

# Non-Surgical Lasers and Intense Pulse Light systems & Light Treatments (High Intensity LED) - Code of Practice 13

# **Purpose**

The purpose of this code of practice (COP) is to support the policy decisions and conditions of licence adopted by the council in respect of special treatments establishments.

# Scope

This COP details specific requirements for class 3B and 4 lasers and intense light systems in addition to those laid down in the regulations prescribing standard conditions applicable to all special treatment premises.

#### **Definitions**

#### Laser

 This is an acronym of light amplification by stimulated emission of radiation. In the beauty industry lasers are generally used for noninvasive cosmetic treatments, such as removal of hair, tattoos, birthmarks, acne scarring, and other blemishes, from the skin or treatment of superficial undesired vascular lesions. The mode of emission of the radiation can be continuous, wave, or pulsed.

#### Class 3B lasers

• Radiation in this class is likely to be dangerous, maximum output into the eye must not exceed 500mW. The radiation can be hazardous to the eye or skin, but viewing of diffuse reflection is generally safe.

#### Class 4 laser

Highest class of laser radiation, diffuse reflection is also hazardous. If
used incorrectly it can cause serious skin and eye injuries and is
capable of setting fire to material. High Intensity LED – light emitting
diodes delivering an output of over 500 milliwatt similar to that of a
Class 4 laser or IPL.



## Intense light systems (ILS)

Intense light systems are generally treated as class 4 lasers. Intense
Pulsed light (IPL) systems fall into this category and are the intense
light system generally used for non-invasive cosmetic treatments
found in the beauty industry. IPL is pulsed or shuttered emission which
gives tissues time to cool between pulses. Other intense light systems
that may be used in this industry may not be filtered or pulsed.

## Expert registered healthcare professional (ERHP)

 The ERHP is a qualified medical practitioner with verifiable clinical expertise in using laser/intense light systems to treat patients/clients.

## Expert dental practitioner (EDP)

• The EDP is a qualified Dental Practitioner with verifiable clinical expertise in using laser/intense light systems to treat patients/clients.

## Laser protection advisor (LPA)

The LPA is the person providing expert advice on laser/ILS safety. The LPA will carry out an audit report (Health &Safety at Work etc. Act 1974), hazard analysis and risk assessment (Management of Health & Safety at Work Regulations 1999) for each laser/ILS installation and advise on training, protective eye wear and ensure local rules are produced, signed, dated and implemented for each installation. The LPA may be external to the business. The LPA shall either be approved by <a href="http://www.rpa2000.org.uk/list-of-certificate-holders/">http://www.laserprotectionadviser.com/</a> or Public Health England <a href="https://www.phe-protectionservices.org.uk/lpa">https://www.phe-protectionservices.org.uk/lpa</a>

#### Local rules

 The local rules are produced by the LPA and are a set of rules specific to each installation, detailing safe working practice and day-to-day safety management.

## Laser protection supervisor (LPS)

 The LPS is usually an employee of the business and is responsible for supervising the work of all laser/ILS authorised users, the safety and security of all laser/ILS, ensuring all users are appropriately trained to



operate the laser/ILS, and that the local rules document is followed on a day to day basis.

#### Authorised user

 The authorised user is the individual who operates the laser/ILS equipment to treat clients.

## Access to expert advice

- The licence holder shall employ the services of an expert medical practitioner (ERHP) to produce the treatment protocol document and to provide ongoing support and advice.
- The licence holder shall employ the services of a certificated laser protection advisor (LPA) to produce local rules and provide ongoing support and advice.
- Both the local rules and the treatment protocol must be available for reference, next to each machine.

#### Local rules

- A local rules document must be produced by a certificated LPA in relation to the licence holder's equipment/premise. The contract of services for the registered LPA must be available to the Council.
- The local rules should be issued, signed and dated by both the employer and the LPA and should be reviewed annually and include a projected date for review. It should be reviewed when there is a change of treatment or any other changes that could affect the client's interest. They must be retained on site.
- Local rules must identify the named person(s) authorised to operate the laser/ILS.
- The laser must only be used in accordance with these rules.
- Authorised users must sign to indicate they accept, understand and agree to work to the local rules procedure.
- Local rules must be available for each installation even if they are being used on a trial basis and must include the following:
  - potential hazards associated with lasers and ILS
  - > controlled and safe access
  - > authorised user's responsibilities
  - > methods of safe working
  - > safety checks
  - normal operating procedures
  - personal protective equipment



- > prevention of use by unauthorised persons
- > adverse incident procedure
- procedure to ensure that unauthorised persons do not operate the laser or ILS when the machine is left unattended by an authorised user

## Treatment protocol

- A treatment protocol must be produced by an ERHP in relation to the licence holder's equipment/premises.
- The treatment protocol should be signed and dated by the ERHP to confirm authorisation, should be reviewed annually and include a projected date for review. It should be reviewed when there is a change of treatment or any other changes that could affect the client's interest. The treatment protocol must be retained onsite.
- A separate treatment protocol should be in place for each laser/ILS in use at the licensed premises.
- The treatment protocol must include the following:
  - > name and technical specifications of the equipment
  - contraindications
  - > treatment technique general
  - > treatment technique hair reduction
  - client consent prior to treatment including checking skin type and pigmentation
  - > cleanliness and infection control
  - > pre-treatment tests and pre-treatment instructions
  - > post-treatment care
  - recognition of treatment-related problems
  - > emergency procedures
  - > permitted variation on machine variables
  - > procedure in the event of equipment failure
  - > written aftercare advice must be provided after the first treatment

## Laser protection supervisor

- A person with onsite, overall responsibility for lasers/ILS must be appointed, this will be the laser protection supervisor (LPS).
- The LPS will ensure the following:
  - > local rules are followed and kept
  - have day-to-day local responsibility for laser safety
  - will inform the LPA if they consider that the existing rules require changing



- ensure that the LPA is advised as soon as possible in the event of an incident occurring
- > inform the Licensing Authority team London Borough of Redbridge in the event of an incident occurring
- ensure all laser/ILS authorised operators are appropriately trained and that the training is documented
- > ensure a register of authorised operators is maintained
- ensure lasers are used only for treatments for which authorised users have been trained and are competent

## Operator responsibility

- While the equipment is being operated the authorised user must be responsible for the safety of all persons in the controlled area, including the client.
- The authorised user must ensure removal of reflective jewellery from self and client.

## Treatment register

A customer treatment register in a hard copy spine glued book must be maintained every time the laser/ILS is operated and must include:

- the name of the person treated and date of birth
- the date and time of the treatment
- the name and signature of the laser/ILS operator, serial number of the laser/IPL (at front of log)
- the nature of the Laser/ILS treatment given and body area
- the treatment parameters
- any accidents or adverse effects
- Patch test and result recorded on client's consultation record
- If separate individual treatment records for each client are kept, which give full details of Laser settings, then this bound book register may be abbreviated to the date, patient name, patient D.O.B. type of treatment, area of treatment, date of treatment and the operator's signature – use a simple glued A5 book. An electronic system can be used instead providing any editing history is clear in this log.

#### Controlled treatment area

- The area around working lasers and intense light systems must be controlled to protect other persons while treatment is in progress.
- Access to the controlled treatment room must be restricted.



- The controlled area must be clearly defined and the laser or ILS may only be used in this room.
- The controlled area must not be an access to other areas.
- No other laser or ILS should be in use in the same controlled area at the same time.
- Suitable warning signs must be displayed on the outside of doors to the controlled area.
- All lasers and ILS must comply with current standards requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (BS EN 60601-2-22 and BS EN60825 for medical lasers and BS EN 60601-2-57 for ILS) and <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/474136/Laser\_guidance\_Oct\_2015.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/474136/Laser\_guidance\_Oct\_2015.pdf</a>
- Lasers must be clearly labelled on the front of the machine with the following information:
  - > identification of the machine
  - > the wavelength or range of wavelength
  - > maximum output power of the radiation emitted
- For all laser and intense light sources with a key switch, formal arrangements must exist for the safe custody of the key, separate from the equipment.
- Only authorised users may have access to the key.
- The operating key must not be left unattended with the laser/ILS equipment.
- Equivalent arrangements must exist for equipment protected by password instead of key.
- Mirrors and other reflective surfaces must be covered or removed when treatments take place.
- All windows in the controlled area should be supplied with nonreflective window coverings such as blinds.

## Protective eyewear

- Protective eyewear shall be provided and clearly marked for the laser and conform to BS EN207.
- All protective eyewear must be marked with the wavelength range and protection offered.
- The specification of the required eyewear must be indicated in the local rules.
- The authorised user shall instruct all personnel in the controlled area to wear goggles suitable for the laser being used.



- Effective eyewear must be worn by everyone within the controlled area whenever there is a risk of exposure to hazardous levels of laser or ILS radiation.
- Protective eyewear must be adequately cleaned and disinfected between treatments.

#### Qualifications

- All authorised users must hold a qualification that meets national occupational standards (NOS) at level 4-6 in a relevant subject. In exceptional circumstances, where NOS qualifications are not available, an assessment will be carried out on an individual basis and further training required as appropriate.
- All authorised users and the LPS must be trained to at least the laser/ILS Safety Core of Knowledge Certificate level covering the syllabus specified in MHRA bulletin DB2008(03)).
- Records of training must be kept at the premise and available at all times by inspecting officers. Records must include the training curriculum.
- All authorised users and the LPS must receive further training on the specific laser/IPL in use. Records of this training must be kept on site and available at all times for inspecting officers. Records must include the training curriculum.
- Records of training must be kept with the local rules.
- All core of knowledge training must be refreshed every three to five years.
- All operators must maintain evidence of continued professional development (CPD) to demonstrate up to date knowledge and skills.

#### Maintenance

- The laser and ILS must be serviced and maintained according to the manufacturers' instructions to ensure they are operating within their design specification.
- A record of service and repairs must be kept on site and available for inspecting officers.
- Lasers and ILS must have an electrical safety test carried out annually.

#### Review

This code of practice will be reviewed regularly and updated in light of current industry guidance and legal opinion. Any changes will be notified to licensees and will be attached as conditions to your licence with effect from the date of the next renewal of your licence.



Up to date copies are available from our Regulatory Services.

#### Further information

Hair and Beauty Industry Authority (HABIA)

1 Top Farm Court Top Street Bawtry Doncaster DN10 6TF 0845 2306080 www.habia.org.uk

Medicines and Healthcare Products Regulatory Agency (MHRA)

Market Towers, 1 Nine Elms Lane, London, SW8 5NQ 020 7084 2000

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
Device bulletin MHRA DB 2008(03)

British Medical Laser Association

Biophotonics Research Unit, Gloucestershire Hospitals NHS Foundation Trust, Great Western Road, Gloucester, GL1 3NN, UK Tel: 08454 225470 Fax: 08454 225485 www.bmla.co.uk

The following London Borough of Redbridge Guidance Notes should be consulted in conjunction with this code of practice:

- GN1 Guidance on Hand Washing
- GN2 Guidance notes on decontamination