

# Target Product Profile

Suction Pump – Respiratory Support

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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.*

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# INTRODUCTION

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At birth, a baby's lungs must transition from fetal to neonatal life in three key ways:

1. fluid in the lungs must be absorbed and replaced with air,
2. lungs must expand fully and regular breathing must be established, and
3. pulmonary blood flow is increased.

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

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

Clinicians periodically need to clear an infant's airway through the use of a suction pump. Safe ranges for neonatal suctioning depending on the size of the infant and are generally considered to be between 60-100mmHg.

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# DEVELOPING A TARGET PRODUCT PROFILE

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## 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 Suction Pump.

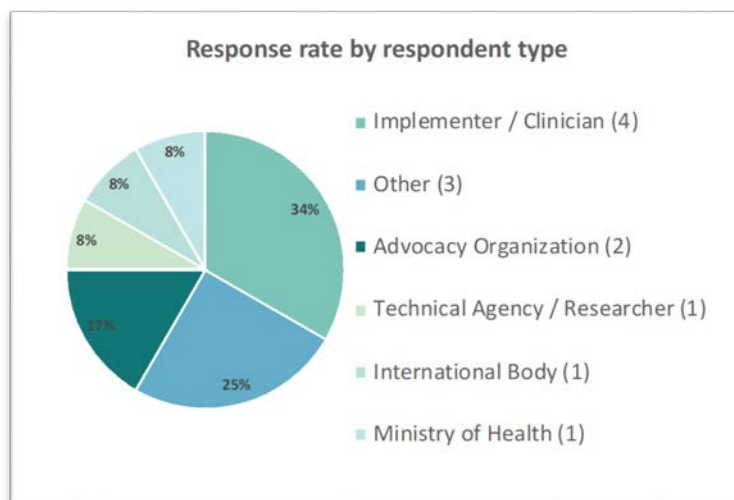
Survey respondents were requested to provide a statement on their level of agreement with each of the proposed characteristics for each TPP. Agreement was scored on a Likert scale ranging from 1 to 5 (1=disagree, 2=mostly disagree, 3= neither agree nor disagree, 4=mostly agree, 5=fully agree) with an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

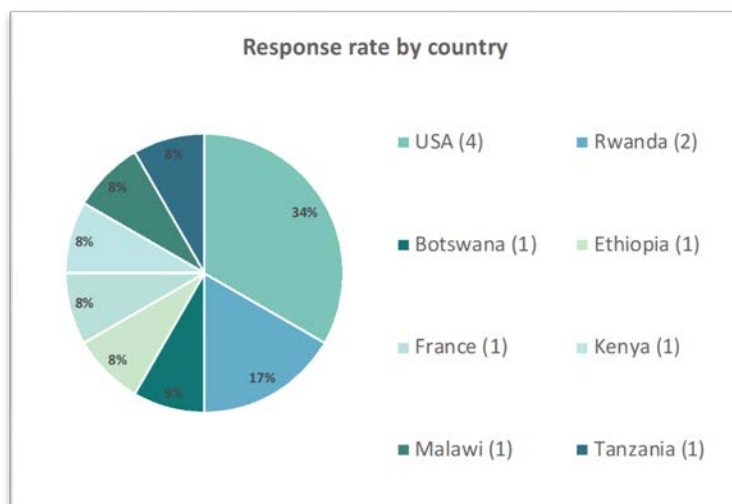
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

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



Respondent type	Percentage
Implementer / Clinician (4)	33%
Other (3)	25%
Advocacy Organization (2)	17%
Technical Agency / Researcher (1)	8%
International Body (1)	8%
Ministry of Health (1)	8%

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



Country	Percentage
USA (4)	34%
Rwanda (2)	17%
Botswana (1)	9%
Ethiopia (1)	8%
France (1)	8%
Kenya (1)	8%
Malawi (1)	8%
Tanzania (1)	8%

# 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 Suction Pump 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 - SUCTION PUMP

Final target product profile for Suction Pump		
Characteristic	Optimal	Minimal
<b>SCOPE</b>		
<b>Intended Use</b>	Aspiration and removal of secretions, bodily fluids and foreign objects from a patient's airway or respiratory support system in the nasal, pharyngeal and tracheal areas	
<b>Target Operator</b>	For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians	
<b>Target Population</b>	Neonates (born at any gestational age and require ongoing care)	
<b>Target Setting</b>	Hospitals in low-resource settings, but, may be used in health facilities based on country guidelines	Hospitals in low-resource settings
<b>SAFETY AND STANDARDS</b>		
<b>Quality Management</b> <sup>1</sup>	ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes	
<b>Regulation</b>	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)	
<b>TECHNICAL CHARACTERISTICS</b>		
<b>Pressure</b>	60-120 mm Hg with continuous adjustment	
<b>Bottle Capacity</b>	1 L	
<b>Noise Level</b>	As low as possible	
<b>Cleaning</b>	Collection vessel easy to clean reusable	
<b>Maintenance</b>	No maintenance or lubrication	
<b>Operation Mode</b>	Adjustable to neonatal setting (60-100 mm Hg)	
<b>PURCHASING CONSIDERATIONS</b>		
<b>Instrument Pricing</b>	<\$100 ex-works	<\$250 ex-works
<b>UTILITY REQUIREMENTS</b>		
<b>Power Source</b>	Mains Power	Mains Power
<b>Voltage</b>	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)	
<b>TRAINING AND MAINTENANCE</b>		
<b>User Instructions</b>	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
<b>Warranty</b>	5 years	1 year



<sup>1</sup> 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: Suction Pump

To arrive at the final TPP for Suction Pump, 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.

### • Pressure

- There was disagreement on both the Optimal and Minimal characteristic. Clinicians agreed that for the minimum end of the range, 60 mm Hg was acceptable. Product developers noted that there is not a significant incremental cost between the upper range between 100 mm Hg or 120 mm Hg. Consensus was achieved in the room (without a Mentimeter vote) that the Minimal should be the same as Optimal.
- *Optimal: 60-120 mm Hg with continuous adjustment*
  - Overall Vote - 100% Agree (n = 18)
  - Clinicians - 100% Agree (n = 13)
  - Excluding involvement with product development - 100% Agree (n = 18)
- *Minimal: 60-120 mm Hg with continuous adjustment (Same as Optimal)*

### • Noise Level

- Consensus was achieved that the sound level characteristic was referring to the operating noise level. Some product developers noted that from a technical standpoint, CE mark requires that this be under 50 decibels for operating noise, however, another participant confirmed that this was simply the minimum end of the range required and that "in operating rooms, the background noise can vary from 50 dBA to 85 dBA". Ultimately, consensus was achieved in the room (without a Mentimeter vote) for both the Optimal and Minimal characteristic to be the same and specify that the "lower the decibel level, the better". The spirit of the conversation emphasized that the noise levels should be as low as possible to protect the babies hearing.
- *Optimal: As low as possible*
- *Minimal: Same as Optimal*

### • Instrument Pricing

- Consensus was achieved in the room (without a Mentimeter vote) to reduce the Minimal price to <\$250 ex-works.
- *Minimal: <\$250 ex-works*

### • 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)*

## 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 Suction Pump), 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: Suction Pump

### Delphi-like survey results for Suction Pump TPP prior to Consensus Meeting (data as of Oct 25, 2019)

Characteristic	Optimal		Minimal		Collated comments from Delphi-like survey
	Optimal requirement	% agreement (n size)	Minimal requirement	% agreement (n size)	
<b>Intended Use</b>	Optimal: Aspiration and removal of secretions, bodily fluids and foreign objects from a patient's airway or respiratory support system in the nasal, pharyngeal and tracheal areas.	<b>92%</b> n = 12	Minimal: Same as Optimal.	<b>91%</b> n = 11	<p>2 comments as summarized below</p> <ul style="list-style-type: none"> <li>Optimal: Ability to provide suction at different maximum settings between 80-120mmHg with variable attachments for suctioning that vary in possible depth (nasal, nasopharyngeal, nasopharyngeal-tracheal) as well as size (Children 12F I think but not sure upper size limit? I'd have to check that one. Infants are 10Fr, neonates are 6-8Fr)</li> </ul> <p>Minimal: (for neonates): Ability to provide suction at different maximum settings between 80-100mmHg with variable attachments for suctioning that vary in possible depth (nasal, nasopharyngeal) as well as size (infants I think are 10Fr, neonates are 6-8Fr)</p>
<b>Target Operator</b>	Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians.	<b>100%</b> n = 12	Minimal: Same as Optimal	<b>100%</b> n = 10	<ul style="list-style-type: none"> <li>0 comments</li> </ul>
<b>Target Population</b>	Optimal: Neonates (<28 days)	<b>91%</b> n = 11	Minimal: Same as Optimal.	<b>80%</b> n = 10	<p>4 comments as summarized below</p> <ul style="list-style-type: none"> <li>Theme: Broaden Age Range <ul style="list-style-type: none"> <li>Children</li> <li>Adults</li> </ul> </li> <li>Theme: Small vs. Sick Newborns <ul style="list-style-type: none"> <li>Small newborn (&lt;2.5kg) parameters will be slightly different from sick newborn parameters. Small newborns need 6-8Fr catheters, 60-80mmHg. Sick (but not small) newborn parameters would be 60-100mmHg 8-10Fr catheters for nasopharyngeal suctioning</li> </ul> </li> </ul>
<b>Target Setting</b>	Optimal: Hospitals in low-resource settings	<b>92%</b> n = 12	Minimal: Same as Optimal.	<b>90%</b> n = 10	<p>2 comments as summarized below</p> <ul style="list-style-type: none"> <li>Theme: Broaden Target Setting Optimal should be health centres (primary)</li> </ul>
<b>International Standard</b>	Optimal: ISO 13485:2016 Medical devices – Quality management systems -	<b>86%</b> n = 7	Minimal: Same as Optimal.	<b>83%</b> n = 6	<p>1 comments</p> <ul style="list-style-type: none"> <li>More specific standards for suction vs. blanket ISO 13485</li> </ul>

	Optimal		Minimal		
	- Requirements for regulatory purposes.				
<b>Regulation</b>	Optimal: CE marking or US FDA Clearance	<b>86%</b> n = 7	Minimal: Same as Optimal.	<b>86%</b> n = 7	1 comments <ul style="list-style-type: none"> <li>○ CE Marking in the medical domain</li> </ul>
<b>Pressure</b>	Optimal: 60-100 mm Hg with continuous adjustment	<b>73%</b> n = 11	Minimal: 60-100 mm Hg	<b>67%</b> n = 9	4 comments <ul style="list-style-type: none"> <li>• Optimal: 60-120 mm Hg</li> <li>• Optimal: recommend adding - continuous adjustment <u>within the full range</u></li> <li>• Canadian policy states 80-100 mm Hg</li> <li>• Need clinical input</li> </ul>
<b>Bottle Capacity</b>	Optimal: 1 L	<b>92%</b> n = 13	Minimal: Same as Optimal.	<b>92%</b> n = 12	2 comments as summarized below <ul style="list-style-type: none"> <li>• For neonatal application only <ul style="list-style-type: none"> <li>○ "I think this depends on how it gets cleaned. I'm not sure that 1L capacity is really necessary? The most you're ever going to suction from a kid is a few mL ... I'd guess 50mL generously. So I'd says 50 x # of patients you can suction without cleaning anything is the capacity?"</li> </ul> </li> </ul>
<b>Noise Level</b>	Optimal: <65 dB	<b>57%</b> n = 7	Minimal: 65 dB	<b>50%</b> n = 6	4 comments as summarized below <ul style="list-style-type: none"> <li>• Recommendation to change Optimal: &lt;=60 and Minimal: &lt;50</li> </ul>
<b>Cleaning</b>	Optimal: Collection vessel easy to clean reusable.	<b>100%</b> n = 13	Minimal: Same as Optimal.	<b>100%</b> n = 12	2 comments as summarized below <ul style="list-style-type: none"> <li>• Collection and patient interface easy to clean and reusable</li> </ul>
<b>Maintenance</b>	Optimal: No maintenance or lubrication.	<b>85%</b> n = 13	Minimal: Same as Optimal.	<b>82%</b> n = 11	4 comments as summarized below <ul style="list-style-type: none"> <li>• Clarity on what is meant by lubrication – nasal saline prior to suctioning?</li> <li>• Maintenance should be required but minimal and/or easy</li> </ul>
<b>Operation Mode</b>	Optimal: Adjustable to neonatal setting (60-100 mm Hg)	<b>77%</b> n = 13	Minimal: Same as Optimal.	<b>90%</b> n = 10	4 comments as summarized below <ul style="list-style-type: none"> <li>• Optimal: 60-120 mm Hg</li> <li>• Optimal: recommend adding - continuous adjustment <u>within the full range</u></li> <li>• Need clarity as to why this is linked to the pressure only. I would maybe think of battery or mains operation mode or electrical or manual operation mode, or adult, pediatric or neonatal operation mode</li> </ul>

	Optimal		Minimal		
<b>User Manual</b>	Optimal: User manual and additional training materials (checklists, videos, guides) in English and local language. Attached to device with labels and markings where possible.	<b>83%</b> n = 12	Minimal: User manual provided.	<b>82%</b> n = 11	2 comments as summarized below <ul style="list-style-type: none"> <li>• Manuals of limited use</li> <li>• English and/or French would be sufficient</li> </ul>
<b>Voltage</b>	Optimal: 110-240V 50-60hz	<b>83%</b> n = 12	Minimal: 220-240V 50-60hz	<b>70%</b> n = 10	3 comments as summarized below <ul style="list-style-type: none"> <li>• Most LMICs use high voltage power</li> <li>• Is there some built-in surge protection? 220V power fluctuates from 200-250 depending per country. Not many data available. It's worth doing some data collection in the countries you work</li> <li>• Kenya single phase voltage is 240V</li> <li>• 110-240v, 50-60 is good for different rating for different countries</li> </ul>
<b>Warranty</b>	Optimal: 5 years	<b>83%</b> n = 12	Minimal: 1 year	<b>64%</b> n = 11	3 comments as summarized below <ul style="list-style-type: none"> <li>• Need to be tender for more than 1yr warranty and service. Maybe you pay for it separately</li> <li>• 1 year is good <ul style="list-style-type: none"> <li>○ Warranties are not useful</li> </ul> </li> </ul>
<b>Instrument Pricing</b>	Optimal: <\$100 ex-works	<b>91%</b> n = 11	Minimal: <\$300 ex-works	<b>70%</b> n = 10	4 comments as summarized below <ul style="list-style-type: none"> <li>• Theme: Discrepancy on whether this is reasonable or not</li> <li>• We just purchased some suction pumps (manual &amp; electric) for within these ranges</li> <li>• Should be cheaper</li> <li>• It's difficult to produce a good quality pump for that price. What about the warranty and training cost, does that come on top of this? I guess so.</li> <li>• What about consumables?</li> </ul>

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# APPENDICES

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## 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 Chepkemai (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 Stryko (Children's Hospital of Philadelphia/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 Moshiri (Muhimbili National Hospital)  
Ronald Mbwasii (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 <sup>2</sup>	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
SpO <sub>2</sub>	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