Biomedical/Clinical Engineering Association of Ireland

BEAI

Aontas Bithleighis Innealtóireacht na hÉireann

Laser Safety

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MISERIS SUCCURRERE

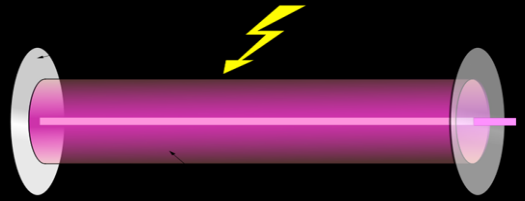
RCSI HOSPITALS

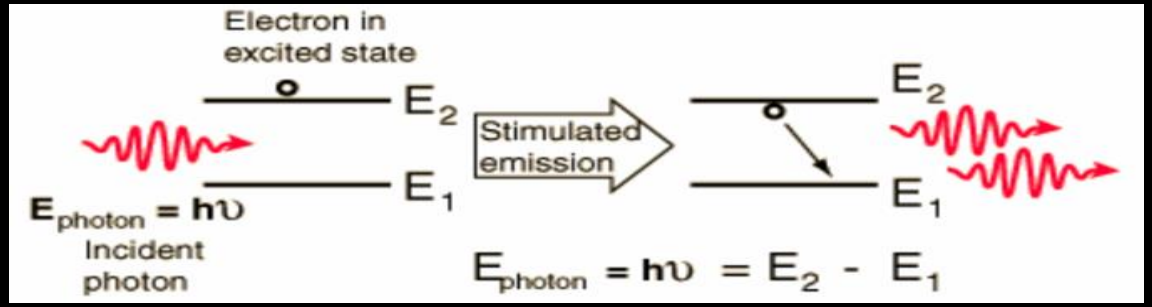
OSPIDÉIL RCSI

How is Laser Light Produced?

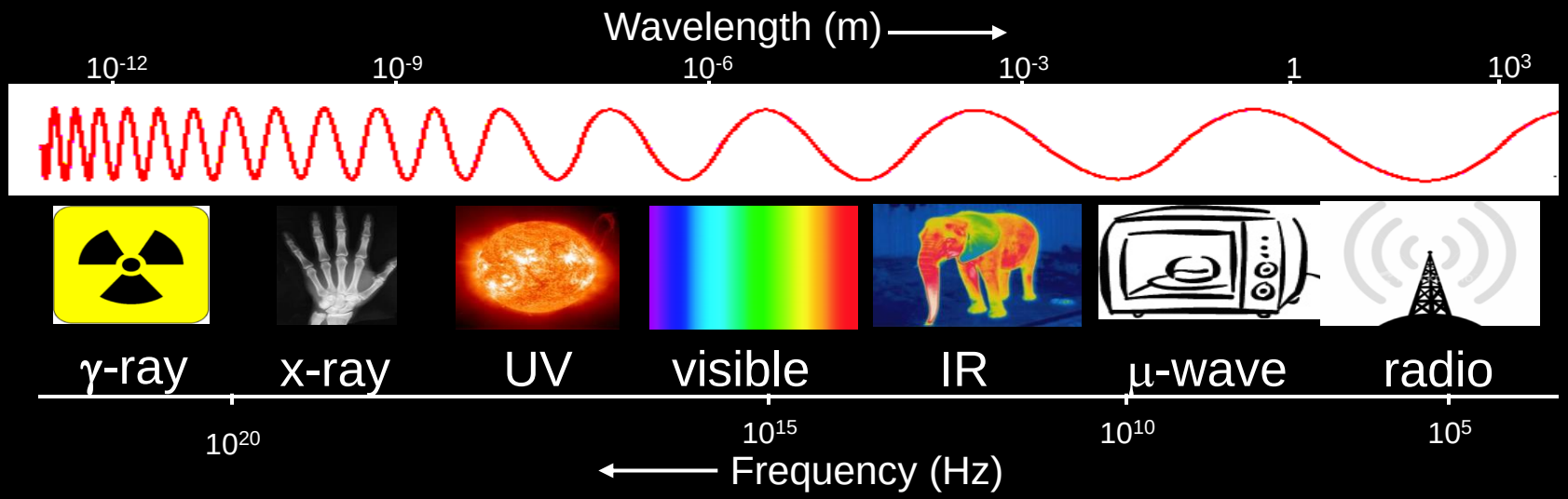
Light Amplification by Stimulated Emission of Radiation

- Light Amplification by Stimulated Emission of Radiation is a mechanism for emitting electromagnetic radiation *via* the process of stimulated emission.





Electromagnetic Spectrum



Optical Radiation

Infrared radiation

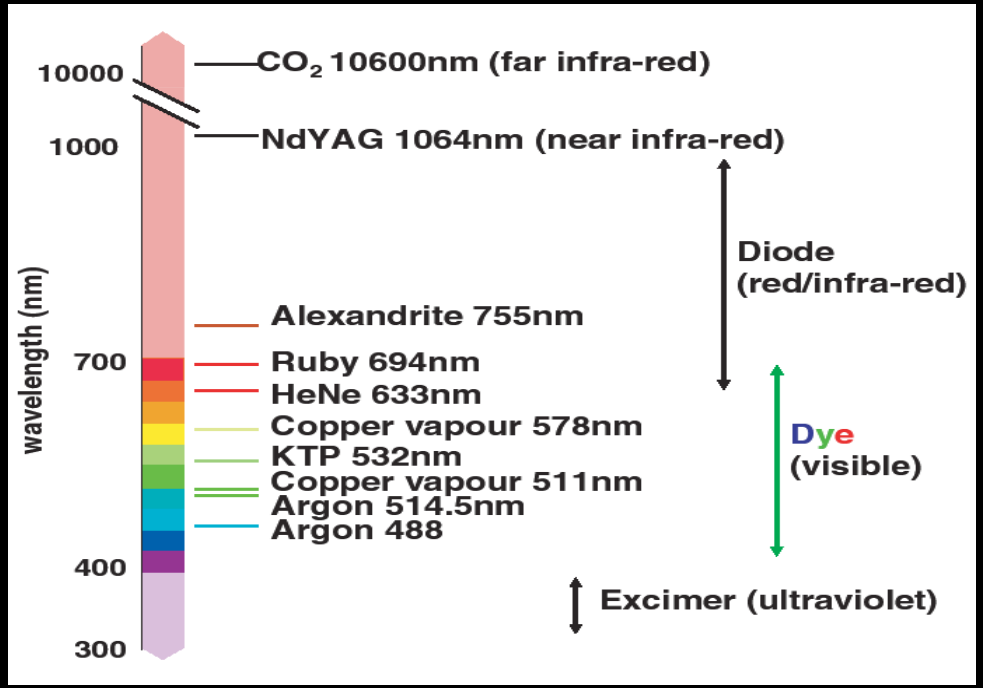
- 780 nm – 10,000 nm
  - IRC 3,000-10,000 nm
  - IRB 1,400-3,000 nm
  - IRA 780-1,400 nm

Visible radiation

- 400 nm - 780 nm

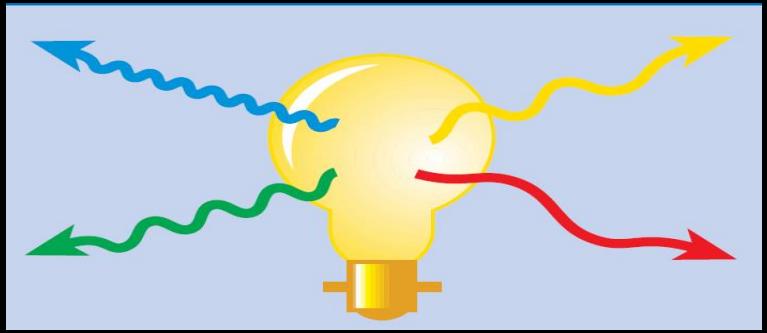
Ultraviolet radiation

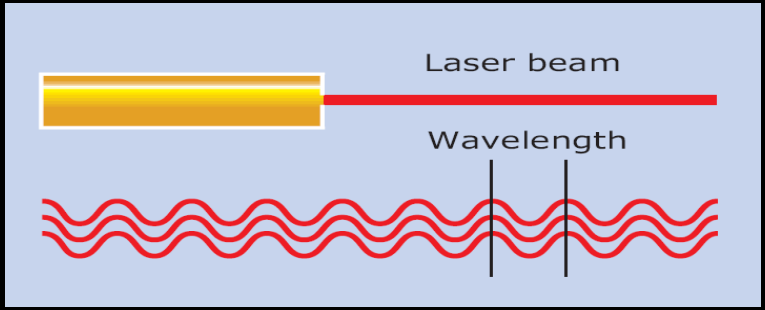
- 100 nm - 400 nm
  - UVA 315-400 nm
  - UVB 280-315 nm
  - UVC 100-280 nm



Characteristics of Laser Light

- Monochromatic
  - Laser light consists of essentially one wavelength.
- Collimated
  - Laser beams are very narrow with little spread.
- Coherent
  - Light is "in step“.



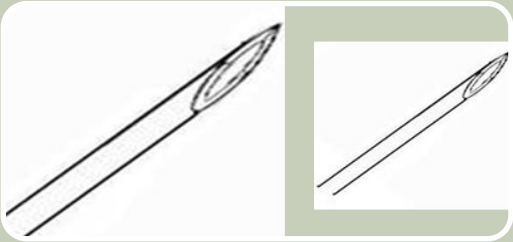


Physical Properties

Energy	Joule (J)	The ability to do work.
Pulse duration (time)	Second (s)	The duration of the pulse. - Some lasers are continuous. - Others have pulsed operation
Power	Watt (W) or Joule/second (J/s)	The rate at which work is done or energy is transferred .
Intensity	Watt per meter^2 (W/m^2)	The power per unit area.

Remember 1 mJ = 10^{-3} J = 0.001 J

Syringe Analogy



Energy

Here energy is the total dose

Power

Depends on the time over which the dose is administered

Intensity

Depends on the area of the needle tip – how easily punctures the skin.

Pulsed Lasers

- Lasers can work continuously over time (Continuous Wave) or in pulsed mode
- Pulses may be as short as a few pico-seconds
- Pulsed lasers are generally used when greater power is required
- Q-switched and mode-locking lasers are types of very high powered, short duration pulsed lasers

Laser Classification

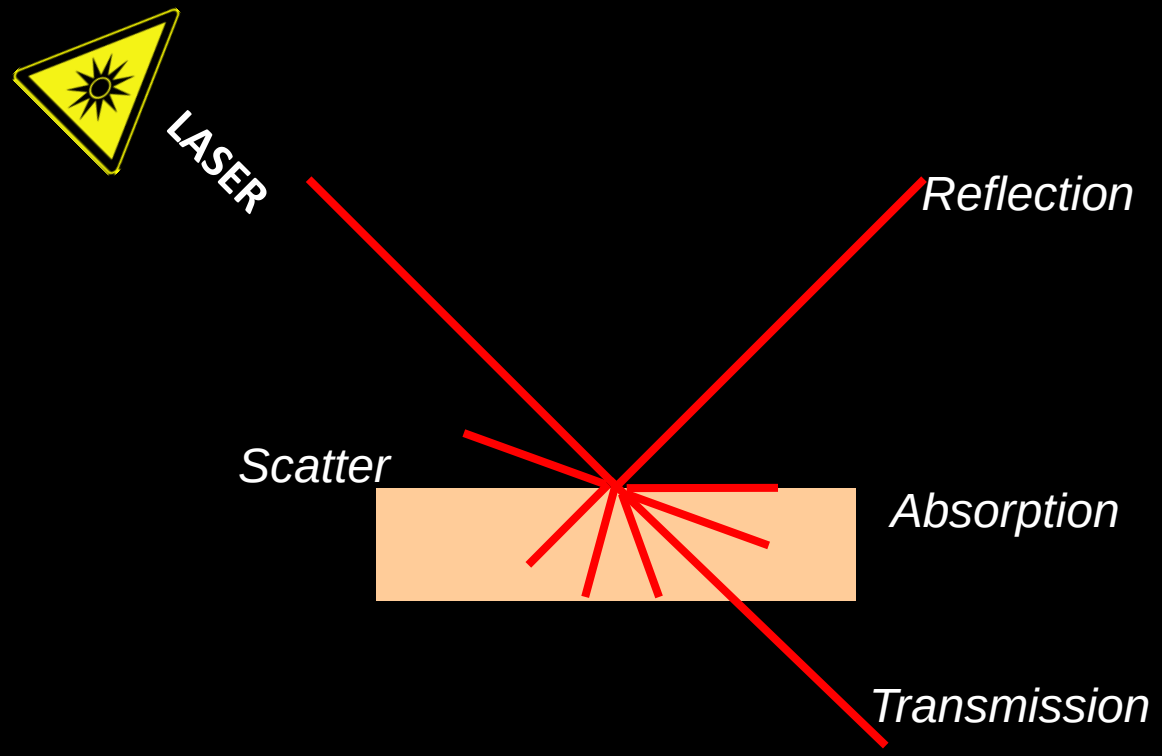
Increasing hazard

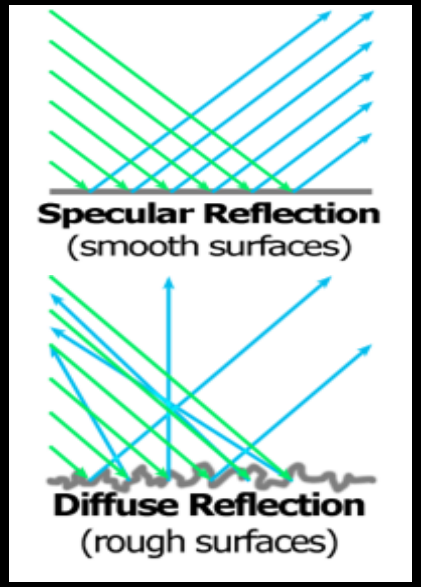
Class	Laser Type	Potential eye or skin hazard
1	Laser completely enclosed or Very low power level	Safe under all conditions in normal use
1M	Low power level & large collimated beam diameter	Low power level & large collimated beam diameter
2	Low power level (<1 mW)	Visible wavelengths only Safe under accidental exposure (Blink reflex of 0.25s)
2M	Low power level & large collimated beam diameter Visible wavelength only	Safe under accidental exposure (Blink reflex of 0.25s) except when magnifying lenses are used
3R	Low power level (<5 mW)	Accidental exposure not hazardous but eye injury possible for intentional exposure
3B	Medium power (<500 mW)	Direct beam dangerous to eye Diffuse/scattered light safe
4	High power (>500 mW)	Direct and diffuse light dangerous to eye & skin Fire hazard

Laser Safety

INTERACTION WITH TISSUE

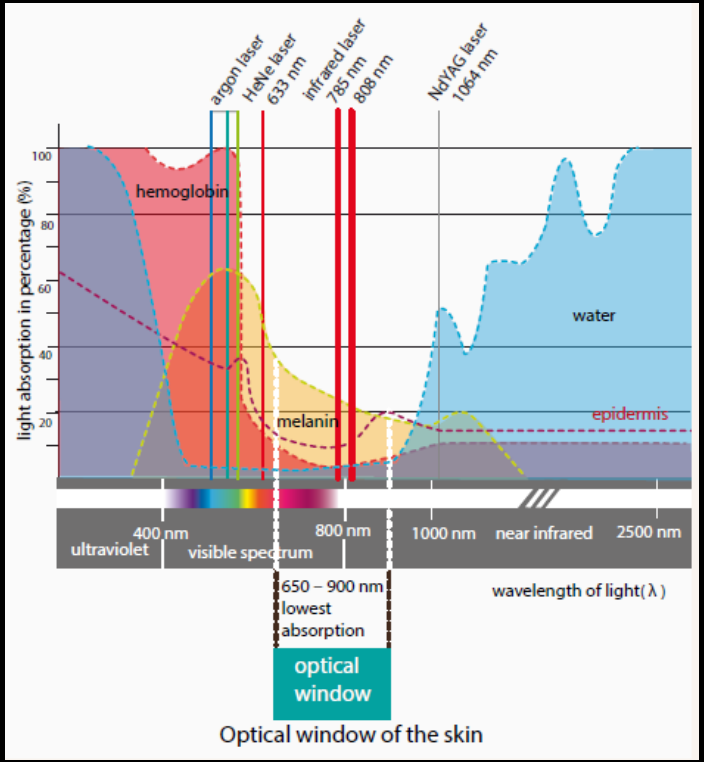
What happens when radiation is incident on matter?





Optical Radiation and Tissue

- Optical radiation is absorbed in the outer layers of the body and its biological effects are mostly confined to the skin and eyes.
- Different wavelengths cause different effects depending on which part of the skin or eye absorbs the radiation, and the type of interaction involved.
- Laser radiation can produce additional effects characterised by very rapid absorption of energy by tissue, and is a particular hazard for the eyes where the lens can focus the beam.



Effects

- The eye and skin are the critical organs for laser damage.
- The biological effects can be broadly divided into:
  - Acute
    Rapidly occurring
  - Chronic
    Occurring as a result of prolonged and repeated exposures over a long time

Biological Hazards

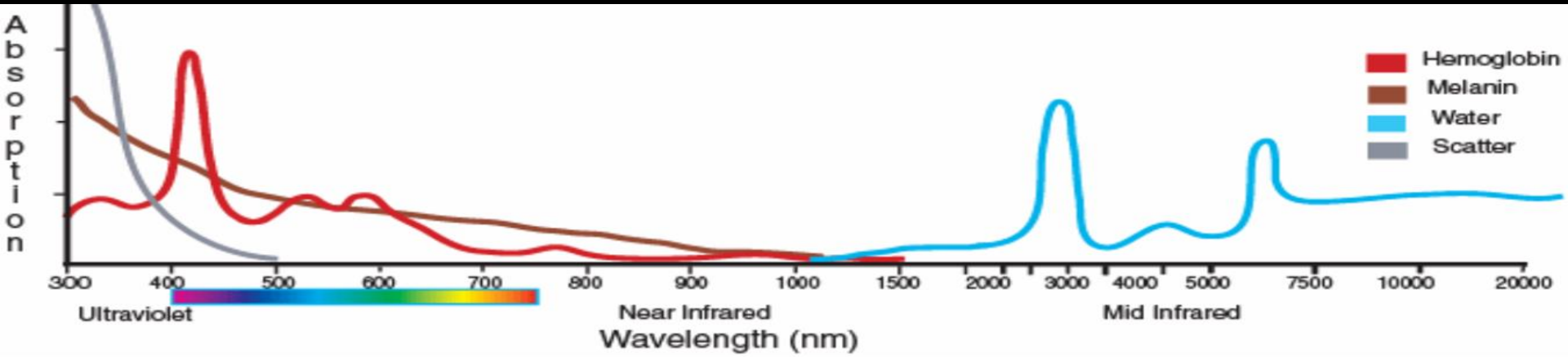
	**Skin**	**Eyes**
Acute	Erythema Thermal skin burns	Photokeratatis Photoconjunctivitis Retinal burns Corneal burns
Chronic	Skin cancer	Cataracts

Absorption of Optical Radiation

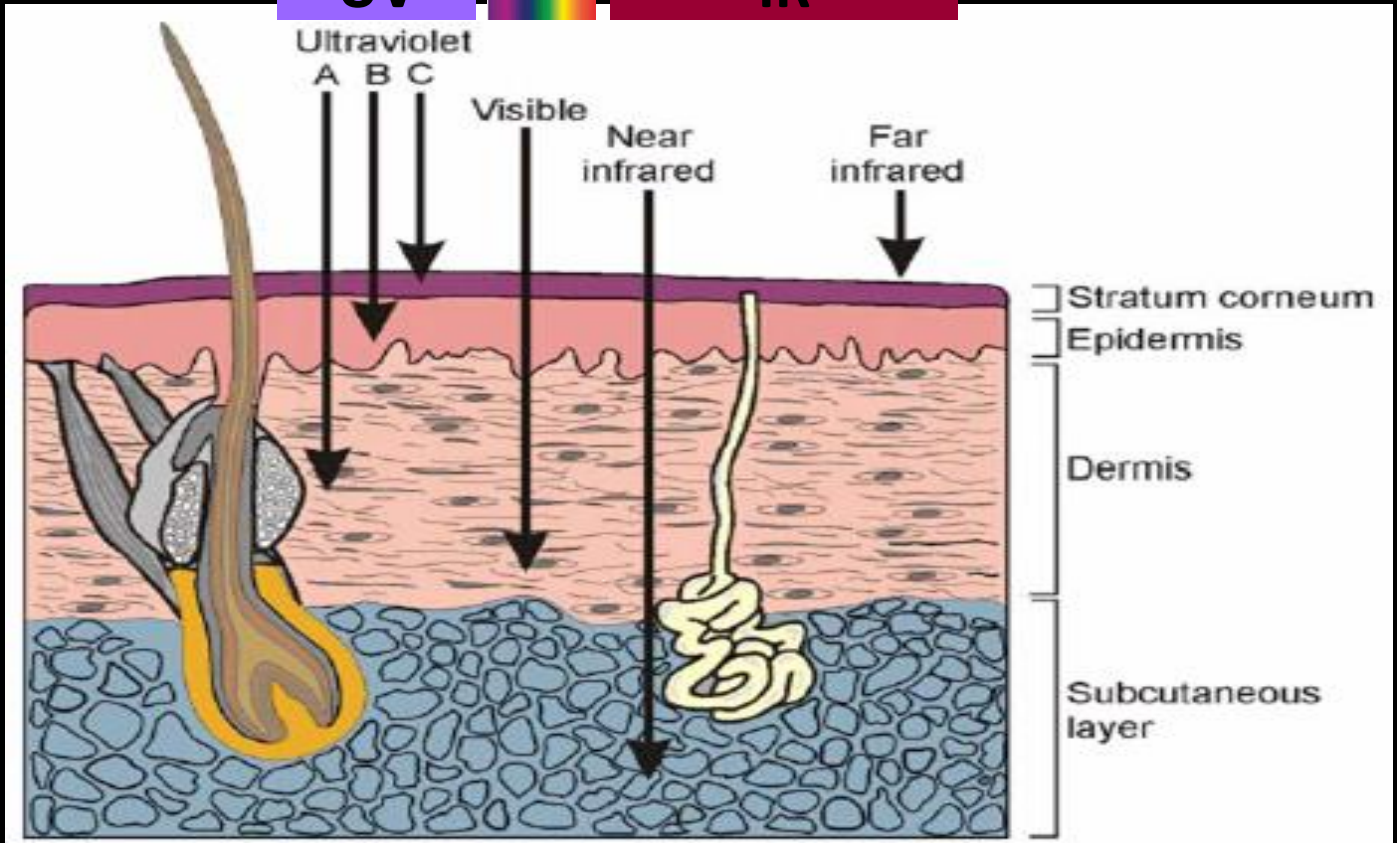
- Radiation must be absorbed to have a photobiological effect
- Radiation is absorbed in matter by atoms/molecules
- The atoms/molecules that absorb the radiation become excited.
- This excitation energy either dissipates as heat or it can lead to chemical reactions.
- Different tissues have different absorption spectra

Wavelength Dependence

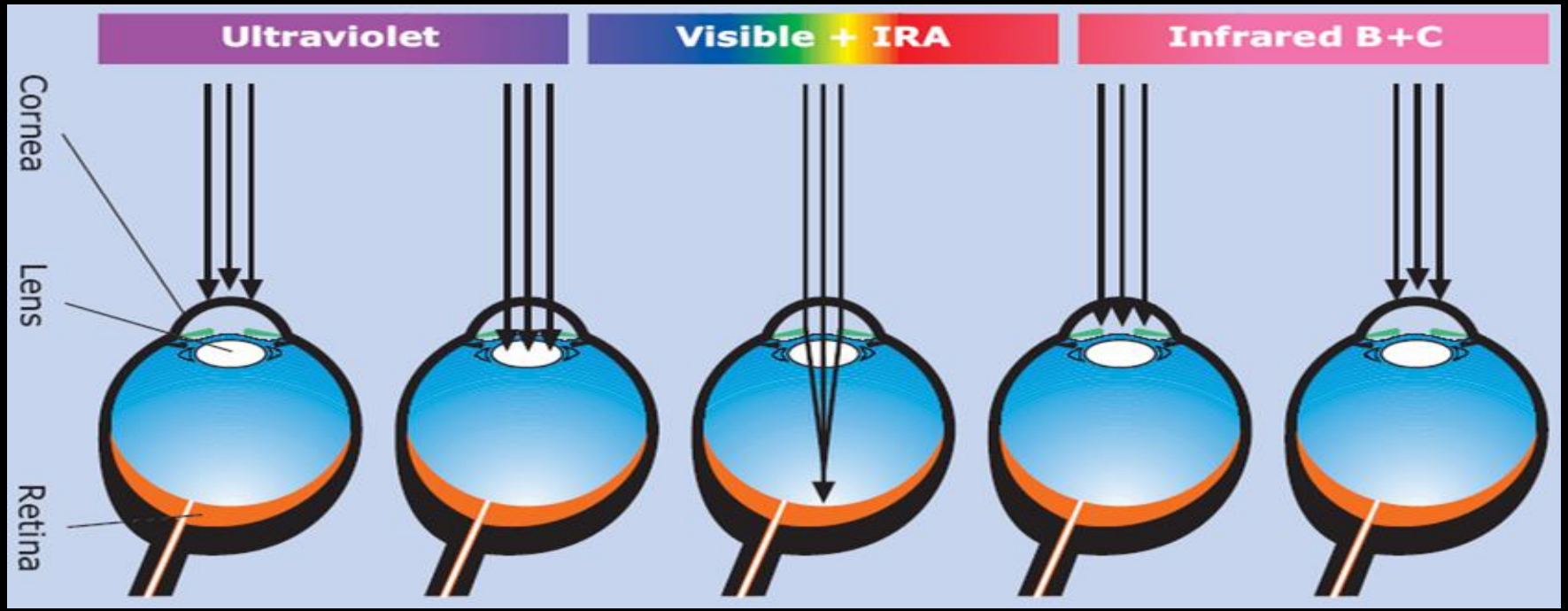
- Water is the dominant absorber in the infra-red region.
- In visible region, absorption determined by Haemoglobin.
- In UV range absorption by DNA proteins including Melanin
- Radiation with wavelengths not strongly absorbed is scattered



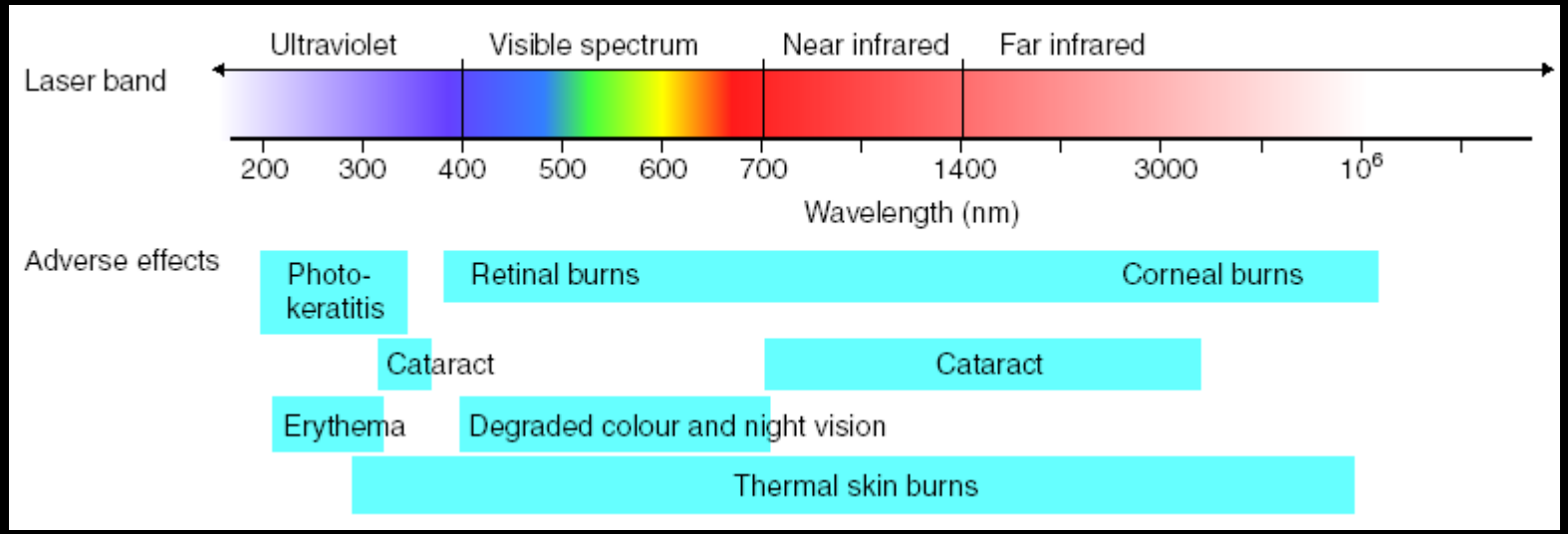
Skin Penetration Wavelengths



Eye Penetration Wavelengths



Laser Radiation Hazard Spectrum



Laser Tissue Interactions

The interaction effects of laser radiation with matter can be grouped into the following:

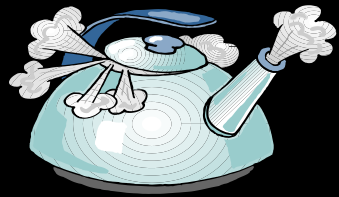
- Photothermal effects
- Photochemical effects
- Photomechanical effects

Photothermal Interaction

- Absorption of some of the laser energy, mainly by water
- Heat produced following absorption causes tissue damage.
- Damage due to heating of tissue depends on
  - wavelength
  - intensity of beam
  - properties of tissue

Thermal Interactions with Tissue

T (°C)	Visual Change	Biological Change
37-60	None	Warming, welding
60-65	Blanching	Coagulation
65-90	White/Grey	Protein denaturisation
90-100	Puckering	Drying
100	Smoke Plume	Vapourisation
Above 100	Carbonisation	300–400°C Tissue blackens, becomes carbonised and begins to outgas and smoke Above 500°C Tissue will burn and evaporate Above 600°C and times >2 s Irreversible processes due to thermal injury



Diffusion of Heat

- Short pulses of laser energy decrease the spread of heat and consequently decrease region of thermal necrosis
- Degree of thermal damage
  - depends on temperature laser heats tissue
  - and diffusion of heat away from irradiated zone
- Heat dissipation depends on tissue consistency and blood flow in the surrounding tissue
  - helps cool impact site

Photochemical Interaction

- Encompass all effects where the light directly induces chemical changes within the matter.
- Energy of radiation may be high enough to cause toxic radicals in the cells or even to cause direct damage to macromolecules of cells, such as DNA.
- Photochemical interactions depend strongly on wavelength.

Photomechanical Interaction

- Obtained using high power, very short pulses of laser of laser light
- Deliver of focused, very high laser intensity over about 50 microns
- Q-Switched Nd:YAG laser in ophthalmology

Photomechanical disruption of tissue

- High laser intensity: breaking of chemical bonds
- Leading to electrical breakdown of medium
- Plasma expands rapidly
- Shockwave produced by collapse of intense plasma destroys tissue

Laser Safety

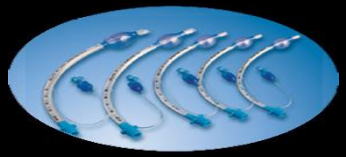
NON OCULAR HAZARDS

Non Ocular Hazards

- Laser Plume
  - The vapours, smoke, and particulate debris produced during surgical procedures using lasers
  - Plume can be controlled by ventilation, safe work practices and personal protective equipment
- Endotracheal Tube –Fire
  - it is important to use a laser-compatible (non-PVC) endotracheal tube
- Thermal Hazards
  - Objects (e.g. beam stops) in the path of a high power laser may become very hot and cause burns if the object is touched
- Additional Laser Emission
  - Can occur in lasers which employ frequency shifting techniques to produce laser emission at a different wavelength to that inside the laser resonator itself e.g. KTP laser
- Collateral Radiation
  - Radiation other than that associated with the primary laser beam, may be produced by system components such as power supplies, discharge lamps and plasma tubes.
- Laser Dyes
  - Certain dyes are highly toxic or carcinogenic.

Example: Laser Plume with Excimer

- A number of viral pathogens have been identified in tears and the ocular surface
- Possibility that viral particles may become part of airborne contaminants ejected at supersonic speed during laser ablation
- 193 nm light of excimer does not disinfect ocular surface
- Laser plume should be considered a potential biohazard
- Use appropriate local ventilation as first line of protection
  - Surgical masks do not exclude all laser-generated plume contents



Endotracheal Tube -Fire

- Familiarity with management of endotracheal fire, to prevent panic, ensure quick, knowledgeable response.
- Disconnect oxygen source and remove any burning objects from the airway
- Irrigate the site with water if the fire is still smouldering.
- Ventilate the patient by mask and re-intubate the patient with as low an fraction of inspired oxygen as possible

Fire– Beam Hazards

- Most common laser-related accident
  - Ignition of flammable material
  - Drapes and covers
- Water source near working area
  - Bowl of water on trolley; Wet towel; Fire blanket
- Fire extinguisher (carbon dioxide)
  - Non reflective paint
  - Check label
  - Cover with non-reflective jacket

Fire - Non-beam hazards

- Flammable material:
  - Solutions containing alcohol
  - Paper towels
  - High level of oxygen in the operative field
  - Cleaning agents

- Consider use of non-flammable cleaning agents (e.g. water-based)

- Any new agent used with a laser: checked for flammability before use

- Use fire-retardant drapes, damp packs or pads

- Put laser system in standby mode when procedure is interrupted or terminated.

Laser Safety

EYE WEAR

Hazards to the eye – Pulsed Lasers

- Pulsed lasers such as the Q-switched Nd:YAG laser (1064 nm);
  - Additional hazard from the possibility of acoustic shock wave generation in the retinal tissue leading to tissue rupture;
  - Can get rapid heating of absorbing tissue causes Thermomechanical injuries, possibly leading to haemorrhaging and damage extending well beyond irradiated area.

Ocular Aversion Responses

- Constriction of pupil
- Squinting
- Blink reflex
  - within about 0.25sec after onset exposure.
  - Not a very strong reaction.
  - Can be over-ridden, can be impaired by drugs etc.
- Looking away

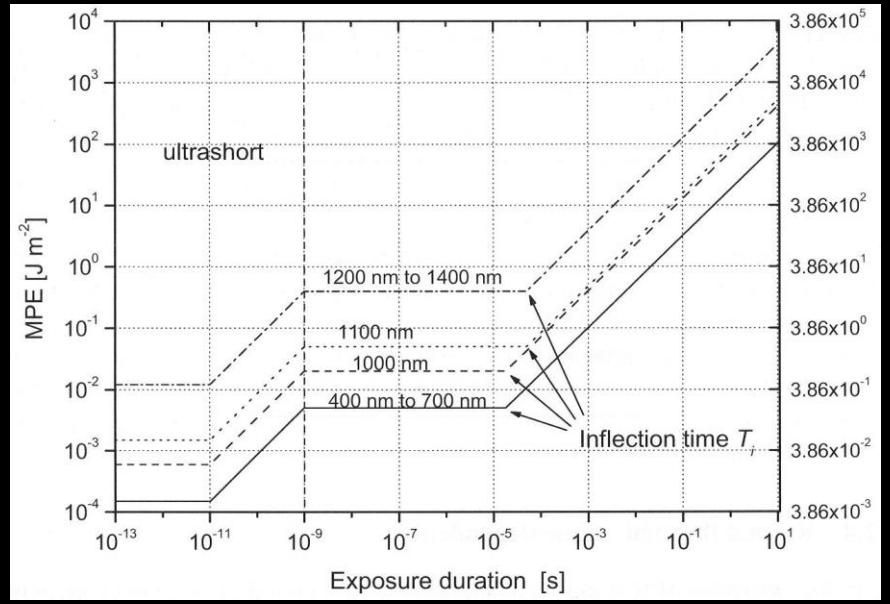
- Exposure levels well above safety limits can result in eye damage within a few milliseconds

- Only work for visible light
  - Ultraviolet: No natural protection as irradiance levels are typically too low to be sensed as heat.
  - Infrared: Cornea very sensitive to heat and produces sensation of pain.
    - Injury may be prevented by reaction to elevated temperature of cornea and if pain is sensed before damage occurs.

Maximum Permissible Exposure (MPE)

- *"Level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eye or skin"* (ANSI 1996)

- MPE is dependent on
  - Pulse repetition rate
  - Laser Wavelength
  - Exposure duration
  - Type of tissue at risk
  - Size of retinal image



Laser Safety Eyewear

- Why is eye protection important?
  - Injuries are generally of a more serious nature when compared to skin burns
  - Ocular injuries (particularly to retina) are generally permanent
  - In extreme cases, laser injuries can lead to partial or sometimes total loss of vision
  - As some lasers are invisible and the retina does not contain pain receptors, an exposure may not be immediately apparent.

Wavelength Dependency

- Goggles to be worn depend <u>on type of laser</u> being used.
- Goggles will only filter laser light in a specific wavelength (colour) range
  - e.g., Nd:YAG laser will penetrate the clear goggles that are used for eye protection against a carbon dioxide laser

Physical factors affecting performance of Eyewear

- Optical Density at a wavelength
  - reduces laser intensity
- Damage Threshold
  - ability to absorb incident energy
- Visible Light Transmission
  - How transparent is it?

Practical aspects of LSE

- Correct eyewear must be worn for laser being used.

- Colour coding (local or informal) of the laser hand-piece and LSE may help to minimize confusion especially in facilities where **multiple laser** wavelengths are available.
  - LSE should not move between laser rooms
- Eye protection must **never be used for deliberate viewing** of laser beam, only to guard against accidental exposure;

- Shareware? Infection control: regular cleaning;

- Regular Inspection: **eye protection that has been exposed to direct laser beam must be discarded**

Laser Safety

REGULATIONS AND LEGISLTATION

Legislation

- Safety, Health and Welfare at Work Act 2008(amendment) SI No. 176 of 2010 re. Artificial Optical Radiation
  - EC Physical Agents (artificial optical radiation) Directive (2006/25/EC)
  - The HSA is the Competent Authority in Ireland

Objectives

- Protect persons from laser radiation by indicating safe working levels of laser radiation
  - Exposure Limit Values
  - introducing a system of classification of lasers and laser products according to their degree of hazard

- To lay down requirements for both user and manufacturer so that proper precautions can be adopted.
  - to establish procedures
  - supply information

Employer Responsibilities

- Make a suitable and appropriate **risk assessment**.
  - measure and or calculate the level of exposure to artificial optical radiation to which his or her employees are exposed.
- Make provisions to avoid or reducing exposure.
- Provide employee information and training.
- Provide appropriate health surveillance

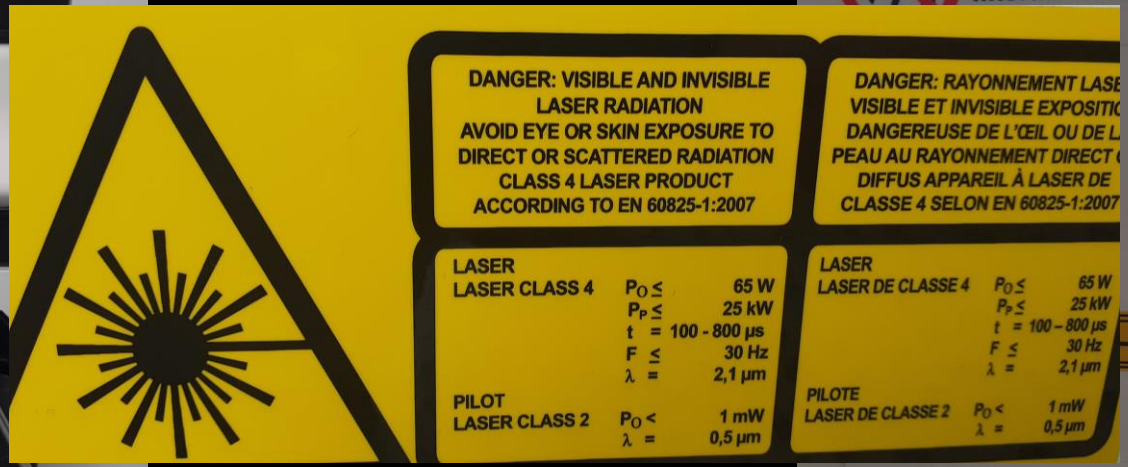
Standards and Recommendations

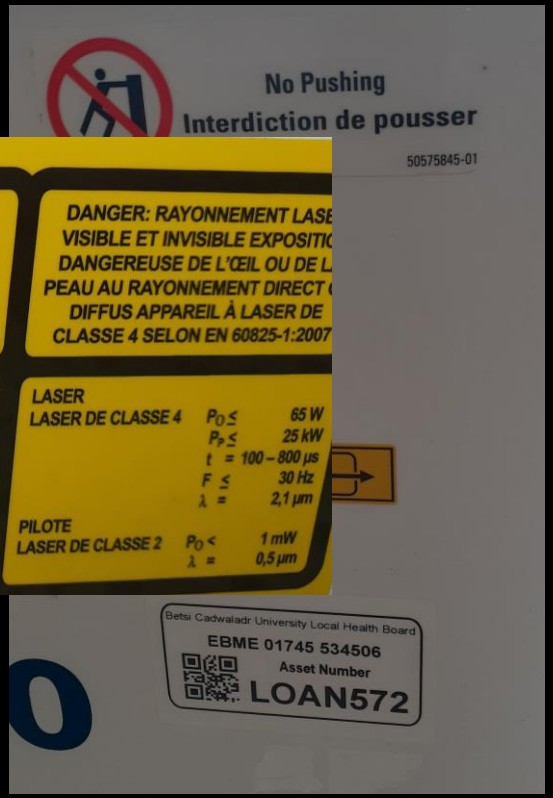
- IEC - International Electrotechnical Commission
  - IEC 60825-x
    - Fundamental laser safety document
    - Defines maximum permissible exposures, accessible emission limits, laser classes, measurement conditions, labeling, engineering controls etc.
  - IEC 601-2-22 'Medical Electrical Equipment'
    - 'Medical Electrical Equipment'
    - Electrical safety
- National Standards Authority of Ireland (NSAI)
  - (adopt IEC standards)
  - HPRA
- CENELEC - European Committee for Electrotechnical Standardization (EN)
- American National Standard
  - ANSI Z136.3-1996 "American National Standard for the Safe Use of Lasers in Health Care Facilities"
- British Standard
  - BS/EN 207, 1999 "Personal eye protection…."
- MHRA (UK) DB 2008(03) Guidance on the safe use of lasers, IPL systems and LEDs
  - Updated guidance for devices used in medical, surgical, dental and aesthetic practices.

Mandatory manufacturers obligations

- Removable key control
- Laser “ready” warning
- Laser “emission” warning visible or audible
- Beam stopper/shutter
- Remote interlock
- Target indicating/aiming device
- Monitoring of output
- Means for ensuring exposure correctly terminated
- Emergency stop
- Enable switch

Permanently warning signs on equipment





Laser Safety

MEDICAL LASER SAFETY INFRASTRUCTURE

Hospital laser safety

- Staff and patient safety
- Reduce exposure to acceptable levels
- Compliance with recommended standards
- Provides general basis for common safe practice within establishment
- Written to suit local circumstances
- Requires consultation with users
- Laser safety committee

Laser safety in hospital

- Staff
  - Laser protection adviser LPA
  - Laser protection supervisor LPS
  - Clinical laser expert
  - Authorised users

- Policies and procedures

Laser policy - key aspects

- Relevance of legislation and guidance
- Duties
- Hazards
- Register of authorised users
- Laser controlled areas
- Record keeping

- Should be specific to
  - ***The clinical procedures***
    - Outline responsibilities/duties
    - Normal operating procedures
  - ***The location***
    - Laser controlled areas
  - ***The laser***
    - Safe Work Practice Sheets
    - Controlled and safe access
- Should be read, and complied with, by all staff
- Staff should be confirmed as trained

Laser Controlled Area

- Where risk of exposure limit being exceeded
  - Nominal Ocular Hazard Distance (NOHD)
    - Depends on wavelength, laser power, beam divergence, beam size at aperture, distance from target
    - 2.2-4.4m Nd-YAG laser

- Boundaries advised by LPA
  - Entire room or dedicated enclosure
  - Windows / doors
  - Signs to designate area

- Occupancy – only if presence required

- Activities within laser controlled area:
  - Operational control by responsible person
  - Control by LPS
  - Eye protection

Room Design

- Matt finish on walls
- Minimum of reflective surfaces
- Use of blinds for windows and alcoves
- Doors
  - Sealed with their frames i.e. no gaps
  - Laser operated away from door

Room Design -Surgical Equipment

- Designed specifically for laser procedures
- Low reflectance – anodised, blackened, matt finish
- However…. Surgical instruments are shiny and highly reflective

Control of Access to Laser Controlled Area

- Interlocks on doors are not recommended
- Illuminated sign at eye level (main entrance)
  - Manual switch, responsibility of operator to use
  - Interlocked to laser, often not feasible
- Sign with laser symbol at eye level (other entrances)
- Laser Key available to authorised personnel only

Signage examples

Foot switches must be covered

Operator should remove foot from control pedal and put laser in standby when laser not in use.

Equipment Management

- Routine service
  - Preventative maintenance
  - Service company or in house (as per defined schedule based on manufacturers recommendations)
- Electrical safety
- Fault reports and action taken
  - Having to turn up the treatment power
  - Error codes on display
  - Laser overheating or cutting out
  - Unusual noise from laser
- Records

Laser Friendly Environment

- Dust
  - No open windows
  - Use high quality filters in air handling units
- Temperature
  - Stable temperature 18-19oC
  - Use thermostatically controlled fans to control temperature in the room
- Humidity
  - Can be controlled by air conditioning unit

Safe Work Practice Sheets

- For each laser / activity
  - Location, laser type
- Work area preparation
  - Safety signs
  - Numbers of goggles
- Laser preparation
  - Cable connection
  - Key switch
- Eye protection
  - Suitable Goggles
  - Moistened eye pads
- Fire safety
  - Fire extinguisher type
- Stand down
  - Switch off sequence
  - Removal/storage of key
- Miscellaneous

LASER SAFETY AIDE MEMOIRE

Checks before switch on

STAFF
- Surgeon on list of authorised users for procedure
- Nurses trained in laser safety
- Number of persons kept to a minimum
- Unnecessary equipment cleared from theatre

PPE/GOGGLES
- One pair for each member of staff present

PATIENT
- Eyes protected or taped shut

LASER
- Plugged in but not turned on

Laser controlled area

LASER SIGNS
- Displayed at all entrance doors

DOORS
- Closed

WINDOW/DOOR VIEWING PANELS
- Blinds closed

Laser start up

GOGGLES ON
- Surgeon instructs **all staff present** to wear goggles

LASER ON
- Laser switched on at key and staff informed

STAND BY
- Laser placed in standby

FIBRE
- Check fibre for any damage using the aiming beam

Laser use

READY MODE
- Laser placed in ready mode prior to treatment or calibration: all staff informed

STANDBY
- Laser placed in standby mode during any interruptions in procedure: all staff informed

FIBRE
- Care taken not to damage fibre

End of laser session

SIGNS
- Laser warning signs should be removed

KEY
- Placed in safe storage

Incidents involving accidental exposure

- Report immediately to head of department and LPS
- Ophthalmic / medical examination within 24 hours
- LPA/LPS investigates and reports to risk management
- Failure of equipment report to Health Products Regulatory Authority (HPRA)
  - EU directive manufacturers of CE marked equipment must report all adverse incidents to competent authority (HPRA)

Incident grab sheets

- Attached to each laser
- In event of an ocular injury/incident grab and take to eye A&E
  - Include telephone numbers of
    - Nearest A&E
    - Laser protection advisor
    - Health and safety officer
    - Occupational health officer
- Laser system details
- Laser setting at time of injury

Introduction

In the event of an ocular injury resulting from a laser an ophthalmologist at the nearest Casualty Eye Clinic should carry out incident an examination. The examination should be carried out as soon as possible after the injury and the information contained in this sheet should be made available to anyone treating the injury. The Laser Protection Adviser should also be contacted within 24 hours of the incident.

Casualty Eye Clinic [redacted]

Laser system

Manufacturer	Spectranetics
Class	IV
Model	3VX-300
Type	Excimer
Wavelength	308 nm

Possible Injury

- Effects upon the eye: Photokeratosis, Cataracts
- Effects upon the skin: Erythema

Name of injured person	
Time and date of injury	
Laser settings at time of injury	

Other comments

Contacts

Laser Protection Supervisor	[redacted]	[redacted]
Laser Protection Adviser	[redacted]	[redacted]

Training syllabus (IEC 60825-8)

- For all working in laser controlled area
  - Laser characteristics/types/classes
  - Equipment management/quality assurance/PPE
  - Tissue interactions/biological and non-biological hazards / precautions
  - Standards/risk management
  - 4 hours
- Training records maintained by LPS

Laser treatment burns claim settled in High Court

A YOUNG woman who claimed she suffered severe burns and blisters after laser treatment to remove hair from her legs has settled her High Court action.

[redacted] company denied her claims.

After talks between the sides [redacted] Lavan the case had been settled and could be put in for mention next October. Mr Justice Lavan adjourned the case.

[redacted] 2004, for a fourth laser hair-removal treatment of a course of six. The lower legs and bikini area were treated, she claimed. She alleged excessive shots of energy were used, and she felt intense pain and suffered multiple severe burns to her skin on both legs.

It was alleged the defendant failed to properly train the therapist concerned in equipment use.

[redacted] so intense she was hysterical. She claimed she was in agony, and took painkillers every four hours. It was four weeks before the blisters healed. A loss of pigment in her left leg was later diagnosed as permanent and she found her legs' appearance embarrassing.

The defence denied the claims. It said relevant industry standards [redacted] was not entitled to damages.

Irish Times

Laser treatment burns claim settled in High Court

Saturday 17 July 2010

Laser Safety

EXAMPLE OF INCIDENTS AND NEAR MISSES

Laser Accidents

Studies of laser accidents have shown that there are usually several contributing factors

- More likely to occur with pulsed laser since normal blink-reflex time does not offer any protection
- Usually no protective eye wear or wrong eye wear was being worn
- Many occur during technical adjustment of the laser
- Lasers in close proximity to anaesthetic gases
- Lack of awareness among users

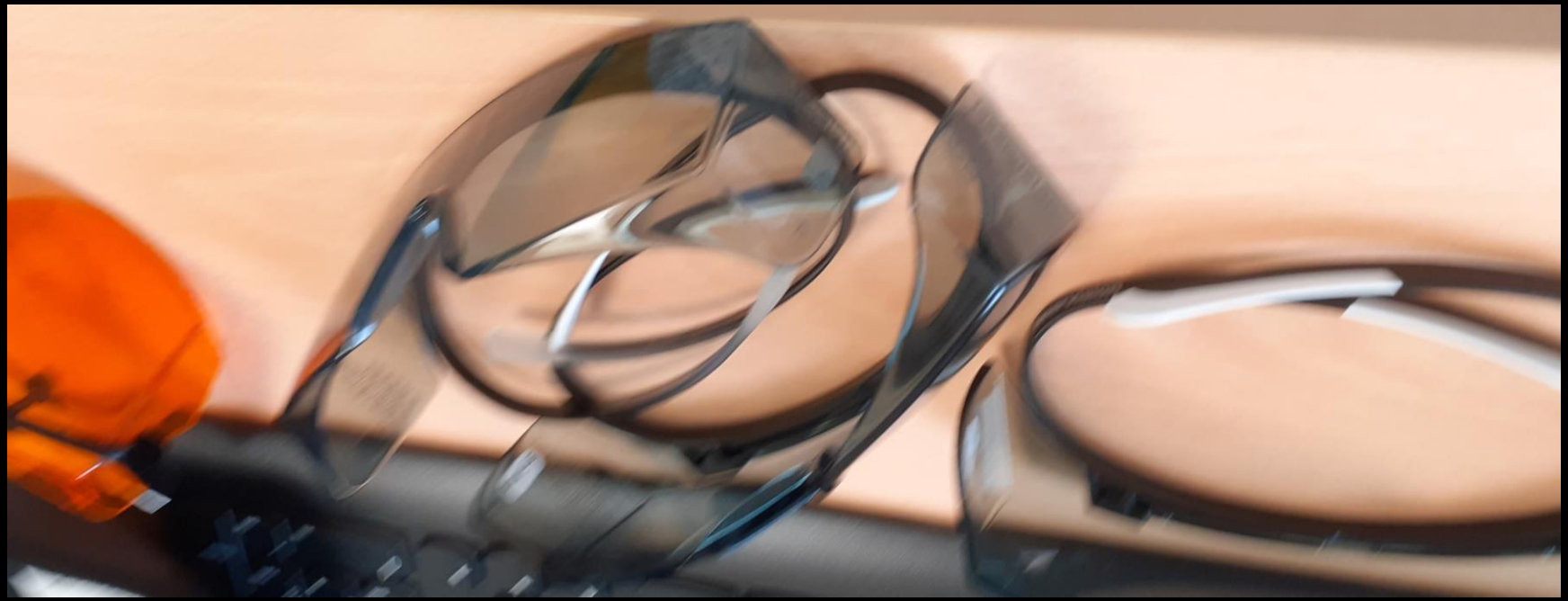
Lack of eyewear

- A postdoctoral employee received an eye exposure to spectral radiation from an 800 nm Class 4 laser beam
- The extremely short pulse (100 fs) caused a 100-micron-diameter burn in the employee's retina
- Although the beam had been blocked during several previous steps in the alignment, it was not blocked in this case
- Neither of the two employees performing the alignment was wearing the appropriate laser eye protection

Engineer alignment accident

- Service engineer working on a laser without realising that the beam was pointing directly at the opening between the double doors into the treatment room
- Doors scorched in a neat 5cm circle covering both doors
- Doors lead to a waiting room which was luckily unoccupied

Eyewear on a new system



Final comments

- Employer is ultimately responsible for health and safety including lasers
- All staff have responsibilities and specific duties
- Written policy and procedures are essential
- Training records
- Service records
- Report incidents / faults