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NEST360°

Target Product Profile

Radiant Warmer – 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 radiant warmers. While hypothermia can be treated using KMC, infants and their caregivers may not be eligible for reasons such as, but not limited to: mother is recovering from surgery or the infant is in need of intensive care.

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

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

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

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

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.

17 respondents participated in the Delphi-like survey for the Radiant Warmer.

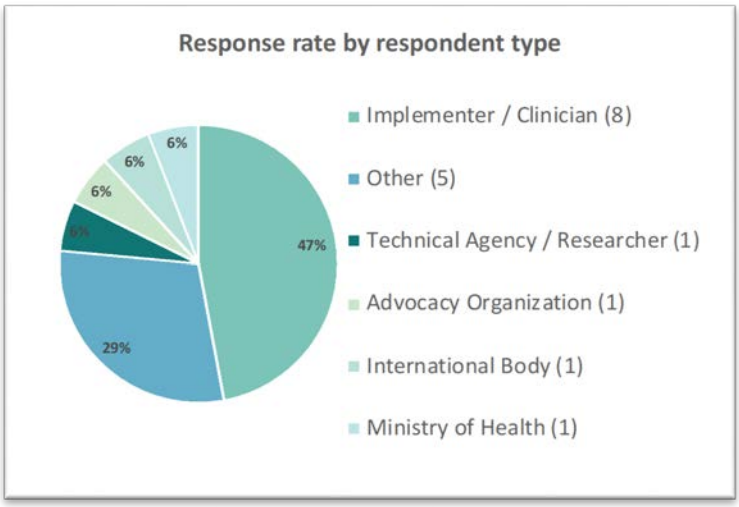
Survey respondents were requested to provide a statement on their level of agreement with each of the proposed characteristics for each TPP. Agreement was scored on a Likert scale ranging from 1 to 5 (1=disagree, 2=mostly disagree, 3= neither agree nor disagree, 4=mostly agree, 5=fully agree) with an 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.

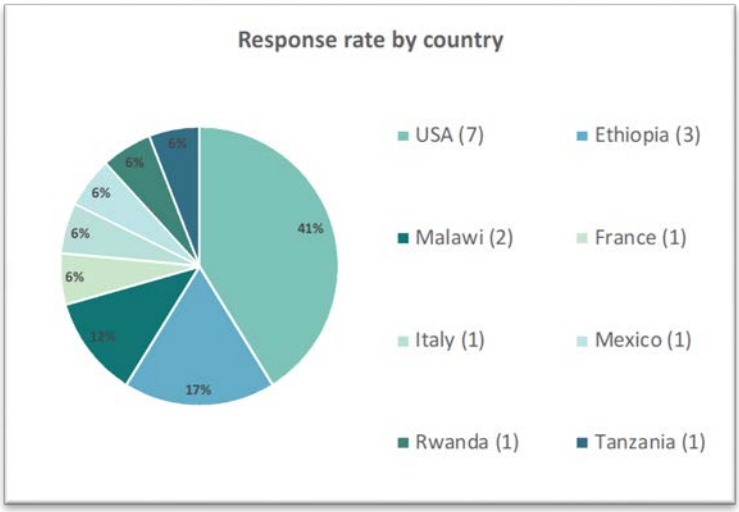
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

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



Respondent type	Percentage
Implementer / Clinician (8)	47%
Other (5)	29%
Technical Agency / Researcher (1)	6%
Advocacy Organization (1)	6%
International Body (1)	6%
Ministry of Health (1)	6%

Figure 2: Summary of response rate by country for Radiant Warmer 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 Radiant Warmer 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 - RADIANT WARMER

Final target product profile for Radiant Warmer		
Characteristic	**Optimal**	**Minimal**
SCOPE		
Intended Use	Treatment and prevention of hypothermia in neonates requiring intensive thermal care	
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	
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	±0.3°C	
Stability	< 0.5°C	
Includes Timer	Yes	
Includes Scale	Yes	No
Mobility	Has wheels; can be moved by one person	
Time to Indicate Accurate Temperature	< 1 minute	< 90 seconds
Uniformity	< 1°C	
Alarm Characteristics	Visual and Auditory	
Alarm Limits	Adjustable	36.5°C-37.5°C
Operating Temperature	Harsh ambient condition, temperature 5-45 °C, humidity 15% to 95%, dusty air, elevation >=2000 meters	Harsh ambient temperature 10-40 °C, humidity 15%-95%, dusty air, elevation up to 2000 meters
Patient Interface	Interface is biocompatible and reusable	Interface is biocompatible
Patient Accessibility and Visibility	Patient is visible and accessible to healthcare worker	
Temperature Control	Based on infant's temperature and includes fail-safe mode	

PURCHASING CONSIDERATIONS		
Consumables	> 12 months before required	> 6 months before required
Instrument Pricing	<$500 ex-works	<$1,500 ex-works
Consumable Pricing	<$50 per year ex-works (includes two probes)	<$100 per year ex-works (includes two probes)
UTILITY REQUIREMENTS		
Power Source	Mains Power	Mains Power
Power Consumption	<250W maximum	<800W maximum
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	

[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: Radiant Warmer

To arrive at the final TPP for Radiant Warmer, 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) to adjust the Optimal and Minimal characteristic to ±0.3°C. Product developers noted that ±0.3°C is required for ISO certification [3].
  - *Optimal:* ±0.3°C
  - *Minimal: Same as Optimal*
- **Includes Timer**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Minimal characteristic to equal the Optimal characteristic. There was agreement in the room to remove the word APGAR from the characteristic and re-title to Includes Timer. The rationale was that when a baby arrives in the NICU they are beyond the APGAR stage. Product developers noted that there is no additional cost to add APGAR timer as it is simply "10-20 lines of code". One clinician mentioned that the challenge is that existing timers do not have an option to alarm at 2 minutes, but rather options for 1 minute, 5 minutes, and 10 minutes.
  - *Optimal: Yes*
  - *Minimal: Same as Optimal*
- **Time to Indicate Accurate Temperature**

- Consensus was achieved in the room (without a Mentimeter vote) to table further discussion on this characteristic until further information is available as additional criteria is needed. Product developers noted that from a technical perspective, given heat transfer and surface temperature, it was challenging to read the temperature of the baby if the sensor was cold or not previously attached to the baby and that the timing would be "constrained by the laws of physics". Clinicians noted that ideally, they would like the temperature to be read in under 60 seconds. A research question to further explore the time required to indicate the accurate temperature of the baby and to measure the time in a standardized way was created.

- **Alarm Characteristics**
  - Consensus was achieved in the room (without a Mentimeter vote) to that the Minimal characteristic should equal the Optimal of Visual and Auditory alarms.
  - *Optimal: Visual and Auditory*
  - *Minimal: Visual*
- **Power Consumption**
  - 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.
  - Consensus was achieved in the room (without a Mentimeter vote) for <800 Watts for the Minimal characteristic. Discussion in the room focused on the fact that the title of the characteristic could vary based on individual interpretation and therefore should be redefined based on the equipment definition.
  - *Optimal: <250W maximum*
  - *Minimal: <800W maximum*
- **Instrument Pricing**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Optimal Instrument Pricing to be <$500 ex-works and the Minimal Instrument Pricing to be <$1,500 ex-works. Participants in the room commented that finding a device on the market below $1,000 is a challenge but innovators should strive for a lower price. Product developers noted that pricing can be reduced when the number of units purchased increases and economies of scale can be realized.
  - *Optimal: <$500 ex-works*
  - *Minimal: <$1,500 ex-works*
- **Consumable Pricing**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Optimal Consumable Pricing to be <$50 per year ex-works and defined as including two probes and the Minimal Instrument Pricing to be <$100 per year ex-works (including two probes). Participants in the room clarified that each probe should last six months, hence two would be adequate for a one year supply. Product developers noted that probes are often damaged due to user misuse (e.g., forcing them in the wrong way) or overload and stressed the importance of "teaching people to treat medical device products like you would treat your iPhone as this is an essential tool".
  - *Optimal: <$50 per year ex-works (includes two probes)*
  - Minimal*: <$100 per year ex-works (includes two probes)*

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, Radiant Warmer).

Delphi-like survey results for Radiant Warmer 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: Treatment and prevention of hypothermia in neonates requiring intensive thermal care.	**88% n = 17**	Minimal: Same as Optimal.	**94% n = 16**	5 comments as summarized below • Theme: A variety of proposed Intended Use language o Place to keep infants warm while doing acute resuscitation (either directly following birth or when they come in septic) o Optimal: Treatment and prevention of hypothermia in neonates requiring intensive thermal care when clinician access is needed o Should also say "not eligible for KMC" o Also for newborns requiring resuscitation immediately after birth (who may not necessarily require 'intensive thermal care' once stabilized)

	Optimal		Minimal		
Target Operator	Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians.	**94%** **n = 16**	Minimal: Same as Optimal	**93%** **n = 15**	2 comments as summarized below • Technology is required regardless of country income
Target Population	Optimal: Neonates (<28 days)	**93%** **n = 15**	Minimal: Same as Optimal.	**100%** **n = 14**	2 comments as summarized below • There are some babies >28 days who may need to use a radiant warmer e.g. KMC babies who clinically deteriorate
Target Setting	Optimal: Hospitals in low-resource settings	**81%** **n = 16**	Minimal: Same as Optimal.	**80%** **n = 15**	5 comments as summarized below • Technology is required in all hospitals with intensive or intermediate neonatal care regardless of country income • Theme: Broaden range to include other levels of the health system o Radiant warmers are also necessary at the health center level, and recommend to avail the equipment at that level as well o I believe it should be available in all CEMONC facilities. In some countries, health centers (lower level that hospitals) can provide

	Optimal		Minimal		
					CEMONC services o Some health centres have deliveries so radiant warmers should be accessible in these settings
International Standard	Optimal: ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes.	**100%** **n = 11**	Minimal: Same as Optimal.	**100%** **n = 10**	0 comments
Regulation	Optimal: CE marking or US FDA Clearance	**82%** **n = 11**	Minimal: Same as Optimal.	**90%** **n = 10**	3 comments as summarized below • CE is essential; FDA is not needed for low income countries, and it is very expensive to obtain
Benchtop Measurement Accuracy	Optimal: ±0.1°C	**92%** **n = 13**	Minimal: Same as Optimal.	**100%** **n = 12**	4 comments as summarized below • Unclear what benchtop vs clinical accuracy means and how that would be measured/reported. Potentially combine? • Clarify if servo or manual • Theme: Overly stringent o Update to ±0.3 °C (should be the same as warming crib, ±0.1°C is way too strict) o Seems overly stringent
Clinical Measurement Accuracy	Optimal: ±0.2°C	**73%** **n = 15**	Minimal: ±0.5°C	**79%** **n = 14**	5 comments as summarized below • Theme: Overly stringent vs. Not strict enough o Optimal: ± 0.1°C |

	Optimal		Minimal		
					Minimal: Same as Optimal o Optimal: ±0.5°C | Minimal: Same as Optimal o Should match warming crib, way too strict
Stability	Optimal: < 0.5°C	**93%** **n = 14**	Minimal: Same as Optimal.	**92%** **n = 13**	2 comments • ± 0.1°C
Includes APGAR timer	Optimal: Yes	**94%** **n = 16**	Minimal: No	**73%** **n = 15**	3 comments as summarized below • Apgar is absolutely necessary during resuscitation • Timing functionality is useful
Includes Scale	Optimal: Yes	**88%** **n = 16**	Minimal: No	**80%** **n = 15**	3 comments as described below • Scale should only be included if it is very reliable, easily calibrated and robust overtime. Otherwise will just be needless complexity that introduces error with very little added efficiency. • It is a "great to be" tool, but not absolutely necessary
Mobility	Optimal: Has wheels; can be moved by one person	**88%** **n = 17**	Minimal: Same as Optimal.	**88%** **n = 16**	3 comments as described below • Has 4 wheels with locking castors. This is standard for radiant warmers and required. Use language that was in 02 concentrator TPP • Can be fixed on a wall or on wheels
Time to Indicate Accurate Temperature	Optimal: < 90 seconds	**71%** **n = 17**	Minimal: < 3 minutes	**69%** **n = 16**	6 comments as described below • A variety of alternative ranges were provided

	Optimal		Minimal		
					o < 30 seconds o < 90 seconds should be Optimal and minimal standard o Time to Indicate Accurate Clinical Temperature: ▪ Optimal: < 3 minutes ▪ Minimal: < 5 minutes o Too strict
Uniformity	Optimal: < 1°C	**100%** **n = 14**	Minimal: Same as Optimal.	**100%** **n = 13**	2 comments as summarized below • "I'm not really sure over what surface area you're referring to it having this uniformity. Seems like more focused surface area, higher requirement of uniformity - if we're talking about the whole bed including the edges (where they baby shouldn't

	Optimal		Minimal		
					be anyway) then less stringent."
Alarm Characteristics	Optimal: Visual and Auditory	**100%** **n = 17**	Minimal: Visual	**56%** **n = 16**	9 comments as summarized below • Theme: Minimal should include audio
Alarm Limits	Optimal: Adjustable	**82%** **n = 17**	Minimal: 36.5°C-37.5°C	**75%** **n = 16**	8 comments as summarize below • Minimal: might increase range a bit depending on accuracy of the instrument • For minimal, would suggest having slightly wider limits (e.g., 36-38°C) • Not realistic, would suggest updating to: o Optimal: +/-0.5 C from baby set temp | Minimal: 36.5°C-37.5°C o Alarm should be able to notify clinicians of hypothermia too • Alarm limits should reflect normothermia • Adjustable is not necessarily preferred. If adjustable pre-set options should be available to avoid user error • The alarm limits should be adjustable as minimal specifications • It is typical to not be able to independently adjust alarms, only to be able to adjust desired temperature of baby. Alarms adjust with desired baby temperature (when temp. is higher

	Optimal		Minimal		
					or lower than desired)"
Consumables	Optimal: > 12 months before required	**87%** **n = 15**	Minimal: > 6 months before required	**79%** **n = 14**	3 comments as summarized below • Reference is not clear. A set of sufficient consumables should be included during technology incorporation to healthcare facility.
Decontamination	Optimal: Easy to clean with common disinfecting agents	**100%** **n = 17**	Minimal: Same as Optimal.	**100%** **n = 16**	0 comments
Maximum Power Consumption	Optimal: <250 Watts	**82%** **n = 11**	Minimal: <800 Watts	**60%** **n = 10**	4 comments as summarized below • Raise minimal to <1000 Watts • The power consumption could be higher than 800 Watts • Ideally should be less
Voltage	Optimal: 110-240V 50-60hz	**86%** **n = 14**	Minimal: 220-240V 50-60hz	**75%** **n = 12**	4 comments as summarized below • 220V is much more important than 110V in low resource countries • 220V applies just to some countries. Minimal should be same as Optimal • Different countries have different voltage rating
Operating Temperature	Optimal: Harsh ambient condition, temperature 5-45 °C, humidity 15% to 95%, dusty air, elevation >=2000 meters	**85%** **n = 13**	Minimal: Harsh ambient temperature 10-40 °C, humidity 15%-95%, dusty air, elevation up to 2000 meters	**83%** **n = 12**	3 comments as summarized below • Suggest making less strict and more realistic • Optimal: Harsh ambient condition, indoor temperature (20-40°C), humidity 30% to 80%, dusty air, elevation <=2000 meters • Should work in any setting / environment • Even it can be beyond this range

	Optimal		Minimal		
Patient Interface	Optimal: Interface is biocompatible and reusable	**93%** **n = 15**	Minimal: Interface is biocompatible	**86%** **n = 14**	3 comments as summarized below • Optimal should be single patient use, to avoid cross-contamination. | Minimal should be reusable. • Should be reusable
Patient Accessibility and Visibility	Optimal: Patient is visible and accessible to healthcare worker.	**88%** **n = 17**	Minimal: Same as Optimal.	**94%** **n = 16**	4 comments as summarized below • Optimal: patient is visible, accessible but also secured (there are side rails that can be put up or down so they don't roll off) on the radiant warmer • Disagree that this should be included in radiant warmer. A radiant warmer by default is open and accessible so this requirement seems unnecessary to include • Need to define "accessibility and visibility' for developers
Temperature Control	Optimal: Based on infant's temperature and includes fail-safe mode	**82%** **n = 17**	Minimal: Same as Optimal.	**81%** **n = 16**	4 comments as summarized below • "So incubators and radiant warmers ... getting people to use servo vs manual is super difficult. EVERYONE in my experience is relying on fail-safes or manual mode because we either don't have or are not sure that servo probes for the patient are actually working. Need to think hard about usability vs added functionality on this" • It's recommended to incorporate the term "Servo-controlled" • Also include as minimal and Optimal

	Optimal		Minimal		
					"a servo and manual mode"
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.	**100%** **n = 17**	Minimal: User manual provided.	**94%** **n = 16**	2 comments as summarized below • Warmers can be dangerous when not administered properly. Patient safety issue requires proper training
Warranty	Optimal: 5 years	**76%** **n = 17**	Minimal: 1 year	**94%** **n = 16**	5 comments as summarized below • 5 years is too long, it is too hard for the companies to ensure that, but 1 year too short. 3 years is the actual expected best standard of warranty • Warranty extensions usually impact on final pricing. Two years warranties are industry accepted • One year is good • No supplier will provide 5 years warranty • Warmer functional issues come up frequently
Instrument Pricing	Optimal: <$500 ex-works	**71%** **n = 14**	Minimal: <$1,000 ex-works	**62%** **n = 13**	7 comments as summarized below • I believe $1,000 should be the minimal requirement in order to have a quality product • Technology cost is above the $1,000 USD mark • Raise to $1500 or $2000? • Will still be expensive for many resource countries • We are talking about low resource setting, and high prices for the equipment will not be feasible for this countries. • Should ideally be as cheap as possible as

	Optimal		Minimal		
					facilities are likely to require numerous • Depends on manufacturer model
Consumable Pricing	Optimal: <$50 per year ex-works	**79%** **n = 14**	Minimal: <$100 per year ex-works	**62%** **n = 13**	4 comments as summarized below • It should be specified the consumable presentation: box/piece/set • Should be as cheap as possible - temperature probes easily break and will be used heavily • We are talking about low resource setting, and high prices for the equipment will not be feasible for this countries

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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