

Laser Safety, Handling, and Regulatory Information

MUST READ: Never operate the laser until you have thoroughly read this document and the laser's operation guides. A class 3B laser is dangerous and has the potential to cause damage and injury. Considering this, ensure that you take all precautions possible, including being fully familiar with and following all the safety recommendations listed here.

Laser Classification

These lasers are classified as a Class 3B laser products as per the IEC/ EN 60825-1:2014 laser safety standard and complies with IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use. All compliances are listed under "Regulatory Compliance" on page 2.

Intended Use

The lasers have been designed for general laboratory or industrial use and as such are not approved nor tested for use in treatment or diagnostics of human or animals and does not comply with European, US or rest of the World requirements for medical device lasers. Neither is the system appropriate for outdoor use or use in extreme conditions such as elevated/lowered temperatures, particle/chemical contaminated environment or vacuum conditions.

Laser Safety Officer

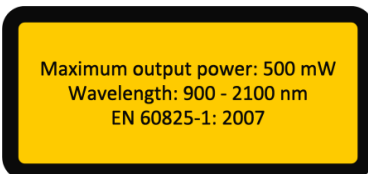
The laser should only be used by staff familiar with laser safety procedures and in facilities appropriate for laser operation. NKT recommends appointing a Laser Safety Officer (LSO) in accordance with valid local and national safety regulations. The LSO should ensure that every user of the system is familiar with the safety aspects of the laser unit and that the laser's operation documents should be clear and present to operators of the laser. Furthermore, any other staff in close proximity of the laser should be aware of any risk in connection with usage of the unit.

Safety Labels

The following labels are fixed to the device chassis. For safe operations of this laser, you must be aware of the location and the meaning of each label. Refer to the laser's *Product Guide* for further information on the labels and their location.



Classification



Product information



Manufacturing



Laser aperture



Laser radiation warning

Warnings

Warning: This laser is a Class 3B laser product and the operation room and operation conditions must comply with CFR21 1040.10, Laser Notice LN50, & IEC / EN 60825-1. If these regulations are not followed you must operate the laser in accordance with local regulations for a Class 3B laser source.

Warning: Using controls, making adjustments, or altering the procedures other than those specified by the guides associated with this laser may result in exposure to hazardous radiation and/or voltages.

Warning: This device emits a Class 3B laser beam from an FC/APC connector at the end of the laser's output fiber or similar. Both a laser aperture and a radiation warning label is affixed at or near the emission aperture. To prevent injury, the beam path must be strictly controlled.

Warning: Using this equipment in a manner not specified by the manufacturer may impair the protection capabilities of the equipment.

Warning: At all times the laser is on, it is advised that you have clear access to the shut-off controls of the laser. Shut-off controls consist of the power supply through the main electrical connection or the emission controls within the user interfaces.

Warning: At all times during system operation, ensure that the beam path is known and controlled. Wear wavelength specific eye and skin protection and ensure everyone in the laser area is aware that the system is in operation. Ensure that remote interlock is in place.

Warning: The laser should only be operated by authorized users who are properly trained in the appropriate safety aspects and of statutory minimum age. To prevent unauthorized and likely unsafe operation by untrained personnel, remove the front panel key from the key switch when the laser is not in use. Store the key in a secure location.

Warning: It is not recommended that you operate the laser without an appropriate interlock connection to e.g. a door or other entry mechanism to the system enclosure. If you bypass this safety feature, NKT Photonics bears no responsibility for any damage, loss or harm caused by accidental laser exposure.

Warning: Never make any modifications, additions or conversions which might affect safety. This also applies to the installation and adjustment of safety devices. Should safety relevant modifications or operational behavior changes occur with the laser, stop the laser device immediately and report the malfunction to NKT Photonics A/S.

Damage Prevention

Caution: If the laser's full or partial beam is obstructed or guided towards flammable materials, it can ignite a fire. Flammable materials include paper, solvents or other similar combustible material. Keep the beam path free from any combustible material and keep a fire extinguisher nearby the laser operation area.

Caution: Avoid spilling fluid onto the laser chassis and accessories. If spillage occurs, remove it immediately using absorbent material. Do not allow spilled fluid to enter into the chassis.

Caution: Avoid spilling fluid onto the electrical system. Place the laser so that in the event of a spillage, the electrical sockets' exposure is minimized.

Caution: Always clean the surface of the equipment with a dry cloth or tissue only. Disconnect the power supply before cleaning the unit.

Caution: Protective Equipment

- Laser Safety Officers are also responsible for the issuing and/or wearing of personal protective equipment. Direct exposure of the eye to the invisible laser beam must be avoided. At all times, proper eye-wear must be worn and maintained according to Personal Protection Equipment at Work regulations.
- Compulsory regulations also require the issuing and/or wearing of personal protective equipment. The necessity of reading the laser's documentation applies especially to persons working only occasionally with the laser.
- Use protective equipment, wherever required by the circumstances or by law.

Caution: Servicing the Laser:

- There are no user serviceable components inside the laser. In case of malfunction, NKT Photonics should be consulted.
- The unit is sealed with a label "WARRANTY VOID IF REMOVED" and it is thus strictly prohibited to remove the chassis cover.

Caution: Storage:

- If required, the laser should be stored in a dry and cool place (15-20°C).
- The optical output should be protected using the mechanical shutter on the front panel of the chassis.
- Avoid exposing the unit to vibrations or mechanical shock.

Caution: Chassis Cleaning

- To clean the chassis, disconnect the power source and use a soft and damp cloth. Do not use solvents or similar cleaning agents on the chassis or any other parts of the laser.

Caution: Emergency Response:

- In the event of an emergency or accident, make sure to have a contingency plan prepared and readily available including response actions and contact persons.

Caution: Disposal

- When disposing the laser, follow local waste regulations.

Regulatory Compliance

CE Mark – Declaration of Conformance for EMI and Safety (IEC)

The lasers listed in this document comply with the requirements of the

Council Directive 2014/30/EU in approximation of the laws of the Member States relating to safe design, use and implementation of lasers, electromagnetic compatibility and the safety of electrical equipment used within certain voltage limits. To evaluate the compliance with these directives, the following standards were applied:

Safety:

- BS EN 60825-1:2014 (laser class 3B) Safety of laser products - Part 1: Equipment classification and requirements
- BE EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: general requirements

Immunity:

BS EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use – EMC requirements

CE Approval

The Declaration of Conformity (DoC) and IEC certificates can be downloaded from:

<https://www.nktphotonics.com/lasers-fibers/support/certificates-and-approvals>

FDA Approval

The Koheras BASIK complies with 21CFR 1040.10 except for deviations pursuant to Laser Notice 50, dated June 24, 2007.

Safety Instructions Governing Specific Operational Phases

Precautions

Take the necessary precautions to ensure that the laser is used only when in a safe and reliable state. In the event of malfunctions, disable the laser device immediately and unplug its electrical power. Have any defects rectified immediately.

Before starting the laser, prepare a site specific Risk Assessment to ensure no persons are at risk. Inform operating personnel before beginning special operations, and appoint a person to supervise the activities. Ensure that the user operation area is adequately secured.

Specific Safety Aspects

Specific safety aspects are:

- Physical hazards related to the system. See the following section: Physical Hazards.
- Protection of the system users against physical hazards. See Section Personnel Safety.
- Proactive measures against these hazards. See the following section: Constructive Safety Features.

Within this classification, the laser is a class 3B laser, and is a potential hazard to the human operator. The class 3B laser beam is also classified as a potential fire hazard. Direct radiation from Class 3B products are a hazard to eyes and skin. Precautions include eye and skin protection, remote interlocks and warning labels.

Physical Hazards

Warning: The laser beam is dangerous to the eyes and skin. The dangers include:

- Direct radiation as it leaves the laser.
- Radiation reflected from a surface.
- Diffused radiation originated from a scattered reflection.

Light

In case of exposure, the laser may provide laser radiation with power levels up to 10 milliwatts for C15 and Y10 modules and 30 and 40 milliwatts for X15 and E15 modules respectively. Except for the Y10 module, the laser's emissions can consist of wavelengths from 1535 to 1580 nanometers. For Y10 modules, emission wavelengths range from 1030 to 1120 nanometers. Despite the non-ionizing nature of the operating wavelengths, damage can still occur to living tissue as a result of heat produced during radiation absorption or via multi-photon absorption. Suitable beam dumps must be used at all times when the laser is operating.

In general, the maximum permissible radiation exposure for the skin is several times greater than for the eye. Safety measures with regard to the radiation hazard are therefore mainly focused on dangers for the eye. Not only is the direct laser beam hazardous, but unchecked reflections of laser light also constitutes a potential hazard.

Personnel Safety

Personnel Protection

Warning:

Risk of serious injury: Always wear wavelength specific laser safety glasses when there is a chance of exposure to radiation from the laser. The filter in protective eyewear provides protection for only a narrow band of wavelengths. Ensure you are wearing the appropriate protective eyewear for the laser device in question. Check with your Laser Safety Officer or other safety personnel for guidance in selecting the appropriate eyewear.

For protective eyewear, the American National Standards Institute (ANSI) standard for the safe use of lasers requires that a set of protective eyewear blocking the appropriate laser wavelength should be worn while operating or servicing class 3B lasers.

Clearly label safety eyewear with their optical density and their specified wavelength protection. To avoid confusion, laser safety eyewear should be kept separate from any other safety eyewear and personal protective equipment.

Using the wrong type of safety eyewear is dangerous. It can be more dangerous to have improper eyewear and a false sense of security than to have no eyewear and take precautions based on the absence of protection. Even if you are wearing protective eyewear, never look directly into the beam; intense laser radiation is capable of destroying the protective filter.

Eye Protection

Warning: Warning:

Potential eye burns: Only use the laser in accordance with its designated use.

The following guidelines describe some of the actions necessary to avoid injury caused by the laser beam. Always follow these guidelines and take additional precautions if necessary.

When eyewear is necessary, make sure it has the proper optical density for the laser wavelength.

All other personnel in the vicinity of the laser must wear protective eyewear.

Permit only qualified personnel to operate the laser.

Never look directly into any laser beam.

Avoid indirect viewing of direct or reflected laser radiation. Specular and diffuse reflections (from reflective surfaces) can be as dangerous as the direct laser beam. Never view the beam directly through optical instruments.

Take precautions to ensure that there are no reflecting objects in the path of the laser beam.

Do not deviate from standard operating procedures when working

with class 3B and class 4 laser equipment.

Use lasers only in approved applications and locations. Take adequate precautions to prevent unauthorized personnel from entering the area where a class 3B laser is operating. Do not use lasers around untrained personnel. Ensure that all personnel in the area observe proper safety precautions.

Report all incidents of exposure to your supervisor.

Clearly display warning signs indicating the laser enclosed area with an additional warning light outside the door.

Adhere to local and national regulations governing the safe use of lasers.

Be aware that maintenance of eyewear includes, but not limited to: inspection, cleaning, testing and training in use. Maintenance should only be performed by competent personnel.

Skin Protection

Warning:

Potential skin burns: if the laser beam is kept motionless for a long period it can burn exposed skin. Only use the laser in accordance with its designated use. Safety interlocks are only to be overruled by authorized personnel.

Although the skin can withstand considerably higher radiation intensity than the eyes, tissue may be burned to a greater or lesser degree, depending on the radiation time and the irradiation intensity.

Avoid contact between the skin and the beam. Reflections of the beam may be as dangerous as the beam itself. Wear appropriate protective clothing to protect the skin whenever necessary.

Fire Protection

Warning:

Fire hazards: Class 3B lasers are potential fire hazards. If the laser beam is kept motionless for a long period it can cause flammable materials to smolder, burn, or explode. Always keep a fire extinguisher in the laser area in case a fire occurs.

Constructive Safety Features

Safety Features

The laser device is equipped with the following constructional safety features:

Appropriate Class 3B label affixed to laser device enclosure (see section Labeling).

All parts of the laser where laser radiation may possibly escape are marked with the appropriate adhesive danger signs (according to IEC 60825).

The laser has an emission indicator LED fitted that indicates laser energy is present or can be accessed.

The laser is equipped with a safety interlock system. In case of an emergency, the laser can be fully switched off (no laser emission) by breaking the interlock line.

Quality Compliance List

All NKT Photonics products are produced under our quality management system certified in accordance with ISO 9001:2015 and in some cases, in accordance with ISO 13485:2016.

