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**OPTICAL SAFETY EVALUATION OF LITEBOOK™ ILLUMINATOR**

Litebook Elite with Enhanced Diffusion (E208422)

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**Executive Summary**

This report provides a safety analysis of human ocular exposure to the visible radiant energy emitted by light emitting diodes (LEDs) employed in the Litebook™ Elite Illuminator with Enhanced Diffusion. The Litebook™ Elite is a light-weight, highly portable, table-mounted unit with a well-diffused array of 24 light-emitting diodes (LEDs) to provide supplemental light for the purpose of phototherapeutic treatment or for correcting the body's natural "biological clock." The report provides measurements of the ocular exposure to an individual using the unit under normal conditions and even under unusual (worst-conceivable case) viewing condition.

This report explains the applicable safety standards used in the US, in Europe and internationally, and provides a comparison of the LED output with those safety standards. Since the LED source dimensions influence the ocular safety, the source size and distribution of sources were measured. This product was improved over the standard Model 2 with the design of an improved, projection optic in the diffusing Reflexite polycarbonate cover, which increases the retinal image size and reduces the brightness of individual LEDs. For reasonable viewing durations of up to 20-45 minutes a day, where the eye is not stationary a margin of safety exists. Under such use, the margin of safety over the exposure limits (ELs) is more than three-fold.

It is therefore concluded that the Litebook™ Elite illuminator with enhanced diffusion is safe for use with appropriate instructions to limit viewing duration and not stare directly at the source; and, based upon current knowledge, it would not be possible for a person to sustain an eye injury from this equipment without unrealistically long viewing durations and steady fixation. The user should be cautioned to discontinue use if persistent afterimages are experienced.



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