

Koheras HARMONIK Laser Safety, Handling, and Regulatory Information

MUST READ: Never operate the laser system until you have thoroughly read this document and the Koheras HARMONIK operation guide. A class 4 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

This laser system is classified as a Class 4 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 3.

Intended Use

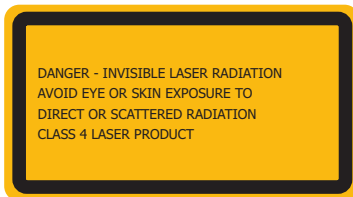
The system has been designed for general laboratory or industrial use and as such is not approved nor tested for use in treatment or diagnostics of human or animals and does not comply with European, US or rest of the World requirements for medical device lasers. Neither is the system appropriate for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

Laser Safety Officer

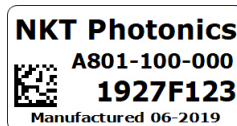
This laser system should only be used by staff familiar with laser safety procedures and in facilities appropriate for laser operation. NKT recommends appointing a Laser Safety Officer (LSO) in accordance with valid local and national safety regulations. The LSO should ensure that every user of the system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

Safety Labels

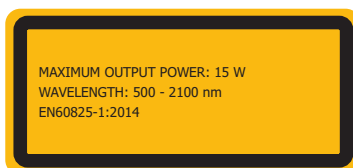
The following labels are fixed to the device chassis. For safe operations of this laser, you must be aware of the location and the meaning of each label. Ensure the labels are attached, complete and legible. Refer to the laser system’s *Product Guide* for further information on the labels and their location.



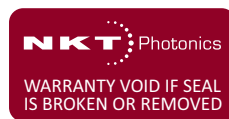
Classification label



Manufacturing label



Product information label



Warranty seal label




Laser radiation warning label




Laser aperture label

Note: If any labels are missing, immediately notify NKT Photonics A/S.

Warnings including Hazards and Injury Prevention

	<p>Warning: This laser is a Class 4 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 4 laser source.</p>
	<p>Warning: Using controls, making adjustments, or altering the procedures other than those specified by the guides associated with this laser system may result in exposure to hazardous radiation and/or voltages.</p>
	<p>Warning: This device emits a Class 4 collimated laser beam(s) from free space open aperture(s) on the chassis. Both a laser aperture and a radiation warning label is affixed at the emission aperture. To prevent injury, the beam path must be strictly controlled.</p>
	<p>Warning: Using this equipment in a manner not specified by the manufacturer may impair the protection capabilities of the equipment.</p>
	<p>Warning: At all times the laser system is on, it is advised that you have clear access to the shut-off controls of the system. Shut-off controls consist of the power supply front panel key switch and emergency stop button, the mains cable of the power supply (unplugging it), or the emission controls within the application user interfaces.</p>
	<p>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 system area is aware that the system is in operation. Ensure that remote interlock is in place.</p>
	<p>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 (if available) when the laser system is not in use. Store the key in a secure location.</p>
	<p>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.</p>
<p>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 system, stop the device immediately and report the malfunction to NKT Photonics A/S.</p>	

Damage Prevention

	<p>Caution: If the laser system'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 system operation area.</p>
	<p>Caution: Avoid spilling fluid onto the laser system chassis and accessories. If spillage occurs, remove it immediately using absorbent material. Do not allow spilled fluid to enter into the chassis.</p>
	<p>Caution: Avoid spilling fluid onto the electrical system. Place the laser system so that in the event of a spillage, the electrical sockets' exposure is minimized.</p>
	<p>Caution: Always clean the surface of the equipment with a dry cloth or tissue only. Disconnect the power supply before cleaning the unit.</p>

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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 Koheras HARMONIK's documentation applies especially to persons working only occasionally with the laser system.
- Use protective equipment, wherever required by the circumstances or by law.

Caution: Servicing the laser system:

- There are no user serviceable components inside the system. 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 system 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 system.

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 local waste regulations.

Regulatory Compliance

Safety:

- BS EN 60825-1:2014 (laser class 4) Safety of laser products - Part 1: Equipment classification and requirements
- EN 61010-1:2010: Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements

Immunity:

- EN 61326-1:2013: Electrical equipment for measurement, control and laboratory use EMC requirements – Part 1: General requirements
- 2004/108/EC Electromagnetic Compatibility

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 unplug 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 is a class 4 (high power) laser, and is a potential hazard to the human operator. The class 4 laser beam is 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 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 system may provide laser radiation with power levels up to 15 Watts. The laser system's emissions consists of wavelengths at either the 1064 nm or 1550 nm ranges. The output is from two free space apertures on the optical module chassis front panel. 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 system 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 system. The filter in protective eyewear provides protection for only a narrow band of wavelengths. Ensure you are wearing the appropriate protective eyewear for the 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 4 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.

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Eye Protection

Warning:

Potential eye burns: Only use the laser system 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 system must wear protective eyewear.
- Permit only qualified personnel to operate the laser system.
- 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 4 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: Direct and reflected laser radiation can burn exposed skin. Only use the laser system 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, or specular reflections of 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 the 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 system 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.

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Constructive Safety Features

Safety Features

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

- Appropriate Class 4 label affixed to laser system device enclosure (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 IEC 60825).

Safety Compliance List

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