

Imagent: the power of the laser diodes

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Introduction

The ISS Imagent utilizes laser-diodes as its light sources. In normal operation, eyes of the user and subject are not exposed to light emitted by the laser-diode sources. The light is contained in the instrument chassis and the fiber optics that carry the light to the measured area of the tissue (head or muscle). The light is finally diffused and absorbed by the tissue investigated. However, it is possible to operate the instrument without the fiber connected to the headgear or confined to the tissue under measurement. In this case, the intensity of light emitted by the fiber can be dangerous if viewed for a prolonged period of time, or with the "aid" of a condensing optic such as a focusing lens.

WARNING: All users and subjects should be informed, and take precautions to not directly view the bottom (output surface) of the sensor(s). No condensing lens (or other optical condenser) should ever be used with the instrument.

Each source channel of Imagent utilizes eight laser diodes, four emitting at 690 nm and four emitting at 830 nm. A total of 32 sources (or four source channels) are available per unit; two or three units can be coupled together allowing for the experimenter to utilize up to 128 excitation sources.

The lasers are turned ON and OFF sequentially through a time-multiplexing; the laser driver circuit is designed to switch between a high drive current ("ON") setting, and a low drive ("OFF") setting. When the circuit is switched to high drive current the laser is ON (emitting of optical power of the order of a few mW); when the circuit is in the OFF setting, the laser-diode emits very little light (below the lasing threshold). Only one laser diode (per measurement channel) is in the ON setting at any time. Each light source is normally held ON for a time interval ranging from 1.6 ms to 60 ms (depending on the acquisition settings). The typical cycle runs from 10 to 16 sources; assuming 10 sources, each on for 60 ms, we have for each second at the most 1-2 pulses; when using 1.6 ms pulse duration, up to 62 pulses per second are emitted by each fiber.

Energy per pulse emitted by the fiber

In the ON setting the laser driver circuit is a feedback controlled constant current source. The current is factory set to produce a fixed laser output power. During this adjustment the laser power is measured using a laser power meter coupled to the laser through a 600 µm core fiber optic patch cable. The drive current of both the 690 nm and 830 nm laser diodes is adjusted to give less than 10 mW of optical power. The OFF setting of the driver circuit is also adjusted. It is adjusted to give an optical output of less than 0.1% of that obtained in the ON setting. The light sources are mounted inside the chassis and coupled to fiber optics via SMA-type connectors. Efficient coupling of light into the fiber optics is achieved using grin lenses. Coupling efficiency has been measured at 50-80% using the 1 ISS MEDICAL TECHNICAL NOTE

400 µm core step-index fibers used by ISS supplied sensors; that is, an average power equal to up to 8 mW for each laser is coupled into the fiber. Since any given laser is switched ON for a duration of 1.6 ms to 60 ms, the

output of the 400 µm fiber optic, the maximum optical energy per pulse is (assuming a 80% coupling efficiency) is 0.48 mJ.

The standard optical fiber has a rated numerical aperture (NA) of 0.37; that is, the input and output maximum acceptance angle for a highly polished fiber would be within a cone with a maximum angle of about 43°. When using silica fibers (utilized in application with fMRI because of their low losses) with NA=0.22 and the light makes a cone of about 25° at the output). The actual fiber tips may not be highly polished, so the cone is actually somewhat diffuse. When using a fiber with NA=0.37, the light beam at 100 mm from the source covers an area with diameter 74 mm; assuming that the light is uniformly distributed, less than 1% of it covers a 7 mm diameter aperture. Since the energy distribution across the emission light cone may not be uniform – as it is the case of a well-focused light beam - this conclusion has been checked by measuring the fraction of power emitted by a well-polished 400 micron fiber at a distance of 100 mm through a 10 mm diameter round power meter. About 30% of the total optical power emitted by the 400 micron core 0.37 NA fiber was detected. When an approximately 7 mm aperture was placed in front of the power meter sensor surface, about 20% of the total optical power was detected. The average power expected to possibly pass through a 7 mm aperture at 100 mm is therefore less than 1.6 mW at both wavelengths.

Laser Safety for the Eye

When addressing laser safety, two situations are generally considered by US and European Safety Standards.

- First, the maximum power that could pass through a 10 mm diameter aperture located at 100 mm (or 200 mm) from the output of the device.
- Secondly, the maximum power that could pass through a 50 mm aperture located at the same distance.

The 10 mm aperture is considered because this is the approximate maximum size of the human pupil; the distances being roughly the minimum focal length to the eye. The 50 mm aperture simulates the use of a condensing lens typical of a viewer add such as a telescope. The large emitter area and divergence angle of the laser and fiber optics greatly reduce the effective power of the laser.

The visible lasers (690 nm) emits less than 1 mW, so it is classified as a class 2 laser even under fault conditions. The invisible lasers (830nm), also emit an average power less than 1mW, so even under fault conditions they are within the class 3R category. These categories are considering ANSI Z136-2007. If the older (pre-2002) standard, the Imagent is considered a class IIIb system, as there are no safety classes that include invisible radiation between class I and class IIIb.

Never view the laser ports, or sensor output fibers using condensing lens with a short focal length. To insure that only Class I levels of optical power reach the eyes when directly viewed with a short foal length condensing lens, the viewer would need to wear protective eyewear with an optical density of at least 7 at 830nm.

Laser Safety for the Tissue

The American National Standards Institute (ANSI) suggests the maximum permissible skin exposure limit (MPE) for 2 ISS MEDICAL TECHNICAL NOTE near infrared light to be below 200 mW/cm² sec.

The most powerful near-infrared illumination used in our protocol generates no more than 800 μ W at the fiber optic tip (which is ON for approximately 0.05 sec). This highly focused signal is then dispersed over an area of approximately 1 cm² resulting in an exposure of about 1 mW/cm² sec, which is approximately **200** times below the MPE.

Near infrared spectroscopy of the tissues (NIRS) is a technique applied in research since 1977 (in neonates, children and adults) and no adverse effects have ever been reported. NIRS is a safe, non-invasive technique. There are no known risks related to the use of NIRS. There is no possibility of physical or physiological harm or pain to the subjects during the measurements. No psychological, social, or legal risk is involved. There is a minimal or no risk, for either the investigator or the subject, of prolonged, direct eye exposure to near-infrared light during placing the sensors.

ISS and ISS Medical are ISO 9001:2000 and ISO13485 certified.

The Imagent is covered by CE-mark. It is not a medical device, and should be used for research only.

For more information please call (217) 359-8681 or visit our website at **www.iss.com**



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