Laser Safety, Handling, and Regulatory Information

MUST READ: Never operate the laser system until you have thoroughly read this document and the its operation guide. Class 4 and Class 3B lasers are dangerous and have 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 laser systems are modular and can include both Class 4 and Class 3B laser products as per the BS EN 60825-1:2014 laser safety standard and complies with IEC/EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use. All compliances are listed under “Regulatory Compliance” on page 2.

Intended Use

The laser system 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 system should only be used by staff familiar with laser safety procedures and in facilities appropriate for laser operation. NKTP 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.

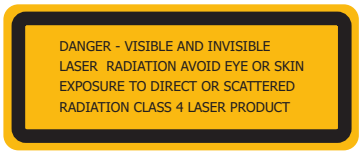
NOTICE OF RISK

This laser system can at times involve substantial risk of injury, property damage, and other dangers. Dangers peculiar to the operation of the laser include, but are not limited to eye injuries including damage to the retina and cornea, harm to the skin including photochemical and thermal burns, ignition or explosion of flammable material.

Safety Labels

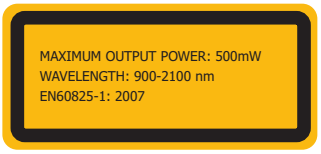
The following labels are fixed to the device chassis. For safe operations of this laser, you must be aware of the location and the meaning of each label. Ensure the labels are attached, complete and legible. Refer to the laser’s Product Description Guide for further information on the labels and their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

Classification - Emission Hazards

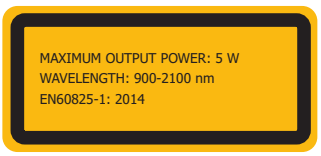


Classification - Emission Hazards

with BOOSTIK 2 W module

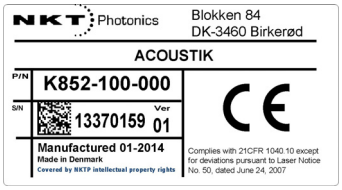


Product Information



Product Information

with BOOSTIK 2 W module



Manufacturing

Laser aperture

Laser radiation warning

Warnings

Warning: This laser system is modular and includes both Class 4 and Class 3B laser products. The operation room and operation conditions must comply with CFR21 1040.10, Laser Notice LN50, and BS EN 60825-1:2014. If these regulations are not followed you must operate the laser in accordance with local regulations for either a Class 4 or 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 multiple Class 3B or Class 4 laser beams from a fiber and its connector affixed to each of the system modules. To prevent injury, the beam paths 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 system is on, it is advised that you have clear access to its shut-off controls. Shut-off controls consist of the power supply front panel key switch and power switch, the mains cable of the power supply (unplugging it), or the emission controls within the application user interfaces. Note that the system is modular and can contain multiple laser module components.

Warning: At all times during system operation, ensure that all beam paths are 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 system 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 device is not in use. Store the key in a secure location.

Warning: It is not recommended that you operate the laser system 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 device, stop it immediately and report the malfunction to NKT Photonics A/S.

Damage Prevention

Caution: If any of the laser system's full or partial beams are 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 amplifier 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 amplifier so that in the event of a spillage, the electrical contact's exposure is minimized.

Caution: Always clean the surface of the equipment with a soft damp cloth or IT equipment tissue only. Disconnect power 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 system. In case of malfunction, NKT Photonics should be consulted.
- The unit is sealed with a "WARRANTY VOID IF BROKEN OR REMOVED" label and it is thus strictly prohibited to remove the chassis cover.

Caution: **Storage:**

- If required, the laser system should be stored in a dry and cool place (15-20°C).
- The optical output facets of inserted modules should be protected using the connector cover.
- Avoid exposing the unit to vibrations or mechanical shock.

Caution: **Chassis Cleaning**

- To clean the chassis, disconnect the power source and use a soft damp cloth or IT equipment cleaning tissue. 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 system, follow regional waste regulations.

Regulatory Compliance

FDA: 21 CFR1040.10 – Performance standards for light-emitting products

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

The laser system 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 4) Safety of laser products - Part 1: Equipment classification and requirements
- IEC/EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: general requirements

Immunity:

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

CE Approval

CE

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

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

Safety Instructions Governing Specific Operational Phases

Precautions

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

Before starting the laser system, 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 system contains both Class 4 (high power) laser and Class 3B laser module components, and are a potential hazard to the human operator. Class 4 laser beams are also classified as a potential fire hazard. Class 4 is the most powerful (and potentially hazardous) category of lasers. Direct and scattered radiation from Class 4 products are an acute hazard to eyes and skin. Precautions include eye and skin protection, remote interlocks and warning labels.

Physical Hazards

Warning: The component laser beams are potentially dangerous to the eyes and skin. The dangers include:

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

Light

In case of exposure, the laser system may provide laser radiation with power levels up to 5 Watts. The laser component emissions consists of wavelengths from 1535 to 1580 nanometers and Y10 component modules have emission wavelengths that 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 amplifier 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 amplifier. 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 both Class 4 and 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.

Lifting the laser – see “The unit is sealed with a “WARRANTY VOID IF BROKEN OR REMOVED” label and it is thus strictly prohibited to remove the chassis cover.” on page 2.

Eye Protection

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 amplifier must wear protective eyewear.
- Permit only qualified personnel to operate the laser amplifier.
- 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 both Class 4 and Class 3B laser equipment.
- Use lasers and laser amplifiers only in approved applications and locations. Take adequate precautions to prevent unauthorized personnel from entering the area where a Class 4 and Class 3B lasers are 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 4 lasers are potential fire hazards. The laser beam can cause flammable materials to ignite or explode. Always keep a fire extinguisher in the laser area in case a fire occurs.

Because of the high output power from a class 4 laser, a wide range of materials can be set on fire. Therefore, take appropriate fire prevention measures when the beam path is open:

- Combustible materials may be ignited by the laser beam or by electrical components inside the laser system. Flammable items must be isolated from the laser beam and from the laser system.
- Paper (circuit diagrams, leaflets, or even posters on the wall), curtains that are not coated with fire retardant, wooden panels or similar materials can be easily set on fire by direct or reflected laser radiation.

- Use only beam stops made of non-flammable materials (not asbestos!).
- Many fluids and solvents (e.g. cleaning agents used for maintenance) are combustible. The intense beam of the laser can ignite vapors from these materials. Prevent the laser beam from contacting flammable materials used in the laser area.
- Move containers of flammable materials as far from the laser system as possible and shield them from the beam with opaque materials. Never place these solutions and vapors in the beam path or near the system.

Constructive Safety Features

Safety Features

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

- Appropriate Class 4 and Class 3B labels are affixed to the laser system chassis (see section Labeling).
- All parts of the laser system where laser radiation may possibly escape are marked with the appropriate adhesive danger signs (according to BS EN 60825-1:2014).
- The laser system has an emission indicator LED fitted that indicates laser energy is present or can be accessed.
- The laser system is equipped with a safety interlock system. In case of an emergency, the laser can be fully switched off (no laser emission) by pulling the interlock line.
- The laser system is modular and comprised of multiple seed and amplifier laser modules. The ACOUSTIK system is equipped with an key switch and power switch. The inserted laser modules can only be switched on with the ACOUSTIK power switch on and its key-switch in the ‘ON’ position. This prevents inadvertent or unauthorized starting of the laser modules. It cannot be operated with the key in the OFF position and the key cannot be removed in the ON position.

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.