laser source.

The power evaluation and calibration procedure is started and continuously performed as the CO_2 source is switched on.

The operator can select the output power level in the range permissible in the selected emission mode.

When the CO_2 source is switched on, and each time the power level is changed while the source is already switched on, the *MultiStar* system starts flashing the "POWER EVALUATION" message on the screen to warn the user that a power evaluation and calibration procedure for that power level is in progress.

During this procedure, the footswitch is automatically disabled, so no laser treatment can be started.

The procedure is intended to verify the real power level provided by the CO_2 laser source and make it agree with the power level selected by the operator, if necessary.

At the end of the procedure, the "POWER EVALUATION" message is cleared.

The following two conditions may occur:

- The measured power level agrees with the selected power level or the procedure succeeds in making them agree.
  In this case, no further message is displayed and the system is ready to operate.
- The measured power level doesn't agree with the selected power level AND the procedure fails to make them agree.
  In this case, a double warning sound is generated and the measured power level currently available is flashing on the screen for about 5 s to warn the operator.
- After 5 s, this value stops flashing and it is taken as the effective treatment power level.

Once the calibration procedure is completed, the *MultiStar* system continues monitoring the measured power level in order to keep stable the output power.

If the measured power level changes so that it does no longer agree with the value displayed on the screen, the system acts as follows:

- If a laser treatment is in progress, i.e. the footswitch is pressed, the new power level is displayed on the screen with black characters on a white background and the internal buzzer produces 5 sounds per second - instead of 1 sound per second - in order to warn the operator as long as he keeps the footswitch depressed.
- If the power levels no longer disagree, the originally set power level is displayed on the screen with standard characters and the standard sound (one per second) generated again.
- If no laser treatment is in progress, a double warning sound is generated and the new power level is flashing on the screen for about 5s to warn the operator.

?? After this period, this value stops flashing and it is taken as the new effective treatment power level.

?? If the detected output power is outside the stipulated limits with respect to the nominal ones, the emission is immediately stopped and the *MultiStar* system displays a HIGH POWER or LOW POWER alarm (see Section 9, “Troubleshooting”).

5.3 Activation of READY mode and treatment

Before pushing the READY key, the attending physician should verify that all persons present in the laser room wear laser protective eyewear DI 10,600 L4

Verify again that

?? all laser safety precautions have been taken,

?? the aiming laser is visible at the treatment site, and

?? the handpiece has been placed onto the desired treatment area.

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

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

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

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

The *MultiStar* is equipped with an easy to operate **"Laser STOP"** button. It is located at the top front of the device (Figure 2). In an emergency, the laser is instantly deactivated when you strongly push this button, thus eliminating any risk for operator and patient.

When the emergency was remedied, restore the functioning of the Laser STOP button by turning it anticlockwise until the button comes out.

5.3.1 Releasing the treatment beam

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

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

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

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

Laser power during treatment

Once you have calibrated the laser power output to the appropriate level for treatment, you can begin treating the patient. During treatment, the system constantly monitors the laser power and compares it to the calibrated power setting.

If during treatment the laser power increases or decreases by more than 20% from the calibrated power output, the displayed value changes to the currently detected power and the warning tone rate increases. If the footswitch remains depressed, treatment will not be interrupted.

“Emission” indicator

The yellow indicator described in the system start-up procedure (see chapter 4.6) also shows the current state of the laser shutter and lights red only when laser emission is in progress.

Internal buzzer

The system is equipped with an internal buzzer, which produces an acoustic signal of fixed length.

The buzzer operates in the following cases:

?? It warns the operator in case a wrong action has been performed, for instance, if you press the footswitch when it is disabled.

?? If a laser treatment is in progress – CO_2 source switched on, footswitch enabled and pressed, shutter open, real power level correct (see “Power evaluation procedure” on chapter 5.2) – a sound is produced every 1s. This pulsed sound is intended to help the operator ‘measure' the treatment time.

?? If a laser treatment is in progress – CO_2 source switched on, footswitch enabled and pressed, shutter open, power level disagreement (see paragraph “Power evaluation and procedure” on chapter 5.2) – five sounds are produced every 1s. This faster pulsed sound is intended to warn the operator that a power mismatch has been detected, that is the real CO_2 output power level no more agrees with the power level found by the power evaluation procedure.

If you intend to interrupt the treatment for some time or if you are finished with the treatment, switch the laser to the safe STANDBY mode by pressing the "St-By“ key. In this state, it is impossible to release laser emission unintentionally.

After a longer period of inactivity in READY mode, the device will automatically switch to the STANDBY mode.

5.3.2 Switching the device off

Exit the READY mode and switch to STANDBY mode.

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

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

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

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

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

5.4 DBASE menu

Figure 11 shows an example of the screen when the DBASE menu is selected.

The CO_2 laser source must be switched off (STANDBY state) otherwise the DBASE menu cannot be entered. A warning sound will be produced if you try to do so, e.g. by pressing the Go Back key.

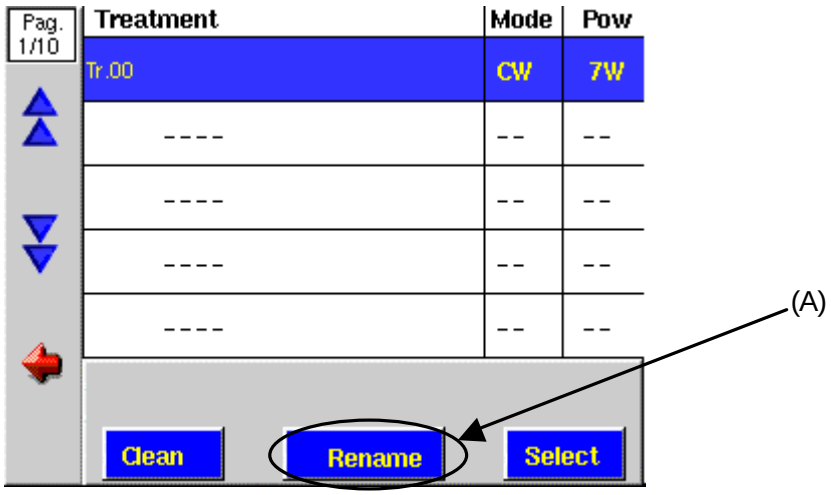

Figure 11: DBASE menu

The *MultiStar* system allows you to store 50 treatment protocols.

At 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.

Once you have found the correct parameters for the treatment, you can save them to the database as treatment protocol, which can thus be recalled the next time the same disease or the same type of disease is to be treated.

5.4.1 How to store a treatment

To store the currently selected treatment parameters, proceed as follows:

1. Set the parameters in the USER menu.
2. Enter the DBASE menu by touching the “DBASE” field in the BASIC menu (Figure 6).
3. Select a blank treatment field by touching any blank row in the current table. This row will now appear highlighted (see Figure 12).
   Use the 'up' or 'down' arrow keys, located on the left side of the screen, to change pages if necessary.
4. Press the “Define treatment using current parameters” field located at the bottom of the screen (highlighted in Figure 12): the current emission parameters are saved in this row with the default name "Tr.##" where "##" is a progressive number (Figure 11).

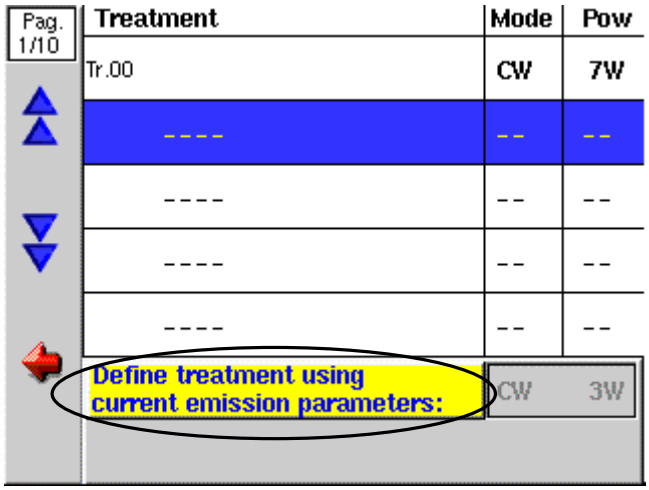

Figure 12: How to store a treatment

5. To change the treatment name, touch the "Rename" key (A) in *Figure 11*. This will bring up the keyboard display shown in *Figure 13*:

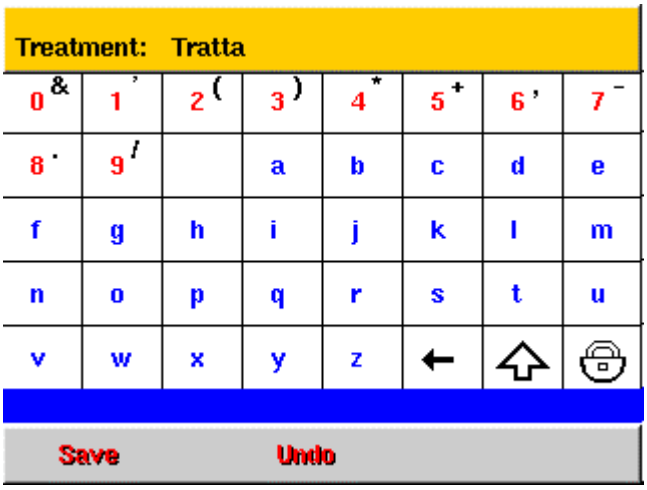

Figure 13: Keyboard to change the treatment name

6. Once the "Save" key is pressed, touch the "Exit" key that appears at the bottom of the screen to return to the DBASE menu.

5.4.2 How to select a treatment

To select a stored treatment, proceed as follows:

?? Enter the DBASE menu by touching the area “DBASE” in the basic menu (*Figure 6*).

?? Select the desired treatment by touching the associated treatment name: the selected storage fields will now appear highlighted.

?? Touch the "Select" key (B) (*Figure 14)*: the USER menu will now appear with the saved parameters displayed.

?? If you want to modify treatment parameters, please refer to the next section.

5.4.3 How to modify a treatment

To modify a stored treatment, follow one of these procedures:

Procedure 1

?? Set the desired parameters in the USER menu (*Figure 7*).

?? Enter the BASIC menu (*Figure 6*) and touch the DBASE field.

?? Select the treatment name associated with the parameters to be changed: the selected field will now appear highlighted.

?? Touch the "Modify treatment using current emission parameters" field (A) (*Figure 14*).

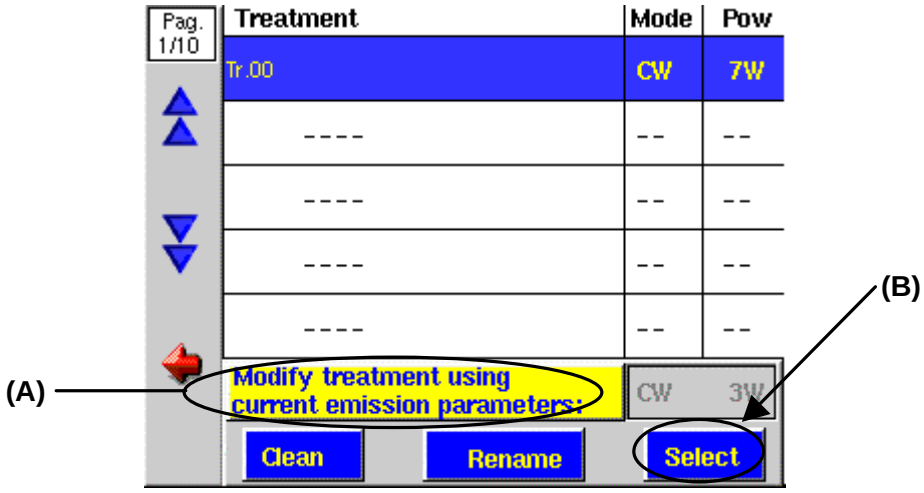

Figure 14: How to modify a treatment

?? Confirm the program query with "Yes" (*Figure 15*). The new treatment parameters will be saved and displayed in the DBase menu.

Figure 15: Modify the treatment or not

Procedure 2

?? Enter the DBASE menu by touching the “DBASE” field in the basic menu (*Figure 6*).

?? Touch the treatment name associated with the parameters to be changed. The selected field will now appear highlighted.

?? Touch the "Select" key (B) in *Figure 14*. This will bring up the modified USER menu (*Figure 16*).

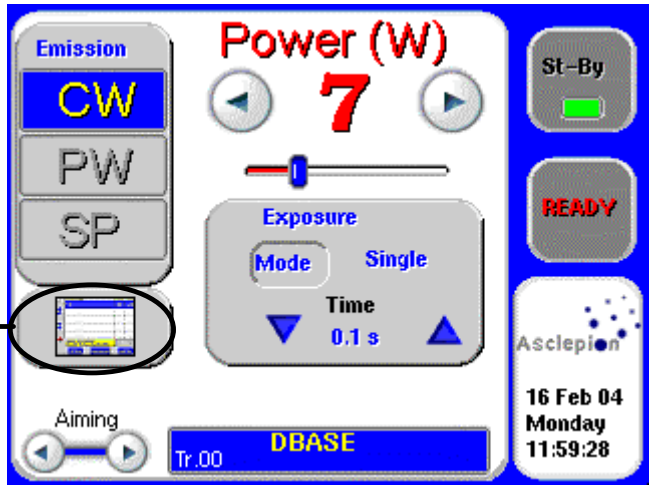

Figure 16: User menu with selected treatment

?? Change the treatment parameters as necessary;

?? Touch the field shown as (A) in *Figure 16*: once the DBASE menu is entered, the system asks you if you want to save the changes (*Figure 17*).

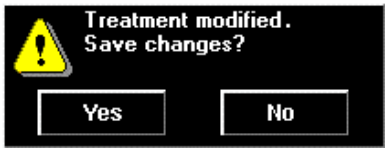

Figure 17: Change the treatment or not

5.4.4 How to delete a treatment

To clear a stored treatment, proceed as follows:

?? Enter the DBASE menu by touching the area “DBASE” in the BASIC menu – (*Figure 6*).

?? Select the treatment name associated with the parameters to be cleaned. The selected field will now be displayed in reverse contrast.

?? Touch the "Clean" field highlighted in *Figure 18*.

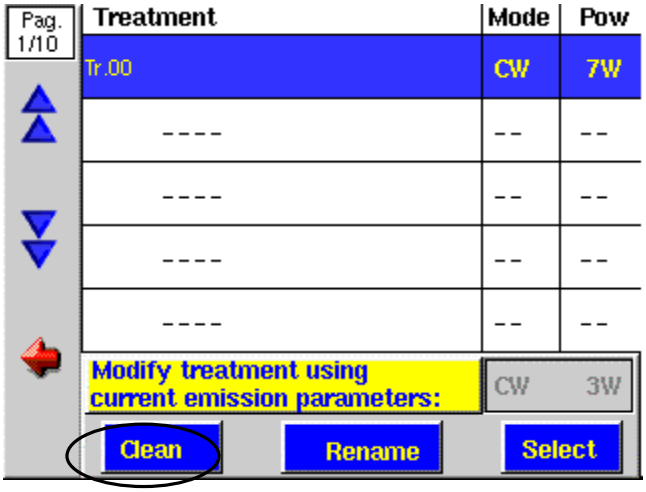

Figure 18: How to clean a treatment

?? Confirm the program query (*Figure 19*). The selected treatment will be cleaned and the saved values lost.

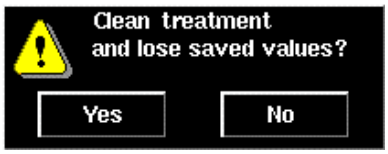

Figure 19: Clean the treatment or not

5.5 SETUP menu

The SETUP menu allows you to set the system time and date, adjust the brightness of the LCD screen and select the language of the user interface. Figure 20 shows an example of the SETUP menu.

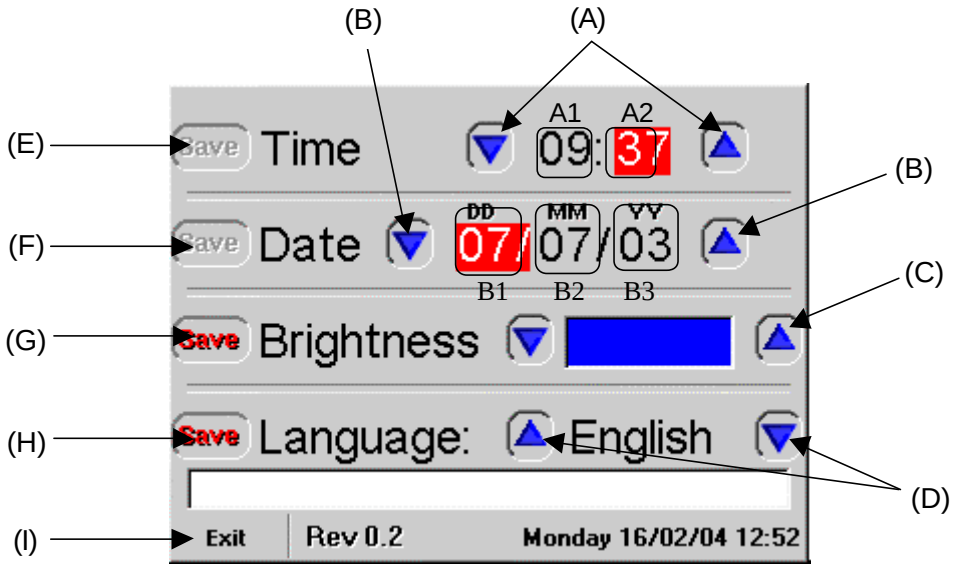

Figure 20: SETUP menu

5.5.1 Setting the time

Press keys **(A)** to change hour and minute previously selected by pressing fields A1 or A2. The parameter to be changed is highlighted by white characters on a red background (see *Figure 20*). Press **(E)** to save the changes.

5.5.2 Setting the date

Touch keys **(B)** to change day, month or year selectable by pressing keys B1, B2 or B3. The parameter to be changed is highlighted by white characters on a red background (see Figure *20*). Press **(F)** to save the changes.

5.5.3 Setting screen brightness

Press key **(C)** to change the brightness: The varied brightness becomes instantly visible on the screen. Press **(G)** to save the change.

5.5.4 Setting the language of the user interface

Use key **(D)** to change the language. Press **(H)** to save the change.

5.5.5 Exit

Press key **(I)** in Figure 20 to quit this menu and return to the BASIC menu. If you failed to save the changes, the program will ask you if you intend to save them.

Figure 21: Save the SETUP settings

Press "Yes" to save changes and quit; press "No" to return to the BASIC menu without saving any changes or press "Undo" to return to the SETUP menu.

6 Accessories

Please note that the Medical Product Act binds you to use only such accessories on the device that have been tested and approved and that are intended for this laser by Asclepion Laser Technologies GmbH.
On request, Asclepion Laser Technologies GmbH will readily send you an updated list of such accessories. We strongly advise against the use of accessories from other manufacturers. Even if an official testing authority should have certified that a specific accessory unit could be used safely, Asclepion Laser Technologies GmbH cannot assume any liability for these products.

The following accessories come with the *MultiStar* system. They can be purchased for replacement if necessary.

Designation	Part No.
Handpieces	xxxx[1]
Luer Tips	xxxx[1]
Scanner	xxxx[1]
Micromanipulators	xxxx[1]
Laparoscope Accessories	xxxx[1]
Microscope & Colposcope Adaptors	xxxx[1]
Articulated Arm Thread Adaptors	xxxx[1]
Laser protective eyewear D,I 10,600 L4	1220

[1] The Manufacturer undertakes to supply, upon request, a detailed accessory list.

7 Maintenance

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

VISUAL INSPECTION OF THE DEVICE

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

CHECK OF COOLING SYSTEM

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

CHECKING THE ACCESSORIES

Check if all accessories are in perfect state.
Frequency: Before every use
To be checked by: Operator of the device

PREPARATIONS FOR RELOCATION / TRANSPORT OF THE DEVICE

Before relocating the device:

- Disconnect the power plug.
- Fix the articulated arm to the arm holder.
- Disconnect the footswitch.
- Disconnect the door interlock plug.

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

For regular safety tests and calibration see chapter 10 “Regular Safety Tests and Calibration”.

8 Cleaning, Disinfection and Sterilization

8.1 Advice for cleaning, disinfection and sterilization of accessories

Multiple use accessories

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

For that, follow the general advice given in Sections 8.2 and 8.3 of this manual.

8.2 General advice for cleaning, disinfection and sterilization

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

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

INSTRUCTIONS:	
Workplace:	Remove dirt from surfaces using a disposable / paper towel.
Storage and transport:	No special requirements. It is advisable to recondition accessory items as soon as possible after their use.
Preparations for cleaning:	No special requirements. Disassemble accessory units by following the instructions for use/cleaning provided.

Cleaning, Disinfection and Sterilization

Manual cleaning:	Equipment: Neutral cleaning agent (e.g. Edisonite Super), brush, running water Procedure: 1. Rinse accessory to remove dirt from the surface (Temperature <30°C) 2. Apply cleaning agent to all surfaces using a brush. NOTE: For cleaning cannulas and blind holes, use a suitable brush to access all parts. Use an ultrasonic cleaning device, if necessary. 3. Hold the accessory under running water for three minutes. In doing so, make sure the water rinses through the cannulas. Blind holes must be filled with water and emptied repeatedly.
Automatic cleaning:	Equipment: Cleaning/disinfecting equipment, cleaning agent (e.g. Edisonite Super) 1. Load accessory parts in the equipment so that water can drain from cannulas and blind holes. 2. Set the standard cycle: Wash at least five minutes and rinse three minutes. 3. When taking the accessory parts out, inspect them visually for dirt. Particularly take care that blind holes and cannulas are clean. Repeat the cleaning cycle or clean the accessory manually, if necessary.
Disinfection:	In manual cleaning, spray disinfectant (e.g. Softasept N or Meliseptol) onto the accessory parts. Let the disinfectant take effect and wipe it off following the instructions of the manufacturer. In automatic cleaning procedures, generally use thermal disinfection (e.g. disinfection temperature: 93°C, time 10 min.)
Maintenance, control and testing:	No special requirements.
Packing:	A standard polyethylene / Tyvek bag can be used. The bag must be large enough for the accessory to allow closing without the seal being strained.
Sterilization:	Vacuum autoclave, at least five minutes at 134°C. 150°C must not be exceeded.
Storage:	No special requirements.

The manufacturer has validated that the instructions given above are SUITABLE for the preparation of the accessory parts for their reuse. The reconditioner is responsible that the actually performed reconditioning procedure yields the desired results with the equipment

and material used and the personnel working in the reconditioning facility. For that, normally validation and routine supervision of the reconditioning procedures are necessary. Likewise, any departure from the provided instructions should be assessed carefully by the reconditioner for efficacy and negative consequences.

8.3 Special advice for handling, cleaning, disinfection and sterilization

Beam delivery system

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

Avoid directly touching optical surfaces.

Handpiece and spacers

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

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

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

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

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

For the reconditioning of handpieces and spacers, observe the general advice given in Section *8.1*.

Clean handpiece lenses before use.

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

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

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

Focusing lens in the handpiece

The focusing lens should be checked by the operator after any important treatment or at most every 10 treatments.

Proceed as follows:

?? Remove the lens holder from the handpiece.

?? Clean the surfaces of the lens with optic paper soaked in acetone.

?? Blow off any residuals with a clean and dry airflow.

?? Reposition the lens inside the lens holder.

The focusing lens is very fragile. Therefore, take extreme care during assembly and disassembly. Avoid scratching the surface while cleaning.

Remember that cotton and some types of paper contain glass fibers that may scratch the surface of the lens.

Use only recommended products.

Complete device

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

Remove (with vacuum cleaners) any eventual solid residues (dust, particles etc.). Avoid the contact of water or other liquids with the device. Dry with soft, clean cloths or chamois.

Cleaning, Disinfection and Sterilization

Users are allowed to clean the external surfaces of the device only. Do not use chemical solvents and/or abrasive detergents. Take care that detergent does not gets into cavities or apertures of the device.

Do not use alcohol to clean the surface of the display.

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

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

9 TROUBLESHOOTING

The *MultiStar* system has an integrated fault management system, which constantly monitors critical situations and displays any detected problem.

This section describes these faults and provides troubleshooting of some problems that can be identified and solved by the operator.

9.1 Fault management

The *MultiStar* system is capable of detecting fault conditions that may be dangerous for the patient, the operator and for the system itself.

As soon as one of these conditions is detected, the system automatically switches to safety mode: the shutter is closed, the CO_2 source is turned off and the footswitch is disabled.

The System Fault screen (see Figure 22) is immediately visible on the LDC display.

Figure 22: System Fault screen

The *MultiStar* system displays only the currently detected fault conditions. In Figure 22, for instance, a TEMPERATURE fault was detected.

The table will be updated immediately in case another fault is detected while the fault menu is already displayed.

Moreover, once a fault is detected, the MultiStar system keeps on displaying a fault related sign even if the fault has been removed: this allows the operator to record the detected faults to eventually inform the technical assistance service.

The message "Any Key to reset" tells the user to press any area of the screen to quit the fault menu and return to the User menu.

Note that you can exit the fault menu only if no fault condition is detected anymore. Otherwise, when you press a key, the fault menu will be displayed again. In this case, only those faults will be displayed with black characters on a red background that haven't been removed yet.

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

1. The Laser STOP button has been unlocked (by turning the red knob anticlockwise until the lock is released and the button jumps out; refer to *Figure 2*).
2. The main fuses on the rear panel of the device (refer to *Figure 3*) are not defective. To check the fine-wire fuses, disconnect the device from the line.
3. The power cord on the rear panel of the device has been connected to the wall socket.
4. The line fuses of the room are not defective.

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

The following types of error messages are possible:

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

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

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

9.2 Error messages and fault removal

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

Improper use or maintenance of the laser system may void the warranty granted by Asclepion Laser Technologies GmbH. Before starting any repair or if you have questions that have not been answered by this manual, contact your service representative (see *Section 11*).

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

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

Error message	Explanation / Corrective action
Interlock	- The door interlock contacts are open or the door interlock plug is not connected (*Figure 4*). Connect the door interlock contacts correctly or activate the door interlock switch. Press any key to reset this fault display. If the fault persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Temperature	- The temperature of the coolant inside the CO_2 laser source or the temperature of the high voltage power supply unit is too high. Do not turn off the system in order to let the coolant cool it down. Wait approximately 2 minutes, and then press any key to reset the fault display. If the fault persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.

Troubleshooting

Error message	Explanation / Corrective action
Shutter	- The laser shutter's detected position is not the same as the shutter's expected position. Press any key to reset the fault display. If the fault persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
High Voltage	- Malfunction of the internal high voltage power supply This fault is displayed if the unit is not properly working. Press any key to reset this fault display. Then press the READY key. If the fault persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Flow	- Internal flow of the coolant is too low. Press any key to reset the fault display. Switch the device off and on again. If the fault persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
Cur.thres.	- Max. current of the internal high voltage power supply is too low. At start up, during the internal self-test procedure, the system verifies the maximum possible CW current value provided by the internal high voltage power supply to the CO_2 laser source. If this value is too low, the "CUR.THRES." fault will be displayed. Turn the device off and on again. If the fault persists or a "HIGH CURRENT" fault is detected, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.

Error message	Explanation / Corrective action
Current zero	- The current provided by the internal high voltage power supply to the CO_2 laser is too low. Press any key to reset the fault display. Then try to switch on the laser source again. If the fault persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
High current	- The current provided by the internal high voltage power supply to the CO_2 laser is too high with respect to the selected power level. Note that the internal tests, which may cause a "HIGH CURRENT" fault, are based on the current value measured at start up. First, press any key to reset the fault display. Then switch on the laser source again. If the fault persists, turn off the system and then turn it on again in order to make the system remeasure the reference current value. If the fault persists or if the "CUR.THRES." message appears, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.
High power / Low power	- The power evaluation procedure detects a wrong output power level. Carefully read paragraph “Power evaluation procedure” in Section *5.2.* Press any key to reset the fault display. Then try to switch on the laser source in order to perform once again the power evaluation procedure. If the fault persists, contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.

Troubleshooting

Error message	Explanation / Corrective action
EEPROM	- An internal memory component doesn't work properly. It may be displayed at the start up of the system or when the CO_2 laser source is switched off (STAND BY key pressed). This fault is not critical regarding the performance of the system, but there might be problems with the management of the treatment programs, i.e. the system might "forget" the changes made by the operator to the treatment programs. If the fault persists contact Asclepion Laser Technologies GmbH or a service representative expressly authorized by Asclepion Laser Technologies GmbH.

If the system detects power fluctuations (MODE set to either CW and PW), the power level on the screen may be displayed with yellow characters instead of red characters once calibration is completed. If laser treatment is in progress when this occurs, the warning tone rate increases. These two conditions are warnings, but no fault conditions. The laser does not go into STANDBY and the operator can continue with the laser treatment.

Troubleshooting

9.3 Possible malfunctions

Problem	Possible Cause	Correctiv action
System does not turn on.	Power cables are not properly connected.	Check and secure power cables.
	Fuses missing or blown.	Install/replace fuses.
	Laser STOP button is pushed in.	Turn it anticlockwise until the button comes out.
	Key switch is not in the ON position.	Insert the key and turn the key switch to the ON position.
System does not fire when footswitch is activated	Laser not in READY mode	Press READY key and wait for LEDs to light up.
	Footswitch not connected	Check footswitch connection.
Poor laser emission or no laser emission from the articulated arm	Damaged optics in lens housing.	Call Technical Service.
	Articulated arm out of alignment.	Call Technical Service.
Aiming beam and CO_2 beam not coaxial	Articulated arm not in operating position.	Unfold the arm as instructed.
	Articulated arm out of alignment or damaged.	Call Technical Service.
Aiming beam is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused	Contaminated or damaged optics in the applicator or articulated arm.	Remove the handpiece (in STANDBY). If the aiming beam is OK at the arm outlet, change the handpiece or clean the handpiece optics (see chapter 8). Otherwise, stop using the system and call Technical Service.
Power displayed after calibration is lower than power selected	System can not deliver the power selected	Carefully read paragraph “Power evaluation and calibration procedure” in Section "Use of the control panel".

If any problems occur that are not stated in the troubleshooting chart or the suggested solutions do not work, call the Manufacturer.

10 Regular Safety Tests and Calibration

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

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

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

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

SCOPE OF ANNUAL SAFETY TESTS

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

Only service technicians who are appropriately qualified and authorized by the Manufacturer are allowed to carry out the annual safety tests and the calibration of the laser power.

The tests should be run in the order specified:

?? Visual inspection of laser source, device and accessories,

?? Check of the coolant level.

The coolant of the MultiStar system is a fluoriniert liquid. Do not introduce in the cooling system any liquids other than the one supplied or recommended by the Manufacturer. The use of improper liquids can permanently damage the laser.

Regular Safety Tests and Calibration

DO NOT DISPOSE OF THE COOLANT IN THE ENVIRONMENT.
Ensure that it is disposed of in compliance with national and local law.

- Measurement of protective-conductor resistance
- Earth leakage test under normal conditions
- Measurement of the actual output powers of the laser at the handpiece; calibration of laser and internal power meter, if necessary,
- Functional test

For routine maintenance procedures see chapter 7 “Maintenance”.

The Manufacturer undertakes to supply, upon written request, circuit diagrams, part lists, setting instructions and any information necessary to the maintenance staff, authorized by the Manufacturer, concerning those parts of the system, which the Manufacturer considers to be reparable.

11 Service

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

If you need assistance by customer service, please get in touch with us via the address or phone number given below. When contacting your service representative of Asclepion Laser Technologies GmbH, always keep the model and the serial number of the device at hand. These numbers are specified on the identification label located at the rear panel of the laser device (refer to *Figure 24* or *Figure 32*).

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

Phone: +49 (0) 3641 220 – 423
Fax.: +49 (0) 3641 220 – 422
E-Mail: info@asclepion.com

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

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

12 Warnings

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

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

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

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

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

Never look directly into the laser exit aperture of the articulated arm or the handpiece even with protective eyewear.

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

Laser plume may contain viable tissue particulates. Use of a laser smoke evacuator with filters is recommended.

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

Warnings

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

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

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

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

13 Labeling

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

The *MultiStar* system contains warning labels placed in appropriate locations. All personnel should be familiar with these labels and their meanings.

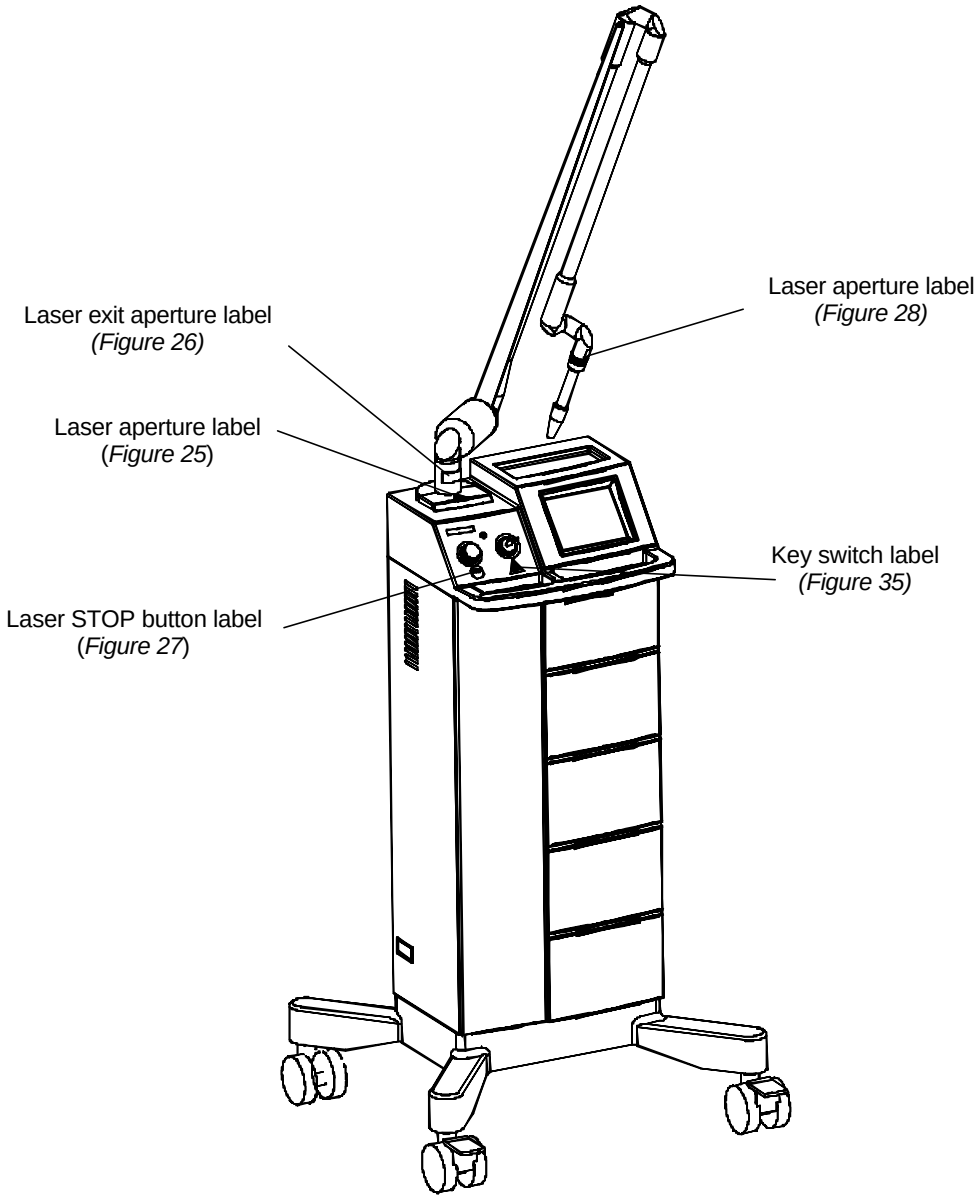

Figure 23: Labels on front panel

Labeling

All labels must be kept in their position and in good condition.
Replace damaged labels immediately.

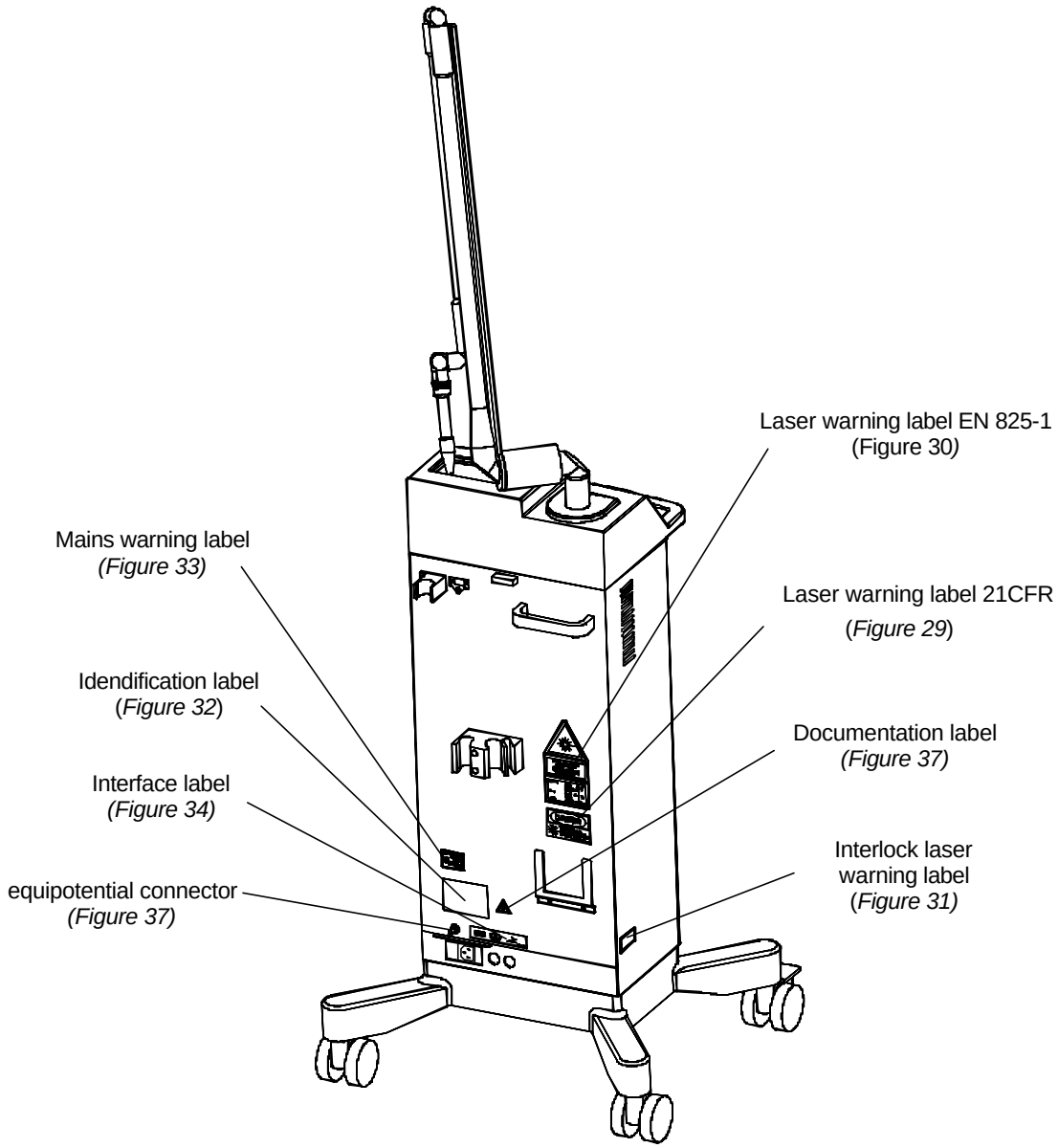

Figure 24: Labels on rear panel

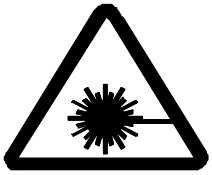

Figure 25: Laser exit aperture EN 60825-1.

This label identifies the aperture from which laser radiation is emitted.

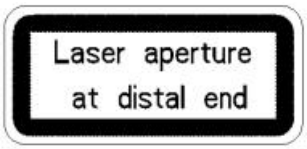

Figure 26: Laser exit aperture 21 CFR.

This label identifies the location of the laser beam exit aperture.

Figure 27: Laser STOP button.

This label identifies the emergency switch for fast laser turn off.

Figure 28: Laser aperture 21 CFR.

This label identifies the aperture from which laser radiation is emitted.

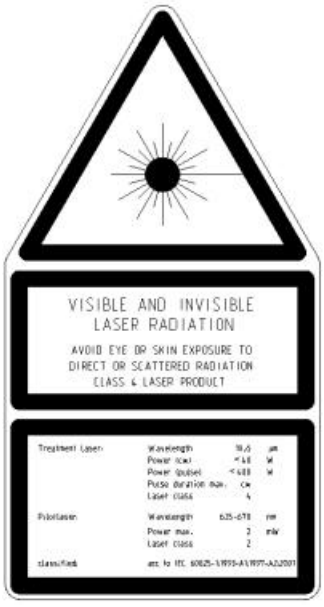

Figure 30: Laser warning. EN 60825-1.

This label indicates the maximum values of energy emission and the classification of the laser source.

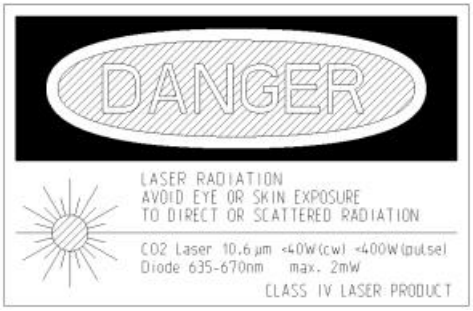

Figure 29: Laser warning label 21 CFR.

This label indicates the maximum values of energy emission and the classification of the laser source.

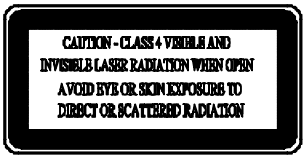

Figure 31: Laser warning sign interlock.

Warning on dangers related to the exposure to laser radiation in case of the removal of panels of the device casing.

Labeling

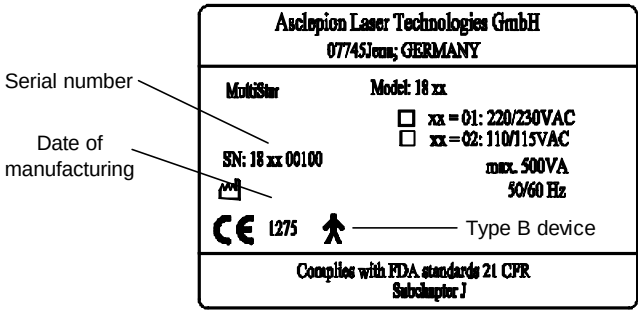

Figure 32: Identification label

Type label with type-specific data of *MultiStar* system.

Figure 33: Mains warning label.

Warning. The technician is prompted to pull the power plug before opening the device.

Figure 34: Interface connectors.

Figure 35: Key switch label.

Caution. The user is advised to remove the key after use.

Figure 36: Equipotential connector

Figure 37: Attention: Observe accompanying documentation.

Warning. The operator is advised to carefully read the user's manual before using the system.

14 Disposal

14.1 System's lifetime

The lifetime has been established based on considerations related to the ageing time of the type or class of the product, rather than to technical considerations on the deterioration of critical parts or components.
The lifetime of the equipment is 5 years.

14.2 Disposal

At the end of the lifetime of the equipment and/or accessories, the material can be disposed of as standard, not dangerous material.
The device must be disposed of in compliance with the European Directive 2000/532/EC, the regulations on electronic waste, and in consideration of relevant local regulations.