

Design of Kangaroo Mother Care Device with Integrated Vitals Monitoring Systems as Alternative to Incubators

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ABSTRACT

Prematurity kills more than 8000 babies annually in Ghana since the organs of these babies are often under-developed which renders them vulnerable to various infections. In order to save the lives of these babies, they are often placed in incubators. In situations where incubators are not available, a kangaroo mother care (KMC) approach is employed. The traditional KMC lacks means of monitoring vitals such as the temperature, SPO₂ level, heart rate and blood pressure of these preterm babies. The practice of the KMC might also pose some inconvenience to the mother since part of the body is exposed. In this project, we integrated the traditional KMC with electronic vitals monitoring system and also addressed the problem of inconvenience of part of the body exposure of the parent practicing KMC. The engineering design process was followed and a functional mockup was constructed. The mockup was tested by comparing the results generated to the results of an existing calibrated devices and the error margins were calculated as 0.62, 0.52, 0.41 and 0.34 for blood pressure (BP), heart rate (HR), temperature and SPO₂, respectively. This device could be an alternative option to baby incubators

Key words: Preterm, incubators, Kangaroo, vitals, prototype.

INTRODUCTION

A premature birth is a birth that takes place more than three weeks before the baby's estimated due date. In other words, a premature birth is one that occurs before the start of the 37th week of pregnancy (Lawn et al., 2013). Historically, the definition of prematurity was 2500 grams (about 5½ pounds) or less at birth. The current World Health Organization (WHO) definition of prematurity is a baby born before 37 weeks of gestation, counting from the first day of the Last Menstrual Period (LMP) (Charpak, Figueroa, & Ruiz, 1998). Such babies are also known as preemies or preterm. Depending on how early a baby is born, he or she can be classified as late preterm (born between 34 and 36 completed weeks of pregnancy), moderate preterm, (born between 32 and 34 weeks of pregnancy), very preterm (born at less than 32 weeks of pregnancy) and extreme preterm (born at or before 25 weeks of pregnancy) (Simkiss, 2004).

The 2016 United Nations Children's Fund (UNICEF-Ghana) report says prematurity kills more than 8000 babies in Ghana annually (Veronez et al., 2017). Preterm babies are highly susceptible to difficulty in breathing and infections which are significant threats to their lives. This is due to the undeveloped organs and systems, causing significant mortality rates. Common complications associated with these babies include hypothermia, apnea, hypotension, and slow heart rate or bradycardia, among others (Randis, 2008). Incubators reduce mortality by providing optimum temperature as well as monitoring the vitals of the preterm baby. In the absence of an incubator, a traditional approach known as the kangaroo mother care (KMC) serves as an alternative means of providing optimal temperature for the baby.

KMC emerged in 1984 and was proposed by neonatologists Edgar Rey and Hector Martinez of

the Instituto Materno infantil in Bogota, Colombia (Charpak et al., 1998). It was initiated as an alternative approach to traditional Neonatal Intensive Care Unit (NICU) care for low-birthweight infants, in response to overcrowded nurseries, scarce and costly resources such as incubators, and high rates of neonatal infection and mortality (Robert, 2003). It is the practice of skin-to-skin contact between an infant and a mother. The overall approach was termed 'kangaroo mother care' (KMC) (Francis & G.B;Priscilla. W;Robert.C.L, 2016). During the practice of KMC, the baby is clad in a diaper and cap, and held in an upright prone position against the bare chest of the parent (most often the mother) and covered with clothing and/or a blanket. The baby is positioned such that (Robert, 2003);

1. The head is turned to one side and in a slightly upturned position. This position helps in breathing and allows eye-to-eye contact between the mother and her baby.
2. The legs and arms are folded.
3. The abdomen is at level with that of the mother's upper abdomen.
4. The bottom of the baby is supported with a sling/binder.

KMC can be categorized as being continuous (20-24 hours per day) and intermittent (1-3 hours per session in the day).

Frequent and exclusive breastfeeding is enhanced during KMC (O'Brien-Abel, 2016). KMC has proven to be a useful method of promoting the health and well-being of preterm babies due to its effectiveness in thermal control, breastfeeding and bonding between the mother and the newborn. However, it lacks a system for monitoring the vital signs of a preterm baby, unlike baby incubators which provide both thermal and vital sign monitoring system. These vitals include heart rate (HR), respiratory rate (RR), SpO₂ level, temperature and blood pressure (BP) (Shaib et al., 2017). In this design, we integrated the traditional KMC with electronic vitals monitoring system and helped reduce the exposure of the mother

practicing KMC. This design has the potential of serving as an alternative approach for incubators and can be used in low resource healthcare facilities lacking baby incubators and homes.

Therefore, there is a need to design a device that would address the shortcomings of the traditional KMC, particularly with the ability to monitor vitals such as BP, temperature, HR and SPO₂ levels of preterm babies. This KMC approach will also allow mothers to go about their daily activities conveniently.

METHODOLOGY

The approach used was the Engineering Design Process (shown in Figure 1). According to the Accreditation Board for Engineering and Technology (ABET), engineering design process is defined as the process of devising a system, component, or process to meet the desired needs. It is a decision-making process, often iterative, in which science and mathematics and engineering science are applied to convert resources optimally to meet a stated objective (Haik, 2014).

The project began with problem identification. Before the problem was clearly stated, a comprehensive understanding of literature relating to preterm mortality and how the KMC approach is helpful in the absence of an incubator was studied. Literature review was carried out throughout the project and a need statement was drawn from the problem identified at the hospitals visited. Benchmarking and market analysis were carried out to survey existing products that addressed the project problem in order to avoid replication of existing designs in the market. For customer requirements, needs were surveyed and prioritized into product requirement which essentially identify the objectives of this project. Detailed breakdown of what the project is to achieve was explicitly defined under this section. The customer's requirements, needs or 'wish lists' were converted into engineering terminologies at the function section of this project and ranked in order of importance. Based on the requirements, a detailed functional structure was developed and engineering characteristics were assigned

to the various requirements as specifications. Concepts were generated with reference to the functional structure using a morphological chart and then evaluated with decision matrices. Among the concepts, the appropriate one was selected and further developed virtually into three-dimensional models using a Computer-Aided Design (CAD) software. Components were also selected using decision matrices. The best selected concept was further developed using a virtual simulation model which predicted how the device will perform. A mock-up was fabricated and tested. The functional mock-up was then evaluated against stated objectives.

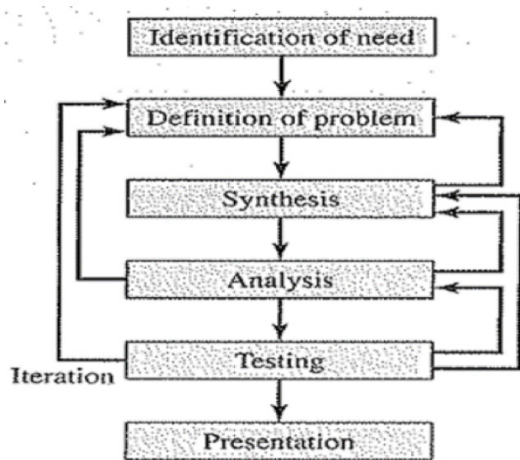


Figure 1:Engineering Design Process (Haik, 2014)

BENCHMARKING

Benchmarking was done to survey existing products that address the project problem in order to avoid replication of existing designs in the market. This was done with literature. It was discovered that; all the existing devices lacked vital monitoring controls. Some of these devices include:

1. Care Plus preterm wrap is a preterm wrap used in practicing the KMC. This device keeps the baby secured in the correct position during the KMC practice and permits skin-to-skin contact. Even

though it allows effective skin-to-skin contact, it lacked vital monitoring controls. (See Appendix 1) shows an image of a Care Plus preterm wrap.

2. Kangaroo Zak is also a preterm wrap used for practicing the KMC. This product comes with multiple wraps which tightly secures the baby in the right position. It also fosters skin-to-skin contact during its use. Main problem of this product is the absence of vital monitoring control as well as its complexity due to its multiple wrap belts. (See Appendix 1) contains an image of a Kangaroo Zak.
3. Piece of cloth is a local preterm wrap also used for practicing the KMC. It involves a piece cloth wrapped round the mother with the baby lying on her chest. This traditional wrap, like the others existing products, enhance skin-to-skin contact and is very simple to use but also lacks vital monitoring controls and can easily untie due to poor or weak fastening. Appendix 1 contains an image of a piece of cloth wrap.

FUNCTIONAL ANALYSIS AND SPECIFICATIONS

THE BLACK BOX MODEL

This model represents the overall operation of the device. It expresses the relationship between inputs and outputs regardless of the details within the ‘black box’. The model comprises of the input (preterm baby) with the corresponding output (baby’s vitals displayed).

Figure 2 below show the black box model of the system.



Figure 2: Black Box Model of the system

FUNCTIONAL STRUCTURE

The functional structure shows the various stages of operation of the device within the black box. It represents how the inputs are processed and utilized to obtain the

desired output as shown in Figure 3 below. Detailed functions of the device were broken down into their respective sub-functions.

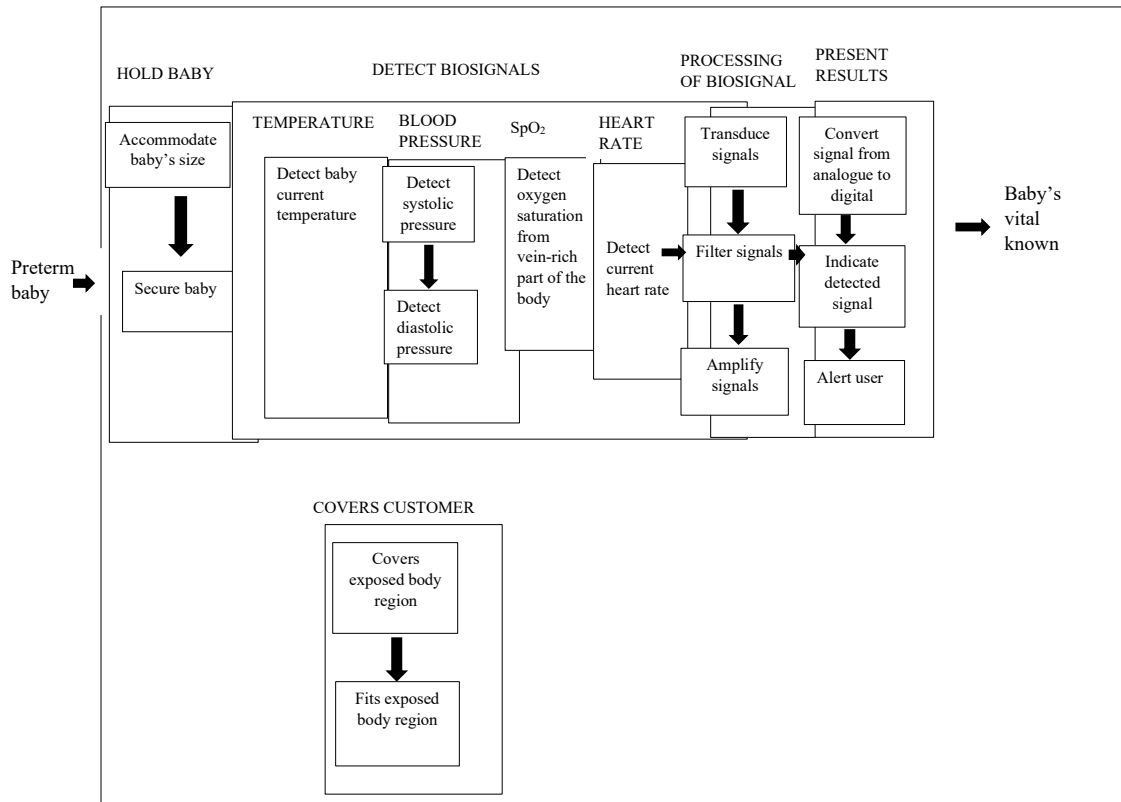


Figure 1: functional structure of device

SPECIFICATIONS AND JUSTIFICATIONS

A specification checklist was generated from customer requirements so as to relate the requirements to their corresponding engineering parameters. Values for these engineering parameters were drawn from literature, brainstorming as well as information obtained directly from the customers. The specification for the device was grouped into two categories: general and functional specifications. As shown in Table 1 and 2 in Appendix 1.

CONCEPT GENERATION

Employing creative brainstorming methods, different solutions were generated in order to address the problem at hand. These solutions were narrowed down into three

separate concepts, with each offering different and unique approaches to addressing the problem.

These concepts were drawn by considering the main objectives of the project which was to monitor the vitals of the preterm baby and accommodate the baby.

Concept 1

This concept consists of two separate units: the vitals monitoring unit and the carrier unit. The carrier unit comprises of an adjustable shoulder and waist straps to effectively secure the baby in the fetal position on the abdominal region of the mother (customer). It also has a large padded inner area to accommodate the size of the preterm baby as well as a back- rest, to support the

back of the baby when the device is being used. The vitals monitoring unit houses the electronic components needed to monitor the vital of the preterm baby. The monitored vitals are displayed on the LCD screen for the user. The customer is always alerted when vitals deviate

from the set threshold limits. The vital monitoring unit is attached to the adjustable waist strap. This concept partially covers the customer abdominal region. Concept 1 is shown in Figure 4 below.

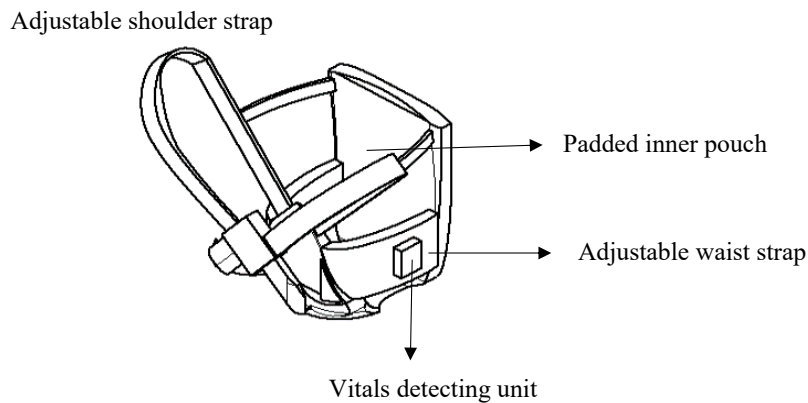


Figure 4: Adjustable strap carrier with vitals detecting unit

Concept 2

This option (Figure 5) entails three separate units, each performing a specific function; vital monitoring unit, a covering unit and a baby holding unit. The baby holding unit comprises of a holding pouch and safety straps for accommodating and securing the baby in a fetal position on the abdominal region of the mother. It has inner padding for baby comfort during its application and a drawstring to support the neck of the baby as it

extends outside of the device. The abdominal covering unit eliminates exposure of the customer's body when practicing KMC.

The vital monitoring unit houses the electronic components needed for the system and also alerts the user when the vitals deviate from the set threshold limits. It is attached to the side of the covering unit, doing (down the waist).

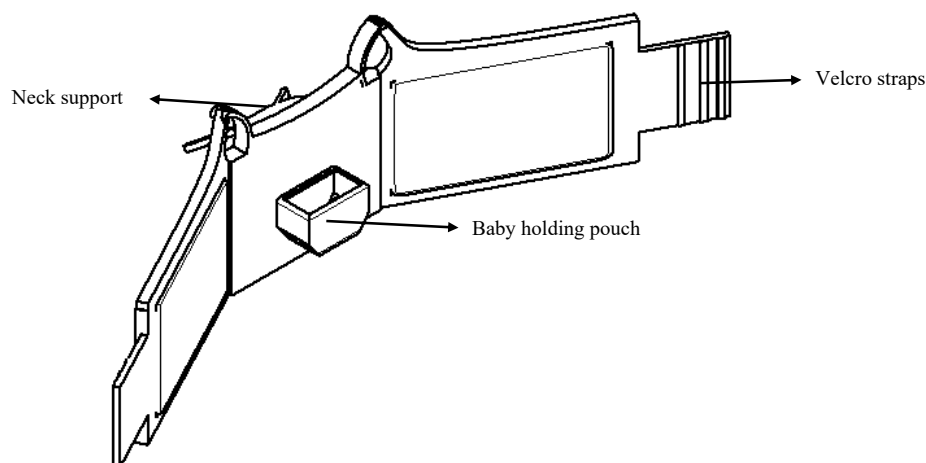


Figure 5: Velcro strap carrier with vitals detecting unit

Concept 3

This option also comprises of three separate units: a vital monitoring unit, carrier unit and an abdominal covering unit. The carrier unit has a padded inner area for accommodating the baby's size and provides comfort. It also has a vital monitoring unit which houses the electronic components. The vitals are displayed, and the unit also alerts the user when vitals deviate from the set

threshold limits. The unit is attached to the covering unit. This concept also has an abdominal covering unit that limits body exposure of the customer when practicing the KMC. This concept, however, lacks a structurally defined strap to properly secure the baby even though the baby fits perfectly within the carrier unit. Concept 3 is shown in Figure 6 below.

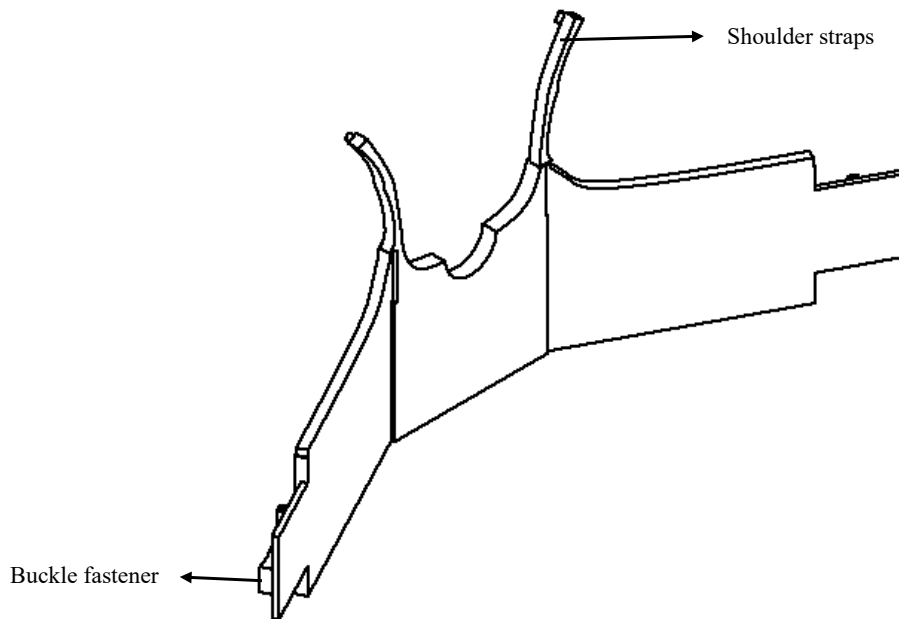


Figure 6: Buckle fastener carrier with vitals detecting unit

SELECTION OF THE BEST CONCEPTS USING DECISION MATRIX

Using the decision matrix tool, all the various concepts were analyzed in order to choose the appropriate concept that best fits the requirements stated. Concept two emerged as the chosen concept.

PRINCIPLE OF OPERATION OF SELECTED CONCEPT

The chosen concept comprises of three separate units: vital monitoring unit, a covering unit and a baby holding unit.

Baby holding unit

The preterm baby is placed in a baby holding pouch within the device and secured firmly to the device with a strap. A blood pressure cuff is then wrap around the upper arm of the baby with the artery mark positioned directly over the brachial artery of the baby. A temperature sensor is embedded in one Velcro strap, and a particle sensor in the other. The temperature velcro strap is wrapped around the other arm of the baby and the particle sensor velcro strap is wrapped around the foot of the baby. The temperature velcro strap detects the temperature whiles the particle velcro strap detects the SpO₂ and heart rate of the preterm baby.

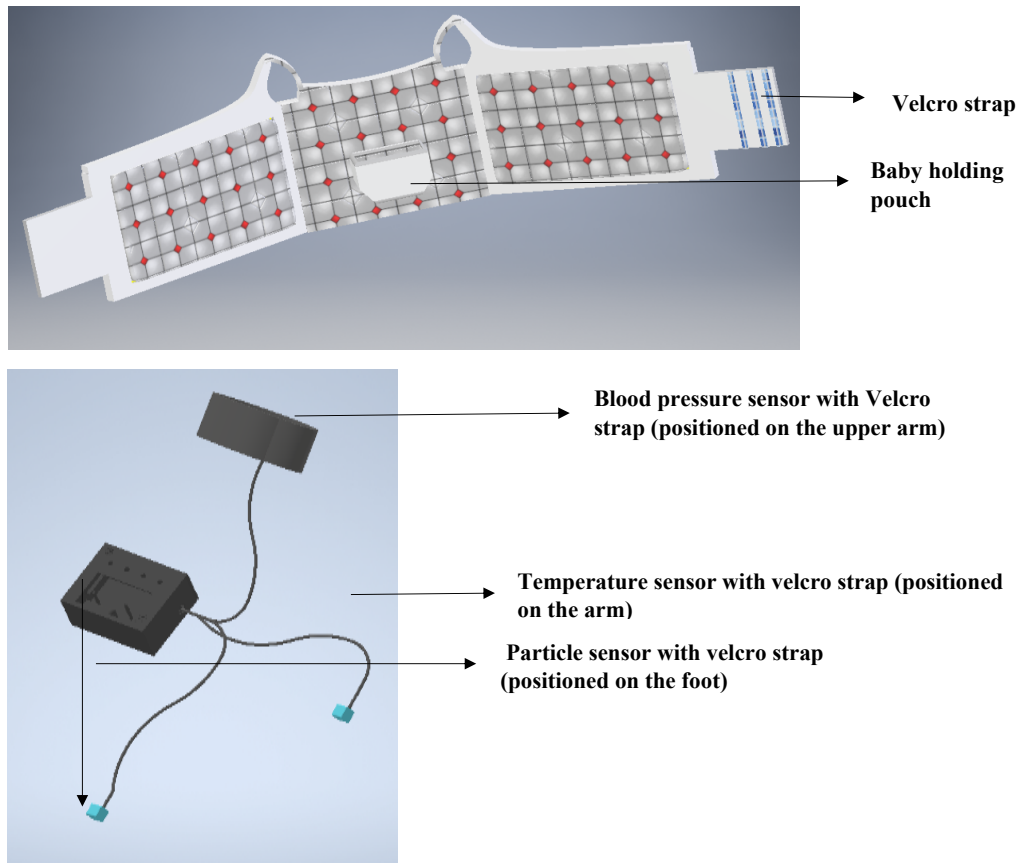


Figure 7a: Different views of selected concept (baby holding and Vital monitoring unit covering unit)

Vital monitoring unit

Powered vital monitoring unit is turned on to initialize all the sensors.

1. Blood pressure monitoring unit

Upon pressing the blood pressure button, measurement of BP starts; the solenoid valve opens and causes the pressure motor to pump air into the cuff which inflates it and causes the major artery in the baby's arm to be blocked. The pressure sensor detects the pressure at which the artery is completely blocked and stores it as the initial pressure signal. The solenoid valve is then open and allow air to escape from the cuff, causing it to deflate. The pressure at which the artery becomes completely

freed is detected by the pressure sensor and stored as the final pressure signal. These pressure signals are amplified, filtered, and transduced by their respective discrete components connected to the microcontroller. The output data is transferred to the microcontroller which read the data and converts it into Binary-coded decimal digits (BCD). The programmed microcontroller then displays these signals as the systolic and diastolic blood pressures of the baby in mmHg on the LCD.

2. Temperature, Heart rate and SpO₂ monitoring unit

The temperature, heart rate and SpO₂ are toggled by a single button. When the button is pressed, the

temperature sensor detects the current body temperature of the preterm baby. The temperature signals are then converted into BCD digits by the programmed microcontroller. The final current body temperature of the baby is displayed in degrees Celsius on the LCD.

Upon pressing the same button, the infrared light from the particle sensor position on the baby's foot passes through the body tissues, enters the blood vessels and measures the amount of light absorbed by the oxygenated blood cells within the blood vessels. The sensor picks up the exact number of times the infrared light was blocked before absorption due to the pulsating flow of the blood. After measurement, the emitted light is received by the sensor and transduced from biosignals into electrical signal before it is transferred to the programmed

microcontroller. The programmed microcontroller converts the data into BCD. The amount of oxygen absorbed is displayed as SpO₂ level in percentage whilst the number of times the light was blocked is also displayed as the heart rate in bpm on the LCD.

3D MODEL OF THE SELECTED CONCEPT

Based on the sketch of the selected concept, AutoCAD Inventor was used to generate a 3D model of the chosen concept. **Figure 7**, **Figure 8** and **Figure 9** represent the different views of the 3D models; the front and inner view of the baby holding unit and the covering unit as well as vital monitoring unit. Detailed drawing of the selected concept with dimensions was done using the same software.

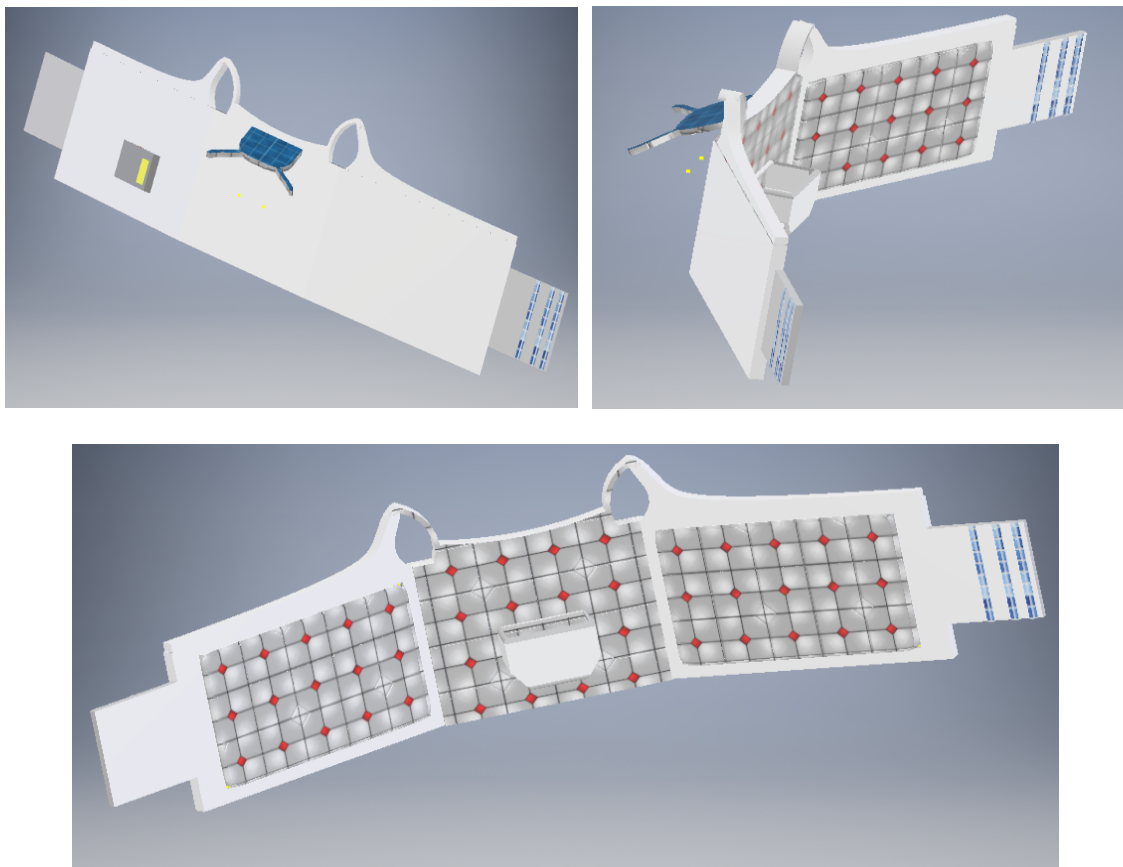


Figure 7b: Different views of selected concept (baby holding and covering unit)

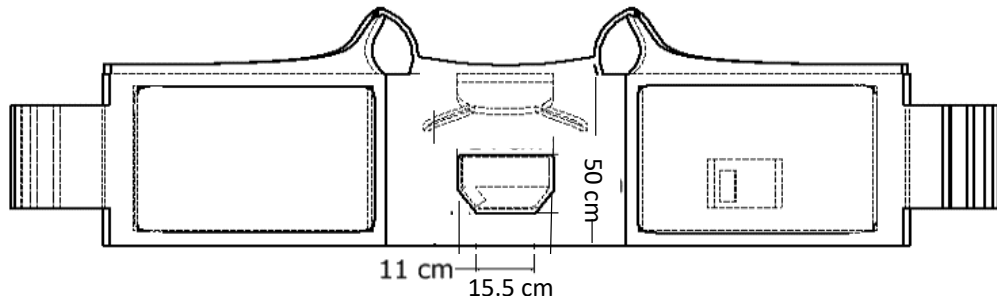


Figure 8: Detailed drawing of selected concept (baby holding and covering unit)

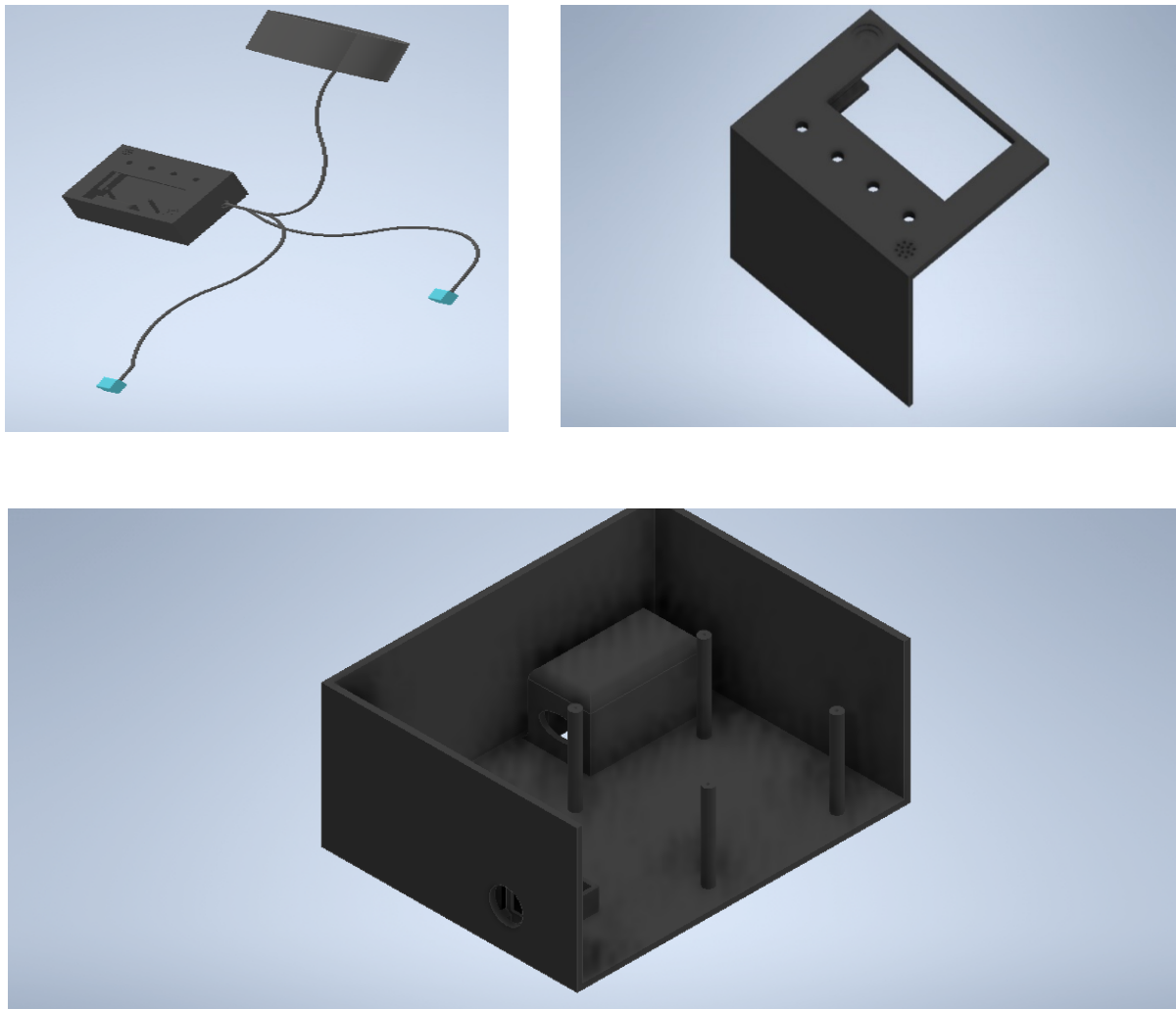


Figure 9: Different views of the vitals monitoring unit

ELECTRONIC SIMULATION

FLOW CHART OF ELECTRONIC UNITS

The flow charts of the various vital monitoring units of the device are shown in Figure 10, Figure 11 and Figure 12 below. The flow charts illustrate the various iterative

processes involved in the electronic circuit of the vital monitoring units in order to achieve the objective of displaying the monitored vitals as well as alerting the customer when some of these vitals deviate from the set threshold limits.

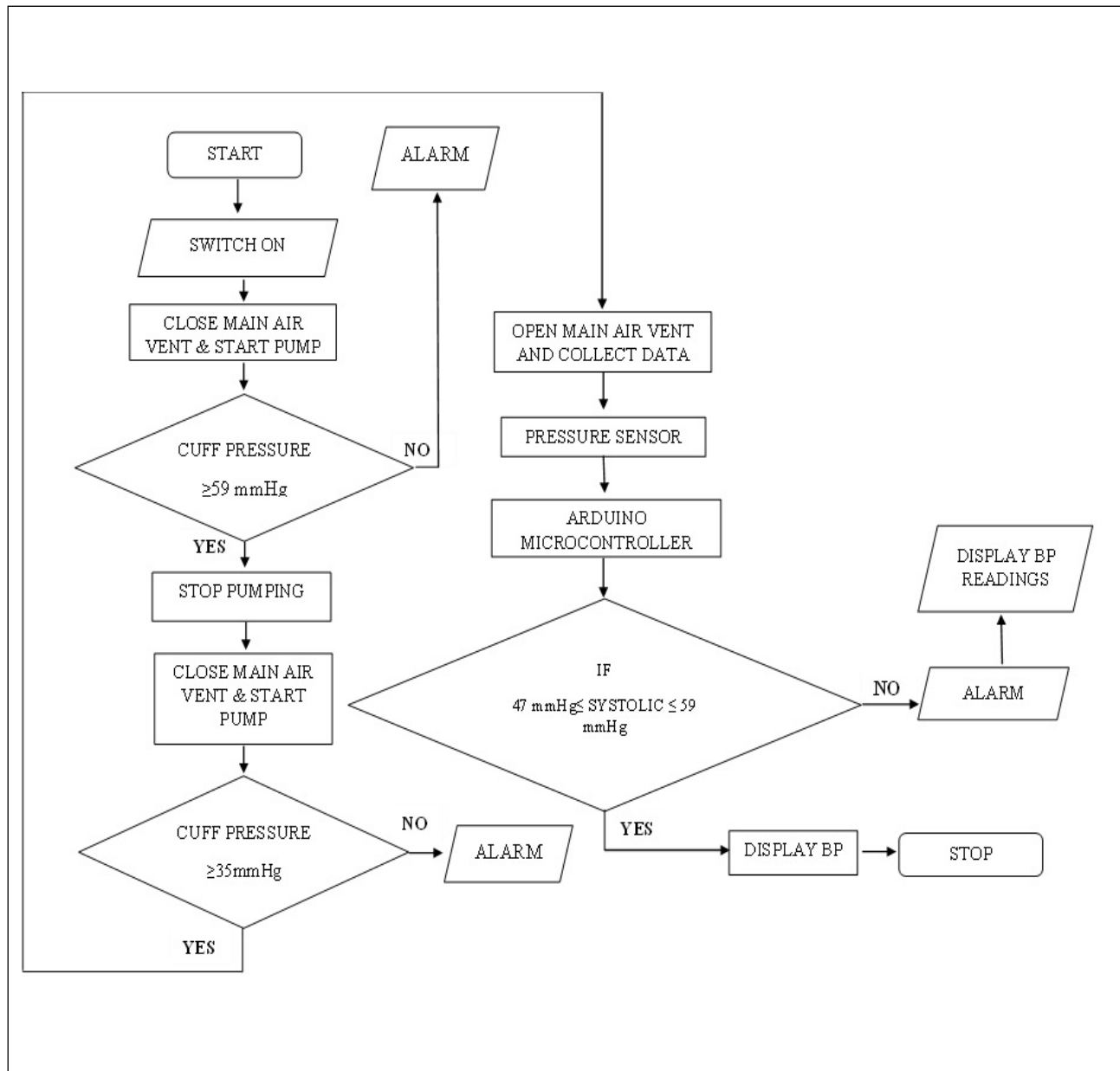


Figure 10: Flow chart of the blood pressure monitoring unit

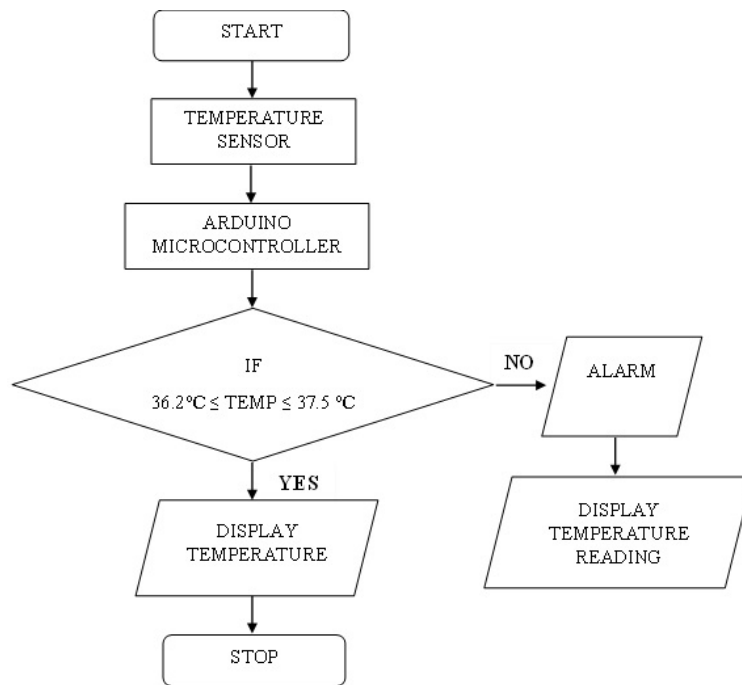


Figure 11: Flow chart of the temperature monitoring unit

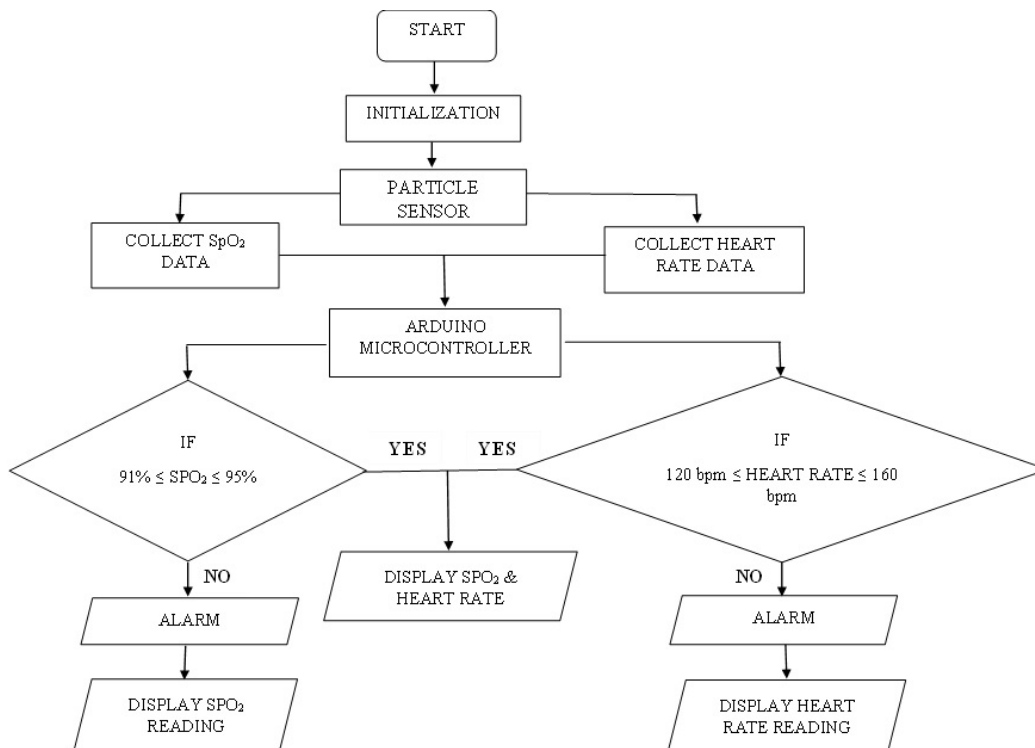


Figure 12: Flow chart of the heart rate and SpO₂ monitoring unit

ELECTRONIC CIRCUIT SCHEMATICS

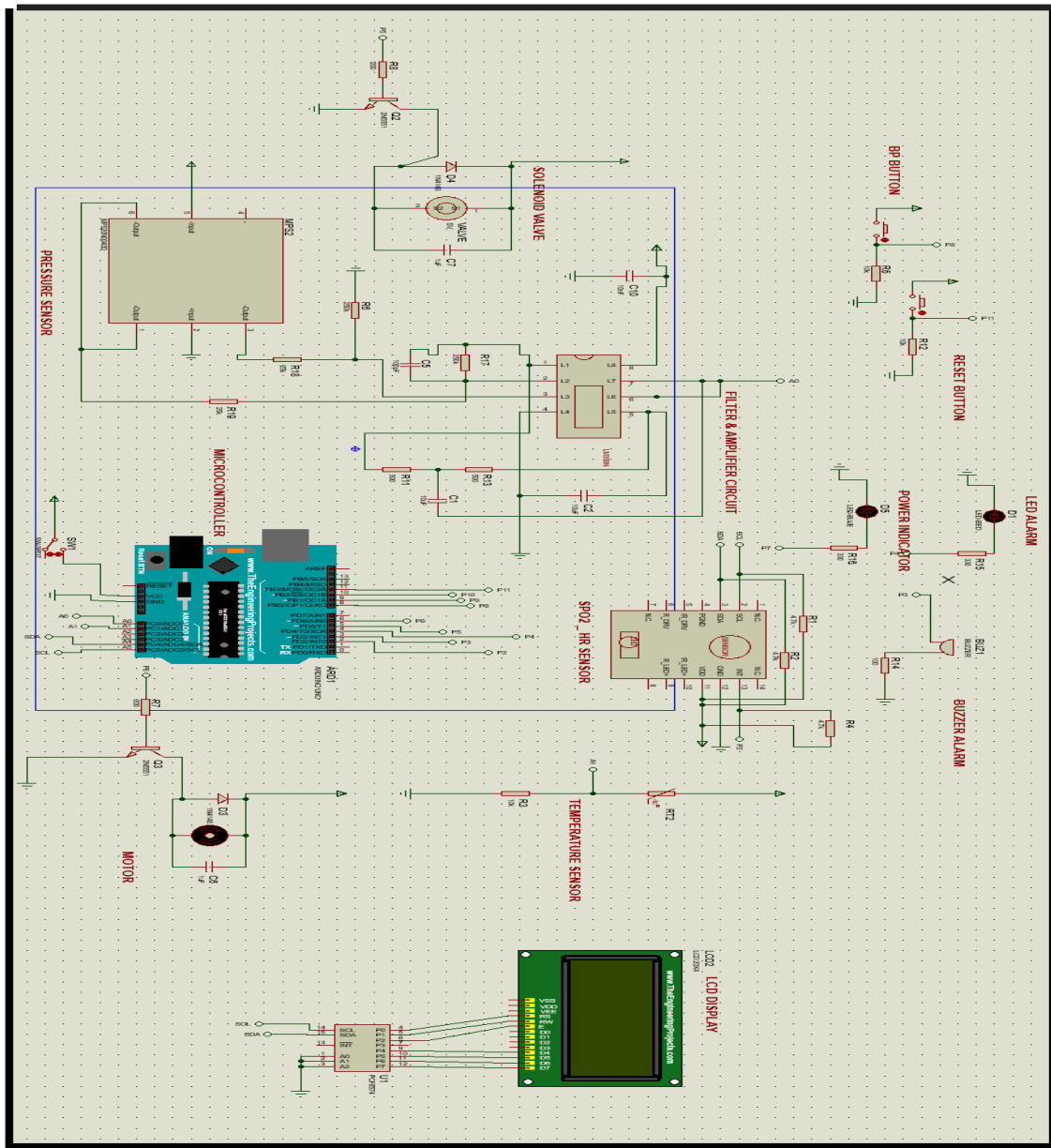


Figure. 13 the electronic schematics circuit

Figure 13 represents the electronic schematics circuit of the vital monitoring units of the mock-up. The device continuously monitors the SpO₂ levels and Temperature of the preterm baby while allowing for momentary monitoring of the infant’s blood pressure. Upon start up, the device initializes the MAX30102 particle sensor (the

SpO₂ and Heart Rate sensor) whilst setting all outputs and inputs device pins. After initialization, the first SpO₂ and Heart rate readings obtained from the MAX30102 sensor, fastened to the foot of the baby, is displayed approximately every 15 seconds after initialization on the (20x4) LCD screen with an indication of whether

or not these readings are in the normal range of the preterm baby ($SpO_2 > 90\%$, $60 \text{ bpm} < \text{Heart Rate} < 100 \text{ bpm}$). The temperature reading, taken from the NTC thermistor attached to the peripheral of the preterm baby, is also displayed after a successful initialization every 15 seconds with an indication of whether that reading is in the normal range of preterm babies ($36.5 \text{ }^\circ\text{C} < \text{Temp} < 37.5 \text{ }^\circ\text{C}$)

For BP, the button is pushed and it activates the BP monitoring system. The values of Systolic and Diastolic Pressures, after a period of about 25 seconds after activation are displayed on the screen and the system checks whether the values lie within the normal range.

After this, the system resets itself to resume the default continuous monitoring mode. If any of these vitals are above or below the normal for a healthy preterm infant, an LED-buzzer alarm sounds to alert the customer of the situation. A reset button was also introduced for restarting the device where the need be and a power button for turning the device on or off.

MOCK UP DESIGN

Figure 14 below shows the breadboard electronic circuit design and Figure 15 represents the final mock-up design.

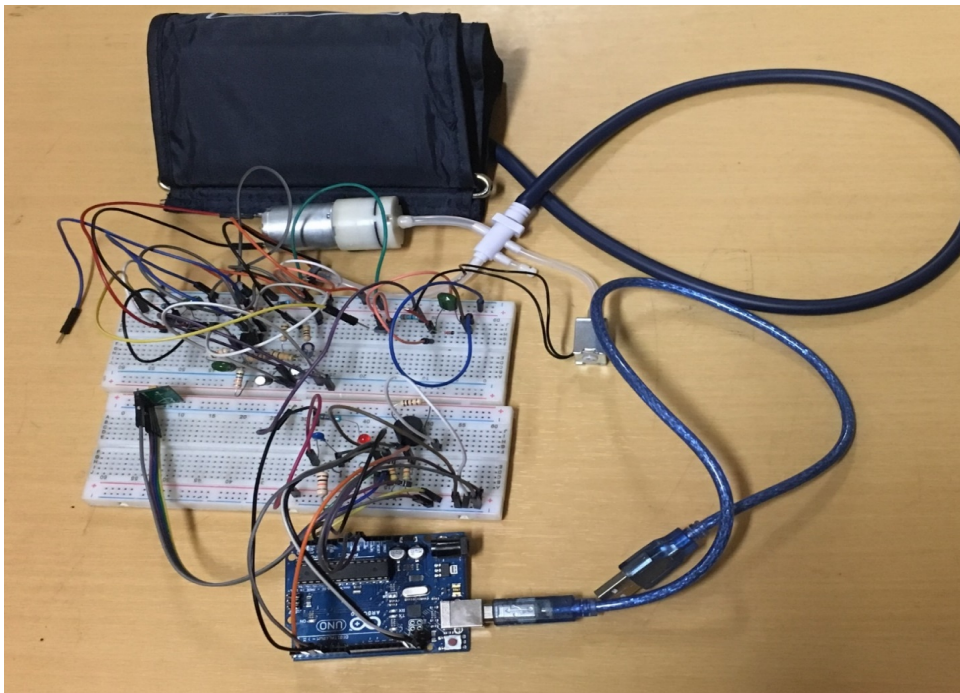


Figure 14: Breadboard electronic circuit design of mock-up



Figure 15: Final mock-up (Baby holding and vitals monitoring units)

MATERIALS AND COMPONENTS

Table 1 shows the materials and components selected for the fabrication of the device.

COMPONENTS	FUNCTION
Arduino Uno	Microcontroller
NTC temperature sensor	Detects the temperature signals of the baby.
MAX30102 particle sensor	Detects the heart rate and SpO2 signals level of the baby.
20 × 4 12C character LCD	Displays the monitored vitals of the preterm baby.
Buzzer and LED	Generates audible sound and flashes of lights to alert the customer.
MS5803-14BA pressure sensor	Detects pressure signals of the baby.
Perfboard	Platform for soldering electronic components.
AAA batteries	Energy for powering the electronic components of the device.

Table 1: Components used in device fabrication

In addition to the components listed in the table, other electronic components such as resistors, capacitors, breadboard, solenoid valve, pressure motor, jumper wires and push buttons were used.

Material selection for the fabrication of the baby holding and the covering unit

The baby holding unit of the device consists of an inner, a middle and an outer part. The inner part of the device houses the preterm baby and due to the delicate nature of a preterm skin, the material to be used for the construction must be soft, comfortable and have wicking properties so as provide a dry feel against the body. The middle part of the device is what provides thermal insulation for the baby. Thus, the material selected should have heat retention properties and be soft. On the other hand, the outer part of the baby holding unit including the abdominal covering unit will support the entire weight of the baby during the practice of the KMC approach.




Therefore, the material to be used must be strong as well as tough. In general, the material to be used for the entire units must be workable, easily available, durable, easy to maintain (clean), light in weight, durable and breathable.

After a thorough research and studies, polymers were considered for the fabrication of the device since they possess majority of the material properties needed. Narrowing it down, cotton (natural polymer) and synthetic polymers like nylon, polyester, polyacryl and polyurethane were considered. Empolying a decision matrix, cotton was used for outer part of the device whiles polyacryl was used for the outer covering of the device. Polyester fibre was chosen as the insulating material.

COMPUTATIONAL TOOLS

Some computational tools used throughout this project include;

Table 2: Computational tools used for the project

Computational tools	Purpose
Proteus Design Suite 	Simulation of electronic circuit
Arduino IDE version 1.8.5 	Programming the microcontroller
AutoCAD Inventor 	Drawing 3D models

FINDINGS AND ANALYSIS

Due to the unavailability of ethical clearance as well as ethical issues associated with performing clinical trials on preterm babies, the team resulted in using its members and other volunteers making a total of 10 as test subjects for validating the functionality of the mock-up. In order to analyze the error margins between the already existing calibrated devices and the developed mock-up, the standard deviations of the values were calculated.

The table below shows the standard deviations calculated for the various vital monitoring units.

stp

Table 3: Standard deviations of the various vital monitoring units.

Monitoring unit	Standard deviation
Blood pressure	0.62
Heart rate	0.41
SpO ₂ level	0.34
Temperature	0.52

The standard deviation or error margin of the mock-up when compared to existing calibrated devices were between the values of 0.62-0.34.

CONCLUSION

In summary, the project was a success which led to the fabrication of a device capable of monitoring the vitals of preterm babies during the practice of KMC. The stated objectives of the project were achieved by employing and systematically following the engineering design process. During testing of the functional mock-up, promising results were obtained despite the fact that the tests were performed on adults rather than preterm babies due to ethical issues. In general, the device constructed was able to monitor the temperature, heart rate, SpO₂ level and blood pressure with minimal error margin (less than 1). It alerted the customer in events that the values did not lie within the threshold values or limits, and the system is also easy to operate, safe and cost effective.

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Appendix 1



Some mothers practicing the kangaroo mother care approach

Source: <https://www.graphic.com.gh/news/general-news/ghana-news-increase-awareness-on-kangaroo-mother-care-rise-ghana.html>



Care Plus preterm

Source: http://www.nurturedbydesign.com/en/kangaroozak/medical-staff_thatis-uses.php



Kangaroo Zak

Source: http://www.nurturedbydesign.com/en/kangaroozak/medical-staff_thatis-uses.php



Piece of cloth

Source: <https://www.mcsprogram.org/march-2-webinar-kangaroo-mother-care-preterm-babies/>

Appendix 2

Table 4: Specification checklist

REQUIREMENTS	DEMAND (D)/ WISH (W)	ENGINEERING PARAMETER
Monitor vitals	Demand	Detect body temperature, heart rate, blood pressure and SpO ₂ level
Alert user	Demand	Response time
Easy to use	Demand	Steps of operation Number of persons to operate
Accommodate baby's size	Demand	Volume of device
Cover abdominal region of the user	Demand	Dimension of user
Portable	Demand	Net mass Dimension of device
Quick feedback time	Demand	Initialization time Feedback generation time
Easy to maintain	Wish	Number of detachable parts Servicing time
Accurate	Demand	Error margin
Cost effective	Wish	Production cost Maintenance cost

Table 4

REQUIREMENT	RANK	DEMAND/ WISH	METRIC	UNIT	TARGET VALUE
Feedback time	10	Demand	Initialization time	s	60
			Feedback generation time	s	60
Easy to operate	10	Demand	Steps of operation	-	≤ 3
			Number of persons to operate	-	1
Portability	10	Demand	Net mass	kg	2.6 *
			Dimension of device (L×B×H)	m	0.5×0.25×0.25 **
Affordability	5	Wish	Production cost	GHC	≤ 600
			Maintenance cost	GHC	≤ 200
Accuracy	10	Demand	Error margin	-	0.1 ***
Easy to maintain	10	Demand	Number of detachable parts	-	≤ 2
			Servicing time	months	6
Power consumption	5	Wish	Energy source	-	DC
			Voltage	V	9

Table 5: General specification table

Power consumption	5	Wish	1. Energy source	1. -	1. DC
			2. Voltage	2. V	2. 9

*(Seaton et al., 2018) **(Shastry & Bhat, 2015) *** (Trigoni, 2014)