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ORIGINAL ARTICLE

Measurements of illuminance in simulated daylight photodynamic therapy

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Abstract

Background: Simulated daylight photodynamic therapy (SDL-PDT) is a new treatment alternative for actinic keratosis. The aim of this study was to show how the illuminance that reaches the target skin area during SDL-PDT depends on the spatial positioning of the patient.

Methods: In this technical validation study, illuminance from the SDL-PDT system IndoorLux© was measured at different angles, directions, and distances from the light sources corresponding to potential target skin areas. Using two different photometers, data from 63 measuring points at seven specific distances from the ceiling were collected at 0°, 45°, and 90° angles, respectively. Illuminance levels ≥12,000 lux were regarded as adequate. Hotspots were defined as adequate measurements in all directions at a specific measuring point at distances of 1.3, 1.5, and 1.8 m from the light sources (i.e., the most common patient treatment positions).

Results: Adequate illuminance levels were more common with photometer 1 (73%) than photometer 2 (57%). Almost all illuminance levels were adequate at a 0° angle with both photometers. Adequate illuminance levels were observed at 82–93% of the measuring points at a 45° angle and 22–47% at a 90° angle. Hotspots were registered with both photometers at all measuring points at 0°; 59–79% of the measuring points at 45°; and 0–21% at 90°.

Conclusion: Patient positioning is important during SDL-PDT. Adequate illuminance is achieved if target skin areas are positioned at 0°–45° angles relative to the light sources, but not at 90° angles.

KEYWORDS
actinic keratosis, basal cell carcinoma, Bowen's disease, illuminance, keratinocyte cancer, photodynamic therapy, simulated daylight photodynamic therapy

1 | INTRODUCTION

Photodynamic therapy (PDT) is a well-known and effective treatment for superficial keratinocyte cancers and precursor lesions including superficial basal cell carcinoma, actinic keratosis, and Bowen's disease.[1] Although PDT is a noninvasive method that can be used to treat large areas of affected skin with good cosmetic results, conventional PDT using artificial red light is painful.[1,2]

There are currently several different light sources for conventional PDT on the market, which have been described elsewhere.[1,3,4] Daylight PDT (DL-PDT) was first introduced in 2008 as a less painful outdoors alternative to conventional PDT, with similar clinical effectiveness.[5]

DL-PDT is weather-dependent. The illuminance required for effective treatment has been reported to be >4 J·cm^{-2} (protoporphyrin IX [PpIX] effective radiant exposure), corresponding to at least 11,000 lux (lx).[6–8] The outdoor temperature needs to be at least 10°C[7,9,10] to avoid that the patient gets cold and uncomfortable during the 2-h illumination period.[8] To be able to use DL-PDT when temperatures are below 10°C, a greenhouse can be used.[11] Also, the patient will be exposed to harmful wavelengths of ultraviolet (UV) radiation during DL-PDT, which requires the use of organic sunscreens to prevent sun damage.[8–10]

Simulated daylight PDT (SDL-PDT) is a further development of DL-PDT, which enables year-round treatment with constant illumination in a controlled indoor environment.[6,12–14] Similar to DL-PDT, SDL-PDT not only minimizes pain, but also removes the disadvantages of weather dependency and exposure to harmful UV radiation.[15] Lerche et al. studied several light sources for SDL-PDT including red (18 W), red (140 W), and white (50 W) light-emitting diode lamps as well as halogen lamps from slide projectors (250 W) and overhead projectors (400 W). Merely the first type did not result in photobleaching of protoporphyrin IX, which has previously been determined to be required for successful treatment.[11,16] Further, Marra et al. showed that even ceramic metal halide lamps generate a sufficient illuminance in photobleaching and concluded that white light is an alternative to daylight PDT.[17] Also, O'Gorman et al. showed that a surgical lamp used for illumination during PDT was as effective as DL-PDT for actinic keratoses, but required patients to wear protective eyewear blocking out all light during the 2-h treatment.[13]

Recently, the novel SDL-PDT light system IndoorLux© (SwissRed AG, Murten, Switzerland) was introduced. It consists of eight ceiling lamps emitting white light installed in a treatment room. Prior to the 2-h SDL-PDT illumination period, a tumor-selective photosensitizing agent (commonly aminolevulinic acid or methyl aminolevulinate) is topically administered to the target skin area of the patient. Compared with conventional PDT, SDL-PDT allows the patient to be treated in an air-conditioned area while seated comfortably with the light sources further away from the skin surface. Moreover, SDL-PDT does not require the use of protective eyewear or sunscreen. To date, two small studies, with 12 and 32 participants respectively, have demonstrated that this particular SDL-PDT light system could be a valid alternative to DL-PDT for mild-to-moderate actinic keratoses.[12,14] Nevertheless, it is unclear how illuminance levels are affected by the position of the patient's target skin area relative to the light sources. The objective of this study was therefore to investigate the illuminance levels acquired during SDL-PDT at different angles, directions, and distances relative to the light sources, mimicking the positioning of the target skin area.

2 | METHODS

This technical validation study was carried out at the Department of Dermatology and Venereology at Sahlgrenska University Hospital in Gothenburg, Sweden, where an IndoorLux© SDL-PDT light system was installed in 2017. The treatment room has eight light sources mounted in the ceiling at a height of 2.42 m from the floor with a 4 × 2 disposition as shown in Figure 1. The total area of illumination is 2.4 m × 1.8 m. The white light produced by the SDL-PDT system covers the whole visible light spectrum, but with the majority of energy in the wavelengths ranging from 560 to 630 nm. The maximum peak wavelength is reached at 586 nm. Thus, the treatment spectrum lies outside the harmful UV range. The manufacturer guarantees a minimum of 12,000 lx in the treatment area. To assure that 12,000 lux is sufficient for an effective dose radiation, we consulted the state-owned National Laboratory for Photometry and Radiometry, RISE Research Institutes of Sweden. In collaboration with photometric experts, a mathematical calculation was performed to convert illuminance exposure (lx·s) into PpIX effective radiant exposure (J/cm^2). For the calculation, the spectral curve of IndoorLux© from the manufacturer was collected and multiplied with the global standard for the Photopic curve V(λ).[18] This calculation correlates the absolute photometric value of 12,000 lux to the radiometric equivalent for the specific spectrum. We found that IndoorLux© produces a sufficient dose for effective treatment of 16 J/cm^2, mainly within the green and red spectra, after 80 min of treatment.

A Hilti PM 2-LG green line projection laser (Hilti Corp, Schaan, Liechtenstein) and a DISTO D1 rangefinder laser (Leica, Arau, Switzerland) were used for demarcation of all reference points marked out with masking tape and a waterproof multimarker. A grid pattern with 63 reference points was laid out on the floor of the SDL-PDT room with a distance of 0.3 m between each point. Photometer 1 was an Elma 1336 (Elma Instruments, Farsta, Sweden) with an overall accuracy of ±3%. Photometer 2 was an LT45 (Extech instruments, Nashua, NH, the United States) with an accuracy of ±3% at angle 0° and an additional ±2% at 30°, ±6% at 60°, and ±25% at 80°. Both photometers were precisely placed at different distances from the light sources directly above each reference point using a laser rod with leg supports (Limit, Alingsås, Sweden). Illuminance measurements were registered at the following distances from the light sources: 0.9, 1.1, 1.3, 1.5, 1.8, 2.1, and 2.4 m (i.e., 2 cm above the floor). This resulted in 441 measuring points (63 reference points × 7 distances from the light sources) from which measurements were collected with both photometers. Individual measurements were performed at nine different angles relative to the light sources: one directly facing the light sources (0° angle), four at a 90° angle relative to the light source (toward the front, back, left, and right), and four at a 45° angle (toward the front, back, left, and right). Thus, a total of 3969 illuminance measurements were carried out with each photometer.

During SDL-PDT, patients are usually seated slightly reclined in an armchair with their legs on a footrest. In this position, the light sources are approximately 1.3 m away from the face and scalp, 1.5 m away

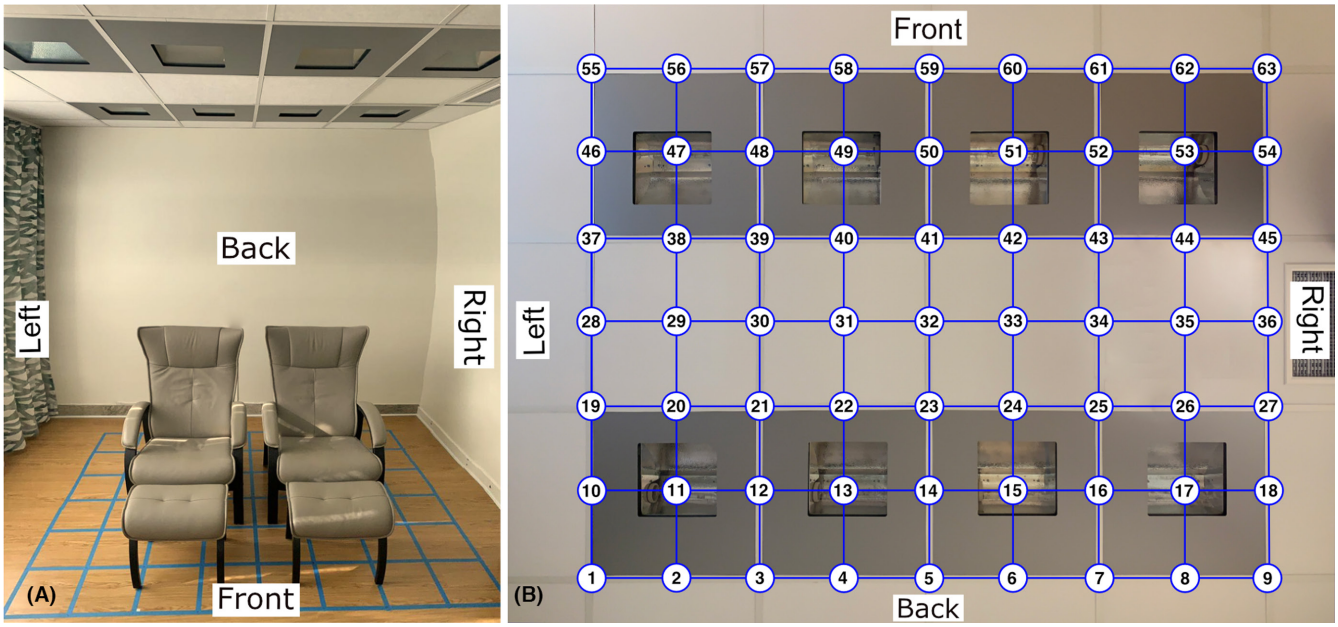


FIGURE 1 Disposition of the light sources in the simulated daylight treatment room. (A) Frontal view of the treatment room with its eight ceiling light sources placed directly above two armchairs, where patients are seated during treatment. The grid on the floor demarcates reference points for illuminance measurements. (B) Worm's eye view of the 63 reference points on the floor grid relative to the light sources

from the torso and upper extremities and 1.8 m from the lower extremities. Special attention was paid to these measuring points since they are of higher clinical relevance. A hotspot was defined as any reference point at a specific distance from the light sources in between 1.3 m and 1.8 m at which all illuminance measurements were adequate, regardless of the direction relative to the light sources.

All measurements were performed by a single investigator. To avoid the impact of sunlight, the treatment room was equipped with light-blocking blinds. The SDL-PDT light system was turned on for 30 min before any measurements were performed according to manufacturer recommendations. All measurements ≥12,000 lx were considered to be theoretically adequate for SDL-PDT to be successful. According to the Swedish Ethical Review Authority, development work and quality insurance without patient involvement do not require ethical approval.

3 | RESULTS

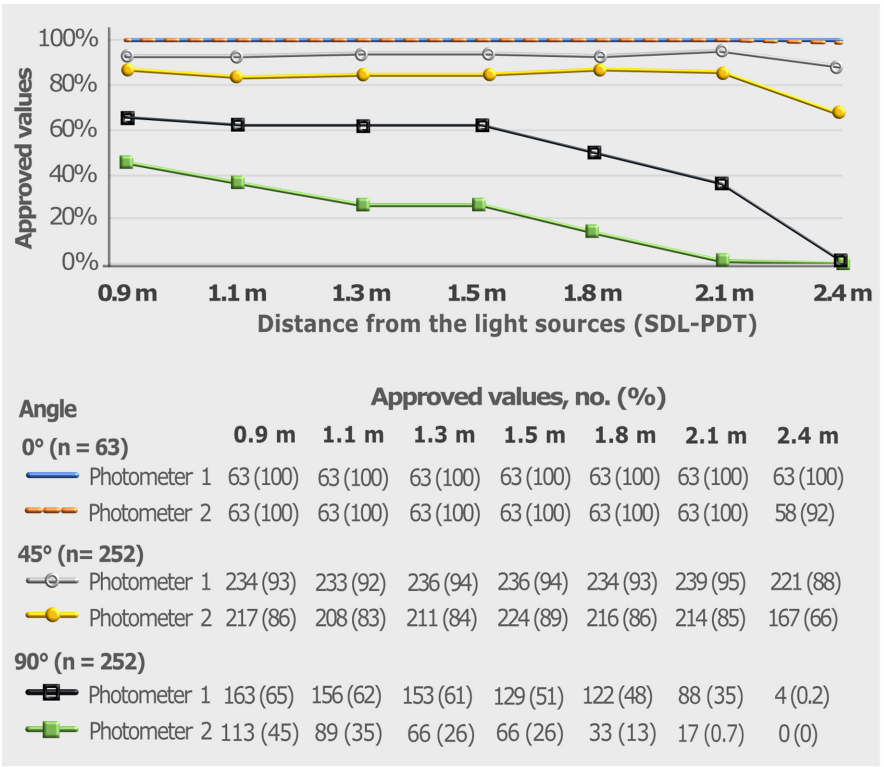
Overall, photometer 1 resulted in a higher rate of adequate measurements (73%, $n = 2895$) than photometer 2 (57%, $n = 2275$). The median illuminance for photometer 1 was 17,630 lx (range 1376–72,290 lx) overall and 18,020 lx (range 1376–49,170 lx) at 1.3–1.8 m from the light sources. For photometer 2, the corresponding levels were 13,390 lx (range 770–50,600 lx) overall and 13,600 lx (range 1150–36,310 lx) at 1.3–1.8 m from the light sources.

Figure 2 shows the proportion of adequate illuminance measurements (≥12,000 lx) at different distances from the light sources. At a 0° angle relative to the light sources, adequate measurements were acquired in 100% of the cases with photometer 1 (441/441; range 12,140–72,290 lx) and 99% with photometer 2 (436/441, range 12,390–56,900 lx). The five inadequate measurements were obtained at measuring points in corners of the grid at floor level (2.4 m).

At a 45° angle, illuminance measurements were adequate in 93% (1632/1764) of the cases with photometer 1 and 82% (1454/1764) with photometer 2. The inadequate levels were obtained in the outer edges of the floor grid at almost every distance from the ceiling to the floor level.

At a 90° angle, 47% (824/1764) of the total measurements with photometer 1, and 22% (385/1764) of the total measurements with photometer 2 were adequate. When the photometers were facing left, the adequate measurements were mainly found on the right half of the room and vice versa. Similarly, when the photometers were facing backward, the adequate measurements were mainly found in the front half of the room and vice versa. In addition, a gradual decrease in the number of adequate measurements was observed closer to the floor level with both photometers.

All illuminance measurements are available in Table S1. Figure 3 shows the adequate illuminance measurements at the clinically most relevant distances from the light sources: 1.3 m (representing the face/scalp area), 1.5 m (torso/upper extremities), and 1.8 m (lower extremities). At a 0° angle, hotspots were identified at all reference points and at all three distances from the light sources with both photometers. At a 45° angle, photometer 1 resulted in hotspots at 79% of the reference points at 1.3 m, 78% at 1.5 m, and 76% at 1.8 m. The corresponding results for photometer 2 were 59% at 1.3 m, 68% at 1.5 m, and 60% at 1.8 m. At a 90° angle, hotspots were attained at 21% of the reference points at 1.3 m, 3% at 1.5 m, and 3% at 1.8 m with photometer 1. No hotspots were achieved with photometer 2 at the 90° angle.



Angle	Approved values, no. (%)						
	0.9 m	1.1 m	1.3 m	1.5 m	1.8 m	2.1 m	2.4 m
0° (n = 63)							
Photometer 1	63 (100)	63 (100)	63 (100)	63 (100)	63 (100)	63 (100)	63 (100)
Photometer 2	63 (100)	63 (100)	63 (100)	63 (100)	63 (100)	63 (100)	58 (92)
45° (n= 252)							
Photometer 1	234 (93)	233 (92)	236 (94)	236 (94)	234 (93)	239 (95)	221 (88)
Photometer 2	217 (86)	208 (83)	211 (84)	224 (89)	216 (86)	214 (85)	167 (66)
90° (n = 252)							
Photometer 1	163 (65)	156 (62)	153 (61)	129 (51)	122 (48)	88 (35)	4 (0.2)
Photometer 2	113 (45)	89 (35)	66 (26)	66 (26)	33 (13)	17 (0.7)	0 (0)

FIGURE 2 Proportions of adequate illuminance measurements (≥12,000 lx) in relation to the distance from the SDL-PDT light sources

4 | DISCUSSION

This study investigated the true illuminance levels acquired in an SDL-PDT room at different distances, angles, and directions relative to the light sources. Our results indicate that optimal patient positioning during treatment is important. When the patient is facing the ceiling at a 0° angle, almost all body parts commonly treated with PDT received adequate illumination (≥12,000 lx). Target skin areas directed at a 45° angle relative to the light sources (e.g., chest or upper arms) were also found to receive adequate illuminance levels if the patient was positioned above the center of the floor grid. However, treatment areas at a 90° angle relative to the light sources (e.g., temples, lateral cheeks, or lateral parts of the extremities) received inadequate illuminance levels in most parts of the SDL-PDT room.

We have found that in SDL-PDT, the most favorable position of the target skin areas is at a 0° angle relative to the light sources. To avoid insufficient illuminance levels and increase the probability of a successful treatment for the body parts that rest naturally at a 45° angle, it is important to position the patient centrally on the floor grid. If possible, 90° angles should be avoided, preferably by repositioning the patient. Inadequate illuminance levels may also result from an attempt to treat symmetrically distributed lesions (e.g., both cheeks or both temples) during the same session. When treating symmetrically distributed lesions, two separate SDL-PDT sessions may have to be planned in order to change the angle of each treatment area to 45° or 0° relative to the light sources.

This technical validation study shows that SDL-PDT illuminance levels are dependent on angles, directions, and distances from the light sources, thus confirming known optical laws of nature. In concordance with our results, the importance of the distance and angle to the light source in SDL-PDT has previously been described.[11,19,20] Another light system has addressed the problems with insufficient illuminance due to the angles at which the light reaches the skin. The Medisun® daylight 9000 booth (Schulze & Böhm GmbH, Brühl, Germany) uses 8 LED spotlight panels placed around the patient's head from the sides and diagonally from above with two lamps in front of the patient and two behind the patient. This system was used on 39 patients with actinic keratoses on the face and/or the scalp achieving an average illuminance of 20,000 lx on all treatment areas resulting in a significant reduction in the number of lesions.[21] Furthermore, the Dermaris is a mobile configuration module light system that uses 4 LED lights, with a treatment area diameter of 20 cm and an illuminance of 20,000 lx.[22] The Dermaris system has shown a 93% cure rate in a study on 293 actinic keratoses on the scalp, although restricting the illuminance to a smaller target skin area.[23] A retrospective study using the same SDL-PDT system as described in our study, demonstrated a 93% complete lesion clearance rate for actinic keratoses grade I–II on the face and scalp in 32 patients with approximately 5 lesions per patient.[12] Similarly, another recently published prospective study of 12 patients with ≥3 lesions per patient treated with the IndoorLux© system showed a clearance rate of 93% for the same diagnosis and anatomical locations.[14]

The strengths of this study include the standardization of the measurements and the large numbers of measurements at different angles, directions, and distances from the light sources in the SDL-PDT treatment room. These measurements were also performed with two different photometers and by a single investigator to avoid inconsistencies. This study also has several limitations. Firstly, illuminance measurements were used instead

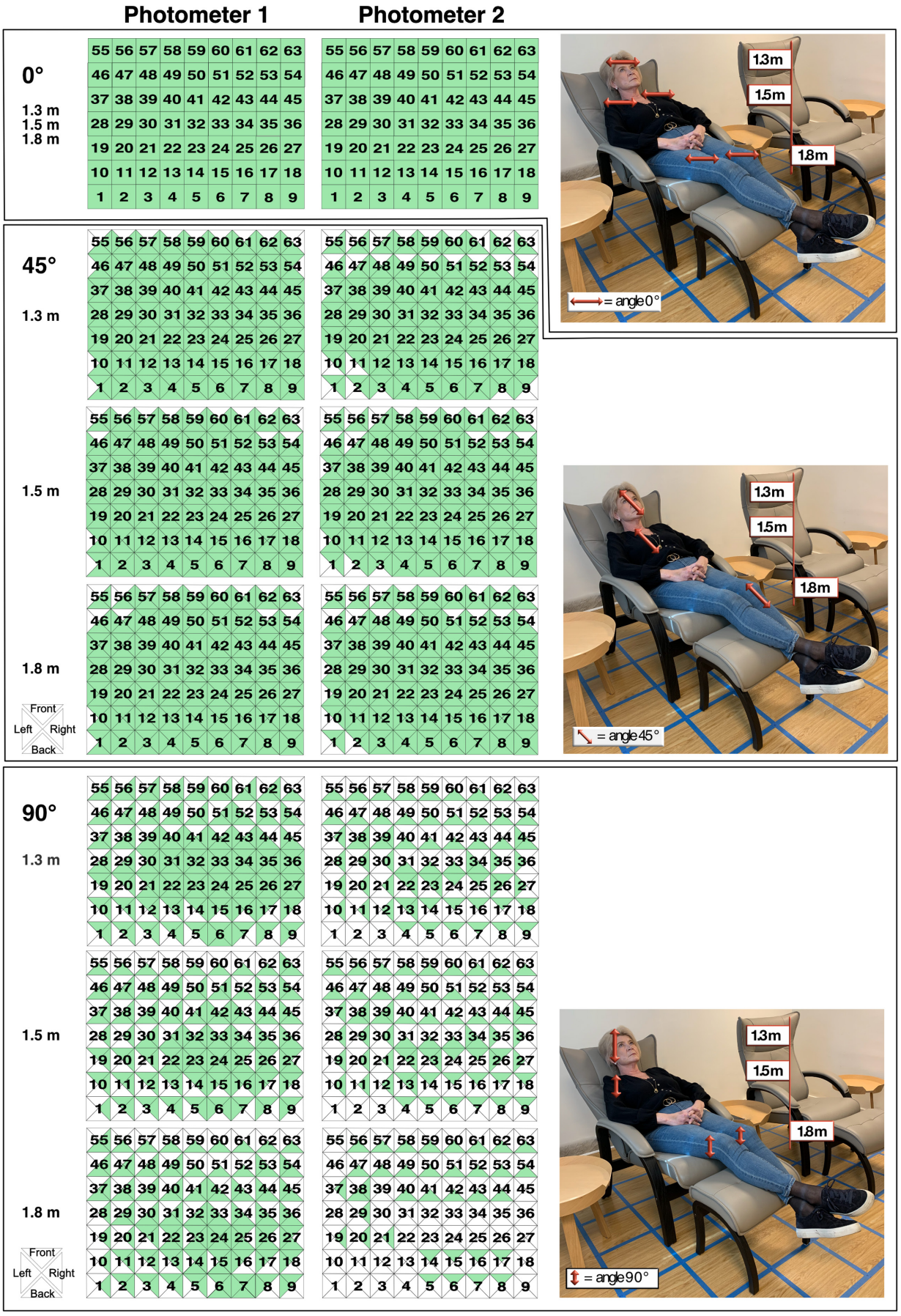


FIGURE 3 Adequate illuminance measurements (highlighted in green) in the most common treatment areas, that is, face/scalp (1.3 m), torso/upper extremities (1.5 m), and lower extremities (1.8), with the patient seated slightly reclined. Numbers 1–63 represent the reference points in the floor grid

of PpIX-weighted irradiance measurements. Nevertheless, according to Kellner et al., the combined effective light dose of the IndoorLux© system within the green and red spectra relevant for PpIX activation is 14.3–24.2 J/cm^2.[12] The emitted light from the IndoorLux© system at 12,000 lux reaches an effective dose of 16 J/cm^2 after 80 min according to the mathematical analysis using the Photopic curve $V(\lambda)$[18] and the spectral curve of IndoorLux©. Furthermore, the two photometers showed disparate illuminance levels, particularly for measurements at a 90° angle. Both photometers had a basic accuracy value of ±3% but at an angle of 80°, photometer 2 had an additional increased error value of up to ±25%. Therefore, it may be of importance for healthcare providers to take the error value into consideration when purchasing a photometer. However, we do not believe that the inaccuracy of the instruments had any significant impact on our overall conclusions. Reasons for disparate values of the two photometers might be power linearity and/or a mismatch of the $V(\lambda)$ filter when measuring high levels in a non-daylight spectrum.

In a real-life situation, healthcare providers may use only one photometer or not measure illuminance at all. If a photometer is used, it might not be the same model as the ones used here. Secondly, our data are solely based on the measurements from an SDL-PDT treatment room at a single center and may not necessarily be representative of the conditions in other treatment rooms and/or when using other SDL-PDT systems. To investigate the external validity of our results, it would therefore be of value to replicate the study in similar treatment rooms that have been implemented in other European countries.

5 | CONCLUSION

Illuminance levels during SDL-PDT are dependent on patient positioning. Adequate illuminance levels during SDL-PDT can always be achieved when treating body parts directly facing the light sources (0° angle). At a 45° angle, adequate illuminance can readily be achieved, especially when the most common skin target areas are positioned at 1.3, 1.5, and 1.8 m above the floor (hotspots). Nevertheless, using SDL-PDT for body parts positioned at a 90° angle relative to the light sources may be ineffective. To ensure illuminance levels ≥12,000 lx during SDL-PDT, we recommend control measurements with a photometer before treatment. Repositioning of the skin target area to a 0° or 45° angle, as well as positioning the patient as centrally as possible in the treatment room, may improve clinical results.

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CONFLICT OF INTEREST

None to declare.

AUTHOR CONTRIBUTIONS

Alexandra Sjöholm and John Paoli contributed to the conception or design of the work. Alexandra Sjöholm collected the data. Alexandra Sjöholm, Magdalena Claeson, and John Paoli contributed to the data analysis and interpretation, drafting of the article, critical revision of the article, and final approval of the version to be published.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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