Optimal	Minimal	Does not meet minimal	Unknown																			
Syringe Pump																						
Evaluated against Target Product Profile (TPP) as repo	orted by manufacturer																					
TPP Characteristic		Minimal Requirement	A	В	С	D	E	F	G	Н	J	K	L	M	N	0	Р	Q	R	S	Т	U
Intended Use	Treatment of conditions requiring precise	administration of drugs and fluids, including but not limited to																				
		hypoglycemia and antibiotics for infection																				
Target Operator	For use in low- and middle-income countries	by a wide variety of clinicans, including nurses, clinical officers, and pediatricians																				
Target Population	Neonates (born at an	y gestational age and require ongoing care)																				
Target Setting	Hospit	als in low-resource settings																				
Quality Management	ISO 13485:2016 Med	ical devices - Quality management systems																				
Regulation	At least one of:	CE marking, approved by US FDA etc																				
Benchtop Measurement Accuracy (for Flow Rate)	±1.0%	±3.0%																				
Flow Rate Requirements		0.1-60 mL/hr																				
Occlusion Detection	Continuous adjustment (fully adjustable)	Adjusted based on pre-set (5, 10, 25 psi)																				
Syringe Requirements	Syringe 5-60m	L, works with multiple syringe types																				
Drug Library	Yes	No																				
Alarm Characteristics		Visual and auditory																				
Size	Si	nall footprint; portable																				
Weight	< 1.5 kg (without batteries)	<5 kg (without batteries)																				
Instrument Pricing	<\$300 ex-works	<\$1,000 ex-works																				
Power Source	Mair	s with rechargable battery																				
Battery	Rechargable battery > 12 hr on single charge	Rechargable battery > 4 hr on single charge																				
Voltage																						
User Instructions	User manual and additional training materials (checklists, videos, guides) in English and local language. Attached to device with labels and markings where possible	User manual provided in at least one national official language																				
Warranty		1 vear																				
Decontamination		with common disenfecting agents																				
		Purchased for evaluations?	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No I	No	No N	o N	0 N	o No	No	No	No	No	No	No
Technical	Does device meet all minimal performance characteristics from TPP?	Verified by lab evaluations on =2 devices by 3 unique users					d not te															
		Heat					iled ini															
Environmental	Is device rugged, durable, easy to maintain	Humidity				h	euristi	cs														
	and repair?	Dust				1																
		Power																				
		Heuristic evaluation	Pass	Pass	Pass	Fail	Fail	Fail	1													
		Houston task effectiveness (Infusion)	100%	50%	67%																	
		Houston task effectiveness (Occlusion)	100%	100%	100%					1	Did not	meet r	required	l speci	ficatio	ns wher	i evalu	ated a	gainst t	he TPP	•	
		Houston SUS <50 50-70 >70	90	71	74																	
Usability	English and local language. Attached to device with labels and markings where possible User manual provided in at least one national of device with labels and markings where possible 5 years 1 year Easy to clean with common disenfecting agents Does device meet all minimal performance characteristics from TPP? Is device rugged, durable, easy to maintain and repair? Heat Bower Heat Is device rugged, durable, easy to maintain and repair? Dust Forward Heuristic evaluation Houston task effectiveness (Infusion Houston task effectiveness (Infusion Houston SUS Can doctors and nurses use the device with minimal training? Fraction of Houston users indicating preferer Malawi SuS Malawi SuS <50 50-70 >70	Fraction of Houston users indicating preferred device	83%	0%	17%	Fa	iled ini	tial														
	minimal training?	i300 ex-works <\$1,000 ex-works	17%	0%	17%		euristi															
			83%	100%																		
		Malawi SUS	76	55	61																	
			50%	33%	17%																	
		NEST Qualified Technology?	Yes	No	No	No	No	No	No	No	No	No	No N				No	No	No	No	No	No
		NEST Qualified rechnology!	163	140	110	110	110	NO	110	NU							110	110	110	NU	NU	NU

Solution 2 mark Productional distanceMaine 2 MagneticationNNN	Optimal	Minimal	Does not meet minimal	Unknown											
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ktoracy4/-10% from 5-30mg/d.4/-20% from 3-30mg/d.ii <td>Linear Bango</td> <td></td>	Linear Bango														
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startery in o electricity single charge. image image <th< td=""><td>Power Source</td><td>No power required</td><td>Mains with rechargable battery</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>	Power Source	No power required	Mains with rechargable battery												
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Mone country's local power grid (e.g., 110- 120 VAC at 60 Hz or 220-240 VAC at S (Hz) No No<			Model must match the voltage and												
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Image: constraint of the second sec	, in the second s														
Purchased for evaluations? Yes Yes Yes No															
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Environmental Is device rugged, durable, easy to maintain and repair? Heat Image: Construction of the state of the sta	Technical	-													
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Usability Can doctors and nurses use the device with minimal training? Heuristic evaluation Houston Task effectiveness (Calibrate) N/A 83% 83% Image: Can doctors and nurses use the device with minimal training? Can doctors and nurses use the device for the control of Houston users indicating preferred device 100% 0% 0% Image: Fraction of Houston (Calibrate) 10% 20% 0%		anu repair :	Dusi												
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Fraction of Malawi users indicating 80% 20% 0%	Usability		Heuristic evaluation Houston task effectiveness (Measure) Houston task effectiveness (Calibrate) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Measure) Malawi task effectiveness (Calibrate)	83% N/A 87 100% 80% N/A	33% 83% 60 0% 60% 40%	66% 83% 63 0% 20% 40%	Did no	t meet	require	d specil		when	evaluat	ed agai	nst the
preferred device 80% 20% 0%	Usability		Heuristic evaluation Houston task effectiveness (Measure) Houston task effectiveness (Calibrate) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Measure) Malawi task effectiveness (Calibrate) Malawi SUS	83% N/A 87 100% 80% N/A	33% 83% 60 0% 60% 40%	66% 83% 63 0% 20% 40%	Did no	t meet	require	d specif		when	evaluat	ed agai	nst the
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NEST Qualified Technology? Yes Yes No	Usability		Heuristic evaluation Houston task effectiveness (Measure) Houston task effectiveness (Calibrate) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Measure) Malawi task effectiveness (Calibrate) Malawi SUS <50 50-70 >70 Fraction of Malawi users indicating	83% N/A 87 100% 80% N/A 95	33% 83% 60 0% 60% 40% 76	66% 83% 63 0% 20% 40%	Did no	t meet	require	d specit		swhen	evaluat	ed agai	nst the

Phototherapy

TPP Characteristic	Optimal Requirement	Minimal Requirement	А	В	C	D	E	F	G	н	1	J	K	L	Μ	Ν	0	Ρ	Q
Intended Use	Treatment of hyperbiliru	binemia in neonates																	
Target Operator	For use in low- and middle-income countries by a wide var pediatric	-																	
Target Population	Neonates (born at any gestational	age and require ongoing care)																	
Target Setting	Hospitals in low-res	source settings																	
Quality Management	ISO 13485:2016 Medical devices -	-																	_
Regulation	At least one of: CE marking, approved by US FDA or another s (e.g., Japan or Austr																		
Irradiance	Standard Phototherapy: 8-10 AND Intens																		_
Effective treatment area	>2000 cm2	>1300 cm2																	_
Peak wavelength	430-490																		_
Light Source	LED																		_
Bulb Lifetime	60,000 hours	44.000 hours																	
Ease of Replacing Bulbs	,	,																	
Irradiance Meter		• • •																	_
Instrument Pricing																			
Power Source																			_
Battery																			_
Voltage	Model must match the voltage and frequency of the purchasi	ing country's local power grid (e.g., 110-120 VAC at 60 Hz																	
User instructions	User manual and additional training materials (checklists, videos, guides) in at least one national 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																	
	• • • •	Purchased for evaluations?	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Technical	Does device meet all minimal performance characteristics from TPP?	Verified by lab evaluations on n=2 devices by 3 users																	
		Heat																	
Environmental	Is device sugged durable easy to maintain and remain?	Humidity																	
	is device rugged, durable, easy to maintain and repair?	Dust																	
		Power																	
		Heuristic evaluation	Pass	Pass	Pass	1													
		Houston task effectiveness (setup & use in high-intensity mode)	100%	100%	100%		г	id not	meet r	equire	nd snor	ificatio	ons whe	an eval	uated a	against	the TP	D	
		Houston SUS <50 50-70 >70	87	93	97		L		meeti	cquire	u spec	incatic	5113 WIN		uuteu e	gamse	the fi		
Usability	Can doctors and nurses use the device with minimal training?	Fraction of Houston users indicating preferred device	25%	25%	50%														
		Malawi task effectiveness (setup & use in high-intensity mode)	83%	75%	not tested														
		Malawi SUS <50 50-70 >70	79	83	not tested														
	Is device rugged, durable, easy to maintain and repair? Dust Power Power Image: Provide rugged, durable, easy to maintain and repair? Power Power Heuristic evaluation Houston task effectiveness (setup & use in high-intensity mode) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred Malawi task effectiveness (setup & use in high-intensity mode) Malawi task offectiveness (setup & use in high-intensity mode) Malawi task offectiveness (setup & use in high-intensity mode) Malawi task offectiveness (setup & use in high-intensity mode) Malawi sus Malawi sus <50 50-70 >70	Fraction of Malawi users indicating preferred device	42%	58%	0%	1													
	Ibs Capable of being replaced by a technician with minimal training and basic tools (screwdrivers) Included Available < \$400 ex-works		Yes	Yes	Yes	1		I		1	1	1	1	1			1	No	

Optimal	Minimal	Does not meet minimal	Unknown
Glucometer			

Evaluated against Target Product Profile (TPP) as reported by manufacturer

Evaluated against Target Product Profile (TPP) as reported by n	nanufacturer														
TPP Characteristic	Optimal Requirement	Minimal Requirement	A	В	С	D	E	F	G	н	1	J	К	L	м
	Quantitative measurment of blood glucos	e for diagnosis and management of													
Intended Use	neonate	25													
	For use in low- and middle-income coun														
Target Operator	including nurses, clinical offi	cers, and pediatricians													
Target Population	Neonates (born at any gestational a														
	Hospitals in low-resource settings, but,											-			
Torget Setting															
Target Setting	may be used in health facilites based on	Hospitals in low-resource settings													
	country guidelines														
Quality Management	ISO 13485:2016 Medical devices - Quality r														
	for regulatory														
Regulation	At least one of: CE marking, approved by L	IS FDA or another strigent regulatory													
Regulation	body of a founding member of IMDRF (e.g., Japan or Australia or Canada)													
Linear range	0-50 mmol/L (0 - 900 mg/dL)	0-20 mmol/L (0 - 360 mg/dL)													
	±6% across whole range	±8% across whole range													
Accuracy	± 0.2 mmol/L at 2.5 mmol/L	± 0.2 mmol/L at 3 mmol/L													
	Quantitative across whole linear range (sho											-			
Results Format	mmol	0													
Deculto Linito	mg/dL OR m											<u> </u>			
Results Units															
Precision	+-2% or 2.5 mg/dL, wh	<u> </u>													
Sample	Whole blood heel stick sample <5 uL	Whole blood heel stick <50 uL													
Calibration	No calibration	Minimal user calibration required													
		Stable for 12 months with harsh													
	Stable for >12 months with harsh ambient														
	conditions (temperature 5-45 °C, humidity	ambient conditions (temperature 10-													
Kit Stability & Storage	15% to 95%, dusty air, elevation >=2000	40 °C, humidity 15%-95% elevation													
Kit Stability & Stolage		up to 2000 meters) and transport													
	meters) and transport stress (48h with	stress (48h with fluctuations up to													
	fluctuations up to 50°C and down to 0°C)	50°C and down to 0°C)													
Equipment Required	Small, portable or hand-held device; device	Small, table-top device; portable													
	free/disposable preferred	device optional													
Instrument Pricing	<\$30 ex-w	orks													
	\$0.05 per test ex-works, ideally with	44.44													
Consumable Pricing	generic strips	\$0.20 per test ex-works													
Power Source	No power required	Mains with rechargeable battery													
	None (i.e. a disposable test that requires	Rechargeable battery, > 100 tests on										-			1
Battery	no electricity)	a single charge													
	no electricity)	Model must match the voltage and										-			
Voltage	None.														
		frequency of the purchasing													
		Purchased for evaluations?	Yes	Yes	Yes	No	No	No	No						
Technical	Does device meet all minimal performance	Purchased for evaluations?	Yes	Yes	Yes	No	No	No	No						
Technical	Does device meet all minimal performance characteristics from TPP?	Purchased for evaluations?	Yes	Yes	Yes	No	No	No	No						
Technical		Purchased for evaluations? Verified by lab evaluations on n = 2	Yes	Yes	Yes	No	No	No	No						
	characteristics from TPP?	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat	Yes	Yes	Yes	No	No	No	No						
Technical Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity				No	No	No	No						
	characteristics from TPP?	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust		not test		No	No	No	No						
	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power				No	No	No	No						
	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Dust Power Heuristic Evaluation		not test		No	No	No	No						
	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power	Did	not test N/A		No	No	No	No						
	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Dust Power Heuristic Evaluation		not test		No	No	No	No						
	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure)	Did	not test N/A 100%	100%								No No		
	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS	Did	not test N/A											
	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70	Did	not test N/A 100% 93	100%										
Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70 Fraction of Houston users indicating	Did	not test N/A 100%	100%										
	characteristics from TPP? Is device rugged, durable, easy to maintain and repair?	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70	Did	not test N/A 100% 93	100%										
Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain and repair? Can doctors and nurses use the device with	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device	Did	not test N/A 100% 93 67%	100% 79 0%										
Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain and repair? Can doctors and nurses use the device with	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Measure)	Did 83% 83 33%	not test N/A 100% 93	100%										
Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain and repair? Can doctors and nurses use the device with	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device	Did 83% 83 33%	not test N/A 100% 93 67% 64%	100% 79 0% 57%										
Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain and repair? Can doctors and nurses use the device with	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Measure)	Did 83% 83 33% Not included in	not test N/A 100% 93 67%	100% 79 0%										
Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain and repair? Can doctors and nurses use the device with	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Measure) Malawi SUS <50 50-70 >70	Did 83% 83 33%	not test N/A 100% 93 67% 64% 79	100% 79 0% 57% 67										
Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain and repair? Can doctors and nurses use the device with	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Measure) Malawi SUS <50 50-70 >70 Fraction of Malawi users indicating	Did 83% 83 33% Not included in	not test N/A 100% 93 67% 64%	100% 79 0% 57%										
Environmental	characteristics from TPP? Is device rugged, durable, easy to maintain and repair? Can doctors and nurses use the device with	Purchased for evaluations? Verified by lab evaluations on n = 2 devices by 3 unique users Heat Humidity Dust Power Heuristic Evaluation Houston task effectiveness (Measure) Houston SUS <50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Measure) Malawi SUS <50 50-70 >70	Did 83% 83 33% Not included in evals	not test N/A 100% 93 67% 64% 79	100% 79 0% 57% 67										

Optimal	Minimal	Does not meet minimal	Unknown																			
Hemoglobinometer																						
Evaluated against Target Product Profile (TPP) as reported by ma	nufacturer																					
TPP Characteristic		Minimal Requirement	A	в	С	D	E	F	G	н	1	J	к	L	м	N	0	Р	0	R	S	Т
	Quantitative determiniation of hemoglobin			-	-	-	-		-			-		_			-		-		-	-
Intended Use	blood																					
	For use in low- and middle-income count	tries by a wide variety of clinicans.																				
Target Operator	including nurses, clinical offic																					
Target Population	Neonates (born at any gestational a																					
Target Setting	Hospitals in low-reso								<u> </u>													
Quality Management	ISO 13485:2016 Medical devices - C								<u> </u>	<u> </u>												-
	At least one of: CE marking, approved by U																					-
Degulation																						
Regulation	body of a founding member of IMDRF (e																					-
Linear Range	0-25 g/dL	4.5-25 g/dL																				
Accuracy	+-1 g/dL	+-1.75 g/dL																				
	Quantitativa seress whole linear range	Quantitative; semi-quantitative																				
Results Format	Quantitative across whole linear range	below 5 or above 25 g/dL																				
Result Units	g/dL OR g	g/L																				
Precision	1.5% CV	2% CV																				
		Whole blood heel-stick sample <25																				
Sample	Whole blood heel-stick sample <10 μ L																					
outupic	No more than 1.2 stone (requiring	μL No more then 4.6 stops (rsi-i							-								-					
Number of Change	No more than 1-3 steps (requiring operator	No more than 4-6 steps (requiring																				
Number of Steps	intervention)	operator intervention)																				
Calibration	No calibration	Minimal user calibration required																				
		Stable for 12 months with harsh																				
	Stable for >12 months with harsh ambient	ambient conditions (temperature 10-																				
	conditions (temperature 5-45 °C, humidity																					
	15% to 95%, dusty air, elevation >=2000	40 °C, humidity 15%-95% elevation																				
	meters) and transport stress (48h with	up to 2000 meters) and transport																				
	fluctuations up to 50°C and down to 0°C)	stress (48h with fluctuations up to																				
Kit Stability & Storage	nucluations up to so c and down to o c)	50°C and down to 0°C)																				
	Const. a sateble so have d hald devices device	Correll table tax devices anotable																				
Equipment Required	Small, portable or hand-held device; device-	Small, table-top device; portable																				
	free/disposable preferred	device optional																				+
Instrument Pricing	< \$200 ex-works	< \$300 ex-works																				-
Consumable Pricing	\$0.05 per test ex-works	\$0.50 per test ex-works																				
Power Source	No power required	Mains with rechargable battery																				
		Model must match the voltage and																				
		frequency of the purchasing																				
	None	country's local power grid (e.g., 110-																				
		120 VAC at 60 Hz or 220-240 VAC at																				
Voltage		50 Hz)																				
Voltage		Purchased for evaluations?	Yes	Yes	Yes	Yes	Yes	Yes	Vac	No	No	No	No	No	No	No	No	No	No	No	No	No
			Yes	Yes	Yes	Yes	Yes	Yes	Yes	NO	INO	NO	INO	No	INO	INO	NO	INO	NO	INO	INO	INO
Technical	Does device meet all minimal performance																					
	characteristics from TPP?	devices by 3 unique users								-												
		Heat																				
Environmental	Is device rugged, durable, easy to maintain	Humidity																				
	and repair?	Dust		Did	not test	t																
		Power				N/A	N/A															
		101101				,//		-														
		Heuristic Evaluation																				
		Houston task effectiveness	33%		100%	100%																
		(Measure)	5570		10070	100/0			ot test,			Did not i	meet re	auired	specific	ations	when ev	aluated	agains	t the TP	P	
		Houston SUS						fai	iled				neerre	quirea	speeme			andated	agains	c the m		
		< 50 50-70 >70	62		92	62		tech	nnical													
	Can doctors and nurses use the device with			1			1	tes	ting													
Usability	minimal training?	preferred device	17%	Did	83%	0%	Did		-													
	in the training.			not			not															
		Malawi task effectiveness (Measure)	100%	test	67%	50%	test															
				-			-															
		Malawi SUS	87		65	62																
		<50 50-70 >70	0,		- 05	02																
1		Fraction of Malawi users indicating								1												
		Fraction of Malawi users indicating	1000/		00/	00/																
		preferred device	100%		0%	0%																
			100% Yes	Yes	0% No		No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

Optimal	Minimal	Does not meet minimal	Unknown																	
СРАР																				
Evaluated against Target Product Profile (TPP) as reported by m	nanufacturer												_							
TPP Characteristic	Optimal Requirement	Minimal Requirement	A	В	С	D	E	F	G	Н	1	J	К	L	М	N	0	Р	Q F	R
Intended Use	To treat respiratory distress and other form																			
	one year of For use in low- and middle-income coun																			
Target Operator	including nurses, clinical offi																			
Target Population	Neonates (born at any gestational	age and require ongoing care)																		
Target Setting	Hospitals in low-res																			
Quality Management	ISO 13485:2016 Medical devices - 0																			
Description	At least one of: CE marking, approved by L																			
Regulation Flow driver	body of a founding member of IMDRF (Integrated (on-board																			
Oxygen Flow Capacity	0-10 L/n																			
Pressure	5-8 cm F													+	<u> </u>					
Total (blended) Flow	0-10 L/n													+	<u> </u>					
Humidification	Yes, Heated Humidification	None																		
	Audio/Visual Power, low-flow, low-	Audio Power																		
Alarms	pressure																			
Accessories	Non-proprietary	Proprietary																		
Consumables	Reusable	Available																		
Instrument Pricing	<\$1,000 ex-works	<\$2,000 ex-works							<u> </u>					-						
Consumable Pricing	<\$10 / patient ex-works Mains with battery backup	<\$15 per patient ex-works Mains Power							<u> </u>											
Power Source	Rechargeable intergrated battery, >6	Ivialits Power																		
Battery	hours on a single charge	None																		
	Model must match the voltage and freque	ncy of the purchasing country's local																		
Voltage	power grid (e.g., 110-120 VAC at 6	Hz or 220-240 VAC at 50 Hz)																		
	User manual and additional training																			
	materials (checklists, videos, guides) in at																			
	least one national language for the country	User manual provided in at least one																		
	of intended use. Attached to device with	national official language																		
User Instructions	labels and markings where possible.																			
Warranty	5 years	1 year				-			<u> </u>											
	5 7 5 6 1 5	Purchased for evaluations?	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
	Does device meet all minimal performance	1																		
Technical	characteristics from TPP?	devices by 3 unique users																		
		Heat																		
Environmental	Is device rugged, durable, easy to maintain	Humidity																		
	and repair?	Dust																		
		Power				_														
		Heuristic Evaluation				-														
		Houston task effectiveness (Setup)	83%	100%																
		Houston task effectiveness																		
		(Titration)	100%	66%	not															
		Houston task effectiveness		1000/	includ															
		(Hat/prong)	50%	100%	ed in			r	Did not	moot re	auirod	cnocific	ations	whon o	atuata	d again	st the T	סכ		
		University CLIC			evals			L	Ju not	meetre	equireu	specific	ations	whene	valuate	u again	st the h	- F		
		Houston SUS	10																	
		<50 50-70 >70	48	58																
Usability	Can doctors and nurses use the device	<50 50-70 >70 Fraction of Houston users indicating																		
Usability	Can doctors and nurses use the device with minimal training?	<50 50-70 >70 Fraction of Houston users indicating preferred device	50%	50%																
Usability		<50 50-70 >70 Fraction of Houston users indicating			0%															
Usability		<50 50-70 >70 Fraction of Houston users indicating preferred device	50%	50%	0%															
Usability		<50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Setup) Malawi task effectiveness (Titration)	50% 50% 0%	50% 50% 25%	0%															
Usability		< <u>50 50-70 >70</u> Fraction of Houston users indicating preferred device Malawi task effectiveness (Setup)	50% 50%	50%																
Usability		<50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Setup) Malawi task effectiveness (Titration) Malawi task effectiveness	50% 50% 0% 25%	50% 50% 25% 75%	0% 75%															
Usability		<50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Setup) Malawi task effectiveness (Titration) Malawi task effectiveness (Hat/prong)	50% 50% 0%	50% 50% 25%	0%															
Usability		<50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Setup) Malawi task effectiveness (Titration) Malawi task effectiveness (Hat/prong) Fraction of Malawi users indicating	50% 50% 0% 25% 25%	50% 50% 25% 75% 75%	0% 75% 0%	-														
Usability		<50 50-70 >70 Fraction of Houston users indicating preferred device Malawi task effectiveness (Setup) Malawi task effectiveness (Titration) Malawi task effectiveness (Hat/prong) Fraction of Malawi users indicating preferred device	50% 50% 0% 25%	50% 50% 25% 75%	0% 75%	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

Optimal Minimal	Does not meet minimal	Unknown
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Flow Splitter

Evaluated against Target Product Profile (TPP) as reported by manufacturer

TPP Characteristic		Minimal Requirement	А	В	C	D		
Intended Use	To allow multiple patients to receive indi	vidually adjusted flow rates from a						
Intended Ose								
Target Operator	For use in low- and middle-income coun	tries by a wide variety of clinicans,						
Target Operator	including nurses, clinical offi	cers, and pediatricians						
Target Population	Ise To allow multiple patients to receive individ rator For use in low- and middle-income countrie ulation Neonates (born at any gestational age ting Hospitals in low-resource settings, but, magement ISO 13485:2016 Medical devices - Quality mar for regulatory pur At least one of: CE marking, approved by US F body of a founding member of IMDRF (e.g. 0-2 L/min ol Each patient has individually co Outputs 5 Erring <\$100 ex-works							
	Hospitals in low-resource settings, but,							
Target Setting	may be used in health facilities based on	Hospitals in low-resource settings						
	country guidelines							
Quality Management	ISO 13485:2016 Medical devices - Quality r	nanagement systems - Requirements						
Quality Management	on At least one of: CE marking, approved by US FD body of a founding member of IMDRF (e.g., 0-2 L/min ntrol of Outputs 5 on Each patient has individually con 5							
Population	Inanagement for regulatory purp on At least one of: CE marking, approved by US FE body of a founding member of IMDRF (e.g., body of a founding member of IMDRF (e.g., 0-2 L/min) per Patient 0-2 L/min trol Each patient has individually color of Outputs 5 n Each flow rate has a visual nt Pricing <\$100 ex-works							
Regulation	ISO 13485:2016 Medical devices - Quality man for regulatory purp At least one of: CE marking, approved by US F body of a founding member of IMDRF (e.g., ber Patient 0-2 L/min trol Each patient has individually co of Outputs 5 Each flow rate has a visu th Pricing <\$100 ex-works nce No/minimal mainte							
Air Flow per Patient	on At least one of: CE marking, approved by US FDA body of a founding member of IMDRF (e.g., Jack patient has individually composed of Outputs of Outputs 0-2 L/min of Outputs 5 n Each patient has a visual ent Pricing ance No/minimal maintena							
Flow Control								
Number of Outputs								
Indication	Each flow rate has a visu							
Instrument Pricing	<\$100 ex-works	<\$600 ex-works						
Maintenance	No/minimal ma	intenance						
	·	Purchased for evaluations?	Yes	Yes	Yes	No		
Taskaisal	Does device meet all minimal performance	Verified by lab evaluations on n = 2						
rechnical	characteristics from TPP?	devices by 3 unique users				Did		
		Heat						
Environmental	Is device rugged, durable, easy to maintain	Humidity						
	and repair?	Dust				mee		
		Power	N/A	N/A	N/A	requ		
		Heuristic Evaluation				ed		
		Houston task effectiveness	80%	100%		spec		
		Houston SUS			1	catio		
		<50 50-70 >70	58	76		S		
		Fraction of Houston users indicating		1000	1	whe		
Usability	Can doctors and nurses use the device	preferred device	0%	100%	Did	evalu		
	with minimal training?	Malawi task effectiveness			not	ted		
		Malawi SUS			test	agair		
		<50 50-70 >70	Did not	test		tthe		
		Fraction of Malawi users indicating				TPP		
		preferred device						
	Dieleffed device							

Optimal Oxygen Concentrator	Minimal	Does not meet minimal	Unknown																						
Evaluated against Target Product Profile (TPP) as reported by ma	anufacturer																								
TPP Characteristic	Optimal Requirement	Minimal Requirement	A	В	C D	E	F	G	Н	1	1	К	L	М	N	0	Р	Q	R	S	t	U I	/ /	v x	
Intended Use	To provide medical oxygen for u	use in a healthcare setting																							
Target Operator	For use in low- and middle-income coun																								
	including nurses, clinical offi	cers, and pediatricians		-			-	_	_														_		_
Target Population	Neonates (born at any gestational a Hospitals in low-resource settings, but.	ige and require ongoing care)				_	-	_	_														_		
Target Setting	may be used in health facilites based on	Hospitals in low-resource settings																							
Quality Management	country guidelines ISO 13485:2016 Medical devices - 0	Juality management systems		<u> </u>			-	_															-	_	
	At least one of: CE marking, approved by U	S FDA or another strigent regulatory		+			+	+							<u> </u>					-			-+		
Regulation	body of a founding member of IMDRF (e.g., Japan or Australia or Canada)																							
Flow Meter	At least 2 with each 0 to 10 LPM flow meter, min incremental 0.5 LPM	At least 1 [flow meter] with 0 to 10 LPM flow meter, min incremental 0.5 LPM																							
Minimal Flow Rate	0.5 LPM (if used without a flow splitter)	2 LPM																							
Flow Rate	10 LPM	8-10 LPM																							
Time to reach 95% of specified performance	<5 Mir							_																	
Oxygen Purity	93%+-3																								
Alarms	Visual and audit	ory alarms																							
Indicators	Clearly labeled or marked with pictures and language. Audible alerts and diagnostic indicator where possible.	UI is easy to understand, numbers and displays are clearly visible.																							
Mobility	Whole unit moveable with wh	eels on at least two feet																							
Oxygen Monitor	Visual and audible status, preferably with	Visual and audible status																					T		
	color coding for early warning																								
Oxygen Outlet	Recessed, replaceab																								
Noise Level	≤ 50 decibels; low	as posisple					-																		
Weight	<30kg	Tomporature 10 40 °C hund "																							
	Harsh ambient condition, temperature 5- 45 °C, humidity 15% to 95%, dusty air,	Temperature 10-40 °C, humidity 15%-95% elevation up to 2000																							
Durability and Robustness	45 C, numidity 15% to 95%, dusty air, elevation ≥ 2000 meters	15%-95% elevation up to 2000 meters																							
	Non-resettable digital or analog meter disp																								
Usage Meter						_		_															_		
Instrument Pricing	<\$500 ex-works	<\$1600 ex-works																							
Power Source	Mains Power	Mains Power				_		-															_		_
Down Consumption	< 275W at 5 PLM	Scales with delivery output — i.e., consumes less power at lower flow																							
Power Consumption	Model must match the voltage and freque	rates. ncv of the purchasing country's local		-		-	-	-	-											-					
Voltage	power grid (e.g., 110-120 VAC at 60	Hz or 220-240 VAC at 50 Hz)																							
	User manual and additional training	,		-			-																-		
	materials (checklists, videos, guides) in at																								
	least one national offical language for the	Instruction manual provided in at																							
	country of intended use. Attached to	least one national offical language																							
	device with labels and markings where																								
User Instructions	possible.																								
User Skill Levell	Minimal to	none																							
Warranty	5 years	1 year																							
	Reduce recessed areas and need for	Easy to clean flat surfaces,																							
	specialized cleaning procedures or	compatible with common																							
Decontamination	products	disinfecting agents						_																	
	Should not need preventative	Should not need preventative																							
	maintenance more than once a year	maintenance more than 4 times a																							
Preventive Maintenance Interval		year (quarterly)				_		_	_														_		
	Minimally trained technic'	Trained technician with training in																							
Technical Skill Maintenance	Minimally trained technician	basic operation and maintenance																							
Cleaning Interval	None required.	Weekly filter cleaning.																							
county merida	Hone required.			-																					
	No specialized tools required	Minimal specialized tools required																							
Tools Required		for sieve bed and filter replacement																							
Filters	Replaceable washa																								
		Purchased for evaluations?	Yes	Yes	Yes N	No No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Technical	Does device meet all minimal performance	Verified by lab evaluations on n = 2																							
recititudi	characteristics from TPP?	devices by 3 unique users																							
		Heat																							
Environmental	Is device rugged, durable, easy to maintain	Humidity																							
	and repair?	Dust																							
		Power																							
		Heuristic Evaluation																							
		Houston task effectiveness	83%	83%	67%																				
		(Setup/report)																							
		Houston task effectiveness (Alarm)	100%	100%	100%																				
		Houston SUS		67	74					0	Did not n	neet re	quired :	specific	ations v	vhen ev	aluated	d again:	st the TI	PP					
		< 50 50-70 >70	83	87	71																				
Usability	Can doctors and nurses use the device	Fraction of Houston users indicating	33%	0%	67%																				
,	with minimal training?	preferred device		1	51.70																				
		Malawi task effectiveness																							
		(Setup/report)	Evolute		anat																				
		Malawi task effectiveness (Alarm)	Evaluation completed																						
		Malawi SUS		andemi																					
		<50 50-70 >70 Fraction of Malawi users indicating	19 p	unuenili																					
		preferred device																							
		NEST Qualified Technology?	Ves	Yes	Yes N		No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

Optimal	Minimal	Does not meet minimal	Unknown																							
Pulse Oximeter																										
Evaluated against Target Product Profile (TPP) as reported by mar																										
TPP Characteristic	Optimal Requirement	Minimal Requirement	A	В	С	D E	F	G	Н	1	J	К	L	М	N	0	Р	Q	R	S	Т	U	v	w 2	X '	/
Intended Use	To continuously monitor oxygen saturat																									
	neonatal pa For use in low- and middle-income coun									_										-						_
Target Operator	including nurses, clinical offi																									
Tarret Danulatian	Neonates (born at any gestational a																			-					_	<u> </u>
Target Population	Neonates (born at any gestational a	ge and require ongoing care)					_	_		-															_	_
Target Setting	Hospitals in low-resource settings, but, may	Hospitals in low-resource settings																								
larget Setting	be used in health facilites based on country	Hospitals in low-resource settings																								
	ISO 13485:2016 Medical devices - Quality m	anagement systems Requirements						_																		
Quality Management	for regulatory																									
	At least one of: CE marking, approved by U	FDA or another stringent regulatory																								
Regulation	body of a founding member of IMDRF (
Pulse rate	25-250 bpm	30-240 bpm																								
Pulse rate accuracy	+/-3 bp	n																								
Pulse rate resolution	1 bpm																									_
SPO2 accuracy	+-2%	+-3%																								
SPO2 range	0-100%	70-100%																								
Alarm characteristics	Visual and auditory	Auditory																								
Alarm limits - PR	Adjustable	80-180 bpm OR 100-180 bpm																								
Alarm limits - SpO2	Adjustab	le																								
Continuous measurement	Yes																									
Patient interface	Neonate specific, biocomp	atible and reusable.																								
	Easily moveable, not pocketable, can be																									
Size	secured	Handheld with dock																								
Weight	<500 g, por	table																								
	-550 g, por																									
Consumables	>12 months before required	>6 months before required with 2																								
constitutiones	s 12 months before required	neonatal probes included in package																								
Instument Pricing	< \$150 ex-works	< \$250 ex-works																		<u> </u>				-	-	-
		< \$80 per year ex-works (two								-							_									<u> </u>
Consumable Pricing	< \$50/year ex-works (two probes)	probes)																								
Power Source	Mains with recharg																_									_
		Rechargeable battery, >6hr on single					_										_									_
Battery	charge	charge																								
	charge	Model must match the voltage and								-																_
		frequency of the purchasing																								
Voltage	None	country's local power grid (e.g., 110-																								
Voltage	None	120 VAC at 60 Hz or 220-240 VAC at																								
		50 Hz)																								
		56112						_												1						-
	User manual and additional training																									
	materials (checklists, videos, guides) in at	User manual provided in at least one																								
User instructions	least one national official language for the	national official language																								
	country intended use. Attached to device	national official language																								
	with labels and markings where possible																									
Training Required	Minima	1																								
Warranty	5 years	1 year																								
Decontamination	Easy to clean with commor																								_	-
	Digitally stored record displaying	Digitally stored record displaying 50								-							_									
Usage Meter	cumulative hours of operation	previous readings or >50 hours																								
	cumulative nours of operation	Purchased for evaluations?	Yes	Yes	Yes	Yes	Ves I	No N	NO.	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
	Does device meet all minimal performance	Verified by lab evaluations on n = 2	105	105	105	105	105 1			110	1 110								110	1 110	1.10		110	110	110	
Technical	characteristics from TPP?	devices by 3 unique users																								
		Heat				Did not t																				
Environmental	Is device rugged, durable, easy to maintain	Humidity				failed in																				
Environmental	and repair?	Dust	Did	not test		heurist	ics																			
	and repair.	Power	510	1		1																				
		Heuristic Evaluation					_																			
				-																						
		Houston task effectiveness	83%	100%	83%																					
		(Setup/report)				-																				
		Houston task effectiveness (Alarm)	100%	100%	83%																					
		11										Didu	not mee	t requi	ed sner	ificatio	ns wher	n evalu	ated ag	ainst th	e TPP					
		Houston SUS	82	90	45							Diai	iot mee	erequi	cu spec	meatro	ino miner	- c v u lu	area ag	annse en						
		<50 50-70 >70				Failed in	itial																			
	Can doctors and nurses use the device with	Fraction of Houston users indicating	33%	67%	0%	heurist																				
Ucability		preferred device				with LN																				
Usability	minimal training?	Adult front Month		1		with LN	IIC																			
Usability	minimal training?	Malawi task effectiveness	83%	83%	58%	aliai																				
Usability	minimal training?	Malawi task effectiveness (Setup/report)	83%	83%	58%	clinica	ns																			
Usability	minimal training?	(Setup/report)	83% 42%		8%	clinica	ns																			
Usability	minimal training?	(Setup/report) Malawi task effectiveness (Alarm)		83% 42%	8%	clinica	ns																			
Usability	minimal training?	(Setup/report) Malawi task effectiveness (Alarm) Malawi SUS				clinica	ns																			
Usability	minimal training?	(Setup/report) Malawi task effectiveness (Alarm) Malawi SUS <50 50-70 >70	42%	42%	8%	clinica	ns																			
Usability	minimal training?	(Setup/report) Malawi task effectiveness (Alarm) Malawi SUS <50 50-70 Fraction of Malawi users indicating	42%	42%	8%	clinica	ns																			
Usability	minimal training?	(Setup/report) Malawi task effectiveness (Alarm) Malawi SUS <50 50-70 >70	42% 80 42%	42% 80 42%	8% 52 16%	clinica																				

Optimal	Minimal	Does not meet minimal	Unknown						
Suction Pump									
Evaluated against Target Product Profile (TPP) as reported by n									
TPP Characteristic	Optimal Requirement	Minimal Requirement	A	В	С	D	E	F	G
Intended Use	Aspirations and removal of secretions, bo								
	patient's airway or respiratory support s For use in low- and middle-income cour								
Target Operator	including nurses, clinical off								
Target Population	Neonates (born at any gestational								
Target Setting	Hospitals in low-res								
Quality Management	ISO 13485:2016 Medical devices -	<u> </u>				-			
Regulation	At least one of: CE marking, approved by U body of a founding member of IMDRF (
Pressure	60-120 mm Hg with cont	inuous adjustment							
Bottle Capacity	1L								
Noise Level	As low as p	ossible							
Cleaning	Collection vessel easy	to clean reusable							
Maintenance	No maintenance of	or lubrication							
Operation Mode	Adjustable to neonatal set	ting (60-100 mm Hg)							
Instrument Pricing	<\$100 ex-works	<\$250 ex-works							
Power Source	Mains Po								
	Model must match the voltage and freque								
Voltage	power grid (e.g., 110-120 VAC at 6								
	User manual and additional training								
	materials (checklists, videos, guides) in at								
	least one national official language for the	User manual provided in at least one							
User instructions	country of intended use. Attached to	national official language							
	device with labels and markings where								
	possible.								
Warranty	5 years	1 year							
	- /	Purchased for evaluations?	Yes	Yes	Yes	No	No	No	No
	Does device meet all minimal performance	1							
Technical	characteristics from TPP?	devices by 3 unique users							
		Heat							
Environmental	Is device rugged, durable, easy to maintain	Humidity							
	and repair?	Dust				-			
		Power				-			
		Heuristic Evaluation				-			
						-			
		Houston task effectiveness (Setup)	100%	33% 100%	100%				
		Houston task effectiveness (Use)	100%	100%	100%	Dic Dic	l not me	et requ	uired
		Houston SUS <50 50-70 >70	80	68	84		pecificat Jated ag		
Usability	Can doctors and nurses use the device with	Fraction of Houston users indicating preferred device	0%	0%	100%	,			
	minimal training?	Malawi task effectiveness (Setup)	75%	50%					
		Malawi task effectiveness (Use)	100%	100%	Did not				
		Malawi SUS <50 50-70 >70	85	85	test				
	1	Executions of Marlandi communications	1	1					
		Fraction of Malawi users indicating preferred device	50%	50%					

Optimal	Minimal	Does not meet minimal	Unknown													
Radiant Warmer																
Evaluated against Target Product Profile (TPP) as reported by man				-				1				-				
TPP Characteristic	Optimal Requirement Treatment and prevention of hypothern	Minimal Requirement	A	В	C	D	E	F	G	Н	1	J	К	L	М	N
Intended Use	thermal															
	For use in low- and middle-income coun				<u> </u>				<u> </u>			<u> </u>				
Target Operator	including nurses, clinical offi															
Target Population	Neonates (born at any gestational a															
Target Setting	Hospitals in low-res															
Quality Management	ISO 13485:2016 Medical devices - (Quality management systems							<u> </u>							
Provide State	At least one of: CE marking, approved by L	JS FDA or another strigent regulatory														
Regulation	body of a founding member of IMDRF (e.g., Japan or Australia or Canada)														
Benchtop Measurement Accuracy	±0.1*0											-				
Clinical Measurement Accuracy	±0.3°C				<u> </u>			<u> </u>	<u> </u>			<u> </u>				
Stability	< 0.5°															
Includes Timer	Yes	-														
Includes Scale	Yes	No														
Mobility	Has wheels; can be mov															
Time to Indicate Accurate Temperature	< 1 minute	< 90 seconds														
Uniformity	<1°C															
Alarm Characteristics	Visual and a	uditory														
Alarm Limits	Adjustable	36.5-37.5°C														
	Harsh ambient condition, temperature 5-45	Harsh ambient condition,														
Operating Temperature	*C, humidity 15% to 95%, dusty air,	temperature 10-40 °C, humidity 15%														
	elevation >=2000 meters	to 95%, dusty air, elevation up to														
		2000 meters														
Patient Interface	Interface is biocompatible and resusable Patient is visible and accessib	Interface is biocompatible			-				-							
Patient Accessibility and Visibility Temperature Control	Patient is visible and accessib Based upon infant's temperature				-				-							
Consumables	> 12 months before required	> 6 months before required														
Instrument Pricing	> 12 months before required < \$500 ex-works	> 6 months before required < \$1,500 ex-works														
	< \$500 ex-works < \$50 per year ex-works (includes two	< \$1,500 ex-works < \$100 per year ex-works (includes						-	-			-				
Consumable Pricing	probes)	two probes)														
Power Source	Mains Power	Mains Power														
Power Consumption	< 250W maximum	< 800W maximum														
	Model must match the voltage and freque	ncy of the purchasing country's local														
Voltage	power grid (e.g., 110-120 VAC at 60	D Hz or 220-240 VAC at 50 Hz)														
	User manual and additional training															
	materials (checklists, videos, guides) in at															
User Instructions	least one national official language for the	User manual provided in at least one														
	country of intended use. Attached to	national official language														
	device with labels and markings where															
	possible.															
Warranty Decontamination	5 years Easy to clean with commo	1 year														
Decontamination	Easy to clean with commo	Purchased for evaluations?	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No
	Does device meet all minimal performance		Tes	Tes	NU	NU	NU	NU		NU	NU		NU	NU	NU	INU
Technical	characteristics from TPP?	devices by 3 unique users														
		Heat			1											
Environmental	Is device rugged, durable, easy to maintain	Humidity			1											
	and repair?	Dust			1											
		Power														
		Heuristic Evaluation														
		Houston task effectiveness	00/	670/	1											
		(Prewarm)	0%	67%												
		Houston task effectiveness	100%	100%												
		(Automatic)	10070	100%												
		Houston task effectiveness	100%	100%												
		(Read/report)														
		Houston task effectiveness (Alarm)	83%	83%												
					-	Did	not me	et requi	ired spe	cificatio	ons whe	en evalu	ated aga	ainst the	e TPP	
		Houston SUS	78	80												
	Considerations and assessed the device with	<50 50-70 >70			-											
Usability	Can doctors and nurses use the device with minimal training?	Fraction of Houston users indicating preferred device	33%	67%												
	initial training:	preferred device			-											
		Malawi task effectiveness (Prewarm)	0%	17%												
	1	Malawi task effectiveness														
		(Automatic)	33%	67%												
	1	Malawi task effectiveness			1											
1	1	(Read/report)	83%	100%												
				_												
			83%	17%												
		Malawi task effectiveness (Alarm) Malawi SUS	83%	17%												
		Malawi task effectiveness (Alarm)	83% 63	17% 63												
		Malawi task effectiveness (Alarm) Malawi SUS	63	63												
		Malawi task effectiveness (Alarm) Malawi SUS <50 50-70 >70 Fraction of Malawi users indicating preferred device	63 50%	63 50%												
		Malawi task effectiveness (Alarm) Malawi SUS <50 50-70 >70 Fraction of Malawi users indicating	63 50%	63	No	No	No	No	No	No	No	No	No	No	No	No

Optimal	Minimal	Does not meet minimal	Unknown
Tomporature Monitor			

Temperature Monitor Evaluated against Target Product Profile (TPP) as reported by manufacturer

Evaluated against Target Product Profile (TPP) as reported by					-	-	-									-	1.	-		1-									
TPP Characteristic	Optimal Requirement	Minimal Requirement	A	B C	D	E	F	G	Н	1	J	к	L N	N	0	Р	Q	R	S	T	U	V	W	Х	Y	Z /	AA B	BB CC	DD
Intended Use	To provide ongoing diagnosis and mor																												
	hyperthe														_		_			<u> </u>			\square				$ \rightarrow $		
Target Operator	For use in low- and middle-income cou																												
	including nurses, clinical off						_	_	_	_	_			_	_		_			-	-		\square				\rightarrow		
Target Population	Neonates (born at any gestational							_	_	_	_				_		_			-	-		\square						
Target Setting	Hospitals in low-re				_		_		_	_	-				_		-			-	-		$ \longrightarrow $				\rightarrow		
Quality Management	ISO 13485:2016 Medical devices -	Quality management systems			_			_		_	_				_			-		-	-		$ \longrightarrow $				\rightarrow		
Regulation	At least one of: CE marking, approved by body of a founding member of IMDRF																												
Benchtop Measurement Accuracy	±0.1°	с																											
Clinical Measurement Accuracy	±0.2 °C	±0.3 C																											
Time to Indicate Accurate Temperature	< 60 seconds	< 90 seconds																											
Alarm Characteristics	Visual and A	uditory																											
Alarm Limits	Adjustable	36.5°C-37.5°C																											
Patient Interface	Interface is biocompatible and reusable	Interface is biocompatible																											
Size	Small footprint; can l																												
Weight	<500 gr	ams																											
Consumables	> 12 months before required	> 6 months before required																											
Instrument Pricing	<\$100 ex-works	<\$200 ex-works																											
Consumable Pricing	<\$50 per year	ex-works																											
Power Source	Mains with rechar	geable battery																											
	Rechargeable battery, >24hrs on a single	Rechargeable battery, >6hrs on a																											
Battery	charge	single charge																											
	Model must match the voltage and freque																												
Voltage	power grid (e.g., 110-120 VAC at 6	0 Hz or 220-240 VAC at 50 Hz)																											
	User manual and additional training																										1		
	materials (checklists, videos, guides) in at																												
	least one national official language for the	User manual provided in at least one																											
User instructions	country of intended use. Attached to	national official language																											
	device with labels and markings where																												
	possible.																												
Warranty	5 years	1 year																											
Decontamination	Easy to clean with commo	on disinfecting agents																											
		Purchased for evaluations?	No	No N	No	No	No N	o No	No	No	No	No	No	No N	No No	No	No	No	No	No	No	No	No	No	No	No	No	No N	lo No
Technical	Does device meet all minimal performance	Verified by lab evaluations on n = 2																											
Technical	characteristics from TPP?	devices by 3 unique users																											
		Heat	1																										
Environmental	Is device rugged, durable, easy to maintain	Humidity	1																										
	and repair?	Dust	1									0.1								-									
		Power	1									Did no	ot meet rec	uired spe	ciricatio	is whe	i evalua	eo agai	ist the	166									
		Houston Satisfaction (SUS)	1																										
	Can doctors and nurses use the device with																												
Usability	minimal training?	Malawi Satisfaction (SUS)	1																										
		<50 50-70 >70	0>70																										
		NEST Qualified Technology?																											
		treat quantee realitology:	110					110	140	110	140	140	110			140	110	140	140	110	140	NO	110	NU	NU	10	.10		0 110

Optimal	Minimal	Does not meet minimal	Unknown																															
Conductive Warmer																																		
Evaluated against Target Product Profile (TPP) as reported by ma																																_		
TPP Characteristic	Optimal Requirement	Minimal Requirement	A	В	С	D	E I	F	G	H I	1	J	к	L	М	N	0	Р	Q	R	S	T	U	V	W	х	Y	Z	AA	BB	CC	DD	EE	FF
Intended Use	Treatment and prevention of hypothermia																																	
Target Operator	For use in low- and middle-income coun including nurses, clinical offi																																	
Target Population	Neonates (born at any gestational a																-	-			-									-			-	
Target Setting	Hospitals in low-res							_														-	-		-				-				-	
Quality Management	ISO 13485:2016 Medical devices - 0																-	-	-	-	-	-	-			-			-	-			+	
	130 13403.2010 Wedical devices - 4	Quality management systems															-				+		-	-	+	+			-			-	<u> </u>	
Regulation	At least one of: CE marking, approved by U body of a founding member of IMDRF (
Form Factor	Enclosed or not enclose	ed (no preference)																																
Benchtop Measurement Accuracy Conductive Surface	Conductive Surface Temperature: Acc																																	
Temperature	temperaute (measured) = ±0.1°																																	
Temperature of Baby (required if servo-controlled)	Accuracy of baby's tem	nperature: ±0.2°C																				1												
Clinical Measurement Accuracy (Compare to another gold	, ,																																	
standard)	Known	Not required																																
Maximum CO2 Concentration (if Enclosed device)	0.50%	6																																
Maximum Temperature (of the conductive surface)	40°C																																	
Humidification (if Enclosed device)	Humidity control for babies less than 1kg	None																																
Surface Temperature overshoot when the temperature control	1°C	1																															-	
Time to Indicate Accurate Temperature of baby	< 90 sec	< 5 min																				-												
Uniformity (if Enclosed, then uniformity of air) (If Not Enclosed,	Air Temperature: < 0.8°C (for enclosed on																																	
then uniformity of mattress)	and not enclosed): High Heat:																																	
Alarm Characteristics	Visual and a																	-				-				1								
								_									-		-		-	-	-		-	-	-		-	-				
Patient Interface	Interface is biocompatible and reusable	Interface is biocompatible																																
Patient Accessibility and Visibility	Patient is visible and accessib																			_			_						_				4	
Temperature Control	Based on infant's temperature and	Manual control and includes fail-																																
	includes failsafe mode	safe mode																	_	_		_	_	_									4	
Operating Conditions	Describe in user manual how warmin temperatures in the ope																																	
Consumables (probes)	> 12 months before required	> 6 months before required																																
Instrument Pricing	< \$500 ex-works	< \$1,000 ex-works																																
Consumable Pricing	< \$50 / year	< \$100 / year																																
Power Source	Mains Po																																	
Power Consumption	< 250W maximum	< 800W maximum																																
Voltage	Model must match the voltage and freque power grid (e.g., 110-120 VAC at 60																																	
User Manual	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 commo	on disinfecting agents																																
		Purchased for evaluations?	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
To the first	Does device meet all minimal	Verified by lab evaluations on n = 2																															-	
Technical	performance characteristics from TPP?	devices by 3 unique users																																
		Heat																																
Environmental	Is device rugged, durable, easy to maintain	Humidity																																
	and repair?	Dust																e					-											
		Power												DIG NO	meet r	require	a speci	rication	s when	evalua	ted aga	inst the	199											
		HOU Satisfaction (SUS)																																
	Can doctors and nurses use the device	<50 50-70 >70																																
Usability	with minimal training?	MW Satisfaction (SUS)																																
		<50 50-70 >70																																
	I	NEST Qualified Technology?	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
			110	NO	NO	140	110	110	NO	110	.10	NO	110	110	140	140	140	140	140	140	140	110	140	140	140	1.0	110	NO	110	110	140	110	1.10	NO

Optimal	Minimal	Does not meet minimal	Unknown																																
Respiratory Rate Apnea Monitor																																			
Evaluated against Target Product Profile (TPP) as reported by ma	anufacturer																																		
TPP Characteristic	Optimal Requirement	Minimal Requirement	A	В	C D	E	F	G	н	I J	К	L	M	N	0	P C) R	S	Т	U	V	w	X Y	Y Z	4	AA BE	3 C(C D	D EE	FF	GG	HH	11	11	Л.
Intended Use	To provide continuous monit																																		
Target Operator	For use in low- and middle-income court																																		
	including nurses, clinical of																																	4	4
Target Population	Neonates (born at any gestation a																																		4
Target Setting	Hospitals in low-resouce settings, but, may be used in health facilites based on country guidelines	Hospitals in low-resource settings																																	
Quality Management	ISO 13485:2016 Medical devices - Quality for regulatory																																		
Regulation	At least one of: CE marking, approved by I body of a founding member of IMDRF (
Apnea Detection	Detect periods of central apnea e	exceeding 20s duration (at 0)																																	П.
Respiratory Rate Accuracy	+/-2 bpm	+/- 5 bpm																																	
Respiratory Rate Range	0-100 b	pm																																	
Alarm	Visual and auditory	An alarm (visual or auditory)																																	
Patient Interface	Interface is biocompatible and reusable	Interface is biocompatible																																	
Respiratory Rate Alarm Limits	Automatically adjust based on patient age	30-60 bpm																																	
Apnea Intervention	Yes	No																																	1
Instrument Pricing	<\$100 ex-works	<\$250 ex-works																																	1
Power Source	Mains with recharg	geable battery																																	
Battery	Rechargeable battery, >24hrs on a single charge	Rechargeable battery, >6hrs on a single charge																																	
	Model must match the voltage and freque	ency of the purchasing country's local																																	1
Voltage	power grid (e.g., 110-120 VAC at 6	0 Hz or 220-240 VAC at 50 Hz)																																	
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.																																		
Warranty	5 years	1 year																																	1
Decontaimination	Easy to clean with commo																																		1
	-	Purchased for evaluations?	No	No	No	No 1	NO NO	No	No	No	No No	No	No	No	No	No	No N	IO N	NO NO	No	No	No	No	No	No	No I	No	No	NO N	IO N	o N	o No	o No	No	1
	Does device meet all minimal performance																																		1
Technical	characteristics from TPP?	devices by 3 unique users																																	
		Heat	1																																
Environmental	Is device rugged, durable, easy to maintain	Humidity	1																																
	and repair?	Dust	1											Did no	t moot r	a visad a	pecificat	ione wi	hon ovalu	otod ogo	inct the														
		Power	1											Did no	t meet n	squired s	specificat	JUIIS WI	ien evalu	ared aga	mst the	IFF													
		HOU Satisfaction (SUS)	1																																
(Jack Ub.)	Can doctors and nurses use the device with																																		
Usability	minimal training?	MW Satisfaction (SUS)	1																																
	-	< 50 50-70 >70																																	
	•	NEST Qualified Technology	No	No	No	No 1	NO NO	No	No	No	No No	No	No	No	No	No	No N	lo N	No No	No	No	No	No	No	No	No I	No	No	No N	IO N	o N	D No	o No	No	
		0,								-												-													-