

DAVID H. SLINEY, Ph.D.
Consulting Medical Physicist
Optical Radiation Hazard Analysis

406 Streamside Drive
Fallston, MD 21047 USA

Telephone (410) 877-1646
FAX (410) 877-1646

10 May 2006

Larry Pederson
The Litebook Company, Ltd.
941 South Railway Street, #6
Medicine Hat, AB T1A 2W3
CANADA

FAX: (403) 526-9444

Dear Mr. Pederson:

In accordance with your request and discussions, I have evaluated the prototype Litebook™ 2.1 which employs improved diffusing optics. I was pleased to see the further improvements in the diffusing lenses above each LED. This should reduce possible concerns about the high brightness of individual LED sources and also reduce glare. Since the same LED emitters are employed in Model 2.1 as the previous model, it was possible to use the same spectral data used in the last report. As stated on the phone, the LED array assembly had come loose from the main body of the unit that contained the diffuser. I tried to position it correctly, but of course it was hard for me to know if the position was optimized for proper light output. I therefore took only the most critical measurements, as I was also very limited in time as you recall, so I look forward to seeing a production unit at some time in the future to confirm these measurements as truly characteristic. The report is dated 14 April, and I will update once you check this draft.

The measured radiance of individual emitters was reduced, which is good. I measured the luminance of the brightest area of the diffuser, which was about $7.2 \text{ cd}\cdot\text{cm}^{-2}$ (less than the value of $10 \text{ cd}\cdot\text{cm}^{-2}$ measured for Model 1.2) or approximately 7 times the luminance of a bright, bare fluorescent lamp. This luminance still exceeds what one can experience in the outdoor environment unless one looks directly at the sun. As a result, staring directly at the source is still uncomfortably bright and may produce afterimages. However, direct on-axis viewing was not what you recommended in your previous guidelines. At angles $30\text{-}45^\circ$ off-axis, it is not really uncomfortable and does not appear to produce afterimages, since the macular area of the retina is not directly illuminated. With its high efficacy, much briefer use periods than what most people have been used to, should be expected.

In any safety guideline for bright light sources, including LEDs, a key issue has been just how long a person would realistically stare directly at a arc lamp, other bright light or, in particular, bright LEDs rich in blue light. The current exposure guidelines emphasize that blue light is most phototoxic for acute exposures.

Sincerely,



David H. Sliney, Ph.D.

DAVID H. SLINEY, Ph.D.
Consulting Medical Physicist
Optical Radiation Hazard Analysis

406 Streamside Drive
Fallston, MD 21047 USA

Telephone (410) 877-1646
FAX (410) 877-1646

OPTICAL SAFETY EVALUATION OF THE LITEBOOK™ ILLUMINATOR Model 2.1 (M/C# 207642)

14 April 2006

Executive Summary

This report provides a safety analysis of the human ocular exposure to the visible radiant energy emitted by light emitting diodes (LEDs) employed in the Litebook™ 2.1 illuminator. The Litebook™ is a light-weight, highly portable, table-mounted unit with an array of light-emitting diodes (LEDs) to provide supplemental light for the purpose of 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 earlier models with the design of an improved, projection optics in the diffusing plastic window cover or optics, 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 nearly six-fold. It is therefore concluded that the Litebook™ illuminator 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 view durations and steady fixation. The user should be cautioned to discontinue use if persistent afterimages are experienced.

INTRODUCTION

Litebook®, Inc. has produced a new model light-weight illuminator fitted with a 6 by 8 array of light-emitting diodes (LEDs) to provide supplemental light for the purpose of "combating winter blues, or correcting the body's natural "biological clock," as in combating the effects of "jet lag" or changing sleep patterns. The purpose of this study was to evaluate the potential optical hazards resulting from viewing the new, Model 2.1 Litebook™. The 24-LED array is mounted in a 10-by-7.8-cm plastic frame and is powered by a 12-V dc plug-in power supply. The traditional Litebook™ instructions recommend use by standing it on a table or counter, so that the face is approximately 30 to 60 cm (12 to 24 inches) from the light source with the

Litebook™ beam directed at the face, but slightly offset to the individual's side each morning. Figure 1 shows how the device is normally used to illuminate the face off-axis, with the LED array positioned approximately 30 to 60 cm from the eyes and displaced from the visual axis by approximately 30-45°. The output irradiance and luminance were measured for the purpose of comparing the emissions with current national and international guidelines for human exposure to bright light. The manufacturer of the Litebook provided spectral properties of the LEDs that were measured by an independent laboratory. Those measurements also provided a luminous efficacy of radiation of 217-245 lumens per Watt (lm/W).

LIGHT EMISSION

The illumination subsystem of the Model 2.1 Litebook™ is composed of 24 "white-light" LEDs. The individual LEDs, appearing bluish-white, were single-quantum-well Nichia Type NSPW500BS(T) LEDs mounted in a rectangular array in a lightweight plastic package. The LEDs are positioned inside the Litebook (Figure 1) behind a hard, clear plastic, slightly diffusing cover with 15-mm diameter, molded Fresnel lenses positioned above each LED. It was assumed that the user could not readily remove the diffuser cover; hence, the safety evaluation considered the normal use condition with the diffuser cover in position. The 5-mm diameter LEDs are positioned in four rows of six with center-to-center distances of approximately 15 mm between each LED within a row. The actual emitting chip potted within the LED lensing plastic enclosure could not be detected, but was completely diffused as examined through a dark magnifying lens. As seen through the diffuser, the LEDs each appeared to be diffuse discs, 12 mm in diameter when observed through a neutral-density filter and using a calibrated rule. Figure 2 shows the typical use position.

MEASUREMENTS

Spectroradiometric Measurements

Spectroradiometric measurements of an earlier Litebook having LEDs with the same emitter and spectral power distribution were made at a distance of 70 cm by the OPTIKON Corporation Ltd., using a Model PR-715 Spectroradiometer, manufactured by Photo Research, Inc., and calibrated with a NIST-Traceable Standard. This also permitted a calculation of the luminous efficacy of radiation, which was at least 240 lm/W. This value was useful in converting any luminance (photopic) measurements to approximate radiometric measurements or *vice-versa*. The LEDs employed in the Litebook contain blue-white emitters which have a spectral peak at approximately 460 nm and fluorescent phosphors which provide a broader, secondary spectral emission peak near 545 nm as shown in Figure 3.



Figure 1. Litebook with earlier number of LEDs (to be replaced with new photograph).

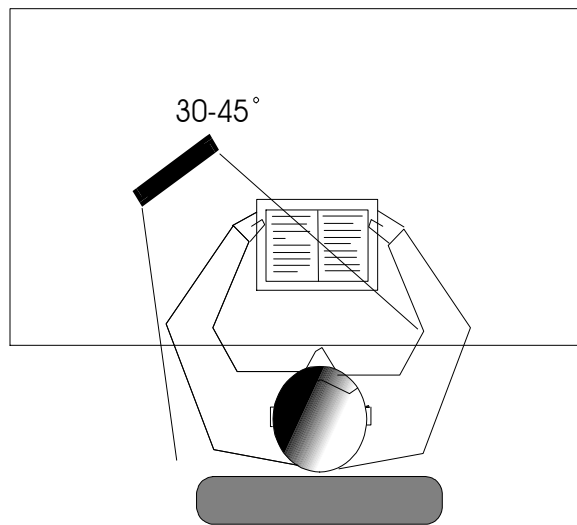


Figure 2. Normal recommended use of the LiteBook

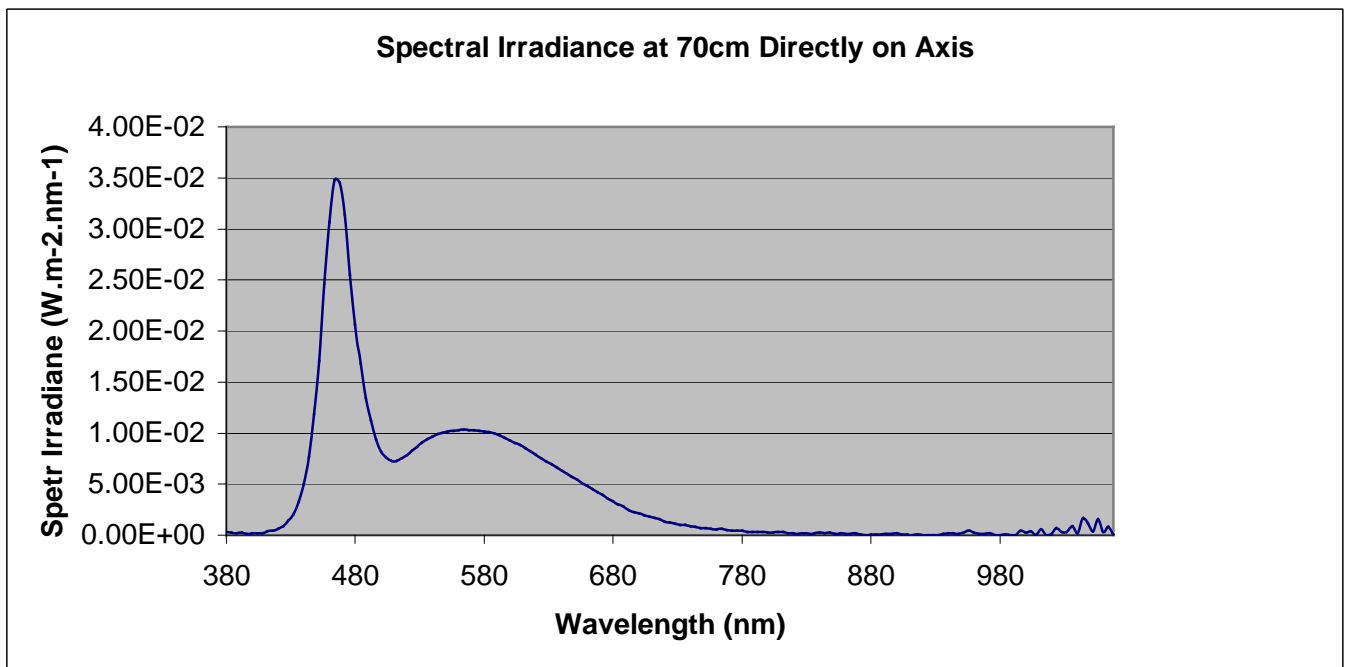


Figure 3. Relative spectral power distribution of the LED array used for relative spectral weighting. Absolute values should be ignored.

Broadband Radiometric Measurements

Measurements of the Litebook™ blue-white light panels were performed using the following primary instrument:

International Light Model 1400A Radiometer/Photometer. International Light, Newburyport, MA, had calibrated both the instrument and three detectors on 21 May 2004:

- a. Model SEL240 (#3682) Detector with Input Optic T2ACT3 (#18613) that had been calibrated to read directly in terms of the ACGIH/ICNRIP UV-Hazard effective irradiance.
- b. Model SEL033 (#3805) Detector with Input Optic W#6874 and Filter F#14299, which had been calibrated to measure irradiance between 380 and 1000 nm. A radiance hood, which limited the field-of-view (FOV) of the detector to 0.45 steradian (sr), was used to directly measure the radiance of the sources.
- c. Model SEL033 (#3805) Detector (with Input Optic W#6874 and Filter UVA#28246), which had been calibrated to measure near-ultraviolet (UV-A) radiation between approximately 315 and 400 nm.

In addition, for an approximate check, a Minolta Luminance Meter was used to measure the panel luminance as a check of the radiance measurements at 30-70 cm.

Measurement Procedure

The total irradiance from the prototype Litebook Model 2.1 was measured on 2 March 2006. The total irradiance emitted by the LED array was measured at several distances (as given in Table 1). The measurement plane was varied from 0 to 100 cm from the front surface of the plastic diffuser of the illuminator. Measurements with a hood to limit the solid angle of acceptance Ω were also made out to a distance of 30 cm as provided in Table 2.

Although ocular exposure to multiple LED sources can produce an increased corneal irradiance, this added energy cannot be imaged in the same area of the retina, hence the multiple sources are not directly additive to the risk. Only if the source images are near each other on the retina do they really increase the risk. Since the individual LED sources are separated (center-to-center) by an angle greater than 0.1 radian (100 mrad) at a 10-cm reference distance for measurements and since each diffused LED source subtends an angle greater than 0.1 radian, each LED is considered independent and must be treated separately when evaluated in accordance with most standards (e.g., IEC 60825-1.2-2001). There is no additivity of the potential retinal hazard from individual LEDs in arrays until the viewing distance is increased, and the images begin to coalesce. The 12-mm diameter (apparent source) and 15-mm separation (center-to-center) distances subtend angles as small as 40 mrad at the closest use distance of 30 cm and angles as small as 20 mrad at 60 cm. The irradiance of freshly illuminated LED arrays and a single LED are shown in Table 1.

Table 1. Radiometric Measurements

Measurement Distance (cm)	Full Array on-axis irradiance (mW·cm ⁻²)	Single, masked diode on-axis irradiance (mW·cm ⁻²)	Average Radiance (mW·cm ⁻² ·sr ⁻¹)	Spot Luminance (cd·cm ⁻²)
1 cm	---	2.2	---	---
10 cm	---	.09	3.1	---
20 cm	---	0.035	2.2	---
30 cm	---	0.020	2.2	---
40 cm	0.42		---	7.2*
50 cm	0.34		---	5.8
60 cm	0.17		---	5.8
80 cm	---		---	5.8
100 cm	0.10		---	---

*Central hot-spot.

Note: Off-axis measurements would have been less because of the high degree of directionality of the emitted beam profile. In proper use with the light directed at the face and illuminating the peripheral retina, the straight, on-axis exposures apply, but because of poorer off-axis imaging, the LEDs would not produce the same sharp image as if viewed directly with the macula.

The effective **ultraviolet irradiance** was also measured using the International Light Model 1400 Radiometer System with Model SEL 240 UV Detector and T2ACT3 Diffuser for effective UV irradiance. The actinic UV irradiance [ACGIH/ICNIRP $S(\lambda)$ spectral weighting] was less than approximately $0.1 \mu\text{W}/\text{cm}^2$, the 8-hour exposure limit. The UV-A measurements also showed very low values—far below the limits.

Radiance and Luminance Determinations

In addition to the irradiance measurements, by using a Minolta spot-luminance meter with a 1° field-of-view, the central and averaged **luminance of individual emitters** was measured for the brightest diodes by measuring at distances of 40-80 cm. At 80 cm, the averaged luminance of the entire emitter area was found to be approximately $5.2 \text{ cd}/\text{cm}^2$. With the spot meter sufficiently close to measure the central LED radiance, the on-axis luminance of the brightest LEDs was $7.2 \text{ cd}/\text{cm}^2$ ($72,000 \text{ cd}/\text{m}^2$). Using the conversion factor of $240 \text{ lm}/\text{W}$, these luminance values correspond to a radiance of $33 \text{ mW}/(\text{cm}^2 \cdot \text{sr})$ for the single brightest LED and to $22 \text{ mW}/\text{cm}^2$ for the full disk. This compares to the $3 \text{ mW}/(\text{cm}^2 \cdot \text{sr})$ measured with the larger area covered by the radiance hood with the far larger solid angle of acceptance using the radiometer at the closer distances.

The **radiance** of a single diffused emitter was measured by isolating a single diffused LED with a metal mask and measuring the irradiance out to 50 cm. This radiance will be used later for comparison with the exposure limits. The radiance L of the source is determined by dividing the beam irradiance E at a given distance, e.g., 30 cm by the solid angle Ω subtended at a distance r of 30 cm. The highest radiance L occurs for a single LED. The irradiance E was $0.020 \text{ mW}/\text{cm}^2$. The solid angle Ω subtended by the 12-mm circular diode source at 30 cm was: $\Omega = A/r^2 = (\pi/4)(1.2 \text{ cm})^2/(30 \text{ cm})^2 = 1.26 \times 10^{-3} \text{ sr}$ and since $E = 20 \mu\text{W}/\text{cm}^2$ this leads to a source radiance $L_e = (3.0 \times 10^{-5} \text{ W} \cdot \text{cm}^{-2})/(1.26 \times 10^{-3} \text{ sr}) = 15.9 \text{ mW} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$. The biologically adjusted blue-light radiance is: $L_B = 0.33 \times 15.9 = 5.2 \text{ mW} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$ since the spectral weighting of the spectral power distribution gave an efficacy of 33%. The equivalent luminance for a single emitter can be calculated by multiplying the radiance L_e by $240 \text{ lm}/\text{W}$, giving $3.8 \text{ cd}/\text{cm}^2$. This value is somewhat lower than the value of $5.2 \text{ cd}/\text{cm}^2$ measured with the luminance spot-meter, since the light is averaged over the entire area of the LED. Furthermore, the spot meter cannot be expected to have a perfect spectral calibration, hence the measurements are in general agreement.

HUMAN EXPOSURE CONDITIONS

The approximate distance between LEDs and the eyes' pupils vary with the individual and the positioning of the Litebook, but generally ranges from 30 to 60 cm. Litebook has typically quoted the LED-to-eye distance as 30 to 60 cm (12 to 24 inches), but emphasizes the range of values depending upon an individual's preference (Figure 2). Under these conditions, the peripheral retina would be illuminated. The Litebook is positioned so that by illuminating the peripheral retina, the central macula (the cone-rich area of central vision) would generally not be directly illuminated when the subject performed visual tasks. *The array of LEDs is **not** intended for direct viewing and lengthy staring at this light source is not expected.* The angular subtense

of either the entire array or for an individual LED at a smallest retinal image size can be calculated. The eye cannot accommodate to sharply focus a light source at distances less than approximately 20 cm (10 cm in the extreme). The angular subtense α is:

$$\alpha = 2 \cdot \tan^{-1} (D_L/2 \cdot r_1) \quad [1a]$$

which for small angles is:

$$\alpha = D_L/r_1 \quad [1b]$$

where D_L is the cross-sectional dimension (e.g., diameter) of the light source, and r_1 is the distance from the light source to the measurement point. It is also possible to calculate the retinal dimensions of an image of a small light source by:

$$d_r = f \cdot \alpha = D_L \cdot f/r_1 \quad [2]$$

where f is the effective focal length of the eye in air (distance of the principal nodal point in front of the retina), and r_1 in this instance is the distance from the light source to the eye (specifically the nodal point). Thus, for the reference distance of 30 cm as measured from the nodal point of the eye (the lens) to the center of the LEDs array, are therefore:

Array of 24: $D_L = 10$ by 7.8 cm; $\alpha = 0.33$ by 0.26 radian; $d_r = 5.6$ by 7.8 mm

Diffused LED: $D_L = 12$ mm; $\alpha = 0.04$ radian; $d_r = 0.68$ mm

The above values are representative. Obviously the images would be one half the above values at a viewing distance of 60 cm from the cornea:

Array of 24: $D_L = 10$ by 7.8 mm; $\alpha = 0.17$ by 0.13 radian; $d_r = 2.8$ by 3.9 mm

Diffused LED: $D_L = 12$ mm; $\alpha = 0.02$ radian; $d_r = 0.34$ mm

These are all extended-source image areas from the standpoint of retinal hazard analysis.

The average radiance of the arrays depends upon the solid angle subtended by the array. The solid angle corresponding to the 0.33 by 0.26 radian linear angles measured at a viewing distance of 30 cm, would be approximately: $\Omega = (0.33)(0.26) = 0.086$ sr. Thus at 100 cm, where $E = 0.1$ $\text{mW} \cdot \text{cm}^{-2}$ then the averaged radiance of the entire array source is: 1.2 $\text{mW} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$.

POTENTIAL HAZARDS

The eye is well adapted to protect itself against overly intense optical radiation (ultraviolet, visible and infrared radiant energy) from the natural environment and mankind has learned to use protective measures, such as hats and eye-protectors to shield against the harmful effects upon the eye from very intense ultraviolet radiation (UVR) and blue light present in sunlight over

snow or sand. The eye is also protected against bright light by the natural aversion response to viewing bright light sources. The aversion response normally protects the eye against injury from viewing bright light sources such as the sun, arc lamps and welding arcs, since this aversion limits the duration of exposure to a fraction of a second (about 0.25 s).

There are at least five separate types of hazards to the eye from intense optical sources:¹

(a) Ultraviolet photochemical injury to the cornea (photo-keratitis) and lens (cataract) of the eye (180 nm to 400 nm).

(b) Thermal injury to the retina of the eye (400 nm to 1400 nm).

(c) Blue-light photochemical injury to the retina of the eye (principally 400 nm to 550 nm; unless aphakic, 310 to 550 nm)²

(d) Near-infrared thermal hazards to the lens (approximately 800 nm to 3000 nm).

(e) Thermal injury (burns) of the cornea of the eye (approximately 1400 nm to 1 mm).

For the LED source used in the Litebook unit, only aspects (c) is relevant, since thermal injury (b) requires optical radiance values characteristics of intense xenon-arc lamps. Therefore this *photochemical* effect was evaluated in detail. To prove beyond any doubt that UVR was of no concern, aspect (a) was also checked by measurement.

HAZARD CRITERIA AND STANDARDS

Currently, there are only two sets of different types of **product** safety standards that apply to the use of LEDs worldwide. These are:

(1) *CIE Standard S009E-2002, Photobiological Safety of Lamps and Lamp Systems*, which was based upon the American National Standard, ANSI RP-27.1-1996, *Recommended Practice for Photobiological Safety for Lamps and Lamps Systems: General Requirements*, published by the Illuminating Engineering Society of North America. These documents are the first in a series of standards, and employ ocular exposure limits that are essentially identical to the Threshold Limit Values (TLVs) for broadband optical radiation published by the American Conference of Governmental Industrial Hygienists (ACGIH). The ACGIH TLVs for visible radiation are also identical to the guidelines for human exposure published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP). ICNIRP recommends that these incoherent guidelines--and not laser guidelines--be applied to LEDs. Additionally, the IESNA standard includes specific guidelines on methods of measurement at realistic viewing distances--not closer than 20 cm--that are not given by the ACGIH. Two criteria apply: ultraviolet radiation and blue light to a blue or white LED.

(2) In Europe, a laser safety standard issued by CENELEC also applies to LEDs: *EN*

60825-1.2 -- Amendment 2 to Safety of Laser Products - Part 1: Equipment Classification, Requirements, and Users' Guide. This was based on IEC 60825-1.2 (2001) Safety of Laser Products - Part 1: Equipment Classification, Requirements, and Users' Guide, the international laser product standard from the International Electrotechnical Commission (IEC). It is worthwhile to note that when the 1984 IEC standard on laser products was revised in a second edition in 1993 (IEC 825-1-1993), a new provision to include LED's, as if they were lasers, was included. The inclusion of LED's by IEC Technical Committee TC-76 (which developed the standard) at the "11th hour" was largely to treat the specific use of infrared LED's in optical fiber communication systems. The many different geometries of other LED products were not properly considered and subsequent amendments have attempted to correct some of these problems in 1996- and 2001. The emission limits were recently updated and made less conservative. Both national and international experts consider the application of laser limits to incoherent sources as **overly conservative**. Under the IEC/CENELEC standard, Class 1 products are the group with the lowest hazard and these do not require any warning label when sold in Europe. For a product to be designated Class 1, it must not only meet the requirements for MPE's at reasonable locations of the human eye but also must pass a test designed to simulate intrabeam inspection by a technician with an eye loupe at close range for 100 seconds even under failure modes. In 2004, an IEC Working Group voted to delete the LED from the scope of IEC 60825-1 and if this is later approved, this standard would not apply to the Litebook.

HUMAN EXPOSURE LIMITS AND HAZARD EVALUATION

The ACGIH and ICNIRP are organizations that recommend human exposure limits to optical radiation. The following limits for ocular exposure to broadband visible radiation are recommended by these organizations for use with LEDs:

Ultraviolet Exposure Hazard

The ACGIH and ICNIRP recommend a maximal daily corneal exposure of 3 mJ/cm^2 effective irradiance, as determined by the UV Hazard $S(\lambda)$ spectral weighting function. The IL 1400 instrument with the SEL240 detector reads directly in $S(\lambda)$ weighted irradiance. For the prototype tested, the measurement was below the sensitivity of the instrument ($0.02 \text{ } \mu\text{W/cm}^2$). Since the permissible exposure limit is $0.1 \text{ } \mu\text{W/cm}^2$ for eight hours, there is more than a safety factor of five even if one were continuously exposed for a full workday. As would be expected from any visible LED, there is no UV hazard from the Litebook.

Blue-Light Photochemical Retinal Hazard

The CIE international standard S-009E-2002 and ANSI RP27.1-1996 lamp safety standards follow the ACGIH TLV³ and ICNIRP guideline to protect the human retina against photoreinitis,⁷⁻¹⁰ "the blue-light hazard." The TLV is an effective blue-light radiance L_B integrated of t s of $100 \text{ J/(cm}^2 \cdot \text{sr)}$, for $t < 10,000 \text{ s}$, i.e.,

$$L_B \cdot t = \Sigma L_\lambda \cdot B(\lambda) \cdot t \cdot \Delta\lambda \leq 100 \text{ J}/(\text{cm}^2 \cdot \text{sr}) \text{ effective} \quad [3]$$

and for $t > 10,000 \text{ s}$ (2.8 hrs.):

$$L_B \leq 10 \text{ mW}/(\text{cm}^2 \cdot \text{sr}) \quad \text{for } t > 10,000 \text{ s} \quad [4]$$

To calculate the maximum direct viewing duration when [4] is not satisfied, this maximum "stare time," $t\text{-max}$, is found by inverting Eqn. [3]:

$$t\text{-max} = 100 \text{ J}/(\text{cm}^2 \cdot \text{sr}) / L_B \quad [5]$$

As measured earlier, the brightest source (single diffused LED) projects a radiance $L = 15.9 \text{ W} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$); however, this is not biologically weighted. Using a spread-sheet program, the spectral irradiance provided by OPTIKON was weighted by the $B(\lambda)$ function which provided a conversion factor from radiance to blue-light radiance of 0.33. Hence the blue-light radiance was: $L_B = 5.2 \text{ mW} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$. From equation [4], this radiance is below the limit for continuous exposure in any day. Staring (fixating) on the direct source for such a length of time is totally unrealistic. This would be equivalent to fixating on a bare lamp for long periods of time. With normal use, the individual looks away and the peripheral retina is exposed to the source, and eye movements will further blur the images of the individual diodes, such that the safety factor is still greater based upon the average radiance of about $1.2 \text{ mW} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$, which corresponds to a blue-light radiance of only: $L_B = [1.2 \text{ mW}/(\text{cm}^2 \cdot \text{sr})][0.33] = 0.4 \text{ mW}/(\text{cm}^2 \cdot \text{sr})$, which is a factor of 25 below the $10 \text{ mW} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$ limit for continuous viewing. There is no blue-light hazard for continuous viewing by current light safety standards provided that there are normal eye movements; and there is a $(10)/(5.2) = 1.9$ -fold safety factor even for staring at a single diode source.

Continuous Viewing

Since the averaged radiance of the array is below the $10\text{-mW} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$) limit for continuous viewing, a warning statement to limit exposure duration is not necessary. However, the current cautionary wording not to stare continuously into the source is still advisable, since, as with any bright light source, needless staring should be avoided. Afterimages will also result. Discomfort glare is strongest when the central retina, the macula, is illuminated; hence, a normal user would find it uncomfortable to stare directly into the source and would naturally follow the arrangement shown in Figure 2, where the source illuminates the peripheral retina. Even so, after-images may be a problem if the individual is quite steady.

Retinal Photochemical Hazard to the Aphakic Eye

The third type of retinal hazard--the aphakic photochemical retinal hazard--is evaluated by spectrally weighting the radiance against the aphakic retinal hazard function $A(\lambda)$.² This photochemical retinal injury hazard is merely an extension of the blue-light hazard and must be analyzed only for individuals with at least one aphakic eye (i.e., an eye with the normal lens removed, as in an older type of cataract surgery). The approach is to substitute $A(\lambda)$ for $B(\lambda)$ in

Eqns. [3] and [5]. For example, the aphakic hazard radiance L-aphake is:

$$L\text{-aphake} = E\text{-aphake}/\Omega \quad [6]$$

$$L_A \cdot t = \sum L_\lambda \cdot A(\lambda) \cdot t \cdot \Delta\lambda \leq 100 \text{ J}/(\text{cm}^2 \cdot \text{sr}) \text{ effective} \quad [7]$$

for $t \approx 10,000 \text{ s}$ (2.8 hrs.).

The device would normally only be used by phakic individuals with normal crystalline lenses in place, as aphakic persons are now extremely rare. Cataract patients today almost all have plastic intraocular lens (IOL) implants and these have a near-ultraviolet (UV-A) absorber; in this case, the $B(\lambda)$ function would apply. However, if by some chance a user had an aphakic eye, the retinal irradiance would increase only slightly in the 435-440 nm band, and the $A(\lambda)$ weighting would increase the value of L_A over that of L_B since, for example, $A(\lambda) = 1.11$ at 425 nm. Nevertheless, the effective L_A would be increased by less than a factor of 1.5 and therefore the safety factor noted previously for the phakic eye would be reduced, but exposures would always be below the limit.

Laser Radiation Standards

Contrary to the recommendations of ICNIRP and ACGIH, the IEC and CENELEC standards 60825 also currently apply the Maximum Permissible Exposures recommended by ICNIRP for laser radiation to LEDs. Although the applicability of the laser safety standard to LEDs is expected to be removed in 2006 or 2007 in the next edition of IEC 60825-1, these should still be evaluated. These MPEs are converted to accessible emission limits (AELs) expressed in power (mW). The AEL varies with wavelength only for wavelengths greater than 550 nm and varies with angular subtense α (which determines correction factor C_6 and with exposure duration. For a source not intended to be viewed (as a single LED die), the photochemical AEL given in the IEC standard for a 100 s time base for a continuous source subtending more than 11 milliradians (as this LED) is:

$$AEL_{\text{phot}} = 4 C_3 \text{ mJ, or } 0.04 C_3 \text{ mW} \quad \text{at a 10 cm measurement distance} \quad [8]$$

Where C_3 is a value between 2 and 3 for this LED, based upon spectral weighting. Since the irradiances were measured with a 7-mm averaging aperture, the irradiance of $0.44 \text{ mW}/\text{cm}^2$ at 10 cm is multiplied by the area of a 7-mm aperture (i.e., 0.385 cm^2) to obtain a measured power of 0.17 mW, which is slightly above the AEL in [8].

There is also a separate thermal AEL, which is:

$$AEL = 0.7 C_6 T_2^{-0.25} \text{ mW} \quad [9]$$

where C_6 is a size correction factor ($C_6 = 33$ for a 5-mm source), $T_2 = 100 \text{ s}$ for this source, and where the measurement must be made at a distance s (less than 10 cm). Hence, for this LED, the AEL is 15.8 mW total radiant power passing through a 7-mm aperture at a distance s :

$$s = 100 \sqrt{\frac{\alpha_{100} + 0.46}{100}} \text{ mm} \quad [10]$$

where α_{100} is the viewing angular subtense of the source at 100 mm. (See Table 10 in amended section 8.2.h from *EN 608025-1.2-2001*, and *IEC 60825-1.2-2001*.) In the case of the single LED viewed through the diffuser, $\alpha_{10} = (12 \text{ mm})(100 \text{ mm}) = 0.12 \text{ radian} = 120 \text{ mrad}$, but α is limited to 100 mrad. The correction factor C_6 is defined as $(\alpha_{10})/(1.5 \text{ mrad}) = 66.7$ and calculating s provides 71 mm. Therefore, the AEL of 15.8 mW must be measured at 71 mm. Using a 7-mm aperture placed at the distance $s_{100} = 100 \text{ mm}$, the measured power was only of the order of 0.1 mW, which demonstrates an enormous safety factor for retinal thermal effects. This means that the more conservative photochemical limit of 0.039 C_3 mW measured over a collecting angle of 110 mrad at 10 cm must apply.

The effective spectral weighting applied in the IEC photochemical laser MPE is quite similar to the above incoherent limits, but more restrictive for wavelengths less than 450 nm. This has little impact upon the risk assessment. The laser MPE is very similar to Equations [3] and [4], and for $t > 10,000 \text{ s}$ (2.8 hrs.) and the blue-weighted radiance L_B is limited to:

$$\text{MPE} = 0.1 \cdot C_3 \text{ mW/cm}^2 \quad \text{averaged over cone angle } \gamma = 110 \text{ mrad at 10 cm} \quad [11]$$

where C_3 has a value greater than 2 for this spectral distribution. An angle of 110 mrad covers an area of the array of 1.1 cm, which would include only one LED, and the maximal measured irradiance of one LED at 10 cm was 0.09 mW/cm^2 . Hence, with a C_3 correction factor larger than 3, the device would be Class 1.

In the US ANSI Z136.1-2000 and ICNIRP exposure guidelines, the same MPE is expressed as a radiance:

$$\text{MPE} = 10 \cdot C_B \text{ mW} \cdot \text{cm}^{-2} \cdot \text{sr}^{-1}$$

averaged over a larger cone angle γ of 110 mrad at the viewing distance (10 cm is the absolute minimum). The measured effective radiance L_B of 0.4 mW/cm^2 certainly suggests that there is a similar safety factor if the laser MPEs were to be applied rather than the incoherent light MPEs. It is clear that by whatever criteria, the array does not emit above the AEL for Class 1.

Laser/LED Hazard Classification

The emitted energy from the LED with diffuser in place does not exceed the AEL for Class 1 and the device is exempt from requirements of IEC 60825-1.1-1998 and EN 60825-1. The manufacturer can self-certify the device as exempt from these requirements and no further tests are required.

IEC 60825-1.2-2001 states in section 1.1 that "Any laser product or LED product is exempt

from all further requirements of this part 1 if -- classification by the manufacturer according to clauses 3.8 and 9 shows that the emission level does not exceed the AEL of Class 1 under all conditions of operation, maintenance, service and failure..."

CONCLUSIONS

The Litebook Model 2.1 and diffused Nichia LED emitters do not pose a potential hazard to the eye by any safety standard and for all possible viewing conditions. Even if one were to fixate on a single diffused LED continuously, this would not exceed the MPE. LEDs are radiance limited and cannot produce exposure levels at the retina that even approach the levels that are known to cause retinal injury, corresponding to a safety factor of roughly 20. In other words, the LEDs would have to emit far more power to pose a serious acute hazard (photomaculopathy) to the retina. This is theoretically impossible for these diffused LEDs. There are also no cognizable hazards to the corneas and lenses of the eyes from even lengthy exposure. The LEDs are shown to pose no hazard to the eye for the intended application when tested against current national and international ocular exposure limits for infrared optical radiation.

The total emitted power is shown—based upon current IEC accessible emission limits—to be well below the Class 1 limit in accordance with IEC 60825-1.1 and in the equivalent European standard EN 60825-11. Furthermore, this standard assumes optically aided viewing with a magnifier, which is unrealistic. It is expected that the applicability of this laser standard to LEDs will be dropped in the near future. The LED array does not exceed exposure limits for the eye during normal, intended use even for a failure mode.



David H. Sliney, Ph.D.

REFERENCES

- 1 American Conference of Governmental Industrial Hygienists (ACGIH) (1998), *TLV's, Threshold Limit Values and Biological Exposure Indices for 1998*, American Conference of Governmental Industrial Hygienists, Cincinnati, OH.
- 2 ACGIH (1992), *Documentation for the Threshold Limit Values*, 4th Edn., American Conference of Governmental Industrial Hygienists, Cincinnati, OH.
- 3 American National Standards Institute/Illuminating Engineering Society of North America (ANSI/IESNA) (1996) *Photobiological Safety of Lamps and Lighting Systems, RP27.1*, New York, IESNA.
- 4 American National Standards Institute/Illuminating Engineering Society of North America (ANSI/IESNA) (1996) *Photobiological Safety of Lamps and Lighting Systems, RP27.3*, New York, IESNA.

- 5 CENELEC, (1996) *EN 608025-1/A11, Amendment 11 to Safety of Laser Products - Part 1: Equipment Classification, Requirements, and Users' Guide*, CENELEC, 1996
- 6 Center for Devices and Radiological Health (CDRH, 1985), *Laser Product Performance Standard*, Title 21, *Code of Federal Regulations*, Part 1040, Washington, DC, Government Printing Office.
7. CIE (Commission International de l'Eclairage, the International Commission on Illumination), CIE Standard S-009E-2002, *Photobiological Safety of Lamps and Lamp Systems*, Vienna, CIE.
8. International Commission on Non-Ionizing Radiation Protection (ICNIRP) (1996) *Guidelines on Limits for Laser Radiation of Wavelengths between 180 nm and 1,000 μm*, *Health Phys.*, **71(5)**: 804-819.
79. International Commission on Non-Ionizing Radiation Protection (ICNIRP) (1997) *Guidelines on Limits of Exposure for Broad-band Incoherent Optical Radiation (0.38 to 3 μm)*, *Health Phys.*, **73(3)**:539-597.
10. International Electrotechnical Commission (IEC) (1998) *IEC 60825-1.1, First Edition - Safety of Laser Products - Part 1: Equipment Classification, Requirements, and Users' Guide*, Geneva, International Electrotechnical Commission, 1998
11. Sliney D. H. and M. L. Wolbarsht (1980) *Safety with Lasers and Other Optical Sources*. New York: Plenum Publishing Corp.
12. Sliney, D.H., (1997). Laser and LED eye hazards: safety standards, *Optics and Photonics News* **7(9)**:31-37.
13. World Health Organization [WHO], (1982), *Environmental Health Criteria No. 23, Lasers and Optical Radiation*, joint publication of the United Nations Environmental Program, the International Radiation Protection Association and the World Health Organization, Geneva.

ANNEX

Dosimetric Concepts in Photobiology

The product of the dose-rate and the exposure duration always must result in the same exposure dose (in joules-per-square centimeter at the retina) to produce a threshold injury. Blue-light retinal injury (photoretinitis) can result from viewing either an extremely bright light for a short time, or a less bright light for longer exposure periods. This characteristic of photochemical injury mechanisms is termed *reciprocity* and helps to distinguish these effects from thermal burns, where heat conduction requires a very intense exposure within seconds to cause a retinal coagulation; otherwise, surrounding tissue conducts the heat away from the retinal image. Injury thresholds for acute injury in experimental animals for both corneal and retinal effects have been

corroborated for the human eye from accident data. Occupational safety limits for exposure to UVR and bright light are based upon this knowledge. As with any photochemical injury mechanism, one must consider the *action spectrum*, which describes the relative effectiveness of different wavelengths in causing a photobiological effect. The action spectrum for photochemical retinal injury peaks at approximately 440 nm.

Retinal Hazards

The principal retinal hazard resulting from viewing bright light sources is photoretinitis, e.g., *solar retinitis* with an accompanying scotoma which results from staring at the sun. Solar retinitis was once referred to as "eclipse blindness" and associated "retinal burn." Only in recent years has it become clear that photoretinitis results from a photochemical injury mechanism following exposure of the retina to shorter wavelengths in the visible spectrum, i.e., violet and blue light. Prior to conclusive animal experiments at that time (Ham, Mueller and Sliney, 1976), it was thought to be a thermal injury mechanism. However, it has been shown conclusively that an intense exposure to short-wavelength light (hereafter referred to as "blue light") can cause retinal injury.

CALCULATING RETINAL EXPOSURE

From knowledge of the optical parameters of the human eye and from radiometric parameters of a light source, it is possible to calculate irradiances (dose rates) at the retina. Exposure of the anterior structures of the human eye to ultraviolet radiation (UVR) may also be of interest; and the relative position of an external light source and the degree of lid closure can greatly affect the proper calculation of this ultraviolet exposure dose in an awake, task-oriented viewing condition. However, for a light source, as in the case of the Litebook, the lid remains open during the exposure and the patient steadies his or her eye. As for short-wavelength light exposures, the spectral distribution of the light source is important.