REQUEST FOR PROPOSALS:

SUPPLY OF PULSE OXIMETER & PROBES

ISSUED 01 November 2019

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ABOUT LIFEBOX

Lifebox Foundation is a non-profit organization dedicated to improving the safety of surgery and anaesthesia in low and middle income countries through tools, training, and partnerships. A registered charity in the United Kingdom and the United States, Lifebox was founded in 2011 by the authors of the WHO Surgical Safety Checklist together with the World Federation of Societies of Anaesthesiologists, the Association of Anaesthetists of Great Britain and Ireland, Brigham and Women’s Hospital, and Harvard T. H. Chan School of Public Health. Lifebox works in three areas of surgical safety: 1) improving anesthesia safety 2) reducing surgical infections, and 3) increasing surgical teamwork.

In its flagship programme, Lifebox procured a low-cost, low-resource adapted pulse oximeter, commonly referred to as the Lifebox Pulse Oximeter or simply the “Lifebox.” The organization has now distributed over 20,000 "Lifeboxes" in more than 100 countries through a frame contract with a pulse oximeter manufacturer. Lifebox usually distributes pulse oximeters together with a safe anaesthesia training workshop delivered via national anaesthesia societies, international and local non-governmental organisations, and hospital systems. With almost 150 workshops and more than 6,000 anaesthesia providers trained to date, Lifebox brings an element of sustainability to surgery and anaesthesia in these countries.

The pulse oximetry market has seen huge growth with new technologies being developed over the past decade. After over 8 years of work, Lifebox wishes to revisit the market to ensure we offer the best device possible - at the best possible price - to serve our objectives.

This Request for Proposals (RFP) reflects Lifebox’s continued commitment to ensuring patients in low- and middle-income countries benefit from safer anaesthesia through monitoring with a high-quality, easy-to-use, and affordable pulse oximeter throughout the perioperative period.

AIM OF THE RFP

The aim of this RFP is to replace an existing frame contract that has seen in excess of 20,000 oximeters distributed to over 100 countries since 2011. Lifebox is seeking a manufacturer with whom we can partner to deliver an affordable and fit-for-purpose pulse oximeter to meet the needs of hospitals in low and middle-income countries. We intend for this partnership to be mutually beneficial and long-lasting. We are looking for a manufacturing partner with the best product for the best price who is also aligned with our mission of improving surgical care in resource-constrained settings and underserved populations around the world. Lifebox is interested in receiving information on products that are preferably regulatory approved and commercially available, but also products under development.
RFP Process

Selection of manufacturer(s) will be through a two-stage process:

- **Stage 1**: Interested 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 unit by the closing date, to be sent to the address listed on the front page.

- **Stage 2**: Shortlisted bidders will be invited to Stage 2 and asked to provide a maximum of 10 sample units for destructive testing and end-user trial as well as additional details on the specifics of their devices.

Stage 1 proposals must be returned by Friday 13 December 2019 5 p.m. GMT. Following the evaluation of these, there will be a period of testing and end user trials prior to final selection and contract award.

The anticipated start date for the contract is August 2020. The contract is expected to be for three (3) years’ duration with an option to extend for up to two (2) further years.

### Indicative Timetable

<table>
<thead>
<tr>
<th>Expected Procurement Timetable</th>
<th>Target Dates 2019-2020</th>
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</thead>
<tbody>
<tr>
<td>1 RFP issued</td>
<td>01 November 2019</td>
</tr>
<tr>
<td>2 Closing date for return of tenders</td>
<td>13 December 2019</td>
</tr>
<tr>
<td>3 Clarification period (if required) and bid assessment</td>
<td>26 Janvier 2020</td>
</tr>
<tr>
<td>4 Testing</td>
<td>February to June 2020</td>
</tr>
<tr>
<td>5 Final evaluation and contract award</td>
<td>by August 2020</td>
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### Selection Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Evidence required</th>
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<tbody>
<tr>
<td>Essential</td>
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<td>-----------</td>
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</tr>
<tr>
<td><strong>1</strong> Ability to manufacture a pulse oximeter which meets or exceeds the specifications set out in Annex 1</td>
<td>A short statement outlining how your proposed pulse oximeter(s) meets the specifications, and noting any requirements that the unit fails to meet or significantly exceeds.</td>
</tr>
</tbody>
</table>
| **2** Ability to deliver a pulse oximeter at the price-point desired | Your estimated price quote(s) at a volume of 2,000 units per year with additional increments over 3 years. (See ‘price point’ in outline requirements below for our maximum price.)

Price quote(s) should include pulse oximeter, one or more reusable probes to address all patient types, one rechargeable battery pack, one device to secure oximeter to a pole, and any charging cable.

Please indicate clearly whether your proposal includes shipping. (See “shipping”; in outline requirements below for information required if your proposal includes shipping.) |
| **3** Ability to work with Lifebox in a mutually beneficial partnership | A short statement outlining how your company could align with Lifebox’s aims and work together with Lifebox. Please include a summary of the national/international markets you currently service, if any. Please note we are particularly interested to receive proposals for innovative models of partnership. |
| **4** Certification | ISO 9001 and ISO 80601 certificate; ISO 13485; EC certification; FDA or any other certificates related to the oximeter and 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).

**OR** copy of any product certifications achieved for other products currently produced by your company or in the past. See some examples listed above. |
<p>| <strong>5</strong> Currently registered and licensed business. | Copy of current business license and registration. |</p>
<table>
<thead>
<tr>
<th></th>
<th>Past success in producing one or more pulse oximeters.</th>
<th>Technical data sheets and any product brochures for the most relevant 1-3 pulse oximeter products and accessories such as battery, probe, charger, etc. your company currently produces.</th>
</tr>
</thead>
</table>
| 7 | Ability to produce at volume                           | A signed statement of bidder’s:  
  - current annual production capacity and estimate of maximum annual production capacity. Please confirm capacity to increase production to an additional 6,000 units per year.  
  - experience providing oximetry products and services to the global markets for at least 3 years  
  - unit sales by territory in the last 3 years demonstrating a proven track record of 5,000 units manufactured (average) per year for the last 3 years. |
| 8 | The company is financially sound                       | Copies of the last three years’ financial reports or other demonstration of your company’s financial soundness.                                                                                     |
| 9 | Acceptable credit rating.                              | Release to Lifebox to review credit rating (an external body may be used to check a bidder’s credit rating).                                                                                           |
| 10| Experience                                             | The bidder must be an original equipment manufacturer of the offered solution or a sole agent for the territories in scope (low- and middle-income countries as defined by the World Bank) and have a contract in place for the term of the contract. The bidder shall make copies of the sole agency agreement on request. |
| 11| Capacity                                               | A short statement describing your disaster recovery policy and availability of this for inspection on request.                                                                                       |
| Preferred |                                                      |                                                                                                                                       |
| 12| The company is environmentally and socially responsible | Evidence of environmental management and fair labour practice, for example compliance with ISO 14001 and SA 8000.                                                                                   |

**Assessment of Proposals**

Lifebox intends to assess the Bidder's responses 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.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
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<tbody>
<tr>
<td>0</td>
<td>No Answer/Unacceptable Response</td>
</tr>
<tr>
<td>1</td>
<td>Poor Response</td>
</tr>
<tr>
<td>3</td>
<td>Acceptable Response</td>
</tr>
<tr>
<td>5</td>
<td>Good Response</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weighting</th>
</tr>
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<tbody>
<tr>
<td>Ability to meet Lifebox specifications</td>
<td>40%</td>
</tr>
<tr>
<td>Pricing &amp; partnership</td>
<td>20%</td>
</tr>
<tr>
<td>Experience &amp; capacity</td>
<td>20%</td>
</tr>
<tr>
<td>Registration</td>
<td>10%</td>
</tr>
<tr>
<td>Financial Stability</td>
<td>10%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100%</td>
</tr>
</tbody>
</table>

Having reviewed the overall score for a Bidder, Lifebox shall inform each Bidder whether it will be invited to the next stage of the procurement.

There will be no feedback to unsuccessful bidders in this process other than to confirm the decision.

**Outline requirements**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of contract</td>
<td>3 years with option to extend for a further 2 years. This is indicative and does not constitute a commitment to a 3 year contract.</td>
</tr>
<tr>
<td>Governing law</td>
<td>The contract will be governed by the laws of England &amp; Wales.</td>
</tr>
<tr>
<td>Currency of contract</td>
<td>USD or GBP</td>
</tr>
<tr>
<td>Volume</td>
<td>Multiple orders totalling 2,000 units per year with potential to grow to 4,000 units in any one year. This is indicative; this RFP does not constitute any commitment to these volumes.</td>
</tr>
<tr>
<td>Product specifications</td>
<td>As outlined in Annex 1 below.</td>
</tr>
<tr>
<td>Probes</td>
<td>Units must be supplied with - at minimum - one standard probe suitable for all ages. However, proposals including 2 probes per unit (standard + paediatric) will be preferred. Neonatal probes will be considered in addition to the proposed probe(s). Manufacturer may respond to this RFP with either Nellcor-compatible or proprietary probes, or both; however, the former may be preferred. Please note: Lifebox has developed a standard probe known as Lifebox LB-01 sensor (details <a href="#">here</a>). Manufacturers are strongly encouraged to review and consider for inclusion in their proposals. Proposals of pulse oximeters compatible with the Lifebox LB-01 sensor are preferred.</td>
</tr>
<tr>
<td>Price point</td>
<td>It is anticipated that bidders will offer variable pricing based on annual volumes. One unit is defined as the pulse oximeter, one or more reusable probes to address all patients, one rechargeable battery pack, one device to secure oximeter 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 150. Replacement 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.</td>
</tr>
<tr>
<td>Payment terms</td>
<td>Lifebox will consider proposals from manufacturers requiring prepayment prior to commencement of manufacturing (for example for small volume order inventory), as well as manufacturers for whom payment is to be made only after delivery of goods. In the case of prepayment, indicate the additional discount that will apply.</td>
</tr>
<tr>
<td>Warranty required</td>
<td>● Minimum 2 years (24 months) for the oximeter device. ● Minimum 1 year (12 months) for probes.</td>
</tr>
</tbody>
</table>
- Indicate cost for an additional 3 years and 5 years’ warranty for the oximeter device, as well as an additional 2 years’ warranty for probes

### Manufacturing lead times
- Ex-stock for orders of less than 200.
- Maximum 4 weeks for orders > 200 units and less than 1,000 units.
- Maximum 8 weeks for orders of more than 1,000 units and less than 2,000.

### Shipping
The selected manufacturer(s) will be required to package all orders, and prepare and supply all documentation necessary for customs clearance into countries where Lifebox is active.

Bidders may make proposals with and without shipping costs. ‘With shipping’ charges at a standard rate for all countries.

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, Lifebox may make assumptions about the likely additional cost of shipping for the purposes of evaluating the overall value of a proposal.

### Customisation
The oximeters must be packed in boxes customised as per Lifebox’s requirements; at a minimum the boxes must display the Lifebox logo (in colour), email address and website.

The oximeter itself must have the Lifebox name and website printed on it in a prominent place; placement of the Lifebox logo on the unit is required.

The oximeter itself must have an indication on how to contact Lifebox in case of problem.

All oximeters should have a protective cover. The oximeter’s protective cover must be yellow to represent Lifebox’s branding. Ideally, the probes should be in the same shade of yellow. Lifebox will provide the colour reference.

Each oximeter box will need to contain the following:
The oximeter display must - at minimum - be able to display in English, French and Spanish. The accompanying manual must correspond to the display language and must be professionally translated. Manual should be available in all six WHO languages (Arabic, Chinese, English, French, Russian and Spanish).

Manufacturer must agree to share with Lifebox full details of all clients placing orders under this frame contract (Note: clients must explicitly confirm that they understand that their details will be shared with Lifebox as a precondition of the order being made).

Manufacturer must provide monthly reports on stock levels and shipments, and provide Lifebox with additional information upon request, such as an end-of-year financial statement.

If bidders have distribution networks or affiliates in any low or middle-income countries, Lifebox would be interested in proposals including 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.)

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. Lifebox will in no case be responsible or liable for those costs, nor shall 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. Lifebox may modify the RFP and the scope of services and goods specified in the RFP at any time.

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

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

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

7. Lifebox has the right to eliminate proposals at any time with no obligation to state the reasons for elimination to the bidder.

8. Lifebox reserves 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 Lifebox's action.

9. 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 Lifebox to contract for the supply of any products or services.

10. 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). Lifebox does not bind itself in any way to select the bidder offering the lowest price.

11. Lifebox may make awards to multiple bidders for the same products.

12. Lifebox reserves 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: 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