USER MANUAL

ENDOTEQ

ENDOTEQ810, ENDOTEQ980,
ENDOTEQ1064, ENDOTEQ1470

This manual is not for use in the USA

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1. Introduction

We sincerely appreciate your business and your decision to purchase the ETQ laser system. The ETQ Laser generates a high-intensity laser beam which may induce injuries if handled improperly. Therefore, this User Manual should be read carefully before using the device. Should you have any further questions regarding safety, the use of the device, or concerning laser and laser radiation, please contact ENDOTEQ Medical Laser Germany. or your local authorized dealer (see Section 10.3 "Sales and Service - Information").

A T T E N T I O N !
We are obliged by local laws to sell this device only to licensed physicians, through our local authorized dealer. The laser unit should be used only by physicians trained by ENDOTEQ or its authorized dealers for proper use.

a. Copyright

This user manual is protected under copyright. The copyright prohibits any duplication of parts or of the entire user manual without an explicit written consent by ENDOTEQ.

Approved copy or parts extracted from this user manual, as licensed by ENDOTEQ shall include references to the original document and author as stated in this original document. Furthermore, this copyright applies to any translated copy of the user manual to other languages.

We would like to point out that this user manual was prepared based on ENDOTEQ proprietary data and to the best of our knowledge. ENDOTEQ reserves the rights to revise, renew or modify any of the included drawings, images or text without further notice. In case of any content change, the revised document will be readily available for the regulatory authorities.

b. Marking and Symbols

The international sign **"Attention"** is mounted on all surfaces, which are hazardous for the user. Before carrying out any further work on such marked parts, please read the user manual or contact your local dealer or contact ENDOTEQ. service department directly.

The laser radiation sign is intended to warn the user against exposure to laser beams radiation by improper handling. The laser beams of this device are not visible. When using the protection goggles to filter the beams, the user can neither identify nor see the beams.

c. Intended Use

The ETQ diode laser family is intended for use in the following medical specialties for surgical applications requiring vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue: Dermatology, Proctology, Phlebology, Otolaryngology, Pulmonology, Thoracic Surgery, General Surgery, Gastroenterology, Orthopedics, Neurosurgery, Dentistry, Gynecology, Urology, and Podiatry. These fields of use are common for medical lasers in the

same power level and wavelength range as the ETQ family and are universally documented in medical literature.

Specifically, based on existing published clinical data and established use of predicate devices, the use of each model should relate to the following fields of use:

ETQ810 – Dermatology, Proctology, Phlebology, Otolaryngology, Pulmonology, Thoracic Surgery, General Surgery, Gastroenterology, Orthopedics, Neurosurgery, Dentistry, Gynecology, Urology, Podiatry
ETQ980 – Dermatology, Proctology, Phlebology, Otolaryngology, Pulmonology, Thoracic Surgery, General Surgery, Gastroenterology, Orthopedics, Neurosurgery, Dentistry, Gynecology, Urology, Podiatry
ETQ1064 – Dermatology, Proctology, Phlebology, Otolaryngology, Pulmonology, Thoracic Surgery, General Surgery, Gastroenterology, Orthopedics, Neurosurgery, Dentistry, Gynecology, Urology, Podiatry
ETQ1470 – Dermatology, Proctology, Phlebology, Otolaryngology, Pulmonology, Thoracic Surgery, General Surgery, Gastroenterology, Orthopedics, Neurosurgery, Dentistry, Gynecology, Urology, Podiatry
ETQ1940 - Dermatology, Proctology, Phlebology, Otolaryngology, Pulmonology, Thoracic Surgery, General Surgery, Gastroenterology, Orthopedics, Neurosurgery, Dentistry, Gynecology, Urology, Podiatry

According to ENDOTEQ's Clinical Evaluation Report, common indications in the Intended use fields include:

Dermatology:	- Laser assisted lipolysis - Percutaneous or transdermal sealing of vessels
Phlebology:	- Endovenous coagulation of magna saphena vein - Endovenous coagulation of side branches - Endovenous coagulation of SSV
Otolaryngology	- Nasal mucosa coagulation (shrinkage/reduction) - Surgical cuts in tonsillectomy - Middle ear surgery (e.g. stapedotomy) - Tracheal treatment of papilloma, granulomas and stenosis
Orthopedica/Neuro	- Percutaneous Laser Disc Decompression (PLDD)
Procto/General Surg	- Treatment of hemorrhoids - Treatment of anal fistula or pilonidal sinus
Podiatry	- Treatment and clearance of nail fungus
Gastroenterology	- Laser photoablation of polyps/adenomas
Dentistry	- Parodontose treatment

	- Endodontic treatment - Frenectomy, gingiva surgery
Gynecology	- Vaporization of lesions
	- Tumor removal - Ablation or resection of endometriosis
Urology	- Prostate treatment, varicocele

When choosing a fiber for a specific indication, the user must consult the fiber manufacturer and the fiber IFU to verify the compatibility of the fiber for the desired indication. In addition, the fiber must be labeled (consult the fiber label and IFU) as compatible to the ETQ laser system (see section 8 for technical details on fiber compatibility).

Contra-indications:

The treatment is contraindicated in all cases where the use of laser as a surgical modality is contraindicated (where heat could present a clinical risk), including where a clinical procedure is limited by anesthesia requirements or site access. In addition, applications at the central nervous system and the central circulatory system are not allowed.

Usability Information

Intended medical indication and body part or tissue type applied per information above

Patient target group: General population (without restrictions)

User profile – trained physician

Use environment – hospital, clinic or office based

Operating principle – per section 2 below.

Applied part contact duration is estimated at <2 hours

ANY SERIOUS INCIDENT IN RELATION TO THE DEVICE MUST BE REPORTED TO THE MANUFACTURER OF THE DEVICE AND TO THE RELEVANT COMPETENT AUTHORITY

CAUTION – The device may only be used by physicians that went through appropriate training and have extensive knowledge of the medical effects and risks involved in using this device, as well as the understanding of how to use this device in accordance with this manual.
Laser equipment not in use should always be protected against unqualified use.

2. Theory and Technical Background of a Diode Laser

This ETQ laser is a diode laser with a laser diode as the beam source. The laser diode can radiate light in a variety of potential wavelengths. The ETQ Laser can be supplied with the wavelengths of 810 nm, 980 nm, 1064 nm, 1470nm, or 1940nm. The laser radiation of the diode is collimated through the optics in the „fast“ and in the „slow“ axis and consequently transferred to a surface of approx. 2mm x 4mm.

The word laser means „light amplification by stimulated emission of radiation“. All laser types include three fundamental elements: The lasing medium (providing atoms), or molecules allowing to amplify the light, an excitation source (the abovementioned molecules or atoms are excited with), and an optical resonator which, similar to a resonant circuit, supports or generates the radiation stimulated by the internal reflection.

Atoms and molecules may have different energy states, which can generate electromagnetic photon radiation changing from one state to the next by means of absorption and consequently by radiation. In their normal state, the electrons of an atom are in the so-called basic or normal state.
By supplying energy through light – or though plasma formation, as noble gas lasers do – electrons are transported into the higher state. The dwell time in the higher state is very short though and the electrons sink back into their original state. During this short phase, the previously stored energy is released again by sending out photons.

The consequently emitting photons have the same wavelength and the same direction within the laser. Inside the resonator cavity, the photons between the two mirrors are compelled to pass through the cavity several times. During this time, they hit further photons thus generating a monochromatic light. To enable light generated in the resonator to be transmitted outward, the initial mirror of the laser is made permeable in parallel.

The laser diode is operated with high current up to 35 amperes and low voltage. The power output varies per individual wavelength. Through PN junctions, only certain layer thicknesses can be reached, and consequently only certain wavelengths can be generated. The current running through the laser diode is generated by current drivers in the electronic system thus allowing the user to control the output power through the touch screen display. Via beam deflection mirrors and coupling ceramic elements the laser light is coupled into a silica glass fiber. The transmission of the various wavelengths is independent from the fiber. Transmissions ranging from 70 to 80 % of the laser power are possible and also may depend on fiber core size.

The laser diode is controlled by an internal electronic system that is adjustable through the device control monitor. The ETQ laser output power as well as pulse length and pulse width can be controlled individually. The laser beam emitted from the diode is polarized and therefore easy to ramp up or down. By means of direct cooling, the diode is kept in a stable operating temperature. The cooling circuit is passive and controls the internal fans, to allow natural or forced convection heat dissipation, depending on the load.

3. Transport and Storage

The ETQ Laser is supplied in a custom made carrying case for ultimate protection during transportation. The carrying case is designed to ensure the user can perfectly stow and transport the ETQ Laser when changing rooms and/or site location..

For deliveries by mail, the carrying case is protected by a special outer cardboard box.

The device should never be exposed to temperatures below 2°C. or above 40°C. The ambient air must be dry and clean. Ambient air humidity exceeding 80% may result in diode layers burning down when switching on the device, so the device will sense humidity and prevent operation at humidity levels equal or exceeding 80%.

The ETQ Laser should be transported and stored only in its original carrying case to avoid damage.

A T T E N T I O N!
The ETQ Laser should be protected against water, moisture, and high humidity!

4. Installation

a. Installation Site

The ETQ Laser should only be installed by ENDOTEQ or its authorized dealer. The user will be given full training on the device as part of installation. Prior to delivery, however, the user needs to make sure a suitable location was prepared for the installation.

The installation site for the ETQ Laser should be accessible and removed from heat and water. Thus, the ETQ Laser should not be installed close to a heater or a sink. Due to its air cooling system, the ETQ Laser should operate in an ambient temperatures that does not exceed 21°C. Higher ambient temperature may result in shorter working times as the device will be switching off earlier to prevent overheating.

If the ambient temperature is too low (below 10°C), the device cannot be started, in order to avoid possible condensation on its internal optics as this might cause permanent damage.

All control elements need to be readily accessible. Fibers connected to the front of the unit during operation should have sufficient space to avoid accidental bending. The air humidity in the treatment room should be monitored and kept below 75%.

A T T E N T I O N!
The ETQ Laser should only be used in an environment per the instructions below in this chapter, including proper use of warning signs, eyewear protection, and proper tools.

b. Room Requirements

Legislation imposes the following requirements to any room in which a class 4 laser (according to EN 60825-1) is operated.

i. Warning Signs

All entrances shall be clearly marked to prevent an outside person from entering the laser working area as this might be hazardous.

- Attach the laser warning sign (triangle with laser symbol) as well as the wavelength marking at each access door.
- Mount a warning lamp above each access door which always has to light up, when the laser is in operation. This ensures warning to prevent accidental entry to the room without protective goggles.
- Store the laser protective goggles at the entrance of the room and make sure they are readily accessible.

ii. Windows Shielding

Windows need to be covered with suitable masking or shielding to prevent laser radiation leakage. For any question or in case of any doubt, please contact your local ENDOTEQ's authorized dealer, or contact ENDOTEQ directly at any time.

iii. Reflecting Surfaces

To avoid possible danger caused by reflected radiation direct or scattered, reflecting surfaces must not be present in the room during operation. Such surfaces may include

- Mirrors
- Pictures with front glass
- Chrome surfaces
- Windows

These surfaces must be either removed or covered with suitable matt type material. Even at the area around the laser fiber port, use only matted, non-reflecting as well as non-combustible instruments and materials.

c. Electrical Connection

The laser is operated with a DC voltage of 19 V, supplied by an external medical grade power supply unit. The power supply unit can be connected to an AC voltage ranging from 100V to 240V at 50Hz-60Hz. Specifications are as labeled on the power supply.
When disconnecting the device, manually disconnect the power cord from the external power supply, and disconnect the external power supply from the laser.

5. Safety Information and Technical Acceptance

a. General

The ETQ Laser is a precision instrument for medical applications. ENDOTEQ has devoted the utmost care for safety aspects during its design and manufacturing as well as implementing intensive testing procedures prior to shipment, to ensure the device you are receiving is safe to use.

It is highly advisable to keep detailed laser safety instructions with the device, and to inform any person using the device of their location.

ENDOTEQ laser devices are classified according to EN 60601-2-22 and EN 60825-1, as a ***Class 4 Laser Product***. As such, to ensure that individuals are not exposed to direct, reflected or scattered laser radiation without appropriate protection, it is necessary prior usage to:

- Create a "*laser treatment controlled area*" within the facility;
- Post appropriate laser warning signs at the entry way to the laser controlled area;
- Use a door, blocking barrier, screen, or curtains to attenuate laser radiation in the entryway;

(A laser treatment controlled area is an area that is appropriately enclosed so that laser radiation which is above the maximum permissible exposure (MPE) does not inadvertently escape the treatment area to injure unsuspecting persons).

Additionally, during laser usage it is necessary to:

- Be under the direct control of authorized laser personnel trained in laser safety and laser operation;
- Have only diffusely reflecting materials in or near the beam path (i.e. reflective items such as mirrors or jewelry must be removed or covered);
- Provide personnel and patients with appropriate eye protection;
- Have high background illumination;
- Have all accessible windows, doorways, etc. covered;
- Have room walls that are rough in texture, dark and non-reflecting;
- Have limited amounts of flammable compounds or substances;
- Provide adequate ventilation, respirators, firefighting equipment, etc. to control all laser hazards;

According to Class 4 Laser Product regulations, the ENDOTEQ Laser is equipped with:

- A secure storage and a power-off switch for the laser when not in use to prevent unauthorized operation;
- A large visible Red "Stop" button for deactivating the laser in the event of an emergency;
- Audible and visible activation warning system to indicate that the laser is in ready mode and operation;
- A master switch to control patient exposure;
- A door interlock switch, which is an interlock plug switch that can be connected to the door. When the door is opened, the device will immediately switch off; however, we also recommend to manually lock the door from the inside to prevent unintentional entry;

Even though the safety information included in this manual is detailed, it is not intend to replace industry standards and guidelines for laser safety. We would recommend reviewing the standard IEC 60825-1:2014+A11:2021 and IEC 60601-2-22:2019 for further details.

Our local dealer's technical support department will gladly answer any questions you may have and provide you with appropriate training as well as assist with obtaining additional industry standards and guidelines for laser safety.

b. Eyewear Protection

A T T E N T I O N!
Never look directly into the laser beam or to the light reflected by the laser beam. Never look directly into the exit of the fiber optics or into the exit of a laser optics (e.g. hand piece) as this will cause serious eye injury.

⇒ Eyewear (safety goggles) is the most important piece of protective equipment needed within the laser treatment controlled area.

Protective eyewear for both the operator and the patient needs to be able to stop laser radiation coming from any direction from striking the eye.

This means the eyewear must have side and top guards and fit snugly around the nose. Laser protective eyewear for the laser operator must also allow visible light to pass through it so that the wearer can see adequately to perform their tasks safely, while at the same time preventing the wavelength emitted by the laser from passing through.

⇒ The most important factor for protective eyewear is that it must protect against the specific wavelength emitted by the laser.
Therefore, use only goggles labeled with the same wavelength as the model of ETQ Laser you are about to use (810 nm or 980 nm or 1064 nm or 1470nm or 1940nm).

NOTE: Eyewear will NOT provide protection for lasers that emit radiation of a different wavelength from that which the eyewear is designed for. Simple safety goggles or glasses must NEVER be used for laser eye protection!

⇒ The second important factor is the optical density number, which defines how much of the laser radiation is reduced when it passes through the protective eyewear.
For ENDOTEQ models 810, 980, and 1064, use laser safety goggles with protection class DLB5 ILB7. For ETQ1940 use laser safety goggles with protection class DILB2.
For ETQ model 1470, use laser safety goggles with protection class DILB2 if using only wide emission fibers (fibers with NA of 0.37 or above such as radial fibers, fistula probe, hemorrhoid probe, or any bare fiber with NA of 0.37 or greater), otherwise use DLB3 ILB2. .

Your ETQ Laser package is supplied with minimum one unit of laser safety goggles, according to the wavelength model, intended to be worn directly (i.e. not to be worn on top of glasses).

Protective goggles that meet all safety requirements can be obtained through your local ENDOTEQ authorized dealer, including special models that can be worn on top of glasses.

- Keep laser eyewear in an opaque case when it is not in use, as the coating can be degraded by exposure to daylight over time.
- Follow the laser eyewear manufacturer's recommendations on shelf life, storage conditions and appropriate cleaning methods.
- Inspect protective eyewear regularly. In case you suspect any physical damage (cracks, dents, scratches, discoloration, layers peeling), DO NOT use; please contact your local ENDOTEQ authorized dealer for replacement.

Should you require any additional information on protective goggles, please contact your local ENDOTEQ's authorized dealer.

c. Electrical Protection

The ENDOTEQ Laser works with a low internal voltage of 19 V. Do not disassemble the unit. Never remove any housing parts as this can cause a serious risk hazard as it may cause irreparable harm to the laser diodes.

Any service to the unit or its accessories should only be carried out by authorized personnel from ENDOTEQ.

The room in which the laser is operated should be kept dry. If the room requires cleaning with water, please make sure the floor has dried out before using the laser.

A T T E N T I O N!
Never work with the device if you notice any visible damage to the console or to the accessories.

A T T E N T I O N!
Never work with the device if you notice any visible damage to outlet plug, or notice the wires have become exposed as a consequence of improper handling.

The ENDOTEQ Laser should undergo a safety inspection every 24 months, carried out by qualified personnel.

d. Explosion and Fire Hazard

A T T E N T I O N!
Never work with the laser in the vicinity of easily flammable anesthetics, easily flammable solutions or material. In particular, please remove combustible plastic or paper elements from and around the working area of the laser. Focusing the red or IR laser beam on flammable materials may ignite these and cause a fire or explosion!
Risk of fire and/or explosion when LASER OUTPUT is used in the presence of flammable materials, solutions, or gases (including endogenous); or in an oxygen enriched environment. High temperatures produced in NORMAL USE of the laser equipment may ignite some materials (e.g.,

cotton wool when saturated with oxygen), and solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.

When working with the laser, make sure the laser is switched from READY mode to STAND-BY mode, in case the treatment has to be interrupted. This will assure that no laser radiation will be emitted due to unintentional stepping on the pedal switch.

e. Protection against Undesired Radiation

Never grip the hand piece or fiber tip with their exit pointing or touching your exposed skin as this may cause burns to the skin; do not focus the laser beam on easily flammable materials as this may cause a fire.
The pedal switch controlling the laser pulse should never be outside the range of the operator holding the laser hand piece/fiber. It is prohibited that any person other than the operator controls the pedal switch.

In operating rooms in which several pedal switches are available, it is particularly important to make sure that the laser pedal switch is within the operator vicinity and recommended to be clearly marked as the ENDOTEQ Laser pedal switch.

A T T E N T I O N !
During a laser treatment, the system is in "Ready" mode. Should the operator need to pause the treatment for any reason; the laser must be switched back to "Stand-by" mode.
The device must be turned off when left without supervision, to prevent usage by unauthorized individuals.

A T T E N T I O N !
Installing and/or operating the ETQ Laser in any other way differing from the one described herein may cause hazardous exposure to radiation. Do not irradiate any surface or material other than the intended clinical use.

f. Protection against Smoke/Plume

Use of laser on soft tissue may result in smoke, fume, or plume which may contain viral and tissue particles. When using the laser, always use laser masks and make use of proper smoke/plume evacuation devices in conjunction with laser use.

A T T E N T I O N !
Caution - Laser fume and/or plume may contain viable tissue particulates. Always use proper smoke evacuation and laser masks when using on tissue.

g. NOHD Safety Distance

For all ENDOTEQ models:

- Diameter beam bundle: 240µm
- Beam Divergence in rad: 0.227

Power P: 28W
Wavelength λ: 810nm
Maximum Permissible Exposure MPE: 945mJ/m²
NOHD: 5.3m

Power P: 28W
Wavelength λ: 980nm
Maximum Permissible Exposure MPE: 2.07J/m²
NOHD: 3.5m

Power P: 24W
Wavelength λ: 1064nm
Maximum Permissible Exposure MPE: 2.85J/m²
NOHD: 3.3m

Power P: 12W
Wavelength λ: 1470nm
Maximum Permissible Exposure MPE: 1.77kJ/m²
NOHD: 13.8cm

Power P: 6W
Wavelength λ: 1940nm
Maximum Permissible Exposure MPE: 1.77kJ/m²
NOHD: 9.8cm

However, this hazard distance is irrelevant as the access to the laser radiation is blocked by the marked operation room for the laser device.
(See also "Room Requirements" Section 4.b and "Eyewear Protection" Section 5.b herein).

h. CE Regulations

The ETQ Laser system was accredited by ITC in accordance with the European directive 93/42 for medical equipment. Therefore the device is labeled with the CE mark CE 0483.
The device was tested for electrical compliance as well as for mechanical safety. All parts used by ENDOTEQ for the ENDOTEQ Laser comply with CE regulations.
Any additional equipment that needs to be attached to the device must require the official approval of the local inspection authority. No modifications for the device are allowed as these may have a serious risk potential and will void the regulatory approval as well as the warranty.

i. External Interlock Plug

At the rear of the console, a removable plug is inserted through a circular socket (see photo below). The external Interlock Plug is marked with a **PINK** marking.
The plug enables main power to the console internal circuitry. Should this plug be pulled out, the console will instantly enter an error mode.
The plug is intended to be used as an additional safety switch by connecting it to the door of the treatment room. Should the door be unexpectedly opened, laser radiation will immediately stop.
Please be advised that the laser can only operate when the plug is fully inserted into the socket.

Image 1 – Interlock Socket

j. Console Protective Housing

The ENDOTEQ Laser has a protection housing optically sealed to prevent laser radiation leakages, and is electrically isolated. The housing should never be opened or modified. Non-authorized personnel should never attempt to carry out any type of service to the console. Console parts should only be removed and replaced by trained ENDOTEQ service technicians.

k. Safety Switch

The ENDOTEQ Laser has an internal safety shutter. This safety switch enables the release of laser radiation and will open when pressing the foot pedal only when the laser is in READY mode. The aiming beam becomes active only when the laser is switched to READY mode. The aiming beam is a low power red laser, similar to laser pointers.

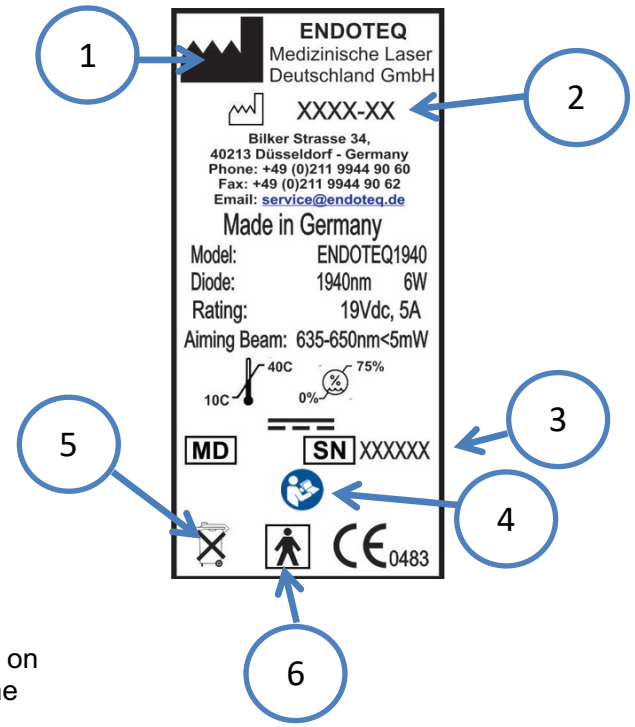
Please note - The safety switch will become enabled only after the laser has successfully finished all internal testing during power up.

l. Manual Reset

When an error occurs (e.g. power instable etc.), the device changes into the STANDBY mode. In order for the device to reactivate itself, simply turn off the power to the ETQ Laser and then turn it on again. If the device does not start again, the error can only be resolved by qualified service personnel. Please contact your local ENDOTEQ's authorized dealer

m. Stickers, Labels and Markings

The ETQ Laser has various warning labels in accordance with the European and international directives, intended to prevent any laser users to become exposed to laser radiation as a result of improper use. You can identify the arrangement of these labels with the following drawings:



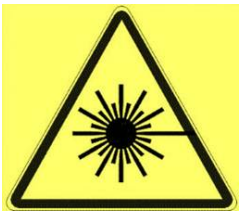
IDENTIFICATION PLATE
According to model: 810, 980, 1064, 1470, 1940 nm (located on the bottom of the unit below the back side)

① Manufacturer
② Date of manufacture
③ Serial Nr. And Part Number
④ See Manual
⑤ No disposal in domestic waste
⑥ Applied Part: Type BF

WARNING LABELS

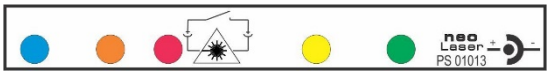
Warning Label Emergency Button

Warning Label fiber output (laser aperture)



Warning Label
Laser Radiation

Socket Label



Warning Label
Laser Radiation

n. Operating Conditions

The ENDOTEQ Laser is not suitable for use with combustible gas mixtures.

- The ENDOTEQ Laser has not been tested for operation in altitudes exceeding 2,000m above sea level (atmospheric pressure of 760hPa – 1060hPa).
- To ensure steady operation in continuous laser mode, device internal cooling must be allowed to operate without any obstruction and in following ambient conditions:
    - Ambient temperature: 10˚C to 40˚C
    - Air humidity: < 75%

o. Electromagnetic Compatibility

The ENDOTEQ Laser complies with the EMC requirements according to IEC 60601-1-2:2014. Guidelines and manufacturer's declaration are described in Section 12.

6. User Information and System Introduction

a. Dispatching and Unpacking the Device

Case unpacking and installing the device is done by ENDOTEQ or its authorized dealer:
Enclosed documents, included in the shipment with the ETQ laser system, need to be filled out and sent back to ENDOTEQ with the support of your local ENDOTEQ dealer.

In the event where the device is transported to the user via a courier delivery services, the consignee should take special care that the parcel was delivered in a proper and undamaged condition.

Any visible damage to the outer packaging shall immediately be reported to the transporter and your local ENDOTEQ authorized dealer. In this case, warranty claims shall only be addressed to the transporter.

Before initial start-up, please read the user manual carefully and fill out the accompanying documents correctly.

A T T E N T I O N !
Do not attempt to perform any type of service or maintenance work to the device. Any calibrations or adjustments that require opening the protective housing, should only be carried out by a service technician trained by ENDOTEQ. This includes also any type of optics cleaning within the laser system.

b. Technical Introduction Training

Upon installation, a staff member from ENDOTEQ or the local authorized dealer will provide introductory training for the ENDOTEQ laser system. The introductory training will cover the device technical abilities as well as overall safety associated with the installation and use of lasers in general and the ENDOTEQ laser in particular.

All individuals working in the vicinity of the laser should attend this introductory training. One individual with the training and experience to knowledgeably administer a laser safety program should be chosen as the person responsible for monitoring and overseeing the control of laser safety.

c. Laser Safety Training

The ENDOTEQ diode laser is designed for medical applications. It may only be used by a physician who received training by an authorized personal or under such physician supervision.

Training for the accompanying personnel is offered in addition to the introductory training, and is given by the local ENDOTEQ authorized dealer service person when installing the device. In this

training, special attention is given for safety in general like the laser protective goggles. It may also provide clinical information as well as references to the indication but DOES NOT represent a clinical training, only a training on safety and technical use of the laser.

In addition to the trainings offered by ENDOTEQ, ENDOTEQ recommends you attend seminars offered by the laser industry. These seminars are designed for personnel who operate the laser, but also for people not working directly with the laser. Seminars such as “laser safety” or “laser application” include the basic principles of the laser and of laser treatment. Moreover, these seminars also cover precautionary measures when working with lasers (e.g. caution in case of combustible materials, the importance of laser protective goggles, etc.).

ENDOTEQ holds a list of recommended courses as well as laser safety courses available, and can be made available directly or through our local dealer at any time.

ETQ Laser operation is limited by a password. We recommend you verify that only personnel that went through the proper training and authorized to use the laser, will be given the password. The password should not be handed to other physicians or personnel unless they went through the recommended training for the device.

d. Medical Introduction Training

The scope of the device medical introduction training is to provide basic information on selected medical applications for the user’s specific intended use. This should be considered as introductory information and does not replace the need of the user to be thoroughly trained and experienced in his specific indications for use.

Where required, it is possible to attend a comprehensive training course held by an experienced physician. Upon request, please contact your local ENDOTEQ authorized dealer, or contact us directly.

e. Medical Device Parts and Accessories

A T T E N T I O N !
Only the parts and accessories as specified by ENDOTEQ in table below can be used with the ETQ Laser. Any use of other non-approved accessories may pose a serious risk hazard to the operator and/or patient; As well as not provide the expected result.

A T T E N T I O N !
Use only fibers supplied by your authorized ENDOTEQ dealer for use with the ETQ system! Verify, using the fiber manufacturer label and IFU that the fiber is compatible with NC type connector and matching the specifications of chapter 8.
Never connect any other type of fiber to the laser system, as this may result in failure of the laser system and potentially hazardous conditions.

The basic ENDOTEQ Laser system includes the following parts (which can be ordered separately at any time):

Part Name	Description	Part Number
Foot Switch	Foot Switch with hinge and cable	FS1
Power Supply	Medical grade power supply with cable	PS01013 + KB01060
Port Protection	Dust cover plug for the fiber port	DCFP1
Carrying Case	Protective case for storage and transportation of the laser and accessories	SC1
Interlock Plug	Interlock plug for interlock socket	KB03005
Protective Goggles	Protective eyewear against laser light 810-1064nm Protective eyewear against laser light 1470nm, 1940nm	4X7L0000669 5X7L0000668

* Protective Goggles are wavelength dependent. There are several models available including types that fit over glasses. Please provide your ETQ Laser model when ordering. If you purchase goggles elsewhere ensure that they meet the safety requirements as detailed in page 15.

Power Supply
The unit utilizes an external power supply – use only the power supply provided by ENDOTEQ or its authorized distributor, PS01013 (model PMP 90F-13-2-B18, 90W Max, 19V, 4.74A) The power supply should be connected only with a cable rated for 10Amps or more. Connect the power supply to the unit by plugging in the power plug into the socket marked on the laser with power plug sign (see page 29 for details). Make sure the power supply is placed in a secure location during treatment such that it cannot be pulled or disconnected from the main unit. The power supply can be wiped clean between procedures using the same methodology described in page 46. Make sure to disconnect the power supply from power before wiping or cleaning.

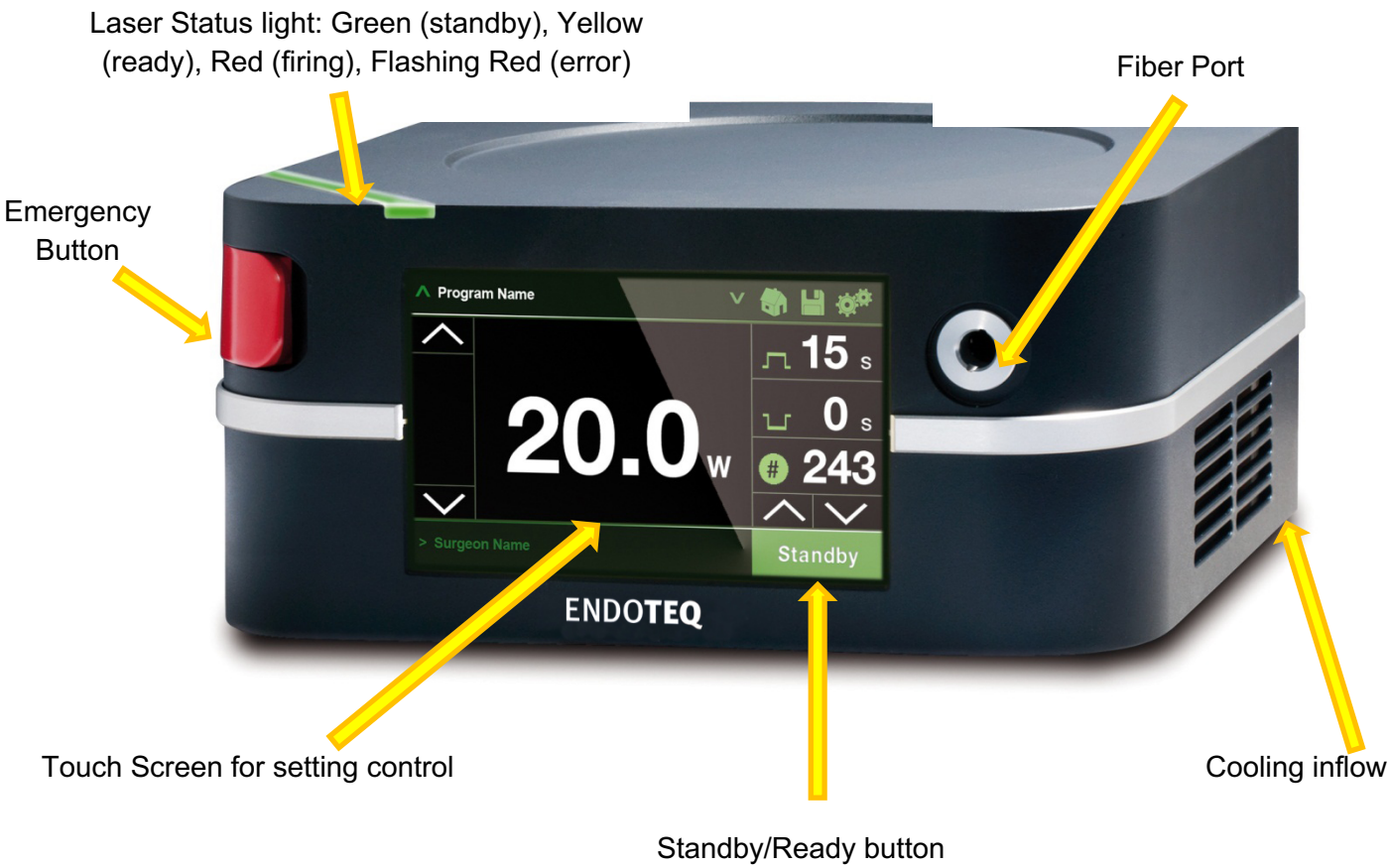
Foot Pedal
Use only the foot pedal supplied by ENDOTEQ or its authorized distributor (model MKF 2S-MED SK12, PN BG11050). The foot pedal is connected to the laser by placing in the foot pedal connector in the socket marked with the blue dot (see page 29 for further details). The foot pedal cover should be pressed gently once to open its cover and can then be activated by pressing the internal pedal. Make sure the laser is in Standby Mode when opening the foot pedal cover. In addition, make sure all personel are wearing goggles when opening the cover. At the end of the procedure, the foot pedal cover should be placed in the closed position for storage. The cable can be disconnected from the laser by gently pulling of the connector. The pedal can be cleaned between procedure using the same methodology described in page 46.

For further information about accessories please contact your local distributor

Warning – Use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the laser as replacement parts for internal components, may result in increased emissions or decreased immunity of the laser. In addition, do not try to rotate the foot pedal switch or diassemble it. If the foot pedal switch is not fully intact, stop the procedure and contact service.

Housing Front

The front panel of the device consists of the following controls and keys:



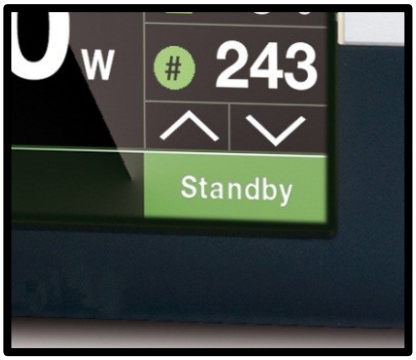
i. ETQ Fiber Port

The ENDOTEQ Laser has a fiber port at the head of the device, intended to incorporate the patented click plug for a wide range of hand pieces and applicators. To protect the fiber port ENDOTEQ inserted the protective cap.

The silver port allows connection of a full range of fiber accessories, from 270 microns and up, as the mating element is part of the fiber.

A T T E N T I O N !
Fibers are not delivered with the laser and should be purchased separately. Use only fibers compatible with NC type connectors.

ii. Standby/Ready Key



The Ready Key is part of the touch screen control buttons on the bottom right hand corner of the screen (see image). As you turn on the laser, the laser will enter Standby mode, and the button will appear as green colored. The color stripe on top of the laser will also light up in green color to indicate status of Standby. To enter Ready mode, press the Standby button once on the screen. The laser will change modes to Ready mode. Both the onscreen button and the light stripe on top of the unit will change color to Yellow to indicate the laser is in Ready mode. Pressing the foot pedal now will fire the laser. If pressed, both the stripe on top of the laser and the on screen button will change color to red to indicate the laser is firing.

When in Ready mode, press the onscreen button again to move the laser back to Standby mode.

Keep in mind, you will not be able to switch from Standby to Ready mode without a fiber plugged into the laser. If you attempt to do so the screen will indicate an error with a fiber icon.

iii. Emergency Stop

The Emergency Stop button is on the top left side of the device. If the Emergency Stop button is pressed while starting the device, the screen will remain black, no LED will highlight and the device will not be able to start as its power supply voltage is cut off.
Solution: Pull up E-STOP, and the device can be started. Make sure fiber is disconnected before restarting the device.

Pressing the E-STOP button while working with the ETQ Laser, will instantly cut off the laser output.
Solution: Pull up E-STOP, and restart the device. Make sure fiber is disconnected before restarting the device.

CAUTION – DO NOT use the Emergency Switch as an on/off button! Turning the machine on and off should only be done through the on/off switch on the back of the unit. Repetitive force on the Emergency Switch may eventually damage it. When transporting the laser, make sure the switch is in the OFF position (inside the machine).

iv. Rear Panel/Sockets

It is prohibited to use the device's sockets for other usages than those detailed here.

Socket	Description	Note	Color Code
Power	Medical Grade Power Supply	Use only ENDOTEQ supplied supply	NA
Foot Pedal	Connector for ENDOTEQ foot pedal	Use only ENDOTEQ supplied foot pedal	Blue
Door Interlock	Enables connection of laser to door interlock for safety	Interlock must be connected for laser to turn on	Pink
Closed	Not active	Not active	Yellow
Aux 1	Not active	Not active	Orange
Aux 2	Not active	Not active	Green

On/Off Button

7. Operation

A T T E N T I O N !
The ETQ Laser may only be operated by personnel that underwent relevant training for the device and that possess the necessary knowledge for the laser's applications.

This part of the manual describes mainly the technical aspect of the device functionality without providing extensive details on its medical use. A more elaborated medical use is detailed at ENDOTEQ's application manuals, which can be obtained through your local authorized distributer.

Device settings as well as various parameters adjustments should only be carried out in compliance with the operating instructions manuals. Any modifications or settings not indicated in the operation manuals may cause malfunctions.

a. Preparation

The ETQ unit requires use of an external power supply. A medical grade power supply unit is included with the basic system. The power supply should be connected to the rear panel at the marked socket. The power supply unit input voltage ranges between 100V and 240V. Due to safety your ETQ should only be operated with the certified power supply distributed by ENDOTEQ. Use of a different power supply may harm the laser unit and void warranty.

Please follow the steps below when preparing the device to operation, in order to avoid unnecessary troubleshooting and possible malfunctions.

- The power supply should be connected to the wall electricity and to the input socket on the back panel of the laser
- The power supply should only be connected when the device is switched off.
- Connect the interlock plug to the back of the unit
- Ensure the fiber port is empty
- Ensure that the fibers and hand pieces to be used are readily available and free of any damage
- Verify there is a sufficient number of protective goggles ready
- Verify proper warning signs have been placed in entrances to the room
- Verify the foot switch has been plugged in properly

A T T E N T I O N !
A warning lamp/s outside the treatment room door/s must be switched on as soon as the laser starts to operate; the doors have to be marked as laser rooms, visible from outside (with the warning signs).

A T T E N T I O N !
The red aiming beam shares the same optical delivery system with the infrared laser beam, thus it provides a very good indication for checking the intactness of the laser optical delivery system.

If the target spot does not appear at the distal end of the laser delivery system, or if it has low intensity, or appears to be diffused, this may indicate a damaged or not properly installed delivery system of the unit, do not use the system and contact service personnel.

i. Installation Site

We recommend placing the ENDOTEQ unit on a solid, secure and even surface. Please verify that the surface is secure and cannot tip over.

b. Starting the Device

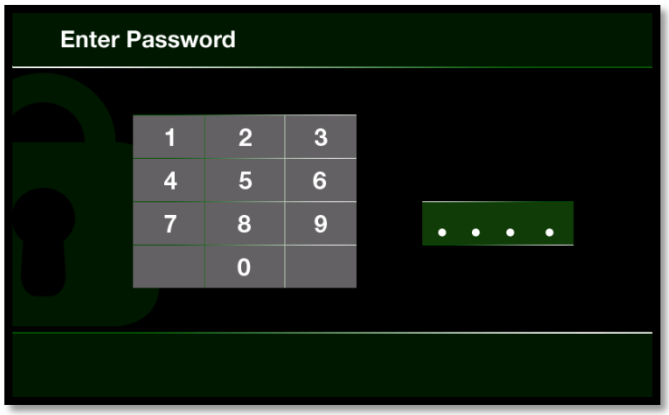
Switch on the device by flipping the on/off button on the rear panel of the unit. The green status on the diagonal stripe of the unit will light up and flash.

The System Check screen will appear after roughly 30 seconds. The green status on the diagonal stripe will change to solid green. The unit will now perform an internal system check and boot up. The green bar will indicate progress of this process until completion.

A T T E N T I O N !
The unit will NOT turn on if a fiber is connected to the device. This is for safety reasons as the laser will activate and fire internally during system check. It is required that no fiber is connected to the system at this time as to avoid accidental firing at the fiber output. Please make sure to disconnect any fiber when turning the unit on.

Once System Setup is complete, the system will display the Enter Password screen. This screen allows only authorized users, having the correct password, to enter the activation screens and use the laser. The initial factory set password is 0000.

A T T E N T I O N !
If the screen is deformed or blank, do not use the System. Please make sure that the password is changed **immediately** once unit is first activated, and that it is protected and provided only to authorized personnel, and changed periodically to ensure safe operation of the unit. See Chapter 7.b.ii.1 on how to change the password.



Enter Password Screen

i. Fiber Coupler / Port

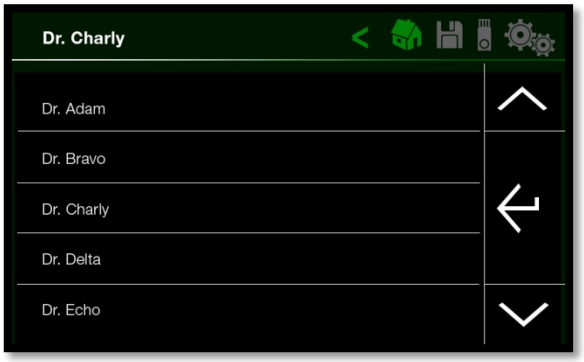
The fiber coupler has a control mechanism which prevents the device from switching into the READY mode as long as no fiber has been connected.

Please do not insert any objects or liquids into this port as this might damage the ceramic disk, used for centering the fiber.

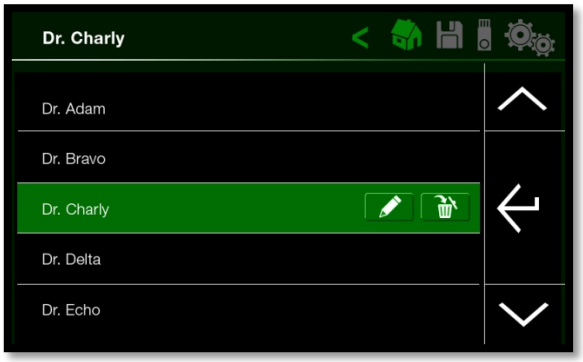
Use and connect only fibers supplied by your authorized dealer and meeting the specification per page 44 of this manual. When connecting a fiber to the system make sure the fiber is fully inserted until it locks into place.

ii. Select a Surgeon / Add a new Surgeon

Choose your name. Select the desired name by pressing the selected line and pressing enter. When activating a line, it will turn green (see image below) and two icons will appear – the edit icon and the trash icon. By pressing the edit icon you can enter the text edit page and change the name of the surgeon.



Select Surgeon Page



Select Surgeon Page (Surgeon Activated)

The edit screen will enable you to enter text in lower case or upper case by pressing the Up arrow. Depressing the Up arrow will revert back to lower case. By pressing the trash icon on the Select Surgeon page you can erase the selected surgeon from the list. If you choose to erase the surgeon a confirmation screen will appear (see below) to verify the deletion is truly intentional. Erasing a surgeon will, by definition, also erase all of the applications associated with this surgeon.

Edit Surgeon/Application Name Page

Delete Surgeon Confirmation Page

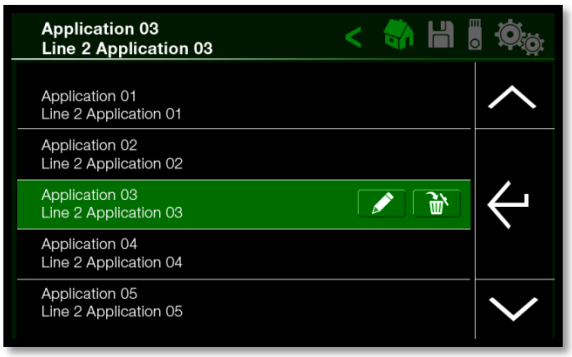
You can add a new surgeon by pressing the first empty line below the last surgeon on the Surgeon Select Page.

iii. Select an Application / Add a New Application

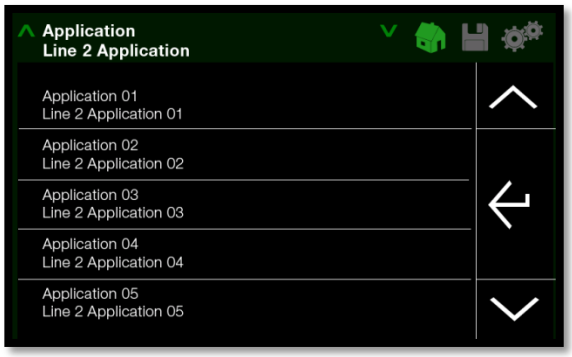
Once a Surgeon was selected, you can proceed to selecting an application. You will be presented with applications relating to the selected surgeon.

Choose the application name. Select the desired application name by pressing the selected line and pressing the enter icon. When activating a line, it will turn green and two icons will appear – the edit icon and the trash icon. By pressing the edit icon you can enter text and change the name of the application (name may include up to two lines of text). By pressing the trash icon you can erase this program from the list.

You can add a new program by pressing the first empty line below the last program.

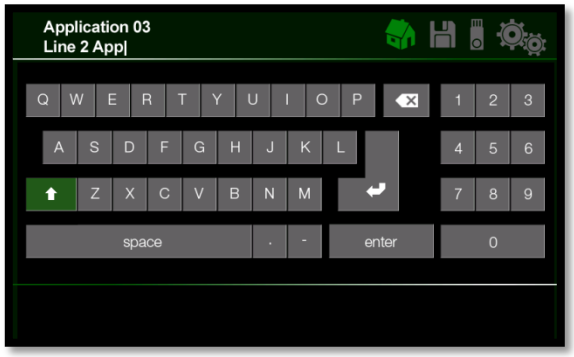


Select Application Page

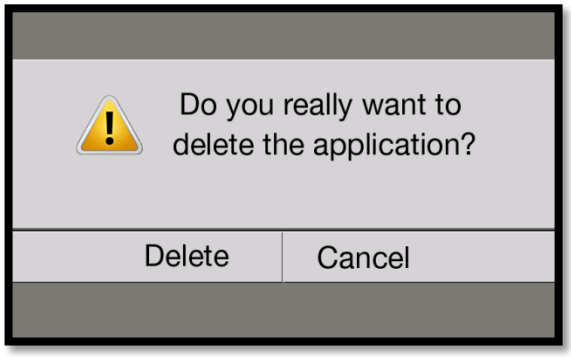


Select Application Page

If you hit the edit icon, you will enter the Edit Application Name Page as seen below. You can enter text in either lower or upper case. If you hit the trash icon, a new page will appear verifying deletion of the application is intentional as seen below.



Edit Name Page



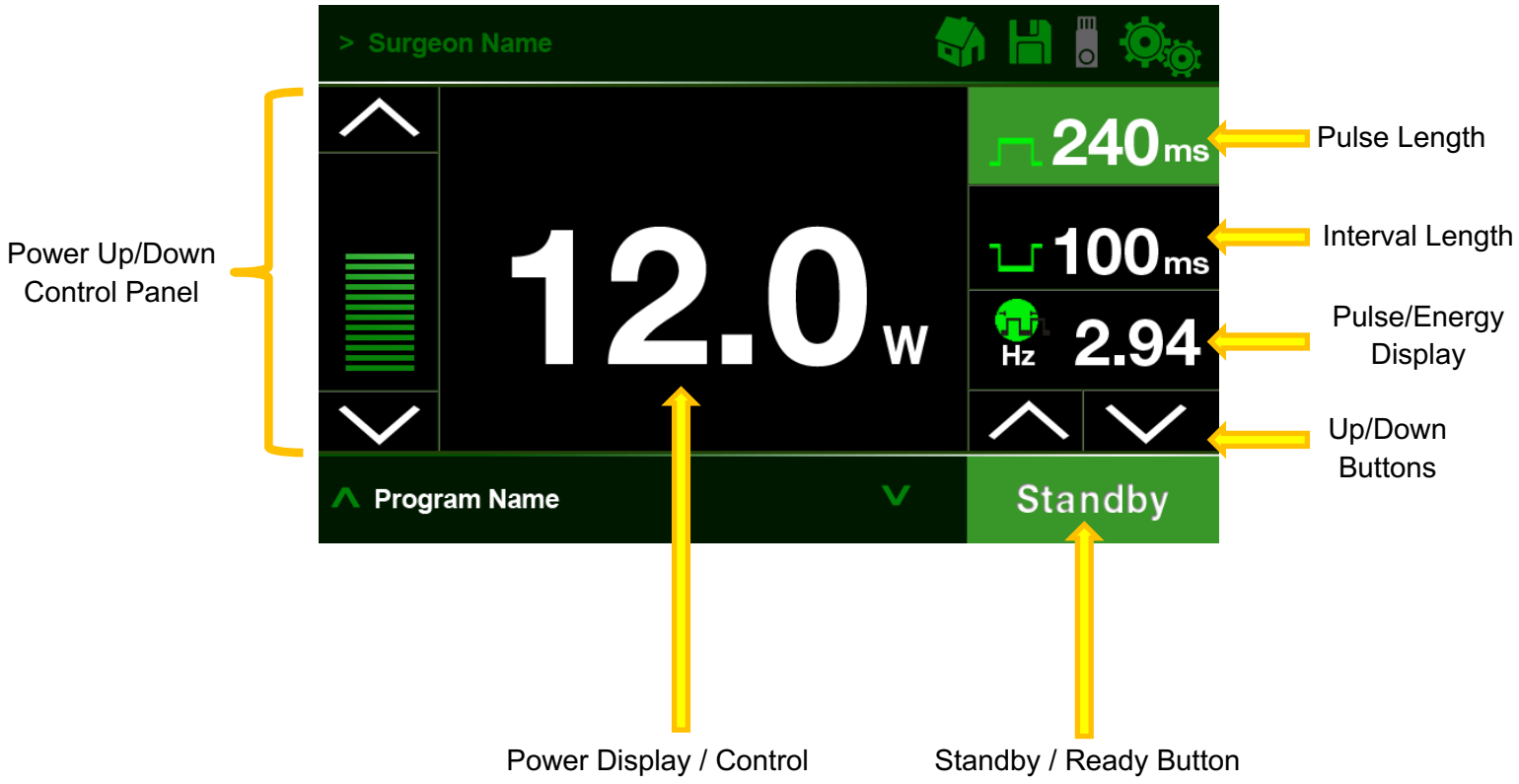
Delete Application Confirmation Page

Once you select an application, press the enter icon to proceed to the Main Menu page.

c. Working with Selected Applications

Once you have selected an application, you will enter the Main Menu which shall display the main laser parameters of the selected application and will also allow you to edit and change them as needed, as well as to store the new settings in the application if changed.

i. Display / Main Menu



The icons and display parameters of the Main Menu are provided in the image above. The power setting of the laser is provided in the center of the screen. This number corresponds to the peak power output from the fiber distal end to the tissue, and given in fractions of Watts. On the right hand side you may read (1) the Pulse Interval which dictates the length of each pulse in the pulse train, or CW for Continuous Wave transmission; (2) the Interval Length, which dictates the Interval time until the following pulse will be transmitted, or SP in case of a Single Pulse transmission; (3) the Energy Display which can be toggled to show 4 different parameters of dosage as described below.

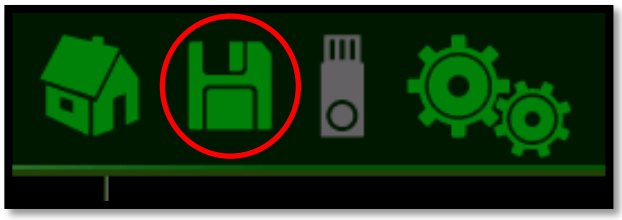
On the top line you may see the current Surgeon selected, as well as Home, Save and Settings icons.
On the bottom line you may see the Program selected, and the Laser Status indicator on the bottom right hand corner showing whether the laser is in Standby or in Ready mode.

1. Changing Parameters

You may change the Peak Power setting as well as the Pulse Length and Interval Length on the main menu by (1) clicking on the parameter to activate its control and (2) clinking on the corresponding arrows to change it. When clicking the parameter it will be highlighted in Green to indicate it may be now changed.

2. Saving Parameters

After changing parameters, the changes may be stored under the program name by clicking the Save icon on the top right hand side.



You may notice that once saved the Save icon will become inactive until a change is made. Once a parameter is changed, the Save icon will again activate to allow saving of the new parameters.

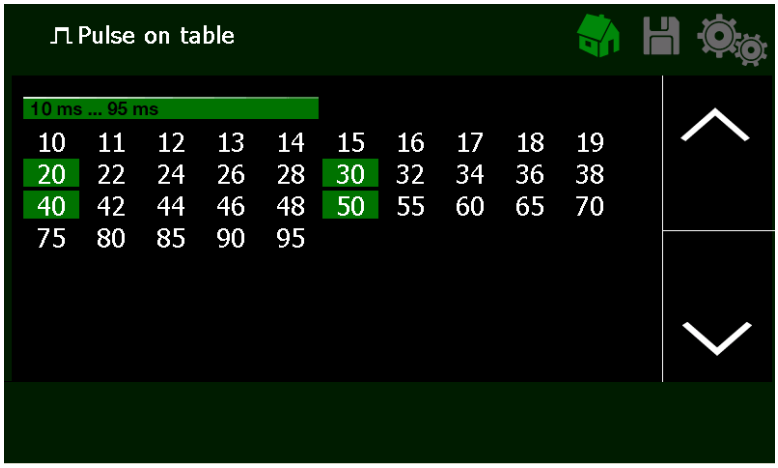
3. Power

The main Peak Power may be changed by clicking on it to activate its control and then by using the arrows and bars on the left hand side to change the setting. The power control is activated when marked in green. Once activated you may change the power setting by either (1) pressing the arrow keys up or down to increase or decrease the power in 0.1W steps or (2) pressing the bar indicator of power on the left directly for immediate and larger changes in power.

4. Pulse Length Adjustment

The Pulse Length may be changed by clicking on it to activate its control and then by using the arrows on the bottom right hand side to change the setting. The Pulse Length control is activated when marked in green. Once activated you may change the setting by pressing the arrow keys up or down to increase or decrease the Pulse Length between the activated settings in a cyclical manner.

The activated settings can be determined by pressing down on the Pulse Length area for more than 2 seconds. The Pulse Length Activation screen will show up as described below.

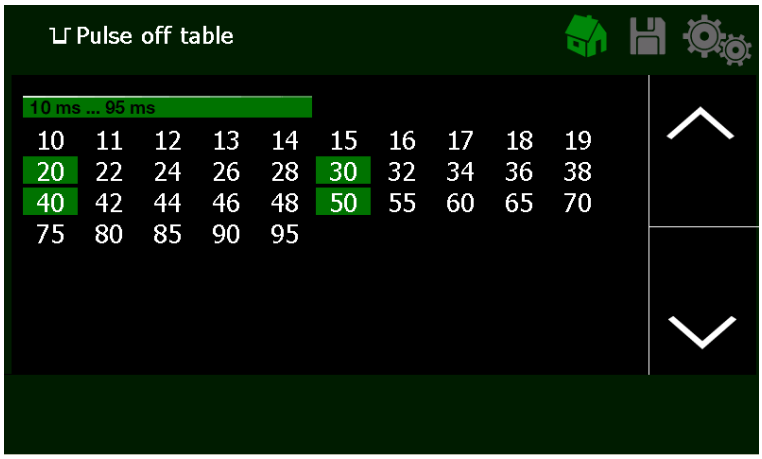


Pulse Length Activation Screen

Activated fields are highlighted in green. Pulse Length activated values may be in micro-seconds, in milli-seconds or in seconds. Movement between the various durations can be achieved by use of the up/down arrows on the right. Once changes are complete, hit the Home icon to go back to the Main Screen. The new activated fields will now be available on the main screen.

5. Pulse Interval Adjustment

The Interval Length may be changed by clicking on it to activate its control and then by using the arrows on the bottom right hand side to change the setting. The Interval Length control is activated when marked in green. Once activated you may change the setting by pressing the arrow keys up or down to increase or decrease the Interval Length in a cyclical manner.
The activated settings can be determined by pressing down on the Interval Length area for more than 2 seconds. The Interval Length Activation screen will show up as described below.



Interval Length Activation Screen

Activated fields are highlighted in green. Interval Length activated values may be in micro-seconds, in milli-seconds or in seconds. Movement between the various durations can be achieved by use of the up/down arrows on the right. Once changes are complete, hit the Home icon to go back to the Main Screen. The new activated fields will now be available on the main screen.

6. Pulse/Energy Display

The Pulse/Energy display may be toggled to show different views of dosage applied to the patient. The toggling is cyclical and is performed by pressing on the icon on the left side of the Energy Display. The following displays may be obtained:

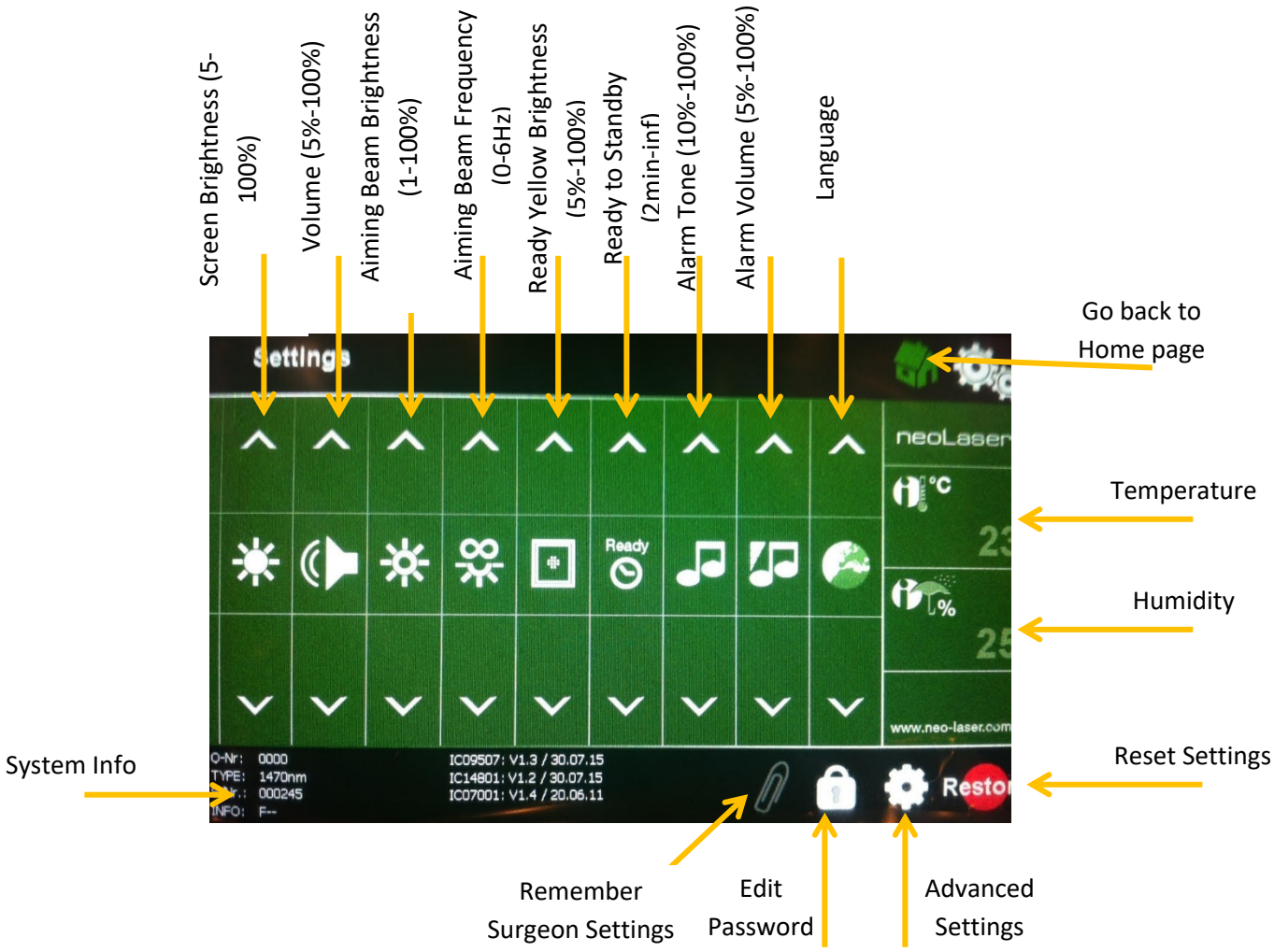
Description	Setting Type	Icon
The rate of pulse transmission in Hz (when not in SP or CW)	Pulse Rate	
The number of pulses transmitted by the laser	Pulse Counter	
The cumulative amount of Energy transmitted by the laser in Joules	Energy Counter	
The Weighted Average Power (W.A.P) transmitted by the laser taking into account both the on and off cycles, in Watts	Average Power	

When using the Pulse Counter setting, the laser will continue to count the number of pulses transmitted to the patient, as long as the laser is in pulsed mode. Pressing the display showing the number of pulses will reset them back to 0.

When using the Energy setting, the laser will continue to accumulate the amount of energy delivered to the patient in Joules. Pressing the display showing the cumulative energy will reset it back to 0.

ii. Settings

The settings screen is accessible from the main menu by pressing the Settings Icon on the top right hand corner of the screen. Once entering the settings screen, all user settings will be easily accessible, each one having its own up/down control button, as can be seen by the image below.



Screen Brightness - Allows altering the brightness of the display screen to match the OR environment. Changes will impact the display immediately

Volume - Enables alteration of overall volume of noise generating functions of the unit (such as feedback sound when pressing an icon).

Aiming Beam Brightness - Allows adjusting the brightness of the red aiming beam from 1% to 100% of the applicable power.

Aiming Beam Frequency - Enables changing the frequency of the aiming beam from 0 Hz (constant) to 6 Hz or infinity. When set to infinity the aiming beam will be on ALL the time including standby mode and ready mode.

Ready Yellow Brightness – Sets the brightness of the yellow LEDs when in Ready mode.

Ready to Standby - Sets the time when idle in Ready mode until the laser will revert automatically back to Standby for safety.

Tone buttons - Enables altering the frequency of the audible alarm of the laser when firing. Please ensure that frequency is appropriate to hear the alarms as necessary

Alarm volume buttons - Enables changing the volume of the sounds emitted by the laser when firing. Please ensure that volume is appropriate to hear the alarms as necessary.

Language - Allows changing the language of the display to match your language of choice. Lanugages supported include English, German, French, Italian and Spanish.

Remember Surgeon Settings icon (paper clip icon) - can be turned on (paper clip dark) and off (paper clip bright). When turned on, the system will remember the last setting used by the surgeon. When turned off, setting will not be stored in memory.

Specific System info relating to versions of software, firmware and hardware are displayed on the bottom left hand corner of the screen. On the right side, the user can read the Temperature of the unit, and the Humidity sensed by the unit. Pressing the Reset button on the bottom right hand corner will reset all settings to the factory set values. The Edit Password button can be pressed to change the password of the laser unit. It is recommended to do so immediately after first use of the system to ensure proper protection of the unit from untrained users.

A T T E N T I O N !
The Advanced Settings button SHOULD NOT be pressed. This button is for use by manufacturer trained personnel only.

Leaving the Settings Page can be done by either pressing the Back button at the top left hand corner, or by pressing the Home icon on the top right hand corner, leading back to the standard Main Menu page.

By pressing the Edit Password icon on the bottom of the screen, you may change the password of the laser unit. Once pressed the password screen will appear and will prompt the user for the old password (0000 if this is the factory set password), and then for the new password, followed by a confirmation of the new password. Passwords are 4 digit numbers.

d. Inserting the Applicator

When the preselected power and pulses comply with the treatment parameters, the applicator can be plugged into the laser aperture.

Gently push the applicator plug into the socket until it firmly "clicks" into place. In case it does not click in correctly, try to twist the plug inside the socket. The groove should be in the “down” position (hour 6) to allow clicking into place in one movement.

If the plug has not properly clicked into place, the device will not change into READY mode, and the ENDOTEQ laser will not work.

Please pay attention to a clearly perceptible “click” when inserting the plug! You may need to twist the plug a bit while its partially inserted in order to be able to fully click it into place.

Once the plug has been locked into place, you can hold the applicator/hand piece in your hand. At this point the infrared radiation can be emitted through the applicator upon activation of the foot pedal. Therefore, please ensure the applicator is aimed away from any person, other than the patient target area, and is not pointed towards flammable materials.

e. Ready/STBY

Once the plug is in place, you may move to READY mode. Switching to READY mode can be performed simply by pressing the STANBY icon on the Main Menu screen.

If the fiber is not plugged in correctly, or not connected at all, a red error screen will appear indicating that a fiber is not plugged in.

Once in READY mode, the icon on the main menu will indicate the laser is in READY mode, and the lighting diagonal stripe on top of the unit will turn Yellow. The laser is now ready for firing and will fire laser energy when the footpedal is pressed. The aiming beam will appear at the fiber tip once in READY mode (if aiming beam frequency is not in infinity mode, otherwise the aiming beam will be active all the time).

If the READY icon will be pressed again, the laser will go back to STANDBY mode, the icon will indicate STANDBY and the diagonal lighting stripe will turn back to Green. The aiming beam will deactivate (if aiming beam frequency is not in infinity mode, otherwise the aiming beam will be active all the time).

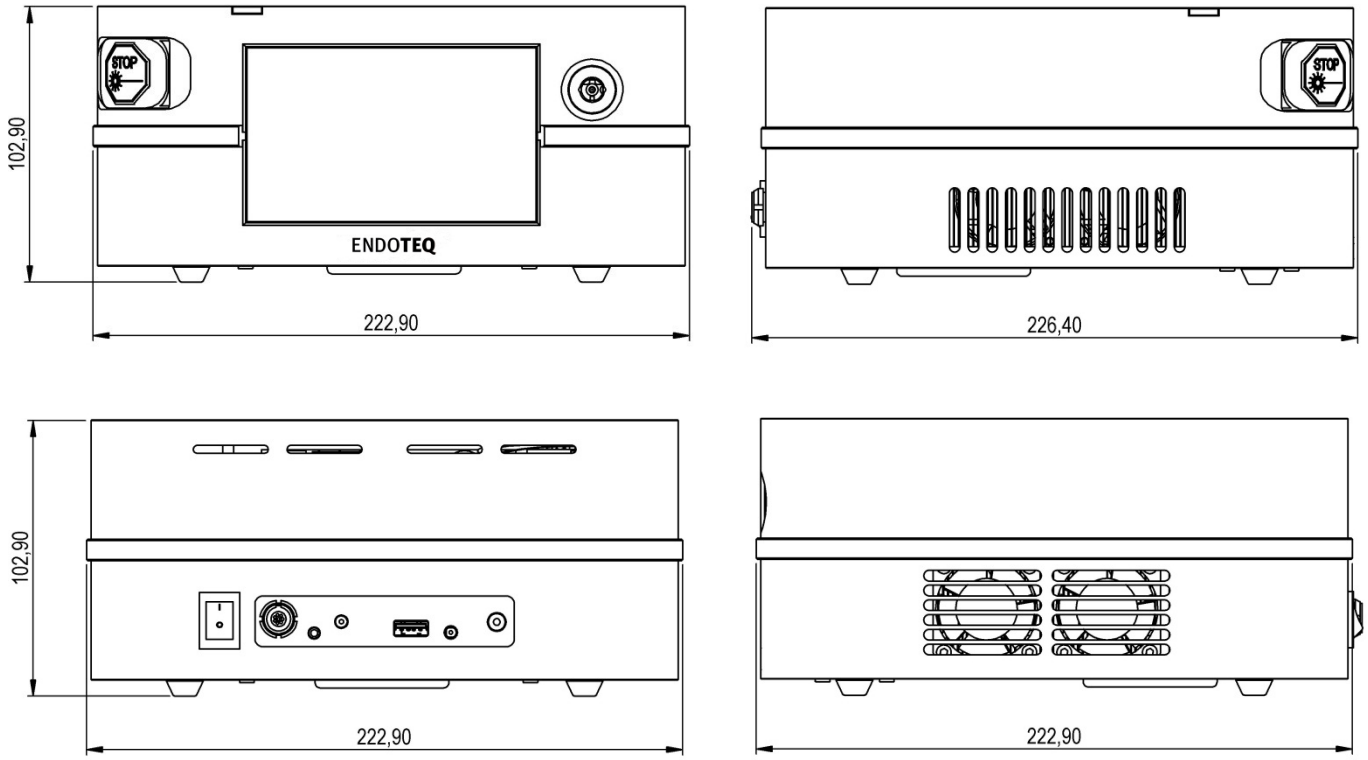
Please remember during pauses in procedure, or when stopping a procedure, to revert immediately back to STANDBY model to ensure safe use of the device.

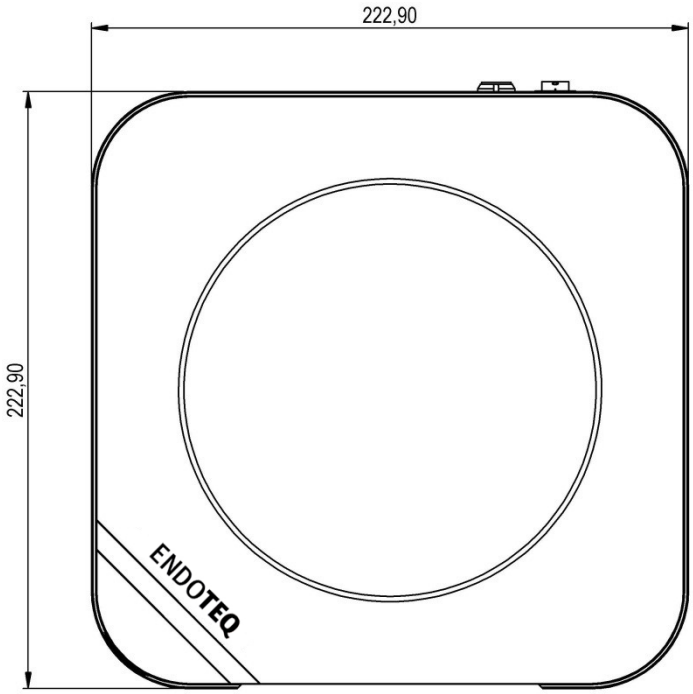
f. Switching Off

The unit may be switched off at any time by pressing the on/off switch on the back of the unit and moving it to the OFF position. Doing so will turn off the machine and will cease laser power immediately.

8. Technical Data

a. Dimensions





b. General

Model ETQ	diode laser
Cooling	internal, forced air convection
Weight	3.5 kg
Dimensions	H 10 cm / W 22 cm / D 22 cm

c. Laser Data

Wavelength	**Power**
810nm ± 20nm	28 Watts max.
980nm ± 10nm	28 Watts max.
1064nm ± 20nm	24Watts max
1470nm ± 20nm	12 Watts max.
1940nm ± 20nm	6 Watts max

Power Accuracy	±20% vs displayed power (per IEC 60601-2-22 requirements)
Display	Digital touch screen display
Pulse lengths	10msec to 30 sec, CW
Shot frequency	Single pulse (SP), 0.02 Hz to 50 Hz
Fiber Spec (810-1470)	Core 270µm to 600µm, compatible with NC type connector, NA ≥0.22
Fiber Spec (1940)	Core 400µm to 600µm, compatible with NC type connector, NA ≥0.22

The user must review the fiber manufacturer label and IFU for clear evidence of compatibility with NC type connector before use. Use only fibers clearly marked with compatibility to NC type connector

The Fiber is considered the applied part type BF

Aiming beam	635-650 nm red <5mW

Operation mode	Continuous wave (CW) or pulsed in variable brightness

d. Power Requirements

External power requirement	100 - 240 V AC, 47/63 Hz, 1.06-0.45A
Power Supply output / Console input	19 V DC, 4.74 A

e. Classification

Laser class 4
(Classification according to IEC 60825-1: 2014)
Aiming beam laser class 2
(Classification according to IEC 60825-1: 2014)
Electrical protection class II
(Classification according to IEC 60601-1)

f. Modifications

Mod#1: SW Revision IC09507 V1.3 30.07.15 and IC14801 V1.2 30.07.15
Mod#3: SW Revision IC09507 V1.4 26.07.16 and IC14801 V1.3 26.07.16
Mod#4: SW Revision IC09507 V1.5 08.02.18 and IC14801 V1.4 08.02.18
Mod#5: SW Revision IC09507 V1.6 23.08.18 and IC14801 V1.5 23.08.18
Mod#6: SW IC14801 V1.6 15.06.23

9. Service

a. Introduction

The device was designed, developed and tested according to research based on state-of-the-art technology. As a rule, similar devices have a service life exceeding 5 years. This product service life is defined to be 5 years in order to guarantee the availability of its spare parts during this period of time. However, to make sure the product is in good working order, the device can display its internals working status through the touch screen display.

In the rare situations when the device does not work, you can use the “Troubleshooting” section included in this manual, to isolate the problem. The solutions given therein will most likely allow you to solve the problem yourself. However if the problem cannot be solved, please contact your local ENDOTEQ’s authorized dealer for technical support.

A T T E N T I O N !
Do not attempt to perform any type of service or maintenance work to the device. Any calibrations or adjustments that require opening of the protective housing should only be carried out by a service technician trained by ENDOTEQ. This includes also any type of optics cleaning within the laser system.

b. Safety Check

A T T E N T I O N !
The device needs to undergo a safety inspection every 24 months carried out by qualified personnel. Inspection shall include verification of calibration per procedure DHF-001-P-038.
Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

In the event where the device is out of order and/or not safe to operate, the operator shall be immediately informed of the hazard originating from this device.

The device must not be operated any longer as soon as it reveals any faults which may pose hazard to the patients, to the operating personnel or third persons, and should be put aside and marked accordingly. In this case, the operator shall immediately inform the responsible regulatory authority and the relevant dealer as well as ENDOTEQ.

A T T E N T I O N !
Please note that the laser device may only be operated by people who can guarantee proper handling due to their training and knowledge as well as due to their practical experience. Responsible people have to be instructed at the place of operation when the device is installed.

c. Care and Maintenance (by the User)

The following care and maintenance can be done by the user.
Before any type of maintenance, always remove the power supply from the ENDOTEQ console, and any fiber applicator that may have been left attached to the unit.

The housing may be cleaned with a damp cloth. Clear water or a neutral cleaning solution (e.g. mild common cleaning solution for household) may be used. Pay attention to never use a wet cloth, because water must not enter the device.

A disinfection of the surface by wiping the surface is possible: Disinfection solutions like DescoseptAF* or a comparable disinfectant (e.g. Mikrozid AF) can be used (*DescoseptAF: Dr. Schumacher GmbH (www.schumacher-online. de)). DescoseptAF solution contains about 42% Ethanol and about 0,05% Didecyldimethylammoniumchlorid.

Also other disinfectants can be used, as if they are not aggressive or contain acids, which affect the material surfaces of medical devices. Following the guidelines of the manufacturers also agents on the basis of quaternary ammonium compounds, as e.g. TPH protect (company Schülke), or Mikrobac® forte from Bode are suitable. According to the manufacturers, these agents can be used on sensitive surfaces (e.g. acrylic glas), or metal (stainless steel (V2A), aluminium, copper, brass) and plastic (PA, PE, PP, PS, PU, PVC, ABS, silicon, rubber, latex, Makrolon®, Plexiglas®, Teflon®).

In case the ETQ is combined with another device, please check the regulations hereof.

Protect the device against water, do not expose to rain or splashes.
Penetrating water may cause a serious malfunction. Do not drop or rinse in any solution or water. Please avoid wet cloths in all cases.

Do not use any chemicals or aggressive agents!
Chemicals or aggressive agents can lead to damage at the surface of the device and damage inside if they penetrate the device.

A T T E N T I O N !
Never look directly into the laser beam emitted from the fiber once the foot switch has been activated, as this will cause a severe eye injury. Always switch off the laser and disconnect it from the power cable when cleaning the console and components.

i. Accessories Cleaning

1. Pedal Switch

Same as cleaning of the laser unit as detailed in 9.C

2. Protective Goggles

Please follow to the letter, the cleaning instructions provided with the protective goggles that were supplied with the system.

As a general rule, never use abrasive chemicals that may harm the goggles coatings, nor use cloth with fiber that can scratch the goggles surface.

If the goggles seem scratched or damaged, please discard and contact your local authorized dealer for a new set.

d. Error Detection

The ETQ was developed and designed as a modular system. In addition, all its components had to undergo rough shake tests as well as temperature testing. In case of an error, you can start by isolating the problem with this manual. In most cases, you should be able to resolve the problem yourself. If the problem persists, please contact your local ENDOTEQ's authorized dealer for technical support.

However, we do hope that the device will work flawlessly for many years.

When an error occurs in the system, the error will be displayed along with a symbol to identify the error (see section 11 - Symbols Description).

Other error causes might be due to:

1. Interlock: The strapping plug should be fully inserted to the device and the door contact switch should be closed.
2. The red EMERGENCY button on the left corner of the device needs to be pulled out

e. System Self Check

In general, a system self-check will initiate automatically after turning on the device, intended to check all important functions. If a failure occurs, you will be informed immediately and the error detail shows up on the screen.

We distinguish between two types of errors:

1. Dynamic errors (interlock errors), i.e. errors that can be easily resolved or resolved after ordering a spare part from ENDOTEQ.

   Such errors may include:
   - Laser EMERGENCY button was pressed down
   - Interlock plug missing, disconnected or defective
   - Pedal switch pressed down when turning on device, or defective

2. Static errors, errors which require contacting ENDOTEQ service department (or the local authorized dealer). For these usually an error message will appear in the display and can assist to identify the problem when calling for service.

f. Troubleshoooting

The following errors cannot be identified by the system self-check and have to be checked by the user:

Problem	Potential Error	Troubleshooting
Laser does not switch on, red fiber error icon displays	Fiber is connected to laser during system start up	Disconnect fiber, reboot laser and connect fiber only when reaching main menu screen.
Screen is black, laser does not switch on	Emergency Stop button is pressed	Verify the Emergency Stop button is pulled out and restart unit.
No aiming beam visible	Laser is in stand-by mode	Aiming beam becomes visible only when the laser is in Ready mode Switch the laser to Ready mode by pressing the Ready icon on the main screen
	Aiming beam brightness set at 0	Increase the parameter for aiming beam brightness
	Fiber is not properly inserted	Twist the fiber connector inside the socket with a light movement inwards to verify proper connection
	Aiming beam diode defective	Contact your ENDOTEQ dealer
No laser beam but aiming beam visible	Pedal switch not plugged in	Check if pedal switch is correctly plugged in and try again
	Pedal switch defective	Contact your ENDOTEQ dealer
	Laser set to very low power	Verify setting of laser power and increase power if too low until interaction observed
No aiming beam and no laser beam	Fiber optics not connected to laser or hand piece not correctly plugged in	Check the correct fitting of the fiber and/or hand piece

For a complete list of error codes, please see Section 11.

g. Proper Disposal

When electronics and other potentially hazardous wastes are improperly disposed of, they can harm public health and the environment. Batteries and e-waste contain toxic heavy metals such as lead, mercury, and cadmium.

Many local governments offer assistance to companies that wish to safely dispose of these products. Contact your local government's recycling or solid waste management department to learn more about the services it provides. This laser must not be disposed in your garbage. ENDOTEQ would be very happy to assist you in the question of how to dispose the device properly.

All the applicators and probes should be disposed according to the valid laws, rules and guidelines of your country. ENDOTEQ will help you to find out which materials have been used to produce your specific probe/applicator.

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CE 0483

10. Customer Service

a. Warranty Information

ENDOTEQ provides a two-year warranty for the ETQ810, ETQ980, ETQ1064, and ETQ1470, and a one-year warranty for the ETQ1940. Within the warranty period, any parts showing a defect will be replaced free of charge. This does not include any optical parts such as hand pieces, fiber optics or built-in elements and purchased parts acquired from a third party. Our warranty covers the repair works and the replacement of defective parts. However, we reserve the right to renew even complete units and to adjust them to the technical progress.
Refer any and all claims or defects to

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Repair works carried out by third parties or modifications of the device void the warranty claim. The use of parts other than those approved together with the device or purchased from other suppliers also voids the warranty for the complete device. Any parts, units or modifications of the device require the explicit written consent of ENDOTEQ.

b. Warranty Consignment, Packaging

A warranty claim for defective parts, malfunction or damage of the housing of the device shall be passed on to ENDOTEQ within 48 hours. Parts returned during the warranty period (upon the explicit request of ENDOTEQ), are subject to the written confirmation by ENDOTEQ. Detailed packaging instructions and information on how to return the device will be provided by ENDOTEQ. The return consignment shall be insured and the costs arising hereof from shall be borne. ENDOTEQ will notify the customer of the return consignment opted for. Any changes as

well as the change of the transporter or the type of dispatch may result in delays in transport and handling. Any other components covered by the warranty claim will be renewed by ENDOTEQ free of charge within the warranty period. We reserve the right to modify the design of the device – if necessary – thus increasing the safety or the functioning of the device. The responsibility for the design as well as any modifications of the device is exclusively incumbent on ENDOTEQ. The customer will be informed about any changes which will be carried out on the premises of ENDOTEQ.

c. Sales and Service Information

For information about sales and service please contact:

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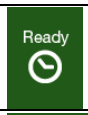
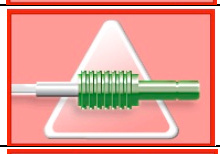
11. Symbols Description

	Display brightness 5-100%		Settings, submenu
	Aiming beam brightness 1-100%		Master Volume
	Aiming beam frequency (0-6Hz and infinity)		Temperature inside
	Brightness of yellow LEDs in Ready (5%-100%)		Ready to Standby Time
	Laser Fire Tone (10-100%)		Air humidity
	Laser Fire Volume (5-100%)		Pick language
	CW in “Pulse On” Field		Save
	Single Pulse in “Pulse Off” Field		Home
	Reset settings back to factory		Remember last setting
	Change Password		

a. Error Messages

Sign	Meaning	Recommended Action
	Door interlock missing	Connect the interlock plug included with the system
	Temperature too low	The environment is too cold for operating the laser
	Operating temperature too high	Please wait until laser cools down to reach a working temperature
	Air humidity too high	The laser should not be operated in this environment
	Fiber missing / plugged incorrectly / plugged during laser startup	Check fiber plug and connection, verify it is not connected during startup
	Ventilation fan blocked	Contact your ENDOTEQ dealer
Error code F00	SW Watchdog error	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F01	Diode current too low	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F02	Diode current too high	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F03	Diode voltage too high (STBY)	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F06	Short in foot pedal (1st switch)	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F07	Short in foot pedal (2nd switch)	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F32	Diode voltage too high	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F38	DtoA converter error	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F47	Checksum error	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F49	Error in SW combination	Reboot system. If appears again Contact your ENDOTEQ dealer
Error code F50	Communications error	Reboot system. If appears again Contact your ENDOTEQ dealer

b. Warning Messages

Sign	Meaning
	Cooling element too hot
	Error… Repeat
	Calibrated parameter is stored
	Please wait

12. Guidelines and Manufacturer's Declaration

WARNING: Use of this laser adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Packing list including all accessories and cables is supplied on page 26. Essential Performance accordingly is defined as radiation of laser energy only when the laser is triggered via its footpedal and having such energy be equal to the setting on the user screen with a tolerance of 20%

Declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group1 Class A	The Laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The Laser is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Laser or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

Declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Laser requires continued operation during power mains interruptions, it is recommended that the Laser be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the Laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	
	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	

Recommended separation distances between portable and mobile RF communications equipment and the Laser				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{12}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

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