BLUEWAVE SAFETY & EFFECTIVENESS

Why don't other companies use BLUEWAVE Technology?

BLUEWAVE™ is patented, which means that other companies don't have access to its technology. None of these other companies has participated in published research in light therapy and haven't paid the price for advancing light therapy technology. Most light therapy companies have been content with putting a full-spectrum lamp in a light box and calling it "light therapy." Because this technology is expensive and specialized, other companies don't have the ability to manufacture it.

Safer than Shade

Experts agree that fully shaded outdoor light is completely safe. BLUEWAVE light is the same as the level of naturally occurring blue light in full shade. And because BLUEWAVE isolates the effective bandwidth of light, all UV and near UV light is never produced. Full spectrum light, by comparison, must use specialized filters to block harmful UV light.[1]

BLUEWAVE™ vs. 10,000-lux

Fluorescent lamps do not naturally produce the effective bandwidth of light, and so their intensity must be increased to 10,000-lux in order to produce a therapeutic benefit.[2] In addition, because BLUEWAVE isolates the effective bandwidth of light, its overall intensity is more than 25 times lower than traditional full-spectrum, 10,000-lux light. Because BLUEWAVE is 1/25 th as intense as standard full-spectrum technology, side effects are not common with BLUEWAVE light.

Ocular Safety Review

BLUEWAVE™ is the only technology that has been subjected to and passed an FDA ocular safety review.[3] BLUEWAVE™ also passes ICNRIP/ACGIH threshold value limits at only 15%[4] (Radiation exceeding 100% is considered potentially hazardous).[5] Also, the NIH's consultant ocular physicist, Dr. David Sliney, has tested and confirmed BLUEWAVE's safety.[6]

Additional Considerations

BLUEWAVE light has been conclusively shown to be the 'action spectrum' of light.[7] This means that of all the wavelengths of light, humans respond to 470 nm light. If this wavelength were unsafe, humans would have naturally adapted over eons of time to a different wavelength of light. The fact that mankind has adapted to 470 nm light is further testament to its safety and effectiveness.

BLUEWAVE™: Clinically tested and Published

BLUEWAVE™ has been clinically proven effective and published in Chronobiology International.[8] This clinical trial specifically investigated the **antidepressant effect** of BLUEWAVE™ light. In addition to this study, several published studies have confirmed 470 nm light to be the most effective wavelength. 470 nm light is advocated by Harvard, Thomas Jefferson, Rush Presbyterian, Rensselaer Polytechnic and several others.

Conclusion

BLUEWAVE Technology is the most thoroughly tested light therapy technology for safety and effectiveness. Several studies have confirmed that 470 nm light is the 'action mechanism' in treating circadian rhythm disorders that result in SAD, sleep, depression and other circadian rhythm problems. In addition, BLUEWAVE™ has been proven safe and effective at shifting circadian rhythms and yielding an antidepressant response.

References & Notations

1. Society for Light Treatment and Biological Rhythms. Consensus statements on the safety and effectiveness of light therapy of depression and disorders of biological rhythms. Light Treatment Biol Rhythms. 1991;3:45-50

2. http://www.lrc.rpi.edu/programs/NLPIP/lightingAnswers/fullSpectrum/comparisons.asp

3. Brainard, G. et al. National Institutes of Health Final Report: Blue LED Light Panel for Treatment of Winter Depression Ref # 1R43MH066453 December 2004

4. **ICNRIP** : International Commission for Non-Ionizing Radiation Protection. The ICNRIP is a body of leading independent experts who deal with potential health hazards arising from radiation exposure, including optical radiation from ultraviolet, visible and infrared light.

   http://www.icnirp.de/what.htm

   ACGIH : The American Conference of Governmental Industrial Hygienists. Industrial hygiene refers to the health of industry workers, and the preventative medical measures used to protect workers. The ACHIH publishes over 400 reference works that list the “Threshold Limit Values” for chemical and biological safety.

   http://www.acgih.org/about/history.htm

5. Published reports of ocular damage have resulted from intensities far in excess of the Threshold Limit Values for light, as determined by the ICNRIP/ACGIH. These independent experts have not only reviewed thousands of light safety studies including blue light, but they also have the benefit of decades of empirical industrial evidence from which they base their findings.

6. NIH consultant physicist, Dr. David Sliney performs safety testing on all Apollo products, including the goLITE, and has certified its safety. (Dr. Sliney is considered by the medical community as a leading expert and has published extensively on ocular safety.)

7. Action spectrum for melatonin regulation in humans: evidence for a novel circadian photoreceptor, J Neurosci. 2001 Aug 15;21(16):6405-12

8. Byrne B. et al. Light Therapy for Seasonal Affective Disorder with 470 nm Narrow-Band Light-Emitting Diodes (LEDs), Chronobiology International 21/4-5/2004, 783.

Published Studies on 470 nm Short Wavelength Light

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• Blocking low-wavelength light prevents nocturnal melatonin suppression with no adverse effect on performance during simulated shift work.J Clin Endocrinol Metab. 2005 Feb 15

• Light-induced melatonin suppression: age-related reduction in response to short wavelength light. Exp Gerontol. 2005 Mar;40(3):237-42. Epub 2005 Jan 5.

• Phase advancing human circadian rhythms with short wavelength light, Neurosci Lett. 2003 May 15;342(1-2):37-40

• Optimization of light and melatonin to phase-shift human circadian rhythms, J Neuroendocrinol. 2003 Apr;15(4):438-41

• LRC Studies Human Response to Light, Discovers Evidence of Mechanism Leading to Melatonin Suppression, Lighting Research Center News, April 6, 2004 http://news.rpi.edu/

BLUEWAVE™ Safety Report

The following is an excerpt from the National Institute of Health (NIH) research grant final report on the efficacy of BLUEWAVE™ short wavelength LED technology:

2. Safety

Confirm safety of this device through a hazard analysis based on accepted federal and industrial guidelines .

The LED light tested in this study emitted narrow band blue light with a concentration of energy at 470 nm, with the majority of light energy of a longer wavelength than the peak sensitivity of phototoxicity (see Figure 1). In addition, an independent hazard analysis following the guidelines of the American Conference of Governmental Industrial Hygienists (ACGIH, 2001) determined both newly developed LED light units (short and long wavelength) to be well within the designated national and international safety guidelines for photobiological safety.

Safety of the units was determined via full characterization of each LED light source, using the International Light Model 1400A Radiometer/Photometer, with two different detectors. The first detector utilized a Model SEL240 detector with input optic T2ACT3 that had been calibrated to read directly in terms of the ACGIH/ICNRIP UV-Hazard effective irradiance. A broad-band visible-near-infrared radiometer detector head, Model SEL003 detector with Input Optic W#6847 and Filter F#14299 was calibrated to measure irradiances between 380 and 1000 nm and utilized to measure photoretinitis, or “blue-light” hazard. A radiance hood limited the field of view of the detector to 0.45 steradian (sr) and was used to directly measure the radiance of the sources. In addition, a Minolta Luminance meter was used to measure the panel luminance as a check of radiance measurements. Although the study anticipated a viewing distance of 50 cm, light safety was assessed at shorter distances as well, including at the panel surface (0 cm).

Conclusion

Measurements of light panels taken with the Model SEL240 detector with input optic T2ACT3 confirmed that no potential hazardous ultraviolet radiation was emitted from the surface of the light panels as the effective irradiance was less than 0.05 µW/cm 2 and therefore, well below the ACGIH/ICNRIP exposure guideline of 0.1 µW/cm 2. In addition, the blue light panel was found to operate at emission levels far below limits recognized as maximal safe exposure limits, at less than 15 % of the limit for even the most potentially dangerous visible wavelengths of 440-445 nm. The Federal Drug Administration was provided with the full report and confirmed the assessment, based on the radiological measurements provided. The report is attached to this summary as well.