User Manual
FOX IV 810

A.R.C. Laser GmbH

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Content

1 Introduction

We appreciate your decision to purchase the FOX IV 810 and wish you a productive and successful usage with this all-round diode laser for ophthalmology.

The FOX IV 810 generates a high-intensity laser beam, which may induce injuries in case of improper handling. Therefore, this User Manual should be read carefully before using the device. If 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.

1.1 Marking and Symbols

The "**General warning sign**" (ISO 7010 W001) indicates general risk. It encourages the user to take care regarding the hazard specified by the supplementary sign. Before carrying out any further works at parts with such marks, please read the user manual or contact your local dealer or contact directly the A.R.C. Laser GmbH service department.

The sign "**Warning; Laser beam**" (ISO 7010 W004) indicates laser hazards. It encourages the user to take care to avoid exposure to a laser beam. The laser beam of this device is not visible to the naked eye nor through protecting googles.

1.2 Intended Purpose

1.2.1 General Purpose

Coagulation and/or carbonization/vaporization of tissue, bony structures or blood

1.2.2 Medical Purpose

The FOX IV 810 is intended to be used for treatments requiring coagulation of retinal tissue or the ciliary body, irradiation of ciliary muscle tissue and treatments in the tear duct containing coagulation or vaporization of soft tissue or bony structures.

The laser effect allows focused treatment of the disease area with minimal impact on the surrounding tissue.

The diode laser FOX IV 810 is intended to be used for the following application fields and indications:

- **Glaucoma** – forms of increased intraocular pressure (IOP)
  - Cyclophotocoagulation in thermal (CPC) or subthreshold mode (µCPC)
- **Retina**
  - Photocoagulation of retinal tissue in retinopathy or retinopathy of prematurity
  - Endophotocoagulation of retinal tissue in case of retinal detachments, retinal tears, retinal breaks, retinal bleedings, retinal breaks or neovascularization
- **Lacrimal duct**
  - Stenosis in lacrimal passage
  - Dacryocystorhinostomy (DCR)

1.2.2.1 Indications and contraindications

Indications

Medical Application indicated	**Indication** from clinical data	**Side and adverse effects**	**Contraindications**
Glaucoma	Treatments requiring irradiation or coagulation of ciliary body in a transscleral application like: - µCPC (application in subthreshold mode targeting the ciliary muscle)- CPC (application in thermal mode to coagulate parts of ciliary body like ciliary processes	pain, discomfort, inflammation, abrasion/lacerated conjunctival or scleral tissue, subconjunctival hemorrhage and swelling. hypotony, (anterior) uveitis, loss or decrease of vision, conjunctival or scleral burns, atrophy or phthisis bulbi, conjunctival hyphema, pop-effect'-tissue disruption, corneal and (cystoid)-macular edema, long lasting anterior chamber inflammation, necrotizing scleritis, scleral thinning, hyposphagma, choroidal hemorrhage, choroidal detachment, anterior chamber flare reaction, hemorrhage of anterior chamber or vitreous body, pupillary distortion, mydriasis, Iatoritis, atonic pupil, neurotropic corneal ulcers (keratitis) Side and adverse effects are less for µCPC treatment than CPC. The risk for inflammation is increased if the swiping motion in µCPC application is interrupted (stop and go).	Inflammation or infection of the eye Forms of Glaucoma not associated with increased ocular pressure (low-pressure glaucoma) Treatment of 3 and 9 o'clock position due to neurovascular structures Areas with implanted filtering or drainage devices as well as any area of thinned sclera or if there is an existing superficial bleeding, which might absorb the laser radiation.
Retina	Treatments requiring coagulation of retinal tissue like • retinopathy, • retinal detachments, retinal tears, • retinal breaks, • retinal bleedings, • or neovascularization	- infection (endophthalmitis), discomfort, pain, bleeding, loss or decrease of vision, anterior chamber reaction/hemorrhage, cataract, vitreous and retinal hemorrhage, choroidal/retinal detachment, choroidal neovas-cularization, pinpoint break of Bruchs membrane, macular dragging, proliferation - normal conventional (non-laser) operation collateral side effects	-
Lacrimal Duct	Treatments requiring coagulation or carbonization/vaporization of tissue, bony structures or blood like tear duct stenosis or DCR (dacryocystorhinostomy)	- Pain, Swelling, Stenosis, Emphysema, false passage, heating of cannula, edema, bleeding, charring, inadequate osteotomies, ecchymosis, swelling, hemorrhage, thermal injury, infection, surface irritation, conjunctival scarring/granulation, synechia - higher failure rates	Unable to remove thick bones

General Contraindications

The FOX IV 810 is not intended to be used for interventions of the central circulatory system (arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior).

Furthermore, the FOX IV 810 is not intended to be used for treatments on the central nervous system (brain, meninges and spinal cord).

1.2.3 Principles of operation and mode of action

The power output of the FOX VI 810 laser can be adjusted peaking an output of 8 W (DCR) or 3 W for posterior and anterior settings.

Higher output power, usually used in lacrimal duct treatments, leads to carbonization or vaporization of tissue. Carbonization allows the physician to remove the tissue, vaporization makes it possible to separate it.

At low power output, which is present in Ophthalmology, heating of tissue or blood results in enzyme denaturation and coagulation of tissue.

The FOX IV 810 is a fiber guided laser. It is used with sterile single use probes which allow current transmission of the laser beam at 810 nm and aiming beam to the target tissue. The Probes can be used in contact and non-contact mode.

The FOX IV 810 is only allowed to be used with authorized Probes by A.R.C. Laser GmbH.

For Glaucoma treatment the approved probes are the Glaucoma Probes (Cyclo Probe: REF HS11025_VE5 and µCPC Probe: REF HS11036_VE5)

For guiding the emitted radiation to the retinal tissue with the purpose of endocoagulation, approved probes are the Endo Probes straight or curved in 23 G and 25 G (REF LL13006s_VE5, LL13010s_VE5, LL13015s_VE5, LL13025s_VE5).

The FOX IV 810 laser can also be coupled with laser-indirect ophthalmoscope (LIO) to coagulate retinal tissue in case of retinopathy.

For DCR treatment the DCR Probe (REF LL13069s_VE5) is approved to guide the laser radiation to the bony structure in the lacrimal duct.

A T T E N T I O N

The device may only be operated by specially trained personnel who are experts in the medical effect and possible dangers of the device. The personnel should have the necessary skills to use the laser in accordance with this manual.

When not in use, the device should always be protected against unqualified use.

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1.3 Theory and Technical Set-Up

The FOX IV 810 is a diode laser with a wavelength of 810 nm. Thanks to special manufacturing processes for the semiconductor material, the A.R.C. Laser GmbH is able to provide this laser device for a certain wavelength. The maximum output power is 8.0 W respectively 3.0 W for anterior and posterior settings. All settings can be adjusted by the user via the display. (See Chapter 6.4)

Due to their nature, laser diodes are very sensitive to voltage fluctuations.

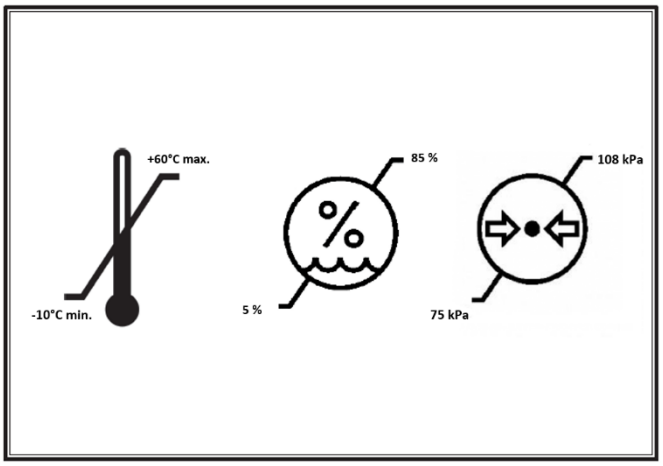
The structure of the internal circuitry of the device as well as the usage of a special power unit supply and battery build up a buffer which absorbs any fluctuations. The high current needed to operate the laser diode is generated by a current driver in the electronics.

The laser radiation is focused into a quartz fiber via a deflecting mirror and a coupling lens. This laser fiber is part of the ophthalmological probes. It has a power transmission in the range of 80 to 90% of the laser power.

2 Transport and Storage

We at A.R.C. Laser GmbH will make sure that the device is packed and transported with the greatest possible care.

Before unpacking the laser, please check the packaging for damage and report any damage immediately to the shipping agent and A.R.C. Laser GmbH. Only remove the packaging in the presence of a representative of the carrier. Make a list of the damaged parts and have this list signed by the courier.



The device should never be exposed to temperatures below -10°C, or above +60°C. The air pressure during transport must be between 1080 hPa and 750 hPa. During storage, a temperature range of +5°C to +40°C must be maintained. The relative humidity during transport and storage must be between 5% and 85%.

A T T E N T I O N

If the laser is transported or stored at a temperature below +5 °C, it can be damaged when starting. Unpack the laser and leave it at least 4 hours at normal room temperature so that the system reaches room temperature.

2.1 Shipping and unpacking the device

Unpacking and installation of the device are usually carried out by an authorized technician or authorized representative of A.R.C. Laser GmbH. After the installation and the correct connection of the device, the technician will put the device into operation and explain its functions and all required safety procedures.

The FOX IV 810 is delivered in a simple and easy to use carrying case for storage and transportation. The carrying case is protected by a special outer box.

The carry case offers space for e.g. the following:

*if ordered

Level 1:
- Accompanying documents, label, etc.
- Laser Safety Goggles*

Level 2:
- FOX IV 810 Laser
- Power supply
- Foot switch

2.2 Return Shipments

If you ship the device back to A.R.C. Laser GmbH, please use the carrying case and the covering box for transportation and shipping.

3 Setup / Installation

3.1 Installation Site

Ensure to provide a suitable location for the device before it is set up!

The FOX IV 810 should be operated in an easily accessible place. The laser should not be operated near a heater as the air cooling works best when the ambient temperature does not exceed 35° C. Higher temperatures can cause the device to switch off due to overheating. A place of installation in direct sunlight can cause an early shutdown and must be avoided in any case.

If the temperature is too low (below 16 °C), the device cannot be started in order to prevent condensation on the internal optics; this could result in permanent damage to the laser.

The device should be set up so that the laser beam is not aimed directly at a door, window or reflective material.

The wiring must be installed in such a way that there are no tripping hazards or other hazards.

The air humidity is monitored internally and must be below 75%.

The dust protection cap (red plug) should be connected to the fiber port, as soon as there is no fiber/ probe connected.

When the device is not in use, it should be stowed in the transport case.

3.2 Room Requirements

The FOX IV 810 is a categorized as a class 4 laser. To provide the most possible safety, the following requirements must be met for any room a class 4 laser is operated in. (according to EN 60825-1)

3.2.1 Marking of Access Points

All entrances must be clearly marked to prevent unintentional or unauthorized entry, which can lead to hazards.

- Please attach the laser warning sign (triangle with laser symbol) as well as the wavelength marking at each access door.
- A warning lamp must be attached above each access door, which always has to be turned on, when the laser is in operation.
- Unintentional entry into the room without safety glasses shall be avoided.
- Please store the laser safety goggles at the entrance of the room and make sure they are readily accessible.

3.2.2 Window shielding

It must be ensured that no laser radiation can escape the room. In particular, windows need to be covered with suitable materials. For any question or in case of any doubt, please contact your local A.R.C. Laser GmbH authorized dealer, or contact directly A.R.C. Laser GmbH at any time.

3.2.3 Reflecting surfaces

To avoid any danger caused from reflected radiation direct or scattered, reflecting surfaces must not be present in the room during operation.

Such surfaces may include:

- mirrors
- pictures behind glass
- chrome surfaces
- windows

Such surfaces should either be removed or covered with suitable matt-type material. In the area around the laser, use only matted, non-reflecting as well as non-flammable instruments and materials.

3.3 Electrical connection

The laser is operated with a DC voltage of 19 V through an external power supply or the internal rechargeable battery pack. A.R.C. Laser GmbH developed this internal battery pack specifically for this device. Only use battery packs and power supplies authorized 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 (50/60 Hz).

3.4 Battery pack

The FOX IV 810 is powered by a lithium-ion battery. If handled incorrectly, the battery pack can burst, cause a fire or even chemical burns. Please note the following points.

- Do not disassemble. Dispose of damaged or leaking batteries in an environmentally friendly manner. Never reuse the battery.
- Never open, crush or drop from a great height or solder anything. Never step on the battery pack. Never strike it with a hard object.
- Do not short circuit and do not allow metal objects to contact the battery.
- Do not expose to high temperature above 60°C such as indirect sunlight or any place located in the sun. The charging temperature must be between 0°C and 45°C. The battery may only be charged with the corresponding power supply.

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

After the life span the battery back is special waste. Disposal may only be carried out via an approved return system. The product shall not be disposed in the household waste.

To ensure that the battery will be disposed properly, hand over the product at end-of-life to the applicable collection point for the recycling of electrical and electronic equipment.

4 Safety Information

4.1 General

The FOX IV 810 laser is a precise working instrument for medical applications. The system has been carefully developed and tested before shipping. In order to offer you and the operating personnel every possible protection, we recommend that you read this section of the operating manual carefully.

The FOX IV 810 laser device is a laser class 4 according to EN 60601-2-22, EN 60825-1 respectively.

Class 4 in the standard describes high-energy lasers and therefore special measures must be taken prior to commissioning in order to ensure safe and trouble-free work with the device. In particular, it must be ensured that the eyes and skin of the operator, the patient and third parties are protected. Laser safety goggles are to be used for eye protection.

The following explanations are not exhaustive. All users of laser devices should enclose the applicable legal regulations and provisions with the device and inform the personnel accordingly. We refer here in particular to the publication “Operation of laser equipment and accident prevention regulations for laser radiation”, which is also available from us. The Medical Device Operator Ordinance (MPBetreibV) also applies.

If the device is to be operated outside of Germany, provisions of the American National Standard Bureau ANSI Z136.3-2018 "American National Standard for the Safe Use of Lasers in Health Care Facilities" and ANSI Z136.1-2014 "American National Standard for the Use of Lasers” must be respected.

This manual is limited to the operation, maintenance and control of the device. The manual is not a guide for the treatment of diseases that can be remedied by lasers.

With regard to supplied accessories such as fibers and probes, the safety, operating and maintenance instructions in the relevant manuals must be respected.

The A.R.C. Laser GmbH cannot be held responsible for damage or damage resulting from improper use.

The warranty of the device expires if the laser has been opened (even partially), modified or repaired by unqualified personnel.

4.2 Eye Safety

As a safety measure against direct or indirect laser radiation, it is necessary that all persons in the room wear laser safety glasses.

When using the laser, only laser safety glasses that are designed for the respective wavelength and on which the CE mark and the appropriate protection class are noted, may be used.

The protection level (LB) for laser safety glasses is determined by the standard EN 207 (personal eye protection). The optical density (OD) describes the attenuation of the radiation through the glasses.

There are different types of laser safety glasses that also allow spectacle wearers to wear a tight goggle on top of their own which are protective to all sides. In particular, the scattered radiation that does not directly come from the front of the eye may present risks resulting from internal reflections on the glasses. Therefore we encourage you to wear laser safety glasses which also guarantee a full protection to the side parts.

A.R.C. Laser GmbH offers a laser safety glasses for FOX IV 810 – *AS01033* with following properties:

- 810 nm: Protection level class DIRM LB 6/ Optical density OD 6+
- full protection to the side parts
- wearable on top of glasses

When using a microscope, either laser safety goggles can be worn or it is possible to install an eye safety filter firmly into the beam path of the microscope. Please note that when using a beam splitter in the microscope, the eye safety filter is installed below the beam splitter to protect all observers at same time.

The protection level (LB) for eye safety filters is determined by the standard EN 60825-1 (safety of laser equipment). The optical density (OD) describes the attenuation of the radiation through the filter.

The following eye safety filters from A.R.C. Laser GmbH are suitable fort the FOX IV 810 and can be seen as external accessories of the laser system:

- BG03017 – ZEISS Eye safety filter 800 – 1100 nm / *protection level D LB8/ Optical density OD5*
- BG03018 – LEICA Eye safety filter 800 – 1100 nm / *protection level D LB8/ Optical density OD5*

The eye safety filters must be firmly installed in the respective microscope and checked by an employee of A.R.C. Laser GmbH or an authorized representative during installation.

A T T E N T I O N

Never look directly into the laser beam or in the light reflected by the laser beam. This will cause damage to your eye.

4.3 Electrical Protection

Never remove any housing parts. Any service to the device or its accessories may only be carried out by authorized personnel by A.R.C. Laser GmbH.

The room in which the laser is operated should be kept dry. If cleaning is necessary, please make sure the floor is dry before using the laser.

A T T E N T I O N

Never work with the device if you notice any visible damage.

Never work with the device if you notice any visible damage on the power plug, or if you notice, that the wires have become exposed.

4.4 Explosion and Fire Hazard

Never work with the laser near 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. There is a fire or explosion hazard if the laser is used in the presence of flammable materials, solutions, or gases or an oxygen-enriched environment.

4.5 Protection against Undesired Radiation

By the usage of a foot switch, the FOX IV 810 emits radiation. The foot switch should never be outside the area of the attending doctor. It is forbidden for anyone other than the attending doctor to trigger the foot switch.

Especially in operating theaters where there are multiple foot switches, it is important to ensure that the laser foot switch is close to the laser device.

4.6 NOHD Safety Distance

The NOHD (Nominal Ocular Hazard Distance) is the distance at which the irradiance is equal to the exposure limit value of the cornea of the eye. The NOHD thus identifies the danger area within which health damage to the eye is to be feared if the laser beam is directly and unprotected.

The NOHD is calculated according to EN 60825-1 and taking into account the permitted power fluctuations (+/- 20%) according to EN 60601-2-22 using the following equation:

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

Calculation of the maximum permissible irradiation (MPE) with an exposure time of 100s and a beam divergence φ=25.4°.

The result is:

MPE:	$\mathbf{31,51\ \frac{W}{m^2}}$
NOHD:	$\mathbf{1,41\ m}$

4.7 CE Regulations

The laser system FOX IV 810 has been approved by the notified body in accordance with the European directive 93/42/EWG,2007/47/EG and 2017/745 (MDR). Therefore, the device bears the CE mark **CE 0123**.

The device has been checked for electrical compliance as well as for mechanical safety. All parts used by A.R.C. Laser for the FOX IV 810 comply with CE regulations or have been tested for approval or suitability by the notified body.

Additional devices that you attach to the device require approval from an official test center. Changes to the device or interventions on you part will void the approval and warranty.

A device book and the test approval number are enclosed with the device.

4.8 RoHS3 Regulations

A.R.C. Laser GmbH operates worldwide and considers the protection of the environment and natural resources as a corporate obligation. Based on individual tests, we can confirm that to the best of our knowledge, the products of A.R.C. Laser GmbH do not contain any substances in any concentration, whose placing on the market is prohibited according to the applicable requirement of Directive 2015/863/EG (RoHS3).

4.9 Protective Housing

The FOX IV 810 laser system has a protective housing. It prevents radiation from the laser from escaping and protects users from touching live parts. This housing shall not be removed.

4.10 Connector and Plugs

Following connectors can be found at the rear panel of the device.

- Foot switch
- AUX 1
- Door-Interlock
- Flash drive port
- AUX 2
- Power supply

The connector may only be used as follows:

Socket	Description	Notes	Colour
Foot switch	Connection of the A.R.C. foot switch – BG03515	Only use A.R.C. Laser approved accessories	Blue
AUX 1	Signal for warning light	Isolated	Orange
Door Interlock	Connecting the door-interlock switch	-	Red
Flash Port	Flash drive connection	Used for service tasks by service personnel and by the device user for personal settings backup.	Yellow
AUX 2	External Powermeter	Currently not in use	Green
Power supply	Charging device PS01013	To charge internal batteries	-

4.11 External Interlock Plug

A door interlock switch is required by the accident prevention regulation. The device is equipped with an interlock connector as standard, which can be replaced by a door interlock switch. The Laser radiation switches off and device switches to Stand-by mode when the door is opened. In addition, the laser cannot be switched to the READY mode when the door is open. An error message appears on the control panel. When the door is closed, the error message disappears and the laser can be switched to READY again.

4.12 Safety shutter / Aiming beam

The FOX IV 810 has an internal safety shutter which is opened up mechanically when a fiber is inserted into the fiber port. As soon as a fiber is connected to the laser correctly, the laser can be set to READY mode by pressing the READY button/ LED.

As soon as the laser is set to READY mode, the aiming beam will appear. The aiming beam is a low-level laser.

4.13 Manual Reset

When an error occurs, the device changes into the STANDBY mode. In that case, you should switch the laser off and on by using the ON/OFF Button on the left. The restart should fix the error due to the automatic recalibration. Please refer to chapter 8.5.5 to identify the error messages.

If the error still occurs, this can only be resolved by qualified personnel. Please contact your local A.R.C. Laser GmbH authorized dealer.

4.14 Reset due to power failure

If the device is disconnected from the mains accidentally - e.g. due to a power failure – it will continue to work without problems, if the battery is sufficiently charged.

If the battery is not sufficiently charged, the device will turn off. In such a case, proceed as follows:

- Plug it into the mains.
- Start the device.

The system recalibrates and deletes all unsaved settings. If there is still an error, it can only be corrected by trained personnel. Please contact the service of A.R.C. Laser GmbH in this case.

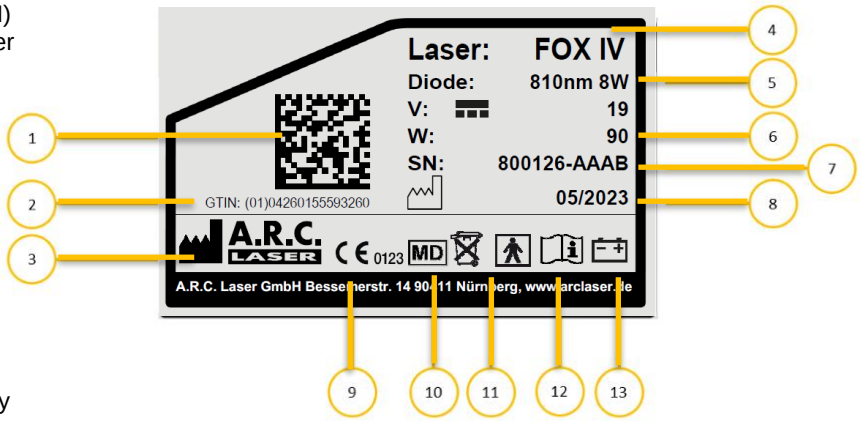
4.15 Stickers and Labels

The FOX IV 810 has various warning labels in accordance with the European and world-wide directives, intended to prevent any users to become exposed to laser radiation because of improper use. Following an example is given to explain the labels:

DEVICE STICKER FOX IV 810

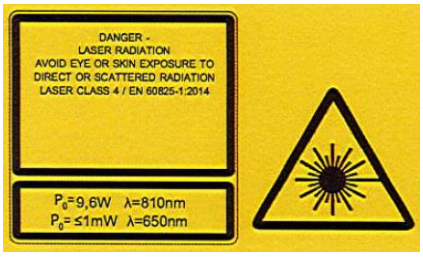
(Located on the inner side of the cover stand)

1. Unique Device Identifier (UDI = Date + SN + GTIN)
2. Global Trade Item Number (GTIN)
3. Manufacturer
4. Laser type and name
5. Wavelength and power
6. Power input
7. Serial number (SN)
8. Production date
9. CE Sign
10. Do not dispose in household waste
11. Applied part type BF
12. Follow User Manual
13. Device usable with battery



WARNING LABELS

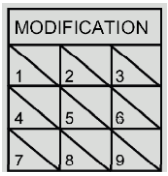
Warning label laser radiation:
Wavelength dependent
(Outer side foot stand)



Warning label fiber port
(on top of the device)

OTHER STICKERS:

Read manual.



Modification-sticker shows the current modification level of the device.

4.16 Operating Conditions

The medical laser FOX IV 810 is not suitable for use in connection with flammable gas mixtures of any kind.

The device is not approved for operation at altitudes above 2,000 m above sea level and only for an air pressure between 1080 hPa and 750 hPa.

The following environmental conditions must be met:

- Ambient temperature: 16 to 35 ° C
- Humidity: <75%

4.17 Electromagnetic Compatibility

The FOX IV 810 laser complies with the EMC requirements according to DIN EN 60601-1-2. Guidelines and manufacturer's declaration are described in chapter 10.

A T T E N T I O N

This device should not be operated immediately adjacent to or stacked with other devices.

This device should not be operated immediately adjacent to portable or mobile wireless communication devices or stacked with portable or mobile wireless communication devices.

For recommended separation distances from portable or mobile wireless communication devices, please refer to Chap. 10.3 Electromagnetic Immunity (2) and 10.4 Recommended separation distances.

RFID systems shall not be used at separation distances less than 0.15 m from the device. Otherwise, degradation of the performance of this device could result.

5 User Information and System Introduction

5.1 Technical Introduction Training

During the installation of the device, instruction is given by an A.R.C. Laser GmbH employee or an authorized representative.

This first instruction essentially relates to the technical use of the device. In addition, essential security-relevant points are dealt with. During the briefing, all persons working in the vicinity of the laser should be present.

5.2 Laser Safety Training

The FOX IV 810 diode laser is designed for medical applications. Only physicians who have been instructed in its operation may use the device. A.R.C. Laser GmbH recommends attending additional seminars to train working with different laser systems.

The A.R.C Laser employee or authorized representative who installs the device will also offer additional training for accompanying personnel. Subject of this briefing are the usage of laser safety goggles and laser safety in particular.

A.R.C. Laser GmbH has a list of recommended courses as well as laser safety courses. These can be requested from us any time.

5.3 Medical Introduction Training

During the instruction of the device, the A.R.C. Laser employee or authorized representative will only give a general overview of the medial applications.

If necessary, there is the possibility to take part in a training course with an experienced physician. Please contact your local A.R.C. Laser authorized representative, or contact us directly.

5.4 Device Parts and Accessories

The basic FOX IV 810 system includes the following parts:

Part-Name	Description	Article-No.
Foot Switch	Foot switch with hinge and cable	BG03515
Power Supply	Power supply, complete	PS01013
Door interlock	Door interlock, angled	KB11024
Carrying Case	Metal case for storage and transportation	VP03500
Outer package	Carton for shipping	VP03101

Laser safety goggles are not part of the basic equipment and are listed separately on the purchasing order. We recommend to order at least three laser safety goggles per device (surgeon, nurse, patient, etc..).

Furthermore, the FOX IV 810 can be adapted to different surgical microscopes. For this purpose, various eye safety filters are available and can be ordered optionally:

Part-Name	Description	Article-No.
Laser Safety Goggles	Laser safety goggles	AS01033
Eye safety filter for microscope	Eye safety filter 800-1100 nm; ZEISS type	BG03017
	Eye safety filter 800-1100 nm; LEICA type	BG03018

For information about other accessories, please contact A.R.C. Laser GmbH or the responsible sales partner.

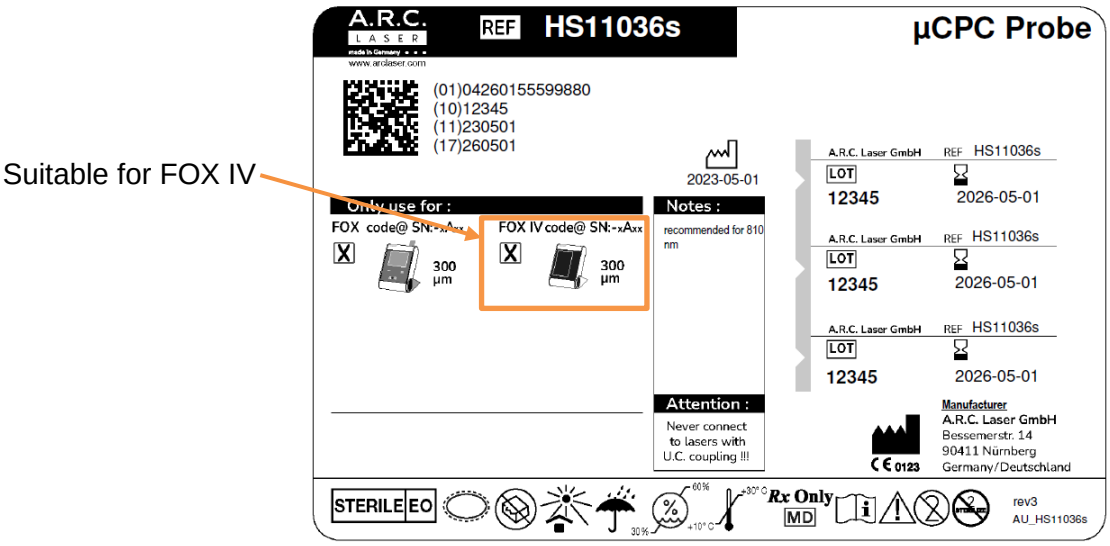
A T T E N T I O N

Only spare parts and applicators which are approved by A.R.C. Laser GmbH are to be used with the device. Accessories that have not been approved can significantly impair the safety and reliability of the device.

The use of accessories, transducers and services other than those which A.R.C. Laser GmbH has determined or provided, may result in increased electromagnetic interference or reduced electromagnetic immunity of the device and could lead to incorrect operation.

5.4.1 Fibers and Probes / Applicators

The FOX IV 810 is a fiber-guided laser. Various probes are used to guide the laser radiation to the treatment area. The appropriate lasers are shown on the label of the applicator. For more information about suitable applicators, please contact A.R.C. Laser GmbH or the responsible sales partner.



A T T E N T I O N

The applicators are glass fibers that can break easily. Handle them with the necessary care when removing them from the packaging and during treatment to avoid fiber breakage. A broken fiber cannot be used for treatment.

5.4.2 Fiber port FOX IV 810

The FOX IV 810 has a fiber port at the head of the device, intended to incorporate the patented A.R.C. Laser click plug for a wide range of hand pieces and applicators.

The 300 µm port is compatible with Endo Probes, Glaucoma Probes and DCR Probes.

300 µm Probes are marked with a *white bending protection* stabilizer right after the fiber plug.

Please follow the instructions in chapter 8.5.4, if no aiming beam is visible in READY mode.

A T T E N T I O N

Since the aiming beam takes the same way through the laser transmission system as the working beam, controlling its appearance is a good way to check the integrity of the laser transmission system. The aiming beam will appear as soon as the device is set to READY mode. If the aiming beam does not appear at the distal end of the laser transmission system, its intensity is weak or if it looks diffuse, the laser transmission system might be damaged. Never use an applicator if the package is damaged or the aiming beam has an irregular shape or is not visible.

6 Operation

This part of the manual describes the technical aspect of the device functionality without addressing medical applications.

Settings and adjustments should only be made in accordance with the operating instructions. Changes or settings that are not described in this manual can lead to malfunctions.

During the treatment, the laser is in READY mode. If the treatment needs to be interrupted, the laser has to be switched to STANDBY mode by pressing the READY button/ LED. The device must always be switched off or locked when unattended to prevent operation by unauthorized third.

The front panel of the device consists of following elements:

Fiber port

The fiber port is used to connect different probes with the patented A.R.C. Laser “click” connector – 300 µm.

For safety of the fiber port, a dust protection is permanently connected to the device.

A T T E N T I O N

Applicators for the FOX IV 810 are labeled with a FOX IV 810– 300 µm pictogram at the product label.

Laser emission signal LED

The laser emission signal shows, if laser radiation is emitted. If radiation is emitted, the LED lights up red.

Laser stop

The Laser Stop button interrupts the READY mode. If the Laser-Stop is activated the device cannot be used and a warning message appears. The laser is immediately deactivated and can only be activated if the warning message is confirmed.

Power button

The device is switched on by pressing the power button down for several seconds until the System LED begins to flash green. To turn the device of, press the Power button.

Touchscreen

With the touchscreen the user is able to change the settings of the laser, like power/ pulse duration or pulse pause of the system. Also, system related settings can be changed, like intensity of the aiming beam, brightness of the display, language, etc..

Side Bar

The side bar has Indications for the status of the ambient humidity, the ambient temperature and the state of the charging level of batteries. In case the temperature or humidity inside the device are out of range, the symbols will light up.

It contains:

Humidity/Temperature LED

When starting the device, it will begin a checkup for humidity and temperature. Whenever one of those parameters are out of the allowed range, the corresponding LED will light up and the device is prevented from starting. In this case a restart is necessary and possible when the device has reached the allowed ambient conditions again.

System LED

The System LED shows the status of the device. If the LED flashes in green, the system starts. If the LED lights up permanently in green, the device is ready to use.

Battery symbol

The battery symbol shows the current charging level of the battery through enlightening of a varying number of LEDs. Charging of the battery is indicated by flashing of the LEDs.

Settings

This button allows to enter system settings. Detailed information in chapter 6.4.

READY button/ LED

When starting the laser, it is in STANDBY mode. The READY button/ LED lights up green. When switched to READY mode, the button color will change to orange. It will stay orange as long as the laser is in READY mode. As soon as it is set to STANDBY mode again, it will turn green again. The mode can be changed by pressing the button.

Plus/Minus-button

The plus and minus buttons can be used to change the laser settings.

A T T E N T I O N

Use of the controls or adjustments other than those specified herein may result in hazardous radiation exposure.

6.1 Preparation

A power supply unit is enclosed with the basic system, which can be connected to the power supply port at the rear panel. It can be used as standard power supply or charge the internal battery. Power supply input voltage ranges between 100V and 240V. For security reasons, the FOX IV 810 is only allowed to be operated with the power supply distributed by A.R.C. Laser.

Please check the following key points when preparing the device for operation, in order to avoid unnecessary troubleshooting or even malfunctions.

- Is the battery charged or is the mains cable at the rear panel connected? – Only connect the power supply if the device is switched off.
- Has the plug for the external interlock been connected? – or, if applicable: Has the door interlock contact been connected to the laser?
- Is an applicator connected? If so, disconnect the applicator during start-up
- Are the applicators that are to be used, free of any damage?
- Is there a sufficient number of protective goggles ready to be used?
- Has the foot switch been plugged in?

It is recommended to place the FOX IV 810 on a dry, solid surface. Make sure that the laser system is standing securely.

A T T E N T I O N

All warning lights outside the treatment room must be switched on before the laser starts to operate. The doors have to be marked accordingly, visible from outside with the warning signs.

6.2 Starting the Device

Start the device by long pressing the power button

The Status-LED flashes in green and is permanently lit, when the laser is ready to use.

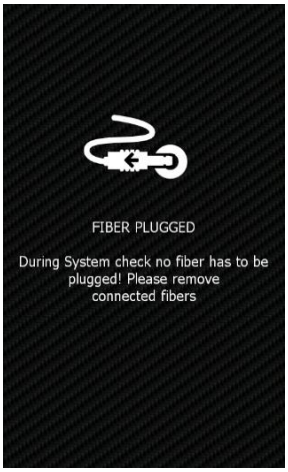
The FOX IV 810 is switched on by pressing down the Power button on the left side of the device for several seconds until the System LED starts to flash green.

When starting the FOX IV 810 laser, it begins with internal system checks and calibration of the capacitive touch screen. After about 10 seconds the start screen will appear. **Do not touch the screen during this stage or an error can appear!**

In case the temperature or humidity inside the device are out of range, the corresponding symbol will light up. The device may only be restarted when it has acclimatized to the room.

When a fiber is connected before switching on the device or inserted during the start-up, following warning occurs:

In this case, unplug the fiber.



A T T E N T I O N

The FOX IV 810 should not be operated for more than five hours at a time. Restart the laser after five hours at the latest so that it can carry out the system check during the start routine. This ensures that undetected error cannot occur.

6.2.1 Entering the password

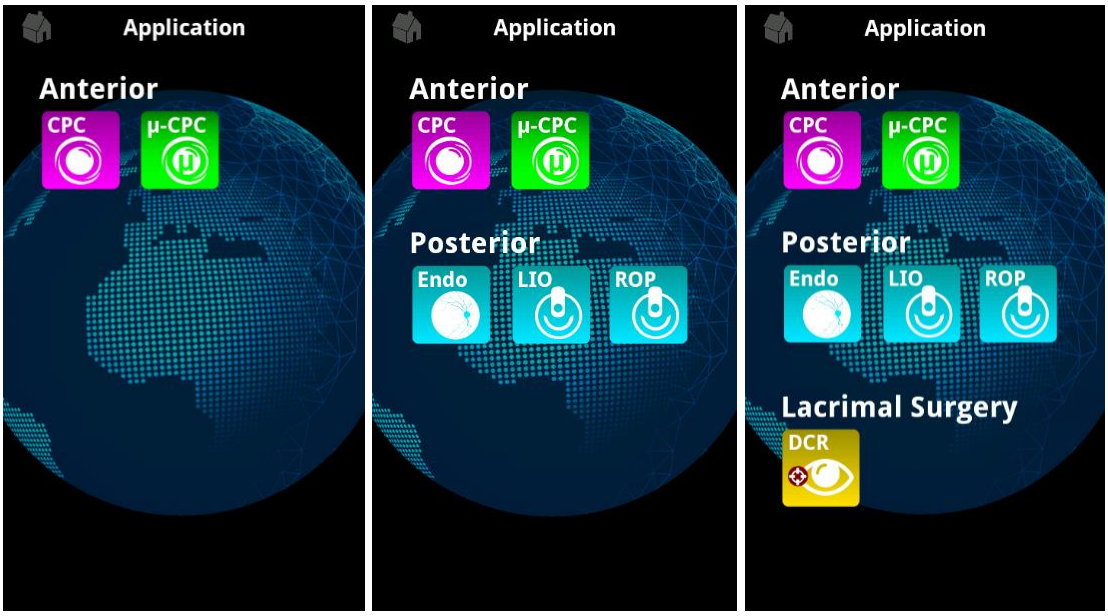
Once the system check has been completed, the locking screen will appear. To continue, the password has to be entered. In the factory setting the password is “**0000**”. See chapter 6.4 to modify the password.

Since this password protects against unauthorized operation of the laser, it should be changed immediately.

6.2.2 Application Menu – select treatment

After entering the correct password, the application menu will appear.

Depending on the configuration of the device and the intended use, one of the following three screens will be displayed:



Up to three application areas can be chosen:

Anterior, **Posterior** and **Lacrimal Surgery**

By clicking the screen the desired treatment can be chosen. Different colors ease the distinction of applications.

Anterior Appications - Glaucoma Treatment:

Select CPC for Cyclophotocoagulation or µCPC for Cyclophotocoagulation by the use of microsecond pulses.

Posterior Applications – Retina Treatment:

Select Endo if endophotocoagulation of the retinal tissue by the use of Endo Probes is desired.

For non-invasive retina coagulation by the use of LIO, please select

LIO – Laser Indirect Ophthalmoscope

ROP – Treatment of Retinopathy of Prematurity by the use of LIO.

For LIO applications, A.R.C. Laser offers Laser Indirect Ophthalmoscopes. Please contact your distributor for more details and pay attention to the user manual of LIO.

A T T E N T I O N

Only LIO provided by A.R.C. Laser can be used with FOX IV 810.

Lacrimal Surgery – DCR Treatment:

Select DCR for Laser- assisted Dacryocystorhinostomy by the use of DCR Probes. Please consult the User Manual of Fibers and Probes for the correct use of the Probes.

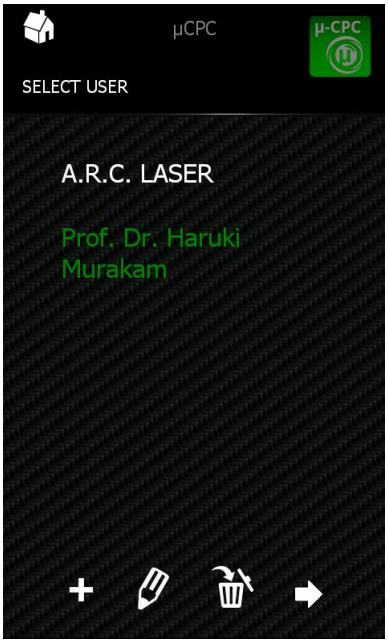
6.2.3 Select or add a user profile

After choosing the desired treatment by clicking, the user selection screen will appear. Every surgeon can adjust the settings according to the preferences and save those settings in his/her own user profile.

The A.R.C. Laser - user contains all intended settings for the specific application. Predefined A.R.C. values cannot be changed or deleted.

Select user profile:

By touching a name, it will be selected and change its color to green. The selection can be confirmed by either double-clicking it or pressing the arrow in the lower right corner. As soon as the user is confirmed, the main application mask will be visible.



Add user profile:

To add a new user profile, press the plus icon (+) in the lower left corner.

Name, first name and title can be added and confirmed by pressing the arrow symbol next to the name.

It will appear as soon as a name has been entered.

Edit user profile:

Select the profile that needs to be edited.

Use the pencil icon in the lower left corner to change the name.

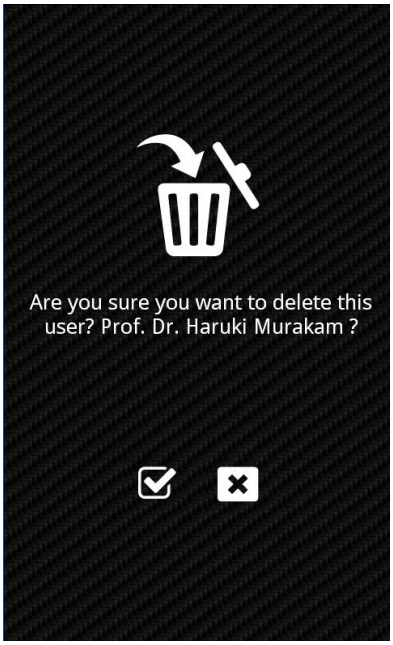
After correcting the name, confirm the input by pressing the arrow symbol next to the name.

Delete user profile:

Select the profile that needs to be deleted.

To delete an existing user, press the bin at the bottom.

Predefined A.R.C. values cannot be changed or deleted.



A T T E N T I O N

The pre-programmed laser parameters for the single applications have to be understood as mere recommendations. This does not exempt the surgeon from checking the values according to his knowledge and the desired interaction with the tissue. If necessary, the preset values must be adjusted.

6.3 Programs and Settings

6.3.1 Universal buttons

The following buttons can be found in every selected application:

6.3.1.1 Back to Application menu

To return to the application menu, tap on the house symbol in the upper left corner of the display. This will directly open the screen for the selection of the application

6.3.1.2 Lock screen for Access Protection

Unauthorized access of a laser can lead to significant harm. Activate the locked screen by pressing the lock icon. The password screen will be displayed. To unlock the system and continue working, enter the password.

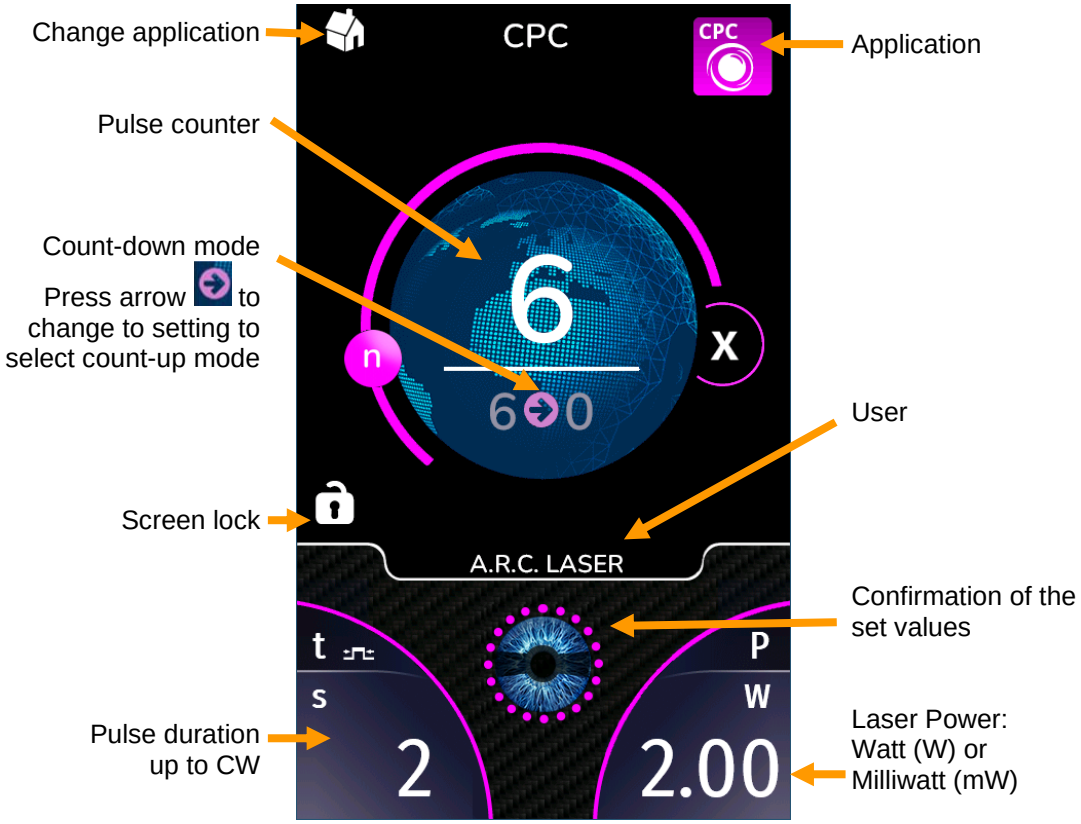
6.3.1.3 Save values

As soon as laser parameters were changed the flash-disk icon appears at the display. To save the changed values, press this button.

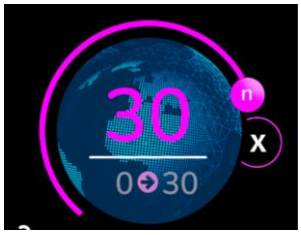
Values and presets of the A.R.C. Laser user can’t be changed or saved.

6.3.2 CPC – Cyclophotocoagulation

After choosing CPC appliccation the following screen will be displayed:



6.3.2.1 Change parameters



Parameters can be changed by clicking on the corresponding value. The selected value will turn purple and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

6.3.2.2 Pulse table

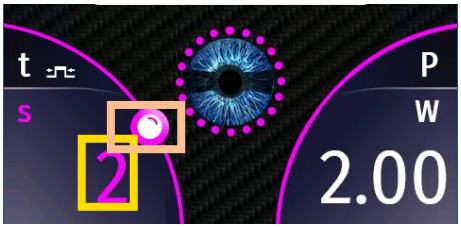
The pulse table shows all available pulse settings for the CPC treatment. All of these settings can be selected with preset A.R.C. User.

Pulse table for CPC:

µ	ms	s						µs	ms						s	
	500	1.0	2.1	1.0	2.1	3.2	4.3	/	/	/	/	/	/	/	/	/
	550	1.1	2.2	1.1	2.2	3.3	4.4	/	/	/	/	/	/	/	/	/
	600	1.2	2.3	1.2	2.3	3.4	4.5	/	/	/	/	/	/	/	/	/
	650	1.3	2.4	1.3	2.4	3.5	4.6	/	/	/	/	/	/	/	/	/
	700	1.4	2.5	1.4	2.5	3.6	4.7	/	/	/	/	/	/	/	/	/
	750	1.5	2.6	1.5	2.6	3.7	4.8	/	/	/	/	/	/	/	/	/
	800	1.6	2.7	1.6	2.7	3.8	4.9	/	/	/	/	/	/	/	/	/
	850	1.7	2.8	1.7	2.8	3.9	5.0	/	/	/	/	/	/	/	/	/
	900	1.8	2.9	1.8	2.9	4.0	5.5	/	/	/	/	/	/	/	/	/
	950	1.9	3.0	1.9	3.0	4.1	10	/	/	/	/	/	/	/	/	/
		2	3.1	**2**	3.1	4.2	CW	/	/	/	/	/	/	/	/	**SP**
CW = continuous wave								SP = single pulse								

Pulse duration

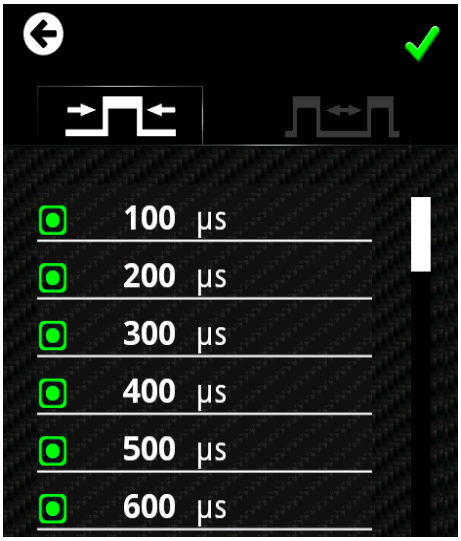
The CPC application provides only settings for the pulse duration. Pulse pauses cannot be modified as the laser is emitted in single pulse mode.



To change the pulse duration, press the current setting. It will turn purple and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

Individualisation of selectable pulse durations

The pulse duration-choices selectable in the duration settings can be individualized with the pulse table. To open the pulse table, select the pulse duration by clicking on the value, then double click it.

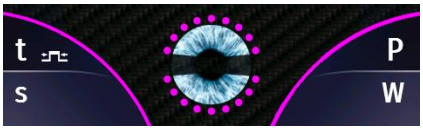


Green values are activated and can be chosen during the selection of the pulse duration. The selection can be saved by clicking the green hook on the top right corner.

Additional pulse durations not included in this list cannot be added. Included values cannot be deleted.

6.3.2.3 Confirmation of the set values

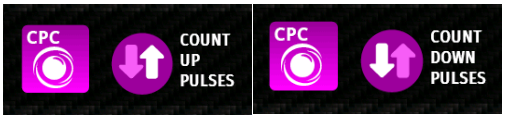
All adjusted values of the CPC application can be confirmed by taping the eye that is located between the pulse duration and power or waiting 5 seconds for confirmation.



6.3.2.4 Counter settings

During the treatment, the device will count the emitted pulses. It is possible to choose between counting up or counting down.

This adjustment can be attained by clicking the counting arrow in the center of the globe or via the settings button on the side bar. (Chapter 6.4)



Press the circle symbol with two arrows to switch the direction of counting.

6.3.2.5 Treatment

Position the patient. Press the READY Button/ LED, The aiming beam becomes visible. Start the treatment by pressing the foot switch after the laser parameters were checked once again.

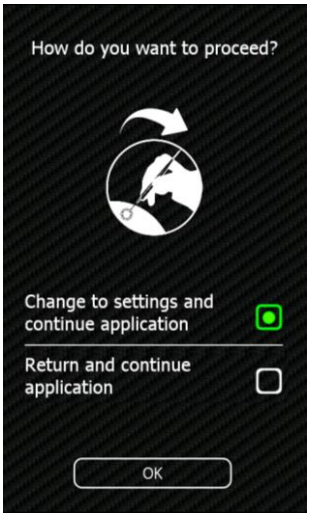
A T T E N T I O N

Any serious incident that occurs with this laser must be reported to the A.R.C. Laser GmbH and the responsible state authority.

6.3.2.6 Interrupt or stop the treatment

Interrupt the treatment

During the treatment it might be necessary to adjust different parameters in the device settings. To assess the settings, press the settings button (gear wheel at side bar). The following screen will appear:

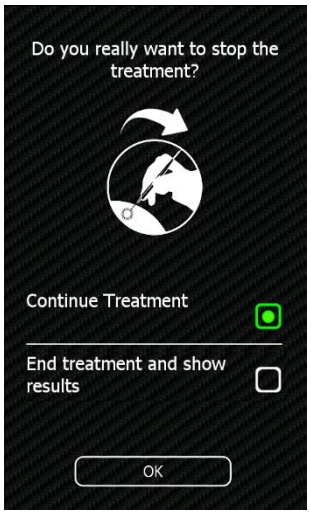


To get to the device settings, tick the first box “Change to settings and continue application” and confirm the choice by pressing OK. The device settings will be displayed. When leaving the settings, the treatment can be continued by pressing the READY button/ LED. Please note that the counter continues to run from the value reached and has not been reset. However, you have the option of adjusting the laser parameters accordingly before returning to ready mode.

To return to the application without changing settings tick the second box “Return and continue application” and confirm the choice by pressing OK. The treatment can be continued by pressing the READY button/ LED.

Stop the treatment

When the treatment is finished, it can be stopped by pressing the READY button/ LED. The following screen will appear:



To continue treatment, tick the first box “Continue Treatment” and confirm the choice by pressing OK. The treatment can be continued by pressing the READY button/ LED.

To end the treatment, tick the second box “End treatment and show results” and confirm the choice by pressing OK. The treatment protocol will be displayed.

6.3.2.7 The Treatment Protocol

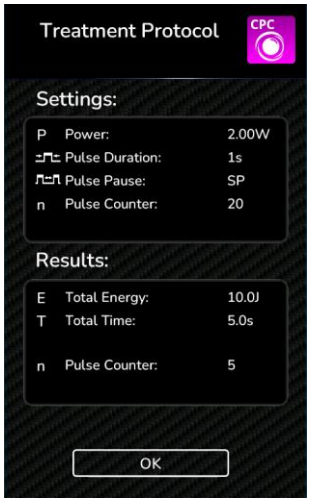
After running the CPC treatment, the system will show a treatment protocol.

In case the protocol has been closed accidentally it can be recalled. Press the gear symbol to attain the settings then click onto the info button.

"Show the last treatment" is now availed to be selected.

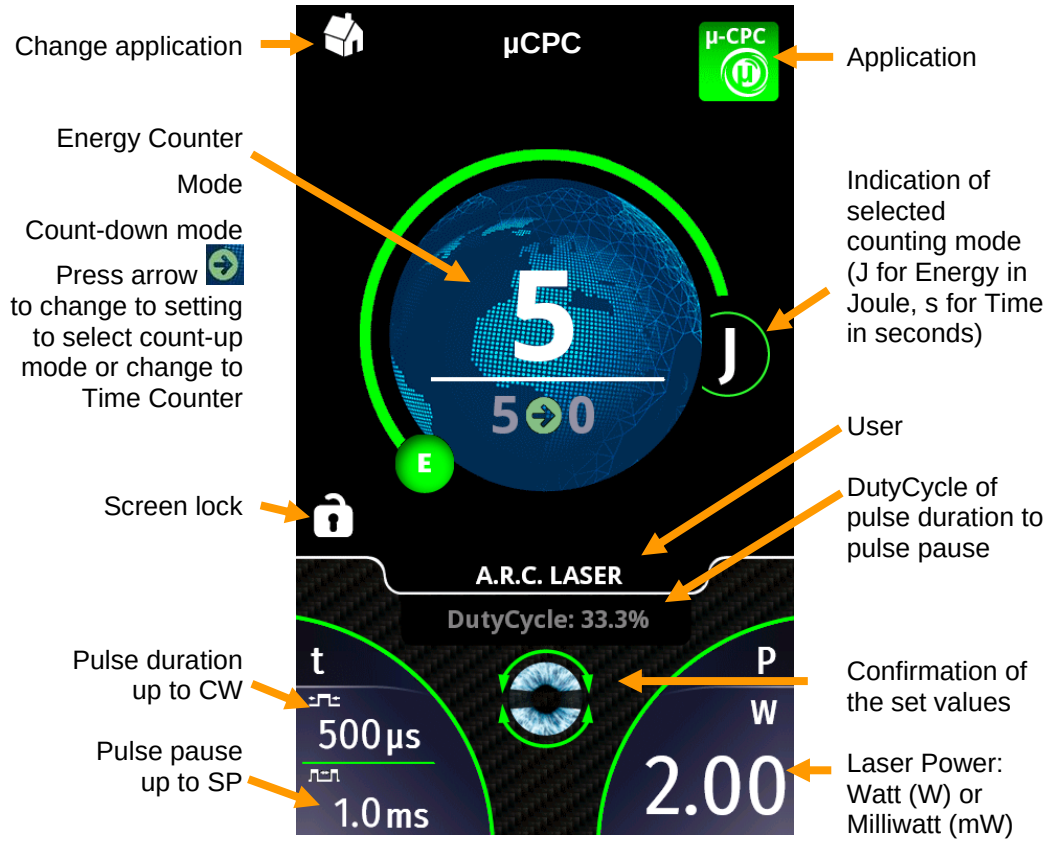
Only the protocol of the last treatment is available and remain stored as long as the device is switched on.

After restart of the device the protocol is refreshed.



6.3.3 µCPC – Cyclophotocoagulation by the use of microsecond pulses

After choosing CPC application the following screen will be displayed:



6.3.3.1 Change parameters

Parameters can be changed by clicking on the corresponding value. The selected value will turn green and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

6.3.3.2 Pulse table

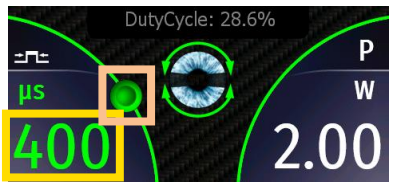
The pulse table shows all recommended settings for the µCPC treatment.

All of these settings can be selected with preset A.R.C. User. For the µCPC application the duration of the pulse and pulse pause can be adjusted.

Pulse table for µCPC:

µs	ms	s				µs	ms					s	
100	/	/	/	/	/	100	**1**	3	40				
200	/	/	/	/	/	200	1.1	4	50				
300	/	/	/	/	/	300	1.2	5					
400	/	/	/	/	/	400	1.3	6					
500	/	/	/	/	/	500	1.4	7					
600	/	/	/	/	/	600	1.5	8					
700	/	/	/	/	/	700	1.6	9					
800	/	/	/	/	/	800	1.7	10					
900	/	/	/	/	/	900	1.8	15					
CW	/	/	/	/	/		1.9	20					
							2	30					
CW = continuous wave						SP = single pulse							

Pulse duration



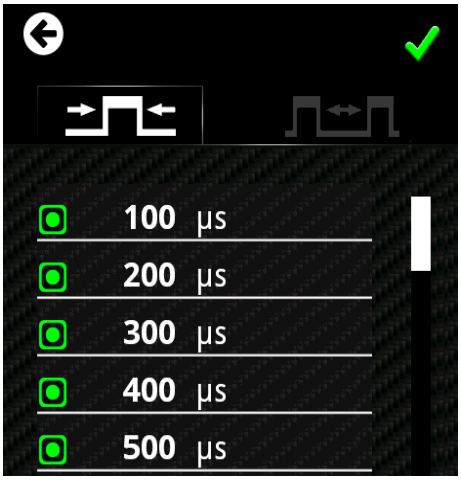
To change the pulse duration, press the current setting. The selected value will turn green and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

Individualisation of selectable pulse durations

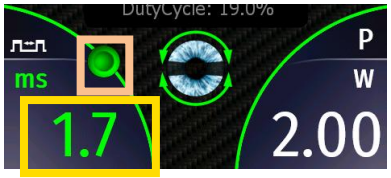
The pulse duration-choices selectable in the settings can be individualized with the pulse table. To open the pulse table, select the pulse duration by clicking on the value and then double click it.

Green values are activated and can be chosen during the selection of the pulse duration. The selection can be saved by clicking the green hook on the top right corner.

Additional pulse durations not included in this list cannot be added. Included values cannot be deleted.



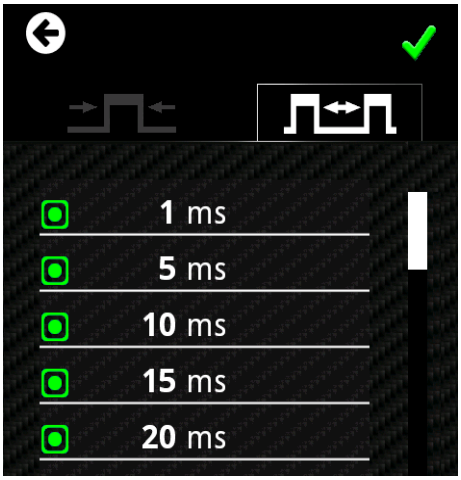
Pulse pause



To change the duration of the pulse pause, presses the current setting. The selected value will turn green and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the menu bar.

Individualization of selectable pause durations

The pause duration-choices selectable in the pause settings can be individualized with the pulse table. To open the pulse table, select the pause duration by first clicking on the value and then double click it.



Green values are activated and can be chosen during pause selection. The selection can be saved by clicking the green hook on the top right corner:

Additional pause durations not included in this list cannot be added. Included values cannot be deleted.

6.3.3.3 Confirmation of the set values

All adjusted values of the µCPC application can be confirmed by taping the eye that is located between the pulse duration and power or waiting 5 seconds for auto save.

6.3.3.4 Counter Settings

Energy or Time counter

µCPC treatment requires the application of a specific amount of energy or a defined laser application time. The counter for these values is located in the center of the display in order to be visible at a glance during the treatment.

The device can either display the applied amount of energy or the time the energy has been applied. Which parameter is displayed

can be identified by the letter on the right side of the globe.

The time counter is indicated by the letter s (seconds), the Energy counter by the letter J (Joule).

It is possible to choose between counting up and counting down the displayed parameter. The direction of counting is indicated by the direction of the counting arrow on the bottom of the globe.

The displayed parameter and the counting mode can be changed in the settings. These adjustments can be attained by clicking the counting arrow in the center of the globe or via the settings button on the side bar. (chapter 6.4)

Select "E" to count the emitted energy or "t" to count the time of emission.

Press the circle with two arrows to switch between the counting modes.

6.3.3.5 Further µCPC settings for acoustic feedback

To facilitate the application of the laser beam during µCPC the FOX IV 810 has a build in acoustic signalling system containing a voice over and a metronome. Both acoustic signals can be adjusted in the main settings individually.

Press the Settings button on the side bar to display the settings. All acoustical settings can be made in the tone menu.

Voice over

The FOX IV 810 has a build in voice over. Every tenth count will be spoken aloud. Volume of the voice over can be adjusted in the settings by clicking the gear symbol. Three different volumes for the voice over can be selected (low, medium, high). Alternatively, the voice over can be switched off. The language of voice over can be changed in the device supported languages at the info settings section.

Metronome

The FOX IV 810 is able to emit a metronome sound for every counted unit to help adjusting the speed of the application. In energy counting mode, the metronome will emit a tone for every Joule of Energy applied. In time counting mode, it will emit a tone after every second of laser emission. The metronome can either be turned on or turned off in the settings.

6.3.3.6 Treatment

Position the patient. Press the READY Button/ LED, The aiming beam becomes visible. Start the treatment by pressing the foot switch after the laser parameters were checked once again.

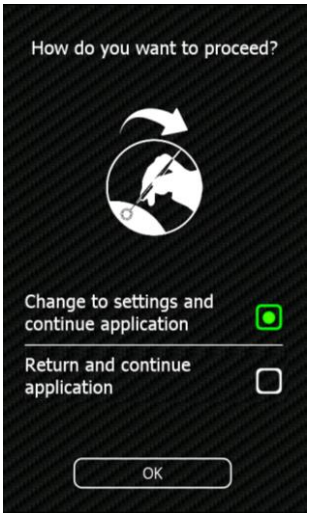
A T T E N T I O N

Any serious incident that occurs with this laser must be reported to the A.R.C. Laser GmbH and the responsible state authority.

6.3.3.7 Interrupt or stop the treatment

Interrupt the treatment

During the treatment it might be necessary to adjust different parameters in the settings. To assess the settings, press the settings button. The following screen will appear:

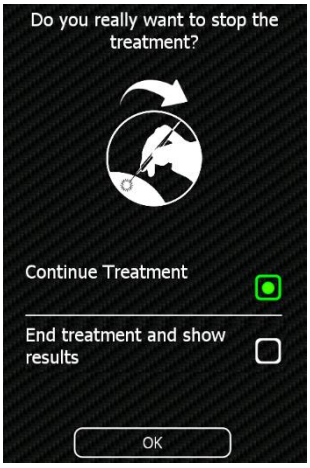


To get to the settings, tick the first box “Change to settings and continue application” and confirm the choice by pressing OK. The settings will be displayed. When leaving the settings, the treatment can be continued by pressing the READY button/ LED.

To return to the application without changing settings tick the second box “Return and continue application” and confirm the choice by pressing OK. The treatment can be continued by pressing the READY button/ LED.

Stop the treatment

When the treatment is finished, it can be stopped by pressing the READY button/ LED. The following screen will appear:



To continue treatment, tick the first box “Continue Treatment” and confirm the choice by pressing OK. The treatment can be continued by pressing the READY button/ LED.

To end the treatment, tick the second box “End treatment and show results” and confirm the choice by pressing OK. The treatment protocol will be displayed.

6.3.3.8 The treatment protocol

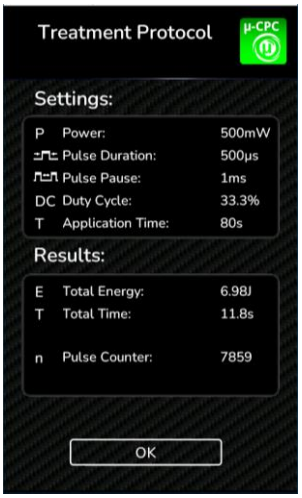
After running the µCPC treatment the system will show a treatment protocol.

In case the protocol has been closed accidentally it can be recalled. Press the gear symbol to attain the settings then click onto the info button.

"Show the last treatment" is now availed to be selected.

Only the protocol of the last treatment is available and remain stored as long as the device is switched on.

After restart of the device the protocol is refreshed.



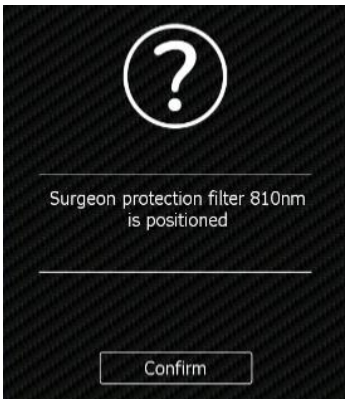
6.3.4 Retina coagulation (Endo - Endocoagulation or LIO Applications)

The following information applies for all treatments of the posterior eye such as Endocoagulation, LIO and ROP.

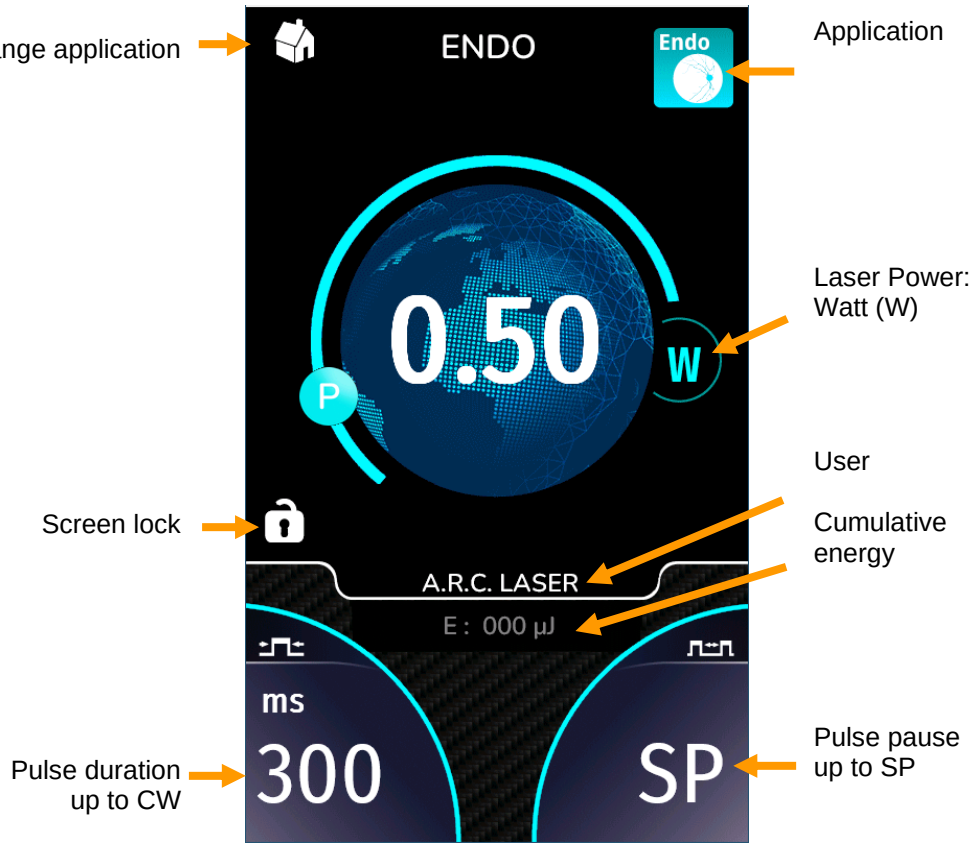
Surgeon protection filter 810nm

To execute the retina coagulation (posterior applications), the surgeon protection filter has to be connected.

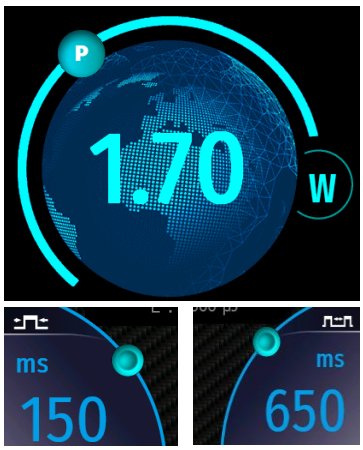
Check the connection and confirm the message displayed on the screen.



After confirming, the following screen will be displayed:



6.3.4.1 Change parameters



Parameters can be changed by clicking on the corresponding value. The selected value will turn blue and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the menu bar.

6.3.4.2 Pulse table

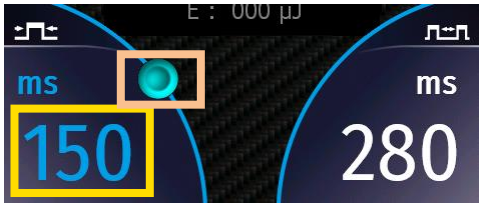
The pulse table shows all recommended settings for the posterior treatment. All of these settings can be selected with preset A.R.C. User.

For the posterior applications the duration of the pulse and pulse pause can be adjusted.

Pulse table for Endo/LIO/ROP:

µs	ms							s		µs	ms							s	
	10	85	180	350	900					/	1	70	150	260	850			1	/
	20	90	190	400	950					/	5	75	160	280	900			1.5	/
	30	95	**200**	450	CW					/	10	80	170	300	950			2	/
	40	**100**	210	500						/	15	85	180	350				2.5	/
	50	110	220	550						/	20	90	190	400				3	/
	55	120	230	600						/	30	95	200	450				3.5	/
	60	130	240	650						/	40	100	210	500				4	/
	65	140	250	700						/	50	110	220	550				4.5	/
	70	150	260	750						/	55	120	230	600				5	/
	75	160	280	800						/	60	130	240	700				10	/
	80	170	**300**	850						/	65	140	250	800				**SP**	/
CW = continuous wave											SP = single pulse								

Pulse duration



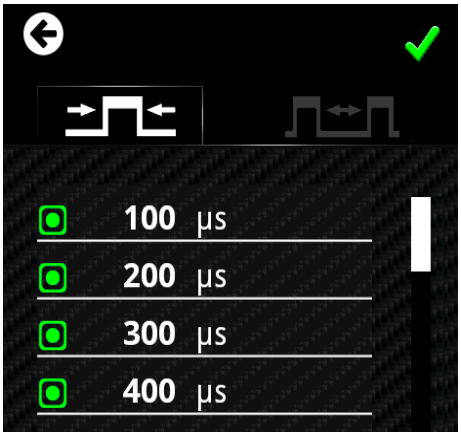
To change the duration of the pulse, presses the current setting. It will turn blue and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

Individualization of selectable pulse durations

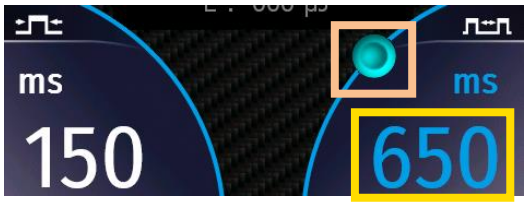
The pulse duration-choices selectable in the settings can be individualized with the pulse table. To open the pulse table, select the pulse duration by clicking on the value and then double click it.

Green values are activated and can be chosen during the selection of the pulse duration. The selection can be saved by clicking the green hook on the top right corner.

Additional pulse durations not included in this list cannot be added. Included values cannot be deleted.



Pulse pause



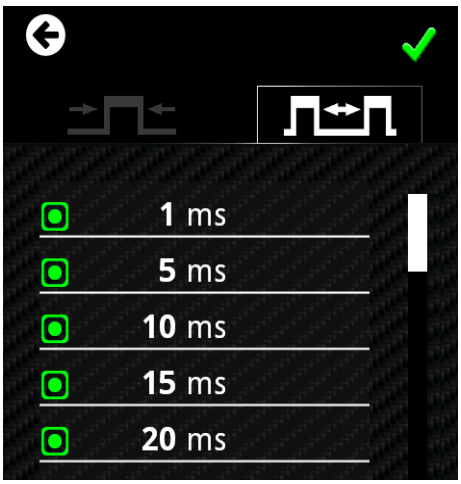
To change the duration of the pulse pause, press the current setting. It will turn blue and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

Individualization of selectable pulse pause durations

The pause duration-choices selectable in the settings can be individualized with the pulse table. To open the pulse table, select the pause duration by first clicking on the value and then double click it.

Green values are activated and can be chosen during the selection of the pulse pause duration. The selection can be saved by clicking the green hook on the top right corner.

Additional durations of pulse pauses not included in this list cannot be added. Included values cannot be deleted.



6.3.4.3 Change displayed treatment information

The FOX IV 810 provides a variety of information for the user that can be found in the middle of the lower screen such as the emitted energy, pulse counter, DutyCycle, average power and frequency of the laser beam. By default, the sum of the emitted energy is displayed.

To change the displayed parameter, press on the current parameter to select it. Drag the blue dot in the lower right corner and move it to different spots on the blue line to choose the desired parameter, or use the plus/minus keys on the side bar.

Selectable parameters:

Energy in Joule:

The displayed energy value is the product of the set power and the actual exposure time, as well as the number of pulses emitted. The displayed unit changes automatically from Millijoule (mJ) to Joule (J) to Kilojoule (kJ) with increased cumulated energy. The counter can be reset by touching the counter numbers at display.

Pulse counter n:

The displayed number indicated the total applied laser pulses. The counter can be reset by touching the counter numbers at display.

DutyCycle in percent:

The displayed DutyCycle value is calculated by pulse duration divided by the sum of pulse duration and pulse pause. To get the value in percent, the value is multiplied by one hundred.

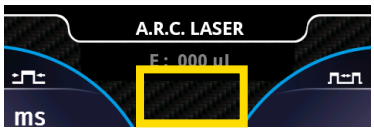
Average power in Watt:

The average power is calculated with the set power and the actual exposure time through set pulse duration and pulse pause. The displayed value changes automatically from Milliwatt to Watt with increased cumulated energy. To calculate this value, the emitted power is divided by the time of emission.

Frequency in Hertz:

The displayed frequency value is calculated by pulse duration and pulse pause per second.

6.3.4.4 Confirmation of the set values



All adjusted values of the posterior applications can be confirmed by taping the blank spot that is located between pulse duration and pulse pause settings or waiting 5 seconds for the device to auto save.

6.3.4.5 Treatment

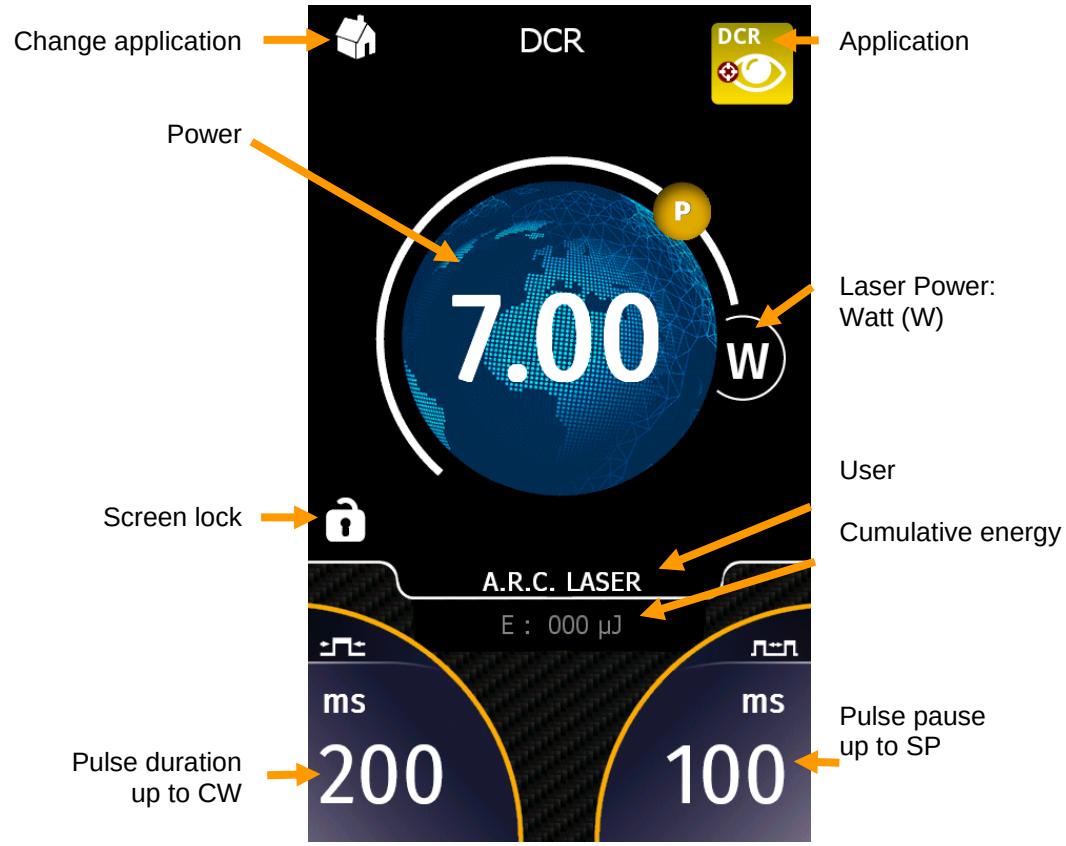
Position the patient. Press the READY Button/ LED, The aiming beam becomes visible. Start the treatment by pressing the foot switch after the laser parameters were checked once again.

A T T E N T I O N

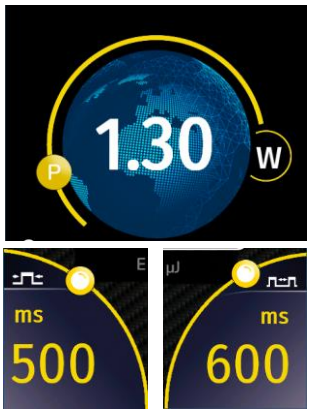
Any serious incident that occurs with this laser must be reported to the A.R.C. Laser GmbH and the responsible state authority.

6.3.5 DCR - Dacryocystorhynostomy

After choosing CPC application the following screen will be displayed:



6.3.5.1 Change parameters



Parameters can be changed by clicking on the corresponding value. The selected value will turn orange and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

6.3.5.2 Pulse table

The pulse table shows all recommended settings for the DCR treatment. All of these settings can be selected with preset A.R.C. User.

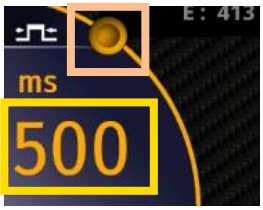
For the CDR application the duration of the pulse and pulse pause can be adjusted.

Pulse table for DCR:

µs	ms							s	
100	1	90	200	450				1	
200	5	100	210	**500**				1.5	
300	10	110	220	550				2	
400	15	120	230	600				2.5	
500	20	130	240	650				3	
600	30	140	250	700				3.5	
700	40	150	260	750				4	
800	50	160	280	800				4.5	
900	60	170	300	850				5	
	70	180	350	900				10	
	80	190	400	950				CW	
CW = continuous wave									

µ	ms							s	
/	1	90	200	450				1	
/	5	100	210	500				1.5	
/	10	110	220	550				2	
/	15	120	230	**600**				2.5	
/	20	130	240	650				3	
/	30	140	250	700				3.5	
/	40	150	260	750				4	
/	50	160	280	800				4.5	
/	60	170	300	850				5	
/	70	180	350	900				10	
/	80	190	400	950				SP	
SP = single pulse									

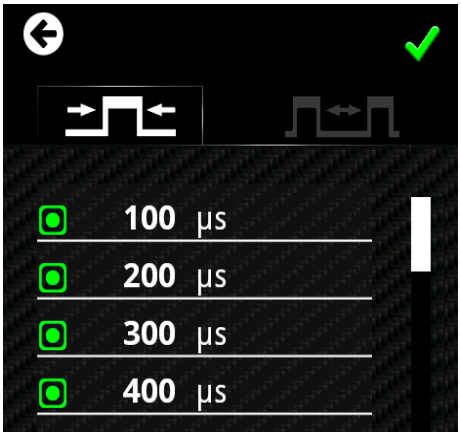
Pulse duration



To change the pulse duration press the current setting. It will turn orange and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

Individualisation of selectable pulse durations:

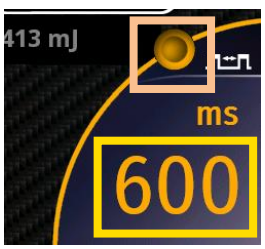
The pulse duration-choices selectable in the settings can be individualized with the pulse table. To open the pulse table, select the pulse duration by first clicking on the value and then double click it.



Green values are activated and can be chosen during the selection of the pulse duration. The selection can be saved by clicking the green hook on the top right corner.

Additional pulse durations not included in this list cannot be added. Included values cannot be deleted.

Pulse pause duration



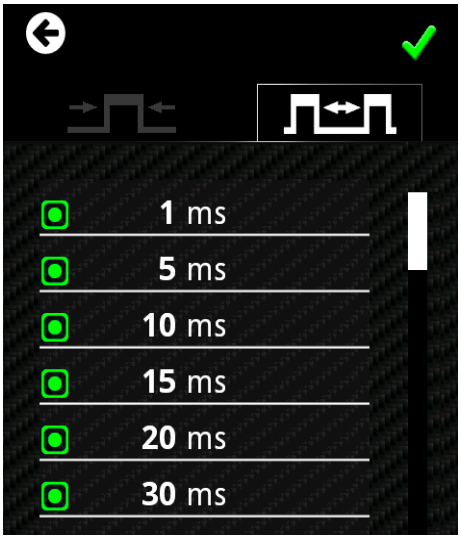
To change the pause duration, press the current setting. The selected value will turn blue and can be adjusted by sliding the point to a different location on the line or by using the plus/minus keys on the side bar.

Individualisation of selectable pause durations:

The pause duration-choices selectable in the pause settings can be individualized with the pulse table. To open the pulse table, select the pause by clicking on the value and then double click it.

Green values are activated and can be chosen during the selection of the pause duration. The selection can be saved by clicking the green hook on the top right corner.

Additional pause durations not included in this list cannot be added. Included values cannot be deleted.



6.3.5.3 Change displayed treatment information

The FOX IV 810 provides a variety of information for the user that can be found in the middle of the lower screen such as the emitted energy, speed, DutyCycle, average power and frequency of the laser beam. By default, the sum of the emitted energy is displayed.

To change the displayed parameter, press on the current parameter to select it. Drag the orange dot in the lower right corner and move it to different spots on the orange line to choose the desired parameter, or use the plus/minus keys on the side bar.

Energy in Joule:

The displayed energy value is the product of the set power and the actual exposure time, as well as the number of pulses emitted. The displayed unit changes automatically from Millijoule (mJ) to Joule (J) to Kilojoule (kJ) with increased cumulated energy. The counter can be reset by touching the counter numbers at display.

Pulse Counter:

The displayed number indicated the total applied laser pulses. The counter can be reset by touching the counter numbers at display.

DutyCycle in percent:

The displayed DutyCycle value is calculated by pulse duration divided by the sum of pulse duration and pulse pause. To get the value in percent, the value is multiplied by one hundred.

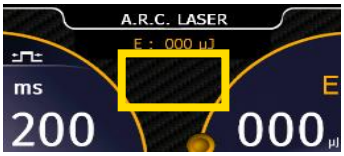
Average power in Watt:

The average power is calculated with the set power and the actual exposure time through set pulse duration and pulse pause. The displayed value changes automatically from Milliwatt to Watt with increased cumulated energy. To calculate this value, the emitted power is divided by the time of emission.

Frequency in Hertz:

The displayed frequency value is calculated by pulse duration and pulse pause per second.

6.3.5.4 Confirmation of the set values



All adjusted values of the posterior applicattions can be confirmed by taping the blank spot that is located between pulse duration and pulse pause settings or waiting 5 seconds for the device to auto save.

6.3.5.5 Treatment

Position the patient. Press the READY Button/ LED, The aiming beam becomes visible. Start the treatment by pressing the foot switch after the laser parameters were checked once again.

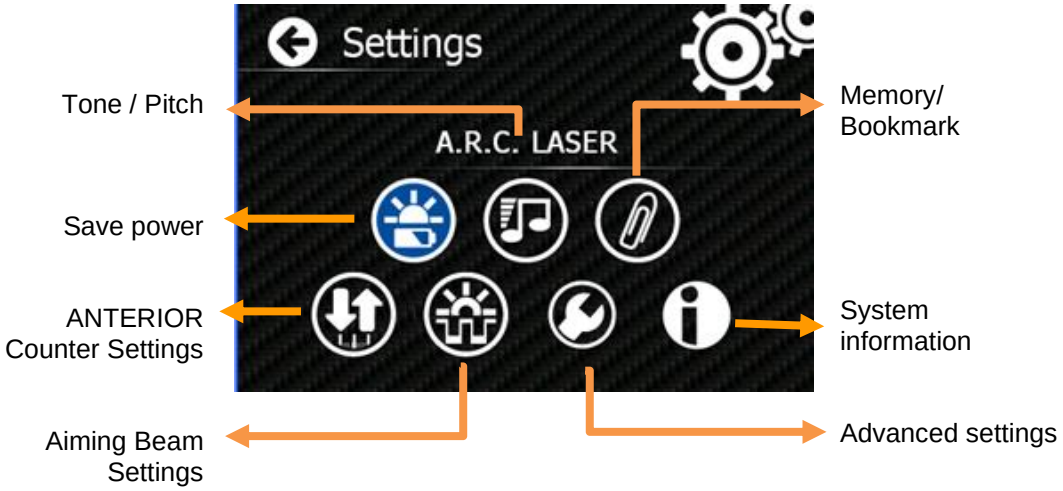
A T T E N T I O N

Any serious incident that occurs with this laser must be reported to the A.R.C. Laser GmbH and the responsible state authority.

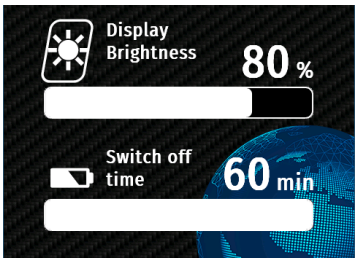
6.4 Settings

Enter the settings screen by touching the gearwheel.

The following setting categories are available.



Save power



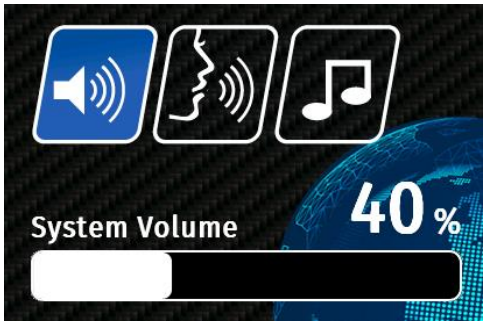
Adjust Display brightness and switch-off time.

Display brightness (10-100%)
Switch-off time (5 – 60 minutes)

Save energy:

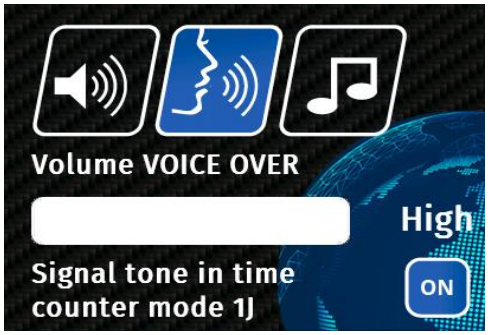
To save energy and the battery we recommend to set the display and aiming beam brightness as low as possible.

Tone / Pitch



Adjust system volume.

System Volume (10 – 100 %)



Audio adjustments for µCPC

Voice over

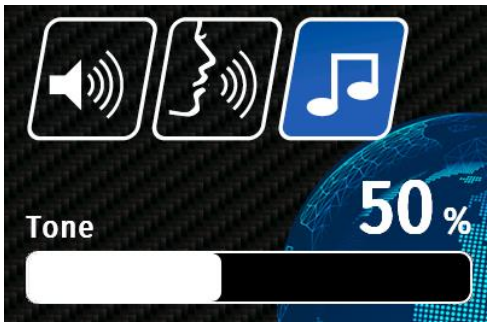
The device announces the time/energy in intervals of 10 J or 10 s.

Voice over settings (off, low, mid, high)

Metronome

Laser gives a signal tone every 1J in energy counter mode or every 1s in time counter mode.

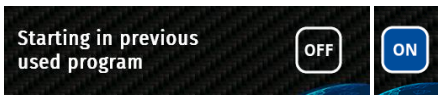
Metronome settings: on/ off



Adjust system tone.

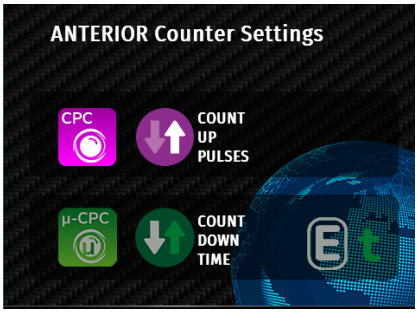
Tone (10 – 100 %)

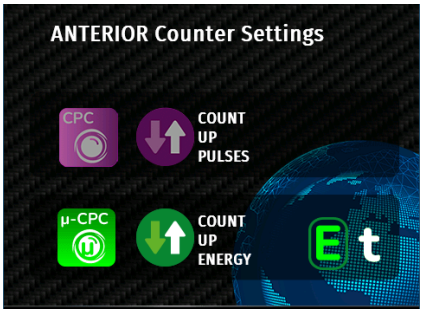
Memory/ Bookmark

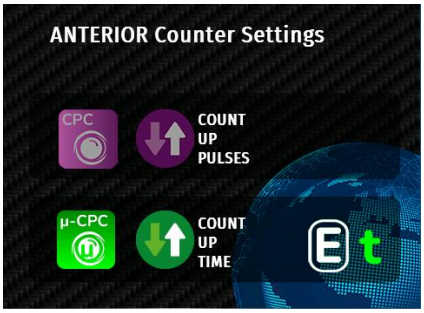


When turning on the device it can start in the application menu or the last used program. When the button is black and says OFF the device will start in application menu. When the button is blue and says ON the device will start in the last used program. To change the setting, click the button.

ANTERIOR Counter Settings





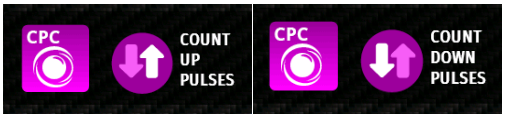


In the ANTERIOR Counter Settings, the counter for CPC and µCPC can be adjusted.
The µCPC counter can be set to Energy counter (see picture in the middle) or time counter (see picture right).

The user can directly access the counter settings by touching the green arrow or pink arrow at the laser parameter screen.
The corresponding counter settings of the current application will be highlighted in the anterior counter setting menu.

CPC:

It is possible to choose between counting up and counting down the emitted pulses.



Press the circle symbol with two arrows to switch the direction of counting.

µCPC

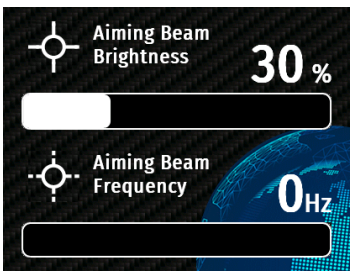
The device either displays the emitted energy or the time the energy has been emitted.

It is possible to choose between counting up and counting down the displayed parameter.

Select "**E**" to count the emitted energy or "**t**" to count the time of emission.

Press the circle with two arrows to switch the direction of counting.

Aiming beam



Set aiming beam brightness and flashing frequency.

Aiming beam brightness

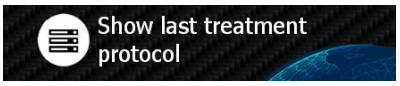
(1-100%)

Aiming beam frequency

(0-10 Hz)

System information

In this seeting submenu it is possible to access the protocol of the last ANTERIOR treatment, set the language and change the password of the device.



Show the last ANTERIOR treatment protocol:

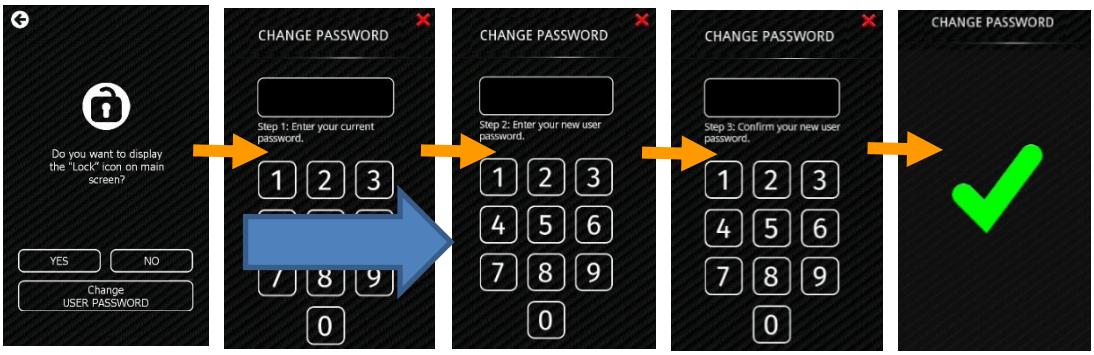
To show the last treatment protocol of CPC or µCPC treatment, you have to press the button with the three bars.
Press the OK button to close the protocol.

Choice of system language:

Select the language in which the device should be operated. The language can be changed using the arrow keys which are located next to the language icon.

Languages: English (EN), German (DE), French (FR), Italian (IT), Spanish (ES).

Enable or disable the lock icon at main screen and change user password.



This screen allows to **change the password of the system** that is requested after the startup routine. The password consists of four digits (default is "0000") and the input field is filled by pressing the number keys. After 4 numbers have been entered, the action is completed.

The questioning routine takes you through the menu:

1. Old password: Enter the current password.

2. New password: Enter the new password.

3. Confirm password: Repeat entering the new password.

6.4.1 Advanced Service Settings

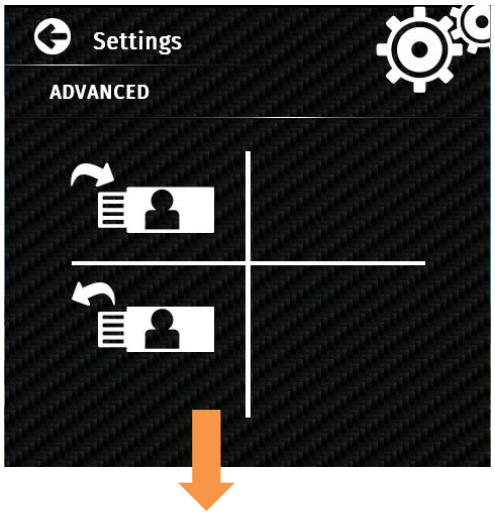
Only trained personnel can make changes in the advanced settings. The advanced settings only can be accessed to with the service password at the advanced settings pin mask.

6.4.2 Advanced User Settings

The advanced user settings can be accessed with the user password at the advanced settings pin mask.

Settings Backup function

At the advanced user settings the current device settings can be exported and imported with an attached USB flash drive.

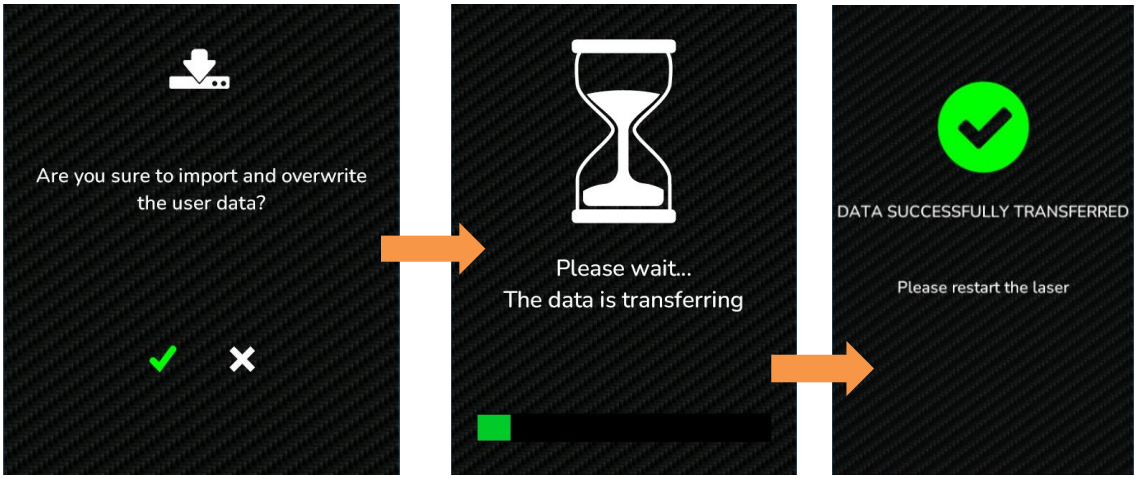


Export 

Tap on the export symbol to export the settings. The symbol changes to green color during the export process. When it turns white again the data is saved (.XML file) and the flash drive can be detached.

Import 

Tap on the import symbol to import the settings. A new confirmation screen will appear that must be confirmed. After that a loading screen with an hour glass and progress bar appears. The successful data import will be indicated by a message screen (laser restart necessary to load the imported settings).



6.5 Insert the applicator

All fibers and probes consist of a A.R.C.Laser quick coupling connector. This connector has an anti-twist protection, which can be recognized by the small notch on the plug.

This ensures an optimal position of the applicator in the fiber coupling, resulting in reproducible power transmission. The connector must click into place.

If the plug has not properly clicked into place, the device cannot be switched to READY mode and the FOX IV 810 will not work. Please pay attention to a clearly perceptible "click" when inserting the plug!

Once the plug has been locked in place, it is possible to change the device into READY mode and laser radiation can be emitted by using the foot switch.

Please do not insert any objects or liquids in the fiber plug, since this could lead to damage of the coupling and the optics.

The dust protection cap (red plug) should be connected to the fiber port as soon as there is no fiber/probe connected.

6.6 READY /STANDBY-mode

When starting the FOX IV 810 it will be set to STANDBY mode by default. This is indicated through the READY button/ LED lighting up green. No laser radiation can be emitted in this mode. By pressing the READY button/ LED, the device will switch to READY mode. An acoustic signal (‘click’) will indicate this switch, to make all nearby people aware that laser radiation can be emitted now. After blinking a few times, the READY button/ LED lights up orange. If the device does not switch to READY, check if the fiber is connected correctly.

While the laser is in READY mode, the aiming beam will be emitted. When the aiming beam is not visible, the issue may be fixed according to the instructions in chapter 8.5.4.

When the device is in READY mode only Settings and STANDBY mode can be accessed.

By pressing the READY button/ LED again, the device will switch back to STANDBY mode.

6.7 Release laser radiation

In order to be able to emit radiation, the laser has to be put into READY mode. When the footswitch is pressed now, laser radiation will be released. During the emission of radiation the laser-emission signal LED lights up and an acoustic warning signal is audible.

6.8 Laser-Stop

The Laser Stop button interrupts the READY mode. If the Laser-Stop is activated the device cannot be used and a warning message appears. The laser is immediately deactivated and can only be activated if the warning message is confirmed.

A T T E N T I O N

The Laser-Stop should only be used in emergencies.

6.9 Power-Save

After four minutes of inactivity, the FOX IV automatically enters a power-save mode to conserve battery power. The aiming beam and the display will get darker.

To end the power-save-mode, touch the screen.

A switch-off time can also be set in the settings. After that, the laser switches off completely and can only be restarted by pressing the power button again.

6.10 Switch-Off

The FOX IV 810 is switched off using the Power button on the left side of the device. To prevent connection issues of the fiber due to dust pollution, insert the red dust protection pin after every usage.

If the FOX IV 810 is not used for a longer time period stow it in its transport case.

Power button

6.11 Charging the battery

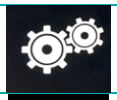
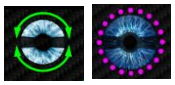
To charge the battery of FOX IV 810 insert the power supply into its socket at the rear panel.

The ongoing charging process is indicated by the animated flashing of the battery symbol. When the device is turned on, the number of illuminated bars of the battery symbol indicates the charging level. As soon as the battery is charged completely, all four bars will be illuminated.

A T T E N T I O N

Only plug in the power supply when the device is switched off to prevent any battery damage!

6.12 Symbols

	Display brightness 10-100 % Sleep mode time (5-60min)		Log-out/ Access protection
	Tone (10-100%) Pitch (10-100%) Voice over Metronome		Advanced settings
	Aiming beam brightness (1-100 %) Aiming beam frequency (0-10Hz)		Change user password
	Starting in previous used program		System information, access to treatment protocol and language
	Pulse duration		Select language
	Pulse pause		Safe laser parameters (not available for user A.R.C. Laser)
	Air humidity, Temperature internal		Charging level of battery
	Settings		Plus / Minus
	Home, application menu		delete
	Anterior counter settings Selection of Energy or Time counter and count mode		In anterior programs: Confirm settings and show application mode
	Count down/up pulses		Count down/up time/Joule
	Metronome on/ off, Metronome on: sound each 1 s or 1 J		Voice Over (off, low, mid, high)
	Protocol of the last treatment		Please wait
	confirm		Return one step back
	edit		add

7 Technical Data

7.1 General Laser Data

Laser	Diode Laser
Wavelength	810 nm
Power*	0.1 - 8 Watt in DCR application 0.1 – 3 Watt in anterior or posterior settings Tolerance +/- 20% of the shown power IEC 60601-2-22
Mode	Continuous wave (cw) Chopped/ pulsed (alternating: pulse duration I pulse pause) Single pulse (SP)
Pulse duration	100 µs up to 60 s; CW
Pulse pause	100 µs up to 60 s; SP
Aiming Beam **Wavelength (colour)** **Optical output power** **Brightness** **Mode**	 650 nm (red) < 1mW variable Continuous wave (CW) or pulsed (1-10 Hz)
Dimensions	H 17.4 cm / W 14.2 cm / D 16.3 cm (with open foot)
Weight	1.53 kg
Power Requirements **External power requirement** **Charger output / Console input**	 100 - 240 V AC, 50/60 Hz, 1.06-0.45 A 19 V DC, 4.74 A
Battery	Integrated rechargeable 10.8 V, 26.4Wh, Li-Ion (by A.R.C. Laser),
Cooling	Active internal with fan
Control/ User Interface	Touch display
Fiber Coupling	A.R.C. Laser 300 µm port
Consumables	Ophthalmological Probes (Endo Probes, Glaucoma Probes, DRC Probes)

7.2 Classifications

Laser class (Classification according to EN 60825)	4
Laser class aiming beam (Classification according to EN 60825)	2
Classification according to MDD/MDR	II b Rule 9
Electrical protection class (Classification according to IEC 60601-1)	II
Certification	CE 0123

8 Maintenance

8.1 Introduction

The device was designed, developed and tested according to the latest technical knowledge. We have set the product life time to 7 years. Additionally, we guarantee the availability of spare parts for 10 years. However, to ensure that everything is working properly, we have made it possible for you to visually check the status displays from the outside.

A T T E N T I O N

There is no need for the laser user to perform routine or service work within the laser system. All adjustments and calibrations that require to open the protective housing must be carried out by trained service personnel. That includes cleaning the optics within the laser. That includes cleaning the optics within the laser as well as battery pack replacement.

8.2 Safety Check

Once within 24 months, the laser should be subjected to a safety check (STK) by trained personnel. The execution of the STK and any faults are to be noted in the device book.

Please note that the medical device book and the STK are not mandatory in every country. Please check the local regulations and laws.

Scope of Safety Check STK

Visual Check

- laser marking (laser class, max. power, wavelength)
- Information signs / warning signs; properly and completely attached
- Check of instructions for use / medical device book
- Condition of the supply line
- Condition of the laser safety goggles / protective equipment
- Overall condition

Functionality Check

- Foot switch
- Beam guidance system / coupling / decoupling / pilot laser
- Check touch screen

Check the necessary monitoring / safety display and signaling unit

- Emission controls (acoustic, visual)
- Laser stop switch (check for function)
- Interlock device (check for function)

Electrical Safety Check

- According to IEC 62353 or DIN VDE 0751, Part 1

Output power measurements

Check the set power with an external power meter (permissible tolerance ± 20%)

A T T E N T I O N
If one or more safety-related points are objected after the safety-related inspection (STK), the device may no longer be operated.

8.3 Cleaning and disinfection by the user

The following maintenance instructions can be carried out by the user. These serve to make your work easier.

Before cleaning / disinfection:

- Switch off the device and disconnected it from the mains
- Unplug the Fiber and charging device
- Insert the red dust protection cap into the fiber port

Cleaning and disinfection:

Always use a damp, but never wet, soft cloth for cleaning and disinfecting.

A T T E N T I O N
During cleaning, the device must always be switched off. Water or disinfectant should never be applied directly to the surface of the device. Make sure to dabble the cloth to then clean or disinfect the device.

First clean the device with clear water and neutral detergent to remove coarse and visible contamination. Make sure that no moisture penetrates into the device.

Furthermore, wipe disinfection is possible.

When choosing the disinfectant, pay attention to the following:

- according to the manufacturer of the disinfectant, the disinfectant should be suitable for non-invasive medical devices
- according to the manufacturer of the disinfectant, the disinfectant should be suitable for wipe disinfection of surfaces
- the disinfectant should be based on alcohol and/or quaternary compounds
- the disinfectant should be suitable for lacquers
- aldehyde-free disinfectant (recommended)

For wipe disinfection, the manufacturers instruction for the disinfectant must be respected. Following possible disinfectants that meet the above-mentioned requirements are listed:

Manufacturer	**Possible disinfectants***
BODE Chemie GmbH	Mikrobac forte, Bacillol 30 Foam
ANTISEPTICA	Arcylan, Biguacid Liquid
Schülke & Mayr GmbH	Acryl-des, antifect AF (N)
Dr. Schuhmacher GmbH	CLEANISEPT; Descosept AF
Ecolab	Incidin Foam, Incidin Pro
Dr. Weigert	Neoform MED AF, neoform MED rapid

*This list is not exhaustive.

8.4 Accessories Cleaning

8.4.1 Laser Safety Goggles

Please follow the cleaning instructions provided with the laser safety goggles in any case. In general, you should never use chemicals for cleaning that can damage the coating of the glasses. Always use soft cloths that do not leave scratches on the surface.

8.4.2 Applicators

All Fibers and Probes for FOX IV 810 are single use, sterile products. Please follow the instruction in the user manual for the Fibers and Probes.

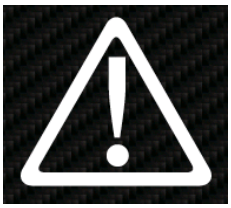
8.4.3 Foot Switch

The general cleaning instructions (see above) must be respected in any case. When cleaning the foot switch, prevent the penetration of water or cleaning agents. Never immerse the foot switch in water or cleaning agents. This could lead to a short circuit.

8.5 Error detection

All components of FOX IV 810 have undergone a rough shake test as well as temperature testing. In case of an error, you can use this manual to isolate the problem and, in some cases, even solve it yourself. If the problem persists, please contact your local A.R.C. Laser authorized representative for technical support.

8.5.1 Error Routine



When an error occurs in the system, the error will be displayed with an error symbol along with an error code to identify the error.

In case that there is no button to confirm, the laser device needs to be restarted.

Common errors might be:

- Battery operation: Make sure the battery has been charged and the laser is switched on.
- Activated foot switch at system start.

8.5.2 Interlock chain

For the laser to be started, operated or activated, several signals are always required, all of which must be in a very specific state. These signals states are defined as an Interlock element of an Interlock chain which are set by hardware components as well as by the CPUs (software) and checked for correct status at system start and main mode.

If one of the Interlock states is out of/invalid range an Interlock message is displayed with an Interlock symbol and description text. These states are checked at system start and main mode.

In case of an Interlock state the device is brought to a safe state with operation being interrupted. The laser doesn't need to be restarted and can be brought back to prior working mode by remedying the cause of the Interlock state.

Common Interlock-elements may be:

- Interlock: The interlock plug should be fully inserted into the device; the door contact switch should be closed respectively.
- Interlock: The Fiber is plugged at system start.

8.5.3 System Check

In general, a system self-check runs 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:

Dynamic errors i.e. errors that can be easily resolved or can be resolved after ordering a spare part from A.R.C. Laser GmbH. These error cases are handled as **Interlock elements** and may include:

- Interlock plug missing, disconnected or defective
- Fiber inserted during system start

Static errors are errors incorporated as a error routine with specific **error code** which require contacting A.R.C. Laser GmbH service department or the local authorized dealer. For these usually an error message will appear on the display and can assist to identify the problem when calling for service.

8.5.4 Troubleshooting

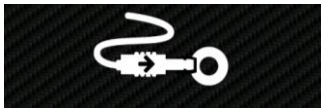
The following errors cannot be identified by the system self-check and have to be checked by the user:

Problem	Potential Error	Troubleshooting
Screen darkens	Laser is in Sleep mode	PowerSave Mode - your FOX IV 810 lowers its power consumption. By pressing/touching the display you can resume to normal mode.
No aiming beam visible	Laser is in Stand-By mode	Aiming beam is only visible when the laser is in READY mode. Switch the laser to READY mode.
	Aiming beam brightness set too low	Increase the parameter for aiming beam brightness in the settings menu  
	Fiber is not properly inserted	Twist the fiber connector inside the socket with a light movement until it clicked into place.
	Fiber is broken	Replace the broken fiber with a new one
	Aiming beam diode defective	Contact your A.R.C. Laser representative
No laser beam but aiming beam visible	Foot switch is not plugged in	Check if the foot switch is correctly plugged in
	Foot switch defective	Contact your A.R.C. Laser representative
No aiming beam and no laser beam	Fiber optics not connected to laser or 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
	Laser diode defective	Contact your A.R.C. Laser representative
No function of side bar	Calibration Error	Please wait, re-calibration is running every minute. Other option: restart the laser device.

8.5.5 Error messages

 “F__”	Indicates an error case. Error symbol with error code.	Device is in an error state, which cannot be resolved by the user.
	Special error case with low laser power at low battery charge: Battery error symbol with error code and description text.	Shut off the device and charge battery.
Note: In case of an error state, the device must be restarted in order to advance with operation.		

8.5.1 Interlock messages

	Door interlock missing/ Door is open.	Check the door interlock connection, connect the interlock plug included with the system or close the door
	Fiber is plugged.	Remove fiber from the device to proceed.
	Fiber is missing or not properly inserted.	Check fiber plug / Insert the fiber with a clicking sound.
	Foot switch activated.	Release foot switch to change to READY mode.
	System temperature too high.	Let the device cool down. (If message persists, contact service)

	System temperature too low.	Let the device warm up. (If message persists, contact service)
	Battery low (25%, 10% respectively).	Charge the battery.
	Battery very low (<=1%). Ready mode activation and operation is prevented.	Plug in power supply and charge the battery.
	Fan failure.	If message persists, contact service.

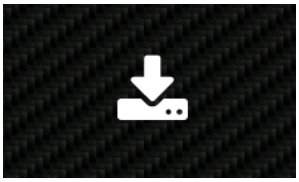
8.5.2 Warning messages

	Laser stop pressed, reading error, values that can't be deleted… These messages often need to be confirmed to proceed.

8.5.1 Status messages

	Please wait.
	Data change/transfer successful.
	Password change successful.
	Battery charge low.
	Battery charge very low.
	Battery charge critical.

8.5.1 Confirmation screens

	Delete user entry?
	User already exists!
	Stop the treatment/How to proceed?
	Display lock symbol in main mask?
	Security question prompt: Protection filter in position?
	Import data?
Confirmation screens must be confirmed by the user in order to proceed.	

8.6 Disposal

The FOX IV 810 is a medical electrical device with internal lithium-ion battery. When disposing the product, the relevant local laws and regulations must be complied with. The device must never be disposed with household waste.

A.R.C. Laser will be glad to assist you with the disposal of the laser. Any costs and risks for the appropriate return of the laser to A.R.C. Laser must be borne by the customer. Please get in touch with our service department.

9 Customer Service

9.1 Warranty Information

A.R.C. Laser GmbH grants you a two-year guarantee. Parts that have a defect will be replaced free of charge within two years. All add-on and purchased parts are exempt from this guarantee. Our guarantee extends to the repair or replacement of defective parts. However, we reserve the right to renew entire assemblies and adapt them to technical progress.

Repairs by third parties or changes to the device will void the warranty. The use of other parts that have not been accepted with the device or obtained from other suppliers will also void the warranty. The attachment of parts or assemblies or other changes to the device requires the express written confirmation by A.R.C. Laser GmbH.

9.2 Warranty Consignments, Packaging

A warranty claim for defective parts, malfunction or damage to the housing of the device must be submitted to A.R.C. Laser GmbH within 24 hours. Parts that are returned during the warranty period (at the express request of A.R.C. Laser GmbH) must be confirmed in writing by A.R.C. Laser GmbH. Detailed packaging instructions and information on how to return the device are provided by A.R.C. Laser GmbH. The return must be insured and paid for by shipper. The insurance and transportation costs are not covered by A.R.C. Laser GmbH. The choice of the return is made by the A.R.C. Laser GmbH communicated to the customer. Changes and amendments in the carrier or the shipping method can lead to delays in transport and processing. All components to be changed under the warranty claim are manufactured by A.R.C. Laser GmbH renewed free of charge within the guarantee period. We reserve the right to make changes to the design of the device - if it appears necessary - to increase the safety or the functionality of the device. The responsibility for the design as well as for changes in the device lies solely with A.R.C. Laser GmbH. Changes will be communicated to the customer and accordingly carried out at A.R.C. Laser GmbH.

9.3 Sales- and Service-Information

For information about sales and service please contact the A.R.C. Laser headquarters:

A.R.C. LASER GmbH
Bessemerstr. 14
D-90411 Nürnberg
Tel: +49 911 21779-0
Fax: +49 911 21779-99
E-Mail: info@arclaser.de
www.arclaser.com

10 Guidelines and Manufacturer's Declaration

10.1 Electromagnetic Emissions

The laser is intended for use in an environment as specified below. The customer or user of the laser should ensure that it is operated in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment - guideline**
Conducted RF-Emissions CISPR 11	EN 55011 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
Radiated RF-Emissions CISPR 11	EN 55011 Group 1/Class B	The laser is only suitable for the environment in professional healthcare facilities
Harmonic distortion	IEC 61000-3-2 Class A	
Voltage fluctuations / flicker	IEC 61000-3-3	

10.2 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-Testlevel**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD)	Enclosure ± 2 kV, ± 4 kV, ± 6 kV contact discharge; ± 2 kV, ± 4 kV, ± 8 kV, air discharge Patient coupling ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV contact discharge; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	IEC 61000-4-2	Floors should be made of wood, ceramic or stone. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Radiated RF electromagnetic fields	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may be used..
Proximity fields from RF wireless communications equipment	see Table 10.4	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may be used..
Rated power frequency magnetic fields	30 A/m 50 Hz or 60 Hz	IEC 61000-4-8	Magnetic fields at the grid frequency that are usually available in domestic or clinical areas may be used.
Electrical fast transients /burst	± 2 kV for power lines ± 1 kV for IO-lines 100 kHz repetition frequency	IEC 61000-4-4	Only the voltage of a typical professional healthcare facility may be used..
Surge voltages (Surges), Line against line	± 0.5 kV, ± 1 kV	IEC 61000-4-5	Only the voltage of a typical professional healthcare facility may be used.
Surge voltages (Surges), Line against grounding	± 0.5 kV, ± 1 kV, ± 2 kV	IEC 61000-4-5	Only the voltage of a typical professional healthcare facility may be used.
Conducted disturbances induced by RF fields	3 V 0.15 MHz to 80 MHz 6 V in ISM-frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	IEC 61000-4-6	Only the voltage of a typical professional healthcare facility may be used.

Voltage dips	0 % UT; ½ cycle at 0°to 315° step 45° 0 % UT;1 cycle, 0° and 70 % UT; 25/30 cycles at 0°	IEC 61000-4-11	Only the voltage of a typical professional healthcare facility may be used. It is recommended to use an uninterruptible power supply.
Voltage interruption	0% UT; 250/300 cycles 0°	IEC 61000-4-11	Only the voltage of a typical professional healthcare facility may be used. It is recommended to use an uninterruptible power supply.
NOTE: UT is the AC mains voltage prior to application of the test level.			

10.3 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-Testlevel	EMV standard	Electromagnetic environment – guidelines
Conducted disturbances induced by RF fields	3 V/m 150 kHz to 80 MHz	IEC 61000-4-6	Portable and mobile 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 FOX IV, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. The field strength of stationary radio transmitters is, as determined by an electromagnetic site survey, at all frequencies smaller than the compliance level. Interference may occur in thevicinity of equipment marked with the following symbol:  If higher IMMUNITY TEST LEVELS than those specified in Table 9 (IEC60601-1-2) are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in 8.10 (IEC60601-1-2).
Radiated RF electromagnetic fields and Proximity fields from RF wireless communications equipment	3 V/m 80 MHz to 2,7 GHz resp. see Table 10.4	IEC 61000-4-3	

10.4 Recommended separation distances between portable and mobile RF telecommunications equipment and the laser

The laser is intended for use in an electromagnetic environment in which the RF disturbances are controlled. The customer or the user of the laser can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the laser - depending on the output power of the communication device, as stated below.

Test frequency MHz	**Frequency band MHz**	**Radio service**	**Modulation**	**Maximum performance W**	**Distance m**	**Immunity test level V/m**
385	380 to 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460 FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0.3	28
710 745 780	704 to 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 801.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Notes:

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