The Accuracy of Temperature Monitoring of the Incubator for Newborns

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ABSTRACT - The objective of this paper is to investigate the performance of the Incubator for Newborns at the departments of intensive care in Jafer Ibn Aouf Reference Children Hospital, is governmental Children specialized hospital. Using the INCU^{TM} Incubator Analyzer to analyzing various aspects of performance of neonatal incubator and its compliance with the set requirements and regulations according to the technical standard IEC (International Electro technical Commission) 60601-2-19. The data used in this study were obtained by interpreting of the performance test results of neonatal incubator. Numerically, According to the results presented in Tables (1 & 3), the neonatal incubator have achieved acceptable performance and sustaining the requirements of the standard IEC 60601-2-19. In other words, the temperature at points T_1, T_2, T_3, and T_4 does not differ from the neonatal incubator average temperature by more than 0.8**°C**, and this temperature does not differ more than 1.5 **°C** from the incubator control temperature. Compared to the established technique, the estimation error is negligible.

Keyword: Neonatal Incubator; Temperature; Performance Test.

المستخلص – الهدف من هذه الورقة التحقيق فى الكفاءة الفنية لأداء أجهزة حضانات الأطفال بمستشفى الأطفال المرجعى (جعفر بن عوف) و هو المستشفى الحكومى المتخصص للأطفال. تم استخدام جهاز (Fluke INCU Incubator Analyzer) لتحليل درجات الحرارة داخل الحضانة وفقاً لمتطلبات ولوائح المواصفة الفنية الخاصة بها (IEC 60601-2-19). تم الحصول على البيانات المستخدمة في هذه الدراسة من خلال تفسير نتائج اختبار كفاءة أداء حاضنة الأطفال حديثي الولادة. عدديا و وفقا للنتائج الواردة في الجداول (1و3) فقد حققت حاضنة الأطفال حديثي الولادة أداء مقبول وحافظت على متطلبات المعيار IEC 60601-2-19 . وبعبارة أخرى فان درجة الحرارة في نقاط T1 و T2 و T3 و T4 لا تختلف عن متوسط درجة حرارة حاضنة الأطفال حديثي الولادة بأكثر من 0.8 درجة مئوية ، ودرجة الحرارة هذه لاتزيد من 1.5 درجة مئوية عن التحكم في درجة حرارة الحاضنة. مقارنة مع التقنية المعمول بها فان مقدار الخطأ المحسوب لا يكاد يذكر.

INTRODUCTION

A neonatal incubator, which is represented in Figure 1 considered as an air conditioned room with special specification which we can control it with respect to the condition of baby in incubator. Incubators are designed to provide an optimal environment for newborn babies with growth problems (premature baby) or with illness problems. The incubator is an isolated area environment with no dust, bacteria, and has the ability to control temperature, humidity, and oxygen to remain them in acceptable.

Newborn babies with growth problems usually have a net body area greater than normal babies from the same age [1].

Hospitals must create a safe environment for patients, relatives and employees. To achieve this goal, like the management of the physical environment and human resources, management of the medical devices is very important.

Here, the main target is the patient safety because of the potential hazards that may be caused by the bad performance of the medical devices. The management of the performance control of medical devices is becoming more prominent as the number of medical devices increases [2].

Temperature measurement is a vital part of daily neonatal care. Accurate measurements are important for detecting deviations from normal values for both optimal incubator

and radiant warmer functioning. The purpose of monitoring the temperature is to maintain the infant in a thermo neutral environmental zone. This physiological zone is defined as the narrow range of environmental temperatures in which the infant maintains a normal body temperature without increasing his or her metabolic rate and thus oxygen consumption [3].

Figure 1: A Commercial Incubator.

Performance test is the measurement of the accuracy of the medical device by using the standard measurement system whose accuracy is known, and is the determination and the record of the deviations. In short, by the performance measurements, it is established whether the neonatal incubator device meet the international standards or not, and the problems are also determined if the device is not adequate to the international standards. The determination and the analysis of the problems of neonatal incubator device are essential in the quality assurance applications.

METHOD

As with any other electro-medical equipment, a neonatal incubator must be calibrated periodically, because its malfunction may cause serious damage to the newborn's health or even lead to the newborn's death. The technical standard IEC 60601-2-19 establishes operating specifications for neonatal incubators, so that a safe environment can be offered for newborns. The INCU Incubator Analyzer is a portable device designed to verify the proper operation and environment of infant incubators.

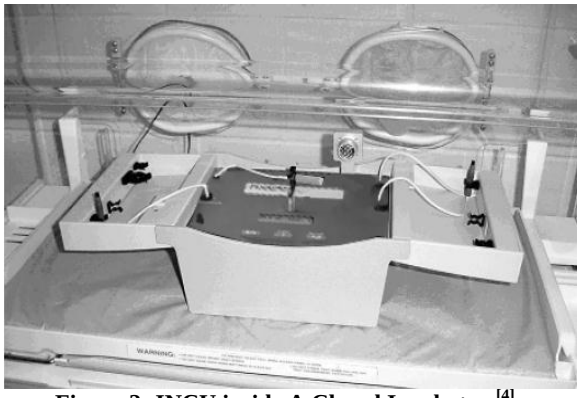

Figure 2: INCU inside A Closed Incubator [4].

Placement of the INCU in the Incubator

With both covers open and fully extended, the INCU has dimensions (length and width) similar to those of a typical infant (non-preemie). The INCU should therefore be placed in an isolate (incubator), in the same manner as an infant would be positioned for normal operation; i.e., centered on the mattress ensuring that air circulation vents, temperature probes, etc. are not blocked or impinged. Figure 2 shows the INCU inside a closed incubator [4].

Data Collection

The following section provides information describing how INCU can be used to perform testing in consideration of the standards.

- Place the INCU into position within the incubator. Refer to Figures 2 for placement of the INCU.
- Place the sensors (T_1, T_2 and T_3) into position.
- Turn on the power.
- Obtain Readings. The unit is now ready to be used as a measuring device.
- Required Precision in the measurements of temperature specified by standard IEC 60601-2-19, Section 8, Item 50.101.2. The measured temperature must not differ from the standard temperature thermometer in more than ±0.8°C. The accuracy of the standard thermometer must be at least 0.05 °C.
- Adjust the incubator temperature control to two operation points, i.e., 32 °C and 36 °C. At each point, wait for the stabilization temperature condition.

- In above step, the average temperature measured by the sensors in each point shall not differ from the average incubator temperature cannot differ by more than ±0.8°C from the average temperature of the incubator within the period of one hour. The incubator average temperature is obtained by means of temperatures measured in regular intervals. Calculate the difference between the mean value at the center and the other sensors readings.

RESULTS

The analysis of the results obtained by the INCU fluke biomedical equipment is presented. The results are related to the perform testing of the temperature inside the incubator used at the departments of intensive care in Jafar Ibn Aouf Reference Children Hospital. For the testing of the Atom V-85 & V-2100G, 10 samples of temperature were acquired from points T1, T_2, T_3, and T_4 was collected as shows in the Tables 1 to 4.

DISCUSSION

During steady state condition, the incubator temperature shall not differ from the average incubator temperature by more than 0.5°c (1°c transportable) during at least 1 hour at the control temperatures of 32°c and 36°c. The user shall check the oscillation from min to max in steady state. The average temperature in each point T_1, T_2, T_3 and T_4 shall not differ from the average incubator temperature (test at a set t of 32°c - 36°c) by more than ±0.8°c (±1.5°c transportable).in any position of the tilted mattress, it shall not differ by more than ±1.0°c (±2.0°c transportable). Calculate manually the difference between the mean value at the center and the other sensors readings. The incubator shall be provided with an indicator of the internal temperature.

The mean value of the reading of this device shall not differ from the average incubator temperature measured by a standard thermometer by more than ±0.8°c (±1°ctransportable), less the standard thermometer error. The standard thermometer shall be accurate within ±0.05°c.Check the difference between the value of the mean value at the center and the one displayed by the indicator. Working as an air-controlled incubator, the average incubator temperature shall not differ from the control temperature by more than ±1.5°C (±2°Ctransportable).Check the difference between the value of the mean value at the center and the set value.

CONCLUSION

The Accuracy of Temperature Monitoring of the Incubator for Newborns at the departments of intensive care in Jafer Ibn Aouf Reference Children Hospital, is governmental Children specialized hospital. A test is performed to check whether the temperatures at T_1, T_2, T_3, and T_4 are adequate after Using INCU^{TM} Incubator Analyzer.

To analyzing the various aspects of performance of neonatal incubator and its compliance with the set requirements and regulations according to the technical standard IEC (International Electro technical Commission) 60601-2-19. Numerically According to the results presented in Tables (1 & 3), achieved acceptable performance and sustaining the requirements of the standard IEC 60601-2-19.In other words, the temperature at points T_1, T_2, T_3, and T_4 does not differ from the neonatal incubator average temperature by more than 0.8°**C**, and this temperature does not differ more than 1.5 °**C** from the incubator control temperature. Compared to the established technique, the estimation error is negligible.

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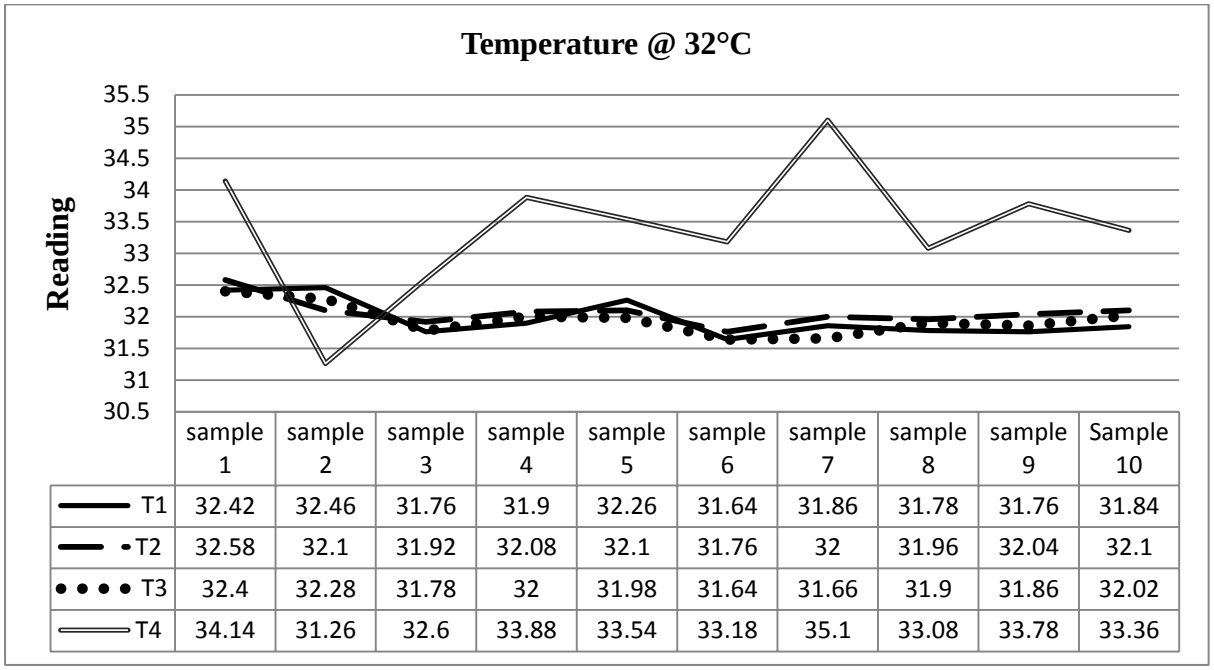
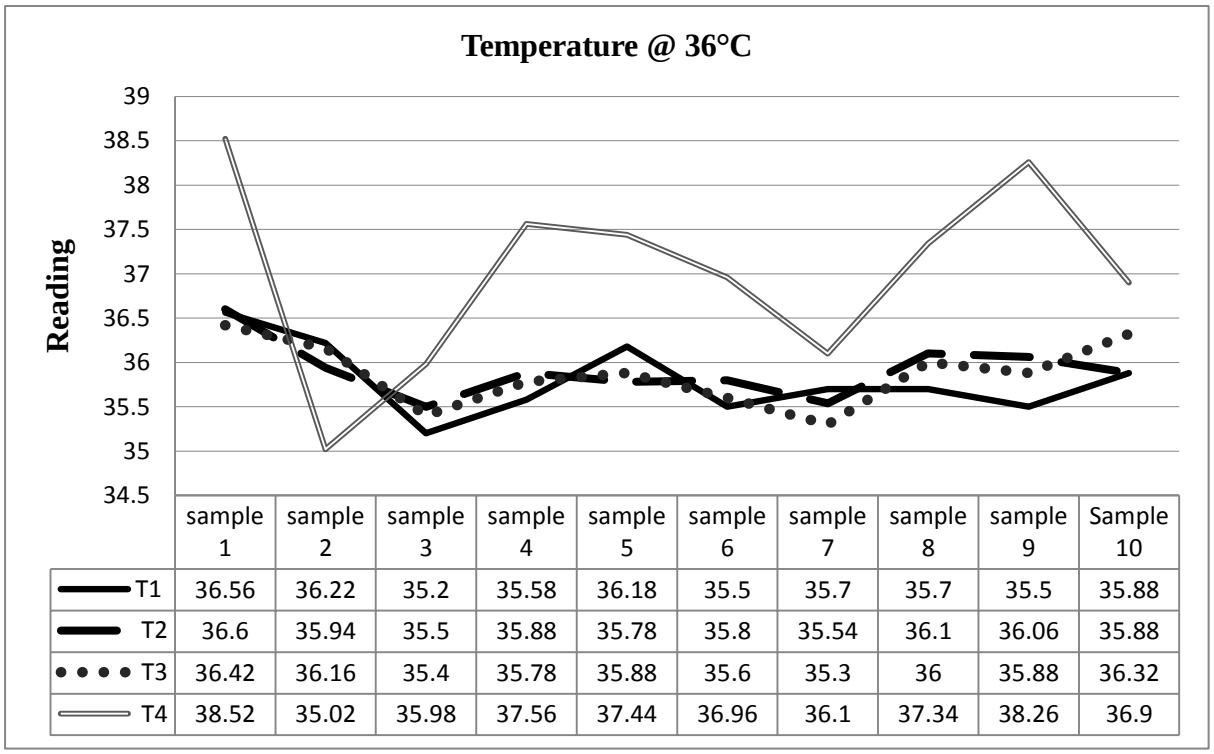


	sample 1	sample 2	sample 3	sample 4	sample 5	sample 6	sample 7	sample 8	sample 9	Sample 10
T1	32.42	32.46	31.76	31.9	32.26	31.64	31.86	31.78	31.76	31.84
T2	32.58	32.1	31.92	32.08	32.1	31.76	32	31.96	32.04	32.1
T3	32.4	32.28	31.78	32	31.98	31.64	31.66	31.9	31.86	32.02
T4	34.14	31.26	32.6	33.88	33.54	33.18	35.1	33.08	33.78	33.36

Figure 3: Results of Temperature Sensors @ 32°C



	sample 1	sample 2	sample 3	sample 4	sample 5	sample 6	sample 7	sample 8	sample 9	Sample 10
T1	36.56	36.22	35.2	35.58	36.18	35.5	35.7	35.7	35.5	35.88
T2	36.6	35.94	35.5	35.88	35.78	35.8	35.54	36.1	36.06	35.88
T3	36.42	36.16	35.4	35.78	35.88	35.6	35.3	36	35.88	36.32
T4	38.52	35.02	35.98	37.56	37.44	36.96	36.1	37.34	38.26	36.9

Figure 4: Results of Temperature Sensors @ 36 °C

Table I: Results of Control Temperature = 32 °C

Sample	Temperature Sensor T1	Temperature Sensor T2	Temperature Sensor T3	Temperature Sensor T4	Average Incubator Temperature
sample 1	32.42	32.58	32.4	34.14	32.04
sample 2	32.46	32.1	32.28	31.26	32
sample 3	31.76	31.92	31.78	32.6	32
sample 4	31.9	32.08	32	33.88	32
sample 5	32.26	32.1	31.98	33.54	32
sample 6	31.64	31.76	31.64	33.18	32
sample 7	31.86	32	31.66	35.1	32
sample 8	31.78	31.96	31.9	33.08	32
sample 9	31.76	32.04	31.86	33.78	31.98
Sample 10	31.84	32.1	32.02	33.36	31.96

Table II: Analysis of the Results of Control Temperature = 32 °C

Sample	T2 - T1	T2 - T3	T2 – T INC	T2 – Testing
sample 1	0.16	0.18	0.54	0.58
sample 2	-0.36	-0.18	0.1	0.1
sample 3	0.16	0.14	-0.08	-0.08
sample 4	0.18	0.08	0.08	0.08
sample 5	-0.16	0.12	0.1	0.1
sample 6	0.12	0.12	-0.24	-0.24
sample 7	0.14	0.34	0	0
sample 8	0.18	0.06	-0.04	-0.04
sample 9	0.28	0.18	0.06	0.04
sample 10	0.26	0.08	0.14	0.1

Table III: Results of Control Temperature = 36 °C

Sample	Temperature Sensor T1	Temperature Sensor T2	Temperature Sensor T3	Temperature Sensor T4	Average Incubator Temperature
sample 1	36.56	36.6	36.42	38.52	36.04
sample 2	36.22	35.94	36.16	35.02	36
sample 3	35.2	35.5	35.4	35.98	36
sample 4	35.58	35.88	35.78	37.56	36
sample 5	36.18	35.78	35.88	37.44	36
sample 6	35.5	35.8	35.6	36.96	36
sample 7	35.7	35.54	35.3	36.1	36
sample 8	35.7	36.1	36	37.34	36
sample 9	35.5	36.06	35.88	38.26	36
Sample 10	35.88	35.88	36.32	36.9	36.04

Table IV: Analysis of the Results of Control Temperature = 36 °C

Sample	T2 - T1	T2 - T3	T2 – T INC	T2 – Testing
sample 1	0.04	0.18	0.56	0.6
sample 2	-0.28	-0.22	-0.06	-0.06
sample 3	0.3	0.1	-0.5	-0.5
sample 4	0.3	0.1	-0.12	-0.12
sample 5	-0.4	-0.1	-0.22	-0.22
sample 6	0.3	0.2	-0.2	-0.2
sample 7	-0.16	0.24	-0.46	-0.46
sample 8	0.4	0.1	0.1	0.1
sample 9	0.56	0.18	0.06	0.06
sample 10	0	-0.44	-0.16	-0.12