

Medical Laser Product Compliance

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Objectives

- ❑ **Laser in Medical Applications**
- ❑ **Type Of Medical lasers**
- ❑ **Laser Class and Hazard**
- ❑ **Laser Classification Responsibilities**
- ❑ **Laser Product Compliance Schemes**
- ❑ **Factors and conditions affecting Laser Classification**
- ❑ **Classification Criteria**
- ❑ **Laser Controls**



Laser in Medical Applications

- **Cosmetic dermatology:**
 - scar revision, skin resurfacing, laser hair removal, tattoo removal
- **Ophthalmology:**
 - Cleaning vision complication after cataract surgery or Lasik
 - Refractive surgery to correct vision or Reattaching detached retinas
 - Treatment of diabetic retinopathy to forestall blindness
- **Dentistry and oral surgery**
- **Surgery and plastic surgery**
- **Cancer diagnosis and treatment**

Type Of Medical lasers

❖ Based upon the intensity of emission radiation

1. Soft Laser - Class I (0.5 mW) or Class II (1 mW)
 - Weak emission and acts on the surface (e.g. dermatology)
2. Mild Laser – Class IIIa (1 – 5mW) or Class IIIb (5 – 500mW)
 - Medium emission and uses for treatment of deeper tissues (e.g. Scanning)
3. Power Laser – Class IV (> 500mW)
 - Strong emission and uses in surgery (e.g. cut, coagulate, evaporate tissues)

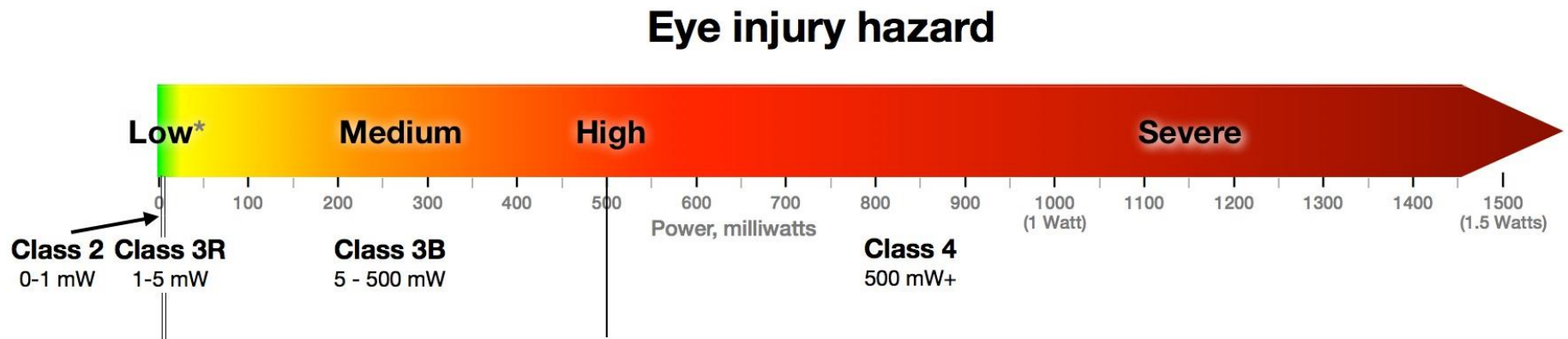
Laser Class

The class of a laser product indicates to the user of the potential of the accessible laser radiation for causing injury.

CLASS	US: FDA/CDRH	IEC 60825 (AMENDMENT 2)
Class 1	<ul style="list-style-type: none"> No known hazards during to eye or skin <i>during normal operation</i> Note: Service Operation may require access to hazardous embedded lasers 	
Class 1M	N/A	<ul style="list-style-type: none"> No known hazards to eye or skin, unless collecting optics are used
Class 2a	<ul style="list-style-type: none"> Visible lasers not intended for viewing. No known hazards up to maximum exposure time of 1000 seconds 	N/A
Class 2	<ul style="list-style-type: none"> Visible lasers No known hazard with 0.25 seconds (aversion response) 	
Class 2M	N/A	<ul style="list-style-type: none"> No known hazard with 0.25 seconds (aversion response) unless collecting optics are used
Class 3a	<ul style="list-style-type: none"> Similar to Class 2 with the exception that collecting optics cannot be used to directly view the beam Visible only 	N/A
Class 3R	N/A	<ul style="list-style-type: none"> Replaces Class 3a (with different limits) 5 x Class 2 limit for visible 5 x Class 1 limit for some invisible
Class 3B	<ul style="list-style-type: none"> Medium-powered (visible or invisible) Intrabeam and specular eye hazard Generally not a diffuse or scatter hazard Generally not a skin hazard 	
Class 4	<ul style="list-style-type: none"> High powered lasers (visible or invisible) Acute eye and skin hazard intrabeam, specular and scatter conditions Non-beam hazard (fire, toxic fumes, etc.) 	



Laser Class hazard



Classification Responsibilities

❖ **Manufacturers:**

- Specify the application the laser product.
- Determine the effective class of the laser product.
- Provide correct classification of a laser product.

❖ **Test Agencies (e.g. CSA, UL, TUV, Intertek, etc)**

- Perform evaluation to determine the effective class of the laser based on the level of its accessible emission in accordance with IEC 60825-1 and may be also with IEC 60601-2-22.
- Issue IEC test report and certificate upon manufacturer's request.



Laser Product Compliance Schemes

❖ **FLPPS/CDRH 21 CFR 1010 and 1040**

- For countries that recognize U.S. FLPPS. This should be considered once the laser product is only sold in U.S.

❖ **IEC 60825-1**

- For countries that recognize IEC 60825 series. This should be considered once the laser product is only sold in Europe.

❖ **IEC 60601-2-22**

- Class 3B and Class 4 medical laser products (e.g. surgical, therapeutic, medical diagnostic, cosmetic)
- Class 3B or Class 4 laser products for veterinary applications.



Laser Product Compliance Schemes (cont.)

❖ **FLPPS/CDRH + Laser Notice # 50**

- For international market. This scheme should be considered. It meet requirements for all countries that have national standards.
- IEC 60825-1 Ed. 2 and IEC 60601-2-22 Ed. 3 are the alternative method for meeting FDA/CDHR requirements.

❖ **FLPPS/CDRH + Laser Notice # 56**

- FDA has not harmonized the requirements of 21 CFR Part 1040 through rulemaking with those of the IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 standards.
- IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 are not the alternative method for meeting FDA/CDHR requirements.



Classification - General

- ❖ The class of a laser product gives an indication to the user of the potential of the accessible laser radiation for causing injury.
- ❖ Classification of a laser product is based on:
 - Determination of the accessible emission level and comparison of that level with the accessible emission limit (AEL) associated with each class.
 - The maximum level of laser radiation that is accessible during conditions of normal operation.
 - The evaluation for determining classification shall include consideration of any reasonably foreseeable and Single-fault condition during operation.

Factors affecting Laser Classification

- Wavelength
- Continuous Wave or Pulsed Operation
- Power or Pulse Energy
- Repetition Rate (PRF)
- Beam Divergence
- Beam Diameter and Profile



Conditions affecting Laser Classification

- **In normal operation**
 - Start-up
 - stabilized emission
 - shut-down of the laser
- **In maintenance and service**
 - configuration that operation may require removal of portions of the protective housing and defeat of safety interlocks.



Classification Criteria

- **Classification of the accessible emission radiation based on:**
 - Combination of Output power and wavelength and time base.

- **Continuous wave (CW) or repetitively pulsed laser**
 - The average power output (Watts)
 - limiting exposure time (sec)

- **Pulse Lasers**
 - The total energy per pulse (Joule)
 - pulse duration
 - pulse repetition frequency
 - Emergent beam radiant exposure

Laser Controls

❖ Engineering

- Protective Housings
- Remote Interlocks / Interlocked doors
- Access Panels
- Master key Switches
- Enclosed beam baths
- Beam attenuators/stops
- Activation warning system



Laser Controls (continued)

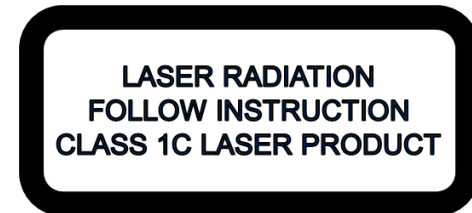
❖ Documentation

- Accompanying document – operational manual or user manual
- Standard Operating procedures
- Maintenance procedures
- Administrative procedures
- Alignment procedures

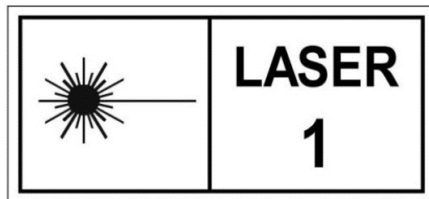


Laser Controls (continued)

❖ Labelling per IEC 60825-1: 2007 (2nd Edition)

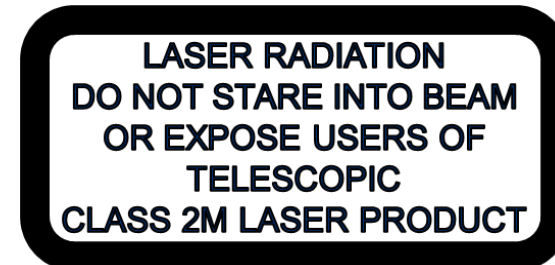


❖ Alternative Labelling per IEC 60825-1: 2014 (3rd Edition)

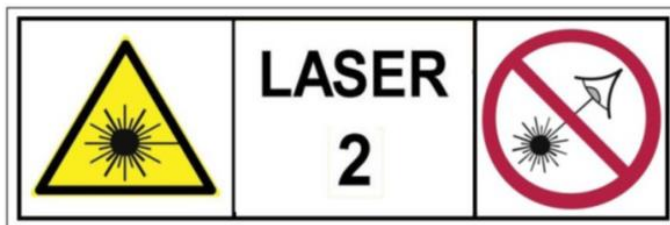


Laser Controls (continued)

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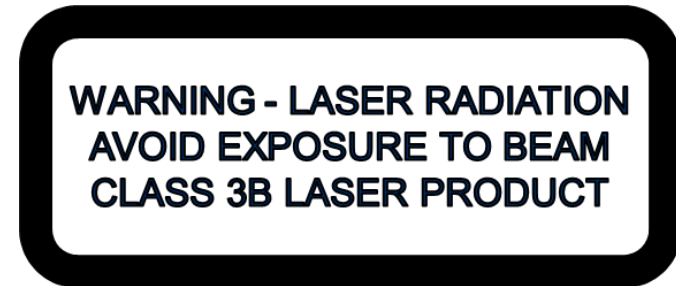
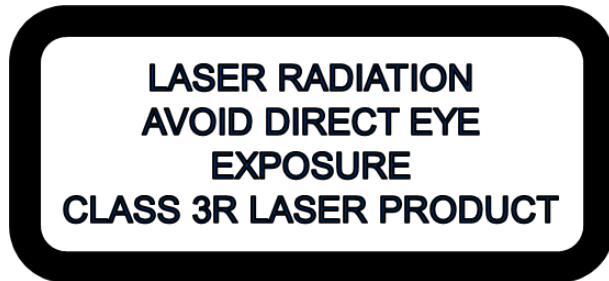


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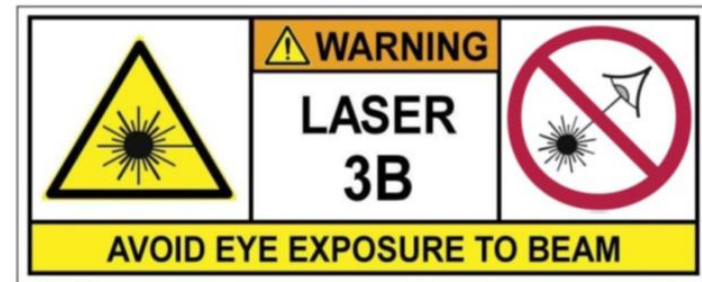


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- ❖ Labelling per IEC 60825-1: 2007 (2nd Edition)

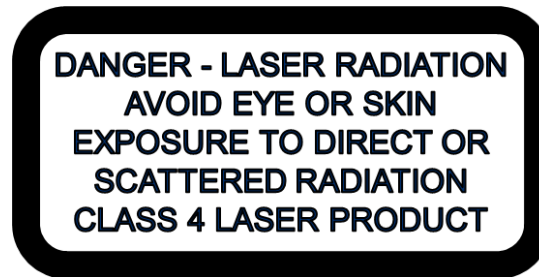


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Laser Controls (continued)

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ONE WORLD ◦ OUR APPROVAL

Thank you!

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