

LIFEBOX LIGHT: REQUEST FOR EXPRESSIONS OF INTEREST

18 December 2018

Background

Lifebox (<http://www.lifebox.org/>) is a charity focused on improving surgical safety globally. We have identified poor quality surgical lighting as a major threat to patient safety in low resource countries and settings. Power outages are common, and the lack of an affordable, robust and fit-for-purpose headlight is a serious threat to the safe conduct of an operation. Lifebox estimates there are 24 million patients annually at risk from poor surgical lighting and over 400,000 surgeons living and working in under-resourced health systems.

We are seeking a manufacturer with whom we can partner to deliver an affordable and fit-for-purpose surgical headlight to address the lighting gap in operating rooms in low and middle-income countries. We have identified an opportunity to deliver a high-quality, Lifebox-branded surgical headlight at a reasonable cost with a margin that can benefit Lifebox safer surgery programmes and our manufacturing partner.

Our target specifications are summarized below:

Component	Category	Specification	Rationale
LED Lighting ^a	Acceptable Illuminance (12 cm spot diameter at working distance)	8,000 lux to >35,000 lux at end of battery pack run time	Provide proper illumination to visualize critical structures in a variety of ambient light settings ranging from no light to high quality overhead OR lights
	Light Color	4500 – 6500 K	Range of color temperature most similar to full-spectrum sunlight best for distinguishing between red and blue colors typical of anatomical structures
	Illumination Spot Size	Adjustable with ideal diameter of 12 cm with narrowest diameter 7 cm (2.75”) or smaller at working distance	Most common essential operations and lower lighting conditions tend to benefit from a larger diameter of 12 cm, not currently offered in some surgical headlights; smaller spot size used with surgical loupes are not essential given low use in LMICs
	Light Component Quality	Device shall maintain the LED within manufacturer-recommended temperature limits at the full	The light must function in LMIC ORs that do not have temperature or humidity control systems

	Light Housing	range of required operating temperatures Adjustable by at least +5° and -60° in cranial-caudal direction measured from the bottom edge of headband around circumference of the head	Illuminate the full-range of common surgical operations including cesarean sections and obstetric fistulas
	Light Uniformity	Lux measurements shall not vary ≥25% over illumination field	Uneven illumination common in recreational headlights can lead to the inability to distinguish important anatomical structures
Mounting	General	Durable material that will not stretch over time with padding and two points of adjustment (circumference & depth)	Durable for operating in LMIC setting, where replacement parts and biomedical technicians are not readily available
	Weight	< 300 grams	Device must be light enough for surgeons to use for extended periods of time
Battery	Quality	High quality from an ISO-9001 manufacturer, ideally with CE marking	Ensure a high-fidelity device built for providing light, regardless of OR income status or regulatory environment
	Run time	2 Batteries; one battery at least 6 hours run time, one battery at least 3 hours run time	Support surgeons working long shifts where down time is insufficient for recharge; support surgeons performing multi-hour operations.
	Charging	Compatible with 100-240 VAC and 50-60 Hz	Accommodates the variety of electricity infrastructures from LMICs and enables continuous charging during modest power dips and surges
	Recharge Time	>90% charge attained in time equivalent to battery pack run time	Battery should be fully charged before the second battery is fully discharged.
	Fixation	Independent from head mounting; placed on waistband or hip pocket	Can decrease weight of head mount to ensure minimal surgeon neck fatigue
	Lifetime	Last for 3500 hours of use including 1200 charging cycles	Should continue to function for 2 years when used an average of 6 hours per day
Durability	Impact	Operates according to specification after a drop from 1-meter height onto concrete	Similar to rechargeable phones, dropping can occur with concrete as one of the most common building materials in LMICs

	Water & Particulate Resistant	Splash resistant, dust protected, ideally attaining IP54 rating	Occasionally, device may be splashed with bodily fluids. Additionally, many LMIC ORs do not have air filtration systems so device will be exposed to particulate matter
	Charging stability	Withstand frequent power surges; automatically continue charging whenever power is in specified range	Power outages are common in LMICs, ideal to have unit continue to function automatically upon return of power to ensure it will be ready for use
	Temperature demands	Operate according to specification at 10°- 40° C and 30% - 90% relative humidity	ORs in LMICs may not be climate controlled requiring a device to function in a variety of temperatures and humidity

Source: Forrester JA, Torgeson K, Weiser TG. Minimum Specifications for a Lifebox Surgical Headlight for Resource-Constrained Settings. *JAMA Surg*. Published online November 14, 2018. doi:10.1001/jamasurg.2018.4205

Lifebox has built a globally-renowned medical device brand by delivering over 18,000 purpose-built pulse oximeters to hospitals in more than 100 developing countries. We are accelerating our technology delivery programs as we add a surgical headlight to our portfolio. By partnering with Lifebox, manufacturers will access a large but hard-to-reach market built on Lifebox’s carefully cultivated relationships with international surgical and anesthesia societies and local health partners in low and middle-income countries worldwide. Our work in the safe surgery space positions us to challenge the market to provide an affordable, fit-for-purpose surgical headlight and distribute it globally.

More information is available on our website at: <https://www.lifebox.org/lifebox-light/>, and a detailed Target Product Profile is at: <https://www.lifebox.org/wp-content/uploads/2018/11/Lifebox-Light-Target-Product-Profile.pdf>

Request for Expressions of Interest: Overview

Lifebox Foundation is seeking to partner with a manufacturer to deliver a high quality and affordable surgical headlight with the most advantageous combination of price, features, and timeline. We intend for this partnership to be durable, mutually beneficial, and build on organizational strengths as well as a sense of mission for improving surgical care in resource constrained settings and underserved populations.

- **Target Price:** we seek the most advantageous price possible. Price quotes should include headband, light, 2 battery packs, charging equipment, carrying case or bag, instructions for use, printed and digital Lifebox training material, and packaging
- **Target Features:** see specifications outlined above, and [Lifebox Headlight Target Product Profile](#).
- **Target Volume:** 500 units in year one, 1,000 units in year two, with a goal to increase volumes over the next 5 years. ***PLEASE NOTE: this is a projection and does not constitute a commitment to purchase these volumes.***
- **Target Timeline:** please submit expressions of interest by **31 January 2019 at 17.00 GMT**. Lifebox aims to identify a manufacturing partner by 30 April 2019 and award a contract by 31 May 2019.

Indicative timeline		Deadline
Stage 1	Expressions of Interest	31 January 2019
Stage 2	Discussions and Product Sample Assessment	31 March 2019
Stage 3	Negotiation and Initial Contracting	30 April 2019
Stage 4	Contract Award	31 May 2019

Process

Lifebox wishes to receive expressions of interest from manufacturers who believe they could provide a product at the desired price and meet or come close to meeting the requirements in the Target Product Profile. As a first step, we request the following information:

	Criteria	Evidence required
Essential		
1	Ability to manufacture a surgical headlight which meets or comes close to the TPP	A short statement of no more than 500 words about why you believe your company could deliver a headlight as described in the Target Product Profile. Please include your estimated price quote(s).
2	Ability to work with Lifebox in a mutually beneficial partnership	A short statement of no more than 500 words about 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.
3	ISO 9001/ISO 13485 certification; and RoHS compliant	ISO 9001 and/or ISO 13485 certificate; RoHS declaration of conformity for at least one product.
4	Currently registered and licensed business.	Copy of current business license and registration.
5	Past success in producing one or more electromechanical products.	Technical data sheets and any product brochures for the most relevant 1-3 surgical headlight products your company currently produces. If you have not yet produced a surgical headlight, but would like to be considered, please provide technical data sheets and product brochures for 1-3 products that best exhibit your company's ability to produce a surgical headlight in the future.
6	Ability to produce at volume	A signed statement of current annual production capacity and estimate of maximum annual production capacity.
7	The company is financially sound	Copies of the last three years' financial reports.

8	Acceptable credit rating.	Release to Lifebox to review credit rating.
Preferred		
9	Currently manufactures a headlight approaching or meeting our TPP	As per 5 above
10	Incorporated for at least three years.	As per 7 above
11	The company is environmentally and socially responsible	Evidence of environmental management and fair labor practice, for example ISO 14001 and SA 8000 certificates.
12	Existing certifications for headlight (or similar product)	<p>Copy of any product certifications achieved for headlight products. Examples: EC Certificate from notified body listing the product model number (CE Marking), RoHS certificate of conformity, IPxx rating certificate, ISTA safe transit testing certificate, medical device Medical Electrical Equipment Electromagnetic Compatibility test report results (IEC 60601-1-2:2014).</p> <p>OR copy of any product certifications achieved for other products currently produced by your company or in the past. See same examples listed above.</p>

Who should submit?

- Manufacturers who believe they may have a current product that would meet or come close to meeting the desired pricing and requirements in the Target Product Profile.
- Manufacturers who believe they could develop a product that meets or comes close to meeting the desired pricing and requirements in the Target Product Profile.

What should be submitted?

Please send the checklist at the end of this document, along with the evidence outlined above to headlight@lifebox.org by **31 January 2019, 17.00 GMT**.

How will EoIs be evaluated?



Companies who do not provide the required evidence that they meet the essential criteria will not proceed to the next stage of the evaluation process.

All companies who provide the requested evidence that they meet the essential criteria will be evaluated for the following components:

- Ability to meet Target Product Profile
- Most advantageous target price
- Potential to work collaboratively with Lifebox
- Financial viability
- Product track record

Lifebox will use these materials to select manufacturers to proceed to the next stage of evaluation, which will include further discussions and product sample evaluation. There will be no feedback to unsuccessful manufacturers, other than to confirm the panel decision.

Lifebox is very flexible in our working arrangements with our partners and would like to encourage innovation. We look forward to further discussions.

To discuss this opportunity in more detail, please contact headlight@lifebox.org.

Lifebox Headlight Search Process: Expression of Interest checklist

Please submit this form along with your EoI.

Name of company	
Address	
Registration no	
Name of primary contact	
Email address	
Telephone number	

Please confirm with a tick (✓) that the following documents have been supplied:

Essential	
A short statement of no more than 500 words about why you believe your company could deliver a headlight as described in the TPP, at or close to the target price	
A short statement of no more than 500 words about how your company could align with Lifebox’s aims, work together with Lifebox and any proposals for partnership models	
ISO 9001/ISO 13485 certificate	
RoHS certificate of conformity for at least one product	
Copy of current business license and registration	
Technical data sheets and any product brochures for the most relevant 1-3 surgical headlight products your company currently produces. If you have not yet produced a surgical headlight, but would like to be considered, please provide technical data sheets and product brochures for 1-3 products that best exhibit your company’s ability to produce a surgical headlight in the future.	
A signed statement of current annual production capacity and estimate of maximum annual production capacity	

Copies of the last three years' financial reports	
Release to Lifebox to review credit rating	
Preferred	
Evidence of environmental management and fair labor practice, for example ISO 14001 and SA 8000 certificates.	
<p>Copy of any product certifications achieved for headlight products. Examples: EC Certificate from notified body listing the product model number (CE Marking), RoHS certificate of conformity,, IPxx rating certificate, ISTA safe transit testing certificate, medical device Medical Electrical Equipment Electromagnetic Compatibility (IEC 60601-1-2:2014).</p> <p>OR copy of any product certifications achieved for other products currently produced by your company or in the past. Examples: see the list above..</p>	

Please submit this checklist, along with the documentation requested, to headlight@lifebox.org by **31 January 2019, 17.00 GMT**.