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RESEARCH ARTICLE

Incubator Analyzer Function Test in Laboratory Scale : Temperature Uniformity, Relative Humidity, Noise Level and Airflow

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Abstract

A function test is conducted to assess the equipment's performance, component function, output, and safety. The aim of the incubator analyzer function test is to determine the performance parameters, including mattress temperature, ambient temperature, humidity, noise, and airflow. In this article, we present an analysis of a prototype incubator analyzer through a comparative test method against a standard incubator analyzer. The testing procedure adheres to SNI IEC 60601-2-19-2014, which outlines special requirements for the basic safety and essential performance of infant incubators. The incubator analyzer prototype was designed using specific components such as PT100 resistive temperature detector, single chip humidity sensor module SHT 11, airflow sensor, microphone amplifier MAX4466 as a sound sensor, and a human-machine interface Nextion display. The function test of the incubator analyzer was conducted at an authorized institution on a laboratory scale. The results indicate that the prototype achieves an accuracy of over 98% for temperature measurement and more than 94% for relative humidity at temperature settings of 32°C and 36°C.

Keywords: comparative test, function test, incubator analyzer, prototype

1. INTRODUCTION

Infant incubators are vital devices that create an optimal environment with appropriate temperature and humidity conditions to support the survival of infants [1]. These devices have been in use since the late 19th century with the primary purpose of maintaining newborns' warmth [2]. With advancements in technology and the growing demand for healthcare services, baby incubators have undergone functional improvements, including the incorporation of air circulation systems [3], and environmental condition sensors like noise detectors, all aimed at ensuring an undisturbed environment for the infants under care [4, 5]. Baby incubators fall under the category of medical devices as life support, according to the International Classification for Standard (ICS) [6]. Therefore, when using baby incubators in healthcare facilities, it is crucial to consider the compliance of the available parameters with reference standards [7]. ensuring safe and secure healthcare services for patients. Routine maintenance and calibration play a vital role in verifying the equipment's output parameters' suitability.

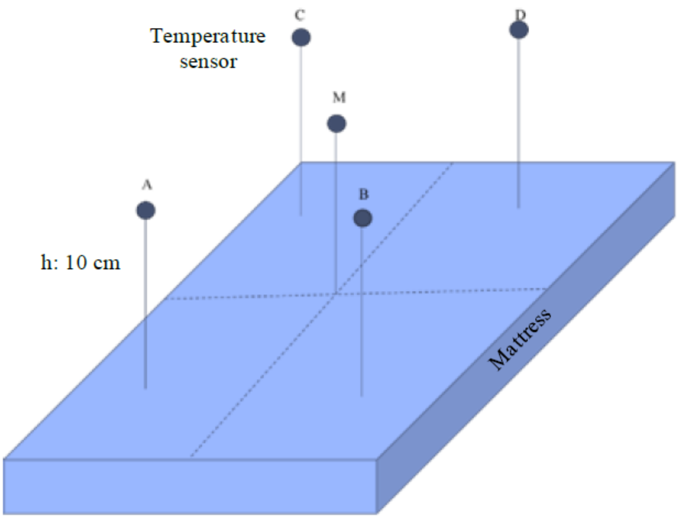

Figure 1. Air temperature sensor placement

The measurement methodology for infant incubators is defined by the Indonesian National Standard, which outlines the special requirements for basic safety and essential performance of infant incubators (SNI IEC 60601-2-19-2014). This standard specifies the physical parameters that must be measured during the calibration of a baby incubator, including enclosure temperature, mattress temperature, humidity, airflow, and noise level. The recommended placement of the temperature sensor is illustrated in Figure 1., where points A, B, C, and D represent air temperature sensors, and point M represents the mattress temperature sensor. These measurement points are positioned in parallel, 10 cm above the mattress. This configuration ensures the measurement of temperature stability in the baby incubator room, which is a crucial factor in preventing incidents such as apnea [8].

Infant incubators are classified as "high individual risk" medical devices and must undergo periodic calibration at least once a year [9]. Calibration involves a series of activities that establish the relationship between the values indicated by the measuring instrument or system and the known values associated with the measured quantity under specific conditions. To maintain the accuracy of its parameters, the baby incubator requires calibration. The equipment used for calibrating or assessing the condition of the baby incubator room is known as the Incubator Analyzer [10]. The Incubator Analyzer is capable of measuring room and mattress temperature (°C), air humidity (%RH), airflow, and noise level (dB) [9]. An infant incubator is considered suitable for use if the difference between the measured values and the reference values falls within the permitted tolerance limits.

Several researchers have reported on the design and development of incubator analyzers. For instance, Azkiyak et al. (2020) developed an incubator analyzer with an Android-based display for measuring humidity parameters and airflow rates [11]. Syarifatul Ainiyah et al. (2020) focused on the development of an incubator analyzer based on data processing on a computer, measuring temperature and humidity parameters [12]. Additionally, Gamze et al. (2018) presented the design and testing of an incubator analyzer that measured parameters such as temperature, humidity, and oxygen concentration [10]. However, based on a literature review conducted by the authors, none of the previously developed products met the four mandatory parameters required by SNI IEC 60601-2-19-2014. Therefore, this study aims to report on the development and testing of an incubator analyzer device that fulfills all four mandatory parameters, namely temperature, humidity, airflow, and noise level.

2. MATERIALS AND METHODS

2.1 Hardware

Hardware refers to physical electronic components with specific functions [13]. In this system, the hardware is categorized into three main parts: the signal/data receiver (sensing layer), the data management system (data processing layer), and the electronic system section for display control (display control layer).

The signal receiving section includes the following sensors: a PT100 resistive temperature detector for temperature measurement, an SHT11 humidity sensor, a GFS131 airflow sensor, and a MAX4466 microphone amplifier for sound detection. The data management system utilizes an Arduino, while the electronic system for display employs a 3.5" Nextion TFT LCD. Additionally, the prototype incorporates a rechargeable battery system as a portable power supply.

2.1.1 Temperature Sensor

The temperature parameter is measured using an RTD (Resistance Temperature Detector) sensor, specifically the PT100 type. This sensor exhibits high accuracy and is made of platinum, hence the name PT (Platinum Temperature). The PT100 sensor is calibrated at $0°C$ with a resistance value of 100 ohms [14]. Its resistance increases with rising temperature. For DIN type PT100 sensors (European standard), the resolution is $0.385\Omega/1°C$, meaning the resistance value increases by 0.385Ω for every 1°C changes.

2.1.2 Air Humidity Sensor

The SHT11 is a single-chip temperature and relative humidity sensor with digitally calibrated outputs [15]. It includes a polymer capacity element for relative humidity sensing and a stretch band for temperature sensing. The sensor outputs are combined and connected to a 14-bit ADC and a serial interface on the same chip. The SHT11 sensor provides accurate output signals with a fast response time. It undergoes calibration in a controlled humidity environment using a hygrometer as a reference. The calibration coefficient is programmed into the OTP memory and used during the measurement process.

The voltage source needed by SHT11 is 5 Volts with 2-wire bidirectional communication. This sensor system has 1 data line that is used for addressing commands and data reading. Data collection for each measurement is carried out by giving addressing commands by the microcontroller. The serial data leg connected to the microcontroller gives addressing commands to the SHT11 Data pin "00000101" for measuring relative humidity and "00000011" for measuring temperature. SHT11 provides humidity and temperature data output on the Data pin alternately according to the clock given by the microcontroller so that the sensor can work. The SHT11 sensor has an ADC (Analog to Digital Converter) in it so that the SHT11 data output has been converted in the form of digital data and does not require an external ADC in data processing on the microcontroller.

2.1.3 Airflow Sensor

The GFS131 is an airflow sensor developed specifically for medical ventilator applications by Xi'an Gavin Electronic Technology Co., Ltd. It operates on the principle of energy transfer due to temperature differences, allowing it to detect gas flow in the pipe [16]. The GFS131 sensor features an internal temperature sensor for calibrating temperature changes along the pipe. It provides a linear analog voltage output, simplifying the conversion of analog data to digital. The sensor offers high accuracy, rapid response, and good repeatability, enabling precise measurement of very small flows.

2.1.4 Noise Level

Sound sensors are employed to monitor changes in sound levels in the environment. The sensor used is the MAX4466, a product of "Maxim Integrated," which combines a microphone and an amplifier module. The module requires a supply voltage of +2.4V to +5.5V and includes an electret microphone with an operating frequency range of 20Hz to 20kHz and a sensitivity of -35 ± 4 dB [17]. An op-amp is utilized to amplify the signal generated by the microphone, making the sound sensor more efficient. The output of the module is a rail-to-rail signal, where louder sounds can reach the maximum input value. The sensor's output exhibits a DC bias value of Vcc/2, so when the measured area is completely silent, the output will provide a constant voltage of Vcc/2 volts.

2.2 Incubator Performance Test

The incubator prototype's performance is evaluated based on the requirements outlined in SNI IEC 60601-2-19:2014, which is an Indonesian national standard that adopts

IEC 60601-2-19:2009, focusing on the basic safety and essential performance of infant incubators.

2.2.1 Incubator temperature stability

The temperature stability test (coded 201.12.1.101on SNI IEC 60601-2-19-2014) ensures that the incubator temperature does not deviate by more than 0.5°C from the average incubator temperature when the temperature conditions are constant. To assess compliance, measurements are conducted at a control temperature of 32°C and 36°C for a minimum duration of 1 hour.

During the temperature stability test, the incubator analyzer prototype demonstrated satisfactory performance. The temperature readings obtained from the prototype closely matched the average incubator temperature. The temperature deviation was well within the acceptable range of 0.5°C, indicating the prototype's ability to maintain stable temperature conditions.

2.2.2 Incubator temperature uniformity

The incubator should function as an enclosed space with air control, maintaining uniform temperature distribution across different locations. The average temperature at designated points A, B, C, and D should not deviate by more than 0.8°C from the average incubator temperature under normal operating conditions. Additionally, even when the mattress is tilted, the temperature difference should not exceed 1°C.

To assess compliance with temperature uniformity, temperature measurements were taken at five specific points parallel to the mattress surface, including the midpoint. These measurements were performed at control temperatures of 32°C and 36°C. The temperature differences between the average incubator temperature (point M) and the values measured at points A, B, C, and D were compared.

The incubator analyzer prototype successfully met the requirements for temperature uniformity. The temperature deviations at points A, B, C, and D were well below the specified limit of 0.8°C. This demonstrates that the prototype maintains consistent temperature distribution across the incubator, ensuring uniform thermal conditions for the infant. Even at extreme inclination angles, the temperature difference remained within the acceptable range of 1°C.

2.2.3 Relative humidity display accuracy

The displayed relative humidity values must exhibit an accuracy of +10% compared to the actual measured values. To assess compliance, relative humidity measurements were performed using a humidity measuring device placed at the center of the incubator enclosure. The control temperature was set within the range of 32°C to 36°C.

The incubator analyzer prototype showed good accuracy in displaying relative humidity. The measured relative humidity values obtained from the prototype closely aligned with the readings from the humidity measuring device. The differences between the displayed values and the actual measured values were within the acceptable range of +10%.

2.2.4 Airflow

The normal use of the incubator mandates that the air speed on the mattress should not exceed 0.35 m/s. The prototype was assessed for compliance with this requirement by measuring the airflow velocity on the mattress.

2.2.5 Noise level in the compartment

Under normal operating conditions, the sound level in the compartment should not exceed 60 dBA. Compliance was assessed by conducting sound level measurements using a microphone positioned 100 mm to 150 mm above the midpoint of the infant tray. The measurements were taken at a controlled temperature of 36°C and maximum humidity. The background sound level in the compartment should be lower than 10 dB below the rated value during the test.

3. RESULTS AND DISCUSSION

3.1 Visual observation

The test was conducted at the Department of Electromedical Engineering's Life Support Laboratory, Poltekkes, Ministry of Health, Jakarta II. Prior to the test, equipment, materials, accessories, and prototypes were prepared. The following equipment was used: a sound level meter, a humidity and room temperature meter, a standard incubator analyzer, and a baby incubator. Through visual observation on the screen display, it was observed that the prototype measuring instrument successfully responded to changes in environmental conditions for parameters such as temperature, humidity, airflow rate, and noise level, as depicted in Figure 2.

Figure 2. Prototype of incubator analyzer

The ability of the equipment to accurately measure the parameters according to the design is a qualitative indicator of its successful functioning. The next step involves quantitative testing to determine the equipment's accuracy.

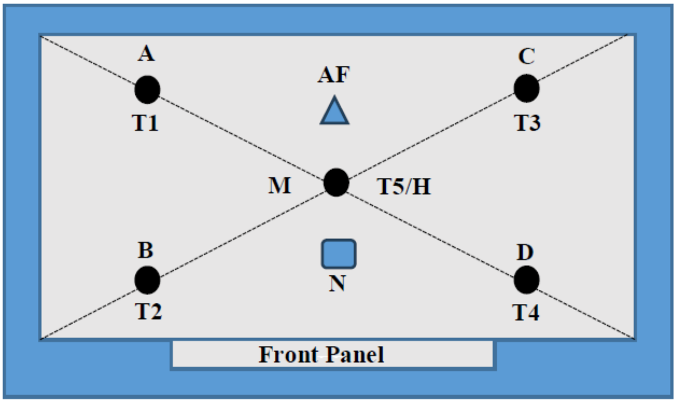

Figure 3. Schematic of sensor placement (top view)

3.2 Performance Test

To perform this test, measurement parameters for temperature, humidity, airflow, and noise level were compared between the designed incubator analyzer measuring device and the reference device. Temperature measurements (T1, T2, T3, T4) were taken at four points (A, B, C, D) located in each corner of the baby incubator with one additional point in the middle (M) for measuring mattress temperature (T5). The other three parameters, humidity (H), noise (N), and airflow (AF) were directly attached to the equipment and positioned in the center of the baby incubator mattress (see Figure 3). Data collection was carried out after the incubator room temperature reached a stable condition, as per the set value, with five repetitions for each data collection.

Prior to the test, environmental measurements were conducted to ensure that the laboratory was suitable for testing purposes. Room conditions were measured using a thermo-hygrometer and a voltmeter. The results confirmed the suitability of the laboratory space for testing (see Table 1).

The temperature uniformity test was conducted at two measurement points: 32°C and 36°C reffering to SNI IEC 60601-2-19-2014. The baby incubator, equipped with an air controller and temperature controller, must comply with the specified average temperature at each point A, B, C, and D, with a maximum deviation of 0.8°C under normal use conditions. Table 2. present the results of the temperature uniformity test for point A, point B, point C, point D, and mattress temperature (M). The results demonstrate that the equipment accurately reads the temperature at each point, with a uniformity value below 0.8°C. This value indicates that the average temperature at each point A, B, C, D, and M, at a temperature setting 32°C and 36°C, differs by no more than 0.8°C, which aligns with the standards used. Additionally, a temperature measurement accuracy of over 98% was achieved, like the reported use of LM35 temperature sensor in the design of the Incu Analyzer equipment by Athavale et al. (2022), and the use of DS18B20 sensor in manufacturing Incu Analyzer equipment, as reported by Ningtias et al. (2021).

The next tests involved the measurement of humidity percentage, noise level,

Table 1. Environmental Conditions

Test description	Results
Room temperature	21.8^oC
Relative Humidity	65.3% RH
Voltage	5.0 VDC

Table 2. Air Temperature in The Incubator Chamber ($^\circ C$)

Baby incubator temperature settings ($^\circ C$)	Temperature sensor placement	Prototype temperature display ($^\circ C$)	Standard temperature display ($^\circ C$)
32.0	A	32,8	33,0
	B	31,9	31,8
	C	31,9	32,2
	D	31,1	32,0
	M	-	33,2
36.0	A	37,2	37,6
	B	35,9	35,9
	C	36,2	36,5
	D	35,0	36,2
	M	-	37,2

and airflow, as shown in Tables 3, 4, and 5, respectively. Each test was performed at chamber temperatures of 32°C and 36°C. Table 3. shows the prototype exhibited a 3% difference in relative humidity compared to the measurements obtained using the standard meter at 32°C, while at 36°C, the difference in % humidity between the prototype and the standard instrument was minimal.

Noise level testing was conducted by conditioning the source of sound interference using the Frequency Sound Generator application. The results at Table 4. revealed a significant difference between the prototype and the standard equipment in terms of noise level measurements. This difference in noise level values could be attributed to variations in the sensitivity of the sensors used, which necessitates further investigation. However, as a reference, it is important to note that the measurement of noise level in a baby incubator, when subjected to normal sound level conditions, should not exceed 60 dBA.

The final parameter tested was the airflow velocity within the baby incubator. The results at Table 5. indicated that both the prototype unit and the measuring instrument yielded the same measurement value of 0.1 m/s for airflow velocity. Under normal operating conditions, the airflow velocity in a baby incubator should not exceed 0.35 m/s.

Table 3. Relative Humidity in INcubator Chamber(% RH)

Baby incubator temperature settings (^oC)	Prototype display (% RH)	Standard display (% RH)
32,0	52,83	55,89
36,0	54,51	54,24

Table 4. Noise Level in Incubator Chamber (DB)

Baby incubator temperature settings (^oC)	Prototype display (DB)	Standard display (DB)
32,0	41,21	54,10
36,0	41,90	53,62

Table 5. Airflow (Meters/Second

Baby incubator temperature settings (^oC)	Prototype display (m/s)	Standard display (m/s)
32,0	0,10	0,10
36,0	0,10	0,10

4. CONCLUSION

The results demonstrated that temperature measurements were obtained from four specific points positioned 10cm above the mattress, yielding consistent values across the mattress surface. Furthermore, the equipment's display screen, which relied on visual observation, effectively presented temperature, humidity, airflow velocity, and noise level parameters in alignment with the design specifications. Based on these test results, it is viable to showcase the analyzer incubator prototype within an appropriate environment to validate the system.

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