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Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE)

Designing and Prototyping of a Portable Cradle Infant Warmer

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A Dissertation Submitted to the Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE), University of Rwanda as partial fulfilment of the requirements for the Master's Degree in Biomedical Engineering.

Supervised by:

Eng. Jean Ngoie and
Dr. Gerard Rushingabigwi

Declaration

I, DUSABIMANA Mellifica Elyse, declare that this dissertation entitled "**Designing and prototyping of a portable Cradle Infant warmer**" is my original work based on research and prototype and has not been submitted for any other degree or professional qualification.

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Date: 2/11/ 2023

Certificate

This is to certify that the project entitled "**Designing and prototyping of a portable Cradle Infant warmer**" is original and work done by Dusabimana Mellifica Elyse [220020523], a MSc. Degree student in Biomedical Engineering.

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ABSTRACT

When premature and low birthweight babies are born, they lack the body fat that is necessary to regulate their temperature, therefore, room temperature can quickly cause the newborn babies' temperature to drop up to less than 36.5 degrees Celsius and may lead to neonatal hypothermia. Data from Rwanda demographic health survey have listed hypothermia as one of the leading causes of neonatal deaths in Rwanda.

One of the existing methods used to keep the baby warm in hospital are linked with different disadvantages, healthcare providers use infant radiant warmers and incubators to prevent newborn hypothermia, however, such equipment are very expensive and not affordable by health facilities, hence there is an emergency need of alternative option to maintain newborn's normothermic.

As a way of delivering innovative, effective, and long-term solutions to this serious problem, the researcher has designed an inexpensive portable cradle infant warmer device which is made of 4 main components which are cradle bed, warmpack heating table and temperature display unit. When this device was tested, the results have showed that the device is designed in a way that it can keep the baby's temperature in the normal range of 36,6 to 37.4-degree Celsius for about one hour and thirty minutes before reheating the warmpack. Based on the results found, the researcher can conclude that, the new thermoregulation device is affective device to keep the newborns warm promote both mental and physical growth of neonates , ultimately can be the best alternative to replace existing methods to keep premature and low birthweight babies warm in the future since it has more benefits compared to existing methods in terms of safety, cost, portability and easy manipulation and it will help to minimize the mortality related to hypothermia in affected babies who does have any other birth problem like respiratory distress or needed phototherapy.

Keywords: Hypothermia, Preterm, Infant warmer, Normothermia, Low birthweight

LIST OF ACRONYMS

AC: Alternating current
CB: Cradle bed

CEBE: Regional Centre of Excellence in Biomedical Engineering and E-health

CST: College of sciences and technology

DHS: Demographic health survey

MOH: Ministry of Health

NST1: National strategy for Transformation

KMC: Kangaroo mother care

PCM: Phase changing material

PCIW: Portable Cradle Infant warmer

LBW: Low birth weight

UR: University of Rwanda

WHO: World Health Organization

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CHAPTER 1. GENERAL INTRODUCTION

Introduction

The permissible body temperature for newborns is between 36.5°C and 37.5°C; any drop below these limits is referred to as hypothermia, which is thought to be life-threatening to the baby [1]. Neonatal hypothermia may result from a newborn baby's temperature rapidly dropping due to room temperature since newborns lack the body fat needed to regulate their body temperatures [2]. Newborn mortality is still a major problem and is greatly impacted by neonatal hypothermia, particularly in places with little resources like Rwanda.

In 2017, 2.5 million children worldwide lost their lives within the first month of life.as indicated by the data from the World Health Organization (WHO), with 25–45% of neonatal death occurring in the first 24 hours [3]. And it has been shown that the prevalence of hypothermia in infants born at hospitals ranges between 32% to 85% and for babies born at home the prevalence ranges between 11% to 92% of all newborns [4].

An estimated 17 million neonates in low-income countries were found to develop hypothermia annually, and the prevalence of 57.2% has been reported in East African countries [5].

According to data from Rwanda's demographic health survey (DHS), there are 15.9 neonatal fatalities for every 1,000 live births in Rwanda, and hypothermia is one of the main causes of neonatal deaths [6].Healthcare providers use infant radiant warmers and incubators to help newborns to maintain safe body temperature [7], however, such equipment is very expensive, not portable, and requires a stable source of electricity to operate, many hospitals as well health centers in Rwanda does not have abilities to afford such medical device, reason why sometimes they are unable to maintain newborns' safe body temperature, and that may lead to neonatal mortality in resource-limited settings when infants are otherwise not in Kangaroo Mother Care (KMC).

KMC is a well-known, successful method that offers a variety of advantages, such as increased lactation and mother-child bonding [8]. However, there are times where it is not feasible such as when KMC does not provide enough heat, when the mother is sick, in circumstances when the mother feels pain or fatigue, in all these situations there is an emergency need of alternative options to maintain newborn's normothermic.

As a way of delivering innovative, effective, and long-term solutions to this serious problem, I am proposing the project of fabricating a portable cradle infant warmer device which will be cost-effective, easy to operate, and safe for children, to ensure that the number of child deaths in

newborns is reduced in Rwanda as well as among the developing countries that don't have access to lifesaving medical technology.

Since existing alternative options to warm premature and low birthweight babies, have been linked with some advantages in terms of affordability, portability in ambulances, and complexity in manipulation, hence I decided to design a portable cradle infant warmer (PCIW) which will come in with extra advantages compared with existing medical devices, the novel device will be easy to manipulate, it will not be expensive, it will be portable in ambulances, and it will not need a continuous power supply, to ensure that every infant who requires temperature control may access ,will be having other neonates problem like breathing, or oxygen saturation problems.

Problem statement

In Rwanda, hundreds of premature and low birth weight infants are born each year[1]. These neonates are more likely to experience hypothermia, which can result in growth hindrance, infection, delayed mental development, and even mortality during infancy and childhood [2]. The high mortality rate of newborns from hypothermia is caused by the fact that many of the Rwandan families giving birth to these children lack access to or cannot afford the cost of conventional neonatal care, which includes the use of incubators and infant radiant warmers to maintain babies' normothermic commonly, in underserved areas where access to standard medical care is difficult[3]. Looking at the high mortality rate of newborns due hypothermia as well as the high-cost existing methods to warm babies in Rwanda, the researcher has proposed to design and prototyping an inexpensive portable cradle infant warmer in response to constraints of access and affordability on existing incubators and radiant warmers. With the intention of minimizing the mortality rate related to hypothermia in premature and low birthweight babies who are stable with no other birth problems like breathing problems.

Research Questions (Hypotheses)

The following four questions are the baselines which guided this study:

1. Why is hypothermia still a cause of death for neonatal patients in rural Rwanda?
2. With the high cost of radiant warmers, what will be the possible advantages in designing a low cost warming medical device that could be made available to healthcare workers and caregivers?

3. What positive impacts will this new medical device have on the high mortality rate of neonates due to hypothermia?
4. Will the novel prototype be affordable compared to existing devices?

1.4 Objectives

1.4.1 General Objective

This project aims to design and prototyping a portable cradle infant warmer

1.4.2 Specific Objectives

To achieve the general objective of this project, the following specific objectives are used as guiding points;

1. To create mechanical and electronic designs of the portable cradle infant warmer
2. To prototype both hardware and software designs of the portable cradle infant warmer
3. To test the laboratory functionality of portable cradle infant warmer

1.5 Study Scope

This study focused on designing and prototyping a portable cradle infant warmer made of 4 components which are cradle bed, warm pack, warm Pak heater and temperature display unit. It was designed by assembling both mechanical and electronic designs and the functionality of the final work was test in the laboratory to see whether it can maintain the temperature in the normal range of 36.5 to 37.5 degrees as recommended by the WHO. All designs and test were done in the biomedical engineer laboratory of Crown health care with the assistance and support of my thesis supervisors and biomedical engineers working in the crown healthcare company.

1.6 Significance of the Study

For the government of Rwanda and health systems, this inexpensive, non-electric and portable infant warmer could be a significant choice in lowering the high yearly neonatal mortality rate where hypothermia is a contributing factor. The project is designed to save life of thousands of neonates dying from hypothermia in Rwanda, reduction up to 90% of maternal and neonatal mortality and provision of high-quality access and affordable health care, that is one of the goals of NST1 which establishes the target of reducing child mortality, ultimately it is in line with the main goal of this project.

This designed device comes in with extra advantages compared with existing medical devices, the novel device is be easy to manipulate, it not be expensive, it will be portable in ambulances, and it will not need a continuous power supply, to ensure that every baby in need of temperature regulation can get it and that no baby dies from being cold.

On the other hand, the results of this project will be published in international biomedical journal with high impact factor, ultimately, they will be disseminated and inform policy makers and all stakeholders in Rwanda even abroad

1.7 Organization

Chapter one gives the introduction on prevalence of hypothermia in newborns and the existing methods and their disadvantages in the management of hypothermia but also this chapter highlight the objectives, the problem statement, significance, the scope and the organization of the study. Chapter two discusses the existing literature related to the present study it all about previous studies conducted in different countries that might give the general picture on existing methods used to manage hypothermia in neonates and their associated drawbacks but this help to identify the existing gap that needed to breached during my study project. In chapter three talks about materials and methods used to design the current medical device but all it highlights all procedures I passed throughout to end with the current product. Chapter four talks about results find after designing, prototyping and testing the designed medical device and finally chapter five discusses on challenges, recommendations and conclusions from the research study.

1.8 Summary

In brief, this first chapter give the idea on general introduction on high prevalence of hypothermia in preterm and low birthweight babies and it highlights the existing methods that are used in the management of hypothermia in neonates and the disadvantages associated with them, it also give the idea on the source of the idea of designing the novel device with extra-advantages compared to existing devices, at the end this chapter the author has stated the main and specific objectives of the study as well as the problem statement ,significance and organization of the study. But, before designing my device I need to know the existing information and identify the gap that need to be breached and all this is revealed in the literature review, hence with the next chapter the researcher is going to see what is the existing information through the literature review

CHAPT ER 2. STATE OF THE ART (RECENTLY RELATED LITERATURE)

Neonatal care places a high priority on temperature control, yet commercially available warming techniques are frequently prohibitively expensive. In low-resource settings, available warming methods are unaffordable and linked to other risks to infant health. For a specific group of neonates who are preterm and low birthweight without any other health issues, the prototype developed in this thesis has the potential to help them in consistence management their body temperature in normal range.

2.1 Definition of neonatal hypothermia and normothermia

The tolerable body temperature for newborns is between 36.5°C and 37.5°C, and any drop below that is deemed hypothermic and potentially fatal to the infant is known as hypothermia[4].WHO classified the neonatal hypothermia as mild hypothermia (36°C to 36.4°C), moderate neonatal hypothermia (32°C to 35.9°C), and severe neonatal hypothermia (less than 32°C) [5].

Neonatal hypothermia can occur at any time and is a major threat to newborn survival during the neonatal period, which lasts from zero to 28 days [6].

Because the neonate is coping with extrinsic fluctuations that contrast the intrauterine conditions, its incidence is higher in the first 24 hours after birth, and infants are more likely to die from hypothermia. Normothermia it is a condition where the human body functions at its optimum when the core body temperature is between 36.5- and 37.5ºC,

2.2 Prevalence of hypothermia in Neonates

Around 125 million newborns are born every year, and 8 million of them die before they turn one, according to the World Health Organization. Of the causes of death, hypothermia accounts for 2.5 million deaths, or more than a quarter of all infant deaths [7].

It is widely acknowledged that neonatal hypothermia is an unsolved problem that contributes to neonatal morbidity and mortality, particularly in resource-limited settings [8]. Globally, it has been demonstrated that the prevalence of hypothermia in infants born in hospitals ranges from 32% to 85%, while the prevalence of hypothermia in babies born at home ranges from 11% to 92 percent of all newborns [8].

The prevalence of neonatal hypothermia varies greatly, but it was recently reported to be 100% in a population of low-birth-weight (LBW) infants in low-resource African settings [9].

For instance in Sub-Saharan African countries, the hypothermia was reported to be, 8.1%(community-based study) to 94.9%(hospital-based study) in Guinea Bissau [10]. One study

specifically focused on the southern region of Ethiopia, where individuals from various sociocultural backgrounds live a pastoralist and semi-pastoral lifestyle, the findings showed that newborn hypothermia prevalence is at 50.3%. [11].

The frequency of neonatal hypothermia was found to be 87% among babies who had no interaction with their mothers after delivery in a cross-sectional study on the condition that involved 300 neonates who were recruited day and night for two months in a periurban hospital in Uganda. [12]. However, the results of another study conducted in Tanzania have shown that the prevalence of hypothermia is estimated to be 22.4% among newborns admitted to Muhimbili medical center [13].

According to a study conducted in Kenya to assess the prevalence of hypothermia and the degree of compliance with WHO thermal treatment recommendations among neonates admitted to Moi Teaching and Referral Hospital, its prevalence is as high as 87% with little local information on the relevant causes[14].

In Rwanda findings from various research have identified a high prevalence of hypothermia in neonates which is around 27% and infants with hypothermia and have a significant association with mortality [15].

2.3 Signs and symptoms of Hypothermia

Hypothermia in the neonatal period can be defined as a body temperature less than 36.5°C (97.6°F)[4]. Premature and low birthweight babies are especially sensitive and frequently suffer from hypothermia[16]. A neonatal's vaso-muscular responses are insufficient to generate enough heat metabolically to maintain the baby's normal temperature. The immaturity of the thermoregulatory system in newborn infants, particularly preterm infants, makes the infant more vulnerable to changes in environmental temperature. When a baby's body temperature lowers, they become lethargic, hypotonic, and have trouble in sucking. As the condition progresses, significant changes in body metabolism take place, resulting in impaired cardiac function, hemorrhage, jaundice, and death [4].

Here are some signs and symptoms of hypothermia in neonates

Acrocyanosis and pale skin

Hypoglycemia

Transient hyperglycemia

Bradycardia

Tachypnea, restlessness, shallow and irregular respirations

Respiratory distress, apnea, hypoxemia, metabolic acidosis

Decreased activity, lethargy, hypotonia

Feeble cry, poor feeding

Decreased weight gain

(Sources [16], [17])

2.4 Consequences of hypothermia in the newborn

Neonatal hypothermia must be treated immediately to prevent serious and even fatal consequences. It has been shown that a baby inside the womb is exposed to a temperature environment that is 5 degrees Celsius higher than the outside temperature, and as a result, the infant suffers effects associated to these differences [16].

Several studies on neonatal hypothermia found that mortality increased by approximately 80% for every degree Celsius decrease in axillary temperature, and that the relative risk of death ranged from two to thirty times higher than when neonatal hypothermia is prevented [18].

The infant is more likely to experience hypoxia, cardiorespiratory issues, and acidosis as a result of increased oxygen demand brought on by the increased cellular metabolism that occurs when the baby struggles to stay warm. These babies are also at risk for hypoglycemia due to the increased glucose consumption necessary for heat production. Hypothermia can result in neurological issues, hyperbilirubinemia, coagulation issues, and possibly mortality if it is not addressed [19].

General Neonatal Hypothermia is known to be a major killer during the neonatal period because it is connected to or worsens severe neonatal conditions like Necrotizing Enterocolitis, which is more obvious, and other disorders that affect newborn survival like respiratory patterns, blood disorders, and gastrointestinal disorders like Necrotizing Enterocolitis [20].

2.5 Factors associated with hypothermia

Several factors, in our population, contributed to neonatal hypothermia: gestation, place of birth, and mode of delivery [21]. Different writings have shown that both physiological and environmental factors may predispose neonates to hypothermia.

2.5.1. Preterm

Findings indicated that only 1-2 percent of all deliveries are preterm, which is defined as occurring at less than 28 weeks or 1000 g, but it causes the bulk of infant morbidity and mortality. Therefore, it is important to give special thought to the potential that prenatal hypothermia contributes to unfavorable newborn outcomes. There is evidence from numerous studies from different nations that preterm delivery and newborn hypothermia are related.[11]. Hypothermia continues to be a significant issue, particularly in the perinatal care of preterm infants. The link between gestational

age and admission hypothermia is also well established, with extremely premature babies being at higher risk [22].

Furthermore, other studies also done in African countries revealed that neonates who were transferred from health centers to our tertiary center were more likely to be hypothermic on admission [21].

2.5 .2 Low birthweight

The newborn infant, especially those with low birthweight, demonstrates immature thermoregulation as compared to an older kid or adult and must therefore be shielded from extremes of cold and heat. Low birth weight (LBW) premature babies are born lacking the adaptations needed for survival outside of the womb. Interventions for the thermoprotection of these vulnerable neonates must start in the birth room. Low birth weight was defined as a newborn weighing less than 2.5 kg at birth. A connection was shown in five studies between hypothermia and a newborn's low birth weight [4].

2.6 Regulation of neonate normothermia

When the baby is inside the uterus, the mother's physiological mechanisms keep the temperature normal. However, when the baby is outside the uterus, the baby must adapt to the external environment using his or her own physiological mechanisms, which are immature at the time and put the neonate at risk for hypothermia. In these situations, caregivers should pay attention to helping babies cope with the environment by using preventative measures [7].

The regulation of normal body temperature in neonate is maintained via different complicated mechanisms including physiological hormonal regulation, the external behavioural factors also play a crucial role in maintaining of the normal body temperatures [8]. In neonate baby, the first source of avoiding hypothermia comes from non-shivering thermogenesis that deals with the use of brown adipose tissue [23]. Understanding the pathophysiology of heat loss and production is a key element in designing the proposed new medical device to keep the newborns normal temperature.

2.7 Existing thermal control methods of hypothermia in neonates

Neonatal growth requires a constant body temperature in order to function properly. Caloric expenditure and oxygen use are minimized when the temperature is maintained. Hypothermia is a risk factor for newborns, particularly preterm and low birth weight infants. Despite the lack of a definitive link between hypothermia and mortality, the danger of morbidities such hypoglycemia

and respiratory distress as well as the connection with death make neonatal hypothermia therapies necessary. One of the methods now employed to prevent hypothermia are:

2.7.1 Incubators and radiant warmers

By providing a heat chain via inter- or intra-hospital transit from the birth room to the neonatal ward, hypothermia can be prevented. This heat chain is normally provided by using radiant warmers and incubators in some hospital and clinical settings.

Incubators are designed to give newborns a secure, regulated environment to dwell in while their important organs grow. It designed in a form of bassinet, and has a setting that can be modified to deliver the perfect temperature as well as the ideal level of oxygen, humidity, and light to the new born infants. If not kept in this carefully monitored environment, many infants, especially those who were premature and had low birth weight, would perish [24].

An incubator's ability to regulate humidity also enables it to prevent the skin of a baby from drying out, becoming brittle, or breaking. An incubator is made in a way that it can track various component at the same time, such as a baby's temperature and heat rate. This monitoring enables caregivers to monitor a baby's health continuously. An incubator will be open on top or have portal openings on the sides, allowing it to be utilized in combination with various medical procedures and interventions in addition to providing information about a baby's vitals [25]. Despite the fact that this medical device has many benefits, it has also been associated with some drawbacks that could limit its potential. Some of these drawbacks include the fact that it is expensive to operate and maintain, that it separates the baby from the family, and that it could be dangerous for the infant due to the warm, moist environment, heating elements, and electricity use. It is also known to be too expensive for the poor population [26].

Radiant Warmer, is a body warming device to provide heat to the body [27]. This device helps to maintain the body temperature of the baby and limit the metabolism rate. Heat has a tendency to go in the direction of the heat gradient, which is from high temperature to low temperature. Some newborn babies lose heat quickly therefore, body warmers offer an artificial assistance to maintain body temperature. Babies are kept on Radiant Warmers for a few hours just after birth in some regions with very cold climates to ensure the baby is stable following birth [28].

In a radiant warmer, an infant is maintained in an open tray with artificial heating produced by a heating mechanism positioned overhead. The heating mechanism is made of quartz and provides

the required heat. It also has a reflecting mechanism that directs the heat to the baby tray [29]. The skin temperature of the baby can be monitored by a temperature measuring knob that is kept continuously attached to the body, the variation in the skin temperature can be seen on a small liquid crystal display panel which continuously shows the body temperature [30]. The heat produced by radiant warmers can be controlled manually by a knob or automatically depending on the radiant heat warmer in order to draw the attention of medical professionals attending the baby. Radiant warmers are equipped with alarms to signal temperature changes and thereby draw their attention [31].

However, this device is also associated with different disadvantages including it is costly to maintain and run, it separates the baby and the family and it is potentially hazardous to the infant from the warm moist environment, heating elements and the use of electricity and it is too expensive. In addition to high cost ,both device are associated with other health threatening problems , the fat that both thermal regulation devices use , high-wattage lights, electric room heaters, and stove coils to regulate babies' body temperature, infants can experience potentially fatal problems.[32]

2.7.2 Kangaroo mother care

In some area of the country electrical sources of external heat may be absent or overused in settings with limited resources, where equipment, electricity, and training on warming methods are not available. This could lead to high rates of hypothermia as well as worries of infection management. The provision of a heat chain is still required, but it requires customization based on the resources available. Since existing warming equipment are expensive, requires a steady source of electricity, and has a potentially limited lifespan without the infrastructure to solve complex maintenance and repairs. Hence people should relies on available natural option to solve the problem of hypothermia [33].

Kangaroo mother care (KMC) was first started in Colombia in 1978 [34]. It is a comprehensive intervention given for all newborns especially for premature and low birthweight (LBW) infants. Kangaroo mother care is the most feasible, readily available, and preferred intervention for decreasing neonatal morbidity and mortality in developed and developing countries, and suitable for use in all settings [35].

In many cultures, kangaroo mother care (KMC), which encourages breastfeeding and motherbaby bonding in infants, is a common practice and well-accepted procedure. It is also thought to be a method of preventing hypothermia by using skin-to-skin contact between the patient and the infant. Early skin-to-skin contact during the first hour of life has been proven to have a strong protective

effect on temperature control and to lower morbidity and death in stable LBW newborns [36]. KMC is a well-established, effective practice with many benefits including improved lactation and bonding between baby and the mother [37]. However, there are times where it is not feasible such as when KMC does not provide enough heat, when the mother is sick, in circumstances when the mother feels pain or fatigue, in all these situations there is an emergency need of alternative option to maintain newborn's normothermic.

2.8 Summary

In this second chapter it is all about the existing literatures, articles published in different journals informing the author and the audience on existing knowledge related to current research project and give the general idea on the gap that needed to filled by the present research project. In general this chapter have shown that neonatal hypothermia remain a problem and it is associated with so many consequences on the babies and in this chapter it has been highlighted that the existing methods to control hypothermia are so expensive and not available in low resources settings and might be associated with some other problems[32], since the gap has been identified on the findings from the previous research done ,the next step is to start the phase of designing and prototyping a novel medical device with extra-advantages compared to the existing methods ,all materials and methods used to achieve to that devices is going to be highlighted in the next chapter (Chapter 3) of Methodology.

CHAPTER 3. RESEARCH METHODOLOGY

In this chapter the methods and approaches used to conduct the study are outlined. This includes the steps undertaken to complete the study, the system design methodology and prototyping of the novel medical device.

3.1 Research Process

This thermoregulation new device was designed in Crown health care biomedical engineering laboratory from June 2022 November 2022.

The current research project was designed based on the following process

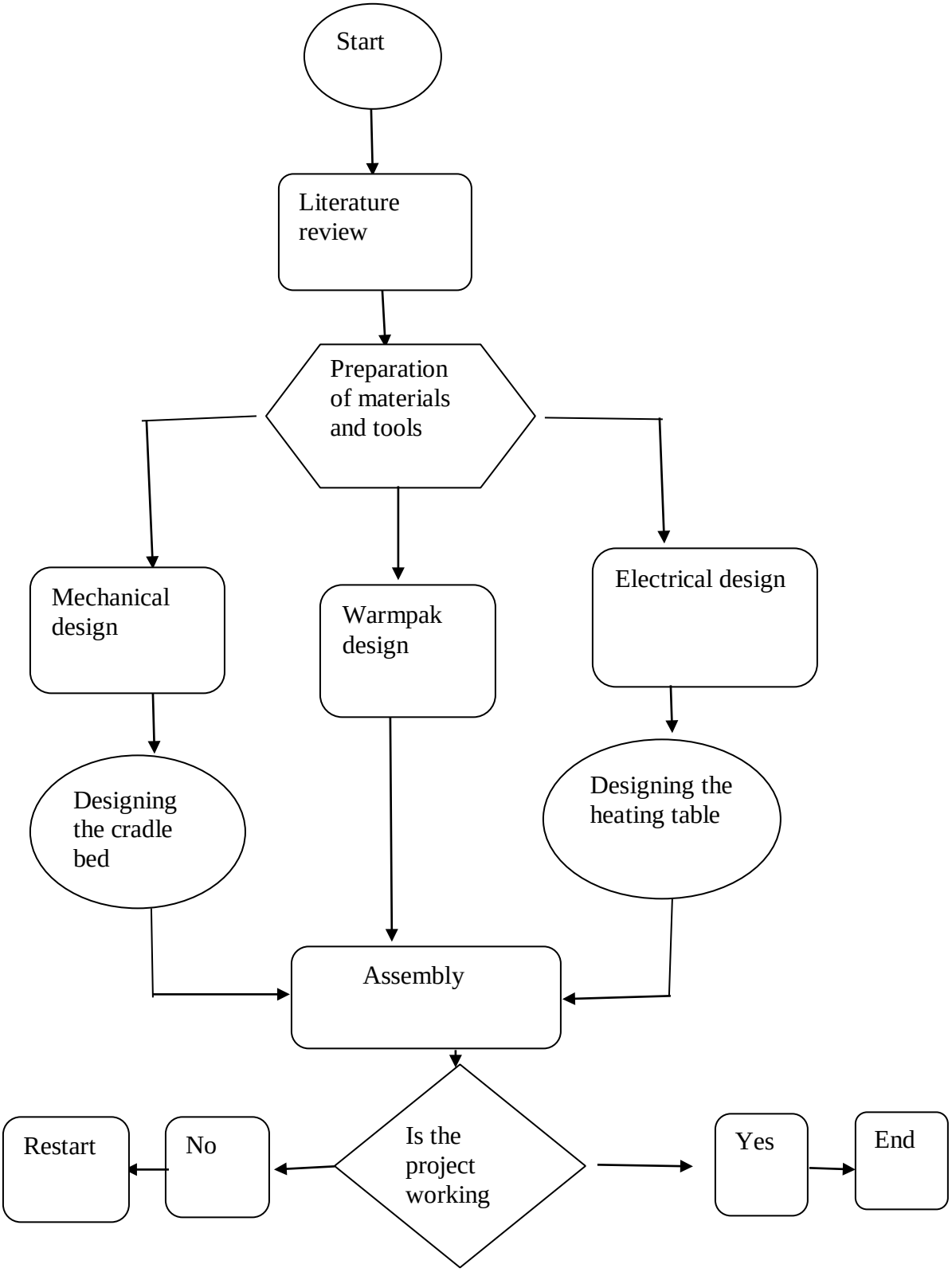


Fig.3. 1: Research process of designing and prototyping the proposed device

3.2 Research Design Method

3.2.1 System Requirements

This medical device is designed in way that it will keep the temperature of the baby at the minimum of 36.5 ℃ and the maximum temperature of 37.5 ℃.

The warmpack should be pre-warmed around 40 minutes till the temperature reach the normal range of 36.5 ^{0}C to 37.5^{0}C before being inserted in the cradle bed

The research has always measured and monitored the temperature inside the cradle bed in an interval of 20 mints. The baseline temperature inside the cradle bed was measured before insertion of heated as way of measuring the effectiveness of the designed device.

If the temperature of the warm pack goes below 36.5^{0}C, the temperature indicator find on the warmpak system will indicate that it is under normal range of too cold state, which means that the warmpak need to be recharged again. And if the temperature goes above 37.5 ^{0}C the temperature indicator will indicate that the temperature has gone beyond the normal range of too hot range which means that the warmpak is full charged and need to be taken out of the warmpak heater.

3.2.2 System Components

This prototype system is made of the following components:

Table.1.1: Table showing the system component of the deigned device.

System component of the prototype	
Component	**Materials**
1.WarmPack	Water layer
	Paraffine wax
	Sodium acetate
	Polyurethane cover
	Temperature indicator
2.Cradle bed	Kitenge cotton
	Insulating tissue
	Belts
3.Heating table	Power cable
	Heating element(220/50W)
	Heat resistant plate

1. **Cradle bed:** For accommodating the baby
2. **Removable warmPak**: Rechargeable elements to produce heat and keep the normal temperature of the baby for at least 1 hour.
3. **Warm Pack heating table:** The only electrical component of the device which is small designed table to heat warmpack when its temperature goes below 36.5^0C.
4. **Temperature indicator unit:** The baby temperature in the cradle warmer will be displayed on display unit of the warmer
5. **Surface thermometer:** To detect the temperature of warmPack and also inside the cradle bed.

3.2.3 Operating flowchart of the novel device

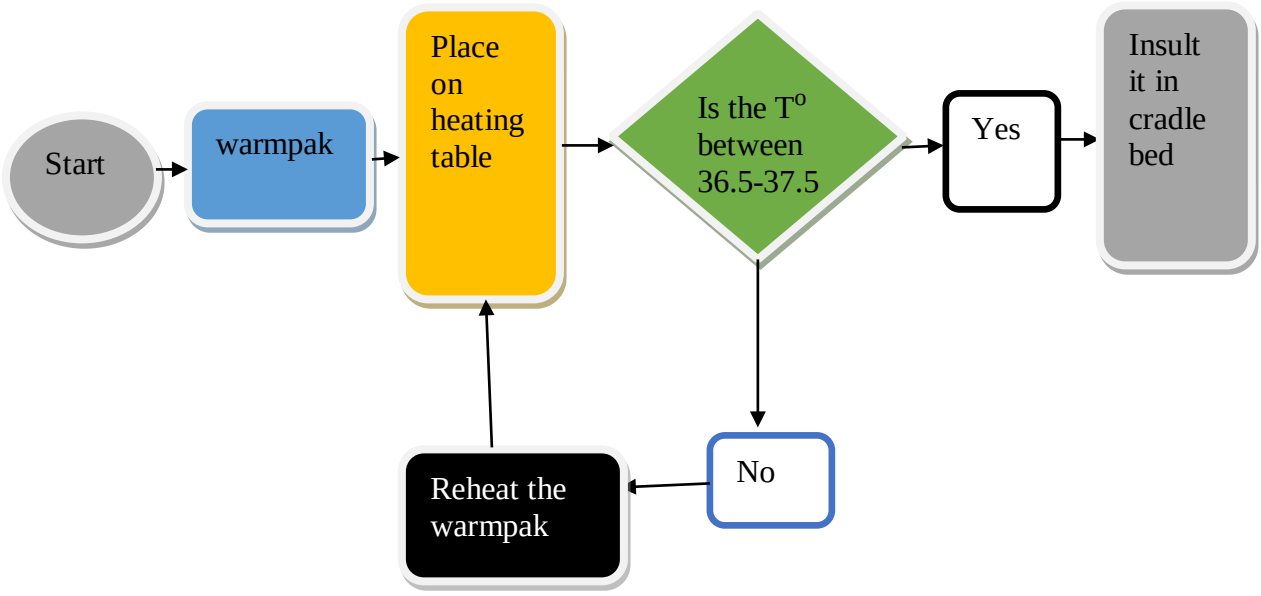


Fig.3. 2: Operating flowchart of the designed device.

3.3.3 Summary

This chapter has described the method used for designing this genuine medical device, it the entire designing process of the device it has also shown the system requirement, the system component and the operation flow chat of the device.

CHAPTER 4. THE PROJECT RESULTS FROM SIMULATION AND/OR IMPLEMENTATION

4.1 Device design description

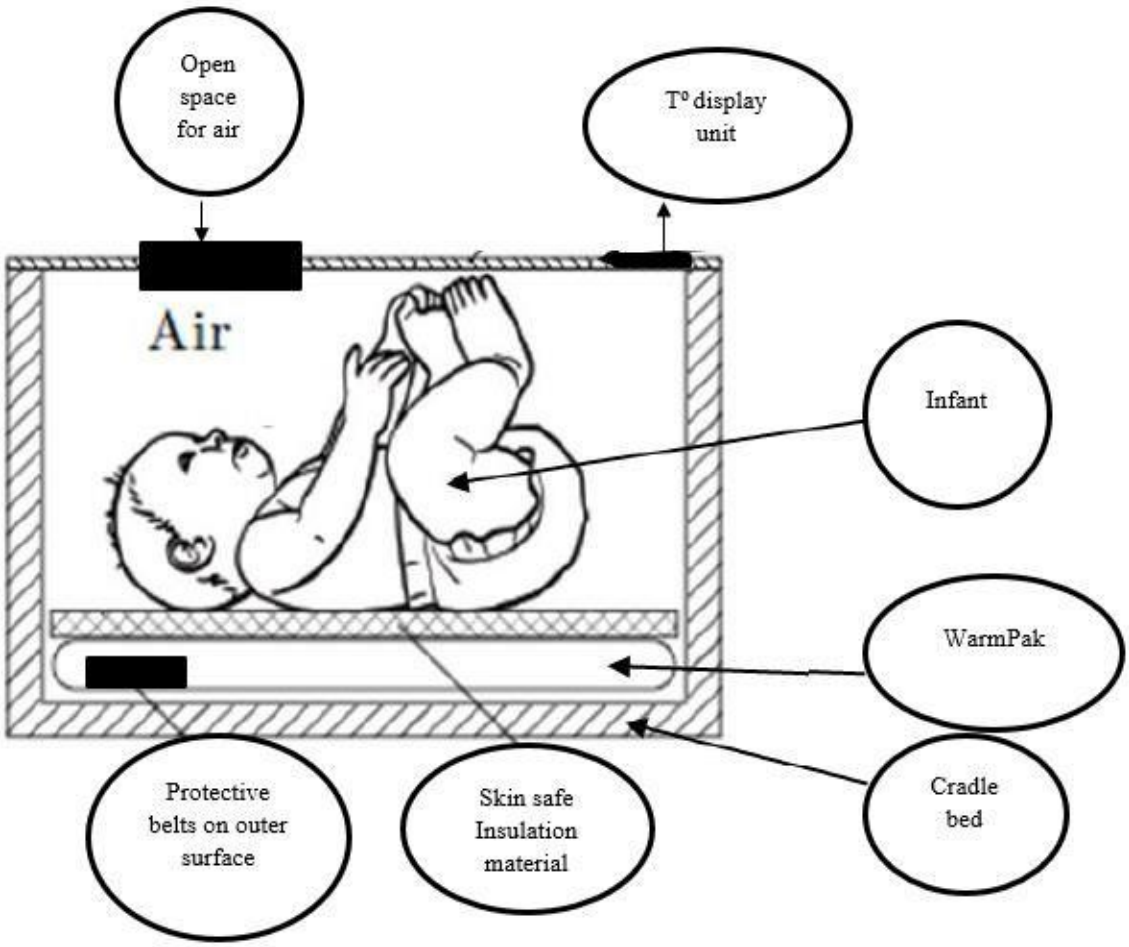


Fig.4. 1: Figure showing the cradle bed device components. The infant is lied on the heated warmpak, attached with temperature display unit aside and visible to users.

This designed medical device is made of 3 main components

4.1.2 Cradle bed

An interface in which the newborn rests, the cradle bed has compartments that hold the newborn and the heated warmpak and ensure that the two are in good thermal contact with each other and provides a warm, insulating microclimate to the newborn. It is made of skin safe insulating material with adjustable belts to secure the baby inside the cradle bed and has temperature display unit.

Fig. 4. 2: Cradle bird components with stick belt and insulating and skin safe materials

4.1.3 Warmpak

The warmpak is designed in way that when heated it absorbs heat from the heater and slowly releases that heat over time. It can keep the normal temperature for about 1 hour before being reheated gain.

It is made of heat resistant polyurethane cover which has two layers –a water layer and phasechange material (PCM) layer made of paraffin wax and sodium acetate mixture . When the warmpack is heated the PCM melts and stores energy and starts release the heat slowly through the water layer that warm the newborn. The water layer eliminates hotspots and provide the uniform warm surface to the newborns. The polyurethane cover cannot melt easily since it has a high melting point of 120 degree Celcius .

When inserted into the cradle bed, the water layer should be facing to serves as the source of warm to the baby. The warmPak maintains a temperature of around 37ºC for at least 1 h and 30 minutes without need to be reheated. The results have been proven through laboratory tests done 3 times and calculated the average temperature and realized that it can maintain the operating temperature for at least 1 hour at an ambient temperature of 25 °C.and it has a temperature display unit to monitor the change of temperature.

Fig.4. 3: Warm pack with two layers: white side is a water layer and black side is PMC layer

4.1.3 Temperature display unit design features

The temperature indicator has been positioned such that it will be visible to the user only when it is correctly inserted into the cradle bed.

The indicator also serves to indicate to the user when the WarmPak is at the right temperature and may be used, and when it has run out of stored heat, and needs to be reheated.

The warmpak is heated around 50 minutes to reach to the operating temperature. Temperature indicator will display one of three states:

1. **Too hot 2. Normal state/ok 3. Too cold**

Fig.4.4:Temperature desplay unit at the operating state of ok.

When the WarmPak is within the correct operating temperature range of (36.5-37.5 °C), the temperature indicator bar will be in the OK region . This indicates that the WarmPak is ready to use, and can be placed into the cradle bed.

Fig.4. 5: Temperature desplay unit at the non-operating state of too cold

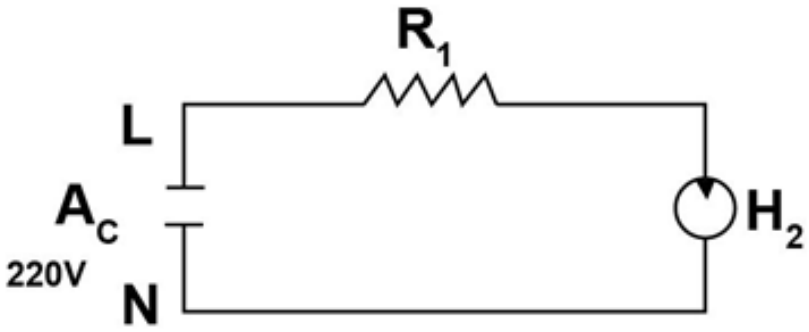
When the WarmPak has given up all the stored heat energy, and drops below the operating temperature threshold, the temperature indicator bar will be in the too cold region as shown. This indicates that the WarmPak has run out of energy and must be immediately removed from the cradle bed. It will need to be recharged in the Heater before it can be re-used.

4.1.4 Warmpak heating table

The warmpak heating table is the only component of the portable cradle bed that require access the AC Power source to heat to warmpak at the operating temperature of 36.5 and 37 °C it can even heat the warmpak and goes up to 40 °C

The warmpak heater table uses the sophisticated mechanism to warm the warmpak and is mainly made mainly by power cable, heating element (220V/50W) and it is covered by heat resistant plate. The warmpak heater table can take around 40 mints to heat the warmpak to the operating temperature in normal conditions if the warmpak is not age and the level of water has not reduced.

Fig. 4. 6: Warmpak heating table with all its components



R: Resistance
H: Heating element

Fig.4.7: Schematic diagram of the heating table's electrical connections.

4.1.5 Surface thermometer for proper testing proper functionality of the device

Surface thermometer is a special thermometer, which was used to record the cradle bed temperature. Surface thermometers are thermodynamically designed to measure surface temperatures. It has been calibrated for use in an ambient temperature of approximately 70°F(21°C). To get the temperature results inside the cradle bed, the researcher has placed the thermometer inside the cradle bed and allow approximately 3 minutes for it to reach stability, and then record the temperature after every 20 mints. In addition, the researcher has started recording the base line temperature (Temperature inside the cradle bed with no heated warmpak) and then processed with measuring the temperature inside the cradle bed with heated warmpak.

Fig.4.8: Special surface thermometer to measure the temperature for both the warm pack.

4.1.6 Temperature results and Discussion on designed device.

The temperature inside the designed device, is one the most important components that might help to measure the functionality of the tested device, with the help of the special thermometer (surface thermometer) the temperature inside the cradle bed was measured in biomedical laboratory, device test department.

It was shown that this designed medical device is able to keep the internal temperature in the range 36.6 to 37.4 ℃ in the period of 1 hour 30 minutes without reheating the warmpak, that means that if the infant is place in cradle infant warmer, the infant's body temperature can stay within the range of 36.6 - 37.4 degrees Celsius within 1 hour 30 minutes of being separated from the parent's body.

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The temperature within the designed device was recorded by the following procedures: The initial or baseline temperature within the device was taken before placing the heated warmpack and it was 25 degrees Celsius and then the researcher heated the warm pack up to 37.5 degree Celsius for about 40 minutes and then the heated warmpak was inserted in the cradle bed and then the research have started recording the temperature inside the cradle bed and it was taken in sequence of time range of 15 minutes within the period time of 1 hour 45 minutes .To assure that the researcher get accurate results ,the experiment was done in three trials and the final temperature was recorded as the average of these three replicates.

The results have shown that the baseline temperature at time 0 (Temperature in cradle bed without heated warmpak) was 25 °C (Room temperature) and then after heating the warmpack to the operating temperature ,the temperature inside the device has raised immediately after insulting heated warmpak , the results indicated 37.4 ℃ inside the cradle bed , just 15 minutes after it was insulted in cradle bed , then the device has indicated a temperature of 37.2 ℃ within 30 minutes of the experiment, the device has shown 37 ℃,36.9 ℃,36.6 ℃,36,6 ℃, 35.9 ℃ within 45,60,75,90,105 minutes respectively during the experimental period. The table below shows the obtained temperature results inside the cradle bed within the testing period of one hour forty-five minutes (1h 45). And the recorded values are the average temperature on three trials.

Table.2.1: The results on the temperature inside the cradle bed taken within 1h45 minutes

Time(minutes)	Temperature (degree Celsius)			
	Trial 1	Trial 2	Trial 3	Average
0	24.8	25.1	25.2	25.03
15	37.4	37.6	37.3	37.43
30	37.2	37.1	37.3	37.20
45	36.9	37.1	37	37.00
60	36.7	36.9	37	36.87
75	36.5	36.6	36.7	36.60
90	36.8	36.4	36.5	36.57
105	35.8	36.1	36	35.97

Temperature values recorded on this table are the average determinations of three experimental trials.

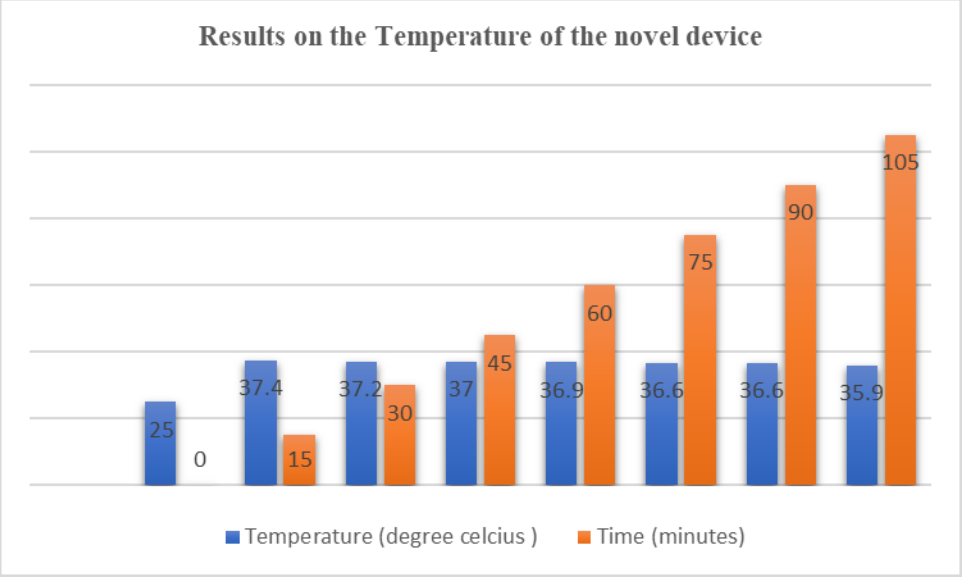

Fig.4.9: Graphical presentation of results of the average temperature measure within the cradle bed within a period of 1 hour 45 minutes

Discussion on obtained results , can be started by saying that the results from this present study are promising results even though the researcher did not test the designed device specifically on newborns because it have not yet approved by authorized institutions but together with supervisors and engineers from Crow Health Care we were able to effectively test the designed end product , and revealed that the designed device have shown to have capability to maintain the normal

temperature in a standardized operating range for about 1 hours 30 minutes .Based on the fact that the initial temperature the cradle bed was 25ºC (without heated warmpak inside).Then, after insulting the heated warmpak the temperature has raised to 37.4 ºC this might due to the fact the PCM layer made of Parrafin and Sodium acetate component components have of melting and start accumulating the heat and transferred the stored heat in water layer [38][39] ultimately raising the temperature inside the cradle bed . The temperature kept raising within 90 minutes of experiment.

On the other hand the researcher has experienced the minimum reduction of the temperature from 36,4 to 35.9 ºC within 105 minutes of experiment this might due to the loss of heat of the warmpak and it can be related with the fact that the warm pack is made of PCM layer made of Paraffin and sodium acetate that have the properties freezing and loose heat when the temperature is reduced as the time increases [38][39], and that indicated that warmpack and needed to be reheated so that it regain the heat to raise the temperature in the normal operating range. In addition to that the new thermal regulation device have shown to have extraadvantages in terms of cost, easy manipulation ,portability and safety because it is free from electricity and promote interaction between baby and the mum when compared to the current infant warmer and incubators.[32].

4.2 Summary

The designed and prototyped device has proven capability to keep the normal temperature in normal range for about 1 hours 30 minutes since the initial Temperature in the cradle bed was 25ºC .Then, after insulting the heated warmpack the temperature has raised to 37.4 ºC when take within 15 minutes after insulting the warmpack in the cradle bed, and the temperature kept raising till it reach to 36.6 ºC after 90 minutes of experiment, but also I have experienced the minimum reduction of the temperature to 35.9 ºC due to the loss of heat of the warmpak and needed to be reheated so that it regain the heat to raise the temperature in the normal operating range.

Thus, based on the finding of this present study, with high confidence the researcher can confirm that he has reached to specified research objectives with effectiveness, efficiency and satisfaction of the end product, based on the ability of the novel device to keep the temperature in the normal standardized range.

CHAPTER 5. CONCLUSION AND RECOMMENDATION

5.1 Conclusion

The results from this present study presented have shown that the designed device is able to maintain the temperature in normal range of 37.4 to 36.6 in the period of one hour and 30 minutes. This indicated that it can be taken as the best alternative device to replace the high-cost existing methods to warm the neonates. This simple, safe, low-cost, non-electric infant warmer could be an important option for governments and health systems in reducing the high annual neonatal deaths in which hypothermia is a contributing cause. It is efficient in maintaining the normal temperature of an infant for 1 hour and 30 minutes, therefore this medical device can be used to save lives of millions of infants across the globe mostly in underserved areas of Rwanda and other Africa countries. No other equipment will be identified to take special care of newborn babies than this portable cradle infant warmer.

Additionally, the design has the ability to keep the temperature normal for about 1h30. As a result, this project can bridge the gap between neonatal incubators and radiant warmers, acting as a more practical, secure, and cost-effective prototype than current warming technologies. The output of the thesis has the potential to reduce the occurrence of temperature-related neonatal problems and to increase the development of these neonates, both mentally and physically.

5.2 Recommendations

Based on the results find from this study we highly recommend both public and private institutions to hugely support this current project so that it can be implemented to save life of newbors who die from hypothermia.

I specifically recommend the MOH to work together with CEBE to assist the researcher to reach to her dream of implementing this project and ultimately minimize the death rate due to hypothermia in low birth weight and premature babies in Rwanda.

APPENDIX

Supplementary **Fig.1:** The warmpak connected to electrical component of the prototype during heating process

Supplementary **Fig.2: The picture showing** the final prototype with a false baby

REFERENCES

[1] H. Survey, *Rwanda*. 2019.

[2] V. Bach and J. P. Libert, "Hyperthermia and Heat Stress as Risk Factors for Sudden Infant Death Syndrome: A Narrative Review," *Front. Pediatr.*, vol. 10, no. April, pp. 1–15, 2022, doi: 10.3389/fped.2022.816136.

[3] C. Hutchinson, "A Clinical Comparison of Radiant Warmer and Incubator Care for Preterm Infants From Birth to 1800 Grams," no. July 2017, 2001, doi: 10.1542/peds.108.2.395.

[4] W. Alebachew Bayih, N. Assefa, M. Dheresa, B. Minuye, and S. Demis, "Neonatal hypothermia and associated factors within six hours of delivery in eastern part of Ethiopia: a cross-sectional study," *BMC Pediatr.*, vol. 19, no. 1, p. 252, 2019, doi: 10.1186/s12887019-1632-2.

[5] N. B. Mathur, S. Krishnamurthy, and T. K. Mishra, "Evaluation of WHO classification of hypothermia in sick extramural neonates as predictor of fatality," *J. Trop. Pediatr.*, vol. 51, no. 6, pp. 341–345, 2005, doi: 10.1093/tropej/fmi049.

[6] M. O. F. Health, "Ministry of Health Neonatal Care Clinical Guidelines," p. 180, 2018, [Online]. Available: https://www.unicef.org/eswatini/media/631/file/UNICEF-SdNeonatal-Guidelines-report-2018.pdf

[7] S. Shrestha, K. Adachi, M. A. Petrini, S. Shrestha, and B. Rana Khagi, "Development and evaluation of a newborn care education programme in primiparous mothers in Nepal," *Midwifery*, vol. 42, pp. 21–28, 2016, doi: 10.1016/j.midw.2016.09.006.

[8] K. Lunze, D. E. Bloom, D. T. Jamison, and D. H. Hamer, "The global burden of neonatal hypothermia : systematic review of a major challenge for newborn survival," 2013.

[9] United Nations, "SDG indicator metadata," pp. 1–28, 2021, [Online]. Available: https://unstats.un.org/sdgs/metadata/files/Metadata-11-03-01.pdf

[10] Onalo R, "Neonatal hypothermia in sub-Saharan Africa : A review," *Niger. J. Clin. Pract.*, vol. 16, no. 2, pp. 129–138, 2013.

[11] G. G. Ukke and K. Diriba, "Prevalence and factors associated with neonatal hypothermia on admission to neonatal intensive care units in Southwest Ethiopia – A cross-sectional study," *PLoS One*, vol. 14, no. 6, pp. 1–13, 2019, doi: 10.1371/journal.pone.0218020.

[12] R. Byaruhanga, A. Bergstrom, and P. Okong, "Neonatal hypothermia in Uganda:

Prevalence and risk factors," *J. Trop. Pediatr.*, vol. 51, no. 4, pp. 212–215, 2005, doi: 10.1093/tropej/fmh098.

[13] K. P. Manji and R. Kisenge, "Neonatal hypothermia on admission to a special care unit in Dar-es-Salaam, Tanzania: a cause for concern.," *Cent. Afr. J. Med.*, vol. 49, no. 3–4, pp. 23–27, 2003.

[14] W. M. Nyandiko, P. Kiptoon, and F. A. Lubuya, "Neonatal hypothermia and adherence to World Health Organisation thermal care guidelines among newborns at Moi Teaching and Referral Hospital, Kenya," *PLoS One*, vol. 16, no. 3 March, pp. 1–11, 2021, doi: 10.1371/journal.pone.0248838.

[15] F. Urubuto *et al.*, "Prevalence, risk factors and outcomes of neonatal hypothermia at admission at a tertiary neonatal unit, Kigali, Rwanda–a cross-sectional study," *J. Matern. Neonatal Med.*, vol. 34, no. 17, pp. 2793–2800, 2021, doi: 10.1080/14767058.2019.1671334.

[16] E. M. Mccall, F. Alderdice, H. L. Halliday, S. Vohra, and L. Johnston, "Interventions to prevent hypothermia at birth in preterm and/or low birth weight infants," *Cochrane Database Syst. Rev.*, vol. 2018, no. 2, 2018, doi: 10.1002/14651858.CD004210.pub5.

[17] M. Shrestha and N. Pokharel, "Hypothermia in newborn babies.," *Nurs. J. India*, vol. 96, no. 11, pp. 255–256, 2005.

[18] K. Lunze *et al.*, "Prevention and management of neonatal hypothermia in rural Zambia," *PLoS One*, vol. 9, no. 4, 2014, doi: 10.1371/journal.pone.0092006.

[19] P. S. Hackman, "Recognizing and understanding the cold-stressed term infant.," *Neonatal Netw.*, vol. 20, no. 8, pp. 35–41, 2001, doi: 10.1891/0730-0832.20.8.35.

[20] M. Qazi, N. Saqib, and R. Raina, "Knowledge regarding prevention of hypothermia in newborns among mothers in Northern India," *Int. J. Res. Med. Sci.*, vol. 7, no. 5, p. 1727, 2019, doi: 10.18203/2320-6012.ijrms20191666.

[21] B. W. Demissie, B. B. Abera, T. Y. Chichiabellu, and F. H. Astawesegn, "Neonatal hypothermia and associated factors among neonates admitted to neonatal intensive care unit of public hospitals in Addis Ababa, Ethiopia," *BMC Pediatr.*, vol. 18, no. 1, pp. 1–10, 2018, doi: 10.1186/s12887-018-1238-0.

[22] Y. H. Yu *et al.*, "Association between admission hypothermia and outcomes in very low birth weight infants in China: A multicentre prospective study," *BMC Pediatr.*, vol. 20, no. 1, pp. 1–9, 2020, doi: 10.1186/s12887-020-02221-7.

[23] B. Girma, B. E. Tolessa, T. T. Bekuma, and B. R. Feyisa, “Hypothermia on admission to a neonatal intensive care unit in Oromia, western Ethiopia: A case-control study,” *BMJ Paediatr. Open*, vol. 5, no. 1, 2021, doi: 10.1136/bmjpo-2021-001168.

[24] WHO, “Incubator , Infant Core medical equipment - Information,” vol. 2011, p. 12113, 2011.

[25] T. Restin, M. Gaspar, D. Bassler, V. Kurtcuoglu, F. Scholkmann, and F. B. Haslbeck, “Newborn incubators do not protect from high noise levels in the neonatal intensive care unit and are relevant noise sources by themselves,” *Children*, vol. 8, no. 8, 2021, doi: 10.3390/children8080704.

[26] Ozdemİrcİ Emre, Ö. Y. Meral, D. Fecir, and C. M. Rahmi, “Reliability assessments of infant incubator and the analyzer,” *Gazi Univ. J. Sci.*, vol. 27, no. 4, pp. 1169–1175, 2014.

[27] M. R. Wolfson and T. H. Shaffer, “Original Article Device for Neonates,” pp. 167–173, 2001.

[28] R. W. Miller, R. L. Brent, and A. K. Brown, “Infant radiant warmers,” *Pediatrics*, vol. 61, no. 1, pp. 113–114, 2008, doi: 10.1542/peds.61.1.113.

[29] R. Warmer and T. Management, “Target product profile,” *Pharmaceut. Med.*, no. March, pp. 247–250, 2014, doi: 10.1093/med/9780199609147.003.0077.

[30] Y. S. Leo, “Radiant Warmer Products,” *Resuscitation*.

[31] PATH, “Thermoregulation Devices,” no. November, 2014.

[32] C. Settings and P. Vaupel, *Water-filtered Infrared A (wIRA) Irradiation*.

[33] A. Bera, J. Ghosh, A. K. Singh, A. Hazra, T. Som, and D. Munian, “Effect of Kangaroo mother care on vital physiological parameters of the low birth weight newborn,” *Indian J. Community Med.*, vol. 39, no. 4, pp. 245–249, 2014, doi: 10.4103/0970-0218.143030.

[34] J. G. Ruiz-Peláez, N. Charpak, and L. G. Cuervo, “Kangaroo Mother Care, an example to follow from developing countries,” *Br. Med. J.*, vol. 329, no. 7475, pp. 1179–1181, 2004, doi: 10.1136/bmj.329.7475.1179.

[35] Olian, “Immediate ‘Kangaroo Mother Care’ and Survival of Infants with Low Birth Weight,” pp. 2028–2038, 2021, doi: 10.1056/NEJMoa2026486.

[36] Enouk, “Kangaroo Mother Care Training Manual,” *Fed. Minist. Heal. Niger.*, no. November, pp. 1–265, 2008.

[37] A. G. Mekonnen, S. S. Yehualashet, and A. D. Bayleyegn, “The effects of kangaroo mother care on the time to breastfeeding initiation among preterm and LBW infants: A meta-

analysis of published studies," *Int. Breastfeed. J.*, vol. 14, no. 1, pp. 12–17, 2019, doi: 10.1186/s13006-019-0206-0.

[38] S. Sinaringati, N. Putra, M. Amin, and F. Afriyanti, "The utilization of paraffin and beeswax as heat energy storage in infant incubator," *ARPN J. Eng. Appl. Sci.*, vol. 11, no. 2, pp. 800–804, 2016.

[39] R. Kumar, S. Vyas, R. Kumar, and A. Dixit, "Development of sodium acetate trihydrateethylene glycol composite phase change materials with enhanced thermophysical properties for thermal comfort and therapeutic applications," *Sci. Rep.*, vol. 7, no. 1, pp. 1–11, 2017, doi: 10.1038/s41598-017-05310-3.