Newborn Technology Landscape

1st Edition Technical Report, Summer 2019

Technologies for Comprehensive Newborn Care in Low-Resource Settings

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The report was prepared by Rebecca Kirby and Kara Palamountain from Northwestern University. We are also grateful for the contributions of subject matter experts in the medical space, including Professor Elizabeth Molyneux, Dr. Josephine Langton and Dr. Jennifer Werdenberg. All reasonable precautions have been taken by the author to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the authors be liable for damages arising from its use.

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
cm^2	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
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[i].

The first 28 days of life – the neonatal period – represent the most vulnerable time for a child's survival. While 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, 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[ii]. Health interventions needed to provide comprehensive neonatal care at facilities and address the major causes of neonatal death, are known and can be cost-effective, however, may be different from other interventions needed to address broader under-5 deaths[iii].

For the first time ever in 2016, the world pledged to end preventable newborn deaths by 2030 (Sustainable Development Goal 3.2)[iv]. 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 per cent of the burden of neonatal deaths in 2016[v]. 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 per cent of these deaths[vi].

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[vii]. 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 Landscaping 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. Breathing Support
2. Monitor & Treat Jaundice
3. Temperature Stability
4. Hydration, Nutrition & Drug Delivery
5. Prevention & Treatment of Infections
6. Point-of-Care Diagnostics

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 and national or regional regulatory approvals and manufacturing standards. Only photographs received from manufacturers and developers were included in this report.

BREATHING SUPPORT

At birth, a baby's lungs 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 extablished, 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, and 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[viii].

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

1. BUBBLE CPAP

INTRODUCTION TO BUBBLE CPAP

In high-resource settings, a mother is given steroids before birth if a baby is anticipated to be born pre-term 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[ix] as well as dramatically decrease progression to intubation or death in both high[x xi xii] and low[xiii xiv] 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 that 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 (FiO2) is a critical feature for preventing blindness and chronic lung disease associated with oxygen administration[xv xvi]. 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, provision, and context when choosing between available bCPAP devices.

COMMERCIALLY AVAILABLE PRODUCTS

Dolphin CPAP - Medical Technology Transfer and Services Co., Ltd

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: Dolphin CPAP is 100% reusable and cleanable, complete all-in-one CPAP treatment and monitoring device. Integrated design includes gas mixing, humidification, PEEP chamber, air compressor and pulse-oximiter in one compact unit 1. PEEP/CPAP Innovative design for safe and easy one hand adjustment Easily visible at front of unit 2. Gas Mixing Electronic mixing for easy, independent adjustment of flow rate and FiO2 Directly set FiO2, no calculations or tables Internal regulator allows safe connection to a variety of oxygen sources 3. Humidifier Automatically refills for 3-days continuous operation Small heated volume for quick warm up Heater power is automatically adjusted to maintain correct humidity and minimize rain-out 4. Patient Circuit Completely reusable Most parts autoclavable Can be chemically disinfected if autoclave is not available Includes internal heater wire and temperature sensors Robust but flexible silicone tubes 5. Pulse Oximeter Pulse-oximetry integrated into the device Masimo SET® technology for accurate, reliable, robust measurements Simple user interface and alarm settings No multi-level menus or complicated button sequences 6. Air Compressor - Integrated air compressor means there is no need for an external air source Completely integrated, no messy external wires or tubes Diaphragm type for clean, long lasting air supply

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
Total flow capability (lpm)	10
Pressure range (cm H20)	10
Total (blended) flow (lpm)	10
Include humidification (Yes/No)	Yes, heated
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	None
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	3,300 USD
Ex-works price of consumables	2.50 USD

Contact Information: MTTS Co., Ltd

info@mtts-asia.com

+84 24 3766 6521

www.mtts-asia.com

Baby CPAP 20 - Diamedica (UK) Ltd

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: 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
Total flow capability (lpm)	20 lpm (10 lpm oxygen and 10 lpm air)

Pressure range (cm H20)	1 - 10 cm H2O
Total (blended) flow (lpm)	20 lpm (10 lpm oxygen and 10 lpm air)
Include humidification (Yes/No)	Yes, heated
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.
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	GB £1,750
Ex-works price of consumables	Silicone nasal prong £8

Contact Information: Diamedica (UK) Ltd

support@diamedica.co.uk

+44 1598 710066

www.diamedica.co.uk

Baby CPAP 10 - Diamedica (UK) Ltd

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:
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
Total flow capability (lpm)	10 lpm (5 lpm oxygen and 5 lpm air)
Pressure range (cm H20)	1 - 10 H2O
Total (blended) flow (lpm)	10 lpm (5 lpm oxygen and 5 lpm air)

Include humidification (Yes/No)	Yes, heated
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.
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	GB £1,450
Ex-works price of consumables	Silicone nasal cannual £8

Contact Information: Diamedica (UK) Ltd


info@diamedica.co.uk Support@diamedica.co.uk


+44 1598 710066

www.diamedica.co.uk

Pumani bubbleCPAP - 3rd Stone Design

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: 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
Total flow capability (lpm)	0-10 L/min
Pressure range (cm H20)	0-10cm H20
Total (blended) flow (lpm)	0-10 L/min
Include humidification (Yes/No)	No
Alarms included in device	Power failure.
Consumables required	Yes.
Accessories required	Patient circuit and nasal prongs.
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@pumani.com


16282367338

www.pumani.com

Seattle PAP - Draeger

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
Total flow capability (lpm)	4-12 l/min
Pressure range (cm H20)	4,5 cm H2O - 10 cm H2O
Total (blended) flow (lpm)	4-12 l/min
Include humidification (Yes/No)	System requires a humidifier (e.g. F&P MR 850)
Alarms included in device	Pressure relief valve at 17 cm H2O /8l/min Flow, Humidifier alarms
Consumables required	Set of consumables
Accessories required	
Voltage requirements	Depending on the local needs

User instructions provided	Instruction for Use in 28 languages
Warranty	
Ex-works price of device	
Ex-works price of consumables	34 US $ + VAT (LMIC)

Contact Information: Draeger


HCA@draeger.com


+49 451 8820

www.draeger.com

NCPAP 300 - Phoenix Medical Systems Pvt Ltd

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: 1. Flow, bubble and Hi-flow Versatile—can be configured for both flow, bubble and hi-flow operation according to your preference 2. 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 3. 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. 4. Battery back up of 3 Hours 5. Display Unit Values of respiratory parameters are displayed in large, bright characters for easy reading 6. Digital Control FiO2 and flow are easily adjustable in accurate concentration through soft touch keys 7.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	CE Mark
Manufacturer of Record	Phoenix Medical Systems Pvt Ltd
Integrated air compressor (Yes/No)	No
Total flow capability (lpm)	0-15 LPM
Pressure range (cm H20)	0 TO 20 cm H20
Total (blended) flow (lpm)	0-15 LPM
Include humidification (Yes/No)	No
Alarms included in device	Air , oxygen input fail, apnea, air pressure, power failure, battery low,

Consumables required	Patient circuit , generators , nasal prongs and head bonnets
Accessories required	
Voltage requirements	110/230V AC
User instructions provided	
Warranty	1 year
Ex-works price of device	3300$
Ex-works price of consumables	140$

Contact Information: Phoenix Medical Systems Pvt Ltd


exports@pmsind.com


+27 71 528 9873

https://www.phoenixmedicalsystems.com/

Portable Transport CPAP - Diamedica (UK) Ltd

Intended Use: Intended 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 - 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

Portable Transport CPAP	
Type of technology	Portable CPAP
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	Trials and CE certification underway. Commercially available within 3 to 6 months.
Manufacturer of Record	Diamedica (UK) Ltd
Integrated air compressor (Yes/No)	Yes
Total flow capability (lpm)	Baby 8 lpm Child 20 lpm
Pressure range (cm H20)	5 - 10 cm H20
Total (blended) flow (lpm)	Baby 8 lpm Child 20 lpm

Include humidification (Yes/No)	Yes, unheated
Alarms included in device	Battery capacity indicator
Consumables required	RAM cannula only
Accessories required	Supplied with all accessories required.
Voltage requirements	12V internal chargeable battery. 8 hours. Recharge voltage 12 - 240V
User instructions provided	Users manual and video to be provided
Warranty	tbc
Ex-works price of device	Target £800
Ex-works price of consumables	tbc

Contact Information: Diamedica (UK) Ltd

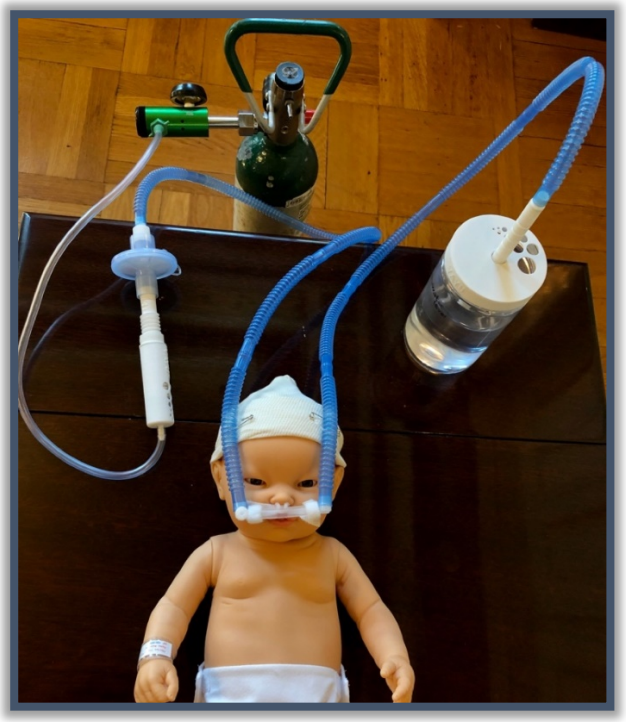

support@diamedica.co.uk


+44 1598 710066

www.diamedica.co.uk

Vayu Bubble CPAP Circuit – Vayu Global Health Innovations

Intended Use: The Vayu bCPAP circuit is intended to provide continuous positive airway pressure in the hospital and pre-hospital environment to spontaneously breathing neonates and infants, up to 10 kg in weight, that require respiratory support due to conditions associated with prematurity, such as Respiratory Distress Syndrome, or other conditions where the physician desires and prescribes CPAP.



Key Features: The Vayu bCPAP circuit provides newborns with affordable and high quality repiratory support. Unlike existing CPAP systems, the Vayu bCPAP circuit does not require electricity or compressed air, only oxygen from a tank or central supply. An innovative ambient air/ oxygen blender allows the user to adjust FiO_2 from 30 to 100%. Flows, pressures, and work of breathing are also comparable to the state of the art CPAP system at < 1% the cost.

Vayu Bubble CPAP Circuit	
Type of technology	Respiratory support system
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	Applying for FDA approval
Manufacturer of Record	
Integrated air compressor (Yes/No)	No
Total flow capability (lpm)	
Pressure range (cm H20)	4-10 cmH_2O
Total (blended) flow (lpm)	4-12 LPM

Include humidification (Yes/No)	Yes
Alarms included in device	No
Consumables required	All components are reusable
Accessories required	None
Voltage requirements	N/A
User instructions provided	Yes
Warranty	No
Ex-works price of device	Estimated $100
Ex-works price of consumables	N/A

Contact Information: Vayu Global Health Innovations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www.vayughi.com

2. PULSE OXIMETER

INTRODUCTION TO PULSE OXIMETRY

Pulse oximeters use a non-invasive sensor to measure pulse rate (PR) and blood oxygenation levels (SpO2) (i.e., percentage of oxygenated hemoglobin in arterial blood). While pulse oximeters do report pulse rate, their primary purpose and utility is to detect SpO2 in infants. According to the World Health Organization, pulse oximetry is the most accurate noninvasive method for detecting hypoxemia. It is used to measure the percentage of oxygenated hemoglobin in arterial blood (SpO2). 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 SpO2 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[xvii].

Low SpO2 levels can indicate that an infant is in respiratory distress and monitoring SpO2 is important in the neonatal period as it can indicate the need for immediate, critical care interventions. Additionally, SpO2 monitoring is critical for infants receiving oxygen therapy or continuous positive airway pressure (CPAP) therapy. Low SpO2 levels during oxygen or CPAP therapy can indicate that escalation or additional care is required. On the other hand, if SpO2 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[xviii] [xix]. 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.).

Rad-8 - Masimo Corporation

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. *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, including indications, contraindications, warnings, and precautions.*	
Key Features: Rad-8: http://www.masimo.com/products/continuous/rad8/	

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"
Consumables required	Resuable and disposable sensor configurations are available
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

Contact Information: Masimo

gjaaron@masimo.com

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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.

uPM60 - UTECH CO.,LTD.

Intended Use: To measure children's SpO2, PR, Respiration rate during pneumonia	
Key Features: uPM60 handheld pulse oximeter is a smart and portable device, providing a fast and reliable measurement of SpO2, 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	
Manufacturer of Record	
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
Consumables required	None
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 260USD per unit
Ex-works price of consumables	The price of SpO2 sensor is USD25 per unit.

Contact Information: UTECH CO.,LTD


lily@chinautech.com.cn


86082595

www.chinautech.com

3. OXYGEN CONCENTRATOR

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% FiO2, 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[xx]. 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.

We have currently not received any submissions for Oxygen Concentrators. 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.

4. FLOW SPLITTER

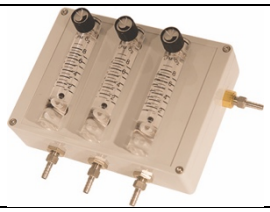
INTRODUCTION TO FLOW SPLITTER

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[xxi] [xxii]. 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[xxiii].

COMMERCIALLY AVAILABLE PRODUCTS

Diamedica Flow Splitter - Diamedica (UK) Ltd

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
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 is 0.1 lpm
Warranty	Flow Splitter
Ex-works price of device	Prices start from GB £350

Contact Information: Diamedica (UK) Ltd

info@diamedica.co.uk

+44 1598 710066

www.diamedica.co.uk

5. SUCTION PUMP

INTRODUCTION TO SUCTION PUMPS

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.

We have currently 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.

6. RESPIRATORY RATE MONITORS

INTRODUCTION TO RESPIRATORY RATE MONITORS

Respiratory rate is a critical vital sign. The causes are many but are commonly due to respiratory pathology. Increased respiratory rate (> 60bpm) 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 SpO2) 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[xxiv]. 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.

Masimo Rad-G - Masimo Corporation

Intended Use: Spot check monitoring of oxygen saturation, respiratory rate, perfusion index, and pulse rate.

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, including indications, contraindications, warnings, and precautions.

Key Features: Masimo partnered with the Bill & Melinda Gates Foundation to develop a combined pulse oximeter that measures oxygen saturation (SpO2) 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 SpO2 cutoffs, and 2) general screening mode - standard user interface with SpO2 and RR continuously measured while the sensor is on the selected site.

Masimo Rad-G	
Type of technology	Respiratory Rate Monitors
Status	Commercially Available (Neonatal sensor still in development)
Regulatory approvals and/or international standards	CE Mark
Manufacturer of Record	Masimo Corporation
Respiratory rate range (bpm)	4-90 RPM
Accuracy (bpm)	1 RPM
Respiratory rate resolution (bpm)	1 RPM
Alarms included in device	
How are alarms set?	There are currently no alarms on the Rad-G device

Consumables required	Rad-G comes with a universal resuable probe and a reusable neonatal sensor will be released in Q3 2019
Describe how cleaned or decontaminated	See page 15 of the user operator guide
Electricity requirements, including voltage, and charging features	100-240VAC, 50/60Hz, 0.6A
Describe the patient interface, specifically for neonates.	Color touch screen with voice assisted feedback
Size and form factor	0.59 pounds (2.9" x 7.8" x 1.0")
Training Required	basic device training and sensor site best practices
User instructions provided	Masimo has the ability to develop customized training material
Warranty	Various options are available
Ex-works price of device	Pricing varies by volume
Ex-works price of consumables	Pricing varies by volume

Contact Information: Masimo Corporation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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.

PRODUCTS IN DEVELOPMENT

Rice University Respiratory Rate and Apnea Monitor - Rice 360 Institute for Global Health

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; Battery-power

Rice University Respiratory Rate and Apnea Monitor	
Type of technology	Respiratory Rate Monitors
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)	0 -120 bpm (anticipated)
Accuracy (bpm)	'+/- 5 bpm (anticipated)
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 1 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. <1/2 day training)
User instructions provided	The device will come with a manual
Warranty	The device will come with a 1 year warranty
Ex-works price of device	TBD
Ex-works price of consumables	TBD

Contact Information: Rice 360 Institute for Global Health

 rice360@rice.edu

 713-348-3071

www.rice360.rice.edu

MONITOR AND TREAT JAUNDICE

Most neonates, term and preterm, will have elevated levels of unconjugated bilirubin and some amount of jaundice during the first 1-2 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 1-2 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 below are technologies both commercially available and in development that allow for the monitoring and treatment of jaundice.

7. SERUM BILIRUBIN TEST

INTRODUCTION TO SERUM BILIRUBIN TEST

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.

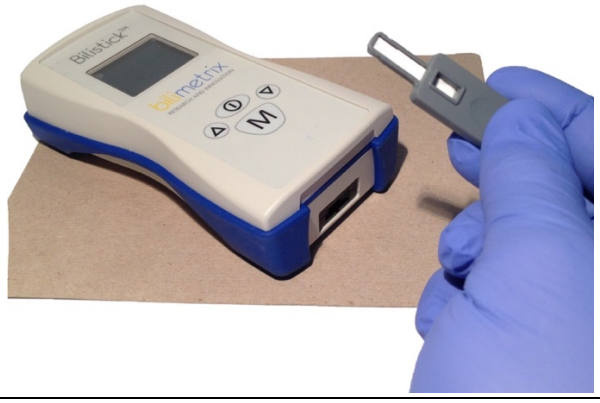
All infants should have a laboratory evaluation of serum bilirubin (with result turn around within six hours) both to diagnose jaundice and to guide treatment of infants receiving phototherapy. In low resource settings though, many facilities do not have the ability to run a blood test, and those that 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 below. Technologies that are only reliable before but not during phototherapy have been excluded.

COMMERCIALLY AVAILABLE PRODUCTS

Bilistick System - Bilimetrix s.r.l.

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 monitoring the bilirubin levels in the blood of newborn infants. Even if it was demonstrated that the Bilistick® System provide accurate results, its use is advised for quick screening of hyperbilirubinemia. 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 µmol/L) with an accuracy comparable to traditional clinical laboratory methods.

Bilistick System	
Type of technology	Serum Bilirubin Test
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 mmol/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	Whole blood / 35 uL
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 must be calibrated once a month 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)
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 °C to 40 °C low humidity, non-corrosive gas atmosphere. - Long-term Storage 1- 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: two years
Ex-works price of device	Bilistick reader price: 750.00 USD
Ex-works price of consumables	Bilistick Test Strips: 2.00 USD

Contact Information: Bilimetrix s.r.l.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www.bilimetrix.net

BiliSpec - 3rd Stone Design

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

BiliSpec	
Type of technology	Serum Bilirubin Test
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	CE Mark expected 2020.
Manufacturer of Record	
How are results presented to user?	Quantitative, mg/dL
Accuracy	Within CLIA Standard
Linear range (mg/dL or mmol/L)	0.4-30 mg/dL
Precision	N/A
Sample type and sample volume required	Whole blood heel stick ~40uL (no centrifuge required)
Steps required to run from sample collection to results output	1. Collect ~40uL of sample onto disposable strip 2. Insert strip into BiliSpec 3. Press button 4. BiliSpec displays bilirubin measurement (mg/dL) 5. Dispose strip
Time to run from sample collection to result output	<1 minute
Calibration required	No consumables required for calibration.

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	BiliSpec is a handheld, portable device that can be used at the patient bedside.
Shelf life, stability, and storage requirements	TBD
Ex-works price of device	TBD
Ex-works price of consumables	TBD

Contact Information: 3rd Stone Design

 info@3rdstonedesign.com

 415 454 3005

www.3rdstonedesign.com

8. PHOTOTHERAPY LIGHT

INTRODUCTION TO PHOTOTHERAPY LIGHT & METER

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, and (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 - 30microW/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[xxv xxvi xxvii].

COMMERCIALLY AVAILABLE PRODUCTS

Firefly Phototherapy - Medical Technology Transfer and Services Co., Ltd

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: The MTTS Firefly is a state-of-the-art phototherapy device designed for effective treatment of neonatal jaundice. Developed in collaboration with Design that Matters (Massachusetts, USA), and East Meets West Foundation (California, USA), the machine features intuitive design, double-sided lighting, compact size, user-friendly control panel, and removable single-infant bassinet. Firefly is designed to treat newborn jaundice in the mother's room – the best way to support mother-child bonding and breastfeeding. Clinical evaluations indicate that Firefly's double-sided design reduces total treatment time by 40% on a typical patient compared to single-sided LED phototherapy, allowing earlier discharge from the hospital, lowering incidence of newborn infection and freeing resources to treat more infants	

Firefly Phototherapy	
Type of technology	Phototherapy Light
Status	Commercially Available
Regulatory approvals and/or international standards	CE Mark, ISO 13485, Other
Manufacturer of Record	MTTS Co., Ltd
Size and Form Factor	Top light - 53 cm x 25 cm Bottom light - 50 cm x 20 cm
Range of irradiance (µW / cm2 / nm)	Top light - 34.8, Bottom light - 50.4
Peak wavelength (nm)	465
Effective treatment area (cm2)	1325
Bulb type	LED
Bulb lifetime (hours)	44,000 hours

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
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	1,500 USD
Ex-works price of consumables	1 USD for an eye patch

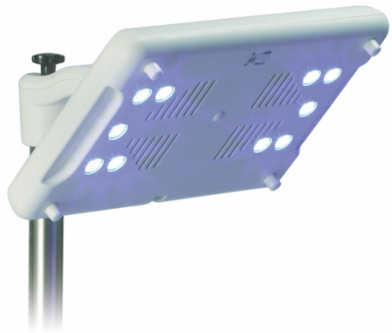
Contact Information: MTTS Co., Ltd


info@mtts-asia.com


+84 24 37 666 521

www.mtts-asia.com

Lullaby LED - General Electric Healthcare

Intended Use: Bilirubin treatment	
Key Features: Optimal 458-nm wavelength; Ideal irradiance levels; Uniform light distribution; Our 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 Light
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	
Come with an Irradiance Meter?	Option
User instructions provided	
Electricity requirements, including voltage, and charging features	
Warranty	

Ex-works price of device	1500
Ex-works price of consumables	500

Contact Information: Ayman Shaheen


ayman.shaheen@ge.com


201000038650

www.gehealthcare.com

Brilliance Pro - Phoenix Medical Systems Pvt Ltd

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.	

Brilliance Pro	
Type of technology	Phototherapy Light
Status	Commercially Available
Regulatory approvals and/or international standards	CE Mark
Manufacturer of Record	Phoenix Medical Systems Pvt Ltd
Size and Form Factor	

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)	
Bulb lifetime (hours)	120,000 hours
Describe if / how bulbs are replaced	
Come with an Irradiance Meter?	Yes
User instructions provided	
Electricity requirements, including voltage, and charging features	
Warranty	
Ex-works price of device	500$
Ex-works price of consumables	25$

Contact Information: Phoenix Medical Systems Pvt Ltd


exports@pmsind.com


+27 71 528 9873

No website information provided

Bili-Hut - Little Sparrows Technologies

Intended Use: Treatment of neonatal hyperbilirubinemia	
Key Features: Narrow bandwidth blue LED, battery operable, ultraportable	

Bili-Hut	
Type of technology	Phototherapy Light
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	FDA, CE (pending)
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 / cm^2 / nm)	Avg irradiance: 45 uW / cm^2 / nm; Peak irradiance 58 uW / cm^2 / nm
Peak wavelength (nm)	463
Effective treatment area (cm^2)	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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TEMPERATURE STABILITY

As many as 85% of infants born in hospitals in low-resource settings (LRS) become cold (defined as <36.5°C)[xxviii]. 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 below are technologies both commercially available and in development that enable temperature stability for neonates.

9. WARMING CRIB

INTRODUCTION TO WARMING CRIB

Warming cribs provide conductive heating either below or around the patient while also allowing health care workers with visibility and access to the baby. Negative outcomes associated with hypothermia can be prevented using warming cribs that carefully control heat.

Neonatal Warming System - 3rd Stone Design

Intended Use: To provide thermal stability for neonates at risk of hypothermia.	**No picture provided**
Key Features: The Warming Crib 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.	

Neonatal Warming System	
Type of technology	Warming Crib
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	CE Mark expected 2021.
Manufacturer of Record	
Benchtop measurement accuracy (+-°C)	Same as clinical.
Clinical measurement accuracy (+-°C)	TBD.
Maximum CO2 concentration	Less than the acceptable amount. TBD.
Maximum temperature (+-°C)	TBD.
Describe the patient interface, specifically how the device responds to a neonate's temperature.	The Warming Crib has a sensor that attaches to the infant's abdomen either using a wearable strap (reusable) or an adhesive patch (disposable). This sensor incorporates a feedback loop that uses the infant's current temperature to determine whether to continue heating the chamber. 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)	±0.8°C
Alarms included in device	Other
How are alarms set?	Alarms are pre-set at factory.
Consumables required	Adhesive patch for sensor attachment (optional).
Describe how cleaned or decontaminated	The Warming Crib is wipeable with standard hospital cleaning products.

Size and form factor	The Warming Crib is table mountable and comes with an optional wheeled cart. It accommodates one neonate at a time.
Training Required	Minimal. Designed for intuitive use.
User instructions provided	TBD
Electricity requirements, including voltage, and charging features	110-240V AC 50-60hz. Integrated surge protection.
Maximum power consumption (W)	<250W
In the event of a power outage, what is the heat retention for your Warming Crib? (e.g., X +-°C loss over X hours)	TBD
Warranty	2 year standard warranty.
Ex-works price of device	TBD.
Ex-works price of consumables	TBD.

Contact Information: 3rd Stone Design

 info@3rdstonedesign.com

 415 454 3005

www.3rdstonedesign.com

10. RADIANT WARMERS

INTRODUCTION TO RADIANT WARMERS

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).

COMMERCIALLY AVAILABLE PRODUCTS

Wallaby Warmer - Medical Technology Transfer and Services Co., Ltd

Intended Use: Restore, stabilize, and control the temperature of the newborn baby.	
Key Features: Focusing on enhanced functionality and clinical performance, the Warmer features safe, automatic control of patient temperature with smart problem detection, safety fallback modes, and LCD displays that show set temperature, temperature alarm, treatment time, total usage time, and heater power level. Moreover, the easy-to-open sidewalls provide access to the patient while keeping them warm and create an ideal ergonomic setting where caregivers can work efficiently.	

Wallaby Warmer	
Type of technology	Radiant Warmer
Status	Commercially Available
Regulatory approvals and/or international standards	CE Mark , ISO 13485, Other
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 1C.
Consumables required	Skin sensor (12 months lifetime)
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)
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
Warranty	1 year
Ex-works price of device	1,750 USD
Ex-works price of consumables	25 USD

Contact Information: MTTS Co., Ltd

info@mtts-asia.com

+84 24 37 666 521

www.mtts-asia.com

Lullaby Warmer - General Electric Healthcare

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	

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.	
Temperature uniformity (+-°C)	
Alarms included in device	Other
How are alarms set?	upper & lower limits
Consumables required	Temp. probe

Describe how cleaned or decontaminated	
Size and form factor	Mattress Size 462 x 640 x 25.4 mm
Training Required	minimal operation training
User instructions provided	
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, & 1 year for the rest of the unit
Ex-works price of device	2800
Ex-works price of consumables	

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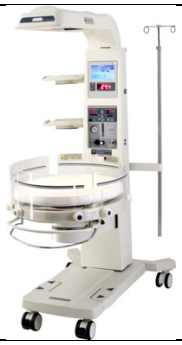
Comprehensive Infant Care System 101 - Phoenix Medical Systems Pvt Ltd

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	CE Mark
Manufacturer of Record	Phoenix Medical Systems Pvt Ltd
Benchtop measurement accuracy (+-°C)	

Clinical measurement accuracy (+-°C)	0.2
Temperature stability (+-°C)	
Describe the patient interface, specifically how the device responds to a neonate's temperature.	
Temperature uniformity (+-°C)	
Alarms included in device	Auditory
How are alarms set?	High and low alarms, probe failure, heater failure, power failure, system failure, Low battery, Spo2, BPM, High/low oxygen concentration, high/low pressure
Consumables required	Temperature probe, Spo2 probe
Describe how cleaned or decontaminated	
Size and form factor	
Training Required	
User instructions provided	
Electricity requirements, including voltage, and charging features	110V-230V 50Hz -
Maximum power consumption (W)	900W
Warranty	1year
Ex-works price of device	10000
Ex-works price of consumables	

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https://www.phoenixmedicalsystems.com/

11. TEMPERATURE MONITORS

INTRODUCTION TO CONTINUOUS TEMPERATURE MONITORS

Given that temperatures less than 36.5°C have been shown to be an independent risk factor for death in neonates[xxix], 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 below 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).

COMMERCIALLY AVAILABLE PRODUCTS

TempWatch - BEMPU Health

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 (<36.5 C), 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	Temperature Monitor
Status	Commercially Available
Regulatory approvals and/or international standards	CE Mark
Manufacturer of Record	BEMPU Health
Benchtop measurement accuracy (+-°C)	
Clinical measurement accuracy (+-°C)	
Time for your Temperature Monitor to indicate accurate temperature (s)	
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	Other
How are alarms set?	The device will beep and flash an orange light when it detects a temperature reading below 36.5 degrees Celsius.
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.
Size and form factor	
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 2.8-3.3V DC operating voltage and is powered by 2 x CR-1620 Coin Battery (2 x 70mAH).
Warranty	1 year
Ex-works price of device	Dependent on market.
Ex-works price of consumables	Dependent on market.

Contact Information: BEMPU Health

hello@bempu.com

1800 425 0192

https://bempu.com/

Temperature Monitor - 3rd Stone Design

Intended Use: To provide temperature measurement of infants in a healthcare 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.	

Temperature Monitor	
Type of technology	Temperature Monitor
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	CE Mark expected 2020.
Manufacturer of Record	
Benchtop measurement accuracy (+-°C)	TBD
Clinical measurement accuracy (+-°C)	TBD
Time for your Temperature Monitor to indicate accurate temperature (s)	<2 minutes
Describe the patient interface, specifically how the device responds to a neonate's temperature.	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	Other
How are alarms set?	Alarms are pre-set at factory.
Consumables required	Adhesive patch (optional).
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	TBD.
Electricity requirements, including voltage, and charging features	Rechargeable battery (standard USB charger 110-220V AC), lasts up to 24 hours
Warranty	2 year standard warranty
Ex-works price of device	TBD
Ex-works price of consumables	TBD

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HYDRATION, NUTRITION & DRUG DELIVERY

12. SYRINGE PUMPS

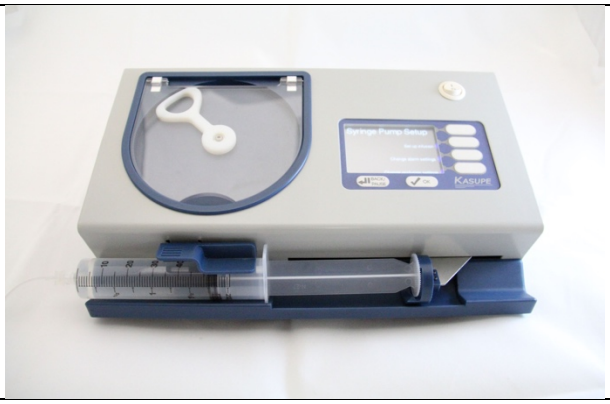
INTRODUCTION TO SYRINGE PUMPS

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[xxx].

The FDA has reported that syringe pumps currently on the market are difficult to use[xxxi]. 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 below are syringe pump technologies for low resource settings.

Rice University Syringe Pump - Rice 360 Institute for Global Health

Intended Use: To provide fluids or antibiotics to neonates with hypoglycemia or infection	
Key Features: The Rice University syringe pump is designed to provide continuous infusion of fluid or antibiotics to neonates. Its features include: Accurate drug delivery; No proprietary consumables; Long battery life; Easy-to-use user interface; Easy maintenance and repair	

Rice University Syringe Pump	
Type of technology	Syringe Pump
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	None; CE marking anticipated
Manufacturer of Record	Unknown
Benchtop measurement accuracy (+-%)	<3%
Clinical measurement accuracy (+-%)	<5%
Flow rate ranges for your Syringe Pump? (mL/hr)	1-60mL/hour
Describe the syringes your Syringe Pump is compatible with (size, proprietary or non-proprietary, etc.)	Any syringe brand/type; 5mL-60mL capacity
Describe how occlusion limits are set on your Syringe Pump are adjusted based upon patient and syringe size.	Occlusion limits are non-adjustable
Describe the patient interface of your Syringe Pump, including how the device interfaces with a neonate.	A syringe is placed on the syringe tray; the patient is connected to the syringe via an IV giving set
Alarms included in device	Other

Describe how cleaned or decontaminated	A syringe is placed on the syringe tray; the patient is connected to the syringe via an IV giving set
Consumables required	Syringes, giving sets (any brand)
Training Required	Minimal (<1/2 day training)
Size and form factor	Portable; can be set at the patient's bedside
User instructions provided	The device will come with a manual
Electricity requirements, including voltage, and charging features	Battery powered; est. battery life 24 hours from full charge
Warranty	The device will come with a warranty
Ex-works price of device	TBD
Ex-works price of consumables	N/A

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PREVENTION AND TREATMENT OF INFECTIONS

13. SEPSIS DIAGNOSTIC

INTRODUCTION TO SEPSIS DIAGNOSTICS

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 and 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[xxxii].

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[xxxiii]. Additionally, there is currently no accepted biomarker for use in low and middle income countries[xxxiv]. 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)[xxxv]. 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.

We have currently not received any submissions for Sepsis Diagnostic Tests. 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.

14. HEMOGLOBIN TEST

INTRODUCTION TO HEMOGLOBIN TEST

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).

Masimo Rad-67 - Masimo Corporation

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, including indications, 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.	

Masimo Rad-67	
Type of technology	Hemoglobin Test
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	
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


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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.

HemoSpec - Rice 360 Institute for Global Health

Intended Use: Diagnosing anemia.

Key Features: The HemoSpec consists of an optical reader and a disposable. Blood is collected directly from a fingerstick or heelstick on the disposable - there is no need to meter volume, mix blood with any reagents, or precisely measure time since collection. The user inserts the disposable into the reader, which provides a quantitative result in less than 1 minute.

HemoSpec	
Type of technology	Hemoglobin Test
Status	Not Yet Commercially Available / In Development
What technology does your Hemoglobin Test utilize?	Spectrophotometry
Regulatory approvals and/or international standards	None; CE marking anticipated
Manufacturer of Record	Unknown
Accuracy	'+/- 1.5 g/dL (anticipated)
Linear range	0-18 g/dL (tested)
Precision	TBD
Sample type and sample volume	Whole blood, >= 10 uL
Describe the steps required to run test, from sample collection to results output.	Collect blood from finger/heelprick onto strip; Seal strip by pressing adhesive tape over the blood-soaked paper; Insert strip into carrier tray and tray into reader; Press sample button, wait for answer.
How much time does it take to run one test, from sample collection to result output?	< 2 min

Calibration required	Yes; anticipated < once per day
Electricity requirements, including voltage, and charging features	Battery-powered
Size and form factor	Portable, approximately 90 x 80 x 75 mm.
Shelf life, stability, and storage requirements	When packaged, strips are stable in heat and humidity
Ex-works price of device	TBD
Ex-works price of consumables	TBD

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15. GLUCOSE TEST

INTRODUCTION TO GLUCOSE TEST

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.

We have currently not received any submissions for Glucose Tests. 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.

OTHER PRODUCTS

COMMERCIALLY AVAILABLE PRODUCTS

BiliCare Neonatal Noninvasive Bilirubin Meter - JAEA MEDICAL SUPPLIES LIMITED

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	
Ex-works price of consumables	

Contact Information: JAEA MEDICAL SUPPLIES LTD.


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www.jaea-medical.com

Light Meter - Medical Technology Transfer and Services Co., Ltd

Intended Use: To determine the light intensity in order to asses 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	

Light Meter	
Type of technology	Light meter
Status	Commercially Available
Regulatory approvals and/or international standards	ISO 13485
Manufacturer of Record	MTTS Co., Ltd
Electricity requirements, including voltage, and charging features	2 AA batteries
Size and form factor	12.5 x 7 x 2.4cm
Shelf life, stability, and storage requirements	5 years
Ex-works price of device	350 USD
Ex-works price of consumables	n/a

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NeoBeat Newborn Heart Rate Meter - Laerdal Global Health

Intended Use: Measure newborn heart rate within seconds of birth to support and guide newborn resuscitation when needed and reduce misclassification of stillbirths.	
Key Features: NeoBeat is a reusable, consumable-free, and easy-to-use heart rate meter that provides an accurate and continuous display of newborn heart rate. NeoBeat takes seconds to put on a newborn's abdomen, and the instantaneous heart rate can help guide neonatal resuscitation. 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 takes seconds to put on the baby and provides a continuous and instantaneous digital display of the newborn HR. -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 monitor
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: PC, 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	150 USD
Ex-works price of consumables	No consumables

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Upright with PEEP Newborn Bag-Mask - Laerdal Global Health

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	CE Mark,Other
Manufacturer of Record	Laerdal Medical Suzhou
Electricity requirements, including voltage, and charging features	NA
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	$25 USD
Ex-works price of consumables	NA

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Lullaby Resus Plus - General Electric Healthcare

Intended Use: Lullaby Resus. Plus helps ensure adequate pressure delivery and oxygenation	
Key Features: Ultimate & 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	
Ex-works price of device	2700
Ex-works price of consumables	

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NoviGuide: Mobile neonatal clinical decision support - Global Strategies

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 clinic, region 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	
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 consumables	Scale- and context-dependent

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ApneBoot - BEMPU Health

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 opposite foot, triggering the nervous system to restart breathing.	

ApneBoot	
Type of technology	Apnea Management Device
Status	Commercially Available
Regulatory approvals and/or international standards	
Manufacturer of Record	BEMPU Health
Electricity requirements, including voltage, and charging features	The device runs on a rechargeable battery. The battery life is 48-60 hrs, after which it can be connected to a power source for charging, which takes 6 hours. It cannot be used while charging. Voltage: 5V & 3V
Size and form factor	
Shelf life, stability, and storage requirements	We provide a warranty of one year for the device and six months for the skin probes.
Ex-works price of device	Dependent on market.
Ex-works price of consumables	Dependent on market.

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Oxygen Reservoir Filling System - Diamedica (UK) Ltd

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. An 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: 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	

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 GB £1,550 Additional 20L reservoir vessels GB £400 Oxygen Reservoir Filling system comes with 100L vessel GB £1750 Additional 100L reservoir vessels GB £600
Ex-works price of consumables	No consumables

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MiraCradle Cooling Mattress - Draeger

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® – 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	

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The Neopenda neoGuard vital signs monitor - Neopenda PBC

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.	
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.	

The Neopenda neoGuard vital signs monitor	
Type of technology	4 in 1 vital signs monitor
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	
Manufacturer of Record	
Electricity requirements, including voltage, and charging features	The neoGuard device uses a rechargeable 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 1-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	
Ex-works price of consumables	

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Bili-ruler - Little Sparrows Technologies

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

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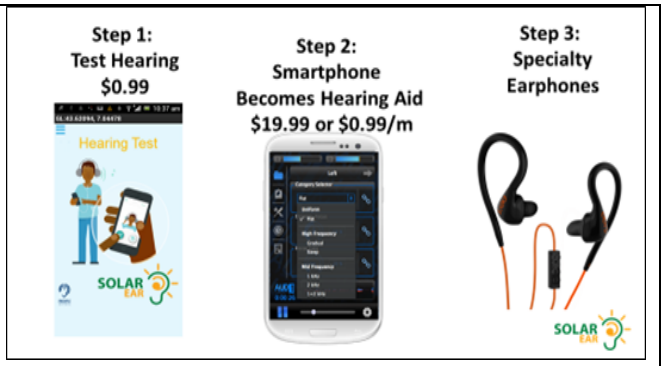
OAE hearing screening for newborns - Solar Ear

Intended Use: The sooner you can detect a hearing loss in a newborn and get her the required amplification, the sooner she will learn to hear, be able to develop speech and have the opportunity to go to a public school. There are very few schools for the deaf in developing countries. It is only through education can you break the cycle of poverty. Also, studies have shown that the price of inclusion of a person with a disability is far lower the cost of exclusion to the local and national government and society.



Key Features: Few hospitals, clinics in developing countries have the equipment nor qualified professionals to test a new born's hearing. We developed the first hearing test using the standard OAE protocol but can be done on an Android cell phone.

OAE hearing screening for newborns	
Type of technology	Hearing test
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	Meet all regulations depending on country
Manufacturer of Record	Solar Ear
Electricity requirements, including voltage, and charging features	Charge as cell phone
Size and form factor	Size of an Android phone and 1 cable connection 1 meter and 2 earbuds
Shelf life, stability, and storage requirements	Life of a Cell phone
Ex-works price of device	$99.00 USD
Ex-works price of consumables	$1.50

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The NeoTree - NeoTree

Intended Use: The NeoTree is intended to improve quality of newborn care through reliable data collection, clinical decision support and improved documentation; promoting a culture of continuous quality improvement amongst newborn health care workers.	
Key Features: The NeoTree is a mobile health application for newborn health care workers 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 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 and feedback of data collected by healthcare workers to a user friendly data dashboard in the local neonatal department displaying summary statistics for key newborn outcomes.	

The NeoTree	
Type of technology	Open source software platform
Status	Not Yet Commercially Available / In Development
Regulatory approvals and/or international standards	
Manufacturer of Record	
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.
Size and form factor	Compatable with any Android device of any size.
Shelf life, stability, and storage requirements	The NeoTree software platform requires one or more tablet devices for use on the ward, and a secure server running Linux to support the backend. Software is maintained by our software development team with regular updates.

Ex-works price of device	Price of the NeoTree system hardware per facility is approximately $500, for a 2 tablet system (tablets cost $100 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 consumables	The price of consumables for the NeoTree per month per facility is approximately $115.

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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.

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