Nd:YAG-Laser MY40 1.3 / MY40e 1.3

English

Operating Instructions and Technical Specifications

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KLS martin GROUP

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1 Product Liability and Warranty

Gebrüder Martin will accept no responsibility for the safety, reliability and proper functioning of the units unless:

- any readjustments, modifications or repairs that become necessary are carried out by persons authorized to perform such work;
- all electrical installations of the respective room comply with the requirements set by pertinent IEC regulations;
- the unit is used in accordance with the Operating Instructions provided. Any modification or repair work performed on the unit by persons not specially authorized by the manufacturer to do such work shall void the warranty given.

The warranty shall also be voided if the user employs optical fibers that have not been approved by Gebrüder Martin. Moreover, the user is strictly required to observe the handling instructions relating to the optical fibers and applicators used. The manufacturer will accept no liability – whether within or after the warranty period – for any damage done to optical components as a result of connecting unclean or defective fibers to the laser unit or the handpiece. The same applies if KLS Martin disposable optical fibers are resterilized and reused.

Our Standard Conditions of Sale as updated from time to time shall apply.

Notice!

The warranty does not cover damage due to improper handling (regarding the unit as well as its accessories). Therefore, read these Operating Instructions carefully prior to operating the unit, making sure that you have a good understanding of everything contained therein.

2 Safety Notices

DIN EN 60825-1 (2003-10)	Safety of laser products – Part 1: Equipment classification, requirements and user's guide
DIN EN 60601-1 (1996-03)	Medical electrical equipment – Part 1: General requirements for safety
DIN EN 60601-1-2 (2002-10)	Medical electrical equipment – Electromagnetic compatibility; Requirements and tests
DIN EN 60601-2-22	Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
BGI 832	"Betrieb von Lasereinrichtungen (Anwendung der Unfallverhütungsvorschrift 'Laserstrahlung'" (BGV B2)) (Regulations for the prevention of accidents – laser radiation)
MDA (MDD)	Medical Devices Act (see Medical Devices Directive / MDD)

Any deviating national provisions and regulations must be observed as well!

2.1 General Provisions

Installation and commissioning (initial start-up of the unit) may only be carried out by qualified persons who have been specially trained and authorized by Gebrüder Martin to perform such work.

Notice!

Any person who is in any way involved in the operation of this unit must be fully familiar with these Operating Instructions. Note that improper handling (i.e. any action not in compliance with the instructions given herein) may lead to personal injury and/or equipment damage.

Improper handling as well as modifications or repairs performed by non-authorized persons shall void the warranty given.

Please do not use the system unless the following steps have been taken:

- Acceptance of the unit by the purchasing department;
- formal appointment of a Laser Safety officer by the owner/operator of the unit (in acc. with § 6 BGV B2 (Germany) or equivalent national regulations concerning the prevention of accidents);
- appointment of a person who is responsible for the unit; familiarization of that person and other staff with the unit;
- setting up of an equipment (medical-devices) log;
- registration of the unit with the respective employers' liability insurance association and the official body responsible for labor safety matters (if applicable);

- handing over of the unit in a ready-for-use condition; appropriate user instruction, to be provided either by Gebrüder Martin or an authorized representative;
- carrying out all safety measures;
- making sure that all operational procedures as well as measures to be taken in cases of trouble/failure are fully understood.
  When using the unit in medical practice, all pertinent regulations for the prevention of accidents (in Germany: VGB 93) must be duly observed. Such medical use includes diagnostic, surgical or therapeutic applications involving laser radiation (in the broadest sense). The operator of the unit and the safety officers (e.g. the Laser Safety officer) are responsible for the proper performance of all safety measures required, thus ensuring that the use of the laser will not pose any danger to the patient, the treating physician or any other person present during laser operation.

Moreover, the following supplementary provisions need to be observed:

- The **MY40 *1.3* / MY40e *1.3*** laser may be operated only by persons who have been duly authorized to perform such work. These staff members need to be fully familiar with the laser unit and must have a full understanding of all safety measures required. The names of these authorized persons must be recorded in the medical devices log.
- The staff instruction should be repeated on an annual basis; all people participating in such training should confirm their participation by signature.
- Whenever the unit is not in operation, it must be protected against unauthorized use (e.g. by locking the supply unit and keeping the key in a safe place).
- The unit must be operated and maintained in accordance with these Operating Instructions; this also applies to the regular safety checks that are required.

The **MY40 *1.3* / MY40e *1.3*** laser	
is a	Class IIb unit (acc. to the Medical Devices Act/Directive)
that classifies as a	Class 4 laser product (acc. to DIN EN 60825-1: 2003-10)
and carries the	CE-mark (in acc. with Directive 93/42/EEC)

We recommend the operator of the unit to keep the following documents easily accessible at any time and to maintain them where appropriate:

- medical devices log or ID card
- Operating Instructions

Accidents involving personal injuries must be reported to the appropriate authority without delay.

2.2 Laser Safety

This unit is a Class 4 laser product, which means that both the laser beam itself and the diffuse laser light reflected from surfaces may be dangerous.

The unit emits radiation in the non-visible spectral range of 1,318 nm. Such radiation may cause irreversible damage to the eyes, skin and other organs!

The laser area represents the area in which the maximum permissible exposure (MPE) values may be exceeded, taking the possibility of an accidental deflection of the laser beam into account as well. All doors providing access to the laser area must be marked by warning lamps.

The following safety measures must therefore be strictly observed:

- Any person present in the laser area during laser operation must have a full understanding of all the dangers posed by laser radiation and must wear protective goggles. The patient's eyes must also be adequately protected.
- It is the responsibility of the owner/operator of the unit to provide suitable protective equipment.
- The organ most endangered by laser radiation is the human eye. Therefore, all persons present in the laser area are required to wear laser protective goggles (rated D 1318 nm L6 or higher) whenever the unit is switched from "standby" to "laser ready" mode, as required by DIN EN 207 with regard to Nd:YAG laser radiation.

Use protective/antilaser goggles – D 1318 nm L6 – in accordance with DIN EN 207 requirements!

- Never make direct eye contact with the red pilot laser light! Note that the above-mentioned protective goggles do not provide protection against the red pilot laser radiation.
- When performing open surgery, the entire operating room is considered as the laser area.
- When manipulating the distal end of the endoscope in the open (i.e. outside of the patient) while the laser unit is on (ready), all persons present in the laser area must wear protective goggles.
- Even for endoscopic applications (with the endoscope used only inside the patient's body), we recommend that all persons present in the laser area should wear protective goggles because there is a potential risk of fiber breakage as a result of damage, with the consequence of radiation escaping into the room.
- Never keep potentially explosive substances in the laser area! Easily flammable materials might catch fire!
- If laser radiation is applied to organs, body cavities or tubular structures that may contain flammable gases or vapors, protective measures must be taken against potential fire and explosion hazards.

- Objects that are capable of reflecting Nd:YAG radiation must either be covered or removed from the laser area. Windows and reflecting walls must also be covered with suitable materials. Besides, adequate protective measures must be taken also if harmful gases, dust, smoke or secondary radiation could be generated, or if potentially explosive gas mixtures could be formed, as a result of the impact of laser radiation on certain substances or materials.
- Instruments that need to be brought into the beam path in the course of the treatment must have such a shape and finish that dangerous reflections are largely excluded.
- The laser area should be kept as small as possible and should be screened off, making sure that it cannot be entered by unauthorized persons. The number of people present in the laser area should always be kept to a minimum.
- At least once a year, all persons working in the laser area must be informed on pertinent safety requirements and measures to be taken, and must be instructed in the proper handling of the laser unit. Such instruction must be recorded, together with a list of all participants.

2.3 Explosion and Fire Hazards

⚠WARNING

Fire hazard!

Class 4 lasers (IEC 60825-1) represent a potential ignition source due to heat building up in the tissue or at the fiber ends. When laser radiation is absorbed, the laser energy is transformed into heat. As a consequence, the reactivity of the irradiated material increases. When working with the **MY40 *1.3*/MY40e *1.3*** laser, the user therefore is required to observe the following measures in order to prevent laser-induced fires and explosions:

- Never use materials that have a high ignition potential (such as flammable liquids of all danger classes) either during or prior to the laser treatment.
- In the case of endoscopic applications, never use oxygen for irrigation purposes.

- Never use materials that have a high ignition potential (such as flammable liquids of all danger classes) either during or prior to the laser treatment.
- If surgical interventions pose a danger of using the laser in the region of the tracheal tube, which could lead to laser-induced tube ignition, it is mandatory to use metal or laser-safe tubes. This also applies, in particular, when using oxidizing gases such as oxygen and nitrous oxide.
- Always be careful when using easily flammable materials (such as pads, compresses, etc.) in the operating area. For example,
  - never direct the laser beam at flammable objects;
  - use only the pilot beam for targeting purposes;
  - moisten potentially flammable materials;
  - switch off the laser beam when it is no longer needed;

— protect the laser unit against accidental operation by switching it from "laser ready" to "standby" mode;

— lock all application systems connected to the laser unit when making a treatment pause.

- In the event of an accidental laser beam release, it must always be guaranteed that neither the patient nor staff members present in the operating room are endangered and that easily flammable materials cannot get ignited.

Notice!

1) Never operate the unit in the vicinity of flammable narcotics or highly volatile mixtures such as alcohol or petroleum spirit (benzine).

2) In the case of endoscopic applications, never use oxygen for irrigation purposes.

2.4 Protecting the Patient

The patient must be protected against injuries caused by improper use of the laser system. This means in particular

- protecting the patient's eyes by means of suitable antilaser goggles or by using a light- and radiation-proof cover,
- protecting those organs and tissues in the surgical field which may not be exposed to laser radiation; use diffuse-reflection or radiation-absorbing materials such as moist towels or compresses for this purpose;
- prevention of laser-induced fires, especially during endolaryngeal interventions,
- effective removal of developing toxic smoke, particularly in the laryngeal region (smoke evacuators are optionally available);
- preventing the ignition of flammable intestinal gases during rectoscopic operations;
- prevention of fires caused by direct laser radiation or hot bare fibers when using artificial respiration techniques such as jet ventilation, particularly in connection with flammable or oxidizing gases.

2.5 Treatment Room Requirements

- All rooms in which the **MY40 *1.3* / MY40e *1.3*** laser is used must be marked at the entryways/doors with a laser radiation warning sign ("laser star" symbol as provided in the accessories kit).
- A warning lamp must be installed at all doors leading to the laser area. When these lamps are on, the laser area may only be entered by authorized persons wearing the required protective goggles.

- As far as possible, all doors leading to the laser area must be kept closed while the laser is being used.
- Surfaces from which the Nd:YAG laser light can be easily reflected should not be used in the laser area or should be adequately covered.

2.6 Safety Requirements Relating to the Laser Unit and its Accessories

- All instruments used should have matte surfaces from which the Nd:YAG laser light is reflected diffusely.
- All optical equipment used for observing the surgical field must have been specially designed for use with lasers. Besides, such equipment may only be used in connection with suitable auxiliary filters that meet the requirements applying to laser protective goggles.
- Focusing handpiece: If no focusing handpiece were used, the laser light would be emitted from the fiber omnidirectionally at a divergent angle of radiation of approx. 25°. For this reason, it is not permitted to use the laser without a properly installed focusing handpiece. (See also focusing handpiece user manual.)
- Never switch on the laser system unless all parts of its housing have been properly installed. Note that laser radiation may be emitted in an uncontrolled manner when the laser unit is open! Moreover, there is the risk of exposure to dangerously high electric voltages or current.
- If the laser unit is found to be in any way defective, the findings must be duly recorded in the medical devices log and reported to the Laser Safety officer. Besides, either Gebrüder Martin or a service technician authorized by Gebrüder Martin to carry out repairs should be contacted as soon as possible. Never use the system any longer in such a case!

2.7 Safety Instructions for the Pilot Laser

The radiation emitted by the red pilot laser (diode laser, wavelength 635 ± 10 nm) is relatively harmless. For example, this type of radiation cannot damage the skin or ignite any materials present in the operating room.

In normal position (“Pilot“ button pressed) the output power of the pilot laser is just 1 mW at a maximum (Class 2, as per DIN EN 60825-1). This means that if the human eye is accidentally exposed to the pilot laser light (either to the beam itself or its reflection from a surface), the lid closure reflex triggered by the glare will protect it.

If a higher pilot beam intensity has been selected ("Pilot x 3“ button pressed), the pilot laser power can reach a maximum of 5 mW (laser class 3A). In this case, the lid closure reflex will only provide sufficient eye protection if a distance of at least 100 mm is maintained between the eye and the point where the beam exits the applicator system (aperture). This increased danger potential is indicated by the fact that the "Pilot x 3” button is illuminated by a yellow backlight when activated.

However, if the lid closure reflex is consciously suppressed, or if the pilot laser light accidentally hits the human eye several times during a working day, eye damage cannot be ruled out.

Notice!

When the unit is in operation (keylock switch on supply unit set to position 2), visible pilot laser radiation will be emitted at the front end of the applicator system (fiber tip, focusing handpiece) unless the pilot laser has been switched off by pressing the (yellow-backlight) pilot laser button. To prevent eye damage, never look towards the exit opening (aperture) of the applicator system when the pilot laser button is on!
While the specified laser protective goggles (D 1318 nm L6) provide adequate protection against Nd:YAG laser radiation, they are ineffective with regard to pilot laser radiation!

It is particularly important to ensure that the fiber end surface and the front lens of the focusing handpiece are in good working order. To check this, follow the instructions given in the "Checking the optical fiber" section and in the Annex (see sections 13.4 and 13.5).

The diffuse reflections produced by the pilot laser light (e.g. when observing the target spot on the tissue) are completely harmless even when using the maximum output power (≤ 5 mW).

To sum it up:
No special eye protection (such as protective goggles) is required in connection with the pilot laser light, provided that the instructions outlined above are duly followed.

2.8 Laser Safety Officer

According to the relevant (German) regulations for the prevention of accidents (relating to laser radiation – BGV B2), the operator of the system is required to formally appoint a Laser Safety officer. This person has the following responsibilities:

- carrying out the required safety measures;
- providing instruction, to all persons involved, on required safety measures and the proper handling of the unit;
- marking the laser area;
- checking the alarm devices for proper functioning;
- ensuring the availability of laser protective goggles;
- ensuring proper application of the unit in the course of the therapy;
- keeping the key of the laser system in a safe place;
- storing the unit in a safe place when not in use;
- ensuring proper connection of the laser system after relocation;
- maintaining the medical devices log (or ID card) properly.

2.9 Surgeon Providing Treatment

The therapeutic application of the unit requires the user to be sufficiently experienced in working with a Nd:YAG laser system.
The treating physician (therapist) is responsible for the safe and proper use of the medical laser system. He/she must ensure that all safety measures are duly observed and must be familiar with laser-specific surgical techniques. The theoretical knowledge and practical expertise that are mandatory for the proper use of the laser in clinical practice should be acquired through attending suitable training courses (basic course in laser medicine, plus specialized training courses or practical work as an assistant).

2.10 Electrical Safety

The unit is a Class 1 system (acc. to DIN EN 60601), which means that it must be connected to a duly grounded supply system in accordance with the specifications contained herein.

- Only the power cord provided may be used.
- Both the power cord and its connector must be in perfect working order and may not be used if in any way defective.

2.11 Grounding the Unit

The unit is grounded via the ground conductor integrated in the power cord. This is an important prerequisite for the safe operation of the unit. If the power cord is connected in accordance with the relevant electrotechnical regulations, proper grounding is automatically ensured.
The yellow-and-green potential equalization cable must be connected to the equipotential bonding conductor provided in rooms used for cardiac interventions (see standard relating to rooms used for medical purposes).

2.12 High-Voltage Danger

High voltages are present both in the laser head and the supply unit of the **MY40 *1.3* / MY40e *1.3***. In order to avoid any danger of injury, the user is required to verify, prior to switching on the unit, that both these devices have been properly connected. Note, moreover, that the user is not entitled to open or dismantle the unit. Any repair or maintenance work that becomes necessary may be carried out only by Gebrüder Martin or by a service technician specially authorized by Gebrüder Martin to perform such work.

2.13 Fuses

Fuses may be replaced only by authorized service personnel. The rear wall of the supply unit features an automatic circuit-breaker (**MY40 *1.3***) that can be tripped and reactivated with the toggle switch. The **MY40e *1.3*** laser, in contrast, has miniature fuses in the same location whose ratings are also indicated on the rear panel.

2.14 Safety Devices

In designing this laser system, we have strictly adhered to the principle of providing utmost user and patient safety in combination with user-friendliness. As a result, the system is extremely easy to use and the technical safety devices incorporated in the system effectively prevent maloperation.
When the system is turned on, it is automatically set to "standby" mode. This means that the laser beam cannot be activated at this stage.
Likewise, the laser beam cannot be activated unless the optical fiber has been connected (error message: "fiber missing").

At the front end of the application system connected to the laser head (at the fiber tip or the distal end of the focusing handpiece), the visible pilot laser radiation is emitted with an output power of <1 mW (Class 2, acc. to DIN EN 60825:10-2004). If a brighter pilot light is required, the user can increase the output power to a value of up to 5 mW by pressing the "Pilot x 3" button (which corresponds to a Class 3A laser).

As soon as the system is ready to emit the laser beam, the "laser ready" button comes on. However, the shutter – as the final safety device in the series – is kept shut until the footswitch is pressed down to release the beam. A second laser alarm lamp, located above the SMA-plus fiber connector jack, will come on as soon as the Nd:YAG laser beam is emitted. Moreover, a clearly audible alarm signal is sounded as long as laser radiation is being released.

As concerns irradiation time, the footswitch has absolute priority over the pulse times selected. This means that the irradiation process is interrupted in any case as soon as the footswitch is released, even though the preset pulse time may not have elapsed yet.

To make sure that the selected irradiation parameters are not accidentally changed while using the laser light, all control panel buttons are rendered inoperable as long as the footswitch is being operated.
The laser output power is automatically kept at a constant level (in accordance with the value selected, but within system-specific tolerance limits) with the help of a microprocessor. In case the system is unable to maintain the selected power level any longer by corresponding lamp current regulation, this is indicated at once – even during the treatment – by the error message "E01" appearing on the A2 display.

NOTICE concerning the "E01" error message (MY40 *1.3* / MY40e *1.3* laser)

After restarting the laser with the keylock switch provided on the supply unit, the system is set to its initial state, which means providing a default power of 10 W. If it is not possible to achieve this output with a lamp current keeping within the specified tolerance range, the laser cannot be put into operation. Another restart is required in this case.

If the laser lamp current exceeds the tolerance limit during laser operation, power output is automatically blocked and the "E01" error code displayed to alert the surgeon to the fact that the laser can no longer provide the set output power.

This state can be cleared by selecting a lower output power. Upon adjusting the power, the laser routinely goes through a new measurement and regulation cycle. This can mean that the "E01" error message disappears as a result. However, you should nonetheless call the Technical Service in any such case!

To alert anybody not allowed access, an external warning lamp can be installed above the door leading to the laser area, to come on whenever the laser is activated. (To connect this "laser operation" warning lamp, proceed in the manner shown in Figure 5.3.) As soon as the laser system is switched on (i.e. set to "standby" mode), the warning lamp circuit is closed.

In the "laser ready" mode, Class-4 infrared laser radiation is emitted at the distal end of the applicator system as soon as the footswitch is operated. Therefore, all persons present in the laser area (i.e. the closed room or screened-off part of a room where dangerous radiation may occur) are required to wear protective goggles while the laser warning lamp is on.
The option of using such an external door contact as part of the safety system is described in the sections 4.6 and 5.3 (Fig. 5.3).

With the emergency stop device, the system can be disconnected immediately in a case of emergency.

2.15 Rating Plates and Warning & Information Signs

Figures 2.1 to 2.6 show the rating plates and warning and information labels affixed to the laser unit.

Fig. 2.1 ***MY40 1.3 / MY40e 1.3*** *rating plates*

Fig. 2.2 *Information label (indicating type of radiation and relevant standard)*

Fig. 2.3 *Laser warning sign with information label*

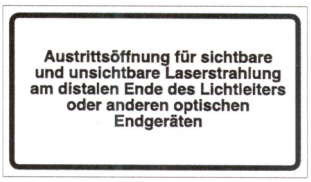


Fig. 2.4 Label affixed next to the beam exit opening

Fig. 2.5 Label affixed next to the output jack for accessories

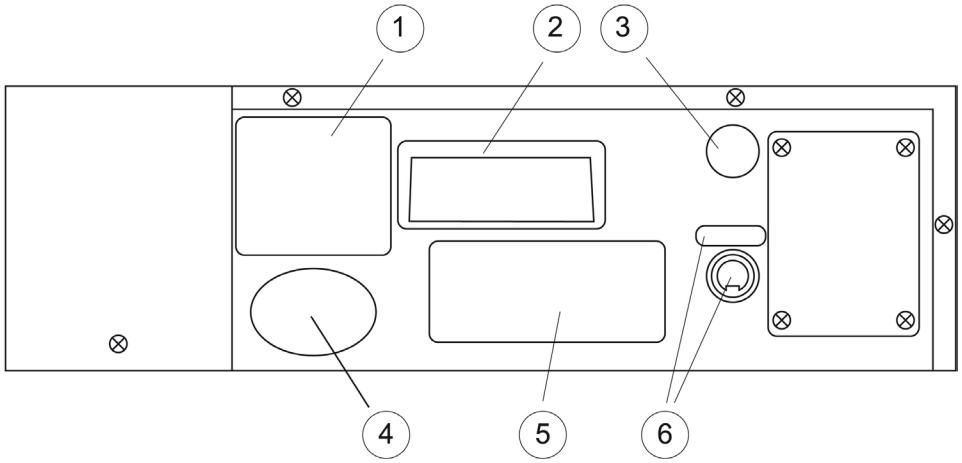


Fig. 2.6 Rear side of laser head

1 Rating plate

2 Handle

3 Optional: keylock switch (separate version)

4 "260 UPGRADE" label

5 Information label (specifying output power)

6 Control contact socket

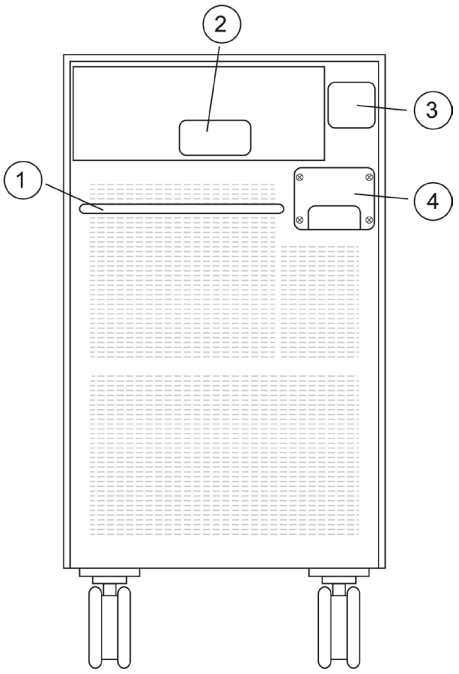


Fig. 2.7 Rear view of supply unit
1 Handle
2 "High Voltage" warning label
3 Supply unit rating plate
4 Footswitch support (hook)

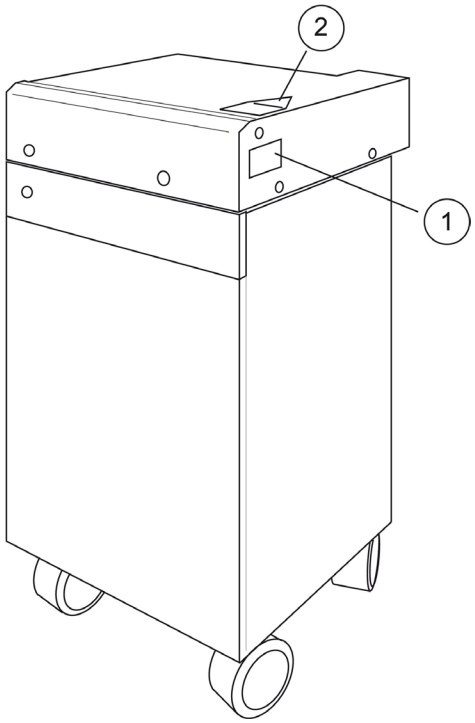


Fig. 2.8 Laser complete
1 "Release of laser radiation" warning label
2 "Class 4 laser" warning label (see Fig. 2.3)

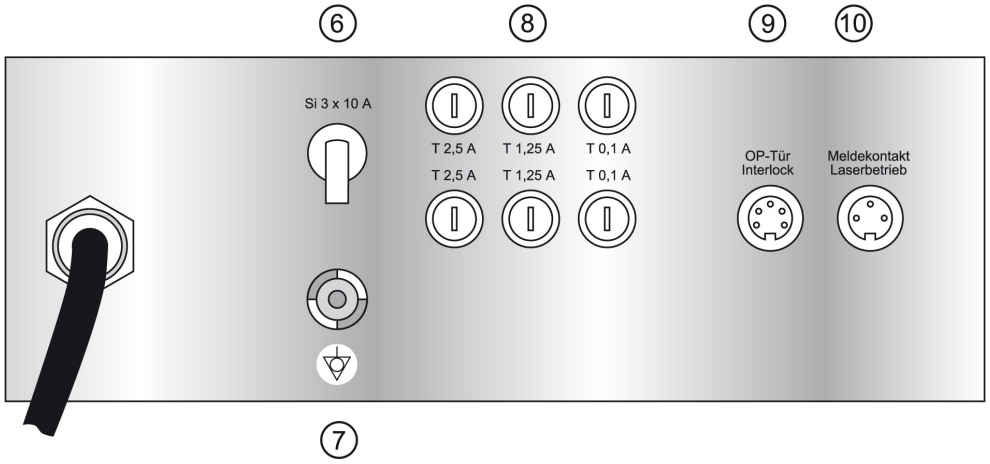


Fig. 2.9 *Fuses, safety device and contacts on the PSU of the **MY40 1.3**'s supply unit*

6 *3-phase automatic circuit-breaker*
7 *PE connector*
8 *Miniature fuses*
9 *OR door interlock socket*
10 *Socket for laser warning lamp*

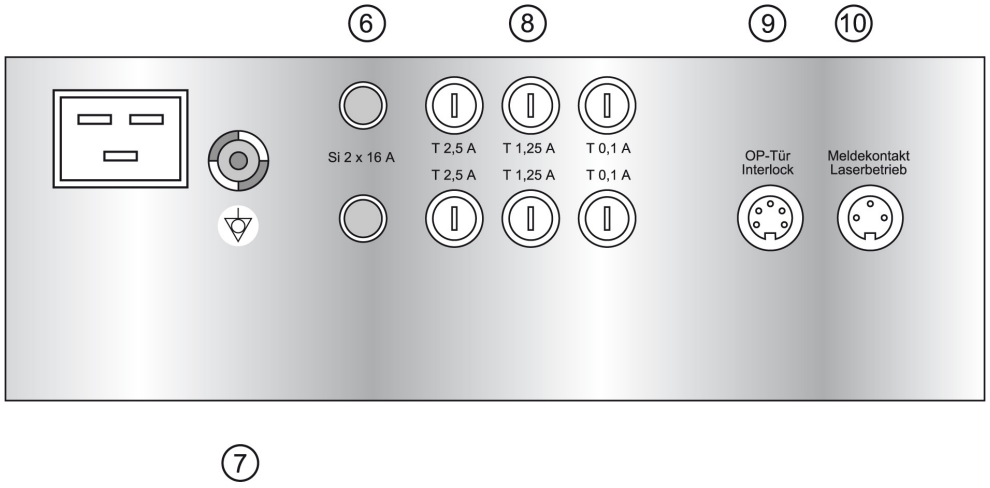


Fig. 2.10 *PSU of the **MY40e 1.3**'s supply unit*

6 *Mains fuses*
7 *PE connector*
8 *Miniature fuses*
9 *OR door interlock socket*
10 *Socket for laser warning lamp*

2.16 Laser Plume

Notice!

Caution! Laser smoke (plume) may contain viable tissue particles.

To protect the user and the patient, a sufficiently powerful evacuator must be used for removing the smoke (plume) generated by the laser. Through connector socket 6 (Fig. 2.6), such an evacuation system can be controlled so that it is automatically switched on shortly before the laser is activated. After the laser has gone into standby mode, the evacuator continues to operate for a preset period of time before it also returns into standby mode.

3 Description of the Unit

3.1 General Information on Laser Theory

LASER is an acronym meaning "Light Amplification by Stimulated Emission of Radiation". The laser (light source) consists of an active medium and an excitation source. This excitation source transforms ("pumps") the active medium from its normal state into a stimulated energy state (high energy level). The medium then starts to return to its normal state (transition to lower energy levels). In this process, photons are emitted. The radiation thus emitted is amplified optically with the help of an optical resonator (resonant cavity) consisting of a highly reflecting mirror and a semitransparent one. Through the semitransparent mirror, part of the laser light is coupled out and is then used for medical purposes.

Main characteristics of the laser light:

1. Collimation – high degree of beam parallelism; very little beam divergence/spread.

2. Monochromaticity – light of a very narrow wavelength range, equivalent to a single color in the spectrum of electromagnetic radiation.

3. Coherence – all photons emitted are in phase (in terms of both space and time).

The active medium (lasing material) can either be a gas, a liquid dye or a solid. Most gas lasers consist of atoms or small molecules or a mixture of both. In the case of the solid-state laser, the active medium consists of atoms or ions doped (bound) in a solid-state host crystal. In the case of the dye laser, the active medium consists of molecules of a relatively high molecular weight, dissolved in a liquid.
For the pumping energy that is needed, either direct current, high-frequency energy or – as in the case of the solid-state laser – light is used. Under specific pumping energy conditions, the so-called "population inversion" phenomenon can be observed with all of the above media. This means that it is possible to induce laser light emission at a specific wavelength that is characteristic for the active medium used. The high light intensity gain is achieved by way of optical back-coupling, which means that the radiation emitted is reflected with the help of (laser) mirrors located in the resonant cavity.

3.2 The Nd:YAG Laser

The continuous-wave (cw) Nd:YAG laser is a solid-state laser which emits high-intensity radiation at a wavelength of 1,318 nm (belonging to the near infrared range of the spectrum). The medium used is a cylindrical YAG (yttrium-aluminum-garnet) crystal doped (mixed) with Nd^{3+} ions (neodymium ions). As excitation/stimulation mechanism for generating the required "population inversion", the intensive light produced by a krypton lamp is used. The emission spectrum of the krypton lamp fits in very well with the absorption spectrum – and thus with the stimulation spectrum – of the Nd^{3+} ions of the YAG host crystal. In order to increase the laser's efficiency, the krypton lamp and the Nd:YAG bar are integrated into a highly reflecting optical reflector body having a special geometry which ensures that most of the spatially emitted lamp light gets focused into the laser crystal.

3.3 Fields of Application

The therapeutic effect produced by the continuous-wave Nd:YAG laser light is based on the conversion of radiation energy into heat, a process that triggers both reversible and irreversible tissue reactions (hyperthermia, coagulation, vaporization). Since radiation in the wavelength range of about 1,000 nm is absorbed only to a relatively low degree, the continuous-wave Nd:YAG laser used here (wavelength λ = 1,318 nm) is particularly well suited for deep-reaching and uniform coagulation of biological tissue. The specific therapeutic effect of this type of radiation mainly depends on the following three factors:

- power density (irradiation intensity)
- irradiation time (treatment/exposure time)
- tissue characteristics

The irradiation intensity achieved on the surface of the tissue depends on:

- the effective distal laser output power (tissue side)
- the diameter of the beam hitting the tissue (which in turn is a function of the distance between the fiber tip and the tissue)

The irradiation intensity can be significantly increased in the focal area by additional beam focusing, for example by using the focusing handpiece available.

The tissue characteristics that are of primary importance with respect to medical laser therapy include:

- tissue absorptivity
- heat conductivity and thermal capacity (particularly, water content and perfusion rate)

It is noteworthy in this connection that these characteristics/parameters may change in the course of irradiation. For example, the absorptivity of the tissue increases as a result of superficial carbonization, which in turn enhances the cutting or ablating effect of the laser beam. This effect is utilized, for example, in connection with the bare fiber technique. Here, the fiber tip is brought in direct contact with the tissue. Given sufficiently high power densities, this first produces a discoloration of the skin in the contact area and subsequently a tissue cutting effect.

The application possibilities of the **MY40 *1.3* / MY40e *1.3*** laser are numerous. This laser is particularly useful in cases where difficult anatomical conditions require high-precision work to be performed in highly restricted surgical sites – thanks to the fact that the laser light can be delivered through thin, flexible quartz fibers that ensure almost loss-free energy transmission. This means less patient strain as well as cost reduction, due to the fact that this type of operation can often be performed on an outpatient basis (or at least means shorter hospitalization times).
The unit allows working on either a contact or non-contact, low-hemorrhage basis. It thus significantly expands the surgeon's range of therapeutic approaches in many fields of application. In conjunction with the optional focusing handpiece or fiber holder, however, this laser system may also be used for many surgical tasks in open surgery.

The main fields of use of the **MY40 *1.3* / MY40e *1.3*** include:

- tumor surgery (especially metastatic surgery)
- pneumology
- bronchology

To ensure the proper use of the **MY40 *1.3* / MY40e *1.3*** in clinical practice, theoretical background knowledge and sufficient practical experience/training are indispensable prerequisites. We recommend attending a further-education or training course on "laser medicine" in order to acquire the specific technical knowledge required. Note also that the proper and safe use of the unit can only be guaranteed if the user duly follows the application instructions contained herein and takes all measures required. Therefore, all authorized users must sufficiently familiarize themselves with the unit by carefully reading these Operating Instructions before using the system for the first time.

3.4 General Description of the System

The **MY40 *1.3* / MY40e *1.3*** laser is a microprocessor-controlled continuous-wave Nd:YAG laser system. Through a flexible optical fiber, a laser output power of up to 40/36 W can be transmitted to the tissue for therapeutic use.

3.5 System Version

The **MY40 *1.3* / MY40e *1.3*** laser system is available in the style shown below, consisting of a laser supply unit and a laser head mounted on top. Thanks to the modular design, the laser head can be separated from the supply unit for servicing.

3.5.1 Stand-alone version

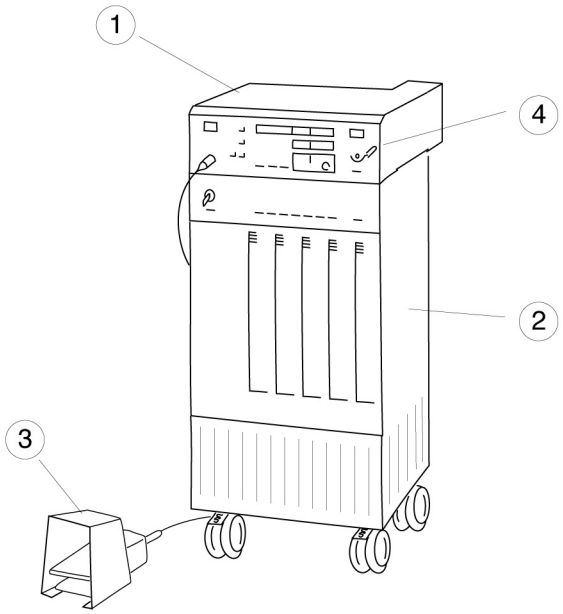


Fig. 3.1 Stand-alone version

1	*Laser head*
2	*Supply unit*
3	*Footswitch*
4	*Fiber connector*

3.5.2 Separate version

Thanks to the modular design, it is possible to install the supply unit and the laser head separately. Both components are connected with each other by means of a supply hose. For example, the supply unit can be installed and operated in an adjacent room, to be controlled via the laser head. The separate version is available as a special model. Both versions are mutually convertible.

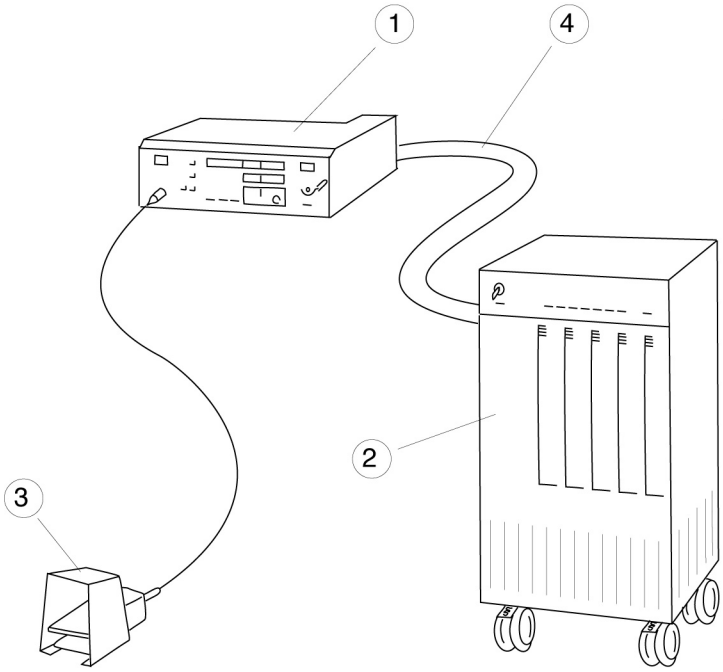


Fig. 3.2 Separate version

1	*Laser head*
2	*Supply unit*
3	*Footswitch*
4	*Supply line*

The **MY40 *1.3* / MY40e *1.3*** includes the following components (scope of delivery):

	Stand-alone version	Separate version
Laser head	✓	✓
Supply unit	✓	✓
Footswitch, two-stage	✓	✓
Deionization cartridge	✓	✓
Fiber test adapter	✓	✓
Castors	✓	✓
Potential equalization cable	✓	✓
Two laser warning labels	✓	✓
Operating Instructions	✓	✓
Flyer	**optional**	**optional**
Supply line		✓ **(MY40 *1.3*)**

3.5.3 MY40 1.3 Power Version

This version of the laser offers the user a distal output power of up to 40 W. A three-phase power supply system is required for operation (to provide the excitation energy needed for generating such a high laser output with the krypton lamp).

3.5.4 MY40e 1.3 Economy Version

This version of the laser offers a distal output power of up to 36 W. As the required excitation energy is lower in this case, the unit can operate on a conventional single-phase power supply. This ensures the universal use of this laser unit.

3.6 260 UPGRADE

Units including this UPGRADE can be used with the thin laser fibers having a core diameter of just 260 µm. In contrast, laser units lacking this upgrade (and the corresponding information label) can be used only with 400-µm or thicker laser fibers. The UPGRADE is available for any **MY40 *1.3* / MY40e *1.3*** laser (to be implemented by Gebrüder Martin's Technical Service). All upgraded laser units feature the following information label on the rear wall of the laser head:

Fig. 3.3 *UPGRADE label affixed to the laser head (see Fig. 2.6, item 4)*

All units manufactured since June 2004 (see manufacturing date) already include the 260 UPGRADE and therefore are compatible with 260-µm bare fibers (79-340-26).

4 Installation

4.1 Preparatory Work

Before the system is delivered, the user is informed on preparatory measures that need to be taken on-site prior to installation.
As the laser head can be separated from the supply unit and supply lines of different lengths are available, the user is given great flexibility to install the system in accordance with personal preferences, taking aspects of user-friendliness, availability and hygiene into account.

4.2 Laser Location

A base of 40x40 cm is required for the laser unit. The laser head has a weight of 12 kg, the supply unit weighs 71 kg.

Notice!

The unit may only be put into service after it has adapted itself to the air temperature of the installation room. This is of particular importance in cases of relocation. If there is a major difference in temperature (especially during the winter months), we recommend transferring the unit to the respective room one day before the installation is carried out.

4.3 Electrical Connection of the MY40 *1.3*

The unit must be connected to a separate CEE outlet conforming to the voltage and power supply requirements indicated on the rating plate located on the unit's rear wall. The non-detachable power cord has a length of 7 m.

Notice!

The laser's power cord must be connected to a CEE socket (16 A) rated for a load of 3 x 1 0 A.

The on-site electrical installation must include a three-phase automatic circuit-breaker with K-characteristic. We recommend installing the following product: ABB type 273 K16. For potential equalization purposes, the cable supplied may be used. It must be connected to the equipotential bonding pin located on the unit's rear wall.

4.4 Electrical Connection of the MY40e *1.3*

The unit must be connected to a separately fused outlet complying with the voltage and power supply requirements indicated on the rating plate located on the unit's rear wall (see section 2.15). The power cord supplied has three conductors including a PE (equipment grounding) conductor and must be used for connecting the supply unit to the supply system.

Notice!

Be sure to use the power cord supplied to connect the laser to the supply system!
This cable must be connected to a grounding socket outlet with a load rating of 16 A. Do not use extension cables or distributors (such as distributing boxes) rated for less than 16 A.

To ensure reliable operation, we recommend protecting the grounding socket outlet with a 16-A fuse. This must be a type "G" or type "K" fuse. An automatic circuit-breaker is not a suitable means of protection in this case (due to the initial current surge).

For potential equalization purposes, the cable supplied may be used. It must be connected to the PE pin located on the unit's rear wall.

4.5 External Warning Lamps

The warning lamps – to be installed clearly visibly over all entryways/doors providing access to the laser area – are automatically switched on and off in accordance with laser operation after

they have been duly connected to the three-pole "laser-operation alarm contact" socket located on the rear wall of the supply unit (see Fig. 5.3).

4.6 OR Door Interlock

An external door contact – as a normally closed contact – may also be optionally integrated into the safety system. In this case, the laser system lapses into the non-ignition state as soon as this contact is opened. At the same time, the "E03" error message is displayed. The unit can then only be used again after the door has been closed and the system has been restarted with the keylock switch located on the supply unit. The door contact must be connected between the contacts 1 and 4 of the four-pole connector socket provided on the rear wall of the supply unit (see item 9, Figs. 2.9 and 2.10, and item 10, Fig. 5.3). The connectable load is 24 V / 0.1 A.
Note, however, that we cannot recommend using such a door contact. The reason is that if the entry door is opened unexpectedly during the treatment, the laser beam will be interrupted, which may create a dangerous situation for the patient. The laser system therefore comes with these contacts bridged by the manufacturer.

4.7 Unpacking the Unit & User's Inspection

All **MY40 *1.3* / MY40e *1.3*** units are subjected to thorough quality inspection and testing prior to shipment. Consequently, the system should be in proper working order when it arrives on the user's premises. Note, however, that the unit may only be unpacked, installed and checked by a person specially authorized by Gebrüder Martin to do such work. Any external defects found – either on the packaging or the unit itself – must be reported to Gebrüder Martin immediately.

4.8 Safety Checks

Prior to handing the system over to the operator/owner, the unit must be checked by an authorized service technician (Technical Service) on the basis of the Safety Check sheet provided by Gebrüder Martin. Subsequently, all system-specific documents are passed on to the operator, who is required to keep them in a safe place. Along with the Operating Instructions, these documents should be available to the Technical Service at any time.

4.9 Handing Over the Unit

After the system has been installed and checked for proper and safe functioning by Gebrüder Martin's authorized service partner, the unit and its accompanying documentation are handed over to the operator. The latter is required to formally appoint a Laser Safety officer in accordance with relevant legal provisions and regulations. All persons attending the required user instruction should be entered in the medical devices log. This equipment log, the user instruction report, the Operating Instructions and the key for the unit are then handed over to a specially appointed person in charge of the unit.

4.10 Service Partners

Service partner contact details are available from
Gebrüder Martin GmbH & Co. KG
KLS Martin Platz 1
D-78501 Tuttlingen, Germany
Tel.: +49 7461 706-0
Fax: +49 7461 706-193

5 Controls, Indicators & Displays and Connections

5.1 Laser Head

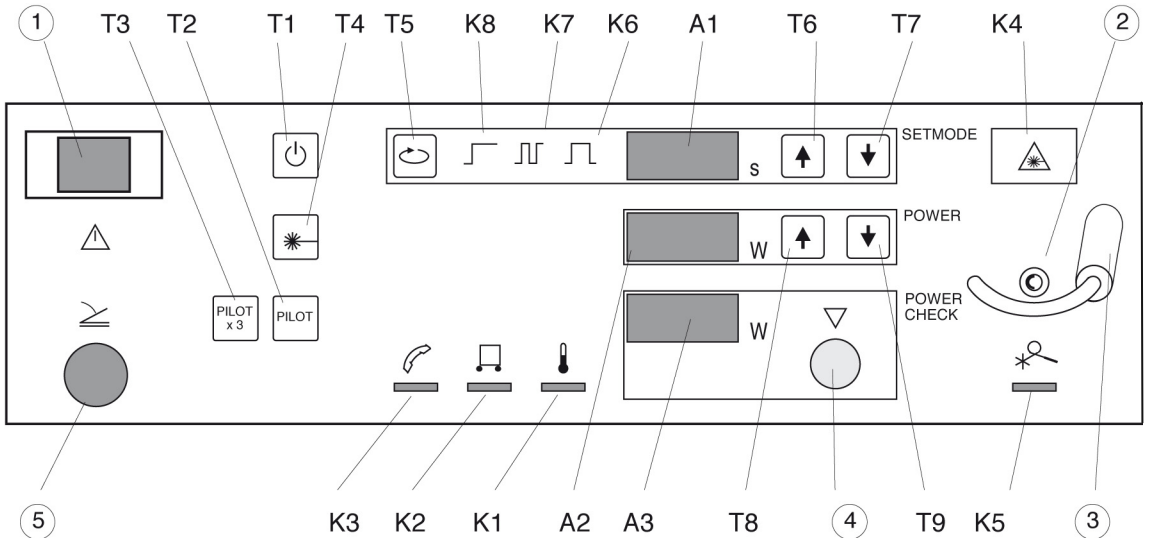


Fig. 5.1: Laser head controls
(A = Display, T = Button, K = Control light; explanations see below)

1 Emergency stop switch
2 SMA-plus connector jack
3 SMA-plus protective flap
4 Opening for fiber testing
5 Footswitch connector socket

	No.	Designation	Function	Explanation
	T1	Standby	Laser in safe condition; unit inoperable; no emission of radiation possible	Standard mode after switching on the unit or if fiber is missing
	T2	Pilot (stage 1)	Pressing this button switches the pilot beam on/off; reduced/safer brightness level	Standard brightness level, also in connection with T4
	T3	Pilot (stage 2)	Pressing this button switches the pilot laser beam on/off; high brightness level	More brightness for better visibility
	T4	Laser ready	Radiation can now be emitted by operating the footswitch	Yellow backlight; comes on only in connection with "Pilot" buttons
	T5	Pulse type selector	Pressing this button allows cyclical selection of operating modes	Standard setting = single pulse
	T6	Increasing pulse duration	Pressing this button (or keeping it pressed) allows incremental (or continuous) increase of pulse length	Standard: 1 s; range: 0.1 s to 10 s
	T7	Reducing pulse duration	Pressing this button (or keeping it pressed) allows incremental (or continuous) decrease of pulse length	Standard: 1 s; range: 0.1 s to 10 s

Table 5.1a: Laser head controls kopf

	No.	Designation	Function	Explanation
	T8	Increasing laser power	Pressing this button (or keeping it pressed) allows incremental (or continuous) increase of laser output power	Standard: 10 W; range: 0.5 W bis 40 (36) W
	T9	Reducing laser power	Pressing this button (or keeping it pressed) allows incremental (or continuous) decrease of laser output power	Standard: 10 W; range: 0.5 W bis 40 (36) W
	K1	Laser head overtemperature	Indicates increasing water temperature by flashing (on-time increases in direct proportion to water temperature increase)	System status indicator
	K2	Supply unit error	Supply-unit error-message signal	For detailed information, see supply unit
	K3	Service	Indicates that unit is defective	Call service technician or Technical Service
	K4	Laser emission indicator	Yellow laser warning symbol lights up as soon as radiation is emitted into the fiber	Functional signal
	K5	Fiber missing	Lights up (red) if no fiber is connected	Fiber connection check via micro-contact
	K6	Single pulse	Indicates "single pulse" mode (= standard setting)	Operating the footswitch releases one pulse of the duration indicated on the A1 display
	K7	Pulse train	Indicates "pulse train" mode	Pulses of the duration indicated on the A1 display are generated continuously
	K8	Continuous-wave operation	Indicates continuous-wave (cw) mode	Upon operating the footswitch, radiation is emitted continuously until footswitch is released

Table 5.1b: Laser head controls

5.2 Supply Unit

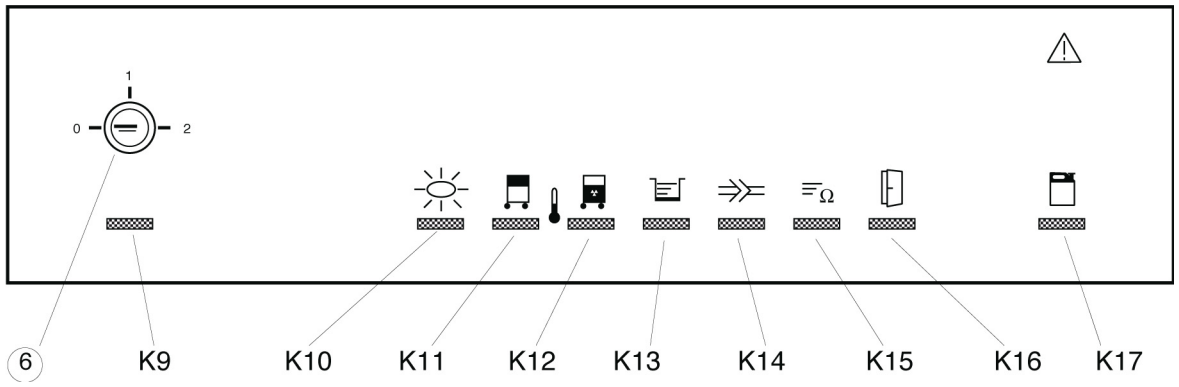


Fig. 5.2: Supply-unit control lights (see explanations below)
6 Keylock switch

No.	Designation	Function	Explanation
K9	POWER-ON lamp	Indicates laser system status (ON/OFF)	Alight (ON) if emergency stop switch is not activated and key has been set to position 1 or 2
K10	Lamp not ignited	Indicates that laser lamp has not come on	Flashes during ignition process
K11	Overtemperature in power supply unit	Power supply unit has been switched off due to overtemperature	PSU cooling insufficient
K12	Overtemperature in cooling system	Thermal overload in cooling system	Cooling water temperature exceeds 60°C (140°F)
K13	Cooling water level too low	Water storage tank level below MIN level	Refill distilled water
K14	Insufficient cooling water flow	Indicates that the water flow in the laser system is insufficient	Connector may be open (not properly inserted)
K15	Cooling water conductivity too high	The deionization cartridge located in the tank may be used up and should be replaced	No immediate action required
K16	Operating-room door interlock open	Signals that door providing access to laser area has been opened; laser operation is interrupted (unit goes into standby mode)	X4 contact interrupted
K17	Cooling Water Refill service light	Indicates that service mode has been selected; normal laser operation is not possible in this mode	Service switch must be set to "0" position

Table 5.2: Supply-unit indicators and controls

5.3 External Electrical Connections

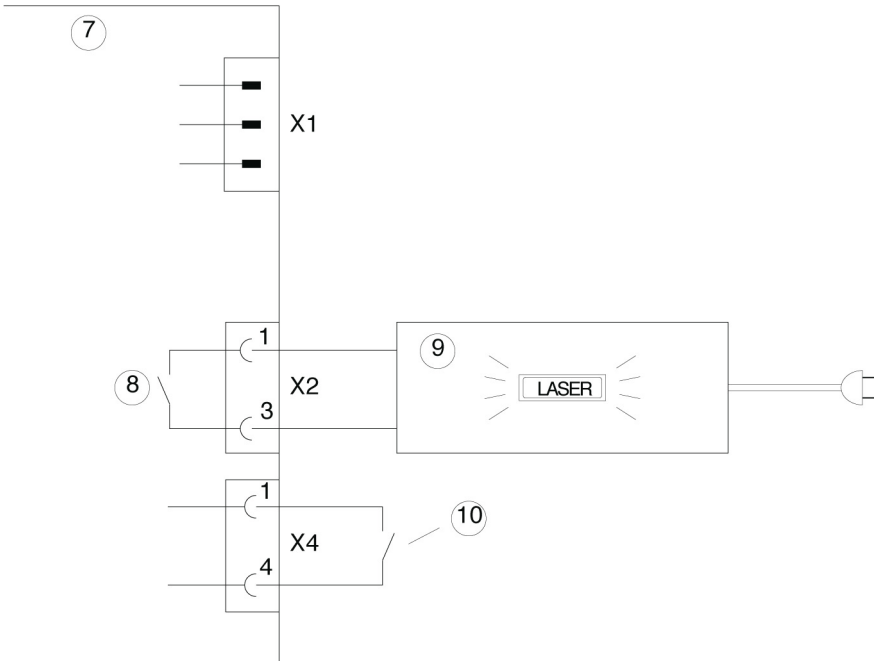


Fig. 5.3: Connections provided on the supply unit
7 Laser supply unit
8 Alarm contact for max. 24 V / 1 A
9 External laser warning lamp
10 Make contact, OR door interlock

X1: Power supply: MY40 *1.3*: 3 x 400 V, 3~, 50/60 Hz, 3 x 10 A. To ensure operational reliability, the CEE socket outlet used must be protected by three 10-A fuses.
MY40e *1.3:* 1x 230 V, 50/60 Hz, 16 A. Be sure to use the power cord supplied!

X2: "Laser-operation alarm contact": This contact is closed as soon as the laser lamp has been started and the laser beam can be activated delay-free. This contact is a potential-free floating contact, allowing connection of a laser warning lamp (max. 24 V/1 A) that must be powered by an external supply source. A special accessories set (item/order no.: 92-790-20-04) is available for connecting such a lamp.

X4: Operating-room door interlock: Whenever the door contact is opened during laser operation, the irradiation process is interrupted at once. To switch on the beam again, the interlock contact must first be closed and the system must be restarted using the keylock switch. The interlock contact must be a floating contact (potential-free). The load to be connected is 24 V / 0.1 A DC. A special accessories set (item/order number: 92-790-21-04) is available for connecting such a contact.

5.4 Fiber test adapter

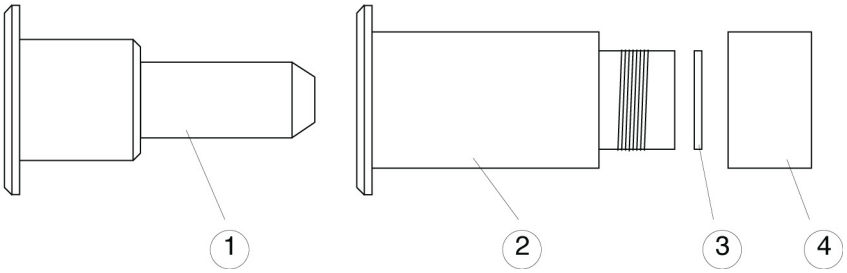


Fig. 5.4: Fiber test adapter
1 Bare fiber insert
2 Basic body, also to be used for focusing handpiece 78-201-00
3 Protective glass
4 Screw-on cap

In conjunction with the built-in fiber testing device, the fiber test adapter allows reliable and high-precision measurement of the effective laser power emitted by the optical fiber. It is possible to work on a sterile basis. The parts 1, 2 and 4 can be treated by gas as well as steam sterilization (autoclave), while protective glass (3) may be treated only by gas sterilization.
Measurement by using the focusing handpiece: use basic body (2) with protective glass (3) and screwed-on cap (4).
Performing measurements on bare fibers or gas-irrigated fibers:
Adapter (1) must be additionally inserted. Insert the fiber into the central opening (2) (see Fig. 5.5) up to the protective glass, then withdraw fiber a little (1–2 mm). Never insert fibers into ventilation hole (3)! This hole is used for irrigation gas discharge when gas-irrigated fibers are employed.

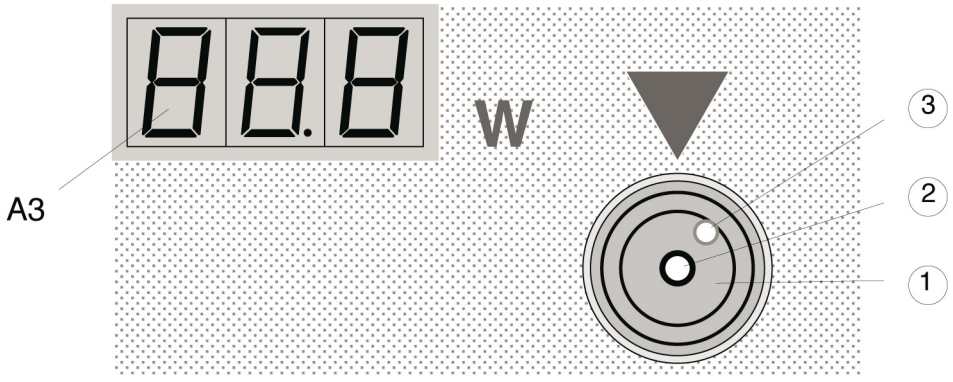


Fig. 5.5: Fiber testing device with fiber test adapter inserted
1 Fiber test adapter
2 Opening for inserting the fiber to be tested
3 Ventilation hole for gas-irrigated fibers
A3 Display indicating the laser power emitted

The A3 display shows the laser output power value in watts. After the fiber test has been carried out, the value displayed will be stored. It can thus be used as a basis for the automatic calculation of the corresponding (i.e. proportionally higher or lower) value if a different laser power setting is selected on the unit. In other words, such extrapolation means that the laser power actually emitted can be indicated, say, for high power values, although the measurement has in fact been made only for a low power setting. This correlation function remains active until either another fiber is used or the unit is switched off.

5.5 Flyer (optional)

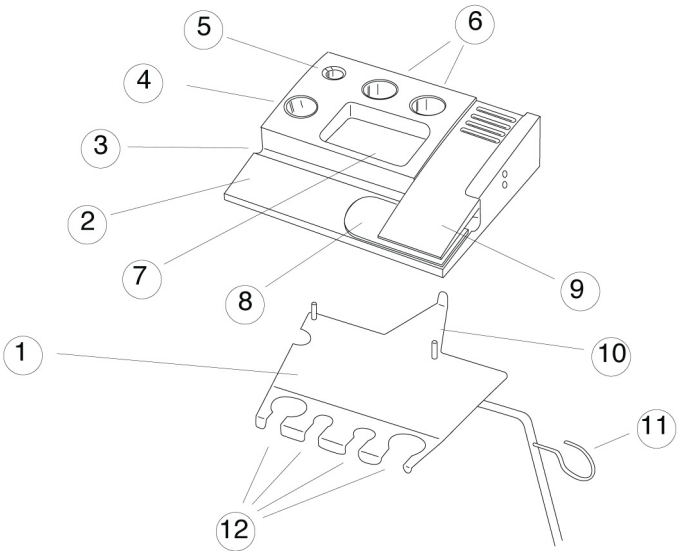


Fig. 5.6 Flyer arm with flyer top (for standard and stand-alone versions)

1 Flyer supporting plate
2 Flyer top
Accommodation facilities for:
3 Fiber holder
4 Focusing handpiece
5 Bare fiber insert
6 Fiber test adapter
10 Protective goggles
11 Fiber hook
12 Endoscopes
Other:
7 Small parts compartment
8 Silicone mat
9 Bare fiber holding clip

The flyer permits the temporary storage or depositing of the laser instruments needed during the intervention. It consists of an arm fitted to the laser head cover, a supporting plate and a removable flyer top. The flyer top can thus be kept within easy reach and close to the surgical field, which allows convenient intraoperative preparation of a bare fiber tip. The flyer supporting plate as such (with the flyer top removed) can be used for keeping different endoscopes available during an operation. The flyer top consists of plastic sterilizable with gas or steam; it can be easily removed by slightly pulling it upwards. The holding clip provided on the right side is used for fixing the distal end of the fiber in place on the silicone mat (8). The silicone mat serves for preparing the bare fiber at its distal end. This mat is also sterilizable by using either steam (autoclave) or gas and can be reordered if required (see Spare Parts section). A description of how to proceed when preparing a bare fiber is given in the Annex.

Notice!

Never use the flyer arm as a handle for moving the laser unit! For transportation purposes, a special handle is provided on the rear side of the supply unit.

The flyer arm (3) features lateral hooks (11) that can be used for coiling up fibers and hanging up the fiber tray when using KLS Martin fibers.

6 Operating the Unit

Attention!

Using the controls, operating elements or setting options in a way other than described herein may lead to dangerous irradiation!

6.1 Preparatory Measures

When setting up the **MY40 *1.3* / MY40e *1.3***, a minimum clearance of 30 cm should be maintained between the unit's rear side and the wall. This distance is required because heated air (generated by the internal cooling system) is discharged at the back of the unit.

Electrical connection:

- Guard the laser area against access by unauthorized persons. Provide laser warning signs and warning lamps at all doors leading to the laser area.
- Cover all surfaces from which the Nd:YAG laser beam could be reflected, using suitable materials.
- Remove all flammable liquids and gases from the laser area.
- Provide protective goggles for all persons present in the laser area (incl. patient).
- Connect OR door interlock and warning-lamp activation contact.

- Provide irrigation liquids and/or irrigation gases if required.

6.2 Footswitch

Position the footswitch so that it can be easily accessed by the operator, then connect it to the laser system (insert plug on front panel of laser head; see Fig. 5.1) and fix the plug in place with the screw cap provided. The footswitch incorporates two action points. The first action point activates the special devices connected to the control output on the unit's rear side. These devices remain activated when the second action point is reached. In addition, the laser beam is activated at this stage.

6.3 Connecting the Optical Fiber

Notice:

The laser features a modified SMA (SMA-plus) jack, which ensures that only fibers with SMA-plus connectors can be used for activating the laser.
The SMA-plus connector has a golden screw cap for identification.

Before connecting the optical fiber, perform a brief inspection as follows:

- Check the fiber for potential defects across its entire length
- Remove the protective caps from the SMA-plus connector and the distal end of the optical fiber
- Check the coupling-in side (SMA-plus connector) for cleanness and potential defects
- Check the distal end for potential damage
- If the distal end of a bare fiber is found to be defective, reprepare the fiber in accordance with the instructions given in the Annex

Please observe the Operating Instructions as well as the instructions provided on the fiber packaging.

- Insert the SMA-plus connector axially into the SMA-plus connecting socket, then finger-tighten the nut (do not use a tool for this!). Upon proper connection of the SMA-plus plug, the K5 ("Fiber missing") indicator will go out.
- Check the fiber with the pilot laser light (see section 6.5).
- Insert the appropriate adapter (as required for the optical fiber system used; see Fig. 5.4) into the fiber testing device located to the left of the SMA-plus jack (see Fig. 5.1, item 4). Verify that the protective glass of the adapter is free from dirt particles, burns and defects.

Notice!

To ensure sterile working conditions, use a sterile adapter for checking the sterile disposable fiber in the fiber testing device. The adapter is autoclavable, while the protective glass can only be treated by gas sterilization.

6.4 Switching on the Unit

- The red emergency stop switch provided on the laser head must be in "pulled" (deactivated) position (see Fig. 5.1). In case this pushbutton has been pressed, deactivate this function first by pulling out the switch.
- Insert the key into the keylock switch located on the supply unit (see Fig. 5.2).
  If the separate version is used, the keylock switch may be optionally located on the rear side of the laser head housing. However, the keylock switch is always used in the same way wherever located.
- Set the keylock switch to position 1 by rotating it clockwise. (It is not possible to withdraw the key in this position.)
- The green K9 control light located beneath the keylock switch comes on, indicating that supply voltage is present. The pump and the fan are started now. For approx. 10 s at a maximum, an automatic self-test is being carried out to check the various functions of the system. During this process, vertical and horizontal bars are alternatingly shown on the display (sections A1–A3).
- Verify during the self-test that the K10–K15 control lights (which are located on the supply unit) light up for approx. 2 s and that the seven-segment fields of the laser head's A1–A3 display sections are functioning properly (however, the first digit of the A1 display must remain dark).
- On the A2 display, the message "E03" will appear. This indicates that the laser lamp has not been started yet (see below). At this stage, this is fully OK and does not mean trouble.
- Set the key to position 2. This sets the K10 indicator flashing, which signals that the laser lamp is now being started. As soon as the ignition process has been completed, the K10 and K2 control lights will go out.

- In case the red K10 laser lamp control light does not go out, reset the keylock switch to position "0". Wait for one minute, then reset the keylock switch to position "1" and then to position "2". The laser lamp should now come on.
- Following lamp ignition, the system automatically performs a functional test based on the default setting of 10 W. During this test, the characters "ctr" appear on the A2 display. Subsequently, the green T1 "standby" button and the K6 ("single pulse") control light will come on. At the same time, the A1 and A2 displays will show the default values "10 W" and "1 s". Moreover, the K5 LED lights up, provided no fiber has been connected. Otherwise, the K5 indicator remains dark and the T2 ("pilot laser stage 1") button lights up yellow instead. This indicates that the pilot laser has been switched on at the low brightness level.

Notice!

All people present in the room must wear antilaser goggles. Avoid direct eye contact with the red pilot laser beam!

- If the optical fiber system has not been connected yet, the K5 ("fiber missing") indicator located beneath the SMA-plus socket will come on. If, however, this light comes on despite the fact that the fiber system has already been connected, check the screw cap on the SMA-plus connector for proper tightening. The K5 ("fiber missing") indicator should go out after the cap has been finger-tightened correctly.

6.5 Checking the Optical Fiber

As a rule, a fiber check should always be performed before starting the therapy as well as when using a new fiber.

- Press the T3 "pilot laser stage 2" button. This selects the highest brightness level for the pilot laser beam.
- Carefully check the fiber for potential damage all around. Should the red pilot laser radiation exit the fiber laterally, this clearly indicates that the fiber is defective.
- Aim the pilot beam vertically at a light-colored (white) surface from a distance of approx. 4 cm. If the fiber is in good working order, the pilot beam must produce a clearly outlined, round, red spot on the surface. If this is not the case – i.e. if the beam image is large and unclear – the fiber must be tested and replaced if necessary.
- Before checking the distal end of the fiber or the focusing handpiece for potential defects, the pilot laser must be switched off by pressing the yellow-backlight pilot laser button (see section 2.7).

6.6 Testing the Optical Fiber

The **MY40 *1.3* / MY40e *1.3*** has been factory-preset so that the preselected laser output power will be available at the distal end of the fiber if a new KLS Martin fiber is used. If necessary, however, a fiber test can be carried out using the fiber testing facility that has been inte-

grated into the system for just this purpose. In this test, the laser power actually emitted at the distal end of the fiber is measured and can then be compared to the preset power value. Any discrepancies occurring between these values are due to factors associated with the transmission efficiency and characteristics of the particular optical fiber system used.

Notice!

When performing measurements with the fiber test adapter, verify that the protective glass is clean. A dirty protective glass may distort the results.

Notice!

The protective glass of the fiber test adapter must be in perfect working order when performing measurements!
A difference in the range of ±10% – i.e. between the value indicated on the A2 display (preset laser output power) and the one indicated on the A3 display (output actually measured at the distal fiber end) – can be considered normal.
For the non-contact technique, the limit values are 25% for the focusing handpiece and 15% for bare fibers and gas-irrigated fibers.
If these limit values are exceeded, check the proximal and the distal ends of the optical fiber system for dirt particles or potential damage; replace the fiber if necessary.
If the fiber has already been used on a contact basis, the transmission losses necessarily exceed the 15% limit, due to the fact that for such applications the fiber has usually been deliberately blackened or contaminated at its distal end in order to increase tissue absorption of the laser energy. Consequently, there are only two possibilities to check a bare fiber used in this way: either prior to its first use or after preparation.

To perform the fiber test, proceed as follows:

- Switch on the laser unit (see section 6.4).
- Subsequently, the preset power and pulse-duration values can be used for fiber testing:
    - Power: 10 W
    - Operating mode: "single pulse"
    - Pulse duration: 1 s

You may also use other parameters for fiber testing, provided that A2 (output power value) is ≥1 W and the pulse duration (i.e. the period during which laser radiation is emitted into the fiber testing device) is ≥1 s.

Notice!

To avoid overtemperature occurring in the fiber testing device, the fiber testing process must be limited to a maximum period of 10 s.

- Insert the appropriate adapter into the fiber testing device.
- Verify that the fiber test adapter of the focusing handpiece contains a properly inserted protective glass.
- Insert the optical fiber system (consisting of fiber and fiber holder or focusing handpiece) into the adapter already located in the fiber testing device, sliding the system in until it contacts the protective glass, then withdrawing it a little (1–2 mm) in order to prevent damage to the protective glass.
- The fiber test adapter has a distinctly chamfered, centric bore into which the optical fiber must be inserted. The off-center bore, in contrast, is just a ventilation opening that is needed in connection with coaxially gas-irrigated fibers. So never insert the optical fiber into the off-center hole, as this would not only damage the fiber but also prevent proper measurement (see section 5.5).
- If the focusing handpiece is used, the gas irrigation function must be switched off while performing the power measurement. Otherwise, the handpiece would be simply pressed out of the adapter due to the gas flow pressure.

Notice!

To maintain sterile working conditions, both the adapter and the protective glass must be sterile. All metal parts of the test adapter can be sterilized either with steam or gas, while the protective glass may only be gas-sterilized.

- Verify that all people present are wearing protective goggles.
- Make the laser system ready for operation by pressing the T4 button.
- Keep the distal end of the optical fiber system inserted in the adapter opening, then operate the footswitch (action point 2).
- Hold the footswitch down for at least one second.
- If the selected output power value (indicated on the A2 display) is changed during the therapy, the value shown on the A3 display will be automatically adjusted proportionally.

- Upon replacing the optical fiber, the value indicated on the A3 display disappears (no value shown).
- Whenever a new fiber is used, the fiber test must be carried out again.

Notice!

If the adapter's protective glass is dirty or impaired by burns or other defects, this may distort the measurement results. Similarly, hot-steam sterilization could adversely affect the transmission characteristics (or efficiency) of the protective glass. Therefore, always use gas for sterilizing the protective glass. Always check this glass for potential defects prior to inserting the adapter; if the glass is found to be defective, replace it with a new one (use genuine KLS Martin replacement parts only!).

To replace the protective glass, remove the screwed-on front cap. Then remove the old protective glass and insert the new one under sterile conditions. Before reinstalling the cap, verify that the little glass plate is positioned properly (lying flat) inside the cap.

6.7 Replacing the Optical Fiber

To replace the optical fiber, proceed as follows:

- Press the T1 button to switch the laser to standby mode.
- Switch off the fiber irrigation function, then disconnect the flexible irrigation tubes from the optical fiber system (if applicable).
- At the proximal end of the fiber, remove the screw cap from the SMA-plus connector, then withdraw the optical fiber from the coupling-in opening of the SMA-plus jack.
- Upon removing the fiber, the A3 display will turn dark and the K5 LED will come on, indicating that no fiber is connected.
- Insert a new fiber, then apply and finger-tighten the screw cap. Once the cap has been tightened properly, the K5 ("fiber missing") indicator goes out.
- Reconnect the fiber irrigation facility (if applicable). Check the optical fiber for potential defects, using the pilot laser light (see sections 6.5 and 12).
- The system parameters previously selected will be retained; in other words, the system settings are not affected by the fiber replacement.
- Test the new fiber (in acc. with section 6.6).

6.8 Setting the Laser System Parameters

The user can set the following parameters: operating mode (single pulse, pulse train, or continuous-wave); laser output power; pulse time/duration. These parameters may be changed at any time and in any sequence after switching on the unit. However, to prevent an accidental change of the irradiation parameters while the laser beam is being used on the patient, the system automatically blocks (i.e. renders inoperable) all buttons as soon as the footswitch is operated.

- **Output power**

Procedure: The output power value is selected with the T8 and T9 buttons (increasing and decreasing the value as required).

Indication: The selected value is indicated on the A2 display.

Explanations: If you want to change the selected power value with the T8 and T9 buttons, you have two options: a) incremental changes by pushing the respective button repeatedly; b) continuous change by keeping the respective button pressed (for at least 1 s).

The output power ranges are 0.5–40 W (**MY40 *1.3*)** and 0.5–36 W **(MY40e *1.3***)

0.5–8 W	adjustable in	0.5-W increments
9–30 W	adjustable in	1-W increments
32–40/36 W	adjustable in	2-W increments

- **Single pulse, pulse train, continuous wave**

The preferred operating mode – single pulse, pulse train or continuous wave – can be cyclically accessed with the T5 button. The selected mode is indicated by the backlit symbol (either K6, K7 or K8).

- **Single pulse, pulse train**

Procedure: With the T6 and T7 buttons, the pulse length/duration can be set (minimum value: 0.1 s; maximum value: 10 s).

Indication: K6 or K7 comes on. The preselected pulse length is indicated on the A1 display.

Explanation: For safety reasons, the footswitch function has been given absolute priority. So as soon as the footswitch is released, the laser beam is blocked at once, irrespective of the pulse time set.
In the "pulse train" mode, the interval (pause) between the pulses usually has the same length as the pulse itself (standard setting = 1:1). However, this ratio can be modified by the Technical Service. The options available are pulse-pause ratios of 1:2 and 1:3. This means that the pauses between the pulses would be twice or three times as long as the laser pulse times set and indicated on the display.
Single pulse mode:
With the footswitch held down, laser emission will be interrupted after the set pulse time has elapsed.
Pulse train mode:
The pulse sequence (and thus the emission of radiation) is maintained as long as the footswitch is held down.

Pulse time storage: The system automatically stores the duration of single pulses and pulse trains until the unit is switched off. When cycling through the operating modes with the T5 button, the last-used time setting is always displayed for the single-pulse and pulse-train modes. This greatly facilitates working if the surgeon must frequently switch between operating modes. After

switching on the unit, however, the standard pulse length of 1 s is always preset for both operating modes.

- **Continuous-wave operation**

Procedure: The duration of the treatment can be selected freely. As long as the footswitch is held down, laser radiation is emitted.

Indication: K8 is on. Moreover, the symbol "CW" is displayed on the A1 display.

6.9 Performing the Laser Treatment

- The preferred pilot laser stage can be selected with the T2 or T3 button. This activates a yellow backlight in the respective button. In "standby" mode, the pilot laser can also be switched off by pressing the backlit button once again.
- Aim the optical fiber at the surgical field.

Notice!

The T4 ("laser ready") button should only be pressed when the laser fiber is pointing at the surgical field and all safety measures for the prevention of laser-induced fires and explosions – as described in section 2.3 – have been duly carried out. When moving the optical fiber freely around, the T2, T3 and T4 buttons should always be deactivated!

Notice!

All persons present in the room must wear protective goggles!

- To make the laser system ready for use, press the T4 button; the yellow backlight will now come on.

Notice!

Before activating the footswitch, once again check the selected treatment parameters on the operator panel for correctness.

- When pressing the footswitch down, the connected equipment (e.g. the gas flow controller or the suction-irrigation pump) are activated (i.e. contact is closed) as soon as the first action point is reached. Once the second action point is reached, laser radiation is released in addition. At the same time, the K4 "laser emission" indicator comes on and an acoustic alarm is sounded as long as irradiation takes place.
- As soon as the preset pulse time has elapsed, the footswitch must be released. However, if the "pulse train" mode has been selected, the footswitch may be held down for the entire treatment period.

- If the footswitch is released before the preset pulse time has elapsed, the laser beam is interrupted at once. In such a case, the footswitch must first be fully released before it can be operated again. The original pulse time will then apply again.

Notice!

Whenever the laser treatment is interrupted for a longer period of time, it is safest to switch the unit to "standby" mode by pressing the T1 button. As long as the green backlight of the T1 button is on, any accidental activation of the laser beam via the footswitch is reliably prevented.

6.10 K1 Indicator Flashing

If the system is used over an extended period of time, the cooling water may heat up (particularly in warm treatment rooms or in the summer months). This may eventually lead to a safety shutdown. For this reason, however, the K1 control light has been provided on the front panel of the laser head (see Fig. 5.1). This indicator starts flashing when the water temperature begins to rise, well before the shutdown temperature is reached. Moreover, the on-time of this indicator will increase – over a range of 0–100% – in direct proportion to the increase in water temperature; so the on-time (or interval between on-times) reliably indicates how much operating time is left before the system will be shut down – which will occur when the K1 light is allowed to come on permanently. In case of a safety shutdown, the system cannot be restarted until the cooling water has cooled down to a temperature of less than 40°C. To achieve this as soon as possible, the cooler fan works at maximum speed while the system is in standby mode. In this case, too, the K1 control light functions as a status indicator, as its on-time will now decrease in accordance with the decrease in water temperature. As soon as K1 goes out, the system can be used again.
However, it is clearly best to avoid such a safety shutdown. Therefore, either take a short break or reduce the laser output power if the K1 on-time reaches a value between 70% and 90%.

6.11 Switching off the Unit

- Press the T1 "standby" button.
- Switch off the fiber irrigation facility and disconnect the flexible irrigation tubes.
- Set the keylock switch to the "0" position (rotate key counterclockwise) on the supply unit, then withdraw the key. Be sure to keep this key in a safe place.
- Disconnect the optical fiber, the fiber test adapter and the footswitch.
- Close the protective flap of the SMA-plus socket.
- Clean all accessories, then store them away.
- Clean and disinfect the outer surfaces of the unit in accordance with hygienic requirements (hospital hygiene regulations), using a suitable cloth. Take care, however, that no liquid will penetrate into the system (e.g. through openings). Never use sprays! Attention: Never spray the SMA-plus jack and never wipe over this socket!

- Cover the laser head with the dust cover supplied. It is important to keep the inside of the unit free from dust at all times!

6.12 Restarting the Unit

When switching the unit off and on again, always wait for approx. one minute before restarting it. Otherwise, it may be that the laser lamp will not come on and the E03 error message is displayed. If this occurs, switch off the unit and wait for one minute, then switch it on again.

6.13 Emergency Shutdown

As the name suggests, the emergency shutdown function – marked yellow and red – may be used only in emergency cases.

Procedure:

- Press the red emergency switch located on the left side of the control panel.
  The laser light emission will be stopped at once, but the water pump will run on for a few seconds to prevent overtemperature in the laser cavity.
- Set the keylock switch (located on supply unit) to the "0" position.
- Before restarting the system, verify that the red emergency shutdown switch located on the laser head is in the "pulled" (deactivated) position.
- Never use the emergency shutdown function for normal system switch-off!

6.14 Relocating the Unit

Under normal (in-house) conditions, the system can be easily moved to another location. For safety reasons, however, it is advisable to remove all accessories from the unit prior to relocation. Note that the unit must be moved with care. Avoid jerks, vibrations, shocks and the like, as such incidents might necessitate a readjustment of the unit by the Technical Service.

Notice!

Never use the flyer arm as a handle. If the unit needs to be lifted up (e.g. for crossing a threshold or some other obstacle), take hold of the supply unit and not the laser head. To move the system, use the handle specially provided for this purpose on the rear side of the unit.

If the unit needs to be transported to another building or over a greater distance in the open, the cooling water must first be drained from the system if outside temperatures are below 0°C. However, this may only be done by an authorized service technician (Technical Service). Subsequently, the system must be refilled with distilled, deionized water (again by an authorized person).

6.15 Special Functions

Some of the buttons located on the control panel can be used in combination to activate and display software-related functions that normally – in part at least – go unnoticed by the user because they belong to the computer's background work. To call up these special functions, it is necessary to press several buttons either sequentially or simultaneously (multiple button activation), whereby it is important to activate (or deactivate) the various buttons in the required order. Besides, some special functions must be activated on a "time" basis, i.e. by pressing a particular group of buttons for a specified (minimum) time.

6.15.1 Energy Sum

The software provides a possibility to display the sum total of the energies applied in the course of the laser treatment (measured in joules). This sum is calculated according to the formula "output power (in watts) times irradiation time (in seconds)". If several irradiations have been applied or pulse trains are used, the individual doses are automatically added up. Each time you switch on the system, the memory is reset to zero. Even if the energy sum display function is inactive, the system still works in the background, thus keeping well track of this parameter. To display the energy sum, the A1, A2 and A3 displays can be activated at any time. First, however, select the preferred operating mode, pulse time and laser output power. To activate the energy sum, use the T1 ("standby") and T5 ("pulse type selection") buttons. Proceed as follows: First press T1 and keep it pressed, then operate T5 in addition. The energy value will now be displayed:

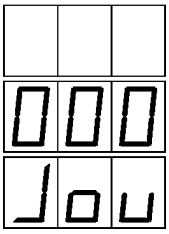
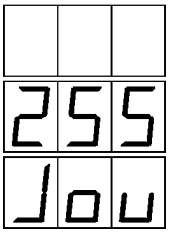


Fig. 6.1: Energy sum display

or, e.g..:



Example: 255 joules

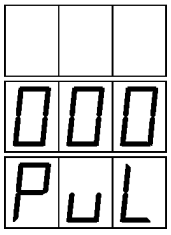
If you want to have the energy sum displayed during the treatment session, proceed as follows: First release/deactivate the T1 button, then the T5 button.
Now make the laser ready for use by pressing the T4 ("laser ready") button, then activate the system with the footswitch. The system will now continually sum up all energy values during the laser operation and show the total on the display. If the laser system has been set to continuous-wave mode, the total energy released is continually calculated, and the corresponding value displayed, as long as the footswitch is operated. In multi-pulse (pulse train) mode, the energy sum is calculated according to the formula "output power times pulse length of the single pulses involved". The maximum energy sum that can be indicated is 99999 J. For this, the A1 and A2 displays are used. The A1 display shows the ten thousands and thousands, while the A2 display is reserved for the hundreds, tens and units. If the calculated dose exceeds the value of 99999 J, the sum displayed will be "99 999 Jou" while the display keeps flashing.
To reset the energy sum to zero, press the two buttons T1 ("standby") and T5 ("pulse type selection") for at least 2 s.
This resets the display contents to "000 Jou".
If the energy sum function is not reset, the system will add up the values of all treatments by

background processing. The sum total can be displayed or deleted by the user at any time. When the system is switched off, the accumulated total is automatically deleted.

6.15.2 Pulse Counter

In pulsed mode, it may be helpful to have the number of emitted laser pulses indicated. The software provides a counter which adds up all of the pulses emitted. When starting the unit, this counter is automatically reset to zero; subsequently, all pulses emitted are counted. The count can be displayed at any time by activating the A1, A2 and A3 displays. First, however, select the preferred operating mode, pulse time and laser output power. The counter can then be displayed with the T1 (“standby”) and T7 ("reducing pulse duration") buttons.

Proceed as follows: First press T1 and keep it pressed, then operate T7. As a result, the following will be displayed:



or, e.g.:

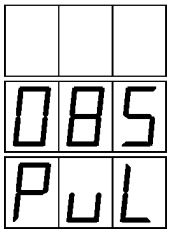


Fig. 6.2: Pulse counter display *Example: 85 pulses*

If you prefer to have the count displayed permanently in order to monitor the counting process, first deactivate the T1 button, then the T7 button.
Now make the laser system ready for operation by pressing the T4 button, then activate the laser beam by operating the footswitch. The pulse counter will now count the pulses emitted during laser operation. In continuous-wave mode, one pulse is counted each time the footswitch is operated (i.e. pressed down). The maximum number of pulses to be displayed is 255. If the number of pulses to be counted exceeds this limit, the display starts flashing, continuously showing "255 PuL“. The pulse counter can be switched off by keeping the T1 (“standby”) and T7 ("reducing pulse duration") buttons pressed for more than 2 s. In this case, the display will be reset to "000 PuL“. Pressing the T1 (standby) button brings the system back to its normal operating state.

6.15.3 Seconds Counter (Activity Time)

In continuous-wave as well as in pulsed mode, the duration of the laser pulses emitted can be measured and the values obtained can be totaled.

Upon switching on the system, the seconds counter is set to zero; subsequently, the system starts adding up the periods of time during which laser radiation is emitted. To indicate the overall irradiation time, the A1, A2 and A3 displays can be activated. First, however, select the preferred operating mode, pulse time and laser output power.

For activating the seconds counter, the T1 (“standby”) and T8 ("increasing laser power") buttons must be used.

Proceed as follows: First press T1 and keep it pressed, then operate T8 in addition. The display will now show the following:

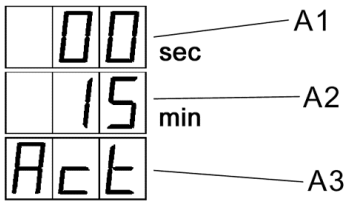


Fig. 6.3: Seconds counter display (Example: 15 minutes)
A1 Seconds
A2 Minutes (max. 90)
A3 “Act” (activity time)

- To have the seconds counter displayed continuously (enabling you to follow up the count), first release the T1 button, then the T8 button.
- Make the system ready for use by pressing the T4 (“laser ready”) button, then activate the laser beam with the footswitch. The seconds counter will now add up the various irradiation times.
- In continuous mode, the period of time during which the footswitch is pressed is measured.
- In pulse-train mode, the counter adds up the on-times of the single pulses involved. The maximum count is 90 minutes. If this limit is exceeded, “00 90 Act” is continuously displayed and the display is set flashing.
- The seconds counter can be cleared by pressing the T1 (“standby”) and T8 (“increasing laser power”) buttons for more than 2 s. This resets the counter to “00 00 Act”.

Pressing the T1 (standby) button brings the system back to its normal operating state.

6.15.4 Operating Hours

The software also provides a function for counting the hours the system has been in use. However, this value only covers those periods during which the laser lamp has been on (ignited). The time total is stored in the system's battery-buffered RAM (Random Access Memory). This counter serves as an indicator for the service life of the laser lamp. It is factory-preset to zero and is reset to zero whenever the laser lamp is replaced. For activating the operating hours meter, the T1 (“standby”) and T6 ("increasing pulse duration") buttons must be used. First press the T1 button and keep it pressed, then operate the T6 button in addition. The operating hours value – hours and minutes – will then be shown in the A1, A2 and A3 display sections.

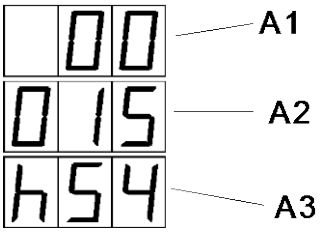


Fig. 6.4: Example: Operating time = 15 hours and 54 minutes

The display format used is a five-digit one: the hours are shown in A1 (thousands) and A2 (units, tens and hundreds); the minutes are indicated in the A3 section on a two-digit basis. The minutes are always preceded by the letter "h".

- Deactivate the T6 button; this resets the system to “standby” mode.
- To have the operating hours permanently displayed, first deactivate the T1 button and then the T6 button. Upon igniting the laser lamp, the operating hours meter will now continuously add up the respective operating times and show the current sum total.

The laser system can be operated as usual while the operating hours are being displayed, as the T1 (“standby”) and T4 (“laser ready”) buttons remain operable following hour meter activation. To activate the laser, use T4 and the footswitch as usual.

- To return to the normal operating state, just press the T1 (“standby”) button.

Notice!

If the laser operating time exceeds 400 hours, this is indicated by an error message (“E40” error code) displayed on the A2 display upon switching on the system. This prompts the user to have the laser lamp replaced by the Technical Service. The “E40” message can be deleted by pressing the T1 (“standby”) button. This returns the system to its normal operating state.

6.15.5 Software Version

To determine the software version on which the system is currently based, switch on the unit as usual, then start the laser lamp. The software version can now be indicated with the T1 ("standby") and T9 ("reducing laser power") buttons.
First press the T1 button and keep it pressed,
then operate the T9 button in addition.
This displays "40 SoF 2.02" (**MY40 *1.3***) or "36 SoF 2.02" (**MY40e *1.3***). Upon releasing one or both of the buttons just mentioned, the display returns to normal (status display). The "software version" function is often helpful for providing the necessary information to your Technical Service representative should problems arise with your system.

7 Accessories

The use of accessories and disposable products is restricted to items marked with the CE label and contained in the following list. This list of approved accessories is subject to modifications. The current version may be obtained from the manufacturer on request.

Notice:

Due to the system's wavelength of 1,318 nm, optical fibers offered by Gebrüder Martin for other laser systems cannot be used with the MY40.

Item Description	**Specifications**	**Item Number**
Laser protective goggles	D 1318 nm L7	79-100-50
Laser protective goggles for spectacle-wearers	D 1318 nm L7	79-100-51

Gas Flow Controller	**Specifications**	**Item Number**
MY GAS 2	Max. pressure 5 bar	78-231-00

Item Description	**Specifications**	**Item Number**
Bare fiber, 260 µm	3 m long, 260-µm core diameter	79-340-26
Bare fiber, 400 µm	3 m long, 400-µm core diameter	79-340-30
Bare fiber, 600 µm	3 m long, 600-µm core diameter	79-340-60
Irrigated fiber, 400 µm	3 m long, irrigated, 400-µm core diameter, 2-mm outer diameter	79-345-30

Focusing handpiece	**Specifications**	**Item Number**
Focusing handpiece, push-on type	Laser focusing handpiece, basic body, for push-on front sleeves	78-201-01
Focusing handpiece, threaded	Laser focusing handpiece, basic body, for threaded front sleeves	78-201-00
Front lens, green	Focal length f = 30 mm	78-210-50
Front lens, lilac	Focal length f = 50 mm	78-210-30
Front sleeve, green, push-on	Short, push-on front sleeve for green or lilac lens	78-202-31
Front sleeve, lilac, push-on	Long, push-on front sleeve for lilac lens	78-202-51
Front sleeve, green, threaded	Short, threaded front sleeve for green or lilac lens	78-202-30
Front sleeve, lilac, threaded	Long, threaded front sleeve for lilac lens	78-202-50
Supply fiber (laser to focusing hand-piece), core diameter 400 µm, length 3 m	Suitable for MY40/MY40e; with irrigation gas supply connector	79-301-40

Table 7.1: ***MY40 1.3 / MY40e 1.3*** *laser accessories*

Limited liability: Gebrüder Martin warrants the perfect condition of these goods. However, such warranty shall not apply to cases of improper handling or reuse of disposable (single-use) products. Under no circumstances will Gebrüder Martin accept any responsibility for consequential damage resulting from the use of this product.

Notice:

Additional user manuals are available for the following products and should be referred to as well:

- "Laser Focusing Handpiece" Instructions for Use (90-594-51)
- "MY GAS 2" Operating Instructions (90-254-51)
- "Fiber Preparation Set" Instructions for Use (90-268-58)

7.1 Nominal Ocular Hazard Distances (NOHD)

For the accessories permitted for use with this laser, the following safety clearances (NOHDs) must be observed, as otherwise the limit values for permissible laser irradiation and irradiation intensity would be exceeded.

MY40 *1.3*

Accessory	**Item/Order Number**	**Specifications**	**NOHD**
Focusing handpiece with green front lens	78-201-01(00) + 78-210-30	f = 30 mm	4 m
Focusing handpiece with lilac front lens	78-201-01(00) + 78-210-50	f = 50 mm	7 m
Bare fiber, 260 µm	79-340-26	260 µm	1.5 m
Bare fiber, 400 µm	79-340-30	400 µm	1.5 m
Bare fiber, 600 µm	79-340-60	600 µm	1.5 m
Irrigated fiber, 400 µm	79-345-30	400 µm	1.5 m

MY40e *1.3*			
Accessory	**Item/Order Number**	**Specifications**	**NOHD**
Focusing handpiece with green front lens	78-201-01(00) + 78-210-30	f = 30 mm	3.6 m
Focusing handpiece with lilac front lens	78-201-01(00) + 78-210-50	f = 50 mm	6.3 m
Bare fiber, 260 µm	79-340-26	260 µm	1.4 m
Bare fiber, 400 µm	79-340-30	400 µm	1.4 m
Bare fiber, 600 µm	79-340-60	600 µm	1.4 m
Irrigated fiber, 400 µm	79-345-30	400 µm	1.4 m

8 Maintenance

In your correspondence with Gebrüder Martin, please always specify the laser model you are working with (incl. the complete serial numbers of the laser head and the supply unit) whenever maintenance or repair issues are concerned. All these details can be found on the rating plate of your unit. Note, however, that a new hardware or software index will be attached next to the rating plate by way of a self-adhesive label whenever the system is updated. This information also needs to be communicated to Gebrüder Martin. When the system is on, you can also access the software version data by pressing the T1 (“standby”) and T9 ("reducing laser power") buttons simultaneously for at least three seconds. This displays the software version code in the A3 display. Whenever the unit shows obvious defects – particularly with regard to the power plug or the connecting cable – the user should have the system repaired as quickly as possible. Besides, the system should be checked and serviced at regular intervals, as this is the only way to ensure optimal operating conditions in the long term.

8.1 Routine Maintenance Work

Visual Inspection & Maintenance	**Frequency / Interval**	**To Be Carried out by:**
Checking, disinfecting and sterilizing the accessories	prior to each operation	hospital staff
Checking the protective glass of the fiber test adapter for dirt accumulation, burns and other defects	prior to calibration	hospital staff, user
Checking the entire optical fiber for potential defects	prior to each operation	hospital staff
Checking the laser warning lamp for proper functioning	daily	hospital staff
Cleaning and disinfecting the unit's external surfaces	as required by in-house regulations	hospital staff
Checking the electrical connections and cables for potential defects	monthly	hospital technician
Checking the cooling water level	twice every year	hospital technician
Refilling distilled, deionized water	as required	hospital technician
Replacing the deionization cartridge	when K15 comes on, or when the cooling water has been replaced	Technical Service
Calibration of power meters	annually	Technical Service
Replacing the cooling water	annually, 12 l	Technical Service
Replacing the krypton lamp	after 400 operating hours	Technical Service
Safety Checks	required annually	Technical Service

Table 8.1: Recommended routine maintenance & inspection schedule

8.1.1 Cleaning and Disinfecting

All external surfaces of the unit, including the front panel, may be cleaned with common non-alcoholic cleaning agents.

Attention!

Be sure that no liquid can enter the system through the unit's openings (such as the SMA-plus jack or the opening of the fiber testing facility).
For this reason, never use a spray for cleaning purposes!
If possible, keep the unit always closed (i.e. cover in place).

The outer surfaces of the unit and its non-sterilizable accessories may be disinfected with a commonly used OR disinfectant; for example:

Bacillol	Bode-Chemie
Meliseptol	Braun-Melsungen
proCura-Spray	proCura
proCura-Heliosept medical-Spray	proCura
Mikrozid Liquid	Schülke & Mayr

Before using the system again after cleaning, verify that no disinfectant residues have been left on the unit.

The protective glass of the fiber test adapter can be taken out after dismounting the screwed-on sleeve. To clean the glass, use a piece of lint-free paper (e.g. lens cleaning paper) together with acetone or pure alcohol. Proceed as follows: Hold the glass by the edges with your fingertips, then put some drops of solvent onto the glass surface. Fold the cleaning paper several times, then wipe off the solvent with the lip of the tissue by moving it over the surface just once. Important: Wipe in one direction, not in a circle! If this is performed correctly, the optical surface will be perfectly clean, showing neither drying marks nor streaks. Subsequently, clean the other side of the glass in the same manner. In the case of very dirty surfaces, allow the solvent to take effect on the surface for some time. If the glass is too dirty or even defective, replace it with a new one.
Whenever the unit is not used, protect it from dust by putting on the dust cover supplied.

8.1.2 Maintenance by Hospital Technician and Staff

To ensure the operational safety and reliability of the laser system during interventions, the cooling water level must be checked twice every year. The optimal water level is halfway between the maximum and minimum marks (see left wall of supply unit). If the water level drops below the minimum mark, cooling water must be added. Note that a lack of cooling water triggers a shutdown (K13 control light).

To refill cooling water, switch off the system, then open the servicing cover located on the front side of the supply unit (this cover features snap locks; take hold of the plate in the upper third, then pull). Now the servicing cover can be conveniently removed downwards by taking it

off its hinges. If the system includes an accessories drawer, it is helpful to pull this drawer a little out prior to removing or installing the servicing cover. Next, remove the screw cap from the tank by rotating the cap counterclockwise. Note that the deionization cartridge is connected to this cap by means of a fastening cord. It is now possible to fill in distilled, deionized cooling water as required. Note that the water must have a conductivity of less than 10 µS/cm. The tank should be filled up to a level of approx. 2 cm below the lower edge of the filling hole.

To reinstall the screw cap and the servicing cover, proceed in reverse order and direction.

The K15 indicator monitors the conductivity of the cooling water. If this indicator lights up in the course of laser application, you may well continue with the treatments scheduled for the day because there is no need for immediate action. To ensure a long service life of the system, however, be sure to replace the deionization cartridge with a new one before starting the next laser working day. The procedure is exactly the same as for refilling cooling water (see above). After the tank's screw cap has been undone, the cartridge can be easily pulled out of the tank with the help of the cap. To detach the cartridge from the cap, open the spring hook provided and remove the fixing cord. The used-up cartridge may be disposed of as part of the normal household garbage.

To install the new deionization cartridge, proceed in reverse order, making sure that the cartridge gets deeply immersed in the cooling water (to ensure its full effectiveness). Should the K15 light still be on after the cartridge has been replaced with a new KLS Martin cartridge and the system has subsequently been in operation for at least 4 hours (without laser lamp ignition), please contact Gebrüder Martin's Technical Service.

In case the K1, K11 or K12 indicator lights up continuously, switch off the system in the manner described above, remove the servicing cover and install a new filter mat. Like in the case of the cartridge, the old filter mat may be disposed of as part of the normal household garbage.

Notice!

If – under extremely hot operating conditions – the control lights K1, K11 and/or K12 come on again soon after filter mat replacement, it may be helpful to remove the mat from the supply unit and operate the unit without it. Note, however, that this would reduce the quality of the ambient air, thus adversely affecting air hygiene.

8.2 Maintenance Work to Be Performed by Technical Service

Whenever the unit has been repaired or modified by Gebrüder Martin's Technical Service, the following must be entered in the medical devices log:

- Nature and scope of the repair work done (e.g. rating-related modifications)
- Date of execution
- Signature of the person carrying out the work

8.3 Safety Checks

Once a year a comprehensive safety check must be carried out in order to ensure that the unit duly conforms to safety regulations. The results of these checks must be recorded in the medical devices log.

Frequency and scope of the safety check to be performed

Frequency:	*annually*
Type of equipment:	*Nd:YAG Laser System*
Class of equipment (MDD):	*IIb*
Serial no. of laser head:	……
Serial no. of supply unit:	
Inv. number:	
Operating hours:	……
Operator/owner:	……
Location:	……

1 Visual inspection

[ ] 1.1 Lettering (laser class, max. power, wavelength, etc.)

[ ] 1.2 Information/warning signs: properly attached and complete?

[ ] 1.3 Operating Instructions / medical devices log

[ ] 1.4 Internal hose connection(s)

[ ] 1.5 Supply line condition

[ ] 1.6 Connecting cable / strain relief

[ ] 1.7 Equipment complete?

[ ] 1.8 Outer surfaces

[ ] 1.9 Optical accessories

2 Functional check

[ ] 2.1 Cooling system

[ ] 2.2 Footswitch, stages 1 + 2

[ ] 2.3 Beam delivery system / coupling in/out / pilot laser

[ ] 2.4 Check membrane keyboard (sealed keypad) for potential defects

[ ] 2.5 Optical accessories

3 Checking the required monitoring/safety and signaling devices for proper functioning

[ ] 3.1 Shutter prevents laser radiation emission at output during preregulation (safety shutter); radiation emission at intervals in multi-pulse operation (resonator shutter)

[ ] 3.2 Laser protective goggles

[ ] 3.3 Output testing (acoustic/optical)

[ ] 3.4 Power meter (internal-external comparison)

[ ] 3.5 Keylock switch

[ ] 3.6 Emergency stop switch (check for proper functioning)

[ ] 3.7 Door interlock (check for proper functioning)

[ ] 3.8 Laser-operation alarm contact (check for proper functioning)

4 Electrical Safety (DIN EN 60601)

[ ] 4.1 Protective conductor resistance: **MY40 *1.3***: ≤ 0.2 Ω / **MY40e *1.3***: ≤ 0.1 Ω

[ ] 4.2 Ground leakage current: **MY40 *1.3***: ≤ 5 mA / **MY40e *1.3***: ≤ 0.5 mA

5 Measuring safety-related output parameters

[ ] 5.1 The preset output power must be measured externally (measuring accuracy better than ±10%) and must then be compared to the value provided by the internal power meter.

[ ] 5.2 Check calibration by using external power meter
0.5, 1, 5, 10, 20, 30 and **MY40 *1.3***: 40 W / **MY40e *1.3***: 36 W
(permitted tolerance: ± 20 %)

Notice!

If the unit is found to be defective in any safety-related way, it must be withdrawn from service until the defects have been remedied.

Measures taken:

[ ] Technical Service notified on: .....

[ ] Unit withdrawn from service on: .....

[ ] Results entered in medical devices log on: .....

Person carrying out the checks/tests:

Date:

Signature:

9 Troubleshooting

9.1 Error Indication

The unit features an automatic self-testing routine that permanently monitors the system, thus ensuring the safety of the patient, the OR team and the laser itself. As soon as an unusual/non-conforming operating condition is detected, this is indicated to the user either by one of the K1–K3, K5 or K10–K17 control lights or by a two-digit error code of the type "E xy" shown on the A2 display (see below).

9.2 Protection in Case of Fiber Burn-Up

The system features a number of safety devices that provide protection against damage caused by defective or non-permissible fibers.

9.2.1 Fiber Coupling-in Temperature Monitoring

If the laser radiation is not properly coupled into the proximal end of the fiber, the residual radiation (i.e. the radiation not entering the fiber) will lead to heat build-up, particularly on the SMA-plus connector. Therefore, the temperature of the SMA-plus socket is constantly monitored by the system. If this temperature rises during laser operation, the system is automatically shut down by the electronic safety device. At the same time, the system goes automatically into "standby" mode. The red "fiber missing" indicator may briefly light up during this process.

9.2.2 Protection Against Fiber Burn-Up

In the event of a major fiber defect, the SMA-plus connector used on the coupling-in side could be destroyed in an explosion-like manner when working with a high laser power. For this reason, a front/cover lens has been integrated into the optical coupling-in system to protect the precisely adjusted optical focusing system against damage caused by fiber burn-up products. As this lens can be easily replaced by the Technical Service, it significantly reduces potential indirect costs caused by defective fibers.

9.2.3 Safety-Related Software

The integrated software of the KLS Martin **MY40 *1.3*** (software version 1.16 or higher) evaluates and reacts to any temperature increase measured by the temperature sensor during laser operation. If the temperature is too high, the system will be blocked and the error code "E13" displayed. In such a case it is not possible for the user to cancel the interlock and resume operation; instead, the Technical Service must be contacted. It is usually possible for the service representative to put the laser back into service after the cover lens has been checked and replaced if necessary, thus keeping the down-time to a minimum.

9.3 Laser Head and Supply Unit Indicators

Control Light	State / Error	System Response	Measures to Be Taken
K1 flashing with increasing on-time	Cooling system temperature increasing	At a cooling water temperature of approx. 40°C, K1 starts flashing, with K1 on-time increasing in direct proportion to the water temperature increase. Error code "E21" displayed when unit is switched on with heated cooling water	The surgeon should note that the laser will be cut off when a temperature of approx. 50°C is reached; see "E21" error code description
K1 continuously on	Overtemperature in laser head > 50°C	Laser goes from "laser ready" into "standby" mode. Error code "E21" displayed when unit is switched on with heated cooling water	Do not switch off unit; allow it to cool down; check cooling air flow for unimpededness; check filter mat in supply unit and replace mat if necessary; see E21 error code description.
K1 flashing with decreasing on-time	Cooling system temperature decreasing	When the temperature drops below 45°C, the on-time will proportionally decrease. K1 goes out at a temperature of < 37°C	Laser system cannot be used until K1 has gone out; operate unit in keylock position 1 until K1 extinguishes
K2 continuously on	Supply unit error	See K10–K17 below	See K10–K17 below
K3 continuously on or flashing	Contact Technical Service	See Table 9.2	Try restart; if malfunction persists, call Technical Service
K5 continuously on	Check SMA plug	Switching laser to "laser ready" mode with the T4 button is not possible	Install the optical fiber; finger-tighten screw cap of SMA-plus connector plug
K10 continuously on	Lamp cannot be started	"E 03" error code; laser operation is not possible	Restart; contact Technical Service if necessary

Control Light	State / Error	System Response	Measures to Be Taken
K11 continuously on	Overtemperature in power supply unit	Power supply unit is off, cooling system remains in operation	Check cooling air flow for unimpededness, check filter mat; turn off and restart unit; replace filter mat if necessary, or contact Technical Service.
K12 continuously on	Overtemperature in cooling system		
K13 continuously on	Cooling water level too low	Both the power supply unit and the cooling system are switched off	Refill cooling tank with deionized water; turn off and restart unit
K14 continuously on	Insufficient cooling water flow	Power supply unit switched off	Check supply line for kinks and close loops; turn off and restart unit; contact Technical Service if necessary.
K15 continuously on	Cooling water conductivity too high	No system response; laser operation still possible for the time being	Replace deionization cartridge; contact Technical Service
K16 continuously on	Operating-room door interlock open	Laser system cannot be used	Close system-monitored door(s) or apply cap with bridge to socket 9, Figs. 2.9/2.10
K17 continuously on	"Refill cooling water" service indicator	Cooling water level and flow rate monitoring system inactive	Set service toggle switch on flow monitor to the "0" position

Table 9.1: Signal indications on laser head and supply unit (indicators K1–K17)

Symptom / Indicator	**Potential Causes**	**Measures to Be Taken**
K9 does not come on after keylock switch has been set to position 1 or 2	1. No power supply 2. Circuit-breaker tripped 3. K9 light defective 4. Emergency stop switch pressed	1. Check cable connection 2. Check circuit-breaker 3. Contact Technical Service
No laser radiation emitted when operating footswitch	1. Footswitch not connected 2. Laser in "standby" mode	1. Connect footswitch 2. Push T4 button to switch laser to "laser ready" mode
K4 does not come on when emitting laser radiation	1. Pilot laser defective 2. Optical system out of alignment	Contact Technical Service

Table 9.2: Other error indications

If the problem cannot be corrected by the recommended measures, contact Gebrüder Martin's Technical Service.

NOTICE!

When covers are removed, laser radiation may be emitted in an uncontrolled manner. Improper handling of the unit may pose a danger of personal injuries! Non-observance of these Operating Instructions may void the warranty given by the manufacturer.

9.4 Error Codes

The **MY40 *1.3* / MY40e *1.3*** laser unit recognizes internal troubles, blocks laser emission where necessary and provides user information in the form of an error code.
Error codes are shown in the A2 ("laser power") display in the following format: "E XY".
In cases of serious malfunction, the K3 control light ("contact Technical Service" / phone symbol) will come on in addition.

Error Code in A2	Service Symbol K3	Error and Status Description	When Does the Error Occur?	Impact on System	Recommended Measures
E01	on	Default value (10 W) not available	Immediately upon switching on the unit	Indicators/displays off; no laser operation possible	Turn off and restart the system
		Control system error; set power value incorrect	After a new output power value has been selected	No laser operation possible	Change power value
		Control system error; laser power out of tolerance range	During operation	Laser switched off	Delete errror by standby, select lower power, activate again
E03	off	Laser lamp does not come on	Can occur in any operating mode	System inoperable	Activate ignition, or restart
E03	off	Laser lamp on			Replace laser head
E11	off	Resonator shutter not working properly	Can occur in any operating mode	No laser operation possible	Release footswitch and press it down again
E12	off	Safety shutter not working properly	Can occur in any operating mode	No laser operation possible	Release footswitch and press it down again
E13	off	SMA contact overtemperature	Upon switching on the unit	No laser operation possible	Call Technical Service
		SMA contact overtemperature	During laser operation		
		No error identifiable	spontaneously		

Table 9.3 Error codes

Error Code in A2	Service Symbol K3	Error and Status Description	When Does the Error Occur?	Impact on System	Recommended Measures
E20	off	Temperature monitoring system triggered into action	During operation; K1 continuously on	Footswitch locked; no laser operation possible	Release footswitch; allow water to cool down (with fan in operation)
E21	off	Interlocking mechanism activated by temperature monitoring system	Cooling water heated at the time of switching on the unit	No laser operation possible; system goes into "standby" mode.	Operate unit in keylock position 1 until the K1 light goes out
E40	off	Lamp operating time exceeded	Immediately upon turning on the unit	This is just a warning! The system can still be used.	Contact Technical Service to have lamp replaced
E50	on	Storage error in RAM / CPU RAM	Upon turning on the unit	System inoperable	Restart
E51	on	Error during data exchange between CPU and hardware	Can occur in any operating mode	System inoperable	Restart
E52	off	Memory error	When selecting new power value	Laser goes into standby mode	Restart
E53	off	Memory error	When selecting new power value	Laser goes into standby mode	Restart
E60	off	General error	Can occur in any operating mode	No laser operation possible	Press T1 ("standby") button
E61	on	General error	During laser operation	System inoperable	Press T1 ("standby") button

Table 9.3 Error codes

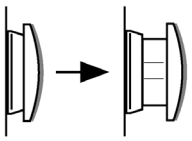
10 Quick Reference User Guide

10.1 Preparatory Checks

Read Operating Instructions

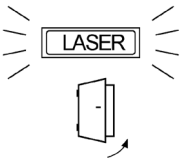
Connect laser system to power supply system

Pull out emergency stop switch



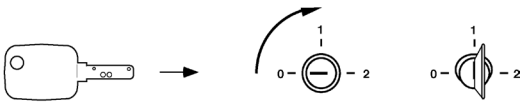
Put on protective goggles

Close doors and activate warning lamp



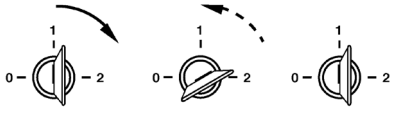
10.2 Switching on the Unit s

Insert key (position "0"), then set it to "1"

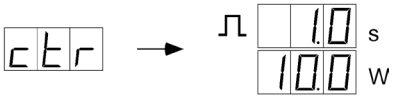


Self-test completed – "E03" displayed

Set key to position "2"



System performs check and activates standard parameters

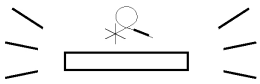


10.3 Setting the Parameters

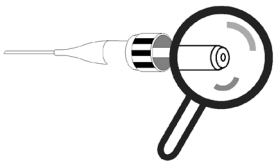
Select laser output power (↑ ↓), pulse type (⎍, ⎍⎍, ⌐) and pulse time

10.4 Connecting the Fiber

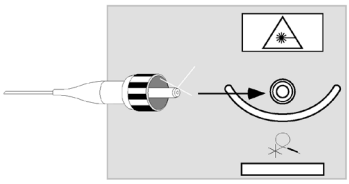
Control light indicates "fiber missing"



Check connector for cleanness



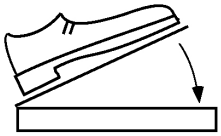
Connect fiber



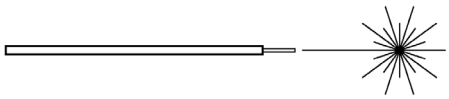
10.5 Starting the Treatment

Press the T4 button ("laser ready"),

then operate the footswitch

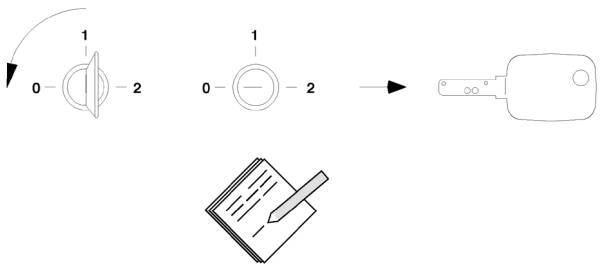


and apply the laser radiation



10.6 Switching off the System

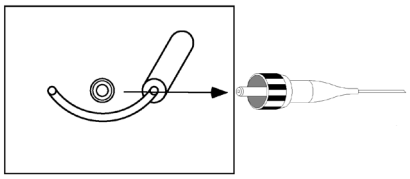
Set keylock switch to the "0" position,
then withdraw key and keep it in a safe place



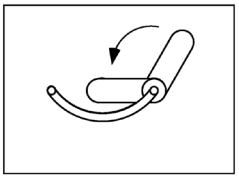
Record the treatment in the log

10.7 Disconnecting the Fiber

Unscrew fiber from connector,



then apply protective flap



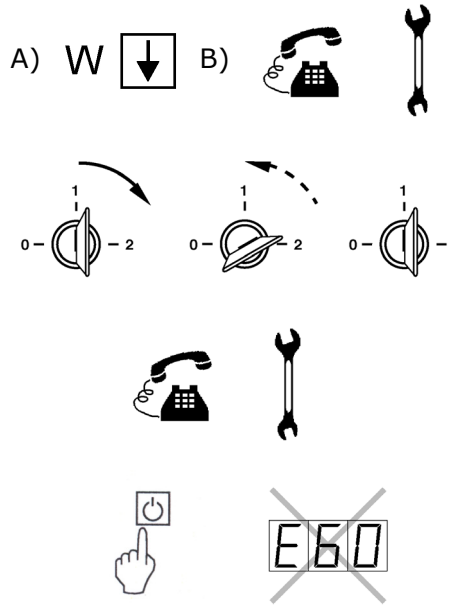
10.8 Error Messages

 E01 Reduce output power or contact Techn. Service

 E03 Ignite laser lamp with keylock switch

 E13 Fiber dirty; contact Technical Service

 E60 Press "standby" button to delete "E60"



11 Technical Data

Laser type	Continuous-wave Nd:YAG las
Laser wavelength	λ = 1,318 ± 30 nm (infrared)
Laser output power	**MY 40 *1.3*** ..... 0.5–40 W ± 20% **MY40e *1.3*** ..... 0.5–36 W ± 20%
Laser class	4
Protection class	I
Type of protection	IP X1
Operating modes	1) ..... continuous-wave (cw) 2) pulsed • single pulse 0.1 s – 10 s • pulse train 0.1 s – 10 s
Pilot laser (laser diode)	Wavelength 635 nm (light-red) ..... 1 mW, continuous-wave adjustable to ..... 5 mW, continuous-wave
Control & monitoring	Microprocessor
Indicators	LEDs, green, contrast-optimized
Control panel	Soft-touch panel, surface wipable
Cooling system	Air-cooled, with closed water circuit
Coolant	Water, 12 l, deionized
Optical fiber connection	SMA-*plus* connect
Numerical laser aperture	NA ≤ 0.2
Laser spot diameter	Laser with 260 UPGRADE ..... ≤ 260 µm Laser without upgrade ..... ≤ 400 µm
Dimensions	Laser head (W × D × H): ..... (406 × 460 × 135) mm Weight: ..... 12 kg (without supply line) Supply unit (W × D × H): ..... (406 × 380 × 780) mm Gewicht: ..... 71 kg
Electrical connection	**MY 40 *1.3*** ..... 3 x 230/400 VAC, 3~, 3 x 10 A, 50/60 Hz **MY40e *1.3*** ..... 230 VAC, 16 A, 50/60 Hz
Power input	**MY 40 *1.3*** ..... 4.4 kVA **MY40e *1.3*** ..... 3.7 kVA Standby ..... approx. 0.8 kVA
Fuses	Fine-wire fuses 2 x T 2.5 A, 2 x T 1.25 A, 2 x T 0.1 A (slow-bl.)
CE-mark:	CE 0297
EMC Directive	89/336/EEC
Safety check	annually

12 Test Certificates

CE 0297 This label certifies that the unit complies with the essential requirements set out in the EU Directive 93/42/EEC relating to medical products. It is located on the rear panel of the unit.

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