

Safety

Relieve pain and suffering and above all else, DO NO HARM...

We at LazrPulsr System consider **SAFETY** to be the **FIRST** and **PRIMARY** above all else. Therefore we take great measures to insure that the LazrPulsr Therapy Systems are among the safest therapeutic lasers on the market today.

Classification of Lasers:

Direct illumination of any light source to human tissue especially the eyes posse's potential risk. Therefor, the FDA has determined the risk factors based on wavelength (color), Power Density (brightness), and collimation (size of tissue area being exposed) and placed them into different classes. The higher the classification numbers the greater the risk. For example:

Class I Light Source: This is considered extremely safe and has few if any restrictions. This classification does not include Lasers, only LED light sources.

Class IIIa: Light therapy devices that utilize lasers within the visible light range and have an optical power density less than 5mW per laser are considered low risk for human use and classified by the FDA as a Class IIIa light emitting device. This is the same classification as all laser pointers.

Class II Medical Physical Therapy Device: The FDA also determines the medical product classification by risk factors. Light therapy devices utilizing Class IIIa lasers such as the LazrPulsr 4X, are classified as a Class II medical therapy device used for physical therapy.

Class IIIb & Class IV: Light therapy devices that utilize infrared or ultraviolet wavelengths and/or have an output of 5mW or greater are considered to pose a significant health risk and are classified as a Class IIIb or Class IV laser. For example, the FDA does not recommend direct exposure, even to skin, for Class IIIb lasers.

The LazrPulsr 4X contains fully collimated true semiconductor laser diodes which produce 635nm wavelength light of the visible range. Each laser diode is powered with less than 5mW of power which makes the LazrPulsr 4X a;

Class IIIa laser device, and

Class II Medical Device for Physical Therapy and for sale by prescription only.