REQUEST FOR PROPOSALS:

SUPPLY OF SIDESTREAM CAPNOGRAPHY DEVICE

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Contact details: Mr Rémy Turc

remy.turc@lifebox.org / +44 2032860402

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About the Smile Train - Lifebox capnography project

Smile Train is well recognized as the global leader in comprehensive cleft care. Smile Train is committed to empowering and training local medical professionals to provide safe, high quality, comprehensive cleft treatment for individuals affected by cleft lip and palate. Since inception, Smile Train has invested in hospital partnerships by providing education and training in areas where there is limited local capacity, enabling our partners to build long-term, sustainable infrastructures for year-round patient care.

To learn more about how Smile Train's sustainable approach has both an immediate and long-term impact, please visit smiletrain.org.

Lifebox is an international non-profit organization seeking to improve the safety of surgery and anesthesia around the world. Co-founded and chaired by Dr. Atul Gawande, Lifebox works to increase anesthesia safety, reduce surgical infection rates, and strengthen operating room teamwork through tools, training, and partnerships. Since its founding in 2011 Lifebox has worked in over 116 countries and trained more than 10,000 healthcare providers. www.lifebox.org

The Smile Train-Lifebox Safe Surgery and Anesthesia Initiative is a multi-year strategic partnership bringing together these two global leaders in surgical care. Through capacity building, innovations, and research, this Initiative will strengthen the surgical systems of over 1,000 hospitals around the world and improve the safety of surgical and anesthesia care for more than 2.6 million surgical patients

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1. Request for Proposals (RFP)

Background

A robust capnography solution allowing for end-tidal CO2 monitoring during surgery in low-resource settings is recognized as a priority for improving anesthesia safety. Due to its technical requirements as well as the cost, capnography is not available in many operating rooms globally.

The aim of the Smile Train - Lifebox Capnography Project is to seek a “capnography solution” that meets the needs of Smile Train partner hospitals in their provision of comprehensive, safe cleft care for children. The technical specifications of this RFP have been specifically designed for the intraoperative care of children, including those having cleft surgery, in low-resource settings. Our hope is that this RFP will identify and procure a robust, easy to use, and affordable capnography device that can help improve anesthesia safety for children around the world.

Suppliers/Manufacturers are encouraged to submit proposals for:

1. a stand alone ETCO2 device and/or
2. a combined ETCO2 & SpO2 monitor.

Product samples that include ETCO2, SpO2 and additional parameters will be accepted

RFP Process

Selection of supplier(s) will be through a three-stage process:

- **Stage 1**: Interested suppliers/manufacturers are invited to submit a response to this RFP, following which there will be a period of open dialogue between Lifebox and any bidders in order for Lifebox to provide responses to requests for information. Proposals may be submitted electronically or in hard copy to the address on the front page. Bidders must also provide 1 (one) sample of a device currently manufactured that is most representative of the device that could be provided in response to this RFP by the closing date, to be sent to the address listed on the front page.

  Only proposals submitted with full supporting documents will be considered. Stage 1 proposals must be returned by 21 November 2021.

- **Stage 2**: Shortlisted bidders will be invited to Stage 2 and asked to provide a maximum of 8 sample units for destructive testing and end-user trial as well as additional details on the specifics of their devices.

- **Stage 3**: final selection, discussion around the manufacturing agreements and contract award

The anticipated start date for the contract is September 2022. The contract is expected to be for 1 years' duration with an option to extend to additional year(s).

Assessment of proposals

Smile Train and Lifebox intend to assess proposals in line with the following scoring and evaluation process, subject to paragraph 'RFP Principles' below (including rights of discretion and elimination).

Each response to the selection criteria will be assessed on a scale of 0 to 5 points against the criteria listed. For responses to score 5 the panel will look for evidence to be provided to support your statements. Responses which score 0 against any selection criteria will be considered to have failed. Lifebox may reject such response without further evaluation and such response shall not proceed to the next round of evaluation.

0	**No Answer/Unacceptable Response**
1	**Poor Response**
3	**Acceptable Response**
5	**Good Response**

The scores for each of the selection criteria will then be weighted to give a mark out of 100. The table below indicates the weightings which will be applied to each of the selection criteria.

Ability to meet the required specifications	40%
Pricing & partnership	20%
Experience & capacity	20%
Registration	10%
Financial Stability	10%
TOTAL	100%

Having reviewed the overall score for a proposal, Smile Train and Lifebox shall inform each bidder whether it will be invited to the next stage of the procurement.

There will be no feedback to unsuccessful proposals other than to confirm the decision.

Indicative Timetable

Expected Procurement Timetable		**Target Dates 2021-2022**
1	RFP issued	w/c 11 October 2021
2	Closing date for return of tenders	21 November 2021
3	Clarification period (if required) and bid assessment	by 19 December 2021
4	Testing	January - May 2022
5	Final evaluation and contract award	June - August 2022

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2. SELECTION CRITERIA

#	Criteria	Evidence required
Essential		
2.1	Ability to manufacture a capnography device which meets or exceeds the specifications set out in Annex 1	Please provide: ● A short statement outlining how your proposed device(s) meets the specifications, and noting any requirements that the unit fails to meet or significantly exceeds, and

		whether you are willing to make any minor modifications to bring the device(s) closer to the specifications if needed.
2.2	Ability to deliver a capnography device at the price-point desired	Please provide your estimated price quote(s) at a volume of 300 / 500 / 1,000 units per year considering the following points: ● Refer to section 3.7 Price point; ● Price quote(s) should include the ETCO2 monitor with a silicone protective cover, a twin connector lead, a gas analyzer lead, 10 reusable sample tubes, a patient connector, one rechargeable battery pack, one device to secure the device to a pole, and any charging cables; ● Indicate clearly whether your proposal includes shipping. (See section 3.11 Shipping; in outline requirements below for information required if your proposal includes shipping).
2.3	Ability to work with Smile Train and Lifebox in a mutually beneficial partnership	Please provide: ● A short statement outlining how your company could align with the Smile Train / Lifebox partnership's aims and work together with Smile Train and Lifebox; ● A summary of any relevant partnerships with commercial or non-profit entities that your company is undertaking.
2.4	Certification	Please provide a copy of the following (where applicable): ● ISO 9001 and ISO 80601 certificate; ● ISO 13485; ● CE certification; ● FDA ● Any other certificates related to the device and its accessories such as probes, battery, etc. *Examples: Good Manufacturing Practices; Standard for Surge Protective Devices (IEC 61643, UL 1449); IP4 (or above) rating certificate, biocompatibility of medical devices (ISO 10993); ISTA safe transit testing certificate, medical device Medical Electrical Equipment Electromagnetic Compatibility test report results (IEC 60601-1-2:2014).*

		● Regulatory approvals of specific jurisdictions and/or countries: FDA (USA), CE (EU), MHLW (Japan), CFDA (China), etc. **OR** ● A copy of any product certifications achieved for other products currently produced by your company or in the past. See some examples listed above; ● Copies of audited reports and findings by certified third parties.
2.5	Currently registered and licensed business.	Please provide: ● A copy of current business license and registration; ● A list of countries where your device is registered.
2.6	Past success in producing one or more capnography product and/or combined capnography & pulse oximeter products	Please provide: ● Technical data sheets and any product brochures for the most relevant 1-3 capnography device(s) and/or combined capnography & pulse oximeter products and accessories such as battery, probe, charger, etc. your company currently produces.
2.7	Ability to produce at volume	Please provide a statement indicating: ● Your current annual production capacity and estimate of maximum annual production capacity. ● Your experience providing capnography and/or combined capnography and oximetry products and services to the global markets for at least 3 years.
2.8	The company is financially sound	Please provide: ● Copies of the last three years' certified financial reports or other demonstration of your company's financial soundness.
2.9	Acceptable credit rating	Willingness for short-listed bidders to allow Lifebox and/or Smile Train to review credit rating (an external body may be used to check a bidder's credit rating).
2.10	Site visit	Willingness to allow site visits, given enough notice.
2.11	Experience	Please provide:

		● A short statement indicating whether the bidder is an original equipment manufacturer or a sole agent of the offered solution; ● If the bidder is a sole agent, a manufacturing contract must be in place for the term of the contract. Please provide evidence of the sole agency agreement.
2.12	Supply chain	Please provide: ● A short statement or certificates confirming that the bidder's suppliers supplying to the Smile Train - Lifebox products adhere to the same standards as the bidder.
2.13	Capacity	Willingness to provide evidence of the disaster recovery policy.
2.14	Record keeping and traceability	Willingness to demonstrate: ● Capability of tracing at serial number/lot number level for finished products and components; ● Proper record keeping for finished goods, in process inventory, return/defective goods and components.
For manufacturers proposing <u>a combined ETCO2 & SpO2 device</u>, please provide elements as stated above (criteria 2.1 to 2.14) as well as additional criteria 2.15 and 2.16		
2.15	Ability to manufacture a combined ETCO2 & SpO2 device which meets or exceeds the specifications set out in Annex 2	Please provide: ● A short statement outlining how your proposed combined device(s) (ETCO2 & SpO2) meets the specifications, and noting any requirements that the unit fails to meet or significantly exceeds.
2.16	Ability to deliver a combined ETCO2 & SPO2 device at the price-point desired	Please provide your estimated price quote(s) at a volume of 300 / 500 / 1,000 units per year: ● Refer to section 3.7 Price point ● Price quote(s) should include the ETCO2 monitor with a silicone protective cover, a twin connector lead, 10 reusable sample tubes, a patient connector, 1 adult SpO2 sensor, 1 pediatric SpO2 sensor, one

		rechargeable battery pack, one device to secure the device to a pole, and any charging cables. ● Indicate clearly whether your proposal includes shipping. (See section 3.11 Shipping; in outline requirements below for information required if your proposal includes shipping.)
Preferred		
2.17	Environmental and social responsibility	Please provide information on the implementation of sustainability in the production and distribution phases of the procurement cycle, with an emphasis on social and environmental responsibility (for example compliance with ISO 14001 and SA 8000).

3. Outline requirements

#	Item	Requirement
3.1	**Length of contract**	1 year with option to extend for a further year(s). This is indicative and does not constitute a commitment to a 2 year contract.
3.2	**Governing law**	The contract will be governed by the laws of New York, USA
3.3	**Currency of contract**	USD
3.4	**Volume**	Multiple orders totalling 300 units per year with potential to grow to 500-1000 units in any one year. This is indicative; this RFP does not constitute any commitment to these volumes.
3.5	**Product specifications**	A stand alone ETCO2 device and/or a combined ETCO2 & SpO2 monitor, as outlined in Annex 1 (capnography requirements) and Annex 2 (pulse oximetry requirements) below.
3.6	**SpO2 Probes**	Units must be supplied with - at minimum - one standard probe suitable for all ages. However, proposals including 2 probes per unit (standard &

		pediatric) will be preferred. Neonatal probes will be considered in addition to the proposed probe(s). Manufacturers may respond to this RFP with either Nellcor-compatible or proprietary probes, or both; however, the former may be preferred.
3.7	**Price point**	Proposals for a standalone ETCO2 device as well as a combined ETCO2 & SpO2 device are welcome. It is anticipated that bidders will offer variable pricing based on annual volumes. **Single ETCO2 device** One unit is defined as the ETCO2 monitor with a silicone protective cover, a twin connector lead, a gas analyzer module, 10 reusable sample tubes, a patient connector, one rechargeable battery pack, one device to secure the device to a pole, and any charging cables. At the requested lower volume levels, the expected unit price would be as low as possible and not be in excess of USD 500. **Combined ETCO2 & SpO2 device** One unit is defined as the ETCO2 & SpO2 monitor, the twin connector lead, the gas analyser module, 10 reusable sample tubes, the patient connector, one or more reusable SpO2 probes to address all patients, one rechargeable battery pack, one device to secure the device to a pole, and any charging cables. At the requested lower volume levels, the expected unit price would be as low as possible and not be in excess of USD 650. Replacement sample lines should not cost more than USD 10. Replacement SpO2 probes should not cost more than USD 20. It may be necessary to source products for one or more regions from a local supplier - indicate any

		impact on pricing schedule offered assuming volume breaks unchanged.
3.8	**Payment terms**	Proposals from manufacturers requiring prepayment prior to commencement of manufacturing (for example for small volume order inventory) will be accepted as will proposals for which payment is to be made only after delivery of goods. In the case of prepayment, indicate the additional discount that will apply.
3.9	**Warranty required**	Standard warranty: ● Minimum 2 years (24 months) for the device and ETCO2 accessories; ● Minimum 1 year (12 months) for SpO2 probes (if applicable); Additional warranty: ● Please indicate the cost for an additional 3 years and 5 years' warranty for the device and ETCO2 accessories; ● Please indicate the cost for an additional 2 years' warranty for SpO2 probes (if applicable).
3.10	**Manufacturing lead times**	● Ex-stock for orders of less than 200. ● Maximum 4 weeks for orders > 200 units and less than 1,000 units.
3.11	**Shipping**	The selected supplier(s) / manufacturer(s) will be required to package all orders, and prepare and supply all documentation necessary for customs clearance to target countries. Bidders may make proposals with and without shipping costs. If offered, shipping must be via a fully tracked and traceable service; a variety of providers should be considered on a regular basis for cost-efficiency. If shipping costs are included in the proposal, bidders must outline whether they insure shipments and if so, what level of insurance is offered.

		If shipping costs are not included in the proposal, assumptions will be made about the likely additional cost of shipping for the purposes of evaluating the overall value of a proposal.
3.12	**Customization**	Manufacturers should be willing to customize the device and packaging according to Smile Train - Lifebox's requirements.
3.13	**Languages**	Device ● The device display must - at minimum - be able to display in English, French, and Spanish. Instruction manual ● The accompanying manual must correspond to the display language and must be professionally translated. ● Manual should ideally be available in all six UN languages (Arabic, Chinese, English, French, Russian, and Spanish).
3.14	**Reporting**	Monthly reports on stock levels and shipments must be provided. Additional information such as an end-of-year financial statement, etc. might be requested periodically.
3.15	**Additional services**	Bidders with distribution networks or affiliates in any low- or middle-income countries are encouraged to share details of how these could be deployed to support the supply of replacement parts such as batteries, as well as facilitate import and distribution in their territories through their own supply chains. Bidders are encouraged to make any added value proposal that they feel will add value to their offer. Bidders are encouraged to propose equipment, packaging, manuals, but also shipping solutions that are eco-responsible (e.g. limited use of plastic packaging, sustainable printing, etc.)

4. RFP PRINCIPLES

1. Each bidder shall bear all costs associated with the preparation and submission of the proposal up to the final award of the contract. Smile Train and Lifebox will in no case be responsible or liable for those costs, nor shall Smile Train and Lifebox be liable for or pay any expenses or losses whatsoever which may be incurred by any bidder in the preparation of its bid, regardless of the conduct or outcome of the RFP process.

2. Each bidder assumes all risks for any resource commitment and expenses that it may incur in respect of submitting a bid and participating in the RFP process.

3. Smile Train and/or Lifebox may modify the RFP and the scope of services and goods specified in the RFP at any time.

4. Smile Train and/or Lifebox may extend any deadlines for any bidder or elect not to exercise any right of rejection or elimination at its sole discretion.

5. Smile Train and/or Lifebox may ask any bidder for clarification of any part of its proposal to assist in the examination, evaluation and comparison of proposals.

6. Smile Train and/or Lifebox may hold negotiations (including on price) with any one or more bidders; Smile Train and/or Lifebox is not committed to offering negotiation sessions with all bidders.

7. Smile Train and/or Lifebox have the right to eliminate proposals at any time with no obligation to state the reasons for elimination to the bidder.

8. Smile Train and/or Lifebox reserve the right to accept or reject any proposal, and to annul the solicitation process and reject all proposals at any time prior to award of contract, without thereby incurring any liability to the affected bidder or any obligation to inform the affected bidder or bidders of the grounds for the Smile Train and/or Lifebox's action.

9. Smile Train and/or Lifebox is not bound to select any of the bidders submitting proposals. Neither the issuance or nor the contents of this document in any way obligates Smile Train and/or Lifebox to contract for the supply of any products or services.

10. Smile Train and/or Lifebox may award the contract to any one or more bidders that it feels best meets its overall requirements (including as to economy and efficiency). Smile Train and/or Lifebox does not bind itself in any way to select the bidder offering the lowest price.

11. Smile Train and/or Lifebox may make awards to multiple bidders for the same products.

12. Smile Train and/or Lifebox reserve the right at any time to extend/revise the scope of

services and goods.

13. All documents must be provided in the English language.

Annex 1: Capnography Specifications 2021

This document provides the minimum requirements for a capnography device which can be used in a variety of settings in low- and middle-income countries for continuously monitoring patients in the operating room, recovery area, intensive care unit and neonatal unit. The settings where Smile Train - Lifebox is active range from city hospital operating theaters to remote clinics with minimal infrastructure. Reliable power supplies are a major problem for many of our users.

All capnography devices and ancillary equipment proposed must conform to the requirements of *ISO 80601-2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors* and latest relevant International Electro technical Commission (IEC) standards.

In addition to ISO 80601 and IEC standards, additional requirements described below are recommended.

The capnography device and ancillary equipment must be capable of being shipped, stored, and operated in a wide variety of climatic conditions.

Essential requirements

1. **Device**

ID	Requirement
1.1	Sidestream (diverted) sampling configuration
1.2	Gas sampling rate 50 ml/min
1.3	Weight less than 2.5kg
1.4	Size less than 30 x 30 x 30 cm
1.5	Device will continue to function while awaiting calibration
1.6	CE Mark regulatory approval

2. **Display**

ID	Requirement
2.1	Device shall display ETCO2 number
2.2	Device shall display ETCO2 capnogram waveform
2.3	Device shall display respiration rate number
2.4	Battery charge status is shown in all display screen modes

2.5	Clearly legible numbers and waveform from 3m, all other information legible from a distance of 1m with illuminance of 215 lux

3. Durability

ID	Requirement
3.1	The device shall be operational within its specification at these environmental operating conditions: ● 10 °C to + 40 °C; ● 30 % to 90 % RH, non-condensing, but not requiring a water vapour partial pressure greater than 5 kPa; ● 86 kPa to 106 kPa atmospheric pressure
3.2	The device shall be operational within its specification after transport or storage in these conditions: ● - 40 °C to + 5 °C without relative humidity control; ● + 5 °C to + 35 °C at a relative humidity up to 90 %, non-condensing; ● >35° C to 70 °C at a water vapour pressure up to 5 kPa

4. Sample Line

ID	Requirement
4.1	Kit includes at least 10 reusable sample line assemblies that can in total withstand 1500 wipe-downs with 70% isopropyl alcohol (5 days (5 wipe-downs)/week x 52 weeks/year x 5 year device lifetime x 15% / 2 assemblies)
4.2	Kink resistant sample line material
4.3	Kit includes 10 reusable filter / water trap per sample line that can withstand the same disinfection cycles as the sample line
4.4	Sample line and filter / water trap connectors are standard luer/luer lock connector for small bore connectors ISO 58011

5. Power

ID	Requirement
5.1	Device shall be powered by mains power
5.2	Device shall recharge battery while in use
5.3	Removable, rechargeable battery with run time ≥ 8 hours after 1500 discharge cycles (5 days/week x 52 weeks/year x 5 year device lifetime + 20%)
5.4	Battery shall recharge to 90% in ≤ 6 hrs

5.5	Should be able to take 100-240 VAC without damage and provide surge protection

6. Power supply

ID	Requirement
6.1	The power supply should operate within the ranges 90-250v and 45-65Hz
6.2	The power supply should have surge protection as per UL1449, IEC61643 for a 20uS pulse of 2000V
6.3	A fuse will protect the power supply (in the external charging unit, user serviceable or self resetting)

Optional requirements

The following features are not required, but would provide enhanced usability and better health outcomes. The presence of these features may influence final selection.

7. Display and case

ID	Requirement
7.1	Device language available in English, French, and Spanish
7.2	Numerical readouts shall be located adjacent to their associated waveforms
7.3	Display shall have an option to show at least five capnography waveforms simultaneously
7.4	Device shall display INCO2 number
7.4	If colors are used to differentiate display items, there will be a different color for each single parameter: respiratory rate, $ETCO_2$, and any others
7.5	If colors are used to differentiate display items, selected colors shall be differentiable by people with the most common types of color blindness including deuteranomaly, protanomaly, protanopia, and deuteranopia
7.6	If it is a handheld device, each device shall come with a lockable case to keep all components together and secure
7.7	For handheld devices, the device can be attached to an IV drip stand pole

8. Durability

8.1	Dust and water protection complies with at least IPX2 (dripping water at 15 deg)
8.2	Meets 60601-1 standards for mechanical durability of a handheld device, even if

	device is not handheld

9. Alarms

ID	Requirement
9.1	Alarm limit settings shall be displayed on the primary monitoring screen adjacent to their associated numerical readout
9.2	Device $ETCO_2$ lower alarm limit shall be 15 mmHg and upper alarm limit shall be 60 mmHg; this alarm limit shall not be adjustable
9.3	Device $INCO_2$ upper alarm limit shall be 5 mmHg; this alarm limit shall not be adjustable
9.4	Device shall have a method for adjusting Interval between breaths at which there should be an apnea alarm; 10 to 40s in 5s increments
9.5	Device respiratory rate default lower alarm limit shall be 7 and default upper alarm limit shall be 25; lower alarm limit shall be adjustable 7- 35; upper alarm limit shall be adjustable 20 - 80
9.6	Device shall include a confirmation when changing from default alarm settings
9.7	Device shall revert to default alarm limits on power up

10. Manual

ID	Requirement
10.1	Routine care and maintenance (cleaning, probe and battery) as well as troubleshooting should be described in the manual
10.2	The manufacturer's manual supplied with the oximeter should contain clear, pictorial operating instructions
10.3	The manufacturer's manual supplied with the oximeter should be available in all six UN languages (Arabic, Chinese, English, French, Russian, and Spanish)

11. Power

ID	Requirement
11.1	Can run with AA batteries
11.2	Compartment for disposable batteries shall prevent liquid ingress into the device

Annex 2: Pulse oximetry specifications 2021

This section is for manufacturers who are able to submit a combined ETCO2 & SpO2 device.

This document provides the minimum requirements for a pulse oximeter which can be used in a variety of settings in low- and middle-income countries for continuously monitoring patients in the operating room, recovery area, intensive care unit and neonatal unit. It can also be used as a spot check device for screening patients in clinics and wards. This latter population will include children and neonates.

All pulse oximeters and ancillary equipment proposed must conform to the requirements of ISO 80601-2-61 pulse oximetry standard and latest relevant International Electro technical Commission (IEC) standards.

In addition to ISO 80601 and IEC standards, additional requirements as described below are recommended.

Essential requirements

1. Device

Please refer to the Device section on the "Annex 1: Capnography Specifications 2021" - page 15.

2. Display

ID	Requirement
2.1	Device shall display SpO2 number
2.2	Device shall display SpO2 waveform
2.3	Device shall display pulse rate number
2.4	Battery charge status is shown in all display screen modes
2.5	Clearly legible numbers and waveform from 3m, all other information legible from a distance of 1m with illuminance of 215 lux
2.6	Device language available in English, French and Spanish

3. Durability

Please refer to the Durability section on the "Annex 1: Capnography Specifications 2021" - page 16.

4. Probes

Two alternate probe solutions will be acceptable;

- Universal reusable probe for patients of all ages.
- A combination of multiple reusable probes covering the same range, including neonates

ID	Requirement
4.1	Compatibility with Nellcor-type preferred
4.2	Probes will be used continuously for up to 6 hours. During this time the patient must not experience significant discomfort or any injury
4.3	Probe cord lengths must be available in 3m and 0.7m configurations

5. Accuracy

ID	Requirement
5.1	The pulse oximeter should be accurate to +/- 2% in the clinical range Spo2 84-100% in all skin colours tested per Clause 201.12.1.101.2 and Annex EE.2 of ISO 80601-2-61:2011 including dark African skin tones. The pulse oximeter should be accurate to +/- 3% in the clinical range SpO2 70-100%
5.2	The pulse oximeter pulse rate should be accurate to +/- 3% in the clinical range 40-240bpm
5.3	These requirements will be met at perfusion levels of 0.2% or lower. This will be tested on a simulator

6. Spot Check Mode

ID	Requirement
6.1	Provides a single reading
6.2	No alarms
6.3	Indicates to user (blip, wave, light, other) when a pulse is detected
6.4	When no pulse is detected the user is given advice on how to correct this (too dark, too light, ambient light, excessive motion etc)

6.5	Retains reading

7. Power

Please refer to the Power section on the “Annex 1: Capnography Specifications 2021” - page 17.

8. Power supply

Please refer to the Power supply section on the “Annex 1: Capnography Specifications 2021” - page 17.

Optional requirements

The following features are not required, but would provide enhanced usability and better health outcomes. The presence of these features may influence final selection.

9. Display and case

ID	Requirement
9.1	Device language available in English, French, and Spanish
9.2	Numerical readouts shall be located adjacent to their associated waveforms
9.3	If colors are used to differentiate display items, selected colors shall be differentiable by people with the most common types of color blindness including deuteranomaly, protanomaly, protanopia, and deuteranopia
9.4	If it is a handheld device, each device shall come with a lockable case to keep all components together and secure
9.5	Device - Touch screen display

10. Sounds

ID	Requirement
10.1	The pulse oximeter should be configured so that the pitch of the sound changes with falling saturations per IEC 60601-1-8
10.2	The oximeter should have an audible beep with each pulse beat - default loudness per ISO 80601-2-61 / 60601-1-8
10.3	The volume should be easily adjustable, and can be silenced
10.4	On starting, the default should be with audible signal and alarms

11. Alarms

ID	Requirement
11.1	Alarm limit settings shall be displayed on the primary monitoring screen adjacent to their associated numerical readout
11.2	Device shall revert to default alarm limits on power up
11.3	Device shall include a confirmation when changing from default alarm settings
11.4	Device default SpO2 lower alarm limit shall be at SpO2 < 90%
11.5	An indicator of signal inadequacy shall be provided to the operator when the SpO2 or pulse rate value displayed is potentially incorrect. A description of the indicator and its function shall be provided
11.6	Low pulse rate alarm and high pulse rate alarm should be visible and audible
11.7	Alarms for pulse rate ranges should be able to be set for an adult or paediatric patient (including neonatal patients) with a simple menu operation
11.8	An alarm should indicate the probe should be checked in the event of the probe coming off the patient
11.9	Alarm should be able to be cancelled for up to two minutes by a single button / action

12. Manual

Please refer to the Manual section on the "Annex 1: Capnography Specifications 2021" - page 18.

13. Performance

ID	Requirement
13.1	Accuracy - performance on patients with motion and / or low perfusion. Manufacturers should indicate their device performance and method of testing

14. Power

ID	Requirement
14.1	Power - Can run with AA batteries
14.2	Power - Compartment for disposable batteries shall prevent liquid ingress into the device
14.3	Power supply - Wireless or USB charging could be advantageous