# Optical characterization of cutaneous transilluminators for eye safety

**Sharon Miller,[1,2,]* Robert James,[1] Robert Landry,[1] and Joshua Pfefer[1]**

[1]*Division of Physics, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, USA*
[2]*Currently with the Electronic Products Branch, Division of Mammography Quality and Radiation Programs, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, USA*
*\*sharona.miller@fda.hhs.gov*

**Abstract:** Cutaneous transilluminators are light-emitting devices used to localize blood vessels for various medical procedures. They are often used in populations that may be at increased risk for skin burns, such as neonates and the elderly. While there is a known potential for skin burns, little is known about the ophthalmic risk from the use of these devices. This paper will report on the laboratory evaluation of the potential ocular hazards from transilluminators (TIs). Our results indicate that transilluminators which incorporate white-light LEDs have emissions that have the potential for producing injury to the retina, especially in patients who may have a reduced aversion response.

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## 1. Introduction

Transillumination with visible light has been used for many years to provide enhanced visualization of subsurface biological structures, including arteries in the foot, hands or wrists of neonates for injections, blood draws and intravenous catheter placement [1]. It is a particularly useful technique for venous cannulation in infants with darkly pigmented skin [2]. First-generation systems were typically based on high-intensity, AC-powered (e.g., halogen) broadband lamps, which delivered light to the skin via fiberoptic probes. An early problem from the use of these transilluminators (TIs) during cannulation procedures was temperature rise leading to thermal injury and erythema caused by prolonged skin contact [3]. The source of these burns has typically been identified as excessive levels of fiberoptically-delivered light [4].

In recent years there has been a trend towards increasing use of battery-powered TIs that incorporate light-emitting diodes (LEDs) [5,6], in part to reduce optical-thermal emissions. As LEDs become more efficient and less expensive, they are becoming more commonly used in devices such as TIs. In 2007, there was a manufacturer recall due to "excessive heating" from these presumably 'cooler' LED devices ["Recall of Neonatal Transilluminator Complete," Biomedical Safety and Standards, Jan 15, 2007]. Although this recall was due to a manufacturing error, it highlights the potential hazard of these devices, especially given the fact that advancements in LED technology have enabled the generation of shorter wavelengths of light at higher intensities. In a recent study, we reported on the photothermal safety of LED-based transilluminators in skin [7]. This work illustrated that temperature generation by current clinical devices can be significant, although not likely hazardous under normal use conditions. In addition to the potential for photothermal injury in skin, these devices represent a potential ophthalmic hazard. However, there is minimal published scientific data regarding the optical output of TIs. It has been known for many years that visible light (400 to 770 nm) can cause damage to the eye, especially at the shorter wavelength end of the spectrum [8]. Intense optical radiation can cause thermal injury and intense visible light can cause photochemical damage to the retina. In fact, visible light can produce photic damage even at low intensity if the exposure duration is long enough. This is due to the fact that photochemical damage follows the law of reciprocity, i.e. the damage depends on the total dose, regardless of whether it is delivered over a short or long time duration [9]. Therefore, the purpose of this study was to evaluate the potential for ocular damage from optical radiation emitted by TIs and to develop experimental methods for quantitative assessment of possible eye injury from these and similar devices.

## 2. Methods

Measurements were performed on six TIs, labeled as TI1 through TI6 to evaluate the potential for ophthalmic injury. As summarized in Table 1, TI1 and TI2 contained both white and red LEDs, whereas the remaining four devices contained red and/or orange LEDs.

**Table 1. TI color characteristics**

| Label | LED colors |
|-------|------------|
| TI1 | Red and White |
| TI2 | Red and White |
| TI3 | Red |
| TI4 | Orange and Red |
| TI5 | Orange and Red |
| TI6 | Orange and Red |

Although there are no published safety limits for optical radiation that apply to this specific type of device, existing standards for general illumination sources can be used to provide an estimate of the hazard. The methods used are based on standard test methods published jointly by the American National Standards Institute (ANSI) and the Illuminating Engineering Society of North America (IESNA) in their ANSI/IESNA Recommended Practice RP 27 series of documents [10]. The limit values used in these documents are based on those published by the American Conference of Governmental and Industrial Hygienists (ACGIH) [11] and are also available in the ICNIRP document on exposure limits to broad-band incoherent optical radiation [9].

Two different optical parameters were determined for each TI: spectral irradiance and spectral radiance.

*2.1 Spectral irradiance*

The spectral irradiance is simply the power per unit area, per unit wavelength, incident on a surface and is measured in W/(cm2*nm) (Fig. 1). This quantity is dependent on the distance from the source.
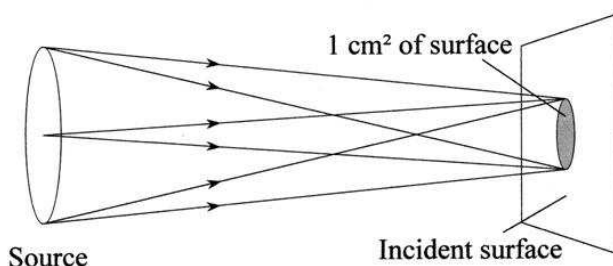


Fig. 1. Irradiance.

The spectral irradiance of all the devices was measured to determine the relative spectral output. Spectral irradiance was measured with a double grating spectroradiometer system (Model OL 754, Optronic Laboratories, Orlando, FL). Measurements were taken at 5 nm intervals (instrument bandwidth was 5 nm with a wavelength accuracy of +/− 0.2 nm). The input of the spectroradiometer was a 15.24 cm diameter integrating sphere with a 7.92 cm$^2$ aperture. The spectroradiometer system was calibrated by measuring the output of a quartz halogen standard lamp, traceable to primary standards maintained by the National Institute of Standards and Technology. Each TI was mounted approximately 10 cm from the input of the integrating sphere so that the sphere collected the emitted radiation from all LEDs simultaneously. The beam pattern overfilled the aperture of the sphere in all cases. For this measurement it was not necessary to collect all of the emitted radiation, since the desired result was simply to obtain the relative spectral irradiance vs wavelength. Each TI was measured over the wavelength range of 380 - 800 nm. Note that these measurements did not

simulate actual use conditions, as they were performed at a distance of 10 cm from each device. For these measurements, the TIs were operated on battery power.

*2.2 Spectral radiance*

The spectral radiance, which can be used to describe the brightness of a source, is a characteristic of the radiating source and is equal to the power emitted from a source per unit area, per unit wavelength, and per unit solid angle. It does not change with distance from the source (as does irradiance). The solid angle is measured in units of steradians (sr) and spectral radiance is measured in units of $W/(cm^2*nm*sr)$ (Fig. 2).
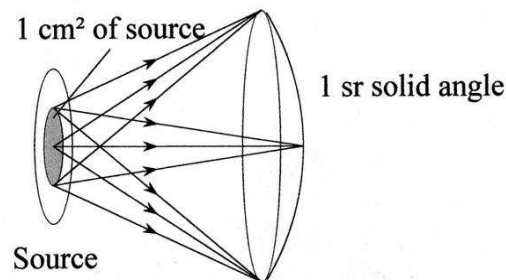


Fig. 2. Radiance.

Radiance is a useful quantity for evaluating retinal hazards since the radiance of the source is directly proportional to the retinal irradiance and known thresholds for damage. For this reason, the measured radiance was used to evaluate the potential retinal hazards associated with the TIs.

The spectral radiance from all devices containing white LEDs was measured and from one device containing red and/or orange LEDs. Spectral radiance was determined with the use of the OL 754 double grating spectroradiometer system and a specialized optical setup (Fig. 3).
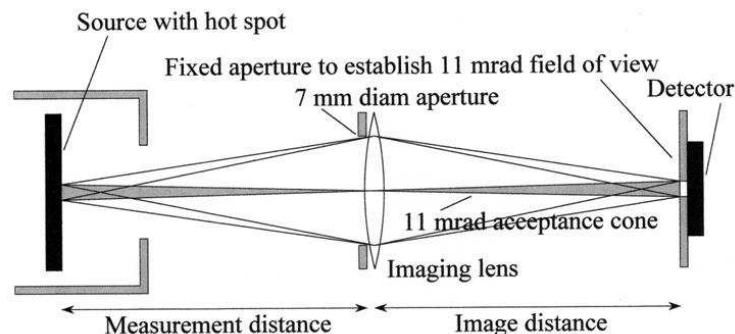


Fig. 3. Set-up used for measurement of spectral radiance distribution.

Radiance (L) was determined using the following equation:

$$L = \frac{\Phi - z^2}{A - a} \tag{1}$$

where z is the distance between two apertures, $\Phi$ is the spectral radiant power, a is the area of the first aperture and A is the area of the second aperture [12]. The spectral radiant power was measured with the use of the OL 754 as further described below. All but one LED of each TI was masked to ensure that no stray light from the surrounding LEDs was included. Thus, the data obtained were from a single LED.

ANSI/IESNA RP 27.1 specifies conditions under which measurements are to be made [10]. This includes the specification that the spectral radiance shall be averaged over an 11 mrad right circular cone field of view. It also specifies that a limiting aperture diameter of 3 mm shall be used. However, we have chosen to use a 7 mm diameter aperture for a more conservative evaluation which takes into account that the eyes of premature infants may be dilated from an ophthalmic examination [13]. In addition, a conservative user distance of 10 cm was used for the measurements to account for an accommodation distance of 10 cm for persons with high myopia. This is normally the closest distance at which the human eye can focus upon a small object [14].

Since the radiating surface in an LED is behind a plastic dome, the optical imaging set-up shown in Fig. 3 was used [15]. The LED contained two hot spots located at opposite ends, approximately ¼ of the diameter from center. In this set-up a 20 Diopter lens is used to form a one-to-one image of the LED hot spot at a lens-to-LED distance of 10 cm. Thus the image is produced at a distance of 10 cm from the lens. The 7 mm diameter aperture is placed at the front surface of the lens and the second aperture that is used to define the field of view is located in the image plane of the LED. In this case, a 1.1 mm diameter aperture is used to establish the 11 mrad field of view specified by ANSI/IESNA RP 27.1. The input of the integrating sphere was positioned so that the sphere collected all of the emitted radiation which passed through the 7 mm and 1.1 mm diameter apertures. The spectral radiant power, $\Phi$ that is used in Eq. (1) is calculated by multiplying the value obtained by the spectroradiometer by the area of the entrance aperture of the integrating sphere. Each device was measured over a wavelength range of 380 - 800 nm and operated from a regulated D.C. power supply (Model E3648A, Agilent Technologies, Inc., Santa Clara, CA) set at 4.5 volts.

In order to determine the output stability of each TI diode, the TIs were oriented with respect to the optical set-up to maximize the reading obtained using a broad-band detector connected to a power meter (Model 350 Optometer, Graseby Optronics, Orlando, FL). Testing showed that under these conditions, the output of the brightest white LED in TI1 was constant to within 1% over a 90 min time period. This set-up was also used to determine the differences between LED output.

*2.3 Hazard analysis*

Wavelengths in the 400 - 1400 nm region are of particular concern for retinal injury. Those wavelengths near 440 nm (blue) have been shown to be the most hazardous to the retina [16]. Two light hazard functions for photochemical injury are included in the RP 27.1 limits, shown in Fig. 4. They are applicable to a wavelength range of 300 - 700 nm. One is the blue light hazard function, and the other is the aphakic hazard function. The difference between these two hazard functions is that the blue light hazard function is intended for use in normal adult eyes with an intact natural lens, while the aphakic function is intended to be used in the case where the natural lens in the eye has been removed. The aphakic hazard function was used for a worst case scenario in this study since infants have higher transmission of UV and visible light through their lens [17] and, in fact, ICNIRP recommends that this weighting function be used for children < 2 yrs old [9].
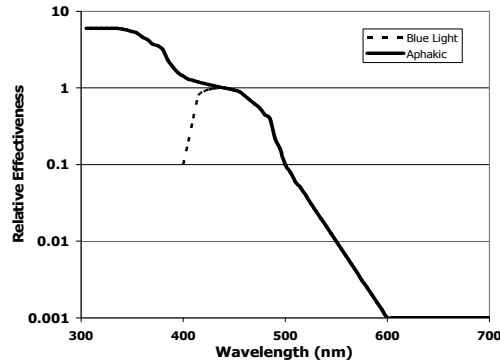
Fig. 4. ANSI/IESNA Blue Light & Aphakic Hazard Functions.

The source spectral radiance was calculated using Eq. (1) and the measurements of spectral radiant power. The spectral radiance calculations were weighted by the aphakic light hazard function and integrated over 380 - 700 nm to obtain the aphakic-weighted radiance of the source. The ANSI/IESNA RP 27.1 photochemical retinal hazard limit for integrated spectral radiance weighted by the aphakic light hazard function is 100 J/(cm$^2$-sr) for exposure times <10,000 seconds. This limit is defined as the threshold limit value (TLV). An exposure time to reach this limit, Time $_{TLV}$, can be calculated by dividing the exposure limit by the aphakic-weighted retinal radiance, $L_A$,

$$\text{Time}_{TLV} = 100 / L_A. \tag{2}$$

TI1 and TI2 devices were the focus of the evaluation for retinal injury, since these contained the white light LEDs. We also evaluated a total of 3 of the TI1 devices, purchased at different times to measure the variability between devices. [For this relative comparison, spectral power was not measured, only total power using the Graseby Optronics meter].The other devices (TI3 – TI6) containing only red and/or orange LEDs were deemed to be far less hazardous due to the relatively low effectiveness for photochemical retinal damage in this wavelength region. However, one measurement of a red and an orange LED was made to confirm this.

ANSI/IESNA RP 27.1 also specifies a retinal thermal hazard limit that is applicable for periods of time from 1 μs to 10 s. The thermal hazard weighting function is defined over the 380 to 1400 nm wavelength range, but is equal to a value of 1.0 over most of the visible wavelength range. We compared the integrated spectral radiance from 380 to 800 nm to the thermal hazard limit of $5/\alpha t^{1/4}$, where α is the angular subtense of the source in radians, which we calculated to be 50 mrads at a distance of 10 cm, and t is the exposure time. Measurements at wavelengths greater than 800 nm were not needed since we determined there was no significant measureable output from any TI at wavelengths greater than 750 nm.

## 3. Results

### 3.1 Spectral irradiance

Figure 5 shows plots of spectral irradiance and aphakic weighted spectral irradiance for TI2 which included both red and white LEDs. Figure 6 shows the same plots for TI5 which included red and orange LEDs. For TI2, the white LEDs had a narrow band of emission centered at 465 nm (bandwidth (BW) ca. 30 nm) and a broad band of emission centered at 560 nm (BW ca. 200 nm). Interestingly, one of the 4 white LEDs in one of the two TI2 devices that were evaluated had a peak emission at 440 nm, instead of 465 nm. For TI1 (spectra not shown) 3 out of 5 of the white LEDs evaluated had a peak emission at 440 nm, instead of 465 nm. Also, for TI2, the red LEDs had a narrow band of emission centered at 645 nm (BW ca.

30 nm). In TI5, the orange LEDs had a narrow band centered at 610 nm (BW ca. 20 nm) and the red LEDs had a narrow band centered at 655 nm (BW ca. 25 nm).
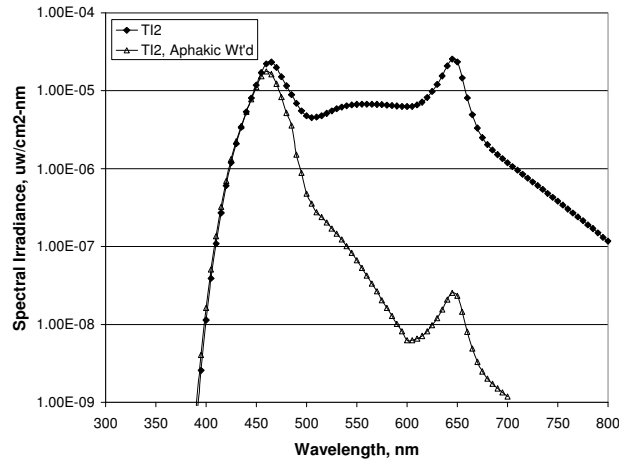


Fig. 5. Graph of the relative spectral irradiance and aphakic weighted spectral irradiance versus wavelength for TI2, which contains red and white LEDs, on a semi-logarithmic plot.
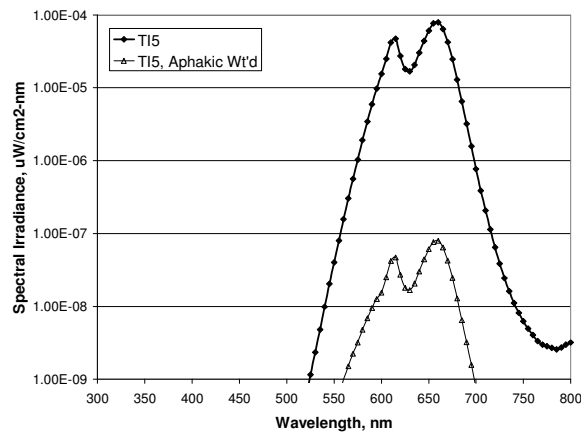


Fig. 6. Graph of the spectral irradiance and aphakic weighted spectral irradiance versus wavelength for TI5, which contains red and orange LEDs.

*3.2 Spectral radiance*

Visually, the LED appeared to have a non-uniform radiating pattern with two clearly defined hot spots on opposite sides of the LED. Measurements were made by carefully locating the 1.1 mm diameter aperture over the hot spot that produced the highest reading using the power meter.

The spectral radiance was weighted with the aphakic action spectrum, integrated and compared to the Time $_{TLV.}$ The mean time to reach the TLV for all the white light LEDs tested was 4.0 minutes, with a std. dev of 1.45 minutes. The range of results for individual white LEDs ranged from 2.06 – 6.7 minutes. Since the output of the LEDs was very stable when operating with the regulated power supply, it appears that the large standard deviation observed is primarily due to (1) our ability to locate the 1.1 mm diameter aperture at the exact same position over the hot spot and (2) variation in output from LED to LED. We measured a total of 4 white LEDs in 3 of the TI1 devices and found that there was a large variation (29 –

36%) between white light LEDs in the same model instrument, and 7% variation between white light LEDs within the same instrument as shown in Table 2.

**Table 2. Variation in relative radiance for 4 different white LEDs for device type TI1.**
**Data for three different devices and two LED positions are presented**

| Device # | 1 | 2 | 2 | 3 |
|---|---|---|---|---|
| LED Position | 1 | 1 | 2 | 1 |
| Mean Relative Irradiance (mW/cm$^2$) | 110.0 ± 4.6 | 69.8 ± 2.2 | 74.7 ± 4.5 | 78.0 ± 2.0 |

It can be shown that if two light sources are less than 0.1 radians apart, the optical radiation from the sources can overlap on the same area on the retina [18]. Since the separation of the white diodes in each TI is less than 0.1 radians at a distance of 10 cm, the output from the two diodes was added together. This results in a range of times to reach the ANSI/IESNA RP 27.1 limit to between 1.03 and 3.35 minutes.

The calculated time to reach the RP 27.1 photochemical retinal hazard limit for the red diode was over 1000 minutes, while for one of the orange diodes, it was over 5000 minutes. It was, therefore, not deemed necessary to measure the radiance of the other red or orange diodes as the retinal hazard weighting factor is so heavily weighted in the blue region compared to the red and orange region. Since one red and one orange LED were calculated to have a large time to reach the limit, it can be safely assumed that the others would also have a large time as well and therefore do not pose a retinal photochemical hazard.

ANSI/IESNA RP 27.1 also specifies a retinal thermal hazard limit that is applicable for periods of time from 1 s to 10 s. The thermal weighted radiance limit is 56.5 W/(cm$^2$-sr) for 10 s. The thermal weighted radiance found for the white light LEDs ranged from 0.64 to 1.24 W/(cm$^2$-sr). Thus, the mean thermal weighted radiance ranged from 45 to 69 times below the limit for 10 s. Therefore, the white light LEDs for the devices tested do not pose a retinal thermal hazard. The red LEDs fell within the same range and the orange LED had an even lower thermal weighted radiance or 0.15 W/(cm$^2$-sr). Therefore, they also are not expected to pose a retinal thermal hazard.

## 4. Discussion and conclusions

In a recent study, our group found that TIs have the potential to induce a significant temperature rise in skin, yet they do not represent a significant safety concern for exposure durations of four minutes or less [7]. Our current research provides quantitative evidence regarding the potential for optical radiation –induced retinal damage, with a particular focus on the short visible wavelengths (i.e., blue light) known to be the most hazardous. Transilluminators used to locate blood vessels have traditionally used white light from a halogen lamp, but more recent devices are available which use red, orange or white LEDs. We evaluated several different models of transilluminators; two of which used white and red LEDs, one that used red LEDs and three that used red and orange LEDs. Although we were most concerned with white LED devices due to their strong emissions at blue wavelengths, we also evaluated the times to reach the safety limit for the red and orange LEDs. As expected, these longer wavelength LEDs represent a much lower potential hazard for retinal damage.

Based on our evaluation, the light levels produced by all the TIs were below the acceptable limits relevant to eye safety. However, the Time $_{TLV}$ is sufficiently short for TI1 and TI2 (1.03-3.35 minutes) that caution is needed to avoid ocular exposure. This is probably not a significant risk for healthy adults, since most individuals utilizing these devices will not be looking directly at the diode emissions for any length of time. However, it may be a risk for neonates who may be more sensitive and may lack a developed aversion response to bright light [19]. Also, Mactier et al showed that the eyes of infants age 40-50 weeks (post-menstrual) are significantly smaller than adult eyes [20]. They estimate that given a constant

luminance at the cornea, the resulting retinal illuminance will be a factor of 3 higher in the young infant eye. However, their results were based on measurements of vitreous chamber depth, which does not take into account the focusing properties of the eye, which may be less efficient in the very young eye. In the worst case scenario – i.e. if the young eye has the ability to focus images to a sharp spot on the retina – the resulting Time $_{TLV}$ would range from 21 seconds to 1.1 minutes. An additional consideration is that increased oxygen levels in the blood will reduce the dose needed to produce damage in the retina. Since some neonates are kept in an enhanced-oxygen environment, this may put them at a higher risk [21].

It is interesting to note that the "white light" diode has peak irradiance in the region of 440 nm or 460 nm, which is in the blue region of the spectrum – the wavelength region to which the retina is most sensitive. It should be noted that the investigators of this study found it quite uncomfortable to look at the white LEDs, even for a brief moment of time. Recently, Morgan et al [22] demonstrated that exposures below the published safety standards for 568 nm light were capable of producing retinal damage. An analysis of the hazard from this wavelength region should be evaluated once appropriate weighting factors have been developed. There is also the question of whether white light is actually necessary for effective transillumination, as the devices that use only red or orange LEDs seem to perform their intended function quite well [23].

We applied the measurement principles from ANSI/IESNA RP 27.1 in this evaluation, which is similar to the method used by Halbritter et al [24]. Problems identified with using this method include lack of reproducibility among untrained staff and difficulties in aligning the hot spot with the 1.1 mm diameter aperture. Instruments that can easily and quickly measure radiance directly from such sources as the LEDs encountered here would be highly desirable.

Given the low cost and increasing popularity of white light LEDs, combined with their increasing power levels and shorter emission wavelengths, it is likely that the need for appropriate techniques for assessing ocular safety hazards in these devices will increase in the future. Four of the six transilluminators measured in this study – those incorporating red and orange LEDs only – do not appear to present a significant eye hazard. Two of the six TIs – the TI1 and TI2, which incorporate white light LEDs, reached the retinal exposure limit in only 1.03-3.35 minutes. This raises the question about potential exposure hazards to the eyes of neonates, which may be more sensitive and may lack a developed aversion response to bright light. Therefore caregivers should avoid shining the bright light of the TIs at the eyes of neonates, infants and children, or any patient who may have a reduced aversion response. We should emphasize that the values obtained are based upon the use of conservative values for the measurements to err on the side of safety. Nonetheless, to minimize the risk of future eye and skin injuries, the development of an international consensus standard for these devices should also be considered.

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