Newborn Technology Landscape

8th Edition Technical Report, December 2022

TECHNOLOGIES FOR NEWBORN CARE IN LOW-RESOURCE SETTINGS

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ABBREVIATIONS

°C	Degrees Celsius
bCPAP	Bubble continuous positive airway pressure
bpm	Beats per minute / breaths per minute
CE Mark	Conformité Européenne – certification mark
cm	Centimeters
cm2	Centimeter squared
CRP	C-reactive protein
CPAP	Continuous positive airway pressure
DHS	Demographic and health survey
FDA	Food and Drug Administration
HIS	Health information system
Hz	Hertz
IMR	Infant mortality rate
ISO	International Standards Organization
IV	Intravenous
KMC	Kangaroo Mother Care
kg	Kilogram
LPM	Liters per minute
LRS	Low resource settings
MCH	Maternal and child health
MDG	Millennium Development Goal
Mg/dL	Milligrams per deciliter
mL/hr	Milliliters per hour
mmol/L	Millimoles per liter
MMR	Maternal mortality rate
MNCH	Maternal, newborn, and child health
MNH	Maternal and neonatal health
nm	Nanometer
NMR	Neonatal mortality rate
PCT	Procalcitonin
PEEP	Positive end-expiratory pressure
PR	Pulse rate
RDS	Respiratory distress syndrome
ROP	Retinopathy of prematurity
SpO2	Peripheral saturation of oxygen
SDG	Sustainable Development Goal
TFR	Total fertility rate
U5MR	Under-5 mortality rate
µmol/L	Micromoles per liter
UNFPA	United Nations Population Fund
USAID	U.S. Agency for International Development
uW	Micro Watts
W	Watt
WHO	World Health Organization

Executive Summary

Globally, 2.5 million children die in the first month of life and more than half of these deaths are due to conditions that could be prevented or treated with access to simple, affordable interventions [1].

The first 28 days of life – the neonatal period – represent the most vulnerable time for a child's survival. Globally, more children than ever before are being born in facilities and there are well-described, low-cost, evidence-based practices to address neonatal mortality. However, three quarters of neonatal deaths (nearly 2 million) happen in the first week of life when a child is still at or near a health facility [2]. Health interventions are needed that can provide comprehensive neonatal care at facilities to address the major causes of neonatal deaths. Many of these health interventions are known and can be cost-effective. These interventions though may be different from other interventions needed to address broader under-5 deaths [3].

For the first time ever in 2016, the world pledged to end preventable newborn deaths by 2030 (Sustainable Development Goal 3.2)[4]. On current trends, more than 60 countries will miss the SDG target of reducing neonatal mortality to at or below 12 deaths per 1,000 live births by 2030. About half will still not reach the target by 2050. These countries carry about 80 percent of the burden of neonatal deaths in 2016[3]. Focused efforts to strengthen the ability of health systems to deliver neonatal care are still needed in sub-Saharan Africa and South East Asia so as to prevent 80 percent of these deaths[1].

To address neonatal mortality, the World Health Organization (WHO) is working with Ministries of Health and partners to expand quality services for sick and small newborns in the first week of life[5]. Critical to the sustainable implementation of quality facility-based services will be equipping not only people, but facilities with neonatal equipment that is high quality, affordable, robust, and appropriate for comprehensive care delivery in low-resource settings.

The Newborn Technology Landscape document is a publicly available document hosted as an online compendium that serves as a resource for the global community. The document is intended to be updated every six months to ensure that the newest technologies available for newborn care in low-resource settings are included.

Introduction

Globally, the largest contributors to neonatal mortality are preterm birth, intrapartum complications, and infection. Many deaths attributable to these causes are preventable through six categories of care:

1. Hydration, Nutrition, and Drug Delivery
2. Infection Prevention and Control
3. Jaundice Management
4. Point-of-Care Diagnostics
5. Respiratory Support
6. Thermal Management

Most neonatal healthcare technologies that support these pathways of care are designed for high-resource settings and are either unavailable or unsuitable for use in low-resource settings. As a result, providers in low-resource settings lack the tools needed to deliver quality, comprehensive, newborn care.

There is an urgent need for neonatal healthcare technologies that are affordable, rugged, effective, simple to use and maintain, and able to operate from various power supplies.

Methodology

The Newborn Technology Landscape (2019) was developed by Newborn Essential Solutions and Technologies (NEST360). The material in this landscape report was gathered from primary sources (e.g., surveys and interviews with technology developers) and all information was directly provided and confirmed by the organizations who submitted responses.

The technologies described in this landscape report were derived by continued outreach to known manufacturers and leading technology developers working within the newborn care space, ranging from established multinational medical device companies to startups and academic groups. Information was provided through questionnaires addressing their technology, intended market, pricing, national or regional regulatory approvals, and manufacturing standards. Only photographs received from manufacturers and developers are included in this report.

Hydration, Nutrition, and Drug Delivery

Small and sick babies have special fluid and nutritional requirements.[6-7]

Intravenous (IV) infusions of water, electrolytes and glucose are given to neonates during the first weeks of life to maintain fluid and electrolyte balances and to provide energy for basic metabolic processes[8]. Fluid therapy requires delivery at precise volumes and flow rates, and fluid overload can be life-threatening[8-9].

Outlined in this section are technologies designed to address fluid delivery in low-resource settings.

Introduction to Syringe Pump

Syringe pumps deliver medication and small quantities of fluids continuously through an intravenous line, and are a "priority medical device" as described by the World Health Organization. In high-resource hospitals, syringe pumps are used to provide rehydration fluids, breastmilk, dextrose to hypoglycemic infants, and antibiotics to infants with infection. In hospitals where syringe pumps do not exist or are unable to be maintained or operated, these fluids are delivered via a gravity-fed IV drip, slow push by nurses, or using burettes. These are all much less accurate methods of delivery, and put infants at significant risk of over/under dosing, medical error, line complications, fluid overload, or hypovolemia. Additionally, since premature babies are likely to need slow introduction to breastmilk over the first week of life, syringe pumps are critical to maintaining normal glucose and hydration until preterm infants are able to tolerate adequate volumes of breastmilk orally or by nasogastric tube. For these reasons, syringe pumps were listed as a pressing technology for improving newborn care in The Global Action Report on Preterm Birth [10].

The FDA has reported that syringe pumps currently on the market are difficult to use [11]. Moreover, existing syringe pumps are expensive, and require costly, brand-specific consumables, making them unsuitable for use outside of high-resource settings. To be effective in reducing infant mortality on a global scale, pumps must be designed with a simple user interface to avoid setup errors and function accurately with the variety of syringe brand and sizes. In addition to withstanding hot and humid environments, the pump must be easily calibrated and maintained by local technicians. Syringe pumps are often unavailable for infants in need of life-saving IV treatment.

Outlined in this section are syringe pump technologies for low-resource settings. Note that technologies within this product category have not yet been evaluated by the NEST360 team for inclusion as a NEST360 Qualified Technology. To learn more about what it means to be "NEST360 Qualified" and how the technologies are qualified by NEST360, please click here.

RELI Delivery System – PATH

Not yet commercially available / In development

Intended Use:

Controlled delivery of fluids or drugs for newborn, infant, child, and adult patient populations.

Key Features:

The RELI Delivery System is designed to provide continuous infusion of fluids or drugs to the patient. Key features include:

- Hybrid power source (manual pneumatic & battery), ideal for use in locations with no source of power or unreliable electricity
- Reusable
- Flow rate can be adjusted during use
- Simple user interface
- Device is compatible with off-the-shelf, non-proprietary tubing and syringes
- Device is easy to maintain and repair
- Low operating costs

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RELI Delivery System

Type of technology	**Syringe Pump**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**None**
Manufacturer of Record	**TBD**
Benchtop measurement accuracy (±%)	**± 3%**
Clinical measurement accuracy (±%)	**Final data have not been produced**
Flow rate ranges (mL/hr)	**0.1 – 200 mL/hr**
Describe the syringes device is compatible with (size, proprietary or non-proprietary, etc.)	**Any syringe brand/type; 5 mL– 60 mL capacity. No proprietary consumables are required.**
Describe how occlusion limits are set	**User selectable backpressure**
Patient interface	**Standard consumables (IV giving set) interface with the patient, not the device itself**
Alarms included in device	**Audible and Visual**
Describe how cleaned or decontaminated	**Device can be cleaned by wiping exterior surfaces with warm water and detergent or with alcohol-free surface disinfectants.**
Consumables required	**Standard syringe and giving set (any brand)**
Training required	**Minimal training (< half-day training)**
Size and form factor	**Portable; can be set at the patient's bedside**
User instructions provided	**Device will have exterior labeling and instruction manual provided**
Electricity requirements, including voltage, and charging features	**Disposable/rechargeable batteries**
Warranty	**TBD**
Ex-works price of device	**Estimated price < $500 USD**
Ex-works price of consumables	**N/A**

Introduction to Other Products

This section is used to capture other newborn technologies within the ***Hydration, Nutrition, and Drug Delivery*** category-of-care.

Baby Scale – Kinlee Health

Commercially available

Intended Use

For use weighing babies.

Key Features

Baby Scale is designed for weight and height measurements of infants and children under the age of 2 years. The tray can be easily moved and child can stand on the scale for weight.

(Tray can be separated)

(Large LCD Displayer)

Baby Scale

Type of technology	**Weighing scale**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE,EN55014-1:2017+A11:2020**
Manufacturer of Record	**Kinlee Health**
Desktop version with electronic control	**Yes**
Weight lock function	**Yes**
LCD display	**Yes**
Tare selection function (taring)	**Yes**
Maxiumum weighing and grade	**20kg/20g**
Weight range	**20g–20kg**
Height measurement in the range	**0–55cm**
Size and form factor	**Size of scale: 58 X 33.5 X 10.6CM** **Size of tray: 56 X 25 X 6CM**
Electricity requirements, including voltage, and charging features	**4 pcsxAA battery or adaptor 220V, 50/60HZ**
Describe how cleaned or decontaminated	**The tray is good quality ABS material that is resistant to mildly corrosive cleaner. The tray is easy to clean by wiping down the external surface.**
Warranty	**One year**
User instructions provided	**We will provide user manual with it statement**
Ex-works price of device	**22-28 USD base on the quantity and option functions**

Contact Information:

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Nifty Feeding Cup – Laerdal Global Health

Commercially available

Intended Use

The Nifty Feeding Cup is a reusable product for feeding breast milk to newborns with breastfeeding difficulties.

Key Features

The Nifty Feeding Cup by Laerdal is a simple to use, easy to clean, and culturally appropriate feeding solution, which allows the infant to control the pace of feeding. Nifty Feeding Cup has been developed and designed through a collaboration between the University of Washington, Seattle Children's hospital, PATH, and Laerdal Global Health.

Nifty Feeding Cup

Type of technology	**Infant feeding cup**
Status	**Commercially available**
Regulatory approvals and/or international standards	**EN 14350-1:2004**
Manufacturer of Record	**N/A**
Electricity requirements, including voltage, and charging features	**None**
Size and form factor	**Mass: Approx. 23.5 g** **Volume: 5 to 40 ml**
Shelf life, stability, and storage requirements	**Made with silicone rubber** **Safe for food contact according to regulation 1935/2004** **Operating Temperature:-18°C to +50°C** **Storage temperature: -40°C to +60°C** **Not made with natural rubber latex**
Ex-works price of device	**Catalogue No. LGH-960-00133** **Nifty Feeding Cup (pack of 50)** **$75 USD (pack of 50)**
Ex-works price of consumables	**N/A**

Contact Information:

Laerdal Global Health

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+47 51 51 17 00 (Norway)

https://laerdalglobalhealth.com/products/nifty-feeding-cup/

Sinapi Feeding Cup – Sinapi Biomedical (Pty) Ltd.

Commercially available

Intended Use

Cup feeding for neonates and infants.

Key Features

- Easily cleaned by hand
- Can be autoclaved
- Can be left in the sun to sterilize
- Can be boiled
- Easy to mix, store, and feed
- Added volume marks for easy reference
- Drinking well to allow neonates and infants to feed at their own pace without a risk for regurgitation
- Non-spill lid for reduced microbial contamination risk

Sinapi Feeding Cup

Type of technology	**Nutrition – Re-usable Feeding Cup**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Manufactured under ISO 13485**
Manufacturer of Record	**Sinapi Biomedical (Pty) Ltd**
Electricity requirements, including voltage, and charging features	**None**
Size and form factor	**Large – 200 ml translucent Cup** **Small – 50 ml Cup**
Shelf life, stability, and storage requirements	**No expiry date as it is a non-sterile product**
Ex-works price of device	**R42.46** **Available in government sector on RT9 transversal contract**
Ex-works price of consumables	**N/A**

Contact Information:

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+27 21 887 5260

www.sinapibiomedical.com

Wema Breast Pump – Maziwa

Commercially available

Intended Use

Breastmilk expression

Key Features

Discreet-design flange, battery powered and rechargeable motor

Wema Breast Pump

Type of technology	**Breast pump**
Status	**Commercially available, sales samples available for order**
Regulatory approvals and/or international standards	**Kenya PPB Approval; FDA Approval**
Manufacturer of Record	**Maziwa's ODM**
Electricity requirements, including voltage, and charging features	**USB Rechargeable Battery/Power Adapter** **Battery Capacity: 2600mAh** **Recharging Time: Charing ≈ 270mins**
Size and form factor	**Product Measurements: 23x17x15cm** **Single package size: 30x25x25 cm** **Single gross weight: 2.000 kg**
Shelf life, stability, and storage requirements	**ISTA standard**
Ex-works price of device	**Pricing varies, please contact VIA Global Health for further information**
Ex-works price of consumables	**N/A**

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Infection Prevention and Control

Neonatal infections are more common where there is limited access to basic health services and where good hygiene practices are lacking.[18]

The most important protective interventions for nosocomial infections are frequent hand-washing, exclusive breastfeeding and facility cleanliness[19-20], but widespread implementation of these interventions is challenging in low-resource settings. Infants (and their mothers) who are malnourished or have a chronic illness are at risk of infection because of immunosuppression and a susceptibility to preterm birth[21]. Premature infants have an increased risk of infection, regardless of the mother's antibody status[9-10].

Outlined in this section are technologies designed to prevent and treat infections in low-resource settings.

Introduction to Sepsis Diagnostic

Neonatal sepsis is a major cause of newborn mortality and must be identified and treated quickly to ensure survival and minimize morbidity. However, it is not easy to diagnose. Due to the immaturity of a neonatal immune systems, natural history of late deterioration, and high morbidity in the presence of a serious bacterial infection, the standard of care in neonates is to treat while simultaneously screening for sepsis with blood, urine, and spinal fluid cultures and microscopy until studies suggest that infection is unlikely to be present. There are some useful guidelines that help to identify neonates and young infants at risk of sepsis and guide clinical management. However, even when these guidelines are used, many more babies receive antibiotics than those who truly have serious bacterial infections and need antibiotics[22].

Serious bacterial infections can be identified by clinical assessment, biochemically (with biomarkers), or microbiologically. However, limited availability of microbiological diagnostic testing in low and middle income countries (LMIC) is a major barrier to safe antibiotic use and shortening courses of treatment. The currently available diagnostic tests have significant barriers in their use and interpretation[23]. Additionally, there is currently no accepted biomarker for use in low- and middle-income countries[24]. The availability, cost, rapidity of results, sensitivity, specificity, predictive value, and the interpretation of results pose challenges for the widespread use of biomarkers. Small studies have described hundreds of biomarkers associated with severe neonatal infections and biomarkers, alone or in combination, that have been used to identify newborn infections: procalcitonin (PCT), C-reactive protein (CRP), tumor necrosis factor-a (TNF-a), interferon-g (IFN-g), interleukin-6 (IL-6), interleukin (IL-8)[25]. The majority of these studies have evaluated biomarkers in combination with C-reactive protein (CRP), already in widespread clinical use for the diagnosis of infection. As an acute-phase reactant, CRP alone is less useful in the earliest phases of severe neonatal infection because it does not peak until 12 to 24 hours after infection and can also be triggered by a non-infectious insult, such as trauma.

Note that technologies within this product category have not yet been evaluated by the NEST360 team for inclusion as a NEST360 Qualified Technology. To learn more about what it means to be "NEST360 Qualified" and how the technologies are qualified by NEST360, please click here.

FINDER – Baebies Inc

Not yet commercially available / In development

Intended Use

Baebies is developing an ultra-rapid, fully integrated platform for diagnosis of bacteremia in neonatal populations. The system is intended to be used in moderate complexity settings by healthcare professionals.

Key Features

Fully autonomous integration with blood culture bottles, providing users with ID/AMR and gram status in real time without the need for any hands-on intervention. Sensitive molecular detection of bacteria allows bacteria ID and gram status to be reported in a quarter of the time compared with conventional blood culture systems, promoting better antibiotic stewardship. In addition to blood culture, the platform will also be able to measure expression levels of various genes from just 125 microliters of whole blood to distinguish between bacterial versus other causes of inflammatory responses.

FINDER

Type of technology	**Sepsis Diagnostic**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**Intend to seek FDA clearance and CE Mark**
Manufacturer of Record	**Baebies, Inc.**
Accuracy	**N/A**
Dynamic range (mg/dL or µmol/L)	**N/A**
Sample type and sample volume required	**ID/AMR Cartridge: Venous blood draw or heel stick (based on provider preference and health of baby). 0.5 mL – 1.0 mL or as standard of care dictates.** **Host Response Cartridge: 125 µL**
Steps required to run from sample collection to results output	**ID/AMR Cartridge:** **1. Inoculate blood into standard blood culture bottle using institution protocols** **2. Couple cartridge to blood culture bottle and insert into FINDER** **3. Run Test** **4. Results provided on tablet screen** **Host Response Cartridge:** **1. Collect 125 µL of blood and introduce into cartridge** **2. Run test** **3. Results provided on tablet screen**
Time to run from sample collection to result output	**ID/AMR Cartridge: 4 - 7 hours for ID/AMR/gram status** **Host Response Cartridge: 15 – 30 minutes for results**
Calibration required	**TBD**
Electricity requirements, including voltage, and charging features	**Standard 110V or 220V power outlet**

Contact Information:

Baebies, Inc.

marketing@baebies.com

www.baebies.com

FINDER

Size and Form Factor	**Tabletop POC-instrument** **Dimensions: 11x9x12 cubic inches** **Weight: 15 lbs**
Shelf life, stability, and storage requirements	**Shelf Life: 12 months at 4˚C** **Operating Conditions** **Altitude: Sea level up to 3,000 meters** **Temperature: 19˚C to 30˚C** **Humidity: 27% to 80% RH**
Ex-works price of device	**TBD**
Ex-works price of consumables per test	**TBD**

Contact Information:

Baebies, Inc.

marketing@baebies.com

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Jaundice Management

Most neonates, term and preterm, will have elevated levels of unconjugated bilirubin and some amount of jaundice during the first one to two weeks of life due to increased levels of unconjugated bilirubin with transient impaired excretion, which is normal in this age group. This condition is particularly prevalent in preterm babies and, if the levels of unconjugated bilirubin are very high and left untreated, may lead to irreversible neurologic damage known as kernicterus.

Phototherapy treats unconjugated hyperbilirubinemia that exceeds safe levels. These levels are based on day of life and risk factors and typically occur within the first one to two weeks of life.

Treatment with blue light phototherapy is necessary to prevent morbidity and mortality from dangerous levels of neonatal jaundice. The blue light is absorbed by bilirubin, which is then broken down in the blood, allowing the infant to excrete the excess bilirubin before it can accumulate and cause permanent brain damage (kernicterus) or death. Jaundice is preventable and treatable; however, kernicterus is permanent and irreversible, resulting in life-long disability.

Outlined in this section are technologies both commercially available and in development that allow for the monitoring and treatment of jaundice.

Introduction to Bilirubinometer

Severe jaundice may not be readily evident to the naked eye until already at dangerously high levels. Additionally, jaundice may not present until several days after birth when an infant has already left the hospital. Thus, early monitoring of bilirubin in at-risk infants is critical in order to prevent severe jaundice, which may result in permanent neurological damage, particularly in premature babies who are at greater risk of death and disability due to jaundice.

All infants should have a laboratory evaluation of serum bilirubin (with result turn around within six hours) both to diagnose jaundice and to guide treatment of infants receiving phototherapy. In low-resource settings though, many facilities do not have the ability to run a blood test, and those that do face many challenges both to run the test and obtain results within a meaningful timeframe.

The ideal solution in a low-resource setting would be a reliable point-of-care test which can test serum bilirubin both before and during phototherapy treatment. Examples of such technology commercially available and in development are outlined in this section. Technologies that are only reliable before but not during phototherapy have been excluded.

The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- BiliDx Bilirubinometer
- Calmark Neo-Bilirubin

To learn more about the five step process, please click here.

BiliDx – 3rd Stone Design

Commercially Available

Intended Use

For diagnosis and monitoring of total serum bilirubin.

Key Features

BiliDx is a point-of-care, low-cost, diagnostic device designed to immediately quantify serum bilirubin levels from a small drop of whole blood. BiliDx offers a faster and more cost-effective means to detect neonatal jaundice in under-resourced settings and determine when phototherapy is needed. BiliDx provides an important tool to monitor the efficacy and progress of phototherapy, ensuring appropriate treatment dosage and duration. Used together, BiliDx and phototherapy have the potential to reduce the morbidity and mortality associated with neonatal jaundice.

BiliDx Bilirubinometer

Type of technology	**Bilirubinometer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Hadleigh Health Technologies**
How are results presented to user?	**Quantitative, mg/dL**
Accuracy	**± 20% from 5 to 30 mg/dL**
Linear range (mg/dL or µmol/L)	**0.4 – 30mg/dL**
Precision	**N/A**
Sample type and sample volume required	**Whole blood heel stick (no centrifuge required)**
Steps required to run from sample collection to results output	**1. Collect blood sample onto disposable strip** **2. Insert strip into BiliDx** **3. Press button** **4. BiliDx displays bilirubin measurement (mg/dL)** **5. Dispose strip**
Time to run from sample collection to result output	**< 10 seconds**
Calibration required	**Minimal**
Electricity requirements, including voltage, and charging features	**Rechargeable, battery operated (standard USB charger 110 – 220V AC), lasts up to 24 hours**
Size and Form Factor	**BiliDx is a handheld, portable device that can be used at the patient bedside**
Shelf life, stability, and storage requirements	**4 year shelf life for strips**
Ex-works price of device	**~900 USD**
Ex-works price of consumables	**~100 USD per 50 pack**

Contact Information:

Hadleigh Health Technologies

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+1 415-650-9537

www.hadleighhealth.com

Bilistick® System 2.0 – Bilimetrix s.r.l.

Commercially available

Intended Use

The Bilistick® System is intended to be used in hospitals, clinics, physician's offices or family counseling under a physician's supervision/direction to assist clinicians in measuring bilirubin levels in the blood of newborn infants for severe hyperbilirubinemia diagnosis. The use of other laboratory methods for results confirmation are left to the user criteria in each case. The expected users of the Bilistick® System are:

- Neonatologists
- Physicians/Pediatricians
- Midwives
- Nurses
- Laboratory technicians

Key Features

The Bilistick® System is a Point-of-Care diagnostic assay able to measure Total Serum Bilirubin (TSB) concentration on whole blood of newborn infants. It is composed by: Bilistick® Reader, a portable rechargeable battery reflectance reader; Bilistick® Test Strips, test strips with a cell-plasma separator coupled with a nitrocellulose membrane, both encased in a plastic cassette; and Bilistick® Sample Transfer Pipettes, used for loading the appropriate volume of blood on the test strip. The test with the Bilistick® System requires the collection of a small blood sample directly from a heel stick or a test tube, by using the Bilistick® Sample Transfer Pipette, and its loading on a Bilistick® Test Strip once already inserted in the reader. The Strip separates the plasma from corpuscular components of the blood and allows the determination of TSB by reflectance spectroscopy using the Bilistick® Reader. The TSB determination by the Bilistick® System does not require the use of reagents simplifying the process of measurement. Once loaded on the strip, the bilirubin concentration result is obtained within few minutes. The Bilistick® System allows the determination of bilirubin concentrations between 1 mg/dL and 40 mg/dL (17 and 684 mol/L) with an accuracy comparable to traditional clinical laboratory methods.

The new Bilistick® System 2.0 has been implemented with Wi-Fi connection, allowing quick and simple access to the Bilistick® Reader User Interface for creating Operator profiles and associate Patients IDs to bilirubin results. Measures information can be easily printed on a label using the optional small and portable Bilistick® System Printer. Morover, this new version allows the Bilistick® Reader to be connected to the hospital network through Wi-Fi or LAN port using HL7 protocol.

Bilistick System 2.0

Type of technology	**Bilirubinometer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485**
Manufacturer of Record	**Bilimetrix s.r.l.**
How are results presented to user?	**Quantitative, mg/dL, Quantitative, mmol/L**
Accuracy	**The prediction of Bilistick® to determine the need of phototherapy showed a sensitivity of 70.6% [65.0 to 75.7%], specificity of 98·5% [97.7 to 99.1%], positive predictive value (PPV) of 92.5% [88.3 to 95.6%] and negative predictive value (NPV) of 92.8% [91.3 to 94.2%].**
Linear range (mg/dL or µmol/L)	**1 mg/dL to 40 mg/dL – 17 µmol/L to 684 µmol/L**
Precision	**± 0.2 mg/dL / ± 3 µmol/L**
Sample type and sample volume required	**Venous whole blood, 2-3 drops (no centrifuge needed)**
Steps required to run from sample collection to results output	**1. Insert Bilistick® Strips in the optical chamber 2. Collect blood sample from the heel stick or a test tube using the Bilistick® Sample Transfer Pipette 3. Load the sample into the strip well 4. Press M key and wait for result 5. Check bilirubin concentration on the reader screen**
Time to run from sample collection to result output	**3 minutes**
Calibration required	**The Bilistick® Reader is adviced to be calibrated once every three months using the Bilistick® Calibration Kit, a set of eight standard calibrating strips.**
Electricity requirements, including voltage, and charging features	**The Bilistick® Reader is powered by a lithium battery charged through a Mini B -USB port (DC 5V – 0.5A – 2.5 W)**

Bilistick System 2.0

Size and Form Factor	**The reader is a handheld portable device (31.3 mm H x 72.9 mm W x 140 mm D) while the test strips are contained in a small plastic cassette (3.70 mm H x 15.00 mm W x 48.65 mm D)**
Shelf life, stability, and storage requirements	**Reader:** • **Storage conditions:** 10 - 40°C low humidity, non-corrosive gas atmosphere • **Long-term storage:** In case of long-term storage, store the reader at 15 - 25°C, low humidity, non-corrosive gas atmosphere **Test Strips:** • **Storage conditions:** 15 - 30°C temperature in its original packing, in a dry atmosphere and protected from light and heat sources • **Shelf life:** 2 years
Ex-works price of device	**Bilistick System price: 1000.00 USD**
Ex-works price of consumables	**Bilistick Test Strips: 2.00 USD**

Contact Information:

Bilimetrix s.r.l.

burke@bilimetrix.net

+39 3936444890

www.bilimetrix.net

Calmark Neo-Bilirubin – Calmark Sweden AB

Commercially Available

Intended Use

Calmark Neo-Bilirubin is a point-of-care diagnostic (POC) test which quantitatively measures total serum bilirubin (TSB) in whole blood from newborn infants. The device is intended to be used by medical staff inside hospital facilities or medical clinics.

Key Features

Calmark Neo-Bilirubin is based on the Calmark POC System and consist of a single-use test cassette and a portable instrument, the Calmark POC-Analyzer. The product line is built on a patented technology where the quantification of bilirubin is performed using a colorimetric detection method.

The test cassette is composed of a plastic shell containing four filters. The construction determines the blood volume and the initiation of the measurements. Test activation is done automatically by the instrument, generating results within minutes.

The filter combination handles high hematocrit and performs a hemolysis free filtration.

Other tests on the Calmark POC platform are Neo-Glucose for accurate measurement of low levels of glucose in newborns and Neo-LDH for measurement of lactate dehydrogenase for fast diagnosis of newborns with suspected asphyxia.

Calmark Neo-Bilirubin

Type of technology	**Bilirubinometer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485:2016**
Manufacturer of Record	**Calmark Sweden AB**
How are results presented to user?	**Quantitative, mg/dL** **Quantitative, µmol/L**
Accuracy	**<150 µmol/L (<9mg/dL) 12.9%** **150-500 µmol/L (9-29mg/dL) 8.8%** **>500 µmol/L (>29mg/dL) 4.1%**
Linear range (mg/dL or µmol/L)	**Quantification range 150-500 µmol/L (9-29 mg/dL). Values below or over are presented as <150 or >500.**
Precision	**<150 µmol/L (<9mg/dL) CV 6,9%** **150-500 µmol/L (9-29mg/dL) CV 5,2%** **>500 µmol/L (>29mg/dL) CV 4,4%**
Sample type and sample volume required	**Whole blood, 2-3 drops (no centrifuge needed)**
Steps required to run from sample collection to results output	**1. Open the lid of the POC -Analyzer and put a new test cassette in the holder.** **2. Apply a sample of whole blood into the intended blood cavity. Fill the cavity completely with approximately 2-3 drops (at least 70 µL).** **3. Close the lid. The measurement starts automatically, and a bar is shown on the screen.** **4. A numeric value will be presented on the screen in the end of the measurement.**
Time to run from sample collection to result output	**2 minutes**
Calibration required	**Automatic calibration, no need for calibration asseccories**

Contact Information:

Calmark Sweden AB

info@calmark.se

+46 (0)734 201 904

www.calmark.se

Calmark Neo-Bilirubin

Electricity requirements, including voltage, and charging features	**The instrument is powered by a Li-Ion battery and is charged through micro-USB connection by using a provided USB- adapter (CE-approved, In 100-240VAC/50-60Hz <500mA, out 5VDC)**
Size and form factor	**Calmark POC-Analyzer is a portable device that can be used at the patient bedside.** **Instrument: WxHxD = 120x93x210 mm** **Single-use Test: WxHxD = 23.2x42.1x8.7 mm**
Shelf life, stability, and storage requirements	**Portable POC-Analyzer:** • **Life cycle: 7 years** • **Storage conditions: Temperature: 10-40°C (50-104°F) Humidity: 10-90% RH** **Single-use test operating conditions:** • **Temperature: 18-28°C (64.4-82.4°F) Humidity: 20-80% RH** **Shelf life 18 months (for test cassette)**
Warranty	**1 year**
Ex-works price of instrument	**~900 USD**
Ex-works price of test cassettes	**~48 USD per 20 pack**

Contact Information:

Calmark Sweden AB

info@calmark.se

+46 (0)734 201 904

www.calmark.se

BiliPic – Bilimetrix USA, LLC

Not yet commercially available / In development

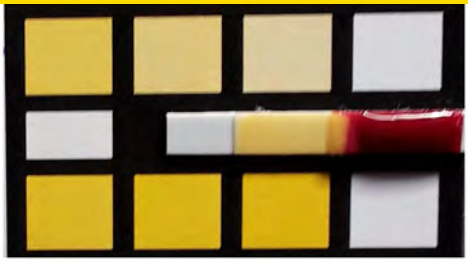
Intended Use

To measure plasma bilirubin concentration.

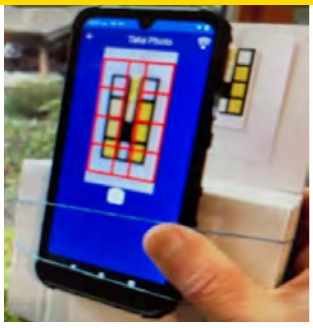
Key Features

- Smartphone POC digital system
- Data sharing
- Management guidelines

Test card with added blood (25-35µL). Blood is added to the teststrip which is then inserted into a reusable test card.



The BiliPic App has a grid to align with the test card. Laying the phone on a Box makes aligning easier (card board box and platform about $2.50). Box can be flat or held to eliminate shadows. Answer appear on the screen 5-20 seconds after photo is taken.



Contact Information:

Richard Wennberg

bilimetrixusa@gmail.com | rpw3450@gmail.com

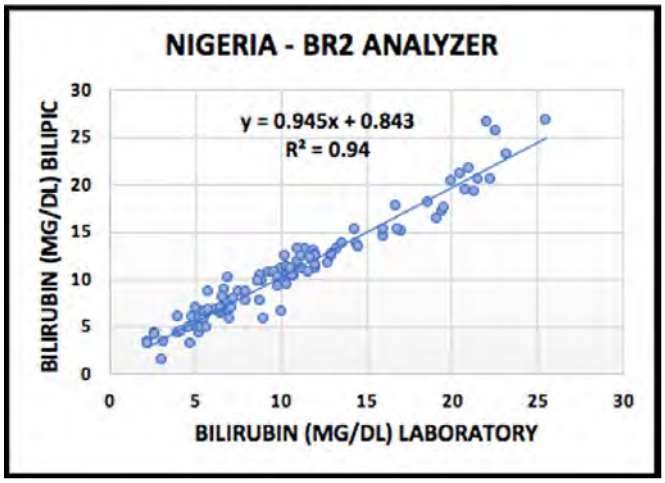
425 482 2748

www.bilimetrixusa.org

BiliPic

Type of technology	**Bilirubinometer**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**None**
Manufacturer of Record	**Bilimetrix USA, LLC**
How are results presented to user?	**Quantitative, results in mg/dL and µmol/L**
Accuracy	**LOA ± 1.3 mg/dL**
Linear range (mg/dL or µmol/L)	**2-29 mg/dL**
Precision	**CV 6% in range 13-18 mg/dL**
Sample type and sample volume required	**Whole blood 25-35 µL**
Steps required to run from sample collection to results output	**1. Sign on to App; select new patient, BiliPic** **2. Add blood with pipette to test strip.** **3. Insert test strip into reference card.** **4. Take photograph** **5. Read plasma bilirubin** **6. (optional) enter birth date, time, weight, exam**
Time to run from sample collection to result output	**1-2 minutes** **Time: blood added to photo ~30 secs** **Time: photo to result 5-20 seconds**
Calibration required	**Self-calibrating. Each new phone is evaluated with standard test cards to verify suitability.**
Electricity requirements, including voltage, and charging features	**Cell phone charger** **Internet connection is optimal for data sharing**
Size and Form Factor	**Using stand or box 3x5x8 inches facilitates aligning camera with test cards. Test strips packaged 20/pk**

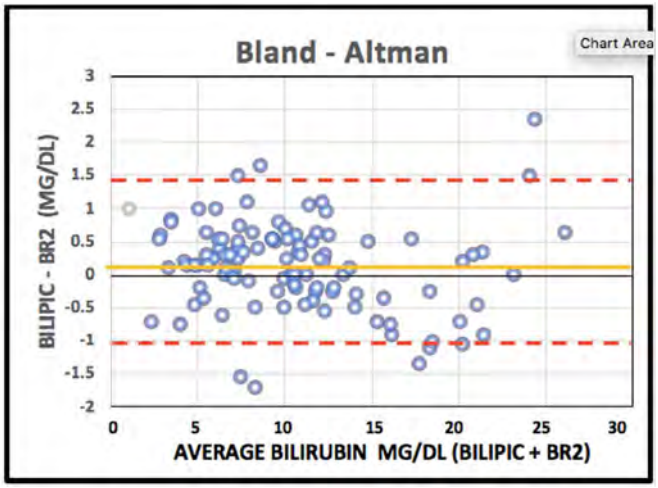
Correlation Bilipic and Laboratory bilirubin (BR2 Analyzer)



BiliPic

Shelf life, stability, and storage requirements	**Test cards: stable 3+ months unless stained** **Strips in sealed package: stable for 2 years** **Storage: 15-40 °C**
Warranty	**None**
Ex-works price of device	**Price of android smartphone ($40-$120). Software/App are free.**
Ex-works price of consumables	**Ex-works price of test strips: $0.80** **Reference cards: $3.50**

Limits of accuracy over-all = ±1.3 mg/dL. ~20% at bilirubin level <5 mg/dL. ~10% at bilirubin levels 15-20 mg/dL



Contact Information:

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Introduction to Phototherapy and Lightmeter

Treatment with blue light phototherapy is necessary to prevent morbidity and mortality for severe cases of neonatal jaundice. The blue light breaks down bilirubin in the blood, allowing the infant to excrete the excess bilirubin before it can accumulate and cause permanent brain damage (kernicterus) or death.

There is a dose dependent response of neonatal hyperbilirubinemia to phototherapy which depends on:

1. Duration of phototherapy.
2. Degree of irradiance given which is dependent on wavelength and type of light used.
3. The amount of body surface area irradiated.
4. The distance of light from patient (this will vary and is based on manufacturers recommendation but is typically 10–30cm).

Phototherapy lights can also be paired with an irradiance meter so that clinicians can determine if the infant is receiving a therapeutic dose of light. Typically, optimal spectral irradiance is 25–30 microW/cm^2/nm, although higher spectral irradiance of 30–35 microW/cm^2/nm may be used in more severe cases. If the dose is too low, clinicians may adjust the placement of the infant, the height or output power of the light, or replace burnt out light elements.

There are many types of phototherapy lights and modalities including LED, spotlights, fluorescent blue lights, halogen lights, and phototherapy blankets. LED lights have been shown to be the safest and most efficacious for administering phototherapy, as they give off the least heat and are associated with the lowest risk of hyperthermia and dehydration; although, this sometimes comes at an increased cost [12–14].

The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- Phoenix Brilliance Pro
- MTTS Colibri Phototherapy
- MTTS Firefly Phototherapy

To learn more about the five step process, please click here.

Brilliance Pro – Phoenix Medical Systems Pvt Ltd

Commercially available

Brilliance Pro

Type of technology	**Phototherapy**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Phoenix Medical Systems Pvt Ltd**
Size and Form Factor	**Information not submitted**
Range of irradiance (uW / cm2 / nm)	**>45µW/cm2/nm**
Peak wavelength (nm)	**450-465nm**
Effective treatment area (cm2)	**>1300**
Bulb type	**LED**
Bulb type (other)	**Information not submitted**
Bulb lifetime (hours)	**120,000 hours**
Describe if / how bulbs are replaced	**Information not submitted**
Come with an Irradiance Meter?	**Yes**
User instructions provided	**Information not submitted**
Electricity requirements, including voltage, and charging features	**Information not submitted**
Warranty	**Information not submitted**
Ex-works price of device	**$500 USD**
Ex-works price of consumables	**$25 USD**

Intended Use

Three out of five children have jaundice to some degree. In approximately 18% of these babies, the condition is severe and requires treatment. Severe jaundice, when left untreated or ineffectively treated, can lead to severe brain damage, a condition called kernicterus, or death. This can be averted simply by reducing the serum bilirubin through phototherapy. Brilliance LEDs last 60 times longer compared with CFLs. Using Brilliance Pro, hospitals can enjoy considerable savings by avoiding costly bulb replacements. Brilliance Pro consumes less than half the power consumed by CFLs. Brilliance Pro is designed to withstand severe power fluctuations without any change in performance. SmartTilt ensures that Brilliance Pro works effectively at any position and along with other pieces of neonatal intensive care equipment. This technology provides light of uniform intensity across the treatment area.

Key Features

- **SmartTilt Technology:** SmartTilt ensures that Brilliance Pro works effectively at any position and along with other pieces of neonatal intensive care equipment. This technology provides light of uniform intensity across the treatment area.
- **Energy Efficient:** Brilliance Pro consumes less than half the power consumed by CFLs.
- **Minimal Maintenance:** Brilliance LEDs last 60 times longer compared with CFLs. Using Brilliance Pro, hospitals can enjoy considerable savings by avoiding costly bulb replacements.
- **Quality:** Brilliance Pro is designed to withstand severe power fluctuations without any change in performance.
- **Therapy Timer:** Treatment times are easily tracked. Readings are displayed on an LCD screen.

Contact Information:

Phoenix Medical Systems Pvt Ltd

exports@pmsind.com

+27 71 528 9873

No website information provided

Colibri Phototherapy – Medical Technology Transfer and Services Co., Ltd (MTTS)

Commercially available

Intended Use

The Colibri Phototherapy is designed to treat neonatal jaundice in a hospital setting. The device is intended to treat infants with mild to severe jaundice. The unique design allows optimal light coverage while being used with infant warmers or incubators.

Key Features

- Standard and intensive modes
- 2-hour internal battery backup (optional)
- Compatible with most radiant warmers and incubators
- User-friendly control panel
- No moving parts, no internal fans
- Adjustable height (115–140 cm from the light source)
- 30W power consumption
- Total system time counter (lifetime)

Colibri Phototherapy

Type of technology	**Phototherapy**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485, CFS**
Manufacturer of Record	**MTTS Co., Ltd**
Size and Form Factor	**60 cm x 55 cm x 155 cm 15kg**
Range of irradiance (µW / cm2 / nm)	**Standard mode – 33.0** **Intensive mode – 57.6**
Peak wavelength (nm)	**455**
Effective treatment area (cm2)	**1500**
Bulb type	**LED**
Bulb lifetime (hours)	**60,000**
Describe if / how bulbs are replaced	**There are 4 LEDs on a panel. Panels can be replaced by trained technician**
Come with an Irradiance Meter?	**Yes (optional)**
User instructions provided	**User Manual, Quick Reference Guide, Instructional videos**
Electricity requirements, including voltage, and charging features	**100-240V AC**
Warranty	**1 year**
Ex-works price of device	**From $900 USD**
Ex-works price of consumables	**$32 USD for 4 LED panel**

Contact Information:

Medical Technology Transfer and Services Co., Ltd (MTTS)

info@mtts-asia.com

+84 24 3766 6521

www.mtts-asia.com

Firefly Phototherapy – Medical Technology Transfer and Services Co., Ltd (MTTS)

Commercially available

Intended Use

The Firefly Phototherapy is designed to treat neonatal jaundice in a hospital setting. The device is intended to treat infants with mild to severe jaundice that are not requiring external warmth. The device is not intended to be used in or in combination with a warmer of any sort.

Key Features

- Double-sided lighting
- 2-hour internal battery backup (optional)
- Compact size
- User-friendly control panel
- Removable single-infant bassinet
- Designed to treat newborn jaundice in the mother's room
- 30W power consumption
- Total system time counter (lifetime)
- Transparent gel mattress
- Transportation trolley

Firefly Phototherapy

Type of technology	**Phototherapy**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485, CFS**
Manufacturer of Record	**MTTS Co., Ltd**
Size and Form Factor	**66 cm x 38 cm x 49.5 cm** **13kg**
Range of irradiance (µW / cm2 / nm)	**Top light - 34.8** **Bottom light - 50.4**
Peak wavelength (nm)	**455**
Effective treatment area (cm2)	**1325**
Bulb type	**LED**
Bulb lifetime (hours)	**60,000**
Describe if / how bulbs are replaced	**There are 4 LEDs on a panel. Panels can be replaced by trained technician.**
Come with an Irradiance Meter?	**Yes (optional)**
User instructions provided	**User Manual, Quick Reference Guide, Instructional videos**
Electricity requirements, including voltage, and charging features	**100-240V AC**
Warranty	**1 year**
Ex-works price of device	**From $1,200 USD**
Ex-works price of consumables	**$32 USD for 4 LED panel**

Contact Information:

Medical Technology Transfer and Services Co., Ltd (MTTS)

info@mtts-asia.com

+84 24 37 666 521

www.mtts-asia.com

Light Meter – Medical Technology Transfer and Services Co., Ltd (MTTS)

Commercially available

Intended Use

To determine the light intensity in order to assess the functionality of the phototherapy unit or prioritize the patient for the stronger lights available.

Key Features

Light meter measures the light irradiance of the phototherapy units.

The control unit can be connected to other sensors such as oxygen, pressure or flow to perform relevant measurements (features available in 2022).

- **Center wavelength:** 450 nm
- **Bandwidth:** 100nm (400-500nm)
- **Measuring range:**
  - Single side: 0.1 – 150.0 µW/cm²/nm
  - Double side: 0.1 – 300.0 µW/cm²/nm
- **Resolution:** 0.1 µW/cm²/nm
- **Cosine characteristics:**
  - ±2% at 30 degree angle
  - ±7% at 60 degree angle
  - ±25% at 80 degree angle
- **Accuracy:** ±3% of reading

Light Meter

Type of technology	**Lightmeter**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485, Certificate of Free Sale**
Manufacturer of Record	**MTTS Co., Ltd**
Electricity requirements, including voltage, and charging features	**2 x AAA batteries**
Size and form factor	**12.5 x 7 x 2.4cm** **0.5kg**
Shelf life, stability, and storage requirements	**5 years** **Ambient temperature 0°C to +50°C** **Humidity: 0% to 90% RH non condensing** **Atmospheric Pressure: 70-106kPa**
Ex-works price of device	**From $620 USD**
Ex-works price of consumables	**$50 USD calibration every 24 months**

Contact Information:

Medical Technology Transfer and Services Co., Ltd (MTTS)

info@mtts-asia.com

+84 24 37 666 521

www.mtts-asia.com

Lullaby LED – General Electric Healthcare

Commercially available

Intended Use

Bilirubin treatment

Key Features

Optimal 458-nm wavelength, ideal irradiance levels, uniform light distribution, LEDs are rated to last up to an incredible 50,000 hours before requiring replacement, only 20-watt power consumption, removable head for seamless use with incubators.

Lullaby LED

Type of technology	**Phototherapy**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark & FDA**
Manufacturer of Record	**General Electric**
Size and Form Factor	**530 mm x 550 mm x 1700 mm**
Range of irradiance (µW / cm2 / nm)	**22 µW/cm2/nm - 45 µW/cm2/nm**
Peak wavelength (nm)	**450-465 nm**
Effective treatment area (cm2)	**50 cm x 30 cm**
Bulb type	**LED**
Bulb lifetime (hours)	**50,000 hours**
Describe if / how bulbs are replaced	**Information not submitted**
Come with an Irradiance Meter?	**Option**
User instructions provided	**Information not submitted**
Electricity requirements, including voltage, and charging features	**Information not submitted**
Warranty	**Information not submitted**
Ex-works price of device	**$1,500 USD**
Ex-works price of consumables	**$500 USD**

Contact Information:

Ayman Shaheen

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201000038650

www.gehealthcare.com

Bili-Hut – Little Sparrows Technologies

Not yet commercially available / In development

Intended Use

Treatment of neonatal hyperbilirubinemia. Narrow bandwidth blue LED, battery operable, ultraportable

Key Features

Narrow bandwidth blue LED, battery operable, ultraportable

Bili-Hut

Type of technology	**Phototherapy**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**Regulatory approvals and/or international standards**
Manufacturer of Record	**Little Sparrows Technologies**
Size and Form Factor	**16" W x 25" L x 12" H (40.64 cm W x 63.5 cm L x 30.48 cm H) (when assembled)**
Range of irradiance (µW / cm2 / nm)	**Avg irradiance: 45 uW / cm^2 / nm; Peak irradiance 58 uW / cm^2 / nm**
Peak wavelength (nm)	**463**
Effective treatment area (cm2)	**170 cm^2**
Bulb type	**LED**
Bulb lifetime (hours)	**Up to 50,000 hrs**
Describe if / how bulbs are replaced	**Bulbs do not require replacing**
Come with an Irradiance Meter?	**No**
User instructions provided	**Instruction for use manual; quick reference sheet**
Electricity requirements, including voltage, and charging features	**100-240V, 50-60 Hz. 20W Capable of operation from 12V source**
Warranty	**Limited manufacturer warranty**
Ex-works price of device	**TBD**
Ex-works price of consumables	**TBD**

Contact Information:

Little Sparrows Technologies

info@littlesparrowstech.com

781-725-2460

www.littlesparrowstech.com

Introduction to Other Products

This section is used to capture other newborn technologies within the ***Jaundice Management*** category-of-care .

BiliCare Neonatal Noninvasive Bilirubin Meter – Jaea Medical Supplies Ltd.

Commercially available

Intended Use

Screening tool for measuring and monitoring bilirubin levels to assess risk of neonatal hyperbilirubinemia.

Key Features

- Trans cutaneous Bilirubin Meter.
- LED transmission technology reduces user variances and need for routine device calibration-Measuring Site, Ear (Scaphoid Fossa).
- High correlation with Total Serum Bilirubin (r=0.9).
- Non-invasive hence reduces need for or number of heelsticks.

BiliCare Neonatal Noninvasive Bilirubin Meter

Type of technology	**Bilirubin meter-transcutaneous/ non-invasive**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485**
Manufacturer of Record	**Gerium Medical Ltd.**
Electricity requirements, including voltage, and charging features	**Input: 100-240VAC, 50/60Hz, 150mA. Output: 5V, 100mA. Battery: Lithium Ion, Voltage 3.7V (Recharge time 4 hrs)**
Size and form factor	**Dimensions: 80mm W x 80mm L x 67mm H Weight: 100gm**
Shelf life, stability, and storage requirements	**Operating Temperature: 0 Degrees Centigrade to 40 Degrees Centigrade Relative Humidity: 30% to 85% Storage Temperature: -10 Degrees Centigrade to +65 Degrees Centigrade**
Ex-works price of device	**Information not submitted**
Ex-works price of consumables	**Information not submitted**

Contact Information:

Jaea Medical Supplies Ltd.

info@jaea-medical.com

254711770857

www.jaea-medical.com

Bili-ruler – Little Sparrows Technologies

Not yet commercially available / In development

Intended Use

Screening tool for neonatal jaundice.

Key Features

Semi-quantitative, low cost POC neonatal jaundice screening tool.

Bili-ruler

Type of technology	**Bilirubin screening tool**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**FDA, CE (pending)**
Manufacturer of Record	**Little Sparrows Technologies**
Electricity requirements, including voltage, and charging features	**No electricity requirements**
Size and form factor	**Approx. 6.5" x 1"**
Shelf life, stability, and storage requirements	**TBD**
Ex-works price of device	**TBD**
Ex-works price of consumables	**N/A**

Contact Information:

info@littlesparrowstech.com

781-725-2460

www.littlesparrowstech.com

Point-of-Care Diagnostics

Access to diagnostic laboratories remains a key challenge in low-resource settings.[15]

Point-of-care diagnostic tests can therefore enable health-care workers to provide more rapid and effective care[16]. Simple, rapid, and affordable point-of-care tests which require minimal or no electricity, a laboratory, or highly trained staff, are now available and widely used for several common conditions in low and middle income countries (LMICs)[17]. These point-of-care tests offer an unprecedented opportunity to reduce inequalities in health, and to help LMICs achieve the health-related Sustainable Development Goals (SDGs)[4–9].

Outlined in this section are technologies designed to provide point-of-care diagnostic testing in low-resource settings.

Introduction to Glucometer

Hypoglycemia is a common metabolic problem in newborns and can result in neurologic complications if left untreated. Small and premature newborns are at increased risk for hypoglycemia. Monitoring blood glucose concentration allows clinicians to intervene with supplemental glucose for at-risk infants. Most common point-of-care glucometers are designed to be accurate at high glucose ranges for management of adult diabetes; few are intended for use or accurate in the low glucose concentrations seen in hypoglycemic newborns.

The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- Nova StatStrip Glucose Hospital Meter System
- Nova StatStrip Xpress2

To learn more about the five step process, please click here.

Calmark Neo-Glucose – Calmark Sweden AB

Not yet commercially available / In development

Intended Use

Calmark Neo-Glucose is a point-of-care diagnostic (POC) test which quantitatively measures low concentrations of glucose in whole blood from newborn infants. The device is intended to be used by medical staff inside hospital facilities or medical clinics.

Key Features

Calmark Neo-Glucose is based on the Calmark POC system and consist of a single-use test cassette and a portable instrument, the Calmark POC-Analyzer. The product line is built on a patented technology where the quantification of bilirubin is performed using a colorimetric detection method.

The test cassette is composed of a plastic shell containing four filters. The construction determines the blood volume and the initiation of the measurements. Test activation is done automatically by the instrument, generating results within minutes.

The filter combination handles high hematocrit and performs a hemolysis free filtration.

Other tests on the Calmark POC platform are Neo-Bilirubin for quantification of total plasma bilirubin in whole blood from newborn infants and Neo-LDH for quantification of lactate dehydrogenase fast diagnosis of newborns with suspected asphyxia.

Calmark Neo-Glucose

Type of technology	**Plasma glucose test**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**CE Mark pending**
Manufacturer of Record	**Calmark Sweden AB**
How are results presented to user?	**Presented as a numeric value on the screen of the portable reader**
Accuracy	**TBD**
Linear range (mg/dL or mmol/L)	**TBD**
Precision	**TBD**
Sample type and sample volume required	**Whole blood, 2-3 drops (no centrifuge needed)**
Steps required to run from sample collection to results output	**1. Open the lid of the POC-Analyzer and put a new test cassette in the holder.** **2. Apply a sample of whole blood into the intended blood cavity. Fill the cavity completely with approximately 2-3 drops (at least 70 µL).** **3. Close the lid. The measurement starts automatically, and a bar is shown on the screen** **4. A numeric value will be presented on the screen in the end of the measurement.**
Time to run from sample collection to result output	**3 minutes**
Calibration required	**Calmark Neo-Glucose is calibrated during manufacturing and does not need recalibration. Every single-use test contains information needed for automatic calibration of the results.**

Contact Information:

Calmark Sweden AB

info@calmark.se

+46 (0)734 201 904

www.calmark.se

Calmark Neo-Glucose

Electricity requirements, including voltage, and charging features	**The instrument is powered by a Li-Ion battery and is charged through micro-USB connection by using a provided USB adapter (CE-approved, In 100-240 VAC/50-60 Hz < 500 mA, out 5 VDC)**
Size and Form Factor	**Calmark POC-Analyzer is a portable device that can be used at the patient bedside.** **Instrument: WxHxD = 120x93x210 mm** **Single-use Test: WxHxD = 23.2x42.1x8.7 mm**
Shelf life, stability, and storage requirements	**Portable instrument :** • **Life cycle: 7 years** • **Storage conditions: Temperature: 10-40°C (50-104°F) Humidity: 10-90% RH** **Single-use test: TBD**
Warranty	**TBD**
Ex-works price of instrument	**TBD**
Ex-works price of test casssettes	**TBD**

Contact Information:

Calmark Sweden AB

info@calmark.se

+46 (0)734 201 904

www.calmark.se

Introduction to Hemoglobinometer

Hemoglobin concentration refers to the amount of the oxygen-carrying protein in the blood, and is a diagnostic for anemia (low hemoglobin) or polycythemia (high hemoglobin).

Outlined in this section are hemoglobinometers for low-resource settings. Note that technologies within this product category have not yet been evaluated by the NEST360 team for inclusion as a NEST360 Qualified Technology. To learn more about what it means to be "NEST360 Qualified" and how the technologies are qualified by NEST360, please click here.

Rad-67 – Masimo Corporation

Commercially available

Intended Use

Spot check monitoring of hemoglobin, oxygen saturation, heart rate, perfusion index, and methemoglobin.

For more information, visit http://www.masimo.com

*The information in this document is provided for basic informational purposes only, and is not intended to constitute a comprehensive overview of Masimo products and technology. While every effort has been made to provide current and accurate information about these products and technologies, Masimo makes no guarantees of any kind about the currency or accuracy of this information. Moreover, federal (USA) law restricts these devices to sale by or on the order of a physician. In using any of these devices, please see instructions for use for full prescribing information, includingindications, contraindications, warnings, and precautions.

Key Features

The Rad-67 is a combined pulse oximeter that measures oxygen saturation (SpO2), heart rate (HR), perfusion index (PI), total hemoglobin (SbHb), and methemoglobin (MetHb). The device is handheld and has a color touch screen.

Rad-67

Type of technology	**Hemoglobinometer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, US FDA Clearance**
Manufacturer of Record	**Masimo Corporation**
Accuracy	**1 g/dL**
Linear range	**8-17 g/dL (note that legally in our validation we cannot hemodylate below 8; there is a linear relationship therefore lower values will still read accurately**
Precision	**0.1**
Sample type and sample volume	**The measure is non invasive**
Describe the steps required to run test, from sample collection to results output.	**Turn device on. Place sensor on toe or finger (depending on patient size). Hit the start button. Wait 30 seconds. Take reading.**
How much time does it take to run one test, from sample collection to result output?	**The measurement time is 30 seconds. Time to prepare patients varies depending on setting.**
Calibration required	**Information not submitted**
Electricity requirements, including voltage, and charging features	**100-240Vac, 50/60Hz, 0.5A**
Size and form factor	**0.8 pounds (7.65" x 3.23" x 0.93")**
Shelf life, stability, and storage requirements	**See page 78 of the user operator guide**
Ex-works price of device	**Pricing varies by volume**
Ex-works price of consumables	**Pricing varies by volume**

Contact Information:

Masimo Corporation

gjaaron@masimo.com

+41 79 267 7963

www.masimo.com

*These products are for professional use only. Federal (USA) law restricts these devices to sale by or on the order of a physician. In using any of these devices, please see instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

Introduction to pH Monitor

pH is an important blood gas measurement that assesses the acid-base status of the blood. pH can be assessed on arterial cord blood as well as peripheral arterial, venous, and capillary blood and, when interpreted with other tests and clinical conditions, provide information on the status of the neonate. Although clinically relevant pH values vary by condition, postnatal age (in minutes/hours), and type of blood sample (i.e., venous, arterial, etc.), pH values below 7.4 can indicate acidosis, which can be either metabolic, respiratory, or mixed. In the newborn setting, blood gas analysis is typically employed in an intensive care setting and can be utilized to augment management of invasive and non-invasive positive pressure respiratory support, sepsis, and perinatal asphyxia. To differentiate between the different types of acidosis, it is necessary to measure not only pH but also pCO^2, pO^2, and base excess.

Currently, we have not received any submissions for pH Monitor. If you are a manufacturer or product developer and wish to include your technology in future versions of this manual, please contact Becca Kirby at: **becca.kirby@kellogg.northwestern.edu.**

Note that technologies within this product category have not yet been evaluated by the NEST360 team for inclusion as a NEST360 Qualified Technology. To learn more about what it means to be "NEST360 Qualified" and how the technologies are qualified by NEST360, please click here.

Introduction to Other Products

This section is used to capture other newborn technologies within the ***Point-of-Care Diagnostics*** category-of-care.

Calmark Neo-LDH – Calmark Sweden AB

Not yet commercially available / In development

Intended Use

Calmark Neo-LDH is a point-of-care diagnostic (POC) test for measuring lactate dehydrogenase (LDH) in whole blood fast diagnosis of newborns with suspected asphyxia. The device is intended to be used by medical staff inside hospital facilities or medical clinics.

Key Features

Asphyxia is a major cause of mortality and neurological damage during birth. The enzyme Lactate Dehydrogenase (LDH) is a unique predictor of asphyxia, demonstrated by increased plasma levels during the first hours after birth. Fast diagnosis is important for effective treatment and recovery but until now, there have not been any POC tests available for LDH [41–43]. Calmark Neo-LDH is based on the Calmark POC system and consist of a single-use test cassette and a portable instrument, the Calmark POC-Analyzer. The product line is built on a patented technology where the quantification of LDH is performed using a colorimetric detection method.

The single-use test cassette is composed of a plastic shell containing four filters. The construction determines the blood volume and the initiation of the measurements. Test activation is done automatically by the instrument, generating results within minutes.

The filter combination handles high hematocrit and performs a hemolysis free filtration. The POC-Analyzer contains a camera, a light source, and a software.

Other tests on the Calmark POC platform are Neo-Bilirubin for quantification of total plasma bilirubin and Neo-Glucose for accurate measurement of low levels of glucose in plasma from newborn infants.[30–32]

Calmark Neo-LDH

Type of technology	**Serum Lactate Dehydrogenase (LDH) Test**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**CE Mark pending**
Manufacturer of Record	**Calmark Sweden AB**
How are results presented to user?	**Presented as a numeric value on the screen of the portable instrument**
Sample type and sample volume required	**Whole blood, 2-3 drops (no centrifuge needed)**
Steps required to run from sample collection to results output	**1. Open the lid of the POC-Analyzer and put a new test cassette in the holder.** **2. Apply a sample of whole blood into the intended blood cavity. Fill the cavity completely with approximately 2-3 drops (at least 70 µL).** **3. Close the lid. The measurement starts automatically, and a bar is shown on the screen.** **4. A numeric value will be presented on the screen in the end of the measurement.**
Time to run from sample collection to result output	**3 minutes**
Calibration required	**Calmark Neo-LDH is calibrated during manufacturing and does not need recalibration. Every single-use test contains information needed for automatic calibration of the results.**
Electricity requirements, including voltage, and charging features	**The intstrument is powered by a Li-Ion battery and is charged through micro-USB connection by using a provided USB- adapter (CE-approved, In 100-240VAC/50-60Hz <500mA, out 5VDC)**

Contact Information:

Calmark Sweden AB

info@calmark.se

+46 (0)734 201 904

www.calmark.se

Calmark Neo-LDH

Size and Form Factor	**Calmark POC-Analyzer is a portable device that can be used at the patient bedside.** **Instrument: WxHxD = 120x93x210 mm** **Single-use Test: WxHxD = 23.2x42.1x8.7 mm**
Shelf life, stability, and storage requirements	**Portable intstrument:** • **Life cycle: 7 years** • **Storage conditions: Temperature: 10-40°C (50-104°F) Humidity: 10-90% RH** • **Single-use test: TBD**
Warranty	**TBD**
Ex-works price of intstrument	**TBD**
Ex-works price of test cassette	**TBD**

Contact Information:

Calmark Sweden AB

info@calmark.se

+46 (0)734 201 904

www.calmark.se

Respiratory Support

Upon birth, a baby's lung must transition from fetal to neonatal life in three key ways:

1) fluid in the lungs must be absorbed and replaced with air,
2) lungs must expand fully and regular breathing must be established, and
3) pulmonary blood flow is increased.

When these three things do not happen, a baby will have respiratory distress. Respiratory distress syndrome (RDS) is when there is deficiency of surfactant that is needed to prevent alveolar collapse; this is especially common in premature newborns.

Oxygen provision is important in the care of newborn infants because many conditions that affect babies in the first days of life can result in low levels of oxygen in the body. Hypoxemia, or low levels of oxygen in the blood, is a life-threatening condition that results in increased mortality and morbidity. Prematurity and respiratory distress syndrome (surfactant deficiency), pneumonia and other severe infections, asphyxia, and difficulties in the transition from fetal to neonatal life can all result in hypoxemia. Yet, despite its importance in acute severe illnesses, hypoxemia is often not well recognized or managed in settings where resources are limited. It is therefore important for health workers to know the clinical signs that suggest the presence of hypoxemia and how supplemental oxygen can appropriately be used as an essential lifesaving treatment [26].

Outlined in this section are technologies that provide breathing and oxygen support in neonates.

Introduction to CPAP

In high-resource settings, a mother is given steroids before birth if a baby is anticipated to be born preterm to help prevent respiratory distress syndrome (RDS). If RDS still occurs, assisted breathing with continuous positive airway pressure (CPAP) is started. If CPAP is not sufficient, intubation, surfactant and/or ventilation may be needed.

In low-resource settings, many facilities lack the resources to implement CPAP. While many companies make newborn CPAP devices, only a few key players design their devices to work in low-resource settings.

Bubble Continuous Positive Airway Pressure (bCPAP) therapy is a common mode of treatment for RDS in premature neonates and for respiratory illness in young children. bCPAP provides a continuous flow of pressurized air into the patient's nostrils via nasal prongs or a mask; this pressure prevents alveolar collapse during exhalation. In high-income settings, early bCPAP is now preferred over mechanical ventilation as first line therapy for respiratory distress syndrome in preterm infants. bCPAP has been shown to promote production of endogenous surfactant[27] as well as dramatically decrease progression to intubation or death in both high[28–30] and low[31–32] income settings.

In low-resource settings, there is a need for bCPAP that is designed for patients who weigh between 1 and 10 kg and that includes an oxygen blender which allows users to provide 21-90% oxygen to the patient when an external oxygen source is connected to the bCPAP. The bCPAP should ideally contain an integrated air-compressor, blender, and patient interface. Although there are short cuts for delivering positive airway pressure to a baby without an appropriate device, these generally rely on pure oxygen sources from oxygen cylinders or concentrators. The ability of a CPAP device to deliver positive pressure at low fractional inspired oxygen concentrations (FiO^2) is a critical feature for preventing blindness and chronic lung disease associated with oxygen administration[31–34]. Humidification, while a feature of some CPAP devices, remains a controversial feature of CPAP in low-resource settings, especially for CPAP devices utilizing compressed ambient air rather than gas cylinder sources.

There are some bCPAP technologies included in this document that are commercially available, however, there is variability in patient interface, presence of humidification, and integration of the air compressor into the CPAP unit. For some, an air compressor is not included with the device and would need to be purchased separately. Procurement officers should consider current evidence, target level of care, infrastructure capacity, availability of human resources, provision, and context when choosing between available CPAP devices.

The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- Diamedica UK Baby CPAP 10
- Pumani bubbleCPAP

To learn more about the five step process, please click here.

Baby CPAP 10 – Diamedica (UK) Ltd

Commercially available

Intended Use

A simple to use, life-saving CPAP device for preterm babies, neonates and infants. Baby CPAP provides safe controllable bubble CPAP for resource-limited settings where the cost of conventional CPAP is prohibitive.

Key Features

The Baby CPAP has been designed to enable CPAP therapy in low-resource settings. It is a completely self-contained unit that supplies up to 95% oxygen and medical air, so there is no need for any costly cylinders of compressed gas. A humidifier ensures appropriate warmth and moisture for the air and oxygen mix to be delivered to the patient. A clear oxygen/air mixing chart allows for easy setting of flow rates and oxygen concentration levels. A voltage protector is fitted to protect the machine from unstable power surges that can damage equipment. Mounted on castors for easy transport between patients. Precision design for simplicity of use, low maintenance and easy servicing. Designed and engineered and manufactured in the UK, robust and built to last. The Baby CPAP comes complete with all accessories needed and includes:

- 1 Diamedica Baby CPAP unit
- 1 bubble pressure bottle
- 1 humidifier bottle
- 2 sets of inspiratory/expiratory tubes with connectors
- 2 nasal cannula kits, including 2 nasal tubing, 4 silicone nasal prongs, 2 baby bonnets, 2 Velcro fixing strap and chin strap
- User/maintenance manual, spare parts list, and training video

Baby CPAP 10

Type of technology	**Bubble CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Diamedica (UK) Ltd**
Integrated air compressor (Yes/No)	**Yes**
Include humidification (Yes/No)	**Yes, heated**
Integrated blender (Yes/No)	**Yes**
Total flow capability (lpm)	**10 lpm (5 lpm oxygen and 5 lpm air)**
Pressure range (cm H20)	**1 – 10 H2O**
FiO2 range (FiO2 %)	**21 – 95%**
Total (blended) flow (lpm)	**10 lpm (5 lpm oxygen and 5 lpm air)**
Alarms included in device	**Power failure, low oxygen concentration, high and low pressure, no flow**
Consumables required	**None**
Accessories required	**None. Comes complete with all accessories. Additional parts can be purchased, as required.**
Patient interface(s) compatibility	**Information not submitted**
Voltage requirements	**230 V 50 Hz**
User instructions provided	**Comes with operating and maintenance manual, and training video**
Warranty	**2 years**
Ex-works price of device	**£1,450 GBP**
Ex-works price of consumables	**Hudson nasal prong £3 GBP Hudson style cannula kit £9 GBP RAM cannula £11 GBP**

Contact Information:

Diamedica (UK) Ltd

info@diamedica.co.uk | support@diamedica.co.uk

+44 1598 710066

www.diamedica.co.uk

Baby CPAP 20 – Diamedica (UK) Ltd

Commercially available

Intended Use

A simple to use, low cost, life-saving respiratory solution for preterm babies, neonates, and infants. Baby CPAP provides safe controllable bubble CPAP for resource-limited settings where the cost of conventional CPAP is prohibitive.

Key Features

The Baby CPAP has been designed to enable CPAP therapy in low-resource settings. It is a completely self-contained unit that supplies up to 95% oxygen and medical air, so there is no need for any costly cylinders of compressed gas. A humidifier ensures appropriate warmth and moisture for the air and oxygen mix to be delivered to the patient. A clear oxygen/air mixing chart allows for easy setting of flow rates and oxygen concentration levels. A voltage protector is fitted to protect the machine from unstable power surges that can damage equipment. Mounted on castors for easy transport between patients. Precision design for simplicity of use, low maintenance and easy servicing. Designed and engineered and manufactured in the UK, robust and built to last. The Baby CPAP comes complete with all accessories needed and includes:

- 1 Diamedica Baby CPAP unit
- 1 bubble pressure bottle
- 1 humidifier bottle
- 2 sets of inspiratory/expiratory tubes with connectors
- 2 nasal cannula kits, including 2 nasal tubing, 4 silicone nasal prongs, 2 baby bonnets, 2 Velcro fixing strap and chin strap
- User/maintenance manual, spare parts list, and training video

Baby CPAP 20

Type of technology	**Bubble CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Diamedica (UK) Ltd**
Integrated air compressor (Yes/No)	**Yes**
Include humidification (Yes/No)	**Yes, heated**
Integrated blender (Yes/No)	**Yes**
Total flow capability (lpm)	**20 lpm (10 lpm oxygen and 10 lpm air)**
Pressure range (cm H20)	**1 – 10 cm H2O**
FiO2 range (FiO2 %)	**21 – 95%**
Total (blended) flow (lpm)	**20 lpm (10 lpm oxygen and 10 lpm air)**
Alarms included in device	**Power failure, low oxygen concentration, high and low pressure, no flow.**
Consumables required	**None. Comes complete.**
Accessories required	**None. Comes complete with all accessories. Additional parts can be purchased, as required.**
Patient interface(s) compatibility	**Information not submitted**
Voltage requirements	**240 V, 50 hz**
User instructions provided	**Comes with operating and maintenance manual, and training video**
Warranty	**2 years**
Ex-works price of device	**£1,750 GBP**
Ex-works price of consumables	**Hudson nasal prong £3 GBP** **Hudson style cannula kit £9 GBP** **RAM cannula £11 GBP**

Contact Information:

Diamedica (UK) Ltd

info@diamedica.co.uk

+44 1598 710066

www.diamedica.co.uk

Dolphin CPAP – Medical Technology Transfer and Services Co., Ltd (MTTS)

Commercially available

Intended Use

The Dolphin CPAP device is designed to provide respiratory support for spontaneously breathing neonatal patients with mild to severe idiopathic respiratory distress syndrome (RDS), mild to severe apnea, atelectasis, hyaline membrane disease (HMD), meconium aspiration syndrome (MAS), transient tachypnea of the neonate (TTN) or lung edema. A pulse oximeter provides continuous, non-invasive monitoring of pulse rate and arterial oxygen saturation. The device is indicated for well- or poorly- perfused patients in a hospital setting. The device is not indicated for patients whose upper airways have been bypassed. The device is to be operated by qualified personnel only.

Key Features

- 100% reusable and cleanable, complete all-in-one CPAP treatment and monitoring device
- battery backup – up to 3 hours of work (no heat or humidity)
- blender – electronic mixing, no calculations or tables, connection to a variety of oxygen sources
- PEEP – innovative design for safe and easy one hand adjustment
- humidifier: quick warm up, automatically refills for 3-days continuous operation
- patient circuit – completely reusable, parts autoclavable or chemically disinfectable
- pulse oximeter – integrated, provided by Masimo SET® technology
- integrated air compressor – blower type, no diaphragm, external wires or tubes
- simple user interface and alarm settings

Contact Information:

Medical Technology Transfer and Services Co., Ltd (MTTS)

info@mtts-asia.com

+84 24 3766 6521

www.mtts-asia.com

Dolphin CPAP

Type of technology	**Bubble CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485, CFS**
Manufacturer of Record	**MTTS Co., Ltd**
Integrated air compressor (Yes/No)	**Yes**
Include humidification (Yes/No)	**Yes**
Integrated blender (Yes/No)	**Yes**
Total flow capability (lpm)	**10**
Pressure range (cm H20)	**1–10**
FiO2 range (FiO2 %)	**21–100%**
Total (blended) flow (lpm)	**10**
Alarms included in device	• **Power failure** • **Heater wire / temp. sensor failure** • **Input O2 pressure too low / too high** • **Input air pressure too low** • **Flow rate too low / too high** • **Humidifier failure** • **Pressure too high (>14 cmH2O)**
Consumables required	**Nasal cannulas**
Accessories required	**Oxygen sensor (every 2–3 years)**
Patient interface(s) compatibility	**Proprietary, Hudson prongs, RAM Cannula**
Voltage requirements	**100–240V AC**
User instructions provided	**User Manual, Quick Reference Guide, Reprocessing Guide, Assembly Video**
Warranty	**1 year**
Ex-works price of device	**From $2,900 USD**
Ex-works price of consumables	**From $1.90 USD**

Fisher & Paykel Healthcare Bubble CPAP System – Fisher & Paykel

Commercially available

Fisher & Paykel Healthcare Bubble CPAP System

Type of technology	**Bubble CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**FDA, CE mark**
Manufacturer of Record	**Fisher & Paykel Healthcare**
Integrated air compressor (Yes/No)	**No**
Include humidification (Yes/No)	**Yes, heated humidification (targeting optimal levels of humidity i.e. 37C/44mgL)**
Integrated blender (Yes/No)	**No**
Total flow capability (lpm)	**4–15**
Pressure range (cm H20)	**3–10**
FiO2 range (FiO2 %)	**21–100%**
Total (blended) flow (lpm)	**4–15**
Alarms included in device	**N//A**
Consumables required	• **Fisher & Paykel Healthcare Circuit Kit (BC151, BC161)** • **Nasal prongs (e.g., Hudson prongs or FlexiTrunk)** • **green oxygen tubing**
Accessories required	• **Blender** • **MR850**
Patient interface(s) compatibility	**Hudson prongs, Fisher & Paykel Healthcare FlexiTrunk**
Voltage requirements	**The MR850 humidifier voltage changes dependent on the country it is for sale**
User instructions provided	**User Manual**
Warranty	**3 years**
Ex-works price of device	**N/A**
Ex-works price of consumables	**N/A**

Intended Use

The Fisher & Paykel Healthcare Bubble CPAP System is intended to provide CPAP to spontaneously breathing neonates and infants who require breathing support due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired and is prescribed by a physician.

The Bubble CPAP System is for use in the hospital clinical environment such as the NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit). The intended patient population is premature and full term neonates up to a weight of 10 kg.

Key Features

Continuous positive airway pressure (CPAP) therapy delivers a heated and humidified blend of air and oxygen while at the same time generating a continuous distending pressure throughout the respiratory cycle.

The Fisher & Paykel Healthcare Bubble CPAP generator is designed to provide consistent pressure through an auto-leveling feature. This design moves excess liquid into a separate chamber from the main pressure-generating section, automatically ensuring that the set pressure does not change with liquid build-up.

Contact Information:

Sadaf Asmaie

Sadaf.asmaie@fphcare.com

949-402-2002

www.fphcare.com

NCPAP 300 – Phoenix Medical Systems

Commercially available

Intended Use

NCPAP 300 is a simple continuous positive airway pressure (CPAP) system designed to provide support to fragile infants suffering from RDS. NCPAP 300 prevents airway closure and maintains the functional residual capacity.

Key Features

- **Flow, bubble and Hi-flow:** Versatile; it can be configured for both flow, bubble and hi-flow operation according to your preference.
- **Safety Alarms:** Continuous digital monitoring of oxygen concentration, pressure and apnea with an alert system if parameters exceed or drop below set limit. The alarm system assures a safe administration of CPAP while protecting the lungs of the infant from damage.
- **Compact Electronic Blender:** Accurate delivery of gases with precise control of the proportion of air and oxygen which will highly improve the safety and efficacy of therapy.
- Battery back-up of 3 hours.
- **Display Unit:** Values of respiratory parameters are displayed in large, bright characters for easy reading.
- **Digital Control:** FiO2 and flow are easily adjustable in accurate concentration through soft touch keys.
- Lightweight patient interface intricately designed to eliminate damage to the nasal septum and delicate nostrils of the infant. Patient interface can be customized to country specific demands.

NCPAP 300

Type of technology	**Bubble CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485, CE Mark**
Manufacturer of Record	**Phoenix Medical Systems Pvt Ltd**
Integrated air compressor (Yes/No)	**Optional**
Include humidification (Yes/No)	**Yes**
Integrated blender (Yes/No)	**Yes**
Total flow capability (lpm)	**15 lpm**
Pressure range (cm H20)	**0 to 20 cm H20**
FiO2 range (FiO2 %)	**21% to 100%**
Total (blended) flow (lpm)	**15 lpm**
Alarms included in device	**Air, oxygen input fail, apnea, air pressure, power failure, battery low**
Consumables required	**Bonnets, prongs, patient circuits**
Accessories required	**Humidifier with chambers, generators**
Patient interface(s) compatibility	**It is universal compatible for patient interface**
Voltage requirements	**230V/110V** **50/60 Hz respectively**
User instructions provided	**User manual will be provided**

Contact Information:

Phoenix Medical Systems Pvt Ltd

exports@pmsind.com

+27 71 528 9873

https://www.phoenixmedicalsystems.com/

NCPAP 300

Warranty	**1 year**
Ex-works price of device	**$3,300 USD / Rs.3.43 lakh including taxes**
Ex-works price of consumables	**$140 USD** **Bubble CPAP consumables: Rs.4000 + tax** **Flow CPAP consumables: Rs.4000+tax** **HFNC Consumables: Rs.4000 + tax**

Contact Information:

Phoenix Medical Systems Pvt Ltd

exports@pmsind.com

+27 71 528 9873

https://www.phoenixmedicalsystems.com/

Portable Transport CPAP – Diamedica (UK) Ltd

Commercially available

Intended Use

ntended for use on babies and infants in a wide range of locations and scenarios, such as in the delivery room, during transport within or between hospitals, when the number of patients in need of CPAP temporarily exceeds the number of larger machines available and during power outages. Internal battery provides 8 hour battery run time.

Key Features

A portable CPAP device for preterm, neonate and paediatric patients in need of pressure support therapy immediately following birth or whilst being transported, internally in the hospital or externally. Safe and flexible device, easy for staff to understand and use, with preset pressures and flows, depending on cannula size. A single device can be used on two patients simultaneously. The main dangers of CPAP stem from oxygen toxicity (ROP) and pneumothorax. The Diamedica portable CPAP has been designed to eliminate, as much as possible, these two conditions.

Safety Considerations:

- **Oxygen toxicity:** Max FiO2 of 38%.
- **Pneumothorax:** Max pressure of <10 cm H2O.
- **CO2 retention:** High pump flow through Y-piece.
- **Septal trauma:** Designed for <80% nares occlusion.
- **Human error:** Single pressure and flow setting.

Contact Information:

Diamedica (UK) Ltd

info@diamedica.co.uk

+44 1598 710066

www.diamedica.co.uk

Portable Transport CPAP

Type of technology	**Portable CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Diamedica (UK) Ltd**
Integrated air compressor (Yes/No)	**Yes**
Include humidification (Yes/No)	**Yes, unheated**
Integrated blender (Yes/No)	**Information not submitted**
Total flow capability (lpm)	**Baby 8 lpm, Child 20 lpm**
Pressure range (cm H20)	**5-10 cm H20**
FiO2 range (FiO2 %)	**Max 38%**
Total (blended) flow (lpm)	**Baby 8 lpm, Child 20 lpm**
Alarms included in device	**Battery capacity indicator**
Consumables required	**RAM cannula only**
Accessories required	**Supplied with all accessories required**
Patient interface(s) compatibility	**Information not submitted**
Voltage requirements	**12V internal chargeable battery. 8 hours. Recharge voltage 12-240V**
User instructions provided	**Users manual and video to be provided**
Warranty	**2 years**
Ex-works price of device	**£800 GBP**
Ex-works price of consumables	**RAM cannula £11 GBP**

Pumani bubbleCPAP – 3rd Stone Design

Commercially available

Intended Use

The Pumani bubbleCPAP is intended for use in treating respiratory distress and other forms of respiratory illness in infants up to one year of age/below 10 kg.

Key Features

Features: Bubble continuous positive airway pressure (bCPAP) is a safe, effective intervention for infants with respiratory distress and is widely used in developed countries. The Pumani bCPAP is a low-cost, easy-to-use, easy-to-repair device to treat infants in respiratory distress, and it has been designed specifically to operate in low-resource settings. Clinical results show that use of the Pumani bCPAP can significantly reduce neonatal mortality in low-resource settings.

Pumani bubbleCPAP

Type of technology	**Bubble CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485**
Manufacturer of Record	**Hadleigh Health Technologies**
Integrated air compressor (Yes/No)	**Yes**
Include humidification (Yes/No)	**No**
Integrated blender (Yes/No)	**Yes**
Total flow capability (lpm)	**0 – 10 L/min**
Pressure range (cm H20)	**0 – 10cm H20**
FiO2 range (FiO2 %)	**21 – 100%**
Total (blended) flow (lpm)	**0 – 10 L/min**
Alarms included in device	**Power failure**
Consumables required	**Yes**
Accessories required	**Patient circuit and nasal prongs**
Patient interface(s) compatibility	**Information not submitted**
Voltage requirements	**220 – 240V**
User instructions provided	**Printed user manual and access to online video support and training library**
Warranty	**2 years standard warranty**
Ex-works price of device	**$900 USD**
Ex-works price of consumables	**Varies**

Contact Information:

Hadleigh Health Technologies

info@hadleighhealth.com

+1 415-650-9537

www.hadleighhealth.com

Seattle PAP – Draeger

Commercially available

Intended Use

The Seattle PAP system is intended to provide nasal continuous positive airway pressure (nCPAP) to patients weighing up to 10 kg (22 lbs) who qualify for non-invasive respiratory support.

Key Features

The Seattle-Positive Airway Pressure (PAP) system is an innovation, which uses the proven advantages of Bubble CPAP therapy, such as oscillatory effects similar to high frequency ventilation combined with an unique design. Seattle-PAP is safe, effective and easy to use. It was designed to:

- Promote infant safety with a uniquely designed pressure manifold with pressure relief valve.
- Safety tube lock to avoid unintended changes of the PEEP level.
- The water trap in the expiratory limb prevents unwanted pressure peaks due to condensation.

Seattle PAP

Type of technology	**Bubble CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, US FDA Clearance, ISO 13485**
Manufacturer of Record	**Draeger**
Integrated air compressor (Yes/No)	**No**
Include humidification (Yes/No)	**System requires a humidifier (e.g. F&P MR 850)**
Integrated blender (Yes/No)	**Information not submitted**
Total flow capability (lpm)	**4-12 l/min**
Pressure range (cm H20)	**4,5 cm H2O - 10 cm H2O**
FiO2 range (FiO2 %)	**Information not submitted**
Total (blended) flow (lpm)	**4-12 l/min**
Alarms included in device	**Pressure relief valve at 17 cm H2O /8l/ min Flow, Humidifier alarms**
Consumables required	**Set of consumables**
Accessories required	**Information not submitted**
Patient interface(s) compatibility	**Information not submitted**
Voltage requirements	**Depending on the local needs**
User instructions provided	**Instruction for Use in 28 languages**
Warranty	**Information not submitted**
Ex-works price of device	**Information not submitted**
Ex-works price of consumables	**$34 USD + VAT (LMIC)**

Contact Information:

Draeger

HCA@draeger.com

+49 451 8820

www.draeger.com

Vayu Bubble CPAP Circuit – Vayu Global Health Innovations

Commercially available

Intended Use

The Vayu bCPAP System provides continuous positive airway pressure to newborns and infants that require non-invasive ventilation due to Respiratory Distress Syndrome, pneumonia, and other acute respiratory conditions.

Key Features

The Vayu bCPAP System provides newborns and infants with high-quality ventilation support. The Vayu bCPAP System does not require electricity or compressed air; but instead, is powered by oxygen from a tank, bottle, or central supply. An innovative ambient air / oxygen blender allows a user to adjust FiO_2 from 30 to 100%. Flows, pressures, and work of breathing are comparable to state-of-the-art CPAP systems.

Contact Information:

Vayu Global Health Innovations

info@vayughi.com

www.vayughi.com

Vayu Bubble CPAP

Type of technology	**Bubble CPAP**
Status	**Commercially available**
Regulatory approvals and/or international standards	**US FDA Emergency Use Authorized (EUA)** **US FDA 510(k) Clearance in progress**
Manufacturer of Record	**Vayu Global Health Innovations**
Integrated air compressor (Yes/No)	**N/A**
Include humidification (Yes/No)	**Yes**
Integrated blender (Yes/No)	**Yes**
Total flow capability (lpm)	**5 – 10 lpm**
Pressure range (cm H20)	**4 – 10 cm H2O**
FiO2 range (FiO2 %)	**21, 30 – 100%**
Total (blended) flow (lpm)	**5 – 10 lpm**
Alarms included in device	**N/A**
Consumables required	**EUA is for single patient use** **Clearance of multi-use device with consumable packs in progress**
Accessories required	**None**
Patient interface(s) compatibility	**Hudson prongs and similar**
Voltage requirements	**N/A**
User instructions provided	**Printed and electronic user manual, Online training course and technical support, Smartphone App**
Warranty	**N/A**
Ex-works price of device	**$400 USD**
Ex-works price of consumables	**$10 USD**

Bubble CPAP Kit with O_2 Blenders – PATH

Not yet commercially available / In development

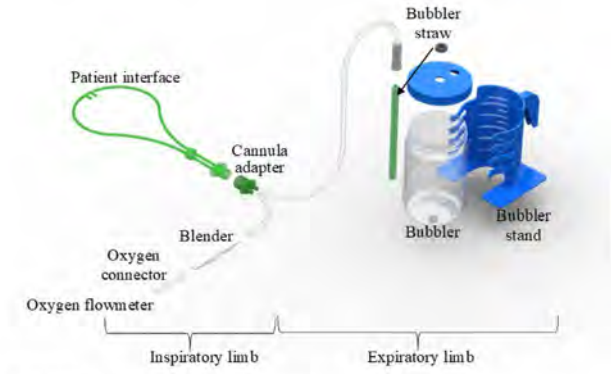

Figure 1: CPAP component diagram.

Intended Use

The PATH Bubble CPAP Kit with O_2 Blenders is intended to provide continuous positive airway pressure at the facility or during transport to spontaneously breathing newborns and infants up to 10 kg in weight that require respiratory support due to Respiratory Distress Syndrome, prematurity, or other conditions where the provider prescribes continuous positive airway pressure (CPAP) therapy.

Key Features

The low-cost PATH Bubble CPAP kit with O_2 Blenders provides newborns with high-quality respiratory support with no requirement for electricity or compressed air. The bCPAP kit reduces time required for setup at the point-of-care and includes two a robust oxygen blenders for use where no source of pressurized air is available. The innovative blenders allows pressurized oxygen from any source (i.e., tank, concentrator, central supply) to be blended with ambient air resulting in 37% or 60% FiO_2. The blenders provides a stable flow of blended gas that may be suitable for use with any bubble CPAP system for young infants where pressurized oxygen is available.

PATH Bubble CPAP Kit with O_2 Blenders

Type of technology	**Bubble CPAP Kit with O_2 Blenders**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**None**
Manufacturer of Record	**TBD**
Integrated air compressor (Yes/No)	**No**
Include humidification (Yes/No)	**No**
Integrated blender (Yes/No)	**Yes**
Total flow capability (lpm)	**2-7 LPM (up to 5 LPM to the patient plus 2 LPM bias flow to bubbler)**
Pressure range (cm H20)	**4 –8 cm H2O**
FiO2 range (FiO2 %)	**37% or 60% FiO2**
Total (blended) flow (lpm)	**2-7 LPM (up to 5 LPM to the patient plus 2 LPM bias flow to bubbler)**
Alarms included in device	**None**
Consumables required	**RAM Cannula. All other components may be reusable.**
Accessories required	**None; all-inclusive kit**
Patient interface(s) compatibility	**RAM cannula or equivalent**
Voltage requirements	**N/A**
User instructions provided	**Yes**
Warranty	**TBD**
Ex-works price of device	**Estimated at <$20 USD**
Ex-works price of consumables	**N/A**

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Introduction to Flow Splitter

A flow splitter allows the output of a concentrator or other oxygen source to be split between multiple patients while independently monitoring and adjusting each flow rate. Each of the outputs should measure from 0-2 liters per minute (LPM or L/min) and should have the same FiO2 as the source gas it is attached to. Please see below for further considerations.

When using an oxygen concentrator or oxygen with neonates, low flow is critical in order to avoid preventable disability including retinopathy of prematurity (ROP) and chronic lung disease. A significant number of preventable childhood blindness due to ROP in low- and middle-income countries (LMIC) has been documented[33-36]. Importantly, this is observed in children at higher birthweights and gestational ages than children in high-income settings, suggesting an association with rapid expansion of neonatal care, perhaps without adequate attention to the quality of care or harms of oxygen administration. Neonatal units seeking to provide comprehensive care should consider the procurement of splitters and flow meters with precision adjustment at a minimum of 0.1 – 0.125 L/min. As health facilities advance, introduction of microcalibrated flow meters with precision finer than 0.1 L/min or oxygen blenders should be considered[37].

The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- Canta Flow Splitter
- CAIRE Chart SureFlow Oxygen Flow Station
- Longfian Oxygen 5-way Flow Splitter

To learn more about the five step process, please click here.

Canta Flow Splitter – Shenyang Canta Medical Tech. Co.,Ltd

Commercially available

Intended Use

Intend for use in hospitals and clinics to connect from one oxygen source to 5 patients.

Key Features

Easy to use, every flowmeter could be adjusted separately.

- Inlet Pressure: 48–345Kpa
- Operating Temperature: 5–45°C
- Storage Temperature: 1–60°C
- Accessories: 1pc connection tubing;
  5pcs Cannula (neonatal avalible)

ITEM	
Type of technology	**Flow splitter**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO**
Manufacturer of Record	**Canta**
How many flow meters?	**5**
Flow rate range and the minimum increment per flow meter (lpm)	**Every flowmeter is 0–2 L** **The minimum increment is 0.125 LPM**
Warranty	**1 year**
Ex-works price of device	**Information not submitted**

Contact Information:

Canta

sunnyliu@canta.com.cn

+86 15940395951

www.cantamedical.com

Diamedica Flow Splitter – Diamedica (UK) Ltd

Commercially available

Intended Use

Intended for use in clinics and hospitals to manage and redirect the flow from a single oxygen source to one or more patients.

Key Features

Diamedica flow splitters allow clinics and hospitals to manage and redirect the flow of oxygen from a single source to multiple patients. A simple flow splitter can enable delivery to as many as eight patients. Each flow meter is adjusted separately to ensure precise control. Flowmeters work by adjusting the flow controller. Diamedica can be make flow splitters to your bespoke requirements..

Diamedica Flow Splitter

Type of technology	**Flow splitter**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Information not submitted**
Manufacturer of Record	**Diamedica (UK) Ltd**
How many flow meters?	**From 3 to 8, as required**
Flow rate range and the minimum increment per flow meter (lpm)	**0–10 lpm although many variations can be supplied to bespoke requirements** **Minimum increment: 0.1 lpm**
Warranty	**Flow splitter**
Ex-works price of device	**Prices start from £350 GBP**

Contact Information:

Diamedica (UK) Ltd

info@diamedica.co.uk

+44 1598 710066

www.diamedica.co.uk

SureFlow Oxygen Flow Station – CAIRE Inc.

Commercially available

Intended Use

Designed to be connected to O_2 Source for providing pediatric flow to up to 5 patients.

Key Features

Easy to use, easy to read. O_2 Inlet, O_2 outlet to up to 5 patients.

SureFlow Oxygen Flow Station

Type of technology	**Flow splitter**
Status	**Commercially available**
Regulatory approvals and/or international standards	**EU: CE Class IIa** **USA: Class I medical device** **Canada: Class II medical device**
Manufacturer of Record	**CAIRE Inc.**
How many flow meters?	**5**
Flow rate range and the minimum increment per flow meter (lpm)	**1/10 lpm to 1 lpm; 1/10 lpm**
Warranty	**3 Years**
Ex-works price of device	**List Price = $821.94 USD**

Contact Information:

Monica Chiacchiari

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www.caireinc.com

Introduction to Oxygen Concentrator

For newborns with breathing difficulties and/or infections, oxygen is vital to survival. Yet, access to oxygen can be scarce in low-resource settings. To meet this need, an oxygen concentrator is a device able to concentrate oxygen from the air for use with a multitude of devices. While use of concentrators is helpful, facilities should always have a power-independent oxygen source, such as a cylinder, available for back up.

Oxygen concentrators typically allow for oxygen administration between 85-100% FiO_2, flows between 2-10 lpm divided between two outlets. The percent oxygen a patient will receive depends on each mode of delivery (i.e., nasal prongs, nasal catheter, facemask, etc.). Passive humidification is sometimes available but recommended against by the World Health Organization[26]. A flow splitter allows the output of a concentrator to be split between multiple patients while independently monitoring and adjusting the flow rate to each. It is important to consider that high flow oxygen concentrators should be paired with an appropriate flow splitter for the safety of the neonate.

The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- Canta V8-WN-NS
- CAIRE Airsep NewLife Intensity 10
- Longfian Jay-10 Dual Flow

To learn more about the five step process, please click here.

Canta Oxygen Concentrator – Shenyang Canta Medical Tech. Co.,Ltd

Commercially available

Intended Use

This device is mainly used for generating medical oxygen above 90%.

Key Features

Stable performance with double flow.

Contact Information:

Canta

sunnyliu@canta.com.cn

+86 15940395951

www.cantamedical.com

Canta Oxygen Concentrator

Type of technology	**Oxygen concentrator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO, CE, RoHS**
Maximum flow rate (lpm)	**8L/min**
Flow outlets and associated flow rate range for each flow meter (lpm)	**Double flow** **0–8L/min for each flow**
Minimum increment on the flow meters (lpm)	**0.5L/min**
Time required to reach 95% of specified performance (minutes)	**5 minutes**
Alarms	**Low purity alarm** **Over heat alarm** **Pressure failure alarm** **Power failure alarm**
Maximum flow rate (lpm)	**8 LPM**
Mobility	**Casters for transport**
Monitoring by the end user	**Internal O2 % monitoring circuit board**
Durability and robustness	**Environment temperature scale: -20°C to 45°C** **Comparative humidity scale: ≤ 95%** **Air pressure scale: 500–1060hpa**
Routine Maintenance	**Filter net: needs to be cleaned by wash and dry twice a month** **Filter paper: needs to be replaced every 1000 hours**
Usage meter displaying cumulative hours of operation (Yes/No)	**Yes; it displays total working hours and current working hours**
Size and Form Factor	**Packing size: 45cm x 39cm x 68cm**
Voltage requirement	**110V and 230V is both OK according to your choice.**

Canta Oxygen Concentrator

User instructions provided	**Operation manual and user manual provided**
Technical training	**Technical training by video teaching and CDS provided**
Warranty	**2 years**
Ex-works price of device	**Information not submitted**

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Canta

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www.cantamedical.com

Eclipse 5 – CAIRE Inc.

Commercially available

Intended Use

Designed to supply oxygen for pediatric patient up to 3 LPM.

Key Features

Transportable oxygen concentrator able to provide pulse or continuous flow oxygen. Technologies on device include: autoSAT technology which automatically adjusts to patient's respiratory rate; Adjustable Rise Time which maxmizes inhaled oxygen; and UltraSense sensistive breath detection technology.

Eclipse 5

Type of technology	**Oxygen concentrator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**FDA 510(k) and CE, approved in many markets**
Maximum flow rate (lpm)	**3 lpm**
Flow outlets and associated flow rate range for each flow meter (lpm)	**Single flow**
Minimum increment on the flow meters (lpm)	**Eclipse 5 is able to run from 0.5 to 3.0 LPM on continuous flow settings, and from 16 mL to 192 mL on pulse flow settings**
Time required to reach 95% of specified performance (minutes)	**The recommended warm-up period is 5 minutes**
Alarms	• **No breath detected** • **Battery** • **Low O2** • **Loss of power** • **Malfunction**
Mobility	**Transportable with a removable rolling cart with adjustable handle**
Monitoring by the end user	**Device comes with visual and audio alerts**
Durability and robustness	**Specifications Operating Temperature: 50–104°F (10–40°C)** **Operating Humidity: 10–95% at an 82.4°F (28°C) dew point** **Transport/Storage Temperature: -4°F to 140°F (-20°C to 60°C)** **Humidity: Up to 95% Non-Condensing**
Routine Maintenance	**Air inlet filter: to be cleaned weekly** **Preventative Maintenances: to be completed on an annual or yearly basis by qualified technician**

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Eclipse 5

Usage meter displaying cumulative hours of operation (Yes/No)	**Usage meter is accessible through menu for the technician**
Size and Form Factor	**It is similar to a small travel suitcase because of its rolling cart with wheels and telescoping handle** **Weight: 18.4 lbs with battery**
Voltage requirement	**AC Power: 100–240 VAC, 50–60 Hz** **DC Power: 12V nominal** **Battery: quantity (2) 95 W-Hr battery packs each containing 7.92 gm of lithium content**
User instructions provided	**User Manual**
Technical training	**Service School training from CAIRE Global Technical Service Team**
Warranty	**3 Years**
Ex-works price of device	**TBD**

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NewLife Intensity 10 Single or Dual Flow – CAIRE Inc.

Commercially available

Intended Use

Treatment of respiratory related illness and disease.

Key Features

10 lpm O_2 Delivery. Please note minimum flow rate of 2 lpm. This is for the "Primary" flow outlet. In order for use at pediatric and infant flow rates, either;

1. remove "Secondary" flow meter and replace with Pediatric flow meter PN FM001-2 (additional training required). "Primary" flow meter must be set at 2 lpm and then "Secondary" flow meter can be adjusted to desired pediatric setting (Dual Flow Model must be used in this scenario);
2. Or use in conjuction with SureFlow Oxygen Flow Station (Either Dual or Single Flow unit can be used here).

NewLife Intensity 10 Single or Dual Flow

Type of technology	**Oxygen concentrator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Australia: Class IIb medical device** **EU: CE Class IIa** **USA: Class II medical device** **Canada: Class II medical device**
Maximum flow rate (lpm)	**10 lpm**
Flow outlets and associated flow rate range for each flow meter (lpm)	**1 for Single Flow Model, 2 for Dual Flow Model** **2–10 lpm is flow rate range for both models**
Minimum increment on the flow meters (lpm)	**2 lpm (See notes above)**
Time required to reach 95% of specified performance (minutes)	**Approximately 2 minutes**
Alarms	**Low O2%, Low Pressure, High Pressure**
Maximum flow rate (lpm)	**10 lpm**
Mobility	**Casters for transport. Not mobile during use.**
Monitoring by the end user	**Internal O2% monitoring circuit board**
Durability and robustness	**Operational Temp: 41–104°F (5–40°C), 15–95%** **Humidity, -381 m to 3,048 m (-1,250 ft to 10,000 ft)**
Routine maintenance	**Intake filter to be cleaned weekly; internal Felt Filter to replaced annually.**
Usage meter displaying cumulative hours of operation (Yes/No)	**Yes**

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NewLife Intensity 10 Single or Dual Flow

Size and Form Factor	**Height: 69.9 cm (27.5 in.)** **Width: 41.9 cm (16.5 in.)** **Depth: 36.8 cm (14.5 in.)** **Weight: 26.3 kg (58.0 lb.)** **Shipping Weight: 29.9 kg (66.0 lb.)**
Voltage requirement	**Two-prong polarized plug Double insulated cabinet** **North American Models: 120 VAC, 60 Hz, 6.0 amps** **Export Models: 230 VAC, 50 Hz, 3.0 amps**
User instructions provided	**User manual, online resources**
Technical training	**Technical training**
Warranty	**3 Years**
Ex-works price of device	**List Price = Single Flow Model: $1,500 USD, Dual Flow Model: $1,600 USD**

Contact Information:

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Introduction to Pulse Oximeter

Pulse oximeters use a non-invasive sensor to measure pulse rate (PR) and blood oxygenation levels (SpO_2) (i.e., percentage of oxygenated hemoglobin in arterial blood). While pulse oximeters do report pulse rate, their primary purpose and utility is to detect SpO_2 in infants. According to the World Health Organization, pulse oximetry is the most accurate non-invasive method for detecting hypoxemia. It is used to measure the percentage of oxygenated hemoglobin in arterial blood (SpO_2). The pulse oximeter consists of a computerized unit and a sensor probe which is attached to the patient's finger, toe, or earlobe. The oximeter displays the SpO_2 with an audible signal for each pulse beat, a pulse rate and, in many models, a graphical display of the blood flow past the probe (the plethysmographic or pulse wave). The technology is robust and cost effective. Pulse oximeters can be used to both detect and monitor hypoxemia, make more efficient use of oxygen supplies, and improve patient monitoring[26].

Low SpO_2 levels can indicate that an infant is in respiratory distress and monitoring SpO_2 is important in the neonatal period as it can indicate the need for immediate, critical care interventions. Additionally, SpO_2 monitoring is critical for infants receiving oxygen therapy or continuous positive airway pressure (CPAP) therapy. Low SpO_2 levels during oxygen or CPAP therapy can indicate that escalation or additional care is required. On the other hand, if SpO_2 remains too high (> 95%) for too long (often a side effect of pure oxygen therapy), newborns can suffer from preventable disability including retinopathy of prematurity (ROP), a condition that can cause permanent blindness, and chronic lung disease[33,34]. One other consideration when using a pulse oximeter is that the reading may not be as accurate in specific situations (e.g., when a neonate's peripheries are cold, when the neonate is anemic, etc.).

Outlined in this section are pulse oximeters for low-resource settings. Please note that the Masimo Rad-G also functions as a continuous pulse oximeter, however, has been included in the Respiratory Rate / Apnea Monitor product category section.

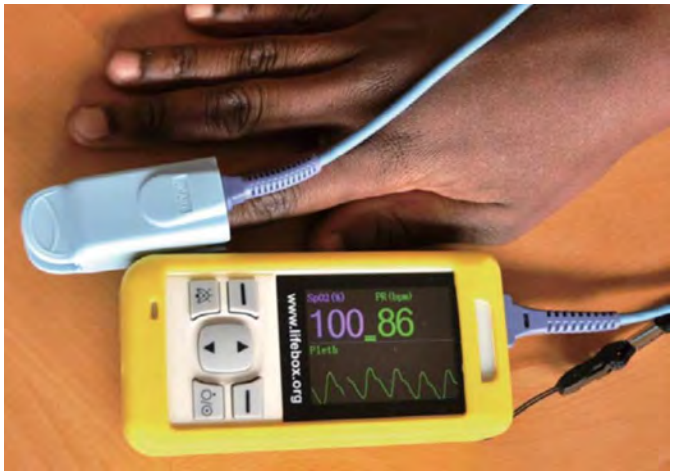
The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- Acare Lifebox
- Bistos BT-710

To learn more about the five step process, please click here.

AH-M1 – Lifebox Foundation

Commercially available



Intended Use

The AH-M1 is a robust, handheld pulse oximeter, suitable for use in the operating room, recovery unit, and ward areas of health facilities in low-to-middle income countries (as per World Bank standards). It is intended for continuously monitoring or spot checking peripheral oxygen saturation (SpO_2) and pulse rate (PR) for adult, pediatric, or neonatal patients.

Key Features

The Lifebox pulse oximeter has a clear display, audible tone and is available with a variety of probes suitable for all ages. It is both battery (rechargeable) and mains powered. The oximeter was selected for Lifebox by a panel of experts from the World Health Organization (WHO) and the World Federation of Societies of Anesthesiologists (WFSA). It is available at low-cost for distribution to medical facilities in low- and middle-income countries.

Contact Information:

Remy Turc

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+ 44 (0)203 286 0402

https://www.lifebox.org/purchase-oximeter/

AH-M1

Type of technology	**Pulse oximeter**
Status	**Commercially available**
Regulatory approvals and/or international standards	**This model is CE marked, meets FDA standards and conforms to IEC 60601-1 and ISO 9919, the international standard for pulse oximetry. In addition, the manufacturer must produce the units under conditions that meet the international standard ISO 13485:2016. The product and manufacturer have been independently examined by DNV GL and found to meet these standards.**
Manufacturer of Record	**Acare Technology Co., Ltd**
Pulse rate accuracy (beats per minute)	**± 2% or ± 1 bpm, whichever is the greater**
Pulse rate resolution (beats per minute)	**1 bpm**
SpO2 range	**0–100%**
SpO2 accuracy	**70–100%: ± 2%**
Alarms included in device	**Visual (high: quick red flashes; medium: slow yellow flashes; low: steady yellow light) and sound alarms.**
How alarms are set	**For neonates, PR high limit: 200, low limit: 100. To modify settings, see user manual, appendix C.1.**
SpO2 alarm limits	**For neonates, SPO2 high limit: 95, low limit: 90. To modify settings, see user manual, appendix C.3.**
Usage data logging and downloading capabilities	**Spot-check: ID from 1 to 99, 300 groups can be stored. Continuous: ID is 0, 60000 groups can be stored. Data cannot be downloaded.**
Continuous measurement provided (Yes/No)	**Yes, as well as spot check**
How cleaned or decontaminated	**Clean the oximeter at least once a week. The sensor must be cleaned after each patient. Detailed instructions in the user manual (Section 8.3 and 8.4).**

AH-M1

Patient interface, specific to neonates	**2.4" colour display 320 x 240 pixels** **Digital SpO2, Pulse Rate, Pleth bar & SpO2 waveform**
Size and Form Factor	**Dimension 123mm (H) x 58.5mm (W) x 28mm (D) Weight < 200g**
Probe compatibility	**Nellcor SpO2 probe compatible**
Consumables required	**Reusable adult probe (included in standard set)** **Reusable paediatric probe (included in standard set)** **Reusable neonatal wrap around probe** **Reusable ear-clip probe**
Accessories required	**Each device is provided with a rechargeable battery, multi-country adaptor and charger, adult and paediatric probes.** **Additional probes can be purchased separately (including neonatal and ear-clip), as well as cradle-chargers and spare batteries.** **Additional educational material provided.**
Electricity requirements, including voltage, and charging features.	**Type Lithium ion rechargeable battery, rated voltage 3.7 VDC** **Charge time: 3 hours to 90%, 4 hours to 100%** **Alternative: Three Type 1.5V, AA alkaline battery** **Duration: Approximately 14 hours** **Requires a 100/220V power supply for recharging**
User instructions provided	**User manual and quick start guide provided**
Training required	**Basic training on how to use the device and place the probes. Educational materials available online free of charge, including user's video guide.**
Warranty	**2 years for the device, 1 year for the probes**
Ex-works price of device	**Unit price: $250 USD (equipment & freight)** **Price may be revised for larger orders**
Ex-works price of consumables	**$25 USD per additional probe** **$10 USD per additional battery**

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https://www.lifebox.org/purchase-oximeter/

Rad-8 – Masimo Corporation

Commercially available

Intended Use

Varies by use case. Masimo develops a range of hand held and desktop pulse oximetry devices.

For more information, visit http://www.masimo.com

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Key Features

Rad-8: http://www.masimo.com/products/continuous/rad8/

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Rad-8

Type of technology	**Pulse oximeter**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, US FDA Clearance**
Manufacturer of Record	**Masimo Corporation**
Pulse rate accuracy (beats per minute)	**no motion +/- 3 BPM, motion +/-5 BPM, low perfusion +/- 3 BPM**
Pulse rate resolution (beats per minute)	**1 BPM**
SpO2 range	**1-100%**
SpO2 accuracy	**No motion neonates 3%; motion neonates 3%; low perfusion neonates 3%.**
Alarms included in device	**Visual, auditory**
How alarms are set	**See section 5 of user operator manual**
SpO2 alarm limits	**See section 5 of user operator manual**
Usage data logging and downloading capabilities	**The Rad-8 can store up to 72 hours of trend data captured at 2 second intervals. The trend data can then be transferred to a PC for evaluation.**
Continuous measurement provided (Yes/No)	**Yes**
How cleaned or decontaminated	**See section 8.5 of user operator manual**
Patient interface, specific to neonates	**LED display of HR, SpO2 etc. No pleth wave form**
Size and Form Factor	**2 lbs 8.2" x 6.0" x 3.0"**
Probe compatibility	**Information not submitted**
Consumables required	**Resuable and disposable sensor configurations are available**

Rad-8

Accessories required	**Information not submitted**
Electricity requirements, including voltage, and charging features.	**100-240 VAC, 50-60 Hz** **Power consumption: 20 VA max** **Battery** **Type: Sealed lead acid** **Capacity: (battery life) up to 7 hours** **Charging time: 8 hours**
User instructions provided	**Masimo can produce customized training material**
Training required	**Basic training on device and sensor placement**
Warranty	**Various options are available**
Ex-works price of device	**Pricing varies by volume**
Ex-works price of consumables	**Pricing varies by volume**

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uPM60 – UTECH CO., LTD.

Not yet commercially available / In development

Intended Use

To measure children's SpO_2, PR, respiration rate during pneumonia.

Key Features

uPM60 handheld pulse oximeter is a smart and portable device, providing a fast and reliable measurement of SpO_2, PR, respiration rate, suitable for adult, pediatric, and neonate, mainly used in hospitals and clinics.

uPM60

Type of technology	**Pulse oximeter**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**Information not submitted**
Manufacturer of Record	**Information not submitted**
Pulse rate accuracy (beats per minute)	**± 2 at 30-250 BPM**
Pulse rate resolution (beats per minute)	**1bpm**
SpO2 range	**0-100%**
SpO2 accuracy	**± 2%**
Alarms included in device	**Visual, auditory**
How alarms are set	**Alarm limits for pulse rate: 80 (low),120 (high)**
SpO2 alarm limits	**Alarm limits for SpO2: 92 (low), 99 (high)**
Usage data logging and downloading capabilities	**There is optional oximetry data management software on uPM60, patient's data can be transferred to PC for analysis, review and printing.**
Continuous measurement provided (Yes/No)	**Yes**
How cleaned or decontaminated	**Clean the pulse oximeter with a soft cloth moistened in water or a mild soap solution. To disinfect the pulse oximeter, wipe the sensor with isopropyl alcohol.**
Patient interface, specific to neonates	**ID, sex, type, and mode. Alarm limits of neonate on pulse rate is bigger than adult.**
Size and Form Factor	**Handheld pulse oximeter, 3.5 inch LCD screen.**
Probe compatibility	**The adult SpO2 sensor is compatible with Nellcor DS-100A**

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uPM60

Consumables required	**None**
Accessories required	**Yes, required SpO2 probes and respiration rate probe**
Electricity requirements, including voltage, and charging features.	**Lithium battery with 4400mAh at 3.7V**
User instructions provided	**The Operation Manual provides installation, operation, and maintenance instructions for health-care professionals and other users, trained in monitoring respiratory and cardiovascular activity.**
Training required	**Training on using and after-sales service**
Warranty	**1 year**
Ex-works price of device	**Estimated price is $260 USD per unit**
Ex-works price of consumables	**Price of SpO2 sensor is $25 USD per unit**

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Introduction to Respiratory Rate/ Apnea Monitor

Respiratory rate is a critical vital sign. The causes are many but are commonly due to respiratory pathology. Increased respiratory rate (> 60 bpm) in newborns can indicate respiratory distress syndrome (RDS), but as with infants and children, a high respiratory rate can also indicate pneumonia, which is the primary infectious cause of childhood death worldwide.

A low respiratory rate or gaps in breathing in infants is likewise indicative of potentially severe health concerns. Apnea of prematurity is a condition in which newborns temporarily stop breathing. Many apneas resolve without intervention, but frequent apnea (often paired with bradycardia and low SpO_2) can indicate an underlying condition such as sepsis, hypoglycemia, or anemia. Apnea of prematurity (AOP), a condition in which newborns temporarily stop breathing due to neurologic immaturity, affects nearly 50% of infants born earlier than 32 weeks gestational age and nearly 100% of those born at fewer than 28 weeks, and may last for several weeks[38]. AOP can be associated with dangerous decreases in heart rate and oxygenation, which, left unchecked, could lead to respiratory arrest, increased morbidity, or death.

In high-resource settings, respiratory rate is monitored using impedance pneumography, which requires expensive patient monitors and delicate electronic sensors. Alternatively in high-resource settings, AOP is monitored by using low nursing ratios (1:2) in conjunction with continuous heart rate and pulse oximetry monitoring. In this setting, a nurse or caregiver would provide a manual intervention in the event of an AOP event causing a low heart rate or oxygen saturation, in order to re-establish normal breathing. In low-resource settings, a nurse, normally faced with high nurse to patient ratios, must rely on limited continuous monitoring capability of heart rate and saturation with most infants only receiving intermittent manual monitoring. Additionally, they should observe the number of breaths a child takes in one minute, a procedure that is both time-consuming and inadequate for monitoring infants at risk of AOP.

Outlined in this section are devices that measure respiratory rate or apnea detection for use in low-resource settings. Some of these technologies may also function as continuous pulse oximeters (e.g., Masimo's Rad-G device).

Note that technologies within this product category have not yet been evaluated by the NEST360 team for inclusion as a NEST360 Qualified Technology. To learn more about what it means to be "NEST360 Qualified" and how the technologies are qualified by NEST360, please click here.

ApneBoot – BEMPU Health

Commercially available

Intended Use

In low-resource clinical settings where hospital staff are scarce, cases of apnea of prematurity are often missed or attended too late. The ApneBoot is intended to provide a first line of defense against prolonged hypoxia and bradycardia by providing vibrotactile stimulation to the sole of a newborn's foot to automatically resolve the apnea without further intervention. If the apnea still does not resolve, the device will continue to alarm, prompting attention from the staff.

Key Features

The ApneBoot continuously monitors oxygen saturation and heart rate through a sensor attached to the foot of a newborn. In the case of apnea, the device alarms and stimulates the foot sole of a newborn through a boot that is strapped on the other foot, triggering the nervous system to restart breathing.

Contact Information:

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ApneBoot

Type of technology	**Apnea management device**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485**
Manufacturer of Record	**BEMPU Health**
Spot check or continuous monitoring?	**It provides continuous monitoring**
What method is used to measure Respiratory Rate?	**The device measures Oxygen Saturation (SpO2) and Pulse Rate (PR). It does not measure Respiratory Rate.**
Are periods of Apnea detection measured?	**Yes. The device measures and also displays the duration of apneas (indicated by bradycardia and desaturation episodes).**
What method is used to measure periods of Apnea?	**ApneBoot works on the principle that every apnea results in desaturation and/or bradycardia. These parameters, the key symptoms of neonatal apnea, are monitored as part of Standard of Care method in NICUs through pulse oximeter devices.** **Since pulse oximetery is a well proven and accurate technology ApneBoot uses an inbuilt pulse-oximeter to monitor oxygen saturation and pulse rate. In the event of apnea, indicated by bradycardia and/or hypoxia, it uses a stimulator that vibrates the foot sole of the infant, stimulating the nervous system to restart breathing. The device also provides an audio-visual alarm to get the caretakers attention to rapidly intervene before any injury can occur.** **The device has an inbuilt algorithm which is clinically validated to accurately identify apnea based on SpO2 and PR values.** **ApneBoot does NOT identify apnea by respiration rate.**
Does your Respiratory Rate/Apnea Monitor have an apnea intervention? (Yes/No)	**Yes. It provides a vibro-tactile stimulation to the foot sole through a foot-worn boot probe.**

ApneBoot

Is your technology specific to newborns and/or include a neonatal probe?	**Yes. The device is specific to neonates and comes with a pulse oximeter probe suitable for newborn use and a stimulator boot that suits even the smallest of newborns.**
Describe the patient interface, specifically for neonates	**The device has a main unit with a GLCD backlit display screen of 70mm X 40mm. The key display parameters shown on the screen are Pulse Rate & SPO2 values,** **It has LED Visual Indication for Alarm, Low Battery & AC Power.** **The device front face has slots for connecting two probes – pulse oximeter probe and the stimulator probe. Each of the probes is applied on the peripheral body sit of a neonate, with stimulator probe applied only on a foot sole.** **The device operates in two modes and has a slider button on the front face for Mode Selection. The two modes are 1) Resolving mode (this keeps the Stimulator features ON) and 2) Only Monitoring mode (this keeps the Stimulator feature OFF) making the device work like a standard pulse oximeter.** **On the back side of the device there is a slot for connecting the AC power cable.** **The device also allows configuring the settings of the device to suit the needs for all neonates. It has a set of buttons to do so. The configurable settings are:** • **Threshold values for SpO2 and PR** • **Stimulation Intensity Level** • **Alarm Volume Level** • **History button to display - Number of bradycardia and desaturations events in last 12 hours**
Has your Respiratory Rate/Apnea Monitor been tested with infants/newborns?	**Yes, it has been tested with newborns in clinical settings, with results published in two journal papers.**
Respiratory rate range (bpm)	**Pulse Rate Range:** **18 to 321 beats per minute (bpm)** **Oxygen Saturation Range:** **(SpO2) 0 – 100%**
Accuracy (bpm)	**SpO2 Accuracy for Neonates: 70-100%** • **No Motion: ±3 digits** • **Motion: ±3 digits** • **Low Perfusion: ±4 digits** **Pulse Rate Accuracy for Neonates** • **No Motion (18-300 bpm): ±3 digits** • **Motion (40-240 bpm): ±3 digits** • **Low Perfusion (40-240 bpm): ±5 digits**
Respiratory rate resolution (bpm)	**N/A**
Alarms included in device	**The device provides an audio-visual alarm with a flashing red light and audio beep in case of alerts.** **The Audio Alarm Alarm system is as per the EN 60601-1-8.**

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ApneBoot

How are alarms set?	**The alarms are set by defining a threshold value for SpO2 and PR, and the duration of those values being true, to trigger the alarm. These values are set through the device menu option.** **These values are preset as per the algorithm in the 'preset mode' but can be customized through menu option.**
Consumables required	**No consumables. The accessories are the pulse oximeter probe and the stimulator boot probe.**
Describe how cleaned or decontaminated	**To clean the probes, it is recommended to wipe all patient contact surfaces with a 70% isopropyl alcohol pad or mild detergent.** **Or a soft cloth dampened with a 10% bleach / 90% water solution.**
Electricity requirements, including voltage, and charging features	**The device runs both on 110-240V AC, 50/60 Hz power supply and on a 3-5 V rechargeable battery with a battery backup up to12 hours. It has a power rating of 12VA Max.**
Size and form factor	**Device dimensions: H 10cm, W 22cm, D 7cm** **Weight: approximately 1 kg**
Training required	**A device set-up and use training on familiarizing the features and configuration settings is required for using the device. The training is simple, should take ~30 minutes and is similar to what training is required for operating a standard pulse oximeter.**
User instructions provided	**The device comes with a detailed manual with key instructions around:** **Indications for Use and Contraindications. ApneBoot is intended to be used in a clinical settings and mobile environments like inter and intra-hospital transport, by trained medical personnel only. It is intended to be used on preterm infants (with stimulation) and all infants (without stimulation).** **ApneBoot identifies apnea through bradycardia and/or hypoxia and not by respiration rate.** **Instructions of use for:** • **Unpacking and inspection before use** • **Setting up the device for use,** • **Explanation of alarms and indications** • **Method of probe placements** • **Operating the different features and configuring the settings** • **Cleaning and maintenance** • **Troubleshooting and safety** **Caution: The device should be used by trained medical personnel only.**

Contact Information:

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ApneBoot

Warranty	**1 year warranty on main unit** **6 months warranty of pulse oximeter and stimulator probes**
Ex-works price of device	**Dependent on market**
Ex-works price of consumables	**Dependent on market**

Contact Information:

BEMPU Health

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Children's Respiratory Rate Monitor (ChARM) CHW Model – Royal Philips

Commercially Available

ChARM (Children's Respiration Rate Monitor)

Intended Use

Spot check breathing / respiratory rate monitor for children under the age of five.

Automatic classification of fast breathing based on the IMCI guidelines set by the World Health Organization (WHO).

For further details, refer to Intended Use section in the Instructions For Use (IFU).

Key Features

Developed taking into account the UNICEF ARIDA Target Product Profile (TPP) for Acute Respiratory disease Aids (ARIDA). Based on proven technology platform, ensuring high accuracy. Rugged design for use in low resource settings which can withstand harsh conditions (rated IP 54 -protected from limited dust ingress & protected from water spray from any direction). Intuitive user interface to facilitate ease of use also for illiterate and innumerate users.

Contact Information:

Royal Phillips

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Respiratory Rate Monitor ChARM CHW model (built-in non-rechargable battery)

Type of technology	**Respiratory rate measurement through 3D accelerometer, with advanced signal processing to measure the specific abdominal motions related to breathing**
Status	**Commercially available and released for shipment into > 50 countries, that accept English, French or Spanish language**
Regulatory approvals and/or international standards	**CE mark Class IIa medical device**
Manufacturer of Record	**Philips India Ltd.**
Spot check or continuous monitoring?	**Spot check**
What method is used to measure Respiratory Rate?	**It uses inertial sensing technology. Accelerometry technology is used to convert chest movement, through a smart algorithm to can distinguish between a breath and movement, into a breath rate**
Are periods of Apnea detection measured?	**No, it is not an apnea monitor**
What method is used to measure periods of Apnea?	**N/A**
Does your Respiratory Rate/Apnea Monitor have an apnea intervention? (Yes/No)	**N/A**
Is your technology specific to newborns and/or include a neonatal probe?	**No, the device measures RR in term newborns until the age of 5 and does not require a probe**
Describe the patient interface, specifically for neonates	**Liquid crystal display**
Has your Respiratory Rate/Apnea Monitor been tested with infants/newborns?	**Yes and validated for use**
Respiratory rate range (bpm)	**10 to 150 breaths per minute**
Accuracy (bpm)	**± 2 breaths per minute when measured under the recommended conditions**
Respiratory rate resolution (bpm)	**1 RPM**
Alarms included in device	**Fast-breathing alarm (both visual and audible) based on WHO IMCI guidelines cut-off rates**

Respiratory Rate Monitor ChARM CHW model (built-in non-rechargable battery)

How are alarms set?	**Automated alarm setting based on WHO IMCI guidelines, age groups**
Consumables required	**None**
Describe how cleaned or decontaminated	**Instructions for Disinfection:** Wipe the patient contact surface of the device and the belt before every use with a clean cloth moistened with 70% Isopropyl alcohol. **Routine Cleaning Instructions:** Wipe the external surfaces of the device and the belt with a cloth dampened in mild soap solution or water. **Refer to further instructions in the IFU.**
Electricity requirements, including voltage, and charging features	**The CHW device comes with a built-in (non replaceable) battery that can do a minimum of 2.000 measurements over over a minimum of 2 year usage.** **Specifically developed for use in settings where re-charging is an issue. Based on an average use by Community Health Workers (CHW) of 2,5 measurement a day (based on UNICEF TPP). The device will last 2.5 to 3 years.**
Size and form factor	**Ultra portable** **Dimensions (H x W x D): 6 x 6 x 2 cm / 2.4 x 2.4 x 0.8 inch** **Weight: 150 grams / 0.33 lb**
Training required	**Basic device handling training in line with standard WHO IMCI guidelines**
User instructions provided	**Device comes with an IFU (Instructions For Use) and additionally with a pictorial based quick reference card. Additionally an online (YouTube) training video is available in English as well as dubbed in French.**
Warranty	**1 year limited warranty**
Ex-works price of device	**Depends on volume.** **CHW list price range €35 EUR – €40 EUR (EXW/Ex. VAT) Pricing subject to volume.**
Ex-works price of consumables	**N/A; no consumables required**

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Children's Respiratory Rate Monitor (ChARM) PHW Model – Royal Philips

Commercially Available

Intended Use

Spot check breathing / respiratory rate monitor for children under the age of five.

Automatic classification of fast breathing based on the IMCI guidelines set by the World Health Organization (WHO).

For further details, refer to Intended Use section in the Instructions For Use (IFU).

Key Features

Developed taking into account the UNICEF ARIDA Target Product Profile (TPP) for Acute Respiratory disease Aids (ARIDA). Based on proven technology platform, ensuring high accuracy. Rugged design for use in low resource settings which can withstand harsh conditions (rated IP 54 -protected from limited dust ingress & protected from water spray from any direction). Intuitive user interface to facilitate ease of use also for illiterate and innumerate users.

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Respiratory Rate Monitor ChARM PHW model (built-in non-rechargable battery)

Type of technology	**Respiratory rate measurement through 3D accelerometer with advanced signal processing to measure the specific abdominal motions related to breathing**
Status	**Commercially available and released for shipment into > 50 countries, that accept English, French or Spanish language**
Regulatory approvals	**CE mark Class 11a medical device**
Manufacturer of Record	**Philips India Ltd.**
Spot check or continuous monitoring?	**Spot check**
What method is used to measure Respiratory Rate?	**It uses inertial sensing technology. Accelerometry technology is used to convert chest movement, through a smart algorithm to can distinguish between a breath and movement, into a breath rate**
Are periods of Apnea detection measured?	**No, it is not an apnea monitor**
What method is used to measure periods of Apnea?	**N/A**
Does your Respiratory Rate/Apnea Monitor have an apnea intervention? (Yes/No)	**N/A**
Is your technology specific to newborns and/or include a neonatal probe?	**No, the device measures RR in term newborns until the age of 5 and does not require a probe**
Describe the patient interface, specifically for neonates	**Liquid crystal display**
Has your Respiratory Rate/Apnea Monitor been tested with infants/newborns?	**Yes and validated for use**
Respiratory rate range (bpm)	**10 to 150 breaths per minute**
Accuracy (bpm)	**±2 breaths per minute when measured under the recommended conditions**
Respiratory rate resolution (bpm)	**1 RPM**
Alarms included in device	**Fast-breathing alarm (both visual and audible) based on WHO IMCI guidelines cut-off rates**

Respiratory Rate Monitor ChARM PHW model (built-in non-rechargable battery)

How are alarms set?	**Automated alarm setting based on WHO IMCI guidelines, age groups**
Consumables required	**None**
Describe how cleaned or decontaminated	**Instructions for Disinfection** Wipe the patient contact surface of the device and the belt before every use with a clean cloth moistened with 70% Isopropyl alcohol. **Routine Cleaning Instructions** Wipe the external surfaces of the device and the belt with a cloth dampened in mild soap solution or water. Refer to further instructions in the IFU.
Electricity requirements, including voltage, and charging features	**The PHW device can conduct a minimum of 4380 measurements over three years of usage with 200 measurements per full charge cycle.** **Power Specifications for Charging Adapter Input Voltage: 100-240V@50/60 Hz, Output Voltage: 5VDC Output Current: > 0.5A**
Size and form factor	**Ultra portable.** **Dimensions (H x W x D): 6 x 6 x 2 cm / 2.4 x 2.4 x 0.8 inch** **Weight: 150 grams / 0.33 lb**
Training required	**Basic device handling training in line with standard WHO IMCI guidelines**
User instructions provided	**Device comes with an IFU (Instructions For Use) and additionally with a pictorial based quick reference card. Additionally an online (YouTube) training video is available in English as well as dubbed in French.**
Warranty	**1 year limited warranty**
Ex-works price of device	**PHW list price range €70 EUR – €75 EUR (EXW/Ex. VAT) – Pricing subject to volume.**
Ex-works price of consumables	**N/A; no consumables required**

Contact Information:

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Rad-G – Masimo Corporation

Commercially Available

Intended Use

Spot check monitoring of oxygen saturation, respiratory rate, perfusion index, pleth variability index, and pulse rate.

For more information, visit http://www.masimo.com

https://www.masimo.co.uk/products/continuous/rad-g/

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Key Features

Masimo partnered with the Bill & Melinda Gates Foundation to develop a combined pulse oximeter that measures oxygen saturation (SpO_2) and respiratory rate from the pleth (RRp). The device was designed from the ground up for rugged use in harsh environments. It has two screening modes:

1. **Pneumonia Mode** – follows IMNCI and IMCI guidelines for RR and SpO_2 cutoffs.
2. **General Screening Mode** – standard user interface with SpO_2 and RR continuously measured while the sensor is on the selected site.

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Masimo Rad-G

Type of technology	**Continuous Pulse Oximeter and Respiratory Rate Monitor**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, FDA cleared**
Manufacturer of Record	**Masimo Corporation**
Spot check or continuous monitoring?	**Rad-G Continuous has a spot check and continuous mode. The continuous mode has alarm functionality.**
What method is used to measure Respiratory Rate?	**Respiration rate can be determined by the plethysmographic waveform (RRp). This method measures respirations per minute (rpm) based on cyclic variation in photoplethysmogram (i.e. pleth or PPG) to establish a respiration rate measurement.**
Are periods of Apnea detection measured?	**N/A**
What method is used to measure periods of Apnea?	**N/A**
Does your Respiratory Rate/Apnea Monitor have an apnea intervention? (Yes/No)	**N/A**
Is your technology specific to newborns and/or include a neonatal probe?	**Rad-G come with 2 probes:** • **1 universal probe working from pediatric to adult patients (3 kg and above)** • **1 probe specifically designed to monitor neonatal patients and above (1 kg and above)**
Describe the patient interface, specifically for neonates	**Color touch screen with voice assisted feedback**
Has your Respiratory Rate/Apnea Monitor been tested with infants/newborns?	**Yes**
Respiratory rate range (bpm)	**Range of 4 rpm to 70 rpm**

Masimo Rad-G

Accuracy (bpm)	**No motion: Adults, Pediatrics (>2 years of age) = 3 rpm ARMS*, ± 1 rpm mean error** **Reference is made to the Operator Manual page 45**
Respiratory rate resolution (bpm)	**1 RPM**
Alarms included in device	**Customizable alarms** **Reference is made to the Operator Manual page 30**
How are alarms set?	**Alarms are customizable in the device's Alarm Menu** **Reference is made to the Operator Manual page 30**
Consumables required	**Sensors**
Describe how cleaned or decontaminated	**To clean the device:** **1. Disconnect the AC Power Supply and ensure the sensor is not applied to the patient.** **2. Wipe the outer surfaces using a dampened soft cloth with one of the recommended cleaning solutions twice or until the surfaces are free of any visible residue.** **3. Wipe twice or until the surfaces are free of any visible residue.** **4. Dry the device thoroughly prior to using on a patient.** **The surfaces of the Rad-G may be cleaned with the following solvents or cleaning agents:** **• 70% Isopropyl Alcohol** **• Glutaraldehyde** **• 10% bleach (5% - 5.25% sodium hypochlorite) to 90% water solution** **• Quaternary ammonium chloride solutions** **• 0.5% hydrogen peroxide**
Electricity requirements, including voltage, and charging features	**100-240VAC, 50/60Hz, 0.6A** **The Rad-G includes a lithium ion rechargeable battery.** **Before using the Rad-G without the AC power connected, check the battery status indicator and ensure that the battery is fully charged. See AC Power Indicator on page 26 in Operators Manual.** **To charge the Rad-G battery, refer to Initial Battery Charging on page 21 in Operators Manual.**
Size and form factor	**Weight: 0.27 kg. (0.59 lbs.)** **Dimensions: 7.4 cm x 19.8 cm x 2.5 cm (2.9" x 7.8" x 1.0")**
Training required	**Basic device training and sensor site best practices**

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Masimo Rad-G

User instructions provided	**Masimo has the ability to develop customized training material.** **Masimo also has the ability to perform remote training.**
Warranty	**Various options are available**
Ex-works price of device	**Pricing varies by volume**
Ex-works price of consumables	**Pricing varies by volume**

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Rice University Respiratory Rate and Apnea Monitor – Rice360 Institute for Global Health Technologies

Not yet commercially available / In development

Intended Use

To monitor respiratory rate in neonates with respiratory disease or distress; to monitor for apnea in neonates at risk for apnea; to intervene during apnea in neonates with apnea.

Key Features

The Rice University respiratory rate and apnea monitor is designed to monitor respiratory rate and detect and intervene during apneic episodes in neonates. Its features include a low-cost stretch sensor with minimal hysteresis for accurate breath detection, no single-use consumables, algorithm to detect non-breathing periods of longer than 15 seconds, vibration to intervene in case of apnea, and battery-power.

Contact Information:

Rice360 Institute for Global Health Technologies

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Rice University Respiratory Rate and Apnea Monitor

Type of technology	**Respiratory rate monitor**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**None; CE marking anticipated**
Manufacturer of Record	**Unknown**
Respiratory rate range (bpm)	**10 -100 bpm**
Accuracy (bpm)	**± 2 bpm**
Respiratory rate resolution (bpm)	**1 bpm (anticipated)**
Alarms included in device	**Visual, other**
How are alarms set?	**Anticipated adjustable alarms**
Consumables required	**Wearable strap with stretch sensor and vibration (est. lifetime one year)**
Describe how cleaned or decontaminated	**The Rice University respiratory rate and apnea monitor can be wiped down with bleach or other common disinfectants. It should not be submerged.**
Electricity requirements, including voltage, and charging features	**Battery powered; est. battery life 10 hours (respiratory rate only)/4 hours (apnea intervention).**
Describe the patient interface, specifically for neonates.	**A reusable strap wraps around the patient's abdomen between the xyphoid and umbilicus. The stretch sensor detects changes in chest wall size.**
Size and form factor	**Small; can clip to patient's bassinet or sit at bedside.**
Training required	**Minimal (est. <half-day training)**
User instructions provided	**The device will come with a manual**
Warranty	**The device will come with a warranty**
Ex-works price of device	**TBD**
Ex-works price of consumables	**TBD**

Introduction to Suction Pump

Clinicians periodically need to clear an infant's airway through the use of a suction pump. Safe ranges for neonatal suctioning depending on the size of the infant and are generally considered to be between 60–100mmHg.

Currently, we have not received any submissions for Suction Pumps. If you are a manufacturer or product developer and wish to include your technology in future versions of this manual, please contact Becca Kirby at: **becca.kirby@kellogg.northwestern.edu.**

The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- 3A Aspeed Professional

To learn more about the five step process, please click here.

Aspeed Suction Pump – 3A

Commercially Available

Intended Use

The 3A Aspeed Suction Pump is a professional unit for clinical secretion aspiration. It features a vacuum regulator, vacuum gauge and a collection container with a protection device to prevent the ingress of liquid into the suction pump. Moreover, the aspirator ensures lifetime lubrication, is easy to handle and simple to use. The Aspeed is reliable, durable, and conveniently silent.

Key Features

- High performance and long-lasting durability
- Easy to maintain
- Low operating noise level
- Autoclavable polycarbonate jar with safety valve for overflow protection
- 99% antibacterial hydrophobic filter for maximum protection

Aspeed Suction Pump

Type of technology	**Suction Pump**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**3A**
Pressure range/vacuum level provided and whether it continuous adjustment	**Low Flow: High Vacuum** **Total Flow: 15 L/min** **Pressure: 0-640mmHg**
Bottle capacity (Liters)	**1 Liter**
Noize level (dB)	**< 70 dB**
User instructions provided	**English version user instruction**
Electricity requirements, including voltage, and charging features	**Supply voltage: AC 100-240V, 50/60Hz**
Warranty	**1 year**
Ex-works price of device	**Information not submitted**

Contact Information:

Silvia Peloni

silvia.peloni@omron.com

0039 030 9133177

ASU-200 portable suction unit – Acare Technology Co., Ltd

Commercially available

Intended Use

Information not submitted.

Key Features

- Portable and simple to operate
- Small size, light weight for carrying
- Fully charged battery runtime 60 minutes

ASU-200 portable suction unit

Type of technology	**Suction Pump**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 60601-1; ISO 60601-1-2; ISO 10079-2** **CE / FDA/ ISO 13485:2016**
Manufacturer of Record	**Acare Technology Co., Ltd.**
Pressure range/vacuum level provided and whether it continuous adjustment	**0 ~ -80Kpa (0 ~ -600mmHg)** **Continuous adjustment**
Bottle capacity (Liters)	**1 Liter**
Noize level (dB)	**< 70 dB**
User instructions provided	**English version user instruction**
Electricity requirements, including voltage, and charging features	**Supply voltage: AC 100-240V, 50/60Hz / DC 18V, 3.34A** **Car charger for DC 12V**
Warranty	**1 year**
Ex-works price of device	**Information not submitted**

Contact Information: (sales support)
Ms. May Wang
info@acarecorp.com
+886-2-22988170
www.acaretech.com

Introduction to Other Products

This section is used to capture other newborn technologies within the ***Respiratory Support*** category-of-care.

Airvo 2 – Fisher & Paykel Healthcare

Commercially Available

Intended Use

The AIRVO 2 is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface. The AIRVO 2 is for patients in hospitals and long term care facilities.

Key Features

Designed to deliver high flow rates with heated humidification to non-intubated adult or paediatric patients. Warm and humidified gas decreases airway inflammation and reduces the caloric expenditure in acute respiratory failure. The maximum flow varies according to manufacturer, going up to 50–70 L/min. A specialized flowmeter and a heated humidifier are incorporated into the unit to deliver heated and humidified gases, through a circuit and patient interface. There is a low level of positive pressure at the patient's airway. The FiO2 can be set by the clinician. The effectiveness of the treatment is related to the high flow generated rather than the proper sealing of the nasal mask to the patient's face (reduced exhaled air dispersion).

Airvo 2

Type of technology	**Airvo 2 – Nasal high flow**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Marked, 510(k) clearance**
Manufacturer of Record	**Fisher & Paykel Healthcare**
Electricity requirements, including voltage, and charging features	**100-115V 2.2 A (2.4A max)** **220 – 240V 1.8 A (2.0 A max)** **No charging features**
Size and form factor	**295 x 170 x 175 mm** **2.2 kg unit only**
Shelf life, stability, and storage requirements	**Shelf life: N/A as is hardware** **Storage Requirements:** **-10 – 60°C and 95% humidity**
Ex-works price of device	**N/A**
Ex-works price of consumables	**N/A**

Contact Information:

Sadaf Asmaie

Sadaf.asmaie@fphcare.com

949-402-2002

www.fphcare.com

Beluga T-piece Resuscitator – Medical Technology Transfer and Services Co., Ltd (MTTS)

Commercially Available

Intended Use

Beluga Resuscitator is a standalone T-piece resuscitator intended to provide positive pressure ventilation during resuscitation of infants.

The device is designed to be used in the delivery rooms together with infant warmers and outside the hospital settings in emergencies, as a battery powered, portable device.

Key Features

The device contains a built-in pump to generate positive end-expiratory pressure (PEEP) and Peak Inspiratory Pressure (PIP) without necessity of any external air sources. An integrated blender and oxygen monitoring function also allows oxygen-rich (> 21% O2) air with accurate fraction of inspired oxygen (FiO2) to be safely delivered to the patient.

Additional functions: rotating touch screen, metronome, alarm volume control.

Beluga T-piece Resuscitator

Type of technology	**Resuscitator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485, Certificate of Free Sale, CE Mark**
Manufacturer of Record	**MTTS Co., Ltd**
Electricity requirements, including voltage, and charging features	**12V DC batteries operated** **Charging from 100-240V AC**
Size and form factor	**20 cm x 22cm x 20 cm** **2.5kg**
Shelf life, stability, and storage requirements	**5 years** **Ambient temperature 0°C to +50°C** **Humidity: 0% to 90% RH non condensing** **Atmospheric Pressure: 70-106kPa**
Ex-works price of device	**From $1,100 USD**
Ex-works price of consumables	**$9 USD**

Contact Information:

Medical Technology Transfer and Services Co., Ltd (MTTS)

info@mtts-asia.com

+84 24 3766 6521

www.mtts-asia.com

Fisher & Paykel Healthcare Neopuff™ Infant Resuscitator – Fisher & Paykel Healthcare

Commercially Available

Intended Use

The Fisher & Paykel Healthcare Neopuff ™ Infant Resuscitator is a manually operated, gas-powered resuscitator which provides assisted respiratory breaths to newborn babies in delivery suites, nurseries and neonatal intensive care units.

Key Features

The Neopuff resuscitator can deliver oxygen levels ranging from 21% through to 100%, from a flow meter or blender.

The resuscitator has a PIP control, as well as a maximum pressure relief valve that prevents the accidental delivery of excessively high pressures.

The Neopuff resuscitator features an accurate, easy-to-read, medical quality manometer, and can be mounted on a pole, rail, wall, infant warmer, or incubator.

Fisher & Paykel Healthcare Neopuff™ Infant Resuscitator

Type of technology	**Neopuff – Infant T-piece resuscitator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE marked**
Manufacturer of Record	**Fisher & Paykel Healthcare**
Electricity requirements, including voltage, and charging features	• **The Neopuff resuscitator does not need to be connected to power** • **The Neopuff needs to be connected to an oxygen or blended oxygen/air**
Size and form factor	**Height/Width/Depth: 250/200/104 mm**
Shelf life, stability, and storage requirements	**Shelf life: N/A as is hardware** **Storage Requirements: 10-50 degrees and 95% humidity**
Ex-works price of device	**N/A**
Ex-works price of consumables	**N/A**

Contact Information:

Sadaf Asmaie

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949-402-2002

www.fphcare.com

Impala Ventilator – Medical Technology Transfer and Services Co., Ltd (MTTS)

Commercially available

Intended Use

Compact ventilator suitable for ambulances and intensive care wards

Key Features

- Portable
- Suitable for emergencies or intensive care wards
- Build-in battery - 4 hours backup
- Integrated blender
- FiO_2 monitoring
- Easy-to-use touch screen
- ACV, SIMV and CPAP modes
- Controlled target PIP and consistent PEEP
- No time restriction on use due to the gas tank limitation

Impala Ventilator

Type of technology	**Ventilator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485**
Manufacturer of Record	**MTTS Co., Ltd**
Performance Specifications	**Integrated air compressor: Blower** **Delivered oxygen concentration: 21 – 100%** **Respiratory rate (Neonatal/Pediatric): 2 – 120bpm** **I:E ratio: 1:9 - 4:1** **Tidal volume (Neonatal/Pediatric): 5 – 300 ml** **PIP: 0 – 60 cm H20** **Pressure limitation: 75 cm H20** **PEEP: 0 – 25 cm H20**
Electricity requirements, including voltage, and charging features	**100 – 240 VAC, 50-60 Hz**
Size and form factor	**20cm x 22cm x 20cm** **2.5kg**
Shelf life, stability, and storage requirements	**Operating:** **Ambient temperature: 5°C to 40°C** **Humidity: 0% to 95% RH non-condensing** **Transport and Storage:** **Ambient temperature: 0ºC to 50ºC** **Humidity: 0% to 95% RH non condensing**
Ex-works price of device	**From $5,700 USD**
Ex-works price of consumables	**Disposable elements of the breathing circuit (flow sensor, filter, mask/ cannula): $33 USD**
Accessories required	**Oxygen sensor (every 2 – 3 years)**

Contact Information:

Medical Technology Transfer and Services Co., Ltd (MTTS)

info@mtts-asia.com

+84 24 3766 6521

www.mtts-asia.com

Lullaby Resus Plus – General Electric Healthcare

Commercially available

Intended Use

Lullaby Resus. Plus helps ensure adequate pressure delivery and oxygenation.

Key Features

Ultimate and effective solution to birth asphyxia.

Lullaby Resus Plus

Type of technology	**Other T piece technology**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**General Electric**
Electricity requirements, including voltage, and charging features	**No electricity required (gas driven)**
Size and form factor	**22 cm x 37 cm x 30 cm**
Shelf life, stability, and storage requirements	**Information not submitted**
Ex-works price of device	**$2,700 USD**
Ex-works price of consumables	**Information not submitted**

Contact Information:

Ayman Shaheen

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201000038650

www.gehealthcare.com

NeoBeat Newborn Heart Rate Meter – Laerdal Global Health

Commercially available

Intended Use

NeoBeat is a heart rate measurement device using dry-electrode technology, with integrated digital display. It provides rapid and accurate presentation of the newborn's heart rate in real time. NeoBeat is intended to be used by healthcare professionals involved in newborn care.

Key Features

NeoBeat is a reusable and consumable-free heart rate (HR) meter. The hands-free device is easy-to-use, and when applied to the newborn, provides an accurate digital display of heart rate. NeoBeat takes seconds to put on a newborn's torso and presents the HR rapidly. With rapid detection of HR, clinicians may have a better understanding of the newborn enabling timely continuation of care. NeoBeat uses dry electrodes to pick up an ECG-based signal, which is recommended by The International Liaison Committee on Resuscitation (ILCOR) 2015 guidelines as the most reliable way to measure newborn HR. Current available methods in low-resource settings include stethoscope or umbilical cord palpation, both of which either require a second pair of hands or interruption in care. NeoBeat comes with a mountable charging stand for quick and easy access to the device.

NeoBeat Newborn Heart Rate Meter

Type of technology	**Heart rate meter**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Laerdal Medical AS**
Electricity requirements, including voltage, and charging features	**Battery: Internal rechargeable lithium-ion button cell, 3.7 V, 120 mAh** **Typical service life of battery: 3 – 6 years depending on use.** **Battery charger:** **Input 100 – 240 V AC, 50 – 60 Hz, 0.3 A** **Output 5 V DC, 1 A** **Max 3 hours charge time, 4 hours continuous run time on full battery**
Size and form factor	**Dimensions: 83 x 87 x 40 mm (3.2 x 3.4 x 1.6 inches)** **Weight: 31 g (1.1 oz)** **Materials: PA, TPU, stainless steel**
Shelf life, stability, and storage requirements	**Temperature: Operating:** **0 – 40 °C (32 – 104 °F)** **Storage/shipping:** **-40 – 70 °C (-40 – 158 °F)** **Shelf life: Rechargeable lithium battery; 3.6 years, depending on use.**
Ex-works price of device	**$160 USD**
Ex-works price of consumables	**No consumables**

Contact Information:

Laerdal Global Health

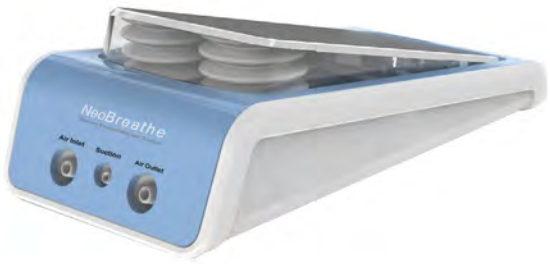
lgh@laerdal.com

+47 51 51 17 00

www.laerdalglobalhealth.com

Neobreathe – Phoenix Medical Systems

Commercially available



Intended Use

Every year Asphyxia kills 8,11,000 babies. These babies can be saved by simple resuscitation followed by suction.

Neobreathe's single person resuscitation care has in built resuscitation + mechanical suction. Its remarkably convenient & user friendly design helps in complete infant care. Neobreathe is a fully mechanical device.It provides positive pressure ventilation & airway suction to infants up to 5 kg's.The device consists of a foot pedal module, a circuit & airway interface (re-useable masks).

Key Features

1. **World's first foot resuscitation care:** Unique foot operating resuscitation unit provides one free hand for CPR
2. **Intergrated suction:** No fear of power cuts, No struggling with tubes.
3. **Ventilation and suction integrated into one system:** With suction and ventilation present in a single unit, suction can be performed easily when needed.
4. **Stable grip & Seal:** Effective seal deigned to prevent upto 50 % of any leakage during procedure. Unit is safe,secure & prevents infection.
5. **Regulated Fio² control:** Inbuilt , low cost , multi point Fio²regulation is available.
6. **PEEP delivery:** Optional peep control improves ventilation in premature babies.
7. **Re-useable pressure manometer:** Neo-breathe has a built in re-useable manometer for continuous pressure monitoring. In turn increases safety and confidence.
8. **Pressure Safety:** It's in-corporated with patient safety measures. Pressure won't exceed more than 40 cmH^2O.
9. **Zero electricity:** Use it anywhere, anytime without need of power.

Neobreathe

Type of technology	**Foot-operated mechanical resuscitator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Phoenix Medical Systems**
Electricity requirements, including voltage, and charging features	**Electricity requirements - N/A** **Charging features - N/A**
Size and form factor	**Physical dimension : 380mm x 186mm x 100mm**
Shelf life, stability, and storage requirements	**Stability- 3 years** **Shelf life - N/A** **Storage temp - 0 to 45°C, hum - 0 to 95%**
Ex-works price of device	**Ex Works US $380 / unit**
Ex-works price of consumables	**Information not submitted**

Contact Information:

Phoenix Medical Systems Pvt Ltd.

exports@pmsind.com

+27 71 528 9873

www.phoenixmedicalsystems.com

Neopenda neoGuard™ vital signs monitor – Neopenda PBC

Commercially available

Intended Use

The Neopenda neoGuard is intended for prescription use only for the continuous non-invasive monitoring of oxygen saturation, pulse rate, respiration rate, and temperature. The product is designed for affordability, usability, and versatility as a stand-alone solution independent of facility infrastructure. neoGuard is commercially available for adult and pediatric patients as well.

Key Features

The Neopenda neoGuard is a wearable vital signs monitor designed to enable more responsive and appropriate medical care of newborns in resource-constrained facilities. Our reusable smart headband continuously measures four critical vital signs: pulse rate, oxygen saturation, respiratory rate, and temperature. Data from multiple devices are wirelessly transmitted and displayed on a central tablet in real time. Health workers are alerted when vitals go outside the healthy range, so that they can attend to newborns in distress immediately and give them the best chance to survive and thrive.

neoGuard™

Type of technology	**4-in-1 vital signs monitor**
Status	**Commercially available in Kenya and Uganda**
Regulatory approvals and/or international standards	**PPB Clearance (from Kenya), CE Mark on neoGuard, and ISO13485 certification for Neopenda**
Manufacturer of Record	**N/A**
Electricity requirements, including voltage, and charging features	**The neoGuard device uses a recharge-able lithium ion battery, optimized for low power consumption. The battery is medical-certified (ICE 62133) and has an approximate run-time of 140 hours continuous use. The device is equipped with a micro-USB type B power supply compatible with 220V current.**
Size and form factor	**The Neopenda neoGuard device is housed in a polyetherimide medical grade plastic case with dimensions = 37.5 x 34.5 x 16 mm. The small sensor device fits into a reusable band, which is designed for comfort, stability, and cleanability. The wearable bands are adjustable for neonates from 28 week gestational age (preterm infants) to one-month old full-term infants.**
Shelf life, stability, and storage requirements	**Device should be stored in a clean, dry place, at room temperature. Recommended environment: temperature 25±5˚C; humidity 60±15%. During transportation, the device will be packaged in a sealed container which may be retained for storage. Shipping conditions shall not exceed 60˚C.**
Ex-works price of device	**Information not submitted**
Ex-works price of consumables	**Information not submitted**

Contact Information:

Sona Shah

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919-622-2487

www.neopenda.com

Oxygen Reservoir Filling System – Diamedica (UK) Ltd

Commercially available

Intended Use

Safeguards oxygen supplies for newborns and mothers in low-resource settings, where oxygen cylinders are costly, or hospital site access is difficult, and electrical supplies unreliable.

Key Features

The system is designed to safeguard oxygen supplies in low-resource settings. It enables a pressure vessel to be filled with oxygen generated from an oxygen concentrator to provide a back up oxygen supply, in the event of power cuts. The system will take oxygen from any appropriate oxygen concentrator and fill either a 20 L or 100 L reservoir vessel to a pressure of 5 bar (75 psi) giving 100 L or 500 L of usable oxygen for supply to patients. Multiple vessels can be supplied. Aluminium vessel is mounted on castors for easy transport around the ward. An excellent solution in low resource settings, where oxygen cylinders can be costly, or hospital site access is difficult. A truly invaluable resource in the event of a power failure, this vessel stores the oxygen produced in advance ready for future use for when you most need it.

Designed and manufactured in the UK, robust and built to last. Key features include:

- Reservoir Pump with oil free 12 volt compressor (rated at 10 bar)
- Integral cooling fans internal 12 volt sealed lead acid battery 12 volt battery charger / power supply
- Pressure control valve (preset at 5 bar)
- On/off switch, mains power lead
- Supply and filling tubes suitable to connect from oxygen concentrator
- Will accept mains power from 95 - 290 volts (50 hz - 60 Hz)
- Weight 13 kg
- Oxygen reservoir vessel
- Supplied in two sizes: 20 L or 100 L
- Over pressure safety valve (pre-set at 7 bar)
- Oxygen flow meter (5 lpm)
- Quick release supply fitting and tube
- Aluminium vessel mounted on castors

Oxygen Reservoir Filling System

Type of technology	**Other**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Information not submitted**
Manufacturer of Record	**Diamedica (UK) Ltd**
Electricity requirements, including voltage, and charging features	**Internal 12 volt sealed lead acid battery, with 12 volt battery charger / power supply. Pressure control valve (preset at 5 bar). On/off switch, mains power lead. Will accept mains power from 95 - 290 volts (50 hz - 60 Hz).**
Size and form factor	**Reservoir Filling Pump: weight 13 kg, dimensions 42 x 23 x 33 cm** **Reservoir Vessel 20L: weight 6 kg, dimensions 25 x 25 x 70 cm** **Reservoir Vessel 100L: weight 13.5 kg, dimensions 40 x 40 x 105 cm**
Shelf life, stability, and storage requirements	**N/A**
Ex-works price of device	**Oxygen Reservoir Filling system comes with 20L vessel £1,550 GBP; additional 20L reservoir vessels £400 GBP** **Oxygen Reservoir Filling system comes with 100L vessel £1,750 GBP; additional 100L reservoir vessels £600 GBP**
Ex-works price of consumables	**No consumables**

Contact Information:

Diamedica (UK) Ltd

info@diamedica.co.uk

+44 1598 710066

www.diamedica.co.uk

TNI softFlow junior – Masimo Corporation

Commercially Available

Intended Use

For spontaneously breathing paediatric and neonatal patients in hospital and home-care environments.

Key Features

- Respiratory support delivered through a soft nasal cannula interface
- Adjustable flow rate from 2 to 15 L/min to meet the inspiratory flow needs of the patient
- Warmed humidification of air/oxygen to help provide therapy comfort and aid in mucus clearance 1,2
- Ability to supplement with 0-12 L/min oxygen depending on patient requirements
- Integrated flow driver provides flow, without the need for dedicated hospital pneumatic systems, in multiple clinical and home settings
- Condensate-free air/oxygen flow for compliant therapy

**These products are for professional use only. Federal (USA) law restricts these devices to sale by or on the order of a physician. In using any of these devices, please see instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.*

TNI softFlow junior

Type of technology	**Nasal High Flow Oxygen Concentrator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Masimo Corporation**
Performance Data	**Adjustable flow rate: 2 to 15 L/min ± 2%, adjustable in 0.5 L/min steps** **Supplemental oxygen support: 0-12 L/min, with FiO2 indicator integrated into the display** **Adjustable humidity: dew point from 30–37°C, adjustable in 1°C steps** **Integrated micro-particle filter** **Variety of nasal cannula prongs to suit a wide range of patient applications**
Electricity requirements, including voltage, and charging features	**Operating voltage: 100-240 V AC 50-60 Hz**
Size and form factor	**Device dimensions:** **W 320mm** **H 210mm** **D 320mm** **Weight: 5.6 kg**
Shelf life, stability, and storage requirements	**3-6 years; depends on daily usage** **Storage requirements:** **Temperature: -25 to +70 °C** **Humidity: < 93 % RH**
Ex-works price of device	**Prices will varies by volume**
Ex-works price of consumables	**Prices will varies by volume**

Contact Information:

Masimo Corporation

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Franck Berthon – Masimo Global Health Specialist

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+41 79 267 7963

www.masimo.com

Upright with PEEP Newborn Bag-Mask – Laerdal Global Health

Commercially available

Intended Use

Upright with Newborn PEEP is designed to provide positive pressure ventilation during newborn resuscitation. Upright with PEEP can be used on all newborns, but PEEP technology is especially beneficial for premature newborns.

Key Features

A self-inflating, manual and reusable bag-mask intended for newborns and infants who require respiratory support. By introducing positive end-expiratory pressure (PEEP), Upright with PEEP Newborn Bag-Mask can help prevent repeated lung alveolar collapse during ventilation, helping recruit lung volume more efficiently, clear fluid from the lungs, and reduce damage to the lung tissue. PEEP is the current standard of care in high-resource settings and is recommended by the International Liaison Committee on Resuscitation (ILCOR) for premature newborns.

Upright with PEEP Newborn Bag-Mask

Type of technology	**Newborn bag valve and mask**
Status	**Commercially available**
Regulatory approvals and/or international standards	**MDR approved, CE Mark**
Manufacturer of Record	**Laerdal Medical AS**
Electricity requirements, including voltage, and charging features	**N/A**
Size and form factor	**Product Size (LxWxH): 73.5*9.3*21.9 cm**
Shelf life, stability, and storage requirements	**Shelf life: 3 years** **Storage temperature: -20°C to 60°C**
Ex-works price of device	**$30 USD**
Ex-works price of consumables	**N/A**

Contact Information:

Laerdal Global Health

lgh@laerdal.com

+47 51 51 17 00

www.laerdalglobalhealth.com

Vayu Oxygen Blender System – Vayu Global Health Innovations

Commercially available

Intended Use

The Vayu Oxygen Blender System provides blended oxygen therapy to newborns and children up to age 5.

Key Features

The Vayu Oxygen Blender System provides patients with low flows of oxygen (adjustable up to 4 LPM) via nasal cannula. The system contains an integrated blender that allows the user to adjust the oxygen concentration from 30 – 100%.

Vayu Oxygen Blender System

Type of technology	**Oxygen therapy**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Approved in Kenya and Tanzania, other local regulatory pending**
Manufacturer of Record	**Vayu Global Health Innovations**
Electricity requirements, including voltage, and charging features	**N/A**
Size and form factor	**Compact breathing circuit**
Shelf life, stability, and storage requirements	**3 year shelf life**
Ex-works price of device	**$75 USD**
Ex-works price of consumables	**$3 USD**

Contact Information:

Vayu Global Health Innovations

info@vayughi.com

www.vayuglobalhealth.org

Aero High Flow Respirator – Aero Therapeutics, Inc

Not yet commercially available / In development

Intended Use

Respiratory Distress

Key Features

Sterlizes, oxygenates, warms, and humidifies air delivered by nasal cannula.

Aero High Flow Respirator

Type of technology	**High Flow Respirator**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**TBD**
Manufacturer of Record	**3 sites in the US TBD**
Electricity requirements, including voltage, and charging features	**12VDC**
Size and form factor	**18 x 18 x 12 inches**
Shelf life, stability, and storage requirements	**1 – 5 years**
Ex-works price of device	**$500 USD**
Ex-works price of consumables	**N/A**

Contact Information:

Aero Therapeutics

Jamison.Langguth@Yale.edu

www.breatheaero.com

AIR (Augmented Infant Resuscitation) – Royal Philips

Not yet commercially available / In development

Intended Use

Newborn Resuscitation quality improvement training tool for trained healthcare providers.

Key Features

The Augmented Infant Resuscitator helps healthcare providers improve and retain their newborn resuscitation skills because it allows providers to engage in **low dose - high frequency training**, without the need for a qualified trainer to be present. Building 'muscle memory'. It does so by providing **instant, objective and actionable feedback** to the trainee. Thus improving the effectiveness of the initial training, ongoing **skills maintenance** (accreditation), and thereby builds the trainee's skills and **confidence**. Additionally it also allows for regulatory bodies to objectively **audit** training programs and **track compliance** (accreditation).

AIR (Augmented Infant Resuscitation)

Type of technology	**Resuscitation quality improvement training tool**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**CE mark**
Manufacturer of Record	**TBD**
Electricity requirements, including voltage, and charging features	**TBD**
Size and form factor	**TBD**
Shelf life, stability, and storage requirements	**TBD**
Ex-works price of device	**TBD**
Ex-works price of consumables	**TBD**

Contact Information:

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Thermal Management

In general, newborns require a warmer environment than adults and the smaller the newborn, the higher the temperature needs to be.

A newborn's ability to stay warm can be easily compromised by the temperature of its surroundings since newborn infants regulate body temperature much less efficiently than adults and lose heat more easily. Low birth weight and premature babies often face even greater risk [56].

As many as 85% of infants born in hospitals in low-resource settings become cold (defined as <36.5°C) [57]. Mortality rates increase with each degree Celsius of temperature lost. While the risks of being too cold are well recognized, hypothermia remains a largely invisible problem in overcrowded newborn units in low-resource settings. Hypothermia in newborns requires rapid diagnosis, which is often difficult in crowded and understaffed wards. Hypothermia not only increases the chances of acidosis, sepsis and RDS, but may indicate the presence of system illness such as infection or hypoglycemia.

Hypothermia can be treated using Kangaroo Mother Care (KMC), blankets/hats, warming cribs, warming mattresses, and radiant warmers. While hypothermia can be treated using KMC, infants and their caregivers may not be eligible for reasons such as, but not limited to: mother is recovering from surgery or the infant is in need of intensive care.

Attempts to warm a cold baby without monitoring temperatures carefully can result in hyperthermia. Rapid swings in temperature – known as thermal shock – can lead to negative outcomes, including death. Additionally, unrecognized fever in infants may lead to delays in treating neonatal sepsis and resulting in increased morbidity.

In high-resource settings, these negative outcomes are prevented by using incubators which continuously monitor and adjust temperature, or, with intermittent monitoring (every 3-4 hours) for infants who are in open cribs. However, incubators cost thousands of dollars and often require delicate sensors and expensive consumables. Existing temperature monitoring devices that are affordable in lower resource settings do not have the features necessary for the accurate detection of hypothermia or are not designed for a clinical setting.

In addition to the risks of hypothermia, pre-term infants and children are at high risk of infection, which can cause hyperthermia. A diagnosis of fever is not conclusive for any of these conditions, but it is a critical early sign of potentially severe illness. In combination with a respiratory rate monitor and pulse oximeter, continuous temperature monitoring can provide guidance to clinicians on what type of treatment to pursue; once treatment has begun, it can indicate whether treatment is working or needs to be increased.

Outlined in this section are technologies both commercially available and in development that enable temperature stability for neonates.

Introduction to Conductive Warmer

Since low birth weight or sick newborns are most vulnerable to hypothermia, the World Health Organization has outlined various methods that can be used to keep high-risk babies warm including kangaroo-mother care, "warm rooms", heated mattresses, radiant warmers, and incubators. These methods vary in their response to addressing the four different ways in which newborns lose heat: radiation, convection, evaporation, and conduction [56].

Conductive warmers provide conductive heating either below or around the patient while also allowing health care workers with visibility and access to the baby. Given the high cost of some warming devices (e.g., incubator, radiant warmer), a need exists in low-resource settings for a technology that is both affordable and easy to use, and that can accurately detect hypothermia while keeping the newborn warm. The advantages of using warming devices include the fact that extra warmth can be given locally instead of having to warm the whole room; temperature control is easier; and newborns can be fully observed and visible. The World Health Organization explains that different devices serve different purposes and advises that incubators are the proper choice for the care of very small newborns during the first few days or weeks. When these babies no longer have acute problems, they can be cared for safely on heated water-filled mattresses. Radiant heaters are best used for resuscitation and interventions where a number of people are involved [56].

Negative outcomes associated with hypothermia can be prevented using warming cribs that carefully control heat. Conductive warmers may be called warming cribs however are distinct from incubators. The intent in the development of this TPP was to provide developers with the opportunity to be innovative in the design process rather than be constrained by existing technologies or preconceived notions that a "crib" must be enclosed.

A need for the creation of a separate TPP for an incubator was identified at the Consensus Meeting. Incubators are the conventional method for maintaining normothermia in preterm and low birthweight neonates. Risks associated with incubator care include hypothermia [44,45]; hyperthermia [46]; nosocomial infections, related to lack of effective cleaning standards [47–49]; and cross-infection from other neonates when incubators are shared, a common practice in low-resource facilities. Failure of incubators to properly regulate temperature may be related to malfunction (e.g., over- or under-heating) [46,49–52], loss of electrical supply [53], ignorance of how to regulate set-points [46], as well as environmental factors [50]. In low- and middle-income countries, where there may be few nurses and doctors available, neonates in incubators may not receive adequate monitoring and serious events (e.g., apnea) may not be detected in time. Due to high purchase cost and poor routine maintenance practices, hospitals in such settings commonly face shortages of functional incubators [42,53–55].

Note that technologies within this product category have not yet been evaluated by the NEST360 team for inclusion as a NEST360 Qualified Technology. To learn more about what it means to be “NEST360 Qualified” and how the technologies are qualified by NEST360, please click here.

IncuBlanket Series 200 (5–8 hours) – Warmilu LLC

Newborn Plus (Large 200-L)

Newborn (Large 200-M)

Preterm (Small 200-S)

Commercially available

Intended Use

For treating and preventing infant hypothermia in prehospital transport, intrahospital transport, and as an additional source of warming when KMC or incubators or radiant warmers are not available. To provide thermal stability for neonates at risk of hypothermia. Designed under the supervision of neonatologists to be safe and easy to use.

Product Components

Reusable (1) IncuBlanket and (1) InstaWarmer Pack

Key Features

Fully non-electric, reusable IncuBlanket Series 200 comes in three (3) sizes to treat and prevent infant hypothermia. Secure thermal environment produced by a chemical heating pack in the back of the blanket that heats to 100% within a few minutes with instant, controlled warmth for 5-8 hours. Heat evenly distributed by infant blanket metalized polyethylene film and polyester layer.

- **Peak Temp:** 102.2°F (39°C)
- **Patients:** Preterm, newborn, and readmitted pediatric patients requiring thermal regulation.
- **Applications:** Thermal regulation or rewarming in prehospital and intrahospital transport, emergency and disaster transport, and to provide warming in the case of power outage or incubator shortage.
- **Ease of access** quick-release buckle and arm flaps allow for intermittent monitoring. Arm and contoured leg flaps permit quick access to the baby for vitals monitoring, blood draws, and heel pricks.
- Wipeable pack can withstand 1,000 lbs of weight. Latex free.

Contact Information:

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http://warmilu.com/

IncuBlanket Series 200

Type of technology	**Conductive Warmer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**US FDA Certificate to Foreign Government and US FDA Certificate of Exportability Section 801(e)(1) and Kenya Pharmacy and Poisons Board**
Manufacturer of Record	**Warmilu LLC**
Benchtop measurement accuracy (±°C)	**±0.1°C @ 30°C to 42°C**
Clinical measurement accuracy (±°C)	**±0.1°C @ 30°C to 42°C**
Maximum CO2 concentration	**Not applicable, like radiant warmer in that the infant's face is never covered and CO2 concentrations do not build up near the face**
Maximum temperature (±°C)	**104°F (40°C)**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**The infant warming blanket has a US-patented heat source pack that slides into the back of the blanket in a separate, zippered pouch compartment. This pack generates warmth that is limited by the pack composition to prevent burns and overheating.**
Temperature uniformity (±°C)	**±0.8°C**
Alarms included in device	**None**
How are alarms set?	**Not applicable, non-electric Warmilu IncuBlanket does not have alarms**
Consumables required	**Pack and blanket are reusable for at least 100 times. Pack and blanket provide at least 500 hours of warmth.**
Describe how cleaned or decontaminated	**The infant warming blanket and pack are wipeable AND washable with standard hospital cleaning products including detergent, bleach, and other germicides. Can clean with standard hot wash cycles. Full list of known and approved EPA-registered disinfectant (i.e., germicidal detergents) available upon request at info@warmilu.com.**

Key Features Continued

- All materials CPSIA compliant, medical- and food-grade for infant use. Fabrics meet the stringent standards set by the US Consumer Products Safety Commission on lead and phthalates and flammability. Can be stored in standard humidity and room temperature.
- Durable for more than 100 standard hot water sterilization washes, machine or manual.
- Clinically evaluated and validated by CNN Award Winning Innovator, Dr. Ranjan Pejaver. Dr. Ranjan Kumar Pejaver is a Pediatrician and Neonatologist in Yeshwanthpur, Bangalore and has an experience of 33 years in these fields.

IncuBlanket Series 200

Size and form factor	**Technical Specifications** **Designed for portability and ease of transport.** **InstaWarmer Weight:** 4.09 lbs (1.855 kg) **InstaWarmer Dimensions:** 16 in x 9 in x 1 in (40.6 cm x 22.8 cm x 2.5 cm) **IncuBlanket 200-L Dimensions:** 24×13.78×2.5" (61x35x6.5 cm) and 1.64 lbs (0.744 kg) **IncuBlanket 200-M Dimensions:** 23inch x 13inch x 2.5inch (58.4 cm x 33cm x 6.5cm) and 1.37 lbs (0.623 kg) **IncuBlanket 200-S Dimensions:** 17.5inch x 10inch x 2.5inch (44.5 cm x 25cm x 6.5cm) and 1.1 lbs (0.5 kg)
Training required	**Minimal – instruction manual included and an online demonstration (pre-recorded videos and video conferencing) available for global customers. Designed for intuitive use.**
User instructions provided	**Instructions for use, user manual, one-page boiling sheet, autoclave instructions for reset, instructional videos on website**
Electricity requirements, including voltage, and charging features	**Completely non-electric N/A**
Maximum power consumption (W)	**N/A**
In the event of a power outage, what is the heat retention for your Conductive Warmer? (e.g., X ±°C loss over X hours)	**5-8 Hours from start time**
Warranty	**2 year standard warranty**
Ex-works price of device	**IncuBlanket Series 200-S Preterm Small: $134.99 USD** **IncuBlanket Series 200-M Newborn Medium: $189.99 USD** **IncuBlanket Series 200-L Newborn Plus Large: $239.99 USD** ****21% to 25% discount available to select teaching hospitals and nonprofit institutions please follow up at info@warmilu.com. Pricing for every IncuBlanket includes one infant warming blanket and one warming pack.**
Ex-works price of consumables	**Refill Packs can be purchased for $50 USD. 200-S Blankets can be purchased for $85 USD, 200-M for $140 USD, 200-L for $190 USD** ****21% to 25% discount available to select teaching hospitals and nonprofit institutions please follow up at: info@warmilu.com**

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http://warmilu.com/

IncuBlanket Wipable Transport Series 300 (4–6 hours) – Warmilu LLC

Commercially available

Intended Use

For treating and preventing infant hypothermia in prehospital transport, intrahospital transport, and as an additional source of warming when KMC or incubators or radiant warmers are not available. To provide thermal stability for neonates at risk of hypothermia. Designed under the supervision of neonatologists to be safe and easy to use.

Product Components

Reusable (1) IncuBlanket and (1) InstaWarmer Pack

Key Features

Fully non-electric, reusable IncuBlanket Series 300 comes in one (1) size to treat and prevent infant hypothermia. Secure thermal environment produced by a chemical heating pack in the back of the blanket that heats to 100% within a few minutes with instant, controlled warmth for 4-6 hours. Heat evenly distributed by infant blanket metalized polyethylene film and polyester layer.

- **Peak Temp:** 102.2°F (39°C)
- **Patients:** Preterm, newborn, and readmitted pediatric patients requiring thermal regulation.
- **Applications:** Thermal regulation or rewarming in prehospital and intrahospital transport, emergency and disaster transport, and to provide warming in the case of power outage or incubator shortage.
- Ease of access quick-release buckle and arm flaps allow for intermittent monitoring. Arm and contoured leg flaps permit quick access to the baby for vitals monitoring, blood draws, and heel pricks.
- Wipeable pack can withstand 1,000 lbs of weight. Latex free.
- All materials CPSIA compliant, medical- and food-grade for infant use. Fabrics meet the stringent standards set by the US Consumer Products Safety Commission on lead and phthalates and flammability. Can be stored in standard humidity and room temperature.
- Durable for more than 100 standard hot water sterilization washes, machine or manual.

IncuBlanket Wipable Transport Series 300

Type of technology	**Conductive Warmer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**US FDA Certificate to Foreign Government and US FDA Certificate of Exportability Section 801(e)(1) and Kenya Pharmacy and Poisons Board**
Manufacturer of Record	**Warmilu LLC**
Benchtop measurement accuracy (±°C)	**±0.1°C @ 30°C to 42°C**
Clinical measurement accuracy (±°C)	**±0.1°C @ 30°C to 42°C**
Maximum CO2 concentration	**Not applicable, like radiant warmer in that the infant's face is never covered and CO2 concentrations do not build up near the face**
Maximum temperature (±°C)	**104°F (40°C)**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**The infant warming blanket has a US-patented heat source pack that slides into the back of the blanket in a separate, zippered pouch compartment. This pack generates warmth that is limited by the pack composition to prevent burns and overheating.**
Temperature uniformity (±°C)	**±0.8°C**
Alarms included in device	**None**
How are alarms set?	**N/A; non-electric Warmilu IncuBlanket does not have alarms.**
Consumables required	**Pack and blanket are reusable for at least 100 times.** **Pack and blanket provide at least 400 hours of warmth.**

IncuBlanket Wipable Transport Series 300

Describe how cleaned or decontaminated	**The infant warming blanket and pack are wipeable AND washable with standard hospital cleaning products including detergent, bleach, and other germicides. Can clean with standard hot wash cycles. Full list of known and approved EPA-registered disinfectant (i.e., germicidal detergents) available upon request at info@warmilu.com.**
Size and form factor	**Technical Specifications** **Designed for portability and ease of transport.** **InstaWarmer Weight: 4.09 lbs (1.855 kg)** **InstaWarmer Dimensions: 16 in x 9 in x 1 in (40.6 cm x 22.8 cm x 2.5 cm)** **IncuBlanket 300-L Dimensions: 32x40x1.75" (81.28x101.6x4.44 cm) and 0.512kg (1.128lbs)**
Training required	**Minimal – instruction manual included and an online demonstration (pre-recorded videos and video conferencing) available for global customers. Designed for intuitive use.**
User instructions provided	**Instructions for use, user manual, one-page boiling sheet, autoclave instructions for reset, instructional videos on website**
Electricity requirements, including voltage, and charging features	**N/A; completely non-electric**
Maximum power consumption (W)	**N/A**
In the event of a power outage, what is the heat retention for your Conductive Warmer? (e.g., X ±°C loss over X hours)	**4-6 Hours from start time**
Warranty	**2 year standard warranty**
Ex-works price of device	**IncuBlanket Series 300-L Universal Newborn Plus Large - $150 USD** ****21% to 25% discount available to select teaching hospitals and nonprofit institutions please follow up at info@warmilu.com. Pricing for every IncuBlanket includes one infant warming blanket and one warming pack.**
Ex-works price of consumables	**Refill Packs can be purchased for $50 USD. 300-L Blankets can be purchased for $100 USD.** ****21% to 25% discount available to select teaching hospitals and nonprofit institutions please follow up at info@warmilu.com.**

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InstaWarmer Pack 100 Series (2–4 hours) – Warmilu LLC

Commercially available

Intended Use

For treating infant hypothermia. Designed under the supervision of neonatologists to be safe and easy to use.

Key Features

Fully non-electric, reusable pack used to treat and prevent infant hypothermia. Chemical heating pack heats to 100% within a few minutes with controlled warmth for 2-4 hours. Warmth lasts longer under clothing or fabric layer. Heat evenly distributed by thermal buffer included in the pack.

- **Peak Temp:** 104°F (40°C)
- **Patients:** Preterm, newborn, and readmitted pediatric patients requiring thermal regulation
- **Applications:** Thermal regulation or rewarming in prehospital and intrahospital transport, emergency and disaster transport, and to provide warming in the case of power outage or incubator shortage.
- 100% Non-Toxic & Food-Grade Materials.
- Wipeable pack can withstand 1,000 lbs of weight. Latex free.
- All materials CPSIA compliant, medical- and food-grade for infant use.
- Can be stored in standard humidity and room temperature.
- Durable for at least 100 cycles. Pack can be recharged through boiling, autoclave, or microwave. Instructions available online.

Contact Information:

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InstaWarmer Pack 100 Series

Type of technology	**Conductive Warmer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**US FDA Certificate to Foreign Government and US FDA Certificate of Exportability Section 801(e)(1) and Kenya Pharmacy and Poisons Board**
Manufacturer of Record	**Warmilu LLC**
Benchtop measurement accuracy (±°C)	**±0.1°C @ 30°C to 42°C**
Clinical measurement accuracy (±°C)	**±0.1°C @ 30°C to 42°C**
Maximum CO2 concentration	**To be used underneath an infant without covering the infant's face**
Maximum temperature (±°C)	**104°F (40°C)**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**The infant warming pack has a US-patented heat composition to prevent burns and overheating**
Temperature uniformity (±°C)	**±0.8°C**
Alarms included in device	**None**
How are alarms set?	**N/A; non-electric Warmilu Pack does not have alarms.**
Consumables required	**Pack and blanket are reusable for at least 100 times.** **Pack and blanket provide at least 500 hours of warmth.**
Describe how cleaned or decontaminated	**The infant warming pack is wipeable using standard hospital cleaning products including detergent, bleach, and other germicides. Can be sterilized by autoclave. Full list of known and approved EPA-registered disinfectant (i.e. germicidal detergents) available upon request at info@warmilu.com.**
Size and form factor	**Technical Specifications** **Designed for portability and ease of transport.** **InstaWarmer Weight: 4.09 lbs (1.855 kg** **InstaWarmer Dimensions: 16 in x 9 in x 1 in (4w0.6 cm x 22.8 cm x 2.5 cm)**

InstaWarmer Pack 100 Series

Training required	**Minimal – instruction manual included and an online demonstration (pre-recorded videos and video conferencing) available for global customers. Designed for intuitive use.**
User instructions provided	**Instructions for use, user manual, one-page boiling sheet, autoclave instructions for reset, instructional videos on website**
Electricity requirements, including voltage, and charging features	**N/A; completely non-electric**
Maximum power consumption (W)	**N/A**
In the event of a power outage, what is the heat retention for your Conductive Warmer? (e.g., X ±°C loss over X hours)	**3 hours or more from start time**
Warranty	**2 year standard warranty**
Ex-works price of device	**InstaWarmer Series 100 - $100 USD** ****21% to 25% discount available to select teaching hospitals and nonprofit institutions please follow up at: info@warmilu.com**
Ex-works price of consumables	**Refill Packs can be purchased for $50 USD** ****21% to 25% discount available to select teaching hospitals and nonprofit institutions please follow up at: info@warmilu.com**

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Celsi Warmer – 3rd Stone Design

Not yet commercially available / In development

Intended Use

To provide thermal stability for neonates at risk of hypothermia.

Key Features

Celsi Warmer is an affordable, durable, easy-to-use alternative to traditional neonatal incubators. The device provides just the right amount of warmth to keep the baby comfortable. The device constantly displays the baby's temperature, has built-in safety features to prevent overheating, and has visual indicators that are easy to read by users. It can be used with any standard bassinet, turning any available bed into a warming bed.

Celsi Warmer

Type of technology	**Conductive warmer**
Status	**Not yet commercially available / in development** **Commercial launch expected 2023**
Regulatory approvals and/or international standards	**CE Mark expected 2023**
Manufacturer of Record	**Hadleigh Health Technologies**
Benchtop measurement accuracy (±°C)	**± 0.3°C**
Clinical measurement accuracy (±°C)	**± 0.3°C**
Maximum CO2 concentration	**N/A**
Maximum temperature (±°C)	**40°C**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**The warming matress has a sensor that attaches to the infant's abdomen either using a wearable belt (reusable) or an adhesive sticker (disposable). This sensor incorporates a feedback loop that uses the infant's current temperature to determine whether to continue heating the mattress. The device constantly displays the baby's temperature, has built-in safety features to prevent burns and overheating, and has visual indicators that are easy to read by users.**
Temperature uniformity (±°C)	**TBD**
Alarms included in device	**Yes**
How are alarms set?	**Alarms are pre-set at factory**
Consumables required	**None**
Describe how cleaned or decontaminated	**The warming matress is wipeable with standard hospital cleaning products.**

Contact Information:

Hadleigh Health Technologies

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www.hadleighhealth.com

Celsi Warmer

Size and form factor	**The warming mattress fits in all standard bassinets. Monitor is elevated on an attached pole.**
Training required	**Minimal; designed for intuitive use.**
User instructions provided	**Yes**
Electricity requirements, including voltage, and charging features	**110-240V AC 50-60hz. Integrated surge protection**
Maximum power consumption (W)	**< 100W**
In the event of a power outage, what is the heat retention for your Conductive Warmer? (e.g., X ±°C loss over X hours)	**N/A**
Warranty	**2 year standard warranty**
Ex-works price of device	**TBD**
Ex-works price of consumables	**TBD**

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DREAM Warmer – Global Newborn Solutions

Not yet commercially available / In development

Figure 1

Figure 2

Figure 3

Intended Use

Complement to Skin to Skin for the prevention and treatment of neonatal hypothermia in resource limited settings (fig 1), either as stand-alone heat source (fig 2) or additive to Skin to Skin care (fig 3).

Key Features

Global Newborn Solutions developed the DreamWarmer, an award-winning, patented, non-electric skin temperature heating pad that is safe, affordable, re-usable, and easy to prepare and clean. It can be used in addition to KMC or as a stand-alone heat source in hospitals, clinics, homes, or on transport.

The DreamWarmer only requires boiled water and can be used for up to 6 hours. It comes with a warming mattress, insulating sleeve, thermos, backpack, and low literacy instructions.

DREAM Warmer

Type of technology	**Conductive Warmer**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**Pending US FDA 510k & 513g clearance and Rwanda FDA in progress**
Manufacturer of Record	**Lawrence Berkeley National Laboratory has made majority of prototypes to date. MicroTek Labs (Dayton, Ohio) manufactured the Phase Change mattresses for the 2019-2020 Rwandan multi-hospital trial. Currently finalizing the commercial manufacturing process.**
Benchtop measurement accuracy (±°C)	**The warming mattress does not come with a temperature sensor. The maximum benchtop temperature measurement of the device is 38.1 °C.**
Clinical measurement accuracy (±°C)	**The warming mattress does not come with a temperature sensor. The maximum temperature is a few degrees higher than 37 °C to distinguish when it is appropriate to put the baby on the device.**
Maximum CO2 concentration	**N/A; there is no excess CO2 concentration as it is not an enclosed space. CO2 is same as ambient air.**
Maximum temperature (±°C)	**38.1 °C**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**If warmer is used as the sole source of external warmth, the infant is laid naked (except a hat and socks if available) onto the warmer and the infant and warmer are wrapped up in a blanket (fig 2). If the warmer is additive to Skin to Skin (STS), the infant is laid naked (except hat and socks if available) on the mother's chest. The warming mattress is wrapped around the infant's back and a blanket is wrapped around the warmer, infant and mother in standard STS fashion (fig 3).**
Temperature uniformity (±°C)	**Because the warmer is made of PCM that moves from liquid to solid at 37 °C, once melted it stays at this temperature for approximately six hours.**

Contact Information:

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DREAM Warmer

Alarms included in device	**There is no audible alarm. The start and stop indicators are visual:** **Start: The temperature indicator is made of orange phase change material that is a few degrees higher than 37 °C to distinguish when it is appropriate to put the baby on the device.** **Stop: When the warmer has transitioned from clear liquid to white solid, it has fallen below the phase change temperature of 37 °C.**
How are alarms set?	**N/A**
Consumables required	**None; warmer consists of the phase change mattress, an insulating sleeve, a thermos for melting the phase change wax, and a backpack for easy storage and portability.** **There are no consumables.**
Describe how cleaned or decontaminated	**It is cleaned by wiping it down with standard hospital cleanser or soap and water. It is designed to have no attached fabric or other features that would be difficult to clean, especially for environments without diapers or washing machines.**
Size and form factor	**18.75 inches (=47.6 cm) long** **11.75 inches (=29.8 cm) wide**
Training required	**Training is minimal, taking only a few minutes. The warmer includes simple, low-literacy instructions. Additionally, there are several videos available that demonstrate use of the warmer.**
User instructions provided	**Low-literacy instructions are printed on the insulating sleeve and thermos.**
Electricity requirements, including voltage, and charging features	**The warmer is heated with < 2 L of boiled water. The water can be boiled with a standard electric tea kettle if electricity is available, otherwise by any means, including coal, firewood or solar.**
Maximum power consumption (W)	**Zero. The warmer is designed to be used without any electricity.**
In the event of a power outage, what is the heat retention for your Conductive Warmer? (e.g., X ±°C loss over X hours)	**N/A; once heated and ready for use, the warmer retains its heat for approximately 6 hours.**
Warranty	**We currently have no warranty. When manufactured commercially, it will come with a six months warranty against manufacturing defects from the date of purchase.**
Ex-works price of device	**$120 USD**
Ex-works price of consumables	**N/A; device has no consumables. There are no accessories. All four components of the device (Fig 1) are offered as a single package.**

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Otter Newborn Warmer – Design that Matters & MTTS

Not yet commercially available / In development

Intended Use

Otter is a newborn conductive warmer designed specifically to prevent newborn hypothermia among admitted patients and during in-hospital transportation, for users with limited training serving remote populations in areas of electricity insecurity.

Unlike the incubators and radiant warmers a rural hospital might receive as donations or through government purchase, the Otter Warmer provides effective newborn warming that is "easy to use right and hard to use wrong" -- in other words the device eliminates the most common sources of user error and product failure.

Key Features

The Otter newborn warmer's internal battery allows the device to provide warming during power interruptions and during hand-carry patient transportation. The device weighs 2.5 kg, for a total carry weight of 5 kg with an average-sized newborn. In prototype bench-testing in 23C (74F) ambient temperature, the internal battery maintained the warmer surface temperature at 36C (97F) for two hours and thirty minutes.

The main components of the Otter Newborn Warmer are the heating element, the battery, the bassinet and the user interface.

Heating Element features:

- In prototype bench-testing at 23C ambient temperature, the heating element required an average of eight minutes to reach 36C.
- The handprint sticker inside the bassinet is intended as a user-cue, to prompt clinicians and family members to touch the bassinet surface. Feeling that the surface is warm is intended to increase user confidence in the warmer's effectiveness.

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Otter Newborn Warmer

Type of technology	**Conductive Warmer**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**IEC 60601, IEC 80601-2-35, will apply for CE Mark and/or FDA certification**
Manufacturer of Record	**MTTS**
Benchtop measurement accuracy (±°C)	**±0.04°C**
Clinical measurement accuracy (±°C)	**N/A (have not done clinical testing)**
Maximum CO2 concentration	**N/A (not enclosed)**
Maximum temperature (±°C)	**40°C**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**Otter is an open-loop warmer and does not depend on consumable skin temperature probes for temperature adjustments. The device maintains the user-set temperature until manually adjusted.**
Temperature uniformity (±°C)	**±0.04°C**
Alarms included in device	**Alarms specified in IEC 80601-2-34 and IEC 60601** • **Over temperature alarm for temperature exceeding 40°C** • **Temperature uniformity alarm for uniformity ±1°C** • **Medium priority alarm for power interruptions**
How are alarms set?	**Alarms (visual LED and audible) can be turned on/off with a button on the UI**
Consumables required	**None**
Describe how cleaned or decontaminated	**The warmer features a seamless polycarbonate bassinet that can be wiped clean with common cleaning solutions such as isopropyl alcohol, diluted bleach or surfanios.**

Battery features:

- The battery can be charged with any 12V DC power source: a standard AC-DC power adapter, a car battery, solar panels, or an automotive cigarette lighter outlet.
- In the production design, Otter will automatically switch from charging the battery pack when connected to external power, to powering the device from the battery pack when external power is lost or intentionally disconnected for hand-carry.
- It may be possible to use Otter in an ambulance. The device is portable and can be powered by a standard 12V automotive cigarette lighter outlet. Newborn safety and comfort are significant concerns, and Otter is not designed as a substitute for a transport incubator.

Bassinet features:

- The Otter bassinet is made from shatter-proof, bio-compatible polycarbonate.
- To improve infection control, the bassinet has a smooth internal surface with no fabric, seams or gaps, and can be wiped clean with common cleaning solutions such as isopropyl alcohol, diluted bleach or surfanios. The Otter bassinet is also sized to fit a single newborn, to discourage bed-sharing.
- The bassinet is small enough that it may be possible to operate in bed next to the patient's mother, to encourage mother-child bonding and to facilitate KMC.

Otter Newborn Warmer

Size and form factor	**Polycarbonate bassinet with attached UI, handles, and battery compartment** **Dimensions: 530mmL, 230mmW, 100mmH** **Weight: 2.5 kg**
Training required	**The device is designed to be intuitive and require minimal user training. A brief 10-minute training provided by the manufacturer on use, cleaning, and alarms is expected to be sufficient.**
User instructions provided	**Manufacturer will provide a user pamphlet with text and captioned images depicting use, in multiple languages.**
Electricity requirements, including voltage, and charging features	**12V DC Power Supply (110/220 AC Converter)**
Maximum power consumption (W)	**36W**
In the event of a power outage, what is the heat retention for your Conductive Warmer? (e.g., X ±°C loss over X hours)	**Device will automatically switch to internal backup battery, to provide uninterrupted warming at set temperature for up to 2h30min.**
Warranty	**Expected to be one year**
Ex-works price of device	**TBD, target is significantly less than the price of a typical radiant warmer.**
Ex-works price of consumables	**None (no consumables or accessories)**

Contact Information:

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Portable Neonate Warmer – Uganda Industrial Research Institute (UIRI)

Not yet commercially available / In development

Intended Use

The intended use of the Portable Neonate Warmer (PNW) is to provide the appropriate thermal protection and temperature monitoring for neonates with hypothermia who are being transported to a health facility from a home in a rural community. The device can be sterilized and has been designed for multiple use.

Key Features

Transport carrier, sleeping bag, temperature monitoring system, and phase change material.

a) Padded transport carrier for the PNW.

b) Wire mesh frame of the transport carrier for the PNW.

c) Testing temperature sensors while simulating the weight of the baby.

d) Sodium acetate heating pad in solid state (pre-activation).

Portable Neonate Warmer

Type of technology	**Warming crib (Portable Neonate Warmer)**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**The Portable Neonate Warmer is still under development and is yet to be tested clinically; however, it has been designed with reference to the following international medical devices standards:** a) IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance-Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. b) IEC 80601-2-35:2009 Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use. c) IEC 60601-2-20:2009 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators. d) ISO-10993-1:1992- Part I Biological Evaluation of Medical Devices, Evaluation and Testing.
Manufacturer of Record	
Benchtop measurement accuracy (±°C)	**The temperature monitoring system shall measure the temperature of the neonate with a minimum accuracy of ± 0.1°C and shall measure the temperature of the Phase Change Material (PCM) with a minimum accuracy of ± 1°C.**
Clinical measurement accuracy (±°C)	**PNW has not been tested clinically**
Maximum CO2 concentration	**The PNW is not fully enclosed; however, airflow tests are yet to be carried out to determine CO2 concentration.**

e) Sleeping bag with adjustable hoods where temperature sensors are retrofitted.

Portable Neonate Warmer

Maximum temperature (±°C)	Sodium acetate is enclosed in a Poly Nylon casing that is partitioned to ensure even distribution of the sodium acetate in the PCM pad which provides heat. A stainless steel spring activator with a 3D printed casing is enclosed in the pad embedded in the sodium acetate. The activator stores sodium acetate anhydrous seed particles and when it is manipulated the particles are exposed to a super cooled solution which acts as a nuclear center of crystallization to molten form. The sodium acetate anhydrous molten particles are clamped between the springs during activation. Surface interactions are responsible for the elevated melting point which increases with increasing hardening of the material. Initial activation of the sodium acetate anhydrous is immersion in a water bath at 95°C, which takes about 5 min for the material to become completely molten. It is then cooled to 58°C and subsequently inserted in the sleeping bag. Padding between the PCM and the contact surface ensures the baby receives a maximum temperature of 37.5°C.
Describe the patient interface, specifically how the device responds to a neonate's temperature.	A temperature sensor (part of the temperature monitoring system) strapped onto the neonate will measure the temperature of the neonate in real time. In addition this system also monitors the temperature of the PCM pad. This is to ensure that the neonate's temperature remains optimal (between 36.5 °C and 37.5 °C as recommended by the WHO) and the PCM pad temperature does not fall below the required threshold. Indicators displayed on the outside of the sleeping bag will indicate whether temperature is within the appropriate ranges.
Temperature uniformity (±°C)	Not yet been measured
Alarms included in device	Yes (LED indicators)
How are alarms set?	Firmware algorithms for monitoring temperature of the contact surface area, heating pad and the baby which subsequently relay feedback of the status to LEDs as indicators either red, amber of green. Indicators displayed on the outside of the sleeping bag will indicate whether temperature is within the appropriate ranges. A buzzer sounds at intervals of one (1) min when temperatures are outside of pre-programmed acceptable bounds. Decibel levels appropriate for neonates are still being established based on the context of use (travelling on a bicycle etc.).

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Portable Neonate Warmer

Consumables required	**The PNW comprises of 4 modules, consumables for each are as follows:** **a) PCM Heating pad**: Sodium acetate salt hydrate **b) Temperature Monitoring System (TMS)**: • Temperature sensor LMT70 • Demultiplexer • Microcontroller (PIC18F4580-I/P-ND) • Regulator (LM340T-5.0/NOPB-ND) • Assorted electronic components that include: Buzzer(668-1028-ND), potentiometer, switch, capacitors, resistors, LEDs, cable(78120-100-ND), Connector female, connector male, IC REG LDO 12V 3A TO220-3, IC REG LDO -12V 1.8A TO220-3, IC REG LDO -5V 1A TO220-3, IC REG LDO 5V 1A TO220-3, LOAD CELL AMP HX711, SOLDER LF SN99 21GAUGE 1LBS, SLDR PASTE NO-CLN SAC305 50G, TRIMMER 10K OHM 0.25W TH • Copper plated printed circuit board, 3D printed sensor casing and housing for electronics • PLA filament for 3D printing and copper plated printed circuit boards **c) Sleeping Bag:** woven cotton, woven polyester, woven Polyethylene Terephlate (PET), cotton & polyester blended fabric **d) Transport Carrier**: wire mesh, mattress padding, canvas
Describe how cleaned or decontaminated	**The sleeping bag which is in direct contact with the neonate can easily have the temperature monitoring system detached and washed. The carrier is made of canvas and can be wiped down with disinfectant.**
Size and form factor	**The PNW shall fit a baby of maximum 50 cm height, 35 cm head circumference, and 3 kg weight and minimum of 31 cm height, 22 cm head circumference, and 0.6 kg weight. The PNW must not exceed a maximum weight of 10 kg (including PCM and the baby).**
Training required	**The intended users are the village health teams. Clinicians from smaller health facilities will be responsible for training the village health teams in rural areas on proper use, installation and maintenance of the portable neonate warmer.**
User instructions provided	**Instructions on how to properly activate the PCM are provided with the PNW**
Electricity requirements, including voltage, and charging features	**The temperature monitoring system utilizes a rechargeable battery**
Maximum power consumption (W)	**Maximum power consumption is 1.1 W with a supply voltage of 5V**

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Portable Neonate Warmer

In the event of a power outage, what is the heat retention for your Conductive Warmer? (e.g., X ±°C loss over X hours)	**Will operate without mains power supply**
Warranty	**Estimated life time is 10 years and estimated shelf life is six (6) months. Maintenance of the electronics, PCM and resistance material padding for the sleeping bag will need to be conducted bi-annually and can be done onsite in a home or community.**
Ex-works price of device	**The price of the warmer including production costs is approximately $90 USD; however, at actual production stage it is anticipated that this cost will be lower, i.e., electronic components in bulk unit prices drop and standardized manufacturing processes for the transport carrier and sleeping bag will reduce at scale.**
Ex-works price of consumables	**The cost of all the consumables and parts for the PNW are approximately $79 USD.**

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Introduction to Continuous Temperature Monitor

Given that temperatures less than 36.5ºC have been shown to be an independent risk factor for death in neonates[40], early recognition and treatment of hypothermia is critical. In overcrowded and understaffed hospital wards, where nursing to patient ratios are often in excess of 1:10 and most infants are not in incubators which continuously record temperature, obtaining temperature readings even 3-4 times per day can be challenging.

In high-resource settings, low nursing to patient ratios and availability of incubators, which continuously monitor temperatures, allows for close monitoring. In settings with high nurse to patient ratios, where incubators are limited, KMC is the preferential warming option. However, some infants require closer monitoring of temperature in open cribs and the ability to continuously monitor temperature and notify staff when an intervention is needed could greatly reduce hypothermia and increase recognition of neonatal fever associated morbidity and mortality.

Outlined in this section are technologies both commercially available and in development that allow for the continuous monitoring of neonatal temperatures outside of a warming device (i.e., radiant warmer or incubator).

Note that technologies within this product category have not yet been evaluated by the NEST360 team for inclusion as a NEST360 Qualified Technology. To learn more about what it means to be "NEST360 Qualified" and how the technologies are qualified by NEST360, please click here.

Rad-G Pulse Oximeters with Infra-red Temperature Monitoring – Masimo Corporation

Commercially available

Intended Use

Spot check monitoring of oxygen saturation, respiratory rate, perfusion index, pleth variability index, pulse rate and spot-check temperature.

Key Features

This device was specifically designed for rugged use in Global Health settings and harsh environments.

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*These products are for professional use only. Federal (USA) law restricts these devices to sale by or on the order of a physician. In using any of these devices, please see instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

Rad-G Pulse Oximeters with Infra-red Temperature Monitoring

Type of technology	**Continuous temperature monitor**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Masimo Corporation**
Benchtop measurement accuracy (±°C)	**Laboratory Accuracy:** **Range surface temperance 34.0 to 43.0°C / 93 to 109.4°F) ±0.3°C (0.54°F**
Clinical measurement accuracy (±°C)	**Clinical Accuracy:** **Range 36.0 to 42.4°C (96.8 to 108.32°F) AdultsPediatrics (>5 years of age) Clinical bias: ±0.25°C (0.45°F)** **LoA: ≤ 1.2°C (2.16°F)** **Clinical Repeatability: ≤ 0.2°C (0.36°F)**
Time for your Temperature Monitor to indicate accurate temperature (s)	**Default 1 minute** **Configurable by user for 1, 2, 3, or 4 minute(s)**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**Color touch screen**
Alarms included in device	**Customizeable alarms**
How are alarms set?	**Customizable alarms** **Reference the Operator Manual (page 43)**
Consumables required	**Sensors**

Rad-G Pulse Oximeters with Infra-red Temperature Monitoring

Describe how cleaned or decontaminated	**To clean the device:** 1. **Disconnect the AC Power Supply and ensure the sensor is not applied to the patient.** 2. **Turn off the device.** 3. **Wipe the outer surfaces using a dampened soft cloth with a mild detergent and warm water solution or one of the recommended cleaning solutions twice or until the surfaces are free of any visible residue. CAUTION: Do not allow liquids to enter the interior of the device.** 4. **Dry the device thoroughly prior to using on a patient.** **The surfaces of the Rad-G may be cleaned with the following solvents or cleaning agents:** • **70% Isopropyl Alcohol (IPA)** • **Glutaraldehyde (Cidex® Plus)** • **0.5% sodium hypochlorite water solution (10% bleach/water solution)** • **Accelerated Hydrogen Peroxide® solutions (Oxivir® TB)** • **Quaternary ammonium chloride solution (Up to 55% alcohol/0.5% quaternary ammonium chloride, such as Ecolab Asepti-Wipe® II Germicidal Wipes or PDI Super Sani-Cloth® Germicidal Wipes)** **CAUTION: Do not use undiluted bleach (5 – 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the device may occur.** **CAUTION: To prevent damage, do not soak or immerse the device in any liquid solution.** **CAUTION: Do not sterilize by irradiation, steam, and autoclave or ethylene oxide.**
Size and form factor	**Weight 0.27 kg. (0.59 lbs.) Dimensions 7.4 cm x 19.8 cm x 2.5 cm (2.9” x 7.8” x 1.0”)**
Training Required	**Basic device training and sensor site best practices**
User instructions provided	**An Operator Manual in English is provided with the device, other languages could be available upon request**

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Rad-G Pulse Oximeters with Infra-red Temperature Monitoring

Electricity requirements, including voltage, and charging features	**100-240VAC, 50/60Hz, 0.6A** **The Rad-G includes a lithium ion rechargeable battery.** **Before using the Rad-G without the AC power connected, check the battery status indicator and ensure that the battery is fully charged. See AC Power Indicator on page 72 in Operators Manual.** **To charge the Rad-G battery, refer to Initial Battery Charging on page 21 in Operators Manual.**
Warranty	**Various options are available**
Ex-works price of device	**Pricing varies by volume**
Ex-works price of consumables	**Pricing varies by volume**

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TempWatch – BEMPU Health

Commercially available

Intended Use

Hypothermia detection and alert.

Key Features

The BEMPU TempWatch is a novel, continuous temperature-monitoring bracelet that alarms if a newborn becomes hypothermic (<36.5ºC), thereby empowering the caretaker to warm the baby well before hypoxia, hypoglycemia, poor growth, or death can occur. The device sits on the wrist of the newborn for a full month in both hospital and home settings.

TempWatch

Type of technology	**Continuous temperature monitor**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**BEMPU Health**
Benchtop measurement accuracy (±°C)	**± 0.3 °C**
Clinical measurement accuracy (±°C)	**The sensitivity and the specificity of the device are 98.6% and 95% respectively for detecting hypothermia**
Time for your Temperature Monitor to indicate accurate temperature (s)	**5 minutes after placing on the wrist**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**The device is fastened on the newborn's wrist 24/7 for 30 days, with the exception of being removed during bathing the baby and daily cleaning the device.**
Alarms included in device	**The device gives an audio visual alarm. A beep sound with blinking orange and blue LEDs.**
How are alarms set?	**The device will beep and flash an orange light when baby experiences cold stress < 36.5 degrees Celsius at the axila. The device has an inbuilt algorithm to correlate the axila-wrist temperature.**
Consumables required	**None**
Describe how cleaned or decontaminated	**In a clinical setting, the TempWatch should be decontaminated with a hospital-approved detergent such as alcohol or chlorhexidine. In home settings where such products are not present, it can be cleaned with a damp cloth and soap or any standard wet wipe used for babies.**
Size and form factor	**Dimensions: 8cm x 2.5cm Weight ~15 grams**

Contact Information:

BEMPU Health

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https://www.bempu.com/

TempWatch

Training Required	**The user must be trained on the dangers of hypothermia, how to fasten the TempWatch correctly on the wrist, the device indications (blue light vs. orange light), and proper cleaning instructions.**
User instructions provided	**1. Fasten the band on the baby's wrist.** **2. Pull the tab to activate the device, and wait for 5 minutes. The bracelet will flash a white light during activation.** **3. After 5 minutes, the bracelet will begin to measure temperature. If it is flashing a soft blue light, the baby is not hypothermic.** **4. If the baby becomes hypothermic, the bracelet will beep and flash an orange light. Please warm the baby immediately.**
Electricity requirements, including voltage, and charging features	**The device has a 3V DC operating voltage and is powered by 2 x CR-1620 Coin Battery (2 x 70mAH)**
Warranty	**Device has a shelf life of two years and a warranty period of 30 days starting from the day of activation**
Ex-works price of device	**Dependent on market**
Ex-works price of consumables	**Dependent on market**

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TempWatch 10X – BEMPU Health

Commercially available

Intended Use

Hypothermia detection and alert.

Key Features

The BEMPU TempWatch 10x is a reusable, novel, continuous temperature-monitoring bracelet that alarms if a newborn becomes hypothermic (< 36.5ºC), thereby empowering the caretaker to warm the baby well before hypoxia, hypoglycemia, poor growth, or death can occur. The device sits on the wrist of the newborn to continuously monitor the tempearture in both hospital and home settings. It is a resuable device with low power rechargable battery. The device can be charged mutliple numbers of times with a simple micro-USB charger and has life of 1 year. With only 5 hours of charging, the device can work for 1 full month and each device can be recharged & reused on multiple babies for 1 full year thereby reducing the monitoring cost per baby for low-resource settings.

TempWatch 10X

Type of technology	**Reusable continuous temperature monitor**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**BEMPU Health**
Benchtop measurement accuracy (±°C)	**± 0.3 degree C**
Clinical measurement accuracy (±°C)	**The sensitivity and the specificity of the device are 98.6% and 95% respectively for detecting hypothermia**
Time for your Temperature Monitor to indicate accurate temperature (s)	**5 minutes after placing on the wrist**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**The device is fastened on the newborn's wrist 24/7 for 30 days, with the exception of being removed once a day to be cleaned.**
Alarms included in device	**The device gives an audio visual alarm. A beep sound with blinking orange and blue LEDs.**
How are alarms set?	**The device will beep and flash an orange light when baby experiences cold stress < 36.5 degrees Celsius at the axila. The device has an inbuilt algorithm to correlate the axila-wrist temperature.**
Consumables required	**No consumables.**

Contact Information:

BEMPU Health

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TempWatch 10X

Describe how cleaned or decontaminated	**Cleaning the device DAILY:** Wipe thoroughly with a wet cloth/ baby wipe/ hand sanitizer/surgical spirit. **Disinfecting before putting it to the next baby:** **STEP 1:** Remove the rubber strap from casing and completely immerse it in boiling water for 10 mins. Dry well. **STEP 2:** Wipe ALL surfaces of the casing and straps thoroughly with cotton dipped in surgical spirit, IPA solution (70% v/v) or similar medical disinfectant. Once dry, put the strap and casing together for use on baby.
Size and form factor	**Dimensions: 2.5 x 3.5 x 8 cm** **Weight ~15 grams**
Training required	**The user must be trained on the dangers of hypothermia and advantages of KMC, how to fasten the TempWatch correctly on the wrist, the device indications (blue light vs. orange light), and proper cleaning instructions.**
User instructions provided	**1. Charge the device until full battery indication comes on.** **2. Turn on the device by sliding the ON switch, wait for the start-up tune to complete and then put the band on the casing.** **3. Fasten the band on the baby's wrist.** **4. After 5 minutes, the bracelet will begin to measure temperature. If it is flashing a soft blue light, the baby is not hypothermic.** **5. If the baby becomes hypothermic, the bracelet will beep and flash an orange light. Please start KMC to keep the baby warm.** **6. Follow the cleaning instructions for daily use.** **7. Follow the cleaning disinfection instructions for using on multiple babies.**
Electricity requirements, including voltage, and charging features	**Operating volatge: 3.2-4.2 V DC** **Power source: 100 mAh Lithium polymer ion rechargeable battery**
Warranty	**Device has a shelf life of one year and a warranty period of one year starting from the day of activation**
Ex-works price of device	**Dependent on market**
Ex-works price of consumables	**Dependent on market**

Contact Information:

BEMPU Health

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Celsi Monitor – 3rd Stone Design

Not yet commercially available / In development

Intended Use

To provide temperature measurement of infants in a health-care setting.

Key Features

The Temperature Monitor provides core body temperature measurement for newborns in under-resourced hospitals. A simple, affordable and durable tool that displays the temperature and provides a rapid way to alert clinical staff of patient hypo or hyperthermia.

Celsi Monitor

Type of technology	**Continuous temperature monitor**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**CE Mark expected 2022**
Manufacturer of Record	**Hadleigh Health Technologies**
Benchtop measurement accuracy (±°C)	**± 0.3°C**
Clinical measurement accuracy (±°C)	**± 0.3°C**
Time for your Temperature Monitor to indicate accurate temperature (s)	**The Temperature Monitor has a sensor that attaches to the infant's abdomen either using a wearable strap (reusable) or an adhesive patch (disposable).**
Alarms included in device	**Low temperature and high temperature**
How are alarms set?	**Alarms are pre-set at factory**
Consumables required	**None**
Describe how cleaned or decontaminated	**The Temperature Monitor is wipeable with standard hospital cleaning products.**
Size and form factor	**The Temperature Monitor is a portable device that can easily be moved between patient bedsides.**
Training required	**None**
User instructions provided	**Yes**
Electricity requirements, including voltage, and charging features	**Rechargeable battery (standard USB charger 110-220V AC), lasts up to 24 hours**
Warranty	**1 year standard warranty**
Ex-works price of device	**TBD**
Ex-works price of consumables	**TBD**

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Introduction to Radiant Warmer

Hypothermia can be prevented using radiant warmers that carefully control heat based on manual settings or the infant's own temperature. Radiant warmers provide heat using an overhead heating source and are preferred for infants who may require greater access or closer short-term monitoring. Radiant warmers are preferred, in the short term, to warming cribs/incubators for infants who are unstable and may require significant intervention (such as resuscitation or invasive procedures).

The following products have been evaluated by the NEST360 team and are determined to be "NEST360 Qualified" technolgoies:

- MTTS Wallaby
- Phoenix NWS-101

To learn more about the five step process, please click here.

Comprehensive Infant Care System 101 – Phoenix Medical Systems Pvt Ltd.

Commercially available

Intended Use

The CIC 101 has been designed to provide warmth to preterm infants and simultaneously meet the critical situations that may arise in providing care for such babies. The CIC 101 is remarkably convenient and user friendly, given its capabilities. The space around the infant is organized efficiently for the convenience of care givers, the mother and visitors. It is easy to clean.

Key Features

- **Secure Thermal Environment:** Infrared radiation produced by a quartz heating element is spread uniformly by a parabolic reflector all over the baby. The heater unit can be swivelled to accommodate mobile X-ray equipment so that transporting the baby is avoided.
- **World's First Oval Shaped Bed:** This Phoenix innovation permits quick access to the baby, which is critical during resuscitation. The bed can also be tilted and rotated.
- **Height Adjustment:** The height of the entire unit may be adjusted according to the convenience of the care giver. The system features foot-operated pedals that leave the hands free.
- **Non-touch System:** The halogen examination lamp is switched on and off using another Phoenix innovation, the non-touch system, which was designed to reduce the risk of spreading infections in hospitals. The care giver just needs to wave his or her hand near a sensor to control the lamp. The brightness of the lamp may be adjusted similarly.
- **Pulse Oximetry:** Oxygen saturation levels are measured non-invasively using well established Masimo Technology.
- **CPAP:** The baby-friendly CPAP unit is compatible with both bubble and flow driven systems. This unit features accurate electronic blending of air and oxygen.
- **Easy-to-Read Display:** The baby's heart rate, temperature and weight trend charts are presented in a form that is easy to interpret. The display provides parents a record of their baby's progress.
- **Trays:** Ample storage space for sterile supplies and instruments is provided by trays that can be placed at six convenient places. The Mayo trays and rugged IV poles support even monitors.

Comprehensive Infant Care System 101

Type of technology	**Radiant warmer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485, CE Mark**
Manufacturer of Record	**Phoenix Medical Systems Pvt Ltd**
Benchtop measurement accuracy (±°C)	**± 0.2 °C**
Clinical measurement accuracy (±°C)	**± 0.2 °C**
Temperature stability (±°C)	**0.1 °C**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**Servo feedback mechanism is used to maintain the infant's temperature**
Temperature uniformity (±°C)	**In effective surface area, temperature distribution will not vary more than 2 °C at center**
Alarms included in device	**Audio and visual alarms**
How are alarms set?	**Based on infant's body temperature, set value can be chosen for which ± 0.5 °C, alarms will be raised accordingly (high/low)**
Consumables required	**Skin temperature probe (reusable or disposable)**
Describe how cleaned or decontaminated	**Yes. It can be cleaned (instructions provided in the user manual)**
Size and form factor	**L=130** **W=76cm** **H=182 – 212 cm (adjustable)**
Training required	**Training requirement for circuit connections, how to use,key feature training, maintenance etc.**
User instructions provided	**User manual will be provided which has assembly instructions**

Comprehensive Infant Care System 101

Electricity requirements, including voltage, and charging features	**230V/110V** **50/60 Hz**
Maximum power consumption (W)	**750 W**
Warranty	**1 year**
Ex-works price of device	**$10,000 USD** **Basic radiant warmer – Rs. 65,000 including tax** **Mid-level radiant warmer - Rs.1.9 lakh including tax** **Higher end radiant warmer - Rs.6.6 lakh including tax**
Ex-works price of consumables	**Disposable patient probe – Rs.650 + tax** **Reusable patient probe – Rs.2250 + tax** **Masimo Spo2 probe – Rs.17,000+ tax** **Thermal reflector – Rs.50 + tax** **T-piece – Rs.1000 + tax**

Contact Information:

Phoenix Medical Systems Pvt Ltd

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https://www.phoenixmedicalsystems.com/

Lullaby Warmer – General Electric Healthcare

Commercially available

Intended Use

Providing a stable, thermoregulated environment that assures a warm, and comfort environment.

Key Features

Versatility, from L&D to NICU Warmer heats to 100% for 12 minutes. Large LED screen provides direct access to key functions. APGAR timer with audible tones at one. Smooth bed tilting of ± 15° continuous positions. The heater module rotates 90° to either side. Heat is evenly distributed via the Calrod® heater.

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Lullaby Warmer

Type of technology	**Radiant warmer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark & FDA**
Manufacturer of Record	**General Electric**
Benchtop measurement accuracy (±°C)	**±0.1°C @ 30°C to 42°C**
Clinical measurement accuracy (±°C)	**±0.1°C @ 30°C to 42°C**
Temperature stability (±°C)	**±0.1°C @ 30°C to 42°C**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**Information not submitted**
Temperature uniformity (±°C)	**Information not submitted**
Alarms included in device	**Other**
How are alarms set?	**Upper & lower limits**
Consumables required	**Temp. probe**
Describe how cleaned or decontaminated	**Information not submitted**
Size and form factor	**Mattress Size 462 x 640 x 25.4 mm**
Training required	**Minimal operation training**
User instructions provided	**Information not submitted**
Electricity requirements, including voltage, and charging features	**230 V ± 10%, 50/60 Hz models; 4 Amps**
Maximum power consumption (W)	**600 W max**
Warranty	**Life time on heating elemnt and one year for the rest of the unit**
Ex-works price of device	**$2,800 USD**
Ex-works price of consumables	**Information not submitted**

Wallaby Warmer – Medical Technology Transfer and Services Co., Ltd (MTTS)

Commercially available

Intended Use

Restore, stabilize, and control the temperature of the newborn baby.

Key Features

- Remote Temperature and object sensing providing full patient protection from overheat if standard skin sensor is disconnected or faulty automatic control of patient temperature with smart problem detection
- Angle adjusted bed (up to 12 degrees)
- Adjustable overhead unit and tray for X-ray procedures
- LCD rouchscreen display
- 3 operational modes (prewarm, servo controlled, manual)
- APGAR socer timer
- 2 procedure timers
- Total system time counter (lifetime)

Wallaby Warmer

Type of technology	**Radiant warmer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, ISO 13485, CFS**
Manufacturer of Record	**MTTS Co., Ltd**
Benchtop measurement accuracy (±°C)	**0.15**
Clinical measurement accuracy (±°C)	**0.15**
Temperature stability (±°C)	**0.9**
Describe the patient interface, specifically how the device responds to a neonate's temperature.	**In BABY MODE, the warmer provides stable control of the baby's skin temperature by automatically adjusting the heater power to compensate for varying physiological and environmental conditions.** **In PREWARM MODE, the warmer provides general alarm free prewarming of the heater and environment above the warmer mattress.** **In MANUAL MODE, the warmer provides user-adjustable heater power and the option to monitor the baby's skin temperature using skin sensor.**
Temperature uniformity (±°C)	**2**
Alarms included in device	**Temperature too high** **Temperature too low** **Skin sensor failure** **Heater element failure** **Power failure**
How are alarms set?	**High/Low Skin Temperature alarms are predefined and cannot be set by the user. In BABY MODE they indicate measured skin temperature higher/lower than set temperature by 1°C.**
Consumables required	**Skin sensor**

Contact Information:

Medical Technology Transfer and Services Co., Ltd (MTTS)

info@mtts-asia.com

+84 24 37 666 521

www.mtts-asia.com

Wallaby Warmer

Describe how cleaned or decontaminated	**Wallaby Warmer has the mattress that can be cleaned with mild detergent. Side panels are from acrylic which can be cleaned with 70% alcohol solution or other similar chemical available at the hospital.**
Size and form factor	**64 cm x 54 cm x 185 cm, integrated bed on 4 caster wheels with lockers (4 locks)** **67kg**
Training required	**No**
User instructions provided	**User manual, assembly instructions, quick reference guide, instructional videos**
Electricity requirements, including voltage, and charging features	**220-240V AC** **(110V AC available on special requests)**
Maximum power consumption (W)	**650**
Additional features include:	**Shelves, drawer, IV pole, cylinders holder, documents holder, t-piece resuscitator.**
Warranty	**1 year**
Ex-works price of device	**From $1,650 USD**
Ex-works price of consumables	**$25 USD**

Contact Information:

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www.mtts-asia.com

Introduction to Other Products

This section is used to capture other newborn technologies within the ***Thermal Management*** category-of-care.

Brammi – Phoenix Medical Systems

Commercially available

Intended Use

This thermo regulation device from Phoenix has been designed specially for the treatment of HIE in NICU's for the critical neonates. This device offers 4 modes which includes both cooling and rewarming of the babies suffering from inadequate supply of oxygen to the brain

Key Features

- Servo controlled cooling and rewarming system with 4 mode options
- Logs data of 10 patients
- Event log upto
- Ease of data transfer using a USB port
- Intelligent safety alarms – both visual and audible alarms
- Intuitive 7 inch TFT graphical LCD display
- Compact and easy to use
- Ease of transportation
- Battery backup up to 1 hr
- Head unit is Bench top mountable – options of mounting on a trolley is available
- Trends can be stored upto

Brammi

Type of technology	**Cooling and Rewarming**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485 and European CE**
Manufacturer of Record	**Phoenix Medical Systems**
Servo Controlled Mode (min / max range)	**Target Rectal Temperature: 32°C / 35°C** **Cooling Phase Duration: 1 hr / 100 hrs** **Final Rectal Temperature: 36°C / 39°C** **Heating Phase Duration: Changes dynamically / 24 hrs**
Constant Mattreess Temperature Mode (min / max range)	**Mattress Temperature: 12°C / 39°C** **Time Duration: 1 hr min 100hrs max**
Cooling Mode (min / max range)	**Target Rectal Temperature: 32°C / 35°C** **Cooling Phase Duration: 1 hr / 100 hrs**
Warming Mode (min / max range)	**Target Rectal Temperature: 36°C / 39°C** **Warming Phase Duration: Changes dynamicaly / 24 hrs**
Skin and Rectal Temperature Probe Specification	**Temperature Range: 6°C to < 50°C** **Accuracy: ±0.2°C** **Resolution: ±0.1°C** **Probe interchangeability: ±0.2°C**
Electricity requirements, including voltage, and charging features	**Electricity – 110-240V, 50/60 Hz, 80 W** **Battery back up – 1 hour** **Charging – 8 hrs from 10 to 90%**
Size and form factor	**Overall dimensions of device: length x width x height 347 mmx 290mm x 203 mm** **Overall weight: approx. 26 kg**
Shelf life, stability, and storage requirements	**N/A**
Ex-works price of device	**TBA**
Ex-works price of consumables	**TBA**

Contact Information:

Phoenix Medical Systems Pvt Ltd

exports@pmsind.com

+ 27 71 528 9873

www.phoenixmedicalsystems.com

Embrace Infant Warmer – Phoenix Medical Systems

Commercially available

Intended Use

A steady supply of electricity is lacking in many hospitals in developing countries, adding to problems of limited resources and overcrowding. Premature infants, lacking the ability to maintain their temperature, must be provided warmth for them to survive.

Embrace is a low-cost solution that maintains the body temperature of premature and low-birth-weight babies at the desired level even with intermittent access to electricity.

The Embrace Warmer can also be used for transporting hypothermic newborn. The Embrace Warmer is an easy-to-use, portable infant warmer that does not need continuous power supply. A medical device, designed for hospitals and ambulances, it is used in NICUs and wards, and for transport, when skin-to-skin care (a part of Kangaroo Mother Care / KMC) is not possible.

Key Features

- **Inexpensive:** The cost of an Embrace Warmer is less than 1% of that of a standard incubator.
- **Effective:** The Embrace Warmer uses an effective phase change material to stabilize rapidly the temperature of an infant suffering from hypothermia.
- **Durable:** It can be reused several times.
- **Portable:** The Embrace Warmer is light and portable. The baby can be held in the mother's arms when the warmer is being used.
- **Hygienic:** Cleaning is easily done using soap and water.
- **Safe:** The Embrace Warmer is simple and intuitive to use. It has been validated through routine safety testing and extensive clinical trials.

Embrace Infant Warmer

Type of technology	**Portable Infant Warmer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Phoenix Medical Systems**
Electricity requirements, including voltage, and charging features	**Electricity - 230V, 50 Hz, 500 W** **Charging - N/A**
Size and form factor	**Physical Dimensions:** **Heater – 440mm x 290mm x 70mm** **Warm Pak – 380mm x 220mm** **Baby Wrap – 520mm x 250 mm**
Shelf life, stability, and storage requirements	**Stability - 3 years (device life time)** **Shelf life - N/A** **Storage temp - 0 to 45°C** **Hum - 0 to 95%**
Ex-works price of device	**Ex Works US $380 / unit**
Ex-works price of consumables	**Information not submitted**

Contact Information:

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Intensive Neonatal Care Incubator INC 200 – Phoenix Medical Systems

Commercially available

Intended Use

The Phoenix INC 200 has been engineered for reliability so that the baby is as safe inside it as in the mother's womb. It is equipped to meet any situation arising in neonatal care, making it vital equipment in the NICU.

Key Features

This equipment is compact. At the same time, its construction is sturdy. It is user friendly, and it has an aesthetic appearance.

- **Acrylic Hood:** The transparent hood an unobstructed view of the newborn from all around.
- **Temperature Control:** The INC 200 has a double-walled canopy to minimize heat loss. The temperature control is precise, providing the ideal environment for the baby.
- **Unrestricted Access:** The canopy has side doors that open downwards. The top can also be opened. Only one hand is needed to open or close the doors. The doors can be opened silently to avoid disturbing the infant.
- **Adjustable Base:** The height of the INC 200 may be adjusted by pushing a foot-operated pedal. This feature makes intubation and other procedures easier for the care giver.
- **Motorized Trendelenburg Position:** Feeding of the baby made easy.
- **Bed:** One of the unique features of the INC 200 is its bed. It can be slid out and rotated simultaneously. This patented bed spells convenience when placing the baby in the INC 200 or removing the baby. Rotation permits special procedures to be carried out on the bed itself.
- **Display:** The trends of the temperature, humidity and Sp02 can be viewed readily. The 7" colour display-cum-control panel has a touch screen.
- **Storage:** Drawers are provided for storing items that are regularly needed in providing care, such as napkins.
- **Built-in Weighing Scale:** The baby's weight can be measured and displayed without moving and disturbing the baby.

Contact Information:

Phoenix Medical Systems Pvt Ltd

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www.phoenixmedicalsystems.com

Intensive Neonatal Care Incubator INC 200

Type of technology	**Neonatal Intensive Care Incubator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark**
Manufacturer of Record	**Phoenix Medical Systems**
Electricity requirements, including voltage, and charging features	**230V 50Hz 700w** **Charging features- N/A**
Size and form factor	**Physical Dimension:** **1500mm (L) x 850mm (W)**
Shelf life, stability, and storage requirements	**Stability - 8 years (device life time)** **Shelf life - N/A** **Storage temp - 0 to 50°C** **Hum - 0 to 95%**
Ex-works price of device	**Ex Works US $5000 / unit**
Ex-works price of consumables	**Information not submitted**

KangaSling – BEMPU Health

Commercially available

Intended Use

Wrap for prolonged Kangaroo Mother Care & easy breastfeeding.

Key Features

KangaSling is a Kangaroo Care sling designed specially for low birth weight babies. It empowers mothers to give prolonged hours of skin to skin care, with reduced physical stress and breastfeeding with ease and modesty. It is designed to safely hold the baby in position allowing the caregiver to remain absolutely hands-free! It is unisex, crafted from high-quality 100% cotton fabric, washable and is designed for repeated use.

KangaSling

Type of technology	**Kangaroo Mother Care Tool**
Status	**Commercially available**
Regulatory approvals and/or international standards	**N/A**
Manufacturer of Record	**BEMPU Health**
Electricity requirements, including voltage, and charging features	**N/A**
Size and form factor	**Dimensions: 280 cm x 62 cm**
Shelf life, stability, and storage requirements	**Up to 1 Year** **Made of 100% cotton fabric** **Reusable** **Stored in room temperature conditions**
Ex-works price of device	**Dependent on Market**
Ex-works price of consumables	**None**

Contact Information:

BEMPU Health

hello@bempu.com

1800 425 0192

www.bempu.com

MiraCradle Cooling Mattress – Draeger

Commercially available

Intended Use

MiraCradle® Neonate Cooler is an affordable passive cooling device which uses the advanced savE ® Phase Change Material (PCM) technology to induce therapeutic hypothermia among newborns suffering from birth asphyxia.

Key Features

MiraCradle® is an affordable solution for developing countries CE marked neonatal cooler that enables controlled cooling of newborn infants to support therapeutic hypothermia (TH) for birth asphyxia.

Phase Change Material (PCM) maintain the temperature of the infant at 33–34°C (91.4–93.2 F) for the entire treatment duration of 72 hours, consistent with current best practices in treatment. Leveraging sophistication in material engineering, the product offers temperature specificity offered by current servo-devices less than one fifth of the cost.

- **SAFE:** Passive cooling system; does not have any electrical supply near the baby.
- **EFFICIENT:** Gives precise temperature control.
- EASY TO USE: Minimal manual supervision required. PCMs can be charged in a normal refrigerator.
- **ECONOMICAL:** Less than 1/5th of the cost of the available electronic devices.
- **LONG LASTING:** The PCMs are designed for repetitive use.

MiraCradle Cooling Mattress

Type of technology	**Cooling mattress**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE**
Manufacturer of Record	**Pluss Advanced Technologies Pvt. Ltd**
Electricity requirements, including voltage, and charging features	**None**
Size and form factor	**Fits in the bassinet measuring at least 66x47 cm of a regular radiant warmer. Weight 4 kg**
Shelf life, stability, and storage requirements	**Phase Change Materials (PCMs) PCMs are special thermal energy storage materials that store and release heat at a particular temperature. Store PCM in refrigerator. Replace PCM and Conduction Mattress after three years from the date of first use or when found damaged, whichever is earlier.**
Ex-works price of device	**Contact Draeger**
Ex-works price of consumables	**Information not submitted**

Contact Information:

Draegerwerk AG & Co. KGaA

HCA@draeger.com

0049 451 8820

www.draeger.com

mOm Essential Incubator – Mom Incubators Ltd (UK)

Commercially available

Intended Use

The mOm Essential Incubator is intended to provide a safe, thermally stable, warm environment for pre-term or term infants who need such an environment.

When the Skin Temperature Probe is appropriately attached to the infant, the mOm Essential Incubator will provide a display of the infant's skin temperature.

Key Features

The mOm Incubator accurately and consistently maintains air temperature for the purpose of assisting infants to maintain normal body temperature. It has been designed for low-resource settings with consideration for energy consumption, hygeine, maintenance, and ongoing running costs. The mOm Incubator has the following features:

- Lightweight: The system weighs 20kg.
- Portable: Collapsible structure means it is easier to transport and store.
- Air temperature control from 30°C to 37°C, in 0.5°C increments.
- Backup battery to provide 60 minutes of power.
- Energy efficient design operating at ~100W in steady state.
- Baby temerature monitoring with optional skin temprature probe.
- Double-walled housing to minimise heat-loss.
- Audio and visual alarms for a number of fault conditions.
- Easy to clean and maintain.

mOm Essential Incubator

Type of technology	**Neonatal incubator**
Status	**Commercially available** **Check www.momincubators.com or @momincubators for updates**
Regulatory approvals and/or international standards	**CE Mark (MDR)** **ISO13485 certified** **Complies with IEC 60601Part 2-19: basic safety and essential performance of infant incubators**
Manufacturer of Record	**Mom Incubators Ltd (UK)**
Electricity requirements, including voltage, and charging features	**100-240V, 50-60Hz** **Internal rechargeable battery to maintain operation for 60 min**
Size and form factor	**70x45x20cm in collapsed state** **Weight 20kg**
Shelf life, stability, and storage requirements	**TBC**
Ex-works price of device	**Contact mOm for more information**
Ex-works price of consumables	**Contact mOm for more information**

Contact Information:

Mom Incubators Ltd (UK)

enquiries@momincubators.com

www.momincubators.com

Cardboard Incubator – Phoenix Medical Systems

Not yet commercially available / in development

Intended Use

Portable incubator which is foldable and can be assembled anywhere and can be disposed. It maintains complete warmth and protection to the baby.

Key Features

This equipment is disposable, compact, user friendly and low cost. It prevents cross infection across baby thus reducing sepsis and no cleaning required after usage. It is fully servo controlled and accurately maintain temperature within 0.5 degree. It has been validated through routine safety testing and extensive clinical trials.

Cardboard Incubator

Type of technology	**Disposable Infant Incubator**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	–
Manufacturer of Record	**Phoenix Medical Systems, India**
Electricity requirements, including voltage, and charging features	**Electricity: 230V, 50 Hz, 500 W** **Charging: NA**
Size and form factor	**1000mm X 600mm**
Shelf life, stability, and storage requirements	**Stability: 8 years (device life time)** **Shelf life: N/A** **Storage temperature: 0 to 50°C** **Humidity: 0 to 95%**
Ex-works price of device	–
Ex-works price of consumables	–

Contact Information:

Phoenix Medical Systems Pvt Ltd

exports@pmsind.com

+ 27 71 528 9873

www.phoenixmedicalsystems.com

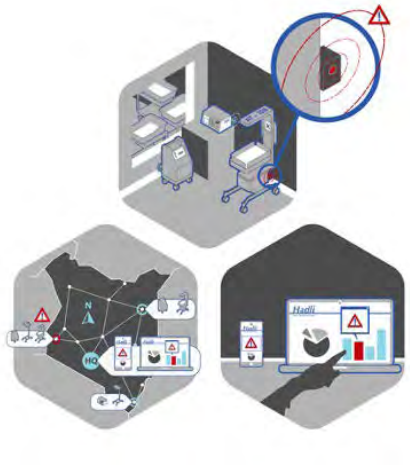
Other Products

Introduction to Digital Support Tools

The use of digital support tools may be able to help healthcare workers in low- and middle-income countries by providing timely and accurate data needed to sustain strong health systems. Digitial support tools may include, but are not limited to: electronic medical records (EMR), clinical decision-support systems (CDSS), medical device and diagnostic equipment monitoring, supply chain tracking, and other mobile health applications. Digital support tools can also help stakeholders supporting clinicians, including governments and distributors, to sustain strong health systems through supply chain and device / equipment management.

Hadli™ Monitoring System – 3rd Stone Design

Commercially available



Intended Use

Equipment usage and environment monitoring.

Key Features

The Hadli™ monitoring system is an automated, remote device monitoring system. Hadli™ collects, analyzes and reports on medical device utilization and environmental conditions in a network of hospitals in sub-Saharan Africa.

Hadli™ automates the data collection process and translates that into insights that address device utilization in hospitals. The Hadli™ system contains monitors on mains-powered medical devices which determine whether the device is on or off, and environmental sensors that collect data on temperature, humidity and power outages. These data are automatically uploaded to the cloud and made available via a user-friendly dashboard that displays actionable alerts and insights, allowing technicians to quickly see and address issues across a large network of hospitals.

Hadli™ Monitoring System

Type of technology	**Equipment monitoring**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE Mark, FCC**
Manufacturer of Record	**Hadleigh Health Technologies**
How is equipment monitored?	**Machine attachment**
Is a wireless remote connection required?	**System includes an integrated wireless remote connection**
Electricity requirements, including voltage, and charging features	**N/A**
Size and form factor	**System includes device monitors, an environment monitor, and a gateway**
Ex-works price of device	**Price varies based on size of installation site**
Ex-works price of any additional services or add-ons required to support technology	**N/A**

Contact Information:

Hadleigh Health Technologies

info@hadleighhealth.com

+1 415-650-9537

www.hadleighhealth.com

Neotree – Neotree

Commercially available

Intended Use

The Neotree system is a low cost, acceptable, feasible and highly usable tool that empowers healthcare professionals in low resource settings to count and care for every newborn. It improves the quality of newborn care through reliable data collection, clinical decision support, education and improved documentation; promoting a culture of continuous quality improvement amongst newborn healthcare professionals.

Key Features

The Neotree system includes a mobile health application for healthcare professionals to use, on a low-cost tablet device at the bedside, to admit and discharge sick and vulnerable newborns. While capturing vital data at admission and discharge, and laboratory results, it provides an interactive platform for clinical decision support and quality improvement according to national guidelines and best available evidence. Key features include: immediate data collection, integrated newborn education, clinical decision support, and feedback of data collected by healthcare professionals to a user-friendly data dashboard in the local neonatal department, displaying summary statistics for key newborn outcomes. To date the Neotree platform has been used in the care of 24,000 babies, by more than 1000 healthcare professionals in four hospitals across Malawi and Zimbabwe.

Neotree is a horizontal intervention which aims to comprehensively address the full range of newborn disorders. It has demonstrated ability to integrate into the national Electronic Health Record system being rolled out in Zimbabwe, and to the most common aggregate data system for healthcare in sub saharan Africa: the DHISv2. The system is locally configurable. Data entry and decision support can be tailored to national guidelines and the resources available within the host facility (medication, equipment and technology). The technology and data generated is locally owned and managed. The Neotree system has been, and can be, readily adapted to incorporate new disease trends in outbreak situations, for example COVID-19 clinical management and infection control guidelines have been incorporated.

Contact Information:

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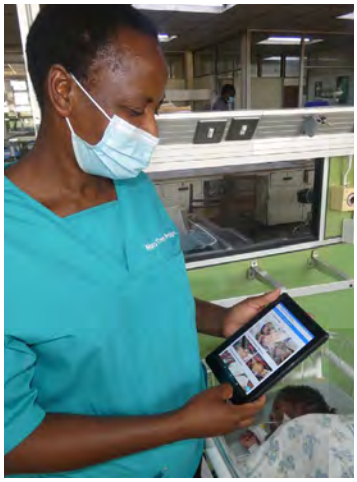
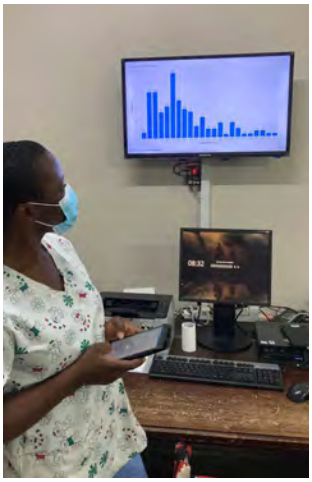




Neotree

Type of technology	**Open source software platform, including a mobile application (suitable for running on a mobile phone or tablet), backend server for managing configuration and customization, processing data (including integrating with different national health systems) and data visualisation.**
Status	**Commercially available. Neotree software is open source and available on github:** **https://github.com/neotree/neotree**
Regulatory approvals and/or international standards	**Approved by local Ministries of Health (Zimbabwe and Malawi) for admission and discharge at project sites**
Manufacturer of Record	**N/A**
Electricity requirements, including voltage, and charging features	**A standard electricity supply is needed for the printer, the wifi router and to charge the tablet devices. Tablet devices have up to 7 hours battery life. Tablets work offline, exporting and synchronising data when a network is available.**
Size and form factor	**Mobile app is compatible with any Android device of any size.** **Backend server can be run on any commodity desktop computer or server running Linux.**
Shelf life, stability, and storage requirements	**N/A**
Ex-works price of device	**Price of the Neotree system hardware per facility is approximately $500 USD, for a 2 tablet system (tablets cost $100 USD and required number is dependent on the patient numbers). Current estimate is approximately one tablet for every 50 patients per month.**
Ex-works price of any additional services or add-ons required to support technology	**The price of consumables for the Neotree per month per facility is approximately $115 USD**

NoviGuide: Mobile neonatal clinical decision support – Global Strategies

Commercially available

Intended Use

NoviGuide provides bedside clinical decision support for health workers who care for newborns, helping them determine when and how to use medical devices, and enabling them to easily report broken equipment and supply shortages. When doctors and nurses use NoviGuide, they generate data that provides insight about the epidemiology of babies seen at the site and how practitioners select among diverse treatment modalities. Powered by this continuous data, the NoviGuide Dashboard provides targeted recommendations to overcome barriers to care at a clinical, regional, or country-level.

Key Features

NoviGuide is a mobile companion for clinicians who care for newborns. Quick, visually engaging, and fully-featured, NoviGuide's dynamic decision trees support providers through a care encounter, expanding lines of questioning in response to danger signs. Complex neonatal care protocols become second nature, with error-prone manual calculations a thing of the past. Babies get rapid, precise care. Care delivery then combines with data collection. Each encounter helps build a picture of the care landscape, data syncing later if connectivity is limited. An Insights Dashboard provides lively visualizations and identifies problem areas, and can connect to a DHIS2 instance. NoviGuide was developed through a co-design process involving neonatal specialists, neonatal pharmacists, software developers, and frontline bedside clinicians providing care in low-resource settings. Following extensive studies in KwaZulu-Natal, South Africa, and Tororo, Uganda, it is ready to serve new clinics in new geographies.

NoviGuide: Tablet-based neonatal clinical decision support

Type of technology	**Decision support software**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Information not submitted**
Manufacturer of Record	**Global Strategies**
Electricity requirements, including voltage, and charging features	**Mobile devices (Android, Fire and iOS). Also available as web-based application.**
Size and form factor	**Mobile devices (Android, Fire and iOS). Also available as web-based application.**
Shelf life, stability, and storage requirements	**Should be kept in a locked cabinet and charged every day or two**
Ex-works price of device	**Scale- and context-dependent**
Ex-works price of any additional services or add-ons required to support technology	**Scale- and context-dependent**

Contact Information:

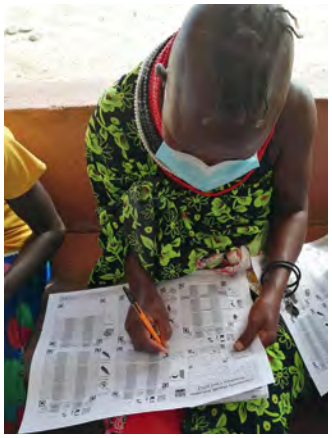
Global Strategies

elon.danziger@globalstrategies.org

415-451-1814

www.globalstrategies.org/projects/noviguide

PaperEMR – Health-E-Net, Ltd. (Nairobi, Kenya)



Commercially available

Intended Use

Information not submitted.

Key Features

Paper-based system for collecting structured data that can be automatically digitized from an image taken using a smartphone or feature phone into an electronic medical record (EMR). This can be used for patient care and record-keeping, documentation for clinical audit and accreditation, and/or for quality improvement practices at individual provider, facility and group levels. The technology, and the data captured, also serve as a starting point for delivering remote services, e.g. referral management, tele-consultations, or laboratory testing.

PaperEMR

Type of technology	**Progressive web app (PWA)**
Status	**Commercially available**
Regulatory approvals and/or international standards	**N/A**
Manufacturer of Record	**Software: Health-E-Net Limited, Kenya** **No specific hardware required. The software works on most devices with a camera and browser, including feature phones without a touchscreen.**
Electricity requirements, including voltage, and charging features	**The PWA can be used on most mobile phones**
Size and form factor	**Mobile devices (Android, Fire and iOS). Also available as web-based application.**
Shelf life, stability, and storage requirements	**N/A**
Ex-works price of device	**N/A**
Ex-works price of any additional services or add-ons required to support technology	**N/A**

Contact Information:

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www.health-e-net.org

Protecting Infants Remotely by SMS (PRISMS) – E-Wall Technologies Company Limited

Commercially available

Intended Use

PRISMS is an innovative technology that uses an algorithm for clinical assessment to support frontline health workers by providing clinical guidance for management of sick and at-risk newborns. PRISMS has three fundamental functions: 1) It guides newborn care by providing instant clinical management decisions based on routine assessment findings, 2) Offers continuous newborn care clinical education to health providers and 3) It empowers health managers with real time surveillance data on burden of neonatal morbidity and quality of care parameters vital for objective decision making, resource allocation and data-driven quality improvement. For the past three years, PRISMS has been tested extensively in the field and demonstrated to: (a) prompt more complete newborn assessment, (b) assist in identifying babies who are ill or at-risk and (c) provide clinical care suggestions.

Key Features

PRISMS technology also referred to as a "pediatrician in your phone" was designed to primarily aid non- pediatricians or neonatologists to effectively manage sick newborns. PRISMS Technology:

1. Guides sick newborn care by providing comprehensive management plans tailored to the presenting conditions of the sick newborn based on routine assessment findings. These plans are based on proven algorithms and sick newborn guidelines and protocols.
2. Offers continous newborn care education which is tailored to the specific learning needs for the individual patient in care.
3. Offers newborn surveillance, objective data driven management decision making and quality improvement data.

PRISMS technology has been tested in Uganda. Our previous studies have shown a reduction in neonatal mortality in all PRISMS supported facilities compared to non-PRISMS facilities. Currently the technology is working in West-Nile Northern Uganda and North East Uganda regions.

PRISMS

Type of technology	**Decision support software**
Status	**Commercially available**
Regulatory approvals and/or international standards	**PRISMS was approved for use in clinical settings by the Uganda Ministry of Health Newborn Steering Committee.**
Manufacturer of Record	**E-Wall Technologies Company Limited**
Electricity requirements, including voltage, and charging features	**PRISMS is Smartphone or tablet-based application. It does not have independent electricity requirements other than those of the devices it is installed on.**
Size and form factor	**The PRISMS apk is less than 40 Mbs and has no form factor except that of the device its installed on.**
Shelf life, stability, and storage requirements	**Depends on the life of an android smart phone and the phone should be keep under keep and lock accessible to authorized personnel only.**
Ex-works price of device	**PRISMS is a subscription-based technology. Current monthly Subscriptions range from 3 USD for basic to 54 USD for premium subscriptions depending on level of back-end support required.**
Ex-works price of any additional services or add-ons required to support technology	**PRISMS is designed to work off telephone networks and off internet when data syncing is not required. The cost to sync data to the PRISMS server has ranged from 3-6 USD per month.**

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SonoMobile – Health-E-Net, Ltd. (Nairobi, Kenya)

Commercially available

Intended Use

Information not submitted.

Key Features

This is a point-of-care ultrasound device that works with a tablet or smartphone to enable nurses to conduct prenatal ultrasound and capture critical parameters. These are then read and reported by a remote radiologist/sonographer. Combining nurse-led scanning with telemedicine for remote reporting radically reduces cost and access to. Point-of-care services can be delivered in a clinic setting or home visit, and data stored and shared for asynchronous reading. Results from a successful pilot of this work, delivering >5,000 scans in private sector clinics in urban informal settlements of Nairobi, Kenya, are available for interested customers to review.:

SonoMobile

Type of technology	**Digital point-of-care ultrasound and app-free user interface**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Probe: FDA marketing approval** **Telemedicine platform: N/A** **Training: Point-of-care ultrasound scanning training for nurses is approved and delivered by the Kenya Medical Training College (KMTC); two cohorts of students have graduated from the course**
Manufacturer of Record	**Probe: Sonostar Technologies Co., PRC** **Telemedicine platform: Health-E-Net Limited, Kenya**
Electricity requirements, including voltage, and charging features	**Both probe and tablet are battery-powered**
Size and form factor	**Probe: ~16x6x2 cm; 477g** **Tablet: Typically a 10" tablet is used**
Shelf life, stability, and storage requirements	**N/A**
Ex-works price of device	**The service is delivered in Kenya at $10 per scan**
Ex-works price of any additional services or add-ons required to support technology	**N/A**

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Walking Doctors' (WD) cloud-based EMR – Walking Doctors

Commercially available

Intended Use

Health care providers working in outpatient and inpatient settings use Walking Doctors' enhanced electronic medical record (EMR) to dramatically increase care quality and efficiency.

Key Features

Walking Doctors' (WD) cloud-based EMR reaches doctors where ever they work. WD evidence-based checklist help doctors and other health care providers quickly organize and act on decisions avoiding errors in care, while managing the business side of medicine: pharmacy, medical records, billing, performance reports and metrics. WD's tools and strategies are logical and sustainable, and organized to gather data for public health and economic impact.

Walking Doctors' (WD) cloud-based EMR

Type of technology	**Electronic Medical Record and Clinical Decision Support Software**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Information not submitted**
Manufacturer of Record	**Walking Doctors**
Size and form factor	**WD is accessed through the cloud and is compatible with any internet-enabled computer, tablet, or mobile device.**
Shelf life, stability, and storage requirements	**The WD system requires an on-site computer, tablet, or mobile device to access the cloud-based platform. All data is stored off-site in WD's secure backend servers, which cryptographically verify each transmission from our app, applying security rules based on the user's identity.**
User Instructions	**User Manual, Quick Reference Guide and Instructional videos.**
Ex-works price of device	**Affordable subscription model adapted to scale and context.**
Ex-works price of any additional services or add-ons required to support technology	**N/A**

Contact Information:

Walking Doctors

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Introduction to Retinopathy of Prematurity (ROP)

Premature babies are at risk of retinopathy of prematurity (ROP), a potentially blinding disease that occurs when the blood vessels of the eye, which normally mature in the last few weeks of pregnancy, develop abnormally. The risk of ROP is directly proportional to the degree of prematurity and exacerbated by hyperoxia, sepsis, blood transfusions and poor nutrition. The more preterm the infant, the higher the risk [60–62]. As the mortality rate of infants decreases in sub-Saharan Africa and neonatal care improves, the burden of retinopathy of prematurity (ROP) is likely to increase as more preterm infants at risk survive [66].

ROP is invisible to clinicians without specialized tools to assess the retina as it is caused by the growth of abnormal blood vessels at the junction of the vascular and avascular retina which then fibrose, shrink and can lead to traction, hemorrhage, retinal detachment and blindness [60–62]. High quality neonatal care is critical to minimize the number of infants affected by ROP. However, for the subset of infants who do develop ROP, prevention of visual impairment and blindness rely on tools and expertise for ROP identification, on-going assessment over weeks to months and effective treatment. Urgent treatment may include laser surgery to the peripheral retina or intravitreal injection of agents which block angiogenic growth factors.

The standard method of diagnosing ROP is an examination by an ophthalmologist using an indirect ophthalmoscope. Challenges to screening, even in high income countries, include lack of ophthalmologists who are willing to screen for ROP for a range of reasons including distance to the neonatal units, legal implications and opportunity costs. In low- and middle-income countries, not only is the lack of ophthalmologists more acute, but the burden of infants who develop treatment requiring ROP is likely to be even greater due to higher variability in neonatal care quality and standards [66].

In all settings there are, therefore, reasons why alternative approaches to bedside screening by an ophthalmologist are highly desirable. The following approaches are being used, or evaluated:

1. Wide-field (120-1300) retinal imaging conducted by a) a visiting ophthalmologist who interprets the image b) a neonatal nurse who sends the image to a local ophthalmologist via telemedicine for grading, and c) a visiting technician, again with remote grading [64].

2. Artificial intelligence using neural network analysis of retinal images is reasonably well established for other retinal conditions, such as diabetic retinopathy, and pilot studies are underway for ROP.

3. Other screening technologies which provide a wide field of view, such as smartphones [63] are also being evaluated.

Major concerns for low- and middle-income countries include the lack of national level screening guidelines, the high cost and limited availability of both screening and treatment technologies, and the lack of human resources available to screen or interpret screening images and provide treatment.

Affordability of the existing technologies poses a huge challenge. For example, the RetCam, which is the international standard for wide-field retinal imaging in infants and children, costs over $100,000 USD [64].

Future approaches using low cost, easy to use and portable digital imaging for infants which can be remotely interpreted by an expert or at the point-of-care using AI technology are critical to developing interventions to offset the disease burden of ROP, particularly in low- and middle-income countries [65]. Outlined in this section are technologies designed to screen or diagnosis retinopathy of prematurity in low-resource settings.

3nethra neo – Forus Health

Commercially available

Intended Use

The 3nethra neo is a mydriatic wide-field digital imaging system used for the photo documentation of paediatric ocular diseases that manifest in infant eyes. The ergonomically designed light weight handpiece allows for single handed operation, and captures 120-degree FOV high resolution images of the paediatric retina. The camera is a speciality device used for paediatric retinal imaging, documentation and management of ocular diseases such as retinopathy of prematurity in premature infants. The camera acquires only digital photographs of the eye and does not provide any analysis or diagnosis. The contact device is easily operated by qualified clinicians and can be deployed in versatile clinical environment such as hospitals. Operating rooms and Neonatal Intensive Care Units (NICU).

Key Features

- Compact and ergonomic design
- High resolution images at 120-degree FOV
- Lightweight and easy to use
- Intelligent intuitive controls and workflow
- Provides historical data as reference to evaluate disease progress
- Telemedicine compatible

3nethra neo

Type of technology	**Digital Wide-field Imaging System**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Yes, the product is US FDA cleared, CE marked and Health Canada registered.**
Manufacturer of Record	**Forus Health**
Product used for screening, prevention or treatment of ROP	**The product is used for the screening and effective management of ROP in newborn premature infants**
Electricity requirements, including voltage, and charging features	**kPa** **Altitude: 0 – 2000 meters** **Power Supply Input: AC 100 – 240V, 50/60 Hz (for DC power adapter 5V/5A)**
Size and form factor	**340g (720g with cable) and 210 (L) X 70 (W) X 60 (H) mm**
User interface of the device for clinicians	**The device is connected to a laptop which would have an imaging software as well to capture and store the patients eye photographs.**
Patient interface of the device, specifically for neonates	**The device is contact based and the outer lens of the camera touches the surface area of the infant's eye. A gel medium is applied on the surface of the eye and the lens. The focal distance is short to achieve wider field of view (120 degree).**
User instructions provided	**Yes**
Training required	**A certified clinical training from an eye hospital is required for the ophthalmic technician. And ophthalmologists will be trained by Forus Health's team on the usage of the device.**
Shelf life, stability, and storage requirements	**All cameras manufactured by Forus Heath have 10 years life. The camera is an electronic device and can be stored in various temp conditions. However, Forus Health recommends standard room temperature while the product is operated on infants.**

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3nethra neo

Describe how cleaned or decontaminated	**Cleaning and disinfection instructions provided here**
Warranty	**2 years**
Ex-works price of device	**$50,000 USD**
Consumables and/or accessories required	**Laptop / PC**
Ex-works price of consumables	**For the international market, the laptops have to be outsourced by the customer as per the required specification.**

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Phoenix ICON GO™ – Phoenix Technology Group, LLC

Commercially available

Intended Use

The Phoenix ICON GO™ system is indicated for general ophthalmic imaging of the retinal, corneal, and external structures of the eye.

Key Features

- A wide-angle, hand-held retinal imaging system that delivers stunning, high-resolution, high-contrast images - on both light and dark retinas
- Light-weight, portable system in rugged, wheeled, waterproof case is ideal for remote screening or large campuses
- Works smoothly with telemedicine
- Powerful, intuitive software with native multi-facility support
- Video and flashback modes with frame-by-frame export ensures a critical image is not missed
- Unique cleaning features make infection control easy and trackable
- Enterprise-grade security built-in with a hardened version of Windows 10 Pro, encryption, role-based user management, and audit logging
- Ready for integration with healthcare information systems with included DICOM connectors

Phoenix ICON GO™

Type of technology	**Wide field hand-held portable fundus camera**
Status	**Commercially available (not registered in all geographies)**
Regulatory approvals and/or international standards	**CE Mark, UL – country-specific registration**
Manufacturer of Record	**Phoenix Technology Group, LLC**
Product used for screening, prevention or treatment of ROP	**Documentation, teaching and longitudinal surveillance**
Electricity requirements, including voltage, and charging features	**Operates on battery. Charges with 220V or 110V AC 50-60 Hz city current**
Size and form factor	**17.5 lbs, 37 lbs in transit case, 55 lbs overall shipping weight** **Unit suitable for tabletop use** **16.8" x 12.7" x 2.2" (holster arm down)** **19.7" x 12.7" (holster arm up-can overhang table)** **28" x 24" x 20" overall shipping dimensions**

Contact Information:

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Phoenix ICON GO™

User interface of the device for clinicians	**An intuitive interface provides access to the key functional screens to enter a patient, capture images and/or video, control the camera capture and illumination functions, review and compare images, create a report, export images and log out of the system.** **The database is encrypted at rest and runs on hardened Windows 10 Pro.** **User logins can be set up as well as individual clinics to facilitate keeping patient lists separate if moving the device between facilities.** **An audit log provides tracking of security events such as user logins and when images are deleted.** **Systems may be interfaced with electronic medical records so that a modality work list can be downloaded in lieu of manually entering patient demographic information.** **Users may capture images using software or hardware footswitch controls.**
Patient interface of the device, specifically for neonates	**The patient demographic screen includes fields for the patient last, middle and first names, Patient ID, MRN, sex, date of birth, birth weight (grams), ethnicity, primary and referring physicians. The current age of the patient is calculated from the date of birth. In a notes field the physician may enter their findings, and pathology.**
User instructions provided	**An Instructions for Use (IFU) PDF may be launched from a button on any screen on the interface for convenient reference.** **Quick Start Guides are provided in the last section of the instructions for use.** **A laminated 5 Field Imaging Guide is delivered as a hard copy reference for users. This describes the standard retinal fields and how to landmark ocular features to create reproducible longitudinal images.** **An optional training kit complete with a model eye is available to facilitate practice and handling of the camera prior to using it on a real patient.**

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Phoenix ICON GO™

Training required	**Users are trained on:** • General hardware and how to safely set up and put away the Phoenix ICON GO™. • Software • Hands-on imaging using a training kit and eye • Hands-on patient imaging • Cleaning and disinfection • Cautions and warnings **Training is delivered using multiple approaches. Core training includes:** • Online training and familiarization presentations are accessed prior to meeting with training staff. The training bundle includes Instructions for Use, a training Syllabus and training presentations • Training Kit practice mannikin and model eye **Hands-on training:** • When possible, in person training is available where a PTG representative will come onsite • When travel is restricted, remote training is facilitated with a PTG representative using teleconferencing technology • In person or remote training on a practice kit is followed by supporting the user during their first clinical imaging session.
Shelf life, stability, and storage requirements	**The Phoenix ICON GO™ should be stored in the accompanying hard roller case. The paired laptop should be stowed in its backpack and secured appropriately so it is protected against loss, damage or theft.** **Two rechargeable Li-ion batteries to power the control box. For short transport and brief storage, batteries can stay in the control box.** **When transporting, ensure the On/Off switch at the back of the control box is Off.** **For shipping and long-term storage, control box batteries should be fully charged and stored in the rolling hard case foam.** **Environmental storage conditions:** **Temperature: -10°C to +55°C** **Relative Humidity: 10% to 95%** **Atmospheric Pressure: 700 hPA to 1060 hPA**

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Phoenix ICON GO™

Describe how cleaned or decontaminated	**The lens and tip of the camera hand piece must be cleaned and disinfected in between patients. The hand piece holster is equipped with a removable soaking cup so that the hand piece lens tip can be soaked when placed in the holster.** **The cleaning procedure for the lens tip is as follows:** • **Wipe with four 70% isopropyl alcohol pre-moist wipes using each one separately;** OR **5-minute soak in a 70% isopropyl alcohol. Since alcohol is used, rinse with sterile distilled water to avoid any corneal damage;** OR **5-minute soak in a 10% bleach solution. Example preparation: 10ml of 6% hypochlorite solution to 90ml of distilled/sterile water, therefore 1:10 dilution of 6% bleach;** OR **30-minute soak in a 6% H2O2 solution; and then rinse with sterile or distilled water to avoid any corneal damage** • **Allow the lens to air dry, or dry it using a soft, clean or sterile tissue or gauze.5-minute soak in 70% isopropyl alcohol. Since alcohol is used, rinse with sterile or distilled water to avoid any corneal damage.** • **Allow the lens to air dry, or dry it using a soft, clean or sterile tissue or gauze.** **The Phoenix ICON GO™ Software includes a Soak Timer that can be used to time soaking of the Phoenix ICON GO™ camera hand piece in disinfection solution.** **Additional high level disinfection solutions are listed in the Instructions for Use.** **Between patients and at the end of all imaging sessions for the day:** • **Wipe down the keyboard and track pad with disinfectant wipes between patients.** • **Wipe down the touch screen monitor with 70% isopropyl alcohol.** • **When moving the system from one facility to another:** • **Clean the system as instructed above** • **Wipe down the exterior of the rolling hard-case with 70% isopropryl alcohol.** • **Wipe down the exterior of the laptop backpack with 70% isopropryl alcohol.**

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Phoenix ICON GO™

Warranty	**2 years**
Ex-works price of device	**Prices are supplied by local distributors in each country or region**
Consumables and/or accessories required	**Yes – coupling gel (typically is a thick gel for Dry-eye) and cleaning solution such as 70% isopropyl alcohol** **Both are available locally in various markets under other brand names**
Ex-works price of consumables	**N/A**

Contact Information:

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Keeler MIO – Keeler Ophthalmic Instruments

Commercially available

Intended Use

ROP fundus examination, imaging and documentation.

Key Features

MIO - head-mounted fundus examination via a smartphone through indirect ophthalmoscopy technique with a condensing lens, supported by KineXis software with automatic fundus image extraction for documentation, patient engagement and analysis of ROP.

Keeler MIO

Type of technology	**Fundus examination, imaging and documentation**
Status	**Commercially available**
Regulatory approvals and/or international standards	**FDA registered**
Manufacturer of Record	**Keeler Inc**
Product used for screening, prevention or treatment of ROP	**Screening of ROP**
Electricity requirements, including voltage, and charging features	**N/A – dependent upon smartphone manufacturer**
Size and form factor	**500g with the outer dimensions boundaries of the headband within 28 x 23 x 22 cm**
User interface of the device for clinicians	**The user interface is via the smartphone screen used on the application KineXis, mounted on the MIO headband**
Patient interface of the device, specifically for neonates	**The neonate fundus is examined while being positioned by the doctor's hand. Output images and notes can be shared with the patient guardians.**
User instructions provided	**Paper IFU and digital instructions via the KineXis software**
Training required	**Indirect ophthalmoscopy technique**
Shelf life, stability, and storage requirements	**N/A**
Describe how cleaned or decontaminated	**70% isopropyl alcohol wipes**
Warranty	**3 years**
Ex-works price of device	**Pricing varies by geography**
Consumables and/or accessories required	**For use with a condensing lens**
Ex-works price of consumables	**Pricing varies by geography**

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3nethra neo HD – Forus Health

Not yet commercially available / In development

Intended Use

The 3nethra neo HD is a compact, portable, and easy-to-use mydriatic wide-field digital imaging system used for the photo documentation of ocular diseases that manifest in human eyes. The ergonomically designed, lightweight hand piece allows for single-handed operation, and captures 130-degree high-resolution images of the posterior and anterior segments of the eye. The device acquires only digital photographs of the eye and does not provide any analysis or diagnosis. The contact device is easily operated by qualified clinicians and can be deployed in versatile clinical environment such as hospitals, operating rooms, and Neonatal Intensive Care Units (NICU).

Key Features

- Compact and ergonomic design
- Digital photo-documentation
- High resolution images at 150-degree FOV when measured from the centre of the eye with 20 Mega Pixel
- Lightweight and easy to use
- Intelligent intuitive controls and workflow
- Provides historical data as reference to evaluate disease progress
- Telemedicine compatible
- Fundus fluorescein angiography (FFA)

3nethra neo HD

Type of technology	**Digital Wide-field Imaging System**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**No**
Manufacturer of Record	**Forus Health**
Product used for screening, prevention or treatment of ROP	**The product is used for the screening of ROP**
Electricity requirements, including voltage, and charging features	**Power supply: AC 100-240 V, 50/60 Hz (for DC power adapter 5V/5A)** **Power consumption: 5-10 Watts**
Size and form factor	**Dimensions of Handheld unit: 210 (L) x 70 (W) x 60 (H) mm** **Weight of handheld unit: 300 g (550 g with cable)** **Dimensions of Transport Package: 650 (L) x 430 (W) x 300 (H) mm** **Weight of Transport Package: 12 Kgs**
User interface of the device for clinicians	**The device is connected to a laptop which would have an imaging software as well to capture and store the patients eye photographs.** **Operating Mode: Single handed operation - Pen Holder Grasp and Fist Grasp**
Patient interface of the device, specifically for neonates	**The device is contact based and the outer lens of the camera touches the surface area of the infant's eye. A gel medium is applied on the surface of the eye and the lens. The focal distance is short to achieve wider field of view (130 degree).**
User instructions provided	**Please see the user manual**
Training required	**A certified clinical training from an eye hospital is required for the ophthalmic technician. And ophthalmologists will be trained by Forus Health's team on the usage of the device.**

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3nethra neo HD

Shelf life, stability, and storage requirements	**All cameras manufactured by Forus Heath have 10 years life. The camera is an electronic device and can be stored in various temp conditions. However, Forus Health recommends standard room temperature while the product is operated on infants.**
Describe how cleaned or decontaminated	**Cleaning and disinfection instructions provided here**
Warranty	**2 years**
Ex-works price of device	**$70,000 USD**
Consumables and/or accessories required	**Optional** **For printing reports: Colour printer** **Trolley Table for NICU: Recommended size: 700 (L) x 500 (W) x 640-800 (H) mm** **PC/Laptop requirement: MS Windows 10 OS based laptop/desktop with** • **i5 processor, 2.4 GHz or higher** • **8 GB RAM or higher** • **500 GB or more hard disk space** • **Display: Full HD (1920 x 1080)** • **USB 3.0** • **1.2Mbps or faster internet connectivity** **The computer must conform to IEC 60950 Ed 2.0 or equivalent standard.** **Operating System: Windows 10 (64 Bit)**
Ex-works price of consumables	**For the international market, the laptops have to be outsourced by the customer as per the required specification.**

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Scleral Transillumination accessories – Smart Telemedicine Solutions (STS)

Not yet commercially available / In development

Intended Use

The intended use is to enhance the performance of retinal images and surgical procedures, avoiding reflexes and artefacts in images (produced by coaxial illumination and lenses reflexes from current lightsources). Via transillumination we can perform retinal actions (imaging, surgery) trough transescleral illumination.

Useful in teaching avoiding an easier learning curve.

Key Features

- Cost efficiency
- Same technique / same accesories (with only addition of light)
- Portability for Telemedicine Networks
- Usefull for other pediatric pathologies (newborn retinal infections, congenital anomalies, tumours, etc)
- Avoids smartphone techonology to perform eye fundus images forgetting about reflexes issue

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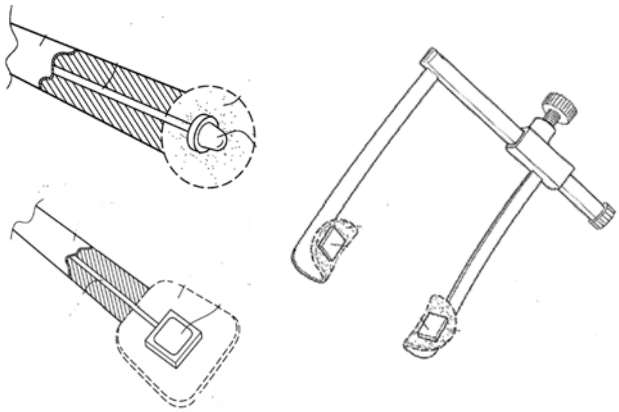

Scleral Transillumination accessories

Type of technology	**ROP Imaging accesories devices project. Eyelid Speculum and Eyeglobe Rotator with LED / fiber optic transillumination**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**US Patent already published.** **Ophthalmic Device For Fundus Examination SAIDMAN; Gabriela ; et al. uspto.report › patents ›** **MONTEOLIVA; Guillermo Andres › Patent 16/358813 Applicant uspto.report › patents ›** **SAIDMAN; Gabriela › Patent 16/358813 Applicant uspto.report › patents ›** **MONTEOLIVA; Guillermo Andres › Patent 16/358813 Inventors uspto.report › patents ›** **SAIDMAN; Gabriela › Patent 16/358813**
Manufacturer of Record	**Information not submitted**
Product used for screening, prevention or treatment of ROP	**Potential usefullness both for ROP screening and treatment (laser, vitrectomy through transescleral illumintation)**
Electricity requirements, including voltage, and charging features	**the portable LED / fiber optics technologies required levels**
Size and form factor	**Portable** **Eyelid speculum and eyeglobe rotators size + any light source console size**
User interface of the device for clinicians	**any ophthalmologist , trained nurse or technician can perform smartphone ROP images avoiding reflexes and artefacts. Learning curve improvement. Ideal for prevention of blindness projects usin portable images. Teleophthalmology**
Patient interface of the device, specifically for neonates	**Secure light** **Secure devices (same as normally used in premature babies screening and treatment**

Scleral Transillumination accessories

User instructions provided	• **Use eyelid speculum as usual in premature babies.** • **Set the additioned lightsource power as you need using the dimmer buttom for light regultation** • **Use the eyeglibe rotator with additional light using the amount of light required by console light dimmer buttom**
Training required	**No training required , except the usual screening funduscopy training. Accesories are the same (wih addition of transillumination safe light)**
Shelf life, stability, and storage requirements	**Same requirements than usual devices and accesories used for ROP screening**
Describe how cleaned or decontaminated	**Depending on the materials used in constructiòn and development, and if its disposable built or not.** **Not disposable: same cleaning than ROP screening accesories**
Warranty	**Evaluation required**
Ex-works price of device	**TBD**
Consumables and/or accessories required	**Depending on the develompent (susteiable systems / electrical charge)**
Ex-works price of consumables	**Evaluation required**

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Introduction to Biomedical Technician (BMET) Toolkit

Many hospitals, especially in low-and-middle income countries, have a shortage of functional medical devices and supplies. Historically, to meet this need, donors have supplied medical equipment, often without considering the local constraints for using, maintaining, repairing, and decommissioning equipment. This has resulted in equipment graveyards, full of broken equipment. Instead, medical supplies and devices should be selected to meet appropriate standards for efficacy, ruggedness and affordability; at the same time, technology management systems must be put in place to procure, steward and replace medical equipment. While biomedical technicians are not directly responsible for providing patient care, understanding the technologies and how they are clinically used can be critical when evaluating the device.

The NEST-ED Technical Modules have been prepared to help technical staff understand the basics of how to use equipment essential to newborn care. More importantly, the Technical Modules support staff in troubleshooting common issues, as well as prepare staff to repair equipment or perform preventative maintenance. Modules may be used by teaching institutions, to supplement current newborn care curricula, or by hospitals, clinical departments and individuals to update their knowledge and to better facilitate the effective and safe use of newborn care equipment. Modules should be used alongside device user and service manuals to provide additional context as needed.

A dedicated maintenance workshop provides a suitable working environment for biomedical equipment technicians (BMET) to perform maintenance work efficiently. In addition to being a place to house a well-organized stockpile of parts and tools, an effective workshop will also provide adequate room, lighting, and utilities such as electricity, water, and medical gases. Although larger facilities may have access to more advanced maintenance tools and equipment, which may be necessary to repair complex equipment, the majority of maintenance procedures can be completed with only a basic set of tools and test equipment.

A basic maintenance workshop will include:

- **Tools:** Basic tool set, soldering iron, digital multimeter, oscilloscope, electrical safety meter, pressure and force gauges.
- **Spare Parts & Components:** Power supplies, common replacement parts and device-specific parts.
- **Infrastructure:** Electricity, water, good lighting, medical gases, workbench, work-holding equipment, filing cabinets, tool and equipment storage space.
- **Consumables:** Solder, electrical tape and heat shrink tubing, cleaning, Infection Prevention and Control and PPE supplies.

A biomedical toolkit can be used to support biomedical engineers and biomedical equipment technicians (BMETs) to effectively evaluate equipment to ensure it lasts to its lifetime potential. The technologies featured in this section are examples of products to be included in a BMET Toolkit and basic maintenance workshop.

4-meter – Medical Technology Transfer and Services Co., Ltd (MTTS)

Commercially available

Intended Use

An instrument for determination of the actual level of sources required for an effective medical therapy.

1. Blue light irradiance measurement: verify irradiance of photo therapy devices during preventive maintenance and normal use

2. O_2 measurement:

- verify purity of O_2 sources (tank, generator, wall) during preventive maintenance
- verify mechanical blender and other blender during preventive maintenance
- leak search inside device and along external tubes during repair and equipment inspection

3. Pressure measurement: verify pressure at Y connector during use

4. Flow measurement: verify ow output of CPAP, Hi- ow and ventilators during preventive maintenance

Key Features

4-meter measures:

- Irradiance of the phototherapy units
- Oxygen level of the gases
- Pressure of the gases
- Flow of the gases

Irradiance measurement specifications:

- **Spectral response:** 400 – 520 nm
- **Measuring range:**
  - Single side: 0.1 – 150.0 µW/cm2/nm
  - Double side: 0.1 – 300.0 µW/cm2/nm
- **Resolution:** 0.1 µW/cm2/nm
- **Cosine characteristics:**
  - ±2% at 30 degree angle
  - ±7% at 60 degree angle
  - ±25% at 80 degree angle
- **Accuracy:** ±3% of reading

Contact Information:

Medical Technology Transfer and Services Co., Ltd (MTTS)

info@mtts-asia.com

+84 24 37 666 521

www.mtts-asia.com

4-meter

Type of technology	**Technical diagnostic tool**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485, CE, Certificate of Free Sale**
Manufacturer of Record	**MTTS Co., Ltd**
Electricity requirements, including voltage, and charging features	**2xAAA 1.5V Alkaline, Non-rechargeable**
Size and form factor	**Height: 148 mm** **Width: 73 mm** **Depth: 17 mm** **Weigh: 200g**
Shelf life, stability, and storage requirements	**Calibration required every 2 years after delivery data; return to MTTS for calibration** **Operation Temperature: 10°C to 40°C** **Storage Temperature: 0°C to 50°C** **Operation Humidity: 30 – 90% RH non condensing** **Storage Humidity: 5 – 90% RH non condensing**
Ex-works price of device	**Light meter (main control unit): from 620 USD** **Accessories:** • **Oxygen meter: 135 USD** • **Flow meter: 135 USD** • **Manometer: 135 USD**
Ex-works price of consumables	**50 USD calibration every 24 months**

ESA609 Electrical Safety Analyzer – Fluke

Commercially available

Intended Use

The ESA609 Electrical Safety Analyzer is a rugged, portable analyzer designed for general electrical safety testing. The ESA609 integrates all functions needed to test medical devices when patient lead testing is not required, including: line (mains) voltage, ground wire (protective earth) resistance, equipment current, leakage current and point-to point tests. Versatile to global electrical safety standards of choice, the ESA609 tests to ANSI/AAMI ES1, NFPA-99, and parts of IEC62353 and IEC60601-1.

Key Features

- Standards compliance include: ANSI/AAMI ES1, NFPA-99, and parts of IEC62353 and IEC60601-1
- Test current consumption up to 20 A for a diverse set of medical devices
- All parameters needed for basic electrical safety testing: Line (mains) voltage, ground wire (or protective earth) resistance, equipment current, ground wire (earth) leakage, chassis (enclosure) leakage, direct equipment leakage, and point to point leakage and resistance
- Global use: the ESA609 will operate at 120 V and 230 V
- Rugged: Rubberized case and Ingress Protection rating of IP30 help prevent damage when dropped
- User-friendly: Quick push-button operation for rapid testing
- Portable: Featherweight (1.5 lb) design, functional strap, and tilt stand make it easy for transportation and operation on-the-go (onsite or offsite)
- Rigorously tested for safety and reliability, with CE, CSA and Australia RCM in addition to Fluke quality
- Two-year extended warranty (no-cost, available after first-year calibration at any authorized Fluke Biomedical Service Center)
- Global support network delivering prompt service and peace of mind to Fluke Biomedical customers worldwide

Contact Information:

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ESA609 Electrical Safety Analyzer

Type of technology	**Electrical Safety Analyzer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE, CSA, Australia RCM**
Manufacturer of Record	**Fluke**
Electricity requirements, including voltage, and charging features	**115 Volt power outlet: 90 to 132 V ac rms, 47 to 63 Hz, 20 A maximum** **230 Volt power outlet: 180 to 264 V ac rms, 47 to 63 Hz, 16 A maximum** **Power input: 115V 20A - 2.6kVA and 230V at 16A - 4.2kVA**
Size and form factor	**Weight: 0.7 kg (1.5 lb)** **Dimensions: (WxDxH) 20 cm x 18 cm x 5 cm (7.9 in x 7.1 in x 2.1 in)**
Shelf life, stability, and storage requirements	**Operation Temperature: 0 °C to 50 °C (32 °F to 122 °F)** **Storage Temperature: -20 °C to 60 °C (-4 °F to 140 °F)** **Humidity: 10% to 90% non-condensing**
Ex-works price of device	**Contact for pricing**
Warranty	**Two-year extended warranty (no-cost, available after first-year calibration at any authorized Fluke Biomedical Service Center, otherwise standard one year warranty applies)**

ProSim 4 Vital Signs and ECG Simulator – Fluke

Commercially available

Intended Use

ProSim 4 vital signs simulator with breakthrough touchscreen technology offers quick and simple one-tap testing for patient monitor performance checks and troubleshooting. Designed to get you in and out of most locations in 60 seconds, this quick-check device offers 12-lead ECG simulation, respiration, IBP and NIBP testing in the palm of your hand. Featuring specialized stay-connected ECG posts to ensure secure lead connections and no-hassle testing, ProSim 4 is the perfect patient simulator for first-call patient monitor quality assurance and safety professionals.

Key Features

- Portable multifunction tester offers 12-lead ECG, respiration, IBP and NIBP simulation
- 90 % smaller and lighter than combined technology of legacy products
- Breakthrough touch screen technology
- One-tap testing for most performance tests and checks
- Easy quick-check patient monitor testing in one minute or less with onboard, customizable patient pre-sets and autosequences
- Integrated, easily-replaceable battery capable of running quick checks all day
- Stay-connected ECG posts for secure lead connections
- Repeatable NIBP testing within 2 mmHg independent of device under test
- Multi-language user interface offers choice of language selection
- Tilt stand design for operation in tight spaces and better viewing angle

ProSim 4 Vital Signs Simulator

Type of technology	**Vital Signs Simulator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE, CSA, C-TICK N10140 , RoHs**
Manufacturer of Record	**Fluke**
Electricity requirements, including voltage, and charging features	**Power: Lithium-ion rechargeable battery** **Battery Life: 4 hours (minimum), 40 NIBP cycles typical**
Size and form factor	**Weight: 0.88 kg (1.93 lb)** **Dimensions: (L x W x H) 18 cm x 9.3 cm x 5.5 cm (7.1 in x 3.7 in x 2.2 in)**
Shelf life, stability, and storage requirements	**Operation Temperature: 10 °C to 40 °C (50 °F to 104 °F)** **Storage Temperature: -20 °C to +60 °C (-4 °F to +140 °F)** **Humidity: 10% to 90% non-condensing** **Altitude: 3,000 meters (9,843 ft)**
Ex-works price of device	**Contact for pricing**
Warranty	**Information not submitted**

Contact Information:
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www.flukebiomedical.com

ProSim 8 Vital Signs and ECG Patient Simulator – Fluke

Commercially available

Intended Use

The 8-in-1 ProSim 8 Vital signs simulator provides test measurements for ECG (including fetal ECG and arrhythmias), respiration, temperature, IBP, cardiac output, NIBP, SpO2, and is capable of testing Rainbow multi-wavelength waveforms.

Key Features

- All-in-one complete monitor testing 80 % smaller and 17 lbs/7.7 kilos lighter than predecessor technology
- 8-in-1 multifunction simulator tests ECG (including fetal ECG and arrhythmias), respiration, temperature, IBP, cardiac output, NIBP, SpO2, and Rainbow multi-wavelength waveforms
- Stay-connected ECG posts for easy/secure ECG snap and lead connections
- Custom SpO2 r-curve for accurate testing of the latest and future oximetry technologies
- Static pressure linearity testing
- Repeatable NIBP simulation (+/- 2 mmHg) for dynamic pressure repeatability testing
- Physiologically synchronized pulses across all parameters
- Barcode scanning and direct data capture and printing functionality
- Onboard, customizable patient pre-sets and autosequences for fast/easy testing
- Multi-language user interface offers choice of language selection
- Integrated, easily-replaceable long-life battery
- Optional PC-interface software offers customizable procedures/checklists to replace bulky service manuals and automated data capture/storage*
- Wireless communication for remote PC control of test device, as well as data transfer and automated regulatory reporting*

**You must have Ansur Test Executive version 2.9.6 or greater on your PC to communicate with the product*

ProSim 8 Vital Signs Simulator

Type of technology	**Vital Signs Simulator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**CE, CSA, C-TICK N10140 , RoHS**
Manufacturer of Record	**Fluke**
Electricity requirements, including voltage, and charging features	**Power: Lithium-ion rechargeable battery** **Battery charger: 100 V to 240 V input, 15 V/2.0 A output. For best performance, the battery charger should be connected to a properly-grounded ac receptacle** **Battery life: 9 hours (minimum), 100 NIBP cycles typical**
Size and form factor	**Dimensions: (L x W x H)** **14.5 cm x 30.2 cm x 8.6 cm** **(5.7 in x 11.9 in x 3.4 in)** **Weight: 1.87 kg (4.2 lb)**
Shelf life, stability, and storage requirements	**Operation Temperature: 10 °C to 40 °C (50 °F to 104 °F)** **Storage Temperature: -20 °C to +60 °C (-4 °F to 140 °F)** **Humidity: 10% to 90% non-condensing** **Altitude: 3,000 meters (9,843 ft)**
Ex-works price of device	**Contact for pricing**
Warranty	**Information not submitted**

Contact Information:
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ProSim SPOT Light SpO2 Pulse Oximeter Tester – Fluke

Commercially available

Intended Use

The ProSim SPOT Light generates known SpO2 saturation, heart rate, perfusion, transmission, artifact noise, and eight different custom r-curves to a pulse oximeter or patient monitor to test device functionality.

Key Features

- Small, portable and lightweight
- Large, easy to read LCD display
- Rechargeable battery lasts 10 hours minimum
- Signal strength indicator
- SpO2 Saturation 80 % to 100 %
- Heart rate: 30 BPM to 245 BPM
- Perfusion: 0.2 %, 2 % and 10 %
- Transmission: dark/thick, normal and light/thin
- Artifacts: respiration and ambient light
- Three editable test sequences
- R-curves: 8 including Masimo, Nellcor and Nonin

ProSim SPOT Light

Type of technology	**Vital Signs Simulator**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Information not submitted**
Manufacturer of Record	**Fluke**
Electricity requirements, including voltage, and charging features	**AC Adapter** **Input Voltage: 100 V ac to 240 V ac** **Input Frequency: 50/60 Hz**
Size and form factor	**Display: 2 1/4 in x 1 1/2 in LCD display** **Size: (WxDxH) 4.8 in x 3.8 in x 1.9 in (12.2 cm x 9.7 cm x 4.8 cm)** **Weight: 8.8 oz**
Shelf life, stability, and storage requirements	**Operation Temperature: 32 ºF to 95 ºF (0 ºC to 35 ºC)** **Storage Temperature: -31 ºF to 122 ºF (-35 ºC to 50 ºC)** **Humidity: 20% to 80% non-condensing**
Ex-works price of device	**Contact for pricing**
Warranty	**Information not submitted**

Contact Information:
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www.flukebiomedical.com

QA-ES III Electrosurgical Tester and Analyzer – Fluke

Commercially available

Intended Use

Complete electrosurgical testing and preventive maintenance for ESU devices with precise power, current, frequency, crest factor and load resistance ranges.

Key Features

- Collect measurements in single and continuous mode
- Connect wirelessly via Bluetooth for easy record retrieval without interference or limitation by cables and wires*
- Comply to all global standards, including ANSI/ AAMI and IEC**
- All-in-one tool: all hardware and software necessary to complete preventive maintenance and troubleshooting is built in to the unit, eliminating the need to purchase or transport additional cables, leads, switch boxes and RECM box
- User-friendly interface: large buttons and LCD screen guide the user through test sequences
- Memory storage of up to 5,000 test records, eliminating the need to download data after the completion of each preventive maintenance or troubleshooting session

**Wireless capabilities not available in all countries. Ask your sales representative for more details.*

***Bipolar leakage testing performed with 200 ohm fixed load.*

QA-ES III

Type of technology	**ESU Analyzer**
Status	**Commercially available**
Regulatory approvals and/or international standards	**Information not submitted**
Manufacturer of Record	**Fluke**
Electricity requirements, including voltage, and charging features	**Power Requirements: 100 V ac, 115 V ac, 230 V ac, 50 Hz / 60 Hz, universal input** **100 V/115 V: 20 VA** **230 V: 30 VA**
Size and form factor	**Size (HxWxL):** **14.5 cm x 35 cm x 47 cm** **(5.75 in x 13.75 in x 18.5 in)** **Weight: 7.5 kg (16.5 lbs)**
Shelf life, stability, and storage requirements	**Operation Temperature: 10 °C to 40 °C (50 °F to 104 °F)** **Storage Temperature: -20 °C to 60 °C (-4 °F to 140 °F)** **Humidity: 10% to 90% non-condensing** **Altitude: 2,000 meter maximum**
Ex-works price of device	**Contact for pricing**
Warranty	**Information not submitted**

Contact Information:
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www.flukebiomedical.com

Introduction to Vital Signs Monitoring

Vital signs are critical for patients to receive accurate triage, diagnosis, treatment and referral. Both spot check and continuous measurement of vital signs such as oxygen saturation (SPO2), pulse rate, and respiratory rate can improve the identification and management of ill patients presenting in primary care facilities in low-resource settings. A vital signs monitor that efficiently measures a combination of vital signs which could include pulse rate, oxygen saturation, respiratory rate, temperature, heart rate, and blood pressure among others, would benefit health care workers who often face high patient volumes, inadequate staffing, and limited time to evaluate and treat ill patients.

Manufacturers are currently developing devices that are able to evaluate multiple parameters or vital signs within a single technology. Bundling vital sign measurements into one multi-functional device may lead to efficiency gains for health workers. The WHO's 2018 Paediatric Quality of Care Standards reinforce the importance of RR, SPO2, and temperature measurements, in addition to blood pressure as essential for assessing and monitoring pediatric emergencies. These measurements, in addition to nutritional status, were all proposed by global stakeholders for inclusion in next generation tools.

Some of the devices featured in other Product Category sections (e.g., Pulse Oximeter, Respiratory Rate Monitor, Temperature Monitor) that offer multiparameter vital sign monitoring are cross-listed here as well.

	Pulse Rate	*Oxygen Saturation*	*Respiratory Rate*	*Temperature*	*Heart Rate*	***Product Category:*** *Pulse Ox*	***Product Category:*** *Resp. Rate Monitor*
Neopenda	X	X	X	X			X
ApneBoot	X	X					
Rad-67	X	X					
Rad-G	X	X	X				X
Rad-G Pulse Ox *with Infrared Temperature*	X	X	X	X			
LifeBox	X	X				X	
Rad-8	X	X				X	
UTECH	X	X				X	

Vital Signs Monitor - tablet assisted IMPALA – GOAL3

Commercially available

Intended Use

Multi-parameter vital sign monitoring system, tablet assisted.

Key Features

- Monitor vital signs of single patient
- Device and training for early detection and proactive patient management
- Central data storage for central patient overview and real-time insight in performance of ward
- Enhanced data-visualization for improved interpretation, prioritization and early detection of deterioration
- Data driven services for optimized performance and quality improvement

Contact Information:

GOAL 3

Jelle@goal3.org

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www.goal3.org

Vital Signs Monitor - IMPALA

Type of technology	**Tablet assisted Vital Signs Monitor with integrated clinical decision support**
Status	**In testing (Malawi & Rwanda) - to be commercially available March 2023 onwards**
Regulatory approvals and/or international standards	**Regulatory approval Malawi expected Q4 2022, Rwanda Q2 2023**
Manufacturer of Record	**GOAL 3**
Device monitors Pulse Rate (Yes/No)	**Yes**
Device monitors Oxygen Saturation (Yes/No)	**Yes**
Device monitors Respiratory Rate (Yes/No)	**Yes**
Device continuously monitors Temperature (Yes/No)	**Yes**
Device monitors Heart Rate (Yes/No)	**Yes**
Device monitors Hemoglobin (SpHb) (Yes/No)	**No**
How are paramaters monitored	**Heart rate** **SpO2** **RR** **Temp** **Movement**
Device is specific to newborns and/or includes a neonatal probe (Yes/No)	**Yes**
Patient interface, specific to neonates	**Probe** **NIBP** **ECG** **BSG**
Device has been tested with newborns	**The device was tested in a pilot study in Mercy James in Malawi with infants of 0-5 years old. The system is currently used in the IMPALA study in Malawi.**

Vital Signs Monitor - IMPALA

Alarms included in device	Vital sign thresholds
How alarms are set	**Alarms are set per patient age group (neonate, pediatric, adult)** **Alarms can be manually adjusted**
Consumables required	**Senors**
How cleaned or decontaminated	**Device and sensors should be cleaned with alcohol based cleaning agents**
Electricity requirements, including voltage, and charging features	**Power: 100-240V, 50/60Hz** **Battery: 6 hours without power** **Charging**
Size and Form Factor	**40x30x40**
Training required	**1. Basic product introduction training** **2. Additional critical care training**
User instructions provided	**In the box we will provide a system manual.** **For daily use we will provide a clinical job aid to help troubleshoot problems and assist with interpreting the output.**
Ex-works price of device	**Depending on country, business model, preferences - get in contact for detailed quotations**
Ex-works price of consumables	**Depending on country, business model, preferences - get in contact for detailed quotations**
Warranty	**2 years + extra options for Service level agreements**

Contact Information:

GOAL 3

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Whatsapp: +316 83 066 007, Call Rwanda: +250 79 144 6939

www.goal3.org

Introduction to Other Products

This section is used to capture other newborn technologies that do not fit into one of the existing product categories. New product categories are created on an ongoing basis.

Lotus – Phoenix Medical Systems

Commercially available

Intended Use

Trolley for receiving a new born babies close to the mother to keep the cord intact. Resuscitation could be done with the cord intact and the neonate could be closer to the mother

Key Features

It is equipped with a mechanism to move the bed close to the mother. The device is compact to be positioned as per the convenience of the doctors. It has a display to show the key parameters of the baby. Height adjustment provides to keep the bed at a desired height for the clinicians.

- 300 mm Height adjustment bed
- Foot operated adjustment
- 4 inch castors with lock
- Removeable basket provides
- Push handle
- Bed rotation and lock
- Display for patient temperature & heart rate near the baby
- Removable baby bed
- Strap blet for avoid baby fall
- Easy to move
- V-Cut for Umbilical cord
- Inbuild battery
- Optional heater arm unit
- Optional resuscitation unit
- Optional SPO2
- Optional display unit for heater and SPO2

Lotus

Type of technology	**Transport Trolley**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485**
Manufacturer of Record	**Phoenix Medical Systems**
Electricity requirements, including voltage, and charging features	–
Size and form factor	–
Shelf life, stability, and storage requirements	–
Ex-works price of device	**TBA**
Ex-works price of consumables	**TBA**

Contact Information:

Phoenix Medical Systems Pvt Ltd

exports@pmsind.com

+ 27 71 528 9873

www.phoenixmedicalsystems.com

Sohum Newborn Hearing Screener – BEMPU Health

Commercially available

Intended Use

Hearing Screening of newborn and babies (0-1.5 years) in Hospitals, Clinics and Health Camps.

To be used by low skilled healthcare workers, Audiologists, ENT specialists, Pediatricians, Neonatologists and Nurses.

Key Features

Sohum hearing screener is a BERA based hearing screening device that is capable to measure the hearing function of the entire hearing pathway till the brainstem and give a screening outcome for purposes of selection for diagnostic evaluation of the hearing function of a newborn. It has inbuilt algorithm to provide results as PASS, REFER or REDO. The device is portable, easy to use by low skilled healthcare workers and work in noisy conditions usingboth reusable and disposable electrodes. It is the only device in the world to have telemedicine software for remote verification by audiologists.

- Displays BERA waveform to support clinical analysis
- Capable of providing the screening at intensities of 35db, 50db, 70db for finding out mild, moderate, severe losses of hearing
- Provides a printable PDF at the end of the test for purposes of evaluation, printing and sharing report with parents or doctors
- Has built-in hardware and software functionalities which are designed to make the device function in noisy conditions
- Capable to connect to the internet via Wi-Fi and external port
- Capable of a printer connection for the purposes of printing the report both with a cable and Wi-Fi

Sohum Newborn Hearing Screener

Type of technology	**ABR – Auditory Brainstem Response**
Status	**Commercially available**
Regulatory approvals and/or international standards	**ISO 13485**
Manufacturer of Record	**Sohum Innovations**
Electricity requirements, including voltage, and charging features	**Internal battery powered – rechargeable** **Battery Type: Rechargeable Lithium- Ion Battery 7.4V 5200mAh (Battery passes all requirements of UL1950)** **AC Adaptor:** **Input: 90~264VAC, 1.80A (rms) for 115VAC, 0.90A (rms) for 230VAC,** **Output: 12V /3A** **Battery Charge time: 4 hours to 100%** **Estimated Battery Life: 60 hearing screening tests, 5 hours of continuous use**
Size and form factor	**Weight: 1.2kg including battery** **Dimensions: 220 X 240 X 70 mm**
Shelf life, stability, and storage requirements	**Store in a dry space and room temperature.** **No expiry date as it has a long life, replaceable battery.**
Ex-works price of device	**Dependent on market**
Ex-works price of consumables	**Dependent on market**

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OAE Hearing Screening for Newborns & Young Children – Solar Ear

Not yet commercially available / In development

Intended Use

According to the WHO, "over 5% of the world's population – or 430 million people – require rehabilitation to address their 'disabling' hearing loss (432 million adults and 34 million children)". Many countries make early hearing screenings mandatory and accessible, but due to the high cost, many children in under resourced communities go undiagnosed. For many of these people, much of the world is inaccessible, even hostile. This product aims to provide easy to use, affordable hearing screening in order for trained community stakeholders to detect a hearing loss before it has become a major roadblock. Detecting hearing losses early allows the families and caregivers of Deaf/HoH infants more time to consider intervention and to ensure the child grows up with access to literacy, speech (verbal or sign), and a supportive community.

Key Features

Few hospitals or clinics in under-resourced countries have the equipment or audiologists to test a newborn's hearing. We are developing an intuitive, smartphone-based otoacoustic emissions (OAE) device that can be used by any adult who receives a short hearing screening training. Our hope is that this will enable universal newborn hearing screening and young children to scale globally.

OAE hearing screening for newborns

Type of technology	**Otoacoustic Emissions (OAE) Hearing Screening Device**
Status	**Not yet commercially available / in development**
Regulatory approvals and/or international standards	**Will meet medical device regulations depending on the country**
Manufacturer of Record	**Solar Ear**
Electricity requirements, including voltage, and charging features	**Charge as a cell phone**
Size and form factor	**Smartphone plus probe and cable**
Shelf life, stability, and storage requirements	**Life of a cell phone**
Ex-works price of device	**< $200 USD**
Ex-works price of consumables	**Exploring how to eliminate consumables**

Contact Information:

Solar Ear

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Draeger
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Kinlee Health
Laerdal Global Health
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Solar Ear
STS (Smart Telemedicine Solutions)
Uganda Industrial Research Institute
UTECH CO.,LTD.
Vayu Global Health Innovations
Walking Doctors
Warmilu LLC

Thank you to the organizations above for their participation. If you are a manufacturer or product developer and wish to include your technology in future versions of this manual, please contact ***Becca Kirby*** *at* ***becca.kirby@kellogg.northwestern.edu****.*

References

If you would like to reference this document, please use the following citation:
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