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# Standards for the use of

## Version 1

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Health Policies and Standards Department

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Health Regulation Sector (2021)





#### INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (6) of 2018 to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector
- Licensure and inspection of health facilities as well as healthcare professionals
- and ensuring compliance to best practice
- Managing patient complaints and assuring patient and physician rights are upheld
- Governing the use of narcotics, controlled and semi-controlled medications
- Strengthening health tourism and assuring ongoing growth
- Assuring management of health informatics, e-health and promoting innovation

The Standards for use of Laser in Dentistry, aims to fulfil the following overarching DHA

Strategic Priorities (2021–2071):

- 1. Promote the healthiest lifestyle for the people of Dubai.
- 2. Lead on prevention and management of non-communicable diseases and mental health.
- 3. Lead the global fight against epidemics and communicable diseases.
- 4. Pioneer a human-centered system that promotes trust, safety and quality of care for patients and their families.
- 5. Make Dubai a model for value-based healthcare.





- 6. Build a resilient end-to-end healthcare supply chain.
- 7. Promote healthcare industry and tourism to become a major economic sector.
- 8. Make Dubai a lighthouse for healthcare governance, integration and regulation.
- 9. Attract, develop and retain healthcare professionals of the future.
- 10. Become a digital and data-driven hub for healthcare research and innovation.
- 11. Strategic Program 5, Initiative 5.3: Develop and launch Dubai Dental Protocol and other relevant

documents related to dentistry.

#### ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts. HRS would like to acknowledge and thank these healthcare professionals for their dedication toward promoting and improving quality and safety of healthcare services in the Emirate of Dubai.

#### **Health Regulation Sector**

**Dubai Health Authority** 





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#### **EXECUTIVE SUMMARY**

The Standards for the use of Laser in Dentistry has been developed to align with the DHA, Strategic Priorities (2021–2071).

This document focuses on the requirements for the safe and effective use of laser in dentistry.

Use of lasers has grown exponentially since it was introduced in 1960. Like all other fields, dentistry has also adopted laser and it has numerous uses in this field. It has modernized and revolutionized conventional dentistry to a certain degree. Beside the positive aspect, lasers may also cause damage to the patients as well as the dentists using the laser equipment. This document elaborates the health facility requirements specific to use of laser in dentistry, the equipment installation, maintenance and training, healthcare professionals and their education, training and privileges and safety measures which have to be taken into serious consideration when lasers are used in dental practice. Hence, when faced with any inadvertent incident, the General Dentist or Dental Specialists/Consultant s using the laser equipment, should be able to manage the patient adequately. These safety measures ensure suitable emergency care and a safe environment for the dentist, dental assistant and the patient involved in the laser treatment.

A report was developed in collaboration with Clinical Governance Committee Office, Dental Medical Liability Committee (MLC) and Health Licensing Department to understand the dynamics and interdependencies related to the subject as well as the current challenges in the Emirate of Dubai. This document is aligned with the following DHA documents:

• DHA, Health Facility Guidelines (HFG), 100 Dental Surgery Unit





- DHA Clinical Privileging Policy
- DHA Guidelines for Managing Health Records
- DHA Guidelines for Patient Consent
- DHA Continuing Professional Development Guideline
- DHA Outpatient care facility Regulation (2012)
- Dubai Health Strategy, 2016-2021
- DHA Guidelines for Medical Advertisement Content on Social Media
- DHA Guidelines on Dental Infection Prevention and Safety
- Unified Professional Qualification Requirement
- Any DHA COVID-19 related policies, standards or guidelines that may be relevant.





#### DEFINITIONS

**Clinical Privileging:** is the process of giving a DHA licensed Healthcare Professional (HP) permission to carry out specific duties as per health facility scope of practice and licensure. This involves the review of credentials and qualifications, training, competence, practical independence and experience.

**Continuing Professional Development (CPD):** is a range of learning activities through which healthcare professionals maintain and develop their knowledge and skills throughout their career to ensure that they retain their capacity to practice safely, effectively and legally within their evolving scope of practice. CPD is also referred to as Continuing Medical Education (CME).

**Dental Clinic**: is a health facility specialized in the "evaluation, diagnosis, prevention and/or treatment (nonsurgical, surgical or related procedures) of diseases, disorders and/or conditions of the oral cavity, maxillofacial area and/or the adjacent and associated structures and their impact on the human body".

Hazard: is any source of potential damage, harm or adverse health effects on something or someone.

**Healthcare professional:** is a healthcare personal working in a health facility and required to be licensed as per the applicable laws in United Arab Emirates (UAE).

**Laser:** is a device, which may produce or amplify electromagnetic radiation in the wavelength range from 810 nm to 1 mm primarily by the process of controlled stimulated emission.

**Laser Controlled area:** is an area where occupancy and activity of those within is subject to control and supervision for the purpose of protection from Laser radiation hazards.

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**Laser Safety Officer:** is one who is knowledgeable in the evaluation and control of laser hazards and has responsibility for the oversight of the control of laser hazards.

**Maintenance:** is performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser product, which are to be performed by the user for assuring the intended performance of the product.

**Maximum Permissible Exposure (MPE):** is the highest level of laser exposure to the eye or skin that is generally considered safe and in a term specific to laser use

**Nominal Hazard Zone (NHZ):** is defined as the area where the level of direct, reflected, or scattered radiation poses a hazard to the skin and eyes during normal laser operation.

**Patient:** is any individual who receives medical attention, care or treatment by any healthcare professional or admitted in a health facility.

**Plume:** is the gaseous by-product and debris from laser-tissue interaction.

Safety: is the condition of being safe from undergoing or causing hurt, injury, or loss.

Wrap: is a frame with a single lens that covers both eyes including side shields.





#### **ABBREVIATIONS**

ALD	:	Academy of Laser Dentistry
ANSI	:	American National Standards Institute
ARTG	:	Australian Register of Therapeutic Goods
CDRH	:	Center for Devices and Radiological Health
CE	:	Conformité Européenne
CFR	:	Code of Federal Regulation
CO <sub>2</sub>	:	Carbon Dioxide
CPD	:	Continuing Professional Development
DHA	:	Dubai Health Authority
ESOLA	:	European Society of Oral Laser Applications
Er: YAG	:	Erbium: Yttrium Aluminium Garnet
FDA	:	Food and Drug Administration
GA	:	General Anesthesia
HRS	:	Health Regulation Sector
IEC	:	International Electro-Technical Commission
LASER	:	Light Amplification by Simulated Emission of Radiation
LIA	:	Laser Institute of America
LSE	:	Laser Safety Eyewear
LSO	:	Laser Safety Officer
MFDS	:	Ministry of Food and Drug Safety





ΜΙΤΙ	:	Ministry of International Trade and Industry
MLC	:	Medical Liability Committee
МОНАР	:	Ministry of Health and Prevention
MPE	:	Maximum Permissible Exposure
NCLC	:	National Council on Laser Certification
Nd: YAG	:	Neodymium: Yttrium Aluminium Garnet
NHZ	:	Nominal Hazard Zone
OD	:	Optical Density
PPE	:	Personal Protective Equipment
PVC	:	Poly Vinyl Chloride
ТМЈ	:	Temporo Mandibular Joint
TFDA	:	Taiwan Food and Drug Administration
UAE	:	United Arab Emirates





#### 1. BACKGROUND

Dental services are the third most sought outpatient services in the Emirate of Dubai, with 1,089,054 dental visits in the year 2019 alone. Periodontal treatments, oral surgeries and root canal treatments contribute to 22.7% of all dental visits. Lately laser is increasingly popular in providing various dental treatment options.

Laser was introduced in 1960, by Theodore H. Maiman. The first laser used specifically for dentistry was a Neodymium-Yttrium Aluminium Garnet (Nd: YAG), developed in 1987 and approved by Food and Drug Administration (FDA) in 1990. Ever since, laser technology has advanced considerably and is used in many different dental specialties like Periodontics, Pediatrics, Endodontics, Oral Surgery and Restorative Dentistry.

In dentistry, the soft tissue application of laser enables dry and bloodless surgery, minimal postoperative swelling, faster post-operative healing and scarring and minimal post-operative pain. In case of hard tissues, laser enables efficient diagnosis of caries, cavity preparation, enamel etching, polymerization of composite resin and sterilization of root canals.

FDA has approved certain dental procedures such as, but not limited to caries removal, gingivectomy, gingivoplasty, coagulation, frenectomies, resection of gingival enlargements, treatment of oral pathologies, polymerization of dental resin materials, scaling, root planning, root canal obturation dentinal hypersensitivity treatment and management of Tempro-Mandibular Joint (TMJ) pain.

Center for Devices and Radiological Health (CDRH) of FDA's Code of Federal Regulation (CFR) 10 has categorised laser devices into four classes. Lasers used in Dentistry such as Diodes,

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Neodymium- Doped Yttrium Aluminium Garnet (ND: YAG), Erbium Yttrium Aluminium Garnet (Er: YAG) and CO<sub>2</sub>, are Class IV lasers. They are high powered and can be hazardous to the eyes and skin **Appendix 1**.

The use of laser in Dentistry has numerous benefits such as ease of use, specificity, efficiency, reduced operative time, reduced cost, high patient acceptance and enhanced patient journey. However, laser application can cause harm if the required safety measure are not implemented. It has become an important concern, as application of this technology is on the rise and the number and range of laser-based technologies have expanded enormously. The use of laser technology in dentistry poses an exposure and injury hazard if not handled properly. The objective of this document is to ensure safe and efficient dental laser services at DHA licensed health facilities

#### 2. SCOPE

2.1. To establish and enforce minimum requirements for DHA licensed General Dentists and Dental Specialists/Consultant who use lasers in their clinical practice, to ensure the provision of the highest level of safety and quality laser dental services to patients at all times.

#### 3. PURPOSE

3.1. To ensure efficient and effective use of laser in dental care provision by DHA licensed General Dentists and Dental Specialists/Consultant in DHA licensed health facilities providing dental laser services in their clinical practice.





3.2. To ensure the safety of healthcare professionals and patients during provision of the laser dental service.

#### 4. APPLICABILITY

4.1. These standards are applicable to DHA licensed General Dentists and Dental Specialists/Consultant providing laser dental services in DHA licensed health facilities.

#### 5. STANDARD ONE: REGISTRATION AND LICENSURE

- 5.1. DHA licensed General Dentists or Dental Specialists/Consultant aiming to provide Dental Laser services shall access the DHA online Licensing Service SHERYAN and ensure the following:
  - 5.1.1. Add/Upgrade Professional Registration
  - 5.1.2. Choose the title- Privilege
  - 5.1.3. Choose the speciality- Laser in Dentistry and apply with relevant documentation as elaborated below in this standard.
- 5.2. The application will be reviewed by the DHA, Licensing team. Additional oral assessment or written assessment may apply.
- 5.3. Once all the criteria elaborated in this standard are fulfilled the applicant will be get the Registration Certificate.
- 5.4. The Health Facility that the applicant is associated/employed with, will have to ensure the following:
  - 5.4.1. Add/Upgrade the Professional License to the existing license OR

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#### 5.4.2. Activate Professional License.

#### 6. STANDARD TWO: HEALTH FACILITY REQUIREMENTS

- 6.1. Laser services in dentistry could be provided in a dental clinic that could be an independent setting or a part of a DHA licensed Hospital, Day Surgical Center or an Outpatient Care Facility.
- 6.2. The treatment room of the dental clinic to provide laser services must incorporate radiation protection requirements in the final specifications of the building plan, where applicable.
- 6.3. The treatment room(s) providing laser service shall have a minimum floor area of twelve(12) square meters.
- 6.4. The treatment room(s) providing laser service shall demonstrate physical barriers for safety, like laser controlled areas and limited access.
- 6.5. The Nominal Hazard Zone (NHZ), which is the area around the patient, where proper safety protocols must be followed, should be restricted to only the patient and necessary healthcare professionals and it must be established according to the type of laser and manufacturer's manual.
- 6.6. The entrance to the NHZ must be marked with an appropriate laser safety sign labelled as "Warning" **Appendix 2.** The sign is normally provided by the manufacturer and also indicates the laser classification, wavelength, maximum power and required Optical Density (OD).
- 6.7. If the treatment room(s) providing laser service has an observation panel, it shall require appropriate window dressing with non-reflective and non-transparent material.

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- 6.8. Doors and windows should be either supervised or operated by remote interlocks during the laser procedures.
- 6.9. Door swing should be oriented to ensure patient privacy. If more than one door opens into the dental clinic providing laser services, it should be placed to ensure it does not compromise the privacy of the patient.
- 6.10. The following protective measures shall be taken in a treatment room(s) providing laser dental service:
  - 6.10.1. Laser used should be in good working condition with all manufacture's safeguards in place.
  - 6.10.2. The walls of the room should be painted with a matt colored paint.
  - 6.10.3. Avoid having reflective/metallic surfaces or mirrors in the room where laser service is provided, if not, ensure that reflective/metallic surfaces or mirrors are covered when providing laser services.
  - 6.10.4. The light used in the room must be non-reflecting.
  - 6.10.5. Windows shall be kept closed and curtain used shall be made of non-reflecting materials.
  - 6.10.6. Treatment couch shall be white colour or covered with white sheet.
  - 6.10.7. Materials used should be flame resistant.
  - 6.10.8. Instruments used should be Carbonized or non-reflective.





6.11. The treatment room shall have provision for room suction units with in-line filters to collect particulate matter to reduce the plume debris and dedicated mechanical smoke exhaust systems with a high efficiency filter to remove substantial amounts of laser-plume particles.

#### 7. STANDARD THREE: LASER EQUIPMENT REQUIREMENTS

- 7.1. Dental Laser equipment approval and specifications.
  - 7.1.1. All dental laser equipment must be approved and registered with the Ministry of Health and Prevention (MOHAP) and shall be approved by at least one (1) of the following recognised authorities (or equivalent) to establish that the product fulfils all the essential safety and environmental requirements:
    - a. Australian Register of Therapeutic Goods (ARTG)
    - b. Conformité Européenne (CE)
    - c. FDA
    - d. Health Canada
    - e. Japan Ministry of International Trade and Industry (MITI)
    - f. Medicines and Healthcare Products Regulatory Agency
    - g. Ministry of Food and Drug Safety (MFDS), Korea
    - h. Taiwan Food and Drug Administration (TFDA).
  - 7.1.2. Dental laser equipment's should include built-in safety features to ensure correct emission of laser energy as follows:





- Emission port shutters to prevent laser emission until the correct delivery system is attached.
- b. Covered foot-switches, to prevent accidental operation.
- c. Control panel to ensure correct emission parameters.
- d. Audible or visual signs of laser emission.
- e. Emergency 'stop' button.
- f. Locked unit panels to prevent unauthorized access to internal machinery.
- g. Key or password protection.
- h. Remote interlocks.
- 7.2. Qualified personnel from the laser company shall install all laser equipment in accordance to the manufacturer's specifications.
- 7.3. Competent personnel from the laser company shall train the General Dentists or Dental Specialists/Consultant to operate the specific laser equipment and related safety aspects and this training shall be documented and available for DHA audit purpose.
- 7.4. Authorised user shall only hold keys required to activate laser equipment. Keys should be marked "LASER for authorised use only" and should be stored in the safe. Alternatively, it could be password protected, to encrypt and store accordingly.
- 7.5. The operating beam should never be activated unless accurately aimed at the operating site. Exception to this is during the "test fire" of the laser to be used, which shall be under the strict supervision of the Laser Safety Officer (LSO) and in accordance with safe practice.

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- 7.6. Neither the aiming nor operating beam(s) shall be directed towards the eyes of the operator, assistant(s) or patient.
- 7.7. The dental clinic shall retain a contract for maintenance of the laser equipment with the manufacturing company or authorized dealer or agent.
- 7.8. The dental clinic shall maintain preventive maintenance and safety maintenance logs.

#### 8. STANDARD FOUR: HEALTHCARE PROFESSIONAL REQUIREMENTS

- 8.1. DHA licensed General Dentists or Dental Specialists/Consultant aiming to provide Dental Laser services should fulfil the following minimum criteria of training.
- 8.2. The postgraduate fellowship, diploma or equivalent certification must be issued by an institution recognized by the Ministry of Higher Education and comprising of the following:
  - 8.2.1. A postgraduate degree similar or equivalent to a postgraduate diploma or a fellowship, which includes a structured training program as well as a detailed postgraduate curriculum such as but not, limited to, postgraduate programs recommend or offered by the European Society of Oral Laser Application (ESOLA) and the Academy of laser Dentistry (ALD).
  - 8.2.2. The postgraduate fellowship, diploma or Training Certification from an institution or laser academy recognised by the Ministry of Higher Education comprising of the following:
    - a. Theoretical and Practical component.





Acquire a minimum of 125 Continuing Professional Development (CPD)
 hours, at the end of the fellowship/training course and must be equivalent
 to DHA standard of CPD hours of 125.

NOTE: CPD hours obtained at a laser conferences are not part of the active constructive postgraduate training and do not count.

- c. Validated by an assessment at the end of the fellowship/training course.
- 8.3. The General Dentist or Dental Specialists/Consultant planning to provide laser services shall be privileged by the Clinical Privileging Committee of a DHA licensed health facility, which is aligned to his/her education, training, experience and competency. A valid copy of the privilege must be maintained in the General Dentist or Dental Specialists/Consultant's file to be accessible for auditing if required. For further details and alignment, refer to the Clinical Privileging Policy on the <u>DHA website</u>.
- 8.4. General Dentist or Dental Specialists/Consultants are prohibited from practising beyond their scope of laser training; however, if the treatment is outside of the scope of practice, the patient should be referred suitably.
- 8.5. Prior to any clinical application of laser, the General Dentist or Dental Specialists/Consultant must have a thorough knowledge of the operation and safety requirements of the specific laser system and should have received hands-on device specific training related to its practical application.





- 8.6. All General Dentist or Dental Specialists/Consultant should receive recognized ongoing CPD training related to a specific type of Laser (hard or soft) as a part of DHA licensure renewal, aligned with DHA, CPD Guideline.
- 8.7. A minimum requirement of 10 CPD points' for the specific laser type per year must be fulfilled to avoid mandatory retraining.
- 8.8. All the staff or other personnel present within the laser-operating field should be well aware of in the general safety practices applicable to the laser operation. They should also be trained for the following:
  - 8.8.1. The meaning of the labels on the equipment.
  - 8.8.2. The health hazards of the equipment, including effects on eyes and skin.
  - 8.8.3. Procedures to control the hazards.
  - 8.8.4. Quality assurance tests.
- 8.9. To ensure that all safety aspects of laser use are identified and enforced where Class III B and Class IV are operated, a Laser Safety Officer (LSO) shall be assigned. This could be a suitably trained and highly engaged laser team member: dentist, dental assistant, registered nurse or a non-clinical team member. The training could be from any recognised institutions similar or equivalent, to the Laser Institute of America (LIA), National Council of Laser Certification (NCLC).
- 8.10. The LSO training should be documented for audit purpose and should be current and updated.





- 8.11. All personnel involved in operating laser device must obtain LSO certification every two years.
- 8.12. Duties of the LSO include the following:
  - 8.12.1. Be up-to-date with all international, federal and local rules and regulations related to laser use in dentistry.
  - 8.12.2. Ensure that all relevant people abide by the federal and local rules and regulations related to the subject.
  - 8.12.3. Ensure to share and update the information related to laser use in dentistry to all General Dentist or Dental Specialists/Consultant using laser.
  - 8.12.4. Obtain written statements that they have read and understood the federal and local regulations and Laser Safety Policy of the health facility.
  - 8.12.5. Ensure all General Dentist or Dental Specialists/Consultant are up-to-date with the use of lasers and CPD requirements related to the subject.
  - 8.12.6. Confirm classification of the laser used at the dental facility.
  - 8.12.7. Read manufacturers' instructions concerning installation, use and maintenance of the laser equipment.
  - 8.12.8. Ensure that all laser equipment is properly assembled for use.
  - 8.12.9. Oversee laser-controlled area/NHZ and limit access.
  - 8.12.10. Post warning signs in appropriate places.
  - 8.12.11. Ensure only authorized users operate the laser equipment.





- 8.12.12. Ensure all relevant healthcare professionals wear appropriate Personal Protective Equipment (PPE), such as eyewear and protective clothing when providing the laser service.
- 8.12.13. Assume overall control for laser use and interrupt treatment if any safety measure is infringed.
- 8.12.14. Maintain a log of all laser procedures carried out, relative to each patient, the procedure and laser operating parameters.
- 8.12.15. Maintain an adverse effects reporting system, to record any accidents during laser use, which could be due to reflective objects in the path of the beam, movement of the beam path, accidental energizing or firing of the laser, bypass of interlocks etc.
  - The log of adverse effect should be stored and maintained as far as the same dental laser equipment is still in use in the providing facility.
  - b. Adverse effects related to equipment faults should be recorded and reported back to manufacturing company as per their policy and ensure that any equipment failure is resolved before reusing the laser equipment.
- 8.12.16. Oversee maintenance protocols for laser equipment.
- 8.12.17. Maintain the following Policies to related to Laser use, but not limited to:
  - a. Clinical Privileging Policy in accordance to DHA Clinical Privileging Policy.
  - b. Informed Consent in accordance to DHA Informed Consent Policy (for Sample refer to Appendix 3).





- c. Incident Reporting Policy/Adverse effects reporting system, to record any accidents during laser use.
- d. Laser Safety Policy to include establishment of quality assurance program, including regular inspection and maintenance of the laser equipment.

#### 9. STANDARD FIVE: CLASSIFICATION OF LASER EQUIPMENT AND HAZARD EVALUATION

- 9.1. Lasers are classified into four broad areas depending on the potential for causing biological damage **Appendix 4**.
- 9.2. Lasers should be labelled with one of the classification to indicate the class and warn users of their potential hazard.
- 9.3. Types of hazards that could be encountered as a result of laser misapplication, are as follows:
  - 9.3.1. **Ocular Hazards** It is the potential injury to the eye, like retinal or corneal burn can occur either by direct emission from laser or from the reflection from mirror like surfaces. Dental instruments have been capable of producing reflections that may result in tissue damage to both the operator and the patient. The use of carbonized or non-reflective instruments has been recommended during laser treatment.
  - 9.3.2. **Tissue Damage** It is the laser-induced damage to the skin and other non-target tissue (oral tissue) which can result from thermal interaction of radiant energy with tissue proteins. Temperature elevations of 21°C above normal body

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temperature (37°C) can produce cell destruction by denaturation of cellular enzymes and structural proteins, which interrupts basic metabolic processes.

- 9.3.3. **Respiratory Hazards/Environmental Hazards** It is the potential inhalation of air borne material in the form of smoke or plume which may be released as a result of surgical application of lasers or the accidental escape of toxic chemicals or gases from the laser itself. This type of indirect secondary hazards can also be called as non-beam hazards.
- 9.3.4. **Combustion Hazards (Fire and Explosion)** In the presence of flammable materials, laser may pose other significant hazards. Flammable solids, liquids and gases used within the dental surgical setting can be easily ignited if exposed to the laser beam. Toxic fumes released, because of combustion of flammable materials present is an additional hazard. Some flammable materials used in dental clinics are waxes, resins, ethanol, acetone, oxygen, nitrous oxide, general anaesthesia etc.
- 9.3.5. **Electrical Hazards (Shock)** As laser systems involve high potential, high current electrical supplies they are associated with lethal potential associated hazards like electrocution, fire or explosion.

#### **10. STANDARD SIX:** SAFETY AND CONTROL MEASURES

10.1. Safety is integral part of providing any dental treatment with a laser instrument. It covers hazard recognition, device safety, environment, dental team and target tissue of the





patient. Most laser accidents and injuries can be prevented if appropriate controls and precautionary measures are recognized and implemented.

- 10.2. The occupational health and safety of all relevant healthcare professionals and staff in operating or assisting in providing dental laser services should be as per international best practice like the American National Standards Institute (ANSI) standards, ANSI Z136.1 "Safe Use of Lasers" (2018) and ANSI Z136.3 "Safe Use of Lasers in Health Care Facilities" (2018). Understanding and adhering to these guidelines will keep both patients and practitioners safe.
- 10.3. It is the responsibility of the management of the dental clinic that all relevant staff are effectively instructed, periodically trained and supervised (if required).
- 10.4. Healthcare professional providing the laser shall have updated training on the specific laser equipment used for treating patients. It is recommended for the health facility management to retain the staff training records to ensure their competence in safe use of the laser equipment.
- 10.5. Before any laser procedure, the clinician should test fire the laser. This affirms that the laser has been assembled correctly and emission of laser occurs through the delivery system.
- 10.6. Protective eyewear should be worn and all other safety measures should be followed. After which, the laser should be deactivated and the patient should be admitted into the treatment room.





- 10.7. The pre-use equipment check could include the following, a record of which should be maintained:
  - 10.7.1. Electric Safety
  - 10.7.2. Output measures (energy, wavelength, beam profile etc.)
  - 10.7.3. Beam alignment
  - 10.7.4. Beam attenuator/ stop
  - 10.7.5. Beam aim
  - 10.7.6. Accuracy of timer
  - 10.7.7. Interlock operation
  - 10.7.8. Filters
  - 10.7.9. Emergency cut-off
  - 10.7.10. Warning lights
  - 10.7.11. Foot switch operation
  - 10.7.12. Laser safety eyewear assessment
  - 10.7.13. Equipment accessories assessment
  - 10.7.14. Fiber connectors at each end.
- 10.8. The NHZ should be defined subject to the laser wavelength, laser fibre size and beam divergence and should be as per the manufacturer's manual.
- 10.9. All people within the NHZ must wear appropriate Laser Safety Eyewear (LSE), specific to the laser in use. Laser safety eyewear should be labelled/coded to indicate its OD and the





wavelengths it will protect against and should be inspected regularly for degradation of the filter by cracks and pitting **Appendix 5.** 

- 10.10.Shielding may be used as an effective method to avoid inadvertent contact of the beam with tooth enamel or root surfaces.
- 10.11. Appropriate power settings and time frames are essential to reduce the risks of undesirable laser effects on teeth and supporting structures.
- 10.12. For the safe use of lasers in dentistry, control measures are required to reduce the possibility of unwanted exposure of patient and personnel to laser radiation. Four categories of control measures are:
  - 10.12.1. Engineering controls
  - 10.12.2. Personal protective equipment
  - 10.12.3. Administrative and procedural controls
  - 10.12.4. Environmental controls
- 10.13. **Engineering controls** Engineering controls are normally designed and built into the laser equipment to provide safety. Engineering controls such as enclosures, interlocks and beam stops are very effective at eliminating hazards. Some of the important engineering controls are as follows:
  - 10.13.1. **Protective Housing:** A laser shall have an enclosure around it that limits access to the laser beam or radiation at or below the applicable Maximum Permissible Exposure (MPE) level. A protective housing is required for all classes of lasers except, at the beam aperture.





- 10.13.2. **Master Switch Control:** All Class IV lasers require a master switch control. The switch can be operated by a key or computer code. When disabled (key or code removed), the laser cannot be operated. To avoid accidental discharge of laser, the equipment shall be switched to standby mode or turned off, between uses.
- 10.13.3. **Optical Viewing System Safety:** Interlocks, filters or attenuators are to be incorporated in conjunction with beam shutters when optical viewing systems such as telescopes, microscopes, viewing ports or screens are used to view the beam or beam-reflection area.
- 10.13.4. **Beam Stop or Attenuator:** Class IV lasers require a permanently attached beam stop or attenuator, which can reduce the output emission to a level at or below the appropriate MPE level, when the laser system is on standby.
- 10.13.5. Laser Activation Warning System: An audible tone or bell and/or visual warning (such as a flashing light) are recommended as an area control for Class III B laser operation. Such a warning system is mandatory for Class IV lasers.

#### **10.14. Personal Protective Equipment**

- 10.14.1. All individuals within the dental treatment room; the dentist(s), dental assistant, patient and any observers such as family/guardian(s) must wear LSE (goggles, glasses, wraps) Appendix 5. LSE is intended to provide a level of protection that may be used to stare directly into the beam.
- 10.14.2. LSE must fit tightly on the face and should be typically worn over prescription glasses.





- 10.14.3. If glasses are used, they must have a frame with two separate lenses including side shields. Prescription strength glasses can be specially ordered.
- 10.14.4. When selecting the protective eyewear, several factors should be considered.

They are as follows:

- a. Wavelength of laser emission.
- b. Maximum permissible exposure limits.
- c. Degradation of absorbing media or filter.
- d. Optical Density (OD) of the eyewear.
- e. Radiant exposure limits.
- f. Need for corrective lenses.
- g. Multiple wavelength requirements.
- h. Restriction of peripheral vision.
- i. Comfort and fit.

**Note**: OD is one of the most important factors to consider when choosing laser protective eyewear.

#### 10.15. Administrative and Procedural Controls

10.15.1. If General Anesthesia (GA) is administered during any dental procedure, in place of the standard Polyvinylchloride (PVC) intubation tube, a red rubber or silastic tube should be used. For further protection, the tube can be wrapped with  $1/3 - \frac{1}{2}$  inch aluminium tape.





- 10.15.2. Highly reflective instruments and those with mirrored surfaces should be avoided since they cause damage to the non-target tissues.
- 10.15.3. A wax spatula or periosteal elevator can be inserted into the gingival sulcus to serve as an effective shield when using laser on soft tissue near teeth.
- 10.15.4. For most applications, it may be advisable to use low power time settings initially before progressing to higher and faster times.
- 10.15.5. When lasers are not actually been used for treatment or if long pauses occur between use, the unit should be placed in a standby mode to prevent inadvertent firing of the laser beam.
- 10.15.6. Most manufacturers provide a cover or metal hood to prevent accidental activation of the laser beam.
- 10.15.7. The foot switch should be covered to prevent accidental operation and should be cleaned and inspected prior to use to avoid being stuck in a position while operating.

#### 10.16. Environmental Controls

- 10.16.1. Evaluation of environmental hazards involves an assessment of three primary aspects of the laser treatment area that should be considered to establish adequate control measures for the particular application, these include the following:
  - a. Physical environment in which the laser is used
    - I. Laser use should be confined to controlled areas with restricted access.





- II. Use of protective laser curtains should be considered to prevent accidental exposures to passers-by.
- III. Fail-safe mechanisms that prohibit the laser from firing when doors are opened are also useful to prevent accidental exposure to persons entering the operating room during laser procedures.
- IV. All entrances to the rooms where laser is used should be clearly marked with a warning signs.
- V. Highly reflective instruments and surfaces should be avoided to prevent reflection of the laser beam onto the non-target tissues.
- b. Potential for injury attributed to direct exposure from the laser beam output and delivery mechanism.
  - To avoid an electrical hazard during the operation of the laser unit, the floor of the operating room must be kept dry.
  - Because laser energy generates heat, care must be taken to avoid the use of flammable and explosive liquid or gases in the operating room.
  - III. Flammable materials such as surgical drapes and gauze sponges may be soaked in sterile saline to reduce the potential of burning by accidental exposure to the laser beam.
- c. Level of training and knowledge of laser safety of the persons.





I. All staff members should receive recognized ongoing training/ Continuing Professional Development (CPD) in the safety aspects of laser use within dentistry, as with other specialties.

#### 11. STANDARD SEVEN: STERILIZATION AND INFECTION CONTROL

- 11.1. Steam sterilization is the standard of care for laser in dentistry.
- 11.2. The small flexible optic fibers, hand-pieces or tips must be steam sterilized and stored in separate sterilization pouches after each use and until ready for next use.
- 11.3. When using fibre-optically delivered lasers it is vital that the port (connecting) end remains clean and oil-free. Therefore, never run the fibre in a sterilizer cycle alongside a high-speed turbine with lubricant.
- 11.4. If an instrument was used to cleave or recleave a fibre during or after a procedure, then it also must be steam sterilized.
- 11.5. The protective housing around the laser, including the control panel and articulating arm (if applicable) should receive the spray disinfectant/wipe/spray disinfectant decontamination method, as do the dental cart and counter tops. Some delivery system components such as the large-diameter Erbium fibre-optic cable are not designed for steam sterilization and must be disinfected in this way.





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#### APPENDICES

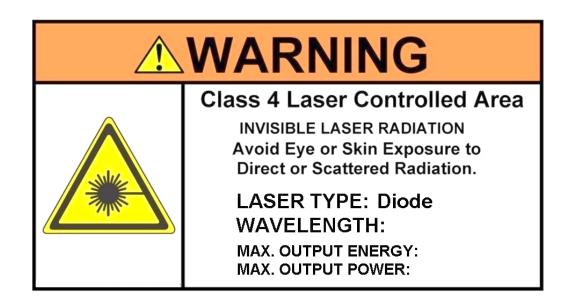
#### **APPENDIX 1:** EXAMPLES OF CLINICAL APPLICATION OF LASERS IN DENTISTRY

LASER TYPE	APPLICATION					
ND: YAG	Soft Tissue and Periodontal Surgery,					
	Root Canal Treatment,					
	Desensitization					
	Analgesia					
CO2	Major and Minor Oral Soft Tissue and Periodontal Surgery					
Diode	Diagnostic,					
	• PAD					
	Tooth Bleaching					
	Periodontal Surgery					
	Endodontics					
КТР	Tooth Bleaching					
	Soft Tissue Surgery					
	Endodontics					
ER, Cr: YSGG	Soft Tissue Surgery					
Er: YAG	Tooth Cavity Preparation					
	Bone Surgery					
<b>NOTE:</b> Certain overlap in clinical application may exist.						





#### **APPENDIX 2:** WARNING SIGN FOR LASER







#### **APPENDIX 3:** SAMPLE OF INFORMED CONSENT FOR LASER DENTAL PROCEDURES

#### Informed Consent for Periodontal Laser Surgery in Dentistry

#### It is important that you understand the following information:

The goal of the laser procedures is to eliminate or remove gum tissue to either improve the appearance of the smile or gain access to a tooth that has not erupted. Generally, laser treatment results in improvement in the intended condition but occasionally the procedure will need to be repeated to get the desired outcome.

#### Alternatives:

There are alternatives to using the dental laser. Those could include more conventional scalpel surgery in the office of another dental professional at an additional fee. Frequently those procedures will involve sedation, which may be helpful in a very apprehensive patient. If you would rather pursue an alternative treatment, please let Dr. Sherick know and he would be happy to discuss those alternatives with you. There is always the option of having no treatment performed though it may compromise the final treatment result.

#### Possible Intraoperative Complications:

1. Burns – There is a risk of accidental injury by the laser energy, which could cause permanent scarring; however, this is very unlikely because the laser energy is carefully metered and contained.

2. Eye Damage – Injury of the eyes is possible if you look into the laser beam. We will provide eye protection that will prevent this but it must be in place at all times when the laser is in operation.

#### **Possible Short-Term Effects of Laser Dental Treatment:**





- 1. Pain or a burning/itching sensation may occur for a few days after treatment. A topical anesthetic and occasionally a local anesthetic will be used to block discomfort during the procedure but occasionally you may still notice discomfort during the procedure. Let Dr. Sherick know and he can administer more anesthetic if needed. The numbing effects of the anesthetic may continue to be felt after the procedure so be careful to avoid lip or cheek biting.
- 2. Redness/Inflammation/Swelling of the tissue will likely be noticed for the first few days. The tissue surrounding the sight of the procedure may feel "tight".
- 3. Wound Healing– Oozing of the tissue in the treated area will usually persist for a short time.
- 4. Allergies– You may experience an allergic reaction to the anesthetics used. If so, please contact the dental clinic.
- 5. You may have a recurrence of a "fever blister" or Herpes Simplex Dermatitis.
- 6. Tissue Hyperpigmentation You may experience a transient darkening of the tissue in the area especially in dark skinned people.
- Tissue Hypopigmentation You may experience lightening of the skin in the area which can be permanent.

#### Possible Long-Term Complications of Laser Dental Treatment:

- Scarring The risk of scarring exists. It is variable and often related to genetic makeup. It can be minimized by carefully following appropriate aftercare instructions.
- 2. Tissue Pigment Changes Soft tissue colour and texture changes may occur. At the junction of treated and untreated areas, a difference in colour, texture, and/or thickness may appear.





 Infection – There is a risk of infection common to all surgical procedures. It can be minimized by proper post-operative care.

#### Anesthetics Employed:

Topical anesthetic will be used either alone or occasionally in combination with an injected local anesthetic. Because of this, certain precautions must be taken:

- 1. The patient must be careful to avoid biting or chewing on the tongue, lip, cheek, or other parts of the mouth when they are numb.
- 2. The anesthetic may make swallowing seem more difficult though the sensation will improve after the effect wears off.
- 3. Let the attending Dentist know if you have ever had an adverse or allergic reaction to anesthetics used in a dental office.
- 4. Let the attending Dentist know if you are or suspect you are pregnant or are breastfeeding.

#### Patient Consent: I understand that:

- Any application of excess heat to the treated area must be avoided for 2-3 days to minimize bleeding and promote healing
- 2. This is an elective procedure and the treatment is not reversible.
- 3. More procedures may be needed to achieve the optimal obtainable result.
- 4. The practice of dentistry and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the results of the procedure. It is not possible to state every complication that may occur because of laser dental surgery. Complications or a poor outcome may manifest weeks, months, or even years after the surgery.

Standards for Laser in Dentistry





I understand this explanation of laser dental surgery and its risks, benefits, and alternatives. I have
had an opportunity to have my questions answered regarding the proposed procedure. I therefore
give consent to having the laser dental surgery.

Patient Name (print):	
Patient/Parent Signature:	Date:
I have been offered a copy of this consent form (initial):	
Witness Signature:	_Date:

#### **APPENDIX 4: LASER CLASSIFICATION AND RELATIVE RISK ANALYSIS TO TISSUE**

	INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)		Short Time Exposure (t)		Long Time Exposure (T)		Skin
INTERI		Magnified	Unprote	Magnified	Unprotect	reflection	exposure
	LASER CLASSIFICATION		cted eye	Exposure	ed eye	ofbeam	to beam
ClassI	Incapable of causing injury during normal operation.	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Class I M	Incapable of causing injury during normal operation, unless	*		*	$\checkmark$	$\checkmark$	$\checkmark$
	collecting optics are used.	THE	$\checkmark$	T	Y	Y	V
Class II	Visible lasers incapable of causing injury in 0.25 s.	$\checkmark$	$\checkmark$	*	*	$\checkmark$	$\checkmark$
Class II M	Visible lasers incapable of causing injury in 0.25 s, unless			W	*		$\checkmark$
	collecting optics are used.		$\checkmark$	*		$\checkmark$	V
Class III R	Marginally unsafe for intrabeam viewing; upto 5 times the						
	Class II limit for visible lasers or 5 times the Class I limit for			*	*	$\checkmark$	$\checkmark$
	invisible lasers.						
Class III B	Eye hazard for intrabeam viewing, usually not an eye hazard			W			
	for diffuse viewing.	*	*	*	*	<u>_!</u>	<u>/!</u>
Class IV	Eye and Skin hazard for both direct and scattered exposure.	*	*	*	*	*	*



- No risk from exposure to laser beam; 🕂 - Caution required to prevent exposure to beam;



- Maximal protection required. Laser beam is dangerous







#### **APPENDIX 5:** LASER SAFETY PROTECTIVE EYE WEAR/GLASSES

	Laser sa	es of Lasers	
1.	810 Diode laser safety glasses (most common)	Protect from 810nm lasers and typically offer protection in a range that spans from 800-830nm. They offer excellent VLT and have light yellow lenses.	
2.	YAG laser safety glasses (have plastic lenses)	Offer protection for lasers operating at 1064nm and generally protect from 900-1100nm. They have green lenses and offer good VLT for dental procedures.	
3.	CO2 laser safety glasses	Protect from CO2 lasers operating at 10,600nm. While dentists less typically use these lasers, they are used for some dental procedures. They offer extremely good VLT and seem very clear.	

Standards for Laser in Dentistry