

Dermatology

Application manual for the FOX laser



980 nm wavelength



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WARNING For your own safety follow all guidelines for handling the equipment and follow the safety instructions in this manual.

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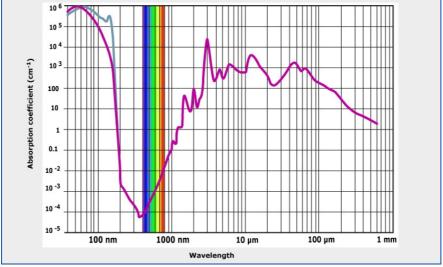
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1) Laser safety

Laser radiation emitted by the FOX laser can cause severe damage to the patient as well as to the user and third persons accompanying the laser use. The FOX laser is classified in the laser class IV. This means that the radiation can cause damage when it is directly applied to any tissue and also if the radiation is scattered or reflected.

The FOX laser radiation is intense and efficient to coagulate and evaporate tissue. The most serious injuries occur, when laser radiation is exposed to the eye. Even low laser power is able to damage the retina of the eye, which is not reversible. This may cause permanent blindness. The danger depends on the wavelength of the radiation and on the dose (energy density per time).



Water absorption

Laser radiation in the wavelength range between 400 and 1400 nm is most dangerous for the eye. The cornea as well as the anterior chamber, the lens and the vitreous body of the eye contain mainly water. The other tissue components (mainly collagen) play a minor role for the laser tissue interaction. Between 400 and 1400 nm wavelength water has very low absorption. Therefore the laser radiation is transmitted very well and nearly the full power reaches the retina, where it is absorbed by the blood and the retinal pigment ephithelium.

The FOX laser emits infrared laser radiation, therefore it is absolutely necessary to wear eye safety goggles when using the FOX laser system. With its intensity (e. g. focused beam), the Fox laser radiation can also do harm to skin or other tissue. The radiation can light up inflammable material.

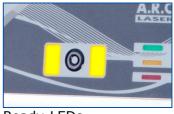




Safety instructions

To avoid any injuries it is important to follow the laser safety instructions:

- 1. Any user of the Fox laser system has to be trained by A.R.C. Laser authorized personal or by someone trained by A.R.C. Laser authorized personal.
- 2. The room / the area, where the laser system is used has to be signed with the laser warning symbols in a way that everyone can easily see that there is a laser area, which should not be entered without the adequate protection while the laser is in use.
- 3. Do not use the system whenever you are not sure that every component works in the dedicated way. Keep an eye on the fiber delivery: The spot shown by the aiming beam should always be round and defined, no scattering should occur. You may test this by using a light paper and holding a focusing hand piece (e. g. HS11009) or a bare fiber end (e. g. LL13001) in a distance of about 5 cm (you have to put the laser on Ready mode / laser safety goggles!).
- 4. Whenever the laser is on Ready mode (2 yellow Ready-LEDs on) every person within the area where radiation from the laser can occur (laser treatment area / laser room) has to wear laser safety goggles which is suitable to protect the eyes from FOX laser radiation.



Ready-LEDs

- 5. The laser has to be used only for the defined application; never irradiate any other material / tissue beside the intended use.
- 6. Special care should be taken to avoid irradiating reflecting materials. Reflected laser radiation can cause the same harm as direct application.
- 7. Switch off the Ready mode of the laser when the laser is not in use; e. g. during operation breaks or at the end of the surgery.



2) Basics of laser application

The intended effect of the laser application is based on the interaction of the radiation with the tissue components. The laser radiation is absorbed, scattered or reflected by the tissue. Air has only little influence on the FOX radiation and therefore the interaction between air and the FOX radiation can be neglected. Reflection plays a major role with metal, glass and other reflecting surfaces.

When we apply the FOX radiation to tissue the reflection is not dominant. Nevertheless it is not zero! When the radiation is scattered in the tissue, it does not influence the absorption. Absorption is mainly responsible for the efficiency of the laser radiation. Absorption means that the FOX laser radiation is converted mainly into heat, which causes the desired effects (coagulation / vaporisation).

With low energy density (big laser spot or low power) the heat which is achieved in the tissue can cause heating of the tissue. The smaller the spot size is, or the higher the power is set, the warmer it gets. There is a limit, when the tissue does no longer tolerate the heating, tissue proteins denaturate, coagulation occurs. The next limit is achieved when tissue water (intraand extracellular water) suddenly evaporates (> 300° C). Tissue is fragmented and destroyed. Cutting / evaporation is achieved.

Temperature effect			
Temperature	Effect		
> 40° C	enzyme induction, membrane disaggregation, edema		
45° – 65° C	tissue damage, reversible or irreversible, dependent on		
	the irradiation time		
> 65° C	coagulation		
> 100° C	dehydration		
> 150° C	carbonisation		
> 300° C	varporisation, ablation (removal of tissue)		
some 1000° C	ionisation, immediate burn (shock wave formation)		



Tissue cutting always needs high energy densities (high power or small spot size). At the cutting edges, respectively beside the evaporation zones the tissue is always affected by the heat (coagulation). The positive effect and advantage of the laser use is that this can stop bleeding from cut vessels (haemostasis). The negative effect is caused directly at the cutting edge where more than 150° C occur. There is a development of carbonization, created by burned carbon, which is toxic and prolongs the healing of the wound.

To avoid extended collateral damage (carbonisation and coagulation) at the cutting edges the application mode of the laser can be modified to a pulsed mode, which causes less damage.

In continuous mode the laser permanently emits radiation. In pulse mode the tissue can cool down between each laser pulse and therefore the side effects of the heating can be reduced.



3) Application

Therapy indications

This chapter gives detailed information on the laser applications. Of course, this chapter cannot compensate for intensive studies of appropriate literature, personal experiences and critical consideration of facts. Nevertheless, this should help every "beginner" as well as each one who is not working on a regular base with the laser. The following indications are average values – no guidelines! They are based on the fundamental experiences of several medical doctors, who are using our lasers every day. Despite all caution from our side, each medical doctor needs to set their parameters individually, observing the indication and the patient to be treated. Changing the parameters may possibly require a change of other settings. Neither author nor manufacturer is liable for treatment failures.

Technique

For coagulation and carbonisation the FOX laser has to be used mainly with the focusing hand pieces HS11008 (blue / 0.3 mm spot size) or HS11009 (red / 0.6 mm spot size). To use these hand pieces the fiber LL13002 (in combination with FOX laser 300 μ m socket) is necessary. This fiber has a fiber plug on each side, which can be either inserted into the fiber coupler of the FOX laser or into the coupler of the hand pieces.





Hand piece

The focus hand pieces are used with our double click fiber LL13002 (300 μ m) or our double click fiber LL11054 (400 μ m).

Thereby add up different laser spot sizes for the focus hand pieces:

Spot size diameter for focus hand pieces			
hand piece	with LL13002 [300 µm]	with LL11054 [400 µm]	
blue (HS11008)	Ø 0.3 mm	Ø 0.4 mm	
red (HS11009)	Ø 0.6 mm	Ø 1.0 mm	
green (HS11010)	Ø 1.0 mm	Ø 2.0 mm	



Treatments

In most of the surgical procedures either continuous mode (cw) or a pulse mode can be selected. Continuous mode causes more haemostasis and more extended collateral damage (higher effective power, faster, more efficient cutting), pulsed mode reduces collateral damage (less effective power, slower, less efficient cutting). The 200 μ m fiber can be also used for surgical procedures, the power necessary for cutting is less than for the 300 μ m fiber due to the higher power density (smaller fiber diameter!).



Pre-treatment tests

The FOX laser does an automatic internal testing on the power output before the device can be used. Keep an eye on the system components. Especially take a look on the fiber delivery: The spot shown by the aiming beam should always be round and defined, no scattering should occur. You may test this, by using a light paper and holding the bare fiber end (LL13001 or LL13003) or the coupler fiber (e. g. LL13002) in a distance of about 5 cm (you have to put the laser on Ready mode). When doing this, be aware to wear safety goggles.

Methods in case of unwanted effects

The application of laser radiation can cause a burning of the tissue, which results in necrosis. Measures to treat burns have to be realized.

Second, the laser radiation causes haemostasis and the tissue gets coagulated. The amount of irreversible damaged tissue depends on the time and extend of the coagulation. Coagulated tissue is not harmful and does normally not cause any problems. In case of overheating of temperature-sensitive areas intensive cooling is recommended. The following clinical procedures should follow the guidelines.

Treatment related issues

Discomfort from the heating which is generated by the laser may occur. To avoid this, the user should follow the application parameter guidelines and avoid too long application times. If possible, cooling can reduce patients discomfort after the treatment. All personal, including the patient, have to wear eye protection goggles; this may lead to decreased vision regarding contrast and color by the personal and surgeon.

In case of any eye injury due to disregard of the eye protection by safety goggles, an ophthalmologist has to be consulted.



Behavior in case of a system error

In case of any failure in the power generation of the laser, the power which is delivered to the patient decreases. Overpower cannot occur as the current for the laser diode is limited by a fuse. Less power than expected results in less effect. When this occurs, the user can check for the fiber delivery first and then for the laser. Any damage to the fiber results in a decrease of the power. A broken fiber shows reflections of the aiming beam at the breakage. The user should not continue the use of the laser and change the fiber.

When he checks the laser a restart results in a new check of the system at the beginning. When the laser measures too low or too high power, the system does not start.

Any error message displayed by the system can be checked in the operation manual. In case of any insecurity or questions please contact your local A.R.C. Laser representative.

Contraindications

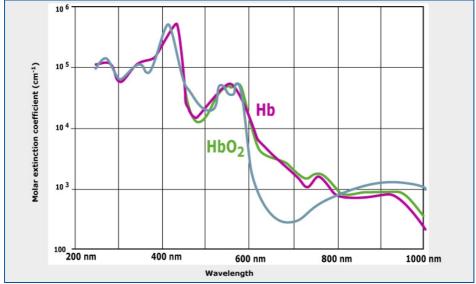
- Using the laser on inflamed tissue
- Using the laser on over-pigmented skin
- Treatment with higher power or longer pulse length than advised, especially for facial teleangiectasias



Coagulation

Vascular lesions

Vascular lesions can be treated with the FOX laser. The laser works through absorption of the laser radiation in haemoglobin and oxyhaemoglobin. The infrared laser radiation has less absorption in the skin, containing melanin as an absorber to the light, than in blood containing haemoglobin and oxyhaemoglobin (theoretical penetration depth is about $10 - 30 \mu m$). The penetration depth of the 980 nm wavelength in aqueous tissue is between 2 - 4 mm. In blood the wavelength is absorbed much better, this means that vessels can be coagulated underneath the skin without skin damage. Nevertheless cooling to



Haemoglobin- and oxyhaemoglobin absorption

the skin is advised and enhances patient comfort. During the treatment, the red color of the blood must turn white / gray immediately after coagulation by the laser radiation. It is important, that the laser beam hits the vessel completely. If the spot is placed besides the vessel, it can't be coagulated in total. As a result, the long term effect of the treatment might not be satisfying. Therefore, follow the vessel very slowly and coagulate it in its full length. Place one coagulation spot next to the other with no or only little overlap; do not irradiate the same area twice. To avoid thermal problems, such as pain, it is advised to cool the treatment area with cool pads or adequate shortly before treatment and directly after treatment. Before treatment the cooling should not be too intensive to avoid contraction of the vessels.



Side effects:

Directly after the treatment, little tissue swelling and increased blood circulation (skin turning slightly red) besides the treated vessel may occur. This disappears after 1 - 2 days. The final result takes 6 - 10 weeks. Any repeating of the treatment should not be done too early; please wait at least 2 months before treating the same areas.

Laser settings for vascular lesions			
hand piece	power [W]	pulse on 几 [ms]	pulse off 납 [ms]
blue (HS11008)	max. 9	50 - 100	400 - 600
red (HS11009)	max. 9	60 - 140	400 - 600
red (HS11009)	max. 9	120 - 160	SP

The maximal pulse lengths should not be used without cooling!!!



Facial teleangiectasias

In contrast to vascular lesions at the body (e. g. legs), facial lesions need little modifications for the treatment. Nevertheless the procedure of the treatment is roughly the same. Facial lesions are more superficial, the skin is less thick and the lesions are mainly smaller. The treatment needs less heat (shorter pulse length) than general vessel coagulation.

Cooling is also advised in the same manner as described on vascular lesions. The treatment can be repeated after 3 - 4 weeks, if there are vessels, which have not been coagulated completely. The final result is visible after 6 - 10 weeks.

Laser settings for facial teleangiectasias			
hand piece	power [W]	pulse on 几 [ms]	pulse off 납 [ms]
blue (HS11008)	max. 9	50 – 90	400 - 600
red (HS11009)	max. 9	60 - 110	400 - 600

The maximal pulse lengths should not be used without cooling!!!



Carbonization

Fibroma

Fibroma are burned out on the surface. You will get a carbonized surface. The CO_2 laser is the better choice, but the FOX laser can be used as well. For treating fibroma some local anesthetics is advised. Carbonization of the fibroma is achieved by using a small spot size (high energy density). The result of the treatment is destroyed tissue (carbonized). The burned tissue will separate from the healthy tissue underneath and fall off in the following days.

Laser settings for carbonization (e. g. fibroma)			
hand piece	power [W]	pulse on 几 [ms]	pulse off 납 [ms]
blue (HS11008)	max. 9	120 – 200	150 – 300
red (HS11009)	max. 9	140 - 230	180 - 300

Problems

Too much pulses on the same spot cause additional heating and therefore additional damage which may lead to scar formation in case of overheating.

Solution: Be cautious when treating this disease for the first time; intermediate pauses during the treatment are advised to control the progress of the surgery.



Surgery / cutting

For the surgery the FOX laser has to be equipped with a bare fiber LL13003 (200 μ m diameter) or LL13001 (300 μ m diameter). To hold the fiber the surgery hand piece (HS11018) can be used. The surgery hand piece can be equipped with different hand piece tips. The standard tip is the 2 cm long bend tip (ZU01024). The tips can be connected to the hand piece by the luer connection and allow easier application and guide the fiber to the desired application area. The fiber has a fiber plug on one side, which has to be inserted into the fiber coupler of the FOX laser.



How to prepare the bare fiber and surgery hand piece for surgery and how to use it:

For removing and entering the fiber in the surgery hand piece, the knob at the end of the hand piece has to be pressed. Please be sure that there is still silicon protection over the fiber; the fiber fixation stops the fiber by pressing on the silicon tube. When the silicon tube is removed the fiber cannot be fixed!

After assembling the hand piece with the hand piece tip, the bare fiber can be inserted in the hand piece. Be sure that the hand piece fixation is open! The end of the bare



fiber should be at least 3 mm longer than the end of the hand piece tip. In case of high power surgery, or long surgery times, increase this distance to 5 mm or more. If the fiber end gets in contact to the hand piece tip during surgery, the hand piece tip warms up and after some time the tip may melt!! Be cautious, a hot hand piece tip can cause thermal damage to any tissue!!! To avoid extended heating of the fiber tip, or even more dangerous, heating of



the hand piece tip, the fiber end has to be cleaned during surgery if it gets covered by burned blood or coagulated tissue or any carbonisation.

To start surgery now, the fiber end can be placed directly on the tissue to be cut (vaporized). If the tissue is light (blond skin), the interaction of the FOX laser radiation with the tissue is not efficient. The penetration depth is 2 - 4 mm and vaporisation can hardly be achieved. Any dark structure (pigment / little carbonisation / color) can enhance absorption and increase efficiency.

It is advised in this case to make the fiber tip "black" before starting surgery. This can be done by firing on a piece of wood or color paper for a short time. This process is called initiation of the laser tissue interaction. The fiber end

now absorbs the laser radiation much better and the surgery is efficient. For surgery with the diode laser FOX, the bare fiber end has to be in contact with the tissue! The cutting procedure is nearly similar to a knife cutting, except that the bare fiber end should only be moved over the tissue in one direction with an angle of less than 90°.



Cutting with FOX Laser

Laser settings for surgery with a hand piece tip			
fiber-Ø [µm]	power [W]	pulse on 几 [ms]	pulse off 납 [ms]
300 (LL13001)	5 – 8	CW	-
300 (LL13001)	6 – 9	20 - 30	4 - 6

For decontamination the fiber end has not to be initiated.

Remember: Continuous mode causes more haemostasis and more extended collateral damage (higher effective power, faster, more efficient cutting), pulsed mode reduces collateral damage (less effective power, slower, less efficient cutting).



Surgery with the Jazz sapphire knife

The Jazz scalpel can be used in any surgery replacing an ordinary steel scalpel. The scalpel cuts like other crystal shaped knifes, e. g. diamond knifes. The body of the Jazz knife is made of sapphire.



The innovation using the Jazz knife is that the knife has a link to the FOX laser via fiber cable which transports laser energy to the knife. The laser radiation is transmitted through the sapphire blade and exits the blade at the tip.

It is possible to use laser radiation to coagulate in addition and parallel to the cutting process. Use the power of 6 - 8 W (max. 10 W) with cw-mode (continuous) for coagulation.

It is also possible to use laser radiation for coagulation without cutting and it is also possible of course to cut with the knife without using coagulation!

Caution:

- Do not bend the fiber cable in a very small radius! Be careful not to break the cable!
- The blade is sharp but brittle, take care, don't touch metal or other hard substances, do not drop the knife and use the blade cover when the blade is not in use (before and after surgery)



Application:

- Do not press the foot switch (laser radiation), in case the knife is not in contact to the tissue or when the knife is not used for coagulation.
- The parallel releasing of laser radiation (foot switch) and the cutting and coagulation process have to be trained!
- The knife has to be used in a steep angle (the angle between the tissue surface and the blade has to be bigger than 45°); the back plane, respectively the axis of the knife has to be nearly perpendicular to the tissue surface.

Cleaning the knife:

- A sterilization process with steam is possible, but reduces the lifetime of the instrument.
- Ultrasound cleaning is not advised.
- Please follow the cleaning instructions of the instrument.





