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Reliability Assessments of Infant Incubator and the Analyzer

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ABSTRACT

Approximately 80% of newborn in Turkey are put in neonatal incubators because of their problematic cases. Incubators used for treatment may adversely affect baby's health seriously, if they adjusts or measures the parameters incorrectly. In this study, complications arisen because of inaccurate adjustment and measurement of incubator parameters were investigated. Current infant incubator analyzers were researched and the deficiencies were evaluated considering the standards and clinical metrology studies. As a result, findings were revealed as one of the current two incubator analyzers don't ensure the standard and the other one doesn't analyze some parameters which affect the baby's health directly.

Key Words: *Neonatal, Infant Incubator, Infant Incubator Analyzer.*

1. INTRODUCTION

In Turkey, 1,279,864 births occurred in 2012 [1] and most of them were put in infant incubators to overcome the distress during the post-natal care or after this period. These incubators can be defined as private cabins with electronic equipment supplying the premature or problematic babies to be able to continue their vital functions without assistance. According to the parameters entered, sound insulated and usually transparent incubators can set the temperature, humidity of the environment and anti-bacterial and filtered clean air as they used to in their mothers' womb. These incubators allow the baby to be monitored and be taken care of. Although the support of the incubators, 14,845 infant deaths occurred in 2012 and 65.9% of the infant deaths occurred within the neonatal period in Turkey [1].

We did an interview with Prof. Dr. Uğur DİLMEN, the clinical chief of Neonatal Intensive Care Units (NICU) of Dr. Zekai Tahir Burak Women's Health Education and Research Hospital, on infant deaths in neonatal periods and the infant incubator effects in this period. He said that more than 80% of neonatal babies are hospitalized within a year in infant incubators and are treated there over a period of 3 days to 7 months. The most common disturbances encountered in neonatal infants are lung problems and Congenital Anomaly. Incubators have an important role in the treatment of such problems.

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Infant incubators that directly affect baby's health make important contributions to the implementation of accurate diagnosis and treatment for the patients. However, the correct diagnosis and treatment are directly related to the reliability of the devices. When the impact of the incubator on baby health is considered, the ambient conditions such as sound level, light level, air ventilation and the quality of the electricity grid come into prominence. Basically, the premature new born baby's nervous system is in a status of general immaturity. The hearing system, the visual and the central nervous ones are the latest to mature and in the premature babies, part of this maturing process, is produced in the systems as neonatal incubators and in the environment of the NICU [2]. Plangangmas et al. [3] proved that sound pressure level (SPL) in an incubator should be tested and kept in the limits of the standards. Because, when operating, if the incubator produces a large amount of SPL, then it might cause a permanent hearing loss. Olivera et al. [4] evaluated SPL in some services of the Instituto de Maternidad, in Argentina and one of the services was Level III NICU. They performed the measurements with a type II sonometer (CENTER 322) and they used an incubator analyzer (FLUKE INCU) for the incubator noise evaluation. They took 29449 data for almost a day with 3 seconds sampling time. They found the maximum noise as 85.4 dBA, the minimum noise as 58.0 dBA and the average value as 63.6 dBA. These values were acceptable results. The volume measurement for an incubator is important for newborns with respiratory insufficiency infant in it. Roske et al. [5] compared the accuracy of volume measurements by different commercial devices using standardized laboratory conditions. They found that the relative volume error of all devices was in conformity with clinically allowed tolerances. Another important subject about the incubators is the quality of the electricity fed the incubator. A stable and high quality power supply is indispensable in order to maintain safety in the modern clinical setting. When a power failure occurs in a hospital, if a medical electric device does not contain an internal power supply, such as a battery, the device stops and the cause is clear. However, when a voltage dip occurs, operation may stop or a malfunction may arise, in some but not necessarily all devices, even though lighting, that gives a visual indication of power supply problem might not be influenced. Rapid voltage changes have a potentially great influence on clinical practice. Hanada et al. [6] tested the voltage dip tolerance on the medical devices. One of the devices was incubator in the NICU. There were two kinds of incubators and when the first one was exposed to voltage dip of 250 ms length, it didn't reboot automatically, power supply switch operation was required to reboot. When the other one was exposed to 100 ms voltage dip, it rebooted automatically. Besides the studies on the importance of the measurement for the incubators, there are studies on contributing to the development of the incubator. The temperature control is very important for the infant health. Term and preterm infants are unable to produce body heat through shivering. Dangers for a postnatal heat loss are: convection, conduction, radiation, evaporation, respiration and perspiration. They can result in a hypothermia, which is defined as a body temperature <36°C, associated especially with a higher mortality [7]. Kaitano developed a digital controller to heat and cool the incubator [8]. Early model temperature control systems used dial-type analogue control devices. Even though these systems may have worked very well in the past, it may be necessary to improve the devices' performance by digitizing the control and display systems. Lam et al. [9] developed a new fluorescence-based temperature sensor for neonatal care. This has a superior property as it is non-contact. This sensor removed the strong adhesive usage obligation to attach the thermistor probe to the body. These strong adhesives increase microbial growth and cause serious skin injuries via epidermal stripping. There is another equipment to keep the infant warm named with infant radiant warmer and this equipment is favored in North America especially [10]. Paley et al. [11] developed a new neonatal transport MR-compatible incubator and monitoring system with a low-cost design. Abdiche et al. [12] designed an active and silent control system, which generates and stabilizes the humidity, according to a set value of water vapor partial pressure, which is the most representative parameter of neonate-environment water loss to produce a stable and controlled micro-climate in incubators.

Electro-medical equipment must be calibrated periodically. As an infant incubator is electro-medical equipment, it must be calibrated too. If calibration isn't realized, its malfunction may cause serious damage to the newborn's health or even lead to the newborn's death [13].

Incubator analyzers are used to understand whether the outputs of them are accurate and reliable or not. According to the results of these analyzers, if necessary, correction is realized by biomedical engineering staff and so the calibration process is completed The requirements for infant incubators, calibration procedure and validation tests are included in the technical standard IEC (International Electrotechnical Commission) 60601-2-19 (Particular requirements for the safety of baby incubators) [14].

In this study, the calibration process of the infant incubators and the evaluation of infant incubator analyzers have been discussed. Besides, the deficiencies of the incubators and the calibration process have been identified. In the second section, infant incubators and their usage purposes are defined. Complications arisen from errors of infant incubators are evaluated in the third section. Calibration of the infant incubators is described in the fourth section. In the fifth section, incubator analyzers and their properties and kinds are evaluated. There is a conclusion comprised with the results of the investigation and suggestion for the last section. As a result of the research, the presences of some missing measurement parameters and the incubator analyzers having not the required measurement capacity have been observed.

2. MATERIALS AND METHODS

Early or problematic neonatal babies cannot keep the body temperature at the necessary and stable level. They need anti-bacterial, fresh, filtered air at constant temperature in a sterile environment with a certain extent of humidity, doctor supervision and nurse care in a quiet,

uninterrupted sleep environment. This environment can be supplied with incubators.

2.1. Infant Incubators

Incubator basically consists of a cabin unit with transparent cover, a controller unit carrying out the functions such as heating, ventilation and humidification of the incubator and a trunk unit. There are a scale for weighing the baby while lying, a led assembly for inserting and removing the x-ray film without disturbing the baby and a mechanical system used for turning or moving the baby right, left or up, down in the cabin unit.

The usage purposes of infant incubators are defined as follows [15]:

- The care and treatment of the infants with structural disorders (congenital anomaly) caused by the birth process,
- The care of infants with respiratory problems,
- The care of infants born from pregnancies with risk (diabetes, high blood pressure, kidney failure, blood incompatibility or pregnancy poisoning, etc.),
- The follow-up and treatment of infants existing asphyxiation (asphyxia) at birth,
- Application of breathing apparatus support to the infants with lungs immaturity,
- The follow-up and treatment of infected infants,
- The follow-up and treatment of very young or very old mothers' babies,
- The phototherapy treatment, follow-up and exchange transfusion of jaundiced infants.

2.2. Complications Caused by Infant Incubator Errors

There are some quantitative values required to be controlled such as temperature, relative humidity, sound level, air flow rate, oxygen saturation and ultraviolet (UV) light intensity for infant incubators. However, there are undefined values such as oxygen saturation and UV light intensity which are not measured integrated with the incubator for all existing devices. There are some measurement devices for measuring the oxygen saturation and UV light but they are not mounted in incubator. Saturation of oxygen and carbon dioxide are the values which are indirect interaction with temperature, relative humidity and air flow rate in the ambient. So these variables should be measured in the incubator.

Two types of incubators are used in Turkey. The lifespan for the products from European origin is 15 years and the lifespan for the products which originate in Turkey is 5 years. Besides, the medical equipment breaks down within average 5 years according to the researches. This situation shows the importance of fault tracking for the medical equipment within periodic intervals. The reasons of the defects may arise from so many errors such as electrical failure, control panel errors. The main measurement faults of the incubators are temperature, oxygen saturation amount and air flow. In addition, the basic problems of the infant incubators according to the report prepared by the World Health Organization (WHO) are caused by the uncontrolled oxygen saturation amount and uncontrolled temperature [16].

The basic reasons for the occurrence of the complications about the incubators are defects of infant incubators, faulty and incomplete calibration of them and the effects of human factor on this process. For example, electrical defects may cause measurement or display errors and if this situation merges with the cabinet faults, the infant may be affected from the electricity.

Faulty devices may cause very important complications on the newborn in the incubator. Deaths and injuries to neonates in incubators have been linked to thermostat failure that caused incubator overheating and infant hyperthermia and to malfunctions or design defects that produced fires and electric shock hazards. Inadequate control over the amount of oxygen delivered in an incubator can cause hyperoxia or hypoxia [16].

Table 1 shows the possible complications encountered if minimum or maximum values of the measurement of the temperature, relative humidity, air flow rate, the volume level and the parameters which should be added to the process such as oxygen saturation and UV light intensity are exceeded. According to the table, the thermostat failures (temperature) may cause from simple situations such as sweating or weakness to more serious problems such as stroke and even renal failure. The ventilator faults (air flow) which have been defined as the most critical faults may cause asphyxia illness. Besides, inaccurate measurement of air flow level affects directly to the oxygen saturation, the relative humidity and the ambient temperature in the incubator.

Several complications such as retinal degeneration, dehydration and diarrhea may occur because of the faults during the control process of the UV for the treatment of the infants in congenital jaundice disease therapy (phototherapy). This situation shows the importance of measurement of UV in the incubator.

2.3. Calibration Method

Calibration is a process that determines the relationship between the values obtained from a measurement with the values corresponding to these measurements and known values under predetermined circumstances. Biomedical calibration should be distinguished from industrial calibration, although both are based on the same logic. Because a medical device without a proper calibration may cause to irreparable consequences.

In calibration, error value of the device to be calibrated is determined by referencing a measurement device with a higher accuracy rate. The devices used in calibration process should be certificated by the foundation which has national and international accreditation.

Table 1.Possible complications in condition of exceeding normal values for the measured parameters.

	Measurement Parameters					
Possible Complications	*Temperature [17]*	*Humidity Amount [18]*	*Oxygen Saturation [19]*	*Sound Level [3]*	*Ultraviolet (UV) Light Energy Amount [20]*	*Air Flow Rate[21]*
	Heat Exhaustion	Dry in skin	Hypoxia	Irregularity in Neonatal İncubator	Retinal Degeneration	Asphyxia
	Sweating	Respiratory Diseases	Diffusing Capacity Reduction	Concentration Disorder	Dehydration	
	Weakness			Increase in Blood Pressure	Diarrhea	
	Fatigue		Circulatory Deficiencies	Increased Heart Rate	Riboflavin Deficiency	
	Headache		Anemia	Acceleration in Respiration	PDA(Patent Ductus Arteriosus)	
	Nausea / Vomiting		Respiratory Problems	Decrease in Brain Fluid Pressure		
	Increased Thirst		Hyperoxia		Bronze Baby Syndrome	
	Muscle Cramps		Cerebral palsy	Sudden Reflexes	Exuviation	
	Hallucination			Headaches	Thrombocytopenia	
	Stroke			Continuous Damage in Inner Ear	Hypocalcemia	
	Renal Failure			Serious Brain Damage	DNA Damage	

The calibration process must be performed by an attentive, well-disciplined and trained specialist person in a controlled environment. As a result of this operation, the properties of the work area, the measurement uncertainty of the measurement system and the system error is determined. All of these features should be recorded on a document called Calibration Certificate or Calibration Report.

There are some deficiencies and non-compliances with the calibrations. They are as follows [22]:

- The calibration certificates are given to the user but they are kept in outside of the usage area of the device and difficult to access.
- The devices to be calibrated or date of calibration is not determined by the user of the device.
- It is thought that the calibrated device works without any error.
- Since allowable or acceptable error tolerances of the measurement and tracking devices aren't known, what will be compared with the results obtained from the calibration is unknown.
- A calibration service is regarded as a purchased document.
- As the benefit of the calibration service is unknown, it is not considered as important.

The national and international references that should be used for calibration process of infant incubators have been standardized with the standard for infant incubators IEC 60601-2-19 (Part 2: Particular Requirements for the Safety of Baby Incubators).

2.4. Infant Incubator Analyzer

Incubator analyzer is a portable device designed to verify the proper operation and environment of infant incubators. This unit focuses on the record in parameters important to the care of infants over time, such as airflow, sound level, temperature (four individual measurement probes), and relative humidity [23]. Considering the importance of the infant incubators, keeping the equipment under continuous tracking, periodic maintenance, repair and calibration is very important. The health of the babies is risked with faulty incubator controls. This situation about the incubator can be exposed with an incubator analyzer. The current incubator is connected to the test unit (analyzer) which has standard values belong to the measurement parameter. This test process allows us to see the current values in the incubator accordance with the standards or not.

It is claimed in the interview with Dr. Uğur Dilmen that the calibration tests are performed in an annual period and there are two types of incubator analyzers in Turkey. One of them is INCU incubator analyzer manufactured by Fluke Biomedical. This device can make measurements in four different parameters as follows;

humidity, temperature, volume level and air flow [23]. The other incubator analyzer used in Turkey is IncuTest manufactured by Datrend System Company. This firm claims that they are the first infant incubator and infant radiant warmer testing system meeting the requirements of the IEC Standards for incubators (IEC 60601-2-19) and radiant warmers (IEC 60601-2-21) [24].

Figure 1. INCU infant incubator analyser [23]

Figure 2: Datrend Incutest infant incubator analyser [24]

Both of the analyzers realize incubator test process in the same way. Test process comprises measuring within a certain time and recording the measurement values for an average of five seconds. It is determined whether the tested device is sufficient or not. This is performed by comparing the recorded values with the existing criteria. Finally, the adequacy of the device is approved with a final report.

In IEC 60601-2-19 standard, in contrast to the information about temperature, humidity, sound level and oxygen saturation, there aren't any criteria about measurement of UV light intensity or the sensitivity of it. But the criteria about UV light intensity is placed in another standard called as IEC 60601-2-50:2009- Particular requirements for the basic safety and essential performance of infant phototherapy equipment [25]. Photometers measured the lamp energy output should be used for optimal treatment. The lamps with energy loss of more than 20% should be replaced. The distance between neonatal and phototherapy lamps should be about 30-40 cm. The energy level obtained from the lamps should be 11mW/cm2/nm [20]. If these criteria aren't met or aren't placed in the standard, the temperature, the humidity and the oxygen saturation measurements are affected from the change in UV light. So various criteria for UV light measurement should be added to the standard for the incubator and the incubator analyzers should make tests about UV light.

There is a criterion about measuring oxygen saturation in the standard. The amount of oxygen should be existing including an error of ± 5% from the set value. The infant incubators used in Turkey don't measure the oxygen saturation and the sensitivity of it in the incubator. But as can be seen from Table 2, if oxygen saturation cannot be in the limits of required values, fatal consequences may be faced with such as cerebral palsy, hyperoxia, hypoxia and respiratory problems. Oxygen saturation calibration cannot be performed with both of the incubator analyzers in Turkey either.

INCU incubator analyzer manufactured by Fluke measures the temperature from four points and this situation is insufficient according to the current standard saying that "The calibrated temperature sensors should be placed to five points on a plane surface parallel to the bed and 10 cm above."

The analyzer manufactured by Datrend System Company fulfills the conditions determined in the current standards in terms of the measurement criteria. However, researches show that it is compulsory for the infant incubators to have oxygen and/or carbon dioxide saturation measurements mounted inside the incubator. In addition to these, the measurement of emitted UV light intensity from the lamps used for phototherapy is important for the baby's health [19, 20]. But, these qualifications don't exist on both of the current analyzers.

3. RESULTS AND DISCUSSION

Neonatal incubators are very important devices. Inaccurate or insensitive measurement or arrangement of the parameters in the incubator may seriously affect the health of our most valuable asset. The health of the babies is risked with faulty incubator controls. Incubator analyzers are used to see the current values in the incubator accordance with the standards or not.

In this research, incubators and incubator analyzers were investigated and the properties and the deficiencies were put forth. There are two types of incubator analyzers used in Turkey and unfortunately they have some missing measurement data which are very important for the baby and the lack of them affects the other parameters. Oxygen saturation and UV light intensity cannot be measured as integrated with the incubator and incubator analyzers but these parameters are very important for the babies. For example, if oxygen saturation in the incubator is measured inaccurately, cerebral palsy may occur or if UV light intensity is set wrongly, the baby may be blind.

As a result, UV light intensity and ambient oxygen saturation should be measured in addition to the current measurement parameters. Oxygen saturation may affect the accuracy of measurement because it is associated with the values such as ambient relative humidity, temperature and air flow rate. The lack of these parameters in the analyzers of infant incubators may lead to serious and even fatal results for the babies.

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CONFLICT OF INTEREST

No conflict of interest was declared by the authors.

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