Annex 1: Lifebox Pulse Oximeter Specifications 2019

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. The settings where Lifebox is active range from city hospital operating theatres to remote clinics with minimal infrastructure. Reliable power supplies are a major problem for many of our users.

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, Lifebox recommends additional requirements described below.

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

Essential specifications

1. **Display**
   - **1.1.** Must be bright and able to be easily read at a distance of 2m, even in the dark.
   - **1.2.** SpO2 and pulse rate digits should be a minimum of 10mm in height, 20mm when no plethysmogram is displayed.
   - **1.3.** Readable in daylight but not direct sunlight.
   - **1.4.** A plethysmograph, displayed as a waveform. An additional bar graph may be an option.
   - **1.5.** Display must - at minimum - be able to display in English, French and Spanish.

2. **Sounds**
   - **2.1.** The pulse oximeter should be configured so that the pitch of the sound changes with falling saturations per IEC 80601-1.
   - **2.2.** The oximeter should have an audible beep with each pulse beat - default loudness per ISO 80601-1-61 /80601-1-8.
   - **2.3.** The volume should be easily adjustable, and can be silenced.
   - **2.4.** On starting, the default should be with audible signal and alarms.

3. **Alarms**

This whole section specifies compliance to 80601-1-61 and 80601-1-61.

3.1. Alarms should be audible, visual and able to be configured by the user, returning to default after every power cycle.

3.2. Alarm should be able to be cancelled for up to two minutes by a single button / action.

3.3. 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.

3.4. The pulse oximeter should have default low saturation alarm at SpO2 < 90%.

3.5. Low pulse rate alarm and high pulse rate alarm should be visible and audible.

3.6. 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.

3.7. If the probe comes off the patient, an alarm should indicate the probe should be checked.

4. Spot Check Mode

4.1. Provides a single reading.

4.2. No alarms.

4.3. Indicates to user (blip, wave, light, other) when a pulse is detected.

4.4. When no pulse is detected the user is given advice on how to correct this (too dark, too light, ambient light, excessive motion etc).

4.5. Retains reading.

5. Power Domains

5.1. The pulse oximeter should be able to operate from both a main power supply and from a battery source. The pulse oximeter must be able to be operated during battery charging.

6. Accuracy

6.1. 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%.

6.2. The pulse oximeter pulse rate should be accurate to +/- 3% in the clinical range 40-240bpm.

6.3. These requirements will be met at perfusion levels of 0.2% or lower, Lifebox will test this on a simulator.

7. 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

Probe requirements are:

7.1. Compatibility with Nellcor-type preferred.

7.2. Probes will be used continuously for up to 6 hours. During this time the patient must not experience significant discomfort or any injury.

7.3. Probe cord lengths must be available in 3m and 0.7m configurations.

Please note: Lifebox has developed a standard probe (details here) which manufacturers are encouraged to review and consider for inclusion in their proposals.

8. Battery

8.1. A rechargeable, replaceable battery should be supplied with each unit.

8.2. Battery life must be at least 8 hours with the display on and alarms fully operational.

8.3. Battery should be able to be recharged to 90% in a maximum of 1 hour and the oximeter should be usable during charging.

8.4. The batteries will be replaceable by the user or at a local service centre.

8.5. The batteries supplied should be distinguishable than one used in domestic appliances (e.g. mobile phone battery, etc.).

8.6. Ideally the unit should also be capable of being powered by AA cells in the event of battery failure.

8.7. There should be a battery reserve indicator (an indicator on the oximeter is preferred)

8.8. Battery capacity at least 70% after 1500 charge cycles. Charge cycle is defined as operating for 8 hours or until the battery is discharged with the display on. This life is maintained regardless of the time the device is connected to mains.

9. Power supply

9.1. The power supply should operate within the ranges 90-250v and 45-65Hz

9.2. The power supply should have surge protection as per UL1449, IEC61643 for a 20uS pulse of 2000V.

9.3. A fuse will protect the power supply (in the external charging unit, user serviceable or self resetting).

10. Manual

10.1. Routine care and maintenance (cleaning, probe and battery) 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 WHO languages (Arabic, Chinese, English, French, Russian, and Spanish).

10.4. The manufacturer should include additional Lifebox training materials, such as a USB key, in the packaging and shipment of the oximeter.

11. General Requirements

11.1. The pulse oximeter should be easily portable, for use in the recovery area, ward or clinic.

11.2. The pulse oximeter should be supplied with an optional device, which can be used to secure the oximeter to a pole, trolley or pillow to prevent accidental damage.

11.3. Equipment should be capable of withstanding falls to a concrete floor from a height of 1m Tested per IEC 60601-1 3rd edition.

11.4. At least IPX4 water resistant.

11.5. All equipment should be easy to clean and biocompatible to ISO10993.

The pulse oximeter, probes, power source, batteries, attachment device and carrying case are specified individually; when the pulse oximeter is combined with any of the ancillary equipment, the combination must meet or exceed all of the standards and requirements.

Additional specifications (not essential)

Note – these features may influence final selection:

Display

- Touch screen

Accuracy

- More advanced oximeters perform better on patients with motion and / or low perfusion. Lifebox prefers an advanced device to facilitate care in this population. Manufacturers should indicate their device performance and method of testing.

Battery

- Ideally the unit should also be capable of being powered by AA cells in the event of battery failure.
- The unit should have protection from use of low quality AA batteries in case they leak into the device.

General requirements

- Multimodal pulse oximeters are devices that measure additional physiological parameters such as respiratory rate. These devices have a potentially promising future and Lifebox would be interested in receiving proposals that include this functionality as part of the oximeter. Manufacturers should indicate their device performance and method of testing.
- Data download facility by USB / bluetooth / wifi or GSM radio

Power supply

- Wireless or USB charging could be advantageous