

Safety Notes

on "Low Level Laser Therapy" (LLLT) Systems

Introduction

These notes aim to introduce physiotherapist, tissue viability nurse, etc. who use low level laser therapy systems to stimulate the healing of tissue lesions and injuries. They are not suitable for users of other types of laser systems, and in particular, not suitable for users of class 4 lasers.

LLLT systems are usually **Class 3B** laser devices. This means that they are not powerful enough to damage skin or cause a fire, but could damage eyes.

They usually emitting invisible infra-red (IR) light. Your natural blink response will not protect you from IR light, so these lasers could cause damage if shone into the eye.

Currently, laser products have 4 safety classes.

Laser Products Classes

- **Class 1** - Cannot cause harm, because either they are too weak to harm even the eye, or the laser beam is completely enclosed in a light-tight box. (e.g. CD players, supermarket barcode readers)
- **Class 2** - if shone for a prolonged period into the eye they would cause harm, but the natural blink reflex will protect the eye. The hazard is similar to that of staring at the Sun on a summer's day. (e.g. laser pointers)
- **Class 3A** - same as class 2, except that if viewed through a magnifying glass, telescope, etc. the beam could cause eye damage before you have time to blink. (e.g. some aiming beams for surgical lasers)
- **Class 3B** - can cause eye damage, either because they are so powerful that you will not blink in time, or because they emit invisible infra-red or ultra-violet radiation, and so you will not blink at all. (e.g. low level therapy lasers)
- **Class 4** - can damage eyes, burn skin, and possibly start fires. (e.g. surgical lasers)

Please note that these **Safety Notes** are written for users of **Class 3B devices only**. They aim to help in operating lasers safely, and do not cover clinical matters such as treatment regimes and contra-indications.

Wavelength

The wavelength of a laser beam denotes its "colour". Different wavelengths have different physiological effects. For example, long wavelength, far infra-red, carbon dioxide laser beams are readily absorbed by the water in cells, and so are good for cutting tissue in surgery. Shorter wavelength, green, argon laser beams are not readily absorbed by water, and so are used in ophthalmic surgery to shine through the liquid in the eyeball and treat the retina.

For lasers, wavelengths are normally quoted in nanometres (nm). Wavelengths between 620 nm and 780 nm are RED. Wavelengths from 780 to 1,400 nm are NEAR INFRA-RED. Currently, LLLT systems use only red or near infra-red beams.

Some of the different wavelength lasers found in our hospitals

Far Infra-Red - carbon dioxide (CO₂) surgical laser (10,600 nm)

Mid Infra-Red - holmium YAG (Ho:YAG) surgical laser (2,100 nm) , niodymium YAG (Nd:YAG) surgical laser (1,060 nm)

Near Infra-Red - LLLT

Red - helium-neon (He:Ne) aiming and alignment lasers (633 nm), LLLT (?)

Orange - *none*

Yellow - copper vapour photodynamic therapy laser (578 nm)

Green - argon ophthalmic surgical laser (515 nm)

Blue - argon ophthalmic surgical laser (477 nm)

Indigo, Violet, Ultra-Violet - *none*

Pulse/Continuous/Frequency

Laser systems can often be operated in different modes.

In **continuous mode** laser radiation is continuously emitted, in the same way that a light bulb continuously emits light when switched on.

In **single pulse mode** a single pulse of laser radiation is given in a fraction of a second, in the same way a flash on a camera gives a single pulse of light.

In **intermittent pulse mode** a series of pulses are given, with gaps in between, like a machine gun firing.

Power, Irradiance, etc.

Where a single pulse is given the "dose" is usually expressed in milli-joules (mJ). This is a measurement of ENERGY. 1000 mJ equals one Joule. It takes 4,200 Joules to raise the temperature of 1 litre of water by 1°C.

Where continuous beams are used the output is expressed in milli-watts (mW) or Watts (1000 mW = 1 W). This is a measurement of POWER. 1 Watt is 1 Joule per second. So, a 100 mW beam operating for 5 seconds will deliver 500 mJ of energy.

Intermittent pulsed beams have a FREQUENCY or PULSE REPETITION RATE expressed in Hertz (Hz). 1 Hz is one pulse per second, 2 Hz is two pulses per second, etc. Manufacturer's sometimes quote the energy of each pulse in Joules, or the power during each pulse in Watts, or the average power during the whole of the exposure. This can make it difficult to compare one system to another.

The IRRADIANCE is the power per unit area, and is usually quoted in mW/cm².

The RADIANT ENERGY is the energy given per unit area, and is usually quoted in J/cm². This is sometimes called "energy density". Some manufacturers recommend around 4 J/cm² as the "ideal treatment dosage".

For most (if not all) LLLT systems the laser radiation spreads out from the probe. Therefore, the greater the distance from the probe, the less the irradiance, and the safer (and less clinically effective) the beam is.

All lasers must have a label on them saying what class they are, what wavelengths they emit, and what maximum powers or energies they produce.

Maximum Permissible Exposure

The maximum permissible exposure (MPE) that is safe for different wavelengths and pulse lengths is defined in a British Standard¹. By definition, Class 3B laser products cannot exceed the MPE for skin, but can exceed the MPE for eyes.

The table below gives the MPEs for the cornea for typical wavelengths used in LLLT.

Wavelength	Uses	MPE (cornea) continuous
670 nm (red)	Bedsore, Ulcers, Open wounds	0.63 W/cm ²
780 (infra-red)	Superficial Muscular or Ligament Lesions	4.6 W/cm ²
820 nm (infra-red)	Muscular or Ligament Lesions	5.6 W/cm ²
850 nm (infra-red)	Deeper Muscular or Ligament Lesions	6.4 W/cm ²

Safety Systems

Because Class 3B and Class 4 laser systems can be dangerous, the Trust has a Laser Radiation Health & Safety Policy, a copy of which is attached to, and forms part of, these notes.

The Policy describes how we have CONTROLLED AREAS, which define where a hazard exists. For LLLT this is usually the cubicle or room in which the treatment takes place. Precautions should be taken to ensure that laser radiation cannot harm people outside the Controlled Area (i.e. curtains and doors closed), and that no-one will enter the Controlled Area without being aware that a laser is in use (i.e. put notices outside area, or lock door).

To ensure that safe practice is followed within the Controlled Area we have LOCAL RULES for each laser. An example is attached.

¹ Radiation safety of laser products, equipment, classification, requirements and user's guide, BS EN 60825:1992
Issue 1/01

To ensure that Local Rules are written and updated, a Laser Protection Supervisor (LPS) is appointed.

The Medical Physics Service provide a Laser Protection Adviser to give advice on technical matters of laser safety.

Safety Eyewear

Because Class 3B lasers can damage the eyes, appropriate laser safety spectacles should be worn by all people in the Controlled Area, both staff and patients.

Note that not all laser safety specs. are suitable for all lasers.

Modern laser eyewear should be labelled with a code such as

"DR 620-700 L2 X ZZ S"

The number in front of the "L" tells you the wavelengths that these specs. are good for, and the number after the L tells you how strong the specs are.

In this example, the specs. are good for lasers operating at wavelengths between 620 nm and 700 nm, and their OPTICAL DENSITY (OD) for these wavelengths is at least 2. An OD of two only lets $1/100^{\text{th}}$ of the laser light through. OD3 lets only $1/1000^{\text{th}}$ through, OD4 only $1/10000^{\text{th}}$, etc.

You can compare the wavelength on the label on your laser with the labelling on your safety specs.

Further Information

You can find some more information on LLLT systems at the following web sites. Note that some are written by manufacturers.

- Thor Laser Systems : <http://laser.uk.com> (*quite useful*)
- USA regulatory authorities: <http://www.fda.gov/cdrh/consumer/laserfacts.html>
- Swedish site (*in English!*): <http://www.laser.nu/>
- SIM-MED LTD: <http://www.therapylaser.com/>

Or by coming to a local laser safety training session -

The Safe Use of Medical Lasers Course

This course aims to introduce staff to safe working practices with medical lasers. Customised training sessions for groups of staff (e.g. theatre nurses/ODA's, junior/senior medical staff, technologists, etc.) can be arranged on request. Contact John Saunderson (01482 676690) to arrange one of these 1½ hour training sessions (for a minimum of six staff) at the time and venue to suit your hospital or department.

This course will involve:

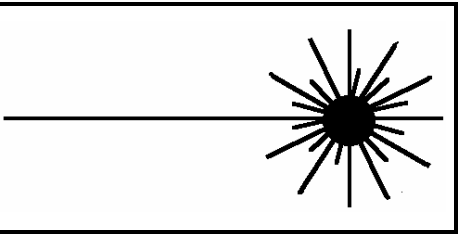
- * Nature of laser radiation - its uses in the health service and its hazards.
- * Safety issues for work with lasers.
- * Discussion on issues of concern to participants

Who will benefit? Laser users, Laser Protection Supervisors, laser operators, and any staff working in areas where lasers are in use.

Or by contacting one of the Trust's Laser Protection Adviser directly.

Mr. John Saunderson
Laser Protection Adviser
Radiation Physics Department
The Princess Royal Hospital
Saltshouse Road
Hull
HU8 9HE
(01482) 676690
john.saunderson@hey.nhs.uk

**RADIATION PROTECTION
POLICY AND PROCEDURES**

<p><u>LASER RADIATION</u> <u>HEALTH & SAFETY</u> <u>POLICY</u></p>	
---	--

HAZARDS

A laser beam consists of a highly concentrated beam of infrared, ultraviolet or visible light. Laser radiation can cause tissue damage, due in the main to rapid heating of the irradiated area. Laser light is particularly hazardous to the eye, as the lens of the eye may focus the laser beam onto the retina, causing an even greater concentration of energy over a small, but critical area. It should be noted that specular (i.e. mirror-like) reflections of laser beams may be just as hazardous as the primary beam itself.

For some very powerful laser beams, even diffuse reflections (e.g. from a matt surface) can be hazardous. Such lasers may also present a fire hazard, particularly where laser beams are used in close proximity to anaesthetic gases.

Laser products are classified and marked according to different degrees of hazard.

- Class 1** **Totally safe.**
(Either visible and so weak that direct viewing is not harmful, or totally enclosed.)
- Class 2** **Safe for accidental viewing.**
(Visible. Blink response is enough to protect eyes.)
- Class 3A** **Safe unless viewed with optical instruments.**
(Visible. Blink response is enough to protect eyes, unless viewed directly with an optical instrument.)

Class 3B Hazardous to eyes. Eye protection needed.

(May be visible or invisible.)

Class 4 Even diffuse reflections may be hazardous to eyes. Eye protection needed.

Direct beam & specular reflections hazardous to eyes. Eye protection needed.

Direct beam & specular reflections hazardous to skin. Skin protection needed.

Fire hazard.

A Maximum Permissible Exposure (MPE) can be calculated for each laser from tables published in BS EN 60825:1991 and elsewhere, if the exposure time and wavelength of the beam are known.

When eye protection is used it is important that the wavelength of the filters matches that of the laser. The Optical Density (OD) should be sufficient to reduce the power density of the primary beam to a level below that of the MPE.

When lasers are used to vaporise a target material (e.g. laser scalpel) fumes will be produced. These could obscure the site of interest, leading to incorrect aiming of the laser beam, or if inhaled present a biological hazard. Therefore proper smoke/fume extraction apparatus must be used, where necessary.

In the rest of this document, the term "laser" is used to refer to class 3A, 3B and 4 lasers only.

LASER CONTROLLED AREAS

A Laser Controlled Area (LCA) must be established around any laser where there is a risk of the Maximum Permissible Exposure (MPE) level being exceeded within that area. The occupancy and activity of all persons within a Laser Controlled Area are subject to control and supervision to prevent exposure to laser radiation in excess of the MPE levels and the boundaries of the Laser Controlled Area will normally be the walls, floor and ceiling of the room. Laser Controlled Areas must be defined in the Local Rules, together with the conditions under which they exist. In so far as is reasonably practicable, no person should be in a Laser Controlled Area while the laser is in use unless that person's presence is required.

Care should be taken to limit the laser beam to the LCA. Doors should be closed, and windows may need to be fitted with fire-resistant curtains. Entrances to the LCA should be labelled with appropriate signs, approved by the Laser Protection Adviser (LPA).

Each operating theatre/outpatient treatment room in which a laser is to be used shall have an approved warning sign at each entrance. Signs should be consistent throughout the department and "secret" until illuminated.

LOCAL RULES

Local Rules for the safe use of lasers for specific purposes must be drawn up for all Lasers. These will define Laser Controlled Areas and should ensure that no person is exposed to laser radiation in excess of the MPE level (unless this is a specific part of that person's treatment as a patient). The Laser Protection Supervisor should ensure that the Local Rules are implemented in the areas for which they are responsible. Lasers should not be used in areas outside those defined in Local Rules without consultation with the Laser Protection Adviser.

GENERAL USER SAFETY MEASURES

- a) The laser should not be fired unless aimed at the chosen tissue site or at a suitable external beam stop. The Operator's role is of crucial importance for "open" systems in which either almost unlimited free-hand aiming of the beam or a fibre transmission system not having a fixed distal termination point.
- b) If there is any hazard to staff, the Laser Operator must warn them orally that the laser is about to be fired the laser or a series of exposures is about to commence.
- c) Adequate protection for the eyes must be worn by all staff who could be exposed to laser radiation in excess of the Maximum Permissible Exposure (MPE) level.
- d) All protective eyewear must be marked to indicate the operational wavelength for which it is suitable and the Optical Density (OD) of the filter at that wavelength. Protective eyewear may not provide adequate protection for viewing the direct beam. (The minimum OD required to reduce the power density of the primary beam to a level below that of the MPE will be calculated by the Laser Protection Adviser.)
- e) The patient's eyes must be protected where appropriate.
- f) Any tubes carrying oxygen or oxidised anaesthetic gas should be protected (e.g. wrapped in aluminium foil) if there is any possibility of their being damaged by exposure to the laser beam.
- g) When a class 4 laser is used care should be taken to avoid the possibility of ignition of flammable materials, particularly in oxygen enriched atmospheres.
- h) Medical lasers should not be operated if any target indicating or aiming device is faulty (e.g. aiming system misalignment with laser beam or aiming beam not present). The alignment of the main laser beam and aiming system should be checked regularly.
- i) The power output or energy indicators incorporated in class 3B and 4 lasers should be calibrated regularly against beam power or energy measurements made with an appropriate meter.

UNTOWARD INCIDENTS

Untoward Incidents include

- inadvertent eye exposure, even where protective eyewear is worn
- inadvertent skin exposure
- fires, however minor
- exposure to laser radiation of an area outside the Controlled Area
- failure of target indicating or aiming device, e.g. aiming system misalignment with laser beam or aiming beam not present
- failure of the beam to terminate correctly

In the event of inadvertent eye exposure, access to the Ophthalmic Department is available through Accident & Emergency at Hull Royal Infirmary.

All Untoward Incidents should be reported to the Laser Protection Supervisor (LPS) and the Laser Protection Adviser (LSA). A standard hospital accident form should be completed.

The Notification of Accidents and Dangerous Occurrences Regulations 1980 may require the reporting of certain Untoward Incidents to the appropriate authorities. Such reporting will normally be made by the LSA in consultation with the LPS and other relevant persons.

When an inadvertent skin or eye exposure has occurred, an estimate of the exposure time is needed, in order to assess whether the Maximum Permissible Exposure (MPE) has been exceeded, and the extent of the risk to the exposed person..

EQUIPMENT LOANS

The Laser Protection Adviser (LPA) should always be consulted before new or loaned laser equipment is used. It will usually be necessary to define a temporary Laser Controlled Area for demonstrations.

MAINTENANCE

Maintenance and adjustment of the laser must only be undertaken by authorised persons with appropriate technical expertise in accordance with manufacturers' instructions. The Laser Protection Supervisor should be informed of all maintenance and adjustments.

If any work is carried out which alters the characteristics of the laser beam, then the LPS and LPA must be informed, preferably in writing. The LPS should then ensure that all Authorised Operators are informed of and understand the changes. Maintenance policy and a record of maintenance work should be kept by the LPS.

Laser Health & Safety: APPENDIX 1

RESPONSIBILITIES

Laser Protection Adviser (LPA): Mr Viv Whitton,
Radiation Physics Department,
The Princess Royal Hospital
Tel. (0482) 676702

The LPA provides help and guidance on the safe use of lasers. The LPA should always be consulted before new or loaned laser equipment is used. The LPA will assist the Laser Protection Supervisor (LPS) in the drafting of appropriate Local Rules. The LPA should be consulted whenever a laser is to be used outside the area defined in the Local Rules for that laser.

Laser safety incidents should be reported to the LPA, who will ensure that an investigation is carried out, and will liaise with the appropriate authorities (e.g. DoH, HSE, etc.)

Duties of Laser Protection Supervisor (LPS)

The LPS is the person “on site” responsible for laser health and safety matters. The LPS should be directly involved with work with lasers, preferably in a line management position that will allow the LPS to exercise close supervision to ensure that work is done in accordance with the Local Rules, though the LPS need not be present the whole time. The LPS will maintain a list of the Authorised Users, the Local Rules and any other relevant records. The LPS should ensure that Local Rules are kept up to date. The LPS is responsible for organising security of the laser equipment’s keys. The LPS must receive sufficient training to ensure an understanding of the LPS responsibilities to all persons within the LCA.

The LPS should be informed immediately of any problems that arise with regard to safe use of the equipment or any accidental exposure to the eyes. Any laser safety incidents should be reported by the LPS to the LPA.

Comment [AU1]:

Authorised Operators

Laser may only be operated by Authorised Operators, or in special circumstances by other persons under the direct supervision of an Authorised Operator. Authorised Operators should be classed as clinical (e.g. surgeons) or non-clinical (e.g. maintenance staff).

Laser Operators should read and understand the Laser Radiation Health & Safety Policy. The Laser Operator is responsible for using the laser in a safe manner for both staff and patients. The Laser Operator should see that eye protection is worn by staff where this is laid down in the Local Rules. If there is any hazard to staff, the Laser Operator must warn them orally when the laser is about to be fired or a series of exposures is about to commence.

Authorised Assistant

Some lasers require a second person to assist the Authorised Operator. For example, most surgical lasers require an assistant to operate the laser console while the surgeon controls the fibre optic, or other delivery system, and a footswitch which fires the laser. The responsibilities of the Authorised Assistant should be detailed in the Local Rule. These duties may include ensuring that all staff in the Controlled Area have goggles, ensuring that warning signs are displayed at entrances, preparing the laser for use, etc. Authorised Assistants should have received training on general laser safety, and should normally have assisted in at least five or six treatments under the supervision of a previously trained Authorised Assistant. A list of Authorised Assistants should be kept by the Laser Protection Supervisor.

Laser Health & Safety: APPENDIX 2

BIBLIOGRAPHY

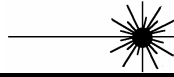
Guidance on the safe use of lasers in medical practice, MDA, 1995, ISBN 1 85839 488 0 (MDA, London)

BS EN 60825:1992, Radiation safety of laser products, equipment classification, requirements and user's guide, ISBN 0 580 20563 0 (BSI)

Author:	J R Saunderson
Date approved:	9 June 1995
Review date:	December 2002

FILE: ajrs\lasers\LASER21.DOC

Laser Local Rules for Health & Safety



CLASS 3B PHYSIOTHERAPY LASER,
HAPPY VALLEY COMMUNITY HEALTH NHS TRUST

The purpose of these Local Rules is to ensure that everyone involved with the use of the laser is aware of the potential hazard and knows the safety precautions which need to be taken.

Laser Protection Adviser (LPA): Mr Viv Whitton
Radiation Physics Department,
The Princess Royal Hospital,
Hull, HU8 9HE
(01482) 676702

Laser Protection Supervisor (LPS): Mrs Jane Doe,
Sunny Street Clinic,
Saesame Street,
Oz,
(020) 7622 3626

The LPS is responsible for ensuring that the Local Rules are observed. She should be informed immediately of any problems that arise with regard to the safe use of the equipment or any accidental exposure to the eyes.

All Authorised Users must read the Local Rules before they use the laser.

Maintenance and adjustment of the laser must only be undertaken by authorised persons with appropriate technical expertise in accordance with the manufacturer's instructions.

Nature of Potential Hazard

Class 3B lasers used in physiotherapy generally consist of semi-conductor lasers emitting both visible red and invisible infra-red light.

If the light from the probe impinges on the lens of the eye, it will be focused on the retina and may cause retinal burning. The resulting retinal damage will cause the vision to be impaired and in the worse case cause total blindness in the affected eye. Damage of this nature is irreparable.

Laser Controlled Areas

Hospital Department

The laser must only be used in curtained off cubicles, with a warning sign clearly displayed at the entrance. During treatment this cubical is designated as a Controlled Area.

Health Centres

The laser should be used in a single examination room. During the treatment this room is designated as a Controlled Area and a warning sign must be displayed clearly on the door.

Domiciliary

In patients' homes, the room in which the treatment is carried out becomes the Controlled Area, and staff must ensure that curtains are closed and that inadvertent access by other persons will not cause a hazard.

If practicable, the laser should always be pointed away from any entrance, wherever it is used. Curtains should be closed to prevent laser light from "escaping the room" where applicable.

Personnel

All personnel in the Controlled Area must wear appropriate protective eye-wear suitable for the type of laser used. This includes the operator and the patient. Other observers should be discouraged, but if necessary for patient care they also must wear protective eye-wear.

Authorised Operators

A register should be kept of all personnel authorised to operate the laser. This register will be kept in the custody of the LPS, who may appoint other authorised clinical operators. All authorised personnel must sign a statement that they have read and understood these Local Rules before they use the laser. A person should normally carry out at least four treatments under the supervision of a previously authorised operator before themselves being authorised.

Security

The laser is operated by a key. One key will be kept in the custody of the LPS. Other keys must be kept securely at Goole Hospital when not in the custody of the authorised operator currently using the laser.

After use, the key **must** be removed from the laser.

The laser **must not** be left unattended with the key in the machine. The key will be clearly labelled as follows: "LASER Authorised Personnel only"

Class 3B Physiotherapy Laser, S&GCH - Register of Authorised Users

Non-clinical operators: Manufacturer's staff
 Medical Physics staff

The following have read and understood the Local Rules governing the safe use of the laser:

<u>Name (PRINT)</u>	<u>Signature</u>
Jane Doe	Jane Doe
Louise Lubby	Lubby Lou
R.T. Builder	X

JRS : 25/03/96