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NEST360°

Target Product Profile

Syringe Pump – Hydration, Nutrition, and Drug Delivery

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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

Small and sick babies have special fluid and nutritional requirements [1,2]. Intravenous (IV) infusions of water, electrolytes and glucose are given to neonates during the first weeks of life to maintain fluid and electrolyte balances and to provide energy for basic metabolic processes [3]. Fluid therapy requires delivery at precise volumes and flow rates, and fluid overload can be life-threatening [3,4].

Syringe pumps deliver medication and small quantities of fluids continuously through an intravenous line and are a "priority medical device" as described by the World Health Organization. In high-resource hospitals, syringe pumps are used to provide rehydration fluids, breastmilk, dextrose to hypoglycemic infants, and antibiotics to infants with infection. In hospitals where syringe pumps do not exist or are unable to be maintained or operated, these fluids are delivered via a gravity-fed IV drip, slow push by nurses, or using burettes. These are all much less accurate methods of delivery and put infants at significant risk of over/under dosing, medical error, line complications, fluid overload, or hypovolemia. Additionally, since premature babies are likely to need slow introduction to breastmilk over the first week of life, syringe pumps are critical to maintaining normal glucose and hydration until preterm infants can tolerate adequate volumes of breastmilk orally or by nasogastric tube. For these reasons, syringe pumps were listed as a pressing technology for improving newborn care in The Global Action Report on Preterm Birth [5].

The FDA has reported that syringe pumps currently on the market are difficult to use [6]. Moreover, existing syringe pumps are expensive, and require costly, brand-specific consumables, making them unsuitable for use outside of high-resource settings. To be effective in reducing infant mortality on a global scale, pumps must be designed with a simple user interface to avoid setup errors and function accurately with the variety of syringe brand and sizes. In addition to withstanding hot and humid environments, the pump must be easily calibrated and maintained by local technicians. Syringe pumps are often unavailable for infants in need of life-saving IV treatment.

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.

10 respondents participated in the Delphi-like survey for Syringe Pump.

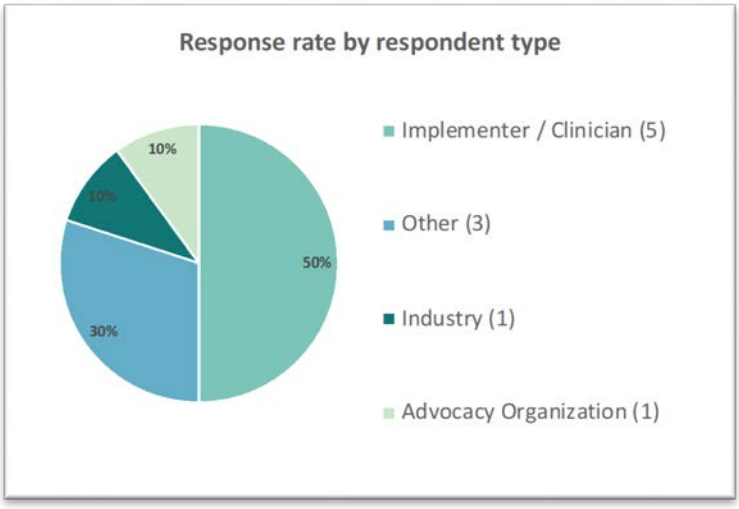
Survey respondents were requested to provide a statement on their level of agreement with each of the proposed characteristics for each TPP. Agreement was scored on a Likert scale ranging from 1 to 5 (1=disagree, 2=mostly disagree, 3= neither agree nor disagree, 4=mostly agree, 5=fully agree) with an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

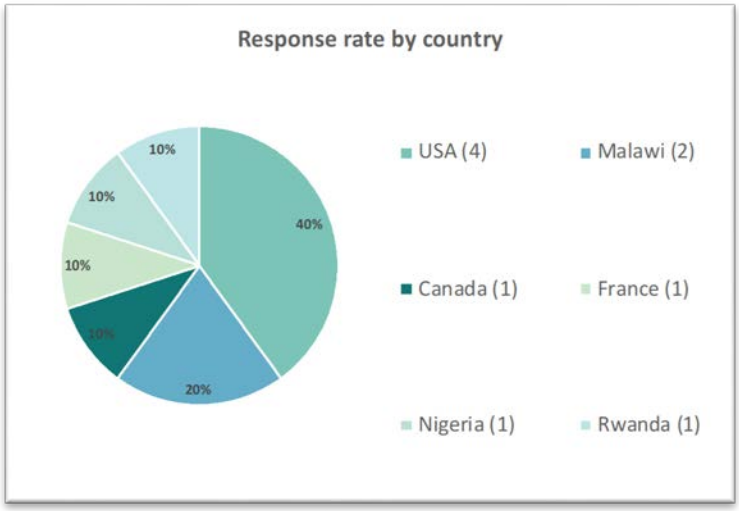
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

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



Respondent type	Percentage
Implementer / Clinician (5)	50%
Other (3)	30%
Industry (1)	10%
Advocacy Organization (1)	10%

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



Country	Percentage
USA (4)	40%
Malawi (2)	20%
Canada (1)	10%
France (1)	10%
Nigeria (1)	10%
Rwanda (1)	10%

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 Syringe 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 - SYRINGE PUMP

Final target product profile for Syringe Pump		
Characteristic	**Optimal**	**Minimal**
SCOPE		
Intended Use	Treatment of conditions requiring precise administration of drugs and fluids; including but not limited to dextrose solution for hypoglycemia and antibiotics for infection	
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 (for Flow Rate)	±1.0%	±3.0%
Flow Rate Requirements	0.1 - 60 mL/hr	
Occlusion Detection	Continuous adjustment (fully adjustable)	Adjustable based on pre-set (5, 10, 25 psi)
Syringe Requirements	Syringe 5-60mL, works with multiple syringe types	
Drug Library	Yes	No
Alarm Characteristics	Visual and Auditory	
Size	Small footprint; portable	
Weight	<1.5 kg (without batteries)	<5 kg (without batteries)
PURCHASING CONSIDERATIONS		
Instrument Pricing	<$300 ex-works	<$1,000 ex-works
UTILITY REQUIREMENTS		
Power Source	Mains with rechargeable battery	Mains with rechargeable battery
Battery	Rechargeable battery, >12hr on single charge	Rechargeable battery, >4hr on single charge

Voltage	Model must match the voltage and frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz)	
TRAINING AND MAINTENANCE		
User Instructions	User manual and additional training materials (checklists, videos, guides) in at least one national official language for the country of intended use. Attached to device with labels and markings where possible	User manual provided in at least one national official language
Warranty	5 years	1 year
Decontamination	Easy to clean with common disinfecting agents	

[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: Syringe Pump

To arrive at the final TPP for Syringe 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.

- **Benchtop Measurement Accuracy (for Flow Rate)**
  - Clarification was added to the Benchtop Measurement Accuracy characteristic to confirm the reference to flow rate. Consensus was achieved in the room (without a Mentimeter vote) for the Optimal and Minimal characteristic. Participants noted that current commercial standards specify ±2-3% and that accuracy is self-declared and listed on the insert, but that a standard does not currently exist. Volume accuracy is dependent on whether the device is being used for administering fluids or drugs.
  - *Optimal: ± 1.0%*
  - *Minimal: ± 3.0%*
- **Clinical Measurement Accuracy**
  - This characteristic was deleted from the TPP as it is not reported or tested.
- **Flow Rate Requirements**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Optimal and Minimal characteristic. There was a lengthy discussion on the tradeoffs of broadening the Minimal and Optimal characteristics to 0.1-60 mL/hr. It was discussed that if cost is not significantly impacted, then clinicians wanted to broaden the range. Product developers noted that from a technical perspective, it was not a challenge to have a broad range, but rather it was dependent on the syringe size and brand since the brand impacts the performance. Product developers were not certain whether a lower limit of 0.1 ml/hr would impact the price. Clinicians clarified that Syringe Pumps designed for administering fluids, may require less stringent accuracy than drug administration. Healthcare workers noted that Syringe Pumps are often used in neonatal units for fluid delivery and that district hospitals do not typically use Syringe Pumps for drug delivery. A question arose on the difference between a Syringe Pump and an Infusion Pump and how the two pieces of equipment differ. Some clinicians noted that increased accuracy would be beneficial from a procurement standpoint since one device could be procured to meet both purposes.
  - *Optimal: .1 to 60 ml/hr*

- *Minimal: Same as Optimal*

- **Occlusion Detection**
  - Consensus was achieved in the room for the Optimal (without a Mentimeter vote) and Minimal characteristic. Participants commented that the normal pressure used to detect an occlusion is usually 0.1 to 15 or 17 psi for an adjustable range. Clinicians confirmed that for the most part, they do not generally change the pressure. Participants in the room confirmed that for neonates, it is important to set specific graduations but the specific numbers do not need to be defined in the TPP. One participant shared an article on "The Safe Use of Infusion Devices" which provided specific pressures for neonates: "In neonates, pressures of 50 mm Hg are typical because of lower flow rates and shorter cannula... Neonatal default settings are much lower (100 mm Hg)," [7].
  - *Optimal: Completely adjustable*
  - *Minimal: Yes (ability to adjust to pre-set pressure)*
  - Overall Vote - 92% Agree (n = 13)
  - Clinicians - 92% Agree (n = 12)
  - Excluding involvement with product development - 91% Agree (n =11)
- **Ability to calculate flow rates based on patient size**
  - This characteristic was not discussed as it was determined that it should be removed from the TPP.
- **Syringe Requirements**
  - Consensus was achieved in the room for the Optimal (without a Mentimeter vote) and Minimal characteristic. Participants removed the "failsafe mode to reject syringes that don't match machine setting" from the Optimal characteristic.
  - *Optimal: Syringe 5-60mL, works with multiple syringe types*
  - *Minimal: Syringe 5-60mL and works with more than 1 syringe type*
  - Overall Vote - 100% Agree (n = 11)
  - Clinicians - 100% Agree (n = 9)
  - Excluding involvement with product development - 100% Agree (n =10)
- **Alarm Characteristics**
  - Consensus was achieved in the room (without a Mentimeter vote) to change the Minimal characteristic to both Visual and Auditory alarms (same as Optimal). Product developers noted that a trade-off exists between the number of alarms and the size of the device.
  - *Optimal: Visual and Auditory*
  - *Minimal: Same as Optimal*
- **Maximum Power Consumption**
  - This characteristic was not discussed as it was determined to remove from the TPP. Note that a new characteristic, Power Source, was added to the TPP.
- **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)*
- **Battery**
  - 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: Rechargeable battery, >12hr on single charge*
  - *Minimal: Rechargeable battery, >4hr on single charge*
- **Weight**

- Consensus was achieved in the room (without a Mentimeter vote) for the Optimal and Minimal characteristic. Clinicians noted that current machines are less than 2kg. Product developers noted that from a technical perspective, battery packs requiring 12 hours on a single charge could make the machine heavier. Clinicians explained that bulk weight accumulates quickly and emphasized the importance of stackability and interlocking devices. A research question for product developers was created to further explore how to optimize the stacking of equipment together and the ability to address concerns with the weight of heavy pumps.
- *Optimal: <1.5kg (without batteries)*
- *Minimal: <5kg (without batteries)*

- **Instrument Pricing**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Optimal and Minimal characteristic.
  - *Optimal: <$300 ex-works*
  - *Minimal: <$1,000 ex-works*
- **Consumable Pricing**
  - Consensus was achieved to remove this characteristic since consumables are purchased separately for Syringe Pumps.

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: Syringe Pump

Delphi-like survey results for Syringe Pump 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 conditions requiring precise administration of drugs or fluids; including but not limited to dextrose solution for hypoglycemia and antibiotics for infection.	**100% n = 9**	Minimal: Same as Optimal.	**88% n = 8**	3 comments as summarized below Theme: Alternative Intended Use provided • Optimal: Treatment of conditions requiring precise administration drugs or fluids; including but not limited to dextrose solution of hypoglycemia, antibiotics for infection and feed advancement in small infants or infants at risk for HIE. I'd have

	Optimal		Minimal		
					to check how many of the essential newborn medicines actually need the meds to go over syringe pump? Mostly we found syringe pumps to be key for administering precise fluids to small infants • Optimal: I would like if it could take every syringe size, would stop when the baby has been filled. It needs to be human proof • Optimal: Treatment of conditions requiring precise administration of drugs or fluids
Target Operator	Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians.	**100%** **n = 10**	Minimal: Same as Optimal	**100%** **n = 9**	0 comments
Target Population	Optimal: Neonates (<28 days)	**80%** **n = 10**	Minimal: Same as Optimal.	**78%** **n = 9**	4 comments as summarized below Theme: Broaden to other Target Populations • Ideally, when thinking about syringe pumps, it would be great if they also are able to be used for diverse needs in a hospital (oxytocin, pediatrics) rather than only for neonates. This can ease burden on hospitals if they have one pump type that can be used across many services • Optimal: Proportionately, you would be using it more on neonates. I would want one or two for my pediatric ward for my hypertensives, convulsing, diabetic children

	Optimal		Minimal		
					• Neonates, pediatrics and adults
Target Setting	Optimal: Hospitals in low-resource settings	**100%** **n = 9**	Minimal: Same as Optimal.	**100%** **n = 8**	0 comments
International Standard	Optimal: ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes.	**83%** **n = 6**	Minimal: Same as Optimal.	**80%** **n = 5**	0 comments
Regulation	Optimal: CE marking or US FDA Clearance	**71%** **n = 7**	Minimal: Same as Optimal.	**67%** **n = 6**	3 comments as summarized below • CE mark is more than adequate • Performance is more important
Benchtop Measurement Accuracy	Optimal: ±1.0%	**57%** **n = 7**	Minimal: ±3.0%	**33%** **n = 6**	6 comments as summarized below • What's the difference between Clinical and Benchtop accuracy? The correct term is flow rate accuracy. Any CE marked product is bound to meet this spec Theme: Too Stringent • If you're loading the maximum amount of something that can be given into the syringe, then it doesn't seem like it matters too much if it's a little fast or a little slow? Max fluids to a neonate in a day is between 150-180ml/kg/day and 1% of that would only be 1.5-1.8ml/kg/day inaccuracy (max 5ml if you guess newborns on average are 2.5kg) per day? I think you could go 5% maybe even 10% and it wouldn't really matter?? Or at least off the top of my

	Optimal		Minimal		
					head I can't think why it would • These errors are very low. Unlikely to make a clinical difference • Way too small! Suggest updating to: Benchtop Measurement Flow Rate and Volume Accuracy • Optimal: ±5% • Minimal: ±10% Theme: Not Stringent Enough • Minimal: Ideally I would want benchtop accuracy to be tighter • Minimal: I would want 2% the smaller volume (e.g., insulin) and neonates I would like it to be more accurate
Clinical Measurement Accuracy	Optimal: ±1.0%	**63%** **n = 8**	Minimal: ±3.0%	**57%** **n = 7**	3 comments as summarized below Too Stringent • Way too small! Suggest updating to: Clinical Measurement Flow Rate and Volume Accuracy • Optimal: ±10% • Minimal: ±15% Not Stringent Enough • Minimal: I would want 2% the smaller volume (e.g., insulin) and neonates I would like it to be more accurate
Flow Rate Requirements	Optimal: 0.5-60mL/hr	**78%** **n = 9**	Minimal: 3-30mL/hr	**63%** **n = 8**	4 comments as summarized below • One respondent said, range of ml/hr for most infants (those less than 3.5kg) will range only 1-12

	Optimal		Minimal		
					mL/hr. Up to 20 mL/hr would accommodate a 5kg infant, up to 40 mL/hr for a 10kg infant. Theme: Additional ranges were suggested • Optimal: I would want to go as low as .25 mL/hr; with antibiotic you may need slower rate and also adrenaline you would want to go sometimes as low as .1 (ICU care) • This needs to be lower if indications is for neonates • The Optimal flow range is misleading because it can be across so many different syringe sizes. Suggest adding clarity to the Optimal and increasing the Minimal to larger • Optimal: 0.5-60 mL/hr (different syringe sizes allowed) • Minimal: 3-60 mL/hr
Occlusion Detection	Optimal: Adjustable	**67%** **n = 9**	Minimal: 5, 10, 25 psi	**71%** **n = 7**	3 comments as summarized below • Maybe I need to educate myself on this, not sure what you would need to adjust the sensitivity for occlusion? Like you get false positives if the IV gauge is smaller or something? • Optimal: I would want the syringe pump to be set at a reasonable amount. I am not clear what reasonable is

	Optimal		Minimal		
					• Occlusion detection is required but the exact alarm setting is not important
Syringe Requirements	Optimal: Syringe 5-60mL, works with multiple syringe types. Failsafe mode to reject syringes that don't match machine settings.	**80%** **n = 10**	Minimal: 5-60mL, proprietary syringes	**56%** **n = 9**	6 comments as summarized below • I'd have to review which essential neonatal medications would benefit from a syringe pump to make a comment on whether or not you needed to accommodate syringe sizes this small and if introducing this complexity seems necessary (We never used syringe pumps for meds in our wards)? If mainly used for fluids then needs to accommodate syringes 50-100ml Theme: Considerations related to proprietary syringes • Working with multiple syringe types should be the minimum - proprietary syringes are really hard for procurement. • If I have to have a proprietary, I would like it without the falange. • This requirement is confusing as proprietary vs non-proprietary is not quantifiable. The minimal should be that the pump works with multiple syringe brands and list the brands most commonly used.

	Optimal		Minimal		
					• Should be able to work with multiple syringe types to avoid downtimes when proprietary syringes are not available for any reason.
Ability to calculate flow rates based upon patient's size	Optimal: Yes	**100%** **n = 8**	Minimal: No	**71%** **n = 7**	3 comments as summarized below • As long as programming rates can be done within the needed range, this is not essential • Optimal: Size might be unrelated to what I am trying to give them. this would only work if it was calibrated for maintenance fluids; you couldn't just have a standard. As long as you can put in the patient size and then select the drug / fluid • I would like to see this as mandatory
Drug Library	Optimal: Yes	**88%** **n = 8**	Minimal: No	**86%** **n = 7**	4 comments as summarized below • Not sure what this is referring to • This is a great feature - not essential as the pump can fully meet needs without it but it can ease programming • Optimal: Not needed • Optimal: If it says give so many mgs, that would be ok. If it says give so many mL, then that would be problematic. It increases the chance of user misinterpretation depending on the

	Optimal		Minimal		
					concentration of drug being added
Alarm Characteristics	Optimal: Visual and Auditory	**100%** **n = 9**	Minimal: Visual	**38%** **n = 8**	5 comments as summarized below Theme: Auditory preferred over visual • Why visual as minimal instead of auditory? • I feel that the minimum alarm requirements should include auditory alarms. In my experience, syringe pumps may be left without close monitoring for several hours. If clinicians are in another room or not in visual sight of the alarm, an auditory alarm would be more beneficial than a visual alarm • Visual and auditory alarms are required as minimal specifications • Minimal: If there was one alarm function, I would prefer it to be auditory over visual
Decontamination	Optimal: Easy to clean with common disinfecting agents	**100%** **n = 9**	Minimal: Same as Optimal.	**100%** **n = 8**	1 comment • Optimally would be able to re-use large (50-100ml) syringes
Maximum Power Consumption	Optimal: <1 Watt	**57%** **n = 7**	Minimal: <5 Watts	**50%** **n = 6**	3 comments as summarized below • Lower power consumption is helpful, but not essential given all the other priority features • What is the rationale for picking these power specs and need for this requirement? Given

	Optimal		Minimal		
					battery powered is a requirement below, then there is no need to include AC power consumption. Also Max power consumption is not indicative of what the device will consume on average over X number of hours of operation (Power draw might be an additional spec needed for all devices) • Specifications not relevant
Voltage	Optimal: 110-240V 50-60hz	**86%** **n = 7**	Minimal: 220-240V 50-60hz	**67%** **n = 6**	1 comment • Depend of the destination country (or 110 V or 220 V)
Battery Power	Optimal: >4hr on single charge	**100%** **n = 9**	Minimal: None.	**38%** **n = 8**	6 comments as summarized below Theme: Minimal should include battery back-up • I think these have to have a battery option, they're really essential • As a minimum, some power battery backup should be included • Minimal: Battery power should be able to handle up to 2 hours of power outages • Minimal: Our power is so unreliable that it would cause me enormous anxiety not to know what is going on so I don't know what has been given when the power goes back on • Must have a battery • Battery backup is necessary to maintain drug administration

	Optimal		Minimal		
					which could be life saving, especially in areas with epileptic power supply
Size	Optimal: Small footprint; portable	**100%** **n = 9**	Minimal: Same as Optimal.	**100%** **n = 8**	1 comment • Small footprint is difficult to define
Weight	Optimal: <7 kg	**75%** **n = 8**	Minimal: <10 kg	**71%** **n = 7**	2 comments as summarized below Theme: Specification not needed • 7-10 kg are both quite heavy for a syringe pump, and weight plays into shipping and distribution costs so lighter is helpful but from a clinical use standpoint the weight is not really important. • Specifications not relevant
User Manual	Optimal: User manual and additional training materials (checklists, videos, guides) in English and local language. Attached to device with labels and markings where possible.	**89%** **n = 9**	Minimal: User manual provided.	**88%** **n = 8**	2 comments as summarized below • User manual at a minimum should be provided hard copy and soft copy, with easy online access • Optimal: should include trouble shooting and how to clean
Warranty	Optimal: 5 years	**78%** **n = 9**	Minimal: 1 year	**88%** **n = 8**	3 comments as summarized below Theme: 5 years too long • Five year warranty would be really great, but not expected as that is longer than most equipment so not essential. • Minimal: most business give 1 year warranty, but adding years shows

	Optimal		Minimal		
					confidence in the product. • No supplier will agree with a 5 year warranty
Instrument Pricing	Optimal: <$1,000 ex-works	**78%** **n = 9**	Minimal: <$2,000 ex-works	**38%** **n = 8**	5 comments as summarized below Theme: Lower Optimal and Minimal • To be competitive with models on the market - and in government procurement processes - the minimal costs should be <$1000 and Optimal even a bit lower. • Optimal: $500 would be more acceptable • Minimal: Only if it was a gift • Needs to be lower • These prices are too high. Consider changing to OPT: $250 and MIN: $1500 This is based on actual quotes
Consumable Pricing	Optimal: <$3 per patient ex-works	**100%** **n = 6**	Minimal: <$10 per patient ex-works	**60%** **n = 5**	1 comment • Optimal: my comment would be that impacted by length of stay of the patient or per episode of illness

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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