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Manual

Medical Diode Laser System
FOX 514 nm

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FOX Laser

The multi-functional green diode laser

with red aiming beam

CONTENT

1 Introduction

We appreciate your decision to purchase the FOX 514 Laser and wishing you a productive and successful usage with this multi-functional laser system.

The FOX Laser generates high-intensity laser beam, which may induce injuries in improper handling. 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 A.R.C. Laser GmbH or your local authorized dealer (see Section 10.3 "Sales and Service - Information").

The FOX 514 laser system has been created especially for ophthalmology. Its special design in combination with the touchscreen and some user buttons allows the physician to safely adjust the laser parameters without having to look at the display – however we recommend to regularly chech the adjustments.

The FOX 514 is a laser of class 4 and a first class medical product of the A.R.C. FOX Laser Family.

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, which holds a valid MDEL (Medical Device Establishment Licence).

1.1 Copyright

This user manual is protected under copyright. The copyright prohibit any duplication of parts or of the entire user manual without an explicit written consent by A.R.C. Laser GmbH.

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We would like to point out, that this user manual was prepared based on A.R.C. Laser proprietary data and to the best of our knowledge. A.R.C. Laser reserve 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.

1.2 Marking and Symbols

The international sign **"Attention"** is attached to all surfaces, which are hazardous for the user. Before carrying out any further works at such marked parts, please read the user manual or contact your local dealer or contact directly to A.R.C. Laser GmbH service department.

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

1.3 Intended Use

The FOX 514 Laser is intended to be preferably used for therapeutically treating diseases of the eye of humans or animals. Especially treatments of the retina which might need a rise in temperature of tissue and/or blood up to coagulation can be provided. The laser can also be used in minimal intervention surgeries in ENT.

To be able to do so, the laser is being used together with a LIO or application fibers/ hand pieces, which lead the aiming beam directly or indirectly on the tissue.

The laser effect has been designed to allow focused treatment of the disease area with minimal impact on the surrounding tissue. Therefore, selecting the right laser parameters are essential to allow minimal pain, avoid injuries and achieve maximum results.

Using the laser in any and all other treatment methods is far superior in terms of traumatization and efficiency and the laser treatment is part of the innovative treatment methods in modern surgery.

The diode laser, model FOX 514, in ophthalmology is intended to be used for retina coagulation e.g. to cure retinal lesions or treat retinal detachment.

The Laser maybe used in the OR (sterile environment) and under normal conditions in the office.

Contraindications are given in case the user is not trained to use laser radiation and is not able to correctly control the emission while guiding the laser beam. It should be fulfilled that the laser is only used in case the user does have experience either after guided surgeries by another experienced surgeon or after training on a model tissue like animal tissue or comparable.

Contraindications are also: using the laser in an environment where gases can be light up or may explode, e.g. when oxygen is used while the patient is in general anesthesia and the laser beam may hit an oxygen-saturated area. Any situation where an uncontrollable risk of irradiation other than the dedicated area is given, e.g. when children may interfere with the laser beam or other persons (e.g. handicapped persons) may interfere with the laser beam unexpectedly.

Another contraindication is given when the necessity to use the laser is not high and alternatives are given and the dedicated area suffers from inflammation. Using laser radiation comes along with transferring heat to the tissue which may worsen inflammation.

Examples for indications and contraindications:

- Conditions under which the retina is not clearly identifiable (e.g. cataract, vitreous opacity)
- Other treatments that are not included in the intended use.

CAUTION – The device may only be used by physicians that undergone appropriate training and have extent knowledge of the medical effects and risks involved in using this device, as well as the understanding for using 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 laser is a mere diode laser with a laser diode as the beam source. The FOX has a wavelength of 514 nm.

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 phosound 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. 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 make the light built up this way in the resonator also accessible outside, the initial mirror of the laser is made permeable in parallel.

The laser diode is operated with high current up to 20 amperes and low voltage. Since the diode is very sensitive to any voltage fluctuations, the battery integrated into the FOX Laser has a buffer preventing any voltage fluctuations at the diode. Doping the individual junctions as well as the individual production processes allows A.R.C. Laser to provide the laser diodes in these wavelengths.

The power output varies per individual wavelengths. Through PN junctions, only certain layer thicknesses can be reached, and consequently only certain wavelengths can be generated.

Current drivers generate the current running through the laser diode 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.

The laser diode is controlled by internal electronic system that is adjustable through the device control monitor. The FOX 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 gets the specified temperature which kept stable. The cooling circuit is passive and control the internal fans, to allow natural or forced convection heat dissipation, depending on the load.

3 Transport and Storage

The FOX Laser is supplied in a custom made carrying case for ultimate protection during transportation. Accessories such as fibers and hand pieces are fully protected as well, as they have dedicated spaces within the carrying case and can transported together with the laser console.

For deliveries by mail, the carrying case is protected by a special outer cardboard box. The carrying case is designed to ensure the user can perfectly stow and transport the FOX Laser when changing rooms and/or site location.

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.

The FOX 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 FOX Laser should be protected against water and moisture!

4 Installation

4.1 Installation Site

Usually, the Fox Laser is installed by A.R.C. Laser GmbH or its authorized dealer, and you will be given full training for the device. Prior to delivery, the user needs to make sure a suitable location was prepared for the installation.

The FOX Laser should be installed at an accessible place - not too close to a heater or next to a sink. The laser should not be operated close to a heater as its air-cooling system works best when the ambient temperature 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, to avoid possible condensation on its internal optics as this might cause a permanent damage.

All control elements need to be readily accessible. The fibers at the front must have sufficient space to avoid accidental bending. The air humidity in the treatment room should be monitored and kept below 75%.

4.2 Room Requirements

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

4.2.1 Warning signs

All ingresses shall be clearly marked to prevent an outside person from entering, as this might be hazardous.

- Please attach the laser warning sign (triangle with laser symbol) as well as the wavelength marking at each access door.
- Please 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.
- Please store the laser protective goggles at the entrance of the room and make sure they are readily accessible.

4.2.2 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 A.R.C. Laser authorized dealer, or contact directly to A.R.C. Laser GmbH at any time.

4.2.3 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.

4.3 Electrical Connection

The laser is operated with a DC voltage of 19 V. Tis power is supplied by its internal battery pack and can be charged by an external power supply unit. A.R.C. Laser developed this internal battery pack specifically for this device. Only use battery packs and power supplies made by A.R.C. Laser GmbH and obtained through the authorized dealer.

The power supply unit can be connected to an AC voltage ranging from 100V to 240V at 50Hz-60Hz. Specifications are as labeled.

4.4 Battery pack

If the battery pack is mishandled, the battery pack can burst, cause a fire or even chemical burns. Observe the following cautions.

- Do not disassemble. Do not handle damaged or leaking lithium ion batteries
- Do not crush and do not expose the battery pack to any shock or force such as hammering, dropping or stepping on it
- Do not short circuit and do not allow metal objects to contact the battery terminals
- Do not expose to high temperature above 60°C (140°F) such as indirect sunlight or place located in the sun
- Do not incinerate or dispose of in fire

Disposal of waste batteries (applicable in the European Union and other European countries with separate collection systems)

This symbol on the battery or on the packaging indicates that the battery provided with this product shall not be treated as household waste.

In case of products that for safety, performance or data integrity reasons require a permanent connection with an incorporated battery, this battery should be replaced by qualified service staff only. To ensure that the battery will be treated properly, hand over the product at end-of-life to the applicable collection point for the recycling of electrical and electronic equipment.

4.5 Dispatching and Unpacking the device

In case unpacking and installing is done under the responsibility of the user:

Take care that the enclosed documents, included in the shipment with the FOX laser system, need to be completed and sent back to A.R.C. Laser GmbH.

Outside Germany, your local A.R.C. Laser dealer will complete the documents.

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 A.R.C. Laser authorized dealer. In this case, warranty claims have to be addressed to the transporter only.

Before initial start-up, please read the user manual carefully to complete the enclosed documents correctly.

5 Safety Information and Technical Acceptance

5.1 General

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

Following the "*Radiation Emitting Devices Act*" of your Country, it is highly advisable to keep with the device, detailed laser safety instructions and inform the person using the device on their location.

FOX 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 secured 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 FOX 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 keeping the document "*Operation of Laser Facilities and Accident Prevention Regulations for Laser Radiation*" which may be obtained through your local authorized dealer.

In addition, you can refer to the regulations of the American National Standard Agency ANSI Z136.3-1996 "*American National Standard for the Safe Use of Lasers in Health Care Facilities*" and ANSI Z136.1-1995 "*American National Standard for the Use of Lasers*".

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.

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 single most important piece of protective equipment needed by persons 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 all directions 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. (514 nm)

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.
OD 8+ for 514nm

Your FOX Laser package is supplied with two units of laser safety goggles, according to the wavelength, intended to be wear directly (i.e. not to be wear on top of glasses).

Protective goggles that meet all safety requirements can be obtained through your local A.R.C. Laser authorized dealer, including special models someone can wear 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 suspected of any physical damage (cracks, dents, scratches, discoloration, layers peeling), DO NOT use; please contact your local A.R.C. Laser authorized dealer for replacement.

Should you require any additional information on protective goggles, please contact your local A.R.C. Laser authorized dealer.

5.2 Electrical Protection

The FOX 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 immediately destroy the laser diodes.

Any service to the unit or its accessories should only be carried out by an authorized personnel by A.R.C. Laser GmbH.

The room in which the laser is operated should be kept dry. For room that needs to be cleaned with the use of 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 FOX Laser should undergo a safety inspection every 24 months, carried out by qualified personnel.

5.3 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 green or IR laser beam on flammable materials may ignite these and cause a fire or expulsion!

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.

5.4 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 in within the operator vicinity and recommended to be clearly marked as the FOX 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. In case of pauses exceeding 1 minute, please press the "Ready" key.
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 FOX Laser in any other way differing from the one described herein may cause hazardous exposure to radiation.

5.5 NOHD Safety Distance

$$NOHD = \frac{\sqrt{\frac{4P}{MPE * \pi}} - Diameter\ Beam\ Bundle}{Beam\ Divergence}$$

For all FOX models:

Wavelength λ:	**514nm**
NOHD:	2.7 m

Wavelength λ:	**810nm**
NOHD:	2.4 m

Wavelength λ:	**940nm**
NOHD:	1.2 m

Wavelength λ:	**980nm**
NOHD:	2.0 m

Wavelength λ:	**1064nm**
NOHD:	1.5 m

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 4.2 and "Eyewear Protection" Section 5.2).

5.6 CE Regulations

The Laser system was accredited by the notified body in accordance with the European directive 93/42 for medical equipment. Therefore, the device is labeled with the CE mark **CE 0123**.

The device was tested for electrical compliance as well as for mechanical safety. All parts used by A.R.C. Laser for the FOX 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.

5.7 RoHS2 regulations

Our company operates worldwide and considers the protection of the environment and natural resources as a corporate obligation. Based on individual tests we can for the products of ARC Laser GmbH confirm that these substances are not present in concentrations according to our knowledge, the marketing of which is prohibited in accordance with the applicable requirement of Directive 2011/65/EG (RoHS2).

5.9 External Interlock Plug

At the rear of the console, a removable plug is inserted through a circular socket (see photo below). The plug when fully inserted enables main power to the console internal circuitry. Should this plug pulled out, the console will instantly shut down.

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 drop to zero.

Please be advised that the laser can only operate when the plug is fully inserted into the socket.

5.10 Console Protecting Housing

The FOX Laser has a protection housing optically sealed to prevent laser radiation leakages, and is electrically isolated. 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 A.R.C. Laser GmbH service technicians.

5.11 Safety Switch

The FOX Laser has an internal safety shutter. This safety switch enables the release of laser beam and will open when pressing the "READY key" followed by the pedal switch.

After starting the laser the FOX begins with internal tests. After he has passed all its internal tests and calibrations, the safety switch can give way for the laser radiation.

The aiming beam becomes active only when the laser is switched to a READY mode, the aiming beam is a low power green laser, similar to laser pointers.

5.12 Manual Reset

When an error occurs (e.g. power instable etc.), the device changes into the STAND-BY mode. Simply close the FOX Laser cover stand and re-open to make sure the device can reactivate itself. If the device cannot be started again, there is an error which can only be resolved by a qualified personnel. Please contact your local A.R.C. Laser GmbH authorized dealer.

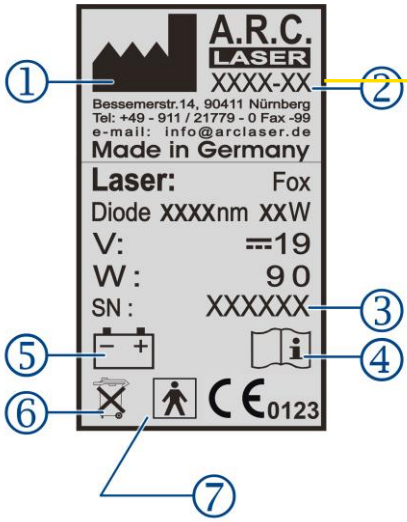
5.13 Stickers Labels and Markings

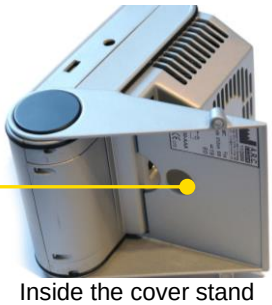
The FOX Laser has various warning labels in accordance with the European directives and Health Canada, intended to prevent any laser users to become exposed to laser radiation because of improper use. You can identify the arrangement of these labels with the following drawings:

IDENTIFICATION PLATE FOX

According to model: 514, 810, 980, 1064 nm (located on the inner side of the cover stand)

① Manufacturer
② Date of manufacture
③ Serial Nr.
④ See Manual
⑤ Battery powered
⑥ No disposal in domestic waste
⑦ Applied Part: Type BF

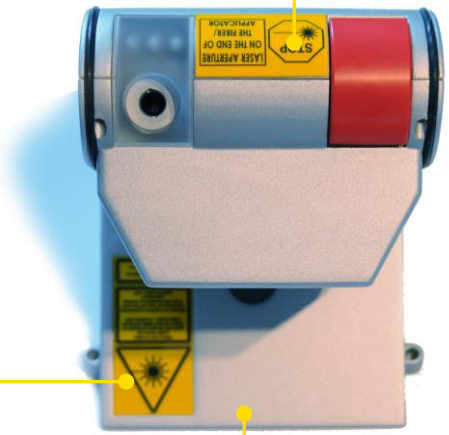



Inside the cover stand

WARNING LABELS

Warning label fiber exit
(Console top)

Warning label laser radiation
(Cover stand top)



Warning label laser radiation
(Cover stand top)

5.14 Operating Conditions:

- The FOX Laser is not suitable for use with combustible gas mixtures.
- The FOX Laser has not been tested for operation in heights exceeding 2,000 m above sea level.
- 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%

Examples of some applications:

- Nasal mucosa hyperplasia (ENT)
- Periodontics treatment (dental application)
- Vessel coagulation (Dermatology)
- Ciliary body destruction (Ophthalmology)
- etc.

5.15 Electromagnetic Compatibility

The FOX Laser complies with the EMC requirements according to DIN EN 60601-1-2:2007-12. Guidelines and manufacturer's declaration are described in Section 12.

6 User Information and System Introduction

6.1 Technical Introduction Training

Upon installation, a staff member from A.R.C. Laser or the local authorized dealer will provide introductory training for the 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 FOX Laser in particular.

All individuals working at the vicinity of the laser should attend this introductory training.

One individual with the training and experience to knowledgeably administer a laser safety program will be chosen as the person responsible for monitoring and overseeing the control of laser safety.

6.2 Laser Safety Training

The FOX diode laser is designed for medical applications. It may only be used by a physician who received training by an authorized personal. In addition to the trainings offered by A.R.C. Laser, A.R.C. Laser GmbH recommends to attend seminars offered by us. These seminars contain topics like “working with different laser systems” such as the diode laser. Moreover, introductions into the laser safety and the use of lasers in general will be covered in these seminars. We recommend you to make sure that only the person holding the password will use the laser. The password should not be handed to other physicians unless they went through the recommended training for the device.

The fact that even personnel not working directly with the laser should attend the "laser safety” or "laser application” courses, has proven to be very useful. Laser safety, the basic principles of the laser and of laser treatment is mainly discussed in these courses. It is particularly important that the operating personnel attend the laser safety courses. In these courses, extensive training is given to master precautionary measures when working with lasers (e.g. caution in case of combustible material, the importance of laser protective goggles etc.) are dealt with in detail.

Training for the accompanying personnel is offered in addition to the introductory, and is given by the local A.R.C. 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 also covers clinical information as well as references to the indication but does not intend to be complete and to be used as is, since each patient may require different parameters.

A.R.C. Laser GmbH holds a list of recommended courses as well as laser safety courses available, and can be retrieved from us through our local dealer at any time.

6.3 Medical Introduction Training

The scope of the device medical introduction training is to provide basic information on selected medical applications for the users specific intended use.

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

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 A.R.C. Laser GmbH. This includes also any type of optics cleaning within the laser system as well as battery pack replacement.

6.4 List of Medical Devices

The FOX Laser packaging includes an enclosed document that contains a list of medical accessories, which should be stored in the carrying case or in the event of larger number of accessories, in a similar protected manner. In case of any damage or suspected malfunction in any of the accessories, please contact your local A.R.C. Laser authorized dealer for technical support.

6.5 Medical Device Parts and Accessories

A T T E N T I O N !
Only the parts and applications as specified by A.R.C. Laser GmbH can be used with the FOX 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.

Available applicators like: fibers, endo-probes, hand pieces and similar parts are described in detail in the corresponding application manuals.

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

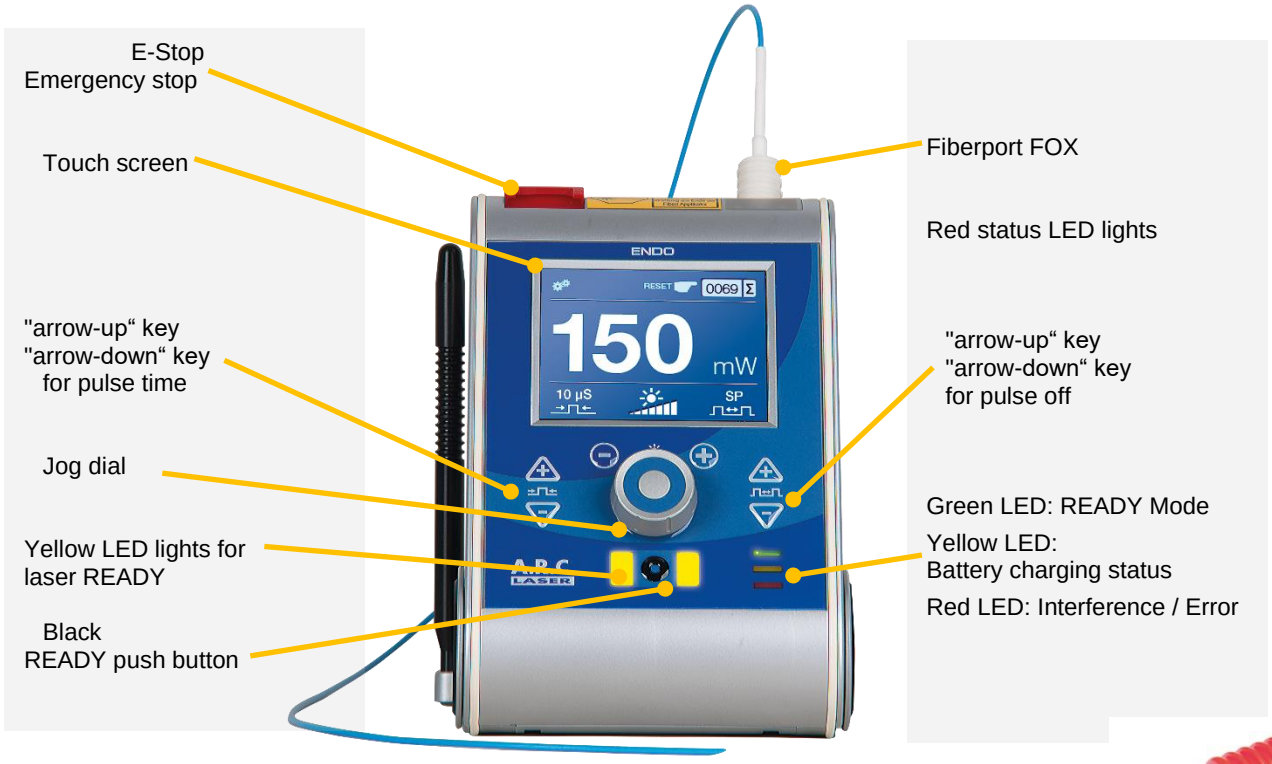
Part-Name	Description	Item-No.
Foot Switch	Foot switch with hinge and cable	BG03808
Power Supply	FOX Battery Charger	PS01013
Device holder	Easy mount to keep the FOX secure	BG03805
Port Protection	Dust cover plug for the fiber port	ME03855
Carrying Case	Protective metal case for storage and transportation of the FOX Laser and its accessories	VP03101-3
Protective Goggles*	Protective eyewear against laser light	AS01009

* Protective Goggles are wavelength dependent. There are several models available including types that fit over glasses. Please provide your FOX Laser model when ordering.

For further information about accessories, please contact your local distributor.

6.5.1 **Housing Front**

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



6.5.1.1 **FOX Fiber port**

The FOX Laser has a fiber port at the head of the device, see Section **Fehler! Verweisquelle konnte nicht gefunden werden.**, intended to incorporate the patented A.R.C. Laser click plug for a wide range of hand pieces and applicators. To protect the fiber port A.R.C. inserted the red protective cap.

The silver port is made for fibers with 300 micron. For devices with the 300-micron port we offer fibers with a white, green or red plug.

A T T E N T I O N !
Fibers and hand pieces which are designed to be reused do have a green plug. They cannot be assigned to the appropriate system in accordance with the color of the plug! In this case the user has to be carefully look at the label of the packaging of the fiber or hand piece!

A T T E N T I O N !
Never work with a tool at the fiber or at the fiber port. Fibers may break – do not bend! Protect fiber ends against dust and dirt. Never use defective fibers.

6.5.1.2 **READY Key**

The READY Key is a black circular push button with two lateral yellow LED guides

Press the *READY Key* button once and release, to switch to READY mode. The two yellow LED guides will start flashing, accompanied by a beeping sound. After approx. 3sec the two lateral yellow LED guides will remain on, indicating that the device is now ready for operation. Pressing the *READY Key* button again, will deactivate the READY mode. A confirmation beeping sound will be heard and the two lateral yellow LED guides will turn off.

6.5.1.3 **Laser STOP, E-STOP**

The E-STOP button is on the top left side of the device. If the E-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.

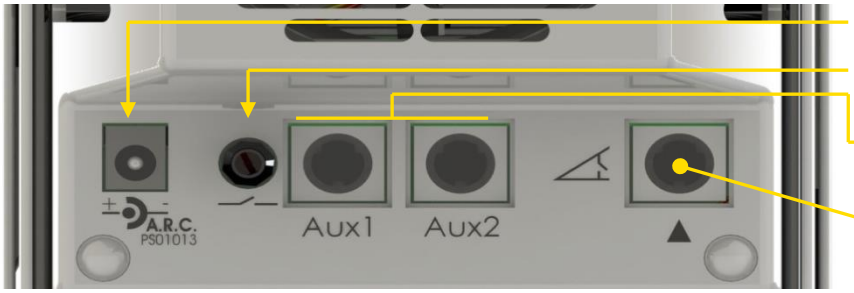
Solution: Pull up E-STOP, and the device can be started (see chapter 7.2)

Pressing the E-STOP button while working with the FOX Laser, will instantly cut off the laser output.

Solution: Pull up E-STOP, and restart the device. (see chapter 7.2)

6.6 Rear Panel

The following connector sockets are located at the rear panel:



6.6.1 Right Side Panel

The following connector sockets are located at the right side panel:

6.6.2 Sockets

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

Socket	Description	Note
Power	Charging device PS01013	To charge internal batteries
Door-Interlock	Connecting the door-interlock switch	
AUX 1	External eye protection filter	U_{max} = 3,3 V; I_{max} = 330mA
AUX 2	Isolated port – works as a remote control to activate warning light	Max. 24V; do not plug in a device
AUX 3	Connector for the A.R.C. PowerMeter	
Foot switch	Connector for the A.R.C. foot switch	
AUX 4 - USB	USB connection for A.R.C. flash drive	Contains helpful information. Do not connect any other USB-device

7 Operation

A T T E N T I O N !
The FOX Laser may only be operated by personnel that undergone relevant training for the device and that proves 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 A.R.C. Laser 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.

7.1 Preparation

The FOX contains an internal rechargeable battery. A power supply unit is included with the basic system, which needs to be connected to the charger port at the rear panel. The power supply unit will shut the charging current when the battery is fully charged. Charger input voltage ranges between 100V and 240V. Due to security reason, your FOX can only be operated with the power supply distributed by A.R.C. Laser.

Please follow the following steps when preparing the device to operation, in order to avoid unnecessary troubleshooting or even possible malfunctions.

- Is the battery charged or is the mains cable at the rear panel connected?
- Please connect the mains when the device is switched off.
- Has the strapping port for the external interlock been plugged in?
  – or, if applicable: has the door interlock contact been connected to the laser?
- The fiber port should be empty.
- Has the A.R.C. Laser USB stick been unplugged from the USB port?
- Are the fibers and hand pieces that are to be used, free of any damage?
- Is there sufficient number of protective goggles ready to be used?
- Has the pedal switch been plugged in?

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 !
Since the aiming beam shares with the laser beam, the same optical delivery system, 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.

7.1.1 Installation Site

We recommend placing the FOX Laser on a solid, even surface. A suction cup mount is included in the carrying case to secure the device.

Cup-Mount

7.1.2 Suction Cup Mount

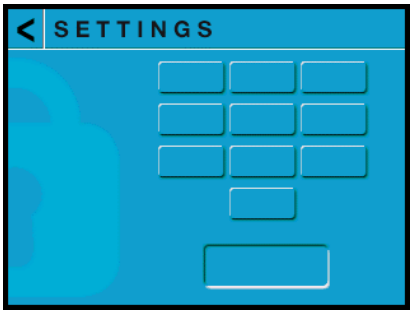
Moisturize the cups and press them firmly onto the even surface. Verify if they position firmly by slightly shaking or pushing the suction cups.

7.2 Starting the Device

Switch on the device by pressing the two **MINUS , PLUS** keys simultaneously for at least two seconds. The green starting LED will begin to flash.

After about 30 seconds, the startup screen will appear.

The FOX Laser executes its system check automatically upon startup.



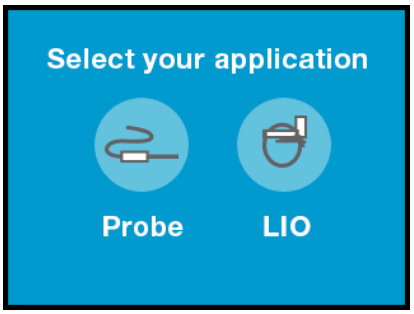
Once the system check has been completed, you have to enter the password (“**0000**”). See chapter 7.3.4.4 to modify the password.

7.2.1 Fiber Port / Fiber Coupler

The fiber coupler has a control mechanism, which can prevent 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.

7.2.2 **Select a Program**



Select your application. In this case program no. 2 has been selected.

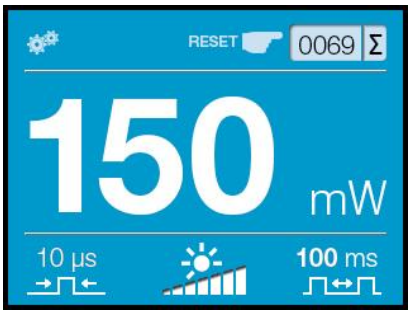
Select the desired application with a finger tip

With the arrow keys, you will get to other applications /programs.

The application selected is highlighted in blue and will be confirmed when you press the OK field. The names of the programs were preset; you can change them at any time.

Change the names of the programs by keeping the relevant field pressed down (2 sec.)

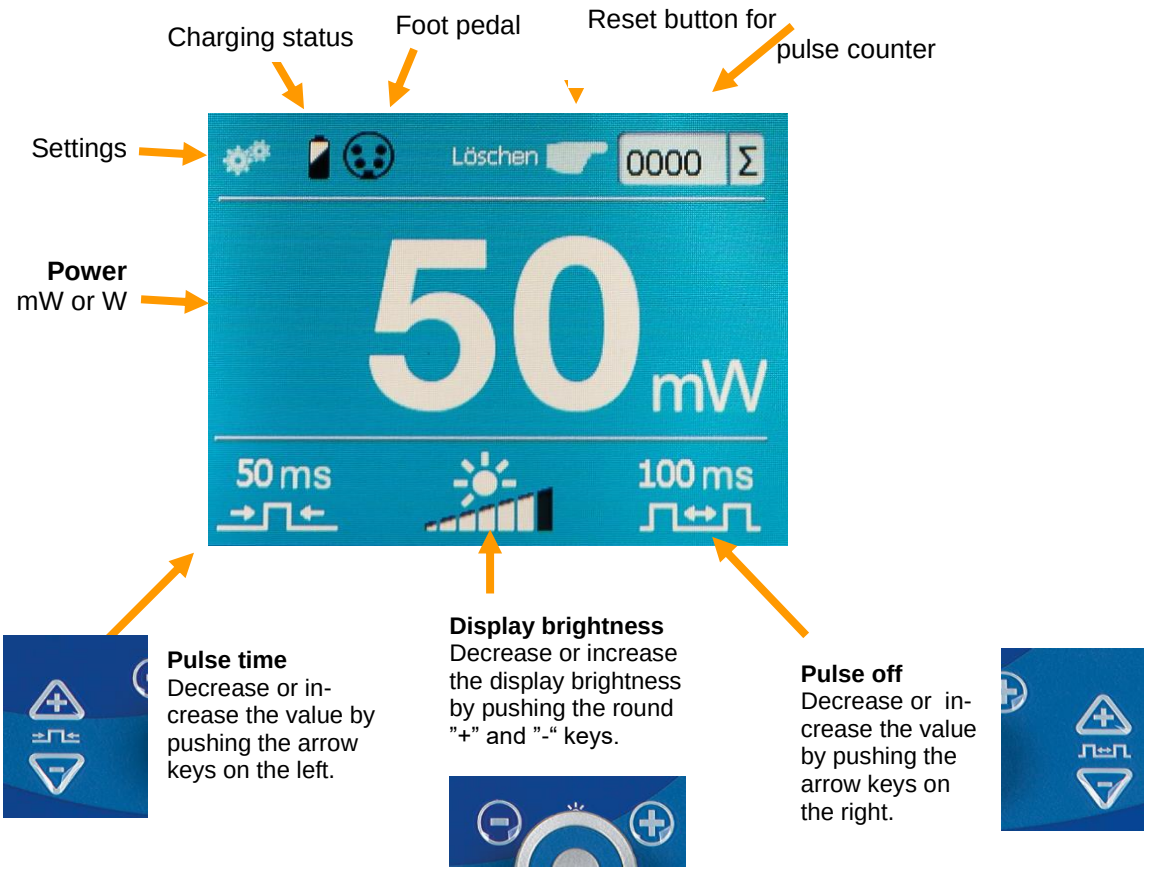
The input screen will appear. Enter the desired name and confirm with the OK key. With the “123” key, you leave the alphabet screen.



7.3 Working with Selected Programs

ATTENTION: We explicitly want to point out that the company's relevant application manuals have to be observed for the applications and settings. For more details on how to apply the laser system *please refer to* the application manual, provided by A.R.C. Laser only.

7.3.1 Display / Main Menu



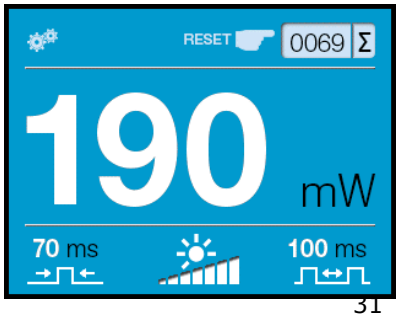
7.3.1.1 Saving parameters

Section 7.2.3 describes how to modify program names. In addition, you can also change the parameters for power / pulse length / pulse interval as described in the following 3 sections.

To store the modified parameters, please press the save button. This button appears only after you change a value.

7.3.1.2 Power

After pressing the power display (Watt), you can adjust its value with its plus or minus-button. By keeping the field pressed down for a little while, a power bar will appear, in which you can directly scroll to the required power value.



The displayed value may vary from the emitted value at the distal tip, by a range of ±20%.

7.3.1.3 Status USB Flash Drive

If inserted the Flash drive icon will show up. In case the drive is defective or not inserted, the display does not show this icon.

7.3.1.4 Pulse Length Adjustment

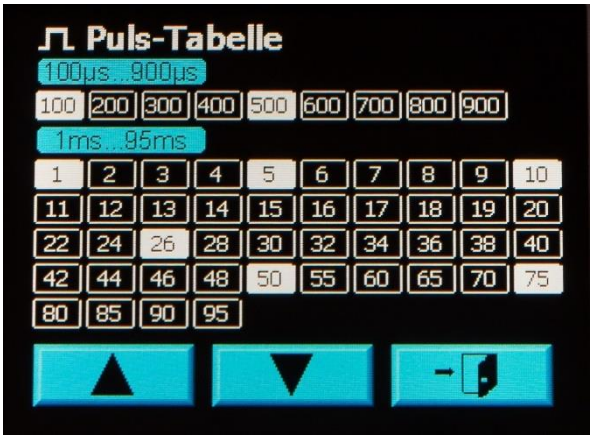
You can adjust the pulse length through the pulse length menu.

Choose your favorite values from this table.

µs	ms							SEC	
100	1	12	26	48	100	210	600	1	7
200	2	13	28	50	110	220	650	1,5	8
300	3	14	30	55	120	230	700	2	9
400	4	15	32	60	130	240	750	2,5	10
500	5	16	34	65	140	260	800	3	15
600	6	17	36	70	150	280	850	4	30
700	7	18	38	75	160	300	900	5	45
800	8	19	40	80	170	350	950	6	CW
900	9	20	42	85	180	400			
	10	22	44	90	190	450			
	11	24	46	95	200	500			
CW = continuous wave									

below: Screen with „Pulse on“ values

When selecting the pulse on values table, changed but not yet saved values will be set to its original value. To get to the “Pulse on” values table hold the button for at least 2 sec.. Highlighted values are preset. Add or deselect values of your interest to modify your presets as necessary. White boxes are selected.



7.3.1.5 **Pulse Interval Adjustment**

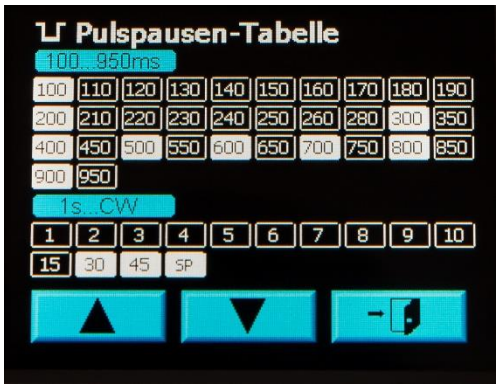
While keeping the pulse interval field pressed down, you will reach the interval release table where you can select (marked) and preset individual parameters.

µs	ms							SEC	
100	1	12	26	48	100	210	550	1	8
200	2	13	28	50	110	220	600	2	9
300	3	14	30	55	120	230	650	3	10
400	4	15	32	60	130	240	700	4	15
500	5	16	34	65	140	260	750	5	30
600	6	17	36	70	150	280	800	6	45
700	7	18	38	75	160	300	850	7	SP
800	8	19	40	80	170	350	900		
900	9	20	42	85	180	400	950		
	10	22	44	90	190	450			
	11	24	46	95	200	500			
SP = single pulse									

Choose your favorite values from this table.

below: Screen with highlighted „Pulse off“ values

When selecting the “pulse off” values table, changed but not yet saved values will be set to its original value. To get to the “Pulse on” values table hold the button for at least 2 sec.. Highlighted values are preset. Add or deselect values of your interest to modify your presets as necessary. White boxes are selected.



Example: If the pulse length is 10 ms and the pulse interval is 10 ms, 50 pulses per second will be applied when the pedal switch is pressed down.
Intervals between the individual laser pulses are important to make sure the tissue treated has sufficient time to cool down.

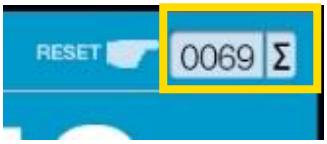
7.3.1.6 **Foot pedal**

This symbol means that the laser is used with a foot pedal with cable.

7.3.1.7 **Charging status**

This sysmbol shows the charging status of the battery.

7.3.1.8 **Pulse Counter**



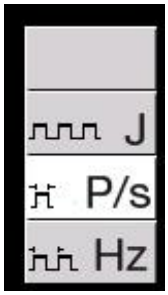
The triggered pulses are accumulated. The device automatically counts the laser pulses triggered by means of the foot pedal or set by pulse repetition rate. The maximum number of pulses registered is 9999.

To reset the field “0000” you need to tip on it.

7.3.1.9 **Energy Counter (J or P/s or Hz)**

Three versions are available in this tally field:

Hold the button for at least 2 sec..



Energy joule: The displayed energy value is the product resulting from the set power and the actual time of exposure as well as the number of pulses triggered. The unit automatically changes from mill joules (mJ) through Joules (J) to kilojoules (kJ), according to the energy added.

Power/second: P/s stands for the result of the power set and the actual time of exposure depending on the pulse length and the pulse interval. The display of the unit also changes automatically
from mW to W according to the setting.

Frequency Hz: The displayed frequency value is calculated from the pulse length and the pulse interval per second, displayed in Hz.

7.3.1.10 **LOCK / Access Protection (not with FOX 514)**

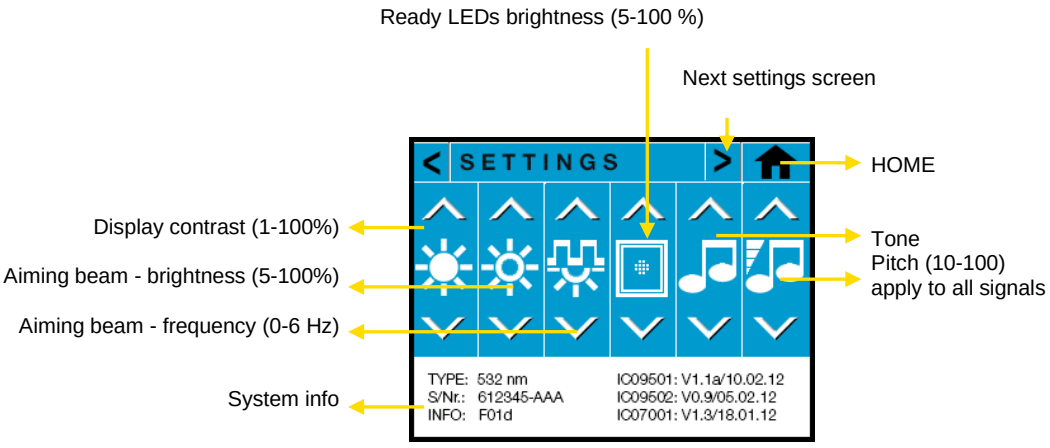
You as an operator have to avoid unauthorized access to the laser. After usage the system has to be locked manually.

By pushing this Button  the FOX laser will be logged out. You will see the password screen.

To proceed your treatment you have to enter the password. (Standard is “**0000**”) A password consists of 4 numbers. By pressing the numeric keypad you fill the input box. After 4 numbers there is an automatic *Return*.

7.3.2 Settings - Submenu 1

Leave the main menu to enter the submenu by pressing the MENU key.

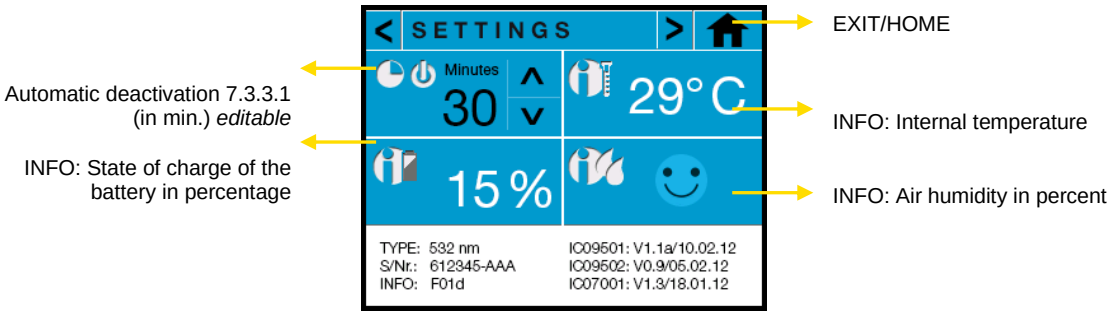


The individual parameters can be adjusted with the up/down buttons.

Reduce Power Consumption: If you do not work with the maximum brightness of the aiming beam, we recommend to reduce the parameter settings and to vary the aiming beam frequency, as maximum power is consumed with maximum setting.
The brighter the display, the higher the power consumption.

7.3.3 Settings - Submenu 2

Leave submenu 1 with the arrow key „right“ and get into the next submenu. Here you can only modify the automatic deactivation.

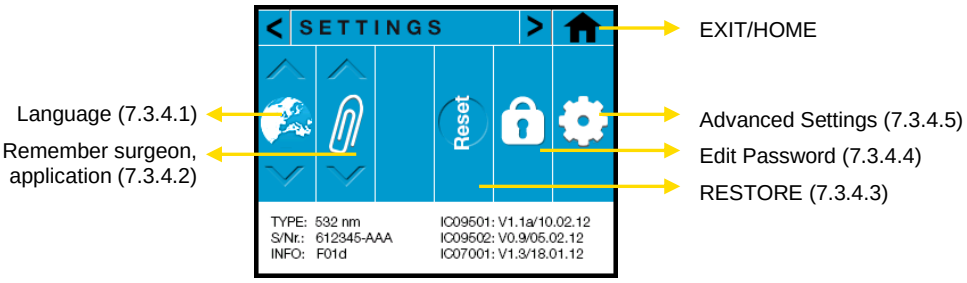


7.3.3.1 Automatic deactivation

Set the time until deactivation. Range: 1-100 minutes.

7.3.4 Settings - Submenu 3

Leave submenu 2 with the arrow key „right“ and get into the next submenu 3. Here you can change the language of your FOX and alter the memory function.



7.3.4.1 Language

Pick your desired language with the arrow buttons

7.3.4.2 Remember surgeon and application (not with FOX 514)

Once you choose the remember icon (indicated dark), you set the Memory-function and the FOX will remember the last settings for surgeon and application. At the next Starting-Routine the screen for Surgeon and Application will be skipped. The Memory is switched off when the clip-icon is bright.

 dark

 bright

7.3.4.3 RESTORE (not with FOX 514)

This function restores default settings and deletes all kind of user settings and modified parameters. Programs and Settings are restored.

7.3.4.4 Edit Password

This screen is to modify your user-password (Standard is “**0000**”) - you need it at the end of the starting process. A password consists of 4 numbers. By pressing the numeric keypad, you fill the input box. After 4 numbers there is an automatic *Return*.

The Routine will guide you through the menu:
① Old Password: Enter the present password
② New Password: Enter your new password.
③ Confirm Password: Re-Enter your new password.

7.3.4.5 Advanced Settings

Only trained personnel should use the features of the advanced setting screen.

7.4 Charging the battery

Insert the Power Supply Art. Nr: PS01013 into its socket at the rear side of the FOX.

Switch on the device according to chapter 7.2. Enter your password, select surgeon and choose a program.

The charging process starts, as soon as the orange LED shows up.

If you might want to switch off your FOX, the charging process will be continued.

As soon as the battery is completely charged, the orange LED will switch off. The green LED will shine on.

7.5 Inserting the applicator

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

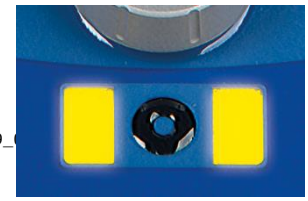
Gently push the applicator plug into the socket until it firmly "clicks" into place. In case it does not click in correctly, try to twist the plug inside the socket.

If the plug has not properly clicked into place, the device will not change into READY mode, and the FOX 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 in place, you can hold the applicator/ hand piece in your hand. At this point, 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 toward flammable materials.

7.6 Ready Key

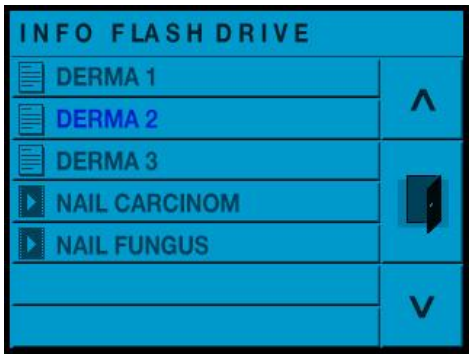


The READY Key is a black circular push button, with two lateral yellow LED guides.

Press the READY Key button once, to switch to READY mode. Upon pressing the two yellow LED guides will start flashing, accompanied by a noticeable beeping sound. After approx. 3sec the two lateral yellow LED guides will remain constantly on, indicating that the device is now ready for operation.

Pressing the READY Key button once again, will deactivate the READY mode. After pressing a single confirmation beep sound will be heard and the two lateral yellow LED guides will turn off and the aiming beam will go out.

7.7 USB flash drive



You can connect the USB flash drive included with the system to the USB port located on the right side of the console. To access the content of the flash drive, you need to touch the Flash-Drive-Symbol on the A.R.C. infoscreen. In the provided flash drive you can find useful information, including videos for a wide range of applications.

Enjoy paging through!

7.8 Switching Off

Switch off the FOX by folding back the cover stand. If you do not plan to use the FOX Laser for a long time, stow the laser in its carrying case.

7.9 Power Save

After 5 minutes of inactivity the FOX automatically goes to Stand-By to save power.

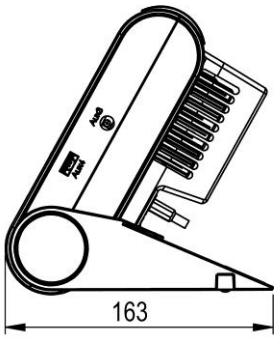
- The TFT screen gets dark
- The green status LED indicates with 1 Hz

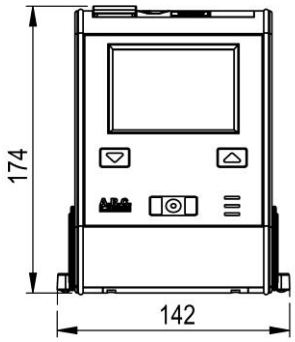
To “wake” the laser just tip the touch screen or one of the blue arrow keys.

After 5 more minutes of inactivity the laser switches off completely. You will need to restart it by pressing both blue arrow keys.

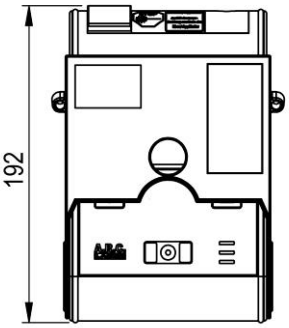
8 Technical Data

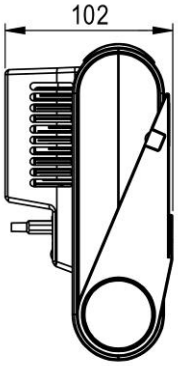
8.1 Dimensions





device open





device closed

8.2 General

Model FOX	Diode laser
Cooling	Internal, forced air convection
Weight	1.2 kg
Dimensions	H 17.4 cm / W 14.2 cm / T 16.3 cm with opened foot
Controlling	Digital touch screen display

8.3 Laser Data

Wavelength	**Power**	**Tolerance**
514 nm	1.5 W max.	±20% of the displayed power according to IEC 60601-2-22 requirements

Wavelength	**Pulse length**	**Shot frequency**
514 nm	100 µs to 30 sec, CW	0.01 Hz to 200 Hz / SP

Aiming beam	650 nm red < 1mW
Operation mode	Continuous wave (CW) or pulsed in variable brightness
Power transfer	Fiber 200µm, 300µm, 400µm, 600µm with or without hand piece

8.4 Power Requirements

External power requirement	100 - 240 V AC, 47 - 63 Hz, 1.06-0.45 A
Charger output / Console input	19 V DC, 4.74 A
Battery	10.8 V, 26.4 Wh, Li-Ion (by A.R.C. Laser)

8.5 Classifications

Laser class 4
(Classification according to EN 60825-1)

Aiming beam laser class 2
(Classification according to EN 60825-1)

Electrical protection class II
(Classification according to IEC 60601-1)

9 Service

9.1 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 10 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 A.R.C. Laser 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 to open the protective housing, should only be carried out by a service technician trained by A.R.C. Laser GmbH. This includes also any type of optics cleaning within the laser system as well as battery pack replacement.

9.2 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.

In the event where the device is out of order and/or not safe to operate, remedial maintenance is required and/or the operator shall be 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. In this case, the operator shall immediately inform the responsible regulatory authority thereof.

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.

9.3 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 battery charger plug from the FOX Laser console, and any applicator that may have left still attached.

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 in any case!

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 FOX 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.

9.3.1 Accessories Cleaning

9.3.1.1 Pedal Switch

Please refer to 9.3 “Cleaning of the FOX”

9.3.1.2 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.

9.3.1.3 Applicators (for non-sterile use)

Please refer to 9.3 “Cleaning of the FOX”

9.4 Error Detection

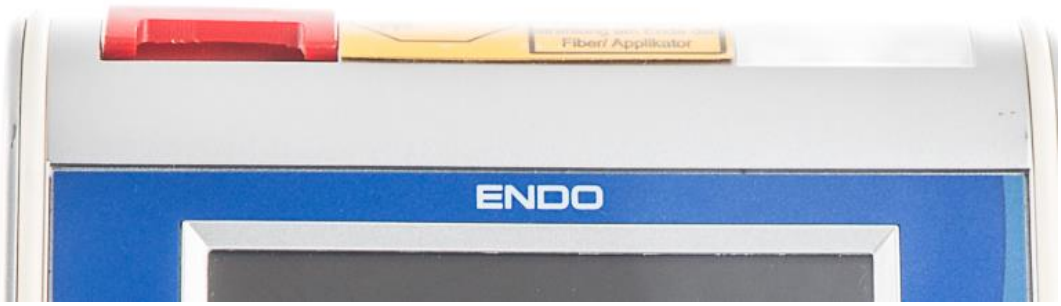
The FOX was developed and designed as a modular system. In addition, all its components had to undergo rough shake tests as well as temperature testing. In case of an error, you can start by isolating the problem with this manual. In most cases, you should be able to resolve the problem yourself. If the problem persists, please contact your local A.R.C. Laser 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:

- Battery operation: Make sure the battery has been charged.
- Interlock: The strapping plug should be fully inserted to the device and the door contact switch should be closed.
- The red DEACTIVATION button on the top of the device needs to be pulled up.



9.5 System Self Check

In general, a system self check will run after turning on the device, and 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 A.R.C. Laser GmbH.

   Such errors may include:

- Laser STOP 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 A.R.C. Laser 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.

9.6 Troubleshooting

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

Problem	Potential Error	Troubleshooting
Screen is black	Laser is in Sleep mode	As a standard, the laser falls asleep after 5 min of inactivity. Touch the display or a blue arrow-key to activate the device.
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
	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
	Fiber is broken	Replace the broken fiber with a new one
	Aiming beam - diode defective	Contact your A.R.C. Laser dealer
No laser beam but aiming beam visible	Pedal switch non plugged in	Check if pedal switch is correctly plugged in
	Pedal switch defective	Contact your A.R.C. Laser dealer
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 or hand piece
	Fiber is broken	Replace the broken fiber with a new one

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

9.7 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. A.R.C. Laser 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. A.R.C. Laser will help you to find out which materials have been used to produce your specific probe/applicator.

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E-Mail: service@arclaser.de

10 Customer Service

10.1 Warranty Information

A.R.C. Laser GmbH provides a two-year warranty. Within these two years, 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

A.R.C. LASER GmbH Bessemerstr. 14, D-90411 Nuremberg

Phone: +49 911 21779-13 (-0), Fax: +49 911 21779-99, Email: service@arclaser.de

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 A.R.C. Laser GmbH.

10.2 Warranty Consignments, Packaging

A warranty claim for defective parts, malfunction or damage of the housing of the device shall be passed on to A.R.C. Laser GmbH within 24 hours. Parts returned during the warranty period (upon the explicit request of A.R.C. Laser GmbH), are subject to the written confirmation by A.R.C. Laser GmbH. Detailed packaging instructions and information on how to return the device will be provided by A.R.C. The return consignment shall be insured and the costs arising hereof from shall be borne. A.R.C. 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 A.R.C. 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 A.R.C. Laser GmbH. The customer will be informed about any changes which will be carried out on the premises of A.R.C. Laser GmbH

10.3 Sales and Service Information

For information about sales and service please contact:

A.R.C. Laser main office:

A.R.C. LASER GmbH

Bessemerstr. 14

D-90411 Nürnberg

Tel: +49 911 21779-13 (-0)

Fax: +49 911 21779-99

E-Mail: info@arclaser.de

Web: www.arclaser.de

11 Symbols Description

	Display brightness 5-100 %		Charging level of battery
	Aiming beam brightness 1-100 %		Temperature inside
	Aiming beam frequency (0-6Hz)		Sleep mode time
	Brightness Ready Button (5-100%)		Air humidity
	Tone (10-100%)		Pick language
	Pitch (5-100%)		State of power supply
	CW in “pulse on” field		Flash Drive inserted
	Single Pulse in “pulse off” field		
	Settings, submenu		Home
	Next screen / Previous screen		Attention
	LOCK / Access Protection		

11.1 ERROR MESSAGES

	State of charge of battery too low	Batteries need to be charged before continuing operation
	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 / or plugged incorrectly	Check fiber plug
	Ventilation fan blocked	Contact your A.R.C. Laser agent.

11.2 Warning Messages

	Change power supply
	Cooling element too hot
	Error ... Repeat
	Calibrated parameter is stored

11.3 Status Messages

 	Please wait
The TFT-Display and Fiber-LED are getting dark and the green Status-LED starts blinking with 1 Hz	PowerSave Mode - Your FOX Laser lowers its power consumption. By pressing any button (despite of TouchScreen) you can resume to normal mode.
The TFT-Display, Fiber-LED, Status LED are dark	E-STOP button is pressed. Pull up E-STOP, and the device can be started.

12 Guidelines and Manufacturer's Declaration

12.1 Electromagnetic Emissions

The laser is intended for use in an environment as specified below. The customer or the user of the laser should ensure that it is used in such an environment.

Immunity tests	**Compliance**	**Electromagnetic environment – guideline**
RF emissions CISPR 11	Group 1/Class B	The laser uses RF energy exclusively for its internal function. Hence, RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1/Class B	The laser is suitable for use in any and all establishments including establishments in residential areas and those directly connected to the public power supply network which also supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

12.2 Electromagnetic Immunity (1)

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

Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	Complies with IEC 60601	Floors should be wood, concrete or ceramic tiles. Where floors are covered with synthetic material, the relative air humidity should be at least 30%.
Fast transient electrical /burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines	Not applicable ± 1 kV	The supply voltage quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	Not applicable	The supply voltage quality should be that of a typical commercial or hospital environment.

Immunity tests	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Voltage dips, short interruptions and variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for ½ cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	The supply voltage quality should be that of a typical commercial or hospital environment. When the user of the laser requires continued operation during power mains interruptions, it is recommended that the laser is powered from its battery or an uninterruptible power supply or an external battery.
Magnetic field with power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields in mains frequency should be those of a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to the application of the test level.			

12.3 Electromagnetic Immunity (2)

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

Immunity tests	IEC 60601-test level	Compliance level	Electromagnetic environment – guidelines
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff} (V_1) 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to the laser, including cables, than the recommended separation distance calculated for the equation applicable to the frequence of transmitter. **Recommended separation distance:** d = [1,17 : V_1] $\sqrt{P}$ d = [1,17 : E_1] $\sqrt{P}$ for 80 MHz to 800 MHz d = [2,33 m/V * vP for 800 MHz to 2,5 GHz where P maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer and *d is the* recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m (E_1) 80 MHz to 2,5 GHz	

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

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

a) The field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with battery. To determine to electromagnetic environment resulting from the fixed RF transmitters, an electromagnetic site survey should be considered. Where the measured field strength in the location in which the laser is used exceeds the applicable RF compliance level indicated above, the laser should be observed to verify the normal operation. Where abnormal power is observed, additional measures may be necessary, such as reorienting or relocating the laser.

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

12.4 Recommended Separation Distance between Portable and Mobile RF Telecommunications Equipment and the Laser

The laser is intended for use in an electromagnetic environment in which radiated RF are controlled. The customer or the user of the laser can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the laser as indicated below – according to the maximum output power of the communication equipment.

Maximum output power rating of the transmitter [W]	**Separation distance according to frequency of transmitter in meter [m]**		
	150 kHz to 80 MHz d = 1,17 1/V * vP	80 MHz to 800 MHz d = 1,17 1/V * vP	800 MHz to 2,5 GHz d = 2,33 m/V * vP
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,73
1	1,17	1,17	2,33
10	3,69	3,69	7,30
100	11,66	11,66	23,30

For transmitters with a maximum output power rating not listed above, the recommended separation distance d in meters (m) can be determined by using the equation applicable to the frequency of the transmitter where P is the maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer list.

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

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

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