


LASER SAFETY DOCUMENTATION



Compiled by Edette O'Dea


APPROVED BY THE LASER SAFETY COMMITTEE, OLCCH



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Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Contents


	Page Number
Laser Safety Committee, Laser Safety Policy	2
Laser Safety Guidelines	8
Standard Operating Procedure on Insertion and Removal of Laser Resistant Eye Shields	15
Cynosure Cynergy Laser	19
Laser Risk Assessment for Cynosure Cynergy Yag / Dye Laser	21
KTP Laser	29
Laser Risk Assessment for the Laser Scope Aura KTP Laser	30
Sharplan Co2 Laser	37
Laser Risk Assessment for the Sharplan 40C Co2	39
Alexandrite Laser	46
Laser Risk Assessment for Cynosure Apogee 5500 Alexandrite Laser (3241)	48
Keeler Diode Laser / Iridex Oculight IPX8	54
Laser Risk Assessment for the Keeler Diode Laser / Iridex Oculight IPX8	55
Standard Operating Procedure of DioBeam	62
Laser Risk Assessment for the DioBeam 830 Diode Laser	67
Parent Information Leaflet – Local Anaesthetic Laser Information	74
Parent Information Leaflet – Information for Laser Hair Removal	76

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

LASER SAFETY COMMITTEE, LASER SAFETY POLICY	
Policy Number	<i>OLCHCLSCLSP-06-2015-GBJG-V1</i>
Date of Issue	<i>June 2015</i>
Approved by	<i>Chair of Laser Safety Committee</i>
Review Interval	<i>2 yearly</i>
Approved By Name: <i>Dr. Rosemary Watson</i> Title: <i>Chair of Laser Safety Committee</i>	Signature Date: <i>May 2016</i> 
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Location of Copies	<i>On Hospital Intranet and locally in department</i>


Document Review History		
Review Date	Reviewed By	Signature
<i>2018</i>		

Document Change History	
Change to Document	Reason for Change

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Contents

		Page Number
1.0	Policy Statement	4
2.0	Definitions	4
3.0	Roles and Responsibilities	4
4.0	Processes	5
5.0	References	6

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

1.0 Policy Statement

Our Lady's Children's Hospital, Crumlin, (OLCHC), will ensure that the risks associated with the use of lasers are minimised. This document sets out the hospital's policy for the provision of laser hazard controls.


This policy replaces all existing policies from 2015 onwards and is due for review in 2018. It will be reviewed during this time as necessary to reflect any changes in legislation and organisational, professional or academic best practice.

2.0 Definitions

- 2.1 Laser Controlled Area: any room where a laser is in use and which is designated as requiring optical hazard controls.
- 2.2 Laser Protection Adviser (LPA): Technical laser safety expert.
- 2.3 Laser Protection Supervisor (LPS): Safety supervisor associated with each laser.
- 2.4 Authorised user: Personnel having the approval of the Laser Safety Committee to operate a specific laser.
- 2.5 Clinical Expert: The lead clinical user associated with each laser

3.0 Roles and Responsibilities

- 3.1 Responsibility for recommending laser safety measures and establishing laser safety policy at OLCHC is delegated to the Laser Safety Committee as set out in the Committee's terms of reference. The committee comprises:
 - (i) Clinical expert laser users from each area.
 - (ii) The Laser Protection Supervisor from each area.
 - (iii) A representative from Hospital Administration.
 - (iv) The Laser Protection Adviser.
 - (v) The Hospital Safety Adviser.
 - (vi) Any other person or persons, proposed by the Medical Board, and deemed to be required by the Hospital Board.
- 3.2. Class 3B, 3R and 4 lasers fall within the Laser Safety Committee's remit.
- 3.3 Each Head of Department in which a laser is used is responsible for the implementation of the Laser Safety Policy in his/her department.
- 3.4 Heads of Dept. must inform the Laser Safety Committee prior to tendering for, purchasing or trialling a new laser.
- 3.4 Heads of Dept. must inform the Laser Safety Committee of any research projects involving lasers, or any intended off-label usage.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

- 3.4 The Laser Protection Advisor (LPA) will advise the Laser Safety committee on technical issues relating to laser safety.
- 3.5 Authorised Users are responsible for the safety of staff and patients with respect to laser hazards during the use of a laser.
- 3.6 Clinical Experts will advise the Committee on proposed amendments to Authorised Users list, with regard to the proposed user's clinical laser experience.
- 3.7 The Laser Protection Supervisor is responsible for the implementation of day to day laser hazard controls, the maintenance of the 'Register of Authorised Users', and the control of documentation for their area.

4.0 Processes

4.1 General

4.1.1 OLCHC will take all necessary steps to ensure compliance with the relevant Legislation and Standards, including the provision of appropriate PPE.

4.1.2 All personnel must verify, prior to use, that their protective eyewear is the correct type, is free from damage, and is cleaned and correctly stored after use.

4.2 Documents & Documentation Control

4.2.1 Each laser will have an associated Risk Assessment and Laser SOP (Laser Specific Safety Guideline)

4.2.2 Risk assessments for each laser will be carried out prior to commissioning of new lasers, or the re-location of an existing laser.

4.2.3 Risk assessments will be reviewed on an annual basis.

4.2.4 Laser Safety SOPs will be issued for each laser prior to being put into service for the first time.

4.2.5 Amendments to documentation relating to Laser Safety policy, including Risk Assessments and Laser SOPs must be approved by the Laser Safety Committee.

4.3 Operational Policy


4.3.1 All staff in the Laser Controlled Area must comply with the Laser Safety Policy and Laser Safety SOP (Local Rules) during laser use.

4.3.2 Use of lasers shall be restricted to those on the relevant Register of Authorised Users.

4.3.3 Accidents, incidents, and hazardous situations and practices, must be reported to the LPS who will bring them to the attention of the Head of Department and LPA.

4.4 Authorisation

4.4.1 Only personnel approved by the Laser Safety Committee as Authorised Users may operate lasers at the hospital.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

4.4.2 **Authorised Users must:**

- (i) Be familiar with the Laser Safety Policy and the Laser SOPs.
- (ii) Have received basic laser safety training approved by the Laser Protection Adviser (generally referred to as the core of knowledge). The core of knowledge may be delivered as a single course or by other appropriate means.
- (iii) Have completed a period of supervision deemed satisfactory by the Clinical Expert for the laser and have demonstrated the required competencies specific to the laser procedure concerned.

OR

Show evidence of competency in the safe use of the same type of laser procedures from previous employment considered acceptable by the relevant Clinical Expert.

4.5 **Training**

4.5.1 All personnel present in a Laser Controlled Area during laser procedures must be familiar with the relevant Laser Safety SOP, and have completed safety training covering a defined Laser Safety Core of Knowledge.


4.5.2 Where it is deemed essential for a staff member who has not received formal laser safety training to be present for a laser procedure, this staff member:

- (i) Must not adjust or use the laser.
- (ii) Must be closely supervised by the Laser Protection Supervisor.
- (iii) Must receive instruction from the LPS on the correct use of laser safety eyewear.
- (iv) Must be scheduled for formal laser training at the earliest practical date.

5.0 **References**

5.1 *S.I. No. 176 of 2010. SAFETY, HEALTH AND WELFARE AT WORK (GENERAL APPLICATION) (AMENDMENT) REGULATIONS 2010. PART 9- Control of Artificial Optical Radiation at Work.*

5.2 *IEC/TR 60825-14 (2004-02) Ed. 1.0. Safety of laser products - Part 14: A User's Guide*

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Laser Safety Committee

Chairperson: Dr. Rosemarie Watson

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Ms. Mary Scully – CNMI Theatre

Ms. Katherine McCreery – Consultant Ophthalmologist

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Mr. Jim Davenport – Clinical Engineer

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Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

LASER SAFETY GUIDELINES


Version Number	V1
Date of Issue	March 2016
Reference Number	LSG-03-2016-RWEOS-V1
Review Interval	2 yearly
Approved By Name: <i>Fionnuala O'Neill</i> Title: <i>Practice Development Coordinator</i>	Signature: <i>Fionnuala O'Neill</i> Date: <i>March 2016</i>
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Location of Copies	<i>On Hospital Intranet and locally in department</i>

Document Review History

Review Date	Reviewed By	Signature
2018		


Document Change History

Change to Document	Reason for Change

Our Lady's Children's Hospital, Crumlin		
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Reference Number:	Version Number: V1	
Date of Issue: November 2018		

CONTENTS

		Page No
1.0	Introduction	10
2.0	Definitions of Guidelines	10
3.0	Definitions / Terms	10
4.0	Applicable to	10
5.0	Objectives of the Guideline	10
6.0	Lasers	10
7.0	Step by Step Laser Safety	13
8.0	References	15
9.0	Bibliography	15

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

1.0 Introduction

The aim is to provide basic guidelines on the safe use of lasers in OLCHC. It has been compiled and issued on behalf of the laser safety committee. It is intended as a brief revision document on good, general laser safety practice for staff working in “Laser controlled areas”. It is not intended as a guide for authorised users (those who operate the laser clinically) or as safety guidance on a specific laser type. It does not replace the requirement for laser safety training

2.0 Definition of Guidelines

Guidelines represent the written instructions about how to ensure high quality services are delivered. Guidelines must be accurate, up to date, evidence-based, easy to understand, non-ambiguous and emphasise safety. When followed they should lead to the required standards of performance.

3.0 Definitions / Terms

LASER is an acronym for Light Amplification by Stimulated Emission of Radiation

Laser advisor: Is available to assist on technical issues related to laser safety e.g. (choice of eyewear or policy development etc.)

Laser protection supervisor: Is responsible for day to day safety of a specific laser

Authorised user: The person who operates the laser clinically

Laser controlled area: Is the room or theatre where the laser treatment is carried out

4.0 Applicable to

All staff working in a laser controlled area, Authorised users, nursing personnel in theatre and outpatient setting.


5.0 Objectives of the Guidelines

It is intended as a brief revision document on good, general laser safety practice for staff working in “Laser controlled areas”

6.0 Lasers

Lasers emit concentrated beams of light. All are classified according to a risk level. Most surgical lasers are Class 4 Lasers this means:

- They present a risk to the eye sight on direct viewing of the laser beam or on diffuse reflection of the beam off a surface
- There beam can start fires
- They can cause skin burns

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

In some areas, like physiotherapy, lower power “Class 3B” or “Class 3R” lasers are occasionally used. These lasers still present an eye hazard on direct viewing, but have lower potential for skin burns and fire ignition.

Technically laser light is called “non-ionising radiation”. This distinguishes lasers from X-ray machines which emit “ionising radiation”. Note that unlike X-ray the risks associated with lasers are essentially acute (any negative impact, like a burn, will have an immediate effect) and that there are none of the health and safety concerns during pregnancy that there are with ionising radiation, such as x-rays.

How it works

Laser Safety in Crumlin is managed by the local laser safety committee. It is the responsibility of this committee to recommend good laser safety practice at the hospital. The committee has produced a set of documents which you have full access to and should be familiar with.

These are:

1. The Hospital Laser Safety Policy
2. Safety Guidelines
3. Detailed SOP's for each laser. Ensure you are familiar with the SOP for the laser you are working with.
4. Risk assessments for each laser. These are detailed documents setting out the risk associated with each Laser


Who to talk to:

- Every laser in OLCHC has a “laser Protection Supervisor” (LPS) associated with it.
- He/she is responsible for day to day laser safety for that Laser.
- Ensure you know who your LPS is for the laser you are working with.
- In the event of incident or suspected incident with a laser, alert the designated LPS in the first instance.
- In addition the Hospital has a “laser safety Adviser” who is available to assist on technical issues on Laser safety (e.g. Choice of safety eyewear, policy development etc.)

The Laser Safety Committee is there to assist laser users. If you have any concerns or queries on laser safety contact the Committee via your LPS

Training: Your first line in reducing risks

- If you are present in a room where a laser is in use then under hospital rules, you must have completed a “laser Safety Training Course”.
- This is sometimes called the “Core of Knowledge” for Laser safety.
- Courses are available annually.
- If it is essential for you to work in the area prior to training then you LPS may allow you to work under close supervision, receive instruction on use of eyewear, and do not use or adjust the laser.
- In addition you should be booked into the next available training course.
- Only people signed off by the hospital's LSC as “authorised users” can operate a laser clinically.
- If you are intending to become a user (e.g. if you are a medic who wants to start using a laser for the first time) contact the LSC.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

- In addition to basic laser safety training remember every laser is different and depending on your level of involvement in setting up a laser, you may also need specific training on that laser.
- Never adjust or set up a laser you are unfamiliar with.
- The clinical Engineering Department will be happy to assist in providing or arranging any specific training you may need.

7.0 Step by Step Laser safety

The “Laser Controlled Area”

The ‘Laser Controlled Area’ is the room or theatre in which the laser is in use. Access to this area is strictly controlled and you must take the appropriate precautions when working in it.

Protecting your eyes


- There is a very real risk to the eyes if you do not wear the correct Laser safety eyewear during the laser procedure.
- Remember Laser goggles are specific to a given laser-goggles from a different laser may afford no protection at all.
- All staff in the Laser controlled area must wear the appropriate safety eyewear.
- The eyewear should fit you snugly with no obvious gaps for a beam to pass through.
- If you have any doubts about the eyewear you are using or the available eyewear appears damaged or uncomfortable to wear, contact your LPS.

Protecting your patients eyes

- It is not just your eyes that are at risk of an accidental exposure during a laser procedure-so are your patient's.
- An anaesthetised patient's closed eyes are not sufficient protection against an accidental exposure.
- Special fully blacked out goggles are available for protecting your patient's eyes during laser procedures.
- In some laser procedures where the laser is used close to the eyes, special protective shields which fit under the eyelids are used.

Controlling access

- Before the procedure starts, all doors into the laser controlled area should be locked.
- The purpose is to limit traffic into the room and to restrict access to personnel who are familiar with laser hazards.
- If you must leave the room, even for just a moment, you must ask the Authorised User (the surgeon operating the laser) before doing so, and ensure there is someone available inside the room to lock the door after you.
- This ensures that access is controlled appropriately.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Keeping the room light tight

- Laser beams from some surgical lasers can travel quite a long way and still be hazardous. To avoid the risk of eye exposure to anyone outside the room, laser controlled areas are designed to be 'light tight', so that there is no possibility of a laser beam accidentally escaping to the outside world.
- Ensure blinds on internal /external windows are closed and again that doors into the room are closed and locked.

Avoid reflections

- Ideally the laser will only be fired at some target tissue in the patient.
- If laser is accidentally fired into the room, we do not want the laser to be reflected off shiny surfaces, and potentially back at a staff member or patient.
- For this reason we try to reduce the number of reflective surfaces in the room.
- Remove or cover any shiny surfaces with a drape
- Remove jewellery or cover with tape.

Reducing Fire risk

- A laser beam striking a flammable material can easily start a fire
- While this should not happen in routine practice, e.g. paper or drapes could ignite a fire.
- Ensure there is a fire extinguisher and fire blanket available in the room before you start the procedure and that you are familiar with their use.
- Its good practice to keep a bowl of saline/water to hand to extinguish any small fire that might start.
- For laser procedures near a patient's hairline, dampen the hair near the surgical site to reduce the potential of fire

The Laser Key


- All surgical lasers are fitted with a key to prevent unauthorised use.
- Your LPS will normally manage access to the key
- The key should not be routinely left in the laser machine when the laser is not in use
- After procedure ensure the key is returned to its proper storage place.
- Some newer lasers dispense with a key and request user to enter a password before the machine can start.

Before you begin

- All lasers in OLCHC are serviced regularly, but like any medical device they are subject to wear and tear.
- Please do an inspection of the laser before you begin.
- If any frayed or damaged, cables, plugs or fittings are evident please notify Clinical engineering
- Most lasers require some level of 'setting up' to attach fibres, hand pieces, footswitches etc.
- Do not attempt setting up the laser unless you are familiar with the device.

ET Tubes

- Standard ET tubes must not be used during Laser airway surgery.
- Standard tubes can catch fire if struck with a beam and start an airway fire with potential for fatality or serious injury
- Only special 'laser resistant' tubes may be used.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Stand by Vs Ready

- All Lasers have two basic modes: " stand-by" and "ready"
- In "stand-by" the laser is warmed up and set up for use, but cannot be fired.
- In "ready" mode the laser will fire if the footswitch/hand piece is pressed.
- The laser should be switched from "ready" to "stand-by" during any pause in use of the laser.
- The Laser operator should communicate clearly with Nursing/CNS when the laser is to be switched between ready/standby.

The Plume

- Some laser procedures generate smoke called 'plume' during procedures.
- To protect against plume a " plume-extractor" should be available for use
- This is used to draw away smoke from the surgical site and filter it.
- In procedures generating plume, you should also wear the high filtration surgical masks

Handling Optics


- Finger marks on the glass of lenses will eat into the coatings on these optics
- Try to keep your fingers away from optics as they can be expensive to replace
- If you notice any marks on the lens inform LPS

8.0 References



This guidance draws from, S 176 (2010) Safety, Health and Welfare at Work (General Application) (Amendment) Regulations 2010, Part 9, Control of Artificial Optical Radiation at Work. An addition to the Standards and Guidelines listed in the Bibliography (Section 7).

9.0 Bibliography

- 9.1 S. . . No. 176 of 2010. SAFETY, HEALTH AND WELFARE AT WORK (GENERAL APPLICATION) (AMENDMENT) REGULATIONS 2010. PART 9- Control of Artificial Optical Radiation at Work.
- 9.2 EC/TR 60825-14 (2004-02) Ed. 1.0. Safety of laser products - Part 14: A Users Guide.
- 9.3 Radiation Protection Division, Health Protection Agency (UK), a Non-Binding. Guide to the Artificial Optical Radiation Directive 2006/25/EC.
- 9.4 Health and Safety Authority, Guidance for Employers on the Control of Artificial Optical Radiation at Work Regulations 2010.
- 9.5 Medicines and Healthcare products Regulatory Agency (UK), Device Bulletin Guidance on the safe use of lasers, intense light source systems and LED's in medical, surgical, dental and aesthetic practices DB2008(03) April 2008.
- 9.6 Laser Safety Policy.
- 9.7 Adverse Incident Reporting Policy, Policy Number SJH: COR (P): 004.
- 9.8 EC 60825-1:2007 Safety of laser products. Equipment classification and requirements.
- 9.9 S EN 207:1999 Personal eye-protection. Filters and eye-protectors against laser radiation (laser eye-protectors).

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

**STANDARD OPERATION PROCEDURE
ON INSERTION AND REMOVAL OF LASER RESISTANT EYE SHIELDS
PRE AND POST LASER TREATMENT**


Version Number	1
Date of Issue	March 2016
Reference Number	IRLRESPPLT-03-2016-EOSRW –V1
Review Interval	2 yearly
Approved By Name: Fionnuala O'Neill Title: Nurse Practice Development Coordinator	Signature Date: March 2016 
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Author/s	Name: Edette O'Dea, CNSp Laser Name: Dr. Rosemarie Watson, Consultant Dermatologist
Location of Copies	On Hospital Intranet and locally in department

Document Review History

Review Date	Reviewed By	Signature
2018		


Document Change History

Change to Document	Reason for Change

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

CONTENTS

		Page No
1.0	Introduction	17
2.0	Definition of Standard Operating Procedure	17
3.0	Applicable to	17
4.0	Objectives of the Standard Operating Procedure	17
5.0	Definitions / Terms	17
6.0	Procedures	17
7.0	Implementation Plan	19
8.0	References	19

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

1.0 Introduction

Eye protection is necessary for both patient and theatre personnel whenever a laser treatment is performed. Permanent visual loss can result from even minor direct retinal exposure to Laser. The patient's eyes must be protected using either glasses or goggles for all laser treatments or corneal protection shields when periorbital laser treatment is performed. All operating room personnel must wear appropriate eye wear - glasses or goggles for the laser machine in use, to ensure correct protection. Check with Laser team if you are unsure of correct goggles to wear
Goggles require regular inspection as scratches may alter optical density.

2.0 Definition of Standard Operating Procedure

The term '**Standard Operating Procedure**' is a way of carrying out a particular course of action.

3.0 Applicable to

Laser theatre personnel, laser operator, laser nurse.

4.0 Objectives of Standard Operating Procedure

- To maintain optimum patient safety
- To ensure appropriate eye protection
- To outline step by step procedures for the insertion and removal of eye shields.
- To ensure clear recording re insertion and removal of shields
- To prevent retention of shield post treatment
- The laser team will determine the eye protection for each patient pre-treatment bearing in mind one eye may require an eye shield and the other eye a goggle!

5.0 Definitions / Terms

- Glasses are also referred to as goggles
- Shield is also referred to as guard

6.0 Procedures


The insertion of the shield is carried out when the patient is anaesthetized and just before Laser treatment.

Equipment required

Eye guard, lacrilube (to lubricate the eye) eye shield sticker

Method of insertion

- Wash hands as per guidelines
- Remove shield from packaging
- Apply lacrilube using non touch technique
- Using thumb and index finger open eyelid with one hand

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

- Fold shield with other hand and insert into eye with nipple facing outer aspect of eye to allow ease of removal post procedure.
- Apply sticker to forehead to prompt removal of eye shield on completion of Laser treatment
- Sign and get countersigned when inserted in appropriate nursing notes

Method of removal

- Open eyelid with one hand
- Hold nipple between fingers and gently remove shield
- Apply fucithalamic eye ointment to eye using non touch technique
- Remove sticker from forehead
- Sign and get countersigned when removed in appropriate nursing notes

7.0 Implementation Plan


This plan was implemented in 2015. All nursing personnel in laser theatre must be informed and made aware of the importance of eye care prior to working in a laser safe environment.

8.0 References

- Laser safety Policy OLCHC 2016
- H Mosely Laser safety 2015
- S W Lanigan lasers in Dermatology, Ocular Hazards 2012
- Smalley PJ Laser safety Management: hazards, risks and control measures 2011
- Alister TS Getting started: Setting up a laser practice 2000
- Cynosure Manufacturer's instructions 1998
- Russell SH, Dinehart, SM, Davis L, Flock ST. Efficacy of Corneal eye shields in protecting patient's eyes from irradiation. Dermatology surg 1996

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Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

1. CYNOSURE CYNERGY LASER

Clinical Expert: Consultant Dermatologist - Dr. Rosemarie Watson

Consultant Dermatologist - Prof. Alan Irvine

CNSp Laser - Ms. Edette O'Dea

(Registrar under supervision)

Laser Protection Supervisors

Ms. Edette O'Dea - CNSp Laser

Technical Specification	
Model:	Cynergy
Manufacturer:	Cynosure
Location:	Laser Theatre 7 Prep Room
Class:	IV
Type:	Dye Laser
Wavelength:	Visible P.D.L. 585 nm and Yag Infrared 1064 nm
Model of Operation	Pulsed
Power/Energy:	Energy densities of up to 20 j /cm ² per pulse.

Hazard

The primary risk of the Cynergy Laser is of damage to the eye. The visible wavelength emitted by the Cynergy, can cause severe burns to the retina, either through direct or reflected exposure. Skin burns are also possible.

The ignition of hair (eyebrows/eye lashes) has been reported using 585nm dye lasers in the presence supplemental oxygen caused, for example, by oxygen leakage from a face mask (*Epstein. 1994*).

The dye and vapors emitted by the dye used in dye lasers is hazardous. Never handle the dye or materials used to clear a dye spill. In the event of a dye leak call local Clinical Engineering staff and follow the SOP for Laser Dye spill. Dye leaks are unlikely in normal operation

Specific Precautions

Observe all general precautions for the safe use of lasers as outlined in the Laser Safety Policy.


Staff and patients must only use the eye protection specified for this laser. Special care should be taken when treating the skin near the eyes. If the area treated is over the eyelid, corneal eye shields are used.

Note: *the Cynergy does have an aiming beam, it is amber / red in colour*

Glass windows are cleaned and replaced if any sign of damage is noted. Full service is carried out 6 monthly.

Be alert to the possibility of ignition, particularly where elevated oxygen levels may be present in the surgical field. When treating near the hairline, eyebrows or any other facial or body hair, keep the hair moist with water or saline.

Do not use flammable substances such as acetone or alcohol in the preparation of patient's skin. Use soap and water if necessary.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
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Only qualified personnel should open the laser covers. Even with the laser switched off removing the covers exposes personnel to lethal voltages.

Cleaning

Spacers are cleaned between each case with Azo wipe (bacterial wipes with 70% alcohol, which dries immediately) and cleaned with Brial solution (a pre measured dose of detergent in a litre of water) at the end of session.


Glass windows are cleaned and replaced if any sign of damage is noted. Clean the exterior of the machine after each session with Brial solution.

Laser Risk Assessment for the Cynosure Cynergy Yag / Dye Laser located in Theatre, OLCCHC

Title of Document: Laser risk assessment for the Cynosure Cynergy Yag/Dye Laser located in Theatre, OLCCHC.	Issue date of Risk Assessment: 16.01.18
Activity/Facility Assessed: Theatre, OLCCHC.	Laser control area: Theatre 7
Laser Protection Supervisor: O. Delaney, CNM.	Laser Protection Advisor: Dr. J. Galligan.
Assessed by: O. Delaney / Dr. J. Galligan.	Review date: 27/11/2015

Background Information

Laser Classification: IV	Model: Cynergy	Manufacturer: Cynosure
Laser Type: Yag/Dye	Wavelength: 1064nm / 582-600 nm	Beam Delivery Device: Fibre and hand piece
Mode of operation: Pulsed	Power/Energy Range: max. 80J (Yag) / max. 10 J (Dye)	Pulse duration for pulsed lasers: 0.3 to 300ms (Yag) / 0.4 to 40 ms (Dye)
NOHD: Waiting on data from manufacturer. 100 meters (manufacturer).		
Aiming Beam: 635 nm, continuous mode < 5 mW, Class 3A.		
Required safety eyewear protection level: 580 - 605 nm D LB4 I LB9, 1064 nm D LB4 I LB9. Have 585-595nm + 1064nm OD+6, 585-590 I L5 590-560 I L6, 1064 IR L6 NOIR. Manufacturer recommends >5.4 at 585 nm and >5.8 at 1064nm.		
Description of Application: Treatment of port wine stains.		
Description of laser environment (incl. access, windows, surfaces, warning lights, and signs): Operating theatre. All entrances are locked with switch on control panel, which acts as an interlock, the warning lights are also activated from a similar switch on the same control panel. Blinds on all windows.		
Persons at Risk: Staff, patient, contracted service personnel, and public.		
Cycle of Interest: All forms of operation including but not limited to approve clinical procedures, all testing, and maintenance.		
Laser is CE marked meets all specifications and has been signed off by LPA: No, pre LPA appointment, laser has been assessed as being appropriate (21/11/2012).		

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


List of Corrective Actions

Hazard	Action required	Completed	Completed by
	Recommend that laser key holders should have copy of Authorised Users list.	Nov-14	EO'D
	Laser Safety SOP to be amended.	Nov-14	EO'D
	Review and replacement of goggles.		
	No by-pass for interlock.		
	Review plume risk, use wand instead of funnel	Nov-14	EO'D & JG


Question 1:	Is this laser appropriate and safe for use in its intended clinical applications and designated laser control area?	Response:				
Hazard:	Environment and People.					

People at Risk:	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to
	Laser device cannot be operated without key.	✓				
	The laser controlled area (LCA) has been designated with physical access restrictions.	✓				
	Warning lights are located above all accesses to the laser controlled area.	✓				
	Laser has electrical, and laser aperture warning labels.	✓				


Administrative Controls:	Laser Safety Committee, Laser Protection Advisor, Laser Protection Supervisor, and Clinical Expert have been appointed.	✓				
	Laser Safety Local Rules (SOP), have been drawn for the laser and this laser controlled area.	✓				
	Processes are in place to restrict access to the laser controlled area.	✓				
	Processes are in place to ensure that warning signs are posted on all entrances to laser control area.	✓				

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


	Processes are in place to ensure that usage is restricted to Authorised Users and to the laser controlled area.	✓				
	Authorised users and assisting staff have received laser safety training, and are familiar with the appropriate policies and procedures.	✓				
	Laser maintenance is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	✓				
	Maintenance is restricted to qualified personnel.	✓				
	Processes are in place to ensure that the laser is routinely verified for correct performance and safety (Performance Verification).	✓				
	No more than one laser is switched on in the laser controlled area.	✓				
	Emergency procedures are in place.	✓				
	Incident reporting and investigating protocols are in place.	✓				
Responsible person:	Laser Safety Committee, Laser Protection Advisor (LPA), Laser Protection Supervisor (LPS), and Clinical Expert.					
Question 2:	Are person's present in the nominal ocular hazard area (NOHA) protected against unintended laser exposure above the maximum ELV?	Response:				
Hazard:	Optical.					
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Windows are completely laser tight.	✓				
	Protective filter/shutter is provided with viewing optics are in good order.			✓		
Administrative Controls:	A process is in place to verify that the beam is on target prior to firing.	□	X		Spot check no longer done, as recommended by agent.	
	All accessories and devices used during the procedure have been approved for use with lasers as being non-reflective.	✓				
	All reflective surfaces have been removed or covered.	✓				
	Patient's eyes, particularly those of anaesthetised patients are protected.	✓				

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


	Staff have been trained in the use and maintenance of protective eyewear and shutters.	✓				
PPE Controls:	Patient and staff laser protection eyewear provided.	✓				
	Protective eyewear is appropriate for this laser and in good order.	✓			Review and replacement in progress.	LPS
	There are adequate numbers of eyewear, and are easily identifiable.	✓			Included in in-service training.	
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 3:	Are person's present in the laser control area protected against unintended laser exposure to the skin above the ELV, and fire?	Response:				
Hazard:	Fire, explosions, and tissue burns.					
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to
Administrative Controls:	All accessories and devices used during the procedure have been approved for use with lasers.	✓				
	Cleaning and disinfecting agents are non-flammable.	✓		☐	Alco wipes and allowed to dry.	
	Processes are in place to ensure that swabs, surgical drapes, and other flammable material located near the field of operation are kept moist with saline or sterile water.	✓		☐		
	Processes are in place to ensure that laser safe endotracheal tubes are used.	☐		✓	Laryngeal mask used.	
	The Anaesthetic Laser Safety SOP is followed.	☐		✓		
	Safety processes are in place for the use of lasers with channelled devices such as endoscopes and canellas.			✓		
	There is an emergency plan in place in case of fire.	✓			No by-pass for interlock.	H&S Officer
	Firefighting equipment is available in laser control area for all cycles.	✓		☐		
PPE Controls:	Gloves are worn to avoid skin exposure from the reflective beam during fibre calibration (UV).	☐		✓		
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 4:	Are processes in place to avoid beam misfires?	Response:				
Hazard:	Unintended absorption of laser beam.					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Beam is activated by a covered footswitch or hand switch.	✓				
	Beam cannot be activated without a delivery device.	✓				
Administrative Controls:	Processes are in place to ensure that laser, fibre, and optics are checked for damage prior to use.	✓				
	Processes are in place to ensure that laser is placed in standby mode when not in use.	✓		<input type="checkbox"/>		
	Processes are in place to ensure that no more than one device footswitch is available to the authorised user at a time.	✓		<input type="checkbox"/>		
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 5:	Are patients and staff adequately protected from potential laser plume hazards?	Response:				
Hazard:	Small particles in the form of bio-aerosols may be released into the environment which may have toxins or carcinogenic constituents.					
People at Risk	Staff and patient.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Processes are in place to ensure that a plume extractor is used during procedure.		X	<input type="checkbox"/>		
Administrative Controls:	The plume extractor maintenance and filter change is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	<input type="checkbox"/>	X	<input type="checkbox"/>		
PPE Controls:	Processes are in place to ensure that high filtration surgical masks are used in addition to laser plume evacuation.	<input type="checkbox"/>	X	<input type="checkbox"/>	When necessary	
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 6:	Are patients treated safely?	Response:				
Hazard:	Adverse reaction to laser treatment, inappropriate and unintended treatment.					
People at Risk	Patient.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	There is an emission light and/or audible alarm during laser fire.	✓				
	Power output is displayed.	✓				
	Processes are in place to ensure that tissue cooling device is checked prior to use.	✓				

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Administrative Controls:	Processes are in place to ensure that treatment parameters are signed off by the Medical Authorised User prior to procedure.	✓				Consultant use only.	
	Clinical Authorised Users have received device specific and treatment specific training.	✓					
Responsible person:	Laser Safety committee, LPA, LPS, and Authorised User.						
Question 7:	Are electrical hazards adequately controlled?	Response:					
Hazard:	Electrical supply.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	
Engineering Controls:	Laser system is enclosed.	✓					
Administrative Controls:	Processes are in place to ensure that electrical cables are verified prior to use for wear and damage.	✓					
	Laser service is restricted to qualified personnel.	✓					
Responsible person:	Laser Safety Committee, LPA, and LPS.						
Question 8:	Are trip hazards adequately controlled?	Response:					
Hazard:	Trip.						N/A
People at Risk	Staff.	Yes	No	N/A	Action / Comments	Assigned to	
Engineering Controls:	Electrical cables can be routed under the floor, or pendants used.	☐		✓			
Administrative Controls:	Processes are in place to ensure that cables are kept clear of access ways.	✓					
Responsible person:	Laser Safety Committee, LPA, and LPS.						
Question 9:	Are mechanical hazards adequately controlled?	Response:					
Hazard:	Laser articulated arm, lasers placed on trolleys.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	
Engineering Controls:	Articulated arm can be secured into laser casing when not in use.		☐	✓			
Administrative Controls:	Processes are in place to ensure that lasers are placed on appropriate trolleys or work surfaces when in use.		☐	✓			
	Articulated arm is secured by staff when not in use.		☐	✓			

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Responsible person:	Laser Safety Committee, LPA, and LPS.					
Question 10:	Are chemical hazards adequately controlled?	Response:				
Hazard:	Dye leak or spill.					
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Laser system is enclosed.	✓		<input type="checkbox"/>		
Administrative Controls:	Chemical spill kit readily accessible.	✓		<input type="checkbox"/>		
	Processes are in place to ensure that chemical spill SOP is followed.	✓		<input type="checkbox"/>		
PPE Controls:	Appropriate masks, gloves and aprons readily accessible as part of spill kit.	✓		<input type="checkbox"/>		
Responsible person:	Laser Safety Committee, LPA, and LPS.					

References: Legislation, Standards and Guidelines for Laser Safety:

- [1] Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation), SI 176 (2010).
- [2] IEC 60601-2-22 ed3.0, 2007: Medical electrical equipment - Particular requirements for safety of diagnostic and therapeutic laser equipment.
- [3] IEC TR 60825-8:2006 Safety of Laser Products - Part 8: Guidelines for the Safe Use of Laser Beams on Humans.
- [4] IEC TR 60825-14 Safety of Laser Products - Part 14: A User's Guide.
- [5] NSAI EN 207 Personal eye protection: filters and eye protectors against laser radiation (laser eye protectors).
- [6] MHRA Guidance on the safe use of lasers, intense light source systems and LEDs, in medical, surgical, and aesthetic practices, 2008.
- [7] A Non-Binding Guide to the Artificial Optical Radiation Directive 2006/25/EC, Radiation Protection Division, Health Protection Agency, Contract VC/2007/0581.

1. KTP Laser

Clinical Expert – ENT Consultant - Mr. John Russell

**Laser Protection Supervisors
CNMII Theatre - Ms. Anne Fitzpatrick**

Technical Specification	
Model	Aura
Location	Theatre
Class	IV
Type	KTP
Wavelength	532nm (Visible)
Mode of operation	Pulsed
Power/Energy	Up to 193W
Aiming beam	Red 5mW Diode Laser III b

Hazard


- The organ at most to damage from the main KTP laser beam is the eye. Light at this wavelength is focused on the retina. This may cause an accidental retinal burn. Accidental irradiation of tissue other than the target tissue will result in a burn or vaporization of tissue.
- The laser has the potential to ignite fires. If alcohol wipes are used on skin/hand pieces for cleaning or disinfection, any alcohol residue left should be wiped away and allowed dry before firing.

Specific Precautions


- Observe all general precautions for the safe use of lasers as outlined in the local rules.
- Laser is stored in alcove across from Theatre 3.
- Use only the eye protection specified for this laser. Laser goggles are colour coded – orange. They are stored in Prep Room 3/4. The key is stored in controlled drug press in Anaesthetic Room 3.
- When used with a microscope or an optical endoscope note that the user of the instrument is at risk from laser reflections carried back to the observer's eyepiece. A microscope or optical endoscope can only be used, where appropriate filters have been fitted to the endoscope or where the operator wears appropriate eyewear. This particular risk does not exist with a video scope.
- Filter is stored in controlled drug press in Anaesthetic Room 3.
- When used with an endoscope firing should only take place with the tip within the patient. However, the risk of a fibre breakage or accidental firing of the laser outside the patient still exists, and personnel in the room must continue to wear protective eyewear.
- In normal clinical use no additional skin protection necessary for staff.

Procedural Precautions

- The fibre must be stripped using the endostar laser fibre stripper.
- You must check that the laser fibre stripper is the correct size.
- Check aiming beam after stripping fibre.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

- The fibre should be checked for kinks and breaks before use. Any leakage of the aiming beam from the length of the fibre indicates a break and the fibre must not be used.
- Excessive bending of the fibre should be avoided.
- When the fibre is delivered via an endoscope the following precautions should be observed:
 - The laser must never be fired while the distal tip is in the endoscope.
 - The fibre must never be fired where the target field is not visible.
 - The laser should only be fired when the distal tip is visible and extending ≥ 7 mm from the end of the scope.
- The patient's eyes are covered and the face and hair are covered in moistened gamgee.
- The scrub nurse must have 2 x 20ml syringes filled with saline on the trolley.


Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Laser risk assessment for the Laser scope Aura KTP Laser located in Theatre, OLCHC

Title of Document: Laser risk assessment for the Laser scope Aura KTP Laser located in Theatre, OLCHC.	Issue date of Risk Assessment: 27/11/2014
Activity/Facility Assessed: ENT	Laser control area: Theatre 3
Laser Protection Supervisor: Anne Fitzpatrick, CNM.	Laser Protection Advisor: Dr. J. Galligan
Assessed by: Anne Fitzpatrick / Dr. J. Galligan	Review date: 27/11/2015


Background Information

Laser Classification: IV	Model: Aura	Manufacturer: Laser scope
Laser Type: KTP	Wavelength: 532 nm	Beam Delivery Device: Fibre
Mode of operation: CW / Pulsed	Power/Energy Range: CW: 10 Watts max.; Pulsed: 160 Watts (peak power).	Pulse duration for pulsed lasers: 1 to 30ms
NOHD: 37 meters		
Aiming Beam: 636 nm +/- 10mn, 6mWatts.		
Required safety eyewear protection level: 532 nm D LB3. Have DR 532 nm LB6, 520-532 OD>4.5. Manufacturer recommends OD > 4 at 532nm		
Description of Application: ENT		
Description of laser environment (incl. access, windows, surfaces, warning lights, and signs): Operating theatre. All entrances are locked with switch on control panel, which acts as an interlock, the warning lights are also activated from a similar switch on the same control panel. Blinds on all windows.		
Persons at Risk: Staff, patient, contracted service personnel, and public.		
Cycle of Interest: All forms of operation including but not limited to approve clinical procedures, all testing, and maintenance.		
Laser is CE marked meets all specifications and has been signed off by LPA: No, pre LPA appointment, laser has been assessed as being appropriate.		


Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

List of Corrective Actions


Hazard	Action required	Completed			Completed by		
	Laser Safety SOP to be reviewed.	Nov-14					
	Recommend that laser key holders should have copy of Authorised Users list.	Nov-14					
	Anaesthesia laser safety SOP.						
	No by-pass for interlock.						
	Review plume risk.	Nov-14					
	Check filter change of plume extractor.						
Question 1:	Is this laser appropriate and safe for use in its intended clinical applications and designated laser control area?	Response:					
Hazard:	Environment and People.						
People at Risk:	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
	Laser device cannot be operated without key.	✓					
	The laser controlled area (LCA) has been designated with physical access restrictions.	✓					
	Warning lights are located above all accesses to the laser controlled area.	✓					
	Laser has electrical, and laser aperture warning labels.	✓					
Administrative Controls:	Laser Safety Committee, Laser Protection Advisor, Laser Protection Supervisor, and Clinical Expert have been appointed.	✓					
	Laser Safety Local Rules (SOP), have been drawn for the laser and this laser controlled area.	✓					
	Processes are in place to restrict access to the laser controlled area.	✓					
	Processes are in place to ensure that warning signs are posted on all entrances to laser control area.	✓					
	Processes are in place to ensure that usage is restricted to Authorised Users and to the laser controlled area.	✓					
	Authorised users and assisting staff have received laser safety training, and are familiar with the appropriate policies and procedures.	✓			Regular in-service performed.		

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


	Laser maintenance is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	✓					
	Maintenance is restricted to qualified personnel.	✓					
	Processes are in place to ensure that the laser is routinely verified for correct performance and safety (Performance Verification).	✓					
	No more than one laser is switched on in the laser controlled area.	✓					
	Emergency procedures are in place.	✓					
	Incident reporting and investigating protocols are in place.	✓					
Responsible person:	Laser Safety Committee, Laser Protection Advisor (LPA), Laser Protection Supervisor (LPS), and Clinical Expert.						
Question 2:	Are person's present in the nominal ocular hazard area (NOHA) protected against unintended laser exposure above the maximum ELV?	Response:					
Hazard:	Optical.						
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Windows are completely laser tight.	✓					
	Protective filter/shutter is provided with viewing optics are in good order.	<input type="checkbox"/>		✓			
Administrative Controls:	A process is in place to verify that the beam is on target prior to firing.	✓					
	All accessories and devices used during the procedure have been approved for use with lasers as being non-reflective.	✓					
	All reflective surfaces have been removed or covered.	✓					
	Patient's eyes, particularly those of anaesthetised patients are protected.	✓					
	Staff have been trained in the use and maintenance of protective eyewear and shutters.	✓					
PPE Controls:	Patient and staff laser protection eyewear provided.	✓					
	Protective eyewear is appropriate for this laser and in good order.	✓			7		
	There are adequate numbers of eyewear, and are easily identifiable.	✓			Included in in-service training.		

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 3:	Are person's present in the laser control area protected against unintended laser exposure to the skin above the ELV, and fire?	Response:					
Hazard:	Fire, explosions, and tissue burns.						
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Administrative Controls:	All accessories and devices used during the procedure have been approved for use with lasers.	✓					
	Cleaning and disinfecting agents are non-flammable.	☐		✓			
	Processes are in place to ensure that swabs, surgical drapes, and other flammable material located near the field of operation are kept moist with saline or sterile water.	✓		☐			
	Processes are in place to ensure that laser safe endotracheal tubes are used.	✓		☐			
	The Anaesthetic Laser Safety SOP is followed.	✓		☐	SOP to be developed		
	Safety processes are in place for the use of lasers with channelled devices such as endoscopes and canellas.	☐		✓			
	There is an emergency plan in place in case of fire.	✓			No by-pass for interlock, with H&S Officer.	H&S Officer	
	Firefighting equipment is available in laser control area for all cycles.	✓		☐			
PPE Controls:	Gloves are worn to avoid skin exposure from the reflective beam during fibre calibration (UV).	☐		✓			
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 4:	Are processes in place to avoid beam misfires?	Response:					
Hazard:	Unintended absorption of laser beam.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Beam is activated by a covered footswitch or hand switch.	✓					
	Beam cannot be activated without a delivery device.	✓					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Administrative Controls:	Processes are in place to ensure that laser, fibre, and optics are checked for damage prior to use.	✓					
	Processes are in place to ensure that laser is placed in standby mode when not in use.	✓		<input type="checkbox"/>			
	Processes are in place to ensure that no more than one device footswitch is available to the authorised user at a time.	✓		<input type="checkbox"/>			
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 5:	Are patients and staff adequately protected from potential laser plume hazards?	Response:					
Hazard:	Small particles in the form of bio-aerosols may be released into the environment which may have toxins or carcinogenic constituents.						
People at Risk	Staff and patient.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Processes are in place to ensure that a plume extractor is used during procedure.	✓		<input type="checkbox"/>	Plume extractor in cases where there is plume.		
Administrative Controls:	The plume extractor maintenance and filter change is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	<input type="checkbox"/>		<input type="checkbox"/>	Verify that filters have are routinely replaced.	Clin Eng.	
PPE Controls:	Processes are in place to ensure that high filtration surgical masks are used in addition to laser plume evacuation.	✓		<input type="checkbox"/>			
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 6:	Are patients treated safely?	Response:					
Hazard:	Adverse reaction to laser treatment, inappropriate and unintended treatment.						
People at Risk	Patient.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	There is an emission light and/or audible alarm during laser fire.	✓					
	Power output is displayed.	✓					
	Processes are in place to ensure that tissue cooling device is checked prior to use.	<input type="checkbox"/>		✓			
Administrative Controls:	Processes are in place to ensure that treatment parameters are signed off by the Medical Authorised User prior to procedure.	✓			Consultant use only.		
	Clinical Authorised Users have received device specific and treatment specific training.	✓					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Responsible person:	Laser Safety committee, LPA, LPS, and Authorised User.						
Question 7:	Are electrical hazards adequately controlled?	Response:					
Hazard:	Electrical supply.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Laser system is enclosed.	✓					
Administrative Controls:	Processes are in place to ensure that electrical cables are verified prior to use for wear and damage.	✓					
	Laser service is restricted to qualified personnel.	✓					
Responsible person:	Laser Safety Committee, LPA, and LPS.						
Question 8:	Are trip hazards adequately controlled?	Response:					
Hazard:	Trip.					N/A	
People at Risk	Staff.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Electrical cables can be routed under the floor, or pendants used.	✓		☐			
Administrative Controls:	Processes are in place to ensure that cables are kept clear of access ways.	✓					
Responsible person:	Laser Safety Committee, LPA, and LPS.						
Question 9:	Are mechanical hazards adequately controlled?	Response:					
Hazard:	Laser articulated arm, lasers placed on trolleys.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Articulated arm can be secured into laser casing when not in use.		☐	✓			
Administrative Controls:	Processes are in place to ensure that lasers are placed on appropriate trolleys or work surfaces when in use.	✓	☐	☐	Own trolley as supplied by agent.		
	Articulated arm is secured by staff when not in use.		☐	✓			
Responsible person:	Laser Safety Committee, LPA, and LPS.						

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Question 10:	Are chemical hazards adequately controlled?	Response:					
Hazard:	Dye leak or spill.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Laser system is enclosed.	<input type="checkbox"/>		✓			
Administrative Controls:	Chemical spill kit readily accessible.	<input type="checkbox"/>		✓			
	Processes are in place to ensure that chemical spill SOP is followed.			✓			
PPE Controls:	Appropriate masks, gloves and aprons readily accessible as part of spill kit.			✓			
Responsible person:	Laser Safety Committee, LPA, and LPS.						

2. SHARPLAN CO2 LASER

Clinical Expert – ENT Consultant - Mr. John Russell

ENT Consultant - Mr. Stephen Hone

(Registrar under supervision)

Laser Protection Supervisors

CNMII Theatre - Ms. Anne Fitzpatrick

Technical Specification	
Model	40c
Location	Theatre
Class	IV
Type	Carbon Dioxide
Wavelength	10600nm (infrared)
Mode of operation	CW/Pulsed
Power/Energy	Up to 40w
Aiming beam	Red 3mW helium neon

Hazard

The primary hazards associated with the CO2 laser are fire and eye damage. The lens and cornea are at risk at this wavelength. The CO2 laser has a very strong fire starting potential. Flammable material accidentally struck by the beam may ignite. This risk is heightened in the presence of increased oxygen levels. Skin burns are also possible.

Specific Precautions


- Observe all general precautions for the safe use of lasers as outlined in the local rules.
- Laser is stored in alcove across from Theatre 3.
- Use only the eye precautions specified for this laser. Goggles for CO2 laser are colour coded purple and stored in Prep Room 3/4.
- Patient's eyes must also be protected. Face and hair are covered with moistened gamgee,
- Key in controlled drug press in Anaesthetic Room 3. Laser attachment to be put on microscope.
- Be alert to the possibility of ignition, particularly where elevated oxygen levels may be present in the surgical field.
- Keep a bowl of saline ready to douse incipient fires and 2 x 20mls syringes of saline on trolley.
- Ensure a fire extinguisher is available.
- Never operate in the presence of flammable anaesthetics or solvents. Any alcohol based prepping and disinfection agents should be allowed to dry thoroughly before laser activation.
- **BE ALERT TO THE POSSIBILITY OF ET TUBE FIRES in CO2 airway surgery.** Severe injury and fatalities have been reported through the ignition of ET tubes. Always use the special laser proof ET tubes provided in CO2 airway/oral surgery. Note that even laser proof tubes can catch fire if struck by laser. ET tube cuffs should be filled with saline. Good practice in anaesthesia for laser surgery must be followed:
 - FiO2 levels to be kept to lowest concentration to maintain acceptable arterial O2 saturation
 - Limit power density to lowest acceptable power density and pulse duration.
 - Do not use nitrous oxide.
 - Surgeons should also consider using non ET tube techniques such as venture, especially for posterior glottis laryngeal lesions, where the risk of striking the ET tube with laser beam is particularly high.

Laser Risk Assessment for the Sharplan 40C CO2 located in Theatre (a/n 1711), OLCHC


Title of Document: Laser risk assessment for the Sharplan 40C CO2 located in Theatre (a/n 1711), OLCHC.	Issue date of Risk Assessment: 27/11/2014
Activity/Facility Assessed: ENT	Laser control area: Theatre 3
Laser Protection Supervisor: Anne Fitzpatrick, CNM.	Laser Protection Advisor: Dr. J. Galligan
Assessed by: Anne Fitzpatrick / Dr. Josette Galligan	Review date: 27/11/2015

Background Information		
Laser Classification: IV	Model: 40C	Manufacturer: Sharplan
Laser Type: CO2	Wavelength: 10,600nm	Beam Delivery Device: Articulated arm and micromanipulator
Mode of operation: CW & pulsed	Power/Energy Range: 40 Watts max.	Pulse duration for pulsed lasers: 0.01 to 1 sec.
NOHD: 90 meters.		
Aiming Beam: HeNe 3mWatts.		
Required safety eyewear protection level: D 10600 LB4 I 10600 LB3. Have OD 5 + at 10,600 nm.		
Description of Application: ENT		
Description of laser environment (incl. access, windows, surfaces, warning lights, and signs): Operating theatre. All entrances are locked with switch on control panel, which acts as an interlock, the warning lights are also activated from a similar switch on the same control panel. Blinds on all windows.		
Persons at Risk: Staff, patient, contracted service personnel, and public.		
Cycle of Interest: All forms of operation including but not limited to approve clinical procedures, all testing, and maintenance.		
Laser is CE marked meets all specifications and has been signed off by LPA: No, pre LPA appointment, laser has been assessed as being appropriate.		


List of Corrective Actions			
Hazard	Action required	Comple ted	Completed by
	Laser Safety SOP to be reviewed.	Nov-14	
	Recommend that laser key holders should have copy of Authorised Users list.	Nov-14	
	Recommend that goggles be replaced with those with IEC rating.		
	Anaesthesia laser safety SOP.		
	No by-pass for interlock.		

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


		Review plume risk with micromanipulator use.	Nov-14				
		Are Super Pulse and Pulsar modes used - No	Nov-14				
		Check filter change of plume extractor.					
Question 1:	Is this laser appropriate and safe for use in its intended clinical applications and designated laser control area?	Response:					
Hazard:	Environment and People.						
People at Risk:	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
	Laser device cannot be operated without key.	✓					
	The laser controlled area (LCA) has been designated with physical access restrictions.	✓					
	Warning lights are located above all accesses to the laser controlled area.	✓					
	Laser has electrical, and laser aperture warning labels.	✓					
Administrative Controls:	Laser Safety Committee, Laser Protection Advisor, Laser Protection Supervisor, and Clinical Expert have been appointed.	✓					
	Laser Safety Local Rules (SOP), have been drawn for the laser and this laser controlled area.	✓					
	Processes are in place to restrict access to the laser controlled area.	✓					
	Processes are in place to ensure that warning signs are posted on all entrances to laser control area.	✓					
	Processes are in place to ensure that usage is restricted to Authorised Users and to the laser controlled area.	✓					
	Authorised users and assisting staff have received laser safety training, and are familiar with the appropriate policies and procedures.	✓				Regular in-service performed.	
	Laser maintenance is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	✓					
	Maintenance is restricted to qualified personnel.	✓					
	Processes are in place to ensure that the laser is routinely verified for correct performance and safety (Performance Verification).	✓					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


	No more than one laser is switched on in the laser controlled area.	✓					
	Emergency procedures are in place.	✓					
	Incident reporting and investigating protocols are in place.	✓					
Responsible person:	Laser Safety Committee, Laser Protection Advisor (LPA), Laser Protection Supervisor (LPS), and Clinical Expert.						
Question 2:	Are person's present in the nominal ocular hazard area (NOHA) protected against unintended laser exposure above the maximum ELV?	Response:					
Hazard:	Optical.						
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Windows are completely laser tight.	✓					
	Protective filter/shutter is provided with viewing optics are in good order.	☐		✓			
Administrative Controls:	A process is in place to verify that the beam is on target prior to firing.	✓					
	All accessories and devices used during the procedure have been approved for use with lasers as being non-reflective.	✓					
	All reflective surfaces have been removed or covered.	✓					
	Patient's eyes, particularly those of anaesthetised patients are protected.	✓					
	Staff have been trained in the use and maintenance of protective eyewear and shutters.	✓					
PPE Controls:	Patient and staff laser protection eyewear provided.	✓					
	Protective eyewear is appropriate for this laser and in good order.	✓			Recommend replace with IEC rating	LPS	
	There are adequate numbers of eyewear, and are easily identifiable.	✓			Included in in-service training.		
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 3:	Are person's present in the laser control area protected against unintended laser exposure to the skin above the ELV, and fire?	Response:					
Hazard:	Fire, explosions, and tissue burns.						
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


Administrative Controls:	All accessories and devices used during the procedure have been approved for use with lasers.	✓					
	Cleaning and disinfecting agents are non-flammable.	✓			<input type="checkbox"/>		
	Processes are in place to ensure that swabs, surgical drapes, and other flammable material located near the field of operation are kept moist with saline or sterile water.	✓				<input type="checkbox"/>	
	Processes are in place to ensure that laser safe endotracheal tubes are used.	✓				<input type="checkbox"/>	
	The Anaesthetic Laser Safety SOP is followed.	✓				<input type="checkbox"/>	SOP in development AU/LPA
	Safety processes are in place for the use of lasers with channelled devices such as endoscopes and canellas.	✓				<input type="checkbox"/>	
	There is an emergency plan in place in case of fire.	✓					No by-pass for interlock. FSO/LPA
	Firefighting equipment is available in laser control area for all cycles.	✓				<input type="checkbox"/>	
PPE Controls:	Gloves are worn to avoid skin exposure from the reflective beam during fibre calibration (UV).	<input type="checkbox"/>				✓	
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 4:	Are processes in place to avoid beam misfires?	Response:					
Hazard:	Unintended absorption of laser beam.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Beam is activated by a covered footswitch or hand switch.	✓					
	Beam cannot be activated without a delivery device.	✓					
Administrative Controls:	Processes are in place to ensure that laser, fibre, and optics are checked for damage prior to use.	✓					
	Processes are in place to ensure that laser is placed in standby mode when not in use.	✓				<input type="checkbox"/>	
	Processes are in place to ensure that no more than one device footswitch is available to the authorised user at a time.	✓				<input type="checkbox"/>	
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 5:	Are patients and staff adequately protected from potential laser plume hazards?	Response:					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Hazard:	Small particles in the form of bio-aerosols may be released into the environment which may have toxins or carcinogenic constituents.						
People at Risk	Staff and patient.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Processes are in place to ensure that a plume extractor is used during procedure.		X	<input type="checkbox"/>	Used when required.		
Administrative Controls:	The plume extractor maintenance and filter change is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	<input type="checkbox"/>		<input type="checkbox"/>	Verify that filters have are routinely replaced.	LPS	
PPE Controls:	Processes are in place to ensure that high filtration surgical masks are used in addition to laser plume evacuation.	✓		<input type="checkbox"/>			
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 6:	Are patients treated safely?	Response:					
Hazard:	Adverse reaction to laser treatment, inappropriate and unintended treatment.						
People at Risk	Patient.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	There is an emission light and/or audible alarm during laser fire.	✓					
	Power output is displayed.	✓					
	Processes are in place to ensure that tissue cooling device is checked prior to use.	<input type="checkbox"/>		✓			
Administrative Controls:	Processes are in place to ensure that treatment parameters are signed off by the Medical Authorised User prior to procedure.	✓			Consultant use only.		
	Clinical Authorised Users have received device specific and treatment specific training.	✓					
Responsible person:	Laser Safety committee, LPA, LPS, and Authorised User.						
Question 7:	Are electrical hazards adequately controlled?	Response:					
Hazard:	Electrical supply.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Laser system is enclosed.	✓					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Administrative Controls:	Processes are in place to ensure that electrical cables are verified prior to use for wear and damage.	✓					
	Laser service is restricted to qualified personnel.	✓					
Responsible person:	Laser Safety Committee, LPA, and LPS.						
Question 8:	Are trip hazards adequately controlled?	Response:					
Hazard:	Trip.					N/A	
People at Risk	Staff.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Electrical cables can be routed under the floor, or pendants used.	✓		<input type="checkbox"/>			
Administrative Controls:	Processes are in place to ensure that cables are kept clear of access ways.	✓					
Responsible person:	Laser Safety Committee, LPA, and LPS.						
Question 9:	Are mechanical hazards adequately controlled?	Response:					
Hazard:	Laser articulated arm, lasers placed on trolleys.					Assigned to	Completion date
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Articulated arm can be secured into laser casing when not in use.	✓	<input type="checkbox"/>	<input type="checkbox"/>			
Administrative Controls:	Processes are in place to ensure that lasers are placed on appropriate trolleys or work surfaces when in use.		<input type="checkbox"/>	✓			
	Articulated arm is secured by staff when not in use.	✓	<input type="checkbox"/>	<input type="checkbox"/>			
Responsible person:	Laser Safety Committee, LPA, and LPS.						
Question 10:	Are chemical hazards adequately controlled?	Response:					
Hazard:	Dye leak or spill.					Assigned to	Completion date
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Laser system is enclosed.	<input type="checkbox"/>		✓			
Administrative Controls:	Chemical spill kit readily accessible.	<input type="checkbox"/>		✓			
	Processes are in place to ensure that chemical spill SOP is followed.			✓			

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

PPE Controls:	Appropriate masks, gloves and aprons readily accessible as part of spill kit.			✓		
Responsible person:	Laser Safety Committee, LPA, and LPS.					

3. ALEXANDRITE LASER

Clinical Expert – Consultant Dermatologist - Dr. Rosemarie Watson

CNSp Laser - Ms. Edette O'Dea

Registrar under supervision

Laser Protection Supervisors

CNSp Laser - Ms. Edette O'Dea

Technical Specification	
Model:	Apogee 5500
Manufacturer:	Cynosure
Location:	Laser store room 2 nd floor Medical Tower
Class:	IV
Type:	Alexandrite
Wavelength:	755 nm
Mode of operation:	Long Pulsed
Power/Energy:	Max 70J
Aiming beam:	630-690nm continuous mode<5mE Class 3A

Hazard

Optical Hazard

The laser emits an intense energy beam of invisible laser light radiation that can cause serious eye damage with direct or even indirect optical contact.

WARNING: Always wear the protective eyewear supplied with the laser system. Failure to wear the appropriate protective eyewear can result in serious eye injury.

Electrical Hazard

The laser system uses potentially lethal electrical components. Do not open the protective panels unless you are trained and authorized to do so.

Hot Water Hazard


The laser uses a hot water system to maintain the laser medium at the proper operating temperature. The water is very hot and could cause scalding. Do not perform any maintenance on the water system while hot. Always let the system cool down before changing the deionising filter or adding deionised or distilled water

Laser-Induced Fire Hazard

When the laser beam contacts an exterior surface, that surface can absorb the laser energy. This raises the surface temperature, whether the surface is skin, hair, clothes or any flammable substance.

Specific Precautions

- Observe all general precautions for the safe use of lasers as outlined in the laser safety Policy.
- Staff and patients must only use the eye protection specified for this laser. Special care should be

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

taken when treating the skin near the eyes.

- Full service is carried out 6 monthly.
- All staff must undertake mandatory laser safety course prior to working with lasers. Be alert to the possibility of ignition, particularly where elevated oxygen levels may be present in the surgical field. When treating near the hairline, eyebrows or any other facial or body hair, keep the hair moist with water or saline.
- Only qualified personnel should open the laser covers. Even with the laser switched off removing the covers exposes personnel to lethal voltages.
- Ensure Fire extinguisher is available in the room.
- Use Smart cool device in conjunction with the Alexandrite: to reduce pain and thermal damage to skin tissue. The unit blows very low-temperature air, at an adjustable rate, onto the part of the patient's body requiring therapy. The analgesia caused by the cold air makes treatment significantly more pleasant for the patient.
- Prior to the therapy the patient has to be instructed about the effects of the use of the skin cooling system. If the patient is feeling increasing discomfort or a sensation of excessive heat or cold he has to inform the appropriate clinical staff.

Plume extractor to be used at all times

Cleaning

- Spacers are cleaned between each case with Azo wipe (bacterial wipes with 70% alcohol which dries immediately) and cleaned with Brial solution (a pre measured dose of detergent in a litre of water) at the end of session.
- Glass windows are cleaned and replaced, if any sign of damage is noted.
- Clean the exterior of the machine after each session with Brial solution.

Laser Risk Assessment for Cynosure Apogee 5500 Alexandrite Laser (3241)


Title of Document: Laser risk assessment for the Cynosure Apogee 5500 Alexandrite Laser (3241) located in Dermatology Unit, OLCHC.	Issue date of Risk Assessment: 27/11/2014
Activity/Facility Assessed: Dermatology Unit, OLCHC.	Laser control area: SF12, Dermatology Treatment Room.
Laser Protection Supervisor: Edette O'Dea.	Laser Protection Advisor: Dr. Josette Galligan.
Assessed by: Dr. J. Galligan / Edette O'Dea.	Review date: 27/11/2015.

BACKGROUND INFORMATION


Laser Classification: IV	Model: Apogee 5500	Manufacturer: Cynosure
Laser Type: Alexandrite	Wavelength: 755nm	Beam Delivery Device: Fibre and hand piece
Mode of operation: Pulsed	Power/Energy Range: max. 70J	Pulse duration for pulsed lasers: 0.4 to 300ms
NOHD: 100 meter (from manufacturer).		
Aiming Beam: 630 nm - 690 nm Continuous mode < 5mW Class 3A.		
Required safety eyewear protection level: 755nm, DLB4. Have 720-1075 DM L5, 750-1064 IR L7. Manufacturer recommends OD > 5.9.		
Description of Application: Hair removal, blue lesions.		
Description of laser environment (<i>incl. access, windows, surfaces, warning lights, and signs</i>): Clinical room adapted for laser use. One access door, locked from inside, controlled key available for emergency access. One window with blind.		
Persons at Risk: Staff, patient, contracted service personnel, and public (parents).		
Cycle of Interest: All forms of operation including but not limited to approved clinical procedures, all testing, and maintenance.		
Laser is CE marked meets all specifications and has been signed off by LPA: Yes		LPA: Dr. Gerry Boyle.

LIST OF CORRECTIVE ACTIONS


Hazard	Action required	Date for action	Completed by
	Review SOP	Nov-14	EO'D
	Review attachment options for plume extractor wand, use wand instead of funnel	Nov-14	JG & EO'D
Question 1:	Is this laser appropriate and safe for use in its intended clinical applications and designated laser control area?		
Hazard:	Environment and People.		
People at Risk:	Staff, patient, contracted service personnel, and public.		
	Yes	No	N/A
	Action / Comments		Assigned to

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


	Laser device cannot be operated without key.	✓				
	The laser controlled area (LCA) has been designated with physical access restrictions.	✓				
	Warning lights are located above all accesses to the laser controlled area.	✓				
	Laser has electrical, and laser aperture warning labels.	✓				
Administrative Controls:	Laser Safety Committee, Laser Protection Advisor, Laser Protection Supervisor, and Clinical Expert have been appointed.	✓				
	Laser Safety Local Rules (SOP), has been drawn for the laser and this laser controlled area.	✓				
	Processes are in place to restrict access to the laser controlled area.	✓				
	Processes are in place to ensure that warning signs are posted on all entrances to laser control area.	✓				
	Processes are in place to ensure that usage is restricted to Authorised Users and to the laser controlled area.	✓				
	Authorised users and assisting staff have received laser safety training, and are familiar with the appropriate policies and procedures.	✓				
	Laser maintenance is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	✓				
	Maintenance is restricted to qualified personnel.	✓				
	Processes are in place to ensure that the laser is routinely verified for correct performance and safety (Performance Verification).	✓				
	No more than one laser is switched on in the laser controlled area.	✓				
	Emergency procedures are in place.	✓				
	Incident reporting and investigating protocols are in place.	✓				
Responsible person:	Laser Safety Committee, Laser Protection Advisor (LPA), Laser Protection Supervisor (LPS), and Clinical Expert.					
Question 2:	Are person's present in the nominal ocular hazard area (NOHA) protected against unintended laser exposure above the maximum ELV?	Response:				
Hazard:	Optical.					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Windows are completely laser tight.	✓				
	Protective filter/shutter is provided with viewing optics are in good order.			✓		
Administrative Controls:	A process is in place to verify that the beam is on target prior to firing.	<input type="checkbox"/>		✓		
	All accessories and devices used during the procedure have been approved for use with lasers as being non-reflective.			✓		
	All reflective surfaces have been removed or covered.	✓				
	Patient's eyes, particularly those of anaesthetised patients are protected.	✓				
	Staff have been trained in the use and maintenance of protective eyewear and shutters.	✓				
PPE Controls:	Patient and staff laser protection eyewear provided.	✓				
	Protective eyewear is appropriate for this laser and in good order.	✓				
	There are adequate numbers of eyewear, and are easily identifiable.	✓			4	
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.	Response:				
Question 3:	Are person's present in the laser control area protected against unintended laser exposure to the skin above the ELV, and fire?					
Hazard:	Fire, explosions, and tissue burns.					
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to
Administrative Controls:	All accessories and devices used during the procedure have been approved for use with lasers.	<input type="checkbox"/>		✓		
	Cleaning and disinfecting agents are non-flammable.	✓		<input type="checkbox"/>		
	Processes are in place to ensure that swabs, surgical drapes, and other flammable material located near the field of operation are kept moist with saline or sterile water.	<input type="checkbox"/>		✓		
	Processes are in place to ensure that laser safe endotracheal tubes are used.	<input type="checkbox"/>		✓		
	The Anaesthetic Laser Safety SOP is followed.	<input type="checkbox"/>		✓		

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

	Safety processes are in place for the use of lasers with channelled devices such as endoscopes and canellas.			✓		
	There is an emergency plan in place in case of fire.	✓				
	Firefighting equipment is available in laser control area for all cycles.	✓		☐		
PPE Controls:	Gloves are worn to avoid skin exposure from the reflective beam during fibre calibration (UV).	☐		✓		
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 4:	Are processes in place to avoid beam misfires?	Response:				
Hazard:	Unintended absorption of laser beam.					
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Beam is activated by a covered footswitch or hand switch.	✓				
	Beam cannot be activated without a delivery device.	✓				
Administrative Controls:	Processes are in place to ensure that laser, fibre, and optics are checked for damage prior to use.	✓				
	Processes are in place to ensure that laser is placed in standby mode when not in use.	✓		☐		
	Processes are in place to ensure that no more than one device footswitch is available to the authorised user at a time.	☐		✓		
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 5:	Are patients and staff adequately protected from potential laser plume hazards?	Response:				
Hazard:	Small particles in the form of bio-aerosols may be released into the environment which may have toxins or carcinogenic constituents.					
People at Risk	Staff and patient.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Processes are in place to ensure that a plume extractor is used during procedure.	✓		☐		
Administrative Controls:	The plume extractor maintenance and filter change is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	✓		☐	Use wand instead of funnel	
PPE Controls:	Processes are in place to ensure that high filtration surgical masks are used in addition to laser plume evacuation.	✓		☐		

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 6:	Are patients treated safely?	Response:				
Hazard:	Adverse reaction to laser treatment, inappropriate and unintended treatment.					
People at Risk	Patient.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	There is an emission light and/or audible alarm during laser fire.	✓				
	Power output is displayed.	✓				
	Processes are in place to ensure that tissue cooling device is checked prior to use.	✓				
Administrative Controls:	Processes are in place to ensure that treatment parameters are signed off by the Medical Authorised User prior to procedure.	✓				
	Clinical Authorised Users have received device specific and treatment specific training.	✓				
Responsible person:	Laser Safety committee, LPA, LPS, and Authorised User.					
Question 7:	Are electrical hazards adequately controlled?	Response:				
Hazard:	Electrical supply.					
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Laser system is enclosed.	✓				
Administrative Controls:	Processes are in place to ensure that electrical cables are verified prior to use for wear and damage.	✓				
	Laser service is restricted to qualified personnel.	✓				
Responsible person:	Laser Safety Committee, LPA, and LPS.					
Question 8:	Are trip hazards adequately controlled?	Response:				
Hazard:	Trip.					N/A
People at Risk	Staff.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Electrical cables can be routed under the floor, or pendants used.	<input type="checkbox"/>	X	<input type="checkbox"/>		
Administrative Controls:	Processes are in place to ensure that cables are kept clear of access ways.	✓				

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Responsible person:	Laser Safety Committee, LPA, and LPS.					
Question 9:	Are mechanical hazards adequately controlled?	Response:				
Hazard:	Laser articulated arm, lasers placed on trolleys.					
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Articulated arm can be secured into laser casing when not in use.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
Administrative Controls:	Processes are in place to ensure that lasers are placed on appropriate trolleys or work surfaces when in use.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
	Articulated arm is secured by staff when not in use.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
Responsible person:	Laser Safety Committee, LPA, and LPS.					
Question 10:	Are chemical hazards adequately controlled?	Response:				
Hazard:	Dye leak or spill.					
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Laser system is enclosed.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
Administrative Controls:	Chemical spill kit readily accessible.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	Processes are in place to ensure that chemical spill SOP is followed.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
PPE Controls:	Appropriate masks, gloves and aprons readily accessible as part of spill kit.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
Responsible person:	Laser Safety Committee, LPA, and LPS.					

References: Legislation, Standards and Guidelines for Laser Safety:

[1] Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation), SI 176 (2010).

[2] IEC 60601-2-22 ed3.0, 2007: Medical electrical equipment - Particular requirements for safety of diagnostic and therapeutic laser equipment.

[3] IEC TR 60825-8:2006 Safety of Laser Products - Part 8: Guidelines for the Safe Use of Laser Beams on Humans.

[4] IEC TR 60825-14 Safety of Laser Products - Part 14: A User's Guide.

4. KEELER DIODE LASER / IRIDEX OCULIGHT IPX8

Clinical Expert - Consultant Ophthalmologist - Dr. Donal Brosnahan

Consultant Ophthalmologist - Dr. Katherine McCeery

**Laser Protection Supervisors
CNMII Theatre - Ms. Anne Fitzpatrick**

Table Specification	
Model	Multilase
Location	Theatre
Class	IV
Type	Diode
Wavelength	780-840nm (near infrared)
Mode of operation	CW/Pulsed up to 5Hz
Power/Energy	Up to 1.5W
Aiming beam	Red 1mW Diode Laser

Hazard

The organ at most risk to damage from the main dryer laser beam is the eye. Exposure to the direct beam or beam reflections can cause severe burns to the retina. A single pulse of the laser is sufficient to cause this damage. The beam must never be directed through windows or open doors. If alcohol wipes are used on skin/hand pieces for cleaning or disinfection, any alcohol residue left should be wiped away and allowed dry before firing.

Specific Precautions

- Observe all general precautions for the safe use of lasers as outlined in the local rules.
- Use only the eye protection specified for this laser. Laser goggles are stored with the laser in the Theatre Equipment Room. Key is stored in controlled drug press in Anaesthetic Room 3.
- Patient's untreated eye must also be protected.

Laser Risk Assessment for the Keeler Diode Laser / Iridex Oculight IPX8 located in Theatre 3, OCLHC

Title of Document: Laser Risk Assessment for the Iridex Oculight IPX8 located in theatre 3, OLOLHC.	Issue date of Risk Assessment: 27/11/2014
Activity/Facility Assessed: Theatre, ophthalmology.	Laser control area: Theatre 3, OLCHC
Laser Protection Supervisor: Anne Fitzpatrick, CNM.	Laser Protection Advisor: Dr. J. Galligan
Assessed by: Anne Fitzpatrick / Dr. J. Galligan	Review date: 27/11/2015


Background Information

Laser Classification: IV	Model: Oculight SLx with Tri-Mode	Manufacturer: Iridex
Laser Type: Solid state diode	Wavelength: 810nm (nominal)	Beam Delivery Device: Indirect ophthalmoscope only.
Mode of operation: CW and pulsed	Power/Energy Range: max. 4 Watts.	Pulse duration for pulsed lasers: 0.025 to 9000 ms
NOHD: 27 meters. (Based on use of indirect ophthalmoscope only).		
Aiming Beam: Red diode, 2mWatt, 650 to 670nm.		
Required safety eyewear protection level: D LB3. (Based on use of indirect ophthalmoscope only and pulse duration of 200 ms).		
Description of Application: ROP Rectinopathy Of Prematurity.		
Description of laser environment (incl. access, windows, surfaces, warning lights, and signs): Operating theatre. All entrances are locked with switch on control panel, which acts as an interlock, the warning lights are also activated from a similar switch on the same control panel. Blinds on all windows.		
Persons at Risk: Staff, patient, contracted service personnel, and public.		
Cycle of Interest: All forms of operation including but not limited to approve clinical procedures, all testing, and maintenance.		
Laser is CE marked meets all specifications and has been signed off by LPA: Yes		LPA: Dr. J. Galligan


List of Corrective Actions

Hazard	Action required	Completed	Completed by
	Interlock by-pass		
	Review of laser safety SOP for theatre	Nov-14	


Question 1:	Is this laser appropriate and safe for use in its intended clinical applications and designated laser control area?	Response:
Hazard:	Environment and People.	

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


People at Risk:	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
	Laser device cannot be operated without key.	✓					
	The laser controlled area (LCA) has been designated with physical access restrictions.	✓					
	Warning lights are located above all accesses to the laser controlled area.	✓					
	Laser has electrical, and laser aperture warning labels.	✓					
Administrative Controls:	Laser Safety Committee, Laser Protection Advisor, Laser Protection Supervisor, and Clinical Expert have been appointed.	✓					
	Laser Safety Local Rules (SOP), have been drawn for the laser and this laser controlled area.	✓					
	Processes are in place to restrict access to the laser controlled area.	✓					
	Processes are in place to ensure that warning signs are posted on all entrances to laser control area.	✓					
	Processes are in place to ensure that usage is restricted to Authorised Users and to the laser controlled area.	✓					
	Authorised users and assisting staff have received laser safety training, and are familiar with the appropriate policies and procedures.	✓					
	Laser maintenance is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	✓					
	Maintenance is restricted to qualified personnel.	✓					
	Processes are in place to ensure that the laser is routinely verified for correct performance and safety (Performance Verification).	✓					
	No more than one laser is switched on in the laser controlled area.	✓					
	Emergency procedures are in place.	✓					
Incident reporting and investigating protocols are in place.	✓						
Responsible person:	Laser Safety Committee, Laser Protection Advisor (LPA), Laser Protection Supervisor (LPS), and Clinical Expert.						

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


Question 2:	Are person's present in the nominal ocular hazard area (NOHA) protected against unintended laser exposure above the maximum ELV?	Response:					
Hazard:	Optical.						
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Windows are completely laser tight.	✓					
	Protective filter/shutter is provided with viewing optics are in good order.	✓		<input type="checkbox"/>			
Administrative Controls:	A process is in place to verify that the beam is on target prior to firing.	✓			Part of training but not included in any document		
	All accessories and devices used during the procedure have been approved for use with lasers as being non-reflective.			✓			
	All reflective surfaces have been removed or covered.	✓					
	Patient's eyes, particularly those of anaesthetised patients are protected.	✓		<input type="checkbox"/>	With the exception of the eye undergoing treatment.		
	Staff have been trained in the use and maintenance of protective eyewear and shutters.	✓					
PPE Controls:	Patient and staff laser protection eyewear provided.	✓					
	Protective eyewear is appropriate for this laser and in good order.	✓					
	There are adequate numbers of eyewear, and are easily identifiable.	✓					
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 3:	Are person's present in the laser control area protected against unintended laser exposure to the skin above the ELV, and fire?	Response:					
Hazard:	Fire, explosions, and tissue burns.						
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Administrative Controls:	All accessories and devices used during the procedure have been approved for use with lasers.	✓					
	Cleaning and disinfecting agents are non-flammable.	✓		<input type="checkbox"/>			

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


	Processes are in place to ensure that swabs, surgical drapes, and other flammable material located near the field of operation are kept moist with saline or sterile water.	<input type="checkbox"/>		✓			
	Processes are in place to ensure that laser safe endotracheal tubes are used.	<input type="checkbox"/>		✓			
	The Anaesthetic Laser Safety SOP is followed.	<input type="checkbox"/>		✓			
	Safety processes are in place for the use of lasers with channelled devices such as endoscopes and canellas.			✓			
	There is an emergency plan in place in case of fire.	<input type="checkbox"/>			<i>No by-pass for interlock.</i>		H&S Officer
	Firefighting equipment is available in laser control area for all cycles.	✓		<input type="checkbox"/>			
PPE Controls:	Gloves are worn to avoid skin exposure from the reflective beam during fibre calibration (UV).	<input type="checkbox"/>		✓			
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 4:	Are processes in place to avoid beam misfires?	Response:					
Hazard:	Unintended absorption of laser beam.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Beam is activated by a covered footswitch or hand switch.	✓					
	Beam cannot be activated without a delivery device.	✓					
Administrative Controls:	Processes are in place to ensure that laser, fibre, and optics are checked for damage prior to use.	✓					
	Processes are in place to ensure that laser is placed in standby mode when not in use.	✓		<input type="checkbox"/>			
	Processes are in place to ensure that no more than one device footswitch is available to the authorised user at a time.	✓		<input type="checkbox"/>			
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 5:	Are patients and staff adequately protected from potential laser plume hazards?	Response:					
Hazard:	Small particles in the form of bio-aerosols may be released into the environment which may have toxins or carcinogenic constituents.						

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

People at Risk	Staff and patient.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Processes are in place to ensure that a plume extractor is used during procedure.	<input type="checkbox"/>		✓			
Administrative Controls:	The plume extractor maintenance and filter change is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	<input type="checkbox"/>		✓			
PPE Controls:	Processes are in place to ensure that high filtration surgical masks are used in addition to laser plume evacuation.	<input type="checkbox"/>		✓			
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.						
Question 6:	Are patients treated safely?	Response:					
Hazard:	Adverse reaction to laser treatment, inappropriate and unintended treatment.						
People at Risk	Patient.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	There is an emission light and/or audible alarm during laser fire.	✓					
	Power output is displayed.	✓					
	Processes are in place to ensure that tissue cooling device is checked prior to use.	<input type="checkbox"/>		✓			
Administrative Controls:	Processes are in place to ensure that treatment parameters are signed off by the Medical Authorised User prior to procedure.	✓					
	Clinical Authorised Users have received device specific and treatment specific training.	✓					
Responsible person:	Laser Safety committee, LPA, LPS, and Authorised User.						
Question 7:	Are electrical hazards adequately controlled?	Response:					
Hazard:	Electrical supply.						
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date
Engineering Controls:	Laser system is enclosed.	✓					
Administrative Controls:	Processes are in place to ensure that electrical cables are verified prior to use for wear and damage.	✓					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

	Laser service is restricted to qualified personnel.	✓							
Responsible person:	Laser Safety Committee, LPA, and LPS.								
Question 8:	Are trip hazards adequately controlled?	Response:							
Hazard:	Trip.							N/A	
People at Risk	Staff.	Yes	No	N/A	Action / Comments	Assigned to	Completion date		
Engineering Controls:	Electrical cables can be routed under the floor, or pendants used.	✓		<input type="checkbox"/>					
Administrative Controls:	Processes are in place to ensure that cables are kept clear of access ways.	✓							
Responsible person:	Laser Safety Committee, LPA, and LPS.								
Question 9:	Are mechanical hazards adequately controlled?	Response:							
Hazard:	Laser articulated arm, lasers placed on trolleys.								
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date		
Engineering Controls:	Articulated arm can be secured into laser casing when not in use.		<input type="checkbox"/>	✓					
Administrative Controls:	Processes are in place to ensure that lasers are placed on appropriate trolleys or work surfaces when in use.	✓	<input type="checkbox"/>	<input type="checkbox"/>					
	Articulated arm is secured by staff when not in use.		<input type="checkbox"/>	✓					
Responsible person:	Laser Safety Committee, LPA, and LPS.								
Question 10:	Are chemical hazards adequately controlled?	Response:							
Hazard:	Dye leak or spill.								
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to	Completion date		
Engineering Controls:	Laser system is enclosed.	<input type="checkbox"/>		✓					
Administrative Controls:	Chemical spill kit readily accessible.	<input type="checkbox"/>		✓					
	Processes are in place to ensure that chemical spill SOP is followed.			✓					
PPE Controls:	Appropriate masks, gloves and aprons readily accessible as part			✓					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

	of spill kit.								
Responsible person:	Laser Safety Committee, LPA, and LPS.								

References: Legislation, Standards and Guidelines for Laser Safety:

- [1] Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation), SI 176 (2010).
- [2] IEC 60601-2-22 ed3.0, 2007: Medical electrical equipment - Particular requirements for safety of diagnostic and therapeutic laser equipment.
- [3] IEC TR 60825-8:2006 Safety of Laser Products - Part 8: Guidelines for the Safe Use of Laser Beams on Humans.
- [4] IEC TR 60825-14 Safety of Laser Products - Part 14: A User's Guide.
- [5] NSAI EN 207 Personal eye protection: filters and eye protectors against laser radiation (laser eye protectors).
- [6] MHRA Guidance on the safe use of lasers, intense light source systems and LEDs, in medical, surgical, and aesthetic practices, 2008.
- [7] A Non-Binding Guide to the Artificial Optical Radiation Directive 2006/25/EC, Radiation Protection Division, Health Protection Agency, Contract VC/2007/0581.

STANDARD OPERATING PROCEDURE OF DioBeam


Version Number	V1
Date of Issue	March 2016
Reference Number	PDB-03-2016-RWEOD-V1
Review Interval	3 yearly
Approved By Name: Fionnuala O'Neill Title: Nurse Practice Coordinator	Signature: <i>Fionnuala O'Neill</i> Date: March 2016
Authorised By Name: Rachel Kenna Title: Director of Nursing	Signature: <i>Rachel Kenna</i> Date: March 2016
Author/s	Name: Dr. Kirsten Fitzgerald Title: Dental Consultant
Location of Copies	On Hospital Intranet and locally in department

Document Review History

Review Date	Reviewed By	Signature
2019		

Document Change History


Change to Document	Reason for Change

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Contents

		Page No
1.0	Introduction	67
1.0	Scope	67
2.0	Standards	68
3.0	References	

Authorised Users

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Clinical Expert: Dr. Kirsten Fitzgerald, Dental Consultant
Dr. Paddy Fleming, Dental Consultant:
Dr. Shaunine Gallagher, Dental Consultant

1.0 Introduction


The Dio Beam 830, is a Dental Therapeutic Laser, which operates in continuous wave (CW) at 500 mWatts. The laser radiation emitted from this laser is 830 nm, is invisible, and it is emitted via a rigid glass fibre. This laser is a class 3B laser, and as such presents an optical hazard to the retina, the lens, and the cornea (burn resulting in injury and/or loss of vision).

2.0 Scope

This document outlines the processes for the safe operation of the Dio Beam 830 described in the introduction of this document, and does not replace the instructions in the Operator's Manual for his lasers or proper training. The safety requirements as set out in the Laser Safety Policy, this SOP, and the laser's Operator Manual apply during the use of this laser.

3.0 Standards

- 3.1 The Dio Beam Laser may only be used in the designated **Laser Control Areas** for this laser, i.e. dental surgery 1 and 2, single rooms on St. Johns Ward.
- 3.2 The Dio Beam Laser can be used by **authorised Laser Users only** i.e. those persons identified as competent and on the current Register of Authorised Users for the Dio Beam Laser (Refer to Laser Safety Policy).
- 3.3 The Authorised User **MUST** ensure that all present in the designated Laser Controlled Area, are wearing laser safety goggles (>725-1028 DM LB6) labelled with Dio Beam, and that they remain in use whilst the laser is powered on.
- 3.4 It is the responsibility of the Authorised User, to ensure that the **patient's eyes are appropriately protected**.
- 3.5 It is the responsibility of the Authorised User to operate the laser as follows:
 - 3.5.1 Ensure that the **warning sign** has been fixed to the access doors.
 - 3.5.2 Ensure that **all doors are closed and that windows are covered** – let staff on ward know that the treatment is being carried out. If surgery 2, is used care should be taken to ensure no one is using balcony as the windows cannot be covered.
 - 3.5.3 Ensure that **bathroom door is closed** in single rooms and ensure **no metal objects** are to be used in the mouth such as mirrors or mouth retractors.
 - 3.5.4 Check and verify that the **laser casing and glass fibred are free from damage**. If damage is observed, **do not use**. Notify laser supervisor.
 - 3.5.5 Ensure that fibre is connected to the laser.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

3.5.6 Ensure the mandatory 'Time Out' is carried out prior to any laser procedure.

3.5.7 Give clear audible communication that laser is going into Ready Mode.

3.5.8 Check / **verify the output** of the Dio Beam and fibre as per instructions in the Dio Beams operator's manual. **Verify that the battery** is adequately charged and record these verifications in the operation notes.

3.5.9 Ensure that laser is only fired when the fibre is aimed at the treatment site of power meter port.

3.5.10 The laser must be place in **holder in case when it is not in use**.

3.5.11 Ensure that the key is removed and securely stored at the end of the procedure.

3.6 It is the responsibility of the Senior Nurse at the end of the procedure, to ensure that the following is completed:

3.6.1 That all laser protective goggles are washed with warm soapy water and dried, checking the integrity of the lens for any cracks or chipping and returned to their cases after use.

3.6.2 That the laser is appropriately cleaned, decontaminated and stored.

3.6.3 That the fibres are appropriated cleaned, decontaminated and stored.


3.7 It is the responsibility of the Authorised User to **record treatment parameters and verification of battery and output** in the operation notes.

3.8 Laser Maintenance and Monitoring:

- Service reports are maintained by the Laser Protection Supervisor.
- 2 yearly services are recommended by manufacturer.
 - Contact: Gert Van Gyseghem, Laser medico, gdc@lasermedico.be
- The Risk Assessment is carried out annually by the Laser Protection Advisor (LPA) and Laser Protection Supervisor (LPS).
- All incidents or near misses are reported electronically on the Hospital's Adverse Incident Report, as per the Adverse Incident Policy:

4.0 References

- *DioBeam Operator's Manual*
- *Laser Safety Policy, Policy No. (To be defined).*
- *Laser Safety Guidelines, Guidelines No. (to be defined).*
- *Cleaning and Disinfection (Environment & Equipment) Policy, Policy No. (To be defined).*

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Laser Risk Assessment for the DioBeam 830 Diode Laser located in the Dental Unit


Title of Document: Laser risk assessment for the DioBeam 830 Diode Laser located in the Dental Unit	Issue date of Risk Assessment: 19/12/2014
Activity/Facility Assessed: Room XX Dental Unit	Laser control area: Room XX Dental Unit, and patient rooms where appropriate controls have been put in place.
Laser Protection Supervisor: Kirsten Fitzgerald	Laser Protection Advisor: Josette Galligan
Assessed by: Josette Galligan	Review date: December 2015

BACKGROUND INFORMATION


Laser Classification: Class 3B	Model: DioBeam 830	Manufacturer: CMS Dental
Laser Type: Diode	Wavelength: 790 - 830 nm	Beam Delivery Device: Rigid fibre
Mode of operation: CW	Power/Energy Range: 400 to 500 mWatts	Pulse duration for pulsed lasers: n/a
NOHD: 21.3 meters		
Aiming Beam: Red LED		
Required safety eyewear protection level: 790 to 850 nm D LB3 or greater		
Description of Application: Treatment of tissue repair.		
Description of laser environment (incl. access, windows, surfaces, warning lights, and signs): The clinical room door can be locked from the inside, and there are blinds on the windows.		
Persons at Risk: Patient, staff, parents/guardians.		
Cycle of Interest: In clinical use, output measurement verification. This device should be sent back to the manufacturer for servicing.		
Laser is CE marked meets all specifications and has been signed off by LPA: J Galligan		LPA: 19/12/2014

List of Corrective Actions


Hazard	Action required	Completed	Completed by
Persons not warned of laser hazard	Signage to be posted on door of clinical or patient room when laser in use.		
Laser incident	Complete Laser Safety SOP and send to Laser Safety Committee		
Eye injury	Remove original two pairs of laser safety goggles, and purchase additional pairs. Note authorise users should ensure good fit to patient prior to laser use.		

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


Infection		Verify cleaning, decontamination & storage of laser glass fibres with infection control				
Airway fire		Review use with intubated patients				
Question 1:	Is this laser appropriate and safe for use in its intended clinical applications and designated laser control area?				Response:	
Hazard:	Environment and People.					
People at Risk:	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to
	Laser device cannot be operated without key.	✓				
	The laser controlled area (LCA) has been designated with physical access restrictions.	✓				
	Warning lights are located above all accesses to the laser controlled area.	<input type="checkbox"/>	X		Signage will posted on the door when in use as LCA	LPS
	Laser has electrical, and laser aperture warning labels.	✓				
Administrative Controls:	Laser Safety Committee, Laser Protection Advisor, Laser Protection Supervisor, and Clinical Expert have been appointed.	✓				
	Laser Safety Local Rules (SOP), have been drawn for the laser and this laser controlled area.	<input type="checkbox"/>	X		In progress	LPS
	Processes are in place to restrict access to the laser controlled area.	✓				
	Processes are in place to ensure that warning signs are posted on all entrances to laser control area.	<input type="checkbox"/>	X		In progress	LPS
	Processes are in place to ensure that usage is restricted to Authorised Users and to the laser controlled area.	✓				
	Authorised users and assisting staff have received laser safety training, and are familiar with the appropriate policies and procedures.	✓				
	Laser maintenance is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.				Should be sent back to manufacturer every 2 yrs.	LPS
	Maintenance is restricted to qualified personnel.	✓			Laser should only be serviced by the manufacturer	LPS
	Processes are in place to ensure that the laser is routinely verified for correct performance and safety (Performance Verification).	✓			Laser output should be verified in the 'detector' located in the combined battery re-charger, power meter and vertical holder prior to use.	Authorised Users
	No more than one laser is switched on in the laser controlled area.	✓				
Emergency procedures are in place.	✓					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


	Incident reporting and investigating protocols are in place.	✓				
Responsible person:	Laser Safety Committee, Laser Protection Advisor (LPA), Laser Protection Supervisor (LPS), and Clinical Expert.					
Question 2:	Are person's present in the nominal ocular hazard area (NOHA) protected against unintended laser exposure above the maximum ELV?	Response:				
Hazard:	Optical.					
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Windows are completely laser tight.	✓				
	Protective filter/shutter is provided with viewing optics are in good order.			✓		
Administrative Controls:	A process is in place to verify that the beam is on target prior to firing.	✓				
	All accessories and devices used during the procedure have been approved for use with lasers as being non-reflective.				To be written in Laser Safety Sop that dental mirrors and metal retractors should not be used.	LPS
	All reflective surfaces have been removed or covered.					
	Patient's eyes, particularly those of anaesthetised patients are protected.	✓			Authorised Users should ensure good fit	Authorised Users
	Staff have been trained in the use and maintenance of protective eyewear and shutters.	✓				
PPE Controls:	Patient and staff laser protection eyewear provided.	✓				
	Protective eyewear is appropriate for this laser and in good order.	☐			The newly purchased pairs (x2) are. The original pairs (x2) are not & should not be kept with the laser. Possibly be given to clinical engineering for minding as they might be useful for another laser in the future.	LPS
	There are adequate numbers of eyewear, and are easily identifiable.	☐	X		Additional paris may be required for parents/guardians	LPS
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


Question 3:	Are person's present in the laser control area protected against unintended laser exposure to the skin above the ELV, and fire?	Response:				
Hazard:	Fire, explosions, and tissue burns.	Response:				
People at Risk	Staff, patient, contracted service personnel, and public.	Yes	No	N/A	Action / Comments	Assigned to
Administrative Controls:	All accessories and devices used during the procedure have been approved for use with lasers.	<input type="checkbox"/>			To be written in Laser Safety Sop that dental mirrors and metal retractors should not be used.	LPS
	Cleaning and disinfecting agents are non-flammable.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Verify cleaning, decontamination & storage of laser glass fibres with infection control	LPS
	Processes are in place to ensure that swabs, surgical drapes, and other flammable material located near the field of operation are kept moist with saline or sterile water.	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
	Processes are in place to ensure that laser safe endotracheal tubes are used.	<input type="checkbox"/>		<input type="checkbox"/>	May be necessary to use a laser safe ET	LPS/LPA
	The Anaesthetic Laser Safety SOP is followed.	<input type="checkbox"/>		<input type="checkbox"/>	Not sure if this laser is safe for use with an ET	LPS/LPA
	Safety processes are in place for the use of lasers with channelled devices such as endoscopes and canellas.			<input checked="" type="checkbox"/>		
	There is an emergency plan in place in case of fire.			<input checked="" type="checkbox"/>		
	Firefighting equipment is available in laser control area for all cycles.	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
PPE Controls:	Gloves are worn to avoid skin exposure from the reflective beam during fibre calibration (UV).	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 4:	Are processes in place to avoid beam misfires?	Response:				
Hazard:	Unintended absorption of laser beam.	Response:				
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Beam is activated by a covered footswitch or hand switch.	<input checked="" type="checkbox"/>				
	Beam cannot be activated without a delivery device.	<input type="checkbox"/>	X		Note in SOP that glass fibre tip should always be attached to the laser before use or calibration.	LPS
Administrative Controls:	Processes are in place to ensure that laser, fibre, and optics are checked for damage prior to use.	<input checked="" type="checkbox"/>			Covered in SOP	

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

	Processes are in place to ensure that laser is placed in standby mode when not in use.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Covered in SOP	
	Processes are in place to ensure that no more than one device footswitch is available to the authorised user at a time.	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 5:	Are patients and staff adequately protected from potential laser plume hazards?	Response:				
Hazard:	Small particles in the form of bio-aerosols may be released into the environment which may have toxins or carcinogenic constituents.					
People at Risk	Staff and patient.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Processes are in place to ensure that a plume extractor is used during procedure.			<input checked="" type="checkbox"/>		
Administrative Controls:	The plume extractor maintenance and filter change is scheduled and performed as per manufacturer's recommendations and as per hospital policies and procedures.	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
PPE Controls:	Processes are in place to ensure that high filtration surgical masks are used in addition to laser plume evacuation.	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
Responsible person:	Laser Safety Committee, LPA, Authorised User, and LPS.					
Question 6:	Are patients treated safely?	Response:				
Hazard:	Adverse reaction to laser treatment, inappropriate and unintended treatment.					
People at Risk	Patient.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	There is an emission light and/or audible alarm during laser fire.	<input checked="" type="checkbox"/>				
	Power output is displayed.	<input type="checkbox"/>		<input checked="" type="checkbox"/>	Only one setting (500 mW), recommend that verified prior to use.	
	Processes are in place to ensure that tissue cooling device is checked prior to use.	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
Administrative Controls:	Processes are in place to ensure that treatment parameters are signed off by the Medical Authorised User prior to procedure.	<input checked="" type="checkbox"/>			32 s ≡ 16 Joules	
	Clinical Authorised Users have received device specific and treatment specific training.	<input checked="" type="checkbox"/>				

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		


Responsible person:	Laser Safety committee, LPA, LPS, and Authorised User.					
Question 7:	Are electrical hazards adequately controlled?	Response:				
Hazard:	Electrical supply.					
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Laser system is enclosed.	✓				
Administrative Controls:	Processes are in place to ensure that electrical cables are verified prior to use for wear and damage.	☐		✓		
	Laser service is restricted to qualified personnel.	✓				
Responsible person:	Laser Safety Committee, LPA, and LPS.					
Question 8:	Are trip hazards adequately controlled?	Response:				
Hazard:	Trip.	N/A				
People at Risk	Staff.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Electrical cables can be routed under the floor, or pendants used.	☐		✓		
Administrative Controls:	Processes are in place to ensure that cables are kept clear of access ways.	☐		✓		
Responsible person:	Laser Safety Committee, LPA, and LPS.					
Question 9:	Are mechanical hazards adequately controlled?	Response:				
Hazard:	Laser articulated arm, lasers placed on trolleys.					
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Articulated arm can be secured into laser casing when not in use.		☐	✓		
Administrative Controls:	Processes are in place to ensure that lasers are placed on appropriate trolleys or work surfaces when in use.		☐	✓		
	Articulated arm is secured by staff when not in use.		☐	✓		

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Responsible person:	Laser Safety Committee, LPA, and LPS.					
Question 10:	Are chemical hazards adequately controlled?	Response:				
Hazard:	Dye leak or spill.					
People at Risk	Staff, patient, and contracted service personnel.	Yes	No	N/A	Action / Comments	Assigned to
Engineering Controls:	Laser system is enclosed.	<input type="checkbox"/>		✓		
Administrative Controls:	Chemical spill kit readily accessible.	<input type="checkbox"/>		✓		
	Processes are in place to ensure that chemical spill SOP is followed.			✓		
PPE Controls:	Appropriate masks, gloves and aprons readily accessible as part of spill kit.			✓		
Responsible person:	Laser Safety Committee, LPA, and LPS.					

References: Legislation, Standards and Guidelines for Laser Safety:

- [1] Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation), SI 176 (2010).
- [2] IEC 60601-2-22 ed3.0, 2007: Medical electrical equipment - Particular requirements for safety of diagnostic and therapeutic laser equipment.
- [3] IEC TR 60825-8:2006 Safety of Laser Products - Part 8: Guidelines for the Safe Use of Laser Beams on Humans.
- [4] IEC TR 60825-14 Safety of Laser Products - Part 14: A User's Guide.
- [5] NSAI EN 207 Personal eye protection: filters and eye protectors against laser radiation (laser eye protectors).
- [6] MHRA Guidance on the safe use of lasers, intense light source systems and LEDs, in medical, surgical, and aesthetic practices, 2008.
- [7] A Non-Binding Guide to the Artificial Optical Radiation Directive 2006/25/EC, Radiation Protection Division, Health Protection Agency, Contract VC/2007/0581.

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Information for Parents / Carers of a child

LOCAL ANAESTHETIC LASER INFORMATION



Introduction


Laser treatment is carried out using Local anaesthetic cream in a laser safe room in the Medical Tower. Response to treatment varies depending on the nature and location of the lesion.

What to expect

1. On your initial visit to the outpatient's clinic, you will be seen by the Consultant and Laser nurse Specialist or you may be referred directly from another consultant
2. Treatment options are discussed and a plan is made for treatment.
3. The decision to carry out treatment using Local anaesthetic is made depending on;
 - the age of the patient ,
 - the size of the lesion to be treated
 - the location of the lesion
4. The number of treatments will depend on the response to the first treatment and the condition treated for example
 - Spider naevi may clear after one treatment
 - Port wine stains could average 6 treatments.

Pre-Treatment Instructions

1. **Tanned skin cannot be treated.** Treatment will be deferred if you have a tan because of the increased risk of scarring. Avoid sun exposure to the area of the skin to be treated and use factor 50 sun protection when outdoors in Ireland between March and October. If you are in a sunny country sun, block should be applied every hour during daylight.
2. Please inform us if your child is being treated for eczema as this can affect the laser treatment.
3. If you have a history of cold sores (herpes simplex infection) please inform the laser nurse. Treatment will be deferred if a cold sore is present.
4. This treatment is usually well tolerated using local anaesthetic cream.
5. There is no need to fast
6. The skin needs to be clean and in good condition

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Day Treatment

Please check in with admissions 10 minutes before you appointed time and proceed to 2nd floor of medical tower

- You will be met by the laser nurse, who will answer any queries you may have
- A photograph will be taken of the area to be treated
- Local anaesthetic cream will be applied which will remain on for at least 45minutes
- Consent will be signed by a parent following consultation with one of the Doctors on the Dermatology team.
- One parent may stay with the patient during the procedure

Safety considerations are important during the laser procedure. The patient and all personnel in the laser room will wear protective eyewear during the procedure to reduce the chance of damage to the eye.


Post Treatment Care

- The treated area may be bruised for 7-10days after treatment. The skin will be fragile and needs gentle handling.
- The application of Aloe Vera for up to 48hrs after treatment will reduce the discomfort and swelling that may be experienced.
- After 48 hrs. apply a daily moisturiser to the treated area until next treatment
- Keep nails cut short to prevent damage to the skin if accidentally scratched.
- Use factor 50 sun protection everyday between March and October to laser treated areas. Repeat application frequently during treatment journey and for at least a year after treatment is complete.
- The laser nurse will call all patients within 2 weeks of treatment to answer any queries and to plan next treatment or outpatient follow up.

Dates for Treatment

*Developed by Edette O'Dea – Laser Nurse Specialist, Dermatology Dept
Date issued: March 2016 Review Date: March 2019*

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Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Information for Parents / Carers of a child

INFORMATION FOR LASER HAIR REMOVAL



Introduction


Excess hair can be due to an excessive amount of hormones, medication, or genetic predisposition. Laser assisted hair removal is an effective method for delaying but not totally eliminating hair growth and the darker the hair the more effective the result. Blonde, red, grey, white or silver hair does not respond to this laser.

What to expect

1. The number of treatments required depends on hair cycle at body site. Everyone will require at least 2-3 treatments at 4-6 weekly intervals before the benefits can be assessed. Six full treatments are offered and then condition is reviewed.
2. Patients usually report that hair regrowth is slower, finer in texture, and more sparse after laser treatment. Blonde hairs may be noted in the areas treated. Hair regrowth can occur more quickly in areas known to produce hair rapidly (chin and upper lip)
3. The laser has been described as feeling like a hot prickly sensation. Certain areas are more sensitive than others such as the upper lip

Pre-Treatment Instructions

1. **Tanned skin cannot be treated.** Treatment will be deferred if you have a tan because of increased risk of scarring. Avoid sun exposure 4-6 weeks before and after treatment.
2. Avoid bleaching, waxing, tweezing or electrolysis 6 weeks prior to treatment or between laser sessions. Shaving or trimming is permitted during your course of treatment only.
3. The area to be treated must not be cut or shaven for a few days before treatment if possible. A photo will be taken for follow up purposes prior to shaving on the day of treatment. Shaving will remove any overlying hair from absorbing energy and burning back onto the skin
4. If you have a history of cold sores (herpes simplex infection) please inform the laser nurse. Treatment will be deferred if a cold sore is present
5. This treatment is usually well tolerated using coolant and Aloe Vera gel. Local anaesthetic cream may be used to treat small areas in exceptional cases at the discretion of the Laser team

Our Lady's Children's Hospital, Crumlin		
Document Name: Laser Safety Guidelines		
Reference Number:	Version Number: V1	
Date of Issue: November 2018		

Day of Treatment

The skin needs to be clean, devoid of cosmetics and creams. When treating the upper lip, the teeth may be protected with saline soaked gauze. The gauze also serves to support the lip during treatment, allowing a surface to push against.

Safety considerations are important during the laser procedure. The patient and all personnel in the laser room will wear protective eyewear during the procedure to reduce the chance of damage to the eye. There is a low risk of **complications** with this treatment however the following may occur

- Incomplete removal of hair
- Pigment /texture change or scar
- Inflammation of the hair follicle resulting in an acne like spot
- Rarely new hair growth may be noted at the edge of the area treated. this occurs in a minority of patients and usually responds to continued treatment
- Blistering/scabbing
- Cold sore activation

Post Treatment Care

1. Immediately after treatment there may be erythema (redness) which may last up to 2-3 days and oedema (swelling) at the treatment site which may last up to 2 hours or longer. The treated area may feel like sunburn for a few days. The application of Aloe Vera for up to 48hrs after treatment will reduce the discomfort and swelling that may be experienced.
2. Ideally wait 24hours before applying make up
3. Use factor 50 sun protection everyday between March and October to laser treated areas. Repeat application frequently during treatment journey and for at least a year after treatment is complete.
4. Anywhere from 5-14 days after treatment, shedding of the surface hair may occur and this appears as new hair growth. **This is not new hair growth.** You can clean and remove the hair by washing or wiping the area with a wet cloth or sponge.
5. There are no restrictions on bathing except to treat the skin gently as if you had a sunburn for the first 24hours

Dates for Treatment

*Developed by Edette O'Dea – Laser Nurse Specialist, Dermatology Dept.
Date issued: March 2016 Review Date: March 2019*