RESEARCH PROTOCOL

Effectiveness of low-cost and simple incubator for premature newborn infants at Special Baby's Care Unit of Ola During Children's Hospital, Freetown, the Republic of Sierra Leone

PROTOCOL TITLE:

Protocol title	Effectiveness of low-cost and simple incubator for premature newborn infants at Special Baby's Care Unit of Ola During Children's Hospital, Freetown, the Republic of Sierra Leone
Short title	Effectiveness of neonatal incubator for premature newborn infants at Ola During Children's Hospital,
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LIST OF ABBREVIATIONS

FOCUS	Facilitating and Organizing Communities to Unite for Sustainable Development
IGPC	Initiative for Global Perinatal Care
AE	Adverse Event
(S)AE	(Serious) Adverse Event
SCBU	Special Care Baby's Unit
EC	ethical committee
ENAP	Every Newborn Action Plan
NMR	neonatal mortality rate

1. PROJECT SUMMARY

Rationale: In order to help premature babies, especially premature babies weighing around 1000 g, reliable equipment to to provide thermoneutral environment to minimize energy consumption of the newborn is prerequisite. However, newborn devices in developed countries are very expensive and have a complex structure mostly operated with electric power supply, and high expertise is required to use them. Low cost, simple and sustainable incubator is required in resource limited settings where electric power supply is frequently unreliable. Development of a low-cost, simple and effective incubator has been undertaken by a Japanese perinatal medical device manufacture, ATOM Co,Ltd., and prototypes of the equipment has been now available. The study aims to examine the effectiveness of the incubator in resource limited settings in Special Care Baby's Care Unit (SCBU) in Ola During Children's Hopspital.

Objective: i **.**verify the effectiveness in the heat retention of a newly developed incubator for premature babies.

Hypothesis: i .Newly developed incubator keeps premature newborn temperature constant.

Study design: This is an intervention study at Ola During Children's Hospital

Study population: Parturients admitted to Ola During Children's Hospital in Freetown, Sierra Leone.

Sample size: During a week period all patients meeting the inclusion and exclusion criteria will be recruited. Based on current rates of admissions in the mentioned services, we expect to recruit at least 6 patients during two weeks data collection period.

Methods: Research is conducted on newborns who meet the criteria and are admitted to Ola During Children's Hospital. A patient is accommodated in the newly developed incubator.

All research will be conducted jointly by the Japanese NGO members (a neonatologist and a nurse) and staff at Ola During Children's Hospital. The Japanese neonatologist will always be stationed at the neonatal center during the study period. Local nurses will measure various parameters of hospitalized newborns.

Main study parameters/primary endpoints: i **.** (incubator) Measure body surface temperature and central temperature of newborns in incubator.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In this study, we are targeting premature babies that have previously been difficult to be saved at Ola During Children's Hospital which may reduce neonatal mortality. Patients are constantly monitored throughout the study to minimize risk. The use of the incubator may result in insufficient heat retention for the patient even though laboratory tests results showed effectiveness of its capability to keep the patent above 37 degree for 3 hours. In order to avoid this problem, a Japanese neonatologist will monitor the patient for 24 hours per day throughout the study period.

2 INSTITUTIONS INVOLVED IN THE PROJECT

2.1 Ola During Children's Hospital

Ola During Children's Hospital is a tertiary children's hospital in Freetown, the capital city of the country. It as 250 beds and accommodates approximately 1,000 admissions and 3,000 outpatient consultations per month (personal conversation). Special Baby's Care Unit is a ward specifically dedicated to newborn infants in and out of the hospital, where more than 60% of the total deaths of the hospital occur. Three pediatrician and several other junior doctors are treating the patients and one medical doctor is assigned to SCBU. Currently 8 bubble Continuous Positive Airway Pressure devices, donated by UNICEF, are operational. Two open infant warmers are operational.

2.2 FOCUS1000

FOCUS 1000 ((Facilitating and Organizing Communities to Unite for Sustainable Development) http://focus1000.org) is a Non-Governmental Organization (NGO) in Sierra Leone that is committed to making the best investment in the most crucial period in a child's life: the first 1000 days.

They have a team of over 100 staff members with a diverse background cutting across public health, medicine, nutrition, education, social sciences, environmental sciences and accounting. They also have a pool of over 120 young professionals that we have trained on data collection using digital technology. The organization has a presence in all 14 districts and 149 chiefdoms in Sierra Leone.

2.3 IGPC

IGPC(Initiative for Global Perinatal Care; https://igpc.jp/) is a Non-Governmental Organization (NGO) in Japan. We provide medical assistance and education in the fields of obstetrics and neonatologyl in Honduras, Nepal and Sierra Leone. Our organization has 30 members including medical doctors, midwives, nurses, nutrition specialists, and social scientists, . In Sierra Leone, we have been teaching obstetric ultrasound to local doctors and nurses at Princess Christianity Maternal Hospital. Its mission is to deliver perinatal medicine for all mothers and babies across the world.

2.4 ATOM MEDICAL

ATOM MEDICAL is a Japanese corporation (https://www.atomed.co.jp/) specialized in medical equipment for peri-natal care medicine. It was founded in 1938 and has been the leading company in Japan as a manufacture producing maternity and neonatal medical devices. The company has 400 employees and its medical devices have been exported to various countries. The company and IGPC have agreed to develop low-cost and effective equipment for premature newborns in resource limited settings and will provide the prototypes of the equipment for our research.

3 BACKGROUND AND JUSTIFICATION

3.1Introducing newborn medical devices to developing countries

We have witnessed a remarkable reduction of the infant mortality rate in the developing countries during the last decade due to internationally concerted efforts to improve access to immunization and primary health care. However, not as much progress in the neonatal mortality rate of these countries has not been achieved as the other indices of maternal and children's health (1). This could be attributed to the fact that perinatal and neonatal medicine requires huge amount of resources, and therefore, can hardly be afforded by the resource-limited countries.

Since Every Newborn Action Plan (ENAP) was launched by World Health Organisation in 2014, the Republic of Sierra Leone has been striving to reduce neonatal mortality rate (NMR), and it was recently rated as one of the top fast progressor countries with highest NMR reductions. However, further efforts should be made to achieve the interim target, namely NMR 15 per 1000 live birth in 2020. Particular emphasis needs to be placed on innovative cost-effective technologies that could function to further boost reductions of NMRs in the country. As was pointed out in ENAP, the leading cause for newborn deaths is prematurity. In order to help these premature babies, especially premature babies weighing around 1000 g, reliable heat retention, respiratory assistance, and nutritional support are essential for their survival.

We have been collaborating with a Japanese manufacture, ATOM MEDICAL Co., Ltd. in order to develop simple and inexpensive perinatal and neonatal medical devices designed for the use in resource limited settings. The purpose of this study is to introduce the simple and cost-effective perinatal and neonatal medical devices in health care facilities in Republic of Sierra Leone. In cooperation with FOCUS1000, we decided to conduct a research at Ola During Children's Hospital.

3.2The importance of incubator

Every hour, an estimated 340 babies die in the first week of birth, of preterm birth and asphyxia, which are the most frequently encountered causes for their deaths. Ninety-nine percent of these deaths occur in low- and middle-income countries(1). Compared with adults, newborns are particularly vulnerable to heat loss. Although passive, low-cost approaches such as the Embrace Infant Warmer are available to prevent heat loss of these newborn babes, they lack cooling functions and, therefore, it cannot control their , temperature(2). In many tropical countries, temperatures in the shade can reach >40 °C in the summer, and at this point, an incubator warmer can put babies at risk of hyperthermia. Advanced incubators exist, but they can cost thousands of dollars. The "Neonurture," a design that takes advantage of locally available replaceable parts of automobiles, is not a viable solution for mass production because it is still too complicate to be assembled and expensive (>$1000) for "bottom of the pyramid" rural users(3). In addition to heat loss, nosocomial

infections are an important cause of infant morbidity and mortality in resource-poor countries, where neonatal deaths toll from sepsis reaches 29% of all neonatal deaths(4),(5). Preterm birth occurs in 11% of live births globally and accounts for 35% of all newborn deaths(6). Because preterm newborns have immature innate and adaptive immunity as compared with term babies, mortality due to inadequate immune system response is high in preterm newborns. Routine medical procedures including respiratory support carry an increased risk of infection and associated longterm morbidity in preterm infants(6). In addition, pediatric respiratory infections appear to contribute to some cases of sudden infant death syndrome(7). We are developing a thermodynamically advanced lowcost incubator suitable for operation in low-resource environments. The incubator features a modular design for multiple purposes. Primarily, it comprises of reusable control modules that have low maintenance requirements and low fixed costs. The incubator features four innovations:

I. The new incubator is made of vinyl tubes and can be washed. it is reusable and easy to maintain. it can be used many times and is clean

II. The incubator has a layer of air-contained tubes like a buoyancy ring and has been proven to have a high level of heat retention.

III. It does not require power supply as it generates heat and humid air from hot water tank stored beneath the bed.

IV. The cost of the incubator is about 1/100 of the incubator used in developed countries.

3.3 The present project

The present project is designed to prove that the thermoneutral conditions necessary for premature newborns to survive can be achieved by simple and low-cost equipment. The study aims to confirm its effectiveness already proven in laboratory tests in resource-limitted conditions at Ola During Childrens Hospital. Currently lack of stable electric power supply serevely hampers the use of conventional incubators at the hospital. The results of the study will demonstrate a possibility for premature newborns weighing around 1 to 2kg to be successfully treated, and therefore increased chance of survival in resource limited conditions. the study also aims to verify whether it is possible to train local staff to learn how to operate the incubator in a short time.

4 STUDY GOAL AND OBJECTIVES

4.1 Objectives

4.1.1 Primary Objective

ⅰ.Verify the heat retention of a new incubator for premature babies

4.1.2 Secondary Objectives

ⅰ.Compare the temperature outside and inside the incubator

4.1.3 Primary Hypothesis

ⅰ.New incubator keeps premature newborn temperature constant

4.1.4 Secondary hypothesis

ⅰ.New incubator can maintain a constant room temperature regardless of the outside temperature

5 STUDY DESIGN

This is an intervention study at Ola During Children's Hospital

5.1Population

5.1.1 Inclusion criteria

In order to be eligible to participate in the interventional study, a patient must meet the following criteria:

- Newborn admitted to Ola During Children's Hospital
- Fulfills inclusion categories defined in Table 1.
- Written informed consent of the patient or his/her formal representative.

5.1.2 Exclusion criteria

- When informed consent cannot be obtained
- Newborns with fatal congenital diseases
- Newborns with critical conditions (breathing disorder, sepsis)
- Newborns under 800g over 2000g
- Fulfills one or more of the two inclusion categories defined in Table 2.

Table 1. Inclusion categories

Inclusion criteria	**Case Definition**
Birth weight	Newborns from 800g to 2000g

Table 2.

Table 2	
Exclusion criteria	**Case definition**
Weight	＜800 ＞2000g
Baby's conditons	Breathing disorders, sepsis, and fatal congenital diseases

1.1 Sample size calculation

During a week period all patients meeting the inclusion and exclusion criteria will be recruited. Based on current rates of admissions in the mentioned services, we expect to recruit at least 6 patients during a week data collection period.

1.2 Study period

The enrollment period will last a week. Demographic and baseline clinical data are recorded on admission while outcome data are captured at hospital discharge. The hospital discharge of the last patient enrolled will be considered the end of the data collection period for this study. The study period will end at completion of data analysis.

6. METHODS

6.1. Study parameters/endpoints

6.1.1 Main study parameter

ⅰ. (Incubator) Measure the following parameters .(SpO2, HR, respiratory rate, Blood temperature, incubator inside temperature, incubator outside temperature, water temperature, incubator inside oxygen concentrate, milk intake, incubator inside humidity, incubator outside humidity)

	SpO2	HR	RR	BT(armpit)	incubator inside temperature	incubator outside temperature	water temperature	incubator inside oxgen concentrate	milk intake(ml)	incubator inside humidity	incubator outside humidity
pre implementatinon											
15 minutes											
30											
45											
60											
90											
120											
150											
180											
210											
240											
270											
300											
330											
360											

6.1.2 Procedure

1. Weigh neonate if weight is > 800 < 2000, and neonate has stable breathing document initial assessment and obtain informed consent from parent
2. Fill the plastic bottle with boiled water and put it in the incubator. We boil clean water by our electric kettle.
3. Assemble incubator
4. Place the bottle in the foil wrap and secure in designated position in the incubator at each end

5. Use hygrometer to confirm that internal incubator temperature is greater than 32 degrees Celsius and less than 37 degrees Celsius.
6. Place neonate inside incubator ensure they are stable.
7. Use data collection sheet to assess each parameter every **15 minutes for the 1st hour** if the baby is stable (maintain the baby's temperature and not change the breathing condition) , we measure the parameter **every 30 minutes.** If the temperature in the incubator exceeds 37° ,open the incubator for 5 minutes and measure the temperature again.
8. Newborn in the incubator always wear a pulse oximeter.
9. Measure without opening the incubator
10. We follow the ODCH doctor's instructions for the interval and methods of feeding.
11. Local nurses observes the newborn in an incubator for 24 hours and then return the newborns to cot.
12. Call a local medical doctor if the newborn has the following problems during our monitoring.: 1) the newborn's respiratory condition deteriorates, 2) the newborn has problem with their feeding patterns and vital signs.
13.Change the hot water to keep the newborn's temperature between 36.5℃ and 37.2℃.
14.Wipe once a day with clean water. When replacing the newborn, disassemble the incubator and disinfect with alcohol.
15. measure the water temperatyure.

6.1.4 Randomization, blinding and treatment allocation

Patients are prospectively recruited on a consecutive basis. No randomization will be performed.

6.2. Study groups

Not applicable.

6.3. Study procedures

6.3.1 Study procedures

6.3.2 Intervention

(incubator)

This product was developed by ATOM and IGPC as shown in Appendix. The incubator is made of vinyl and water tank made of plastic. The mattress uses thermal insulation to prevent direct contact with the newborn. In experiments, we have confirmed that incubators can be kept warm for more than 3 hours with a single hot water change. Also in the experiment, the temperature of the doll's surface did not become so high as to cause burns.

6.4. Safety consideration and follow up

6.4.1 Withdrawal of individual subjects

Patients can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

The study participants have the right to contact the ethics and review committee if they raise any issue or concern with the study (Office of the Sierra Leone Ethics and Scientific Review Committee, Ministry of Health and Sanitation, Directorate of Policy, Planning & Information (DPPI) Youyi Building, Fifth Floor, East Wing).

6.4.2 AE

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

6.4.3 SAEs

Serious adverse event or serious suspected adverse reaction: An adverse event or suspected adverse reaction is considered “serious” if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalizations may be considered serious when, based upon appropriate medical judgment they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

6.4.4 Relationship to Study Product

The assessment of the AE’s relationship to study product will be done by the licensed study physician indicated on the Form FDA 1572 and the assessment will be part of the documentation process. Whether the AE is related or not, is not a factor in determining what is or is not reported in this trial. If there is any doubt as to whether a clinical observation is an AE, the event should be reported.

In a clinical trial, the study product must always be suspect. The relationship to study product will be assessed for AEs using the terms related or not related:

Relate-There is a reasonable possibility that the study product caused the AE. Reasonable possibility means that there is evidence to suggest a causal relationship between the study product and the AE.
Not Related – There is not a reasonable possibility that the administration of the study product caused the even

6.4.5 Adverse Event Evaluation

The investigator or designee is responsible for ensuring that all adverse events (both serious and non-serious) observed by the clinical team or reported by the subject which occur after the subject has signed the informed consent are fully recorded in

the subject's medical records. Source documentation must be available to support all adverse events.

A laboratory test abnormality considered clinically relevant (e.g., causing the subject to withdraw from the study, requiring treatment or causing apparent clinical manifestations, result in a delay or dose modification of study treatment, or judged relevant by the investigator), should be reported as an adverse event.

The investigator or sub-investigator (treating physician if applicable) will provide the following for all adverse events (both serious and non-serious):

- Event term (as per CTCAE)
- Description of the event
- Date of onset and resolution
- Outcome of event

An expected adverse event is an event previously known or anticipated to result from participation in the research study or any underlying disease, disorder, or condition of the subject. The event is usually listed in the Investigator Brochure, consent form or research protocol.

An unexpected adverse event is an adverse event not previously known or anticipated to result from the research study or any underlying disease, disorder, or condition of the subject.

6.4.6 Reporting Procedures for Serious Adverse Events

For the purposes of safety reporting, all adverse events will be reported. Adverse events, both serious and non-serious, and deaths that occur during this period will be recorded in the source documents. All SAEs should be monitored until they are resolved or are clearly determined to be due to a subject's stable or chronic condition or intercurrent illness(es). Related AEs will be followed until stabilization.

6.4.7 SAE Reporting Requirements

Participating investigators (all sites) must report all serious adverse events to the Lead Site Principal Investigator within 24 hours of discovery or notification of the event. The participating investigator must also provide follow-up information on the SAE until final resolution.

Investigative sites will report adverse events to their respective IRB according to the local IRB's policies and procedures in reporting adverse events.

7. DATA MANAGEMENT AND STATISTICAL ANALYSIS

7.1 Data management

All patients will be identified with a unique study identification code. A logbook with the matching between patient number and name will be stored digitally and in paper. The paper version will be stored behind a lock and the digital form will be protected with a

password. The logbook will be the only document containing patient identifier information. Data will be stored an additional 15 years after the study's completion.

7.1.2 Data capture

Data is collected on paper checklists and case report forms (CRFs) and subsequently transcribed onto an Internet–based electronic CRF (https://www.kobotoolbox.org). Access to the data–entry system is protected by a personalized username and password. Patients are identified with a study identification code, hence there will be no patient identifier data transcribed on the online CRF.

7.1.3 Data sharing

Data derived from this study will be shared with the clinical team directly responsible for patient's care and with hospital leadership and management team for monitoring and/or audit purposes. Specifically, a copy of the final expert report performed with the conventional apparatus will be attached to the patient's clinical chart to be visualized by the clinical team responsible for patient's care. After publication of the primary results, on request the pooled dataset will be available for secondary analysis, after judgment and approval of scientific quality and validity of the proposed analysis by the steering committee.

7.2 Statistical analysis

This study only records biological parameters and temperature. If we get past neonatal mortality data at Ola During Children's Hospital , we compare the survival rates using Kaplan-Meier method.

8 PROJECT MANAGEMENT

8.1 Project steering committee

There will be a project steering committee led by the principal investigator and project coordinator to follow up all the project phases and to overcome possible problems. Yuichi Kodaira, Shusaku Kobori, Isatu M Mustapha, Nellie Bell are responsible for study design, quality assurance and report writing. Local investigators and coordinators of data collection: Yuichi Kodaira.

8.2 Dissemination of results and publication policy

The results of this study will be published in a peer–reviewed medical journal. We have no restrictions in publication of outcomes of this study.

8.3 Problems anticipated

Although this study is an interventional study, the treatment that is performed in the study is the usual neonatal treatment. Patients are constantly monitored throughout the study to minimize risk.

8.4 Timeline of project

Ethical Clearance: November-December 2019
Training of operators: Jan 2020
Data Collection and Data entry: Feb 2020
Data analysis: Mar-Apr 2020

Preliminary results: May 2020
Final report: July 2020

8.5 Amendments

Amendments are changes made to the research protocol after a favorable opinion by the accredited ethical committee (EC) has been given. All amendments will be notified to the EC that gave a favorable opinion. Non-substantial amendments (typing errors and administrative changes) will not be notified to the accredited EC and the competent authority, but will be recorded and filed by the sponsor.

8.6 Temporary halt and (prematurely) end of study report

In the unlikely event of a temporary halt or early stopping of the study, the investigator/sponsor will notify the accredited EC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient included. The investigators will notify the EC immediately of a temporary halt of the study, including the reason of such an action. In case the study is ended prematurely, the investigators will notify the accredited EC within 15 days, including the reasons for the premature termination. Within one year after the end of the study, the investigators will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited EC.

9 ETHICS AND INFORMED CONSENT

9.1 Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki (revision Fortaleza, Brazil, October 2013). Approval to carry out this study will be sought from the relevant Review Board of Sierra Leone Ethics and Scientific Review Committee.

9.2 Informed consent process

An investigator or designee will describe the protocol to potential subjects face-to-face. The key information about the purpose of the study, the procedures and experimental aspects of the study, risks and discomforts, any expected benefits to the subject, and alternative treatment will be presented first to the subject.
Subjects will also receive an explanation that the trial involves research, and a detailed summary of the proposed study procedures and study interventions/products. This will include aspects of the trial that are experimental, the expected duration of the subject's participation in the trial, alternative procedures that may be available and the important potential benefits and risks of these available alternative procedures.

9.3 Benefits and risks assessment

In this study, we are targeting premature babies that have previously been difficult to help at Ola During Children's Hospital, which may reduce neonatal mortality. New neonatal devices are made over conventional neonatal devices. In addition, the safety of these devices has been confirmed by experiments, and there is almost no risk.

10 BUDGET AND OTHER SUPPORT FOR THE PROJECT

Doctors and nurse are will be giving a little token as a research fee after the research. However, the newborn device will be provided by Atom Co., Ltd.

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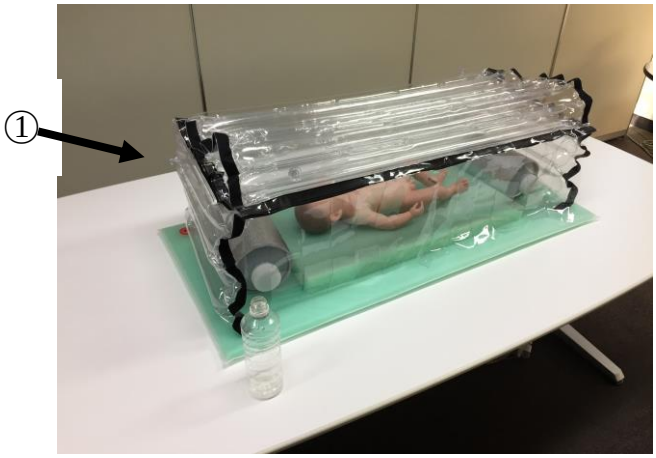
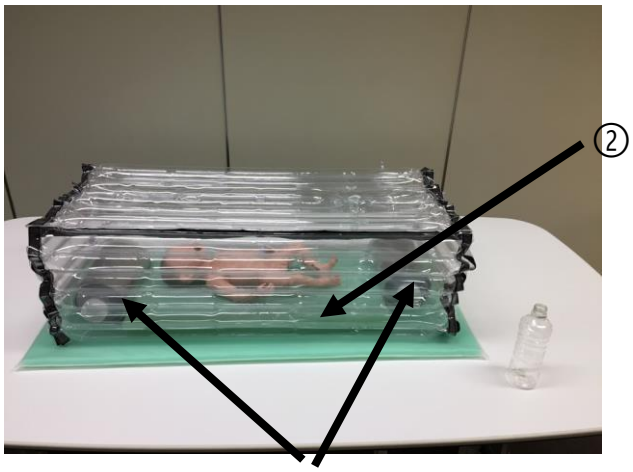
12.APPENDIX

Neonatal Management Package - Instructions for use

1. Purpose
    I. Warmer
        This product is intended to warm the inside of the unit and prevent a neonate from developing hypothermia.
2. Name of each component
    I. Warmer





Number	Name	Function
①	Hood	To secure internal air isolation and gain visibility of the inside.
②	Mattress	To lay a neonate down.
③	Hot water bottles	To warm up the inside of the unit with hot water in the bottles.

3. Performance test results

The results of the performance tests conducted for the warmer are as follows.

- Heat insulation capacity

  Pour 2 liters of 38 Degree Celsius water, the average normal body temperature of neonates, into an aluminum can and place it inside of the warmer as a testing model of a neonate. Measure the core temperature of the testing model and count the time until it becomes lowered to 35 Degree Celsius, which is the temperature causing hypothermia, with an ambient temperature and humidity outside of the warmer set at 25 Degree Celsius and 50 % RH respectively. The measurement result is as shown below Figure 1.

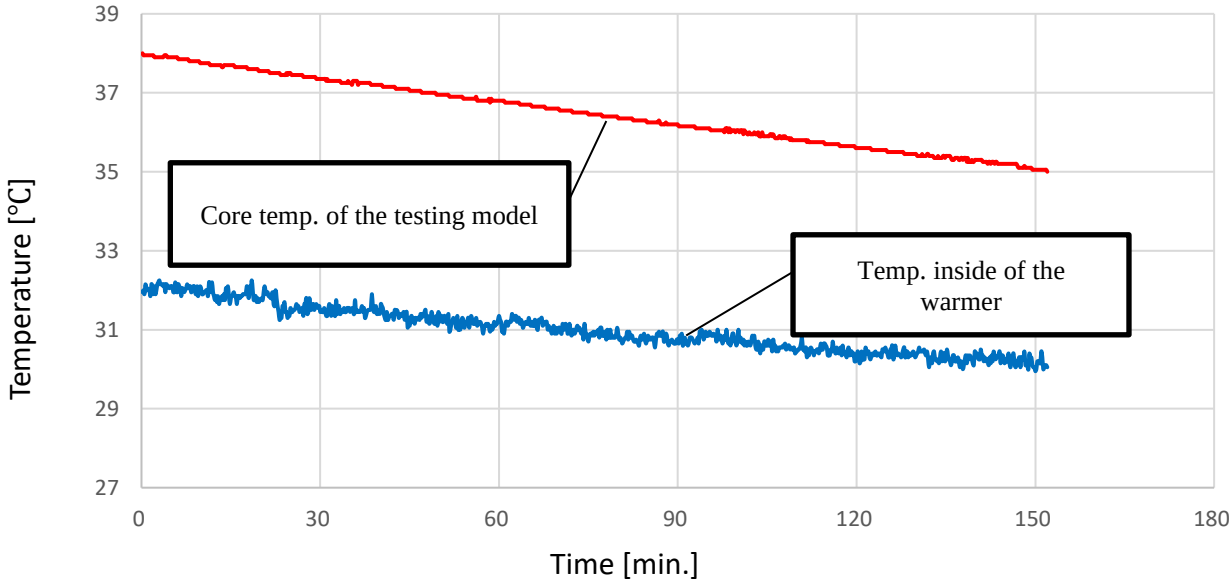


Figure 1 – The test result obtained from the evaluation on the heat insulation capacity performed by the testing model of a neonate

From Figure 1, it was proven that this product was able to keep warming the testing model of a neonate for a little over 150 minutes with the temperature inside of the warmer being kept at 32 ~30 Degree Celsius during that period.

- Comparison between the core and back temperatures of the testing model

Due to the nature of this product which supplies heat from under the mattress, the risk associated with the use is a potential scald on the surface skin of the back of a neonate, which the heat source has the closest contact with. To confirm safety, the back and core temperatures of the testing model of a neonate placed inside of the warner were measured for comparison with an ambient temperature and humidity outside of the warmer set at 25 Degree Celsius and 50 % RH respectively. The measurement result is as shown below Figure 2.

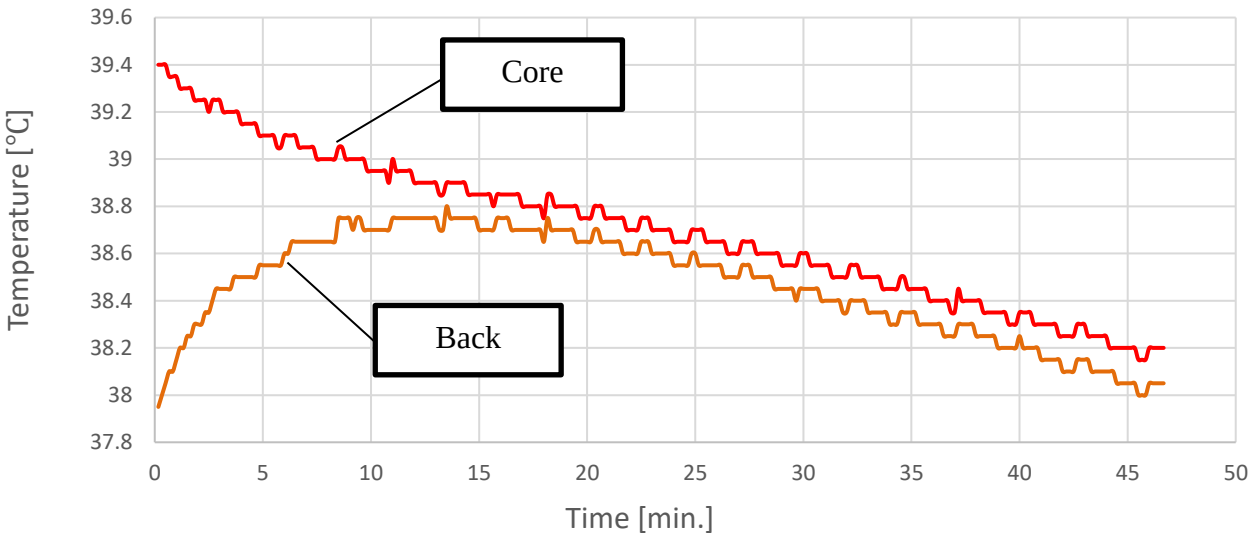


Figure 2 – The test result obtained from the comparison made between the core and back temperatures of the testing model of a neonate

From Figure 2, it was proven that since the temperature applied to the back did not exceed the core temperature, there should be no risk of scald with this product.