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NEST360°

Target Product Profile

Glucometer – Point-of-Care Diagnostics

1ST EDITION, MARCH 2020

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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.

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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

Access to diagnostic laboratories remains a key challenge in low-resource settings [1]. Point-of-care diagnostic tests can therefore enable health-care workers to provide more rapid and effective care [2]. Simple, rapid, and affordable point-of-care tests which require minimal or no electricity, a laboratory, or highly trained staff, are now available and widely used for several common conditions in low- and middle-income countries (LMICs) [3]. These point-of-care tests offer an unprecedented opportunity to reduce inequalities in health, and to help LMICs achieve the health-related Sustainable Development Goals (SDGs) [4,5].

Hypoglycemia is a common metabolic problem in newborns and can result in neurologic complications if left untreated. Small and premature newborns are at increased risk for hypoglycemia. Monitoring blood glucose concentration allows clinicians to intervene with supplemental glucose for at-risk infants. Most common point-of-care glucometers are designed to be accurate at high glucose ranges for management of adult diabetes; few are intended for use or accurate in the low glucose concentrations seen in hypoglycemic newborns.

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.

13 respondents participated in the Delphi-like survey for the Glucometer.

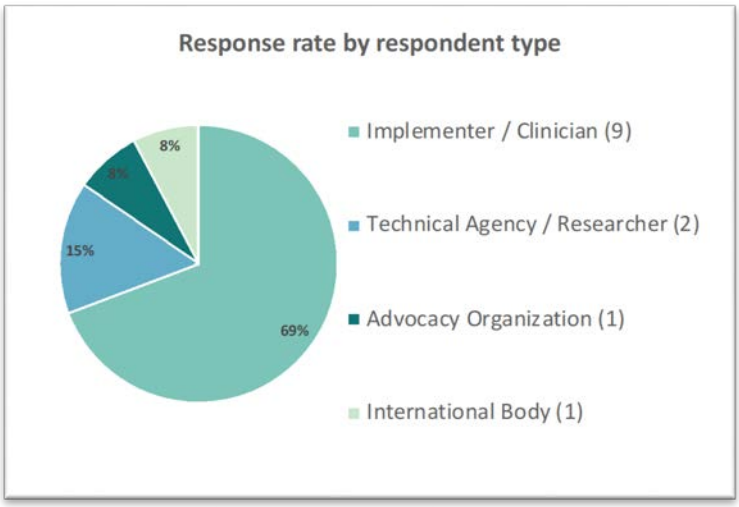
Survey respondents were requested to provide a statement on their level of agreement with each of the proposed characteristics for each TPP. Agreement was scored on a Likert scale ranging from 1 to 5 (1=disagree, 2=mostly disagree, 3= neither agree nor disagree, 4=mostly agree, 5=fully agree) with an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

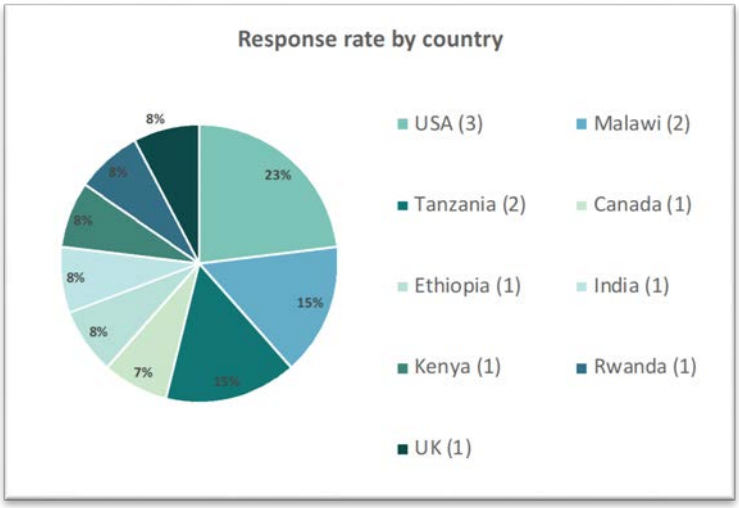
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

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



Respondent type	Percentage
Implementer / Clinician (9)	69%
Technical Agency / Researcher (2)	15%
Advocacy Organization (1)	8%
International Body (1)	8%

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



Country	Percentage
USA (3)	23%
Malawi (2)	15%
Tanzania (2)	15%
Canada (1)	8%
Ethiopia (1)	8%
India (1)	8%
Kenya (1)	8%
Rwanda (1)	8%
UK (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 Glucometer 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 - GLUCOMETER

Final target product profile for Glucometer		
Characteristic	**Optimal**	**Minimal**
SCOPE		
Intended Use	Quantitative measurement of blood glucose for diagnosis and management of neonatal	
Target Operator	For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians	
Target Population	Neonates (born at any gestational age and require ongoing care)	
Target Setting	Hospitals in low-resource settings, but, may be used in health facilities based on country guidelines	Hospitals in low-resource settings
SAFETY AND STANDARDS		
Quality Management [1]	ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes	
Regulation	At least one of: CE marking, approved by US FDA or another stringent regulatory body of a founding member of IMDRF (e.g., Japan or Australia or Canada)	
TECHNICAL CHARACTERISTICS		
Linear Range	0-50 mmol/L (0-900 mg/dL)	0-20 mmol/L (0-360 mg/dL)
Accuracy	± 6% across the whole range ± 0.2 mmol/L at 2.5 mmol/L (± 3.6 mg/dL at 45 mg/dL)	± 8% [2] ± 0.2 mmol/L at 3 mmol/L (± 3.6 mg/dL at 54 mg/dL)
Results Format	Quantitative across whole linear range (should be able to switch between mg and mmol)	
Result Units	mg/dL OR mmol/L	
Precision	±2% or 2.5 mg/dL, whichever is greater	
Sample	Whole blood heel-stick sample <5 µL	Whole blood heel-stick sample <50 µL
Calibration	No calibration	Minimal user calibration required
Kit Stability & Storage	Stable for >12 months with harsh ambient conditions (temperature 5-45 °C, humidity 15% to 95%, dusty air, elevation >=2000 meters) and transport stress (48h with fluctuations up to 50°C and down to 0°C)	Stable for 12 months with harsh ambient conditions (temperature 10-40 °C, humidity 15%-95% elevation up to 2000 meters) and transport stress (48h with fluctuations up to 50°C and down to 0°C)
Equipment Required	Small, portable or hand-held device; device-free/disposable preferred	Small, table-top device; portable device optional
PURCHASING CONSIDERATIONS		
Instrument Pricing	<$30 ex-works	
Consumable Pricing	$0.05 per test ex-works, ideally with generic strips	$.20 per test ex-works

UTILITY REQUIREMENTS		
Power Source	No power required	Mains with rechargeable battery
Battery	None (i.e. a disposable test that requires no electricity)	Rechargeable battery, >100 tests on a single charge.
Voltage	None.	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)

[1] *There was not 75% voting agreement on the Minimal characteristic. Please refer to the TPP Report discussion for additional detail.*
[2] *Source: https://www.westgard.com/2019-clia-changes.htm CLIA proposed changes define Accuracy as ±8%. Current CLIA standard is* ± 6 mg/dL or ± 10% (greater). *These changes are proposed as of Feb 2019.*

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: Glucometer

To arrive at the final TPP for Glucometer, 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.

- **Results Format**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Minimal characteristic to be the same as Optimal and to add the ability to change between mmol/L and mg/dL in both settings.
  - Optimal: Quantitative across whole linear range (should be able to switch between mg and mmol)
  - Minimal: Same as Optimal
- **Precision**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Minimal characteristic to be the same as Optimal. Participants noted that the range of commercially accepted equipment is <5% CV for neonates.
  - *Optimal: ±2% or 2.5 mg/dL, whichever is greater*
  - *Minimal: Same as Optimal*
- **Instrument Pricing**
  - Consensus was achieved in the room (without a Mentimeter vote) for the Minimal and Optimal characteristic to be <$30 ex-works. Participants noted that devices exist for $20 that are approved for at-home use only, while devices approved and tested for use in sick neonates can cost $500-$900 ex-works. Given the current market gap, a research question was developed to consider pressure testing the market for off-label use of adult glucometers in neonates.
  - *Optimal: <$30 ex-works*
  - *Minimal: Same as Optimal*
- **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. In this specific case, the language used in the Optimal and Minimal characteristic were adjusted during this harmonization review following the vote.
  - *Optimal: None (i.e. a disposable test that requires no electricity)*

- *Minimal: Rechargeable, >100 tests on a single charge*

- **Voltage**
  - There was agreement in the room that all characteristics relating to Utility Requirements (e.g., Back-up Battery; Battery Power; Batteries; Voltage; Power Requirement; Maximum Power Consumption; Response During Power Outage; Surge Protection, Electrical Plug) be reviewed and harmonized following the TPP meeting. In this specific case, the language used in the Optimal and Minimal characteristic were adjusted during this harmonization review following the vote.
  - *Optimal: None*
  - *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 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: Glucometer

Delphi-like survey results for Glucometer 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: Quantitative measurement of blood glucose for diagnosis and management of neonatal hypoglycemia	**85% n = 13**	Minimal: Same as Optimal.	**82% n = 11**	4 comments as summarized below • We need this also for neonatal ***hyper***glycemia • Optimal use would not be restricted to neonates • Minimal use can be restricted to neonates/infants • At a minimum, the device could be semi-quantitative and indicate normal - low - severely low
Target Operator	Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians.	**92% n = 13**	Minimal: Same as Optimal	**91% n = 11**	3 comments as summarized below Theme: Broaden to include additional Target Operators • Include nurse aides and community healthcare workers • Ideally usable by patients and community health workers

	Optimal		Minimal		
Target Population	Optimal: Neonates (<28 days)	**77%** **n = 13**	Minimal: Same as Optimal.	**73%** **n = 11**	6 comments as summarized below Theme: Broaden to include additional age ranges • This should be available to use in any baby - consider the KMC baby who was born at 1.2kg and is now 5 weeks old • Would consider need for this over first 3 months of life, particularly for preterm/LBW babies • Need for children up to 13 years • Yes, but can be used in other ages too • Adaptable to all levels of population
Target Setting	Optimal: Hospitals in low-resource settings	**77%** **n = 13**	Minimal: Same as Optimal.	**73%** **n = 11**	5 comments as summarized below Theme: Broaden to include additional settings • This should be available both within healthcare facilities and hospitals of all levels • Ideal target settings should include health posts, clinics, traditional birth attendants • Sometimes the community healthcare workers need this too
International Standard	Optimal: ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes.	**100%** **n = 6**	Minimal: Same as Optimal.	**100%** **n = 5**	0 comments
Regulation	Optimal: CE marking or US FDA Clearance	**100%** **n = 6**	Minimal: Same as Optimal.	**100%** **n = 5**	0 comments
Linear Range	Optimal: 0-50 mmol/L (0-900 mg/dL)	**85%** **n = 13**	Minimal: 0-20 mmol/L (0-360 mg/dL)	**75%** **n = 12**	2 comments • Minimal: 20 mmol/L would be too low for hyperglycemia; 40 mmol/L would be better • Optimal range (if you're trying to pick a

	Optimal		Minimal		
					device that could be used outside neo unit) I understand 0-900 mg/dL though seems like anything over 500 mg/dL in peds will generally have the same management (don't know about adults) • Minimal range of 0-300 mg/dL for neonates • Do any actually read to 50 mmol/L? • 0-600 mg/dL may be needed
Accuracy	Optimal: ± 0.2 mmol/L at 2.5 mmol/L (± 3.6 mg/dL at 45 mg/dL)	**77%** **n = 13**	Minimal: ± 0.2 mmol/L at 3 mmol/L (± 3.6 mg/dL at 54 mg/dL)	**75%** **n = 12**	4 comments as summarized below • +/- 0.1 may be better • +- 0.2 at entire linear range • So in neonates this range of accuracy for minimal requirement seems too large? Hypoglycemia is 25-30mg/dL in a JUST BORN baby. Later on its <60 mg/dL so having a range of accuracy of 20mg/dL seems too broad? I'm also not familiar w/what the standards are for current POC vs serum glucose measurements
Results Format	Optimal: Quantitative across whole linear range	**100%** **n = 12**	Minimal: Quantitative; semi quantitative at <2 mmol/L	**55%** **n = 11**	7 comments as summarized below • Minimal: In hospital, you need quantitative so you can follow up and give treatment. For home use and community it should be color coded and the actual figures • Semi quantitative OK <25mg/dL • Quantitative better • Is sufficient to have low set at 2 mmol/L • better to have quantitative across the whole range. May be < 1mmol could be semi quantitative

	Optimal		Minimal		
					• If semi quantitative at <2 mmol/L could only be useful in the first 48-72 hours of life. Thereafter, cut-off needs to be higher
Result Units	Optimal: mg/dL OR mmol/L	**85%** **n = 13**	Minimal: Same as Optimal.	**82%** **n = 11**	2 comments summarized below • mmol/L only
Precision	Optimal: +-2% or 2.5 mg/dL, whichever is greater	**83%** **n = 12**	Minimal: 5% CV	**67%** **n = 9**	5 comments as summarized below • up to 2.5mg/dL seems ok, 2% seems too permissive even for Optimal? • Not sure I fully understand but a precision error of 2% seems large when measuring hypoglycemia where small variants can make a significant difference • convert our units
Sample	Optimal: whole blood heel-stick sample <5 µL	**100%** **n = 12**	Minimal: whole blood heel-stick sample <50 µL	**80%** **n = 10**	3 comments as summarized below • Needs as small amount of blood as possible • Existing glucometers require very little blood
Calibration	Optimal: No calibration	**92%** **n = 12**	Minimal: Minimal user calibration required	**91%** **n = 11**	2 comments as summarized below • Need calibration • Better without calibration
Kit Stability & Storage	Optimal: Stable for >12 months with harsh ambient conditions (temperature 5-45 °C, humidity 15% to 95%, dusty air, elevation >=2000 meters) and transport stress (48h with fluctuations up to 50°C and down to 0°C)	**91%** **n = 11**	Minimal: Stable for 12 months with harsh ambient conditions (temperature 10-40 °C, humidity 15%-95% elevation up to 2000 meters) and transport stress (48h with fluctuations up to 50°C and down to 0°C)	**90%** **n = 10**	2 comments as summarized below • Should work in any setting / environment

	Optimal		Minimal		
Equipment Required	Optimal: Small, portable or hand-held device; device-free/disposable preferred	100% n = 13	Minimal: Small, table-top device; portable device optional	92% n = 12	2 comments as summarized below • Table-top too big for glucose monitoring
Voltage	Optimal: 110-240 50-60hz	78% n = 9	Minimal: 220-240 50-60hz	57% n = 7	3 comments as summarized below • Should be battery operated
Power Requirement	Optimal: >4hr on single charge	85% n = 13	Minimal: None	75% n = 12	5 comments as summarized below • Batteries should be rechargeable with electricity • Minimal: does seem like you would need battery power option? • Simple battery device which does not require electricity will be ideal • Was minimal and Optimal reversed here?
Instrument Pricing	Optimal: <$30 ex-works	82% n = 11	Minimal: <$100 ex-works	30% n = 10	6 comments as summarized below • Minimal: $100 seems very high • A device that will cost less than what is available in the market will be ideal, the market price of the current price is around $20. • This seems very high for a glucometer • Good glucometers are available for $30 • Minimal needs to be cheaper than 100$. There are good glucometers for $10-20 on the market
Consumable Pricing	Optimal: $0.05 per test ex-works	90% n = 10	Minimal: $1.50 per test ex-works	33% n = 9	6 comments as summarized below • Current state-of-the art blood glucose strips (e.g. Freestyle Lite or Bayer Contour) are around $1.00, so $1.50 seems too much • $0.2 may be reasonable

	Optimal		Minimal		
					• Minimal: current tests cost $1 or 100 KES • The strip cost is more than the machine cost within six months • $1.50 seems high per test • The price of the glucometer itself is not so important as the cost of the strips, which can be prohibitive. Also major barrier to use is the incompatibility of many glucometer strips between different brand machines. Would be hugely beneficial to have generic strips to use on different glucometer machines

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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)
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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