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Faculty of Engineering and IT

Calibration Device For Neonatal Intensive Care Unit(NICU) Devices

جهاز معايرة لأجهزة وحدة العناية المركزة لحديثي الولادة

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Abstract

More than 4 million babies die worldwide each year within a month of birth, with 3.9 million of these deaths occurring in developing countries. Approximately 25% of these deaths are attributed to complications from premature birth, most commonly poor thermoregulation, water loss, and neonatal jaundice. Infant incubators provide stable temperatures, relative humidity, and airflow values. The radiant warmer adjusts the infant's temperature after birth in an open system, and phototherapy is a device used to treat hyperbilirubinemia by exposing the infant to blue light radiation within a wavelength range of 425 to 475 nanometers. The effectiveness of hyperbilirubinemia treatment depends on the amount of light energy emitted, expressed in microwatts/cm². Periodic calibration should be performed on infant incubators, radiant warmers, and phototherapy devices to monitor their performance, reduce technical errors, and protect infants from complications that may lead to death.

This study aims to develop a calibration device that measures temperature, humidity, airflow, and noise in infant incubators and radiant warmers, as well as the light intensity of phototherapy devices. The device integrates the calibration of all three systems into a single, high-accuracy, low-cost unit. This research also contributes to the ability to display the values of temperature, humidity, airflow, noise, and light intensity on a mobile phone through an HTML-based user interface.

The main design consists of the DS18B20 temperature sensor, the DHT22 humidity sensor, the F662 airflow sensor, the KY-038 noise sensor, the MLX90614 skin temperature sensor, the AS7262 phototherapy intensity sensor, the ESP32 controller unit, and an HTML user interface to display the sensor values.

The resulting design was compared with the standard or calibrated Intensive Care Unit Analyzer (Fluke Biomedical INCU II). The study concluded that the lowest error rates were observed for the air temperature sensors ID T1(1.09%°C), T2(1.09%°C), T3(1.44%°C), T4(0.87%°C), and T5(-0.47%°C), the skin temperature sensor (1.5%°C), the humidity sensor (2.63%RH), the noise sensor (%-0.79dB), the airflow sensor (-0.76%m/s), and the phototherapy intensity sensor (%). After evaluation, the device can be used as an intensive care unit analyzer for calibrating infant incubators, radiant warmers, and phototherapy devices.

Authorization

We authorize university of EIU faculty of Engineering to supply copies of our graduation project document to libraries, organizations or individuals on request. The faculty, also authorized to use it in local or international competitions.

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Dedication

As we stand together on this momentous occasion, we dedicate this project to the countless individuals who illuminated our path.

This journey wasn't a solo expedition, but a collaborative effort fueled by late nights, shared determination, and an insatiable thirst for knowledge. We are deeply grateful to our families and loved ones who provided unwavering support and unwavering belief in our collective dream. Their encouragement was the wind beneath our collective wings, propelling us forward even when the road seemed daunting.

We would like to express our deepest gratitude to Professor Dr. Mohammed Al-Olofi and Dr. Mohammed Faisal for their valuable guidance, patience, and constructive criticism, which provided us with invaluable direction. We also extend our sincere appreciation to all our mentors who encouraged us to think critically and push the boundaries of our understanding.

To our fellow graduates, this achievement is a testament to the power of collaboration. We shared countless study sessions, brainstormed until the wee hours, and celebrated each breakthrough with infectious enthusiasm. We learned the importance of communication, the strength that comes from diverse perspectives, and the sheer joy of discovery when shared with a supportive team.

Looking back, this journey feels like a whirlwind of emotions, filled with moments of collective doubt and moments of pure, unbridled joy. Most importantly, this project has taught us invaluable lessons about resilience, the importance of asking questions, and the sheer satisfaction of pushing beyond our perceived limitations as individuals and as a group.

So, as we stand at this milestone, we dedicate this project to all of you who have been our guiding light. Thank you for believing in us, even when we doubted ourselves, and for celebrating every step of the way. Here's to new beginnings and the exciting possibilities that lie ahead, together!

Acknowledgment

Before and above all, we would like to record our endless thanks to Allah for everything he gives us. We are eternally grateful for the countless opportunities for growth and knowledge He has bestowed upon us.

We would like to express our sincere appreciation and profound thanks to Dr. Mohammed Al-Olofi for his invaluable guidance, encouragement, and scientific expertise. His constructive criticism, helpful supervision, and unwavering belief in our abilities were instrumental in shaping this project and propelling us forward. We are particularly grateful for Dr. Mohammed Faisal, and his dedication to our success instilled within us the strength and motivation to overcome challenges and persevere through difficult moments.

We are also deeply grateful to our families for their unwavering support, encouragement, and unwavering belief in us. Their patience and understanding during countless late nights and moments of frustration were invaluable. Their constant love and support provided a safe haven and a source of strength throughout this journey.

Finally, we would like to extend our thanks to our friends and colleagues for their support and camaraderie throughout this endeavor. Their insightful discussions, shared experiences, and moments of laughter helped us maintain focus and provided a sense of community during challenging times. We are particularly grateful to Eng. Ebrahim Al-Adhrai for his valuable assistance in designing the external structure of the project, We also extend our sincere thanks to Eng. Ahmed Al Hammadi for his valuable assistance in resolving our software issues that hindered us. His willingness to share his knowledge and cooperate with us greatly contributed to resolving and improving the functionality of the final product.

We are truly grateful to all of you for your contributions to this project. Your support and guidance have been instrumental in our success.

Supervisor Certification

I certify that the preparation of this project entitled

……,

prepared by ……

……..

was mad under my supervision at ……. department as partial fulfillment of the requirements of bachelor degree in …….

Supervisor Name

Signature

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Examiner Committee

Project Title :……...

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List of Abbreviations

Acronym	Definition
NICU	Neonatal Intensive Care Unit
WHO	World Health Organization
ISO	International Organization for Standardization
ICU	intensive care unit

Chapter 1

Introduction

Chapter 1: Introduction

1.1 Overview

Every year, about one million babies die in developing countries due to premature birth. Premature babies are born before their organs are mature enough to allow average survival after delivery. Because premature babies are at risk of oxygen deprivation, hypothermia, and many other adverse conditions, they need special care and attention [1][2]. One of the main problems faced by newborns is inadequate thermoregulation. The temperature in the womb is 38ºC [3]. If heat loss is not prevented and continues, the baby develops hypothermia and is at increased risk of developing health problems and dying [4].

Neonatal care units are a vital component in supporting premature and critically ill babies, and rely on advanced medical equipment such as incubators, radiant warmers, and phototherapy units. These devices are designed to maintain precise environmental conditions that help ensure healthy growth and functional stability for newborns.
Incubators provide a closed environment where temperature and humidity are carefully regulated to mimic the natural conditions inside the mother's womb, helping to protect babies from temperature fluctuations that could pose a significant risk to their health. Radiant warmers are used in emergency situations or during rapid resuscitation procedures to provide direct and immediate thermal support to babies. Phototherapy units are the primary treatment option for neonatal jaundice, as the intensity of regulated blue light helps break down excess bilirubin in the baby's blood, reducing the risks associated with this common health condition.
Despite significant advances in the technology of these devices, their effectiveness is affected by operational factors such as the accuracy of temperature, humidity levels, airflow, light intensity, and sound levels within the care environment. Variations in these parameters resulting from malfunctions or inaccuracies in the devices can lead to serious complications that affect the health outcomes of newborns.

To ensure the safety of the infant incubator, radiant warmer, and phototherapy units, there are devices that test the performance of the previous devices, but they are expensive and not available in some countries, so we planned to design a low-cost and effective calibration device to calibrate these medical devices as a single unit, which contributes to raising the level of accuracy and safety during their use.

1.2 Problem Statement

The intensive care unit (ICU) for preterm infants is one of the most important units in the hospital, It is common that preterm infants are underweight and incomplete in some internal organs and their bodies cannot control the temperature, If the child is not treated with NICU, he will be at high risk, because of the lack of adaptation to the new

environment, so should put children who are in such a situation within the NICU unit in order to ensure them with an environment similar to the mother's womb. In the current trends, 37 million children will die before their fifth year between 2022 and 2030, half of them newborn children, the report of World Health Organization (WHO). [14].
So we need infant incubators that contain newborns and provide them with an accurate performance, which ensures them to stay healthy and without any other complications. In addition, bilirubin leads to yellowing of the skin and eyes of the child as a result of decomposition of red blood cells, and it is the main reason that cause jaundice, New figures show Approximately 80% of preterm newborns develop clinical jaundice in the first week after birth.[15].

So the phototherapy (blue light), whose wavelength is between 460 and 490 (nm) is used to remove bilirubin which is related directly to jaundice.
In order to ensure the quality of both infant incubator and phototherapy and radiant warmer performance, the engineers conduct periodic inspections to verify these devices using high cost international analyzers which depend on international standards.

Manual calibration processes can often be time-consuming and prone to human error, potentially failing to achieve the required level of accuracy.
Moreover, inconsistent calibration may result in suboptimal device performance, which could negatively impact both the child and treatment outcomes. In addition to the unavailability of calibration devices that include both infant incubator and phototherapy and radiant warmer.

This study aims to develop a calibration device for NICU incubators, radiant warmers, and phototherapy equipment, focusing on low cost, high accuracy, and ease of use. Additionally, the system provides a user-friendly HTML-based interface that enables real-time control and monitoring from various devices such as smartphones, tablets, and computers via a web browser, with communication established through Bluetooth and Wi-Fi technologies.

1.3 Project Objectives

General Objective:

This project involves the design and development of a calibration device for neonatal care equipment, ensuring accurate performance monitoring. Examples include incubators, reading warmer, phototherapy units, and other devices critical for the safety and well-being of newborns.
The device is based on advanced sensors and utilizes an **ESP32 control unit** to display and measure vital parameters such as temperature, humidity, airflow, sound levels, and light intensity (including the irradiance of phototherapy light). It is equipped with a digital interface for ease of use and employs advanced sensor technologies to enhance accuracy, safety, and efficiency in modern neonatal care systems.

Specific Objectives:

1. Ensuring Compliance with International Standards: Aligning the calibration device design with global healthcare and safety standards, such as those set by the World Health Organization (WHO) and the International Organization for Standardization (ISO) for medical devices.
2. User-Friendly Interface: Incorporating a digital screen to display measured data clearly and make it easily accessible for healthcare professionals.
3. Cost-Effectiveness: Designing the device to be affordable, making it accessible for healthcare facilities with limited resources.
4. Enhancing Equipment Calibration: Providing a reliable and efficient tool for calibrating neonatal care devices to ensure optimal performance and safety in newborn care.

1.4 Project Scope and Limitations

1.4.1 Project Scope

1.4.1.1 Main Objective:

The primary goal of this project is to develop a battery-operated portable calibration device that integrates the calibration functionalities for three critical neonatal care devices:

1. Incubator: Calibration of temperature, humidity, sound intensity and airflow[5].
2. Radiant Warmer: Calibration of heat intensity and surface temperature [6].
3. Phototherapy Device: Calibration of light intensity and wavelength for optimal neonatal jaundice treatment [7].

This project aims to improve the accuracy of these medical devices, ensuring better outcomes for premature infants and minimizing medical errors in neonatal care settings [2].

1.4.1.2 Expected Deliverables:

- A compact, lightweight, and portable calibration device.
- Operable on rechargeable batteries for increased mobility and usability in remote or resource-limited settings.
- A user-friendly digital interface for displaying calibration results.
- Affordable production cost, capped at $500, to make it accessible for hospitals with limited budgets.

1.4.1.3 Core Features

1. For Incubators:
   Measurement and adjustment of temperature, humidity, and airflow [8].
2. For Radiant Warmers:
   Measurement and adjustment of heat intensity and surface temperature.
3. For Phototherapy Devices:
   Measurement and adjustment of light intensity and wavelength.

1.4.1.4 Target Users

- Neonatal intensive care units (NICUs) in hospitals.
- Rural and remote healthcare facilities.
- Training centers for medical device operation [9] .

1.4.2 Project Constraints

1.4.2.1 Technical Constraints

1. Measurement Accuracy:
   The device must ensure a calibration accuracy of at least ±0.5% for all parameters.
2. Integration of Functions:
   The design must allow seamless integration of the three calibration functionalities in a single device without compromising accuracy or efficiency.
3. Battery Life:
   The device should provide a minimum operational time of 4-6 hours on a single charge, making it viable for mobile use [5] .

1.4.2.2 Time Constraints

- Project Timeline:
  Completion of the design, development, and testing phases within six months.
- Quality Assurance:
  Allocating sufficient time for comprehensive testing to validate the device's performance and compliance with industry standards.

1.4.2.3 Financial Constraints

- Project Budget:
  The overall project budget must not exceed $500, necessitating the use of cost-effective yet reliable components [6].
- Operational Costs:
  Ensuring the device has low operational and maintenance costs post development.

1.4.2.4 Regulatory Constraints

- Compliance with Standards:
  The device must meet international standards for medical devices, such as ISO 13485
- Certifications:
  It must adhere to FDA and CE regulations for approval and market acceptance.

1.4.2.5 Environmental Constraints

- Size and Portability:
  The device must be compact and lightweight to facilitate easy transportation.
- Ruggedness:
  It should be durable and able to function reliably in varying environmental conditions, including rural healthcare settings [6].

1.5 Project Methodology

1.5.1 Introduction

The project methodology aims to clarify the technical and technical steps followed to design a comprehensive calibration device that combines calibration Devices for the care of premature babies (nursery, heating, phototherapy) that work on batteries. so using the Various sensors and built-in technologies. In this part, the methodology

followed will be explained step by step from the analysis of the problem and the To carry out the tests.

1.5.2 project implementation steps

1. **analyzing the problem and determining the requirements** through the analysis of standard standards for nursery, heating and phototherapy devices ، To determine the basic variables that need to be calibrated such as temperature, humidity, air flow and light intensity.
2. **specify the specifications of the device** as the type of digital display screen used to display measurements, power source, device weight،And types of sensors.
3. **selection of components and tools**, which include (measurement sensors, electronic control unit, power supply, HTML user interface ،Design and programming software).
4. **electronic and software design:**
   - Programming the system by writing codes using the Arduino IDE in ++C, to ensure that the sensors are read and processed the data is on the 32ESP module.
   - Acquire the values from the sensors and present the data through an HTML user interface.
5. **device testing and calibration of sensors:**
   - Perform tests on the devices and compare the sensor readings with standard calibration devices to ensure accuracy and document any differences and debugged by programming the code**.**
   - Energy consumption test to evaluate the performance of the batteries and the duration of operation of the device under continuous conditions of use**.**
   - Test the integration between the ESP32 module, sensors and HTML user interface and ensure accurate data display.
6. **documenting and analyzing the results** by recording the data resulting from the tests and comparing them with the standard readings and using Analyze the differences to find out how accurate the developed calibration device.
7. after confirming the correctness of all the previous steps, the device will been released in the local market and collect comments and suggestions Users, if any, to enable continuous improvement of the device.

1.5.3 The tools used

- **sensors:**

1. AS7262, use to measure light intensity in phototherapy equipment [10].
2. F662, used to measure air flow in an incubator [11].
3. DHT-22, used to measure the humidity in the incubator [12].
4. Sound Sensor(KY-038), used to measure sound intensity level.
5. DSI18B20 Digital Temperature Sensors, used to measure the air temperature in the incubator and radiant warmer.
6. Skin Temperature (MLX90614), used to measure the skin temperature in the incubator and radiant warmer.

- **Control unit:**
  ESP32, to act as a main processor to process data from sensors and display it on the HTML user interface [13].

- **Power circuit:**
  1. BMS, to charge and discharge batteries.
  2. Lithium batteries (3.7v), to operator the device.

- **software:**
  Arduino IDE program, to write codes and program the ESP32.

1.6 Document Organization

The rest of this document is organized as follows:

Chapter 1: Introduction (you are reading it now)

Chapter 2: Literature Review: The current literature reviews and the challenges related to the calibration of neonatal care devices, highlights available calibration techniques, and emphasizes the importance of measurement accuracy in improving the health outcomes of infants.

Chapter 3: Project Design: The technical design of the device includes advanced electronic components, such as microcontroller units and sensors. An interactive digital interface will be used to facilitate the calibration process and enhance its accuracy.

Chapter 4: Describes and covers the assembly of the device, including the integration of hardware and software. Comprehensive tests will be conducted to verify the device's performance and measurement accuracy.

Chapter 5: Results and Discussions: The results obtained from the system tests will be presented, along with a thorough discussion and evaluation of the device's performance compared to international standards.

Chapter 6: Conclusions and Recommendations: summarizes the main outcomes of the project, focusing on achievements and challenges. Recommendations for future improvements and potential expansions of the calibration system will be provided.

Chapter 2
Background and Literature Review

Chapter 2: Background and Literature Review

2.1 Background

In this section we will review the back ground of the incubator and Radiant Warmer phototherapy.

2.1.1 infant incubator

2.1.1.1 Historical Background

Incubators are used to stabilize and maintain the thermal balance in premature and newborn babies. In the year 1907 the pediatrician Pierre Budin described in his book The nursling the connection between mortality and rectal temperature. Newborns whose rectal temperature was warmed to 36–37 ◦C reached a survival rate of 77%, however in babies with rectal temperature between 32.5 ◦C and 33.5 ◦C the survival rate was only 10%.

It is assumed that incubators were used by the Egyptians as early as 200 AD. In the year 1947, a specially designed incubator was launched onto the market by the American physician Chapple. This incubator was the forerunner of present-day incubators, including a trans- parent acrylic glass cover, a bacteria filter for air intake, an integrated air circulation system, air humidification, and an alarm device against overheating, which was first put into practice in this model [16].

Figure 2-1 First Incubator

Premature babies are not capable of maintaining their thermal balance independently [17]. The ratio of body surface to body volume of a newborn is 2.7 times higher than that of an adult. In neonates with birth weight of 1000 g the ratio is 4 times higher. Loss of warmth can occur basically in four ways:

1. Heat conduction by release of heat to the mattress
2. Convection (cooling by airflow)
3. Evaporation from the skin
4. Thermal radiation from babies to the surrounding area.

Loss of warmth is reduced by vasoconstriction. By increasing vessel resistance, the extremities are cooled first, before the body temperature falls. Comparison between body temperature and peripheral parts of the body enables an early indication of thermal imbalance [18]. Only newborn children have brown fat tissue, which lies between the shoulder blades, behind the heart and the large vessels. These energy reserves have limited ability to maintain normal body temperature. Newborns are also not capable of producing warmth by increasing muscle activity (shivering). Due to their thin skin, more liquid is lost by evaporation from premature babies than from mature newborns.

Cold stress must absolutely be avoided for the following reasons:

- Less intake of oxygen, e.g., with a negative influence on the development of the lungs due to insufficient surfactant production. Hence, breathing problems could develop, which would have to be compensated by artificial respiration.
- Metabolism will be influenced negatively, e.g., hypoglycemia or metabolic acidosis (too low pH). The risk of pathological jaundice (icterus gravis) is increased.
- Increased danger of infection.
- Negative effect on growth.

It is therefore necessary to keep the core temperature constant and dehydration through perspiration at a minimum.

2.1.1.2 Construction and Function of an Incubator

Incubators create a microclimate, which can differ considerably from the surrounding air. In this microclimate, temperature, humidity, and oxygen content can, up to a certain limit, be regulated individually. Furthermore, the incubator isolates the patient in terms of protection from pathogens which could be transferred via the air. As a rule, incubators are designed for body weight up to 5 kg. The user can adjust the height as well as the inclination of the mattress. This allows good ergonomics and easy access to the patient by nursing staff. The incubator can also be lowered to allow for optimal mother–child contact

External Components of the infant incubator

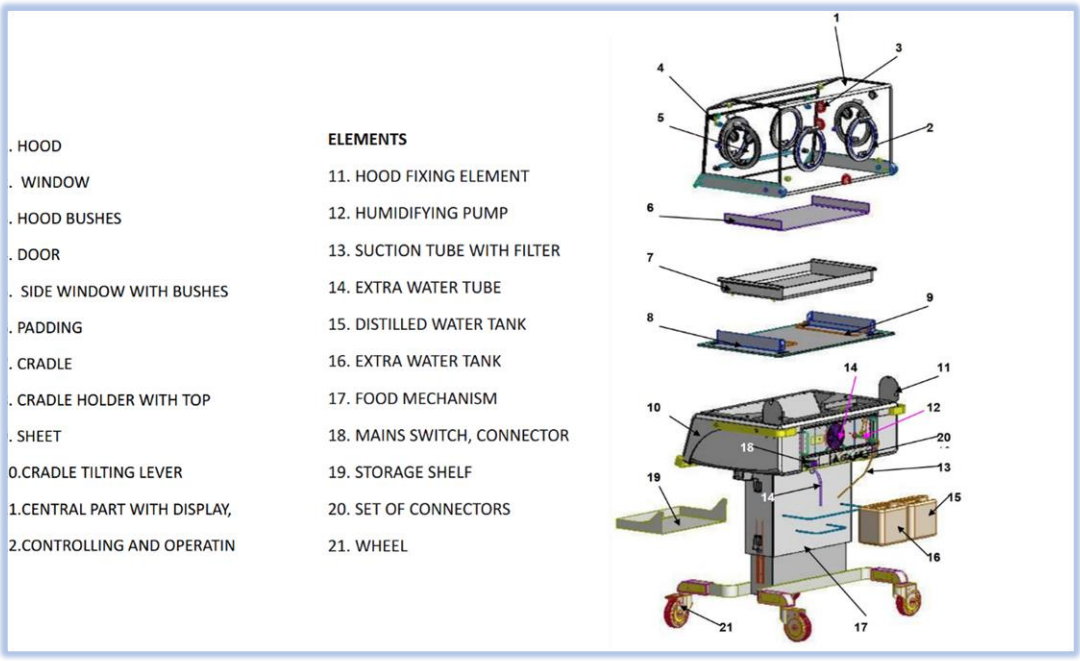


Figure 2-2 External Components of the infant incubator

Temperature Regulation

The incubator sucks in room air via an exchangeable air filter. The room air is heated by a heating element, which has a fan in the middle. The warm air is conducted via a ventilation shaft along the long sides of the incubator to the patient. As a result, a shield of warm air is formed. This shield reduces the cooling of the incubator when it is open. As a rule, the air is released at the front end. The air temperature is measured by several NTC (negative temperature coefficient thermistor) sensors. The challenge for the manufacturer is to create a draught-free, homogeneous atmospheric environment. The fan (aerator) has to meet special requirements, e.g.,it has to run as silently as possible, to avoid stress and the danger of hearing damage to the patient. Incubators run at operating noise of less than 50 dB(A). In future developments, the goal is to lower this noise level even further.

The user has two possibilities to control the temperature of the incubator:

1. Air temperature regulation: The user chooses a suitable air temperature. The temperature is measured by means of a temperature sensor in the incubator and compared with the set level (point). The set temperature in the incubator is thus kept constant. If the actual temperature differs from the set temperature, the user will be informed by an alarm signal. As a rule, the alarm limit is ±1.5 ◦C from the set level (point).
2. Skin temperature regulation: The user places a skin temperature sensor on the thorax, and a second one can be attached to the extremities. The desired temperature on the thorax is set by the user. The incubator regulates the air temperature de- pending on the skin temperature. If the actual temperature

differs from the set temperature, the user will be informed by an alarm signal. As a rule, the alarm limit is ±0.5 ◦C from the set point.

Incubators are not capable of cooling. At high outside temperatures and with large babies, the set temperature cannot be maintained. The temperature can, depending on the type of incubator, be set from 20 ◦C to 39 ◦C at 0.1 ◦C intervals.

- **Regulation of Humidity**

Two construction principles are used to create moisture: either water is evaporated over a heater and then, after cooling, passed into the incubator, or it is created over a heated washbasin in the incubator cell. Humidity is measured using capacitive components. Moisture is necessary not only to maintain the thermal balance of the baby but also to moisten the mouth, nose, and throat. The relative humidity can usually be set between 30% and 99%. The user has, depending on the model, two possibilities to control the humidity:

1. Manual humidity regulation: The user chooses a suitable relative humidity. The relative humidity is measured by means of a humidity sensor and compared with the set level.
2. Automatic humidity regulation: In the automatic mode the relative humidity will be increased at higher air temperature.

Depending on the temperature, air can hold different levels of humidity, so that when dropping below a critical temperature accumulation of condensation occurs, whereas at higher temperatures, moisture can be absorbed.

As a result of the ratio of the outside temperature to the high inside temperature, there is the danger of condensation accumulating on the incubator glass. This may limit the possibility to monitor the baby. The effect is increased when humidity > 70% is chosen. Numerous manufacturers offer optional interior glass for better isolation. In practice, these have not become well established, especially because condensation between the two glass panels cannot be wiped away by nursing staff without great effort.

Incubators are not capable of drying air. If a humidity set level is chosen which is lower than the surrounding air humidity, the actual value achieved will never be lower than the surrounding humidity.

- **Regulation of Oxygen**

As an option, with all equipment available on the market, the air can be oxygenated. The air, depending on the construction of the incubator, can be oxygenated up to 70 vol. %. With stationary incubators the oxygen is supplied via the central gas supply. With transportable incubators for ambulance or helicopter transport, operation is

possible via the central gas supply as well as from gas bottles. The oxygen in the incubator is measured by fuel cells, which are applied also in long-term respirators. Due to the potential danger of a wrong dose of O 2 , O 2 testing is designed to use two measuring devices. The signals from two fuel cells are compared with each other. If the values differ considerably from each other, the fuel cells can be automatically or manually calibrated by the user.

- **Scales**

Not only body temperature but also body weight is an important diagnostic parameter in neonatology. Today's technology implements scales into the incubator. In this way, cold stress is avoided for the newborn when it is weighed in compartment air in the incubator instead of on conventional scales in room air.

- **X-ray Drawer**

To make handling of necessary x-rays easier, in newer incubator models a drawer is built in under the mattress. Common x-ray cassettes can be inserted into this drawer. In this way, the newborn is not laid down directly onto a cold, hard x-ray plate.

2.1.1.3 Incubator Models

Incubators are basically divided into three types of models.

- **Stationary Incubators**

These are used for long-term care of premature and newborn babies in recovery rooms and intensive care units (Fig. 2-3), (Fig. 2-4).

Figure 2-3 Stationary incubator (courtesy of Draeger)

Figure 2-4 Stationary incubator

➢ **Transport Incubators**

These are used for in-house transport from the delivery room to the pediatric intensive care unit or for transfer to other clinics by vehicle or helicopter. The latter incubators have their own electricity supply via accumulators as well as a gas supply via gas bottles. In the hospital or in the vehicle the equipment can be supplied with energy via the 220 V network and via the central gas supply, in order to save the mobile energy supply. Incubators mounted on a chassis with vibration absorbers are adapted to a standard retractable carriage (gurney). Due to limited space during transport, e.g., in helicopters, as well as the short transport times, the humidification option is not available in these devices. Intensive care transport incubators are equipped with a respirator, a patient control monitor, a syringe pump, and a suction device (Fig. 2-5), Fig. 2-6.

Figure 2-5 Transport incubator with gurney (courtesy of Draeger).

Figure 2-6 Transport incubator

➢ **Special Incubators**

For examinations in magnetic resonance imaging (MRI), there are nonmagnetic transportable incubators, which can be inserted into the MRT. With this apparatus, air humidification and artificial ventilation are also possible as well as being fitted with a pulse oximeter for monitoring the patient. The apparatus is also suitable for thorax and brain examinations. The problem of in-house transportation can be considerably simplified by a novel transport concept. Until now, for therapy each baby had to be looked after in a reanimation unit, then transferred in a transport incubator from the delivery room or the sectio-op to the children's ward to the place of treatment. This means repeated relocation (shifting) and therefore cold stress for the newborn, as well as the danger of unintended manipulation of infusion and respiration tubes (Fig. 2-7).

Figure 2-7 Incubator for in-house transportation with dock Ing carriage (courtesy of University Hospital Freiburg and General Electric Company)

Usually, newborns are initially treated in reanimation units, i. e., a warming bed with a heated gel mattress and an integrated radiant heater (radiator). After stabilization in the delivery room, patients are often transferred to intensive care within a few minutes. Babies are not transferred to stationary incubators until they are in the intensive care unit. So, patients are relocated twice at room temperature and experience cold stress. The reanimation unit and the transport incubator must go through a time-consuming upgrade process. To improve this situation, a stationary incubator with an integrated heat radiator is connected to a docking carriage (trolley). Thus, this incubator can be used as an initial reanimation unit. On the docking carriage (trolley), all the necessary relevant equipment can be found for an intensive care unit: respiration equipment, aspiration (suction, extraction), patient monitor, syringe pumps, and a hand anesthesia bag. The docking carriage (trolley) is equipped with O 2 and pressurized air bottles to

ensure breathing during transport. The trolley is connected to the incubator without using tools. After arrival at the neonatal intensive care unit, the trolley is then connected directly in the intensive care room to carry on with therapy using the ward's equipment. Using this concept, cold and shifting (relocation) stress can be minimized (reduced). Resources are saved, and handling by staff is facilitated.

2.1.1.4 Risks of Incubator Therapy

- **Temperature**

As described above, stabilization of body temperature of newborns is of great importance. Therefore, tightly controlled temperature monitoring is indispensable. For newborns, the rectal temperature is measured every 2 h. If the baby is thermally stable, the cycle can be expanded to 4 h. If the baby cools, it is called hypothermia. If the child is warmed by the incubator to over 37 ◦C, it is called hyperthermia.

As a result of increased liquid loss due to hyperthermia, electrolyte dysfunction can result. Further outcomes are hyperventilation and tachycardia. In thermostable children, skin temperature correlates very well with body temperature. Therefore, use of the skin temperature regulation operating mode simplifies the suitable choice of temperature by the user.

On no account should skin temperature regulation be used for children who are in a state of shock, because in this situation unintentional hyperthermia could occur. Also for babies with fever, skin temperature regulation is only to be used with great care, because in this case the skin temperature is higher than the body temperature. Very early premature babies experience extreme perspiration, resulting in high fluid loss, in the first days of life. A further exception is the patient experiencing shock, or skin surface temperature due to infection, which will cause unreliable readings on the incubators skin temperature monitoring.

- **Oxygen Therapy**

Oxygen treatment can pose a high potential risk for incorrect dosage. Therefore, when administrating O 2, arterially measured O2 partial pressure must be deter- mined. With O2 therapy it is indispensable to monitor the patient continuously with a pulse oximeter or a transcutaneous O 2 probe. If there is undersupply (hypoxemia), then there is the danger of respiratory insufficiency resulting in apnea. Continuous undersupply of O 2 can cause brain damage.

Overdose of O 2 (hyperoxemia) in premature babies before the 39th week of gestation can lead to serious eye damage. It can even cause retinal detachment, a very serious retinopathy.

Oxygen is associated with the danger of explosion and fire hazard. Therefore, for safety reasons, after disinfecting the hands, one should wait until the disinfectant has dried. For this reason no disinfectant or inflammable liquids such as alcohol or benzine should be put in or on the incubator.

- **Hygiene**

Due to the warm climate and high humidity, an incubator is an ideal breeding ground for germs, leading to an additional risk of infection for the newborn. There- fore, after terminating the treatment of a patient, or after 7 days at the latest, a new incubator must be provided and the used incubator carefully cleaned and wiped with disinfectant. In particular, excessive build-up of condensation in the interior of the chamber is a risk for early fungal or bacterial contamination.

- **Unsolved Problems**

The following points should be given special consideration in a newborn's environment:

- Total reduction of noise, and the possibility to regu late light entering the chamber.
- It should be noted that, although no limits on electromagnetic fields in patient healthcare environments have been reported, their effect on heart rate and physiological functions will become an issue [19].
- A problem noticed in the field is international standardization of holders for patient gurneys. To ease international patient transport it is desirable to implement international standardization in the future.

2.1.2 Radiant Warmer

2.1.2.1 introduction

Incubators and radiant warmers are used to maintain the body temperature of newborn infants. This is best done so that the energy expended for metabolic heat production is minimized. The heat output of these devices is usually regulated by servo control to keep the skin temperature constant at a site on the abdomen where a thermistor probe is attached.

In incubators, air temperature can also be controlled as an alternative to skin temperature servo control. Increased ambient humidity, heat shields and clothing have been used to decrease the evaporative or no evaporative heat loss of infants in incubators under certain conditions. Double-walled incubators, by adding a second 7 inner layer of Plexiglas, reduce radiant heat loss. They may also reduce total heat loss, but only if air temperature is controlled rather than skin temperature. The minimal oxygen consumption under a radiant warmer is the same or perhaps slightly higher than it is for the same infant in an incubator. Compared with incubators, the partition of body heat loss is quite different under radiant warmers. Radiant warmers increase convective and evaporative heat loss and insensible water loss but eliminate radiant heat loss or change it to net gain. A heat shield of thin polyethylene film can be used with a radiant warmer to reduce heat loss by convection and evaporation. The major advantage of the radiant warmer is the easy access it provides to critically-ill infants without disturbing the thermal environment. Its major disadvantage is the increase in insensible water loss

produced by the radiant warmer. Most infants can be safely and adequately cared for in either incubator or radiant warmer bed. A 400 watt radiant warmer placed 50 cm. above the baby will be sufficient. This method is effective only if the room temperature is kept high (above 25 °C/77 °F). Spot lights or bulbs are dangerous because they focus the heat and may burn the baby Figure 2-8 [20].

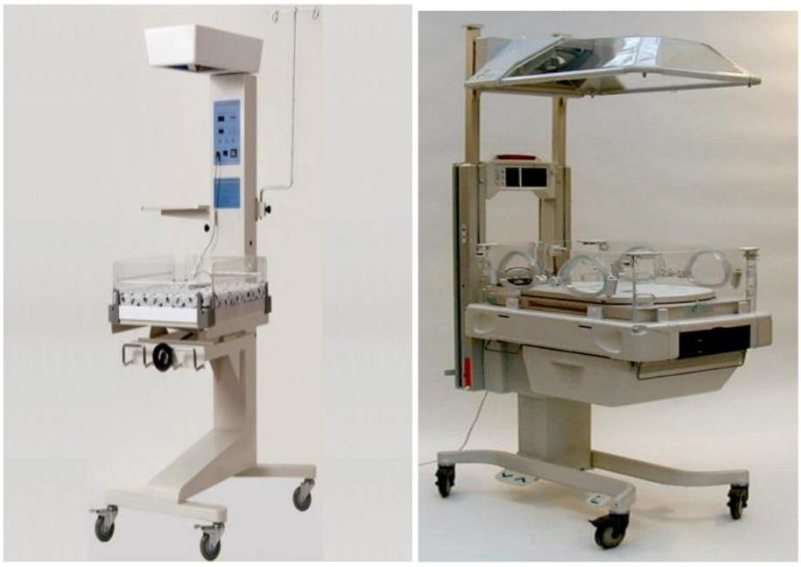


Figure 2-8 Radiant Warmer infant incubator

2.1.2.2 Principle of Operation – Radiant Warmer

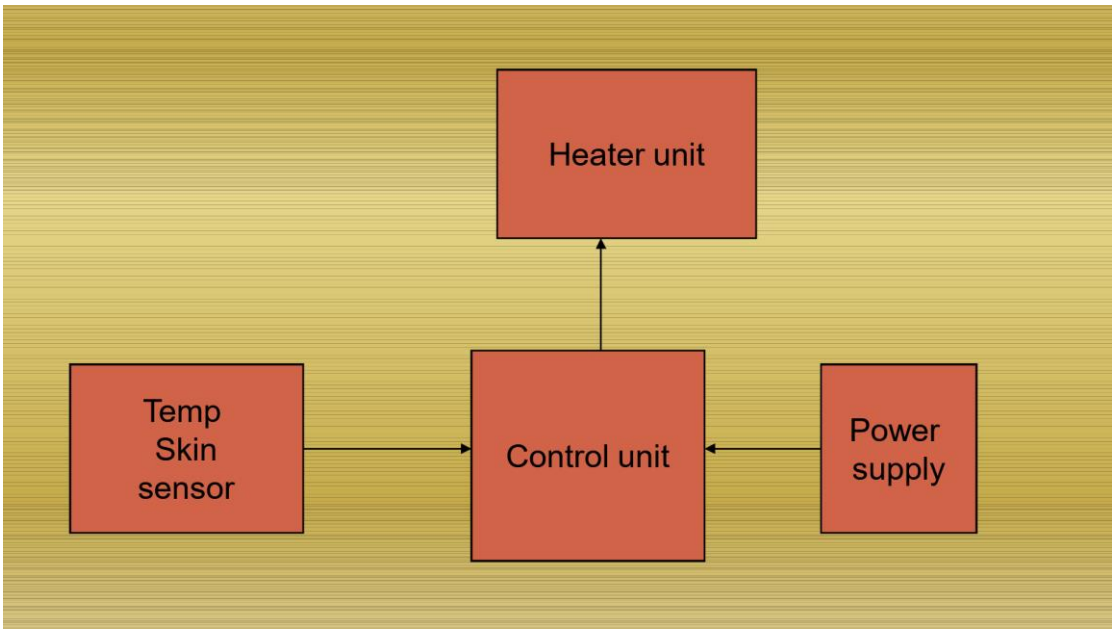


Figure 2-9 Principle of Operation - Radiant Warmer

2.1.2.3 Clinical Problem

Radiant warmers may be used both within the Nursery ward and the Laboure or Obstetrics ward. Warmers are used exclusively for newborn or infant patients. Newborn babies can drop their body temperature within minutes. They must be kept warm from the moment of birth, during their time in the Laboure ward and when transferred to the nursery. Even small drops in temperature increase the likelihood of mor utility [20],[21], [22].

Radiant warmers may be used on all neonatal patients admitted to the nursery ward, but is especially critical for those with prematurity, low birth weight, reduced growth, low body temperature or undergoing procedures.

2.1.2.4 Assessment

However warm a room may feel to an adult, a neonate can lose heat. This heat loss in neonatal patients is rapid, with low body temperature (hypothermia) directly contributing to mortality [20] [23]. Radiant warmers use overhead heating elements to provide radiating heat ensuring maintenance of normal body temperature (normothermia).

Newborn babies lose heat through four main mechanisms (Figure 2-10) [24].

- Evaporation: water loss through the skin.
- Radiation: heat radiating from the warmer patient towards cooler surfaces (e.g., windows or walls).
- Conduction: direct heat travelling from warmer surface of the skin to the cooler mat or cot on which the patient rests.
- Convection: air currents move heat away from the skin/body.

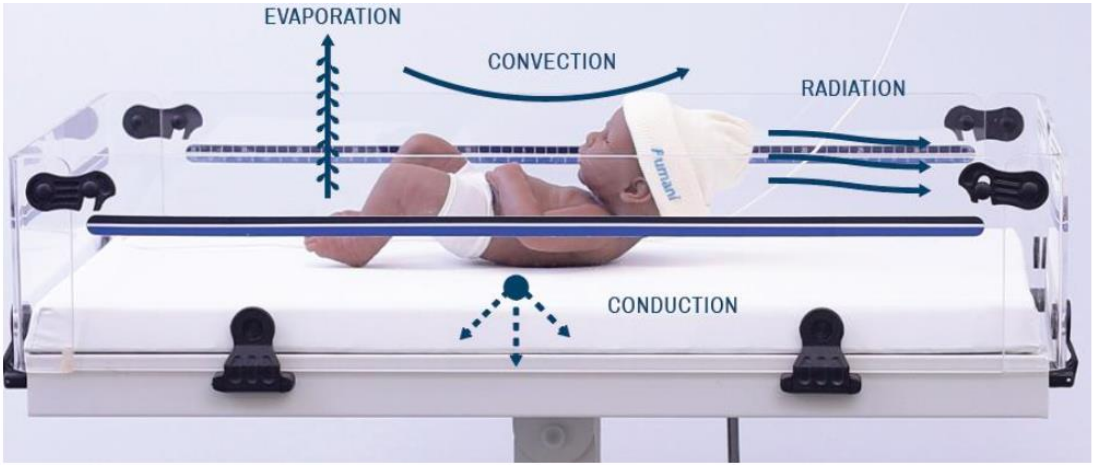


Figure 2-10 Mechanisms of heat loss

Radiant warmers provide infants with a radiating heat to minimize heat loss and energy requirements for heat production, decreasing the risks of low blood sugar and increased work of breathing associated with hypothermia. (Figure 2-11) Radiant warmers provide

an area where resuscitations, procedures, and short-term observation can take place while keeping the baby warm. Warmers may vary in complexity, including only heating functionality or heating functionality with resuscitation and oxygen equipment. All warmers include a temperature probe that provides information on the patient's temperature. (Figure 2-12)**.**

Figure 2-11 Typical radiant warmer

Figure 2-12 Typical temperature probe

Normothermic axillary temperature in neonates ranges from 36.5°C to 37.5°C. [22],[24] Every effort must be made to keep a baby's temperature within the normal range as temperature below 36°C is an independent risk factor for death in newborns.[21], [23].

2.1.2.5 How It Worke

Radiant warmers heat in various modes, the names and availability of which may vary based on device: (Figure 2-13)

- **Prewarm**: provides constant low heat for a short amount of time (typically 10 minutes or less) to warm the cot underneath the warmer. Prewarming protects the patient from conductive heat loss caused by a cold mattress.
- **Automatic**: also called **servo** or **baby mode**; uses a temperature probe on the baby to automatically adjust heat provided to maintain the patient's temperature within an acceptable range.
- **Manual**: provides a constant, adjusting heat that is set by the user. **Patients should never be left unattended if being treated in manual mode.**

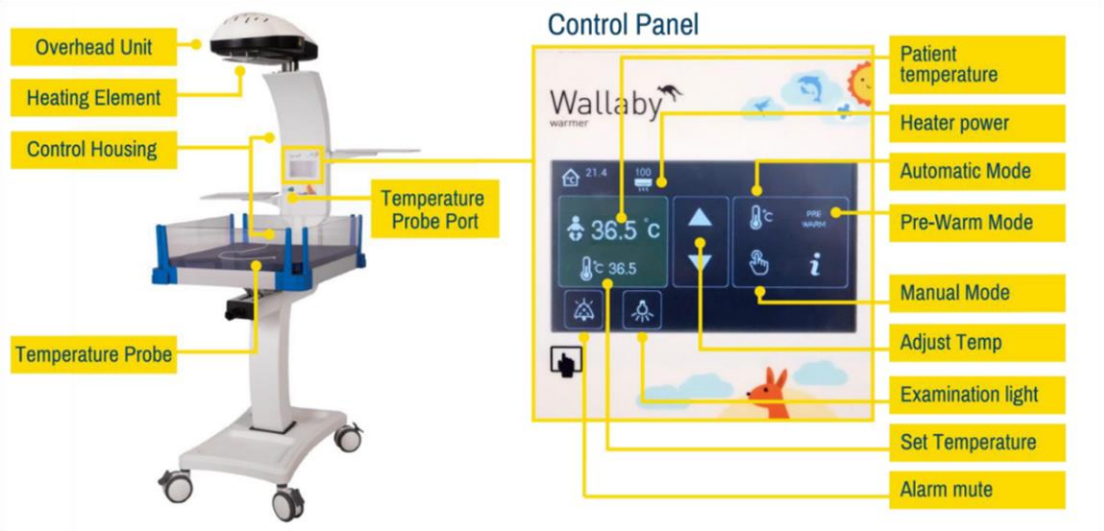
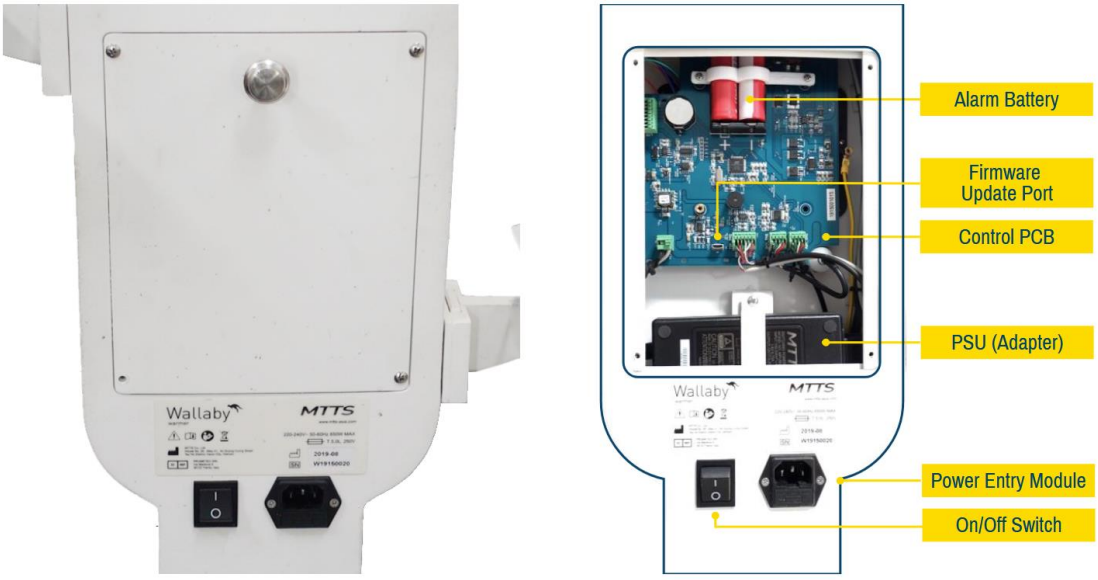


Figure 2-13 Major external components & modes of a radiant warmer.

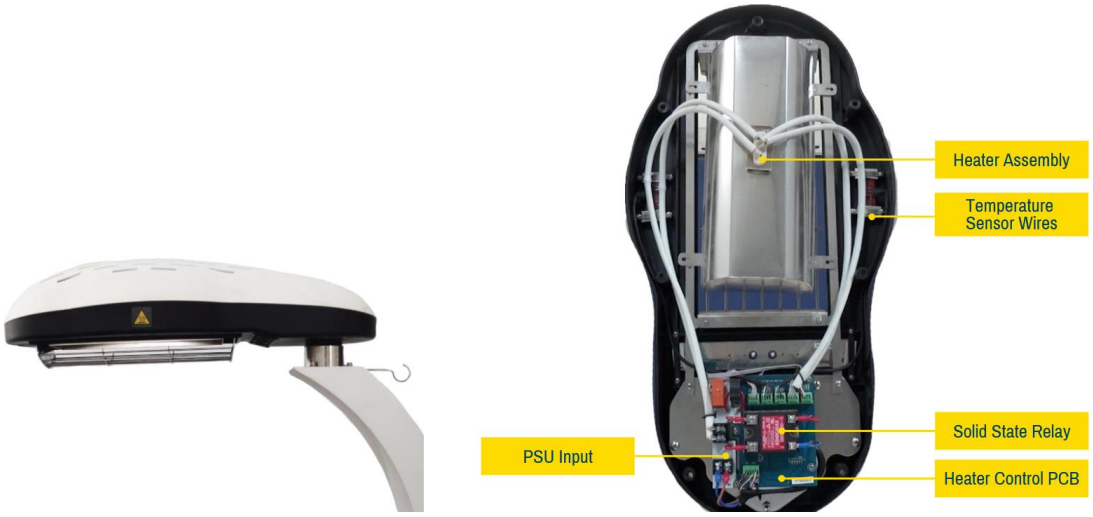
A radiant warmer consists of a mounted overhead heating mechanism that may be transported or kept stationary with lockable castors. This heating mechanism consists of heating elements (typically made of ceramic or quartz). In both types of **heating elements**, an optically designed parabolic reflector is fitted into the heating element housing to direct the heat energy towards the **baby cot**. The baby cot may be part of the radiant warmer or the heating elements may be independent (as in phototherapy lights). Heat output from the heating elements is controlled by the main controller, which in turn is dictated by user input. In some units, a separate module is fitted to control the heater output.

The core temperature of the baby is continuously monitored by the **temperature probe** connected to the device and placed over the baby's liver. Body temperature changes can be seen in real-time on a small LCD panel. Radiant warmers are also fitted with **audiovisual alarms** to attract the attention of the medical or technical staff when a problem occurs.

Standard internal device components are annotated below in **Figures 2-14** and **2-15** Components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to service and user manuals if model in use is different from the displayed version.



Figures 2-14 Major internal components of a radiant warmer control housing.



Figures 2-15 Major internal components of a radiant warmer overhead unit.

2.1.2.6 Typical Device Flow: (Figure 2.7)

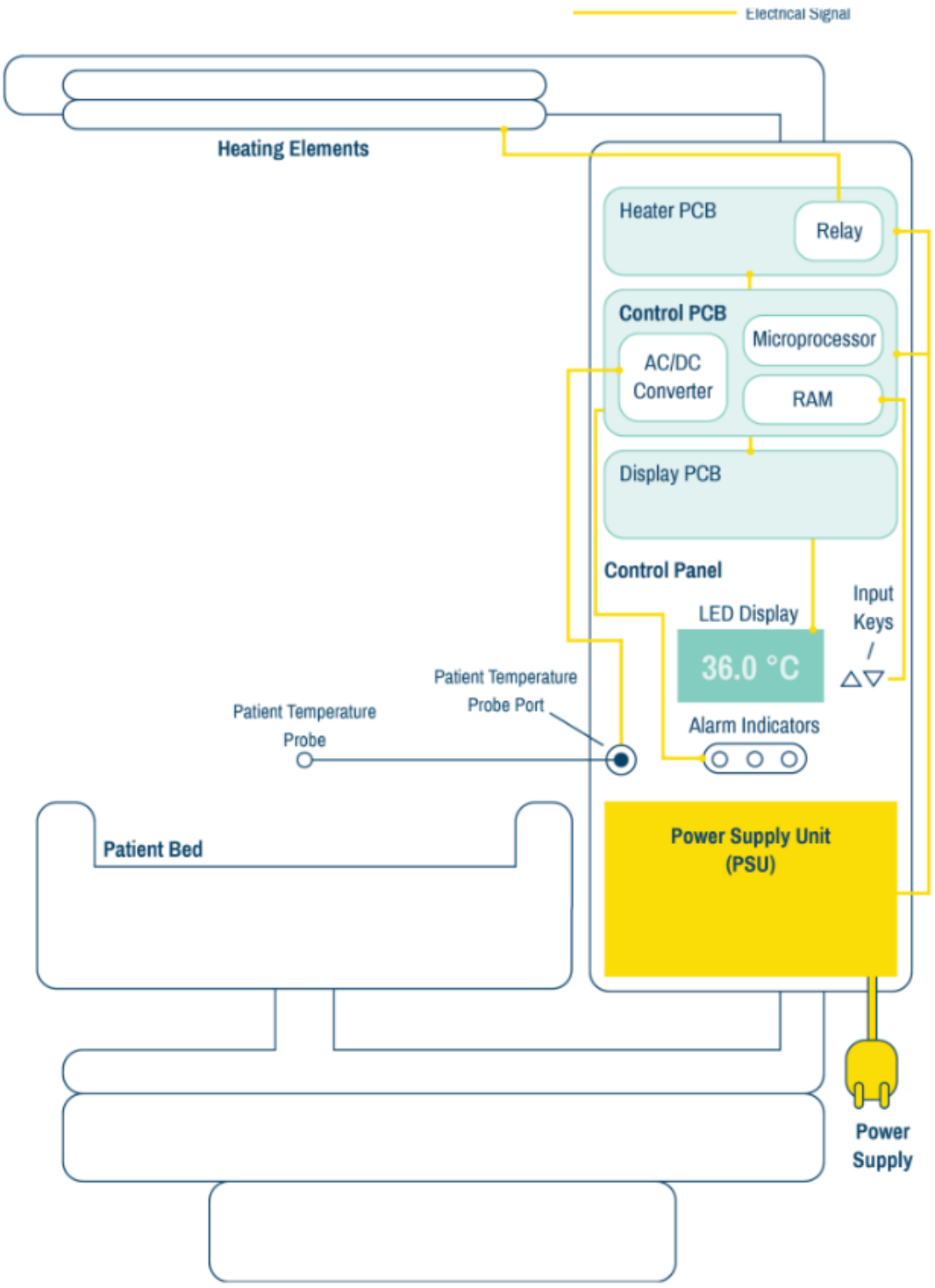


Figure 2-16 Typical Device Flow

2.1.2.7 MAIN COMPONENTS

he following device components should be similar regardless of model. However,

specific locations, visual setup and component type may vary by brand and device model. Refer to model service and user manuals if different from the displayed model for more device-specific information.

- **Power switch** is usually a rocker switch located on the back or side of the unit. This switch must be in the "on" position to power the radiant warmer and view the control panel.
- **control panel**, usually located on the front of the radiant warmer, includes functions for operating the radiant warmer and a display of readings to assist in clinical care. Most control panels include an LCD that displays readings from the temperature probe, the set temperature for the warmer, the heat power output, fault codes, alarms, and other status readings based on the manufacture's design. Radiant warmer controls may be located on an LCD touchscreen or may be physical buttons, knobs, or switches on the warmer. These controls are used to select the warming mode, set desired patient temperature and adjust heater output. Some radiant warmer control panels will maintain settings from the last use. For this reason, always advise the clinical or nursing staff to check the settings before initiating a patient.
- **Patient temperature probe** The manufacturer includes a patient temperature probe that is designed to be used with their radiant warmer model. The patient temperature probe is made up of a sensor, cable and attachment head. The patient temperature sensor should be placed on the baby's skin over the liver to read the body temperature: (Figure 2-17).

Figures 2-17 Typical temperature probe

The patient temperature probe sensor is typically made of a thermocouple that measures and feeds the patient's temperature back to the control PCB's microcontroller. The microcontroller uses the patient's temperature readings to provide feedback to the control system, which will adjust the heater output based on the comparison between

the actual baby core temperature measured by the probe and the user set value (as in servo/automatic mode) or to turn off the heater (as in manual mode).

- **Patient temperature probe port** The patient temperature probe port on the unit is designed to fit the manufacture's specified patient temperature probe cable. The port end of the cable is inserted into the port. This cable links the control system and the patient temperature probe to provide the patient's temperature readings to the PCB microcontroller.
- **Power Supply Unit (PSU)** are located internally in the radiant warmer and are usually linear or switch-mode power supplies. The main function of the PSU is to convert 110/220 VAC mains power to low voltage regulated DC power for use in other electronic circuits in the system as per design. PSUs typically include a transformer, rectifiers, voltage regulators, and filters.
- **Control PCB** includes the microcontroller and regulates all the system operations and electronic circuits. All auxiliary control units, if fitted, report to the main control PCB. The control system's microcontroller performs regular self-tests during operation. Whenever the system detects an issue with the temperature control system or working state, the device will issue a corresponding visual or audio alarm. The LCD, the heater output, alarms, and monitoring of system operations are controlled through the control PCB. Comparator circuits on the control PCB compare the signal from temperature probes and the set temperature value (as in servo/automatic mode). It uses this input to control the heater output using relays (either solid state or electromechanical) which switch the heating element on/off to maintain the set temperature.
- **Heating elements** There are two main types of heating elements used in radiant warmers: ceramic and quartz. They are usually between 800 W or 1000 W, and they release radiant heat in the far infrared wavelength that is easily absorbed by the neonate's body:
  - **Ceramic heating elements** use a heating wire (e.g., nichrome) encapsulated in a ceramic material. When power is applied the ceramic plate warms and radiates heat to the cot.
  - **Quartz heating elements** consist of a coiled heating element enclosed in a quartz tube. When electricity is applied, the quartz warms, and radiates heat to the baby cot.

  Both ceramic and quartz elements use an optically designed parabolic reflector that is fitted to project heat energy onto the baby cot.
- **Internal battery** Usually rechargeable, the internal battery operates alarms and temperature monitoring and display for 6 to 8 hours during power failure. The internal battery is usually linked to the control PCB and, in most modern models, is recharged as the radiant warmer is in use on mains power.
- **Firmware** Radiant warmer firmware is the software that carries out the basic functions of the radiant warmer. This software is stored in the memory within the radiant warmer's hardware. The manufacturer may issue occasional updates

to the firmware that will need to be applied to existing radiant warmers per the manufacturer's instructions.

- **Audiovisual alarms** the control PCB's microcontroller performs regular self-tests during operation. Whenever the system detects an issue with the temperature control system or working state, the device will issue a corresponding visual and/or audio alarm or error code. The common alarms found on radiant warmers are:
  - **Temperature Alarm:** works only in servo/automatic mode. It activates when the baby's temperature (measured by the patient temperature probe) deviates from the user set temperature by ±0.5 to 1°C (depending on model). A visual alarm flashes and is followed by an audible alarm.
  - **Probe Failure Alarm:** works only in servo/automatic mode. It activates when the probe fails electronically, or when the probe is disconnected from the warmer. During a probe failure, the heater deactivates and a visual alarm flash followed by an audio alarm.
  - **System Failure Alarm:** activates when systems fail or calibration deviates from expected values.
  - **Heater Failure Alarm:** activates when a heater defect is detected.
  - Power Failure: activates when a power failure is detected. Battery power supports this audible alarm during power outages.

  Manufacturers may include different alarms and error codes based on model. Refer to the manufacturer user or service manual for a complete description of alarms and error codes.
- **Baby cot** Some radiant warmers include an attached baby cot. The cot often includes removable side panels that should be in place and secure when the baby is in the cot to prevent falls. The cot may also include a knob underneath the cot to adjust the position of the cot.

2.1.2.8 Management

These instructions are helpful for a biomedical engineer or technician both in user training and in assessing the appropriate functionality of the device. Management covers how to use the radiant warmer, including set up for a patient, patient commencement, care whilst on the device and removal of the patient from the device.

➢ **Setting Up for a Patient**

1. Plug power cable into the radiant warmer figures 2-18 Plug power cable into a wall socket & surge protector if available. Switch on the power (Figures 2-19).
2. Select manual setting at 25% or Prewarm setting (if available on model). (Figures 2-20).

Figures 2-19 Switch on the power

Figures 2-20 Select manual or Prewarm setting.

Figures 2-18 Plug power cable into the radiant warmer

1. 3 Plug temperature probe into the infant temperature probe port. (2-21) Hold temperature probe in hand and move hand directly under overhead heating elements to check for heat. (2-22) You should be able to feel heat emitting from the heating elements and observe the temperature displayed on the radiant warmer begin to steadily increase. (2-23)
2. 4 Prewarming is critical to prevent rapid conductive heat loss in neonatal patients. Always advise the clinical or nursing staff to allow bedding to warm while waiting for the baby to arrive in the nursery, be transferred to the radiant warmer, or be delivered in the Laboure ward.

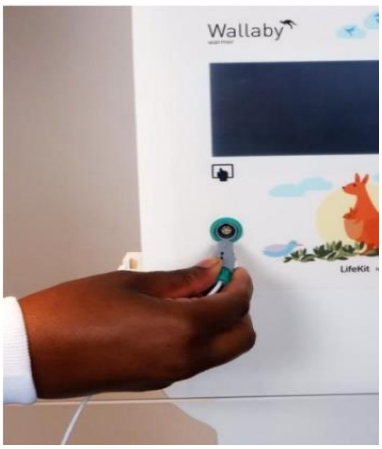


Figure 2-21 Plug in the temperature probe warmer.

Figure 2-22 Pass the temperature probe underneath the heating.

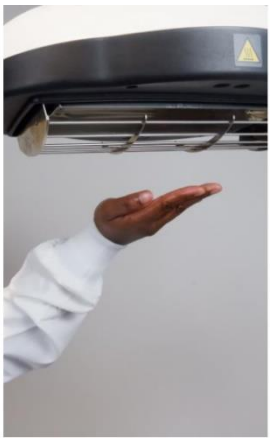


Figure 2-23 Feel heat emitted from elements warmer.

2.1.2.9 Preventive Maintenance

After Each Use

- ❖ Turn off, unplug and allow the radiant warmer to cool. Use gauze & 70% alcohol to wipe:
  - Temperature probe, including cable and plug head
  - Control panel
  - Power button
  - Mattress
  - Bassinet walls & floor
- ❖ Visually inspect radiant warmer components.

Weekly

- ❖ Test the heating elements and temperature probe :
  - Plug in the machine. Connect the temperature probe. Turn the power switch to ON. Leave the machine on for 1 minute.
  - Hold the temperature probe in the palm of your hand and hold your hand near the overhead heating elements. Slowly move it from the part of the heating element closest to the stand, moving towards the outside end of the heating element. You should feel your hand progressively heat as it moves and see the temperature reading on the machine steadily increase.
- ❖ Document cumulative hours and preventive maintenance actions taken.

Monthly

- Perform Weekly preventive maintenance steps.
- Test the power loss alarm: while the radiant warmer is plugged in and turned on, turn off the power at the wall socket. An alarm should sound.
- Check the operation of the baby cot, tilting mechanism and drawers.
- Document cumulative hours and preventive maintenance actions taken.

2.1.3 Phototherapy

2.1.3.1 Clinical Problem

Phototherapy lights are used exclusively within the newborn care ward for newborn patients displaying symptoms of high bilirubin levels (jaundice)

Jaundice is symptomatically shown by the yellowing of skin and whites of the eyes. Phototherapy may be considered for neonates with jaundice based on the age at which they show symptoms, measured or estimated blood bilirubin concentrations or with specific complications with which they present.

2.1.3.2 Assessment

Infants have a large volume of bilirubin in the bloodstream because they have a high red cell mass (hemoglobin) and rapid red blood cell breakdown in the first days of life. Unconjugated bilirubin released by red blood cell breakdown cannot be rapidly removed by a newborn's immature liver, leading to an excess of unconjugated bilirubin and jaundice.

Phototherapy uses blue light transmitted on the patient's skin within the wavelengths of 425 to 475 nm [25]. to break down unconjugated bilirubin to a water-soluble, non-toxic form that can be easily excreted [26]. Phototherapy lights may be integrated into units with overhead (Figures 2-24), over- and underbody (Figures 2-25), or flexible blanket lights. (Figures 2-26) Most phototherapy units can be used in tandem with other devices (e.g., radiant warmers, incubators, and oxygen therapy).

Figure 2-24 Overhead phototherapy unit.

Figure 2-25 Over & under the body phototherapy unit.

Figure 2-26 Flexible phototherapy blanket.

Phototherapy lights are most effective when providing blue or green light within 425 to 475 nm via LEDs. Other types of bulbs providing blue light within 425 to 475 nm (e.g., halogen or fluorescent) are less effective for treating jaundice, have a shorter lifetime, and are not as sustainable for long term use. Halogen and fluorescent bulbs are less energy efficient than LEDs; as they lose energy in the form of heat, they may also create a potential risk for hyperthermia or evaporative water loss.[27],[28] Other types of phototherapy are also used, but are typically not recommended:

- UV lights: not recommended for neonatal therapy due to increased melanoma risk associated with childhood UV exposure.
- Natural sunlight: historically used prior to wide availability of phototherapy devices; natural sunlight is not ideal due to increased challenges with temperature control of the patient and UV radiation risks.
- Filtered sunlight: there is emerging evidence that devices that filter sunlight, while requiring close monitoring in order to prevent temperature instability, can

be used in babies > 2.2 kg in tropical climates to treat neonatal jaundice.[29],[30];[31],[32].

There are different methods to determine need for phototherapy, all of which rely on measuring or estimating the bilirubin levels in the blood. Bilirubin levels can be measured using a blood test or transcutaneous devices.[33],[34] Levels can also be estimated through visual assessment using the Kramer's scale. (Figures 2-27).

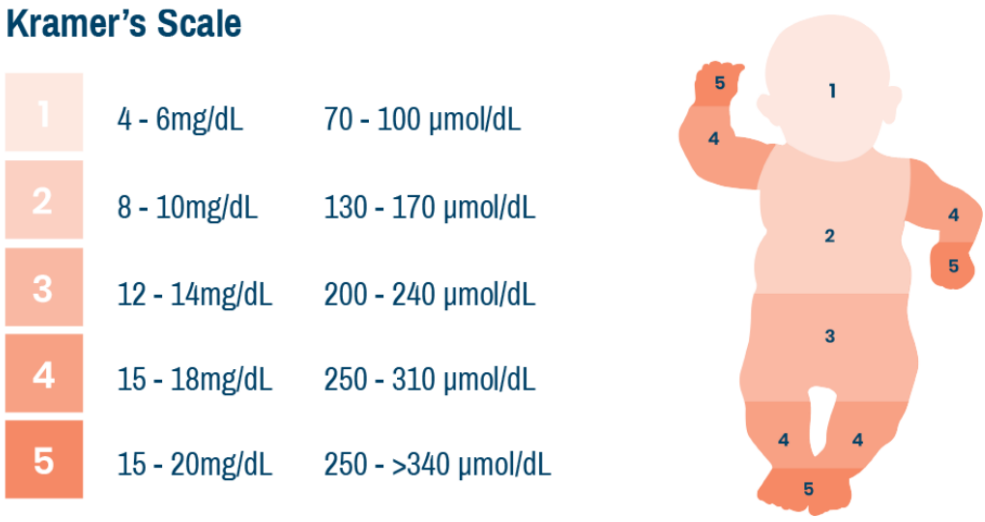


Figure 2-27 Kramer's Scale visual assessment areas.

Physical assessment for jaundice should be made in natural or white light to ensure results are accurate. Blood serum measurement of bilirubin levels is the gold standard for jaundice assessment. Both transcutaneous bilirubin and the Kramer's scale are less accurate approximations of serum bilirubin levels, particularly after phototherapy has begun [35].

Most jaundiced patients require treatment for 24 to 48 hours, and typically do not require treatment for any longer than seven days. If jaundice persists, further investigation into the cause of the jaundice should be advised.

2.1.3.3 How It Worke

A phototherapy unit is a light. Phototherapy lamps emit a spectral irradiance (µW/cm2), which is optimized when the light source is set to the recommended distance (height) from the patient. Most phototherapy lights' output can be adjusted to a standard or intensive mode depending on patient needs:

- **Standard**: provides normal-range spectral irradiances for conventional phototherapy (25-30µW/cm2) at recommended distance from the patient.

- **Intensive**: provides higher spectral irradiances for intensive phototherapy (30-35 µW/cm2) at recommended distance from the patient).

Standard external and internal device components are annotated below in Figures (2-28) and (2-29). Components should be similar regardless of model. However, specific locations, visual setup and component type may vary by brand and device model. Refer to service and user manuals if model in use is different from the displayed version.

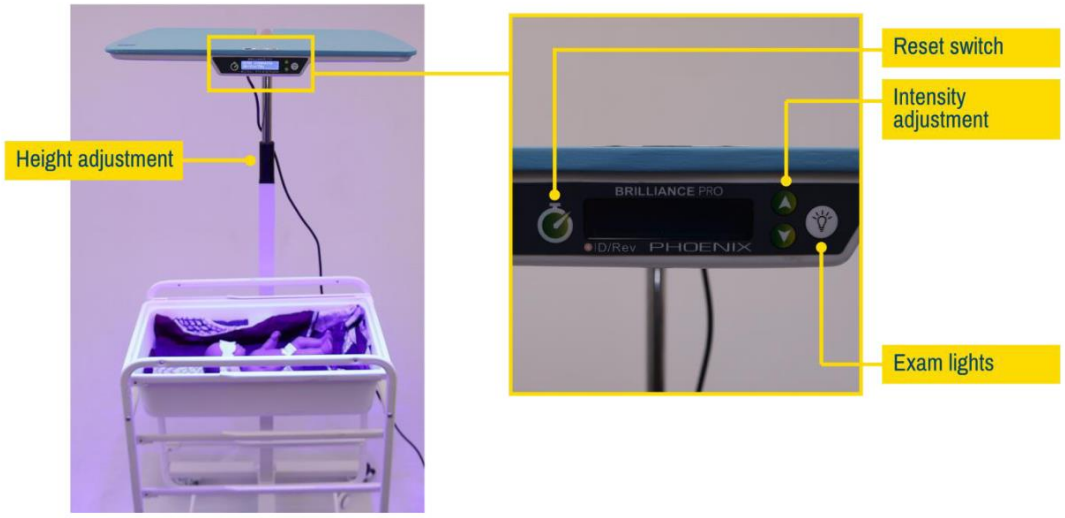


Figure 2-28 External components of a phototherapy light.

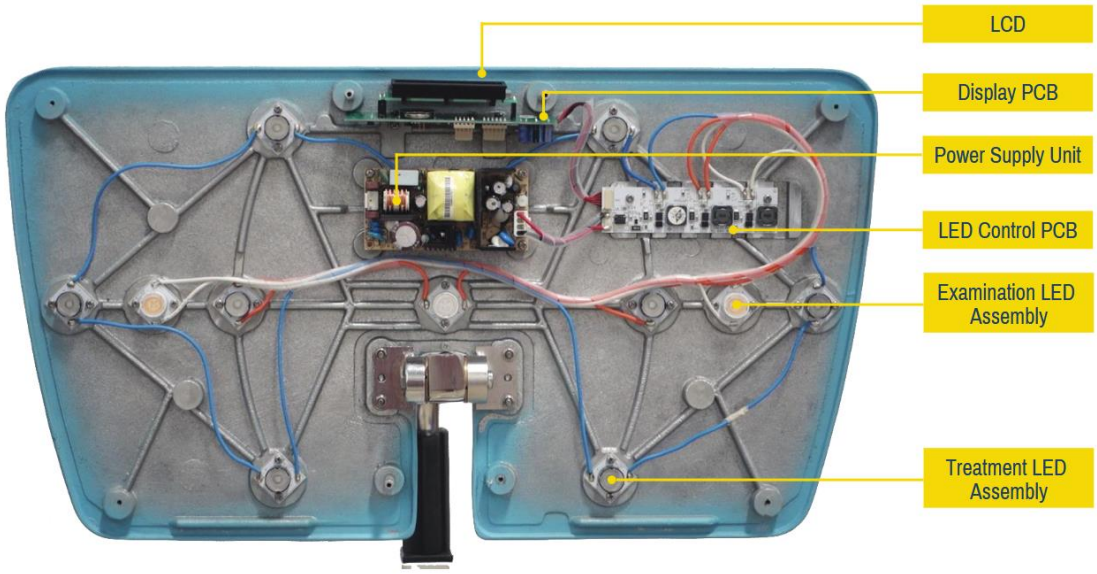


Figure 2-29 Internal components of a phototherapy light.

2.1.3.4 Preventive Maintenance

After Each Use

- ❖ Turn off and unplug phototherapy light. Use gauze and 70% alcohol or diluted chlorine to thoroughly wipe:
  - Phototherapy light meter, including cable and plug head if applicable
  - Control panel
  - Power button
  - Mattress and cot (if part of device)
- ❖ Visually inspect phototherapy light components.

Weekly

- ❖ Document cumulative hours run and preventive maintenance actions taken.
- ❖ Test the therapeutic irradiance of the phototherapy light:
  - Plug in phototherapy device. Turn on and check for blue light from the overhead light elements. NOTE: Some phototherapy lights may have white examination lights. In most models, if light emitting from this type of device is white, it is not therapeutic. Check the device manual or research the device to determine if the device is meant for phototherapy.
  - Turn on light meter if available. Read the irradiance in Standard Brilliance mode at 40 cm.

Monthly

- ❖ Perform Weekly preventive maintenance steps.
- ❖ Check the caster wheels for proper movement and brake functions.
- ❖ Document cumulative running hours and preventive maintenance actions taken.

Annually

- ❖ Perform Quarterly preventive maintenance steps.
- ❖ Confirm supply of spare power supply units, light meters, control PCBs, LEDs and power cables are adequate to support estimated replacement for next year.
- ❖ Document cumulative running hours and preventive maintenance actions taken.

2.1.4 calibration

Accurate medical calibration is vital for patient care and safety. Calibration ensures that medical devices used for diagnosis, treatment, and monitoring are performing correctly. Without proper calibration, there is a risk of incorrect diagnoses, ineffective treatments, and patient harm. This search explores the importance of medical calibration, the processes involved, and the challenges faced by healthcare providers.

2.1.4.1 Definition

Medical calibration is the process of ensuring that medical devices provide accurate and consistent readings by comparing them to a known standard. This is crucial for devices used in diagnosis, treatment, and monitoring to perform reliably. **Calibration ensures that the equipment is functioning correctly and providing precise measurements.**

2.1.4.2 Types of Medical Equipment Requiring Calibration:

Various types of medical equipment need regular calibration, including:

- Diagnostic tools like MRI machines, CT scanners, and X-ray machines.
- Treatment devices such as infusion pumps and radiation therapy machines.
- Monitoring equipment like ECG machines and blood pressure monitors.

2.1.4.3 role of calibration

1- Preventing Misdiagnoses

Calibration is crucial in preventing misdiagnoses. When medical equipment is not calibrated correctly, it can give inaccurate readings. **These incorrect readings can lead to wrong diagnoses**, which can harm patients. Regular calibration ensures that devices provide accurate data, helping doctors make the right decisions.

2- Avoiding Treatment Errors

Proper calibration also helps in avoiding treatment errors. If a device is not calibrated, it might deliver the wrong amount of medication or therapy. This can be dangerous for patients. By ensuring that all equipment is calibrated, healthcare providers can avoid these potentially life-threatening mistakes.

3- Maintaining Consistent Monitoring

Consistent monitoring of patients is essential for their safety. Calibrated equipment ensures that patient monitoring devices, like heart rate monitors and blood pressure cuffs, provide reliable data. This consistency helps in tracking a patient's condition accurately over time.

4- Initial Assessment and Baseline Measurement

The first step in the calibration process is the initial assessment. This involves evaluating the medical equipment to understand its current performance. Technicians measure the device's output and compare it to a known standard. This step helps in identifying any discrepancies or deviations from expected results.

5- Adjustment and Fine-Tuning

Once the initial assessment is complete, the next step is adjustment and fine-tuning. Technicians make necessary adjustments to the equipment to align its readings with the standard. This may involve tweaking settings or replacing parts. The goal is to ensure that the device provides accurate and reliable measurements.

6- Documentation and Compliance

The final step in the calibration process is documentation and compliance. Every adjustment and measurement taken during the calibration process is recorded. This documentation is crucial for ensuring transparency and traceability. It also helps in meeting regulatory requirements and maintaining compliance with healthcare standards.

2.1.4.4 Strategies for Effective Calibration

- Adherence to Manufacturer Guidelines: Follow the manufacturer's recommended calibration schedules and procedures for each device.
- Qualified Personnel: Ensure that skilled and certified professionals perform calibrations to maintain accuracy and compliance.
- Record-Keeping: Maintain comprehensive records of calibration schedules, procedures, and results for audits and compliance purposes.
- Regular Audits: Conduct periodic audits to assess the effectiveness of the calibration program and make necessary adjustments.
- Investment in Training and Technology: Continuously invest in training for staff and updated calibration technology to keep pace with advancements

2.1.4.5 Common Calibration Issues

Maintaining calibrated medical equipment is essential, but it comes with several challenges:

- **Frequency**: Determining how often to calibrate each device can be tricky. Factors like usage, environmental conditions, and manufacturer recommendations must be considered.
- **Cost and Resources**: Calibration needs specialized tools and trained personnel, sometimes requiring equipment to be sent to external facilities. This can be costly and logistically challenging for healthcare institutions.
- **Downtime:** During calibration, equipment might be unavailable, causing disruptions in patient care schedules.
- **Technological Advancements:** Keeping up with the latest calibration methods for newer equipment can be demanding.

2.1.4.6 Regulatory and Ethical Considerations

Compliance with Healthcare Standards

Medical devices must meet strict regulations to ensure they are safe and effective. These rules are set by international and national bodies like the **International Organization for Standardization (ISO)** and the Food and Drug Administration (FDA). Compliance with these standards is crucial to prevent **unfortunate incidents** and ensure patient safety.

Ethical Implications of Accurate Calibration

Accurate calibration of medical devices is not just a technical requirement but an ethical one. Algorithmic bias in AI systems, for example, can lead to disparities in healthcare. Ensuring devices are correctly calibrated helps in providing fair and equal treatment to all patients.

Legal Consequences of Neglect

Failing to properly calibrate medical devices can have serious legal consequences. Healthcare providers and manufacturers can face lawsuits and penalties if their devices cause harm due to improper calibration. Adhering to regulatory standards and guidelines is essential to avoid these legal issues.

2.2 Literature Review

2.2.1 Introduction

Premature infant care devices such as incubators, warmers, and phototherapy devices are widely used to improve the survival chances of newborns with health problems. The effectiveness of these devices depends on the accuracy of measuring thermal and optical indicators, however, studies show that the lack of regular calibration of these devices leads to treatment errors that may threaten the lives of children. This project aims to fill this gap by developing a portable, battery-operated calibration device that provides a practical and effective solution that meets the needs of hospitals in remote areas and enhances the accuracy of these devices.

The World Health Organization reports that 20-30% of medical errors in neonatal units are due to inaccurate incubators and phototherapy devices due to lack of calibration Accuracy of incubators and phototherapy devices due to lack of calibration [36].

2.2.2 The importance of the devices included in the project

- **Incubator**

The incubator provides a controlled environment for premature babies, and works to control temperature, humidity, air flow and sound intensity Any calibration error exposes babies to heat stress, infection, hearing problems or dehydration. Increasing the risk of heat stress A recent study suggests that temperature deviations in uncalibrated incubators can be as high as ±2°C [37].

- **Radiant Warmer**

Radiant warmers are used to regulate body temperature in premature infants Inaccurate

temperature measurements can who are at risk of hypothermia. lead to overheating or underheating, putting the baby at risk. 18% of warmers used in rural hospitals operate outside the permissible accuracy range due to lack of regular calibration. [38]

- **Phototherapy**

Used to treat neonatal jaundice by reducing bilirubin levels in the blood and The effectiveness of the device depends on the accuracy of the light intensity and wavelength, which are the two main factors in the effectiveness of the device. Low light intensity in uncalibrated phototherapy devices reduces the effectiveness of treatment by 30% [39].

2.2.3 Importance of Calibration in Medical Devices

Calibration is an essential process to ensure the accuracy of medical devices and improve treatment outcomes. Uncalibrated devices lead to inaccurate results, which increases the rates of medical complications in remote areas. Hospitals suffer from a lack of appropriate calibration equipment due to the high cost or complexity of the devices, and the importance of having a portable battery-powered device to perform calibration operations becomes increasingly important. 60% of hospitals in rural areas lack the necessary calibration devices to ensure the accuracy of medical devices [40].

2.2.4 Current technologies and their limitations

Current commercial calibration devices are expensive and complex and require constant power sources, making them unsuitable for use in remote areas. There are also no integrated devices to calibrate several types of devices such as incubators, warmers, and phototherapy in one device. Most calibration devices available in the market do not support integration with multiple devices and are not suitable for use in remote areas due to their reliance on electricity [41].

2.2.5 Importance of the project and the gaps it fills

- **Scientific aspects**

Providing a multi-functional device capable of calibrating various devices such as incubators, heating devices and phototherapy. Using modern technologies such as microcontrollers (ESP32) and providing accurate sensors to measure temperature, light, humidity, air flow and sound intensity.

- **Application aspects**

A portable battery-operated device, suitable for use in remote areas and hospitals with limited resources with a low cost compared to commercial devices, reducing medical risks resulting from uncalibrated medical devices. This project aims to provide a compact solution for calibrating medical devices in areas with limited capabilities, which reduces medical error rates and improves the quality of care [42].

2.3 Challenges and future trends

2.3.1 Challenges

- **Technical challenges**

  1- Accuracy in measurements Achieving high accuracy in calibrating different variables such as temperature, humidity, airflow, light intensity, and wavelength is complex, especially when multiple functions are integrated into a single device and sensor drift over time can affect the accuracy and reliability of the device. Maintaining calibration accuracy across multiple variables requires advanced sensors and frequent calibration [37].

  2- Integrating multiple functions Designing an integrated device that can calibrate incubators, heaters, and phototherapy devices without affecting performance and ensuring smooth interaction between sensors and the control system is among the challenges and difficulties.

  The main challenge in integrating multiple functions is to ensure consistency in performance and avoid interference [40].

  3- Battery Performance We developed a battery-powered device that provides long operating hours (4-6 hours) without compromising on performance accuracy and addressing the power consumption challenges resulting from multiple sensors and a digital user interface. Power efficiency is a critical factor in portable medical devices, especially those intended for remote areas [42].

- **Financial Challenges and Resources**

  Cost management and balancing cost and performance to keep the device within a $500 budget while maintaining quality and reliability and providing high-quality sensors and components at reasonable prices, especially in resource-constrained environments. Low-cost medical devices face significant challenges in achieving cost efficiency without sacrificing functionality [41].

- **Regulatory challenges**
  It is compliance with the required standards to ensure safety, reliability and adherence to strict international standards such as (ISO 13485).

- **Environmental challenges**
  Portability and durability to ensure that the device is lightweight and durable enough for use in rural and remote environments and to design a device that adapts to the environment and operates reliably in a variety of environmental conditions, including high humidity, changing temperatures, and other factors.

2.3.2 Future trends

Improving accuracy and performance by developing advanced sensors that reduce measurement deviation over time to improve the accuracy and reliability of calibrators, integrating artificial intelligence algorithms to detect errors in real time and adjust calibration automatically, and improving energy efficiency by obtaining innovative batteries such as lithium polymer batteries or solid-state batteries to increase operating time and using low-energy components and high-efficiency sensors to reduce energy consumption. Expanding the capabilities and integration of the device to include calibration of other medical devices for neonatal and pediatric care and designing a modular system that allows the device to be easily updated or integrated with hospital management systems. Also, enhancing accessibility by developing low-cost manufacturing techniques to make the device available to resource-limited healthcare environments and collaborating with non-profit organizations to subsidize the cost of the devices for hospitals in developing regions.

2.4 Conclusion:

this chapter has demonstrated how a multifunctional, user-friendly, and cost-effective portable calibration device can bridge existing gaps in medical device calibration for infant incubators, radiant warmers, and phototherapy units. Despite the technical, financial, regulatory, and environmental hurdles inherent to its development, these challenges serve as catalysts for innovation. By focusing on enhanced accuracy, energy efficiency, and broad accessibility, the proposed device not only addresses critical calibration needs today but also paves the way for more reliable and equitable neonatal care across diverse clinical settings.

Chapter 3

Project Design

Chapter 3: Project Design

3.1 Introduction

This chapter dives deep into the hardware components that form the foundation of this project. We'll meticulously dissect each component, exploring its functionalities and its applications.

3.2 calibration devices to measure infant incubator, infant warmer and phototherapy parameter according to IEC standards.

- **INCU Incubator Analyzer**

Figure 3-1 INCU Incubator Analyzer

The INCU incubator analyzer is designed to test and perform preventative maintenance on infant incubators and radiant warmers while simultaneously measuring airflow, relative humidity, sound, and four independent temperatures, the INCU fits inside the incubator and operates as a stand-alone device or with a personal computer for automated testing, INCU software lets technicians upload setup parameters and download the test results to a PC file, or print the data in reports with full-color charts and graphs.

- **INCU II Incubator - Radiant Warmer Analyzer**

Testing incubators and radiant warmers regularly is essential to validate their performance and ensure the safety and comfort of infants, The Fluke Biomedical INCU II Incubator/Radiant Warmer Analyzer simplifies testing and verifying baby incubators, transport incubators, and radiant warmers are safe and conform to global IEC 60601-2- 19 and IEC 60601-2-21 performance standards, Portable

and intuitive-to-use, with a large easy-to-ready LCD screen, the INCU II incubator tester operates as a stand-alone device, simultaneously testing, and storing temperature, airflow, sound, humidity, and other common environmental and operational parameters. Along with standard tests, its on-

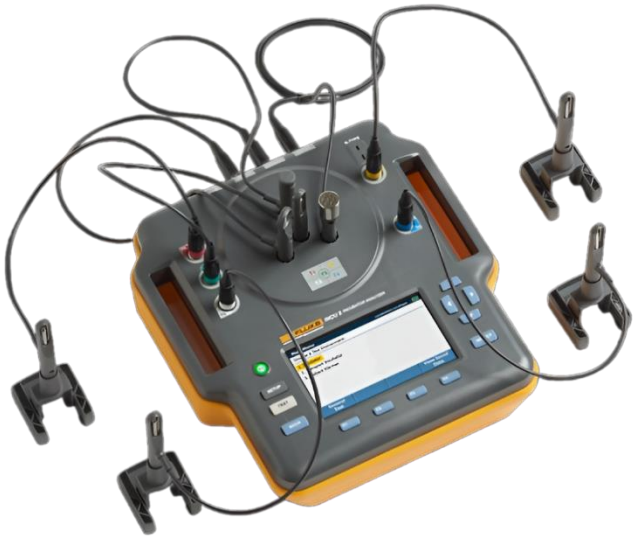


Figure 3-2 INCU II Incubator - Radiant Warmer Analyzer

board automation lets you create customized test groups; The INCU II incubator analyzer also simplifies test analysis and reporting. Not only are real-time results displayed, but Pass/Fail indicators make it quick to troubleshoot, and pinpoint issues. An Excel add-in allows for detailed test analysis with visual graphs, and the option of creating one-off and standardized reports.

Pairing the Skin Temperature Heater Assembly (STHA) Accessory with the INCU II, the accuracy of the incubator/radiant warmer's skin temperature probe can be measured within minutes. However, despite the vast amount of research in humans and animals concerning mechanisms of action, biological effects, complications, and clinical application, there is a considerable dearth of information about how phototherapy acts, what is the ideal dose to ensure clinical efficacy and how it should be administered.

- **DALE 40 Phototherapy analyzer**

Figure 3-3 DALE 40 Phototherapy analyzer

The DALE40 Phototherapy Radiometer is designed for the accurate measurement of light radiation in the blue part of the spectrum from 400 to 480 nanometers, Phototherapy exposure in this range is used in the treatment of hyperbilirubinemia in newborn children.

The DALE40 provides continuous measurement of irradiation by simply placing the detection probe under the phototherapy light (fluorescent lamps only). In addition to verifying output power, the DALE40 saves costs by eliminating premature replacement of lamps. Light measurement is according to the percent response given the wavelength characteristics curve. The detector probe, included with the unit, has a wide angle lens which matches the cosine receiving function of human skin.

3.3 Hardware component

3.3.1 power supply

Figure 3-4 power supply

The device is powered by rechargeable batteries that ensure continuous operation during use. A dedicated charging and discharging circuit is integrated into the system to manage battery health and provide stable voltage levels to the components. The power supply unit includes a standard charger, which replenishes the batteries when connected to an external power source. This design allows the device to operate independently without being tethered to a power outlet, making it suitable for mobile or emergency medical environments such as neonatal intensive care units (NICUs).

3.3.2 step-down transformer

Dc to Dc, from 24v, 12v to 5v, 9v and universal serial bus (USB) power supply step down voltage regulator convertor which supplies the circuit.

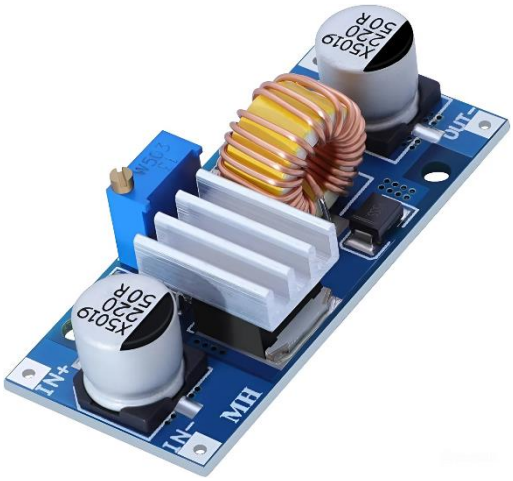


Figure 3-5 step-down transformer

3.3.3 ESP32 (Microcontroller unit)

The ESP32 is an advanced microcontroller chip developed by Espressif Systems, designed to provide integrated solutions for Internet of Things applications.

It features a dual-core Xtensa LX6 processor operating at up to 240 MHz and supports Wi-Fi and Bluetooth (classic and BLE) wireless communication technologies, making it an ideal platform for developing smart, connected devices

Figure 3-6 ESP32 (Microcontroller unit)

- **Kay Features**

1. Wireless Communication Support: It features built-in Wi-Fi and Bluetooth to facilitate data exchange with servers or other devices.
2. High Performance: Thanks to its dual-core processor, the module can perform data processing operations with high efficiency.
3. Programming Flexibility: It can be programmed using various environments, such as the Arduino IDE, ESP-IDF, and Micro Python.
4. Support for multiple interfaces: including UART, I2C, SPI, PWM, ADC, and DAC, allowing communication with various types of sensors and actuators.
5. Small size and low power consumption: making them suitable for wearable or battery-powered applications.
6. Internal flash memory: These often come in capacities ranging from 4 to 16 MB, allowing for the storage of programs and data.

- **Applications**

1. Monitoring vital signs: such as heart rate, oxygen saturation (SpO2), and temperature using medical sensors.
2. Telehealth systems: to measure and collect patient data and transmit it to doctors and healthcare centers via the internet.
3. Smart alert systems: such as low blood sugar or high blood pressure alerts.
4. Smart measuring devices: such as digital thermometers and respiratory rate monitors.
5. Environmental monitoring in patient rooms: by measuring temperature, humidity, ventilation, and air quality.

6. Intelligent control of medical devices: such as drug pumps or smart intravenous infusion systems.
7. Mobile robots and autonomous vehicles (AGVs): Navigation management and remote sensing connectivity via Wi-Fi or BLE-Mesh.
8. Energy management and smart meters: Measure power and quality (PF, frequency) and send data to SCADA or the cloud for peak reduction.
9. Safety and access control systems: Wireless emergency stop buttons and RFID/BLE systems for controlling equipment operation and recording events.
10. Environmental and emissions monitoring: Measure gases (CO_2, VOC) and fine particulate matter (PM2.5) and send alerts when limits are exceeded.

3.3.4 HTML user interface:

HTML user interfaces form the foundation for web-based applications, providing the structure and presentation layer that users interact with online. When integrated with the ESP32 microcontroller, they open new horizons for embedded applications and the Internet of Things (IoT).

The HTML user interface is the visual and interactive part of a web application built using Hypertext Markup Language (HTML), typically enhanced with CSS for styling and JavaScript for dynamic behavior. This interface defines the elements that users see and interact with in their browsers, from texts and images to forms and navigation components. When used with the ESP32, it allows control over physical devices.

- **Kay Features**

1. ESP32 Compatibility: A small web server can be hosted on the ESP32 to serve HTML interfaces.
2. Device Control: Ability to control sensors and actuators connected to the ESP32 through the web interface.
3. Wireless Connectivity: Leverage the built-in WiFi and Bluetooth capabilities of the ESP32.
4. Low Power Consumption: Design simple interfaces suitable for the limited resources of the ESP32.
5. Real-Time Data Processing: Display and update sensor data instantly.
6. Responsive Design: Adapt the display to various screen sizes using CSS media queries.
7. Remote Control: Access devices connected to the ESP32 over the internet.

- **Applications**

1. Smart home systems and control of household devices.
2. Environmental monitoring stations for measuring temperature, humidity, and air quality.

3. Smart irrigation systems and agricultural control.
4. Energy monitoring and management.
5. Industrial control and automation.
6. Security and surveillance systems.
7. Connected medical devices and health monitoring.
8. Robot control interfaces.
9. Low-cost IoT applications.
10. Location tracking and navigation systems.

3.3.5 Sensors Used:

3.3.5.1 DSI18B20 Digital Temperature Sensors:-

The DS18B20 (often typed as "DSI18B20") is a waterproof, 1-wire digital temperature sensor from Maxim Integrated/Dallas. Key points:

- Digital output: communicates over a single data line (plus ground), using the "1-Wire" bus protocol.
- Temperature range: −55 °C to +125 °C.
- Resolution: user-selectable from 9 to 12 bits (0.5 °C down to 0.0625 °C steps).
- Unique 64-bit ROM ID: each device can be individually addressed on a shared bus.
- Power options: powered conventionally (3.0–5.5 V) or "parasite-powered" from the data line.

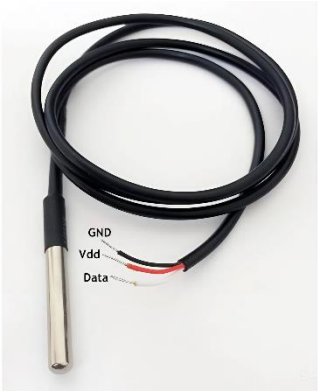


Figure 3-7 DSI18B20

- **Kay Features**

1. Simplicity & wiring economy: Only two wires (data + ground) needed, even when chaining dozens of sensors on one bus.
2. High accuracy & resolution: ±0.5 °C accuracy over –10 °C to +85 °C, with up to 0.0625 °C resolution at 12-bit.
3. Unique addressing: Each sensor's built-in 64-bit ID makes multi-point measurements easy without extra chip-select lines.
4. Wide operating range Operates from −55 °C up to +125 °C, suitable for harsh or sterilization-cycle environments.
5. Waterproof probe options: Pre-packaged in stainless steel housings for direct immersion in fluids or chamber monitoring.

6. Low cost & readily available: Widely used in hobbyist, industrial and medical fields—$2–5 per sensor in single quantities.

- **Applications**

1. Incubator & O_2 chamber control Precise monitoring of air and fluid temperatures to keep neonatal/patient-isolation chambers within ±0.5 °C.
2. IV fluid-warmer feedback: Inline probes ensure warmed saline or blood products remain in safe temperature bands before delivery.
3. Cryotherapy and sterilization cycles: Validation of −55 °C cooling or +121 °C autoclave profiles, thanks to the wide operating range.
4. Portable patient monitors: Ambient and skin-contact probes feed into microcontrollers (e.g. ESP32, STM32) for real-time display.
5. Lab instruments & analytical devices: PCR machines, calorimeters or spectrophotometers use DS18B20s for block-temperature stability.
6. Cold-chain tracking: Data-logging of vaccine or reagent temperatures during transport, with multi-sensor arrays on one bus.

3.3.5.2 humidity sensor (DHT22)

The DHT22 (also known as AM2302) is a low-cost digital sensor that measures both temperature and relative humidity. Internally, it combines a capacitive humidity sensing element with a thermistor for temperature measurement. The sensor's microcontroller samples the analog signals, converts them to digital form, and transmits a calibrated 40-bit data packet over a single-wire serial interface.
Typical specifications include:

1. Humidity range: 0 – 100 % RH
2. Humidity accuracy: ±2 % RH (20 – 80 % RH)
3. Temperature range: −40 °C – +80 °C
4. Temperature accuracy: ±0.5 °C
5. Resolution: 0.1 °C / 0.1 % RH
6. Sampling rate: ~0.5 Hz (once every 2 s)

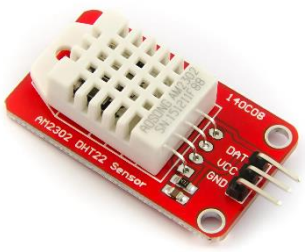


Figure 3-8 humidity sensor (DHT22)

- **Key Future**

1. Digital Output & Simplicity: Single-wire digital protocol eliminates the need for external ADCs, simplifying microcontroller interfaces.
2. Good Accuracy & Resolution: ±2 % RH and ±0.5 °C provide reliable environmental data for most engineering applications.
3. Wide Operating Range: Operates from −40 °C to +80 °C and 0 – 100 % RH, suitable for indoor and many outdoor conditions.
4. Low Power Consumption: Standby current is typically under 50 µA, making it suitable for battery-powered or portable devices.
5. Cost-Effective & Readily Available: Widely produced and inexpensive (< $10 USD), with robust community support and libraries for Arduino, Raspberry Pi, and other platforms.
6. Compact Form Factor: Roughly 15 mm × 25 mm × 7 mm, easily integrated into compact medical or wearable systems.

- **Applications**

1. Incubator & Neonatal Care: Continuous monitoring of temperature and humidity in infant incubators to ensure neonatal safety and comfort.
2. Pharmacy & Vaccine Storage: Environmental logging in refrigerators or storage cabinets to maintain cold-chain integrity for temperature-sensitive medications and vaccines.
3. Hospital HVAC Monitoring: Feedback for climate control systems in operating rooms, patient wards, or isolation rooms to reduce infection risks and improve patient comfort.
4. Laboratory Environmental Chambers: Maintaining strict humidity and temperature profiles for biological assays, cell cultures, or reagent storage.
5. Wearable Health Devices: Integration into smart patches or portable monitors for personal environmental exposure logging in respiratory therapy or allergy management.
6. Telemedicine & Remote Patient Monitoring: IoT-enabled modules that relay environmental data alongside physiological metrics (e.g., a home spirometer with ambient logging).

3.3.5.3 Flow Rate Sensor (F662).

The F662 is the vertical-profile variant of Degree Controls' F660/F662 board-mounted digital air-velocity sensor platform. It combines dual-element thermal sensing to measure airflow velocity and temperature in a tiny footprint (7 × 10 mm), and can be soldered directly to a PCB or plugged into a surface-mount socket for easy service. In its default mode it communicates velocity readings over UART (3.3 V TTL), or—with a simple resistor on the address pin—over I²C (up to 32 devices on one bus). It operates from a 5 V DC supply and covers velocities from 0.15 m/s to 20 m/s (30–4 000 fpm), with ±5 % of reading accuracy ± offset.

Figure 3-9 Flow Rate Sensor (F662)

- **Key Futures**

1. Ultra-compact & board-mountable: Smallest footprint (7 × 10 mm) maximizes placement flexibility inside tight electronics or ducted assemblies.
2. Wide, accurate range: Measures 0.15–20 m/s (30–4 000 fpm) with up to ±5 % of reading ± offset, suitable for low to high-velocity applications.
3. Dual sensing (velocity + temperature): Integrated temperature compensation ensures consistent readings across –5 °C to +60 °C ambient.
4. Digital interface & multi-drop capability: Native UART for simple point-to-point links, or I²C (via address-setting resistor) for up to 32 sensors on one bus.
5. Low power & fast response: Refresh time ≈ 400ms, and only milliamps of standby current—ideal for battery-powered or always-on systems.
6. Serviceable design: Can be wave-soldered or socketed for field replacement without reflow.

- **Applications**

1. Ventilators & Anesthesia Machines: Monitoring inspiratory/expiratory flow for precise tidal-volume delivery and alarm triggering.
2. CPAP/BiPAP Respiratory Therapy: Tracking airflow to maintain set positive airway pressures and detect mask leaks.
3. Spirometry & Pulmonary Function Testing: Capturing patient breath profiles and flow-volume loops for diagnostics.
4. Clean-air Hoods & Incubators: Ensuring proper laminar airflow rates in neonatal or isolation chambers.
5. Electronics Cooling in Medical Devices: Guard-banding internal board temperatures by watching cooling-fan airflow across PCBs.

3.3.5.4 Sound Sensor (LM363)

The LM363 sound sensor module is a compact, low-power circuit designed to detect ambient sound intensity and translate it into electrical signals. At its core is an electret condenser microphone that picks up pressure variations, followed by an onboard

op-amp (typically an LM393 comparator) and peak-detection circuitry. The module runs from 3.3 V to 5 V, exposes both:

- Analog Output (AO): a voltage proportional to the instantaneous sound amplitude
- Digital Output (DO): a binary HIGH/LOW signal whenever the sound level crosses a user-set threshold (adjustable via a trimmer potentiometer).

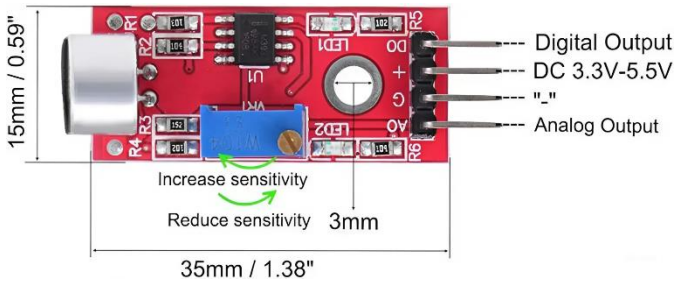


Figure 3-10 Sound Sensor (LM363)

- **Key Futures**

1. Dual-Mode Output: Offers both analog (continuous measurement) and digital (threshold-triggered) outputs for flexible interfacing.
2. Adjustable Sensitivity: Onboard potentiometer lets you fine-tune the trigger level, accommodating environments from quiet labs to noisy workshops.
3. Microcontroller-Friendly: Simple 4-pin interface (VCC, GND, AO, DO) makes it plug-and-play with Arduino, Raspberry Pi, STM32, etc.
4. Low Cost & Low Power: Typically, under $5 and draws only a few milliamps, ideal for battery-powered and large-scale deployments.
5. Compact & Rugged: PCB size around 3.4 × 1.6 cm with a mounting hole for easy chassis integration.

- **Applications**

1- General Prototyping & DIY

- Noise-Activated Switches: Clap- or voice-triggered lights, fans, or door locks.
- Audio Level Meter: Simple VU-meter visualizers with LEDs or analog gauges.
- Security & Alarm Systems: Trigger sirens or cameras when unexpected loud noises occur.
- Robotics & IoT: Enable sound-responsive behaviors in robots or networked sensors (e.g., turning on a recording when noise spikes).

2- Medical Equipment Prototyping

- Cough & Respiration Monitoring: Early-stage designs for tracking patient cough frequency or snore detection in sleep studies.

- Patient-Assist Controls: Voice-activated call buttons or environmental controls for mobility-limited users.

- Hospital Noise Monitoring: Baseline devices to log and alert when sound levels in ICUs or wards exceed recommended limits.
- Rehabilitation & Speech Therapy Aids: Simple feedback tools for patients practicing vocal exercises.

3.3.5.5 Skin Temperature (MLX90614).

The MLX90614 is a factory-calibrated, digital infrared (IR) thermometer sensor designed by Melexis. It measures object temperature without contact by detecting the infrared energy emitted by the surface. Internally, it incorporates:

1. A thermopile IR detector
2. A 17-bit analog-to-digital converter (ADC)
3. An integrated signal conditioning unit
4. A non-volatile EEPROM for calibration and configuration data
5. A digital communication interface (SMBus/I²C)
6. Key specifications include a typical measurement range of −70 °C to +380 °C, an accuracy of ±0.5 °C (in the 0 °C to +50 °C range), and a resolution of 0.02 °C.

Figure 3-11 Skin Temperature (MLX90614).

- **Key Futures**

1. Non-contact measurement
- Eliminates risk of cross-contamination and infection (critical for medical use)
- Suitable for moving or hard-to-reach objects

2. High accuracy & resolution
- ±0.5 °C accuracy in core body-temperature range
- 0.02 °C resolution for fine temperature differentials

3. Digital output & easy interfacing
- SMBus/I²C interface simplifies integration with microcontrollers (e.g., Arduino, STM32)
- 17-bit ADC yields a wide dynamic range

4. Low power consumption
- Typical supply current ~600 µA (standby)
- Ideal for battery-powered or portable devices

5. Compact, robust package
- TO-39 metal can or SMD package options
- Wide ambient operating range (−40 °C to +125 °C)

6. On-board calibration & emissivity setting

- Factory calibration against black-body standards
- Programmable emissivity register allows compensation for different surface materials.

- **Applications**

1. Medical thermometry

- Forehead and skin-temperature contactless thermometers.
- Neonatal incubator surface monitoring.
- Patient monitoring pads.

2. Building automation & HVAC

- Air-duct temperature sensing.
- Occupancy-based climate control.

3. Industrial temperature monitoring

- Motor windings and bearing surface checks.
- Hot-spot detection in electrical panels.

4. Consumer electronics & appliances

- Infrared thermometers for cooking/grilling.
- Smart home temperature sensors.

5. Automotive systems

- Cabin temperature comfort sensors.
- Battery-pack thermal monitoring.

6. Research & robotics

- Temperature feedback for robotic grasping tasks.
- Environmental sensing in drones or unmanned vehicles.

3.3.5.6 Phototherapy Sensor (AS7262)

The AS7262 is a compact, six-channel digital spectral sensor from ams OSRAM, designed to measure discrete bands across the visible light range. It integrates six filtered photodiodes (centered at roughly 450 nm, 500 nm, 550 nm, 570 nm, 600 nm, and 610 nm), an onboard ADC, and an I²C interface. In a phototherapy context, it can be used to monitor the spectral quality and intensity of therapeutic lamps (e.g., blue light for neonatal jaundice, red/near-infrared for wound healing).

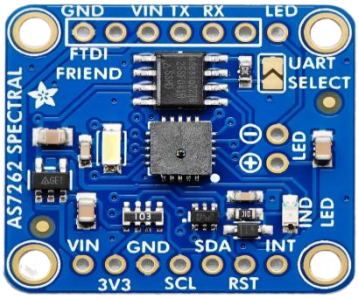


Figure 3-12 Phototherapy Sensor (AS7262)

- **Key Futures**

1. Narrow-Band Spectral Resolution: Allows precise monitoring of the specific therapeutic wavelengths (e.g. ~460 nm for bilirubin breakdown, ~630 nm for photo biomodulation).
2. Digital, Calibrated Output: Onboard ADC and factory calibration deliver direct readings in spectral radiance/counts without external amplification.
3. I²C-Bus Interface: Simple two-wire connection (SDA/SCL), easily integrates with microcontrollers (Arduino, STM32, Raspberry Pi).
4. Compact & Low-Power: Module footprint ~5 × 5 mm; typical current draw < 10 mA, ideal for portable or battery-operated phototherapy devices.
5. Programmable Integration & Gain: Software-selectable integration times (2 ms to 1 s) and gain settings (×1 to ×64) enable adaptation to both low- and high-intensity light sources.

- **Applications**

1. Neonatal Jaundice Phototherapy: Real-time monitoring of blue-light irradiance (~460 nm) to ensure therapeutic dose while avoiding over-exposure.
2. Dermatological Photo biomodulation: Calibration and feedback control for red (~630 nm) and near-infrared light sources used in wound healing and anti-inflammatory treatments.
3. UV-Free “Visible” Phototherapy: Devices targeting psoriasis or eczema that employ visible wavelengths; the AS7262 can verify output in the 550–610 nm bands.
4. Research & Development: Laboratory characterization of new lamps, LEDs or fiber-optic delivery systems for photomedicine.
5. Portable/Home-Use Devices: Integration into wearable or handheld phototherapy units to provide patient feedback on delivered dose and lamp degradation over time.
6. Multi-Modal Treatment Systems: Coordinating different spectral channels (blue, green, red) in combination therapies—e.g., simultaneous antimicrobial (blue) and healing (red) light.

Chapter 4

Implementation and Test

Chapter 4: Implementation and Test

4.1 Introduction

The implementation and testing phase of this project constitutes a pivotal milestone in realizing the vision of an automated calibration system that ensures the safety and quality of infant incubators, warmers, and phototherapy devices. This chapter delves into the detailed processes for integrating sensing and automated-control technologies alongside advanced calibration standards, with the objective of improving the efficiency and precision of incubators, warmers, and phototherapy units while ensuring full compliance with established safety requirements in neonatal care. By examining testing methodologies, calibration challenges, and field-validation results, this chapter provides a comprehensive overview of how theoretical concepts are translated into tangible, practical innovations that enhance the reliability of medical equipment for newborns.

4.2 Block diagram

This section describes the block diagram of components and connections between each component.

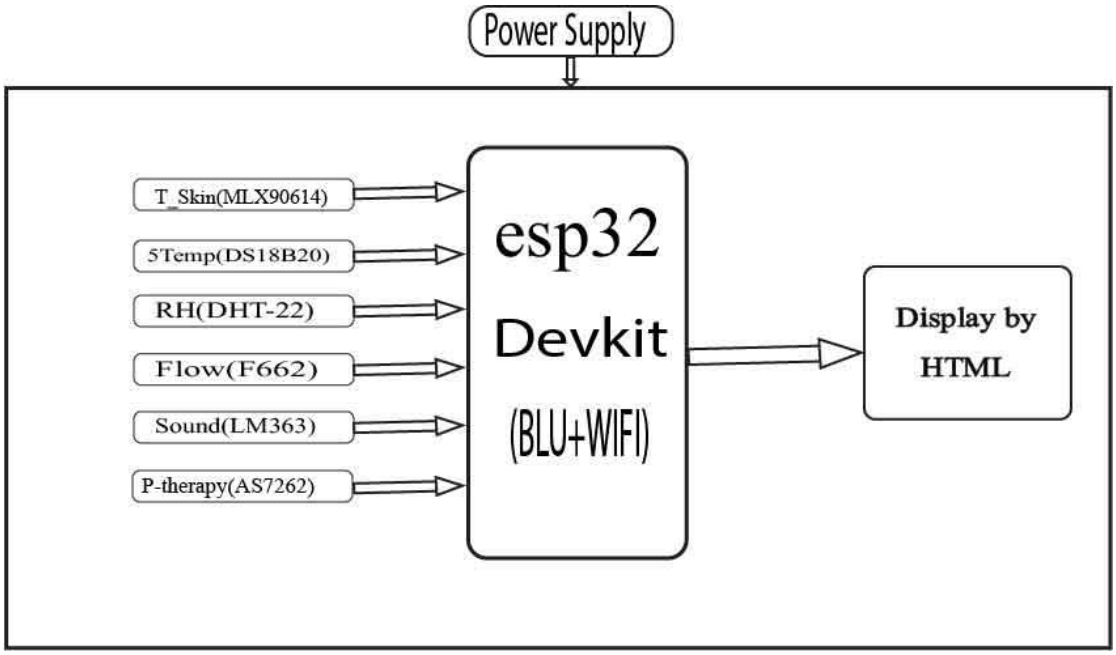


Figure 4-1 Block diagram

4.3 system architecture:

4.3.1 Hardware Components:

1. Sensors: This may include Temperature (skin, environment), flow rate, humidity, light and sound.

2. Control and Signal Processing Unit: This may include Microcontrollers(esp32)
3. User Interface and Data Logging: This may include an HTML-based display interface (accessed via a web browser or local network), input interface (touchscreen), and communication ports (USB, Bluetooth, or Wi-Fi).
4. Power Supply: This may include Main Power Supply and Backup Battery.
5. Fixed and Adjustable Structure: This may include External Structure (Aluminum or Reinforced Plastic) and Insulating Shell.

4.3.2 Software Components:

The Component	**Main Function**
User Interface (UI)	Display values, receive commands, navigate calibration menus
Main Control Unit	Manage workflow, schedule calibration, coordinate components
Sensor Reading	Receive sensor readings (temperature, humidity, light, sound, Air Flow)
Data Processing	Filter, convert, and calibrate sensor data
Calibration Algorithms	Execute calculations and standards for each device
Logging and Storage System	Save calibration results for documentation or export
Reporting System	Generate and display calibration reports
Communication Unit	Transfer data (USB, Wi-Fi, Bluetooth) or receive updates

Table 4-1 Software Components

4.3.3 Inputs

- Sensor readings: these include (temperature, humidity, light intensity, Sound and airflow or pressure).
- User commands (device selection, start/stop calibration, reference input).
- Calibration standards (reference values for comparison).

4.3.4 Outputs

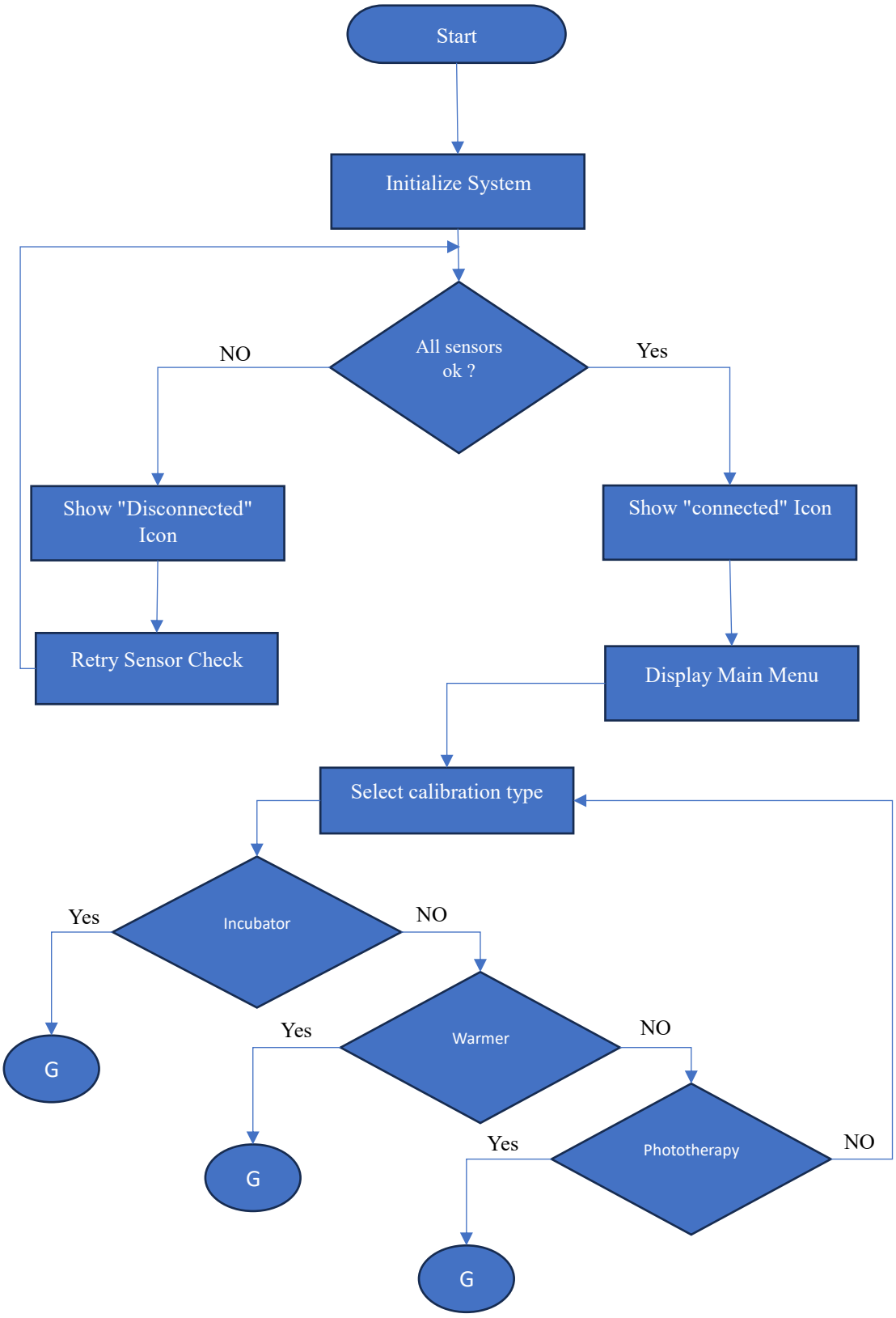
- Displayed results on the screen (temperature/humidity/light values/Sound level/air flow, calibration status).
- Calibration reports (PDF/CSV file or printout).
- Data transfer to computer or mobile device (USB/Bluetooth/Wi-Fi).

4.3.5 Processing Unit

- **Microcontroller (ESP32).**

  - Runs all software modules.
  - Interfaces with sensors, storage, and communication ports.
  - Executes calibration algorithms in real-time.
  - Must have enough ports and processing power for all required tasks.
  - Supports external communication.

4.4 Flow Chart



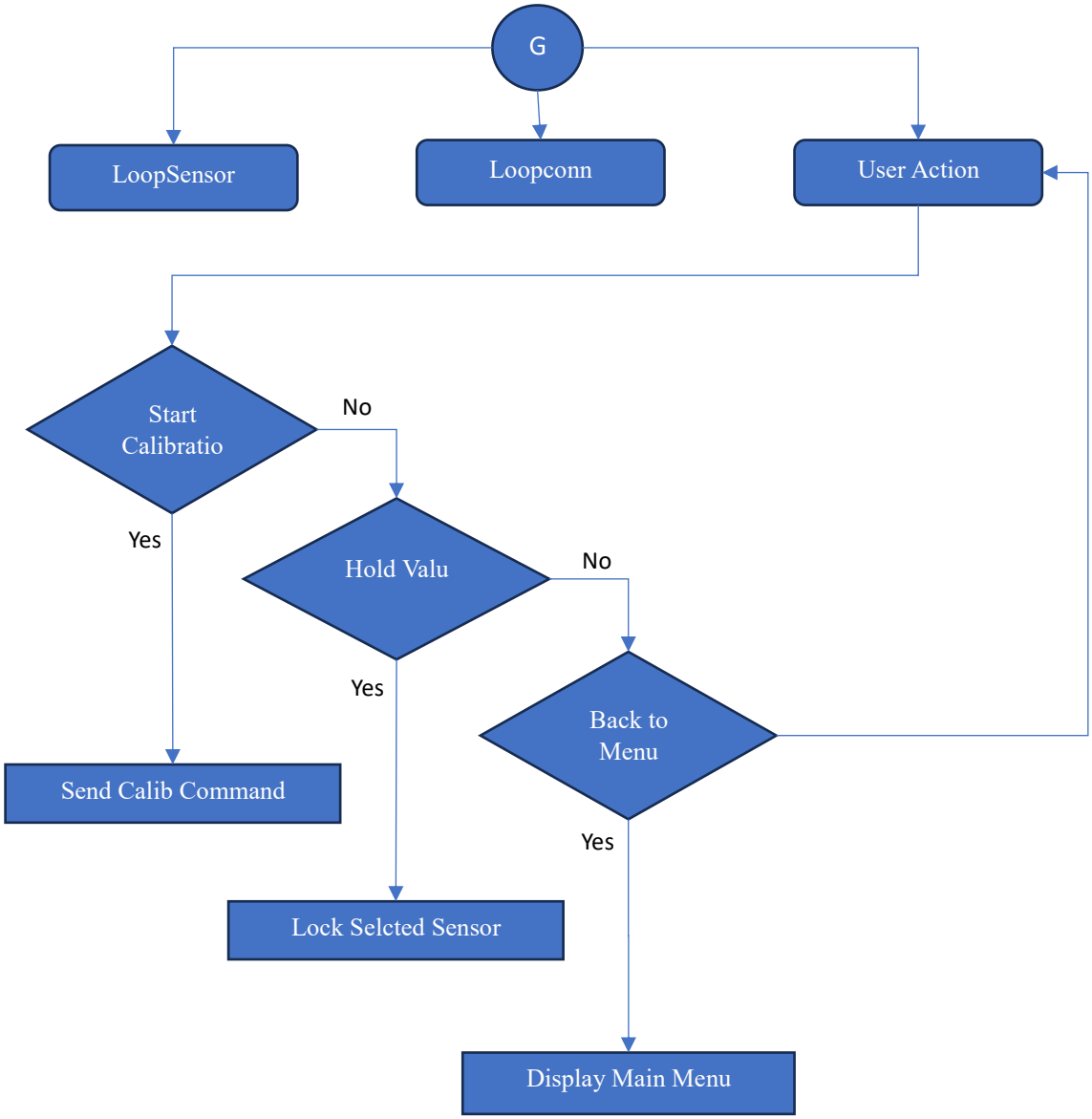


Figure 4-2 Flow Chart

4.5 Calibration Accuracy Classification

4.5.1 Introduction

Calibration accuracy is a fundamental element in ensuring the safety and efficiency of medical devices, as the quality of medical results directly depends on the accuracy of measurements. The classification of calibration accuracy begins with collecting pre-calibration information, which includes the device's technical specifications, manufacturer recommendations, and operating conditions. A general procedure is then followed to obtain results by comparing measured values with reference values using approved calibration models such as standard solutions or reference measuring devices. Finally, a thorough review process is conducted to ensure the results comply with the required standards, guaranteeing the device's reliable performance and safe continued use.

4.5.2 General diagram for result analysis.

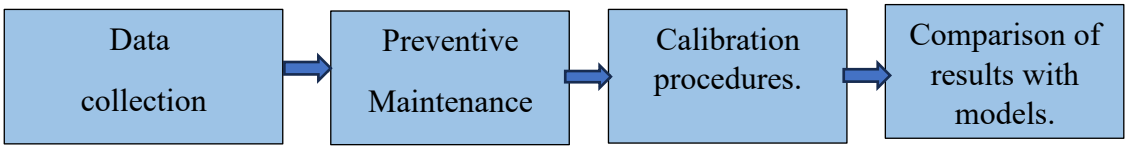


Figure 4-3 General diagram for result analysis

4.5.3 Pre-Calibration Information

- **Physical condition**
  - No physical damage to case, display, mounts, cart, or components.
  - Switches and controls operable and correctly aligned.
  - Display intensity adequate for daytime use.
  - Control numbers, labeling, and warnings present and legible.
  - Inlets and hoses.
  - Power cord, accessory cables, charge.
  - Filters and vents clean

- **Electrical safety**
  Electrical safety is calibrated using a specialized device designed to assess and verify electrical safety parameters. This device measures the integrity of the electrical current, the ground (earth) current, and the leakage current to ensure compliance with safety standards.

- **Preventive Maintenance.**

1. Infant incubator and Radiant Warmer :-
   - Clean cooling vents and filters.
   - Inspect and clean ducts, heater, and fans.
   - Inspect gaskets for signs of deterioration.
   - Inspect port closures and port sleeves.
   - Replace battery every 24 months.
   - Complete model-specific preventive maintenance.

2.Phototherapy Unit :-

- Inspect bulbs.
- Complete model-specific preventive maintenance.

4.5.4 Calibration Models

- **Infant Incubator**

Performance testing
Verify unit operates on battery
Fan operation
Warm up time ± 20 %
Air temperature accuracy ± 1 °C
Skin temperature accuracy ± 0.3 °C
Temperature overshoot ± 2 °C
Relative humidity ± 10 %
Air flow <0.35 m/s
Air temperature alarms set incubator @ 36
Skin temperature alarms set incubator in skin mode @ 36
High temperature protection <40 °C
Noise level <60 dB normal conditions
Alarm function
Complete model-specific performance testing

Figure 4-4 performance testing of infant incubator

- **Radiant Warmer**

Performance testing
Verify unit operates on battery
Fan operation
Temperature accuracy ± 0.3 °C
Temperature alarms
Alarm function
Complete model-specific performance testing

Figure 4-5 performance testing of radiant warmer

- **Phototherapy**

Performance testing
Timer accuracy ± 0.5 %
Output accuracy (> 198 µW/cm2) (< 1760 µW/cm2)
Alarm function
Complete model-specific performance testing

Figure 4-6 performance testing of phototherapy

4.5.5 Calibration procedures and comparison of results with benchmarks.

1. Data collection, electrical safety procedures, and routine maintenance of the medical device.
2. Operating the calibration device and the medical device (incubator, warmer, and phototherapy).

3. Preparing the calibration device and installing the sensors in their correct positions.
4. Applying the calibration steps according to the specific form for international standards and calculating the error rate based on reference results.

Chapter 5

Results and Discussion

Chapter 5: Results and Discussion

5.1 Introduction:

In this chapter, the results obtained from the development and evaluation of the integrated calibration device—which combines the infant incubator, radiant warmer, and phototherapy unit—are presented and analyzed. The effectiveness, accuracy, and ease of use of the device were studied through a series of tests and comparisons with standard calibration procedures, with the Fluke device adopted as a reference standard for measurements. Additionally, the challenges faced by the team during the implementation and testing phases are discussed to provide a comprehensive understanding of the strengths and limitations of the device. This chapter also explores the potential implications of these findings within the context of neonatal care and medical equipment calibration, and suggests possible directions for future improvement and research.

5.2 Comparison the Results (Experimental Results of the Integrated Device and Comparison of results with the Fluke device).

5.2.1 Calibration Results for the Infant Incubator

- **Temperature Sensors (DS18B20)**

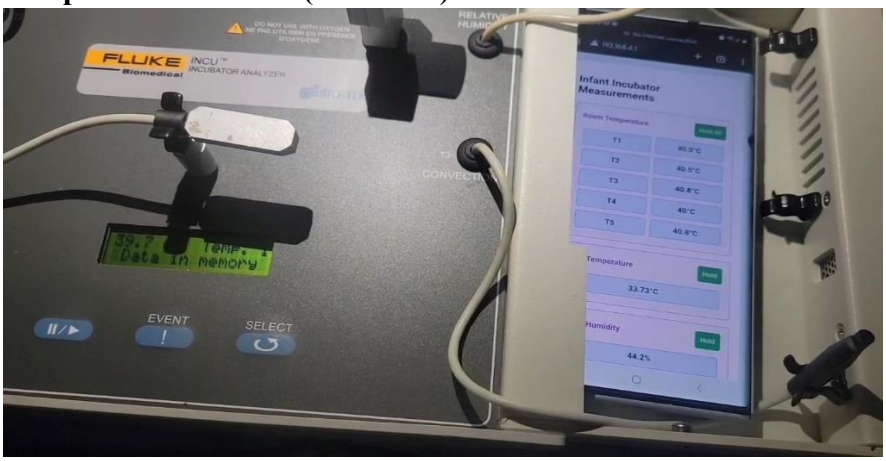


Figure 5-1 Temperature Sensors (DS18B20)

Sensor	Value	Fluck	Error
T1	40.5 C	39.7 C	1.97%
	37.7 C	37.4 C	0.79%
	37.5 C	37.3 C	0.53%
T2	40.5 C	39.7 C	1.97%
	37.7 C	37.4 C	0.79%

	37.5 C	**37.3 C**	**0.53%**
T3	**40.8 C**	**39.7 C**	**2.69%**
	38 C	**37.4 C**	**1.57%**
	37.7 C	**37.3 C**	**1.06%**
T4	**40 C**	**39.7 C**	**0.75%**
	37.7 C	**37.4 C**	**0.79%**
	37.7 C	**37.3 C**	**1.06%**
T5	**40.8 C**	**39.7 C**	**2.69%**
	36.5 C	**37.4 C**	**-2.46%**
	36.7 C	**37.3 C**	**-1.63%**

Table 5-1 Temperature Sensors (DS18B20)

- **Relative Humidity Sensor (DHT-22)**

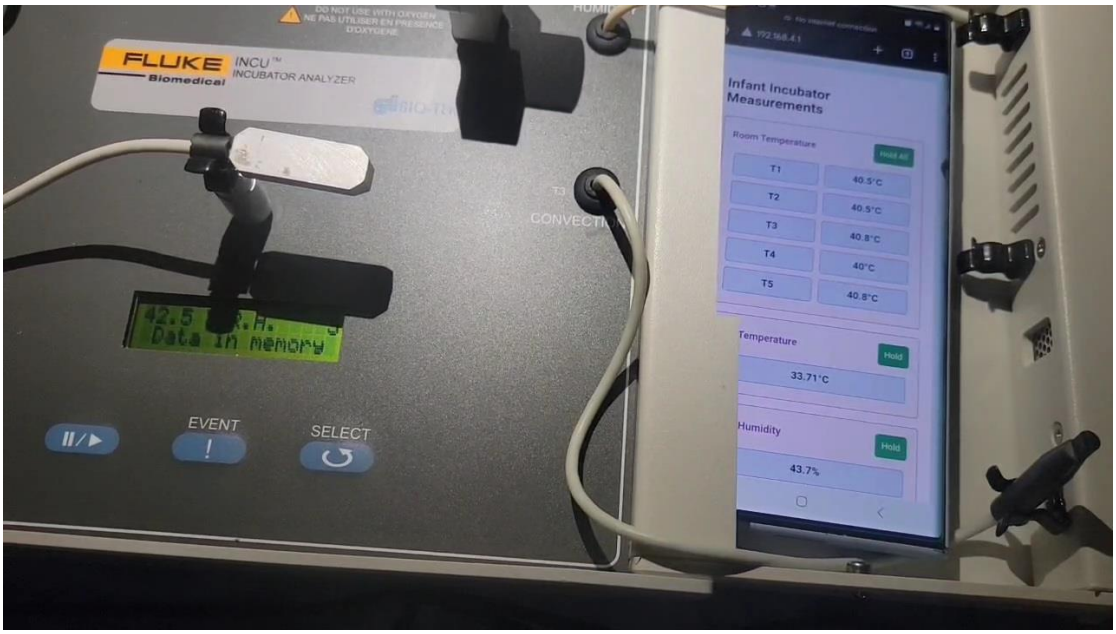


Figure 5-2 Relative Humidity Sensor (DHT-22)

Sensor	Value	Fluck	Error
DHT-22	**43.7** RH	**42.6** RH	**2.5%**
	50.3 RH	**49.7 RH**	**1.2%**
	61.5 RH	**58.9 RH**	**4.2%**

Table 5-2 Relative Humidity Sensor (DHT-22)

- **Skin Temperature (MLX90614)**

Sensor	Value	Fluck	Error
MLX90614	33.65	33.2	1.3 %
	33.66	33.2	1.3 %
	33.79	33.13	1.9 %

Table 5-3 Skin Temperature (MLX90614)

- **Sound Sensor (KY-038)**

Sensor	Value	Fluck	Error
KY-038	59	59.2	-0.34 %
	53	58	-9.4 %
	39.7	39.9	-0.50 %

Table 5-4 Sound Sensor (KY-038)

- **Air Flow (F662)**

Sensor	Value	Fluck	Error
F662	0.10	0.09	10 %
	0	0	0 %
	0	0	0 %

Table 5-5 Air Flow (F662)

5.2.2 Calibration Results for the Radiant Warmer

- **Temperature Sensors (DS18B20)**

Sensor	Value	Fluck	Error
T1	40 C	39.7 C	0.75%
	37.7 C	37.4 C	0.79%
	37.5 C	37.3 C	0.53%
T2	40 C	39.7 C	0.75%
	37.7 C	37.4 C	0.79%
	37.5 C	37.3 C	0.53%
T3	40.3 C	39.7 C	1.48%
	38 C	37.4 C	1.57%
	37.7 C	37.3 C	1.06%
T4	40 C	39.7 C	0.75%
	37.7 C	37.4 C	0.79%

	40 C	**39.7 C**	**0.75%**
T5	**37.7 C**	**37.4 C**	**0.79%**
	37.5 C	**37.3 C**	**0.53%**
	40.3 C	**39.7 C**	**1.48%**

Table 5-6 Temperature Sensors (DS18B20)

- **Skin Temperature (MLX90614)**

Sensor	Value	Fluck	Error
MLX90614	**33.7 C**	**33.66 C**	**0.11%**
	33.7 C	**33.66 C**	**0.11%**
	33.79 C	**33.13 C**	**1.9%**

Table 5-7 Skin Temperature (MLX90614)

5.2.3 Calibration Results for the Phototherapy Unit

- **Light Intensity Sensor (AS7262)**

Sensor	Value	Fluck	Error
AS7262	**450**	**461**	**-2.44%**
	459	**461**	**-0.43%**
	475	**474**	**0.21%**

Table 5-8 Light Intensity Sensor (AS7262)

5.3 Evaluation of Device Efficiency and Usability.

The device operates with high efficiency, thanks to the use of highly accurate sensors imported from abroad. The device's efficiency was validated through calibration using original calibration devices of the Fluke brand and was tested on multiple types of infant incubators, infant warmers, and phototherapy devices.

The device is user-friendly, as it can be accessed from any smartphone or computer. The system includes a menu to select one of the three devices. Upon selection, the corresponding calibration sensors are activated automatically, and the readings are displayed instantly and directly.

5.4 Challenges and Difficulties During Implementation and Testing.

We encountered numerous challenges and difficulties during the implementation of the project, the most notable of which were:

1. The unavailability of accurate sensors in Yemen and the Arab region; importing them from abroad is costly and time-consuming.

2. Limited access to information due to the scarcity of expertise in the field of medical device calibration within Yemen.
3. Complexity in installing and programming the sensors, as each sensor requires a specific voltage supply, operates based on a different principle, and involves highly complex programming codes.
4. Difficulty in calibration and testing, since Yemen has only two calibration laboratories, and the calibration procedures are time-consuming.
5. Designing the external frame of the device posed additional challenges due to the detailed structure and the complexity of sensor placement, which affects their accuracy. Therefore, a precise design was adopted according to standard calibration device specifications, and the frame was produced using 3D printing in a sleek, compact, and lightweight form.

5.5 Analysis of Results in the Context of Previous Studies and Objectives.

The results showed positive outcomes when compared to previous studies. Several studies were analyzed, and lessons were drawn from their shortcomings and advancements, which were then further developed based on available resources. Key points of distinction included:

1. The integration of calibration functions for three different devices into a single unit — a concept not previously implemented in any known study.
2. The development of a display system that presents data from all three devices, unlike some previous studies which focused on a single device, in addition to a more intuitive user interface that distinguishes this system from others.
3. The accuracy of the sensors used was in line with some studies and surpassed others. This level of precision is typically found only in devices manufactured by major companies using internationally certified calibration laboratories.
4. The external design was distinguished by its form, size, and weight, making it more portable and user-friendly.
5. The battery capacity was increased, allowing the device to operate for over three hours in contrast to other devices that last for only about one hour.

Chapter 6

Conclusions and Recommendations

Chapter 6: Conclusions and Recommendations

6.1 Conclusion:

In conclusion, this study successfully achieved its goal of developing a comprehensive calibration device capable of measuring temperature, humidity, airflow, noise, and phototherapy light intensity for infant incubators, radiant warmers, and phototherapy units. By integrating multiple sensors into a single, low-cost, and accurate system, the device offers a practical solution for improving neonatal care, particularly in developing countries where access to high-end medical analyzers may be limited. The comparison with the standard ICU analyzer (Fluke Biomedical INCU II) confirmed the device's reliability, with minimal error rates across all measured parameters. Additionally, the implementation of a mobile HTML-based interface enhances accessibility and ease of use. This tool has the potential to contribute significantly to routine calibration procedures, thereby minimizing technical errors, enhancing device performance, and ultimately reducing the risks to newborns' health.

6.2 Recommendations for future work:

1. **High-Precision Sensor**

Developing high-precision sensors to measure temperature, humidity, noise, and infrared radiation, aiming to accurately monitor the environmental and physiological conditions of neonates without being affected by surrounding factors. This approach aligns with recent advancements in medical sensor technologies. Some studies are focusing on enhancing sensors within infant incubators to measure skin thickness and multi-level humidity.This development improves the calibration accuracy of devices in realistic conditions, providing enhanced protection for preterm infants inside the incubator or under a radiant warmer.

- Reason for postponing implementation:
  - The high cost of precision sensors.
  - Technical complexity, as it requires high-precision electronics and signal isolation circuits.
  - Unavailability of these components locally and difficulty importing them from abroad.
  - Limited time to develop the prototype and conduct the necessary testing.

2. **Phototherapy Optimization**

An intelligent system that automatically adjusts the intensity and duration of blue and green light exposure based on real-time bilirubin level readings through a skin-contact optical sensor. It also utilizes spectrally adjustable LED lights to enhance bilirubin absorption without increasing heat exposure. This system contributes to reducing treatment duration, avoiding excessive UV or

heat exposure, and enables real-time assessment of treatment effectiveness and immediate adjustment if necessary.

- Reason for postponing implementation:
  - Lack of tools for real-time bilirubin measurement.
  - Dependence on advanced and expensive infrared sensors.
  - Complexity of algorithms required to estimate bilirubin elimination rate.
  - Need for long-term clinical studies to ensure system effectiveness and safety.

3. **Self-Calibration & AI Integration**

Using machine learning algorithms to analyze accumulated data and monitor sensor performance over time, allowing automatic periodic calibration without human intervention. These systems can also predict performance deviations and detect potential malfunctions early, thus reducing medical errors and lowering maintenance costs.

- Reason for postponing implementation:
  - The need for large and diverse training datasets to avoid bias and ensure accuracy.
  - High processing power requirements to run AI algorithms, particularly in compact portable devices.
  - Challenges related to power consumption and space limitations inside the device.

4. **SD-Card Memory**

Adding an SD card slot to store a complete calibration log and facilitate easy data transfer to hospital systems or computers. This enhancement enables comprehensive historical archiving for each device and simplifies tracking and auditing for research or quality assurance purposes.

- Reason for postponing implementation:
  - SD cards are prone to loss or theft and require robust encryption and software protection.
  - Integrating this feature requires redesigning the device's internal layout to accommodate the card slot and ensure connection to the motherboard.
  - Limited time to implement this modification in the current prototype.

5. **Developing a User Interface with Graphical Charts of Sensor Readings**

Designing a touchscreen interface that displays time-series charts for sensor readings such as temperature, humidity, light intensity, and noise levels, with an option to export data as PDF files. This development provides clear analytical insights for faster and more accurate decision-making and facilitates training for medical and nursing staff.

- Reason for postponing implementation:

- Touchscreen displays are not available locally and are difficult to import.
- High cost and long lead time required to procure them.
- The need for powerful graphics processors and complex software systems, which increase maintenance and update challenges.
- The screen's exposure to moisture and radiation in a medical environment requires special protection to maintain device efficiency and safety.

References

1. Zermani, M. A., E. Feki, and A. Mami. "Building simulation model of infant-incubator system with decoupling predictive controller." IRBM 35, no. 4 (2014): 189-201
2. Hollywood, Mark, and Eleanor Hollywood. "The lived experiences of fathers of a premature baby on a neonatal intensive care unit." Journal of Neonatal Nursing 17, no. 1 (2011): 32-40.
3. Cockcroft, Sarah. "How can family centred care be improved to meet the needs of parents with a premature baby in neonatal intensive care?." Journal of Neonatal Nursing 18, no. 3 (2012): 105-110.
4. Yeler, Osman, and Mehmet Fevzi Koseoglu. "Performance prediction modeling of a premature baby incubator having modular thermoelectric heat pump system." Applied Thermal Engineering 182 (2021): 116036.
5. WHO Report. (2022). "Safety in Neonatal Care." Retrieved from the World Health Organization website.
6. Garcia, M., & Ahmed, R. (2020). "Portable Calibration Devices for Medical Use." Journal of Biomedical Science, 33(4), 210-225.
7. 3. Mayo Clinic. (2022). "Infant Jaundice Diagnosis and Treatment." Retrieved from mayoclinic.org.
8. BSI Group. "ISO 13485 Medical Devices Standard." Retrieved from bsigroup.com.
9. 5. Healthy Newborn Network. (2022). "Infection Prevention and Care Bundles in Neonatal Units." Retrieved from healthynewbornnetwork.org.
10. Adafruit Industries. "AS7262 Light Sensor Datasheet," 2022.
11. Honeywell. "F660/F662 Flow Sensor Specifications,"2021.
12. Arduino. "DHT-11 Sensor Datasheet," Arduino.cc, 2019.
13. Espressif Systems. "ESP32 Technical Reference Manual," 2020.
14. http://ye-mj.net/news_details.php?sid=2444.
15. F. Zannad, N. Agrinier, and F. Alla, "HF burden and therapy," Eur. Eur. Pacing Arrhythm. Card.Electrophysiol. J. Work. Groups Card. Pacing Arrhythm. Card. Cell. Electrophysiol. Eur. Soc. Cardiol., vol. 11 Suppl 5, pp. v1-9, Nov. 2009. https://doi.org/10.1093/europace/eup30.
16. H. Frankenberger, A. Güthe: Inkubatoren (TÜV Rheinland, Cologne 1991).
17. K. Bauer, C.P. Speer: Pädiatrie (Springer, Berlin, Heidelberg 2001).
18. H. Brück, P.A. Püschner: Thermomonitoring (Drägerwerk, Lübeck 1996).
19. R. Antonucci, A. Annalisa, V. Fanos: The infant incubator in the neonatal intensive care unit: Unresolved issues and future developments, J. Perinat. Med. 37, 587–598 (2009).

20. Miller, S. S., Lee, H. C. & Gould, J. B. Hypothermia in very low birth weight infants: distribution, risk factors and outcomes. J. Perinatol. 31, S49–S56 (2011).
21. Laptook, A. R. et al. Admission Temperature and Associated Mortality and Morbidity among Moderately and Extremely Preterm Infants. J. Pediatr. 192, 53-59.e2 (2018).
22. Perlman, J. M. et al. Part 7: Neonatal Resuscitation: 2015 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations (Reprint). PEDIATRICS 136, S120–S166 (2015).
23. Mullany, L. C. et al. Hypothermia and associated risk factors among newborns of southern Nepal. BMC Pediatr. 8, 13 (2010).
24. Essential elements of obstetric care at first referral level. (World Health Organization, 1991).
25. Granati, B. et al. Efficacy and safety of the 'integral' phototherapy for neonatal hyperbilirubinemia. Results of a follow-up at 6 years of age. Clin. Pediatr. (Phila.) 23, 483–486 (1984).
26. Maisels, M. J. Phototherapy for Neonatal Jaundice. N Engl J Med 358, 2522–2525 (2008).
27. Kumar, P., Chawla, D. & Deorari, A. Light-emitting diode phototherapy for unconjugated hyperbilirubinaemia in neonates. Cochrane Database Syst. Rev. CD007969 (2011) doi:10.1002/14651858.CD007969.pub2.
28. Morris, B. H. et al. Efficacy of phototherapy devices and outcomes among extremely low birth weight infants: multi-center observational study. J. Perinatol. Off. J. Calif. Perinat. Assoc. 33, 126–133 (2013).
29. Slusher, T. M. et al. Filtered sunlight versus intensive electric powered phototherapy in moderate-to- severe neonatal hyperbilirubinaemia: a randomised controlled non-inferiority trial. Lancet Glob. Health 6, e1122–e1131 (2018).
30. Slusher, T. M. et al. Safety and efficacy of filtered sunlight in treatment of jaundice in African neonates. Pediatrics 133, e1568-1574 (2014).
31. Slusher, T. M. et al. A Randomized Trial of Phototherapy with Filtered Sunlight in African Neonates. N. Engl. J. Med. 373, 1115–1124 (2015).
32. Vreman, H. J. et al. Evaluation of Window-Tinting Films for Sunlight Phototherapy. J. Trop. Pediatr. 59, 496–501 (2013).
33. Nagar, G., Vandermeer, B., Campbell, S. & Kumar, M. Reliability of Transcutaneous Bilirubin Devices in Preterm Infants: A Systematic Review. PEDIATRICS 132, 871–881 (2013).
34. Hassan Shabuj, M., Hossain, J. & Dey, S. Accuracy of transcutaneous bilirubinometry in the preterm infants: a comprehensive meta-analysis. J. Matern.-Fetal Neonatal Med. Off. J. Eur. Assoc. Perinat. Med. Fed. Asia Ocean. Perinat. Soc. Int. Soc. Perinat. Obstet. 32, 734–741 (2019).

35. Nagar, G., Vandermeer, B., Campbell, S. & Kumar, M. Effect of Phototherapy on the Reliability of Transcutaneous Bilirubin Devices in Term and Near-Term Infants: A Systematic Review and Meta-Analysis. Neonatology 109, 203–212 (2016).
36. WHO Report. (2022). Safety in Neonatal Care. Retrieved from WHO Official Website.
37. Smith, J., et al. (2021). Calibration Challenges in Neonatal Devices. Journal of Neonatal Technology, 45(3), 123-134.
38. Brown, T., & Lee, K. (2020). Advances in Neonatal Incubators. Pediatric Medical Research, 50(2), 101-115.
39. Jones, P., et al. (2019). Phototherapy Device Calibration. Medical Device Technology, 12(4), 215-228.
40. Garcia, M., & Ahmed, R. (2020). Portable Calibration Devices for Medical Use. Journal of Biomedical Science, 33(4), 210-225.
41. Zhang, L., & Wang, Y. (2021). Modern Calibration Techniques for Medical Devices. Biomedical Technology Review, 28(5), 102-118.
42. Kumar, R., et al. (2023). Battery-Operated Calibration Systems for Rural Hospitals. Biomedical Engineering Innovations, 45(1), 67-78.
43.