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NEST360°

Target Product Profile

Temperature Monitor (Continuous) – Thermal Management

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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

In general, newborns require a warmer environment than adults and the smaller the newborn, the higher the temperature needs to be. A newborn's ability to stay warm can be easily compromised by the temperature of its surroundings since newborn infants regulate body temperature much less efficiently than adults and lose heat more easily. Low birth weight and premature babies often face even greater risk [1].

As many as 85% of infants born in hospitals in low-resource settings become cold (defined as <36.5°C) [2]. Mortality rates increase with each degree Celsius of temperature lost. While the risks of being too cold are well recognized, hypothermia remains a largely invisible problem in overcrowded newborn units in low-resource settings. Hypothermia in newborns requires rapid diagnosis, which is often difficult in crowded and understaffed wards. Hypothermia not only increases the chances of acidosis, sepsis and RDS, but may indicate the presence of system illness such as infection or hypoglycemia.

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

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

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

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

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

In high-resource settings, low nursing to patient ratios and availability of incubators, which continuously monitor temperatures, allows for close monitoring. In settings with high nurse to patient ratios, where incubators are limited, KMC is the preferential warming option. However, some infants require closer monitoring of temperature in open cribs and the ability to continuously monitor temperature and notify staff

when an intervention is needed could greatly reduce hypothermia and increase recognition of neonatal fever associated morbidity and mortality.

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.

12 respondents participated in the Delphi-like survey for the Temperature Monitor (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.

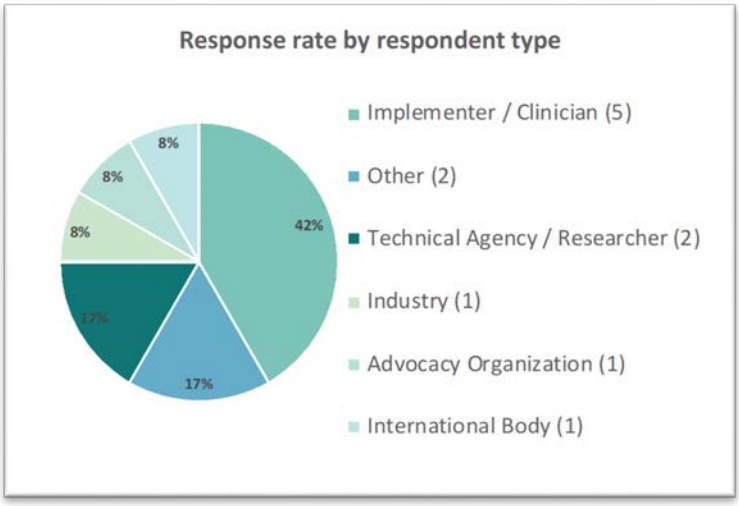
For each characteristic in each product category, a percentage agreement was calculated for both the Minimal and Optimal requirements. The percentage agreement was calculated as the ratio of the sum of number of respondents who selected 4 and 5, to the sum of numbers of respondents who gave any score (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.

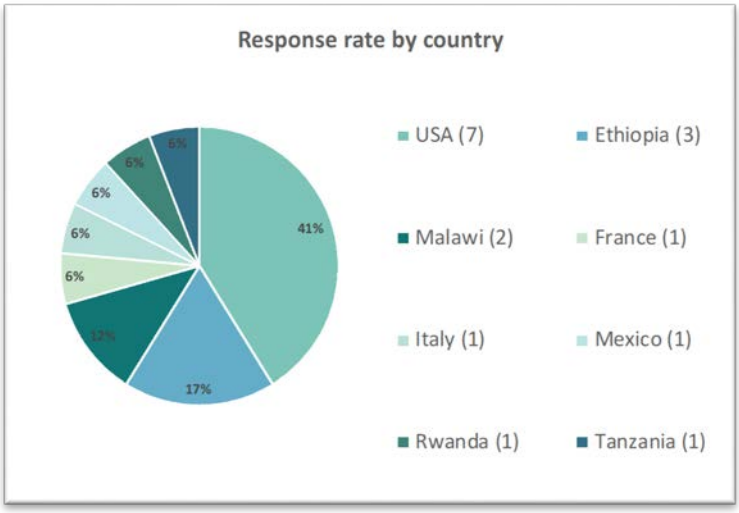
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

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



Respondent type	Percentage
Implementer / Clinician (5)	42%
Other (2)	17%
Technical Agency / Researcher (2)	17%
Industry (1)	8%
Advocacy Organization (1)	8%
International Body (1)	8%

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



Country	Percentage
USA (7)	41%
Ethiopia (3)	18%
Malawi (2)	12%
France (1)	6%
Italy (1)	6%
Mexico (1)	6%
Rwanda (1)	6%
Tanzania (1)	6%

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 Temperature Monitor (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 - TEMPERATURE MONITOR (CONTINUOUS)

Final target product profile for Temperature Monitor (Continuous)		
Characteristic	**Optimal**	**Minimal**
SCOPE		
Intended Use	To provide ongoing diagnoses and monitoring of treatment of hypo- and hyperthermia	
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		
Benchtop Measurement Accuracy	±0.1°C	
Clinical Measurement Accuracy	±0.2°C	±0.3°C
Time to Indicate Accurate Temperature	< 60 seconds	< 90 seconds
Alarm Characteristics	Visual and Auditory	
Alarm Limits	Adjustable	36.5°C-37.5°C
Patient Interface	Interface is biocompatible and reusable	Interface is biocompatible
Size	Small footprint; portable and can be left at bedside	Same as Optimal
Weight	<500 grams	Same as Optimal
PURCHASING CONSIDERATIONS		
Consumables	> 12 months before required	> 6 months before required
Instrument Pricing	<$100 ex-works	<$200 ex-works
Consumable Pricing	<$50 per year ex-works	

UTILITY REQUIREMENTS		
Power Source	Mains with rechargeable battery	Mains with rechargeable battery
Battery	Rechargeable battery, >24hrs on a single charge	Rechargeable battery, >6hrs on a single charge
Voltage	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
Warranty	5 years	1 year
Decontamination	Easy to clean with common disinfecting agents	Same as Optimal

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

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Consensus Meeting Summary: Temperature Monitor (Continuous)

To arrive at the final TPP for Temperature Monitor (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.

- **Clinical Measurement Accuracy**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Minimal characteristic to be ±0.3°C.
  - *Minimal: ±0.3°C*
- **Time to Indicate Accurate Temperature**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Optimal and Minimal characteristic.
  - *Optimal: < 60 seconds*
  - *Minimal: < 90 seconds*
- **Alarm Characteristics**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Minimal characteristic to be both Visual and Auditory and equal to the Optimal characteristic. Clinicians noted that the ability to silence the auditory alarm (e.g., if baby has a fever) but maintain a visual alarm would be useful. Product developers noted that according to the International Standards, "means shall be provided to inactive the alarms" [4].
  - *Optimal: Visual and Auditory*
  - *Minimal: Visual and Auditory (same as Optimal)*
- **Alarm Limits**
  - Consensus was achieved in the room for the Minimal characteristic to be 36.5°C-37.5°C. A vote was conducted to determine the lower bound of this range limit for the Minimal characteristic.

- *Minimal: Lower bound of 36.5°C or 36°C*
- Overall Vote - 74% voted "36.5°C" (n = 19)
- Clinicians - 81% voted "36.5°C" (n = 16)
- Excluding involvement with product development - 75% voted "36.5°C" (n = 16)

- **Battery (previously titled 'Battery Power')**
  - 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.
  - There was a discussion in the room emphasizing the importance of reliable power supply for minimum of 24 hours. Clinicians noted that the intention is to leave the device on for 24 hours, hence the time period. Discussion in the room encouraged product developers to be creative (e.g., device could plug into wall, connect with other devices, etc.). Clinicians noted a preference to avoid wired connections to mains and emphasized that "there are already too many wires". There was agreement in the room that if the device was not connected to a mains power source, constant power for 24 hours would be required, however, if it was connected to a mains power source, then 12 hours back-up for power shedding would be sufficient for the Optimal characteristic. For the Minimal characteristic, if the device was not connected to a mains power source, constant power for 24 hours would be required, however, if the device was connected to a mains power source, then at least 6 hours of back-up for power shedding should be required.
  - *Optimal: Rechargeable battery, >24hrs on a single charge*
  - *Minimal: Rechargeable battery, >6hrs on a single charge*
- **Voltage**
  - 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 and 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)*
- **Instrument Pricing**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Minimal characteristic to remain unchanged at <$200 ex-works for Instrument Pricing. Participants noted that since no products currently exist on the monitor to continuously monitor temperature (i.e., not a spot check thermometer) it is difficult to quantify a price.
  - *Minimal: <$200 ex-works*

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), 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, Temperature Monitor (Continuous)).

Delphi-like survey results for Temperature Monitor (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 provide ongoing diagnoses and monitoring of treatment of hypo- and hyperthermia.	**91% n = 11**	Minimal: Same as Optimal.	**90% n = 10**	3 comments as summarized below • Intended use of this is hard to imagine. • Possibilities are: preventing HYPO thermal in babies who: o (1) don't have mother's available for KMC o (2) are too sick for KMC o (3) are transitioning from KMC to more time open crib • If the aim is to build Comprehensive, NOT intensive newborn care units, temperature monitoring (if worth the lift, which I'm not convinced it is) would be really targeted? • Diagnosis is different than measurement--> diagnosis can be up to the clinician, but the temperature monitor should provide an accurate readout that informs the diagnosis. • Need to define skin temp vs. core temp
Target Operator	Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians.	**100% n = 10**	Minimal: Same as Optimal	**100% n = 9**	2 comments as summarized below • Maybe refer to training levels or years of training • There could be application for home-use of CHWs
Target Population	Optimal: Neonates (<28 days)	**100% n = 10**	Minimal: Same as Optimal.	**78% n = 9**	2 comments as summarized below • May be useful if accurate in older children. • Perhaps population should also include all young infants under 3 months of age
Target Setting	Optimal: Hospitals in low-resource settings	**90% n = 10**	Minimal: Same as Optimal.	**67% n = 9**	3 comments as summarized below • Useful in additional settings o Home o Community o Lower-level health centres o Transport of small and sick newborns

	Optimal		Minimal		
International Standard	Optimal: ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes.	**86%** **n = 7**	Minimal: Same as Optimal.	**83%** **n = 6**	2 comments as summarized below • "Accuracy less of an issue" • See feedback from other Product Categories
Regulation	Optimal: CE marking or US FDA Clearance	**71%** **n = 7**	Minimal: Same as Optimal.	**67%** **n = 6**	2 comments • These devices require minimal regulation
Benchtop Measurement Accuracy	Optimal: ±0.1°C	**86%** **n = 7**	Minimal: Same as Optimal.	**83%** **n = 6**	4 comments as described below • Should increase to +/-0.3 C to match warming crib and radiant warmers • 0.1 C is way too strict • Theme: Benchtop vs. Clinical is not understood • This will not alter a clinical decision
Clinical Measurement Accuracy	Optimal: ±0.2°C	**78%** **n = 9**	Minimal: ±0.5°C	**71%** **n = 7**	2 comments as summarized below • Should increase, way too strict, should match warming crib and radiant warmer o Optimal: ±0.5°C o Minimal: Same as Optimal • 0.1. For a home thermometer its 0.2
Time to Indicate Accurate Temperature	Optimal: < 90 seconds	**50%** **n = 8**	Minimal: < 3 minutes	**29%** **n = 7**	5 comments as summarized below • I'm not sure I understand this parameter? Is this how often the monitor refreshes? If so, then I think the interval could be longer • Presuming this device would also be used for spot check of temperature (as opposed to continuous monitoring), I would suggest <30 seconds for Optimal and <90 seconds for minimal-essential for clinicians to be able to obtain temperature measurements quickly in a high-volume, resource-constrained environment • Too long • Much faster. For a home thermometer it's 3s • Way too short! Also should specific clinical (not benchtop) - manufacturers could list benchtop instead because it is a lot faster. Suggest update to: Time to Indicate Accurate Clinical Temperature o Optimal: < 3 minutes o Minimal: < 5 minutes

	Optimal		Minimal		
Alarm Characteristics	Optimal: Visual and Auditory	**80%** **n = 10**	Minimal: Visual	**56%** **n = 9**	5 comments as summarized below • Theme: Minimal should include audio • Depends on the use case. Almost never needed unless continuous monitoring
Alarm Limits	Optimal: Adjustable	**78%** **n = 9**	Minimal: 36.5°C-37.5°C	**57%** **n = 7**	4 comments as summarized below • Not sure why this would be adjustable? Seems like it should just be set at the cut offs for fever and hypothermia? 36.5 and 38? • Technically easy to make this wider • This depends on the type of alarm (visual or auditory), but as with all alarms they should be pre-set. • Take this down to 35.5C-37.5°C
Consumables	Optimal: > 12 months before required	**89%** **n = 9**	Minimal: > 6 months before required	**75%** **n = 8**	2 comments as summarized below • Depends on use... How will you quantify? Are there shelf life considerations?
Decontamination	Optimal: Easy to clean with common disinfecting agents	**90%** **n = 10**	Minimal: Same as Optimal.	**89%** **n = 9**	1 comment as summarized below • Cleaning and disinfecting is not the same
Battery Power	Optimal: >4 hour on single charge	**80%** **n = 10**	Minimal: None	**56%** **n = 9**	5 comments as summarized below • Must have battery • Optimal battery life of 7 days (with sampling frequency of 5 minutes). A study of a related device in India reported battery life up to 28 days with sampling frequency of 5 minutes (https://innovations.bmj.com/content/4/2/60). • Minimal battery life of 24 hours (with sampling frequency of 5 minutes)
Voltage	Optimal: 110-240V 50-60hz	**89%** **n = 9**	Minimal: 220-240V 50-60hz	**63%** **n = 8**	3 comments as summarized below • Consider whether it is actually possible to have 110-220v? isn't it switched from one to the other before use if it's made for both?
Patient Interface	Optimal: Interface is biocompatible and reusable	**100%** **n = 10**	Minimal: Interface is biocompatible	**88%** **n = 8**	0 comments
Size	Optimal: Small footprint; portable and can be left at bedside	**100%** **n = 10**	Minimal: Same as Optimal.	**78%** **n = 9**	4 comments summarized below • Could the minimum standard be a handheld portable temperature monitor and probe with a dock?

	Optimal		Minimal		
					• Small footprint is difficult to measure • Small increases likelihood of disappearing
Weight	Optimal: <500 grams	**100%** **n = 9**	Minimal: Same as Optimal.	**88%** **n = 8**	1 comment See feedback from other Product Categories with Weight
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.	**89%** **n = 9**	Minimal: User manual provided.	**88%** **n = 8**	2 comments See feedback from other Product Categories with User Manual
Warranty	Optimal: 5 years	**100%** **n = 9**	Minimal: 1 year	**71%** **n = 7**	3 comments as summarized below • 5 years is too long | 1 year is too short
Instrument Pricing	Optimal: <$100 ex-works	**75%** **n = 8**	Minimal: <$200 ex-works	**57%** **n = 7**	4 comments as summarized below • Raise minimal price to $300? • I wonder if I would want a dedicated temperature monitor at all.... why not have one that also monitors SPO2, heart rate? • If it's just temp, should be much less, the tech isn't that crazy • Difficult to suggest target price, as unclear whether this monitor would provide continuous temperature monitoring and, if so, at what frequency measurements would take place. Further, it would be helpful to know if the device would include Bluetooth or a related wireless system to enable data storage and/or remote monitoring (this would be ideal). A digital neonatal thermometer costs less than $5 in most low-resource settings ($5 for pack of 8 in Uganda), whereas combination monitor (temp/HR/SpO2) is estimated to cost ~$50/device including sensor and tablet interface. Presuming this temp monitor would provide continuous measurements, I would provisionally suggest an Optimal target price of <$50 though clearly

	Optimal		Minimal		
					depends on measurement frequency and wireless data transmission capability
Consumable Pricing	Optimal: <$50 per year ex-works	**86%** **n = 7**	Minimal: Same as Optimal.	**83%** **n = 6**	2 comments as summarized below • Ideally it's reusable and doesn't require consumables • Depends on use. Impossible to say

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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