

Research Article

Advanced Development of BLUI Blanket Phototherapy Prototypes to Reduce the Heat Produced by LEDs to Meet Phototherapy Standards in Neonatal Jaundice

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Received: 29 August 2023; **Manuscript No:** JDAR-23-116911; **Editor assigned:** 31 August 2023; **PreQC No:** JDAR-23-116911 (PQ); **Reviewed:** 14 September 2023; **QC No:** JDAR-23-116911; **Revised:** 19 September 2023; **Manuscript No:** JDAR-23-116911 (R); **Published:** 26 September 2023; **DOI:** 10.4303/JDAR/236260

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Abstract

Background: Jaundice in newborns has caused a diagnostic challenge for doctors. Almost every newborn has an increase in serum bilirubin, and more than 50% look yellow during the first week of life. The development of phototherapy lamps has been widely carried out. The most recent one is phototherapy with a blanket model that has been developed and used in developed countries.

Method: The purpose of this study is to find out how to reduce the temperature of the touch surface so that it is included in the safe category for use, which is around 37°C-38°C. The temperature generated by the blanket system must be considered to keep the baby comfortable using it.

Results: Based on improvements in the parallel circuit arrangement in BLUI Blanket PROTO-3, it is proven that a suitable parallel circuit can reduce temperature, or it can be stated that there is no overheating sign in the cables, connectors, and LED strip lights. The voltage to be set on the voltage regulator is about 7.5V DC. This LED phototherapy blanket received a certificate of passing the test from the Indonesian Ministry of Health's BPFK with an average light radiation intensity capability of 7.8 $\mu\text{W}/\text{cm}^2/\text{nm}$. The temperature parameter, after setting the voltage regulator to 7.5V DC, the average temperature produced is around 36.15°C.

Conclusion: The strength of the radiation intensity produced by BLUI Blanket PROTO-3 has met the criteria for a safe threshold target according to phototherapy equipment standards by considering 2 crucial parameters: Light intensity and temperature.

Keywords: Bilirubin blanket; BLUI blanket; Phototherapy; Blanket phototherapy

Introduction

Jaundice in newborns has caused a diagnostic challenge to doctors for hundreds of years. Almost every newborn has an increase in serum bilirubin compared to normal adults, and more than 50% look yellow during the first week of life [1]. According to UNICEF data, cases of newborn mortality in Indonesia are still relatively high at around 23 deaths per

1000 births [2]. Based on the available data, jaundice cases accounted for 9% of the total deaths [3]. Unfortunately, the distribution of health facilities in Indonesia has not been evenly distributed, so many areas, primarily rural and even urban, do not yet have the tools to carry out baby care [4]. One of the treatments for jaundiced babies is phototherapy to lower their bilirubin levels [5,6]. Phototherapy lamps have been widely developed, starting from conventional tube lamp models, LED lamps, fiber optics, and others [7,8]. The most recent is blanket phototherapy, a blanket model developed and used in developed countries [9].

The initial concept of the phototherapy blanket product started from a series of LED lights arranged on a board that could be bent to become portable and developed during its use [10]. It is very rigid physically, but in terms of lighting, it meets the standards of needs in caring for jaundiced babies. The pioneer of the product prototype became the benchmark for developing phototherapy blankets designed nowadays.

In the field of medical devices, Indonesia is only a consumer or importer because very few domestic products of medical devices are made in Indonesia, so they always buy foreign products. The government has a program regarding efforts to increase domestic production, one of which is medical devices [11]. Therefore, since then, many researchers have developed research results and downstream them through domestic medical device manufacturers. At this time, Indonesia has not yet started the development of phototherapy blankets using LED lights.

In 2020, the initial development of phototherapy blanket

research with Indonesian local wisdom began, and produced a prototype still in the internal laboratory testing stage [12]. The evaluation results of the prototype made 2 main points, namely regarding the specifications of the LED lamps used and the temperature of the touch surface. After in-depth observation, it turned out that the prototype used an LED light that did not follow its designation for caring for jaundiced babies [13]. Even though the color of the resulting lamp is blue, which follows the color of phototherapy lamps in general, because the product is not licensed/branded, there is no information on the wavelength data sheet produced from the LED lamp. In addition, the article's results show that the temperature of the touch surface (the plastic cover that will touch the skin) is too warm up to 47°C. This value is above the safe threshold, which should be in the range of 37°C-38°C.

Therefore, the 2nd prototype will use LED strip lights that match the wavelength to care for jaundiced babies in the 450 nm-470 nm [14]. The 5050 SMD 60 LED/m product from Ilker Elektronik [15]. In the datasheet, this product has a wavelength in the 463 nm-467 nm range spectrum, which corresponds to the wavelength of light for treating jaundiced babies. The purpose of this study is to find out how to reduce the temperature of the touch surface so that it is included in the safe category for use, which is around 37°C-38°C. Several things that will be tried in the test are regarding the overall electrical circuit and the addition of heat-absorbing components. In addition, the 2nd prototype will be attempted to enter the clinical trial stage with a jaundiced baby as the object so that a fixed specification can be taken, which can be used as a benchmark for the next design.

Methodology and Materials

Methodology

Network repair: Recommendations from LED strip light manufacturers for installing many LED strips in parallel are suggested, as shown in Figure 1 [15]. In the 1st prototype, the connection circuit made was not in accordance with the recommendations for installing LED strip lights. Figure 2 shows that the circuit in the 1st prototype uses the concept of paralleling 6 strips, and each group of 6 strips will be paralleled back to one central power cable [12]. Another mistake is the use of the wrong cable size.

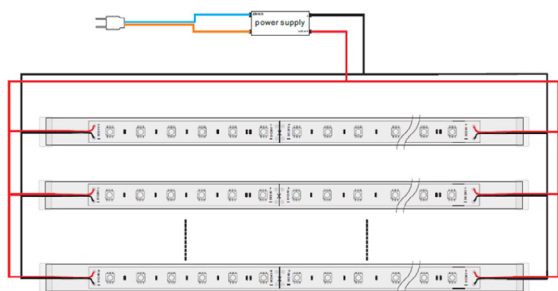


Figure 1: Connection diagram for single color LED strip

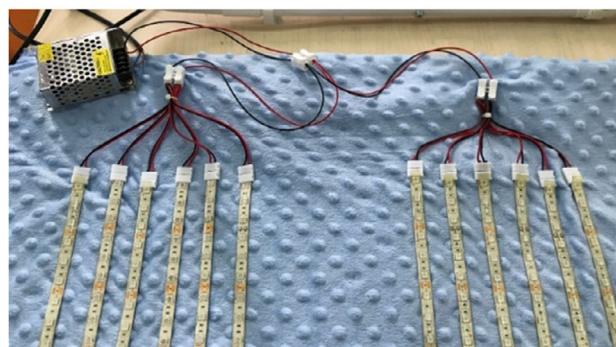


Figure 2: The unrecommended parallel circuit in the first prototype

In theory, if parallelized, the main power cable (the end of all parallel circuits) should be larger than the cable from each LED strip. Such parallel connection (at 1 junction) causes current to build up at one point and causes overheating in the cable connector.

Based on the irradiance unit for measuring phototherapy lamps, namely $\mu\text{Watt}/\text{cm}^2/\text{nm}$, it was suggested by the examiners of the Health Facility Security Office (BPFK) to make a layout arrangement of LED strip lights that have a square area (the same distance) of each LED array, both vertical and horizontal [16]. In Figure 3, the distance specification for each LED is 1.6 cm, so if we add a strip next to an existing strip, we need about 1.6 cm from the LED to the other LED.

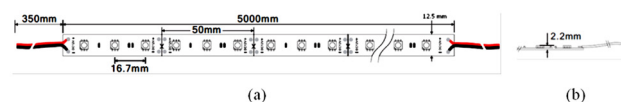


Figure 3: Illustration of the dimensions of the SMD 5050 LED Strip, (a) Top view and spacing dimensions, (b) Side View

In Figure 4, the LED distance to the side (X side) is not the same as the top side (Y side). So, it needs an improvement at the X and Y distances by shifting the LED strip, which results in more LED strips being used for the same blanket area in the 1st prototype. The result of improving the distance of each LED is shown, which shows the exact distance between X and Y.

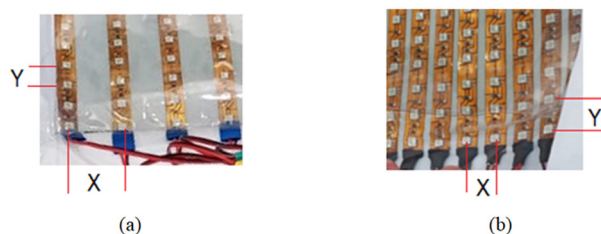


Figure 4: Comparison of LED spacing, (a) Before (unwanted), (b) After (as desired)

Improvement of the electrical arrangement and layout is one of the methods that will be implemented in the subsequent development. In addition, all electrical connectors and cable sizes used are changed according to their designation.

Therefore, the safety point can be maintained.

Heat absorber: Phototherapy blankets are used like blankets in general, ensuring that the blanket's inner surface will be in contact with the baby's skin. Therefore, the temperature generated by the blanket system needs to be considered to keep the baby comfortable using it. Although LED lamps are known as lamps with heat emissions, which tend to be lower than incandescent and fluorescent lamps, the temperature generated on the mounting surface can reach 60°C [15]. This causes the 1st prototype to produce a touch surface temperature of up to 47°C because there has been no effort to reduce the heat generated.

The desired temperature measured on the touch surface between the blanket layer and the baby's skin is an average baby temperature, which is around 37°C-38°C. Various ways to reduce heat will be sought from these provisions, either from the LED system itself or supporting components. Generally, one way to reduce the temperature produced by LEDs is by adding thermal grease and heat sinks [17]. However, with the limitations of the phototherapy blanket shape and the flexibility of the blanket, this method cannot be used for this product. The resulting temperature is from the energy given to the LED. So if the power can be reduced, then there is a tendency for the temperature to decrease, with the consequence that the lumen or light level will decrease according to the decrease in the energy supplied, in this case, reducing the voltage that will be given to the LED system [18]. This method will be tested by reducing the voltage that enters the system using a voltage regulator so that the decrease in power and temperature and the effect of the minimum irradiance value are needed in caring for jaundiced babies.

Besides electricity, heat absorption can be focused on how to reduce the transfer of heat that has been generated by the LED to the outermost touch surface (baby's skin). If we add a component that is placed as an LED intermediary to the touch surface, the challenge is to find a material that is still translucent so that the light from the LED can still penetrate the object, namely the baby. One method that will be applied is to use a layer of window film. In several studies for conventional phototherapy lamps and even the use of window films in the interior, there were significant results in reducing the temperature from the entrance to the system [19]. In addition, in the fashion sector, polyester is widely used to reduce the temperature received by the body so that it can be used as an additional component as a heat absorber and also provides comfort for the baby when they use it [20].

Parameter measurement (temperature and irradiance): The dimensions or areas of the blanket that will be developed in the second prototype are the same as the first prototype, with a total size of about 50 cm × 50 cm in the form of a square. However, because the phototherapy blanket has no regulation on measuring it, it is customized to the unit of the calculated parameter. The irradiance value will be measured on the surface in contact with the baby's skin. The measurements are made based on the area because it is

an arrangement of LED [21].

Figure 5 illustrates the total area of the blanket, which is 50 cm × 50 cm. The measurements were made at 25 points with the same size of 10 cm × 10 cm to determine the average temperature distribution and irradiance value of each area.

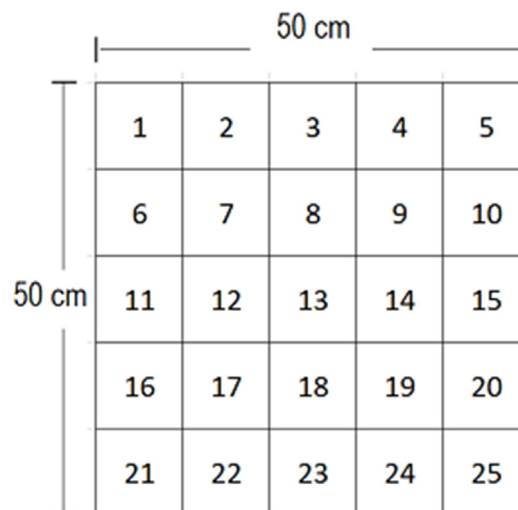


Figure 5: Schematic of the temperature and irradiance data collection area on the phototherapy blanket

Materials

Circuit improvements and addition of components: Improvements in electrical circuits include appropriate cable dimensions and cable connectors as shown in Figure 6. Parallel circuit cables to be strung at least 1 level above the factory default cable of the LED strip light so that current distribution can flow properly. It is also ensured that the copper fiber cable is used to maintain product flexibility when folded.

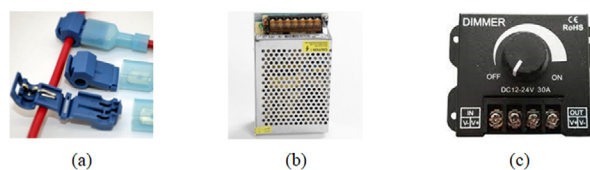


Figure 6: Additional electrical components to be used in the second prototype

The LED strip lights used have 12V DC electrical specifications. Therefore, a power supply converter is needed from 220V AC to 12V DC and will be used with a maximum specification of 8.3 A, as shown. To adjust the DC voltage that will enter the LED strip light circuit, a 12V DC voltage regulator is needed, as shown.

Heat absorber auxiliary components: Window film: The window film that will be used is the Solar Gard LX 70, shown in Figure 7 [22]. It is considering the 72% VLT value correlated with the incoming light or darkness of the window film. The VLR value is 9%, which means the mirror effect of the window film. The greater the percentage, the more mirror the window film has from the

outside (one way). While the UVR value is up to 99%, which means that ultraviolet light is rejected. The 95% IRR value corresponds to the rejected infrared rays (heat rays from the warmer exterior). The TSER value of 55% is related to the total ability of the window film to decline heat. The darker and the heat-rejecting TSER value of the window film, the better the window film [23].



Figure 7: LX70 Solar Gard window film

Polyester (Dacron): The polyester (Dacron) that will be used is the stuffing material for the pillow, but a sheet with a thickness of 1 cm will be used, as shown in Figure 8. Its porous texture, while still being compressed, is an advantage to reducing heat due to an air-insulating medium in it.



Figure 8: Polyester dacron coating

Clear plastic, foam, rigid fabric, and blanket: Clear plastic is used for an additional layer on the window film and the rigid fabric's media to be installed. The foam used is in the form of sheets with a thickness of about 0.5 cm, which serves as a cushion so that the baby is comfortable when the blanket is placed on hard media. Rigid fabric is used as the laying medium of the arranged LED strips. Blankets are used as the outermost layer or wrapping of all materials and the baby inside.

Experimental setup

Table 1 describes the measuring instruments used in the laboratory and by the testing party certified by the Health Facility Security Office (BPFK). The following Figure 9 illustrates the experimental scheme of data collection that has been improved. The power meter was installed before the main cable was connected to the 220V electricity supply to determine the power used in every setting change. A 220V AC to 12V DC power supply converter is needed to make the power supply suitable for LED strip lights.

Table 1: List of measuring tools used

No	Measuring tools	Brand	Function
1	Multitester/AVO meter	Heles UX-369 No. serial 1610154743	Measuring electrical parameters (voltage, etc.)
2	Power meter	Taffware KWE-PM01	Measuring electricity consumption
3	Thermometer infrared	Intell instruments smart sensor AR 320 No. serial 01177548	Measuring surface temperature
4	Phototherapy radiometer	Olympic 22 No. serial 7641	Measuring light intensity
5	Electrical safety analyzer	Fluke Biomedical ESA 615 No. serial 2519026	Measuring system electrical safety
6	Baby incubator analyzer	Fluke INCU II No. serial 42750017	Measuring temperature
7	Thermohyrometer	Fluke 5020A No. Serial 2.08.08.06.011.01	Measuring environmental conditions (temp and Rh)

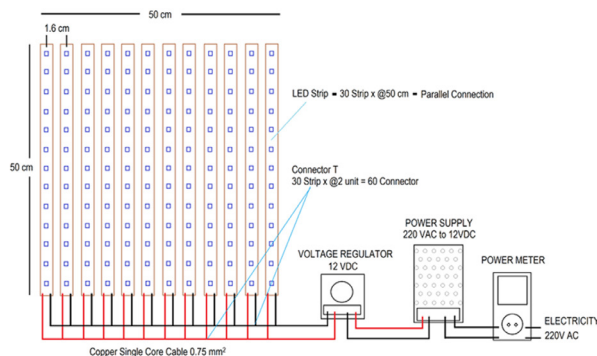


Figure 9: The electrical circuit arrangement during the data collection process

A voltage regulator is required to change the voltage settings, which affects the voltage entering the lamp circuit.

The changes in the procedure for connecting cables follow the recommendations of the LED strip light manufacturer. Changes in voltage will impact changes in light levels (lumen). Then, the light level will affect the temperature and intensity of the light produced by the LED. These two parameters will be measured as the purpose of this study.

Results and Analysis

Blanket model

The whole composition of the components in the phototherapy blanket is presented in Figure 10 below. All the parts are arranged into one blanket when the baby is used and wrapped. Figure 11 shows a blanket model that resembles a pocket to store a series of LED strip lights inside. The top polyester (Dacron) helps make the area touched to the baby's skin comfortable, as a warmth

absorber produced by the LED strip light as a blanket model that resembles a pocket and an additional layer that is glued with Velcro, the series of LED strips can be easily inserted and removed. Thus, other components outside the LED strip series can be washed repeatedly to maintain cleanliness.

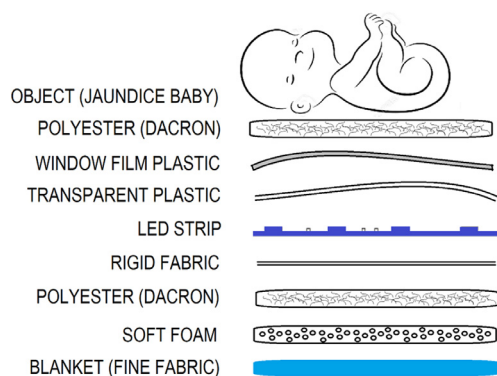


Figure 10: The components arrangement in the phototherapy blanket

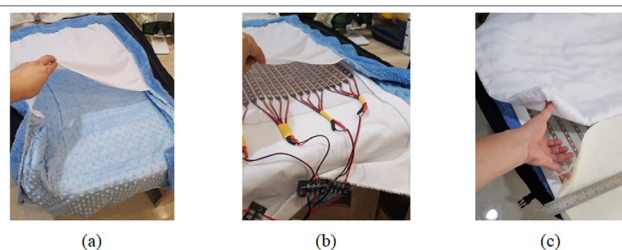


Figure 11: View of the phototherapy blanket, (a) Part of the blanket with a pocket model, (b) A series of LED strips in a blanket pocket, (c) Additional polyester lining

A combined series of LED strip lights comprising window film plastic, transparent plastic, LED strips, and rigid fabric. These components can be easily removed and put back in to simplify the installation and cleaning process for the blanket and the lamp circuit. It demonstrates the upper polyester layer as a medium that makes the baby's skin touch area comfortable, as well as additional heat absorption.

Test results

Before the test results explanation of the final prototype, Figure 12 shows the change stages of each prototype that have been developed. It is the 1st prototype (BLUI Blanket PROTO-1) with a questionable specification of LED strip

light. The electrical circuit used in this product still utilizes a parallel path, which is not recommended (6 wires joined together). An additional layer of polyester (Dacron) has not been added to the blanket structure. The 2nd prototype (BLUI Blanket PROTO-2) with LED strip lights that are already following the specifications and already have an additional layer of polyester (Dacron) when it is used. However, there has been no improvement in the electrical circuit. The BLUI Blanket PROTO-1 and BLUI Blanket PROTO-2 products have not used a voltage regulator.

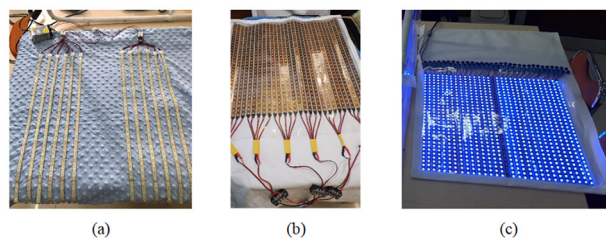


Figure 12: Development of each prototype, (a) BLUI blanket PROTO-1, (b) BLUI blanket PROTO-2, (c) BLUI blanket PROTO-3

Meanwhile, it is the 3rd prototype (BLUI Blanket PROTO-3) that will be tested for clinical trials. This product is an improvement from the previous products. It has a polyester (Dacron) layer, a voltage regulator, and an electrical circuit that follows the provisions. The three products were tested in the laboratory, especially the temperature parameters. Table 2 shows the results of the comparison of the products. Based on the outcome of the tests carried out independently with an infrared thermometer on the touch surface of each prototype, it can be seen that there has been a decrease in temperature. The temperature has decreased in BLUI Blanket PROTO-2 and BLUI Blanket PROTO-3, which have used appropriate LED strip lights, even though it is still above the safe threshold. Based on improvements in the parallel circuit arrangement in BLUI Blanket PROTO-3, it is proven that a suitable parallel circuit can reduce temperature, or it can be stated that there is no overheating sign in the cables, connectors, and LED strip lights. The temperature produced on the BLUI Blanket PROTO-3 reaches 41.2°C with a note that the voltage regulator is set in complete 12V condition. Therefore, in the next test, how much voltage will be set to reach the safe temperature limit but still reach the required light intensity value limit will be calculated.

Table 2: Comparison of measurement results

Parameters and measurement conditions	BLUI Blanket PROTO-1	BLUI Blanket PROTO-2	BLUI Blanket PROTO-3
Ambient temperature	31.7°C	27.8°C	30.3°C
Surface temperature (after 30 minutes)	46.8°C	45.7°C	41.2°C
Hot wires and connectors	Yes	Yes	No
Foam and polyester (Dacron)	Not available	Available	Available
LED strip quantity	16	30	30
Power supply	DC 12V/5A	DC 12V/8.3A	DC 12V/8.3A
Voltage regulator	Not available	Not available	set to 12V

The BLUI Blanket PROTO-3 product results will be taken to the Health Facility Security Office for testing according to standards. Based on the explanation, the measurement was divided into 25 test areas, especially the value of light intensity distribution. Figure 13 shows the conditions when the light intensity and temperature data were taken on the BLUI Blanket PROTO-3 phototherapy blanket. The voltage to be set on the voltage regulator is about 7.5V DC. This consideration was taken after being discussed by the examiner that with a setting of 7.5V DC, LED lights still produce the minimum light intensity value for the standards specified in Indonesia for phototherapy equipment [24].

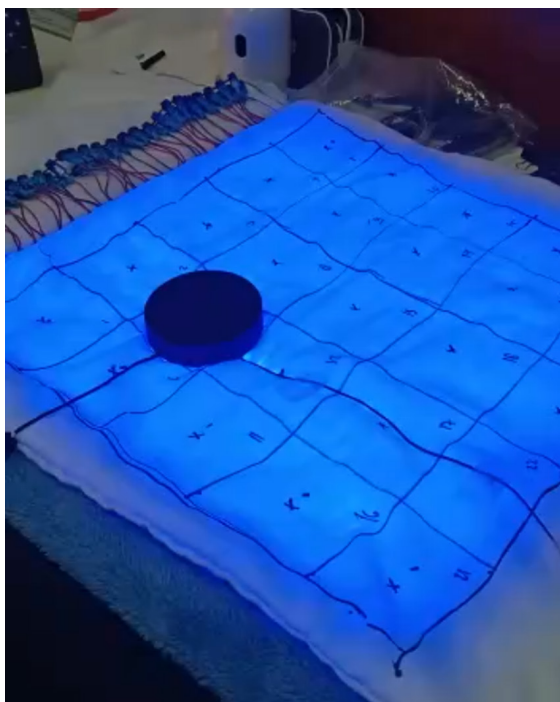


Figure 13: Testing the light intensity and temperature of the BLUI

Table 3: Results of light intensity on mattress surface

Measuring point	Data collection					Mean	Standard deviation	Relative standard deviation
	1	2	3	4	5			
1	6.8	6.7	6.7	6.7	6.9	6.8	0.1	1.32
2	8.4	8.4	8.4	8.4	8.4	8.4	0	0
3	8.2	8.3	8.3	8.3	8.3	7.3	0	0.54
4	7.1	7.1	7.1	7.1	7.1	7.1	0	0
5	6.6	6.6	6.7	6.8	6.7	6.7	0.1	1.25
6	6.9	7	7	6.8	6.8	6.9	0.1	1.45
7	8.8	8.8	8.8	8.8	8.8	8.8	0	0
8	8	8	7.9	8	8	8	0	0.56
9	7.7	7.7	7.7	7.7	7.7	7.7	0	0
10	7.7	7.7	7.9	7.8	7.8	7.8	0	1.08
11	8.6	8.6	8.6	8.5	8.5	8.6	0.1	0.64
12	7.8	7.8	7.9	7.9	7.9	7.9	0	0.7
13	8	7.9	7.9	7.7	7.7	7.8	0.1	1.71
14	7.5	7.5	7.5	7.6	7.6	7.5	0.1	0.73
15	7.5	7.5	7.8	7.8	7.8	7.7	0.1	2.14

blanket PROTO-3 phototherapy blanket

Table 3 shows the results of the 25 points made as the distribution of data collection that the light intensity values are varied from one another but are still within normal limits. Data was collected 5 times for each point to examine the consistency of the resulting values. From 125 data collections, the average light intensity produced was $7.8 \mu\text{W}/\text{cm}^2/\text{nm}$. The International Electrotechnical Commission (IEC) has not set a minimum or maximum irradiation because the optimal phototherapy irradiation has not been determined [25]. The American Academy of Pediatrics (AAP) defined the required light intensity value of $8\text{-}10 \mu\text{W}/\text{cm}^2/\text{nm}$ in 1994 as a standard condition based on conventional irradiation [26].

Meanwhile, the minimum limit set in Indonesia is only around $4 \mu\text{W}/\text{cm}^2/\text{nm}$. Based on the test results, the values obtained are above the minimum limit [24]. The BLUI Blanket PROTO-3 phototherapy blanket has passed the test regarding light intensity.

Meanwhile, from the temperature parameter, after setting the voltage regulator to 7.5V DC, the average temperature produced is around 36.15°C . The safe limit determined by BPFK is 37°C . By considering the 2 essential parameters, light intensity, and temperature, BLUI Blanket PROTO-3 has met the requirements. It also stated by BPFK that the product has passed the TEST [27].

Final specification

From the test results, it can be concluded that the specifications for the BLUI Blanket PROTO-3 phototherapy blanket were obtained. This specification can be a reference for further development. Table 4 shows the final specifications of the BLUI Blanket PROTO-3 phototherapy blanket, and Figure 14 shows the final product of BLUI Blanket PROTO-3.

16	8.3	8.3	8.3	8.3	8.3	8.3	0	0
17	7.8	7.8	7.8	7.8	7.8	7.8	0	0
18	8.1	8.2	8.2	8.1	8.2	8.2	0	0.67
19	7.6	7.6	7.6	7.5	7.5	7.6	0.1	0.72
20	6.8	6.8	6.8	6.8	6.8	6.8	0	0
21	7.7	7.7	7.7	7.7	7.7	7.7	0	0
22	8.6	8.6	8.6	8.6	8.6	8.6	0	0
23	8.1	8.1	8.1	8.1	8.1	8.1	0	0
24	8.2	8.2	8.2	8.3	8.3	8.2	0.1	0.66
25	7.1	7.2	7.1	7.1	7.1	7.1	0	0.63

Table 4: Final specifications of BLUI blanket PROTO-3 phototherapy blanket

Items	Specification
LED lights	
Brand	Ilker. Code 5102. Case 5050 SMD. 60 LED/m. Blue
Quantity	30 Strip × @50 cm
Electrical connection type	Parallel
Glass film plastic coating	LX70 Solar Gard
Blanket	
Total dimension	70 cm × 90 cm × 3.5 cm
Layer arrangement	-
Box power supply	
Power supply	220V AC-50/60 Hz
Power supply	Converter 220V AC to 12V DC/8.3A
Setting voltage regulator	7.5V DC
Cooling fan	12V DC/4 Watt
Power consumption	42 Watt



Figure 14: The final product of BLUI blanket PROTO-3

Discussion

Based on a study published in 1996, presented in Figure 15 below, shows that there is a direct relationship between the radiation used and the level of decrease in serum bilirubin under phototherapy. The data below demonstrates a saturation point where increasing radiation at $40 \mu\text{W}/\text{cm}^2/\text{nm}$ did not result in additional efficacy. However, the maximum effective dose of phototherapy is not known yet. This LED phototherapy blanket received a certificate of passing the test from the Indonesian Ministry of Health's BPFK with an average light radiation intensity capability of $7.8 \mu\text{W}/\text{cm}^2/\text{nm}$. With the above radiation intensity capability based on the graph, after the first 24 hours of irradiation, this phototherapy blanket has the ability to reduce serum bilirubin levels by approximately 20% of

total bilirubin levels before phototherapy [28].

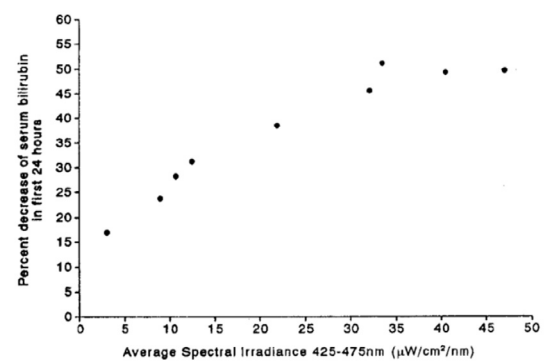


Figure 15: The relationship between the average spectral irradiance and the decrease in serum bilirubin concentration. Term infants with nonhemolytic hyperbilirubinemia were exposed to a special blue light (Phillips TL 52/20W) with different intensities. Spectral irradiance was measured as the average of the head, trunk, and knee readings.

The proximity of the light source to the exposed body surface, based on the data from Figure 16, shows that this blanket can provide a consistent effect with the amount of radiation produced. It shows that when the distance between the light source and the baby decreases, there is an increase in spectral radiation [28]. It also shows the differences in the radiation produced at 425 nm to 475 nm wavelengths by different fluorescent tube lamps.

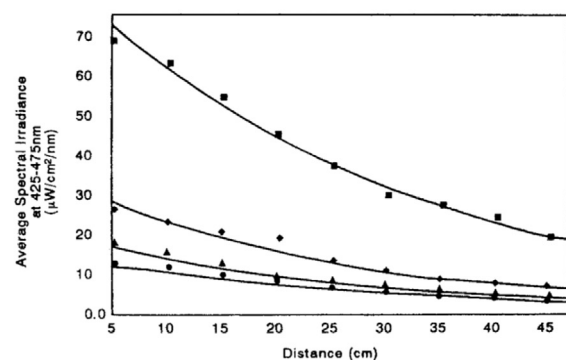


Figure 16: The effect of the light source and distance from the light source to the baby on mean spectral radiation at 425 nm to 475 nm using a commercial radiometer (Olympic Bilimeter Mark II) and averaging measurements taken at different locations at each distance (the irradiance at the center of the light is much higher than at the edges). The phototherapy unit is equipped with 8, 24-inch fluorescent tube lights, in special blue, General Electric 20-W F20T12/BB tubes; blue light, General Electric 20-W F20T12/B tube; daylight blue, 4 General Electric 20-W blue tubes F20T12/B and 4 Sylvania 20-W daytime tubes F20T12/D, daytime,

Sylvania 20-W Daylight tubes F20T12/D. The curves were plotted using a linear curve (True Epistat, Epistat Service, Richardson, TX).

To determine the efficacy of this developed blanket and whether it can reduce heat according to the research above, it is necessary to conduct a preliminary study on patients with physiological jaundice without complications or have risk factors for neurotoxicity. The challenges in this research were the accumulation of heat generated by the tool and the heat generated by the baby, which had not been measured when the test was carried out at BPFK. This preliminary research data can be used as references for further research or development of blankets, including the use of a flexible LCD electrical circuit or a better cable circuit, as well as the potential for developing a voltage regulator based on baby temperature or LEDs with the use of a microprocessor.

Conclusion

This LED phototherapy blanket received a certificate of passing the test from the Indonesian Ministry of Health's BPFK. The average light radiation intensity capability is $7.8 \mu\text{W}/\text{cm}^2/\text{nm}$, and the average temperature produced is around 36.15°C . BLUI Blanket PROTO-3 has met the requirements.

Acknowledgement

The researcher thanks Lembaga Pengelola Dana Pendidikan (LPDP) Ministry of Finance of Republic Indonesia and Universitas Trisakti.

Conflict of Interest

Authors have no conflict of interest to declare.

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