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NEST360°

Target Product Profile

Pulse Oximeter (Continuous) – Respiratory Support

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This report was prepared by Rebecca Kirby and Kara Palamountain from Northwestern University with input from UNICEF and other stakeholders. The document summarizes consensus achieved at a meeting on target product profiles for newborn care in low-resource settings, convened by NEST360°. This document was finalized following consideration of all comments and suggestions made by meeting participants at the Consensus Meeting.

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Note to the reader
Because of the richness of the discussion, and in an attempt to keep this report simple and readable, this report aims to convey the themes addressed in each session, rather than attempting to provide a chronological summary of the dialogue.

Disclaimer: The TPPs do not replace or supersede any existing UNICEF TPPs. The TPPs do not constitute tender specifications, nor is UNICEF bound to tender or procure products that arise as a result of these TPPs. UNICEF may require regulatory approval and proof of compliance to quality management and product-specific international standards for tendering purposes.

INTRODUCTION

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 established, and
3. pulmonary blood flow is increased.

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

Oxygen provision is important in the care of newborn infants because many conditions that affect babies in the first days of life can result in low levels of oxygen in the body. Hypoxemia, or low levels of oxygen in the blood, is a life-threatening condition that results in increased mortality and morbidity. Prematurity and respiratory distress syndrome (surfactant deficiency), pneumonia and other severe infections, asphyxia, and difficulties in the transition from fetal to neonatal life can all result in hypoxemia. Yet, despite its importance in acute severe illnesses, hypoxemia is often not well recognized or managed in settings where resources are limited. It is therefore important for health workers to know the clinical signs that suggest the presence of hypoxemia and how supplemental oxygen can appropriately be used as an essential lifesaving treatment [1].

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 non-invasive 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 [1].

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 [2,3]. 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.).

DEVELOPING A TARGET PRODUCT PROFILE

Overview

Manufacturers need Target Product Profiles (TPPs) at an early stage in the medical device and diagnostic development process. These TPPs help inform the ideal targets and specifications and align with the needs of end users. TPPs outline the most important performance and operational characteristics as well as pricing. In the TPPs to follow, the term "Minimal" is used to refer to the lowest acceptable output for a characteristic and "Optimal" is used to refer to the ideal target for a characteristic. The Optimal and Minimal characteristics define a range. Products should meet at least all of the Minimal characteristics and preferably as many of the Optimal characteristics as possible. TPPs should also specify the goal to be met (e.g. to initiate treatment), the target population, the level of implementation in the healthcare system and the intended end users.

For the NEST360° Newborn Care in Low-Resource Settings Target Product Profiles, an initial set of TPPs were developed listing a proposed set of performance and operational characteristics for 16 product categories. The development timeline envisioned in the TPPs was four years, although some commercially available technologies may fit some of the criteria already. For several of the characteristics, only limited evidence was available and further expert advice was sought from additional stakeholders.

Delphi-Like Process

To obtain this expert advice and to further develop the TPPs, a Delphi-like process was used to facilitate consensus building among stakeholders. The initial TPPs were sent to a more comprehensive set of stakeholders including clinicians, implementers, representatives from Ministry of Health, advocacy organizations, international agencies, academic and technical researchers and members of industry. In total, 103 stakeholders from 22 countries participated in the TPP development process via survey.

47 respondents participated in the Delphi-like survey for the Pulse Oximeter (Continuous).

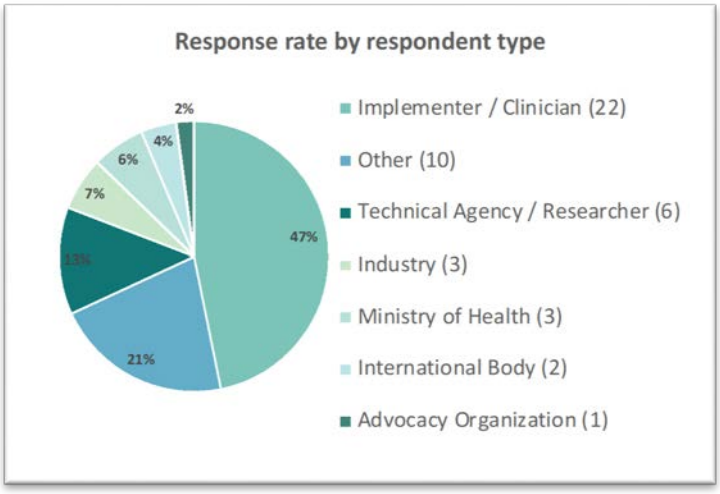
Survey respondents were requested to provide a statement on their level of agreement with each of the proposed characteristics for each TPP. Agreement was scored on a Likert scale ranging from 1 to 5 (1=disagree, 2=mostly disagree, 3= neither agree nor disagree, 4=mostly agree, 5=fully agree) with an option to opt out with the selection of "Other - Do not have the expertise to comment". If participants did not agree with the characteristic (i.e., selected 3 or below) they were asked to provide an explanation with comments. Participants who agreed with the statements could also provide comments however were not explicitly asked. In total, over 1,780 comments were reviewed and summarized in this report.

For each characteristic in each product category, a percentage agreement was calculated for both the Minimal and Optimal requirements. The percentage agreement was calculated as the ratio of the sum of number of respondents who selected 4 and 5, to the sum of numbers of respondents who gave any score (from 1 to 5 where 5=fully agree, 4=mostly agree, 3=neither agree nor disagree, 2=mostly disagree and 1=disagree). Consensus for the survey characteristics was pre-specified at greater than 50% of respondents providing a score of at least 4 on the Likert scale.

A classic Delphi process requires at least two rounds of survey ahead of an in-person meeting. Initially, two rounds of the survey were planned, but since 50% consensus for most characteristics was reached after the first round survey, a second round survey was not initiated. Survey results are detailed by characteristic in the individual product category sections.

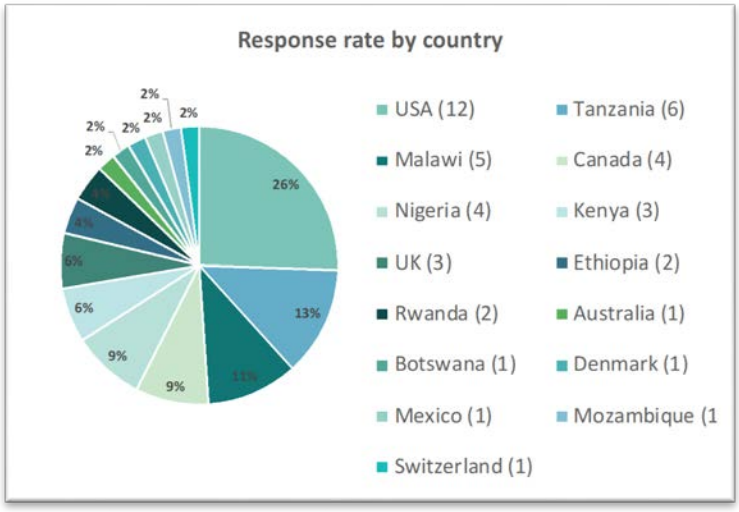
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

Figure 1: Summary of organizational affiliation for Pulse Oximeter (Continuous) TPP from Delphi-like Survey prior to Consensus Meeting (data as of Oct 25, 2019)



Respondent type	Percentage
Implementer / Clinician (22)	47%
Other (10)	21%
Technical Agency / Researcher (6)	13%
Industry (3)	6%
Ministry of Health (3)	6%
International Body (2)	4%
Advocacy Organization (1)	2%

Figure 2: Summary of response rate by country for Pulse Oximeter (Continuous) TPP from Delphi-like Survey prior to Consensus Meeting (data as of Oct 25, 2019)



Country	Percentage
USA (12)	26%
Tanzania (6)	13%
Malawi (5)	11%
Canada (4)	9%
Nigeria (4)	9%
Kenya (3)	6%
UK (3)	6%
Ethiopia (2)	4%
Rwanda (2)	4%
Australia (1)	2%
Botswana (1)	2%
Denmark (1)	2%
Mexico (1)	2%
Mozambique (1)	2%
Switzerland (1)	2%

Consensus Meeting

On November 20 - 22, 2019 over 69 stakeholders gathered in Stellenbosch, South Africa to focus on building further consensus on areas of discrepancy in opinion within the 16 TPPs. More specifically, characteristics on which fewer than 75% of the respondents agreed, or on which a distinct subgroup disagreed, were discussed. Consensus Meeting moderators presented the results and comments from characteristics with <75% agreement from the Delphi-like survey, the moderators then solicited additional feedback on each characteristic with <75% agreement from the Consensus Meeting participants, and then a proposed change to the TPP characteristic was discussed amongst Consensus Meeting participants. In some cases, Consensus Meeting participants nearly universally agreed on proposed changes. In other cases, Consensus Meeting participants failed to reach 75% consensus on proposed changes. If consensus was not achieved after two votes on proposed changes, meeting participants agreed to move forward and the disagreement is noted in this report.

Methodology for Mentimeter Voting Results: Certain proposed changes to TPP characteristics, for which a distinct subgroup disagreed, were anonymously voted on using Mentimeter.com to determine the overall level of agreement and disagreement amongst the Consensus Meeting participants. The Mentimeter Voting Results are presented throughout this report in three distinct categories:

I. Overall vote – Includes all Consensus Meeting participants who voted on Mentimeter.com. To eliminate the possibility of duplicate votes, all respondents were asked to enter their name (to be viewed only by the report authors) and blank (potentially duplicate votes) were eliminated from the overall vote.
II. Clinicians – Includes all Consensus Meeting participants who voted on Mentimeter.com and who designated themselves as a Clinician on Mentimeter.com.
III. Excluding involvement with product development - Includes all Consensus Meeting participants who voted on Mentimeter.com minus those who indicated on a Declaration of Interest form that they are 'currently or have been involved in the development of a candidate technology or product' specific to the Product Category being voted on.

Of the 133 stakeholders that were invited to the meeting, 69 participants were able to attend. Participants comprised country representatives, stakeholders from technical and funding agencies, researchers, implementers and civil society organizations, and representatives from companies working on newborn care technologies (see Appendix B for the Consensus Meeting Participant List). An overview of the discussion for Pulse Oximeter (Continuous) and final consensus achieved is included in this report. Most characteristics discussed are presented in this report, however, overarching characteristics that applied to all product categories were discussed in unison and are included in the NEST360° Newborn Care in Low-Resource Settings Target Product Profiles. These characteristics are: Target Operator; Target Population; Target Setting; Quality Management; Regulation; User Manual/Instructions; Warranty; Power Source; Battery; Voltage; Power Consumption.

FINAL TPP - PULSE OXIMETER (CONTINUOUS)

Final target product profile for Pulse Oximeter (Continuous)		
Characteristic	**Optimal**	**Minimal**
SCOPE		
Intended Use	To continuously monitor oxygen saturation (SpO2) and pulse rate (PR) for neonatal patients	
Target Operator	For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians	
Target Population	Neonates (born at any gestational age and require ongoing care)	
Target Setting	Hospitals in low-resource settings, but, may be used in health facilities based on country guidelines	Hospitals in low-resource settings
SAFETY AND STANDARDS		
Quality Management [1]	ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes	
Regulation	At least one of: CE marking, approved by US FDA or another stringent regulatory body of a founding member of IMDRF (e.g., Japan or Australia or Canada)	
TECHNICAL CHARACTERISTICS		
Pulse rate	25-250 bpm	30-240 bpm
Pulse rate accuracy	± 3 bpm	
Pulse rate resolution	1 bpm	
Sp02 Accuracy	± 2%	± 3%
Sp02 Range	0-100%	70-100%
Alarms	Visual and Auditory	Auditory
Alarm Limits - PR	Adjustable	80-180 bpm OR 100-180 bpm [2]
Alarm Limits - Sp02	Adjustable	
Continuous Measurement	Yes	
Patient Interface	Neonate specific, biocompatible and reusable	
Size	Easily moveable, not pocketable, can be secured	Handheld with dock
Weight	<500 grams, portable	
PURCHASING CONSIDERATIONS		
Accessories		
Consumables	>12 months before required	>6 months before required with 2 neonatal probes included in package

Instrument Pricing	<$150 ex-works	<$250 ex-works
Consumable Pricing	<$50 per year ex-works (two probes)	<$80 per year ex-works (two probes)
UTILITY REQUIREMENTS		
Power Source	Mains with rechargeable battery	Mains with rechargeable battery
Battery	Rechargeable battery, >24hr on single charge	Rechargeable battery, >6hr on single charge [3]
Voltage	None	Model must match the voltage and frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz)
TRAINING AND MAINTENANCE		
User Instructions	User manual and additional training materials (checklists, videos, guides) in at least one national official language for the country of intended use. Attached to device with labels and markings where possible	User manual provided in at least one national official language
Training Required	Minimal	
Warranty	5 years	1 year
Decontamination	Easy to clean with common disinfecting agents	
Usage Meter	Digitally stored record displaying cumulative hours of operation	Digitally stored record displaying 50 previous readings or >50 hours

[1] There was not 75% voting agreement on the Minimal characteristic. Please refer to the TPP Report discussion for additional detail.
[2] There was not 75% voting agreement on this characteristic. Please refer to the TPP Report discussion for additional detail.
[3] There was not 75% voting agreement on this characteristic. Please refer to the TPP Report discussion for additional detail.

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Consensus Meeting Summary: Pulse Oximeter (Continuous)

To arrive at the final TPP for Pulse Oximeter (Continuous), we conducted a pre-meeting survey to prioritize the items for discussion at the Consensus Meeting for characteristics that achieved below 75% agreement in the survey results. An overview of the discussion at the Consensus Meeting of these characteristics is included below.

- **Pulse Rate**
  - Clinicians in the room agreed that the Minimum characteristic should be aligned with the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [4, p. 126]. Note that for the Pulse Rate Accuracy, the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [4, p. 126] specify ± 3 bpm. International NGOs suggested that manufacturers be more transparent in sharing clinical outputs on data accuracy so that buyers can have assurance of claim. While consensus was achieved on the values of measurement, clinicians emphasized that guidance or protocols for behavior if a value falls outside of these ranges is not currently defined and would be helpful.
  - *Minimal: 30-240 bpm*

- Overall Vote - 100% Agree (n = 39)
- Clinicians - 100% Agree (n = 27)
- Excluding involvement with product development - 100% Agree (n = 35)

- **Alarms**
  - There was disagreement on whether the Minimal characteristic should require both an auditory and visual alarm. Clinicians discussed that auditory alarms are better at drawing attention, especially when wards may be short-staffed. Product developers confirmed that an auditory alarm was slightly more expensive than a visual alarm and that having both alarms added roughly $3 to the overall cost. Two concerns with auditory alarms were mentioned (alarm fatigue and noise levels impacting baby), however, clinicians agreed that this was a critical alarm and therefore, the benefits of an auditory alarm to stress the importance outweigh the concerns. Following the Consensus Meeting, one participant commented that "Inability to disable alarms for more than 2 min is a critical safety issue. The ability to configure the default alarm is critical. This will address almost all the discussion we had on this issue."
  - *Minimal: Auditory*
  - Overall Vote - 84% Agree (n = 38)
  - Clinicians - 85% Agree (n = 27)
  - Excluding involvement with product development - 86% Agree (n = 35)
- **Alarm Limits – Pulse Rate (PR)**
  - There was disagreement suggesting a wider range for the Minimal characteristic and a discussion of whether the range should be fixed or variable (i.e., users can set the range). Some clinicians felt that the range should be fixed for certain levels of care (e.g., secondary or primary level) while others thought that having a factory setting pre-programed but that could be adjusted would provide flexibility. Some users noted the flexibility would be helpful for trainings and where altitude could present challenges. Clinicians noted that they rarely vary the factory settings (when asked the last time they adjusted the setting, one replied "over four months ago"). Product developers noted that there is no impact to the alarm limits from a technical standpoint. A healthy debate ensued on whether the alarm should sound at 80 bpm or 100 bpm for the lower bound for the Minimal characteristic (agreement in room for 180 bpm for the upper bound). Those in favor of 80 bpm argued "you don't want the alarm to constantly be going off and contributing to alarm fatigue". Consensus was ultimately not achieved on whether the lower bound should be 80 or 100 bpm.
  - *Optimal: Adjustable*
  - *Minimal: 80-180 bpm OR 100-180 bpm *see discussion above as the voting was split and consensus was not achieved**
  - *Minimal: Fixed value or variable*
    - Overall Vote - 75% voted "fixed" (n = 36)
    - Clinicians - 76% voted "fixed" (n = 25)
    - Excluding involvement with product development - 76% voted "fixed" (n = 34)
  - *Minimal: Lower bound of 80 or 100 bpm*
    - Overall Vote - 59% voted "80 bpm" (n = 27)
    - Clinicians - 59% voted "80 bpm" (n = 22)
    - Excluding involvement with product development - 58% voted "80 bpm" (n = 26)
- **Alarm Limits – Sp02**
  - There was disagreement on the Minimal characteristic with similar commentary on the concern of alarm fatigue ("it is not helpful if the alarm is sounding permanently on a sick child") and the impact of altitude on the lower range limit. There was a discussion reviewing the Pre-Meeting survey comments for the Minimal characteristic:
    - Adjustable: "You want to set the alarm according to the environment; e.g., the altitude might impact the levels you want and normal values of oximetry may be lower"
    - Non-Adjustable: Adjustability of the alarms increase risk of user error and/or use on a different patient population
    - Partially Adjustable: "Should be closed settings not fully adjustable. For example 1) neonate setting 2) infant setting 3) pediatric setting, etc."
  - Consensus was achieved in the room (without a Mentimeter vote) that the range should be adjustable for the Minimum, as well as the Optimal, to provide flexibility based on the patient type.

- *Minimal: Adjustable*

- **Consumables**
  - Agreement was reached in the room on clarification that the consumables in question were to be specified as two neonatal probes (designed for and tested in newborns). Clinicians in the room commented that two neonatal probes should be included in the package when initially purchased. Product developers noted that measuring by a period of time can be challenging since it's often difficult to prove whether the probes have been used improperly. One consideration was changing the measurement to the strength of the probe rather than the length of time. Furthermore, product developers noted that the cabling on the sensor of the probe is the weakest part and that the lifespan will decrease if twisted around improperly. Some users mentioned a preference for reusable probes while others mentioned that disposable probes "fit better" and were therefore preferred. Consensus was achieved in the room (without a Mentimeter vote).
  - *Minimal: >6 months before required with 2 neonatal probes included in package*
- **Size**
  - For the Optimal characteristic, many different configurations were noted including: easily movable; not docked, not "pocketable". Specifically, clinicians commented that the device should be "moveable, but not too small that it can be taken away from the unit". The idea of "chaining" the device in the unit to avoid being moved was mentioned. Clinicians noted that for continuous monitoring, they prefer the display screen to be larger so that it is readable from a certain distance. One participant emphasized that often times, there is limited space available in the NICU and there may be limited table space available for a benchtop device. Therefore, a handheld device that could be mounted to the side of the crib could prove useful.
  - *Minimal: Easily moveable, not pocketable, can be secured (same as Optimal)*
    - Overall Vote - 96% Agree (n = 27)
    - Clinicians - 95% Agree (n = 19)
    - Excluding involvement with product development - 96% Agree (n = 26)
- **Usage Meter**
  - There was disagreement on the Minimal characteristic for the usage meter. Product developers noted that digitally storing recorded memory adds a significant cost to the device and for a Minimal standard, this would be too onerous to require manufacturers to include for a small device. From a technical standpoint, the challenge was installing the feature for measurement, not the timing (i.e., how many hours of memory were captured). Clinicians suggested storing for roughly 12 hours (overnight period) or for 6 hours (typical nurse shift). Clinicians were open to other non-digital ways to document the data since a mapping of the digitally stored patient data linked to the true record of the patient chart currently does not exist. There was a discussion as to whether the purpose of usage meter was for manufacturers to record cumulative hours of usage, or, for the clinicians to store historical data recordings. For ISO certification standard, usage data must be stored [5].
  - *Optimal*: Digitally stored record displaying cumulative hours of operation
  - *Minimal*: Digitally stored record displaying 50 previous readings or >50 hours
  - *Minimal: Do we need a digitally stored record memory?*
    - Overall Vote - 84% voted "no" (n = 32)
    - Clinicians - 91% voted "no" (n = 23)
    - Excluding involvement with product development - 84% voted "no" (n = 30)
- **Battery (previously titled 'Battery Power')**
  - Discussion on the Minimal characteristic for Battery Power (retitled to 'Battery') focused on the difference between a spot check and continuous monitoring device. For a continuous monitoring device, participants mentioned that the battery life should ideally last longer and that the device should be able to be used when plugged in and charging. The WHO tabletop specification requires more than 6 hours according to the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [4, p. 130]. Lack of consensus in voting was likely due to the fact that for a spot-check Pulse Oximeter, >12 hours on a single charge would be preferred. However, for a continuous Pulse Oximeter, >6 hours on a single charge, consistent with the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [4, p. 130] would suffice. Following the Consensus Meeting, one participant commented that "Battery duration of more than one hour

will be very difficult (costly). You will need to specify the conditions for testing this requirement. Most battery performance deteriorate over time. Battery indicator is critical."
  - There was agreement in the room that all characteristics relating to Utility Requirements (e.g., Back-up Battery; Battery Power; Batteries; Voltage; Power Requirement; Maximum Power Consumption; Response During Power Outage; Surge Protection, Electrical Plug) be reviewed and harmonized following the TPP meeting.
  - *Minimal: Should the battery power last >6hr or >12hrs?*
    - Overall Vote - 59% voted ">6hr" (n = 32)
    - Clinicians - 62% voted ">6hr" (n = 21)
    - Excluding involvement with product development - 60% voted ">6hr" (n = 30)
  - *Optimal: Rechargeable battery, >24hr on single charge*
  - *Minimal: Rechargeable battery, >6hr on single charge*
- **Instrument Pricing**
  - There was disagreement on the Minimal characteristic for ex-works price of the device (inclusive of warranty and two probes for neonatal use). Some participants noted that the ex-works price was misleading given that there are several mark-ups added and that the landed cost may be easier for buyers to understand. Product developers noted that $100 ex-works is not feasible for a continuous measurement device (i.e., not a "finger pulse ox").
  - *Minimal: <$250 ex-works*
    - Overall Vote - 85% Agree (n = 20)
    - Clinicians - 92% Agree (n = 13)
    - Excluding involvement with product development - 85% Agree (n = 20)
- **Consumable Pricing**
  - There was disagreement on the Minimal characteristic for consumable pricing which, for the basis of the discussion, was assumed to be two neonatal probes per year. Technical developers discussed that the probes were an expensive component and that the current cost per probe is $20-$40 per probe ex-works with an average lifespan of 6 months.
  - *Minimal: <$80 per year ex-works (two probes)*
    - Overall Vote - 86% Agree (n = 14)
    - Clinicians - 88% Agree (n = 8)
    - Excluding involvement with product development - 86% Agree (n = 14)
- **Voltage**
  - As noted in the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [4, p. 68], "In the case of oxygen therapy products, poor power conditions can significantly harm electrically powered oxygen concentrators, as well as pulse oximeters that require power directly from a mains source, or require recharging from a mains source". There was disagreement on the Minimal characteristic and whether a separate TPP was needed for a voltage stabilizer, although it was noted the WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices [4, p. 133] does provide technical specifications for voltage stabilizers specific to those paired with oxygen therapy products. Agencies noted the importance of considering global ranges in development. From a technical perspective, a message to clinicians was to ensure that facilities install "grounding" (e.g., use of a metal rod). One proposal was to clear safety guidelines for medical device voltage per country.
  - There was agreement in the room that all characteristics relating to Utility Requirements (e.g., Back-up Battery; Battery Power; Batteries; Voltage; Power Requirement; Maximum Power Consumption; Response During Power Outage; Surge Protection, Electrical Plug) be reviewed and harmonized following the TPP meeting.
  - *Optimal: None*
  - *Minimal: Model must match the voltage and frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz)*

The following characteristics were not discussed at the TPP Consensus Meeting explicitly, however, additional comments were received and incorporated into the discussion:

- **SPO2 Range**
  - With regard to the SP02 range, Pre-Meeting survey comments highlighted that "Saturation at 0% is not clinically meaningful", "there is no method available for calibrating pulse oximeters below 70%", and that "[readings are] never accurate or clinically useful below 70%". One participant responded that while oxygen therapy ideally would have started before the patient reaches these levels, there may be value and "clinical utility to ensure that the patient IS resaturating".
- **Decontamination**
  - Pre-Meeting survey comments highlighted the need to clarify appropriate disinfection agents. Comments received from an international NGO provided further clarification noting that each country has their own decontamination protocol since the WHO only provides guidance rather than explicit protocol. The guidance provided specifies super-basic mild soap solution, not submerging the device, and wipe-able in the case of contact with bodily fluid, and ability to use scheduled disinfectant [6]. While the process of decontaminating would likely be carried out by an IPC specialist, it is important for the manufacturer to control their Ingress Protection (IP) rating.
- The following Product Specific ISO Standards were highlighted in the Pre-Meeting survey responses:
  - ISO 80601-2-61(current 2017) specific to pulse oximetry, title: Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment, and provides guidance on accuracy claims and validation. and ISO13485
- Additional considerations received from participants are as follows:
  - "We should specify the conditions / context for accuracy testing. In newborns the within subject (breath by breath) variation in SpO2 within a single minute when the SpO2 is below 95% is > 3% RMSD. ISO only requires testing in adults. Currently ISO accuracy is < 4% RMSD. Neonates at low SpO2 will be at least this for a "minimal" requirement."
  - "Motion, perfusion, skin color and external light interference are key issues that have not been addressed."
  - "Devices need to be cleanable, waterproof (to a degree- IPX rating), drop and vibration tolerant."

Broad Themes and Considerations

At the Consensus Meeting, the following additional themes emerged and are summarized below:

Instrument Pricing

In order to provide a consistent measure of pricing, the ex-works price is included in the TPPs. Participants highlighted that ex-works pricing is not a true measure of landed cost and is often vastly understated to what a procurement agent will pay. One participant from an international NGO noted that there is a "minimum 30% mark-up on the ex-works price." The rationale for using the ex-works price is that it is a reliable measure that can be used for consistent comparison across geographies since distributor markups vary by country and geography.

Utility Requirements

A significant portion of the discussion was devoted to deliberating on how equipment can be designed to work in health facilities with limited electrical infrastructure. Designing the equipment for low-resource conditions often requires back-up batteries which adds to the expense of the technology, as well as the size of the equipment which can pose a challenge in crowded newborn wards. Some participants noted that rather than designing equipment for these facilities with limited electrical infrastructure, to consider whether a broader investment in electrical infrastructure would be a better use of funds. This inherent tradeoff was discussed multiple times when electrical characteristics were discussed.

Additionally, there were a variety of characteristics in the initial survey that related to Utility Requirements (i.e., electricity and power) that varied slightly in title across the TPPs. During the TPP Consensus Meeting, participants agreed that all characteristics relating to Utility Requirements (includes Back-up Battery; Battery

Power; Batteries; Voltage; Power Requirement; Maximum Power Consumption; Response During Power Outage; Surge Protection, Electrical Plug) be reviewed and harmonized following the TPP meeting across the product categories. These characteristics have since been reviewed and harmonized into four distinct characteristics (Power Source, Battery, Voltage, and Power Consumption) in the final TPPs.

- **Power Source** - This defines the desired power source for the device and can be broken down into the following categories:
    - *Mains power* - device must be plugged into a mains power source for use
    - *Mains with battery backup* - device must be plugged into a mains power source for use, however, in the case of a power failure, the device has a battery backup that can last a specified period of time
    - *Mains with rechargeable battery* - device has a rechargeable battery that operates both when the device is charged by a mains power source, or, when the device is plugged in (e.g., a mobile phone)
    - *Battery is disposable and replaceable*
    - *No power required (i.e., disposable device)*
- **Battery** - This includes the length of time the rechargeable or disposable battery should function
- **Voltage** - This specifies the preferred voltage conversion if the Power Source utilizes Mains Power. Note that for certain technologies (i.e., Bilirubinometer, Glucometer, Hemoglobinometer, pH monitor, and Pulse Oximeter (Continuous)), the Voltage characteristic is included in reference to the rechargeable battery charger requirements. For example, while the Optimal Voltage characteristic is "None" (i.e., no charging is necessary), the Minimal Voltage characteristic should conform to "the voltage and frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz)" to ensure that the charger for the battery is compliant.
- **Power Consumption** - This specifies the maximum Watts of electricity that the device should consume

Ideally, all devices should be developed to withstand power surges and voltage spikes.

Note that comments received in the Pre-Meeting survey report highlighted the importance of the correct frequency in electrical plugs. It was noted that a universal adaptor would not safely support the conversion of 60Hz equipment to 50Hz and that a machine relying on this method could fail in a short period of time (applicable to Oxygen Concentrator, Warming Crib, Radiant Warmer).

Delphi-like Survey: Pulse Oximeter (Continuous)

Delphi-like survey results for Pulse Oximeter (Continuous) TPP prior to Consensus Meeting (data as of Oct 25, 2019)

	Optimal		Minimal		
Characteristic	**Optimal requirement**	**% agreement (n size)**	**Minimal requirement**	**% agreement (n size)**	**Collated comments from Delphi-like survey**
Intended Use	Optimal: To continuously monitor oxygen saturation (Sp02) and pulse rate (PR) for neonatal patients.	**91% n = 44**	Minimal: Same as Optimal.	**86% n = 42**	9 comments as summarized below • Theme: Spot Checking vs. Continuous Monitoring • Spot checking SpO2 is appropriate and adequate for assessment and monitoring of most newborns requiring oxygen therapy. A recent trial in Nigeria by Hamish Graham et

	Optimal		Minimal		
					al demonstrated that intermittent monitoring was also effective • Closer monitoring, which may or may not involve continuous monitoring, is important for preterm neonates on oxygen (and some other very sick or deteriorating neonates)
Target Operator	Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians.	**93%** **n = 43**	Minimal: Same as Optimal	**98%** **n = 42**	6 comments as summarized below • Theme: Broaden Users • Add 'nurse assistants' and 'community health workers' • Non licensed providers make up a significant proportion of the healthcare workforce. Pulse oximetry monitoring is simple to learn so it does not exclusively require licensed providers if they are not available (i.e. in lower levels of the healthcare system) • Optimal would be if a lay person could use it
Target Population	Optimal: Neonates (<28 days)	**80%** **n = 44**	Minimal: Same as Optimal.	**80%** **n = 41**	12 comments as summarized below • Theme: Broaden age range or specify weight range • Typically manufacturers specify a weight range not an age range • Pulse oximetry is useful in small hospitals and clinics where newborn care might be a small part of their workload, and any oximeter should be used also for older children • Optimal/minimal would be <28days but also compatible for infants 1-6 kg • Make upper weight higher if aiming to care for older sick infants (upper limit then probably 8-10 kg)
Target Setting	Optimal: Hospitals in low-resource settings	**77%** **n = 44**	Minimal: Same as Optimal.	**74%** **n = 43**	19 comments as summarize below • Theme: Broaden vs. Narrow Target Setting o Lower levels of the health system if oxygen available and resources adequate o Other units of the hospital o Potentially higher income counties o Personnel in some primary hospitals (versus secondary and tertiary hospitals) are not well trained on how to use pulse oximeters o In every birthing unit o Community settings Minimal: hospital in resource-limited settings, Optimal: health centres (primary)

	Optimal		Minimal		
International Standard	Optimal: ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes.	**81%** **n = 32**	Minimal: Same as Optimal.	**77%** **n = 30**	11 comments as summarized below • Theme: Add to Additional International Standards vs. Irrelevance • Consider inclusion of ISO 80601-2-61(current 2017) specific to pulse oximetry, title: Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment, and provides guidance on accuracy claims and validation. • Alternatively, some respondents commented that having ISO13485 does not necessarily lead to good performance
Regulation	Optimal: CE marking or US FDA Clearance	**75%** **n = 36**	Minimal: Same as Optimal.	**71%** **n = 34**	12 comments as summarized below • Theme: Add more flexibility v. irrelevance of characteristic • Consider additional 'or' options: o Other Stringent Regulatory Authorities – Japan or Australia or Canada o Consider regulatory bodies of Low- and Middle-Income Countries o Some respondents did not think that regulatory approval necessarily translated to good performance
Pulse Rate	Optimal: 25-250 bpm	**77%** **n = 39**	Minimal: 60-200 bpm	**51%** **n = 37**	23 comments as summarized below • Theme: Wide Variety of Suggested Ranges o WHO / UNICEF Interagency Specification is 30-240 bpm o One respondent said, meaningful HR ranges for infants are: ▪ <60 (when compressions start) ▪ <100 (when ventilation support starts) ▪ >180 (tachycardia definition) ▪ >220 (concern for cardiac tachyarrythmias). o Other respondents also suggested the following ranges: ▪ Optimal range: 40-230 bpm | minimal range: 50-200 bpm ▪ 25-240 bpm ▪ 25-120 bpm ▪ 25-200 bpm ▪ > 250 bpm, perhaps 300 bpm ▪ 25-250 bpm ▪ 30-240 bpm ▪ 30-250 bpm • Not a technical challenge

	Optimal		Minimal		
Pulse Rate Accuracy	Optimal: +-3 bpm	**88%** **n = 41**	Minimal: Same as Optimal.	**82%** **n = 38**	10 comments as summarized below • Theme: Additional Suggested Ranges o WHO / UNICEF Interagency Specification is +- 3 bpm o +- 3 bpm at 90% is much different than at 50% o +- 3 bpm should be over 10 second average o +- 15% o +- 2 bpm (to align with devices already on market) o +- 5 bpm would be sufficient o Consideration should be made for movement and low perfusion o Consideration for saturation levels and average time
Pulse Rate Resolution *(corrected from 'Pressure')*	Optimal: 1 bpm	**94%** **n = 36**	Minimal: Same as Optimal.	**94%** **n = 33**	3 comments as summarized below • WHO / UNICEF Interagency Specification is +- 3 bpm •
Sp02 Accuracy	Optimal: +-2%	**91%** **n = 43**	Minimal: +-3%	**80%** **n = 41**	12 comments as summarized below • Theme: Accuracy Data at Various Perfusion / Movement Conditions o UNICEF SD/WHO specs will be +/- 3% for neonates, and most devices that make claims will not go beyond this because you cannot carry-out a lab desaturation (breathdown) on a neonate to validate otherwise. o "SpO2 accuracy (in the range at least 70-100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions." o For both minimal and Optimal (whatever the accuracy threshold is chosen to be for each), at least the detection range and motion/no-motion should be specified in order to compare apples to apples • Require as 'Optimal' that proof of accuracy data be available, as we have found that many are unable to provide supporting data showing compliance to ISO
Sp02 Range	Optimal: 0-100%	**81%** **n = 42**	Minimal: 70-100%	**75%** **n = 40**	18 comments as summarize below • Theme: Additional Suggested Ranges o Saturation at 0% is not clinically meaningful o There is no method available for calibrating pulse oximeters below 70%

	Optimal		Minimal		
					o Never accurate or clinically useful below 70% • Some cardiac conditions the SpO2 is showing lower values (in the 60ies), therefore I would prefer a range of 50 - 100%
Alarms	Optimal: Visual and Auditory	**98%** **n = 43**	Minimal: Visual	**60%** **n = 42**	21 comments as summarized below • Theme: Auditory is More Useful than Visual o Auditory might be less expensive o Consider waveform and auditory pulse tone o Lower tone as the heart rate or SPO2 lowers • Theme: Add detail on when alarms are triggered o ISO 80601-2-61 re. alarms: a cause for alarm when probe site must be changed (necessary on neonatal skin) o WHO-UNICEF spec requires audible and visual alarms for: ▪ low/high saturation ▪ low/high pulse rate ▪ sensor error or disconnect ▪ system error ▪ low battery o Audible and visual alarms for low/high saturation and pulse rate, threshold set by user • Alarm override and temporary silencing function
Consumables	Optimal: >12 months before required	**88%** **n = 40**	Minimal: >6 months before required	**64%** **n = 39**	19 comments as summarized below • Theme: Clarify what is meant by consumable o Probes are accessories? o Consider disposable single-use sensors as consumable • Theme: Ideally consumable should last more than 6 months o Deliver 12 months of stock o Improve wiring at connection points without increasing costs • Ideally, there would be no consumables
Alarm Limits - PR	Optimal: Adjustable	**95%** **n = 40**	Minimal: 80-160 bpm	**70%** **n = 37**	15 comments as summarized below • Theme: Wide Variety of Suggested Ranges o Ranges ▪ 50 – 200 bpm - less than 60bpm starts compressions; 200bpm would be minimal in my mind. Knowing >220 is helpful but is also a rare case

	Optimal		Minimal		
					scenario (for tachyarrhythmias) ▪ 160 bpm is too low for an upper limit - suggest using 180 / 200 bpm as upper limit to avoid frequent alarming in the "borderline" babies with HR 160 - 180 bpm which may be due to crying or restlessness instead of illness ▪ 50-120 bpm ▪ 80-180 bpm ▪ I would also want the device to get an alarm at 60 bpm in any resuscitation situation o Non-Adjustable - Adjustability of the alarms increase risk of user error and/or use on a different patient population o Partially adjustable - should be closed settings not fully adjustable. For example 1) neonate setting 2) infant setting 3) pediatric setting, etc. • "In a district hospital, I would want the alarms to be locked; in a tertiary I prefer the alarms to be adjustable."
Alarm Limits - Sp02	Optimal: Adjustable	**92%** **n = 39**	Minimal: 88-99%	**59%** **n = 39**	18 comments as summarized below • Theme: Wide Variety of Suggested Ranges o Ranges: ▪ <88% ▪ 75% ▪ 80% ▪ 85% ▪ 90-95% (respondent cited as WHO recommendation) o Adjustable: ▪ Make this a minimal requirement too ▪ Adjustment is important because you want to set the alarm according to the environment; e.g., the altitude might impact the levels you want and we have highlands in Nigeria where normal values of oximetry may be lower ▪ MUST ALWAYS be adjustable or at least able to turn off ▪ It is not helpful if the alarm is sounding permanently on a sick child o Non-Adjustable - Adjustability of the alarms increase risk of user error

	Optimal		Minimal		
					and/or use on a different patient population o Partially adjustable - should be closed settings not fully adjustable. For example 1) neonate setting 2) infant setting 3) pediatric setting, etc.
Continuous Measurement	Optimal: Yes	**95%** **n = 41**	Minimal: Same as Optimal	**84%** **n = 38**	9 comments as summarized below • Theme: Spot Checking vs. Continuous Monitoring • Spot checking SpO2 is appropriate and adequate for assessment and monitoring of most newborns requiring oxygen therapy • Closer monitoring, which may or may not involve continuous monitoring, is important for preterm neonates on oxygen (and some other very sick or deteriorating neonates)
Decontamination	Optimal: Easy to clean with common disinfecting agents	**98%** **n = 43**	Minimal: Same as Optimal	**98%** **n = 40**	3 comments as summarized below Theme: Need clarity on which disinfecting agents are appropriate
Patient Interface	Optimal: Neonate specific, biocompatible and reusable.	**90%** **n = 41**	Minimal: Same as Optimal	**87%** **n = 38**	9 comments as summarized below • Theme: Broaden range to include sensors / probes for other patient populations o Older infants o Children • Mothers
Size	Optimal: Small footprint, left at bedside with dock.	**74%** **n = 42**	Minimal: Handheld with dock.	**78%** **n = 40**	14 comments as summarized below • Theme: Size and/or Configuration may need to consider additional insights o Comments on Handheld ▪ May be cheaper ▪ More easily displaced ▪ May not allow for continuous monitoring ▪ More easily used across patients without cleaning ▪ Shorter connection cables ▪ Shorter battery life o Comments on Docking ▪ May prevent loss ▪ May limit use at bedside ▪ Need to ensure recharge is possible at bedside while also being used o Comments on other configurations Rolling, portable pulse oximeters reduce loss and allow for continuous and spot-checking

	Optimal		Minimal		
Training Required	Optimal: Minimal	**84%** **n = 43**	Minimal: Minimal	**80%** **n = 41**	9 comments as summarized below • Theme: 'Minimal' is too subjective; need something more specific • Users need to be trained on the significance of monitoring • Most of training is not on the device but the application of the sensor and the interpretation of information • More specificity required, both with respect to minimum user qualifications and time - e.g., "A health care worker with at minimum a nursing degree can be trained in a 2-day workshop" or "A community health worker can be trained in a 1-week course", etc... Ideally should not require training or training built into device or easily accessible via phone
User Manual	Optimal: User manual and additional training materials (checklists, videos, guides) in English and local language. Attached to device with labels and markings where possible.	**85%** **n = 41**	Minimal: User manual provided.	**85%** **n = 40**	15 comments as summarized below • Focus on limits of the pulse oximeter • One manual per ward versus one per device • Manual should be easily found online • Not necessarily the responsibility of the manufacturer All claims must be filed with the regulatory dossier, so this is not as straight forward as a simple translation. Appropriate, professional translations are a must and are costly to the manufacturer. Additionally, local language varies greatly across a country and is often-times not even the official language of the country and so this may not be a reasonable ask of manufacturers
Usage Meter	Optimal: Digitally stored record displaying cumulative hours of operation.	**76%** **n = 37**	Minimal: Digitally stored record displaying 50 previous readings or >50 hours.	**72%** **n = 36**	17 comments as summarized below • Theme: Clarify what is meant by usage meter o To determine if device is used o To determine if device needs to be serviced o Historical record of data is helpful for continuous monitoring while record of readings is useful for spot-checking o Change 'meter' to 'storage' or 'memory' o Useful for research purposes for 72 hours of readings o Useful for overnight readings for 12-24 hours at higher level facilities but probably out of scope for most neonatal units. Could add a lot to cost

	Optimal		Minimal		
Voltage	Optimal: 110-240V 50-60hz	**83%** **n = 36**	Minimal: 220-240V 50-60hz	**66%** **n = 35**	16 comments as summarized below • Applicable to the battery charger and charging station • The requirements for power input voltage/frequency and plug type of the equipment must be chosen according to the local electrical supply. Source: https://www.220-electronics.com/media/images/world-voltage-map.gif • Voltage can always be corrected with step-up / step-down transformers; however, these come at an added cost. So whether the cost be borne by the purchaser (Caribbean, Central- or South-American countries w/ 120V) or the manufacturer who makes devices that can work across all contexts • Frequency needs to be appropriate for frequency rating of specific country, as this is something that cannot be corrected and though 50 Hz can be used in a 60 Hz system, it is hard on the device and it will be compromised Voltage stabilizers and surge suppressors are important to consider
Battery Powered	Optimal: >24hr on single charge	**93%** **n = 40**	Minimal: None	**36%** **n = 36**	23 comments as summarized below • Theme: Clarify what is meant by 'None': o Backup power is a must have o Optimal: rechargeable batteries with ability to swap out to standardly available batteries (e.g. AA) o Minimal: rechargeable batteries o Can device be used while charging? • Theme: Wide variation in length of battery backup o 30 minutes o 1 hour o 8 hours o 12 hours (cited as UNICEF-WHO specification) 24 hours
Weight	Optimal: <500 grams, portable	**83%** **n = 40**	Minimal: Same as Optimal	**82%** **n = 39**	10 comments as summarized below • Theme: Varying opinions on the need to specify weight o Portable may be better for Minimal o "Clinicians would rather work with a 2kg device that works well than a 200g device that doesn't"

	Optimal		Minimal		
					o Less portable is viewed as more robust o Portability may lead to disappearance of device WHO-UNICEF interagency spec is less than 400g for a handheld device (no weight maximum for tabletop device)
Warranty	Optimal: 5 years	**80%** **n = 40**	Minimal: 1 year	**82%** **n = 38**	13 comments as summarized below • Theme: 5 years may be unrealistic • UNICEF-WHO spec is 2 years recommended, at least 1 year mandatory • Optimal should by 2 years • To honor a 5 year warranty, you will have to have strong in-country representation • "Any manufacturer that I have ever spoken to was more than willing to extend a warranty (to 2, maybe 3), but at a cost" "What might be more useful is that during any procurement, consideration be given to establishing a SLA with an in-country rep. In this case, you can "swap out" in the event of a break-down, and there is no discussion of warranties"
Instrument Pricing	Optimal: <$150 ex-works	**80%** **n = 35**	Minimal: <$250 ex-works	**65%** **n = 34**	12 comments as summarized below • Theme: Extremely price-sensitive geography and even $250 was viewed as too expensive by some respondents • Optimal price was viewed as potentially overly ambitious for bedside rather than handheld type • This device needs to be better than devices sold in high-income countries so may be tough to hit target price • Cheaper options available • Would need to understand quality of the device before paying this much I think you could safely set "Optimal" to <$100, and "Minimal" to <$175 for ex-works, including 1 probe (min) and 1 year warranty on unit
Consumable Pricing	Optimal: <$50 / year ex-works	**79%** **n = 33**	Minimal: <$100 per year ex-works	**47%** **n = 34**	16 comments as summarized below • Theme: Extremely price-sensitive geography and $100 was viewed as too expensive by some respondents o "Generic probes cost much less than that, and last more than a year" o Too costly if above $50 / year • Theme: Provide more specificity for quantity and type of consumable

	Optimal		Minimal		
					o Differentiate between a consumable (disposable probe) and spare (reusable probe). I am assuming that this question is about reusable probes. I think you could safely set "Optimal" to <$40, and "Minimal" to <$80 for ex-works, probes have 6 mo. warranty for 2 disposable probe and 2 reusable probe

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APPENDICES

Appendix A: Delphi-like Survey Respondent Organizational Designation

3rd Stone Design
Abuja University Teaching Hospital
Alex Ekwueme Federal University Teaching Hospital Abakaliki
Baylor College of Medicine
BC Children's Hospital
Burnet Institute
CCBRT Dar es Salaam
CENETEC-Salud
Center for Public Health and Development (CPHD)
Children's Hospital of Philadelphia
Christian Medical College, Vellore
Clinton Health Access Initiative
College of Medicine, University of Lagos
College of Medicine, University of Malawi
Dartmouth
Day One Health
Diamedica UK Ltd
D-Rev
Egerton University - Nakuru County Referral Hospital
ETH Zurich
Fishtail Consulting
FREO2 Foundation Australia
Global Strategies
Hawassa University
Independent Biomedical Engineer
Institute for Healthcare Improvement
intelms.com
Kamuzu Central Hospital
Kamuzu College of Nursing
Kemri-Wellcome Trust
Kenya Paediatric Association
Komfo Anokye Teaching Hospital
Malawi-Liverpool Wellcome Trust
Mama Lucy Hospital
Masimo
Mbarara University of Science and Technology
McGill University Health Centre
McMaster University
Medecins Sans Frontieres
Mediquip Global Limited
Ministry of Health, Senegal
mOm Incubators
MRC Gambia at LSHTM
Muhimbili National Hospital
Muhimbili University of Health and Allied Sciences (MUHAS)
Neopenda
No designation listed (10)
Pediatric and Child Health Association in Malawi

Pumwani Hospital
Queen Elizabeth Central Hospital
Rice 360 Institute for Global Health
Royal Children's Hospital and Centre for International Child Health (University of Melbourne)
Save The Children
Texas Children's Hospital
The University of Queensland
UCSF and London School of Hygiene & Tropical Medicine
UNICEF
University of Alabama at Birmingham
University of British Columbia
University of Global Health Equity
University of Maiduguri Teaching Hospital, Maiduguri
University of Nairobi
UNTH, Enugu

Appendix B: Consensus Meeting Participation

Albert Manasyan (University of Alabama Birmingham)
Anna Worm
Antke Zuechner (CCBRT)
Audrey Chepkemoi (Moi Teaching and Referral Hospital)
Bentry Tembo (Kamuzu Central Hospital)
Bev Bradley (UNICEF)
Casey Trubo (D-Rev)
Chishamiso Mudenyanga (Clinton Health Access Initiative)
Danica Kumara (3rd Stone Design)
Daniel Wald (D-Rev)
Edith Gicheha (Kenya Pediatric Research Consortium)
Emily Ciccone (University of North Carolina - Chapel Hill)
Emmie Mbale (PACHA)
Grace Irimu (University of Nairobi)
Guy Dumont (The University of British Columbia)
Helga Naburi (Muhimbili National Hospital)
Jeffrey Pernica (McMaster University)
John Appiah (Kumfo Anokye Teaching Hospital)
Jonathan Strysko (Children's Hospital of Philidelphia/Princess Marina Hospital)
Joy Lawn (London School of Hygiene and Tropical Medicine)
Lincetto Ornella (WHO)
Liz Molyneux (College of Medicine, Malawi)
Lizel Lloyd (Stellenbosch University)
Mamiki Chise
Marc Myszkowski
Maria Oden (Rice University)
Martha Franklin Mkony (Muhimbili National Hospital)
Martha Gartley (Clinton Health Access Initiative)
Mary Waiyego (Pumwani Maternity Hospital)
Matthew Khoory (mOm Incubators)
Melissa Medvedev (University of California, San Francisco; London School of Hygiene and Tropical Medicine)
Msandeni Chiume (Kamuzu Central Hospital)
Naomi Spotswood (Burnet Institute)
Norman Lufesi (Ministry of Health Malawi)
Pascal Lavoie (University of British Columbia)
Queen Dube (College of Medicine, Malawi)
Rachel Mbuthia (GE Healthcare)
Rebecca Richards-Kortum (Rice University)
Rhoda Chifisi (Kamuzu Central Hospital)
Rita Owino (GE Healthcare)
Robert Moshiro (Muhimbili National Hospital)
Ronald Mbwasi (Kilimanjaro Christian Medical Centre)
Sam Akech (KEMRI-Wellcome Trust Research Programme)
Sara Liaghati-Mobarhan (Rice University)
Sona Shah (Neopenda)
Steffen Reschwamm (MTTS)

Steve Adudans (CPHD/MQG)
Thabiso Mogotsi (University of Botswana)
Walter Karlen (ETH Zurich)
Zelalem Demeke (Clinton Health Access Initiative)

Appendix C: 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
µmol/L	Micromoles 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