unicef
for every child

NEST360°

Target Product Profile

Phototherapy Light – Jaundice Management

1ST EDITION, MARCH 2020

v1.2

Table of Contents

Acknowledgements
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.

NEST360° is made possible by generous commitments from the John D. and Catherine T. MacArthur Foundation, the Bill & Melinda Gates Foundation, The ELMA Foundation, the Children's Investment Fund Foundation, The Lemelson Foundation, the Ting Tsung and Wei Fong Chao Foundation and individual donors to Rice 360°.

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

Most neonates, term and preterm, will have elevated levels of unconjugated bilirubin and some amount of jaundice during the first one to two weeks of life due to increased levels of unconjugated bilirubin with transient impaired excretion, which is normal in this age group. This condition is particularly prevalent in preterm babies and, if the levels of unconjugated bilirubin are very high and left untreated, may lead to irreversible neurologic damage known as kernicterus.

Phototherapy treats unconjugated hyperbilirubinemia that exceeds safe levels. These levels are based on day of life and risk factors and typically occur within the first one to two weeks of life.

Treatment with blue light phototherapy is necessary to prevent morbidity and mortality from dangerous levels of neonatal jaundice. The blue light is absorbed by bilirubin, which is then broken down in the blood, allowing the infant to excrete the excess bilirubin before it can accumulate and cause permanent brain damage (kernicterus) or death. Jaundice is preventable and treatable; however, kernicterus is permanent and irreversible, resulting in life-long disability.

Treatment with blue light phototherapy is necessary to prevent morbidity and mortality for severe cases of neonatal jaundice. The blue light breaks down bilirubin in the blood, allowing the infant to excrete the excess bilirubin before it can accumulate and cause permanent brain damage (kernicterus) or death.

There is a dose dependent response of neonatal hyperbilirubinemia to phototherapy which depends on: (1) Duration of phototherapy; (2) Degree of irradiance given which is dependent on wavelength and type of light used; (3) the amount of body surface area irradiated; and (4) the distance of light from patient (this will vary and is based on manufacturers recommendation but is typically 10-30cm).

Phototherapy lights can also be paired with an irradiance meter so that clinicians can determine if the infant is receiving a therapeutic dose of light. Typically, optimal spectral irradiance is 25 -30microW/cm2/nm, although higher spectral irradiance of 30-35 microW/cm2/nm may be used in more severe cases. If the dose is too low, clinicians may adjust the placement of the infant, the height or output power of the light, or replace burnt out light elements.

There are many types of phototherapy lights and modalities including LED, spotlights, fluorescent blue lights, halogen lights, and phototherapy blankets. LED lights have been shown to be the safest and most efficacious for administering phototherapy, as they give off the least heat and are associated with the lowest risk of hyperthermia and dehydration; although, this sometimes comes at an increased cost [1-3].

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.

25 respondents participated in the Delphi-like survey for the Phototherapy Light.

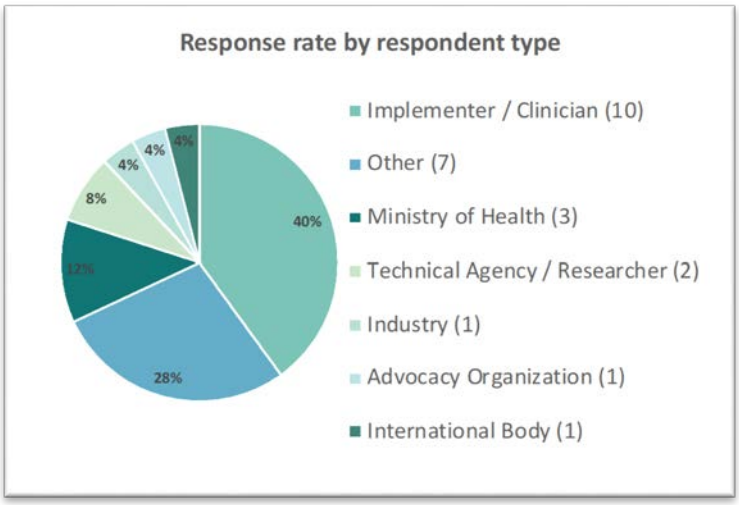
Survey respondents were requested to provide a statement on their level of agreement with each of the proposed characteristics for each TPP. Agreement was scored on a Likert scale ranging from 1 to 5 (1=disagree, 2=mostly disagree, 3= neither agree nor disagree, 4=mostly agree, 5=fully agree) with an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

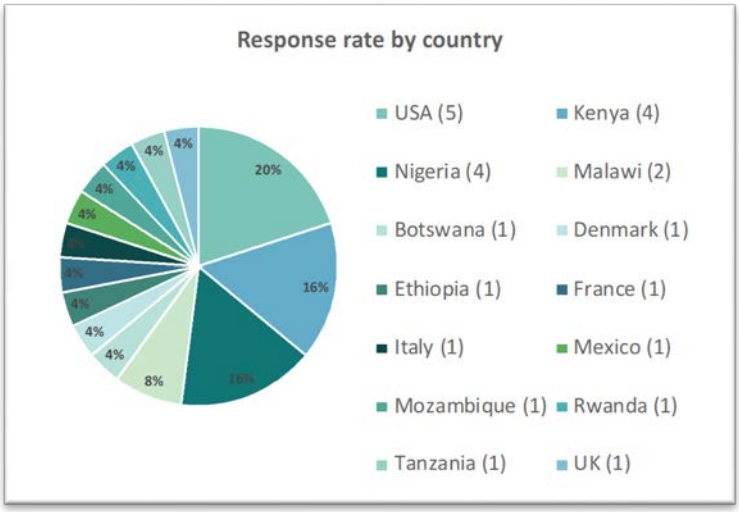
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

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



Respondent type	Percentage
Implementer / Clinician (10)	40%
Other (7)	28%
Ministry of Health (3)	12%
Technical Agency / Researcher (2)	8%
Industry (1)	4%
Advocacy Organization (1)	4%
International Body (1)	4%

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



Country	Percentage
USA (5)	20%
Kenya (4)	16%
Nigeria (4)	16%
Malawi (2)	8%
Botswana (1)	4%
Denmark (1)	4%
Ethiopia (1)	4%
France (1)	4%
Italy (1)	4%
Mexico (1)	4%
Mozambique (1)	4%
Rwanda (1)	4%
Tanzania (1)	4%
UK (1)	4%

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 Phototherapy Light 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 - PHOTOTHERAPY LIGHT

Final target product profile for Phototherapy Light		
Characteristic	**Optimal**	**Minimal**
SCOPE		
Intended Use	Treatment of hyperbilirubinemia in neonates	
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		
Irradiance	Standard Phototherapy: 8-10 uW/cm2/nm AND Intensive Phototherapy: >30 uW/cm2/nm	
Effective Treatment Area	>2000 cm2	>1300 cm2
Peak Wavelength	430-490 nm	
Light Source	LED	
Bulb Lifetime	60,000 hours	44,000 hours
Ease of Replacing Bulbs	Capable of being replaced by a technician with minimal training and basic tools (screwdrivers)	
Irradiance Meter	Included	Available
PURCHASING CONSIDERATIONS		
Instrument Pricing	<$400 ex-works	<$1,000 ex-works
UTILITY REQUIREMENTS		
Power Source	Mains with battery backup	Mains Power
Battery	Provides battery backup	None
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

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

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

Consensus Meeting Summary: Phototherapy Light

To arrive at the final TPP for Phototherapy Light, 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.

- **Effective Treatment Area**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Optimal characteristic that the Effective Treatment Area would be expanded to measure >2000 cm^2 and the Minimal would be adjusted to >1300 cm^2. Clinicians emphasized the importance of expanding the Optimal Effective Treatment Area to be equal to the base size of a basinet or incubator at 2000 cm^2 even though some guidelines (e.g., AAP) specify that effective surface area is1800 cm^2 (60 x 30 cm) [4-5]. Product developers warned against increasing the size for the purpose of using one machine for multiple babies while clinicians acknowledged that in low-resource settings, this often occurred despite knowing that this wasn't the proper use of the device. Clinicians also noted that increasing the Optimal Effective Treatment Area was necessary to accommodate larger babies ("chubby chaps") and movement ("squiggly wigglies").
  - *Optimal: >2000 cm^2*
  - *Minimal: >1300 cm^2*
- **Irradiance Meter**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Minimal characteristic to be adjusted and specify that an irradiance meter is available for use but that it is not required to be bundled with every phototherapy light purchase. The concern expressed was that this would add an additional cost to the price of the phototherapy light. Clinicians and product developers agreed that an irradiance meter could be purchased separately (estimated cost between $100 - $300) or one could be shared across the unit. There was a discussion that broader guidelines/toolkits for procurement officers on the minimal infrastructure requirements should be developed so that hospitals who purchase a Phototherapy Light also ensure that an Irradiance Meter is available.
  - *Minimal: Available.*
- **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)*

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

- **Battery**
  - Participants commented that ideally, a battery back-up should be available internal to the device. Additionally, ideally the device should not be damaged by cycling of power/voltage spikes in the case of a power surge. The Optimal characteristic for Battery includes "Provides battery backup" in response to this point.

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: Phototherapy Light

Delphi-like survey results for Phototherapy Light 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 of hyperbilirubinemia in neonates.	**100% n = 24**	Minimal: Same as Optimal.	**100% n = 22**	0 comments
Target Operator	Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians.	**96% n = 23**	Minimal: Same as Optimal	**95% n = 22**	1 comment • Technology is widely used regardless of country income
Target Population	Optimal: Neonates (<28 days)	**100% n = 23**	Minimal: Same as Optimal.	**100% n = 21**	1 comment • Would potentially be useful up to 40 days
Target Setting	Optimal: Hospitals in low-resource settings	**88% n = 24**	Minimal: Same as Optimal.	**91% n = 22**	2 comments • Technology is required regardless of country income • Not necessarily low-income countries
International Standard	Optimal: ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes.	**100% n = 15**	Minimal: Same as Optimal.	**93% n = 14**	1 comment • "ISO standardizes across the board - yes, it should. If it doesn't meet the ISO standards, does that mean it is not effective? If it meets the regional standards, that would be okay, but it's

	Optimal		Minimal		
					preferred that it meets ISO standards."
Regulation	Optimal: CE marking or US FDA Clearance	**83%** **n = 18**	Minimal: Same as Optimal	**88%** **n = 17**	6 comments as summarized below • Theme: Reduce regulatory options or add more flexibility • CE Mark alone is sufficient • Consider additional 'or' options: o Other Stringent Regulatory Authorities – Japan or Australia or Canada o Consider regulatory bodies of Low- and Middle-Income Countries
Irradiance	Optimal: Standard Phototherapy: 8-10 uW/cm2/nm AND Intensive Phototherapy: >30 uW/cm2/nm	**94%** **n = 18**	Minimal: Same as Optimal	**94%** **n = 16**	2 comments as summarized below • Need clinical reference • The luminous flux depend of the distance of measurement.
Effective Treatment Area	Optimal: >1300 cm2	**73%** **n = 15**	Minimal: Same as Optimal.	**79%** **n = 14**	5 comments as summarized below • Needs to be bigger: o 1920 cm2 o 1250 cm2 o Should cover the whole baby and baby should be naked, without pampers o Need clinical reference
Peak Wavelength *(corrected from 'Pressure')*	Optimal: 430-490 nm	**100%** **n = 19**	Minimal: Same as Optimal.	**100%** **n = 17**	1 comment • Can also be 425-475 nm
Light Source	Optimal: LED	**100%** **n = 23**	Minimal: Same as Optimal.	**100%** **n = 21**	1 comment • Recommended and safer. New technology and longer life span

	Optimal		Minimal		
Bulb Lifetime	Optimal: 60,000 hours	**95%** **n = 21**	Minimal: 44,000 hours	**89%** **n = 18**	5 comments as summarized below • Most manufactures have shelf life of 50,000 hours. That is a reasonable number • 1,000 hours is something accepted by industry standards as minimal requirement • Agree, but need clarity on if this is as reported by manufacturer or actually tested. It is assumed that irradiance levels reduce as hours increase. In my mind this spec means that at "44,000 hours" the irradiance level still meets the initial spec of >30 irradiance • There is no more bulbs in the equipment we are talking about LED
Ease of Replacing Bulbs	Optimal: Capable of being replaced by a technician with minimal training and basic tools (screwdrivers)	**90%** **n = 21**	Minimal: Same as Optimal.	**85%** **n = 20**	5 comments as summarized below • Theme: Remove this characteristic or change to adapt to LED o Given the long duration of LED, it is expected that machines will be trashed before light expires. Hence, changing the light is not that essential in LED Phototherapy o Recommend changing Optimal to: bulbs last lifetime of device o Recommend changing minimal to: Capable of being replaced by a technician with minimal training and basic tools o "LEDs bulbs should not be

	Optimal		Minimal		
					replaced by a technician. Bulbs will burn out at the end of life of the unit and should be returned to manufacturer. this is the replacement cycle of the devices." • Very important - can't keep replacing everyday bulbs. Spare bulbs need to be available. Don't want to have to request them on a one-off basis from the US
Irradiance Meter	Optimal: Included	**75%** **n = 20**	Minimal: Same as Optimal.	**72%** **n = 18**	8 comments as summarized below • Theme: Can be made available separately • Theme: 1 can be used across whole hospital to reduce cost • Change 'Included' to 'Available'
Voltage	Optimal: 110-240 50-60hz	**74%** **n = 19**	Minimal: 220-240 50-60hz	**72%** **n = 18**	8 comments as summarized below • Suppliers should offer either a single unit capable of running of 110-240 volt, or have two different versions, one of 110 volt and another for 220 -240 volt.
Response During Power Outage	Optimal: Provides battery backup internal to device	**91%** **n = 23**	Minimal: Is not damaged by cycling of power/voltage spikes	**81%** **n = 21**	6 comments as summarized below • Theme: Minimal is not in correct category as it does not directly relate to the Optimal. Possibly a separate spec? • Recommendation to make to Characteristics 1. Battery backup: Optimal - provides battery backup internal to device; minimal – none 2. Protection from power surge: Optimal - is not damaged by

	Optimal		Minimal		
					cycling of power/voltage spikes; minimal: none
User Instructions	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 = 23**	Minimal: User manual provided.	**95%** **n = 22**	4 comments as summarized below • Theme: Training materials will likely need to be developed separate from the manufacturer
Warranty	Optimal: >5 years	**78%** **n = 23**	Minimal: ≥1 year	**82%** **n = 22**	10 comments as summarized below • Theme: 5 years too long • Suggested Ranges: 2 years To honor a 5 year warranty, you will have to have strong in-country representation. All an extended warranty is a degree of assurance of the above, and this will come at a cost. Manufactures of concentrators willing to extend a warranty from 2-5 do so 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 take care of any major PPM requirements, as well as "swap out" in the event of a break-down, and there is no discussion of warranties and no need for spares and an in-country source for consumables.
Instrument Pricing	Optimal: <$400 ex-works	**95%** **n = 20**	Minimal: <$1,000 ex-works	**75%** **n = 20**	9 comments as summarized below • Theme: Geography is extremely price sensitive and even $400 was viewed as the maximum • Optimal is too low and may impact quality of device provided • Current brands are $2,000 (may not be ex-works) • $400-500 maximum • Too expensive • Pricing ought to be reasonable for LMIC budgets and not prohibitive

REFERENCES

[1] Kumar, P., Chawla, D., & Deorari, A. (2011). Light-emitting diode phototherapy for unconjugated hyperbilirubinaemia in neonates. *Cochrane Database of Systematic Reviews, 2011*(12). https://doi.org/10.1002/14651858.CD007969.pub2.

[2] Morris, B. H., Tyson, J. E., Stevenson, D. K., Oh, W., Phelps, D. L., O'Shea, T. M., … & Higgins, R. D. (2013). Efficacy of phototherapy devices and outcomes among extremely low birth weight infants: Multi-center observational study. *Journal of Perinatology, 33,* 126-133. https://doi.org/10.1038/jp.2012.39.

[3] Eggert, P., Stick, C., & Schröder, H. (1984). On the distribution of irradiation intensity in phototherapy: Measurements of effective irradiance in an incubator. *European Journal of Pediatrics, 142,* 58-61. https://doi.org/10.1007/bf00442593.

[4] American Academy of Pediatrics Subcommittee on Hyperbilirubinemia. (2004). Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. *Pediatrics, 114*, 297-316. https://doi.org/10.1542/peds.114.1.297.

[5] International Electrotechnical Commission. (2000). *Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment.* (IEC 60601-2-50). Retrieved from https://webstore.iec.ch/publication/2669.

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