

Jersey Care Commission Code of Practice regarding Class 3B and Class 4 Lasers

TABLE OF CONTENTS

- Section 1 Introduction and overview
- Section 2 <u>Treatment protocols and procedures</u>
- Section 3 <u>Training and competencies</u>
- Section 4 <u>Treatment environment</u>
- Appendix 1 LPA Registration
- Appendix 2 <u>Glossary of terms</u>

References

Section 1 Introduction and overview

This Code of Practice has been developed to ensure laser practitioners and premises in Jersey meet local legislation requirements for registration with the Jersey Care Commission, whilst maintaining compliance with the British Medical Laser Association Essential Standards.

Laser procedures are regarded as a regulated activity under the Nursing Homes (Jersey) Law 1994. Furthermore, the Nursing Homes (General Provisions) (Jersey) Order 1995 states specifically the use of:

- (i) A class 3B laser product
- (ii) A class 4 laser product

The law also states that anyone who carries on or intends to carry on a regulated activity without being registered shall be guilty of an offence and liable to a fine.

This code of practice is specifically for non-surgical aesthetic applications of Class 3B and Class 4 lasers and reflects essential arrangements for safety and quality in the provision of the non-surgical use of the lasers.

The Jersey Care Commission (the Commission) registers laser use for treatments including, but not limited to:

- removal of hair
- removal of tattoos/micropigmentation and benign pigmented lesions
- skin rejuvenation
- vision correction.

These are carried out in a variety of settings to include health centres, dental practices, and beauty salons.

The Commission will complete an annual inspection and send an inspection report to the Laser Protection Supervisor (LPS). The LPS is an individual within the premises who is responsible for ensuring that all laser practitioners are appropriately trained and comply with current regulations.

The LPS must complete a laser Core of Knowledge safety course, including safety management aspects that allow them to perform their role effectively and be

repeated at least every 5 years. The LPS must maintain evidence of Continuing Professional Development (CPD) to demonstrate knowledge and skills relevant to the treatment. CPD reflects training needs in response to changes in equipment, practice, and the treatment environment.

Section 2 Treatment protocols and procedures

A treatment protocol, produced by an Expert Registered Healthcare Professional (ERHP) with relevant experience in this field must be followed. The ERHP is an expert doctor, dentist, clinical scientist or registered nurse with verifiable clinical expertise in using laser to treat patients/clients and who can demonstrate that they have the necessary knowledge and expertise to produce a protocol. The ERHP must also be registered with their appropriate professional body. A treatment protocol should set out the necessary pre-treatment checks and tests, how the procedure is to be applied, the acceptable variations in the settings used, and when to abort a treatment. A separate protocol must be in place for each laser treatment and must include:

- Contraindications and conditions requiring special consideration
- technique
- obtaining client informed consent before treatment
- record keeping requirements and treatment process (step by step guidance)
- cleanliness and infection control in the treatment area
- pre-treatment tests
- post-treatment care
- recognition of treatment related problems
- procedure if anything goes wrong
- permitted variation on machine variables.

Laser Practitioners must ensure client safety by:

- Checking with clients if they have any medical condition or having/have had treatment or any medication for which laser treatment would be a contraindication
- where appropriate, covering the skin outside the area being treated
- where appropriate, checking the skin type and pigmentation before treatment.

The LPS must appoint a suitably qualified Laser Protection Advisor (LPA). LPA's are specialists who ensure the safe use of lasers and help the client meet the regulatory requirements. They develop safe systems of work which are set out in Local Rules for the use of laser devices, and reviewed annually by the LPA, including when they are being used on a trial or demonstration basis. Local rules will cover:

- Potential hazards associated with lasers
- 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 personnel
- adverse incident procedures
- procedure in the event of equipment failure.

The LPA is generally the person who will provide 'Core of Knowledge' courses for laser practitioners so they may achieve the minimum competency level as part of their initial training.

Evidence should show that the LPA has conducted an initial site audit and produced a risk assessment of the establishment's laser-controlled area. Due to the remote location of Jersey, a site audit can be conducted remotely using a combination of a questionnaire to be completed and signed by the laser provider, together with specified photos and video. The LPA will require an annual report from the LPS and a fresh virtual audit if there are any major changes such as new equipment or change of room. The risk assessment must be signed and dated, and a date must be included for subsequent review. The IPS will incorporate the risk assessment into the service's overall risk assessment framework.

The LPA conducts a site audit every four years.

The local rules document will be kept available in the laser-controlled area, signed and dated by the LPS and the LPA and reviewed annually.

A Supplier's Declaration of Conformity (sDoC) must be kept on file for the LPA or the Commission to view. This document certifies the electrical safety compliance of nonmedical energy-based devices, as many service providers import directly from manufacturers (rather than via a UK distributor). This is issued either by the manufacturer or their EU/UK representative. The sDoC is much simpler to consider than copies of CE certificates of compliance, as the sDoC should cover all the key statements and be signed by an accountable person.

A register must be maintained of the named practitioner/s authorised to operate lasers. Practitioners must sign to indicate they accept, understand, and agree to work to the local rules.

A treatment register must be maintained every time the laser is operated, including:

- The name of the client being treated and date of birth
- Date and time of treatment
- Name and signature of practitioner
- Nature of the treatment given
- The treatment parameters
- Any accidents or adverse effects.

Before any treatment is given, written consent must be obtained by the practitioner along with an explanation of risks, benefits, and potential complications of treatment.

Additional arrangements must be in place for seeking consent from clients under 18 years of age.

Section 3 Training and Competencies

All laser practitioners must demonstrate evidence of having attended laser operator training (evidence should include the training curriculum) which is system specific and treatment specific. All certificates should be held in the establishment and viewed upon request.

All laser practitioners must attend a laser Core of Knowledge safety training course of a minimum of three hours duration as described in the joint BMLA/IPEM/SRP approved core of knowledge syllabus or the MHRA September 2015 Guidance (1,4). The Core of Knowledge training must be repeated at least every five years with evidence of training certificates. The certificates must include who provided the training and its contents.

Typical course content:

- Basic principles of laser generation and review of laser technology
- Laser hazard classification
- Meaning of associated warning labels
- Principles of quality assurance
- Emission characteristics of different types of equipment
- Laser-tissue interaction mechanisms
- Penetration of light of different wavelengths through skin and eye
- Dangers of central versus peripheral retinal damage
- Hazards to eye and skin from accidental exposure
- The concept of Maximum Permissible Exposure and Nominal Ocular Hazard Distance
- Principles of risk assessment
- Laser safety management including the role of the Laser Protection Adviser, Laser Protection Supervisor, Local Rules and Controlled Area
- Risks associated with accidental reflections
- Personal protection measures including eye protection
- Hazards to the client, e.g. endotracheal tube ignition, photosensitive medication reaction, etc.
- Incidental hazards, including electrical, fire explosion and plume emission
- Relevant legislation, standards, and guidelines

• How to deal with an adverse event or accidental exposure

Laser operator training is usually carried out by the manufacturer or the supplier at the time of installation. After this, training may be provided to additional practitioners by either the LPS, manufacturer/supplier or an individual who has been designated the training supervisor. This does not replace the 'Core of Knowledge' training.

All staff using lasers must maintain evidence of Continuous Professional Development (CPD) to demonstrate knowledge and skills relevant to the treatments carried out. CPD must reflect training needs in response to changes in equipment and technology, practice, and the treatment environment. Update training may include private study, reading articles, attendance at meetings, exhibitions, learning and training events. A written record should be kept demonstrating evidence of attendance and programme of study.

Section 4 The treatment environment

The area around working lasers must be controlled to protect other persons while treatment is in progress. The area must be clearly defined and not used for other purposes whilst laser treatment is being carried out.

Suitable warning signs must be clearly visible on the outside of doors to the controlled area.

All lasers must comply with current standards (e.g. BS EN 60601-2-22:2020 for medical lasers including but not limited to having labels in accordance with standards, identifying the model, their wavelength or range of wavelengths and the maximum pulse fluence/energy/power of the radiation emitted.

Effective protective eyewear must be worn by everyone within the controlled area whenever there is a risk of exposure to hazardous levels of laser radiation, as advised by the LPA. The specification of the eyewear should appear on the eyewear, must be indicated in the Local Rules document and the specification must be to at least this level.

For all laser sources with a key switch, arrangements must exist for the safe custody of the key, separate from the equipment. Only authorised users will have access to the key. Equivalent arrangements exist for equipment protected by passwords instead of a key switch.

The operating key must not be left unattended with the laser equipment. The Local Rules must stipulate that unauthorised persons do not operate the laser when the machine is left unattended by an authorised person.

Laser equipment must be serviced and maintained according to the manufacturer's instructions. A record of servicing and repairs is kept on the premises.

Lasers must have a portable appliance test (PAT) carried out annually.

Windows in the controlled area should be covered with blinds and mirrors or other highly reflective surfaces (such as TV/video monitors and glass cabinets) must be covered during laser treatments to prevent potentially hazardous reflections.

There must be access to hand wash facilities, soap, and paper towels. Treatment couches to be cleaned between each client with detergent/disinfectant wipes.

Staff have access to disposable gloves and aprons when required.

A pedal operated bin is required to collect waste including paper towel, couch towel, disposable gloves, aprons etc.

A CO2, powder or other suitable fire extinguisher for use on electrical fires must be on the premises and serviced according to the label.

The employer must have evidence of valid public liability insurance.

Appendix 1 LPA Registration

The Laser Protection Advisor (LPA) should be knowledgeable and have expertise in matters relating to the evaluation of laser hazards and have responsibility for advising on their control.

- A list of organisations which run LPA certification schemes is available in: Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices MHRA 2015
- The RPA2000 LPA Certification ~Scheme can be found at: <u>LPA Certification</u> <u>Scheme – RPA 2000</u>
- Public Health England operate a certification scheme for their own staff.
- The Association of Laser Safety Professionals (ALSP) has a list of certified LPAs on <u>Find an LPA – The Association of Laser Safety Professionals (ALSP)</u> (laserprotectionadviser.com)

Appendix 2 Glossary of terms Class 3B Lasers

Class 3B lasers produces intense optical radiation and the wavelengths must not exceed 500mW. Can cause eye and skin irritation if not used safely.

Class 4 Lasers

The highest class according to the potential harm it can cause. Typically used for medical and therapeutic treatments including hair removal, tattoo removal. Can cause skin burns, eyesight damage or set fire to materials if not used correctly.

Laser Protection Supervisor (LPS)

The LPS is an individual within a laser establishment who is responsible for ensuring that all laser practitioners comply with the Local Rules and follow them on a day-today basis and are appropriately trained to operate each laser.

Laser Protection Advisor (LPA)

The LPA is the person providing expert advice on laser safety. The LPA advises on laser safety training, the suitability of protective eyewear and ensuring that Local Rules are produced, signed, dated and implemented for each installation. The LPA is an external advisor.

Expert Registered Healthcare Professional (ERHP)

The ERHP is an expert doctor, dentist, clinical scientist or registered nurse with verifiable experience in using laser to treat patients/clients and who can demonstrate that they have the necessary knowledge and experience to produce a treatment protocol. They must be registered with their own professional body.

Continued Professional Development (CPD)

CPD is a commitment to ongoing lifelong learning. This identifies opportunities to learn something new, refresh existing knowledge, improve skills or simply keep up to date with the latest developments within a particular industry or profession.

References

The Nursing Homes (Jersey) Law 1994. Accessed: <u>Nursing Homes (Jersey) Law</u> <u>1994</u>

Nursing Homes (General Provisions) (Jersey) Order 1995. Accessed: <u>Nursing</u> <u>Homes (General Provisions) (Jersey) Order 1995</u>

British Medical Laser Association 2017 *Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in non-surgical Applications.* Accessed: <u>BMLA Essential Standards - BMLA</u>

British Medical Laser Association 2019 *Treatment Guidelines for the use of Laser* and Intense Light Devices for Hair Reduction and Treatment of Superficial Vascular and Benign Pigmented Lesions. Accessed: <u>TREATMENT GUIDELINES FOR THE</u> <u>USE OF LASER AND INTENSE PULSED LIGHT DEVICES FOR HAIR</u> <u>REDUCTION AND TREATMENT OF SUPERFICIAL VASCULAR AND BENIGN</u> <u>PIGMENTED LESIONS (bmla.co.uk)</u>

Medicines and Healthcare products Regulatory Agency (MHRA) 2015 *Lasers, intense light source systems and LED's – Guidance for safe use in medical, surgical, dental and aesthetic practices.* Accessed: <u>Laser_guidance_Oct_2015.pdf</u> (publishing.service.gov.uk)

Health Education England 2015 Developing people for health and healthcare Part one: Qualification requirements for delivery of cosmetic procedures: non-surgical cosmetic interventions and hair restoration surgery. Accessed: <u>HEE Cosmetic</u> <u>publication part one.pdf</u> The British Standards Institution 2024 *Ensuring conformity with medical devices*. Accessed: <u>Medical devices (bsigroup.com)</u>