Unit Specification

UBT449 – Core of Knowledge for Laser and Light Devices

Unit reference number: K/650/6627

Level: 4
Guided Learning (GL) hours: 5

Overview

The aim of this unit is to develop learners' knowledge and understanding of the core knowledge required when operating laser and light devices. It covers the core knowledge of laser and light including safety legislation, electromagnetic radiation, and tissue interaction. This unit has been mapped against the MHRA Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental, and aesthetic practices.

Learning outcomes

On completion of this unit, learners will:

LO1 Comprehend laser safety legislation, measures, and management

LO2 Comprehend risk assessments, hazards, and safety

LO3 Comprehend laser and light technologies – (radiation and tissue interaction)

Version 1

Unit content

LO1 Comprehend laser safety legislation, measures & management

Laser safety Legislation
Taught content
Specific legislation relating to Class 3B, and 4 medical lasers are followed. Specific legislation of the country you are working in is of the utmost importance. The list of legislation below is not an exhaustive list: • The Control of Artificial Optical Radiation at Work Regulations • Care Standards Act 2000 and the bodies responsible for the enforcement of this Act in England, Scotland, Wales, and Northern Ireland. (Healthcare Commission in England, the Independent Healthcare Inspectorate Wales, the Care Commission in Scotland, and in Northern Ireland, regulation is covered under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 • Control of Substances Hazardous to Health Regulations 2002 (COSHH) • Electricity at Work Regulations • Health and Safety at Work etc. Act 1974. Note: known in Northern Ireland as the Health and Safety at Work (Northern Ireland) Order 1978 • Health and Safety (Safety Signs and Signals) Regulations 1996 • Management of Health and Safety at Work Regulations 1999 • Council licencing in England • The Medical Devices Directive: Includes most other medical devices, ranging from first aid bandages to X-ray equipment. Lasers, IPLs and LEDs are covered by this Directive. National Minimum Standards – introduced in 2002 by the department of Health. They are essential standards that ensure patients/clients receive treatment in accordance with safe and proper procedures from a trained and competent operator in a safe environment. National minimum standards in Wales are regulated by the Healthcare Inspectorate Wales (HIW), in Northern Ireland it is overseen by RQIA, the CQC in England, and the Healthcare improvement in Scotland • Personal Protective Equipment at Work Regulations 1992. These regulations require the employer to provide appropriate and adequate protective equipment to their employees where the risk to the employee cannot be adequately controlled by any other means (for example, protective eyewear) • Personal Protective Equipment Regulations 2002. Regulations cover CE marking and supply issues. Compliance with BS EN 207 and BS EN 208 are a requirement under these regulations • Private and Voluntary Healthcare Regulations (England) 2001. These cover several issues including the regulation of Class 3B and 4 lasers as well as IPL systems that may be used in the private healthcare sector. Regulations with a similar scope have been drafted by the Welsh, Scottish and Northern Ireland Authorities • Provision and Use of Work Equipment Regulations 1998 • Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995

Safety Standards

Taught content

Specific safety standards relating to Laser and light equipment. Any medical equipment that has an electrical component linked with it should meet the appropriate safety requirements. Although equipment standards are widely used, they are not mandatory

- BS EN 60601-1: Medical electrical equipment (General)
- BS EN 60601-2-22: Medical electrical equipment (Laser)
- BS 60601-2-57: Medical electrical equipment (IPL)
- BS EN 60825-1: Safety of laser products and the recommendation of appointing an LSO

Equipment Management

Taught content

- The importance of equipment management and implementing equipment management and quality control procedures
- The importance of having an equipment management policy and the information to be included within the policy
- The importance of liaising with the LPS and, where necessary, the LPA before purchasing, loan and demonstration of new equipment
- How much and what type of information to be obtained from the manufacturer or supplier regarding use, installation and how the product meets the clinical and operational needs
- How to conduct a full and thorough risk assessment before the equipment is first used
- The importance of the machinery being properly installed by the manufacturer or supplier
- The importance of pre-use checks being carried out at installation time. The LPA and LPS should carry out pre-use equipment checks once machinery has been installed. How these can also be carried out in the presence of the clinic/hospital representative by the medical physics department or electrical and biomedical engineering unit. Examples of pre-use equipment checks are below (not all these checks are applicable to every device):
    - Electrical safety
    - Output parameters (energy, wavelength, beam profile, temporal pulse shape, etc.)
    - Beam alignment
    - Beam stop, shutter or attenuator
    - Aiming beam
    - Accuracy of timer (if applicable)
    - Interlock operation
    - Filters
    - Emergency cut-off
    - Warning lights
    - Footswitch operation
    - Protective eye-wear assessment
    - Equipment accessories assessment
    - Fibre connectors
    - Full and accurate records should be kept of the above checks
- The importance of keeping equipment records and ensuring that machinery is serviced by an appropriate professional, on a regular basis

- Appropriate quality assurance checks are completed on the Laser and IPL equipment. These checks should be undertaken daily/weekly by the authorised users. Examples of checks can include:
    - Check the laser/IPL output stops when the footswitch or finger-switch is released
    - Check the device's alignment of the aiming beam with the therapeutic beam
    - Check filters for scratches or wear and tear. Clean or replace if appropriate
    - Check all system alarms and lights are operating appropriately
    - Assess all device accessories such as cables and connectors ensuring they are undamaged and fit for purpose
    - Check for scratches or signs of wear and tear on the lenses of protective eye wear
    - All protective blinds, windows and doors are working correctly and are undamaged
    - Warning lights are in good working order
    - All warning signs are undamaged and illuminated signs work correctly
    - Interlock operations are working correctly
    - Annual or bi-annual checks should also be carried out. They will be like the initial pre-use tests
- The importance of keeping an equipment fault log for each device. The fault log should be easily accessible for inspection by the LPA, service engineer or NHS/government inspector. Details of faults including error codes should be logged. Each fault should be signed by the person who saw it and countersigned by the LPS, departmental safety manager, or other designated signatory
- How any equipment modification or change in its operational use may have safety implications linked to it. All potential equipment modifications/change of use should be discussed with the LPA and LPS. How risk assessments should be reviewed if equipment has been modified
- The implications of Local Rules (working procedures) and how these are clinic/establishment specific
- What type of advice is covered by the Local Rules
    - Nature of hazard to persons (users and patients)
    - Defined region and limits of the treatment area
    - A register of authorised users and associated responsibilities, including any restrictions of use, contact point for laser protection supervisor and laser protection adviser
    - Controlled and safe access to the treatment area
    - Training needed by the people using or helping to use the laser/IPL
    - Personal protective equipment, especially eyewear
    - Methods of safe working, including layout of equipment
    - Normal operating procedures
    - Explanations and instructions on pre-use safety checks
    - Adverse incident and equipment faults – how to report and where to log them
    - Management safety structure (for example, manager, consultant, LPA, LPS and users)
- Ensure that the Local Rules are updated and modified, to allow for any modifications to equipment
- When purchasing equipment accessories, ensure they are suitable for both the make and model of optical radiation device
- How to ensure accessories are CE marked as a medical device

Safety Management
Taught content
• Safety procedures and policies governing optical radiation equipment use, including the Local Rules, and controlled area • Role and responsibilities of the: - Laser Protection Adviser (LPA) - Laser Safety Officer (LSO) - Laser Protection Supervisor (LPS) - Authorised User • The requirements for an LPA in England, Scotland, Wales, and Northern Ireland • Training required for the assisting staff (authorised laser assistants) and other healthcare staff, that is equipment-based training, safety training (Core of Knowledge course) and procedural training

LO2 Understand risk assessments, hazards, and safety

Nature of Hazards
Taught content
• The types and range of potential damage Lasers, IPLs and LEDs have to the eyes and skin of patients, clients, and equipment users • The effects of exposure to optical radiation on tissue and skin, eyes, fire hazards and smoke inhalation • The dangers to patients and clients such as stray optical radiation (laser/IPL), eye injury, skin burn from damaged external filter (IPL), skin burn from hot spots on filter (IPL), burn/infection risk from broken optical fibres, risk of fire; external (endotracheal tube ignition) and internal (body cavity), risk of mistreatment • The dangers to staff and how they may be controlled, that is optical radiation risks, risk of fire, laser plume emissions, unexpected adverse events

Safety Administration
Taught content
• The legal requirement of a risk assessment under regulation 3 of the Management of Health and Safety at Work Regulations 1999 • The principles of risk assessment. Risk assessments should include determining the hazards associated with these 4 areas: - Equipment (purchased/loan/demonstration) - Personnel who may be at risk: ▪ authorised user ▪ patients/clients ▪ other staff who work in the area – cleaners ▪ maintenance staff ▪ contractors ▪ visitors ▪ others - Procedure(s) - Location • The roles that the LPA, LPS, authorised users and the employer have in the drafting and review process of the risk assessment. It is the responsibility of the employer to ensure the risk assessment is completed • The importance of the Local Rules in complying with Health and Safety at Work Act 1974 and Control of Artificial Optical Radiation at Work Regulations 2010 • Recognise the issues that should be included in the Local Rules and the need for them to be reviewed regularly and updated when necessary • The requirements under The Control of Artificial Optical Radiation at Work Regulations 2010 to conduct assessment of the risk of adverse health effects to an employee's eyes from workplace exposure to artificial optical radiation • How to report adverse incidents to the MHRA and to other authorities including the devolved administrations. The LPA, LPS and manager should record any adverse events and discuss if the equipment needs to be taken out of service

Safety Mechanisms and Controlling Hazards
Taught content

• The Laser controlled area and the safety measures to be taken into consideration for controlling safety:
  - Principles of maximum permissible exposure (MPE)
  - Nominal ocular hazard distance (NOHD)
  - Blinds and barriers
  - Door interlocks/keypad locks
• Controlling access when the Laser or IPL is in use
• The meaning of warning labels and signs associated with optical radiation equipment. Signs should comply with the Health and Safety (Safety Signs and Signals) Regulations 1996 and related standards such as BS EN 60825-1
• The use and removal of warning signs for the laser-controlled area
• Awareness of Laser and IPL equipment safety, for example, safety key or smart card, if the unit is password protected, if a foot switch is required, standby and ready mode
• Alternative arrangements for different scenarios such as out of normal working hours; environment cleaning or equipment sanitisation; service engineer visits
• The hazard control procedures, including the use of personal protection
• The hazards from reflections or absorption of the optical radiation beam with respect to instruments, or reflective surfaces like walls, ceilings, windows, or other equipment
• Accidental exposure risk and safety measures to reduce that risk
• The importance of using the correct protective eyewear for the different wavelengths of laser/IPL devices for the patient and operator
• The correct type of protective eyewear to be worn when treating above the neck, areas of the body away from the face, and for laser and IPL procedures such as endoscopes, laparoscopes, or a slit lamp
• The criteria that protective eyewear must meet including the regulations and standards.
• Appropriate PPE – single use items as appropriate, such as sterile disposable gloves (latex free), specialised hand and clothing protection
• The importance of wearing white/pale uniforms and covering clients' dark clothing and the risks if this is not adhered to
• The possible causes of surgical fires
• The key areas for preventing fires when using laser/IPL equipment, electrical hazards of Laser and IPL
• How to respond to surgical fires
• Other thermal and operational issues that can cause serious burns to people. This can include Laser thermal and operating issues such as optical fibres, aiming beam, mirrors and beam stops, endoscopic sheath, metallic tubing, and instruments. It can also include IPL thermal and operational issues such as applicator cleaning and heat effects
• Smoke plume issues and effects on the operator/healthcare worker and their patient
• Regulations regarding smoke plume exposure and preventative measures that will protect staff, patients/clients

LO3 Understand laser and light technologies – (radiation and tissue interaction)

Optical radiation devices
Taught content
• Laser is an acronym for 'light amplification by stimulated emission of radiation' • Understand the properties of Laser including lasing materials, collimated, monochromatic, spatially coherent • Laser output mechanisms, that is continuous wave, gated or chopped CW mode, and Q-switched • Different types of lasers used in medical applications, for example, Excimer, Ruby, Alexandrite, Diode, Nd:YAG, CO2 • Laser delivery systems for medical, surgical, dental, or aesthetic application. Examples include Beam delivery systems, Fibre delivery systems • Typical clinical applications for Laser, for example, in Dentistry, Dermatology, General surgery • The properties and delivery mechanisms of Intense pulsed light (IPL) • Intense pulsed light (IPL) applications, for example clinical, and aesthetic applications of IPL systems • Wavelengths and applications of Light emitting diodes (LEDs)

Optical radiation effects/tissue interactions
Taught content
• Electromagnetic spectrum and where Laser and IPLs appear on the spectrum, for example types of electromagnetic radiation, Wavelength in nanometres, and frequency • Effects of optical radiation on tissue, that is photo-thermal effect, photo-mechanical effect, photo-chemical effect, and photo-ablative effect

Classification of Lasers and IPLs
Taught content
• Laser classification scheme (Class 1-4) including the types of lasers within each class and the hazard to eyes or skin • IPL classification scheme. The standard IEC 62471 Photobiological safety of lamps and lamp systems provides information on lamp classification that includes IPL systems

Assessment requirements

Learners must complete all assessment requirements related to this unit:

1. Theory Examination

1. Theory Examination

Learners must complete an externally set and externally marked theory examination for this unit. This will consist of a multiple-choice question paper, which is mapped to the relevant assessment criteria stated below.

The theory examination will test knowledge and understanding from across learning outcomes 1-3. Learners should use the unit content sections of this unit to aid revision since exam questions will test the full breadth of this content over time.

Learning Outcome	**Assessment Criteria**
LO1 Comprehend laser safety legislation, measures & management	1.1 Laser safety Legislation
	1.2 Safety Standards
	1.3 Equipment Management
	1.4 Safety Management

Learning Outcome	**Assessment Criteria**
LO2 Comprehend risk assessments, hazards, and safety	2.1 Nature of Hazards
	2.2 Safety Administration
	2.3 Safety Mechanisms and Controlling Hazards

Learning Outcome	**Assessment Criteria**
LO3 Comprehend laser and light technologies – (radiation and tissue interaction)	3.1 Optical radiation devices
	3.2 Optical radiation effects/tissue interactions
	3.3 Classification of Lasers and IPLs

Document History

Version	Issue Date	Changes	Role
V1.0	01/04/2023	First published	Product and Regulation Coordinator