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Development of a proposed Laser Safety Protocol (LSP) for the prevention of eye and skin hazards in Biomedical Laser facilities

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Abstract
Usage of LASER radiation applications is very widespread in numerous specific areas of Biomedical Sciences with proven clinical and treatment results. Furthermore, the apparatus used in Biomedical applications are classified in highest power and danger categories (class 3B or 4). Thus, establishing and keeping necessary laser safety measures is crucial for the assurance of health, safety, ergonomics conditions and specially for the prevention of eye and skin hazards, both for biomedical scientists and patients in health and care units of any scale. To our knowledge, the existing protocols in relevant literature, are quite limited and depict only the basic Laser Safety guidelines. The subject of this study is the development of a complete and detailed Laser Safety Protocol to be implemented in all biomedical facilities. The novelty of the proposed LSP is that it is formulated both in extended verbal instructions and, principally, in a “matrix form”, well defined procedure.

KEYWORDS
biomedical sciences; laser safety protocol; eye and skin hazards

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1. INTRODUCTION

During the past few decades, the implementations, both surgical and non-invasive, of laser radiation in biomedical sciences have become very wide-spread, due to the unique advantages and the characteristic features of laser radiation, compared

to other light sources. These characteristic properties of Laser radiation are depicted in the terms of high monochromaticity, directionality, intensity and coherence. Nevertheless, the same properties that constitute the advantages of LASER radiation are also responsible for its great hazardousness [1,2,3]. The consideration of this fact becomes more crucial, especially after realizing that the Laser devices used in Biomedical applications are of the highest power and danger categories (class 3B or 4), [4,5].

For this reason, many countries worldwide have enacted official rules and regulations in order to ensure the safe use of Laser radiation in Biomedical facilities [6,7,8], (IEC60825-1, IEC60825-2, IEC60825-4, IEC60825-6, IEC60825-7, IEC60825-12), USFDA Code of Federal Regulations (art.21, vol.8)", "ANSI Z136.1 (American National Standard Institute)" for instance.

2. MATERIALS AND METHODS

The purpose of the present study is to develop a complete and detailed Laser Safety Protocol to be implemented in all biomedical facilities [9,10], in order to minimize the risks for the health (mainly eye and skin hazards) of any person involved, patients, doctors, biomedical scientists, nurses, attendants, and maintenance staff. The novelty of the hereby proposed LSP is that it is formulated both in extended verbal instructions and, principally, in a, well defined, Yes/No "matrix" procedure.

The below proposed complete Laser Safety Protocol is structured in a detailed 3-part matrices: In the first part, the main technical characteristics of the LASER device are depicted. The other two parts are structured in a form of a YES/NO questionnaires, which perform an extremely detailed investigation of both the device and the facility safety prerequisites.

The hereby proposed Laser Safety Protocol is intended to be suitable for implementation in all Biomedical facilities and with the use of which, the Laser Safe Officer (LSO) or Laser Safety Inspector (LSI) would have the ability to check in detail the compliance or not with the international widely accepted requirements and specifications of LASER safety operation.

3. RESULTS

The following well established and worded in detail series of procedures form the first part of the proposed Laser Safety Protocol-LSP. It is formulated in extended verbal instructions, that provide practical and easy use in clinical biomedical applications and it is quite similar to the existing, "traditional" Laser Safety Protocols. The instructions have been grouped in such a way as to include all aspects of the use of medical lasers in clinical settings. They are used as a quick reference guide for developing and implementing a Laser safety program that will comply with existing standards.

3.1. "LSP" procedure-VERBAL:

- All personnel (device operators, nursing staff, Laser Safety Officer, etc.) should be aware of the area of use of the Lasers and there should be controlled access to these areas.
- The nominal hazard zone (NHZ) must be defined in such a way as to avoid inadvertent exposure to the laser beam.
- The personnel inside the NHZ must be exclusively authorized.
- These personnel must be informed about the protective measures to be taken.
- There must be appropriate signage posted at all entrances to warn bystanders of potential hazards.
- The doors to the NHZs should remain closed and the windows covered.
- Everyone inside the NHZ must wear appropriate safety glasses which have been approved by the Laser Safety Officer (LSO).
- The protective glasses must be suitable for the wavelength of the emitted beam and be marked with optical density.
- The patient's eyes and eyelids should be protected respectively with glasses, liquid pads or metal/plastic eye-shields.
- Exposure to smoke produced during laser surgery should be limited by the use of mechanical controls.
- High filtration surgical masks.
- Wall absorption units with filters.
- Smoke extraction units.
- Microparticles of tobacco cause bacterial and viral infection. There is also the potential for mutations and possible carcinogenicity.
- All persons in the treatment area should be protected from exposure to eye, skin and other non-target tissues.
- The exposed tissues around the area where the laser operation is performed should be protected by using saturated aqueous solutions which will also slow down the fire.
- Anodized, non-reflective or matte instruments should be used near the surface where the beam is incident.

- When an optical fiber is used to carry the laser beam through an endoscope, the end of the fiber must extend beyond the end of the endoscope because most endoscope covers are flammable and easily destroyed by the emitted heat.
- All persons in the treatment area should be protected from the ignition hazards that a Laser may cause.
- Fire is one of the major hazards of laser use. Intense heat can ignite flammable solids, liquids and gases.
- Free flow of oxygen can lead to rapid spread of fire.
- Fire extinguishers and water/saline should be readily available.
- Endotracheal tubes used should have protection to minimize fire hazards. This is because standard endotracheal tubes are flammable.
- All personnel should be protected from electrical hazards associated with Laser use.
- Visual inspection of the equipment should be done after the device is set up for use.
- The documents with the regular maintenance and repair work of the device should be present. The Laser Safety Officer (LSO) should review and approve the use of the equipment after maintenance.
- All personnel (device operators, nursing staff, Laser safety officer, etc.) should be educated and update their knowledge and skills.
- Education and training programs should be specific to the Laser devices and applications made in the specific clinical environment.
- Laser safety policies and procedures should be developed in relation to the individual applications being made, as well as accepted standards / protocols.
- Periodically reviewed and revised versions should be available and readily available to staff.
- Establishment of guidelines for Quality Assessment.
- Committee on Laser Safety - Administrative and Procedural Controls.
- Education and Training Programs.
- Medical Surveillance and Safety Audits.
- Equipment Maintenance (Laser Service and Maintenance).

3.2. "LSP" procedure-MATRIX”

In this part of the proposed Laser Safety Protocol we present the specific feature of LSP in which, we believe, the great novelty and originality of our method is found.

The Laser Safety Officer (LSO) or Laser Safety Inspector (LSI) is supposed to visit the Biomedical Laser facility, where the apparatus is placed, and perform an autopsy to investigate the compliance or not with the official legislation and regulation requirements of LASER safety operation.

As mentioned above, the inspection is principally formulated, in a “matrix form”, well defined procedure.

First, in a preliminary matrix, we report the technical characteristics of the Laser device under inspection, as they are listed in the manufacturer's user manual.

Subsequently, the main matrix is divided in two parts, A and B. Part A focuses on the device and user characteristics and part B investigates the facility standards, meaning the prerequisites of the area where the Laser apparatus is placed. In the left column of the matrix, the prerequisite safety criteria are depicted and in the right column is examined the degree of compliance of each criterion, in a Yes / No form. In addition, the matrix is designed in a way that also allows the inspector to imprint his own comments regarding, both, the overall safe operation of the device and the adequacy of the facility.

The matrix consists of nearly 70 different requirements that provide an extensively detailed inspection.

This “LSP-matrix” is presented below:

LASER SAFETY PROTOCOL - (LSP)

DEVICE TECHNICAL CHARACTERISTICS

Manufacturer:
Model:
Serial Number (S/N):
Type: (Diode, Alexandrite, CO_2, etc.)
Wavelength(s) (nm):
Operating mode: (CW, Pulsed, etc.)
Hazard category (class): (3B or 4)
Energy density (J/cm^2):

Max. Power (W):	
Pulse Repeatability (Hz):	
Pulse Duration (msec):	
Facility-Place of installation:	

COMPLIANCE WITH SAFETY SPECIFICATIONS & REQUIREMENTS

A. DEVICE SAFETY STANDARDS	
A.1. User and Safe Operation Manual:	Y/N
A.2. Device certification (compliance with Greek legislation and international regulations):	Y/N
A.3 Protective Housing:	Y/N
A.4 Access Prevention:	Y/N
A.5. Beam Delivery System:	Y/N
A.6. Beam Delivery Disconnect:	Y/N
A.7. Key-Switched Master Control:	Y/N
A.8. Remote Interlock Control Connector:	Y/N
A.9. Beam Shutter:	Y/N
A.10. Fire Prevention:	Y/N
A.11. Electrical circuit breaker:	Y/N
A.12. Safe Operation Precautions:	Y/N
A.13. Corrosion Precautions:	Y/N
A.14. Eye protection:	Y/N
A.15. Power On/Off Switch:	Y/N
A.16. Software Protection:	Y/N
A.17. Emergency cutoff switch:	Y/N
A.18. Semi-automatic circuit breaker:	Y/N
A.19. Laser beam emission indicators:	Y/N
A.20. Remote Lock Sensor:	Y/N
A.21. Ventilation system:	Y/N
A.22. Cooling system:	Y/N
A.23. Skin cooling system:	Y/N
A.24. Tags / Apparatus Marking:	Y/N
A.25. Operation, Maintenance and Repair:	Y/N
B. FACILITY SAFETY STANDARDS	
B.1. Safe placement:	Y/N
B.2. Protective housing:	Y/N
B.3. Beam barriers:	Y/N
B.4. Enclosed beam:	Y/N
B.5. Remote beam observation:	Y/N
B.6. Focused beam:	Y/N

B.7. Beam power reduction filters:	Y/N
B.8. Adequate lighting:	Y/N
B.9. Use of optical fibers:	Y/N
B.10. Window coverings:	Y/N
B.11. Beam management documented:	Y/N
B.12. Reflective materials remote from the beam path:	Y/N
B.13. Diffuse reflected beam hazard (Class 4):	Y/N
B.14. Authorization updated:	Y/N
B.15. Authorization posted:	Y/N
B.16. Standard Operation Procedure-(SOP):	Y/N
B.17. Standard Operation Procedure posted:	Y/N
B.18. Communication in an emergency event:	Y/N
B.19. User and safe operation manual available:	Y/N
B.20. Proper operator training:	Y/N
B.21. Appropriate eye protection (goggles of minimum proposed optical density OD 5+ or 6)	Y/N
B.22. Appropriate skin protection	Y/N
B.23. Adequate room ventilation / Mask usage (recommended retention value for suspended particles with a diameter of 5-10 μm):	Y/N
B.24. Space ventilation system (removal of combustion/sublimation microparticles, suggested value 500 lt/min):	Y/N
B.25. Hazards from nearby flammable materials:	Y/N
B.26. Hazards from toxic media and dyes:	Y/N
B.27. Dangers from refrigerants and compressed gases in general:	Y/N
B.28. High voltage hazards:	Y/N
B.29. Therapeutic bed grounding:	Y/N
B.30. Hazards from other sources of indirect radiation:	Y/N
B.31. Explosion hazards:	Y/N
B.32. Fire hazards:	Y/N
B.33. Water supply:	Y/N
B.34. Fire extinguisher:	Y/N

4. DISCUSION & CONCLUSIONS

A complete and detailed Laser Safety Protocol (LSP) has been developed and presented in this study. Its originality and novelty lie in the fact that it isn't restricted in verbal instructions only, but it is mainly structured in a two part "matrix form" which include multitudinous different prerequisites and criteria, that provide an extensively detailed inspection.

We believe that the hereby developed LSP is easy to report and provides a brief, yet holistic evaluation. The audit is conducted by Laser Safety Officer (LSO) or Laser Safety Inspector (LSI), who examines whether the Biomedical Laser device, user and facility under consideration, fully meets all the international requirements and specifications of safe operation.

Most presumably, the next step of our research is the proposed LSP to be practically implemented in actual Biomedical Laser facilities. In this way, its so claimed advantages would be checked and it would possibly be supplemented with new criteria.

Furthermore, it is obvious that there is still thorough research needed, concerning the crucial subject of Laser Safety Protocols, so that maximum assurance of the health of all implicated personnel can be obtained.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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