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Radiometric Technique to Assess the Qualification of Phototherapy Luminaire for Jaundice Treatment

KEYWORDS: Hyperbilirubinemia, Phototherapy, Irradiance, Uncertainty.

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ABSTRACT *The most common therapeutic intervention used for the treatment of hyperbilirubinemia is phototherapy. The effectiveness of neonatal hyperbilirubinaemia treatment depends directly on the exposure to blue light (λ ≈ 450 nm) expressed by irradiance in W/m2. To assess the efficacy of the light source, a radiometric method was setup to ensure the competence of phototherapy devices (luminaire) to the standard international and national requirements. In this work, nine types based on fluorescent lamps which found to provide a uniformity higher than the minimum standards requirements (0.45 - 0.75), and four types based on Light Emitting Diodes (LEDs) phototherapy devices provide a uniformity (0.05 - 0.42). While as the irradiance levels obtained from lamps (< 8 – 26.7 µW/cm2/nm) and (33.3 – 122.2 µW/cm2/nm) from LEDs. Hence, NIS provides traceability to customer through unbroken chain of phototherapy radiometer calibrated as irradiance response in W/m2. Uncertainty model includes (calibration of the reference detector, distance effect, drift of the calibration, repeatability, and the resolution of the measuring device) are studied.*

INTRODUCTION

Phototherapy is the most commonly used therapeutic regimen in newborn care, being the choice manipulation for jaundice. It has been used since 1958 for the treatment of neonatal hyperbilirubinaemia [1][2]. Jaundice appears in approximately 50% of newborn infants at the first week of their life [3][4][5]. The aim of phototherapy is to decrease the level of unconjugated bilirubin in order to prevent acute bilirubin encephalopathy, hearing loss and kernicterus. The decrease of Total Serum Bilirubin (TSB) during phototherapy is a result of the formation of photoisomers. It causes unconjugated bilirubin to be mobilised from the skin by structural isomerisation to a water soluble form (lumirubin) that can be excreted in the urine [6].

The decision to start phototherapy is based on the level and rate of rise of serum bilirubin, the gestational and postnatal age of infant and the underlying cause of the hyperbilirubinaemia. The efficacy of phototherapy in reducing TSB depends on physical and biological parameters as: the light wavelength, irradiance, bilirubin level, birth weight, surface area exposed, skin thickness and pigmentation of the jaundice [7][8][9][10] describe optimal phototherapy as blue light in the emission spectrum of 400 nm to 550 nm delivered at an optimum light irradiance to the largest possible body surface area. Previous studies showed a dose response relationship between light irradiance and decrease of TSB. The efficiency of phototherapy depends on the photochemical transformation of bilirubin in areas exposed to light. This reaction alters the molecular structure of bilirubin and allows photoproducts to be eliminated by the kidneys and liver without being metabolically transformed. Therefore, the basic mechanism of action of phototherapy is the use of photoenergy to transform bilirubin into more hydro-soluble products [6][11]. Many studies had done to manage the neonatal jaundice using irradiance of wavelengths from 420 to 500 nm. [12][13].

In this work, a radiometric setup was developed to test and compare the validity of different flourecencent and LED's light sources for international and national standards. The parameters affecting the measurements results (uncertainty budget) was evaluated and calculated for different phototherapy luminaries.

Fluorescent tubes are the most common type of light source used. Blue, green and white fluorescent tubes have been seen in use. Fluorescent tubes have the advantage of being inexpensive but their light intensity (irradiance) reduces with time [14]. Users are advised by manufacturers to change the lamps after a specified number of hours of use, which may range from 1000 to 2000 hours [14]. In recent years Light Emitting Diodes (LEDs) have been incorporated into phototherapy units. LEDs have the advantage of power efficient, portable devices and low heat production so that they can be placed very close to the skin of the infants. They are also durable light sources with an average life span of 20000 hours. Blue LEDs have a narrow spectral band of high intensity monochromatic light that overlaps the absorption spectrum of bilirubin [15][16].

MATERIAL AND METHODS

A set up based on mini-spectrometer for relative spectral power distribution and standard radiometer for absolute irradiance measurement from phototherapy lamps is used, respectively. A mini-spectrometer, Model C10082CA from Hamamatsu, with appropriate input optics (monochromator with optical fiber and CCD image sensor) is used as a wavelength tunable-filter radiometer to evaluate the spectral power distribution, shown schematically in Fig.1.Light to be measured is guided into the entrance port of spectrometer through an optical fiber and the spectrum meas-

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ured with the built-in CCD image sensor is output through the USB port to a PC for a data acquisition. An optical fiber that guides light input from external sources (Phototherapy lamp) allows a flexible measurements setup.

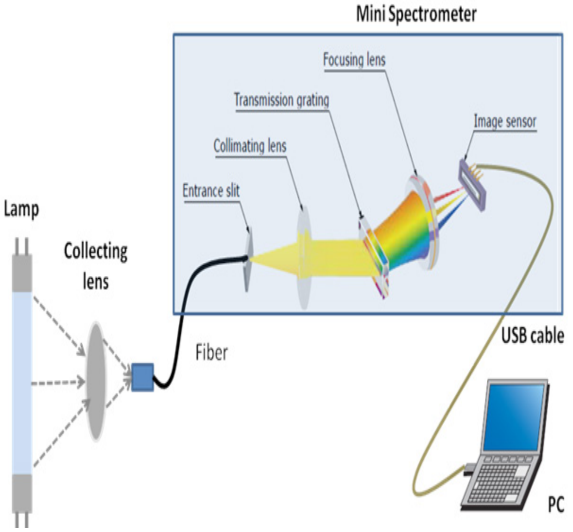

Figure 1: NIS setup for measuring the spectral power distribution based on mini-spectrometer from Hamamatsu.

On the other hand, to ensure the phototherapy luminaire competence to fulfill the requirements of the national and the international standards, the absolute irradiance levels produced from a phototherapy luminaire using a standard radiometer is shown in Fig. 2. It is based on measuring the irradiance levels of a luminaire at distance of 50 cm at different irradiated points using a standard calibrated radiometer model 268BLUE from the United Detector Technology (UDT) Inc. According to the requirement of the stranded the irradiated area is a rectangle sheet, its dimension defined as 30 cm * 60 cm. The tested luminaire were aligned horizontally parallel to the irradiated area, also their centers aligned to be at the same line perpendicular to both. The irradiance levels are measured at different points spread over the irradiated area each separated by not more than 10 cm. So the irradiated area was divided into 3 rows and 5 columns resulting of 15 measured points as shown in (Fig. 2). The irradiance levels have been measured for five times at the center of each of the above mentioned area cell.

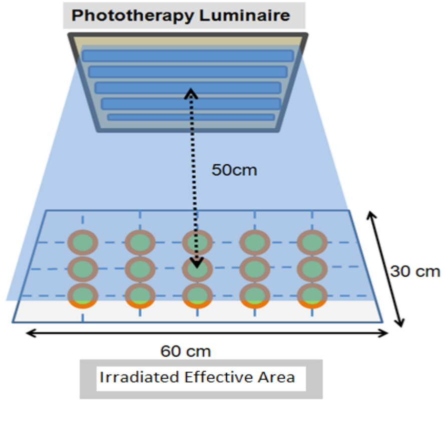

Figure 2: NIS setup for testing a phototherapy luminaire

In this study, nine types based on fluorescent lamps and four types based on Light Emitting Diodes (LEDs) phototherapy devices inside the Egyptian markets are studied.

RESULTS AND DISCUSSION

- **Spectral Power Distribution Measurements:**

Phototherapy luminaire devices under test of in use lamps-from different manufactures are classified into four groups; three of them are florescent and the last one LED coded as following:

i. Green lamps group (coded G1 and G2).
ii. White lamps group (coded W1,W2 andW3).
iii. Blue lamps Group (coded B1,B2,B3 andB4).
iv. Blue LEDs group (coded LED1,LED2,LED3,and LED4).

Results of their relative spectral power distribution are shown in figures 3-6.

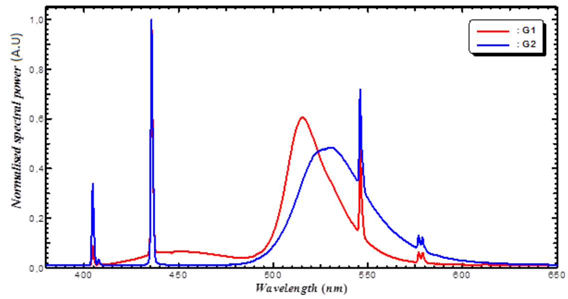

Figure 3: Output spectra of green lamps group.

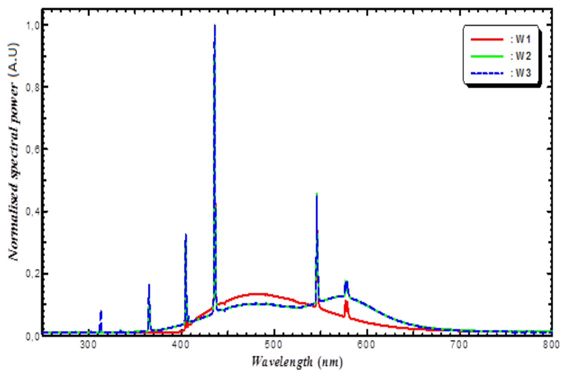

Figure 4: Output spectra of white lamps group.

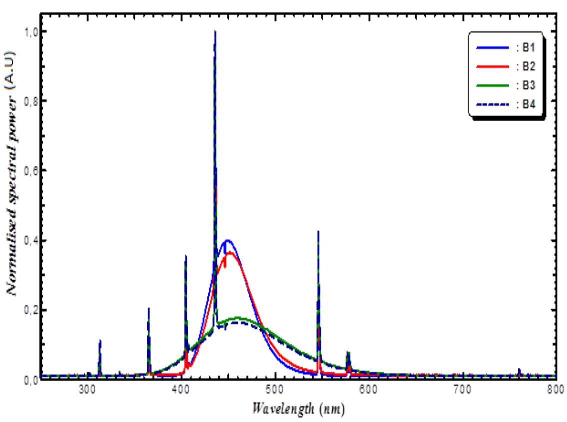

Figure 5: Output spectra of blue lamps group

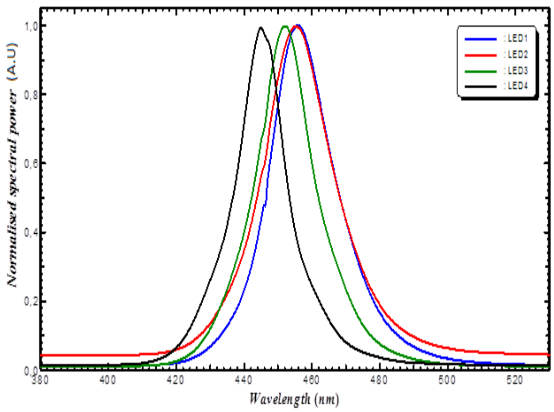

Figure 6: Output spectra of LED sources group

It is found that blue sources (either fluorescent or LED) emit a spectra that fit and fulfill the requirements of the national and the international standards in the range 400 nm-550 nm region as well as its high intensity irradiation. On the other hand, green phototherapy lamps emit bands beyond the purpose of interest while white phototherapy lamps emit bands of lower intensity than blue sources. This result is matching with the preliminary study which states that "blue tubes are most effective because they provide light predominantly in the required spectrum". [17].

Figure 7 reveals this comparison between all lamp samples in providing relative power predominantly in the required spectrum (400 nm - 550 nm) and how much UV hazard radiation from each lamp.

It shows that LED spectrum is approximately free of UV radiation and has more intense output than the other lamps as well as longer life time. The same benefits achieved from the blue lamps especially coded B1 and B2 as they are special blue sources with also low UV radiation amount.

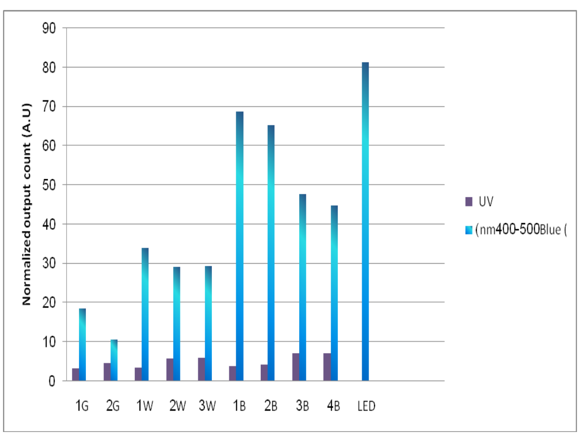

Figure 7: UV and Blue outputs of the studied sources.

- **Irradiance and Uniformity (G factor)Measurements:**

The absolute spectral irradiance in W/m²/nm (which expresses the phototherapy dose) and uniformity (G factor) was calculated to insure the fulfillment of the requirements with the national and the international standards.

Several and different phototherapy luminaries types are used in hospitals, manufactures, laboratory....etc. Commonly, to get the desired irradiance (dose) and uniformity (expressed by G factor), they use either four to six parallel fluorescent lamps-based luminaire type or LED-based luminaire type with a special design.

Absolute spectral irradiance for Bilirubin (E_{bi}) in the range 400 nm and 550 nm in (W/m²/nm) is given by the following integration [18][19][20] .

$$E_{bi} = \int_{400nm}^{550nm} E_{\lambda}(\lambda) d\lambda \qquad (1)$$

Where E(λ)is the measured irradiance at an individual wavelength (λ) in (W/m²/nm).

According to standards requirements, normal phototherapy level is 8-10 μW/cm²/nm and intensive phototherapy level is greater than 30μW/cm²/nm. Luminaries under test must be complying with the previous standard implementation and rationale phototherapy levels.

On the other hand, G factor, which represent the luminaire uniformity, is defined as the ratio of the lowest irradiance level $E_{bi(min)}$ to the highest irradiance level $E_{bi(max)}$ on the effective surface area, given by equation 2.

$G = E_{bi(min)} / E_{bi(max)}$...................................... (2)

According to standard requirement, the ratio of $E_{bi(min)}$ / $E_{bi(max)}$ must be greater than 0.4, i.e (G < 0.4). [18][19][20]

Fig.8 shows the total irradiance form nine different luminaries which used the pervious coded lamp sources.

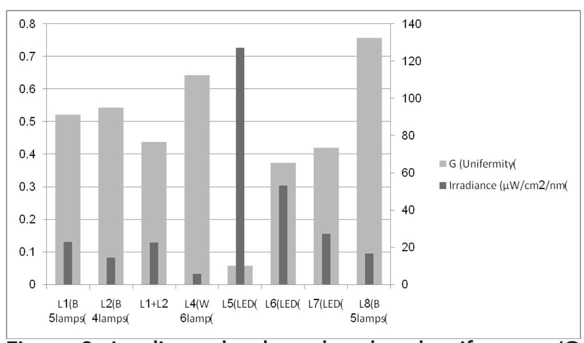

Figure 8: Irradiance level produced and uniformoty (G factor) calculated from differant luminaires.

Fig.8 shows that L5 (LED) luminaire has the highest irradiance than the others and the L8 (B5lamps) Luminaire has the highest G factor .

Two luminaire in this study was excluded (L4 and L5) due to their failing to fulfill the standard requirements. The L4 produce very low irradiance level below the 8μW/cm2/nm and L5very low G value < 0.4.

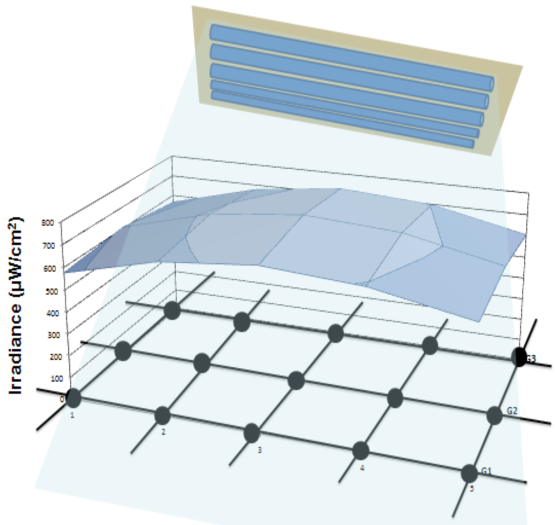

Figure 9: Sample of the irradiance-unifermity distribution ovcer the irradiated area for lamp luminaire

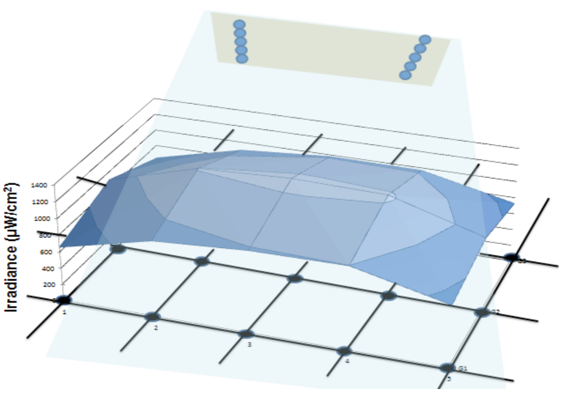

Figure 10: Sample of the irradiance-unifermity distribution ovcer the irradiated area for LED luminaire

Figures 9 and 10 are samples of the irradiance levels for two different luminairs with their uniformity distribution for each row of the irradiated area. It clarify that the uniformity distribution is nearly equal over the irradiated area of the lamp luminaire and has a noticeable difference in the LED luminaire .

MEASUREMENT UNCERTAINTY

$$E_{bi} = \int_{400nm}^{550nm} E_\lambda(\lambda)d\lambda \qquad (1)$$

The mean integral total irradiance for Bilirubin E_m between all measured points onto the effective surface area by the irradiated standard radiometer, corrected for dark irradiance.i.e: $E_m = \overline{E_b}$.

The associated uncertainty must be quoted whenever the results of a measurement are reported. This tells the user about the precision with which the measurement was made. Uncertainty analysis is thus a fundamental part of metrology.

Evaluation of the uncertainty is done by the Guide to the expression of Uncertainty in Measurement (GUM) method. This method is adopted and described in details by International Organization for Standardization (ISO) [21]. The standard uncertainty $u(x_i)$ to be associated with input quantity x_i is the estimated standard deviation of the mean given by [22].

$$u(x_i) = s(\overline{X}_i) = (\frac{1}{n(n-1)}\sum_{k=1}^{n}(X_{i,k} - \overline{X}_i) \qquad (3)$$

Where $\overline{X}_i$ is the mean and n is number of measurements. The combined standard uncertainty $u_c(y)$ is obtained by combining the individual standard uncertainties u_i, these can be evaluatedet as type A and Type B. That is,

$$u_c^2(y) = \sum_{i=1}^{N}\left(\frac{\partial f}{\partial x_i}\right)^2 u^2(x_i). \qquad (4)$$

Type A uncertainty, Evaluated by using the statistical distribution of the results: σ = Standard Deviation / n = no. of measurements while Type B evaluations – uncertainty estimates from any other information. This could be information from past experience of the measurements, from calibration certificates, manufacturer's specifications, from calculations, from published information, and from common sense.

For the determination of the phototherapy irradiance the following model of evaluation is used at the mean total irradiance Em = 657 μW/cm2. Uncertainty components used is:

$$E_m = E_s + \delta E_l + \delta E_d + \delta E_r + \delta E_{res} \qquad (5)$$

The symbol means:

$E_s =$ Uncertainty due to reference standard:The calibration certificate for the reference standard gives a value of irradiance responsivity equal to 4.6 x 10^{-2} A/W/cm^2 (at 450 nm) with an associated expanded uncertainty of 1.68 % (k = 2).

δE_l= Distance effect on the irradiance measurements between the phototherapy irradiated source and the effective surface area; Calculated by using the inverse square law:

$$\frac{E_1}{E_2} = \frac{d_2^2}{d_1^2} \qquad (6)$$

The uncertainty value due to the distance effect calculated as equation 6 which drived from equation 5, taking in concederation the uncertainty value of the measuring micerometer (0.001μm)

$$U_{distance} = \left(1 - \frac{D_1^2}{(D_1 + 0.001)^2}\right) * 100 \qquad (7)$$

δE_d = Drift of the standard. The drift of irradiance of the reference standard is estimated from annual calibrations with estimated rectangle distribution, in our case, it is ± 1 μW/cm²(k= 2).

$$U_{\text{long term drift}} = U_{\text{old cal}} - U_{\text{new cal}} / \sqrt{3} \quad (8)$$

$\delta E_{r}=$ Repatibility: standard deviation of the mean of a measurment repeated 5 times.

$$(U_{\text{repeatability}}) = \left[\frac{STDEV}{\sqrt{n}}\right] \quad (9)$$

$\delta E_{res} =$ Resolution of the reference phototherapy radiometer: The expanded uncertainty of ±0.0001μW/cm² (k = 2) is assigned to the irradiance meter readings at the irradiance level of 657 μW/cm².

$$U_{\text{display res}} = \text{resolution} / 2 * \sqrt{3} \quad (10)$$

After collecting all the uncertainty components, the compiened uncertainty calculated by equation (10):

$$\text{Combined uncertainty } U_c = \sqrt{\sum U^2} \quad (11)$$

$$\text{Expanded uncertainty} = 2\, U_c \quad (12)$$

The reported standard uncertainties are based on a standard uncertainty multiplied by a coverage factor k=2 which provides a level of confidence of approximately 95%.

Table 1. Uncertainties accompanied with the phototherapy irradiance measurement.

Source of uncertainty	Type	Probability Distribution	Value (μW/cm²)	Divisor	Standard Uncertainty (μW/cm²)
Calibration of reference detector	B	Normal	11	2	5.5
Distance effect	B	Normal	0.131	1	0.131
Drift	B	Rectangle	1	$\sqrt{3}$	0.577
Repatibility	A	Normal	0.202	1	0.202
Resolution	B	Rectangle	0.0001	$\sqrt{3}$	$5.7*10^{-5}$
Combined Standard Uncertainty		Assumed			5.565
Expanded Uncertainty		Assumed Normal (k=2)			±11.130 = (±1.7 %)

Table. 1 shows the uncertainty components accompanied with the phototherapy irradiance measurement. The Uncertainty contribution in the irradiance measurement is calculated by the GUM method using the GUM work bench software, and equal to 1.7 % at k=2 .

The uniformity G of the total irradiance for bilirubin defined as the ratio of the lowest irradiance level $E_{bi(min)}$ to the highest irradiance level $E_{bi(max)}$ on the effective surface area, given by the following equation:

$$G = \frac{E_{bi(min)}}{E_{bi(max)}} \quad (13)$$

According to the standard requirement, the ratio $E_{bi(min)}$ / $E_{bi(max)}$ must be greater than 0.4. Calculated G in this measurement is equal to 0.6.

CONCLUSION

A radiometric method to ensure the competence of phototherapy sources (luminaire) to the standard international and national requirements are built up at NIS. Thus, NIS provides traceability to customer through unbroken chain of phototherapy radiometer calibrated as irradiance response in W/m². Uncertainty model includes all parameters accompanied with the measurements are studied. Performance evaluation of phototherapy devices is depending on accurate measurements of the irradiance levels and its distribution over the irradiated surface using a previously calibrated phototherapy radiometer. Selection of the standard device to perform the required medical service basically depends on good evaluation of the available phototherapy devices. Although, performance evaluation leads to improve the quality of treatment, it can provide accurate doses. Periodical measurements of the irradiance levels give serious information of the phototherapy performance and its possibility to serve its continuity in the provision of medical service required. The accompanied uncertainty with measurement is equal to 1.7 %.

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