

# Initial Pneumonia Device Short Listing Exercise

## REPORT

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Established in 2003, Malaria Consortium is one of the world's leading non-profit organisations specialising in the prevention, control and treatment of malaria and other communicable diseases among vulnerable populations. Our mission is to improve lives in Africa and Asia through sustainable, evidence-based programmes that combat targeted diseases and promote child and maternal health.

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## 1. Background

Pneumonia is currently the leading cause of death in children worldwide. According to the World Health Organization (WHO), this disease kills an estimated 1.1 million (18% of the total deaths) of children under five years old every year, which represents more than AIDS, malaria and tuberculosis combined. 60% of these deaths occur in just 10 countries in South Asia and Sub-Saharan Africa<sup>1</sup>.

Pneumonia is a form of acute respiratory infection that affects the lungs and it has several causative agents, including bacteria, viruses and fungi. In low income settings, most of pneumonia infections in children are bacterial and are caused by *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Infected children can be treated with antibiotics, but the WHO calculates only around 30% of children with pneumonia receive the antibiotics they need, and this is caused in part by the lack of appropriate and/or timely diagnosis.

### 1.1 Diagnosis of Pneumonia

The WHO guideline for the Integrated Management of Childhood Illnesses (IMCI)<sup>2</sup> prescribes the methodology to assess suspected pneumonia in children under-five years of age in resource-poor settings. It focuses on various signs, which include measuring the respiratory rate of children suspected with pneumonia.

The lungs are made up of small sacs called alveoli, which fill with air when a healthy person breathes. In a pneumonia patient, alveoli are filled with pus and fluid, which makes breathing painful and limits oxygen intake. Therefore, respiratory rate increases and oxygen concentration in blood is reduced. Thus, fast respiratory rate and low blood oxygen concentration are taken as signs of pneumonia infection.

Since the 1990s, WHO and UNICEF have facilitated pneumonia diagnosis by supporting Community Health Workers (CHWs) with the use of a one-minute Acute Respiratory Infection (ARI) timer to assist in determining the length of time required to measure the respiratory rate in children. ARI timers have been distributed in over 70 countries in the last years and in many occasions they are used in combination with coloured counting beads<sup>3</sup>. However, recent field research has identified the need to improve the current diagnostic tool/ARI timer and increase its effectiveness as a diagnostic aid<sup>4</sup>.

The “Pneumonia: Improving Diagnosis Workshop” took place in Copenhagen on 31st January and 1st February 2013, and included participants from WHO, Bill and Melinda Gates Foundation (BMGF), USAID and representatives from civil society, industry and academia. In this workshop characteristics of the ideal device for diagnosis of pneumonia in low-income settings were defined, and it was agreed that a device to be used for this purpose should:

- Be easily placed in contact with the child for the shortest time possible
- Not distract the patient or CHW during the assisted diagnosis process
- Measure accurately the respiratory rate
- Provide a qualitative indicator of parameters relative to the age of the child

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<sup>1</sup> WHO, Pneumonia Fact sheet N°331 Reviewed November 2013.

<sup>2</sup> WHO and UNICEF. 2005. Handbook IMCI Integrated Management of Childhood Illness. ISBN 92 4 154644 1.

<sup>3</sup> UNICEF Innovation. Website: <http://unicefinnovation.org/projects/strengthening-pneumonia-diagnostic-tools-low-resource-settings>

<sup>4</sup> UNICEF Supply Division. 2013. Pneumonia Diagnostics: Current Outlook and Perspectives.

- Communicate the parameters in a way that can be easily communicated to the child's parents or guardian
- Be robust, durable and able to withstand extreme environmental conditions
- Not need disposables, renewables or such (e.g., electrodes, masks, mouth pieces, probes or sensors)
- Rely on renewable energy, whether through rechargeable cells or battery
- Have a clean, but sophisticated look, adding to its credibility
- Be lightweight, compact, easy to clean with disinfectant, water resistant and culturally acceptable.

In addition, devices should show information in colours other than green or red, in order to be used by colour-blind people and be suitable for use on different skin tones.

## 1.2 Malaria Consortium and the Pneumonia Project

Malaria Consortium is an international organisation dedicated to the control of malaria and other communicable diseases throughout Africa and South East Asia. Malaria Consortium is going to implement an eighteen-month grant to carry out operational research on pneumonia diagnostic tools in Cambodia, Ethiopia, Uganda and South Sudan.

To overcome the challenges with existing respiratory rate counting devices, several research groups have developed easy to use applications ("Apps") for use on mobile phones. A limited number of the mobile phone respiratory rate Apps have been evaluated in small, often statistically underpowered clinical studies, but there has not been a comprehensive comparison of the clinical performance, usability and acceptability of multiple Apps in an endemic setting. Similarly, technologies such as accelerometry have been applied to respiratory rate measurement and the clinical performance and usability of these methods in endemic settings is unknown.

A priority need is clinical evaluation of these new technologies compared to the UNICEF timer, including an assessment of the acceptability and usability of these new approaches from the perspective of the short trained community health worker, clinical staff working in peripheral facilities and below the level of registered nurse, as well as the caregiver. Children who are taken for treatment late are at risk of developing severe pneumonia; the inability of health care workers to adequately recognize danger signs and urgently refer children to a higher level of care, leads to the death of many children. Hypoxemia has been identified as a predictor for morbidity and mortality in children with respiratory illness. While pulse oximetry (POx) is a reliable and non-invasive method for identifying hypoxemic children, POx devices are rarely available outside the higher-level facilities in resource-constrained countries.

## 2. Methodology

The short listing of devices for the diagnosis of pneumonia was carried out separately for respiratory rate counters and for pulse oximeter devices. The search for appropriate respiratory rate counters was based on the list of devices (158 items) provided by the organization PATH (Program for Appropriate Technology in Health)<sup>5</sup>. The pulse oximeter devices list was produced based on the own search of information. Both lists, summarized in

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<sup>5</sup> PATH. "Landscape of Respiratory Rate Counters Available and In-Development. Working Draft". October 4, 2013.

the tables shown in the Results section were created according to the following classification criteria:

<b>Cost</b>	The cost effectiveness and affordability of the product
	The existence of recurring costs and rates of consumption of any consumables during the life cycle of the product
	Cost and burden to government procurement
<b>Robustness</b>	The duration of life cycle replacement, to be measured in years
	The recharge frequency, duration, and life span of battery cells and charger
	The need for a maintenance / care regime and recycling options
<b>Scale / Applicability</b>	The products ability to reach urban, rural, regional or global scale, fit and adaptability
	User context and cultural sensitivity
	Manufacturer supply capacity, scalability and sustainability
<b>CHW Skills</b>	Need for literacy and numeracy, to be measured in terms of high, medium or low necessity
	Need for training, to be measured in terms of minutes, hours, weeks in duration
	Familiarity with technology, to be measured in terms of whether based on analogue, mobile/smart phone or computer based technology
<b>Accuracy / Scope</b>	The level of sensitivity and specificity
	The level of automation, to be defined in terms of whether the device is dependent on human count, assisted count or fully automated count
	The level of decision making support, to be defined in terms of whether there is a classification, a classification to remedy, or a classification to remedy and treat
	The level of functionality, to be defined in terms of whether the device measures breaths, multiple data points or multiple data points beyond pneumonia
<b>Credibility</b>	The level of community trust the device inspires in how the device reads and presents the test results
<b>Extensibility</b>	The presence and need for hard coding
	Whether the device is a single device or provides a platform base for additional functions
<b>Availability</b>	Whether the device is available to be tested at the next stage of the process

Once the initial information about each device was obtained and its suitability for the project was assessed, manufacturers were contacted per email and telephone to obtain further technical specifications and prices.

### 3. Results

#### 3.1 Respiratory rate counters

Respiratory rate counters have been divided into categories according to the PATH report as shown on Table 1.

Method		Description
<b>Non-Automated</b>		
<b>Manual count</b>	Analogue device	Timer used to inform the observer when to start and stop counting RR.
<b>Assisted count</b>	Counting beads	Colour-coded string of beads eliminates the need for an observer to remember breath count and indicates diagnosis according to the child's age. Must be used in combination with a timer.
	Digital device	Stand-alone digital tally counter with built-in one-minute timer eliminates the need for an observer to remember breath count by having the user press a button to register each breath.
	Mobile software application	Software-based mobile phone or tablet application with timer eliminates the need for an observer to remember breath count by having the user press a button or touch the screen to register each breath.
<b>Automated</b>		
<b>Exhaled breath</b>	Humidity	RR derived from oronasal moisture sensors measuring increases in humidity in exhaled breath.
	Temperature	RR derived from oronasal temperature sensors measuring increases in temperature in exhaled breath.
	Air pressure	RR derived from oronasal sensors measuring increases in air pressure in exhaled breath.
	Carbon dioxide (ETCO <sub>2</sub> )	RR derived from oronasal capnography measuring carbon dioxide concentration in exhaled breath.
	Oxygen (ETO <sub>2</sub> )	RR derived from oronasal oxygen sensors measuring decreases in oxygen concentration in exhaled breath.
<b>Thoracic effort</b>	Thoracic circumference	RR derived from belt sensors measuring changes in thoracic circumference with respiration.
	Thoracic motion	RR derived from sensors measuring changes in thoracic motion with respiration.
	Tidal volume	RR derived from electrodes measuring changes in lung volume with respiration.
<b>Respiratory sounds</b>	Oronasal	RR derived from acoustic respiratory signals collected from exhaled breath near the oronasal area.
	Tracheal	RR derived from acoustic respiratory signals collected from the throat or neck.
	Thoracic	RR derived from acoustic respiratory signals collected from the chest, back, or armpit.
<b>Indirect Effects on Cardiovascular Physiology</b>	Electrocardiogram (ECG)	Waveform morphology programs and signal processing techniques derive RR indirectly from the ECG measured using ECG electrodes.
	Photoplethysmogram (PPG)	Waveform morphology programs and signal processing techniques derive RR indirectly from the PPG measured using pulse oximetry.
	Arterial Blood Pressure (ABP)	Waveform morphology programs and signal processing techniques derive RR indirectly from arterial blood pressure.
	Peripheral arterial tonometry (PAT) waveforms	Waveform morphology programs and signal processing techniques derive RR indirectly from PAT waveforms.

Table 1. Types of Respiratory Rate counters and methods for the diagnosis of pneumonia. Source: PATH report.

Respiratory rate counters are divided into two major categories: non-automated and automated devices. Non-automated devices include tools that support the manual counting of chest movements, by indicating when to start and stop counting. Within the manual count devices, only the currently implemented UNICEF ARI timers are included (See Picture 1). The other devices support an assisted count, by automating or negating the need for manual counting of each chest movement. Assisted count devices include three sub-categories: counting beads, digital devices and mobile software applications. Counting beads refer to the ARI counting beads currently implemented in some African countries (See Picture 2) and are used in combination with ARI timers. The digital devices include the Philips Breath Counter undergoing field tests in Malawi and other similar devices.



Picture 1: ARI timer. Source BMGF



Picture 2: Counting beads. Source BMGF

Mobile software applications in the category of assisted count work when CHWs tap the screen or press buttons by each chest movement. They represent a good option because most of them can be downloaded for free and since they work on a smartphone, they are portable and displays are easy to understand. However, some of them have been designed for its exclusive use with iPhones, which could significantly increase the cost of their implementation.

Automated devices are based on the measurement of several different parameters in order to derive respiratory rate. Within this category four groups are included, based on what they measure: exhaled breath, thoracic effort, respiratory sounds and indirect effects on cardiovascular physiology. In general, few of the devices in this category were considered appropriate for the study, either because of the elevated cost, lack of suitability for their use with children and newborns, because they were not portable or because they could be difficult to understand by CHWs.

One example of a potentially unsuitable device is the device designed to measure exhaled breath through humidity using a mask over the patient's face. In this case, paediatric or newborn sizes would be required and the risk for cross-infections could be increased when being applied for different patients. Other approaches that are not appropriate for children and neonatal, are ones based on the measurement of air pressure using spirometry. This is not possible to apply within this age range. Other methods to calculate respiratory rate are based on the measure of body temperature by applying sensors on the skin. However, these are, in general, difficult to be used with children under 5 years of age, since the technique requires the patient to keep still. For this reason, several research groups are working towards the development of sensors for non-contact measurement of respiratory rate. Unfortunately, these approaches are still in development and not currently available for field testing.

Many of the devices that measure respiratory rate have been designed for the monitoring of vital signs of patients within healthcare facilities, in post-surgical situations for example, or to be used in sleep laboratories. Therefore, most of these are difficult to adapt for use in rural African or Asian health conditions, since they are based on the use of sophisticated equipment which is often not-portable and of high cost. Also, they have typically been developed to be



used to send information to a central information system within the health facility where the patient is monitored, rather than as a stand-alone tool.

Within the category of devices that measure respiratory sounds, another group of mobile phone applications is included. This seems to be a good option because of the ease of use, the potential for increased credibility by CHWs and their affordability. However, none of these have been tested with children and neonatal and the results may not prove accurate enough since they need to measure the sounds produced by the exhaled breath, which is of a lower volume compared to an adults.

Table 2. Respiratory Rate Counters

Nr.	Method	Description	Developer	Source of information	Cost	Robustness	Scale/Applicability	CHW Skills	Accuracy/Scope	Credibility	Extensibility	Availability
Non-automated												
Assisted count												
1	Digital devices	Philips Breath Counter	Philips	Brochure: <a href="http://www.design.philips.com/philips/shared/assets/design_assets/pdf/nvbD/august2009/Fighting_pneumonia.pdf">http://www.design.philips.com/philips/shared/assets/design_assets/pdf/nvbD/august2009/Fighting_pneumonia.pdf</a>	Information not available (not available commercially)	Solar energy. No need for batteries. Suitable to be used with children and newborns. Already tested in the field.	Portable. Non-contact measurement. Appropriate for its use in the field.	Easy to understand for non-skilled CHW	No information on accuracy.	All of CHW appreciated the simplicity and beauty of the device in the field studies	Respiratory rate	No longer under development.
2	Mobile Software applications	Malaria Consortium inSCALE mobile Application	Malaria Consortium and CommCare	website: <a href="http://www.youtube.com/watch?v=QpEHkpZjsLg">http://www.youtube.com/watch?v=QpEHkpZjsLg</a>	No information on cost.	Smartphone batteries.	Portable. Non-contact measurement. Appropriate for its use in the field and with children and newborns. Available in Portuguese.	Easy to understand for non-skilled CHW	No information on accuracy.	Potential for high credibility (information displayed on a smartphone)	Respiratory rate and other disease symptoms.	Available for research.
3		7Breaths	Clinical Software Solutions	website: <a href="https://itunes.apple.com/us/app/7breaths-respiratory-rate/id663101259?mt=8">https://itunes.apple.com/us/app/7breaths-respiratory-rate/id663101259?mt=8</a>	Free mobile application. Compatible with iPhone, iPad, and iPod touch. This app is optimized for iPhone 5.	iPhone batteries	Portable. Non-contact measurement. No information about suitability for its use with children and newborns	Easy to understand for non-skilled CHW	No information on accuracy (not intended for clinical diagnosis)	Potential for high credibility (information displayed on an iPhone)	Respiratory rate	Commercially available
4		Respiratory Rate Recorder	Woodswest Ltd	website: <a href="https://itunes.apple.com/us/app/respiratory-rate/id573065068?mt=8">https://itunes.apple.com/us/app/respiratory-rate/id573065068?mt=8</a>	Free mobile application (download from iTunes). Requires iOS 3.2 or later. Compatible with iPhone, iPad, and iPod touch.	iPhone batteries	Portable. Non-contact measurement. No information about suitability for its use with children and newborns	Easy to understand for non-skilled CHW	No information on accuracy (not intended for clinical diagnosis)	Potential for high credibility (information displayed on an iPhone)	Respiratory rate	Commercially available

5	RespCount 1.0	Neal Kraus	website: <a href="http://www.ddcode.com/mobile/re/respcount.html">http://www.ddcode.com/mobile/re/respcount.html</a>	0,99 USD. iPhone price (160 USD in India). Compatibility: Requires iOS 4.3 or later. Compatible with iPhone, iPad, and iPod touch. This app is optimized for iPhone 5.	iPhone batteries	Portable. Non-contact measurement. No information about suitability for its use with children and newborns	Easy to understand for non-skilled CHW	No information on accuracy (not intended for clinical diagnosis)	Potential for high credibility (information displayed on an iPhone)	Respiratory rate	Commercially available	
6	RRate	BC Children's Hospital (Mark Ansermino)	website: <a href="https://play.google.com/store/apps/details?id=ca.bccw.rrate">https://play.google.com/store/apps/details?id=ca.bccw.rrate</a>	Free mobile application. Smartphone price needs to be added.	Smartphone batteries.	Portable. Non-contact measurement. Designed to be used with children and newborns.	Easy to understand for non-skilled CHW	No information on accuracy.	Potential for high credibility (information displayed on a smartphone)	Respiratory rate	Commercially available	
<b>Automated</b>												
<b>Exhaled breath</b>												
7	Carbon Dioxide (ETCO2)	SureSigns® VM1	Philips	website: <a href="http://www.healthcare.philips.com/main/products/patient_monitoring/products/suresigns_vm1/">http://www.healthcare.philips.com/main/products/patient_monitoring/products/suresigns_vm1/</a>	No information on price.	<b>Battery:</b> internal lithium ion 10.8 - 11.1 V, Operating time: 6 hours with continuous SpO2	Suitable for adult, pediatric and neonatal use. Portable monitor.	Need for training of CHWs. Displays shows several values.	SpO2 measurement range: 0 - 100%, Accuracy range depends on sensor, Heart Rate measurement range: 30 to 300 bpm, Heart Rate accuracy: ±2% or ± 1 bpm, whichever is greater.	Potential for credibility	SpO2 and CO2 measurement parameters	Commercially available
<b>Thoracic Effort</b>												
8	Tidal Volume	BodyGuardian®	Preventice	Website: <a href="http://www.preventice.com/products/bodyguardian/">http://www.preventice.com/products/bodyguardian/</a>	No information on price.	Smartphone battery.	Portable. No information about suitability for its use with children and newborns	Need for training of CHWs. Displays shows several values.	No info available on accuracy.	Potential for credibility	EKG, heart rate, respiration rate, and activity level.	Commercially available. FDA clearance.

9		IntelliVue Cableless Respiration Pod	Philips	Brochure and FDA submission: <a href="http://incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577243/577247/582646/583147/PM_-_IntelliVue_Cableless_Measurement_brochure.pdf">http://incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577243/577247/582646/583147/PM_-_IntelliVue_Cableless_Measurement_brochure.pdf</a> %3fnodeid%3d6834979%26vernum%3d3	No information on price.	No information on type of batteries.	Portable. No information about suitability for its use with children and newborns	Need for training of CHWs. Displays shows several values.	No info available on accuracy.	Potential for credibility	Pulse and respiration rate, blood pressure, and arterial oxygen saturation.	Commercially available (FDA submission)
10	Thoracic motion	Equival™ EQ01 LifeMonitor	Philips - Equivital	Brochure: <a href="http://www.healthcare.philips.com/pwc_hc/main/homehealth/sleep/equivital/pdf/Equival_Sales_Sheet.pdf">http://www.healthcare.philips.com/pwc_hc/main/homehealth/sleep/equivital/pdf/Equival_Sales_Sheet.pdf</a>	No information on price. Need for platform (computer) to see results of data captured by sensor.	Li Ion rechargeable battery. Temperature Sensing Range: -10°C to 60°C	Portable. Not validated for newborns and children.	Need for training of CHWs. Displays shows several values.	No info available on accuracy.	Potential for credibility	ECG, HR, Core & Skin , Temperature, Respiratory Rate and others	Commercially available
11		Equival™ EQ02 SEM	Vivonoetics	Website: <a href="http://vivonoetics.com/products/sensors/equivital/">http://vivonoetics.com/products/sensors/equivital/</a>	No information on price. Need for platform (computer) to see results of data captured by sensor.	Up to 48 hours battery	Portable. Not validated for newborns and children.	Need for training of CHWs. Displays shows several values.	No info available on accuracy.	Potential for credibility	ECG, HR, Core & Skin , Temperature, Respiratory Rate and others	Commercially available. FDA and CE marked.
12		inspire™ Infant Respiratory Rate Sensor (IRISS)	GuardIt and Project HOPE	Website: <a href="http://guardit.com/portfolios-3-columns/inspire-child-breathing-monitor/">http://guardit.com/portfolios-3-columns/inspire-child-breathing-monitor/</a>	Information not available (not available commercially)	Ruggedized for Harsh Environments	Portable. Suitable for its use with children and newborns	Easy to understand for non-skilled CHW	Designed specifically for diagnosis of pneumonia.	Potential for high credibility	Respiratory rate and oximeter (additional sensor). Used on a child in any position.	Available for research. An improved device will be ready to be tested in the field in June 2014.
13		Philips Vital Signs Camera	Philips	Website: <a href="http://www.vitalsignscamera.com/">http://www.vitalsignscamera.com/</a>	Free mobile application. iPad or iPhone 4S price needs to be added	Ipads has to be placed on a stable place.	Portable. No information about suitability for its use with children and newborns	Easy to understand for non-skilled CHW	No information on accuracy. Not intended for diagnosis or for clinical monitoring or decision making.	Potential for high credibility	Respiratory rate and heart rate	Commercially available

14		Respiratory Rate 1.1	Serdar Yagci	website: <a href="https://itunes.apple.com/us/app/respiratory-rate/id538726900?mt=8">https://itunes.apple.com/us/app/respiratory-rate/id538726900?mt=8</a>	Free mobile application. iPhone price needs to be added. Requires iOS 5.0 or later. Compatible with iPhone, iPad, and iPod touch.	iPhone has to be placed on chest.	Suitable for children and babies under 1 year old (but need for the child to be still)	Easy to understand for non-skilled CHW	No information on accuracy. Not intended for medical diagnosis.	Potential for high credibility	Respiratory rate	Commercially available
15		RespiSense™ Infant Breathing Monitor	RespiSense	website: <a href="http://www.respiSense.com/en/index.php">http://www.respiSense.com/en/index.php</a> website 2: <a href="http://www.healthchecksysteMS.com/respiSense_baby_monitor.cfm">http://www.healthchecksysteMS.com/respiSense_baby_monitor.cfm</a>	80 to 100 USD	ER14250M battery	Portable. Recommended for baby's first year	Easy to understand for non-skilled CHW	No information on accuracy. Not intended for medical diagnosis.	Potential for credibility	Doesn't show respiratory rate. Only if baby stops to breath. Data need to be uploaded in internet to analyse RR.	Commercially available
16		ZephyrLIFE™ BioPatch™	Zephyr	Data sheet and website: <a href="http://www.zephyranywhere.com/healthcare/">http://www.zephyranywhere.com/healthcare/</a>	No information on price.	Battery Type: Rechargeable Li Ion; Battery Life: 24 Hours per charge. Water Resistant up to 1m.	Portable sensor but need for platform (computer) to see results of data captured by sensor. No information about suitability for its use with children and newborns	Need for training of CHWs. Displays shows several values.	Heart Rate Range: 0 – 240 BPM (± 1 BPM); Respiration Rate: 0 – 70 Breaths per Minute (± BPM),	Potential for credibility	Heart Rate, R-R Interval, Respiration Rate, ECG, Activity Level, Position, Posture	Commercially available
<b>Respiratory Sounds</b>												
17	Oronasal	Breath Counter 1.1	Softrove (Pvt.) Ltd	For android: <a href="https://play.google.com/store/apps/details?id=com.softrove.app.bc&amp;hl=en">https://play.google.com/store/apps/details?id=com.softrove.app.bc&amp;hl=en</a> for iPhone: <a href="https://itunes.apple.com/us/app/breath-counter/id599505398?mt=8">https://itunes.apple.com/us/app/breath-counter/id599505398?mt=8</a>	Free App. Smartphone price needs to be added.	Smartphone batteries.	No information about suitability for its use with children and newborns	Easy to understand for non-skilled CHW	Not intended for diagnosis or for clinical monitoring or decision making.	Potential for high credibility	Respiratory rate	Commercially available

18	Breath Health Tester Pro	Sirius Studio	website: <a href="https://play.google.com/store/apps/details?id=org.app.breath_rate&amp;hl=en">https://play.google.com/store/apps/details?id=org.app.breath_rate&amp;hl=en</a>	0,76 euros download. Smartphone price needs to be added.	Smartphone batteries.	No information about suitability for its use with children and newborns	Easy to understand for non-skilled CHW	Not intended for diagnosis or for clinical monitoring or decision making.	Potential for high credibility	Respiratory rate	Commercially available	
<b>Indirect Effects on Cardiovascular Physiology</b>												
19	Electrocardiogram (ECG)	LifeTouch HRV011	Isansys	Article and website: <a href="http://www.isansys.com/en/products/sensors">http://www.isansys.com/en/products/sensors</a>	Approximately 200 USD.	72 hours (Normal mode). Information on Power Supply: Not user accessible	Portable sensor but based on the use of a "hospital gateway" (central information system where information of sensors is sent). No information about its suitability with children and newborns	Need for training of CHWs. Displays shows several values.	Specifications: Respiration 4 - 100 breaths per minute	Potential for high credibility	Heart rate, respiration rate and heart rate variability. Allows monitoring.	Commercially available
20	Photoplethysmogram (PPG)	ihealthMonitor V 1.1.4	peng li	website: <a href="https://itunes.apple.com/us/app/ihealthmonitor/id639073690?mt=8">https://itunes.apple.com/us/app/ihealthmonitor/id639073690?mt=8</a>	Free Mobile Application (iTunes download). Requires IOS 6.1 or later. Compatible with iPhone, iPad, and iPod touch. This app is optimized for iPhone 5. Monitor price needs to be added.	iPhone batteries. Monitor batteries.	Portable. No information about its suitability with children and newborns	Need for training of CHWs. Displays shows several values.	No information on accuracy.	Potential for credibility	Respiratory rate, Heart Rate, Oxygen saturation and blood pressure.	Commercially available
21		ViSi® Mobile™	Sotera Wireless	Website: <a href="http://www.visimobile.com/">http://www.visimobile.com/</a>	No information on price.	Battery Type Li-Ion, 3.7 V., 2000 mAh, single cell Operating Time 12-24 hours (depending on use profile), Charge Time Less than 4 hours	Portable sensor but needs for platform (computer) to see results of data captured by sensor. No information about its suitability with children and newborns.	Need for training of CHWs. Displays shows several values.	Heart rate accuracy range: 0 to 240 BPM; Respiration Rate accuracy Range: 3 to 50 BR/min; SpO2 Accuracy Range: 70 to 100%; Pulse Rate accuracy range: 30 to 240 BPM	Potential for credibility	Blood pressure, Pulse oximetry, Heart Rate and ECG, Respiration Rate and Skin Temperature	Commercially available. FDA clearance.

### 3.2 Pulse Oximeter devices

There are currently several types of pulse oximeters available in the market, but for this report only portable pulse oximeters were considered. After an initial market-wide screening of potential models and brands, a selection of 24 devices was included in the final shortlist. These were divided into four main categories:

- Mobile application
- Fingertip Pulse Oximeter
- Handheld Pulse Oximeter
- Wrist Oximeter
- Any Position Oximeter

In order to measure oxygen saturation in blood through a mobile phone application it is necessary, in addition to a smartphone or iPhone, to also have an external finger sensor. Most of these applications can be downloaded for free; however the price of the phone and the sensor has to be also included when thinking on this approach. Oxygen values of the patient are shown on the display of the phone and can be easily understood by non-skilled CHWs. However, the majority of the mobile phone applications has not been designed for clinical purposes and have not been tested with children and newborns yet (or there is no information currently available).

Fingertip Pulse Oximeters are the most affordable option for measuring oxygen saturation (SpO<sub>2</sub>) in blood, and almost all of them show values of pulse rate in addition to the SpO<sub>2</sub>. A selection of fingertip pulse oximeters suitable to be use with children and showing display values in blue and black was conducted (See Table 3). A limitation found within this category is that some of the fingertip pulse oximeters designed for paediatric use have a limited age range of 2 to 13 years old or 15 kg weight and they are therefore not suitable for use with neonatals.

Handheld Pulse Oximeters tend to be more expensive than Fingertip Pulse Oximeters and are designed for professional rather than for home use. Many of them are suitable for adults, children and newborns, since oxygen is measured using a finger external sensor that can be purchased separately for paediatric and neonatal use. As with fingertip Pulse Oximeters, handheld oximeters show values of SpO<sub>2</sub> and pulse rate in different colours on the display, but, in general, they would need additional training of CHWs because they are more complex to operate.

Devices included in the Wrist Pulse Oximeters category were designed to show several values (SpO<sub>2</sub> and pulse rate only, or these plus other vital signs) on the screen and to transfer information via Bluetooth to a monitoring system, either on a computer or a mobile phone. There is no information available on their suitability for use with children and newborns, but since measurement is carried out by placing the pulse oximeter on the wrist, these types of devices may not be suitable for children under 5 years old.

Finally, only one suitable device was included in the category of “any position oximeter” and corresponds to the Inspire™ approach designed specifically for the diagnosis of pneumonia. This device includes not only pulse oximetry, but it also measures respiratory rate and it can be used with children and newborns in different positions. Unfortunately, an improved version of this device will not be available for field tests until approximately June 2014.

Table 3. Pulse Oximetry Devices

Nr	Description	Developer	Development Stage (updated info 2014)	Cost	Robustness	Scale/Applicability	CHW Skills	Accuracy/Scope	Credibility	Extensibility	Availability
<b>Mobile applications</b>											
1	iOximeter	Safe Heart	<p>website 1: <a href="http://safeheartus.com/">http://safeheartus.com/</a></p> <p>website 2: <a href="https://play.google.com/store/apps/details?id=com.ioximeter&amp;hl=en">https://play.google.com/store/apps/details?id=com.ioximeter&amp;hl=en</a></p> <p>website 3: <a href="http://www.indiegogo.com/projects/ioximeter">http://www.indiegogo.com/projects/ioximeter</a></p>	Free application. iOximeter (59 USD) and smartphone (100 USD) price needs to be included	Requires no batteries. Powered by the headphone jack.	Portable. No information about its use with children and newborn.	No need for too much training. SpO2 could be confused with pulse rate.	<b>SpO2 measurement:</b> Range: 70% - 100%, Accuracy: $\pm 2\%$ ; <b>Pulse rate measurement:</b> Range: 40 bpm-250 bpm	Display on mobile phone	Blood Oxygen Saturation and Pulse Rate.	Commercially available soon (April 2014)
2	ihealthMonitor V 1.1.4	Keliwei	<p>website: <a href="https://itunes.apple.com/us/app/ihealthmonitor/id639073690?mt=8">https://itunes.apple.com/us/app/ihealthmonitor/id639073690?mt=8</a></p>	Free Mobile Application (Can be downloaded from iTunes). Requires iOS 6.1 or later. Compatible with iPhone, iPad, and iPod touch. This app is optimized for iPhone 5. Information on the price of the monitor not available.	iPhone standard battery. No information on portable monitor batteries.	Portable. No information about its use with children and newborn.	Need for training. Displays shows a lot of different values and the use of an extra portable monitor needs	No information available on accuracy. Information from monitor is transferred via Bluetooth to the iPhone.	Display on portable monitor.	Electrocardiography (ECG), Blood pressure (NIBP), Pulse oximetry (SpO2), pulse rate and respiration rate. User can review the measured data by days, hours and minutes. User can also upload the measured results to the web cloud server, in order to obtain professional diagnosis and analysis.	Commercially available
3	iSpO2™ Pulse Oximeter	Masimo	<p>website: <a href="http://www.ispo2.com/default.aspx">http://www.ispo2.com/default.aspx</a></p>	150.00 USD (Amazon) (plus iPhone price). Compatible with iPad Air, iPhone 5, iPad (3rd generation), iPhone 4S, iPod touch (4th generation), iPhone 4, iPhone 3GS	Ability to export data history into .CSV (comma separated values) files for use with text editing and spreadsheet programs such as Microsoft Excel.	Portable. No information about its use with children and newborn.	No need for too much training. SpO2 could be confused with pulse rate and perfusion index.	No info available on these specifications (non medical device).	Mobile phone display. Color display gives readings and graphs to trend measurements over time.	Measures oxygen saturation and pulse rate and perfusion index	Commercially available
4	The Phone Oximeter™	BC Children's Hospital and LionsGate Technologies	<p>website: <a href="http://www.phoneoximeter.org/">http://www.phoneoximeter.org/</a> website 2: <a href="http://lgtmedical.com/products/phone-oximeter/">http://lgtmedical.com/products/phone-oximeter/</a></p>	Not commercially available. Need to add smartphone price.	Requires no batteries. Powered by the headphone jack.	Portable. Suitable for children and newborn	Can be used by non-specialist healthcare workers and even patients at home	No info available on these specifications	LCD display; audio, serial and USB connectivity	SpO2 (oxygen saturation)	Commercially available soon.



5	Wireless Pulse Oximeter	iHealth	website: <a href="http://www.ihealthlabs.com/health-and-fitness-products-wireless-wireless-pulse-oximeter_80.htm">http://www.ihealthlabs.com/health-and-fitness-products-wireless-wireless-pulse-oximeter_80.htm</a>	70 USD (iHealth website). iPhone price needs to be added (Compatibility with: iPhone 4S+, iPad 3+, iPad Mini, iPod touch 5th generation+)	<b>Power:</b> Battery, 3.7V li-ion, 300mAh. <b>Operation environment:</b> 5°C-40°C; Humidity <80%; Storage environment: -20°C-55°C; Humidity <95%	Portable. Finger pulse oximeter. The device has been tested on an open heart surgery with a child of about 3 or 4 years old, but there is no further experience.	No need for too much training. SpO2 could be confused with pulse rate.	<b>SpO2 measuring range:</b> 70-99%; SpO2 accuracy: 70-99%, ±2%; <70%, no definition; <b>Pulse rate measuring range:</b> 30-250bpm; Pulse rate accuracy: ±2bpm or ±2% larger one	Display on sensor: LED. The same information can be seen on the iPhone display (need to download mobile application).	spot-check blood oxygen saturation (SpO2) and pulse rate (BPM)	Commercially available
<b>Finger Pulse Oximeter</b>											
6	Finger Pulse Oximeter	Shanghai Berry Electronic Tech co. Ltd	Factsheet: <a href="http://www.berry-med.com/en/pro_show.asp?id=18">http://www.berry-med.com/en/pro_show.asp?id=18</a>	25-30 USD (Alibaba.com). Smartphone price needs to be added.	Resist to environmental light and weak perfusion ability.	Usable in scopes of hospitals, families, community health care, sports health care and so on. Information from pulse oximeter is transferred via Bluetooth to the smartphone.	No need for much training on its use, but display could be difficult to understand for non-skilled CHWs (it shows different values).	No information available on accuracy.	Display on smartphone or computer.	SpO2 and pulse frequency. Testing spo2 and pulse frequency, via bluetooth transmission, pulse waveform and the stick figure can be shown on the screen of mobile phones and computers.	Commercially available
7	DP2043 - Fingertip Pulse Oximeter	Narang Medical limited	website: <a href="http://www.narang.com/diagnostic-equipments-products/pulse-oximeters/">http://www.narang.com/diagnostic-equipments-products/pulse-oximeters/</a>	33,60 USD (Narang Medical)	Low power consumption. Auto shut-off with no signal for 5 seconds.	Portable. Optional sensor for children and newborn	No need for too much training. SpO2 could be confused with pulse rate	No information available on accuracy.	LCD screen display SpO2, PR, and SpO2 waveform, Small & lightweight design.	Oxygen Level and Pulse Rate measurements,	Commercially available
8	DP2047 - Fingertip Pulse Oximeter	Narang Medical limited	website: <a href="http://www.narang.com/diagnostic-equipments-products/pulse-oximeters/">http://www.narang.com/diagnostic-equipments-products/pulse-oximeters/</a>	50,40 USD (Narang Medical)	Low power consumption, Auto shut-off with no signal for 5 seconds,	Portable. Suitable for adult, pediatric and neonate	No need for too much training. SpO2 could be confused with pulse rate	No information available on accuracy.	LCD screen display SpO2, PR, and SpO2 waveform, Small & lightweight design	Oxygen Level and Pulse Rate measurements. Build-in memory, with PC software analyzing.	Commercially available
9	Pediatric Pulse Oximeter - Portable Heart Rate Monitor for Children	Global Care Market	website: <a href="http://www.globalcaremarket.com/us/pediatric-pulse-oximeter-for-children.html">http://www.globalcaremarket.com/us/pediatric-pulse-oximeter-for-children.html</a>	53 USD	<b>Power Supply:</b> Voltage 3.6 rechargeable lithium battery × 1. Battery working hour: 10 hours	Portable. Pediatric use. For use with children as young as 3 years old and as old as 12 years old	No need for too much training. SpO2 could be confused with HR	<b>SpO2 Measuring Range:</b> 0% - 100%; <b>PR Measuring Range:</b> 30bpm - 250bpm, (the resolution is 1bpm)	Pulse rate value display, bar graph display; A pulse rate sound indication; Display Mode: Segment LCD display	SpO2 and PR value display. LCD display (black numbers)	Commercially available

10	SPO Medical PulseOx 6000™	SPO Medical	website: <a href="http://www.spomedical.com/">http://www.spomedical.com/</a>	250.74 USD (Vitality Medical)	Long lasting battery: 500 hours	Portable. For pediatric use (no specification on age range).	No need for too much training (easy to understand display)	Suitable both for home and professional use. No information available on accuracy of measurements.	LCD display. Easy-to-read illuminated LCD with bi-directional readings	Oxygen saturation (SpO2) and heart rate	Commercially available
11	Pediatric Finger Pulse Oximeter Choice MD300C5	Amperor	website: <a href="http://www.amperordirect.com/pc/c-pulse-oximeter/choice-mmed-finger-oximeter-md300c54.html">http://www.amperordirect.com/pc/c-pulse-oximeter/choice-mmed-finger-oximeter-md300c54.html</a>	50 USD	<b>Battery:</b> 2 AAA Alkaline or rechargeable batteries; Low power consumption, automatically power off; Low power indicator. <b>Operation time:</b> 30 hours under normal conditions.	Portable. Pediatric use. For children weighing 33-100 lb or 15-45 kg.	No need for too much training. SpO2 could be confused with pulse rate	<b>SpO2:</b> Measurement range: 70-99%; Accuracy: @80%-99%, ±2%; @70%-79%, ±3%; Resolution: ±1%. <b>Pulse rate:</b> <b>Measurement range:</b> 30-235 BPM; Accuracy: 30-100: ±2 BPM; 101-235: ±2%; Resolution: ±1 BPM. Suitable to be used for clinical and home purposes.	Small & lightweight design (total 25g without batteries). Dual color OLED display with 10 levels of brightness	Display: SpO2, pulse rate, bar Graph, SpO2 waveform. FDA approved.	Commercially available.
12	BV Medical Pediatric Finger Pulse Oximeter	BV Medical	website: <a href="http://bvmedical.com/catalog/index.php?main_page=product_info&amp;cPath=70&amp;products_id=192">http://bvmedical.com/catalog/index.php?main_page=product_info&amp;cPath=70&amp;products_id=192</a>	100 USD (Drugstore.com)	2 AA Batteries,	Portable. Finger pulse oximeter. Blue numbers. Suitable for pediatric use.	No need for too much training. SpO2 could be confused with pulse rate	SpO2 Range: 0-100%, SpO2 Accuracy: ± 2% (70%-99%), unspecified <70%; Pulse Range: 30-250 bpm, Pulse Accuracy: 2%	Display shows SpO2 and pulse rate. Blue numbers.	Oxygen level and Pulse rate. Recommended for home use.	Commercially available
13	Pediatric Pulse Oximeter OclaveTech 300PN	Clinical Guard	website: <a href="http://www.clinicalguard.com/pediatric-pulse-oximeter-p-75.html">http://www.clinicalguard.com/pediatric-pulse-oximeter-p-75.html</a>	79 euros (Clinical Guard)	<b>Battery:</b> Type: 2 AAA Alkaline batteries, Operation time: 30 hours of normal operation. <b>Environmental:</b> Operating Temperature: 5C-40C; Storage Temperature: -10C – 40C; Operating humidity: 15%RH-80%RH; Storage Humidity:10%RH-80%RH	Portable. Pediatric use. The age range for pediatric use is 2 -13 years and there is a minimum weight of 35lbs. or 16kg.	No need for too much training. SpO2 could be confused with Heart Rate.	<b>SPO<sub>2</sub>:</b> Range: 0%-99%; Resolution: 1%; Accuracy: 80%--99%, ±2%; 70%--80%, ±3%; 0%-69%, unspecified. <b>Pulse Rate:</b> Range: 0-235 BPM; Resolution: 1bpm; Accuracy: ±2bpm or ±2%	One button operation. Display: Type: OLED; Parameter: spo2, PR, bargraph, spo2 waveform; Mode: 6 display modes	4 parameters reading (SpO2, PR, Heart beat bar-meter, and heart beat waveform).	Commercially available.

## Handheld Pulse Oximeter

14	DARAY V202 handheld pulse oximeter	DARAY Medical	Brochure: <a href="http://www.medscope.co.uk/images/V202.pdf">http://www.medscope.co.uk/images/V202.pdf</a>	199.00 GBP (Excluding VAT at 20.00%) (Medscope). Additional sensors for children and newborns (85 GPB each)	AA alkaline batteries or rechargeable batteries	Portable. Suitable for children and newborns with additional sensors.	No need for too much training. SpO2 could be confused with pulse rate	SpO2: Measurement range 35% - 99%, Accuracy $\pm 2\%$ (70-100%), (0-69%) unspecified. <b>Pulse rate:</b> Measurement range 30 - 250 bpm, Accuracy $\pm 2$ bpm	Large, bright LED displays. Red numbers.	Oxygen saturation (SpO2) and pulse rate	Commercially available
15	Handheld Pulse Oximeter Model:AH-MX	LifeBox	website: <a href="http://www.lifebox.org/">http://www.lifebox.org/</a>	\$250/£160/€192. They have also a donation programme.	Battery: 3 AA Alkaline batteries or NIMH rechargeable battery (optional) or Lithium ion rechargeable battery (option). Runtime: 14 hours standard use	Portable. According to WHO specifications. Adult, Pediatrics and neonatal patients	Need for training of CHWs. SpO2 and Pulse Rate shown on display but several buttons.	SpO2: Range 0 100%, Resolution 1%, Accuracy 70% to 100%: $\pm 2\%$ , Refreshing rate < 13 seconds; <b>Pulse Rate:</b> Range 25-250 bpm, Resolution 1 bpm, Accuracy $\pm 2\%$ or $\pm 1$ bpm, whichever is the greater Refreshing rate < 13 seconds.	Display: Type 2.4" color display 320 x 240 pixels, Digital SpO2 , Pulse Rate, Pleth bar & SpO2 waveform	Oxygen saturation (SpO2) and pulse rate	Commercially available
16	UT100 Handheld Pediatric Pulse Oximeter	UTECH Co. Ltd	website: <a href="http://cqutech.en.alibaba.com/product/536336740-209738566/2_8_inch_UT100_Handheld_Pulse_Oximeter_with_CE.html">http://cqutech.en.alibaba.com/product/536336740-209738566/2_8_inch_UT100_Handheld_Pulse_Oximeter_with_CE.html</a>	USD115/1 unit; USD110/1 unit for 10 unit	<b>Power supply:</b> AC power: 100-240VAC,47-63Hz, Four AA 1.5V alkaline or Ni-MH cells. <b>Environment Specification:</b> Operating temp:0 to 45°, Storage temp:-20 to 60°, Relative humidity:30 to 95%(operating),10 to 95%(storage)	Portable. Adult, Pediatric and Neonate use	Need for training of CHWs. SpO2 and Pulse Rate shown on display but several buttons.	SpO2: Range:0-100%, Accuracy: $\pm 2$ at 70-100%; <b>Pulse rate:</b> Range: 30-250bpm, Accuracy: $\pm 2$ at 30-250bpm	Color LCD Display and screen rotation.	SpO2 and pulse rate	Commercially available
17	A360 Handheld Pulse Oximeter	Aeon Technology	website: <a href="http://www.aeon-med.com/medicalequipment/A360_Handheld_Pulse_Oximeter.html">http://www.aeon-med.com/medicalequipment/A360_Handheld_Pulse_Oximeter.html</a>	No information on price.	4x AAA Alkaline battery or rechargeable 1000MAH Li Battery	Portable. Optional sensor for children and newborn	No need for too much training. SpO2 could be confused with pulse rate	SpO2 display: 35% to 99%; Pulse rate display: 0- 250 bpm	Big size 2.8 inch colour TFT LCD display for SPO2/PR/Pulse bargraph/plethysmog ram	SpO2 and pulse rate	Commercially available
18	DP2049 - Handheld Pulse Oximeter	Narang Medical limited	website: <a href="http://www.narang.com/diagnostic-equipments-products/pulse-oximeters/">http://www.narang.com/diagnostic-equipments-products/pulse-oximeters/</a>	133,00 USD (Narang Medical)	Low power consumption,	Portable. Suitable for adult, pediatric and neonate	Need for training. Display shows only two values but there are several buttons.	No information available on accuracy.	Large LED Display of SpO2, PR, and Pulse Bar, Durable, Compact and Lightweight. Audible/Visual Alarms with Adjustable Alarm Limits	SpO2 and pulse rate. Can Be Used for Spot-Check or Continuous Monitoring.	Commercially available

19	AstraPulse 3i™	SDI Diagnostics	Brochure and website: <a href="http://www.sdidiagnostics.com/astrapulse/astrapulse3i.php">http://www.sdidiagnostics.com/astrapulse/astrapulse3i.php</a>	449.99 USD (Medical Diagnostic Equipment and Supplies)	Low power consumption. Up to 24 hrs continuous use. 2AA Alkaline or NiMH or Li rechargeable cells. <b>Operating temperature:</b> 0°C – 50°C, <b>Storage temperature:</b> -10°C – 60°C, <b>Operating humidity:</b> 15% - 95% RH, <b>Storage humidity:</b> 10% - 95% RH	Portable. Suitable for Adult, Pediatric Neonatal use	No need for too much training. SpO2 could be confused with pulse rate	SpO2: Range: 0-255bpm, Resolution: 1%, Accuracy: 70%-100% : ±2%; <b>Heart (Pulse) Rate:</b> Range: 10-255bpm, Resolution: 1bpm, Accuracy: ±2bpm or ±2%	Display - SpO2, Pulse Rate (PR), SpO2 Wave form (pleth or line). Blue numbers.	SpO2 and pulse rate	Commercially available
20	Digital Palm Pulse oximeter for babies	Shanghai Berry Electronic Tech co. Ltd	website: <a href="http://berrymed.en.alibaba.com/product/1052244599-218673207/Digital_Palm_Pulse_oximeter_for_babies.html">http://berrymed.en.alibaba.com/product/1052244599-218673207/Digital_Palm_Pulse_oximeter_for_babies.html</a>	80-100 USD (Alibaba.com)	Resist to environmental light and weak perfusion ability. Interface: can be used to insert spo2 probe and cable. <b>Charging function:</b> using 2 AA batteries	Portable. Suitable for hospitals, families, communities, sports health care and other scope. For hospital's operation room, ICU, clinic section office, Out-patient department, sickroom and emergency treatment. It is suitable for Adult, Pediatric, Infant (Neonatal).	No need for too much training. SpO2 could be confused with Heart Rate.	<b>SpO2 Range:</b> 35-99% (Accuracy: ±2% at 70-99%) <b>Pulse Rate:</b> 30-255bpm (Accuracy: ±2% at 30-255bpm )	Large screen LDC display.	SpO2 and pulse frequency. Conventional testing mode and continuous monitoring mode	Commercially available
21	Hopkins Neonatal Pulse Oximeter With Adult Sensor / Infant Pulse Oximeter With Adult Sensor	Hopkins Medical Products	website: <a href="http://www.hopkinsmedicalproducts.com/product.jsp?path=1 2375 5662&amp;id=23641">http://www.hopkinsmedicalproducts.com/product.jsp?path=1 2375 5662&amp;id=23641</a>	169.95 USD (Hopkins Medical Products). Kit includes Pulse Ox Unit, Newborn Y-Probe Sensor, 10 Latex-Free/ Adhesive-Free Neonatal Probe Wraps, 10 Alcohol Cleaning Wipes, and a Royal Blue Zippered Case	<b>Power Supply:</b> 2x AAA Alkaline Batteries; Supply voltage: 3.0VDC; Operating current: ≤40mA. <b>Environment Specification:</b> Operating Temperature 41°F to 104°F, (5°C to 40°C); Operating Relative Humidity 30% to 80%; Operating Pressure 10.2 PSI to 15.4 PSI (70 kPa to 106 kPa); Storage Temperature -4 °F to 140 °F (-20 °C to 60 °C); Storage Humidity 10% to 95% (noncondensing); Storage Pressure 7.3 PSI to 15.6 PSI (50 kPa to 107 kPa); Electro-Magnetic Compatibility Group I Class B	Portable. Adult and neonate use.	No need for too much training. SpO2 could be confused with pulse rate	<b>SpO2 Performance Measurement:</b> Range 70% to 100%; SpO2 Accuracy not greater than 3% for SpO2 range from 70% to 100. <b>Pulse Rate Range:</b> 30 to 240 bpm; Pulse Rate Accuracy ±2bpm or ±2% (whichever is greater)	Rotating display; Audible alarm; 4-Color OLED; 4 Rotating Views	SpO2 and pulse rate	Commercially available

Wrist Pulse Oximeter

22	WristClinic™	Telcomed	website: <a href="http://www.telcomed.ie/allinone-bt.html">http://www.telcomed.ie/allinone-bt.html</a>	No information on price.	No information on batteries.	Portable. Multilanguage support. WristClinic transmits data wirelessly via Bluetooth. It is designed to support communication with devices running Windows™ mobile OS or Nokia mobile phones (J2ME). No information on its use with children and newborn.	Need for training. Several values shown on display and many command buttons.	No information on accuracy.	LCD screen	Heart rate, 1 lead ECG, Blood pressure, Heart rhythm regularity, Respiratory rate, Oxygen saturation (SpO2), Body temperature.	Commercially available
23	Berry CE OLED Bluetooth Wrist Pulse Oximeter for Blood Oxygen Pulse Oximetry	Shanghai Berry Electronic Tech co. Ltd	website: <a href="http://berrymed.en.alibaba.com/product/855044044-218673207/Berry_CE_OLED_Bluetooth_Wrist_Pulse_Oximeter_for_Blood_Oxygen_Pulse_Oximetry.html">http://berrymed.en.alibaba.com/product/855044044-218673207/Berry_CE_OLED_Bluetooth_Wrist_Pulse_Oximeter_for_Blood_Oxygen_Pulse_Oximetry.html</a>	45 - 50 USD (Shanghai Berry - Alibaba)	2 standard 1.5V AAA alkaline batteries	Portable. No information about its use with children and newborn. Function with USB interface, computer playback, Windows analysis software platform.	No need for too much training. SpO2 could be confused with pulse rate	SpO2 Range: 35-99% (Accuracy: ±2% at 70-99%), <b>Pulse Rate:</b> 30-255bpm (Accuracy: ±2% at 30-255bpm)	OLED display, pulse waveform and numerical value can be displayed. Blue numbers	SpO2 and pulse frequency.	Commercially available. CE certification.
<b>Any Position Pulse Oximeter</b>											
24	inspire™ Infant Respiratory Rate Sensor (IRISS)	GuardIt and Project HOPE	website: <a href="http://www.inspirelivinginc.com/">http://www.inspirelivinginc.com/</a>	Information not available (not available commercially)	Ruggedized for Harsh Environments	Portable. Suitable for its use with children and newborns	Easy to understand for non-skilled CHW	Designed specifically for diagnosis of pneumonia.	Easy to understand display	Respiratory rate and oximeter (additional sensor). Used on a child in any position.	An improved version will be available for research in June 2014

## 4. Challenges and Recommendations

The current gold standard method for the diagnosis of child pneumonia in low-income settings is the ARI Timer combined in some occasions with coloured counting beads. However, field research in Uganda and Ghana<sup>6</sup> described flaws in this approach and showed that improved methods are urgently needed. In this section, some suggestions based on the research carried out for the “Initial Pneumonia Device Short Listing” for the use of alternative tools are made.

### *Respiratory rate counters*

In general, for the diagnosis of pneumonia in rural low-income settings in Africa and Asia where the project will take place, few respiratory rate counters seem appropriate. After the screening of the list of devices provided by PATH, it can be concluded that the most appropriate devices are still under development and that using methods that derive respiratory rate from other parameters (such as Electrocardiography (ECG), Photoplethysmography (PPG) or other vital signs) require the use of further equipment, are too expensive or could result in confusing the CHWs further.

Taking into account only respiratory rate counters that are commercially available (or available for research studies), devices that seem to be the most suitable for implementation in the study are mobile phone software applications. In this category, two different applications can be distinguished: the ones that are used as counters using the phone screen to tap with each chest movement and the ones used by measuring the exhaled breath. This last category could be difficult to use with children under 5 years old because of the small volume of exhaled air.

Mobile phone applications also demonstrate some drawbacks, including the lack of validation in paediatric ages, the fact that most of them are not designed for clinical purposes and that some of them have been developed to be used exclusively with iPhones, which could increase the price of the approach. However, using a smartphone still represents a good option and would allow the use of different types of applications for diagnosis on the same apparatus, for example, by combining applications to measure respiratory rate by tapping on screen and measuring exhaled breath.

### *Pulse oximetry devices*

In general, suitable pulse oximeters for the diagnosis of pneumonia in children and newborns in rural conditions in Africa and Asia seem to be the Fingertip Pulse Oximeters, which are very easy to use (one single button) and provide with an on-the-spot result. The ones with LCD screens (show black numbers) are specially recommended. Some of them are designed exclusively for paediatric use, and others are also suitable for neonates. In general, Chinese and Indian manufacturers have affordable prices. Drawbacks on this device category could be that some of them have been developed for home rather than for professional use, and that oxygen saturation values could be confused with pulse rate values, which are also depicted on the screen.

Alternatively, Handheld Pulse Oximeters with a paediatric and/or neonate sensor could be also used.

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<sup>6</sup>Ipsos Synovate Ghana. (2012). Innovation for Pneumonia Diagnosis in Community-Based Case Management. Product Development Research in Northern Ghana.

*Next steps*

Based on this initial analysis, it is recommended that a further technical analysis is done to help create a device shortlist of possible devices to be taken forward for field analysis.

## ANNEX 1 – RESPIRATORY RATE COUNTERS PICTURES

### Respiratory Rate Counter 1

Philips Device

*Picture expected*

### Respiratory Rate Counter 2

Malaria Consortium inSCALE mobile app (CommCare)



### Respiratory Rate Counter 3

Clinical Software Solutions 7Breaths



Tap the lungs each time you see the chest wall rise

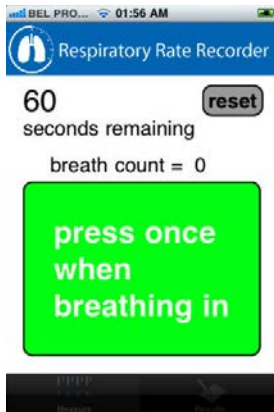


Mode: Sample over 1 min(s)



### Respiratory Rate Counter 4

Woodsweb Respiratory Rate Recorder



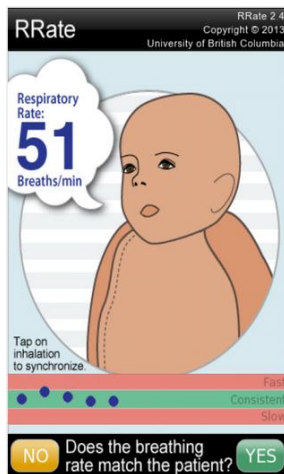
### Respiratory Rate Counter 5

RespCount 1.0

No picture available for this mobile application.

### Respiratory Rate Counter 6

RRate



### Respiratory Rate Counter 7

Philips SureSigns® VM1



**Respiratory Rate Counter 8**  
Preventice BodyGuardian®



**Respiratory Rate Counter 9**  
IntelliVue Cableless Respiration Pod



Mobile CL air hose



Mobile CL  
Transmitter cradle



Mobile CL  
Respiration Pod Attachment

**Respiratory Rate Counter 10**  
Equivital™ EQ01 LifeMonitor



**Respiratory Rate Counter 11**

Equivital™ EQ02 SEM



**Respiratory Rate Counter 12**

Inspire™ Infant Respiratory Rate Sensor (IRISS)



**Respiratory Rate Counter 13**

Philips Vital Signs Camera



**Respiratory Rate Counter 14**

Respiratory Rate 1.1

**Instruction**

Lay down on a flat surface on your back. Touch the start button. Place your iPhone between your ribcage and stomach as in the image. Breathe normally. After approximately 30 seconds you will hear a signal indicating the completion of the process.

**Start****Respiratory Rate Counter 15**

RespiSense™ Infant Breathing Monitor

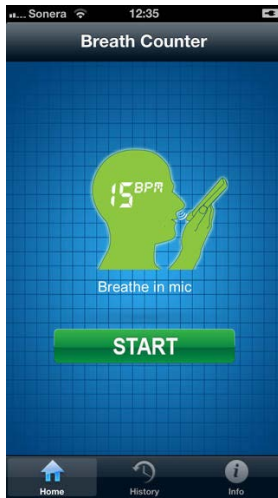
**Respiratory Rate Counter 16**

ZephyrLIFE™ BioPatch™



**Respiratory Rate Counter 17**

Breath Counter 1.1



**Respiratory Rate Counter 18**

Breath Health Tester Pro



**Respiratory Rate Counter 19**

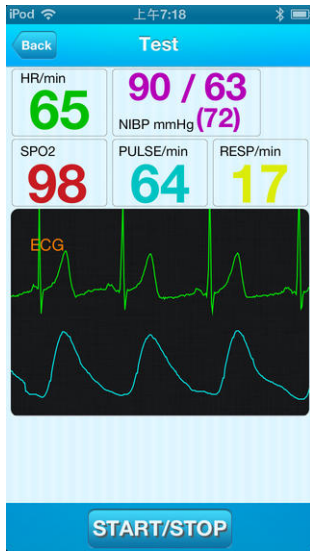
LifeTouch HRV011



This low-cost, wireless cardiac monitor resembles a lightweight Band-Aid strip that adheres to a patient's body.



**Respiratory Rate Counter 20**  
ihealthMonitor V 1.1.4



**Respiratory Rate Counter 21**  
ViSi® Mobile™



## ANNEX 2 – PULSE OXIMETERS PICTURES

### FINGER PULSE OXIMETERS

#### Pulse Oximeter 6

Shanghai Berry Electronic Technologies Finger Pulse Oximeter



#### Pulse Oximeter 7

Narang Fingertip Pulse Oximeter DP2043



#### Pulse Oximeter 8

Narang Fingertip Pulse Oximeter DP2047



**Pulse Oximeter 9**

Global Market Pediatric Pulse Oximeter Portable Heart Rate Monitor for Children

**Pulse Oximeter 10**

SPO Medical PulseOx 6000™

**Pulse Oximeter 11**

Amperor Pediatric Finger Pulse Oximeter Choice MD300C5





**Pulse Oximeter 12**

BV Medical Pediatric Finger Pulse Oximeter

**Pulse Oximeter 13**

Pediatric Pulse Oximeter OvtiveTech 300PN

**HANDHELD PULSE OXIMETERS****Pulse Oximeter 14**

Daray Handheld Pulse Oximeter



**Pulse Oximeter 15**

LifeBox Handheld Pulse Oximeter

**Pulse Oximeter 16**

UT100 Handheld Pediatric Pulse Oximeter

**Pulse Oximeter 17**

Aeon A360 Handheld Pulse Oximeter



**Pulse Oximeter 18**

Narang DP2049 - Handheld Pulse Oximeter



**Pulse Oximeter 19**

AstraPulse 3i™



**Pulse Oximeter 20**

Shanghai Berry Digital Palm Pulse oximeter for babies



**Pulse Oximeter 21**

Hopkins Neonatal Pulse Oximeter With Adult Sensor / Infant Pulse Oximeter With Adult Sensor



**WRIST PULSE OXIMETERS**

**Pulse Oximeter 22**

Telcomed WristClinic Bluetooth



**Pulse Oximeter 23**

Shanghai Berry Wrist Pulse Oximeter



**ANY POSITION PULSE OXIMETER**

**Oximeter 24**

Inspire™ Infant Respiratory Rate Sensor (IRISS)

