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COMPARISON OF NORMATIVE PARAMETERS IN POST-MARKET SURGICAL LIGHTING.

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Abstract: The quality of a surgical light plays a fundamental role in the context of surgery, directly influencing the results and patient safety. The certification process for this equipment is governed by various standards, including NBR IEC 60601-2-41. In this study, two surgical lights installed in the operating room were selected, one with an LED lamp and one with a halogen lamp, from the University Hospital of the University of São Paulo. These datasets were then processed using dedicated software to derive precise values of the lights under examination. The results in relation to the optical requirements were measured and evaluated according to the requirements of the standard. Both lights performed adequately in relation to the requirements of the standard.

1. INTRODUCTION

The quality of a surgical light plays a fundamental role in the context of surgery, directly influencing results and patient safety. As an essential tool for illumination during surgical procedures, the right surgical light provides clear and precise lighting, allowing surgeons to accurately visualize the operating field. Ideal lighting minimizes reflections and distortions, requiring detailed consideration of surgical lighting variables. [2]

The certification process for this equipment is governed by various standards, including NBR IEC 60601-2-41: Electromedical Equipment: Requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis [1]. This standard provides a set of tests that assess the essential performance of surgical luminaires.

The evaluation criteria was based in five parameters:

A. Central Illuminance: Measures the light intensity at the center of the light. The maximum allowed value is 160,000 Lux.[1]

B. Light Field Diameter: Determines the size of the illuminated area at 50% (d50) and 10% (d10) of the central illuminance. Measurements are taken from a distance of 1 meter from the light, and the uniformity is checked using light distribution curves.

C. Color Rendering Index (CRI): Measures how accurately the light shows colors, which is important for distinguishing different tissues. The CRI should be between 85 and 100 [1][3].

D. Chromatic Coordinates: Measure the color accuracy using specific boundary points. The measured coordinates must fall within a area defined by the standard [1].

E. Color Temperature: Given in Kelvin, it affects the color appearance of the light. The standard [1] range is from 3000K to 6700K, where lower values are more reddish and higher values are more bluish.

It's interesting that after the initial certification tests, equipment should be monitored with a certain frequency regarding its essential performance. Equipment may, by chance, undergo changes in component qualities, suffer from maintenance that doesn't use original components, among other factors. With these alterations, there may be variations in the analyzed results from post-market tests compared to certification tests. The objective of this study is to verify the results of equipment that are already in use and whether they possess the values and essential performance within the established norms to which they were subjected. It was also possible to analyze the evolution and differences in surgical lighting technologies, specifically comparing incandescent lamps with LED lamps.

2. MATERIALS AND METHODS

1. *Equipment Under Evaluation*

Two surgical lights installed at the University Hospital of the University of São Paulo were selected. The surgical light identified as Light A is an LED spotlight (Steris, Harmony Vled, USA). The surgical light identified as Light B is a halogen lamp focus (Maquet, Hanaulux Blue, Sweden).

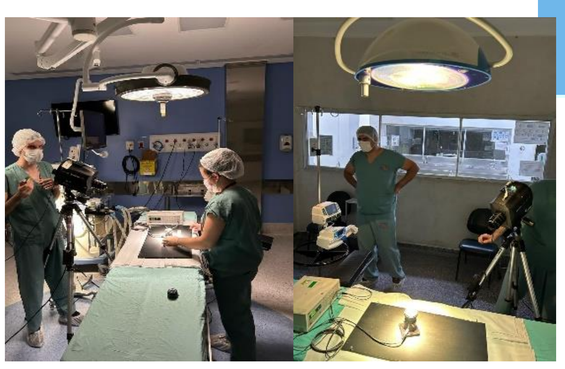

Fig. 1 Light A and B evaluated

2. *A. Central Illuminance and B. Light Field Diameters (d10,d50)*

To measure the maximum illuminance, the lights were aligned one meter from the surface of the calibrated photometer sensor (Optronics, Diglux 9500, USA). With the photometer aligned, a small movement was made to locate the point of maximum illuminance in the central region. For light field diameters, from the alignment made for maximum illuminance, the photometer was moved in one centimeter steps on the vertical and horizontal axes, with the aid of a scale, as shown in Figure 2.

Fig.2 The photometer in position for measurements

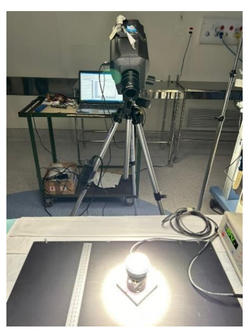

Fig. 3 Spectroradiometer and reflectance standard positioned to acquire spectral data from the focus.

3. *C. Color Rendering Index (CRI), D. Chromaticity coordinates and E. Color temperature, color rendering indices (RA and R9)*

These parameters were obtained from the spectral data measured with a spectroradiometer (Photoreserach, PR705, USA) and a calibrated reflectance standard, as shown in Figure 3. The spectroradiometer was positioned at an angle of 45º to the horizontal and at 50 cm distance from the reflectance standard. The acquired data is compiled using the CIE13_3W software that uses the CIE 13.3 measurement method, which is the method required by the standard [4], and R9, which is the red color index [5]. The compiled values are then compared with the radiation values and the results are obtained.

3. RESULTS

1. *A. Maximum Illuminance and B. Light Field Diameters*

Table 1 shows the maximum illuminance values for each of the lights. Table 2 shows the light field diameter d10, d50 and uniformity ratio values obtained from the measurements on the vertical and horizontal axes.

Equipment	Maximum lluminance (lux)
Light A	130,000
Light B	34,440

Table 1: Maximum illuminance values for luminaires A and B

Equipment	d10 (mm)	d50 (mm)	Ratio d50/d10
Light A	160	80	0.50
Light B	290	150	0.52

Table 2: Light Field diameter and uniformity ratio for lights A and B

Figures 4 and 5 show the light distribution profile graphs for the two luminaires.

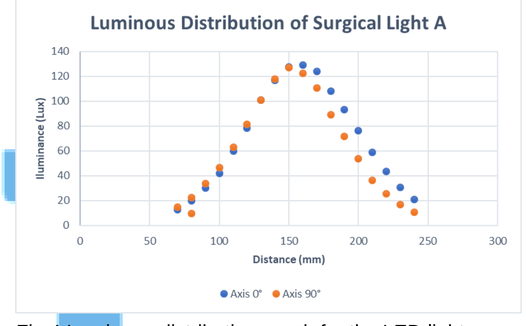

Fig.4 Luminous distribution graph for the LED light.

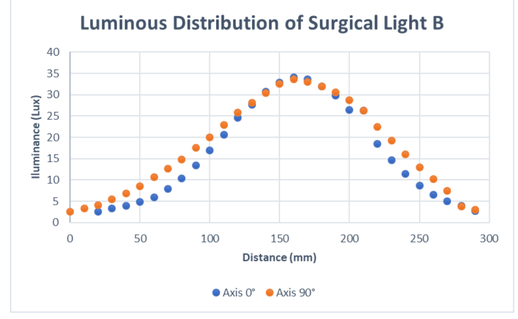

Fig.5 Luminous distribution graph for the halogen light.

2. *C. Color Rendering Index (CRI), D. Chromaticity coordinates and E. Color temperature, color rendering indices (RA and R9)*

Table 4 shows the values obtained for color temperature, RA, while Figure 6 show the chromatic coordinate values measured for both lights.

Equipment	Color temperature (K)	RA
Light A	4629	96.03
Light B	3934	93.40

Table.4 Color temperature and RA values for lights A and B

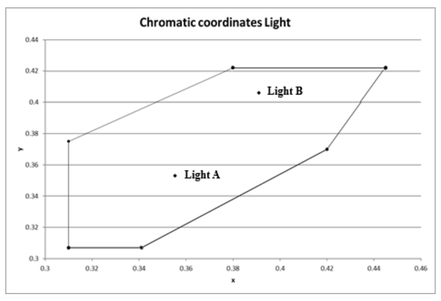

Fig.6 Chromatic coordinate graph for Light A and B.

4 CONCLUSIONS

For the maximum illuminance requirement, both luminaires had values below 160 kLux. For the distribution the d10 and d50 values are reasonable. With regard to the chromaticity coordinates, both luminaires have the coordinate point within the geometric figure specified by the standard. Embracing normative testing in the post-market phase offers significant advantages, enhancing patient safety even further. This research demonstrates that conducting normative tests in surgical environments is entirely feasible through collaborative efforts among all stakeholders.

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