



Ophthalmology

Application manual for the FOX 514 Endo laser



514 nm wavelength



Bessemerstr. 14
90411 Nürnberg
phone: +49.911.21779-0
fax: +49.911.21779-99
info@arclaser.de
www.arclaser.de

WARNING

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

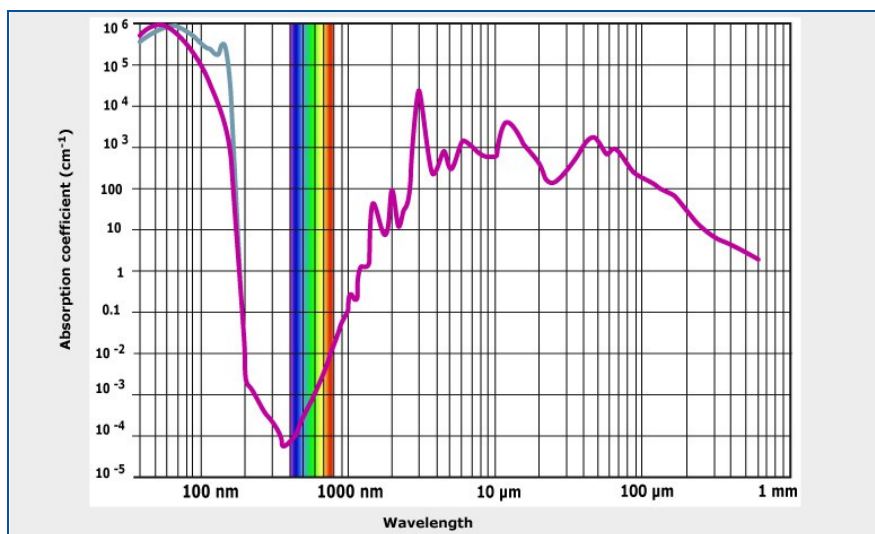
CONTENT

1) Laser safety.....	4
Safety instructions.....	5
2) Basics of laser application.....	6
3) Application.....	7
Indications / Contraindications.....	7
Technique.....	7
Pre-treatment tests.....	8
Treatments.....	8
Therapy indications.....	8
Endocoagulation.....	8
Retina coagulation by indirect ophthalmoscope	9
Methods in case of unwanted effects.....	10
Treatment related issues.....	10
Behavior in case of a system error.....	10
Treatment parameters.....	11

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 unexpectedly to an unintended eye or in an unintended way to the intended 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



Water absorption

wavelength of the radiation and on the dose (energy density per time).

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 epithelium.

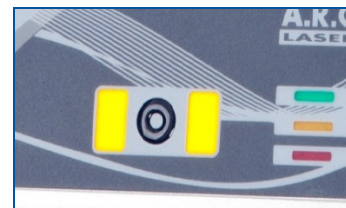
The FOX laser emits visible laser radiation, it is absolutely necessary to wear eye safety goggles when using the FOX laser system. For the combined use with the microscope, the microscope has to be equipped with an eye protection filter, than the surgeon can work without eye goggles.

With its intensity, 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 an endo probe (e.g. LL13015s) in a distance of about 5 cm to the paper (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.
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.



Ready-LEDs

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 effect (coagulation).

The basics of laser tissue interactions are explained quickly: 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 denature, coagulation occurs. The next limit is achieved when tissue water (intra- and extracellular water) suddenly evaporates ($> 300^{\circ}\text{C}$). Tissue is fragmented and destroyed. Cutting / evaporation is achieved.

Temperature effect	
Temperature	Effect
$> 40^{\circ}\text{C}$	enzyme induction, membrane dis-aggregation, edema
$45^{\circ} - 65^{\circ}\text{C}$	tissue damage, reversible or irreversible, dependent on the irradiation time
$> 65^{\circ}\text{C}$	coagulation
$> 100^{\circ}\text{C}$	dehydration
$> 150^{\circ}\text{C}$	carbonisation
$> 300^{\circ}\text{C}$	vaporisation, ablation (removal of tissue)
some 1000°C	ionization, immediate burn (shock wave formation)

In continuous mode the laser permanently emits radiation. In pulse mode the laser can be used to automatically apply laser radiation with a predetermined pulse length at a set frequency one after the other.

3) Application

Indications / Contraindications

Retina by endocoagulation	
indications	contraindications
<ul style="list-style-type: none">· securing pre-existing retinal breaks· iatrogenically produced retinal breaks· retinotomies· panretinal photocoagulation· coagulation of bleeding retinal surface neovascularization	<ul style="list-style-type: none">· existing decreased transparency of the optics (e.g. cataract, cloudy vitreous)· direct application to the macula

The use of the FOX 514 in combination with a Laser indirect Ophthalmoscope (LIO) is possible and offers a very mobile treatment option. The FOX 514 (battery driven!!) and the Keeler LIO (battery driven!!!) are both easily transportable (carrying cases!!) and do not need any mains, therefore electricity independent working anywhere is possible!

However, the most common use of the LIO is in prematures and for retinopathy of prematurity in most cases 810nm wavelength is preferred.

Technique

For the use of the FOX laser, the laser has to be equipped with a laser fiber. The fibers have a fiber plug on one side, which has to be inserted into the fiber coupler of the FOX laser.



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 an endo probe (e.g. LL13006s) 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.

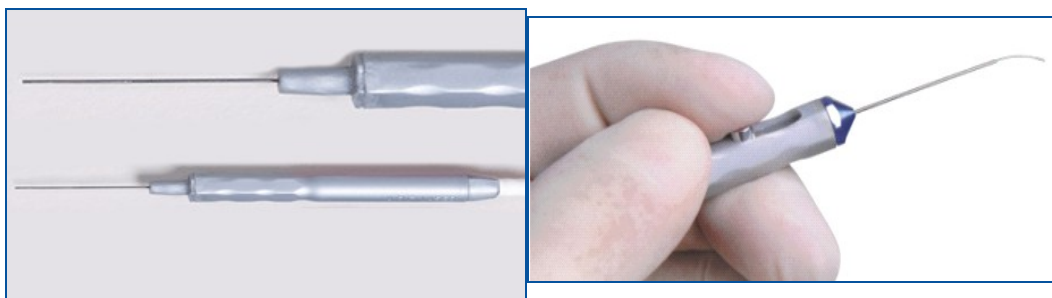
Treatments

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.

Endocoagulation

Endo coagulation should never be done in contact to the retina. Keep a small distance to the retinal surface.



hand piece
single use
LL13006s (23 G, straight)
LL13010s (25 G, straight)
LL13025s (23 G, curved 30°)
LL13015s (25 G, curved 30°)
LL11057s (23 G, 0-20°, flexible)

Retina coagulation by indirect ophthalmoscope

Photocoagulation for the retina with indirect ophthalmoscope can be used for mobile application (LIO and laser work with battery!!) and in very special cases also for the Retinopathy of Prematurity (ROP) treatment.

Converging lens can be used for the treatment with 20-40 dpt. The below parameters are generating with 28 dpt converging lens:

Power: 200 – 350 mW, Pulse length: 200 ms*

*Haidong Shan, Yinqing Ni, Kang Xue, Jia Yu, Xin Huang^{1,2}; Type 1 Retinopathy of Prematurity and Its Laser Treatment of Large Preterm Infants in East China; PLOS ONE | DOI:10.1371/journal.pone.0144313 December 16, 2015



Methods in case of unwanted effects

The application of laser radiation can cause vaporization if the energy density is high enough. This may result in unwanted tissue fragmentation (cutting). Tissue fragmentation instead of coagulation can occur if the surgeon applies laser radiation at the same position for a too long time, the same as with too much power.

In case bleeding occurs due to tissue fragmentation, immediately enhance the distance between the hand piece tip and the area irradiated, this reduces the energy density (bigger spot size) and helps to stop the bleeding through low power heating.

Treatment related issues

The amount of irreversible damaged tissue depends on the time and extend of the radiation. Discomfort from the heating which is generated by the laser may occur. 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. For endo coagulation, the eye protection filter for the microscope has to be mounted and the interlock cable from the filter to the laser has to be connected. The eye protection filter in the microscope protects the surgeon, who is not wearing goggles in this case.

In case of any eye injury due to disregard of the eye protection by safety goggles, a clinical center specialized on eye care 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.

Treatment parameters

Endocoagulation			
hand piece	power [W]	pulse on τ [ms]	pulse off τ [ms]
LL13006s	0,2 – 0,4	200 (150 - 250)	SP
LL13009s	0,2 – 0,4	200 (150 - 250)	SP
LL13010s	0,2 – 0,4	200 (150 - 250)	SP
LL13011s	0,2 – 0,4	200 (150 - 250)	SP
LL13014s	0,2 – 0,4	200 (150 - 250)	SP
LL13015s	0,2 – 0,4	200 (150 - 250)	SP

For repeat mode operation, a pulse off time of 300 to 400 ms or longer (lower frequency) can be used.

