

PUBLIC PROTECTION DIVISION
222 UPPER STREET, LONDON N1 1XR
STANDARD CONDITIONS
FOR PREMISES PROVIDING NON-SURGICAL LASER/IPL TREATMENTS
London Local Authorities Act 1991-2000

These conditions are to be read in conjunction with the Standard Conditions for Special Treatment Premises. Other conditions may be added to licences if circumstances warrant this.

General

1. All lasers/IPLS shall comply with current standards (BS EN 60601-2-22 for medical lasers and BS 60601-2-57 and shall display labels identifying them, their wavelength or range of wavelengths and the maximum output power of the radiation emitted. The labels shall be clearly visible on the front or side of the machine.

2. The licence holder shall employ the services of an Expert Medical Practitioner to produce a 'treatment protocol' document. This document must be kept on site and be available for inspection on request of an authorised officer. (Appendix A outlines the information required in this document).

If there are changes made to the equipment in use, the procedures or to the treatment room an Expert Medical Practitioner must again be employed to amend the 'treatment protocol' where necessary.

3. The Licence holder, using the services of a qualified Laser Protection Advisor (LPA), shall produce 'local rules' for the use of the laser/IPL equipment (A specimen local rules document is attached as Appendix B).

The 'local rules' must be updated if there are changes made to the equipment in use, the procedures or to the treatment room, if these affect the safe use of the laser/IPL.

4. A suitably qualified member of staff on the premises shall be identified as the laser protection supervisor they will have day to day to responsibility of ensuring the local rules are followed.

5. All authorised users of the laser/IPL equipment shall be trained to at least the Core of Knowledge Certificate level and records of such training shall be kept on site with the local rules. Any training on the specific equipment in use at the premises shall also be recorded. Such training should be refreshed every 3-5 years.

6. A treatment register shall be completed every time the laser/IPL is operated, including the following information:

- a) the name of the person treated (including a second means of identification);
- b) the date and time of treatment;
- c) the name and signature of the laser/IPLS operator;
- d) the nature of the laser/IPLS treatment given;
- e) the treatment parameters;
- f) any accidents or adverse effects.

Laser/IPL Controlled Area

7. The area around working lasers/IPL shall be controlled to protect other persons while treatment is in progress. The controlled area shall be clearly defined and not used for other purposes.

8. A suitable safety warning sign or light entry system which complies with current British Standards shall be in place on the door of the controlled area.
9. The door to the controlled area shall be fitted with a suitable device which can be operated from the outside in an emergency.
10. Any windows in the controlled area shall be fitted with opaque blinds approved by the LPA.
11. The controlled areas shall be kept clear of clutter, mirrors shall be avoided and jewellery shall not be worn.
12. Surfaces within the controlled area shall be of a matt or eggshell finish.
13. Protective eyewear shall be worn by everyone within the controlled area whenever there is a risk of exposure to laser/IPL. All protective eyewear shall be marked with the wavelength range and protection offered as detailed in the local rules document. They shall be in a clean serviceable condition.
14. The laser protection supervisor shall ensure that the key to the laser/IPL equipment is kept in a secure and separate area when not in use. Only authorised users shall have access to the key.
15. Laser/IPL equipment shall be serviced annually and a record kept of servicing and repairs with the local rules document.

APPENDIX A

Laser/IPL Treatment Protocol Document

A treatment protocol must be produced by an expert medical practitioner (EMP) in relation to the equipment/premises of the licence holder.

The treatment protocol sets out the necessary pre-treatment checks and tests, the manner in which the laser/IPL is to be applied, the acceptable variations in the settings used and when to abort a treatment.

A separate treatment protocol should be in place for each laser or IPL equipment in use at the licensed premises.

1. The treatment protocol must include the following:
 - a) name and technical specifications of the equipment;
 - b) contraindications;
 - c) treatment technique – general;
 - d) treatment technique – hair reduction;
 - e) client consent prior to treatment;
 - f) cleanliness and infection control;
 - g) pre-treatment tests;
 - h) post-treatment care;
 - i) recognition of treatment-related problems;
 - j) emergency procedures;
 - k) permitted variation on machine variables;
 - l) procedure in the event of equipment failure.

APPENDIX B

LASER/IPL LOCAL RULES SPECIMEN DOCUMENT

The following example is presented as a **guide to format only**; it is not presented as model rules. Local rules should be appropriate to the particular type of optical radiation device, the intended application, the associated risks and local circumstances.

LOCAL RULES FOR THE SAFE USE OF LASER AND IPL EQUIPMENT

Nature of hazards to persons

The laser can cause injury to the skin and eyes from both the direct and scattered beams. The aiming beam may also be hazardous. Safe use of the laser (or IPL) depends upon strict adherence to the following rules:

Controlled Area designation and access

1. The room in which the laser/IPL is used is designated a 'Controlled Area' and the laser should only be used in this area. Approved warning signs should be fitted to the door.
2. A notice should be fixed to the laser/IPL indicating that its use is subject to the Local rules.

Register of Authorised Users

3. A register should be kept of personnel authorised to operate the equipment.

Laser Protection Supervisor

4. One Authorised User should be nominated Laser Protection Supervisor to ensure that the register is maintained and the local rules are adhered to.

Restriction of use to Authorised Persons

5. The equipment should only be used by an Authorised User.
6. If another person is judged by the Laser Protection Supervisor, in consultation with the Laser Protection Adviser, to be suitable to use the equipment, the name may be added to the register, provided the person has signed a statement that they have read and understood the local rules. A copy of the signed statement should be sent to the Laser Protection Adviser.
7. A copy of the register will be kept with the key and the Laser Protection Supervisor will instruct the key holder to issue the key to the Authorised Users only.

Need for training of all persons

8. Authorised Persons using the laser/IPL or assisting in the procedures should be sufficiently trained in the safe performance of their duties.

Operator responsibility

9. It is the responsibility of the equipment Authorised User to be aware of the nature of the hazard involved and to be familiar with the manufacturer's operating instructions.
10. During the operation of the laser/IPL the Authorised User is responsible for the safety of all persons present, including the patient and themselves.

Protective eyewear

11. Protective eyewear should be provided and clearly marked for the laser. It is important that the correct goggles are used e.g. the use of a coloured sticker or other identifier on the goggles matches a similar identifier on the laser/IPL.

12. The Authorised User should instruct all personnel in the Controlled Area to wear goggles suitable for the laser being used, unless they are viewing the treatment site through protective microscope optics.

Methods of safe working

13. Other procedures should not be undertaken in the Controlled Area while the laser is in use. No more than one laser or IPL should be switched on during the client treatment. The laser/IPL should be switched off, prior to initiating use of a different optical radiation device. This good working practice would help to reduce the risk of an unanticipated adverse event.
14. When the laser/IPL is in operation the number of persons in the room should be kept to a minimum.
15. The laser/IPL should not be enabled to fire unless it is directed towards the treatment site or a beam stop.
16. The Authorised User should be careful to avoid reflections of the beam from instruments in close proximity to the beam path and pay particular attention to the possibility of exposure of their own skin. Instruments with diffusely reflecting surfaces should be used when available, rather than those which give rise to specular reflections.
17. The risk of shattering a glass intra-ocular lens implant should be noted.
18. Whenever the device is unattended by an Authorised User, the laser should be switched off and the key withdrawn and placed in safe custody by the Authorised User.

Normal operating procedures

19. The operating procedure as laid out in the treatment protocol document should be observed.

Adverse incident procedures

20. If an actual or suspected incident occurs, an eye examination should be carried out within 24 hours, and the Laser Protection Adviser contacted as soon as possible.

Laser Protection Adviser

21. For further information, please contact the Laser Protection Adviser.

Laser Protection Adviser:

Telephone Number (Office):

Telephone Number (Home):

Application of local rules

22. The laser should only be used in accordance with these local rules.
23. Authorised Persons should sign statements that they have read and understood these local rules.